

CIRBI Next-Generation Onboarding FAQ

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General

What is CIRBI?

Advarra's Center for IRB Intelligence (CIRBI) is a cloud-based, fully validated, 21 CFR Part 11 compliant electronic IRB management platform. CIRBI simplifies the way sponsors, CROs, and researchers submit and manage their studies by providing an easy-to-use set of self-building SmartForms that maximizes efficiencies and reduces errors.

Why is Advarra moving customers to a new version of CIRBI?

Advarra has developed the next generation of the CIRBI platform to improve the look, feel, and efficiency of CIRBI for an overall improved user experience.

The CIRBI next-generation platform should feel modern yet familiar to all users and will provide increased stability.

Will I still have access to the current CIRBI platform after transitioning to CIRBI next-generation?

Yes. The current CIRBI platform will remain available to allow customers to access historical records. You will maintain access and your current CIRBI log in credentials and continue working there until your submissions migrate in July.

What's happening with the current CIRBI platform?

We recognize that there have been challenges with current CIRBI's performance. While we work toward moving all CIRBI users into the new platform, we are reinforcing the current system with increased resources and optimizing configurations to improve overall performance.

How is CIRBI next-generation different from the current CIRBI platform?

CIRBI next-generation functions just as the current version of CIRBI does, just much more efficiently. In addition, the new platform has a refreshed look and feel with no changes to existing workflows or functionality.

Is "CIRBI next-generation" the product name?

No. "CIRBI next-generation" is the interim phrase we are using for clarity when referring to the new platform. The product name remains CIRBI for both the current version and new version of the platform.

Does this change the IRB submission process?

No. All IRB submission requirements remain the same in CIRBI next-generation. You will experience subtle changes in navigating to your submission, but the SmartForm questions and requirements remain the same.

Can I access prior studies in the current CIRBI platform once my active studies have migrated to the new platform?

Yes. Each user will retain access to the current CIRBI platform and will be able to access historical data.

Will CIRBI next-generation be integrated with other Advarra products?

Yes. CIRBI next-generation will continue to be enhanced to work with Advarra SSO and other Advarra products over the coming months.

Is CIRBI next-generation enabled with Advarra SSO?

It is not yet integrated with Advarra SSO. We are planning to enable the new platform with Advarra SSO at a later date. You will receive more details prior to the move to SSO.

My organization uses Advarra Connect. Do I need to take any action to enable Connect for CIRBI next-generation?

No action is needed. The criteria for protocols to be eTMF-enabled will migrate when your submissions migrate to the new platform. Your existing mapping rules will be used for integration to your eTMF. If any updates are required, your Integration Services contact will reach out to your organization.

Will the CIRBI next-generation platform be available as a tile on the Advarra One homepage?

Since the new CIRBI platform is not yet enabled with Advarra SSO, it is not yet available via the Advarra One homepage. We plan to have it enabled at a later date. Users will then be able to access CIRBI via a tile on the Advarra One homepage. Please be assured we will communicate any changes well in advance.

User Activation/Registration

Will my CIRBI user login credentials change?

You will maintain your login credentials for the current CIRBI platform. However, to access and work from CIRBI next-generation, you need to activate a new CIRBI next-generation account. This includes setting up security questions and a new password for the new system.

You will receive an email invitation from no-reply@advarracloud.com when it's time for you to set up your new CIRBI account.

My current CIRBI password doesn't log me in to CIRBI next-generation.

Your current CIRBI login credentials will not work for you to access CIRBI next-generation. You need to create a new password for CIRBI next-generation by clicking the link in the user activation email you will receive from no-reply@advarracloud.com.

What email address will my user activation email come from?

Your user activation email will come from no-reply@advarracloud.com. All other communications from Advarra regarding the transition to CIRBI next-generation will come from notices@advarra.com.

I'm having trouble logging in to CIRBI next-generation. How do I get support?

Please contact support-CIRBI@advarra.com if you experience issues activating your account or logging in.

Does the PI have to activate their new account in CIRBI next-generation before a protocol can be moved over?

No. PI accounts will be migrated with the submissions, and they will receive notifications immediately.

Migration

How will I receive updates about my migration to the new platform?

Advarra will send email communications from the following email addresses:

- Notices@advarra.com
- No-reply@advarracloud.com

To ensure you are fully informed of the upcoming system upgrade, these should be on your organization's allowlist.

When will I begin IRB submissions in the CIRBI next-generation platform?

You will begin working on migrated protocols in CIRBI next-generation after your submissions have migrated to the new platform. This will take place the week of July 13. You will also begin all new IRB submissions in CIRBI next-generation this week. Advarra will email you with more detailed timelines prior to your user activation and submission migration dates.

Please note that any future study or site-level submissions for existing protocols must be done in the current CIRBI platform until they show as "**Migrated**" in the CIRBI next-generation platform.

How will I know if my studies have successfully migrated to the CIRBI next-generation platform?

Migrated studies will populate in the My Studies tab of your dashboard and display a **Migrated** status. Migrated studies will have a "**Migrated**" status in the current CIRBI platform and a "**Migrated**" label in the CIRBI next-generation platform.

Do I need to take any action on my active studies in the current CIRBI platform?

If you have any IRB submissions in process at the time of migration, those will continue to process and be completed in the current CIRBI platform. The submission will be migrated to CIRBI next-generation after completion.

What is migrated from my current system to the CIRBI next-generation platform?

Your current organization and user details will migrate into CIRBI next-generation, followed by all active submissions.

