Data Use Agreements

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Data Use Agreements (DUAs)

- Several PCT Collaboratory projects have reported delays of 6+ months because of DUA issues

- Study teams are encouraged to start working on DUAs as soon as possible – potentially even before the protocol is finalized

What types of challenges do projects face?

- Getting an example / template DUA
  - Teams that are new to the role of study coordinating center may not have prior examples of successfully-negotiated DUAs
  - Most institutions will have generic templates within their offices of research / contracts, but may need to be modified to fit the specifics of a PCT
  - Institutions will usually share agreements when asked, but sometimes have concerns if they are to be distributed broadly

What types of challenges do projects face? (2)

- Signatories may not just be academic medical centers
  - Trials can enroll from private clinics, which may be part of a larger corporate chain that must sign the DUA
  - Relevant data may also be “owned” by the EHR/technology vendor, requiring a separate agreement
  - If linking trial data to external sources, each data holder may also have a separate DUA
- Each data holder may also have restrictions on how their data can be shared or further disseminated
- Enthusiasm of the data holder to participate in the project can also influence the time it takes to negotiate a DUA – willingness to get to “yes”

What types of challenges do projects face? (3)

- Level of consent / data requested may play a role
  - If requesting personal health information (PHI), expect greater restrictions / scrutiny, particularly around data breeches – notification period (days vs. hours), suspected/confirmed, etc.
  - Many trials that are leveraging EHR data may be able to operate on a Limited Data Set, which results in fewer hurdles than with PHI
  - Even if de-identified data are requested, institutions may have concerns if the size of the cohort is over a certain threshold (e.g., 100K patients) – can have ramifications for more common conditions or studies with a “usual care” observational control cohort

Start the DUA conversation early!

- If certain elements of the protocol are unworkable from the perspective of the data holder / DUA, will need to go back and revise the design
  - Even if the DUA must follow the protocol, better to have initial conversations up front to ensure issues are identified sooner rather than later