Clinical Research Priority Areas
Background and Crosswalk Information

The essential requirement to support clinical research is to create an interoperability framework with sufficient specificity to be comparable across venues of research and care. To meet this requirement, as shown below, there are some specific new interoperability standards that need to be harmonized to automate clinical research interactions. Electronic health records (documenting observations from clinical care) provide a window into the clinical care process and form the baseline from which clinical research can make health care improvements. Most importantly, the integration of clinical care records with the research process will speed up the translation of research findings to the actual point of care.

After initial consultation with subject matter experts in industry, the National Institutes of Health (NIH), the Food and Drug Administration (FDA), the Department of Health and Human Services (HHS), standards groups such as CDISC, pharmaceutical industry stakeholders and the clinical community; we have identified ten priority areas that represent features or functions of the Nationwide Health Network (NHIN) that are important for the more rapid translation of research findings to evidence-based care. Five of these can be advanced in the **near term**. Some of them can be fit into the existing working group structure; some are unique to clinical research. The priority activities are:

- **Primarily fits into existing working groups:**
  - **Lab results** – fits into the EHR Working Group – Diagnostic tests used in clinical care settings are often also necessary for assessment of continuation of patient participation in a clinical study. Access to these data is important for researchers in order to avoid unnecessary repetition of tests and is feasible provided that the data are (1) de-identified and (2) comparable across laboratories and locations. Specificity of laboratory reporting standards will be extremely useful for longitudinal and biosurveillance studies as well.
  - **Documentation of patient and family histories** – fits into the Consumer Empowerment Working Group - this information is very important for predicting disease susceptibility, determining the need for preventive clinical care, and assessing the cost effectiveness of preventive measures for health outcome research. Standards are needed to provide these histories in an electronic, interoperable form.
- **Would require Clinical Research Working Group**:
  - **Facilitation of recruitment for clinical studies** – patients who are eligible for clinical studies, and would be willing to participate, are often unaware that the studies are available or are not aware of the benefits of participating. Physicians and other caregivers who work with patients who are eligible for clinical studies (e.g., psychiatrists, oncologists) can help patients identify the studies that may benefit them (such as rare disease studies, etc.). A specific set of standards can be identified that will support communication with patients and their physicians via the NHIN.
  - **Administrative features** – helping research participants and their physicians coordinate standard treatments and research protocols, to include required clinic appointments, tests and examinations. What is needed is interoperable technology support to communicate changes of address, marital status, etc., which is especially important for subject retention in long-term research projects. This is currently a manual process and many research patients are lost to follow-up. NHIN support would also be necessary to communicate research study results back to the patients and their physicians over time.

- **Providing services for data anonymization, identification and de-identification** – these are essential services for clinical research. Development of a tested, consensus view of the best way to manage anonymization of patient records for clinical research would be very helpful to the whole community. There are a number of techniques being studied, but a consensus is needed in order to obtain real value from the electronic health records while ensuring patient privacy. In addition, clinical researchers will participate in the development of standards for the protection of privacy, confidentiality, and integrity of data for research activities.

The five additional priority areas shown below are either less feasible in the near term or are beneficial (but not critical) for initial clinical research interoperability implementation:

- **Adverse Event Detection** – includes logic and information to identify potential adverse events and requires very structured vocabularies with aggregation of medication lists, problem lists, clinical notes and laboratory data from a number of sources. If this can be accomplished, it would allow much more rapid and specific identification of adverse events. The quality of care and the burden of managing adverse events would be greatly improved. The standards needed to implement integrated adverse event reporting are currently under development and will not be ready for HITSP consideration by the January, 2007 meeting. When the standards are ready, their implementation will become a high priority because they will address the need for public trust in the safety of the research process. This is one area where healthcare IT can make a critical difference. By collaborating with the other working groups, we can integrate the needs of the clinical research activities with those of the rest of the NHIN stakeholders in a manner that is most efficient for implementation.
- **Automated Case Report Forms** – includes automated collection of data from the patient record. Structured vocabularies, harmonization of existing standards (so that data would be comparable across sites) and the creation of some new standards will all be required for case reports to be communicated electronically. The benefit to physicians who enroll their patients in clinical trials would be immense. Rapid detection of adverse events would be possible and this would also improve the safety of research.
- **Post-intervention tracking** – includes collection of longitudinal data after the conclusion of clinical trial, so that the efficacy and long term effects of an intervention can be assessed. This area could cover assessment of quality of life, improvement in symptoms, adverse events, outcomes, etc.
- **Support for Translational Research** – intended to allow translational researchers to study de-identified patient histories, symptoms and diagnoses in relation to specific diseases or conditions to track genetic, proteomic, etc. influences on disease progression.
- **Patient Consent Management** – provides an on-line repository of patient informed consent documents so that current researchers can easily view and manage the associated data permissions and also so that patients can consent to secondary use of their information. If necessary, a researcher would be able to locate patients to request secondary use of their data, perhaps through an “honest broker” if the data has been de-identified.

