#### Sack to Oracle Help Center

If you are a site manager that currently works in Oracle Clinical One Platform Platform, this is your go-to guide for all site-related issues.

Note: All tasks in this guide can be performed in both **Production** and **Training** modes.



# Manage subjects: What do you want to do?

# Add and screen a subject

**1.** On the Home page, click either the name of the study (to enter study data) or the Training Mode button (to practice).

Can't see the study on the Home page?

- 2. Along the top, make sure **Subjects** is selected, and click **Add Subject**.
- 3. Answer the questions on each form, and click **Save** and then **Screen**.

Need to screen fail or rescreen a subject?







**4.** Take note of the subject number, and click **Return to All Subjects**.

**Note**: In a rollover study, subjects are no longer screened since they've already been screened in the original study.

Read detailed instructions or **D** watch training!

# 2 Enter data, complete a visit, and dispense kits

#### Did you start the visit before scheduled?

- **1.** On the Home page, click either the name of the study (to enter study data) or the Training Mode button (to practice).
- 2. Click the **Subjects** tab if it is not already selected.
- **3.** Locate the subject to update. To filter your view of subjects, enter some or part of the subject number in the **Search** field in the upper right above the table of subjects.
- **4.** Depending on what your next step is, do one of the following:
  - To start a scheduled visit, locate it in the **Next Visits** column. Click that visit.
  - To start an Adverse Event (AE) or Concomitant Medications (CM) event, click an entry in the **AE/CM** column.
  - If you want to dispense during an unscheduled visit, locate the subject, select the checkbox next to the subject, and choose Unscheduled visit from the Manage subjects drop-down.
- 5. Answer the questions on each form, and click **Save** and then **Randomize** or **Dispense**.

**Note:** A scheduled visit is only complete after you answer all of the required questions. If you don't have the subject's answer to one or more questions, flag the question. Read step-by-step instructions on flagging questions.

- 6. After you click **Dispense**, do one of the following:
  - If the subject is allowed to titrate, choose whether to maintain the current dose, titrate up, or titrate down, and click **Next**.
  - If the subject brought back any reusable kits to the site, mark the kits as reusable on the Reusable Kits pop-up, and click **Continue to Dispensation**.

Add Subject	Mar	nage Subjects 💌	
All countries	٠	All sites -	All subje
		Subject	
•		BC3 Screened	0 Tot
•		BC2 New	0 Tot
•		BC1 New	0 Tot
•		MHC2 New	0 Tot
-		MHC1	0 Tot



- If your study features devices managed through an Oracle mHealth connection, activate each device.
- 7. If needed, answer queries or update your answers on certain queries.

Can't click Randomize or Dispense? Did you run into an error? Can't find the subject's kit? Need to find the kit numbers to dispense? Don't know how to answer a query? Titrated up or down in error? Dispensed a device in error? Read detailed instructions or watch training!

# **3** Enter data in a repeating form

- **1.** On the Home page, to enter study data, click the name of the study or click Training Mode to practice.
- 2. Click the **Subjects** tab if it is not already selected.
- **3.** Locate the subject to update. To filter subjects, enter part of the subject number in the **Search** field on the upper right above the table.
- 4. Locate the scheduled visit in the **Next Visits** column.
- 5. Repeating forms are displayed in a table view. If this is the first time you add data in a repeating form, double-click anywhere in the first row of the table. If you already added a repeating form and you want to add a new one click the Add button in the upper right corner of the form section.
- The form appears in a new pop-up window. Answer the questions on the form and click Save.



- **7.** To edit or modify values in a repeating form, double-click the table row where the data is displayed. Edit the data and click **Save**.
- **8.** When you have finished adding data in the repeating form, click **Save**.

Read detailed instructions or **>** watch training!

## 4 Mark a subject as complete

- **1.** On the Home page, click either the name of the study (to enter study data) or the Training Mode button (to practice).
- 2. Along the top, make sure **Subjects** is selected.
- 3. Select a subject with a checkbox in the upper-right corner of their avatar.
- 4. From the Manage Subjects drop-down, select Complete or Withdraw.
- 5. Click Complete Study.
- 6. Confirm the decision, and click **Complete Study**.
- 7. If a study completion visit opens, complete it now or later. A subject's status is updated to **Complete** only when all of their visits in a study are completed.

