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New PET Probes: A new way to streamline the IND process for FDA approval

Los Angeles, CA USA – June 4, 2014 - A recent article published in Molecular Imaging and Biology, the journal of the World Molecular Imaging Society, discusses a streamlined and cost-effective approach to obtain Investigational New Drug (IND) approvals from the Food and Drug Administration (FDA) for positron emission tomography (PET) imaging probes. The article "de-mystifies" the process and provides a straightforward description on how to achieve approval for an imaging trial.

Using PET probes developed at UCLA, the Department of Molecular and Medical Pharmacology demonstrated the approach that can successfully be applied to obtain FDA approval of phase1 INDs in an academic site efficiently and at a reasonable cost.

"The low percentage transition of probes to investigations in humans can be attributed in part to the perception that complex regulatory requirements at high cost are associated with filing for an IND. We believe the information we have provided in our article presents a simpler, low cost approach for allowing more academic sites to transition their promising PET probes to the clinic" notes the author, Dr. Sherly Mosessian.

Dr. Michael Phelps states, "Our goal at UCLA is to apply university resources wherever appropriate to do our part to simplify, lower costs and increase quality in technologies and processes to expand the diversity of PET molecular imaging diagnostics to accommodate more diagnostic decisions in more diseases - both for developing better treatments and better use of existing ones to improve patient outcomes."

According to the study it is critical for academic sites to have a streamlined and cost-effective approach to translate PET imaging probes from preclinical research to clinical investigations and investigate the degree to which preclinical findings for these probes apply to humans.

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