Building the next-gen pharma lab

DIGITALLY CONNECTED, ENVIRONMENTALLY SUSTAINABLE

#GetTheFutureYouWant

Capgemini RESEARCH INSTITUTE

Executive Summary

Investments in lab transformation are set to accelerate

A cutting-edge laboratory environment is at the core of an innovative and competitive pharma organization and is critical to meet industry demand for innovative therapies, reduced time to market, increased approval rates, reduced costs, and regulatory requirements. Most pharma organizations are rethinking their approach to lab structure and operation with an emphasis on accelerating digitalization, leveraging AI, improving processes, and building the right skills and culture. Our research reveals that larger organizations plan to invest 6.5% of their revenue in lab transformation initiatives by 2025, up from 4% today.

Most labs are at the pilot or proof-of-concept (PoC) stage of transformation

The majority of organizations are still in the early stages of transformation, with only one in 10 of those surveyed having partially or fully scaled their efforts. When we assessed them against the critical dimensions of lab transformation maturity, only 15% could be categorized as “leaders”. Labs continue to confront challenges in data, technology, people, and processes as they strive for transformation.

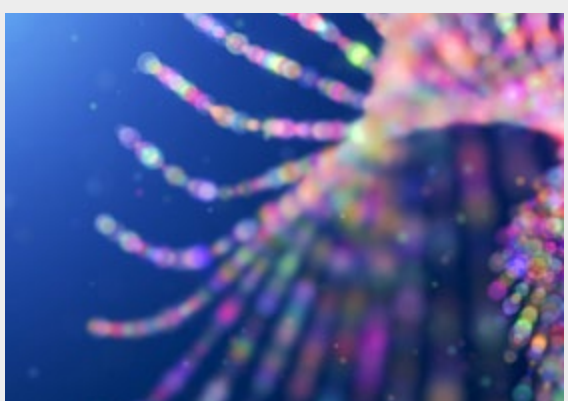
Leaders are already reaping benefits

Our assessment model shows that leaders, that are strong on both foundations (including tools, technologies, data, architecture, and connectivity) and enablers (including vision, strategy, people, processes, culture, and skills) are reaping benefits at scale. Almost half are already reducing time to market, human error, late-stage failures, and costs as a result of their efforts.

How to build a next-gen lab

Based on our research and experience, we believe the following are key considerations:

- **Strategize your transformation approach:** Assess the current maturity of your labs and develop a clear vision, roadmap, and KPIs for transformation.
- **Design a future-ready architecture:** Legacy technologies and infrastructure are major barriers to lab transformation for 90% of organizations. Prepare a blueprint of lab reference architecture, tools, and technologies to guide and help in achieving continuous improvement.
- **Build intelligence through strong data foundations:** Focus on FAIR (findable, accessible, interoperable, and reusable) data principles to eradicate data silos, enable global collaboration, and increase efficiency of work performed in labs.
- **Augment human intelligence with AI:** From target identification during drug discovery to automated in-process testing for quality control, AI and generative AI will play a significant role in assisting labs in critical processes.



- **Optimize your processes:** Ensure efficient operational continuity through harmonized, automated, and integrated processes and workflows.
- **Collaborate with the ecosystem:** Foster the right culture and mindset to strengthen collaboration and facilitate open innovation in next-gen labs. An interconnected ecosystem of industry players to connect data, insights, platforms, and instruments helps accelerate drug discovery and development.
- **Strengthen talent capabilities:** Virtually all (97%) of organizations in our survey find hiring scientists with a mix of domain as well as digital/data expertise a challenge. Help plug the skills gap by hiring, upskilling, reskilling, and partnering to capitalize on the “lab-as-a-service” model.
- **Embed sustainability across products, processes, and operations:** Adopt a green chemistry approach to reduce waste, conserve energy, and eliminate use of hazardous substances.

Who should read this report and why?

This report, packed with actionable recommendations, empowers pharma and biopharma organizations to build next-gen, future-ready labs. It primarily caters to business and technology executives across strategy, innovation, R&D, pre-clinical trials, clinical trials, analytical method development (AMD), manufacturing process development, regulatory affairs, pharmacovigilance, product safety, pharmacology, quality, digital, data, analytics, and technology functions.

Drawing on a comprehensive survey of 702 senior executives (from R&D, quality, and process development labs) at large pharma and biopharma organizations exceeding $500 million in annual revenue, this report provides a tool for organizations to assess their maturity on critical transformation "foundations" and "enablers". Beyond outlining the ***"why",*** this report also dives into the ***"how"*** of successful lab transformation, exploring practical steps and considerations. The recommendations span lab transformation vision and design, talent and structure, partnerships and methodologies, technologies, and architecture, and are corroborated by in-depth qualitative insights from over 10 industry leaders.

"Next-gen labs will deploy digital technologies such as automation, predictive analytics, and AI across the lifecycle. People, processes, tools, and technologies will come together to provide a seamless experience"

Associate Director at a large pharma

Introduction

Pharma[1] companies today face a range of issues, including low drug approval rates, rising drug discovery costs, pressure to accelerate timelines, ever-evolving regulatory requirements, and supply chain uncertainties. Labs (including R&D labs, quality labs, and process development labs) are vital to the "molecule-to-medicine" value chain. By leveraging digitalization, automation, robotics, and next-generation analytics – supported by the right set of strategies, processes, people, culture, and partners – future-ready pharma labs will play a critical role in addressing these global health challenges with greater speed, accuracy, and impact.

Organizations are looking to create future-ready "next-gen" labs to drive scientific breakthroughs. However, aside from a few high performers – what we call "leaders" – our research shows that lab transformation progress is generally patchy.

So, what is it about these leaders that allows them to create more agile, efficient, collaborative, flexible, and sustainable labs? And how can others emulate them to create and scale next-gen labs?

To answer these questions, we conducted a global survey of more than 700 respondents within R&D, quality, and process development labs from 235 pharmaceutical (producing chemical or small-molecule drugs) and biotechnology (producing biologics or large-molecule drugs) organizations across the US, UK, Switzerland, France, Germany, Japan, and India.

We also conducted in-depth interviews with life sciences executives to complement the quantitative insights. For more details on the survey sample, please refer to the research methodology.

Introduction

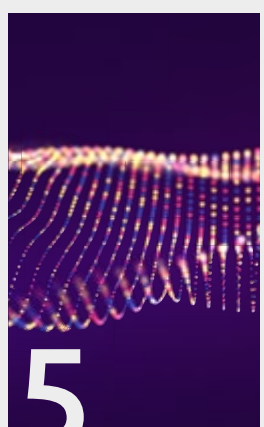
Based on our research, the report focuses on the following questions:

What are the key forces driving lab transformation initiatives today?

What is the state of current and planned investment in lab transformation initiatives?

Where are organizations now in their lab transformation journey?

What are the key data-, technology-, people-, and process-related barriers to transformation?



Who are the leaders and what are the benefits they achieve?

How do you build a next-gen lab and what can we learn from the leaders in this field?

01 LABS PLAY A KEY ROLE IN THE "MOLECULE-TO-MEDICINE" VALUE CHAIN

The demand for accelerated timelines is driving change

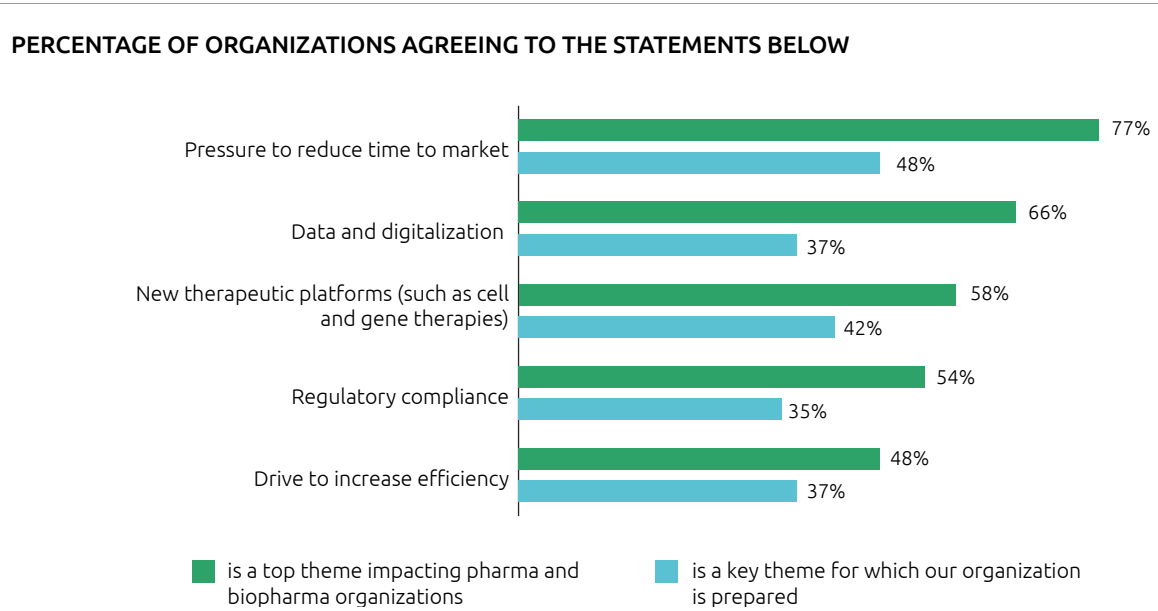
Pharma companies, on average, spend $2.8 billion per drug approval.[2] Only around 12% of drugs entering clinical trials are ultimately approved.[3] Mounting R&D costs, low approval rates, and lead-time challenges, as well as the increasing complexity of new gene and cell therapies, are forcing pharma organizations to rethink their approach.

As shown in figure 1, pressure to reduce time to market impacts 77% of pharma organizations. Sylvain Demanze, Senior Analytical Scientist at AstraZeneca says, ***"Typically, the design make test analyze (DMTA) cycle can take anything from a few weeks, if you are lucky, to several months per integration. Within a drug discovery project, you need to go through this cycle 10, 20 or 30 times. …if you can go through this iteration more quickly, you can progress your pipeline of projects quicker."***[4] Only 48% of organizations feel prepared for this acceleration.

While 58% of organizations say new therapeutic platforms (such as cell and gene therapies[5], etc.,) are a key theme, only 42% are prepared for this trend. Novo Nordisk Foundation has recently invested $136 million in the development of a new clinical cell therapy manufacturing hub in Denmark. The hub incorporates both process-development labs and a manufacturing base.[6]

FIGURE 1.

The need for faster drug development, digitalization, and a shift towards innovative therapies are impacting pharma organizations globally



Source: Capgemini Next-Gen Pharma Lab Survey, October 2023, N=235 pharma and biopharma organizations, N=702 respondents from pharma and biopharma labs.

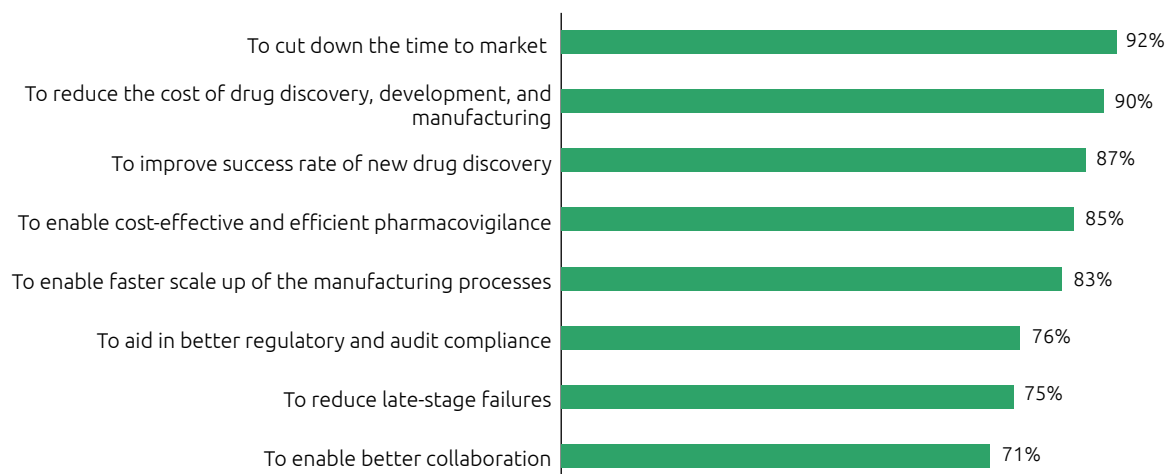
Lab ecosystems can address industry pressures and emerging trends

Pharma organizations are rethinking approaches to lab structure and operation, with an emphasis on accelerating digitalization. AstraZeneca is strongly focused on digitizing its labs through data-driven science, artificial intelligence (AI), digital-enabled lab workflows, and connected lab instruments. For instance, the company is using AI to deduce the best molecules across 70% of their small molecule chemistry projects.[7]

FIGURE 2.

Accelerating timelines, reducing costs, improving approval rates, and increasing efficiency are the top drivers of lab transformation initiatives

PERCENTAGE OF ORGANIZATIONS RANKING THE BELOW AMONG TOP DRIVERS FOR LAB TRANSFORMATION INITIATIVES

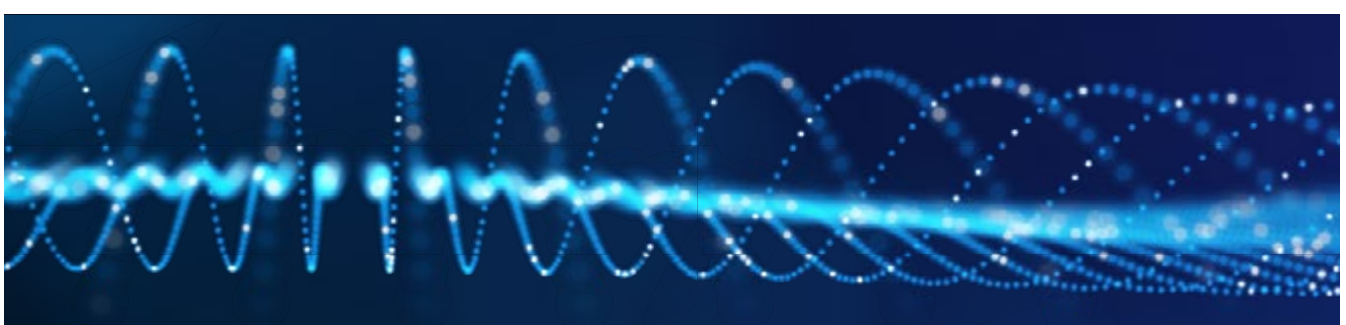


Source: Capgemini Next-Gen Pharma Lab Survey, October 2023, N=702 respondents from pharma and biopharma labs, N=235 pharma and biopharma organizations.

The top drivers of lab transformation closely align with the key themes impacting the industry:

- **Reduced time to market:** 92% of pharma organizations surveyed rank "accelerating time to market" in the top five drivers for lab modernization, digitalization, and transformation initiatives. By country, 96% of pharma organizations headquartered in India, 93% in the US, and 93% in the UK rank this as a top driver.
- **Reduced costs:** Reducing costs at every stage of the lifecycle is paramount for 90% of organizations surveyed (95% in Switzerland).
- **Improved success rates:** 87% of surveyed organizations (96% in the UK, 92% in France, and 88% in Japan) looking to digitalization and transformation to improve success rates.
- In addition, 83% aim to scale up manufacturing faster through lab transformation initiatives, especially those targeted at improving the efficiency of process development and quality labs.

