How a Defined Informatics Entity is the Key to Bridging Pharma's Data Divide

When the health authorities began placing further emphasis on medicinal product data standards, the overlap between regulatory operations and systems beyond the regulatory scope became increasingly apparent. Interoperability with other key functions – clinical, pharmacovigilance, quality, supply chain and others – was needed to implement xEVMPD and IDMP, which in turn led to the development of suites of software to manage cross-functional processes. However, technology solutions don't address the knowledge gaps between regulatory and other functions and the informatics that are integral to managing product authorisation and life cycle maintenance. Timm Pauli, Head of R&D Informatics at PharmaLex, explores this rapidly changing regulatory environment and the role of a defined cross-functional informatics entity – within R&D or beyond – in bridging the divide between the various functions and the technology and data that supports these functions.

For many years, pharmaceutical companies have operated in silos. Clinical, regulatory, pharmacovigilance, quality and manufacturing all held their data separately, each with their own product dictionaries. As regulators have sought to streamline the exchange of product information through standardisation and harmonisation – most notably with the plans to implement Identification of Medicinal Product (IDMP) standards – companies have needed to find their own ways to build cross-functional knowledge sharing.

What makes these functional separations all the more problematic is that not only is there a barrier in terms of processes, but there are also complex information technology requirements to address, which has been exacerbated with the advance of digitisation.

I would argue that the most effective way to harmonise and break down the divide is through a defined entity within the organisation that traverses these different functions to bring processes and systems together across the product lifecycle. Such an entity might best be defined as an R&D informatics function, whose primary objective is to provide the architectural backbone or foundation to support and enable harmonised decision making and to build effective interfaces across interconnected functions.

Protecting the Core Value

To understand why a defined R&D informatics capability is the link that organisations are crying out for, consider the overarching purpose of a pharmaceutical company – to develop and bring drugs to market. As such, I would argue that a company's core value is its marketing authorisations and marketed products. It's about developing and getting those products to market, keeping them on the market through efficient product maintenance and maximising their potential with regards to value and geography through appropriate market access programs and marketing authorisation programs to more regions and market.

The marketing authorisation consists of information from different areas, each created and maintained with separate processes, tools and systems. Non-clinical, clinical, quality assurance, regulatory operations, pharmacovigilance and manufacturing all work to support and maintain the marketing authorisation.

The challenge has been that these various functions have historically been poorly harmonised – a situation that is still the case in many companies. Despite many attempts at automation (or semi-automation), use of simple tools as well as the introduction of new digital technologies, creating the dossier and maintaining the marketing application still requires many manual steps, built on unstructured or semi-structured documents rather than structured data. Inevitably, this increases the risk of human error and inconsistency across those different processes and systems. After authorisation, product maintenance was further separated from product development, creating additional divides. But the move to digital systems means this separation is starting to dissipate, for example, with recognition that clinical as well as CMC-related information (Chemistry, Manufacturing and Controls) that is key to the marketing authorisation is also important for authorised products.

The European Medicines Agency has made its own changes in response to growing recognition of the overlap across the product lifecycle. While there has been a distinct divide between defining and processing the same or similar information in clinical trials and post-authorisation (i.e. approved marketing authorisations), the agency has made efforts to merge these in one master data approach, known as SPOR data management services (substance, product, organisation and referential).

Combining Expertise

Given the divide that has existed – between functions and between different parts of the lifecycle of a product – it is clear that a person or, preferably, entity, is needed to bridge the silos. Such a function would need to understand the processes and problems that various parts of the R&D organisation encounter, be able to translate these challenges into potential technology solutions and align those solutions with the way they are implemented by IT experts.

An R&D informatics entity should be staffed by people who can traverse various disciplines – from the clinical phase to development of the marketing authorisation to distribution and beyond – and translate the information process requirements for the rest of the organisation. It's important to specify that this expertise is not about IT infrastructure but rather about informatics across R&D.

This defined entity would not be the ultimate decision-maker but rather an advisory function to enable other departments to be compliant and collaborative in an efficient and sustainable way. Experts within this R&D informatics function would support colleagues in other parts of the business with recommendations on innovative solutions that fit both the needs of the department and the broader corporate informatics strategy.

An R&D informatics entity could ensure that any technology that one function decides to incorporate would be able to interface with solutions in other functions, not only in regards to technology aspects – which might be the domain of the IT department -- but also in regards to process support and information management. They would also be able to help map an integrated and harmonised data model with standardised terminologies, so when pharmacovigilance talks about a product, they speak the same language as regulatory affairs. It's about guiding the different functions to ensure consistency from a technology and data perspective so that each function is processing and using information in a coherent way. Finally, and most importantly, R&D informatics must ensure that the combination of technology, data

management approach and processes comply with the regulatory and legal requirements.

