

IMPACT OF CHANGES IN DTL INDIVIDUAL TASK STATUS:

Notes: The data that is entered in the DTL Components of RIPPLE are transferred to the NCI DTL. In addition, information is sent to RIPPLE by the NCI DTL including start and end dates, new template revisions, changes in status of the DTL and individual task assignments.

Over the course of the trial, the credentialing for an individual may change from requirements met to requirements not met. For example, if an individual's CTEP registration status is no longer "active" as the annual renewal was not completed. In this case, the following would happen:

1. The relevant task assignments for this individual would be changed to "inactive" and an end date would be populated by the DTL and status reason will state "QI/CI re-approval is required".

2. A duplicate task assignment for this individual would be created with a task status of "pending" as credentialing requirements are not met. As the individual's task assignments are now "pending" their access to some systems will be restricted (e.g., read only access in OPEN) and they should not be performing any tasks which are not active.

IF THE PARTICIPANT IS THE ONLY INDIVIDUAL ASSIGNED TO A MANDATORY TASK:

The overall status of the site DTL will also change to "unapproved". This means:

(a) Site registration status is no longer active and enrollments are no longer permitted.

(b) Other individuals on the DTL remain compliant and therefore their task assignments remain "active" and their access to systems is not affected.

(c) New task additions and removals will not be processed until either the individual's credentialing requirements are now met OR another individual who meets the credentialing requirements is assigned that mandatory task(s).

3. A notification would be sent by CTEP to the individual with the credentialing issue. A notification that the task is "inactive" would be sent by RIPPLE to the affected individual.

(d) A notification is sent to the CI and DTL-A(s) of the status change and the reason.

IF THE PARTICIPANT IS NOT THE ONLY INDIVIDUAL ASSIGNED TO A MANDATORY TASK:

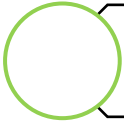
Overall status of the site DTL will remain as "approved" and the issue will only be at the level of the individual task assignments.

ONCE THE CREDENTIALING IS RESOLVED:

Notes: From the NCI DTL perspective, all task additions do not require QI/CI approval. Therefore, if the credentialing issue is resolved (e.g., CTEP registration status is now active) there are various scenarios.

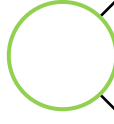
DOES THE NCI DTL REQUIRE QI/CI APPROVAL?

YES

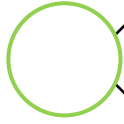


(i) The task assignment will change to "awaiting CI approval".

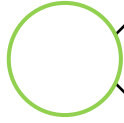
NO



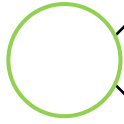
(i) The task assignment will automatically be changed to "active" and a start date will be populated. However, the status reason will indicate QI/CI re-approval of the task is required.



4. CCTG requires QI/CI approval of all additions and removals. Therefore, all tasks in this situation will be sent for QI/CI approval.



5. Move onto 'Approving DTL Tasks After the Initial DTL Approval'.



6. Once all mandatory tasks have at least one individual with an "active" status, the overall DTL status will change back to "approved" which will in turn permit enrollments to resume on the trial.