



# Moving from clinical trials to commercialization

The expanding risk landscape for emerging pharmaceutical companies and tips to help keep yours on track.

# Moving from clinical trials to commercialization

Clinical trials are now complete, and your pharmaceutical company is ready to begin commercial production to take your innovative new drug to market. It's an exciting time, and it is easy to think that the difficult work is mostly behind you.

However, the pharmaceutical industry is full of cautionary tales from companies who clear trials with a new drug only to fall short of expectations or are derailed by factors they've discounted. According to a recent article from McKinsey & Company,<sup>1</sup> there are several key areas companies in this sector should focus on as it pertains to risk management. They include:

- Involving C-level executives in the risk management process.
- · Making risk management an enterprise-wide initiative.
- Focusing on new and emerging threats, as well as regulatory compliance and monitoring.

As your organization transitions to commercial production, it faces a host of new issues, and developing plans for addressing them safely is key. Failure to manage these risks could result in a significant interruption to your operations, non-compliance with pharmaceutical regulations, reduction in the quality of your product and much more. Risk management is likely not the top item on your to-do list, but it may be one of the most important issues for you to address.

# Consider your organization's answers to the following questions:

- Is your organization prepared if a patient or group of patients files a products liability lawsuit?
- Where are the weaknesses in your supply chain and manufacturing processes?
- · How is your organization handling staff training on approved drug uses, and what can be done more effectively?
- How secure is your organization's network and what technology and/or policies do you have in place to protect sensitive data?

<sup>1</sup>Expanding horizons for risk management in pharma



While the potential risks your organization will need to manage are vast, there are four specific areas which can be especially problematic for the continued health of your growing business.



# **Expanding your manufacturing capacity**

Increasing your manufacturing capacity to meet commercial demand can lead to many potential risks, such as sourcing new vendors, managing the quality and safety of your product, and ensuring that you have a plan for exposures within your supply chain. Potentially crippling manufacturing risks can spring up from multiple directions. Understanding and planning for these exposures can help keep your organization on a growth trajectory.



# Maintaining your technology and information security

Data breach exposures are everywhere, and as your pharmaceutical company expands its operations, your data risks grow as well. Understanding where your exposures are, securing your customer and trial data, and understanding the risks associated with your vendors' access to data are key to reducing the likelihood of a reputation-shattering or business-interrupting incident.



### Developing a post-market surveillance plan

Just because drug trials are behind you doesn't mean there are no new lessons to be learned about your product. From pharmacovigilance and failure-to-label concerns to understanding real-world evidence about how your product is working, addressing your post-market surveillance risk is vital.



### Scaling your team

Your growing team is tasked with expanding the business and discovering new markets and customers. Adequate training, understanding approved product uses and being able to recognize potential off-label use by doctors and patients, are all key exposures that need to be planned for. Managing typical business risks, like those which arise from having your team members on the road and traveling internationally, is also key to controlling your growing risks.

On the following pages, you'll find a deeper analysis of each of these key risk areas, as well as examples of how things can go wrong. Use this guide to help your leadership team and investors understand the risks associated with moving from clinical trials to commercialization as you plan for your company's continued growth and success.

Important note: The risks described in this document are intended to facilitate consideration and evaluation, and are not necessarily based on actual events. In addition, they are not a representation that coverage exists or does not exist for any claim or loss under any insurance policy or bond sold by Travelers or other carriers. Coverage depends on the facts and circumstances involved in the claim or loss, all applicable policy or bond provisions, and any applicable law. Some risks may not be insurable. Companies should consult an independent agent or broker to evaluate what coverage is right for them.

The "actions to consider" described in this document are also intended to facilitate consideration and evaluation of how risks can be mitigated. These are not direct guidance or advice on what actions should be taken. Other actions may be appropriate, depending on the circumstances. Companies should consult an independent agent or broker to evaluate what risk management products or services are right for them.

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# **Expanding your manufacturing capacity**

Your product is out of clinical trials and into commercial production, meaning your manufacturing needs are now significantly different than they were just a few months ago. Are your current vendors still your best option? Is your supply chain capable of providing the new, higher ingredient quantities needed? What about quality? Maintaining the quality of ingredients and processes is critical, as allegations of a manufacturing defect or contamination are common in products liability lawsuits.



