Breakout Session I
Clinical Challenges and Related Software/Informatics Requirements

Topic: Identify and prioritize current informatics challenges posed for quantitative data acquisition and extraction, analysis and data integration using an array of sensors (imaging and other bio sensors, including molecular profiling/genomic methods), and the methods needed to support the ultimate goal of assisting with clinical decision making.

Recommendation:

- Develop standards and shareable vocabularies for clinical, imaging, and genomic data – building on such initiatives as NLM's SNOMED licensing
- Establish and fund a "lead institute" at NIH to foster those standards and formalize a process for data sharing
- Foster a handful of demonstrations and projects that effectively combine computer sharable data from clinical imaging and genomic data sources
- Collaborate with, and encourage, current clinical electronic health record (EHR) initiatives through interagency policy initiatives (e.g.: reimbursement, research, routine health reporting requirements)
- Efforts to proceed with EHR must have a plan for including office and outpatient practices, harmonizing those data with hospital-based EHR while consistent with HIPAA compliance.
- Continue to encourage computer systems interoperability and favor open-source computer software solutions with policy implementation coordinated by multiple NIH ICs

Topic: Review the impact of clinical data-acquisition protocols and methods for the different front-end platform technologies on the implementation of the informatics software tools and identify new methods or technologies required to address barriers to progress.

Recommendation:

- Continued encouragement of standards development for existing and new technology methodologies (X-ray, CT, NUC/PET, US, MRI, MRS) such as DICOM acquisition standards to further the goal of evolving anatomic, functional and molecular data as integratible information
- An integrated approach should be taken to device procedures, technology platforms, quantification, visualization, and interpretation
- The challenge is not just technologic but also educational, with currently inadequate training for data collection
- Need standards for clinical data, clinical biomarkers and imaging that is funded and coordinated by the several governmental agencies. This effort should include CMS and FDA. Device manufacturers can be encouraged to participate in this process by expectation of validation requirements as new technology emerges.

Topic: Identify sources of uncertainty in clinical data collection that may influence the ability to perform reliable quantitative measurements and data integration, and thereby propose methods or solutions that may require research investments for addressing such problems.

Recommendation:

Sources of uncertainty may be attributable to either human or technologic factors.

- Human factors arise from: data which is inaccurate at its inception; incomplete data, or invented data. As clinical knowledge evolves on an experiential basis there is often a lack of strong evidence base in many clinical areas which may permit untoward influence of judgment, opinion, and experience
- Technology factors may arise from differing age or versions of technology in use which fail to keep pace with clinical change or merely a lack of willingness to purchase and utilize appropriately accurate technology. Additionally, programming errors, and lack of interoperability may extend the breadth of uncertainty.

Recommendations:

- Bring current electronic health record (EHR) users into the research fold to utilize available data and show its utility and increase published research showing differences in outcomes and evidence of efficiencies in time and cost. Move from system information in silos to integration
- Work with government and insurance payors to utilize data already gathered in authorization and payment processes, and detailing and "report card" data already in use by utilizing quality/performance improvement data already available via partnerships with JCAHO and NCQA
- Provide strong leadership and decision making in support of the President's efforts to improve use of effective technology in healthcare.
- Operationalize artificial intelligence focused on systems and their effectiveness in the context of actual healthcare delivery.

Topic: Identify existing or planned clinical trials that may be targeted or enhanced as short-term demonstration projects to test the performance of emerging informatics tools in support of clinical decision-making (See NIH Road map: Re Engineering the Clinical Research Enterprise/NECTAR).

Recommendation:

- NIH clinical trials, sponsored by NCI, NHLBI and other IC's as well as EHR implementations occurring at NIH Clinical Center and in leading healthcare facilities, offer available testbeds for demonstration projects and development of 'best practice' models of healthcare management. Investigator commitment and recognition of the experimental opportunities in these informationally enriched environments could accelerate technological refinement. NECTAR cancer networks and caBIG efforts could be leveraged to extend informationally advanced routine care to disease

research applications. The structural uniformity required in clinical trials, though different from the more permissive free text found in medical records may offer an edge for promoting data element and vocabulary standards

- Continued emphasis on promotion and evolution of standard data definitions (e.g. HL7, etc) for sponsored clinical trials could hasten adoption and propagation of structural reform. Incentives for data sharing will enhance the need for common data elements.

