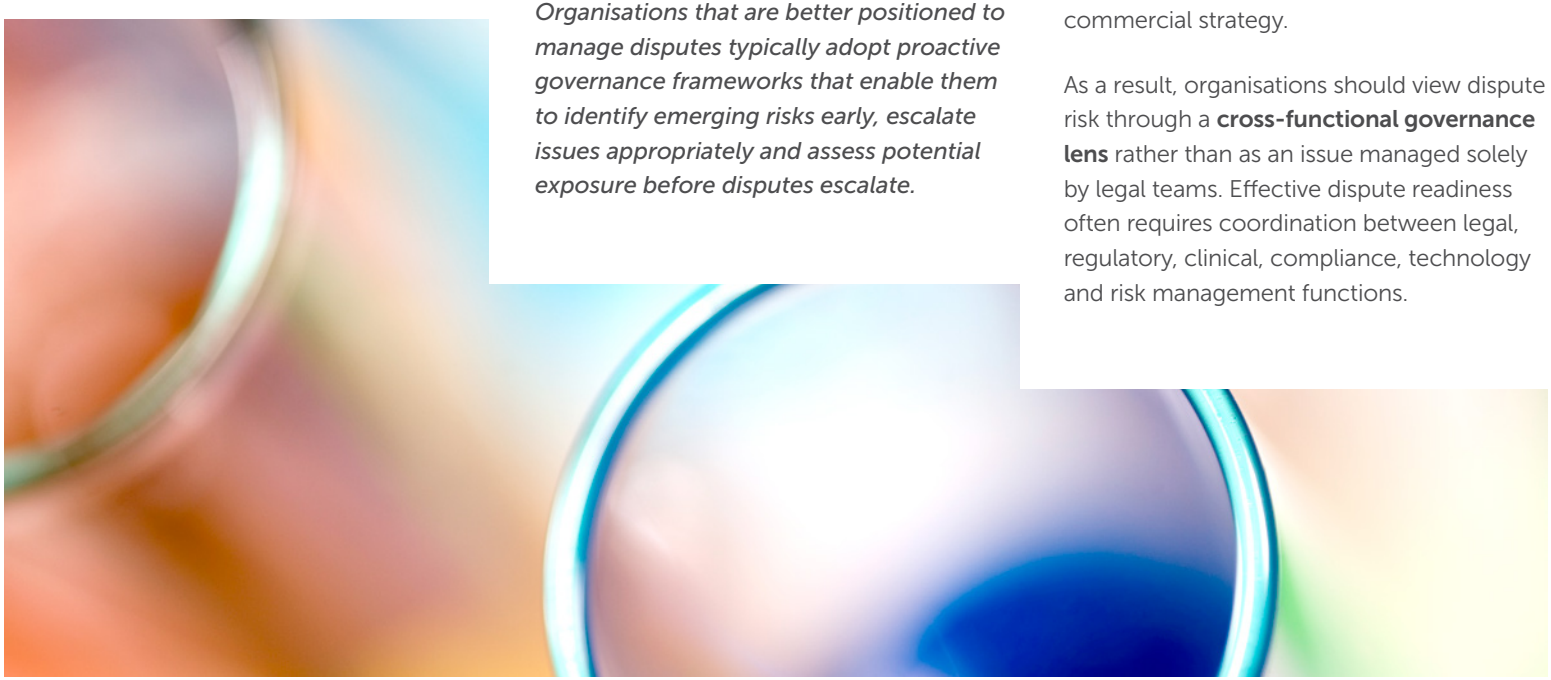
Part III – Strategic considerations for life sciences organisations

As regulatory scrutiny intensifies and technological innovation accelerates, life sciences organisations must adapt their governance, risk management and compliance frameworks.

The following chapters explore practical strategies that organisations can adopt to manage emerging legal risks, strengthen regulatory compliance and mitigate the likelihood of future disputes.

3.1 Dispute readiness for life sciences organisations

How organisations can identify early warning signals and assess dispute exposure.



Life sciences organisations are operating in an environment characterised by increasing regulatory scrutiny, rapid technological innovation and expanding litigation risk. As the preceding chapters illustrate, disputes in the sector may arise from a wide range of sources, including regulatory enforcement, product safety concerns, clinical trial outcomes, privacy incidents, intellectual property disputes and the deployment of emerging technologies such as AI.

