

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:

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

Two ways to create Bulk submissions:

- 1. From a submission (parent) that has already been signed and submitted to NAMSA for same test code to perform and same active proposal.
- 2. 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:

a. 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

Submission Q-94163-S2	0240020		+ Follow	Update Submission	Duplicate Submission	Generate Submission Document 🔻
Test Article Lyon Bulk Parent	Control Article	Project Lyon Bulk Testing 1007				Generate Shipping Labels Document Send for Signature
	~	> ~	>	~		Create Bulk Submissions Share Subm



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

HOME	PROJECTS	SUBMISSION	S PROPOSALS	HELP CE	NTER	Q Sean	:h		×	P
			0	Create Bulk	Submissions				Ì	
ion 63-S20						Cancel	Create New Test Article	Submit		sion [
	Parent Submission	1								
<u>nt</u>	Test Article	\sim	Test Article ID	\sim	Qty		 Expiration 	\sim	. 1	
	Lyon Bulk Parent		65432		1		2024-10-28			
	Created Submissic	ons								d
	Test Article	<u> </u>	✓ Test Article ID	~	Qty	~	Expiration	~		E
ame 240020 ht Specifi				No record	s to display				Ţ	
t Article I	·						Cancel Save & N	ew Finist		e Curr
					Lab Study N	ame Sele	cted for Submis Status		Comr	ments (

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

	Create Bu	lk Submissions		ŕ
Test Article Article Name				•
Lyon Bulk Parent				
Test Article ID	Test Article Quantity Submitted	Test Article Quantity Units	Expiration Date	
65432	1	Units 💌	Oct 28, 2024	
Sterilization and Sterility	Test Article Prep: Special Instructions			
Not sterilized (non-sterile) 🛛 🔻	Lyon Bulk Parent			
		4		
Lab Studies				
			Cancel Save & New	Finish

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

Test					
Article Name					
Lyon Bulk Child 91					
Test Article ID	Reference Number	Te	st Article Identifier		Test Article Quantity Submitted
65432 C91	Lyon Bulk 123		Lot	*	1
Test Article Quantity Units	Expiration Date	Ste	erilization and Sterility		Test Article Prep: Special Instructions
Units	▼ Oct 28, 2024	曲	Not sterilized (non-sterile)	-	Lyon Child 91

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

Test	Article	Quantity Units	Expiration Date	Sterilization and Ster	rility	Test Article Prep: Special Instructi	ons
U	nits	*	Oct 28, 2024	前 Not sterilized (no	on-sterile) 💌	Lyon Bulk Parent	
							10
La	b Stu	dies					
		Name	✓ PO#		✓ Associate	d Validation	\sim
	1	CYT-14-1-72H	231231				
	2	LAL-01-0	PO-30042	4	FrBulkPar		_
						Cancel Save & New	Finish



			Create Bull	k Submissions				
Test Article	~	Test Article ID	\sim	Qty	✓ E	quiration	\sim	
			No record	s to display				
			New Tes	st Article				
est Article								
cie Name								
yon Bulk Child 91								
Article ID	Refe	rence Number 🕚		Test Article Identifier		Test Article Qua	ntity Submitted	0
5432 C91	Ly	yon Bulk 123		Lot 💌 1				
Article Quantity Units	Expir	ration Date		Sterilization and Sterility Test Article Prep: Special In			: Special Instructi	ons
Inits	• 0	ct 28, 2024	苗	Not sterilized (non-sterile)	Ŧ	 Lyon Bulk Child 91 		
ab Studies								
Name		✓ P0	D#	\checkmark	Associat	ed Validation		\sim
1 CYT-14-1-72H		23	1231 C91					
2 LAL+01+0		PC	D-300424 C91		FrBulkC	91		

- 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

		C	reate Bul	k Submissio	ns		
					Cancel	Create New Test Article	Submit
arent Submission							
Test Article	~ 1	fest Article ID	\sim	Qty	~	Expiration	\sim
Lyon Bulk Parent	6	5432		1		2024-10-28	
Freated Submissions							
Tes	~	Test Article ID	\sim	Qty	~ E	xpiration	~
1 Lyon Bulk Child 91		65432 C91		1	2	024-10-28	

- 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"