Cenk Ündey, PhD, Head of Pharmaceutical Technical Development Data and Digital Organization at Genentech, an independent subsidiary of Roche adds, ***"The benefits of digitalization include enabling seamless data and information flow across the development value chain and into manufacturing. This increases development teams' productivity while advancing the pipeline activities."***[8]



Investments in lab transformation are set to accelerate

Increasingly, a connected, cutting-edge lab environment is regarded as the core of an innovative and competitive pharma organization. A recent survey from Forrester highlights that 69% of lab heads believe they will lose competitive advantage if they fail to connect and automate their labs.[9]

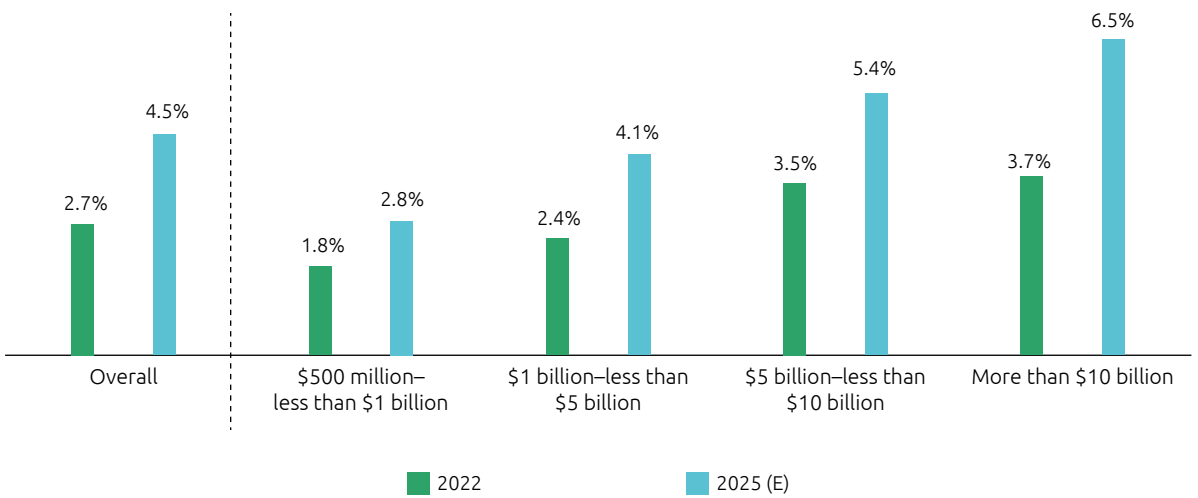
Our research showed that nearly 75% of respondents say they have begun lab modernization and the remaining 25% are strategizing their approach. These numbers are consistent across all three types of pharma labs in the survey (R&D, process development, and quality), underlining the universal nature of this imperative to transform.

On average, in 2022 organizations spent 2.7% of revenue on initiatives related to modernization, digitalization, and transformation of their labs. They plan to spend nearly 4.5% of revenue on this by 2025 (see figure 3). Organizations with revenue of $500 million–$1 billion typically spent around 1.8% in lab transformation in 2022, whereas larger organizations ($10 billion+ revenue) spent around 3.7%.

FIGURE 3.

Large organizations plan to invest nearly 7% of revenue in lab transformation initiatives by 2025

TOTAL INVESTMENT IN LAB TRANSFORMATION AS A % OF ORGANIZATIONAL REVENUE



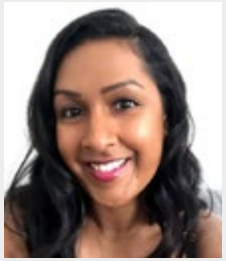
Source: Capgemini Next-Gen Pharma Lab Survey, October 2023, N=702 respondents from pharma and biopharma labs, N=235 pharma and biopharma organizations, N=35 organizations in the revenue range $500 million–less than $1 billion, N=126 organizations in the revenue range $1 billion–less than $5 billion, N=28 organizations in revenue range $5 billion–less than $10 billion, N=46 organization with revenue more than $10 billion.

Nearly half (48%) of organizations anticipate that they will require two to five years to transform their labs. A significant minority (17%) feel they will require at least five years, whereas 35% believe they can complete transformation within the next couple of years.

Roche is developing the Integrated Core Lab, with centralized automation that will include a single user interface that can run the entire system. The aim is to eliminate human error from tasks where human interaction is not required, improve efficiency, and reduce turnaround time.[10]

~7%

of revenue of large organizations is expected to be invested in lab transformation initiatives by 2025



"Digital transformation led by AI is a key contributor to our success and will hopefully help bring solutions faster to patients."

NIVETHA PATERSON
Head of Scientific Services for North America, Sanofi

02 MOST ORGANIZATIONS ARE IN THE EARLY STAGES OF LAB TRANSFORMATION

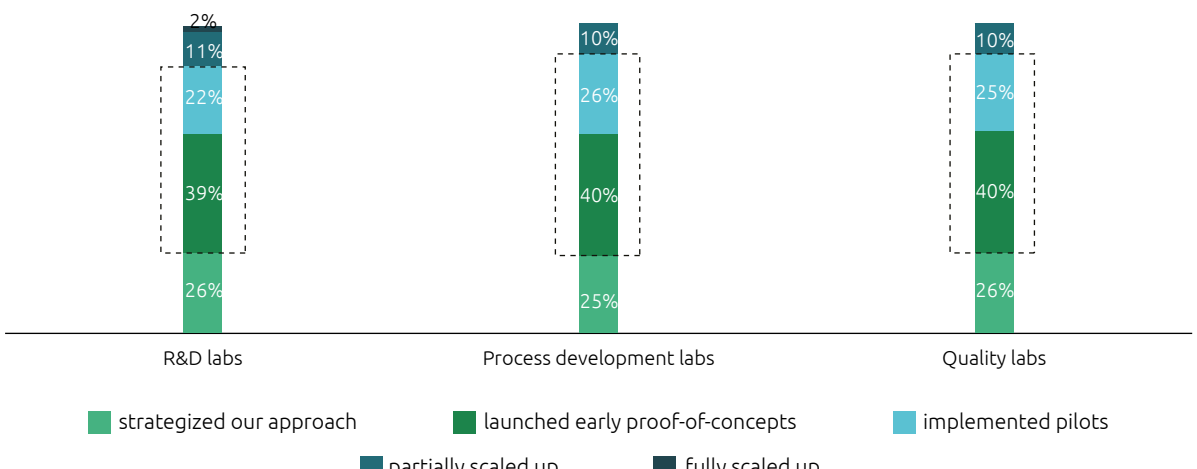
Most labs are at pilot or PoC stage

Many organizations are yet to advance beyond pilots and proof-of-concept (PoC) in their lab transformation journeys, as figure 4 shows.

Sophie Bailes, Director, Digital Transformation AstraZeneca says, *"When we talk about digital technologies, it's 10% technology and 90% people … If you're doing a small pilot or PoC where you maybe have one lab or one project, how do you then scale that? That's part of the engagement piece, change management and that peer-to-peer support. [By using this collaboration piece] we've moved to now having VR technology in the lab for instance. You have to deliver digital transformation through everybody – not through our leaders, not through one group."*[11]

FIGURE 4.
Only 1 in 10 organizations have scaled their lab modernization, digitalization, and transformation initiatives

FOR OUR LABS MODERNIZATION AND DIGITALIZATION INITIATIVES, WE HAVE:



Note: Numbers do not add to 100 percent due to rounding off
Source: Capgemini Next-Gen Pharma Lab Survey, October 2023, N=702 respondents from 235 pharma and biopharma labs, N=371 respondents associated with R&D labs, N=311 respondents associated with process development labs, N=309 respondents associated with quality labs in pharma and biopharma organizations.

CURRENT TECHNOLOGY-, PROCESS-, AND PEOPLE-RELATED CHALLENGES

Pharma and biotech labs are under mounting pressure to increase R&D productivity, reduce costs and time to market, and become more sustainable while also developing new and promising cures. ***"Throughput and speed are the key challenges in achieving the vision for the lab of the future,"*** notes Janet Nikolovski from Janeta Consulting Group. As labs strive to meet these goals, they must address multiple challenges – from heterogeneous unstructured high-volume data, to siloed lab equipment and processes, and a shortage of skill sets such as data management, analytics, an AI.

Data- and technology-related challenges

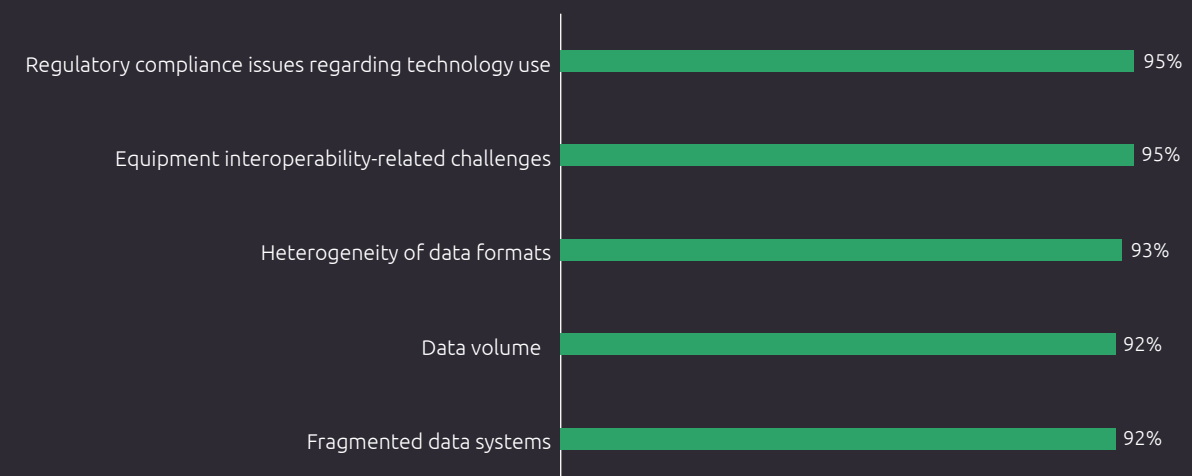
Data is the foundation for accelerated, cost-efficient, and high-quality drug discovery and development. In our survey, 9 out of 10 organizations believe that dealing with huge volumes of data is one of their biggest challenges. With the adoption of new cell and gene therapies, and with increasing use of multiomics analysis[12], data volume is increasing at an unprecedented pace. One human genome sequence alone requires more than 200 gigabytes of storage. It is estimated that 40 exabytes will be needed to store the world's genomic data by 2025. For comparison, every word ever spoken by humans would need just five exabytes of storage.[13] A senior director from the R&D arm of a leading pharmaceutical company elaborates, ***"We generate a huge amount of data from omics, genomics, genetic screens, etc., Oftentimes we don't make the best use of this data because it is not connected in the right way, and we end up running the same experiment multiple times."***

93%

of organizations say heterogeneity of data formats is a challenge for their labs.

FIGURE 5.
Data size and complexity is among the key challenges facing labs

PERCENTAGE OF ORGANIZATIONS IDENTIFYING THE FOLLOWING AS TOP DATA- AND TECHNOLOGY-RELATED CHALLENGES



Source: Capgemini Next-Gen Pharma Lab Survey, October 2023, N=702 respondents from pharma and biopharma labs, N=235 pharma and biopharma organizations.

The heterogeneity of data collected adds another layer of complexity for 93% of organizations surveyed (see figure 5). This data can be structured or unstructured, manual, or digital, and can range from real-world data (such as electronic health records, imaging and lab data, claims and billing data, genomics data, etc.), to clinical trials data, partner or vendor data, research papers, lab notes, and pharmacovigilance data, as well as operational data around inventory, schedules, instruments, etc. This all needs to be integrated and/or cross-compared to allow for meaningful analysis. Christos Varsakelis, team lead in AI/ML, Janssen Pharmaceutical Companies, Johnson & Johnson says, ***"If we worked at Target and were capturing point of sales information from a cash register, that is all highly structured [data] … In a lab … we have a much more diverse and challenging dataset to deal with."***[14]

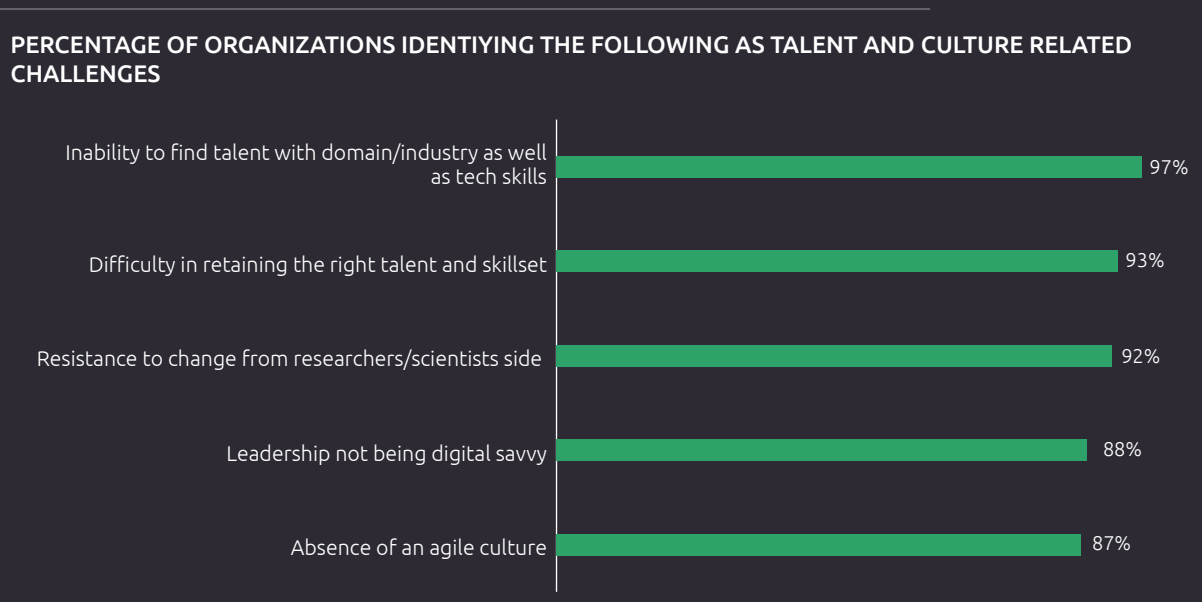
Any new methodology adopted in the lab must be approved by the relevant regulatory body. Unsurprisingly, 95% of organizations identified regulatory compliance issues related to technology use as a key challenge and a further 95% highlighted equipment interoperability.

Skill- and culture-related challenges

Lab professionals need the right analytical skills to derive insights from data. However, 97% of organizations see a challenge in finding scientists with a mix of domain as well as digital/data expertise (see figure 6). The vast majority (87%) also mentioned the absence of an agile digital culture as a challenge.

FIGURE 6.

Hiring people with the right mix of skills is a challenge for labs today



Source: Capgemini Next-Gen Pharma Lab Survey, October 2023, N=702 respondents from pharma and biopharma labs, N=235 pharma and biopharma organizations.

