

Class is meant to *supplement* other training, not as all inclusive training. This session will *not* be recorded, but this PowerPoint can found:

<https://medschool.ucla.edu/research/research-infrastructure/administrative-support/department-of-medicine-office-of-research/fund-management-training>

Clinical Trials

Pre-Award: OnCore

UCLA DEPARTMENT OF MEDICINE
OFFICE OF RESEARCH ADMINISTRATION
ZOOM TRAINING

Summary

- OnCore - Overview
 - Clinical Trial workflow
 - Notifications for Study Team & Fund Managers
- OnCore – Fund Manager Access & Tasks
 - Configure Invoicing Parameters
 - Verify Milestones
 - Study Team Budget Signoff
 - FAU Entry
 - View Subject Data

CT Key Terminology & Acronyms

- Clinical Research Informatics Systems (CRIS)
- Clinical Trial Agreement (CTA)
- Clinical Trials Management System (CTMS)
- Financial Coverage & Activation (FCA)
- Industry (IND)
- Invoiceable (INVBL or P/Pass Thru)
- Outside Safety Report (OSR)
- Research Quality (RQ)
- Serious Adverse Event (SAE)

OnCore – Overview

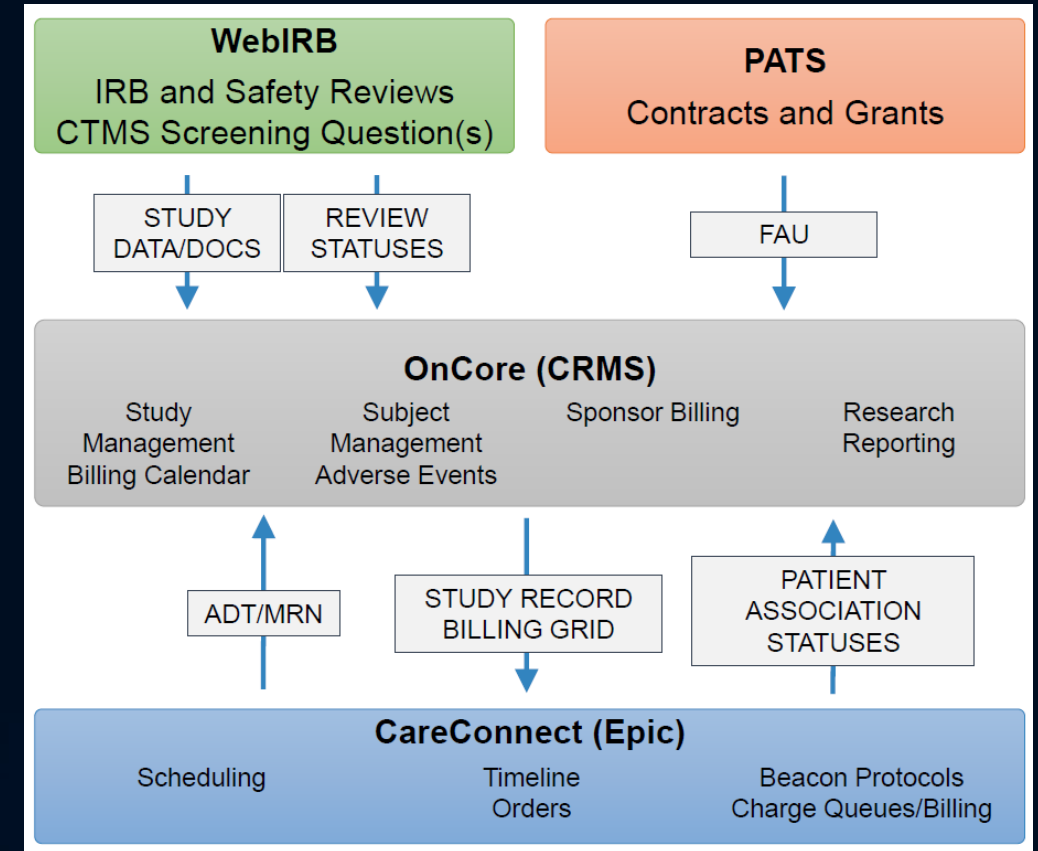
PRE-AWARD

OnCore

- OnCore allows us to use one program to manage multiple components of clinical trials. It automates the flow of information between UCLA based systems including WebIRB, PATS and CareConnect.
- Fund Managers have an administrative role with broad access in OnCore.
 - Protocol and subject search
 - Access to subject reports
 - View timeline of specifications
 - subject calendar information, etc
- OnCore users must complete required training before having access to the system.
- Email notifications are triggered by various actions in OnCore when you or someone else performs a specific action.

How is OnCore used in Clinical Trials?

