

Insuring Life Sciences: Smart Strategies for Legal Leaders

*From Clinical Trials to D&O
Coverage to IP Infringement*

May 10, 2023



Speakers



Heather Turner
CEO
Carmot
Therapeutics



Cristina Varner
SVP, National Life
Science and Digital
Health &
Telemedicine
Practice Leader
Newfront



Eric Tausend
Senior Director of
New Business
Development
Newfront



Arturo
Perez-Reyes
Cyber Lead
Strategist
Newfront



Eric Long
Executive Vice
President
Newfront

Agenda

- 01 Country Specific Policies for Clinical Trials
- 02 Management Liability Insurance
- 03 Intellectual-Property Risk
- 04 Top 10 Best Practice Insurance Management Processes

Country Specific Policies for Clinical Trials

What to consider when purchasing clinical trials insurance

- ✔ **Compliance with regulatory requirements** is vital to successful implementation of international human clinical trials
- ✔ **A US-based Product Liability/Clinical Trial policy will not meet the regulatory guidelines** in most countries
- ✔ **Many of these countries mandate that insurance coverage be placed with an Insurer that is locally licensed** to underwrite insurance “in country”
- ✔ **A separate no-fault policy is frequently needed,** often written in local language
- ✔ The **limits of insurance** that the sponsor is required to purchase **vary from country to country**
- ✔ Many countries **obligate the sponsor to evidence proper insurance coverage before an ethics committee (EC)** to approve a clinical trial
- ✔ Many territories require that an **insurance policy period span the full duration of the clinical trial** including patient follow-up, rather than the more common 12-month policy period
- ✔ **Contract Research Organizations (CROs) should not procure insurance on the Sponsor’s behalf.** They are not licensed insurance brokers and, as such, cannot manage a claim on the Sponsor’s behalf

What to consider when choosing your clinical trial insurance broker

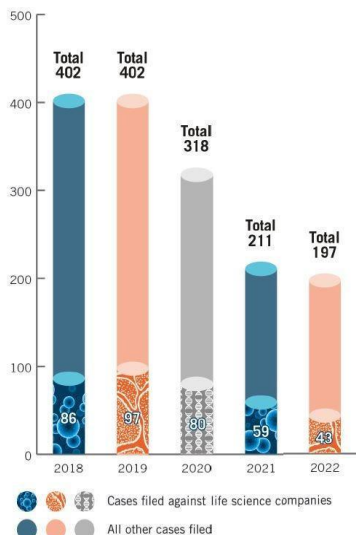
- ✔ **Your insurance broker should understand the challenges faced by the life sciences industry** and have the experience and expertise to enable you to make the best decisions and implement the right solutions.
- ✔ Insurance broker should **work in partnership with insurance carriers** to ensure a Sponsor obtains broad and compliant coverage.
- ✔ **Access to a user-friendly electronic portal accessible 24/7** from anywhere in the world to navigate country insurance requirements and streamline clinical trial submissions in over 160 countries.
- ✔ Important that **your insurance partner provides efficient, reliable and time-sensitive service.** Expedient certificate and policy issuance is very important to meet rigorous clinical trial timelines.
- ✔ The broker should have **access to global regulatory and compliance information** to ensure Sponsors have the correct advice.
- ✔ It is critical that **claims management SOPs** with insurance partners include attorneys that reside in each country and speak the local language.

Management Liability Insurance

02

Public Company D&O Claims Trends

Number of class action securities fraud cases filed from 2018–2022 (Total cases filed compared to cases filed against life science companies)



Decrease in Litigation

Total filings against life sciences companies in 2022 (43 lawsuits) represented a 27.1% decrease from the previous year, and a 51% decrease from five years prior.



Consistent Proportion of Filings

Consistent with recent years, life science companies remain a popular target of securities class action lawsuits, accounting for nearly one in four filings.



Claims Against Smaller-Sized Companies

In 2022, about 60% of the life sciences companies named in securities class action complaints had a market capitalization of \$500M or less. This trend represents a slight increase from filings in 2021 and 2020.



Litigation Venue

Consistent with historic trends, the majority of suits were filed in the Second, Third and Ninth Circuits. Within these Circuits, the Northern and Central District Courts of California had the second most suits nationally.



