IDMP: WHAT IS IT GOOD FOR?

For those who have glanced at the ISO standards for the Identification of Medicinal Products (IDMP), let alone read them, know that it's overwhelming! They are full of terms, definitions, and data modeling information. What does it all mean? How can they best be used in industry? What are the agencies doing with them?

In 2012, five ISO standards were released which make up the framework for IDMP. They describe, in detail, all the pieces of data needed to describe an approved drug that is available for sale in jurisdictions that a Health Authority oversees. The information is derived in a top-down fashion where the highest level is a unique ID that defines what exactly is approved by the Health Authority. This includes the following types of information:

- Approval information: procedure/application/submission numbers, approval and marketing dates, etc.
- Label information: indications, undesirable effects, interactions, etc.
- Pharmaceutical product (how the drug is administered to the patient) information: ingredients, dosage amount, route of administration, device information, etc.
- Packaged medicinal product (how the drug is manufactured) information: ingredients, packaging, device information, etc.
- Organization information: manufacturers, marketing authorization holders, health authorities, etc.

These standards were updated in 2017 to clarify some of the relationships and data needed in this data model.

As the regulatory agencies are determining how to implement these standards, there are many systems and processes that companies can employ now to in order to not only be compliant but to gain a competitive advantage in how to capture and maintain their data.
WHAT DO WE HAVE TO COLLECT FOR IDMP?

There are over 200 discrete fields described in the standards. Each product will have a different amount of fields that are required, and due to the relationships of data may need to multiply some of the fields numerous times. Sometimes one set of data fields is used instead of other fields. Investigational and approved drugs have slightly different data models.

Yes, most of the data needed to complete the required IDMP fields are probably only found somewhere in documents and are unstructured. They are descriptions about the drug substance, product, or other aspects of the approval that were country specific or not needed in a system before, but computers can now handle vast amounts of data, and we can use different software to gather and control this data. For example, marketing status will be required for IDMP and today it is being tracked sporadically and in various places. When this information becomes structured it can be used consistently and effectively across any organization. IDMP could be a simple report of that data, if the right tools and processes are in place. Each department needs to get out of their silos and realize it is all company data. The handoffs of data can be automatic instead of manual, and the data can be treated as an asset. This will help drive efficiencies between departments and allow for better analytics.

DESIGNING A WINNING STRATEGY

Understanding the drug development lifecycle is essential to identifying where the data should be captured. Do not approach it from a purely IT / systems perspective. Business processes and the day-to-day operations is a critical foundation to feeding the data model and eventually the IDMP requirements. Implementing the correct data model will allow a company to collect data from the source, once, and eventually will keep all the data needed for a robust label harmonized in one location, and allowing the regional differences to be tracked easily.

IMPLEMENT A THOROUGH AND FLEXIBLE SOLUTION

Each company will have their own needs and approach. The solution can be a purely compliance approach, where it replaces the EVMPD solution and collects only the data needed, alternatively, and a more optimal approach, would be to tackle IDMP with a more comprehensive strategy. The scope of a more comprehensive solution can also vary greatly. Each functional area that contributes data will need to be involved. Applicable computer systems that are already in place may be impacted. Many processes will need to be updated and some new ones will need to be written to ensure the accuracy of the data.
BUILD A DATA MODEL THAT SUITS THE NEEDS OF THE COMPANY, WITH A BUSINESS DRIVER THAT ALSO ADDRESSES THESE COMPLIANCE REQUIREMENTS

TURN YOUR COMPANY’S DATA INTO AN ASSET

In order to make the data into an asset that can be used for IDMP reporting and better communications throughout your organization, Data Governance and processes need to be implemented and augmented with technology to control the quality and relationships of the information. There also needs to be a strong connection with IT and data architecture in order to develop the information flow diagrams to understand where and when the data is used. The governance group will identify data stewards who will own the data, no matter which system it resides in. The governance group can then monitor the input of data into the originating source system, and ensure the correct proliferation of this data to the other systems that need it. A committee also needs to be formed in order to resolve any disputes in the ownership and use of the data. Systems that can be implemented to support the data assets should include data dictionaries to keep the definitions and rules of each data element, data hubs to gather and transform the data in multiple other systems, monitoring tools to identify outliers and data errors, and analytics tools to create robust reporting and look for new ways to use the collected data.

