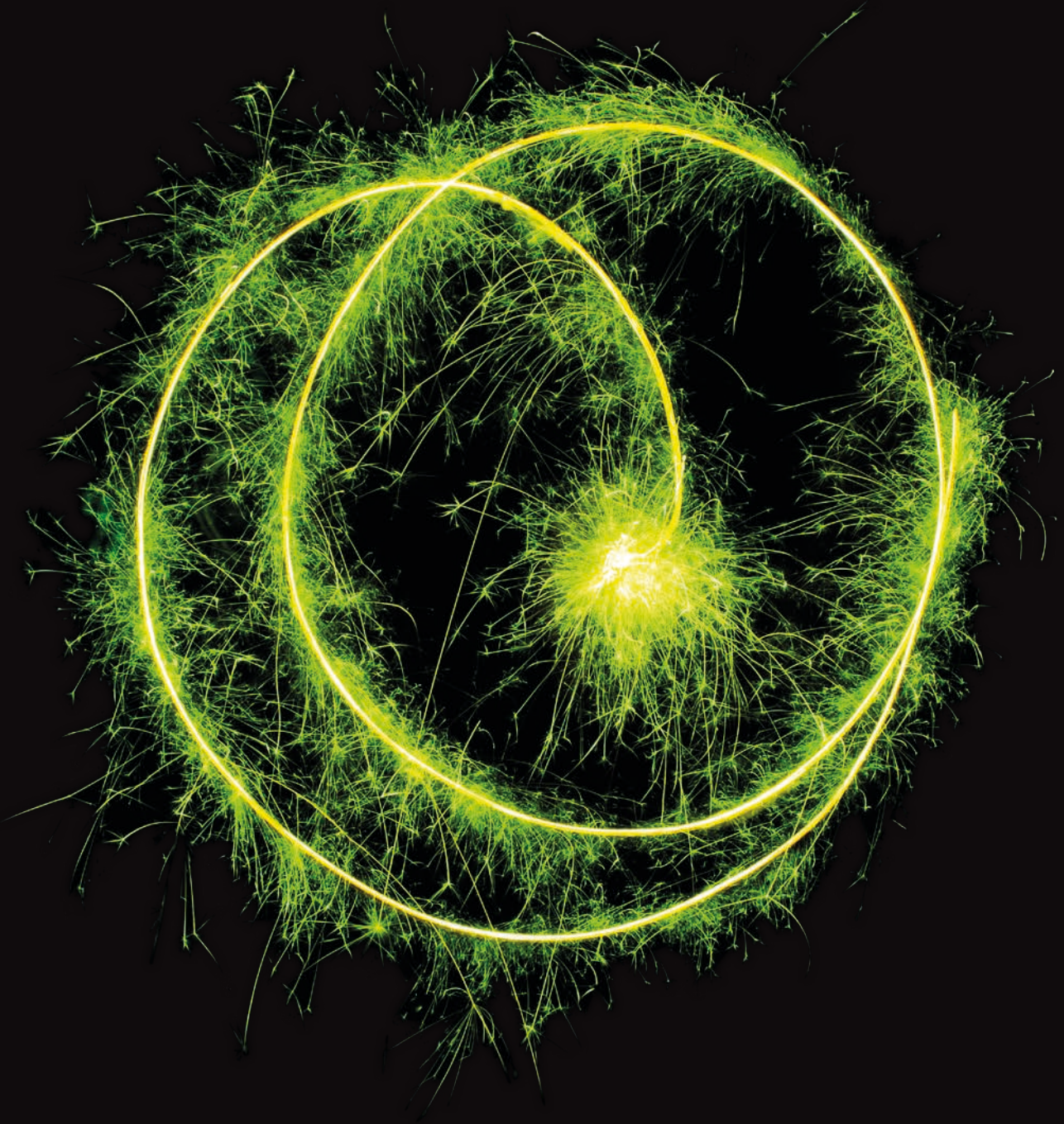


Deloitte.



