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
Is there a need for a PINTAD position?

- I feel it has or will...: 32%
- I feel there is little to no...: 35%
- I believe there are...: 44%

Your opinion:

- I feel there is little to no...: 44.44%
- I believe there are...: 44.44%
- I think there is little to...: 51.66%
- I feel I have an obligation...: 44.44%
- I feel I have an obligation...: 44.44%

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