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Comments on DMC's: Promoting Best Practices to Address Emerging Challenges

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Context

- Expert panel - Fleming et al., *Clinical Trials 2017*
- Survey and focus groups - Calis et al., *Clinical Trials 2017*
- CTTI – DMC recommendations - *Clinical Trials to appear*

Can we be more scientific than experts, surveys, and focus groups?

Comments 1

- **Experience / Training**
  - What type of training/experience?
  - Adaptive designs
  - CITI – type certification (at least)
- **Indemnification**
  - Industry and government
  - Look for it in the contract
  - Can be done with government trials

Comments 2

- **Maintaining Confidentiality**
  - Reports can be A versus B, but code should be revealed so one can interpret report
- **DMC Meeting Format**
  - Open, Closed, Executive
- **DMC Charters**
  - Should cover all essentials, but not too detailed
- **DMC Recommendations**
  - Consensus achieved by voting

Comments 3

- **DMC Member Contract**
  - Independent scientist, not a consultant
  - Conflicts of interest - financial, intellectual, disclosure, actionable
- **SDAC -** wide range of experience
    - Preparation of reports
    - Presentation at meetings
    - Knowledge of trial
- **Integration of Regulatory Authorities**
  - Observation or even better, service on DMC’s

Increasing DMC Workload

- Single trial
- Network – multiple trials
- Portfolio – single product – multiple trials
- Randomized trials, open label extension studies
- Review of new protocols
- Review of primary papers

Can we be more scientific than experts, surveys, and focus groups?

- **Items to collect more systematically include**
  - Characteristics of DMCs
  - DMC processes
  - DMC outcomes

ClinicalTrials.Gov

*	Required
*§	Required if Study Start Date is on or after January 18, 2017
[*]	Conditionally Required

- **Data Monitoring Committee**

  Definition: Indicate whether a data monitoring committee has been appointed for this study. The data monitoring committee (board) is a group of independent scientists who are appointed to monitor the safety and scientific integrity of a human research intervention, and to make recommendations to the sponsor regarding the stopping of the trial for efficacy, for harms or for futility. The composition of the committee is dependent upon the scientific skills and knowledge required for monitoring the particular study. Select Yes/No

DMC Characteristics

- Number of members
- Prior DSMB training/experience
- Expertise represented
- Indemnification

DMC Processes

- Frequency of meetings
- Types of meetings – teleconference, face-to-face
- SDAC expertise
- DSMB member remuneration
- Meeting format – executive, open, closed
- Independent scientist contract

DMC Outcomes

- Trial continued to scheduled conclusion
- Stopped early
  - Efficacy
  - Safety
  - Futility
  - Other

THANK YOU!