

This session will *not* be recorded, but this PowerPoint can found

<https://medschool.ucla.edu/research/researcher-resources/administrative-support/department-medicine-office-research-administration/fund-management-training>

Clinical Trials

Post-Award: Calc/Financial Tracking

UCLA DEPARTMENT OF MEDICINE
OFFICE OF RESEARCH ADMINISTRATION
ZOOM TRAINING

Summary & Goals

- Overview of Clinical Trials financial management
- Introduction of CT Calc Template for tracking & invoicing
 - How to determine available staff salaries and other related costs
 - How to incorporate projections from clinical trials
 - Live demo of CT Calc Template
- Best practices & tips

CT Financial Management

CLINICAL TRIALS

Overview

- It is important to understand and analyze the financial performance of each CT to allow good financial management for a *healthy* account
- Using the financial tool Clinical Trial (CT) Calc Template, it offers:
 - summary of earnings and staff salary projections
 - a clear list of all billable research-related items in relevant categories
 - invoice/payment tracking that allows quick identification of any payment issues/discrepancies

CT Key Terminology

- **Earnings** - money obtained in return for labor or services
- **Financial Projection Module (FPM)** – a UCLA Dean's Office Program tool (often used by Fund Managers) to add/edit future projections to ledger figures
- **Projection** - an estimate or forecast of a future situation based on present data (i.e. to predict available account balance based on current appropriations and expenditures)
- **Revenue** – is a total amount of income generated by services related to UCLA's primary operations. Revenue is income and considered earned when UCLA has substantially met obligations agreed upon in the contract for payment.

CT Calc Template

CLINICAL TRIALS

CT Calc Template

- The **CT Calc Template** is a tool that integrates Clinical Trial (CT) contract (payment terms) and financial data (such as administrative fees, patient/visit earnings, invoiceable items, etc.) used for financial tracking including invoice management
- The five sheet CT Calc Template represents the “meat and potatoes” of CT finances. It is a standard that provides a comprehensive overview of the study’s financial status as well as future projections, including available staff salaries
- Utilizing OnCore to retain the data necessary to complete the CT Calc Template

Getting Started & Key Components

- Key materials to have:
 1. CT Calc Template
 2. UCLA (internal) budget
 - Tip: Retrieve *latest* budget from OnCore
 3. Contract / Award Snapshot
 - Note: Be sure to work off the *latest* award/contract executed
 4. OnCore
 - [OnCore Navigation Fund Manager Access to CRA and Subject Console](#)
 - [OnCore Navigation: Subject Visits/Procedures Completion Report](#)

Tip: Contact [DOM CT](#) if you need to be added as protocol staff

Key Components

1. CT Calc Template

- Utilized to efficiently manage financial activity including patient visits, sponsor invoices and payments, and staff salary projections

2. UCLA (Internal) Budget

- Important to determine subject related visits as well as Study Team salaries
- Workload analysis is necessary to determine the salaries of the staff members who will be working on the protocol
- It defines costs to be billed-to-study or billed-to-patient/insurance
- Access *latest budget*: OnCore > Menu > Financials > Financials Console > Select Protocol > Attachments > Sort “Financial Attachment Details” by most recent “Version Date”

Key Components

3. **Contract / Award Snapshot** Review certain pre-award clinical research payment terms to assess and determine milestones for payment
 - Obtain **Snapshot**: [ORA Online Resource Center](#) > Reports: Advanced Search & Snapshot Report > Enter "Fund Number" or "IRB Number" > Search
4. **OnCore** provides a systematic way of tracking, accessing and reporting on overall clinical trial activity and productivity. Subject-specific visits are generated to provide subject visit data which directly drives financial management functionality.
 - [OnCore Navigation: Subject Visits/Procedures Completion Report](#)
[OnCore](#) > Menu > Reports > Reports > JCCC Reports: Subject Procedure Completion / Subject Visit Completion
 - [OnCore Navigation Fund Manager Access to CRA and Subject Console](#)
 - [OnCore](#) > Menu > Subjects > CRA Console > Select Protocol > Select MRN# of specified subject > Calendar

Note: If unable to access/view protocol, request to be added to protocol staff by contacting [DOM CTP](#)