Connecting the parts

Developing an integrated
IDMP strategy

Contents

The evolving regulatory landscape	1
Developing the right strategy	5
Impact of ISO on the life sciences industry	6
Contacts	7

The evolving regulatory landscape

The life sciences industry and regulatory landscape have evolved significantly over the past few years, experiencing a shift from local, discrete regulations to regulations with a global impact. These new regulations demand regional integration and have evolved from a greater need for the harmonisation and standardisation of information. Traditionally, and in some cases even today, individual departments within life sciences companies are working independently, in silos, to address various regulatory demands.

However, as new global regulations require seamless end-to-end (E2E) solutions, life sciences companies are realising the need to evolve and leverage synergies across various regulatory initiatives and run company-wide projects that will benefit the business. As a result, life sciences companies will need to take their regulatory strategy to a higher level.

Figure 1. Evolution of the regulatory landscape within the life sciences industry



Two major trends, globalisation and integration, have become evident as the regulatory landscape evolves over time. These trends are integral to the changes seen across the regulatory universe with upcoming regulations focusing on a global agenda (Figure 1). Several key drivers and enablers are supporting this evolution in the regulatory landscape including:

- The need for increased patient safety
- The demand for improved access to information globally
- Stronger customer voice demanding changes
- Advancements in technology and capabilities

The evolving regulatory landscape, together with the need for better public healthcare and greater patient safety, form the basis of regulatory changes across the life sciences industry. The upcoming regulatory initiatives seek to harmonise and simplify the rules by improving transparency and product traceability within the life sciences industry. This will further enable greater collaboration across regulatory agencies and aid in the exchange of information globally. These upcoming regulations (Figure 2) will affect both pharmaceutical and medical devices companies across the product lifecycle (from discovery to commercialisation in the markets).

Figure 2. Changing regulatory universe



The regulatory initiatives shown in Figure 2 share synergies with each other and highlight the need for an integrated view of regulatory compliance. An example of one such synergy is the International Organisation for Standardisation (ISO) Identification of Medicinal Products (IDMP) and Clinical Trial Regulations. ISO IDMP focuses on standardisation and harmonisation and defines the format in which product information is collected and reported. The Clinical Trial Regulation is expected to use the ISO standards as the basis for collection of clinical trial related information. Given the synergies across these two regulations, life sciences companies should plan strategically and leverage common data synergies across the entire regulatory universe, in order to improve efficiencies and optimise resource effort.

