



USE R TO TRACK AND VISUALIZE BIOLOGICAL SAMPLE STATUS

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INTRODUCTION

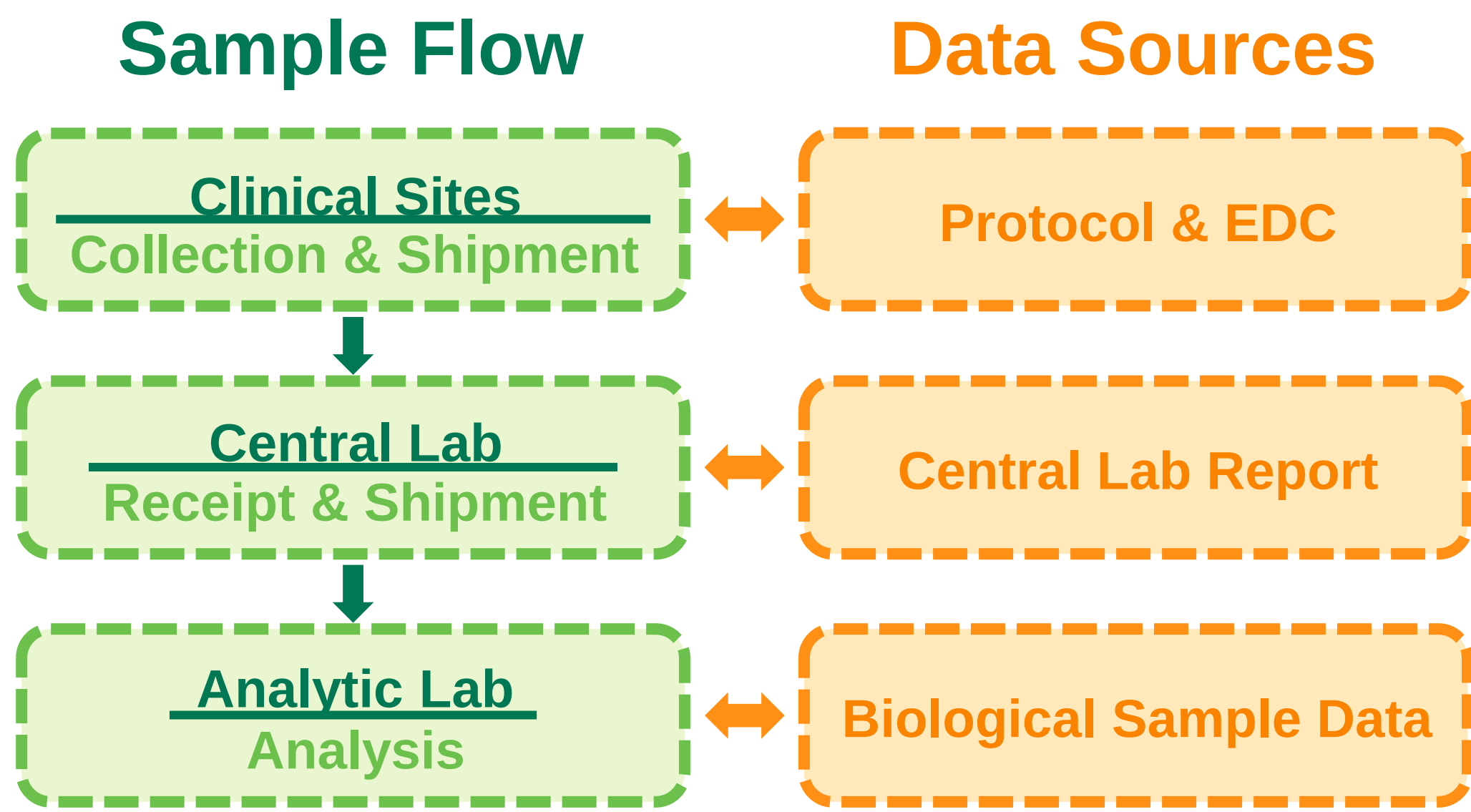
Clinical trials often collect biological samples to facilitate safety monitoring and assessments of the investigational product or device. Sample tracking is essential in ensuring accurate and timely assessments for informed decision making. However, manual sample tracking may be operationally challenging because:

- 1. The process from sample collection to analysis may involve multiple parties and vendors, and the sample metadata are scattered across various databases and web portals;
 - 2. Different assessments may have different sampling schedules and sampling schedules may change due to amendments of the study protocol;
 - 3. Large quantities of samples also add to the complexity.
- Thus, our goal is to use R to programmatically digest relevant data about samples (referred to as sample metadata) and create intuitive tools to streamline the sample tracking process.

METHOD

In a generalized sample flow, samples move from clinical sites to the central lab (if utilized) to analytic labs. In order to track samples, we use the data already being collected at each stage along the sample flow. These sample metadata are readily available and do not require additional data collection.

