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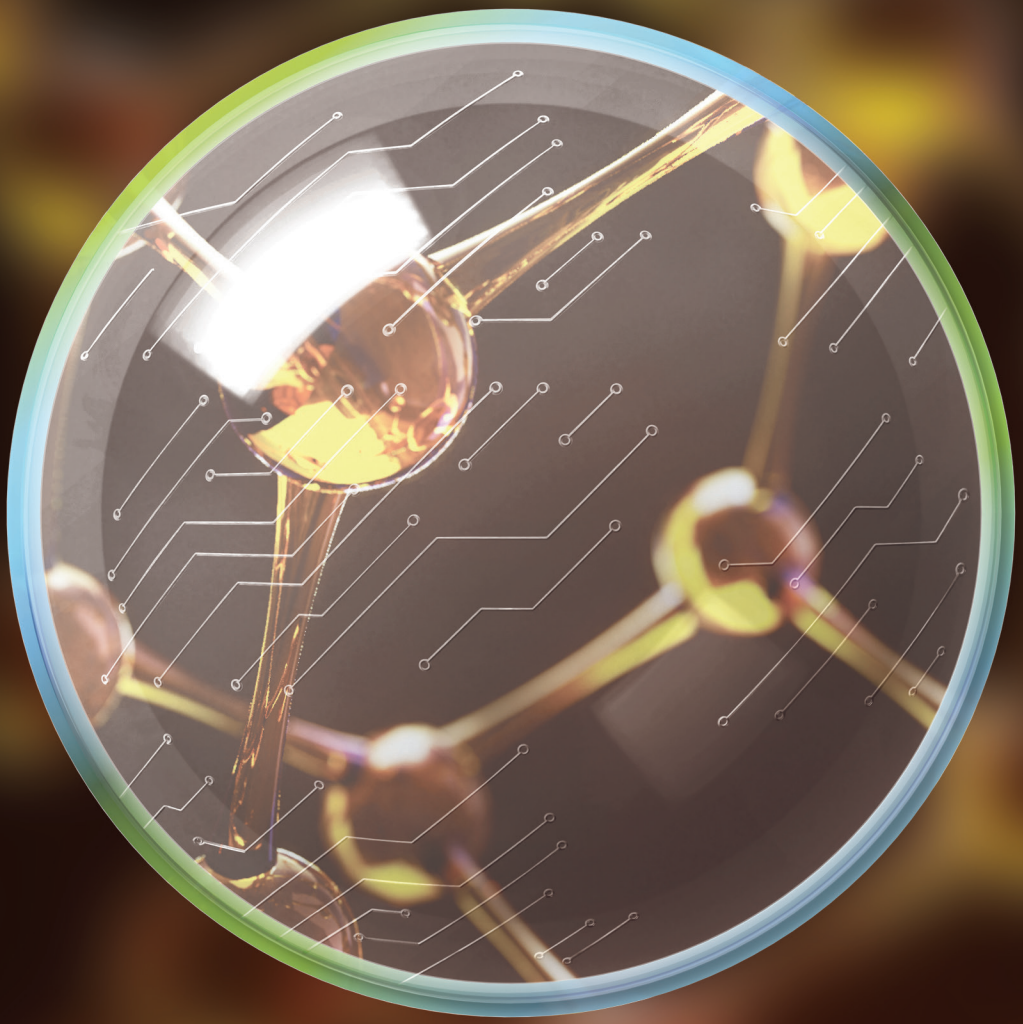

# Life Sciences Industry Accounting Guide

## Revenue Recognition

March 2024

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# Contents

# Preface

The life sciences ecosystem encompasses a wide array of entities that discover, develop, and manufacture health care products. Such entities include pharmaceutical manufacturers; biotechnology companies; medical device, diagnostic, and equipment manufacturers; and service companies such as drug distributors, contract research organizations (CROs), contract manufacturing organizations (CMOs), and health technology companies.

Finance and accounting professionals in the life sciences industry face complex issues and must exercise significant judgment in applying existing rules to matters such as research and development (R&D) costs, acquisitions and divestitures, consolidation, contingencies, revenue recognition, income taxes, financial instruments, and financial statement presentation and disclosure. The 2024 edition of Deloitte's *Life Sciences Industry Accounting Guide* (the "Guide") addresses these and other relevant topics affecting the industry this year. It includes interpretive guidance, illustrative examples, recent standard-setting and rulemaking developments (through March 8, 2024), and key differences between U.S. GAAP and IFRS® Accounting Standards. In addition, this Guide discusses (1) accounting and financial reporting considerations associated with the macroeconomic and geopolitical environment that apply specifically to the life sciences industry, (2) environmental, social, and governance (ESG) matters that have become topics of increased focus, and (3) the impact of the Inflation Reduction Act of 2022 (IRA).

Appendix B lists the titles of standards and other literature we cited, and Appendix C defines the abbreviations we used. Key changes made to this Guide since publication of the 2023 edition are summarized in Appendix D.

We hope the Guide is helpful in navigating the various accounting and reporting challenges that life sciences entities face. We encourage clients to contact their Deloitte team for additional information and assistance.

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# Chapter 2 — Revenue Recognition

## 2.1 Introduction

In May 2014, the FASB and the International Accounting Standards Board (IASB®) issued their final standard on revenue from contracts with customers (the "revenue standard" or the "standard"). Issued by the FASB as ASU 2014-09 (codified primarily in ASC 606) and by the IASB as IFRS 15 and subsequently amended, the standard outlines a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers. Further, the standard supersedes most legacy revenue recognition guidance, including industry-specific guidance.

Upon issuing the revenue standard, the FASB and IASB formed a joint revenue transition resource group (TRG). The purpose of the TRG was not to issue guidance but instead to seek and provide feedback on potential issues related to implementation of the revenue standard. By analyzing and discussing potential implementation issues, the TRG helped the boards determine whether to take additional action, such as providing clarification or issuing other guidance (in the form of additional ASUs, in the case of the FASB).

ASU 2014-09 states that the core principle of the standard's revenue recognition guidance is that an "entity shall recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services." The ASU indicates that an entity should perform the following five steps in recognizing revenue:

- "Identify the contract(s) with a customer" (step 1).
- "Identify the performance obligations in the contract" (step 2).
- "Determine the transaction price" (step 3).
- "Allocate the transaction price to the performance obligations in the contract" (step 4).
- "Recognize revenue when (or as) the entity satisfies a performance obligation" (step 5).

The following graphic summarizes the five-step model for recognizing revenue under ASC 606:

| | |
|---|---|
| **1. Identify the contract with a customer** | • A contract is an agreement between two or more parties that creates enforceable rights and obligations.<br>• A contract can be written, oral, or implied by an entity's customary business practices.<br>• For a contract to exist under ASC 606, the following five criteria must be met:<br>  ◦ The parties to the contract have approved the contract.<br>  ◦ The entity can identify each party's rights.<br>  ◦ The entity can identify the payment terms.<br>  ◦ The contract has commercial substance.<br>  ◦ It is probable that the entity will collect the amount to which it expects to be entitled. |
| **2. Identify the performance obligations** | • A performance obligation is the promise to transfer to the customer a good or service (or bundle of goods or services) that is distinct.<br>• Distinct goods and services should be accounted for as separate units of account.<br>• Entities need to determine whether a good or service (or bundle of goods or services) is "capable of being distinct" and "distinct in the context of the contract."<br>• A series of substantially the same goods or services for which control transfers over time and that have the same pattern of transfer is accounted for as a single performance obligation. |
| **3. Determine the transaction price** | • The transaction price is the amount the entity expects to be entitled to in exchange for transferring promised goods or services to the customer.<br>• The transaction price may include fixed amounts, variable amounts, or both.<br>• To determine the transaction price, entities should consider the effects of:<br>  ◦ Variable consideration.<br>  ◦ The constraint on estimates of variable consideration.<br>  ◦ Significant financing components.<br>  ◦ Noncash consideration.<br>  ◦ Consideration payable to the customer. |
| **4. Allocate the transaction price** | • The transaction price (from step 3) is allocated to each performance obligation identified (from step 2).<br>• On the basis of its specific circumstances, an entity would use one of the following approaches to allocate the transaction price to the performance obligations:<br>  ◦ Allocate according to each performance obligation's stand-alone selling price.<br>  ◦ Allocate a discount or variable amount to a specific performance obligation (or bundle of specific performance obligations) if certain criteria are met. |
| **5. Recognize revenue when (or as) performance obligations are satisfied** | Requires consideration of:<br>• Revenue recognition when (or as) control of the good or service is passed to the customer.<br>• The criteria for satisfying performance obligations and recognizing revenue over time.<br>• Measurement of progress toward satisfying performance obligations to determine a pattern of revenue recognition over time.<br>• Indicators of when performance obligations are satisfied and when to recognize revenue at a point in time. |

In addition, ASU 2014-09 requires significantly expanded disclosures about revenue recognition, including both quantitative and qualitative information about (1) the amount, timing, and uncertainty of revenue (and related cash flows) from contracts with customers; (2) the judgment, and changes in judgment, exercised in the application of the revenue standard; and (3) the assets recognized from costs incurred to obtain or fulfill a contract with a customer.

The sections below discuss some of the key accounting considerations under the revenue standard for life sciences entities. For more detailed information about the revenue standard, see Deloitte's Roadmap *Revenue Recognition* and its *TRG Snapshot* series.

## 2.2 Scope

The standard's revenue guidance applies to all contracts with customers as defined by the standard except those that are within the scope of other topics in the *FASB Accounting Standards Codification* (the "Codification"). For example, the guidance does not apply to contracts within the scope of ASC 842 (leases). In addition, certain provisions of the standard's revenue guidance also apply to transfers of nonfinancial assets, including in-substance nonfinancial assets that are not an output of an entity's ordinary activities (e.g., intangible assets such as intellectual property [IP] rights). Such provisions include guidance on recognition (including determining the existence of a contract and control principles) and measurement.

Some of the more common issues that life sciences entities have faced when considering the scope of the revenue standard are discussed below.

### 2.2.1 Collaborative Arrangements

As life sciences entities continue to adapt to an ever-changing marketplace, some may increasingly look to enter into or expand collaborations with third parties for the development or commercialization of certain drug candidates or medical products in an effort to share in both the costs and risks associated with such activities.

Collaborative arrangements frequently involve activities such as R&D, regulatory activities, manufacturing, distribution, sales and marketing activities, and general and administrative tasks. Often, a governance structure (e.g., a joint steering committee) is established to facilitate decision-making during the terms of the endeavor. In collaborations, the parties may allocate responsibility for individual activities to each other or share the responsibility for one or more activities under a joint operating arrangement. Joint operating activities may involve the joint development and ultimate commercialization of IP related to a potential new drug candidate, R&D, marketing (including promotional activities and physician detailing), general and administrative activities, manufacturing, and distribution activities. On the basis of contractually defined terms, the participants share in the profits or losses associated with these joint activities.

Such arrangements are often complex and can vary significantly in scope, terms, and conditions as well as risk mitigation objectives. The following are common forms of these arrangements:

- *Codevelopment and comarketing arrangements* — Joint operating agreements in which both parties to the agreement assume roles and responsibilities.
- *Copromotion arrangements* — Agreements in which companies partner together and use each company's commercial capabilities and experience to promote a product (owned by one of the parties) in various markets.

Upon entering into a collaborative arrangement, the participants frequently exchange up-front license fees and agree to subsequent payments based on the achievement of milestones during drug development, as well as future royalties and profit- or loss-sharing provisions.

As noted in Section 2.2, the revenue standard applies to all contracts with customers. ASC 606-10-15-3 defines a customer as "a party that has contracted with an entity to obtain goods or services that are an output of the entity's ordinary activities in exchange for consideration."

The Background Information and Basis for Conclusions of ASU 2014-09 explains that the relationship between a customer and a vendor varies from industry to industry and that companies will therefore have to consider their own facts and circumstances to determine who is a customer in an arrangement. For many contracts, this will not be very difficult to determine; however, paragraph BC54 of ASU 2014-09 provides examples of arrangements in which the facts and circumstances would have to be assessed, including "[c]ollaborative research and development efforts between biotechnology and pharmaceutical entities or similar arrangements in the aerospace and defense, technology, and healthcare industries, or in higher education."

The example below illustrates how an entity would determine whether an arrangement is a collaborative arrangement and, if so, whether it should be accounted for under ASC 606.

**Example 2-1**

Biotech B (the reporting entity) and Pharma P enter into an agreement to research, develop, and commercialize drug X. Biotech B will perform the R&D, and Pharma P will commercialize the drug. Both parties agree to participate equally in all activities that result from the research, development, and commercialization. Biotech B concludes that a collaborative arrangement exists because both parties are active participants and have agreed to share in the risks and rewards.

Despite this conclusion, however, there still could be a vendor-customer relationship as a result of some of the activities between the participants in accordance with the collaborative arrangement. If such a relationship exists, those parts of the contract that are related to the vendor-customer relationship may need to be accounted for under ASC 606.

### Connecting the Dots

ASC 606 does not change the guidance in ASC 808 on the income statement presentation, classification, and disclosures applicable to collaborative arrangements within the scope of the revenue standard. It is important to understand that a contract could be within the scope of both the revenue standard and the guidance on collaborative agreements, as indicated in paragraph BC55 of ASU 2014-09:

> The Boards noted that a contract with a collaborator or a partner (for example, a joint arrangement as defined in IFRS 11, *Joint Arrangements*, or a collaborative arrangement within the scope of Topic 808, Collaborative Arrangements) also could be within the scope of Topic 606 if that collaborator or partner meets the definition of a customer for some or all of the terms of the arrangement.

This is important because companies may have to assess the scope of both ASC 606 and ASC 808 for these types of arrangements. In addition, the Background Information and Basis for Conclusions of ASU 2014-09 does not preclude companies from analogizing to the guidance in ASC 606 when accounting for collaborative arrangement transactions within the scope of ASC 808. See Section 2.2.1.2 for considerations relevant to applying ASC 606 by analogy to collaborative arrangements.

When an entity enters into a collaboration, management must consider whether the arrangement meets the U.S. GAAP definition of a collaborative arrangement to determine whether the arrangement is subject to the requirements of ASC 808. The legal characterization of an arrangement (e.g., as a collaboration or a collaborative arrangement) does not necessarily make the arrangement qualify as a collaborative arrangement under U.S. GAAP.

ASC 808-10-20 defines a collaborative arrangement as a "contractual arrangement that involves a joint operating activity" and involves two (or more) parties that are both of the following:

- "[A]ctive participants in the activity."
- "[E]xposed to significant risks and rewards dependent on the commercial success of the activity."

On the basis of these criteria, some types of collaborations in the industry may not meet the definition of a collaborative arrangement and therefore would not be within the scope of ASC 808. For example, certain arrangements in which one party solely provides financial resources for an endeavor and is generally not an active participant would not meet the definition of a collaborative arrangement. Alternatively, arrangements between two parties that involve codevelopment, comarketing, or copromotion activities, as well as the sharing of risks and rewards based on the success of such activities, would generally meet the definition of a collaborative arrangement.

A collaboration can begin at any point in the life cycle of an endeavor (e.g., during the R&D phase or after a product has been commercially launched). The facts and circumstances associated with the arrangement will dictate whether the parties (1) represent active participants and (2) are exposed to significant risks and rewards.

ASC 808-10-15-8 cites the following examples of situations in which active participation may exist:

a. Directing and carrying out the activities of the joint operating activity
b. Participating on a steering committee or other oversight or governance mechanism
c. Holding a contractual or other legal right to the underlying intellectual property.

In addition, ASC 808-10-15-11 lists circumstances that might indicate that participants are not exposed to significant risks and rewards:

a. Services are performed in exchange for fees paid at market rates.
b. A participant is able to exit the arrangement without cause and recover all (or a significant portion) of its cumulative economic participation to date.
c. Initial profits are allocated to only one participant.
d. There is a limit on the reward that accrues to a participant.

Further, in accordance with ASC 808-10-15-12, an entity should also consider other factors when evaluating participants' exposure to significant risks and rewards, including (1) the "stage of the endeavor's life cycle" and (2) the "expected duration or extent of the participants' financial participation . . . in relation to the endeavor's total expected life or total expected value."

For collaborations that meet the U.S. GAAP definition of a collaborative arrangement, ASC 808 provides guidance on income statement presentation, classification, and disclosures. However, before the issuance of ASU 2018-18 (which is discussed below), ASC 808 did not address recognition or measurement matters, such as (1) determining the appropriate unit of account or (2) when the recognition criteria are met. Thus, even for a collaboration within the scope of ASC 808, entities were required to look to other GAAP (possibly by analogy) to determine the appropriate recognition and measurement for the activities subject to the arrangement, as discussed below.

When determining the appropriate income statement presentation of amounts recorded as a result of a collaborative arrangement, entities also will need to separately evaluate (1) transactions with third parties outside of the arrangement and (2) transactions between collaboration participants. ASC 808 requires that each collaboration participant report costs incurred and revenue generated from transactions with third parties in its income statement in accordance with the principal-versus-agent guidance in ASC 606-10-55-36 through 55-40. The participant in the collaborative arrangement that is deemed the principal participant for a given transaction should record the transaction on a gross basis in its financial statements, notwithstanding the presence of cost sharing or cost allocation of such amounts on the basis of the terms of the agreement.

In addition, participants will need to evaluate the appropriate income statement presentation for payments between the collaboration partners (e.g., as a result of expense reimbursements or profit sharing). When such payments are within the scope of other authoritative accounting literature, entities should apply the income statement classification requirements on the basis of the relevant provisions of that literature. If the payments are not within the scope of other authoritative accounting literature (e.g., ASC 606), the income statement classification for the payments is based on an analogy to authoritative accounting literature or — if there is no appropriate analogy — a reasonable, rational, and consistently applied accounting policy election.

### *2.2.1.1 Clarifying the Interaction Between ASC 808 and ASC 606*

In November 2018, the FASB issued ASU 2018-18, which made targeted improvements to the guidance on collaborative arrangements in ASC 808, including the following clarifications:

- In the evaluation of whether a transaction in a collaborative arrangement is within the scope of ASC 606, the unit of account is a distinct good or service.
- When the collaborative participant is a customer for a good or service (or bundle) that is distinct, the recognition, measurement, presentation, and disclosure requirements of ASC 606 should be applied to the transaction (i.e., the distinct good or service [or bundle]).
- An entity in a collaborative arrangement is precluded from presenting a transaction as revenue from a contract with a customer if the collaborative participant counterparty is not a customer.

While the amendments in ASU 2018-18 primarily affected the guidance in ASC 808, the ASU also amended ASC 606-10-15-3 to remove the following guidance:

> A counterparty to the contract would not be a customer if, for example, the counterparty has contracted with the entity to participate in an activity or process in which the parties to the contract share in the risks and benefits that result from the activity or process (such as developing an asset in a collaboration arrangement) rather than to obtain the output of the entity's ordinary activities.

### *2.2.1.2 Collaborative Arrangements Outside the Scope of ASC 606*

In determining the accounting for collaborative arrangements outside the scope of ASC 606, many entities have historically applied revenue recognition guidance by analogy. These entities often conclude that the collaborative activities do not represent separate deliverables (i.e., they conclude that there is one "unit of account" which represents the right to actively participate in the collaborative arrangement over its term and to share in the profits or losses from the underlying endeavor).

Before the FASB issued ASU 2018-18, we believed that when analogizing to authoritative accounting literature, an entity should apply all (as opposed to limited) aspects of that literature to the extent applicable. For example, suppose that a biotechnology company entered into a collaborative arrangement with a pharmaceutical company and, as part of the collaboration, (1) provided the pharmaceutical company a license to use IP related to a drug candidate and (2) performed R&D services jointly with the pharmaceutical company. The biotechnology company may have concluded that while the arrangement meets the definition of a collaborative arrangement in accordance with ASC 808, none of its elements are within the scope of ASC 606. Nevertheless, the biotechnology company may have further concluded that revenue literature (e.g., ASC 606) represents appropriate authoritative guidance that the company should apply by analogy to determine the unit(s) of account, recognition, and measurement. Accordingly, if the company concluded that the license is not a distinct performance obligation, the revenue literature would require the license and R&D services to be combined for accounting purposes. Further, with respect to the appropriate income statement presentation for consideration allocated to the combined unit of account (in this case, the license and R&D services), such consideration would generally be presented consistently in the same category for income statement presentation purposes given the conclusion that the license and R&D services should be combined for accounting purposes.

However, as noted above, the FASB issued ASU 2018-18 in November 2018. Although the Board decided to provide unit-of-account guidance in ASC 808 and align that guidance with the guidance in ASC 606 for distinct goods or services, the Board decided not to include recognition and measurement guidance for nonrevenue transactions in a collaborative arrangement. The Board's reason for not including such guidance was to avoid developing a "one size fits all" accounting model for the various types of collaborative arrangements. The decision to align the unit-of-account guidance with the guidance in ASC 606 for distinct goods or services is limited to the context of assessing the scope of the revenue guidance. As noted in paragraph BC31 of ASU 2018-18, "the Board decided to continue to permit an entity to apply the revenue guidance in Topic 606 by analogy or, if there is no appropriate analogy, as a policy election, **without requiring the entity to apply all the guidance in Topic 606**, as long as it presents the transaction separate from revenue recognized from contracts with customers" (emphasis added). Accordingly, it is possible for an entity to conclude on the basis of its facts and circumstances that ASC 606 represents an "appropriate analogy" for determining the nonrevenue unit(s) of account but may not represent an appropriate analogy for recognizing or measuring such unit(s) of account. In such a case, the above guidance would support a conclusion that analogizing to ASC 606 could be limited to an entity's determination of the unit(s) of account. The entity would then be required to establish a policy that is "reasonable, rational, and consistently applied" as long as the nonrevenue transaction is presented separately from any revenue recognized from contracts with customers under ASC 606.

### *2.2.1.3 SEC Comment Letter Themes Related to Collaborative Arrangements*

**Examples of SEC Comments**

- You state . . . that . . . you entered into a collaboration agreement with [Entity A] pursuant to which you granted [A] an exclusive right to develop and commercialize [Compound B], excluding the [Territory C], and a co-exclusive license in the U.S. to develop and commercialize [Compound B]. You state . . . that the agreement contains four material components. Please address the following:
  - Tell us how you applied ASU 2018-18 to determine that part of the agreement should not be accounted for under ASC 606. In this respect, tell us why the collaborative partner is not considered a customer within the unit of account under ASU 2018-18 that would be required to be accounted for under ASC 606.
  - For the portion of the agreement you believe is outside ASC 606, clarify what authoritative literature you are using or what methodology you are using to account for the non–ASC 606 portion. Refer to ASC 808-10-45-3.
  - Explain why the entire $[X] million was allocated to the components accounted for under ASC 606 and why some of the amount was not required to be allocated to the other material components of the agreement.
  - Please clarify the nature of the transition date discussed . . . , why that date determines if you are the principal for the product sales, and if at that point, reimbursements will also be recorded as revenue. Clarify how the fact pattern compares to Example 3 in ASC 808-10-55-11 through 55-14 and provide any authoritative support.
- [Y]ou entered into the [collaboration agreement with Entity X] to jointly develop and commercialize [Product A]. You state that you identified two performance obligations, consisting of the delivery of the licenses and your participation on joint steering and other collaboration committees. Your accounting policy . . . states that for collaboration arrangements with multiple performance obligations, such as granting a license and performing research and development activities, you allocate the upfront and milestone payments under a relative standalone selling price method. It is not clear why amounts for research and development in the [collaboration agreement with X] are not considered a performance obligation nor why . . . you record cost reimbursement payments to you from [X] as a reduction of research and development expense rather than as revenue. It appears to us that your separation, measurement, allocation and classification of amounts related to the [collaboration agreement with X] is inconsistent with your accounting policy . . . and with your accounting for your agreement with [Entity Y]. Please provide us an analysis with reference to authoritative literature supporting your accounting for the [collaboration agreement with X]. Also, provide us proposed revised accounting policy disclosure to be included in future filings addressing this inconsistency or tell us why revised disclosure is not necessary.
- Please provide us the following terms governing the [X] collaboration, as well as your consideration of providing additional disclosure pursuant to ASC 606-10-50:
  - Quantify the amount allocated to each performance obligation.
  - Describe and quantify the methods and assumptions used to determine standalone selling price for each collaboration.
  - Provide a range of milestone and other payment obligations to be received by stage (e.g. development, regulatory and commercialization).

**Examples of SEC Comments (continued)**

- With regard to the $[X] million non-refundable, upfront license fee received in the [collaboration agreement with Entity A] and the estimates made in accounting for the agreement, please tell us:
  - [M]ore specifically what you mean by "Therefore, there was significant judgment applied in determining a reasonable, rational method of recognizing revenue under the [collaboration agreement with A], with the Company considering the guidance in ASC 606 Revenue from Contracts with Customers," and whether and, if so, to what extent you analogized to ASC 606 or other literature and, if not, the basis in the accounting literature for the accounting you applied to separate, allocate, measure and recognize amounts within the collaborative arrangement,
  - [T]he amount allocated to each of [Compound B] and [Compound C] and your consideration of disclosing the amount allocated to each of [Compound B] and [Compound C] separately,
  - [H]ow you determined the five years over which you will complete development activities for [Compound B] when we note the FDA accepted a New Drug Application . . . ,
  - [Y]our basis in the accounting literature for recognizing milestone payments when achieved addressing regulatory milestones separately from sales milestones,
  - [W]hy you record reimbursement for [X]% of your development activity expenses incurred as a reduction to research and development costs rather than as part of the transaction price for purposes of recording revenue given your accounting for research and development activities as a performance obligation that you recognize using the proportional performance method,
  - [T]he basis in the accounting literature for presenting . . . the co-promote loss as negative revenue rather than as an expense, and
  - [T]he breakout showing the amount and type of regulatory versus sales milestone related to the $[X] million in milestone payments upon [Compound B] regulatory approvals and first commercial sale events in certain major markets and an additional $[X] million in milestone payments upon [Compound C] regulatory approvals and first commercial sale events in certain major markets.
- We note you considered the nature of the remittance of the net pre-tax profits to [Entity A] and ultimately concluded that an accounting policy of recording these net costs as a component of Other operating expense, net is a "reasonable, rational, and consistently applied accounting policy election" which accurately reflects the nature of these costs. Please address with more specificity why your characterization of the amounts [A] shares with you as Net Revenue and the amounts you share with them as Other operating expense, net is a consistently applied policy election.
- Based on your response, it appears that you are applying ASC 808-10 to the 50-year collaboration Agreement entered into in [year X]. In this regard, please describe to us the extent you have considered ASC 808-10-15-6, which sets forth, in part, that "participants shall reevaluate whether an arrangement continues to be a collaborative arrangement whenever there is a change in either the roles of the participants in the arrangement or the participants' exposure to significant risks and rewards dependent on the ultimate commercial success of the endeavor."
- Please address the following comments with regard to your accounting and disclosures for the License and Research Collaboration Agreement with [Company A].
  - Please expand your future filings to describe all material terms of the agreement, including the specific amount for the upfront payments, and the development and [commercialization] milestone payments. For the tiered royalty arrangement, please disclose the royalty term and quantification of the royalty rate, or a range no greater than 10 percentage points per tier.
  - Please provide us an analysis, and revise your future filings if necessary, of the components you have identified under this agreement that would fall under ASC 808 *Collaborative Arrangements* and the components under ASC 606 *Revenue from Contracts with Customers*. In your analysis, tell us how you have considered the unit of account guidance under ASC 808-10-15-5B.

Collaborative arrangements are common among biotech and pharmaceutical companies. As part of registrants' application of the revenue standard and the guidance in ASU 2018-18 on clarifying the interaction between ASC 808 and ASC 606, registrants need to evaluate whether transactions between partners in a collaborative arrangement are within the scope of the revenue standard. Inquiries to registrants have also focused on matters such as:

- The registrant's accounting policies regarding separation (i.e., unit of account) and allocation (i.e., when multiple units exist) for collaborative arrangements.
- Supplemental explanation of:
    - The registrant's determination and disclosure of (1) the separation, allocation, recognition, and classification principles that were used to account for payments between collaboration partners and (2) the factors that led the registrant to conclude that it is the principal (or agent) in transactions with third parties.
    - The authoritative literature that was used to make the determinations in items (1) and (2) above.
- Enhanced disclosure, when material, about the registrant's collaborative arrangements, including the overall effect of the collaborative arrangements on the financial statements, the nature and timing of payments between the parties, and the range of royalties to be paid under the arrangements.

