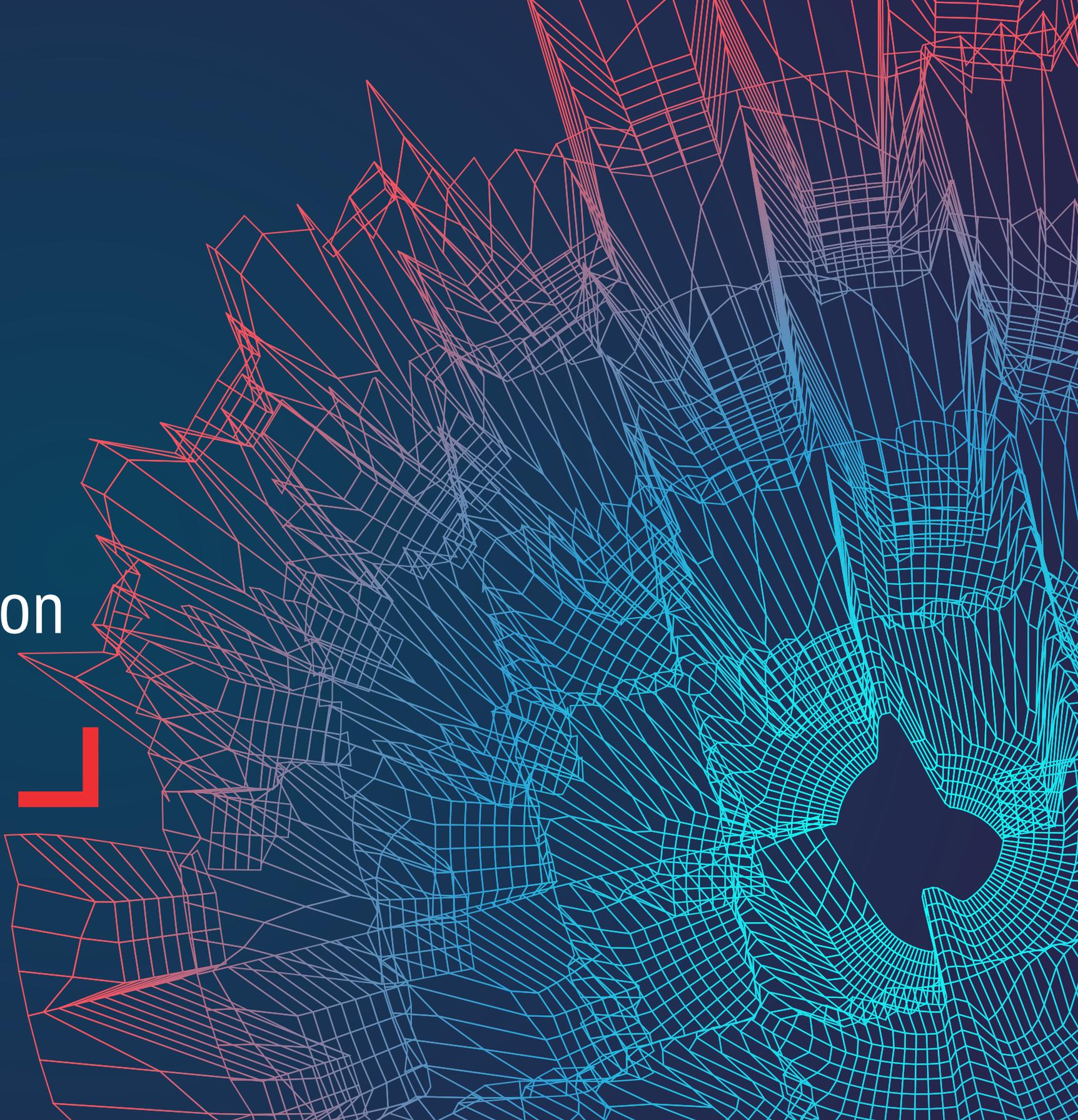


**Baker
McKenzie.**

**Life Sciences Business
Evolution Series**
How Digital Transformation
and Data Are Shaping
Business Models



Foreword

Intertwined Value Chains Are Reshaping Life Sciences Business Models

Traditionally, the life sciences industry has grown through innovation, acquisition and geographical expansion. Now, life sciences companies must evolve their business models to address market saturation, more complex global regulatory regimes in terms of compliance, law lag due to new innovative and digital products entering the market, R&D cost inflation and pressure on healthcare expenditures. A survey conducted by Baker McKenzie in collaboration with Informa Pharma Intelligence looked at how pharmaceutical, biotech, medical devices and medtech companies plan to leverage new and existing sources of growth over the next 10 years.

This first report of a three-part Life Sciences Business Evolution Series explores how important digitally-enabled strategies are in addressing changing patterns of demand and streamlining go-to-market approaches. For example, digital tools and platforms are helping companies transition from product-only offerings to product-service hybrids, oriented to patient mapping, pre-diagnostics solutions and enhanced treatment administration. These intertwined value chains will increasingly shape the life sciences industry of the future. The area of digital therapeutics also shows incredible promise for better patient care and outcomes through the enhanced use of real world evidence and advanced analytics.

Digital transformation continues to propel the reshaping of business models, with different emphases for the Americas, Europe and Asia Pacific, depending on the maturity of the market and interplay of life sciences companies and other healthcare organizations in the broader ecosystem. Globally, respondents noted that accelerated digitalization (31%), changing demand patterns (38%) and the need for rapid product/service development (34%) have shaped their businesses the most. These changes signal the evolution of interlinked value chains driven by digitalization efforts which, according to over 250 global respondents, are most evident in clinical (73%) and support (69%) functions.



Foreword (continued)

Data management and analytics are top of mind as life sciences businesses look to safely collect, use, store and monetize vast amounts of data — advanced analytics are critical to targeting and optimizing R&D and product/service launches. Our survey identified three key areas of focus:



Managing Data Volume Is Key

Digital monitoring has implications ranging from supply chain management to the transfer and monetization of data as well as symptom tracking, among others.

- Data analytics (56%), cloud technology (55%) and monitoring (55%) are the top three focus areas, currently.



Data Privacy & Compliance Could Curtail Data Monetization

The deluge of sensitive data is putting a focus on reducing risk in the storage, transfer and sharing of data, vis-à-vis global regimes.

- Respondents are focused on data management (53%) and data analytics/solutions (44%), with 57% of life sciences businesses considering the latter as a new revenue source.



Appetites Are Ripe for All Things Digital

Digitalization will accelerate the ability to provide better and more acute diagnoses, treatment and monitoring, as well as patient self-management.

- In two to five years, up to 70% of respondents will be pursuing digital therapeutics and AI as part of their digital transformation efforts.

Explore how digitalization is shaping life sciences business models, including current actions, risks and pertinent legal areas for businesses to navigate. Later installments of the series will explore other key facets related to corporate growth and the trajectory of therapeutic growth areas for life sciences businesses.



