BRIGHT Research Partners Services

Clinical and Regulatory Strategy

Study Design and Approval
- Create and maintain Master and Site Files
- Identify, qualify and contract key vendors
- Study Protocol development
- Statistical strategy and analysis
- Statistical and randomization plan development
- Case Report Form development
- Informed Consent development
- Investigator's Brochure development

Study Site Establishment
- Investigator and Site selection, qualification, budget and agreements
- IRB and EC management
- Safety Committee planning, selection, and support (CEC, DSMB)

Study Start-up and Launch
- Manage and control investigational device process
- Develop, implement, and support
  - Database and Data Management Plan
  - Monitoring
  - Training

Regulatory Assessment
- Identification of applicable regulation and guidance
- Requests for Classification or Designation

Global Regulatory Strategy Development
- Q-submission (pre-submission) packet & meeting support for regulatory, pre-clinical and clinical inquiries
- Regulatory planning for original and modified technologies

Clinical and Regulatory Execution

Study Execution
- Site initiation visits
- Subject enrollment support

Study Management
- Assess impact of changes (planned and unanticipated) and perform related documentation updates and reporting
- Monitor sites
- Assess adverse events and complete related documentation and reporting
- Manage Safety Committee and Key Vendors (core labs, database)

Study Close-out
- Perform Data Analysis
- Write Final Report
- Perform site closure activities
- Close and transfer study records

Global Market Authorization, Registration, and Licensure
- U.S.: 510(k), IND/IDE, de novo, HDE, PMA
- EU: Technical file documentation and design dossiers for CE Mark
- Canada and Rest of World (RoW): Registrations and license applications

Labeling, Marketing Claims, Promotional and Advertising Materials
- Content development
- Compliance review

Ongoing Regulatory Support
- Device listing and establishment registration
- Regulatory file documentation
- Supplements/amendments
- Interim and annual reports
- Agency and Regulatory Body communications and meeting support

Other Services
- Auditing (IRB, Study) and Inspection Preparedness Activities (FDA and Notified Body)
- Board and executive presentations
- Investment (VC) due diligence
- Key Opinion Leader (KOL) introductions and networking
- Literature reviews
- Medical coding (MedDRA and WHO-DDE)
- Procedure development (sponsor, core lab, study-specific)
- Study rescue
- Documentation, Registration and Administrative Support

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