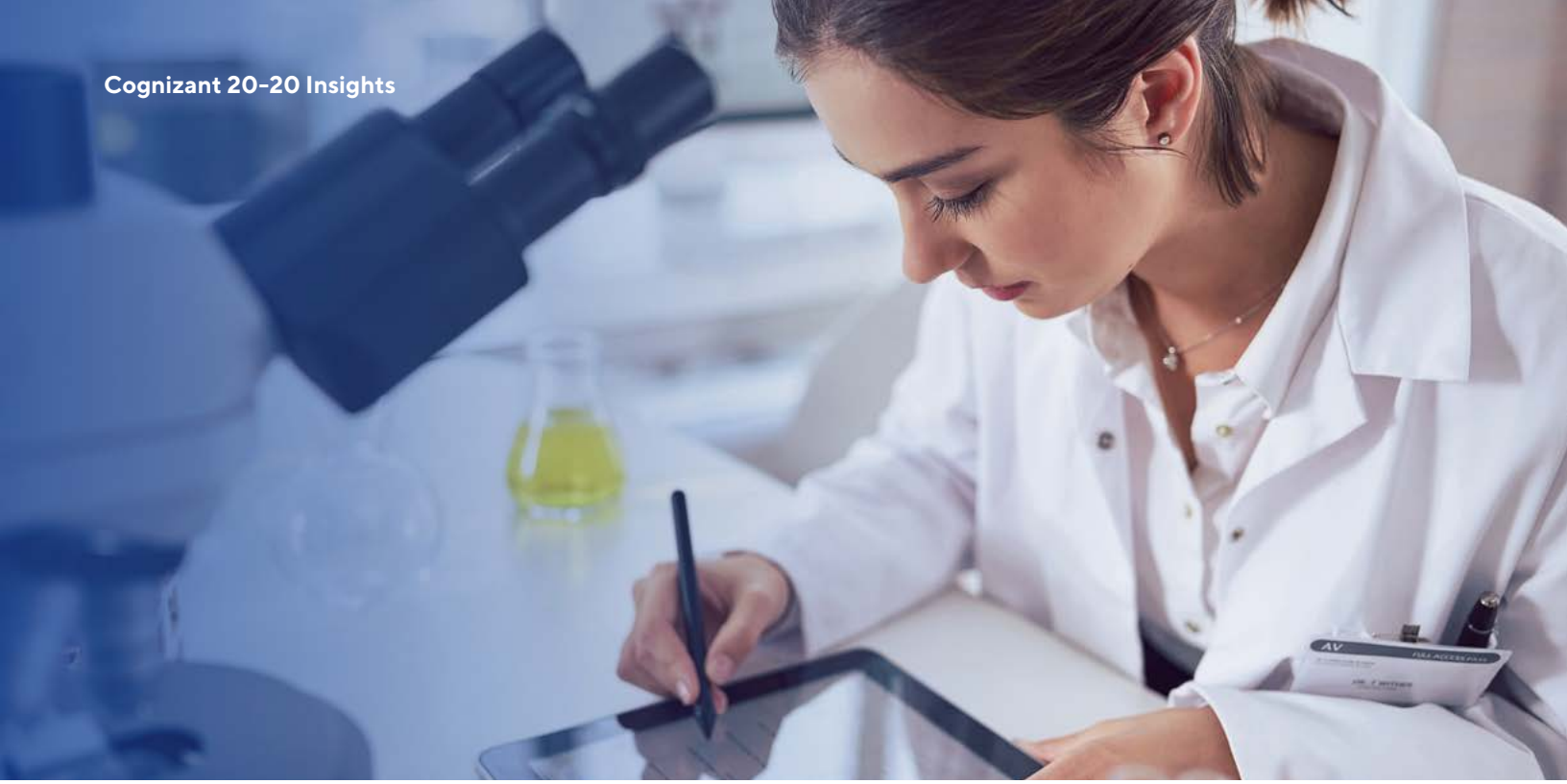

Digital Business

To Be Digital, Pharma Labs Must Bridge the Gap Between Legacy Systems & Connected Tools

As they navigate IoT adoption, scientific labs must find a way to integrate existing equipment and resources with emerging technologies, and shift to data-driven experimentation and decision-making.

