
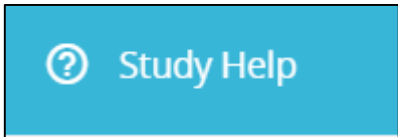


C4891002 Quick Reference Guide




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*****Note - Receipt of Investigational Product has been split out as its own document. Please access the “Help Documents” link in Impala 2.0 to view this document.***

Help Documents (All users)

 <p>Help documents are available via the Impala 2.0 End User System.</p>	<p>Please click on “Study Help” located in the top right corner of the Dashboard to access:</p> <ul style="list-style-type: none"> • This study specific Quick Reference Guide • Impala 2.0 Data Correction Request Form • Receipt of Investigational Product guide <ul style="list-style-type: none"> ○ Contains information on how to confirm Receipt of Investigational Product 	
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Pfizer Clinical Support Help Desk Call Tree Options

	<p>The Pfizer Clinical Support Help Desk can be reached at (+1) 877-433-2619</p> <ul style="list-style-type: none"> • For Account Provisioning (Exostar/SIP account set up) <ul style="list-style-type: none"> ○ Option 8: US CO Central Design, Pfizer Account Provisioning
	<ul style="list-style-type: none"> • For Impala Support: -> Option 3 and select between the five options below: <ul style="list-style-type: none"> ▪ Option 1: Impala Account request, Access modification/Password resets ▪ Option 2: All other Impala issues ▪ Option 3: Pfizer Learning Center Webpage (Impala Training Related Issues) ▪ Option 4: Impala Kit Verify ▪ Option 5: Shipment Notification Support
	<p>Outside of USA Toll Free Dialing information:</p> <ul style="list-style-type: none"> • Please use the following link to find the correct calling code for the country in which you are currently located: https://www.business.att.com/collateral/access.html • The Pfizer Clinical Support Help Desk is in the United States, so please locate the country you are dialing from. There will be no need for a PIN as the Help Desk number is a toll-free number. <ul style="list-style-type: none"> ○ Dial the AT&T Direct Toll-Free Access code provided + 877-433-2619 (<i>Pfizer Clinical Support Help Desk</i>)

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- Translation services are always available when calling the Pfizer Clinical Support Help Desk.
 - Please identify your preferred language and the Helpdesk analyst will conference in a translator.


NOTE: If you are unable to call the Pfizer Clinical Support Help Desk for any reason, an alternate contact method is by email: impala@pfizer.com

- The Pfizer Clinical Support Help Desk email box is monitored 24/5 during the United States **business week**. However, the Pfizer Clinical Support Help Desk can be reached at **(+1) 877-433-2619** for any urgent issues anytime 24/7, including holidays.


Impala 2.0 User Account Access (All users)

 **New Impala 2.0 account:** Request IRT system access via the *Access Request for Pfizer Applications* link on the [Shared Investigator Platform \(SIP\)](#) Pfizer Sponsor Homepage. IRT System Training must be completed in the [Firecrest Portal](#) before access can be granted.

Impala 2.0 training is located in Firecrest under the Study Specific Portal.

 **Already have an Impala 2.0 Account?**
If you have already completed the Impala 2.0 Training previously for a different Impala 2.0 study; please contact the Pfizer Clinical Support Help Desk at (+1) 877-433-2619 to request to have this study added to your existing Impala 2.0 account.

Impala 2.0 Study Roles and Account Types (All users)

 When requesting an Impala 2.0 account it is critical that you identify your role on the study clearly to the Pfizer Clinical Support Help Desk. Failure to do so could result in improper access being granted.

Site Break Blind (PI, Sub-I, or Medical Designee)	Site No Break Blind (Site Coordinator)
Screen	Screen
Randomize	Randomize
Assign Drug	Assign Drug
Change Subject Status	Change Subject Status
Request Report	Request Report

C4891002 Quick Reference Guide



Please take time to review the roles above and understand what your remit is for this study.

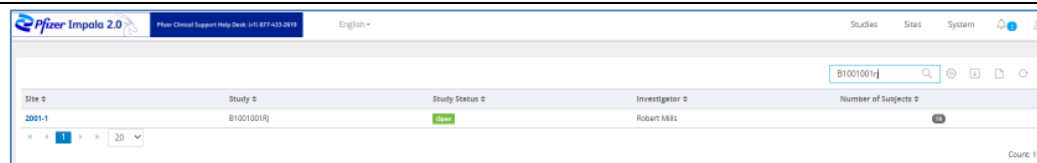
- If there is any uncertainty, please contact your site monitor prior to requesting your Impala 2.0 account.
- Only one account type should be requested per study.
- It is very important that account details are specific to an individual and **must not** be shared with anyone.

Logging into Impala 2.0 (All users)

The Impala 2.0 link is available on the SIP Pfizer Sponsor Homepage and the SIP Study Workspace (appropriate permissions needed).

- Site staff may also access outside of SIP via the Exostar portal at <https://secureaccess.exostar.com>.

- If a user has permissions to more than one protocol or site, they will be presented with a list to choose from
- If only involved with one Protocol / Site, the page will only display one Protocol/Site
- Current Protocol / Site number is visible on every Impala 2.0 screen



Subject Visit Date and Visit Completion Messages (All users)

All visits logged in Impala 2.0 will require you to confirm the visit date displayed on the screen.

- This is the date the transaction is completed and **cannot** be changed.
- Accessing the system at the time of the subject visit is **required**.
- Confirm the Visit Date, then click '**Next**' to proceed with logging the visit.

Confirm Subject Visit Date

Visit Date **21-Jan-2020**

Cancel

Next

After the completion of each visit, a Visit Complete dialog box will be displayed. The information will include:

- The completed Visit Number
- Subject Number (SSID)
- Next IRT Visit date
- Click '**Done**' to return to the Subject page.

Visit Complete


Visit 0 is completed for subject 20011010.

Next IRT visit should be scheduled for: **20-Nov-2020**

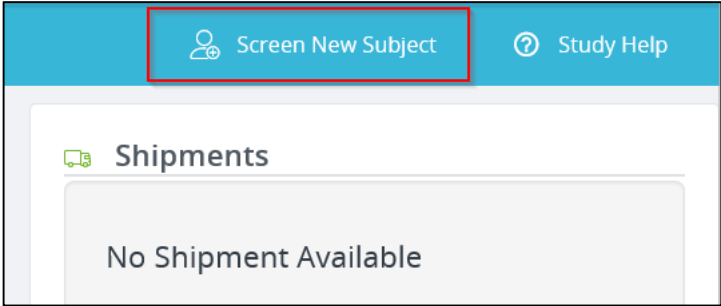


Done

C4891002 Quick Reference Guide

<p>Out of Visit Window:</p> <ul style="list-style-type: none"> If visit is registered outside the protocol defined visit window [visit duration plus/minus interval] an Out of Visit Window message is displayed <ul style="list-style-type: none"> Select Yes to continue registering visit transaction Select No to halt visit transaction and return to subject summary 	<div style="border: 1px solid black; padding: 10px; background-color: #f0f0f0;"> <p>Out Of Visit Window</p> <ul style="list-style-type: none"> Subject is outside next visit acceptable window. Do you wish to continue? <div style="display: flex; justify-content: flex-end; gap: 10px;"> ✓ Yes ✗ No </div> </div>
---	--

Screening (Site No Break Blind and Site Break Blind users)			
<div style="display: flex; flex-direction: column; gap: 5px;"> <div> 🚩 Accessing the system at the time of each IRT visit is required. </div> <div> 🚩 Impala 2.0 is the source of the Single Subject ID (SSID) number. </div> </div>			
Visit Description	Function	To access, Click on:	Result in Impala 2.0
Screening	Screen Subject	'Screen New Subject' <div style="border: 1px solid black; padding: 5px; margin: 5px 0; display: inline-block;">  Screen New Subject </div> Or 'Add' <div style="border: 1px solid black; padding: 5px; margin: 5px 0; display: inline-block;"> + Add </div>	8-digit Screening Number (SSID) assigned

C4891002 Quick Reference Guide

<ul style="list-style-type: none"> From the Site Dashboard, click 'Screen New Subject' 	
<ul style="list-style-type: none"> Or, from the 'Subjects' page list, click 'Add' 	
<p>Collect Subject Data</p> <p>At Screening the system is collecting the following Subject Data:</p> <ul style="list-style-type: none"> Gender Race Ethnicity <ul style="list-style-type: none"> Select the correct choices from the drop-down lists and click 'Next'. 	

