WEBINAR SUMMARY

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Pink Sheet
Informa Pharma Intelligence

A Practical Approach and Lessons Learned From Aligning Regulatory Master And Reference Data With SPOR

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Gary Wilson, Managing Director & Co-Founder of CorrIT, Creator of the SPORIFY web application

KEY TAKEAWAYS

- The SPOR system is being implemented in a stepwise manner as some of its pillars require migrating existing data from current systems first.
- Aligning existing regulatory data with SPOR has five key implications for the industry.
- Synchronization capabilities will be key in ensuring companies' data definitions and workflows are up to date. SPORIFY can help.
- Data standards for medicinal products will continue to evolve and will eventually likely converge geographically.

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OVERVIEW

In February 2021 the European Medicines Agency (EMA) published Identification of Medicinal Products (IDMP) data standards for the submission and maintenance of data on medicinal products, with the goal of homogenizing nomenclature, formats, and procedures. Currently life sciences companies often use different names for the same substances and products across their regulatory, supply chain, pharmacovigilance, and clinical functions.

To streamline the implementation of the IDMP standards, the EMA has developed the substances, products, organizations, and referentials (SPOR) data management program, which refers to the four domains of master data relevant in pharmaceutical regulatory submissions. Companies need to align their reporting capabilities with SPOR in order to simplify data sharing across functions, improve interoperability, and reduce data silos across the European medicines regulatory network. This will benefit biopharma by enabling the EMA to get better access to interconnected data and make faster regulatory decisions.

SPORIFY is an effective, efficient tool that automates and simplifies the process.

CONTEXT

These two experts from IQVIA and SPORIFY discussed the implications of SPOR for biopharmaceutical companies operating in the EU and steps that companies can take to accelerate alignment and compliance with the new guidance, including the use of SPORIFY.

KEY TAKEAWAYS

The SPOR system is being implemented in a stepwise manner as some of its pillars require migrating existing data from current systems first.

The foundational data management service of the SPOR system is the Referentials Management Service (RMS), which stores referential master data, that is, lists of terms used to describe the attributes of medicinal products (i.e., units of measurement, routes of administration, and dosages). It is designed to serve as a central repository for all reference data used across the European medicines regulatory network and will eventually incorporate substance-related lists sourced from the Substance Management Service (SMS) when it is launched next year, as well as lists linked to the Organization Management Service (OMS) once those have been updated.

Aligning existing regulatory data with SPOR has five key implications for the industry.

These implications for industry are:

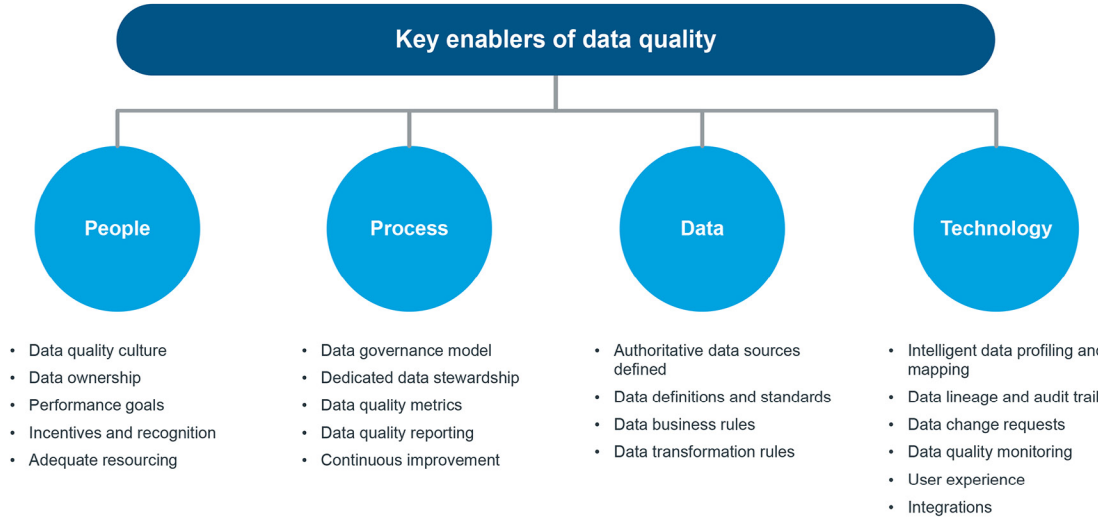
1. Global organizations **need to be able to map and translate between internal data sources and SPOR** perspectives for reference and organizational data.
2. **Alignment with RMS and OMS** data to support regulatory activities **is a must**.
3. The **scope of medicinal products data** to maintain alignment **will only grow** over time, both in terms of procedural and functional scope.
4. Organizations that have centralized procedure policies **have to act now** to ensure that they can continue to **carry out regulatory activities** without a negative impact. Now is the time to prepare.

