



CONTRACT RESEARCH ORGANIZATIONS

IMPROVING THE STANDARDS OF
CLINICAL TRIALS ON CLOUD



About the Client

Our client is one of the top Life Sciences Companies in the world which caters various therapeutic areas and has a wide range of supplies for some of the feared diseases of our time. They apply their deep expertise in the field of pharmaceuticals, innovative methodologies and cutting edge technologies to find sustainable solutions to the health care challenges prevailing in this world.

Our Client Ockham, is also a Contract Research Organization (CRO) executing many long term Clinical Trials/Data Analysis studies in more than 25 countries for industry leading Pharmaceutical Companies.

The challenge

They had valuable historical data of all studies in different data formats under different systems covering multiple therapeutic areas. Significant amount of study planning and tracking information were also in thousands of spreadsheets. Many GBs of data was exchanged between the client and their customers on a weekly basis.

Client depended on many manual operations for accessing and analysing data for BI. These insights were not only important to track the studies but also to predict various inflection points of studies still in the planning stage. This manual processing resulted in a long time to obtain these valuable insights and quality reports were not available throughout the organization.

Integrate the data from Study budgets, Clinical Trial Management System, Timesheets, HR & Payroll data, Vacation management system and Finance and Invoicing system and create data lake. The data from the disparate data sources couldn't be integrated seamlessly.

The existing system's inefficiency to handle unstructured data was affecting the quality of the business intelligence derived. The client was expecting an intuitive and a responsive user interface to generate various reports and dashboards.

Why AWS

AWS is designed to host quick and secure applications. AWS provides a simple, cost effective, fully managed built in data ware house solution which can scale indefinitely to large volumes of data. It integrates seamlessly with other services and provides a lot of scope for automating the whole life cycle of the CRO model using its SDKs.

The services simplify the following

- Scale to handle terabytes of data
- Automate the CRO lifecycle using its various SDK and platform agnostic API interfaces
- Auto scale up to cater to peak loads and auto scale down to minimize cost.
- Continuous monitoring features and zero maintenance of the PaaS services.
- Compliance to HIPAA and other prevailing stringent industry standards
- AWS utilizes an end to end approach, to secure and harden the infrastructure including physical, operations and software measures.

AWS Cloud with its scalable, reliable and secure global infrastructure simplifies the infrastructure provisioning for this project. The pre-built, time tested services and its frameworks helps develop components at a better momentum than a traditional data center application and ensures quality deliverables at a shorter mileage. It eventually reduces the TCO of the application with a lower capex and at a better profitability.

Why 8KMiles

8KMiles with its unique combination of Cloud and Analytics expertise was the ideal partner. 8KMiles solution architects did a comprehensive assessment of the platform architecture and recommended the adoption of CloudEz and moving the entire platform to the cloud.