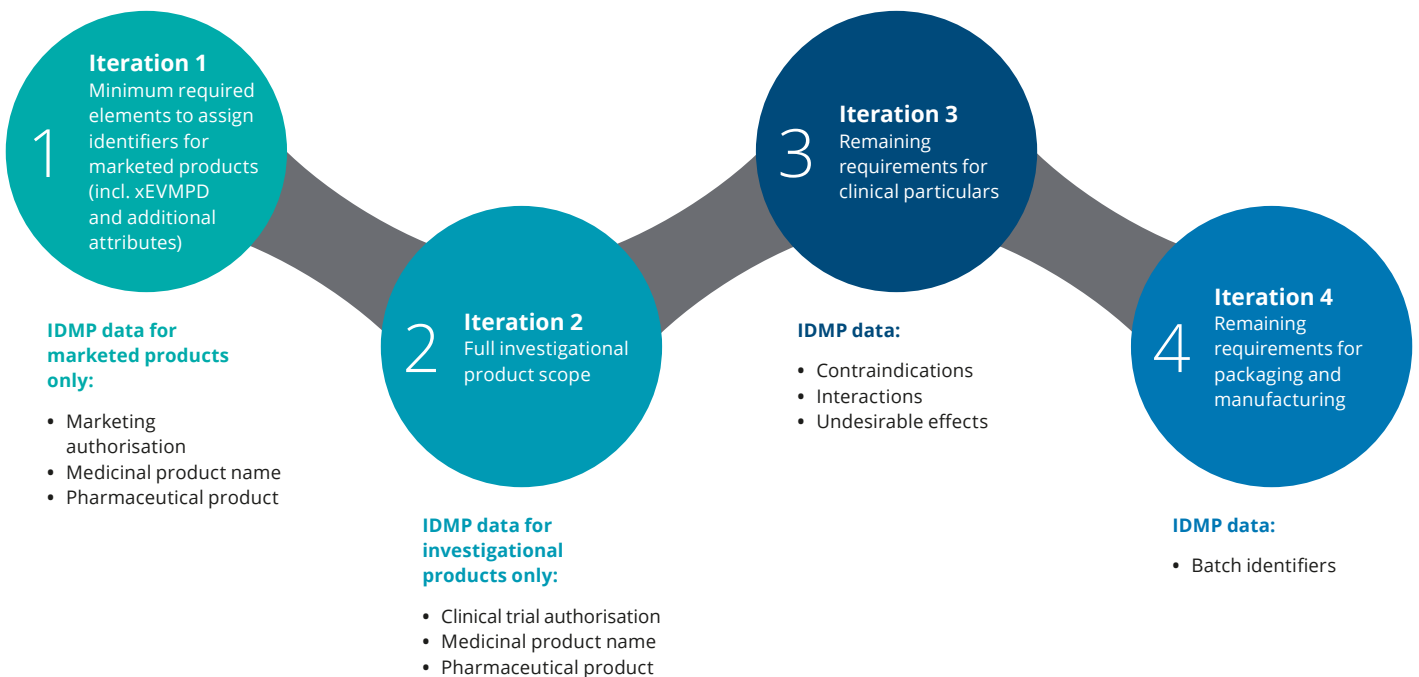
It is important for life sciences companies to proactively prepare for these regulatory changes now, as they will have a significant impact on current and future revenue streams, operating models and resources. To deliver these changes, pharmaceutical companies will need to work towards an E2E vision on technology and safety, integrate processes and systems, and determine new capabilities and data landscapes that will be required to implement these regulations in practice.

Showcase: ISO IDMP standards

ISO IDMP is an example of a global regulatory initiative that will require E2E solutions. ISO IDMP regulations aim to uniquely identify pharmaceutical products, enable standardisation of product information, and aid in the exchange of information between pharmaceutical companies and global regulators.

