Streamlined Flow Cytometry Data QC Through Interactive Visualization

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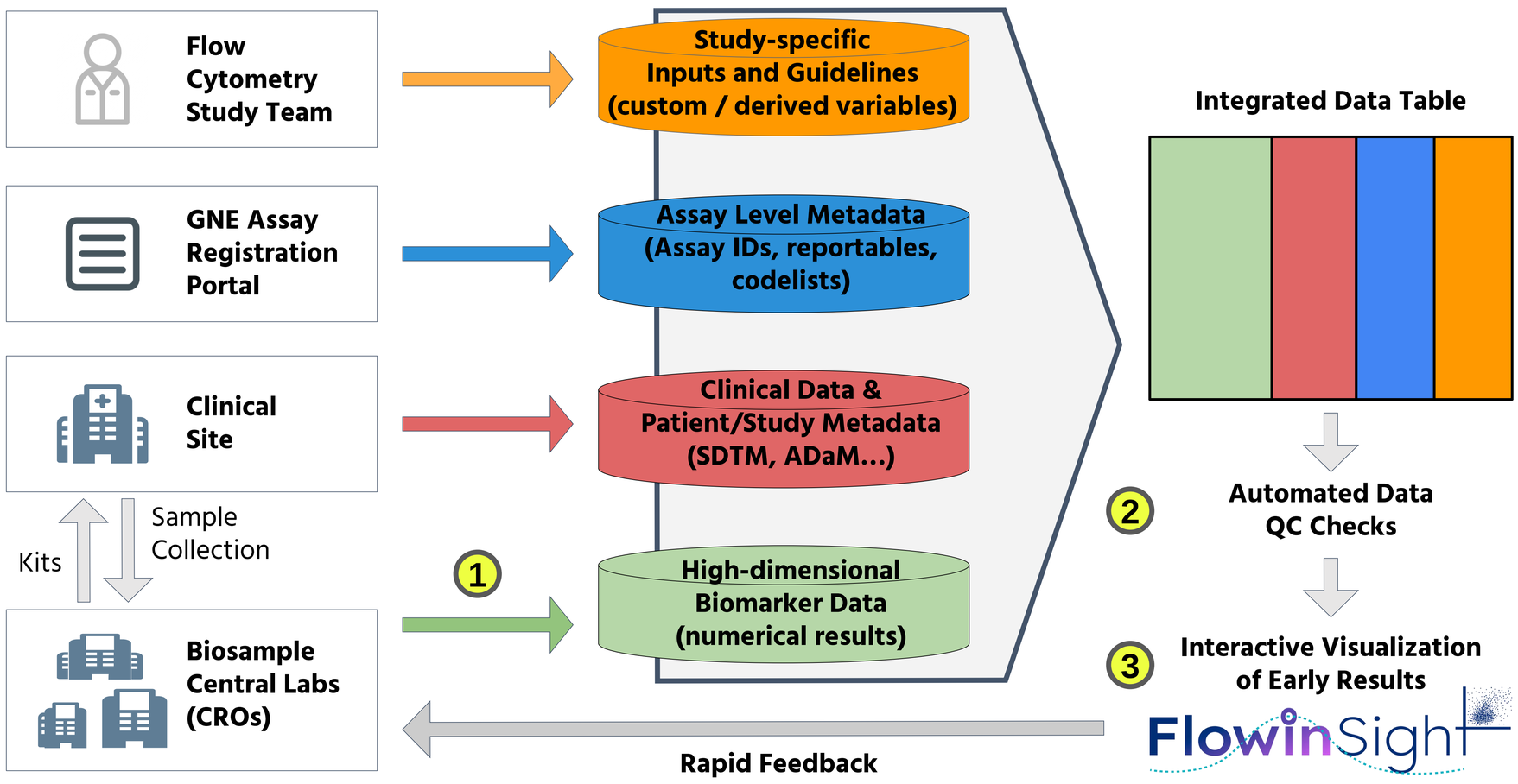
Flow cytometry assays serve as invaluable exploratory endpoints in clinical trials, aiding in assessing a therapy's impact on its target. In early-phase clinical trials, multi-color flow cytometry is pivotal for evaluating therapy effects on the immune cell population. Timely analysis is crucial for dosage efficacy and safety assessment, as well as early trend identification. Real-time plot generation enables scientists to visualize and interpret the data as longitudinal changes from baseline. The escalating data volume and complexity underscore the need for automation and quick visualization of the plots to make informed decisions swiftly. To accomplish this, we developed an automated process to merge the clinical data with the biomarker data and the sample metadata received from the CROs. The output is used in the FlowinSight app that we developed, enabling the generation of real-time plots, empowering scientists to promptly identify outliers and take swift corrective actions. Additionally, automated quality checks are performed to assess completeness, consistency, accuracy, and correctness by comparing biomarker metadata received from the CRO with clinical and assay metadata. The output is visually presented in the app at patient and visit levels, enabling scientists and operation leads to quickly sift through the issues and take rapid corrective actions.

