



Stack 20 Impact Analysis: Study Runner & Study Build System Changes

Scheduled Release - 31 January 2026





Release Reasons

Stack 20 introduces a more flexible and intuitive form-access permission model that simplifies configuration for study teams and enhances overall usability. This update also addresses several reported issues, resulting in a more predictable and reliable experience for end users.

Enablement Details

Auto-On

Ready on Day 1



Automatically available

Configurable

User Configurable



Requires Configuration

Requestable

Request Assistance



*Requires Enablement,
Product Support Request*

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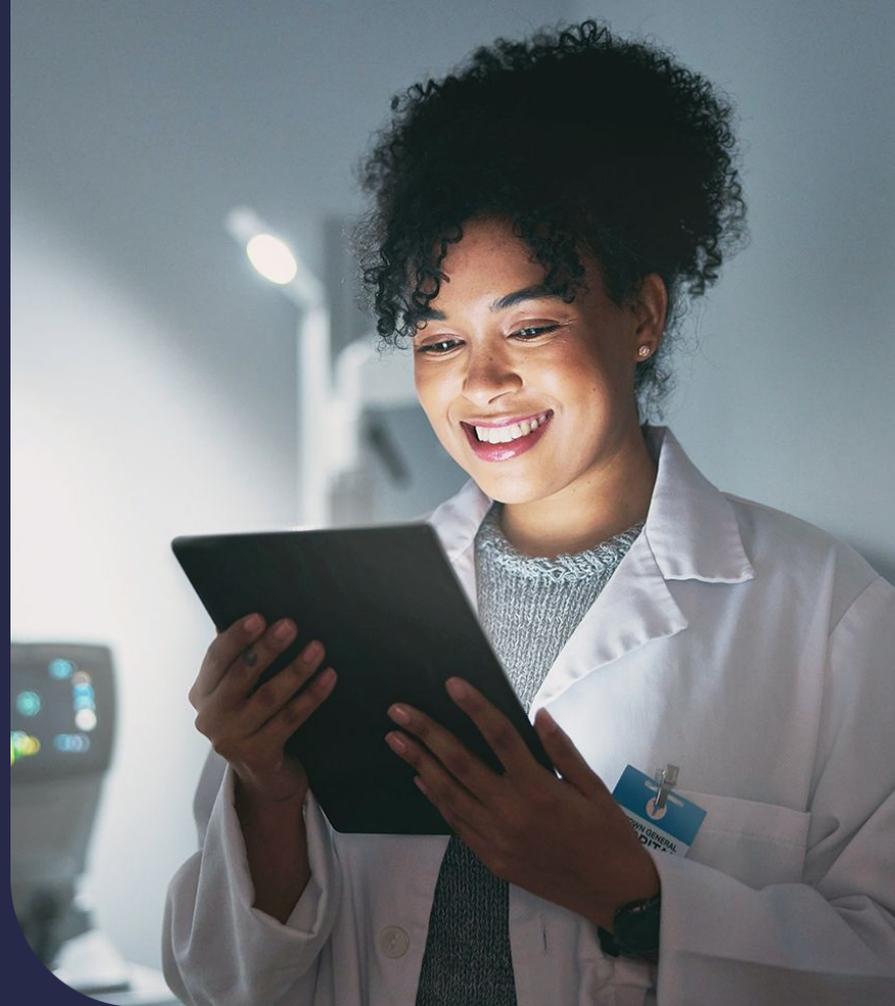
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New Features



Configurable Form Permissions

Administrators can now configure form-level access (Read Only, Review, Edit) per role directly within the Create Role and Edit Role screens, providing greater flexibility and control. Access can be customized per role for each form type:

- **Forms with manual permission tags** can have any access level or have access removed entirely.
- **Contact forms** default to Edit access for CRCs & Investigators and to No Access for all other user roles. If a manual permission tag is applied, its access level overrides the default contact form access in Study Runner.
- **Untagged forms** allow configuration of access levels. To revoke access, use permission tags.

The screenshot shows the 'Edit Role' interface for the 'Clinical Research Coordinator' role. The role is based on the 'Clinical Research Coordinator' base role. The description is: 'Site-level role with permission to create, view, edit, and remove records; add and update queries; import data.'