5. Organizations that do not have centralized procedure policies **should be planning** how to **align and prepare** for the expanded use in 2022 of RMS and OMS data to support additional regulatory activities.

> Successfully aligning data with SPOR is fundamentally a data quality exercise requiring the careful planning and implementation of key enablers across people, process, data, and technology to deliver successfully.
>
> *Jens-Olaf Vanggaard, IQVIA*

Mr. Vanggaard noted that there are many other elements that companies need to get right internally to ensure that people, processes, data, and technology complement each other in the journey toward successful alignment of data. Those elements include—but are not limited to—company culture, data ownership, data mapping, data governance and management models, adequate resourcing, and intelligent automation of tasks such as data profiling and mapping.

Figure 1: Successful alignment of data with SPOR is all about data quality



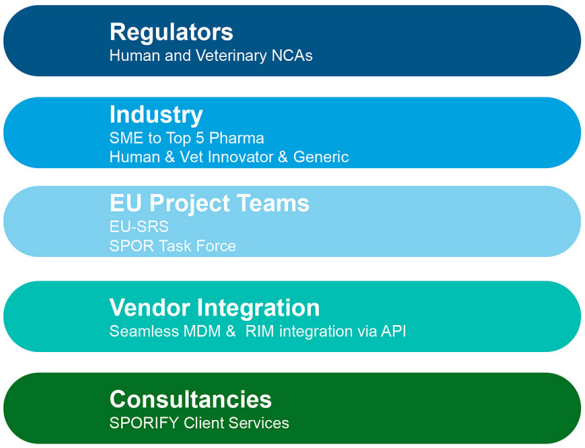
It all starts with people assembling a cross-functional data operations committee that can drive the initiative and form a cross-functional data management team coming together on a regular basis to review and approve any SPOR-related activities prior to submission to the EMA or for internal implementation.

Synchronization capabilities will be key in ensuring companies' data definitions and workflows are up to date. SPORIFY can help.

Because SPOR data management services are designed with the assumption that their content will be continuously updated, biopharma organizations are expected to design similarly adaptive internal workflows. However, manually verifying and continually updating databases that contain enormous amounts of data is impractical, if not impossible. Data management solutions such as SPORIFY can help companies simplify and manage this process by acting as a mapping and synchronization tool between proprietary systems and SPOR.

SPORIFY is a purpose-built, comprehensive, controlled vocabulary management solution with preconfigured integrations to EMA SPOR services. It provides out-of-the-box, automatic synchronization of all data changes from SPOR. SPORIFY has an intuitive user interface that provides for automatic matching of a company's terms with the following data domains: referential, organizations, and substances. It also centralizes and manages SPOR OMS change requests and has notification service alerts to all data changes and filters notifications in which a user is interested. SPORIFY has user management with role-based access control, providing administrator oversight and audit trails. It is interoperable with other vendors and tools.

