MEETING SUMMARY

MEETING SUBJECT:	**Pharma Imaging Group 2012 Telecon**
DATE / TIME:	**24Feb2012 / 11:00am EST**
ATTENDEES:	**Jim Conklin, David Mozley, Andrew Buckler, Barbara Chandler, Colin Miller, David Rauh, Ed Somer, Greg Goldmacher, Howard Higley, Jesse Bowden, Jim Frost, Julie Blair, Linda Bresolin, Mark Schmidt, Neru Munshi, Orhan Suleiman, Patricia Cole, Paul Garrett, Rick Jacobs, Rick Taranto, Rikki Waterhouse, Terri B, Tin Lee, Vahe Ghararaman, Walter Wolf, Yuying Hwang**
PREPARED BY: (printed & signature)	**Allison Andrews**
LOCATION	**Teleconference**

SUMMARY: Discussion of 2011 FDA guidance on imaging endpoints and QIBA progress.

DISCUSSION POINTS:

1.	**2011 FDA Guidance on Imaging**
	• Revised draft (incorporating prior feedback) will be circulated for approval within FDA in April 2012
	• Jim Conklin: Was this discussion useful?
	  o David Mozley: "Uplifting and encouraging".
	  o Orhan Suleiman: Division is sensitive to feedback so it will be addressed.
	• Patricia Cole: Is the next step a draft or the final document?
	  o Jim Conklin: Dwayne will attend the March call. This will be solicitation of final input from PIG (a couple of issues not settled). Then April will be the release of the next version for approval within FDA.
	• Jim Conklin: Final guidance will be issued in October.
	• David Mozley: The FDA has received thousands of comments; some were conflicting. Some were presented as critical issues. These will be brought up again.
	• Rick Jacobs: A little concerned that the March revision won't be "editable" by us. They're listening, but not sure what will be conveyed in the guidance.
	• Jim Conklin: They are open for feedback from the stakeholders.

	• Colin Miller: Guidelines are a "provocative document". It will be good to discuss again in March. • Jim Conklin: If anyone has specific questions, bring them to the March call.

2.	**Documentation of PIG Meetings**
	• Jim Conklin: Is the documentation of the meetings useful?
	  o Overall response – very useful, positive impact
	• Jim Conklin: We will continue issuing them. If any egregious errors are found, contact Jim. With so many stakeholders, it is hard to get everyone's input in a timely manner. There won't be agreement on everything.
	• Jim Conklin: Should we look into a repository to store the documents?
	  o Linda Bresolin: Not a problem. Will look into and discuss with Dan Sullivan to start the process. This will depend on the size of the files.
	  o Jim Conklin: Very small amount of data, just minutes and presentations
	• David Mozley: In the past, we haven't had the energy to do the minutes and post them. This year is experimentation and next year, this responsibility can be transitioned to a large organization. This year, give feedback on how much work this is.
	• Jim Conklin: We will continue to do this through the end of September.

3.	**QIBA** – Andrew Buckler presentation
	• QIBA progress over the last 6 months
	  o Review and consolidate process and structure
	  ▪ Authoring, review, and testing of documents - UPICT protocols and profiles
	  • steps are evolving, documentation on QIBA wiki
	  ▪ IB roadmap and approach– putting QIBA work into context
	  ▪ Team structure and governance – steering, modality, and technical committees
	  o Response to taskforce recommendations
	  ▪ UPICT now part of QIBA – better coordination of developing protocols
	  ▪ Leadership succession planning – asking leaders for their commitment for now, and considering how to select successors
	  o Detailed workgroups
	  ▪ Metrology workshop – comparing performance of various methods
	  ▪ Joint QIBA/RIC committee – proposal to RSNA to establish image warehouse to support QIBA activities. Decision process is underway and looking positive. User needs, technical means, and

	policies are under discussion by the committee. o Other ▪ Formation of U/S effort – Selecting the first U/S biomarker that might be pursued ▪ Acceptance to start DWI-MR effort ▪ Compliance models – Different "actors" can choose how they comply with profiles. SC working on how to test/certify compliance. ▪ Feedback to agency re: clinical trials guidance – Not in conflict with PIG feedback, but different ▪ Data resources for qualification of vCT and FDG-PET • Meetings with FNIH – will release quarterly updates • ACRIN, QIBA groundwork, open request for donations from Pharma companies ▪ Dissemination of documents to other groups – others are interested in this work. There is a formal list of how to disseminate the documents to everyone involved. o Good progress across NIBIB funded projects – Trying to converge these – on target. • Linda Bresolin: Working with RSNA board to extend commitment to support for longer time, not renew at each annual meeting. Now committed to support at current levels for 3 years. • Jim Conklin: How much volumetry in early stage work? o David Mozley: Merck requires quantifying volumes now. We start with segmentation, then extract diameters from volume. This started with solid tumors, and has now moved to the liver and spleen, as well as brain tumors. Volumetry for CHF is on the way. We consider this non-competitive information. o Howard Higley: Confirm what Andrew Buckler said. FNIH – lung and lymphoma trials undergoing continued analysis as well as accrual. Have approached companies that have posted exploratory endpoints such as volumes on clinicaltrials.gov. Encouraging core labs and pharma to become more involved. • Patricia Cole: Hippocampal volume is being developed for enrichment of trial populations. o David Mozley: This will be discussed further with PIG after the March call.
4.	**Announcements** • March meeting will be last Friday in March. Dwayne Rieves will be in attendance. • Jim Frost: What was the conflicting feedback the FDA received? Can we prepare

	for this before the March call? o Jim Conklin: We will ask Dwayne for information to discuss during the next call. • Jim Conklin: Email Jim Conklin or David Mozley with ideas of issues PIG can take up after the March call.