

# Reference Guide: Qualification Plan and Full Qualification Package Drug Development Tool Qualification Process

The screenshot displays the CDER NextGen Portal homepage. At the top left, the FDA logo and 'CDER NextGen Portal' are visible. The main content area features a large image of hands holding a tablet. On the left, the text reads 'Welcome to CDER NextGen Your direct line to the FDA' with a 'Learn More' button. On the right, a 'Sign In' form is shown, including fields for 'username@email.com' and a password, a 'Sign In' button, and a 'Sign up' link for new users. Below the sign-in form, a section titled 'Some Things To Keep In Mind | User Terms & Conditions' lists three points regarding government information system access and consent.

**Sign In**

username@email.com

\*\*\*\*\*

I have read and agree to the Terms and Conditions stated above and below

**Sign In**

Need help signing in?

Don't have an account? [Sign up](#)

**Some Things To Keep In Mind | User Terms & Conditions**

1. You are accessing a U.S. Government information system. This information system is provided for U.S. Government-authorized use only.
2. Unauthorized or improper use of this system may result in disciplinary action, as well as civil and criminal penalties. Authorized use of this system consists of industry submissions of data related to the use cases for which the system is intended.
3. By using this information system, you understand and consent to the following:
  - You have no reasonable expectation of privacy regarding any communication or data transiting or stored on this information system. At any time, and for any lawful Government purpose, the government may monitor, intercept, and search and seize any communication or data transiting or stored on this information system.
  - Any communication or data transiting or stored on this information system may be disclosed or used for any lawful Government purpose.

FDA Home | [Browser Requirements](#) | [Contact Tech Support](#) | [FAQ](#) | [A to Z Index](#) | [Follow FDA](#) | [FDA Voice Blog](#) | [Privacy](#) | Powered by **CDER** INFORMATICS

