

CTTI-DMC - Production

Intro1 Thank you for taking the time to complete this survey about Data Monitoring Committees. The answers you give are confidential and completely anonymous, and they cannot be linked back to your email or personal information in any way. In order to further protect your confidentiality, please do not cite specific trials, sponsors, investigational products, or other potentially revealing information pertaining to projects on which you have worked in any free-text responses. The survey should take you less than 15 minutes to complete and must be completed in a single session. To ensure that your responses are recorded, do not exit from the survey or web browser until you've completed the entire survey. If you have any questions, or would like assistance in completing the survey, please contact the study staff at ctti-dmcproject@duke.edu.

Intro2 This survey is intended to gather information about the current use and conduct of Data Monitoring Committees and will be used to inform activities and recommendations of the Clinical Trials Transformation Initiative Data Monitoring Committee project. Occasionally, these committees are referred to as Data Safety Monitoring Boards or DSMBs. For purposes of simplicity, we will use Data Monitoring Committees, or DMCs for short, throughout this survey. A DMC is an independent group of individuals that review the ongoing conduct of clinical trials to monitor patient safety and efficacy and make recommendations to the sponsor to ensure the validity and integrity of the trial. For the purposes of this survey, we define an external DMC to be a group of individuals that conduct these activities outside of the sponsor organization. Conversely, we define an internal DMC to be a group of individuals that conducts these activities within the sponsor organization. In thinking about the questions in this survey, please consider all DMCs you have experience with, but unless specifically mentioned, please answer for what is the most common or most typical in the DMCs. If you are unsure of how to answer a question, please give the best answer you can or skip the question if it doesn't apply to you.

Role What is your role and interaction with DMCs?

- I am currently, or have in the past, served as a member of a DMC. (1)
- I oversee organization of DMCs at a Pharmaceutical Industry Sponsor (2)
- I oversee organization of DMCs at a Medical Device Industry Sponsor (3)
- I oversee organization of DMCs at an Academic Institution (4)
- I oversee organization of DMCs at a CRO (Contract Research Organization) on behalf of the trial sponsor (5)
- I oversee organization of DMCs at an ARO (Academic Research Organization) on behalf of the trial sponsor (6)
- I oversee organization of DMCs at a government sponsor (7)
- I provide statistical support for DMCs within a private/contract Statistical Analysis Center or CRO (8)
- I provide statistical support for DMCs within an academic Statistical Analysis Center or ARO (9)
- None of the above (997)

Answer If What is your role and interaction with DMCs? None of the above Is Selected

Redirect This survey is intended for people who have direct interactions with Data Monitoring Committees. If you chose "None of the above" in the previous question by error, please click the BACK option and select the appropriate role. If none of the previous roles apply, but you still feel you qualify to provide input, please select "Continue to Survey". Otherwise, please select "End Survey".

- Continue to Survey (1)
- End Survey (2)

If End Survey Is Selected, Then Skip To End of Survey

Answer If Continue to Survey Is Selected

Role_Other Please describe your interactions with DMCs which you feel qualifies you to provide input with this survey

MEM_EXP DMC Member Experience

dmc_num In your career, on how many DMCs have you served?

- Less than 5 committees (1)
- About 5-10 committees (2)
- About 11-20 committees (3)
- More than 20 committees (4)

dmc_yrs Over how many years have you served on DMCs in your career?

- Less than 1 year (1)
- About 1-3 years (2)
- About 4-6 years (3)
- About 7-10 years (4)
- More than 11 years (5)

curr_serve Are you currently serving on any DMC?

- Yes (1)
- No (0)

Answer If Are you currently serving on any DMC? Yes Is Selected

num_curr On how many DMCs are you currently serving?

- 1 (1)
- 2-3 (2)
- 4-6 (3)
- 7-10 (4)
- 11-15 (5)
- 16 or more (6)

Answer If Are you currently serving on any DMC? No Is Selected

last_serve How long has it been since you last served on a DMC?

- Less than 1 year (1)
- About 1-3 years (2)
- About 4-6 years (3)
- About 7-10 years (4)
- 11 years or longer (5)

chair_exp Have you ever had experience as a DMC Chair?

