MEETING SUMMARY

MEETING SUBJECT:	**Pharma Imaging Group 2012 Telecon #1/9**
DATE / TIME:	**27Jan2012 / 11:00am EST**
ATTENDEES:	**Jim Conklin, David Mozley** **Rafel Rieves, MD, Director, FDA MIPD** **Alex Gorovets, MD, FDA MIPD** **PIG Stakeholders**
PREPARED BY: (printed & signature)	**Allison Andrews**
LOCATION	**Teleconference**

SUMMARY: Discussion of 2011 FDA guidance on imaging endpoints.

DISCUSSION POINTS:

1.	**Introduction** • 2011 FDA guidance on imaging endpoints • Dwaine Rieves – FDA spokesperson • Draft guideline – work on digesting comments, recurring themes • Work toward finalizing within timelines o On target to finalize by Oct 2012
2.	**How to Implement Guidelines** • Concern: notion of integrating Protocol, Charter, and Imaging Manual. If they're all one document, then changing the imaging manual would require a protocol revision, dealing with IRB reviews, etc. • Option to view charter as ensemble of documents including Manuals and SOP documents • Intended to highlight items for sponsors moving toward imaging endpoints • Tied to product development – therapeutic divisions will give more input • All changes for all documents go through IRB • Challenges: derivatization of process. Start with a protocol, and then multiple people over extended time produce documents derived from protocol, and the

	documents don't match up.
	• Want internal consistency among documents
	• Primary endpoint – loss of fidelity in timepoint
	• After documents are generated, some people review to make sure sponsor has appropriate fidelity of ensemble
	• Some input has been received from therapeutic divisions – positive response
	  o Emphasis of drug developers to come to therapeutic divisions up front
	  o Not a lot of comment on technicality

3.	**Questions and Answers**
	• Jim Conklin: Is 2007 table of contents (TOC) still appropriate? Should charter include TOC?
	  o Useful to include
	  o Option of including as appendix
	  o Dwaine Rieves: The goal is for the guidance to be useful. If TOC is useful to include in the guidance, they can work towards that (as appendix).
	• David Mozley: Further explanation of timeline. Will there be another chance to touch base? What about trials already going 3 or 4 years? Classify as standardization, classify as essential?
	  o Dwaine Rieves: Draft out of MIPD 01Apr2012. This takes about 5 months to go through FDA editors, council, and Therapeutic divisions. The priority items will be integrated into the document. For ongoing studies, there are already solid protocols without the guidance, and these should not be affected.
	• Alex Gorovets: This is guidance, not a requirement or rule. Studies will not be required to use this.
	• Jim Conklin: Requirement to report incidental findings is a major concern (liability, licensure, etc).
	  o Dwaine Rieves and Alex Gorovets will look into this.
	• Mark Schmidt. Janssen: When automated tools are used for quantitative analysis, what are the requirements?
	  o If imaging component is involved in applying the treatment properly, then that imaging has to be something that is validated/qualified.
	• Hard to address certain aspects without specifics of protocols
	• Primarily for therapeutic trials
	• Jim Conklin: Is this restricted for Phase II or III studies? Will there be subsequent guidance for early development?
	  o Alex Gorovets: This guidance is directed at confirmatory trials. Not meant

	to guide internal decision making in early phase.
	• Jim Frost: Can we meet before this is implemented?
	• David Clunie: Will there be another chance for public comments?
	  o Dwaine Rieves: No this might be the only chance.
	  o Late March could be a possibility once there is a solid working paradigm
	  o Welcome the opportunity to discuss again
	• David Mozley: Last Friday of every month
	  o Like to schedule next meeting with FDA the last Friday of March
	  o This topic will be at the top of the agenda
	• Jim Frost: What is a law and what is a suggestion?
	  o Dwaine Rieves: This will be made clear in next version.