

PHARMA IMAGING GROUP

MEETING SUMMARY

MEETING SUBJECT:	Pharma Imaging Group 2013 Telecon
DATE / TIME:	28JUN13 / 11:00 AM EST
PREPARED BY:	Barbara Chandler, Annette Schmid
LOCATION:	Teleconference

DISCUSSION POINTS:

1	<p>FNIH/IMPACT</p> <p>Dr. Geoffrey Oxnard, medical oncologist at Dana Farber, was a guest at the meeting and shared slides about the Foundation for the National Institutes of Health (FNIH) Imaging Metrics for Precision Analysis of Clinical Trial results (IMPACT) outlining the effort to collect Phase 2 imaging, perform 1D, 2D and 3D measurements and show that the data can be used as prognosticators of Phase 3 results.</p> <p>The slides are on the QIBA wiki http://qibawiki.rsna.org/index.php?title=Pharma Imaging Network for Therapeutics and Diagnostics %28PINTAD%29</p> <p>Dr. Oxnard also related that:</p> <ul style="list-style-type: none">• The imaging collected will be from lung, colorectal, renal and some breast cancer studies, avoiding prostate and ovarian data.• It will be a 2 year effort to acquire imaging and measurements before results will be determined.• FDA has been at the table since early on but it's too early to discuss whether the data will determine if it's worth developing the case for a surrogate endpoint. <p>Annette asked Dr. Oxnard to keep PINTAD in the loop with updates.</p>
2	<p>PFS Audit Methodology</p> <ul style="list-style-type: none">• Annette contacted Lori Dodd and she is interested in attending a PINTAD meeting to discuss the audit methodology.<ul style="list-style-type: none">○ Will try to schedule for 26JUL13 after polling PINTAD members about their availability○ If critical mass available, will collect questions by 19JUL13 to send ahead of the meeting○ Ohad Amit has also been invited to participate.• DIA still very interesting in potential meeting.<ul style="list-style-type: none">○ Will have sidebar discussions with FDA○ Annette encouraged everyone if speaking with FDA about the audit methodology, to let them know you think it's a good idea to have the DIA workshop to discuss the challenges and advantages○ Suggested to add topic of why independent reviews were put in place in the 1990s. Need to revisit institutional memory.• What are CROs saying when approached by sponsors? It would be useful to

have a consistent approach during this period of uncertainty.

- Currently no implementable solution
- Not convinced of financial savings
- Some are focusing on good quality site assessments
- Questions about whether the statistical methods are adequate
- Some sponsors doing 100% site and central reads and then their own internal analysis.
- Will add substantial time at the end of a trial. This cost is not being considered.

5 Next meeting 26JUN2013, 11:00 AM EST