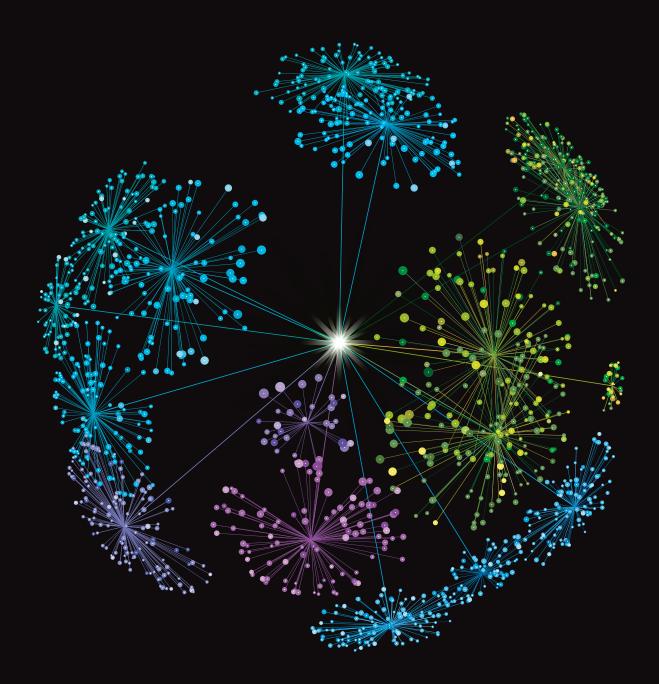
# **Deloitte**



**Seize the digital momentum** Measuring the return from pharmaceutical innovation 2022

January 2023

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### Deloitte Centre for Health Solutions

#### The Deloitte Centre for Health Solutions: Turning evidence into action

We are the research arm of Deloitte's Life Sciences and Health Care practices. The UK Centre's team of researchers, working in partnership with colleagues from the US Center for Health Solutions, aim to be a trusted source of relevant, timely and reliable insights on emerging trends, challenges and solutions. We combine creative thinking, robust research and our industry experience to develop evidence-based perspectives on some of the biggest and most challenging issues to help our clients to transform themselves and, importantly, benefit the patient.

At a pivotal and challenging time for the industry, we use our research to encourage collaboration across all stakeholders, from pharmaceuticals and medical innovation, health care management and reform, to the patient and health care consumer.

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# Foreword

Welcome to *Seize the digital momentum: Measuring the return from pharmaceutical innovation 2022*, the thirteenth annual report from the Deloitte Centre for Health Solutions exploring the performance of the biopharmaceutical industry (biopharma) and its ability to generate returns from investment in innovative new medicines. Since 2021 much of the world has successfully adjusted to life where COVID-19 is more endemic as vaccines and treatments reduced the risk and severity of illness. However, geopolitical turmoil and a global cost-of-living crisis has continued to drive serious instability in the health landscape.

The significant uptick in the internal rate of return (IRR) of investment in innovation seen in 2021 was due largely to the emergency use approval (EUA) of several new treatments and vaccines developed, manufactured and approved in record time. However, as some of these approved assets moved into commercialised portfolios and out of the scope of our analysis, the IRR has declined back to pre-pandemic levels with portfolios projected returns similar to the pre-pandemic years. In addition to our traditional analysis of R&D productivity, we therefore consider what companies might do to improve their IRR for patients and investors.

Between 2010 and 2022 our *Measuring the return from innovation* series has tracked the projected return on investment that an original cohort of 12 leading biopharma companies might expect from their late-stage pipelines using a comprehensive and consistent methodology. For the past eight years we also tracked the performance of a cohort of four more specialised biopharma companies (reduced to three in 2020 due to the merger of one of these four companies with an original company). In addition, the year-on-year declines in the IRR showed the performance of the two cohorts was converging, so in 2020 we extended our analysis to create a cohort of the top 20 companies by R&D spend and therefore provide a more comprehensive view of the industry's overall performance.

This year's report presents our analysis of the performance of the combined cohort (original plus extension) from 2013 to 2020, and the top 20 cohort for the three years 2020 to 2022. Until 2020, the combined cohort had seen a near decade-long decline in projected R&D productivity, reflecting the challenges faced by the industry. However, in 2020 and 2021, for the first time since 2014, the average IRR saw a small uptick in 2020 and a significant uptick in 2021, suggesting signs of a potential reversal in the declining trend. The ability of the industry to bring high impact assets to market rapidly was remarkable and it appears to have been unique.

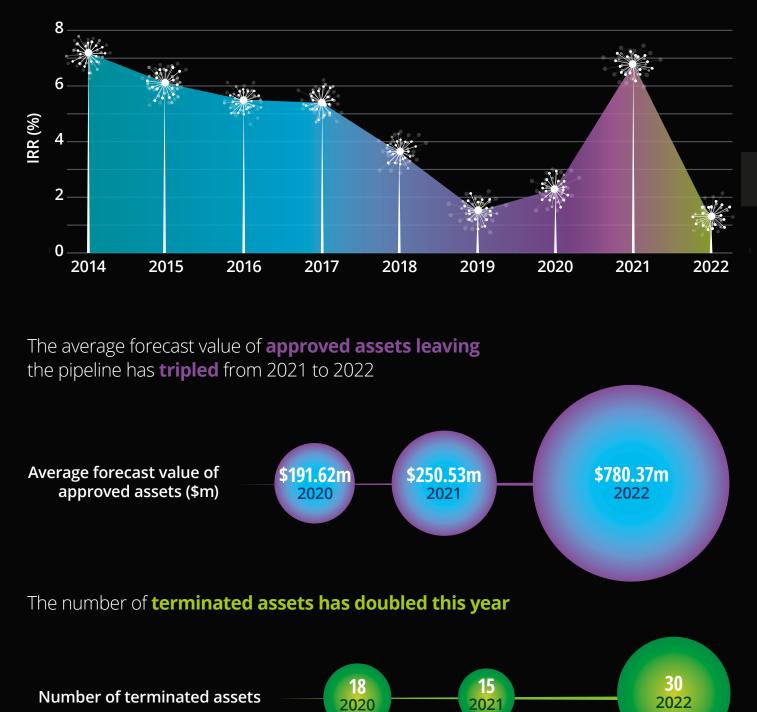
This year, our 2022 analysis shows a return to the IRR experienced before the pandemic reflecting the ongoing realities of the challenges to the industry – increasing costs with declining returns. Despite the reduction in IRR, the spread of individual company IRRs has narrowed compared to previous years meaning the decline is, in part, due to the absence of high value company outliers.

Interestingly, after a decline over the past five years in the proportion of forecast revenue from self-originated assets, there has been a significant rise, from 29 per cent in 2021 to 51 per cent in 2022 reflecting a reduction in reliance on external assets. While the step change in improved productivity that we anticipated in our 2021 report, *Nurturing growth*, is yet to be realised, our core thesis remains that the lessons we identified last year still apply and that there are actions to be taken immediately to: seize the opportunities of digitalisation bolstering meaningful data collection and analysis for decentralised clinical trials; broaden clinical trial diversity to advance equity and improve clinical outcomes for all; and pivot toward environmentally sustainable R&D operations while improving efficiency.

We explore these themes in our report and as always, we welcome your feedback in our discussions this year.

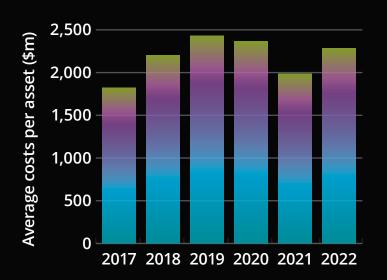
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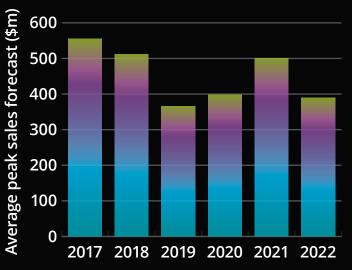


### R&D returns have **returned** to the **declining** trend evident pre-pandemic

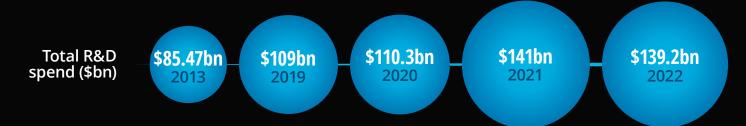
Average cost to bring an asset to market has **risen** to pre-pandemic levels after a dip in 2021



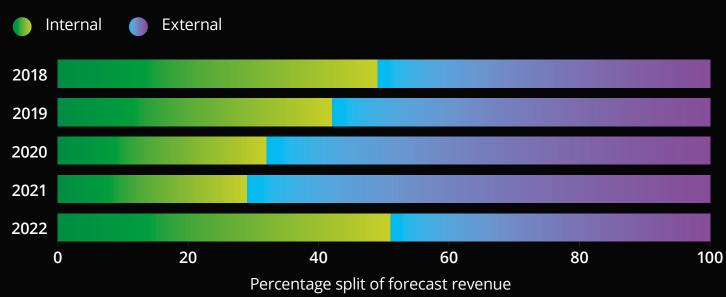
At the same time, average peak sales forecasts per asset have also **dropped** following the high-value forecasts of 2021



### Total R&D spend has remained close to the high levels seen in 2021



The proportion of forecast revenue from **internally** sourced assets has **increased significantly** in 2022 following a declining trend



# Executive summary

Investments in biopharmaceutical (biopharma) research and development (R&D) continue to fuel innovation and shape the future of health. However, this year's analysis demonstrates that despite impressive examples of innovative products the step-change in improved productivity seen in 2021 has not continued. Indeed, our analysis shows the average internal rate of return (IRR) from R&D investment has declined below the pre-pandemic level. On a positive note, the pandemic has accelerated the digitalisation of the industry and increased pharma's awareness of the need to take urgent action to widen the diversity of clinical trial participants. There has also been a greater commitment to reducing the environmental footprint of the industry.

#### About the report

This is the 13th in our series of annual reports on Measuring the return from pharmaceutical innovation, providing insights into the state of biopharma R&D since 2010. Our inaugural report analysed the average IRR that a cohort of 12 largecap biopharma companies might expect to achieve from their late-stage pipelines. However, between 2010 and 2015, the IRR fell from 10.1 per cent to 4.2 per cent, suggesting that smaller more dynamic and flexible R&D units were better equipped to confront the challenges of biopharma R&D. To test the theory in 2015 we added an extension cohort of four smaller, more specialised companies and calculated their IRR back to 2013. Our analysis showed that in 2013 the extension cohorts IRR was much higher than our original cohort's (17.4 compared to 4.8).

