

Subject – Status and Tracking Calendar Visits

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Subject – Status and Tracking Calendar Visits

CRA Console

This console is designed to provide subject information at a protocol level. When a protocol is selected in the CRA Console, it displays the subjects who have been accrued, which subject forms have been completed and are yet to be completed, a list of serious adverse events (SAEs), visits outside of tolerance, and other subject deviations in this protocol. The CRA Console also indicates which subjects need to review and accept a more recent version of the consent form.

CRA Console
 Protocol No.: UC-19-1 Library: Oncology PI: Chung, Leslie Sponsor: Astex Pharmaceuticals, Inc
 Protocol Target Accrual: 300 Accrual To Date: 0 Protocol Status: OPEN TO ACCRUAL
 RC Total Accrual Goal (Upper): 10 IRB Expiration: 06/05/2020
 Short Title: This is a test study.

Accrual Details
 Page Size: 100 Filter: Page 1 of 1

Study Site	Research ID	Last Name	First Name	Seq No.	Form	Label	Status	Status Date	Ver	Last Visit	Last Visit Date	Select
Keck Hospital of USC	1160480	TEST	TEST				CONSENTED	06/13/2020	1			

Switch Calendar Versions: 1 (12JUL2019) Replace Versions
 Select All: None Accrual
 Include PHI
[Save Preferences](#)

Subject Console

This console allows you to view subject information within the context of a protocol. The console provides access to a subject’s demographic information, the protocols the subject is associated with, what consent forms the subject has signed, their eligibility status, etc.

Subject Console
 Protocol No.: UC-19-1 Protocol Status: OPEN TO ACCRUAL Subject Status: CONSENTED
 Research ID: 1169480 Subject Name: TEST TEST Sequence No.: History

Subject Demographics

Research ID: 1169480
 Last Name: TEST First Name: TEST Middle Name: Suffix: Last Date Known Alive: Eligible Date: Ethnicity: Other

Birth Date: 11/11/1971 Gender: F Race: Other
 Subject Comments: Additional Subject Identifiers: No information entered

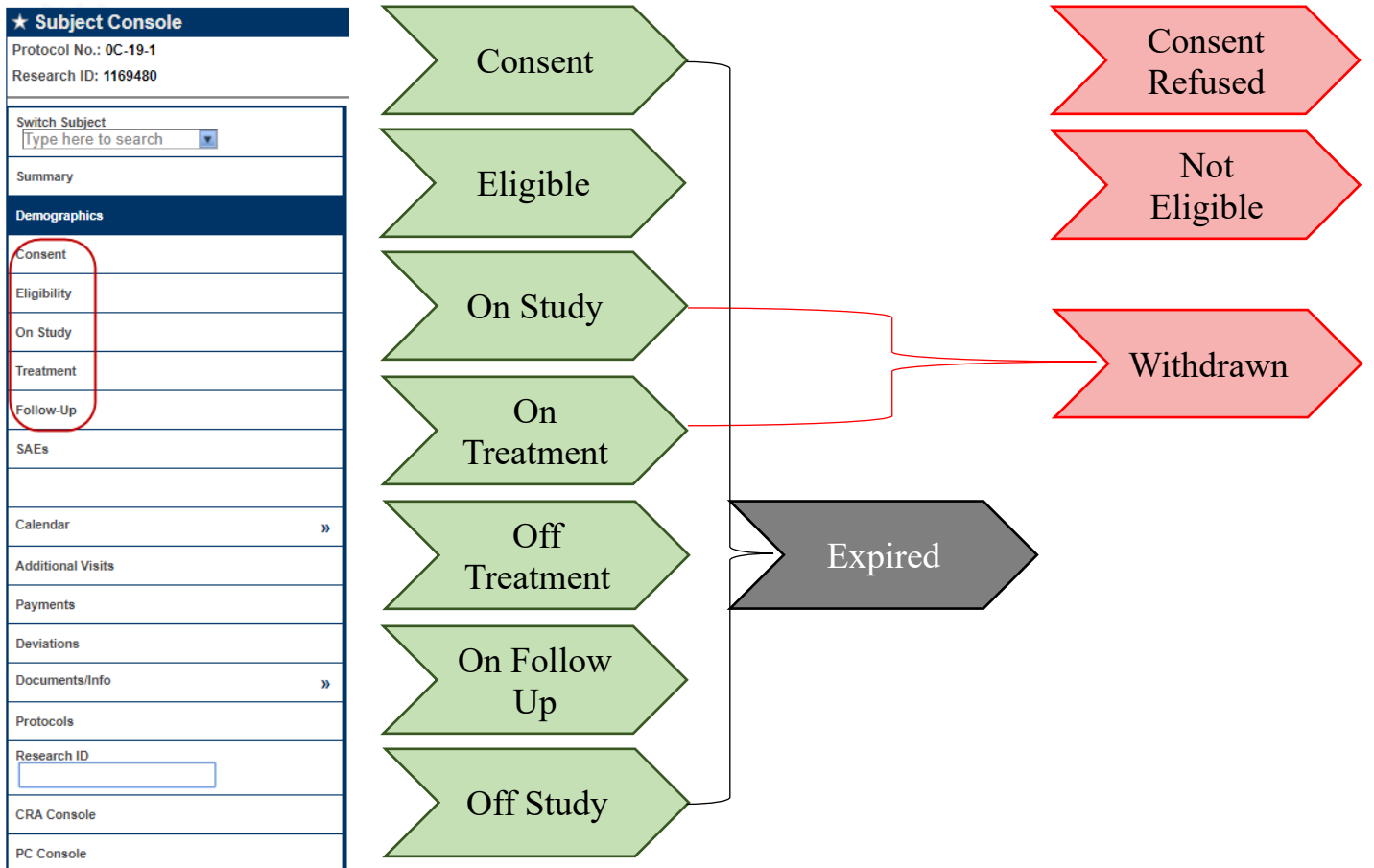
Contact Information

Name: TEST TEST Primary: Address: 4850 SUNSET BLVD. City: LOS ANGELES State: California ZIP: 90027 Country: Phone No.: (213)555-1212 Email Address: Emergency Contacts: No information entered

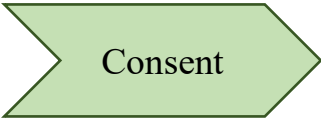
Subject – Status and Tracking Calendar Visits

Subject Statuses

Subjects in OnCore can progress through several statuses during the course of the protocol. The vertical tabs in the Subject Console (Consent, Eligibility, On Study, Treatment, Follow-Up) allow you to record this status information. These statuses triggers visit segment in the subject calendar.



Subject – Status and Tracking Calendar Visits

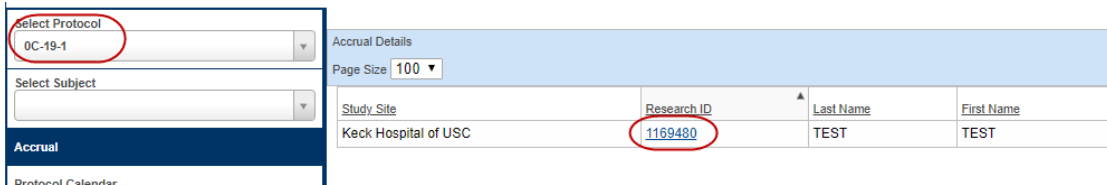


Subject understands and agrees to the details in the consent form.

