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Abstract

Background

People living with ALS (PLWALS) and their caregivers (cALS) have stated that they are often not presented with clinical trial opportunities even though they may meet eligibility criteria and are willing to travel to recruiting trial sites. To empower PLWALS and cALS to identify appropriate clinical trial opportunities, ALS advocates created ALS Signal: A Clinical Trials Dashboard in 2020 (1). ALS Signal consolidates clinical trial data from multiple sources into an easy-to-use tool that empowers non-professionals to easily find clinical trials that might be of interest and facilitates more informed discussions with their neurologist. There are two key sections of Signal that are most often used. The first is the "Clinical Research" section that lists all currently active disease modifying interventional ALS trials being conducted worldwide. The second is "Canada & US Trials" which lists every trial site in Canada and the United States currently recruiting PLWALS for trials listed in the Clinical Research section.

ALS Signal was developed and is managed by I AM ALS volunteers. It has had over 20,000 unique page views since launch in 2020. The goal is to refresh the dashboard on a bi-weekly basis. Because the update process was time consuming, the commitment to have an accurate and up-to-date dashboard every two weeks was challenging.

Objectives

To create a methodology for automating updates of ALS Signal that reduces the time commitment and improves the accuracy of the information presented.

Methods

To automate the update of the Clinical Research section for trials that are listed on clinicaltrials.gov a Microsoft Excel spreadsheet was created to accommodate a full download of ALS trials which is compared to data from the prior update. New trials, along with changes to trial status and location, are automatically flagged.

To automate the Canada & US Trials section, a Visual Basic program was added to the Excel spreadsheet to extract individual site information for select trials that are recruiting patients.

Results

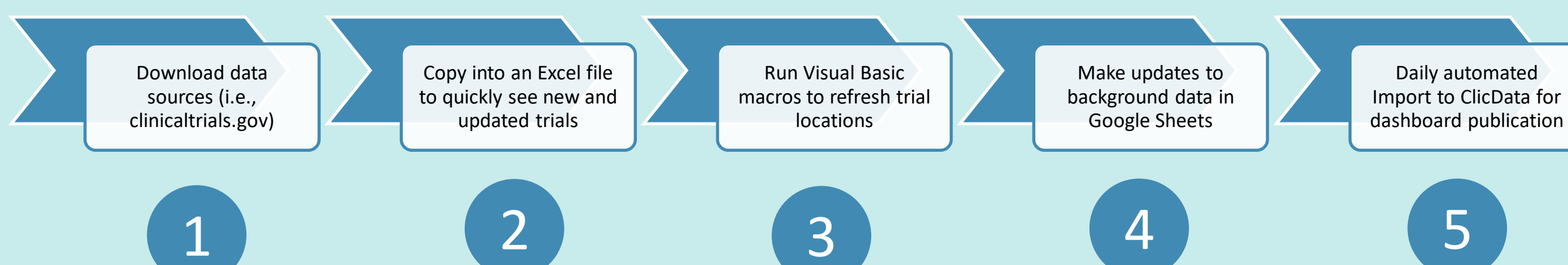
Since the introduction of automation, the trials listed on clinicaltrials.gov have been updated and loaded to ALS Signal by a single individual on a bi-weekly schedule. Inconsistencies between the data and ALS Signal were discovered and corrected. PLWALS and cALS can rely on ALS Signal for accurate and up-to-date information.