Between 2013 and 2019 the expected returns of the original cohort continued to fall year-on-year while the much higher returns experienced initially by the extension cohort fell more dramatically resulting in a convergence in the IRR of the two cohorts to an all-time low in 2019. In 2020, against the backdrop of the start of the COVID-19 pandemic, we saw a small uptick in the average IRR. We also expanded our analysis to calculate the average IRR of the top 20 pharma companies by R&D spend, to give a more comprehensive overview of the industry. While the composition of the cohort may have changed, we have continued to apply the same consistent and objective methodology which focuses on each company's late-stage pipeline (assets that are in Phase II with breakthrough therapy designation, Phase III or filed as of 30th April each year). In measuring the IRR (as a proxy of R&D productivity) we calculate the average cost to develop the assets in each company's pipeline and the expected sales from these assets once launched. As assets are approved or terminated their forecast revenues are removed from the late-stage pipeline and new assets that move into the scope of our analysis are added.

### Measuring the return from pharmaceutical innovation

In 2021 we observed a notable rise in average IRR to 6.8 per cent, driven by high forecast values for COVID-19 assets (including vaccines and treatments) and one high-value late-stage neurological asset. This resulted in two companies with IRRs that were significant outliers. However, as some of these approved COVID-19 assets moved into the commercial portfolio, the IRR has declined again to 1.2 per cent. Indeed, the forecast value of approved assets leaving the pipeline has tripled from 2021 to 2022. Moreover, despite the reduction in IRR, the interquartile range of individual company IRRs has narrowed compared to previous

years and therefore this decline can, in part, be attributed to the absence of a high value company outlier.

In 2022, the top 20 companies spent a total of \$139 billion on R&D, a two per cent decrease in underlying R&D expenditure compared to 2021 (\$141 billion). The average cost to develop an asset was \$2,284 million, an increase of \$298 million from 2021, mainly due to an increase in average cycle time length as the impact of COVID-19 on cycle time acceleration has not continued. Moreover, the average cost to develop an asset from discovery to launch is in line with the pre-pandemic 2018-2020 data.

In 2022, only one of the companies we analysed is predicted to achieve average forecast peak sales greater than \$1 billion across all their assets, and only five companies improved their projected peak sales per asset compared to 2021. In 2022, average forecast peak sales per pipeline asset for the combined cohort decreased from \$500 million in 2021 to \$389 million in 2022. However, the 2022 value is almost identical to the forecast peak sales of 2020. This decline in average forecast peak sale per asset is driven mainly by the number of high-valued assets that have left the pipeline this year.

### A large uptick in the forecast of self-originated assets

After observing a continuous decline in the proportion of forecast revenue from selforiginated assets over the past five years, there has been a significant rise, from 29 per cent in 2021 to 51 per cent in 2022. Consequently, over half of the forecast revenue from the late-stage pipeline is now being generated in-house. This notable increase in the revenue share of selforiginated assets can be partly attributed to the addition of five new blockbuster assets, including a high forecast COVID-19 therapeutic. The proportion of selforiginated assets by volume count has increased by four per cent from 2021 to 2022, with 35 percent of total assets being generated in-house.

#### Transforming R&D through digitalisation, diversity, and sustainability

This year's analysis demonstrates that the step change in improved productivity that we anticipated in our 2021 report, Nurturing growth, is yet to be realised. Our 2021 report highlighted key learnings from the accelerated development of COVID-19 vaccines and therapies that we believed could help biopharma companies improve their R&D productivity. However, the increase in cycle times and cost to develop an asset, alongside lower average forecast peak sales, which we have seen in this year's analysis, suggests that it may be too early for the lessons from the pandemic to have an impact. While we continue to believe that these lessons will make a difference, we have reflected on the immediate actions that we believe will help transform R&D productivity in greater detail. These are:

- optimising digitalisation to bolster meaningful data collection and analysis for decentralised clinical trials
- broadening clinical trial diversity to advance equity and improve clinical outcomes for all
- pivoting toward environmentally sustainable R&D operations while improving efficiency.

As noted last year, the pandemic has accelerated biopharma's approach to digitalisation, instilling it into every aspect of work, and using it to transform the experiences of patients and partners. Digital transformation road maps spanning years were suddenly deployed in months, bringing about radical changes in how companies conduct operations and paving the way for more innovation in clinical trials. This acceleration has continued with the adoption of AI technologies helping to:

- energise drug discovery and trial design
- improve patient and trial site selection
- monitor and manage patients remotely
- reduce the need for travel while improving adherence and reducing attrition
- optimise data collection and collation and consolidate all data on to a shared cloud-based analytics platform.

Biopharma companies and industry stakeholders have acknowledged the need to address the access, awareness, and trust issues that can limit racial and ethnic diversity in clinical trials. Differences in age, life experiences, and genetics can all influence how individuals respond to treatments and interventions. To increase our understanding of treatment effectiveness, clinical trials need to be inclusive of racial and ethnic minority groups, as well as other populations. This requires companies to put diversity at the forefront of their study design; as the more diverse the clinical trial participants, the more companies will learn about the safety and efficacy of the potential medicine. Working with communities and building a network of trusted community-based trial sites could help engage more diverse study populations and build trust in medical research, and in turn, could potentially reduce development cycle times.

The pharma industry is facing growing pressure to improve their environmental footprint across the product lifecycle with most companies adopting ambitious and measurable sustainability targets.

Given 80 per cent of a pharma product's environmental impact is determined in the design phase, adopting a sustainability-bydesign mindset can improve productivity through optimising raw material use, reducing energy and water consumption, and minimising waste and pollution without compromising quality or safety. Moreover, developing study guidelines that require new products to be made in green labs, champion virtual trial design, minimise staff travel and ensure the trial is necessary and managed efficiently, are within the pharma companies' control. Adopting transparent qualitative and quantitative metrics to analyse the changes will be essential in ensuring pharma companies deliver their environmental sustainability targets. To optimise outcomes, scientists and other staff involved in clinical trials need to be trained in the use of digital and Al-enabled innovation and in the adoption of novel 'green' technologies.

#### The clinical trial of tomorrow

Tomorrow's clinical trials will be tailored to the convenience, medical, and behavioural needs of diverse patient populations impacted by diseases. With trial decentralisation as the norm, the virtual clinical trial of the future will place a lower burden on patients. It will be data-rich due to the high frequency and volume of measurement and reduce the environmental impact due to reduced travel, fewer research centres and minimised patient nonadherence and dropouts. Such clinical trials will fundamentally improve the productivity and cost-effectiveness of drug development through purpose-led digital innovation. At an industry level, the central pillars of R&D will be the establishment of clinical trial networks, an ingrained focus on sustainability and extensive collaboration across the health ecosystem will form the central pillars of R&D.

# Measuring the return from pharmaceutical innovation

Our annual *Measuring the return from pharmaceutical innovation* report series analyses the projected IRR that biopharma companies can expect to earn from their latestage pipelines. In this thirteenth report of our series, the considerable flux of the geopolitical landscape, rising inflation rates and major disruption to global supply chains has had an inevitable influence on R&D investment priorities. This year's analysis demonstrates the step change in improved productivity that we anticipated in our 2021 report is yet to be realised. The successful approval of several high value assets, cycle times remaining long and R&D costs continuing to grow has resulted in the IRR declining in 2022 to 1.2 per cent, from 6.8 per cent in 2021.

#### Introduction to this report

Our report series Measuring the return from pharmaceutical innovation has provided insights into the state of biopharma R&D since 2010. Our inaugural report analysed the return on investment that 12 large-cap biopharma companies (our original cohort) might expect to achieve from their latestage pipelines. Over the last 13 years, the composition of our cohort has evolved to now include the top 20 companies by 2020 R&D spend, see Figure 1. Compared to last year's report, Nurturing growth, 2020 and 2021 figures have been restated to include the top 20 companies. See the appendix for a breakdown of the combined cohort and top 20 cohort.

### Methodology for calculating the return from pharmaceutical innovation

While the composition of the cohort may have changed, we have consistently applied the same methodology which focuses on each company's late-stage pipeline. We use two inputs to calculate the IRR:

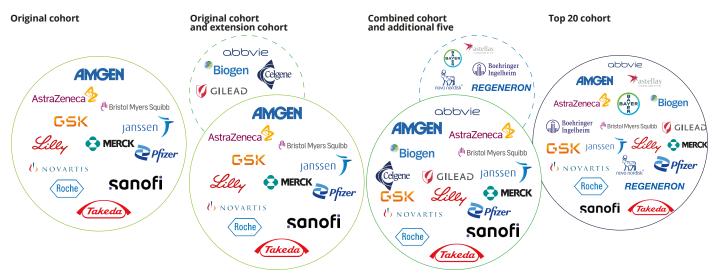
- the total R&D expenditure incurred by a company in bringing their assets to launch (based on publicly available information from audited annual reports and readily available data from thirdparty data providers)
- a forecast estimate of the risk-adjusted future revenue that these assets could expect to earn following launch for 21 years (revenue forecasts provided by GlobalData).\*

As assets are approved, forecast revenues move from the late-stage pipeline into the commercial portfolio and together with terminated assets, move out of scope of our analysis. Our analysis also accounts for multiple factors including:

- forecast revenue splits where a particular asset is in development for multiple indications
- the impact of in-licencing and mergers and acquisitions (M&A) on R&D costs
- success rates in late-stage development
- the impact of clinical cycle times
- the cost of failure due to the inherent risks in undertaking R&D.

<sup>\*</sup> The types of assets included are: New Chemical Entities (NCEs), New Biological Entities (NBEs), significant line extensions expected to result in a measurable uplift in revenues, reformulations, fixed dose combinations and biosimilars.

#### Figure 1. The composition of our cohorts over time, 2010-2022



#### 2010-2014

Our analysis of this cohort between 2010 and 2014 indicated a steep decline in the average IRR with an inverse correlation between IRR and company size.

#### 2015-2019

In 2015, we added an extension cohort of four smaller, more specialised companies and retrospectively analysed their R&D investments back to 2013. Over the subsequent four years the IRR of the original cohort fell year-on-year and the much higher returns of the extension cohort fell more dramatically, leading to a convergence in the performance of both cohorts. The acquisition of an extension cohort company by an original company in 2020 reduced the extension cohort to three companies.

#### 2020-2021

Consequently, in our 2020 analysis, we merged the original and extension cohorts to create a 'combined cohort' of 15 companies with performance data tracked back to 2013. In 2020, we also expanded our analysis once again to measure the IRR of five further biopharma companies to give an even broader picture of the overall industry.

#### 2022

We now have three years of data points for the additional five companies with trends beginning to emerge, and these are closely correlated to the results of the combined cohort dataset. Therefore, including the data points of the additional five companies in the total company cohort does not have a measurable impact on the overall data. Our data set now covers the top 20 pharma companies by R&D spend. This year, like in 2021, we have additionally conducted the IRR analysis without emergency use approval (EUA) COVID-19 therapeutics and vaccines to obtain a view of the industry without the impact of the pandemic assets. However, the EUA assets in the pipeline continue to accumulate R&D costs and therefore are included in the main analysis displayed throughout this report.

We are continually working to improve the methodology and modelling underpinning this analysis and reviewing the assets included in our pipeline year-on-year to ensure accuracy and continuous improvement. Therefore, some numbers have been adjusted and restated, but a consistent and objective approach is applied across all companies and corresponding cohorts each year. The accompanying methodology annex provides more detail.

