DOCUMENTS
Adverse Event Report
Advertisement
Approval to Ship Drug
Assent
BioSketch
CAP Certification
CLIA Certification
CLIA Certification Waiver
Clinical Trial Resp Log
Clinical Trial Site Info Form
Confidentiality Agreement
Conflict of Interest
Contract
Correspondence
CV
Data Use Agreement
DEA Form 223
Debarment Letter
Drug Destruction Policy Form
EDC Assessment
Electronic Signature Form
Enrollment Log
FDA 1572
FDA Compliance Letter
Feasibility Questionnaire
Financial Disclosure
FWA Assurance Number
Gender & Minority Enroll Form
HC No Objection Ltr
HIPAA Authorization
Human Subj Protection Training
IDB Amendment
Informed Consent Form (ICF)
Instructions for Use
Interest Letter/Form/Pack
Inv Drug Brochure Sign Page
Inv Summary of Patient Data
Investigator Agreement
Investigator Drug Brochure
IRB Adv Approval Letter
IRB Amendment Approval Letter
IRB Approval Letter
IRB Close-Out Letter
IRB Membership Roster
IRB Registry Number
IRB Renewal Letter
IRB/IEC Correspondence
JACHO Certification
Lab Certification

DOCUMENTS (cont.)
Lab Normals
Master Subject Log
Medical License
Memo
Monitor Activity Documentation
NIH MOA MOU
Other
Package Insert
Personnel Report
Protocol
Protocol Amendment
Protocol Amendment Sign Page
Protocol Signature Page
Protocol Synopsis
Qualified Inv Undertaking
REBA
REBA Waiver
Regulatory Document Checklist
SCOTT Approval
Screening Logs
Signature Log/Auth Form
Site Information Sheet
Site Selection Documentation
Site Visit Log
State Required Document
State/Provincial Certification
Test Article Documentation
TGA Approval
Trial Specific Document

TRAINING
ACC (Annual Meeting)
AHA (Annual Meeting)
Booster Visit
Certification Training
CRA Training
EDC Training
Human Research Training
InForm Training
Investigator Meeting
Novice Investigator Training
On-Site Training
Pathology Training
Radiology Training
Steering Committee Meeting
Surgical Certification
Teleconference Training
Therapeutic Area Annual Mtg
Trial Specific Training
Web Based Training
Web Conference

MILESTONES
Activated for Enrollment
All Patient Follow-Up Complete
Close-Out Pack Sent
Close-Out Pack Complete
Contract Executed
Contract Sent
Core Lab Approval
Device Sent
Enrollment Complete
First Subject Enrolled
First Subject Randomized
First Subject Screened
Interest Letter/Form/Pack
Investigational Product Order
Investigational Product Sent
IRB Approval
IRB Meeting
IRB Submission
Lab Supplies Sent
Reg Docs to Sponsor
Reg Pack Received
Reg Pack Sent
Reg Pack Sent for 2nd Review
Regulatory Complete
Regulatory Docs sent to FDA
Review Commmittee Approval
Review Committee Submission
Site Hand Off
Site Qualified
Site Selection Form Complete
Site Training Complete
Starter Box Sent
Trial Master File Review

OTHER REQUIREMENTS
General Site Information
Site Qualification