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Stack 20.2 Impact Analysis: Study Designer & Study Runner Changes

Scheduled Release - 25 July 2026

Release Reasons

Stack 20.2 expands form-building in Study Designer with library search-and-reuse from the form card, a dedicated PII (encrypted) item type, and the ability to build and edit eConsent forms directly within Form Designer. It adds a bulk participant creation API for studies using system-generated IDs, and aligns module names across the product — including renaming OpenClinica Participate to OpenClinica eCOA. The release also includes calendaring, coding, and form reliability improvements and fixes.

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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

Search and Reuse Forms from the Form Card

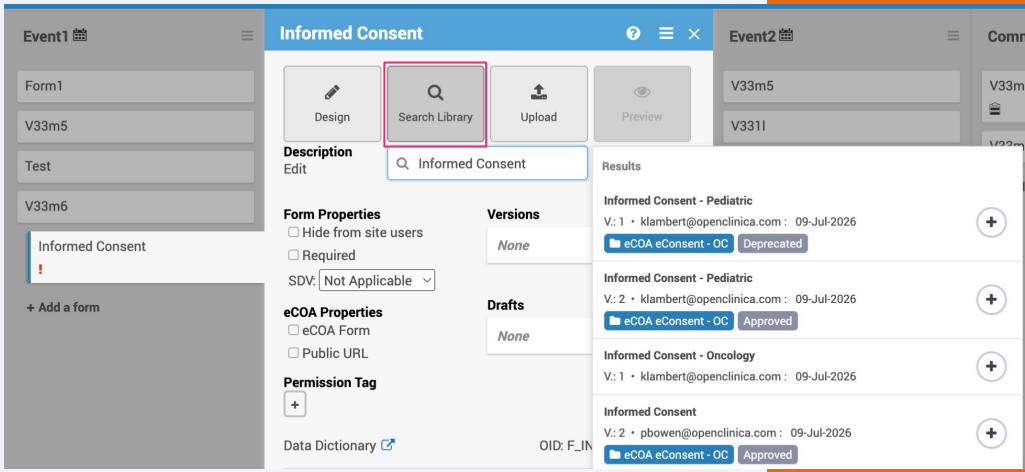
Auto-On

Change Summary

A new Search Library button on the form card lets you search your form library and add an existing form directly to the card without leaving Study Designer. You can search by form name, owner, question labels, or form labels, preview any result before adding it, and add it to the form card as a new version.

Scope of Impact

User impact:	Data Managers can find and reuse existing forms during event configuration without leaving the form-addition workflow, reducing effort and duplicate form creation.
Operational impact:	Simplifies study build and form reuse. Available within the existing form-addition process; no separate enablement by study.
Data impact:	No direct impact to study data or subject data collection.



Risks and Recommendations

The primary risk is selecting a similarly named form or template if results are not reviewed before adding; preview each result before selecting. These risks are low and limited to study configuration workflow rather than live data capture.

Visible

Data Manager

New PII (Encrypted) Item Type in Form Designer

Change Summary

Form Designer now includes a dedicated PII (encrypted) item type for collecting sensitive personally identifiable information such as a first name or email address. Previously this required adding a text item and manually setting its Use External Value to "contactdata"; the new item type handles that configuration automatically. The encryption itself works exactly as before, and existing forms with manually-configured encrypted PII now appear as this new type.

Scope of Impact

User impact:	Data Managers can add encrypted PII items directly, with no manual configuration. Existing manually configured encrypted PII items are displayed as the new type.
Operational impact:	Removes a manual, error-prone configuration step when collecting encrypted PII.
Data impact:	No change to how data is encrypted or stored; encryption behavior is unchanged. Existing encrypted PII items are reclassified for display only.

Risks and Recommendations

Risk is low. Existing manually-configured encrypted PII items will appear as the new item type when the form is opened in Form Designer. There is no change to encryption or stored data.

Auto-On

Visible

Data Manager

Build and Edit eConsent Forms in Form Designer

Change Summary

You can now build and edit eConsent forms directly in Form Designer, with full access to eConsent-specific features. The option to add an eConsent Signature item is available when the study's eConsent module is in Active or Pending status and the form is in a non-repeating Visit event.