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*Trench Rossi Watanabe and Baker McKenzie have executed a strategic cooperation agreement for consulting on foreign law

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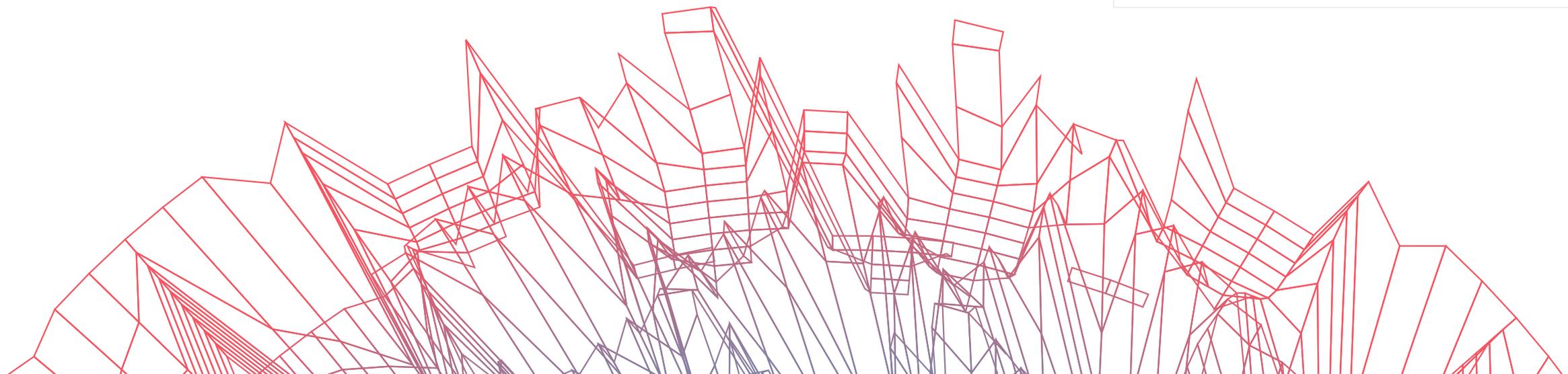


Methodology

All findings across three flagship reports in the Life Sciences Business Evolution Series are gleaned from a custom survey conducted by Baker McKenzie in collaboration with Pharma Intelligence in late 2021.

Over 250 life sciences respondents from North America, Latin America, Europe and Asia Pacific were consulted on their thoughts relating to the changing market conditions, challenges and opportunities affecting life sciences business models, growth patterns, funding and shifting operational dynamics.

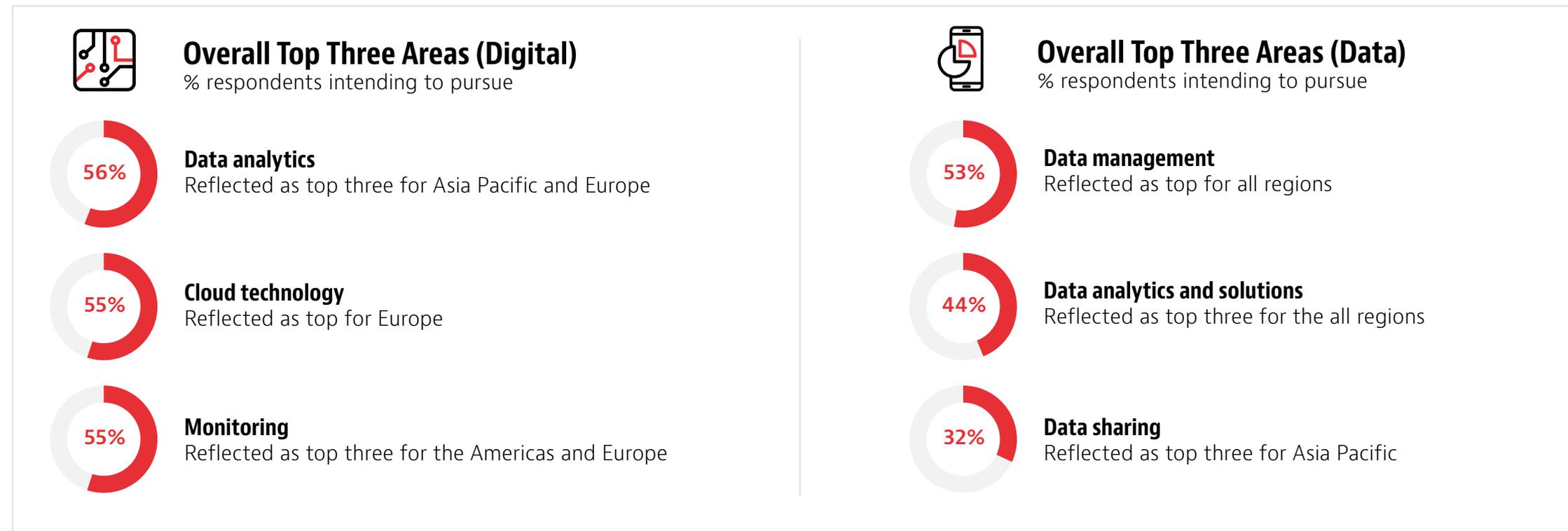
Respondents include executives C-suite, EVP/SVP, Head of, Director, Manager, General Counsel, Assistant General Counsel in various business functions including clinical operations, business development, IT, clinical research, strategic operations, quality, R&D, regulatory, commercialization, digital transformation, market access, medical affairs, operations, sustainability and legal.





1.1 Current Areas of Focus on Digitalization and Data

Data, cloud technology and monitoring dominate the current digital landscape, while issues of data management, data analytics and data sharing are top of mind globally, across all regions. However, digital growth strategies are set to shift in the next five to ten years.





1.1

Americas

The leading three areas of digital focus are monitoring (61%), apps (61%) and business support platforms (59%), illustrating the growing importance of virtual patient management to hard-pressed health systems.

Digital therapeutics and AI/automation were more significant over the five-to-ten year term. A strong focus on data management (53%) and analytics (48%) indicates that shifting data regulation and laws could be drawing businesses' attention to these areas.

Asia Pacific

Respondents are currently the most focused on data analytics (44%) and telehealth (43%), and current areas of data interest center mostly on data management (49%).

However, in five to ten years, more advanced modalities such as AI/automation (25%), apps (24%) and digital therapeutics (23%) were cited as areas of interest.

Europe

Respondents cite cloud technology (67%) and data analytics (66%) as key current digital growth strategies. Over the next five to ten years, preferences shift to telehealth/remote monitoring (16%), apps (15%) and AI/automation (14%). This suggests a long-term commitment to digital as a core component of more holistic product offerings.

Notably, data is already a key driver of current strategies in Europe, with 55% of respondents active in data management, 43% in analytics and solutions and one-third in data sharing.



