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
• 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…