C4891002 Quick Reference Guide

<p>Confirm Collected Data</p> <ul style="list-style-type: none"> Review data collected Click 'Next' to proceed -or- Click 'Back' to go to the previous screen and update any data that has been entered incorrectly. 	<div data-bbox="850 300 1730 623"> <div>Confirm Collected Data</div> <div> <div>⚠ Please confirm all data have been entered accurately prior to submitting.</div> <div> <div>GenderMale</div> <div>RaceAmerican Indian or Alaska Native</div> <div>EthnicityNot Hispanic or Latino(a) or of Spanish Origin</div> </div> <div> <div>Back</div> <div>Next</div> </div> </div> </div>
<p>Screen Confirmation</p> <ul style="list-style-type: none"> Confirm that you wish to screen a new subject, by clicking 'OK' 	<div data-bbox="850 659 1761 1011"> <div>Screen Confirmation</div> <div> <div>Please confirm that you wish to screen a new subject</div> <div> <div>Cancel</div> <div>OK</div> </div> </div> </div>
<p>Visit Complete</p> <p>When the subject has been successfully screened a message will display at the top of the screen.</p> <ul style="list-style-type: none"> Click 'Done' to close the dialogue box 	<div data-bbox="850 1011 1875 1110"> <div> <div>i</div> <div>Subject successfully screened: 10001036</div> <div>x</div> </div> </div>

C4891002 Quick Reference Guide

	<div><div>Visit Complete</div><div>Visit: Screen is completed for subject 10001036. Next IRT visit should be scheduled for 24-Apr-2023</div><div>Done</div></div>
--	---



Pfizer Clinical Support Help Desk: (+1) 877-433-2619

C4891002 Quick Reference Guide

Screen Confirmation Report

- Upon completion of the screening function, a Screening confirmation report will be sent to the email address associated to user's account.



Pfizer Clinical Support Help Desk: (+1) 877-433-2619

C4891002 Screen Confirmation Report

Transaction Date: 27-Mar-2023 19:39:40 GMT

Study Code:	C4891002	Site Address:	1 Main Street
Site Code:	1000-1		Groton, CT 06498
Investigator:	Joe Impala		United States


Subject 10001036 Information

Subject Status: Screened
Screen Date: 27-Mar-2023
Visit ID: Screen
Visit Description: Screen




Subject Data Details

Ethnicity: Not Hispanic or Latino(a) or of Spanish Origin
Race: Native Hawaiian or Other Pacific Islander
Gender: Male

Re-Screening

-  Re-screening is permitted for this study, subject will be screened and new SSID assigned. Please ensure that the original SSID status is set to screen-fail in Impala 2.0.

Randomization (Site No Break Blind and Site Break Blind users)

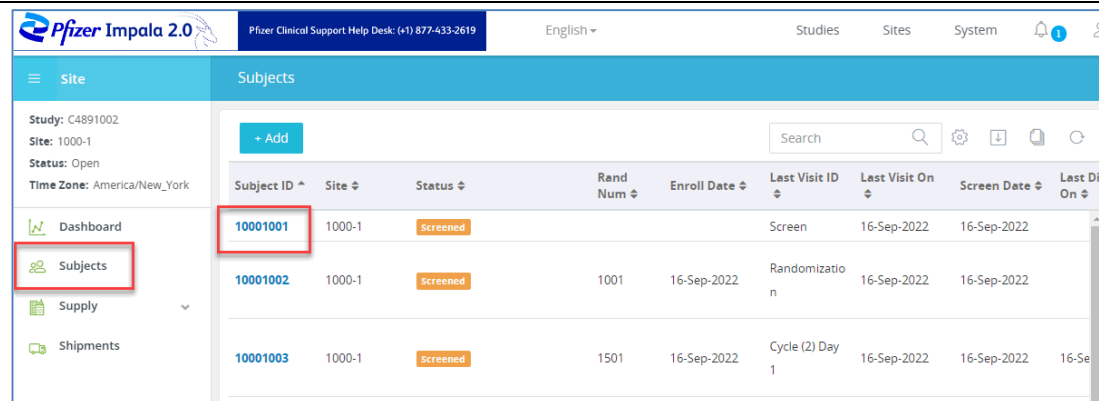
-  **Accessing the system at the time of each IRT visit is required.**
 - Make certain you are scheduling your subjects in accordance with the protocol defined visit windows.
-  **Before Enrollment/Randomization, ensure the initial shipment of Investigational Product has been received in Impala 2.0 (See Receipt of Investigational Product Guide in the Study Help Link).**
-  **Site personnel must not dispense Kit(s) to the subject until the Impala 2.0 Enrollment Confirmation/Subject Visit Confirmation Report has been received at the site. This will help ensure that the correct Kit(s) are dispensed to the subject.**
 - If the Impala 2.0 Confirmation Report is not received in a timely manner the report can be regenerated. Please follow the instructions on how to regenerate confirmation reports under the ["Confirmation Reports"](#) section in this document.

Visit Description	Function	To access, Click on:	Result in Impala 2.0
Randomization	Randomize Subject	Subject ID (Subject Page) Randomization Visit Button 	Randomization Number generated (recorded on CRF)

C4891002 Quick Reference Guide

To Randomize the subject:

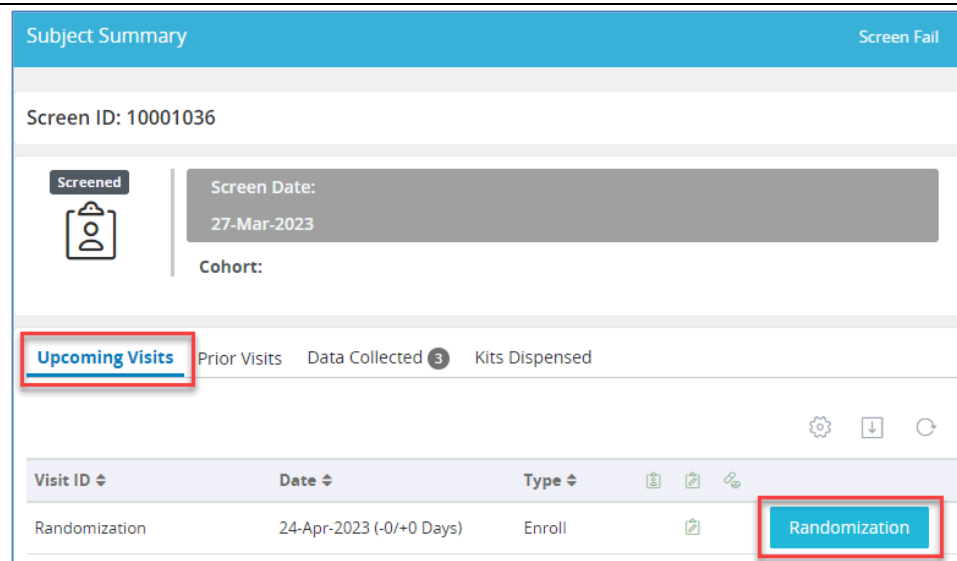
- Locate the Subject from the Subject List
- Click on the Subject ID to access the Subject record



Subject ID	Site	Status	Rand Num	Enroll Date	Last Visit ID	Last Visit On	Screen Date	Last Dis On
10001001	1000-1	Screened			Screen	16-Sep-2022	16-Sep-2022	
10001002	1000-1	Screened	1001	16-Sep-2022	Randomization	16-Sep-2022	16-Sep-2022	
10001003	1000-1	Screened	1501	16-Sep-2022	Cycle (2) Day 1	16-Sep-2022	16-Sep-2022	16-Sep-2022

Upcoming Visits tab

- Click the **Randomization** visit button



Visit ID	Date	Type	Randomization
Randomization	24-Apr-2023 (-0/+0 Days)	Enroll	Randomization

C4891002 Quick Reference Guide

Enroll Subject Confirmation

- The site user will be presented with the Enroll Subject confirmation screen
- The site must select ‘Save’ to proceed
- To cancel the transaction click ‘Cancel’

When the subject has been successfully randomized/enrolled a message will display at the top of the screen displaying the rand number. **This message disappears quickly.**

Enroll Subject

Please confirm that you wish to enroll the current subject: 10001036

Cancel

Save

i

Subject 10001036 has been enrolled to randomization number 8006.

x

Statement Confirmation:

Completion of Randomization/Enrollment:

- Ensure Cycle 1 Day visit is logged within 3 days of randomization
- Click ‘**OK**’ on the Statement Confirmation screen to complete the randomization/enrollment.

Statement Confirmation

To complete Enroll Subject action, please read the following message(s):

• Please ensure the Cycle 1 Day 1 visit is logged within 3 days of randomization.

Cancel

OK

C4891002 Quick Reference Guide

<p>No data is being collected by the site user but the system requires this message for Impala 2.0 configurations.</p> <ul style="list-style-type: none"> Click 'Next' to continue 	<div style="border: 1px solid #ccc; padding: 10px; background-color: #f9f9f9;"> <div style="background-color: #e0e0e0; padding: 5px;">Confirm Collected Data</div> <p style="margin-top: 10px;">No data collection needed at this time. Please click NEXT to continue.</p> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> Cancel Next </div> </div>
<p>Visit Completion message After the completion of this visit, a Visit Completion dialog box will be displayed.</p> <p>This information will include:</p> <ul style="list-style-type: none"> The completed Visit Description <ul style="list-style-type: none"> Click 'Done' to return to the Subject page. 	<div style="border: 1px solid #ccc; padding: 10px; background-color: #f9f9f9;"> <div style="background-color: #e0e0e0; padding: 5px;">Visit Complete</div> <div style="border: 1px solid #ccc; padding: 5px; margin-top: 10px;"> Visit: Randomization is completed for subject 10001036. </div> <div style="display: flex; justify-content: flex-end; margin-top: 10px;"> Done </div> </div>



Pfizer Clinical Support Help Desk: (+1) 877-433-2619

C4891002 Quick Reference Guide

Enrollment Confirmation Report:

The confirmation report will be sent to the email address associated to user's account.



