

DUE DILIGENCE CHECKLIST

FOR LIFE SCIENCES

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Helping biotechs and pharma organizations prepare for successful fundraising, partnering and securely sharing documents with partners and investors.

DUE DILIGENCE CHECKLIST BACKGROUND

Biotech companies understand the importance of aligning with strategic partners in order to advance their drug candidates to market. To do so, it is important to have everything a potential partner, acquirer or investor would need to see in order to make an informed decision organized in a virtual data room. The following due diligence checklist is an example of the materials that should be populated in a virtual data room from the earliest stages of the drug development process.

Remember, although it would be logical to assume that strategic alliances are more likely to be formed the farther your drug candidate is along the drug development process, the reality is that many deals are done early. In fact, data shows that as many as 50 to 60 percent of deals done in recent years were done at pre-clinical or discovery stages. This underscores the importance of having a virtual data room populated with comprehensive due diligence materials available at all times.

I. CORPORATE OVERVIEW

- Corporate Presentation
- Executive Team
- Advisory Board
- Corporate Structure

Include information on the overall company and its focus.

II. INVESTMENT OVERVIEW

- Non-Confidential Introduction
- Confidential Introduction
- Q&A Responses

Include information that can be accessibility staged for the different levels of the due diligence process

III. COMMERCIAL STRATEGY

- Commercial Overview
- Market Research
- Competitive Analysis
- Commercial Forecasts

IV. PRE-CLINICAL PROGRAM

- Program Overview
- Completed Studies
- On-Going Studies
- Planned Studies

Include a description of all studies, timing and status

V. CLINICAL PROGRAM

- Program Overview
- Completed Studies
- On-Going Studies
- Planned Studies

Include a description of all studies, timing and status

VI. REGULATORY

- Investigator's Brochure
- (IB)
- IND
- Regulatory
- Conversions
- Other
 - Orphan
 - Quality
 - SOPs

Include all current documents and an archive of historical regulatory documents

VII. INTELLECTUAL PROPERTY

- Patent Estate
- Granted Patents
- Pending Patents
- Other Legal

Include all U.S. and foreign patents and applications owned by and/or used in the course of business

VIII. MANUFACTURING

- Facility Overview
- CMO/CDO Contracts
- Process/Process
- Validation
- Other
 - Polices & Procedures
 - Inspections
 - Certificates



Contact us to have the file structure above pre-populated in a ShareVault data room, or download the Excel version and simply drag and drop the folders into your ShareVault.



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