

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

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## 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 applicable 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.

## Goals

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

## 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 predominately external 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.
- 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 (Figure 1) to standardize submissions. The form ensures consistency in capturing study/design overview and updates, enrollment data, data integrity metrics, safety metrics and analysis data.
- Designed a Reviewer Checklist (Figure 2) to enhance focus, consistency, and standardization across committee evaluations.

### Ensured Member Training and Engagement:

- 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.

Figure 1: PDSMC Monitoring Form Excerpt

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**Pediatric Data and Safety Monitoring Committee (PDSMC) Monitoring Form**  
Study Updates

12. Complete the tables below to provide an overview of enrollment to date.

a. Participant Enrollment Status by Site (aggregate data)

Study Site	Total Screened	Total Enrolled	Total Treated	Total <12 years	Total ≥ 12 years	Total On Therapy	Total Off Therapy	Total On Active Follow-Up	Total Off Study	Total Expired

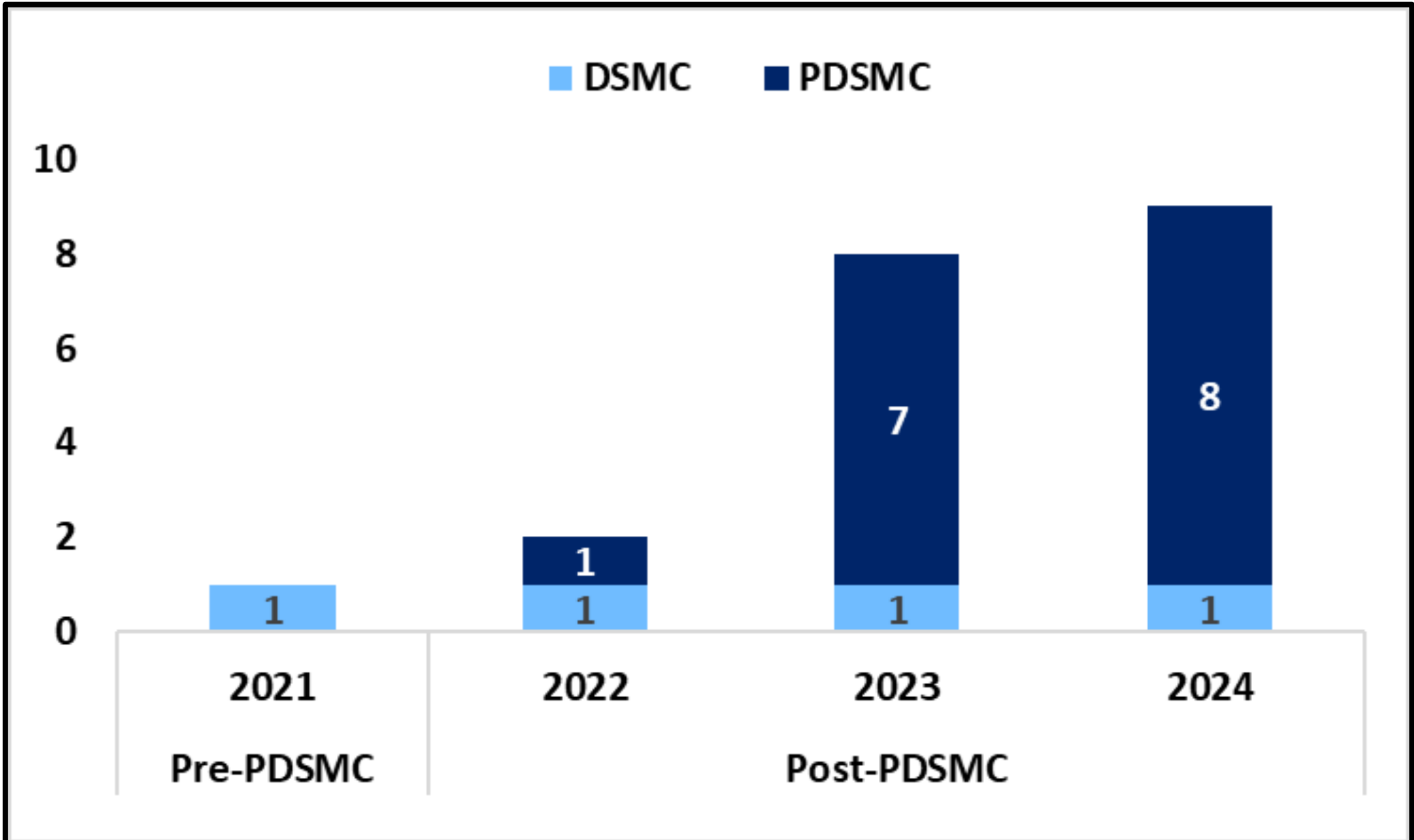
b. Enrolled Participants (participant-level data)

Participant Number	Study Site	Dose Level	Date of Enrollment	Age at Enrollment	On Therapy Date	Off Therapy Date	Off Therapy Reason	Off Therapy Explanation	Off Protocol Date	Survival Status Date (If Known)	Cause of Death
							Choose an item.				

