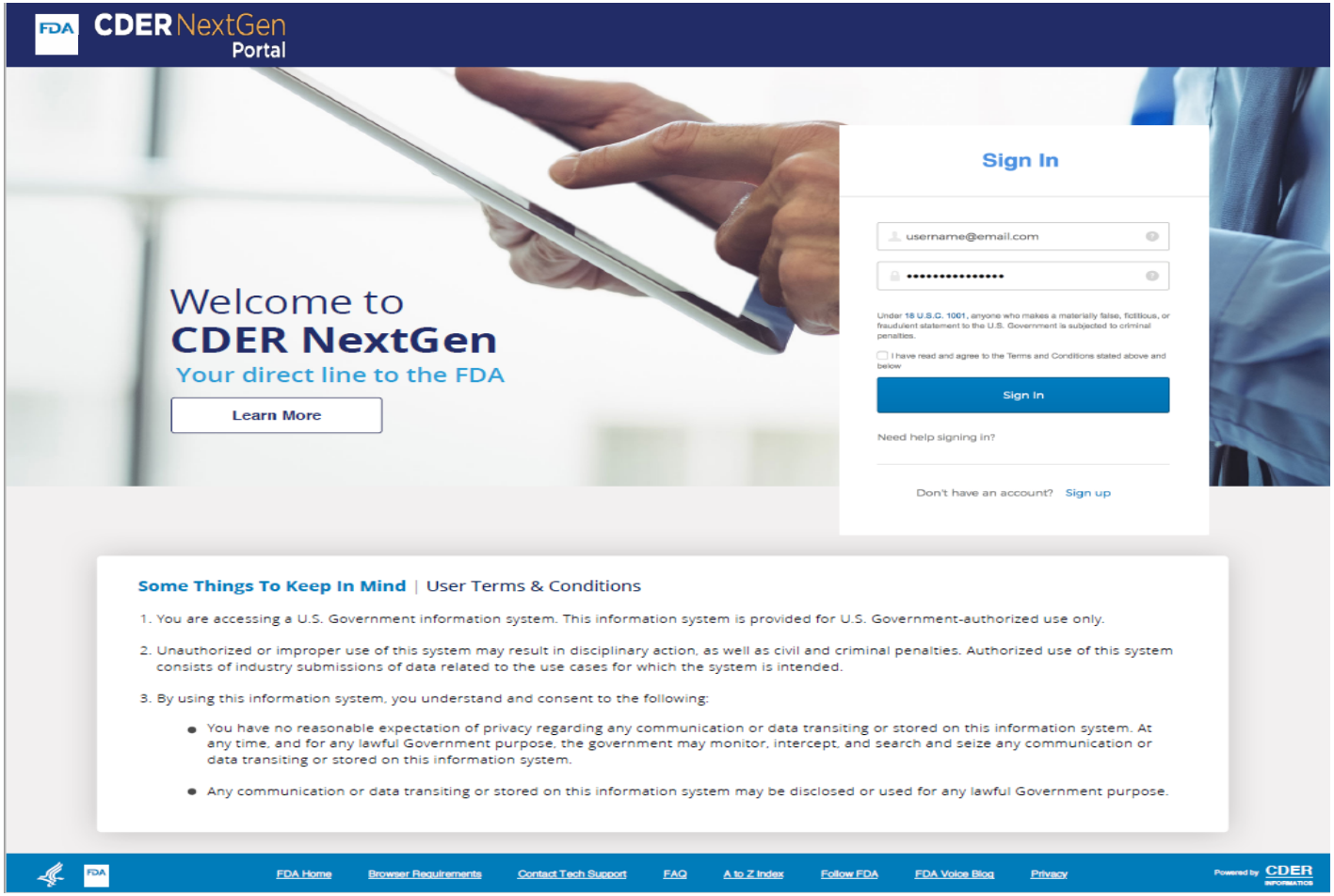
Reference Guide:
Qualification Plan and Full Qualification Package
Drug Development Tool Qualification Process



