Combining Clinical and Claims Data

Please provide any feedback regarding Scenario #1 in the comment form below or by clicking here.

Max Researcher at Advanced Research Institute wants to conduct a study on drug safety for cardiac conditions that will require combining clinical and claims data to create an aggregated data set of complete records for individual patients. This will be secondary analysis and will not require any new data collection. Max will work with a Coordinating Center to access the data.

Max obtains approval from the Advanced Research Institute's IRB for the Human Nature protocol. The approval does not have bearing on the release of records from the other organizations.

Advanced Research Institute must enter into a Data Use Agreement with the Data Sites. The agreement specifies that various data sites (i.e., covered entities) will abide by the HIPAA minimum necessary standard for the release of health information to be used in the Human Nature research study (the study contains only data analysis protocol).

Using the list of approved patients identified by their research unique identifier, Max loads the list into the Research Information System and submits the list in an electronic request to the Coordinating Center. The request specifies the patients enrolled in the protocol using their research unique identifiers, assigned by Coordinating Center.

Once the Coordinating Center System receives the request for data sets from Advanced Research Institute (on behalf of Max Researcher) it prepares a limited data set to share with Max by doing the following:

1. It correlates with patient **research unique identifiers** supplied in the request with data-site-specific identifiers for each intended data site and it identifies four sites that store relevant data sets.
2. The Coordinating Center System adds technical criteria corresponding to the approved data set to be supplied by each site.
3. It submits separate requests to each of four data sites.
    - Each data site receives a list of patients using the site local identifier and returns the matching set of records defined in the Data Use Agreement.
4. The Coordinating Center System processes the responses (success/failure) and the data returned from each data site and returns the data sets to Advanced Research Institute system (Research Information System)

The Research Information System combines the data such that Max Researcher can accomplish the goals of the protocol for the Human Nature study.

Title	Response
Description	At the request of the researcher, data sets stored by a variety of data sites are aggregated for the purpose of supporting an approved data analysis protocol for a research study.
Primary actor /participant	Researcher (end-user) using Research Info System
Support actor /participant	Coordinating Center System, Data Site (Datamart) System
Preconditions	• Research organization, Coordinating Center, and Data Site use standard-based interoperability to exchange information in a secure environment. • Researcher has approval from IRB to request data for a list of enrolled participants. • Research unique identifiers are used to request data to protect the identity of patients so there is a low risk of re-identification. • The Coordinating Center provides identity correlation across data sites using a network-wide ID. • The Coordinating Center has mapped the data sites that store relevant information for a given protocol/study. • All sites have executed a DUA authorizing the Researcher's organization and its approved representatives to request and receive a minimum data set and use the data set for a research study.
Postconditions	• Researcher has access to data set and is able to analyze/combine them for a specific research study.
Alternatives	• DUA or study expired, the Researcher does not have access to the data anymore. • Information was sent electronically from data site to the Research Information System that combines the data sets. • The researcher could come from a data site. An academic might have access to EMR clinical data locally but not have the longitudinal data from administrative claims, and researchers at health insurers do not have access to EMR clinical data.
Considerations	Researchers must access multiple, separate portals to obtain data to be linked.
Data Elements Considered	Electronic data from multiple sites
Purpose of the Data Collection	Clinical care, administrative purposes

Purpose of Data Use	Analysis under a specific research protocol
Terms of Transfer to the Data Holders	Usual care, Notice of Privacy Practices
Terms of Transfer to Researchers	IRB approval

Unknown macro: 'iframe'