3.2 EDC Study Go-Live Checklist

This checklist helps study teams confirm that an OpenClinica study is ready to be published to the Production environment. Reviewing these items before go-live helps reduce risk and supports a smooth transition to active study operations.

 Note: This checklist addresses study configuration within OpenClinica only. You are responsible for completing all internal requirements for approvals, validation, training, and change control in accordance with your organization's SOPs.

Before Publishing to Production

Study Overview

Review and confirm the following:

- The study name displayed in OpenClinica is correct and approved for end-user visibility.
- The expected number of participants is configured correctly.
- If applicable, enrollment is configured to stop automatically once the target number of participants is reached.
- Participant ID configuration has been reviewed and approved:
    - System-generated participant IDs, or
    - Manually entered participant IDs, based on study requirements.

Study Visits and Events

Review visit and event configuration:

- All required study visits and events have been created.
- Each event has been reviewed to confirm:
    - Repeating versus non-repeating behavior

    - Visit-based versus common event configuration

- Visit schedules and calendaring rules reflect the approved study protocol.
- Notification rules, if used, have been reviewed and tested.
- If advanced scheduling rules were implemented by a solutions consultant:
    - All applicable scenarios have been tested.
    - Test results have been reviewed and approved.

Forms and Data Collection

Review form setup and behavior:

- All study forms are finalized, approved, and available in the appropriate visits.
- Forms appear in the correct order within each visit.
- Any required supporting files (for example, images or CSV files) have been uploaded.
- Form behavior has been reviewed and approved, including:
    - Required field configuration
    - Visibility to site users
    - Participate Properties
    - Source Data Verification (SDV) settings
    - Default form versions
        - **Note**: Additional version management can be performed under Site Settings once published.
- Permission tags have been assigned to forms and user roles(if applicable). Blinding or masking requirements have been reviewed and validated.

Roles, Access, and Permissions

Review user access and permissions:

- All required user roles are configured.
- Permissions for each role align with study responsibilities.
- Permission tags, if used, have been validated to ensure appropriate access.
- Access restrictions for blinded or masked users have been confirmed.

After Publishing to Production

Post-Publication Configuration

After publishing the study to Production and prior to collecting participant data, complete the following steps:

- Configure site-specific settings in Study Runner, as applicable (for example, Consent form versions and Public URL form links).
- Set the study status to **Available**.
- Add all applicable sites to the Production study.
- Invite users to the Production study and assign appropriate roles and site access.

Data Review and Monitoring

Verify that data review and monitoring configurations are correctly implemented:

- The Participant Matrix, Query Matrix, and Common Event tables display the expected information.
- Configured Data Review Tables align with defined study workflows.
- Monitoring and review processes support the study’s oversight and compliance requirements.

PII / PHI Reminder

If the study collects Personally Identifiable Information (PII) or Protected Health Information (PHI), verify in the audit log that the data is appropriately masked based on the contact data module and permission tags.

Functional approval by Kate Lambert. Signed on 2025-12-16 5:14PM

Approved for publication by Paul Bowen. Signed on 2025-12-22 5:31PM

Not valid unless obtained from the OpenClinica document management system on the day of use.