

## Moving $^{68}\text{Ga}$ -labeled DOTA PET Imaging Agents Towards Approval

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Gallium-68-labeled somatostatin analogs ( $^{68}\text{Ga}$ ]DOTATOC, DOTATATE, and DOTANOC) have been identified as important imaging agents to detect and manage neuroendocrine tumors (NETs) and have been shown to be superior to the approved product –  $^{111}\text{In}$ -octreotide. In September 2012, the Society of Nuclear Medicine and Molecular Imaging (SNMMI) established a formal  $^{68}\text{Ga}$  Users Group under their Clinical Trials Network (CTN) to advance the use of these  $^{68}\text{Ga}$ -labeled analogs for the imaging of NETs in the US. The Users Group has had regular conference calls and recently met at the SNMMI Annual Meeting in June 2013 to address challenges to drug availability, FDA approval, and reimbursement. An immediate, achievable goal of this group is to develop an Investigational New Drug (IND) template for the  $^{68}\text{Ga}$ -DOTA agents that qualified sites could then utilize to file their own IND. Included in the IND is a template protocol containing basic inclusion/exclusion criteria, dosing information, safety procedures, adverse event reporting, and detailed imaging acquisition guidelines. Members of the Users Group have also developed a chemistry manufacturing section that defines harmonized end-product specifications that sites can incorporate into their IND. Additionally, generic data collection forms and a draft informed consent form are also being drafted so that they can be adapted to fit the individual site's protocol and regulatory requirements. *Prospectively* defining and harmonizing chemistry and imaging study parameters from all study sites will allow multiple sites to combine their respective clinical trial data thereby simulating a multicenter trial which allows for pooling of data for an NDA. This poster will present a brief history of  $^{68}\text{Ga}$  agents and their use in PET imaging, the progress made to date by the SNMMI/CTN  $^{68}\text{Ga}$ -DOTA Users Group and ongoing plans to obtain reimbursable approval for  $^{68}\text{Ga}$ -labeled somatostatin analogs for the imaging of neuroendocrine tumors.