### 2.2.2 Arrangements Involving Medical Device Consumables

The revenue standard does not apply to contracts with customers (or portions thereof) that fall within the scope of other applicable guidance, such as ASC 842 (leases). Some entities may need to obtain an understanding of the new leasing standard as well as their lease contracts to determine the full scope of customer arrangements that fall within the scope of ASC 606. For example, to facilitate the sale and use of medical device consumables, medical device companies may place equipment for free at the customer's location for a multiyear term. In exchange for the placed equipment, the customer is typically required to commit to a minimum purchase of consumable products during that term.

To determine how this type of arrangement should be accounted for under the revenue standard, the reporting entity should first consider whether the placement of equipment meets the definition of a lease under ASC 842. If the arrangement includes elements that meet the definition of a lease, the lease-related elements of the arrangement would need to be accounted for under the lease accounting literature unless the entity qualifies for and elects the lessor practical expedient under ASC 842-10-15-42A. If the arrangement does not meet the definition of a lease and no other literature is directly applicable, the revenue standard would be applied to the entire arrangement. For additional considerations related to the new leasing standard, see Chapter 11.

### 2.2.3 Sale or Outlicensing of IP Rights

Life sciences entities frequently sell or outlicense IP rights (e.g., in-process research and development [IPR&D] or developed product rights) in exchange for future milestone payments, royalties, or both (i.e., variable consideration).

Determining the accounting model to apply to arrangements involving the transfer of IP rights requires significant judgment. Accounting for these transactions depends on whether the transfer involves (1) the sale of IP rights, (2) the license of IP rights, or (3) the sale of IP rights together with other inputs and processes that meet the definition of a business:

- *Sale of IP rights* — The revenue standard's provisions apply to transfers of nonfinancial assets, including in-substance nonfinancial assets that are not an output of an entity's ordinary activities (e.g., intangible assets such as IP rights). The following example in ASC 610-20-55-17 through 55-19 illustrates how an entity would account for the sale of a nonfinancial asset in exchange for variable consideration:

**ASC 610-20**

***Example 3 — Sale of a Nonfinancial Asset for Variable Consideration***

**55-17** An entity sells (that is, does not out license) the rights to in-process research and development that it recently acquired in a business combination and measured at fair value of $50 million in accordance with Topic 805 on business combinations. The entity concludes that the transferred in-process research and development is not a business. The buyer of the in-process research and development agrees to pay a nonrefundable amount of $5 million at inception plus 2 percent of sales of any products derived from the in-process research and development over the next 20 years. The entity concludes that the sale of in-process research and development is not a good or service that is an output of the entity's ordinary activities.

**55-18** Topic 350 on goodwill and other intangibles requires the entity to apply the guidance in this Subtopic to determine the amount and timing of income to be recognized. Therefore, the entity applies the derecognition guidance in this Subtopic as follows:

a. The entity concludes that it does not have a controlling financial interest in the buyer.
b. The entity concludes that the contract meets the criteria in paragraph 606-10-25-1.
c. The entity also concludes that on the basis of the guidance in paragraph 606-10-25-30, it has transferred control of the in-process research and development asset to the buyer. This is because the buyer can use the in-process research and development's records, patents, and supporting documentation to develop potential products and the entity has relinquished all substantive rights to the in-process research and development asset.
d. In estimating the consideration received, the entity applies the guidance in Topic 606 on determining the transaction price, including estimating and constraining variable consideration. The entity estimates that the amount of consideration that it will receive from the sales-based royalty is $100 million over the 20-year royalty period. However, the entity cannot assert that it is probable that recognizing all of the estimated variable consideration in other income would not result in a significant reversal of that consideration. The entity reaches this conclusion on the basis of its assessment of factors in paragraph 606-10-32-12. In particular, the entity is aware that the variable consideration is highly susceptible to the actions and judgments of third parties, because it is based on the buyer completing the in-process research and development asset, obtaining regulatory approval for the output of the in-process research and development asset, and marketing and selling the output. For the same reasons, the entity also concludes that it could not include any amount, even a minimum amount, in the estimate of the consideration. Consequently, the entity concludes that the estimate of the consideration to be used in the calculation of the gain or loss upon the derecognition of the in-process research and development asset is limited to the $5 million fixed upfront payment.

**55-19** At inception of the contract, the entity recognizes a net loss of $45 million ($5 million of consideration, less the in-process research and development asset of $50 million). The entity reassesses the transaction price at each reporting period to determine whether it is probable that a significant reversal would not occur from recognizing the estimate as other income and, if so, recognizes that amount as other income in accordance with paragraphs 606-10-32-14 and 606-10-32-42 through 32-45.

- *License of IP rights* — In contrast to the accounting for a sale of IP, for a licensing transaction in which consideration is tied to the subsequent sale or usage of IP, the revenue standard provides an exception to the recognition principle that is part of step 5 (i.e., recognize revenue when or as control of the goods or services is transferred to the customer). Under this sales- or usage-based royalty exception, an entity would not estimate the variable consideration from sales- or usage-based royalties. Instead, the entity would recognize revenue at the later of when (1) the subsequent sale or usage occurs or (2) the performance obligation to which some or all of the sales- or usage-based royalty has been allocated is satisfied (or partially satisfied).
- *Sale of IP rights together with other inputs and processes that meet the definition of a business* — ASC 610-20 does not amend or supersede guidance that addresses how to determine the gain or loss on the derecognition of a subsidiary or a group of assets that meets the definition of a business. Gains or losses associated with such a transaction will continue to be determined in accordance with ASC 810-10-40. As discussed in Section 4.2.5, entities should establish an accounting policy for the initial and subsequent measurement of this type of arrangement.

### 2.2.4 Contracts That Include Both Revenue and Nonrevenue Elements

When a contract includes both revenue and nonrevenue elements, some of which are within the scope of other standards, any separation and initial measurement requirements of the other standards are applied first and the deliverables within the scope of the revenue model are ascribed any residual amount, as provided in ASC 606-10-15-4.

**ASC 606-10**

**15-4** A contract with a customer may be partially within the scope of this Topic and partially within the scope of other Topics listed in paragraph 606-10-15-2.

a. If the other Topics specify how to separate and/or initially measure one or more parts of the contract, then an entity shall first apply the separation and/or measurement guidance in those Topics. An entity shall exclude from the transaction price the amount of the part (or parts) of the contract that are initially measured in accordance with other Topics and shall apply paragraphs 606-10-32-28 through 32-41 to allocate the amount of the transaction price that remains (if any) to each performance obligation within the scope of this Topic and to any other parts of the contract identified by paragraph 606-10-15-4(b).

b. If the other Topics do not specify how to separate and/or initially measure one or more parts of the contract, then the entity shall apply the guidance in this Topic to separate and/or initially measure the part (or parts) of the contract.

For example, if a contract with a customer includes performance obligations subject to ASC 606 and an equity component that is within the scope of other authoritative literature regarding separation, measurement, or both, the equity component would be recognized and measured in accordance with the applicable authoritative literature, with the residual transaction price recognized under ASC 606.

If there are no separation or initial measurement requirements in those other standards, the requirements in ASC 606 are applied. That is, the guidance in ASC 606 is the default guidance to be used if there is no other relevant guidance.

The examples below illustrate the application of ASC 606-10-15-4.

**Example 2-2**

Biotech X enters into two arrangements with Pharmaceutical Company Y. The first arrangement is a license and collaboration arrangement that X has determined is within the scope of ASC 606 and consists of one combined performance obligation. The second arrangement is a share purchase arrangement whereby X sells shares of its common stock to Y.

Biotech X determines that the two arrangements should be accounted for as a single arrangement under ASC 606. It accounts for the common stock purchased by Y under applicable authoritative literature. The fair value of the common shares is excluded from the consideration that is allocated to the revenue unit of account. To the extent that the consideration for the common shares exceeds the fair value, the excess is allocated to the revenue unit of account.

**Example 2-3**

Biotech X and Pharmaceutical Company Y enter into an arrangement in which X agrees to sell shares of its common stock to Y in exchange for consideration. In accordance with the arrangement, Y is entitled to receive information on the development of IP being developed by X and has a right of first refusal in connection with a future sale or license of this IP. The consideration paid by Y for the shares of common stock is at a premium (i.e., the consideration exceeds the fair value of the shares).

Biotech X accounts for the common stock purchased by Y under applicable authoritative literature. However, X determines that the excess of consideration over the fair value of the shares of common stock is associated with another element in the arrangement that is, in substance, a contract to perform R&D services. Consequently, X must further assess the appropriate accounting literature to apply to this R&D element (e.g., ASC 606 if Y represents a customer) to determine the appropriate accounting for the transaction price that is allocated to the R&D element.

## 2.3 Identify the Contract (Step 1)

For contracts within the scope of ASC 606, the first step of the revenue standard is to determine whether a contract exists, for accounting purposes, between an entity and its customer.

**ASC 606-10**

**25-1** An entity shall account for a contract with a customer that is within the scope of this Topic only when all of the following criteria are met:

a. The parties to the contract have approved the contract (in writing, orally, or in accordance with other customary business practices) and are committed to perform their respective obligations.
b. The entity can identify each party's rights regarding the goods or services to be transferred.
c. The entity can identify the payment terms for the goods or services to be transferred.
d. The contract has commercial substance (that is, the risk, timing, or amount of the entity's future cash flows is expected to change as a result of the contract).
e. It is probable that the entity will collect substantially all of the consideration to which it will be entitled in exchange for the goods or services that will be transferred to the customer (see paragraphs 606-10-55-3A through 55-3C). In evaluating whether collectibility of an amount of consideration is probable, an entity shall consider only the customer's ability and intention to pay that amount of consideration when it is due. The amount of consideration to which the entity will be entitled may be less than the price stated in the contract if the consideration is variable because the entity may offer the customer a price concession (see paragraph 606-10-32-7).

A contract does not have to be written to meet the criteria for revenue recognition; however, it does need to create enforceable rights and obligations.

Some of the more common issues that life sciences entities have faced when considering step 1 of the revenue standard are discussed below.

### 2.3.1 Parties That Are Relevant to the Determination of Whether a Contract Exists

Given the number of entities involved in the distribution channel or pricing chain within the life sciences industry, questions have arisen about which parties are relevant to the determination of whether a contract exists. For example, for a pharmaceutical company, does a contract for purposes of step 1 include only the contract between the pharmaceutical company and the wholesaler, or does it also include "downstream" contracts with others in the pricing chain to whom discounts or rebates may be provided?

The criteria in ASC 606-10-25-1 that need to be in place to establish that a contract exists are intended to demonstrate that there is a valid and genuine transaction between an entity and *its customer* and that the parties to the contract have enforceable rights and obligations that will have true economic consequences. For a traditional pharmaceutical company, the wholesaler to which the company's products are shipped would generally represent the customer. In these circumstances, other parties that may be involved in the distribution channel or pricing chain do not represent the company's customers and therefore are irrelevant to the determination of whether a contract exists for accounting purposes. However, life sciences entities should keep in mind that any pricing adjustments (e.g., rebates, chargebacks) that are payable as result of this type of arrangement may represent variable consideration that is required to be estimated and potentially constrained under step 3 of the model.

### 2.3.2 Identifying the Payment Terms

A contract must include payment terms for each of the promised goods and services in an arrangement for an entity to determine the transaction price. The payment terms do not need to be fixed, but the contract must contain enough information to allow an entity to reasonably estimate the consideration to which it will be entitled for transferring the goods and services to the customer.

**Example 2-4**

Pharmaceutical Company X has received approval from a foreign government to sell Drug A to government hospitals in advance of obtaining full market authorization in the jurisdiction. During this "early access period" in which X's application for full marketing authorization is being evaluated by the foreign government, X will be paid a preliminary price by the government hospitals. During this same period, X will be negotiating with the foreign government the final price to be paid to X. Upon obtaining full marketing authorization and completing pricing negotiations, X will be required to rebate to the foreign government the difference between the preliminary price and the final price.

In this fact pattern, payment terms may have been established between X and the government hospitals because X can (1) determine, for example, when payment is due and that the consideration is variable and (2) reasonably estimate the amount of consideration to which it will ultimately be entitled on the basis of the ongoing negotiations with the foreign government.

In a manner similar to how Pharmaceutical Company X in the example above obtains approval to sell a product in a foreign jurisdiction before receiving full market authorization to do so, a drug company may obtain advance approval to sell a product in the United States under the FDA's Accelerated Approval Program. The FDA describes the nature of the program on its Web site as follows:

> The FDA instituted its Accelerated Approval Program to allow for earlier approval of drugs that treat serious conditions, and fill an unmet medical need based on a surrogate endpoint. A surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. The use of a surrogate endpoint can considerably shorten the time required prior to receiving FDA approval.
>
> Drug companies are still required to conduct studies to confirm the anticipated clinical benefit. If the confirmatory trial shows that the drug actually provides a clinical benefit, then the FDA grants traditional approval for the drug. If the confirmatory trial does not show that the drug provides clinical benefit, FDA has regulatory procedures in place that could lead to removing the drug from the market.

The example below illustrates the determination of whether a drug company that obtains advance approval under the FDA's Accelerated Approval Program may recognize revenue from the sale of its product.

**Example 2-5**

Pharmaceutical Company X has received FDA approval under the FDA's Accelerated Approval Program to sell Drug A to customers in advance of obtaining traditional FDA approval for Drug A. As part of its contracts with its customers, X agrees to provide rebates if traditional approval of Drug A is not received. Pharmaceutical Company X concludes that it is probable that a significant reversal of revenue will not occur.

On the basis of the identified payment terms, X determines that the contingent rebates represent variable consideration that should be recognized to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

### 2.3.3 Price Concessions

As part of determining whether a valid and genuine contract exists, an entity is required to evaluate whether it is probable that the entity will collect substantially all of the consideration to which it is entitled under the contract. However, the consideration to which an entity is ultimately entitled may be less than the price stated in the contract because the customer is offered a price concession. Price concessions are a form of variable consideration and need to be analyzed when the transaction price is being determined (as part of step 3 of the model). However, as part of step 1, an entity would evaluate whether it is probable that the entity will collect the consideration to which it will be entitled for providing goods or services to a customer after considering any price concessions. This evaluation requires aspects of step 3 to be performed in conjunction with step 1.

Differentiating between credit risk (i.e., the risk of collecting less consideration than the amount the entity legitimately expected to collect from the customer) and price concessions (i.e., entering into a contract with a customer with the expectation of accepting less than the contractual amount of consideration in exchange for goods or services) may be difficult. Entities will need to use significant judgment in determining whether they have provided an implicit price concession or have accepted a customer's credit risk. This is particularly true of entities in highly regulated industries, such as health care and consumer energy, which may be required by law to provide certain goods and services to their customers regardless of the customers' ability to pay. Because of the nature of these arrangements, entities will need to evaluate all of the relevant facts and circumstances of their arrangements to determine whether they have provided implicit price concessions or whether the anticipated receipt of less than the total contractual consideration represents credit risk.

Example 2 in ASC 606-10-55-99 through 55-101, which is reproduced below, illustrates how a life sciences entity would evaluate implicit price concessions when assessing whether the collectibility criterion is met.

**ASC 606-10**

Example 2 — Consideration Is Not the Stated Price — Implicit Price Concession

**55-99** An entity sells 1,000 units of a prescription drug to a customer for promised consideration of $1 million. This is the entity's first sale to a customer in a new region, which is experiencing significant economic difficulty. Thus, the entity expects that it will not be able to collect from the customer the full amount of the promised consideration. Despite the possibility of not collecting the full amount, the entity expects the region's economy to recover over the next two to three years and determines that a relationship with the customer could help it to forge relationships with other potential customers in the region.

**55-100** When assessing whether the criterion in paragraph 606-10-25-1(e) is met, the entity also considers paragraphs 606-10-32-2 and 606-10-32-7(b). Based on the assessment of the facts and circumstances, the entity determines that it expects to provide a price concession and accept a lower amount of consideration from the customer. Accordingly, the entity concludes that the transaction price is not $1 million and, therefore, the promised consideration is variable. The entity estimates the variable consideration and determines that it expects to be entitled to $400,000.

**55-101** The entity considers the customer's ability and intention to pay the consideration and concludes that even though the region is experiencing economic difficulty it is probable that it will collect $400,000 from the customer. Consequently, the entity concludes that the criterion in paragraph 606-10-25-1(e) is met based on an estimate of variable consideration of $400,000. In addition, based on an evaluation of the contract terms and other facts and circumstances, the entity concludes that the other criteria in paragraph 606-10-25-1 are also met. Consequently, the entity accounts for the contract with the customer in accordance with the guidance in this Topic.

## 2.3.4 Contract Term

Determining the term of the contract is an important step in the revenue recognition process since the contract term could affect the identification of promises under the contract, the transaction price, and disclosures. ASC 606 provides guidance on determining the contract duration, including the effect of termination clauses and contract renewals. The contract term is determined on the basis of the period over which the parties to the contract have present enforceable rights and obligations.

**ASC 606-10**

**25-3** Some contracts with customers may have no fixed duration and can be terminated or modified by either party at any time. Other contracts may automatically renew on a periodic basis that is specified in the contract. An entity shall apply the guidance in this Topic to the duration of the contract (that is, the contractual period) in which the parties to the contract have present enforceable rights and obligations. In evaluating the criterion in paragraph 606-10-25-1(e), an entity shall assess the collectibility of the consideration promised in a contract for the goods or services that will be transferred to the customer rather than assessing the collectibility of the consideration promised in the contract for all of the promised goods or services (see paragraphs 606-10-55-3A through 55-3C). However, if an entity determines that all of the criteria in paragraph 606-10-25-1 are met, the remainder of the guidance in this Topic shall be applied to all of the promised goods or services in the contract.

In the life sciences industry, CROs typically enter into long-term contracts with their customers to perform clinical trial management services. Because of the high failure rates in the clinical development process, it is customary for CROs in the industry to provide the customer the right to terminate the contract with the CRO without cause. The customer is often required to give a specified notice of termination (e.g., 30 days) and to compensate the CRO for all work performed through the date

of termination, as well as for any noncancelable arrangements the CRO has entered into and any wind-down activities required to close the study. In addition, some contracts may include a termination fee for early cancellation of a study.

#### *2.3.4.1 Termination Clauses and Penalties*

When contracts have termination clauses and penalties, the duration of the contract is predicated on the contract's enforceable rights and obligations. Accordingly, regardless of whether one or both parties have the right to terminate the contract, an entity would need to evaluate the nature of the termination provisions, including whether any termination penalty is substantive. For example, an entity would assess factors such as (1) whether the terminating party is required to pay compensation, (2) the amount of such compensation, and (3) the reason for the compensation (i.e., whether the compensation is in addition to amounts due for goods and services already delivered). Substantive termination penalties suggest that the parties' rights and obligations extend for the duration of the contract term.

A contract's accounting term could be less than the contract's stated term if a termination penalty is not substantive. For example, a 12-month stated contract term could, in effect, be a month-to-month contract if the contract could be terminated each month and the termination penalty is not substantive. An entity will need to carefully consider the effect of nonsubstantive termination penalties on the timing and amount of revenue to be recognized.

Because the assessment of termination clauses and penalties focuses on legally enforceable rights and obligations, certain economic factors such as economic compulsion should not be considered. Rather, the assessment depends on whether the terminating party is required to compensate the other party. For example, an entity may have a long-term agreement with a customer for a unique good or service that is critical to the customer's operations. If the agreement allows the customer to terminate it at any point and there are no contractual penalties if the customer does not purchase any goods or services, a contract for the purchase of additional goods or services does not exist even if it is highly likely that the customer will not terminate the agreement.

The economic considerations related to forgoing a discount on optional purchases would not be viewed as a substantive penalty suggesting that the parties' rights and obligations extend for a longer contract term. The discount on optional purchases should be assessed for the existence of a material right instead. Therefore, while an "economic" penalty may be incurred by a customer that elects not to purchase future but optional goods at a discount, that economic penalty would not rise to the level of a substantive penalty that lengthens the contract term.

The determination of whether a termination penalty is substantive requires judgment and would be evaluated both quantitatively and qualitatively. For example, data about the frequency of contract terminations may be useful in such a determination (i.e., a high frequency of payments made to terminate contracts may suggest that the termination provision is not substantive). Determining the enforceable term of a contract that includes termination provisions (e.g., cancellation fees) may be challenging, particularly when only the customer has a right to terminate the contract. When a customer has a right to terminate the contract without penalty, such termination provision is substantively the same as a renewal provision, as supported by both paragraph BC391 of ASU 2014-09 and Q&A 8 of the FASB staff's *Revenue Recognition Implementation Q&As* (the "Implementation Q&As").

In practice, CROs often experience a low frequency of payments made to terminate contracts, which may suggest that the termination provisions are substantive. A substantive termination penalty is evidence of enforceable rights and obligations on the part of both parties throughout the period in which the substantive termination penalty applies.

#### 2.3.4.1.1 Termination Clauses in License Arrangements

As noted in Section 2.3.4.1 above, an entity needs to evaluate the nature of termination provisions, including whether any penalties are substantive (i.e., whether the transfer of any consideration from the customer to the entity is substantive). Careful consideration is required in the evaluation of whether giving up license rights is a form of penalty.

Implementation Q&As 7 and 8 include the following factors that an entity should consider when determining whether a termination penalty is substantive:

- Whether the terminating party is required to pay compensation.
- The amount of such compensation.
- The reason for the compensation (i.e., whether the compensation is in addition to amounts due for goods and services already delivered).

The example below illustrates how an entity would determine whether a license arrangement includes a substantive termination penalty.

**Example 2-6**

Company A, a pharmaceutical company in the United States, owns and maintains a portfolio of patents related to an antibiotic that treats life-threatening diseases. On February 23, 20X8, A grants Customer B (a pharmaceutical company in Ireland) the exclusive right to use its patented drug formula to commercialize and supply the antibiotic in Europe. The IP is fully developed, and regulatory approval has been obtained; therefore, B is able to commercialize the IP. Company A has determined that the patented drug formula is functional IP and that therefore, the license grants B the right to use the IP.

In exchange for the exclusive right to use the patented drug formula, B agrees to pay A the following amounts:

- An up-front fee of $300 million.
- Annual fixed fees of $50 million payable at the end of each year in which the contract is effective.
- Sales-based royalties of 5 percent of B's sales of the antibiotic in Europe (recognized in accordance with the sales-based royalty exception in ASC 606-10-55-65).

The contract states that B has the exclusive right to use the patented drug formula through the patent term, which expires in 10 years (i.e., the contract ends when the patent expires). Notwithstanding the stated contract term, the contract states that B may terminate the contract before the expiration of the patent by providing three months' notice to A. All amounts already paid by B are nonrefundable in the event of early termination. The contract does not include an explicit termination penalty (i.e., B is not required to pay additional cash consideration to A upon early termination); however, upon early termination, the right to the patented drug formula in Europe would revert back to A, and A would be able to relicense the patented drug formula to a different pharmaceutical company in Europe. Unless B terminates the contract before the end of the stated term, A would not be able to benefit from licensing the patented drug formula to a different pharmaceutical company in Europe (i.e., A would receive this benefit only upon B's early termination of the contract).

Under these facts, A's contract to license the exclusive right to use its patented drug formula to B contains a substantive termination penalty. As previously discussed in Section 2.3.4.1, it is important for an entity to evaluate the nature of the termination provisions in its contracts to determine the appropriate contract term for applying ASC 606.

**Example 2-6 (continued)**

In this example, A's contract to license the patented drug formula to B does not include an explicit termination penalty. That is, B can terminate the contract before the end of the stated term by providing three months' notice without paying additional cash consideration to A. Although the contract does not require B to pay additional cash consideration to A upon early termination, in the event that B terminates the contract early, the exclusive license rights related to the patented drug formula would revert back to A. Company A would then be able to license the patented drug formula to another customer in Europe for the remainder of the patent term, which it would not have been able to do if B had not terminated the contract. Therefore, although B is not paying additional cash to A upon termination, B is providing consideration (i.e., something of value) to A, and A is receiving something of value from B (i.e., the right to relicense the patented drug formula), upon termination. Although Implementation Q&As 7 and 8 focus on compensation as additional cash that an entity's customer would pay to the entity upon termination, compensation may also include noncash consideration that is of value to the entity. The fact that B is forfeiting its rights to the patented drug formula and providing A with something of value (i.e., the ability to relicense the patented drug formula to another customer in Europe) from the forfeiture upon early termination represents a substantive termination penalty in the contract.

In accordance with Implementation Q&As 7 and 8, the substantive termination penalty suggests that the parties' rights and obligations extend for the duration of the stated contract term. That is, the contract term is 10 years.

## 2.3.5 Contract Modifications

**ASC 606-10**

**25-10** A contract modification is a change in the scope or price (or both) of a contract that is approved by the parties to the contract. In some industries and jurisdictions, a contract modification may be described as a change order, a variation, or an amendment. A contract modification exists when the parties to a contract approve a modification that either creates new or changes existing enforceable rights and obligations of the parties to the contract. A contract modification could be approved in writing, by oral agreement, or implied by customary business practices. If the parties to the contract have not approved a contract modification, an entity shall continue to apply the guidance in this Topic to the existing contract until the contract modification is approved.

**25-11** A contract modification may exist even though the parties to the contract have a dispute about the scope or price (or both) of the modification or the parties have approved a change in the scope of the contract but have not yet determined the corresponding change in price. In determining whether the rights and obligations that are created or changed by a modification are enforceable, an entity shall consider all relevant facts and circumstances including the terms of the contract and other evidence. If the parties to a contract have approved a change in the scope of the contract but have not yet determined the corresponding change in price, an entity shall estimate the change to the transaction price arising from the modification in accordance with paragraphs 606-10-32-5 through 32-9 on estimating variable consideration and paragraphs 606-10-32-11 through 32-13 on constraining estimates of variable consideration.

Contract modifications can frequently happen in the normal course of business. Any time an entity and its customer agree to change what the entity promises to deliver or the amount of consideration the customer will pay (i.e., creates or changes the enforceable rights or obligations in a preexisting contract), there is a contract modification.

The first step in the identification of a contract modification is to assess whether, for a contract accounted for under ASC 606, there has been a change in the contract's scope or price, or both. The second step is to determine whether the parties to the contract have agreed upon the change. As defined above, contract modifications must be agreed to by both parties (written, orally, or through customary business practices). That is, both parties must agree to change the enforceable rights and obligations of the contract.

As noted above, CROs in the life sciences industry often enter into long-term contracts with their customers to perform clinical trial management services. Changes in the scope of these contracts is common in the industry.

If a CRO and its customer agree upon a change to a contract and the change qualifies as a contract modification under ASC 606-10-25-10 and 25-11, the CRO will be required to evaluate the appropriate accounting for that contract modification.

If a change in a contract qualifies as a contract modification under ASC 606-10-25-10 and 25-11, the entity must assess the goods and services and their selling prices. Depending on whether those goods and services are distinct or sold at their stand-alone selling prices, a modification can be accounted for as:

- A separate contract (see ASC 606-10-25-12).
- One of the following (if the modification is **not** accounted for as a separate contract):
  - A termination of the old contract and the creation of a new contract (see ASC 606-10-25-13(a)).
  - A cumulative catch-up adjustment to the original contract (see ASC 606-10-25-13(b)).
  - A combination of the items described in ASC 606-10-25-13(a) and (b), in a way that faithfully reflects the economics of the transaction (see ASC 606-10-25-13(c)).

### *2.3.5.1 Contract Modification Accounted for as a Separate Contract*

**ASC 606-10**

**25-12** An entity shall account for a contract modification as a separate contract if both of the following conditions are present:

a. The scope of the contract increases because of the addition of promised goods or services that are distinct (in accordance with paragraphs 606-10-25-18 through 25-22).
b. The price of the contract increases by an amount of consideration that reflects the entity's standalone selling prices of the additional promised goods or services and any appropriate adjustments to that price to reflect the circumstances of the particular contract. For example, an entity may adjust the standalone selling price of an additional good or service for a discount that the customer receives, because it is not necessary for the entity to incur the selling-related costs that it would incur when selling a similar good or service to a new customer.

When an entity accounts for a contract modification as a separate contract in accordance with ASC 606-10-25-12, the entity's accounting for the original contract is not affected by the modification. Any revenue recognized through the date of the modification is not adjusted, and remaining performance obligations will continue to be accounted for under the original contract. The new contract is accounted for separately from the original contract and on a prospective basis.

