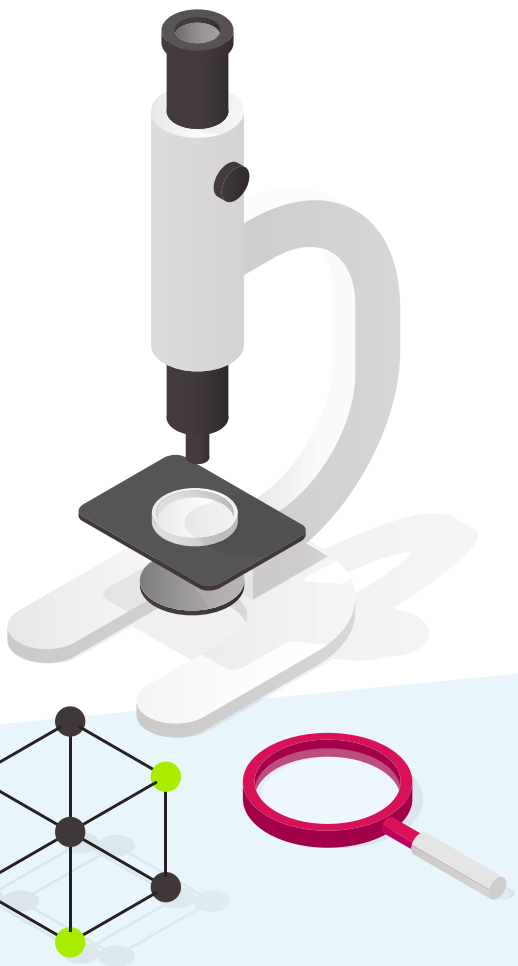
Exposures during the research & development lifecycle



There are many types of life science companies involved in the research and development (R&D) of new drugs and medical devices, but they generally fall into two camps, biotechnology firms that develop the drug or device, and service organizations who help bring those products to market.

The exposures that biotechs and service organizations face will evolve throughout the R&D process, and how quickly each company moves through this journey will depend on their individual product but can take anywhere from a few months to a few years.

We've outlined the phases of the R&D process to help you talk to your life science clients about the key exposures they face they discover, develop and test their products.

Discovery

Initial research into the disease

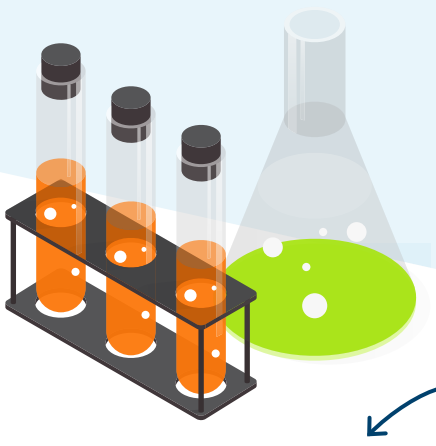
▶ Companies are relatively uncomplicated at this stage, with a handful of employees and limited tangible assets. They'll have limited reliance on supply chain partners but may use an external consultant or license technology from a third party. Their primary liabilities include directors & officers liability, public and employer liability as well as basic property cover.

Supply chain partners & consultants

Biotechs will often bring in subject matter experts to advise them during these phases, or they may license IP from a third party to support their work. Those offering services to a biotech must think about protecting their professional liability, unintentional breaches of contract and use of intellectual property.

Development

The process for confirming and then refining a molecular target



▶ The biotech may develop their product at a third-party pre-clinical testing laboratory. This can expose them to property losses and business interruption, and it is also the first time their stock moves and is stored out of their control.

Pre-clinical testing

Using animal models to determine the safety and efficacy of the drug for human trial approval.

Contract research service (CRS)

CRS firms are hired by biotechs to perform testing that will help them prove the safety of their drug and gain approval to conduct a human clinical trials. Testing is expensive and the failure rate is high, so CRS firms will have a significant professional indemnity exposure as errors during this process could lead to substantial financial loss.

Manufacturing

Initial production of the product

▶ To facilitate a clinical trial, the biotech will need to produce a large amount of the product. This process is often outsourced to one or more CMOs, which means the stock could be exposed to loss, temperature and atmospheric changes while in transit or at partner sites. Their business interruption exposure has also increased at this stage.

Contract manufacturing organization (CMO)

Among other things, a CMO will manufacture stock for the biotech to use in a clinical trial. Quality control is essential, as any errors in production, contamination, delays or damage to the stock could impact the trial, cause bodily injury to participants or result in financial loss to the biotech, for which the CMO would be responsible.

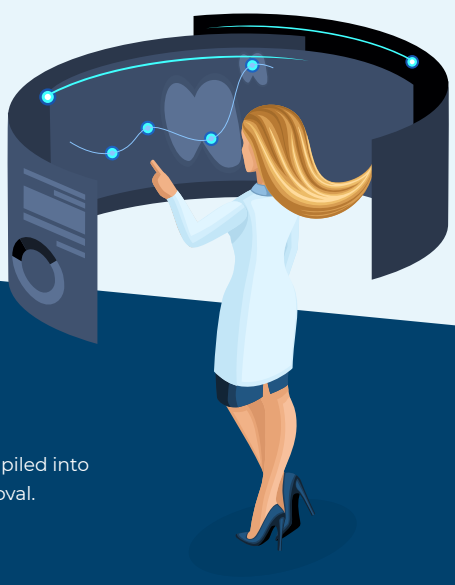
Clinical testing

Clinical testing will determine the efficacy and safety of the product. There are four phases of testing, referred to as Clinical Trials Phase I to IV.

▶ During testing, a biotech is now exposed to the risk of causing actual bodily injury or harm as result of adverse reactions to their investigatory drug. They will continue to have property damage and business interruption exposures, but to a lesser degree as the stock may be split over several locations and will diminish with use.

Clinical research organization (CRO)

A CRO may take on responsibility for recruiting patients, in addition to creating protocols and running the trial. They may be exposed to financial loss claims if the trial is mismanaged or generates inaccurate data, and they can also be liable for bodily injury claims. CROs are also exposed to general liability and employer liability losses as a result of facilitating the testing.



Product approval

With support from consultants, the clinical trial data is compiled into a report and submitted to regulators for market approval.

For more information about CFC's life science insurance products for business, visit our website, or contact the team at lifescience@cfcunderwriting.com.