Marked a subject as complete in error?

Read detailed instructions or **>** watch training!



**Does the subject need to transfer?** Contact your CRA for assistance.

To withdraw a subject:

**1.** On the Home page, click either the name of the study (to enter study data) or the Training Mode button (to practice).

Add Subject	tanage S	lubjects 💌		
Su	Comple	ete or Withdraw go	Next Visits	Previou
• 💽 T	Sign		Baseline (10-Jun - 11-Jun)	L Screen
• 💽 T	Transfe Code 8	er Break	Week 2 (29-Mar - 04-Apr)	Basel
• 🕘 👎	Replac	e Kits eduled Visit		Withdr
TS 3.	0001	0 Total	Week 6 (25-Sep - 25-Sep)	Unscher



- 2. Along the top, make sure **Subjects** is selected.
- **3.** Select the subject to withdraw.
- 4. From the Manage Subjects drop-down, select Withdraw.
- 5. Confirm the withdrawal, enter a reason, and click **Withdraw**.
- 6. If your study has a withdrawal visit, you can complete it now or later.

Withdrew a subject in error?

Read detailed instructions or **D** watch training!

## 6 Enroll a subject in a rollover study

If your study allows you to enroll subjects in a rollover study you now see a rollover question in the study completion form.

- **1.** On the Home page, click either the name of the study (to enter study data) or the Training Mode button (to practice).
- 2. Along the top, make sure **Subjects** is selected.
- 3. Select a subject with a checkbox in the upper-right corner of their avatar.
- 4. From the Manage Subjects drop-down, select Complete or Withdraw.
- 5. Click Complete Study.
- **6.** Fill out the study completion form attached to the visit. When you reach the rollover question, if the subject consents, select **Yes** from the **Select Answer** drop-down to enroll the subject in the rollover study.
- 7. Click Complete Study.



Study: P01	-123-A3		meset ta			Ho Ho	me	Subje	cts 9	4 Sup	plies	III Re	port	ts & Archives	( Analytics
Back to Subjects	Manage Sub	ject v				1.1.1				86.	View M	der 📰		Question Hin	t fint
Subject 016-012 •	Current Visit Check 10	Previous Vit	Check 8	Check 7	Check 6	Check 5	Check 4	Check 3	Ched	2	Check 1	A Screenin	*	Select Yes if the ing in Rollover st if the subject will	subject will participat udy BT-31. Select Ni not be participating.
Forms & Data	🖙 Stu	dy Completi	on										T		
Date of Dosing Vital Signs	•	. Date study pa	rticipation	ended				18 . *	May *	2018			l		
Comea Image Study Completion	•	Primary reaso	n for comp	letion/disc	ontinuation			Select An	Dwør						
Pinal Consent	• •	. Subject partic	ipating in r	ollover stu ct will be erv	dy ofied			Select Ar	iswer	Ŧ			1		

Read detailed instructions.

					# Home	Subjects	% Supplie	s Reports & Archives	( Analytics
	View: All		* Site	TS 3. Testing	* Sea	ch for Subject	0	Subject History	
								T S 3-0004	0
L Screening								Screened 12-Jun-2020   09:35 (CDT	-05:00)
Week 2 Baselr	e L Screening								
Week 4 Week	2 Baseline	L Screening							
							P		

# 7 Perform a code break

A code break unblinds a subject's treatment arm. Depending on the study protocol, Oracle Clinical One Platform might automatically withdraw a subject that you unblind using a code break, and you might be required to complete a withdrawal visit

- **1.** On the Home page, click either the name of the study (to enter study data) or the Training Mode button (to practice).
- 2. Along the top, make sure **Subjects** is selected.
- 3. In the table, select the checkbox to the left of the subject you want to unblind.
- 4. Above the table of subjects, from the Manage Subjects drop-down, select Code Break.
- 5. Click Continue.
- **6.** Confirm the subject number and study name, and select the checkbox to confirm the code break.
- 7. Indicate if an adverse event occurred, and click **Unblind**.
- 8. Review the unblinding results for the subject, and click one of the following options:

> If the study has a withdrawal visit, click **Start Withdrawal Visit**. You can complete the visit now or later.