Allegations

Allegations were consistent with prior years, focusing on misrepresentations regarding product efficacy and safety (49% of claims), regulatory hurdles (40%), unlawful conduct (21%) and M&A/IPO/transaction activity (25.6%)

U.S. Public D&O Market Environment

Life Science Rate Trend Q4 2022



RISK PROFILE

Publicly-traded life science companies are differentiated predominantly by: clinical/regulatory stage (with earlier stage companies generally viewed more favorably); cash runway; and indication. With other factors (e.g. claims history and market cap) playing a lesser role.



FAVORABLE CONDITIONS

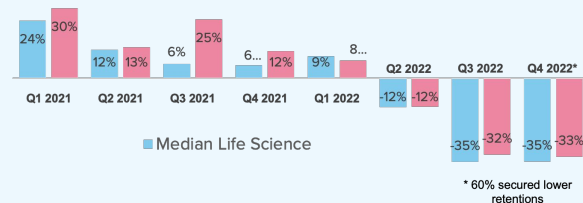
Aggressive budgets set by newer market entrants and some legacy insurers, combined with a lack of IPO opportunities, created a more competitive renewal environment in 2022. Renewal results are contingent upon risk profile, but we expect the bulk of renewals in 2023 will see some form of premium relief and, potentially, retention reductions, with recent IPOs or de-SPACs seeing the greatest improvements.



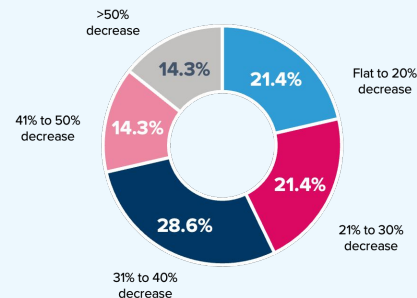
EXCESS LAYERS

A more competitive excess rate environment resulted in many clients achieving greater savings on excess layers than primary. Excess rates have historically ranged from around 65% to 85% with current rates nearer the low point of that range. Companies with challenging risk profiles may see excess rates at the top end of the range.

Renewal Rate Trend



Q4 2022 Rate Change Distribution



OUTLOOK

Many insurers are hopeful premium reductions will slow in the second half of 2023. Newfront expects the pricing environment to remain favorable, but for clients that significantly improved programs at last renewal, replicating the level of improvement in 2023 may be challenging.

D&O Takeaways for In-house Counsel

1

Get involved in the process

2

Be familiar with your policy before you have a claim

3

Ensure that you have appropriate limits

4

Thoughtfully select your insurers

5

Understand that D&O policies are not “off the shelf”

Employed Lawyers Liability Insurance

What is it?

Professional liability insurance to protect in-house attorneys against allegations of malpractice

- Potential claimants include: creditors, customers, vendors, competitors, shareholders, employees, and government regulators (bar associations)
- Types of claims: negligent advice; defamation, breach of fiduciary duty, malicious prosecution

Who is an Insured Person?

Employed lawyer is often defined as “any person admitted to practice law anywhere in the world who is, was or becomes a full-time or part-time employee of an Organization for the purpose of providing legal services to the Organization.”

Typically, coverage will extend beyond employed lawyers, to also include legal assistants/paralegals, as well as contract and temporary attorneys.

What does it cover?

When purchased on a standalone basis, coverage extends beyond legal services rendered to the employer, to include pro-bono activities, notary services, as well as moonlighting services

What does it cost?

Relatively inexpensive (depending on size of legal department and limits purchased)

Can often be included as part of the D&O policy at no added cost, but there are potential drawbacks to this approach

Intellectual-Property Risk

03

What is at risk?

Tangible versus intangible assets

Agrarian economy key asset is tangible: land

Industrial economy key assets are tangible: the means of production

Knowledge economy value is driven by intangible assets

Research, knowledge, communication networks, brand, intellectual property

Risk management of intellectual assets

- Identify and quantify assets
- Protect and mitigate loss
- Transfer and finance exposures

Value of IP

Goes far beyond GAAP definitions of “intangible assets” like goodwill

Exclusivity

The value of an IP asset comes from the legal right of owners to bar competitors from using it.