Process-related challenges

Labs, and particularly those dedicated to biopharma processes, are inherently heterogeneous and prone to variability. Thus, issues related to sample representativeness, time delays, operating condition variations, likely changes in sample during storage and transportation, sterile process, use of toxic chemicals and reagents, etc., crop up. As organizations diversify into new advanced therapy medical products (ATMP), processes become even more complex with new demands on workflows to synergistically combine both computational and experimental approaches.

Clinical studies today also involve more decentralization, complex protocols, larger numbers of stakeholders, and a variety of technologies, all of which make the execution more complex and less efficient. In our research, 92% of organizations recognize that process complexity ranks high in the challenges labs face.

"Throughput and speed are the key challenges in achieving the vision for the lab of the future"

JANET NIKOLOVSKI
Janeta Consulting Group.

Only a minority of organizations are "leaders"

To understand where organizations are on the journey towards next-gen labs, our survey covered a number of critical elements. As seen in figure 7, these elements fall into two groups: the "foundations" and the "enablers" of transformation.

- **The foundations** comprise the *what* of transformation, including the tools, technologies, data, architecture, and connectivity required to create the next-gen labs.
- **The enablers** cover the *how* of transformation, including the vision, strategy, people, processes, culture, and skills required for future-ready labs.

FIGURE 7.
Key elements of next-gen lab transformation

Note: Please see the Appendix for more details on sub-parameters included for both the dimensions.
Source: Capgemini Research Institute analysis.

Based on these elements, we identified four cohorts: “visionaries”, “leaders”, “innovators”, and “beginners”.

15%

of the organizations surveyed fall into the leaders category, where they lead in both foundations and enablers.

60%

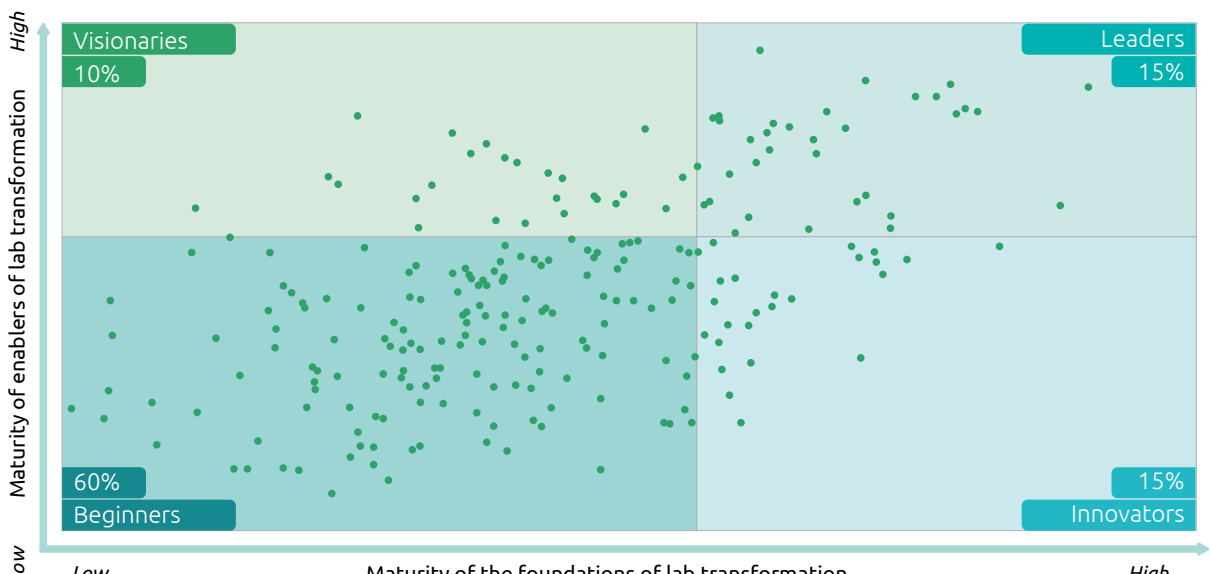
fall into the beginners category, falling behind in both dimensions.

25%

do well in only one dimension.

FIGURE 8.

Only 15% of organizations are mature (leaders) in terms of lab transformation



Source: Capgemini Next-Gen Pharma Lab Survey, October 2023, N=702 respondents from pharma and biopharma labs, N=235 pharma and biopharma organizations.

What makes an organization a leader, visionary, innovator, or beginner?

	BEGINNERS (at early stages of both foundations and enablers of lab transformation)	**INNOVATORS** (advanced in foundations of lab transformation, but at early stages of enablers of lab transformation)	**VISIONARIES** (advanced in enablers of lab transformation, but at early stages of foundations of lab transformation)	**LEADERS** (advanced in both foundations and enablers of lab transformation)
LAB STRATEGY AND VISION	No dedicated strategy or vision in place.	Lab vision aligned with organizational goals but not fully integrated into standard processes.	Have started developing a clear, holistic strategy for future lab functions.	Dedicated strategy, digital vision, and a detailed roadmap in place, with clear milestones to monitor and scale the progress of transformation initiatives.
PROCESSES AND WORKFLOWS	Siloed processes, many manual and paper-based processes.	Integrated workflows and on-demand services.	Islands of connected workflows.	Collaborative and autonomous processes.
AUTOMATION	Low/basic level of automation.	Fully digitized, advanced analytics.	Initial digitalization and analytics.	AI-driven, advanced predictive analytics, and intelligent workspaces facilitating reproducible experimentation; using data and AI for good laboratory practices (GLP), good manufacturing practices (GMP), and regulatory filings.
TECHNOLOGY	Standalone applications and instruments, legacy systems.	Laboratory Information Management System (LIMS), Lab Execution System (LES), Scientific Data Management System (SDMS), instrument integration to support digitalized processes.	Customized, on-premise with few integrations.	Integrative, cloud-native, seamless digital integration across devices and labs.

(Continue on the next page...)

	BEGINNERS (at early stages of both foundations and enablers of lab transformation)	INNOVATORS (advanced in foundations of lab transformation, but at early stages of enablers of lab transformation)	VISIONARIES (advanced in enablers of lab transformation, but at early stages of foundations of lab transformation)	LEADERS (advanced in both foundations and enablers of lab transformation)
DATA	Siloed data sources, non-digitized data.	Integrated data platforms exist, but querying and reporting takes time.	Integrated data platforms exist alongside legacy platforms, which makes data discovery and exploration confusing.	Unified data platforms leveraging cloud and self-service tools
KNOWLEDGE MANAGEMENT	Struggling to ensure knowledge continuity within labs and across labs.	Unable to adequately create, share, and reuse knowledge across different labs.	Able to collaborate across diverse disciplines including chemistry, biology, informatics, and engineering.	Seamless knowledge management across the organization, embrace open innovation practices.
TALENT AND SKILLS	Minimal focus on transforming talent and skills.	Struggle to reskill and upskill while trying also to capitalize on new tech opportunities.	Focus on developing digital and data-science skills among scientists.	Along with hiring and partnering, continuous focus on upskilling for digital and data-science skills among scientists, and an organizational culture that appeals to digital talent.
SUSTAINABILITY	Sustainability is not factored in when designing labs and processes.	Some focus on sustainability – mainly through considering energy efficiency of equipment, waste audit, etc.	Sustainability KPIs set for labs, a lab culture is fostered that promotes sustainability, regular impact assessment of APIs and finished goods conducted throughout the lifecycle.	Adopt green chemistry principles, technology, and techniques such as miniaturization, etc., to focus on sustainability; develop product-specific target sustainability profiles, actively focus on reducing emissions throughout the value chain.

As organizations strive to become leaders, they must adopt a contextual solution for their labs that comprises prioritized technology and process initiatives derived from a well-crafted custom lab strategy and roadmap.

03 LEADERS ENJOY ACCELERATED TIMELINES, OPTIMIZED COSTS AND GREATER APPROVAL RATES

Our survey shows that those organizations leading the lab transformation efforts are already reaping benefits at considerable scale (see figure 9).

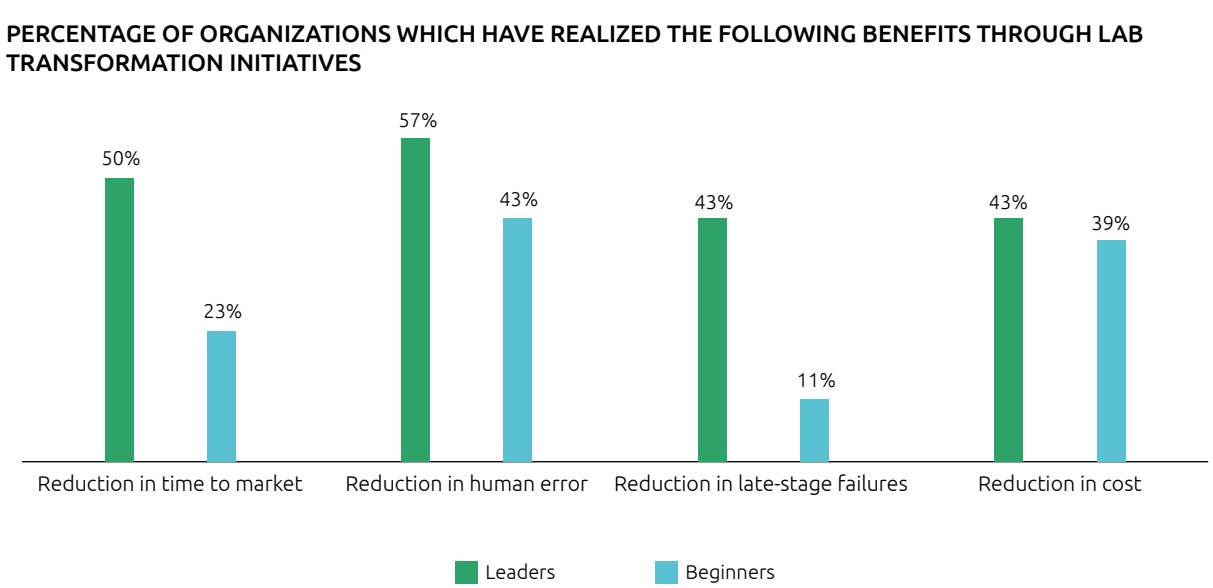
We also noted that the net income growth rate in the last year for the leaders is 33 percentage points higher than the average for surveyed organizations.[15]

57

of leaders have witnessed a reduction in human errors due to their lab digitalization and modernization initiatives

FIGURE 9.

Leaders have accelerated time to market, reduced errors, higher approval rates, and optimized costs compared to beginners



Source: Capgemini Next-Gen Pharma Lab Survey, October 2023, N=98 pharma and biopharma organizations that are either piloting or partially/fully scaling lab transformation initiatives, N=14 leader organizations that are either piloting or partially/fully scaling lab transformation initiatives, N=56 beginner organizations that are either piloting or partially/fully scaling lab transformation initiatives.

50

of leaders have realized reduction in time to market through lab transformation initiatives

Leaders witness reduced time to market

Digitalization has empowered labs to accelerate the pace of breakthrough discoveries. As figure 9 shows, 50% of leaders have reduced time to market through lab transformation measures compared to 23% of beginners. Nivetha Paterson, Head of Scientific Services for North America, Sanofi says, ***"Digital transformation led by AI is a key contributor to our success and will hopefully help bring solutions faster to patients."***

Our research shows that 50% of respondents from quality labs, 46% from R&D labs, and 39% from process development labs expect to see a reduction in time to market in the next three years through their ongoing efforts on lab transformation.

- Cerevel, a neuroscience biotech company, screened nearly 3 million different molecules for lead identification – a time-consuming and expensive process. Cerevel's Chief Scientific Officer, John Renger, believes that using cloud-based solutions for target and lead identification will save at least three years on average in discovering a new drug: ***"We can get there faster, get there cheaper, and get drugs to patients much more quickly without as many failures."*** [16]
- GSK uses digital twins in their drug development as well as manufacturing processes. Matt Harrison, Head of Sciences, Digital Innovations and Business Strategy in Vaccines, GSK adds, ***"Through the use of digital twins, faster, less wasteful, more cost-effective vaccine development and manufacturing is possible, which ultimately helps improve the health of millions of people around the world."*** [17]
- Quality control is also increasingly digitalized. Modern labs use digitalization, automated process controls, and in-process monitoring and testing, thus minimizing quality issues, and saving time as well as costs.

In the table below we show some indicative use cases where digitalization can reduce time to market.

TARGET IDENTIFICATION	LEAD IDENTIFICATION	LEAD OPTIMIZATION	PRECLINICAL TESTING AND DEVELOPMENT	CMC PROCESSES	CLINICAL TRIALS (PHASE I, II, III)	QUALITY, APPROVAL AND PHARMA-COVIGILANCE
Text mining of scientific literature for identifying potential targets	Automation and robotics for dispensing, screening plates, etc. to enable high through-put screening of millions of compounds	Cutting down on long manual iterations using machine learning and computational techniques like predictive modeling	Image and data analysis of high content screening data Modelling biological systems	Process simulation by technologies such as digital twins, scale-up modeling and stability modelling, use of co-bots	Optimizing clinical trials and recruitment Generating synthetic data Supply chain modelling	Documentation Text mining to provide early alerts

- Planning and executing operational processes like lab scheduling, inventory management, trace and track samples
- Monitoring and maintaining lab equipment
- Time-sink activities like waiting for experiments, extracting and transferring data from instruments, pipetting, etc.
- Analyzing and drawing insights from numerous, unrelated , multidimensional data points
- ELN and LIMS for data capture and workflow management
- Training new scientists and technicians using AR/VR

Source: Capgemini Research Institute analysis.

Leaders show reduced human error

Human error accounts for more than 80% of process deviations in the pharmaceutical and related industries.[18] With use of electronic notebooks (ELNs), LIMS, automation, and cloud solutions, such errors can be reduced, and the integrity and traceability of data can be ensured.An Associate Director at a large pharma says, ***"In recent years there has been a move towards instruments like liquid handlers and bioreactors, which automate many of the manual tasks and reduce the possibility of errors –clean, closed systems, automated as far as possible, just to avoid the human error."*** Figure 9 shows that 57% of leaders reduced human error as a result of their lab transformation initiatives.

Leaders show accelerated approval rates

Late-stage failure is one of the leading concerns for labs and pharma companies. Taking a drug from pre-clinical research to marketing can take 12 years or longer,[19] and the later a drug candidate fails, the more expensive it is.

Drug development failures are usually attributed to:[20]

- lack of clinical efficacy (40–50% of cases);
- unmanageable toxicity (30% cases);
- poor drug-like properties (10–15% of cases); or
- lack of commercial need/poor strategic planning (10% of cases).

While not all failures are attributable to a deficiency or gap in knowledge, many late-stage failures can be avoided through rigorous decision-making supported by robust data and analytics. When surveyed, 43% of leaders say they can reduce late-stage failures by focusing on lab transformation, compared to 11% of beginners (see figure 9). By lab type, 28% of respondents from quality labs, 25% from R&D labs, and 23% from process development labs have already seen a reduction in late-stage failures as a result of transformation initiatives.

Data and analytics can be leveraged in R&D labs to terminate poor drug candidates early and thus reduce late-stage failures by:

- using AI and machine learning (ML) computational tools to improve drug screening processes;
- identifying patterns and linkages in genetic and other omics data;
- simulating pharmacological responses related to safety and efficacy, pharmacokinetics of the drug and exposure at target site;[21]
- establishing optimum dosage and dosing regimen; and
- identifying patient sub-populations likely to have a favorable risk-benefit profile.