# **THE RISK:** Supply chain interruption

Political turmoil has prompted a supplier of a key ingredient to temporarily halt production. With no other identified vendors who can supply the ingredient, your organization has no choice but to slow production and miss filling orders.

# Supply chain management

Having a diverse and well-sourced supply chain for key materials can help keep your organization's manufacturing processes running at capacity. Changes in your supply chain are not likely to be made frequently. However, as you ramp up your manufacturing, you may need to source larger quantities of materials than your current vendors can supply. Qualifying new suppliers can take time and validating that they can meet your specifications is crucial. Whether you source from specialty suppliers or purchase products as a commodity, quality is paramount regardless of the vendor.

On occasion, factors beyond your control can interrupt your supply chain. Should you experience an abrupt, unplanned change, you will need to ensure that your product will continue to meet quality standards. Retaining multiple suppliers for critical materials can help assure you that there is a proven alternative in place should a supplier experience a business interruption.





# Expanding your manufacturing capacity (cont.)

The following steps can help your organization actively manage its supply chain and avoid several common issues:



Have all agreements reviewed by legal counsel experienced in multi-state or international contract law

(V) Know your suppliers and who supplies them

Require approval for any supplier process change

🕢 Develop a rigorous quality control program

Arrange for independent product testing

Have a backup plan in place before something goes wrong

Occument and retain everything related to your supply chain

Take the <u>Supply Chain Pressure Test</u> to find out how vulnerable your organization is.





**THE RISK:** Manufacturing standards and product safety

As demands for your product increase, your long-term manufacturing partner struggles to keep up with new order quantities. To optimize their process, they make a tweak to their systems that creates small inconsistencies in product formulation, causing some medication doses to fall short of agreed-upon standards. If you don't identify the formulation error before your product hits the market, it could cause significant issues for patients using the medication and may ultimately result in a lawsuit.

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# Expanding your manufacturing capacity (cont.)

# **Product safety**

As manufacturing ramps up, how do you ensure that quality control standards will be met with the increase in production? Is your manufacturer able to switch to substandard ingredients or a different manufacturing process without your knowledge? Are you protected if they do so? What systems do you have in place for consistent product and process monitoring?

A robust quality assurance program can help to address many potential manufacturing issues. From process and material controls to formal inspection and testing protocols, your quality assurance guidelines can make the difference between continued growth or a potentially devastating loss.

# Key implementation steps include:

- Transferring risk through active management of suppliers, and understanding local guidelines and regulations
- Managing supplies and imported goods
- Building safety into designs and processes
- Keeping essential records, including those pertaining to design, approval, sourcing, manufacturing, packaging and shipping
- **⋘** Enabling and reviewing customer feedback

The World Health Organization (WHO) offers a <u>variety of resources</u> that can help you develop or enhance your quality control programs.





# **THE RISK:** Airborne particles at the factory

Your new contract manufacturer operates with different systems and machinery than your former vendor, leading to an increase in the number of particles in the air. Without proper safety protocols, this could cause long-term harm to the workers at the facility, potentially exposing your company to workplace liabilities.

### **Workplace safety**

The safety of your employees and contractors is vital, but scaling up and the speed it may require, including hiring new vendors or incorporating new processes in production, can increase risks related to workplace safety. Making this a priority and incorporating safety protocols into your daily operational plans, and your organization's overall mission, can help ensure that worker safety is always top of mind. That can help protect the well-being of your workforce and your business, particularly when scaling up.

# Consider these steps as you implement or update your workplace safety plan:

- Evaluate risks, including past incidents and near misses
- Create (or update) a formal plan, and get commitment from all levels of the organization
- Communicate the plan within the organization and with key vendors; train employees and contractors
- Monitor, evaluate and improve as needed

Check out these key components of a safety management program.

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# Maintaining your technology and information security

According to the <u>2019 Travelers Business Risk Index</u>, cyber exposures are the top concerns for business owners across sectors. Every month, new data breaches in the healthcare industry make news.<sup>2</sup> A data breach can have a significant impact on the reputation and financial stability of an organization. Knowing where your data exposures are is key.



# THE RISK: Patient data security

From social engineering to ransomware attacks, there are many ways in which hackers will try to gain access to your data. Any unauthorized access can cause significant issues for your organization, especially if the data collected during clinical trials (which can include health history information on trial participants) is accessed. Any breach of this type can lead to significant financial, regulatory or reputational issues for your organization.

