



Global Life Sciences Risk Outlook 2023 — Executive Summary

WTW Global Life Science Survey

How is the industry adapting to rapid change?

The life science industry is in a period of transformation, from new clinical trial models and evolving regulatory approvals to digitalization and automation of processes. Though hugely promising, these rapid advances can be difficult to adapt to in the short term. They also raise ethical and legal questions, around issues such as data privacy and consent and health equity.

To find out what the industry is thinking about these trends, and a range of other opportunities, risks and challenges, we asked more than 600 industry leaders and decision makers for their views.

This is an executive summary of the survey's main findings. The full report with detailed analysis and risk management insights can be downloaded from the WTW website.

About our survey

When:

September 2022.

Who:

626 senior decision makers, including CEOs, directors and managers of risk, finance, operations, research and legal.

Where:

Countries across Europe, North America, Asia-Pacific and Latin America.

Sectors:

Pharmaceutical and biotech, contract manufacturing, medical devices, contract research organizations, generic/specialty drug manufacturers, diagnostic labs, neutraceutical and over the counter.

Business type:

Combined research and manufacturer (37%), established research business (35%), established manufacturer (20%), pre-revenue developmental (8%).

Size:

87% of companies with annual revenue over \$100 million, 13% up to \$100 million.

Read the full report with detailed analysis which can be downloaded from the WTW website. Please note through this Executive Summary we have shown the stats across all regions combined but there was some location variation which we discuss further in the global report.



Top risks

Greatest risks to business success in the next three-five years

Internal factors

- | | |
|--|-----|
| 1. Data privacy/informed consent | 46% |
| 2. Labelling and packaging | 44% |
| 3. Product safety failure/product recall | 40% |
| 4. M&A risks | 39% |
| 5. Talent acquisition and retention | 38% |

External factors

- | | |
|--|-----|
| 1. Environment/climate change/
extreme weather | 44% |
| 2. Cost and availability of inputs including
materials and energy | 43% |
| 3. Cyber risks | 40% |
| 4. Changing or increasing legislation | 39% |
| 5. Social inflation/rising cost of litigation | 36% |

Participants were asked to select five and rank in order of level of risk

Objectives and strategy

Firms are focusing on collaborations and M&A over new products

The rapid development of vaccines and drugs to combat Covid-19 demonstrated what could be achieved when scientists, businesses and regulators work together to achieve common goals. This experience seems to have changed attitudes in the industry. Our survey suggests that businesses are prioritising industry collaborations over other strategic priorities, while taking a cautious approach to new product development and stock market listings in a time of continuing uncertainty.

- Industry collaborations emerged as the sector's greatest opportunity over the next two years, named by **35%** of respondents among their top five business opportunities. **30%** put strategic acquisitions and industry collaborations among their top three strategic objectives.
- Only **16%** said launching new products and **12%** IPOs. This could reflect a desire to pause and recover after a period of high activity, including the rush to develop new vaccines.
- **38%** also put M&A among their top internal risk factors.

New technologies and working methods

Rapid change brings huge opportunity and uncertainty

The life science sector is in a period of transformation. Digitalisation, new technologies, new clinical trial models and medical advances, such as gene and cell therapies, not only promise to revolutionise healthcare but also the way the industry works. We found that businesses are both excited by the potential of these changes and anxious about the disruption they can create and the potential risks.

- **53%** said wearable tech was among their top five opportunities from digital transformation over the next three years. **52%** said automation and **50%** artificial intelligence.
- New clinical trial models (**34%**), cell therapies (**32%**), and increased technology in production (**31%**) were all ranked among the sector's top five greatest business opportunities in the next two years.
- But **56%** named potential complications of new vaccine technologies among the top three emerging themes that could have a negative impact over the next three to five years, which could reflect nervousness about potential long-tail liabilities. **45%** said the same about evolving regulation of clinical trials.



ESG risks

Data privacy and informed consent is the top risk to success

As the sector becomes more dependent on data to inform strategy and drive innovation, firms are also more conscious not only of the opportunities but also the risks this brings. With the rise of digital healthcare, life science companies are coming under increasing scrutiny from regulators, courts and the public for how they use patient data and how they obtain their consent.

- **52%** said that improved data and data access was among their top five opportunities from digital transformation over the next three years.
- But **46%** of respondents named data privacy and informed consent among the top five internal factors posing the greatest risk to their business success in the next three to five years. **38%** named data privacy as one of their top three ESG governance risks.

Health and race equity is rising up the agenda

Calls for equity in health treatment and outcomes, and access to medicines, are growing louder around the world.

Respondents to our survey saw both the benefits this could bring and also the potential risks if the industry does not make enough progress in these areas.

