



External

Synetra™ Client Portal

Work Instructions

The life science business of
Merck KGaA, Darmstadt, Germany
operates as MilliporeSigma in
the US and Canada.

BioReliance®

Purpose

To provide clients with clear, concise, and comprehensive guidance on sample submission and shipment via the Synetra™ Client Portal.

Scope

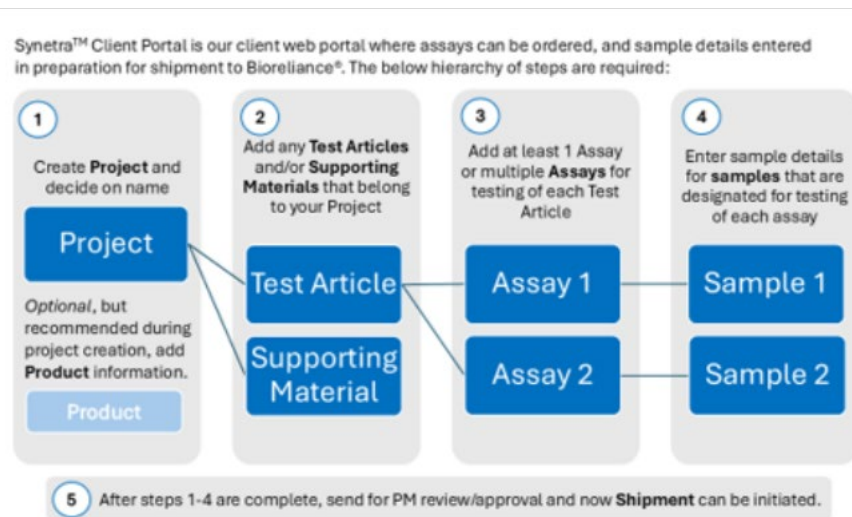
This document aims to ensure that clients can efficiently navigate the Synetra™ Client Portal sample submission process and any adjacent features and functionalities. The work instruction (WI) outlines step-by-step procedures for key tasks such as sample submission.

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- I. System Overview
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I. System Overview

The portal architecture and key components consist of a central project element that encompasses subcomponents such as Test Articles, Supporting Materials, Assays, and Samples. Projects are intended to help with the organization of subcomponents. These elements can be defined as the user sees fit but should take into consideration that the goal is to create a structure that enables easy access to similar or related information (e.g. submissions, reports) later.



II. User Access and Login

Once an authorized representative account has been created, or a sub-user added, the new user will receive an email notification. The user must follow the link provided in the email to create a new password to gain access to the portal.

The reset password function located underneath the password field can be utilized if a user forgets their password. A link will be sent to the user's account, and it must be accessed within 24 hours of the request.

III. Creating a Project

Prior to submitting any test samples, you must first **create a Project**.

1. A project can be created from the home page by clicking on a **Quick Action** to 'Create Project' (see image 1) or by navigating to the **Project Details** page by clicking 'Projects' in the left navigation bar and 'Create Project' once on the Projects page (see image 2).

Image 1. Quick Actions Widget on Home Page

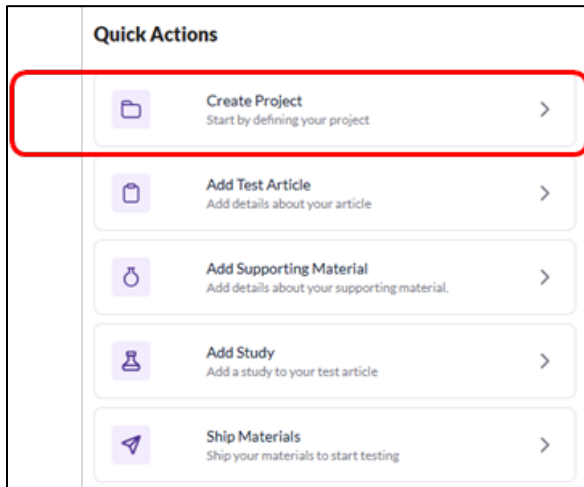
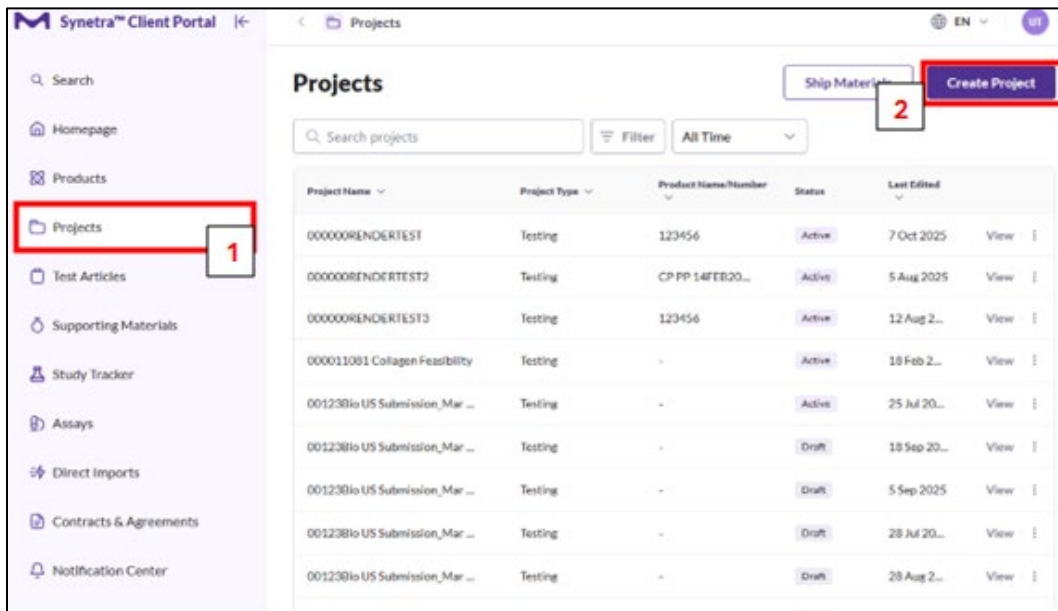


