

## ISMIRM 2010

### **Trial and Tribulations: Multicenter Trial Headaches and Their Cures Trying Drugs and Devices: Safety and Liability—Trials Using Devices**

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In recent years there has been much interest in using the soft tissue contrast and other properties of MRI, such as thermal mapping, to guide therapies, and a number of companies have emerged with systems for therapy or placement of therapeutic devices. However, the MR environment and the traditional MR regulatory environment pose unique challenges for all parties typically involved in an MR guided device trial. In this talk, some of the typical challenges and considerations will be presented:

#### View from the Device Manufacturer

- Our timelines are short and our investors expect us to meet aggressive milestones
- Why does it take so long to establish a contract for pre-clinical or clinical research at a University site?
- Oh no—now we need a 3-way agreement with the MR Scanner Manufacturer?!
- How can I figure out what components of the University's MR scanner are FDA cleared and which are not?

#### View from the MR Scanner Manufacturer

- Our collaborators at a university site have access to many investigational SW/HW components as part of our research agreement. How can we make sure everyone knows what is FDA-cleared and what is investigational and that we are protected?
- How do we setup a 3-way agreement with the University and the Device Manufacturer—what do we have to consider?
- What information do we need to share with the Device Company so that they can do their trial? Interfaces? Confidential information?
- Assuming the trial is successful, what is the path for the Device to interface with our scanner? Is there a reasonable product development pathway and regulatory approval path?

#### View from the University Investigators

- Why do we need all these contracts?
- How can I make sure the device company and the MR manufacturer really understand the risks and logistical issues of doing the trial?
- How do I protect the confidential information of both the Device Manufacturer and the MR Scanner Manufacturer and get these agreements in place?
- I wrote my own pulse sequences and made my own RF coil for the trial—can those be used in the Device trial?