### Projected returns from innovation have declined this year

Last year we witnessed a notable rise in IRR to 6.8 per cent, driven by high forecast value COVID-19 assets (including vaccines and treatments) and one high-value latestage neurological asset. The neurological asset has subsequently underperformed post-launch and is no longer seeking approval outside the US. The IRR has declined in 2022 to 1.2 percentage points, see Figure 2. This is driven by the successful approvals of high value forecast assets which have been commercialised, including COVID-19 assets, and therefore left the scope of our analysis, as shown in the waterfall charts later in this report (Figure 6). Indeed, while the return on investment is not improving year-on-year, the absolute revenue for the cohort is trending upward without interruption. Reported pharma segment sales in FY2021 have increased by 80 percentage points since FY2010, from \$365 billion to \$656 billion. This includes an 11 per cent increase from FY2020 to FY2021.

Despite this low percentage point IRR, the interquartile distribution of individual company IRRs has narrowed compared to previous years and therefore this decline can be attributed, in part, to the absence of a high value company outlier that was consistently witnessed in previous years. Last year, three top performing companies achieved forecast returns greater than 18 per cent, but the top performer this year is forecast significantly lower at only 7.6 per cent.

In 2022, we also see a decrease in the range in performance between the top and bottom performer at 25.9 percentage points (top performer +7.6 per cent, bottom performer -18.3 per cent) compared to the range of 29.7 percentage points (top performer +19.8 per cent, bottom performer -9.9 per cent) witnessed in 2021. While only five companies improved their average forecasted IRR in 2022 compared to 2021, 14 companies are forecasted to achieve positive returns.

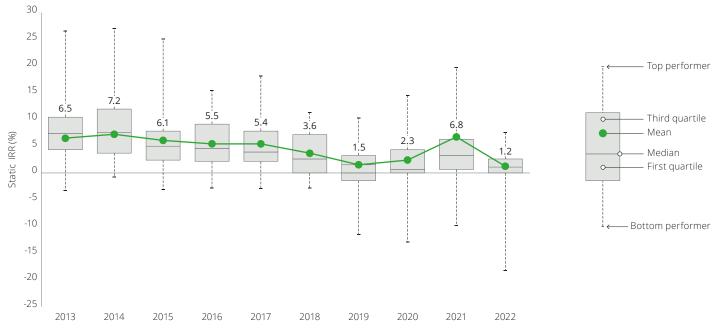
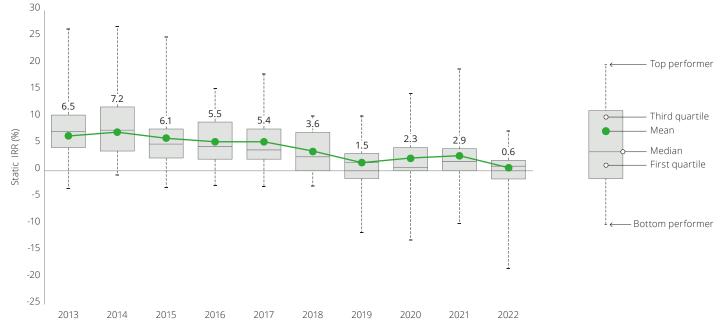


Figure 2. Return on late-stage pipeline, 2013-22

Source: Deloitte analysis, 2022.

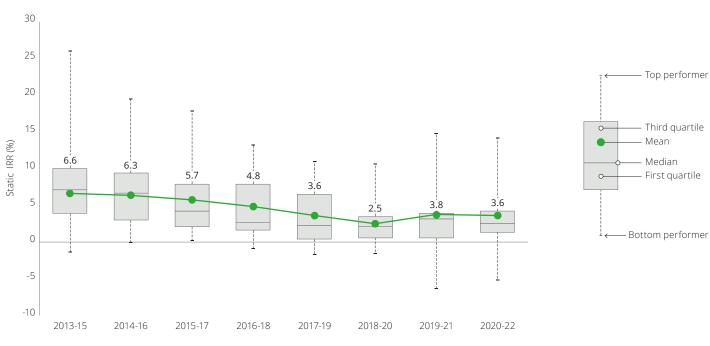
Please note: 2013-2019 data includes the 15 companies of the combined cohort; 2020-2022 data includes the results of the top 20 companies by 2019 R&D spend. See appendix 1 for the data of each cohort. Compared to last year's report 2020 and 2021 figures have been restated to include the top 20 companies by R&D spend as of 2020.



#### Figure 3. Return on late-stage pipeline, 2013-22, without EUA assets

Source: Deloitte analysis, 2022.

Please note: 2013-2019 data includes the 15 companies of the combined cohort; 2020-2022 data includes the results of the top 20 companies by 2019 R&D spend. See appendix 2 for the data of each cohort. Compared to last year's report 2020 and 2021 figures have been restated to include the top 20 companies by R&D spend as of 2020.



#### Figure 4. The three-year rolling average IRR 2013-15 to 2020-22

Source: Deloitte analysis, 2022.

Please note: 2013-2019 data includes the 15 companies of the combined cohort; 2020-2022 data includes the results of the top 20 companies by 2019 R&D spend. See appendix 3 for the data of the combined cohort. Compared to last year's report 2020 and 2021 figures have been restated to include the top 20 companies by R&D spend as of 2020.

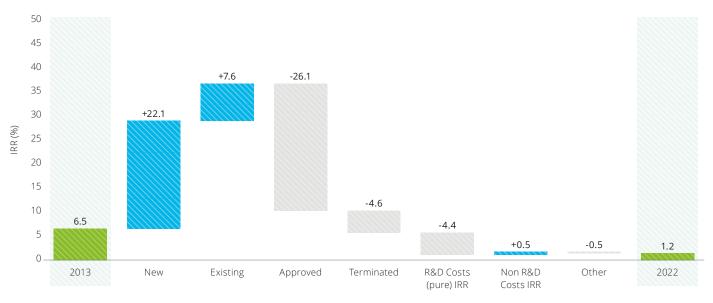
This year, the asset with the highest forecast in our analysis is a COVID-19 therapeutic, granted EUA by the EMA and FDA. There are seven EUA assets included in our pipeline this year, four of which had their EUA granted in our 2021 analysis period but have not yet received full approval for use. We have additionally analysed the pipelines of the companies without these assets. This results in the IRR decreasing to 0.6 per cent, from 2.9 per cent in 2021, see Figure 3. This decrease in IRR is driven by the successful commercialisation of several high-value late stage assets.

### Three-year rolling average returns remain steady

On a three-year rolling average basis, the forecast IRR has decreased slightly to 3.6 per cent for 2020-22, down from 3.8 per cent in 2019-21 (see Figure 4). Despite the year-on-year variation, the three-year rolling average returns have remained stable since 2017-19. Indeed, despite the recent volatility in IRR and low value achieved in 2022, this year's rolling average is above the 2.5 per cent witnessed in 2018-20 and equal to the value of 2017-19 with a much smaller distribution across the interquartile range despite the large outliers.

### Drivers of change for the decline in returns

Figure 5 presents the aggregate drivers of change between 2013 and 2022. As we see every year companies continue to innovate by investing in new assets, with the overall effect of this investment being a growth in IRR of 22.1 percentage points. However, the rate at which companies have been replenishing the forecasted late-stage pipeline value has not previously been enough to counteract the commercialisation of assets, with a net impact of pipeline replenishment value being -4.0 percentage points since 2013. The 4.4 percentage point decline in IRR due to R&D costs is caused by the rising costs of R&D over the timeframe. Indeed, the companies analysed spent an average of \$139 billion on R&D in 2022, compared to just \$85 billion in 2010 for the same set of companies.



#### Figure 5. Drivers of change in the IRR, 2013-22

Source: Deloitte analysis, 2022.

*Please note: 2013-2019 data includes the 15 companies of the combined cohort; 2020-2022 data includes the results of the top 20 companies by 2019 R&D spend. See appendix 4 for the data of the combined cohort.* 

Focusing in on the drivers of change between 2021 and 2022, Figure 6 demonstrates that despite the continued positive impact of pharma companies innovating by investing in the development of new assets, the value of projected returns from existing late-stage pipeline assets has declined this year. This is driven by several high-value forecast late-stage assets delaying their anticipated launch date by two to three years. Negative trial data for two late-stage oncology assets has had a significant impact on the anticipated forecast for existing assets. However, the 2020 to 2021 increase in IRR was the highest year-on-year increase due to existing assets since our analysis began in 2010, see appendix 6. Therefore, the drop in value of existing assets following such high-value approvals was expected. These successful high-value approvals which remove the assets from our R&D pipeline have also led to an overall decrease in IRR this year.

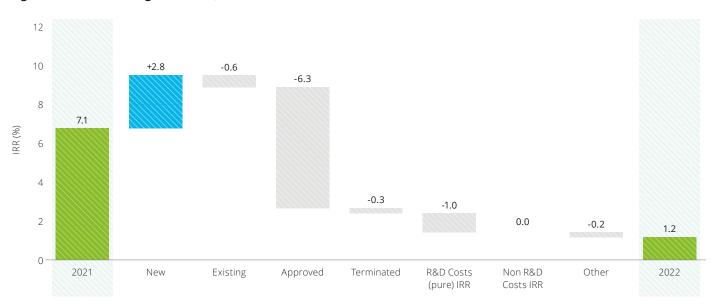
Indeed, the forecast value of approved assets leaving the pipeline has tripled from 2021 to 2022. In 2022, \$780 million of assets were successfully commercialised from our pipeline, an increase of 310 per cent from 2021 (\$251 million). The approval of a COVID-19 vaccine which previously held an EUA license and one high-value late-stage neurological asset which has underperformed post launch drive this step change increase in value of approved assets.

Our analysis shows that the number of terminated assets this year has doubled from 15 in 2021 to 30 in 2022, including six forecasted blockbuster indications. Recently there has been considerable flux in the geopolitical landscape. The resulting cost-of-living crisis, major disruption to global supply chains and high inflation has resulted in pharma companies assessing which assets are resilient to an economic and geopolitical downturn and where they want to prioritise investment into R&D.

Although it can take many decades to assess the full scale of impact individual policy and regulations have in pharma, the recently passed Inflation Reduction Act (IRA) may affect the dispensing and prescription landscape in the US. Specifically, it will lower the cost of prescription drugs and save millions of US citizens thousands of dollars per year, e.g., establishing a \$35 monthly cap per prescription for insulin covered by a Medicare prescription drug plan and insulin delivered through traditional pumps. Its top line impact may not have been felt yet, but it is already affecting the R&D investment decisions. This has resulted in some companies terminating clinical trials of candidate drugs expected to price at very high levels or high-risk drugs in development and may partly explain the changing trends witnessed in our 2022 analysis.