There is no economic difference between (1) a modification of an existing contract with a customer that includes additional *distinct* goods or services at their *representative stand-alone selling prices* and (2) a completely new contract entered into by the two parties for goods or services at their representative stand-alone selling prices. Therefore, a modification of an existing contract should be accounted for as a new contract that is separate and apart from the existing contract when (1) there are additional *distinct* goods or services promised to a customer *and* (2) those goods or services are in exchange for consideration that *represents the stand-alone selling prices* of the additional distinct promised goods or services.

Because a modification to a CRO contract often may not add "distinct" goods or services at a price that reflects the stand-alone selling price of those goods or services, such a modification is generally not accounted for as a new contract separate from the original contract. Instead, as further discussed below, this type of modification is typically (1) viewed as part of a single performance obligation that is partially satisfied on the date of the modification and (2) accounted for as if it were part of the original contract.

A modification that results in a decrease in scope cannot be accounted for as a separate contract because the criterion in ASC 606-10-25-12(a) specifying an *increase* in the scope of the contract is not met.

Some contract modifications may meet the criterion in ASC 606-10-25-12(a) because they include additional promised goods or services that are distinct. To conclude that these contract modifications should be accounted for as a separate contract, an entity should be able to demonstrate that the price of the contract increases by an amount of consideration that reflects (1) the entity's stand-alone selling prices of the additional promised goods or services and (2) any appropriate adjustments to that price that take into account the circumstances of the particular contract. This may be challenging in certain arrangements in which stand-alone selling prices are not readily determinable. For example, life sciences entities frequently enter into collaborative arrangements that are accounted for under ASC 606, as discussed in Section 2.2.1.2. Occasionally, these arrangements are modified to include additional compounds that the collaboration partners agree to develop. Questions may arise about how an entity should apply ASC 606-10-25-12(b) since similar compounds may not have been previously sold or licensed to other parties. See Section 2.6 for a discussion of factors that an entity should consider when assessing the stand-alone selling price. Given the judgment required in making this determination, consultation with an entity's accounting advisers is recommended.

### *2.3.5.2 Contract Modification Not Accounted for as a Separate Contract*

**ASC 606-10**

**25-13** If a contract modification is not accounted for as a separate contract in accordance with paragraph 606-10-25-12, an entity shall account for the promised goods or services not yet transferred at the date of the contract modification (that is, the remaining promised goods or services) in whichever of the following ways is applicable:

a. An entity shall account for the contract modification as if it were a termination of the existing contract, and the creation of a new contract, if the remaining goods or services are distinct from the goods or services transferred on or before the date of the contract modification. The amount of consideration to be allocated to the remaining performance obligations (or to the remaining distinct goods or services in a single performance obligation identified in accordance with paragraph 606-10-25-14(b)) is the sum of:
   1. The consideration promised by the customer (including amounts already received from the customer) that was included in the estimate of the transaction price and that had not been recognized as revenue and
   2. The consideration promised as part of the contract modification.

b. An entity shall account for the contract modification as if it were a part of the existing contract if the remaining goods or services are not distinct and, therefore, form part of a single performance obligation that is partially satisfied at the date of the contract modification. The effect that the contract modification has on the transaction price, and on the entity's measure of progress toward complete satisfaction of the performance obligation, is recognized as an adjustment to revenue (either as an increase in or a reduction of revenue) at the date of the contract modification (that is, the adjustment to revenue is made on a cumulative catch-up basis).

c. If the remaining goods or services are a combination of items (a) and (b), then the entity shall account for the effects of the modification on the unsatisfied (including partially unsatisfied) performance obligations in the modified contract in a manner that is consistent with the objectives of this paragraph.

A contract modification that does not meet the requirements outlined in Section 2.3.5.1 is not accounted for as a separate contract. Therefore, an entity would have to determine how to account for a blended contract that now includes one or both of the following:

- An original agreement plus or minus some other goods or services.
- A change in the amount of consideration due under the modified arrangement.

The determination of which model to use depends on whether the remaining goods or services (the originally promised items and the newly promised items) are *distinct* from the goods and services already provided under the contract.

In accordance with ASC 606-10-25-13(a), if the remaining goods or services are distinct from the goods or services already provided under the original arrangement, the entity would in effect establish a "new" contract that includes only those remaining goods and services. In this situation, the entity would allocate to the remaining performance obligations (or distinct goods or services) in the contract (1) consideration from the original contract that has not yet been recognized as revenue and (2) any additional consideration from the modification. Such a situation would arise when there is a modification to a contract that contains (1) remaining distinct performance obligations or (2) a single performance obligation accounted for as a series of distinct goods or services under ASC 606-10-25-14(b).

In contrast, in accordance with ASC 606-10-25-13(b), if the contract modification results in remaining goods and services that are not distinct, the entity should account for the modification as though the additional goods and services were an addition to an incomplete performance obligation. This may be the case when a CRO's contract with a customer contains one performance obligation and the parties modify the terms to change the scope of the services provided. In this instance, a measure of progress, such as costs incurred, would typically be used to recognize revenue over time. For example, suppose that just before the modification, the entity's performance was 30 percent complete. After the modification, the entity may determine that its performance is only 25 percent complete because the scope of the single performance obligation increased (or is 35 percent complete because the scope of the single performance obligation decreased). As a result, an updated revenue figure is calculated on the basis of the revised percentage, and the entity would record a cumulative catch-up adjustment.

The FASB and IASB recognized that there may be contracts in which some performance obligations include remaining goods or services that are distinct from the goods or services already provided under the original arrangement, while other performance obligations include remaining goods and services that are not (i.e., a change in scope of a partially satisfied performance obligation). The boards decided that in those circumstances, it may be appropriate for an entity to apply both models to a single contract, in the manner described in ASC 606-10-25-13(c), on the basis of an assessment at the performance obligation level. An entity would do so by considering whether, for the performance obligations that are not yet fully satisfied (including those that are partially satisfied), the remaining goods or services to be transferred in accordance with the promise are distinct from the goods or services previously transferred. No change would be made to revenue recognized for fully satisfied performance obligations.

## 2.4 Identify the Performance Obligations (Step 2)

Step 2 is one of the most critical steps in the revenue framework since it establishes the unit of account for revenue recognition. This step requires an entity to identify what it has promised to the customer. The entity then determines whether a promise or multiple promises represent one or more performance obligations to the customer. To accomplish this, the entity should determine whether the promises in the contract are distinct. ASC 606-10-25-19 notes that a "good or service that is promised to a customer is distinct if both of the following criteria are met":

a. The customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (that is, the good or service is capable of being distinct).

b. The entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (that is, the promise to transfer the good or service is distinct within the context of the contract).

Further, ASC 606-10-25-22 states that "[i]f a promised good or service is not distinct, an entity shall combine that good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct. In some cases, that would result in the entity accounting for all the goods or services promised in a contract as a single performance obligation."

The standard's guidance on determining whether a customer can benefit from a good or service on its own or together with other readily available resources is generally consistent with the legacy guidance in ASC 605-25 on determining whether a good or service has "stand-alone value."

To help an entity assess whether its promises to transfer goods or services to the customer are separately identifiable, ASC 606-10-25-21 identifies the following factors "that indicate that two or more promises to transfer goods or services to a customer are **not** separately identifiable" (emphasis added):

a. The entity provides a significant service of integrating [the] goods or services with other goods or services promised in the contract . . . In other words, the entity is using the goods or services as inputs to produce or deliver the combined output or outputs specified by the customer. . . .

b. One or more of the goods or services significantly modifies or customizes, or are significantly modified or customized by, one or more of the other goods or services promised in the contract.

c. The goods or services are highly interdependent or highly interrelated. In other words, each of the goods or services is significantly affected by one or more of the other goods or services in the contract. For example, in some cases, two or more goods or services are significantly affected by each other because the entity would not be able to fulfill its promise by transferring each of the goods or services independently.

In the life sciences industry, CROs often provide multiple services for their pharmaceutical and biotechnology customers. For example, CROs may help design studies, recruit investigators (physicians), recruit patients, help manage clinical trials, monitor safety, and write reports on study results. These services are generally considered to represent a single performance obligation because they are not "separately identifiable."

Some of the other more common issues that life sciences entities have faced when considering step 2 of the revenue standard are discussed below.

### 2.4.1 License of IP Bundled With Other Services

Arrangements involving the license of IP and other services (e.g., contract R&D services or contract manufacturing services) are common in the life sciences industry. For example, biotechnology companies frequently enter into license and development arrangements with pharmaceutical companies, and contract manufacturers frequently enter into license and supply arrangements with pharmaceutical companies.

Life sciences entities that grant a license bundled with other services (e.g., contract R&D services or contract manufacturing services) may need to use significant judgment when determining whether the goods or services in a contract (1) are capable of being distinct (have stand-alone value) and (2) are not highly interdependent or highly interrelated and do not significantly modify or customize one another (are separately identifiable). While the analysis of whether the goods or services are capable of being distinct is generally consistent with the analysis of stand-alone value under legacy guidance, the "separately identifiable" concept may require entities to account for a bundle of goods or services, which may have represented separate units of account under legacy guidance, as a single performance obligation (unit of account) under the revenue standard.

### 2.4.2 Feasibility of Performance of the Same Services by Another Vendor

In the evaluation of whether a license of IP and contract R&D services (or contract manufacturing services) are separate performance obligations, an entity may need to consider whether it is feasible for another vendor to provide the same services.

ASC 606-10-55-367 through 55-372A, relevant parts of which are reproduced below, include two fact patterns that illustrate how the determination of whether it is feasible for another life sciences entity to provide the same services affects the analysis of whether the "capable of being distinct" criterion is met.

**ASC 606-10**

Example 56 — Identifying a Distinct License

**55-367** An entity, a pharmaceutical company, licenses to a customer its patent rights to an approved drug compound for 10 years and also promises to manufacture the drug for the customer for 5 years, while the customer develops its own manufacturing capability. The drug is a mature product; therefore, there is no expectation that the entity will undertake activities to change the drug (for example, to alter its chemical composition). There are no other promised goods or services in the contract.

*Case A — License Is Not Distinct*

**55-368** In this case, no other entity can manufacture this drug while the customer learns the manufacturing process and builds its own manufacturing capability because of the highly specialized nature of the manufacturing process. As a result, the license cannot be purchased separately from the manufacturing service.

**55-369** The entity assesses the goods and services promised to the customer to determine which goods and services are distinct in accordance with paragraph 606-10-25-19. The entity determines that the customer cannot benefit from the license without the manufacturing service; therefore, the criterion in paragraph 606-10-25-19(a) is not met. Consequently, the license and the manufacturing service are not distinct, and the entity accounts for the license and the manufacturing service as a single performance obligation.

*Case B — License Is Distinct*

**55-371** In this case, the manufacturing process used to produce the drug is not unique or specialized, and several other entities also can manufacture the drug for the customer.

**ASC 606-10 (continued)**

**55-372** The entity assesses the goods and services promised to the customer to determine which goods and services are distinct, and it concludes that the criteria in paragraph 606-10-25-19 are met for each of the license and the manufacturing service. The entity concludes that the criterion in paragraph 606-10-25-19(a) is met because the customer can benefit from the license together with readily available resources other than the entity's manufacturing service (that is, because there are other entities that can provide the manufacturing service) and can benefit from the manufacturing service together with the license transferred to the customer at the start of the contract.

**55-372A** The entity also concludes that its promises to grant the license and to provide the manufacturing service are separately identifiable (that is, the criterion in paragraph 606-10-25-19(b) is met). The entity concludes that the license and the manufacturing service are not inputs to a combined item in this contract on the basis of the principle and the factors in paragraph 606-10-25-21. In reaching this conclusion, the entity considers that the customer could separately purchase the license without significantly affecting its ability to benefit from the license. Neither the license nor the manufacturing service is significantly modified or customized by the other, and the entity is not providing a significant service of integrating those items into a combined output. The entity further considers that the license and the manufacturing service are not highly interdependent or highly interrelated because the entity would be able to fulfill its promise to transfer the license independent of fulfilling its promise to subsequently manufacture the drug for the customer. Similarly, the entity would be able to manufacture the drug for the customer even if the customer had previously obtained the license and initially utilized a different manufacturer. Thus, although the manufacturing service necessarily depends on the license in this contract (that is, the entity would not contract for the manufacturing service without the customer having obtained the license), the license and the manufacturing service do not significantly affect each other. Consequently, the entity concludes that its promises to grant the license and to provide the manufacturing service are distinct and that there are two performance obligations:

a. License of patent rights
b. Manufacturing service.

### Connecting the Dots

Determining whether R&D services or manufacturing services are separately identifiable from licenses can require significant judgment. While "bright lines" do not exist, the stage of development may be relevant to the determination of whether R&D services are expected to significantly modify or customize the IP (e.g., R&D services for early-stage IP frequently involve activities that lead to changes in a drug compound's formulation, dosing levels, and manufacturing process, whereas R&D services for later-stage IP may only involve validating the drug's efficacy).

Similarly, if the manufacturing of an API is performed to support R&D services, the manufacturing and R&D may not be distinct because the company cannot fulfill its promise to perform R&D independently from its promise to manufacture the API. Conversely, manufacturing of an approved product may be more likely to be "distinct" if another party could perform the services.

## 2.4.3 Contractual Requirement to Use the Entity's Services

A revenue arrangement for the license of IP and contract R&D services (or contract manufacturing services) may contain a contractual requirement that the entity's customer must use the entity's services. A contractual requirement that the entity's customer must use the entity's R&D services (or manufacturing services) does not change the evaluation of whether the promised goods and services are distinct. In accordance with ASC 606-10-55-150F, "[t]his is because the contractual requirement to use the entity's . . . services does not change the characteristics of the goods or services themselves, nor

does it change the entity's promises to the customer." Specifically, paragraph BC100 of ASU 2014-09 notes the following:

> The Boards observed that the assessment of whether the "customer can benefit from the goods or services on its own" should be based on the characteristics of the goods or services themselves instead of the way in which the customer may use the goods or services. Consequently, an entity would disregard any contractual limitations that might preclude the customer from obtaining readily available resources from a source other than the entity.

Accordingly, if the license and the services are otherwise capable of being distinct and separately identifiable, the license and the services would be accounted for as two performance obligations.

### 2.4.4 Assessing the Availability of Alternative Service Providers and Its Impact on the Identification of Performance Obligations

The illustrative examples in ASC 606 provide certain facts used to support a determination of whether a promised good or service is distinct and therefore a separate performance obligation. However, some facts may vary between examples while the conclusions are consistent. For instance, in Example 11, Case C (ASC 606-10-55-150A through 55-150D), one of the facts provided to support the conclusion that the equipment and installation services represent two performance obligations is that others can provide the installation services. However, in Example 11, Case E (ASC 606-10-55-150G through 55-150K), the conclusion that the equipment and specialized consumables are two performance obligations is reached even though the specialized consumables are not available from other entities. This is because the entity in the example would be able to fulfill each of its promises in the contract (i.e., each promise to provide an item of equipment and consumables) independently of the other promises.

If a good or service (e.g., installation service) is unavailable from alternative providers, or available from only a limited number of alternative providers, an entity is not precluded from considering the good or service to be a separate performance obligation. The unavailability of a good or service from alternative providers is a factor for an entity to consider in evaluating whether the good or service is distinct (and therefore a separate performance obligation), but that factor is not individually determinative (as noted in the examples cited above). Entities need to use judgment in evaluating whether a promise to provide a good or service, in addition to other goods or services, is capable of being distinct and is distinct within the context of the contract (i.e., separately identifiable) in accordance with ASC 606-10-25-19. In making that determination, an entity may focus on why a good or service is or is not available from other providers, especially when evaluating the following factors in ASC 606-10-25-21 to conclude on whether the good or service is separately identifiable:

- Whether there is a significant service of integrating goods or services.
- Whether the good or service significantly modifies or customizes another good or service.
- Whether the good or service and one or more other goods or services are highly interdependent or highly interrelated.

For example, if an entity sells medical device equipment and provides installation of that equipment, the determination of whether the installation services are available from another entity would be a factor to be considered in the evaluation of whether the installation is distinct within the context of the contract, but that factor alone would not be determinative. It is important for the reporting entity to consider why the installation is unavailable from (or available from only a limited number of) alternative providers to determine whether the installation is separately identifiable in accordance with ASC 606-10-25-21. For example, if the entity has a standard installation process that does not significantly customize or modify the equipment for the entity's customer, the entity may conclude that the installation is separately identifiable regardless of whether there are no other installation providers or only a limited number of

such providers. However, installation services that are unique and significantly modify or customize the equipment for the customer may suggest that the services are not separately identifiable and therefore are not distinct within the context of the contract.

**Connecting the Dots**

In the life sciences industry, manufacturing facilities and processes are frequently required to be approved by regulators (e.g., the FDA). The absence of alternative facilities with regulatory approval to manufacture a particular product can affect the "distinct" analysis for arrangements involving a license of IP and manufacturing services.

Similarly, biotechnology companies that enter into revenue arrangements with pharmaceutical companies are frequently required by contract to participate in a joint steering committee in addition to licensing a drug candidate and performing R&D services. Although the obligation to participate in a joint steering committee could be determined to be a promised service, it may not represent a "distinct" service unless, for example, other parties could perform the service and the service does not involve a significant integration of other goods and services in the arrangement.

### 2.4.5 Warranties

Companies that offer a warranty on their products sold (e.g., medical devices) must assess whether the warranty represents a distinct service that should be accounted for as a separate performance obligation.

It is important to determine what type of warranty an entity offers to a customer because the way in which revenue is recognized will vary depending on that determination. An entity should determine whether it offers the customer an assurance-type warranty or a service-type warranty. An assurance-type warranty provides the customer with the peace of mind that the entity will fix or possibly replace a good or service if the original good or service was faulty. It is the type of warranty with which most customers are familiar. In contrast, a service-type warranty provides the customer with a service that is incremental to the assurance that the good or service will meet the expectations agreed to in the contract.

An entity may need to use judgment to determine whether a warranty is a service-type warranty (i.e., performance obligation). This is important because, depending on the outcome of the entity's assessment, consideration could be allocated to the performance obligation and consequently change the pattern of revenue recognition.

To assess the nature of a warranty, an entity should consider whether the warranty provides an additional service. It is easy to make this determination if the warranty is sold separately. A contract is considered separately priced if the customer has the option of purchasing the contract for an expressly stated amount separate from the price of the product. As discussed in paragraph BC371 of ASU 2014-09, an entity could also separately negotiate a warranty with a customer and determine that a performance obligation exists.

However, a warranty does not necessarily have to be separately sold or separately negotiated to be considered a performance obligation. To determine whether a warranty is a performance obligation, an entity should consider various indicators in accordance with ASC 606-10-55-33.

A warranty that provides a service **in addition to** the entity's assurance that the goods or services transferred to a customer will function as intended or meet agreed-upon specifications would represent a separate performance obligation. Accordingly, the entity would need to allocate a portion of the transaction price to the separate service and recognize the related revenue when (or as) performance is completed even when this warranty is neither separately priced nor separately negotiated.

If the warranty merely provides what ASC 606-10-55-30 describes as "assurance that the related product will function as the parties intended because it complies with agreed-upon specifications," the assurance is not a service and therefore not a separate performance obligation. For an assurance-type warranty obligation incurred in connection with the sale of a product (i.e., an obligation that is not separately priced or sold or otherwise a separate performance obligation), the costs associated with providing the warranty would be accrued in accordance with ASC 460-10 (see ASC 606-10-55-32).

Assessing the substance of the promise in a warranty arrangement that is neither separately priced nor separately negotiated often will require judgment. To aid in such an assessment, ASC 606-10-55-33 lists three factors that an entity should consider in determining whether a warranty provides the customer with a service in addition to the entity's assurance that the good or service complies with agreed-upon specifications: (1) whether the warranty is required by law, (2) the length of the coverage period, and (3) the nature of the tasks that are promised.

See Section 5.5 of Deloitte's Roadmap *Revenue Recognition* for information related to the evaluation of warranty arrangements.

**Example 2-7**

Company A offers its customers a program under which it would provide them with a free drug vial replacement whenever a drug vial is damaged or broken by a physician before the drug is administered to a patient (subject to a maximum number of drug vials annually per customer). The drug vial replacement program is not separately priced.

Because A has promised to provide a service of replacing a drug vial in situations beyond those addressing manufacturing defects, A determines that the program represents a separate performance obligation that is not separately priced. Therefore, A should (1) determine the stand-alone selling price of the drug vial replacement service and allocate an appropriate portion of the transaction price to it and (2) recognize that portion as revenue over the period in which the drug vial replacement service is provided.

### 2.4.6 Application of the Series Provision in Life Sciences Arrangements

Entities in the life sciences industry may enter into service arrangements with other entities in the industry as part of their product development process or commercialization strategies. For example, the developer of a drug compound or other IP may enter into an arrangement with a CRO for clinical research services ("R&D services"). These R&D services may involve various tasks such as patient enrollment, clinical trial site management, and activities related to regulatory filings. While the two entities agree to a set of objectives, the CRO providing the R&D services may not promise or guarantee an end result. Instead, the CRO satisfies its performance obligation to the IP developer by giving the developer access to clinical professionals to advance the R&D efforts toward agreed-upon objectives. Given the nature of such R&D services, the services may not be performed consistently or consecutively over the service period, and their nature and scope may change as the work progresses.

Conversely, a life sciences entity may commercialize its approved pharmaceutical products by retaining an outsourced sales team to promote and sell its products. The nature of the selling services may differ from R&D services in that each day's service is not modified or customized by another day's service, one day's service is not an input with another day's service that results in a combined output, and the services performed on different days are not highly interdependent or highly interrelated.

An entity's application of ASC 606 to a contract with a customer may be affected by whether the entity determines that its promises to the customer represent (1) a single combined performance obligation comprising multiple activities that are not distinct or (2) a single performance obligation consisting of a series of distinct increments. Specifically, the application of the guidance on allocating variable consideration, accounting for contract modifications, and providing disclosures related to remaining performance obligations differs for a series of distinct increments of goods or services. We believe that the determination of whether R&D or selling services provided by entities in the life sciences industry represent a series may require significant judgment.

The first step in the evaluation of whether an entity's promise to provide R&D or selling services to a customer represents a series is to assess whether the nature of the promise is one of the following:

- The delivery of a specified quantity of goods or services.
- A stand-ready obligation to provide an indefinite amount of goods or services during a specified period.

If the nature of the promise is to deliver a specified quantity of goods or services, the entity must determine whether *each good or service* is distinct, is substantially the same as the other goods or services, and has the same pattern of transfer to the customer as that of the other goods or services. If, on the other hand, the nature of the promise is to stand ready for a specified period, the entity must determine whether, for *each increment of time*, its promise of standing ready to provide the R&D or selling services is distinct, is substantially the same as its promise for each of the other increments of time, and has the same pattern of transfer to the customer as its promise for each of the other increments of time.

Contracts in the life sciences industry to perform R&D services appear in various forms. For example, some contracts may include a license to IP in addition to the R&D services. If it is determined that the license and the R&D services are both within the scope of ASC 606 but are not distinct promises (or if the customer already has control of a license and the entity's only promise in the contract is to provide R&D services), the series guidance may not apply to the combined performance obligation if the R&D services provided throughout the development period are cumulative in that each increment of service builds on and is dependent on the increments that precede it (i.e., such services would not be considered distinct within the context of the contract). This could be the case when the R&D activities performed on a particular day significantly modify the results of R&D performed on previous days in such a way that the R&D services performed on different days are highly interdependent, highly interrelated, or both. In such a case, the R&D services would generally be accounted for as a single combined performance obligation consisting of multiple activities that are *not* distinct, as opposed to a series of distinct increments of time or service. In certain other cases, R&D services may meet the criteria to be accounted for as a series, as illustrated in the example below.

**Example 2-8**

Entity X, a CRO, enters into an arrangement with Pharma, the developer of a new drug compound, to perform daily R&D services for Pharma as needed during phase III clinical trials by giving Pharma access to clinical professionals. In exchange for the R&D services provided to Pharma, X will receive a daily fee per person and success-based milestone payments.

The activities to be performed may vary each day as X and Pharma work toward agreed-upon objectives in connection with the phase III clinical trials. While the activities may vary by day, they represent fulfillment activities associated with providing the daily R&D services and do not represent separate promises in the arrangement. Further, X has determined that such services are readily available in the marketplace and are not cumulative because each day's research and corresponding results are not dependent on the prior day's research; thus, each day of services does not build on activities that precede it, and each day of services and the activities that precede it are not integrated, interdependent, or interrelated. That is, no day of services significantly affects either X's ability to fulfill another day of services or the benefit to Pharma of another day of services.

Entity X determines that Pharma is a customer within the context of providing the services and therefore likewise concludes that the services are within the scope of ASC 606. In addition, X determines that the services to be provided to Pharma meet the criteria in ASC 606-10-25-27(a) for recognition of revenue over time since the services performed during each increment of time contribute to Pharma's development of the drug compound and thereby allow Pharma to simultaneously receive and consume the benefits provided by X's performance as each task is performed.

**Nature of the Promise**

Entity X determines that the nature of its promise is to stand ready to provide daily R&D services as needed during phase III clinical trials. Accordingly, X must assess whether, for each increment of time, its promise of standing ready to provide the R&D services (1) is distinct, (2) is substantially the same as its promise for each of the other increments of time, and (3) has the same pattern of transfer to the customer as its promise for each of the other increments of time.

**Distinct**

Pharma benefits from each day of services on its own since the services contribute to Pharma's development of the drug compound and are readily available in the marketplace. Consequently, X concludes that each increment of services is capable of being distinct.

In addition, X determines that each increment of services is distinct within the context of the contract. This is because each day of services (1) does not significantly modify or customize another day of services and (2) does not significantly affect X's ability to fulfill another day of services or the benefit to Pharma of another day of services since the R&D services are not cumulative, as noted above.

**Substantially the Same**

Entity X determines that for all of the increments of time during which R&D services are performed, its promise of standing ready to perform those services is substantially the same. While the specific tasks or services performed during each increment of time will vary, the nature of the overall promise to provide Pharma with daily R&D services remains the same throughout the contract term.

**Same Pattern of Transfer**

Entity X determines that the services have the same pattern of transfer to Pharma because both criteria in ASC 606-10-25-15 are met. The criterion in ASC 606-10-25-15(a) is met because each distinct service meets the criteria in ASC 606-10-25-27 to be a performance obligation satisfied over time since Pharma simultaneously receives and consumes the benefits provided by X as X performs. The criterion in ASC 606-10-25-15(b) is met because the same measure of progress (in this case, a time-based output method) would most likely be used to measure the progress of X toward satisfying its promise to provide the daily R&D services.

**Conclusion**

On the basis of the above, X concludes that the R&D services are a series and accounts for them accordingly.

A similar conclusion might be reached for outsourced selling services. For example, each day of selling services may meet the criteria to be accounted for as a series for the following reasons:

- The selling services are distinct because:
  - The customer can benefit from the sales force activities each day as the sales force promotes and sells the pharmaceutical products.
  - Each day (or increment) of selling services does not affect any other day (or increment) of selling services. That is, each day's services may not be modified or customized by another day's services, one day of services is not an input with another day of services that results in a combined output, and the services performed on different days are not highly interdependent or highly interrelated. That is, the entity providing the selling services can satisfy its promise to transfer selling services each day separately from a subsequent day of services.
- All increments (i.e., days) of the selling services are substantially the same (i.e., providing a comprehensive selling service). The volume of services may vary as a result of factors such as attrition of the sales representatives, the doctors' offices visited, and the different selling activities conducted each day, but the nature of the promise is the same each day and the customer benefits from the services in the same manner each day.
- The customer simultaneously receives and consumes the benefits of having an outsourced sales force selling its pharmaceutical products. That is, the customer benefits from each increment of service (i.e., day, week, or month). In addition, if the contract were to be terminated, a third party would not need to reperform the selling services already provided since the customer would have already benefited from the sales that were made. As a result, each increment of service is distinct and is satisfied over time, and the same method (time elapsed) would most likely be used to measure the service provider's progress toward complete satisfaction of the performance obligation to transfer each distinct service in the series to the customer.

### 2.4.7 Framework for Identifying Immaterial Promised Goods or Services

ASC 606-10-25-16A states, in part, that an entity "is not required to assess whether promised goods or services are performance obligations if they are immaterial in the context of the contract with the customer." This guidance should not be applied to a customer option to acquire additional goods and services that provides a customer with a material right in accordance with ASC 606-10-55-41 through 55-45.

ASC 606-10-25-16A and 25-16B provide the following guidance on immaterial promised goods or services:

**ASC 606-10**

**25-16A** An entity is not required to assess whether promised goods or services are performance obligations if they are immaterial in the context of the contract with the customer. If the revenue related to a performance obligation that includes goods or services that are immaterial in the context of the contract is recognized before those immaterial goods or services are transferred to the customer, then the related costs to transfer those goods or services shall be accrued.

