N-SIDE

WHITEPAPER

Sanofi improves clinical trial monitoring with N-SIDE Suite

Contents

"How can I monitor my study and manage my clinical supplies better?"
Trial supply managers often ask themselves how they can be more efficient and proactive in clinical trial monitoring.

It is well known that successfully managing clinical supplies is a challenge due to the high level of uncertainty involved, the increasing complexity and costs of clinical trials.

Trial supply managers need to start planning their strategy well before the trial starts. Without any data from the patients in the trials to use yet, clinical supply management before study start is based mostly upon clinical assumptions about how the trial is thought to unfold. These assumptions account for about 80% of the information used to plan for the trial. The different components of these assumptions include:

- Recruitment plan - how fast different patients will enroll in the study and where
- Patient titration behavior - if and when patients will need to change the dosage of their medication in the study
- Drop-out rate - when and how many patients will discontinue their participation in the study
- Body surface area (BSA)/Weight range probabilities - if the dosage of medication dispensed to patients is dependent on a factor such as their body surface area or weight, these assumptions give a percentage of the breakdown of patients expected to fall into different body surface area / weight ranges.

These **assumptions will later be followed through clinical trial monitoring** once the study starts. In addition to these clinical assumptions, information about the distribution routes, vendors and Interactive Response Technology* (IRT) set up needs to be taken into account to build the clinical supply planning.

At Sanofi, for each study managed with an IRT system, the Clinical Supply team uses the Supply App and Dashboards from the N-SIDE Suite for their clinical supply management.

The clinical and supply assumptions are inputs used by the Supply App to optimize the planning for the supply strategy. The optimized supply strategy and forecasts include an optimized Investigational Medicinal Product (IMP) planning including quantities needed and packaging release dates. Additionally, this supply strategy provides a clear risk analysis identifying when and where the risk can appear. Thanks to this, **trial supply managers are able to manage risk proactively and avoid any delay in patient dispensing**. The Clinical Supply team also uses these results to set-up the IRT for the specificities of the study and plan their depot resupplies.

Before study start, the strategic decisions and clinical supply planning are based on the best assumptions about how the trial is expected to evolve.

Luckily, with clinical trial monitoring, all of the assumptions are adjustable once real data is available throughout the duration of the study.

Why is monitoring so critical?

Trial supply managers monitor on-going clinical trials for a number of reasons. First, trial supply managers must ensure that the current strategy is still efficient. For example, if patient recruitment is faster in one region or country than expected, changes may need to be made in depot resupply or even IMP packaging plans. Second, monitoring the trial enables trial supply managers to be proactive in realigning the strategy. Clinical trial monitoring helps avoid firefighting activities and allows managers to mitigate risk with timely and effective actions. This leads to the final, most important, reason - to ensure that there is no risk for a patient to miss a dispensing visit. With efficient clinical trial monitoring, trial supply managers can respond quickly as soon as the realities of what is happening in the trial deviate from the assumptions.

Sanofi's new clinical trial monitoring approach

Sanofi has implemented a new solution to improve clinical trial monitoring: using the monitoring dashboards from the N-SIDE Suite. These dashboards help trial supply managers compare real, live study data coming from the IRT on a daily basis with the study plan and statistics efficiently and easily. Sanofi trial supply managers can find the answer to daily questions such as ***"what is my study status today?"*** in one click. Color coding in the dashboard helps identify quickly any KPIs for the study that are out of bounds. These monitoring dashboards also help identify when the dispensing, i.e. planning for the quantity and timing of the IMP available for patients over the course of the study, deviates from the thresholds.

"With the help of monitoring dashboards from the N-SIDE Suite, as a trial supply manager, I know precisely the status of my trials. I am empowered to manage supplies for my trials efficiently while proactively managing risk."