### The average number of assets in development has plateaued

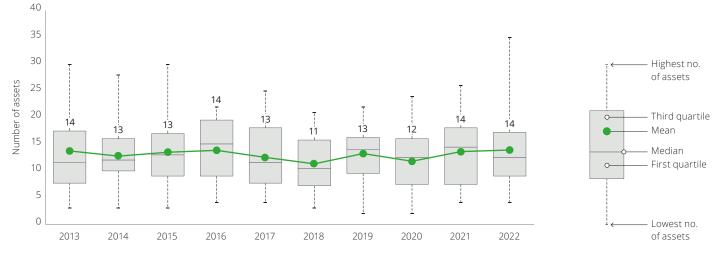
There has been a slight increase in overall asset numbers in the last year from 273 (2021) to 278 (2022). This is the lowest year-on-year increase since 2018, but the average number of late-stage assets across the companies remains stable. Consistent with previous years, there is a substantial range in the companies with the lowest number of assets (four) and the largest number of assets (35) as shown in Figure 7. The largest number of assets in a company's late-stage pipeline since our analysis began occurred this year due to a major acquisition by one of the combined cohort companies, resulting in the high outlier in this data.



#### Figure 6. Drivers of change in the IRR, 2021-22

Source: Deloitte analysis, 2022.

Please note: See appendix 5 for the data of the combined cohort.



#### Figure 7 . Average number of assets in the late-stage pipeline, 2013-22

Source: Deloitte analysis, 2022.

Please note: 2013-2019 data includes the 15 companies of the combined cohort; 2020-2022 data includes the results of the top 20 companies by 2019 R&D spend. See appendix 7 for the data of each cohort. Compared to last year's report 2020 and 2021 figures have been restated to include the top 20 companies by R&D spend as of 2020.

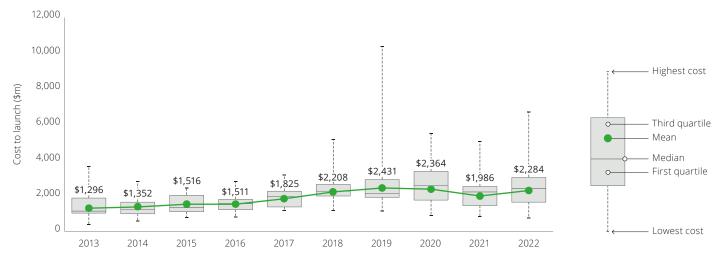
As discussed in Deloitte's publication M&A trends in life sciences – H1 2022 dealmaking, the pandemic boosted life sciences dealmaking to record levels in 2021 and this trend was predicted to continue.1 However, both the number and value of M&A deals fell in the first half of 2022. from 205 deals and a value of \$130 billion in the first half of 2021, to only 112 deals and a value of \$55 billion in the first half of 2022.<sup>2</sup> This decline has been attributed to increased caution exercised by purchasers due to economic, geopolitical and regulatory uncertainty.<sup>3,4</sup> Furthermore, the pharmaceutical sector saw a 13 per cent decrease in deal value and a nine per cent decrease in deal volume in O3 2022 compared to Q2.5 Despite this, pharmaceuticals emerged as the most active M&A segment of the life sciences industry, with immunology, oncology and CNS having the highest deal values, and oncology, CNS and infectious disease having the largest numbers of deals.6,7

Nevertheless, dealmaking in 2022 has not met the expectations set by most stakeholders - where a 'bumper year' was predicted due to favourable market conditions such as increased cashflows due to COVID-19 assets and a need for replenished pipelines. Consequently, an uptick in investment in de-risked late-stage assets in particular has been predicted.<sup>8,9</sup>

### The average cost to develop an asset from discovery to launch has increased

In 2022, the companies analysed spent a total of \$139 billion on R&D, corresponding to a decrease of two per cent in underlying R&D expenditure compared to 2021 (\$141 billion). Figure 8 shows that the average cost to develop an asset was \$2,284 million, an increase of \$298 million from 2021. This increase in 2022 compared to 2021 is due mainly to increasing average cycle time length. The anticipated impact of COVID-19 on cycle time acceleration last year has not continued.

The distribution of costs to develop an asset has also increased compared to 2021, from a range of \$4,239 million (highest cost: \$5047 million, lowest cost: \$808 million) to \$5,437 million (highest cost: \$6716 million, lowest cost \$739 million). Despite these increases, the average cost to develop an asset from discovery to launch is comparable to the pre-pandemic 2018-2020 data.



#### Figure 8. Average R&D cost to develop a compound from discovery to launch, 2013-22

Source: Deloitte analysis, 2022.

Please note: 2013-2019 data includes the 15 companies of the combined cohort; 2020-2022 data includes the results of the top 20 companies by 2019 R&D spend. See appendix 8 for the data of each cohort. Compared to last year's report 2020 and 2021 figures have been restated to include the top 20 companies by R&D spend as of 2020.





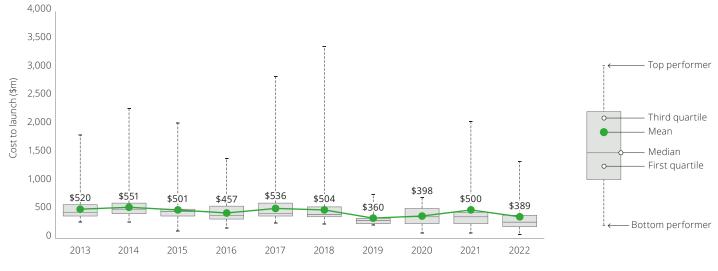
Many therapy areas maintained or even decreased their cycle times in 2022. However, cycle times for oncology increased and remained far higher than other therapy areas at 11.6 years, driving this overall increase, see figure 9. Although oncology is the most active area of drug development, the Tufts Center for the Study of Drug Development estimate that oncology clinical trials take approximately 30-40 per cent longer to complete than for other drugs.<sup>10</sup> This increased length has been attributed to a number of factors, including greater trial complexity and challenges in patient recruitment and retention.11

This corroborates with research which has found oncology and rare disease trial completion rates to be far lower than other therapy areas, and also include more geographical sites and create greater volumes of data, all contributing to longer cycle times.<sup>12</sup>

### Average forecast peak sales have declined

In 2022, only one of the companies we analysed achieved forecast peak sales per asset greater than \$1 billion, and only five companies improved their projected peak sales per asset compared to 2021. Furthermore, in 2022, average forecast peak sales per pipeline asset for the combined cohort decreased from \$500 million in 2021 to \$389 million in 2022 as shown in Figure 10. The 2022 value is almost identical to the forecast peak sales of 2020. Moreover, if COVID-19 EUA assets are excluded, the average peak sales forecasts decline from \$340 million in 2021 to \$284 million in 2022. This decline in average forecast peak sale per asset is driven by the number of high-value forecasted assets which have left our pipeline this year.

#### Figure 10. Average forecast peak sales per pipeline asset, 2013-22



Source: Deloitte analysis, 2022.

Please note: 2013-2019 data includes the 15 companies of the combined cohort; 2020-2022 data includes the results of the top 20 companies by 2019 R&D spend. See appendix 9 for the data of each cohort. Compared to last year's report 2020 and 2021 figures have been restated to include the top 20 companies by R&D spend as of 2020.

#### A large uptick in the proportion of forecast revenue from self-originated assets

As discussed previously, the average forecasted revenue per pipeline asset in the late-stage pipeline of the 20 companies analysed has decreased to \$389 million in 2022 from \$500 million in 2021. As displayed in Figure 11, the revenue composition across innovation sources has also shown a notable change. After witnessing a continuous decline for five years, there has been a significant increase in the proportion of forecast revenue from self-originated assets from 29 per cent in 2021 to 51 per cent in 2022. Therefore, over half of the forecast revenue from the late-stage pipeline is now being generated in-house. This notable increase in the share of self-originated assets can be partly attributed to the addition of five new blockbuster assets.

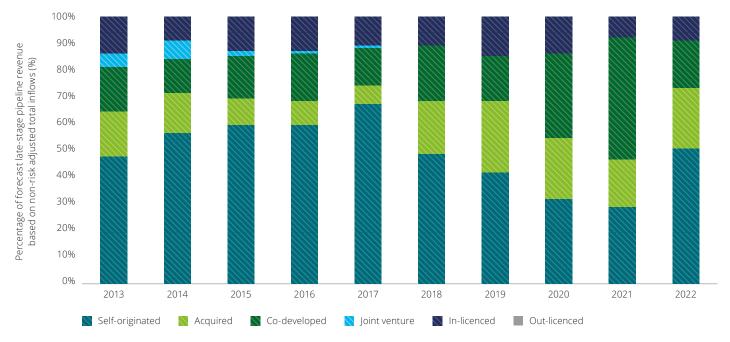
The substantial decrease in proportion of co-developed asset revenue, from 46 per cent in 2021 to 18 per cent in 2022 has also contributed to this shift in distribution. A substantial proportion of 2021's forecast revenue from co-developed assets was dominated by high-value COVID-19 assets, along with the fast track of a high-value neurological asset which have now received full approval.

For the last five years, the composition of the late-stage pipeline has been consistent with regard to the proportions of sources of innovation when analysed by absolute number of assets, see Appendix 11. However, there are small year-on-year differences. For example, the number of self-originated assets has increased by four per cent from 2021 to 2022, with 35 per cent of total assets being generated in-house.

### Therapy area composition remains consistent

This year, the late-stage pipeline composition by therapy area has followed a similar trend as 2021 (see Figure 12). The relative proportion of pipeline focused on central nervous system, metabolic, cardiovascular, infectious diseases and immunology have largely remained the same.

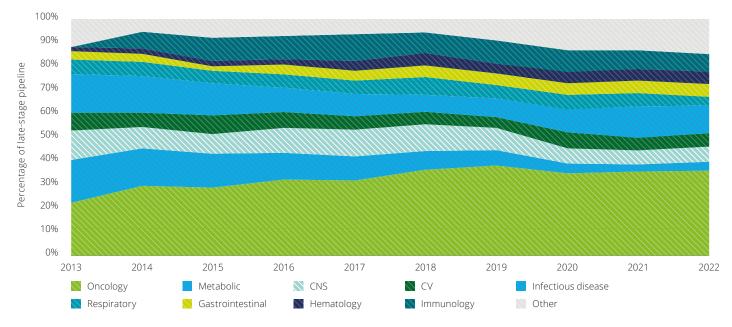
The proportion of the pipeline focused on respiratory diseases has decreased by two percentage points, to its lowest proportion in the last ten years. This has been replaced by the relative increase in focus on 'other' therapy areas by two per cent. This is predominantly driven by an increased focus on genetic disorders, genito-urinary system and sex hormones, and ophthalmology. As in previous years, the proportion of pipeline focused on oncology is still paramount with 36 per cent of the pipeline assets developed for oncology.



#### Figure 11. Proportion of late-stage pipeline forecast sourced from internal and external sources, 2013-22

Source: Deloitte analysis, 2022.

