

# Front & Center

## Digital Automation Becomes Reality in the Life Sciences

**D**igital transformation is no stranger in the life sciences industry. Drug innovators have long recognized that the adoption of digital technology can optimize business and reporting processes, future-proof compliance, streamline collaboration, and boost in research and development productivity. At the same time, drug companies have long struggled with digital transformation, from early artificial intelligence (AI) engines that performed poorly to virtual trials that are just as challenging to execute as conventional programs.

While the promises of some past technology failed to deliver, Sankesh Abbhi, President and CEO of ArisGlobal, says times have changed. “The industry has been exposed to a lot of hype around innovative technologies for years such as large vendors introducing AI engines that didn’t work as promised... We believe we are finally at the point of reality in terms of the promise of digital transformation and its benefits to clinical development, product safety, regulatory, medical affairs and other key areas,” he explains.

With this backdrop, where does the life sciences industry stand today in terms of digital transformation, and what solutions are on the table that create more results than hype?

### Top Three Life Sciences Digital Transformation Trends

As technology providers like ArisGlobal take a more pragmatic approach to the development of concepts like AI, Abbhi says hype about digital solutions is giving way to reality in three core areas:

**1. Data across the enterprise.** Technology providers initially focused on solu-

tions that addressed specific challenges for specific departments, teams, or studies—and often existing in stand-alone systems. These early efforts unintentionally exacerbated existing tendencies to collect and hoard data within operating units and teams rather than sharing data across the enterprise.

Now, however, Abbhi believes the latest end-to-end platforms streamline information sharing and data accessibility/availability to improve and accelerate outcomes across clinical, regulatory, safety, medical affairs, and other departments.

“We’re seeing movement away from legacy point solutions (sometimes still on-premise) with siloed data that’s difficult for other teams to access and toward end-to-end platforms that can streamline the flow of data across teams,” he says.

**2. Data analytics takes hold.** There’s also a great deal of conversation within the life sciences industry around harnessing big data and analytics to improve the product development process and gain real-time understanding of the information being collected, according to Abbhi.

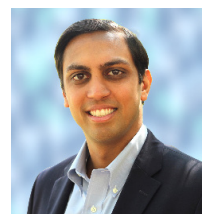
In the late 1990s and early 2000s, as enterprises expanded across national boundaries and continents through organic growth, mergers, and acquisitions, firms found themselves responding to multiple regulatory, reporting, and pharmacovigilance standards. The growth in clinical trial sites in Eastern Europe, Latin America, Asia Pacific, and Africa added additional operational and regulatory complexities. Local and regional operations understood local needs, but headquarters had no effective means to monitor performance

throughout the organization in anything close to real time. Stalled reporting led to delayed decision making, missed opportunities, and missed deadlines.

But, Abbhi says technology specialists like ArisGlobal are addressing this issue with novel solutions that make it possible to quickly and effectively process and analyze large sets of structured and unstructured data thanks to cognitive computing, machine learning, natural language processing, and cloud processing to improve knowledge sharing, real-time. ArisGlobal offers the first (and only) system to deliver automation and cognitive computing to safety case processing.

**3. Rise of AI and cognitive automation.** The third digital transformation trend is movement toward automation. Drug development is only getting tougher, with more complex regulations, greater data volumes/more diverse sources putting a strain on teams, and static budgets. “Automation is really one of the few avenues we have to increasing speed to market while maintaining quality within R&D,” Abbhi says.

Another noteworthy driver in the automation trend is the COVID-19 pandemic and the social distancing restrictions, which forced sponsors to be open minded and efficient about the implementation of virtual clinical trials and ushered in a renewed need for automated solutions. “Many companies are responding by doubling down on automation as a way of introducing operational transformation,” Abbhi states.



**Sankesh Abbhi**  
President and CEO  
ArisGlobal

## From Hype to Real Results

Reflecting on these trends, Abbhi says his company created a solution that addresses all these digital transformation needs. His top priority was to have a cloud-based, end-to-end software platform with the ability to be deployed efficiently across an entire R&D organization with uniform functionality, reliability, reporting, and data security. Other priorities that were once dreams—intuitive user experience and user interface design, integrated business and reporting processes with internal and external stakeholders, compliance assurance across jurisdictions as regulatory and reporting requirements evolve over time, seamless collaboration between sites, teams, and functions across the organization, R&D enhanced by intelligent automation—were made reality.