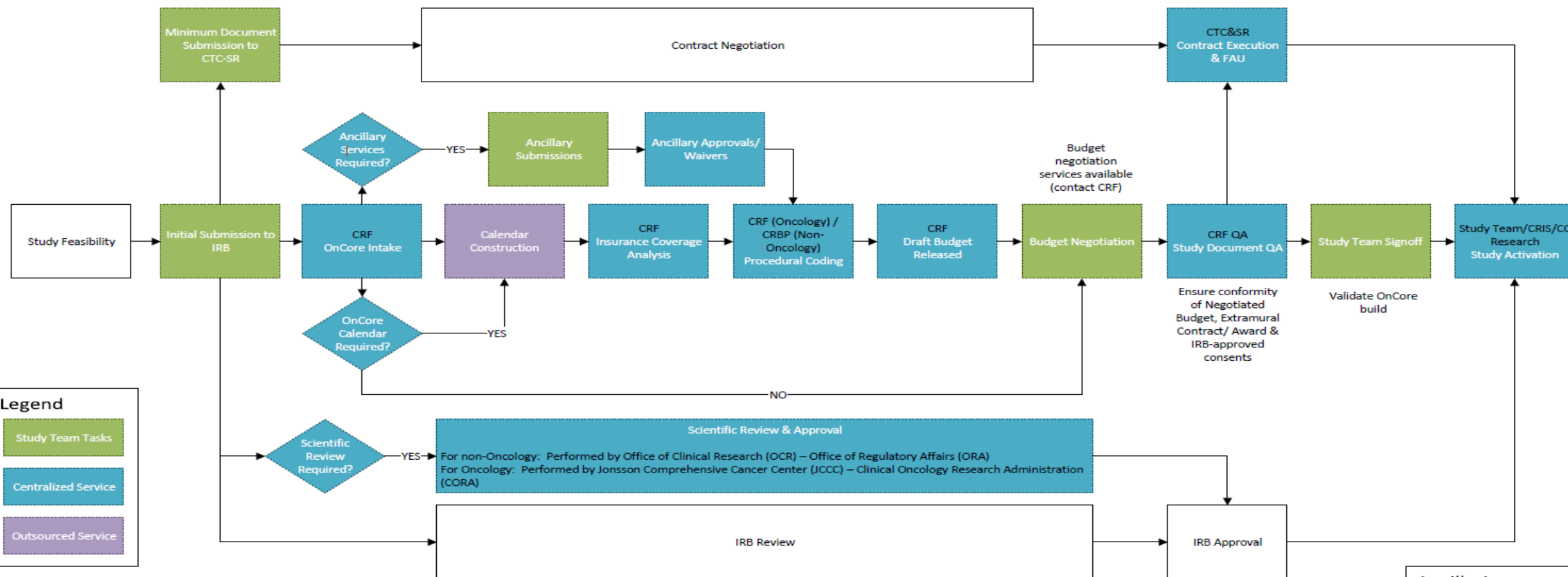
- OnCore is a **clinical trials management system (CTMS)** used at UCLA for the management of clinical trials in clinical research. The system maintains and manages planning, performing and reporting functions at the study and subject level along with participant contact information, tracking deadlines and milestones.
- OnCore automates the flow of information between UCLA based systems including WebIRB, PATS and CareConnect.



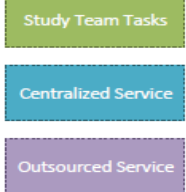
Pre Award Start-Up

Industry-Supported Clinical Research: Study Activation

Enterprise workflow
Version 2.7 - Implementation
date: 12/28/2023



Legend



Centralized Service

CRF: Clinical Research Finance Team
CRBP: Centralized Research Business Partners
CRIS: Clinical Research Information Systems
CTC&SR: Clinical Trials Contracting and Strategic Relations
CRF QA: Clinical Research Finance Quality Assurance
CC Research: CareConnect Research

Ancillaries

Anesthesiology
Cellular Therapy
CTRC
Investigational Pharmacy
Lab/Pathology
Ophthalmology
Radiology

OnCore - Roles & Training

- For system security and compliance, [training](#) is [required](#) for access to [OnCore](#).
 - [OnCore Training Suite](#)
 - [OnCore Roles and Responsibilities](#)

- Training Grid for Fund Manager (DOM Non-Hem/Onc)

OnCore Role	RSCH100 Fundamentals	RSCH160 Financials Management	RSCH210 Study Management	RSCH215 Subject/Patient Management
Fund Manager (FM)	Mandatory	Mandatory	Optional	Optional

- Training Grid for Fund Manager (DOM Hem/Onc)

OnCore Role	RSCH100 Fundamentals	RSCH165 Financials Management	RSCH210 Study Management	RSCH216 Subject/Patient Management	RSCH170 Research Billing – Charge Reviewer
Fund Manager (FM)	Mandatory	Mandatory	Optional	Optional	Optional