- Yes (1)
- No (0)

sci_dis With which scientific discipline do you most closely associate yourself? (Please select all that apply)

- Biostatistics (1)
- Epidemiology (2)
- Basic Science (3)
- Physician (4)
- Non-M.D. Clinician (5)
- Medical Ethics (6)
- Pharmacology/Pharmacotherapy (7)
- Patient Advocacy (8)
- Biomedical Informatics (9)
- Biomedical Engineering (10)
- Clinical Research (11)
- Other (please describe) (997) _____

trial_exp What has been your involvement in, or what is your experience in conducting clinical trials? (Please select all that apply)

- I have been an Investigator conducting clinical trials. (1)
- I have worked as a Sponsor specifically on management of clinical trials. (2)
- I have worked at a CRO/ARO specifically on management of clinical trials. (3)
- I have been a patient in a clinical trial. (4)
- I have worked as a patient advocate providing input into conduct of clinical trials. (5)
- I have no involvement in, nor any experience with conducting clinical trials. (6)
- Other (please describe) (997) _____

irb_exp What is your experience serving on an IRB or knowledge of IRB functions? (Please select all that apply)

- I have served on an IRB. (1)
- I have interacted with IRBs as an Investigator, Sponsor, or CRO/ARO. (2)
- I have limited knowledge of IRB functions. (3)

ABOUT_DMCs DMC Purpose and Types of DMCs

rank_act All DMCs have as their primary purpose to protect the interests and safety of subjects and ensure the ethical conduct of the trial. Among the following, please order by rank from 1-7 (by dragging and dropping from top to bottom) which activities you view as the most important specific activity (1) to the least important activity (7) for DMCs to perform?

- _____ To review individual adverse event reports (1)
- _____ To review individual serious adverse event reports (2)
- _____ To review accumulating or summary adverse event reports overall (3)
- _____ To review accumulating or summary adverse events by treatment arm (4)
- _____ To review both summary adverse events and primary outcomes by treatment arm to assess the benefit to risks (5)
- _____ To increase the integrity of the trial by reviewing, recruitment, adherence to the protocol and quality of data (6)
- _____ Other (If no other, leave blank with a rank order of 7) (997)

req_opt Are the DMCs that you have been on, or interacted with:

- Required by the sponsor for the clinical trial (1)
- Deemed optional by the sponsor for the clinical trial (2)
- A mix of both in the DMCs I've worked with (3)
- I'm not sure whether the DMCs are required or optional (999)

Answer If Are the DMCs that you have been on, or interact with: A mix of both in the DMCs I've worked with Is Selected

req_opt2 You've indicated that you have been on a mix of both required and optional DMCs, we would like for you to indicate which is the most common in your experience:

- Required by the sponsor for the clinical trial (1)
- Deemed optional by the sponsor for the clinical trial (2)
- Really, it's an even mix of the two! (3)

trialtype Thinking again about all the DMCs on which you have served or with which you have interacted, are they:

- Drug Trials (1)
- Device Trials (2)
- I have experience with both types (3)

Answer If Thinking again about all the DMCs on which you have served or with which you have interacted, are they: I have experience with both types Is Selected

trialtype2 Is there one type that tends to occur more often than the other?

- Drug Trials (1)
- Device Trials (2)
- An even split of the two (3)

int_ext With what types of DMCs have you had experience? (Hover over the blue word to read our definition of internal vs. external.)

- Internal DMCs (1)
- External DMCs (2)
- Both types (3)

Answer If What types of DMCs have you experience with? Both types Is Selected

int_ext2 Is there one type of DMC that tends to occur more often than the other?

- Internal DMCs (1)
- External DMCs (2)
- An even split (3)

phase What phase of trials do your DMCs cover? (Please select all that apply.)

- Phase I (1)
- Phase II (2)
- Phase III (3)
- Phase IV / Post-Marketing Trials (4)
- Other (please describe) (997) _____

adapt Do you participate in or interact with DMCs for "adaptive design trials"? Here, we define an "adaptive design trial" as one in which key trial characteristics (like randomization proportions, sample size, treatment arms, eligibility criteria, etc.) evolve according to prospectively defined rules during the trial, in response to information accruing within the trial itself.

- Yes (1)
- No (0)

If No Is Selected, Then Skip To Thinking of all the DMCs that you hav...

adaptexp For the DMCs of trials with an Adaptive Design; does one of the members of the DMC have expertise in adaptive design trials?

