

Quantitative MR in Multi-Center Clinical Trials

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Magnetic Resonance Imaging has a wide variety of applications in the clinical trials process, largely due to the many different imaging endpoints that can be measured using MR. The unique flexibility of these systems has proven to be both a blessing and a curse to those attempting to deploy MR in multi-center clinical trials, however, as it becomes increasingly difficult to ensure that results obtained at one center are comparable to those at another. This section will briefly review the benefits of including quantitative MR imaging in clinical trials, then explore in detail the challenges presented by the need to develop a detailed MR protocol that is both effective and implementable across many different MR systems and software versions. Practical solutions to these challenges will be presented, with concrete examples from current clinical trials. An outline of this section is presented below.

1. Overview
2. Motivation
 - a. Flexibility
 - b. Availability
 - c. Direct window into MOA
3. Challenges
 - a. Protocol development
 - Harmonization among manufacturers
 - Compensation for varied software versions
 - b. Site evaluation and training
 - On-site vs. remote training
 - Phantom scanning and evaluation
 - Volunteer scanning
 - c. Site monitoring
 - Phantoms
 - Patient data
4. Examples
 - a. Imaging cartilage
 - Structural imaging
 - Functional imaging
 - b. DCE-MRI
 - Unique challenges
 - Predictive value for anti-angiogenic drug development
5. Conclusions