

Creation of a National Cohort

- What is the problem the cohort is trying to solve? Can we develop a set of compelling use cases?



Possible use cases (more needed)

- Identification and testing of biomarkers and predictive strategies for a wide range of common diseases
- Unbiased quantitative determination of risk (environmental exposure, genetic penetrance, GxE)
- Powerful test bed for mHealth applications to health maintenance and chronic disease management
- Opportunity for rigorous test of pharmacogenomics
- “The Human Knockout Project” – determining phenotype of loss of function mutations for many human genes
- Test bed for improving utility of EHRs for all participants
- Opportunity to test the ability of health care delivery systems to respond quickly to evidence – learning system



Creation of a National Cohort

- What is the problem the cohort is trying to solve? Can we develop a set of compelling use cases? Is there a risk of being too prescriptive and hypothesis-limited?
- What's the right blend of bringing existing cohorts together, and starting new ones?
- What's unique about this initiative?
- Why is 1 million the right number? Need more?
- How does the cohort support discovery and also allow testing of interventions?
- How critical is it that point-of-care health care delivery is included in cohort structure?
- How will health disparities be addressed?



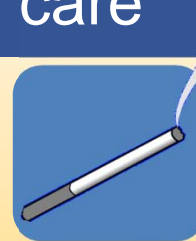
Creation of a National Cohort (cont.)

- Are children included?
- Sustainability? Value grows over time.
- Need to learn from prior successful and unsuccessful cohort projects
- Need to link up with other international cohort projects
- Define the basic phenotype, lab, and genotype data to be sought for all participants
- Consider more than one tier:
 - Fully engaged, fully participating, with EHRs, laboratory data,..
 - EHRs and permission for recontact only – “Cohort Lite”



Participants as Partners

- Partners aren't just "at the table", they're planning the meal (and bringing the food) – avoid the patient subcommittee model! Joint membership is the goal.
- How do we identify those who can fairly represent the participant voice for this initiative?
- What research data is returned to participants?
- Need to define specific consequences of violation of the prohibition against re-identification – look at GA4GH ethics position
- Can anyone join? Or do you have to have certain characteristics (like an interoperable EHR)?
- Emphasize the opportunity to contribute to a larger national purpose, not just one's own care



mHealth Technologies

- Need rigorous assessment of the analytical validity of health Apps that will be used for medical decisions.
- Then need rigorous evaluation to see if these Apps actually improve outcomes: a role for the cohort?
- What to do about potential barriers in such a rapidly-evolving field?
 - IRBs
 - HIPAA
 - Regulation of devices
- Privacy, security, and safety must be addressed
- Develop an array of incentives to encourage participants to maintain connectivity



Informatics Requirements and EHRs

- Need the EHR system for the cohort to facilitate discovery AND implementation
- Blue Button technology needs to become practical quickly
- Beyond provider-entered data
 - mHealth data from participants
 - Include participant-reported outcomes (like PROMIS)
 - “My Research Chart”
- Access to claims data and the death master file is crucial
- Centralized or federated structure? Leaning toward federated but need complete review of prior lessons
- Expect exponential growth in data and plan for that



Data Access and Sharing

- Don't make access process unduly complex
- Anticipate extensive interest in depletable samples, need a system to adjudicate requests
- Which parts of the research effort need to be HIPAA compliant? CLIA compliant? FISMA compliant?
- Will cohort participants support data sharing equally with public and private sector researchers?
- Need to provide training opportunities for data users?



Next Steps

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Next Steps

- Stand Up the Working Group of the ACD
 - Name members (February 2015)
 - Collect further information based on output from this meeting
 - Begin outlining the plan
 - Interim Report to the ACD in September to inform NIH decisions in FY16
- Consultation and Information Collection
 - Cohort leaders
 - mHealth folks
 - Potential participants
- Governance and Coordination
 - Inter-agency coordination mechanism (FDA, ONC, DoD, VA, WH)
 - Trans-NIH implementation team a la BRAIN, BD2K





Yes, it was historic!



And the world has been watching....

- **Videocast: 1741 total unique views**
- **WebEx: 623 total unique views**
- **Twitter: 3813 total Tweets**



We need to follow Woodrow Wilson: i.e. continue to borrow your brains....

- Think further about these issues as you head homeward
- Send us additional thoughts:
 - Kathy.Hudson@nih.gov
- Please return our phone calls, and be prepared to drop everything if we ask you to come to another workshop



*Make no little plans;
they have no magic to
stir men's blood and
probably themselves
will not be realized.
Make big plans; aim
high in hope and work.*

~ Daniel Burnham

