**Key observations and recommendations from DIA workshop in October 1st and 2nd 2015 on Oncology Clinical Trials: Central Audit methods for Site Interpretation, Bethesda, MD**

→ Link to meeting http://www.diaglobal.org/en/conference-listing/meetings/2015/10/central-audit-methods-for-site-image-interpretation-in-clinical-trials

* Published audit methods1,2
  + Are mathematically sound but carry practical challenges
  + Will not result in substantial savings
  + Carry significant risks with respect to timelines/delay to market, quality, and cost
* Given the importance and responsibility for all actors in clinical trials, it is recommended to handle site image interpretations according to the principle of “trust but verify”. This could be achieved by
  + A novel method (to be identified)
  + Blinded Independent Central Read
* While truly double blinded trials do not require central reads, the consensus among experts, including regulatory leaders, is oncology trials are rarely, if ever, completely double blinded
* Novel methods should monitor and improve site performance
  + Monitor site performance
    - Timeliness
    - Traceability / auditability
    - Documentation of expertise
    - Standardization of assessments
  + Improve site performance
    - Training
    - Accountability
    - Process standardization
* Alternatives/options
  + Ongoing confirmation reads for eligibility
  + Confirmations of PD

1Dodd LE, Korn EL, Freidlin B, Gray R, Bhattacharaya S. An audit strategy for progression-free survival. Biometrics 2011; 67: 1092-1099.

2Amit O, Mannino F, Stone AM, Bushnell W, Denne J, Helterbrand J, Burger HU. Blinded independent central review of progression in cancer clinical trials: results from a meta-analysis. European Journal of Cancer 2011; 47: 1772-1778.