From Ideas to Implementation: ETH Zurich Helps Researchers Leverage Digital Innovation to Build Actionable Endpoints

ETH Zurich Applies CTTI's Digital Health Trials Recommendations

SUMMARY

ETH Zurich has been renowned as one of the top universities in the world for science and technology since 1855, when the founders of modern-day Switzerland created it as a center of innovation and knowledge. Today, the university is reinforcing that reputation by building programs and platforms to help young academics and budding entrepreneurs develop novel clinical trial endpoints through the use of digital technology. This case study details how ETH Zurich leaned on CTTI's Digital Health Trials Recommendations to create a digital trial intervention platform, as well as an advanced studies program focused on creating the optimal digital clinical study design to address modern global research challenges.

GOAL(S)

Positive changes in endpoints, or the trial outcomes being measured, are the best way to show regulators evidence that a new therapy is clinically meaningful for patients. Endpoints determine which data are collected during a clinical trial, and therefore what is eventually known, or not known, about the therapy tested. When more precise and meaningful endpoints for a condition gain acceptance by regulators, the time and costs of bringing new therapies to market are reduced, the burden of trial participation on patients and caregivers drops, and our understanding of how new therapies affect activities of daily living improve. That's why the recent explosion of digital tools is so exciting for researchers. Digital endpoints developed from tools like an accelerometer or smart watch have the potential to unlock a whole host of new and improved measures, which would allow the research community to identify those that are most meaningful and convene around them. Recognizing the potential to improve and accelerate research, ETH Zurich wanted to support the rising generation of researchers in identifying and validating these endpoints to deliver better, faster therapies.

CHALLENGES

Digital technologies with the capacity to capture clinical measures are relatively new across the research enterprise, so many in the field are still finding their way when it comes to identifying and validating these endpoints. Fortunately, the head of ETH Zurich's Institute of Translational Medicine had formerly worked in an industry environment with a leading drug developer that was trailblazing novel approaches to digital endpoints. He wanted to bring that innovation to his students at ETH Zurich, but found that academia was lacking the infrastructure to bring digital endpoints to life. He and his team embarked on a two-part mission: 1) to develop an infrastructure to support the development of novel digital endpoints within ETH Zurich and 2) to train ETH Zurich students so they could enter the workforce with the skills to develop endpoints that accelerate outcomes for patients.

SOLUTION(S)

CTTI's Digital Health Trials Recommendations—and specifically its Novel Endpoints Recommendations—offer guidance on how to best use digital health technology in ways that are useful to sponsors and accepted by regulators. The director of ETH Zurich's Institute was familiar with these recommendations because he served as one of the Team Leaders for CTTI's Novel Endpoint Acceptance project, and he brought CTTI's insights back to his team in academia. The ETH Zurich team also looked to CTTI's broader recommendations, including those focused on how to manage data and test a digital health technology, as they built out their Digital Trial Intervention Platform and educational offering.

TAKING ACTION

While the digital platform and educational offering had similar aims to improve research, their creation required two distinct approaches.

Digital Trial Intervention Platform
To create a technology platform capable of generating human evidence for new medical solutions, there were myriad considerations. That's why the team at ETH Zurich built their Digital Trial Intervention Platform (dTIP) around three interdisciplinary expert units staffed with clinical trials, data management and regulatory experts. One of the team's first critical priorities was finding a way to integrate digital tools and the flood of data streams they produce into the platform with Good Clinical Practice (GCP) compliance.

"It is both an opportunity and a challenge that today's digital devices are not limiting like conventional tools in terms of what you want to measure," said the head of ETH Zurich's Institute of Translational Medicine. "Without clarity around a specific endpoint, we often overmeasure and create a graveyard of data that is never used. We wanted the dTIP to offer a very streamlined, GCP-compliant data flow to help researchers identify exactly what they want to measure upfront, supporting an emergence of new digital endpoints to advance novel therapies."

The focus on collecting the minimum data set necessary to address endpoints aligns with CTTI's first recommendation for managing data, which suggests that researchers avoid speculative "fishing" for data when the study endpoints are well understood. Instead, CTTI recommends applying a Quality by Design approach early in the research process to define and refine decisions about the quantity of data to be collected. The ETH Zurich team built the dTIP to capture from disparate data sources, including wearable devices. They also offer consultation to help research teams with everything from selecting the wearable device or sensor to device provisioning and data flow management. Once selected, the dTIP performs data validation to ensure quality. And when the data collected is fit for analysis, the database is locked to avoid any modification—a critical measure to ensure the credibility of the study and the validity of results obtained.

Advanced Studies Program
With the dTIP infrastructure coming into place, the ETH Zurich team set out to accomplish its second goal: training ETH Zurich students to successfully translate ideas to measurements and measurements to validated endpoints. To that end, ETH Zurich launched a Master of Advanced Studies ETH digital Clinical Research (MAS diCR) program in 2021. Underpinned by learnings found in CTTI's Digital Health Trials Hub, the new continuing education program teaches participants how to navigate clinical research in the rapidly changing environment of new digital diagnostics and technologies, with a focus on employing patient-centric approaches. The curriculum of the MAS diCR aims to foster a deeper understanding of the potential of digital clinical research in the context of its regulatory, ethical and practical environment.

IMPACT

Today, the dTIP, a fully launched ETH technology platform, is actively supporting both clinical and non-clinical researchers in clinical evidence generation. ETH Zurich's learnings from establishing the dTIP and implementing a new curriculum on novel endpoints were recently on display at the Digital Measures conference co-hosted by ETH and the Foundation of the National Institutes of Health (FNIH) Biomarkers Consortium. The conference drew global experts from across the research ecosystem and focused on establishing pathways from remote digital monitoring to evidence generation. In the future, ETH Zurich is planning to track metrics of success via an assessment of new trials that includes digital biomarkers and subsequent progress in new therapeutic options.

ADVICE

ETH Zurich feels that there's no time to waste in leveraging technology to develop novel endpoints, given their ability to help address unmet medical needs in diseases where traditional endpoints are insufficient or do not capture the full spectrum of disease activity. To this end, the university is committed to joining forces across the industry. This sentiment is what drove ETH leadership to CTTI, an organization that prides itself in uniting stakeholders across the research ecosystem to improve outcomes. But ETH believes even more must be done to enhance knowledge-sharing around meaningful endpoints so that future researchers can better capture treatment effects, improve patient outcomes, and advance the development of much-needed therapies.

"One good endpoint can unlock a whole field," said the head of ETH Zurich's Institute of Translational Medicine. "With new advances in technologies, it is incumbent on us as an industry to not only push for new, high-quality endpoints, but also to support the next generation in clearing the pathways to bring them to fruition. At the end of the day, we are all here to bring better therapies to patients in need, and at ETH Zurich, we are proud that the dTIP and advanced studies program are important steps in that direction."

ORGANIZATION

ETH Zurich

CONTACT

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ORGANIZATION TYPE

Academia

IMPLEMENTATION DATE

2020

TOPIC

Novel Endpoints

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