

Biomarker Qualification Program (LOI and LOS)

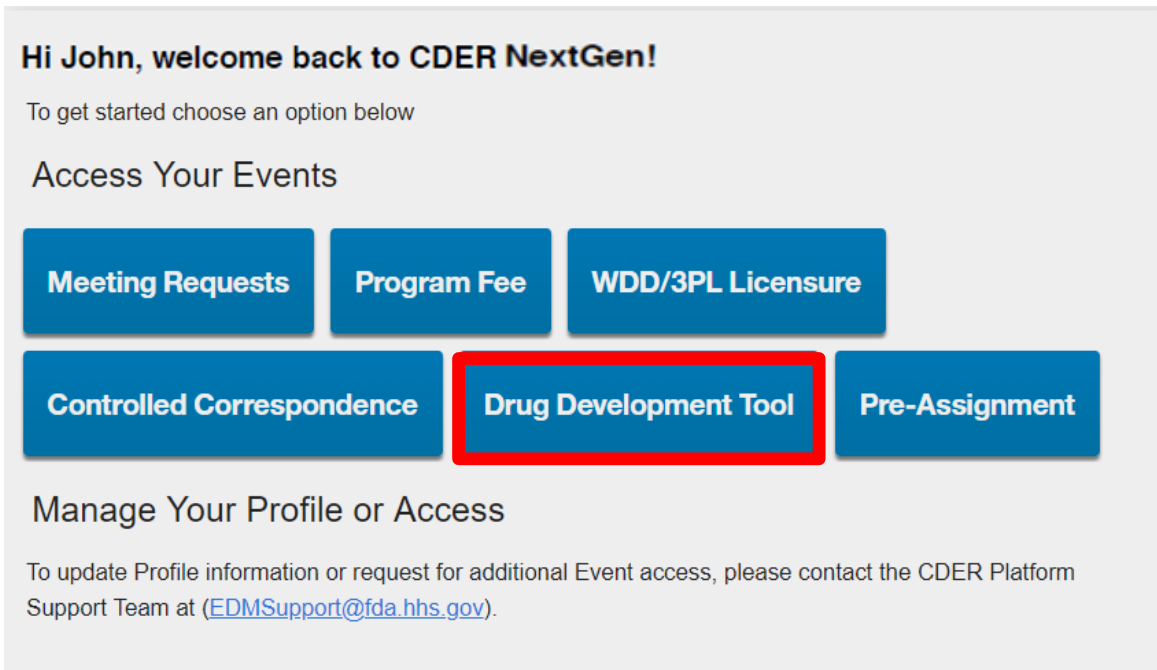
Biomarker Qualification Program (LOI and LOS)

A biological marker or biomarker is a characteristic that is objectively measured and evaluated as an indicator of normal biologic processes, pathologic processes or biological responses to a therapeutic intervention. For Biomarker Qualification Program Type, you are allowed to submit a Letter of Intent or a Letter of Support. The Letter of Support (LOS) is for the Biomarker Program only and is a step prior to the DDT Qualification process. This section describes how to submit a Letter of Intent or Letter of Support in the DDT Qualification Process for Biomarker Qualification Program.

Create New LOI or LOS: Biomarker Qualification Program

Once you have logged into the Portal, you must create a new LOI for a DDT program.

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).

Biomarker Qualification Program (LOI and LOS)

Create New LOI or LOS: Biomarker Qualification Program

Step 2. You will be directed to the Drug Development Tool page, **click Create New LOI.**

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)
There are no submissions.					

[View Submitted DDT](#)

Saved Drug Development Tool

Program Type	Last Saved Date/Time (EST)
There are no submissions.	

[View Saved Request](#)

Biomarker Qualification Program (LOI and LOS)

Completing LOI or LOS: Biomarker Qualification Program

Step 3. Enter in the Program Name.



There is a 100 character limit.

Step 4. Select the DDT Program Type
Biomarker Qualification Program

Note: You have the following other options to select from;

- Animal Model
- Clinical Outcome Assessments

Step 5. Click Next.