<https://edm.fda.gov/>

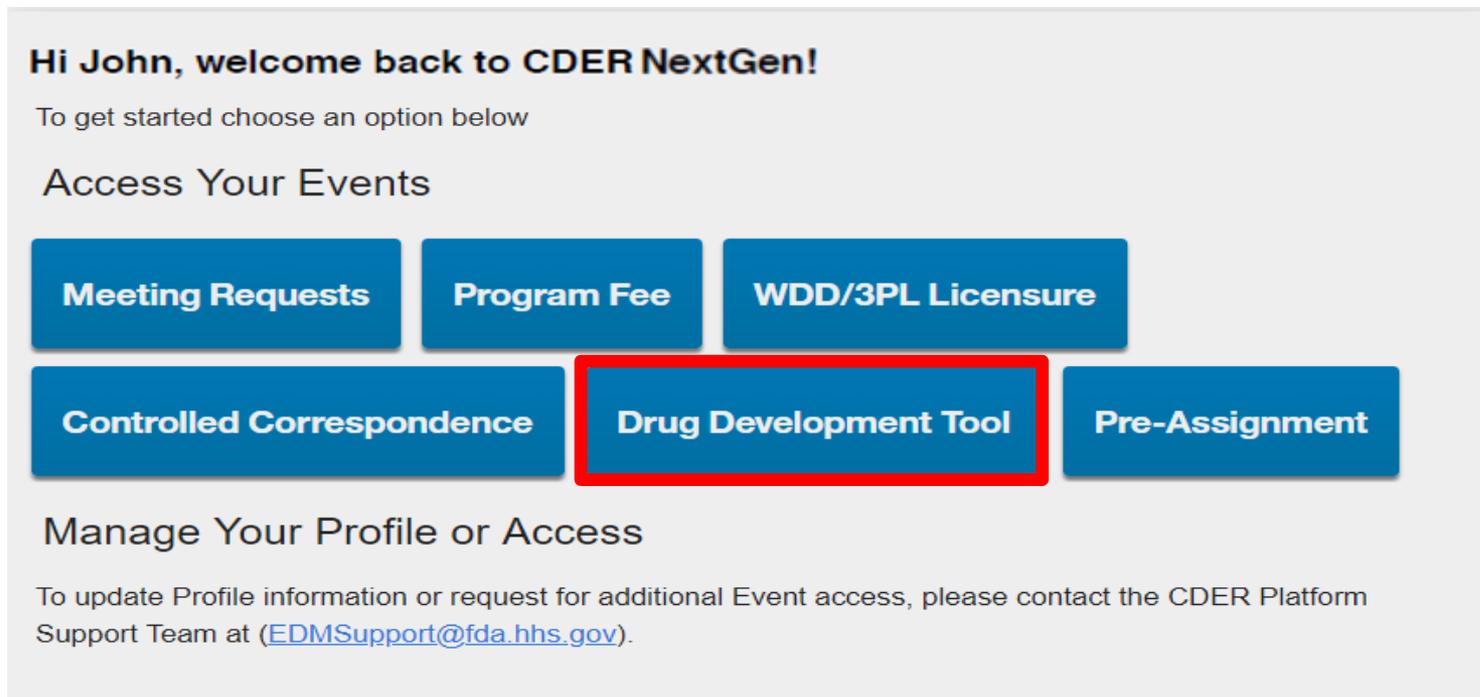
# Qualification Plan

# Qualification Plan

The Qualification Plan is the second DDT Stage submission for FDA to review. A QP submission can be submitted only after the DDT has received an “Accepted” LOI. This section describes how to submit a Qualification Plan (QP).

## Completing a Qualification Plan (QP)

**Step 1.** Once you landed on the Portal homepage, click on **Drug Development Tool**.



**Hi John, welcome back to CDER NextGen!**

To get started choose an option below

Access Your Events

- Meeting Requests
- Program Fee
- WDD/3PL Licensure
- Controlled Correspondence
- Drug Development Tool**
- Pre-Assignment

Manage Your Profile or Access

To update Profile information or request for additional Event access, please contact the CDER Platform Support Team at ([EDMSupport@fda.hhs.gov](mailto:EDMSupport@fda.hhs.gov)).

# Qualification Plan

## Completing a Qualification Plan (QP)

**Step 2.** Highlight and select the “Accepted” LOI previously submitted.

**Step 3.** Click View Submitted DDT.

Drug Development Tool [Create New LOI](#)

### Submitted Drug Development Tool

[FDA Updates](#) [Open DDT](#) [All DDT](#) [Closed DDT](#)

To make modifications and/or continue your submission please select the applicable event and click the “View Submitted DDT” button

Filter by DDT Status:  [Apply](#)

DDT Number	Program Type	Program Name	DDT Stage	DDT Status	Last Submitted Date/Time (EST)
000254	Clinical Outcome Assessments	Test 03	Letter of Intent	Accepted	5/13/2019, 1:37 PM
000332	Biomarker Qualification Program	Test 02	Letter of Intent	Withdrawn	5/13/2019, 10:14 AM
000238	Clinical Outcome Assessments	COA 3	Letter of Intent	Withdrawn	5/13/2019, 9:44 AM
000250	Clinical Outcome Assessments	COA 0509	Full Qualification Plan	Qualified	5/9/2019, 3:08 PM

[View Submitted DDT](#)

# Qualification Plan

## Completing a Qualification Plan (QP)

**Step 4.** Review Recent Activity for the DDT Number selected, then **click Continue Submission.**

Review Recent Activity for DDT Number 000254

### Submitted Drug Development Tool

DDT Status:  Status Date:

Document Type	File Name	Communication Interaction	Submission Date (EST)	Document Status
Accepted Letter	Test LOI Accepted Letter.PDF	FDA Communication	05/13/2019, 01:37 PM	Not Reviewed
Letter of Intent	Test LOI Submission.pdf	Submitted to FDA	05/13/2019, 10:42 AM	Submitted Document

[View Selected Document](#)

### Submission/Response Summary

### Contact Information

[Close](#) [Withdrawal Request](#) [Continue Submission](#)

# Qualification Plan

## Completing a Qualification Plan (QP)

**Step 5.** The Context of Use will be prepopulated from what was provided during the LOI stage. Modify the context of what is being submitted if necessary for the Qualification Plan.

