

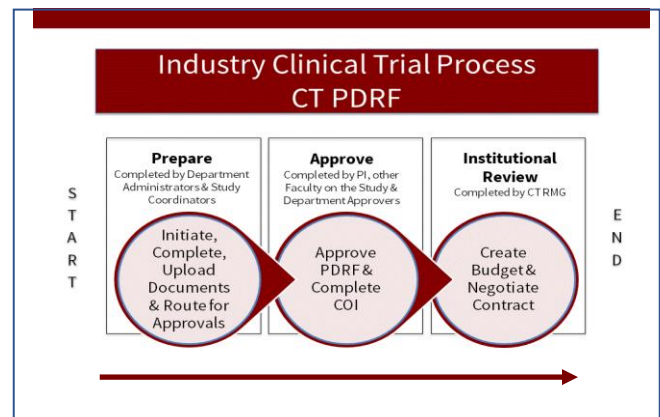
Frequently Asked Questions about CT -PLEASE READ CAREFULLY TO EXPEDITE INTAKE PROCESS

1. How does the CT PDRF fit into the startup process managed by CT RMG?
2. What clinical trial documents need to be submitted by study team to CT RMG?
3. What budget information is required to submit a CT PDRF?
4. Why was my CT PDRF assigned back to me as a Minor Edit?
5. Why was my CT PDRF assigned back to me as a Major Edit?
6. How can a PI make a correction to COI section after CT PDRF has been routed for approval?
7. Do we use a CT PDRF for submitting study documents for an amendment?
8. When does the SeRA system update study team on status of CT PDRF?

1. How does the CT PDRF fit into the startup process managed by CT RMG?

The CT PDRF uses the SeRA system as an end-to-end process to track study startup tasks.

Prepare: A study team member, the clinical research coordinator or a department research administrator, logs into SeRA to initiate a CT PDRF, enters basic information about the study, uploads required study documents, and then routes **upfront** the CT PDRF for faculty and department approvals.



Approve: Routing the CT PDRF for approvals prior to submission to CT RMG Intake, ensures that any faculty financial disclosures are managed early in the startup process and likewise department approvals are collected early on. After approvals are in place, CT PDRF is routed to CT RMG Intake Queue.

Institutional Review completed by CT RMG:

- Confirm study meets all 4 criteria to process as an industry-sponsored clinical trial
- CT PDRF is assigned to Clinical Trial Research Process Manager (CT RPM)
 - If required, CT RPM will initiate a **Coverage Analysis (CA) Task** (10 day turnaround) from Stanford Hospital & Clinics (SHC)
- SPO is established
 - Set up an **Award Transaction** in SeRA to track status of Clinical Trial Agreement (CTA) and assign to a Clinical Trial Contract Officer (CT CO) to work on in parallel to CT RPM working on the budget
- Schedule a Kick Off (KO) Meeting with study team, CT RPM and CT CO.
 - For studies requiring a CA Task, scheduling starts after CA Task has been completed.
- CT RPM works with study team to develop budget and negotiates with sponsor
- CT CO reviews and negotiates CTA
- After budget approved by both PI and sponsor, CT RPM enters budget details and uploads final versions of budget and compliance documents into CT PDRF.
- Once study has been approved by Stanford IRB, CT RPM reviews and approves CT PDRF.
- After CT PDRF approved, CT CO executes CTA and issues the Award Approval Notification (AAN) in SeRA

Ideally while the CT PDRF is in the Institutional Review stage, the IRB is reviewing the study's eProtocol submission so that the study follows an expedited path and the CTA may be executed shortly after the Stanford IRB has approved the protocol.

Go to SPO Project Summary page to confirm CT RPM & CT CO assignment:

Recent Transactions						
	ID#	Type	Started	Completed	Status	Assignee
Open	AW852056	Award - New	01/05/2021	-	In Progress	Shefa Saulat
	PR851106	Proposal - New	12/10/2020	-	In Progress	William Ngo

Go to the SPO Proposal Transaction Home page to see Transaction History and status of Coverage Analysis