On the Drug Development Tool Information pages, the submitter has the following options:

- Save as Draft
- Next
- Delete Submission

Create Drug Development Tool

Drug Development Tool Information

1a. Please create a Program Name. *

0 / 100 characters

1b. What is the DDT Program Type? *

Select One ▾

Select One

Animal Model

Biomarker Qualification Program

Clinical Outcome Assessments

Save As Draft **Next** Delete Submission

Biomarker Qualification Program (LOI and LOS)

Completing New LOI or LOS: Biomarker Qualification Program


Step 6. Select a biomarker type that will be associated with the request.

2. Select a Biomarker Type that will be associated with the request. *

Select One
Histologic
Molecular
Physiologic
Radiographic
Other

Please enter the biomarker type not listed.

10 / 75 characters

 If you select 'Other', you must enter manually Biomarker type not listed in the dropdown above. There is a 75 character limit.

Step 7. Select a biomarker category that will be associated with the request.

3. Select a biomarker category that will be associated with the request. *

Select One
Select One
Diagnostic
Monitoring
Pharmacodynamic/Response
Predictive
Prognostic
Safety
Surrogate Endpoint
Susceptibility/Risk

Required Prompts



Note: Any prompt that is denoted with an asterisk is a required prompt. Prompts other than marked asterisk are optional.

Biomarker Qualification Program (LOI and LOS)

Completing New LOI or LOS: Biomarker Qualification Program

Step 8. Select the Drug Development Space that will be associated with the request.

4. Select the Drug Development Space that will be associated with the request. *

Pre-Clinical

Early-Phase Clinical Trials

Late-Phase Clinical Trials

Post-Marketing

Step 9. Answer the question, Is the request related to a composite biomarker (e.g. more than one defined characteristic)?

5. Is the request related to a composite biomarker (e.g. more than one defined characteristic)? *

Yes

No

Step 10. Enter the Patient Population.

6. Enter Patient Population (e.g. Age, Disease State, Disease). *

0 / 75 characters

Biomarker Qualification Program (LOI and LOS)

Completing New LOI or LOS: Biomarker Qualification Program

Step 11. This question distinguishes whether you are submitting a Letter of Intent or Letter of Support. Select the answer **Requesting Letter of Support or Submitting Letter of Intent** for the question “What are you submitting for?”

7. What are you submitting for? *

- Requesting Letter of Support
- Submitting Letter of Intent

Biomarker Qualification Program Type

Note: For Biomarker Qualification Program Type, you are allowed to submit a Letter of Intent or a Letter of Support. Both require documentation upload.


Alternate Contact, Partner Organization and Documentation

Alternate Contact

The alternate Point of Contact is an individual within your organization that should also receive email notifications regarding updates to the DDT submission. Providing an Alternate Contact applies to Animal Model, COA, and Biomarker DDT requests. This section describes how to enter an alternate contact information.

