

1 Overview

This document is intended for Centre Representatives (CENREPs), Roster Administrators (RRAs), Participant List Delegates (PLDs), and Participant List Administrators (PLAs) to clean up potential discrepancies in Trial Participant List (PL) Roles or RIPPLE Roles at their centre. A list of Trial PL Roles or RIPPLE Roles will be attached for review and taking appropriate actions.

2 Scenarios & Actions

2.1 Trial PL Roles Cleanup

Table 2.1 shows all the identified Trial PL Role discrepancies in RIPPLE with different scenarios and the corresponding actions to be taken by centres. Each set of duplicates may have a different **Role, Delegated Duties, Requested Start Date** or **Effective Start Date**; or with **Role/Delegated Duties** discrepancies.

To remove duplicate records, go to RIPPLE Trial Participant List web page, click “Remove” button and indicate a “Requested Stop Date”. If the “Participation Status” is “Active” once changes are made the QI or PLD will need to approve all changes. Otherwise, the duplicate entries will be removed immediately if the “Participation Status” is “Pending”.

If a scenario requires old records to be removed and new records to be added, make sure:

- That both the Requested Start Date for new record(s) and the Requested Stop Date for the record(s) being removed are set as today’s date so there are no gaps in trial participation.
- That all credentialing requirements are met prior to making changes to ensure the new record can become active immediately upon approval.
 - Check this by clicking on the Details link under the Actions column for one of the duplicate roles. If any of the Role Requirements listed on the page have failed, use the resolution link provided to fix the issue.
- That the QI or PLD should approve all removals and additions at the same time to ensure that there are no gaps in trial participation.

Table 2.1 Trial PL Duplicates with Different Scenarios and the Corresponding Actions

No.	Role	Delegated Duties	Requested Start Date	Effective Start Date	Actions
(A)	Same	Same	Same	Same	<ul style="list-style-type: none"> • Remove the duplicate(s) by setting the Requested Stop Date as today’s date.
	Name	Role	Delegated Duties	Requested Start Date	Effective Start Date
	Dr. Sub Investigator	SI	1, 2, 3, 6, 10, 11, 14, 15, 16, 17, 19, 20, 21, 22, 23	2017-JUN-28	2017-JUN-28
	Dr. Sub Investigator	SI	1, 2, 3, 6, 10, 11, 14, 15, 16, 17, 19, 20, 21, 22, 23	2017-JUN-28	2017-JUN-28

Trial PL Role and RIPPLE Role Cleanup User Guide

Version: V002

Date: 2022-July-26

No.	Role	Delegated Duties	Requested Start Date	Effective Start Date	Actions
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(B) Same Different Same Same

If all duties apply:

Name	Role	Delegated Duties	Requested Start Date	Effective Start Date
Addy CRA	ACRA	2, 10, 11, 14, 15, 16, 17, 20, 21, 22, 23	2013-NOV-11	2015-JAN-27
Addy CRA	ACRA	20, Other	2013-NOV-11	2015-JAN-27

- Remove the duplicate(s) by setting the Requested Stop Date as today's date. At the same time, add a new record with the Requested Start Date as today's date with all applicable duties.

If only one set of duties applies:

- Remove the duplicate(s) by setting the Requested Stop Date as today's date

(C) Same Same Different Same

- Remove the duplicate(s) with the Requested Start Date that does not match their participation on the trial by setting the Requested Stop Date as today's date

Name	Role	Delegated Duties	Requested Start Date	Effective Start Date
Addy CRA	ACRA	2, 10, 11, 14, 15, 16, 17, 20, 21, 22, 23	2018-JUN-21	2018-AUG-28
Addy CRA	ACRA	2, 10, 11, 14, 15, 16, 17, 20, 21, 22, 23	2018-AUG-17	2018-AUG-28

(D) Same Same Same Different

- Remove the duplicate(s) with the Effective Start Date that does not match their participation on the trial by setting the Requested Stop Date as today's date

Name	Role	Delegated Duties	Requested Start Date	Effective Start Date
Dr. Sub Investigator	SI	2, 6, 10, 11, 14, 15, 16, 17, 19, 20, 21, 22, 23	2021-JUN-28	2021-JUL-06
Dr. Sub Investigator	SI	2, 6, 10, 11, 14, 15, 16, 17, 19, 20, 21, 22, 23	2021-JUN-28	2021-JUL-08