Pfizer Clinical Support Help Desk: (+1) 877-433-2619

C4891002 Enrollment Confirmation Report

Transaction Date: 27-Mar-2023 19:44:55 GMT



Study Code:	C4891002	Site Address:	1 Main Street
Site Code:	1000-1		Groton, CT 06498
Investigator:	Joe Impala		United States

Subject is Enrolled to Study

Visit Information:

Subject ID:	10001036
Subject Status:	Active
Visit ID:	Randomization
Visit Description:	Randomization
Randomization Date:	27-Mar-2023
Randomization Number:	8006
Treatment Group:	D [Dose Level 2 ARV-471 (PF-07850327) 200mg + palbociclib 75mg]

Subject Visits for Cycle 1 Day 1 (Site No Break Blind and Site Break Blind users)

-  **Accessing the system at the time of each IRT visit is required.**
 - Make certain you are scheduling your subjects in accordance with the protocol defined visit windows.
-  **Site personnel must not dispense Kit(s) to the subject until the Impala 2.0 Subject Visit Confirmation Report has been received at the site. This will help ensure that the correct Kit(s) are dispensed to the subject.**
 - If the Impala 2.0 Subject Visit Confirmation Report is not received in a timely manner the report can be regenerated. Please follow the instructions on how to regenerate confirmation reports under the ["Confirmation Reports"](#) section in this document.

Visit Description	Function	To access, Click on:
Cycle 1, Day 1	Assign Drug	Subject ID (Subject Page) Available Visit Button
Visit: Cycle 1, Day 1 Treatment Group D	<u>Treatment Group D</u> D [Dose Level 2 ARV-471 (PF-07850327) 200mg + palbociclib 75mg] Dispenses Palbo 75mg and ARV-471 100mg Bottle	


C4891002 Quick Reference Guide

- Under the Upcoming Visits tab, Click the **Day 1** button.

Note: the planned visit date for Cycle 1 day 1 is projected as 28 days from Randomization (because future cycles will follow this interval) but C1D1 should be planned for less than or equal to 3 Days from Randomization.

Subject Summary
Discontinue

Screen ID: 10001036

Active


Enroll Date: 27-Mar-2023

Rand #: 8006 Screen Date: 27-Mar-2023

Cohort: Study Lead-in

Treatment Group:
D [Dose Level 2 ARV-471 (PF-07850327)
200mg + palbociclib 75mg]

Upcoming Visits

Prior Visits




Data Collected 4

Kits Dispensed

Visit ID ⌵

Date ⌵

Type ⌵

Day 1	03-Apr-2023 (-0/+0 Days)	Planned	<div style="border: 1px solid #0099cc; padding: 2px 10px; color: white; display: inline-block;">Day 1</div>
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Statement which shows at every drug assignment:

Beginning at Cycle 2, this statement explains drug assignment rules. Not relevant at C1D1 visits which is a fixed dispensation.

Statement Confirmation ✖

To complete Dispense Drug action, please read the following message(s):

- The following statements are applicable beginning at Cycle 2:**
- DO NOT log the Day 1 visit if palbociclib dose is delayed. Instead, click CANCEL and log an Unplanned Visit to assign ARV-471 (PF-07850327).
- Once palbociclib is restarted, log the Day 1 visit to assign palbociclib and ARV-471 (PF-07850327).
- Select "None" if ARV-471 (PF-07850327) is not being dispensed
- Select "None" if permanently discontinuing any drug type (including palbociclib)

Cancel

OK

C4891002 Quick Reference Guide

Dispense Confirmation

Visit Dispensing Options:

Only Cycle 1 Day 1 visit is a fixed dispensation.

- Click **'Confirm'** on the Dispense Confirmation screen to complete the drug assignment.
- The system will dispense the appropriate kits

Dispense Confirmation

Please confirm that you wish to dispense drug to subject: 10001036

Cancel

Confirm

Click **'Done'** to complete the Drug Assignment.

Dispensing complete for Visit: Day 1

Please dispense the following kit(s) to 10001036

Discrete Numbered Kits

Kit ID ↕	Type ↕	Kit Desc ↕	Expiry Date ↕
80022	Blinded	ARV-471 (PF-07850327) 100 mg Bottle 60 ct	01-Jan-2050
94023	Blinded	Palbociclib 75 mg Bottle 23 ct (C489)	01-Jan-2050

Count: 2

Done

C4891002 Quick Reference Guide

<p>No data is being collected but the system required this message.</p> <p>Click 'Next' to continue</p>	<div><div>Confirm Collected Data</div><div>No data collection needed at this time. Please click NEXT to continue.</div><div><div>Cancel</div><div>Next</div></div></div>
<p>The Visit Complete message is displayed.</p> <p>Click 'Done' to complete the transaction.</p>	<div><div>Visit Complete</div><div>Visit: Day 1 is completed for subject 10001036.</div><div>Done</div></div>
<p>Kits Dispensed Tab:</p> <p>Site users can use the 'Kits Dispensed' tab to review all drug assignment visits and kits dispensed</p>	<div><div>Subject Summary</div><div>DiscontinueReplace Kit</div><div>Screen ID: 10001036</div><div><div>Active</div><div>Enroll Date: 27-Mar-2023</div><div>Rand #: 8006</div><div>Cohort: Study Lead-in</div><div>Treatment Group:</div><div>D [Dose Level 2 ARV-471 (PF-07850327) 200mg + palbociclib 75mg]</div><div>Screen Date: 27-Mar-2023</div></div><div><div>Upcoming Visits</div><div>Prior Visits</div><div>Data Collected</div><div>Kits Dispensed</div></div><div><div>Visit ID</div><div>Date</div><div>Assigned Dose</div><div>Kits Dispensed</div><div>Note</div></div><div><div>Study Lead-in Cycle (1) Day 1</div><div>27-Mar-2023</div><div>80022 (ARV-471 (PF-07850327) 100 mg Bottle 60 ct) , 94023 (Palbociclib 75 mg Bottle 23 ct (C489))</div></div></div>



Pfizer Clinical Support Help Desk: (+1) 877-433-2619

C4891002 Quick Reference Guide

Subject Visit Confirmation Report

- Upon completion of each Visit, a Subject Visit Confirmation Report will be sent to the email address associated to your user's account.
- Follow your IP manual for instructions on verification of dispensation and IP reconciliation.



Pfizer Clinical Support Help Desk: (+1) 877-433-2619

C4891002 Subject Visit Confirmation Report

Transaction Date: 27-Mar-2023 19:55:23 GMT

Study Code:	C4891002	Site Address:	1 Main Street Groton, CT 06498 United States
Site Code:	1000-1		
Investigator:	Joe Impala		

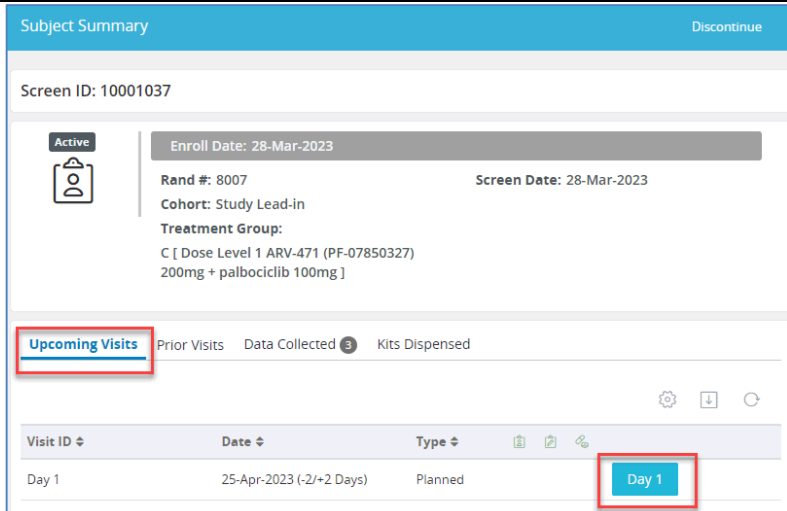
Subject 10001036 Completed Visit

Subject Status:	Active
Visit Date:	27-Mar-2023
Visit ID:	Study Lead-in Cycle (1) Day 1
Visit Description:	Day 1
Randomization Number:	8006

Subject Dispense Kit

Visit ID	Dispensing Date	Kit	Kit Desc	Qty	Expiry Date
Study Lead-in Cycle (1) Day 1	27-Mar-2023	80022	ARV-471 (PF-07850327) 100 mg Bottle 60 ct	1	01-Jan-2050
Study Lead-in Cycle (1) Day 1	27-Mar-2023	94023	Palbociclib 75 mg Bottle 23 ct (C489)	1	01-Jan-2050