Form Permission Tags

Form Type	Access Level
Untagged Forms	Read Only
Contact Forms	Edit
Adjudication	Manual Permission Tags
Safety	Manual Permission Tags

Module Permissions

Insight Module	Access
Show Reports Link	<input type="checkbox"/>

At the bottom right, there are 'Cancel' and 'Save' buttons.



Auto-On

Visible

Data Manager

Existing roles automatically retain their current permissions. Customers with studies using manual permission tags on contact forms will receive separate guidance prior to Stack 20 deployment.

Configurable Form Permissions, CONT.



Auto-On

Improved visibility of form and access types:

- **Study Designer:** contact forms now display a dedicated icon
- **User Roles page:** now lists tag names and access levels



Settings User Roles Modules

Successfully edited role Clinical Research Coordinator. For users currently logged in, this can take a few minutes to take effect.

User Roles

Access to form data (read only, review, edit) is configurable for all user roles. [Create](#)

Role	Description	Access	Actions
Clinical Research Coordinator (Clinical Research Coordinator - SITE)	Site-level role with built-in permissions to manage participants (add, view); manage events (schedule, view, add, remove, restore); import data; restore/remove form data they have access to, and manage contact data.	<input type="checkbox"/> Untagged Forms: Edit <input type="checkbox"/> Contact Forms: Edit <input type="checkbox"/> Manual: Edit	Edit
Data Entry Person (Data Entry Person - STUDY)	Study-level role with built-in permissions to manage participants (add, view); manage events (schedule, view, add, remove, restore); import data; and restore/remove form data they have access to.	<input type="checkbox"/> Untagged Forms: Edit	Edit

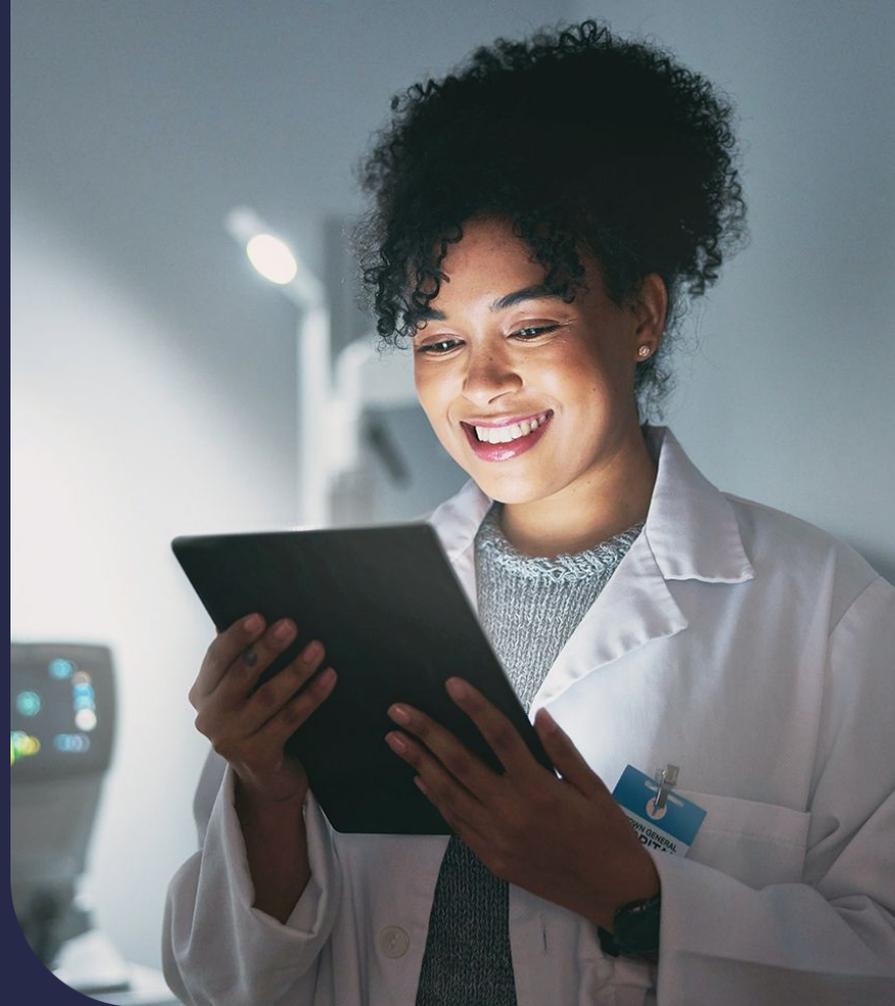
All other permissions — such as scheduling events, adding participants, closing queries, and removing records — remain role-based. Roles with permission to close queries will have this access for any forms the user can open in Edit or Review mode. Roles with access to remove forms will have this access for any forms the user can open in Edit, Review, or Read Only mode.