**Step 6. Click Attach Document.**

**Step 7.** The QP is a mandatory document for submission. Select **Qualification Plan Submission** as the Document Type.

**Step 8. Click Browse**

**Step 9.** Select document you want to upload.

 Allowable formats to upload are PDF, MS Word, MS Excel, SAS, MP4. The maximum file size upload is 45MB and macros aren't allowed.

**Step 10. (Optional)** Provide a brief description of the document.

**Step 11. Click Confirm Attachment.**

Continue Submission for DDT Number 000254

### Update Proposed Context of Use (optional)

The below field contains the most current Proposed Context of Use. If applicable, update the Proposed Context of Use.

\* Provide the proposed context of use for this DDT submission.

4 / 2000 characters

test

### Document Attachment

In this submission, it is mandatory to attach a Qualification Plan Submission.

Attach Document

### Document Attachment

In this submission, it is mandatory to attach a Qualification Plan Submission.

### Attach Document(s)

\* Select Document Type

Select One

Select One

Data Set

Qualification Plan Submission

Other

Allowable Formats: PDF, MS Word, MS Excel, SAS, MP4

Maximum File Size Upload is 45MB and macros are not allowed

Brief Description

0 / 300 characters

Confirm Attachment

Cancel Attachment

# Qualification Plan

## Completing a Qualification Plan (QP)

**Step 11.** Review all information in summary page then click the checkbox that you acknowledge this information is final when sent to the FDA.

I acknowledge that this information is final when sent to the FDA

Save as Draft

Submit To FDA

Back

Delete Submission

**Step 12.** Click Submit To FDA.

**Step 13.** You will be directed to a confirmation page that displays your Qualification Plan submission for the same DDT Number. An email will also be sent with this confirmation.

### Qualification Plan Submitted to FDA

Thank you for submitting your Qualification Plan for DDT Number 000254 and DDT Program Type Clinical Outcome Assessments.

For technical support, contact the CDER Platform Support Team ([EDMSupport@fda.hhs.gov](mailto:EDMSupport@fda.hhs.gov)). Please include your DDT Number and associated DDT Program Type in your email.