- Yes (1)
- No (0)
- Unknown (999)

adaptneed Do you believe there are special DMC needs in the context of adaptive design trials?

- No (0)
- Yes, special training for the DMC members (1)
- Yes, other special needs (997) _____

size What is the typical size of the committees on which you have been or with which you have interacted?

- Less than 3 members (1)
- 3-4 members (2)
- 5-7 members (3)
- 8-9 members (4)
- More than 10 members (5)

CHRTR_CON DMC Charters and Contracts

charter Is there typically a DMC Charter?

- Always (1)
- Most of the Time (2)
- Sometimes (3)
- Rarely (4)
- Never (5)
- Not Sure (999)

If Rarely Is Selected, Then Skip To How useful do you consider a DMC char...If Not Sure Is Selected, Then Skip To How useful do you consider a DMC char...If Never Is Selected, Then Skip To How useful do you consider a DMC char...

char_topic What does the Charter specifically address? (Please select all that apply)

- Confidentiality (1)
- Intellectual Property (2)
- Conflict of interest (3)
- Financial disclosure (4)
- Specific Member Responsibilities (5)
- Meeting Format (6)
- Timing of Meetings (7)
- Document retention procedures (8)
- Reporting Instructions after DMC meetings (9)
- Synopsis of the Protocol (10)
- Outline of data to be reviewed (11)
- Blinding procedures (12)
- Whether additional analyses can be requested by the DMC (in addition to pre-defined analyses in the SAC) (13)
- Statistical guidelines for early termination for benefit, harm or futility (14)
- List of DMC members and their contact information, including chair (15)
- Vacancy appointments (16)
- Other (please describe) (997) _____

Answer If What does the Charter specifically address? (Select ALL that apply.)
Whether additional analyses can be requested by the DMC Is Selected

char_add You indicated that the charter addresses whether additional analyses can be requested by the DMC. Please describe what the mechanisms are for requesting these additional analyses.

char_auth Who is usually the primary author of a DMC Charter?

- DMC Chair (1)
- Sponsor (Commercial or Government) (2)
- CRO or ARO (3)
- Other (please describe) (997) _____

char_input Do DMC members have the opportunity to provide input into the charter?

- Always (1)
- Most of the Time (2)
- Sometimes (3)
- Rarely (4)
- Never (5)
- Not sure (999)

char_use How useful do you consider a DMC charter in providing the information needed to carry out the responsibilities of the DMC?

- Very Useful (1)
- Somewhat Useful (2)
- Neutral (3)
- Only A Little Bit Useful (4)
- Not Useful At All (5)

contract Is there a formal contract with DMC members?

- Always (1)
- Most of the Time (2)
- Sometimes (3)
- Rarely (4)
- Never (5)
- Not sure (999)

If Rarely Is Selected, Then Skip To Thinking about all experiences with D...If Never Is Selected, Then Skip To Thinking about all experiences with D...If Not sure Is Selected, Then Skip To Thinking about all experiences with D...

con_std Is the initial contract a standard legal contract or has it been customized for DMC use?

- Standard legal contract with few specifics for DMCs (1)
- Customized contract made specifically for a DMC (2)

con_topics What does the contract typically contain? (Please select all that apply)

- Confidentiality (1)
- Intellectual Property (2)
- Conflicts of Interest (3)
- Indemnification (4)
- Responsibilities (5)
- Independence from sponsor (6)
- Timing and frequency of meetings (7)
- Rates (8)
- Remuneration for unscheduled meetings (9)
- Remuneration for work done by DMC members outside of regular DMC meetings (10)
- Terms of Replacement or dismissal (11)
- Sunshine Act reporting requirements (12)
- Other (please describe) (13) _____

rates Thinking about all experiences with DMCs, how is remuneration determined? (Please select all that apply)

- No Remuneration (1)
- One Time Payment for committee work as a whole (2)
- Hourly Rates (3)
- Per Meeting or Per Teleconference Rates (4)

Answer If Thinking about all experiences with DMCs, how is remuneration determined? (Select ALL that apply.) Per Meeting or Per Teleconference Rates Is Selected

rates_mtg You indicated that remuneration can be determined on a per meeting or per teleconference basis. Are face-to-face meetings priced differently from teleconference or webex meetings?