1. Navigate to Subjects-> CRA Console



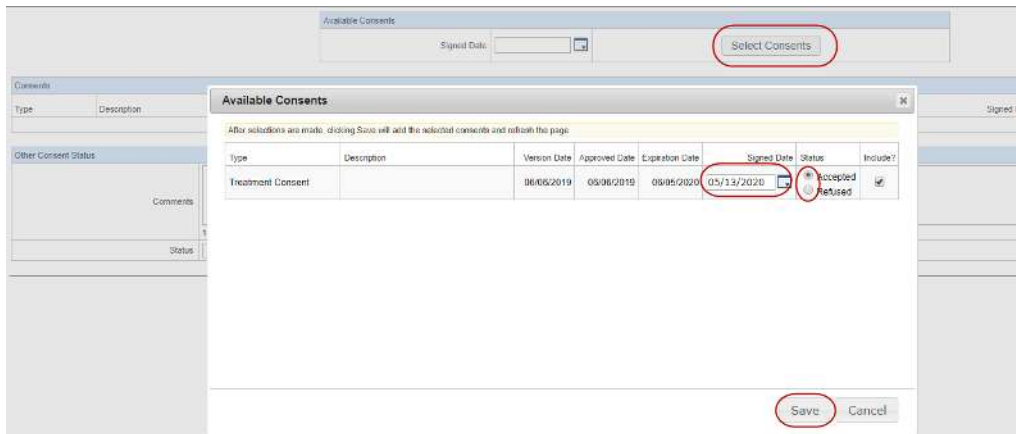
2. Select a Protocol
3. Click on the Research ID



4. Click Consent
5. Click Update



6. Click Select Consents
7. Enter Signed Date
8. Select Status
9. Click Save



Subject – Status and Tracking Calendar Visits

10. Click Close

Coordinators are required to upload signed ICF and HIPAA forms for registered patients. Sponsor payments will not be processed if missing forms are not in OnCore. It is essential a timely upload of documents to avoid payments delay.

11. Click Documents/Info -> Attachments

12. Click Add

13. Select Document Type from the drop-down (HIPAA or Signed Treatment Consent or Signed Treatment Reconsent)

14. Click on File (select file to upload; ICF and HIPAA can either be a combined file or separate)

15. Enter Version Date

16. Click Add

17. Repeat 5-9 to upload additional file

Document Type	File Name / URL	Description	Version Date	Created Date	Created User	Edit	Delete?
HIPAA	HIPAA.PDF		05/13/2020	05/13/2020	CHUNGLES	Edit	Delete?

Subject – Status and Tracking Calendar Visits

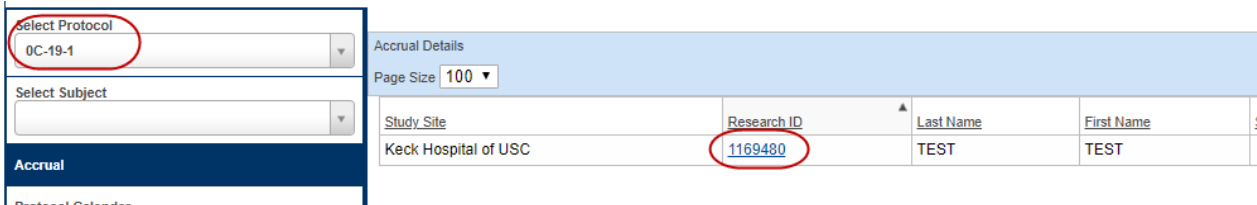


Subject has been evaluated and meets all criteria (Screening).

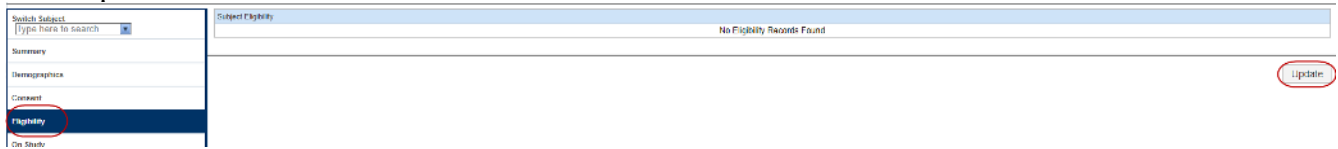
1. Navigate to Subjects-> CRA Console



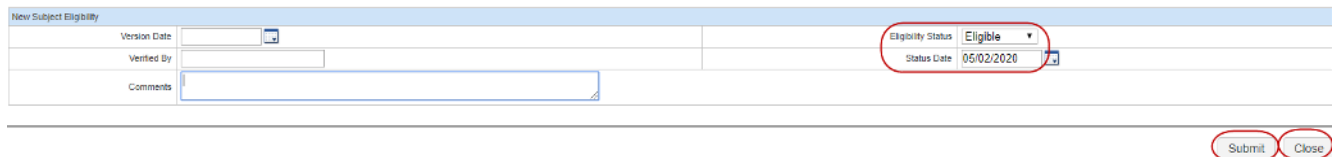
2. Select a Protocol
3. Click on the Research ID



4. Click Eligibility
5. Click Update



6. Select Eligibility Status from the drop-down
7. Enter Status Date
8. Click Submit
9. Click Close



Subject – Status and Tracking Calendar Visits

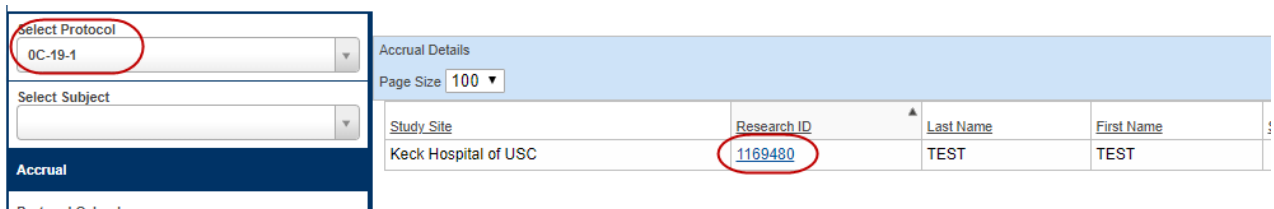
Not Eligible

Subject has been evaluated and does not meet all criteria (Screening). However, some studies allow subject to re-screen after a screen failure. When ready to re-screen, register the patient using the same ResearchID but different Sequence No. Make sure to upload the new signed ICF and HIPAA to the corresponding record.

