Improving clinical trials using AWS Services

The current cost to bring a new drug to market is estimated to exceed

$2 billion

and clinical trials can account for up to two-thirds of the total research & development costs. The traditional clinical trial process that was designed for mass-marketed blockbuster drugs no longer meets the emergent needs of life science companies. These companies have shifted to more targeted therapeutics and precision medicine, which are focused on smaller, geographically distributed patient segments.

Pioneering companies are turning to the Amazon Web Services (AWS) Cloud to modernize their clinical trial process by utilizing analytics and artificial intelligence to optimize studies, securely collaborate and share data, and incorporate mobile technologies. AWS offers HIPAA-eligible capabilities that can help life science organizations accelerate trial timelines, optimize processes, and reduce overall trial costs by:
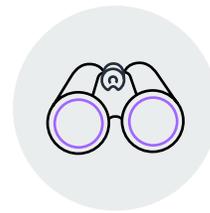
| Finding and recruiting patients using smart analytics	Facilitating global data management	Utilizing remote or in-patient site monitoring	Predicting lack of adherence	Detecting adverse events

The 'Clinical Trials 2.0' program at AWS is geared towards facilitating wider adoption of cloud-native services to assist with data ingestion from disparate sources, provide cost-optimized and reliable storage, and enable analytics. The program also provides the granular access control, end-to-end security, global scalability, and utilization of artificial intelligence and machine learning (AI/ML) needed to advance clinical trials more efficiently.

In 2018, the Clinical Trials Transformation Initiative (CTTI) provided recommendations regarding leveraging mobile technologies for capturing holistic, high quality, attributable patient data and submission to the U.S. Food and Drug Administration (FDA). Using mobile technologies can help increase trial participation and reduce the length and cost of clinical trials.

Clinical trials transformation: Mobile data capture

Below is a common, HIPAA-eligible architecture pattern that AWS customers are using to incorporate mobile technologies into their clinical trials for improved access and better evidence generation.
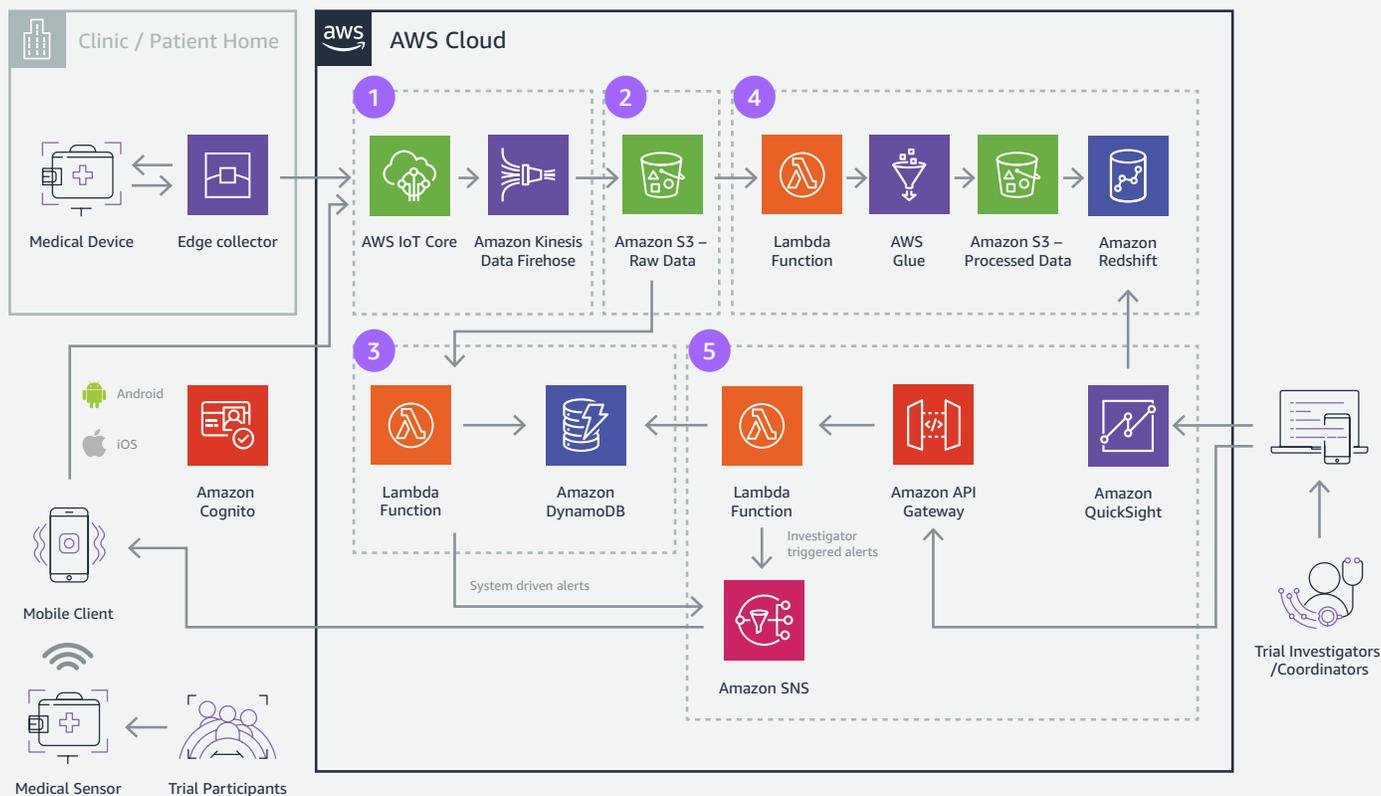
1 COLLECT DATA

