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Teckro for Exploratory Phase Dose Escalation Studies

How interconnected content and communication make a world of difference

Exploratory phase dose escalation studies often rely on fast, easy communication between all study stakeholders to move on time and on budget. This use case explores a typical experience, versus the speed and efficiency possible with Teckro.

Before Teckro: Passive, Slow, Siloed Communications

It's 09:15 on any Friday.

A busy oncologist PI is doing rounds in the oncology ward. She gets Mr Doe's hematology results back from the lab which show significant neutropenia. This is new.

Mr Doe was scheduled to be a participant in a dose escalation Phase 1 study of a new immune-oncology drug. But now he doesn't satisfy the inclusion criteria for the trial.

The oncologist phones the trial coordinator at her site but she's not answering. The oncologist resolves to phone her later. Somewhat inevitably, after a tough, busy day - she forgets.

Frustrated Sites and Study Teams

Next Monday: The coordinator notices that Mr Doe's EDC hasn't been entered and checks pharmacy for release of trial meds. After confirming patient non-attendance with the oncologist, she completes the paperwork for exclusion. The CRAs phone is off because he's on a flight, so an email and text are sent instead.

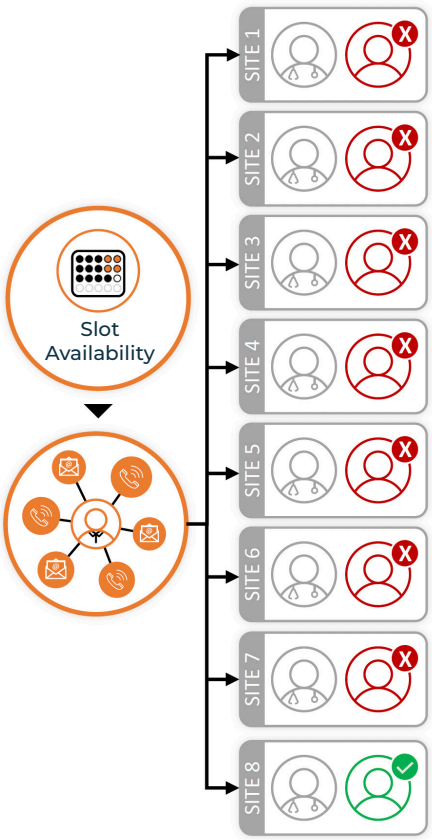
Wednesday: The CRA finally has a moment for emails and sees a trial slot hasn't been filled. He emails the study team but it gets stuck in his outbox. It's two more days before he realizes and resends.

Monday (week +1.4): The email is read and acknowledged by the study team, who email all 8 trial sites that a slot vacancy has arisen. It's three more days before all sites have seen it.

Friday evening (week +2): Coordinators and PIs at the 8 sites get a moment to check the protocols.

Monday (week +2.4): One site notifies study team of likely patient for the slot who can be accommodated in their ward in two weeks' time.

Friday (week +4): The patient is dosed according to vacant slot.



Frustrated Budgets and Timelines

A decision on next dose escalation, including dose escalation meeting of PIs, is **pushed back by 4 weeks,** but only 3 of the 8 PIs can make the new date. The meeting is eventually held **7 weeks after the original schedule**. The trial eventually finishes **6 months behind schedule.**

The study team get extra help to collate call records, SMS messages, WhatsApp messages and emails for the eTMF so it's ready for inspection. **This takes three weeks.**

After Teckro: Two-Way Communication Highway

It's 09:15 on any Friday.

A busy oncologist PI is doing rounds in the oncology ward. She gets Mr Doe's hematology results back from the lab which show significant neutropenia. This is new.

Mr Doe was scheduled to be a participant in a dose escalation Phase 1 study of a new immune-oncology drug. But now he doesn't satisfy the inclusion criteria for the trial.

The oncologist opens Teckro on her phone and sends a quick message to the site coordinator, CRA and study team. The oncologist gets on with the rest of her day.

Faster Slot Management

Upon receipt of the news, the study team **immediately send** a message to all 8 sites to say that a slot has become vacant. All the PIs, coordinators and CRAs receive a Teckro **push notification** which prompts them to view the message inthe app (even those traveling).

The message contains a **link directly to the inclusion and exclusion criteria** in the digitized protocol, within Teckro. PIs and coordinators review the information and consider whether they have a suitable patient.

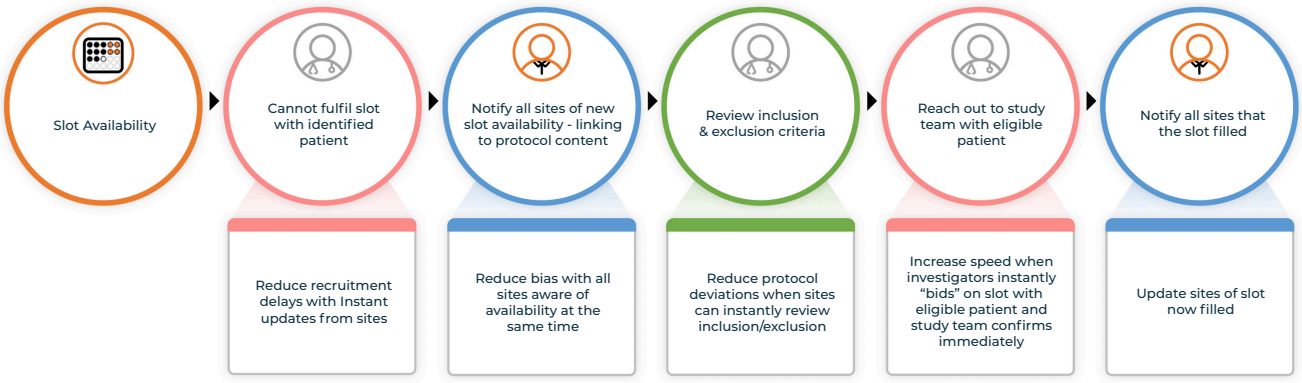
The coordinator at Mr Doe's site can see the vacancy is being managed and completes the paperwork for the patient's exclusion.

