Google Cloud

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Improving the collection of patient-reported real-world data

Including patient-generated and patient-reported data in Clinical Trial data submissions to US Food and Drug Administration is becoming increasingly important for Life sciences organizations. An open source platform will accelerate use of digital technology for data capture from participants and make patient participation in studies more rewarding and convenient.

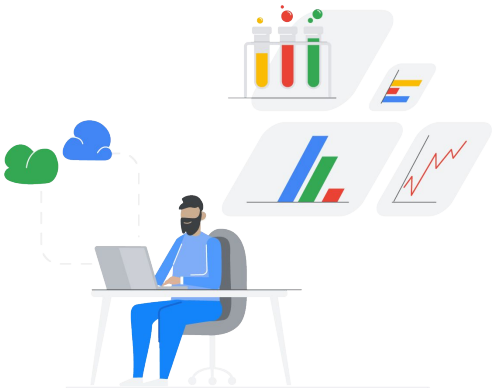
About Boston Technology Corporation

Boston Technology Corporation applies technical expertise in mobile, web, and cloud-based app development and provides skilled technical staffing solutions to bring patient-centric programs into the digital age.

By observing and collecting data, ancient peoples learned which herbs, foods, and methods worked to cure ailments. During the centuries that followed, scientists delivered many important discoveries, while opportunity-driven “snake oil” salesmen promoted cure-all elixirs with bogus ingredients. To help consumers understand the difference, the US Congress passed the Pure Food and Drugs Act in 1906, establishing the Federal Drug Administration (FDA). After the tranquilizer Thalidomide caused serious birth defects, the 1962 Drug Amendments directed the FDA to rely on scientific testing, proof of safety, and evidence of a drug's efficacy before approving it.

Today, the FDA oversees many well-controlled studies. The process for studying candidate medicines and medical devices is, however, complex and lengthy. Although the intention is to ensure safety and efficacy for all who will benefit from these advancements, each additional day a clinical trial lasts can feel like a lifetime to those urgently waiting for a breakthrough in the care of a disease, injury, or congenital condition.

In a quest to improve the treatment study process without compromising consumer safety, the FDA joined forces with the Boston Technology Corporation to build a platform that gives clinical trial administrators one-click access to all the necessary digital components for designing, planning, and executing studies.



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Offering an extensible, modular platform for content-driven studies

"We wanted to create a web portal that makes it easy for clinical trial administrators to configure protocols, surveys and other data collection instruments, and to support participant enrollment," says Shyam Deval, president of the Boston Technology Corporation. "We worked with the FDA, Harvard Pilgrim Health Care Institute, and a company called LabKey to build the first version of the platform. The initial pilot study was run by Kaiser Permanente, and now two clinical trials are running on the platform." In 2020, the platform won the prestigious Federal Labs Impact Award, Deval notes proudly. "We are now working with Google Cloud to make it more capable, more functional, and richer and easier to deploy."

The platform is scalable and extensible, Deval explains, helping administrators "run multiple, simultaneous studies and visualize each study's progress." It also makes studies less time-consuming and laborious for participants, who can fill out study surveys on their mobile devices or share information via wearables that collect and send de-identified data to secure stores, where scientists and regulators can analyze it. Such convenience improves patient recruitment and retention.

Because the platform is open source and integrates with third party systems, researchers can dynamically collect, de-identify, and join data from electronic health records, claims and billing, and product and disease registries, making this data available, Deval says, "for regulatory submission, market access, or for research and development." Data may also come from observers who report outcomes, such as patient family members, investigators at study sites, or clinicians. The assembled data provides real-world evidence scientists and regulators can use to assess the potential benefits or risk of a medical product.

Shyam Deval,
President, Boston
Technology Corporation

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Using real-world data to improve health

The FDA is encouraging the industry to use such real-world data in a number of ways. Drug and device makers can use patient-generated data in clinical trial and post-marketing studies as evidence of product efficacy for regulatory approvals. Scientists can use it for observational research. Clinicians can analyze data collected directly from patients via questions or device sensors to manage care, while hospital administrators and health plans can use the data to optimize their operations.

The FDA MyStudies platform on Google Cloud supports four different models for collecting real-world data to meet security and privacy requirements. This flexibility allows study managers to tailor each study design around the participants. “Supporting diverse decentralized real-world data collection models makes it easier for that push towards virtual trials, because you're no longer constrained by the platform or the protocol,” Deval explains. The platform’s electronic consent eligibility process accelerates enrollment and on-boarding, helping studies move faster.

With minimal software development, study administrators can launch multiple types of studies, authoring content through a web application and publishing it to mobile apps or to existing applications through a gateway app. “The configuration and launch of the study becomes an instrument for design management,” says Deval. “The mobile apps are based on standard frameworks, like research kit and research stack.”

Ready, set, go

Tailoring app functionality to the needs of different therapeutic areas significantly improves the patient experience, encouraging a higher level of engagement, more involved care management from providers, fewer patient drop-offs, and higher medication compliance. Improved patient participation and compliance in turn lead to better evidence, speedier trials, and higher rates of approval. “FDA MyStudies on Google Cloud will improve the ability to perform research that leads to better patient outcomes,” Deval asserts.

Medical product safety and efficacy is, and always will be, the FDA’s primary goal. Until recently, this meant compromising speed to market. The MyStudies platform built on Google Cloud lays the foundation for the public and private sectors to study treatments more quickly and thoroughly, and to provide real-world evidence that can help the world’s researchers discover future treatments and clinicians improve patient outcomes.

To learn more about
Google Cloud Healthcare and Life Sciences visit:
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