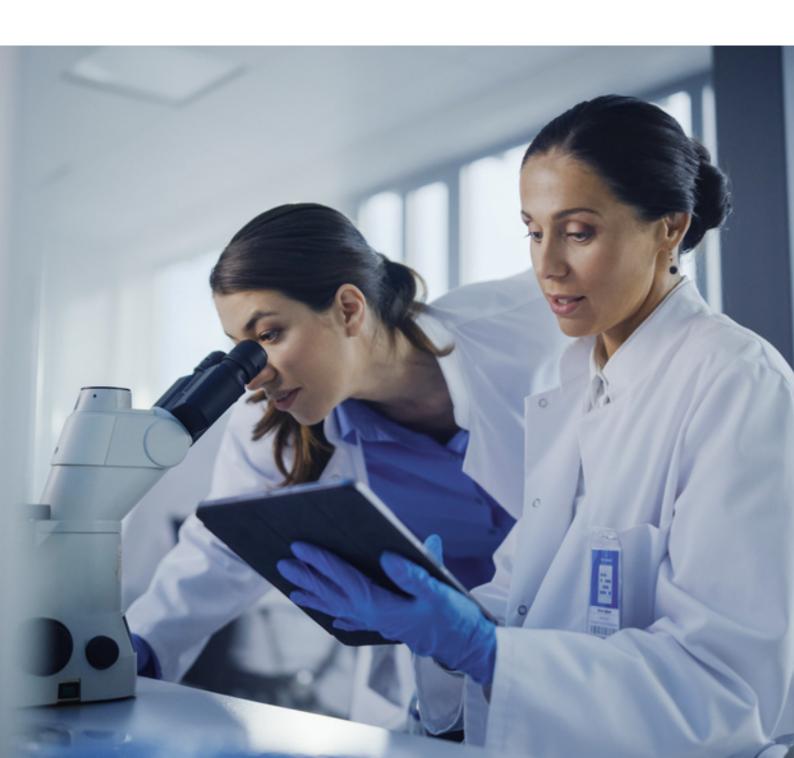


# American biotechnology corporation pivots to Decentralized Clinical Trials



### About the customer

The customer is an American biotechnology corporation that is dedicated to pursuing groundbreaking science to discover and develop medicines for people with serious and life-threatening diseases for the past four decades. Established in 1976, the company is historically regarded as the first biotechnology company in the world.

This case study showcases how IoT HCLTech – IoT WoRKS™, helped the biotechnology corporation move closer to patients by implementing Decentralized Clinical Trials (DCT). This enabled the customer to address challenges related to patient recruitment, site activation, secure data transfer and regulation compliance.

# Customer challenges

To make clinical trials easier for patients, the customer was looking for an experienced technology partner who could support an end-to-end remote management of clinical trials globally i.e., starting with patient recruitment, engagement and management across the trial lifecycle including post market clinical surveillance. The customer faced the below listed challenges in their endeavor:



#### **Accelerating Patient Recruitment**

The customer saw low patient recruitment volumes with multiple cases of early withdrawal of patients during trials

#### **Site Activation and Management**

Shorten study start-up/activation with fewer contract negotiations and less site training needs across multiple locations





#### **Regulatory Compliance**

Improving and ensuring compliance to regulatory guidance i.e., HIPAA, GDPR, 21 CFR Part 11, EU Annex 11 needed for a successful trial

#### Digital patient engagement and assessment

Implementing a tele-visit platform for care giver-patient communication for risk management





#### **Improve Patient Monitoring**

Employ Medical Devices and Wellness Questionnaires to collect real-time patient information to improve patient monitoring and reduce the risk of adverse events.

# Our solution

To enable clinical trials faster, improve the experience for both patients and doctors, and accelerate the pivot of bringing the trials to patients rather than patients coming to a trial site, HCLTech − IoT WoRKS™ designed, developed and deployed the Decentralized Clinical Trials (DCT) solution.

As part of the engagement, HCLTech provisioned, configured and deployed medical devices as part of the patient enrolment and onboarding process. The DCT solution's patient mobile app provides the ability to capture and securely transmit, electronic patient reported outcomes (ePRO) and wearable device data to an AWS IoT platform. This data is then be visualized by the doctor to ensure patient well being and trial compliance.

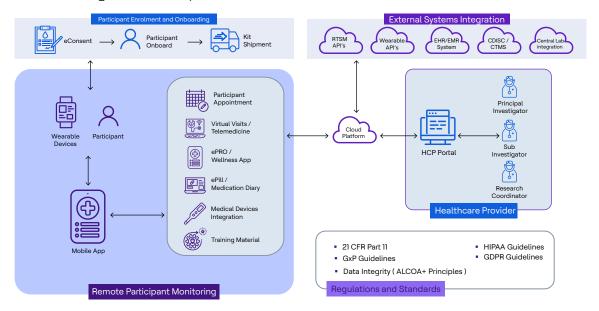
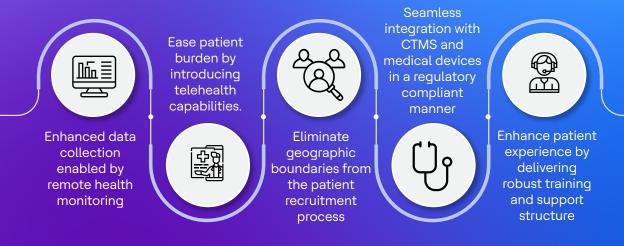


Figure 1: DCT deployment architecture

DCT is modeled on 'direct to patient' interaction technology, leveraging wearables and home-based physiological devices, geared up to help pharmaceutical companies reduce study timelines lower site burden and speed enrollment by screening and consenting patients remotely, provide multilingual global study support through provisioned and/or BYO devices, provide patient and site support services as well as develop custom study, site, patient reports on demand.

# Benefits derived

With the implementation of the solution, the customer was able to derive the below business benefits:



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