Accenture Life Sciences

New Science. Transformative Patient Outcomes.

Driving digitalization at scale in the lab

Fuel productivity and collaboration for faster innovation



The convergence of higher business expectations, increased data complexity, and unprecedented speed of development and trials requires changes in the way the biopharma industry works.

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About the research

We surveyed 118 industry leaders from scientific labs on how companies are using digitalization to improve processes in treatment development. To better understand how biopharma companies are leveraging new technologies within the early discovery/research stage of the drug product lifecycle, Accenture conducted the research cited within this report. We compare and contrast these findings to <u>a prior study</u> conducted in 2019.



Areas or stages of development/ commercialization process in which they interact with lab/scientific data:



Executive summary



In many ways, the past two years of the COVID-19 pandemic have felt long and slow. But this period of public health crisis has also seen lightning-quick systemic changes for the biopharma industry—particularly in terms of the speed and processes for developing life-saving vaccines and therapies. Never before has the industry been able to respond with such efficacy, accuracy, and safety in such a short timeframe.

But that's only part of the story. The speed of COVID-19 vaccine development also heightened expectations for the entire industry—especially in Research and Development (R&D) and QC/Manufacturing (QC/M) laboratories—to increase the volume of new treatments and accelerate the pace to file. The genome for COVID-19 was sequenced and shared globally at an unprecedented pace from when the virus was first identified in China.¹ Effective vaccines were created, trialed, and distributed in about a year. That left biopharma executives, policymakers, providers, and patients all asking the question: **Can we move just as quickly for other conditions and diseases?** In 2021, Accenture published From Billions to Millions², which put the cost of bringing a new treatment to market at between \$2.6B and \$6.7B (including the cost of capital and cost of failure), and showed that R&D spend is rising for each new treatment. Strategic plays and digital transformation can help biopharma companies realize savings of \$1.2-1.7B per successful medicine, bringing costs from billions down to millions. Accenture has also found that the rise in New Science³—an evolving, unique combination of the best in science and health technology—is creating enhanced capabilities in the value chain and new revenue streams. However, our Pre-pandemic Survey⁴ looking at biopharma labs showed that their digital transformation needed to accelerate. Of 128 industry leaders surveyed for our 2019 report, 40% had not yet begun to apply digital solutions to their R&D and QC/M labs, and another 37% were merely piloting new offers (often for six months or more).



Executive summary

The question now is: **How much has changed in scientific labs since COVID-19? And has digital transformation sped up in response?**

Our follow-up survey conducted during the pandemic offers some encouragement: digital transformation in biopharma labs is progressing (Fig. 1). However, we also found that advancements with talent and technology aren't happening at the needed pace, and transformation is occurring unevenly across different types of labs.

Without consistent digital adoption across lab types, it is more challenging to harmonize processes, increase Probability of Technical and Regulatory Success (PTRS), eliminate bottlenecks to rapid progression to market, and turn labs into a new source of value. If digital capabilities cannot be expanded across the organization, there's a gap in value realization and upfront investment that may never be closed. Billions stay billions rather than becoming millions.

If the period from 2020 to 2022 has taught us anything, it's that everyone must pick up the pace. There is an opportunity to reimagine and accelerate the way that treatments, therapies, vaccines, and other transformative treatments are produced.

Fig. 1. Lab transformation post-COVID-19



69%

21%

of respondents said they are taking actions to digitalize their labs.

are piloting, scaling up, or in a phase of widescale adoption.



Digital transformation progress in scientific labs



Progress in scientific labs

The COVID-19 pandemic response proved that it's possible to compress decades of R&D and QC/M processes into months. Digital transformation is part of that acceleration, and our surveys show that it is as much about mindsets and ways of working as it is the actual technology.

Our 2021 survey found that more biopharma labs had begun to explore proof-of-concepts, and others that had already shifted toward digital labs began to scale—truly changing how people work (Fig. 2).

While this is encouraging, digital exploration and adoption are occurring at an uneven pace. View this in combination with the accelerated pace of digital transformation, and it indicates a widening gap between transformation leaders and the rest of the biopharma sector (Fig. 3).

