

Sample Collection, Orchestration and Reconciliation (SCORE)

Automated reconciliation and monitoring of sample collections

The success of clinical trials depends on a pharmaceutical company's ability to conduct biological specimen analysis properly. Sample collection requirements in such trials are becoming more complex due to precision medicine and focused biomarker analysis.

The guidelines specified in a protocol document are manually transcribed into legacy systems, spreadsheets, or collaboration systems and then emailed by study coordinators to site personnel. The logistics around the trial are typically in "visit files," which specify the subjects that are scheduled to provide samples.

An amendment in the protocol document only confuses the downstream process. This quasi-manual approach or methodology often leads to the undesirable result of sufficient samples not being collected or adequately recorded.

Finally, without a comprehensive catalog of samples for each trial, the sponsor's R&D team has no visibility as to what is available in the biobanks for in-silico research and whether there is broad consent to use those samples.

Digitizing end-to-end sample collection processes with SCORE

To address the common barriers, improve clinical trial efficiency, and optimize the use of scientific assets, Virtusa has developed an innovative solution called SCORE that enables automated reconciliation, monitoring, and reuse of biosample data.

The solution is designed with detailed workflows required by Good Clinical Practice, GCP. The SCORE framework focuses on the early stages of a trial, digitizing protocol documents, creating logistic plans, ensuring sample collection according to plan, registering, identifying, and linking samples, enabling secondary use, integrating with clinical operations, and assay data management systems. SCORE comprises of several modular layers – **Plan, Ingest, Decide, Consent, Resolve, and Core**:

SCORE Plan is a Digital Process Automation based solution for capturing and processing biosample collection plans

SCORE Ingest is a flat-file data upload, transformation, mapping, and translation solution to allow data submissions from external sources

SCORE Decide is a highly configurable business rules design, and execution component that allows execution of custom rules on transmitted as well as stored biosample data, and other upstream information

SCORE Consent is a Digital Process Automation based solution to provide the link between patient informed consent templates and secondary use requests

SCORE Resolve is a Digital Process Automation based solution for handling violations of business rules such as failed sample data quality checks and collection plan deviations

SCORE Core is a centralized component storing biosample lineage and identification, immutable biosample properties, and biosample events



Solution benefits

Increased efficiency

- 30% reduction in manual effort to transcribe data from the protocol document
- Single source of data for sample collections, eliminating manual trackers
- Proactive monitoring of the sample collection process-via visualizations to show progress

Reduced costs and improved study protocol execution

- Enhances automation capabilities of sample data tracking and reconciliation
- Faster and agile development of contracts and lab manuals
- Reduces the burden on highly skilled resources for manual data entry

Improved compliance

- Improves data quality and integrity for submissions
- Provides end-to-end traceability and consistency
- Increases accuracy for total sample volumes with informed consent

Automated and accurate reconciliation

- Uses sample collection information and compares to the schedule of sample collections
- Allows continuous monitoring of sample collections and can extend to Sample Tracking
- Simplifies in-silico research requests by quickly identifying consent
- Combines structured and unstructured data by applying natural language processing algorithms
- Creates a structured plan for visits, subjects, and samples to be collected
- Provides a detailed report of all the samples collected
- Creates a series of workflow steps through an intuitive user interface
- Provides a visual dashboard showing in-progress status, including gaps in the sample collection process
- Stores all data using a common (Sample Registry), controlled vocabulary and provides prescriptive and predictive analytics using AI and ML

A leading global pharmaceutical organization accelerated the sample collections process using SCORE Plan:

A leading global pharmaceutical organization partnered with Virtusa to design, develop and deliver a digitized sample collection process with SCORE.

After reconciling the sample collection process gap, we developed a digitized and authoritative catalog for sample entry, a reconciliation tool to ensure the minimum sample collection thresholds are met, and a patient data repository for recording results.

For more information, please contact marketing@virtusa.com or visit www.virtusa.com/industry/life-sciences