### Preclinical Development of Technology

- **Clinical Planning**
  - Regulatory Strategy
  - Protocol Development
  - Legal Input
  - Risk Assessments

- **Study Logistics**
  - Develop Risk-Based Oversight Plans (PM, DM, RBM, Auditing)
  - Identify Needed Resources (EDC, eTMF, DSMB)
  - Vendor Evaluation and Selection

### Clinical Trial Lifecycle

#### Risk Assessments
- **Clinical Planning**
- **Study Logistics**

#### Proactive Risk-Based Oversight & Subject Protection
- **Study Implementation**
- **Ongoing Study Management**

#### Study Integrity & Evaluable Data
- **Study Closeout**
- **Regulatory Submission and Product Approval**

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