

Creation of the Pediatric Data & Safety Monitoring Committee: Providing Pediatric Expertise and Independent Oversight for MSK-Sponsored Pediatric Studies

D. Diaz-Leyton, X. Lekperic, K. Napolitano, C. Kolenut, S. Hanley, A. Rodavitch, C. Houston, B. Widemann, J. Bender

Memorial Sloan Kettering Cancer Center

1. Background

In accordance with Cancer Center Support Grant (CCSG) guidelines, Memorial Sloan Kettering (MSK) follows a structured Data and Safety Monitoring Plan (DSMP) for oversight of investigator-initiated trials (IITs). Historically, the Data and Safety Monitoring Committee (DSMC) and Data and Safety Monitoring Board (DSMB) monitored all MSK-sponsored IITs, including pediatric studies. As MSK's pediatric research portfolio expanded, the need for specialized, independent oversight to enhance objectivity, reduce institutional bias, and improve transparency became evident.

2. Goals

Enhance institutional data and safety monitoring (DSM) strategy by integrating specialized, independent oversight for pediatric IITs.

3. Solutions and Methods

Established the Pediatric Data and Safety Monitoring Committee (PDSMC) as an independent oversight committee:

- Defined scope and responsibilities to enhance pediatric IIT monitoring, focusing on safety, data integrity, study progress, and compliance.
- Appointed committee leadership, with an external chair for unbiased oversight and regulatory compliance, and two internal chairs for institutional coordination.
- Recruited a predominately external committee of pediatric oncologists and statisticians for specialized oversight.
- Streamlined external member onboarding (e.g., legal agreements) to improve efficiency.

Integrated pediatric-specific workflows into MSK's DSM strategy:

- Developed Standard Operating Procedures (SOPs) to formalize committee structure, scope, decision-making, and review criteria. SOPs complement existing DSMC/B versions.
- Defined monitoring criteria to determine which studies require PDSMC oversight.
- Transitioned eligible pediatric studies from DSMC to PDSMC for specialized review.
- Implemented a quarterly meeting schedule to comply with institutional DSMP.
- Leveraged Tableau activation dashboards to identify new studies requiring PDSMC oversight.
- Implemented a pipeline tracker to ensure timely monitoring of new studies and track existing studies.

Implemented standardized tools modeled after DSMC/B templates:

- Created a PDSMC Monitoring Form to standardize submissions. The form ensures consistency in capturing study/design overview and updates, enrollment data, data integrity metrics, safety metrics (e.g., SAEs), and analysis data (e.g., interim analysis, stopping rules).
- Designed a Reviewer Checklist to enhance focus, consistency, and standardization across committee evaluations.

Ensured member training and engagement:

Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Completed Project

- Developed structured training materials to align members with institutional expectations and DSM best practices.
- Engaged members in the creation of key operational tools (e.g., SOPs, Form), ensuring collaborative and transparent committee operations.
- Conducted onboarding sessions to ensure effective participation and alignment with newly established workflows.

4. Outcomes

- Integrated PDSMC into MSK's DSM strategy, improving efficiency and transparency for 7 pediatric IITs (2 transferred from DSMC and 5 new studies).
- Expanded MSK's pediatric DSM expertise by increasing pediatric DSM reviewers from 1 to 9, which enhanced specialized oversight.
- Strengthened external engagement by nearly tripling external DSM experts at MSK (5 to 14), which enriched multidisciplinary input and expertise.
- Improved standardization with structured review tools tailored to pediatric studies for clearer expectations and consistent submissions.

5. Lessons Learned and Future Directions

Lessons Learned:

- Training materials must be tailored to provide institutional context for external members.
- Standardizing legal onboarding workflows reduce bottlenecks and delays.

Future Directions:

- Expand PDSMC portfolio and membership expertise (e.g., hematology).
- Leverage technology to enhance coordination and efficiency.
- Strengthen ongoing education and training for members.