Molecular imaging is the visualization, characterization, and measurement of biological processes at the molecular and cellular levels in humans and other living systems.

**CURRENT PROBLEMS**

- Industry has not yet recognized the importance of defining PET imaging parameters at the front-end of clinical trial design (not after the protocol is complete and sites have been selected).
- Deviations in radiopharmaceutical manufacturing practices by those providing PET agents.
- Inadequate protocol- and procedure-specific training and materials for imaging study personnel.
- Disparity in the validation requirements and parameters of clinical PET equipment being used at clinical sites.
- Selection of clinical sites without qualified PET imaging centers that are validated on a defined schedule to ensure standardization of data.
- Variation in imaging methodology = non-reproducible data unsuitable to support NDA incorporation in clinical trials.

**MOLECULAR IMAGING EXAMPLES**

**Response to Therapy: FDG PET/CT Imaging**

**WHY PET/CT VS CT ALONE?**

- Guide physicians in adapting treatment plans in response to cellular changes.
- Assess patient response to specific therapies and the effectiveness of a specific treatment regimen.
- Determine extent, severity or progression of oncologic disease.
- Identify the optimal biopsy location for disease confirmation.
- Plan the most effective therapy based on the unique biological characteristics of the patient and the molecular properties of a tumor/disease.

**MOLECULAR IMAGING CAN HELP TO:**

- Assess patient response to specific therapies and the effectiveness of a specific treatment regimen.
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**HOW WE CAN HELP**

CTN offers the pharmaceutical industry and investigators assistance in key areas:

- **Scanner Validation and Phantom Program:** Standardize PET/CT scanners used in multicenter clinical trials. This unique phantom testing program compares image quality and quantitative measurements at data devices and image noise similar to clinical imaging conditions and cost rates. Phantoms are available for oncology, neurology, brain and cardiology trials.
- **Education:** Assist research personnel in the requirements for performing clinical research by offering a comprehensive curriculum that includes courses on the importance of following the study protocol, good clinical practice guidelines and federal regulations for clinical trials.
- **Trial Design:** Encourage industry to develop the most accurate imaging protocol at the front end of their trial design. Imaging trial design experts are available in oncology, neurology and cardiology.
- **Imaging and Manufacturing Sites Registries:** Maintains an international registry of sites that have the ability to provide standardized molecular imaging data to support therapeutic trials. CTN’s “reporting tool” provides industry partners with vital information on over 400 clinical imaging and radiopharmaceutical manufacturing sites around the world to aid in selecting qualified sites and determining where investigational biomarkers are available.
- **Centralized IND:** Provide access to investigational molecular imaging biomarkers for use in clinical research. Drug companies “cross-reference” the CTN IND for the imaging agent being used with their investigational drug.

**CTN NUMBERS AS OF 6-30-12**

- 29 Countries in the CTN Imaging Site Registry
- 126 Sites with CTN-Validated PET/CT Scanners
- 202 CTN-Validated PET/CT Scanners

**CTN-VALIDATED PET/CT SCANNERS (202)**

- US (147)
- UK-Europe (25)
- Australia (8)
- Canada (8)
- Asia (14)

**MOLECULAR IMAGING CAN HELP TO:**

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**Molecular Imaging is not only an essential component for the diagnosis and management of diseases, it can also contribute to more efficient and cost-effective healthcare by ensuring use of the most appropriate therapies and sparing patients from unnecessary treatment. Incorporating molecular imaging in clinical research offers an additional mechanism for clinicians to make better treatment decisions, and it is becoming a vital part of NDA applications. However, implementing it in an appropriate manner that provides reproducible data and supports the therapeutic drug is crucial. The Clinical Trials Network (CTN) of the Society of Nuclear Medicine and Molecular Imaging (SNMMI) was founded in 2008 to address this issue.**