2020-11-13

Date

November 13th, 2020

Time

12:30pm - 1:15pm

Attendees

MITRE Caroline PotteigerSalim Semy Rob DingwellLauren Levine

ACS CAN Mark Fleury

UTSW Brandi Cantarel Melanie Hullings

BreastCancerTrials.org Elly Cohen

Action items

- [x] Lauren - set up meeting with Caroline, Salim, Zach, and Rob.
- [x] Salim - draft a set of questions for the UCSF consult.

Discussion notes in blue. Decisions in green. Action items in red.

Planned Agenda Topics

- **<Hold for hot topics from project team>**
    - HL7 Biomedical Research and Regulation Group agreed to sponsor this project!
- **Past Action Items 11/06**
- **CoP next week - need to reschedule.**
- **Engagement Update**
    - TrialJectory - meeting scheduled for 11/12.
    - Ciitizen - met with them on 11/12
        - 1) Test how well the optimized patient data elements filter clinical trials. Run a match with only optimized patient data elements and compare with comprehensive patient record match.
        - 2) mCODE-enable the matching service and cancer card.
    - TriNetX - internal discussions
    - Inspirata - continuing discussions.
        - Could work with UCSF dataset. Inspirata has an NLP engine that could work with unstructured data.
    - Informa - acquired TrialScope. Conversation scheduled for next week.
        - Mark spoke with them a few weeks ago. They have a private trial database. Can understand what trials the competition is running. Previously mentioned they were not interested in searching for clinical trials.
    - Meeting next week for site engagement.
    - RXL CRO showed interest. Mark following up.
- **Phase 1 Update**
    - Working on IRB approvals for UTSW (Phase 1B) and MITRE/Cancer Insights (Phase 1A)
        - Phase 1A -
            - MITRE IRB has been re-submitted and DUA has been approved.
        - Phase 1B -
            - Melanie is working on the submissions.
            - MITRE is working on the DUA.
    - Massive Bio - in progress.
        - Getting initial results, but they need some work.
        - Lauren - set up meeting with Caroline, Zach, Rob,
    - UCSF - consult is occurring next week.
        - What mechanisms exist for us to access the data under CodeX with multiple organizations? Other CodeX use cases? Prefer to not to create individual DUAs.
        - Salim - draft a set of questions to ask (legal, what data exists).
- **Phase 1 Analysis**
    - ACS CAN intern
        - Fellow was hired - starts on Monday
            - For any DUAs being signed, she would need to see the data.
                - Trying to figure out how to structure DUAs so it's not just between organizations, but under CodeX as a whole so everyone on the team can view the data.
            - Help write protocols, review data, analyze data, etc.

- Plan for analysis?
    - Potential elements to add - measurable disease (bone metastasis is not eligible), line of therapy
    - Potential elements to remove - elements that may not be readily available (histology, biomarkers)
    - If something is not present, how do we know it's because it's absent or it just wasn't recorded?
        - Caroline meeting with spec team next week.
- Salim/Caroline met with statistician on 11/12.
- Our analysis on how many "true matches" there are is going to depend on how many total matches come back
    - 1 match in 5 = good filtering, 20 matches in 100 = bad filtering
- Patient data elements we add must be populated by both clinical trials and what's available from the patient record.
- False negatives are ones we really want to eliminate and make sure they don't happen.