

# THE GREATEST THREAT TO R&D COMPANIES – A LOSS IN THE LAB

## Business Continuity Planning for Life Science Companies

Research and development projects consume vast resources—human and capital—and bumps in the road can greatly impact revenue, operating expenses, results, liability and property. Whether your business is creating a medical device or discovering a new vaccine, it's your research lab that offers the greatest potential and greatest threat.

And if unprepared, a loss in the lab can be catastrophic. Yet, in spite of these threats, few companies are prepared for these risks and haven't contemplated the insurance ramifications. We see time and again that the same companies that spend countless hours pouring over data, often fail to even scratch the surface of their projects from a risk management perspective.

Not all risk is created equal. Just ask a scientist. An early loss or interruption of an R&D project can cause a minor setback or a major, negative financial impact. It depends on many variables. Not only does a loss interrupt the project, but the trickledown effect can cause subsequent projects to be stalled or, worse, cancelled, leaving researchers with unproductive time, costly materials unused, and deadlines missed. Additionally, a loss could impact a company's future revenue stream.

It's not all bad news: Many potential losses can be avoided entirely or effectively mitigated if properly identified and addressed. And, some losses are insurable.

We recommend the following three steps:

1. Assess & Manage Risk
2. Quantify the Potential for Loss
3. Be Able to Document the Nature and Scope of Potential/Actual Loss



**BY DANIEL BRETTLER**

*Senior Vice President, Life Science & Technology Practice Leader, Conner Strong & Buckelew*



**KENNETH R. PIÑA, RPH, JD**

*Co-editor of "A Practical Guide to Food and Drug Law and Regulation"*

**CONNER  
STRONG &  
BUCKELEW**

## ASSESS AND MANAGE RISK

Time and again we hear the same question, “Our company wants to assess our risk, but where do we begin?” It’s simple really: Look deeper. Look where you have vulnerabilities or exposures. Look at your people, your processes and your procedures.

No matter the size of your company, an enterprise-wide risk assessment and management program is your best proactive defense against a potential loss. The cost of developing and maintaining such a program is less than you may think and the money saved in “disasters averted” can make a huge difference to your operation. Additionally, taking these steps can highlight the value of your executive team.

Conner Strong & Buckelew generally recommends a “crawl, walk, run” approach to adopting Enterprise Risk Management (ERM) techniques, recognizing the pragmatic need to capture “real victories” while also addressing more significant needs that could take longer to mitigate. Significantly, many identified risks take little time and expense to remedy—they simply require the focused, dedicated effort that results from a process, as well as an assigned accountability.

While there are many ways to get started, here are some ideas that are specific to the R&D area:

### 1. Isolate each project and determine current project stage.

In order to know how much risk exists in each individual project, it’s important to determine what percentage of the project has been completed and how much work is left. In addition, what is the length of your shortest project? How about your longest project? Knowing how much time has been put into a project and potentially how much of an investment is left can help give you a glimpse into where the risk lies.

### 2. Determine whether or not projects are interdependent.

In other words, if one project is interrupted or fails, would it cause another one to be delayed or fail completely? To effectively protect your company from loss, you must understand if and where there is a domino effect that could lead to a broader intellectual property and financial loss.

### 3. Identify how researchers are assigned to projects.

This is important and often overlooked. If a project is interrupted, stalled or worse, fails, and a researcher was solely hired to work on that one project, will the individual have work to do? What will the researcher do with their time? Will they be a productive or non-productive asset?



### 4. What obstacles will keep you from getting an interrupted project back up and running again?

Oftentimes, while tracking the details of an R&D project, companies lose sight of what will happen if a project is interrupted. Will the materials, equipment and personnel be available? Can regulatory validation be accomplished in a reasonable time frame? At what delay and what cost?

### 5. Look at the big picture. It’s important to review your overall R&D budget.

Do you budget on a project-by-project basis? What percentage of the budget is related to internal work versus outsourced projects? Also, keep in mind your ongoing operating expenses related to projects, like payroll. You must understand what the total annual investment is so you can properly protect your organization.

