



SNM Moves Forward in Making Clinical Trials Group a Reality

The Society of Nuclear Medicine has undertaken the initial steps needed to initiate and develop a multicenter clinical trials group called Molecular Imaging and Radionuclide Therapy Trials (MIRT²). This exciting initiative will create the ability for the society to contribute to current and future nuclear medicine clinical practice in a positive and unbiased way. This effort has been supported by a grant from the former Nuclear Medicine Industry Association–North America (NMIA–NA). “This important initiative can help the continued success of nuclear medicine in clinical practice, in drug development, and in the emerging molecular imaging field,” said Alexander J. McEwan, MD, chair of MIRT².

MIRT² members are finalizing the framework and infrastructure necessary to establish support for innovative trials of both diagnostic and therapeutic radiopharmaceuticals. Over time, these small trials are expected to encompass all the interests and possible applications of molecular imaging and diagnostic and therapeutic nuclear medicine. For example, clinical trials may be run to evaluate the effectiveness of new therapeutic radiopharmaceuticals or of using PET imaging as a surrogate marker for clinical outcomes when evaluating new therapeutic interventions.

The group’s members have discussed and identified four promising clinical protocols—two therapeutic and two diagnostic—for future development. It is hoped that at least one of these protocols will be completed and ready for discussion at SNM’s 52nd Annual Meeting in Toronto. According to McEwan, the first patients could be enrolled in trials by the end of the year.

The infrastructure that has been developed to support MIRT² includes a steering committee, with involvement by all councils and centers; standard operating procedures; and processes for protocol evaluation and review. Ethics and conflict of interest guidelines are being established, and a qualifying questionnaire has been developed to assist in identifying investigators and clinical sites to participate in MIRT² trials. This questionnaire has been sent to 11 major oncology sites in the United States and Canada that have been identified as possible participants in the initial trials. MIRT² is examining a potential partnership with an established commercial imaging laboratory that is capable of managing the medical images obtained as part of MIRT² protocols.

Medical professionals know that systematically conducted clinical trials are the safest and fastest way to introduce new radiopharmaceuticals and to expand the role of existing products. SNM is uniquely positioned to study and evaluate many facets of radiopharmaceutical development. McEwan believes that, with implementation of this initiative, the society could quickly become a major resource for the clinical community. “With the MIRT² program, the possibility exists to really make a difference in patient management by facilitating the transition of newly developed radiopharmaceuticals into clinical practice and by using nuclear medicine techniques to help drug development,” he said. Clinical trials would allow the U.S. nuclear medicine community to cultivate a niche expertise in radiopharmaceutical development. The ultimate goal for MIRT² is to enable, facilitate, and expand the clinical use of new and current radiopharmaceuticals.

Over the past 10 years, there has been a profound change in medicine because of advances in cellular and molecular biology. However, nuclear medicine’s potential “is limited unless it can overcome a number of unprecedented challenges that threaten its continued growth,” said McEwan. Due to increasing regulatory requirements, lack of availability of key radioisotopes, and declining interest in development by industry due to lack of investment return and limited reimbursement, there has been a decline in the introduction of new radiopharmaceuticals for diagnosis and therapy. For these reasons, SNM is committing to the long-term development and growth of a cooperative group structure. MIRT² is now actively seeking outside grants and collaborations to fund the program.

Over the next several months, the group will involve a wider circle of members. A MIRT² Web site is in the planning stages, and in the future, members will be able to electronically submit proposals for clinical sites for ongoing trials and/or new protocols for MIRT² to consider. Special thanks go to MIRT² and NMIA members who have worked long and hard for this program. ❀



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