Return to Home

---

## Full Qualification Package

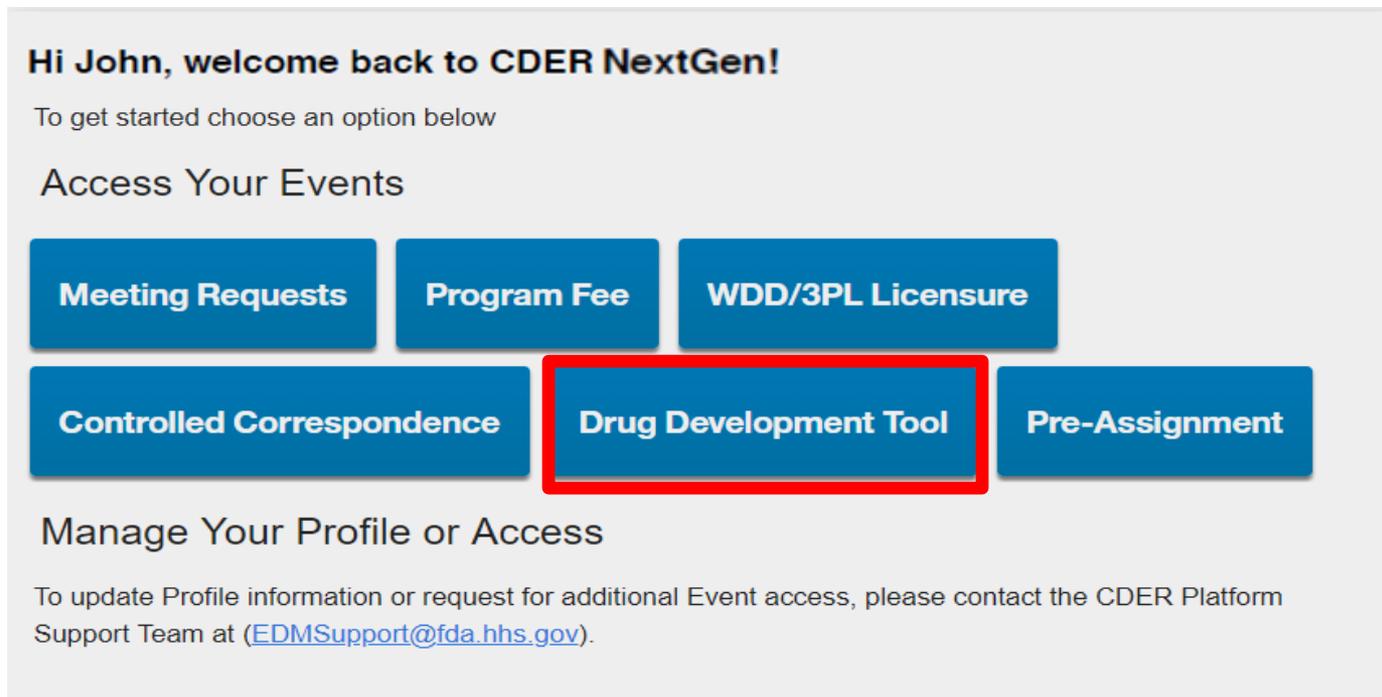
---

# Full Qualification Package

The Full Qualification Package (FQP) is the third DDT Stage submission for FDA to review. A FQP submission can be submitted only after the DDT has received an “Accepted” QP. This section describes how to submit a Full Qualification Package (FQP).

## Completing a Full Qualification Package (FQP)

**Step 1.** Once you landed on the Portal homepage, **click on Drug Development Tool.**



Hi John, welcome back to CDER NextGen!

To get started choose an option below

Access Your Events

- Meeting Requests
- Program Fee
- WDD/3PL Licensure
- Controlled Correspondence
- Drug Development Tool**
- Pre-Assignment

Manage Your Profile or Access

To update Profile information or request for additional Event access, please contact the CDER Platform Support Team at ([EDMSupport@fda.hhs.gov](mailto:EDMSupport@fda.hhs.gov)).

# Full Qualification Package

## Completing a Full Qualification Package (FQP)

**Step 2.** Highlight and select the “Accepted” Qualification Plan previously submitted.

**Step 3.** Click View Submitted DDT

Drug Development Tool [Create New LOI](#)

### Submitted Drug Development Tool

[FDA Updates](#) [Open DDT](#) [All DDT](#) [Closed DDT](#)

To make modifications and/or continue your submission please select the applicable event and click the “View Submitted DDT” button

Filter by DDT Status:  [Apply](#)

DDT Number	Program Type	Program Name	DDT Stage	DDT Status	Last Submitted Date/Time (EST)
000254	Clinical Outcome Assessments	Test 03	Qualification Plan	Accepted	5/14/2019, 11:53 AM
000332	Biomarker Qualification Program	Test 02	Letter of Intent	Withdrawn	5/13/2019, 10:14 AM
000238	Clinical Outcome Assessments	COA 3	Letter of Intent	Withdrawn	5/13/2019, 9:44 AM
000250	Clinical Outcome Assessments	COA 0509	Full Qualification Plan	Qualified	5/9/2019, 3:08 PM

[View Submitted DDT](#)

# Full Qualification Package

## Completing a Full Qualification Package (FQP)

**Step 4.** Review Recent Activity for the “Accepted” Qualification Plan DDT Number selected, then click **Continue Submission**.