Key Components

- The CT Calc Template consists of 5 primary sheets to track & calculate:
 1. Summary – overall financial status
 2. Arm, Part, Cohort – procedure and Staff/PI earnings
 3. Payment Reconciliation – account receivables
 4. Administrative Invoiceables
 5. Procedure Invoiceables

Sheet 1 - Summary

- Provides a summary of the workbook to provide financial information “at-a-glance”
- It centralizes various data in the workbook to summarize several categories to provide a financial overview
- Data on the Summary such as header information and contract payment terms would need to be manually entered. The amounts in specific categories will automatically calculate UCLA’s direct costs while incorporating all costs associated once data is entered in all other worksheets.
- Used to provide an overall forecasted amount that will be paid to account based on revenue

Sheet 2 - Arm, Part, Cohort

- Arm, Part, Cohort: overview of per subject visit totals and breakdown of visit earnings by Procedure vs Staff vs PI
- Tracks subject visit history and indicates completed milestones:
 - To separate procedure section to ensure the breakdown of projections for contracted salaries
 - By using OnCore Reports to track per subject visits completed
- Note: Some contracts will specify subject visits to be auto-paid upon completed eCRFs (Electronic Case Report Forms). Invoicing may not be necessary for these terms, however maintaining the data for purposes of projections is essential.

Sheet 3 - Payment Reconciliation

- Routine payment reconciliation offers compliance within our organization
- Enter data from payment schedule the sponsor provides
- Payments are often missed or have discrepancies. Spend less time figuring out what costs are owed and identify overpayments “at-a-glance”.
- Tip: It is important to establish a good relationship with sponsor surrounding payments. Having payments sent on time goes a long way in having healthy account balances. It is one of many critical factors in establishing positive relationships with your sponsors.

Sheet 4 - Administrative Invoiceables

- Tracks invoiceable **Administrative Items** that:
 - Are not related to study procedures
 - Require Study Team time and effort to conduct the overall framework of study initiation, maintenance, closure and needed to ensure the continued success of the clinical trial

Sheet 5 - Procedure Invoiceables

- Tracks invoiceable **Procedure Items** that:
 - Are not applicable towards study team salaries
 - May not occur for all subjects and will need to be invoiced based on contract terms
- Special considerations for these items determined as Invoiceable Procedures on contract and are items outside of per subject visit milestones
- Tip: If you have any questions on study related visits/procedures performed, inquire with the Study Team

Additional Documents

- The following reports are recommended to be saved with the CT Calc
 - OnCore reports used for subject visit data completion
 - QDB revenue account reports
- Save back-up for any study specific items performed for the purposes of the clinical trial that occurred outside of budget/contract in file
 - 3rd party invoices
 - Emails from sponsor agreeing to cover/reimburse costs

Projections

- UCLA Financial Projection Module (FPM) is an automated system in which projections are stored
- To project clinical trial finances, you must have a understanding of both the **historical conduct and any key changes** that may impact its future operating balance
- Projections give you the insight you need to make good data-driven decisions for your clinical trials
- *Refer to later slide 29 for FPM Projections instructions*
- *The CT Calc workbook is essential- it can't help you predict the future but it can help you plan for it*

Common Misconceptions

- Study Team confirms patients enrolled & now sponsor can be invoiced
 - *FALSE* - Sponsor's acting monitor is the main line of communication between the sponsor and UCLA's PI, ensuring that the trial is conducted and documented properly. Once data is reviewed and approved, it then goes to sponsor.
- Executed contract payment terms are auto paid upon completed CRFs, so payments will arrive timely
 - *FALSE* – Missed/delayed payments are common so consistent tracking and follow-up is necessary

Live Demo of CT Calc Sheet

CLINICAL TRIALS

CT Calc Template - Summary

SPONSOR					
ACCOUNT FAU					
PROTOCOL					
IRB					
PI					
PROJECT START DATE					
ONCORE STATUS					
FUND MANAGER					

Payroll (Salary+Benefits)	EARNED	PAID	Total
Direct Totals	ITD		
STAFF	\$ -		\$ -
PI	\$ -		\$ -

