



# Your IP at risk in collaborations!

## Ten steps to protect your R&D investment within partnerships

The R&D landscape is changing for the life sciences industry and it is increasingly important to collaborate to carry out key activities across the drug development lifecycle. Partnerships of many sorts can deliver tremendous benefits through innovative technologies, lower costs, greater speed and agility, and a range of talents and expertise not practical to maintain within a single organization.

The value generated in a partnership is realized today not through a final report and a compound at the bottom of a test tube, but rather through the creation, capture, and exploitation of the resulting knowledge, records, and intellectual property (IP). There are also substantial risks associated with partnerships that, if not addressed effectively, can put your entire project's investment in jeopardy. Listed here are ten common risks associated with protecting IP in R&D collaborations - with strategies to overcome these risks and maximize your rewards.

1. **Quality recordkeeping?** Bringing new drugs and diagnostics to market requires approvals by patent and regulatory agencies. Your efforts may be perfect, but the weak link in your strategy may be outside your firewall, where your partner's recordkeeping practices may be putting your filings at risk if they do not strictly adhere to documented practices. This includes following SOPs for signing and witnessing lab records, as well as ensuring the evidence trail is fully documented. Do you know how to identify and avoid the hazards of inconsistent practices that may jeopardize your IP? Are all of your partner's recordkeeping practices up to international regulatory standards? Will regulatory agencies agree with your assessment? You must enforce common recordkeeping practices as rules every partner must play by.

2. **Paper Lab Notebooks?** It is not easy to monitor your partner's paper lab notebooks for compliant recordkeeping. They are also hard to secure, but easy to lose or to falsify records. Paper notebooks are not searchable, not readily shared, and it is difficult to track due diligence in reducing concepts to practice. Beyond IP, there may be unknown scientific gaps and missing data and procedures. What happens if a critical employee leaves? Is the scientist's data fully documented and organized for future use? What are the risks associated with recovering lab data and records from handwritten paper lab notes? Consider an electronic lab notebook (ELN) for accessible, searchable, and readily usable and auditable lab records.

3. **Hidden data risks?** Can you ensure that your partners have no undisclosed adverse data that might reveal potential issues with drug safety, efficacy, or stability? Have scientists past or present made any notes or collected evidence that fails to support to your scientific hypotheses? Have you reviewed raw data to minimize potential for scientific misconduct? You must be able to search data archives to identify gaps in knowledge, unsubstantiated conclusions – or any signs of skeletons in the attic – to assess scientific risks. Then you can retest or take actions to mitigate risks. There are always unknowns, but instituting good data management practices and technologies such as ELNs, LIMS, and DMS helps minimize the cost of these data risks later in the project by finding issues early. You might also uncover buried treasure in these repositories. The CERF ELN is well suited to review the lifecycle of R&D data.

4. **Preserving records?** To protect your IP, your partner must do more than simply capture good records. Regulatory agencies require many records be retained long-term (beyond the end of the patent). You must ensure that your partner manages records in compliance with all the appropriate international regulations. This includes: 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.

Furthermore, records must be future-proofed. The solution is to develop collaborative IP and records management strategies and use an ELN like CERF with secure and non-proprietary digital technologies.

**5. Regulatory compliance?** If your partner is not maintaining compliant recordkeeping systems then your IP in the project is at risk. Your joint compliance strategies must extend to maintaining institutional controls over physical and electronic data and systems as well. 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. Paper-based systems are hard to maintain and audit.

**6. Accurate and complete records?** What are your partner's practices for maintaining integrity of lab data and records? Could you detect any instances of deliberate scientific fraud – such as alterations of data or missing/falsified lab results? Do patent and regulatory findings match the raw data? Take steps to enable real-time access and monitoring of data, plus periodic audits. An ELN facilitates this.

**7. Reinventing the wheel?** Are you able to find and reuse scientific knowledge – such as key lab methods and assays, and procedures to prepare materials or analyze data? Time is critical for patents, and finding critical data – or essential expertise – quickly may be the difference in gaining a crucial patent. Insist on readily searchable knowledge-bases for lab data, documents, and records. Best is to be able to integrate, synthesize, and mine all the information your partners generate for your collaborative projects – for speed, decision-making, to gain new valuable insights, and to minimize scientific risks. Are you agile enough?

**8. Disclosure of data?** Your partner's release of data before filing patents is also your release. Prevent inappropriate or inadvertent disclosures of information with policies that govern presentation/publishing of data in conferences, papers, grants, meetings, and communications (including email, chat, wikis). Enterprise information systems facilitate sending of links to only those with suitable access privileges, and track the use and flow of data to protect your IP. CERF supports the controls and review processes.

**9. Prepared for legal proceedings?** Regulatory, patent, and government funding agencies all require proper recordkeeping. This includes access to raw data, properly signed and witnessed documentation of the scientific evidence trail, and key data used to prove findings. Are you ready to provide this on demand today? Would you or your partner have to redo work if challenged to produce data and records? U.S. Federal Rules of Civil Procedure have changed recently and may require producing electronic lab records in original electronic form – are you prepared? Will agencies agree with your records management practices? Is IP managed properly in your partnership? What will happen if you need to bring your joint lab records to court next month? Make sure you are ready to protect your IP. CERF is designed to help.

**10. Are you the IP risk in the partnership?** Everyone in the extended organization has the responsibility to identify and address potential hazards in order to protect the intellectual assets that are the true value produced by R&D projects. Implementing an ELN is a great time to assess and improve your practices.

**Conclusion.** Protecting lab data and records is critical to securing IP. Partnerships are essential for business reasons, but they create additional IP risks that must be addressed. As you enter into collaborative R&D projects, be sure to assess risks and implement controls and best practices into your partnerships. Be able to trust - and to verify - because your success is at stake. See whether CERF can help you retain controls and drive the greatest rewards from your investment in research and development.

**About us:** *Rescentris, Inc. is the provider of the Collaborative Electronic Research Framework "CERF" - enterprise software to help organizations protect their R&D investments and intellectual knowledge assets. CERF combines electronic lab notebook (ELN) and scientific content management to collect, secure, share, and leverage data and lab records in collaborative projects.*