

# PHARMA IMAGING GROUP

## MEETING SUMMARY

<b>MEETING SUBJECT:</b>	<b>Pharma Imaging Group 2013 Telecon</b>
<b>DATE / TIME:</b>	<b>26APR13 / 11:00 AM EST</b>
<b>PREPARED BY:</b>	<b>Barbara Chandler, Annette Schmid</b>
<b>LOCATION:</b>	<b>Teleconference</b>

### DISCUSSION POINTS:

1	<b>Name change poll results</b> <ul style="list-style-type: none"><li>• There were 26 responses with 16 (61.54%) voting in favor of changing Extended Pharma Imaging Group (Extended PIG) to Pharma Imaging Network for Therapeutics and Diagnostics (PINTAD)</li><li>• With no objections raised at the meeting, the new name was adopted.</li></ul>
2	<b>ODAC PFS Audit</b> <ul style="list-style-type: none"><li>• Annette summarized the discussion from the March meeting.</li><li>• Anyone planning to attend the Society of Clinical Trials Annual Meeting in Boston, 19-22MAY2013 was asked to contact Annette if they would like to meet with other PINTAD members also attending. Link to meeting website <a href="http://www.sctweb.org/public/home.cfm">http://www.sctweb.org/public/home.cfm</a></li><li>• Interest in joint DIA/FDA meeting – there were 18 responses to the poll with 17 (94.44%) interested in attending.<ul style="list-style-type: none"><li>○ Pharma with publicly voiced interest in attending include: Sanofi, Merck &amp; Co Inc, Merck KGaA, Roche, J&amp;J, with another 3-5 expressing interest to Perceptive</li><li>○ Tentative agenda for PFS audit meeting:<ul style="list-style-type: none"><li>▪ Financial implications</li><li>▪ Impact on trial timeline</li><li>▪ Logistical/operational challenges to Sponsors and imaging CROs</li><li>▪ Potential risks to trial data</li><li>▪ Design options</li><li>▪ Regulatory acceptance</li></ul></li><li>○ Add integration of the draft FDA guidance document – currently no one is aware of any progress</li><li>○ Who to contact at FDA? Dwaine Rieves has mentioned he is not the appropriate contact, someone from office of Oncology Drug Products, Annette will reach out to Pat Keegan</li><li>○ Meeting should be in the Washington, DC area to facilitate attendance by FDA</li><li>○ EMA guidance urged caution on audit method<ul style="list-style-type: none"><li>▪ Annette will send guidance to group</li><li>▪ Identify the best person at EMA to invite</li></ul></li><li>○ Annette will notify DIA of interest from PINTAD and share DIA's response</li><li>○ Next step to form subcommittee to plan meeting</li></ul></li></ul>

3	<b>Foundation for the National Institutes of Health (FNIH) Howard Highley Quantitative imaging as biomarkers</b> <ul style="list-style-type: none"><li>• Quantitative imaging as biomarkers</li><li>• Reassessing data from completed Ph3 trials to see if CT volume can be data mined retrospectively</li><li>• Larry Schwartz and Geoffrey Oxnard will be asked to give slide presentation to PINTAD</li></ul>
4	<b>David Clunie: DICOM headers to include the NCT (ClinicalTrials.gov registry number)</b> <ul style="list-style-type: none"><li>• David did not attend the meeting but sent an email about this topic.</li><li>• Respond to him with your comments.</li><li>• Will discuss further at next meeting.</li></ul>
5	<b>Next meeting 31MAY2013, 11:00 AM EST</b>