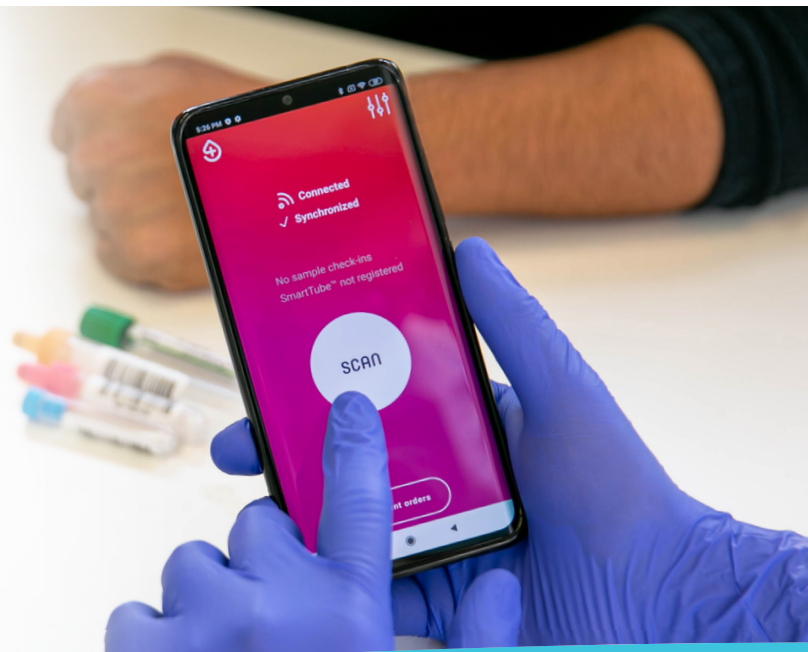


NAVIFY[®] Sample Tracking

An integrated pre-pre-analytic solution to phlebotomy support and more



The pathway to diagnosis

The pathway to disease diagnosis is a multi-step process that requires the tracking of the patient's diagnostic sample from start to finish to ensure the accuracy of the final clinical decision. The diagnostic journey of a patient's sample is defined by the pre-pre-analytical (PPA), pre-analytical, analytical, and post-analytical phases.¹ The PPA phase consists of patient identification and sample collection, handling, and transportation. The PPA phase is essential in linking the results of the diagnostic test to the patient and steering their care. However, the most common patient sample errors occur during the PPA phase. Common issues that arise in the PPA phase of a patient sample journey are typically outside of the laboratory's control, but must be monitored according to ISO 15189. Complications due to lack of process standardization, staff training, and insufficient data documentation during the PPA phase can have significant consequences for both the laboratory and the patient. For example, if a patient is required to provide a new sample due to an error, the patient may experience discomfort, decreased trust, and importantly, delays in treatment. For the laboratory, re-sampling increases operating costs and decreases laboratory productivity. In North American and European hospitals, a single pre-analytical error on average costs \$208 USD and in total such errors account for approximately 0.7% of total operating costs.²

Phases



Post-analytic

Errors laboratories currently control

Analytic

Pre-analytics

Pre-pre-analytics

Errors normally outside laboratory control

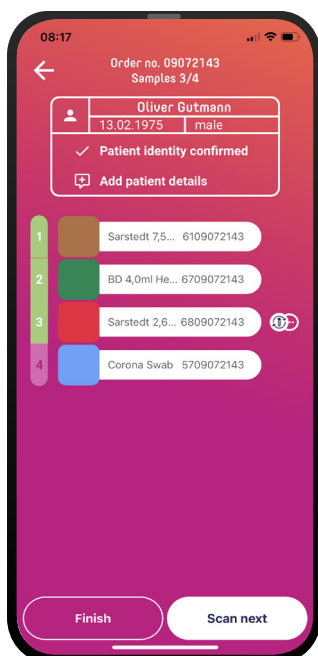
The diagnostic iceberg

The pain points of the PPA phase of the sample journey are well known to clinical laboratories and the diagnostic industry. Several companies have attempted to address the pain points of the PPA phase by offering digital solutions to support sample collection, transport, and reception. However, there is no single solution that can examine the full PPA journey of a patient's diagnostic sample. Most PPA solution vendors work in specific areas of the sample journey, making it a significant challenge for laboratories to identify and manage the right combination of PPA services to meet their unique sample workflow needs.