Flow Cytometry Data Integration



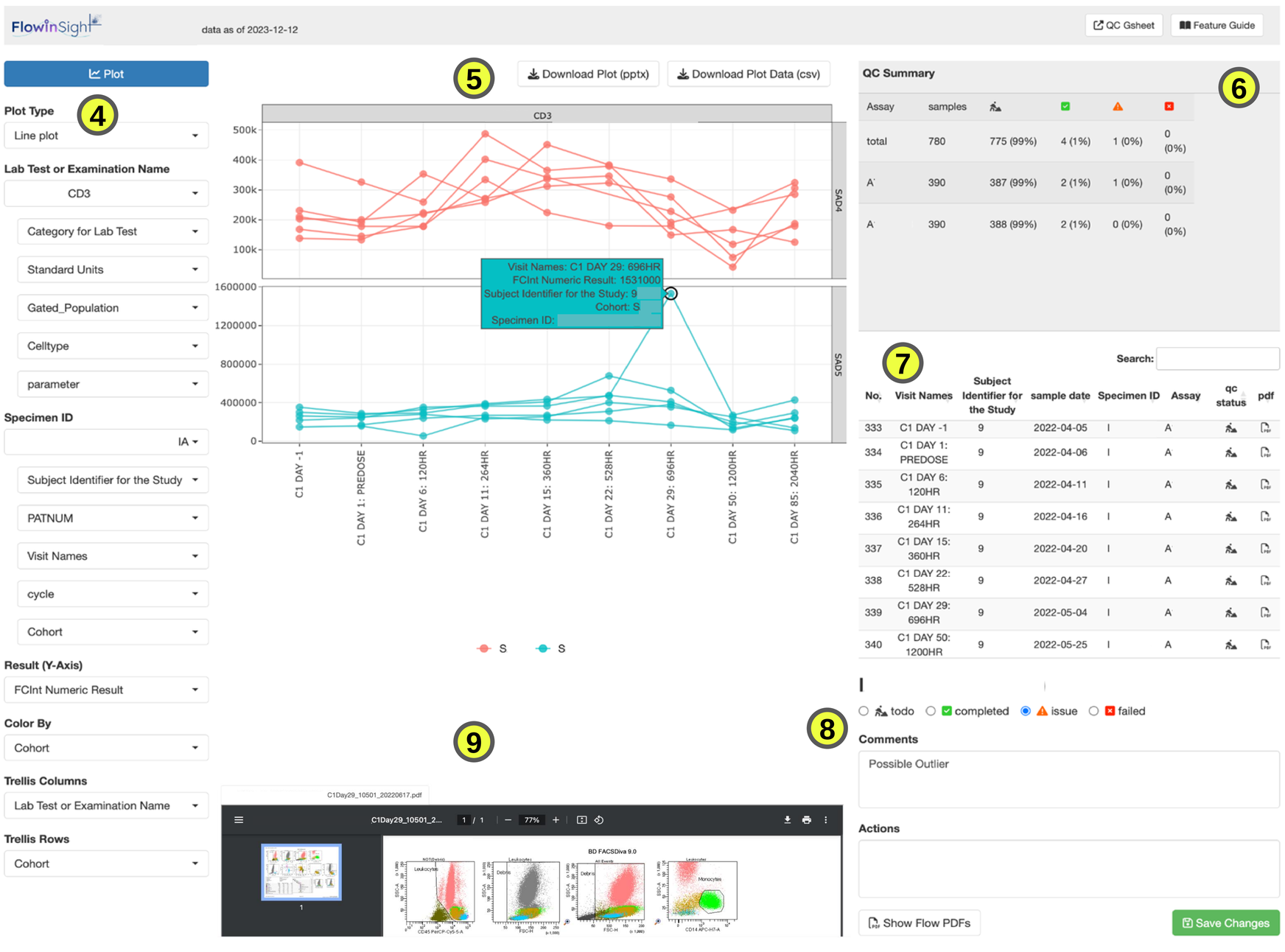
Data QC Process

1 File and Sample Reconciliation
- Data mismatch between CRO's raw data, numerical report and sample manifests
- Missing raw data files or sample IDs

2 Integration Validation
- Duplicate samples
- Wrong data format
- Missing clinical data
- Missing results / failed calculations
- Missing background tube / baseline value
- Missing/excess reportables
- Values not matching codelists
- Visit/date mismatch between numerical report and clinical data
- Missing / incomplete output data

3 Visual Data QC
- Outlier detection
- Gating errors
- Unexpected trends over time

Visual Data QC Application



Features

4 **Dropdown Menus** to select a subset of reportables and samples.

5 **Interactive Plots** with hover feature to instantly view sample metadata.

6 **QC Summary** to keep track of QC progress, broken down by assay.

7 **Sample Table** lists all currently available samples in the study, alongside a QC status. (gsheet updated via Google API)

8 **Comment Form** to assign QC status and take notes about individual sample-assays. Reactive to marking samples in the plot (black circle)

9 **Raw Data PDF viewer** allows pulling up gating information of the selected sample at the click of a button

Tech Stack

- Developed 4 study-agnostic R packages for reconciliation, integration, validation, and visualization
- CRON scheduled regular data updates

R, Shiny, golem, Google Sheets

Acknowledgements: Hanson Ho, Pranay Dogra, Aaron Schroeder, Alberto Robert, Sean Lear, William Pratcher, Hailey Garme, Yoonhee Choi, and Christina Cormier