Discussion

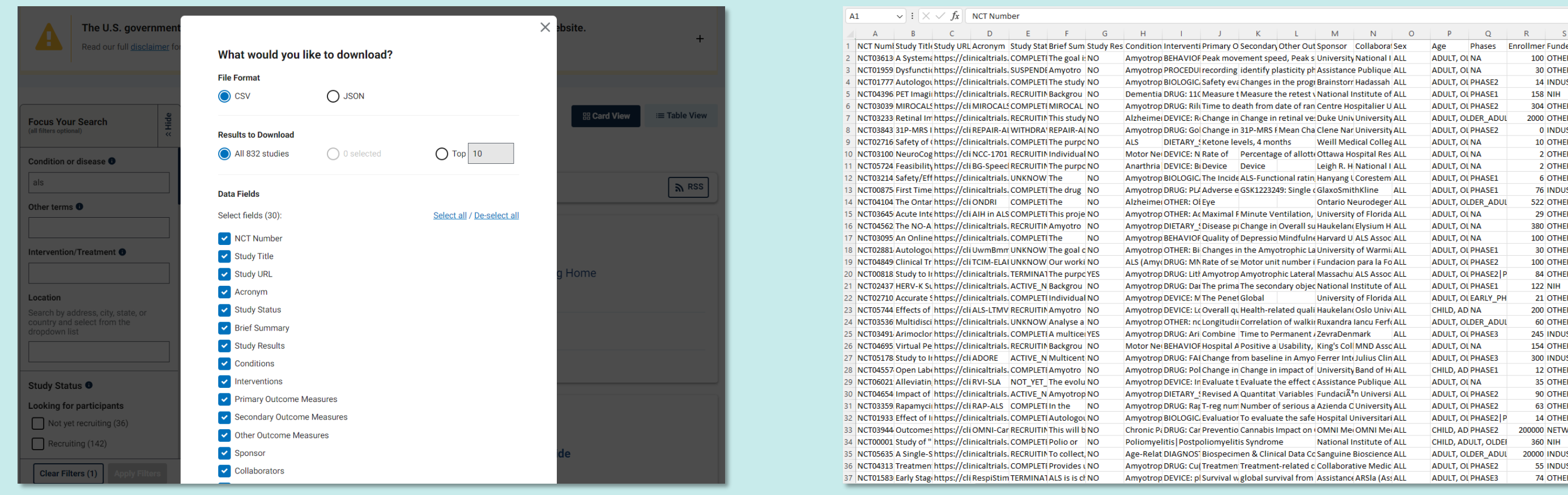
When a new tool like ALS Signal is introduced to the patient community it is important to develop a plan to resource its maintenance to ensure the tool is accurate and up to date.

The original update process for Signal relied upon volunteers scanning available trials for recent updates, then comparing new vs old to determine what was new and what had changed. The process for updating the Canada & US trials was even more manually intensive and time consuming.

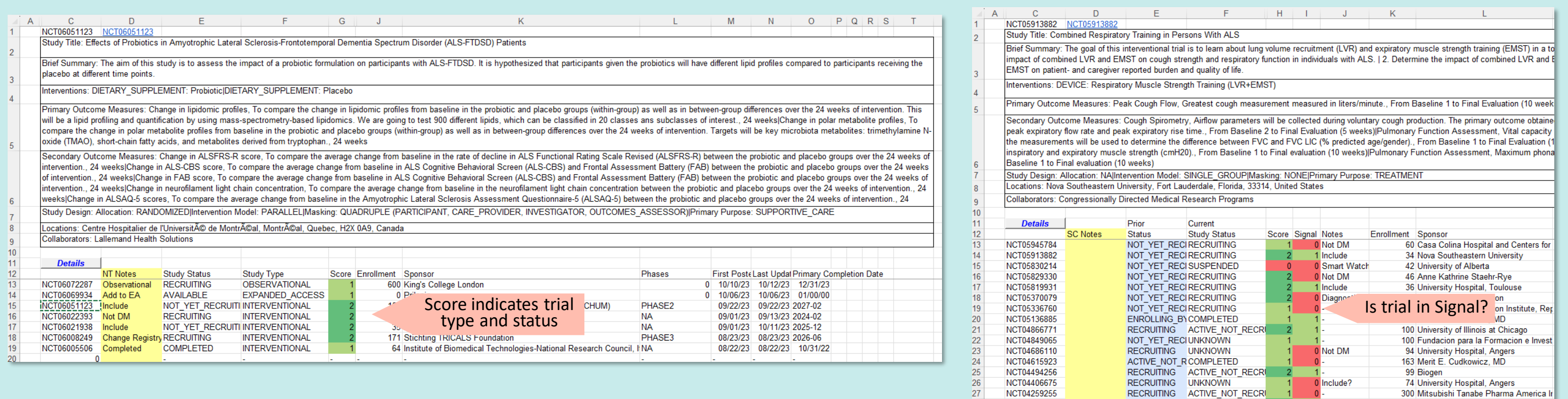
The new update process, depicted schematically below, substantially reduces the time commitment and improves the accuracy and reliability of the data in the dashboard. Currently, updating trials not listed on clinicaltrials.gov remains a manual process.