Executive Summary

In the face of unrelenting digital-powered change across nearly every industry, scientific labs have languished. Relying on manual processes, lab teams perform complex experiments with a disjointed mix of modern instruments and disparate, aging systems, possibly older than the scientists operating them. Society trusts these complicated environments to determine the safety of new drugs, among other things. And despite being on the cutting edge of science, most labs struggle to enable legacy systems to work effectively with emerging connected equipment and a variety of digital technologies.

Attention to better management of information has become critical: a spike in the number of Federal Drug Administration (FDA) warning letters citing data integrity from the Center for Drug Evaluation and Research over the past few years is a frightening indicator that labs must address the technology gap, and soon.

November 2018

Cognizant

In addition to minimizing regulatory risks, labs and their parent organizations stand to reap great rewards by adopting digital more aggressively. Internet of Things (IoT) connected technologies such as sensors, beacons and communication systems can infuse lab operations with greater operational efficiencies.

Effective use of the IoT and related digital technologies promise better, faster, data-driven decision-making by consolidating information from processes across lab locations in real time. The outcome? Better process control and greatly reduced cost of operations. Even more exciting, preventing data loss and improving process outcomes ensure faster time-to-market — especially important in today's ultra-competitive market where preclinical development costs top $1 billion,[1] and where patient lives may hang in the balance.

More specifically, Gartner's Michael Shanler says that "by leveraging analytics across the portfolio of IoT-enabled capabilities and connecting previously disconnected data elements generated from the existing instrumentation, performance can be monitored and new insights can be generated. IoT efforts set the stage for "laboratory of the future" (LoTF)."[2]

Navigating this ambitious change will require labs to move from their existing legacy systems and processes to new digital and IoT capabilities, but they face this shift with limited budgets and a mandate to avoid disrupting lab operations. We believe the best way forward is for labs to adopt the IoT in ways that enhance legacy equipment as new capabilities are added. Successful execution will streamline lab operations and provide bandwidth for lab teams to better focus on data analysis and usage strategies.

Steps for labs toward data-driven decision-making

Based on our engagement experiences with clients across the life sciences industry, the transition to IoT won't be fast or easy. IoT adoption across the industry is relatively low, due partly to the industry's demonstrated risk-averse nature and concerns about patient privacy. For the next few years, some industry analysts anticipate IoT will merely help improve repeatable lab operations.

But the true business value is in standardizing guidelines for data, methods and instrument control. Doing so requires taking a hard look at existing instruments and equipment, most of which represent large capital investments.

Therefore, making IoT work in labs means retrofitting and integrating. To succeed, we believe there are three actionable steps for labs:

- Create a bridge between IoT and existing investments.
- Evolve from bridging gaps to using data as a foundation.
- Shift decision-making behavior from post-mortem to in-process.

Bridging IoT and existing investments to turbocharge performance

Tepid IoT adoption makes it difficult to operate efficiently. Labs of the future will find a way to bridge the technology gap, not just for the benefit of data management but to support an up-and-coming workforce of "digital natives" who expect systems to be intuitive to use, and are increasingly likely to quit a job with substandard technology.[3]

It's a huge undertaking: most instruments have a 15 year lifecycle before refresh, even when new, smarter devices are available. This is why retrofitting, or adding sensors to existing equipment, can extend the life span and value of existing instruments.

Testing and experimentation are complicated and can consume hours, days or weeks. In a traditional lab, when an error occurs, an instrument goes out of range or data is not as expected, users must either shut down the test and start over or allow it to finish before starting over. However, by connecting legacy infrastructure with new digital capabilities, such as replacing a reactor's data file output with either sensors or applications programming interfaces (APIs) that transmit data to a decision support dashboard, lab personnel can monitor performance and tweak experiments (i.e., to avoid out-of-range scenarios) that improve process efficiency.

