

NAMSA 360 - BULK SUBMISSIONS

Bulk Submissions is a new feature in NAMSA 360 where you can create multiple submissions using existing submission data rapidly by changing only a few fields. Please refer to Appendix 1 at the end of this document for the list of fields that can be modified

Note: If you need to change other fields (e.g. “Test Code”, “Description”, “Composition”, “Clinical use”, etc) you should use the duplicate feature of the system instead of the use bulk copy function.

Features of Bulk Submissions:

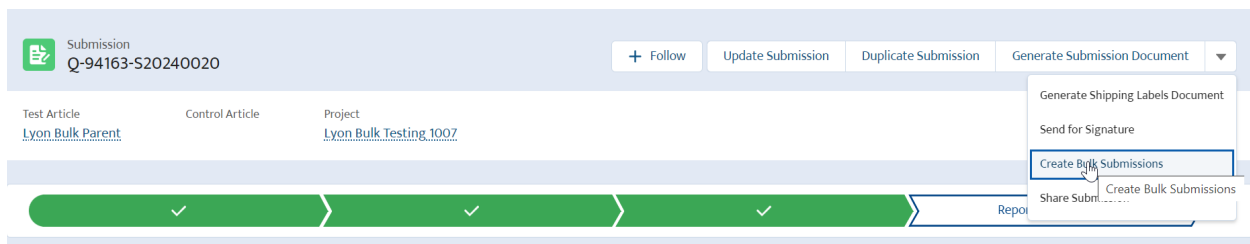
- Create multiple submissions for same test codes by changing a few key fields that would differ from the original submission
- Sign only 1 document instead of multiple documents using the Adobe Sign process
- This single signature applies to ALL the submissions created under this process thereby saving time
- Submissions created using this process are also unique submissions that can be edited individually

Two ways to create Bulk submissions:

- From a submission (parent) that has already been signed and submitted to NAMSA for same test code to perform and same active proposal.
- From a new submission that is being created (parent) in draft status from a proposal and use that data to create multiple submissions

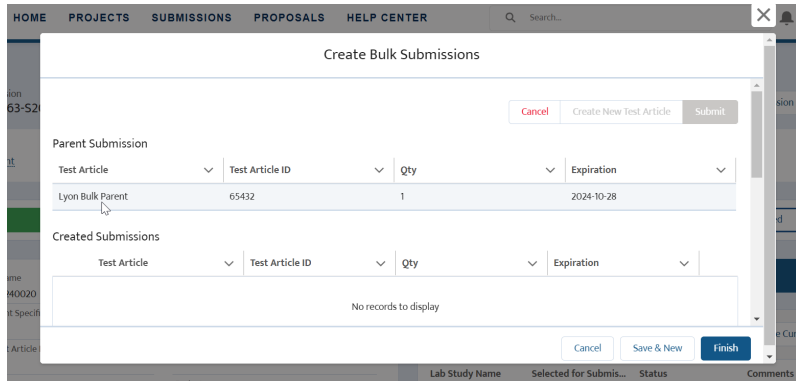
From a Submitted submission:

- Navigate to the parent submission that you want to copy from and click on “Create Bulk Submissions” from the dropdown in the top right corner

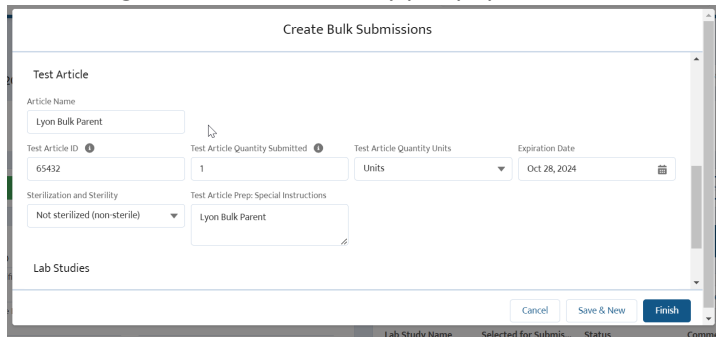


The screenshot shows the submission details for 'Q-94163-S20240020'. The interface includes a header with the submission ID and a dropdown menu with options: '+ Follow', 'Update Submission', 'Duplicate Submission', and 'Generate Submission Document'. Below this, there are fields for 'Test Article' (Lyon Bulk Parent), 'Control Article', and 'Project' (Lyon Bulk Testing 1007). A progress bar at the bottom shows three steps with checkmarks. The 'Generate Submission Document' dropdown menu is open, showing options: 'Generate Shipping Labels Document', 'Send for Signature', 'Create Bulk Submissions', and 'Share Submission'. The 'Create Bulk Submissions' option is highlighted with a blue border and a mouse cursor.