Collect real-time, streaming data from medical devices and personal wearables. These are typically connected to an edge node or a smartphone to provide sufficient computing resources for streaming data to AWS IoT Core, which can then be configured to write data to Amazon Kinesis Data Firehose in near real-time. The edge node/smartphone uses AWS IoT SDKs to publish and subscribe device data to AWS IoT core using various AWS provided authentication methods. Customers can use the Amazon Kinesis server-side encryption feature, to achieve encryption-at-rest. Amazon Kinesis provides a scalable, highly available way to achieve loose coupling

between data-producing (medical devices) and data-consuming (Amazon Lambda) layers.

AWS can also capture additional data, such as Case Report Forms (CRF), Electronic Medical Records (EMR), medical images utilizing Picture Archiving and Communication Systems (PACS), laboratory data (Labs), and other Patient Reported Outcomes data (ePRO). AWS provides multiple tools and services to effectively and securely connect to these data sources, allowing customers to ingest data in various volumes, varieties, and velocities.

② STORE DATA

After data is ingested from the devices and wearables used in the clinical trial, AWS Lambda is used to store the raw data copy on Amazon Simple Storage Service (Amazon S3), where it can be used for historical analysis and pattern prediction. Using Amazon S3 life cycle policies, customers can periodically move their data to Amazon S3 Glacier, to further optimize their storage costs.

Amazon S3 offers a highly available and durable, infinitely scalable data storage infrastructure; simplifying most data processing, backup, and replication tasks. Customers can also choose to encrypt their data at rest and in motion using various encryption options available on Amazon S3.

③ DATA PROCESSING – FAST LANE

After collecting and storing a raw copy of the data, Amazon S3 is configured to publish events to AWS Lambda and invoke a Lambda function by passing the event data as a parameter. The Lambda function is used to extract key information, like adverse event notifications, medication adherence, treatment schedule management, and more from the incoming data. Lambda is used to process this information and store it in Amazon DynamoDB, along with encryption at rest, which powers a clinical trial status dashboard. This dashboard alerts clinical trial coordinators in real time so that appropriate interventions can take place.