### 6. Back up your work. It’s the most basic advice from an IT professional: save early and often.

Within R&D, it’s an equally important mantra. But, it’s not that simple. What type of system do you use? Is it reliable? Effective? How frequently does it save your work? By saving critical project materials, you can minimize interruption effect. Each R&D project should be assessed individually to determine the appropriate back-up system that maximizes your potential, while minimizing cost and interruption to your workflow.

### 7. Consider what duplication exists in critical project materials.

Is an important compound the building block for multiple projects within your company? It’s often the case that separate projects share a similar source material or equipment. What steps can you take to ensure the safety of this important resource is protected?

---

## QUANTIFY THE POTENTIAL FOR LOSS

Once you have looked below the surface to expose where your risks lie, the next step is to assess what your specific loss impact would look like over a given period of time. You need to quantify losses in a variety of categories should a loss or interruption occur. When quantifying loss, companies must also address the potential impact on revenue and operating expenses—How would a delay in taking a product to market impact the overall revenue/expense picture?

One of the most commonly missed areas when assessing risk is lost productive time of employees. If you hired a researcher or technician to work on one specific project and that project is interrupted, what would that individual do? Could you transition them to another project? If not, are you obligated to retain them? What if the work in one project is halted and interrupts another project? Will those employees be without work too? Essentially, depending on the structure of your organization—the work flow and the project correlation—your risk could be limited to a specific segment of your operations or could have a domino effect causing significant delays to multiple projects, decreased revenues, unproductive employees, and ultimately, a negative bottom line impact.

Another overlooked area is hidden losses. Do not discount your incoming cash flow. Money from corporate partners and incoming grants could also be affected by interrupted projects and the length of time it takes to get them back on track. You must account for future company revenue as well as what you're currently bringing in money-wise.

---

## BE ABLE TO DOCUMENT THE NATURE AND SCOPE OF POTENTIAL/ACTUAL LOSS

The last essential point in protecting your company is being able to prove a loss. It's absolutely essential that you work to create best practices for internal documentation. You must have a system of routinely backing up documents and processes so that in the event of an interruption you will be able to get the project back up and running as efficiently as possible—and without burning up additional resources. Importantly, source documents, not those that need to be manufactured after the loss, will prove valuable.

It is recommended that records be backed up and duplicated on a monthly or quarterly basis. Of course,

it is worth mentioning that the very best way to back up documents is to do so in real time. However, there can be a heftier cost associated with real-time duplication. Also, once the documents are backed up and duplicated you should allocate a place to keep them where they will be protected and available should an interruption occur and you need to review them. Again, source documents proving the completed stages of your research, help quantify and prove your loss.

Last but not least, many R&D organizations within the life science space work with third-party companies throughout varying stages of the project process. It's important to not only include basic insurance requirements in these contracts and specificity on which party will be responsible for damaged property, but also include provisions for additional financial loss and consequential losses that may be related.

---

## CONCLUSION

R&D projects are risky. When successful, they offer tremendous rewards. But they also pose danger because of the amount at stake. A loss at any point, depending on the project and its relationship to your business, can have a crippling impact. It can negatively influence your financial success, employee productivity and material production. The goal isn't to simply remove risk—the risk is where your reward lies—the goal is to insure your business in the event of a loss or at least understand the risk you may choose to assume.

Proactively performing an assessment of R&D risks and developing strategies to manage these risks through the use of Enterprise Risk Management techniques is an important consideration. Annual ERM assessments not only help to prevent losses, they also serve as a valuable tool to help senior management focus limited resources on projects and issues that have the greatest impact upon the organization's ability to achieve both short and long term strategic objectives.

Bottom line—properly assessing and managing risk, quantifying loss and, if necessary, proving loss, will help you and your organization be successful. So, go ahead, take a dive beneath the surface and see what a difference it will make.



CONNER  
STRONG &  
BUCKELEW