In this environment, effective dispute management requires more than reactive legal responses once litigation begins. Organisations that are better positioned to manage disputes typically adopt proactive governance frameworks that enable them to identify emerging risks early, escalate issues appropriately and assess potential exposure before disputes escalate.

Disputes are increasingly complex and interconnected

Many disputes in the life sciences sector arise not from a single legal issue but from the interaction of multiple regulatory, technological and operational factors.

For example, a cyber incident affecting patient data may trigger privacy enforcement action, regulatory scrutiny, contractual disputes with research partners and potential shareholder litigation. Similarly, issues arising during clinical trials may lead to regulatory investigations, product liability claims and reputational consequences affecting commercial strategy.

As a result, organisations should view dispute risk through a **cross-functional governance lens** rather than as an issue managed solely by legal teams. Effective dispute readiness often requires coordination between legal, regulatory, clinical, compliance, technology and risk management functions.

Identifying early warning signals

In many cases, disputes are preceded by warning signs that initially appear as operational or regulatory issues rather than legal problems.

Examples of early warning indicators may include:

- adverse clinical trial events or unexpected safety signals;
- regulatory correspondence or requests for information;
- significant product complaints or quality issues;
- cybersecurity incidents or attempted intrusions;
- internal whistleblower reports or compliance concerns;
- disputes with research partners, suppliers or contract research organisations; and
- negative media coverage or public criticism of clinical or data practices.

Organisations that establish clear escalation pathways for such issues are often better able to assess potential legal exposure before disputes escalate into formal litigation or regulatory proceedings.

Strengthening governance and escalation frameworks

A key element of dispute readiness is ensuring that organisations have governance structures capable of identifying and responding to emerging risks.

Effective governance frameworks typically include:

- clearly defined internal escalation procedures for legal and regulatory issues;
- cross-functional committees overseeing compliance, data governance and emerging technologies;
- board or executive oversight of significant regulatory and litigation risks; and
- defined processes for responding to regulatory inquiries or investigations.

These governance structures help ensure that emerging issues are evaluated through both operational and legal perspectives before they develop into disputes.

Integrating legal oversight into technology deployment

As the earlier chapters illustrate, many emerging disputes in the life sciences sector arise from the use of new technologies, particularly in areas such as AI, digital health platforms and large-scale health data analytics.

Legal and compliance teams should therefore be involved early when organisations deploy technologies that may affect patient data, clinical decision-making or medical device functionality.

Early legal involvement can assist organisations in identifying regulatory obligations, managing intellectual property issues and mitigating privacy or consumer law risks before technologies are deployed at scale.

Reviewing insurance and risk transfer strategies

Insurance remains an important mechanism for managing the financial consequences of disputes. However, as discussed in the preceding chapter, coverage gaps may only become apparent once litigation or regulatory proceedings commence.

Organisations should therefore regularly review their insurance programs to ensure that coverage aligns with evolving risks. Particular attention may be required where organisations:

- conduct clinical trials in multiple jurisdictions;
- launch new therapeutic products or medical devices;
- deploy AI-enabled technologies or digital health platforms;
- handle large volumes of sensitive health data; and
- expand into new markets with different regulatory environments.

Regular engagement with insurance brokers and advisers can help ensure that coverage limits, exclusions and territorial scope remain appropriate as the organisation's risk profile evolves.

Questions for legal counsel and executive teams

In addition to formal governance frameworks, life sciences organisations may benefit from periodically assessing dispute readiness by considering key strategic questions.

Dispute readiness area	Questions for organisations and leaders
Governance and oversight	■ Are potential legal and regulatory risks escalated to legal counsel early in the decision-making process? ■ Does the organisation have clear internal procedures for managing regulatory inquiries and investigations? ■ Is there effective communication between legal, regulatory, technology and clinical teams?
Data governance and technology deployment	■ How are privacy, cybersecurity and AI governance risks assessed when deploying new technologies? ■ Are data governance frameworks aligned with evolving privacy and cybersecurity expectations? ■ Are appropriate contractual protections in place when sharing data with research partners or technology providers?
Regulatory preparedness	■ How does the organisation monitor evolving regulatory expectations from bodies such as the Therapeutic Goods Administration (**TGA**), the Office of the Australian Information Commissioner (**OAIC**) and the Australian Competition and Consumer Commission (**ACCC**)? ■ Are internal compliance frameworks regularly reviewed against emerging regulatory risks?
Insurance and financial exposure	■ Do current insurance policies adequately cover the organisation's key operational risks, including cyber incidents, clinical trials and product liability? ■ Have policy limits been stress-tested against potential litigation scenarios?

