Drug Development Tool (DDT)

Reference Guide

Click [here](#) to access the CDER NextGen Portal.

Supported Browsers: Google Chrome, Microsoft Edge and Mozilla Firefox

Table of Contents

Introduction

Welcome to the Drug Development Tool Reference Guide! This guide describes the process for qualifying drug development tools intended for potential use, over time, in multiple drug development programs. Drug Development tools (DDTs) are methods, materials or measures that aid drug development. DDTs include, but are not limited to, Biomarkers, Clinical Outcome Assessments (COA) and animal models for drug development. This reference guide provides submission instructions for interactions between the Center of Drug Evaluation and Research (CDER) and the entity proposing the DDT for qualification (the submitter).

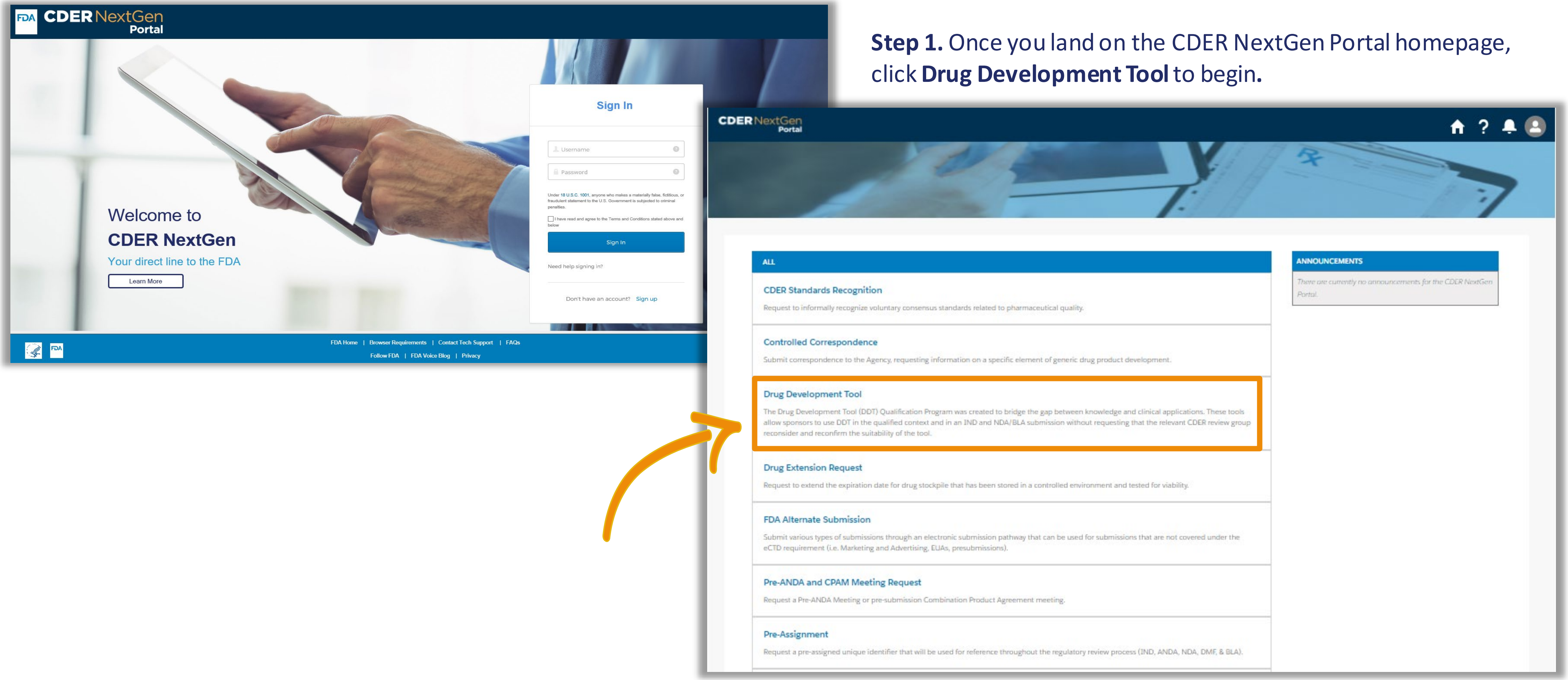
For business assistance regarding Biomarker Qualifications Program, contact (CDER-BiomarkerQualificationProgram@fda.hhs.gov)

For business assistance regarding Animal Model, contact (CDERAnimalModelQualification@fda.hhs.gov)

For business assistance regarding Clinical Outcome Assessments, contact (COADDTQualification@fda.hhs.gov)

CDER NextGen Portal Homepage

Step 1. Once you land on the CDER NextGen Portal homepage, click **Drug Development Tool** to begin.



Submitting a Letter of Support
(Only Biomarker Qualification Program Type)

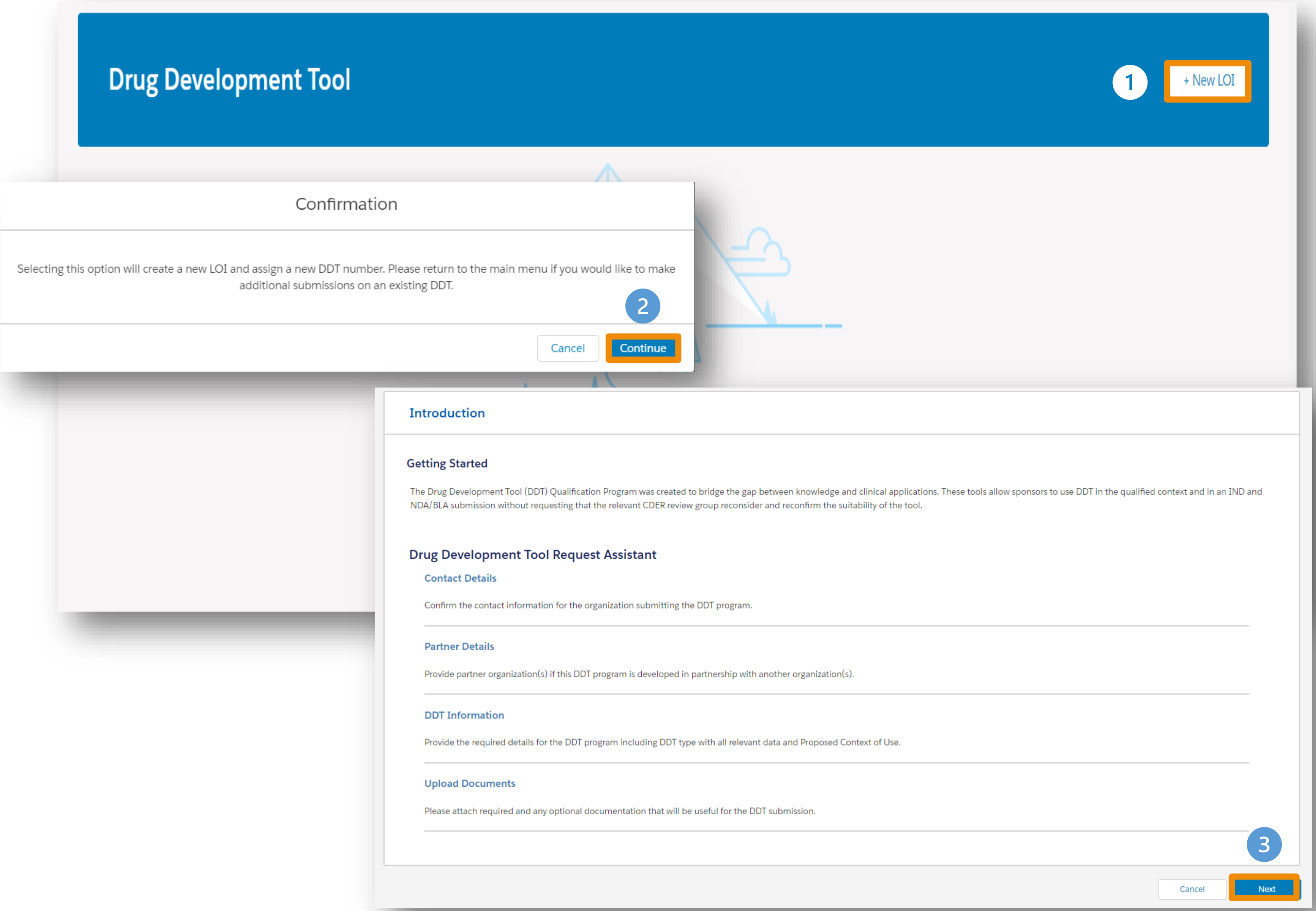
Drug Development Tool

Create a Submission

Step 1. Click **+ New LOI.**

Step 2. Click **Continue** if you would like to create a new LOI/LOS and be assigned a new DDT number. Return to the main menu if you would like to make additional submissions for an existing DDT.

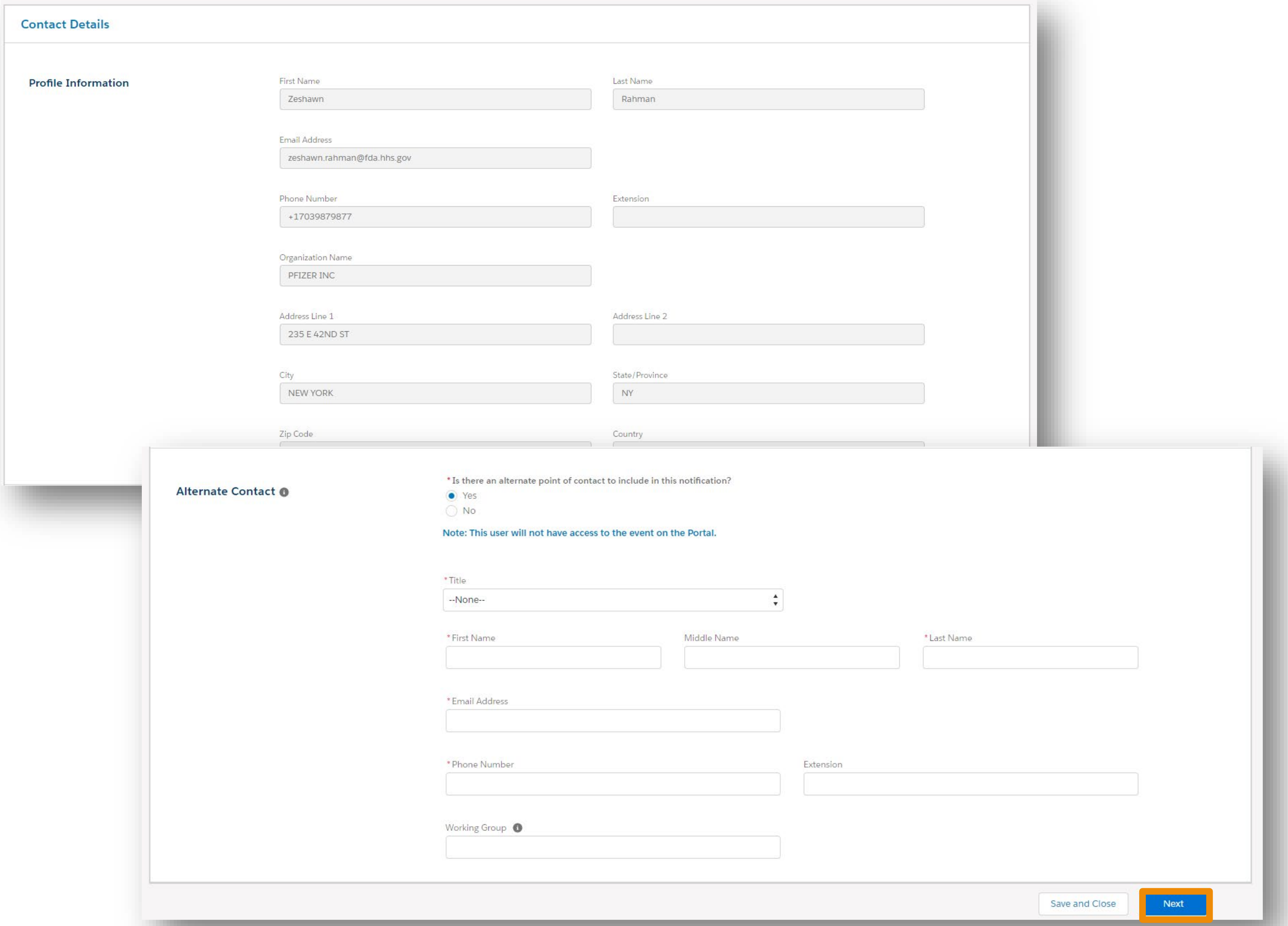
Step 3. Review the **Getting Started** information for submitting an **LOS/LOI.** Then click **Next.**



Contact Details

Step 4. Review the pre-populated information in the Profile Information section.

Step 5. If there is an alternate point of contact, select Yes and provide the information requested. Then click **Next**.