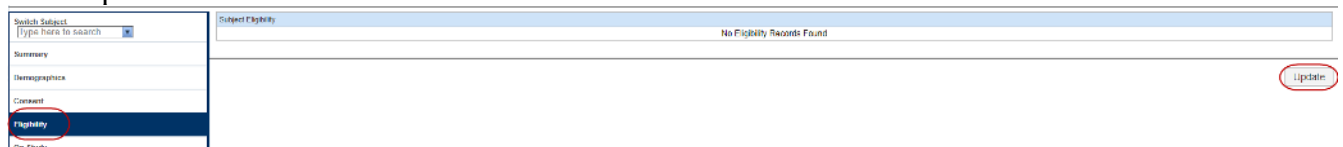
1. Navigate to Subjects-> CRA Console



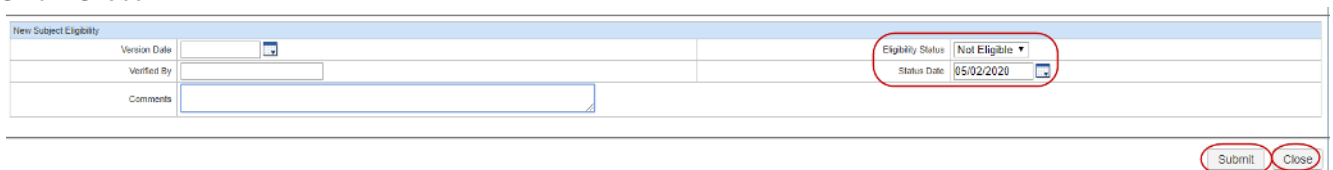
2. Select a Protocol
3. Click on the Research ID



4. Click Eligibility
5. Click Update



6. Select Eligibility Status from the drop-down
7. Enter Status Date
8. Click Submit
9. Click Close

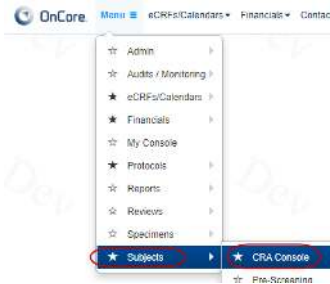


Subject – Status and Tracking Calendar Visits



Subject has a recorded Consent and a status of Eligible.

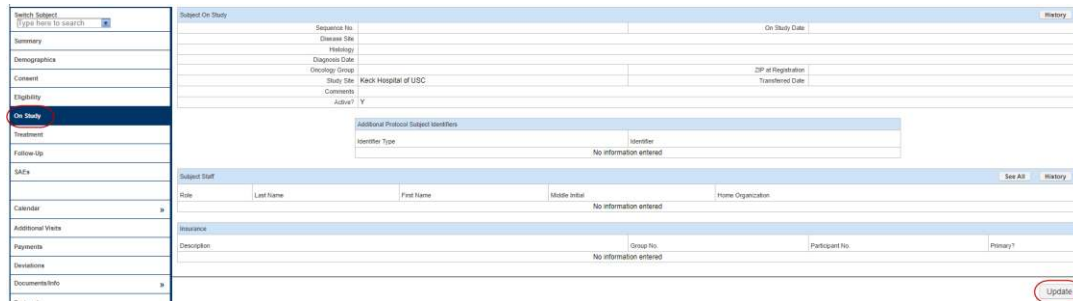
1. Navigate to Subjects-> CRA Console



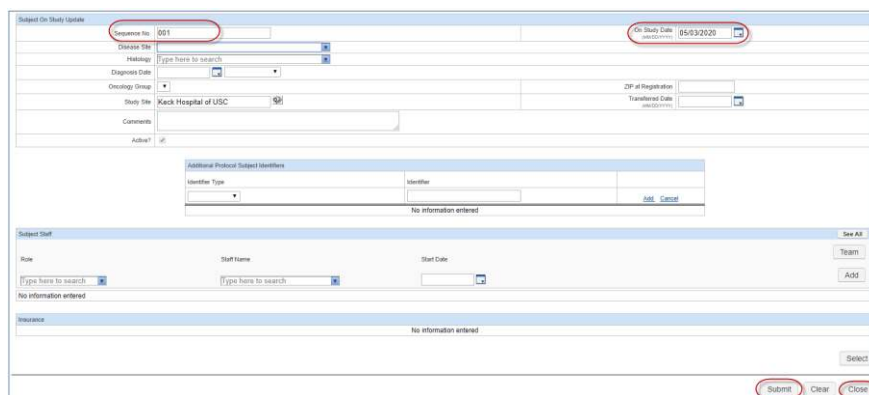
2. Select a Protocol
3. Click on the Research ID



4. Click On Study
5. Click Update



6. Enter Sequence No (Subject protocol no from sponsor or IVRS)
7. Enter On Study Date
8. Click Submit
9. Click Close



Subject – Status and Tracking Calendar Visits



Subject has been enrolled on an Arm and will begin Treatment.

1. Navigate to Subjects-> CRA Console



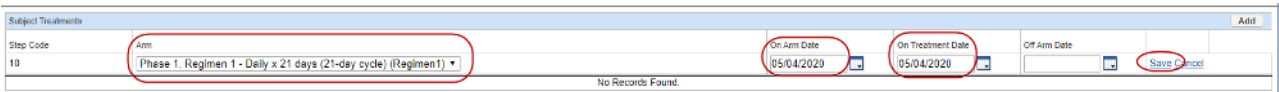
2. Select a Protocol
3. Click on the Research ID



4. Click Treatment
5. Click Add

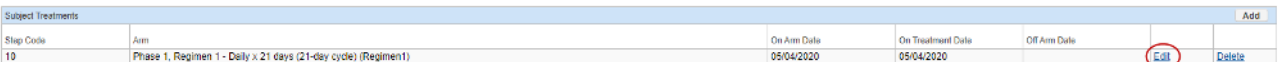


6. Select Arm from the drop-down
7. Enter On Arm Date
8. Enter On Treatment Date
9. Click Save



When a patient is assigned to a specific Arm and switches to another Arm at a later point.

10. Click Edit



11. Enter Off Arm Date
12. Click Save



13. Click Add
14. Select Arm from the drop-down
15. Enter On Arm Date
16. Enter On Treatment Date
17. Click Save



Subject – Status and Tracking Calendar Visits

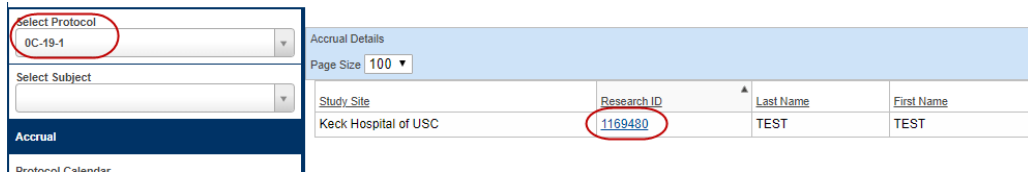


Subject will receive no additional Arm Treatment.

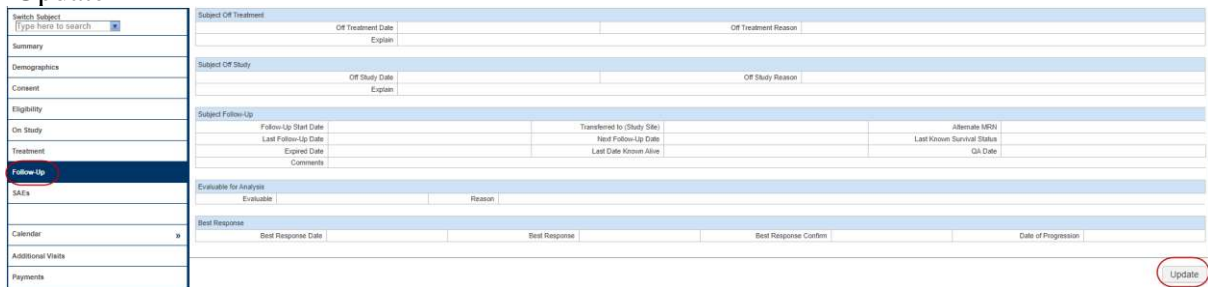
1. Navigate to Subjects-> CRA Console



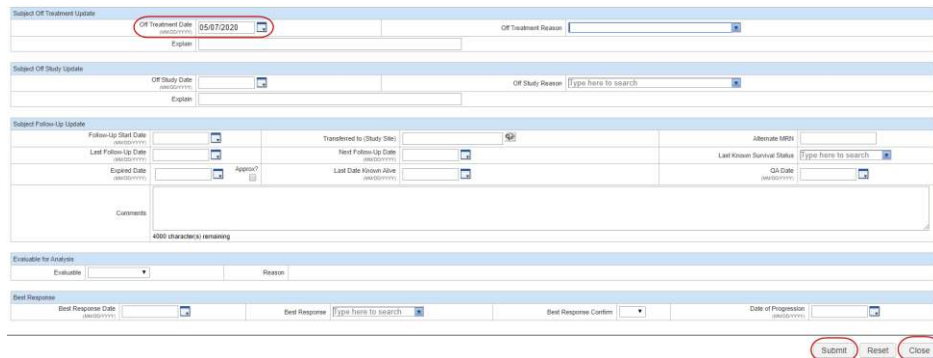
2. Select a Protocol
3. Click on the Research ID



