

OnCore System Work Instruction Document

Subject Management: Tip Sheet

Prepared For: OnCore Version 2020R2
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The URL for OnCore is <https://OnCore.ynhh.org>

For more information about OnCore please visit the project website at <http://OnCore.yale.edu>

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Subject Administration

In OnCore, a subject is a person who is participating in a protocol, who is considering participating, or who is being evaluated for their eligibility to participate. Each subject record in OnCore represents one patient who is registered to a protocol. A person might have several subject records in OnCore if they are participating on more than one study or if they register to a study multiple times.

Some information in OnCore is stored at the patient level; this information is the same throughout OnCore, no matter what protocol you are looking at. The patient information includes the MRN, demographics, address, emergency contact info, expiration date. If this information is updated anywhere in OnCore, it is reflected in all subject records for that patient.

Other information in OnCore is stored at the subject level; this information is specific to the person's enrollment on a particular study. The subject information includes the Sequence No., consent dates and versions, eligibility criteria, study site, treatment and follow-up start dates, and visit details. When this data is entered or updated in a subject record, it does not change any other subject records.

To insure proper billing compliance:

- Subjects must be Consented in OnCore on the day of signing consent, close of business day.
- Subsequent visits must be occurred in OnCore within 24 hours after visit completion.

Getting started in the CRA Console

CRA Console

Protocol No.: CAR0815 Library: Cardiology PI: Investigator, Irene Sponsor: Bayer Healthcare Pharmaceuticals, Inc.

Protocol Target Accrual: 50 Accrual To Date: 15 Protocol Status: OPEN TO ACCRUAL

Research Center Total Accrual Goal (Upper): 60 IRB Expiration: 01/06/2017

Short Title: Pre-hospital Administration of Thrombolytic Therapy With Urgent Culprit Artery Revascularization

Select Protocol: [Type here to search]

Select Subject: [Type here to search]

Accrual

Forms by Status (Queried) »

Protocol Calendar

Monitoring Visits

SAEs

Deviations

FAQs

Accrual Details

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Study Site	Patient MRN	Last Name	First Name	Seq No.	Arm	Level	Status	Status Date	Ver	Last Visit	Last Visit Date	Select
West Clinic	SU1919616	Hoagland	Jacquelyn	CAR-7	2		ON FOLLOW UP	03/29/2015	3	D30	04/27/2015	<input type="checkbox"/>
South Clinic	AB16852VY ^{BB}	Johnson	Jody	CAR-6	1		ON FOLLOW UP	12/07/2015	3	D30	01/04/2016	<input type="checkbox"/>
South Clinic	VZ82196PM	Mallouk	Susan				NOT ELIGIBLE	08/11/2015	2			<input type="checkbox"/>
South Clinic	VG801418Y ^{BB}	Feraca	Roland				CONSENTED	02/02/2015	2			<input type="checkbox"/>
South Clinic	HK19612O6	Sterlitt	Donna				NOT ELIGIBLE	03/26/2015	2			<input type="checkbox"/>
South Clinic	PG86163C6 ^{BB}	Bailey	Wayne	CAR-11	1		ON TREATMENT	02/06/2015	3	D1	02/06/2015	<input type="checkbox"/>
North Clinic	ER71653DD	Garton	Ken	CAR-1	1		ON FOLLOW UP	07/26/2016	3	D1	02/07/2015	<input type="checkbox"/>
North Clinic	II187051Q		Sophia	CAR-2	1		ON TREATMENT	06/04/2015	3	D1	06/04/2015	<input type="checkbox"/>
North Clinic	BS64707KS ^{BB}	Poly					ON STUDY	04/22/2015	3			<input type="checkbox"/>
North Clinic	HH											<input type="checkbox"/>

The CRA Console provides a summary of subject information, including each subject's study site, sequence number, treatment arm, and current status.

Use the CRA Console to find a subject record, then click the Patient MRN to open that subject's record.

Registering Subjects

First, choose a Study Site

Study Site* [Type here to search]

Find Fields

Patient MRN []

Last Name []

Birth Date []

Clear Find

New Subject Details

Patient MRN* []

Last Name* []

First Name* []

Middle Name []

Suffix []

Birth Date* []

Gender* []

Ethnicity* []

Expired Date []

Last Known Alive Date []

Race*

- American Indian or Alaska Native
- Asian
- Black or African American
- Native Hawaiian or Other Pacific Islander
- Unknown
- White

Approx? Not Avail?

