

Government, Academic and Non-Profit sponsors

1. Determining Need for a DMC
 - How do you determine whether a DMC is needed for a particular trial?
 - How are primary responsibilities of the DMC defined?
 - What flexibility do you have on:
 - Use of a DMC?
 - Responsibilities of a DMC?
2. DMC Member Selection
 - How do you determine the composition of the DMC?
 - What qualifications do you prefer of DMC members?
 - How do you decide to include on a DMC
 - A patient advocate?
 - An ethicist?
 - How do you determine the independence of a potential DMC member?
3. Training
 - How do you propose we best train new prospective DMC members?
 - What role should government play in this type of training?
 - Do you perceive DMC members to be a scarce resource?
4. Use of a CRO or ARO
 - Do you involve CRO/ARO in DMC operations?
 - What impacts the decision to involve a CRO/ARO in DMC operations?
5. DMC Charter
 - Do you typically have a DMC charter?
 - How can the charter be improved to better serve the DMC?
6. Other Issues
 - What are special considerations for DMCs overseeing network trials?
 - What are the most significant challenges you have with DMCs?
 - Are there any other issues you would like to raise for discussion?

Industry sponsors

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 - How do you determine whether a DMC is needed for a particular trial?
 - How are primary responsibilities of the DMC defined?
 - What flexibility do you have on:
 - Use of a DMC?
 - Responsibilities of a DMC?
2. DMC Member Selection
 - How do you determine the composition of the DMC?
 - What qualifications do you prefer of DMC members?
 - How do you decide to include on a DMC
 - A patient advocate?
 - An ethicist?
 - How do you determine the independence of a potential DMC member?
3. Training
 - How do you propose we best train new prospective DMC members?
 - What role should government play in this type of training?
 - Do you perceive DMC members to be a scarce resource?
4. Sponsor-DMC Communication
 - How involved is the sponsor in DMC meetings?
 - How much collaboration between the sponsor and DMC is there with generation of the SAP?
 - What is the process by the sponsor for determining whether to accept recommendations made by the DMC?
5. Use of a CRO or ARO
 - What impacts the decision to involve a CRO/ARO in DMC operations?
 - If DMC establishment and operation is outsourced, how do you qualify vendors for DMC services?
 - How involved are CRO reps in running meetings?
 - How do you select your Statistical Analysis Center?
6. DMC Charter
 - Do you typically have a DMC charter?
 - How can the charter be improved to better serve the DMC?
7. Other Issues
 - What are the most significant challenges you have with DMCs?
 - Are there any other issues you would like to raise for discussion?

Regulators and IRB Representatives

1. Determining Need for a DMC
 - How should it be determined whether a DMC is needed for a particular trial?
 - Do you think DMCs are appropriately, over, or under used?
2. Role of the DMC
 - What should be the primary responsibilities of a DMC?
 - What should the role of DMCs be in detection of unanticipated safety signals?
 - Should recommendations made by the DMC be binding?
3. Interaction with DMCs
 - Do you review the DMC charter?
 - Do you evaluate the qualifications of DMC members?
 - Do you think it is your role to request a DMC when one was not already planned?
4. Communication with DMCs
 - To what extent should the DMC communicate with the IRB and/or FDA?
 - What information do you receive from the DMC?
 - What information would you like to receive?
 - To what extent should the DMC communicate with various personnel conducting the trial (investigators, steering committee, endpoint adjudication committee)?
5. Training
 - What training should the DMC receive beyond protocol-specific information?
 - How can we best train new prospective DMC members?
 - Do you perceive DMC members to be a scarce resource?
6. Other
 - Are there any other issues you would like to raise for discussion?

DMC members

1. DMC Role

- What is the DMC's role in commenting on trial design?
- What should the DMC do if external information becomes available that impacts the initial design of the trial?
- What shouldn't the DMC do?
- When should DMCs be provided with efficacy data?
- What are the biggest factors influencing your ability to perform your role?
- What compromises the independence of the DMC?

2. DMC-Sponsor Interaction

- How involved is the sponsor in meetings?
- How much collaboration between the sponsor and DMC is there with generation of the SAP?
- How can the charter be improved to better serve the DMC?
- What challenges have you faced with sponsors or CROs?

3. DMC Member Qualification

- What constitutes a qualified DMC?
- What background is necessary to serve as a DMC member?
 - Does this differ if you are a DMC chair?
 - Does this differ whether or not it is an industry vs government sponsored trial?

4. Training

- Can you describe situations for which you wish you had received training or others were better trained? Or you wished your colleagues were better trained?
- What type of training would help prepare you to make decisions about modifying a trial?
- How can we best train new prospective DMC members?

5. Other

- Are there any other issues you would like to raise for discussion?

Patients/Patient Advocate DMC member

1. Role

- What is the primary role of a DMC?
- What was your primary role on the DMC?
- What do you think is the appropriate role for a patient advocate member on a DMC?
- What makes a DMC truly independent?
- Are there particular types of trials you think it is especially important for patients/advocates to participate?

2. Contributions

- Did you have an input into operational decisions/documentation (e.g. the Charter or Statistical Analysis Plan)
- Did you feel compelled to “go along” with the “experts” or were you able to disagree effectively?
- What value did you add to DMC deliberations?

3. Selection and Training

- How were you selected as a DMC member?
- What is the best method for recruiting patients/patient advocates for future studies?
- Were you trained to serve as a DMC member prior to joining the committee?
- How can we best train new prospective DMC members?

4. Liability

- Did you understand there to be any risk of liability related to your involvement?
- Did that make you reluctant to participate?
- If liability was not a concern to you, was there specific information provided to you that make you feel comfortable?

5. Challenges

- What has been the greatest challenge in participating on a DMC?

6. Other Items

- Would it be an advantage or disadvantage for research participants to be aware that a DMC exists?
- Do you perceive DMC members to be a scarce resource?
- Are there any other issues you would like to raise for discussion?

Statistical Analysis Centers (mix of CRO, ARO, or stand-alone)

1. SAC Interactions with DMCs
 - Describe communication practices between the SAC and DMC
 - Are communication pathways between the DMC and the SAC defined at the start of the trial?
 - Are Analysis Plans typically defined in the charter? Any suggestions to improve charters?
 - What are the “best practices” for reporting to the DMC so they can best make decisions about study safety and efficacy?
2. SAC Interactions with Sponsors
 - Describe communication practices between the SAC and sponsor.
 - Does the analysis report follow a pre-specified analysis plan and format set by the Sponsor?
 - Are Sponsors informed of requested changes to datasets/analyses?
3. Training and Qualification
 - How knowledgeable are DMC members **regarding analysis methods and process**? How can we best train DMC members?
 - How knowledgeable are Sponsors?
 - What training should SAC programmers/statisticians have?
 - What are the specific expectations of the statistician presenting the analysis report to the DMC?
4. Challenges
 - What challenges have you had working with Sponsors relative to DMC methods and process
 - What challenges have you had working with DMCs?
5. Opportunities
 - What are the “best practices” for working with Sponsors relative to DMC methods and process?
 - What are the “best practices” or guidelines for working with DMCs?
6. Other Discussion
 - Do you perceive DMC members to be a scarce resource?
 - Are there any other issues you would like to raise for discussion?