"In recent years there has been a move towards instruments like liquid handlers and bioreactors, which automate many of the manual tasks and reduce the possibility of errors – clean, closed systems, automated as far as possible, just to avoid the human error."

Associate Director at a large pharma

Leaders witness reduced costs

Lab digitalization and transformation have significant potential to impact costs: 43% of leaders have seen a cost reduction due to their transformation initiatives (compared to 39% of beginner organizations). Novartis is using AI to optimize the structures of promising molecules to enable faster compound design and selection. By deploying BenchSci, an AI tool that derives actionable knowledge from scientific publications, Novartis accelerated projects by months and saved approximately $14 million over three years.[22]

Our research also shows that leaders have realized sustainability-related benefits through lab transformation. Nearly 36% say they have seen a carbon footprint reduction compared with only 18% of beginner organizations.

WHAT IS A NEXT-GEN LAB?

Next-gen labs continuously evolve their technology, infrastructure, ways of working, skills, and culture, thereby enabling them to accelerate drug discovery, increase approval rates, and shorten therapy development cycles. An Associate Director at a large pharma adds, ***"Next-gen labs will deploy digital technologies such as automation, predictive analytics, and AI across the lifecycle. People, processes, tools, and technologies will come together to provide a seamless experience."***

Figure 10 shows our vision of a next-gen lab. It:

- is data-powered;
- utilizes high-throughput screening, automation, and robotics for faster efficient processes, while unlocking scientists' time to focus on innovation;
- converges multiple disciplines, analytics, and emerging technologies such as AI/ML, 5G, augmented reality (AR)/virtual reality (VR), digital twins, etc., to improve productivity and accelerate discovery;
- incorporates synthetic biology[23] tools to define new paradigms of drug discovery;
- leverages a service ecosystem for on-demand activities;
- is adaptable to changing regulations around new technologies and approaches; and
- fosters future-ready skills and a collaborative and ethical culture in a shared, flexible, and sustainable lab space.

The next-gen lab transformation is a journey and a continual process.

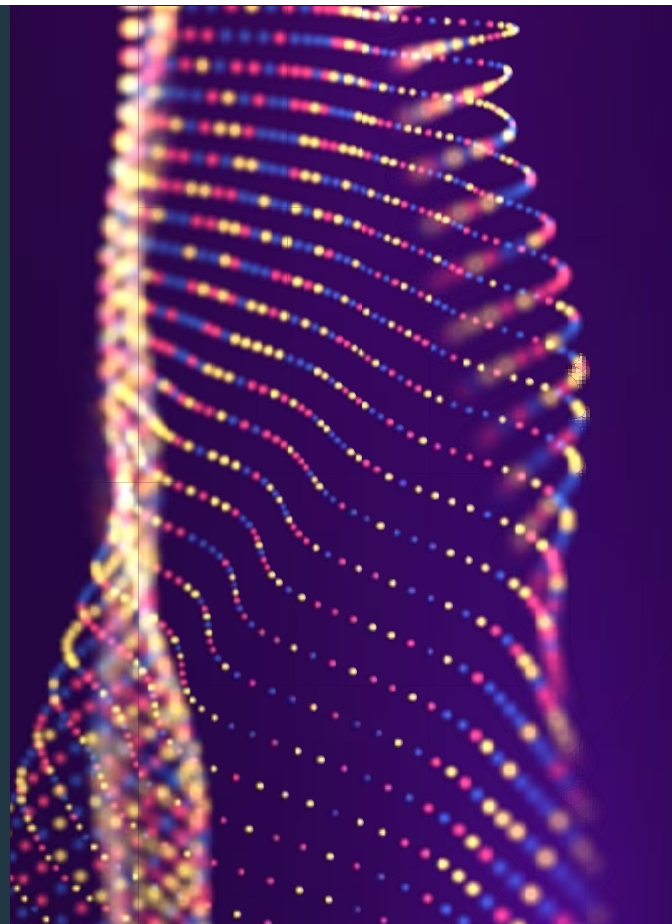
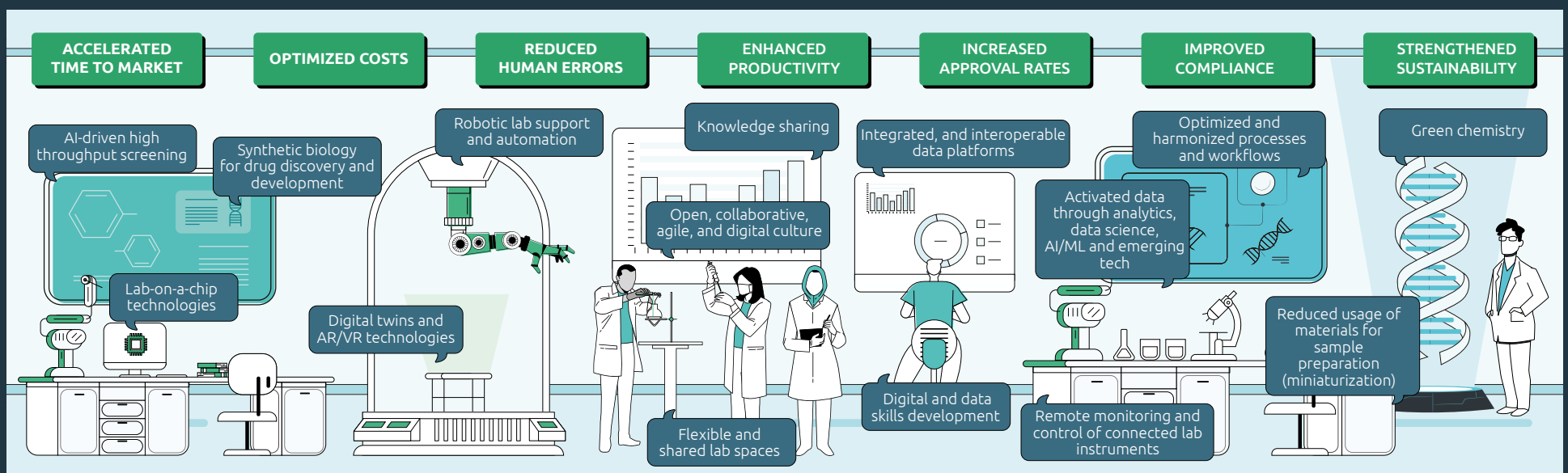


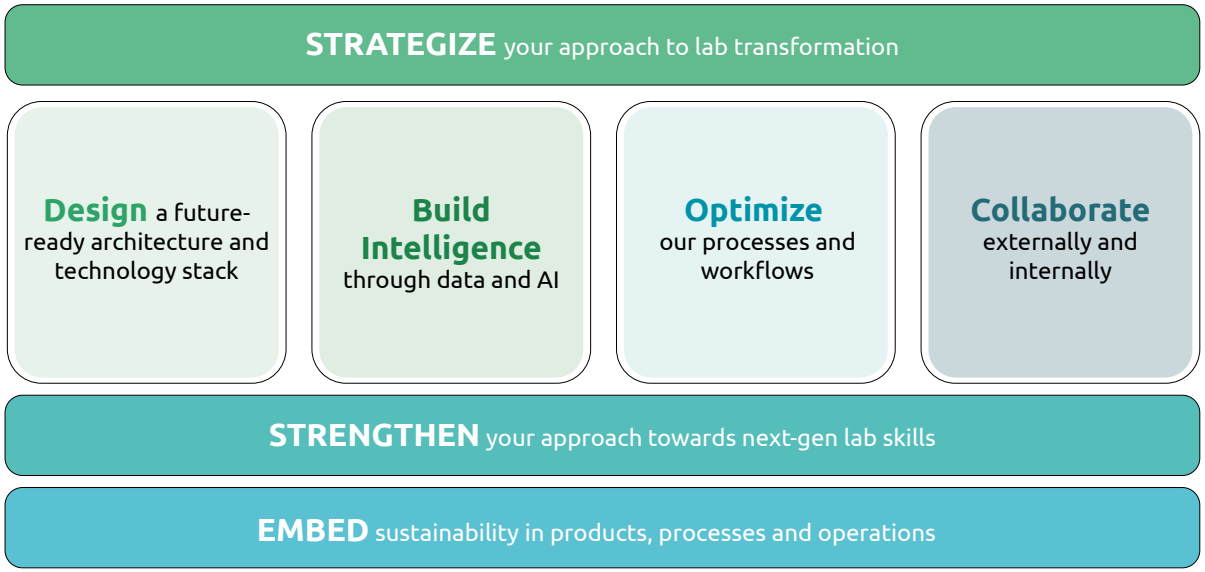
FIGURE 10.
The next-gen pharma lab



Source: Capgemini Research Institute analysis.

04 HOW TO BUILD A NEXT-GEN PHARMA LAB: LEARNINGS FROM THE LEADERS

FIGURE 11.
A framework for building next-gen labs



Source: Capgemini Research Institute analysis.

We have identified a number of key capabilities that are critical for building a next-gen pharma lab (see figure 11).

1. STRATEGIZE YOUR APPROACH TOWARDS LAB TRANSFORMATION

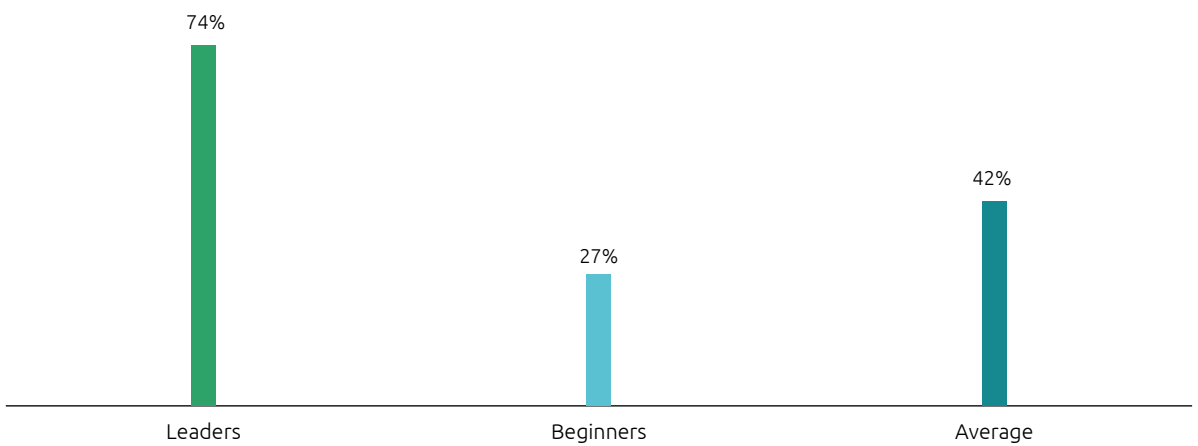
Many labs today are on this journey but are not yet able to scale the transformation efforts.

As a first step, organizations need to assess the current state of their labs using the maturity framework (figure 8). The next step is to define a future state and design an implementation roadmap with clear KPIs so performance towards defined goals can be regularly monitored (see figure 12). Sanjay Nandawadekar, Director IT from Cipla Limited, a leading Indian pharmaceutical major elaborates, ***"Organizations have to define what they want to do with data. They may have multiple objectives, such as ensuring compliance, creating a lab, process optimization or ROI, and for that they require a strategy."*** [24]

FIGURE 12.

Most leaders continuously monitor their progress on lab transformation goals

PERCENTAGE OF ORGANIZATIONS AGREEING TO THE STATEMENT: "WE REGULARLY MONITOR OUR PERFORMANCE ON THE DEFINED GOALS ON LAB MODERNIZATION AND TRANSFORMATION"



Source: Capgemini Next-Gen Pharma Lab Survey, October 2023, N=702 respondents from pharma and biopharma labs, N=235 pharma and biopharma organizations, N=35 leader organizations, N=141 beginner organizations.

There is also a need to showcase ROI to ensure management buy-in. In our research, 81% of organizations mentioned "uncertainty of ROI" as one of the top organizational barriers to creating next-gen labs. Oliver Hesse, Head of Biotech Data Science and Digitalization, Bayer Pharmaceuticals elaborates, ***"Pharma companies are far behind many industries in terms of digitalization. Partly … from being over-focused on avoiding risk or waiting for the proper use case. That's a trap – you have to take a more holistic view."***[25] Showcasing small wins can help to build momentum within the organizations. The key is to think big, plan thoroughly, start small, scale fast, and evolve.

"Organizations have to define what they want to do with data. They may have multiple objectives, such as ensuring compliance, creating a lab, process optimization or ROI, and for that they require a strategy"

SANJAY NANDAWADEKAR
Director IT, Cipla Limited

2. DESIGN A FUTURE-READY ARCHITECTURE AND TECHNOLOGY STACK

Overall, 76% of organizations agree that the level and pace of technology adoption in their labs has accelerated post COVID-19. Next-gen labs will have seamlessly integrated systems and instruments to facilitate the frictionless movement of work packages across labs.

The first step in leveraging technology to build a future-ready lab is to prepare a blueprint of lab reference architecture, tools, and methods to guide continuous improvement of lab services. Only 44% of organizations we surveyed have a custom-made blueprint of lab reference architecture.

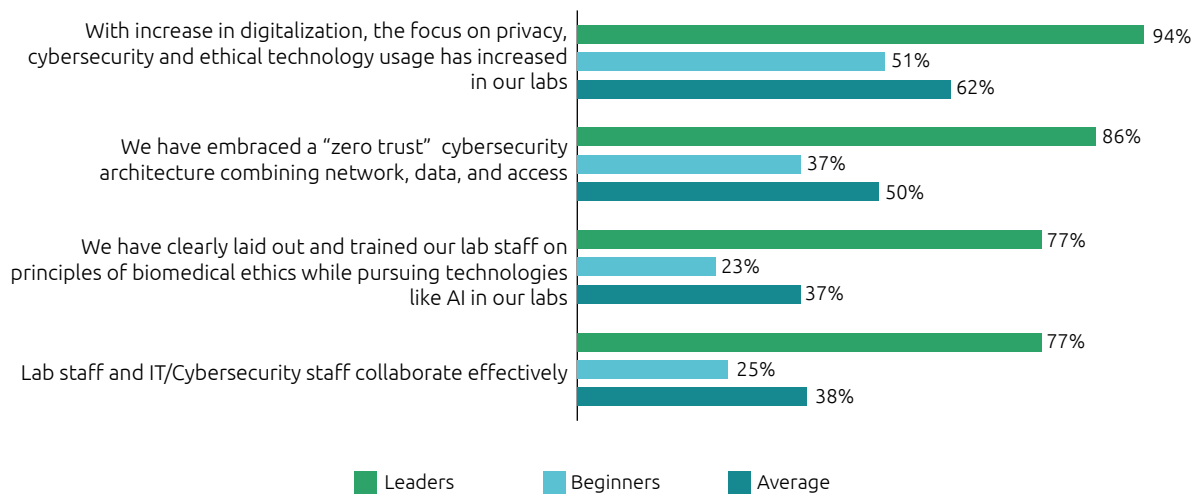
Moreover, 90% rank "legacy technologies and infrastructure" among the top barriers to lab transformation. To create a strong tool stack and technology estate, organizations need to focus on:

- **Cloud and connectivity systems:** LIMS/ELNs and the internet of things (IoT) can transform the lab environment from manual and/or disconnected islands to largely connected automated systems, improving overall scientist and lab productivity. Scalable cloud deployment provides an integrated data platform for analytics and standardizes processes across teams and location, accelerating the speed of discovery. In this way, Moderna sequenced its mRNA COVID-19 vaccine in two days and released the first clinical batch 25 days later.[26] Our research shows that only 23% of organizations use Integrated LIMS, with only 25% leveraging cloud-based systems.
- **Security:** Labs need to secure themselves against regulatory and safety breaches, cyber-attacks, or system failures. Only one-third (34%) of responding organizations have IT teams trained to address specific cybersecurity needs. Figure 13 highlights some best practices followed by leaders.

