

The Pros and Cons of Using Virtual Data Rooms for Due Diligence



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Pharmaceutical and biotech companies, strategic partnering divisions of contract research organizations (CROs) and investment firms are entering into alliances and joint ventures at an ever-increasing pace.¹ As the incidence of these product-based investing transactions increases, so does the number of hours and resources needed to conduct due diligence. In an effort to trim escalating due diligence costs and reduce transaction time, companies are increasingly using electronic databases and virtual data rooms (VDRs)^{2,3} to allow access to confidential information simultaneously by multiple users and to permit central version control.

This article discusses why these virtual tools are gaining popularity and explains some of the reasons they cannot deliver the complete answer to streamlining the product partnering and investment due diligence process.

For the purposes of this article, the potential partner (seller) is the entity owning the product(s) and/or intellectual property (IP) and desiring capital/resources/additional IP/etc. The partner (buyer) is the entity conducting the due diligence investigation and considering providing the desired services, additional IP and capital. Due diligence is the process of investigating an investment or partnering opportunity to mitigate risk.

Types of Electronic Databases

Investing venture capital in pharmaceutical products is risky business, requiring careful evaluation of the potential investment and/or prospective partner company. All venture capital firms and company investment arms perform due diligence prior to investing money or becoming involved in a partnership arrangement. Part of this evaluation involves reviewing confidential data. This review is typically performed by an initial electronic transfer (usually via email) of less-proprietary electronic data followed by a data room visit by a group of experts to view highly confidential information in hard copy. These experts are usually matched peer to peer, i.e., partner to potential partner.

Two types of electronic databases may be encountered in the due diligence process. The first type of electronic database is limited to the traditional on-site data room environment where computers are used instead of hard-copy information. The computers have access to an internal database (e.g., created by the internal information technology department [IT], or vendors like Documentum and Core Dossier). Direct access to electronic documentation in this style is limited by access time and the number and quality of computers and viewing screens. Although these databases could be accessed remotely, for purposes of confidentiality, partners are rarely granted such access.

The second type of database is part of an Internet-based system. A virtual data room (VDR) is an Internet site with limited access that is controlled using a secure logon supplied by the vendor/authority, which can be disabled at any time.⁴ Because most information is confidential, restrictions are applied using digital rights management to limit the viewer's ability to release it to third parties by forwarding, copying or printing. VDRs are the focus of the remainder of this article.

Internet Based Data Rooms

To address historic concerns regarding travel costs, time constraints of R&D and commercial experts, and the inability to track data sharing, vendors have created Internet-based solutions that allow the posting and tracking of an almost unlimited amount of data. (What limitations do exist are primarily cost-related.) A seller or potential partner can post selected documents—including clinical data, regulatory data, commercial data and intellectual property data—on such Internet-based sites. Because the posting fee is usually on a per-page basis, potential sellers may wish to post the minimum amount of data needed to close the transaction. The partner, on the other hand, usually wishes to see all the data and may request additional documents to be posted as quickly as possible.



Advantages

Historically, most documents were viewed on site or sent via email or postal mail. While they are still effective means of communication today, these transmissions are difficult to trace (i.e., files can be printed, copied or shared) and can be time consuming. Also, very large electronic documents often must be broken down into smaller pieces to permit passage through corporate email filters. The combination of the highly proprietary and confidential nature of the diligence information and the lack of control raises issues for sellers.

In contrast, electronic databases and VDRs can be quickly populated with electronic documents by a small number of individuals. Document size can range from small (e.g., basic business presentations, early discovery findings, platform technologies, preclinical or pre-IND documents) to very large (e.g., an entire NDA submission in CTD format). In addition to speed, these methods offer the ability to tightly control and measure access (i.e., read only, no printing, etc.). As such, VDRs have been gaining popularity—especially among those who work in the pharmaceutical industry’s in-licensing sector.

The benefits of a VDR are weighted more in favor of sellers than buyers. One key advantage for sellers is simplifying the conduct of the due diligence process by permitting access to more than one buyer simultaneously. This is especially true for an outlicensing/auction process. If the seller can use this approach to minimize staff inconvenience and redundancy, the return on investment (ROI) is justifiable.

