

Quality Management Plan for the National Children's Study

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How will we assure the quality of the data collected by the National Children's Study?

What is a Quality Management Plan?

- A QMP is a policy statement describing how an organization shall comply with quality system requirements.
- Quality systems encompass the management and technical activities necessary to plan, implement, document, and assess the effectiveness of QA and QC operations.
- The QMP provides the blueprint for how the Coordinating Center, Study Laboratories, Clinic Testing Facilities, Repository, and IT Contractor will plan, implement, document, and assess its quality system for the work to be performed.

Scope:

The National Children's Study Quality Management Plan will serve as a high-level "umbrella" Quality Assurance document for the entire National Children's Study. It will:

- Address how quality assurance (QA) and quality control (QC) activities will be coordinated, integrated, and monitored over the course of the 21+ year Study
- Identify specific roles, authorities, and responsibilities of the various Agencies/Offices and Centers involved with the Study
- Identify needs for QA documents and the procedures for reviewing:
 - Organization-specific Quality Management Plans and Quality Assurance Project Plans (QAPP)
 - Measurement-specific Standard Operating Procedures (SOP)
- Be based on EPA's Requirements for Quality Management Plans (QA/R-2) which can be found on the Web at www.epa.gov/quality/qs-docs/r2-final.pdf

Challenges to Quality Management in the National Children's Study

- Geographic diversity with 100+ different locations and 30+ investigator teams
- Multiple laboratories and other facilities
- Complexity and scope of proposed measures
- Multi-disciplinary nature of the Study

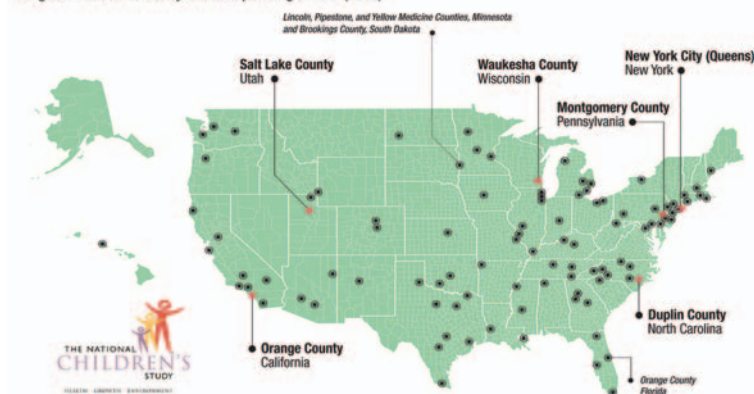
Consistency of operations, procedures, and in-depth Quality Assurance are needed to meet the Study objectives and test Study hypotheses.

The QMP will identify how the following are to be addressed in the Study:

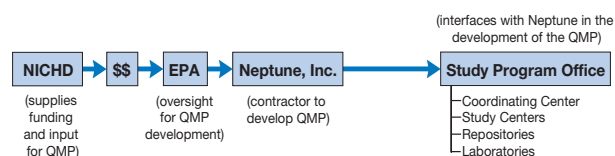
- Management and Organization
- Quality System Components
- Personnel Qualifications and Training
- Procurement of Data and Analyses
- Document and Records
- Computer Hardware, Software, and Data Processing
- Planning and Implementation of Work Processes
- Assessment and Response

National Children's Study Locations

Vanguard locations: Study Centers awarded (bold)
Vanguard locations: Study Centers pending award (italic)

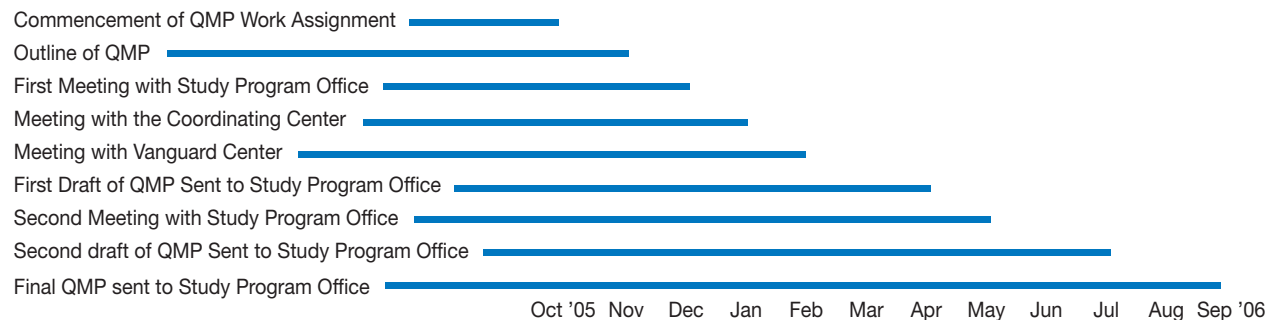


Development of the Quality Management Plan (QMP)



Although this work was reviewed by EPA and approved for publication, it may not necessarily reflect official Agency policy.

Timeline for the National Children's Study Quality Management Plan 2005–2006



IMPLEMENTING THE NATIONAL CHILDREN'S STUDY:
SCIENTIFIC PROGRESS, CHALLENGES, AND OPPORTUNITIES

STUDY ASSEMBLY MEETING

November 29–30, 2005 • Washington, DC