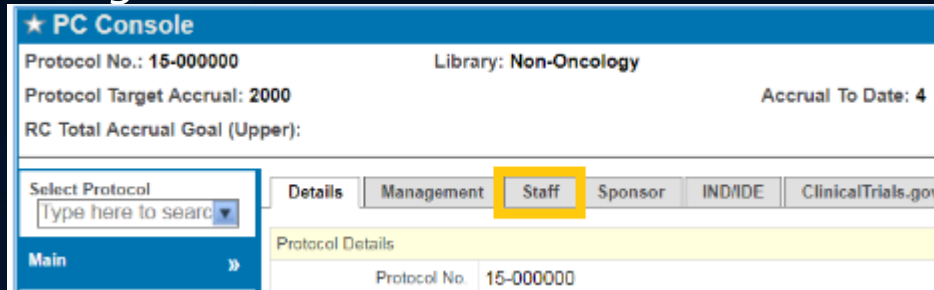
OnCore – Study Team/Protocol Staff

- Who is my **Study Team (ST)**?
 - Inquire with PI to find out (primary/common roles include Study Coordinator, Regulatory Coordinator, Research Assistant, Data Manager)
 - Tip: Establish an intro meeting to discuss roles and set up regular weekly/biweekly meetings to discuss study updates, including billing/invoice
- If **CTSI -CSE services** (study support *outside* of DOM), such as Study Activation and Clinical Research Coordinating are being utilized, take the opportunity to facilitate a meeting with them
 - Tip: you may want to check with PI if they have already established meetings so that you may join in on future meetings
 - If PI is unsure of Study Team contacts you may request an introduction by contacting the Office of Clinical Research (OCRCoordinator@mednet.ucla.edu) and CC: Sarahmay Sanchez (SOSanchez@mednet.ucla.edu), Director of CSE, CTSI - Office of Clinical Research

Note: **Relationship building is key!** Fund Managers should be working very closely with Study Teams

OnCore – Study Team/Protocol Staff

- The OnCore Protocol Staff tab displays the Study Team Staff associated with the protocol/study
 - *Navigation: OnCore > Menu > Protocols > PC Console > Horizontal Tab: Staff*



The screenshot shows the OnCore PC Console interface. At the top, it displays 'Protocol No.: 15-000000' and 'Library: Non-Oncology'. Below this, it shows 'Protocol Target Accrual: 2000' and 'Accrual To Date: 4'. A section labeled 'RC Total Accrual Goal (Upper):' is also visible. On the left, there is a 'Select Protocol' dropdown menu with the text 'Type here to search'. Below this is a 'Main' button. On the right, there are several tabs: 'Details', 'Management', 'Staff' (which is highlighted with a yellow box), 'Sponsor', 'IND/IDE', and 'ClinicalTrials.gov'. Below the tabs, there is a 'Protocol Details' section showing 'Protocol No. 15-000000'.

- Tip: If you are unable to view a Protocol, it most likely means you are not added/assigned to the protocol. You may request that your Regulatory contact add you as staff.
- Study Team (includes Fund Managers) will receive OnCore email notifications based on assigned role
 - OnCore notifications include protocol progress updates and reminders to complete tasks within OnCore

OnCore – Notifications

SENDER / CONTACT(S)	RECIPIENT(S)	EMAIL SUBJECT	ACTION
CRIS Admin crisadmin@mednet.ucla.edu 310-267-2273 (7-CARE)	TO: Study Team	#131: Ancillary Approval or Waiver uploaded - IRB# / PI Name / Division / Sponsor / Protocol	Notification of Ancillary documents (servicing dept – approval/waiver) uploaded
CRIS Admin crisadmin@mednet.ucla.edu 310-267-2273 (7-CARE)	TO: Negotiator CC: Study Team /Fund Manager	#119: Review of Released Budget Document Uploaded - IRB# / PI Name / Division / Sponsor / Protocol	Negotiator to initiate “Budget Out” calendar negotiations with funding agency <ul style="list-style-type: none"> • Fund Managers- Budget Out Checklist • Financial Management (Non-HemOnc Studies) • Financial Management (HemOnc Studies)
CRIS Admin crisadmin@mednet.ucla.edu 310-267-2273 (7-CARE)	TO: Negotiator CC: Study Team, Research Quality	#133: Financials Budget In Response Uploaded - IRB#	Research Quality reviews and uploads “Budget In” for certification after negotiator uploads & finalizes negotiated budget
CRIS Admin crisadmin@mednet.ucla.edu 310-267-2273 (7-CARE)	To: Negotiator / Fund Manager CC: Research Quality, Study Team	Protocol No.: IRB # - Budget Signoff Notification	Fund Manager to review the OnCore Budget that was entered by FCA and complete the “Study Team” Budget Signoff for All 3: Parameters , Milestones and “Study Team Signoff” .
<i>Coverage Analysis</i> <i>OnCore calendar/budget</i> CoverageAnalysis@mednet.ucla.edu	TO: PI CC: Contract Officer, Fund Manager, Study Team	Final Budget Signoff - IRB# / PI Name / Division / Sponsor / Protocol	Study received Final Budget Signoff (Coverage Analysis releases budget)
CRIS Admin crisadmin@mednet.ucla.edu 310-267-2273 (7-CARE)	TO: PI, Study Team	Protocol No.: IRB # - Protocol Status [OPEN TO ACCRUAL] Notice - Status Date	Study is open for accrual and study team can begin to register subjects <ul style="list-style-type: none"> • Fund Manager: Enter FAU Specify the FAU in the Internal Account No. field in the Hospital Account No. field. • Access & Attach Ancillary Documents • Study Team: Manage Subjects