Quantification

The asset generates a measurable amount of economic value. Example: it increases the valuation of the firm

Or it enhances the value of other assets associated with it or the firm. Example: a brand vs a reputation

Future benefits

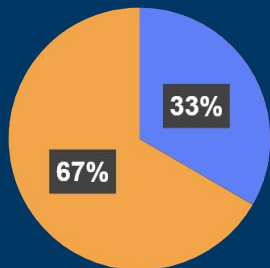
IP will be monetized by integrating it into a product

It will be monetized by the sale or licensing of IP to third parties

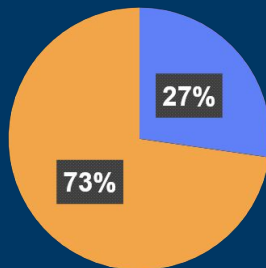
It will contribute value by raising barriers to entry, reducing the threat of substitutes, or creating FUD

GAAP vs Market Cap

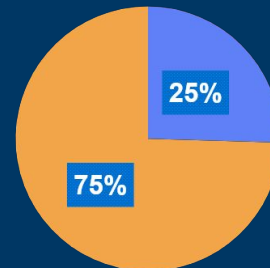
Novo Nordisk



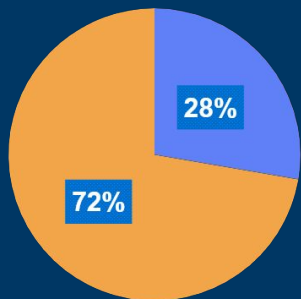
Moderna



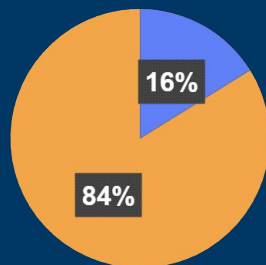
Incyte



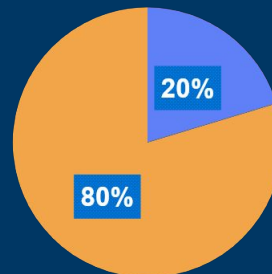
Jazz Pharma



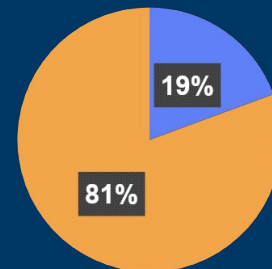
Vertex



Novartis



Merck



IP Perils

Litigation is the continuation of competition by other means

Title

- Cost to secure and defend
- Impact of loss is impairment or loss of the asset

First party

- Cost is enforcement expenses
- Impacts from loss of market position or firm valuation

Third party

- Cost of defense
- Impacts are injunctions and court-ordered damages

IP litigation: frequency and severity

In the US, there are **5,000** and **6,000** patent case filings each year.

In 2020, US courts awarded **\$4.67 billion** in patent damages.

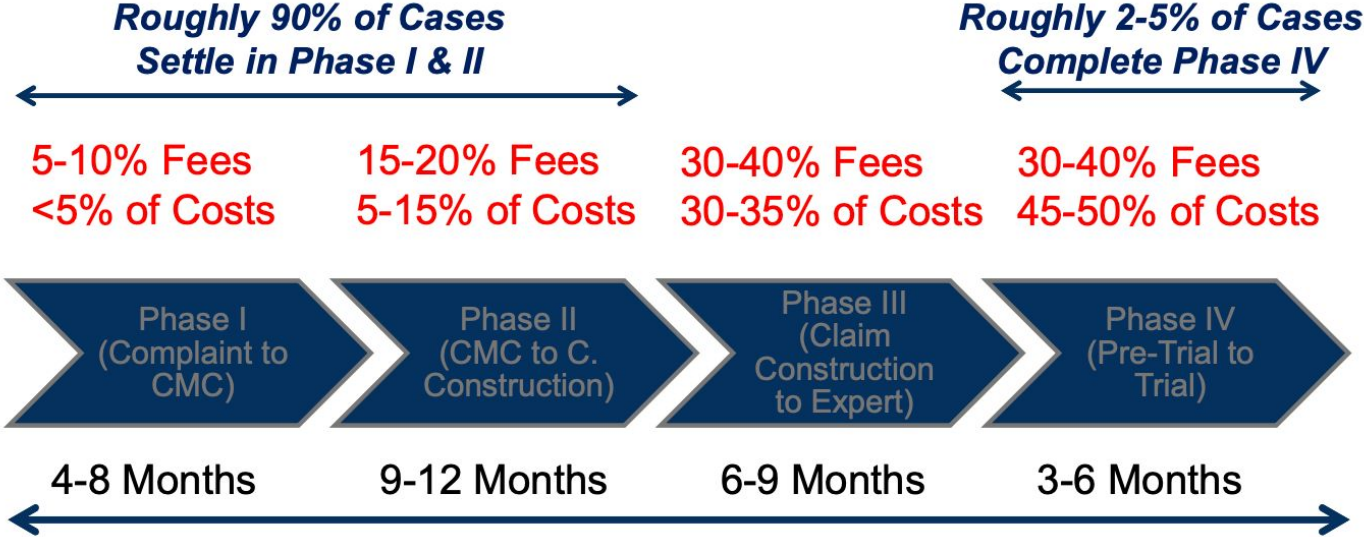
The average cost was between **\$2.3 million** and **\$4 million**.

