Imaging in drug trials – Pharmaceutical perspective

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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!