Image 2. Project Details Page



2. Once prompted to **select your project type** from the list as shown in image below, select and click 'Continue'.

Image 3: Project Type Selection

Create Project [Close]

1 Project Type Selection

2 Basic Information

3 Review Project

Project Type Selection
Select the project type to enter the relevant information.

Testing
Testing project type include Lot Release, Characterization, Autologous Therapeutic and Raw Material Testing.

Stability Testing
Testing of the same product/molecule over time and different storage conditions.

Viral Clearance Studies
Study performed to measure capacity of the manufacturing process steps to inactivate or remove viruses and other agents.

Cell Bank or Virus Stock Manufacturing
This involves the manufacturing/production of cells or virus banks to be used in support of drug development and manufacturing.

Custom Method Development & Validation
This involves the development and validation of specific testing methods tailored to the unique

Continue

3. Complete the '**Basic Information**' section of the **Project** per the field descriptions below.
 - a. **Project Name**- enter a descriptive name for project
 - b. **Purchase Orders**- the first time a purchase order (PO) is used, click 'Add New Purchase Order' and follow the prompts to name and upload a PO. Once the PO is added, it will become available to select from the drop-down for future submissions.
 - More than one PO can be added to a Project, and in cases where different POs are being used for Test Articles, all relevant POs should be added.
 - c. **Quote/Contract Number**- the first time a quote or proposal is used click 'Add New Quote/Contract' and follow the prompts to name and upload a quote/contract. Once the Quote/Contract is added, it will become available to select from the drop-down for future submissions.
 - More than one quote/contract can be added to a Project, and in cases where different quotes/contracts (including amendments) are being used for Test Articles, all relevant quotes/contracts should be added.
 - d. **Product**- this is an optional field, but it is highly recommended for easy reference, allowing users to quickly look up what has been submitted and tested for a specific product. The first time a product is used, click 'Add New Product' and follow prompts to enter the product name. Once a product has been added, it will become available to select from the drop-down for future submissions.
 - e. **Company Shipping Address**- select from the available options in the drop-down menu, which are directly sourced from our ERP system based on previously provided information. This information will be included in Final Reports/CoAs.

- f. **Company Billing Address**- select from available options in the drop-down menu, which are being sourced from our ERP system based on information previously provided. This information will be used for invoicing.
- g. **Billing Contact**- select from available options in the drop-down menu, which are being directly interfaced from our ERP system based on information previously provided. This information will be used for invoicing.
- h. Is there a Quality Service Agreement (QSA) in place?
- i. Is the project funded by the government?

Image 4: Project Basic Information

Create Project [Close]

Project Type Selection
Completed

2 Basic Information

Review Project

Basic Information
Enter the project detail like name and related documents.

Project Name
[Text Field]

Purchase Orders [Info Icon]
[Dropdown Menu]
Add New Purchase Order

Quote/Contract Number
[Dropdown Menu]
Add New Quote/Contract

Product (Optional)
[Dropdown Menu]
Add New Product

⚠ If this work is supporting the development, manufacturing and ultimately release of a drug product, you need to complete the Product Field so you can track your work and tie it back to the development and release of your product.

Company Shipping Address
[Dropdown Menu]
Provide your company shipping address for inclusion on your Certificate of Analysis (CoA).

Company Billing Address
[Dropdown Menu]
Provide your company billing address for inclusion on your digital invoices.

Billing Contact
[Dropdown Menu]

Is there a Quality Service Agreement(QSA) in place between your company and MilliporeSigma?
 Yes
 No

Is this project funded by the government?
 Yes
 No

[Back] [Continue]

- 4. Once complete, click '**Continue**'. A 'Review' window will open, with a summary of all completed information. If updates need to be made to previously entered information, the 'Back' button should be selected.