Topic: Identify and prioritize future informatics challenges posed when undertaking patient-specific molecular screening, diagnosis and treatment.

Recommendation:

- Personalized medicine intended to reliably characterize disease risk and choose the particular therapeutic regimens that would be effective for that unique individual, requires gathering disparate information including components of an individual's genetic profile. Some accommodation must be made culturally and legally to protect patient privacy while striking a balance that permits medical science progress intended to achieve improved human health.

Topic: Explore the impact of humanization of research (including drug discovery), expanding clinical information (as outlined in the 2003 AAMC report), and phenotyping of humans (Human Genome Project), thereby leading to proposals for long-term research emphases.

Recommendation:

- The problem and objectives must be framed so as to be addressable not by one IC but as an overall NIH effort and needs to be open and linked to other efforts like WHO to have the widest impact. Movement toward these goals requires an NIH-wide initiative to identify the necessary financial funding and harmonize the grants processes such that individual investigator and hypothesis-driven research share more cross discipline objectives. Solutions must acknowledge the potential influence of CMS, FDA and industry in the conduct of clinical trials and at present there is no infrastructure in place nor demonstration projects that involve effective data standards and data-sharing between the various participants in the clinical trials process.
- Considerably greater emphasis has to be placed on standard methods of recording and exchanging data like HL7 and SNOMED in order to accelerate the timeline.

Topic: Develop recommendations for developing a broad consensus for prioritization of identified clinical and research challenges so that informatics tools requirements can be

recognized and developed in a timely way [See NIH roadmap: Research teams of the Future].

Recommendation:

- Electronic health all communities need to work together to standardize with the same strategy and provision must be made for incentives for collaborations and disincentives for isolated solutions. This implies empowering a national informatics infrastructure for prioritization.
- A key wedge to this progress can occur with the increasing dissemination of HER systems but individual vendor solutions should be capable of data sharing and valid data transfers. Governmental (e.g. NIH and DOD, VA, etc) and health-plan impending deployment of these EHR systems would be beneficial only if they create and use data transfer capable instrumentation.
- Medical schools, as part of their educational mission, have not yet focused on formal clinical e-medical training and informatics and such commitment is needed to change our culture.
- Building infrastructure must consider extensibility since it is likely we currently have only 1% of the data for genomics that we will have in the next five years. A 'change management plan' must be inherent in publicly available data banks
- The lessons learned from the Human Genome project is that we need a grand vision that is well articulated and compelling with a major leadership champion. Recent Presidential announced emphasis on this subject should be followed up and sustained and more convincingly sold to the public.

Topic: Develop recommendations for more rapid physician acceptance of informatics software tools for data interpretation and clinical decision-making.

Recommendation:

- Develop tools in conjunction with early electronic health record (EHR) adopters to move the decision support to the physician-patient interface. These tools need to be managed by researchers to accomplish updates as the data from research is analyzed
- Continue to increase use and training in technology in medical school, residency, and post residency training through partnerships with educators and professional specialty organizations across all levels of healthcare providers
- Survey offices/facilities which are not adopting technology to identify reasons and what factors would improve rate of adoption. Human factors monitoring, some of which may be accomplished through remote network processes may be employed to identify bottlenecks, both user-originated and attributable to quality of service of software/network.
- Provide software research to assist physicians and facilities in identifying what is available and what the utility and efficiency factors are for different products
- Increase literature and seminar topics related to use of software with focus on patient outcomes

- Consider partnerships with insurance and/or drug detailers to provide computer basics to isolated practices.
- Increase data feedback of interest to physicians – personal, regional, specialty, etc, whatever data is available for analysis and incorporate information frameworks that address the totality of the health-providing environment, incorporating new and currently un-incorporated data components such as patient preference and consent. These items may create a demand pull if they also incorporate elements which satisfy the patient's ability and demand for information
- Encourage development of recursive adaptive information systems that evolve and accommodate user-specific knowledge structures
- Explore and make recommendations for how testbeds, model systems and the clinical trials infrastructure (e.g. the NIH roadmap, NECTAR, caBIG) can accommodate and incorporate the more recent advances in informatics software tools, using them to develop 'best practices' benchmarks