Creat	te Bulk Submissior	าร

						Cancel	Create New Test Article	Submit
Parent	Submission							
Test A	rticle	∽ Te	st Article ID	~	Qty	\sim	Expiration	\sim
Lyon B	ulk Parent	65	432		1		2024-10-28	
reate	d Submissions							
	Test Article	\sim	Test Article ID	~	Qty	√ Ex	piration	~
1	Lyon Bulk Child 91	2	65432 C91		1	20	24-10-28	
2	Lyon Bulk Child 92	•0	65432 C92		1	20	24-10-28	•

k. Click "Submit" to create the submissions



I. System will display the Bulk Submission screen

	NAMSA & HOME PROJECTS	SUBMISSIONS PRC Sulk Submission submitted s Number of submissions created: 2	successfully X rch	🤌 Koushik Shaha 👻
	Bulk-10_2024-087	Edit Send for Signature Bulk Submission Document	Files (0) Title Owner Last Modified Size	Add Files
	V Information Bulk Submission Name Bulk-10_2024-087 Testing Location	Button to generate Bulk Submission document	Agreements (0)	New
	NAMSA Lyon Number of copies created		Submissions (2) Submission that Article Test Article Quantity S Expiration	New Date
Parent Submission Name	Template Submission Q:94163-520240020 Template Included in bulk	Project Lyon Bulk Testing 1007 Account Meditech Startup Test	6-HE2-20240020 (huu Birg Curi & 1 KLHIG-270240020 (huu Birg Curi & 1	24 View All
	 Signature Information Adobe_Sign_Recipient_Contact 	Meditech Startup Test	Activity History (0)	
	Adobe Sign Recipient Email	/ /		
	 System Information Created By Koushik Sheha - No CPQ , 10/14/2024 8 	Child Documents Generated		
	Last Modified By Koushik Shehe - No CPQ, 10/14/2024 8	157 AM		

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

NAMSA & HOME PROJECTS	SUBMISSIONS PRC Ocument Generation	on Initialized X	rch	🤌 Koushik Shaha 🗸
Bulk Submission Bulk-10_2024-087	Edit Send for Signature Bulk Submission Document	Files (0)		Add Files
		Title Owner	Last Modified	Size
✓ Information				
Bulk Submission Name Bulk-10_2024-087	Status draft	Agreements (0)		New

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

8 Bulk Submission Bulk-10_2024-087	Edit Send for Signature	Bulk Submission Document		Files (1)				Add Files
				Title	Owner	Last Modified	Size	
✓ Information				BulkCopySub	Rajesh Pennam	10/14/2024 12:29 PM	124KB	Ŧ
Bulk Submission Name	Status		L.					Mary All
Bulk-10_2024-087	draft							
Teoting Location	Signature Status							

o. Once the file is visible click on "Send for Signature" to send it to the signer's email address

NAMSA 🗁 HOME PROJECTS	SUBMISSIONS PRC Successfully Set Submission docum	nt For Signature rent sent to kshaha@namsa.com for signa	ture. × ^{irch}		
Bulk Submission Bulk-10_2024-087	Edit Send for Signature Bulk Submission Docu	ument Files (1)			
		Title	Owner	Last Modified	Size
✓ Information		BulkCopySub.	Rajesh Pennam	10/14/2024 12:29 PM	124KB
Bulk Submission Name	Status				
Bulk-10 2024-087	draft				

- 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.

Bulk Submission Bulk-11 2024-002 Edit Send for Signature Bulk Submission Document Files (2) Upload Files Title Owner Last Modified Size NAMSA 360 B... User1709227810471609... 11/4/2024 10:21 AM ✓ Information 613KB -Bulk Subr Status BulkCopySub... User1700597551354400... 11/4/2024 10:13 AM 134KB -Bulk-11 2024-002 signed Testing Location Signature Status View All NAMSA Lyon ø Signed Number of copies created 1 Agreements (1) New ✓ Template Submission Agreement Name Date Sent (Date) Recipient (Contact) Agreement Status Template Submission NAMSA 360 Bulk Sub... 11/4/2024 Koushik Shaha Signed Ţ Q-96435-520240002 Bulk Valid testing posal Number View All Q-96435 ı ø test please ignore ided in bulk Template 1 test please ignore I Submissions (3) New ✓ Signature Information Test Article Submission Name Test Article Quantity S... Expiration Date Adobe Sign Recipient Contact Q-96435-520240002 Bulk Valid test Parent 114 1 11/29/2024 ÷ Koushik Shaha Adobe Sign Recipient Email Q-96435-520240736 Bulk Valid test Child 1141 1 11/29/2024 Ŧ kshaha@namsa.com 1 Q-96435-S20240737 Bulk Valid test Child 1142 1 11/29/2024 Ŧ I agree to NAMSA's terms and conditi 1

