Future-proofing your life science business

Understanding and navigating the evolving risk landscape

Willis Towers Watson

The life science sector is being transformed. Technology is reaching into every aspect of healthcare, blurring the boundaries between tech and medicine.

The pandemic triggered the fastest vaccine approval in history and accelerated the digitalisation of healthcare. The revolution in gene and cell research continues to bring forward exciting new therapies. Within this changing landscape new risks are emerging, which have left insurance markets playing catch up.

Our webinar on 2 December 2021 looked at these trends, how they are impacting liability, how the insurance market is responding, and what you can do mitigate the risks.

This review gives an overview of the key talking points and learnings from the webinar.

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Data sharing and linking: the implications for liability

As the trend towards digitalisation of medicine gathers pace, concerns are growing about who is using the huge volumes of data it generates and for what purpose? Kirsten Beasley, Head of Willis Towers Watson's Bermuda Office, examined the emerging liability issues and potential mitigations.

All the major stakeholders in life science have an interest in generating value from data. Governments and patients want to find the insights that will improve healthcare and maximise social benefit, just as pharma and biotech companies need to mine data in order to learn about patients and develop new, innovative treatments.

The greatest benefits can come through data sharing, and linking and synthesising data from different sources to create richer datasets and deeper insights. However, this is where the potential pitfalls lie.

Key questions and liability considerations

Organisations should ask themselves a few basic questions before they share, link or reuse data:

- Are patients fully aware that it's happening?
- Do they know which other organisations can see their data and what they will do with it?
- Is the data being reused for a different purpose than it was collected for?
- Will that be for valid research or will the data be monetised for commercial gain?

The answers to these questions could determine whether data is being wrongly processed or misused, bringing potential liabilities into play.

How is liability evolving?

While this is still a nascent area that has yet to play out in the courts, potential risks are emerging.

Privacy: as data protection regulations and decisions evolve, organisations could unwittingly stray into privacy breaches if they don't have adequate consent for their purpose.

Discrimination: if patient data gets factored into healthcare insurance algorithms, could it lead to people being denied cover? Or more widely, people might be refused loans or mortgages, get turned down for jobs or educational opportunities, or simply face stigmatisation based on how their data is interpreted.

Duty of care: as the law in this area develops, courts and legislators may decide organisations owe a duty of care to people's medical data just as they do to the person themselves.

Research shows people want more control over their data, especially if it is being used for commercial gain.

As the uses of data expand in ways never envisaged even a few years ago, it may be time to revisit the way in which it's collected, how people are informed and the quality of the consent they give.

Improving your data governance

So how can organisations make the most of the opportunities and innovations that data can bring while reducing the risk of data misuse? Providing better information and having good policies and governance around patient and customer data can help. Strategies might include:

- Looking again at your consent mechanisms (see table on the right) and making sure that patients can choose how all their different types of health data is used, by whom and for what purpose.
- Creating independent oversight structures for data management and having an audit mechanism to ensure appropriate uses.
- Helping people make informed choices through public awareness and engagement campaigns and publishing your data reuse practices and policies.
- Carrying out purpose-of-use reviews and introducing data reuse requests.
- Considering benefit sharing agreements with your stakeholders – so people are aware of what they get from sharing their data.
- Viewing the current regulations as the floor, not the ceiling. Remember that the sector is evolving rapidly. If you raise your standards now, you'll be ahead of the game when the regulators catch up with developments.

Raising the bar for consent

As discussed above, consent is evolving as the uses of data expand. Tickbox or blanket consent may no longer be enough to protect organisations from claims resulting from misuse of data.

Already under GDPR regulations in Europe, consent must be opt-in and we can expect the standard of consent required in the healthcare and life science fields to rise further in the coming years.

But what kind of consent do you need? There's a range of models and levels of granularity. There is no ideal here – it's about having appropriate consent for the type of data and the use that you make of it.

Consent models	Degree/nature of granularity
Blanket consent	Consent to an unlimited range of options with no restrictions.
Broad consent	Consent to an unspecified variety of future research projects subject to a few restrictions.
Tiered consent	Data subject can choose to give broad consent for specific types of purposes, users, institutions etc.
Meta consent	Data subject can express how and when they want to be asked for consent in the future. A form of tiered consent whereby people can choose differing levels of consent for different categories: e.g. users, uses, institutions etc.
Specific informed consent	Consent for each differing use (and user) of data at every point in time.

What insurance cover is available?

Current insurance policies covering privacy and information security do not specifically cover the potential for liability arising out of data mining, linking, reuse or misuse. Insurers may yet develop solutions as the market evolves. In the meantime, the answer may lie in a bespoke cover designed around your specific risks and needs rather than an off-the-shelf policy.

Product liability: how the market is evolving

There's a disconnect between the rapid growth of life sciences and the shrinking availability of product liability insurance for the sector. Ed Hunter, Life Sciences Broking Leader, Willis Towers Watson, looked at the reasons behind this contraction and how life science businesses can manage their risks in a changing market.