- Yes, higher rates for face-to-face meetings (1)
- No, same rate as teleconferences/web ex meetings, but includes travel and expense costs (0)
- Not sure (999)

Answer If Thinking about all experiences with DMCs, how is remuneration determined? (Select ALL that apply.) No Remuneration Is Not Selected

rates_set Who sets the remuneration rates?

- Sponsor (Commercial or Government) (1)
- DMC members (2)
- Negotiated between DMC and Sponsor (3)

SCHEM_COND Scheduling and Conduct of DMCs

mode How are DMC meetings typically conducted?

- Face-to-Face (1)
- Remote (Teleconference or WebEx style) (2)
- Remote video conference (3)
- Mix of Remote and In-Person for the same DMC (4)

sched_all Who sets the planned schedule for the frequency of the meetings?

- Sponsor (1)
- CRO (2)
- Investigator (3)
- DMC itself (4)
- Joint decision between stakeholders (5)

freq What is the typical frequency of meetings in the schedule, or what triggers the occurrence of a meeting?

- Only ad hoc by the CRO or Sponsor (1)
- Only ad hoc by occurrence of an SAE (2)
- Only regularly scheduled meetings (3)
- Combination of regularly scheduled meetings plus ad hoc meetings as needed (4)
- As a function of the fraction of patients recruited or events observed (5)
- Other (please describe) (997) _____

Answer If What is the typical frequency of meetings in the schedule, or what triggers the occurrence of a m... Only Regularly Scheduled meetings? Is Selected Or What is the typical frequency of meetings in the schedule, or what triggers the occurrence of a m... Combination of regularly scheduled meetings plus ad hoc meetings as needed? Is Selected

freq_reg You mentioned Regularly Scheduled as a frequency of meetings. Please specify what that schedule typically is:

- Monthly (1)
- Quarterly (2)
- Semi-Annually (3)
- Annually (4)
- Other (please describe) (997) _____

add_sched Does the DMC have the authority to schedule an additional meeting outside the pre-defined meeting schedule?

- Always (1)
- Most of the Time (2)
- Sometimes (3)
- Rarely (4)
- Never (5)
- Not Sure (999)

level_cont What do you generally see as the level of contact between the Sponsor and DMC members? (Please select all that apply)

- At a DMC meeting's opening session (1)
- Throughout the entirety of DMC meetings (2)
- Regular Interaction outside of the DMC meetings (3)
- Other (please describe) (997) _____

cont_pref What would you PREFER to see as the level of contact between the Sponsor and DMC members? (Please select all that apply)

- At a DMC meeting's opening session (1)
- Throughout the entirety of DMC meetings (2)
- Regular interact outside of the DMC meetings (3)
- Other (please describe) (997) _____

recommend Thinking about all the DMCs with which you have had experience, were the recommendations of the DMC accepted by the Sponsor or CRO?

- Always (1)
- Most of the Time (2)
- Sometimes (3)
- Rarely (4)
- Never (5)
- Not Sure (999)

STATS_SAPs DMC Statistical Support and Statistical Analysis Plans

stat_supp Who typically provides the DMC statistical support? (Please select all that apply)

- Provided by the Sponsor's internal resources (1)
- CRO (2)
- Supported by academic research institutions independent of sponsor or CRO (3)
- A statistician on the DMC committee (4)
- Not sure (999)

SAP_exist Is there a Statistical Analysis Plan (SAP) for the DMC?

- Always (1)
- Most of the Time (2)
- Sometimes (3)
- Rarely (4)
- Never (5)
- Not Sure (999)

If Rarely Is Selected, Then Skip To End of Block
If Never Is Selected, Then Skip To End of Block

SAP_docum Where is the SAP documented?

- Protocol, Main Body (1)
- Protocol, Appendix (2)
- Stand Alone Document (3)
- DMC Charter (4)
- Not sure (999)

SAP_deviat Can the DMC deviate from the SAP?

- Always (1)
- Most of the Time (2)
- Sometimes (3)
- Rarely (4)
- Never (5)
- Not Sure (999)

SAP_input Can the DMC provide input or change the SAP?