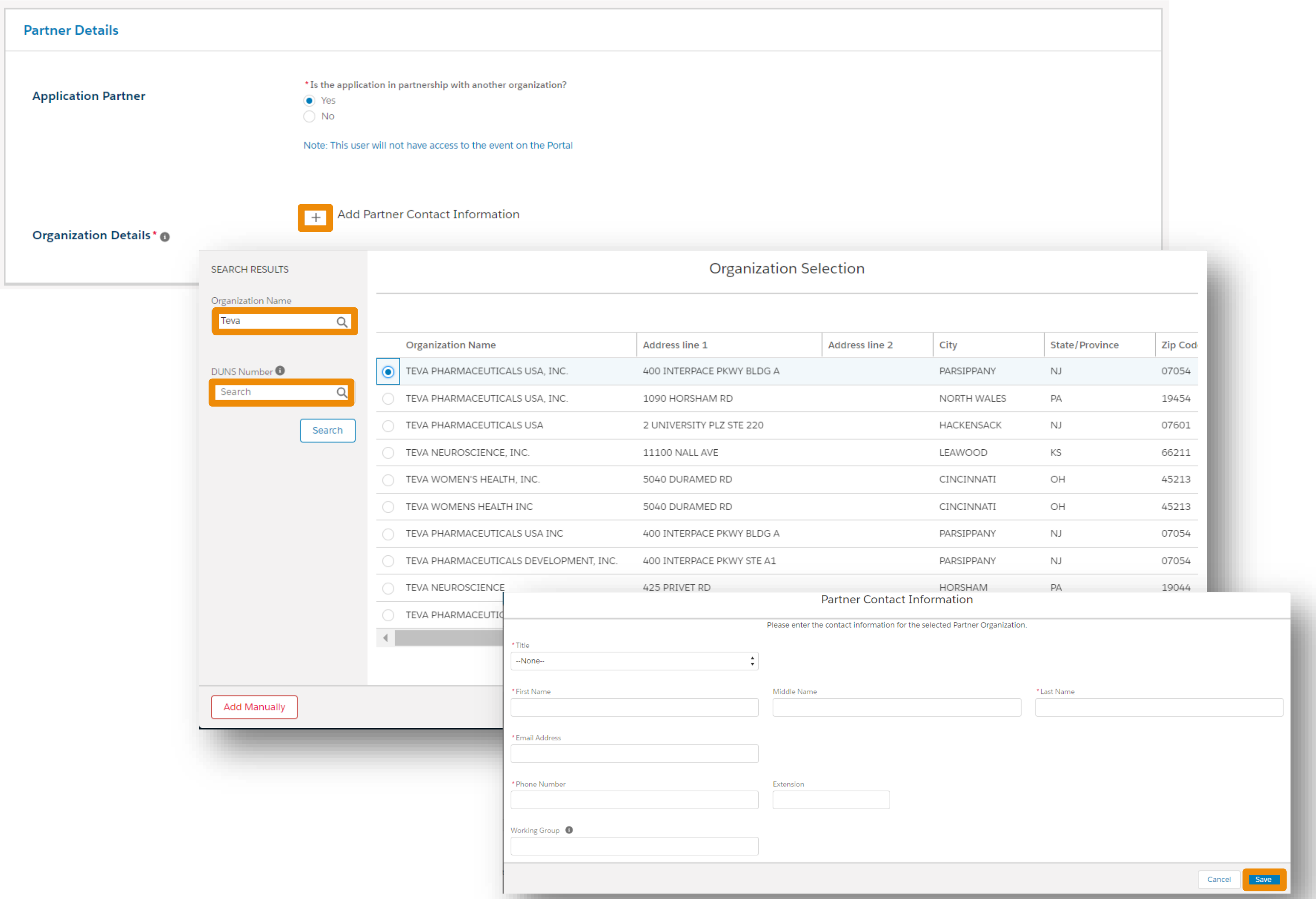
Partner Details

Step 6. Select **Yes** or **No** if the application is in partnership with another organization.

Step 7. If **No**, then click **Next**. If **Yes**, click on the **+** icon to add Partner Contact Information.

Step 8. Enter the Organization Name or DUNS Number, then click **Search**.

Step 9. Enter the contact information requested then select **Save** then click **Next.**



DDT Information

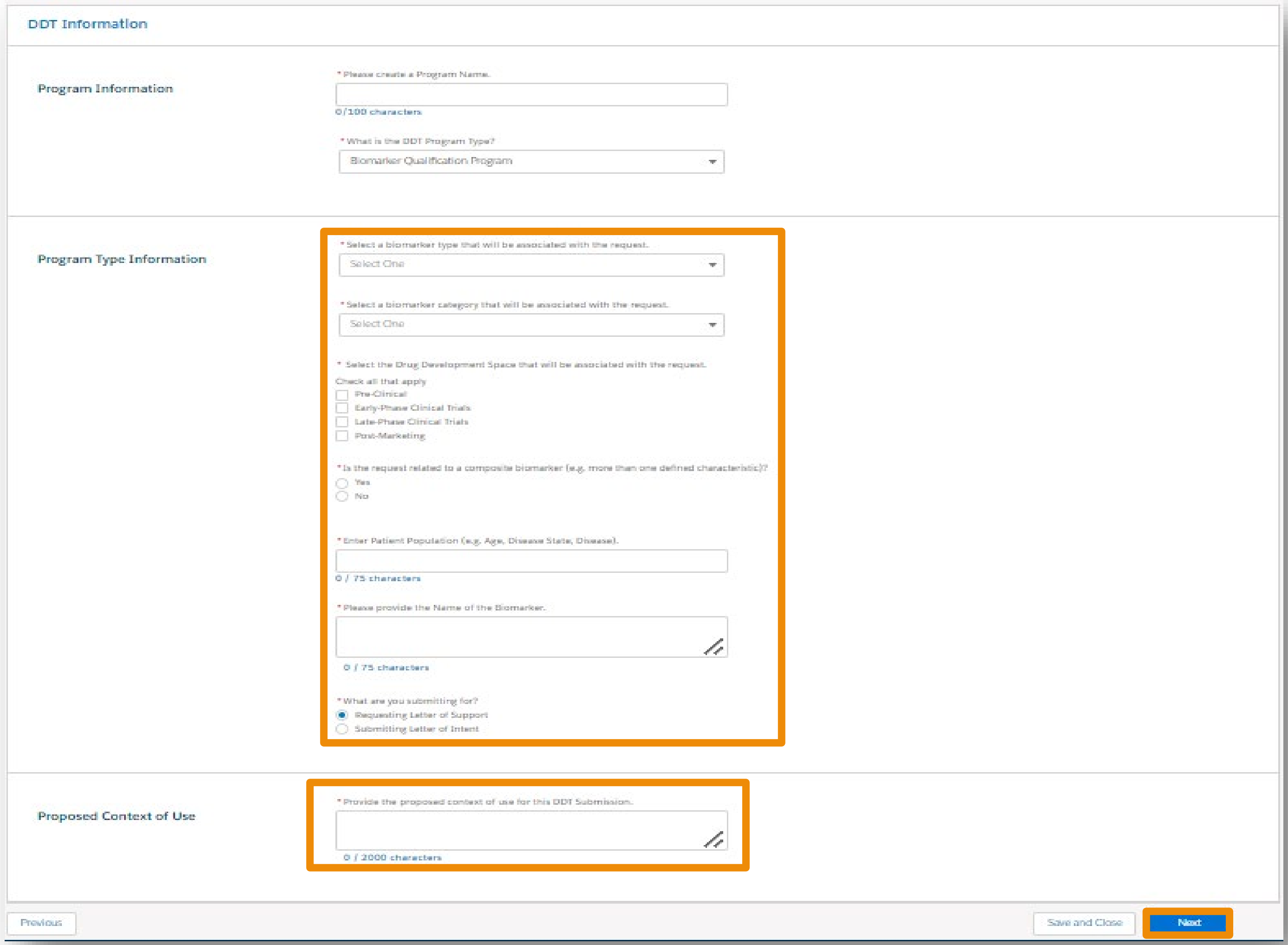
Step 10. In the DDT Information section, enter a **Program Name**.

Step 11. Select "**Biomarker Qualification Program"** from the **DDT Program Type** drop-down menu.

Step 12. Provide a response to all the required information.

Step 13. Select **Requesting Letter of Support** when asked "What are you submitting for?"

Step 14. Provide the Proposed Context of Use for this DDT Submission in the text box then click **Next**.



Upload Documents

Step 15. Upload a **Letter of Support** by clicking the arrow and selecting **Upload Files.** Browse your computer and select a file to upload or drag and drop a file into the designated area on the screen.

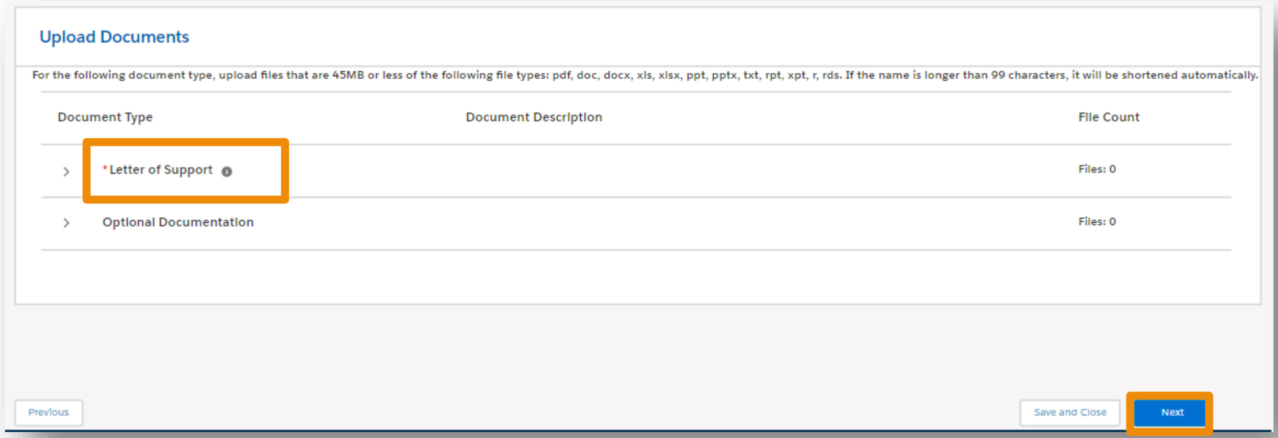
Step 16. Provide optional documentation if needed.

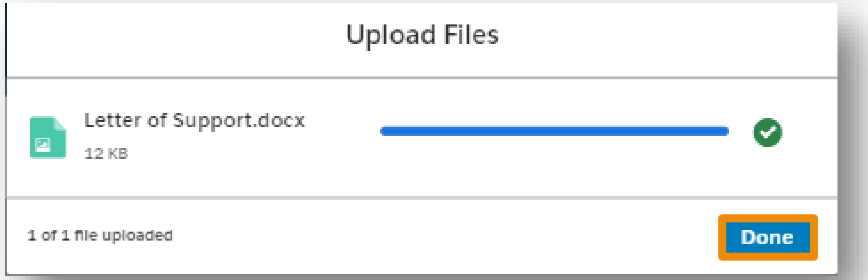
Step 17. Once the document has been uploaded, click Done.

Step 18. Click **Next.**

It is mandatory to upload a "**Letter of Support**" as part of this submission.

The allowable formats for uploading a document are pdf, doc, docx, xls, xlsx, ppt, pptx, txt, rpt, xpt, r, and rds. The maximum file size allowed is 45MB per file.





Review and Submit

Step 19. Review your entry for accuracy.

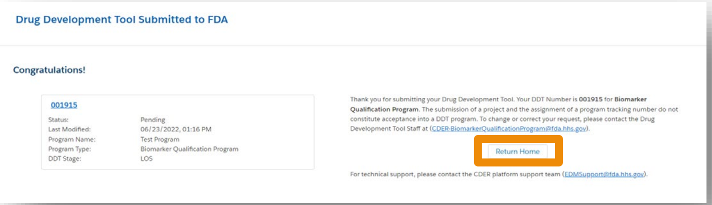
Step 20. Prior to submitting, you will have the option to either **Save as Draft** or **Delete** your submission.