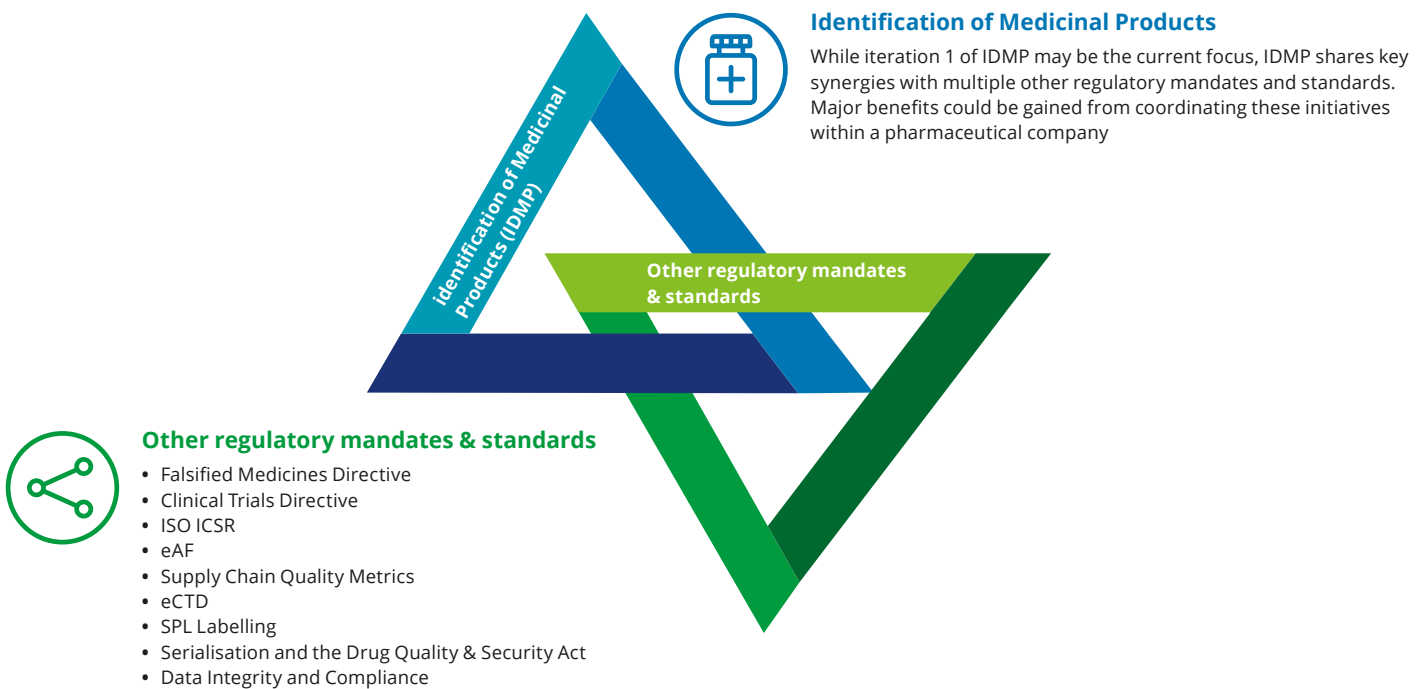
The European Medicines Agency (EMA) is taking an iterative approach to implementing the ISO IDMP standards, which provides the industry time to comply with the regulatory mandate. The illustration below highlights the five iterations for data submission (see Figure 3).

Figure 3. Illustrative breakdown of IDMP iterations



Despite the iterative approach of IDMP, the regulation shares a range of commonalities with other regulatory mandates, and will form the basis as a data standard for many of these future regulations (see Figure 4). By considering IDMP as a part of a much larger regulatory landscape of initiatives, it will allow life sciences companies to leverage commonalities and synergies.

