

Assay Results Data Handling for Complex Biomarkers

THE SITUATION

A global pharmaceutical company recognized that 20% of clinical assay result datasets were consuming 80% of resources in terms of collecting, merging and formatting the results suitable for loading into clinical data repositories. The majority of assays (the “80%”) fall into the established data management process; they are well established mature methods and are available through larger commercial labs. These assay results are typically consolidated through the Central Laboratory vendor and provided to the Sponsor as regular well formatted and sample reconciled data feeds. The other problematic “20%” display some or all of the following characteristics:

- Novel, new specialty assays and technologies
- Complex biomarker assays: multiple parameters, high content, high data volume
- Performed by smaller specialty or academic labs
- Performing labs often have lower level IT skills and capabilities to undertake data reformatting
- Performing labs often have limited resources to perform data reformatting and data QC activities

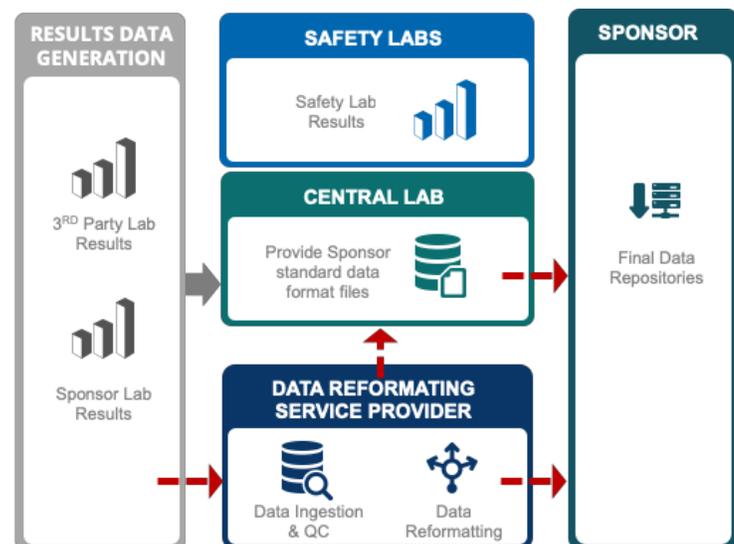
These datasets are highly valuable (often being key differentiators in a trial) and yet require a significant investment in resources to process. The company, therefore, sought a solution that would combine leading-edge technology with clinical assay data management services to ingest, process, and reformat these challenging datasets for integration into the more formalized clinical data processing stream.

THE SOLUTION

The result data handling process is a component of the sponsor’s overall clinical assay data management landscape. ResultWorks engaged with key stakeholders in the development of requirements specifically targeting the reformatting of clinical trial assay result datasets that do not easily proceed through the established process.

The solution was aimed at these key use cases:

- Complex or novel biomarker result datasets from specialty analytical labs which lack the technical or resource capabilities to provide assay result datasets in the sponsor-prescribed format
- Analytical labs internal to the sponsor for which reformatting result datasets to data transfer specifications is not a high value-add activity
- Datasets that require rapid turnaround from receipt-through-reformatting in order to be quickly assessed for adaptive design decision-making
- Datasets that must be reformatted for delivery to Central Lab vendors or directly to the Sponsor (as shown by red dashed arrows in figure on right)



ResultWorks applied its methodology to guide requirements developed around the vision for ingestion and processing of these challenging clinical assay results and facilitated the search for a technology and services solution vendor with the following capabilities to fulfil that vision:

- Clinical assay results data management services
- Technology-driven solution platform to automate dataset ingestion, formatting, and quality control

- Ability to interact with third party specialty labs
- Scientific expertise with biomarker datasets
- Ability to merge sample metadata and sample accessioning information with result data
- Dataset storage and facilitated access for sponsors, as necessary
- Ability to mask and de-identify datasets
- Validated technology systems and processes

Planning details were developed outlining the process for piloting the preferred solution providers that were identified.

KEY BENEFITS

Problem & Solution Characterization: Working collaboratively across functional areas, the biggest challenges (i.e., the 20%) were clearly characterized and the desired data flow and handling requirements were defined.

Approach: Leveraging its ResultMethodology, ResultWorks created an implementable strategy for evaluation and piloting phases and aligned the client team on the approach.

Results: Two third-party suppliers were selected to pilot data formatting solutions. Engagement of the suppliers enabled the Sponsor to have high quality and more timely access to results in the prescribed data format and to direct valuable internal scientific resources to more value-add work.

“We’ve made a significant amount of progress in terms of our thinking!”

“ResultWorks added value by keeping us moving rapidly through the whole process.”

- Associate Director,
Translational R&D IT

For more information, visit our website www.resultworksllc.com or contact us at marketing@resultworksllc.com.