FIGURE 13.

Leaders focus on strong digital security foundations and culture

PERCENTAGE OF ORGANIZATIONS AGREEING TO THE STATEMENTS BELOW



Source: Capgemini Next-Gen Pharma Lab Survey, October 2023, N=702 respondents from pharma and biopharma labs, N=235 pharma and biopharma organizations, N=35 leader organizations, N=141 beginner organizations.

- **Immersive technologies:** Technologies such as voice-operated virtual lab assistants and AR/VR for training, and guided lab operations and maintenance, can reduce human effort, increase consistency, and reduce scope for error. An India-based pharmaceutical organization reported that their company uses AR/VR to train new employees on high-performance liquid chromatography (HPLC) system. Pfizer used AR during COVID-19 to diagnose and repair equipment remotely.[27] GSK is exploring the use of digital twins with high-throughput experimentation to produce data needed to confirm theories and thereby accelerate the vaccine R&D process.[28]

86%

of leaders have embraced a "zero trust" cybersecurity architecture

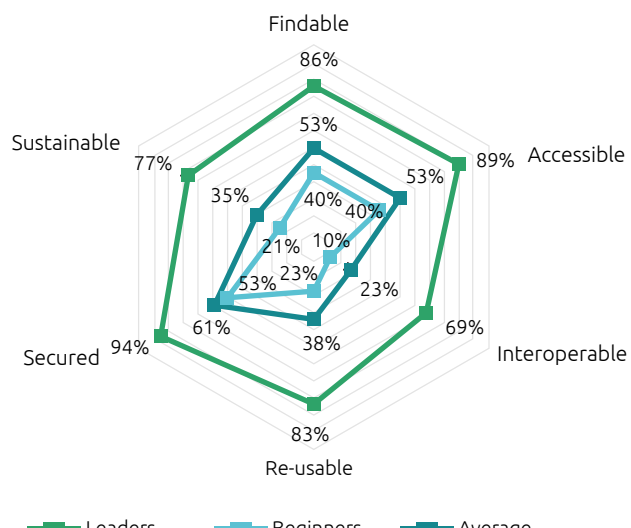
3. BUILD INTELLIGENCE THROUGH DATA AND AI

Create a data-driven lab with data standardization, harmonization, quality management, governance, and activation

Data-related challenges rank high for 90% of organizations surveyed. Dr. Haydon Boehm, Head of Commercial Marketing – Connected Lab, Merck Group says, ***"Up to 70 percent of research is currently not reproducible, often due to the***

FIGURE 14.
Leaders focus on FAIR, secured, and sustainable data

SCIENTIFIC DATA IN OUR ORGANIZATION IS



Source: Capgemini Next-Gen Pharma Lab Survey, October 2023, N=702 respondents from pharma and biopharma labs, N=235 pharma and biopharma organizations, N=35 leader organizations, N=141 beginner organizations.

inability to find the original research data, or because the experimental conditions are inconsistently or inadequately cataloged."[29] Poor data quality and redundant or lost data can cost companies 15%–25% of their operating budget.[30]

Making data FAIR (findable, accessible, interoperable, and reusable), as well as secured and sustainable, helps eradicate silos, enables global collaboration, increases the efficiency of lab work, and improves compliance. Our research shows that most leaders use FAIR data principles in their lab processes (see figure 14). Organizations should also focus on developing standardized data ontologies for complex knowledge graphs and on enabling self-service data access.

Penny Smee, Director and Senior Product Owner for R&D Tech, GSK adds, *"For us digital transformation is firstly, enabling CMC scientists to automate the capture of laboratory data from instrument to experimental meta data with key principles of FAIR embedded at source to accelerate medicine development. Secondly, enabling CMC scientists and data scientists to access and utilize all captured data to answer questions/use cases in an automated, data-integrity-driven manner and accelerate data collation tasks from small local activities to large global activities such as regulatory filing … for GMP or non-GMP."*[31]

To create an appropriately data-driven lab based on FAIR principles, organizations need to:[32,33]

1. **Enable "findability" by centralization of data:** For data to be physically findable it needs to be centralized. Organizations could achieve this through physical and virtual centralization e.g., a data lake or a hub-and-spoke model, where data is kept in domain-specific storage and a catalog directs users to its location. As Figure 15 shows, 74% of leaders say they have a data lake. For data to be useable, it must first be harmonized, standardized, and labeled.

2. **Enable accessibility and security by defining transparent access models and methods:** Accessibility means making the right data available to the right people, at the right time, with the right supporting information. Data access should be restricted as needed (for privacy, etc.,) and only as open as allowed under licensing or other regulations. Among the leaders, 69% say that "data from previous research is securely stored and is easily accessible and reproduceable as needed," compared to 49% overall (see figure 15). A focus on enterprise data governance and policies on data privacy, ethics, and security are also required.

3. **Enable interoperability through standardization:** Having accessed data, the next challenge is to put it to productive use. Isolated datasets rarely yield their full meaning and value until connected to and merged. Data scientists can, therefore, spend half their time "data wrangling."

   Organizations need to focus on developing systems that exchange information seamlessly with the full understanding of each dataset's origins, context, and meaning. These systems rely on structured formats (e.g., JSON, SML, RDF, API) and controlled vocabularies, ontologies, and synonym libraries to ensure each system can seamlessly interpret each piece of information. In our research, 57% of leaders say they use standards such as Allotrope Data Format (ADF) and Standardization in Lab Automation (SiLA-2) to ensure data is interoperable and instruments can communicate with each other.

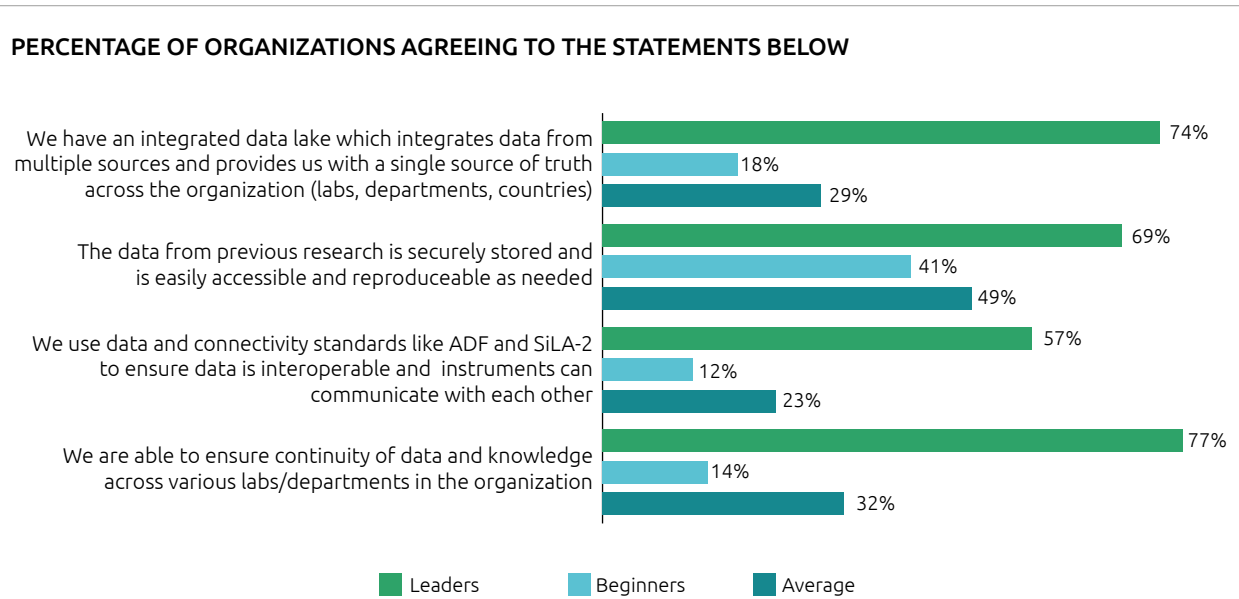
4. **Enable data and research reusability through data provenance and fostering a data culture:** The approach towards data, process and technology governance should facilitate data and research reproducibility in labs. As well as automatic capture of relevant meta-data, users need to be able to see the original context of the data, including the processes performed on it.

   For effective reuse, the importance of right culture cannot be undermined. Researchers may be reluctant to share "their" data, so it is important that organizations establish good sharing practices, provide suitable support and structures, and create incentives for FAIR data sharing. In our research, 77% of leaders say they ensure continuity of data and knowledge across various labs/departments, versus 14% of beginner organizations (see figure 15).

5. **Enable sustainability by considering "data footprint," a key aspect in data governance:** Data storage consumes large amounts of energy and must be factored into an organization's sustainability strategy. However, many organizations lag on this – only 45% of responding organizations across sectors said that sustainability of data (in data production, storage, and access) is a key consideration in overall data governance. Moreover, only 39% said they had drafted policies for conserving energy during data storage.[34]

FIGURE 15.

Leaders focus on accessibility, reproducibility, integration, and continuity of data in their labs



Source: Capgemini Next-Gen Pharma Lab Survey, October 2023, N=702 respondents from pharma and biopharma labs, N=235 pharma and biopharma organizations, N=35 leader organizations, N=141 beginner organizations.

Creating an AI-led digital lab platform that supports every phase of the data lifecycle brings a wealth of insights and ideas about new business models that could be developed by activating this information.

Central to the delivery of these data-centric services is a platform that allows self-service of the required tools. In our research, 94% of leaders have implemented self-service analytics for lab researchers and staff. This is a means of integrating the biochemical and the data technologies needed in next-gen pharma labs: (big) data-streaming tools, data governance tools, biochemical software tools, and data visualization and analysis tools.

94%

of leaders have implemented self-service analytics for lab researchers and staff

Use AI augmented with human expertise to innovate and reduce time to market

Lifeng Wang, Associate Director, Takeda Pharma says,: ***"AI and machine learning will be the trend for the new version of lab, especially in drug discovery."*** During a period of explosive growth in biomedical data, data analytics and AI are proving transformative in speeding up drug discovery, optimizing formulations, and predicting and monitoring outcomes while reducing costs and improving efficiency. ***"Our ambition is to become the first pharma company powered by artificial intelligence at scale, giving our people tools and technologies that focus on insights and allow them to make better everyday decisions."***, said Paul Hudson, CEO, Sanofi while talking about the roll-out of plai, its AI app.[35]

We identified the most widely adopted AI use cases as follows:

- More than 50% of R&D labs are using/planning to use AI for analyzing molecular structure, clinical trials data, and medical images for clinical trials in the next 12 months.
- In process development labs, in the next 12 months nearly 60% will use AI extensively for formulation optimization, supply chain optimization, scale-up modelling, and personalized medicines. US-based biotech startup Insitro has made a significant breakthrough in using machine learning to detect liver disease through bone scans.[36]
- In QC labs, 60% of organizations will use AI in in automated batch release, image analysis and microscopy, and automated testing and inspection in the next 12 months.

It is important to augment AI with human involvement. An executive from Japanese pharma company, Astellas says, ***"Our human-in-the-loop drug discovery platform integrates humans, AI, and robots and revolves around a DMTA cycle – design, make the compound, test the effects, and analyze. … one specific example of this approach reduced the time it took from hit compound to acquisition of a drug candidate compound by about 70%."***[37]

GENERATIVE AI: ACCELERATING PHARMA R&D AND OPERATIONS

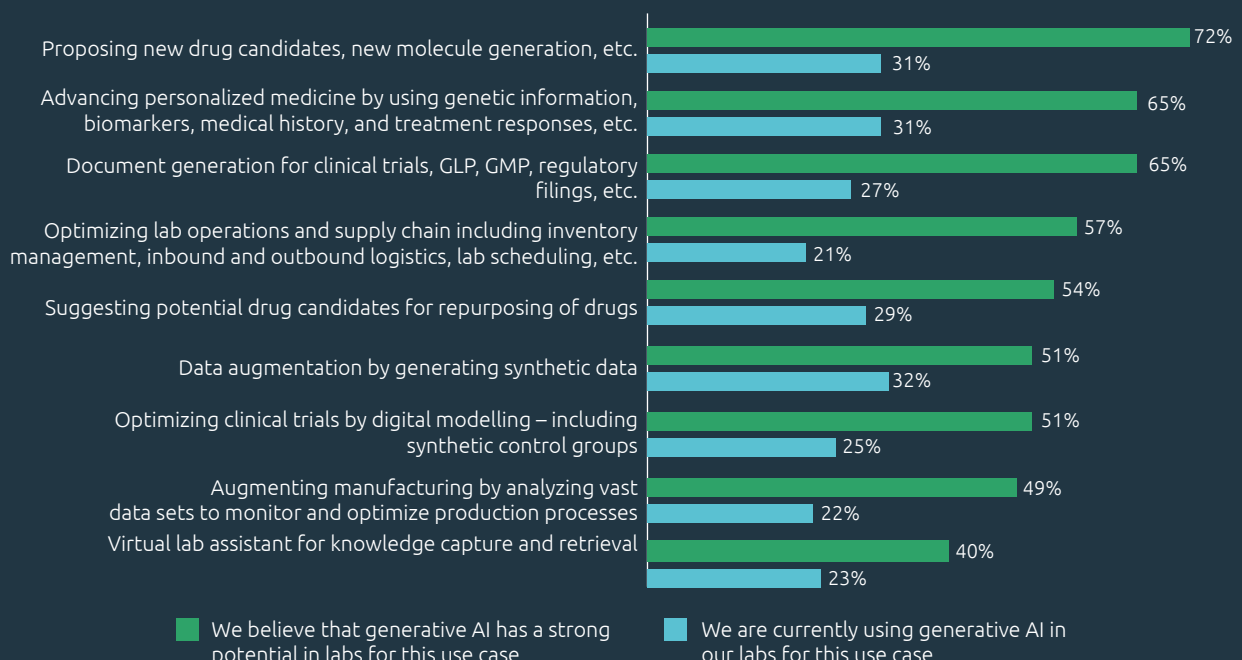
Bio-tech organizations including Cradle, Basecamp Research, Arzeda, Biomatter Designs, Cambrium, and Absci are designing new proteins from scratch using generative AI.[38] Insilico Medicine, a Hong Kong and NY headquartered biotech company, is using AI for end-to-end drug discovery. It is in the final stages of developing an experimental drug for the incurable lung disease idiopathic pulmonary fibrosis. Traditional methods would have cost more than $400 million and taken up to six years. But with generative AI, it took 10% of the cost and a third of the time to reach the first phase of clinical.[39] Figure 16 shows the use cases with most potential and highest current usage.

Organizations' R&D strategies should look to generative AI to support both short- and long-term goals. In the short term, this means reviewing organizing data and identifying productivity gains across functions. Focused applications such as small molecule de novo generation will likely already be delivering value. The second wave of longer-term, targeted opportunities will impact the clinical arena, from operations to patient experience.

