Clinical Trial Continuum Chart

I

PHASE I - IDE APPROVAL AND CLINICAL STUDY START-UP

- FDA Negotiations and Responses
- Clinical Site Qualification and Selection
- Reimbursement Review and Analysis
- Plan Investigator / Coordinator meetings
- CTA, LoA Development and Approval

II

PHASE IIA - CLINICAL PHASE (INITIATION)

- Ongoing Communication with FDA
- Clinical Site Qualification and Selection
- Initiate Site Qualification Visits
- CTA, LoA Development and Approval (Inclusion of New Sites)
- Coverage Support for IDE Category B Devices

PHASE IIB - CLINICAL PHASE (INTERIM)

- Patient Enrollment
- Data Collection
- Interim Monitoring Visits
- Data Management
- Interim Study Statistical Analysis
- Coordinate Payments to Study Vendors, per CTA LoA Terms

PHASE IIC - CLINICAL PHASE (COMPLETION)

- Resolution of Outstanding Queries
- Site Close-Out Visits
- Database Lock
- PMA Development and Submission

III

PHASE III - REGULATORY SUBMISSION

- Summary of Safety and Effectiveness Data/Labeling
- Statistical Analysis for Post-Approval Study Planning
- PMA Submission
- Pre-Approval Payor Messaging

IV

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