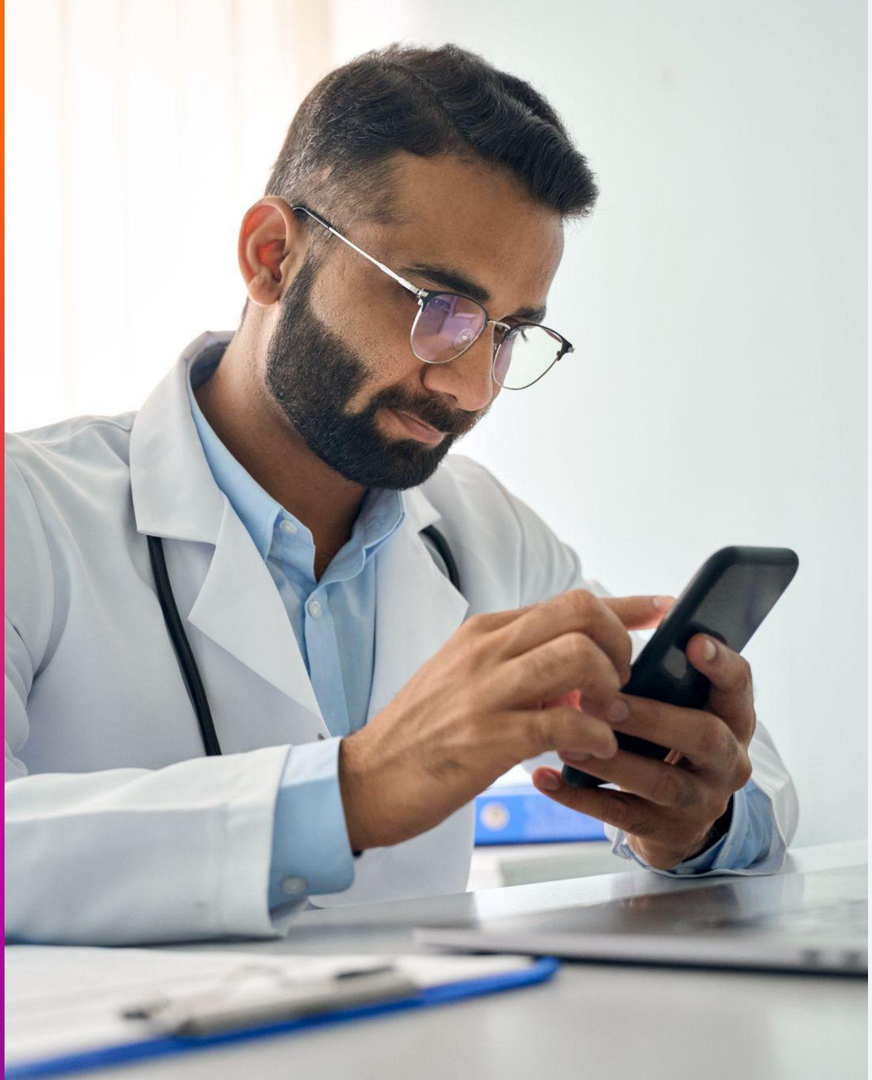
OpenClinica

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.

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Enablement Details

Auto-On	Configurable	Requestable
Ready on Day 1	User Configurable	Request Assistance
Automatically available	*Requires Configuration*	*Requires Enablement, Product Support Request*