https://edm.fda.gov/

CDER INFORMATICS

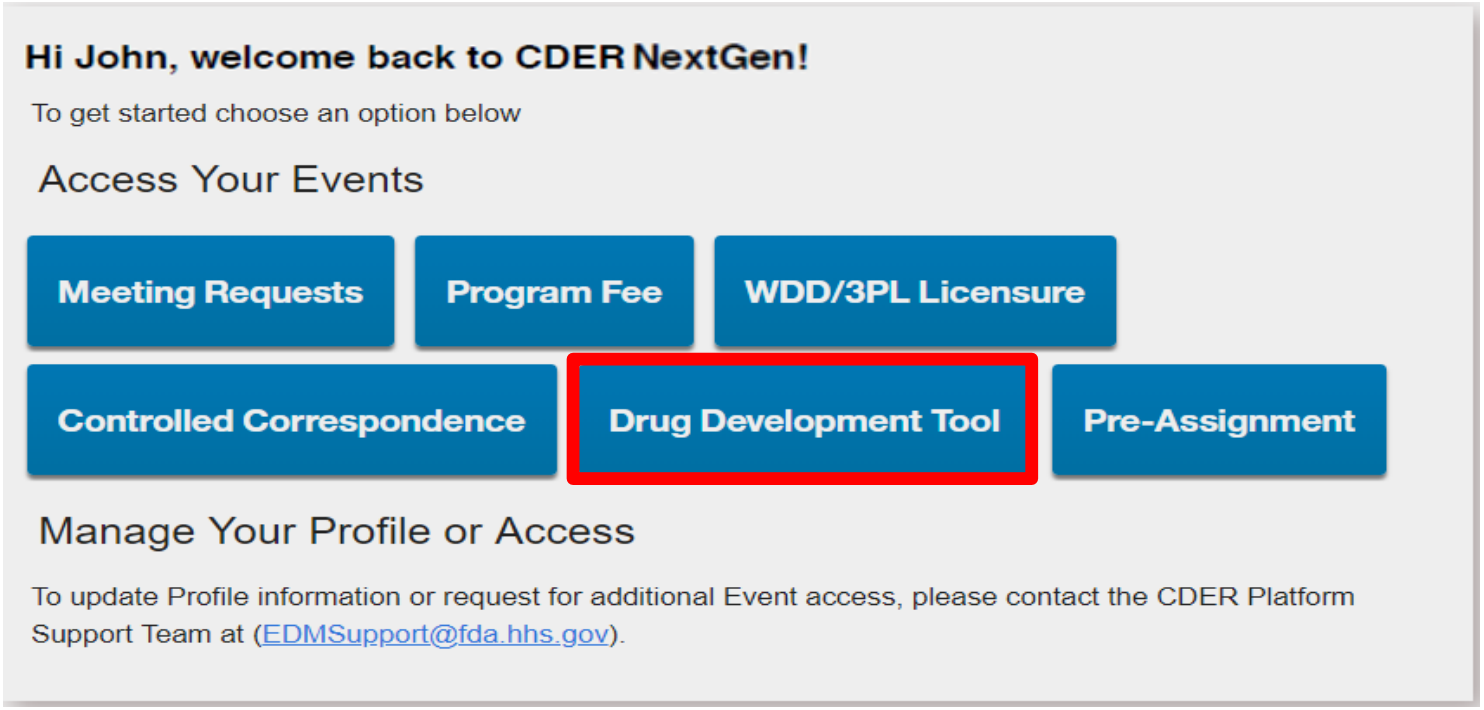
Qualification Plan

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.**

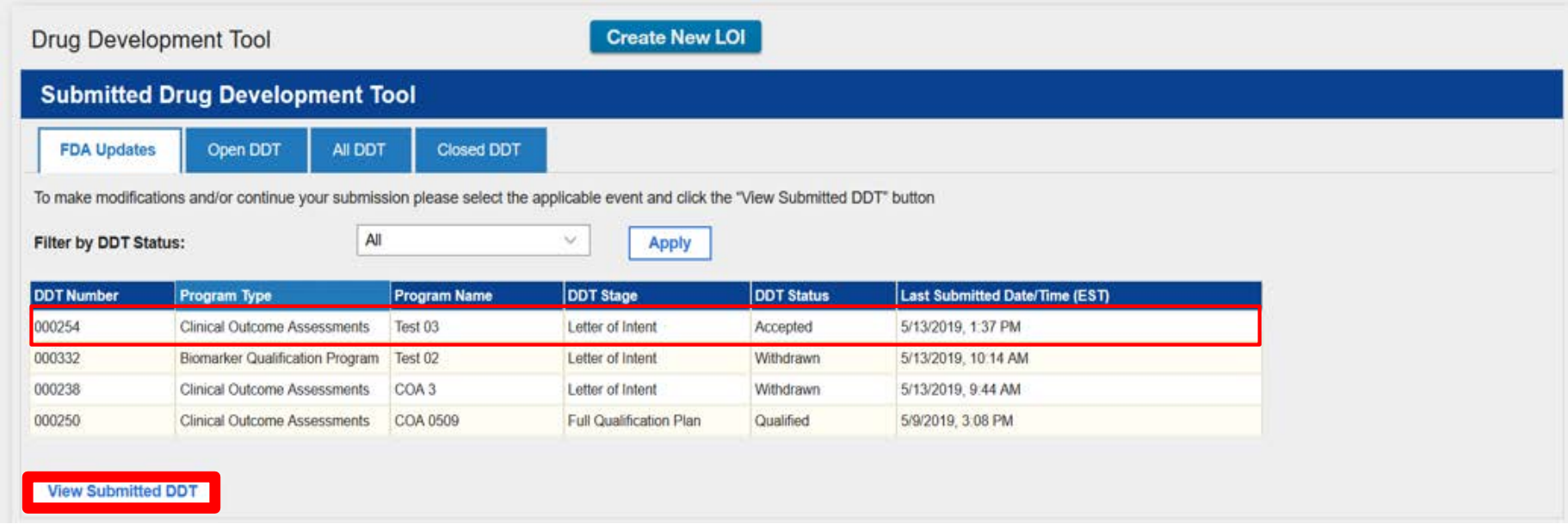