C4891002 Quick Reference Guide

<p>Visit: Cycle 1, Day 1 Treatment Group C</p> <ul style="list-style-type: none"> Under the Upcoming Visits tab, Click the Day 1 button. <p>Note: the planned visit date for Cycle 1 day 1 is projected as 28 days from Randomization (because future cycles will follow this interval) but C1D1 should be planned for less than or equal to 3 Days from Randomization.</p>	<p><u>Treatment Group C</u> C [Dose Level 1 ARV-471 (PF-07850327) 200mg + palbociclib 100mg] Dispenses Palbo 100mg Bottle and ARV-471 100mg Bottle</p> 
<p>Statement which shows at every drug assignment:</p> <ul style="list-style-type: none"> Beginning at Cycle 2, this statement explains drug assignment rules. Not relevant at C1D1 visits which is a fixed dispensation. 	<p>Statement Confirmation</p> <p>To complete Dispense Drug action, please read the following message(s):</p> <ul style="list-style-type: none"> The following statements are applicable beginning at Cycle 2: DO NOT log the Day 1 visit if palbociclib dose is delayed. Instead, click CANCEL and log an Unplanned Visit to assign ARV-471 (PF-07850327). Once palbociclib is restarted, log the Day 1 visit to assign palbociclib and ARV-471 (PF-07850327). Select "None" if ARV-471 (PF-07850327) is not being dispensed Select "None" if permanently discontinuing any drug type (including palbociclib) <p>Cancel OK</p>

C4891002 Quick Reference Guide

Dispense Confirmation
Visit Dispensing Options:

Only Cycle 1 Day 1 visit is a fixed dispensation.

- Click **'Confirm'** on the Dispense Confirmation screen to complete the drug assignment.
- The system will dispense the appropriate kits

Click **'Done'** to complete the Drug Assignment.

Dispense Confirmation

Please confirm that you wish to dispense drug to subject: 10001037

Cancel

Confirm

Dispensing complete for Visit: Day 1

Please dispense the following kit(s) to 10001037

Discrete Numbered Kits

Kit ID ↕	Type ↕	Kit Desc ↕	Expiry Date ↕
80151	Blinded	ARV-471 (PF-07850327) 100 mg Bottle 60 ct	01-Jan-2050
96032	Blinded	Palbociclib 100 mg Bottle 23 ct (C489)	01-Jan-2050

Count: 2

Done

C4891002 Quick Reference Guide

<p>No data is being collected but the system required this message.</p> <p>Click 'Next' to continue</p>	<div><div>Confirm Collected Data</div><div>No data collection needed at this time. Please click NEXT to continue.</div><div><div>Cancel</div><div>Next</div></div></div>
<p>The Visit Complete message is displayed.</p> <p>Click 'Done' to complete the transaction.</p>	<div><div>Visit Complete</div><div>Visit: Day 1 is completed for subject 10001037.</div><div>Done</div></div>
<p>Kits Dispensed Tab:</p> <p>Site users can use the 'Kits Dispensed' tab to review all drug assignment visits and kits dispensed.</p>	<div><div>Subject Summary</div><div>DiscontinueReplace Kit</div><div>Screen ID: 10001037</div><div><div>Active</div><div><div>Enroll Date: 28-Mar-2023</div><div>Rand #: 8007</div><div>Cohort: Study Lead-in</div><div>Treatment Group:</div><div>C [Dose Level 1 ARV-471 (PF-07850327) 200mg + palbociclib 100mg]</div><div>Screen Date: 28-Mar-2023</div></div></div><div><div>Upcoming Visits</div><div>Prior Visits</div><div>Data Collected</div><div>Kits Dispensed</div></div><div><div>Visit ID</div><div>Date</div><div>Assigned Dose</div><div>Kits Dispensed</div><div>Note</div></div><div><div>Study Lead-in Cycle (1) Day 1</div><div>27-Apr-2023</div><div>80151 (ARV-471 (PF-07850327) 100 mg Bottle 60 ct), 96032 (Palbociclib 100 mg Bottle 23 ct (C489))</div></div></div>



Pfizer Clinical Support Help Desk: (+1) 877-433-2619

C4891002 Quick Reference Guide

Subject Visit Confirmation Report

- Upon completion of each Visit, a Subject Visit Confirmation Report will be sent to the email address associated to your user's account.

Follow your IP manual for instructions on verification of dispensation and IP reconciliation.



Pfizer Clinical Support Help Desk: (+1) 877-433-2619

C4891002 Subject Visit Confirmation Report

Transaction Date: 27-Apr-2023 21:02:42 GMT

Study Code:	C4891002	Site Address:	1 Main Street
Site Code:	1000-1		Groton, CT 06498
Investigator:	Joe Impala		United States

Subject 10001037 Completed Visit

Subject Status:	Active
Visit Date:	27-Apr-2023
Visit ID:	Study Lead-in Cycle (1) Day 1
Visit Description:	Day 1
Randomization Number:	8007

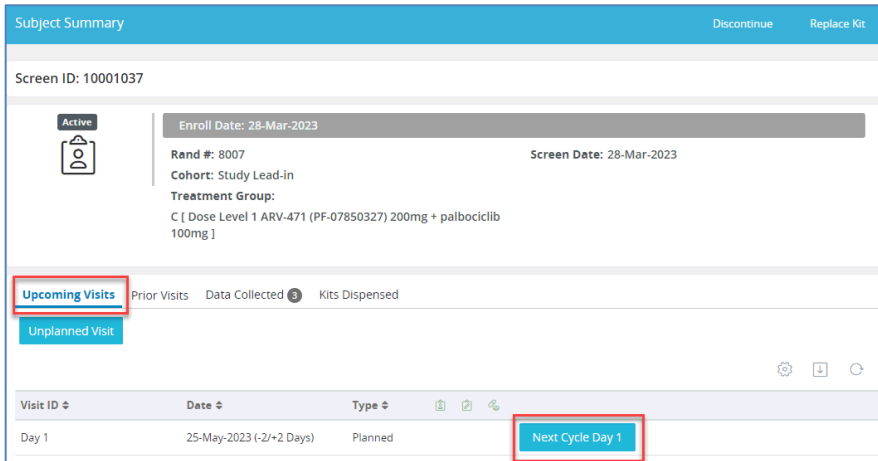
Subject Dispense Kit

Visit ID	Dispensing Date	Kit	Kit Desc	Qty	Expiry Date
Study Lead-in Cycle (1) Day 1	27-Apr-2023	80151	ARV-471 (PF-07850327) 100 mg Bottle 60 ct	1	01-Jan-2050
Study Lead-in Cycle (1) Day 1	27-Apr-2023	96032	Palbociclib 100 mg Bottle 23 ct (C489)	1	01-Jan-2050

Subject Visits for Cycle X, Day 1 (Site No Break Blind and Site Break Blind)

- 🚩 **Accessing the system at the time of each IRT visit is required.**
 - Make certain you are scheduling your subjects in accordance with the protocol defined visit windows.
- 🚩 **Site personnel must not dispense Kit(s) to the subject until the Impala 2.0 Subject Visit Confirmation Report has been received at the site. This will help ensure that the correct Kit(s) are dispensed to the subject.**
 - If the Impala 2.0 Subject Visit Confirmation Report is not received in a timely manner the report can be regenerated. Please follow the instructions on how to regenerate confirmation reports under the ["Confirmation Reports"](#) section in this document.

Visit Description	Function	To access, Click on:
Cycle X, Day 1	Assign Drug	Subject ID (Subject Page) Available Visit Button

Visits Cycle X, Day 1	Treatment Groups C and D
<p>To register a scheduled IRT visit</p> <ul style="list-style-type: none"> Locate the Subject from the Subject List Click on the Subject ID to access the Subject record <p>Under Upcoming Visits tab, Click the 'Next Cycle Day 1' Button.</p>	<p>Treatment Group C:</p>  <p>Treatment Group D:</p>

C4891002 Quick Reference Guide


Subject Summary

Discontinue

Replace Kit

Screen ID: 10001036

Active



Enroll Date: 27-Mar-2023

Rand #: 8006

Screen Date: 27-Mar-2023

Cohort: Study Lead-in

Treatment Group:

D [Dose Level 2 ARV-471 (PF-07850327) 200mg + palbociclib 75mg]

Upcoming Visits




Prior Visits Data Collected 5 Kits Dispensed

Unplanned Visit

Visit ID

Date

Type

Day 1

03-Apr-2023 (-0/+0 Days)

