Proposed Methodology Standards for Standards for the Individual Participant-Level Data Meta-Analysis (IPD-MA)

At its July 24, 2018 meeting, PCORI’s Board of Governors accepted the PCORI Methodology Committee’s proposal to update the PCORI Methodology Standards with this proposed new category of four new standards. The Board also approved a public comment period, from July 24 and September 21, 2018. Click here for more information.

IPD-1: Specify the research question(s) that will be addressed through the IPD-MA and describe the specific information the IPD-MA will provide that other approaches would not.

Explain why the IPD-MA will address limitations of other potential approaches for answering the research question(s), including study-level meta-analysis.

IPD-2: Describe the proposed governance structure for the IPD-MA in the protocol and study reports.

The proposed governance structure should be designed to encourage investigator collaboration and improve the strength and quality of the research. The protocol and study reports should describe the following:

- Roles, relationships, and decision-making authority of the research team leading the IPD-MA, the trial investigators who have carried out the eligible studies, and the relevant stakeholders in the design, management, conduct, and interpretation of the IPD-MA
- Payment model to support investigator participation and data acquisition, as applicable
- Data use agreements, reflective of the IPD-MA study protocol and intended analyses, for each source of IPD requested and obtained

IPD-3: Use systematic, reproducible methods to identify studies for inclusion in the IPD-MA.

Describe the approach to ensuring that all relevant published and unpublished studies are considered for inclusion. Record the number of studies and participants identified and screened, assessed for eligibility, and included in the IPD-MA. Document and explain the reasons for exclusion of studies.
IPD-4: Specify the design and planned analyses of the IPD-MA in a protocol, document any changes, and report significant amendments and modifications.

Develop a protocol and register it on PROSPERO prior to commencing work. In the study protocol, researchers should:

- Describe the data acquisition and management approaches used to maintain data integrity and protect personal health information (see IR-7). Data should be requested on all randomized participants eligible for the IPD-MA, even if they were not included in the final analyses of an original trial.
- Document the processes used to check accuracy of data and correct and harmonize data, including conferring with the original trial investigators.
- Describe the approach to assess the quality of the data, including assessing risk of bias in individual studies.
- Describe the statistical analysis plan, which should include pre-specification and justification of the hypotheses within different types of participant subgroups, including whether these will be analyzed at the participant or study level; outcomes (and outcome measures), including whether these are main or additional analyses; and the analytical methods used.
- If the IPD-MA plans to include examination of unexplained between-trial heterogeneity, specify the intended factors to be explored; the evidence base supporting the factors’ hypothesized role; and the proposed analytic approach, including dependent and independent variables.

All amendments and modifications to the protocol should be documented, and any significant changes (e.g., outcome definitions, analytic approaches, additional analyses) should be reported in the publicly available protocol.