Consider other advantages:

- Newer databases have more features for customizing searches for different document types.
- Databases are customizable, limited usually only by cost, imagination and time.
- Electronic databases have the ability to restrict access to key individual reviewers and decision makers. They can allow access to different areas at different times depending upon clearance level (i.e., limited vs. full).
- Systems can track and document the amount of viewing time, limit use to read only and prevent printing and saving.
- Smaller firms, usually resource-constrained, can use VDRs to save time for executives who might otherwise

spend it on due diligence activities.

- Electronic databases are very efficient and can even trace and juxtapose written electronic conversations with electronic Q&A sessions so that written documentation of all issues discussed can be made available and referenced at a later time.
- In a global industry, remote data access reduces the travel burden.
- Remote data access also allows switch-like control of access to data in different electronic “rooms” as well as control of timing (e.g., for one week only, 8:00am–5:00pm daily, etc.).

Disadvantages

Due to the length of the drug development process (often more than five years before reaching phase 2 or 3) and the use of different vendors, documents usually come from different sources and often utilize different software programs (e.g., Microsoft Word, Excel and PowerPoint, Portable Document Format (PDF), etc.). Thus, it may be impossible to cross-search and view multiple documents at the same time.

As stated previously, the benefits of a VDR favor the seller, not the buyer. The seller can make it difficult for buyers to have the same access to documents and discuss them with the same information at hand. Limiting or preventing printing means a computer is necessary to view the documents. Sellers can also eliminate the ability to download documents, thereby complicating buyer team collaboration.

Consider these other disadvantages:

- VDRs reduce the time for face-to-face interaction. This can hinder the line of thinking or questioning between seller and buyer that often generates additional questions from different functional area experts. It is the author’s experience that a back-and-forth question and answer session—involving multiple functional experts from both sides—often quickly identifies the real issue behind an issue, e.g., dosage change or problem identified in FDA meeting minutes that might otherwise require more time-consuming and less-spontaneous interaction.
- A “gatekeeper” must be assigned to ensure that documents are controlled

and posted in a timely manner. This can entail special passwords and sometimes provides the impetus for potential partners to require every individual who views the confidential documents to sign a CDA, as opposed to one signature for the entire team, making the process cumbersome for the buyer's due diligence team.

- Physically, it is difficult to review electronic documents for prolonged periods of time. Prolonged computer screen viewing can lead to eye, neck and back strain and fatigue.
- Despite advances in technology, difficulty persists in comparing information between disparate formats (e.g., searching Word, PDF and PowerPoint files at the same time).
- VDRs can include real-time question-and-answer periods via virtual chat rooms; however, potential sellers tend to discourage this because personnel need to be made available for such discussions. Online chat can provide immediate feedback and group interaction, but lacks the opportunity to read nonverbal clues (see next bullet).
- VDRs limit nonverbal assessment. For example, since most language (more than 60%)⁵ and meaning is expressed not in words, but, rather, through gestures, expressions and body language, it may be more difficult to gauge the ability of a seller's management team to deliver on a future clinical drug development program.
- Involving legal counsel to review documents with possible redaction may be a burdensome process with electronic records. For instance, some privacy laws may limit information that may be included about the potential partner's employees.

Summary

Virtual data rooms are growing in popularity and can provide a useful adjunct to due diligence activities. They can be a central repository for confidential data. VDRs can also offer controlled access to data outside a physical data room environment and allow potential

partners increased flexibility.

Despite their advantages, VDRs cannot substitute for face-to-face or group interactions that allow immediate feedback. They are biased in favor of the seller due to cost savings gained by avoiding the need to run through the due diligence process individually with a number of buyer companies.

REFERENCES

1. PriceWaterHouseCoopers report. "Global Pharmaceutical Company Partnering Capabilities Survey—Summary of Results," 2000.
2. Merrill DataSite website, virtual data rooms. www.datasitedeal.com/seo15/?c1=fall06-due+dil&source=adwords&kw=due%20diligence (Accessed 25 January 2008.)
3. Due Diligence Database website. www.dunwalke.com/gideon/legal/background/DesidnBk/map_rah.htm (Accessed 25 January 2008.)
4. Wikipedia. http://en.wikipedia.org/wiki/Data_room (Accessed 25 January 2008.)
5. Henman L. "Keys to Nonverbal Communication: It's Not Always What You Say." www.growmybusiness.com/managing-small-business/articles/cm_whatYouSay.asp (Accessed 4 February 2008.)



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