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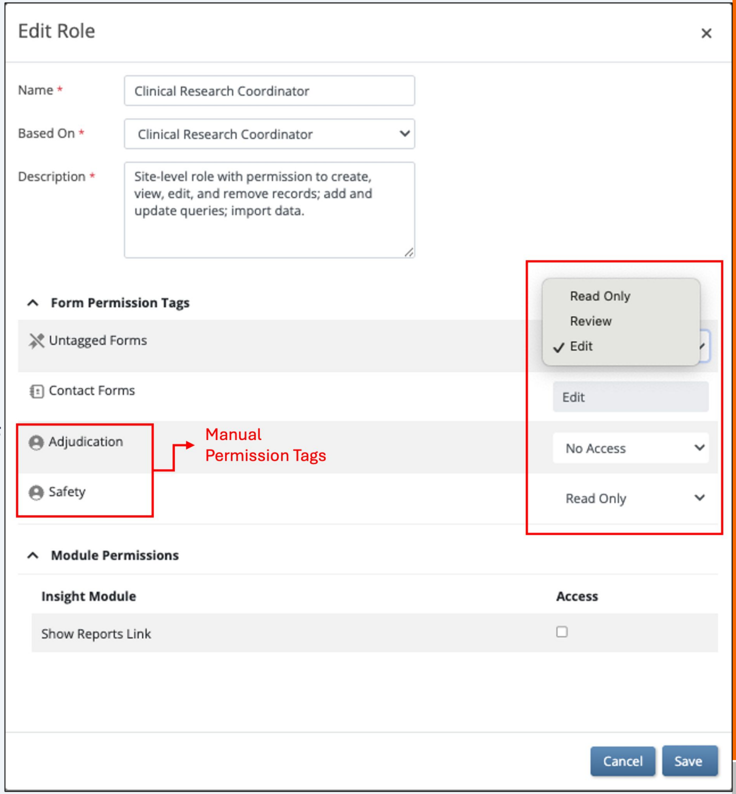
New Features

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.



Auto-On

Visible

Data Manager

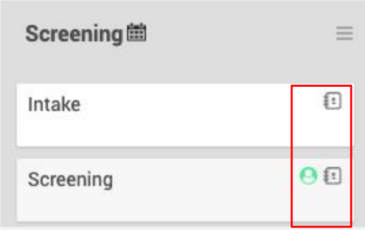
Existing roles automatically retain current permissions. No action is required for seamless transition to Stack 20.

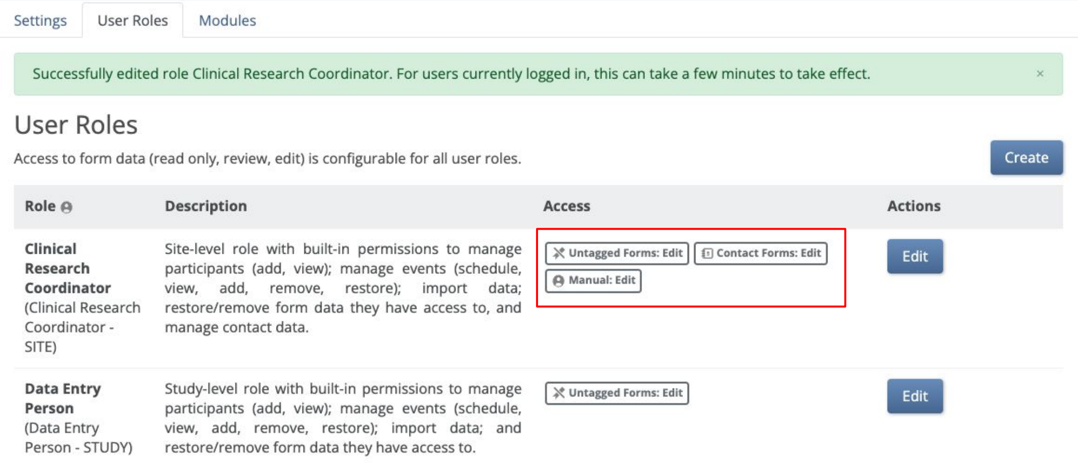
Exception: Studies where a manual permission tag is applied to contact form. More information is available here.

Configurable Form Permissions, CONT.

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.	Untagged Forms: Edit; Contact Forms: Edit; 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.	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.