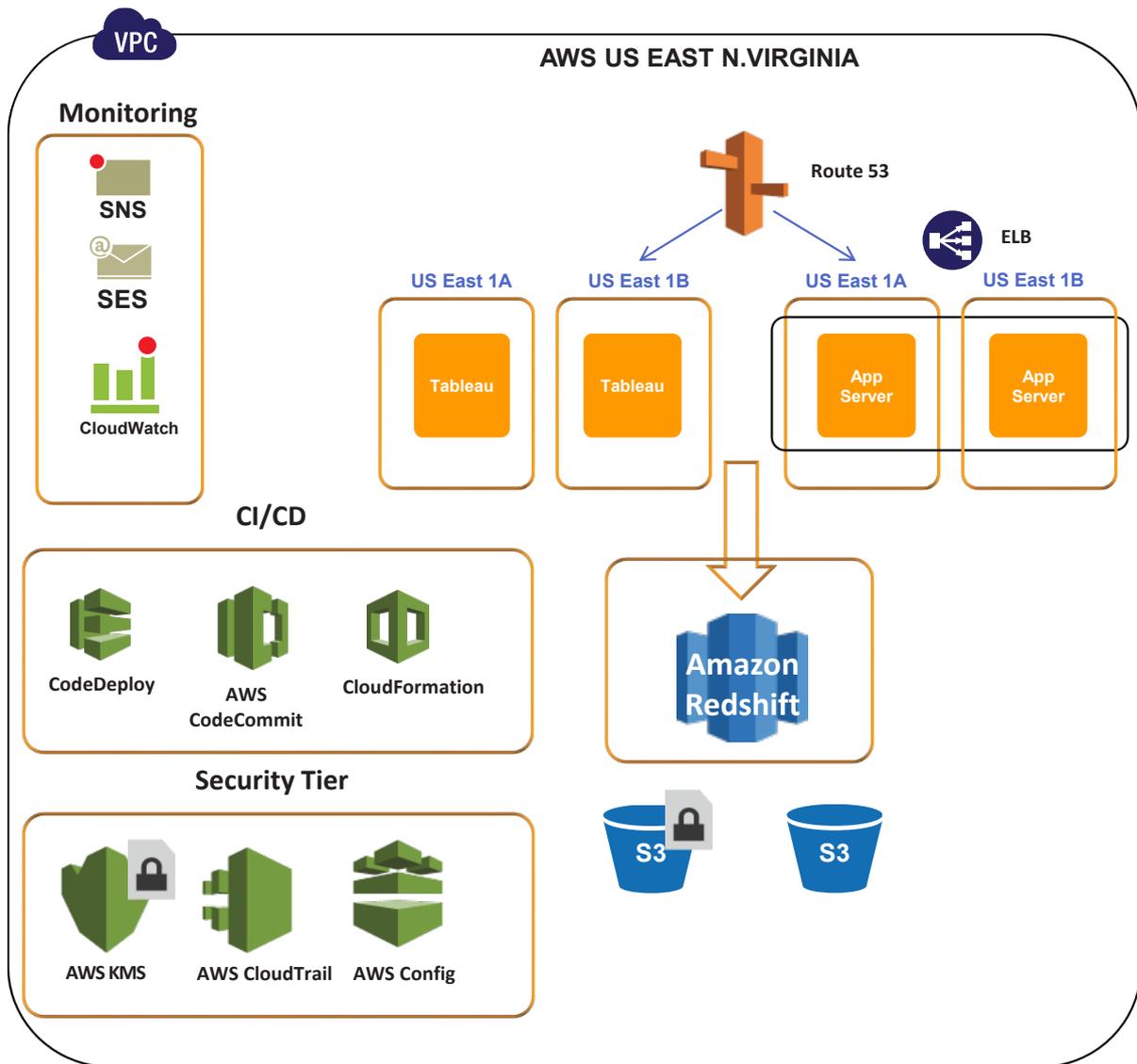
8KMiles Differentiators

- RWE domain knowledge: 8KMiles is the partner of choice for RWE implementations at many of the top pharmaceutical and life sciences organizations. We bring years of experience in RWE solutions.
- CloudEz: 8KMiles is leader in building GxP cloud solutions for complex life sciences use cases such as Genomics and Big Data for many years. The CloudEz platform brings quality, durability and repeatability to your GxP cloud implementations
- Analytics: World class analytics leadership in handling big data, machine learning, prediction, and visualization. In addition to life sciences, we have helped many industries from cyber security to advertising, adopt cutting edge analytics technologies

Our Solution

Once the client awarded the Cloud and Analytics services contract, 8KMiles started setting up a scalable and secure HIPAA compliant Cloud Infrastructure. The following features were implemented using an Agile approach

- Develop a SaaS based solution on AWS Cloud.
- Implement ETL through a batch process to ingest and store in a staging layer using Amazon S3 which can scale indefinitely.
- Deploy a terabyte scale data warehouse using Amazon Redshift to perform aggregations and analytical calculations.
- Automatic backups and cross region backups created to handle failures at any layer in the architecture.
- Isolated, secure Virtual Private Cloud with customizable network configurations
- The clients facing component requests were inspected with 3 layers of security using OS firewalls, security groups and perimeter security at the network level.
- The persistent storage, analytical components were deployed to a secured private zone which cannot be accessed by any system from the internet.
- All the components of this architecture were monitored using Amazon Cloud Watch. Automatic alarms set in place if the compute, storage thresholds were crossed.
- Automatic alerts and notifications configured for alarms, information, system notifications etc.
- Every action to the system is captured using the log mechanism and audit trail is maintained for a period of 12 months.
- The entire platform was fully managed using a DevOps approach to change management and operations.



Benefits

In a span of 4 months, full stack analytics re-engineering approach delivered various benefits. Client was able to 'democratize' the insights across the organization and there was a single source of 'truth' in the newly created data warehouse. Some quantitative benefits included saving about \$100K per quarter obtained due to the changes in the budgeting process that were performed based on the insights obtained. Data ingestion was an order of magnitude faster and new data sources could be added in a seamless manner. Easier integration with machine learning models to perform predictive analytics and prescribe business insights. Full compliance to HIPAA standards

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