GlobalTrace Supports National Study of SARS-CoV-2 Vaccines:

Tracks and Expedites Processing of Hundreds of Thousands of Biospecimens

Introduction

The Division of Microbiology and Infectious Diseases (DMID) within the US National Institute of Allergy and Infectious Diseases (NIAID) supports research to control and prevent diseases caused by virtually all human infectious agents except HIV. Currently, DMID is conducting a study of participants previously vaccinated against SARS-CoV-2 to evaluate the safety and immunogenicity of additional doses of prototype and variant vaccine candidates, alone or in combination. (Participants may or may not have had prior SARS-CoV-2 infection.) The primary outcome measures of the trial are immunoassay analyses of biospecimens.

Emmes is serving as the Statistical and Data Coordinating Center for DMID, as it has for over 25 years. The complex flow and volume of specimens in the trial required using Veridix's GlobalTrace specimen tracking and inventory system. The system streamlined specimen management across a web of locations and provided visibility throughout what would otherwise be an opaque anddisjointed process.

The Challenge: Complex Flow of Critical Specimens

The COVID-19 Variant Immunological Landscape (COVAIL) trial is a randomized, open-label, non-placebo controlled trial being conducted at 22 sites across the US. The multi-stage, adaptive trial was designed to add arms depending on public health needs and as new vaccine platforms and/or variant lineage spike vaccines become available.

Biospecimens are the "crown jewels" of the trial, as the primary outcome measures are immunoassay results (specifically, geometric mean neutralization titers using SARS-CoV-2 variant-specific, S-pseudotyped viruses and different strains of live SARS-CoV-2). Multiple aliquots of blood serum collected from each participant are sent from sites to a central repository and then selected to be assayed according to a "picklist" developed by statisticians. The selected aliquots are then sent to eight different laboratories for analysis, with the results being sent to Emmes' Data Coordinating Center

Given that samples traverse a network of 31 locations in the process (and that each entity has its own, separate inventory tracking system), it is challenging to oversee the disposition of samples.

Ultimately, aside from the inefficiencies that cause delays and waste resources, working without a tracking system on such a study has the potential to make some information irretrievable and rendering some samples unusable.

31
Locations

1,270
Subjects

379,329
Specimens

10
Weeks to Database Lock

The Veridix Solution: Global Trace, A Centralized System to Oversee Biological Specimenss

DMID adopted GlobalTrace for the COVAIL study, due to the volume of samples involved in the trial and the fact that staff at the agency's Clinical Materials Services (CMS) contractor were already familiar with the application. Site personnel not yet familiar with the GlobalTrace software were trained via a video self-learning module that culminated in a competency quiz.

GlobalTrace streamlined and recorded the shipment, receipt, and selection of samples all along the "supply chain," as samples were sent from sites to the repository and then to testing laboratories. Features that introduced efficiencies and eliminated human error included:

- Barcoding on sample labels (which ensured that derivative samples could be traced back to the original)
- Batch scanning when creating and receiving shipments
- Electronic shipping manifests
- Automated linkage with the tracking systems of major carriers
- Alerts for repositories and labs of incoming shipments
- Temperature tracking
- Integration with data stored in the EDC system
- Secure data uploads
- Automatic updates to specimen status and history whenever a specimen was acted upon

Importantly, GlobalTrace allowed the sponsor (and anyone with the appropriate permission) to track a specimen – and its lineage – across the whole clinical network.

> "For our team here at Duke, GlobalTrace has been the most user-friendly specimen system we have used over the last 22 years conducting clinical trials. GlobalTrace is easy to use, and a very intuitive system to organize and retrieve specimens easily. It is a simple system and, therein, lies its strength."
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> **- Duke Vaccine and Trials Unit**

The Results: Automation Reduced Manhours and Sped Database Lock

The COVAIL database is now locked, and immunoassay results have been recorded on a staggering number of specimens: 379,329. It is difficult to imagine how the study could have progressed so smoothly without the automation provided by GlobalTrace.

At every step along the way, GlobalTrace expedited and recorded specimen-related activities, saving hours in answering queries about the status of a specimen, reconciling a patchwork of separate inventories and shipment records, generating picklists, and selecting specimens for analysis according to those picklists.

DMID had on-demand insight into where specimens were at all times and did not have to ask for separate reports from every participating laboratory. With this up-to-date inventory, the sponsor could make informed decisions about specimen usage and the agency's ability to meet its research goals with existing specimens.

And, because all the specimen-related data was contained in one system and was integrated with the EDC, no reconciliation of records was necessary at the end of the trial. This saved weeks of laborious effort, allowing the database to be locked exceptionally quickly – in just ten weeks.