



Clinical Research Functional Requirements for the NHIN

**Testimony to the National Committee on Vital and
Health Statistics**

July 2006

Broad Support from a Diverse Community of Clinical Research Stakeholders

Industry Participants

- AstraZeneca
- Bristol-Myers Squibb
- Pfizer
- Wyeth
- Intel
- Accenture

Additional Participants

- AHRQ
- NIH-NCRR
- NCI Center for Bioinformatics
- *FasterCures*
- Several Academic Medical Centers

Alignment

- The Nationwide Health Information Network (NHIN) can and will be a key enabler to:
 - improving public health by transforming Clinical Research,
 - expediting the development of new ways to prevent and treat disease, and,
 - improving the lives of Americans through better, safer disease prevention and treatment options.

Initial Priorities – NHIN Use Cases

- Post-marketing drug safety surveillance,
- Connecting patients to clinical trials, and
- Appropriate care –
 - Establishing patient care standards through outcomes, pharmacoeconomic, and personalized medicine research.

NHIN Requirements for Clinical Research

- ACN-01.10,
- ACN-01.11,
- ACN-01.12,
- ACN-01.13,
- ACN-02.5.2.11,
- ACN-03.2.2,
- ACN-03.3.9,
- ACN-03.3.11,
- ACN-06,
- ACN-06.1,
- ACN-06.3.

That Focus Aligned with Broader Clinical Research Community

- *FasterCures*, the NIH National Center for Research Resources (NIH/NCRR) and the Agency for Healthcare Research and Quality (AHRQ) independently sponsored a meeting of Clinical Research stakeholders to determine:
 - how to include Clinical and Translational Research in the design of the NHIN and other HIEs.
- Identify the highest priority Clinical Research use cases, and there was agreement upon:
 - connecting patients to clinical trials, and,
 - enhancing post-marketing drug safety & surveillance

Key Principle

- Consider patient needs and patient care as the first priority.

Outcomes from June NHIN Open Forum

- Drug safety surveillance use case aligns well with Biosurveillance use case:
 - Reasonable starting point
- Asked by NCVHS sub-group to consider:
 - Funding and investment models
 - Engagement with patient advocacy groups

Going Forward

- Need for:
 - Private/public collaboration
 - Broader involvement
 - Prototyping to prove concepts
- Proposal for a Clinical Research AHIC Working group

“Minimum but essential” core network functional requirements

- **The core NHIN must be able to:**
 - **Identify that a record or document is associated with a unique patient.**
 - **Allow all pieces of health information about a given patient from all data source systems that connect to the NHIN be located and designated as belonging to that unique patient**
 - **Provide infrastructure that includes**
 - **the identification and implementation of messaging,**
 - **document exchange, and**
 - **terminology standards to support health information exchange**
 - **ensure data security and patient privacy by thoroughly controlling access to patient health information**

‘Minimum but essential’ for edge systems linking to the network

- **Edge systems must be capable of several functions when connecting to the NHIN :**
 - **Have well-defined processes, policies, and enabling technology to capture, store, and report clinical data in accordance with standards for clinical research data capture and management.**
 - **Anonymize and re-identify patient health information for various audiences based on agreed security and access rights.**
 - **Semantically normalize health information to accepted messaging and terminology standards before transmitting messages or documents through the NHIN**
 - **Contain the necessary patient identification services necessary to link data to a unique patient and record locator services capable of handling requests for data from the NHIN**

Standards for consideration to support the functional requirements

- **Many different categories of patient health information are required to fully enable the Clinical Research use cases**
- **Each type of data must be standardized into accepted terminologies and formats to support data analytics**
- **Standards are critical...leverage existing work of HITSP**

In summary...

- NHIN will be transformational in improving Clinical Research and Public Health
- Essential next step in remaining competitive in Biomedical Research globally
- Urge further work to ensure Clinical Research is addressed in NHIN functional requirements
- The patient is waiting...