

Building a **Secure AWS Foundation** for Clinical Environments

Establishing a secure, well-managed, and extensible AWS environment to support multiple governance models and secure clinical trial-data hosting.

ABOUT

North Carolina Based Clinical-Stage Biotech:

This clinical-stage biotechnology company located in Winston-Salem, North Carolina, is developing a transformative proprietary and innovative cell therapy platform with the potential for treating Chronic Kidney Disease. As the company grew, its needs evolved, and the organization sought to consolidate, migrate, and host their most valuable asset— sensitive clinical trial data—from associated CROs in an AWS Cloud environment.

With security, control, extensibility, and resource isolation chief among their specific needs and objectives, this case study summarizes how this growing Biotech realized its outcome of establishing a federated, multi-account AWS environment for its Clinical Trial data with the support of RCH Solutions.

Challenge

This Biotech's Need for a Secure, Multi-Account AWS Environment

The organization needed specialized evaluation, consultation, and recommendations across the company to address the operational and technical challenges they faced in accessing, sharing and managing their data.

In rapid growth mode as they progressed through clinical trials, and with data hosted externally within several different CROs, the company's senior IT strategist and Chief Technology Officer, knew that the team needed to quickly and efficiently get control of their data, and migrate this critical asset in-house.

However, ensuring secure hosting for the first of this company's trial data deliverables would require a well-managed and extensible Cloud environment, which the company had not yet established. This environment would need to support multiple governance models as data needs evolve, and also sustain a new set of Life Sciences-oriented computing environments for processing and analyzing this critical data.

Aware of the company's reputation and prior customer successes, this organization's stakeholders and executives selected RCH to lead both the strategic and tactical effort.

Expert Consultation and Execution Services from RCH Solutions

RCH Solutions—a specialized provider of scientific and Cloud computing services exclusively within the Life Sciences—has spearheaded the Sci-T Managed Services model. This approach is holistic, cross-functional and science-centered, which means the company is focused on supporting the teams' particular computing demands vertically (technology, operating systems, applications, and workflows/best practices) and horizontally (strategy, roadmap development, execution/implementation, accountability). The result is a very specialized set of solutions designed and executed to enable you to reach your project goals on time and within budget.

RCH recommended a set of remote expert consulting services to strategize, architect, design, build, and support the AWS Cloud implementation and lead the data migration, including:

- Consulting support for final architecture and encryption key management
- Data Analysis including location, accessibility, and usability based on FAIR data principles
- AWS organizations with a master account used for control / consolidated billing
- Turbot (via a Software as a Service (SaaS) offering) for rules and governance (Turbot can also be hosted in their AWS environment but has a higher price-point; thus, the recommendation is to start as SaaS)
- AWS Integration with their Active Directory
- AWS Transit Gateway to provide network mesh-style connectivity between AWS accounts
- IT Services Accounts for IT-related services spanning the AWS environments
- Additional AWS account(s) and VPC(s) tailored for Data Hosting and Scientific Compute
- Site-to-Site VPN connectivity
- S3 storage
- Organization-specified permissions scheme for S3 data
- Architecture and Implementation documentation
- Ongoing Platform CloudOps / Run support
- Ongoing evolutionary support and services

And based on the following AWS Cloud best practices and services:

- Infrastructure as Code (IaC) via AWS CloudFormation (excluding AWS Account creation and Turbot stand-up and its initial configurations)
- Operation System Configuration Management (build-automation)
- Turbot configuration(s) for:
 - IT Services hosting.
 - Clinical Prod hosting.
 - Clinical non-Prod (Dev/Test/Experimental) hosting.
- CloudWatch/CloudTrail as Cloud-native log collection/alerting/alarming.
- No 2-factor Authentication for batch/compute-at-scale components
- AWS FSx for NetApp ONTAP for NFS services to support Posit project sharing