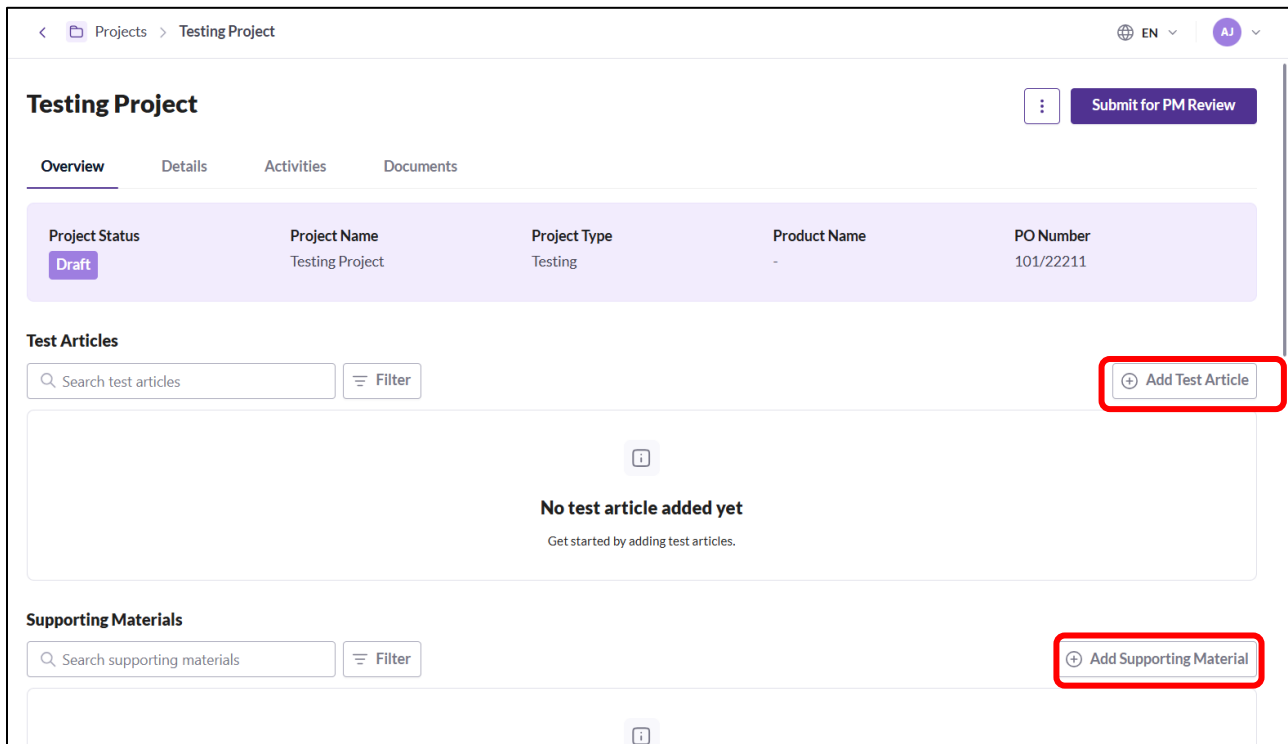
5. Once all information is entered correctly, click the '**Create Project**' button at the bottom of the review screen.

IV. Submitting Samples

Once your Project is created, the **Project Detail Page** will open. Continue the submission process by completing the options to 'Add Test Article' and 'Add Supporting Material' (as shown in Image 5).

- **Test Articles** are the materials that are being sent for testing and eventual reporting.
- **Supporting Materials** are materials that are used in support of Test Article testing and can include media, reagents, buffers, references, controls, or serum. These would not have direct testing.

Image 5: Project Detail Page



Test Article Addition

1. To add a **Test Article**, click 'Add Test Article' button.
2. Enter in the test article **Basic Information** as shown in Image 6.
Note: in cases where one or more PO or Quote(s) were entered at the Project level, designate which PO and Quote correspond to each test article from the drop-down.

Image 6: Test Article Basic Information

Basic Information

Enter the test article name and related information.

Test Article Name/Designation ⓘ

Please provide the test article name exactly as you require it to appear in the final report (please include the lot number, if applicable)

Authorized Representative for Reports Only ⓘ

Testing Type

Species of Origin

Sample Identification

Purchase Order

Add New Purchase Order

Select purchase order to be used in this Test Article.

Quote/Contract Number

Add New Quote/Contract

Select quote/contract number to be used in this Test Article.

3. Enter test article **Safety Information** as prompted and shown below in Image 7.

Image 7: Test Article Safety Information

Safety Information

Enter the safety information of your test article.

Biosafety Level [See Details](#)

BSL-1 Sample may contain well-characterized infectious agents that are not known to consistently cause disease in immunocompetent adult humans.	BSL-2 Sample may contain infectious agents which may cause disease as a result of exposure and pose moderate hazards to infection in our personnel and the environment.	BSL-3 Sample may contain indigenous or exotic infectious agents that may cause serious or potentially lethal disease through the inhalation route.
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For rDNA Samples

Live
 Inactivated
 Attenuated
 None

Can contact with this test article cause infection in humans?

Yes
 No

Does the test article contain any virus sequences?

Yes
 No

Has the test article been genetically modified? (Applicable only to assays conducted in the UK.)

