Hello, my name is Kaitlin Maciejewski. I am a biostatistician at the Yale Center for Analytical Sciences.

YCAS houses the ClinicalTrials.gov Team at Yale University, which is the centralized office for ClinicalTrials.gov for the institution. I created the Clinical Trials Dashboard with Shiny to help our office track registration and results.

Food and Drug Administration Amendments Act (FDAAA) 2007 is a law that requires certain clinical trials to report results. It effectively came into force for all trials due after January 2018.

Since 2021, the Food and Drug Administration and the National Institutes of Health have increased citations and notifications for institutions in non-compliance with required results reporting on ClinicalTrials.gov. Many studies still do not submit results to ClinicalTrials.gov; some do not publish results after 3 years following study completion.

Institutions are limited by a system which provides useful data, but additional steps are required to effectively track and monitor ongoing activity or plan for future actions. The data that administrators can download from the Protocol Registration and Results System (PRS) is not simple to utilize for tracking. Some institutions develop their own programs and procedures that may not be reproducible elsewhere.

Transparency groups such as FDAAA Trials tracker summarize compliance with mandated reporting to motivate academic institutions and companies to improve compliance. Private companies like TrialAssure have developed software to monitor compliance, but this comes with a cost. To date, there are a lack of low-cost solutions to help institutions remain compliant.

The Clinical Trials Dashboard aims to increase compliance by making tracking registration and results status simple, transparent, and reproducible.

An administrator uploads the csv files downloaded from the Protocol Registration and Results System and the dashboard merges, aggregates, and flags studies for review.

The left side of the dashboard includes simple instructions for a user about what files to download and what the dashboard can do. On the right, a user would upload their csv files. For this presentation, I have sample data pre-loaded. We see the files are loaded successfully and click “go”

The dashboard starts with a tour to guide users.

Date range and aggregation controls are on the sidebar; drop-down selectors allow users to filter study types of interest such as results status, FDAAA-status, NIH-funded.

Plotly line plots show interactive metrics for study registration and results.

Average number of days to publish registration

Average number of tries to publish registration (goal is 2)

Average percent success **within second try**

Average number of days for CTgov to respond

Tabular versions of the data are also presented.

We see similar plots and metrics for results.

Average number of days to publish results

Average number of tries to publish results (goal is 2)

Average percent success within second try

Average number of days for CTgov to respond

Results published in 12 months from end of study

Days published past primary completion date

Downloads include retrospective report as displayed in the dashboard; prospective results, including NIH-defined clinical trials, due in next quarter; and a file with parsed contact information to plan compliance activity.

The PRS system generates expected results or updates for some studies, but not for NIH-defined clinical trials. To 'flag' NIH defined clinical trials, institutions must enter the grant number and then populate the collaborator field to include NIH funders. Within the dashboard, dates for expected results, 1 year after study start date, were created.

This results file shows the tabulated registration and results data for the date range and aggregation as selected in the dashboard, as well as a summary table of number of prospective updates and details about the studies with updates in the next quarter.

The csv file shows study details including contact information for records which have expected updates, including expected results, in the next quarter. This information could easily be used in a mail merge to contact investigators to remind them of upcoming deadlines.

This is a low-cost (transparent, and reproducible) solution for academic institutions which utilizes information from the PRS. Users – who may not be familiar with data merging – do not have to interact with the data. This adds identifiers of NIH applicable trials, which the PRS system lacks. We hope this will help institutions monitor studies, and meet compliance.

Next steps: continue using at Yale, share with other institutions, refine given any feedback

Acknowledge Yale Clinical and Translational Science Award CTSA UL1TR001863

Thank you for attending my virtual talk!