GOAL: CREATE A MORE EFFICIENT AND TIMELY APPROVAL PROCESS FOR NEW AND NON-PROPRIETARY RADIOTRACERS AND RADIOTHERAPEUTICS BY THE U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Objective: Optimize evidentiary requirements for the approval of new radiotracers

- Strategy – Develop recommendations regarding risk to benefit ratio for radiotracer approval
- Strategy – Develop recommendations to adjust non-clinical testing requirements to reflect limited dose of diagnostic imaging drugs administered to patients
- Strategy – Develop guidelines mapping the process leading to approval of a new MI agent with a biochemical or imaging biomarker indication
- Strategy – Develop recommendations to establish definitions of ‘utility’ or ‘benefit’ for indications based on nonclinical data, including evidence from the literature, coupled with clinical data when available
- Strategy – Review FDA regulations for accelerated approval to determine how these may be applied to imaging drugs
- Strategy – Develop recommendations to create a category of ‘conditional approval’ for new MI agents proven to be safe (with a sunset provision allowing for time to demonstrate efficacy)

Objective: Optimize evidentiary requirements for the approval of radiotherapeutics

- Strategy – Develop guidelines mapping the process for approval of a new radiotherapeutic
- Strategy – Develop recommendations to establish definitions of ‘utility’ or ‘benefit’ for indications based on nonclinical data, including evidence from the literature, coupled with clinical data when available
- Strategy – Review FDA regulations for accelerated approval to determine how these may be applied to radiotherapeutics

Objective: Engage FDA in dialogue on SNMMI’s recommendations of possible pathways to improving the review and approval process

- Strategy – Provide FDA with an advance copy of the white paper to allow for inclusion of agency feedback
• Strategy – Engage FDA Advisory Panels (MIDAC, ODAC, etc) to seek feedback and approval of recommendations

• Strategy – Engage FDA in a discussion on allowing the immediate clinical use of PET agents once an ANDA for PET agents (that have been developed and previously used in the PET community) is submitted and accepted

• Utilize a coalition of stakeholders to engage the FDA

**Objective:** Improve clinical access and reimbursement for non-approved radiolabeled agents under development (traditional IND) or under an Expanded Access IND

• Strategy – Facilitate use of expanded access INDs

• Strategy - Facilitate cost recovery for radiolabeled agents under development and expanded access INDs

• Strategy – Work with a coalition of stakeholders to disseminate educational information to the community

• Strategy – Work with FDA to include educational sessions at societal meetings (SNMMI Annual Meeting)

• Strategy – Work with the SNMMI Committee on Coding and Reimbursement to define the process for reimbursement