For example, one U.S.-based global pharmaceuticals company, using a diverse mix of equipment, took a staggering eight weeks just to create a routine to run one of its frequent

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experiments. To speed this process, the company partnered with us to implement a lab performance management solution that included both IoT data support and various other data connections for the disconnected legacy equipment. By making legacy equipment accessible by the lab user for the first time, users could create the same experiment in under 15 minutes, which reduced overhead by 99%. This streamlined setup frees IT resources and reduces complexity, but more important, it enables lab personnel to focus on lab data analysis and interpretation, the most important activities in any lab.

Adopting processes and technologies that accommodate legacy equipment, such as the aforementioned example, or retrofitting existing instruments with smart sensors, means labs can keep their existing equipment and systems even as they take advantage of new, data-enabled processes.

Applying data as a foundation

Data is rapidly becoming the most valuable resource in any organization. But operational data today is often closed and static, locked inside various separate systems. As a decision center, the lab is a prime candidate to take advantage of technologies such as advanced forms of artificial intelligence (AI) in the form of machine learning (ML), which depends on data for training meaning-making algorithms.

Today, most labs track data manually in spreadsheets and disconnected databases. We believe labs must create a data management strategy that will allow growth and flexibility as they digitally mature.

In an informal survey of lab personnel that we recently conducted,[4] more than one-third of participants named data-related issues as one of their top three challenges. Frequent themes included equipment monitoring and instrument integration — areas core to a lab's ability to function, and for which labs will need to find future solutions while also addressing today.

We find that digital labs must be able to manage not only more diverse intervals of data transfer but also a broad scope of sources, sizes and formats. Today, most legacy systems are designed to handle only discrete packets of transactional data, but future-focused labs should adopt cloud-based informatics platforms that are natively designed to ingest, manage and analyze live data streams — as long as the system can also support the lab's current legacy environment.

While such capabilities are long overdue, most labs are not ready to take the plunge. In our survey, 53% of lab participants self-identified their IoT adoption as "None" (which we defined as "No IoT devices used; no real-time data generated"). This underscores a big gap between today's capabilities and future opportunities.

Shifting decision-making from post-mortem to in-process

Labs need to be able to predict their operational demands. This requires a deep analysis and more proactive management of data, assessing results across past, present and future dimensions. Labs today are adept at analyzing the past, which provides insights into why failures occurred. However, with the advent of connected devices, labs can also manage the present by monitoring and directing in-range operations in real time. And if current trends in AI-powered ML continue, data will help labs predict the future, making it easier to identify and prevent risks.

But first, labs must change the way they manage data — by creating a technology landscape that can collect, distill and deliver insights from near-real-time data. Done well, users can identify experiments that are at-risk, and then intervene, thus helping prevent loss from experiments.

For example, a research lab with specimens that require consistent temperatures must ensure that the equipment containing those samples does not venture outside of range parameters. Reaching a temperature too high or low, even for a minute, could decimate the entire collection of samples. This loss can cost thousands of dollars, and is completely preventable by moving from post-mortem to near-real-time monitoring of the equipment's temperature.

In a continuous monitoring scenario, lab personnel would receive notification immediately when temperatures begin to encroach on undesirable levels, well before the danger zone, and thus would have time to react. For labs, preventing sample loss in this way will generate real business impact.

As lab personnel adapt and become less reactive and more proactive in their intervention in at-risk experimental activities, they will be better positioned to predict suboptimal outcomes before they impact operational efficiency and effectiveness. Predicting operational needs requires technology that can move beyond near-real-time status display to determining trends based on various factors, both known and unanticipated.