To help laboratories gain greater control over the quality of their samples and find the right PPA providers, Roche has developed NAVIFY Sample Tracking, a cloud-based tool that directly interfaces with PPA solution vendors and the laboratories information system (LIS) to provide fast, secure, and pre-integrated PPA innovation into any laboratory workflow. As a cloud-based solution, NAVIFY Sample Tracking is fully flexible and scalable to meet each laboratory's unique PPA needs. This case study discusses the synergism between the NAVIFY Sample Tracking team, the Center for Blood Coagulation Disorders and Transfusion Medicine (CBT), and Smart4Diagnostics (S4DX).

NAVIFY Sample Tracking case study: phlebotomy support with CBT and S4DX

In phlebotomy, the sample collection process is a crucial step where the phlebotomist obtains the blood sample, verifies important patient information, and records notes regarding the phlebotomy. The accuracy of these tasks is essential to prevent PPA issues. The most common PPA pain points identified during the blood sample collection process are tube filling errors (13%), patient identification errors (9%), inappropriate containers (8%), empty tubes (7%), and missing tubes (3%).³



PPA pain points addressed in this case study

13%	Tube filling error
9%	Patient identification error
8%	Inappropriate container
8%	Request procedure error
7%	Empty tube
3%	Missing tube
2%	Non-refridgerated sample
1%	Order mis-interpreted
11%	Others

“The susceptibility to errors in preanalytics is particularly high, as there are no standardized systemic solutions.”

PD Dr. med. Johannes Kruppenbacher,
Lab Owner, Center for Blood Coagulation
Disorders and Transfusion Medicine

The German based company S4DX offers digital solutions for blood sample collection, transport, and data analytics. For this case study, the S4DX sample collection application communicated with NAVIFY Sample Tracking. This digital solution can be used via an app (Android/iOS) or web browser to match patients and their samples. Within the app, time stamps are collected, a real-time order overview is provided, and the phlebotomists can take notes regarding the phlebotomy.

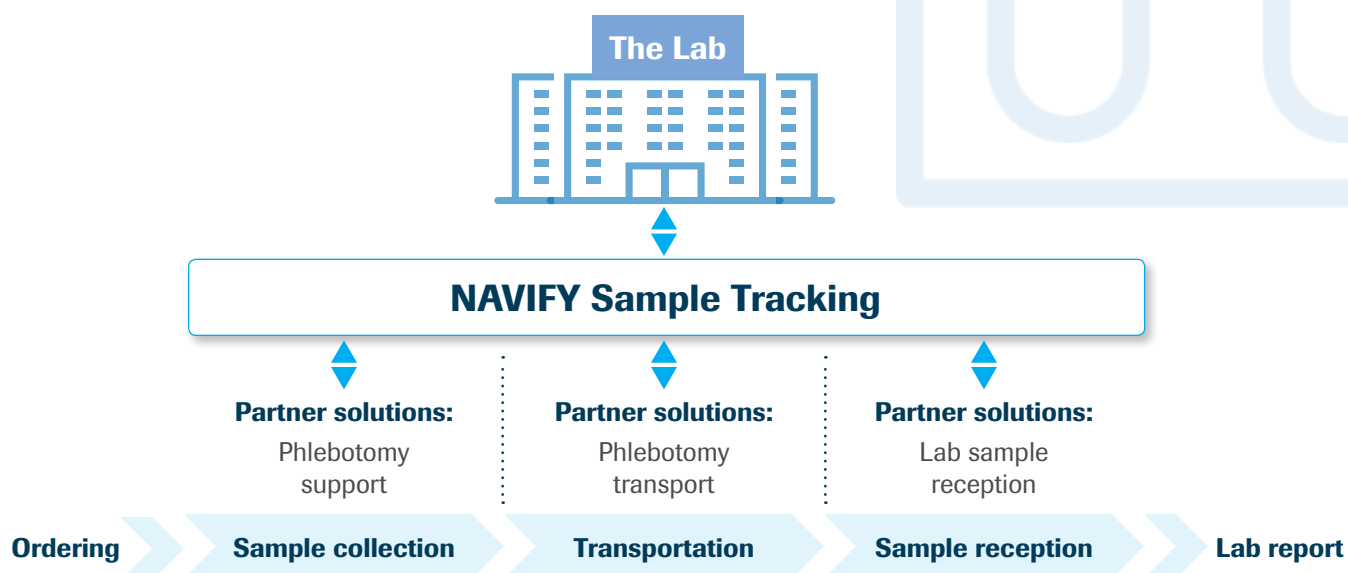
The CBT was selected to test NAVIFY Sample Tracking and S4DX System. The CBT is an interdisciplinary center that combines outpatient treatment and analytical diagnostics. Currently, the blood sample workflow at CBT is an end-to-end (E2E) process, with the patient, phlebotomist, laboratory, and clinician all under one roof. The blood sample collection process at CBT was not digitized and relied on barcodes and hand written records that were manually digitized by highly trained in-house staff. This approach increased personnel costs, limited their ability to scale operations, and was prone to input errors. This unique E2E process and willingness to digitize processes provided the ideal environment to test how sample collection applications communicating with NAVIFY Sample Tracking could be linked to CBT’s LIS.