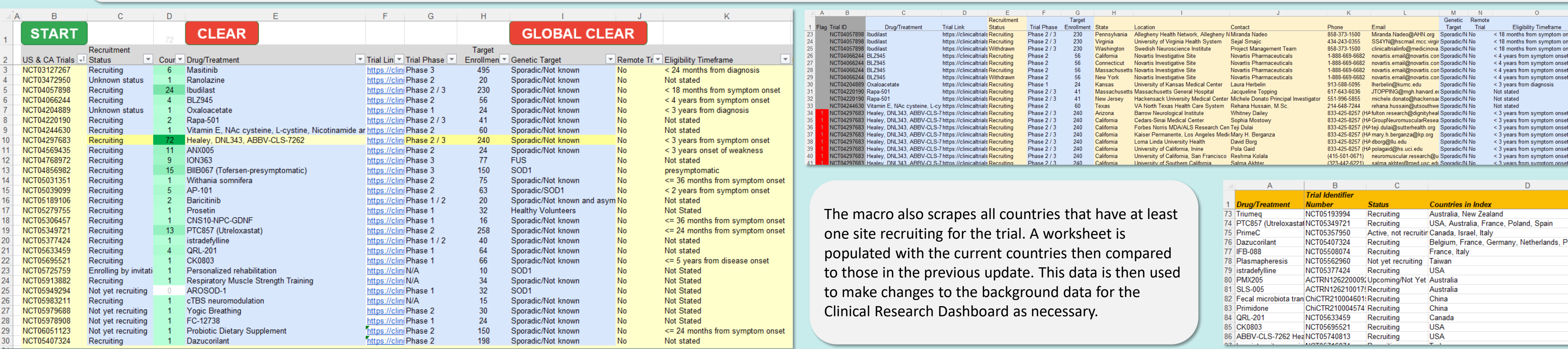
1 A search for ALS as "Condition or disease" in clinicaltrials.gov is conducted, then all available fields are downloaded into a CSV formatted flat file. The flat file is copied into the Excel spreadsheet. Time: approximately 1 minute



2 New trials and those with a status change immediately emerge on separate worksheets. The Details button fills rows 2-9 with more granular trial information. This information is used to update the background data for the Clinical Research Dashboard. Time: Instantaneous.



3 For trials recruiting in the US and Canada, a Visual Basic macro is used to first clear existing data then scrape individual site recruiting status, location (state, institution), contact, phone and email. Other pertinent information is extracted from the data used to inform the Clinical Research Dashboard ensuring consistency. A separate worksheet is populated with that data which is then used to overwrite the existing data providing a full refresh at each update. Time: 2 Minutes



