



Monday Morning Practice Pearls #49

Peraton Data Manager FAQs

Who do the Peraton DMs report to?

- The DMs report to their assigned DM Team Lead. There are 4 DM Team Leads which include Keith O'Neill, Irina Titarenko, Alejandra Chipana Cordero and TBD (vacancy). Coverage for the vacant Supervisor position is team specific and provided by the 3 other Supervisors.
- The Peraton reporting chain is below:
- *DM* → *DM Team Lead* → *DM Manager* (Christine Gordon) → *Program Manager* (Elena Byrley) → *PO*
- The Peraton contract is directed and overseen by Project Officer (PO) Allison Wise.

Who do I contact with questions or concerns?

- You are welcome to contact anyone in the reporting chain with questions or concerns.

How do I know which DM will be assigned to my upcoming protocol?

- The DM Team Lead will notify you which DM will be assigned to support your protocol upon notification of upcoming protocol or protocol approval. Notification will be made in person or via email.

Can I request a specific DM?

- Peraton DMs are a shared resource across all CCR teams. While every effort is made to maintain continuity (same DM with same PI/team), this is not always possible. DM assignments are made based on several factors including workload, types of assignments and expertise.

What is the timeframe for DMs to enter the data into the database?

- DMs are expected to have data entered into the database within 10 business days of source document availability.
 - *Reminder: this means that progress notes need to be written in a timely fashion after clinical visit or other patient contact (e.g., 24-48 hours)*
- DM Team Leads and Management run reports and conduct ad hoc reviews to verify deadlines are met.

What is the timeframe for DMs to resolve discrepancies, clarifications and queries?

- DMs are expected to respond to discrepancies, clarifications and queries within 5 business days of issue.

What reports can the DM run from J-Review?

- DMs can run numerous canned reports from J-Review including:
 - Continuing Review
 - FDA Report
 - Adverse Events
 - Demographics
 - Con Meds
 - Study Drug Admin
 - Responses
 - Open Discrepancies
 - Lab Grade Change Summary

Can DMs create a new custom report in J-Review?

- The DM will escalate requests for custom reports to their Team Lead and Manager for review. Simple line reports taking less than 1 hour are typically completed. Anything that takes more than 1 hour of DM time or any Programmer time to complete requires CCR OD approval.

How do DMs prepare for SMVs & Audits?

- DMs are expected to prepare for SMVs & Audits by performing QC of their data for accuracy and completeness within 5 days of receipt of the SMV or Audit Letter. Additionally, the DM Team Lead is expected to review for accuracy & completeness.