Personal Health Information (PHI), including information collected on participants from your clinical trials, is held to a higher standard than other types of data. The "Privacy Rule" in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) defines PHI as all "individually identifiable health information." This includes information relating to:

- An individual's past, present or future health condition.
- Treatment given to an individual.
- · Any healthcare payment an individual has made.

# HIPAA specifies the following general rules for safeguarding PHI for covered entities:

- Ensure the confidentiality, integrity and availability of all e-PHI compiled, received, maintained or transmitted.
- Identify and protect against reasonably anticipated threats to data security or integrity.
- Protect against reasonably anticipated impermissible uses or disclosures.
- Ensure workforce compliance.

Data security isn't just focused on patient data, however. Understanding the cyber regulatory landscape in the countries in which you operate is also critical, as information security legislation can vary widely. New, stricter laws that potentially increase the burden on your organization to secure and protect your data are being passed regularly. Those same laws make the penalties for failure to protect your customer or patient data more severe. Presently, fines under the European General Data Protection Regulation (GDPR) can amount to up to 4% of annual global turnover or €20,000,000, whichever is *greater*.³ Several recent fines under GDPR include:

- A hospital in the Netherlands was fined €460,000 for failure to secure its patient records.
- Following a digital attack on its website, an airline in the UK was fined £183,000,000.



<sup>2</sup>The 10 Biggest U.S. Healthcare Data Breaches of 2018

<sup>3</sup>The GDPR – How does it affect Pharmaceutical companies





# Maintaining your technology and information security (cont.)

These are only some of the fines levied in the first seven months of 2019 under GDPR. Regulators across the globe are focusing on data security and protecting digital assets, and a single incident can be devastating for growing organizations.

# Steps you should consider to help protect your organization before a breach occurs include:



Encrypting and backing up your data

Proactively managing your vendor data exposures

Oeveloping and following a data protection and destruction protocol

Procuring cyber insurance that includes business interruption coverage and liability

Source: 9 Key Elements of a Data Security Policy



# **THE RISK:** Vendor network security

As your product prepares to go to market and you scale up your production, you develop several new vendor relationships. As you share data with your new vendors to get them operating on your behalf, your mission-critical information is exposed on a new vendor's unsecured system.

So, what can you do? Ensuring that you and your vendors manage data security at the same required levels, and making sure that you have a contractually secured right to audit their systems (or requiring them to share independent audit results with you) are important steps. This allows you to monitor how they are securing their networks, helping to keep your vital information and data safe. As part of your vendor network auditing program, you should consider the following questions:

- Is your data stored on-site or off-site, who has access to the facility or data and how are access rights managed?
- How quickly, and by what means, does your vendor need to notify you if there is a breach?
- Does your vendor have adequate cyber insurance, and are you covered as an additional insured under their program?
- What happens to the data stored on your vendor's system if the relationship is terminated?

What about the vendors your business partners work with – is any information shared with multiple parties down the process chain? Your data is held to the same security standard no matter who owns the system that stores it, and you are responsible for poor security practices multiple steps away from your organization.

Also consider who would want access to your systems and data. From competitors looking for your trade secrets to bad actors looking to hold your data (and business) for ransom, risks to your systems can come from multiple sources. Having security protocols in place, such as multi-factor authentication and assuring that computers and storage devices with sensitive data are properly encrypted and protected, can help minimize the risks. Ensuring your backups are not vulnerable to the same attack vectors as your main systems is also key and can help you keep your business online with minimal disruption should a breach or ransomware attack hit you. You can't eliminate all of the risks to your systems and data, but you can take steps to minimize the impact.

Source: Are Cyber Attacks Threatening Your Business?





# Developing a post-market surveillance plan (cont.)

Once your pharmaceutical product is in the market, the post-market surveillance phase of product maintenance begins. Post-market surveillance helps your pharmaceutical company understand how your product is being prescribed, how it is performing and whether or not there are any side effects or unexpected issues. A robust program is critical to ensuring your organization can properly monitor the marketplace, make appropriate adjustments to the labeling of your product and issue timely product notifications based on field results.