- **50%** named health and race equity among the top three emerging themes that will have a positive impact over the next three to five years.
- **42%** put issues related to health and race equity and access to medicines among their top three ESG social risks



Clinical trials

The industry is embracing new clinical trials but with some birthing pains

New clinical trial models, including the use of adaptive, hybrid and decentralized trials, offer huge potential to speed up the trial process and widen participation. However, the path to implementation may not be smooth for all adopters.

Many respondents said these new trials were a major loss factor, though some of this may reflect the disruption caused to all trials during the pandemic. We also found some doubt about the effectiveness of risk management processes around clinical trials, which may be related to the rapid pace of change.

- **44%** said hybrid, virtual and decentralized trials were among their greatest loss factors over the last two years.
- **53%** thought evolving regulation of clinical trials was among the emerging themes that have a positive impact over the next three to five years – but **45%** said it would have a negative impact.
- **30%** said although they had risk management processes in place, they may not always operate consistently and effectively.

Pandemic impact

Covid-19 left a deep legacy but caused fewer losses than expected

Despite disruption, businesses suffered fewer risk-related losses over this period than they had expected. The pandemic accelerated changes and adaptations, from virtual ways of working and trialling to the use of AI and machine learning and speed of processes and regulation, which should bring efficiencies and growth in future years.

- **45%** said losses since 2020 were either lower or much lower than expected.
- Repurposing drugs for new use cases (**24%**), an increase in automation (**23%**) and accelerated approval processes (**21%**) were named among the greatest long-term impacts of the pandemic.



Risk landscape

Enterprise risks are increasingly critical in life science

Perceptions of risk seem to have shifted. Whereas once firms might have been focused on core risks, such as product liability, property and D&O, our survey suggests they are now concerned about a much wider range of enterprise risks affecting their ability to do business.

This suggests that, as the sector matures, life science companies face the same pain points and headaches as many other sectors outside of the healthcare economy.

- **44%** named environment, climate and extreme weather among their top five external risks, **43%** said cost and availability of inputs, **40%** cyber risks, **36%** supply chain disruption and **36%** social inflation including the rising cost of litigation. **33%** said intellectual property.
- **40%** named product safety and recall among their top five internal risks, with **44%** concerned about labelling and packaging issues. **39%** said M&A, **38%** talent acquisition and retention, and **36%** problems recruiting to clinical trials.
- **40%** named cyber risk among their greatest external risk factors. This may reflect increased threats to the sector. The UK's National Cyber Security Centre (NCSC) reported over 200 attacks specifically related to the pandemic, including on vaccine research.¹

¹ <https://www.ncsc.gov.uk/files/Annual-Review-2020.pdf>



Risk management/approach to insurance

Some firms struggle to manage intellectual property risks

Intellectual property is the lifeblood of most life science businesses. Yet it emerged as the risk area with the lowest standardised approach to risk management in our survey. While larger companies will have sophisticated internal systems for managing these risks, some mid-market firms may struggle to understand and quantify them.

New technologies such as wearables and AI may change companies' IP risk profiles and their risk management strategies may not have caught up yet. They may also find it difficult to transfer risks effectively due to a lack of insurance solutions that meet the sector's specific needs.

- **69%** agreed that insurance for IP risks was mission critical or necessary.
- But **50%** of firms said that they either had no standardized risk management process for intellectual property or that it did not operate consistently or effectively.

Climate-related weather risks are not well covered

As the impact of climate change bites, extreme weather damage is seen as a top risk. But many businesses appear not to have cover for the business interruption costs of a weather event, while a substantial minority have no cover for extreme weather risks in their supply chain.

- Although **57%** said they were insured for the business interruption costs of a weather event. **35%** said their insurance covered property damage only. **5%** were unsure if business interruption was covered and **2%** said they had no property insurance.
- **26%** said extreme weather in the supply chain could damage their business but they have no insurance to cover this.



Geopolitics is the biggest roadblock to addressing risks

With the conflict in Ukraine and instability in other global regions impacting supply chains, it's not surprising that political risk tops the list of factors that could get in the way of effective risk management.

- **53%** said geopolitical risk was the biggest challenge in addressing risk over the next three to five years.

Priorities and challenges vary across regions

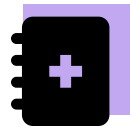
Interesting variations emerged between global regions when we asked about their top three strategic objectives for the next two years – and the greatest obstacles to achieving them.

Accelerating the R&D pipeline was a top priority for **50%** in Latin America, but only **16%** in Asia-Pacific and North America, where new products are less of a priority now. Industry collaborations to accelerate innovation produced a similar disparity, named by **46%** in Latin America as a top priority but only **24%** in APAC.

Looking at obstacles to achieving strategy, Latin America was most concerned about a lack of suitable acquisition targets (**32%**). Europe sees supply chain disruption as the biggest obstacle (**29%**), while APAC is affected more than others by internal culture not aligned with objectives (**27%**) and capacity constraints (**23%**).