Scope of Impact

User Impact	Data Managers can now build and edit eConsent forms, including adding the eConsent Signature item, directly in Form Designer.
Operational Impact	Data Managers no longer need to create eConsent forms using the form template — they can build and configure them directly in Form Designer. The eConsent Signature item is available when the study's eConsent module is Active or Pending and the form is in a non-repeating Visit event.
Data / Audit Impact	No direct impact to collected study or subject data. The change affects form configuration only.

Risks and Recommendations

Risk is low. Existing manually-configured eConsent items will appear as the new item type when the form is opened in Form Designer. There is no change to collected study or subject data.

User Configurable

Visible

Data Manager

Bulk Participant Creation API (System-Generated IDs)

Auto-On

Change Summary

A new API endpoint is available for studies that use system-generated participant IDs, letting API users add up to 1,000 participants to a site in a single request without calculating or supplying participant IDs externally.

Scope of Impact

User impact:	API users can bulk-create up to 1,000 participants per request for studies using system-generated IDs, without managing IDs externally.
Operational impact:	Reduces effort for large participant loads in studies configured to use system-generated participant IDs.
Data impact:	Creates participant records via the API; the endpoint generates IDs and returns the result. No impact to existing data beyond the participants created.

Risks and Recommendations

Risk is low. Confirm the study is configured for system-generated participant IDs before use, and validate the created participants after a bulk request. Limited to the participants created in the request.

Visible

Data Manager/ CRC/ Investigator

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Changes & Fixes

Module names updated to reflect our product rebrand

Auto-On

Change Summary

As part of our broader product rebrand, several modules on the Modules page have been updated to match: Participate is now eCOA, Unite is now EHR-to-EDC, Insight is now Reporting and Analytics, and Randomize is now Randomization. Recruit, eConsent, and Code are unchanged. Functionality is unchanged across all modules.

Scope of Impact

User impact:	Users will see the updated module names across the Modules page and, for eCOA, throughout Study Designer, Study Runner, and the API documentation. No functionality changes.
Operational impact:	Documentation, training materials, screenshots, or internal references that use the previous names (Participate, Unite, Insight, Randomize) should be updated to the new names.
Data impact:	No impact to study data, audit trails, or API behavior. The change is limited to display names.

Risks and Recommendations

Low risk of temporary confusion for users familiar with the previous names. Update participant-facing and internal documentation to reflect the new names, with particular attention to the Participate-to-eCOA rename, which appears across multiple areas.

Visible

Data Manager/ Administrator

Coding Respects Study and Site Status

Auto-On

Change Summary

Coding now respects a study or site's Locked, Frozen, or In Design status when determining which coding actions are allowed, consistent with other actions. Frozen allows coding; Locked and In Design do not. No changes have been made to Available status, which continues to allow coding actions.

Scope of Impact

User impact:	Users will find coding actions allowed or prevented according to the study or site status, consistent with how other actions already behave. Coding remains available in Available and Frozen statuses.
Operational impact:	Coding workflows now align with study/site lifecycle status. Coding remains available in Available and Frozen statuses. Teams should expect coding to be unavailable in Locked or In Design statuses.
Data impact:	No direct impact to existing coded data; the change governs which coding actions are permitted based on status.

Risks and Recommendations

Low risk. The change enforces existing status conventions for coding in Locked, Frozen, and In Design statuses only. Available status is unchanged. Confirm study and site status is set appropriately, since status now governs coding availability.

Visible

MedDRA Coder/ Reviewer

eCOA (Previously Participate) and Invitation Status Set to Invited when Access Code is Sent

Auto-On

Change Summary

A participant's eCOA status (previously Participate status) and Invitation status are now set to Invited whenever their access code or login link is sent — whether through a manual invitation, a Calendaring notification, or a Legacy Rule. Previously, automated notifications left these statuses as Created, which caused confusion about whether participants had been invited.

Scope of Impact

User impact:	eCOA status and Invitation status now both reflect Invited after any send, including automated notifications, giving an accurate view of who has been invited.
Operational impact:	Improves accuracy of participant status tracking. Teams relying on either status to gauge invitation progress will see consistent results across manual and automated sends.
Data impact:	Affects both the eCOA and Invitation participant status values following a send. No impact to collected form or subject data.

Risks and Recommendations

Low risk. Status reporting that previously distinguished Created from Invited for automated sends will now show Invited for both eCOA status and Invitation status; confirm any reports or workflows keyed on that distinction still behave as intended.

Visible

CRC / Investigator

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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