Coordinators at two of the sites have checked medical records and confirmed that they each have a suitable patient. They quickly send direct messages to the study team.

The study team responds and confirms the slot with the coordinator who has the patient able to attend earliest.

The slot is filled without a day lost.

Monday (week +1.4): Mr Frost attends the site and enters the study, filling the vacant slot successfully.



Faster Dose Modifications

A decision on next dose escalation, including dose escalation meeting of PIs, occurs on schedule. Teckro communication tools streamline the consensus decision. At trial end, the study team send all communications in Teckro to the eTMF. Fully audit trailed, 21 CFR Part 11 compliant. Inspection ready.

Time saved: dramatic. Stress relieved: immense.

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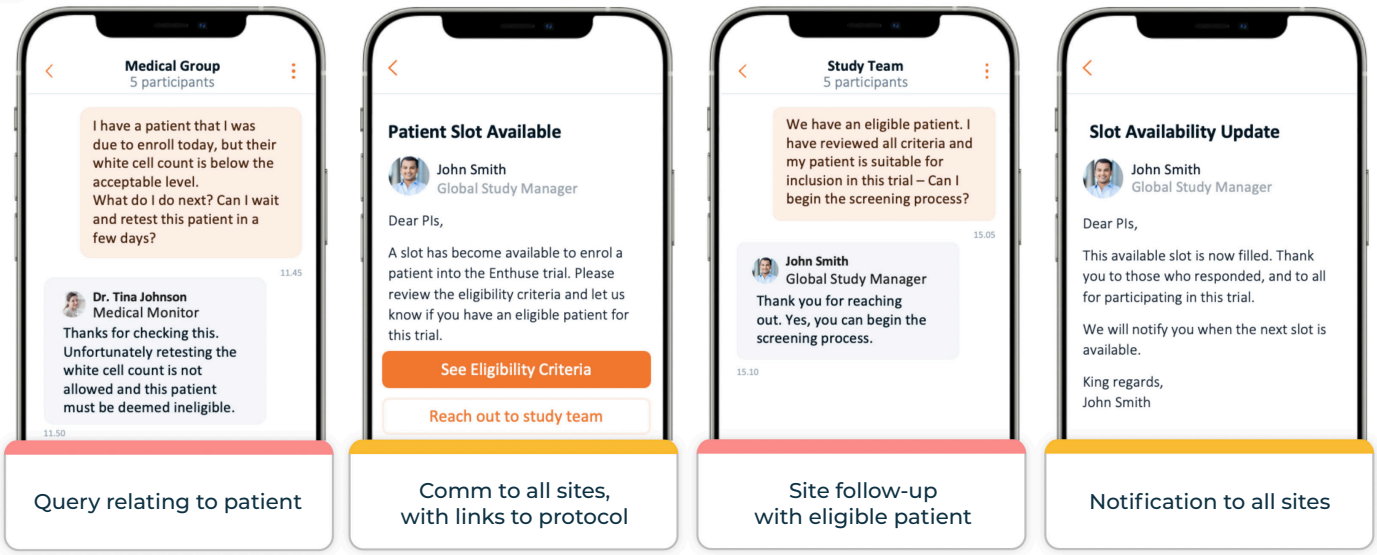

Query relating to patient

Comm to all sites, with links to protocol

Site follow-up with eligible patient

Notification to all sites

The Brave New World of Teckro

Traditional forms of clinical trial communication are slow, increase site burden, and frustrate study timelines and budgets. Communication tools need to be simple, intuitive and mobile to support real-time information sharing and allow for trials to pivot quickly and efficiently if a patient is excluded - particularly in dose escalation studies. Busy CRAs and sponsors need to easily and automatically capture communications into inspection-ready study files.

As your interconnected digital protocol, Teckro unlocks a fast, reliable and compliant network of information sharing to and from the study team and across all trial sites; at all vital junctures of exploratory phase studies. The right message gets to the right people at the right time. Solutions are found and course corrections are made. Decisions are agreed and promptly disseminated. Ultimately, the trial proceeds as planned, even when faced with obstacles that would ordinarily cause weeks of delays.

Your Interconnected Digital Protocol

For sites:

- Instant access to approved protocol amendments
- Ease & transparency in communications
- Awareness of trial activities – cohort openings, slot availability, etc
- Direct feedback to study team
- All communications in central location for filing

For sponsors:

- Speed of filing cohorts and reduced recruitment delays
- Faster enrollment
- Reduction in turnaround time for dose level decisions
- Direct feedback from sites and PIs
- Inspection ready

Have a question about your clinical trial? Teckro the answer

For more information or to request a demo, visit **teckro.com**

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