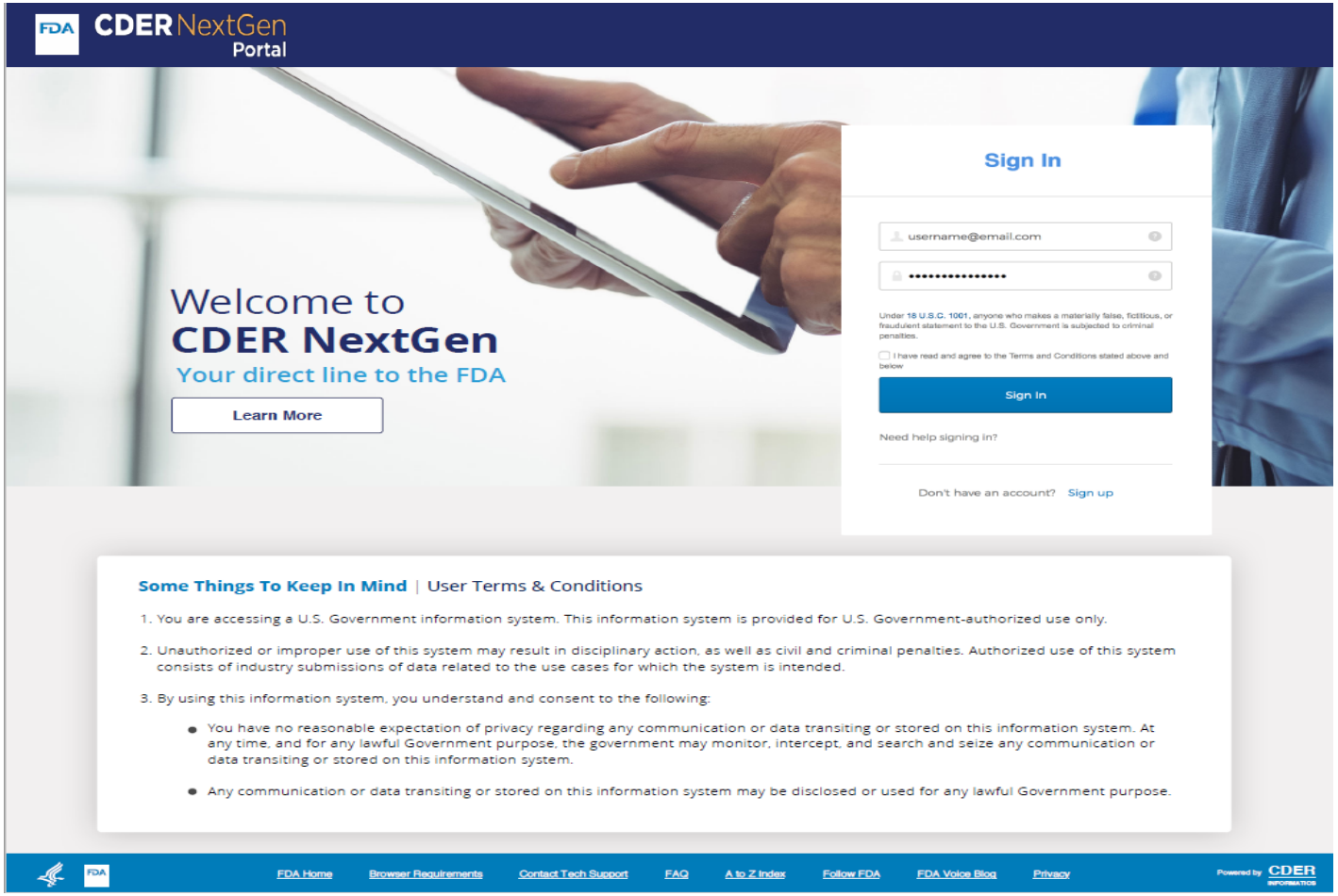
Reference Guide:
Withdrawal Request and Amendment Submission
Drug Development Tool Qualification Process