These priority areas involve several issues surrounding data flow, work flow, architecture, policy/regulation, and/or data access and control which are either barriers and/or enablers to implementation. Some general barriers and enablers to these priority areas include:

- Harmonizing the standards across electronic health records and clinical research applications, particularly in regards to harmonizing terminologies and development of standards for emerging research topics, such as genomics.
- Developing a strong understanding of the requirements for electronically-enabled clinical research work flows. This work has been done on paper, until now, or has not been done on a wide scale at all. Will require understanding of the data and process needs of stakeholders.
- Provide educational and workflow support tools to enable clinicians to collect clinical research-related data in a form that is specific enough to be comparable across venues without being an undue burden on the clinicians' limited time. For example, in some studies it is important to note whether a blood pressure measurement was taken when the patient was sitting or standing.

In order to implement the **near term priority areas**, the following specific barriers or enablers would be considered:

- Recruitment for Clinical Trials – would require education of providers concerning the desirability and process for enrolling their patients in clinical trials. Would also require better aggregation of data required to assess potential eligibility in such a way that it fits into the normal physician office workflow.
- Lab results – harmonization of laboratory terminologies would be required, as would ensuring that the results were recorded with the degree of specificity needed to ensure that the results were comparable across locations and usable for research purposes (e.g., would have to identify the test method used to obtain the results).
- Documentation of Patient and Family histories – terminologies and representation methods will have to be developed so that the needs of the clinicians and patients providing the data are accommodated (e.g., clarity, ease of use), while the needs of the research community are met (e.g., specificity)
- Administrative features – a clear understanding of the workflows required to support collection of clinical trial data in the clinical environment is needed.
- Patient consent management – further work to harmonize standards in this area is needed, as well as coordination with IRBs and other regulatory bodies and obtaining buy-in from consumer bodies to ensure that the consent process is clear and implementable.

The recommended priorities would be most likely to be successful if they are coordinated via a working group. The working group can integrate the needs of clinical research into the existing work groups, where they fit, and can coordinate the harmonization of standards for the use cases where clinical research requires new activities that do not fit into the existing working groups. The table below is built on a presentation shown at a recent NHIN meeting, enhanced to show how the clinical research working group and its activities would fit into the AHIC overall strategy.

	Biosurveillance	**Consumer Empowerment**	**Chronic Care**	**EHR**	**Clinical Research**
Standards Harmonization	Clinical care researchers can review these standards to see if they can be harmonized to support other secondary uses, such as epidemiology and population health.	Clinical care researchers can review standards for patient and family history and medication history to ensure that secondary uses of the data for clinical research will be feasible.	Clinical researchers can identify specific data that can be contributed to longitudinal studies of chronic care outcomes.	Clinical researchers can identify specific laboratory test interoperability requirements that will enhance our ability to compare results across venues of care. Some patient history data is captured in EHRS and could be harmonized to meet clinical research needs.	Clinical research standards will be presented where needed. These will have to do, initially, with activities such as identification of patients who are eligible for clinical trials. Harmonization of terminologies and ontologies needed to support clinical research (such as BRIDG and CDISC) can be done here.
Compliance Certification	Clinical researchers can work with these groups to ensure that the certification criteria are appropriate to produce system interoperability at a level that supports priority research needs.				Clinical researchers can create certification criteria for areas priority activities

		such as identification of potential research recipients, which are not covered in other working groups.
NHIN	Clinical researchers can work with the existing working groups in this area to ensure that the certification standards are compatible with the requirements of the research community for the priority areas.	Clinical researchers can provide specific requirements for the NHIN developers that relate to the recruitment of patients in clinical trials and overall clinical research support.
Privacy and Security	Clinical researchers can work within the existing working groups to identify any specific privacy and security issues that will arise in secondary uses of their data for research purposes (e.g., medication histories, family histories). It is also essential that the privacy and security standards are implemented in such a way that they build trust across the patient community in general and for clinical research studies in particular.	There are very specific privacy and security requirements for clinical research, such as anonymization, management of consents, etc. that this working group can define.