Figure 2: PDSMC Reviewer Checklist Excerpt

1. Previous Review: Are there any concerns with how comments from the last PDSMC review have been addressed?	Yes	No	N/A
2. Data: Are there issues with data integrity? (e.g., data analyses conducted to date, database compliance, sufficient data entry, site data reporting, etc.)	Yes	No	
3. Compliance: Are there concerns with adherence to the protocol’s biostatistical plan? (e.g., design/statistical compliance [achieve endpoints, interim analysis], data collection/management, etc.)	Yes	No	
4. Study Progress: Are there concerns with the study progressing as planned and meeting its objectives? (e.g., accrual, site progress, large number of inevaluable participants, etc.)	Yes	No	
5. Safety: Are there concerns with the safety of the trial (e.g., toxicity trends, dosing)?	Yes	No	
6. Risk/Benefit: Are there concerns with the potential benefit to study participants?	Yes	No	

Figure 3: Expansion of Pediatric DSM Expertise

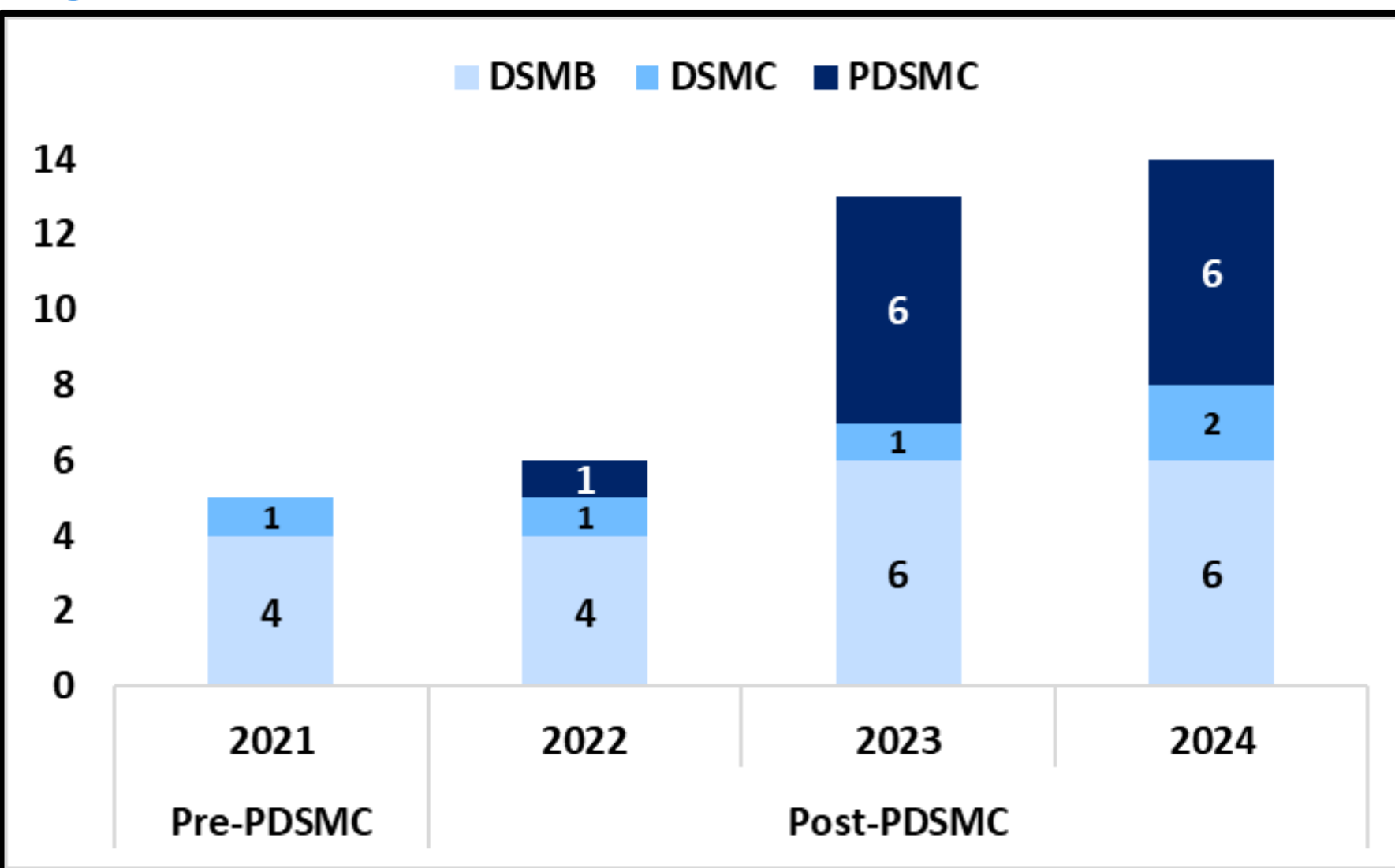


## Outcomes

### The inclusion of the PDSMC Committee enhanced DSM oversight at MSK by:

- Establishing dedicated pediatric-specific oversight beginning with a portfolio of 7 MSK IITs (including 2 transferred from DSMC).
- Expanding MSK’s pediatric DSM expertise by increasing pediatric DSM reviewers from 1 to 9 (Figure 3), which enhanced specialized oversight.
- Strengthening external engagement at MSK by nearly tripling the number of external experts (Figure 4) across DSM committees (from 5 to 14), enriching multidisciplinary input and expertise.
- Improving standardization with structured review tools tailored to pediatric studies for clearer expectations and consistent submissions.

Figure 4: External Expertise Across DSM Committees



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