

Pharma Imaging Network for Therapeutics and Diagnostics (PINTAD)

MEETING SUMMARY

MEETING SUBJECT:	PINTAD 2014 Telecon
DATE / TIME:	25APR14 / 11:00 AM EST
PREPARED BY:	Barbara Chandler, Annette Schmid
LOCATION:	Teleconference

DISCUSSION POINTS:

1	<p>Image Data Sharing in Clinical Trials with two guest discussants</p> <ul style="list-style-type: none">. Dr. Geoffrey Oxnard (Dana Farber Cancer Institute): drawing from his experience with FINH - Volumetric CTa. Dr. Daniel Sullivan (Duke University/chair QIBA/scientific advisor to RSNA): drawing from his experience with Imaging Data Warehouse (QIDW) <p>Dr. Oxnard spoke about VOL-PACT (Volumetric CT for Precision Analysis of Clinical Trial results):</p> <p>Goals to:</p> <ul style="list-style-type: none">▪ Assess feasibility of images from completed Phase 3 trials▪ Simulate Phase 2 results▪ Develop qualitative metrics for improved prediction of trial results <p>The focus is on solid tumors that are not highly chemo-sensitive, eg, lung, colon, renal melanoma and some breast cancer, but not lymphoma.</p> <p>Challenges and hurdles include:</p> <ol style="list-style-type: none">1) The ethical challenge – is there IRB acceptance? Yes, but de-identified images for reanalysis don't need IRB approval.2) Technical logistics – the process of translating from internal/proprietary structures to analyzable sets that are de-identified. There's been lots of buy in from pharma on this.3) Legal hurdles – pharma are now prepared with appropriate safe guards to share imaging. <p>Dr. Oxnard is optimistic that within 2–3 months imaging from several trials will be available. There are current collaborations with Sanofi. Details are being discussed with GSK. Talks are ongoing with Pfizer, Genentech and Amgen. The hope is to have 6-12 trials over the next year.</p> <p>They will not reanalyze PFS or calculate response rate, but look at early efficacy signals, earlier than PFS. The data from each trial will be examined separately. Both 1D and 3D measurements will be included. The goal is to establish more sensitive methods that are rigorous and reliable to provide certainty when transitioning from Phase 2 to Phase 3. This may allow for endpoints to be met earlier.</p> <p>The software currently being used is an algorithm developed by Dr. Larry Schwartz at his lab, although there is no commitment to any one software. The analysis is planned to take</p>
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	<p>place in academic labs.</p> <p>It's more difficult to collect scans if the intent is to share them with others. That's not the intent now, but Dr. Oxnard is amenable to discussing this.</p> <p>Dr. Oxnard's slides will be shared with these meeting minutes on the QIBA website.</p> <p>Dr. Dan Sullivan spoke about Quantitative Imaging Biomarker Alliance (QIBA) Imaging Data Warehouse. The purpose of this early effort is data sharing and to replicate results. Eventually data will be available for other users. One goal is to minimize constraints that exist with other warehouses.</p> <p>Dr. Sullivan shared a screenshot of the website. A link is available on the QIBA website, https://www.rsna.org/QIBA.aspx. You will need to apply to RSNA for access. Currently all images are of phantoms. The group is working on adding clinical images. There are 110 users in 11 communities. The site has advanced search options. It's built on Kitware by Midas, an open source software.</p> <p>QIBA is looking for collaborative opportunities. Bob Ford is scheduled to talk about strategies for getting QIBA profiles implemented. Data sharing is the goal. Data needs to be de-identified and approved by the IRB of the facility that acquired the data.</p> <p>NCI also has an effort, the Quantitative Imaging Network (QIN), which is grant funded to individual sites. While it's related to quantitative imaging biomarkers, the focus is on the research and clinical validation of biomarkers.</p>
2	<p>The following point on the agenda was not discussed on 25APR14 due to lack of time: Reader Variability/ Secondary Reads- a thing of the past?</p>
3	<p>Next meeting Friday, 30MAY14 11:00 am ET</p>