Please note: 2013-2019 data includes the 15 companies of the combined cohort; 2020-2022 data includes the results of the top 20 companies by 2019 R&D spend. See appendix 10 for the data of each cohort. Compared to last year's report 2020 and 2021 figures have been restated to include the top 20 companies by R&D spend as of 2020.



#### Figure 12. Late-stage pipeline composition by therapy area, 2013-22

Source: Deloitte analysis, 2022.

Please note: 2013-2019 data includes the 15 companies of the combined cohort; 2020-2022 data includes the results of the top 20 companies by 2019 R&D spend. See appendix 12 for the data of each cohort. Compared to last year's report 2020 and 2021 figures have been restated to include the top 20 companies by R&D spend as of 2020.

#### Leveraging innovation platforms to replenish pipelines may entail changes to R&D operations

Traditionally biopharma companies have depended on acquisitions of small and large molecules to replenish their pipelines. Our analysis shows that modalities other than small molecules and antibody therapies now account for more than 20 per cent of the late-stage pipeline of the companies analysed.

Over the past few years, the clinical and therapeutic validation of innovation platforms (e.g., cell and gene therapies, mRNA) have created an alternative approach for companies to leverage these to build future pipelines. This has required biopharma companies to move away from a disease-centric mindset to using innovation platforms to produce a range of assets against several diseases. For instance, biopharma companies can apply mRNA technology to create platform vaccines against influenza, HIV, hepatitis C, malaria and tuberculosis as well as therapeutics in oncology. Leveraging this technology for pipeline replenishment may entail altering resource allocations and prioritising funding to advance innovation platform development and use. Unconventional talent sourcing (e.g., experts from academic medical centers) and upskilling existing R&D personnel on new platform technologies will enable the full potential of these platforms to be realised.

At the same time, bringing to market a greater number of these new therapies (such as cell therapies) also necessitates highly coordinated cross-functional planning and alignment. Deloitte's research on operating models for cell and gene therapies highlights how commercialisation needs to change to build a value chain around the patient, seamlessly coordinating specimen collection, therapy manufacturing, and delivery.<sup>13</sup>

# Transforming R&D through digitalisation, diversity, and sustainability

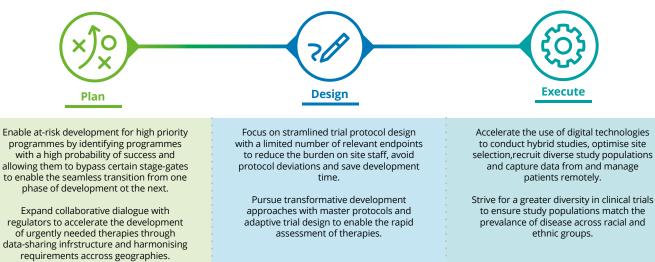
While there are increasing signs of productivity improvements, such as more widespread adoption of digitalisation and increasing focus on diversity, in the operation of clinical trials, cycle times remain long and R&D costs continue to grow. There are challenges for both clinical trial professionals and trial participants. These include recruitment and retention, design and implementation (including improving diversity of trial participants), and safety and efficacy issues. A common denominator driving advances in clinical trials is moving to a decentralised model encompassing data connectivity and being able to seamlessly connect clinical trial data to real-world data (RWD) to improve recruitment, clinical development success rates and accelerate innovation.

This year's analysis demonstrates the step change in improved productivity that we anticipated, in our 2021 report Nurturing growth is yet to be realised.<sup>14</sup> It is clear that revitalising today's clinical trials for a healthier tomorrow will require thoughtful digitalisation of clinical trial processes to create a seamless experience for patients and staff. This could drastically improve trial efficiency, enhance scientific rigor, and expand health equity. In parallel, as our recent report Embedding environmental sustainability into pharma's DNA found improving R&D efficiency can also address the urgent need to collectively reduce the sector's environmental footprint.15

#### The findings from Nurturing Growth

Our Measuring the returns from pharmaceutical innovation 2021 report highlighted key learnings from the accelerated development of COVID-19 vaccines and therapies that could help biopharma companies improve R&D productivity, see Figure 13.<sup>16</sup> While many companies in our cohort may have begun to do so, these efforts will take time to have a material impact. At the same time, geopolitical instability and extreme weather conditions have emphasised the importance of a more sustainable approach to R&D. Given the increase in cycle times and cost to develop an asset alongside lower average forecast peak sales seen in this year's analysis, we have expanded our evaluation of actions needed to execute the transformation of R&D:

- optimising digitalisation to bolster meaningful data collection and analysis for decentralised clinical trials
- broadening clinical trial diversity to advance equity and improve clinical outcomes for all
- pivoting toward environmentally sustainable R&D operations while improving productivity.



#### Figure 13. Incorporate the lessons from the R&D approaches adopted for COVID-19 into routine clinical development

Source: Deloitte analysis, 2021

#### Optimising digitalisation to bolster meaningful data collection and analysis for clinical trials

The pandemic has accelerated biopharma's approach to digital innovation, instilling it into every aspect of work, and using it to transform the experiences of patients and partners. Digital transformation road maps spanning years were suddenly executed in months, bringing about radical changes in how companies conduct operations.<sup>17</sup> Digitalisation of the clinical trial process is improving the productivity of R&D. Biopharma companies are increasingly using digital tools and artificial intelligence (AI) technologies to improve trial design, enhance trial recruitment and retention, facilitate data collection and monitoring, enable more robust data analytics and increase the efficiency of dossier submission. In the future, the availability of rich data sets and Al-driven analytics will drive the development of highly effective personalised therapies without the need for large-scale clinical trials.

### Decentralised trials are becoming more mainstream

Digitalisation is also powering the increase in decentralised clinical trials (DCTs) – see sidebar. From capturing e-consent to using telehealth and sensors for virtual check-ins and remote assessments, digital technologies are both generating real-world trial data and reducing or eliminating the need travel.<sup>18</sup> Access to and engagement in trials can be greatly enhanced by involving trusted community care providers and by bringing medical research directly to where people live or work. According to Deloitte's 2022 US health care consumer survey, offering clinical trials from home or virtually would increase consumers' willingness to participate in a clinical trial by nearly 20 percentage points and offering clinical trials at a convenient site would increase willingness by nearly ten percentage points.<sup>19</sup>

### Defining decentralised clinical trials

DCTs combine patient-centred design and innovative technologies, such as telemedicine, sensorybased technologies and wearable medical devices, to improve the overall experience of patients and physicians. DCTs can be fully virtual or hybrid. Virtual trials use remote monitoring and diagnostics, home health providers, digital capture of consent data, and direct-topatient drug distribution. A hybrid approach requires some physical site attendance, for example an initial on-site screening. DCTs can improve access for a wider demographic of participants who might otherwise not take part in site-based research. According to a study by IQVIA, decentralised trials reduced time to the first patient enrolled by 49 per cent and reduced protocol deviations by 54 per cent.<sup>20</sup> Such trials also reduce the overall trial timeline and yielded a return five times the original investment in phase II deployments and 14 times the investment for phase III deployment, according to a Tufts Center for Drug Development study.<sup>21</sup>

Long-term collaboration and investment through partnerships with communitybased sites, retailers, technology vendors and others will improve the success of DCTs. However, understanding the digital literacy and ability of diverse groups of patients to use digital monitoring devices and then customising solutions accordingly will be key to capturing high-quality outcome data.

### Enhancing data collection and quality through digital tools

Advancements in digital innovation have yielded technologies that enable continuous monitoring of clinical trial participants and the collection of more meaningful and accurate data in real-time. According to *Deloitte's 2022* US Health Care Consumer Survey of 4,545 people, consumers are increasingly using digital tools to monitor or measure their health and wellness.<sup>22</sup> Indeed, 49 per cent said they were using wearables, digital assistants, or smart devices to measure fitness/health improvement, an increase from 42 per cent in 2020 and 28 per cent in 2015. As people become more comfortable with such tools and have a more vested interest in health and wellness, participation in trials may be enabled further.

For biopharma, early engagement with regulatory authorities to align on objectives, study design and use of digital biomarkers or surrogate endpoints will be of critical importance to embed remote data collection into trials more widely. In January 2022, the FDA issued guidance for the selection and use of wearables and apps in clinical trials including discussing the appropriateness of the technology with the regulators prior to use. The FDA requires companies to consider five factors that may influence the reliability and acceptability of the data generated.<sup>23</sup>

#### Expanding the use of real-world data

The increased adoption of digital tools and advancements in technological capabilities are enabling enhanced use of real-world evidence or data (RWE/D) in clinical trial design and execution. Since 2017, Deloitte has tracked the biopharma industry's efforts to expand the use of RWE/D across the product life cycle. Deloitte's Real world evidence 2022 benchmarking study found that more than half of biopharma companies say they expect to use RWE/D data for innovative R&D use cases such as building regulatory grade synthetic arms or designing adaptive trials, within the next three years with goals to reduce time to market or to reduce the cost of executing clinical trials.<sup>24</sup>

By investing in technology and partnering with hospitals and electronic health record (EHR) companies, biopharma companies can link RWD with other data collected during the clinical trial to derive more longitudinal insights into the efficacy of new therapies and their impact on patients' lives. Beyond data access, deriving insight requires anonymising and de-identifying patient data through techniques such as tokenisation to ensure compliance with HIPPA (Health Insurance Portability and Accountability Act) and other standards. A survey by Datavant found that 62 per cent of biopharma leaders in the US expect new privacy-preserving technologies, such as tokenisation, to support faster innovation in drug development.25

#### **Tokenisation of clinical trials**

The 'tokenisation' of clinical research participants links information from trials to RWD on the same patients. By tokenising clinical trial data, life science companies gain the ability to link real-world data to their clinical trial data, without unblinding the study or compromising the privacy of trial participants. To date the differences in data regulation and standards means it is deployed only in the US.<sup>26</sup>

#### Enhancing the efficiency of clinical trials

Cloud, AI and machine learning (ML) technologies can automate and enhance the efficiency of trial operations. Deloitte's 2021 *Biopharma digital transformation report* based on a survey of 150 biopharma leaders found that 81 per cent are currently prioritising investments in AI and 71 per cent in cloud technology.<sup>27</sup> Leaders identified the top value levers realisable through digital innovation as improving research productivity (95 per cent), reducing drug discovery costs (76 per cent) and improving pipeline diversity (67 per cent). The benefits of AI and ML in R&D include:

• Improving study design: ML algorithms can analyse past study protocols and their results – including those that failed – to provide the study team with suggested enhancements to protocol design, thus improving efficiency, and likelihood of trial success. ML algorithms can also analyse RWD to match patients to trials based on disease and socioeconomic and behavioural characteristics, helping to increase adherence and reduce dropout rates.

#### • Standardising data collection:

Al algorithms, combined with an effective digital infrastructure, could enable the continuous stream of clinical trial data to be cleaned, aggregated, coded, stored and managed. The standardised data elements can auto-populate required reports such as trial dossiers and analysis templates.