(E) Same Same Different Different

- Remove the duplicate(s) with the date that does not match their participation on the trial by setting the Requested Stop Date as today's date

Name	Role	Delegated Duties	Requested Start Date	Effective Start Date
Ethics CRA	ECRA	10	2018-AUG-27	2018-NOV-06
Ethics CRA	ECRA	10	2021-JUN-15	2021-JUN-15

(F) Same Different Same Different

If all duties apply:

Name	Role	Delegated Duties	Requested Start Date	Effective Start Date
Addy CRA	ACRA	10, 21	2018-JAN-25	2018-JAN-25
Addy CRA	ACRA	14	2018-JAN-25	2021-MAY-28

- Remove both records by setting the Requested Stop Dates as today's date. At the same time, add a new record with the Requested Start Date as today's date with all applicable Delegated Duties

If only one set of duties applies:

- Remove the duplicate by setting the Requested Stop Date as today's date

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No.	Role	Delegated Duties	Requested Start Date	Effective Start Date	Actions
(G) Same Different Different Same If all duties apply:					
					<ul style="list-style-type: none"> Remove both records by setting the Requested Stop Dates as today's date. At the same time, add a new record with the Requested Start Date as today's date with all applicable Delegated Duties
					<p>If only one set of duties applies:</p> <ul style="list-style-type: none"> Remove the duplicate by setting the Requested Stop Date as today's date
(H) Same Different Different Different If all duties apply:					
					<ul style="list-style-type: none"> Remove all the duplicates by setting the Requested Stop Date as today's date. At the same time, add a new record with the Requested Start Date as today's date with all applicable Delegated Duties
					<p>If only one set of duties applies:</p> <ul style="list-style-type: none"> Remove the duplicate by setting the Requested Stop Date as today's date
(I) Individual assigned ACRA/ECRA roles with overlapping duty 10 only					
					<ul style="list-style-type: none"> Remove the ACRA role by setting the Requested Stop Date as today's date
(J) Individual assigned PCRA and ACRA roles with overlapping duty(ies)					
					<p>If all PCRA duties apply:</p> <ul style="list-style-type: none"> Keep the PCRA role Remove ACRA role by setting the Requested Stop Date as today's date <p>If additional PCRA duties apply:</p> <ul style="list-style-type: none"> Remove both the PCRA and ACRA records by setting the Requested Stop Date as today's date. At the same time, add a new PCRA record with the Requested Start Date as today's

No.	Role	Delegated Duties	Requested Start Date	Effective Start Date	Actions
					date with all applicable Delegated Duties
(K)	Individual has more than one PPHARM/PHARM/PTECH roles				<ul style="list-style-type: none"> Keep the highest-level Role that reflects current role/participation (PPHARM > PHARM > PTECH) Remove the other roles by setting the Requested Stop Date as today's date
Name	Role	Delegated Duties	Requested Start Date	Effective Start Date	
Prince Pharmacist	PPHARM	15, 16	2015-FEB-16	2015-MAR-13	
Prince Pharmacist	PHARM	15, 16	2016-DEC-06	2016-DEC-13	

2.2 RIPPLE Roles Cleanup

Table 2.2 shows all the identified RIPPLE Role discrepancies with different scenarios and the corresponding actions from centres.

To remove PLA/PLD roles, log into RIPPLE, hover over “Centre Administration”, then click “Ripple Roles”. Under the tab “All Ripple Roles”, select the record(s) to be removed, click the checkbox in column ‘Remove’ and then select “Remove Selected” at the bottom of the page. In the pop-up “Confirm Remove” window, click “Remove” to confirm the removal.

To remove RRA roles, Centre Representatives (CENREPs) please complete and approve the RRA Designation Form from RIPPLE resource page and indicate the RRAs to be removed and the new RRAs to be assigned. For coverage purposes each centre must designate a minimum of 2 RRAs (and a maximum of 3).

