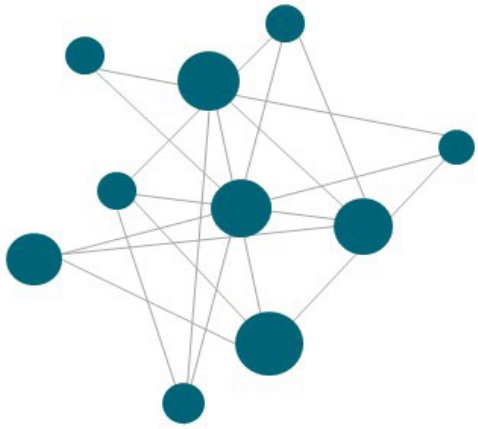
Using Informatics Tools for Clinical Study Design and Feasibility Assessment: Taking a Structured Approach

Clinical informatics tools are an invaluable resource to help investigators identify patient populations of interest, iterate and refine study eligibility criteria, prepare for study design/biostatistics consults, assess potential partner sites for multi-site studies and make data-driven decisions about joining existing trials. This checklist provides a structured approach to finding the **right tool for the right job**, and using it in a strategic, goal-directed way.



Step 1. Identify your research topic

Where are you clinically curious?

- ◯ Types of patients or clinical scenarios
- ◯ Settings of clinical care or preventive services
- ◯ Current healthcare evidence gaps
- ◯ Health disparities

Step 2. Select the best data source

What type of search are you trying to do?

- ◯ Wide and Thin (better for exploring trends and variability, and for multi-site studies)
- ◯ Narrow and Thick (better for local studies and very granular information from EHR records)

Step 3. Conduct cohort discovery

Operationalize your clinical specifications into data informatics queries

- ◯ Understand data coding schema
  For example: Diagnosis, procedures, labs, drugs dispensed
- ◯ Nested cohorts
  For example: Diagnosis -> + Procedure ->+ Comorbidity -> +Time
- ◯ Logic statements
  For example: A and B; A or B; A but not B

Step 4. Validate and iterate

Validate

- ◯ Gut check. The wisdom of your clinical experience.
- ◯ Might the findings indicate coding disparities?
- ◯ Also consider using established, validated codes (often found in the clinical epidemiology/health services research literature)

Iterate

- ◯ Review and revise
- ◯ Balance study eligibility criteria (inclusion/exclusion factors) with feasibility

Step 5. Decide

Does my study look feasible? Is a multi-site study needed?
Should I join a proposed multi-site study, or not?

Don't forget. This is a starting point for your feasibility assessment. Also factor in …

- ◯ Your ability to reach potential patients & invite participation
- ◯ A patient's willingness to participate
- ◯ Whether other trials are trying to recruit the same cohort

Step 6. Abstract

Study feasibility justification (de-identified)

- ◯ Funding proposals
- ◯ IRB review

A starting point for study accrual … after IRB approval (re-identification)

QUICK TIP: Consult your LOCAL CTSA!

They have expertise and can connect you to resources in clinical informatics, research design, and best-practices to support clinical trial development and participant recruitment.

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