• Predicting optimal site and country selections: Predictive analytics can utilise historical trial performance data to help study planning teams optimise site and country mix for large scale, multicentre trials, giving visibility into realistic expectations on study start-up and enrolment timescales. Biopharma companies are increasingly seeing contract research organisations (CROs) that have invested in data science skills and talent as strategic partners as they provide access not only to specialised expertise, but also to a wide range of potential trial participants.<sup>28</sup> By 2020, 75 per cent of clinical trials were outsourced.<sup>29</sup>

### Broadening participant diversity to advance equity and scientific rigor

Differences in age, life experiences, and genetics can all influence how individuals respond to treatments and interventions. To account for these factors and increase our understanding of treatment effectiveness, clinical trials need to be inclusive of racial and ethnic minority groups, as well as other populations. The more diverse the clinical trial participants, the more we can understand and learn about the safety and efficacy of the potential medicine and its impact on different populations. Working with communities and building a network of trusted community-based trial sites could help engage more diverse study populations and build trust in medical research, while also potentially reducing development cycle times.

### Engage trusted community resources to enhance trial awareness

Awareness of clinical trials is often seen as the first step to enhancing participation. Yet nearly 20 per cent of consumers in the US had never heard of a clinical trial, according to Deloitte's *2022 US health care consumer survey*.<sup>30</sup> Asian, Black and Hispanic respondents were nearly twice as likely as white respondents to have never heard of a clinical trial. Many biopharma companies have recognised this. Deloitte's survey of Pharmaceutical Research and Manufacturers of America (PhRMA) member companies found 81 per cent said lack of patient awareness is a top barrier to trial participation.<sup>31</sup> Biopharma companies and industry stakeholders have acknowledged the need to address access, awareness, and trust issues that can limit racially and ethnically diverse participation. Regulatory authorities are also committed to enhancing racial and ethnic diversity in study designs and drug applications. While the industry is pursuing various strategies to overcome these barriers, there is consensus on the need to meet patients where they live and where they already interact with trusted health care providers in the community.<sup>32</sup>

Deloitte research on consumer sentiments around community-based solutions and their impact on clinical trial participation found that community-based organisations, such as pharmacies and community health centres, are the most trusted entities to share health care information and to improve the patient experience. By building sustainable relationships with community-based health organisations biopharma companies can leverage community-based resources to improve awareness of clinical studies and ultimately enhance the diversity of trial participation.<sup>33</sup> Case study 1 highlights how an academic medical centre in the US is engaging cultural ambassadors from specific communities to enhance diverse participation in clinical trials.

Reduce the burden of clinical trial

**participation through decentralisation** Many pharmaceutical companies and industry stakeholders have recognised the

importance of decentralisation to not only

expedite trials and better engage patients

biopharma companies can engage diverse

sites to ensure adequate representation in

but also enhance diverse and equitable

participation. Figure 14 highlights how

clinical studies.

#### CASE STUDY 1

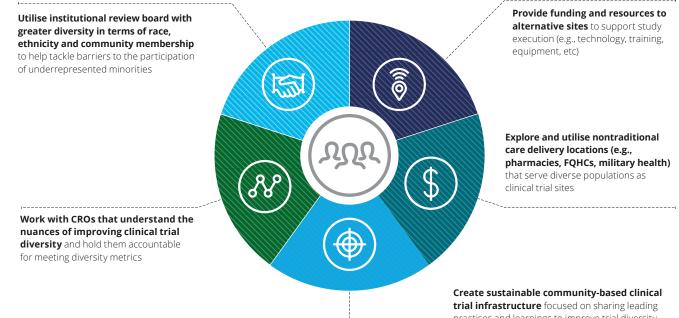
#### Engaging cultural ambassadors to enhance diversity in clinical studies

In the US, The Yale Center for Clinical Investigation has set up a cultural ambassador programme involving community-based partnerships with the African Methodist Episcopal Zion (AME Zion) Churches of Connecticut and several Hispanic or Latinx leaders including the Junta for Progressive Action.

As part of this programme, cultural ambassadors, who are respected community members, engage in advocacy and education to drive awareness and encourage participation in clinical studies within their communities. Working with these ambassadors has also helped clinical research teams identify and understand the needs of the community and develop educational materials that were culturally and linguistically inclusive.

The programme has enabled success in the recruitment and retention of racially and ethnically diverse participants. In 2020, the Yale School of Medicine sponsored more than 2,111 active trials, with approximately 27,800 participants, including approximately 31 per cent underrepresented minorities. In some individual studies, with the direct support of the cultural ambassadors, underrepresented minorities represent more than 90 per cent of total enrolment.<sup>34</sup>

#### Figure 14. Identifying and developing sites focused on treating underrepresented populations



practises and learnings to improve trial diversity

#### Pivoting toward environmentally sustainable R&D operations while improving productivity

The pharma industry is facing growing pressure to improve their environmental footprint across the product lifecycle with most companies adopting ambitious and measurable sustainability targets. Eighty per cent of a pharmaceutical product's environmental impact is determined in the design phase.<sup>35</sup> Creating a product with the smallest possible environmental impact will require biopharma companies to emphasise sustainability early in the product lifecycle. As discussed in our recent publication Embedding environmental sustainability into pharma's DNA, adopting a sustainability-by-design mindset, can improve productivity through optimised raw material use, reduced energy and water consumption, and minimised waste and pollution without compromising quality or safety. Moreover, developing study guidelines, championing virtual trial designs, minimising their own travel and ensuring the trial is necessary and efficient are all within the pharma companies' control.36

As the end-to-end visibility of R&D is increased through productivity driven initiatives, these data-driven insights can be used to recognise hotspots of waste and inefficiency and target interventions where they are most needed. The transformational change required to meet pharma's net-zero targets needs to be underpinned by evidence-based insights and an enhanced awareness, including educating scientists to innovate, develop and adopt novel 'green' technological and scientific advances.

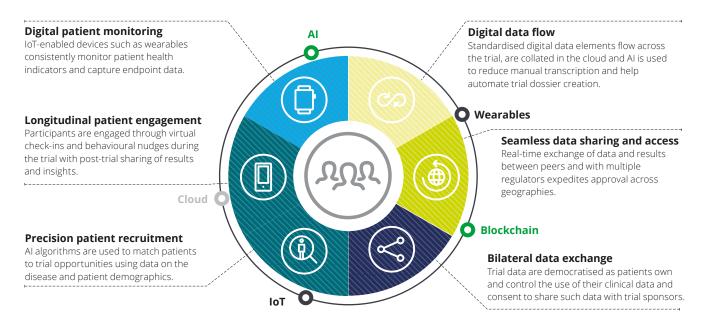
While, traditionally, businesses are conditioned to protect intellectual property, the journey to net zero, highefficiency and minimised use of natural resources necessitates an ecosystem wide collaborative approach to magnify impact beyond a company's own operations and address climate change at a systems level. Sharing solutions, best practices, learnings and even IP can save time, effort and costs, as the industry collectively strives to reduce its environmental footprint.

#### The clinical trial of tomorrow

In this section, we paint a picture of the technology-driven, diverse, and sustainable clinical trial of tomorrow that can be achieved as companies revitalise current development paradigms.

Tomorrow's clinical trials will be tailored to the convenience, medical, and behavioural needs of diverse patient populations impacted by diseases. With trial decentralisation as the new norm, the virtual clinical trial of the future will place a low-burden on patients, be data-rich due to the high frequency of measurement and reduce the environmental impact due to reduced travel, fewer research centres and minimised patient nonadherence and dropouts. Such clinical trials will fundamentally transform drug development and cut development timelines through the following:

#### Figure 15: Sample digital innovations for seamless clinical trials of tomorrow



#### Purpose-led digital innovation:

Figure 15 highlights how a purpose-led portfolio of digital technology investments can enable companies to innovate and create a seamless clinical trial experience for patients and digitalise workflows for investigators and trial staff.

#### Establishment of clinical trial

**networks:** Sustained efforts to build community-based trial infrastructure have created an extensive network of alternative trial-ready sites closer to where patients live or work. These sites have the requisite data infrastructure and highly trained investigators to run studies which ensure representative medical research. Such infrastructure is complemented by community-based health care practitioners and trusted community representatives actively socialising trial opportunities with patients across geographies, races and ethnicities expediting diverse enrolment.

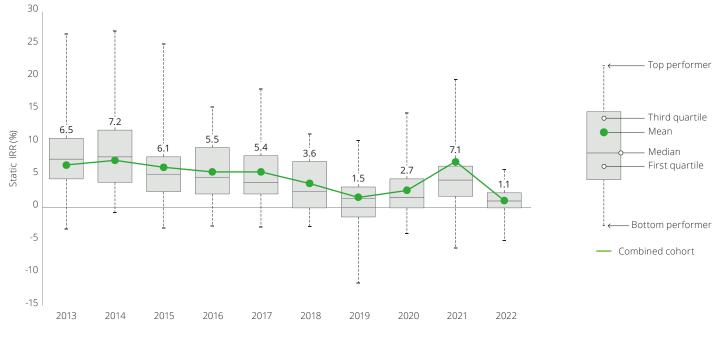
#### Ingrained focus on sustainability:

Leadership commitment, employee education and initiatives have created a cultural focus on sustainability in trial operations. This includes portfolio decision-makers and trial designers actively assessing the value of developing a drug against the impact of such trial activities on the environment. To ensure scope 3 emissions targets are met biopharma companies have worked with their suppliers, CRO partners and other third parties to prioritise sustainability across all operations. Transparent industry frameworks and methods are widely used enabling companies to assess the carbon footprint, emissions and waste from their studies.

Extensive collaboration: Collaboration among biopharma companies, regulators, CROs and tech vendors has created libraries of digital endpoints to power virtual studies and validated medical and consumer-grade sensors for remote data collection. In parallel, companies have adopted data privacy-preserving technologies to manage sensitive patient data, instilling a sense of confidence among patients to share long-term RWD. This data is actively being fed back into the R&D process for faster innovation. Parallel multi-country data submissions and approvals are the norm as major regulators have harmonised their guidance around decentralised trial conduct and expedited review pathways are in place. .

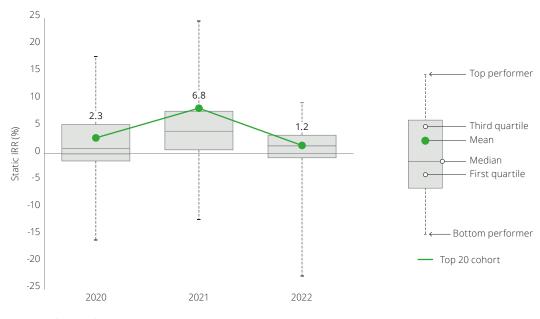
# Appendix

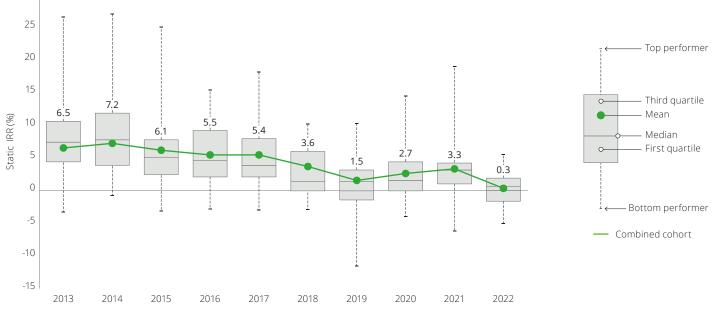
#### Appendix 1A. Return on late-stage pipeline of the combined cohort, 2013-22



Source: Deloitte analysis, 2022.

