



Stack 20.1 Impact Analysis: Study Runner & Study Build System Changes

Scheduled Release - 25 April 2026





Release Reasons

Stack 20.1 introduces integrated LMS functionality, including configurable required training and in-application learning resources. These enhancements support onboarding, compliance, and controlled study access. This release also adds form search in Study Designer to streamline form discovery and reuse, along with additional user experience improvements and issue fixes that enhance overall usability and reliability.

Enablement Details

Auto-On

Ready on Day 1



Automatically available

Configurable

User Configurable



Requires Configuration

Requestable

Request Assistance



*Requires Enablement,
Product Support Request*

Table of Contents

Click on a [hyperlinks section](#) to jump through the slide deck

1. [New Features](#)
 1. Integrated Training
 2. Study Designer Search
2. [Changes & Fixes](#)
3. [Index: Tickets, Info, & Links](#)





New Features



Integrated Training

Change Summary

OpenClinica supports both role-based required training for study access and optional in-application training content for onboarding and ongoing user education.

This functionality allows Data Managers and Administrators to configure required training at the role level. Required training status is displayed on the User Roles page and the Share page to provide visibility during study setup and user management.

When a user is assigned to a role with required training that has not been completed, the system redirects the user to the Training page before access to Study Runner is permitted. After all required training for that role has been completed, the user is returned to Study Runner.

The system also includes optional training content that users may access within the application to support onboarding, reinforce key workflows, and provide ongoing educational resources independent of study access enforcement.

i This update does not block users from accessing other studies where

- no training is required or
- the training requirement is already satisfied.



User
Configurable

Visible

All Users

Integrated Training

Scope of Impact

All studies have access to in-application training resources by default. Configurable role-based training does not affect studies by default.



User
Configurable

User Impact	When required training is enabled, users assigned to impacted roles must complete the applicable training before accessing Study Runner. If required training is newly added or updated in an existing study, those users may lose Study Runner access until the new training is completed. Optional in-application training remains available for onboarding and familiarization even when training is not required for role access. Users who previously completed applicable training in the legacy LMS will not need to retake that training in OC4.
Operational Impact	Enabling role-based required training adds an administrative configuration step for User Managers. If enabled or updated in an active study, advance communication is required due to potential interruption of user access. Training status is visible on the User Roles and Share pages to support oversight during study setup and user management. Migration of legacy training completion records supports continuity during rollout and transition to OC4.
Data / Audit Impact	Audit log entries are created for individual module completion and completion of all required role-based training. Legacy training completion data, including completed courses and completion dates, will be migrated into OC4 at release to preserve historical training records during transition from the legacy system. No direct impact to study data collection is expected; impact is limited to user access control and training traceability.

Visible

All Users

Integrated Training

Risks

The primary risk associated with this change is interruption of user access to Study Runner if required training is enabled or updated during an active study and users have not completed the newly required training.

There is also a risk of operational disruption if role-based training requirements are introduced without advance communication or without giving users sufficient opportunity to complete training before enforcement.

Misconfiguration of required training at the study or role level may unintentionally restrict access for users who need to perform active study responsibilities.

Recommendations and Mitigations

For in-flight studies, OpenClinica recommends allowing a grace period for users to complete applicable training before enabling required training for study access, with planned communication to affected users in advance.

Where possible, users should be directed to complete applicable role-specific training in advance through the **Resource Center** before required training is enforced. This can help reduce disruption to ongoing study activities and minimize the risk of unexpected loss of access.

Optional in-application training content may also be used to prepare users ahead of enforcement and support smoother onboarding and transition to role-based training requirements.

If required training is not needed for a study, no action is required and there is no user impact.