Table 2.2 Different Scenarios of RIPPLE Role Discrepancies and the Corresponding Actions

Scenarios	Actions				
(A) Individual with duplicate PLA roles for the same trial, or for both ALL and individual trials	<p>If the member has a duplicate PLA role for the same trial:</p> <ul style="list-style-type: none"> Remove PLA duplicate(s) with the more recent Assignment Date <p>If the member indeed has PLA roles for ALL trials:</p> <ul style="list-style-type: none"> Remove the other trial-specific PLA roles <p>If the member only has PLA roles for specific trials:</p> <ul style="list-style-type: none"> Remove the ALL trial and add/keep applicable specific trials 				
Name	Trial	Role	Role Status	Assignment Date	
PL Administrator	AB12	PLA - Participants List Administrator	Active	2020-JAN-20	
PL Administrator	AB12	PLA - Participants List Administrator	Active	2019-NOV-26	
Name	Trial	Role	Role Status	Assignment Date	
PL Administrator	ALL	PLA - Participants List Administrator	Active	2021-FEB-14	
PL Administrator	TR10	PLA - Participants List Administrator	Active	2021-MAY-07	

(B) Individual with both RRA and PLAs

- Remove PLA role(s)

Name	Trial	Role	Role Status	Assignment Date
Remote Rosadmin	ALL	PLA - Participants List Administrator	Active	2021-AUG-30
Remote Rosadmin	n/a	RRA - Remote Roster Administrator	Active	2021-MAR-09

(C) Inactive member with active RRAs, PLAs, PLDs

- Remove active RRA/PLA/PLD role(s)

Name	Trial	Role	Role Status	Assignment Date
Inactive Rosadmin	n/a	RRA - Remote Roster Administrator	Active	2019-OCT-22

(D) Individual with both active QI and PLD roles on the same trial

- Remove active PLD role

Name	Trial	Role	Role Status	Assignment Date
Dr. Quali Investigator	AB12	PLD - Participants List Delegate	Active	2020-JAN-01

Name	Role	Delegated Duties 	Requested Start Date	Effective Start Date
Dr. Quali Investigator	QI	1, 2, 3, 6, 10, 11, 14, 15, 16, 17, 19, 21 	2019-DEC-01	2019-DEC-01

3 Reminders

RRAs will receive monthly reminders if their centre has any Trial PL Role or RIPPLE Role that needs to be reassigned or removed.

3.1 Trial PL Role Email Notification Template

To: RRAs
From: ripple@ctg.queensu.ca
Subject: CCTG Duplicate Trial PL Role Cleanup Notification – CAXX
Message:
Duplicate Trial PL Role Cleanup Notification

Centre Code: CAXX
Institution: CAXX Institution Name
Month DD, YYYY

Greetings,

CCTG has identified duplicate PL role entries at your centre as attached. Please carefully review each record and take appropriate actions.

Please contact the RIPPLE Team at ripple@ctg.queensu.ca if you have any questions.

Thank you for your attention on this matter,
The CCTG RIPPLE Team

This is an automatic message. Please disregard this message if the above duplicate entries have already been cleared up.

(Below is the template for the attached Excel report)

RIPPLE URL	Trial	Name	Role	Delegated Duties	Requested Start Date	Effective Start Date	Participation Status	Scenario

3.2 RIPPLE Role Email Notification Template

To: RRAs
From: ripple@ctg.queensu.ca
Subject: CCTG RIPPLE Role Cleanup Notification - CAXX
Message:
CCTG RIPPLE Role Cleanup Notification

Centre Code: CAXX
Institution: CAXX Institution Name
Month DD, YYYY

Greetings,

CCTG has identified discrepancies in assigned RIPPLE roles at your centre as attached. Please carefully review each record and take appropriate actions.

Please contact the RIPPLE Team at ripple@ctg.queensu.ca if you have any questions.

Thank you for your attention on this matter,
The CCTG RIPPLE Team

This is an automatic message. Please disregard this message if the above duplicate entries have already been cleared up.

(Below is the template for the attached Excel report)

RIPPLE URL	Name	Member Status	Trial	Role	Assignment Date	Scenario

4 Revision History

Version Number	Version Date	Brief Description of Revision(s)
V001	January 7, 2022	Initial Release
V002	July 27, 2022	Addition of Scenario (D) under section 2.2