

DCRI INDEPENDENT DATA MONITORING COMMITTEE SUPPORT

Advancing Safety, Efficiency, and Outcomes

WHO WE ARE

The Duke Clinical Research Institute (DCRI), the world's largest academic clinical research organization and part of the Duke University School of Medicine, is known for conducting groundbreaking multinational clinical trials, managing major national patient registries, and performing landmark outcomes research.

DCRI's Clinical Trials Statistics Group manages all aspects of operations in support of Independent Data Monitoring Committees (IDMC), also known as Data Safety Monitoring Boards (DSMB). We work with sponsors and study leadership to provide the highest level of support for IDMCs.

WHAT WE DO

DCRI's IDMC capabilities include:

- Identification of IDMC members
- Management of IDMC member contracting and payments
- Development of the IDMC charter
- Creation of the Statistical Analysis Plan (SAP)
- Execution of the SAP
- Consultation on design and interpretation of statistical analyses
- Coordination of IDMC meetings, minutes, and meeting documentation
- Attendance at IDMC meetings to present statistical analyses
- Archival of IDMC materials

OUR EXPERIENCE

The DCRI has more than 30 years of experience supporting IDMC activities. The DCRI and Duke are also active in the Clinical Trials Transformation Initiative (CTTI), helping to define and deliver improvements in IDMC formation, activities, and governance.

As founding members of CTTI, we are independently committed to the application of the CTTI recommendations, including improvements in IDMC organization and operations.

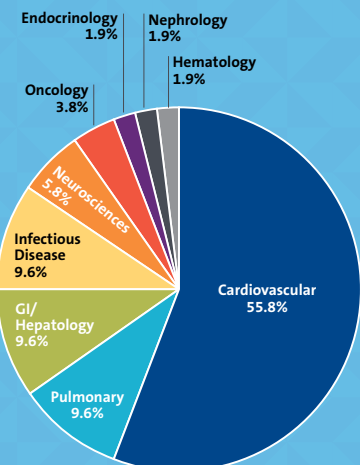
Since 2012, we have provided IDMC support to 52 projects (45 individual trials and 7 programs) in multiple therapeutic areas.

Resources

The DCRI offers experienced teams of biostatisticians and programmers who work in partnership with Duke University faculty experts on IDMC activities. Typical project teams include:

- Faculty/reviewing biostatistician
- Lead biostatistician
- One or more statistical programmers
- IDMC coordinator

IDMC Experience by Therapeutic Area



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Find out more about IDMC support at the DCRI.

David Gee

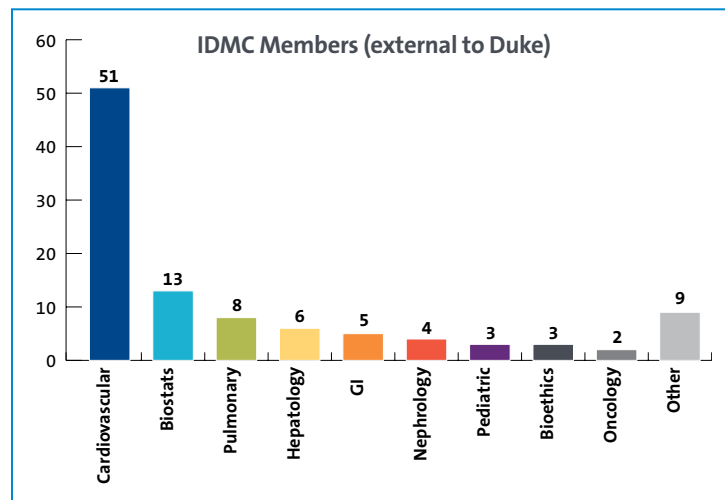
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dcri.org/our-services/biostatistics

COLLABORATIVE PARTNERSHIPS AND ACCESS TO MEMBERS

The DCRI has formed collaborative partnerships on trials with a wide range of entities, including both industry and government sponsors.

In addition, Duke University employs or is affiliated with many of the global leaders in their respective therapeutic areas. This internal access serves as a tool for identification of members who will serve on IDMCs. In addition, the DCRI has access to more than 100 potential members external to Duke from around the globe.



The DCRI is a nonprofit academic research organization dedicated to the improvement of patient care through innovative research. Using their experience and cutting-edge knowledge, our biostatisticians and clinical experts bring advantages to stakeholders worldwide by helping them achieve research objectives, discovering innovative solutions, meeting regulatory standards, and maintaining cost-effectiveness.



From **thought leadership**

to **clinical practice**



Duke Clinical Research Institute