Transaction History					
	Task	Status	Assignee	Assigned	Completed
PI - Paul Y Kwo	Prepare PDRF	Completed	Angela Jean Fuller	03/03/2021 09:49 AM	03/03/2021 01:00 PM
	Approve PDRF (PI)	Completed	Paul Y Kwo	03/03/2021 01:00 PM	03/03/2021 01:14 PM
	Approve PDRF	Completed	Susan Lydick	03/03/2021 01:14 PM	03/03/2021 02:45 PM
Institutional Review	Institutional Review	Reassigned	RMG Intake Queue	03/03/2021 02:45 PM	03/03/2021 04:10 PM
		Reassigned	Jason Lopata	03/03/2021 04:10 PM	03/03/2021 04:40 PM
		In Progress	Diana Jean Cook	03/03/2021 04:40 PM	
	Prepare Coverage Analysis	Reassigned	Coverage Analysis Intake	03/04/2021 08:52 AM	03/04/2021 09:00 AM
		Reassigned	Avi Sonar	03/04/2021 09:00 AM	03/04/2021 10:09 AM
		In Progress	Joel Viramontes-Gallegos	03/04/2021 10:09 AM	

2. What clinical trial documents need to be submitted to CT RMG?

We encourage you to use SeRA as the electronic filing cabinet for your study i.e. if not all study documents are ready or provided by the sponsor at the same time, the CT PDRF can be used as a central storage place as you collect a complete set of documents. Please do not route and submit CT PDRF until you have all required documents. If a required document is not available, please upload correspondence instead to provide explanation as to why you are proceeding with submission (e.g., if contract not provided email confirmation Sponsor is willing to use Stanford contract template).

The Proposal & Attachments section lists study documents necessary for initiating the CT study set up process for Agreement subtypes: Sponsor Protocol & Subcontract.

- Protocol
- Contract i.e. Clinical Trial Agreement (CTA)
- Sponsor Payment Schedule -this may be included in the CTA as the Budget Exhibit or provided as a separate Excel or Word file
- CTRU Pricing – upload completed CTRU Workbook (available on CTRU website)
- Informed Consent Form – sponsor’s version or Stanford ICF

- Completed Workbook – Only required for Pediatric studies or studies using only LPCH services. Always start with the most current [Budget & Billing Workbook](#) downloaded from the Spectrum website:

<https://med.stanford.edu/spectrum/study-team-resources/shc-and-sch-researcher-tools.html>

Workbooks are **not** required to be submitted by study teams for industry sponsored studies with adult populations and services at SHC. These studies will be forwarded by a CT RPM to SHC and the workbook will be established by the hospital's Coverage Analysis consultants.

For the Agreement subtype - PI Initiated Protocol, submit all documents from the list above that are available and at a minimum always submit a Protocol or summary of the Scope of Work (SOW).

3. What budget information is required to submit a CT PDRF?

The CT PDRF collects very minimal budget information, your research personnel effort estimates which serve as a starting point for discussion with your CT RPM.

An industry-sponsored CT budget usually involves a negotiation process based on a fixed per patient budget with quarterly or monthly payments generated by completed Case Report Forms (CRFs). The CT PDRF requests **research personnel per patient effort estimates**, represented by the number of hours per patient excluding any effort related to study start-up activities or conditional procedures not required per protocol for all patients that will be compensated by the sponsor with an invoiced item.

To estimate per patient effort for each research team member or role (PI, study coordinator, research nurse, if responsibilities are shared only included effort required once) review the protocol's Schedule of Events and consider all protocol procedures requiring effort and then calculate how much time is required per patient to complete each study visit and then add up all the hours to reach a total # hours per patient for each person involved in conducting the study.

For the PI, this estimate is entered on the PI & Project Location section:

The screenshot shows a web form titled "Principal Investigator & Project Location (Proposal - New)". At the top, it displays "SPO #207457" and "Agreement Type: Industry Clinical Trial". The form is divided into sections. The "Principal Investigator" section includes a dropdown menu for the PI name, which is currently blank. Below this, there are fields for "Email: mignot@stanford.edu", "Phone: (650) 725-6517", and "Department: Psych/Sleep Medicine". A checkbox labeled "PI is an Academic Council member" is present. The "Effort Type" section has three radio button options: "Academic/Summer Appointment", "Calendar Appointment", and "Per Patient". The "Per Patient" option is selected and highlighted with a red rectangular box. Below this, the "Effort" field is set to "10" with the label "Hours per patient". At the bottom of the form, there are two checkboxes: "Is all of the PI's effort charged directly to this project?" (with "Yes" and "No" buttons) and "Is this person identified in the proposal as Key Personnel?" (with "Yes" and "No" buttons).