# THE RISK: Inadequate monitoring program



Your pharmaceutical product, approved by the FDA to treat a specific issue related to kidney function, seems to also reduce joint inflammation for patients with arthritis. Several doctors begin prescribing the medication to arthritic patients without kidney issues. Your marketing team learns of the new treatment protocol and begins developing content specific to the treatment of arthritis. In the absence of regulatory approval of the new use of the product, you may face significant legal issues due to off-label promotion, which could result in a multimillion-dollar civil penalty under the False Claims Act.

A focused monitoring program enables your organization to uncover new indications and uses for your product, while determining what steps you'll need to take to secure appropriate regulatory approvals. Having a formal process in place for monitoring, apart from your sales team, is vital and can lead to lucrative new markets for your existing product. Additionally, your monitoring program can help identify side effects from product usage and the need to update labels accordingly. This can help you avoid "failure-to-label" or "failure-to-warn" lawsuits from patients using your product and experiencing side effects.

# Profit vs Revenue Chaly Sates Wolume

# Consider the following actions when developing your post-market surveillance program:

- Monitor quality of manufacturing and materials to assure product purity.
- Track and record all feedback received from the field.
- · Follow up on all adverse reports and document everything.
- Involve counsel when additional regulatory approval is needed.
- Update product labels as needed.

**Pharmacovigilance** is a key component of post-market surveillance and relates to the detection and assessment of pharmaceutical effects and the prevention of adverse outcomes. Following the thalidomide disaster in the early 1960s, pharmacovigilance was recognized as a necessary component of pharmaceutical production and an obligation within the industry. A strong pharmacovigilance program shows that a company is both responsible and circumspect and, when enacted properly, can enhance patient care and safety of medicines used.

The WHO's publication, <u>The Importance of Pharmacovigilance</u>: <u>Safety Monitoring of medicinal products</u>, is a great resource to bolster the topics in this issue and help implement a formalized program for your organization.



# Developing a post-market surveillance plan (cont.)

**Real-world evidence** (RWE) of drug outcomes and side effects can help your company discover new markets and gain approval for off-label uses more quickly than going back through the trials process. Regulatory agencies are becoming more accepting of RWE from the post-market phase when analyzing drugs for new usage approvals. One clear example of increased reliance on RWE is the 21st Century Cures Act, passed in 2016 in the U.S. The goal of the act is to speed the development of new medical products to patients who need them by relying on RWE instead of

going back through clinical trials.

Although randomized clinical trials are the gold standard for medical and scientific evidence needed to support FDA medical product approval decisions, they are often conducted in specialized and controlled research settings and can be time-consuming and costly. At the end of a development program, randomized clinical trials can still leave critical questions unanswered, particularly about the effects of a medical product after it is used by a broader population over an extended period. We are using powerful new scientific computing and data storage technologies to enhance our capabilities of gaining valuable information from RWE.



Your post-market surveillance program must include several required components and should include other elements that are often part of such a program but not required by statute. The <u>U.S. Food and Drug Administration offers a number of reports and guides</u> to help you get your processes up and running. Key considerations include:

- Maintaining quality of manufacturing and materials to assure product purity.
- Tracking and recording all feedback received from the field, and implementing corrections as needed.
- · Following up on all adverse reports and documenting everything.
- Establishing clear communication protocols for "Dear Doctor" letters to healthcare providers for any regulatory or legal changes.
- Updating product labels as needed.

Having a robust post-market surveillance program in place could help your team identify and address potential problems before they become unmanageable, and help you identify new, and – lucrative – markets for your product.





# Developing a post-market surveillance plan (cont.)



**THE RISK:** Marketing an unapproved use

After hearing through unofficial channels that your new product for kidney function also seems to help individuals struggling with arthritis, your marketing team develops a campaign targeting rheumatologists and touting the medication as an option for their patients.

# Product promotion and usage

The clinical trials provided your organization with an approved indication for your product. Making sure your sales and marketing team understands and works within that use case is vital. Marketing your product for a use not approved by the regulatory approval process can be a significant risk for your organization. Off-label promotion often leads to civil lawsuits and can even lead to criminal penalties. Verdicts in these suits are often in the tens or hundreds of millions of dollars and have even hit \$3 billion.4

### To avoid issues around an unapproved use, follow these tips:

Don't provide doctors or patients with free samples of drugs for unapproved uses.

Establish a formal review process for dissemination of materials from outside sources.