https://edm.fda.gov/

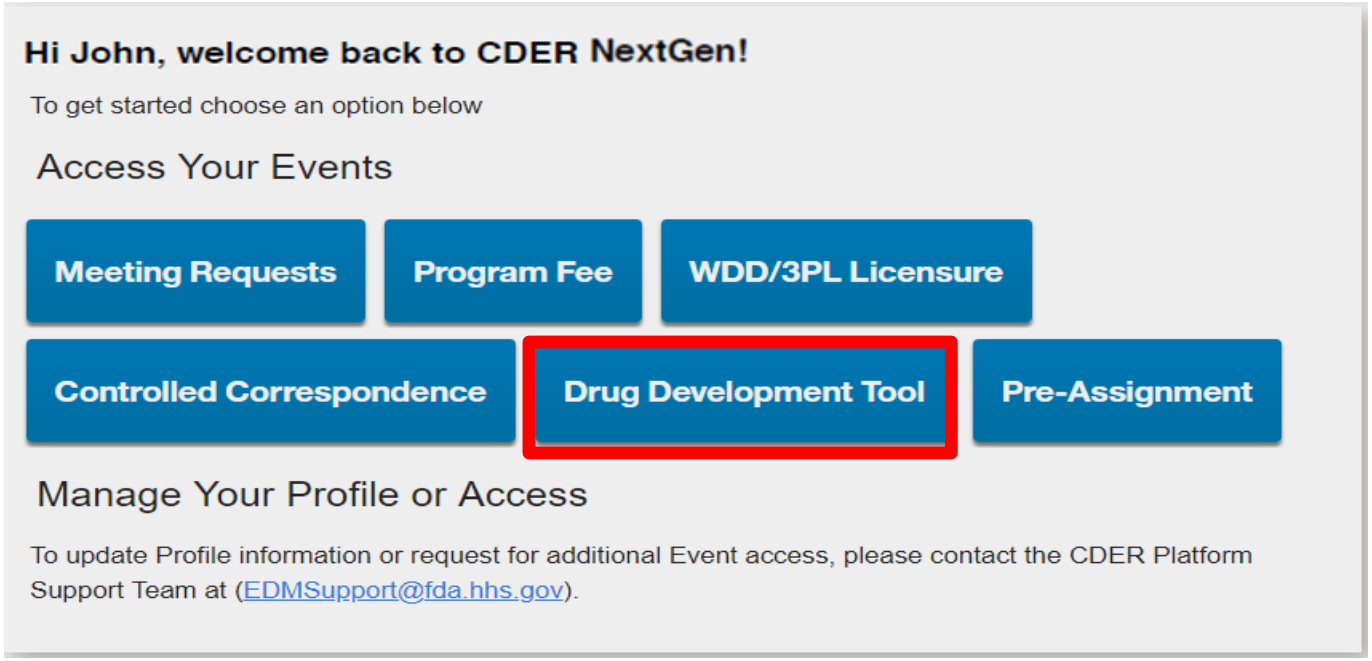
Withdrawal Request

Withdrawal Request

A Requestor may submit a Withdrawal submission for a DDT at any time. The DDT will not be officially Withdrawn until the FDA sends a Withdrawal Acknowledgement Letter. This section describes how to submit a Withdrawal Request.