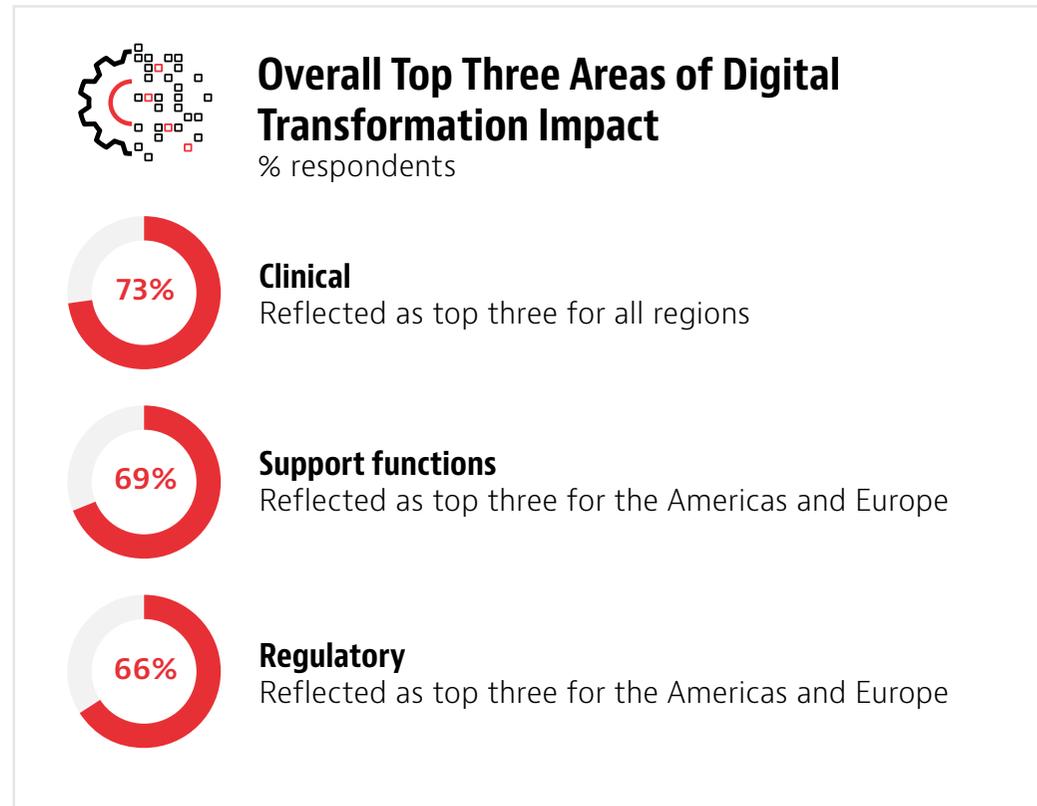
"It is often said that data is the new currency. Like currency, it is critically important that organizations use both appropriate and practical security measures for the use, storage and transfer of data. One thing organizations can do is to make sure they have an incident response plan in the event of data loss and actually test this plan to see if it meets the organization's needs."

Stephen Reynolds
Data & Technology Partner, Chicago



1.2 Impact of Digital Transformation

While respondents in the Americas and Europe are mostly aligned in their digital priorities, responses from Asia Pacific reveal the complexity of the life sciences landscape in terms of varied business priorities and the unique challenges in each region.



Asia Pacific Spotlight

Respondents cited that manufacturing (70%) was most impacted by digital transformation. This could be due to the fact that this region is home to large-scale producers of Active Pharmaceutical Ingredients (API) in addition to business delays and recovery and resilience efforts arising from the pandemic.

More than two-thirds of respondents in this region also say digital transformation efforts have affected commercialization, indicating the influence on go-to-market strategies, likely due to a higher concentration of sellers of finished products. Asia Pacific businesses may be slightly behind the curve in applying digitalization to core functions such as manufacturing and marketing, but nonetheless are determined to reap the benefits of new technologies.





1.2

Americas and Europe

Respondents from the Americas and Europe had similar experiences in terms of where digital transformation had the most impact. In Europe, respondents saw the most significant positive impact of digital transformation in clinical development (71%), where data generation, collection and analysis are crucial to pipeline yields. This was followed closely by support functions (70%) and regulatory/R&D (both 60%). In the latter, digitalization benefits extend from drug target identification to interactive devices and streamlined interfaces with regulatory agencies.

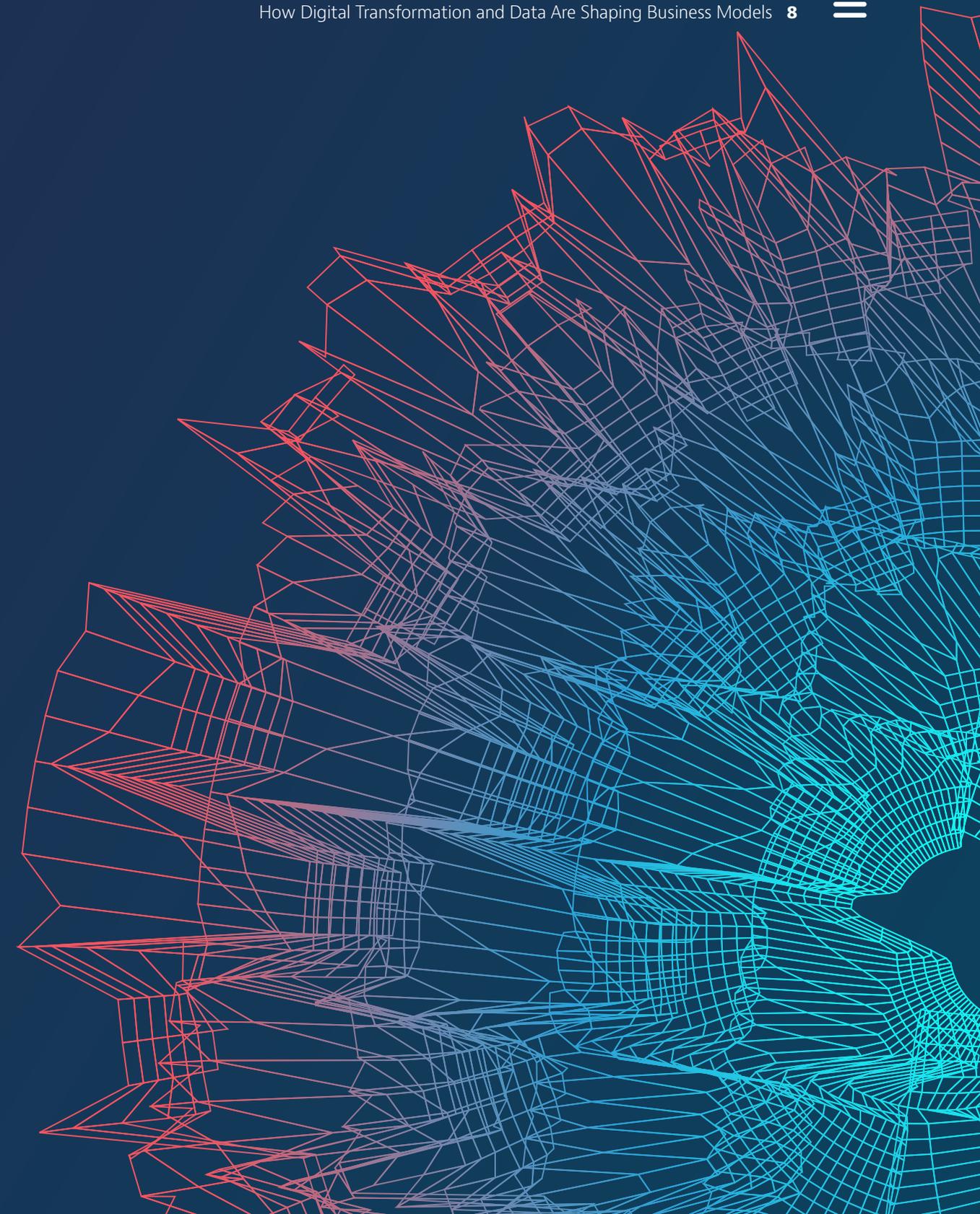
Respondents in the Americas placed more emphasis on regulatory (73%) than support functions (71%), implying that agencies such as the US Food and Drug Administration (FDA) are ahead of the curve on digital interaction.