Set realistic sales goals based only on approved uses.

Source: Medical Product Communications That Are Consistent With the FDA-Required Labeling

Even if your marketing materials are compliant, your sales team must be vigilant about any off-label uses. Usage may be considered off-label when a pharmaceutical product has been prescribed or administered in an unapproved way, whether by indication, patient age or dosage. The practice is quite common, with more than 20% of prescriptions written in the U.S. for off-label uses.<sup>5</sup>

While off-label usage is both common and legal for prescribers, it is important for your sales team to be aware of the non-approved uses they hear about from doctors and clinicians. Be sure that any communications on these topics are routed through your organization's medical affairs team, not sales. Any response by the sales team could result in an off-label promotion lawsuit.

<sup>4</sup>GlaxoSmithKline to Plead Guilty and Pay \$3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data <sup>5</sup>Off-Label Drug Use: What You Need to Know



As your organization grows, it isn't just manufacturing that needs to scale up; your team will also likely need to expand to meet new business realities. Adding staff is exciting, but can also increase the risks you face, especially in the pharmaceutical industry. There are several areas in which you'll need to train your staff to keep your organization running smoothly and compliant.

# THE RISK: Insufficient employee training



In a rush to fill open sales positions, you hire a salesperson with a problematic driving history. While on the road for your organization, the salesperson causes an accident that severely injures multiple occupants of another vehicle. During litigation, the injured parties' legal counsel looks at your hiring and new employee training practices and finds that the salesperson's driving history was not reviewed before an offer was finalized. Additionally, he was not offered vehicle training when hired. These oversights can expose your organization to a significant legal judgment.

# Developing a formal training program

A new hire training program is a great way to onboard your new hires and help them understand how your organization and industry operate. It is also an opportunity to set clear guidelines as to what is expected of them while working for your firm. While no training program can guarantee you'll avoid problems, there are some key areas it should cover. One critical step in defining a curriculum is to identify the types of training your new employees will need, both in terms of skills-based and awareness-based training. Some of your onboarding will be valuable for all new hires, while other portions should be tailored to the specific requirements of a department or position.



Once your program is established, it is important that it is completed by every new hire, every time. Individual hiring managers instituting their own training programs, or not offering any training to their new team members, can cause a host of additional legal exposures. And training isn't just for new employees. Ongoing training is important in terms of refreshing skills or knowledge, and to ensure your team keeps pace with changes to equipment, processes or programs.

Source: How to Onboard and Train Employees into a Safety Culture

### A note about automotive risks

Despite technological innovations, much of the sales process in the pharmaceutical industry still takes place face to face, which means your sales team will be on the road to meet with current and prospective clients. Protecting both your employees and your business with a broad commercial auto policy is vital to the future growth of your business.

Source: Tips for Selecting Safe Drivers for Your Business

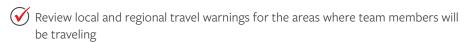


### THE RISK: Global business travel

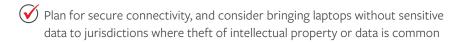
As your operations ramp up, members of your operations team must travel internationally to meet with business partners and potential vendors. What happens if a member of your staff is injured while overseas? Are medical services in the area adequate? If the injured party requires medical transportation back to your home country, how will those expenses be covered?

# Global business travel risks

Sometimes things go wrong when your team is traveling for business. From an injury to a stolen laptop, many issues are more complicated when they take place in a foreign country. Understanding the region where your team is traveling and being prepared if something goes wrong can keep a minor inconvenience from turning into a major problem. Consider these steps before your team travels internationally:







✓ Identify where local healthcare facilities are and what coverage will be needed

Encourage team members to consult with a medical professional and secure their medications before traveling

Source: Insights for High-Tech Manufacturers on Managing Global Risks



# Summary

Moving from clinical trials to commercialization can create a variety of new risks you'll need to manage. Let's take another look at the specific risks identified and highlight the specific actions you can consider to help reduce the risks for your organization.

# The risk: Supply chain interruption

Actions to consider: Actively manage your supply chain with the following steps:

- Know regulations and standards.
- Have all agreements reviewed by legal counsel.
- Know your suppliers and who supplies them.
- Require approval for any supplier process change.
- Develop a rigorous quality control program.
- · Arrange for independent product testing.
- · Have a backup plan in place before something goes wrong.
- Document everything related to your supply chain.