Yes
 No

4. Review all information prior to clicking the 'Add Test Article' button to finalize the addition.

Image 8: Review Safety Information and Add Test Article

Add Test Article To 000000RENDETEST

Quote/Contract Number R-1222222

Safety Information

Biosafety Level	-
For rDNA Samples	None
Can contact with this test article cause infection in humans?	No
Does the test article contain any virus sequences?	No
Has the test article been genetically modified? (Applicable only to assays conducted in the UK.)	No

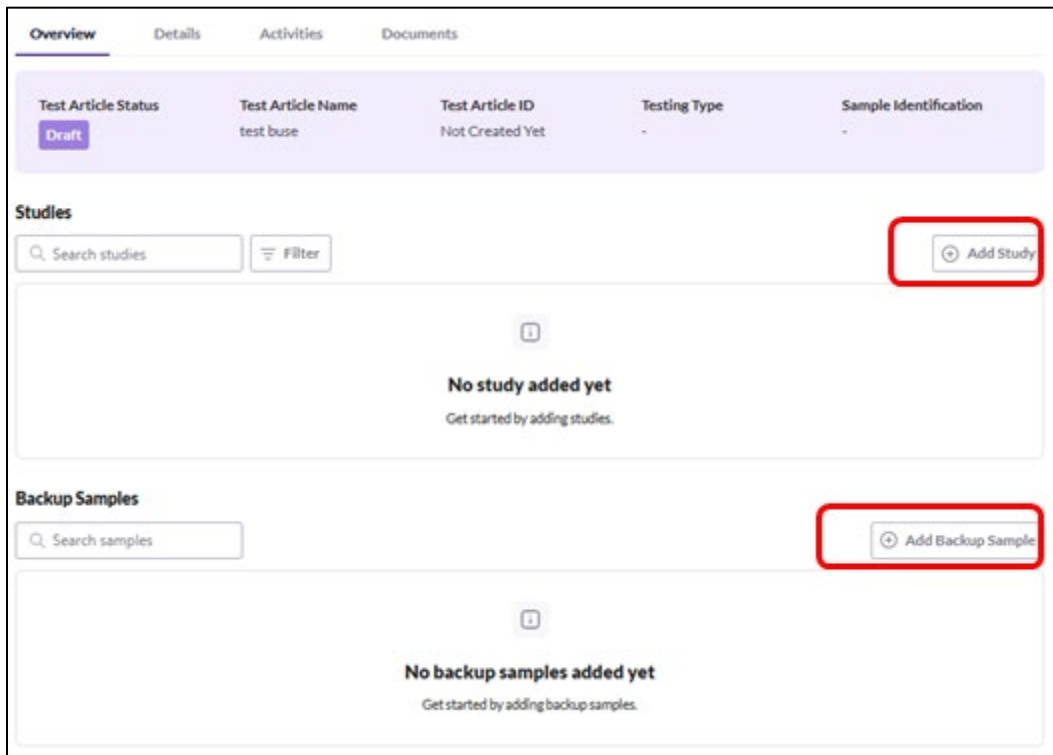
[Back](#) [Add Test Article](#)

5. Once a Test Article is available, the **Test Article Detail page** will be displayed.

Study / Sample Addition

1. **Studies** and corresponding **samples** should be added by clicking 'Add Study', as shown in Image 9. In cases where backup material will be provided as needed and there is no direct assay association, the 'Add Backup Sample' button should be selected.

Image 9: Adding Study / Sample Addition



2. Once 'Add Study' is selected, enter and select the assay number or title for the assay of interest and select from the available drop-down menu.
3. Once the assay is selected the following information will be displayed (as shown in Image 10):
 - a. **Assay ID & Title**- this is to confirm the assay selected is the correct assay. For more information about the assay click 'See Assay' where you will be taken to the assay information page that contains all assay details, including technical specification and validation summary report.
 - b. **Preferred Volume**- this shows the minimum preferred volume based on the assay. In cases where sample does not meet this requirement, please discuss with your PM.
 - c. **TAT**- this represents the standard Turn Around Time for the assay, and in cases where the lab currently has a queue and the standard TAT is not achievable, the new expected TAT will be shown in red.
4. In addition, all assay-specific questions will be available and require a response.
5. Once all fields are completed, progress to the next section by clicking 'Next'.

Image 10: Assay Information

Add Study To Project

1 Assay Information

2 Sample Information

3 Review Study

Assay Information

Each study includes one assay with its sample and any necessary materials. Select the assay and enter the required information.

Assay ID & Title ⓘ

003800.BSV: 28-DAY IN VITRO ASSAY FOR THE PRESENCE OF VIRAL CONTAMINANTS ▾

Select the assays listed in your contract. You can search by assay ID or title.

Assay ID & Title [See Assay](#)

003800.BSV: 28-DAY IN VITRO ASSAY FOR THE PRESENCE OF VIRAL C...

Preferred Volume

3 cell lines need 1 x 12 ml frozen cell lysate @ 10⁷ cells/ml...

TAT

35 days

Assay Comments (Optional) ⓘ

0 / 1000

Does the test sample contain live virus or a virus sequence?

▾

Has this test sample matrix been tested previously in this assay?