When Co-investigator faculty effort (in addition to PI per patient effort) is budgeted, enter effort estimate into the Project Personnel / Stanford Investigators Section by completing and routing an Investigator Details form.

Faculty Personnel Details - [REDACTED]

(Proposal - New)

SPO #207414
 Emmanuel Mignot
 School of Medicine (VAAA)
 Title

Agreement Type: Industry Clinical Trial

Sponsor: Merck & Co., Inc.

Investigator Details **Approvers & FYI's**

Investigator Details

Role * **Faculty Member Name ***

Co-Investigator [REDACTED]

Email: clete@stanford.edu Phone: Department: Psych/Sleep Medicine

Effort Type

Academic/Summer Appointment ?

Calendar Appointment

Per Patient

Effort 5 hours per patient

All Effort Direct Charged to Project

Which Dept/Lab/Institute will approve this research? Psych/Sleep Medicine (XMYQ) x v

Is this person identified in the proposal as Key Personnel? ?

The per patient effort estimates for the Study Coordinator (SC) and all the other research personnel are entered in the Project Personnel / Additional Personnel section:

Additional Personnel Personnel Details - TBD Personne.

(Proposal - New)

SPO #207414
 School of Medicine (VAAA)
 Title

Agreement Type: Industry Clinical Trial

Sponsor: Merck & Co., Inc.

Additional Personnel

Institution *

Type/Role * Study Coordinator v

Person to be determined

Name * v

Effort Type *

Calendar Appointment ?

Per Patient

Effort * 55 hours per patient

Alternatively, there is also an option in the CT PDRF to include effort estimates based on annual Full Time Equivalent (FTE):

Investigator Details Approvers & FYI's

Investigator Details

Role * Faculty Member Name *

Co-Investigator [Dropdown]

Effort Type Academic/Summer Appointment Calendar Appointment Per Patient

Effort 2 % effort

Person-months : .24

All Effort Direct Charged to Project Yes No

Which Dept/Lab/Institute will approve this research? [Dropdown]

Is this person identified in the proposal as Key Personnel? Yes No

Your CT RPM will use an estimated FTE to calculate a per patient effort cost for the CT budget based on additional assumptions as to the study duration and Stanford's target enrollment. These details are entered into the Admin & Sponsor Details section.

Administrative & Sponsor Details (Proposal - New)

SPO #207414 Sponsor: Merck & Co., Inc.

School of Medicine (VAAA) Agreement Type: Industry Clinical Trial

Title

Show All Administrative Details Project Contacts Sponsor Details

Administrative Details

Proposal Start Date * 11/01/2020

Proposed Study Duration * Years: 5 Months: 0

Proposal End Date * 10/31/2025

Patient Population Adult Pediatric

Total Number of Stanford Patients * 50 Add Study Arm

Arm #	Name	Patients	Edit	Delete
1	control	25		
2	intervention	25		

During the study's KO meeting, the effort estimates will be discussed and confirmed in context of the entire budget. In addition, at this time many other budget details will be reviewed and confirmed.

4. Why was my CT PDRF assigned back to me as a Minor Edit?

For CT RMG to confirm the sponsored project's Agreement type (Industry Clinical Trial or Contract) is set up correctly, we review all study documents so if any required documents are missing, then the CT PDRF will be returned with a note requesting the missing document. Once you have received this document, it can be uploaded. This edited CT PDRF does not need to be re-routed and your next action is to return for Institutional Review.

Stanford | SeRA

Edit Proposal

Details: Leelo Kask has routed a Proposal in SeRA to you for corrections. After you make the corrections, return the transaction from the Actions menu. If you have any questions about why you are being sent this email, please contact [Leelo Kask](#) who initiated this action.
Note: The proposal will not be re-routed for approvals which are already complete.

Proposal: SPO: 207749
Transaction: PR842173
Principal Investigator: JW Day (jwday)
Administering Dept: Neurology (XBYE)
Sponsor: Biogen MA, Inc.
Title: A Phase 4 Study of chocolate for Patients With ADHD - Test

[Go to the PDRF ->](#)

Please do not reply to this email. Need technical help? Please submit a [Help Ticket](#).