PER SUBJECT	Total Amount	DIRECT
Subject per (Arm/Part/Coh)	0	ITD
Earnings for Procedure Costs	\$0	\$0
Earnings for Staff Salary Costs	\$0	\$0
Earnings for PI Salary Costs	\$0	\$0
Per Patient Subtotal	\$0	
SCREEN FAILURES	0	
Earnings for Procedure Costs	\$0	\$0
Earnings for Staff Salary Costs	\$0	\$0
Earnings for PI Salary Costs	\$0	\$0
Screen Fail Subtotal	\$0	
Total	0	\$0

START-UP FEES	\$0	\$0
ADMIN MAINTENANCE COSTS	\$0	\$0
PROCEDURAL INVOICEABLES	\$0	\$0

PAYMENT TERMS:	TOTAL AMOUNT EARNED TO DATE	\$0	\$0
Initial Payment: \$ -	TOTAL AMOUNT PAID TO DATE		\$0
Regular Payment:	TOTAL AMOUNT OWED TO DATE	\$0	\$0
Final Payment:			
Holdback % (if applicable) 0%			
Submit Invoice To:			
	LAST PAYMENT RECEIVED: (DATE)		
	CALC SHEET LAST UPDATED: (DATE)		
Sponsor Contact Person:			
Notes/Comments:			

CT Calc Template - Summary

- **Header** – Enter division name & Clinical Trial information using Contract/Award Snapshot
- **Payroll Totals/Paid** – run Salary Expense report and insert total
- **Payment Terms** – Enter from Contract
 - **Initial Payment** – Will auto-populate on Administrative Invoiceables tab
 - **Regular Payment** – Enter summary of payment terms and schedule/frequency
 - **Final Payment** – Enter summary of payment terms
 - **Holdback %** – Enter only if applicable (typically up to 10%)
- **Total Amount Paid to Date** – Run Revenue account and insert total
- **Submit Invoice To** – Enter contact information including Bill To Name, Address, email.
Note: if not indicated in Contract, ask Study Team
- **Notes/Comments** – Note any special agreements (i.e. travel, pt reimbursement, additional accrual)

CT Calc Template– Arm, Part, Cohort

- **GOAL** – To calculate visit earnings (total visit vs Staff vs PI) based on completed visits
- **PROCEDURES**
 - **Total Per Patient (Date)** – enter date when contract was signed for full execution
 - **Per Patient Visit Totals** – copy & paste from UCLA budget
 - **Visit Type/Name** – copy & paste from UCLA budget
 - **Subject ID #** – enter subject Sequence No. from OnCore
 - **Cost per subject** – enter visit totals for completed visits based on OnCore Calendar
- **STAFF SALARY**
 - **Per patient visit Staff Salary totals** – copy & paste direct costs from UCLA budget under Staff Salary category/grid for study team staff such as Study Coordinator, Data Manager, Research Assistant (add more rows as needed)
- **PI SALARY**
 - **Per patient visit PI Salary totals** – copy & paste direct costs from UCLA budget under PI Salary category/grid

SPONSOR			
ACCOUNT FAU			
PROTOCOL			
IRB			
PI			
PROJECT START DATE			
ONCORE STATUS			
Procedures			
Total Per Patient	(Date)	\$ -	\$ -
Subject ID #	Balance	Screening	Day 1
(Sequence No.)			
Cost		\$ -	\$ -
	\$0.00		
	\$0.00		
	\$0.00		
	\$0.00		
	\$0.00		
	\$0.00		
Total	\$0.00		
Staff Salary			
Subject ID #	Balance	Screening	Day 1
(Sequence No.)		0	0
Cost		\$ -	\$ -
0	\$0.00	\$ -	\$ -
0	\$0.00	\$ -	\$ -
0	\$0.00	\$ -	\$ -
0	\$0.00	\$ -	\$ -
0	\$0.00	\$ -	\$ -
0	\$0.00	\$ -	\$ -
Total	\$0.00		
PI Salary			
Subject ID #	Balance	Screening	Day 1
(Sequence No.)		0	0
Cost		\$ -	\$ -
0	\$0.00	\$ -	\$ -
0	\$0.00	\$ -	\$ -
0	\$0.00	\$ -	\$ -
0	\$0.00	\$ -	\$ -
0	\$0.00	\$ -	\$ -
0	\$0.00	\$ -	\$ -
Total	\$0.00		

