Pharma Imaging Network for Therapeutics and Diagnostics (PINTAD)

MEETING SUMMARY

MEETING SUBJECT:	**PINTAD 2014 Telecon**
DATE / TIME:	**25JUL14 / 11:00 AM EST**
PREPARED BY:	**Barbara Chandler, Annette Schmid**
LOCATION:	**Teleconference**

DISCUSSION POINTS:

1	Sarah Sherlock, PhD presented "Incidental Findings in Clinical Trials".
	
	Sarah Sherlock is the Imaging Lead, Clinical and Translational Imaging at Pfizer.
	
	While there is no official guidance on incidental findings in a clinical trial, Sarah discussed findings discovered unexpectedly which are unrelated to the purpose of the study.
	
	Factors to consider:
	• Informed consent
	• Information flow to the patient
	• Risks/costs
	• Legal responsibility and liability
	• Ethical considerations
	
	Important to address up front how to handle incidental findings. Is finding exclusionary or a safety risk to the patient?
	
	Suggested path forward:
	• Incidental findings need to be addressed in informed consent form.
	• Clarify with all parties how incidental findings will be handled.
	• Where do we draw the line?
	  ○ Suspected vs confirmed findings?
	  ○ Major/minor?
	  ○ When reads are not in real time?
	• Sponsor and CRO to create a plan
	
	During Q and A discussed:
	• Opt out box on informed consent form
	• Genetic vs imaging findings
	• Is there responsibility for failure to report?
	• Bob Ford discussed one company's SOP
	  ○ with form completed by independent radiologist
	  ○ including confirmation of receipt by Medical Monitor
	  ○ reporting anything of significance, eg, pulmonary emboli, not fracture in RA study
	• Assume someone at the site looks at the images
	• Do we need to specifically look for incidental findings or is it part of the review process?
	• It's not the radiologist's responsibility to determine if the finding is an adverse event from treatment.

	• Is it a potential benefit for patients to participate in a trial knowing they may be notified of incidental findings? • How often have central radiologists found something not identified by the sites? Is it duplicate information? Annette offered to draft a few bullets about next steps for PINTAD regarding incidental findings. Discussion will continue at a future meeting.
2	The following point on the agenda was not discussed on 27JUN14 due to lack of time but will be discussed at the next meeting: Reader Variability/ Secondary Reads - a thing of the past? Future QIBA presentations at PINTAD may include PET and volumetrics. Gudrun Zahlmann from Roche will present at the next meeting on the QIBA MRI activities.
3	**Next meeting** Friday, 29AUG14 11:00 am ET