Qualification Plan

Completing a Qualification Plan (QP)

Step 2. Highlight and select the "Accepted" LOI previously submitted.

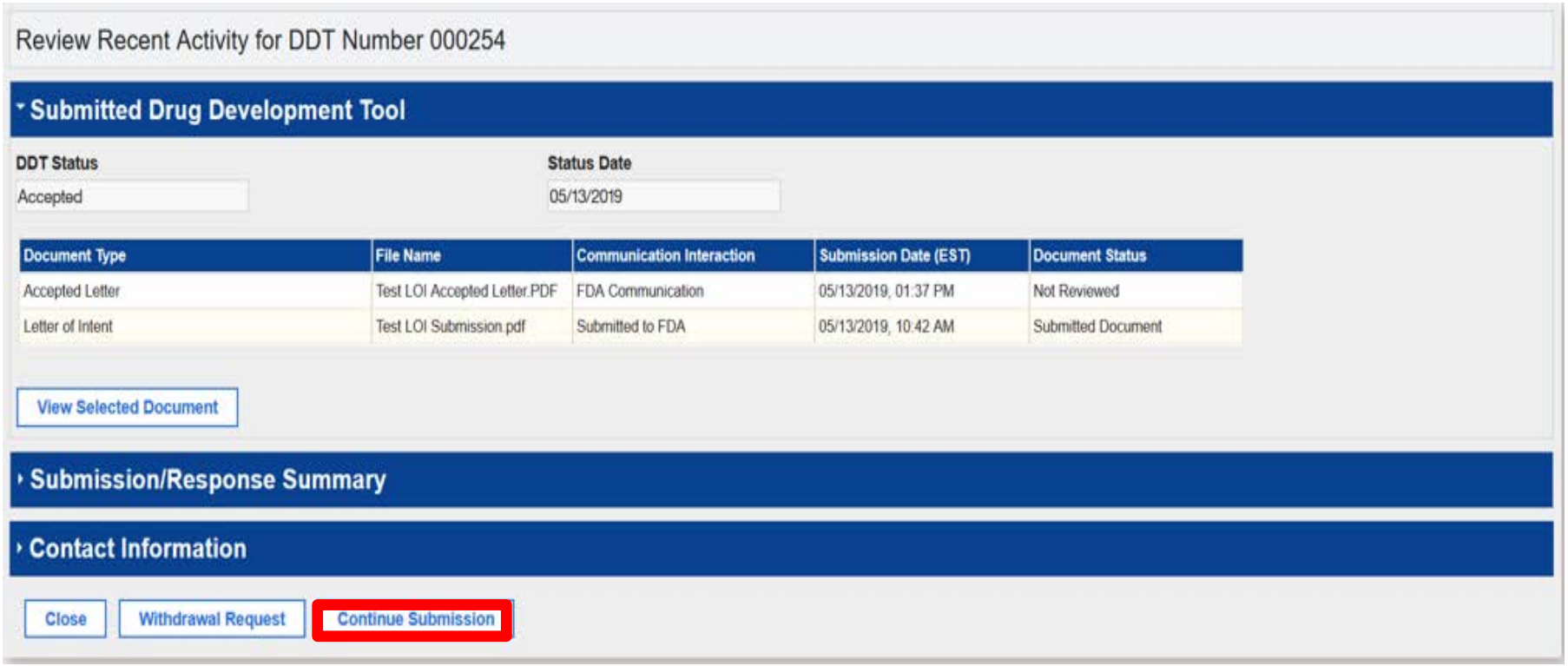
Step 3. Click View Submitted DDT.