# The risk: Manufacturing standards and product safety

**Actions to consider:** Explore these steps as part of a product liability protection program:

- Transfer risk through active management of suppliers.
- · Manage supplies and imported goods.
- Build safety into designs and processes.
- Keep essential records.
- Enable and review customer feedback.

# The risk: Airborne particles at the factory

Actions to consider: Implement a safety management program:

- · Evaluate risks, including past incidents and near misses.
- Create (or update) a formal plan, and get commitment from all levels of the organization.
- · Communicate the plan within the organization and with key vendors, and train employees and contractors.
- · Monitor, evaluate and improve as needed.

# The risk: Patient data security

Actions to consider: Follow the HIPAA general rules for safeguarding PHI:

- · Ensure the confidentiality, integrity and availability of all e-PHI compiled, received, maintained or transmitted.
- Identify and protect against reasonably anticipated threats to the security or integrity of the information.
- Protect against reasonably anticipated impermissible uses or disclosures.
- Ensure workforce compliance.

### The risk: Vendor network security

Actions to consider: Ensure you have the right to audit your vendor's networks, and that you can answer the following questions:

- Is your data stored on-site or off-site, who has access to the facility or data, and how are access rights managed.
- · How quickly, and by what means, do your vendors need to notify you if there is a breach.
- · Does your vendor have adequate cyber insurance, and are you covered as an additional insured under their program.
- What happens to the data stored on your vendor's system if the relationship is terminated.



# The risk: Inadequate monitoring program

**Actions to consider:** Develop and implement a comprehensive program:

- Monitor quality of manufacturing and materials to assure product purity.
- Track and record all feedback received from the field.
- Follow up on all adverse reports and document everything.
- Involve counsel when additional regulatory approval is needed.
- Update product labels as needed.

# The risk: Marketing an unapproved use

Actions to consider: Keep your approved uses in mind and avoid the following:

- Don't provide doctors or patients with free samples of drugs for unapproved uses.
- Establish a formal review process for dissemination of materials from outside sources that mention unapproved usage.
- Set realistic sales goals based only on approved uses.

# The risk: Insufficient employee training

**Actions to consider:** Determine if these conditional-offer screenings are relevant to your hiring process:

- Eligibility for employment in the country where hiring is taking place.
- Driving record check for any employee who will be operating a vehicle.
- Background checks applicable to the position.
- Drug screening.
- Medical fitness based on job requirements.

### The risk: Global business travel

Actions to consider: Help staff prepare for risks they'll face when traveling:

- Review local and regional travel warnings.
- Safeguard personal identification and documents.
- Plan for secure connectivity.
- Identify where local healthcare facilities are and what coverage will be needed.
- · Secure medications and check with a medical professional before traveling.



# Insurance can help you manage risks

Risks to your company's success can come from multiple directions, and each has the potential to significantly disrupt your growth plans. How can you help protect your company and its success? One way is to work with an insurance carrier that has decades of experience working with companies in the life sciences space and that offers a substantial suite of coverages to protect your business.

Travelers brings the same innovation and dedication to our work that life sciences companies demonstrate in theirs. Our team, from our underwriters with extensive experience in the sector to our risk control professionals who help companies protect their businesses and reputations, is committed to life sciences. Our claim professionals have the right experience and expertise to handle the most complicated and high-exposure claims. Turn to Travelers for your life sciences sector insurance needs, including:

# Products/completed operations liability coverage, including for clinical trials

# CyberFirst®

Technology errors & omissions liability coverage

Network & information security liability coverage

Communications & media liability coverage

📝 Employed legal professional liability coverage

Expense reimbursement coverage

### **MedFirst®**

Products/Completed operations liability coverage

Frrors & omissions liability coverage

Information security liability coverage

Global Companion<sup>SM</sup> Business Auto

Umbrella Property

**Workers Compensation** 

Experience and innovation make Travelers the clear choice to protect your pharmaceutical company as you move from clinical trials to commercialization.



# Travelers provides solutions for life sciences companies

The risk landscape for growing pharmaceutical companies is constantly evolving, and companies must stay vigilant to stay on track. Travelers understands the unique needs of companies in this sector and will be there to help manage the risks as they grow and expand.



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