Co-creation drives success

NAVIFY Sample Tracking is designed to deal with the complexity of interconnected PPA solutions. To facilitate its development, the NAVIFY Sample Tracking team created a “sandbox” where the solution could be tested and improved with guidance from the end users. The co-creation process allowed for the optimization of the data flow between the LIS, NAVIFY Sample Tracking, and S4DX application.

Goals of the collaboration between Roche, CBT, and S4DX

- **Scale Operations:** increase the high standard of sample quality and tracking at CBT, allowing them to scale their operations to include external sample collection without compromising high quality standards
- **Quality Improvements:** digitize the blood sample collection process at CBT and improve their insights into the samples
- **Interoperability of IT systems:** test the connectivity between the S4DX Application, NAVIFY Sample Tracking, and CBT's LIS

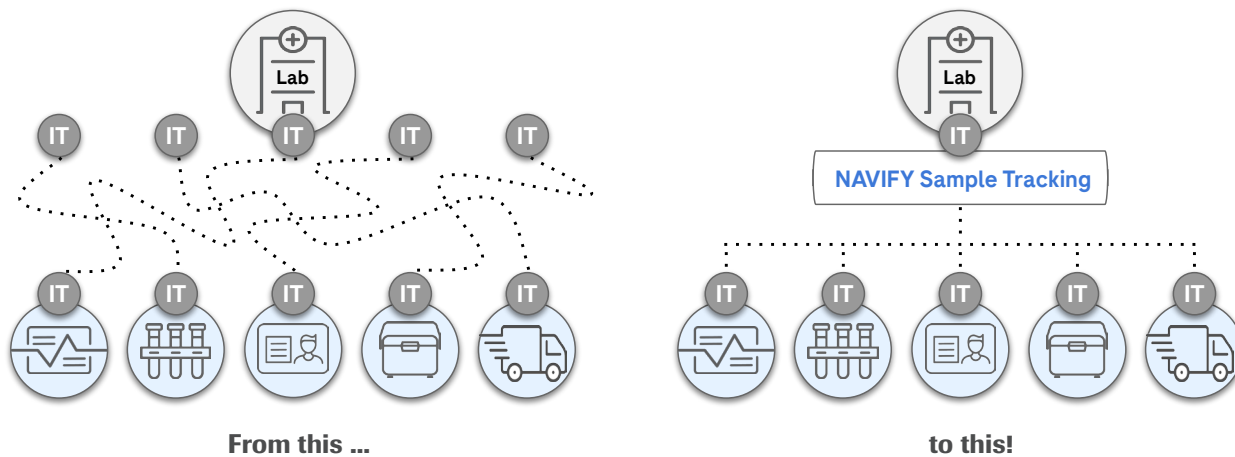


Integration Engine: NAVIFY Sample Tracking

An unmet need in the field of laboratory medicine and PPA monitoring is a mechanism for the multiple focused PPA solutions on the market to connect with the LIS. To address this major gap, Roche has developed NAVIFY Sample Tracking, which offers a unified approach to connect multiple PPA solution options to a LIS without the need for each new PPA solution to integrate individually to the LIS. Roche is fostering an ecosystem of PPA partner solutions to make it simple and cost-effective for these companies to connect their product to any LIS. These collaborations will provide laboratories with multiple trusted PPA providers to choose from to solve their specific needs.

“Insight and tracking of the sample PPA will improve the quality of procedures performed in the lab by improving the traceability of the sample journey and decreasing the number of issues.”

Dr. rer. nat. Philipp Westhofen, Lab Head, Center for Blood Coagulation Disorders and Transfusion Medicine

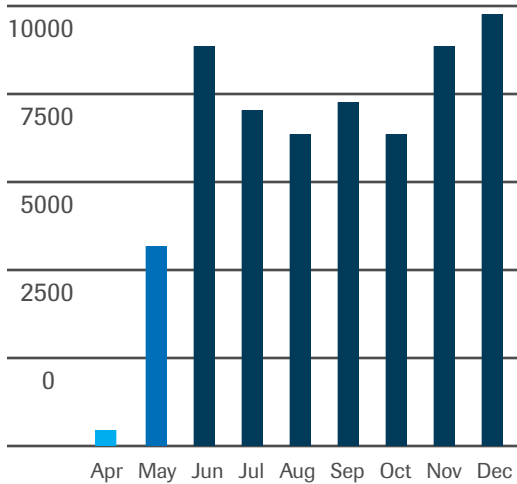


NAVIFY Sample Tracking:

