

ISMRM/SMRT Forum

How to do a multicenter neuroimaging study:

A Technologists' Perspective

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MRI neuroimaging is being utilized in multicenter trials throughout the MR community. The successful model involves early involvement of MR professionals, site training, site feedback and site support by the sponsor and MR coordinating center. Clearly in any realistic study the MR protocol will need to be developed and validated across multiple hardware and software platforms. While it is possible to incorporate so called Works in Progress (WIP) or non-commercial pulse sequences, this complicates the study and is, in general, a problem at the technologists' level as it requires significant support from local imaging scientists, from personnel associated with the coordinating center and/or application scientists from the equipment vendor.

It is likely that some qualification scans may be required in the study and it is also increasingly likely that some type of phantom may be required either as a pre-study qualifier or as a standard scanned at each subject visit. This may have an impact on scheduling and on acceptance of the scans by the coordinating center.

Requirements for the Site

Realistically, the sites should be pre-screened for qualification and interest in performing the studies. Budgetary issues such as phantom measurement time and additional duties outside of routine technologist duties should be discussed. A relevant point person involved in MR imaging such as a MR lead technologist, MR Chief Technologist, Research Technologist, or Technologist assigned to the protocol should be included in all discussions. Key personnel should complete any IRB requirements. MR imaging Protocol and Data transfer requirements should be tested at site prior to initiation. Documentation requirements performed at the time of the study must be reviewed by key personnel. Ideally, on-site training or multi-site user training with the technologist or lead technologist responsible in attendance should be scheduled work out any logistical issues prior to enrollment. Good Clinical Practice Guidelines (GCP) should be reviewed with each participant at the site. IRB requirements must be complete prior to study initiation. A study coordinator, preferably one with MR imaging knowledge should visit the site prior to initiation and as needed depending on performance to ensure compliance. Subject cooperation and team availability should be taken in account when arranging scheduling. Quality Control feedback should be timely and expectations for rescans if required should be clear.

Requirements for the Coordinating Center

Site coordinators responsible for management of MR imaging studies should possess MR knowledge. Qualifications of MR personnel should be documented according to GCP. IRB requirements must be complete prior to study initiation. Expectations for all data

processes should be presented to the site prior to initiation. MR imaging protocol should be clearly written and outlined in a user -friendly document and tested prior to implementation. Documentation requirements performed at the time of the study should be kept to a minimum Data transfer guidelines should be straightforward and user friendly. Quality Control feedback should be directed to the MR personnel in a timely manner. Coordinating Center should provide feedback to the Sponsor for any QC/ data handling issues in a timely manner. Coordinating Center should provide well -documented policy and procedures for data management in clinical trials as required and be prepared for an audit by the sponsor.

Requirements for the Sponsor

Sponsor should clearly outline expectations prior to study initiation. Sponsor should interact with the Coordinating Center on a routine bases to resolve any queries or data quality issues in a timely manner. Site nuances ie publication agreements, should be addressed prior to accrual. Payment process should be reviewed prior to site initiation.

Recommendations

A well-planned, well- documented process that includes all key personnel is critical to success of a multicenter neuroimaging study.