

**Clinical Informatics Working Group Breakout Session
BD2K AHM Friday, November 13th 2015**

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Summary of the Discussion

Two Major Topics Discussed by this Group:

1. Data Alignment and Linking– aligning omics data and patient generated health data (so can gather complete data on some people):

- Blue Button – how can we help move this forward? Maybe have BD2K sit at the table to inform ONC on research needs for EHR data?
- FHIR
 - Background on FHIR:
 - A derivative of 25 years of thinking in HL7; they try to get a framework that's awkward and strip it now that's RESTful...which implies APIs, which implies machine readable
 - Allows programmers to get specific data (on specific level) from EHR.(at atomic level change level).
 - This standard is getting tracking with 2 key groups: some of the vendors, lots of developers.
 - Should BD2K take this on? Many institutions (not all) are endorsing it. Maybe BD2K should endorse it also. This might also dovetail nicely with the API Working Group.
- Action item:
 - Chris Chute (Hopkins) can lead this to get BD2K buy in
 - Ask the BD2K Standards Coordinating Center to help heavy lifting

2. Informed Consent –ResearchKit solved the problem of consent for many, so we can learn much from it. If the group could focus on ~1K words of consent to help do the job right, then the issue of sharing (including allowing patients to decide what data they want to be shared) could be greatly advanced.

- This is an important gap idea that this BD2K clinical subgroup can help advance the field.
- Many sources of consent currently available now, but would be helpful to develop one that is endorsed by BD2K and provide the software needed for interested users -- users that include not just within BD2K but also outside of BD2K, such as Precision Medicine Initiative and other clinical researchers
- Have some standards and best practices developed by BD2K would be very helpful.
- This is a discreet area that we can rally after, and we should be focused.
- Apple's mobile app works well because they have worked out the consumer perspective.
- BD2K can say, here's an app that works for consent – could have great weight for IRBs, which is a key audience we have to convince
- We can maybe do the 30% of content based on shared interests, and then let other experts add their elements themselves (e.g. genomics, other -omics, etc.)
- Stay focused, so not worry about being comprehensive, such as oral consent for the visually impaired

- Additional elements and components to consider: results reporting; mHealth component, making sure participants understand what they are really consenting to (have quizzes). There are different tiers of consent based on defined levels of data security
- Have some training center target lay people to educate patients on elements of consent – e.g., what is meant by de-identified data.
- What about the following as potential next steps?
 - Assemble as many of the NIH consents as feasible, identify BD2K centers who are enrolling human subjects and who are not? Concern that this would simply lead to cataloguing without any concrete outcomes or helpful products
 - Maybe we can do rapid prototyping when the Android version of ReserachKit comes out later (being worked on). But is ResearchKit is the right model?
- Action item: ask BD2K coordinating centers (CC) to help out with heavy lifting:
 - If so, Zak can ask them to query the group and find out if there is convergence.
 - Potential deliverable:
 - Text and reference apps (we need to have a framework, and then concrete language)
 - Zak and/or Ida can talk to all the 4 CCs, especially regarding:
 - Participant education – Training CC
 - Work stream of this working group (calls, minutes, get buy-in from other centers) – Centers CC

Other Topics Raised (were not extensively discussed):

1. Linking clinical data with biomedical data

- At the NIH, we're looking at rare disease- using genomics techniques; it's useful to connect phenotypes and genotypes – to understand mechanism of diseases; a lot of databases are not to god standards. Speaks to API, etc.
 - Requires lots of work to make all this happen. It's amazing all the diff obstacles are there. E.g. Insurance co. have problem figure out how to link their database.

2. API – getting data out of EHR (against the OHDSI, i2b2 models)

3. Patient linking across multiple databases (probabilistic linking)

4. Privacy and Security – ethics of data sharing

5. Provenance