OnCore – Budget in / Study Team sign off Notification

- There are 4 action items to complete when receiving these email notification that Fund Manager must complete for OnCore to trigger the next action item.
 - Parameters
 - Milestones
 - Specifications - Study Team Sign-Off
 - FAU Entry
- After a budget has been negotiated or finalized, you can define the Parameters and Milestones for which the sponsor has agreed to pay receiving the notification “Specification Status: Budget Signoff”.
 - The first step is to [retain copy of the contract](#) that is considered final and may be in route. Be sure to ask the negotiating party (may be contract officer or negotiator of budget) for final draft (prior to signatures) of contract.
 - Secondly, set parameters in the Financials Console which affect the protocol's budget reports and sponsor invoices.
 - Then set Milestones which define specific protocol- or subject-related event/s that can be invoiced according to a study payment schedule.
 - Lastly, Study Team Sign Off indicates the calendar is awaiting your approval.
 - After receipt of another OnCore notification to enter the Fund Accounting Unit (FAU) in OnCore and also receiving the FAU from [ORDM](#), Fund Manager are required to ensure a research guarantor is applied to the research encounter in CareConnect when a research visit occurs.

OnCore – Parameters

PRE-AWARD

Configure Invoicing Parameters

- Invoice Parameters are used for data to reflect on your invoices sent to sponsor. Entering data here should be captured from the (final proposed) contract information.
- Financial Coordinators can set budget parameters for details such as the study's rate base for charge master events, indirect withholding amounts, and rules for invoicing screen failures and SAEs, as agreed upon in the CTA. Predetermined costs can be programmed for milestone events such as consents, enrollments, cycle/visit completions, and SAEs to allow efficient invoicing after the event is logged by the research team.
- 3 sections
 1. Budget Related
 2. Invoice Related
 3. Remit To / Bill To
- *Navigation: OnCore > Menu > Financials > Financials Console > Parameters tab*

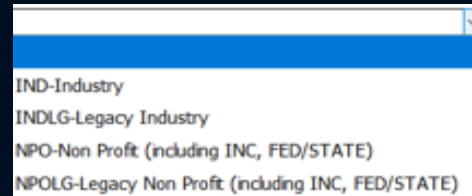
Parameters – Section 1: Budget Related

*Navigation: OnCore > Menu > Financials > Financials Console > **Parameters** tab*

1. Click on **Update** located on bottom right

2. **Select Protocol** by entering IRB#

3. For **Rate Base**, select applicable agency



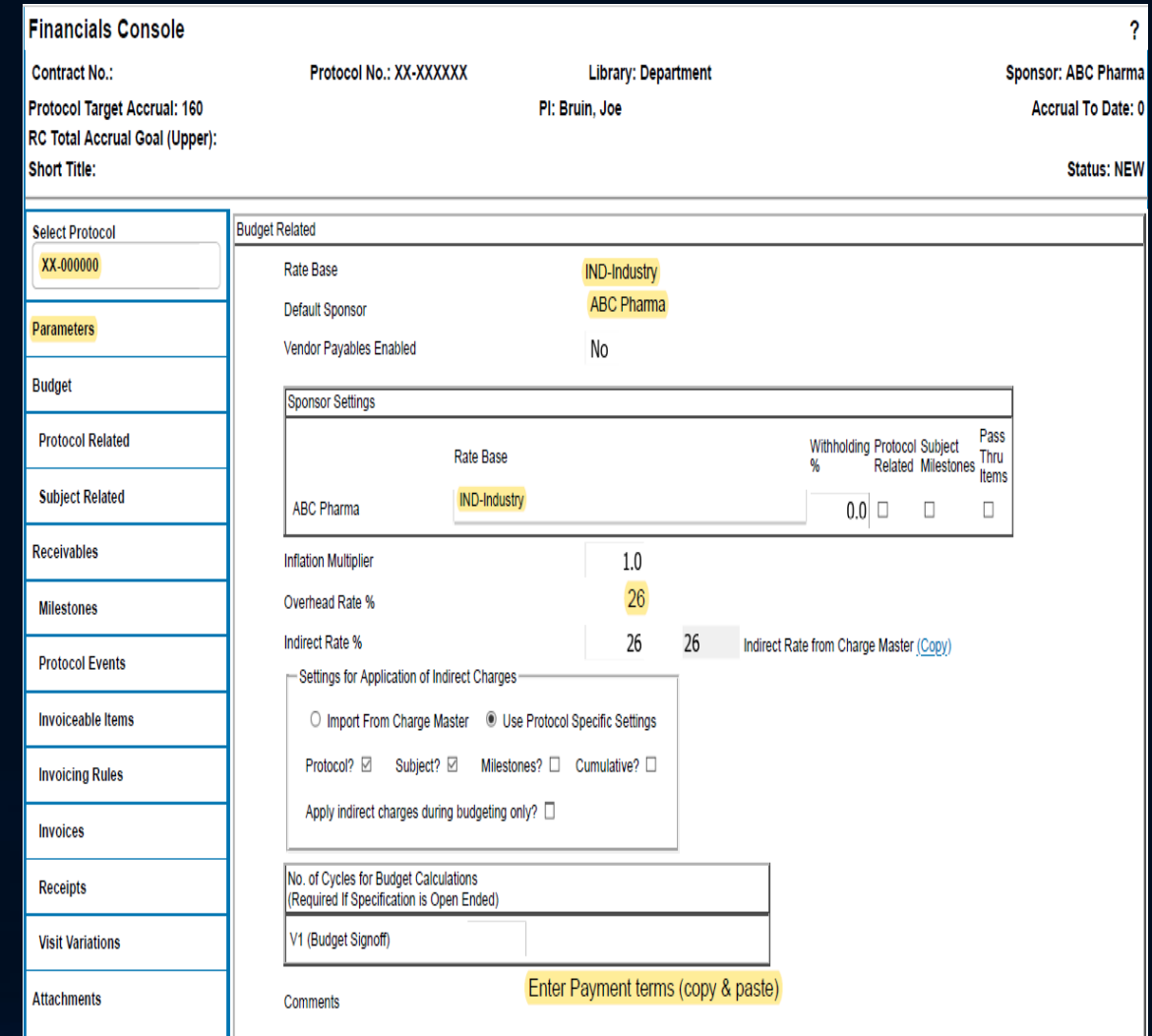
A dropdown menu showing the following options: IND-Industry, INDLG-Legacy Industry, NPO-Non Profit (including INC, FED/STATE), and NPOLG-Legacy Non Profit (including INC, FED/STATE). The 'IND-Industry' option is currently selected and highlighted in blue.