“Industry, regulatory authorities and stakeholders have embraced digitalization at warp speed, partially in response to COVID-19. Particularly in the R&D space, clinical trial design, recruitment and retention are undergoing a digital transformation that is braced by the understanding that when pharma leverages digitalization, we can realize an increase in participant access, enable robust collection of data and generally create greater efficiencies to lower costs and decrease healthcare disparities. The FDA is championing the advancement of healthcare through digital health innovation across products and the product lifecycle, from increasing its talent with digital health expertise to releasing industry guidance focusing on digital health content.”

Khelin Aiken

FDA Regulatory & Compliance Partner, Washington DC





1.3 Navigating Risk

Overall, respondents cited compliance as the largest risk area. Data-related risks such as IP protection, data storage and data management also featured strongly. Regional outlooks show some variance, particularly for Asia Pacific, where almost one in three respondents cited supply chain continuity and cross-border data governance issues as key areas of risk.



As supply chain and trade complexities continue to impact many businesses in the region, these areas of risk not only relate to digitalization and data but the core of business strategies from an operational perspective. Specifically, in Asia Pacific, 34% of respondents cited **supply chain matters** as their top priority. This may reflect a focus on localization, which has spurred smart manufacturing, such as the use of data analytics to manage inventories and drug distribution or the use of AI for quality control during production. Shifting regulation and trade challenges also feature as concerns, as respondents named government actions and antitrust issues (both 31%) as focus areas for legal advice.



“For life sciences companies, supply chain disruption places products and businesses at risk. Moreover, such disruption can also have severe consequences for the delivery of healthcare. For example, products might have a limited shelf life and therefore cannot be delayed by a shipping bottle-neck, or hospitals, having placed orders for medical devices, rely on them being delivered on time. This makes supply chain continuity a must have. Increasingly, life sciences companies are looking to new data driven tools capable of assisting with identifying supply chain disruption risk factors that companies then use to develop viable contingency plans such as replanning a supply route if indicators for supply disruption are present.”

Anne Petterd
Head of International Commercial & Trade
Asia Pacific, Sydney



1.3



“In our **Connected Compliance** research findings, compliance leaders report that not only are their organizations implementing technology with little consideration for risk, but also that compliance is shut out of conversations relating to critical technology decision making. It is especially important for life sciences companies handling sensitive patient data to consider the intertwining myriad of issues related to data privacy, technology and regulatory compliance. Creating a shared responsibility for compliance across the organization and breaking down internal silos is key.”

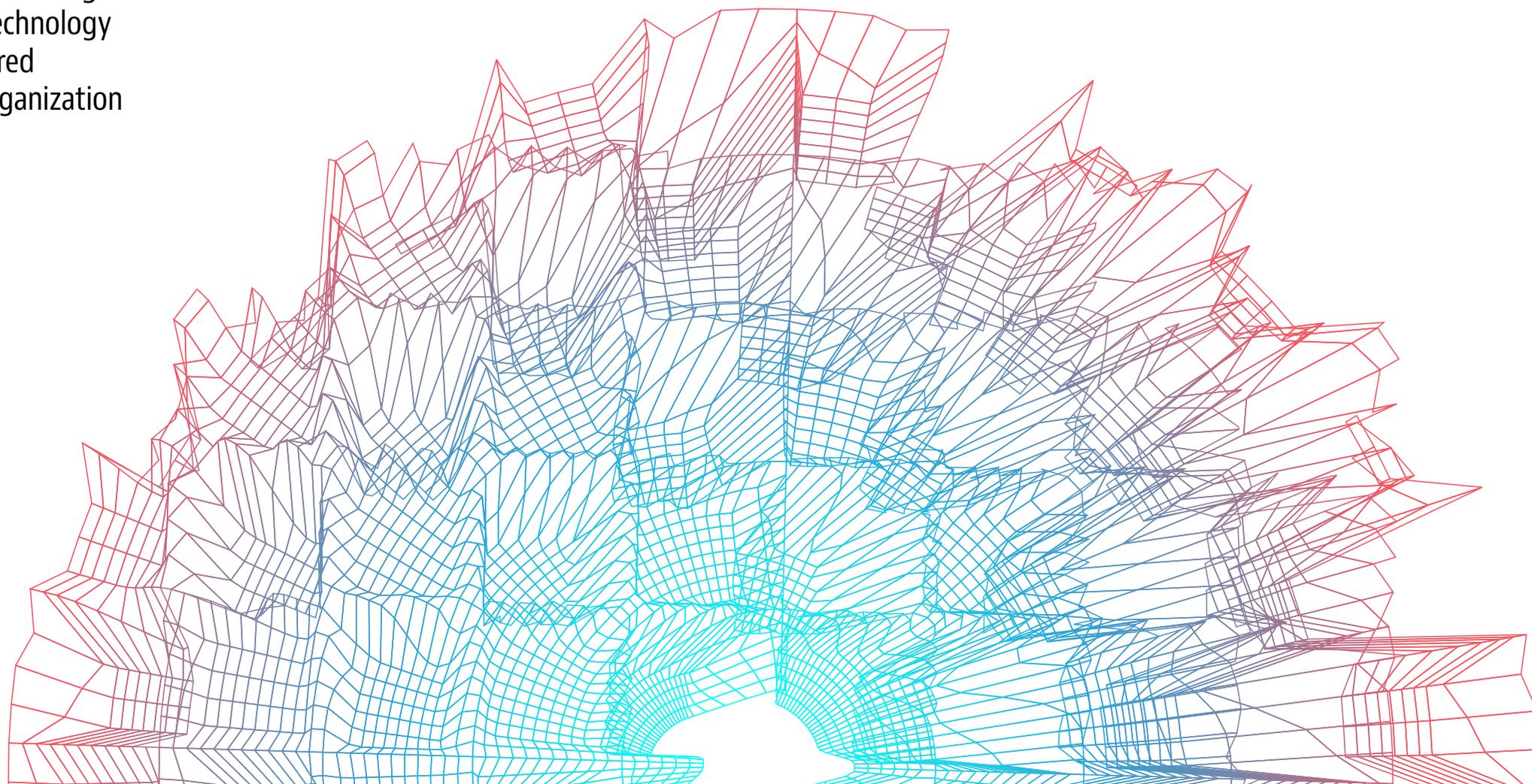
Joanna Ludlam
Global Co-Chair, Compliance & Investigations,
London

Visit Our Connected Compliance Site



Life sciences respondents from the Americas cited compliance (36%), data storage/management (36%) and IP protection for data (33%) as key risk areas, broadly mirroring survey responses in Europe, where digital again figured strongly among perceived areas of risk.