Planned

Next Cycle Day 1

<p>Statement explains several aspects of drug assignment</p>	<div style="border: 1px solid #ccc; padding: 10px;"> <div style="background-color: #e6e6fa; padding: 5px;">Statement Confirmation</div> <p>To complete Dispense Drug action, please read the following message(s):</p> <ul style="list-style-type: none"> • The following statements are applicable beginning at Cycle 2: • DO NOT log the Day 1 visit if palbociclib dose is delayed. Instead, click CANCEL and log an Unplanned Visit to assign ARV-471 (PF-07850327). • Once palbociclib is restarted, log the Day 1 visit to assign palbociclib and ARV-471 (PF-07850327). • Select "None" if ARV-471 (PF-07850327)is not being dispensed • Select "None" if permanently discontinuing any drug type (including palbociclib) <div style="display: flex; justify-content: space-between; margin-top: 10px;"> Cancel OK </div> </div>
<p>Visit Dispensing Options: 'Next Cycle Day 1' visit is a choice dispensation for each of the following:</p> <ul style="list-style-type: none"> • Palbociclib • ARV-471 (PF-07850327) 	<div style="border: 1px solid #ccc; padding: 10px;"> <div style="background-color: #e6e6fa; padding: 5px;">Visit Dispensing Options</div> <p>Please select the dispensing option for subject: 10001036</p> <p>Palbociclib - Select appropriate dose level. Select 'None' only if palbociclib is being permanently discontinued</p> <p>Choose One *</p> <div style="border: 1px solid #ccc; height: 25px; width: 100%;"></div> <p>ARV-471 (PF-07850327)</p> <p>Choose One *</p> <div style="border: 1px solid #ccc; height: 25px; width: 100%;"></div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> Cancel Next </div> </div>

C4891002 Quick Reference Guide

Treatment Group C

C [Dose Level 1 ARV-471 (PF-07850327) 200mg + palbociclib 100mg]:

Palbociclib:

- Palbociclib 100 mg Bottle 23 ct
- Palbociclib 75 mg Bottle 23 ct
- None

ARV-471 (PF-07850327)

- ARV-471 (PF-07850327) 100 mg Bottle 60 ct
- None

Note: 75mg Bottle of Palbociclib is offered for an approved dose reduction of Palbociclib.

Once subject is dose-reduced to 75mg Palbociclib, the choice of 100mg Palbociclib will not be offered at subsequent planned visits.

Treatment Group C:
Visit Dispensing Options

Please select the dispensing option for subject: 10001037

Palbociclib - Select appropriate dose level. Select 'None' only if palbociclib is being permanently discontinued

Choose One *

ARV-471 (PF-07850327)

Choose One *

Palbociclib 100 mg Bottle 23 ct
Palbociclib 75 mg Bottle 23 ct
None

Cancel

Next

Visit Dispensing Options

Please select the dispensing option for subject: 10001037

Palbociclib - Select appropriate dose level. Select 'None' only if palbociclib is being permanently discontinued

Choose One *

ARV-471 (PF-07850327)

Choose One *

ARV-471 (PF-07850327) 100 mg Bottle 60 ct
None

Cancel

Next

C4891002 Quick Reference Guide

Visit Dispensing Options: Choose from each dropdown

Treatment Group D
D [Dose Level 2 ARV-471
(PF-07850327) 200mg +
palbociclib 75mg]:

Palbociclib:

- Palbociclib 75 mg
Bottle 23 ct
- Palbociclib 100 mg
Bottle 23 ct
- None

Note: 100mg Bottle of
Palbociclib is offered for Cycle
5 visits and later where dose
was approved to be increased
to 100mg Palbociclib.

ARV-471 (PF-07850327)

- ARV-471 (PF-
07850327) 100 mg
Bottle 60 ct
- None

Dispense Confirmation

Treatment Group D:

Visit Dispensing Options

Please select the dispensing option for subject: 10001036

Palbociclib - Select appropriate dose level. Select 'None' only if palbociclib is being permanently discontinued

Choose One *

ARV-471 (PF-07850327)

Choose One *

Palbociclib 75 mg Bottle, 23 ct
Palbociclib 100 mg Bottle, 23 ct (for dose increase at Cycle 5 or later, if protocol allows)
None

Cancel

Next

Visit Dispensing Options

Please select the dispensing option for subject: 10001036

Palbociclib - Select appropriate dose level. Select 'None' only if palbociclib is being permanently discontinued

Choose One *

ARV-471 (PF-07850327)

Choose One *

ARV-471 (PF-07850327) 100 mg Bottle 60 ct
None

Cancel

Next

C4891002 Quick Reference Guide

- Click **'Confirm'** on the Dispense Confirmation screen to complete the drug assignment.

Treatment Group C:

Dispense Confirmation

Please confirm that you wish to dispense drug to subject: 10001037

Cancel

Confirm

Treatment Group D:

Dispense Confirmation

Please confirm that you wish to dispense drug to subject: 10001036

Cancel

Confirm

- Click **'Done'** to complete the Drug Assignment.

Treatment Group C:

Dispensing complete for Visit: Day 1

Please dispense the following kit(s) to 10001037

Discrete Numbered Kits

Kit ID ↕	Type ↕	Kit Desc ↕	Expiry Date ↕
80160	Blinded	ARV-471 (PF-07850327) 100 mg Bottle 60 ct	01-Jan-2050
96034	Blinded	Palbociclib 100 mg Bottle 23 ct (C489)	01-Jan-2050

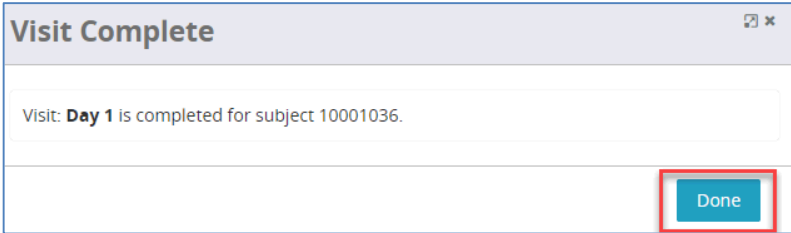
Count: 2

Done


C4891002 Quick Reference Guide

	<p>Treatment Group D:</p> <div><div>Dispensing complete for Visit: Day 1</div><div><p>Please dispense the following kit(s) to 10001036</p><p>Discrete Numbered Kits</p><table><thead><tr><th>Kit ID</th><th>Type</th><th>Kit Desc</th><th>Expiry Date</th></tr></thead><tbody><tr><td>80025</td><td>Blinded</td><td>ARV-471 (PF-07850327) 100 mg Bottle 60 ct</td><td>01-Jan-2050</td></tr><tr><td>94024</td><td>Blinded</td><td>Palbociclib 75 mg Bottle 23 ct (C489)</td><td>01-Jan-2050</td></tr></tbody></table><p>Count: 2</p><div>Done</div></div></div>	Kit ID	Type	Kit Desc	Expiry Date	80025	Blinded	ARV-471 (PF-07850327) 100 mg Bottle 60 ct	01-Jan-2050	94024	Blinded	Palbociclib 75 mg Bottle 23 ct (C489)	01-Jan-2050
Kit ID	Type	Kit Desc	Expiry Date										
80025	Blinded	ARV-471 (PF-07850327) 100 mg Bottle 60 ct	01-Jan-2050										
94024	Blinded	Palbociclib 75 mg Bottle 23 ct (C489)	01-Jan-2050										
<p>No data is being collected but the system required this message.</p> <ul style="list-style-type: none">Click 'Next' to continue	<div><div>Confirm Collected Data</div><div><p>No data collection needed at this time. Please click NEXT to continue.</p><div><div>Cancel</div><div>Next</div></div></div></div>												
<p>The Visit Complete message is now displayed.</p> <ul style="list-style-type: none">Choose 'Done' to complete the transaction.	<p>Treatment Group C:</p> <div><div>Visit Complete</div><div><p>Visit: Day 1 is completed for subject 10001037.</p><div>Done</div></div></div>												

C4891002 Quick Reference Guide

	<p>Treatment Group D:</p> 
<p>Subject Visit Confirmation Report</p> <p>Upon completion of each Visit, a Subject Visit Confirmation Report will be sent to the email address associated to your user's account.</p> <p>Follow your IP manual for instructions on verification of dispensation and IP reconciliation.</p>	<p>Treatment Group C:</p>

C4891002 Quick Reference Guide



Pfizer Clinical Support Help Desk: (+1) 877-433-2619

C4891002 Subject Visit Confirmation Report

Transaction Date: 27-Apr-2023 21:18:39 GMT

Study Code:	C4891002	Site Address:	1 Main Street Groton, CT 06498 United States
Site Code:	1000-1		
Investigator:	Joe Impala		

Subject 10001037 Completed Visit

Subject Status:
Active

Visit Date:
27-Apr-2023

Visit ID:
Study Lead-in Cycle (2) Day 1

Visit Description:
Day 1

Randomization Number:
8007

Subject Dispense Kit

Visit ID	Dispensing Date	Kit	Kit Desc	Qty	Expiry Date
Study Lead-in Cycle (2) Day 1	27-Apr-2023	80160	ARV-471 (PF-07850327) 100 mg Bottle 60 ct	1	01-Jan-2050
Study Lead-in Cycle (2) Day 1	27-Apr-2023	96034	Palbociclib 100 mg Bottle 23 ct (C489)	1	01-Jan-2050

Treatment Group D:

C4891002 Quick Reference Guide



Pfizer Clinical Support Help Desk: (+1) 877-433-2619

C4891002 Subject Visit Confirmation Report

Transaction Date: 27-Mar-2023 19:55:23 GMT

Study Code:	C4891002	Site Address:	1 Main Street
Site Code:	1000-1		Groton, CT 06498
Investigator:	Joe Impala		United States

Subject 10001036 Completed Visit

Subject Status:	Active
Visit Date:	27-Mar-2023
Visit ID:	Study Lead-in Cycle (1) Day 1
Visit Description:	Day 1
Randomization Number:	8006

Subject Dispense Kit

Visit ID	Dispensing Date	Kit	Kit Desc	Qty	Expiry Date
Study Lead-in Cycle (1) Day 1	27-Mar-2023	80022	ARV-471 (PF-07850327) 100 mg Bottle 60 ct	1	01-Jan-2050
Study Lead-in Cycle (1) Day 1	27-Mar-2023	94023	Palbociclib 75 mg Bottle 23 ct (C489)	1	01-Jan-2050

Unplanned Visits (Site No Break Blind and Site Break Blind)

- 🚩 **Accessing the system at the time of each IRT visit is required.**
 - Make certain you are scheduling your subjects in accordance with the protocol defined visit windows.
- 🚩 **Site personnel must not dispense Kit(s) to the subject until the Impala 2.0 Subject Visit Confirmation Report has been received at the site. This will help ensure that the correct Kit(s) are dispensed to the subject.**
 - If the Impala 2.0 Subject Visit Confirmation Report is not received in a timely manner the report can be regenerated. Please follow the instructions on how to regenerate confirmation reports under the ["Confirmation Reports"](#) section in this document.