4. **Default Sponsor** – select sponsor

5. **Rate Base** – select agency again

6. **Overhead Rate** – enter rate

7. **Comments** (optional) – enter payment terms (copy & paste) from CTA



The screenshot shows the 'Financials Console' interface. At the top, it displays contract and protocol information: Contract No., Protocol No. (XX-XXXXXX), Library (Department), Sponsor (ABC Pharma), and Accrual To Date (0). Below this, a sidebar on the left contains a list of tabs: Select Protocol, Parameters (highlighted), Budget, Protocol Related, Subject Related, Receivables, Milestones, Protocol Events, Invoiceable Items, Invoicing Rules, Invoices, Receipts, Visit Variations, and Attachments. The main area is titled 'Budget Related' and contains several sections. The 'Rate Base' section shows 'IND-Industry' selected. The 'Default Sponsor' section shows 'ABC Pharma'. The 'Vendor Payables Enabled' section shows 'No'. The 'Sponsor Settings' section is a table with columns for Rate Base, Withholding %, Protocol Related, Subject Related, Milestones, and Pass Thru Items. The 'Rate Base' column shows 'IND-Industry' and '0.0'. The 'Inflation Multiplier' is set to '1.0'. The 'Overhead Rate %' is set to '26'. The 'Indirect Rate %' is set to '26', with a link to 'Indirect Rate from Charge Master (Copy)'. The 'Settings for Application of Indirect Charges' section has two radio buttons: 'Import From Charge Master' (unselected) and 'Use Protocol Specific Settings' (selected). Below these are checkboxes for 'Protocol?' (checked), 'Subject?' (checked), 'Milestones?' (unchecked), and 'Cumulative?' (unchecked). There is also a checkbox for 'Apply indirect charges during budgeting only?' (unchecked). The 'No. of Cycles for Budget Calculations' section is empty. The 'Comments' section at the bottom has a text area with the placeholder 'Enter Payment terms (copy & paste)'.

Parameters – Section 2: Invoice Related

Based on the CTA, enter **Screening Failure (SF)** details, if applicable. A screen failure occurs when a subject is marked as ineligible in the Subject Console. Screen failures will appear in the Invoiceable Items tab if Screen Failed is set up as a milestone.

- The **SF Invoice Ratio (Not Eligible: Enrolled)** indicates the sponsor can be billed for x number of subjects deemed ineligible, for every y number of eligible subjects.
 - **Enrollment Status**
 - **Eligible:** indicates the number of subjects that must be considered "enrolled" in order for you to bill the sponsor for the number of screen failures indicated in the "Not Eligible" field
 - **Not Eligible:** indicates the number of screen failures
 - This ratio applies only after the value set in the **Initial Invoiceable Screening Failures** field is reached, and up until the **Maximum Screening Failures** is met
- **No. of SAEs** indicates the first Serious Adverse Event on the protocol for which the sponsor will receive an invoice
- **No. of OSRs** indicates the first Outside Safety Report/external SAE on the protocol for which the sponsor will receive an invoice

Invoice Related			
Screening Failures Invoice Ratio (Not Eligible : Enrolled)	<input type="text" value="1"/> :	<input type="text" value="5"/>	Enrollment Status <input type="text" value="ELIGIBLE"/>
Initial Invoiceable Screening Failures	<input type="text" value="5"/>		Maximum Screening Failures <input type="text" value="999"/>
No. of SAEs After Which Sponsor Will Be Invoiced	<input type="text" value="3"/>		
No. of OSRs After Which Sponsor Will Be Invoiced	<input type="text" value="5"/>		Maximum Invoiceable OSRs <input type="text" value="999"/>
Milestone Invoiceable Visit Prerequisite	<input type="text" value="Occurred"/>		


Parameters – Section 2: Invoice Related (cont.)