Next

6. The **Sample information** will be required as listed below, this includes:
 - a. **Label ID**- this should match the label exactly as it is shown on the material that will be sent.
 - b. **Storage Condition**- select the temperature required to store the sample
 - c. **Physical Description**- select the most appropriate match from the drop-down.
 - d. **Shipping Condition**- select the condition under which the material will be shipped.
 - e. **Expiration Date**- while optional, if the material has an expiry date, this information should be provided.

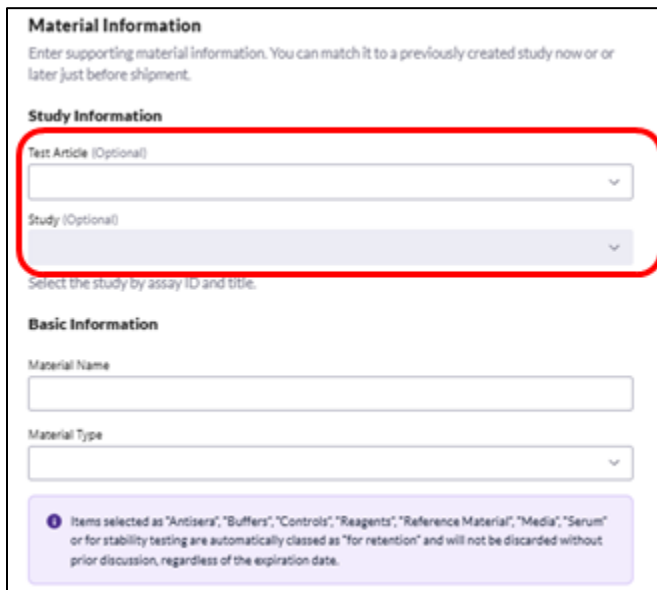
- f. **Sample Volume details-** This section includes an optional field labeled 'Unique Vial Identifier', which should be used when this level of detail is required for inclusion in a COA/Final Report or for a specific container designated for a particular test.
 - g. *Note: if utilizing the 'unique label identifier' field, the 'Number of Units' entered should always be '1'.*
 - h. If utilizing the 'unique label identifier' field or have more than one sample volume click 'Add Volume' to include additional details.
6. Once all details have been entered and reviewed, click 'Add Study' at the bottom of the page and the new study associated with the previously entered Test Article will be visible.
7. If additional studies/assays need to be added to the same test article, repeat the same steps above.
8. Similarly, if additional Test Articles need to be added, the same test article addition process should be followed from above.

Adding Supporting Materials

In cases when a **Supporting Material needs** to be added instead of a Test Article, this can be done directly from the homepage in the Quick Actions Widget or from the Project Detail Page.

1. Click on **'Add Supporting Material'** and follow prompts to enter material information (as shown in Image 11a and 11b).
2. When submitting a Supporting Material that is intended to be used only for a specific Test Article and Study, the fields listed as optional for 'Test Article' and 'Study' should be completed to select the corresponding values. This will allow the linkage to be made between these items for visibility to Contract Testing lab operators.
3. If the Supporting Material can be used across different Test Articles and Studies, the optional fields should be left blank.
4. All remaining fields should be populated in a similar fashion to the Test Article.

Image 11A: Supporting Material



Material Information
Enter supporting material information. You can match it to a previously created study now or later just before shipment.

Study Information

Test Article (Optional)
Study (Optional)

Select the study by assay IU and title.

Basic Information

Material Name
Material Type

i Items selected as "Antisera", "Buffers", "Controls", "Reagents", "Reference Material", "Media", "Serum" or for stability testing are automatically classed as "for retention" and will not be discarded without prior discussion, regardless of the expiration date.

Image 11B: Supporting Material

The screenshot shows a form for entering supporting material details. It includes several dropdown menus for 'Storage Condition', 'Physical Description', 'Shipping Condition', and 'Species of Origin'. There is a date picker for 'Expiration Date (Optional)'. A text area for 'Material Comments (Optional)' has a character count of '0 / 1000'. Below this is a section titled 'Material Volume 1' with three input fields: 'Number of Units', 'Volume (Per Unit)', and 'Unit of Measurement'. There is also a 'Unique Label Identifier (Optional)' field and an 'Add Volume' button at the bottom.

5. When all fields are complete, click 'Next'.
6. Enter Safety Information.
7. Once all fields are complete, click 'Next'.
8. Confirm the accuracy of all details that have been entered on the review page. Proceed to 'Add Supporting Material'.

Submit for Project Manager (PM) Review

PM review can begin after adding test articles, corresponding studies, samples, and supporting materials to the project.

1. From the Project Detail Page, click '**Submit for PM Review**' at the top right side of the page and all available Projects and Test Articles that are complete and ready to be sent will be visible.

Image 12: Submitting for PM Review

Item Selection
Select the test articles and supporting materials you want to submit for PM Review.

⚠️ "Review Readiness" indicates whether the item is ready for PM review. If the status is "Needs Completion" required fields must still be filled, and the item cannot be selected here.