(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

NAMSA 💮

Tect Article Control Article Lyon Bulk Child 91	Pri Ly	lect on Bulk Testing 1007
· ·		Submitted to NAMISA
Submission Name Q-94163-520240049	/	Status Submitted to NAMSA
Submission Name Q-94/953-520240049 Reported Client Specific Number	/	Status Submitted to NAMSA Testing Location O NAMSA Lyon
Submission Name Q-94163-520240049 Reported Client Specific Number Client Specific Number Client Article Receipt Date O-1Week	/	Status Submitted to NAMSA Testing Location ① NAMSA Lyon Proposal Contact
Suberitation Name Q-94483-520340049 Reported Client Specific Namber ① Estimated Test Article Receipt Date ② O-11Web Signature Stebss Signed	/	tatus Submitted to NAMESA Teating Location Proposil Contact Project Contact Project Contact

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

si A	ibmissions								Your saved submi	ssions	
24 Mems + Sorted by Submission Name + Filtered by All submissions + pdated a few seconds ago				Q, Search this li	a_	*· . C /		6 T	No s	No saved submissions found	
	Submission Name † 🛛 🗸	Spons V	Project 🗸	Test Arti 🗸	Status v 0	~ 0 ~	Created 🗸	Last Moc			
	Q-80635-520240078	Medtech S	RF32 Degassi	RF32 Degass	Reporting Co	User1	3/12/2024 10	10/8/. ^	Bulk Submissions		
	Q-84521-520240008	Medtech S.,	Test Project	Implant Devi	Submitted t	User1	1/3/2024 2:2	6/11/2	Bulk Submission Name	Signature Status	Created Date
	Q-84521-520240009	Medtech S.,	Test Project	Implant Devi	Draft	User1	9/25/2024 10	9/25/.	Bulk-10_2024-087	Signed	10/14/2024 8:57 AM
	Q-84521-520240010	Medbech S	Test Project	Implant Devi	Draft	User1	9/25/2024 10	9/25/.	Bulk-10_2024-086		10/11/2024 9:56 AM
	Q-84521-520240011	Medbech S.,	Test Project	Implant Devi	Draft	User1	10/3/2024 12	10/3/:	Bulk-10_2024-085		10/10/2024 2:02 PM
	Q-84521-520240085	Medtech S.,			Draft	kshaha	3/20/2024 3	3/20/	Bulk-10_2024-082		10/10/2024 1:45 PM
	Q-64521-520240086	Medbech S			Draft	kshehe	3/20/2024 3:	3/20/	Bulk-10_2024-081		10/10/2024 1:44 PM
	Q-84521-520240191	Medbech S.,	Test Project	Implant Devi	Draft	cswan	6/1/2024 11:3	6/1/2	Bulk-10_2024-070		10/10/2024 10:56 AM
	Q-84521-520240192	Medtech S	Test Project	Implant Devi	Draft	cswan	6/2/2024 4:1	6/2/2	Bulk-10,2024-069	Signed	10/10/2024 2.54 AM
	Q-84521-520240193	Medtech S.,	Test Project	2002	Draft	cswan	6/2/2024 4:2	6/2/2	Bulk-10_2024-068	Signed	10/9/2024 6:30 AM
	Q-84521-520240194	Medtech S.,	Test Project	Implant Devi	Draft	cswan	6/3/2024 1.3	6/5/2	Bulk-10_2024-067	Signed	10/8/2024 10:19 AM
	Q-84521-520240227	Medtech S	Test Project	Implant Devi	Draft	cswan	6/6/2024 4:4	6/6/2	Bulk-10_2024-065		10/8/2024 10:07 AM
	Q-84521-520240229	Medtech S	Test Project	Implant Devi	Draft	Gaelle	6/6/2024 5:0	6/6/2	View All		
	0.0473 (303)037	11-0-0-7	Test Desired	Involunt Davi	Draft	CD100	6/10/2024 21	6/10/	L	-	-

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.

							Cancel	Create New Test Article	Submit	
Parent Submission 🕞 Include in Bulk Submission										
Test Article		~	Test Article ID	\sim	Qty		\sim	Expiration	\sim	

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)