These results suggest many businesses are still struggling to get back to their pre-pandemic strength, albeit facing different challenges in each region.

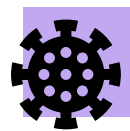
Key life science trends to watch in 2023



The rise of real world evidence: Acceptance of data collected outside of clinical trials, from sources such as electronic health records and mobile devices, will accelerate. This is helping scientists to study how patients use and respond to drugs in real world situations, speeding up drug development.



Health equity in drug treatments: With more real-world data that accurately represents different races and backgrounds, life science businesses will be better able to develop drugs and medical devices that meet the needs of the population.



Cell and gene therapies: Expect more new therapies based on mRNA technology to emerge following on from the success of COVID-19 vaccines. Gene therapies offering personalized treatments that stop disease in its tracks are also getting nearer to reality.



Data mining and repurposing of drugs: More life science businesses are using artificial intelligence (AI) to mine data on existing drugs to find potential new uses for conditions including rare diseases that lack investment in new drug development.



Bioengineering and bioprinting: Having grown small patches of the heart muscle and blood vessels inside laboratory animals and generating simple structures such as cartilage using 3D printing, scientists are getting nearer to synthesizing complex human tissues.

For more information, please contact:

Asia

Ben MacCarthy

Head of Casualty, Asia

+852 2195 5885

benjamin.maccarthy@wtwco.com

Australia and New Zealand

Tracy Grant

Healthcare Practice Leader

AU: +61 478 305 955

NZ: +64 21 195 7146

tracy.grant@wtwco.com

Belgium

Beata Kaczynska-Lombardi

Global Pharma and Health Sciences Industry Lead

+32 2 663 87 09

beata.kaczynska-lombardi@wtwco.com

Denmark

Kasper Dybmark

Partner, Large Accounts

+45 88 13 98 66

kasper.dybmark@wtwco.com

Germany

Martin Carbon

Managing Director

+49 69 15055534

martin.carbon@wtwco.com

Ireland

Tina O’Keeffe

Head of Healthcare and Life Sciences

+353 21 420 7708

tina.okeeffe@wtwco.com

Italy

Paolo Molteni

Chief Commercial Officer

+44 20 3124 7775

paolo.molteni@wtwco.com

North America

John Connolly

North American Practice Leader – Life Sciences

+1 610-254-5686

john.a.connolly@wtwco.com

Sandie Mullen

North American Broking Leader, Life Sciences

+1 913-344-2553

sandie.mullen@wtwco.com

Steve Feick

Director, Life Sciences Practice

484-846-1288

steve.feick@wtwco.com

South America

Eduardo Michelin

Director

+55 11 2161-6040

eduardo.michelin@wtwco.com

UK

Edward Hunter

Life Sciences Broking Leader

+44 20 3124 6477

edward.hunter@wtwco.com

Neil Emerson

Head of GB Life Sciences

+44 7507 763508

neil.emerson@wtwco.com

Disclaimer

WTW offers insurance-related services through its appropriately licensed and authorised companies in each country in which WTW operates. For further authorisation and regulatory details about our WTW legal entities, operating in your country, please refer to our WTW website - <https://www.wtwco.com/en-GB/Notices/global-regulatory-disclosures>.

It is a regulatory requirement for us to consider our local licensing requirements. The information given in this publication is believed to be accurate at the date of publication in December 2022. This information may have subsequently changed or have been superseded and should not be relied upon to be accurate or suitable after this date.

This publication offers a general overview of its subject matter. It does not necessarily address every aspect of its subject or every product available in the market and we disclaim all liability to the fullest extent permitted by law. It is not intended to be, and should not be, used to replace specific advice relating to individual situations and we do not offer, and this should not be seen as, legal, accounting or tax advice. If you intend to take any action or make any decision on the basis of the content of this publication you should first seek specific advice from an appropriate professional. Some of the information in this publication may be compiled from third party sources we consider to be reliable, however we do not guarantee and are not responsible for the accuracy of such. The views expressed are not necessarily those of WTW. Copyright WTW 2022. All rights reserved.

About WTW

At WTW (NASDAQ: WTW), we provide data-driven, insight-led solutions in the areas of people, risk and capital. Leveraging the global view and local expertise of our colleagues serving 140 countries and markets, we help you sharpen your strategy, enhance organisational resilience, motivate your workforce and maximise performance. Working shoulder to shoulder with you, we uncover opportunities for sustainable success — and provide perspective that moves you. Learn more at [wtwco.com](https://www.wtwco.com).



[wtwco.com/social-media](https://www.wtwco.com/social-media)

Copyright © 2022 WTW. All rights reserved.
FPS 4071474 WTW-80155/12/2022

[wtwco.com](https://www.wtwco.com)