To be clear, a digital strategy doesn't mean simply adding technology across labs; what's required is looking beyond the lab to the entire organization. Such an effort is as much—or more—about people than technology, and reimagining how people work and interact with each other. A dedicated focus on talent and skilling is the key enabler of successful transformation, allowing people to connect their scientific responsibilities with new technology that in turn connects the different labs to each other, across the enterprise. But it's important to look closely at each different lab type, and the challenges unique to the people and processes in each environment.

Fig. 2. Rise in digital lab focus



Fig. 3. Transformation pace and productivity

72% Said the pandemic has given rise to a digital strategy, but the pace of digital transformation has accelerated for just 39%.

39% reported being more productive, while 27% said that they are now less productive.

Different labs, different needs



Different labs, different needs

Distinct environments and challenges exist across the lab ecosystem and understanding them can enable digital transformation.

Research labs: Use a high volume and variety of data, bringing together complex datasets to identify new drug targets, disease models, biological processes, and novel therapeutics.

Development labs: Focus on product and process development, along with technology transfer.

QC/Manufacturing labs: Drive quality monitoring and standardized processes,

balance "high volume, low mix, low complexity" testing and "low volume, high mix, high complexity" analysis.⁵

Although the lab types are unique and require their own specific talents, processes, and technologies, they are interconnected and symbiotic. Therefore, all labs should be assessed and treated as equally capable of driving enhanced value. Digitize one lab type at the expense of another, and investments in digital transformation may not deliver long-term results or value. **That's why it's critical to look at the specific opportunities to drive change across each lab type.**





Research

How are these labs unique?

Research labs need specialized skills along with creative thinking and open experimentation.

In our latest survey, respondents identified supporting New Science⁶ and supporting internal/external collaboration as the most important business drivers.

How are they progressing on digitization?

These labs should see an estimated 2x growth in digital transformation over the next 2 years. **17% of respondents indicate that most of their research labs embrace digital and 39% state that their research labs will undergo digital transformation within the next two years.**

What are the barriers to progress?

The top barriers to progress are technology competence and specialized skills. This is important because such specialization (e.g., biologist + bioinformaticist) are needed across future scientists. **The 39% stating that their research labs will undergo digital transformation indicates that the industry is primed for change, but there is caution with access to these unique skillsets.**



Development

How are these labs unique?

The role of development labs is evolving and accelerating, making connectivity to research and QC/M a necessity. **The key business drivers for these labs are supporting New Science and increased pace to file.**

Development labs need to be able to support the wave of new therapeutics with their unique process needs.

How are they progressing on digitization?

There's an estimated 3x growth in digital transformation ahead for development labs over the next two years. However, development labs lag research in use of digital technologies. **9% of respondents indicate that most of their development labs currently embrace digital, with 27% indicating three-quarters of their development labs will undergo digital transformation within the next two years.**

What are the barriers to progress?

Development labs are squeezed from either side (research and QC/M). While increased pace to file is a key business driver, this is slowed by both clinical and nonclinical delays (manufacturing issues, QC/M challenges and more). **The top barrier to transformation in development labs is the need for a strategy that enables both upstream and downstream connectivity.**



QC/Manufacturing

How are these labs unique?

QC/M labs have been leading on digital adoption and transformation for the past few

years and are expected to continue this trend. Because these labs follow highly structured and standardized processes, they have high potential for digital adoption.

How are they progressing on digitization?

QC/M requires new technology and ways of working to be more efficient, to reduce the time that samples spend in QC/M and to reduce the time to batch release while increasing transparency and predictability. **38% of respondents say that most of their QC/M labs embrace digital. 62% say most QC/M labs will undergo digital transformation in the next 2 years. We estimate a 2x rate of growth in digital transformation for QC/M labs.**

What are the barriers to progress?

The primary barriers to continued transformation are adopting technology at scale, building skills, and a holistic strategy. But these barriers are being more proactively addressed than those in research and development labs.

Different labs, different needs



QC/M labs face fewer barriers, but they're blazing a trail to digital adoption that Research and Development can and should follow, especially as treatments become increasingly complex. Ten years ago, the world's best-selling drug was Pfizer's cholesterol-fighting treatment Lipitor^{®7}, with an active pharmaceutical ingredient (API) containing 33 carbon atoms. Today, the best-seller is AbbVie's Humira[®], an anti-inflammatory treatment with 6,428 carbon atoms. The testing process is also becoming more complex. A QC/M lab might only test one component of a drug API that is made into the final product at another facility, where it will be analyzed again more holistically. This complexity affects the entire R&D value chain.