Perhaps a good comparison with the R&D informatics entity would be an architect – a person, or group of people, who can support the entire process, who understand the material (or technologies) and can share expertise on what would be most effective when building the complete structure. The experts within the defined entity therefore need to have a specific set of resources and capabilities to effectively bridge the divide between the functions and required informatics.

Finding Synergies

To address issues of data inconsistency and informatics barriers, the R&D informatics team might start by identifying synergies and similarities in each function. While each function is focused on their own issues and requirements, there are inevitably similarities with some approaches or ways challenges are addressed. By monitoring and understanding what is happening in various functions, the informatics team can identify seemingly independent changes and find those overlaps or synergies to create greater efficiency.

These differences, yet synergies, are evident in how each department talks about and understands a simple term such as a "product". What does a "product" mean? For regulatory, the term "product" is often used as a synonym for a marketing authorisation or a registration – even though this is not entirely correct. For manufacturing and supply chain, it generally means a manufactured item which is delivered to various markets under different marketing authorisations. In pharmacovigilance processing of adverse events typically focuses on the active substance, which plays the main role in the medical assessment. All ways in which the term "product" is used are understandable as they each emphasise different aspects of a "product", but they aren't all the same thing, and the term "product" can be confusing. With the ISO standards of IDMP, especially those that refer to the regulated pharmaceutical product information (ISO 11616) and regulated medicinal product information (ISO 11615), we finally have a clear definition and terminology of many terms in this domain.

For the informatics defined entity, it's about understanding those differences and coming up with the proper data model or terminology to cover those differences. The informatics team also needs to understand how changes in one department affect other functions. That's because if one department changes its systems or how they process information, it could impact processes in another department, such as the use of pharmacovigilance data in regulatory submissions or leveraging regulatory data for adverse event monitoring. It is about understanding how data is used in various functions and therefore how change might impact seemingly unrelated processes in other departments.

Finding these synergies and bridging the gap between functions is important when it comes to interacting with the regulatory authorities, where that separation is irrelevant. To regulators, it doesn't matter whether information or data comes from pharmacovigilance, regulatory or manufacturing – it is all part and parcel of the same product. It's important, therefore, that companies start to mimic that in their organisations and think the way the regulators think. And the only way this is likely to be achieved is through process and informatics harmonisation enabled by a defined entity that understands the regulatory space, including how changes and developments from the health authorities will impact decisions over solutions and processes.

Making the Right Changes

Harmonisation has been a priority for the health authorities for many years and EMA has been looking at how it can address its own issues with disconnected regulations and technical requirements. Initially, the agency sought to address inconsistencies through a telematics management board, but that endeavour only oversaw about half of the agency's IT and informatics projects – always with the additional complexity of aligning EMA's strategy with those of the EU's National Competent Authorities. A few years ago, the agency adopted an information management strategy,[1] focused on achieving interconnected IT systems for managing and sharing information on medicines. The information management strategy has several overarching objectives that aim to harmonise the agency, both in terms of digital adoption as well as business process. These include:[2]

- enabling the business to benefit from process optimisation by putting in place platforms on which to bring together business processes and related data including scientific knowledge
- enabling digital ways of working, better collaboration and information security through putting in place a single collaboration platform that integrates what is delivered today via multiple solutions
- fostering more agile ways of working by promoting a culture of collaboration among all EMA's services without compromising IT governance practices
- putting in place Master Data Management to support standardisation, data consistency and data quality when used in different initiatives and business cases, by EMA and Telematics systems and by other stakeholders

The EMA, despite its many challenges as a body made up of 26 member states, has been moving in the right direction in terms of bridging its informatics divides; the pharmaceutical industry now needs to catch up and do the same. Some companies are on the right track, but many still have extremely disconnected systems and processes, which mean those inter-function gaps continue to be a problem.

These gaps will become glaringly obvious with the connection between the Product Management Services (PMS) of SPOR and the submission of variations. Going forward, any variations for a product will only work if the product datasets in the SPOR database are correct and complete. The benefit of such an approach is companies applying for a change to their authorisation won't have to start from scratch in terms of filling out forms and providing product details to the authorities. Companies will only be required to provide the ID number of the product in the SPOR database. In the long run, this process will make the daily business of regulatory, which is submitting variations, much easier, while accelerating the review process and, most importantly, improving safety oversight for patients.

Harmonising cross-functional processes will not only be key to meeting this changing regulatory environment but will also reduce the risk of non-compliance and improve overall business efficiency.

REFERENCES

1. https://www.ema.europa.eu/en/about-us/how-we-work/information-management
2. https://www.ema.europa.eu/en/documents/report/information-management-strategy-2020-2022_en.pdf

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