Completing a Withdrawal Request

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

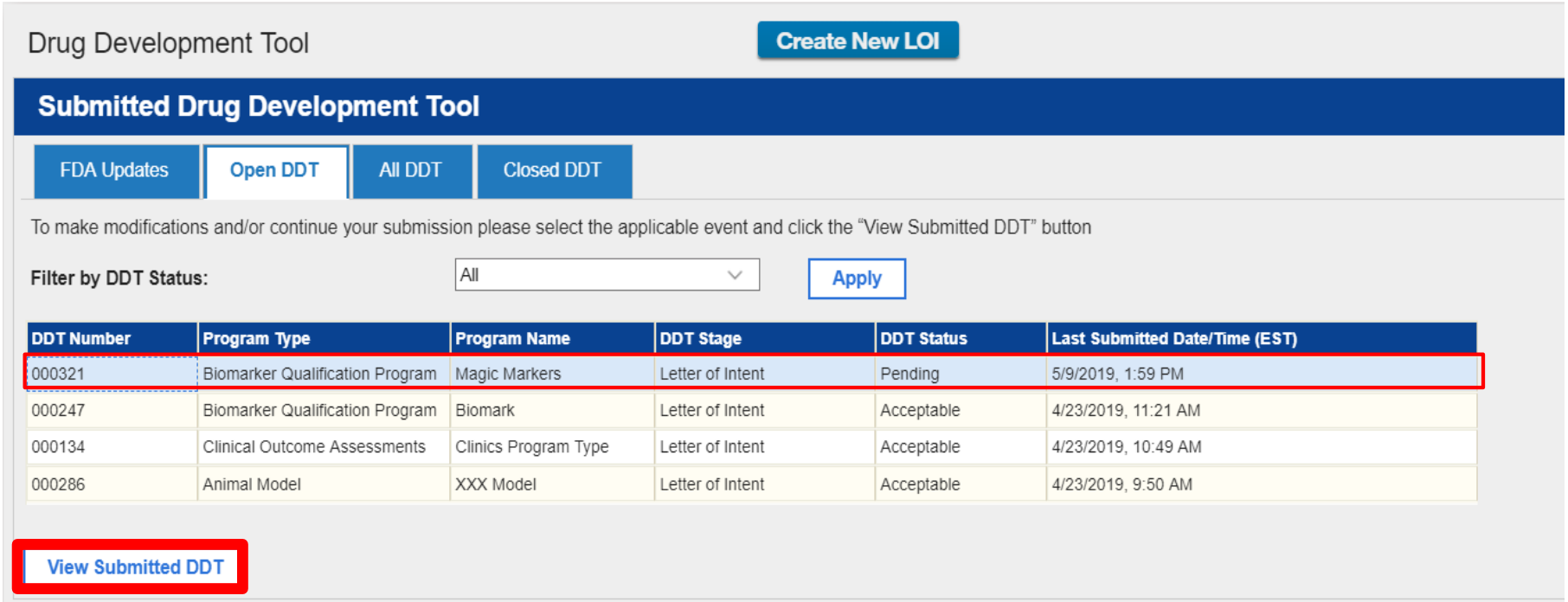


Withdrawal Request

Completing a Withdrawal Request

Step 2. Highlight and select the DDT Number you would like to submit a withdrawal request for.

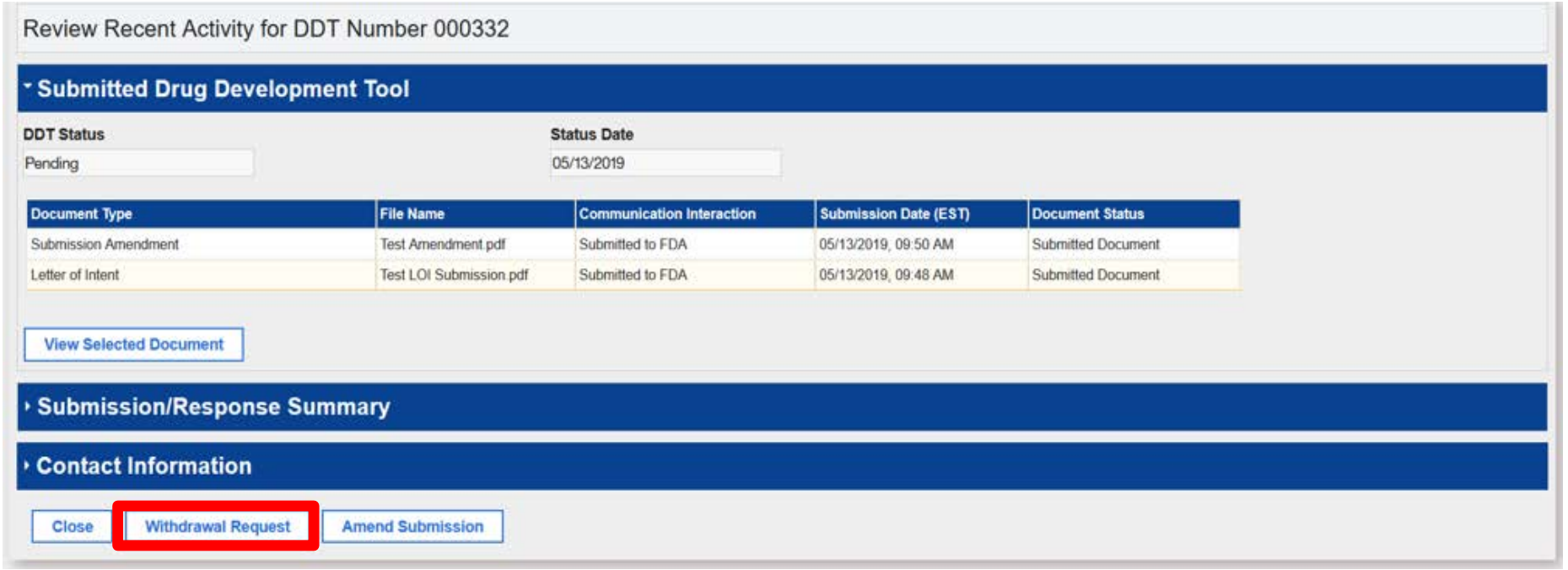
Step 3. Click View Submitted DDT.



