Two Topic Imaging Workshop

1) Standards for imaging endpoints in clinical trials

2) PET drug manufacturing

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Why standardization?

Imaging endpoints frequently used in multicenter clinical trials

- challenges in data quality/verification
- poor standardization = variability
- standardization guidance due by 2011
Why PET CGMP?

PET current good manufacturing practices (CGMP) published 12/2009

- NDAs/ANDAs must be submitted for all PET drugs “for clinical use” by 12/2011

- working toward NDA/ANDA submission
...our goals

1) Public input to help identify:
   - What to standardize?
   - How to standardize?

2) FDA PET drug manufacturing tutorial:
   - What do I need to do?
   - How do I do it?
In standardization discussions…..

- Consider major contemporary imaging modalities: U/S, nuclear med, CT, radiography, MR…other?

- Concepts

- Applicable to current and future clinical trials…multiple purposes…not necessarily to “validate a biomarker” nor “establish clinical correlates”
In PET discussions….

Focus on practical aspects of submission…expectations are set

Engage with questions and solutions
Standardization

Speaks for itself!