**25-16B** An entity shall not apply the guidance in paragraph 606-10-25-16A to a customer option to acquire additional goods or services that provides the customer with a material right, in accordance with paragraphs 606-10-55-41 through 55-45.

In light of the wording in ASC 606-10-25-16A and 25-16B, stakeholders have asked about the framework an entity should use to identify a potential good or service that is immaterial in the context of the contract. We believe that the following considerations are relevant to the assessment of whether a good or service is immaterial in the context of the contract:

- An entity may conclude that a potential good or service is immaterial in the context of the contract if the estimated stand-alone selling price of the potential good or service is immaterial (quantitatively) compared with the total consideration in the contract (i.e., the amount that would be allocated to such good or service is immaterial in the context of the contract).
- An entity may conclude that a potential good or service is immaterial in the context of the contract if it determines that the customer does not consider the potential good or service to be material to the contract (i.e., the entity would evaluate qualitative factors, including the customer's perspective, in determining whether a potential good or service is immaterial in the context of the contract).
- An entity may conclude that a potential good or service is immaterial in the context of the contract if it determines that the customer would have entered into the contract and paid the same (or similar) consideration if the potential good or service was excluded from the contract.

For example, a medical device company might offer basic training or education services for equipment that it sells to a hospital. The value of this type of service may be immaterial (quantitatively) compared with the total consideration in the contract. Further, the basic training or education may not be a service that the customer considers to be material to the contract.

In addition, we think that when an entity performs an assessment to identify immaterial promised goods or services, it should also consider the guidance in ASC 606-10-25-16B on customer options (i.e., potential material rights) as well as the SEC staff's view of "material" as discussed in SAB Topic 1.M.

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As noted above, an entity should not apply the guidance in ASC 606-10-25-16A to a customer option to acquire additional goods or services that provides the customer with a material right. For example, a life sciences company may have a practice of providing customers with the ability to purchase 12 weeks of treatment at list price with an option to purchase an additional 12 weeks of treatment at a significantly discounted price if it is determined that the patient is benefiting from the treatment and additional treatment will be helpful. This type of discount on future treatments based on the efficacy of a drug during the initial treatment period may represent a material right. Similarly, arrangements that include the delivery of free drugs after a contractually defined purchase volume has been achieved may include a material right. Options that are deemed to represent material rights — and, therefore, a performance obligation — would result in a deferral of revenue associated with that performance obligation, as discussed below.

### 2.4.8 Customer Options for Additional Goods or Services (Material Rights)

An entity's contract with a customer may give the customer a choice of whether to purchase additional goods or services; such a choice is typically referred to as an option for additional goods or services. Entities are required to identify options for additional goods or services because in certain circumstances, such options can lead to performance obligations. As explained in paragraph BC386 of ASU 2014-09, the FASB and IASB realized that it could be difficult to differentiate between (1) an option for additional goods or services that was paid for by the customer and (2) a marketing or promotional offer for which the customer did not pay. The first type of option for additional goods or services would be identified as a performance obligation to which consideration must be allocated in accordance with step 4 of the revenue standard.

To help entities determine whether an option for additional goods or services is a performance obligation, the boards included the concept of a material right in the revenue standard. If an entity determines that an option for additional goods and services is a material right, the option should be considered a performance obligation. However, an entity will need to use judgment to determine whether a material right exists.

A material right in a contract is provided to a customer only if the customer would not have received it without entering into that contract. The guidance in the revenue standard describes an example of a material right as an option that provides the customer an incremental discount beyond the discounts that are typically given (considering the class of customer).

When an option is identified as providing a customer with a material right, the option is identified as a performance obligation. A portion of the transaction price is then allocated to the option and recognized when (or as) (1) the future goods or services related to the option are provided or (2) the option expires.

#### *2.4.8.1 Determining Whether an Option for Additional Goods or Services Represents a Material Right*

In determining whether an option for future goods or services is a material right, an entity should (1) consider factors outside the current transaction (e.g., the current class of customer) and (2) assess both quantitative and qualitative factors. Further, an entity should also evaluate incentives and programs to understand whether they are customer options designed to influence customer behavior (i.e., an entity should consider incentives and programs from the customer's perspective) because this could be an indicator that an option is a material right.

When determining whether a contract option provides a material right, entities should consider not only the quantitative significance of the option (i.e., the quantitative value of the benefit) but also previous and future transactions with the customer as well as qualitative factors. Specifically, qualitative features such as whether the rights accumulate are likely to provide a qualitative benefit that may give rise to a material right. In accordance with ASC 606-10-25-16B, entities should not apply the guidance in ASC 606-10-25-16A on assessing whether promises for immaterial goods or services are performance obligations to the assessment of whether a contract option provides a material right (i.e., an optional good offered for free or at a discount may not be material for an individual contract but could be material in the aggregate and accounted for as a material right).

An entity should consider its customer's reasonable expectations when identifying promised goods or services. A customer's perspective on what constitutes a material right might consider qualitative factors (e.g., whether the right accumulates). Therefore, a numeric threshold alone might not determine whether a material right is provided by a customer option in a contract.

See Examples 49 through 52 in ASC 606-10-55-336 through 55-356 for examples of how an entity would determine whether an option provides a customer with a material right.

The above issue is addressed in Implementation Q&As 12 through 14 (compiled from previously issued TRG Agenda Papers 6, 11, 54, and 55). For additional information and Deloitte's summary of issues discussed in the Implementation Q&As, see Appendix C of Deloitte's Roadmap *Revenue Recognition*.

#### *2.4.8.2 Likelihood That an Option for Additional Goods or Services Will Be Exercised*

Stakeholders have raised various issues related to whether an entity should assess optional purchases provided to customers to determine whether the customer is economically compelled — or highly likely — to exercise its option(s).

Some business models include arrangements under which a vendor will sell an up-front good or service and also provide the customer with an option to purchase other distinct goods or services in the future that are related to the up-front good or service (e.g., a specialized piece of equipment, such as an infusion pump, and an option to buy specialized consumables that will be needed for its operation, such as infusion tubes used to deliver intravenous medications). Such arrangements may include features that result in a degree of economic compulsion such that there is a very high level of confidence that the customer will exercise its option (e.g., purchase infusion consumables in addition to purchasing the infusion pump).

In such circumstances, when it is highly probable, or even virtually certain, that the customer will exercise its option, the additional goods or services should **not** be treated as performance obligations under the contract. The treatment of customer options is explained in paragraph BC186 of ASU 2014-09, in which the FASB and IASB clarified that "the transaction price does not include estimates of consideration from the future exercise of options for additional goods or services," making no reference to the probability that those options will be exercised.

Accordingly, irrespective of how likely it is that a customer will choose to purchase additional goods or services, the entity should not treat those goods or services as performance obligations under the initial contract. Instead, the entity should evaluate the customer option (in accordance with ASC 606-10-55-41 through 55-45) to determine whether it gives rise to a material right.

The above issue is addressed in Implementation Q&A 21 (compiled from previously issued TRG Agenda Papers 48 and 49). For additional information and Deloitte's summary of issues discussed in the Implementation Q&As, see Appendix C of Deloitte's Roadmap *Revenue Recognition*.

### 2.4.9 Medicare Coverage Gap Discounts

As a result of the Patient Protection and Affordable Care Act, entities participating in Medicare Part D must provide Medicare beneficiaries in the Medicare coverage gap (or "donut hole") with a 50 percent discount and annual increases to a maximum of 75 percent in their Medicare prescription drug coverage. See Section 2.4.9.1 for a discussion of updates to the donut hole resulting from the IRA.

No accounting literature directly addresses the accounting for discounts offered to individuals in the Medicare coverage gap. We believe that under ASC 606, either of the following two methods would be an acceptable policy election:

- *Specific identification approach* — Under this approach, each individual patient purchase is a separate contract and cannot be combined with future "expected" but optional purchases. Accordingly, the consideration due and payable for each individual purchase is attributable to that individual sale. Coverage gap subsidies are viewed as a form of variable consideration attributable to individual sales of products to specific customers in accordance with ASC 606-10-32-6. As a result, the estimate of variable consideration specific to each individual transaction is recorded at the point of sale. In a manner similar to the accounting for any form of variable consideration, an entity would estimate the variability (i.e., the occurrence or nonoccurrence of a future coverage gap discount in accordance with ASC 606-10-32-8) and apply the constraint guidance (ASC 606-10-32-11 and 32-12) before recognizing revenue when control of a purchased pharmaceutical drug is transferred into the distribution channel.

- *Material right approach* — Coverage gap subsidies constitute a material right in accordance with ASC 606-10-55-42. In effect, entities have entered into contractual arrangements with the U.S. government on behalf of Medicare-eligible patients in which the entities offer significant discounts on future purchases through the Medicare channel (i.e., all sales with Medicare-eligible patients throughout the year are "linked"). Under this approach, entities allocate a portion of the transaction price between current sales and the material right, which represents the discount to be provided on future sales to any Medicare-eligible patient within the coverage gap, and recognize the value of the material right in revenue when the coverage gap subsidies are used. This approach is inappropriate if rebates are expected to be made early in the year (as is the case for certain high-priced drugs) because it would be inappropriate to record a contract asset for what otherwise represents optional purchases.

#### *2.4.9.1 Drug Pricing Impacts of the Inflation Reduction Act*

The IRA, which President Biden signed into law on August 16, 2022, includes the following provisions related to pharmaceutical drug pricing:

- *Drug price negotiation* — Selected drugs covered by Medicare Parts B and D will be subject to mandatory price negotiations with Medicare beginning in 2026, with negotiated prices subject to a cap. The number of drugs selected for negotiation will increase from 10 in 2026 to 20 in 2029 and subsequent years. The expenditure data used to determine the drugs selected for negotiation will be related to the period from June 1, 2022, to May 31, 2023. The pricing negotiation period began October 1, 2023.
- *Inflation rebate* — Certain drugs covered by Medicare Parts B and D for which prices are rising at a higher rate than that of inflation will become subject to rebates. Under Medicare Part B, the rebate will first be due with respect to the first quarter of 2023. Under Medicare Part D, the rebate will first be due with respect to the period from October 1, 2022, to September 30, 2023. The initial Medicare Parts B and D benchmark period, with the Consumer Price Index for Urban Consumers (commonly known as CPI-U) used to calculate future inflation rebates, is as of January 1, 2021. On February 9, 2023, the Centers for Medicare & Medicaid Services issued initial guidance on rebatable drugs to the following:
  - Pharmaceutical manufacturers of Part B rebatable drugs and other interested parties.
  - Pharmaceutical manufacturers of Part D rebatable drugs and other interested parties.
- *Medicare Part D benefit redesign* — The Medicare Part D coverage gap (i.e., donut hole) created under the Medicare Modernization Act in 2003 will be eliminated, and as of January 1, 2025, manufacturers will be subject to mandatory discounts on brand drugs in the initial coverage and catastrophic coverage phases. In effect, the change will cap the out-of-pocket spending for Medicare Part D costs at $2,000 per year starting in 2025. The change will be phased in starting in 2024 by capping the out-of-pocket costs at approximately $3,250 in that year.

Implementation of this legislation is expected to be carried out through additional actions by regulatory authorities.

### Connecting the Dots

With the exception of the Medicare Part D inflation rebate, many of the IRA's drug pricing provisions will have staggered effective dates beyond 2022 (the year of the IRA's enactment). Accordingly, life sciences entities should assess the potential financial statement impact of such provisions and, to the extent material, consider disclosure of the anticipated current and future impact on the results of operations, financial position, liquidity, and capital resources in MD&A. For example, potential financial statement impacts may include those related to the following:

- *Inflation rebates* — Inflation rebates represent a form of variable consideration that will become payable if prices of certain drugs covered by Medicare Parts B and D are rising at a higher rate than that of inflation (beginning in 2022 for Part D and 2023 for Part B). Under the revenue standard, an entity must include some or all of an estimate of variable consideration in the transaction price when the entity concludes that it is probable that changes in its estimate of such consideration will not result in significant reversals of cumulative revenue in subsequent periods.
- *Medicare Part D benefit redesign* — The IRA includes a Medicare Part D benefit redesign that, as of January 1, 2025, eliminates the requirement for entities participating in Medicare Part D to provide Medicare beneficiaries in the Medicare coverage gap with a discount in their Medicare prescription drug coverage. However, manufacturers will be subject to mandatory discounts on brand drugs in the initial coverage and catastrophic phases. Under this mandatory discount program, manufacturers generally must offer (1) a 10 percent discount when a beneficiary has satisfied the deductible and incurred costs less than the out-of-pocket threshold and (2) a 20 percent discount when a beneficiary has incurred costs greater than or equal to the out-of-pocket threshold. Because these discounts will vary depending on the costs incurred by the beneficiary, we believe that the specific identification approach and the material right approach methods described above will continue to represent an accounting policy election that entities should consistently apply.
- *Indirect impacts of the IRA on other estimates of variable consideration* — Discounts provided by manufacturers as a result of Medicare drug price negotiations may affect the determination of other estimates of variable consideration. For example, because Medicare prices affect the determination of "best price" used in Medicaid and 340B Drug Pricing Program drug price calculations, estimates of variable consideration associated with those programs may be affected. In addition, manufacturers of non-negotiated drugs in classes with a negotiated Medicare price may need to increase rebates to remain on formularies, which could affect an entity's estimates of variable consideration.

## 2.4.10 Shipping and Handling Activities

Shipping and handling activities are often provided by life sciences entities as part of a revenue arrangement. When goods are shipped free on board (FOB) shipping point, title passes to the buyer when the goods are shipped, and the buyer is responsible for any loss in transit. On the other hand, when goods are shipped FOB destination, title does not pass to the buyer until delivery, and the seller is responsible for any loss in transit.

It is important to understand the shipping terms of an arrangement to determine when control of the good is transferred to the customer. This is because the shipping terms often trigger some of the key control indicators (e.g., transfer of title and present right to payment). Therefore, a careful evaluation of shipping terms is critical to the assessment of transfer of control.

When control is determined to be transferred upon shipment, the seller should consider whether the risk of loss or damage that it assumed during shipping gives rise to another performance obligation (a distinct service-type obligation) that needs to be accounted for separately in accordance with the revenue standard. For example, such risk may represent another performance obligation if goods are frequently lost or damaged during shipping.

Further, entities should consider the practical expedient under U.S. GAAP (ASC 606-10-25-18B, added by ASU 2016-10) that allows entities the option to treat shipping and handling activities that occur after control of the good is transferred to the customer as fulfillment activities. Entities that elect to use this practical expedient would not need to account for the shipping and handling as a separate performance obligation. Instead, when the practical expedient is elected and revenue for the related good is recognized before the shipping and handling activities occur, the entity should accrue the costs of the shipping and handling activities at the time control of the related good is transferred to the customer (i.e., at the time of sale).

Entities should also consider the guidance in ASC 606-10-25-18A, which explains that shipping and handling activities performed before control of a product is transferred do not constitute a promised service to the customer in the contract (i.e., they represent fulfillment costs).

## 2.5 Determine the Transaction Price (Step 3)

In step 3 of the revenue standard, an entity determines the "transaction price," which, as stated in ASC 606-10-32-2, represents "the amount of consideration to which an entity expects to be entitled in exchange for transferring promised goods or services to a customer, excluding amounts collected on behalf of third parties (for example, some sales taxes). The consideration promised in a contract with a customer may include fixed amounts, variable amounts, or both." Because the transaction price is an expected amount, estimates are inherently required. When determining the transaction price, an entity is required under ASC 606-10-32-3 to "consider the effects of all of the following":

- "Variable consideration."
- "Constraining estimates of variable consideration."
- "The existence of a significant financing component in the contract."
- "Noncash consideration."
- "Consideration payable to a customer."

The effects of these elements are particularly relevant to life sciences entities, as explained in the sections below.

### 2.5.1 Variable Consideration

ASC 606-10-32-6 explains that variable consideration may arise "because of discounts, rebates, refunds, credits, price concessions, incentives, performance bonuses, penalties, or other similar items" and that the promised consideration can vary "if an entity's entitlement to the consideration is contingent on the occurrence or nonoccurrence of a future event" (e.g., when "a product [is] sold with a right of return or a fixed amount is promised as a performance bonus on achievement of a specified milestone"). In the life sciences industry, common forms of variable consideration include returns, chargebacks, rebates, cash and volume-based discounts, promotions, shelf stock adjustments, and other adjustments to revenue, as well as royalties, development-based milestones, and sales-based milestones.

### *2.5.1.1 Methods of Estimating Variable Consideration*

Regardless of the form of variability or its complexity, once variable consideration is identified, an entity is required under ASC 606-10-32-8 to estimate the amount of variable consideration to determine the transaction price in a contract with a customer by using either the "expected value" method or the "most likely amount" method, "depending on which method the entity expects to better predict the amount of consideration to which it will be entitled." As ASC 606-10-32-8 explains, the expected value is "the sum of probability-weighted amounts in a range of possible consideration amounts. An expected value may be an appropriate estimate of the amount of variable consideration if an entity has a large number of contracts with similar characteristics." ASC 606-10-32-8 further states that the most likely amount is "the single most likely amount in a range of possible consideration amounts (that is, the single most likely outcome of the contract)."

In the life sciences industry, it may be appropriate for an entity to estimate development-based milestones by using the most likely amount method since the achievement of a milestone has only two possible outcomes (an entity either achieves the milestone or does not achieve it). Other forms of variable consideration may be estimated under the expected value method. For example, estimates of returns under the expected value method may take into account factors such as the following:

- The period in which returns can occur.
- Experiences with products (or the inability to apply such experiences to current products).
- Availability of information about product levels and the age of the product in the distribution channel.
- Predictability of market conditions and competition (e.g., competitive entry of a similar or generic product).
- The current stage in the product life cycle (i.e., initial product launch vs. end/maturity of product life).
- Historical, current, and projected demand.

In addition to the factors listed above, the following factors may be relevant to the development of estimates of variable consideration in the form of chargebacks and rebates under the expected value method:

- The existence of product-specific historical information about chargebacks and rebates.
- The availability and specificity of customer-specific pricing information (including contractual arrangements with retailers, insurance providers, or governmental agencies).
- Information about the specific retailer and consumer product sales mix (to understand which customer pricing arrangement is applicable).
- The availability and specificity of customer inventory levels.

In applying the expected value method to these types of estimates, life sciences entities are not necessarily expected to develop complex modeling techniques to identify all possible outcomes of variable consideration. Although we think that it is appropriate for an entity to be pragmatic in deriving an estimate by using one of the required methods, we do not think that it is appropriate to use a method described as management's best estimate as either the most likely amount or the expected value of variable consideration. Consequently, we would encourage an entity to document the basis for any conclusion that its approach aligns with the estimation methods of ASC 606.

### *2.5.1.2 Price Protection Arrangements*

Life sciences entities sometimes enter into price protection arrangements, under which wholesalers are reimbursed for any difference between the current sales price and the lowest price offered during a specified subsequent period (e.g., one year).

Under the revenue standard, an entity must include some or all of an estimate of variable (or contingent) consideration in the transaction price (which is the amount to be allocated to each performance obligation and recognized as revenue) when the entity concludes that it is probable that changes in its estimate of such consideration will not result in significant reversals of cumulative revenue in subsequent periods. In price protection arrangements, the transaction price would therefore include an estimate of expected price protection determined under either the expected value method or the most likely amount method (i.e., whichever method the entity expects to better predict the amount of consideration to which it will be entitled), with revenue recognized when control is transferred to the distributor.

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Instead of providing a retroactive discount, price protection arrangements may be structured to provide a discount on future purchases if a life sciences company sells its products to another customer at a lower price during a specified subsequent period. In these circumstances, the entity should consider whether the price protection arrangement conveys a material right to buy products at a lower price in the future. If a material right is determined to exist, this would represent a separate performance obligation to which a portion of the transaction price would need to be allocated. If a material right does not exist (e.g., because the discount applies only to future purchases and is not based on the volume of past purchases), there would be no impact on current sales, and future sales would be recognized at the discounted prices.

### *2.5.1.3 Price Appreciation Rights*

In contrast to price protection arrangements created to benefit the customer for subsequently reduced prices, life sciences entities may have price appreciation clauses in contracts with customers that are created to benefit the entity. Price appreciation clauses may allow the entity to charge the customer for any increases that the entity may make during the year (e.g., as the difference between the old and new wholesale acquisition costs for the product multiplied by the number of units of the product still held by the customer in inventory). An entity should assess whether the potential price appreciation in contracts with such clauses should be accounted for as variable consideration to be included as an estimate in the transaction price or whether the price appreciation should be treated as a contract modification when the price change occurs under ASC 606-10-25-10 through 25-13.

In arrangements with price appreciation rights, the transaction price would include an estimate of expected price appreciation to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty about whether a price increase will occur is subsequently resolved. In these circumstances, a life sciences entity will need to consider its past business practices of raising prices and its intentions with respect to such increases. For any such estimates that are included in the transaction price, a life sciences entity will need to estimate the amount of inventory that the customer will have on hand at the time of the price increase, as well as any resulting "gross-to-net" deductions (e.g., chargebacks, rebates, returns, and other similar adjustments) that will increase as a result of the increase in the wholesale acquisition cost.

### *2.5.1.4 New Product Launches With a Right of Return*

Under the revenue standard, the uncertainty associated with whether a product may be returned is treated, for measurement purposes, consistently with the uncertainty associated with other variable consideration. That is, under ASC 606-10-55-25:

> An entity should . . . determine the amount of consideration to which the entity expects to be entitled (that is, excluding the products expected to be returned). For any amounts received (or receivable) for which an entity does not expect to be entitled, the entity should not recognize revenue when it transfers products to customers but should recognize those amounts received (or receivable) as a refund liability. Subsequently, at the end of each reporting period, the entity should update its assessment of amounts for which it expects to be entitled in exchange for the transferred products and make a corresponding change to the transaction price and, therefore, in the amount of revenue recognized.

The amount of historical information and evidence needed to support the estimates and assumptions regarding returns can vary depending on whether the product was (1) a modification of an existing product, (2) similar to other products in the market (i.e., an "analog"), or (3) a completely new product. Obtaining sufficient evidence for new products may be difficult when the company does not have a relevant history for an analog or a clear competitive advantage that allows for more predictable sales. When using an analog to aid in the estimation of returns, life sciences entities are encouraged to document the basis for their conclusions that the analog is similar to the product being sold. Typically, this documentation should reflect that the analog is part of a similar therapeutic class, provides a similar mechanism of treatment, and targets similar customers and markets.

### *2.5.1.5 Pay-for-Performance Arrangements*

Pay-for-performance arrangements are becoming increasingly more common in the life sciences industry. Pay for performance in health care gives financial incentives to clinicians for better health outcomes. Clinical outcomes, such as longer survival, can be difficult to measure, so pay-for-performance systems usually measure process outcomes. Also known as "value-based purchasing," this payment model rewards physicians, hospitals, medical groups, and other health care providers for meeting certain performance measures for quality and efficiency. It provides a disincentive to caregivers for poor outcomes, medical errors, or increased costs.

Under the revenue standard, pay-for-performance arrangements represent another form of variable consideration. In a manner similar to the accounting in the examples above, a life sciences entity with these types of arrangements must include some or all of an estimate of variable consideration in the transaction price when the entity concludes that it is probable that changes in its estimate of such consideration will not result in significant reversals of cumulative revenue in subsequent periods.

### *2.5.1.6 Retroactive Payback Provisions*

In certain countries, companies are required to pay rebates to the country's government health care system if domestic industry sales exceed specified thresholds in a given year. If the threshold is exceeded, the portion of the payback allocated to an individual company is based on that company's current market share (or sales) in relation to the industry as a whole.

Under the revenue standard, an entity would account for the retroactive payback provision as a retroactive rebate (i.e., variable consideration) and possibly use the expected value method to estimate it, subject to the constraint.

### *2.5.1.7 Volume-Based Rebates*

A life sciences entity may offer its customers rebates or discounts on the pricing of products or services once specific volume thresholds have been met. That is, an entity may either retrospectively or prospectively adjust the price of its goods or services once a certain volume threshold has been met.

A volume rebate or discount that is **retrospectively** applied should be accounted for under the revenue standard as variable consideration (rather than as a customer option to be evaluated as a potential material right). In accordance with ASC 606-10-32-6, which specifically includes discounts and rebates as a form of variable consideration, the "promised consideration also can vary if an entity's entitlement to the consideration is **contingent on the occurrence or nonoccurrence of a future event**" (emphasis added).

However, an offer to **prospectively** lower the price per unit (once certain volume thresholds are met) should not be accounted for as variable consideration. Rather, when a volume rebate or discount is applied **prospectively**, an entity will need to evaluate the facts and circumstances of each contract to determine whether the rebate or discount represents a material right and therefore should be accounted for as a performance obligation. As part of this evaluation, entities would consider whether the offer to the customer is at a price that would reflect the stand-alone selling price for that good or service, in accordance with ASC 606-10-55-43.

### *2.5.1.8 Discounts Provided to Group Purchasing Organizations*

Life sciences companies frequently enter into agreements with group purchasing organizations (GPOs) to provide discounts to hospitals that are affiliated with the GPOs. Distributors of the life sciences companies' products then request reimbursement of the discounts provided to the life sciences companies' hospital customers.

In accordance with the revenue standard, a life sciences company should treat these discounts as variable consideration and possibly use the expected value method to estimate the discounts, subject to the constraint.

In addition to providing these discounts, life sciences companies frequently pay administrative fees to GPOs to fund the expenses of GPO members. To determine the appropriate classification of these administrative fees as a reduction of revenue or as an increase to operating expense, a life sciences company should consider the relationships between the vendor, the GPO, and the GPO member to determine whether the GPO is a customer. For example, the company might consider the GPO to be a customer if the GPO is a related party of the GPO member or if there is a mechanism to pass through the administrative fee from the GPO to the GPO member. In those situations, the company may be required to reflect the fee as a reduction of revenue.

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Similar questions related to income statement classification may arise regarding payments made by life sciences companies to not-for-profit entities (NFPs) or other organizations that fund copay assistance programs to defray the cost of high-priced drugs. Specifically, there may be questions about whether these payments represent consideration paid to an indirect customer (e.g., because the contribution funds are ultimately used by patients to purchase the company's products). While these payments may have been classified in expense under legacy guidance, life sciences companies are encouraged to evaluate their facts and circumstances to determine whether these payments represent a form of variable consideration under the revenue standard.

In June 2018, the FASB issued ASU 2018-08, which clarifies the scope and accounting guidance for contributions received and contributions made. Specifically, the ASU indicates that its amendments are intended, in part, to help entities evaluate "whether transactions should be accounted for as contributions (nonreciprocal transactions) within the scope of [ASC 958] or as exchange (reciprocal) transactions subject to other guidance," such as ASC 606. The ASU explains that while the issues it aims to address have been long-standing, "the amendments in [ASU 2014-09] place an increased focus on the issues because those amendments add new disclosure requirements and eliminate certain limited exchange transaction guidance that was previously contained in [ASC] 958-605."

#### *2.5.1.9 Contingent Development-Based Milestone Payments*

Life sciences entities often perform R&D activities in exchange for fixed consideration and milestone or bonus payments if predetermined objectives are achieved. For example, a CRO may enter into an agreement with a pharmaceutical company to perform a clinical trial in exchange for fixed consideration plus a milestone payment if it screens a specified number of patients for enrollment in the clinical trial within a specified period.

In accordance with the revenue standard, a life sciences company should consider contingent development-based milestone payments as variable consideration. It may be appropriate to estimate the milestone payments by using the most likely amount method since a milestone has only two possible outcomes (the entity either achieves the milestone or does not achieve it).

In the fact pattern described above, the CRO may consider its experience in screening patients for enrollment for similar types of trials for other pharmaceutical companies when determining whether to include the milestone payment in its estimate of the transaction price.

See Section 2.10.5 for discussion of the accounting for sales-based milestone payments.

### 2.5.2 Constraining Estimates of Variable Consideration

Since revenue is one of the most important metrics to users of financial statements, the FASB and IASB and their constituents agreed that estimates of variable consideration are useful only to the extent that an entity is confident that the revenue recognized as a result of those estimates will not be subsequently reversed. Accordingly, as noted in paragraph BC203 of ASU 2014-09, the boards acknowledged that some estimates of variable consideration should not be included in the transaction price if the inherent uncertainty could prevent a faithful depiction of the consideration to which the entity expects to be entitled in exchange for delivering goods or services. Thus, the focus of the boards' deliberations on a mechanism to improve the usefulness of estimates in revenue as a predictor of future performance was to limit subsequent downward adjustments in revenue (i.e., reversals of revenue recognized). The result of those deliberations is what is commonly referred to as the "constraint."