Then, use the Find Fields to search for an existing patient record....

...or enter New Subject Details to create a new patient record

Add Clear All Close

Subject sequence numbers

Subject sequence numbers (Patient ID number from sponsor) needs to be populated in the “on study” tab in OnCore to reconcile invoices.

Subject Status

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.



Always update subject status to reflect the subjects’ proper status. Once subjects go off study be sure to populate the off-study date. Calendars are set up in segments linked to a subject’s status. If you need assistance knowing which status will populate a segment you can contact OnCore Support to assist you.

If you see something like this on your calendar:

	Follow Up	Off Study
ET Visit 28@28Days	Follow-Up Visit	End of Study 1@1Days
18	1	19
ET Visit ^d	W8^e	End of Study ^d
	06/26/2018	

It means that you have skipped a status and need to correct it or you will never be able to occur the ET Visit.

Visit Check-in

Be sure to mark all visits as Occurred, Missed or NA

Visit Details

Visit Date c, d

Visit Status

Planned
 Occurred
 Missed
 N/A

When occurring a visit be sure that all information is correct.

1. If a procedure in the procedures list was done on a different date than the visit date, fill in the date for that individual procedure.
2. If a procedure in the procedures list was missed and not completed, check the missed box.
3. If a procedure in the procedures list does not apply for this subject for this visit, check the N/A box.
4. When you have a procedure alternative for YCCI Research Charges or a Choose ePayment Amount, you must choose an option from the dropdown or mark as N/A if it does not apply.

Procedures							
Procedure	Procedure Date	SOC	SOC Modifier	Missed	Missed Count	N/A	
Neurological exam	<input style="width: 80px;" type="text"/>	<input checked="" type="checkbox"/>	<input type="radio"/> Q0 <input checked="" type="radio"/> Q1 <input type="radio"/> U	<input type="checkbox"/>	<input type="text" value=""/>	<input type="checkbox"/>	
Adverse Events	<input style="width: 80px;" type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="text" value=""/>	<input type="checkbox"/>	
C-SSRS	<input style="width: 80px;" type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="text" value=""/>	<input type="checkbox"/>	
Questionnaires	<input style="width: 80px;" type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="text" value=""/>	<input type="checkbox"/>	
HRU Research Charges	<input style="width: 80px;" type="text"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="text" value=""/>	<input type="checkbox"/>	
<div style="display: flex; align-items: center;"> <div style="border: 1px solid black; padding: 2px; margin-right: 5px;"> <input type="text" value=""/> </div> <div style="border: 1px solid black; padding: 2px;"> CSRU RN HRU RN </div> </div>							

View PDF Clear Submit Close Submit And Close

If your subject gets off schedule, you can reset the subjects calendar.

After you occur the visit select the “Reset Calendar” dropdown and select “All Visits”

Visit Details

Visit Date c, d

Visit Status

Planned
 Occurred
 Missed
 N/A

Visit Tolerance +/-5

Visit Description

Data Collection Completed Date

Monitored Date

Collection Location

Collection Time (mmmm)

Reset Calendar?

Submitted Date

Updating the version of a calendar

If a new version of your calendar is released and you need to update the subjects to the new version.

1. Select subjects that need to be updated.
2. Switch Calendar Versions dropdown to version you want to update to.
3. Click Replace Versions

Yale University	388949650	Doe_388949650	Jane_388949650	81289		OFF STUDY	11/21/2017	1	-3	11/21/2017	<input type="checkbox"/>	
Yale University	388971540	Doe_388971540	John_388971540	80996-1446	BLD	OFF TREATMENT	11/13/2017	1	6	1	11/13/2017	<input checked="" type="checkbox"/>
Yale University	388967394	Doe_388967394	Jane_388967394			OFF TREATMENT	08/17/2017	1	-3		08/17/2017	<input checked="" type="checkbox"/>
Yale University	388952982	Doe_388952982	Jane_388952982	80721-1313	BLD	ON TREATMENT	07/31/2017	1	42		05/08/2018	<input checked="" type="checkbox"/>

Switch Calendar Versions 1 (31MAY2016) Replace Versions

1 (31MAY2016) [Select All](#) | [None](#)

2 (27JUL2017) View PDF

[Save Preferences](#)