Withdrawal Request

Completing a Withdrawal Request

Step 4. Click Withdrawal Request.



Withdrawal Request

Completing a Withdrawal Request

Step 5. Provide the reason for the withdrawal.

Step 6. Answer the question, if you would like to attach a supporting document. If the answer is Yes to attaching supporting document, then **click Attach Document.**

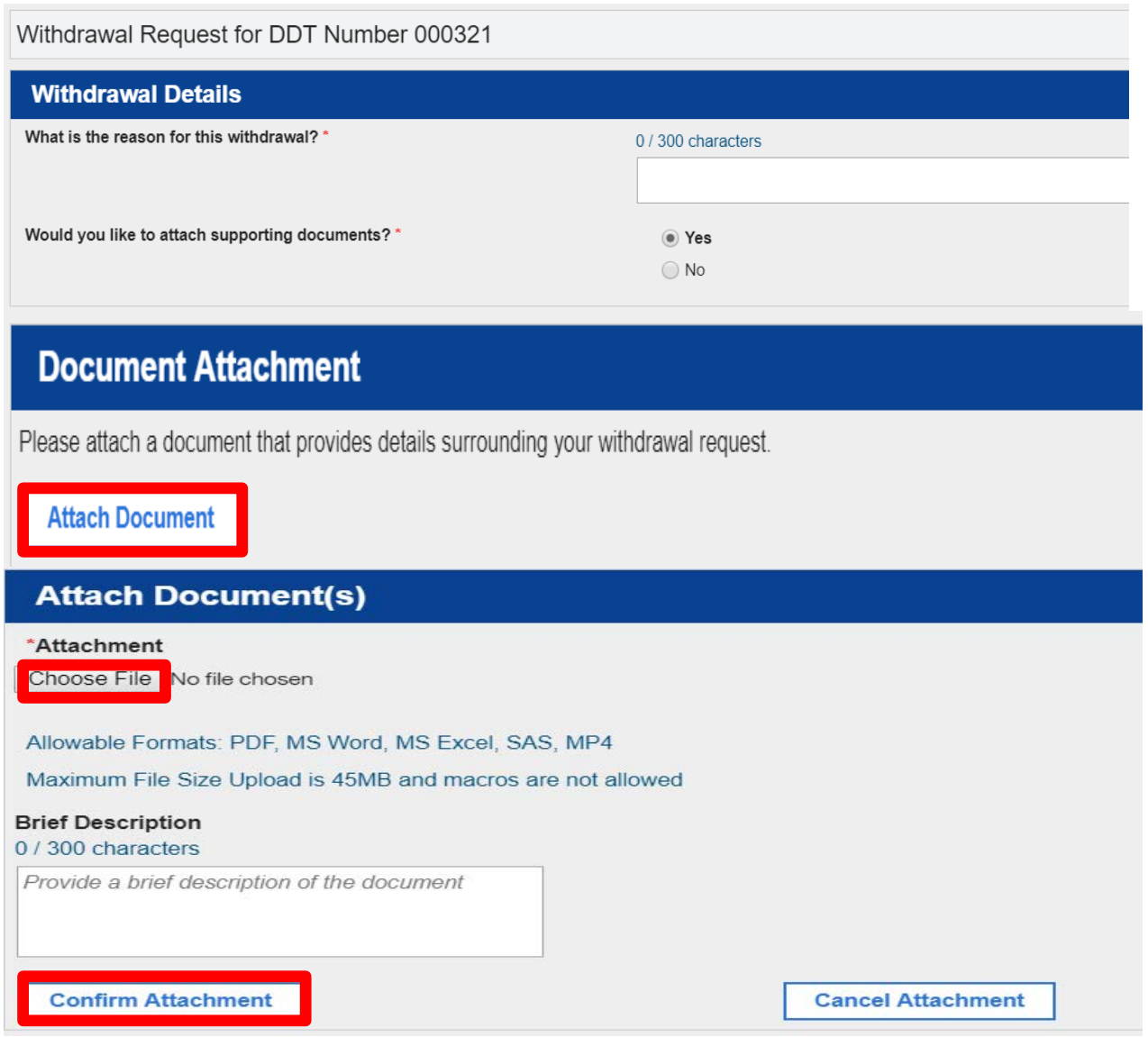
Step 7. Click Choose File.