Figure 4. Synergies between IDMP and other regulations



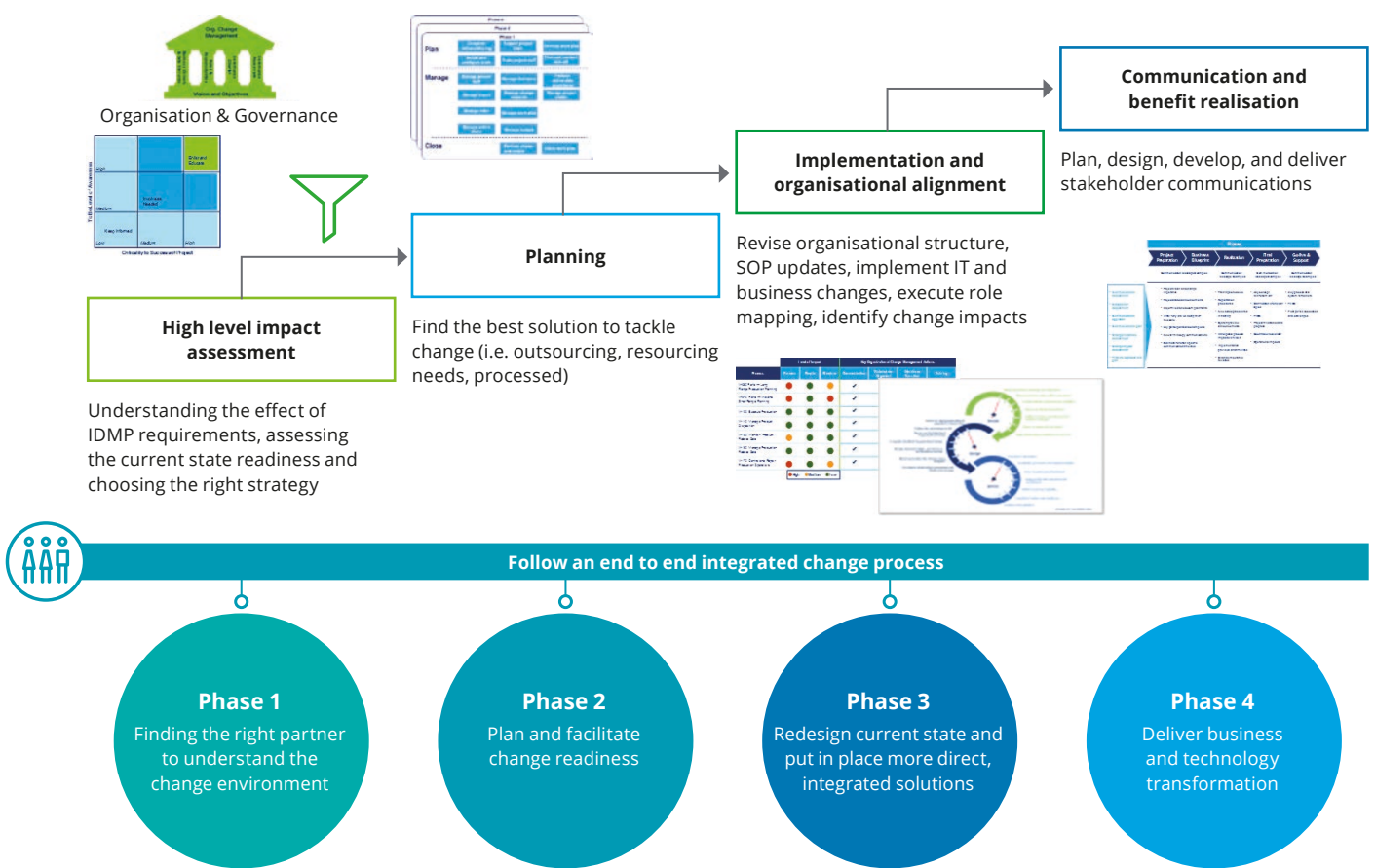
With IDMP specifically, the implementation guidelines are expected to be released in 2018. Pharmaceutical companies will be expected to submit Iteration 1 IDMP data in 2019 for products active in the EU market.

The timing for the roll out of standards has provided life sciences companies with a window of opportunity to re-evaluate their strategic plans for IDMP and other regulatory initiatives. Companies can reassess their current and future desired states and define a business case based on best practices.

Developing the right strategy

Pharmaceutical companies should evaluate individual and collective impacts of ISO IDMP and other upcoming regulations on people, data, process and technology, and be proactively prepared to manage the changes in regulations. A change of this scale generally leads to change in business operating models and IT transformations highlighting the need for an end to end integrated change process (see Figure 5). Pharmaceutical companies need to plan strategically and take a well-structured approach to implement such a complex regulatory change.

Figure 5. From complex regulation to an impactful change



In order to deliver the change, pharmaceutical companies should:

- Understand the regulatory requirements and create awareness – **What is changing?**
- Understand the impact on business processes and identify any gaps or pain points – **What is the impact and its extent?**
- Identify the remediation plan and actions – **Fix the foundation**
- Identify and create a strategic vision for implementing the change – **Define the way forward**
- Analyse if people/data/system/processes need to be improved – **Strengthen the vision with a robust business case**
- Present the business case – **Secure budget and management buy-in**
- Define implementation strategy based on the vision – **Next steps**

The key to a successful, ongoing and steady IDMP programme implementation is to understand the changes required, define the strategic vision and support it with a strong business case. By doing so, companies can gain management buy-in and deliver real change.

