PI Training Requirements

Contents

PI Training Requirements	1
Clinical Research IO (CRIO)	1
Advarra IRB:	3
Medidata Training:	3
Cenduit Solutions	5

Clinical Research IO (CRIO) This is our software that we will be using to track patient visits. The below training will teach you how to use the system. That said, you'll always have a CRC available to help you with navigating this environment as well.

- You'll receive an invite into CRIO via email. Login and reset your password. Please remember this login as you'll need to login once/week to sign off on patient charts. Login Link: <u>https://app.clinicalresearch.io/login</u>
- 2. Click on the help button in the bottom right corner.

y Dashboard	1	
Visits to Complete	Visits to Sign Off	
Today's Rema	ining Visits (0) Show visits for ME ALL	My Tasks
		1 Draft Progress Note
		Prime Study Tasks
	No Visits Today Enjoy the rest of the day off!	1 Draft Progress Note

3. Click on "Academy." This will redirect you to a new environment.



4. Click on "Add Available Courses" and then please enroll in "Investigator Training" (25 minutes) and "Investigator Certificate" (8 minute test over the material).



5. Once completed with the certificate please send to me: Jill@CardioRenalInstitute.com

Advarra IRB: This is the Institutional Review Board (IRB) or ethics committee that oversees research. Yesterday (10/11/2022) I registered you in that system.

 You should have received an email that is asking you to login and update your password. That's all I need you to do in this module. You will likely never need to login to this module again as the CRCs take care of this and we have our own logins. We do, however, need you to be registered as the study is your responsibility and this allows Advarra to send you any updates needed.

Medidata Training: This is the database for Novartis. Once we complete the study procedures in CRIO (above) Farrah adds this data into Medidiata and that is how Novartis receives and analyzes the data. You will need to sign into this 1/month to sign off on visits. This training will give you access.

- You will have received an invite into Medidata via email. Find that email (or let me know if you don't have it and I'll ask that it's resent) and login and update your password. Again, please remember all passwords (I use LastPass to remember and save all passwords securely).
- You'll likely see an environment that looks a bit like this (you'll only have one study in there).
 #medidata

*					Help - Switch User - Jill Heinz -	
Apps RAVE RTSM	Studies (4)			٩		
worldwide-scilex rho-skk TissueGene RAVE Modules	AV001 Bave Modules Bave EDC	SKK SI-6603-1133 Bave RTISM Bave EDC	BP-103-02 Bitwe EDC Bave Modules Bitwe RTSM	GC-15302 Bave EDC Bave EDC MEDS.Reporter Bave Modules Bave Architect Roles	No rending invitations eLearning (0) WL No Pending eLearning	
worldwide-scilex icon-averitas TissueGene RAVE EDC						

3. On the right side please click on Invitations if there is a (1) to the left of it. If there is a (0) there then the Novartis study should already show up as what looks like a stack of pancakes on the main screen. If there is a (1) you'll need to accept the invite.

Help	o ← Switch User ← Jill Heinz ←			
Q	Tasks			
	Invitations (0)			
	No Pending Invitations			
TGC-15302	eLearning (0)			
	No Pending eLearning			
<u>DS Reporter</u> <u>ve Modules</u> <u>Architect Roles</u>				

 Once you've accepted the invite into Novartis click on the eLearning that will likely have at least one training noted as (1) next to it. This will take you to the eLearning page.

estanting estates (in four, and estated)							
Name	Status	Passing %	Required	Duration	Prerequisite	Certificate	For
Medidata Classic Rave EDC Essentials for Clinical Research Coordinators	Completed View Completions	80	ø	25 mins		PDF	SKK SI-6603-1133
Medidata Rave RTSM Randomization Desi gn	Completed View Completions	80		25 mins		PDF	
Medidata Rave RTSM: Logistics for Shippe IS	Completed View Completions	80		15 mins		PDF	
Medidata Rave RTSM Logistics for Site Us ers	Completed View Completions	80	۲	10 mins		PDF	▶ <u>Show (2)</u>
Medidata Balance Unblinding	Completed	80		5 mins		PDF	

- 5. Yours should only have 2-3 trainings in there max (mine has more simply because CRCs have many more activities to conduct in this environment). You will likely have a training teaching you to sign off on visits. Another training will likely teach you how to unblind the study should there be a medical emergency necessitating this (very unlikely).
- Complete all trainings assigned in this section and please send email me any certificates that are you receive. The certificates can be found in the 7th column and it will allow you to download a PDF version.

Prerequisite	Certificate	For
	PDF	SKK SI-6603-1133
	PDF	
	PDF	
	PDF	▶ <u>Show (2)</u>
	PDF	

Cenduit Solutions. This is the system we use to randomize patients. If I'm being honest, you'll likely never need to go into this program as the CRCs will handle it. That said, we can NOT enroll patients without you at least having an account.

- 1. You will have received an invite into Cenduit via email. Find that email (or let me know if you don't have it and I'll ask that it's resent) and login and update your password.
- 2. That's all you have to do for this module- we just need you to have access and, at this time, I don't believe there is a PI specific training for you to conduct in this study platform.