

Managing Subject Calendar Versions

Study calendars allow tracking of subject visits using the subject status dates to plan expected study visits. OCTA develops calendars during study activation using protocol documents including schedule of assessments. OnCore identifies the protocol version of a calendar in several places, using the format:

V1 (V4.0; 08/18/21) V[Calendar Version] ([Protocol version + date])

New subjects are automatically added to the most recent calendar version. Subsequent calendar versions may be developed to incorporate protocol amendments. These are released after amended coverage analysis is finalized and contract is executed. Subject calendar versions are managed by the study team and should be updated as new calendar versions are released.

Viewing subject calendar version

Current Subject Calendar Version can be seen from CRA Console > Accrual under "Ver" on the Accrual Details table, or from Subject Console > Calendar next to "Current Subject Calendar Version."

CRA Console													?
Protocol No.: TRAINING-PROTO	edicine			PI:	Seearc	ee, Ch	arles	Sponsor: Pfizer					
Protocol Target Accrual: N/A			Ассги	al To Date:	20				I	Protoc	ol Status	OPEN TO AC	CRUAL
UCSF Total Accrual Goal (Upper): N/A											IRB Expiration	on: N/A
Short Title: ZZ_Account_Trainin	g_Protocol												
Select Protocol TRAINING-PROTOCOL-01 V	Accrual Details											All	~
Select Subject	Page Size 100 🗸								Filter: RHN	15400		Pag	e 1 of 1
	Study Site	Subject MRN	Last Name	First Name	<u>Seq.</u> No.	Arm	Level	Status	Status Date	Ver.	<u>.ast</u> /isit	<u>Last Visit</u> Date	Select
Accrual	University of California San Francisco	<u>RHN5400</u>	Mouse	Minnie	001	ArmA		ON TREATMENT	05/10/2022	3	C3D1	07/05/2022	
Brotosol Calondar													

CRA Console > Accrual Details

Subject Console > Calendar

★ Subject Console												?
Protocol No.: TRAINING-PROTOCOL-0	1		Protoco	Protocol Status: OPEN TO ACCRUAL Sub					bject Status: ON TREATMEN			
Subject MRN: RHN5400	:	Subject Nar	ne: Minnie I	louse			Se	Sequence No.: 00				
Switch Subject	lendar Orphane	d Visits										
Type here to search	reeze Panes	Summary	Manag	e Optiona	Segment	s						
Summary	ent Subject Calenda	r Version - V3										
Demographics		Treatment								Follo	ow U	р ^
Proce Consent Togo	edure For	ms Screening	Treatment A 7 Cycles @	rm A 28Days						Follo	ow U	p
<u>Ingg</u>	le l'ul Screen	1	2	3	4	5	6	7	8	1	2	3
Eligibility		Screening	C1D1	C2D1	C3D1	C4D1	C5D1	<u>C6D1</u>	<u>C7D1</u>	М3	M6	M
Plann	ied Date	04/26/2022	05/10/2022	06/07/2022	07/05/2022	08/02/2022	08/30/2022	09/27/2022	10/25/2022			
On Study Visit	Status	Occurred	Occurred	Missed	Occurred							
Visit	Date	04/26/2022	05/10/2022	06/07/2022	07/05/2022							



Migrating subjects to new calendar version

The calendar version can be changed from CRA Console > Accrual by checking the select box for subjects to-be-updated, choosing the newer version in the "Switch Calendar Versions" dropdown list, and clicking the "Replace Versions" button. Please be aware: this change cannot be undone!

Switch Calendar Versions 1 (V1.1; 10/13/21) V **Replace Versions**

Steps to migrate subject calendars from CRA Console:

- 1. Check "Select" checkboxes for subjects to migrate
- 2. Select from "Switch Calendar Versions" dropdown box the calendar version to migrate
- 3. Click "Replace Versions" and confirm

Accrual Details Page Size 100 V									Filter:		Page	e 1 of 1
Study Site University of California San Francisco	Subject MRN TESTTRAIN	Last Name TESTTRAIN	First Name TEST	<u>Seq. No.</u> 59944	Arm	<u>Level</u>	Status ON STUDY	Status Date 06/02/2022	<u>Ver.</u> 1	<u>Last Visit</u>	Last Visit Date Sek	lect
						2	Switch Calenda	r Versions 2 (V2	2.0; 05	5/21/22) 🗸	Replace Version Select <u>All N</u>	s3) None

Another method for updating individual subject calendar versions is to choose the newer version from the "Switch Version" dropdown list on the Subject Console > Calendar page. A preview of the newer version will be displayed and clicking "Replace Version" will confirm the change.