If you want automated [Invoicing Reminders](#), enter the following details:

- [Notification Frequency \(Months\)](#) Reminder of your choice. Example, if Entering 3 here. Setting a notification frequency of every 3 months (Jan 1, Apr 1, June 1, Oct 1)
- [Number of Invoice reminders to send after study closure](#) Number of reminders sent once protocol has a completed status (Abandoned, Terminated, or IRB Study Closure)
- [Notification Start Date](#) The date on which notifications are activated. If you enter 4/15/2020 in here, for example, your first notification will occur on 6/1/2020
- [Notification Comments](#): Any other information you wish to add regarding the notifications

The invoicing reminder notification is an email that will go to the Financial Billing Contact and the Financial Coordinator listed on the protocol. [This function is currently being used by DOM](#)

- If you wish to modify [who](#) this notification goes to and what it says, check the [Adding Notifications](#) tip sheet

Invoicing Reminder	
Notification Frequency (Months)	<input type="text" value="3"/>
Number of invoice reminders to send after study closure	<input type="text" value="1"/>
Notification Start Date (MM/DD/YYYY)	<input type="text" value="04/01/2020"/> 
Notification Comments	<input type="text" value="Invoicing Reminder is set for the 1st of the month of Jan, Apr, June, and Oct."/>

Parameters – Section 3: Remit to / Bill to

- Refer to the CTA to locate payment terms and enter sponsor billing information, as well as UCLA remit payment information
- The [Remit To / Bill To Details](#) should match the contract
 - This allows you to keep a record of all relevant addresses
 - If you need to add the Sponsor # or PO #, add it to the Contact line
- Once all information has been entered, click [Add](#) just left of section and the information will populate into the appropriate section below
- The [Bill To](#) sponsor is required to facilitate sponsor invoicing and payment reconciliation

Update Remit To / Bill To Details

Bill To ▼

Organization Name	Bristol-Meyers Squibb	Contact	Sponsor PO#: BMS0001
Address Line1	123 BMS Lane	Address Line2	
City	New York	State	NY
Phone	123-456-7890	ZIP	11111
Active?	<input checked="" type="checkbox"/>	Email	

Submit Cancel

Remit To

Center for Clinical Studies Jane Doe 123 CCS Lane St. Louis MO 63110	Edit
---	----------------------

Bill To

Payor	Active?
Bristol-Meyers Squibb Sponsor PO#: BMS0001 123 BMS Lane New York NY 11111	Y Edit

Submit Clear Close

OnCore – Milestones

PRE-AWARD

Setting up Protocol Budget to Verify billable Milestones

- After a budget has been negotiated or finalized, you can define the milestones for which the sponsor has agreed to pay. A milestone defines a specific protocol or subject related event that can be invoiced according to a study payment schedule. Tabs will appear across the top of the Milestones page indicating the subject/protocol calendar version and the latest budget version date in parentheses next to the version.
- Invoiceable items are based on the milestones and pass thru procedures defined for a version of the calendar with which the visit was created.
- Enter the data from agreed negotiated budget between both UCLA and funding agency & enter total costs inclusive of overhead. This function is important for review so that invoice can be sent for patient visits.
- *Navigation: OnCore > Menu > Financials > Financials Console > Milestones tab*

Milestones

- *Navigation: OnCore > Menu > Financials > Financials Console > Milestones tab*
- Refer to the CTA to enter milestone information
 1. In the **Financials Console**, select the **Milestones** vertical tab
 2. Click **Update**
 3. A new window for **Protocol Events/Visits** will open
 4. Select only those visits that have amounts reflected on your budget. Do not enter amounts for items separate from schedule.
 5. Click **Submit** and then **Close**

Financials Console
 Contract No.:
 Protocol Target Accrual: 160
 RC Total Accrual Goal (Upper):
 Short Title:

Protocol No.: XX-XXXXXX
 Library: Department
 PI: Bruin, Joe
 Sponsor: ABC Pharma
 Accrual To Date: 0
 Status: NEW

Select Protocol
 XX-XXXXXX

Parameters
 Budget
 Protocol Related
 Subject Related
 Receivables
Milestones
 Protocol Events
 Invoiceable Items
 Invoicing Rules
 Invoices
 Receipts
 Visit Variations
 Attachments

V1 (Budget Signoff)