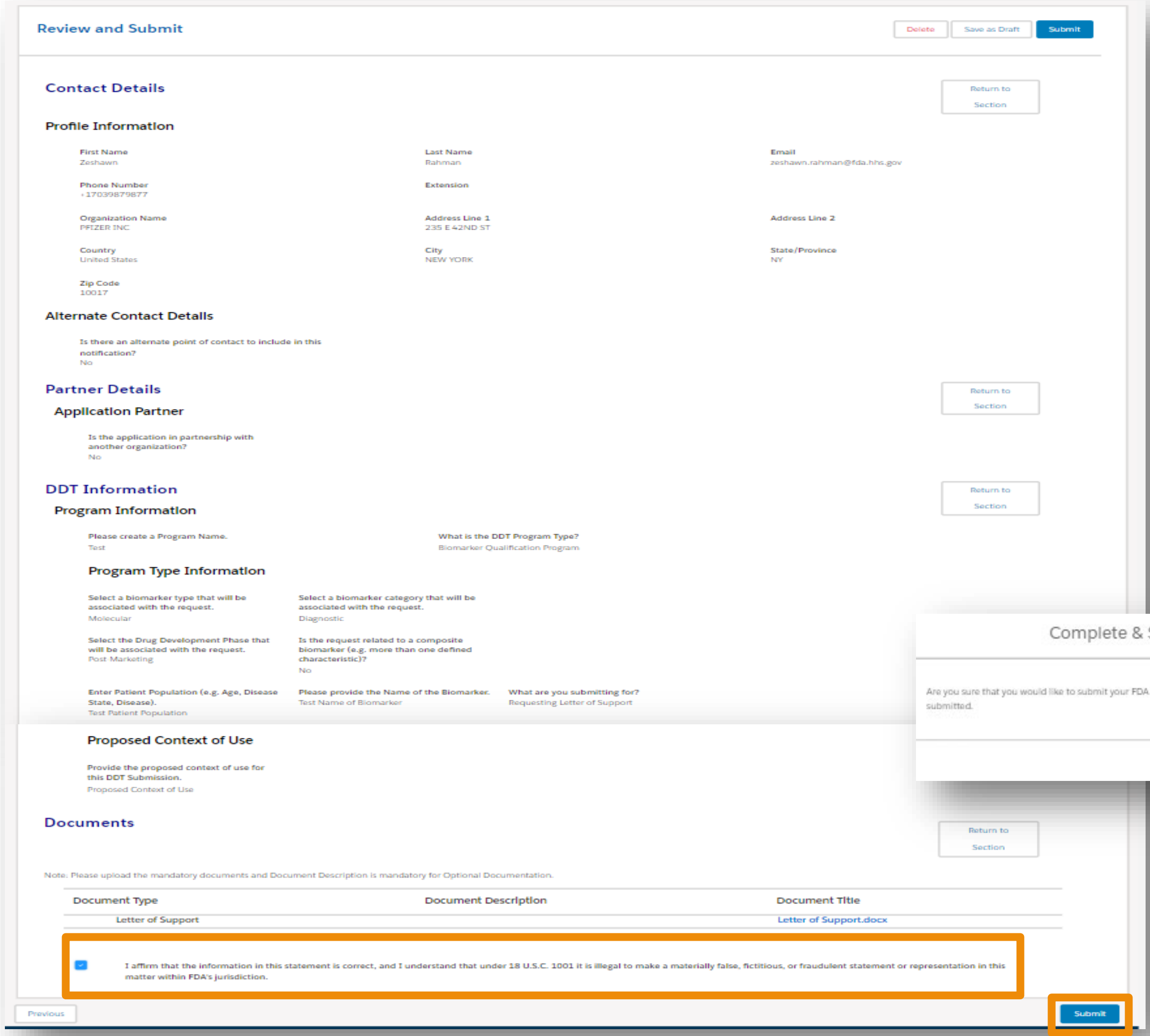
Step 21. Click the check box verifying that information you provided is accurate.

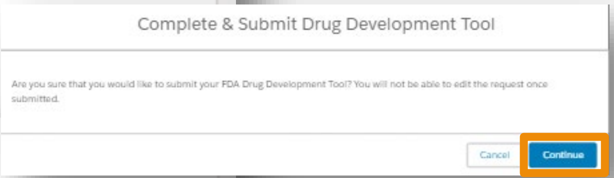
Step 22. Once ready, click **Submit.**

Step 23. A confirmation message will appear, and a confirmation e-mail will be sent.

Step 24. You may now click **Return Home.**







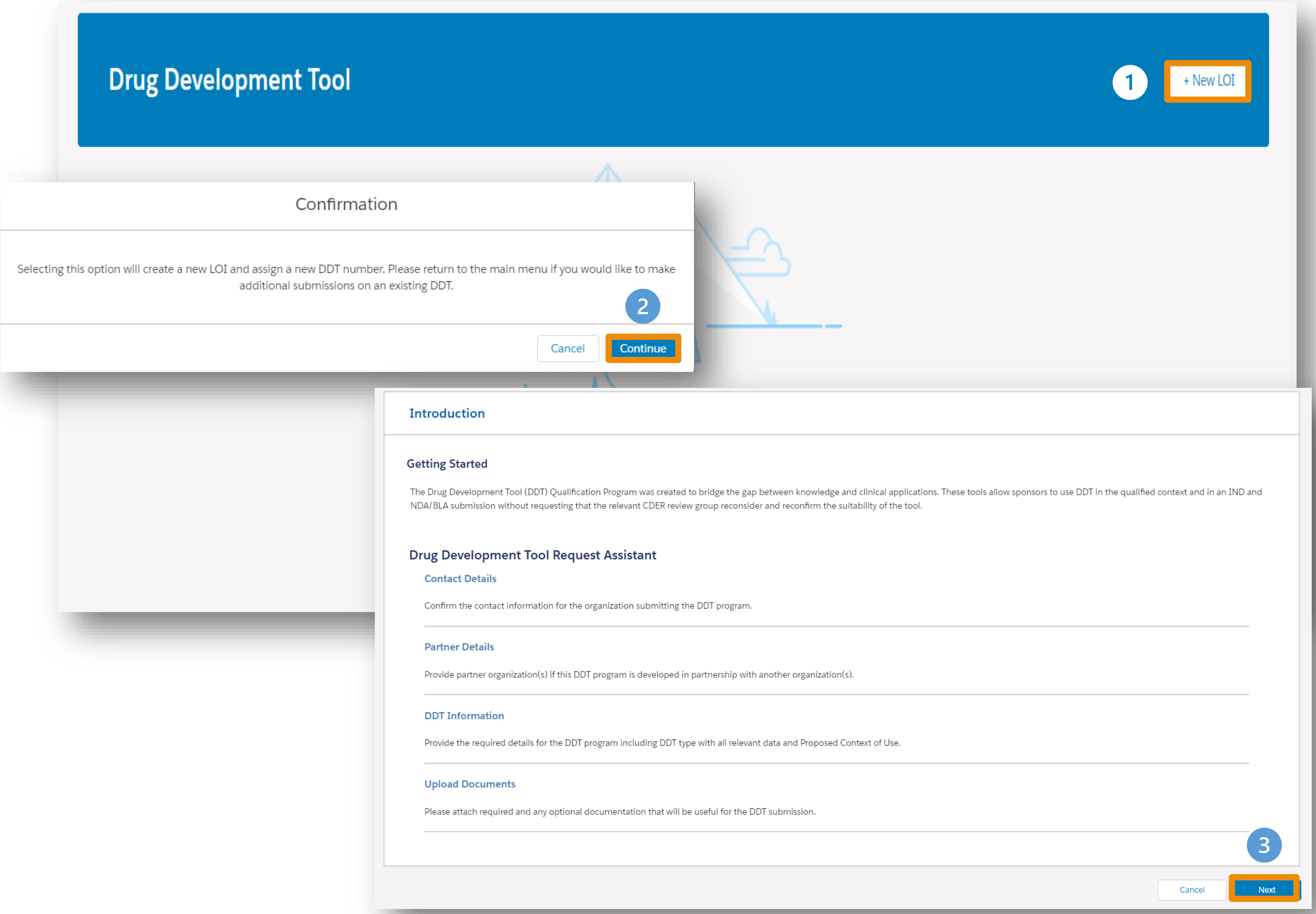
Submitting a Letter of Intent (All Program Types)

Create a Submission

Step 1. Click **+ New LOI.**

Step 2. Click **Continue** if you would like to create a new LOI and be assigned a new DDT number. Return to the main menu if you would like to make additional submissions for an existing DDT.

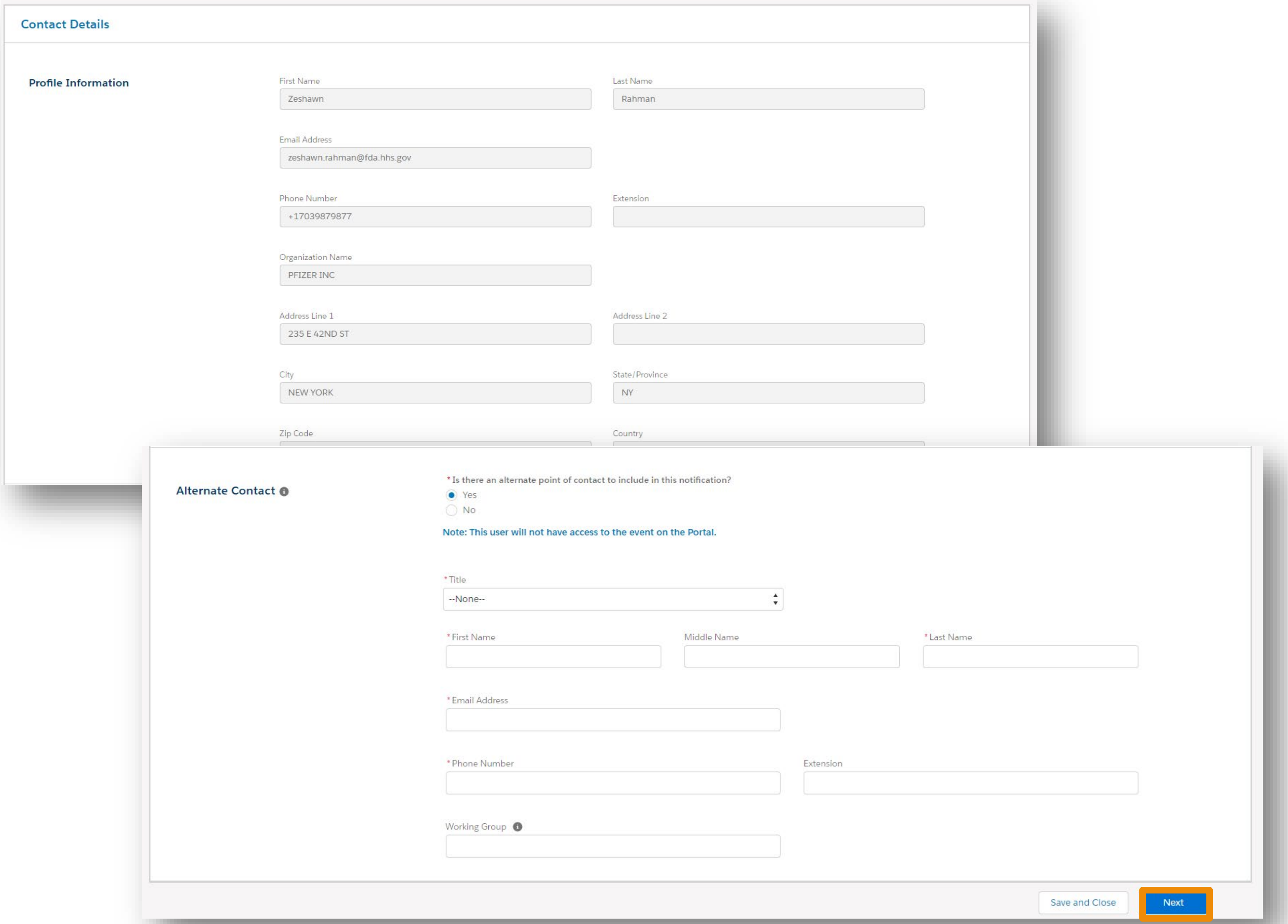
Step 3. Review the **Getting Started** information for submitting an LOI. Then click **Next.**



Contact Details

Step 4. Review the pre-populated information in the Profile Information section.

Step 5. If there is an alternate point of contact, select Yes and provide the information requested. Then click **Next**.