Figure 2: Who uses SPORIFY



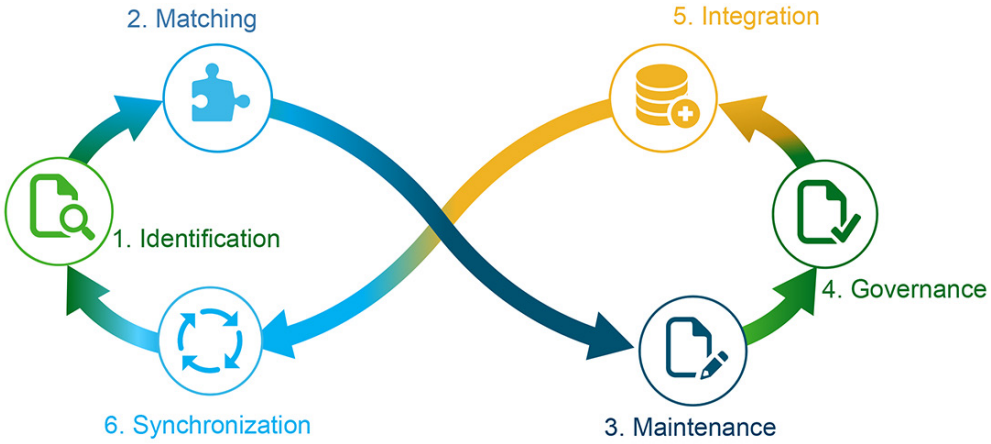
> If you were to do this manually, you would need to know which lists to map to, what the [SPOR] terms are, and what they will eventually be, and there still might be discrepancies between your local term and the SPOR term. SPORIFY takes care of this automatically and only needs a small piece of information from you to get started.
>
> *Gary Wilson, CorrIT*

The mechanism that enables SPORIFY to run this automation is its powerful built-in suggestion engine. It takes the source data provided by a company and runs it through a series of different checks against SPOR to eventually return the closest available item that it finds.

SPORIFY follows a six-step approach to data management

1	Identification	Identify data sources you would like to match to controlled vocabularies
2	Matching	Link local data identifiers to controlled data identifiers
3	Maintenance	Create local or external change requests as required
4	Governance	Review the data and establish a single source of trust (Golden Record)
5	Integration	Push the Golden Record to your production systems (MDM or RIM)
6	Synchronization	Check the source and target data changes and notify users of changes

Figure 3: SPORIFY – Getting Started



An important lesson in implementing SPORIFY is that SPORIFY is not 100% prescriptive in how an organization does things. Implementation is an iterative process that often starts with a pilot and involves multiple rounds of trial and error where refinements are made over time.

Data standards for medicinal products will continue to evolve and will eventually likely converge geographically.

The IDMP data standards are a dynamic international convention and as such are expected to continue to acquire new dimensions and grow in sophistication. Global life sciences organizations that do business in Europe and go through the process of aligning their internal data management systems with SPOR today will not have expended all these efforts to be compliant in just one particular geographic and regulatory region. Rather, as IDMP standards incrementally become the norm in other parts of the world, organizations that take a global approach will be in a strong position to leverage those capabilities in jurisdictions outside Europe, which is especially relevant for those biopharma organizations that are truly global players.

BIOGRAPHIES

Jens-Olaf Vanggaard

Senior Director, Global Safety, Regulatory and Quality Solutions, IQVIA

Jens-Olaf Vanggaard is Senior Director of Global Safety, Regulatory and Quality Solutions with IQVIA. He is responsible for leading the Regulatory Solutions practice and has more than 15 years of experience providing advisory and project implementation services within Clinical Development and Regulatory Affairs. Jens-Olaf has strong domain expertise within Regulatory Information Management (RIM), IDMP, Data Governance and Master Data Management from a Regulatory Affairs and Pharmacovigilance perspective. He received his M.Sc. in Business Administration and Computer Sciences from Copenhagen Business School.

Gary Wilson

Managing Director & Co-Founder of CorrIT, Creator of the SPORIFY web application

Gary holds a BSc (Hons) in Computer Science from Griffith College Dublin and has over 18 years industry and consultancy experience. Since the launch of SPORIFY in 2017, CorrIT has assisted many pharmaceutical organizations and regulators with their implementation and integration of SPOR Master Data Services and Controlled Vocabularies as they move towards IDMP implementation.