CT Calc Template – Payment Reconciliation

- **GOAL** – To reconcile visit earnings with sponsor payments (ran from ledger revenue account and provide an overview of what visit payments are still paid/unpaid)
- **UCLA Payment Report (EARNED)** – will auto-populate based on completed visits from Arm/Part/Cohort sheet
- **Sponsor Payment Report (PAID)** – manually insert sponsor paid amounts for each completed visit
 - If **new study** – Send an introductory to sponsor payment contact and request they send a notification of payment details/copy you on correspondences, when check is submitted for auto-payment for patient visits including invoiceables
 - If **active study** – Send email to sponsor and request a detailed payment report including:
 - Subject ID #
 - Visit Name and Date of Service completed
 - Item name for Administrative/Procedure Invoiceable
 - Check Date / Amount / Number
 - If **Holdback%** is applicable, visit totals including holdback will auto-calculate and should be compared to sponsor paid amount for reconciliation (Tip: highlight any discrepancies and inquire with sponsor)

[illegible]

CT Calc Template– Administrative Invoiceables

[illegible]

CT Calc Template– Administrative Invoiceables

- **GOAL** – to calculate earnings of Administrative Invoiceables
- **START-UP FEES** – copy & paste applicable items from UCLA budget (only if matching contract)
 - Reference [CT Industry Budget - Invoiceable Salary Related Costs](#) for items applicable to Staff salaries
- **ADMINISTRATIVE FEES** – copy & paste applicable items from UCLA budget (only if matching contract)
 - Reference [CT Industry Budget - Invoiceable Salary Related Costs](#) for items applicable to Staff/PI salaries
 - To calculate salaries, use formula: TOTAL COSTS divided by 1.26 (overhead rate) and insert value to applicable study member (Staff, PI, both*, none)
 - *Note: Some items are applicable to both Staff & PI. Ask negotiating party of Rate breakdown for Staff & PI.
- **SCREEN FAILURES (SF)** – verify default of Screening Visit per patient total with contract and note any maximums/caps
 - Rates auto-populated – Do NOT overwrite
 - Salaries will auto-populate

CT Calc Template – Procedure Invoiceables

- **GOAL** – to calculate earnings of Procedural Invoiceables and track payment amounts
- **Procedure Items** – copy & paste applicable items from UCLA budget (only if matching contract) and corresponding Rate and Max/Cap (if applicable)
 - Note: For every **Procedure Item**, there should be a corresponding **Pro Item section/breakdown**.

					1 PRO ITEM:	0						
	Procedure Item	Rate	Costs	Max/Cap	Sequence No.	Visit	DOS	Costs	Invoice#		Paid Amount	Unpaid Amount
1		\$ -	\$ -					\$ -			\$ -	\$ -
2		\$ -	\$ -					\$ -			\$ -	\$ -
3		\$ -	\$ -					\$ -			\$ -	\$ -
4		\$ -	\$ -					\$ -			\$ -	\$ -
5		\$ -	\$ -					\$ -			\$ -	\$ -
6		\$ -	\$ -				TOTAL	\$ -			\$ -	\$ -
7		\$ -	\$ -		2 PRO ITEM:	0						
8		\$ -	\$ -		Sequence No.	Visit	DOS	Costs	Invoice#		Paid	Unpaid
9		\$ -	\$ -					\$ -			\$ -	\$ -
10		\$ -	\$ -					\$ -			\$ -	\$ -
	TOTAL EARNED		\$ -					\$ -			\$ -	\$ -
								\$ -			\$ -	\$ -
	Paid		\$ -					\$ -			\$ -	\$ -
							TOTAL	\$ -			\$ -	\$ -
	Unpaid		\$ -		3 PRO ITEM:	0						
					Sequence No.	Visit	DOS	Costs	Invoice#		Paid	Unpaid
								\$ -			\$ -	\$ -
								\$ -			\$ -	\$ -
								\$ -			\$ -	\$ -
								\$ -			\$ -	\$ -
							TOTAL	\$ -			\$ -	\$ -