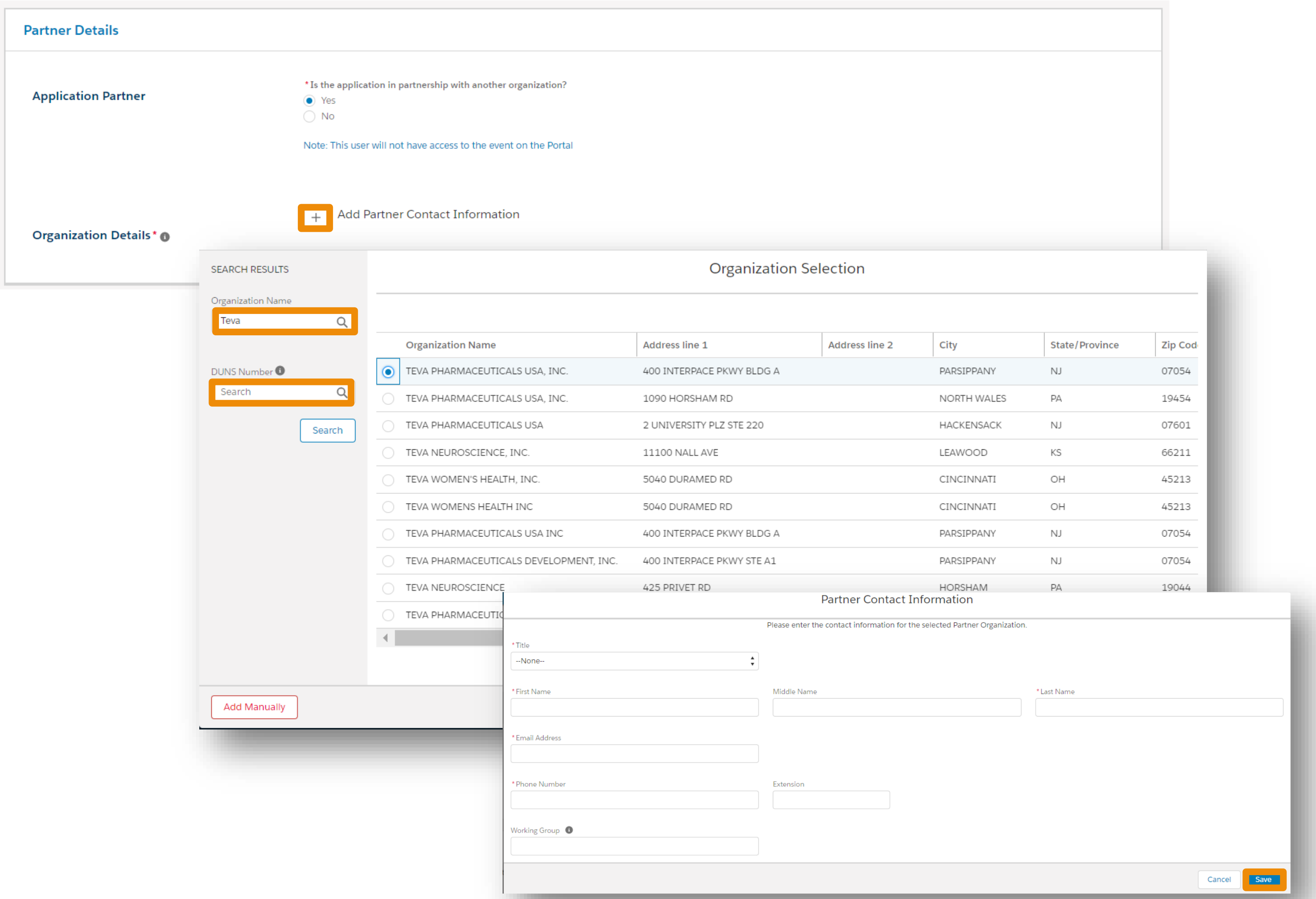
Partner Details

Step 6. Select **Yes** or **No** if the application is in partnership with another organization.

Step 7. If **No**, then click **Next**. If **Yes**, click on the **+** icon to add Partner Contact Information.

Step 8. Enter the Organization Name or DUNS Number, then click **Search**.

Step 9. Enter the contact information requested then select **Save** then click **Next**.

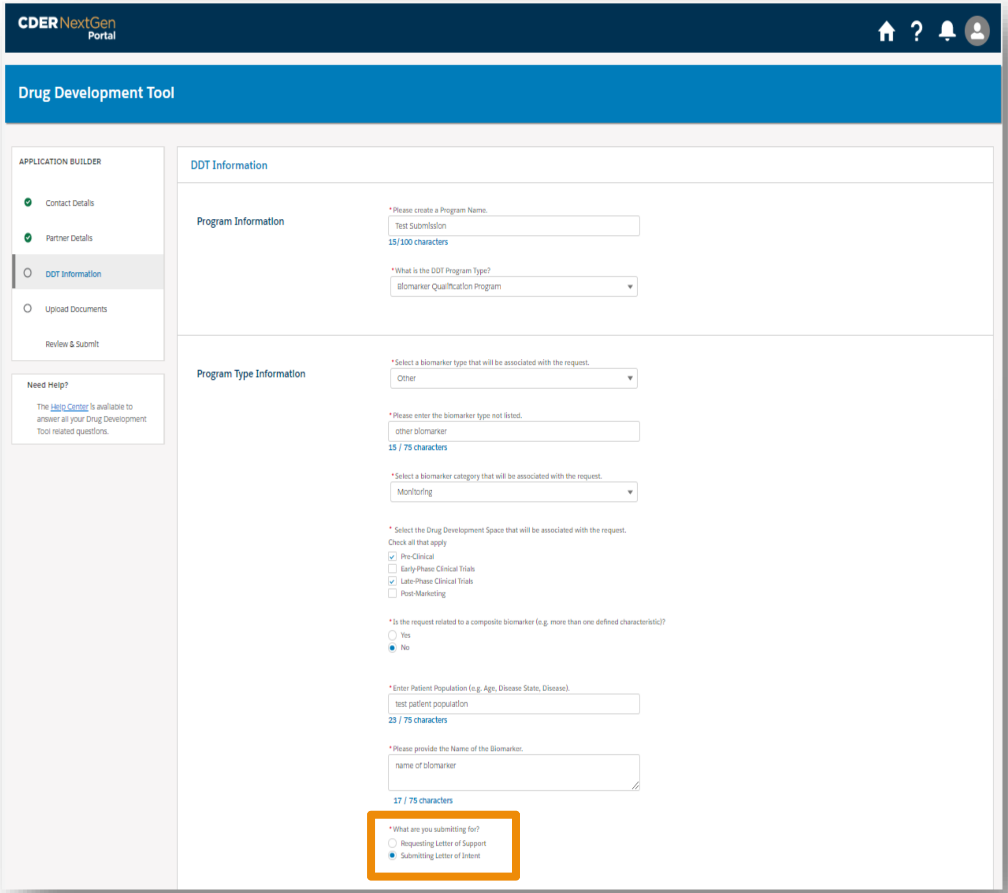


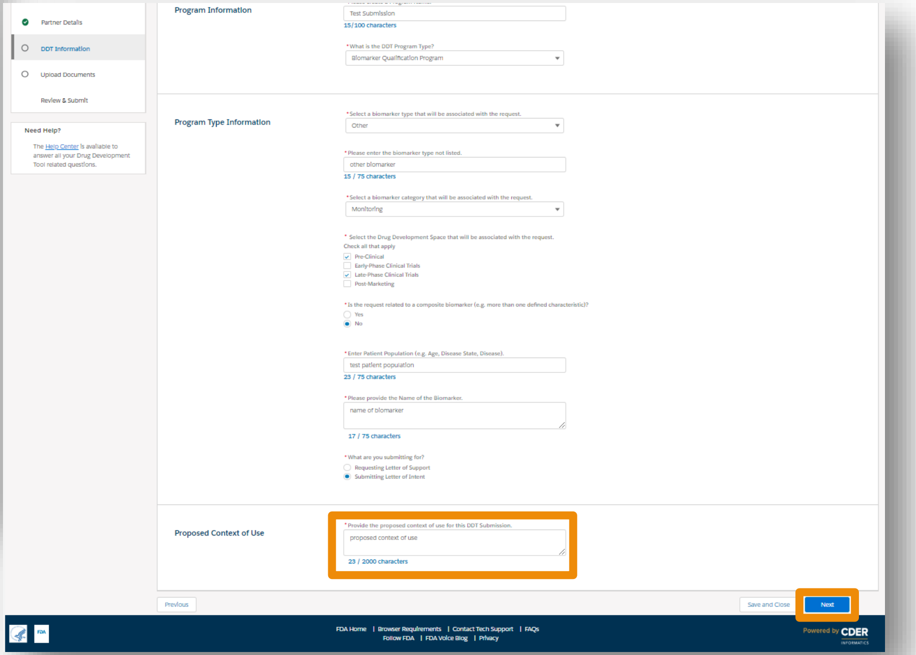
DDT Information

Step 10. In the **DDT Information** section, enter the information requested.

Step 11. If asked to select "What are you submitting for?, select **Submitting Letter of Intent.**

Step 12. Provide the Proposed Context of Use for this DDT Submission in the text box then click **Next**.





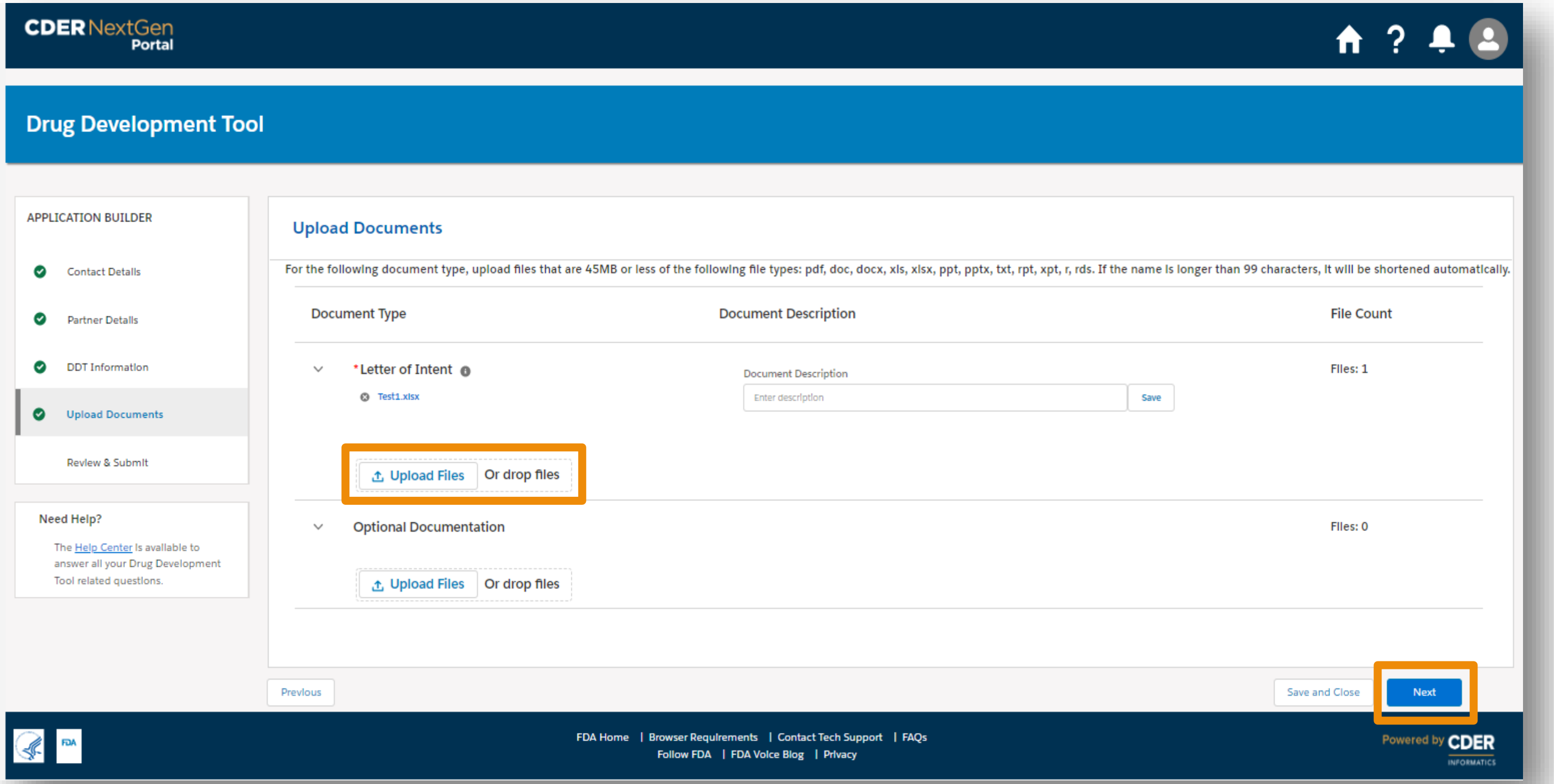
Upload Documents

Step 13. Upload a **Letter of Intent** by clicking the arrow and selecting **Upload Files.** Browse your computer and select a file to upload or drag and drop a file into the designated area on the screen.

Step 14. Provide optional documentation if needed.

Step 15. Once the document has been uploaded, click Done.

Step 16. Click **Next.**



It is mandatory to upload a "**Letter of Intent**" as part of this submission.

The allowable formats for uploading a document are pdf, doc, docx, xls, xlsx, ppt, pptx, txt, rpt, xpt, r, and rds. The maximum file size allowed is 45MB per file.

FDA

Review and Submit

Step 17. Review your entry for accuracy.