Qualification Plan

Completing a Qualification Plan (QP)

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

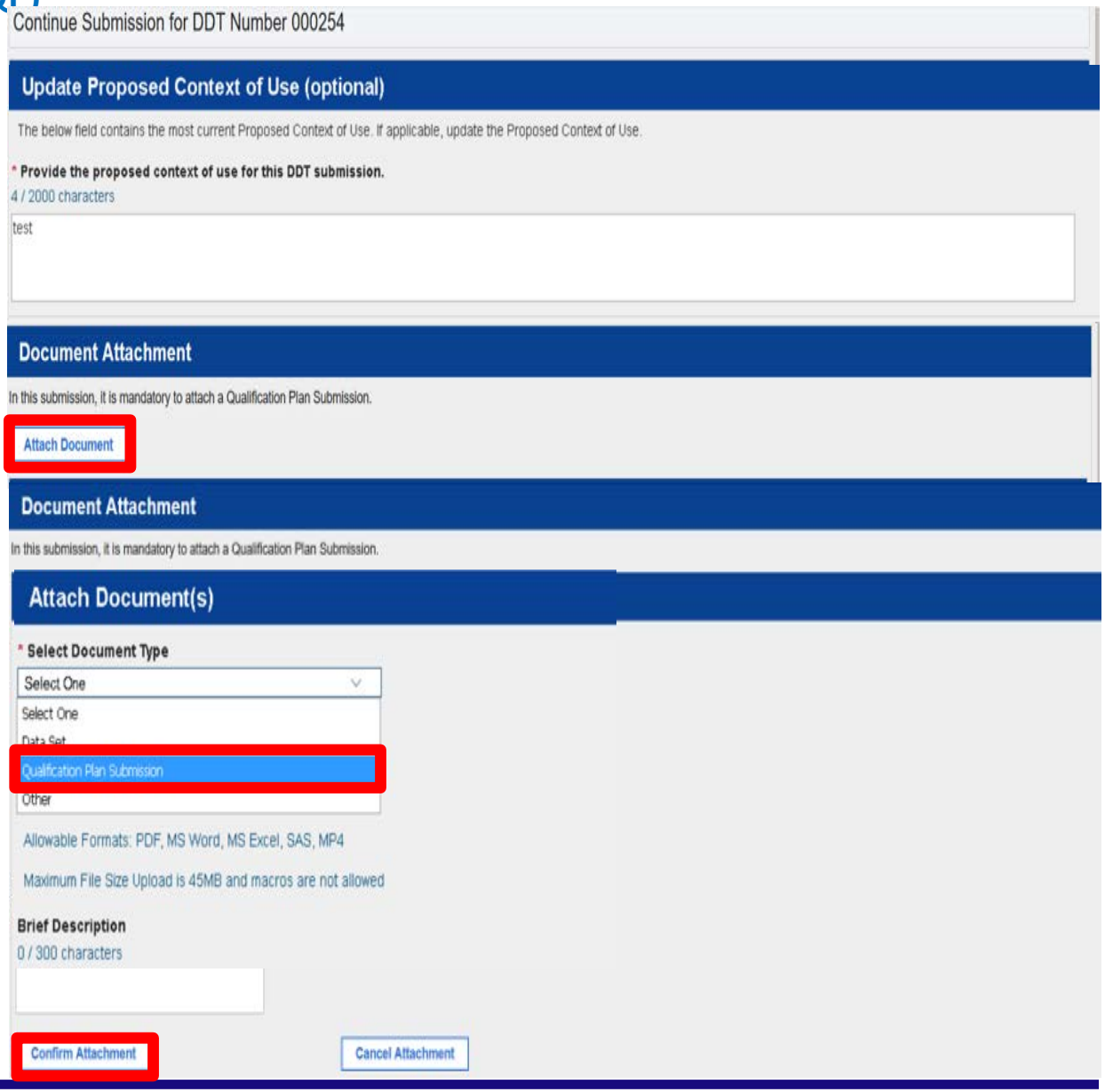
Step 8. **Click Browse**

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.