USE THE IDMP FRAMEWORK AS A BASE

IDMP was written to provide a unique ID to an approved drug in a country or territory. While that is great for Health Authorities, industry tends to look at the data from when the active ingredient is discovered and then built up. When the data elements from IDMP are broken into smaller groupings, the real benefit can be used in industry. Breaking the model apart will allow companies to use the information as needed. Identifying the sources of information and updating those systems to the new IDMP criteria would be the better approach. If this is not possible, using data transformation and a separate database to store the updated information will suffice. One would then create the relationship model between the data to get the best reporting structure.
HEALTH AUTHORITY IMPLEMENTATIONS

**EMA IMPLEMENTATION: SPOR**

The EMA will be implementing IDMP in a phased approach more commonly known as SPOR for Substance, Product, Organization, and Referential data. SPOR replaces xEVMPD in 2018 and is required for all approved drugs in the EU. In 2020, IDMP information will be required for all development products.

The EMA has delivered services for Referential and Organization Management. The first phase of Substance and Product Management is currently targeted for the end of 2018.

**GLOBAL IMPLEMENTATION**

While not all of the ICH regions are implementing IDMP at or about the same timeframe, there is a push to have this standard adopted globally. The standard will make it easier to reuse data and provide greater transparency to not only regulators and sponsors, but also prescribers and patients.

**HEALTH CANADA**

Health Canada has notified some industry forums in December 2017 that there will be a Notice of Intent published in the 4th Quarter of 2018. This will provide an overview of their implementation plan as their timelines are in development.

**FDA IMPLEMENTATION**

The FDA will be working in parallel with the EMA for their implementation of IDMP. Final implementation guides will be available for Industry in 2019.

STAYING CURRENT ON ALL CHANGING REGULATIONS AND REQUIREMENTS IS NECESSARY TO ENSURE PROPER REPORTING TO THE HEALTH AUTHORITIES
BENEFITS OF IDMP FOR THE EU AND BEYOND

There are four areas that will benefit from the implementation of IDMP: Clinical Trials, Pharmacovigilance, Regulatory Submissions, and GMP Inspections. Data standards driven at the clinical trial phase can be utilized throughout the lifecycle of the product. These data standards will improve the quality of data, therefore leading to more accurate safety reporting. Consistent data standards will lead to greater reusability across regulators. The availability of the manufacturing data will streamline inspections and aid in recalls or identification of alternate supply. If a company implements a comprehensive solution for the EU IDMP requirements well, they will be able to leverage what is in place and gain value across all regions, strategically advancing their business operations by providing efficiencies not otherwise possible.


IDMP PREPAREDNESS: WHAT CAN BE DONE TODAY

Align with SPOR
- Ensure you have Super Users and Users identified and registered
- Check your companies data and send in appropriate change requests

Identify IDMP data elements to be implemented first
- Identify source system/document for these data elements
- Put processes in place to ensure internal compliance of data

Ensure internal data governance model is in place
- Ensure business is empowered in the structure
- Ensure you have clear ownership
- Roles and responsibilities need to be established

Prepare for data maintenance
- Identify change agents
- Have established change control in place
- Identify the sources new and updated information

ARE YOU READY?

PREPARATION NOW WILL ASSIST IN SEAMLESS TRANSITION WHEN IDMP IS FULLY IMPLEMENTED
Pyxa offers a unique holistic view of processes, data and requirements, to enhance operations and ensure compliance for IDMP implementation.

- We assess the “As-Is” state in a quick and efficient manner, identifying areas of weakness, risks and gaps. We work cross-functionally to develop the IDMP “to-be” state, ensuring alignment and endorsement across the respective functions.

- We develop change management, communication, training (class room or e-learning) and implementation plans and materials to support the successful rollout of the IDMP process.

Pyxa is managed by a team of three seasoned partners and comprised of a solid team of consultants with prior blended expertise in industry and management consulting.

Pyxas Solutions is comprised of a dynamic team of management consultants and R&D subject matter experts specializing in cross-functional R&D delivery stemming from activities led by Regulatory Affairs.