At the same time as developing and/or using AI models, organizations need to establish strong governance principles and build safeguards against risks (such as intellectual property and copyright infringement, cybersecurity and data privacy vulnerabilities, biased outputs, AI "hallucinations," etc.,) so as to build trust amongst business leaders, users, and regulators.

FIGURE 16.

Generative AI accelerates the way pharma organizations develop, produce, and commercialize new treatments



Source: Capgemini Next-Gen Pharma Lab Survey, October 2023, N=702 respondents from pharma and biopharma labs, N=235 pharma and biopharma organizations.

REVOLUTIONIZING MEDICINE WITH SYNTHETIC BIOLOGY

Synthetic biology is a field of science that involves redesigning organisms for practical purposes by engineering them with new abilities.[40] Susan Hockfield, Professor of Neuroscience and President Emerita at the Massachusetts Institute of Technology (MIT) told us, ***"Nature is brilliant at solving technical problems. Our role is to recognize nature's solution and adapt it to our needs. Synthetic biology [means] genes can be reconfigured … in living organisms. … Future innovations will be an amalgamation of these biological tools with physics and engineering."***

This interdisciplinary field combining biology, engineering, computer science, and biotechnology has revolutionary applications that could dramatically impact medicine, agriculture, and environmental sustainability. Jennifer Doudna, Nobel Prize laureate and co-inventor, CRISPR-Cas9 adds, ***"It is important to remember that what we're talking about here is effectively changing evolution."***[41]

With its capability to harness power from nature, synthetic biology has the potential to open up a new era of pharmaceutical discovery and development. For example:

- Merck's Sitagliptin (Januvia), the world's 74th-most-prescribed drug, is produced using synthetic biology techniques because its key constituent-stereospecific amine is difficult to manufacture through solely chemical methods.[42,43]
- DNA-based and RNA-based vaccines are among the most impactful applications of synthetic biology in mainstream adoption. During the pandemic, clinicians could administer the first dose of the first COVID-19 vaccine candidate in a first-in-human trial just 66 days after the viral genome was released.[44]
- Synthetic biologists have gone beyond simply designing materials; they are now constructing intricate systems by "wiring" genetic parts into

"Nature is brilliant at solving technical problems. Our role is to recognize nature's solution and adapt it to our needs. Synthetic biology [means] genes can be reconfigured … in living organisms. … Future innovations will be an amalgamation of these biological tools with physics and engineering"

SUSAN HOCKFIELD
Professor of Neuroscience and President Emerita at the Massachusetts Institute of Technology (MIT)

circuits, akin to building electronic circuits. This allows for the creation of such innovative solutions as biomedical sensors that detect disease-relevant metabolites in the blood and trigger the production of therapeutic compounds.[45]

- Synthetic biology allows use of bacteria as a micro-machine for such tasks as delivering pharmaceutical molecules or proteins and transfecting nucleic acids into host cells.[46]

Technologies such as AI can turbocharge synthetic biology through applications in areas such as protein engineering, gene sequence optimization and strain engineering, by analyzing metabolic pathways, modelling cellular processes, and automating and optimizing experiment design. Seattle-based startup, Arzeda, uses generative AI to design enzymes and protein sequences.[47]

Amy Webb (CEO of the Future Today Institute and Professor of Strategic Foresight at New York University Stern School of Business) and Andrew Hessel (co-founder of Humane Genomics Inc) while speaking to us mentions, ***"Progress in artificial intelligence has provided a significant boost to the field, as the better AI becomes, the more biological applications can be tested and realized. As software design tools become more powerful and DNA print and assembly technologies advance, developers will be able to work on more and more complex biological creations. One important example: we will soon be able to write any virus genome from scratch."***[48]

The rise of cloud and distributed computing also allow processing of larger datasets – aiding scientists to perform genetic and DNA sequencing at more rapid pace.

Synthetic biology demands next-gen labs that focus on rapid development, seamless multi-disciplinary fusion, automation of complex workflows with high levels of accuracy and repeatability, and use of emerging technologies.

4. OPTIMIZE YOUR PROCESSES AND WORKFLOWS

Ensure efficient operational continuity through harmonized, automated, and integrated processes

Most labs struggle with disparate work processes and systems. **Process harmonization** enables the R&D set-up to unlock synergies from cross-lab processes and insights and allows pharma organizations to operate as truly global set-ups. Figure 17 shows the heightened focus of leaders on automation and process harmonization, though there is clear scope to take automation to the next level through remotely managed and monitored labs.

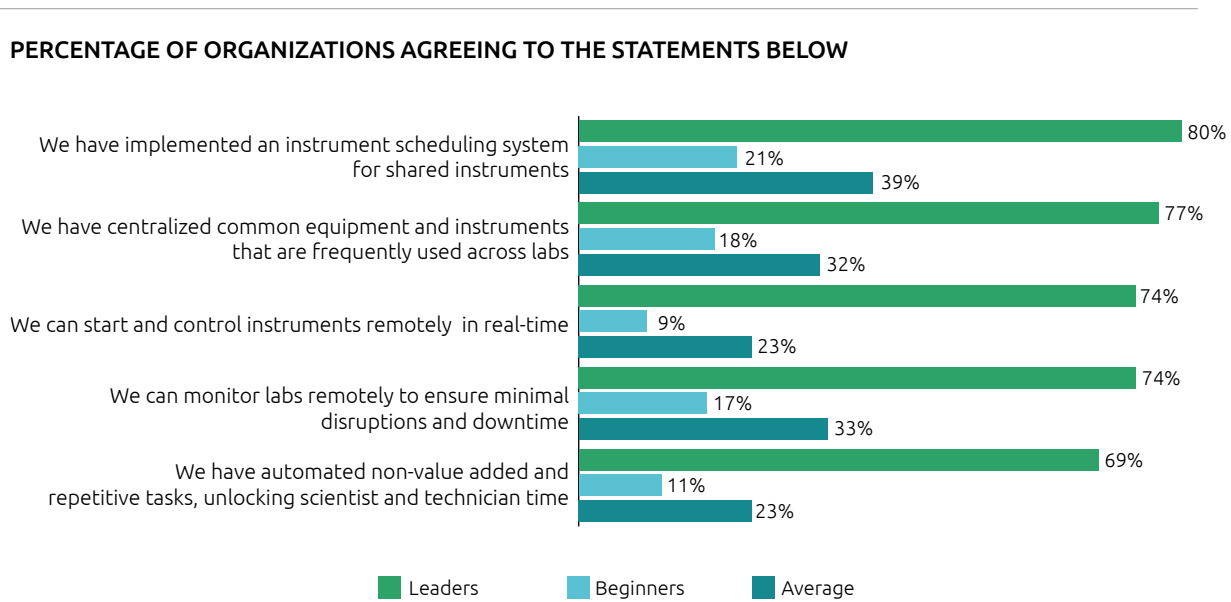
As the concept of **"shared labs"** becomes prevalent, optimizing activities like inventory management, instrument scheduling, preventive maintenance, and process harmonization also increase in significance. Giulia Rancati, Market Solutions lead for R&D says, *"We're enhancing resource control and investment strategies, especially as we adopt a shared lab concept. Data, including power consumption, equipment logs, and calendar bookings, contain insights into instrument utilization. Shared labs require insights into instrument usage to guide decisions on procurement, whether to buy, rent, or lease. We also optimize maintenance and placement based on usage patterns. Our focus is enabling data-driven decisions on CapEx, OpEx, and scientific workflows."*[49]

According to our research 80% of leaders have implemented an instrument scheduling system for shared instruments.

Process automation is also critical to remove process friction, generate efficiencies, and reduce effort and errors. Automation means experiments can be started, stopped, and monitored remotely, thus saving time and avoiding exposing lab staff to unsafe working conditions. An Associate Director at a large pharma adds, *"Remote management [and automation] can have a role to play in making the labs safer and sustainable for scientists and technicians by minimizing the exposure to hazardous substances and processes."*

The use of robotics also increases the consistency and accuracy of lab operations and a lab's ability to handle hazardous materials or maintain sterile conditions. Automated process and quality controls, robotics, in-process testing, and parametric release also enables GLP, GMP, and regulatory compliance.

FIGURE 17.
Leaders harmonize and automate lab processes to a greater extent



Source: Capgemini Next-Gen Pharma Lab Survey, October 2023, N=702 respondents from pharma and biopharma labs, N=235 pharma and biopharma organizations, N=35 leader organizations, N=141 beginner organizations.

Another means of achieving a continuous, repeatable workflow is through the use of l**ab-on-a-chip[50] and microfluidic systems[51]** to miniaturize and automate lab processes. These technologies allow organizations to reduce sample and reagent volumes, enable high-throughput screening, shorten analysis time, reduce cost, and create a smaller footprint.

However, islands of automation are not the complete solution. Inconsistent interfaces and varying data requirements between different tools make it hard for the scientific community to use and maintain the associated technologies. Creating an **integrated system** that combines the entire spectrum of tools for generating molecules, making predictions, and designing experiments empowers researchers to combine their scientific expertise with AI techniques without needing deep technical knowledge of the system itself. Paramahamsa Maturu, Associate Director, Clinical Trials, Bristol Myers Squibb says, ***"Once you put the tissue in the instrument, after few hours, without any manual intervention, you should receive the slide pictures and magnifications, along with preliminary analysis ready on your own computer."*** This level of integration reflects the expectations of most interview respondents regarding next-gen labs.

Leverage partnerships to offload certain activities, and capitalize on the "lab-as-a-service" model

Our survey shows that leaders have a heightened focus on core competencies and offload many non-core or non-competitive core processes to partners. We note that 89% of leaders take this approach. Collaborating with strategic partners frees up bandwidth for core scientific work and brings in the necessary expertise and agility for certain core operations. For example, analytics is currently a strategic capability for labs, but the existing skillset does not allow for leveraging its full potential. Bringing in external expertise in analytics and its enabling pillars such as data management, cloud, and cyber security, can be a game changer in accelerating and reducing the cost of discovery. In our research, "lab-as-a-service" model is already being explored by 38% of organizations, while 55% plan to forge future partnerships around this.

5. COLLABORATE EXTERNALLY AND INTERNALLY

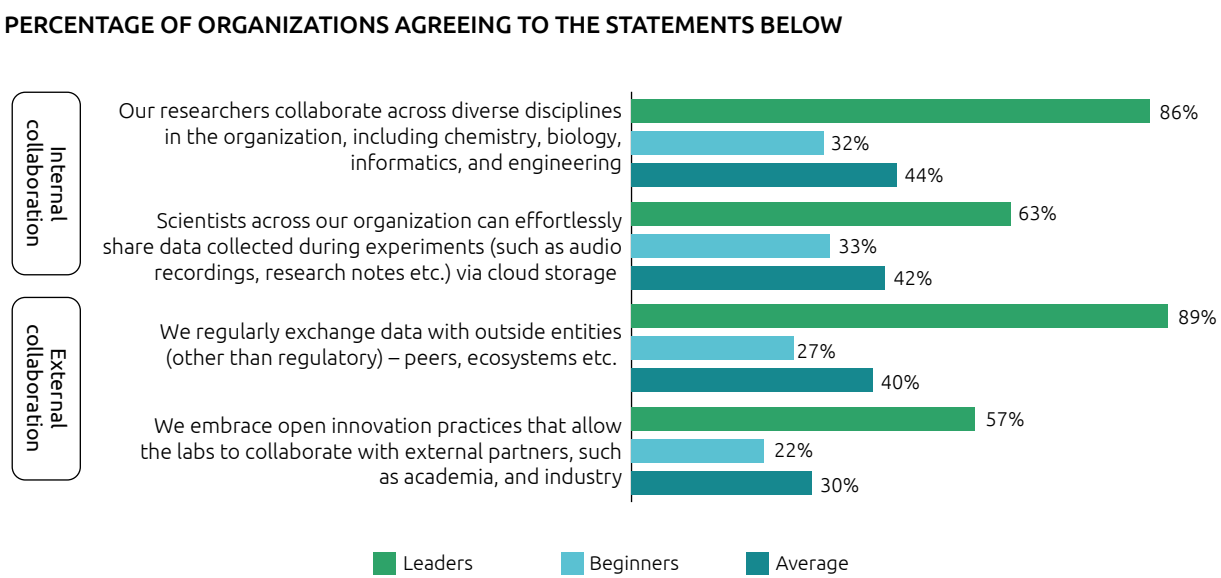
The scientific work of pharma is becoming more widely distributed geographically and organizationally. Next-gen labs demand and enable greater collaboration within and outside the organization. Monika Lessi, VP, Head of Corporate Innovation and R&D, Bayer elaborates, *"A lab is where we experiment with new ideas to find solutions to new challenges. It's about breaking down the walls of the physical laboratory but also the walls between disciplines."* [52]

"Once you put the tissue in the instrument, after few hours, without any manual intervention, you should receive the slide pictures and magnifications, along with preliminary analysis ready on your own computer."

PARAMAHAMSA MATURU
Associate Director, Clinical Trials,
Bristol Myers Squibb

FIGURE 18.

The modern lab promotes multidisciplinary discovery and open innovation



Source: Capgemini Next-Gen Pharma Lab Survey, October 2023, N=702 respondents from pharma and biopharma labs, N=235 pharma and biopharma organizations, N=35 leader organizations, N=141 beginner organizations.

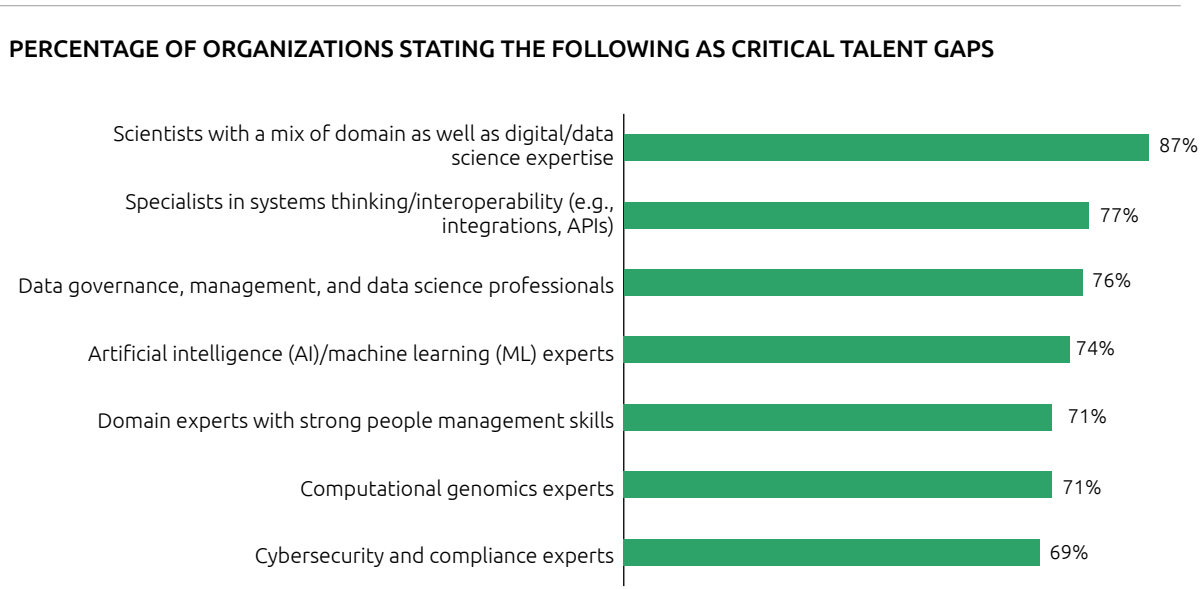
Organizations that are leaders in digitalization are ahead on internal collaboration too (see figure 18). Advanced communication technologies, connected processes, harmonized data, and having a "single source of truth" play a key role in strengthening collaboration and facilitating open innovation. Fostering the right culture and mindset is key. And the mindset of researchers reluctant to adopt digital lab platform (DLP) tools such as ELNs and LIMS is an obstacle to progress in this area. To overcome this, Bayer has put in place a dedicated team of biotech engineers to work closely with lab users to put their needs at the forefront of a custom-built digital platform.[53] Dr Mark Goulding, Director and Business Project Lead – Performance Materials and Early Research, Merck says, ***"Moving from a paper-based workflow to a digital system is a profound cultural change with a potential major impact on the people in our labs."***[54]

The next-gen pharma lab requires an interconnected ecosystem of industry players to connect data, insights, platforms, and instruments to support acceleration of drug discovery and development.

