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!