That's why transformation should not be based on patchwork digital solutions for particular labs. The objective should be to bring the entire lab ecosystem into a new era of efficiency, productivity, and innovation—one that can scale and be flexible to accommodate the creation of new, highly specialized treatments, as well as take on major shifts in industry focus—such as responding to a global pandemic.





Although our survey shows wide agreement on the question of when digital transformation will happen in labs (in the next 12-24 months), the more important question is HOW.

In the previous sections, we highlighted how each lab type is unique, the top barriers, and how to enable transformation across each lab type. Across all labs, there are five components that should be in place for a truly successful digital transformation. These are:

Skills and talent: Individuals should possess the correct skills, such as data science and the sooner people can be upskilled, the faster a digital transformation can take place.

Strategic vision: A clear lab strategy and tactical roadmap should be in place to enable enterprise wide transformation. Laying out a vision that demonstrates the advantages of lab digitization, and the rewards it delivers to both individuals and the enterprise, is likely to help accelerate the journey.

Technology competence: Foundational and low code approaches should be available to

enable a strategic vision. This is an important competence for organizations and much less an insurmountable challenge to overcome.

Modern practices: Adoption of modern approaches such as agile, DevOps, cloud, and other new ways of working will enable speed and flexibility.

Organizational constructs: Connectivity between the business and IT is important to enable the digital lab through refreshed governance models, enabling collaboration and communication across functions.

While the different types of labs assign more importance to different aspects of the digitaltransformation objective, there is plenty they agree upon too. Through a focus on these five components, it affords everyone involved the opportunity to play a role in the process, and work together on ways to make the transformation faster and ultimately successful across the enterprise simultaneously, in lieu of a slower, disjointed approach.

Enablers to transformation are ultimately all about finding the right mix of talent and technology

Research

These labs need the right talent to match new technology, which often means new skills are needed. Upskilling existing teams is the top enabler for achieving a speedy and scalable digital transformation. For example, traditional biologists may need a deeper understanding of sequencing and computational analysis.

Moving forward, research labs need to identify people who understand or can learn how to connect the science to the technology. Research talent also needs a clear understanding of how the entire lab ecosystem feeds into the enterprise-level digital transformation strategy.



Development

Development labs face unique upstream and downstream pressures which make them challenging to modernize.

Think of it in terms of the <u>digital thread</u>. The key enabler of digital transformation in Development labs is implementing modern approaches with agility, and using technology to connect with Research and QC/M labs. Focusing on development and its digital connection to the other lab types will catalyze digital transformation within the lab ecosystem, and possibly enterprise-wide.



It's clear from our research and our work with clients that QC/M labs have been the early focus of digital transformation efforts. But there's still room to run here, as many biopharma companies have yet to begin the transformation journey. Fortunately, there are many success stories to emulate.



QC/M Case study

A journey to efficiency in global QC/M labs

Consider Accenture's work with a global biopharma company that had QC/M labs around the world operating under siloed, discordant, and inefficient processes. It didn't have a holistic view of lab performance or insights to inform enterprise-level decision-making. Accenture gathered key QC/M lab staffers at workshops to align each site around industry best practices and to gather data on individual site processes. Just months later, the company began implementing an agile approach for bringing all the company's QC/M sites into

alignment. A new cloud-based system keeps the lab in synch and delivers data-driven insights to help the company consistently improve.

Having a defined governance model plus a clear lab strategy and vision is the key enabler of digital transformation in QC/M labs. It can be a relatively speedy process that quickly delivers value by making these labs leaner, faster, and more efficient. Even if a company is moving from "high volume, low mix, low complexity" treatments to "low volume, high mix, high complexity" drugs, QC/M labs that are aligned in scale and strategy are flexible enough to handle the shift.

Accelerating transformation



Accelerating transformation

Digitalization is needed both within and across labs. Rather than information and data flowing one direction (Research handing off a compound to Development for process and trials, and Development handing off that information to QC/Manufacturing), data should flow throughout the lab ecosystem. Each lab type is aware of the others' progress and processes, staying informed about how to proceed for the best possible end result.