Step 8. Select the document you would like to upload for the Withdrawal Request.

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. Provide a brief description of the document.

Step 10. Click Confirm Attachment.



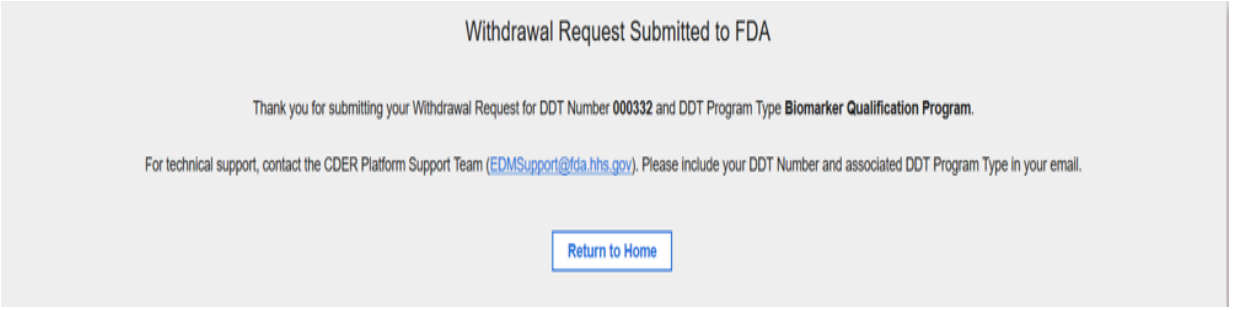
Withdrawal Request

Completing a Withdrawal Request

Step 11. Review all information uploaded and **c**lick the checkbox that you 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 Withdrawal Request for the same DDT Number. An email will also be sent with this confirmation.



