#ExperienceTeckro

Improving Clinical Trial Compliance

How a Top 10 sponsor reduced protocol deviations with Teckro

In the intensely competitive space of oncology, this Top 10 sponsor was looking to improve agility, efficiency, and speed in the development of its drug. Specifically, the clinical operations team wanted to reduce the likelihood of protocol deviations. Considering the large number of sites and the length of the trial, the team determined that essential to this reduction would be enabling sites to stay up to date with protocol changes. With the current, approved study instruction at their fingertips, sites can make the right decisions for patients while staying compliant with the protocol.

This strategy has been proven effective.

Phase III
Breast Cancer

- 199 sites in 29 countries
- 1,066 participants
- 4 years

65% fewer deviations

2x faster participants randomized

✓ always the current, approved protocol

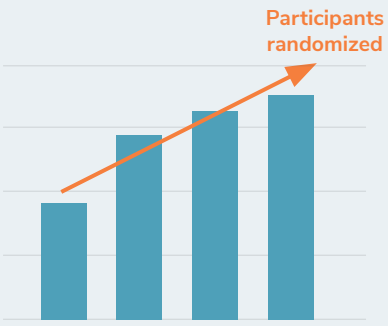
Quickly Confirming Eligibility

Sites that used Teckro from the study start immediately saw value in having answers on their mobile phones. Moving the protocol to the point of care helped users quickly determine which participants matched the eligibility criteria. Sites using Teckro randomized participants at double the rate of sites not using Teckro.

Adhering to the Protocol

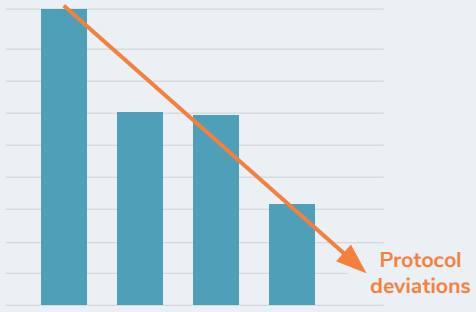
Sites using Teckro to guide their decisions also had fewer protocol deviations than those not using Teckro. Although the study team was concerned about sites tracking to the current, approved version, regardless of the number of amendments, Teckro handled version control with ease and managed a key source of protocol deviations.

Sites Using Teckro Randomize Participants Faster



Sites more actively using Teckro to guide clinical trial decisions randomize participants faster compared with those not on Teckro.

Sites Using Teckro Have Fewer Protocol Deviations



Sites more actively using Teckro to guide clinical trial decisions have fewer deviations per randomized participant compared with those not on Teckro.

teckro

Developing Good Habits from the Start

Sites that relied on Teckro as a clinical study resource from the study start had more consistent use. We analyzed performance for a site in France that began use from the site initiation visit (SIV). They enrolled their first patient in less than a month after the SIV and maintained a steady rate of enrollment from that point until the end. They also had no deviations in this timeframe.

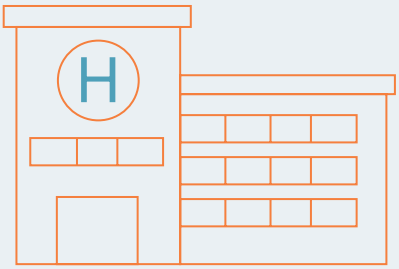
Representative Example of Positive Site Performance with Teckro

Teckro searches by site staff 63

JAN 2021	FEB 2021	MAR 2021	APR 2021

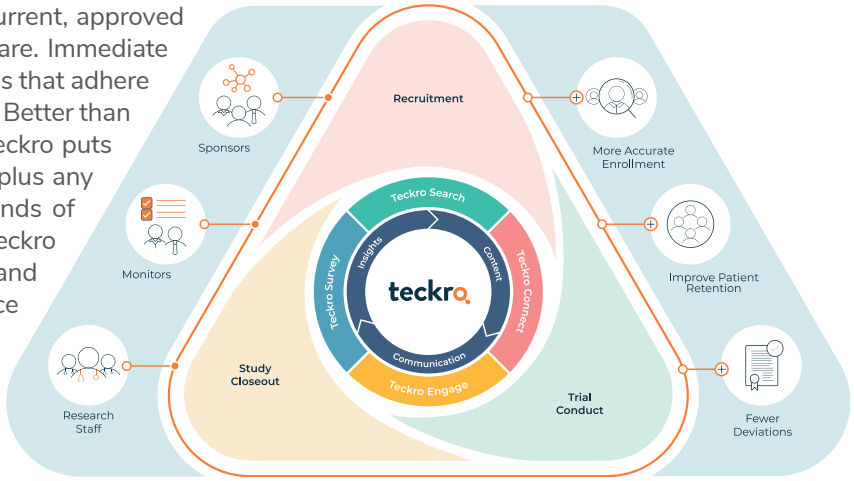
Patients randomized 4

Protocol deviations 0



How Teckro Contributes to Quality and Compliance

Teckro supports compliance by making the current, approved protocol instantly accessible at the point of care. Immediate answers guide research staff to make decisions that adhere to the protocol at every step of the clinical trial. Better than any "cheat sheet" or quick reference guide, Teckro puts the correct, approved version of the protocol plus any other supporting study documents in the hands of research personnel on their smartphones. Teckro then ensures that protocol amendments and other document updates are available to reduce the risk of anyone following the wrong version of the protocol.



Teckro also gives sponsors new levels of visibility into site activities and insights to drive optimal site engagement throughout the study. Keyword search trends highlight areas where sites need more information and clarification, driving safer, faster, and compliant studies. With Teckro as the go-to resource for sites, sponsors can measure site engagement and drive toward better trial outcomes, including faster and more accurate enrollment, better data integrity, and, as we saw in this example, fewer protocol deviations.

Sponsors and monitors can also leverage Teckro to proactively manage compliance. Study teams can send targeted study alerts to sites synced with visit schedules and prompt, remind and assist sites with optimal execution. For example, timely reminders can provide specific recommendations for an upcoming visit or instructions regarding a specific procedure. A sponsor can also alert investigators about a specific change to the protocol and advise on any impacts to the study execution. As a compliant, secure communication channel with sites, sponsors can also measure the effectiveness of their messages by tracking open rates. Teckro is also 21 CRF Part 11 compliant, so there's a full audit trail as all communication sent via Teckro is easily exportable, if required to be filed in the study's trial master file.

Teckro is also a quick and secure channel for sites to ask questions directly to a group of sponsor study experts from the point of care. Via their smartphones, sites have direct access to a group of study experts to guide best practices and decision-making in accordance with the protocol. Site staff can have confidence in the information they receive through Teckro because it comes directly from the sponsor's select group of study experts. They can then make informed and accurate decisions while the patient is still in front of them.

Have a question? Teckro the answer.

For more information visit teckro.com