#### Appendix 1B. Return on late-stage pipeline of the top 20 cohort, 2020-22



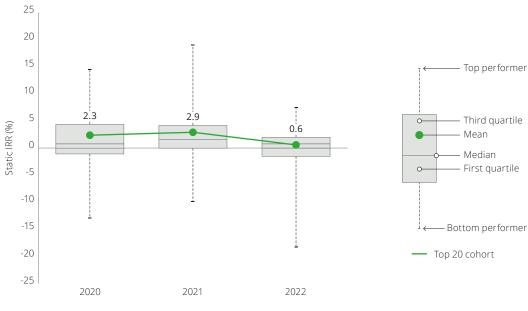


#### Appendix 2A. Return on late-stage pipeline of the combined cohort, 2013-22, without EUA assets

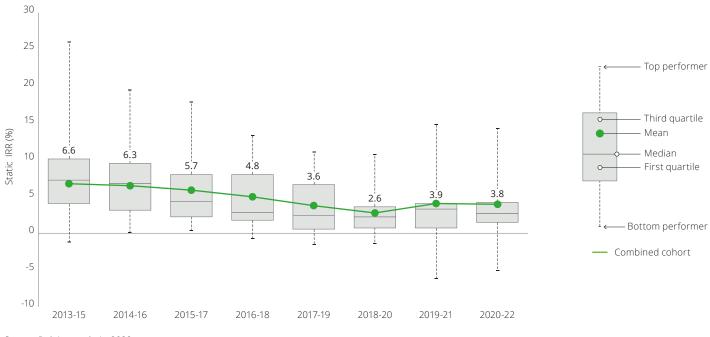
Source: Deloitte analysis, 2022.

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#### Appendix 2B. Return on late-stage pipeline of the top 20 cohort, 2020-22, without EUA assets



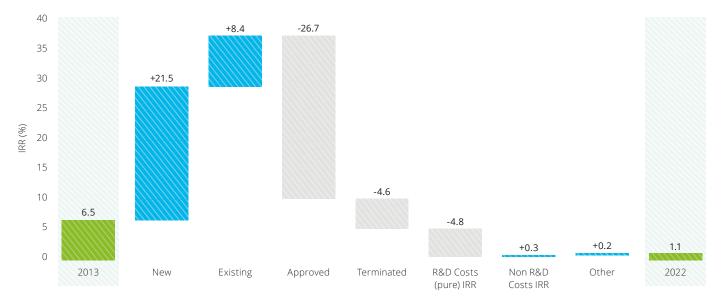
Source: Deloitte analysis, 2022.



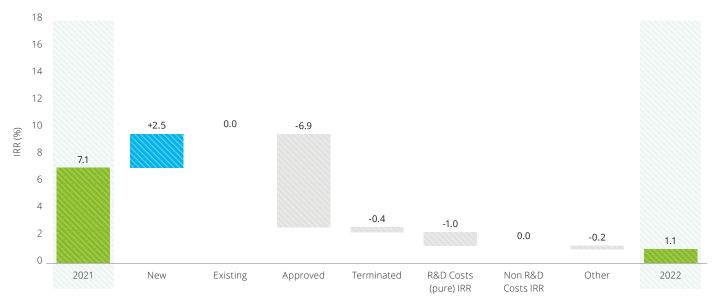
#### Appendix 3. The three year rolling average IRR for the combined cohort 2013-15 to 2020-22

Source: Deloitte analysis, 2022.

#### Appendix 4. Drivers of change in the IRR of combined cohort, 2013-22



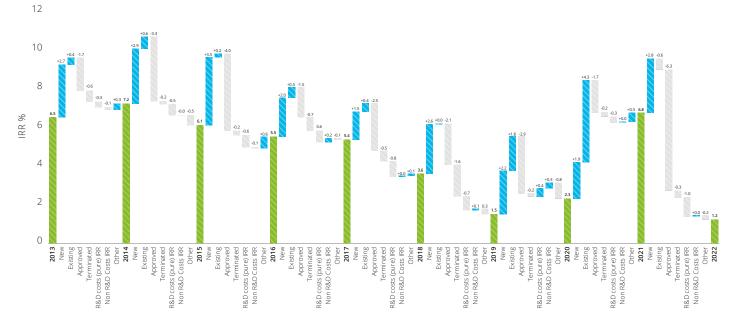
Source: Deloitte analysis, 2022.

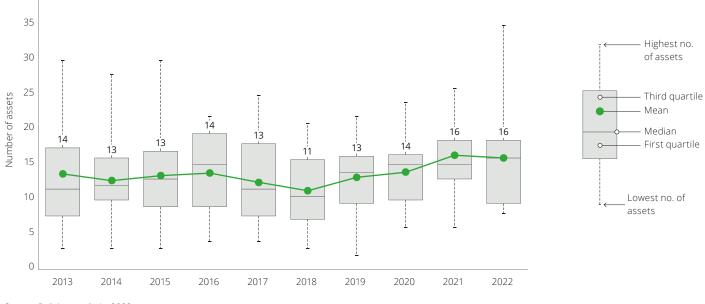


#### Appendix 5. Drivers of change in the IRR of the combined cohort, 2021-22

Source: Deloitte analysis, 2022.

#### Appendix 6. Year-on-year drivers of change in the IRR, 2013-22

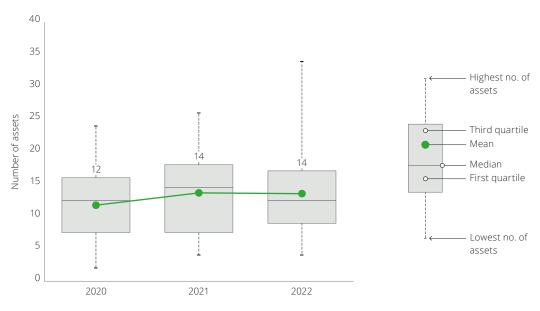




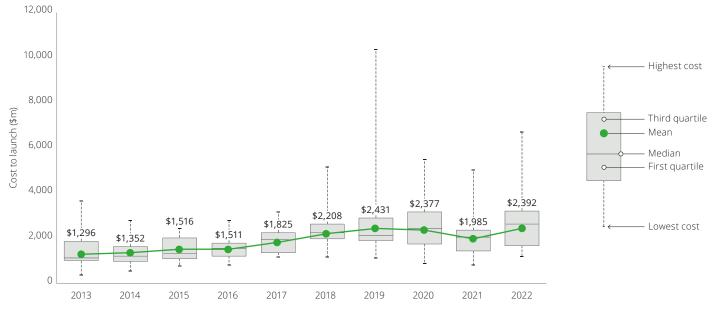
#### Appendix 7A. Average number of assets in the late-stage pipeline of the combined cohort, 2013-22

Source: Deloitte analysis, 2022.

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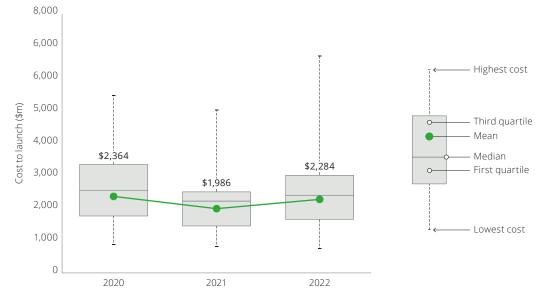


#### Appendix 7B. Average number of assets in the late-stage pipeline of the top 20 cohort, 2020-22

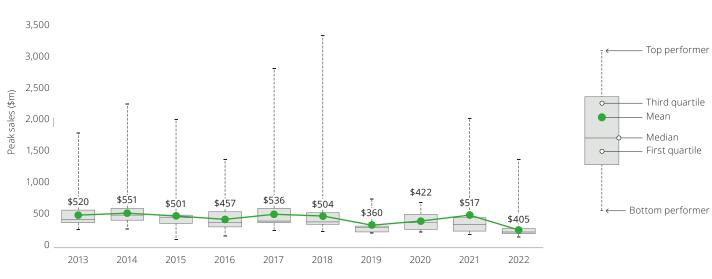


#### Appendix 8A. Average R&D cost for the combined cohort to develop a compound from discovery to launch, 2013-22

Source: Deloitte analysis, 2022.



#### Appendix 8B. Average R&D cost for the top 20 cohort to develop a compound from discovery to launch, 2020-22



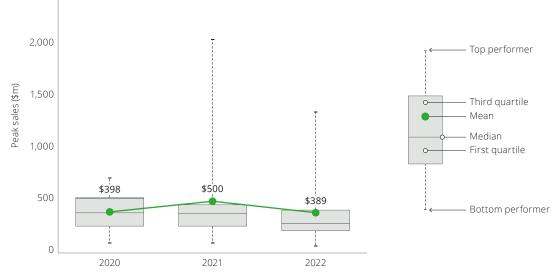
#### Appendix 9A. Average forecast peak sales per pipeline asset of the combined cohort, 2013-22

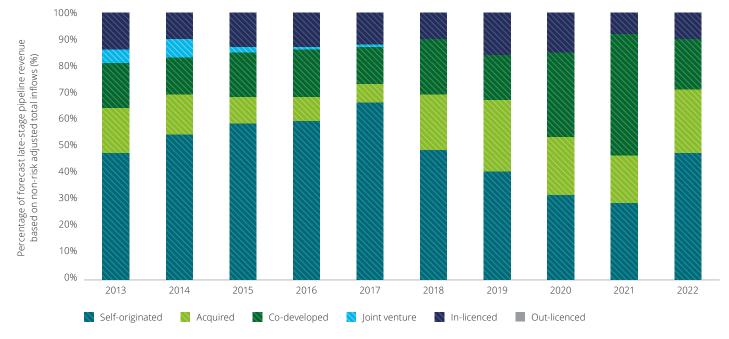
Source: Deloitte analysis, 2022.