4. Click Follow-Up
5. Click Update



6. Enter Off Treatment Date
7. Click Submit
8. Click Close



Subject – Status and Tracking Calendar Visits

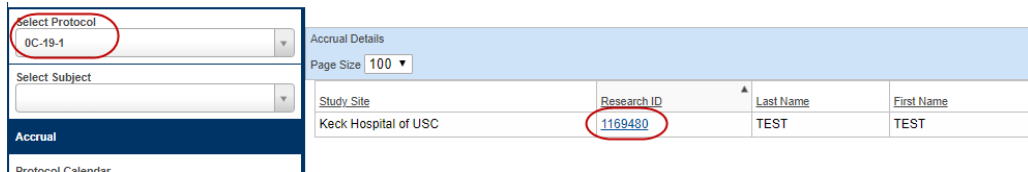


Subject will receive Follow-Up and all Arm Treatment complete.

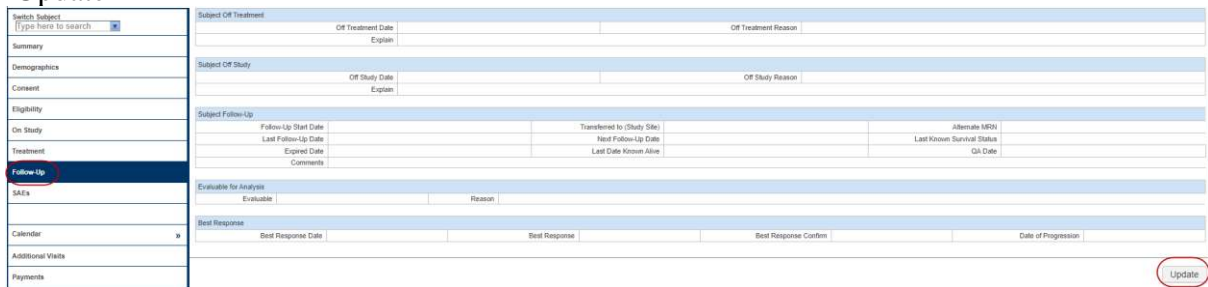
1. Navigate to Subjects-> CRA Console



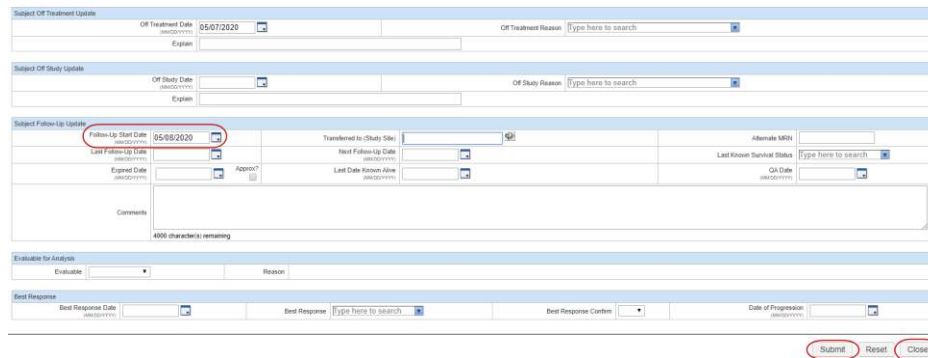
2. Select a Protocol
3. Click on the Research ID



4. Click Follow-Up
5. Click Update



6. Enter Follow-up Start Date
7. Click Submit
8. Click Close



Subject – Status and Tracking Calendar Visits

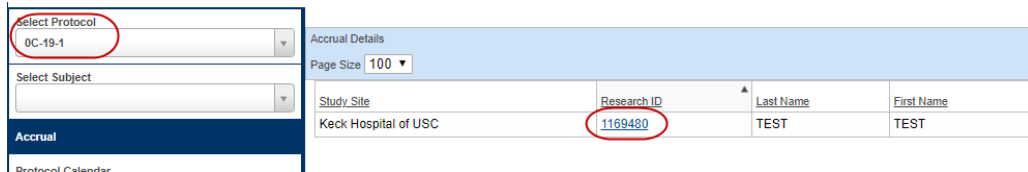


Subject completed all visits and no longer in the study.

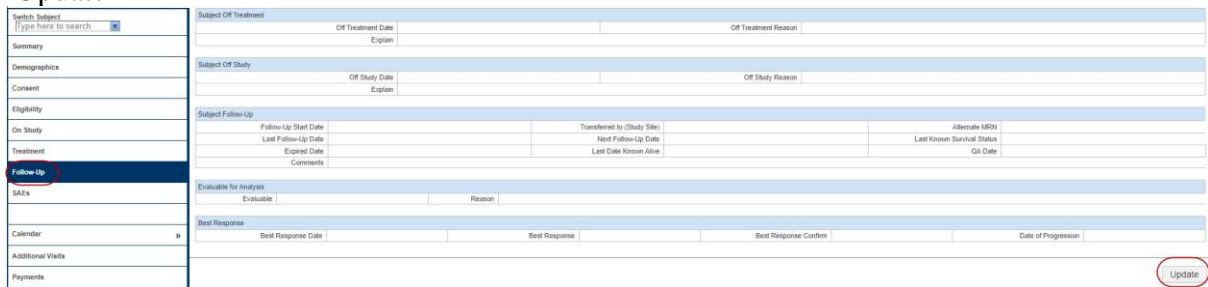
1. Navigate to Subjects-> CRA Console



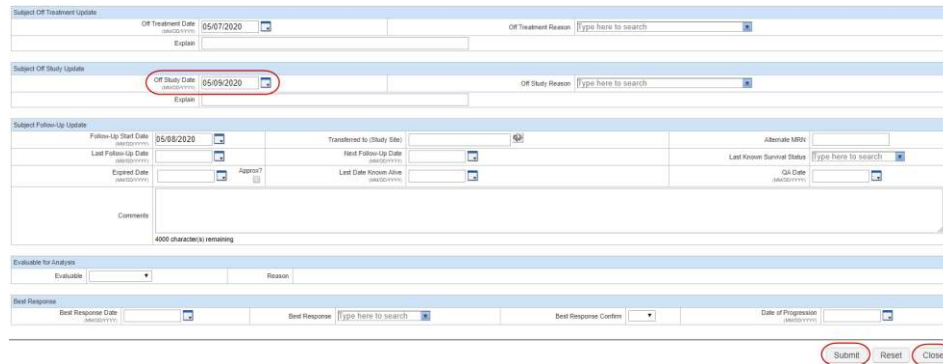
2. Select a Protocol
3. Click on the Research ID