Test Articles

1 test article selected

Test Article Name	Testing Type	Review Readiness
<input type="checkbox"/> test23 eth 2	Lot Release Testing	Needs Completion ⚠️
<input type="checkbox"/> latest test 2	Lot Release Testing	Needs Completion ⚠️
<input type="checkbox"/> new rend2	Lot Release Testing	Needs Completion ⚠️
<input checked="" type="checkbox"/> VC sample 2	Raw Material Testing	Ready for Review
<input type="checkbox"/> test article base test 3	-	Needs Completion ⚠️

You have viewed 1-5 of 6 results Page 1 of 2

Supporting Materials

0 material selected

Material Name	Material Type	Review Readiness
<input type="checkbox"/> bbbb 2	Control	Needs Completion ⚠️
<input type="checkbox"/> aabbcc	Control	Needs Completion ⚠️
<input type="checkbox"/> dsadasd	Media	Needs Completion ⚠️

Cancel Submit for PM Review

2. Select all project and/or test articles to send that are in 'Ready for Review' status (as shown in Image 12) and click 'Submit for PM Review' at the bottom of the page.

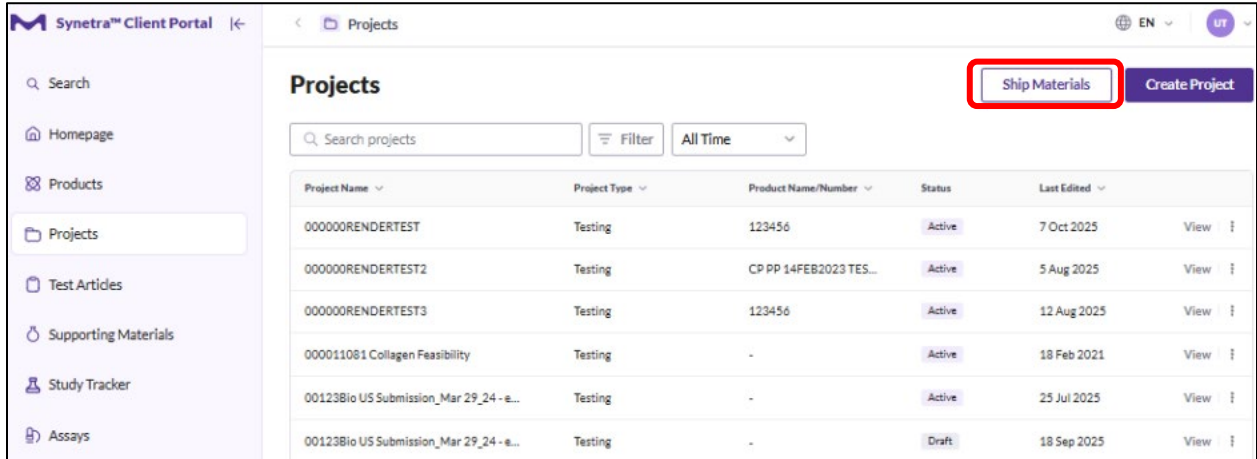
This is not the final step, as there's still a requirement to complete a shipping step to provide details about shipment. The preferred timing for completion of the shipment step is after PM approval of the submission.

Note: In cases where time is critical and samples need to be shipped immediately, please proceed with shipment prior to confirmation of PM approval.

Shipment of Samples

1. Navigate back to the 'Projects' page by clicking 'Projects' in the navigation bar.
2. Click on 'Ship Materials'.

Image 13: Shipment of Materials



3. A material selection page will open that lists all projects and their associated test articles and supporting materials available to ship (see Image 14).
4. Click the check box to all items to be included in the shipment.
5. Then click 'Next'.

Image 14: Material Selection

Material Selection
 Select the samples and supporting materials you want to ship to our sites. Enter the information for each site separately by clicking 'Ship Materials' for each one.

⚠ Please select only the materials that will be shipped to the same site.

Sprint 17 Demo Project comments 0/3 material selected ▾

Sprint 17 Demo Project PM review 1/1 material selected ▲

TA sprint 17 PM review Biosafety Level: BSL-2

❗ This test article has remaining 'Action Required', please do not ship samples until in approved status.

1 material selected

Material Type & Volume	Label ID & Shipping Condition	Assay Title & ID
<input checked="" type="checkbox"/> Test Material 2 x 1 ml	vial label 1111 Cold Packs	Trypsin Functionality Test BP6T0600.BUK • UK Lab

submission_QA1_template1.1 0/1 material selected ▲

Supporting Materials

0 material selected

Material Type & Volume	Label ID & Shipping Condition	Material Name
<input type="checkbox"/> Serum 1 x 1 mg	INET-3532-Test2 Dry Ice	INET-3532-Test2 BSL-3

TS01 Bio US Submission_Apr 11 2023 0/1 material selected ▾

6. Enter all shipment information as shown in Image 15, including:
 - a. **Ship Date**- this is the date tentative shipment date for the samples
 - b. **Receiving Site Address**- choose the receiving site from the drop-down menu.
 - c. **Courier Name**- is optional but can help in cases where an expected shipment has not arrived.
 - d. **Tracking Number**- is optional but can help in cases where an expected shipment has not arrived. In cases where a shipment includes more than 1 tracking number please click 'Add Tracking Number' to add additional numbers.
Note: The Contract testing lab is not responsible for tracking of shipments and this information is only being requested to assist our receiving teams, in exceptional cases.

