

PEDSnet Study Designation Terms and Expectations

- Registration with ClinicalTrials.gov, if appropriate
- Use of PEDSnet’s streamlined regulatory and contractual resources
- Participation in the tracking of network efficiency metrics (e.g., regulatory - time to multi-site IRB approval)
- Furnishing of study documentation in the form of a data package to the Coordinating Center within 12 months of completion of the final analysis. Package must include:
 - Study protocol, including original version and all amendments
 - Analysis files used to generate the published reports
 - Statistical code used to generate the analysis files
 - Data Quality Assessment for data domains and elements outside current CDM
- Acknowledgment of the study’s status as a PEDSnet study in all websites, reports, presentations, and manuscripts
- Submission of a report on lessons learned from successes and failures to the Coordinating Center within 12 months from the completion of the final analysis, which will be deposited in the PEDSnet Commons.