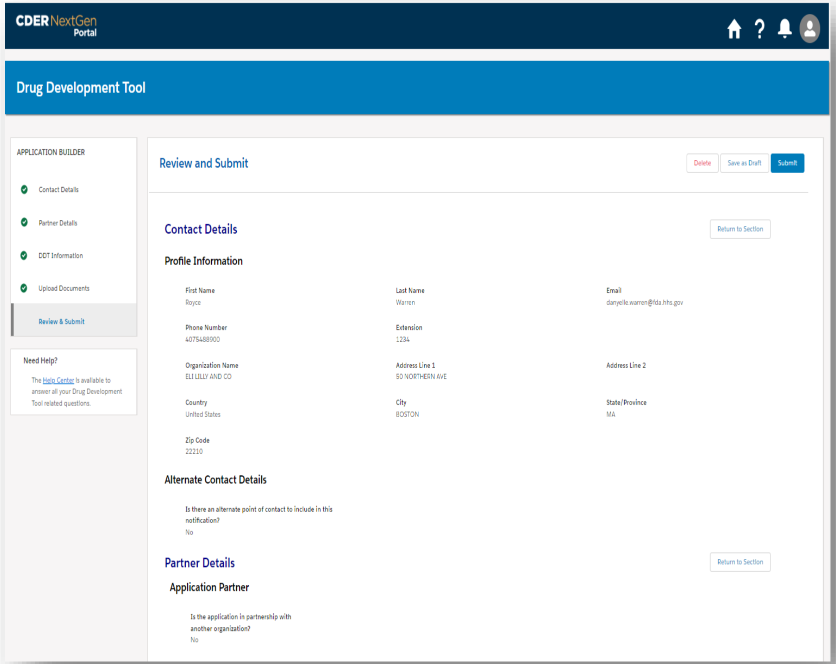
Step 18. Prior to submitting, you will have the option to either **Save as Draft** or **Delete** your submission.

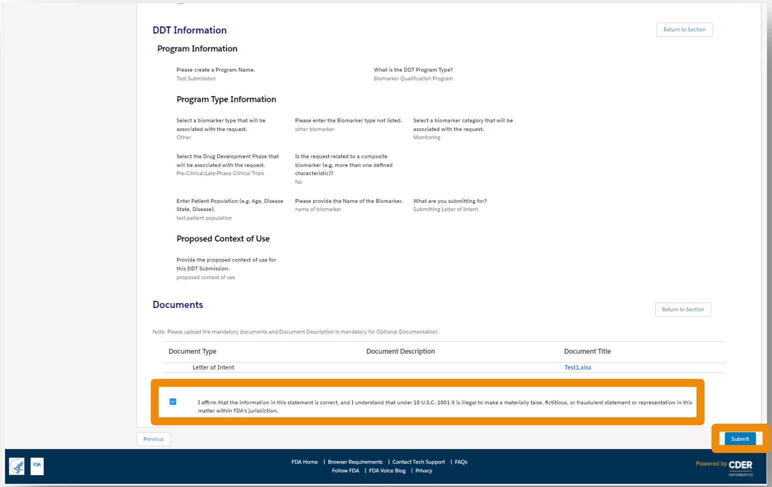
Step 19. Click the check box verifying that information you provided is accurate.

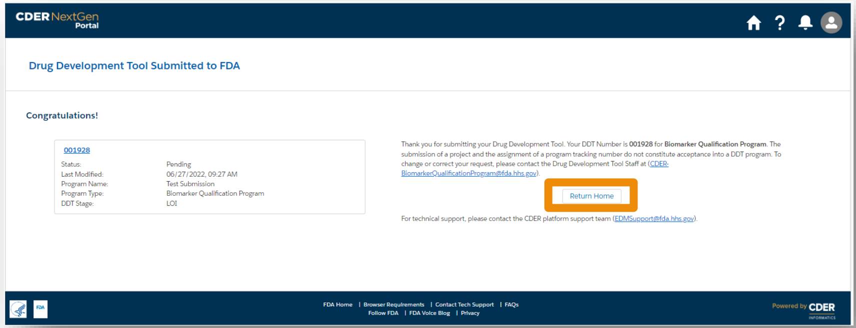
Step 20. Once ready, click **Submit**.

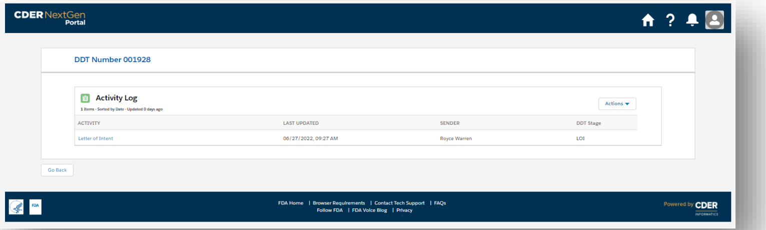
Step 21. A confirmation message will appear, and a confirmation e-mail will be sent.

Step 22. You may now click **Return Home**









Submitting a Pre-Qualification Plan (Pre-QP) or Qualification Plan (QP)
(All Program Types)

Drug Development Tool

Submitting a Pre-QP (Optional before QP)

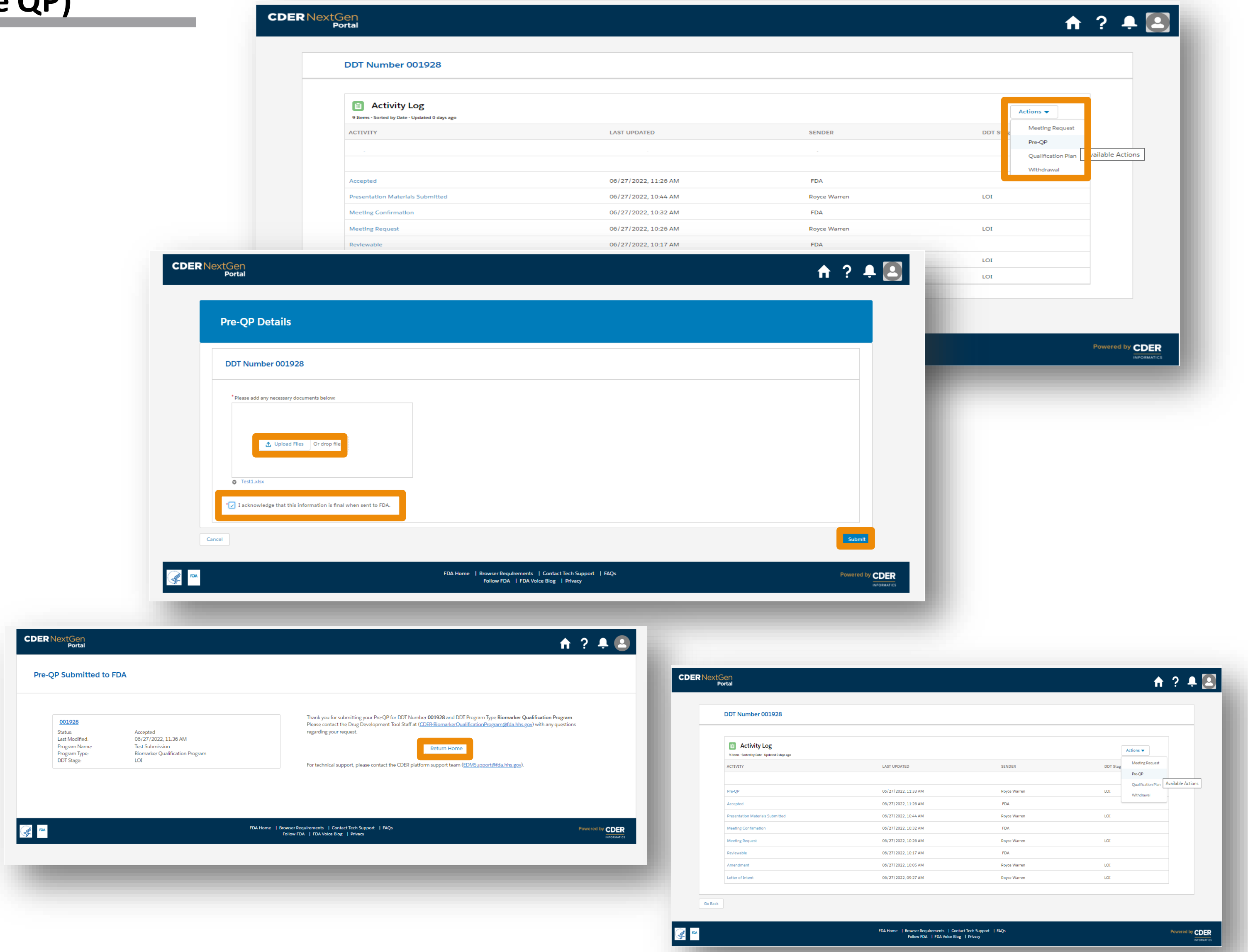
Step 1. Within the Drug Development Tool use case, navigate to the **Activity Log** by selecting your DDT Number from the landing page, click the **Actions** dropdown and then select **Pre-QP**.

Step 2. Upload any necessary documents by clicking the arrow and selecting **Upload Files.** Browse your computer and select a file to upload or drag and drop a file into the designated area on the screen.

Step 3. Once the document has been uploaded, click **Done**.

Step 4. Click the check box acknowledging that information you provided to the FDA is final. Then click **Submit.**

Step 5. On the confirmation screen click **Return Home.**



Submitting a QP

Step 1. Within the Drug Development Tool use case, navigate to the **Activity Log** by selecting your DDT Number from the landing page, click the **Actions** dropdown and then select **Qualification Plan**.

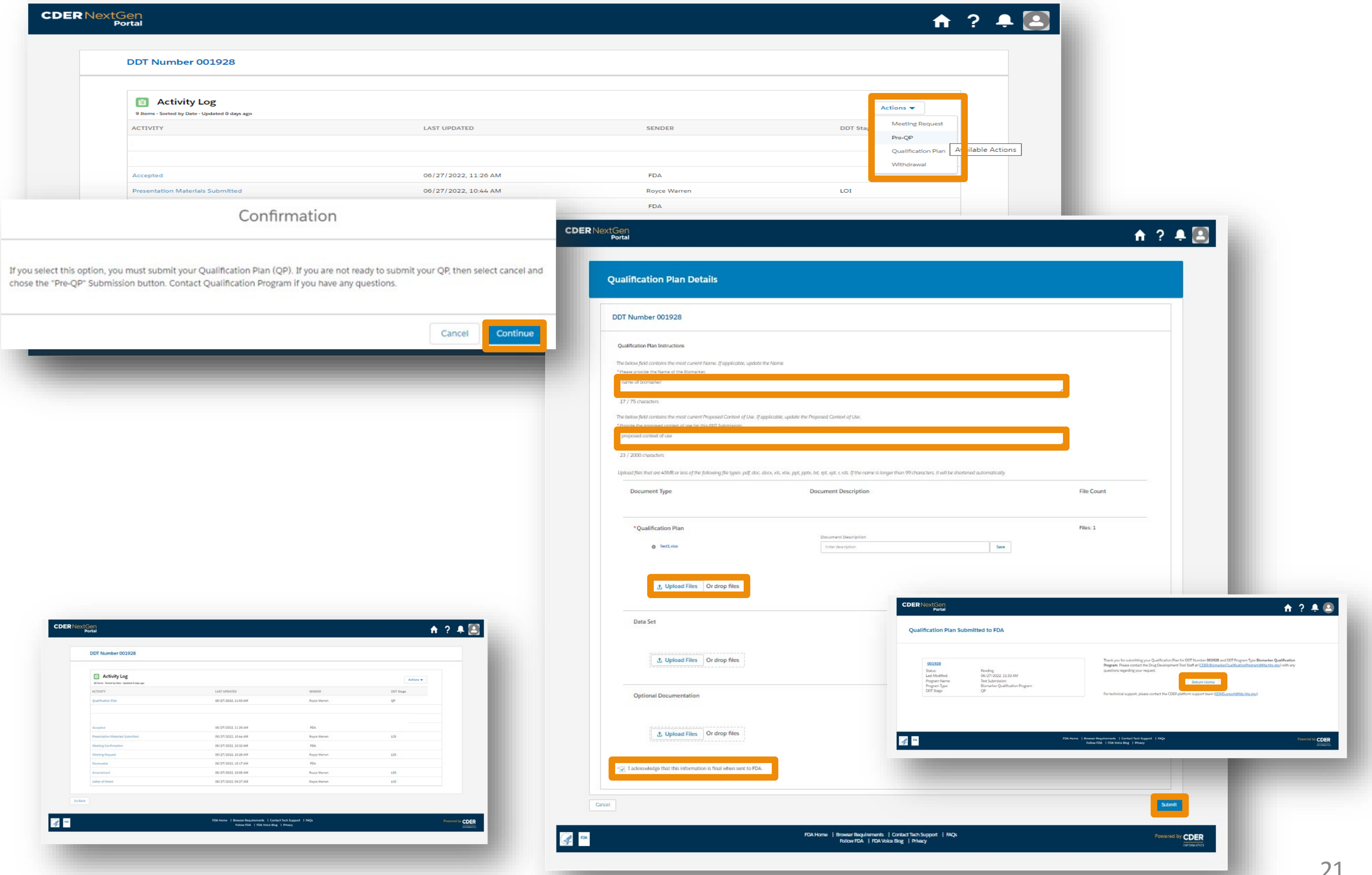
Step 2. Click **Continue** on the pop-up screen.

Step 3. In the **Qualification Plan Details** page, provide the requested information.

Step 4. Upload the **Qualification Plan** by clicking the arrow and selecting Upload Files. Browse your computer and select a file to upload or drag and drop a file into the designated area on the screen.