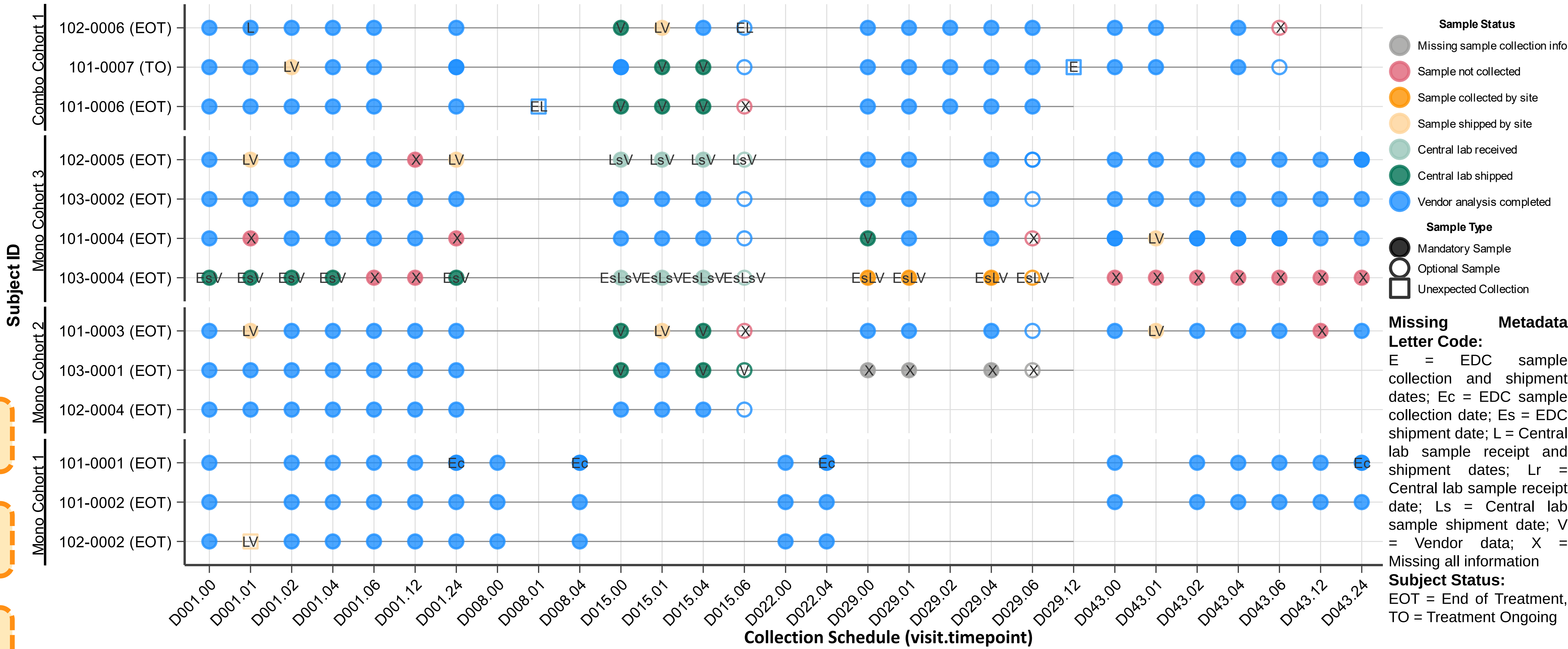
A toolbox of one listing and one graph was developed using R. For each type of assessment, the sampling schedule per study protocol was extracted and converted into a programming-friendly dataset. This dataset was then merged with sample collection and shipment data from the Electronic Data Capture (EDC), central lab database, and biological sample data by subject ID and collection timepoints. To create the final listing, the sample status indicator and missing metadata flag were derived based on the available metadata of a sample. Lastly, a concise sample status plot was produced to visualize the statuses and missing information of all samples for all subjects.



EXAMPLE TOOLBOX

Subject ID	Treatment Arm	Protocol Version Consented	Subject Discontinued from Trt. Flag	Latest Study Visit	Combined Collection Visit/Timepoint	Sample Status Indicator	Missing Metadata Indicator	Sample Collection Type Indicator
Protocol Collection Visit/Timepoint	EDC Collection Visit/Timepoint	EDC Sample Collection Date	EDC Sample Shipment Date	Central Lab Collection Visit/Timepoint	Central Lab Sample Receipt Date	Central Lab Sample Shipment Date	Analytic Lab Collection Visit/Timepoint	Analytic Lab Sample Analysis Flag/Date

The above table shows the header of an example of a basic sample tracking listing. This listing is usually structured as one row per collection timepoint per sample per subject. It may be extended to accommodate samples with back-up aliquots or other situations of multiple collections per timepoint by adding additional indicator variables. It is also possible to expand the use of this sample tracking listing for data reconciliation.



The colors of symbols indicate sample status – the furthest stage in the sample flow a sample has data for. The shapes of symbols indicate the collection type of a sample. The overlaying letter codes indicate any missing metadata in the sample flow from prior and later stages of a sample. Horizontal dark grey lines indicate study visits that subjects had completed. Collection schedules are concatenations of study visit and collection timepoint, separated by a dot. Study visit is represented in days. Timepoint 00 indicates pre-dose and others indicate the number of hours post-dose.

SUMMARY

This toolbox provides complete and detailed information for each sample in one listing, visualizes the statuses of all samples for all subjects per each biological assessment, and is customizable and flexible to adapt to different biological samples and clinical trials. It has been implemented to a pilot study and has increased the efficiency and accuracy of sample tracking. For the next step, the toolbox may be deployed as a dashboard to allow real-time update and interactive data/graphic drill-down.

CONTACT INFO

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