The global life science sector is expanding rapidly. Around the world, more patients are gaining access to healthcare, driving rising demand for pharmaceuticals and medical devices. Innovations in biotechnology are leading to new drugs and personalised treatments. Ageing populations mean more patients needing treatment for longer.

However in recent years, we have seen global product liability capacity for life sciences fall sharply to roughly half the size it was 10 years ago.

We estimate there is only $500 million capacity available for life sciences, chiefly in the U.S. supported by a handful of insurers in the UK and Bermuda.

Market size	*Product liability capacity*
$1.27 trillion Pharma[1]	**$1 billion** 2011
$752 billion Biotech[2]	
$455 billion Medical devices[3]	**$500 million** 2021

[1] www.statista.com/statistics/263102/pharmaceutical-market-worldwide-revenue-since-2001/
[2] www.grandviewresearch.com/industry-analysis/biotechnology-market#:~:text=The%20global%20biotechnology%20market%20size%20was%20estimated%20at%20USD%20752.88,USD%201%2C006.68%20billion%20in%202021
[3] www.fortunebusinessinsights.com/industry-reports/medical-devices-market-100085

What's driving the contraction in capacity?

A succession of negative events in recent years, including class actions related to faulty hip and knee replacements, and the ongoing opioid crisis, have led some insurers to bring in blanket life science exclusions and others to exit the market. The general liability market used to top-up gaps in cover provided by specialist life science insurers on an excess basis. But that has also dried up and very little excess capacity remains.

Emerging issues

Product contamination during manufacturing

Another factor influencing the current tight insurance market is a perceived surge in recall activity related to contamination. In 2018, potentially carcinogenic nitrosamines were found in products for treating high blood pressure, and also in drugs used for diabetes, stomach acid and smoking cessation. The U.S. Food and Drug Administration (FDA) found that nitrosamines can be introduced during manufacturing or as a result of the conditions in which products are stored. With more product recalls likely, this could have a further impact on insurers' willingness to cover life science risks.

Vaccine development

The rush to develop vaccines for COVID-19 was one of the biggest product development drives in history. In these extraordinary circumstances, many governments provided non-fault compensation for vaccine harms to support and speed innovation. This effectively closes down public claims for vaccine injury in those countries. Although, technically, claims can still be brought for product defects under consumer protection legislation, these would not succeed as long as the vaccine has been made correctly.

Insurers have been reluctant to cover vaccines under product liability as they were nervous about the potential long-term side effects. However, there is some appetite returning in the product liability market for companies that can provide heightened levels of trial data, depending on the quantity of vaccines that will be produced, the revenues expected and the territories served.

CBD products

Many life science companies are launching new medical products based on cannabidiol (CBD), also known as medical cannabis. However insurers are reluctant to include these products as part of their product liability cover. Where they do, cover is often restricted to products that can be applied to the skin rather than those that are ingested. Typically, companies need to agree inclusion of CBDs with their insurer and may be required to set up a standalone tower for the CBD exposures.

Hybrid clinical trials

Clinical trials are changing, partly in wake of COVID-19. Most trials are now a hybrid of remote and in-person activity. This has increased recruitment to trials, since participants don't have to travel as much to the trial centres. However, the reduction in face-to-face engagement comes with increased risk – for example that signs will be missed which should have led to a patient being removed from the trial. Or that participants will not be monitored effectively when they leave the trial. Companies moving into hybrid trials need to check that their insurance will still cover these scenarios. It's vital to get appropriate informed consent, and have very clear procedures, information and instructions for patients.

Data mining and repurposing of drugs

During the pandemic, health systems looked to find drugs already approved for other uses which could be repurposed to treat COVID-19 patients – often mining existing clinical trial data using artificial intelligence (AI) to accelerate the process. This has created a model that could be used to find existing drugs for other conditions including rare diseases that lack investment in new drug development.

Generally, product liability insurers have been relaxed about repurposing as the indication changes required are relatively minor and the products have already been tested for efficacy and safety. However, companies should make sure they have robust and comprehensive safety data appropriate for the use they intend.

Managing risks

Although we have seen dramatic changes in the life science sector, the fundamentals of risk have not changed.

It's the failure to warn patients that poses the biggest risk in product liability.

The largest awards of recent years have been against companies that failed to fully disclose all the potential side effects. Life science businesses should be able to demonstrate robust evidence of safety and clearly and honestly communicate risks and benefits with patients.

Cell and gene therapy: risks, mitigations and solutions

Cell and gene therapies are the new frontier of life science, offering potentially transformative treatments for everything from cancer to malaria. But what do businesses entering this sector need to consider? Neil Emerson, GB Practice Leader, Life Sciences, Willis Towers Watson, examined the risk factors, potential mitigations and the implications for insurance.