2,500

4,000

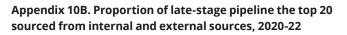


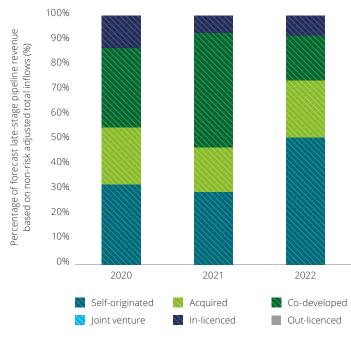


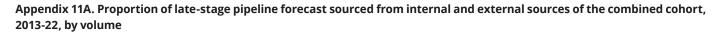


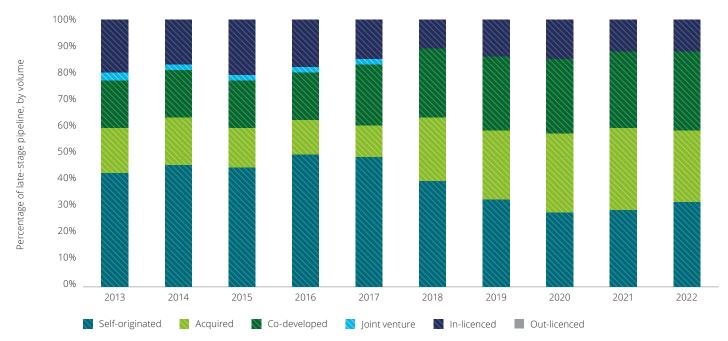
Appendix 10A. Proportion of late-stage pipeline the combined cohort sourced from internal and external sources, 2013-22

Source: Deloitte analysis, 2022.



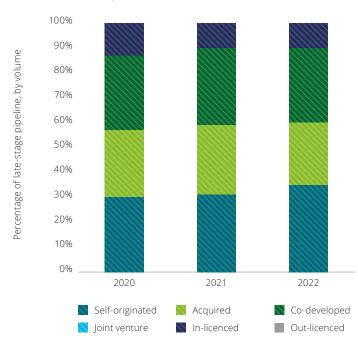


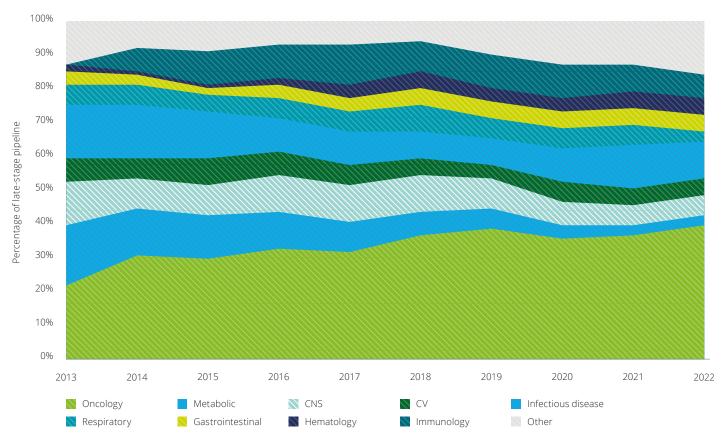




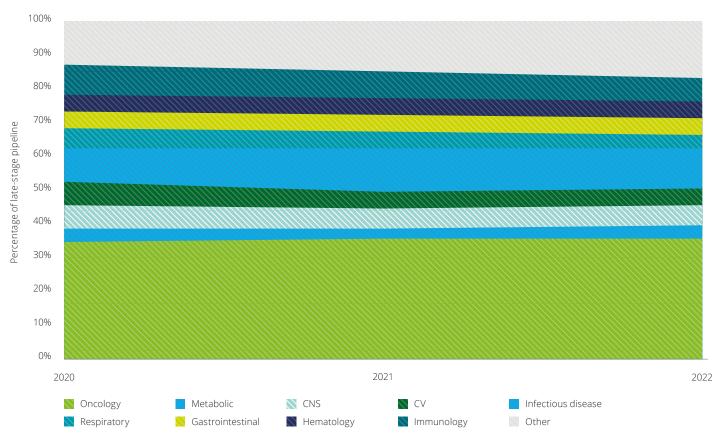
Source: Deloitte analysis, 2022.

Appendix 11B. Proportion of late-stage pipeline forecast sourced from internal and external sources of the top 20 cohort, 2020-22, by volume





#### Appendix 12A. Late-stage pipeline composition of the combined cohort by therapy area, 2013-22



#### Appendix 12B. Late-stage pipeline composition of the top 20 cohort by therapy area, 2020-22

# Endnotes

1. The M&A trends in life sciences shaping 2022, Deloitte, August 2022. See also: https://www2.deloitte.com/us/en/pages/life-sciences-and-health-care/articles/ mergers-and-acquisitions-trends-survey-life-sciences.html

2. Ibid.

- 3. IQVIA Pharma Deals: Half-year review of 2022, IQVIA, 27 September 2022. See also: https://www.iqvia.com/library/white-papers/iqvia-pharma-deals-half-year review-of-2022
- 4. Pharma dealmaking hit by greater scrutiny of prices and competition, Financial Times, 28 February 2022. See also: https://www.ft.com/content/697f27b3-6b23-4326-95b5-02c25623eee2
- 5. Pharmaceuticals Industry Mergers and Acquisitions Deals by Top Themes in Q3 2022, GlobalData, 25 October 2022. See also: https://www.globaldata.com/store/ report/healthcare-industry-m-and-a-deals-by-theme-quarterly-analysis/

6. Ibid.

- 7. The M&A trends in life sciences shaping 2022, Deloitte, August 2022. See also: https://www2.deloitte.com/us/en/pages/life-sciences-and-health-care/articles/ mergers-and-acquisitions-trends-survey-life-sciences.html
- Pfizer Leads Big Pharma M&A In 2022 But Is There More To Come?, Pharma Intellgence, 12 October 2022. See also: https://scrip.pharmaintelligence.informa. com/SC147191/Pfizer-Leads-Big-Pharma-MA-In-2022--But-Is-There-More-To-Come?vid=Pharma
- 9. The M&A trends in life sciences shaping 2022, Deloitte, August 2022. See also: https://www2.deloitte.com/us/en/pages/life-sciences-and-health-care/articles/ mergers-and-acquisitions-trends-survey-life-sciences.html
- 10. Impact Report: Analysis and insight into critical drug development issues, TUFTS University, May 2021. See also: https://f.hubspotusercontent10.net/ hubfs/9468915/TuftsCSDD\_June2021/images/May-Jun-2021.png
- 11. Ibid.
- 12. Protocol Design and Performance Benchmarks by Phase and by Oncology and Rare Disease Subgroups, National Library of Medicine, 12 August 2022. See also: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9373886/
- 13. Cell and gene therapies, Deloitte, 17 April 2020. See also: https://www2.deloitte.com/us/en/insights/industry/life-sciences/operating-models-for-gene-cell-therapy-manufacturing-process.html
- 14. Measuring the return from pharmaceutical innovation 2021, Deloitte, January 2021. See also: https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/ life-sciences-health-care/Measuring-the-return-of-pharmaceutical-innovation-2021-Deloitte.pdf
- 15. Embedding environmental sustainability into pharma's DNA, Deloitte, October 2022. See also: https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/ life-sciences-health-care/deloitte-uk-embedding-environmental-sustainability-into-pharma-dna.pdf
- 16. Measuring the return from pharmaceutical innovation 2021, Deloitte, January 2021. See also: https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/ life-sciences-health-care/Measuring-the-return-of-pharmaceutical-innovation-2021-Deloitte.pdf
- 17. Biopharma digital transformation: Gain an edge with leapfrog digital innovation, Deloitte. See also: https://www2.deloitte.com/content/dam/Deloitte/it/ Documents/life-sciences-health-care/DI\_Life\_sciences\_digital\_innovation.pdf
- 18. Clinical Trials Can Make Anyone a Hero, Sanofi, 20 May 2021. See also: https://www.sanofi.com/en/science-and-innovation/stories/clinical-trials-can-makeanyone-a-hero
- 19. Broadening clinical trial participation to improve health equity, Deloitte, 4 October 2022. See also: https://www2.deloitte.com/us/en/insights/industry/healthcare/increasing-diversity-clinical-trials.html
- 20. DCTs Deliver Big ROI, IQVIA. See also: https://www.iqvia.com/-/media/iqvia/pdfs/library/white-papers/dcts-deliver-big-roi.pdf?\_=1667419934882
- 21. Assessing the Financial Value of Decentralized Clinical Trials, National Library of Medicine, 14 September 2022. See also: https://www.ncbi.nlm.nih.gov/pmc/ articles/PMC9473466/
- 22. Broadening clinical trial participation to improve health equity, Deloitte, 4 October 2022. See also: https://www2.deloitte.com/us/en/insights/industry/healthcare/increasing-diversity-clinical-trials.html
- 23. FDA Releases Guidance for Wearables and Apps in Clinical Trials, FDA Map, 6 January 2022. See also: https://www.fdamap.com/fda-releases-guidance-forwearables-and-apps-in-clinical-trials.html
- 24. Getting real with real-world evidence (RWE), Deloitte. See also: https://www2.deloitte.com/us/en/pages/life-sciences-and-health-care/articles/real-worldevidence-benchmarking-survey.html
- 25. The future of health data: A 2022 Life Sciences Industry Insights Report, Datavent, 2022. See also: https://datavant.com/wp-content/uploads/2022/09/Datavant-Market-Report.pdf
- 26. Use of Real-World Evidence to Drive Drug Development Strategy and Inform Clinical Trial Design, National Library of Medicine, January 2022. See also: https:// www.ncbi.nlm.nih.gov/pmc/articles/PMC9299990/

- 27. Biopharma digital transformation: Gain an edge with leapfrog digital innovation, Deloitte, 8 December 2021. See also: https://www2.deloitte.com/us/en/insights/ industry/life-sciences/biopharma-digital-transformation.html
- 28. Intelligent clinical trials, Deloitte. See also: https://www2.deloitte.com/content/dam/insights/us/articles/22934\_intelligent-clinical-trials/DI\_Intelligent-clinical-trials.pdf
- 29. Embedding environmental sustainability into pharma's DNA, Deloitte, October 2022. See also: https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/ life-sciences-health-care/deloitte-uk-embedding-environmental-sustainability-into-pharma-dna.pdf
- 30. Broadening clinical trial participation to improve health equity, Deloitte, 4 October 2022. See also: https://www2.deloitte.com/us/en/insights/industry/healthcare/increasing-diversity-clinical-trials.html
- 31. Enhancing clinical trial diversity, Deloitte, 11 November 2021. See also: https://www2.deloitte.com/us/en/insights/industry/life-sciences/lack-of-diversity-clinical-trials.html
- 32. Broadening clinical trial participation to improve health equity, Deloitte, 4 October 2022. See also: https://www2.deloitte.com/us/en/insights/industry/healthcare/increasing-diversity-clinical-trials.html
- 33. Ibid.
- 34. Enhancing clinical trial diversity, Deloitte, 11 November 2021. See also: https://www2.deloitte.com/us/en/insights/industry/life-sciences/lack-of-diversity-clinical-trials.html
- 35. Reducing environmental impact through product design and packaging, Takeda. See also: https://www.takedajobs.com/sustainability-by-design
- 36. Embedding environmental sustainability into pharma's DNA, Deloitte, October 2022. See also: https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/ life-sciences-health-care/deloitte-uk-embedding-environmental-sustainability-into-pharma-dna.pdf

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