6. STRENGTHEN YOUR APPROACH TOWARDS NEXT-GEN LAB SKILLS

There is a growing need for multidisciplinary experts with digital expertise in next-gen labs. Many scientists lack the quantitative and computational expertise to analyze the massive amount of data labs generate. Figure 19 highlights talent gaps within critical technology areas in labs today:

FIGURE 19.
The skills gap between traditional scientific methods and the data-intensive nature of digital science is widening



Source: Capgemini Next-Gen Pharma Lab Survey, October 2023, N=702 respondents from pharma and biopharma labs, N=235 pharma and biopharma organizations.

Pharma organizations need to plug this skills gap by hiring, upskilling, reskilling, and partnering. Creating an appeal to technology talent is also crucial, as this highly skilled group frequently experiences "cultural fit" challenges within traditional organizations. They generally require autonomy, opportunities to grow, insights into business metrics, and support in enhancing their skills. In our research, 91% of leader (versus 43% of beginner) organizations say that their culture appeals to digital talent.

A scientist and people lead at a leading global pharmaceutical major says, ***"Bridging the science-data gap is easier if you train someone who is already familiar with our lab's data generation and evaluation procedures and is informed about the bigger scientific context within which the data will be utilized."***

65%

of pharma organizations agree that a next-gen lab will reduce the consumption of natural resources and energy associated with wet experimentation

7. EMBED SUSTAINABILITY IN PRODUCTS, PROCESSES, AND OPERATIONS

In 2019, the total climate footprint of healthcare (hospitals and laboratories) was 4.4% of total global emissions, or two gigatons of CO2-equivalent – the same annual greenhouse gas emissions as 514 coal-fired power plants.[55] Laboratories typically consume 5 to 10 times more energy per square foot than office buildings.[56]

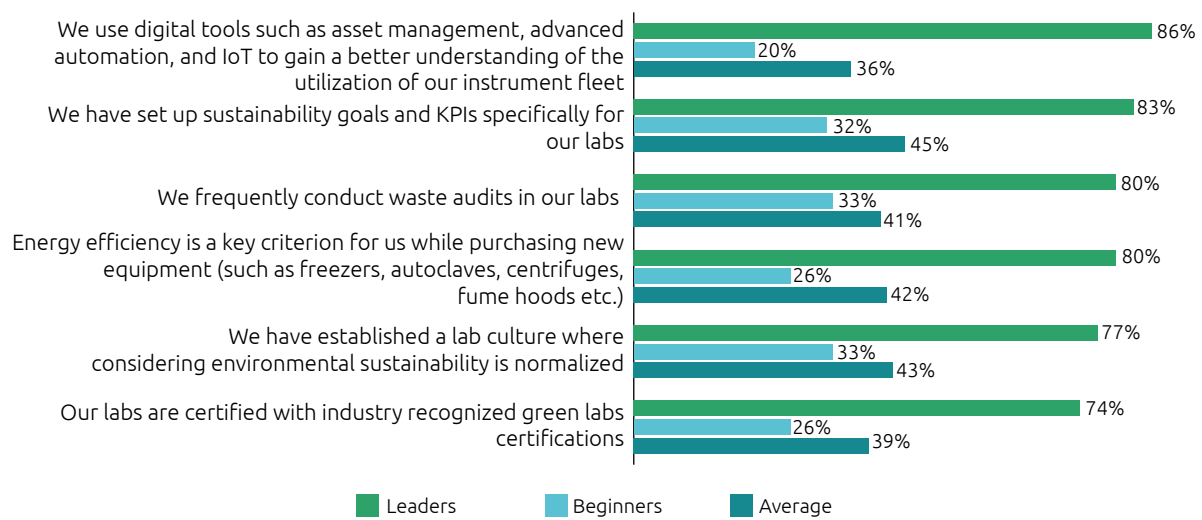
Most organizations visualize their next-gen labs as sustainable – 65% of organizations surveyed agree that a next-gen lab will reduce the consumption of natural resources and energy associated with wet experimentation. Over half (51%) also believe that a sustainable next-gen lab will help them meet their net zero targets more quickly. Moreover, 80% of leaders say they have already witnessed cost savings (through reduced resource consumption, lower energy bills and waste disposal costs, and fewer costs associated with regulatory compliance, etc.,) by focusing on sustainability initiatives in labs.

Many leading pharma organizations are moving towards more sustainable labs by focusing on **"green chemistry"** principles. As defined by the United States Environmental Protection Agency (EPA), green chemistry is a framework based on 12 principles that encourage chemists to use greener chemicals, processes, or products to maximize the efficiency of experiments, and to find new ways to reduce waste, conserve energy, and eliminate the use of hazardous substances. For example:

- AstraZeneca in partnership with Leonori Group at the University of Manchester has explored the use of light as a clean, environmentally friendly reagent to develop two novel photocatalytic reactions to make anilines – a common synthetic building-block widely used in drug design.[57]
- Scientists at Pfizer have identified alternatives to rare and precious metals, such as palladium, platinum, and iridium, to aid in the formation of chemical bonds during pharmaceutical manufacturing. The alternatives, such as nickel, produce less waste and are more readily available and cheaper.[58]

FIGURE 20.
Leaders follow sustainability practices in lab processes, operations, equipment, and technology

PERCENTAGE OF ORGANIZATIONS AGREEING TO THE STATEMENTS



Source: Capgemini Next-Gen Pharma Lab Survey, October 2023, N=702 respondents from pharma and biopharma labs, N=235 pharma and biopharma organizations, N=35 leader organizations, N=141 beginner organizations.

Organizations can increase the sustainability of their work in quality labs by reducing the number of repeat tests and saving resources by **increasing automation of standard QC tests**. Our research indicates that 60% of respondents from quality labs are already doing this.

In addition, all pharma organizations should conduct regular **impact assessments** (e.g., on carbon emissions, pollution, waste, loss of biodiversity, soil erosion/degradation, etc.,) for active pharma ingredients (APIs) and finished products throughout their lifecycle. Currently, only 32% of respondents from process development labs say they measure this.

Conclusion

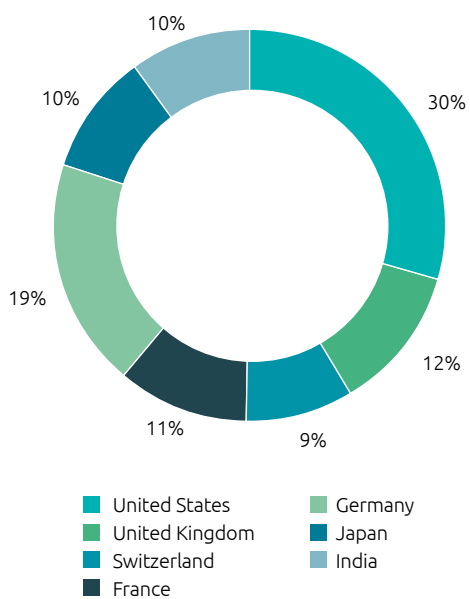
Labs play an integral role in the “molecule-to-medicine” value chain, directly impacting pharma's most critical goals: accelerating breakthroughs, optimizing costs, and improving drug approval rates. Foundational data principles, such as FAIR, and transformative technologies, such as automation, robotics, connectivity, and cloud computing, are reshaping lab processes and operations across R&D, quality, and process development labs. The convergence of emerging technologies, including AI/ML, generative AI, and synthetic biology, is opening a new interface for scientific exploration and drug discovery, creating next-gen future-ready labs.

The key to unlocking the full potential of the next-gen lab lies, not just in the technology itself, but in human-centric design, putting scientists at the center of this transformation. The new paradigm of a next-gen lab will be built on the cornerstones of innovation, collaboration, flexibility, sustainability, transparency, and responsible development. With so much on the agenda, labs need to design a robust strategy and roadmap, that clearly prioritizes the technologies, processes and practices needed to realize a future-ready lab.

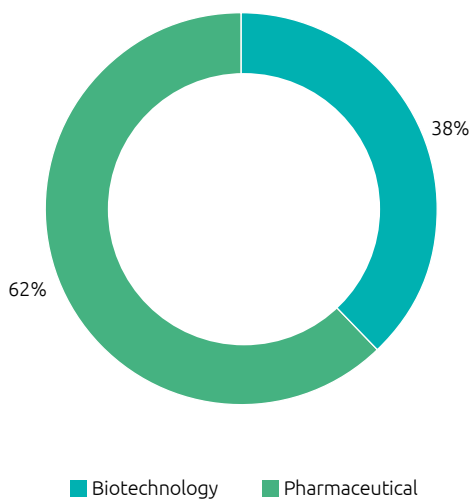
Research methodology

To understand the current digital maturity and future expectations of pharma labs, we conducted a global quantitative survey in October 2023 across seven different countries. We targeted 702 respondents across 235 organizations, with 85% of organizations having an annual revenue of more than $1 billion. Executives surveyed were director level and above. The distribution of executives and their organizations is provided in the following figures.

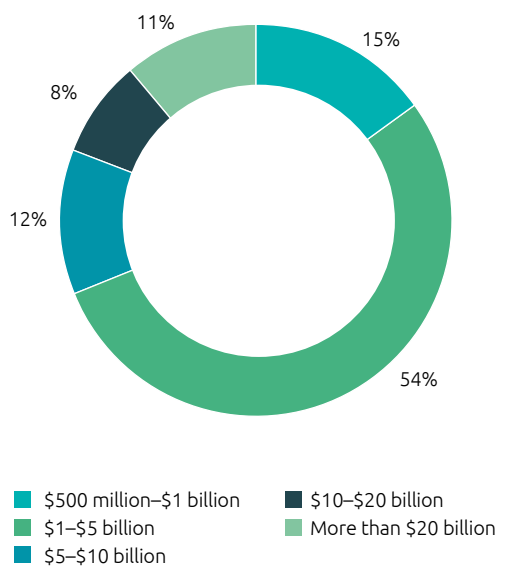
ORGANIZATIONS BY HEADQUARTERS



ORGANIZATIONS BY SECTOR



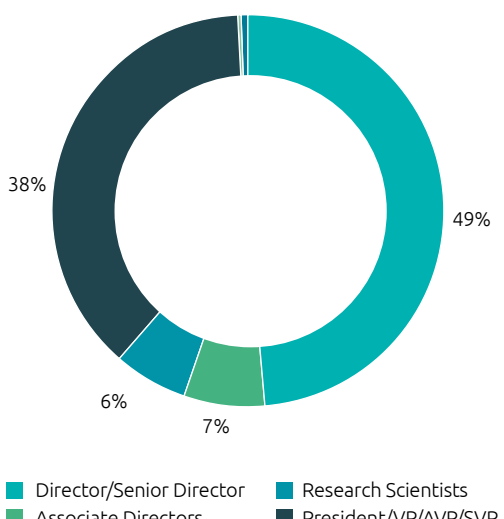
ORGANIZATIONS BY ANNUAL REVENUE



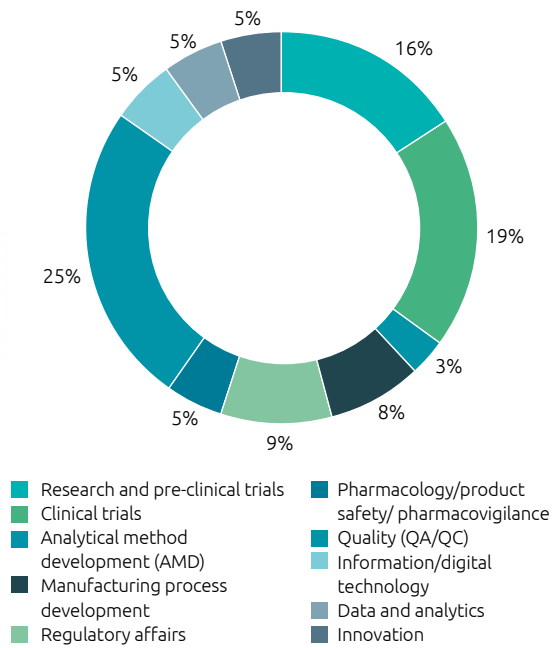
Source: Capgemini Next-Gen Pharma Lab Survey, October 2023, N=702 respondents from pharma and biopharma labs, N=235 pharma and biopharma organizations.

The study findings reflect the views of the respondents to our online questionnaire for this research and are aimed at providing directional guidance. Please contact one of the Capgemini experts listed at the end of the report to discuss specific implications.

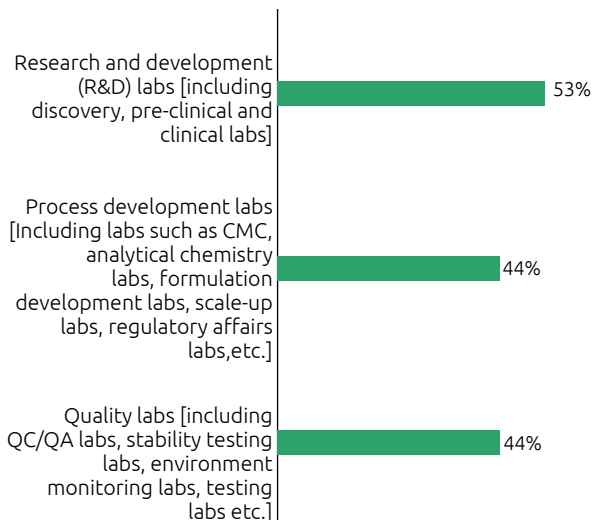
RESPONDENTS BY DESIGNATION



RESPONDENTS BY DEPARTMENT/ FUNCTION



RESPONDENTS BASED ON THE LABS THEY ARE ASSOCIATED WITH



Source: Capgemini Next-Gen Pharma Lab Survey, October 2023, N=702 respondents from 235 pharma and biopharma labs, N=371 respondents associated with R&D labs, N=311 respondents associated with process development labs, N=309 respondents associated with quality labs in pharma and biopharma organizations.

