

Understanding Data Monitoring Committee Conflict of Interest Limitations



For sponsors utilizing a data monitoring committee in their trial designs to monitor for emerging safety signals, lack of effect, and/or futility of treatment, understanding data monitoring committee conflict of interest limitations is important to ensuring an objective view of the data from a trial. Where we see these conflict of interest considerations put to the test most often is in rare disease trials where the available pool of informed experts can be just as small as the patient populations under study. As explained in FDA's final [guidance](#) for industry on this topic, core considerations for avoiding potential conflicts of interest in data monitoring committee member selection include:

- **Financial interests.** Here, careful consideration must be given to whether any prospective committee member holds ownership interests in the sponsor entity or stands in a position to benefit financially from the outcome of the trial. This can include equity or stock interests, employee or temporary employee status, paid consulting or advisory board relationships with the sponsor, prior research funding from an institution involved in the study, whose product is being evaluated in the study or competes with a product being evaluated in the study, among other things. FDA generally recommends against appointing any committee members with *ongoing* financial relationships to the trial's sponsor.
- **Other roles in the trial.** Those individuals entering subjects into and conducting a trial stand in a considerable conflict position given their knowledge of interim data emerging from subjects at their trial site which could influence the recruitment or monitoring trends of those individuals for the trial. As such, FDA generally recommends against appointing any committee member who is serving as an investigator in the trial the data monitoring committee would oversee. Additionally, FDA disfavors appointment of any members that have had input into the design of the trial or are involved in the conduct of the trial in any other role for similar reasons.
- **Intellectual conflicts.** Perhaps most challenging to evaluate and navigate in rare disease trials is the risk to objectivity that strongly held views of prospective data monitoring committee members could play in their ability to review the data in a fully objective manner. This could include prospective committee members with strong views on the relative merits of the intervention under study vs. others under development. Additionally, FDA recommends against appointing committee members with strong relationships to or personal differences with trial investigators or to sponsor employees which are likely to cloud their objectivity.

FDA recognizes the tension that sponsors must navigate between placing a high value on independence and avoidance of conflicts of interest in the composition of its data monitoring

committees, on the one hand, and understanding the importance of a well-informed data monitoring committee to the effective oversight of emerging data from a trial, on the other. While there is no one-size-fits all approach, data monitoring committee charters and sponsor conflict of interest policies can be helpful in this regard to establish and document the sponsor's limitations on engagement and interaction with the committee and vice versa. The more interconnected the sponsor-developer and investigator communities become, the more challenging it may become for sponsors, particularly those in the rare disease space, to ensure the objectivity of its data monitoring committees.