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

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:
     o Use of a DMC?
     o 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
     o A patient advocate?
     o 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?