Auto-On

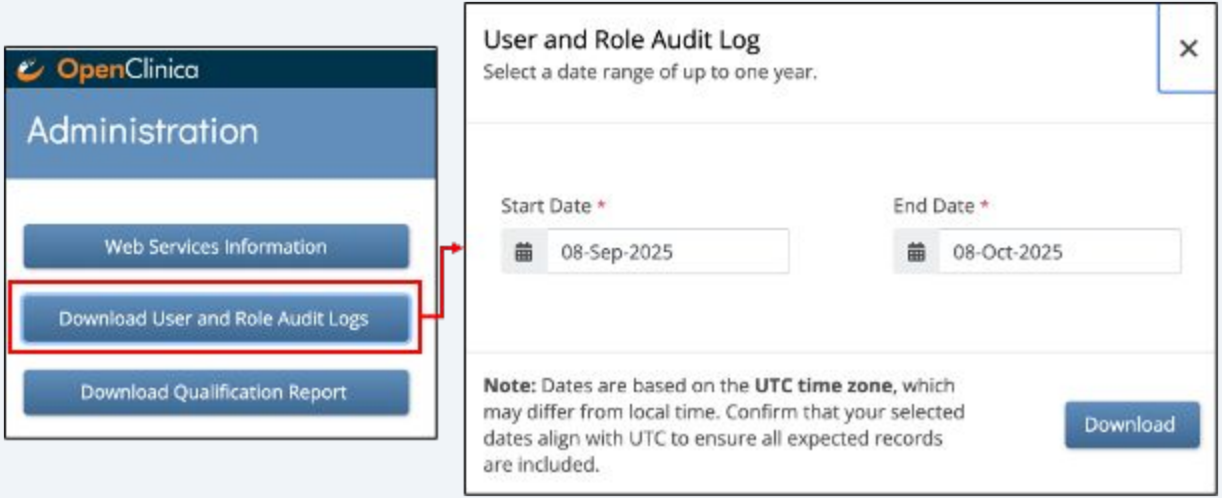
Visible

Data Manager

Changes & Fixes

Filter User and Role Audit Log Download by Date

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.



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.

Auto-On

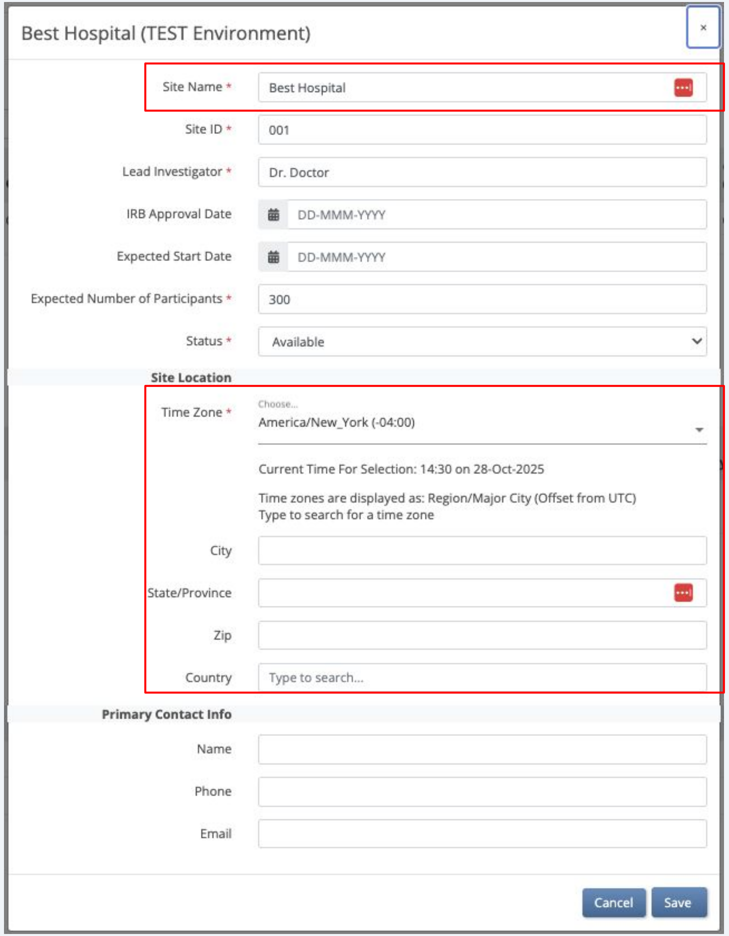
Visible

Admin User

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.



