Clear Roadmap of Requirements Allows Roche to Speed Multiple Sclerosis App Development

Roche applies CTTI's Digital Health Technologies Recommendations

SUMMARY
Roche is developing an app to measure impairment in people living with multiple sclerosis. The team wanted to understand the requirements the app must have to be Good Clinical Practice (GCP) compliant and for the data to be acceptable for regulatory decision making. CTTI's Digital Health Technologies (DHT) recommendations offered the development team a framework for the quality requirements to more rapidly navigate the required components.

GOAL(S)
New digital technologies offer an opportunity to get much closer to the patient experience and how they are affected every day. However, while use of digital health technologies for data capture has the potential to transform clinical trials, many organizations lack a clear roadmap for making this vision a reality. When Roche wanted to take its proof-of-concept-stage multiple sclerosis impairment measurement app to pivotal clinical trials, it needed a framework for 1) understanding the requirements to comply with GCP and 2) how to bring the development team into alignment on why these requirements were important.

CHALLENGES
The Roche team was challenged by the fact that the app had been initially developed in 2017 as a simple proof-of-concept that would not be used to inform any decisions and thus did not require GCP compliance. This Proof of Concept app would move into the development stage and needed to now comply with GCP requirements. The digital health team needed a compelling case to help the software development staff understand what requirements needed to be met and why they were crucial to protecting the patient and data integrity of the tool. Digital health technologies that capture measures for endpoints have special requirements that are not considered in a typical computer system validation, and those needed brought to the fore.

SOLUTION(S)
CTTI's Digital Health Technologies recommendations and resources address these challenges, which can hinder the use of digital health technologies in clinical trials. With this comprehensive guide, stakeholders across the clinical trials enterprise can start to benefit from the potential advantages of using digital health technologies— including capturing “real world” data from patients. For the Roche team, the recommendations offered a clear and organized way of understanding what GCP requirements were needed for their multiple sclerosis impairment measurement app and when each should ideally be implemented.

TAKING ACTION
Following CTTI’s guidance, the Roche team brought together key stakeholders across development, regulatory, statistics and quality functions via a workshop. To show the group in practical terms the necessity of the required adjustments to the app, the statistics group presented use cases of what may happen if these requirements were not implemented. For example, what would happen if a patient’s child picked up the phone momentarily? Without proper protections and coding in place, the data integrity of the app would be compromised. Following the workshop, the entire group collaborated to prioritize what requirements should be implemented on the very first app release versus others that could be brought in on subsequent releases.

IMPACT
The Roche development team feels strongly that CTTI’s recommendations offered a significant time savings in application development, versus what would have been required for sourcing and assessing requirements independently. The recommendations also offered various communication formats, allowing the Roche team to choose more or less detail depending on the specific audience the requirements were being shared with.

ADVICE
The Roche team believes CTTI’s DHT recommendations should be essential reading for anyone seeking to bring a digital technology to market in today’s complex quality and regulatory environment. Roche suggests these cross-functional teams collaborate early and often in the development process— implementation of GCP requirements after the fact causes unnecessary burden and challenge. Although developing these technologies requires careful navigation, the potential to better understand the patient’s lived experience is a tremendous value that makes the effort a worthy investment.

ORGANIZATION
Roche

CONTACT
Lada Leyens

ORGANIZATION TYPE
Industry

IMPLEMENTATION DATE
2020

TOPIC