# Data Transformation to Accelerate Time to Market and Address Product Shortages in Life Sciences Post-pandemic

**Frits Stulp of Iperion, a Deloitte business, predicts that a wave of data-driven transformation that began in 2022 will enhance insights and decision-making, allowing life sciences companies to gain a competitive edge and provide better patient experiences.**

Last year was another challenging one for the Life Sciences industry. On top of residual pandemic-related challenges and supply chain issues, the ever-adapting Regulatory environment has continued to set new standards and enforce new requirements. Those companies that have managed to keep pace with the changes can expect to start reaping some of the rewards of their efforts over the coming year. Others still have work to do, but as new waves of digital transformation promise new process efficiency burdens should start to reduce and improved patient experiences will gradually become a reality.

Here's a roundup of some of the most notable developments of the last year, and what's likely to be a growing focus in 2023.

**Streamline Processes Across the EU**

In terms of drug development and clinical trials, EU Clinical Trial Regulation and more specifically the Clinical Trial Information System (CTIS) presented one of the main practical changes of 2022, and the transition to the new registration system has begun in earnest now. From February this year all new clinical trials applications must be submitted via the new portal yet a good many companies are not yet well set up for this, leaving work still to do.

The aim with the EU developments is to harmonise and streamline processes across the diverse region, making it a less daunting location for conducting clinical trials. Persistent anomalies between countries continue to trigger enquiries however, and this year all kinds of companies will be trying to figure out how to navigate the new requirements and overcome any residual complexity.

**Data Governance is Key**

Supply chain issues, driven by the pandemic, continue to present problems – a situation that has been exacerbated during the winter, when demand has been at an all-time high. Even though the worst of the recent crisis appears to be over, there is now an extended mandate – certainly in Europe – to monitor and manage any shortages of medicinal products and medical devices. That's both at an industry level, and by EU member states.

The onus is on the industry now, to capture and provide the right data during major events and public health emergencies. This may require formal data mapping – to identify where the relevant data sits within a company, and who can provide it. Given that efficiency and accuracy of these insights are critical when public health is at stake, it is essential that the industry is prepared. Forward-thinking companies will see this as an opportunity to review existing data governance, determining where the relevant data sits within their organisations, for instance, and how it might be provided to the EMA most efficiently.

The increased speed of regulatory processes seen during the pandemic has set a precedent, and the only way to maintain that pace over the longer term is to modernise. ISO IDMP standards remain pivotal to the expanding and transforming role of data.

But this requires more proactive data governance, if companies are to truly harvest the power of their data, and it's something they'll need to navigate this year alongside

other internal and external pressures – alleviating the increasingly critical but hugely labour-intensive burden of data management.

**Challenging Norms**

Necessity being the mother of invention, much faster regulatory processes materialised during the pandemic – from rapid access to scientific advice and rolling reviews, to accelerated assessments and other possibilities under compassionate-use programmes. Improvements were also seen in the drug development process itself.

Ultimately, the pandemic forced out-of-the-box thinking and helped identify weaknesses in existing systems. We've seen old norms being challenged in clinical trials, for instance, as the result of issues that peaked in the pandemic, including those linked to subject recruitment. These issues have helped inspire alternative approaches to trials and their design – including decentralised trials, faster data sharing, and increased collaboration across parties.

Having an agreed model for data that multiple stakeholders and collaborators can work with is potentially transformational. The European project on substances (the EU-SRS database), which went live on January 24, illustrates what's possible here. Using the same data model, software and also scientific standards per substance class enables increased exchange with FDA, WHO and other regulators.

**Data is the Answer**

Applying the lessons of the past few years to reduce the time to patients of the latest advances in Life Sciences is key. As escalating cost and resourcing pressures threaten safe access to healthcare for all, the drive for new care models is strong.

Data lies at the heart of many of the proposed solutions. These include increasingly sophisticated patient self-care propositions (using devices for condition monitoring and management), and first-line care provision by high-street pharmacies.

High quality, standards-based data will underpin operational efficiency and increase automated processes,. There is no time to wait for regulators to take the lead on data strategy and/or process innovation. And there is certainly no reason to delay data-driven transformations that will ultimately benefit patients.

**Frits Stulp**

Frits Stulp is managing director of Iperion – a Deloitte business, and Life Sciences partner within Deloitte where he leads a team of regulatory/IDMP experts to deliver value to both pharma companies as well as regulators. With a background as Program Manager and Advisor in information management, process design and regulatory compliance, he is an expert in the implementation of both XEVMPD and ISO IDMP requirements and the digitalization of regulatory data and processes. Frits works within the broader Life Sciences/risk division of Deloitte in the Netherlands. This article combines the latest opinions and insights from across that team.

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