

Where it all started - 2008

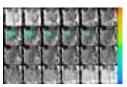
- DCE-MRI is not routine standard of care, but increasingly used clinically
- Current radiological practice is not quantitative
- Manufacturers have different implementations of pulse sequences that result in wide range of contrast response characteristics
- Manufacturers have nothing with which to compare
- Economic challenge to manufacturers in supporting clinical trial applications vs clinical routine
- Economic challenge to manufacturers in clinical trials vs clinical routine

- DCE-MRI is used in early phase clinical studies
- There is increasing interest in clinical use as well
- The diversity in technical solutions will remain due to the lack of economic benefits to the vendors.
 The task is to come up with solutions to harmonize image biomarker results across vendors.
- Image quality is a major issue for all quantitative imaging
- Manufacturers are focusing on technology not biological validation.
 We have to deal with it for almost all exploratory types of activities.

Transport III

Definition of work items on DCE-MR

- If we want to use *K*^{trans} as a quantitative measure in a multicenter trial,how can we assure quality and comparable quantitative results? => profile
- Phantom study
 - Understand phantom landscape and practical issues
 - Understand DCE-MRI imaging protocol across different manufacturers' scanners for comparable results
 - Understand the problem space with regard to (protocol)





DCE-MR work streams

- Literature review
- Main result: Profile
 - Based on literature evidence define a claim on ktrans and IAUGC
 - Describe in detail how the claim can be fulfilled in a clinical trial setting
- Identified gaps → 'groundwork' projects on:
 - Phantom design and testing
 - Phantom analysis software





DCE-MR Workstream continued

- Profile writing process was refined while going forward and getting more experienced
 - Writing is done by a smaller group of committee members
 - Committee enlarge excellent for first committee reviews
 - After reaching committee consensus 'public comment' period started with pre-identified international experts
 - Groundwork projects ongoing in parallel



DCE-MR Workstream continued

- Publicly reviewed profile published 13 December 2011
- New groundwork project needs were identified:
 - Phantom and adjustment of analysis software with final outcome of a report
 - Introduction of concept of 'Digital Reference Objects' to simulate parameter ranges and resulting images to test DCE analysis software
 - Clinical test retest
 - Need identified to have a central data repository for pahntom data, DROs



DCE-MR Workstream continued

- What do we have now for DCE-MR?
 - Publicly reviewed profile
 - Tested phantom (technical validation, clinical validation)
 - Phantom analysis software
 - DROs
 - Data repository
- How can this be used practically compliance to DCE-MR profile



From DCE-MR to PDF-MR

- Anti-angiogenic drugs and other targeted therapies led to questions regarding MoA that go beyond perfusion
- Committee decision to investigate DWI MR due to clinical care as well as clinical trial needs
- Renaming DCE-MR into PDF MR committee
- DWI work based on DCE-MR experience
 - Literature search
 - Profile drafting
 - Ground work projects (same concepts)





