

SNM Submits Imaging Endpoint Comments to FDA

On October 18, 2011, SNM submitted comments on U.S. Food and Drug Administration (FDA) draft guidance for industry on Standards for Clinical Trial Imaging Endpoints. In the guidance, FDA addressed imaging standards for obtaining and interpreting medical images used to measure efficacy endpoints in confirmatory (phase 3) clinical trials. Several of the recommendations offered by SNM focused on the need for clarification of specific statements included in the guidance, such as whether imaging data would be considered valid if trials did not conform to the standard but were used as secondary endpoints and/or in phase 1/2 trials and whether FDA intends to require that a baseline scan be repeated for trial inclusion.

The draft guidance included instructions for vendor-specific equipment/platforms and urged sponsors to use only FDA-approved or -cleared analytic software. Because of the very limited role of some specialized software in the clinic, SNM also directed FDA to stipulate specifications that would qualify software for FDA approval, thereby informing users of the essential elements that equipment or software should include (as an alternative approach to specifying only pre-approved software).

The guidance requires sponsors to provide information on specific vendors, models, versions, and upgrades of all hardware/software used in a trial. Although this information is important and could be collected throughout the study, the SNM recommended that it not be required before study

initiation, because it is typically not obtained until after the approval and start of the trial. The SNM concurred with FDA on the importance of providing guidance when using phantoms for site qualification and image quality monitoring. The SNM's Clinical Trials Network, with its standardization efforts, may be in a position in the near future to supply this type of information to sponsors and sites.

In addition, the guidance mentions quantification as an adjunct to visual interpretation. SNM recommended that FDA more fully reflect this essential element in the guidance text in recognition of advancements in PET cameras, reconstruction parameters, and radiopharmaceuticals that facilitate more accurate measurements of quantitative values.

SNM applauded the efforts of the FDA to standardize imaging procedures when an imaging endpoint is used in a clinical trial of a therapeutic or biologic drug product. This guidance will prove valuable for sponsors of trials and provide areas for discussion with imaging professionals. See the SNM comments at: <http://interactive.snm.org/docs/SNM%20Comments%20on%20Imaging%20Endpoints%20Guidance.pdf>.

The draft guidance is available at: <http://interactive.snm.org/docs/Draft%20Guidance%20on%20Media%20Fills.pdf>

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of Nuclear Medicine. The final scope of NMAA practice is determined by each hospital's committee on privileges. We should regard this step as further evolution in the practice of nuclear medicine. We evolved from general physicians, doing nuclear medicine as a sideline, to fully trained nuclear medicine physicians, and now to partially trained nuclear medicine physicians. The shortage of fully trained

nuclear medicine physicians makes the NMAA an essential element in continued growth of molecular imaging. NMAAs are equipped to run clinical trials and move our specialty forward while still ensuring high standards of care for patients.

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