ASC 606-10-32-11 and 32-12 describe the constraint and provide guidance on how it should be applied.

**ASC 606-10**

**32-11** An entity shall include in the transaction price some or all of an amount of variable consideration estimated in accordance with paragraph 606-10-32-8 only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

**ASC 606-10 (continued)**

**32-12** In assessing whether it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur once the uncertainty related to the variable consideration is subsequently resolved, an entity shall consider both the likelihood and the magnitude of the revenue reversal. Factors that could increase the likelihood or the magnitude of a revenue reversal include, but are not limited to, any of the following:

a. The amount of consideration is highly susceptible to factors outside the entity's influence. Those factors may include volatility in a market, the judgment or actions of third parties, weather conditions, and a high risk of obsolescence of the promised good or service.
b. The uncertainty about the amount of consideration is not expected to be resolved for a long period of time.
c. The entity's experience (or other evidence) with similar types of contracts is limited, or that experience (or other evidence) has limited predictive value.
d. The entity has a practice of either offering a broad range of price concessions or changing the payment terms and conditions of similar contracts in similar circumstances.
e. The contract has a large number and broad range of possible consideration amounts.

Importantly, the constraint does not apply to sales- or usage-based royalties derived from the licensing of IP; rather, consideration from such royalties is only recognized as revenue at the later of when the performance obligation is satisfied or when the uncertainty is resolved (e.g., when subsequent sales or usage occurs). See Section 2.10 for additional discussion.

Inherent in ASC 606-10-32-12 are three key aspects of the assessment necessary for an entity to determine whether an estimate of variable consideration in a contract with a customer should be constrained in an entity's transaction price:

- The likelihood of a reversal in the cumulative amount of revenue recognized (i.e., a qualitative aspect).
- The magnitude (or significance) of the potential reversal in the cumulative amount of revenue recognized (i.e., a quantitative aspect).
- The threshold that triggers a constrained estimate (i.e., the use of "probable").

The determination of whether to constrain estimates of variable consideration may require significant judgment depending on the nature of the revenue stream being estimated. For example, it may be unnecessary for an entity to constrain revenue on the sale of established pharmaceutical products to wholesalers for the following reasons:

- Variable consideration (e.g., rebates, discounts) may not be highly susceptible to factors outside the entity's influence (e.g., volatility in a market, the judgment or actions of third parties, a high risk of obsolescence).
- The uncertainty about the amount of consideration may be resolved in a shorter period.
- The entity may have significant experience with similar types of contracts or with contracts that have predictive value.
- The range of price concessions is narrow.

In contrast, it may be necessary to constrain a significant portion of revenue on the sale of IPR&D, a nonfinancial asset, in exchange for future development milestones and royalties and sales-based milestones since the likelihood of reversal in the cumulative amount of revenue recognized could be high and the magnitude of the potential reversal could be significant. The uncertainty associated with revenue related to such a transaction arises from a number of factors:

- Before regulatory approval, uncertainty may arise from potential delays with clinical trials, success of competitor trials, or an inability to obtain regulatory approvals.
- After regulatory approval, uncertainty may arise from product safety concerns, manufacturing issues, potential product recalls, the introduction of competitor products, or possible sales and distribution channel issues.
- Both before and after regulatory approval, the amount of consideration to be received may be highly susceptible to factors outside the entity's influence because success is predicated on the efforts of the party to which the IPR&D was sold.

Although the guidance on constraining estimates of variable consideration is intended to avoid significant downward adjustments in revenue after it has been recognized, we generally do not think that it would be appropriate to constrain 100 percent of an estimate of variable consideration. That is, we do not think that the factors in ASC 606-10-32-12 could be so significant that an estimate of variable consideration should be entirely constrained from the transaction price. This concept is different from a $0 *estimate* of variable consideration. A 100 percent constraint on an estimate of variable consideration that is not $0, however, would generally go against the measurement principle of ASC 606, which is to include in the transaction price the amount to which an entity expects to be entitled for its performance so that the entity can provide financial statement users a better prediction of future revenues.

While the above is a general interpretation, there are exceptions in the revenue standard that may allow for a 100 percent constraint on an estimate of variable consideration. Example 25 in ASC 606-10-55 discusses an exception in which market-based factors are a significant driver of variability in the transaction price. Also, in paragraph BC415 of ASU 2014-09, the boards discuss their rationale for providing an exception for sales- or usage-based royalties in a license of IP.

**Connecting the Dots**

Milestone payments that are due upon regulatory approval are inherently based on factors outside the entity's control. As a result, life sciences companies that use a most likely method to estimate variable consideration may conclude that the variable consideration associated with a regulatory approval milestone is $0 before regulatory approval. However, there may be certain cases in which a milestone earned upon regulatory approval becomes probable before the approval date. For example, when an authorized generic of an existing branded drug is under FDA review, an entity may determine before the actual approval date that approval is likely to occur. Contrast that with a new drug compound for which there is no competitor on the market. In this case, it may be more difficult to assert probability in advance of the actual approval date.

### 2.5.3 Subsequent Changes in the Transaction Price

It is common for a life sciences entity to enter into a contract with a customer that entitles the life sciences entity to variable consideration in the event that the customer receives regulatory approval as a result of the R&D activities performed by the life sciences entity. Because the variable consideration is contingent on the customer's receipt of regulatory approval, the life sciences entity is required to estimate the amount of variable consideration to include in the transaction price. The life sciences entity may conclude that such variable consideration should be constrained until regulatory approval is obtained.

In certain circumstances, the uncertainty related to variable consideration may be resolved shortly after the end of the reporting period. When additional information (e.g., regulatory approval notification or denial) is received after the end of the reporting period and before the date on which the financial statements are issued or are available to be issued, an entity should refer to the guidance in ASC 855 on accounting for subsequent events. Paragraph BC228 of ASU 2014-09 states the following:

> The Boards noted that in some cases, an entity might make an estimate of the amount of variable consideration to include in the transaction price at the end of a reporting period. However, information relating to the variable consideration might arise between the end of the reporting period and the date when the financial statements are authorized for issue. The Boards decided not to provide guidance on the accounting in these situations because they noted that the accounting for subsequent events is already addressed in Topic 855, Subsequent Events, and IAS 10, *Events after the Reporting Period*.

ASC 855 distinguishes between recognized subsequent events (ASC 855-10-25-1) and nonrecognized subsequent events (ASC 855-10-25-3) as follows:

**ASC 855-10**

**25-1** An entity shall recognize in the financial statements the effects of all subsequent events that provide additional evidence about conditions that existed at the date of the balance sheet, including the estimates inherent in the process of preparing financial statements. See paragraph 855-10-55-1 for examples of recognized subsequent events.

**25-3** An entity shall not recognize subsequent events that provide evidence about conditions that did not exist at the date of the balance sheet but arose after the balance sheet date but before financial statements are issued or are available to be issued. See paragraph 855-10-55-2 for examples of nonrecognized subsequent events.

However, ASC 855 does not provide direct guidance on how to account for additional information about regulatory approval or denial that is received after the end of the reporting period and before the date on which the financial statements are issued or are available to be issued. We believe that the conclusion to account for information received regarding the regulatory approval process as either a recognized or a nonrecognized subsequent event will be based on the facts and circumstances and may require significant judgment. Accordingly, entities are encouraged to consult with their accounting advisers.

### 2.5.4 Significant Financing Components

In certain contracts with customers, one party may provide a service of financing (either explicitly or implicitly) to the other. Such contracts effectively contain two transactions: one for the delivery of the good or service and another for the benefit of financing (i.e., what is in substance a loan payable or loan receivable). The FASB and IASB decided that an entity should account for both transactions included in a contract with a customer when the benefit of the financing provided is significant.

**ASC 606-10**

**32-15** In determining the transaction price, an entity shall adjust the promised amount of consideration for the effects of the time value of money if the timing of payments agreed to by the parties to the contract (either explicitly or implicitly) provides the customer or the entity with a significant benefit of financing the transfer of goods or services to the customer. In those circumstances, the contract contains a significant financing component. A significant financing component may exist regardless of whether the promise of financing is explicitly stated in the contract or implied by the payment terms agreed to by the parties to the contract.

In determining the transaction price, an entity adjusts the promised amount of consideration to determine the cash selling price of the good or service to be delivered and reflect the time value of money if the contract has a significant financing component. The direction of the financing component (i.e., whether financing is provided to the entity through an advance payment or to the customer through payments in arrears) is irrelevant to the assessment, and as a result of the adjustment to the transaction price, the entity could recognize interest expense or interest income.

However, ASC 606-10-32-18 provides a practical expedient under which an entity does not need to adjust the promised amount of consideration for the effects of a significant financing component "if the entity expects, at contract inception, that the period between when the entity transfers a promised good or service to a customer and when the customer pays for that good or service will be one year or less."

Life sciences entities often receive advance payments for services. For example, payments are often required by CROs in advance of performing clinical trials, or by third-party manufacturers to secure manufacturing capacity.

Entities must use judgment in determining whether a significant financing component exists. However, ASC 606-10-32-17 notes that a contract with a customer would not have a significant financing component if certain factors exist. The table below describes the factors of greatest relevance to life sciences entities and examples of arrangements in which these factors may apply.

| Factor (ASC 606-10-32-17) | Example |
|---|---|
| "A substantial amount of the consideration promised by the customer is variable, and the amount or timing of that consideration varies on the basis of the occurrence or nonoccurrence of a future event that is not substantially within the control of the customer or the entity." | Royalty arrangements, in which variability is provided to confirm the value of goods delivered. |
| "The difference between the promised consideration and the cash selling price of the good or service (as described in paragraph 606-10-32-16) arises for reasons other than the provision of finance to either the customer or the entity, and the difference between those amounts is proportional to the reason for the difference. For example, the payment terms might provide the entity or the customer with protection from the other party failing to adequately complete some or all of its obligations under the contract." | Customer withholds consideration until the achievement of a certain milestone and to protect against nonperformance.<br><br>Customer is required to pay up front to secure supply of a good. |

### 2.5.5 Noncash Consideration

When providing goods or services, an entity may receive noncash consideration from its customers (e.g., goods, services, shares of stock). It is not uncommon for companies in the life sciences industry to enter into revenue transactions with customers that involve receiving products from the customer as consideration (e.g., supplies). Step 3 requires entities to include the fair value of the noncash consideration in the transaction price. Paragraph BC248 of ASU 2014-09 states the FASB's and IASB's rationale for this requirement: "When an entity receives cash from a customer in exchange for a good or service, the transaction price and, therefore, the amount of revenue should be the amount of cash received (that is, the value of the inbound asset). To be consistent with that approach, the Boards decided that an entity should measure noncash consideration at fair value." Further, in issuing ASU 2014-09 and IFRS 15, the boards included guidance stating that changes in the fair value of noncash consideration for reasons other than its form would be subject to the variable consideration constraint in ASC 606-10-32-11 through 32-13 (paragraphs 56 through 58 of IFRS 15).

ASC 606-10-32-21 and 32-22 require an entity to first look to measure the estimated fair value of the noncash consideration at contract inception and then consider the stand-alone selling price of the goods or services promised to the customer only when the entity is unable to reasonably estimate the fair value of the noncash consideration.

## 2.5.6 Consideration Payable to a Customer

ASC 606-10-32-25 through 32-27 establish requirements related to consideration payable to a customer. Consideration payable to a customer includes cash amounts[1] that an entity pays, or expects to pay, to the customer (or to other parties that purchase the entity's goods or services from the customer). An entity should account for consideration payable to a customer as a reduction of the transaction price and, therefore, of revenue unless the payment to the customer is in exchange for a distinct good or service (typically resulting in the recognition of an asset or expense).

ASC 606-10-32-25 establishes that consideration payable to a customer includes equity instruments granted in conjunction with the sale of goods or services. In addition, ASC 718-10-15-5A provides that "[i]f share-based payment awards are granted to a customer as payment for a distinct good or service from the customer, then an entity shall apply the guidance in paragraph 606-10-32-26." Under ASC 606-10-32-26, if the payment to the customer is in exchange for a distinct good or service that the customer transfers to the entity, the entity should "account for the purchase of the good or service in the same way that it accounts for other purchases from suppliers."

For share-based payments issued as consideration payable to a customer in accordance with ASC 606 (i.e., share-based consideration payable to a customer that is not in exchange for distinct goods or services), entities must measure and classify share-based sales incentives by applying the guidance in ASC 718. Accordingly, entities should measure share-based sales incentives by using a fair-value-based measure on the grant date, which would be the date on which the grantor (the entity) and the grantee (the customer) reach a mutual understanding of the key terms and conditions of the share-based sales incentive. The resulting measurement of the share-based sales incentive should be reflected as a reduction of revenue in accordance with the guidance in ASC 606 on consideration payable to a customer. After initial recognition, the measurement and classification of the share-based sales incentive continues to be subject to ASC 718 unless (1) the award is subsequently modified when vested and (2) the grantee is no longer a customer.

### *2.5.6.1 Identifying Payments Within the Scope of the Requirements Related to Consideration Payable to a Customer*

In accordance with ASC 606-10-32-25, consideration payable to a customer includes the following:

a. Cash amounts that an entity pays, or expects to pay, to the customer (or to other parties that purchase the entity's goods or services from the customer)

b. Credit or other items (for example, a coupon or voucher) that can be applied against amounts owed to the entity (or to other parties that purchase the entity's goods or services from the customer)

c. Equity instruments (liability or equity classified) granted in conjunction with selling goods or services (for example, shares, share options, or other equity instruments).

An entity should account for consideration payable to a customer as a reduction of the transaction price and, therefore, of revenue unless the payment to the customer is in exchange for a distinct good or service (typically resulting in the recognition of an asset or expense).

[1] For a list of additional items included in consideration payable to a customer under ASC 606-10-32-25, see Section 2.5.6.1.

An entity should assess the following payments to customers under ASC 606-10-32-25 to determine whether they are in exchange for a distinct good or service:

- Payments to customers that result from a contractual obligation (either implicitly or explicitly).
- Payments made on behalf of customers that are considered in-substance price concessions because the customer has a reasonable expectation of such payments (either implicitly or explicitly).
- Purchases made on behalf of customers in lieu of making cash payments to those customers.
- Payments to customers that can be economically linked to revenue contracts with those customers.

While an entity is not required to separately assess and document each payment made to a customer, an entity should not disregard payments that extend beyond the context of a specific revenue contract with a customer. Rather, an entity should use reasonable judgment when determining how broadly to apply the guidance on consideration payable to a customer to determine whether the consideration provided to the customer is in exchange for a distinct good or service (and is therefore an asset or expense) or is not in exchange for a distinct good or service (and is therefore a reduction of revenue).

Payments made to third parties on behalf of customers can come in many forms and may not necessarily be incentives paid to a customer's customer to be deemed consideration payable to a customer. In determining whether a payment made to a third party is on behalf of a customer, the entity making the payment should consider whether it receives a distinct good or service from the third party. Further, in determining whether a payment made to a third party is on behalf of a customer, the entity making the payment might consider whether it is acting as a principal or as an agent when the customer receives the good or service provided by the third party. For example, if an entity (1) sells a service to a customer, (2) pays a third party for a distinct good that is provided to the customer for free, and (3) is the principal in providing that good to the customer because it obtains control over that good before the good is transferred to the customer, the entity may determine that the payment made to the third party should be reflected as cost of sales. In this circumstance, the good provided to the customer may be considered a separate performance obligation in the entity's revenue contract with the customer. By contrast, if the entity is an agent in facilitating the provision of the good to the customer, the payment made to the third party could be deemed consideration payable to a customer because the payment is being made on behalf of the customer.

### *2.5.6.2 Presentation of Consideration Payable to a Customer*

When an entity enters into an agreement to sell products to a customer, the transaction with the customer may also involve the customer's supplying goods or services to the entity. The contract may be structured in such a way that the consideration payable by the entity to the customer for those goods or services is separately identified. Alternatively, the contract may be structured in such a way that it includes a single amount payable by the customer to the entity that reflects the net of the value of the goods or services provided by the entity to the customer and by the customer to the entity. When the fair value of the goods or services can be reasonably estimated, the accounting outcome should be the same in either circumstance.

The goods or services supplied by the customer should be accounted for separately if both of the following conditions are met:

- Those goods or services are "distinct."
- The entity can reasonably estimate the fair value of the goods or services that it will receive (which may not correspond to any amount specified in the contract for those goods or services).

If both of these conditions are met, the fair value of the goods or services received from the customer should be accounted for in the same way the entity accounts for other purchases from suppliers (e.g., as an expense or asset). If any consideration payable to the customer with respect to those goods or services exceeds their fair value, the excess should be accounted for as a reduction of the transaction price.

If either or both of these conditions are not met, any consideration payable to the customer with respect to those goods or services should be accounted for as a reduction of the transaction price.

The examples below illustrate the application of this guidance.

**Example 2-9**

An entity sells goods to a customer for $10,000 and, as part of the same arrangement, pays that customer $1,000 to provide a service. If the service is determined to be distinct and its fair value can be reasonably estimated (as being, for example, $600), a portion of the contractually stated amount will be recognized as a reduction of the transaction price for the sale of goods to $9,600 ($10,000 minus the $400 payment made to the customer in excess of the fair value of the service received).

**Example 2-10**

An entity sells goods to a customer for $10,000 and, as part of the same arrangement, pays that customer $1,000 to provide a service. If the service is not determined to be distinct or its fair value cannot be reasonably estimated, the transaction price for the sale of goods will be reduced to $9,000 ($10,000 minus the full amount payable to the customer).

The requirements above apply irrespective of whether the consideration related to the goods or services supplied by the customer is separately identified in the contract. If the contract is net settled (i.e., the customer is required to pay cash and provide distinct goods or services as payment for the goods or services provided by the entity to the customer, and the entity does not make a cash payment to the customer for the distinct goods or services provided by the customer), the noncash consideration guidance would apply.

### Connecting the Dots

Questions related to income statement classification may arise about payments made by a pharmaceutical manufacturer and a wholesaler in accordance with a distribution service agreement. Under such an agreement, the wholesaler performs certain distribution and logistics services for the manufacturer, such as providing the manufacturer with periodic reports of inventory on hand and inventory sold through to the wholesaler's customers during the period, in exchange for inventory management fees. Although described as fees for specific services outlined in the agreement, such costs are typically classified as a reduction of revenue by the manufacturer because the fee paid to the wholesaler is not in exchange for distinct goods or services transferred to the manufacturer.

### 2.5.7 Applying the Guidance on Consideration Received From a Vendor

ASC 705-20 is a Codification subtopic that ASU 2014-09 added to provide specific guidance on consideration received from a vendor.

**ASC 705-20**

**25-1** Consideration from a vendor includes cash amounts that an entity receives or expects to receive from a vendor (or from other parties that sell the goods or services to the vendor). Consideration from a vendor also includes credit or other items (for example, a coupon or voucher) that the entity can apply against amounts owed to the vendor (or to other parties that sell the goods or services to the vendor). The entity shall account for consideration from a vendor as a reduction of the purchase price of the goods or services acquired from the vendor unless the consideration from the vendor is one of the following:

a. In exchange for a distinct good or service (as described in paragraphs 606-10-25-19 through 25-22) that the entity transfers to the vendor
b. A reimbursement of costs incurred by the entity to sell the vendor's products
c. Consideration for sales incentives offered to customers by manufacturers.

**25-2** If the consideration from a vendor is in exchange for a distinct good or service (see paragraphs 606-10-25-19 through 25-22) that an entity transfers to the vendor, then the entity shall account for the sale of the good or service in the same way that it accounts for other sales to customers in accordance with Topic 606 on revenue from contracts with customers. If the amount of consideration from the vendor exceeds the standalone selling price of the distinct good or service that the entity transfers to the vendor, then the entity shall account for such excess as a reduction of the purchase price of any goods or services acquired from the vendor. If the standalone selling price is not directly observable, the entity shall estimate it in accordance with paragraphs 606-10-32-33 through 32-35.

**25-3** Cash consideration represents a reimbursement of costs incurred by the entity to sell the vendor's products and shall be characterized as a reduction of that cost when recognized in the entity's income statement if the cash consideration represents a reimbursement of a specific, incremental, identifiable cost incurred by the entity in selling the vendor's products or services. If the amount of cash consideration paid by the vendor exceeds the cost being reimbursed, that excess amount shall be characterized in the entity's income statement as a reduction of cost of sales when recognized in the entity's income statement.

**25-4** Manufacturers often sell their products to resellers who then sell those products to consumers or other end users. In some cases, manufacturers will offer sales discounts and incentives directly to consumers — for example, rebates or coupons — in order to stimulate consumer demand for their products. Because the reseller has direct contact with the consumer, the reseller may agree to accept, at the point of sale to the consumer, the manufacturer's incentives that are tendered by the consumer (for example, honoring manufacturer's coupons as a reduction to the price paid by consumers and then seeking reimbursement from the manufacturer). In other instances, the consumer purchases the product from the reseller but deals directly with the manufacturer related to the manufacturer's incentive or discount (for example, a mail-in rebate).

The recognition guidance in ASC 705-20-25 on consideration received from a vendor has certain conceptual similarities to the measurement guidance in ASC 606-10-32 on consideration payable to a customer.

ASC 606-10-32-25 states that an "entity shall account for consideration payable to a customer as a **reduction** of the **transaction price** and, therefore, of revenue unless the payment to the customer is **in exchange for a distinct good or service** (as described in paragraphs 606-10-25-18 through 25-22) that the customer transfers to the entity" (emphasis added). Under ASC 606-10-32-26, "[i]f consideration payable to a customer is a payment for a distinct good or service from the customer, then an entity

shall account for the purchase of the good or service **in the same way that it accounts for other purchases** from suppliers. If the amount of consideration payable to the customer exceeds the fair value of the distinct good or service that the entity receives from the customer, then the entity shall account for such an excess as a reduction of the transaction price" (emphasis added).

Similarly, under ASC 705-20-25-1 and 25-2, an entity will need to determine whether consideration from a vendor is **in exchange for a distinct good or service** (as described in ASC 606-10-25-19 through 25-22) that the entity transfers to the vendor. If an entity concludes that consideration received from a vendor is related to distinct goods or services provided to the vendor, the entity should account for the consideration received from the vendor **in the same way that it accounts for other sales** (e.g., in accordance with ASC 606 if distinct goods or services are sold to a customer). If the consideration is not in exchange for a distinct good or service and is also unrelated to the items described in ASC 705-20-25-1(b) and (c), the entity should account for consideration received from a vendor as a **reduction** of the **purchase price** of the goods or services acquired from the vendor. Also similar to the guidance in ASC 606-10-32-25 and 32-26 is the requirement in ASC 705-20-25-2 that any excess of the consideration received from the vendor over the stand-alone selling price of the good or service provided to the vendor should be accounted for as a reduction of the purchase price of any goods or services purchased from the vendor.[2]

Notwithstanding the similarities between ASC 705-20 and ASC 606, determining whether an entity is a customer or a vendor in certain arrangements may be challenging. There are certain arrangements in which an entity may enter into one or more contracts with another entity that is both a customer and a vendor. That is, the reporting entity may enter into one or more contracts with another entity to (1) sell goods or services that are an output of the reporting entity's ordinary activities in exchange for consideration from the other entity and (2) purchase goods or services from the other entity. In these types of arrangements, the reporting entity will need to use judgment to determine whether the other entity is predominantly a customer or predominantly a vendor. This determination might not be able to be made solely on the basis of the contractual terms. In such cases, the reporting entity will need to consider the facts and circumstances of the overall arrangement with the other entity.

To determine whether the other entity is predominantly a customer or predominantly a vendor in the arrangement, the reporting entity should consider both qualitative and quantitative factors, including the following:

- The extent to which the goods or services purchased from the other entity are important to the reporting entity's ability to successfully sell its products and services to customers, or the extent to which the goods or services purchased from the reporting entity are important to the other entity.
- The quantitative significance of the reporting entity's past, current, and expected future (1) purchases from the other entity and (2) sales to the other entity.
- The extent to which the reporting entity sells other products and services to the other entity.
- The historical relationship between the reporting entity and the other entity.
- The pricing of the reporting entity's products and services sold to the other entity as compared with the pricing of products and services that the reporting entity sells to other customers of similar size and nature.

[2] If an entity concludes that the consideration received from a vendor was not in exchange for a distinct good or service that the entity transferred to the vendor, the entity will be required under ASC 705-20-25-1 to (1) determine whether the consideration received was either a reimbursement of costs incurred by the entity to sell the vendor's products or consideration for sales incentives offered to customers by manufacturers and (2) account for the consideration received accordingly.

- The pricing of the other entity's goods and services purchased by the reporting entity as compared with the pricing of similar goods and services that the reporting entity purchases from other vendors.
- The substance of the contract negotiation process or contractual terms between the reporting entity and the other entity, which may indicate that (1) the reporting entity is the customer and the other entity is the vendor or (2) the other entity is the customer and the reporting entity is the vendor.
- The payment terms and cash flows between the reporting entity and the other entity.
- The significance of other parties involved in the arrangement.

## 2.6 Allocate the Transaction Price to the Performance Obligations (Step 4)

In step 4 of the revenue standard, an entity allocates the transaction price to each of the identified performance obligations. For a contract containing more than one performance obligation, the allocation is generally performed on the basis of the relative stand-alone selling price of each distinct performance obligation. However, as discussed in Chapter 7 of Deloitte's Roadmap *Revenue Recognition*, there are exceptions that allow an entity to allocate a disproportionate amount of the transaction price to a specific performance obligation. For example, an entity may allocate a discount to a single performance obligation rather than proportionately to all performance obligations if certain factors indicate that the discount is related to a specific performance obligation.

In addition, in arrangements that include a license of IP along with ongoing services (e.g., R&D or manufacturing) that represent distinct performance obligations, an entity is required to allocate the total transaction price between the license and the services. If a history of selling the services or IP separately does not exist, the entity will need to estimate the stand-alone selling price of each performance obligation by using one of the following methods:

- *Adjusted market assessment approach* — Under this method, an entity considers the market in which the good or service is sold and estimates the price that a customer in that market would be willing to pay. In addition, the entity considers a competitor's pricing for similar goods or services as adjusted for specific factors such as position For example, a life sciences company may need to consider the specific rights associated with the license, the stage of development of the underlying IP, and the projected cash flows over the license period. In some cases, it may be appropriate to use a Monte Carlo analysis, a scenario-based discounted cash flow method, an option pricing model, or a similar valuation technique to estimate the stand-alone selling price of the license.  Regarding the R&D services, prices of similar services offered in the marketplace may be considered.
- *Expected cost plus a margin* — Under this method, an entity estimates the stand-alone selling price by considering the costs incurred to produce the product or service plus an adjustment for the expected margin on the sale. This method may be appropriate for an entity to use when it determines the selling price of R&D or manufacturing services by considering the level of effort necessary to perform the services.
- *Residual approach* — This approach may only be used if the entity sells the same good or service to different customers for a broad range of amounts, making the consideration highly variable, or the entity has not yet established a price for that good or service and the good or service has not previously been sold. Under this method, the entity deducts the observable stand-alone selling price of other goods and services in the contract from the total transaction price to determine the stand-alone selling price of the remaining goods and services.

In many other respects, the allocation model under the revenue standard may be similar to the model under legacy guidance, except for the revenue standard's elimination of the selling price hierarchy required under legacy guidance.

## 2.7 Determine When to Recognize Revenue (Step 5)

In a manner consistent with the core principle of the revenue standard — "an entity shall recognize **revenue to depict the transfer of promised goods or services to customers** in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services" (emphasis added) — step 5 focuses on recognition (i.e., **when** it is appropriate to recognize revenue).

The revenue standard requires an entity first to determine, at contract inception, whether *control of* a good or service is *transferred over time*; if so, the entity would recognize the related revenue over time in a manner consistent with the transfer of the good or service over time to the customer. If the entity cannot conclude that control is transferred over time, control is considered to be transferred at a point in time. As a result, the entity must determine at what specific point in time to recognize the related revenue. While generally speaking, goods are transferred at a point in time and services are transferred over time, this is not the case in all circumstances. Some of the more common issues that life sciences entities have faced when considering step 5 are described below.

### 2.7.1 When Revenue Recognition Over Time Is Appropriate for Goods (e.g., Contract Manufacturing)

Contract manufacturing is common in the life sciences industry. Entities that are delivering goods (e.g., contract manufacturers and other entities in customer manufacturing arrangements) should carefully analyze the contractual arrangement in accordance with the three criteria in ASC 606-10-25-27 to determine whether the promise in the contract to construct and transfer goods to the customer is a performance obligation that will be satisfied over time or at a point in time.