“We wanted to build the industry’s most powerful R&D technology platform to streamline collaboration between teams, deliver efficiency via automation and help our customers get actionable intelligence from data,” says Abbhi.

How did ArisGlobal move the needle from hype to reality? While IT giants used an informatics-centric approach of AI to produce biopharma engines that proved unsuccessful, ArisGlobal took a fresh view of automation. “Automation is a spectrum, not an entity,” says Abbhi. At one end of the automation spectrum are more basic, repetitive tasks that require little knowledge work. At the other end are knowledge-based activities. Most elements within the product development process lie somewhere on that spectrum. ArisGlobal wanted to use a combined approach to automation, one that “transforms R&D by eliminating many of the repetitive, manual administrative tasks that were pulling people away from more value-added activities,” as well as leverage cognitive uses such as natural language processing and machine learning (ML).

With the help of industry companies, ArisGlobal pinpointed real-world automation use cases within the product development spectrum. In particular, the company focused on historically manual, resource-intensive processes across clinical development, patient safety, regulatory affairs and medical affairs.

The firm applied different automation technologies to each task. For instance, ArisGlobal incorporated AI/ML into its platform in the LifeSphere Safety Signal and Risk Management application, which “helps companies better understand risk-benefit profile by crunching multiple datasets and applying advanced machine learning algorithms.”

Driving LifeSphere is the cognitive computing engine, Nava, a fusion of commercial and proprietary automation technologies that provides flexibility to address different use cases. “If you look at pharmacovigilance automation, for example, we’re applying rule-based automation, robotic process automation, natural language processing, and machine learning to drive huge efficiency gains,” says Abbhi.

This approach is quite different from other platforms that expanded quickly across R&D but have little compliance or content understanding. “Our end-to-end platform offers a unique combination of breadth and depth because we are focused on building automation use cases across the life sciences product development lifecycle,” Abbhi states.

Abbhi acknowledges, however, that having feature-rich products is only as good as your end-user experience. So, the LifeSphere platform delivers a supportive user experience and an intuitive user interface, which are key levers to speed buy-in, acceptance, and application of a single platform across the organization.

Several industry companies are already seeing the benefits of this unique approach to automation:

- In 2018, the Food and Drug Administration selected the both the LifeSphere Safety and Medical Affairs platforms to automate the agency’s pharmacovigilance system to intake, triage, and process safety reports. The system also provides end-to-end processing of product quality defect reports as it tracks and responds to queries from professional and consumer sources.
- Boehringer Ingelheim, a top 20 global biopharma, recently announced via its corporate LinkedIn page that it has just gone live with ArisGlobal’s

next-generation LifeSphere Safety platform, becoming the first company in the industry to have an automated pharmacovigilance system in production. This represents a key milestone after many years of automation hype across the wider industry.

- A series of large, midsize and emerging biopharmas are in line to roll out the same automation technology over the coming months. ArisGlobal’s own time and motion studies have shown an initial 77% gain in efficiency. Efficiencies are expected to improve with experience, an important benefit given that pharmacovigilance is largely a cost center as well as a key contributor to patient safety.

## Summary

The ultimate goal of life sciences technology solutions is to bring safer products to market more quickly by accelerating R&D, reducing risk and streamlining collaboration. A single end-to-end platform like LifeSphere enables firms to break down siloes by making collaboration the easy, obvious way to handle data collection, storage, and reporting across workflows and with stakeholders inside and outside the enterprise.

Abbhi says to expect innovation to continue in this vein: “We’re looking to further unify our platform, with a deep emphasis on streamlining the flow of content and collaboration around the development of content. We’re also excited to roll out new automation functionality across our product domains.”

## Additional Resources

The LifeSphere platform brings cloud-based intelligent automation to multiple aspects of biopharma, including:

- Clinical development: [www.arisglobal.com/products/lifesphere-clinical-total-clinical](http://www.arisglobal.com/products/lifesphere-clinical-total-clinical)
- Safety: [www.arisglobal.com/products/lifesphere-safety](http://www.arisglobal.com/products/lifesphere-safety)
- Regulatory: [www.arisglobal.com/products/lifesphere-regulatory/](http://www.arisglobal.com/products/lifesphere-regulatory/)
- Medical affairs: [www.arisglobal.com/products/lifesphere-medical-affairs](http://www.arisglobal.com/products/lifesphere-medical-affairs)