As Gartner's Hype Cycle report concludes, "Expanded use of machine learning automated and human-augmented models will translate into less error from bias, which is inherent in manual exploration processes. It will reduce the time users spend on exploring data, while giving them more time to act on the most relevant insights from data. It will also give front-line workers access to more contextualized analytical insights and guided recommendations to improve decision-making and actions."[5]

This is an exciting prospect, but labs must change their data consumption behaviors before they begin to imagine contextualized data analysis. By transitioning decision-making to current and predicted data, rather than past events, labs will narrow the gap for embracing advanced forms of AI such as ML.

Looking ahead: digital maturity defined

The lab of the future will require technology that enables change and provides a path for labs to embrace continual operational improvements. There is no one-size-fits-all solution, as all labs are in different states of maturity and have different end-state goals.

Instead, labs need a solution that is flexible and can accommodate changing needs. Marrying the right digital capabilities with legacy systems will enable labs to achieve significant efficiencies. Such integration would:

- Minimize the time and steps required to set up and run experiments that involve live data feeds for monitoring.
- Maximize institutional knowledge of protocols within and across labs.
- Decrease the time spent searching for protocols from master lists.
- Decrease process noncompliance with near-real-time process monitoring for compliance across steps and their parameters.
- Improve the ability of instrument management.
- Decrease the time and steps required for management of lab users.

With the adoption of capabilities that effectively bridge the technology gap, labs can successfully change their decision-making behaviors and data-management processes. The result will ensure that the data integrity issues flagged by the FDA in recent years are a thing of the past.

Labs can move forward with this directive today, by implementing lab performance monitoring products, such as Cognizant Lab Insights, that provide a toolkit for bridging the gaping legacy and IoT gap in data acquisition. This is a straightforward first step that will open up important efficiencies, not only in experiment monitoring, but also lab operations more generally, through better resource and staff utilization realized from the reduced focus on manual manipulation of instruments. Once equipped with access to data monitoring from a lab performance tool, labs will be more empowered to begin to create a data foundation and enhanced decision-making behaviors.

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Endnotes

1 DiMasi JA, Grabowski HG, Hansen RA, "Innovation in the pharmaceutical industry: new estimates of R&D costs," Journal of Health Economics, 2016; 47:20-33.

2 Hype Cycle for Life Science Research and Development, 2018, Gartner®, Published 27 July 2018

3 Penn Schoen Berland, "Dell & Intel Future Workforce Study Global Report (2016)," www.emc.com/collateral/analyst-reports/dell-future-workfoce-study-global.pdf.

4 Cognizant, Technology Solutions survey, "Visualize the Lab," October 9, 2018; participants were leaders at approximately 50 labs across North America, Latin America and Europe, including animal, process and research facilities.

5 Hype Cycle for Life Science Research and Development, 2018, Gartner, Published July 27, 2018.

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Arvind Naganathan Ramakrishnan is a Venture Leader in Cognizant's Life Sciences business unit. He has over 20 years of experience in the pharmaceuticals industry and extensive background in lab process and technology improvement projects. In his current role, Arvind focuses on solving key industry challenges he has observed throughout his career. Among his responsibilities, Arvind leads the development of the Cognizant Lab Insights solution. He spends much of his time working with scientists, lab managers and partners across multiple lab types to identify ways of applying digital thinking and tools to simplify the complex and critical processes they run. He has a bachelors degree in biochemistry from Jaya College of Arts & Science, and a master's degree in biotechnology from Guru Ghasidas University. Arvind can be reached at Arvind@cognizant.com | www.linkedin.com/in/arvindlabinsights/.