Visit Description	Function	To access, Click on:
Unplanned Visit (1UPV) 2 UPV visits are allowed after each visit, as needed.	Assign Drug	Subject ID (Subject Page) Available Visit Button (Unplanned Visit)

Unplanned Visits have been configured for this study to:

- Assign ARV-471 (PF-07850327) if Day 1 of the next cycle of Palbociclib is delayed.
- Assign Palbociclib if dose needs to be reduced during a cycle.

Screen ID: 10001036

Active

Enroll Date: 27-Mar-2023

Rand #: 8006

Cohort: Study Lead-in

Treatment Group:

D [Dose Level 2 ARV-471 (PF-07850327) 200mg + palbociclib 75mg]

Screen Date: 27-Mar-2023

Upcoming Visits
Prior Visits
Data Collected 6
Kits Dispensed

Unplanned Visit

Visit ID
Date
Type

Day 1
03-Apr-2023 (-0/+0 Days)
Planned

Next Cycle Day 1

C4891002 Quick Reference Guide

<p>Statement Confirmation:</p> <p>A message is displayed explaining when it is appropriate to log an unplanned visit.</p>	<div style="border: 1px solid #ccc; padding: 10px; background-color: #f9f9f9;"> <div style="background-color: #e0e0e0; padding: 5px;">Statement Confirmation</div> <p>To complete Dispense Drug action, please read the following message(s):</p> <ul style="list-style-type: none"> Log an unplanned visit to: Assign ARV-471 (PF-07850327) if Day 1 of the next cycle of palbociclib is delayed. Assign palbociclib if dose needs to be reduced during a cycle, as applicable. <div style="display: flex; justify-content: space-between; margin-top: 10px;"> Cancel OK </div> </div>
<p>Unplanned Visit Dispensing Options: Choose from each dropdown</p> <p>Treatment Group C C [Dose Level 1 ARV-471 (PF-07850327) 200mg + palbociclib 100mg]:</p> <p>Palbociclib:</p> <ul style="list-style-type: none"> Palbociclib 75 mg Bottle 23 ct None <p>Note: 75mg Bottle of Palbociclib is offered for an approved dose reduction of Palbociclib.</p>	<p>Treatment Group C:</p> <div style="border: 1px solid #ccc; padding: 10px; background-color: #f9f9f9;"> <div style="background-color: #e0e0e0; padding: 5px;">Visit Dispensing Options</div> <p>Please select the dispensing option for subject: 10001037</p> <div style="margin-top: 10px;"> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 5px;"> Palbociclib Choose One * </div> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 5px;"> ARV-471 (PF-07850327) Choose One * </div> </div> <div style="margin-top: 10px;"> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 5px;"> Palbociclib 75 mg Bottle 23 ct </div> <div style="border: 1px solid #ccc; padding: 5px;"> None </div> </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> Cancel Next </div> </div>

C4891002 Quick Reference Guide

Once subject is dose-reduced to 75mg Palbociclib, the choice of 100mg Palbociclib will not be offered at subsequent planned visits.

ARV-471 (PF-07850327)

- ARV-471 (PF-07850327) 100 mg Bottle 60 ct
- None

Treatment Group D

D [Dose Level 2 ARV-471 (PF-07850327) 200mg + palbociclib 75mg]:

Palbociclib:

- Palbociclib 75 mg Bottle 23 ct
- None

Note: 75mg Bottle of Palbociclib is offered for an approved dose reduction of Palbociclib IF subject was increased to 100mg at Cycle 5 or later.

Visit Dispensing Options

Please select the dispensing option for subject: 10001037

Palbociclib

Choose One *

ARV-471 (PF-07850327)

Choose One *

ARV-471 (PF-07850327) 100 mg Bottle 60 ct
None

Cancel

Next

Treatment Group D:

Visit Dispensing Options

Please select the dispensing option for subject: 10001036

Palbociclib

Choose One *

ARV-471 (PF-07850327)

Choose One *

Palbociclib 75 mg Bottle, 23 ct
None

Cancel

Next

C4891002 Quick Reference Guide

<p>ARV-471 (PF-07850327)</p> <ul style="list-style-type: none"> • ARV-471 (PF-07850327) 100 mg Bottle 60 ct • None 	<div> <div>Visit Dispensing Options</div> <div> Please select the dispensing option for subject: 10001036 </div> <div> <div> Palbociclib </div> <div> Choose One * </div> <div> </div> </div> <div> <div> ARV-471 (PF-07850327) </div> <div> Choose One * </div> <div> <div> ARV-471 (PF-07850327) 100 mg Bottle 60 ct </div> <div> None </div> </div> </div> <div> <div>Cancel</div> <div>Next</div> </div> </div>
<p>Dispense Confirmation</p> <p>Click 'Confirm' on the Dispense Confirmation screen to complete the drug assignment.</p>	<div> <div>Dispense Confirmation</div> <div> Please confirm that you wish to dispense drug to subject: 10001036 </div> <div> <div>Cancel</div> <div>Confirm</div> </div> </div>

C4891002 Quick Reference Guide

Dispensing Complete

- Click **'Done'** to complete the Drug Assignment.

Dispensing complete for Visit: 1UPV

Please dispense the following kit(s) to
10001036

Discrete Numbered Kits

Kit ID ↕	Type ↕	Kit Desc ↕	Expiry Date ↕
80034	Blinded	ARV-471 (PF-07850327) 100 mg Bottle 60 ct	01-Jan-2050
94026	Blinded	Palbociclib 75 mg Bottle 23 ct (C489)	01-Jan-2050
			Count: 2

Done

The Visit Complete message is now displayed.




- Choose **'Done'** to complete the transaction.

Visit Complete

Visit: **1UPV** is completed for subject 10001036.


Done



C4891002 Quick Reference Guide

	<p>“INSUFFICIENT SUPPLY” ERROR MESSAGE MAY RESULT IN A MANUAL DRUG ASSIGNMENT. PLEASE UNDERSTAND THAT ANY MANUAL DRUG ASSIGNMENT CALL TO THE PFIZER CLINICAL SUPPORT HELP DESK MAY TAKE UP TO 1 HOUR TO COMPLETE.</p>	<div style="border: 1px solid #ccc; padding: 10px; background-color: #f9d5d5; margin: 10px auto; width: 80%;">  Dispensing Failure: Insufficient Supply at Site. Please contact the Helpdesk. </div>
<div style="display: flex; align-items: flex-start;"> <div style="margin-right: 10px;">  </div> <div> <p><u>Awareness Related to Kit Assignment Expiry Date</u></p> <ul style="list-style-type: none"> In rare circumstances the Pfizer Clinical Support Help Desk will manually assign a Kit(s) that is known to expire prior to the subject's next scheduled drug assignment visit. <ul style="list-style-type: none"> Pfizer Clinical Support Help Desk will communicate this at the time of the manual assignment. Please consult the Impala 2.0 Subject Visit Confirmation Report generated at the time of the Manual Drug Assignment Visit Date to identify the Kit(s) that will expire prior to the subject's next scheduled drug assignment. Please communicate to the subject the expiration date and reinforce the need to return for additional supplies prior to that date. <ul style="list-style-type: none"> Document the discussion with the subject in the source documents. Please contact Pfizer Clinical Support Help Desk to obtain additional or replacement Kit(s) assignments prior to the expiry recorded on the Impala 2.0 Subject Visit Confirmation Report. Please contact your monitor if you have any questions. </div> </div>		

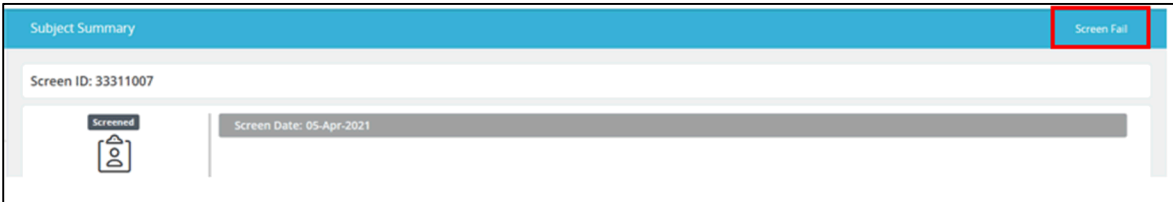
C4891002 Quick Reference Guide

Subject Statuses (Site No Break Blind and Site Break Blind users)

 Register the status change in Impala 2.0 in as soon as it occurs to accurately predict drug supplies for your site.