Legal frameworks have struggled to keep pace with technology and emerging products driven by digitalization efforts. With companies taking a “data as an asset” approach, 32% of all responses saw risks in IP protection for data and storage/management. All of these were outweighed, however, by compliance (34%), as companies test the stringent regulatory boundaries for life sciences with their new digital capabilities.



1.4 Strong Legal Support Needed to Chart Change

Over the next one to two years, one-third of all respondents cite data issues and the impact of government actions as key areas where they expect to seek legal advice, related to the overall impact of digital transformation on their business models. Labor and employment, life sciences collaborations and tax were other priority areas for legal advice.





1.4

Regional outlooks show a slight variation in focus beyond data and digitalization or the impact of government regulations, due to different market-specific influences.

Around one-third of respondents from the Americas are keen to get support on collaboration and partnership with other life sciences companies, and 32% plan to seek tax-related advice. Respondents from Europe cite more traditional areas of concern, including employment and labor issues (36%), just 2% higher than respondents from the Americas.

In Asia Pacific, **supply chain matters** including supply chain diversification and managing downstream supply risks remain the top area in which respondents seek legal support (34%).



“Automation of work and the introduction of new technologies have prompted life sciences organizations to re-skill, restructure and redefine their workforce. The pandemic has accelerated a trend of hybrid working, including across borders, and companies now have greater access to a global talent pool. However, change does not come easy, particularly when workforces are demanding ultimate flexibility on scope, hours and location. That brings with it a bundle of employment, immigration, social security, tax, IP and data protection law issues that companies will need to unpick as they work out what their workforce policies of the future should look like and how flexible they are willing to be.”

Julia Wilson
Employment & Compensation Partner, London

Empowering Life Sciences Companies, Globally

Baker McKenzie's top 50 Healthcare & Life Sciences clients comprise of:

- 9 of the 10 pharmaceutical companies listed in the 2021 Global Fortune 500
- 7 of the 10 largest medical devices companies ranked in the 2021 Global Fortune 500
- 13 of the top 20 biopharma revenue generators globally



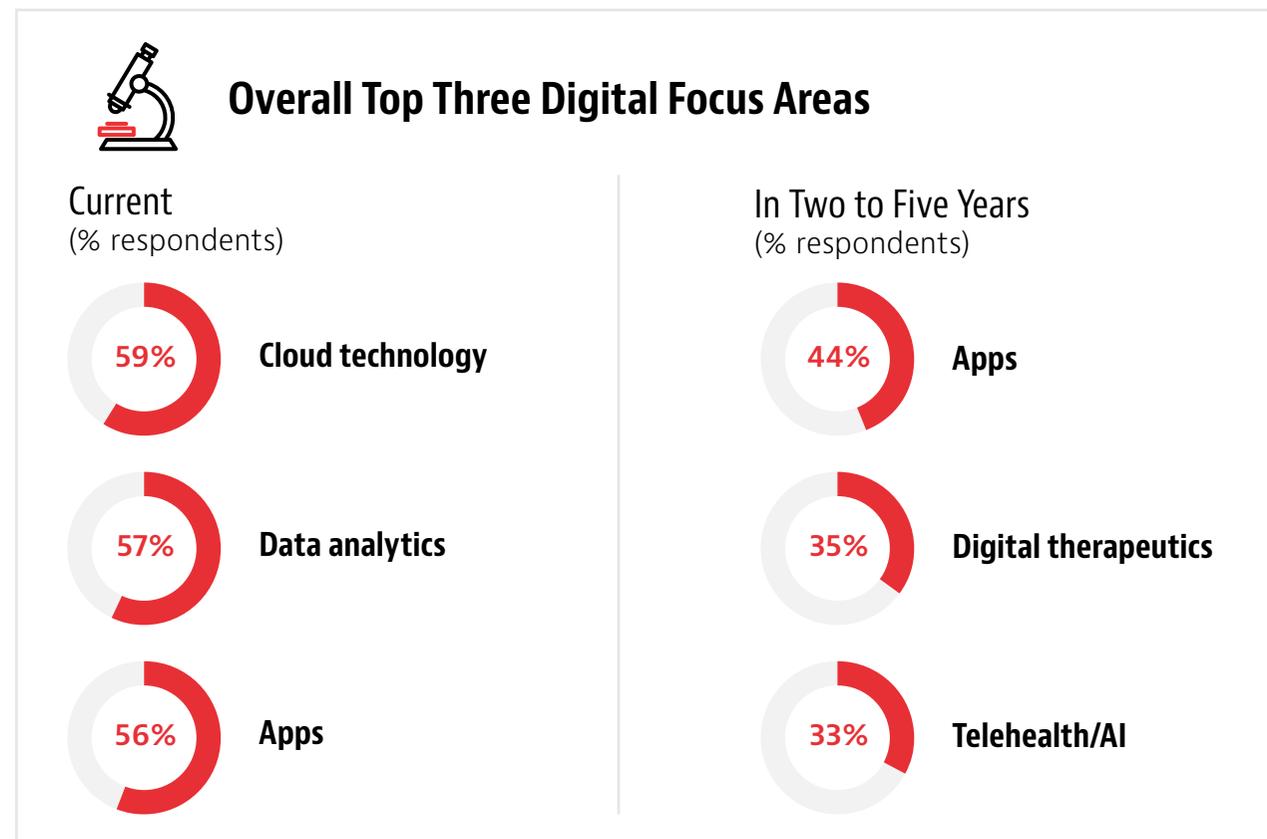
“Life sciences businesses continue to recognize the opportunities presented by more powerful uses of data while seeking to manage the related risks. For example, in our 2021 Digital Transformation and Cloud Survey, 98% of Healthcare and Life Sciences respondents indicated they are currently investing in cybersecurity, and data privacy and cybersecurity ranked as top concerns for cloud adoption. Careful legal planning and involvement in relation to managing digital assets and data throughout the life cycle of a product or service, can help businesses grow with confidence.”