Visible

Data Manager



Changes & Fixes



Filter User and Role Audit Log Download by Date



Auto-On

The User and Role Audit Log download now includes required Start Date and End Date filters, allowing Admins to limit the log to a specific time range (up to one year). If more than one year of audit data is needed, multiple downloads can be performed.

The image shows a screenshot of the OpenClinica Administration interface. On the left, the 'Administration' menu is visible with three buttons: 'Web Services Information', 'Download User and Role Audit Logs' (highlighted with a red border), and 'Download Qualification Report'. A red arrow points from the highlighted button to a modal window on the right. The modal window is titled 'User and Role Audit Log' and contains the text 'Select a date range of up to one year.' Below this, there are two date pickers: 'Start Date *' with the value '08-Sep-2025' and 'End Date *' with the value '08-Oct-2025'. A 'Download' button is located at the bottom right of the modal. A note at the bottom of the modal states: 'Note: Dates are based on the UTC time zone, which may differ from local time. Confirm that your selected dates align with UTC to ensure all expected records are included.'

Visible

Admin User

This enhancement improves system performance by preventing full log downloads for very large datasets, reducing the risk of slowdowns or crashes and making it less likely that the log files will be too large to open in Excel or other spreadsheet applications.

Site Time zone Consistency

Site time zones are now automatically shared across all studies that use the same site. When a time zone is set for a site in one study, it will be applied consistently wherever that site appears.

Only Admins can edit settings that are shared across studies — including the site's time zone, name, and location — ensuring consistency and preventing unintentional changes to other studies by non-Admin Data Manager users.

The screenshot shows a web form for a site named 'Best Hospital' in a 'TEST Environment'. The form is divided into several sections:

- Site Information:** Includes fields for Site Name (Best Hospital), Site ID (001), Lead Investigator (Dr. Doctor), IRB Approval Date, Expected Start Date, Expected Number of Participants (300), and Status (Available).
- Site Location:** This section is highlighted with a red box. It contains:
 - Time Zone:** A dropdown menu set to 'America/New_York (-04:00)'. Below it, text indicates the current time for the selection is 14:30 on 28-Oct-2025 and that time zones are displayed as Region/Major City (Offset from UTC).
 - City:** An empty text input field.
 - State/Province:** A dropdown menu.
 - Zip:** An empty text input field.
 - Country:** A text input field with the placeholder 'Type to search...'.
- Primary Contact Info:** Includes fields for Name, Phone, and Email.

At the bottom right of the form are 'Cancel' and 'Save' buttons.



Auto-On

Visible

Admin User

Removal of CRFs in the View Events Page

The ability to perform actions on CRFs from the View Events Page is being removed. The Participant Matrix and Participant Details page provide direct access to CRFs, so this CRF section of the “View Events” page was not needed. Additionally, this did not account for Calendaring changes to CRF properties (ex. visible/editable) and therefore could potentially become out of sync with the Participant Details Page view.

OpenClinica CAR-T Study: Cleveland Clinic (OH001) | Change | Share | Settings

Enter Participant ID View

Alerts & Messages > Enter or Validate Data for CRFs in Enrollment

Quick Access > My Queries

Recent OH001-002 Edit Study Event

Participant ID	OH001-002
Study Event	Enrollment
Participant OID	SS_OH001002

Start Date 01-Nov-2019

End Date/Time

Event Status completed

Last Updated by bbbOC19crc (01-Nov-2019)

CRFs in this Study Event:

CRF Name	Version	Status	Last Modified by:	Actions
Eligibility	2	<input checked="" type="checkbox"/>	root	

View this Participant's Record Exit



Auto-On

Visible

Data Entry User

Insight - Addition of Medical Coding Data

OpenClinica's Code module, first released in Stack 19.4, will now integrate fully with OpenClinica Insight, allowing you to build reports using any medical coding (MedDRA) data in your studies. Insight will contain:

- All coded MedDRA LLT/SOCs, mapped to their respective verbatim item data
- The full MedDRA hierarchy of all coded terms
- All audit log events associated with MedDRA coding

For those studies using automatically integrated privileges in Insight, these data will be considered the same as tagged study-level clinical data.