Function	To access, Click on:	Required to perform the function	Result in Impala 2.0
Change Subject Status	Subject ID (Subject Page) 'Screen Fail'  Or 'Discontinue' 	Choose pre-defined reason Enter effective date of completion	Subject's status changed

From the Subject Page click **Screen Fail**:



The screenshot shows the 'Subject Summary' header. Below it, the 'Screen ID: 33311007' is displayed. Underneath, there is a 'Screened' status with a person icon and a 'Screen Date: 05-Apr-2021'. The 'Screen Fail' button is located in the top right corner of the page and is highlighted with a red rectangular box.


From the Subject Page click **Discontinue**:

C4891002 Quick Reference Guide

Subject Summary
Discontinue

Screen ID: 33311009

Active




Enroll Date: 11-May-2021

Rand #: 30
Screen Date: 10-May-2021



Treatment Group: T [PF-06863135]

Current Status	New Status	Instruction	
Screening	Screen Failed	<p>If a subject is unable to continue in the trial prior to being randomized, please change the subject's status to "Screen Failed".</p> <ul style="list-style-type: none"> Select the available reason from the drop-down Enter the effective date Click 'Confirm' A Screen Fail Confirmation Report will be generated 	<div style="border: 1px solid #ccc; padding: 10px;"> <div style="background-color: #f0f0f0; padding: 5px; border-bottom: 1px solid #ccc;"> Screen Fail Confirm ✕ </div> <p style="font-size: small; margin-top: 10px;">Please confirm you wish to screen fail subject : 10071020</p> <div style="background-color: #fff9c4; padding: 5px; margin: 5px 0;"> WARNING: Subject will no longer be eligible to participate in the study </div> <div style="margin-bottom: 10px;"> Choose A Reason * Subject failed screening - refer to CRF </div> <div style="margin-bottom: 10px;"> Screen Fail Date * 23-Jan-2020 </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> Cancel Confirm </div> </div>
Active	Discontinued Treatment	<p>If a subject is unable to continue in the trial after being randomized, please change the subject's status to "Discontinued Treatment".</p> <ul style="list-style-type: none"> Select the available reason from the drop-down Enter the effective date Click 'Confirm' 	<div style="border: 1px solid #ccc; padding: 10px;"> <div style="background-color: #f0f0f0; padding: 5px; border-bottom: 1px solid #ccc;"> Confirm Discontinue Subject ✕ </div> <p style="font-size: small; margin-top: 10px;">Please confirm you wish to discontinue subject : 10071025</p> <div style="background-color: #fff9c4; padding: 5px; margin: 5px 0;"> Warning: Subject will be dropped from the study </div> <div style="margin-bottom: 10px;"> Choose a reason* Subject discontinued - refer to CRF </div> <div style="margin-bottom: 10px;"> Discontinued Date :* 23-Jan-2020 </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> Cancel Confirm </div> </div>

C4891002 Quick Reference Guide

		<ul style="list-style-type: none"> • A Subject Discontinuation Confirmation will be generated 	
<p> Please contact the Pfizer Clinical Support Help Desk if your subject was screened in error or is incorrectly in a status of “Screen Failed” or “Discontinued Treatment”. The Impala 2.0 system will <u>only</u> allow you to change the status once per subject.</p>			

Confirmation Reports and Requesting a Report (Site No Break Blind and Site Break Blind)

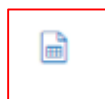
-  Subject and Shipment specific reports will be automatically emailed to all site users, upon the completion of each function in Impala 2.0.
-  For inspection readiness, please ensure you are keeping confirmation reports in your source documents.

C4891002 Quick Reference Guide

Prior Visits tab

Subject specific reports can be regenerated from the Subject page, Prior Visits tab

- Select the '**Prior Visits**' tab
- Click the report icon associated to the Visit for the missing report
- Download, print, and/or save the report



Screen ID: 33311009

Active

Enroll Date: 11-May-2021

Random #: 30

Treatment Group: T [PF-06863135]

Screen Date: 10-May-2021

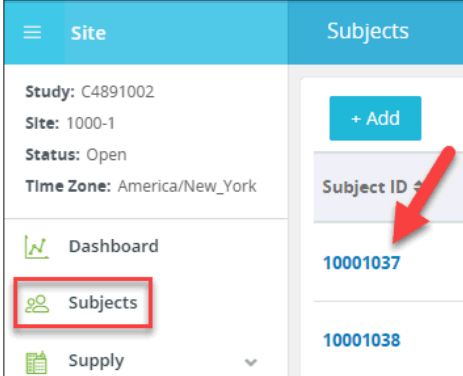

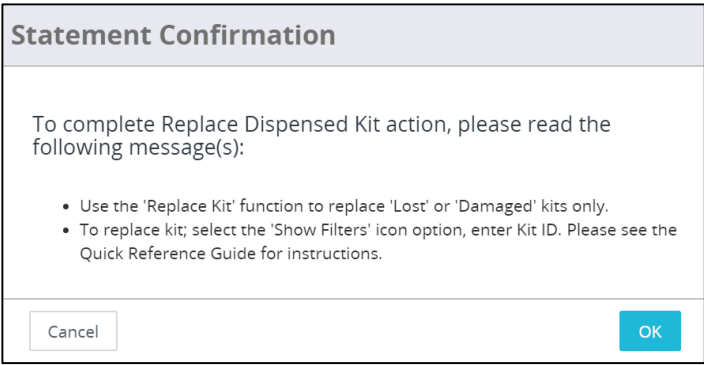
Upcoming Visits **Prior Visits** Data Collected Kits Dispensed

Visit ID	Date				
0	10-May-2021				
1	11-May-2021				
Treatment Cycle (1) Day 1	11-May-2021				
Treatment Cycle (1) Day 8	11-May-2021				
Treatment Cycle (1) Day 15	21-May-2021				

Replace Kit (assigned to Subject) (Site No Break Blind and Site Break Blind)

Function	To access, Click on:	Required to perform the function	Result in Impala 2.0
Replace Kit (Replace drug for subject)	Subject ID (Subject Page) Replace Kit <div style="background-color: #0099cc; color: white; padding: 5px; text-align: center; width: fit-content; margin: 5px auto;">Replace Kit</div>	Kit number Select New Kit Status	Kit ID status changed (Replacement Kit dispensed for subject)
<div style="display: flex; align-items: center;"> <div style="width: 15px; height: 15px; background-color: red; margin-right: 5px;"></div> The 'Replace Kit' function is used to replace lost or damaged kits that have been assigned to a subject. </div>			

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<p>To replace a kit for a subject, locate the Subject ID from the 'Subjects' Page</p> <ul style="list-style-type: none"> Click on the Subject ID to access the Subject record 	
<p>From the Subject's Summary</p> <ul style="list-style-type: none"> Click 'Replace Kit' 	
<p>Statement Confirmation</p> <p>Once Replace Kit is selected, the system will only provide a kit/kits from the last Drug Assignment Visit to replace.</p> <p>Upon clicking 'Replace Kit', replacement instructions are provided</p> <ul style="list-style-type: none"> Review the Statement on the Screen and click 'OK' 	