Appendix

PARAMETERS CONSIDERED FOR DEVELOPING THE MATURITY FRAMEWORK:

CATEGORY	THEME	STATEMENT
FOUNDATIONS OF LAB TRANSFORMATION	Data	• We are able to track the data quality dimensions of completeness, consistency, validity, and accuracy for all of our data. • We can source, clean, prepare, integrate, and provide access to data at the speed that the labs need.
	Lab architecture	• We have developed a custom-made blueprint of lab reference architecture, tools, and methods.
	Emerging technologies	• We are using AI/ML technologies in our labs. • We are using bioengineering to design novel drug delivery systems, create personalized medicine approaches, and develop innovative diagnostic tools.
	Cloud & connectivity	• Cloud and robotics technologies are already enabling remote and virtual experimentation in our labs.
	Automation	• Physical and digital robots automate lab processes (such as sample preparation, pipetting, standard analytical testing etc.)
	Cybersecurity	• We regularly conduct vulnerability assessments on all lab software, equipment, and connected devices.

(Continue on the next page...)

CATEGORY	THEME	STATEMENT
ENABLERS OF LAB TRANSFORMATION	Strategy & investments	• Our labs have a strategic long-term roadmap with established priorities for managing modernization and transformation initiatives. • Our senior leadership is fully committed to appropriate investments in resources and technology to make our labs data-powered.
	Organizational structure	• The way our labs are currently organized is conducive to efficient utilization of resources.
	Processes & methods	• We have harmonized our lab processes to the extent possible. • We adopt green chemistry principles to improve environmental sustainability
	Competency & skills	• We upskill our scientists, researchers, etc., on the right set of soft skills (e.g., being open to learn and unlearn) to help them to adapt to the new ways of working.
	Collaboration/ Knowledge Sharing	• We have set up cross-functional agile teams, including lab/project lead, lab technician, as well as data scientists.
	Digital culture	• People naturally think of digital technologies when we consider ways to improve our labs

References

1. In this research, we use “pharma” to describe both pharmaceutical (producing chemical or small-molecule drugs) and biopharmaceutical (producing biologics or large-molecule drugs) organizations.
2. NLM,” Estimated research and development investment needed to bring a new medicine to market, 2009-2018,” March 3, 2020.
3. Congressional Budget Office, “Research and development in the pharmaceutical industry,” April 2021.
4. Pharma IQ, “Highlights from Future Lab Informatics 2022,” November 22, 2022.
5. Cell therapy is the prevention or treatment of human disease by the administration of cells that have been selected, multiplied, and pharmacologically treated or altered outside the body; Gene therapy is a technique that modifies a person’s genes to treat or cure disease. Source: ScienceDirect; US Food and Drug Administration.
6. Biopharma Dive, “Novo Nordisk parent backs cell therapy manufacturing facility,” September 21, 2023.
7. AstraZeneca, “Digitising our labs and unleashing the power of data and AI,” September 26, 2022.
8. Genetic Engineering & Biotechnology News, “Biomanufacturers take a two-pronged approach to digitalization,” August 14, 2023.
9. Forrester, “The lab of the future is here: It is just not evenly distributed,” January 2021.
10. Roche, “Integrated Core Lab: The lab of the future,” accessed November 28, 2023.
11. AMG World, Smart Labs, Automation & Technology Europe Virtual Summit, December 2021.
12. Multiomics analysis is an approach where datasets of different omics groups including genome, proteome, epigenome, and microbiome are combined during analysis.
13. National Human Genome Research Institute, “Factsheet,” April 5, 2022.
14. Pharma IQ, “Highlights from Future Lab Informatics 2022,” November 22, 2022.
15. Capgemini Research Institute analysis; Financial data of the organizations surveyed for the research.
16. CNBC, “Google Cloud launches A.I.-powered tools to accelerate drug discovery, precision medicine,” May 16, 2023.
17. GSK, “Digital twin: using advanced technology to accelerate vaccine development,” May 30, 2022.
18. World Pharma Today, “Avoiding human error in pharmaceutical manufacturing,” accessed November 29, 2023.
19. Globela Pharma, “Role of Research and Development in Modern Pharmaceutical Industry.”
20. National Library of Medicine, “Why 90% of clinical drug development fails and how to improve it?” July 2022.
21. PubMed/AAPS, “Why drugs fail in late stages of development: case study analyses from the last decade and recommendations,” March 13, 2018.
22. Novartis, “Novartis in Society Integrated Report 2021,” accessed November 29, 2023.
23. Synthetic biology is an interdisciplinary field combining biology, engineering, computer science, and biotechnology.
24. Indian Chemical News, “Digitalization is the key to best lab performance: Experts,” June 9, 2021.
25. Nature.com, “Pharma labs are getting AI-ready to stay ahead of the curve,” accessed December 11, 2023.
26. AWS, “Moderna on AWS,” 2021.
27. Pfizer, “Applying the latest digital technology to optimize COVID-19 vaccine efforts,” 2021.
28. GSK, “Digital twin: Using advanced technology to accelerate vaccine development,” May 30,2022.
29. Pharma IQ, “What is the digital lab?,” April 22, 2021.

30. USGS, “Value of Data Management,” accessed December 11, 2023.

31. Lab of the Future Europe, 2023, “Interview on Digital Transformation,” September 2023.

32. Capgemini, “How to go FAIR: The key business decisions to be made,” July 4, 2022.

33. Capgemini, “The FAIR data principles: The key to unlocking the value of your R&D data,” July 7, 2022.

34. Capgemini Research Institute, “The data-powered enterprise,” November 2020.

35. Sanofi, “Press Release: Sanofi “all in” on artificial intelligence and data science to speed breakthroughs for patients,” June 13, 2023.

36. Medriva, “Leveraging AI for Early Detection of Liver Disease: A Significant Breakthrough by insitro,” January 8, 2024.

37. Outsourcing Pharma, “Blending human knowhow, Artificial intelligence aids drug discovery,” call August 2,2022.

38. Forbes, “This company is using generative AI to design new antibodies,” January 10, 2023.

39. Nvidia,” Quicker Cures: How Insilico Medicine uses generative AI to accelerate drug discovery,” June 27, 2023.

40. National Human Genome Research Institute, “Synthetic biology,” August 14, 2019.

41. Capgemini Research Institute, “Conversations for Tomorrow, Edition 5,” August 2022.

42. Nature, “Synthetic biology 2020–2030: Six commercially-available products that are changing our world,” December 11, 2020.

43. ClinCalc, “The Top 300 of 2020,” 2021.

44. Nature, “Synthetic biology speeds vaccine development,” September 20, 2020.

45. Nature, “Living factories of the future,” March 16, 2016.

46. Science Direct, “Engineered bacteria as drug delivery vehicles: Principles and prospects,” September 2022.

47. Wall Street Journal, “AI accelerates ability to program biology like software,” September 19, 2023.

48. An excerpt from “The genesis machine: Our quest to rewrite life in the age of synthetic biology,” by Amy Webb and Andrew Hessel; Capgemini Research Institute, Capgemini Research Institute, “Conversations for Tomorrow, Edition 5,” August 2022.

49. Lab of the Future - Europe, “Giulia Rancati Interview,” 2023.

50. A lab-on-a-chip is a miniaturized device that offers the solution of conducting multiple-sample biological and biochemical analyses in a single platform.

51. Microfluidics is both the science and application that manipulates small volumes of fluids (picoliters) within microminiaturized channels or devices. Microfluidic systems serve as the foundation for lab-on-a-chip devices, providing the means to precisely control and manipulate fluids on a small scale.

52. Cambridge Independent, “Future labs will 'break the walls of your mind,” November 22, 2019.

53. Nature Research, “Pharma labs are getting AI-ready to stay ahead of the curve” accessed December 11, 2023.

54. Pharma IQ,” What is the digital lab,” April 22, 2021.

55. My Green Lab, “Strategic plan 2021–2023,” accessed December 11, 2023.

56. NREL, “Laboratories for the 21st Century: An introduction to low-energy design,” accessed December 11, 2023.

57. AstraZeneca, “Striving for sustainable drug discovery using Green Chemistry,” May 27, 2022.

58. Pfizer, “Green Chemistry: A more sustainable approach to medicine development,” November 23, 2022.

Key contributors

Thorsten Rall
Executive Vice President, Group Life Sciences Global Industry Lead, Capgemini
thorsten.rall@capgemini.com

Brian Eden
Vice President, Group Life Sciences Technical Operations Lead, Capgemini
brian.eden@capgemini.com

Raghunandan Hanumanthu
Vice President, Head of Life Sciences Industry Platform, Capgemini
raghunandan.hanumanthu@capgemini.com

Matthew Thompson
Managing Consultant, Life Sciences, Capgemini Invent
matthew.thompson@capgemini.com

Rayan Hashim
Pre-sales Manager, Life Sciences, Capgemini Engineering
rayan.hashim@capgemini.com

Amit Kakatkar
Director, Life Sciences, India Industry Platform, Capgemini
amit.kakatkar@capgemini.com

Justin Melnick
R&D Transformation Partner, Life Sciences, Capgemini Engineering
justin.melnick@capgemini.com

Jerome Buvat
Head of the Capgemini Research Institute
jerome.buvat@capgemini.com

Subrahmanyam KVJ
Senior Director, Capgemini Research Institute
subrahmanyam.kvj@capgemini.com

Nancy Manchanda
Program Manager, Capgemini Research Institute
nancy.manchanda@capgemini.com

Tvishee Kumar
Senior Manager, Capgemini Research Institute
tvishee.kumar@capgemini.com

The key contributors would like to thank Marisa Slatter and Siva S Chidambaram from Capgemini Research Institute for their contribution to this research.

The key contributors would also like to thank Sutharson Veeravalli, Nirlipta Panda, Sumit Mehta, Jignesh Khakhar, Manuel Joaquim Garrido, Harsh Madan, Karthik C, Ravindra Sane, Gabriel Airiau, Arijit Chatterjee, Harsh Vardhan Singh, Justin Calfo, Suday Karkera, Sam Genway, Mark Roberts, Srinivas Sarangapurkar, Bruce Fairley, Angela Liu, Xavier Henrion, Anushri Chauhan, Frédéric Burger, Déborah Pome, Igal Slama, Gert-jan Schoppert, Punam Chavan, Ashwani Kumar, and Jaydeep Neogi for their contribution to the report.

About the Capgemini Research Institute

The Capgemini Research Institute is Capgemini's in-house think tank on all things digital. The Institute publishes research on the impact of digital technologies on large traditional businesses. The team draws on the worldwide network of Capgemini experts and works closely with academic and technology partners. The Institute has dedicated research centers in India, Singapore, the United Kingdom, and the United States. It was recently ranked number one in the world for the quality of its research by independent analysts.

Visit us at www.capgemini.com/researchinstitute/

For more information, please contact:

THORSTEN RALL
Executive Vice President
Group Life Sciences Global Industry Lead Capgemini
thorsten.rall@capgemini.com

BRIAN EDEN
Vice President
Group Life Sciences Technical Operations Lead Capgemini
brian.eden@capgemini.com

JUSTIN MELNICK
R&D Transformation Partner, Life Sciences Capgemini Engineering
justin.melnick@capgemini.com

MATTHEW THOMPSON
Managing Consultant, Life Sciences Capgemini Invent
matthew.thompson@capgemini.com

AMIT KAKATKAR
Director, Life Sciences, India Industry Platform Capgemini
amit.kakatkar@capgemini.com

RAYAN HASHIM
Pre-sales Manager, Life Sciences Capgemini Engineering
rayan.hashim@capgemini.com

NEXT-GEN LABORATORIES SOLUTIONS

To accelerate drug discovery, increase approval rates and reduce cycle times

In the context of modern scientific research, the efficiency and innovation of your laboratory are crucial. Recognizing this, we offer a specialized approach to transform your current laboratory environment into a more effective and future-ready facility.

Our method involves a thorough understanding of your laboratory's unique challenges and goals. This insight forms the basis of a customized strategy, incorporating advanced technology and optimized processes to enhance your current operations.

Strategy, technology and service

Our Next-Gen Laboratories Solutions offer is not about wiping the slate clean. It's a process that aligns the strategies of your organization with the needs of your IT professionals and researchers. Together, we'll look at the big picture, including your organization's strategic goals, your research needs today and in the future, budgets, new technologies and more. We'll consider your entire laboratory network to help prioritize each lab's goals, aligning their work with each other, and with your overarching strategy. And we'll go into the details, down to the ergonomics of your lab setup.

Here's some of what you can expect:

- An integrated, living blueprint with a tailored set of tools that enable your labs to be continually redesigned and upgraded;
- A wide range of technology and process solutions that connect workflows, optimize them, and accelerate scaling;
- NextGen analytics, data science and reporting capabilities that speed up insights;
- A service ecosystem that offloads select processes to partners, letting scientists focus on what they do best.

The lab of the future won't appear out of thin air. It will be the result of years of your experience, our capabilities, and a clear focus on strategic thinking.

Our Next-Gen Laboratories Solutions bring your capabilities up to the limit of what's technologically possible today. And this in turn brings your patients access to quality, safe and state-of-the-art treatment options, advancing human health one step further.

To explore how our Next-Gen Laboratories Solutions offer can assist in evolving your laboratory's capabilities, we invite you to reach out for a detailed discussion. Together, we can set a course towards a more efficient and innovative future for your research endeavors.

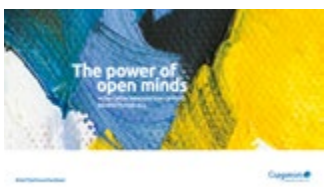
NOTES

NOTES

NOTES

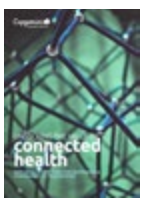
More Capgemini Research Institute publications

Harnessing the value of generative AI: Top use cases across industries



The power of open minds: How open innovation offers benefits for all

Conversations for tomorrow #5: Breathe (in)novation



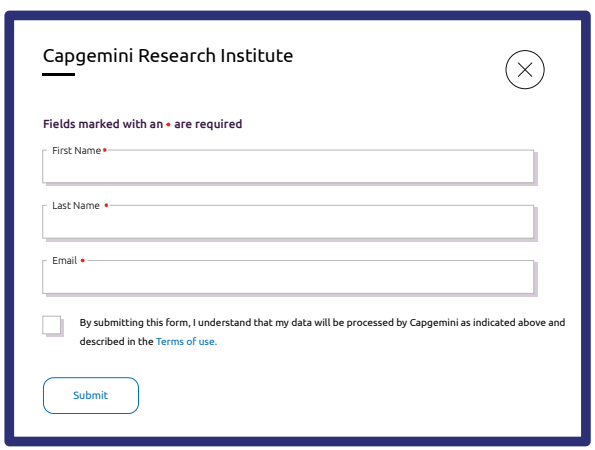
Unlocking the value in connected health

The data-powered enterprise: Why organizations must strengthen their data mastery

Digital mastery: How organizations have progressed in their digital transformations over the past two years

Subscribe to latest research from the Capgemini Research Institute

Receive copies of our reports by scanning the QR code or visiting
https://www.capgemini.com/capgemini-research-institute-subscription/



About Capgemini

Capgemini is a global leader in partnering with companies to transform and manage their business by harnessing the power of technology. The Group is guided every day by its purpose of unleashing human energy through technology for an inclusive and sustainable future. It is a responsible and diverse organization of nearly 350,000 team members in more than 50 countries. With its strong 55-year heritage and deep industry expertise, Capgemini is trusted by its clients to address the entire breadth of their business needs, from strategy and design to operations, fueled by the fast evolving and innovative world of cloud, data, AI, connectivity, software, digital engineering, and platforms. The Group reported in 2022 global revenues of €22 billion.

Get the Future You Want | **www.capgemini.com**