

Imaging in drug trials – Pharmaceutical perspective

Linda M. Velasquez, MS, CCRC
Imaging Operations, Bristol-Myers Squibb

CTSA IWG activities at ACRIN meeting
Wednesday, Sept. 29, 2010
Arlington, VA

Imaging in Clinical Trials

Imaging biomarkers in drug development focus on physiologic, biochemical, and molecular properties of the compounds and their targets

- Imaging biomarkers provide tools for:
 - Noninvasive sequential/multiple sampling (virtual biopsy)
 - Qualitative localization/Quantitative assessment
 - Assessment of mechanism of action /target validation
 - Monitoring /prediction of therapeutic drug treatment response
 - Optimizing drug dosing/dose schedule
 - Creating opportunities for personalized medicine

Imaging Operations

- *Academia - CCRC* - 'Standard' imaging
 - Not very prescriptive
 - Protocol defined modality / time point
 - Site SOPs – acquisition / analysis
 - Quantitative assessment required
- *BMS - LVO* - 'Standard'/'Exploratory' Imaging
 - Associated with early phase treatment protocols
 - Additional guidelines - acquisition / analysis
 - Site SOPs – scanner QA/QC
 - Quantitative assessment required

60+% acceptable data

Imaging Impact

Need to improve quality/quantity of submitted data

- Standardization of images / data across sites
 - Allows for completion of the study sooner and with much less time, effort and money
 - Ensures robust dataset supporting critical decisions
 - Early Phase – progression to full development
 - Late Phase – regulatory contributions
 - Supports development/validation of response assessment criteria
 - Repeatability
 - Benefits patients; asset moves faster through the regulatory process and sooner to market
 - Personalized medicine

Imaging Core Labs

Leverage imaging core lab/CoE expertise optimizing oversight and maximizing quality

- Site / Scanner qualification
- Pro-active patient/scan tracking
- Multiple acceptable submission methods
- Real-time QA/QC scans and data
- Very prescriptive
 - Scanner qualification
 - Image acquisition
 - Data / image submission
 - Image analysis

Site Selection

Typical Expectations

- Feasibility questionnaire
 - Modality specific question bank
- Technical evaluation
 - Scanner, equipment and contact details; completed by imaging staff
- Image manual training
 - WebEx/TC; occasionally on-site
 - Participants should include: imaging physician, technologist, study coordinator
- Qualified site registry
 - Site imaging capabilities will feed into site selection tool

Site Contributions

Sponsor expectations for participating imaging sites:

- Communication between the clinical team and imaging team
- Assurance that required imaging qualification and training procedures are completed prior to subject scanning
- Adherence to image acquisition and analysis guidelines ensuring consistent results
- Accuracy and consistency in image/data collection
 - Timely image / data submission

Site/Sponsor Partnership

Supporting the imaging component of a clinical trial provides:

- Development/implementation of state of the art imaging
 - New methodologies
 - Image acquisition techniques
 - Image analysis tools
- Critical data enabling the progression of state of the art assets
- Participation in advances in imaging and drug development

Culture Shift

Continuous improvement

- Sponsor/site shift supporting imagers as PI/Co-PIs
- Allowing imaging capabilities to influence site selection
- Supporting standardization of protocol, charter, acquisition guideline and data point collection
 - Sensitivity to local SOPs allowing ranges as possible
- Site shift from standard of care to research imaging
- Enabling scanner qualification to encompass many trials
 - SNM / ACR accreditation

Thank you!