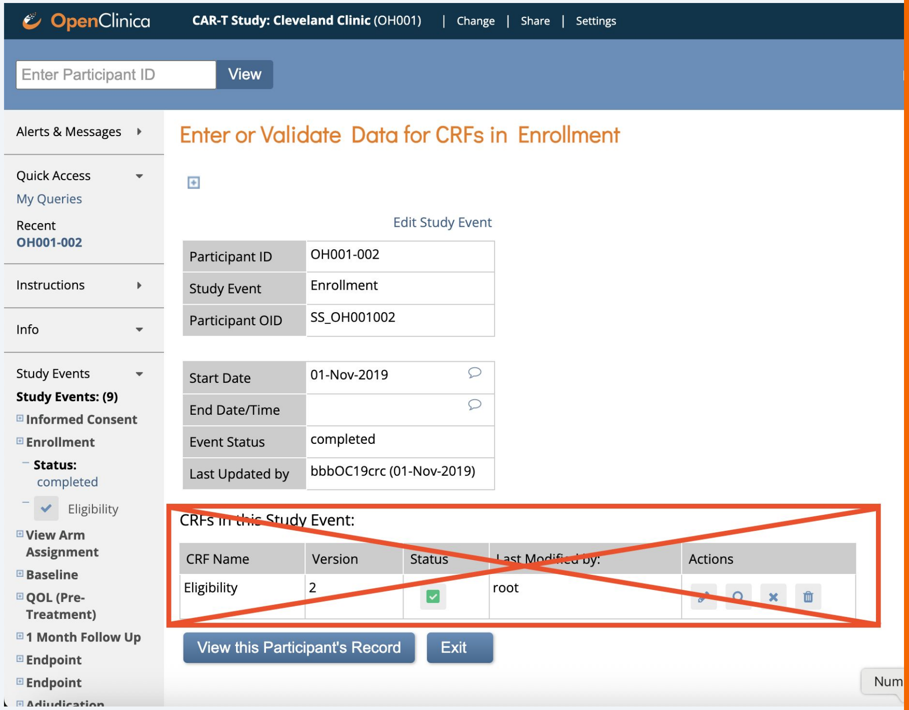
Auto-On

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.



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

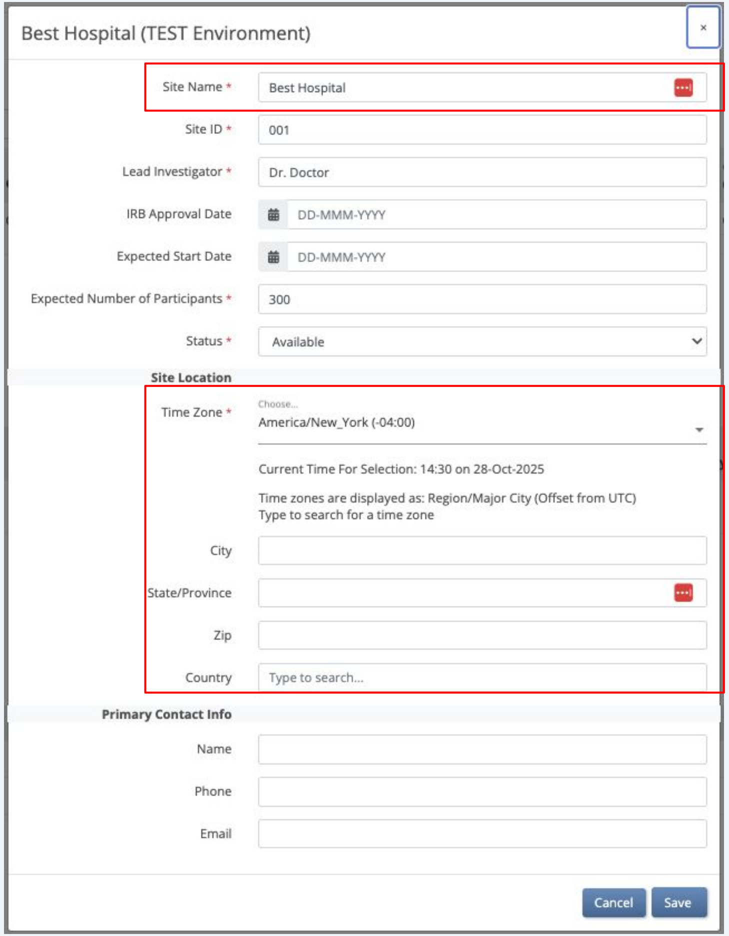
Admin User

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.



Auto-On

Visible

Admin User

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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.

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Thank you