Breast Cancer Review Session Notes

Questions were posed to stimulate the discussion:

1. If investigators wanted to launch a project similar to the GPC Breast Cancer Study now, how would they do it? What lessons have been learned?
2. What types of data from the research warehouse can we keep or get for all patients, irrespective of medical record consent? Any variables that were used to select the cohort? Other variables such as treatment?
3. What should we do as the logical next study together?

Summary of discussion:

1. **Investigators should plan resources for recruitment and enrollment methods (e.g. by telephone) that can improve medical record consent rates**

   Most study questions require some clinical patient or tumor characteristics that are only available in the medical record. This means that the ~30% of survey respondents who did not provide signed consent to obtain medical records are automatically excluded from these analyses and the answers to some study questions are constrained by small sample size as a result. We discussed whether it would be possible to obtain a waiver of consent from the IRB but subsequent discussions with IRB staff indicate that this would not be approved because we are contacting patients. Future projects will also be more focused (the GPC Breast Cancer Study was a general purpose survey) and required sample size will be part of protocol development.

2. **The GPC should establish a standardized method for incorporating study IDs with the i2b2 warehouse**

   There were difficulties re-linking survey respondents to the correct records in i2b2 at 2 of the sites. While these problems were fortunately resolved, this was a situation that could have resulted in the loss of EMR data for almost one-fourth of consented subjects.

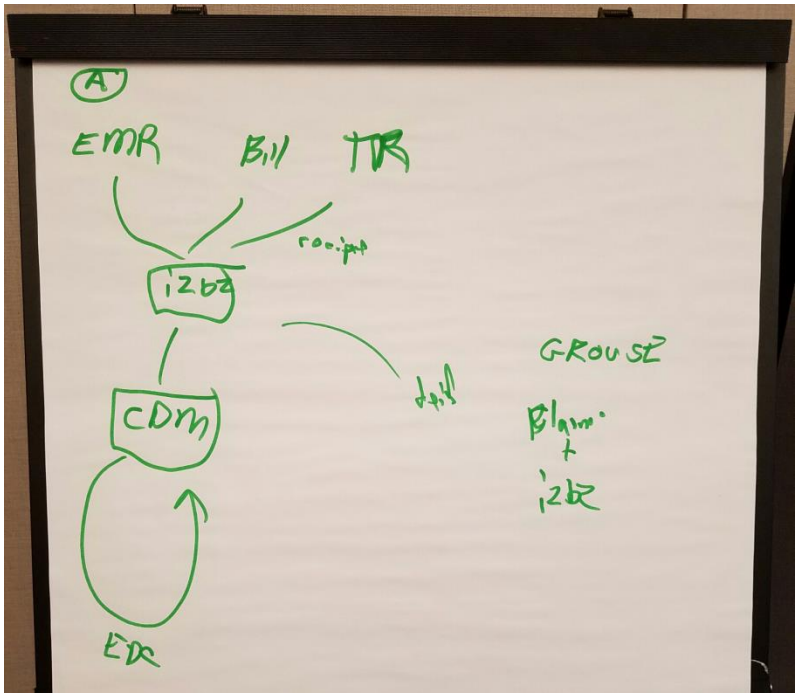
3. **Soon after obtaining subject consent, the lead site research team should obtain the actual MRN for the patient and maintain a study ID to MRN linkage for all consented subjects** [this specific recommendation is post hoc based on the discussion]

   It is the honest brokers' responsibility to maintain links between study ID and the rest of a patient's warehouse data. Best research practices and IT practices should include recovery mechanisms and redundancies to protect against unexpected events. This solution is simple and clearly allowable for consented subjects.

4. **Consider creating a well-characterized research-identifiable (e.g. actual dates rather than shifted dates) cohort of GPC breast cancer patients.**

   Marshfield has made extensive use of a well-characterized cohort of patients with which they can conduct retrospective analyses and from whom they can sample and invite patients to participate in specific IRB-approved studies. In addition to supporting efficient retrospective analyses, for prospective studies researchers would have the advantage of fully understanding the population they are studying and how they compare with the underlying population. Operationally, the GPC honest broker would distribute a query to each site and clean and standardize the data returned in order to create a single analysis-ready dataset. It seems that it would be worthwhile to do this once (refreshing periodically)

rather than for every research project. We will soon know (with the results of the second data pull for our consented survey respondents) how close we are to standardized data that can be quickly combined. Russ reminded us that with GROUSE we now have Medicare claims data form 2011-2013 that are already stored centrally at KUMC.



5. **Consider amending the GPC Data Sharing Agreement to provide for sharing contact information with a coordinating site for efficient recruitment and enrollment.**

   The original protocol for the *Share Thoughts on Breast Cancer Study* called for the coordinating site to distribute the study materials directly to patients (under cover letters from each participating site). This would reduce costs and lower barriers to participating in a multicenter prospective observational study (e.g. investigators don't have to identify a survey research team to be able to participate). It is possible to execute Business Associates Agreements between a coordinating site and each participating site but that seems to run counter to the purpose of having a Consortium and is not scalable across multiple projects. Alternatively, investigators must be advised to plan for substantial resources for recruitment/enrollment/participation monitoring at each site.