Switch Version 2 (V2.0; 05/21/22) V

Replace Version

Steps to migrate subject calendars from Subject Console > Calendar page:

- 1. On bottom left of page, select from "Switch Version" dropdown the calendar version to migrate
- 2. Page will load with a preview of the newer version
- 3. Click "Replace Version" button.

Freeze Panes	Summary	Mana	ge Optiona	al Segmer	nts	Freeze Panes	Summary	Mana	ge Option	al Segmer	nts	
urrent Subject Calenda	r Version - V	'1				Current Subject Caler	dar Version - V	1				
		Treatment						Treatment				
Procedure	Forms	Enrollment 1@1Days	Treatment 5 Cycles @	7Days		Procedure Taggla Full Server	Forms	Enrollment Treatment 1@1Days 5 Cycles @14Days		14Days		
loggie Full Screen		1	2	3	4	<u>Toggie Full Screen</u>		1	2	3	4	
		<u>D1</u>	<u>C1D1</u>	C2D1	C3			D1	C1D1	C2D1	C	
Planned Date		12/04/2021	12/04/2021	12/11/2021	12/	Planned Date			12/04/2021	12/18/2021	01	
/isit Status			Occurred			Visit Status						
/isit Date			12/04/2021			Visit Date						
Central) Biopsy Tissue ¹	Adverse Event Report (CRF 97) V4		x	x	x	(Central) Biopsy Tissue 1	Adverse Event Report (CRF 97) V4		x	x	x	
CRC with Difforantial						CRC with Differential						
Calendar Footnotes	_					Calendar Footnotes						
T. test toot not	e					1. test foot	note					
Switch Version 1			Printal	ble Subject	Cale	Switch Version 2 (V	2.0: 05/21/22)	~	Printa	ble Subject	Ca	



Orphaned Visits

When a visit has been removed from the new version of a calendar, migrating subjects to the new version result in Orphaned Visits. Access these under Subject Console > Calendar > Orphaned Visits.

★ Subject Console											
Protocol No.: ZZ-AMI			Protocol Stat	Subject Status: ON TREAT							
Subject MRN: TESTTRAIN			Subject I	Subject Name: TEST TESTTRAIN							
Switch Subject	CalendarOr	phaned Visits									
Type here to search 💌	Freeze Pane	s Summary	Manage Optional Segme	nts							
Summary	Current Subject (Calendar Version - V	/2								
Forms by Status	ms by Status » Procedure			Treatment			Follor			v Up	
Forme By Visit			Forms	Enrollment 1@1Days	t Treatment 5 Cycles @14Days				Followup		
Points by visit	<u>Toggie Full Screen</u>	1		1	2 <u>(C)</u>	3 <u>(C)</u>	4	5	6	1	2
				<u>D1</u>	<u>C1D1</u>	<u>C2D1</u>	<u>C3D1</u>	<u>C4D1</u>	<u>C5D1</u>	W1	W2
	Planned Date			01/01/2022	01/01/2022	01/15/2022	01/29/2022	02/12/2022	02/26/2022		
Demographics	Visit Status			Occurred	N/A	N/A					
	Visit Date			01/01/2022	01/01/2022	01/15/2022					
Consent	(Central) Biopsy Tissue ¹		Adverse Event Report (CRF 97) V4		x	x	x	x	x		
Eligibility	CBC with Differential			x	x	x	x	x	x	x	x
On Study											

The Orphaned Visits page shows any occurred visit belonging to an earlier calendar version that was removed during subject calendar migration. The page displays the visit and its original calendar version.

★ Subject Console						?			
Protocol No.: ZZ-AMI		F	Protocol Status	Subject Status: ON TREATMEN					
Subject MRN: TESTTRAIN	Subject Name: TEST TESTTRAIN Sequence								
Switch Subject	Calen	dar Orphar	ned Visits						
Type here to search 💌	Orphane	d Visits							
Summary	Visit	Phase	Segment	Visit Date	Visit Status	Calendar Version			
Forms by Status	<u>C1D1</u>	Treatment	Treatment	01/03/2022	Occurred	1			
, , , , , , , . ,	<u>C2D1</u>	Treatment	Treatment	01/10/2022	Occurred	1			
Forms By Visit									

Clicking into a visit brings up the Subject Visit Update page, the detailed calendar version - including the protocol version - can be seen on the top right corner of the Visit Detail section.

Subject Visit Upo	date		User: Robert Till
Protocol No.: ZZ-AMI Subject MRN: TESTTR	RAIN	Protocol Status: OPEN TO ACCRUAL Subject Name: TEST TESTTRAIN	Subject Status: ON TREATMENT Sequence No.: 001
Visit Details		Phase: Treatment Visi	it: C1D1 Version: V1 (12/04/2021) History
Visit Date	01/03/2022	Visit Status Planned Occurred Missed N/A	
Visit Description		Reset Calendar? All Visits	v