When will migrations occur?

Your current organization and user details will migrate into CIRBI next-generation prior to your User Activation. Your active submissions will migrate to CIRBI next-generation the week of July 13. Submissions continue to

migrate from current CIRBI to the CIRBI next-generation platform daily (Tuesdays through Fridays) as they are completed in current CIRBI.

Are all studies (both active and inactive) being migrated to the CIRBI next-generation platform?

No. Only active studies will be migrated into the new system. Information regarding inactive and closed studies will remain accessible to you in the current CIRBI platform.

All completed submissions for active studies will be migrated to the CIRBI next-generation platform to preserve the historic information and relationships between submissions.

Will closed studies migrate to CIRBI next-generation?

Closed studies will remain in the current CIRBI system and will not be migrated to CIRBI next-generation at this time.

What will happen to my documents and data stored in the current CIRBI platform? Will this carry over to the new platform?

Data within the current CIRBI platform will not be impacted. Active studies and submissions related to those studies will be migrated into the next generation of CIRBI along with key related data and documents.

What process will Advarra use to ensure my study information is properly migrated?

The Advarra team has previously conducted similar IRB data migration projects. Using proven processes, the Advarra team will ensure the migration is done efficiently and securely.

The process involves extensive validation to confirm data integrity, including data comparison using database scripts, comparison of import script logs with the input data, and executing import files in a validation environment.

Where can I find my archived studies?

You will retain access to your historic instance of CIRBI for any archived data you may need. We will be sure to provide advance notice prior to making any changes to the current platform.

How do I submit a modification to an existing study in CIRBI during the migration?

Any new submissions will be created and managed in the new CIRBI platform after your submissions have migrated. This will take place the week of July 13. Advarra will email you with more detailed timelines prior to your user activation and submission migration dates.

If you need to submit a modification to an active study using the current CIRBI platform, please contact your Client Success Coordinator so that we can manage this scenario in the best way for you and your organization.

Will we lose our draft initial submissions in the current CIRBI platform?

Only approved and completed IRB submissions will be migrated. Submissions in **Pre-Submission** or other **In Process** states will not be migrated and will remain in the current CIRBI system until completed.

Will investigator and site information migrate over to the CIRBI next-generation platform?

Site information, including address, phone number, and website, will be migrated. Some investigator data will also be migrated, while some will need to be re-entered in the new CIRBI. Investigator data that will migrate to the new platform includes name, contact information, CV, and audit entries.

To use the IRB Ready feature that pre-populates submission forms, investigators will be asked to complete profile information on their first site submission or single-site protocol in the CIRBI next-generation platform.

Am I able to add new submissions in current CIRBI once I have migrated to the new CIRBI platform?

After your organization migrates to the new CIRBI platform, we will prevent new submissions in the current CIRBI platform.

Will submitting sites be able to access protocol level submissions?

Site users have access to the study(ies) the user is assigned to as a contact in CIRBI.

Will we still receive an email alerting us that action is needed, as we do in CIRBI currently?

Yes, you will receive both an email and in-application notification.

Will there be any downtime during the migration process?

Users should not experience any downtime during the migration process.

Legal/Contracts/QA

Will there be any changes to the invoicing processes?

No, the move to the new CIRBI platform makes no changes to how you are invoiced.

Who would I reach out regarding system validation documentation for CIRBI next-generation?

Please contact qualityassurance@advarra.com.

Who should I contact about auditing Advarra's IRB?

Please contact qualityassurance@advarra.com.

Does this impact my contract with Advarra?

No, the move to the new CIRBI platform has no impact on your existing contract with Advarra.

Will the name of documents listed on approval letters match the names of the documents posted on CIRBI next-generation?

The experience in CIRBI next-generation will be the same as your current CIRBI experience in regards to the naming convention of documents and approval letters.

Resources

Where can I find additional resources?

The below CIRBI next-generation resources are also available for users:

- **CIRBI Next-Generation Documentation Website** - This website (linked within the footer of the CIRBI next-generation application) contains system documentation for the CIRBI next-generation platform in addition to paths for training and support. You can access these materials after you activate your new user account and have access to the new platform. Simply click the link in the footer and select the CIRBI tile.
- **CIRBI Next-Generation Onboarding Resources** - FAQs and Onboarding Guides are available on the CIRBI Next-Generation Documentation website referenced above. The Onboarding Guide is a detailed overview of what you can expect week-to-week during your transition to the new platform.

What training is available for me to learn about the CIRBI next-generation platform?

Advarra has the following training materials specific to the CIRBI next-generation platform available:

- **CIRBI Next-Generation Training Modules** - New eLearning modules specific to CIRBI next-generation are available for you to learn more about the platform.
 - If you have an [Advarra University](#) account, you can find these modules there.
 - If not, we recommend you complete this training through the [Advarra IRB Training Portal](#). You can find information on how to register for an IRB Training Portal account and which modules are specific to CIRBI next-generation in the Onboarding Resources section of the Documentation website.
 - Please note that training is recommended, not required.
- **The next-generation of CIRBI self-guided demo** – Take a tour of the new platform to learn how its modern visuals and updated features enhance and optimize the submission process.

How can I suggest features or improvements to the new CIRBI next-generation platform?

Please send any enhancement ideas to your Client Success Coordinator.

How do I get support?

There are dedicated support paths for both the current CIRBI platform and the CIRBI next-generation platform. If you have questions about your move to CIRBI next-generation, please contact support-CIRBI@advarra.com.