Of course, given the piecemeal approach many biopharma companies have taken up to now, the digital-transformation journey will be unique for everyone. But whether a company is at the foundational, transformational, or aspirational stage, all efforts should first be focused on building the framework, in four steps:

1. Settle on a vision. Regardless of which lab type is farther along in its digital evolution, leaders must develop a short- and long-term strategy that lays out a roadmap for transforming the entire organization—not just the labs.



2. Get to know your labs. Once the vision is in place, it's time to take a close look at the labs individually and in aggregate. Zero in on their unique needs, strengths, and weaknesses, with an eye toward how digitalization can help. What's holding them back? In what ways are they ahead of the game? Use the answers to inform and shape the digital transformation strategy in line with the broader vision.

Research: Upskill/attract new talent to remove barriers between wet and dry labs for analysis to build trust between scientists.

Development: Establish agile processes and the associated technologies for data connectivity between research and QC/M labs.

QC/Manufacturing: Refine legacy governance models to enable speed, flexibility, and efficiency tied to a defined strategy.

Accelerating transformation

3. Decouple the data. Silos, whether operational or informational, tend to be the enemy of positive change. This is especially true for biopharma data. Break up large, monolithic lab applications that have become sources of technical debt and barriers to transformation. By knocking down barriers to information sharing across the different lab types and allowing easier flow and access, an enterprise can start to see and realize the value of transformation.

4. Invest. There will always be hard decisions that come with change, but the best path forward is to make as few choices as possible. Invest in both the foundational and the transformational, in areas of both low and high risk. The most critical investment, however, isn't in technology, but in talent and developing your people's skills.

The fourth point, above, is perhaps the most important—and is also often the most challenging concept for biopharma companies to get behind. After all, it's not uncommon for an innovative global company to rely on rigid, expensive, highly customized legacy systems that are difficult to change or adapt. But this



can be overcome, and must be enabled through your lab talent. Digital transformation is only successful when it works for both people and processes.

Imagine a biopharma lab ecosystem where researchers leverage prior work, real world evidence, and public research efforts to quickly identify novel disease targets, as well as potential new therapeutic pathways. Much of this will happen digitally, using models supported by AI/ML and digital twins, significantly reducing the amount of follow-up work in the physical lab. But it all starts and ends with your talent, and people having the skills, tools, and technology to collaborate effectively across different lab types.

Granted, every biopharma or biotech company is different; but the formula to reach a new digitally enabled destination is the same. While all labs may not be created equally, they should all be treated as equally important parts of a system that will deliver sustained operational and business results through faster, more interconnected data and processes.

Accelerating transformation

Labs are the lifeblood of a biopharma organization. And the experts who work in the labs have spoken about the barriers and enablers of digital transformation. Listening to and acting on their opinions will accelerate the journey toward better business in the form of bigger breakthroughs.





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Definitions

The following definitions were provided to those surveyed:

Digitalization (also Digital herein):

Digitalization is leveraging technology to change a business model or process to invoke new value-producing capabilities. It is not simply moving from analogue to digital.

Adoption:

Adoption occurs when a digital technology has been implemented either in part or in full and is being used so that the expected value from the revamped business model or process is being achieved to a measurable degree.

About Accenture

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About Accenture Life Sciences

Accenture's Life Sciences group is committed to helping our clients make a meaningful impact on patients' lives by combining new science with leading edge technology to revolutionize how medical treatments are discovered, developed, and delivered to people around the world. We provide end-to-end business services as well as a broad range of insight-driven services and solutions in strategy, consulting, digital/analytics, technology, and operations in all strategic and functional areas—with a strong focus on R&D, Sales & Marketing, Patient Services, and the Supply Chain.

We have decades of experiences working with the worlds, most successful Biopharma, Biotech, MedTech, Distributor, Digital Health, Contract Research, and Manufacturing companies to innovate and improve their performance and across the entire Life Sciences value chain to better serve patients and stakeholders. Accenture's Life Sciences group connects more than 20,000 skilled professionals in over 50 countries who are personally committed to helping our clients achieve their business objectives and deliver better health and economic outcomes.

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