7. Once shipment information is complete, click 'Next'.

Image 15: Shipment Information

The screenshot shows a form titled "Shipment Information" with the instruction "Select the shipping destination and provide the carrier information." The form contains the following fields and options:

- Ship Date:** A text input field with a calendar icon on the right.
- Receiving Site Address:** A dropdown menu.
- Choose where to ship the materials:** A heading for the next section.
- Courier Name (Optional):** A dropdown menu.
- Tracking Number 1 (Optional):** A text input field.
- + Add Tracking Number:** A button to add more tracking numbers.
- Information Box:** A purple box with an information icon and text: "Customers are responsible for managing shipments with their preferred couriers. The tracking information field serves to provide visibility into the shipment's current status and location as needed."

8. The Retention Information section will be displayed. Enter all fields as shown in Image 16.

Image 16: Retention Information

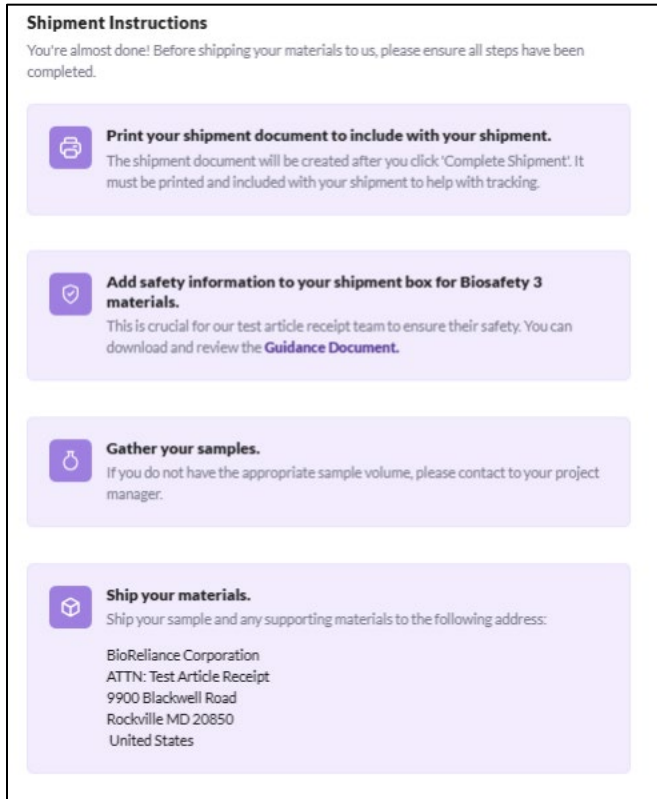
The screenshot shows a form titled "Retention Information" with the instruction "Select instructions for the shipping container and sample retention." The form contains the following fields and options:

- How many shipping containers are included in the shipment?:** A text input field.
- Do the shipping containers need to be returned?:** Radio buttons for "Yes" and "No".
- Are there any temperature monitors included in the shipment?:** Radio buttons for "Yes" and "No".
- Information Box:** A yellow box with a warning icon and text: "For return of temperature monitors and/or shipping containers, shipping label(s) with the address of return must be included with the shipment along with this shipment document."
- Do you want your samples to be returned?:** Radio buttons for "Yes" and "No".

9. Click 'Next' once all fields in the section are complete.
10. Review all details entered to confirm accuracy then click 'Next'.

11. A summary of Shipment Instructions will be displayed as shown in Image 17.

Image 17: Shipment Instructions



12. Click 'Print your shipment document to include with your shipment' and include a copy in every shipping container (e.g. box) that will be shipped.

13. If supplemental safety information is required per the sample type, please also include the supplemental safety information in the shipment.

V. Tracking Submissions

1. Users can click on the 'study tracker' function from the left navigation bar to access tracking information.
2. Individual study information can be identified by using the 'search studies' field
3. If interested in a specific subgroup of studies, select the 'Filter' option which will open a new dialog with several filtering options available for selection. Once selections are complete, 'Apply Filters' should be selected to display results.