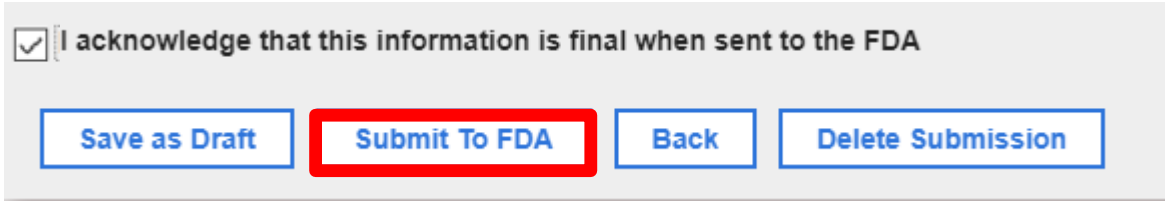
Step 11. Click Confirm Attachment.



Qualification Plan

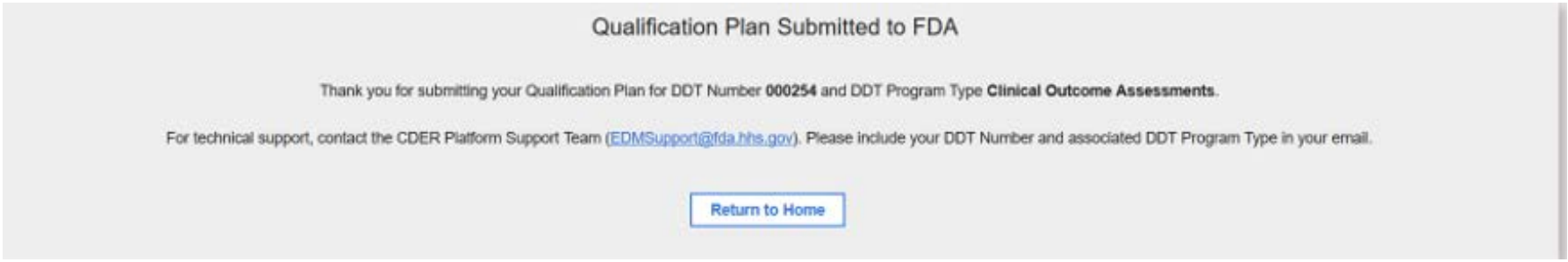
Completing a Qualification Plan (QP)

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



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.



