



CARA Hub for Data Safety Monitoring Committees

CARA Hub is a cloud-based enterprise platform designed for secure collaboration with internal staff and external experts. It enables the creation of specific workspaces for Data Safety Monitoring Committees, enhancing collaboration while maintaining strict confidentiality and compliance with regulatory requirements.



CARA Hub simplifies complex processes for Data Safety Monitoring Committees to manage collaboration and approval of the documents, clinical data, meetings and tasks associated with managing your studies and ensuring compliance.

The CARA Hub ensures that DSMCs can operate with maximum efficiency and security, fostering collaboration while maintaining strict control over data access and full traceability for audits.

Uses



Safety Monitoring Committees (SMCs)

Collaborate on blinded study data, ensuring participant safety and study integrity.



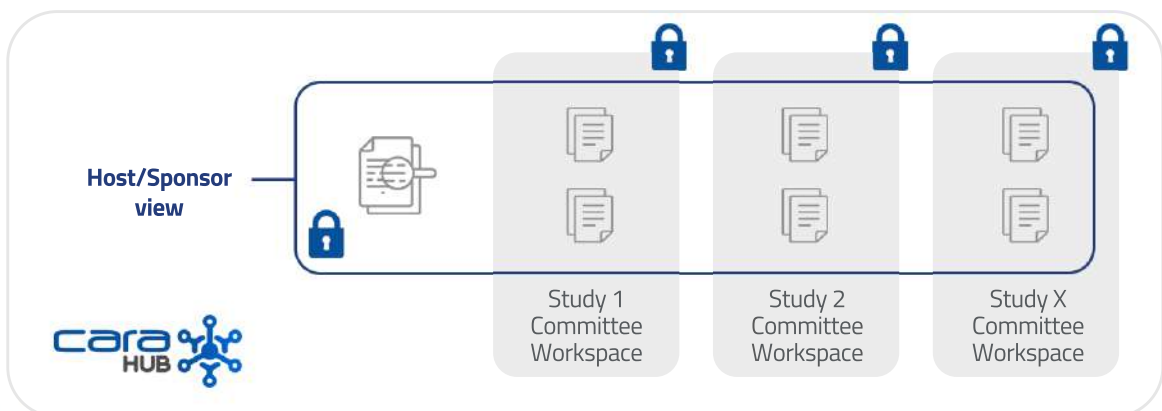
Data Monitoring Committees (DMCs)

Efficiently handle both internal and external members, managing unblinded data with strict access controls.



Regulatory and Compliance Reporting

Automate the collection of signatures, document tracking, and audit reporting for seamless regulatory submissions.



How does it work?



Secure Collaboration Workspaces

- Spin up separate DSMC workspaces per study in minutes using templates for roles, documents, data, meetings and tasks.
- Invite both internal (company employees) and external (independent experts) users to participate.
- Documents can be secured as either open (viewable by all committee members) or closed (restricted to specific members).



Meeting & Task Management

- Plan and schedule meetings with integrated templates to manage tasks, capture participant data, and track progress.
- Includes support for Microsoft Teams links, meeting minutes, and action item tracking, streamlining administrative tasks.



Document & Data Security

- All data and documents remain within the CARA Hub, ensuring no unauthorized duplication or sharing.
- Version control, audit trails, and data encryption safeguard confidential information.
- Integration with in-house systems and LDAP/AD allows easy user management without the need for IT intervention.



Real-Time Collaboration & eSignatures

- Collaborate in real-time on documents and data, allowing edits, comments, and secure reviews.
- Allow both internal and external users to upload / create new content.
- Schedule and complete tasks through to collecting eSignatures, ensuring compliance with regulatory standards.



Reporting and Tracking

- Use standard reports or quickly add your own to track the progress of meetings, tasks and documents in a study.
- Track and report on metrics and SLAs to ensure ongoing process improvements.



Templates & Workflows

- Pre-configured templates for DSMC meetings, action tracking, and document workflows.
- Seamless collaboration for report reviews, committee minutes, recommendations, charters, and agreements.

Benefits



Confidentiality and Security:

With its advanced role-based permissions, the CARA Hub ensures that sensitive study data, including blinded and unblinded reports, are securely managed.



Compliance-Ready:

Fully auditable and compliant with industry regulations such as 21 CFR Part 11, eSignatures, and GxP standards.



Efficiency:

Streamline the DSMC process with integrated tools for managing documents, tracking and reporting on study progress and tasks, and facilitating real-time collaboration across global teams.



Scalability:

Ideal for managing a growing number of DSMCs, the platform can easily handle an increase in committees, studies, and participants, ensuring seamless operations.