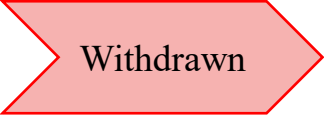
4. Click Follow-Up
5. Click Update



6. Enter Off Study Date
7. Click Submit
8. Click Close



Subject – Status and Tracking Calendar Visits

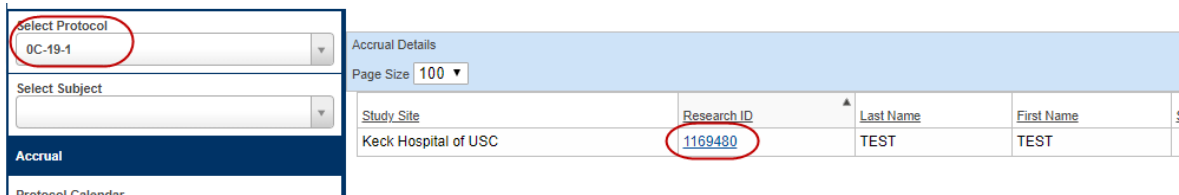


At some point after being presented with a consent form, the subject changes his/her mind and no longer consents to treatment and withdraws from the study.

1. Navigate to Subjects-> CRA Console



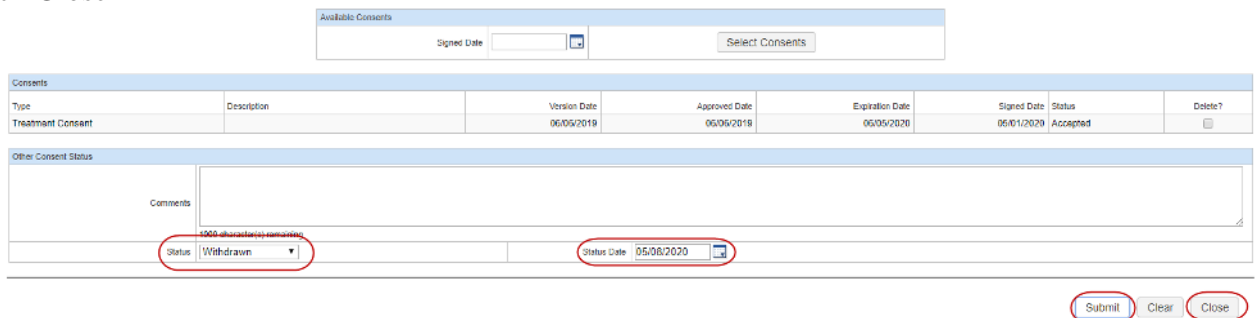
2. Select a Protocol
3. Click on the Research ID



4. Click Consent
5. Click Update



6. Select Status from the drop-down
7. Enter Status Date
8. Click Submit
9. Click Close

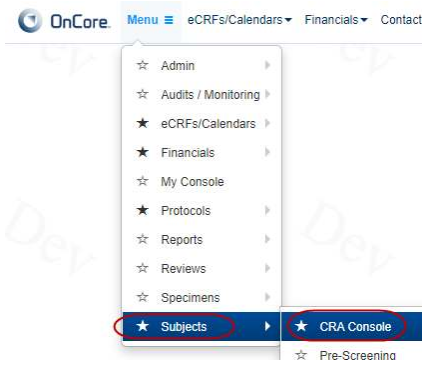


Subject – Status and Tracking Calendar Visits

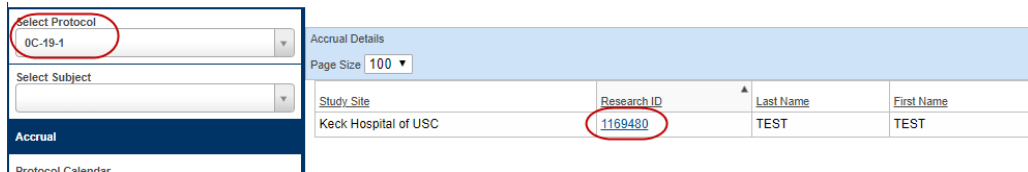


Subject is no longer alive (may or may not be related to treatment or procedures received during the study).

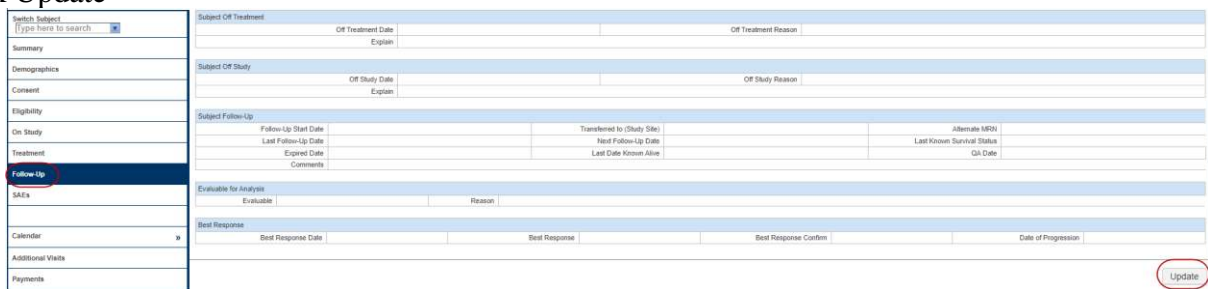
1. Navigate to Subjects-> CRA Console



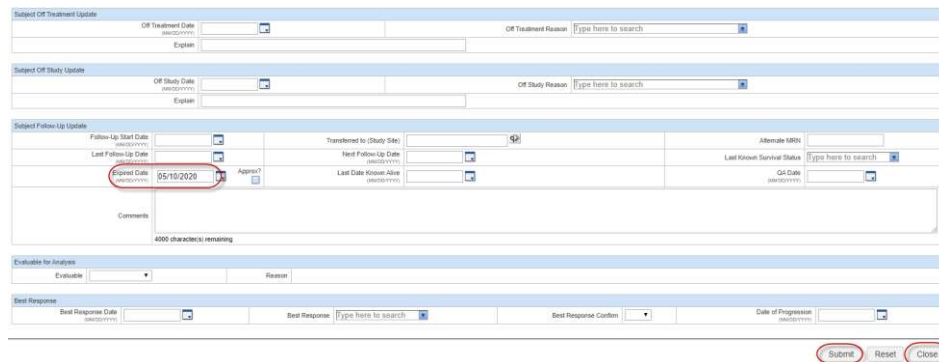
2. Select a Protocol
3. Click on the Research ID



4. Click Follow-Up
5. Click Update



6. Enter Expired Date
7. Click Submit
8. Click Close



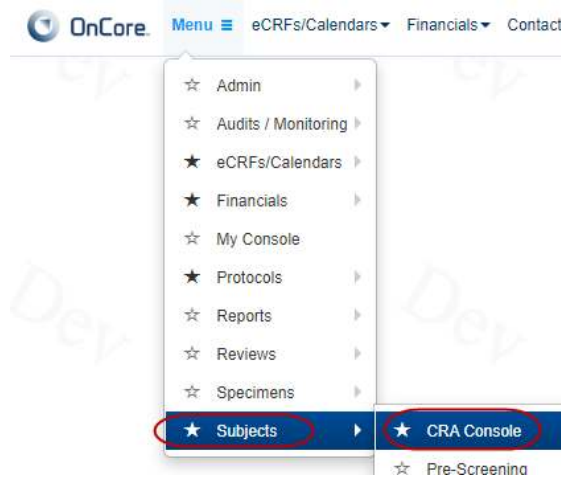
Subject – Status and Tracking Calendar Visits

Viewing Protocol Calendar

A protocol calendar will display ALL visit schedule, expected procedures as well as the billing designations. It is typically built in segments triggered by date entered in the Subject Console.