Subject Milestones

Sponsor: ABC Pharma
 Refresh

Treatment Arm	Event/Visit	Total Negotiated Costs (Calculated)	Total Negotiated	Sponsor Amount
	Screening - S1/ Wk -8 week from BL (+/- 7 days) V1	2498.50	4461.00	4461.00
	Screening - S2/ Wk -3 week from BL (+/- 7 days) V2	2274.50	0.00	0.00
BLD BLD: Blinded	BL - BL V3	3374.50	0.00	0.00
BLD BLD: Blinded	Treatment - W4 V4	3085.50	0.00	0.00
BLD BLD: Blinded	Treatment - W8 V5	2636.50	0.00	0.00
BLD BLD: Blinded	Treatment - W12 V6	3545.50	0.00	0.00
BLD BLD: Blinded	Treatment - W16 V7	2636.50	0.00	0.00
BLD BLD: Blinded	Treatment - W20 V8	2636.50	0.00	0.00
BLD BLD: Blinded	Treatment - W24 V9	3937.50	0.00	0.00
BLD BLD: Blinded	Treatment - W36 V10	2636.50	0.00	0.00
BLD BLD: Blinded	Treatment - W48 V11	3589.50	0.00	0.00
BLD BLD: Blinded	Treatment - W52 V12	844.00	0.00	0.00
BLD BLD: Blinded	Treatment - W60 V13	2636.50	0.00	0.00
BLD BLD: Blinded	Treatment - W72 V14	3400.50	0.00	0.00
BLD BLD: Blinded	Treatment - W84 V15	2636.50	0.00	0.00
BLD BLD: Blinded	Treatment - W96 V16	2729.50	0.00	0.00
BLD BLD: Blinded	Safety FU V17	0.00	0.00	0.00
	Early withdrawal - Early with-drawal	3152.50	0.00	0.00

Update

TIP – Open Final Budget to reference during reviewing/entering of Milestones

OnCore – Study Team Signoff

PRE-AWARD

Study Team Signoff

- After the Fund Manager has verified the Principal Sponsor, configure Invoicing Parameters and billable Milestones, they are to complete a final signoff of the Budget. This will allow the Centralized Teams to move the process forward.
- **TIP** - Good to send Research Quality a follow-up email to let the team know that sign off has been completed.
- **Navigation:**
OnCore > Menu
> eCRFs/Calendars
> Specifications
> Status History tab
> *Study Team Signoff*

Protocol/Specification	Status	Created User	Created Date	Modified User	Modified Date
	New	YHELMY	09/23/2015		
	Completed	MABRAZADO	10/07/2015		
	Coverage Analysis Signoff	MABRAZADO	10/07/2015		
	CPT Entry Signoff	MABRAZADO	10/07/2015	CASE83787	12/02/2016
	Budget Signoff	KBH4VSAR	02/09/2016		

Strikethrough means that the status was undone.

Study Team Signoff

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This step should be completed only after all Pre-Award tasks are completed.

OnCore – FAU Entry

POST-AWARD

To assure appropriate billing –FAU Entry

- Once an email notification from Office of Research Data Management /ORA is received by FM with assigned FAU, this should trigger the FM to enter FAU into OnCore.
- Fund Managers and/or Regulatory Coordinators must **enter the FAU in OnCore prior to opening the study for accrual**. This is one of the *mandatory* tasks that are required in the study activation process, and is required to ensure a research guarantor is applied to the research encounter in CareConnect when a research visit occurs.
 - Tip: *Note*: Only one FAU is allowed in the Internal Account No. field. Any changes made to the FAU will send a notifications to the CareConnect, CRIS or CSI team, and any applicable ancillary departments to route charges to the correct guarantor and ensure proper billing occurs.
- **Navigation**: *OnCore > Menu > Protocols > PC Console > Management tab*

FAU Entry

1. *Navigation:*
OnCore > Menu >
Protocols > *PC*
Console

2. Select Protocol
by entering IRB#

3. Select horizontal
Management tab

4. Click *Update*

5. Enter the FAU
number into the
Internal Account
No. field

★ PC Console

Protocol No.: 15-000000

Library: Non-Oncology

PI: Naeim, Arash

Sponsor: Transmedics

Protocol Target Accrual: 2000

Accrual To Date: 1

Protocol Status: OPEN TO ACCRUAL

RC Total Accrual Goal (Upper): 50

IRB Expiration: 05/31/2019

Select Protocol

2

Main

Treatment

Institution

Accrual

Status

Reviews

Documents/Info

Eligibility

Protocol Calendar

Notifications

Annotations

Deviations

Details

3 Management

Staff

Sponsor

IND/IDE

ClinicalTrials.gov

Management Details

History

IRB No.	15-000000	Pharmacy No.		Priority Score		
SRC No.		SRC Review Required	No	DSMB Review Frequency (months)		
CTRC Participation	No	CTRC No.		CTRC Approval Date		CTRC Category
Comments						
Coding Scheme	CTCAE v4.0	Automated MRN	No	Automated Sequence No.	No	Use Randomization Algorithm
Internal Account No.	5	Hospital Account No.		Allow Duplicate Enrollment?	No	
Allow On Treatment date to be entered before On Study date		No	Populate On Follow-Up Date with Off Treatment Date		No	

Administrative Groups

Management Group

No information entered

Flowchart

Flowchart

Path

No information entered

4 Update

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OnCore – Subject Data

POST-AWARD

OnCore - Subject Data in CRA Console

After contract execution and study team has open study to accrual in OnCore, Fund Managers can review study activity.