Adam Aft
Global Co-Lead Technology Transactions, Chicago

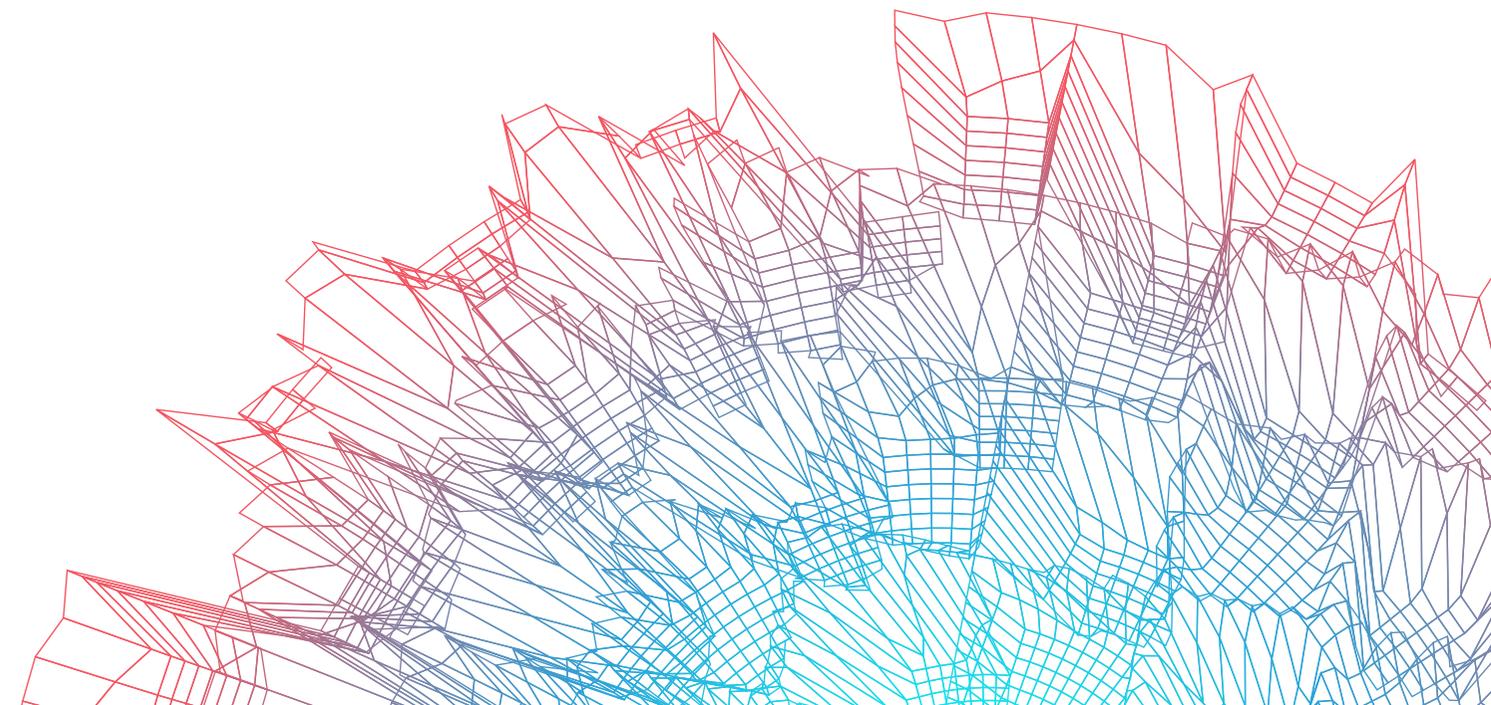
2 Subsector Trajectories

While pharma and biotech companies' digital priorities are based around operational efficiency, medical device and medtech respondents see digital efforts as a key part of their offering. Both subsectors are concerned about potential data issues, as well as partnerships with other life sciences companies, with medical device and medtech respondents additionally concerned about how government actions might impact their operations.

2.1 Pharma and Biotech

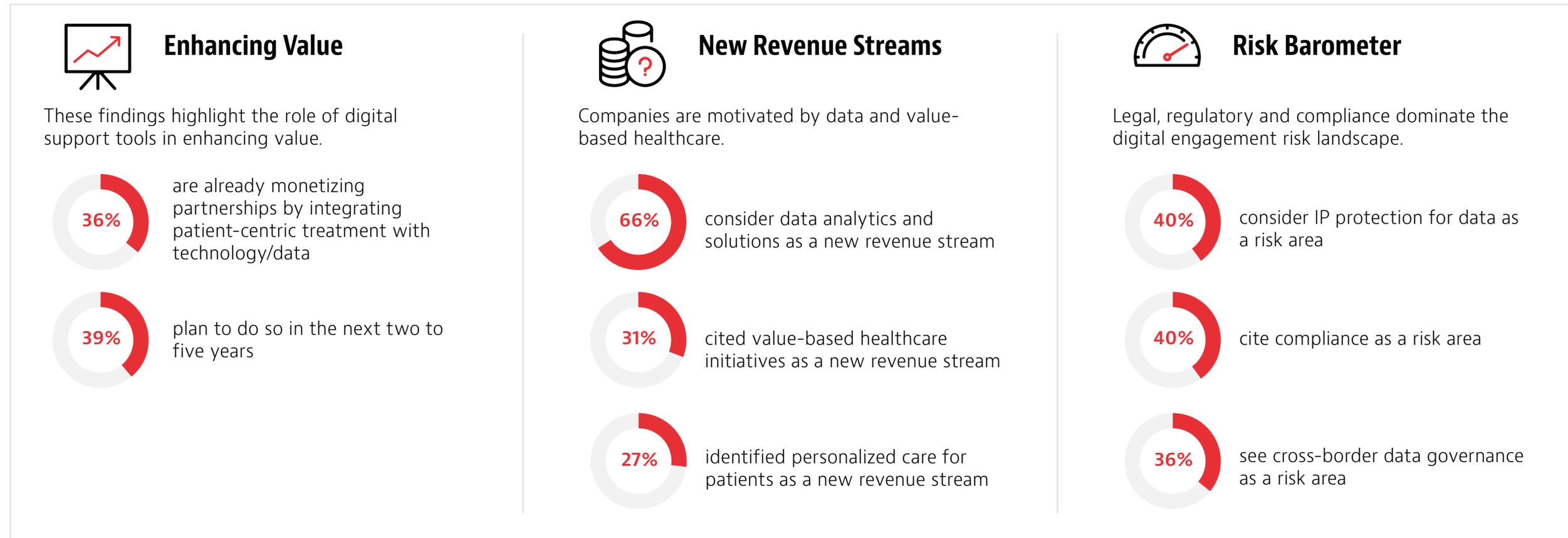


Companies in this sector are storing, managing and analyzing vast quantities of data in secure, accessible locations such as the cloud. Pressures to deploy technology at the services of increasing patient outcomes and speed to market have also put digital transformation efforts at the center of activities, from discovery and clinical trials to supply chain management and customer profiling.



2.1

Within the next five years, upwards of 70% of respondents intend to focus on cloud technology, upwards of 80% on data analytics and upwards of 90% on apps. Cloud technology integration is a way to store large volumes of data, while managing cost pressures. The rising interest in apps can be tied to an accelerated focus on the demand for virtual solutions, catalyzed by the pandemic. These apps will unlock the potential to better educate, monitor and manage patients, ensure treatment adherence and encourage the shift toward decentralized clinical trial models.