- Screening/Pre-Treatment – consent signed date
- Treatment – treatment arm, on/off arm date, on/off treatment date
- Off Study – off treatment date, off study date
- Follow-up – follow-up start date

1. Navigate to Subjects-> CRA Console



2. Select a Protocol

3. Click Protocol Calendar

Protocol Calendar	Treatment		Regimen2: Phase 1, Regimen 2 : Daily x 14 days (21-day cycle)												Follow Up											
	Screening 1@1Days	Treatment Regimen 1 6 Cycles @21Days	Screening 2	C1D1 2,2	C1D2 2	C1D3 2	C1D4 2	C1D5 2	C2D1 2	C2D2 2	C2D3 2	C2D4 2	C2D5 2	C3D1 2	C3D2 2	C3D3 2	C3D4 2	C3D5 2	C4D1 2	C4D2 2	C4D3 2	C4D4 2	C4D5 2	Off Treat-Regimen 2	30 Day Safety FU 30@30Days	Long
ASTX029 PO	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R
SAEs	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R	R
Deviations			R	R	R	R																				
FAQs	R																									
Register Subject	R	R																								
Full physical exam 1	R																									
Symptom-directed pt 1		S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S	S
Height	R																									
Weight	R	S			S																					

Subject – Status and Tracking Calendar Visits

Viewing Subject Calendar

Subject calendar defines a schedule of visits and what procedures will be performed based on the Treatment Arm the subject is assigned.

1. Navigate to Subjects-> CRA Console



2. Select a Protocol
3. Click on the Research ID



4. Click Calendar -> Calendar

Procedure column displays the name of lab, panel or procedure

Planned Date row displays the subject's schedule visit dates.

Visits that have been activated based on the status date appear as links

X indicates labs, panels or procedures supposed to take place

Screening	C1D1*	C1D2*	C1D3*	C1D4*	C2D1*	C2D2*	C2D3*	C2D4*	C3*	C4D1*	C4D2*	C4D3*	C4D4*	On Treatment Regimen 1 @ 1Days
Screening	C1D1*	C1D2*	C1D3*	C1D4*	C2D1*	C2D2*	C2D3*	C2D4*	C3*	C4D1*	C4D2*	C4D3*	C4D4*	On Treatment Regimen 1 @ 1Days
Planned Date	05/01/2020	05/04/2020	05/05/2020	05/11/2020	05/19/2020	05/25/2020	05/26/2020	06/01/2020	06/08/2020	06/15/2020	07/05/2020	07/12/2020	08/17/2020	
Visit Status	Occured													
ASTX029 PO		X	X	X	X			X	X	X	X	X	X	
ASTX029 PO Dispensation		X	X	X	X			X	X	X	X	X	X	
Dosing Compliance Information				X	X	X				X	X	X	X	X
Informed Consent	X													

Subjects transferred from one Treatment Arm to another Treatment Arm will have multiple calendar treatment. To view calendar based on the treatment arm.

5. From the subject calendar, scroll down and select the treatment arm calendar to view

u. Beginning 3 months after the 30-day Safety Follow-up visit, subjects will be contacted by teleph...

AN. As Needed

Regimen1
Regimen2
Arm Regimen1

Subject – Status and Tracking Calendar Visits

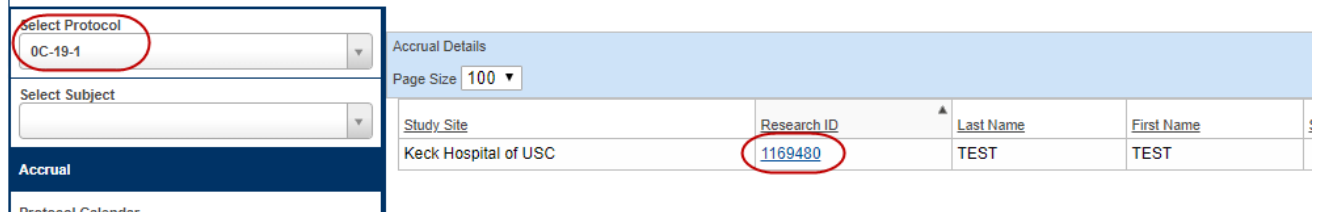
Entering Subject Visits

Verifying a visit involves submitting visit information, which consequently updates the status of the visit.

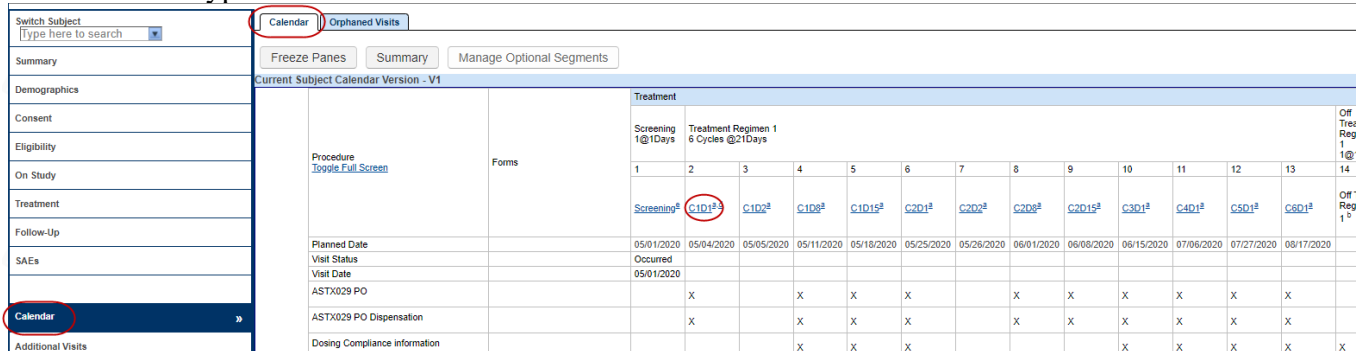
1. Navigate to Subjects-> CRA Console



2. Select a Protocol
3. Click on the Research ID



4. Click on Calendar -> Calendar
5. Click on Visit hyperlink



Subject – Status and Tracking Calendar Visits

6. Enter Visit Date
7. Select Occurred
8. Enter Procedure Date (if it's different than the Visit Date)
9. Mark procedure as Missed or NA (if necessary)
10. Select the procedure occurred if there are different types available (if necessary)
11. Click Submit and Close

Subject Visit Update User: Leslie Chung

Protocol No.: LES-TRAIN Protocol Status: OPEN TO ACCRUAL Subject Status: ON TREATMENT
 Research ID: 979762 Subject Name: ONE KTESTR Sequence No.:

Visit Details Visit: Cycle 1 Day 1 | History

Visit Date: 05/10/2020 Visit Status: Planned **Occurred** Missed N/A Visit Tolerance: +/-3

Reset Calendar?: No (dropdown menu: No, All Visits, Current Cycle)