Insight: Dispute readiness is becoming a strategic capability

For life sciences organisations, dispute readiness is increasingly a strategic capability rather than a reactive legal function.

Organisations that proactively identify emerging risks, strengthen governance frameworks and integrate legal oversight into operational decision-making are generally better positioned to manage disputes efficiently and protect long-term commercial value.

In an environment where regulatory expectations are evolving rapidly and technological innovation is accelerating, dispute readiness will remain an essential component of effective risk management across the life sciences sector.

3.2

Looking ahead: the future of disputes in life sciences

How emerging dispute trends are shaping strategy, investment and innovation

Lead author: Simone Mitchell, Partner and Life Sciences Lead

"The regulatory and technological landscape facing life sciences organisations is evolving rapidly. Dispute readiness will increasingly depend on how effectively organisations integrate governance, compliance and innovation."

Simone Mitchell

The dispute landscape for life sciences organisations in Australia is evolving rapidly. Scientific innovation, expanding regulatory oversight and the growing use of digital technologies are creating new opportunities for the sector while simultaneously increasing legal complexity.

As the preceding chapters illustrate, disputes in the life sciences sector are no longer confined to traditional areas such as patent litigation or product liability claims. Organisations are increasingly encountering disputes arising from regulatory enforcement, data governance, cybersecurity incidents and the deployment of emerging technologies such as AI.

Looking ahead, several developments are likely to shape the future dispute environment for the life sciences sector. These trends are likely to influence not only how disputes arise, but also how organisations structure governance frameworks, manage regulatory risk and make strategic investment decisions.

Privacy reform and the expanding regulation of health data

One of the most significant developments likely to affect the life sciences sector in the coming years is the continued evolution of Australia's privacy framework. Organisations operating in this sector routinely collect and analyse highly sensitive information, including clinical trial data, patient health records and genetic information. As digital health technologies and data-driven research become increasingly central to innovation, regulatory scrutiny of how this information is handled is expected to intensify.

The next phase of reforms to Australia's privacy framework – commonly referred to as the **'tranche 2' reforms** – is expected to progress during 2026. Earlier government consultation processes and responses to the Privacy Act Review indicate that these reforms may significantly reshape Australia's privacy regime, with potentially substantial operational implications for organisations handling sensitive health information.

One proposed reform is the introduction of a **'fair and reasonable' test** governing the handling of personal information. Under this model, organisations may be required to demonstrate that their collection, use and disclosure of personal information is fair and reasonable in the circumstances, even where consent has been obtained.

For life sciences organisations, this reform could have important implications for activities such as:

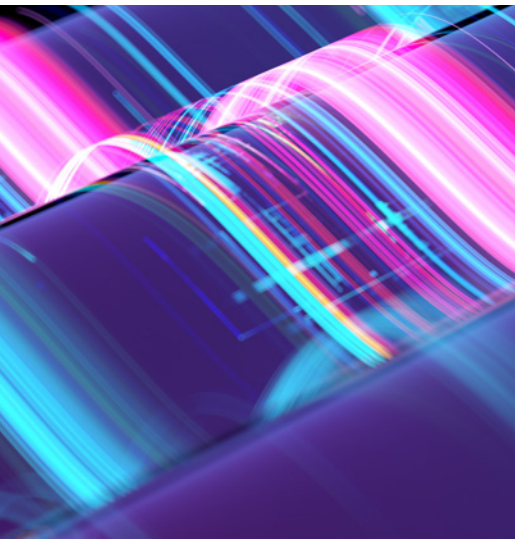
- clinical trials and research programs;
- patient support initiatives;
- digital health platforms and connected medical devices; and
- large-scale health data analytics projects.

Further reforms may also introduce **expanded individual rights**, such as rights relating to the deletion of personal information or objections to certain forms of data processing. In addition, proposals to broaden the definition of personal information may expand the categories of information subject to privacy regulation, particularly in relation to online identifiers and device-generated data.

Another proposal is the potential **removal of the small business exemption**, which could bring a larger number of health technology start-ups and emerging life sciences organisations within the Privacy Act framework for the first time.

Implication for organisations:

Life sciences organisations should begin preparing for a more demanding privacy regulatory environment by strengthening data governance frameworks, reviewing consent and data-use practices, and ensuring that privacy and cybersecurity considerations are embedded in technology and research initiatives.