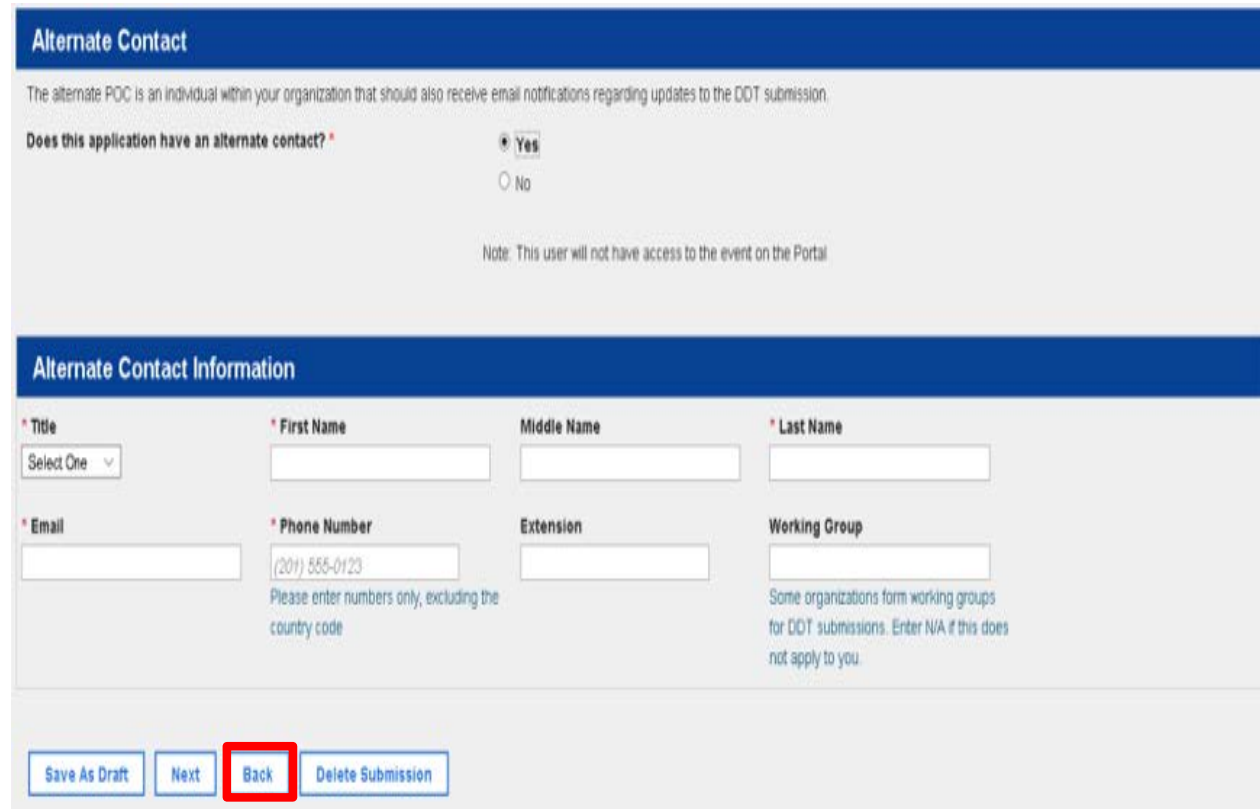
Alternate Contact

Step 1. Answer the question “Does this application have an alternate contact?”

 If yes, please note this user will not have access to the event on the Portal.

Step 2. If your answer is Yes, please enter the following information for the alternate contact;

- Title
- First Name
- Middle Name
- Last Name
- Email Address
- Phone Number Extension
- Working Group



Alternate Contact

The alternate POC is an individual within your organization that should also receive email notifications regarding updates to the DDT submission.

Does this application have an alternate contact? * Yes No

Note: This user will not have access to the event on the Portal

Alternate Contact Information

* Title

* First Name

Middle Name

* Last Name

* Email

* Phone Number
Please enter numbers only, excluding the country code

Extension

Working Group
Some organizations form working groups for DDT submissions. Enter N/A if this does not apply to you.

Step 3. Click Next.

Working Group


Some organizations form working groups for DDT submissions.

Partner Organization

This section describes how to enter a Partner's Contact information. Providing Partner Organization applies to Animal Model, COA, and Biomarker DDT requests.

Partner Organization Selection

Step 1. Provide an answer to the question "Is this application in partnership with another organization?"

 If yes, please note this user will not have access to the event on the Portal but will receive any submission notification on behalf of the submitter.

Step 2. Click Next.

Provide Partner for this Application

Application Partner

Is this application in partnership with another organization? *

Yes
 No

[Save As Draft](#) [Next](#) [Back](#) [Delete Submission](#)

Partner Organization

This section describes how to enter a Partner Contact information.

Partner Organization Selection

Step 3. If your answer is Yes, search and select your Partner Organization that you will be submitting on behalf of. If you can't find your Partner Organization, click **Enter Organization Manually**.