The recent success of genetically engineered mRNA vaccines for COVID-19 accelerated progress in the cell and gene therapy sectors, increased collaboration, attracted a flood of money into research and development from both governments and investors and opening the doors for new therapies.

Although relatively few treatments have yet been approved, funding has reached almost £20 billion and there were more than 20 initial public offerings (IPOs) in the sector in the first half of 2021 alone.

As the technology advances, barriers to development are falling.

For example, the production of the viral vectors used to deliver genetic information into cells are becoming more consistent and gene editing tools such as Crispr/Cas9 are becoming increasingly reliable. Improvements in manufacturing processes are also reducing costs and bringing scalable volume production nearer.

But significant problems and complexities remain for businesses entering this market, with implications for risk management strategies and insurance.

Cell and gene therapy (CGT) development

2,600+
cell and gene therapy trials worldwide[4]

1,320
trials are sponsored by the biotech industry[4]

243
trials are in phase 3 of development[4]

10-20
new product approvals annually expected by the U.S. FDA by 2025[5]

[4]https://alliancerm.org/sector-report/h1-2021-report/
[5]www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-peter-marks-md-phd-director-center-biologics

Unknown long-term side effects

- **Risk factor:** cell and gene therapies are new technologies. It's impossible to be certain about how they will impact patients in the long-term. Because gene editing, in particular is difficult or impossible to reverse, these effects could cause lifelong damage. It can be difficult for insurers to model the risks, which can range from fevers and high blood pressure to severe illness or disease.
- **Mitigation:** companies can reduce risks by meeting and exceeding regulatory requirements. Carry out robust risk evaluation and extend clinical trials for as long as is needed. If your insurer has a problem with a long trial, you may be able to break it down into smaller units.
- **Insurance implication:** most insurance policies will be written on a claims-made basis, which typically does not extend far beyond the next renewal. This makes it essential to review the retroactive dates and extended reporting periods to make sure you get the cover you need.

Complex supply chain dependencies

- **Risk factor:** these therapies often rely on a complex web of suppliers contributing to their development and manufacture. Any weak link in this chain can potentially put the whole project in jeopardy.
- **Mitigation:** review your supply chain resilience. Avoid being reliant on a single supplier or location if possible. Consider multi-sourcing and nearshoring supply.
- **Insurance implication:** insurers will treat the risk profile of your contractors as an extension of your own operations. You will be expected to demonstrate that you understand the physical characteristics of risk involved and have strong business continuity plans in place.

Scaling up and transition to market

- **Risk factor:** the journey from lab to commercial development is a long-term commitment. Clinical trials for gene therapies often take up to 15 years with many stages in the transition to market.
- **Mitigation:** to smooth this path, it's vital to keep tight control of quality and choose your contract development manufacturing organization (CDMO) and other critical partners carefully.
- **Insurance implication:** carry out a dynamic business impact analysis for each stage of development, including all the partners involved, and check your contractual liabilities.

Product sensitivity

- **Risk factor:** products are difficult to manufacture and sensitive to environmental changes such as temperature, humidity and contamination. This makes transportation between countries problematic.
- **Mitigation:** work with specialist logistics partners and consider manufacturing sensitive components closer to patients.
- **Insurance implication:** insurers will be concerned about any risk of contamination or damage from your logistics chain.

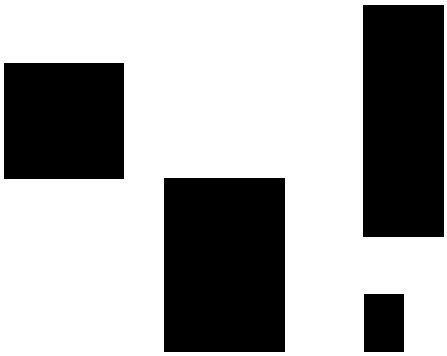
Access to market

- **Risk factor:** the customers for these products will be healthcare systems and medical insurance companies. At present, their budgets and payment models don't include CGTs and this will need to change before the market can move forward.
- **Mitigation: c**onsider flexible payment models including outcome-based payments.
- **Insurance implication:** engage and collaborate with your payers early so your insurer will be clear on your approach.

Conclusion

The life science sector is evolving rapidly, posing challenges for regulators and insurers.

- Huge amounts of data are being generated during clinical trials and product development. How its used, or misused, could become a highly contested area, with the limitations and liabilities to be decided in the courts. Businesses can get ahead of this curve by reviewing and improving their data governance, especially through informed and appropriate consent.
- Many insurers have withdrawn from providing product liability in the life science space, stung by large class actions and recent controversies. New and emerging issues look likely to test the market further. Clever risk management and creative insurance solutions will be needed to support continued innovation in the industry.
- Cell and gene therapies have the potential to revolutionise healthcare, promising personalised treatments and reversal of chronic health conditions. But huge uncertainties remain around the impacts and side effects. Businesses in this field should carry out comprehensive risk evaluations and review their partnerships and contracts to protect themselves against potential future liabilities.



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