CT Calc Template – back to Summary

- **Almost there!** After setting up the sheets and entering updated data, go back to the **Summary** sheet to run a couple more reports to insert amounts
 - **PAID Salary Expense Report** (run salary expense report)
 - Open Excel > Add-Ins > Dean's Office Programs: QDB/GLPPP FPM Adhoc Reporting > PP (Column) UCPATH Employee Sum (be sure that REPORT app for ORGANIZATIONAL is selected) > Next > Organization Unit for UCPATH Employee Sum, enter Department # > Next > enter "Account-CC-Fund" > Next > Select timeframe of award *and* [X] Date Source: Ledger Year/Month (paid) > Next > Finish
 - From QDB report, insert Staff + PI salary totals into Summary- Payroll (paid) amounts
 - **Total Amount Paid to Date** (run revenue report)
 - Open Excel > Add-Ins > Dean's Office Programs: QDB/GLPPP FPM Adhoc Reporting > FS (column) Detail –All > Next > enter "fund" > Find accounts > Select revenue account (257000) > OK > Next > select "ITD" > select "Appropriations" and "Expenses" > Next > Finish

FPM Projection

- **GOAL** – to project revenue of a clinical trial account
- **CT Calc Summary sheet** – Total owed column Direct costs amount inserted into FPM to incorporate the projections when running your statements
 - By entering **Owed Direct Cost amount in FPM** will display the projected amount of income when running your monthly account statements
 - Remove the projected income/revenue when the payment actually gets processed, otherwise the revenue will get double counted.
- Access Jump Server > Dean's Office Programs: FPM > select "Income & Expense" tab > select "Income & Non Salary Expense" > Add > in Edit section, enter "Account, CC, Fund " and select "Sub 08" > select Category: "Appropriation/Income" > enter "Description" (Amount owed from Sponsor) > enter "(negative) \$ amount" > [X] Lump Sum > [X] Assess F&A > Save

The screenshot displays the Financial Projection Module (FPM) interface. At the top, a summary bar shows 'TOTAL AMOUNT OWED TO DATE' as \$0 and 'Direct Total Owed' as \$0. The main window is titled 'Financial Projection Module - Main Menu - Catherine Y. Rujanuraks - [Income & Non-Salary Expense]'. The 'Income & Expense' tab is selected. The 'Edit' section shows the following details:

- Account: XXXXX, CC: , Fund: , Project: , Sub: 08, Dept Code: , Desc: , Category:
- Notes:
- To/From Dept:
- Fund End: 4/27/2022, Project End: 4/27/2022
- Amount: -1,500
- Category: Appropriation/Income
- Description: Amount Owed from Sponsor
- Monthly: ☐ Monthly, ☒ Lump Sum
- Assess F&A: ☒
- Program: , PI ID:

At the bottom, a table lists the entry:

Dept	Account	CC	Fund	Project	Sub	Category	Description	Amount	Lump Sum	F&A
					08	Appropriation/I	Amount Owed from Sponsor	-1,500	Yes	Yes

The 'Add' button is highlighted with a red box. The bottom right corner indicates 'No. of records: 1'.

Best Practices & Tips

CLINICAL TRIALS

Best Practices & Tips

- Update Calc Workbooks *monthly* when running statements and performing ledger reconciliations
 - Sponsor payment amounts from ledger reports should be entered into the Calc sheets
 - Invoiceable items will appear on ledger reports as recharges (type entry (TE) 59)
- When sponsor payment is delayed, request from sponsor check details (copy of front/back of check *and* breakdown of amount). This will allow for internal tracking of payment.
- When payment hits the revenue account this is considered payment received and not when sponsor has indicated “payment was issued” or when payment notification was sent
- Being proactive and regularly updating the Calc Workbook allows for timely receivables

Links from Today's Class

- DOM Clinical Trials Fund Manager Manual Chapters
 - [CT Key Terminology](#)
 - [CT Calc Template](#)
 - [CT Industry Budget - Invoiceable Salary Related Costs](#)
- CareConnect (OnCore) Tipsheets
 - [OnCore Navigation Fund Manager Access to CRA and Subject Console](#)
 - [OnCore Navigation: Subject Visits/Procedures Completion Report](#)
- Clinical Trial Support & Contacts
 - [DOM CTP](#) (DOMCTP@mednet.ucla.edu)

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!