- b. Bulk submission creation screen shows up with some Parent data listed under “Parent Submission” section



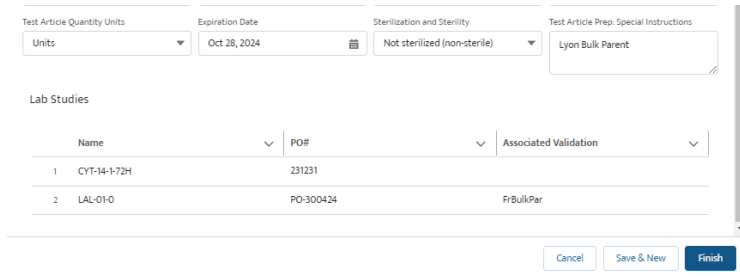
- c. Scroll down to the “Test Article” section. This is where you will create submissions. Please note that changeable data are already pre-populated from the Parent submission



- d. Edit the fields that need to be changed for the new submission Test Article



- e. Scroll down to the “Lab Studies” section and click on the pencil icons next to PO# and “Associated Validation” to edit those values for the new submission, if required



Create Bulk Submissions

| Test Article | Test Article ID | Qty | Expiration |
|-----------------------|-----------------|-----|------------|
| No records to display | | | |

New Test Article

Test Article

Article Name
Lyon Bulk Child 91

Test Article ID: 65432 C91 Reference Number: Lyon Bulk 123 Test Article Identifier: Lot Test Article Quantity Submitted: 1

Test Article Quantity Units: Units Expiration Date: Oct 28, 2024 Sterilization and Sterility: Not sterilized (non-sterile) Test Article Prep: Special Instructions: Lyon Bulk Child 91

Lab Studies

| Name | PO# | Associated Validation |
|----------------|---------------|-----------------------|
| 1 CYT-14-1-72H | 231231 C91 | |
| 2 LAL-01-0 | PO-300424 C91 | FrBulkC91 |

- f. Click “Save & New” if you want to continue creating more submissions
- g. Screen displays with some data of the new submission created under the “Created Submissions” section

Create Bulk Submissions

Parent Submission

| Test Article | Test Article ID | Qty | Expiration |
|------------------|-----------------|-----|------------|
| Lyon Bulk Parent | 65432 | 1 | 2024-10-28 |

Created Submissions

| Test Article | Test Article ID | Qty | Expiration |
|----------------------|-----------------|-----|------------|
| 1 Lyon Bulk Child 91 | 65432 C91 | 1 | 2024-10-28 |

- h. Repeat Steps c-g for each new submission that you want to create
- i. When all new submissions have been created, click “Finish”
- j. The screen displays Parent and all new submissions created under “Created Submissions”

Create Bulk Submissions

Parent Submission

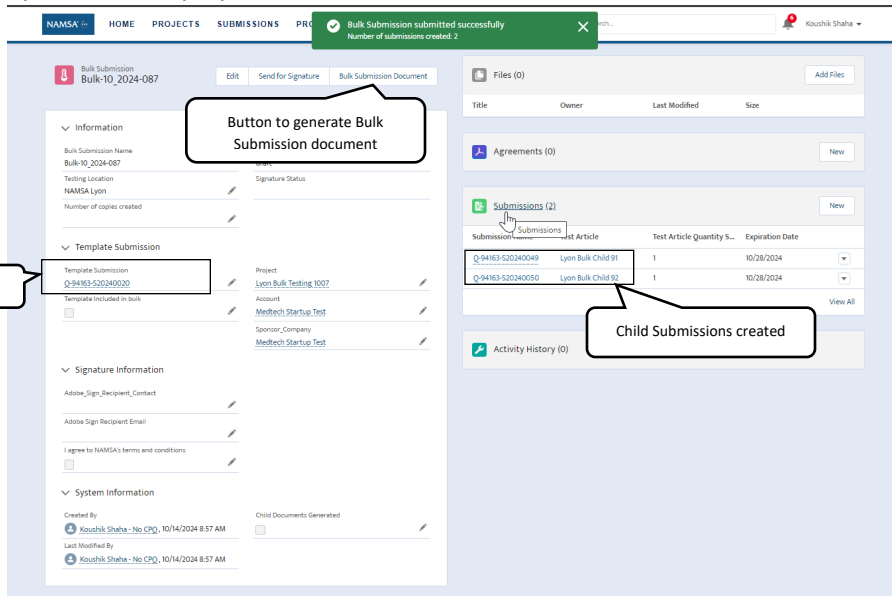
| Test Article | Test Article ID | Qty | Expiration |
|------------------|-----------------|-----|------------|
| Lyon Bulk Parent | 65432 | 1 | 2024-10-28 |

