SOLUTION SHEET

Data Monitoring Committee Services

PharPoint has extensive experience supporting and managing Data Monitoring Committees (DMCs). Biostatisticians at PharPoint are routinely involved in DMCs whose outcomes may affect cohort enrollment, dose escalation/de-escalation, study modifications, and study continuation.

To overcome DMC challenges surrounding logistics and processes, PharPoint dedicates ample time to properly supporting DMC members and ensuring effective communication. This includes a training program to support members who are new to the DMC process, along with study-specific training to ensure committee needs are transparent from the start.

Experience providing DMC services since **2007**

300+ DMC meetings as independent or voting statistician

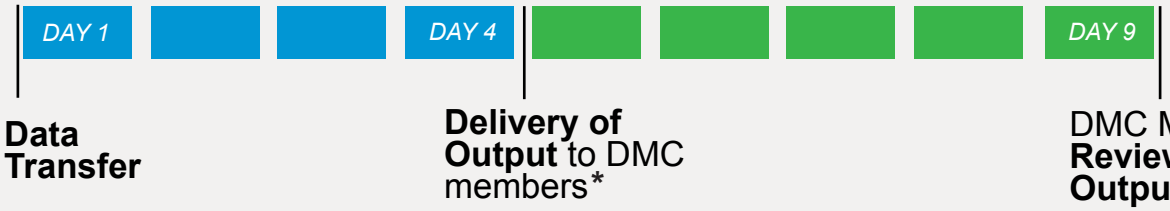
Statistician participation in **160+** unique protocols

PHARPOINT'S DMC SERVICES INCLUDE:

- DMC charter development, authoring, & review
- Committee member selection
- DMC member training on design and analyses interpretation
- Administrative management, including scheduling and facilitating DMC meetings
- Table, figure, and listing (TFL) preparation and distribution
- High-level summary report to accompany DMC TFL output
- Statistical design and support for mid-study adaptations and efficacy evaluations
- Archival of documentation to support Trial Master File (TMF) filing at study conclusion

QUICK TURNAROUND

DMC Analyses are created using the same programs developed for final analysis, with quick turnaround to minimize chance of enrollment pauses.



Dependent on timely receipt of clean data

Your DMC members are experts within their fields: but have they received proper training on their DMC responsibilities and analysis interpretation?

According to a 2015 CTTI survey, **only 8% of DMC members indicated having been trained in DMC process*,** despite their belief that such training would have been valuable. To meet this need, PharPoint can provide DMC Member Training courses, including both general & study-specific sessions on topics such as:

GENERAL SESSIONS

- Fundamental Clinical Trial Design & Operations
- Responsibilities within a DMC
- Importance and Expectations of a DMC from a Regulatory Perspective
- DMC Case Studies

STUDY-SPECIFIC SESSIONS

- DMC Charter Review
- Practical Considerations - Study Design
- Statistical Monitoring Methods & Analyses Interpretation
- Perspectives from the Independent Statistician

*https://ctti-clinicaltrials.org/wp-content/uploads/2021/07/CTTI_DMC_Meeting_Summary.pdf

Contact our business development team to learn more about PharPoint's DMC services.
pharpoint.com/contact

PHARPOINT RESEARCH