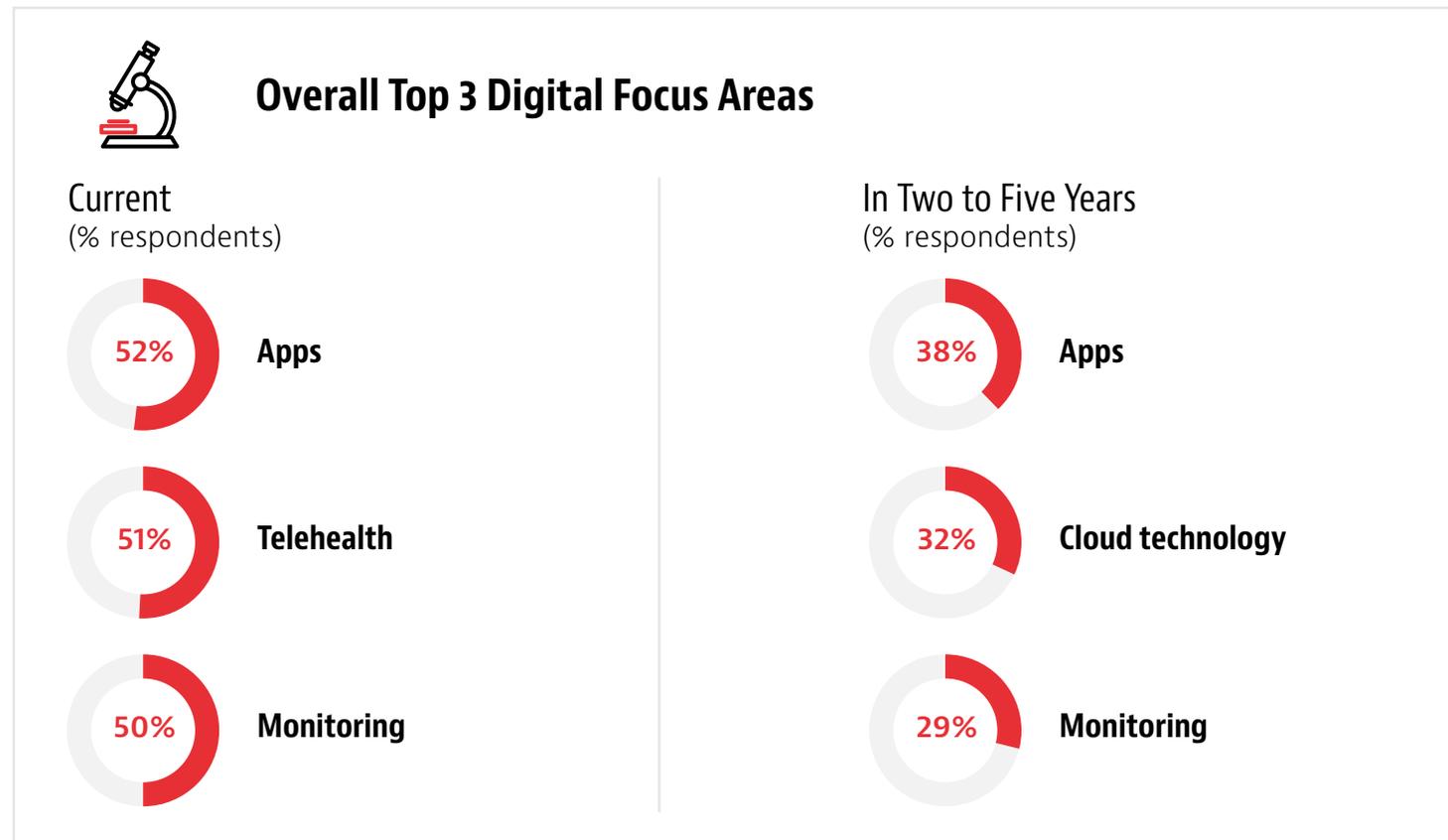
“Protecting IP is crucial as the protection afforded to data requires a different approach that can drive a company’s ability to leverage the value of data alongside or instead of products under new and emerging business models. Life sciences companies should have a clear understanding of the IP rights available and the process for protecting innovations across the business, from creation through to development, manufacturing and marketing, as well as in dealing with third parties such as investors, developers and manufacturers.”

Hiroshi J. Sheraton
 Intellectual Property Partner, London

2.2

2.2 Medical Devices and Medtech

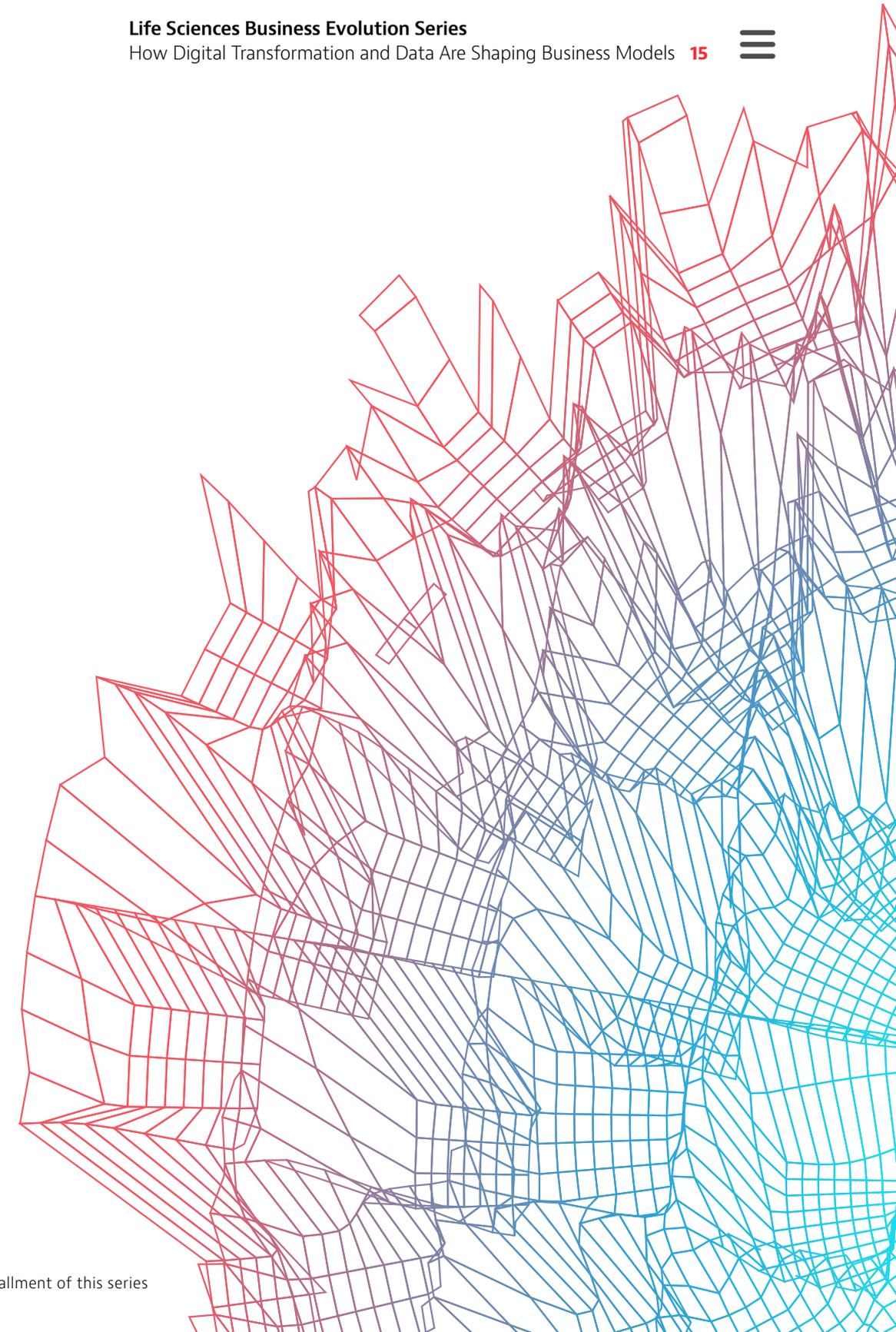
Medical devices and medtech respondents are looking to evolve their businesses by adopting product-service hybrid models. As such, legal and regulatory implications are front and center of the change journey. Within the subsector, traditional medical device companies, in particular, are set to continue adapting to a world where data and digital tools have become intrinsic to business renewal.