- Provides communication between the LIS and partner solutions specializing in PPA tracking to ensure that collected sample information is stored in the LIS
- Helps laboratories choose trusted partner solutions and lower the barrier to integrate the new solution of choice into their LIS
- Provides visibility into blindspots of the testing procedures, thus improving the quality, efficiency, and productivity of the laboratory
- Enables smaller, partner solutions to collaborate with laboratories and provide cost effective solutions for integrating their tool with NAVIFY Sample Tracking and the partnering LIS
- Provides state-of-the-art data privacy and security tools that are compliant with local and global regulations, only allowing outbound connections to the system

60,000 blood samples successfully digitalized

- ▶ ■ Connectivity testing phase
- Pilot/user testing
- NAVIFY Sample Tracking fully implemented



Issue reporting percentage snapshot*

0.5%
filling level

0.1%
tube mismatch

0.6%
difficult collection

*Approximately 8000 out of 60,000 samples

Improved quality and efficiency of laboratory processes

The NAVIFY Sample Tracking team achieved full connectivity between the S4DX System, NAVIFY Sample Tracking, and CBT's LIS. During the 8 month case study, PPA information from approximately 60,000 samples were successfully digitalized and provided to CBT's LIS using the S4DX System.

The following information was collected and stored digitally using the S4DX System: sample ID, patient ID confirmation, sample collection timestamp, order completion timestamp, patient pre-draw status of blood pressure and sobriety, and the sample quality indicators of filling volume and missing sample due to stopped blood flow. Furthermore, through the S4DX System, laboratory personnel were able to collect and confirm important patient information, such as fasting status, pregnancy status, and blood pressure.

This digital window into the sample collection process allows for CBT to easily identify and measure the rates of specific issues. Immediate insight into sample information and identification of potential issues will be invaluable for CBT when they expand their operations to external sites. Improved visibility to the sample collection process will allow for quicker and more efficient detection and resolution of issues.

Increased insight to sample information will allow CBT to explore trends within the data, such as distribution of workload throughout the month, potential correlations between phlebotomy notes (such as blood pressure) and the diagnostic results, and comparison of error rates between internal vs external locations. The head of the CBT laboratory described the digital data collected under this collaboration as "gold" for their laboratory operations.

“Prenalytics is key for the quality of test results. It is essential for the best possible diagnosis, like every other part of the overall analysis!”

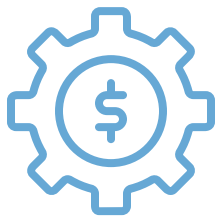
PD Dr. med. Johannes Kruppenbacher, Lab Owner, Center for Blood Coagulation Disorders and Transfusion Medicine

Phlebotomy support using NAVIFY Sample History and S4DX is ready for use in your laboratory

The communication between the LIS, NAVIFY Sample Tracking, and S4DX System provided significant value to CBT and their sample processes, even with only one PPA solution vendor collecting data digitally at one time point. The vision for NAVIFY Sample Tracking is to support several PPA solution vendors, offering each laboratory a holistic approach for their PPA needs. The effort to establish the communication between NAVIFY Sample Tracking and S4DX digital solution can now be leveraged at any laboratory that employs NAVIFY Sample Tracking, with significantly less IT time required.

NAVIFY Sample Tracking is a comprehensive, flexible solution designed to support laboratories with the right combination of services from an ecosystem of reliable providers. By implementing NAVIFY Sample Tracking and gaining visibility into PPA of samples, laboratories will ultimately improve the quality of results delivered to patients. NAVIFY Sample Tracking offers more control of laboratory samples with less complexity and will help reduce the cost caused by sample issues and requests for retests.

NAVIFY Sample Tracking saves costs while improving quality



Bring costs down through fewer errors



More cost-effective use of time and resources



Proactive, data-driven improvements

¹Plebani, Mario. "The detection and prevention of errors in laboratory medicine." *Annals of clinical biochemistry* vol. 47,Pt 2 (2010): 101-10. doi:10.1258/acb.2009.009222

²Green SF. The cost of poor blood specimen quality and errors in preanalytical processes. *Clin Biochem.* 2013;46(13-14):1175-1179. doi:10.1016/j.clinbiochem.2013.06.001

³Carraro P, Plebani M. Errors in a stat laboratory: types and frequencies 10 years later. *Clin Chem.* 2007;53(7):1338-1342. doi:10.1373/clinchem.2007.088344