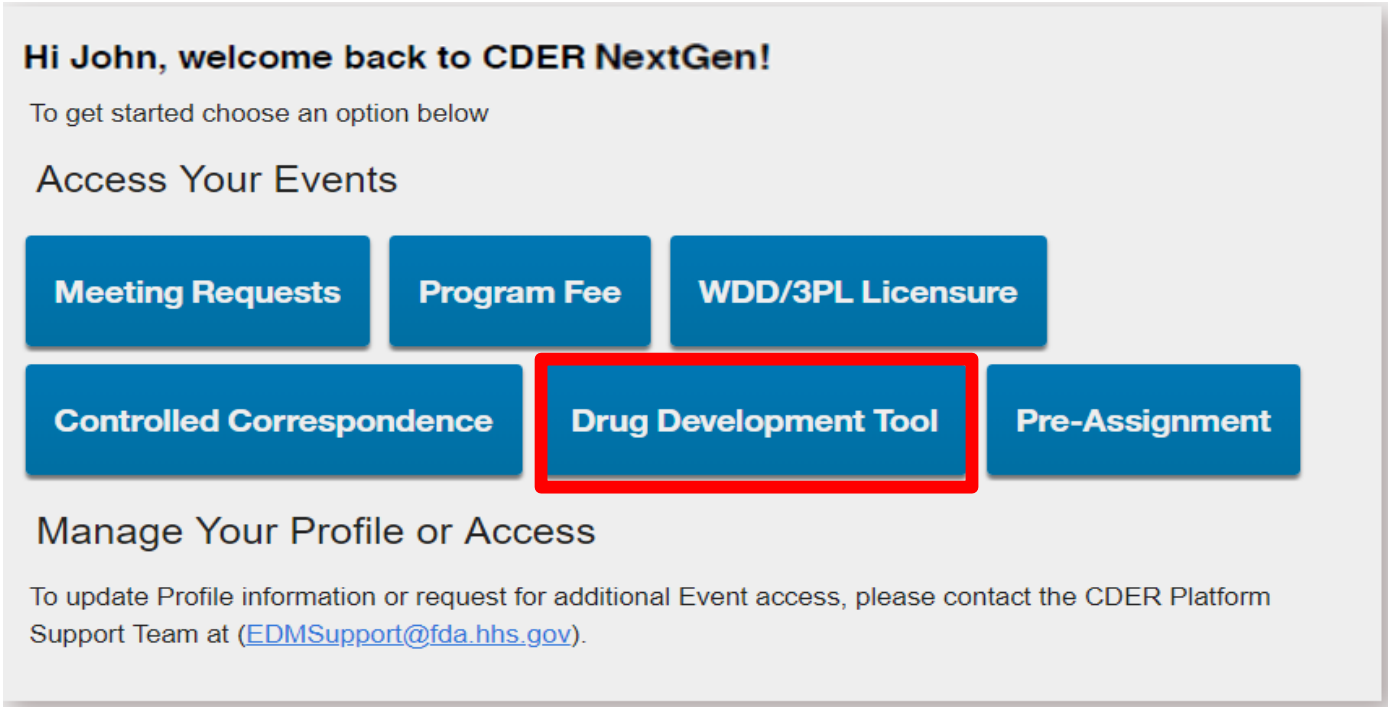
Full Qualification Package

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.**

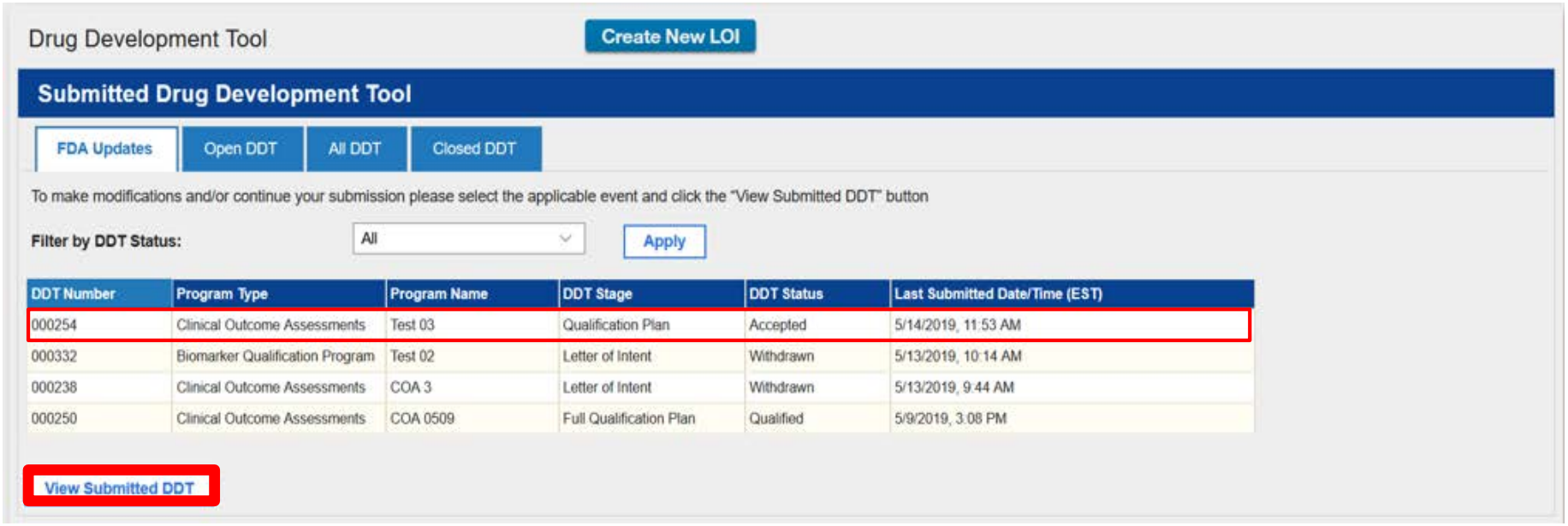


Full Qualification Package

Completing a Full Qualification Package (FQP)

Step 2. Highlight and select the "Accepted" Qualification Plan previously submitted.