④ DATA PROCESSING – BATCH

For historical analysis and pattern prediction, the staged data (stored in Amazon S3), is processed in batches. Using AWS Batch, an easy and efficient batch computing service, current and historical data is mined to derive actionable insights, which is stored on Amazon S3. From there, data is loaded into Amazon Redshift, a cost-effective, petabyte-scale data warehouse offering. Customers may also leverage Amazon Redshift Spectrum to extend data warehousing out to exabytes without loading any data to Amazon Redshift, as detailed in this blog post. This allows trial coordinators to get an all encompassing picture of the clinical trial, enabling them to react and respond faster. Optionally, this data can also be fed to an Artificial Intelligence/Machine Learning component to further automate the analytics, helping to optimize costs and improve the quality of clinical trial management.

⑤ VISUALIZE AND ACT ON DATA

Once the data is processed and ready to be consumed, customers can leverage a host of Business Intelligence (BI) tools like Amazon QuickSight, a cloud-native business intelligence service from AWS that offers Amazon Redshift connectivity. Amazon QuickSight is serverless and can be rolled out to your audience in hours. Customers can also use a host of third party reporting tools, such as TIBCO Spotfire Analytics, Tableau Server, Qlik Sense Enterprise, and others, which can use a Java Database Connectivity (JDBC) or Open Database Connectivity (ODBC) connection with Amazon Redshift. The real-time data processing (step 3) combined with historical-view batch processing (step 4), empowers Contract Research Organizations (CROs), study managers, trial coordinators, and other entities involved in the clinical trial journey to make effective and informed decisions at a speed and frequency which was previously unavailable.

Using Amazon Simple Notification Service (Amazon SNS), real-time feedback based on incoming data and telemetry, along with notifications from study managers/coordinators, is sent to patients via text messages, mobile push notifications, and/or emails. Amazon SNS provides fully-managed pub/sub messaging for microservices, distributed systems, and serverless applications; and is designed for high-throughput, push-based, many-to-many messaging. These alerts and notifications can be based on current

Key AWS Partners for Clinical Trials
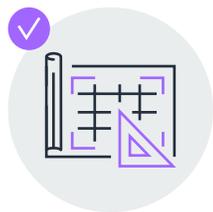
INTELLIGENT TRIAL PLANNING

Knowledgent | **part of Accenture**

Intelligent trial planning using data insights to design protocols with better potential for adherence, decreasing the overhead of patients recruitment and locating sites

From design to feasibility analysis in **minutes vs. 4–6 weeks**

Scenario planning to **enable optimal execution + up to a 20% cost reduction**

Greater accuracy shortens timeline = **Hundreds of thousands of dollars per month saved**

SYNTHETIC CONTROLS

medidata

Medidata's Synthetic Control Arm™ and Synthetic Control Database™ are constructed utilizing standardized, fit-for-purpose data from over 15,000 previous clinical trials and 4.2 million patients.

Synthetic Control Arm™ employs precise statistical matching from a vast pool of historical trial controls to patients in the experimental arm of a clinical trial. This approach can improve a Sponsor's estimation and confidence in interpreting uncontrolled treatment response rates, enabling better decisions on which therapies to advance, while minimizing/replacing the need for control patients.

TRIAL PARTICIPANT MONITORING

Philips HealthSuite

Philips HealthSuite Digital Platform is a secure and compliant data integration platform that enables the use of IoT and the integration of patient-reported outcomes and other relevant data sources in clinical trials.

Embed HealthSuite digital platform to enhance your clinical trials:

- Increase the breadth of data while decreasing costs and reliance on a physical trial site
- Improve data quality and accuracy of data for submission.

MESSAGING STANDARDS

ConvergeHEALTH
by Deloitte.

Deloitte's ConvergeHEALTH™ platform is a patient engagement suite that aligns services, workflows and interactions to support clinical trials as well as individualized patient journeys. The platform collects and analyzes interaction data that enhances the understanding of patient experience on behavioral, clinical, and socioeconomic dimensions.

Increase connectivity with trial participants via the ConvergeHEALTH™ platform and applications, and aggregate patient data from multiple sources to connect both clients and external vendor data into a single view for all patient interactions.