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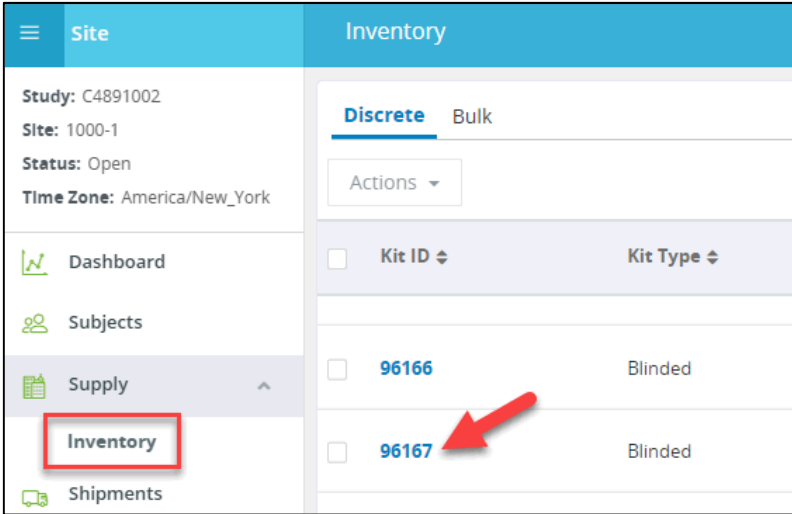
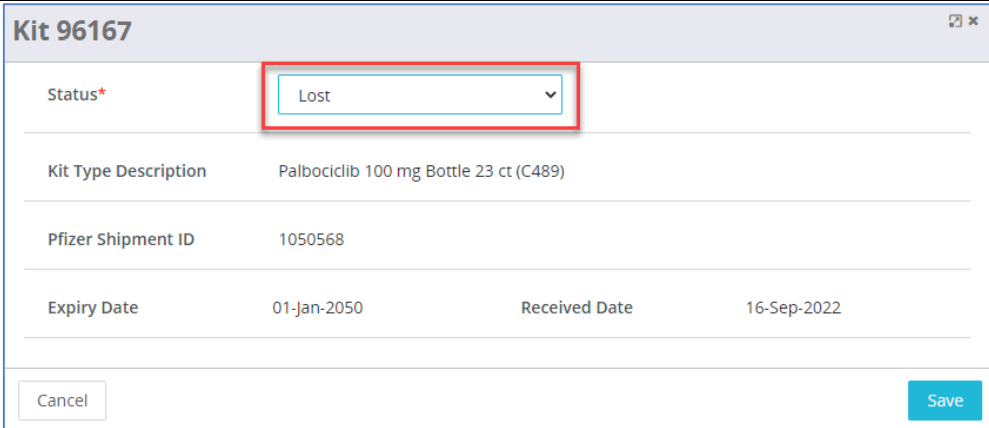
<p>Replaceable Kit</p> <ul style="list-style-type: none"> To select the Kit ID to be replaced <ul style="list-style-type: none"> Click on the Kit ID 	<div style="border: 1px solid #ccc; padding: 10px;"> <p>Replaceable Kit ✖</p> <div style="text-align: right; margin-bottom: 10px;"> ⚙️ ⬇️ 📄 🔄 </div> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>ID ⬇️</th> <th>Type ⬇️</th> <th>Discrete/Bulk ⬇️</th> <th>Lot ⬇️</th> <th>Visit ⬇️</th> <th>Quantity ⬇️</th> <th>Dispensed Date ⬇️</th> <th>Description ⬇️</th> </tr> </thead> <tbody> <tr> <td style="color: #007bff;">80105</td> <td>Blinded</td> <td>Discrete</td> <td>Blinded</td> <td>Study Lead-in Cycle (3) 1UPV (2)</td> <td></td> <td>03-Apr-2023</td> <td>ARV-471 (PF-07850327) 100 mg Bottle 60 ct</td> </tr> <tr> <td style="color: #007bff;">94043</td> <td>Blinded</td> <td>Discrete</td> <td>Blinded</td> <td>Study Lead-in Cycle (3) 1UPV (2)</td> <td></td> <td>03-Apr-2023</td> <td>Palbociclib 75 mg Bottle 23 ct (C489)</td> </tr> </tbody> </table> <p style="text-align: right;">Count: 2</p> <p style="text-align: center; margin-top: 10px;">Cancel</p> </div>	ID ⬇️	Type ⬇️	Discrete/Bulk ⬇️	Lot ⬇️	Visit ⬇️	Quantity ⬇️	Dispensed Date ⬇️	Description ⬇️	80105	Blinded	Discrete	Blinded	Study Lead-in Cycle (3) 1UPV (2)		03-Apr-2023	ARV-471 (PF-07850327) 100 mg Bottle 60 ct	94043	Blinded	Discrete	Blinded	Study Lead-in Cycle (3) 1UPV (2)		03-Apr-2023	Palbociclib 75 mg Bottle 23 ct (C489)
ID ⬇️	Type ⬇️	Discrete/Bulk ⬇️	Lot ⬇️	Visit ⬇️	Quantity ⬇️	Dispensed Date ⬇️	Description ⬇️																		
80105	Blinded	Discrete	Blinded	Study Lead-in Cycle (3) 1UPV (2)		03-Apr-2023	ARV-471 (PF-07850327) 100 mg Bottle 60 ct																		
94043	Blinded	Discrete	Blinded	Study Lead-in Cycle (3) 1UPV (2)		03-Apr-2023	Palbociclib 75 mg Bottle 23 ct (C489)																		
<p>Replace Kit Confirm</p> <ul style="list-style-type: none"> Choose a reason for replacement (damaged or lost) Click 'Confirm' 	<div style="border: 1px solid #ccc; padding: 10px;"> <p>Replace Kit Confirm ✖</p> <p style="font-size: 0.9em; color: #666;">Please confirm you wish to replace the following kit for subject: 10001037</p> <div style="margin-top: 10px;"> <div style="display: flex; justify-content: space-between;"> <div>Kit ID:</div> <div>94043</div> </div> <hr/> <div style="display: flex; justify-content: space-between;"> <div>Kit Type:</div> <div>Blinded</div> </div> <hr/> <div style="display: flex; justify-content: space-between;"> <div>Kit Desc:</div> <div>Palbociclib 75 mg Bottle 23 ct (C489)</div> </div> <hr/> <div style="display: flex; justify-content: space-between;"> <div>Choose a reason:*</div> <div style="border: 1px solid #add8e6; padding: 2px;"> <div style="background-color: #f0f8ff; padding: 2px;">▼</div> <div style="border: 1px solid #ff0000; padding: 2px;"> <div style="background-color: #f0f8ff; padding: 2px;">Kit is damaged</div> <div style="background-color: #f0f8ff; padding: 2px;">Kit is lost</div> </div> </div> </div> <hr/> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> Cancel Confirm </div> </div> </div>																								



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<p>Replace Kit Completed</p> <p>The Replace Kit Completed message indicates the replacement kit with expiry date</p>	<div><div>Replace Kit Completed</div><div><div><div></div><div>Please dispense kit 94055 expiry date: 01-Jan-2050 to subject 10001037. This is to replace kit 94043.</div></div></div><div><div>Close</div></div></div>
<p>Replace Kit Confirmation report</p> <p>A confirmation report will be sent to the email address associated to your user’s account.</p>	<div><div><div><div></div><div>Pfizer Clinical Support Help Desk: (+1) 877-433-2619</div></div><div><div>C4891002 Replace Kit Confirmation Report</div><div>Transaction Date: 14-Apr-2023 12:20:12 GMT</div><div><div><div><div>Study Code:</div><div>C4891002</div></div><div><div>Site Code:</div><div>1000-1</div></div><div><div>Investigator:</div><div>Joe Impala</div></div></div><div><div><div>Site Address:</div><div>1 Main Street Groton, CT 06498 United States</div></div></div></div></div><div><div>Dispensing details for Subject 10001037</div><div><div><div>Replacement Kit ID:</div><div>94055</div></div><div><div>Visit ID:</div><div>Study Lead-in Cycle (3) 1UPV (2)</div></div><div><div>Dispense Date:</div><div>14-Apr-2023</div></div><div><div>Reason:</div><div>Kit is damaged</div></div><div><div>Note:</div><div>Replaced kit 94043 for Visit Study Lead-in Cycle (3) 1UPV (2). Reason is Kit is damaged.</div></div><div><div>Expiry Date:</div><div>01-Jan-2050</div></div></div></div></div></div>

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Change Kit Status (in Inventory) (Site No Break Blind and Site Break Blind)			
Function	To access, Click on:	Required to perform the function	Result in Impala 2.0
Change Kit Status (in Inventory)	Supply/Inventory Click on Kit ID	Kit number Kit must be in <u>Available</u> status	Kit ID status changed (to <i>Damaged</i> or <i>Lost</i>)
<ul style="list-style-type: none"> Click on the 'Supply' menu item Click on 'Inventory' Select Kit to be changed by clicking on the Kit ID 			
Select the appropriate status for the kit: <ul style="list-style-type: none"> Lost or Damaged Click 'Save' to continue. 			

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Site Kit Status Change Confirmation report:

A Site Kit Status Change Confirmation report will be sent to the email address associated to your user's account.



Pfizer Clinical Support Help Desk: (+1) 877-433-2619

C4891002 Site Kit Status Change Confirmation

Transaction Date: 14-Apr-2023 12:31:38 GMT

Study Code:	C4891002	Site Address:	1 Main Street
Site Code:	1000-1		Groton, CT 06498
Investigator:	Joe Impala		United States

Details of the kits with modified statuses

Kit ID	Old Status	New Status
68056	AVAILABLE	LOST

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Document History

Version #	Version Date	Author	Details	PPW Version #
1.0	28-Apr-2023	Kim Esposito	Original Version	1.0

Document Approval Record

Document Name:	C4891002 Impala 2.0 Quick Reference Guide
Document Title:	C4891002 Impala 2.0 Quick Reference Guide

Signed By:	Date(GMT)	Signing Capacity
Todd, Brian Kenneth	28-Apr-2023 17:30:25	Business Line Approver
Brennan, Christopher	02-May-2023 18:11:43	Data Verification
Valentino, Elizabeth	02-May-2023 19:21:29	Author Approval
Esposito, Kim M	02-May-2023 19:29:22	Author Approval