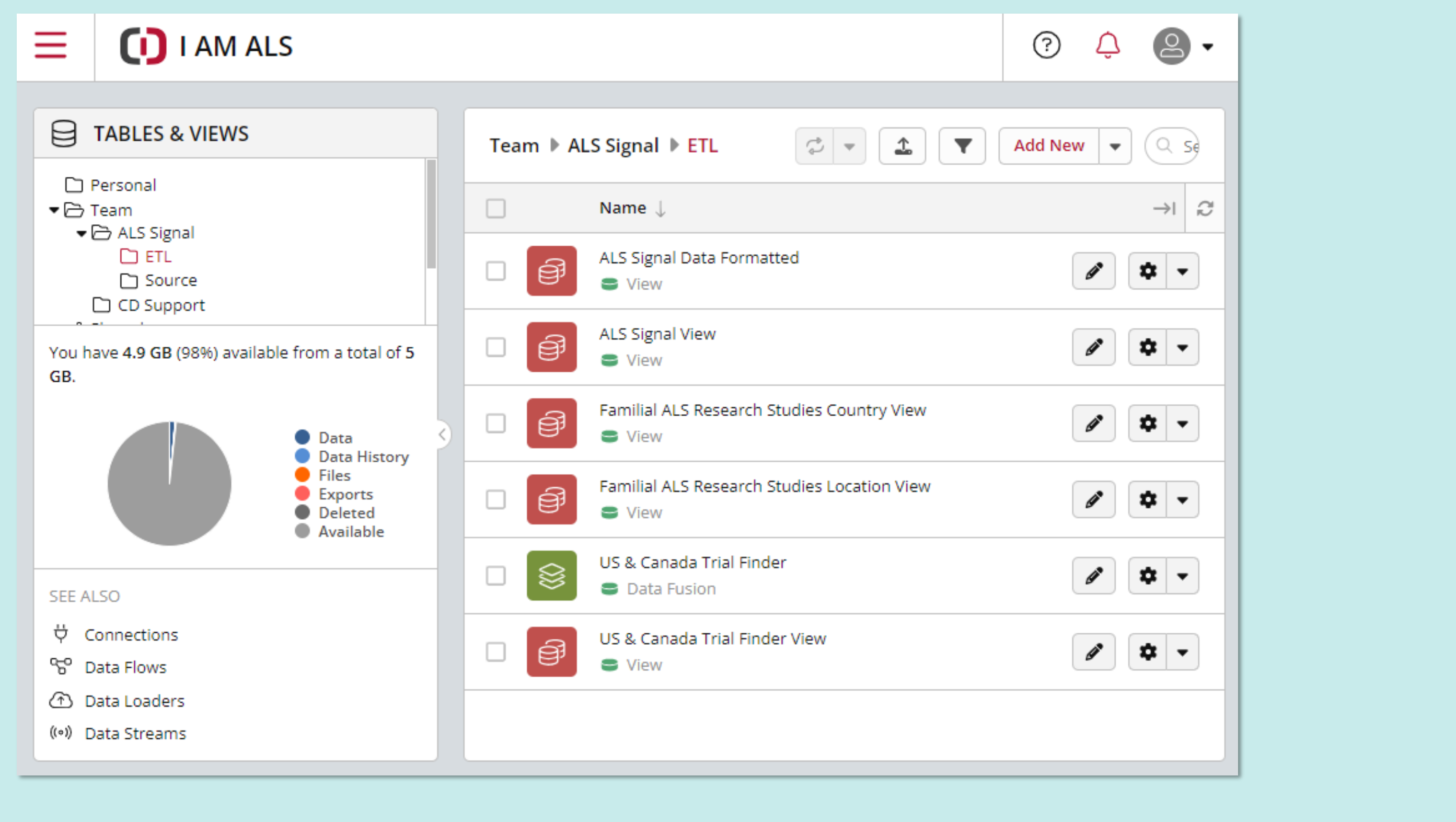
The macro also scrapes all countries that have at least one site recruiting for the trial. A worksheet is populated with the current countries then compared to those in the previous update. This data is then used to make changes to the background data for the Clinical Research Dashboard as necessary.

- ### Other Features and QC Checks:
- Does data for trials match clinicaltrials.gov?
 - Are data descriptions consistent?
 - Are all Canada and US trials included in trial finder?
 - Have trial sites been added or deleted?
 - Counts of trials by Phase, recruiting status, and country
 - Counts of enrollment by phase, recruiting status, and country

4 A "live" Google Sheets spreadsheet is maintained in a site accessible to the ClicData platform. This is the background data used to update Signal. It includes reference data that isn't displayed in Signal but some of which can be accessed by double clicking the trial. Time: 15 minutes - ~1 hour



5 Data are cleaned and transformed prior to publication. Time: Seconds and occurs without human intervention



References

1. Orsulak C, Sethi N, Carnival D, Lecker, M. I AM ALS presents ALS Signal: A Clinical Trials Dashboard. 31st International Symposium on ALS/MND 2020. Poster CLT-09.

