Medidata Clinical Cloud (MCC) Validation

Medidata develops, validates, installs, maintains and supports all components of Medidata's cloud-based, Software as a Service (SaaS) platform, i.e., the Medidata Clinical Cloud (MCC), in a manner consistent with a broad range of national and international clinical, data protection/data privacy and electronic record/electronic signature (ER/ES) regulatory requirements. Medidata has created and maintains regulatory compliance summaries, which are available to clients upon request, that outline how Medidata complies and/or helps our clients comply with these regulatory requirements.

Medidata has documented procedures describing the breadth of activities conducted and services provided in all aspects of Medidata's SaaS operating model. These documented procedures, as well as the validation artifacts generated as a result of the execution of these procedures, are available for client review both during client audits and on an ongoing basis.

Medidata Software Development Life Cycle (SDLC)/ Validation Approach and the Validation Portal

All software offered by Medidata is developed in accordance with our SDLC processes based on an agile development methodology. In addition to software being continuously tested during the 'sprint' of an agile development cycle, significant integration testing, regression and full validation take place for every major release. Much of Medidata's software testing is automated, enabling the execution of large volumes of tests quickly, as needed. Medidata gives advance notice of upcoming software releases and provides a pre-release period so our clients can adequately plan for a release, have an opportunity to test new software and get familiar with any new features. As we enter into the pre-release period, the product is fully validated and documented, and the validation package can be made accessible to clients remotely through our Validation Portal, as described below.

The Validation Portal is a cloud application developed by Medidata that captures all artifacts and deliverables generated as a result of the execution of and in accordance with the Medidata SDLC. This dynamic portal is an integral part of the work effort adhered to by all Medidata development personnel for all Medidata products. Use of the portal simplifies the collection and organization, as well as viewing, of our validation deliverables. The portal is accessible to clients through an iMedidata account, thus facilitating the review of product validation packages remotely prior to product release.

The Key Benefits of the Medidata Validation Portal:

- Access full validation transparency: Gain unobstructed insight into Medidata's validation process at no additional cost. This level of visibility is unique in the industry.
- Eliminate redundant testing: View all the testing Medidata has done, and focus your resources on other areas of importance to your organization.
- Review documentation at your own pace: Determine your own schedule for eviewing documents.
- Review documentation from any location: Access the audit documents anywhere with an Internet connection.
- Stop unnecessary travel: Save the time and costs associated with traveling to Medidata to conduct an on-site audit.

By having access to the most current version of the validation package, clients are able to optimize their own User Acceptance Testing efforts. The Validation Portal has the potential to reduce audit costs for clients and for Medidata by reducing on-site audit days and to speed product adoption as clients will be able to review our tests and reduce the scope of their own testing.

The availability of the Validation Portal to our clients reflects a high-degree of transparency, which we believe is unique in our industry and aligns with our cloud model.

MCC Validation Plan

Medidata prepares a Validation Plan for each product release. Components of the MCC Validation Plan include, but are not limited to:

- System overview, including a brief synopsis of the functionality enhancements being introduced with the system version, as well as the issues to be resolved with the system version
- Description of validation environment sites, including identification of environment components (e.g., server(s), workstations and laptops, host operating system, application dependencies, reporting software, host browser requirements and database software)
- Validation overview, including the identification of all Medidata-defined validation activities executed for the system version, along with the identification of all Medidata-defined validation SDLC deliverables that are to be created within the scope of the validation
- List of Medidata quality system documents (QSDs) (i.e., policies, standard operating procedures, work instructions) required for the operation and maintenance of the system
- Medidata-defined acceptance criteria, risk assessment and impact assessment
- Medidata-defined validation approach, including a description of the installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ) testing approaches, which also includes explicit mention of the regression testing to be conducted, broadly covering the full system (i.e., not just the new features, enhancements and defect corrections of a specific version release)

MCC Validation Summary and Validation Certificate

Medidata prepares a Validation Summary at the conclusion of each validated release. Components of the MCC Validation Summary include, but are not limited to:

- Scope (software components covered and not covered as part of the validation, as well as any assumptions associated with the validation effort)
- Comprehensive list and status for all validation activities and validation/SDLC deliverables as defined in the Medidata Validation Plan (described above), as well as any other pertinent activities not specifically identified in the Validation Plan
- Reference to the test summary reports and release documents for all software products that have been developed by Medidata
- Reference to documents required for generic (i.e., not client-specific) system operation
- Results of the execution of the Medidata-defined validation approach, including a description of the results of IQ, OQ (including list of issues resolved in the system release) and PQ testing execution
- Identification of unit testers and declaration of unit test completion
- Deviations, if any, from the Medidata Validation Plan
- Impact analysis (issues found and resolved during validation)
- Statement of system release

In case there are any limitations or issues to be taken into account for the operation of the MCC, the Validation Summary clearly addresses such issues.