You can select up to three (3) Partner Organizations. Please follow the Multiple Partner Selection Instructions to add more than one organization.

Step 4. To manually add the Partner Organization please enter the following information: Organization Name, Address and DUNS.



A DUNS number is a unique nine digit identification number issued by Dun & Bradstreet (D&B) for each physical location of a business. Please enter 999999999 if your organization does not have a DUNS number.

Step 5. Click **Add Organization**.

Partner Organization Selection

Search and select your Partner Organization that you will be submitting on behalf of. You can select up to three (3) Partner Organizations.

Organization Name
the

Multiple Partner Selection Instructions

To add multiple partners:

1. Click on the row to highlight the first organization
2. Click the "Select Organization" button below the table
3. Continue highlighting additional organizations and clicking "Select Organization" one-by-one

Organization Name	Full Address	DUNS
THE DODGE COMPANY INC	9 PROGRESS RD, BILLERICA, MA, 01821, US	001045517
THE GREAT ATLANTIC & PACIFIC TEA CO INC	2 PARAGON DR, MONTVALE, NJ, 07645, US	001367366
THERMO FISHER SCIENTIFIC INC	168 3RD AVE, WALTHAM, MA, 02451, US	001409673
THE MENTHOLATUM COMPANY	707 STERLING DR, ORCHARD PARK, NY, 14127, US	002105757
THE BULLEN COMPANIES	1640 DELMAR DR, FOLCROFT, PA, 19032, US	002373462

Please note that at most 100 records will be displayed.

Multiple Partner Selection Instructions

To add multiple partners:

1. Click on the row to highlight the first organization
2. Click the "Select Organization" button below the table
3. Continue highlighting additional organizations and clicking "Select Organization" one-by-one

Manual Add

* Organization Name

* Country

* State/Province

* Street Address Line 1

Street Address Line 2

* City

* Zip Code/Postal Code

* DUNS

Allowable format: Nine digit numeric code (i.e. 123456789) – If N/A then type 999999999

Partner Organization

This section describes how to enter a Partner Contact information.

Partner Organization Selection

Step 6. Click Next.



The submitter has the option to Remove Organization or Remove All Organizations selected.

Organization Name	Full Address	DUNS
THE DODGE COMPANY INC	9 PROGRESS RD, BILLERICA, MA, 01821, US	001045517
THE GREAT ATLANTIC & PACIFIC TEA CO INC	2 PARAGON DR, MONTVALE, NJ, 07645, US	001367366
THERMO FISHER SCIENTIFIC INC.	168 3RD AVE, WALTHAM, MA, 02451, US	001408673
THE MENTHOLATUM COMPANY	707 STERLING DR, ORCHARD PARK, NY, 14127, US	002105757
THE BULLEN COMPANIES	1640 DELMAR DR, FOLCROFT, PA, 19032, US	002373462

Please note that at most 100 records will be displayed.

Select Organization

Enter Organization Manually

Selected Partner Organization

Organization Name	Full Address	DUNS
Test Organization Name	123 Test Street, Washington, DC, 20009, US	999999999

Remove Organization

Remove All Organizations

Save As Draft

Next

Back

Delete Submission

Partner Organization

This section describes how to enter a Partner Contact information.

Partner Contact

Step 7. Please enter the following information for the Partner Contact;

- Title
- First Name
- Middle Name
- Last Name
- Email Address
- Phone Number Extension
- Working Group

Step 8. Click Next.



Click ‘Update Selection’ if you want to update the organization name. This will redirect you to the Partner Organization Page.

Organization Name	Full Address	DUNS
TERSERA THERAPEUTICS LLC	309 2ND AVE SE STE 200, CEDAR RAPIDS, IA, 52401, US	015364437

* Title: Select One

* First Name: [Text Box]

Middle Name: [Text Box]

* Last Name: [Text Box]

* Email: [Text Box]

* Phone Number: (201) 555-0123
Please enter numbers only, excluding the country code

Extension: [Text Box]

Working Group: [Text Box]
Some organizations form working groups for CDOT submissions. Enter N/A if this does not apply to you.