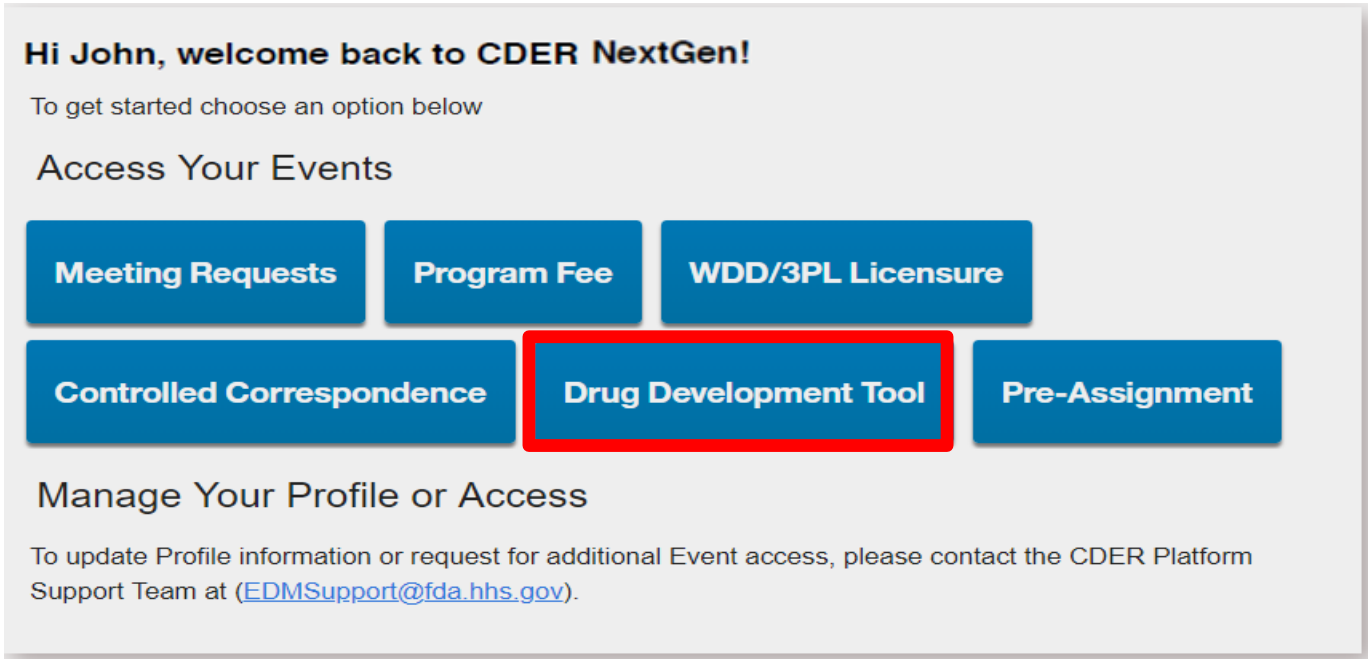
Amendment Submission

Amendment Submission

Amendments can be submitted after any submission stage during the DDT Qualification process. Amendments can be additional research papers, or information a Requestor wishes to add to the DDT submission for FDA review. This section describes how to submit an amendment.

Completing an Amendment Submission

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

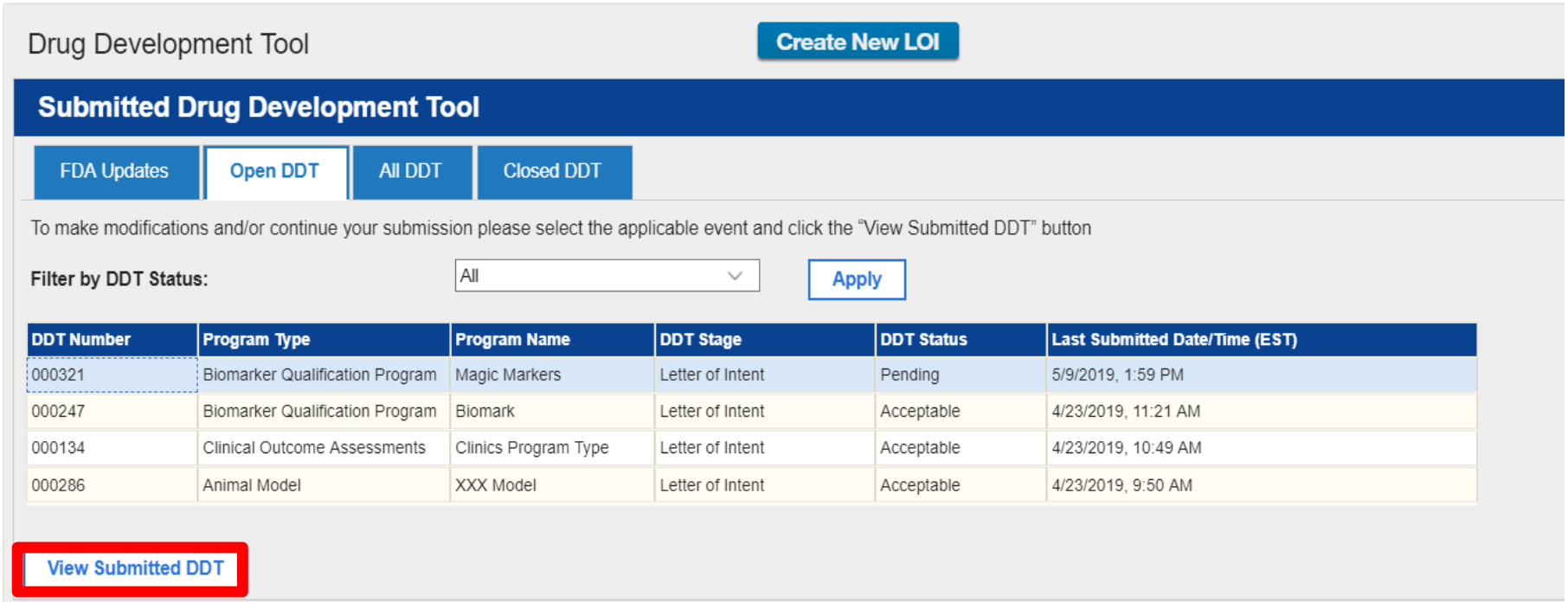


Amendment Submission

Completing an Amendment Submission

Step 2. Highlight and select the DDT Number you would like to submit an amendment submission for.