If an entity's obligation to produce a customized product meets one of the criteria in ASC 606-10-25-27 for revenue recognition over time (e.g., the entity's performance does not create an asset with an alternative use, and the entity has an enforceable right to payment for performance completed to date), revenue related to that product would be recognized as the product is produced, not when the product is delivered to the customer.

For example, an entity that has a contract with an original equipment manufacturer (OEM) to produce a customized part for the OEM's product would meet the criteria for revenue recognition over time if the customized part has no alternative use other than as a part for the OEM's product and, as stated in ASC 606-10-25-29, the entity has an enforceable right to payment for performance completed to date "at all times throughout the duration of the contract." ASC 606-10-25-28 and 25-29 as well as ASC 606-10-55-8 through 55-15 provide detailed guidance on whether an asset has an alternative use to the entity and whether an entity has an enforceable right to payment for performance completed to date. An entity would need to carefully analyze the contractual arrangements and the specific facts and circumstances to determine whether those criteria are met.

If it concludes that revenue should be recognized over time, the entity would then be required to select a method of recognizing revenue over time that most faithfully depicts the entity's performance to date for producing the product. Therefore, contract revenue should be recognized as the entity performs (i.e., as the product is produced) rather than when the product is delivered to the customer.

In certain contract manufacturing arrangements of life sciences entities, inventory that is being manufactured has no alternative use (e.g., because the product cannot be redirected to another customer), and the contract terms provide the right to payment for performance completed to date in an amount that approximates the selling price of the work in process (e.g., recovery of the costs incurred plus a reasonable profit margin) if the contract is canceled. In these arrangements, revenue should be recognized over time as inventory is manufactured.

Entities may need to use judgment when evaluating some of these arrangements (e.g., when contracts are silent or unclear about whether a right to payment exists). We believe that when a contract's written terms do not specify the entity's right to payment upon contract termination, an enforceable right to payment is presumed not to exist. However, if the contract with the customer does not specify by its written terms the entity's right to payment upon contract termination and the entity asserts that it has an enforceable right to payment for performance completed to date, we would expect the entity to:

- Support its assertion on the basis of legislation, administrative practice, or legal precedent that confers upon the entity a right to payment for performance to date, as stated in ASC 606-10-55-14(a). This analysis would need to demonstrate that an enforceable right to payment (as defined by ASC 606) exists in the relevant jurisdiction. The fact that the entity would have a basis for making a claim against the counterparty in a court of law would not be sufficient to support the existence of an enforceable right to payment.
- Assess whether relevant legal precedent indicates that similar rights to payment for performance completed to date in similar contracts have no binding legal effect, as stated in ASC 606-10-55-14(b).

### 2.7.2 Impact of Shipping Terms on Revenue Recognition Over Time

Shipping terms in a contract that require a customer to pay only at a specific point in time (e.g., FOB destination) do not preclude the contract from meeting the criterion in ASC 606-10-25-27(c) for revenue recognition over time (specifically, the enforceable right to payment condition).

The guidance in ASC 606-10-55-12 makes clear that an enforceable right to payment "need not be a present unconditional right to payment" and that an entity may have "an unconditional right to payment only . . . upon complete satisfaction of the performance obligation." In these circumstances, the guidance states, "an entity should consider whether it would have an enforceable right to demand or retain payment for performance completed to date if the contract were to be terminated before completion **for reasons other than the entity's failure to perform as promised**" (emphasis added).

When a contract's shipping terms require an entity's customer to pay only at a specific point in time (e.g., FOB destination), the possibility that the entity will not be paid if the goods are lost in shipment would represent "the entity's failure to perform as promised" and should be disregarded in the entity's assessment of whether the performance obligation meets the criterion in ASC 606-10-25-27(c) for revenue recognition over time (i.e., when an entity is assessing whether it has an enforceable right to payment, it should presume that it will perform as promised and that the goods will be delivered). Accordingly, the conclusion that the entity has an enforceable right to payment is not precluded when the contract's payment terms require payment only at specific points in the production or delivery process. Those payment terms may be overruled by contractual rights that give the entity an enforceable right to demand or retain payment (if the entity performs as promised). Therefore, the fact that the customer would not be required to pay for the goods if they were lost in transit would not, by itself, preclude the contract from meeting the criterion in ASC 606-10-25-27(c) for revenue recognition over time.

### 2.7.3 Methods for Measuring Progress

When a performance obligation is satisfied over time, an entity must select a measure of progress (e.g., time elapsed, labor hours, costs incurred) to depict its progress toward complete satisfaction of that obligation.

In accordance with ASC 606-10-25-33, appropriate methods of measuring progress include:

- *Output methods* — ASC 606-10-55-17 states that output methods "recognize revenue on the basis of direct measurements of the value to the customer of the goods or services transferred to date relative to the remaining goods or services promised under the contract." These methods include "surveys of performance completed to date, appraisals of results achieved, milestones reached, time elapsed, and units produced or units delivered."
- *Input methods* — ASC 606-10-55-20 states that input methods "recognize revenue on the basis of the entity's efforts or inputs to the satisfaction of a performance obligation (for example, resources consumed, labor hours expended, costs incurred, time elapsed, or machine hours used) relative to the total expected inputs to the satisfaction of that performance obligation."

In discussing the selection of a measure of progress, paragraph BC164 of ASU 2014-09 states:

> The [FASB and IASB] decided that, conceptually, an output measure is the most faithful depiction of an entity's performance because it directly measures the value of the goods or services transferred to the customer. However, the Boards observed that it would be appropriate for an entity to use an input method if that method would be less costly and would provide a reasonable proxy for measuring progress.

The above statement from paragraph BC164 of ASU 2014-09 does **not** mean that it is preferable for an entity to use an output method when measuring progress toward complete satisfaction of a performance obligation. As stated in paragraph BC159 of ASU 2014-09, an entity does not have a free choice in selecting an appropriate method of measuring progress toward complete satisfaction of a performance obligation but should exercise judgment in identifying a method that fulfills the stated objective in ASC 606-10-25-31 of depicting an entity's performance in transferring control of goods or services promised to a customer (i.e., the satisfaction of the performance obligation).

Neither an input method nor an output method is preferred since each has benefits and disadvantages that will make it more or less appropriate to the facts and circumstances of each contract. While an output method is, as stated in paragraph BC164 of ASU 2014-09, conceptually preferable in a general sense, an appropriate measure of output will not always be directly observable; and sometimes, an apparent measure of output will not in fact provide an appropriate measure of an entity's performance. Information needed to apply an input method is more likely to be available to an entity without undue cost, but care should be taken to ensure that any measure of an entity's inputs used is reflective of the transfer of control of goods or services to the customer.

Considerations that may be relevant to the selection of a measure of progress include the following:

- An output method would not provide a faithful depiction of the entity's performance if the output selected fails to measure some of the goods or services transferred to the customer. For example, a units-of-delivery or a units-of-production method may sometimes understate an entity's performance by excluding work in progress that is controlled by the customer. (See paragraph BC165 of ASU 2014-09.)
- An input method may better reflect progress toward complete satisfaction of a performance obligation over time when (1) the performance obligation consists of a series of distinct goods or services that meets the criteria in ASC 606-10-25-14(b) to be treated as a single performance

obligation and (2) the effort required to create and deliver the first units is greater than the effort to create the subsequent units because of the effect of a "learning curve" of efficiencies realized over time. (See paragraph BC314 of ASU 2014-09.)

- An entity applying an input method must exclude from its measure of progress the costs incurred that (1) do not contribute to the entity's progress in satisfying a performance obligation (e.g., the costs of unexpected amounts of wasted materials) and (2) are not proportionate to the entity's progress in satisfying the performance obligation (e.g., the cost of obtaining goods from a vendor that accounts for most of the product's cost). (See ASC 606-10-55-21.)

**Connecting the Dots**

In the life sciences industry, CROs often incur out-of-pocket expenses and "pass-through costs" related to payments made to investigators (physicians) who participate in the clinical studies being conducted. Under the revenue standard, if the CRO activity is part of a combined performance obligation, these costs should generally be included in a CRO's measure of progress when a cost-based input measure is used to recognize revenue over time.

### *2.7.3.1 Consideration of Straight-Line Measure of Progress*

Although ASC 606-10-55-16 through 55-21 provide guidance on when an entity would use an input or output method in measuring progress toward the complete satisfaction of a performance obligation, the guidance does not prescribe the use of either method. However, an entity does not have a "free choice" when selecting a measure of progress. While an entity may use either type of method, the actual method selected should be consistent with the clearly stated objective of depicting the entity's performance (i.e., the entity's satisfaction of its performance obligation in transferring control of goods or services to the customer).

Although ASC 606 does not permit an entity to default to a straight-line measure of progress on the basis of the passage of time (i.e., because a straight-line measure of progress may not faithfully depict the pattern of transfer), ASC 606 does not prohibit the use of a straight-line measure of progress, and such a time-based method may be reasonable in some cases depending on the facts and circumstances. Sometimes, for example, the nature of the entity's promise in a contract is to "stand ready" for a period rather than to provide the goods or services underlying the obligation (e.g., to perform on a joint steering committee, provide regulatory approval assistance when necessary, or both). In the case of a stand-ready promise, the customer obtains (i.e., receives and consumes) a benefit from the assurance that a service or resource is available ("standing ready") when and if needed or desired. For a stand-ready obligation that is satisfied over time, an entity may measure progress toward complete satisfaction of the performance obligation by using one of various methods, including time-based, input, and output methods. An entity would need to use judgment to select an appropriate measure of progress on the basis of the arrangement's particular facts and circumstances.

### *2.7.3.2 Use of a Multiple Attribution Approach (as Compared With a Single Method for Measuring Progress)*

Life sciences entities such as CROs often provide multiple services for their customers (pharmaceutical and biotechnology entities). For example, CROs may help design studies, recruit investigators (physicians), recruit patients, help manage clinical trials, monitor safety, and write reports on study results. If an entity concludes that its contract with a customer contains a single performance obligation (i.e., in the context of the contract, the various services to be performed are not distinct) and that the performance obligation is satisfied over time, the entity is required to identify an appropriate measure to depict progress toward complete satisfaction of its performance obligation (see ASC 606-10-25-31 through 25-37).

For performance obligations meeting the requirements for revenue recognition over time, the entity must select a method for measuring progress toward satisfaction of the performance obligation.

Although the revenue standard indicates that an entity should apply a single method to measure progress for each performance obligation satisfied over time, stakeholders have questioned whether an entity may apply more than one method to measure progress toward satisfaction of a performance obligation that contains multiple goods and services bundled and recognized over time. In addition, stakeholders have questioned whether it would be acceptable to apply two different methods for measuring progress even though the contract has only one performance obligation.

The FASB staff notes that the revenue standard clearly indicates that "using multiple methods of measuring progress for the same performance obligation would not be appropriate."[3] Accordingly, the staff concludes that an entity should use a single measure of progress for each performance obligation identified in the contract.

In addition, the FASB staff observes that selecting a common measure of progress may be challenging when a single performance obligation contains more than one good or service or has multiple payment streams, although it emphasizes that the selection is not a free choice. Further, the staff notes that while a common measure of progress that does not depict the economics of the contract may indicate that the arrangement contains more than one performance obligation, it is not determinative. However, a reexamination may suggest that the contract includes more performance obligations than were initially identified.

The above issues are addressed in Implementation Q&As 47 and 48 (compiled from previously issued TRG Agenda Papers 41 and 44). For additional information and Deloitte's summary of issues discussed in the Implementation Q&As, see Appendix C of Deloitte's Roadmap *Revenue Recognition*.

**Connecting the Dots**

The revenue standard requires an entity to identify a single measure of progress that appropriately depicts its progress toward complete satisfaction of the performance obligation. As a result, CROs have generally concluded that input measures should be used under ASC 606.

## 2.8 Consignment Arrangements

Although physical possession is an indicator that control has been transferred to the customer, ASC 606-10-25-30(c) cautions that there are some arrangements in which physical possession may not be indicative of control. One example is a consignment arrangement.

Consignment arrangements occasionally exist in the life sciences industry (e.g., a medical device may be delivered to a hospital under a consignment arrangement until the device is needed for a surgery). Under ASC 606, the accounting for consignment arrangements may be consistent with legacy U.S. GAAP if control of the products delivered to a consignee is not transferred until the consignee sells the products to a third party.

[3] Quoted from Implementation Q&A 47.

## 2.9 Government Vaccine Stockpile Programs

In August 2017, the SEC issued an interpretive release (the "2017 release") updating the Commission's previously issued guidance on accounting for sales of vaccines and bioterror countermeasures to the federal government for placement into stockpiles related to the Vaccines for Children Program or the Strategic National Stockpile. The update was aimed at conforming the SEC's guidance with ASC 606.

Under the guidance in the 2017 release, vaccine manufacturers should recognize revenue when vaccines are placed into U.S. government stockpile programs because control of the vaccines has been transferred to the customer. However, these entities also need to evaluate whether storage, maintenance, or other promised goods or services associated with vaccine stockpiles are separate performance obligations. The guidance in the 2017 release applies only to the stockpile programs discussed in that release and is not applicable to any other transactions.

## 2.10 Licensing

Under the revenue standard, the framework used to account for licensing of IP is essentially the same as the framework used to account for a sale of goods or services. That is, the five-step model is generally applied to licensing transactions as well. However, licensing of IP can take many forms, and the economics and substance of such transactions can often be difficult to identify. Determining how to account for licensing transactions will often depend on the specific facts and circumstances and will require professional judgment. To help preparers exercise such judgment, the revenue standard provides supplemental guidance on recognizing revenue from contracts related to the licensing of IP to customers. The scope of the guidance includes all licenses that provide a customer with rights to IP, except for certain software hosting arrangements.

In the evaluation of how to account for a licensing transaction under the revenue standard, it is important for an entity to consider each of the five steps in the model (although, as discussed below, certain exceptions are provided for licensing transactions). Specifically, an entity will need to do each of the following:

- *Step 1: Identify the contract with the customer* — This step includes identifying the counterparty that is the customer, evaluating the enforceable rights and obligations (including implicit rights) of each party to the contract, and determining whether amounts under the contract are collectible.
- *Step 2: Identify the performance obligations under the contract* — This includes determining whether the entity's obligation to transfer a license to a customer results in (1) a single promise that will be satisfied (i.e., a single performance obligation) or (2) multiple performance obligations. This step could also involve determining whether the license of IP is the predominant element in the arrangement.
- *Step 3: Determine the transaction price* — This includes identifying and, potentially, measuring and constraining variable consideration.
- *Step 4: Allocate the transaction price* — This includes considering whether the residual method could be used for determining the stand-alone selling price of one (or a bundle) of the performance obligations.
- *Step 5: Determine when control of the license is transferred to the customer* — This includes determining whether the license is transferred at a point in time (for a right to use IP) or over time (for a right to access IP).

Some of the key judgments an entity will need to make are likely to be in connection with step 2 (identify the performance obligations), step 4 (allocate the transaction price), and step 5 (recognize revenue) of the model. As part of step 2, an entity will need to evaluate license restrictions (and changes in any such restrictions) when determining whether the restrictions merely define the licenses (which may be the case when the restrictions are related to time or geography) or, in effect, give rise to multiple performance obligations (which may be the case when the restrictions change over the license period and require the entity to transfer additional rights to the customer).

As part of step 5, when an entity is determining whether it has granted a customer a right to use or a right to access its IP, it will need to assess the nature of the promised license to determine whether the license has significant stand-alone functionality. For licenses with significant stand-alone functionality, ongoing activities[4] of the licensor do not significantly affect the license's functionality (i.e., its utility). However, certain licenses do not have significant stand-alone functionality and require ongoing activities from the entity to support or maintain the license's utility to the customer. The nature of an entity's license of IP will determine the pattern of transfer of control to the customer, which is either at a point in time (if the customer is granted a right to use the IP) or over time (if the customer is granted a right to access the IP).

### Connecting the Dots

It is common in the life sciences industry for an entity to transfer a license of IP along with R&D services to the customer as a single performance obligation. The license may not be capable of being distinct without the R&D services. That is, the R&D services performed by the entity may be novel, requiring the entity to provide the R&D services for the customer to benefit from the license. In determining when revenue should be recognized for the single performance obligation with two promised goods (the delivery of the license and R&D services), the entity must determine whether the single performance obligation is satisfied over time or at a point in time. In this type of transaction, the criteria in ASC 606-10-25-27(a) and (b) for recognizing revenue over time may be met. The entity may conclude that the criterion in ASC 606-10-25-27(a) is met if it determines that the work that it has completed to date (related to the R&D services) would not need to be substantially reperformed by another entity if the other entity were to step in to fulfill the remaining performance obligation to the customer (since this would mean that the customer simultaneously receives and consumes the benefits provided by the entity's performance of the R&D services as the entity performs those services). In addition, the entity may conclude that the criterion in ASC 606-10-25-27(b) is met if it determines that (1) the customer obtains control of the license (i.e., the customer has the ability to direct the use of, and obtain substantially all of the remaining benefits from, the license) and (2) the R&D services provided will simultaneously enhance the license.

Alternatively, life sciences entities may enter into a contract with a customer to perform R&D services and provide the customer with an option to exclusively license the IP resulting from the R&D services at a stated price during the period in which the R&D services are performed or for a certain specified period after performance of the R&D services is completed. The option is priced at its stand-alone selling price and therefore does not represent a material right. The promise to provide R&D services may represent a single performance obligation; if so, the entity must determine whether the performance obligation is satisfied over time or at a point in time. In this type of transaction, the criterion in ASC 606-10-25-27(a) for recognizing revenue over time may be met. The entity may conclude that the criterion in ASC 606-10-25-27(a) is met if it determines that the work that it has completed to date (related to the R&D services) would not need to be substantially reperformed by another entity if the other entity were to

[4] These do not include activities that transfer one or more goods or services to the customer (e.g., maintenance activities), which an entity must assess to determine whether they constitute separate performance obligations.

step in to fulfill the remaining performance obligation to the customer (since this would mean that the customer simultaneously receives and consumes the benefits provided by the entity's performance of the R&D services as the entity performs those services).

For licensing transactions in which consideration is tied to the subsequent sale or usage of IP, the revenue standard provides an exception to the recognition principle that is part of step 5 (i.e., recognize revenue when or as control of the goods or services is transferred to the customer). Under this sales- or usage-based royalty exception, an entity would generally not be required to estimate the variable consideration from sales- or usage-based royalties. Instead, ASC 606-10-55-65 requires an entity to "recognize revenue for a sales-based or usage-based royalty promised in exchange for a license of intellectual property only when (or as) the later of the following events occurs:

a. The subsequent sale or usage occurs.

b. The performance obligation to which some or all of the sales-based or usage-based royalty has been allocated has been satisfied (or partially satisfied)."

**Connecting the Dots**

In the application of the sale- or usage-based royalty exception in ASC 606-10-55-65, it would not be appropriate for an entity to omit sales- or usage-based royalties from its financial statements merely because the associated sales data were received after the end of the reporting period or were not received when the financial statements were issued or available to be issued.

Some of the more common issues that life sciences entities have faced when considering the licensing guidance of the revenue standard are discussed below.

### 2.10.1 License Versus In-Substance Sale of IP

An entity may license IP to a customer under an arrangement that gives the customer exclusive use of the IP for either a perpetual term or a period that is substantially the same as the IP's useful life.

Stakeholders have questioned whether these arrangements would be within the scope of (1) the licensing implementation guidance in ASC 606-10-55-54 through 55-65B or (2) the general recognition and measurement model in the revenue standard, which could result in a different pattern of revenue recognition. Specifically, concerns have been raised about the application of the sales- or usage-based royalty exception. The FASB considered, but rejected, expanding the scope of the royalty recognition constraint because of complexities in legal differences between a sale of IP and a license of IP. More specifically, the FASB noted in the Background Information and Basis for Conclusions of ASU 2016-10 that an entity should not distinguish between licenses and in-substance sales in deciding whether the royalty exception applies. We generally believe that the legal form of the transaction will determine which revenue accounting guidance (i.e., the guidance on estimating royalties or the guidance on applying the royalty recognition constraint) is applicable.

### 2.10.2 Determining Whether Contractual Provisions Represent Attributes of a License or Additional Rights

A contract with a customer may contain provisions that limit the customer's use of a license of IP to a specific period, a specific geographic region, a specific use, or a specified number of targets. For example, an entity may license drug distribution rights to a customer that can be (1) used for three years, (2) made available only to consumers in North America, (3) used only for a specific drug indication, and (4) used on a specified number of targets. Often, such restrictions will be attributes of the license. That is, the restrictions will define the rights the customer has under the license. However, some

restrictions, or changes in restrictions over time, will require an entity to transfer additional rights to a customer. Specifically, ASC 606-10-55-64 and 55-64A clarify that (1) certain contractual provisions indicate that an entity has promised to transfer additional rights (i.e., an additional license) to a customer and (2) promises to transfer additional rights should be accounted for as separate performance obligations. When a license of IP is limited to a specified number of targets, the arrangement may allow for the customer to substitute targets (often referred to as "substitution rights"). An entity will need to carefully evaluate whether these substitution rights represent attributes of the license or may require the entity to transfer additional rights to the customer.

The following factors (not all-inclusive) may be helpful in an entity's determination of whether a substitution right represents an attribute of the license or may require the entity to transfer additional rights to the customer:

- *Whether the contract provides for a fixed number of targets* — The entity should consider whether the customer can substitute one or more of the targets listed in the contract at inception ("existing targets") for one or more other existing targets that the customer previously designated. If so, this implies that (1) the entity transferred the substitution right to the customer at contract inception and (2) the substitution right is an attribute of the original license.
- *Whether the exercise of the substitution right changes the number of targets allotted to the customer* — The entity should evaluate whether a substitution right that allows the customer to substitute one or more existing targets for one or more other existing targets that the customer previously designated changes the total number of targets allotted to the customer. For example, a customer may purchase the right to research three targets (Target A, Target B, and Target C). If the customer initially designates Target A, has the right to substitute another existing target for Target A, and loses the right to continue research on Target A, the total number of targets allotted to the customer will still be three (i.e., the same number of targets available to the customer at the inception of the contract), indicating that the substitution right is an attribute of the license.
- *Whether the entity is required to transfer an exclusive license to the customer in the event that the substitution right is exercised* — For example, when the customer exercises its substitution right, it may obtain an exclusive right to the substitute target. This may imply that the entity has provided an additional right to the customer since the entity is no longer able to license that substitute target to a third party. However, if it is unlikely that the entity would exclusively license that substitute target to a third party during the term of the contract because of the nature of the underlying field of study, the entity may not be transferring any additional rights to the customer upon the customer's exercise of its substitution right.
- *Whether, in the event that the substitution right is exercised, the entity is required to transfer to the customer additional rights that did not exist at contract inception* — In the analysis of whether the substitution right is an attribute of the license, it is important to understand whether the substitution right transfers to the customer additional rights that did not exist at contract inception. For example, if the customer can obtain control of newly developed IP that it did not control when the license was transferred up front, the entity is transferring additional rights to the customer upon the customer's exercise of the substitution right.

The determination of whether contractual provisions related to a license of IP represent an additional promise may require significant judgment. Contractual provisions (restrictions) that define the scope of a license of IP that has already been transferred to a customer would generally not be accounted for as a separate performance obligation. For example, a restriction that limits the use of a license to a five-year period would be an attribute of the single license. However, contractual provisions that define additional rights that will be transferred at a future date would generally be accounted for as a separate performance obligation, as illustrated in the example below.

**Example 2-11**

An entity transfers to a customer a two-year license of IP that can be used only in Jurisdiction A during year 1 but can be used in both Jurisdiction A and Jurisdiction B during year 2. In this example, the customer does not obtain control of the license in Jurisdiction B until year 2. That is, in year 2, the entity must transfer additional rights that entitle the customer to use the license in Jurisdiction B. Although the entity transfers the license to use the IP in Jurisdiction A at the beginning of year 1, the entity must still fulfill a second promise to deliver the license to use the IP in Jurisdiction B in year 2. Further, although the license of IP obtained by the customer in year 1 may be the same license of IP that will be used in year 2 (i.e., the customer currently controls the right to use or access the IP), the customer is precluded from using and benefiting from that license in Jurisdiction B until year 2. The obligation to transfer additional rights to the customer at the beginning of year 2 should be identified as an additional performance obligation under the contract with the customer.

### 2.10.3 Identifying the Nature of the License

In determining whether to recognize revenue from a license of IP over time or at a point in time, an entity needs to determine the nature of the licensing arrangement. The nature of the arrangement is determined on the basis of the entity's promise to the customer and whether that promise (1) provides access to the IP throughout the license term (i.e., "right to access") or (2) provides a right to use the IP as it exists at the point in time when control of the license is transferred to the customer (i.e., "right to use"). Revenue from a license that grants a right to access an entity's IP is recognized over time since the customer simultaneously receives and consumes the benefits of the entity's IP throughout the license periods (i.e., meets the requirement in ASC 606-10-25-27(a)). Revenue from a license that grants a right to use an entity's IP is recognized at the point in time when control of the license is transferred to the customer.

To assist in the evaluation of whether the license provides the customer with a right to access or right to use the entity's IP, the revenue standard distinguishes between two types of IP: (1) functional and (2) symbolic.

Examples of licenses of functional IP could include software, drug compounds and formulas, and completed media content. In accordance with ASC 606-10-55-62, the nature of a license to functional IP that is distinct will provide a customer with the right to use an entity's IP (i.e., point-in-time revenue recognition) unless (1) the entity's ongoing activities that will not transfer promised goods to the customer (i.e., those not deemed to be additional promised goods to the customer) will significantly change the utility of the license and (2) the customer is contractually or practically required to use the updated IP once available. If these criteria are met, the nature of the license is a right to access the entity's IP (i.e., a license for which revenue is recognized over time). As discussed in paragraph BC58 of ASU 2016-10, the FASB expected that at the time of issuance of ASU 2016-10, the criteria in ASC 606-10-55-62 "will be met only infrequently, if at all." Consequently, revenue from a license of drug compounds and formulas that represents a distinct performance obligation would generally represent a right to use

an entity's IP and would be recognized at the point in time when control of the license is transferred to the customer. However, ASC 606-10-55-58C states the following:

**ASC 606-10**

**55-58C** Notwithstanding paragraphs 606-10-55-58A through 55-58B, revenue cannot be recognized from a license of intellectual property before both:

a. An entity provides (or otherwise makes available) a copy of the intellectual property to the customer.
b. The beginning of the period during which the customer is able to use and benefit from its right to access or its right to use the intellectual property. That is, an entity would not recognize revenue before the beginning of the license period even if the entity provides (or otherwise makes available) a copy of the intellectual property before the start of the license period or the customer has a copy of the intellectual property from another transaction. For example, an entity would recognize revenue from a license renewal no earlier than the beginning of the renewal period.

**Connecting the Dots**

Because revenue from customer renewals of licenses of IP cannot be recognized before both of the conditions in ASC 606-10-55-58C are met, revenue from a renewal of a right-to-use license is not recognized until the beginning of the renewal period, rather than when the parties agree to the renewal.

### 2.10.4 Considerations for Determining Whether a License Is Predominant

Under the sales- or usage-based royalty exception to the revenue standard's general rule requiring an entity to include variable consideration in the transaction price, if an entity is entitled to consideration in the form of a sales- or usage-based royalty, revenue is not recognized until (1) the underlying sales or usage has occurred and (2) the related performance obligation has been satisfied (or partially satisfied). That is, an entity does not estimate the amount of a sales- or usage-based royalty at contract inception; rather, revenue would be recognized when (or as) the subsequent sales or usage occurs (under the assumption that the associated performance obligation has been satisfied or partially satisfied).

As explained in ASC 606-10-55-65A, the sales- or usage-based royalty exception applies "when the royalty relates only to a license of intellectual property or when a license of intellectual property is the **predominant** item to which the royalty relates (for example, the license of intellectual property may be the predominant item to which the royalty relates when the entity has a reasonable expectation that the customer would ascribe significantly more value to the license than to the other goods or services to which the royalty relates)" (emphasis added).

In the life sciences industry, licenses are often included with R&D services, manufacturing services, or both, with consideration in the form of a sales-based royalty. When the license and the services do not qualify as separate performance obligations, an entity will need to use significant judgment to assess whether the IP license is "the predominant item to which the royalty relates."