Step 5. Click the check box acknowledging that information you provided to the FDA is final. Then click **Submit**.

Step 6. On the confirmation screen click **Return Home**.



Submitting a Pre-Full Qualification Plan (Pre-FQP) or Full Qualification Plan (FQP) (All Program Types)

Drug Development Tool

Submitting a Pre-FQP (Optional before FQP)

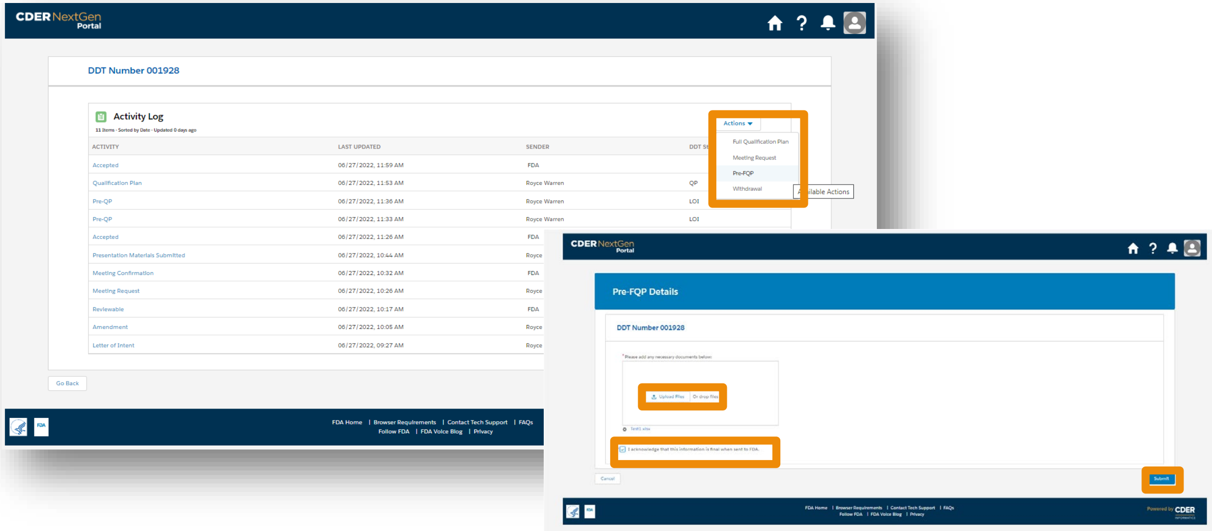
Step 1. Within the Drug Development Tool use case, navigate to the **Activity Log** by selecting your DDT Number from the landing page, click the **Actions** dropdown and then select **Pre-FQP**

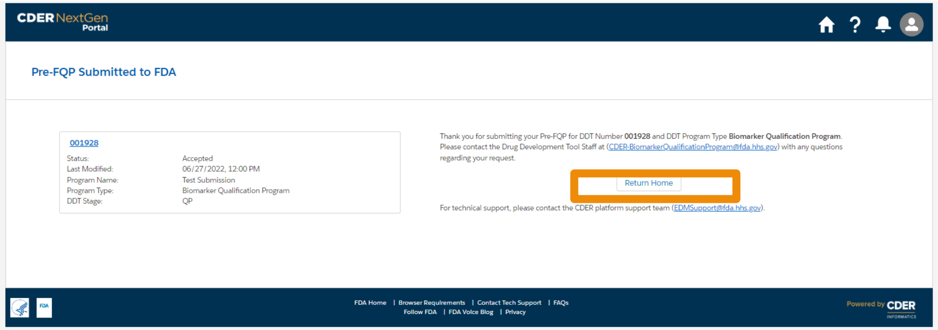
Step 2. Upload any necessary documents by clicking the arrow and selecting **Upload Files.** Browse your computer and select a file to upload or drag and drop a file into the designated area on the screen.

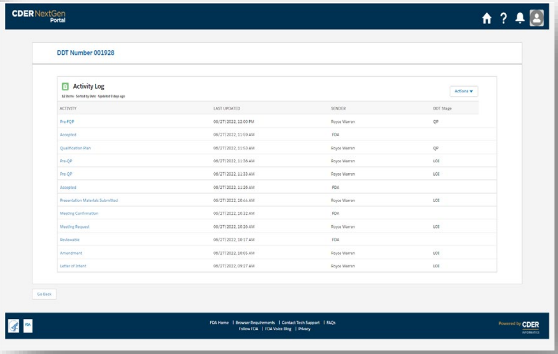
Step 3. Once the document has been uploaded, click **Done.**

Step 4. Click the check box acknowledging that information you provided to the FDA is final. Then click **Submit.**

Step 5. On the confirmation screen click **Return Home.**







Submitting an FQP

Step 1. Within the Drug Development Tool use case, navigate to the **Activity Log** by selecting your DDT Number from the landing page, click the **Actions** dropdown and then select **Full Qualification Plan**

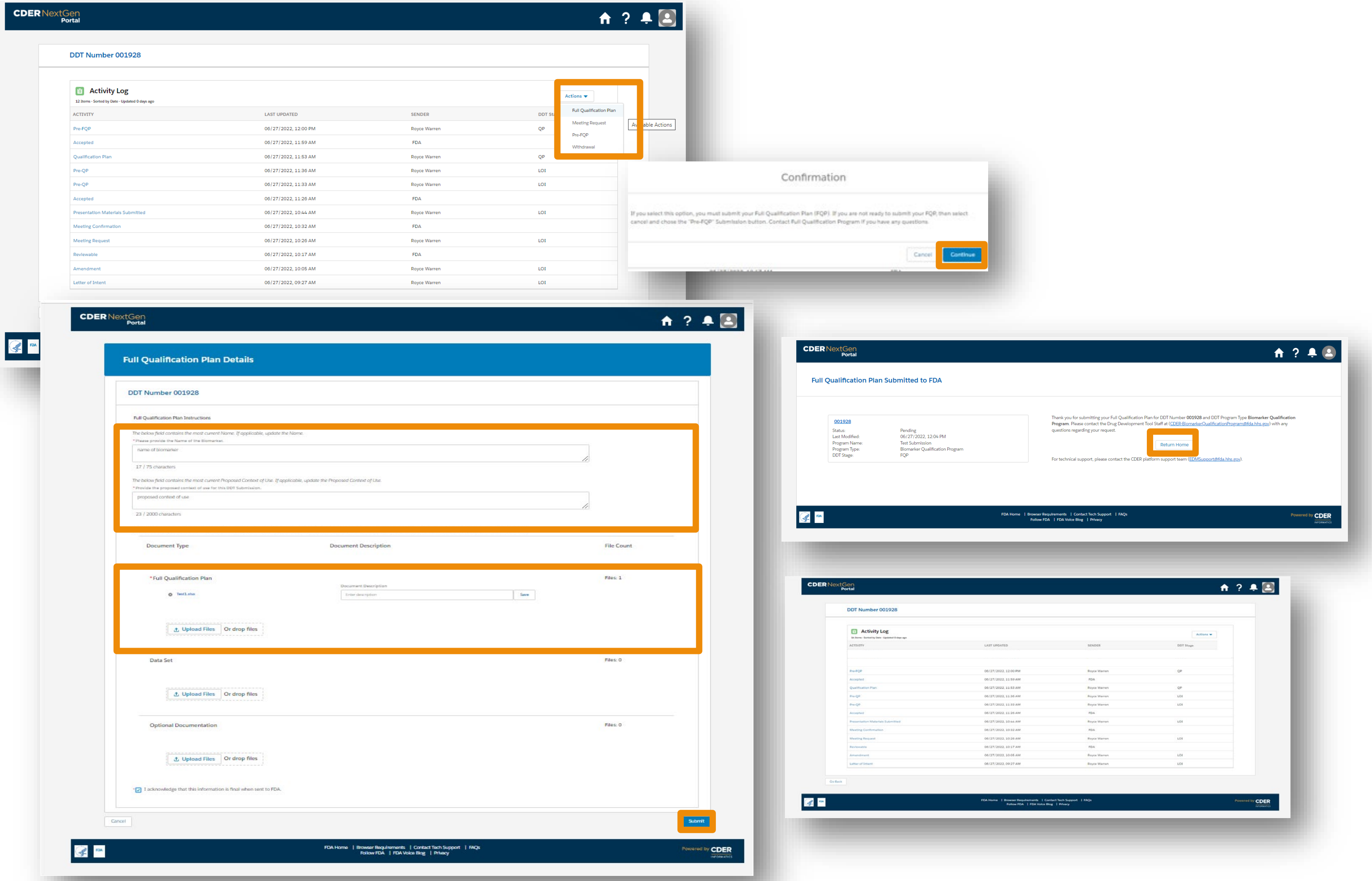
Step 2. Click **Continue** on the pop-up screen.

Step 3. In the **Full Qualification Plan Details** page, provide the requested information.

Step 4. Upload the **Full Qualification Plan** by clicking the arrow and selecting **Upload Files.** Browse your computer and select a file to upload or drag and drop a file into the designated area on the screen.

Step 5. Click the check box acknowledging that information you provided to the FDA is final. Then click **Submit.**

Step 6. On the confirmation screen click **Return Home.**



Submitting an Amendment

Amendment

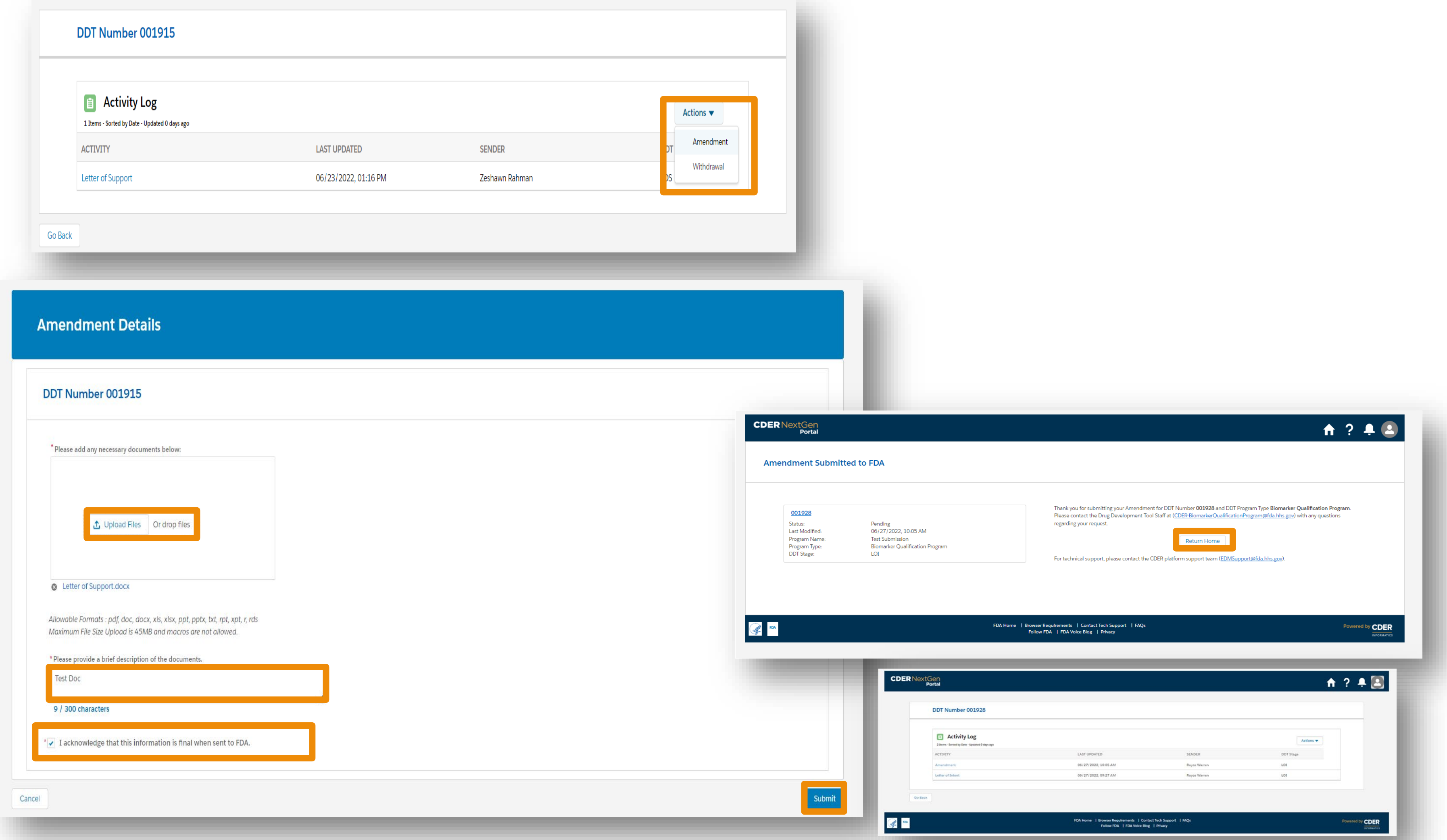
Step 1. Within the Drug Development Tool use case, navigate to the **Activity Log** by selecting your DDT Number from the landing page, click the **Actions** dropdown and then select **Amendment**.