- Fund managers (FM) have access to [View Subject Data in CRA and Subject Console](#) for studies that they are listed as protocol staff
- For this to work, check with your study team to ensure subject visit data has been updated in OnCore and is also updated regularly.
 - Study teams should be providing regular updates to subject visit data to avoid delays on invoicing and projected receivables to PI's CT accounts.
- Note: FMs are not responsible for subject management but [subject data and visit reports](#) are needed for financial management (i.e. update Calc sheets and invoicing)
- *Navigation: OnCore > Menu > Subjects > [CRA Console](#) or [Subject Console](#)*

View Subject Data in CRA and Subject Console

1. *Navigation: OnCore > Menu > Subjects > CRA Console*

2. Enter/[Select Protocol](#)

3. Select vertical tab [Accrual](#)

4. Click on Subject [Initials](#)

Note: Fund Manager (FM) access does not permit FMs to view MRNs or Subject Names. Please refer to the [Patient Initials or Seq. No.](#), which is used for the subject ID to identify a patient on a study

CRA Console

Protocol No.: XX-XXXXXXLibrary: Non-OncologyPI: Bruin, JoeySponsor: XYZ Pharmaceutical

Protocol Target Accrual: 300Accrual To Date: 1Protocol Status: OPEN TO ACCRUAL

RC Total Accrual Goal (Upper): 15IRB Expiration: 08/25/2022

Short Title: RUN123

Select ProtocolXX-XXXXXX

Select Subject

Accrual

Protocol Calendar

Monitoring Visits

Financial Events

SAEs

Deviations

FAQs

Accrual Details

Page Size 10Filter:Page 1 of 1

Study Site	Initials	Seq No.	Arm	Level	Status	Status Date	Ver	Last Visit	Last Visit Date
UCLA Westwood	JSQ				CONSENT WAIVED	07/20/2020	1	Screen B	12/09/2020
UCLA Westwood	TM				CONSENT WAIVED	07/20/2020	1	Screen B	11/19/2020
UCLA Westwood	SS	RUN01	BLD		ON TREATMENT	12/11/2020	1	Wk 24 Day 168	05/27/2021
UCLA Westwood	AG				CONSENT WAIVED	06/26/2020	1	Screen A	07/09/2020

Accrual

Include PHI ☐View PDF

[Save Preferences](#)

View Subject Data in CRA and Subject Console

5. After clicking subject initials, you will be redirected to [Subject Console](#)

6. Click on horizontal tab [Calendar](#) to view subject data

Note: Completed visits will be indicated by [Visit Status: Occurred](#) & completed procedures will be marked with an 'X'

Protocol No.: XX-XXXXXX

MRN: *****

Protocol Status: OPEN TO ACCRUAL

Subject Name: SS

Subject Status: ON TREATMENT

Sequence No.:

Switch Subject

Type here to search

Calendar

Orphaned Visits

Freeze Panes

Summary

Summary

Current Subject Calendar Version - V1

Demographics

Consent

Eligibility

On Study

Treatment

Follow-Up

SAEs

Calendar

Additional Visits

Payments

Deviations

Documents/Info

Protocols

MRN

CRA Console

PC Console

Procedure

Toggle Full Screen

Screen A 1@1Days

Screen B 1@30Days

Treatment 1,3,7,10,14,21,28,31,38,42,45,56,84,168,252,336,363,364,448,532,616,700@700Days

Screen A^a

Screen B^b

Day 1^c

Wk 1 (Phone) Day 3

Wk 1 Day 7

Wk 2 (Phone) Day 10

Wk 2 Day 14

Wk 3 (Phone) Day 21

Wk 4 Day 28

Wk 4 (Phone) Day 31

Wk 5 (Phone) Day 38

Planned Date

Visit Status

Visit Date

Informed consent

Inclusion/exclusion

Demographics and baseline disease characteristics

Randomization

Prior and concomitant medications[#]

Medical history

Height

Weight in clinic

Weight at home

Dispense weight and IP diary

1

2

3

4

5

6

7

8

9

10

11

10/01/2020

10/02/2020

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Who do I Contact if I have a CT OnCore Inquiry?

- DOM Clinical Trial Program (DOMCTP@mednet.ucla.edu)
 - Add/assign OnCore staff user to protocol
 - Fund Manager training support including OnCore navigation
 - Assistance with Study Team/Fund Manager Task List and invoice management
 - Other general inquiries
- CRIS Admin (CrisAdmin@mednet.ucla.edu; 310-267-2273)
 - Technical support for OnCore access & training

Links from Today's Class

- OnCore
 - Training [Request Courses](#)
 - Tipsheet: [OnCore Notifications](#)
 - Tipsheet: [Personalize Your OnCore Favorites Bar](#)
 - TIP: [Recommended Favorites](#) for Fund Managers
 - [Reports](#)
 - [My Console](#)
 - [Protocols > PC Console](#)
 - [Subjects > CRA Console](#)
 - [Financials > Financials Console](#)
 - [Financials > Coverage Analysis Console](#)
 - [eCRFs/Calendars > Specifications](#)

Survey Link

<https://forms.gle/QaMyquTmKtNDEj1k8>

We appreciate if you would take a few moments to complete a short 7 question anonymous survey to help us improve your training experience. Thank you!