BRIGHT Research Partners Services

A Clinical Research Organization (CRO) for medical device-focused research

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
- 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 (On-Site and Remote)
    - 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
- Venture capital (VC) investment 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
- Other documentation, registration, and administrative support

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