

# ***Pharma Imaging Network for Therapeutics and Diagnostics (PINTAD)***

## **MEETING SUMMARY**

<b>MEETING SUBJECT:</b>	<b>PINTAD 2014 Telecon</b>
<b>DATE / TIME:</b>	<b>27JUN14 / 11:00 AM EST</b>
<b>PREPARED BY:</b>	<b>Barbara Chandler, Annette Schmid</b>
<b>LOCATION:</b>	<b>Teleconference</b>

### **DISCUSSION POINTS:**

<b>1</b>	<p>Ira Smalberg, MD presented “Local Evaluator and Secondary Reader Issues in Oncology Clinical Trials”</p> <p>Dr. Smalberg is a board certified radiologist, a local evaluator at Tower Imaging Medical Group and a core lab reviewer. He discussed:</p> <ul style="list-style-type: none"><li>○ The local evaluator model including separate clinical and research needs, typical struggles, communication challenges</li><li>○ The email survey of 565 abdominal imaging radiologists at 55 US NCI-funded cancer centers: Quantitative Imaging in Oncology Patients: Part 1, Radiology Practice Patterns at Major U.S. Cancer Centers (Tracy A. Jaffe, Nicholas W. Wickersham and Daniel C. Sullivan: AJR 2010)</li><li>○ Draft FDA Guidance for Industry: Standards for Clinical Trial Imaging Endpoints (August 2011): reader selection, reader fatigue, site qualifications</li><li>○ Training and performance metrics of local and central readers</li><li>○ ODAC decision July 2012 that permits sponsors to rely on investigator RECIST 1.1 assessments using an audit methodology</li><li>○ Future goals for local radiology sites including enhanced technology</li></ul> <p>During Q and A the question about incidental findings was raised. This will be discussed further at another PINTAD meeting.</p>
<b>2</b>	<p>The following point on the agenda was not discussed on 27JUN14 due to lack of time but will be discussed at the next meeting:</p> <p>Reader Variability/ Secondary Reads- a thing of the past?</p> <p>Future QIBA presentations at PINTAD may include PET and volumetrics.</p>
<b>3</b>	<p><b>Next meeting</b> Friday, 25JUL14 11:00 am ET</p>