

Genentech Overhauls its Informed Consent Form to Minimize Patient and Site Burden

Genentech Applies CTTI's Informed Consent Recommendations

SUMMARY

Genentech's Early Clinical Development team recognized the burden of lengthy and confusing informed consent forms, not only on patients, but also on investigators and their teams. They set out to overhaul the existing form, leaning on CTTI's Informed Consent guidelines to bring a streamlined form to life.

GOAL(S)

Informed consent is one of the most important aspects of research, serving as the baseline for protecting human subjects in clinical research. However, for many patients already struggling with a clinical issue, a lengthy and technical form can cause information overload and emotional overwhelm. Genentech saw opportunities to streamline its informed consent template to make it more digestible and patient-friendly, so the Early Clinical Development team set out to give the template an overhaul. How could Genentech use the informed consent form to truly inform, but not overwhelm?

CHALLENGES

Most organizations (and people in general) are averse to change, and that aversion is even more pronounced when the subject in question officially works as it stands. Genentech's informed consent form wasn't "broken" per se, it got the job done and the organization was already comfortable with the original form. That entrenched mindset of "the way we've always done it" would pose a challenge to Genentech's effort.

SOLUTION(S)

Early in the informed consent overhaul effort, Genentech surveyed the existing literature and discovered CTTI's Informed Consent Recommendations, which propose solutions to optimize the informed consent process and enhance participant understanding of trial information to inform their decision-making. The Early Clinical Development team reached out to CTTI for guidance and decided on a two-tier consent form that allowed for patients to grasp critical understanding of the overarching trial in Tier I (e.g., overall study design and timing) and dive further into more nuanced details in Tier II (e.g., specific schedule of assessments and associated procedures' risks). This allowed for a "choose your own adventure" type of approach where patients had all information at their fingertips but could go from high level to detailed at their own pace.

TAKING ACTION

Genentech realized they needed input from across the organization and beyond to get the effort right. Their informed consent overhaul team included representation from clinical scientists, legal, medical editing, quality and compliance, regulatory, biosamples, pharmacokinetics, and more. The project leads asked the team to reflect on two core questions: 1) what do patients need to know and 2) what do patients want to know. It was a collaborative negotiation that required the team to set aside individual experiences and consider the collective goal. For example, one team member recalled a study during which five paragraphs needed to be added to an informed consent and therefore felt strongly that this section should remain. However, upon a vote from the rest of the team that this experience was rare and atypical, the group agreed it was not essential. Once the draft of the new informed consent template was complete, Genentech consulted with CTTI for review as well as several study coordinators and two central IRBs.

IMPACT

Genentech's original informed consent form was 36 pages, and the project team reduced it to 22, a nearly 40 percent reduction. The new template has been well received and although it was completed in 2017, it is still in use today.

ADVICE

CTTI's recommendations offered Genentech the research and scientific rationale for why an informed consent overhaul was a good idea, which helped bring colleagues on board with the effort faster than starting from scratch. The collaborative and diverse team in Early Clinical Development was central to getting the overhaul right, as was including the IRB and study coordinator review. If Genentech could go back and do it again, they would include a patient on the team as well. Overall, the project was a success, and Genentech's other clinical development teams have moved to adopt the Early Clinical Development informed consent form.

ORGANIZATION

Genentech-a member of the Roche Group

CONTACT

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ORGANIZATION TYPE

Industry

IMPLEMENTATION DATE

2017

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