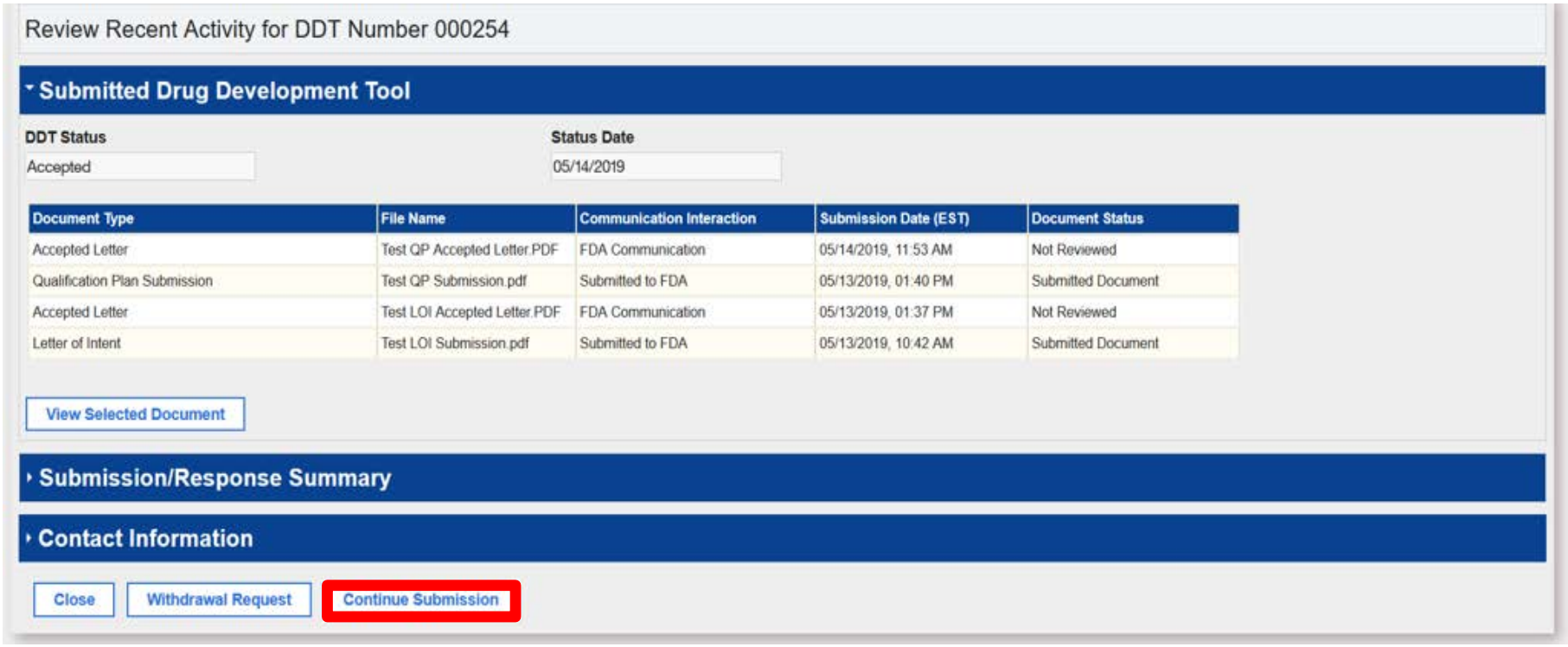
Step 3. Click View Submitted DDT



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.**



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.

