The National Children's Study Information Management System (IMS)

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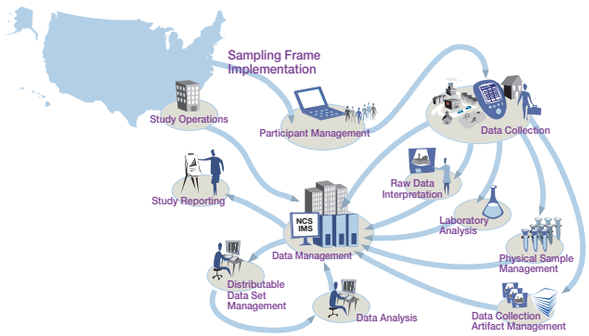
Background

The National Children's Study requires connectivity between diverse locations and the ability to collect and analyze volumes of complex data. The National Children's Study Information Management System (IMS) must support Study activities wherever they occur. Therefore, the IMS team set out to understand the unique characteristics of the Study and the needs that the IMS must address. Just as the National Children's Study will evolve throughout the implementation, the IMS will continuously evolve throughout the full life of the Study.

Complex and Diverse Study Characteristics

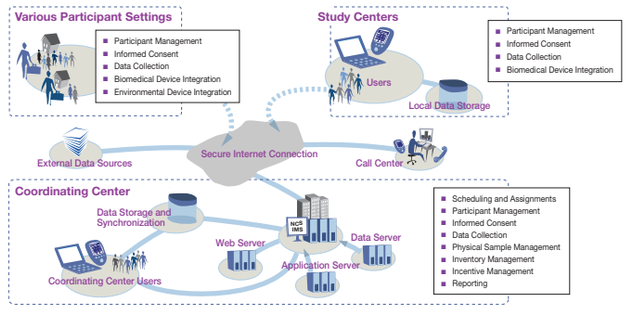


- National in scope with diverse site locations
- Takes a broad approach to "environment" with extensive types of clinical and environmental data to be collected
- Long-term in design with evolving study operations and technologies
- Examines many questions…changing in unimaginable ways over time
- Results will be made public as the Study progresses to facilitate information sharing while maintaining participant privacy
- Involves partners from multiple government agencies, as well as from public organizations and private companies to meet the needs of all stakeholder groups
- Uses state-of-the-art technology to provide the most accurate and reliable results possible while taking advantage of information collected by others (e.g., in legacy systems)

IMS Development Approach

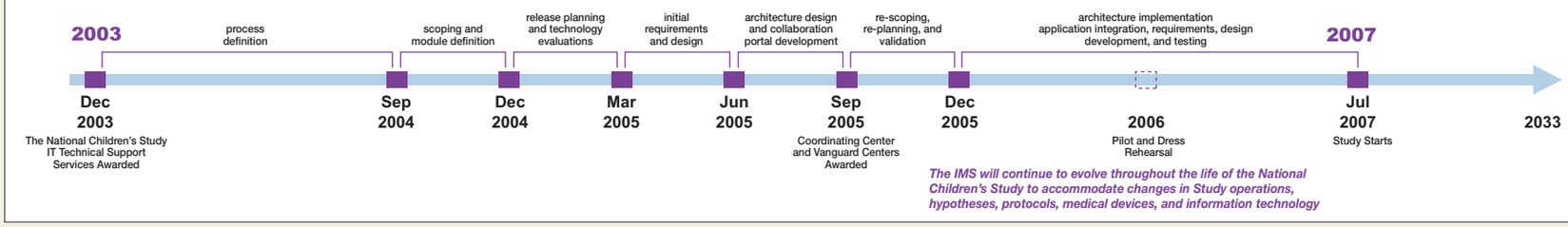
- Define Study processes and requirements with key stakeholders
- Perform technology assessments to evaluate the use of existing products
- Pilot key technical concepts to support technology decisions
- Utilize an iterative approach to deliver incremental results and accommodate evolving requirements
- Track progress, ensure stakeholder representation, and facilitate decision-making

IMS Technology Driven by the Study Characteristics



- **Accessible** – There are multiple locations with differing levels of connectivity. IMS must allow for data collection even if the network is unavailable (e.g., data may be collected remotely and must synchronize with the central database).
- **Comprehensive** – The wide range of environmental and health measures require the IMS to support an extensive range of data collection functions and technologies.
- **Flexible** – The IMS must be able to accommodate continuously evolving requirements, including changing hypotheses, new scientific instruments, updated protocols, and new technologies.
- **Secure** – The IMS must employ stringent security controls (e.g., encryption, authentication) to prevent inappropriate information disclosure and possible data loss, while ensuring that the correct information is provided to the intended people.
- **User-Focused and User-Friendly** – The IMS must be tailored to extremely diverse user populations, accommodate the objectives of multiple stakeholder groups, and support communication between all those involved in the Study.
- **Integrated** – The IMS must employ the most recent technological advances to meet the ongoing needs of the Study while ensuring seamless integration with multiple existing information sources.

Providing an IMS Solution for Today with an Eye Toward the Future



The IMS will continue to evolve throughout the life of the National Children's Study to accommodate changes in Study operations, hypotheses, protocols, medical devices, and information technology

Implementing the National Children's Study:
Scientific Progress, Challenges, and Opportunities

Study Assembly Meeting

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THE NATIONAL CHILDREN'S STUDY
HEALTH GROWTH ENVIRONMENT