Impact of ISO IDMP on the life sciences industry

The upcoming changes in the regulatory environment will have an organisation-wide impact on the life sciences industry. Companies need to focus on cross-functional collaborative regulatory initiatives to take advantage of synergies across the upcoming regulations and create harmonised, global, integrated programmes to plan for compliance. Delays and changes in regulation mandated timelines have given companies an opportunity to re-assess the collective impact of upcoming regulations and plan strategically to address regulatory demands.

As the clock ticks and we head closer to 2020, the life sciences industry will start realising the impact and indirect benefits of implementing IDMP standards. IDMP will not only help align on a common set of regulated product master data, feeding multiple regulations, but will also create greater operational efficiencies that will help organisations achieve the overarching goal, of better healthcare and greater patient safety (see Figure 6).

Figure 6. Outcomes of IDMP implementation

Outcome focused

The focus and volume of attributes will shift significantly as we progress through the IDMP iterations. Not only will the number of attributes increase, but the type of data will change from regulatory to manufacturing



IDMP awareness

As the industry becomes more aware of IDMP, applications will extend to accommodate IDMP. Data will be tailored such that it is captured at the source

Integration across multiple systems

Master data management enabled solutions will lead the drive towards greater integration across multiple systems. Data governance and technology will be innately linked



Exchange of structured information

The exchange of structured information will be led by labelling and Module 3 (quality by design)



These outcomes will significantly benefit both industry and society, and help improve patient safety. In addition, IDMP will have the following benefits:

- **Submission efficiency** – Increased data submission in IDMP leads to a decrease in structured submission components in eCTD
- **Improved insights** – enhanced decision making through integrated data insights
- **High quality authoritative data** – authoritative data will be improved across the product lifecycle

Ultimately, the effect of IDMP on the pharmaceutical industry will revolutionise ways of working, especially for those companies that use it to drive greater operational efficiencies.

Contacts



David Hodgson

Partner, Deloitte UK
DTTL Global LSHC Risk Advisory Leader
davhodgson@deloitte.co.uk



Fiona Maini

Director, Deloitte UK
Lead, Centre for Regulatory Excellence
fmaini@deloitte.co.uk



Michael Graf

Director, Deloitte Switzerland
Lead, IDMP Solutions
mgraf@deloitte.ch



Kurt Conger

Consulting Managing Director,
Deloitte USA
Deloitte Information Management
Strategy
kconger@deloitte.com



Marcel Lissinna

DC Specialist Leader, Deloitte USA
Deloitte Lead IDMP USA
mlissinna@deloitte.com

Announcements

We would like to thank Namita Pai and Ultan Whelan for their contribution

Notes



Deloitte refers to one or more of Deloitte Touche Tohmatsu Limited (“DTTL”), a UK private company limited by guarantee, and its network of member firms, each of which is a legally separate and independent entity. Please see www.deloitte.co.uk/about for a detailed description of the legal structure of DTTL and its member firms.

Deloitte LLP is the United Kingdom member firm of DTTL.

This publication has been written in general terms and therefore cannot be relied on to cover specific situations; application of the principles set out will depend upon the particular circumstances involved and we recommend that you obtain professional advice before acting or refraining from acting on any of the contents of this publication. Deloitte LLP would be pleased to advise readers on how to apply the principles set out in this publication to their specific circumstances. Deloitte LLP accepts no duty of care or liability for any loss occasioned to any person acting or refraining from action as a result of any material in this publication.

© 2017 Deloitte LLP. All rights reserved.

Deloitte LLP is a limited liability partnership registered in England and Wales with registered number OC303675 and its registered office at 2 New Street Square, London EC4A 3BZ, United Kingdom. Tel: +44 (0) 20 7936 3000
Fax: +44 (0) 20 7583 1198.

Designed and produced by The Creative Studio at Deloitte, London. J11458