- Always (1)
- Most of the Time (2)
- Sometimes (3)
- Rarely (4)
- Never (5)
- Not Sure (999)

ID_DMCs Identification of DMC Members

ID_self How have you been identified to participate in the DMCs on which you have served? (Please select all that apply)

- Sponsor Contacted Me (1)
- CRO or ARO managing the study contacted me (2)
- Asked by current members or chair of the DMC to join (3)
- Asked by a colleague with knowledge of the study (who isn't currently serving on the DMC) (4)
- Other (please describe) (997) _____

ID_assist Do you assist in identifying other members for DMCs?

- Yes (1)
- No (0)

Answer If Do you assist in identifying other members for DMCs? Yes Is Selected

ID_others How do you identify other members? (Please select all that apply)

- Served concurrently with them on other DMCs (1)
- Served with them in the past on DMCs (2)
- Colleagues who have been on DMCs, but haven't served with them in the past (3)
- Colleagues who have never served on DMCs but have expressed interest (4)
- Training program participants (5)
- Other (please describe) (997) _____

DMCTRAIN DMC Member Training

DMCTrain01 Have you ever been formally trained to serve on a DMC (outside of the initial organizational study-specific DMC meeting)?

- Yes (1)
- No (0)

Answer If Have you ever been trained to serve on a DMC No Is Selected

DMCTrain02 Would you have preferred to have been trained before serving on a DMC?

- Yes (1)
- No (0)

Answer If Have you ever been trained to serve on a DMC Yes Is Selected

DMCTrain03 Did the training occur before or after joining your first DMC?

- Before (1)
- After (2)

Answer If Did the training occur before or after joining your first DMC? After Is Selected

DMCTrain04 Would you have preferred to have been trained BEFORE serving on your first DMC?

- Yes (1)
- No (0)

Answer If Have you ever been trained to serve on a DMC Yes Is Selected

DMCTrain05 Briefly describe the training that you received.

DMCTrain06 Do you think it would be beneficial to have some DMC experience prior to receiving training?

- Yes (1)
- No (0)

DMCTrain07 Would you be willing to mentor a "new" DMC member?

- Yes (1)
- No (0)

DMCTrain08 Are you aware of any training programs for DMCs (other than one you may have participated in yourself)?

- Yes (1)
- No (0)

Answer If Are you aware of any training programs for DMCs (other than one you may have participated in your... Yes Is Selected

DMCTrain09 Briefly describe any other training programs of which you are aware, if you haven't already described it above.

Answer If Are you aware of any training programs for DMCs (other than one you may have participated in your... Yes Is Selected

DMCTrain10 Do you encourage other DMC members to obtain training?

- Always (1)
- Most of the Time (2)
- Sometimes (3)
- Rarely (4)
- Never (5)

INDEP_DMC Independence of DMCs

Pressure Have you ever felt pressured to make a particular decision one way or another?

- Yes, often (1)
- Yes, sometimes (2)
- Yes, once in a while (3)
- No, never (0)

Answer If Have you ever felt pressured to make a particular decision one way or another? No, never Is Not Selected

PressWho Who has applied the pressure to make the decision? (Please select all that apply)

- Other DMC members (1)
- Investigator (2)
- Industry Sponsor (3)
- Government Sponsor (4)
- CRO or ARO (5)
- Other Individuals outside of the DMC (6)
- Other (please describe) (997) _____

Answer If Have you ever felt pressured to make a particular decision one way or another? No, never Is Not Selected

PressExpl If you would like, you may provide further explanation of the types of pressure you have felt in making decisions within the DMC. Alternatively, you may click Next to

skip to the next question. Please remember to keep any identifying information out of your responses.

Consequenc Have you ever suffered adverse consequences for making a particular decision on a DMC?

- Yes, multiple times (1)
- Yes, but only once or twice (2)
- No, never (0)

Answer If Have you ever suffered adverse consequences for making a particular decision on a DMC? No, never Is Not Selected

ConseqExpl If you would like, you may provide further explanation of the adverse consequences you have suffered for making decisions within the DMC. Alternatively, you may click Next to skip to the next question. Please remember to keep any identifying information out of your responses.

TrueIndep Do you believe that the DMCs you have served on have been able to function truly independently?

