Clinical Trial Management

Validated Cloud

Business Need

A Clinical Trial Management System (CTMS) is designed to manage processes and large amounts of data involved with clinical trial management and clinical study management. As more Life Sciences companies are looking to take advantage of cloud-based solutions, CTMS providers find themselves in need of scalable qualified hosting solutions to meet customer demand.

Building, maintaining and supporting a qualified environment is a capital- and labor-intensive endeavor. In addition, having a qualified hosting solution is only partly sufficient; the hosting solution must be able to demonstrate compliance with various regulations. During the sales cycle, potential customers conduct vendor assessments regarding the security and quality of the hosting solution. As part of this auditing process, the company needs to get a passing grade for its technology and documentation stack.

Solution

Every company that works with clinical data requires a fully qualified environment with a robust Quality system to ensure compliance. Validated Cloud provides and manages all aspects of compliance requirements and services to ensure ongoing compliance and security.

Validated Cloud offers a fully qualified and secure hosting platform compliant with 21 CFR 820, 21 CFR 11, HIPAA, Annex 11 and ISO 13485:2003. The Validated Cloud environment has been qualified since its inception by the people who have worked in the Life Sciences industry for years supporting close to three hundred scientific applications.

A Validated Cloud platform can start small and grow as the customer base expands. The CTMS implementation is also fully serviced by the application support team that has been supporting Life Sciences clients for years.

Benefits

The Validated Cloud offers an ideal platform for CTMS providers. By choosing the Validated Cloud's SaaS (Software as a Service) offering to deploy a CTMS solution, the company gets not only a fully managed compliant hosting platform, but also the support for the product sales cycle as well as optional application support:

- Architecture for a Scalable Solution.
- Change region of service delivery when needed.
- Assistance with RFP responses and security/quality questionnaires.
- Provide managed services to support DB/OS/Security auditing.
- Transparency to the Clinical Trial Sponsor.
- Optional validated application support: let Validated Cloud be your Tier 1 or Tier 2 support. Validated Cloud was built by people who have worked in the Life Sciences industry for years supporting scientific applications in GxP and non-GxP environments.
- Optional disaster recovery: with fully redundant qualified production data centers in California and Massachusetts, Validated Cloud ensures access to validated systems in case of a disaster.
- Options available for Europe and North America.

For references for this case study, contact us at info01@validatedcloud.com.