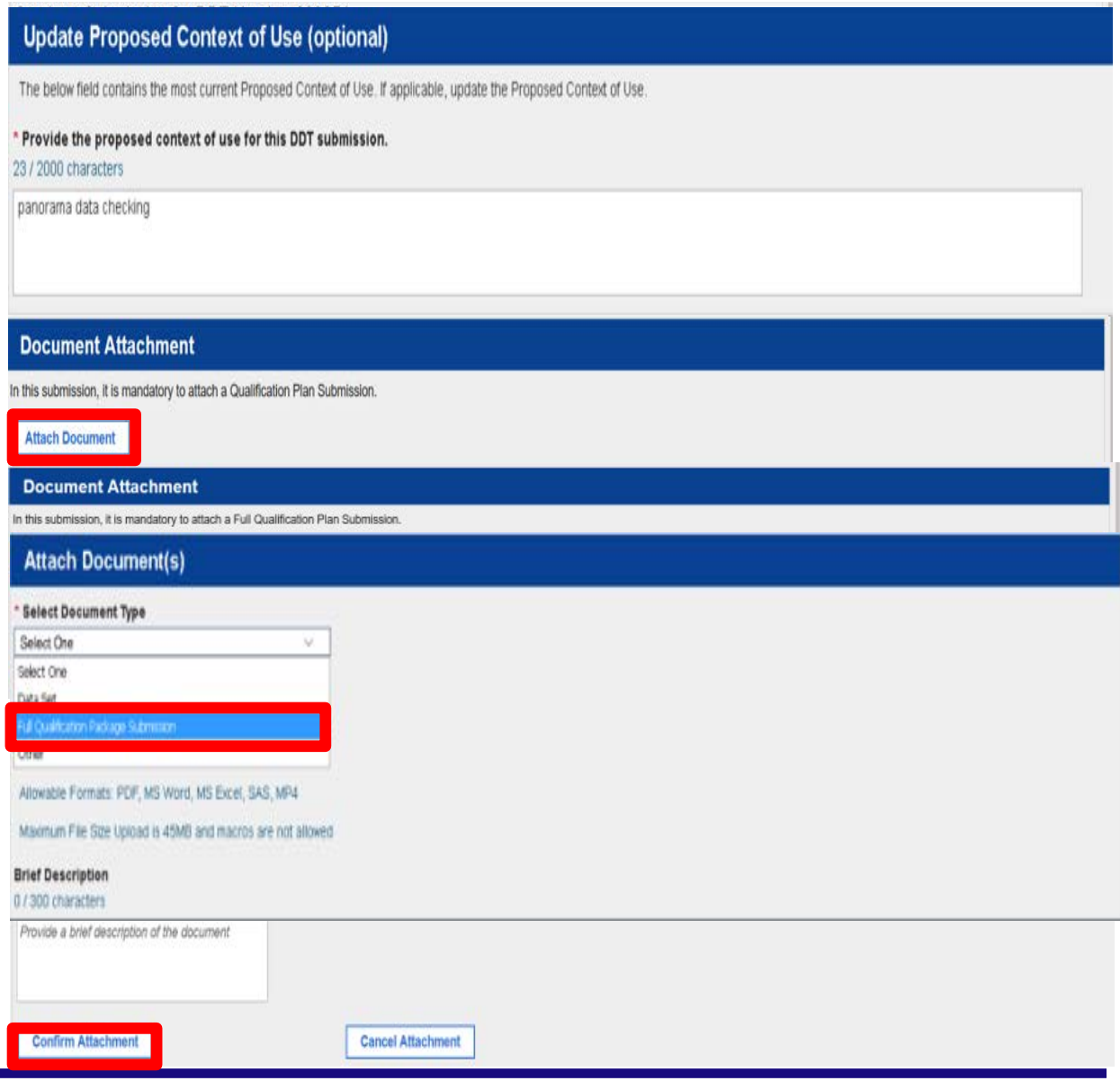
Step 8. **Click Browse.**

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.

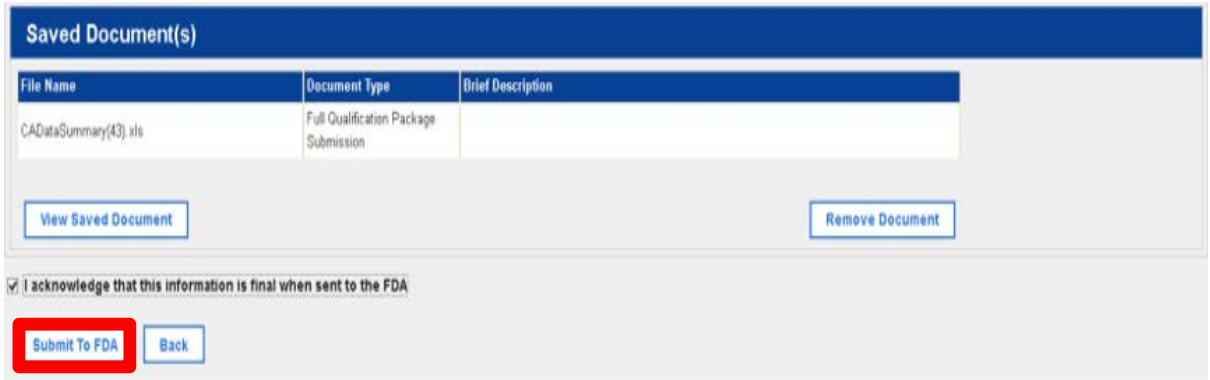
Step 10. **Click Confirm Attachment**.



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.



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.

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.

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.