Review Recent Activity for DDT Number 000254

**Submitted Drug Development Tool**

DDT Status:  Status Date:

Document Type	File Name	Communication Interaction	Submission Date (EST)	Document Status
Accepted Letter	Test QP Accepted Letter.PDF	FDA Communication	05/14/2019, 11:53 AM	Not Reviewed
Qualification Plan Submission	Test QP Submission.pdf	Submitted to FDA	05/13/2019, 01:40 PM	Submitted Document
Accepted Letter	Test LOI Accepted Letter.PDF	FDA Communication	05/13/2019, 01:37 PM	Not Reviewed
Letter of Intent	Test LOI Submission.pdf	Submitted to FDA	05/13/2019, 10:42 AM	Submitted Document

[View Selected Document](#)

**Submission/Response Summary**

**Contact Information**

[Close](#) [Withdrawal Request](#) [Continue Submission](#)

# Full Qualification Package

## Completing a Full Qualification Package (FQP)

**Step 5.** The Context of Use will be prepopulated from what was provided during the LOI stage. Modify the context of what is being submitted if necessary for the Full Qualification Package

**Step 6. Click Attach Document.**

**Step 7.** The FQP is a mandatory document for submission. Select **Full Qualification Package Submission** as the Document Type.

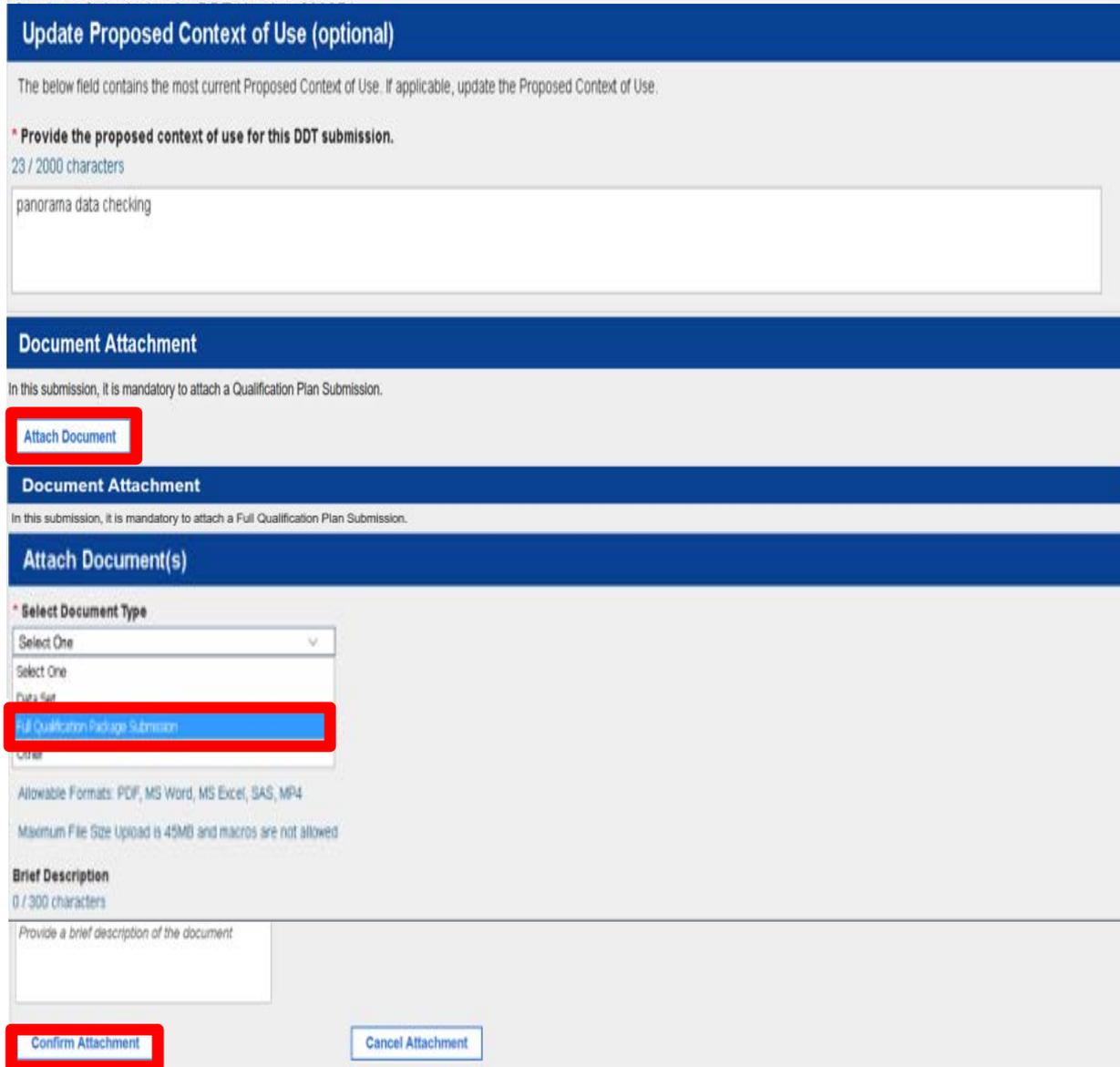
**Step 8. Click Browse.**

**Step 8.** Select document you want to upload.

 Allowable formats to upload are PDF, MS Word, MS Excel, SAS, MP4. The maximum file size upload is 45MB and macros aren't allowed.

**Step 9. (Optional)** Provide a brief description of the document.

**Step 10. Click Confirm Attachment.**



The screenshot displays a web interface for submitting a Full Qualification Package (FQP). It is divided into several sections:

- Update Proposed Context of Use (optional):** A text area for updating the context of use. A note states: "The below field contains the most current Proposed Context of Use. If applicable, update the Proposed Context of Use." A red box highlights the "Attach Document" button below this section.
- Document Attachment:** A section with a note: "In this submission, it is mandatory to attach a Qualification Plan Submission." A red box highlights the "Attach Document" button.
