

PHARMA IMAGING GROUP

MEETING SUMMARY

MEETING SUBJECT:	Pharma Imaging Group 2013 Telecon
DATE / TIME:	31MAY13 / 11:00 AM EST
PREPARED BY:	Barbara Chandler, Annette Schmid
LOCATION:	Teleconference

DISCUSSION POINTS:

1	<p>PFS Audit Methodology</p> <ul style="list-style-type: none"> • Update from the Society of Clinical Trials Annual Meeting/Audit Methodology discussion in Boston, 19-22MAY2013 <ul style="list-style-type: none"> ○ Laurie Dodd (author Method A), Ohad Amit (author Method B), Rajeshwari Sridhara/ FDA, David Raunig/iCRO, Janice Pogue/ McMaster University and Jackie Bosch/ McMaster University presented. ○ At the center of the Dr Sridhara's discussion was data shared in the recent publication Assessment of Audit Methodologies for Bias Evaluation of Tumor Progression in Oncology Clinical Trials. <ul style="list-style-type: none"> ▪ She concluded Audit method should not eliminate central review. ▪ Further work needed with data to be published. ○ David focused on the evaluation of the 27 studies used in the initial papers and the cost savings. ○ His slides will be posted on the QIBA website. ○ He plans to write a letter to the editor about the meta-analysis based on 8 rather than 27 of the original studies. • Annette suggested inviting Drs Dodd and Amit to a PINTAD meeting, collecting key questions and sending them in advance. • DIA meeting <ul style="list-style-type: none"> ○ Deborah Michaels was encouraged by the PINTAD poll results showing sponsors' interest. ○ FDA statistician was luke warm and somewhat reluctant. ○ Soonest the meeting can be scheduled is early next year. ○ Add topic of integrating clinical data to the agenda.
2	<p>QIBA Annual Meeting Update</p> <ul style="list-style-type: none"> • Metrology workshops and 5 papers to be published • Data imaging warehouse includes only phantom imaging so far, asked RSNA board to approve adding clinical imaging, potential to house data for future use
3	<p>Foundation for the National Institutes of Health (FNIH) Howard Highley Quantitative imaging as biomarkers</p> <ul style="list-style-type: none"> • Larry Schwartz and Geoffrey Oxnard will present slides at June PINTAD meeting.
5	<p>Next meeting 28JUN2013, 11:00 AM EST</p>