User
Configurable

Visible

All Users

Study Designer Search



Auto-On

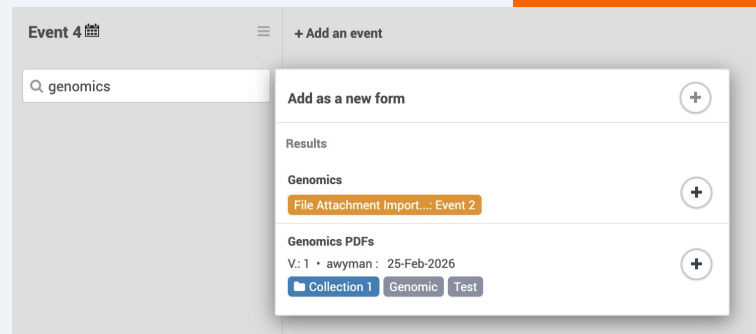
Change Summary

A new **Study Designer Form Search** feature has been introduced to streamline form discovery and reuse during event configuration. This enhancement allows users to search for and add existing forms either from within the current study or from the Form Designer Library directly within the form-addition workflow. The feature is available within the existing form-addition process and does not require separate enablement by study.

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Scope of Impact

User impact	Reduces effort and time required to find and reuse forms when adding forms to an event.
Operational impact	Simplifies study build workflows and may reduce unnecessary duplicate form creation.
Data impact	No direct impact to study data or subject data collection.



Risks

The primary risk is user confusion during transition if users are accustomed to the prior form-addition workflow. There is also a possibility that users may unintentionally select an existing form or library template with a similar name if they do not review results carefully.

These risks are considered low and are limited to study configuration workflow rather than live study data capture.

Visible

Data Manager



Changes & Fixes



Signed Participant Site Reassignment

Change Summary

OpenClinica now allows signed participants to be reassigned to a new site. Previously, participants in Signed status could not be moved. With this update, participant signatures remain in place and Signed status is retained after reassignment.

Scope of Impact

This change affects workflows involving participant site reassignment. It applies only when study teams move a signed participant from one site to another and does not affect participants who are not reassigned.

User impact:	Authorized users can reassign signed participants to a new site without losing signatures or Signed status.
Operational impact:	This reduces administrative burden and increases flexibility when participant site changes are required.
Data impact:	Existing signatures and Signed status are retained after reassignment, with no expected loss of participant status information.

Risks and Recommendations

The primary risk is operational misuse if participant reassignment is performed without appropriate site management oversight. Study teams should confirm that reassignment is appropriate before moving signed participants between sites. Any internal procedures related to participant transfer between sites should be updated accordingly.



Auto-On

Visible

Data Manager

Participant Dashboard Submit Button Relabeling

Change Summary

The participant-facing dashboard button used to finalize all form data entry within an event has been relabeled from “Let’s move on” to **Submit All**. No underlying functionality or workflow behavior has changed.

Scope of Impact

This change affects the participant-facing event submission button label only and does not impact study configuration, permissions, or submission logic.

User impact:	Participants will see the updated Submit All label when completing and submitting form data for an event. The revised label is intended to more clearly describe the action performed.
Operational impact:	This change may require updates to participant-facing documentation, training materials, or screenshots that reference the previous button label. No operational workflow changes are expected.
Data impact:	No impact to study data, audit trails, or form submission behavior is expected. The change is limited to user interface text.

Risks and Recommendations

There is a low risk of temporary confusion for participants or study teams familiar with the previous label. However, because the new label more directly reflects the action performed, overall usability is expected to improve.

Any participant-facing instructions, onboarding content, or support documentation that references the previous button label should be updated to reflect **Submit All**.



Auto-On

Visible

Participants

Default Form Designer Style Update

Change Summary

The default Form Designer style setting has been changed to **Simple-Single Page** to make initial form creation more intuitive. This default allows Data Managers to add multiple items and quickly preview the full form on a single page, making it easier to review item layout and confirm how items interact when form logic is applied. By contrast, the previous default displayed one item per page, which required more clicks and made it harder to evaluate the overall form experience.

Scope of Impact

This change affects the default style selected for new forms in Form Designer and does not affect existing forms.

User impact:	Users creating a new form will see Simple-Single Page selected by default.
Operational impact:	Improves the intuitiveness of initial form setup with no impact to existing forms.
Data impact:	No impact to study data, form content, or auditability is expected.

Risks and Mitigations

There is a low risk of temporary adjustment for users accustomed to a different default style setting.

Training materials, screenshots, or guidance related to initial form creation should be reviewed and updated if they reference the previous default style.



Auto-On

Visible

Participants



Index: Tickets, Info, & Links



Complete Release Notes

Please review the full list of changes and their associated tickets on the OpenClinica 4 – Release Notes 2026 page [here](#).

Thank you