**Design Study**

Learn About Feasibility and Regulatory Requirements

- **Cohort Finding**
- **Evaluate Study Feasibility**
- **IRB Approval**
- **Regulatory Support and Resources**
- **Protocol Development**
- **Consent Development**
- **FDA Device (IDE) Submission**
- **FDA Drug or Biologics (IND) Submission**
- **Scientific Review**
  - Explore Funding Opportunities & Budget Preparation
  - **Identify Funding Opportunities**
  - **Proposal Preparation and Submission**
  - **Data Management Planning**
  - **Set Up Research Budgets**
  - **Overview of Coverage Analysis**
  - **Billing Codes and Research Pricing Information**
  - **CTSI Integrating Special Populations Program (ISP)**
  - Seek Study Design Assistance & Resources
  - **Request a CTSI Ethics Consultation**
  - **Research Data Management Best Practices (Consultation)**
  - **Review Project for HIPAA, Privacy & IT Security Requirements**
  - **Biostatistics - Information and Consultation**
  - **Study Design - Information and Consultation**
  - **Clinical Data Related to Research - Electronic Health Record**