Six Ways the Shift to Digital Will Redefine Product Development in 2022

This past year has seen life sciences companies settle into new operating models and digital ways of working, many of whom have come to realise that a return to the pre-COVID-19 days is no longer a necessity. The innovations and advancements achieved over the last year have paved a path toward long-term change across research and development.

Fueled with insights from having stronger and more reliable data, the industry will reach new levels of efficiency and speed to enable patient-centric care. Here's how we see this becoming a reality in 2022 and beyond.

Patient and Site Centricity Will Define the Future of Clinical Trials
During COVID-19, the industry accelerated the adoption of decentralised trial capabilities to bring more study activities directly to patients. However, predictions that pharma would adopt an entirely virtual model that diminished research sites' role has already been proven wrong.

The industry is now moving toward a hybrid clinical trial model with some decentralised elements. Sites (and the investigator) will continue to play a central role as touchpoints for patient engagement and retention. As more clinical data is captured electronically, we'll see faster, better-managed trials that accelerate the delivery of new therapies.

In addition to more effective data management, greater patient and site centricity will drive further change in studies. Some of the decentralised clinical trials that ran in 2020 and 2021 weighed patients down by requiring the use of multiple digital applications, while research sites felt constrained with a multitude of point solutions that made it more challenging to manage trials. Now, as they work to reduce the technology burden on patients, more sponsors will minimise the digital applications and portals that they require sites to use. This will allow sites to spend less time on administrative tasks and more on patient safety and care.

Drug Development Will Increasingly Depend on One Consistent Source of Information
As research and development teams work to reduce the number of solutions they use, many realise the importance of maintaining high-quality data. In studies, as an example, patient information must be aggregated and cleaned if data from new sources, such as smartwatches and sensors, is to connect to clinical and clinical operations data. Companies that can't do this will have to hurdle big challenges to learn from past events to improve operations.

In the coming year, we expect to see more companies adopt data management applications that will automate and speed up this work by ingesting, aggregating, and cleaning data so that it's easier to analyse, report on, and share.

GSK[1] and Novartis[2] are among the companies focusing on data quality and moving toward real-time interactive dashboards, using a platform approach that simplifies the sharing of information. Instead of just storing info in a data lake and then analysing it, this approach deals with the disparity of data and their sources, whether entered manually or sent from wearable devices. The result will be a single source of data that will deliver better cross-functional collaboration by enabling information to flow across different functions within drug development quickly.

Artificial Intelligence Will Deliver Greater Efficiency Gains Across the Clinical Ecosystem
The adoption of advanced electronic trial master file (eTMF) applications has quadrupled since 2014,[3] shifting the industry from manual tasks to digital operations. This has fueled positive change in the industry and enabled organisations to manage their TMF more actively and optimise their processes. In 2022, artificial intelligence (AI) in TMF will help life sciences drive more efficiencies and strategic process improvements for long-term success.

One leading clinical-stage biotechnology company applied AI within its eTMF to accelerate document processing. In doing so, they found that site management documents were frequently duplicated during the handoff between the site start-up team and the monitor's first on-site visit after site activation. With AI to auto-classify documents, they could speed the processing of documents and deliver greater visibility across teams – lowering the risk of having duplicate records.

AI offers tangible ways to improve day-to-day operations and replace transactional processes, like document classification, with strategic activities that support continuous improvement. We expect to see more stories around the effective application of AI in clinical research to enable flexibility and speed.

Pharmacovigilance Transformation Accelerates
Research and development may have been one of the last areas in the industry to modernise operations. However, the use of new processes, business models, and technology has had a major impact on clinical and regulatory management. Pharmacovigilance is now catching up as more companies reinvent case intake and processing while also meeting their document management needs. Safety departments are also taking a more proactive approach earlier in drug development and investigating new technologies for signal detection, analysis, and management.

Automation and finding new ways to process data will be vital to improving patient safety and maintaining compliance in 2022. So will simplifying data management systems, their validation, and ongoing maintenance. We've seen a rapid increase in life sciences companies, from small visionaries to large enterprises, modernise pharmacovigilance data management[4] to simplify safety operations.

As tech modernisation continues, safety teams will focus on managing their end-to-end pharmacovigilance processes and data more holistically, in a more efficient and compliant way.

Diagnostics and Pharma Form Stronger Partnerships for Personalised Treatment
The genomics revolution is picking up as costs drop and disease

states expand, driving increased collaboration between genomics organisations and pharma companies. These partnerships will redefine precision medicine with innovative companion products (CDx) personalised for patients and therapeutic areas. As a result, companies will be able to identify risk of adverse events or opportunities to adjust treatments for higher efficacy much faster.

With a collaborative, patient-centric model, the gathering and exchange of outcomes will be key for future advancements. This will lead to a shift toward more connected, digital landscapes that enable seamless and automated data exchange across stakeholders.

European Regulatory Requirements Drive Significant Advancements in Operations

The industry has been preparing for EU MDR and IVDR for almost five years, and still, additional work remains to ensure compliance once these regulations take effect. This is critically important as companies adapt to changing market conditions and growing global demand.

As an example, an area in need of modernisation is claims management. Claims are continuing to get narrower and more specific. Companies should connect their regulatory and marketing content operations to adequately manage claims under these new requirements. Regulatory teams that benefit from running end-to-end claims management processes can drive quicker content reviews and approvals, better compliance, and increase insights into actionable data like claim usage and campaign performance.

As the second's tick closer towards the full implementation of EU MDR and IVDR, the industry will continue to strengthen their operations and establish a robust data foundation, improve connections across teams, and drive transparency into data and content. If companies can do this, they will be ready come implementation time.

The Shift to Digital Speeds Innovation in Life Sciences

With more change expected, an increasing number of life sciences companies are taking drastic steps to modernise their operations. The industry is accelerating toward digital and connected systems[5] to drive efficiency and speed across product development. The good news is that positive change is happening across R&D, supported by advanced technologies. This will help EU companies keep up with ever-changing market dynamics – from new regulatory changes like IDMP to increasing patient expectations – and fast-track the development and delivery of potentially life-changing products to the patients that need them.

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