SOCIETY OF NUCLEAR MEDICINE AND MOLECULAR IMAGING

CLINICAL TRIALS NETWORK

CTN VISION

The CTN will take a leadership role in advancing the use of radiopharmaceuticals and optimizing the use of molecular imaging in clinical trials and dissemination into clinical practice.

CTN Mission

Advance the use of molecular imaging biomarkers in clinical trials through standardization of chemistry and imaging methodology. This includes using imaging biomarkers during the course of drug development, as well as bringing new radiopharmaceuticals to regulatory approval.

CTN Goals

Goal 1: Ensure high quality PET and SPECT imaging in the conduct of drug development clinical trials

Rationale:
Past experience in clinical trials involving PET imaging has often resulted in a large fraction of inadequately performed imaging studies.

Objectives:

1. Demonstrate the value of molecular imaging in clinical trials
    a. Gather metrics from completed studies to derive successful imaging rates

2. Educate and assist clinical trial imaging sites to be effective and successful in clinical trials involving PET imaging.
    a. Update and maintain registry and phantom program
    b. Assist with the design of study - specific imaging protocols
    c. Develop standardized imaging protocols, standardized image acquisition guidelines/imaging methodology for PET Radiopharmaceuticals

3. Outreach to the community for exploring need for SPECT

4. Develop marketing and outreach plan to CROs, pharmaceutical companies, biomarker developer companies
    a. Revise pricing model

Goal 2: **Work towards use and approval of new radiopharmaceuticals**

Rationale:
The CTN is uniquely positioned with the FDA, NCI, industry, and the academic nuclear medicine community to assist in defining the pathways toward regulatory approval of new radiopharmaceuticals.

Objectives:

1. Collaborate in the broader SNMMI initiative of the FDA Task Force

2. Develop the plans for FACBC, Ga-68 DOTA agents, FLT and other non-proprietary agents
    a. Drug development plans including timelines and cost for each agent
    b. Funding plan for each agent
    c. Discuss specifics with makers of precursors on availability and cost

3. Assist biomarker developers with the development of their proprietary radiopharmaceuticals

Goal 3: **Facilitate access to investigational PET radiopharmaceuticals for multicenter clinical trials**

Rationale:
Standardization is essential for multicenter clinical trial design to allow the use of resultant data for FDA approval. Historically, this has been very difficult to achieve.

Objectives:

1. Creation, approval, and maintenance of centralized INDs to facilitate standardization in multicenter clinical trials

2. Develop and maintain a comprehensive set of IND templates for non-proprietary RPs

3. Develop templates for IRB approval (consent form)

4. Ensure proper Chemistry, Manufacturing, and Controls (CMC) documentation suitable for FDA-acceptance for multicenter-produced radiopharmaceuticals produced under a CTN-held IND

5. Expand and maintain a comprehensive manufacturer's registry of molecular imaging radiopharmaceutical manufacturers

6. Identify barriers to the use of FLT in clinical trials

Goal 4: **Provide education and training for the use of molecular imaging in clinical research**

Rationale:
It is essential to provide this training to clinical and imaging research personnel, since the conduct of clinical trials is not part of the typical clinical training.

Objectives:

1. Maintain and expand the course curriculum on the conduct of clinical trials

2. Condense and consolidate the supplemental courses into packages

3. Market courses and packages
    a. CROs
    b. Technologist schools/program directors
    c. Pharmaceutical and biomarker developer companies
    d. QIN
    e. Chapter meetings and Road Shows

4. Webinar series, on demand lecture series, and live workshops featuring a variety of clinical research topics will be offered:
    a. Present programs at the national society meetings:
    b. Annual workshops at the SNMMI Conjoint Mid-Winter Educational Symposium
    c. Annual categorical and CE sessions at the SNMMI Annual Meeting
    d. Develop a standardized program and expert speaker panel to be made available to SNMMI regional chapter meetings and other non-imaging societies (e.g. ASCO, ASTRO, DIA)

Goal 5: Develop a plan to ensure fiscal sustainability

Rationale:
The CTN should be revenue neutral or positive.

Objectives:

1. Continue to pursue pharmaceutical companies, foundations, and governmental agencies for philanthropic support

2. Develop a business plan to market products including fee-for-service programs including educational programs, phantom program, and consulting services
    a. Work to support grant-funded efforts that utilize the capabilities of the CTN
    b. Develop specific consortiums of industrial partners to fund clinical trials of nonproprietary Agents

Goal 6: Expand the depth of leadership, committee membership, and possibly technical staff personnel

Rationale:
Continuity is important in these long term projects and programs.

Objectives:

1. Continue, and possibly expand, internship program

2. Establish a physician/doctoral level fellowship program

3. Identify gaps and fill technical staff needs

4. Establish succession plan for CTN leadership and committee chairs (vice-chairs)