Workshop on audit methods

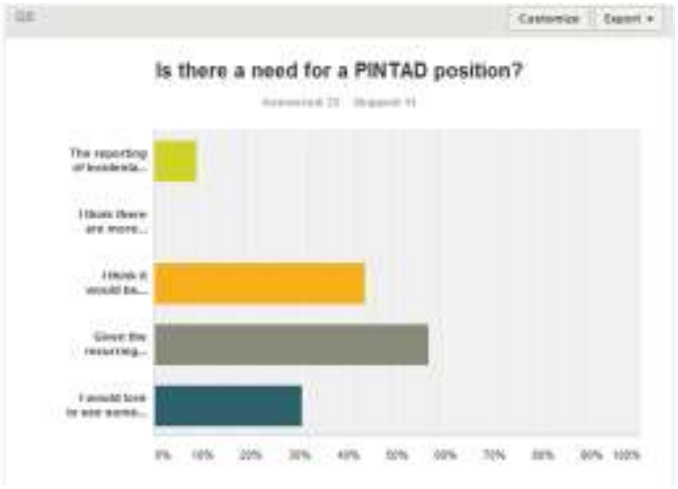
- Earlier this year we had decided we would like to see a workshop on audit methods
  - Established an organizing committee
    - Pat Cole/ Takeda
    - Debra Michaels/ DIA
    - Andrea Perrone/ Merck
    - David Raunig/ ICON
    - Susanta Sarkar/ Sanofi
    - Steven Sun/ Janssen
    - Annette Schmid/ PAREXEL
  - Wendy Hayes/ BMS and Josy Breuer/ Bayer volunteered to critically review the draft agenda

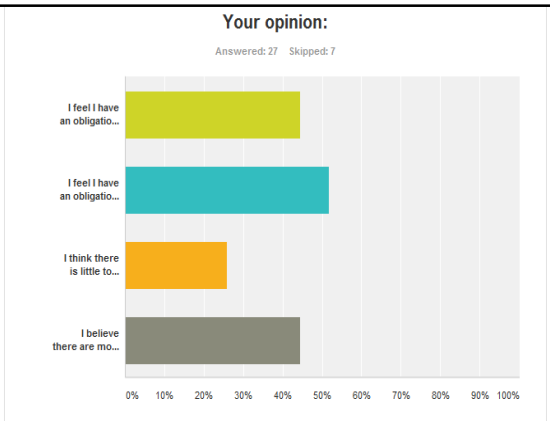
- To allow easy participation for the FDA we decided on location Washington, DC
  - Challenging to get a commitment from member of the FDA to participate- finally looks as if there is some movement
- 1.5 day meeting, March 2015
  - To recognize options for audit methods
  - Identify the key challenges and advantages
  - Synthesize enhance cost-benefit analysis of such audits

- Now in the process of identifying speakers
- Vision- report with recommendation as outcome, in addition to a published paper
  - Preparatory meeting for speakers
  - Brief presentations with sufficient time for discussion

Incidental Findings Reporting

- **34** members responded- > 50% radiologists, and about 50/50 involved in central reads/ pharma
- The great majority of respondents would like to see a PINTAD position or guidance on the Reporting of Incidental Findings- only two respondents thought there is no need





Answer Choices	Responses
I feel I have an obligation to report any "significant" findings that appear incidental to me- even if I were an independent reader	44.44% 12
I feel I have an obligation to report any life-threatening or grave conditions that may be averted or treated - even if I were an independent reader	51.85% 14
I think there is little to no benefit in the reporting of Incidental Findings by independent reviewers	25.93% 7
I believe there are more risks than benefits associated with the reporting of Incidental Findings in the context of redacted imaging and clinical data. Lawsuits will be inevitable	44.44% 12
Total Respondents: 27	

- **84%** of the respondents agreed that the "primary" responsibility for the reporting of Incidental Findings Should be with the licensed healthcare professionals at the treatment facility that enrolled the patient
- **~50 %** of the respondents suggested -Should always be reported when noticed (85% of those who answered the question)
- **58%** Independent readers are ill-positioned to report on Incidental Findings as they may read the cases with a significant temporal delay
- **55%** Independent readers are ill-positioned to report on Incidental Findings as they only have a redacted imaging data set and patient history
- **45%** Independent readers are ill-positioned to report on incidental findings as they may not be licensed to practice medicine in the jurisdictions of the trial subject

- The majority of respondents suggested that if there is a central reporting it should be shared with the sites (75%- 18r)
- About 50% of the respondents (17r) agreed "The contracts with imaging vendors should specify how and to whom Incidental Findings noted by independent readers will be reported"

Comments

- Key concerns around
  - Legal implications
  - Practical implications (ranging from the process to the clear definitions)
  - Time/ cost implications on the read
  - Philosophical concerns

Next Steps

- Get legal feedback, overview of regulations
- Get bioethics feedback