Step 2. Upload any necessary documents by clicking the arrow and selecting **Upload Files.** Browse your computer and select a file to upload or drag and drop a file into the designated area on the screen.

Step 3. Provide a brief **description** of the document being uploaded.

Step 4. Click the check box acknowledging that information you provided to the FDA is final. Then click **Submit.**

Step 5. On the confirmation screen click **Return Home.**



Submitting a Meeting Request

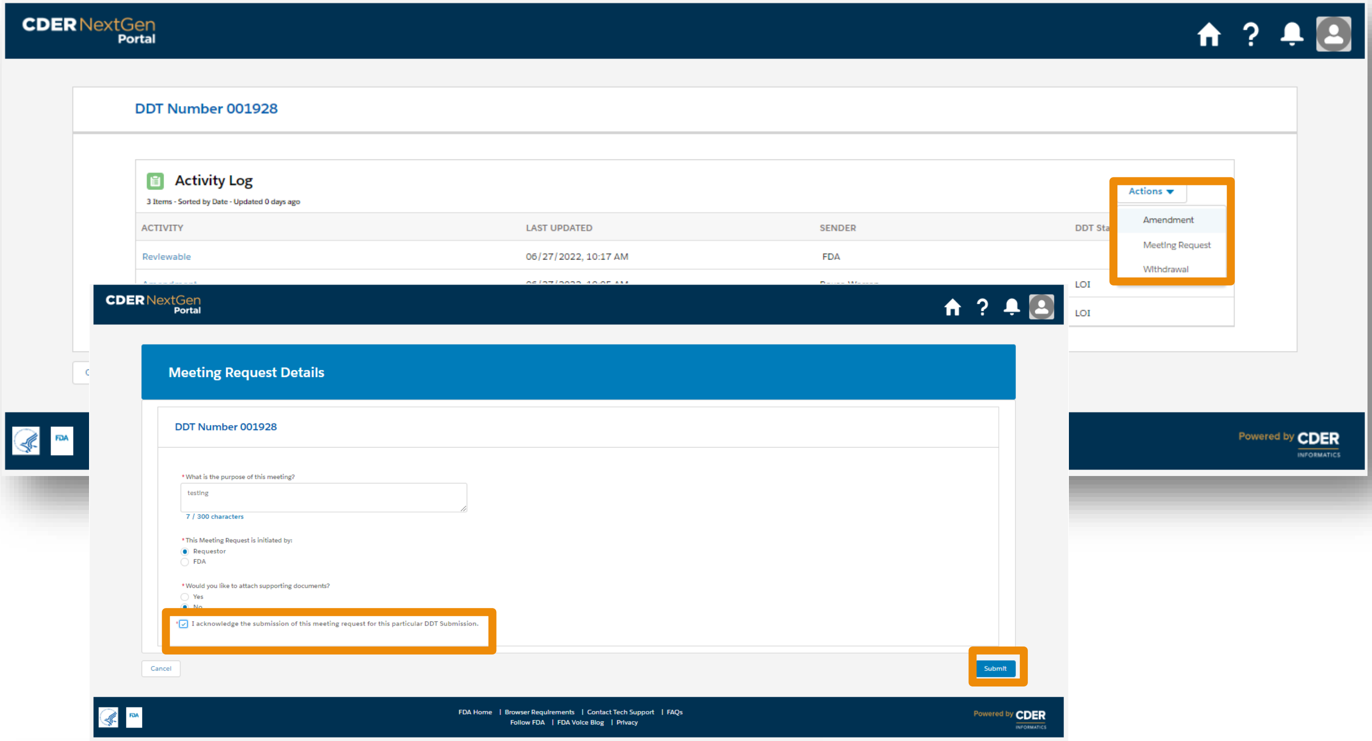
Submitting a Meeting Request

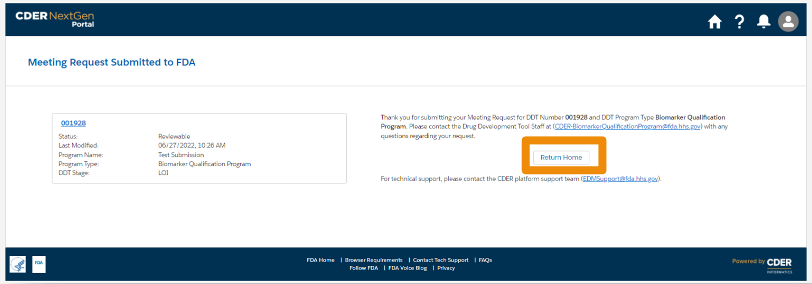
Step 1. Within the Drug Development Tool use case, navigate to the **Activity Log** by selecting your DDT Number from the landing page, click the **Actions** dropdown and then select **Meeting Request.**

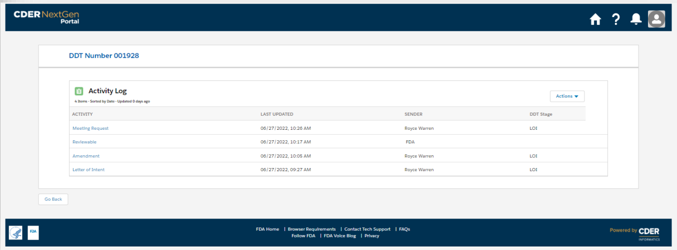
Step 2. Provide your response to the requested information and select whether you would like to attach supporting documents. If **yes,** upload any necessary documents by clicking the arrow and selecting **Upload Files.** Browse your computer and select a file to upload or drag and drop a file into the designated area on the screen.

Step 3. Click the check box acknowledging that information you provided to the FDA is final. Then click **Submit.**

Step 4. On the confirmation screen click **Return Home.**



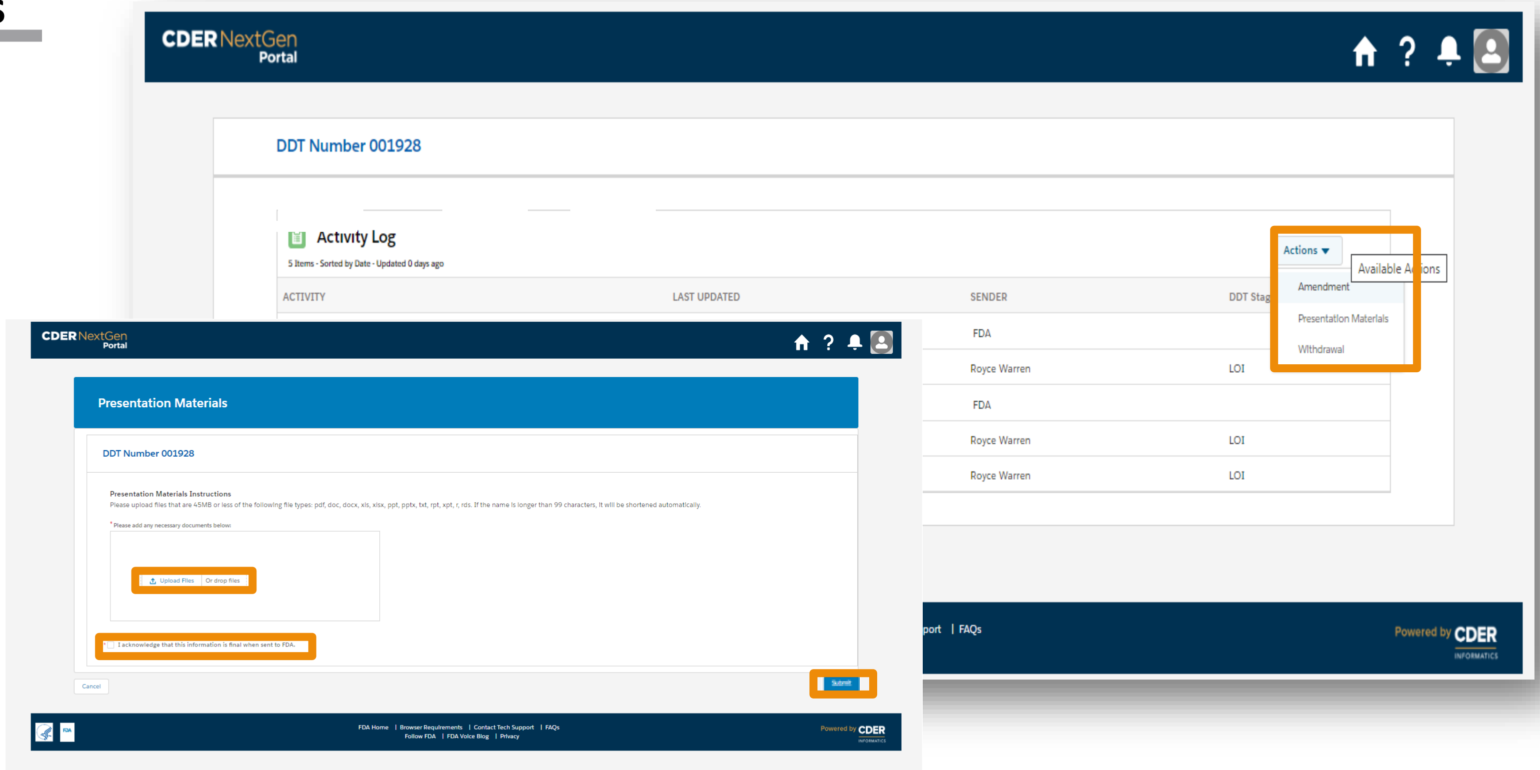




Submitting Presentation Materials

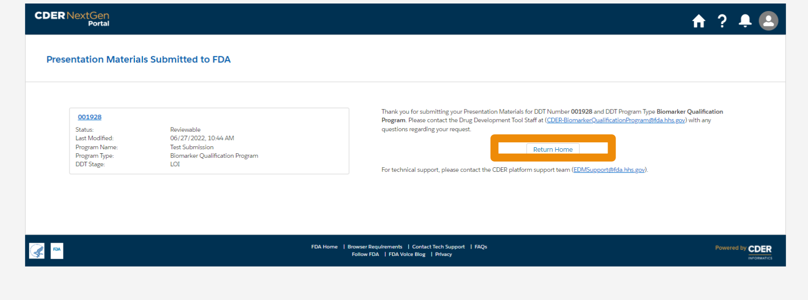
Submitting Presentation Materials

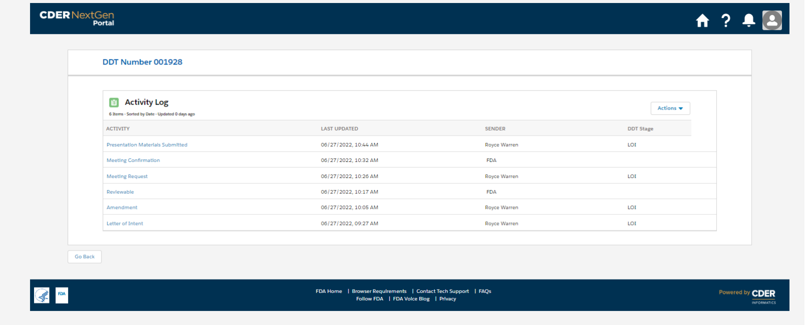
Step 1. Within the Drug Development Tool use case, navigate to the **Activity Log** by selecting your DDT Number from the landing page, click the **Actions** dropdown and then select **Presentation Materials.** *This action can be performed after Meeting Request has been confirmed by FDA.*



Step 2. Upload the any necessary documents by clicking the arrow and selecting **Upload Files.** Browse your computer and select a file to upload or drag and drop a file into the designated area on the screen.