- Always (1)
- Most of the Time (2)
- Sometimes (3)
- Rarely (4)
- Never (5)
- Not Sure (999)

FREETEXT To end the survey, we would like to ask your opinions on any areas of improvement or best practices you have identified during your interactions with DMCs.

Problems Briefly describe any problems you have had while serving on, or interacting with DMCs.

Improvemen Briefly describe what areas of improvement could be addressed in DMCs.

BestPract Briefly describe any best practices you would recommend while serving on, or interacting with DMCs.

SPON_ID Identification of DMC Members

ID_sponsor How do you identify potential DMC members? (Please select all that apply)

- They have served on previous DMCs for my specific studies (1)
- They have served on DMCs for other studies I'm aware of (2)
- Recommended to me by others as having DMC experience (3)
- Recommended to me based on their expertise or reputation, with no or unknown DMC experience (4)
- Literature search (through journal articles and listed references of other publications) (5)
- Training program participants (6)
- I do not identify potential DMC members (7)
- Other (please describe) (997) _____

SponsorSOP Are there standard SOPs at the sponsor organization governing conduct of DMCs?

- Always (1)
- Most of the Time (2)
- Sometimes (3)
- Rarely (4)
- Never (5)
- Not Sure (999)

SPONTRAIN DMC Member Training

SpTrain01 Do you require members to be trained before joining the DMCs for your particular studies?

- Always (1)
- Most of the Time (2)
- Sometimes (3)
- Rarely (4)
- Never (5)
- Not Sure (999)

SpTrain02 Are you aware of any training programs for DMCs?

- Yes (1)
- No (0)

SpTrain03 Have you led a training program yourself?

- Yes (1)
- No (0)

Answer If Have you led a training program yourself? Yes Is Selected

SpTrain04 Briefly describe the training program you have led:

SpTrain05 Have you participated in a training program?

- Yes (1)
- No (0)

Answer If Have you participated in a training program? Yes Is Selected

SpTrain06 Briefly describe the training program in which you have participated:

SpTrain07 Do you offer or suggest training programs for the studies that you manage?

- Always (1)
- Most of the Time (2)
- Sometimes (3)
- Rarely (4)
- Never (5)
- Not Sure (999)

SpTrain08 Briefly describe any other training programs of which you are aware, if you haven't already described them above.

SAC_SURVEY Statistical Analysis Center interactions with DMCs

SAC_01 Do you provide reports for DMCs?

- Yes (1)
- No (0)

If No Is Selected, Then Skip To To end the survey, we would like to a...

<p>if needed? (8)</p> <p>Is the biostatistician who prepared the report present at DMC meetings? (9)</p> <p>Is there a biostatistician present with expertise of statistical monitoring methods and interim stopping decisions when the DMC report is reviewed? (10)</p>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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SAC_03 What proportion of reports are made up of graphics (e.g. figures)?

- 75% or more (1)
- about 50% (2)
- about 25% (3)
- Less than 25% (4)
- No graphics at all (5)

SAC_04 Do you have adequate resources (e.g. appropriate computer software) to prepare graphic reports?

- Always (1)
- Most of the Time (2)
- Sometimes (3)
- Rarely (4)
- Never (5)
- Not Sure (999)

SAC_05 With whom is the SAC contracted?

- Sponsor (1)
- CRO (2)
- ARO (3)
- Investigator (4)
- Other (please describe) (997) _____

SAC_06 Have you ever been unable to fulfill a DMC request due to the confines of the contract with the sponsor?

- Yes (1)
- No (0)

SAC_07 How is the SAC reimbursed for additional work outside pre-defined meetings and analyses?

- Hourly (1)
- New negotiated rate based on requested work (2)
- Not reimbursed for additional work (3)
- Other (please describe) (997) _____
- Not Sure (999)

SAC_08 Do you have access to unblinded data?

- Always (1)
- Most of the Time (2)
- Sometimes (3)
- Rarely (4)
- Never (5)
- Not Sure (999)

SAC_09 How do you firewall the unblinded analysis team from sponsor and investigators?

SAC_text To end the survey, we would like to ask your opinions about areas of improvement and best practices that you may have identified during your interactions with DMCs

SAC_10 Briefly describe any problems you have had in providing statistical support to DMCs?

SAC_11 Briefly describe what areas of improvement could be addressed in this area?

SAC_12 Briefly describe any best practices that you have experienced?