The subject's status changes to **Withdrawn** even if you don't complete the visit.

> If the study doesn't have a withdrawal visit, click **Done**.

The subject's status changes to Withdrawn.

Read detailed instructions or **N** watch training!



							•
				# Home	Subjects	% Suppl	ies II Reports & Archives (3) Analytics
	View: All	26 10 2	<ul> <li>Site TS 3 - Testing</li> </ul>	• Search	for Subject	٩	Subject History
fisits							T5 3-0004
							Q. Screened 12-Jun-2020   09-35 (CDT -05:00)
Screening							
d Week 2 Baseline	L Screening						
Week 4 Week 2	Baseine	1 Screening					
						ŀ	

#### What happened?

- I need to change an answer.
- I screen failed a subject in error.
- I randomized a subject in error.
- I need to randomize after a randomization failure.
- I need to decide what to do with a subject who cannot titrate.

### **Receive a shipment**

**1.** On the Home page, click either the name of the study (to enter study data) or the Training Mode button (to practice).

Can't see the study on the Home page?

- 2. Along the top, click **Supplies**, and make sure the **Shipments** tab is selected.
- 3. From the Filter by Status drop-down, select In Transit.
- **4.** Select the checkbox next to the shipment that arrived, and on the right, review the kits in the packing list against the kits in the shipment.
- 5. Click Add Shipment to Inventory.
- **6.** 6. Follow the steps prompted as required according to the temperature excursion settings in your study:

**Note**: Some steps may not be required for your study.

- a. Temperature excursion? Enter Temperature monitor status.
- **b.** Quarantined kits? Select the kits with Quarantined status.
- c. Damaged kits? Select them, and select the Damaged status.
- d. Missing kits? Select them, and select the Missing status.

**e. Review** the kit list and make sure every kit is tagged accordingly. Remaining kits will be added to inventory as available.

7. Click Finish.

Read detailed instructions or **N** watch training!



	😤 Home	1 Subjects	& Supplies	ul Rer	oorts & /	Archives	@ Analy	tics
			A opposite					
	Site:	SKC - Skin Health C	lenter		A Shipn	nent Deta	ils	
					1 Call			
	Search by Share	unt 10 9 01 mar	Tracet		Kit Statu	s. •		
					Ø Dame	iged		9
Status	Created Date	Ship Date	Tracking Numb	er	Q. Missi	10	Status	
In Transit	08-May-2018	08-May-2018		M	T Pre-q	uarantined	In Transit	-
				~	8	1134	In Transit	
						1245	h Transit	
						1344	In Transit	
					8	1363	hin Transit	
					8	1396	In Transit	
					8	1571	In Transit	
					8	1622	In Transit	
					0	1657	<ul> <li>In Transit</li> </ul>	
						1690	<ul> <li>In Transit</li> </ul>	
					8	1723	<ul> <li>In Transit</li> </ul>	
						2036	h In Transit	
					Cancel	Add St	ipment to inver	story
					4	Downloa	d Order Form	

# 10 Reconcile kits

Some studies require kit reconciliation. If you're not sure whether this step is required, contact your CRA.

- **1.** On the Home page, click either the name of the study (to enter study data) or the Training Mode button (to practice).
- 2. Along the top, make sure **Subjects** is selected.
- **3.** Select the subject who returned the kit.
- 4. On the right in **Subject History**, click the kit.
- 5. From the Kit Status drop-down, select Returned to Site.
- 6. Specify the returned and missing units and a reason, and click **Update Kit**.

Read detailed instructions or **b** watch training!