The average length of preparation was **three years** before trial.

Patent-infringement suits settle at a rate of **95%** to **97%**.

Patent troll lawsuits **grew 500%** in the last decade.

Patent-litigation timeline



2.4 Years (Average)

How do you manage IP?

Prepare for the worst; expect the best; and take what comes

—Hannah Arendt



Do you seek freedom to operate opinions?



Do you license or seek IP indemnities from customers, suppliers, vendors?



Do you regularly monitor IP in your industry sector?



Have you created and implemented IP policies and procedures?



Do you have an IP committee? Do you have an in-house or outside IP counsel?



Do you have experience with IP disputes or litigation management?

IP and insurance

Gaps in your insurance coverage for half of your IP.

None for patents and secrets

Four kinds of IP

1. Trademarks
2. Copyrights
3. Patents
4. Trade Secrets

Limited insurance

GL – Coverage is limited to copyright and trademark in advertising

Cyber, PL, E&O, Media – Coverage is limited to copyright and trademark

IP insurance

Covers patents and trade secrets; can back contractual indemnities

Can also cover copyright or trademark

IP Insurance

Specialized line of coverage that few brokers know or place

Comes in six flavors

1. Liability
2. Abatement
3. Invalidation
4. Reps & warranties
5. Deal-facilitation
6. Alternative-risk

Limited markets

1. IPISC
2. Kiln
3. Liberty
4. CFC
5. RPX

Differences

Adverse selection
Two-step underwriting
Non-commodity pricing
High deductibles
Co-insurance
Can back indemnities

Top 10 Best Practice Insurance Management Processes

04

Top 10 best practices for risk & insurance

- 1 Engage your broker in strategic plans** including IPO, M&A, etc as there are insurance implications and also deal tools available such as RWI.
- 2 Work with broker to create an informed plan around the local insurance requirements** for planned global clinical enrollment.
- Launch **early renewal updates** and develop a **pre-renewal strategy** with broker.
- Develop a **contractual review process of Indemnification and Insurance provisions of contracts** with your broker.
- Plan for claims** (IRP, tabletops, etc) to adhere with insurance policy terms and panel of resources.
- 6 Avoid claims** – e.g. train entire employee population on recent phishing trends and build processes for out of band authentication (OOBA).
- 7 Early reporting of claims.** engage broker following receipt of complaint to avoid undue friction or denials for late reporting.
- 8 Proactively schedule quarterly risk & insurance reviews** with your broker.
- 9 Monitor large capex investment and changes with supply chain** in CDMO's, CRO's, 3PL's, etc to make sure there is limit adequacy in StockThroughPut.
- 10 Leverage technology** to make your job easier.

Q&A

Thank you

If you would like more information or have further questions please contact:

- Cristina Varner | cristina.varner@newfront.com
- Eric Tausend | eric.tausend@newfront.com
- Arturo Perez-Reyes | arturo.perez-reyes@newfront.com
- Eric Long | eric.long@newfront.com



License #0H55918 Newfront Disclaimer: The information provided is of a general nature and an educational resource. It is not intended to provide advice or address the situation of any particular individual or entity.

Any recipient shall be responsible for the use to which it puts this document. Newfront shall have no liability for the information provided. While care has been taken to produce this document, Newfront does not warrant, represent or guarantee the completeness, accuracy, adequacy or fitness with respect to the information contained in this document. The information provided does not reflect new circumstances or additional regulatory and legal changes. The issues addressed may have legal or financial implications, and we recommend you speak to your legal and financial advisors before acting on any of the information provided.

Newfront
∞