Step 3. Click the check box acknowledging that information you provided to the FDA is final. Then click **Submit.**





Step 4. On the confirmation screen click **Return Home.**

Submitting an Information Request Response

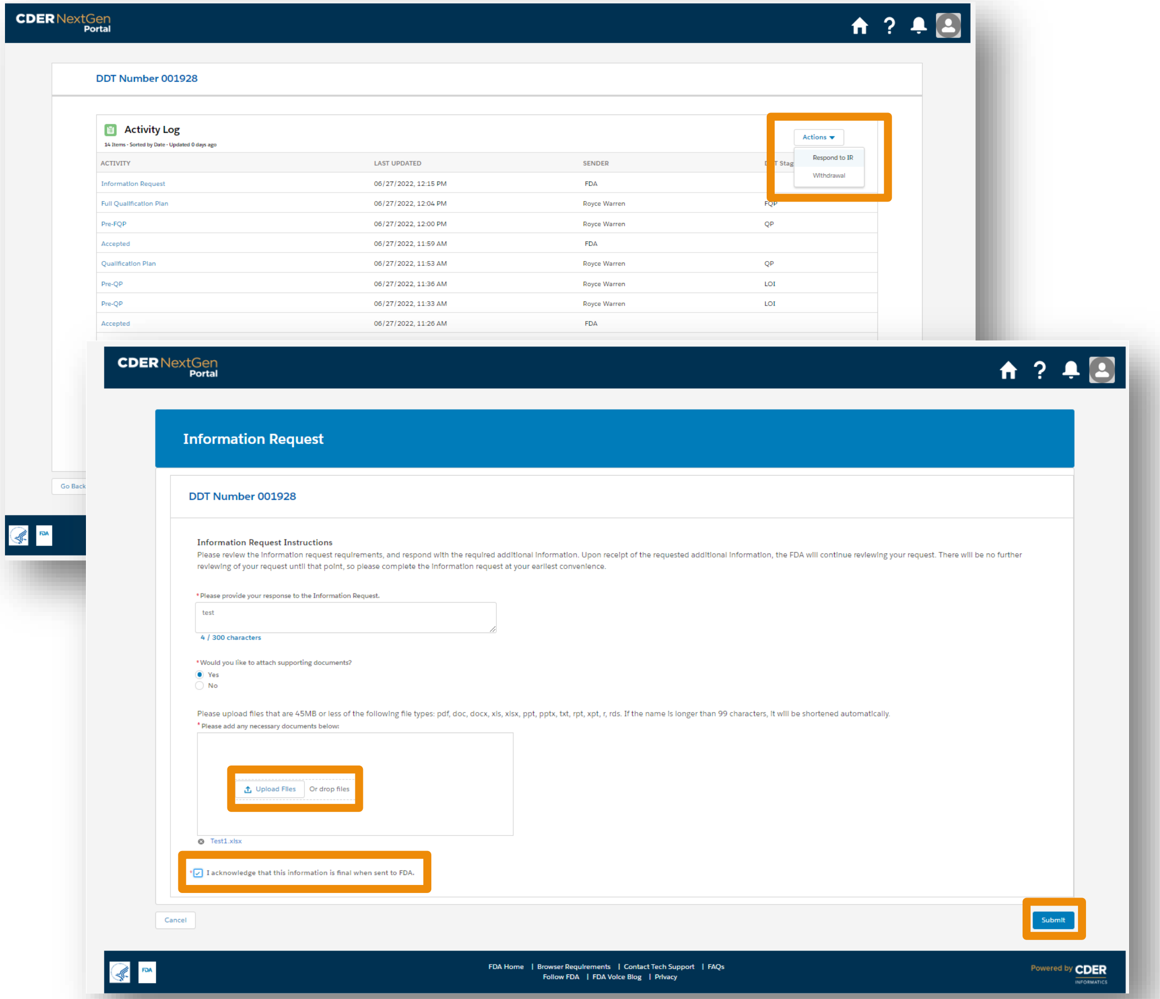
Submitting an Information Request Response

Step 1. Within the Drug Development Tool use case, navigate to the **Activity Log** by selecting your DDT Number from the landing page, click the **Actions** dropdown and then select **Respond To IR.** *This action can be performed after FDA sends an Information Request.*

Step 2. Provide your response to **the Information Request** and select whether you would like to attach supporting documents. If **yes,** upload any necessary documents by clicking the arrow and selecting **Upload Files.** Browse your computer and select a file to upload or drag and drop a file into the designated area on the screen.

Step 3. Click the check box acknowledging that information you provided to the FDA is final. Then click **Submit.**

Step 4. On the confirmation screen click **Return Home.**



Submitting a Withdrawal Request

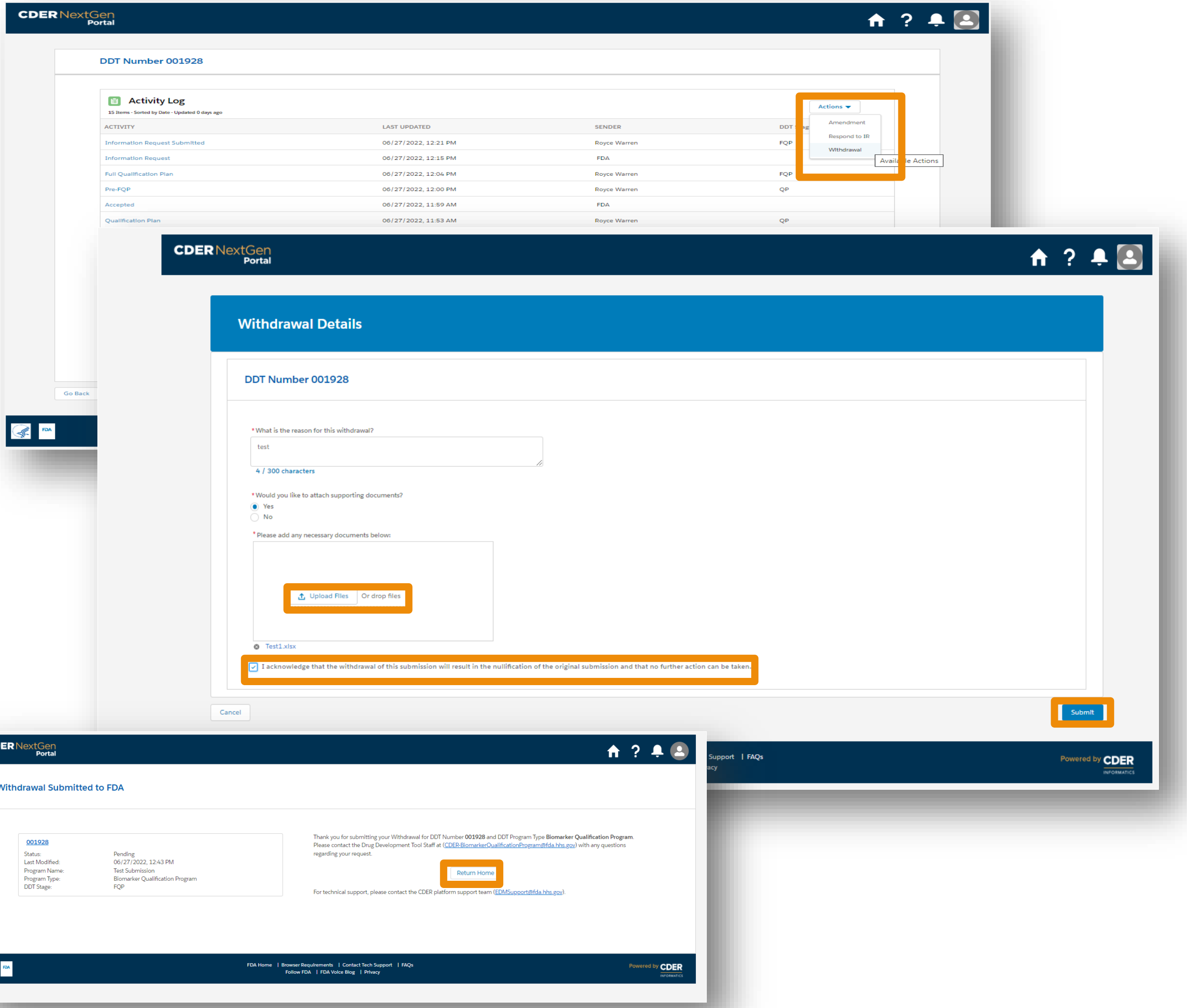
Submitting a Withdrawal

Step 1. Within the Drug Development Tool use case, navigate to the **Activity Log** by selecting your DDT Number from the landing page, click the **Actions** dropdown and then select **Withdrawal.** *This action can be performed at any point except once the DDT is qualified.*

Step 2. Provide your response to **the Withdrawal** and select whether you would like to attach supporting documents. If **yes,** upload any necessary documents by clicking the arrow and selecting **Upload Files.** Browse your computer and select a file to upload or drag and drop a file into the designated area on the screen.

Step 3. Click the check box and then click **Submit.**

Step 4. You can now click **Return Home** to exit.



Activity Log and Notifications

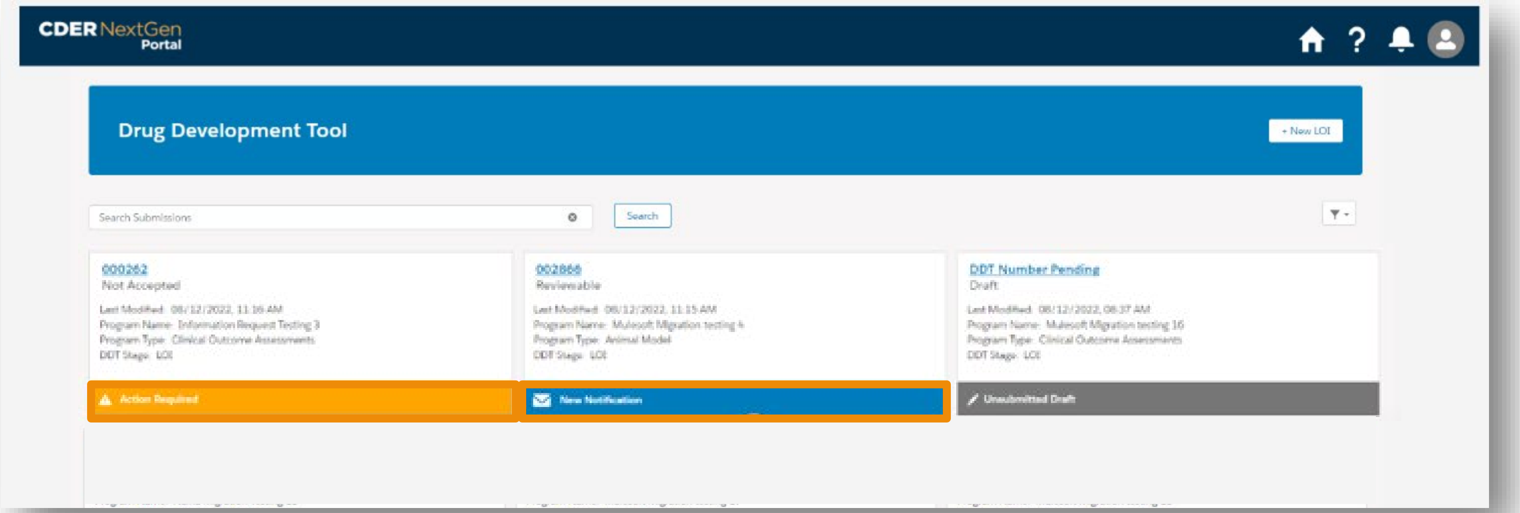
Activity Log and Notifications

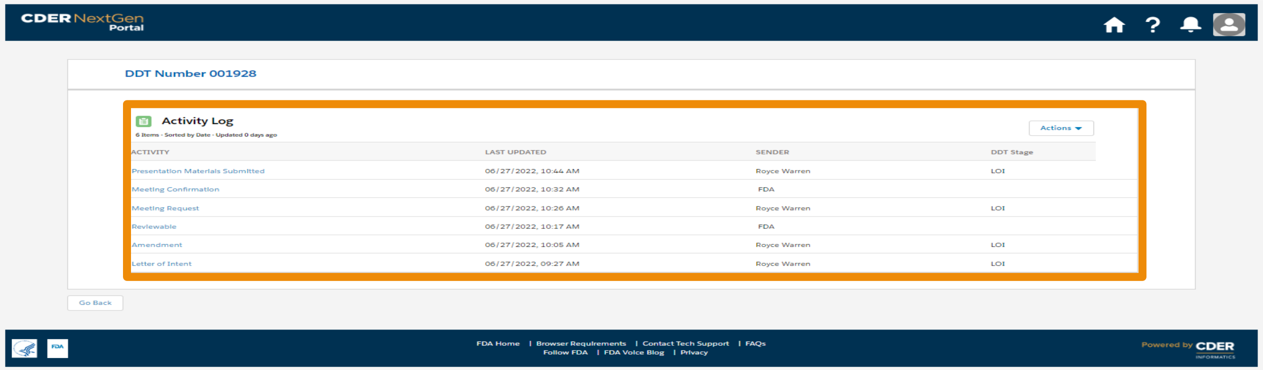
After submitting your LOI or LOS, you can view notifications from the FDA on your DDT landing page, as indicated by the following banners:

- **Action Required**
- **New Notification**

Step 1. To view a notification, click on a DDT Number to be redirected to the Activity Log:

- An **Action Required** is an **Information Request** from the FDA
- A **New notification** is an FDA's update or response to the LOI/LOS submission





Technical Support and Resources

CDER NextGen Portal Support & Resources

The CDER NextGen Portal (https://edm.fda.gov/) has many resources for support.

CDER NextGen Portal Announcements

Your Portal home page contains **portal announcements** so users are always in the know.

Learn More Information

Everything related to the portal events can be found on the **"Learn More"** link. On the event home page, users can find the "Learn More" link to **Reference Guides and FAQs.**

CDER NextGen Portal Video Tutorial

When available, the "**Video Tutorial**" will contain **1-4 minute video clips** on how to complete submissions for events on the portal.

Technical Support

For all technical support, contact **CDER Platform Support Team** at EDMSupport@fda.hhs.gov.