Created Submissions

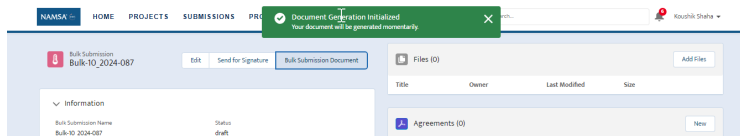
| Test Article | Test Article ID | Qty | Expiration |
|----------------------|-----------------|-----|------------|
| 1 Lyon Bulk Child 91 | 65432 C91 | 1 | 2024-10-28 |
| 2 Lyon Bulk Child 92 | 65432 C92 | 1 | 2024-10-28 |

- k. Click “Submit” to create the submissions

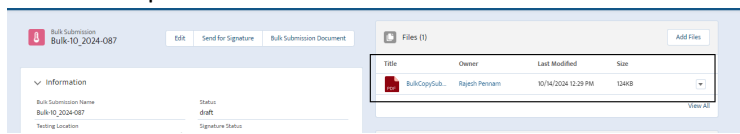
I. System will display the Bulk Submission screen



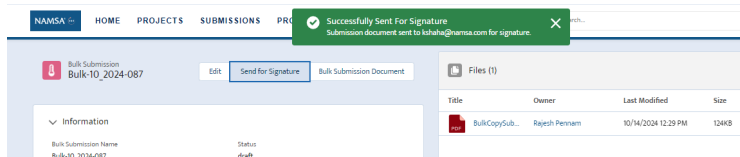
m. Click on Bulk Submission to generate bulk submission document. The following message will be displayed briefly



n. When the file has been generated it will display under Files (you will need to refresh your screen a few times. Please note that it might take a few second to a few minutes to generate this file – this depends on the number of child submissions created). You may click on the document Title to view the pdf



o. Once the file is visible click on “Send for Signature” to send it to the signer’s email address



p. Follow the standard Adobe sign signature process to complete the signature process as with other submissions.

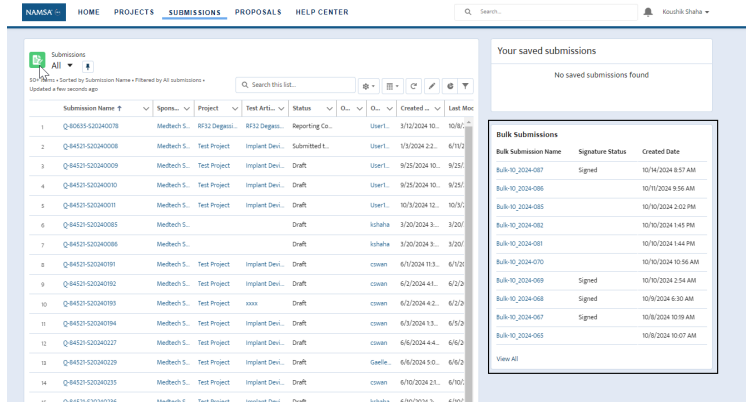
q. Once the bulk submission signed, you can click on the Submissions list view and locate the submissions just created.

(You can also navigate to the created submissions by clicking on the child submissions list highlighted in the screenshot in I above).

- r. Note the following in **each** of the submissions created
 - i. Submission status is changed to signed

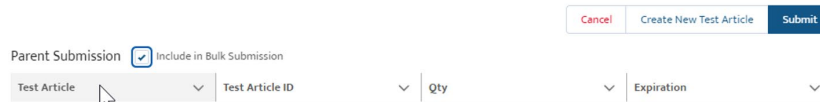
- ii. The unsigned individual submission and the signed bulk submission documents are visible under Lab Submissions in each individual submission page

- s. You may also visit the Bulk Submission page from the Submissions tab of NAMSA 360 by clicking on the appropriate bulk submissions you created in the Bulk Submissions related list view



From a new submission that is being created (parent) from a proposal

- a. Create a new submission from a proposal available in NAMSA 360 normally
- b. DO NOT generate the submission document and DO NOT send for signature
- c. When you are on the submissions page that you just created, follow steps 1.a. through 1.j. above
- d. Check the box next to Parent Submission to “Include in Bulk Submission”. This will include the parent submission in the Bulk submission document so you do not have to sign multiple times.



- e. Continue with steps 1.k. through 1.r. to complete the submission creation and signing process.

Appendix 1

List of fields that can be modified during the Bulk Submission process. Please note that certain fields will appear on the screens ONLY if they were included in the parent submission (the submission you are creating the bulk submissions from). This is denoted below as “(if applicable)”.

- Test Article Name
- Test Article ID
- Test Article Reference
- Test Article Identifier
- Quantity Submitted
- Expiration Date (if applicable)
- Sterility (if applicable)
- Sterilization Date (if applicable)
- Test Article Prep: Special Instructions (if applicable)
- Purchase Order

- Associated Validation (if applicable)
- Control Article ID (if applicable)
- Control Article Quantity (if applicable)
- Control Article Expiration Date (if applicable)
- Control Article Sterility (if applicable)
- Control Article Sterilization Date (if applicable)