AI and emerging technology disputes

AI is rapidly becoming embedded across the life sciences sector, from drug discovery and clinical research to diagnostics and digital health platforms. While these technologies offer significant opportunities to accelerate innovation and improve healthcare outcomes, they also raise new legal and regulatory questions.

As AI systems play a greater role in clinical decision-making, data analysis and patient interaction, disputes may arise in areas such as:

- liability for AI-assisted clinical decisions;
- regulatory classification of AI-enabled medical devices;
- governance of training datasets and data ownership;
- IP rights; and
- transparency and accountability in automated decision-making.

Courts and regulators globally are only beginning to address these issues, meaning that legal frameworks will likely continue evolving as AI technologies become more widely deployed across healthcare systems.

Implication for organisations:

Organisations deploying AI technologies should ensure that governance frameworks address both technical and legal risks, including data governance, IP rights, transparency obligations and regulatory compliance for AI-enabled medical technologies.

Increasing regulatory scrutiny across the sector

Regulatory oversight of the life sciences sector is also expected to continue intensifying. Regulators in Australia – including the Therapeutic Goods Administration (**TGA**), the Office of the Australian Information Commissioner (**OAIC**) and the Australian Competition and Consumer Commission (**ACCC**) – have increasingly demonstrated a willingness to pursue enforcement action where regulatory obligations are not met.

This trend reflects broader policy objectives relating to consumer protection, patient safety and the governance of emerging technologies. As regulatory expectations evolve, organisations may face greater scrutiny of areas such as clinical trial conduct, advertising practices, product safety monitoring and the handling of health information.

Regulatory investigations may increasingly precede or accompany litigation, meaning that disputes may emerge from regulatory processes rather than traditional commercial conflicts.

Implication for organisations:

Life sciences organisations should ensure that compliance frameworks remain aligned with evolving regulatory expectations and that internal escalation processes allow potential issues to be addressed before they develop into formal enforcement proceedings.

Cross-border disputes and global litigation exposure

Life sciences disputes are also becoming increasingly international in nature. Pharmaceutical products, medical devices and digital health platforms frequently operate across multiple jurisdictions, exposing organisations to regulatory oversight and litigation risk in different legal systems.

For example, product liability claims relating to pharmaceuticals or medical devices may involve coordinated proceedings across multiple countries. Similarly, cyber incidents affecting health data may trigger regulatory investigations and litigation in several jurisdictions simultaneously.

These developments mean that organisations must increasingly consider legal risk through a global lens, particularly where products, clinical trials or data platforms operate across borders.

Implication for organisations:

Organisations should ensure that governance frameworks, regulatory strategies and insurance programs account for cross-border dispute exposure and the potential for coordinated international regulatory investigations.

Preparing for a more complex dispute environment

Taken together, these developments suggest that disputes in the life sciences sector will continue to evolve alongside scientific and technological innovation.

For organisations operating in this environment, legal risk management will increasingly require a proactive and integrated approach. This may include:

- strengthening governance frameworks across legal, regulatory and technology functions;
- monitoring emerging regulatory developments in areas such as privacy and AI;
- implementing robust data governance and cybersecurity measures; and
- ensuring that insurance programs reflect evolving technological and regulatory risks.

Ultimately, organisations that integrate legal risk management into their broader innovation and governance strategies will be better positioned to manage disputes and navigate the complex regulatory environment shaping the future of the life sciences sector.

Final insight: Disputes will increasingly follow innovation

The life sciences sector has long been defined by scientific and technological innovation. New therapies, medical technologies and research methods continue to transform healthcare outcomes and create significant opportunities for growth. Yet as innovation accelerates, so too does the complexity of the legal and regulatory environment surrounding it.

Disputes are increasingly emerging at the intersection of science, technology and regulation. For life sciences organisations, the challenge will be ensuring that governance, compliance and risk management frameworks evolve at the same pace as the innovations they support.

Organisations that anticipate emerging risks, strengthen oversight and integrate legal risk management into their innovation strategies will be best positioned to navigate the disputes landscape ahead.

For organisations operating at the intersection of healthcare, science and technology, dispute readiness will increasingly be defined not by how disputes are defended, but by how effectively risks are anticipated and managed before disputes arise.

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MinterEllison is Australia's leading independent law firm enhanced by specialist consulting.

Our dedicated, full-service, multidisciplinary life sciences team advise across the life sciences product and business lifecycle – from concept to commercialisation, and beyond.

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