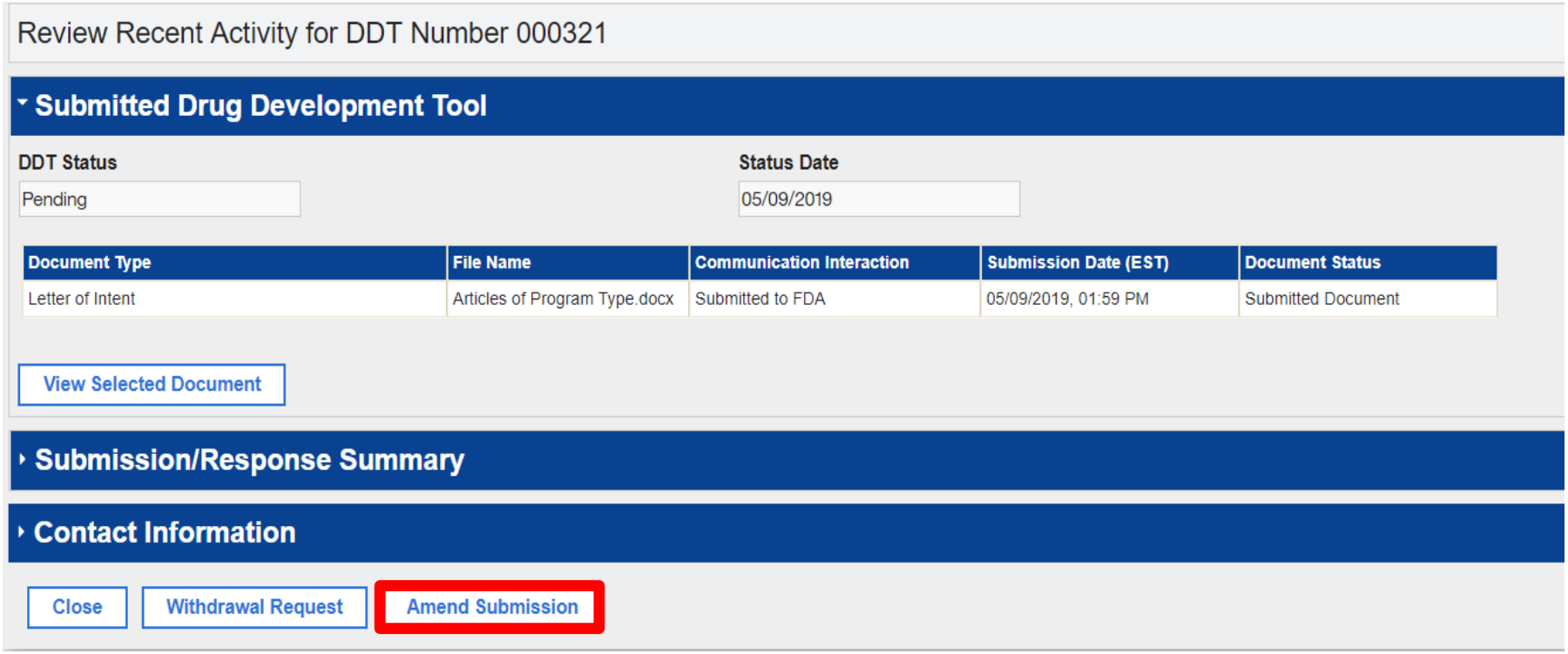
Step 3. Click View Submitted DDT.



Amendment Submission

Completing an Amendment Submission

Step 4. Click Amend Submission.