# **11** Destroy kits, or ship kits to a drug destruction facility

Some studies require kit destruction, which can occur either at your site (if the site is drug destruction capable) or at a depot that is a drug destruction facility. If you're not sure whether this step is required, contact your CRA.

Before you can perform these steps, your CRA has to mark kits as **Pending Destruction**.

- On the Home page, click either the name of the study (to enter study data) or the Training Mode button (to practice).
- **2.** To destroy kits at your site:

**a.** Destroy kits outside Oracle Clinical One Platform according to the protocol and any relevant SOPs.

**b.** Along the top, click **Supplies**, and click the **Inventory** tab.





	A Home	L Subje	cts	A Sup	plies	II Rep	orts & Aro	hives	(d) A	nalytics
				Site: TS 3	- Testing	540 3		a Kit S	Settings	
								Kit Nur Kit Typ	nber e	1231 V Blister Pack
× ~		Search by	Kit Number	9	Filter by	Statue	*			Update Ki
ventory Mana	gement			×						
					Units	Missing Units	Balance I			
Kit Number	1231 🗸	* Kit Status					1			
Kit Type	Blister Pack	I record cess	Vesen							
		* Reason for Cha	ange							
		Materials in the ki contaminated]	it have been							
							-			
				_						
		Can	cel Us	date Kit						
Junishie .		12.449.2019	16	-b						
✓ Avalatie		12-400-2019	16							
4 Dispensed		19-Aug-2019	16							
La Dispensed		20-Aug-2019	16							
✓ Available		12-Aug-2019	16							
		17-Aug-2019	16							
✓ Available										

- c. From the Status drop-down above the table, select Pending Destruction.
- d. On the right, below Inventory Management, select Update Kit.
- e. From the Kit Status drop-down, select Destroyed.
- **f.** Enter a reason, and click **Update Kit**.

Read detailed instructions or **>** watch training!

- **3.** To ship kits to a drug destruction depot:
  - **a.** Along the top, click **Supplies**, and make sure the **Shipments** tab is selected.
  - **b.** From the **Filter by Status** drop-down, select **Pending Destruction**.

**c.** Select a shipment, and on the right, click **Download List of Kits**. We recommend printing the report.

**d.** Fulfill the shipment outside Oracle Clinical One Platform.

Read detailed instructions.

# 12 What if something happens to a kit or shipment?

What happened?

- A subject lost or damaged a kit.
- A kit was lost or damaged at our site.
- A kit wasn't dispensed to a subject.
- A kit was dispensed in error.
- A shipment didn't arrive.
- A device can't be activated.



## 13 What if we need extra supply for a clinic day?

- **1.** On the Home page, click either the name of the study (to enter study data) or the Training Mode button (to practice).
- 2. Along the top, click **Supplies**, and make sure the **Shipments** tab is selected.
- **3.** Click **Request Shipment**.

Don't see the button? This study doesn't allow sites to request shipments. Contact your CRA for assistance.

**4.** Enter a reason, and click **Request**.

Read detailed instructions or **D** watch training!



		alexand .		1.11 1.1.1		Internet Internet Internet		
				Site 1001 - Davis C	inic +	a Shipment Details		
Skipnents Ski Inventory Request Skipnent +	Search by Stepment () Q. / Aller by Stepment ()							
Shipment ID		Status	Created Date	Ship Date	Tracking Number	request a shipment for a clinic day.		
POCStudy251		Received	14-Jun-2020	14-Jun-2020				
POCSNaj261	-	Received	12-Jun-2020	15-Jun-2020				
POCSkudy221	Request Ship	ment		15-Jun-2020				
	in the second se	son for Change Other						
		Edta sh reviewe	tipment required for FDA d kits					
			Cancel Reque	2				
			-	5				

## Find out more about **Clinical One Suite**



Copyright © 2023, Oracle and/or its affiliates. All rights reserved.

About Oracle Contact Us Products A-Z Terms of Use & Privacy Cookie Preferences Ad Choices

#### Can't find what you need?

Write to us at clinical\_one\_doc\_feedback\_us\_grp@oracle.