The revenue standard does not define "predominant." However, ASC 606-10-55-65A notes that the license may be predominant "when the entity has a reasonable expectation that the customer would ascribe significantly more value to the license than to the other goods or services to which the royalty relates." Consequently, life sciences entities should consider the customer's perspective of value and the relative importance and value of the promised goods or services. For example, in a combined license and R&D arrangement, an entity might consider the remaining clinical trial studies that need to be completed and the expected size of the market upon approval. Since different interpretations may arise in practice and the consequences of these differences could be significant to the timing of revenue recognition, entities are encouraged to contemporaneously document the basis for their conclusion on whether the license, rather than the other services, is predominant.

### 2.10.5 Applicability of the Sales- or Usage-Based Royalty Exception to Sales-Based Milestones, Development-Based Milestones, or Guaranteed Minimum Royalties

The sales- or usage-based royalty exception would apply to sales-based milestones because the payment becomes due on the basis of the subsequent sales to the customer. However, the exception cannot be applied to development-based milestone payments because these payments are not contingent on the sales to or usage by the customer. In addition, the exception cannot be applied to guaranteed minimum royalties because those payments are essentially fixed consideration. However, the exception would apply to any variable royalty consideration that exceeds the fixed (guaranteed minimum) portion.

**Connecting the Dots**

In certain license arrangements, a milestone payment is due upon the first commercial sale of a product by the licensee. That is, such a payment does not represent a guaranteed minimum since it becomes due and payable only upon the achievement of a sale. Accordingly, we believe that an entity may (1) consider this type of milestone payment to be similar to a sales-based milestone payment because it is payable only upon a sale of the drug and (2) recognize it in a manner consistent with the guidance on sales- or usage-based royalties.

### 2.10.6 Interaction of Sales- or Usage-Based Royalty Exception With Measuring Progress Towards Satisfaction of a Performance Obligation

When applying the sales- or usage-based royalty exception, an entity typically would recognize revenue when (or as) the customer's subsequent sales or usage occurs. However, if the sales- or usage-based royalties accelerate revenue recognition as compared with the entity's satisfaction (or partial satisfaction) of the associated performance obligation, the entity may be precluded from recognizing some or all of the revenue as the subsequent sales or usage occurs.

ASC 606-10-55-65 specifies that revenue from a sales- or usage-based royalty promised in exchange for a license of IP is recognized only when (or as) the later of the following events occurs:

a. The subsequent sale or usage occurs.

b. The performance obligation to which some or all of the sales-based or usage-based royalty has been allocated has been satisfied (or partially satisfied).

Accordingly, revenue should be deferred if, and to the extent that, recognition based on subsequent sales or usage (i.e., criterion (a)) is judged to be in advance of satisfaction of a performance obligation (i.e., criterion (b)). Royalty arrangements can differ greatly between entities and between contracts. Further, the timing of the recognition of royalties can depend on the nature of the underlying IP (i.e., right to access or right to use) as well as the structure of the royalty payments. Therefore, the determination of whether revenue from royalties should be deferred will depend on an analysis of the specific facts and circumstances.

Consider the example below, in which the parties agree to a variable royalty arrangement with declining royalties in return for the license of functional IP.

**Example 2-12**

An entity enters into a contract to provide a customer with a noncancelable license to the entity's IP. The entity determines that the license is a right-to-use license (i.e., a license for which revenue is recognized at a point in time) for a three-year period. The customer's estimated sales are expected to be approximately equal for each of the three years under license. For the use of the IP, the agreement requires the customer to pay the entity a royalty of 10 percent of the customer's sales in year 1, 8 percent of the customer's sales in year 2, and 6 percent of the customer's sales in year 3.

The entity should account for the royalty payments in a manner consistent with the legal form of the arrangement and in accordance with the exception to the variable consideration guidance for licenses of IP that include a sales- or usage-based royalty. Consequently, the entity would include the royalties in the transaction price on the basis of the applicable contractual rate and the customer's sales in each year and then, in accordance with ASC 606-10-55-65, recognize revenue at the later of when (1) the "subsequent sale or usage occurs" or (2) the "performance obligation to which some or all of the sales-based or usage-based royalty has been allocated has been satisfied (or partially satisfied)." Because the license is a right-to-use license for which control is transferred at the inception of the contract, the "later" of the two conditions is met when the subsequent sales occur.

## 2.11 Presentation

### 2.11.1 Contract Assets and Contract Liabilities

**ASC 606-10**

**45-1** When either party to a contract has performed, an entity shall present the contract in the statement of financial position as a contract asset or a contract liability, depending on the relationship between the entity's performance and the customer's payment. An entity shall present any unconditional rights to consideration separately as a receivable.

**45-2** If a customer pays consideration, or an entity has a right to an amount of consideration that is unconditional (that is, a receivable), before the entity transfers a good or service to the customer, the entity shall present the contract as a contract liability when the payment is made or the payment is due (whichever is earlier). A contract liability is an entity's obligation to transfer goods or services to a customer for which the entity has received consideration (or an amount of consideration is due) from the customer.

**ASC 606-10 (continued)**

**45-3** If an entity performs by transferring goods or services to a customer before the customer pays consideration or before payment is due, the entity shall present the contract as a contract asset, excluding any amounts presented as a receivable. A contract asset is an entity's right to consideration in exchange for goods or services that the entity has transferred to a customer. An entity shall assess a contract asset for impairment in accordance with Topic 310 on receivables. An impairment of a contract asset shall be measured, presented, and disclosed in accordance with Topic 310 (see also paragraph 606-10-50-4(b)).

**Pending Content (Transition Guidance: ASC 326-10-65-1)**

**45-3** If an entity performs by transferring goods or services to a customer before the customer pays consideration or before payment is due, the entity shall present the contract as a contract asset, excluding any amounts presented as a receivable. A contract asset is an entity's right to consideration in exchange for goods or services that the entity has transferred to a customer. An entity shall assess a contract asset for credit losses in accordance with Subtopic 326-20 on financial instruments measured at amortized cost. A credit loss of a contract asset shall be measured, presented, and disclosed in accordance with Subtopic 326-20 (see also paragraph 606-10-50-4(b)).

A contract with a customer creates legal rights and obligations. The rights under the contract will generally give rise to contract assets as the entity performs (or accounts receivable, if an unconditional right to consideration exists); and contract liabilities are created when consideration is received (or receivable) in advance of performance. Each reporting period, an entity is required to assess its financial position related to its contracts with customers. Depending on the extent to which an entity has performed and the amount of consideration received (or receivable) by the entity under a contract, the entity could record a contract asset or a contract liability.

Receivables should be recorded separately from contract assets since only the passage of time is required before consideration is due. That is, receivables are only subject to credit risk. In contrast, contract assets are subject to more than just credit risk (i.e., they are also subject to performance risk). For example, a contract asset would exist when an entity has a contract with a customer for which revenue has been recognized (i.e., goods or services have been transferred to the customer), but customer payment is contingent on a future event (i.e., satisfaction of additional performance obligations or other events). As discussed in paragraph BC323 of ASU 2014-09, the FASB and IASB believed that making a distinction between contract assets and receivables was important to financial statement users.

ASC 606-10-45-5 addresses the use of alternative descriptions for contract assets and contract liabilities as follows:

**ASC 606-10**

**45-5** This guidance uses the terms *contract asset* and *contract liability* but does not prohibit an entity from using alternative descriptions in the statement of financial position for those items. If an entity uses an alternative description for a contract asset, the entity shall provide sufficient information for a user of the financial statements to distinguish between receivables and contract assets.

Paragraph BC321 of ASU 2014-09 notes the FASB's and IASB's observation that "some industries have historically used different labels to describe contract assets and contract liabilities or may recognize them in more than one line item either in the financial statements or in the notes." ASC 606 does not prohibit an entity from using alternative terms or from using additional line items to present the assets and liabilities, but it requires an entity to provide appropriate disclosures that adequately describe the assets and liabilities.

Terms that are commonly used in practice to describe contract assets and contract liabilities include, but are not limited to, the following:

- *Contract assets* — Unbilled receivables, progress payments to be billed.
- *Contract liabilities* — Deferred revenue, unearned revenue.

**Connecting the Dots**

In the life sciences industry, CROs typically enter into long-term contracts with their customers to perform clinical trial management services. Revenue from these services is generally recognized over time. It is not uncommon for a CRO to perform under a contract in such a way that performance to date exceeds the amounts of consideration received (or receivable) and the CRO records a contract asset. For example, a CRO may have to meet certain contractual milestones, such as patient enrollment metrics or investigator site approval, before having a right to bill.

There is diversity in practice on how CROs present these amounts in the statement of financial position and the descriptions used for these amounts. ASC 606 indicates that an entity should provide sufficient information for a user of the financial statements to distinguish between receivables and contract assets. One presentation option is to present accounts receivable, unbilled services (i.e., services for which the right to bill is contingent solely on the passage of time), and contract assets (contingent on a future event) as individual line items in the statement of financial position. Alternatively, certain CROs may present one line item in the statement of financial position for amounts that are contingent solely on the passage of time (e.g., accounts receivable and unbilled services) and another line item for amounts that are contingent on events other than the passage of time (e.g., contract assets), then disclose the composition of the balance in the financial statement footnotes. Either approach is acceptable provided that the disclosures are sufficiently clear to enable a financial statement user to understand the nature and composition of the entity's accounts receivable and contract assets, including whether contract assets are conditioned on something other than the passage of time.

### 2.11.2 Government Grants

In the life sciences industry, it is common for an entity that is not an NFP to receive government grants in support of R&D activities of the entity that are not associated with a customer-vendor relationship and are therefore outside the scope of the revenue standard. Because there is no authoritative guidance under U.S. GAAP on accounting for government grants received, life sciences entities have considered applying sources of nonauthoritative accounting guidance and literature by analogy when accounting for government grants. With respect to recognition, measurement, and income statement presentation, some entities may have adopted an accounting policy of applying IAS 20 by analogy; depending on the nature of the grant, such a policy may have resulted in accounting for a particular grant as (1) a reduction of an asset, (2) an offset to an operating expense, or (3) income. In light of the lack of authoritative U.S. GAAP related to the accounting for government grants, it is critical for an entity to disclose its accounting policy for government grants when such amounts are material to the entity's financial statements. See Section 13.1 for more information, including a discussion of recent standard-setting activity related to disclosures about government assistance.

### 2.11.3 Principal-Versus-Agent Considerations

As noted in Section 2.2.1, ASC 808 requires that each collaboration participant report costs incurred and revenue generated from transactions with third parties in its income statement in accordance with the principal-versus-agent guidance in ASC 606-10-55-36 through 55-40. The entity that is identified as the principal in a transaction will recognize revenue based on the *gross* amount of consideration to which the entity expects to be entitled in exchange for the specified good or service transferred. In contrast, the entity that is identified as the agent in a transaction will recognize revenue based on the *net* amount of consideration to which the entity expects to be entitled in exchange for the specified good or service transferred.

Application of the principal-versus-agent guidance that affects whether a life sciences entity recognizes revenue based on gross or net amounts is not limited to collaborative arrangements. For example, business development transactions in the life sciences industry frequently involve transition service arrangements in which the seller performs certain transition services for the buyer (e.g., distribution, billing, and collections) while marketing authorizations are obtained by the buyer to sell pharmaceutical product in the jurisdiction. To determine whether the buyer should report revenues on a gross or a net basis during the transition period, the buyer should assess whether the nature of the seller's promise to the customer is a performance obligation to provide the specified goods or services itself (i.e., the seller is a principal) or to arrange for those goods or services to be provided by the buyer (i.e., the seller is an agent), as indicated in ASC 606-10-55-36.

In accordance with ASC 606-10-55-36A, an entity should determine the nature of its promise by identifying the specified goods or services to be provided to the customer and assessing whether it controls each specified good or service before that good or service is transferred to the customer. When making this determination under the revenue standard, the entity may be required to use significant judgment.

**Example 2-13**

**Transition Services Agreement**

Company X acquires Subsidiary Y from Company Z in exchange for cash consideration. The acquisition is accounted for as a business combination under ASC 805. Subsidiary Y is a manufacturer of pharmaceutical products, and Z is the distributor of those products. Company Z has the necessary licenses and authorizations required to distribute the products, whereas X does not.

Companies X and Z enter into a transition services agreement (TSA) under which Z will continue performing distribution services for Y's products for one year following the acquisition. Under the TSA, Z will hold legal title to, and have physical possession of, the products before they are distributed to customers. Company X has discretion in establishing the prices for the products, has the right to determine which customers the products are sold to, and bears the risk of loss for the inventory of the products.

Company X determines that it is the principal in the TSA with Z because X controls the products before they are transferred to customers. Company X has the right to direct the use of, and obtain substantially all of the remaining benefits from, the products.

**Example 2-14**

**Direct Title Arrangement**

Company A recently received FDA approval for Product X but does not yet have all of the state distribution licenses required to sell their product throughout the United States. While waiting to receive all of the state distribution licenses, A enters into an agreement with a third-party logistics company (the "3PL") to use the 3PL's distribution licenses to sell Product X. The 3PL will take legal title to, and physical possession of, the product. However, A has the right to determine which customers Product X is sold to, has the right to determine the price at which Product X is sold, and is primarily responsible for fulfilling the promise to provide Product X to its customers.

Company A determines that it is the principal in the arrangement with the 3PL because A controls Product X before it is transferred to the customer. Company A has the right to direct the use of, and obtain substantially all of the remaining benefits from, the asset (i.e., Product X).

## 2.12 Disclosure Requirements

As discussed in paragraph BC327 of ASU 2014-09, some of the main criticisms of the prior revenue guidance from regulators and users of the financial statements were related to disclosure requirements. Many entities' disclosures contained boilerplate language that, broadly speaking, regulators and users found to be inadequate and lacking in cohesion with other disclosures, thus making it difficult for users to understand entities' revenues, judgments related to revenue, and how revenue was related to an entity's overall financial position. In addition, while disclosure has been a focus of the FASB and SEC in recent years, that focus has been primarily related to disclosure overload and extensive disclosures required on topics such as pensions, stock compensation, fair value, and income taxes. In response to stakeholder feedback, the FASB has aimed to make disclosures more effective, better coordinated, and less redundant. Although this has been an overall focus of the FASB and SEC, the lack of disclosure on revenue was highlighted as a key area for improvement during the development of the revenue standard.

As a result, one of the goals of the FASB and IASB in the revenue project was to provide financial statement users with more useful information through improved disclosures. ASC 606-10-50-1 outlines the objective of the revenue standard's disclosure requirements as follows:

**ASC 606-10**

**50-1** The objective of the disclosure requirements in this Topic is for an entity to disclose sufficient information to enable users of financial statements to understand the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. To achieve that objective, an entity shall disclose qualitative and quantitative information about all of the following:

a. Its contracts with customers (see paragraphs 606-10-50-4 through 50-16)
b. The significant judgments, and changes in the judgments, made in applying the guidance in this Topic to those contracts (see paragraphs 606-10-50-17 through 50-21)
c. Any assets recognized from the costs to obtain or fulfill a contract with a customer in accordance with paragraph 340-40-25-1 or 340-40-25-5 (see paragraphs 340-40-50-1 through 50-6).

Some of the more common issues that life sciences entities have addressed when considering the disclosure requirements of the revenue standard are discussed below.

### 2.12.1 Level of Aggregation or Disaggregation

To comply with the "entity-wide" disclosure requirements of ASC 280, many life sciences companies disclose revenues from products for major medical treatments, revenues from different types of services (e.g., clinical development services vs. commercial services), revenues attributed to the entity's home country and foreign countries, and the individual customers (e.g., wholesalers) whose purchases constitute 10 percent or more of the entity's revenues. Entities are encouraged to document their consideration of the disaggregation categories outlined in ASC 606.

### 2.12.2 Satisfied Performance Obligations

ASC 606 requires disclosure of the amount of revenue recognized in the current period that is related to amounts allocated to performance obligations that were satisfied (or partially satisfied) in previous periods (e.g., because of changes in the variable consideration constraint). For example, development- or approval-based milestone payments related to the delivery of a functional license of IP may have been fully constrained because of the uncertainty of achieving the milestones. Once the milestone payments are no longer constrained, an entity would be required to disclose the milestone payments recognized in the current period that are related to amounts allocated to performance obligations that were satisfied (or partially satisfied) in previous periods.

### 2.12.3 Gross-to-Net Disclosures

Many pharmaceutical companies currently disclose a rollforward of gross-to-net balance sheet reserves in MD&A. Some registrants also disclose a reconciliation of gross and net sales as reported in the income statement. Some life sciences companies have considered including these types of disclosures in the footnotes to the financial statements to meet certain variable consideration disclosure requirements of the revenue standard, such as those related to disclosure of changes in estimates associated with the transaction price and estimates associated with the variable consideration.

### 2.12.4 SEC Comment Letter Themes Related to Disclosures

The SEC staff's comments to registrants in the life sciences industry regarding revenue recognition have primarily focused on (1) gross-to-net adjustments and (2) multiple-element arrangements.

#### *2.12.4.1 Gross-to-Net Adjustments*

**Examples of SEC Comments**

- To the extent that re-estimates of prior year gross-to-net variable consideration [are] significant in future periods, please represent to us that you will disclose herein the impact on your product sales and operating results and include in your financial statements the disclosure required by ASC 606-10-50-12A.
- Please explain to us why adjustments to prior year estimates of gross-to-net variable consideration in the aggregate of up to [X]% of total revenues are not material to your financial statements taken as a whole. In this regard, [X]% of your total revenues for the first half of [year 2] equating to approximately $[X] million appears that it could at least be quantitatively material to operating loss and pre-tax loss for the first half of [year 2] and to your customer allowances liability at December 31, [year 1]. In addition, prior period adjustments of that magnitude could significantly impact trends and explanation thereof could be meaningful disclosure for investors.

**Examples of SEC Comments (continued)**

- You identify product revenue recognition as a critical accounting estimate. Given the magnitude of your net product sales and your gross-to-net adjustments as previously conveyed in your quarterly earnings conference calls, please address the following:
  - Provide us a roll forward of the accrual of each gross-to-net adjustment type (whether reflected as an allowance against accounts receivable or a liability) that depicts the following for each annual period from [date 1] to [date 2] and for the six-month period from [date 3] to [date 4]:
    - Beginning balance;
    - Current provision related to sales made in current period;
    - Current provision related to sales made in prior periods;
    - Actual returns or credits in current period related to sales made in current period;
    - Actual returns or credits in current period related to sales made in prior periods; and
    - Ending balance.
  - Tell us the amount of and reason for significant fluctuations in the provision from period to period for each type of gross-to-net adjustment, and the amount and reason that changes in your estimates of these items had on your revenues and operations.
- Please revise future filings to include all of the disclosures required by ASC 606-10-50, as applicable. For example, provide the qualitative and quantitative disclosure about the significant judgments and changes in judgments, including inputs and assumptions, related to your accounting for returns, rebates and discounts, as set forth in ASC 606-10-50-1(b), 50-17, and 50-20, a description of the payment terms under 50-12, and disaggregated revenue under 50-5.

The recognition of revenue in the life sciences industry relies heavily on estimates and assumptions related to returns, chargebacks, rebates, discounts, promotions, shelf stock adjustments, and other adjustments to transaction prices that affect revenue. ASC 606-10-50-12A requires an entity to "disclose revenue recognized in the reporting period from performance obligations satisfied (or partially satisfied) in previous periods (for example, changes in transaction price)." The SEC staff has commented on registrants' disclosures of these types of changes in estimates in variable consideration, including the magnitude and nature of any current-period adjustments to estimates made in prior periods. The staff has also requested that registrants provide a rollforward of the accruals for each gross-to-net adjustment in MD&A, including similar disclosures of current-period adjustments related to sales made in prior periods.

### *2.12.4.2 Multiple-Element Arrangements*

**Examples of SEC Comments**

- You state that the development and manufacturing services for the [X] agreements are viewed as a single performance obligation and therefore the upfront payments, future research and development reimbursement payments and any potential additional development milestone payments under each agreement will be deferred until the commencement of commercial manufacturing. Please address the following:
  - Identify for us each of the promised goods or services in these agreements including the transfers of licenses and explain how you determined that you only had a single performance obligation under the guidance in ASC 606-10-25-14.
  - With reference to ASC 606-10-25-23 to 25-26, explain to us why revenue is deferred until commencement of commercial manufacturing and how you considered that you have already transferred the licenses and begun providing development services.
  - Explain to us whether you intend to recognize revenue over time or at a point in time, and why with reference to ASC 606-10-25-30 or 25-31, as applicable.
- Please address the following as it relates to your determination that the performance obligations represented a single performance obligation since the license, clinical development and manufacturing and supply obligations were not distinct:
  - [H]ow your statement . . . that [Customer X] was not granted any other rights to, or benefits from, the intellectual property is consistent with . . . the agreements. The agreements appear to give [X] the right to use [Product A] as necessary to . . . seek and obtain Regulatory Approval for the Licensed Product in the Field in the Territory.
  - [W]hy the license and research and development services, either alone or combined, are not capable of being distinct from the manufacturing services pursuant to ASC 606-10-25-19a. In this respect, the subcontracting and sublicensing rights . . . and step-in rights in . . . the agreements appear to indicate there may be available resources outside of the company that could provide the research and development services and supplies. Refer also to Example 56, Case B in ASC 606-10-55-371 through 55-372. In this regard, we note in Case A that an approved drug is provided in the contract with manufacturing services, for which no other promised goods or services are included in the contract, which appears to be contrary to the company's facts and circumstances.
  - [W]hy the license and research and development services, either alone or combined, are not separately identifiable from the supply obligation and thus do not meet the criteria in ASC 606-10-25-19b. In this regard, it appears due to the subcontracting and sublicensing rights, the license and research and development services are not inter-related with the manufacturing services pursuant to ASC 606-10-25-21c. Refer also to Example 56, Case B, ASC 606-10-55-372A.

**Examples of SEC Comments (continued)**

- As it relates to your determination that revenue from the combined performance obligation should be recognized at a point in time upon the supply of the drug, please address the following:
  - Your response states that you intend to recognize revenue at the point in time in which [Customer X] achieves control over batches supplied. However, you also state that you will recognize revenue as product is delivered to [X] based on the quantity supplied compared to the forecasted quantity of the drug to be supplied over the term of the agreements, which would appear to be an over time measurement. Please clarify this apparent inconsistency. Please also explain how you intend to estimate the forecasted quantity of the drug to be supplied over the term of the agreements and how this estimate would be deemed to be a reasonable measure of progress considering the guidance in ASC 606-10-25-36.
  - Your response [to the initial comment letter] states that [the company] will "start satisfying its performance obligation only upon supply of the drug after issuance of regulatory marketing approvals." Explain how you considered the contract duration guidance in ASC 606-10-25-3 which states that the guidance in this Topic should be applied to the duration of the contract (that is, the contractual period) in which the parties to the contract have present enforceable rights and obligations. In this regard, it would appear that the enforceable rights and obligations under these contracts began at their effective dates . . . . Accordingly, it is unclear to us why an over time measurement of your performance obligation would not be recognized over the entire contractual period.
  - Explain how you considered the guidance in ASC 606-10-25-27(c) in determining whether your performance obligation is being satisfied over time. In this regard, address the following:
    - Clarify whether your performance under the contracts [creates] an asset with alternative future use. In this regard, explain whether you are contractually restricted from developing [Compound A] for your or any other entity's benefit as long as the [X] agreements are in effect.
    - Explain whether you have an enforceable right to payment for performance completed to date under the contracts. In this regard, it would appear that you would have the full right to the non-refundable upfront payments (at a minimum) even in the event that the drug does not receive regulatory approval and enter the commercialization phase.
- We acknowledge your . . . determination that the performance obligations represented a single performance obligation since they were not distinct. Please tell us the following information so we may further evaluate your response:
  - [W]hy you did not identify the research and development services, which appear to be required under the contract to get [Product A] through regulatory approval, as a separate performance obligation. . . .
  - [W]hy the license and research and development services, either alone or combined, are not capable of being distinct from the manufacturing services pursuant to ASC 606-10-25-19a. In this respect, the subcontracting rights under . . . the agreement appear to indicate that there may be available resources outside the company that could provide the research and development services and supplies. Refer also to Example 56, Case B in ASC 606-10-55-371 through 55-372.
  - [W]hy the license and research services, either alone or combined, are not separately identifiable from the manufacturing obligation and thus do not meet the criteria in ASC 606-10-25-19b. In this regard, it appears due to the subcontracting rights, the license and research services are not inter-related with the manufacturing services pursuant to ASC 606-10-25-21c. Refer also to Example 56, Case B, ASC 606-10-55-372A.
  - [I]f you will be compensated separately for any research and development services, such as the technical development activities discussed in . . . the agreement, how you intend to account for those payments.
  - [I]f you will be compensated separately for the supply of goods under the Supply agreement beyond the upfront fee and milestone payments received, and if so, whether or not the compensation includes a normal profit margin.

**Examples of SEC Comments (continued)**

  - [W]hy control has transferred upon manufacturing the vials for [Customer A] pursuant to ASC 606-10-25-23.
  - [H]ow you intend to estimate the expected vials to be produced during the contract term of the supply agreement and how the estimate would be deemed to be a reasonable measure of progress pursuant to ASC 606-10-25-36.
- Regarding the [agreement], for which you determined the total transaction price to be $[X] million, please provide us your analysis of the accounting for the agreement which explains why you did not recognize any portion of the consideration for the license upon transfer of the license at inception of the agreement. Address:
  - If you concluded the license was distinct from the other obligations and why or why not,
  - If you concluded the license was a right to use license or a right to access license and why,
  - The standalone selling prices determined for each performance obligation and how you determined such,
  - Why you did not recognize the guaranteed minimum royalty payments as fixed consideration upon transfer of the license at inception of the agreement, and
  - Why you combined the license with the services to arrange for supplies.
- [Y]ou disclose that if you are unable to reasonably estimate royalty revenue or if you do not have access to the information, you record royalty revenue when the information needed for a reliable estimate becomes available. Please tell us how this policy complies with the requirement in ASC 606-10-55-65 to reflect royalties upon the later of subsequent sale or the satisfaction of the performance obligation to which the royalty has been allocated. In your response, tell us when the information needed for a reliable estimate becomes available in comparison to the period of actual sale.
- We note you have identified certain complementary products as separate performance obligations that are satisfied over the [X-] year warranty period. Please address the following:
  - Explain in more detail the nature of the complementary products and how you evaluated these arrangements under ASC 606-10-25-19 to 25-22.
  - Tell us the time period over which these performance obligations are recognized. In this regard we note your disclosure the performance obligations are satisfied over the [X-] year warranty period. However we note that all of your deferred revenue is classified as a current liability on your balance sheet.

As discussed in Section 2.10, licensing arrangements in which an entity transfers a license of IP along with other services (e.g., R&D or manufacturing services) are common in the life sciences industry. Application of the revenue standard's accounting and disclosure requirements to such licensing arrangements has been a topic of focus for the SEC staff. Registrants in the life sciences industry have received staff comments asking them about how they determined (1) the number of performance obligations in a licensing arrangement and (2) the period(s) in which consideration allocated to each performance obligation should be recognized. In addition, the staff has inquired about the significant judgments made in the determination of whether a registrant provided a customer with a right-to-use or a right-to-access license, as well as about a registrant's considerations related to the application of the sales- or usage-based royalty exception (e.g., in arrangements involving guaranteed or minimum royalty payments).

### 2.12.5 Elective Relief for Nonpublic Entities

The Background Information and Basis for Conclusions of ASU 2014-09 explains that one of the goals of ASC 606 is to improve the revenue disclosure guidance under U.S. GAAP. As a result of the disclosure requirements in ASC 606, financial statement users will have better information to help them make financial decisions. However, when the FASB was developing the revenue standard, it received feedback from nonpublic entities related to (1) the increased costs that nonpublic entities would incur to meet the improved disclosure requirements and (2) questions about why nonpublic entities should be required to provide the same level of disclosure as public business entities (PBEs) given that users of nonpublic-entity financial statements, typically debt holders, have greater access to management. The FASB considered the costs and benefits of its disclosure package and decided to provide various relief to nonpublic entities.