The Validation Certificate is the final validation artifact and represents Medidata's affirmation that validation has been completed successfully and the associated software product is ready for production release.

MCC Installation

Full computerized system validation (CSV) of the MCC incorporates the software produced as installed on the platform (hardware and software) accessible to our clients.

The associated procedures adhered to by Medidata personnel ensure that documented evidence is created for the installation of components, testing of components for correct configuration and correct functionality after installation, and verification that all components have been installed and configured in accordance with defined requirements.

Standard change management plans (CMPs) for core infrastructure components (e.g., servers, operating systems) are developed following a platform qualification process, resulting in the creation of platform requirements, installation checklists and operational qualification of the system. Once qualification is complete, the installation checklist is included in a CMP, which is used for all subsequent installations of the platform.

The IQ of the MCC software itself reflects adherence to a predefined IQ plan, as well as IQ execution results. Once product validation is complete, the installation program and script forms a component of a standard CMP, which is used for all subsequent installations. In addition, CMPs are developed, executed and documented for all changes made to all production environments, thus ensuring environments are changed, upgraded and implemented accurately and correctly, maintaining the validated state of the software.

MCC Release for Production Use

Medidata has documented procedures in place describing the formal MCC release to production, and adheres to those procedures. Medidata creates and maintains the related documented evidence of every deployment.

Every installation of product from validation to pre-release to production is fully qualified. Each unique installation event consists of three essential components: standard infrastructure templates, standard change procedures and repeatable verification steps. Medidata documents that the production installation is equivalent to the validation installation, and our process confirms this result.

Reliance on external services is not unique to public cloud computing and companies offering SaaS solutions. For example, Medidata routinely relies on internet service providers and antivirus vendors to keep hosted systems connected and secure. Public cloud vendors used by Medidata (e.g., Amazon Web Services (AWS)) provide a very deep and rich set of services, upon which Medidata relies. These services enable Medidata to leverage a resource pool that spans physical locations and to configure products to failover to alternate hosting environments, which aids in meeting availability and performance service level agreements (SLAs). As with all public cloud solutions, Medidata maintains separation of the virtual resources (e.g., server instances, storage allocated for data) from the physical hardware on which they run. Medidata uses access management systems and encryption for the deployment and management of all such product and server instances to ensure that only appropriate Medidata personnel have access, and that unauthorized 3rd parties have no access to the contents of those instances (including data).

Medidata maintains a number of controls to ensure each product is installed and operated per expectations, such as the infrastructure templates used to provision servers that host Medidata's products. While AWS provides base Amazon Machine Images (AMIs), which are designed to work out of the box, Medidata never uses those directly to host any products in production. Instead, we harden and reconfigure the base AMIs to meet Medidata's exact requirements, which are then tested and promoted for use in validation, pre-release, and production.

Additionally, Medidata employs repeatable verification procedures to ensure the full suite of MCC products are always in a qualified state and performing as expected. Medidata maintains tested procedures for refreshing and/or moving systems to unaffected areas of the public cloud as a means of mitigating any external factors with the potential to impact the installation or operation of the system.

Generic MCC installation reports are generated for all installations in production and are included with change management documentation, which is available for client review.

Conclusion

Medidata's established and proven processes, partnerships with best in class technology providers and relentless attention to security ensure the MCC SaaS solution is always of high quality, always available and always safe.

About Medidata

Medidata Solutions is the leading global provider of cloud-based solutions for clinical research in life sciences, transforming clinical development through its advanced applications and intelligent data analytics. The Medidata Clinical Cloud™ brings new levels of productivity and quality to the clinical testing of promising medical treatments, from study design and planning through execution, management and reporting. We are committed to advancing the competitive and scientific goals of global customers, which include over 90% of the top 25 global pharmaceutical companies; innovative biotech, diagnostic and device firms; leading academic medical centers; and contract research organizations.

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