



Case study

Proactive consent review helps pediatric studies stay ahead of FPI

Medable platform solutions used: eConsent, Medable Studio, eCOA, Televisit

Therapeutic area: Pediatric vaccines, Pneumococcal

Geography: South Africa: Zulu, Sesotho, Setswana

Participants: 100+

Client: Top-5 pharma

Partner overview

A top-5 global pharmaceutical company partnered with Medable to support two pediatric vaccine studies in South Africa.

Given the trial demographics, parents and guardians were central to success, as they consented on behalf of their children while also supporting their study activities.

According to the sponsor, the pre-FPI (first patient in) patient experience (including consent, caregiver onboarding, etc.) was quintessential to the studies' success. Medable and the sponsor established a close working relationship very early in the process, establishing standards for defined roles, responsive communication, and shared ownership of action items.

The result was a smooth path through study build and UAT, while Medable's proactive review also uncovered inconsistencies in informed consent materials early enough for the sponsor to address them before FPI.

Key outcomes & insights

- Timely detection of inconsistencies enabled rapid ICF amendments and subsequent IRB re-approval well ahead of FPI, protecting study timelines.
- Evaluated consent materials from the perspective of the parents and guardians who would actually provide consent to ensure the materials were appropriate.
- Progressed key startup activities ahead of targeted timelines, supported by an approximately six-month runway before planned FPI.
- Completed UAT without configuration-related functionality issues identified.

Understanding the challenge

Pediatric studies introduce considerations that go beyond simply digitizing an informed consent form. To start, children's parents or legal guardians, not the participants themselves, would be the individuals reviewing and providing informed consent (infants and toddlers are not capable of signing or e-consenting on their own behalf).

Thus, Medable needed to build the digital experience from the perspective of the parent or guardian using it, not the participant. At the same time, the studies had to progress through build, UAT, data transfer activities, and other startup milestones while accommodating evolving sponsor requirements.

Additionally, during development, the rules and requirements for informing participants were updated, impacting the downstream consent process.

Medable's approach

Close partnership created a smoother path to FPI

From the start, both teams defined clear roles, owned action items through completion, and communicated frequently. Questions moved quickly in both directions, so issues were surfaced and resolved rather than becoming late-stage blockers.

Starting well ahead of the planned FPI gave both teams the runway to move smoothly through build and UAT, and to address changes before launch.

Adapting to evolving requirements without derailing startup

During development, the client faced a major standards change that would impact the studies' configuration. Medable built the capability in phases and incorporated it ahead of FPI, avoiding any risk to study readiness.

Medable conducted an internal review of the informed consent forms (ICFs) through the lens of the parents and guardians who would actually use them. The platform required no new build for this; the review process added an extra layer of diligence specific to a pediatric population.

Deep understanding of caregiver and pediatric needs

Because participants were infants and toddlers, we reviewed every ICF to confirm the language was consistently written to the caregiver, not the child. For example, references such as "your baby" or "your child" experiencing certain symptoms had to be uniform across all consent materials for both studies.

Medable provides ICF review and guidance for our clients. In this instance, Medable's review surfaced discrepancies in the informed consent materials. Rather than simply configuring what had been provided, Medable flagged the inconsistencies to the sponsor and requested clarification.

Forms changed

The flagged discrepancies triggered an additional round of IRB review and approval, scheduled specifically to correct and re-validate the ICFs before FPI. This gave the sponsor time to revise the affected consent forms and complete a second approval cycle ahead of participant enrollment, turning a potential downstream issue into a manageable pre-launch fix.

Medable also prepared participant user guides for caregivers as part of its standard study support materials, so caregivers were informed about all aspects of participation.



We have seen a clear improvement in turnaround times, and such focus on quality from your PMs. That really helps build our team's confidence..."

Study team, top-5 global pharmaceutical company

Conclusion

For pediatric studies, successful technology delivery requires more than building to specification. It requires understanding how the solution will be experienced during the day-to-day reality of the trial. This means identifying risks early and working closely enough with the sponsor to resolve them before they affect the study.

Don't let consent surprises delay FPI, let's review your pediatric study together.

Contact us at www.medable.com.