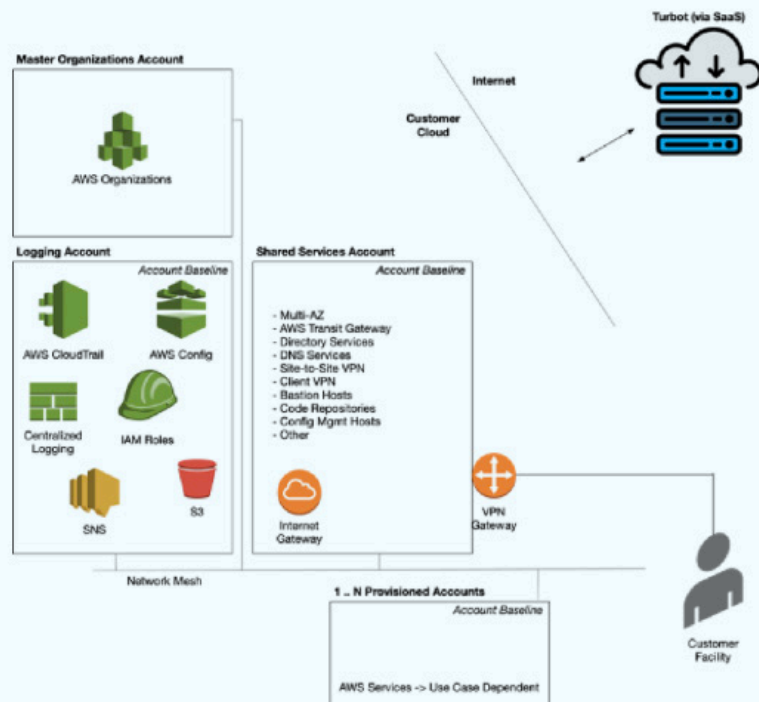
Service Delivery: A Crawl, Walk, Run Approach For Success

RCH recommended a phased approach for implementing and evolving this organization's Cloud environment, as it allows for the identification and mitigation of potential risks in smaller, more manageable increments, minimizes the impact of any unforeseen issues, better controls costs, provides for scalability testing, and helps align stakeholders on the need to have vs. nice to have enhancements, among other benefits. In particular, they approached this project in the following stages:

- **Foundation:** Developing a secure, well-managed, and extensible AWS environment to support multiple governance models as needs evolve and ensuring secure hosting for the first of their Trial data deliverables.
- **Integration:** Architecting and implementing a set of life sciences-oriented computing environments for the processing and analyzing of data, including two compute environments in AWS, the priority being to provide computing services for Research and Clinical (non-regulated).
- **Qualification:** Evolving their Cloud platform to be fully Qualified so that the organization can run entirely Validated application services in AWS, creating a multi-faceted Cloud environment that would support Validated and more experimental, non-validated processing.

RCH recommended a proven and validated architecture for its AWS foundation to initiate this effort. Components included:

- Transit Gateway (Network Mesh)
- Master Account
 - AWS Organizations
 - No Default VPC
- Logging Account
 - CloudTrail
 - AWS Config
 - Centralized Logging
 - S3
 - SNS
- Shared Services Account
 - Access Points (site-to-site VPN, client VPN, Bastion Hosts)
 - Active Directory
 - DNS
 - Other
 - S3 services
- Clinical Computing Account
- Multi-AZ
- All AWS services supporting Research workflows
- Up to three (3) additional AWS accounts instantiated to support the addition or separation of computing initiatives





Results

A Secure and Well-Managed Multi-Faceted Cloud Environment for This Growing Clinical-Stage Biotech

RCH provided a strategy, technical recommendation, and build that created a multi-faceted AWS Cloud environment that supported validated and more experimental, non-validated processing. The company now has a secure, well-managed, and extensible AWS environment that supports multiple governance models and ensures secure hosting for its trial data. The team can now effectively process and analyze their data in Life Sciences-oriented computing environments, including analytics.

Today, RCH continues to help the organization evolve its Cloud computing environment in preparation for continued clinical success and beyond.



About RCH Solutions

RCH Solutions (RCH) is a global provider of Bio-IT expertise, helping Life Sciences and Healthcare companies of all sizes clear the path to discovery. For more than 30 years, RCH has provided focused experience and unmatched specialization in designing and deploying cross-functional IT strategies, supporting R&D infrastructure, and offering workflow best practices that solve enterprise and scientific computing challenges.



Are you interested in working with us?

Contact the RCH team to learn how we can support your advanced scientific computing and IT needs.

discover@rchsolutions.com