- Document Attachment:** A section with a note: "In this submission, it is mandatory to attach a Full Qualification Plan Submission." A red box highlights the "Attach Document(s)" button.
- Attach Document(s):** A section for selecting a document type. A dropdown menu is open, showing "Select One" and "Full Qualification Package Submission" (highlighted with a red box). Below the dropdown, it lists "Allowable Formats: PDF, MS Word, MS Excel, SAS, MP4" and "Maximum File Size Upload is 45MB and macros are not allowed".
- Brief Description:** A text area for providing a brief description of the document. A note says: "Provide a brief description of the document".

At the bottom of the form, there are two buttons: "Confirm Attachment" (highlighted with a red box) and "Cancel Attachment".

# Full Qualification Package

## Completing a Full Qualification Package (FQP)

**Step 11.** Review all information in summary page then click the checkbox that you acknowledge this information is final when sent to the FDA.

Saved Document(s)		
File Name	Document Type	Brief Description
CADDataSummary(43).xls	Full Qualification Package Submission	

I acknowledge that this information is final when sent to the FDA

**Step 12.** Click Submit To FDA.

**Step 13.** You will be directed to a confirmation page that displays your Full Qualification Package for the same DDT Number. An email will also be sent with this confirmation.

### Full Qualification Package Submitted to FDA

Thank you for submitting your Full Qualification Package for DDT Number **001643** and DDT Program Type **Animal Model**.

For technical support, contact the CDER Platform Support Team ([EDMSupport@fda.hhs.gov](mailto:EDMSupport@fda.hhs.gov)). Please include your DDT Number and associated DDT Program Type in your email.

## **Technical Support and Resources**

# CDER NextGen Portal Support & Resources

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

## 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**.

## Technical Support

For all technical support, contact **CDER Platform Support** at [EDMSupport@fda.hhs.gov](mailto:EDMSupport@fda.hhs.gov).

## Portal Video Tutorials

The “**Video Tutorials**” contains 1-4 minute video clips on how to complete submissions for events under the “**Learn More**” section on the portal.