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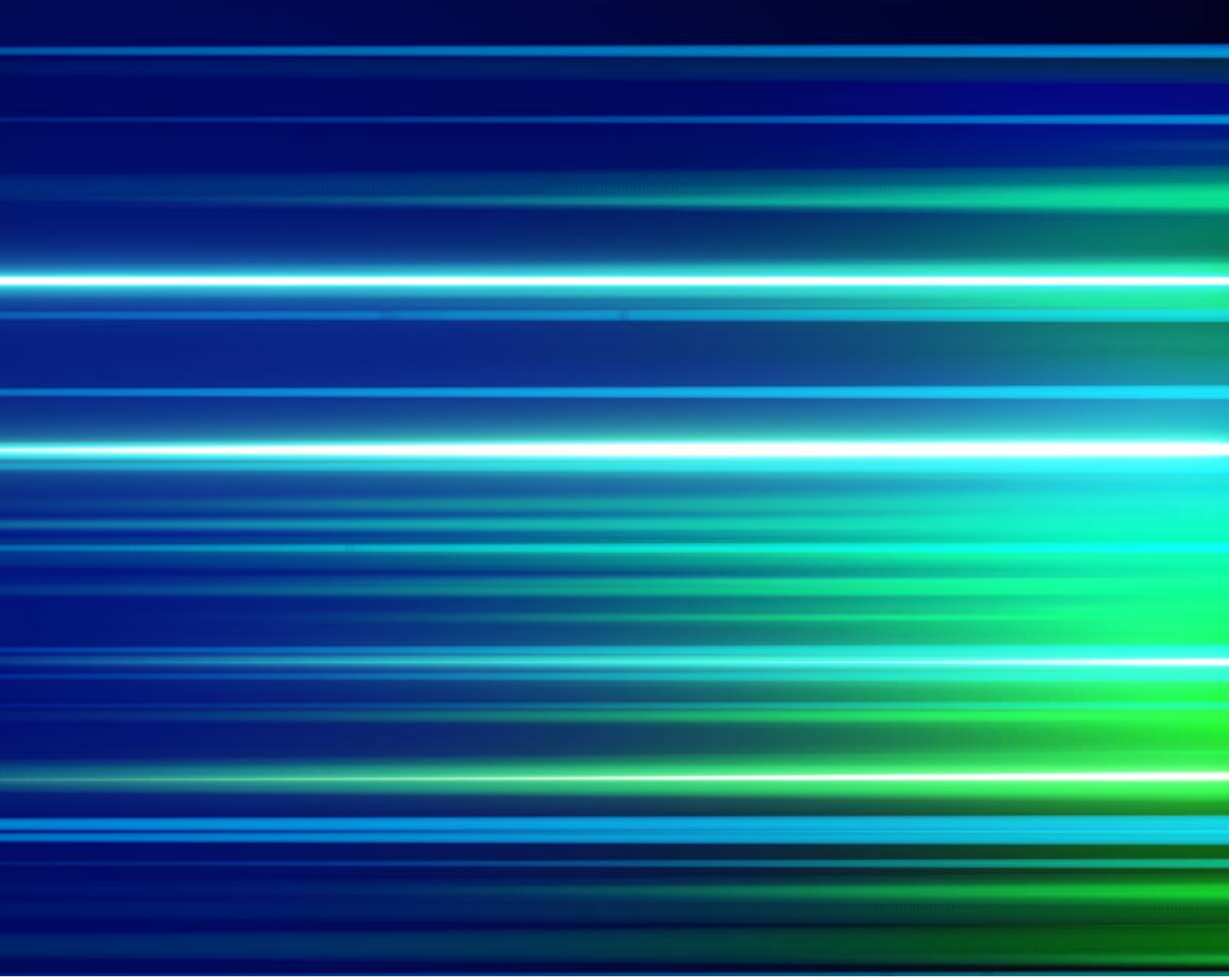

About Cognizant

Cognizant (Nasdaq-100: CTSH) is one of the world's leading professional services companies, transforming clients' business, operating and technology models for the digital era. Our unique industry-based, consultative approach helps clients envision, build and run more innovative and efficient businesses. Headquartered in the U.S., Cognizant is ranked 195 on the Fortune 500 and is consistently listed among the most admired companies in the world. Learn how Cognizant helps clients lead with digital at www.cognizant.com or follow us @Cognizant.

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