Return for Institutional Review

Actions

- Save
- Reassign
- Return for Institutional Review**
- Terminate

5. Why was my CT PDRF assigned back to me as a Major Edit?

If after reviewing study documents, CT RMG determines the sponsored project's **Agreement type (Industry Clinical Trial)** needs to be corrected to **Contract**, then the CT PDRF will be returned as a Major Edit and will need to be re-routed for approval. This action will be discussed with study team during the study's KO meeting or prior to sending for correction.

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Correct PDRF

Details: Leelo Kask has requested corrections be made to the PDRF related to the following proposal. After you make the corrections, click "Submit for Approvals" from the Actions menu. If you have any questions about why you are being sent this email, please contact [Leelo Kask](#) who initiated this action.

Proposal: SPO: 207749
Transaction: PR842173
Principal Investigator: JW Day (jwday)
Administering Dept: Neurology (XBYE)
Sponsor: Biogen MA, Inc.
Title: A Phase 4 Study of chocolate for Patients With ADHD - Test

[Go to the PDRF ->](#)

Please do not reply to this email. Need technical help? Please submit a [Help Ticket](#).

Return for Institutional Review

6. How can a PI make a correction to COI section after CT PDRF has been routed for approval?

A correction to COI may be completed either by Major Edit with re-routing to PI/Dept approvers or by submitting a HelpSU ticket. Please discuss with your CT RPM to determine best option.

7. Do we use a CT PDRF for submitting study documents for a budget amendment?

No, currently we are not using the SeRA system as part of the CT RMG Intake process for budget amendments. Please complete the CT RMG Amendment Intake form and submit with study documents by email: rmg_ct_intake@stanford.edu

8. How does the SeRA system update study team on status of CT PDRF?

There are 2 automated notifications sent out by the SeRA system and also the study team may go to the **CT PDRF Transaction Log** that provides insight into the current status of Budget Development Activities. (See below)

- When the CT PDRF has been reviewed and approved by all required approvers, the SeRA system will provide notification that the CT PDRF is under Institutional Review (see FAQ#1)

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PDRF Ready for Institutional Review

Details: The following Proposal Development & Routing Form (PDRF) has been approved by all parties and is ready for Institutional review and approval.

Proposal: SPO: 207749
Transaction: PR842173
Principal Investigator: JW Day (jwday)
Administering Dept: Neurology (XBYE)
Sponsor: Biogen MA, Inc. (BIOGEN)
Proposal Title: A Phase 4 Study of chocolate for Patients With ADHD - Test

[Go to SeRA →](#)

Please do not reply to this email. Need technical help? Please submit a [Help Ticket](#).

- When the CT PDRF has been approved by the CT RPM

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JW Day is a participant in a sponsored research project

Details: This email is for your information. JW Day has been approved to participate in the following sponsored research project.

Proposal: SPO: 207749
Transaction: Proposal - New (PR842173)
Principal Investigator: JW Day (jwday)
Administering Dept: Neurology (XBYE)
Sponsor: Biogen MA, Inc.
Title: A Phase 4 Study of chocolate for Patients With ADHD - Test

[Go to the PDRF →](#)

Please do not reply to this email. Need technical help? Please submit a [Help Ticket](#).

Also, a study team can also look for budget/contract status on the CT PDRF Transaction Logs:

Budget Development Activities		
Budget Managed by CCTD	Yes	No
Activity ↑	Added On/By	Comment
SeRA Transaction Assigned To +Comment	11/03/2020 (Jason Lapata)	
Draft Budget Sent to PI/Coordinator for review +Comment	03/01/2021 (Sarah E. Doadi)	2/26/21; Conf call with SC. to review budget details. (Sarah E. Doadi 03/01/2021) 📄
PI/Coordinator Approve Final Budget +Comment	03/02/2021 (Sarah E. Doadi)	
Budget Sent to Sponsor +Comment	03/03/2021 (Sarah E. Doadi)	3/3/2021: Sent budget to sponsor. (Sarah E. Doadi 03/11/2021) 📄
Sponsor Approves Final Budget +Comment	📄 📄	
PDRF in Approvals stage +Comment		
Institutional Review & Approval +Comment		
Budgeting Complete and PDRF Routing Initiated +Comment	📄 📄	
Send to Department to Complete +Comment	📄 📄	
First Actionable Document Received +Comment	📄 📄	
Kick-Off Meeting +Comment	11/24/2020 (Stella Underwood)	