The table below summarizes the disclosure requirements of ASU 2014-09 that a nonpublic entity may elect not to apply.

| Category | Disclosure Requirements | Election Available to Nonpublic Entities |
|---|---|---|
| Disaggregation of revenue | Disaggregate revenue into categories that depict how revenue and cash flows are affected by economic factors. | Yes[5] |
| | Sufficient information to understand the relationship between disaggregated revenue and each disclosed segment's revenue information. | Yes |
| Contract balances | Opening and closing balances (receivable, contract assets, and contract liabilities). | No |
| | Amount of revenue recognized from beginning contract liability balance. | Yes |
| | Explanation of significant changes in contract balances (using qualitative and quantitative information). | Yes |
| Performance obligations (including remaining performance obligations) | Qualitative information about (1) when performance obligations are typically satisfied, (2) significant payment terms, (3) the nature of goods or services promised, (4) obligations for returns or refunds, and (5) warranties. | No |
| | Amount of revenue recognized from performance obligations satisfied in prior periods (e.g., changes in transaction price estimates). | Yes |
| | Transaction price allocated to the remaining performance obligations: | |
| | • Disclosure of quantitative amounts. | Yes |
| | • Quantitative or qualitative explanation of when remaining performance obligation amounts will be recognized as revenue. | Yes |

[5] At a minimum, a nonpublic entity must disclose revenue that is disaggregated in accordance with the timing of transfer of goods or services (e.g., goods transferred at a point in time and services transferred over time) and qualitative information about how economic factors affect revenue and cash flows.

(Table continued)

| Category | Disclosure Requirements | Election Available to Nonpublic Entities |
|---|---|---|
| Significant judgments and estimates | Qualitative information about determining the timing of: | |
| | • Performance obligations satisfied over time (e.g., methods of measuring progress, why methods are representative of the transfer of goods or services, judgments used in the evaluation of when a customer obtains control of goods or services). | Yes[6] |
| | • Performance obligations satisfied at a point in time — specifically, the significant judgments used in the evaluation of when a customer obtains control. | Yes |
| | Qualitative and quantitative information[7] about: | |
| | • Determining the transaction price (e.g., estimating variable consideration, adjusting for the time value of money, noncash consideration). | Yes |
| | • Constraining estimates of variable consideration. | No |
| | • Allocating the transaction price, including estimating stand-alone selling prices and allocating discounts and variable consideration. | Yes |
| | • Measuring obligations for returns, refunds, and other similar obligations. | Yes |
| Contract costs | Qualitative information about: | |
| | • Judgments made in determining the amount of the costs incurred to obtain or fulfill a contract. | Yes |
| | • The method the entity uses to determine the amortization for each reporting period. | Yes |
| | Quantitative information about: | |
| | • The closing balances of assets recognized from the costs incurred to obtain or fulfill a contract, by main category of asset. | Yes |
| | • The amount of amortization and any impairment losses recognized in the reporting period. | Yes |
| Practical expedients | Disclosure of practical expedients used. | Yes[8] |

See Chapters 15 and 16 of Deloitte's Roadmap *Revenue Recognition* for more information about the revenue standard's disclosure requirements, including those that nonpublic entities may elect not to apply. In addition, see Deloitte's April 11, 2018, *Heads Up* for more information about what private companies should know about the revenue standard.

[6] The election available to nonpublic entities applies only to the requirement to disclose information about why the methods used to recognize revenue over time provide a faithful depiction of the transfer of goods or services to a customer. Nonpublic entities are still required to disclose the information about the methods used to recognize revenue over time in accordance with ASC 606-10-50-18(a).

[7] This includes the methods, inputs, and assumptions used in an entity's assessment.

[8] However, nonpublic entities that have elected the practical expedient or policy election in ASU 2021-02 are required to disclose the practical expedient or policy election used.

# Appendix B — Titles of Standards and Other Literature

## AICPA Literature

### Accounting and Valuation Guides

*Assets Acquired to Be Used in Research and Development Activities*

*Valuation of Privately-Held-Company Equity Securities Issued as Compensation*

### Clarified Statements on Auditing Standards

AU-C Section 501, "Audit Evidence — Specific Considerations for Selected Items"

AU-C Section 620, "Using the Work of an Auditor's Specialist"

## FASB Literature

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ASC 105, *Generally Accepted Accounting Principles*

ASC 205, *Presentation of Financial Statements*

ASC 210, *Balance Sheet*

ASC 220, *Income Statement — Reporting Comprehensive Income*

ASC 230, *Statement of Cash Flows*

ASC 235, *Notes to Financial Statements*

ASC 250, *Accounting Changes and Error Corrections*

ASC 260, *Earnings per Share*

ASC 270, *Interim Reporting*

ASC 275, *Risks and Uncertainties*

ASC 280, *Segment Reporting*

ASC 310, *Receivables*

ASC 320, *Investments — Debt Securities*

ASC 321, *Investments — Equity Securities*

ASC 323, *Investments — Equity Method and Joint Ventures*

ASC 326, *Financial Instruments — Credit Losses*

ASC 330, *Inventory*

ASC 340, *Other Assets and Deferred Costs*

ASC 350, *Intangibles — Goodwill and Other*

ASC 360, *Property, Plant, and Equipment*

ASC 405, *Liabilities*

ASC 410, *Asset Retirement and Environmental Obligations*

ASC 420, *Exit or Disposal Cost Obligations*

ASC 440, *Commitments*

ASC 450, *Contingencies*

ASC 460, *Guarantees*

ASC 470, *Debt*

ASC 480, *Distinguishing Liabilities From Equity*

ASC 505, *Equity*

ASC 605, *Revenue Recognition*

ASC 606, *Revenue From Contracts With Customers*

ASC 610, *Other Income*

ASC 705, *Cost of Sales and Services*

ASC 710, *Compensation — General*

ASC 712, *Compensation — Nonretirement Postemployment Benefits*

ASC 715, *Compensation — Retirement Benefits*

ASC 718, *Compensation — Stock Compensation*

ASC 720, *Other Expenses*

ASC 730, *Research and Development*

ASC 740, *Income Taxes*

ASC 805, *Business Combinations*

ASC 808, *Collaborative Arrangements*

ASC 810, *Consolidation*

ASC 815, *Derivatives and Hedging*

ASC 820, *Fair Value Measurement*

ASC 825, *Financial Instruments*

ASC 830, *Foreign Currency Matters*

ASC 832, *Government Assistance*

ASC 835, *Interest*

ASC 840, *Leases*

ASC 842, *Leases*

ASC 845, *Nonmonetary Transactions*

ASC 848, *Reference Rate Reform*

ASC 855, *Subsequent Events*

ASC 860, *Transfers and Servicing*

ASC 905, *Agriculture*

ASC 915, *Development Stage Entities*

ASC 930, *Extractive Activities — Mining*

ASC 944, *Financial Services — Insurance*

ASC 946, *Financial Services — Investment Companies*

ASC 948, *Financial Services — Mortgage Banking*

ASC 954, *Health Care Entities*

ASC 958, *Not-for-Profit Entities*

ASC 960, *Plan Accounting — Defined Benefit Pension Plans*

ASC 970, *Real Estate — General*

ASC 985, *Software*

## ASUs

ASU 2010-27, *Other Expenses (Topic 720): Fees Paid to the Federal Government by Pharmaceutical Manufacturers* — a consensus of the FASB Emerging Issues Task Force

ASU 2011-06, *Other Expenses (Topic 720): Fees Paid to the Federal Government by Health Insurers* — a consensus of the FASB Emerging Issues Task Force

ASU 2014-09, *Revenue From Contracts With Customers (Topic 606)*

ASU 2014-10, *Development Stage Entities (Topic 915): Elimination of Certain Financial Reporting Requirements, Including an Amendment to Variable Interest Entities Guidance in Topic 810,* Consolidation

ASU 2014-15, *Presentation of Financial Statements — Going Concern (Subtopic 205-40): Disclosure of Uncertainties About an Entity's Ability to Continue as a Going Concern*

ASU 2014-16, *Derivatives and Hedging (Topic 815): Determining Whether the Host Contract in a Hybrid Financial Instrument Issued in the Form of a Share Is More Akin to Debt or to Equity* — a consensus of the FASB Emerging Issues Task Force

ASU 2015-16, *Business Combinations (Topic 805): Simplifying the Accounting for Measurement-Period Adjustments*

ASU 2016-01, *Financial Instruments — Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities*

ASU 2016-02, *Leases (Topic 842)*

ASU 2016-10, *Revenue From Contracts With Customers (Topic 606): Identifying Performance Obligations and Licensing*

ASU 2016-12, *Revenue From Contracts With Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients*

ASU 2016-13, *Financial Instruments — Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*

ASU 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments* — a consensus of the FASB Emerging Issues Task Force

ASU 2016-16, *Income Taxes (Topic 740): Intra-Entity Transfers of Assets Other Than Inventory*

ASU 2016-17, *Consolidation (Topic 810): Interests Held Through Related Parties That Are Under Common Control*

ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash* — a consensus of the FASB Emerging Issues Task Force

ASU 2016-20, *Technical Corrections and Improvements to Topic 606,* Revenue From Contracts With Customers

ASU 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business*

ASU 2017-04, *Intangibles — Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment*

ASU 2017-11, *Earnings per Share (Topic 260); Distinguishing Liabilities From Equity (Topic 480); Derivatives and Hedging (Topic 815): (Part I) Accounting for Certain Financial Instruments With Down Round Features, (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests With a Scope Exception*

ASU 2017-12, *Derivatives and Hedging (Topic 815): Targeted Improvements to Accounting for Hedging Activities*

ASU 2018-07, *Compensation — Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*

ASU 2018-08, *Not-for-Profit Entities (Topic 958): Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made*

ASU 2018-10, *Codification Improvements to Topic 842,* Leases

ASU 2018-11, *Leases (Topic 842): Targeted Improvements*

ASU 2018-17, *Consolidation (Topic 810): Targeted Improvements to Related Party Guidance for Variable Interest Entities*

ASU 2018-18, *Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606*

ASU 2019-01, *Leases (Topic 842): Codification Improvements*

ASU 2019-04, *Codification Improvements to Topic 326,* Financial Instruments — Credit Losses*, Topic 815,* Derivatives and Hedging*, and Topic 825,* Financial Instruments

ASU 2019-05, *Financial Instruments — Credit Losses (Topic 326): Targeted Transition Relief*

ASU 2019-10, *Financial Instruments — Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates*

ASU 2019-11, *Codification Improvements to Topic 326,* Financial Instruments — Credit Losses

ASU 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*

ASU 2020-01, *Investments — Equity Securities (Topic 321), Investments — Equity Method and Joint Ventures (Topic 323), and Derivatives and Hedging (Topic 815): Clarifying the Interactions Between Topic 321, Topic 323, and Topic 815* — a consensus of the FASB Emerging Issues Task Force

ASU 2020-02, *Financial Instruments — Credit Losses (Topic 326) and Leases (Topic 842): Amendments to SEC Paragraphs Pursuant to SEC Staff Accounting Bulletin No. 119 and Update to SEC Section on Effective Date Related to Accounting Standards Update No. 2016-02*, Leases (Topic 842)

ASU 2020-03, *Codification Improvements to Financial Instruments*

ASU 2020-04, *Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting*

ASU 2020-05, *Revenue From Contracts With Customers (Topic 606) and Leases (Topic 842): Effective Dates for Certain Entities*

ASU 2020-06, *Debt — Debt With Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*

ASU 2021-01, *Reference Rate Reform (Topic 848): Scope*

ASU 2021-04, *Earnings per Share (Topic 260), Debt — Modifications and Extinguishments (Subtopic 470-50), Compensation — Stock Compensation (Topic 718), and Derivatives and Hedging — Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options* — a consensus of the FASB Emerging Issues Task Force

ASU 2021-05, *Leases (Topic 842): Lessors — Certain Leases With Variable Lease Payments*

ASU 2021-07, *Compensation — Stock Compensation (Topic 718): Determining the Current Price of an Underlying Share for Equity-Classified Share-Based Awards* — a consensus of the Private Company Council

ASU 2021-08, *Business Combinations (Topic 805): Accounting for Contract Assets and Contract Liabilities From Contracts With Customers*

ASU 2021-09, *Leases (Topic 842): Discount Rate for Lessees That Are Not Public Business Entities*

ASU 2021-10, *Government Assistance (Topic 832): Disclosures by Business Entities About Government Assistance*

ASU 2022-01, *Derivatives and Hedging (Topic 815): Fair Value Hedging — Portfolio Layer Method*

ASU 2022-02, *Financial Instruments — Credit Losses (Topic 326): Troubled Debt Restructurings and Vintage Disclosures*

ASU 2022-03, *Fair Value Measurement (Topic 820): Fair Value Measurement of Equity Securities Subject to Contractual Sale Restrictions*

ASU 2022-04, *Liabilities — Supplier Finance Programs (Subtopic 405-50): Disclosure of Supplier Finance Program Obligations*

ASU 2022-06, *Reference Rate Reform (Topic 848): Deferral of the Sunset Date of Topic 848*

ASU 2023-01, *Leases (Topic 842): Common Control Arrangements*

ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*

## Concepts Statements

No. 5, *Recognition and Measurement in Financial Statements of Business Enterprises*

No. 8, *Conceptual Framework for Financial Reporting — Chapter 4*, Elements of Financial Statements

## Invitation to Comment

No. 2022-002, *Accounting for Government Grants by Business Entities: Potential Incorporation of IAS 20,* Accounting for Government Grants and Disclosure of Government Assistance*, Into Generally Accepted Accounting Principles*

## Proposed ASUs

No. 2017-280, *Consolidation (Topic 812): Reorganization*

No. 2019-500, *Income Taxes (Topic 740): Disclosure Framework — Changes to the Disclosure Requirements for Income Taxes (Revision of Exposure Draft Issued July 26, 2016)*

No. 2019-800, *Codification Improvements*

## Other

FASB Staff *Revenue Recognition Implementation Q&As*

## IFRS Literature

IFRS 2, *Share-Based Payment*

IFRS 3, *Business Combinations*

IFRS 9, *Financial Instruments*

IFRS 10, *Consolidated Financial Statements*

IFRS 11, *Joint Arrangements*

IFRS 12, *Disclosure of Interests in Other Entities*

IFRS 15, *Revenue From Contracts With Customers*

IFRS 16, *Leases*

IAS 1, *Presentation of Financial Statements*

IAS 7, *Statement of Cash Flows*

IAS 10, *Events After the Reporting Period*

IAS 12, *Income Taxes*

IAS 17, *Leases*

IAS 20, *Accounting for Government Grants and Disclosure of Government Assistance*

IAS 21, *The Effects of Changes in Foreign Exchange Rates*

IAS 27, *Separate Financial Statements*

IAS 32, *Financial Instruments: Presentation*

IAS 37, *Provisions, Contingent Liabilities and Contingent Assets*

IAS 38, *Intangible Assets*

IAS 40, *Investment Property*

## IRC

Section 78, "Gross Up for Deemed Paid Foreign Tax Credit"

Section 162(a), "Trade or Business Expenses; General"

Section 163(j), "Interest; Limitation on Business Interest"

Section 174, "Amortization of Research and Experimental Expenditures"

Section 197, "Amortization of Goodwill and Certain Other Intangibles"

Section 382, "Limitation on Net Operating Loss Carryforwards and Certain Built-In Losses Following Ownership Change"

Section 409A "Inclusion in Gross Income of Deferred Compensation Under Nonqualified Deferred Compensation Plans"

Section 422, "Incentive Stock Options"

Section 423, "Employee Stock Purchase Plans"

## PCAOB Literature

Release No. 2017-001, *The Auditor's Report on an Audit of Financial Statements When the Auditor Expresses an Unqualified Opinion and Related Amendments to PCAOB Standards*

Auditing Standard 3101, *The Auditor's Report on an Audit of Financial Statements When the Auditor Expresses an Unqualified Opinion*

## SEC Literature

### CF Disclosure Guidance

Topic No. 9, "Coronavirus (COVID-19)"

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### Final Rule Releases

No. 33-10786, *Amendments to Financial Disclosures About Acquired and Disposed Businesses*

No. 33-10890, *Management's Discussion and Analysis, Selected Financial Data, and Supplementary Financial Information*

No. 33-11126, *Listing Standards for Recovery of Erroneously Awarded Compensation*

No. 33-11275, *The Enhancement and Standardization of Climate-Related Disclosures for Investors*

No. 34-95607, *Pay Versus Performance*

## FRM

Topic 1, "Registrant's Financial Statements"

Topic 3, "Pro Forma Financial Information"

Topic 5, "Smaller Reporting Companies"

Topic 7, "Related Party Matters"

Topic 10, "Emerging Growth Companies"

Topic 12, "Reverse Acquisitions and Reverse Recapitalizations"

## Interpretive Releases

No. 33-9106, *Commission Guidance Regarding Disclosure Related to Climate Change*

No. 33-10403, *Updates to Commission Guidance Regarding Accounting for Sales of Vaccines and Bioterror Countermeasures to the Federal Government for Placement Into the Pediatric Vaccine Stockpile or the Strategic National Stockpile*

## Proposed Rule Release

No. 33-11048, *Special Purpose Acquisition Companies, Shell Companies, and Projections*

## Regulation S-K

Item 101, "Description of Business"

Item 103, "Business; Legal Proceedings"

Item 201, "Market Price of and Dividends on the Registrant's Common Equity and Related Stockholder Matters"

Item 302, "Supplementary Financial Information"

Item 303, "Management's Discussion and Analysis of Financial Condition and Results of Operations"

Item 305, "Quantitative and Qualitative Disclosures About Market Risk"

Item 308, "Internal Control Over Financial Reporting"

Item 402, "Executive Compensation"

Item 404, "Transactions With Related Persons, Promoters and Certain Control Persons"

Item 407, "Corporate Governance"

Item 503, "Prospectus Summary"

## Regulation S-X

Rule 1-02(w), "Definitions of Terms Used in Regulation S-X (17 CFR part 210); Significant Subsidiary"

Article 2, "Qualifications and Reports of Accountants"

Rule 3-01, "Consolidated Balance Sheet"

Rule 3-02, "Consolidated Statements of Comprehensive Income and Cash Flows"

Rule 3-05, "Financial Statements of Businesses Acquired or to Be Acquired"

Rule 3-09, "Separate Financial Statements of Subsidiaries Not Consolidated and 50 Percent or Less Owned Persons"

Rule 3-10, "Financial Statements of Guarantors and Issuers of Guaranteed Securities Registered or Being Registered"

Rule 3-12, "Age of Financial Statements at Effective Date of Registration Statement or at Mailing Date of Proxy Statement"

Rule 3-14, "Special Instructions for Financial Statements of Real Estate Operations Acquired or to Be Acquired"

Rule 3-16, "Financial Statements of Affiliates Whose Securities Collateralize an Issue Registered or Being Registered"

Rule 4-08(g), "General Notes to Financial Statements; Summarized Financial Information of Subsidiaries Not Consolidated and 50 Percent or Less Owned Persons"

Rule 4-08(n), "General Notes to Financial Statements; Accounting Policies for Certain Derivative Instruments"

Rule 5-02, "Commercial and Industrial Companies; Balance Sheets"

Rule 5-03, "Commercial and Industrial Companies; Statements of Comprehensive Income"

Article 8, "Financial Statements of Smaller Reporting Companies"

Rule 10-01(b), "Interim Financial Statements; Other Instructions as to Content"

Article 11, "Pro Forma Financial Information"

Rule 11-01 "Presentation Requirements"

Rule 11-02(a), "Preparation Requirements; Form and Content"

Article 15, "Acquisitions of Businesses by a Shell Company (Other Than a Business Combination Related Shell Company)"

## SAB Topics

No. 1.B.3, "Financial Statements; Allocation of Expenses and Related Disclosure in Financial Statements of Subsidiaries, Divisions or Lesser Business Components of Another Entity: Other Matters"

No. 1.M, "Financial Statements; Materiality"

No. 5.A, "Miscellaneous Accounting; Expenses of Offering"

No. 5.Y, "Miscellaneous Accounting; Accounting and Disclosures Relating to Loss Contingencies"

No. 14.B, "Share-Based Payment; Transition From Nonpublic to Public Entity Status"

No. 14.D, "Share-Based Payments; Certain Assumptions Used in Valuation Methods"

- No. 14.D.1, "Expected Volatility"
- No. 14.D.2, "Expected Term"

## Securities Act of 1933

Rule 144, "Persons Deemed Not to be Engaged in a Distribution and Therefore Not Underwriters — General Guidance"

### Securities Exchange Act of 1934

Rule 17a-5, "Reports to Be Made by Certain Brokers and Dealers"

Section 3(a)(80), "Definitions and Application of Title; Emerging Growth Company"

Section 13(a), "Periodical and Other Reports"

Section 15(d), "Supplementary and Periodic Information"

## TRG Agenda Papers

TRG Agenda Paper 6, *Customer Options for Additional Goods and Services and Nonrefundable Upfront Fees*

TRG Agenda Paper 11, *October 2014 Meeting — Summary of Issues Discussed and Next Steps*

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TRG Agenda Paper 44, *July 2015 Meeting — Summary of Issues Discussed and Next Steps*

TRG Agenda Paper 48, *Customer Options for Additional Goods and Services*

TRG Agenda Paper 54, *Considering Class of Customer When Evaluating Whether a Customer Option Gives Rise to a Material Right*

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### AICPA Accounting Statement of Position

96-1, *Environmental Remediation Liabilities*

### EITF Abstracts

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Issue No. 01-8, "Determining Whether an Arrangement Contains a Lease"

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Issue No. 01-10, "Accounting for the Impact of the Terrorist Attacks of September 11, 2001"

Issue No. 03-17, "Subsequent Accounting for Executory Contracts That Have Been Recognized on an Entity's Balance Sheet"

Issue No. 08-6, "Equity Method Investment Accounting Considerations"

Issue No. 09-2, "Research and Development Assets Acquired in an Asset Acquisition"

Issue No. 09-4, "Seller Accounting for Contingent Consideration"

### FASB Concepts Statement

No. 6, *Elements of Financial Statements* — a replacement of FASB Concepts Statement No. 3 (incorporating an amendment of FASB Concepts Statement No. 2)

### FASB Interpretation

No. 14, *Reasonable Estimation of the Amount of a Loss* — an interpretation of FASB Statement No. 5

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## Other

### California Climate Legislation

AB-1305, *Voluntary Carbon Market Disclosures*

SB-253, *Climate Corporate Data Accountability Act*

SB-261, *Greenhouse Gases: Climate-Related Financial Risk*

### IFRS® Sustainability Disclosure Standards

IFRS S1, *General Requirements for Disclosure of Sustainability-Related Financial Information*

IFRS S2, *Climate-Related Disclosures*

# Appendix C — Abbreviations

| Abbreviation | Description |
|---|---|
| **AETR** | annual effective tax rate |
| **AFS** | available for sale |
| **AFSI** | adjusted financial statement income |
| **AI** | artificial intelligence |
| **AICPA** | American Institute of Certified Public Accountants |
| **AIN** | AICPA Accounting Interpretation of an APB Opinion |
| **AMT** | alternative minimum tax |
| **ANDA** | abbreviated new drug application |
| **APB** | Accounting Principles Board |
| **API** | active pharmaceutical ingredient |
| **ARO** | asset retirement obligation |
| **ASC** | FASB Accounting Standards Codification |
| **ASR** | accelerated share repurchase |
| **ASU** | FASB Accounting Standards Update |
| **AUD** | Australian dollar |
| **BCF** | beneficial conversion feature |
| **BEAT** | base erosion anti-abuse tax |
| **BEMTA** | base erosion minimum tax amount |
| **BPD** | branded prescription drug |
| **C&DIs** | Compliance and Disclosure Interpretations |
| **CAM** | critical audit matter |
| **CAQ** | Center for Audit Quality |
| **CARES Act** | Coronavirus Aid, Relief, and Economic Security Act |
| **CCF** | cash conversion feature |

| Abbreviation | Description |
|---|---|
| **CECL** | current expected credit loss |
| **CFC** | controlled foreign corporation |
| **CIMA** | Chartered Institute of Management Accountants |
| **CMO** | contract manufacturing organization |
| **CRO** | contract research organization |
| **CSRD** | Corporate Sustainability Reporting Directive |
| **DTA** | deferred tax asset |
| **DTL** | deferred tax liability |
| **EBITDA** | earnings before interest, taxes, depreciation, and amortization |
| **ED** | exposure draft |
| **EDGAR** | SEC electronic data gathering, analysis, and retrieval system |
| **EGC** | emerging growth company |
| **EITF** | Emerging Issues Task Force |
| **ELOC** | equity line of credit |
| **EPS** | earnings per share |
| **ESA** | energy service agreement |
| **ESG** | environmental, social, and governance |
| **ESPP** | employee stock purchase plan |
| **ESRS** | European Sustainability Reporting Standards |
| **EUR** | euros |
| **Exchange Act** | Securities Exchange Act of 1934 |
| **FASB** | Financial Accounting Standards Board |
| **FAST Act** | Fixing America's Surface Transportation Act |

| Abbreviation | Description |
|---|---|
| **FDA** | U.S. Food and Drug Administration |
| **FDII** | foreign-derived intangible income |
| **FOB** | free on board |
| **FPI** | foreign private issuer |
| **FRM** | SEC Division of Corporation Finance Financial Reporting Manual |
| **FVO** | fair value option |
| **FVTOCI** | fair value through other comprehensive income |
| **GAAP** | generally accepted accounting principles |
| **GenAI** | generative artificial intelligence |
| **GHG** | greenhouse gas |
| **GILTI** | global intangible low-taxed income |
| **GloBE** | Global anti-Base Erosion |
| **GPO** | group purchasing organization |
| **HAFWP** | how and for what purpose |
| **HFI** | held for investment |
| **HFS** | held for sale |
| **HVAC** | heating, ventilation, and air conditioning |
| **IAS** | International Accounting Standard |
| **IASB** | International Accounting Standards Board |
| **IBNR** | incurred but not reported |
| **ICFR** | internal control over financial reporting |
| **IFRIC** | IFRS Interpretations Committee |
| **IFRS** | International Financial Reporting Standard |
| **IIR** | investigator-initiated research |
| **IP** | intellectual property |
| **IPO** | initial public offering |
| **IPR&D** | in-process research and development |
| **IRC** | Internal Revenue Code |
| **IRS** | Internal Revenue Service |
| **ISO** | incentive stock option |

| Abbreviation | Description |
|---|---|
| **ISSB** | International Sustainability Standards Board |
| **IT** | information technology |
| **ITC** | invitation to comment |
| **JOBS Act** | Jumpstart Our Business Startups Act |
| **LCD** | liquid-crystal display |
| **LIBOR** | London Interbank Offered Rate |
| **LIFO** | last in, first out |
| **M&A** | merger and acquisition |
| **MD&A** | Management's Discussion & Analysis |
| **MNE** | multinational enterprise |
| **MSL** | medical science liaison |
| **NDA** | new drug application |
| **NFP** | not-for-profit (entity) |
| **NIH** | National Institutes of Health |
| **NOL** | net operating loss |
| **NOPA** | notice of proposed adjustment |
| **NQSO** or **NSO** | nonqualified stock option |
| **OCA** | SEC's Office of the Chief Accountant |
| **OCI** | other comprehensive income |
| **OECD** | Organisation for Economic Co-operation and Development |
| **OEM** | original equipment manufacturer |
| **PBE** | public business entity |
| **PCAOB** | Public Company Accounting Oversight Board |
| **PCC** | Private Company Council |
| **PIPE** | private investment in public equity |
| **PP&E** | property, plant, and equipment |
| **PRV** | priority review voucher |
| **PTRS** | probability of technical and regulatory success |
| **Q&A** | question and answer |
| **QIP** | qualified improvement property |

| Abbreviation | Description |
|---|---|
| **R&D** | research and development |
| **R&E** | research and experimental |
| **REC** | renewable energy certificate |
| **REMS** | risk evaluation and mitigation strategy |
| **RIM** | retail inventory method |
| **ROU** | right of use |
| **SaaS** | software as a service |
| **SAB** | Staff Accounting Bulletin |
| **SEC** | U.S. Securities and Exchange Commission |
| **Securities Act** | Securities Act of 1933 |
| **SEPA** | standby equity purchase agreement |
| **SOX** | Sarbanes-Oxley Act of 2002 |
| **SPAC** | special-purpose acquisition company |
| **SPPI** | solely payments of principal and interest |
| **SRC** | smaller reporting entity |
| **S&P 500** | Standard & Poor's 500 Index |
| **TD** | Treasury Decision |
| **TDR** | troubled debt restructuring |
| **TRG** | transition resource group |
| **TRWG** | IFRS Foundation Technical Readiness Working Group |
| **TSA** | transition services agreement |
| **USD** | U.S. dollars |
| **UTB** | unrecognized tax benefit |
| **VIE** | variable interest entity |
| **VWAP** | volume-weighted average daily market price |
| **XBRL** | eXtensible Business Reporting Language |

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