Julie Pencole,
Clinical Trial Supply Manager and N-SIDE Supply App Key User and Expert, Sanofi

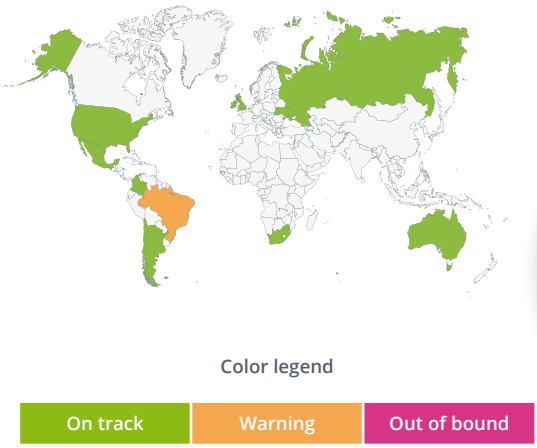
All Sanofi trial supply managers have access to their own portfolio of trials within the N-SIDE Suite and can efficiently visualize them in the monitoring dashboards. In the past, multiple systems were checked in the process of monitoring if trials were on track. Now all of the information needed for **clinical trial monitoring is centralized in the dashboards and the data is visualized which makes monitoring easier and more efficient**. Using these dashboards for clinical trial monitoring allows the trial supply managers to know where to focus their attention so that they can be more efficient and react in time.

To common clinical trial monitoring questions, such as **"my dispensing is out of bounds, but where and by how much?"** the global and local dispensing dashboards provide a comprehensive answer. These dashboards visualize the existing forecasts as well as their associated boundaries. Patient enrollment forecasts and actual data from the trial are displayed with the minimum and maximum thresholds that the current supply strategy will cover. At a glance, trial supply managers can see the data they need in response to questions such as:

- Are patients entering the study at the targeted time and location?
- Is the dispensing occurring as expected?
- Is there randomization unbalanced at the local level?
- Are patients still in the study as planned?

Because the monitoring dashboards in the N-SIDE Suite can be filtered by country, local depot, trial supply managers can deep dive into the data to easily visualize the answers they need.

Monitoring dashboards from the N-SIDE Suite



Are the recruitment and dispensing on track?

The global and local randomization dashboards also make the link between changes in dispensing and the study recruitment. Each day in their clinical trial monitoring, trial supply managers can compare the number of patients randomized versus the minimum/maximum number planned. If a deep-dive analysis is needed at local level, the local randomization dashboards can help. There is also clear color coding to quickly identify the countries that exceed the planned thresholds. This thorough analysis at local level enabled with the local randomization dashboard is essential since the IMP supply to the depots is closely tied to the local recruitment plan.

Sanofi trial supply managers can easily share the recruitment that they observe in the dashboards with their colleagues from the Clinical Trials Operations teams. This helps them to align across departments on the recruitment assumptions. Further, enables better forecasting of future recruitment based on the current tendencies that they can analyze together with the dashboards.

With the monitoring dashboards from the N-SIDE Suite, Sanofi has seen three main benefits leading to study success:

- First, the clinical supply manager can focus on strategic decision making and realignment. This is thanks to time saved on operational tasks involved in clinical trial monitoring by using these dashboards.
- Secondly, there is improved communication between all clinical supply and study team stakeholders.
- Lastly, and most importantly, clinical supply managers know that they are ensuring patient treatment with a risk-controlled and optimized IMP supply chain.

**IRT : Interactive Response Technology is software that enables activities such as randomization into clinical trial and dispensing medications in a blinded & unblinded trial. Site status, Patients history, site stock and depot stock are data managed by the software.*

Julie Pencole
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ABOUT N-SIDE

N-SIDE is a deeptech company that empowers organizations in the life sciences and energy sectors to make better decisions and optimize the use of critical resources.

We're doing so by combining deep industry expertise with applied mathematics and artificial intelligence into easy to use and cutting-edge software that transforms uncertainty and complexity into deterministic outcomes.

In Life Sciences, we streamline the clinical supply of pharmaceutical and biotech companies by accelerating clinical plans, mitigating risks and curbing drug waste.

In Energy, we accelerate the transition towards renewables and electrification by enabling leading grids and market players in making better, faster and safer decisions.

N-SIDE is ranked among the Best Workplace™ of the Great Place to Work® Institute Belgium and is also a certified B Corporation™.

For more information, visit **www.n-side.com**