Submitted Date: Locked Date:

Procedures History

[Expand All](#) [Collapse All](#)

Procedure	As Needed	Procedure Date	SOC	SOC Modifier	Missed	Missed Count	N/A	Location
Vital Signs	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
ECOG performance status	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
[.] Ejection fraction (ECHO/MUGA scan)	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
Charge Master Events								
78472-78473 Gated Heart Planar	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	USC
Charge Master Events								
93306 Echo Transthoracic w/ Doppler Complete	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	USC
93306 Echo Transthoracic w/ Doppler Complete (Fac Fee)	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
93306 Echo Transthoracic w/ Doppler Complete (Pro Fee)	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
93321 Doppler Echocardiography Heart	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
93325 Doppler Echocardiography (color flow add-on)	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
Study treatment dispensing	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
Serum chemistries	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
Magnesium ^{AN}	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
Uric Acid ^{AN}	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
Clinical Trial Unit (CTU) Services								
CT/MRI	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
Biop	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
70544-70546 MRI Head w/o & w/ Contrast	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
70551-70553 MRI Brain Stem w/o & w/ Contrast	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
Biop	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
70540-70543 MRI Orbit/Face/Neck w/o & w/ Contrast	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
71550-71552 MRI Chest w/o & w/ Contrast	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
72195-72197 MRI Pelvis w/o & w/ Contrast	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	
Central Shipping and Handling	<input type="checkbox"/>	<input type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>	

Foot Notes
 c Visit Procedure Footnote
 AN As Needed

Submit And Close

Subject – Status and Tracking Calendar Visits

Entering Additional (unscheduled) Procedures

Sometimes during research visit, additional procedures that are not part of the schedule of events are performed based on the physician’s judgement.

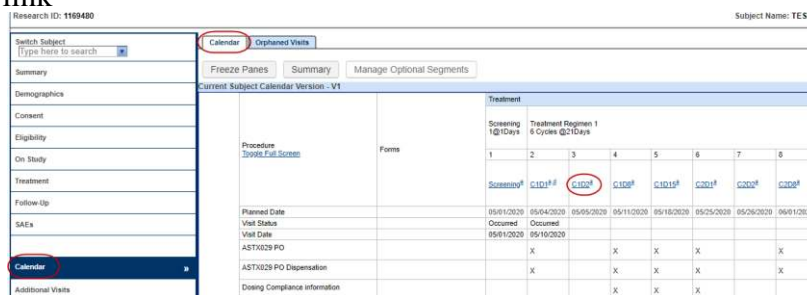
1. Navigate to Subjects-> CRA Console



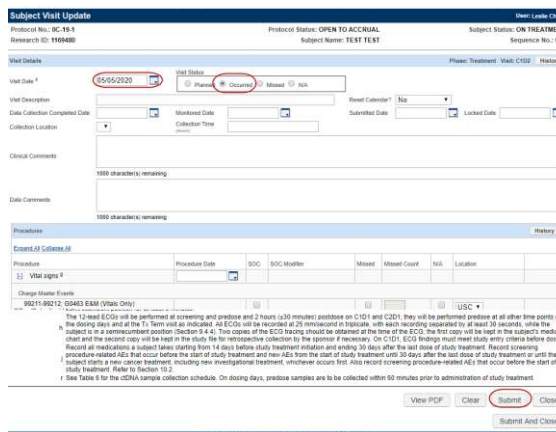
2. Select a Protocol
3. Click on the Research ID



4. Click on Calendar -> Calendar
5. Click on Visit hyperlink



6. Enter Visit Date
7. Select Occurred
8. Click Submit



Subject – Status and Tracking Calendar Visits

9. Click Additional Procedures
10. Select Procedure to add
11. Click Submit

The screenshot shows the 'Procedure Add' dialog box with the following table:

Event Code	Additional Event ID	Event Description	Forms	Select?
		12-lead ECG		<input type="checkbox"/>
		Additional blood pressure (BP) and heart rate		<input checked="" type="checkbox"/>
		Adverse Events		<input type="checkbox"/>
		ASTX029 PO		<input type="checkbox"/>
		ASTX029 PO Dispensation		<input type="checkbox"/>
		Bone Scan (Conventional Care)		<input type="checkbox"/>
		Bone Scan (research)		<input type="checkbox"/>
		CBC w/ differential (local lab)		<input type="checkbox"/>
		Central Lab Blood Draw		<input type="checkbox"/>

Buttons at the bottom of the dialog box: **Submit** (circled in red), Clear, Close.

Buttons at the bottom of the main interface: **Additional Procedures** (circled in red), Billing Slip, View PDF, Delete, Clear, Submit, Close, Submit And Close.

12. Enter Reason for adding
13. Click OK

The screenshot shows the 'Reason for adding' dialog box with the following text input field:

Reason for adding: Request by physician

Buttons: **OK** (circled in red), Cancel.

Buttons at the bottom of the main interface: **Submit And Close** (circled in red), Additional Procedures, Billing Slip, View PDF, Delete, Clear, Submit, Close.

14. Click Submit and Close

Subject – Status and Tracking Calendar Visits

Deleting Visit entered

Deleting a visit removes all information and returns the visit to a Planned status. A visit cannot be deleted if the visit has been added to an Invoice.

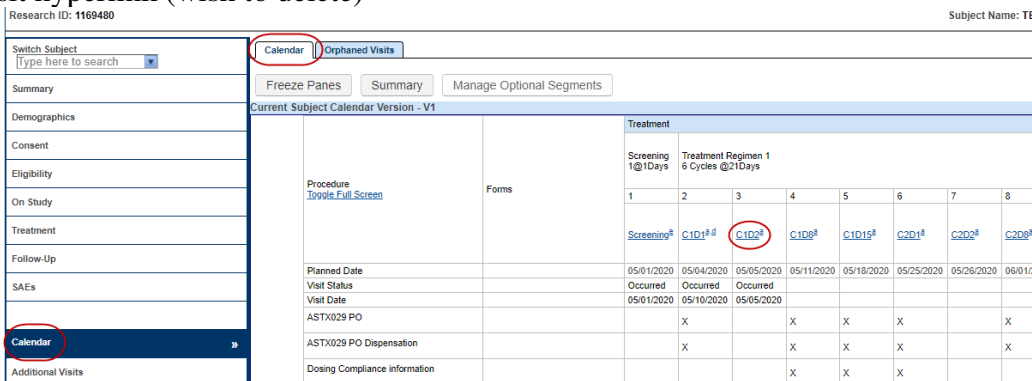
1. Navigate to Subjects-> CRA Console



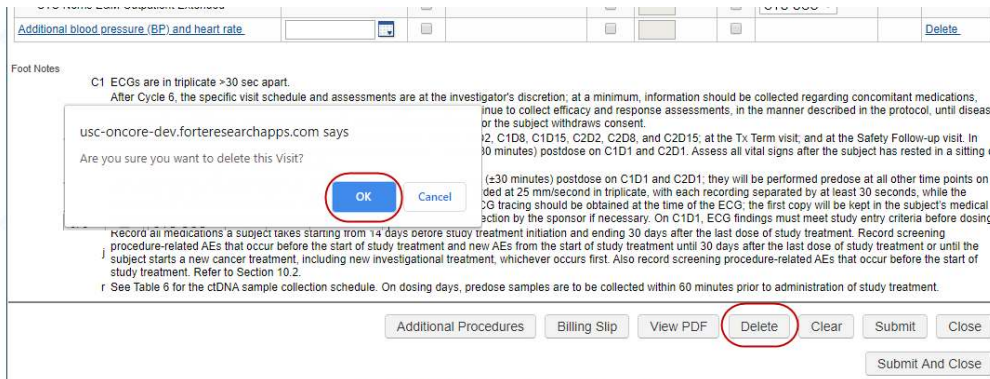
2. Select a Protocol
3. Click on the Research ID



4. Click on Calendar -> Calendar
5. Click on Visit hyperlink (wish to delete)



6. Click Delete
7. Click OK



Subject – Status and Tracking Calendar Visits

Adding additional (unscheduled) visit

Subjects participating on clinical trials might require additional unscheduled visits during the study. Additional visits are not visible in the subject calendar.

