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## Six risks to intellectual property

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While partnerships play an increasingly critical role in the drug development lifecycle, a poorly structured partnership can expose your intellectual property (IP) to considerable risk. By understanding six common sources of risk, you can take steps to protect your investment.



### Documentation

If collaborators have inconsistent documentation practices, you must assume that IP defense will be judged on the lower of the two standards. Your investment can be put at risk if a partner does not share your compliance with appropriate local and international regulations including: signing and witnessing lab records, fully documented evidence trails, and recent US procedural requirements to keep electronic lab records in their original electronic form. If a partner were to lose data or witnessed signatures, you run the risk either of failing to adequately support your claims or that the partner might subsequently falsify this information to redress the losses.

### Advanced disclosure

Disclosure of data before patents are filed is always a concern, but this risk is exponentially greater in a collaborative environment. Policies relating to the presentation or publishing of data can vary greatly between organizations, particularly in academic environments that place greater weight on public disclosure. Technology has also increased the number of communication channels, including conferences, papers, grants submissions, webcasts, email, chat, podcasts, and wikis. Each new communication medium makes it that much more difficult to monitor a partner's activities.

### Adverse data

Failure to identify and address adverse data findings is another source of risk for research organizations. During legal proceedings for patents or efficacy, these 'skeletons' can put your investment at risk. Recognize the implications of the procedural and technical measures that your partner uses to identify potential issues with drug safety, efficacy, or stability; as well as notes or collected evidence that fails to support your scientific hypotheses.

### Organizational risks

When considering the risks of collaboration, it's natural to focus on paper and electronic records. Unfortunately, even the company's personnel policies can create risk for your investment. If a partner loses a scientist affiliated with your project, you can lose access to months – even years – of knowledge. If the only other record of the scientist's work is a paper notebook, the odds of recovering that knowledge fall dramatically.

#### Patent filing and defense

Once the research is completed, your partner must assist in identifying and protecting your research. This includes: findings that match the raw data, human readable and printable records in acceptable forms (such as XML and PDF), preservation of time/date stamps and signatures by inventors and witnesses, preservation of the audit trail for the records, and authenticating that the records are original and have not been tampered with.

#### Preservation

Even after a patent has been protected, your partner's procedures could still undermine the profitability of your investment. Regulatory agencies require many records be retained long-term, in some cases beyond even the end of the patent. This includes disaster recovery, data backup, role-based access controls, audit trails, computer system security, and other measures that will help safeguard your R&D investments. Indeed, you must even look beyond the partner's procedures and consider their longevity as well. If the company may not survive to meet regulatory requirements, you must address the preservation of critical IP.

#### Conclusion

Partnerships can deliver tremendous benefits through innovative technologies, lower costs, greater speed and agility, and a range of talent and expertise not practical to maintain within a single organization. However, the value generated in a partnership is realized not through the contents at the bottom of a test tube, but rather through the creation, capture, and exploitation of the resulting knowledge, records, and intellectual property (IP). With great opportunity comes great risk, increasing the necessity of protecting your investment by enforcing adequate procedural and technical controls both within your organization and within your partner's. Be certain you can trust – and verify – the results of collaboration; your success is at stake.

*Jeff Spitzner, Ph.D., has more than 20 years experience in management of scientific software and biotechnology companies and has been recognized as a leader in electronic lab notebooks (ELNs), bioinformatics, and knowledge management. He is currently President and Chief Science Officer of Rescentris, and is the visionary for information solutions to protect R&D investments and improve science and business performance. He received his Ph.D. from The Ohio State University, where he is now Adjunct Asst. Professor of Biomedical Informatics, and postdoctoral studies at MIT.*

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