Auto-On

Visible

Admin User

Fixing Site State/Province Fields

Prior to Stack 20, the State/Province field in the Site creation and edit dialogs allowed entry of excessively long values. This could result in sites becoming inaccessible—failing to appear on the Share page and therefore unable to be edited. Although the site still appeared on the Change Studies screen, users cannot access it.

This is fixed in Stack 20, preventing new edits to sites from violating the 20 character limit.

OpenClinica will notify customers with affected sites once the review is complete.

Best Hospital (TEST Environment)

Site Name * Best Hospital

Site ID * 001

Lead Investigator * Dr. Doctor

IRB Approval Date DD-MMM-YYYY

Expected Start Date DD-MMM-YYYY

Expected Number of Participants * 300

Status * Available

Site Location

Time Zone * Choose... America/New_York (-04:00)

Current Time For Selection: 14:30 on 28-Oct-2025

Time zones are displayed as: Region/Major City (Offset from UTC)
Type to search for a time zone

City

State/Province

Zip

Country Type to search...

Primary Contact Info

Name

Phone

Email

Cancel Save



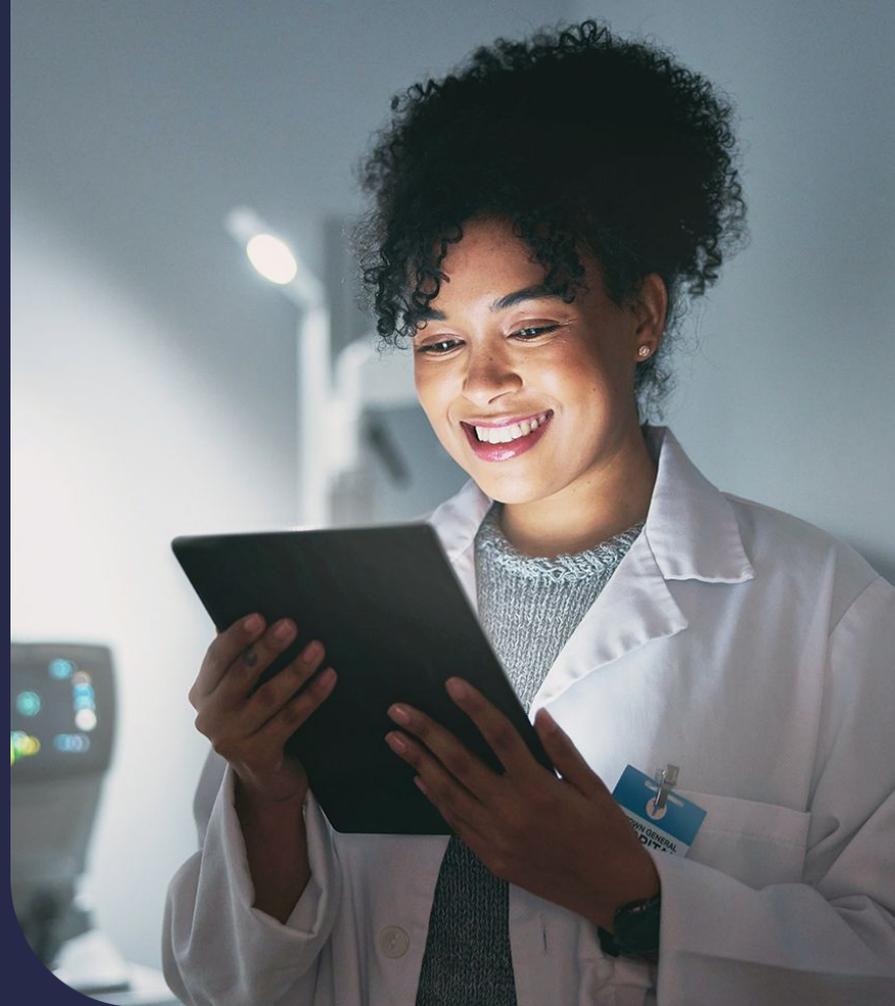
Auto-On

Visible

Admin User



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