Future-proofing With Legal Advice

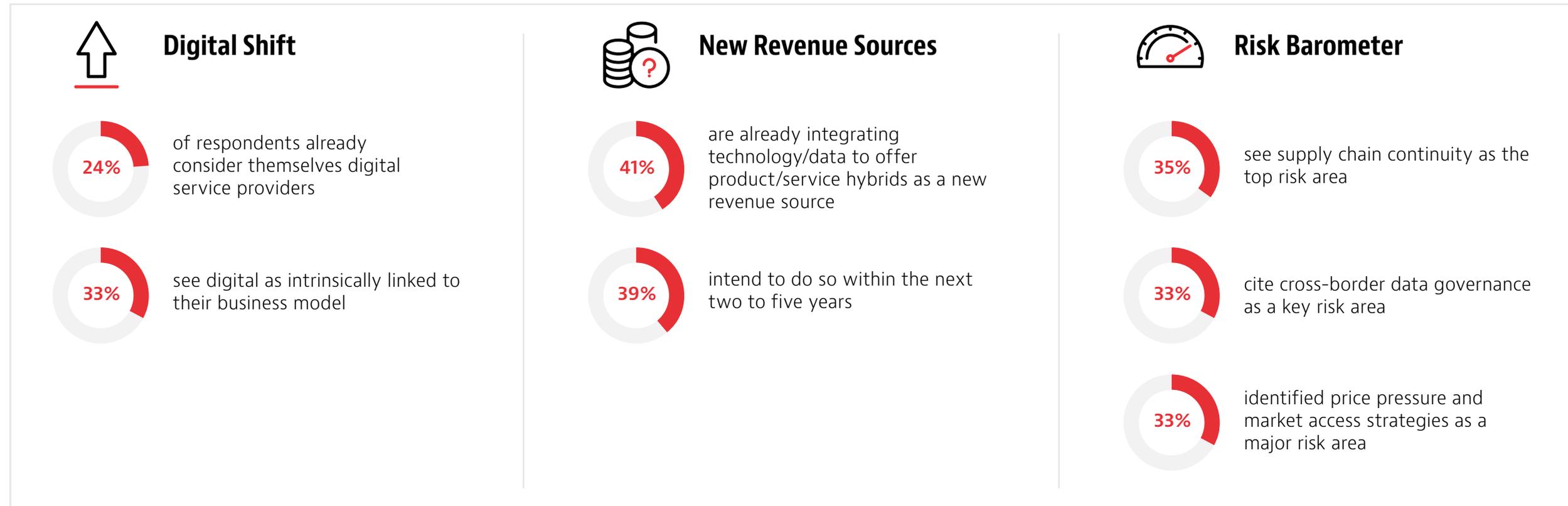
Commercial implications of business model shifts are prompting medical devices and medtech respondents to seek legal advice in areas such as government actions (39%), partnerships with other life sciences companies and other industry sectors including technology and PE/VC funds (35% and 31%, respectively) and data issues (31%) within the next one to two years. As such, regulations and laws around collaboration and data, as well as funding considerations, will shape the landscape to come.*

*To be covered in more detail in the next installment of this series





2.2



“Government action can greatly facilitate the evolution of life sciences business models. In particular, pharma and biotech companies can benefit from grants, incubators and incentives, boosting the adoption of digital and data tools through clinical trials. In turn, digitalization can also facilitate speed to market, development of drugs and drug approval. As medtech companies evolve and take on hybrid product-service models, it will be essential to continue adopting and integrating digital and data tools.

In general, the future of life sciences collaboration is also contingent on potential regulatory shifts, should new devices and products cross and require new approvals. Companies will need to have strong IP protection for data and manage cross-border data governance as well.”

Henrique Frizzo
Partner at Trench Rossi Watanabe*, Sao Paulo and Head of Healthcare and Life Sciences Latin America

*Trench Rossi Watanabe and Baker McKenzie have executed a strategic cooperation agreement for consulting on foreign law.



3 Conclusion — Growth at a Glance

Change has been in motion, in many ways accelerated by the pandemic. For many companies, the ability to adapt to new business conditions has generated a need to assess, transform and safeguard their renewed business models.

At the crux of rapid and prolonged change is the crucial dive into specific areas of digital transformation and the increasing importance of life sciences data. Life sciences businesses are now, more than ever, integrating digitalization into the core of their business models. Over half (57%) of respondents are considering data analytics and solutions as a potential revenue source. Within this set, almost one-third say personalized care for patients is a key motivation, and 29% are motivated by value-based healthcare initiatives. Additionally, one in four respondents say they are interested in differentiating their product and/or service offering.

In order to shape and implement new business models, companies must be both bold and strategic. This involves identifying key areas of business and legal support. Respondents in this research resoundingly emphasize two key issues: data-related issues and the impact of government action(s). Again, such concerns translate into identified risks which center very much around digital and data issues such as compliance, data storage and management and IP protection for data.

Digital transformation and healthcare data are double-edged swords. While they present a realm of advantages, they also bring new legal challenges and amplify existing ones. The impact of government actions is a significant concern for respondents across the globe as are legal issues arising out of collaboration and partnerships with other life sciences companies. Tax and employment and labor issues are major concerns as well. In addition, the healthcare and life sciences industry has always been highly regulated, plagued by lack of regulatory harmonization and regulatory voids across the globe. These problems have increased and taken on greater relevance in light of digital transformation and the importance of data within the industry.





3

Conclusion (continued)

Digital transformation cannot be treated as an isolated goal. To the contrary, it poses a new and critical need for interaction among multiple stakeholders, many of whom are vastly different. Businesses should consider these four key areas:



Data/tech-savvy actors are essential for digital transformation and data issues, but cannot function without meaningful interaction with digital health professionals.



Regulators around the world must improve their knowledge of digital transformation and data.



Regulators would greatly benefit from sharing their thoughts around new legislation with other regulators and industry players.



Digital transformation represents a drastic cultural transformation, especially for patients. Interaction with patients to lead them through the transformation and gain their trust is essential to success.

Digitalization is no doubt a frame of reference for how life sciences business models have begun to evolve and will continue to do so over the next five to ten years. However, the far-reaching impact of digital transformation on businesses and indeed the life sciences ecosystem will affect other key aspects of business renewal such as patterns of growth, funding, supply and manufacturing, as well as the nature of collaboration and partnerships.

Upcoming reports from Baker McKenzie's Life Sciences Business Evolution Series will explore these themes and more, citing key steps businesses can take to capture growth.

Complementary to this series, we invite you to explore our **Hyper-Hybridity** report, which explores challenges, priorities and potential collaboration pathways in digital health, as well as our upcoming 2021 Digital Transformation and Cloud Survey report, which features key trends for digital transformation and cloud strategies for businesses.





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