Image 18: Study Tracker

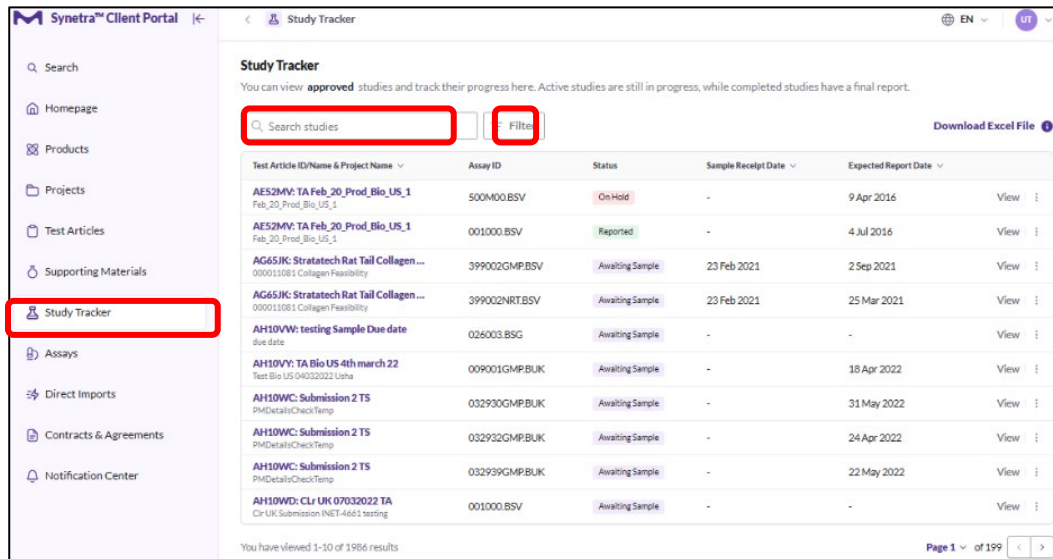
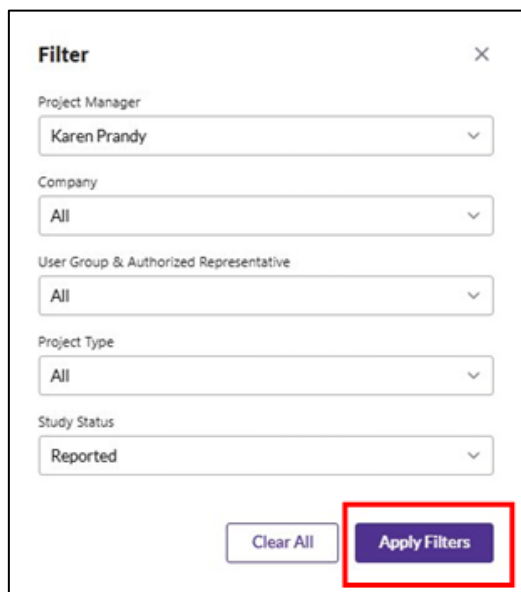


Image 19: Filter



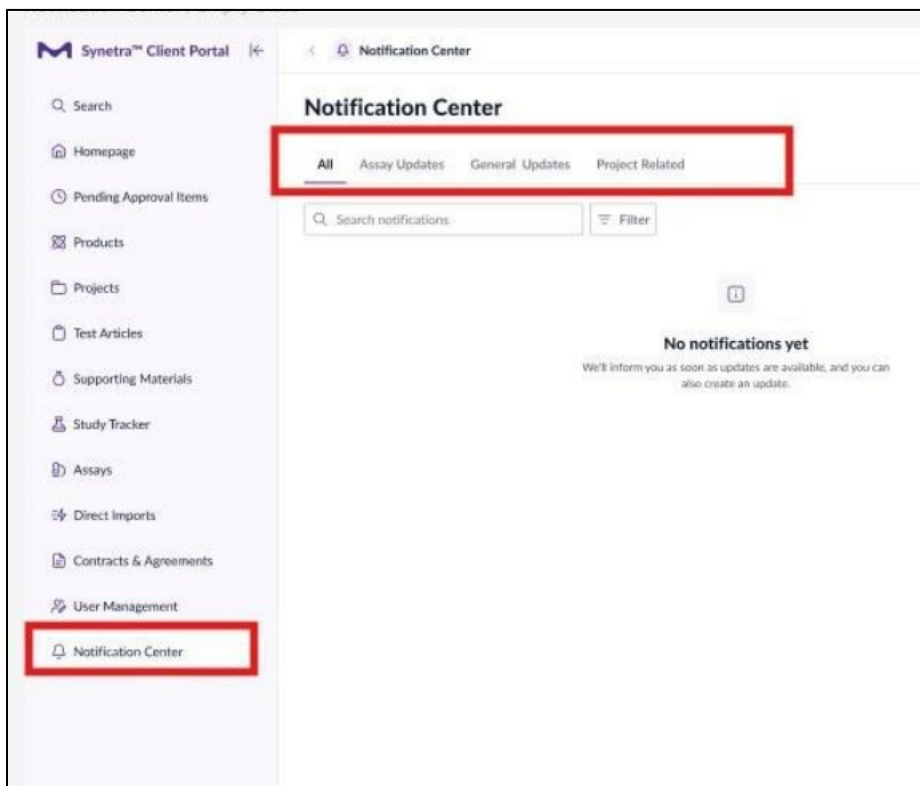
VI. Accessing Reports

Once a study is in the reporting phase, the option to select the 'reporting' button becomes available. When 'reporting' is selected, 'expected report date', 'actual report date', associated 'Event Number(s)', 'Preliminary report' details and applicable attachments will be displayed and accessible for download.

VII. Managing Notifications

Notifications related to Assay Updates, General Updates, User response, and Action(s) required can be found in the Notification Center.

Image 20: Notification Center





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