Amendment Submission

Completing an Amendment Submission

Step 5. **Click Attach Document**

Step 6. **Click Browse.**

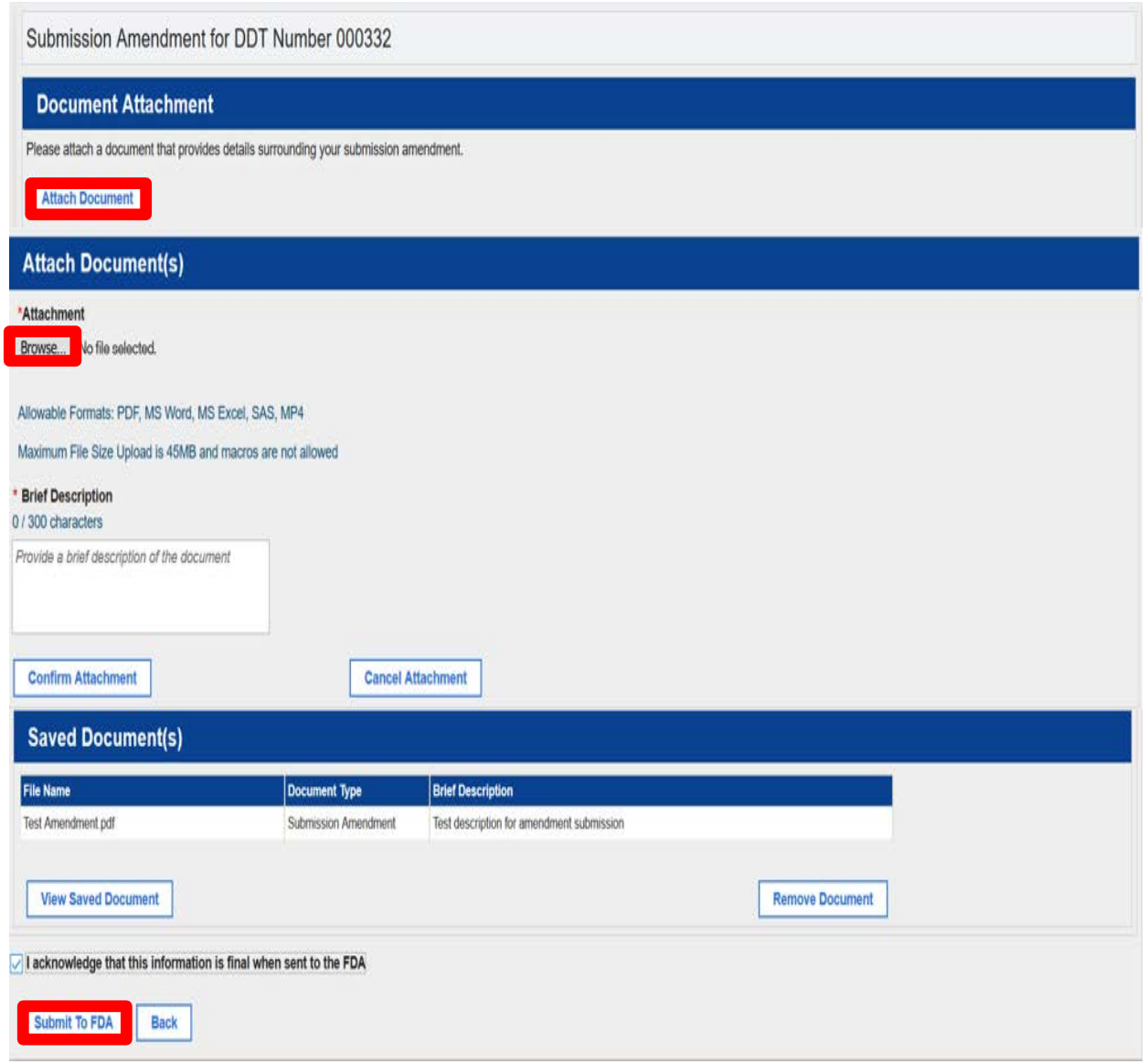
Step 7. Select the document you would like to upload for the amendment submission.

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 8. Provide a brief description of the document.

Step 9. **Click Confirm Attachment.**

Step 10. Review information uploaded.



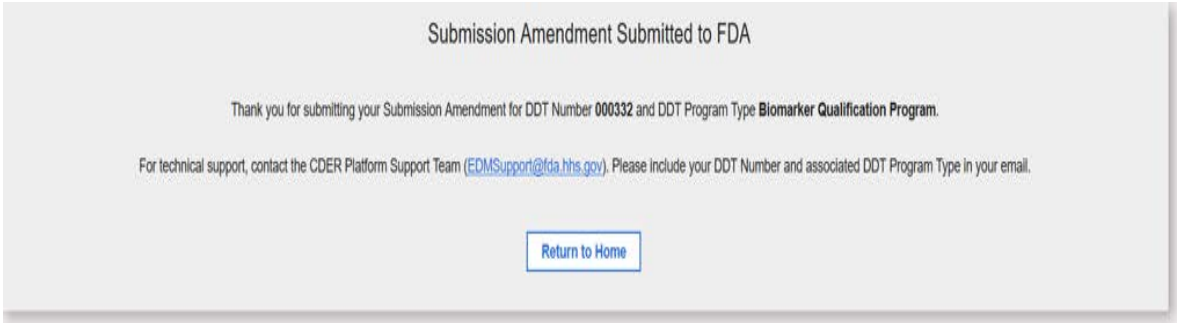
Amendment Submission

Completing an Amendment Submission

Step 11. Click the checkbox that you 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 Submission Amendment 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.