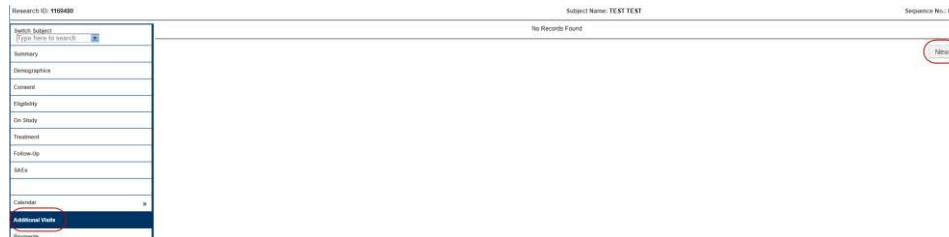
1. Navigate to Subjects-> CRA Console



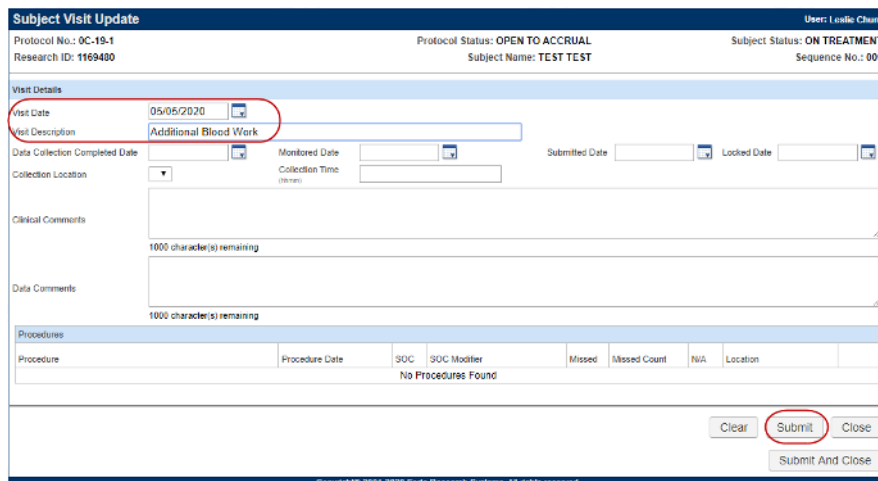
2. Select a Protocol
3. Click on the Research ID



4. Click on Additional Visits
5. Click New



6. Enter Visit Date
7. Enter Visit Description
8. Click Submit



Subject – Status and Tracking Calendar Visits

9. Click Additional Procedures
10. Select Procedure to add
11. Click Submit

12. Enter Reason for adding
13. Click OK

14. Click Submit and Close

Subject – Status and Tracking Calendar Visits

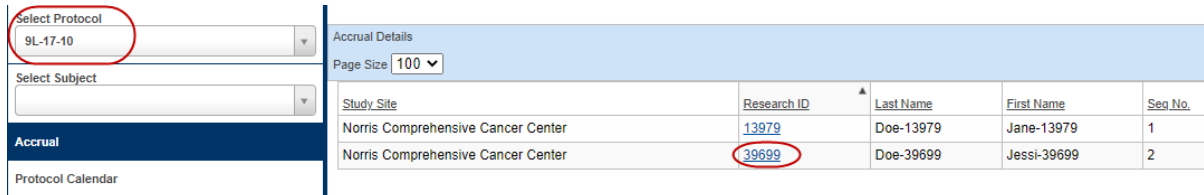
Switch Calendar Version

New calendar version is created during amendments or changes need to be made to an existing version due to some errors or missing information. Subjects are not automatically upgraded to a new calendar version, and subjects are not required to be upgraded. Depending on the protocol amendment, the schedule of events might change for new subjects enrolled on the study, but existing subjects might be allowed to continue treatment and finish on their original schedule.

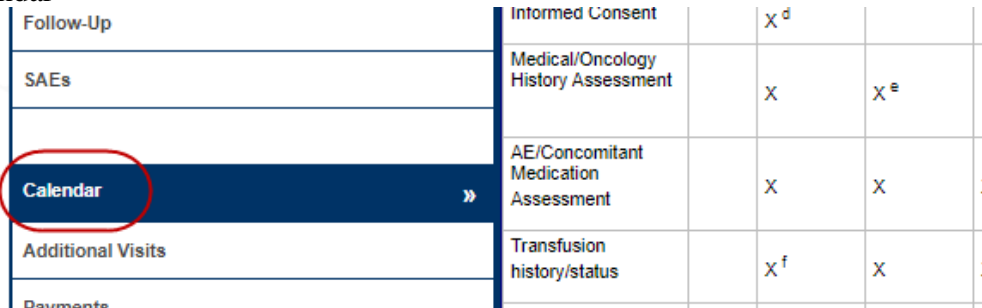
1. Navigate to Subjects-> CRA Console



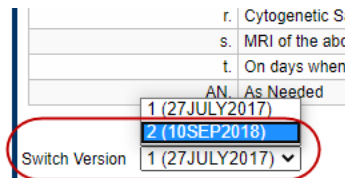
2. Select a Protocol
3. Click on the Research ID



4. Click on Calendar



5. Scroll all down the page
6. Select the calendar version to switch



Subject – Status and Tracking Calendar Visits

7. Click Replace Version

AN. As Needed

Switch Version

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Replace Version

8. Click Orphaned Visits

These visits are from a previous calendar version and are not associated with any visits on the subject’s current calendar version. These may be due to the change of visit name or the visit is no longer valid on the current calendar. These visits are retained under the Orphaned Visits and can’t be viewed on the main calendar.

Calendar	Orphaned Visits	Visit	Phase	Segment	Visit Date	Visit Status	Calendar Version
	Orphaned Visits						
		Cycle 1.D.1	Treatment	Treatment	02/15/2018	Occurred	2
		Cycle 1.D.15	Treatment	Treatment	03/01/2018	Occurred	2
		Cycle 2.D.1	Treatment	Treatment	03/15/2018	Occurred	2
		Cycle 2.D.15	Treatment	Treatment	03/29/2018	Occurred	2
		Cycle 3.D.1	Treatment	Treatment	04/12/2018	Occurred	2
		Cycle 4.D.1	Treatment	Treatment	05/10/2018	Occurred	2
		Cycle 5.D.1	Treatment	Treatment	06/07/2018	Occurred	2
		Cycle 6.D.15	Treatment	Treatment	06/21/2018	Occurred	2
		Cycle 6.D.1	Treatment	Treatment	07/05/2018	Occurred	2
		Cycle 7.D.1	Treatment	Treatment	08/02/2018	Occurred	2