Buttons: Save As Draft, Next, Back, Delete Submission

Required Prompts



Note: Any prompt that is denoted with an asterisk is a required prompt. Prompts other than marked asterisk are optional.

Documentation

This section describes how to upload documentation. Providing documentation applies to Animal Model, COA, and Biomarker DDT requests.

Drug Development Documentation

Step 1. Provide a short description on what is being submitted.

 There is a maximum 2000 character limit.

Step 2. Click **Attach Document**.

Provide Description and Documents

Proposed Context of Use

* Provide the proposed context of use for this DDT submission.
0 / 2000 characters

Drug Development Documents

In this submission, it is mandatory to attach a Letter of Support.

Attach Document

Documentation

For this submission, it is mandatory to attach a Letter of Intent or Letter of Support to complete this qualification process.

Documentation

Drug Development Documentation

Step 3. Select Letter of Intent or Letter of Support for Document Type.

Step 4. Click Choose File.

Step 5. Search and Select the document you would like to be uploaded.



The allowable formats for uploading a document are PDF, MS Word, MS Excel, SAS, MP4. The maximum file size upload is 45 MB and macros aren't allowed.

Step 6. (Optional) Provide a brief description of the document.



There is a 300 character limit.

Step 7. Click Confirm Attachment.

Drug Development Documents

In this submission, it is mandatory to attach a Letter of Intent.

Attach Document(s)

*** Select Document Type**

Select One

*** Attachment**

Choose File No file chosen

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

Provide a brief description of the document

Confirm Attachment **Cancel Attachment**

Documentation

Drug Development Documentation

Step 8. Confirm document was attached to the table.



Submitter can View Saved Document or Remove Document after uploading document.

Step 9. Click Review Submission Information.

Saved Document(s)

File Name	Document Type	Brief Description
Articles of Program Type.docx	Letter of Intent	

[View Saved Document](#) [Remove Document](#)


[Save as Draft](#) [Review Submission Information](#) [Back](#) [Delete Submission](#)

Documentation

This section describes how to review and submit the Letter of Intent or Letter of Support.

Review Drug Development Tool Summary

Step 1. Review all information in tabs entered then click the checkbox that you acknowledge that this information is final when sent to FDA.

 On the Review Summary Page, you are able to make edits to your submission. You can do the following:

- Attach Document
- Remove Document
- Update Profile
- Delete Submission
- Save as Draft
- Go Back to previous page

Step 2. Click **Submit To FDA**.

Step 3. You will be directed to a confirmation page that displays your DDT Number for the Program type you are submitting for.

Submission/Response Summary

Question	Response
1a. Please create a Program Name.	COA test 1
1b. What is the DDT Program Type?	Clinical Outcome Assessments
2. Select the Type of COA that will be associated with the request.	Patient Reported Outcome (PRO) Assessment
3. Provide the disease state.	Test
4. Select the Patient Population for the COA Request.	Adult

Contact Information

[Update Profile](#)

Selected Organization(s)

Organization Name	Full Address	DUNS Number	Designation
VERTEX PHARMACEUTICALS INC	50 NORTHERN AVE, BOSTON, MA, 02210, US	602478257	Applicant

Point of Contact(s)

Title	Name	Email	Phone Number	Extension	Designation	Working Group
N/A	Abisola Olasupo	Abisola.Olasupo@fda.hhs.gov	(571) 226-6942		Applicant	N/A

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

[Save as Draft](#) [Submit To FDA](#) [Back](#) [Delete Submission](#)

Drug Development Tool Submitted to FDA

Thank you for submitting your Drug Development Tool.

Your DDT Number is **000641**.

The submission of a project and the assignment of a program tracking number do not constitute acceptance into a DDT program.

For technical support, contact the CDER Platform Support Team at edmsupport@fda.hhs.gov.

[Return to Home](#)

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