

## Introduction

This quick reference guide provides Lead Academic Organization (LAO), accruing LAO, and Affiliated Organization (AO) staff with a high-level overview of the study and accruing LAO and AO activation requirements for the Cancer Prevention Clinical Trials Network (CP-CTNet). This document includes the following four infographics: *Study Activation* (page 2), *Accruing LAO or AO Activation to a Study* (page 3), *Accruing LAO or AO Activation to a Protocol Amendment Approved When a Study is Open to Accrual* (page 4), and *Accruing LAO or AO Activation to a Protocol Amendment Approved When a Study is Closed to Accrual* (page 5). For more information about the process of study and accruing LAO and AO activation for CP-CTNet, see [SOP 01-03 Accruing LAO and AO Activation](#) and the [CP-CTNet Accruing LAO and AO Activation Checklist for LAOs](#). See the table below for a list of acronyms used throughout this document.

Acronym	Definition
AO	Affiliated Organization
CIRB	Central Institutional Review Board
CP-CTNet	Cancer Prevention Clinical Trials Network
DCP	Division of Cancer Prevention
DMASC	Data Management, Auditing, and Statistical Center
LAO	Lead Academic Organization
PIO	Protocol Information Office
PSU	Protocol Status Update Form
SSW	Study-Specific Worksheet

Contact the DMASC Education and Training Team at [Training\\_CP-CTNet@frontierscience.org](mailto:Training_CP-CTNet@frontierscience.org) with questions about this quick reference guide.

## Study Activation

Study activation is the process of opening a study to enrollment and data entry once the study has received final approval from DCP and **has been implemented in the Stars registration/randomization system (Stars) and Medidata Rave by DMASC**. This infographic provides an overview of the steps to activate a CP-CTNet study.



The LAO and DMASC receive the DCP Final Study Approval letter from DCP PIO.



DMASC emails the LAO to notify them that the study has been implemented in Stars and Medidata Rave, and is ready to open for enrollment and data entry once the accruing LAOs and AOs are ready.



The LAO submits the PSU to DCP PIO to indicate that the study is active.



DCP PIO emails the LAO to acknowledge receipt of the PSU, which indicates that DCP PIO submitted the PSU to the CIRB. The LAO is responsible for notifying the accruing LAOs and AOs that the study is active. All accruing LAOs and AOs may now submit their SSWs to the CIRB.

## Accruing LAO or AO Activation to a Study

Accruing LAO or AO activation to a study is the process of ensuring that an accruing LAO or AO meets all requirements and has the necessary systems access to participate in a study. This process results in permission being granted to enroll participants and enter data for a given study. This infographic provides an overview of the steps to activate an accruing LAO or AO to a study.



The LAO works with the accruing LAO or AO to ensure that all requirements for accruing LAO or AO activation are met as per the [CP-CTNet Accruing LAO and AO Activation Checklist for LAOs](#).



The LAO emails DMASC to confirm that the accruing LAO or AO has met all activation requirements as per the [CP-CTNet Accruing LAO and AO Activation Checklist for LAOs](#).



DMASC activates the accruing LAO or AO in the Protocol Approval module in Stars.



DMASC sends a *Confirmation of Site Activation* email to indicate that the accruing LAO or AO is officially open to accrual in Stars. This email is sent to the LAO, the accruing LAO or AO, the DCP Study Team, the DCP Regulatory Contractor, and DCP PIO.



The LAO and accruing LAO or AO file the *Confirmation of Site Activation* email in their electronic or paper essential records binder for the study.



The LAO maintains a tracking list which includes the initial activation date for each accruing LAO and AO.

## Accruing LAO or AO Activation to a Protocol Amendment Approved When a Study is Open to Accrual

Depending on the nature of the protocol amendment, all the steps involved in the initial activation of an accruing LAO or AO may not need to be followed when activating an accruing LAO or AO to a protocol amendment when a study is open to accrual. This infographic provides an overview of the steps to activate an accruing LAO or AO to a protocol amendment that is approved when a study is open to accrual. **Note:** DMASC implements the CIRB- and DCP-approved protocol amendment in Medidata Rave (if needed) concurrently with the steps below.



DMASC implements the CIRB- and DCP-approved protocol amendment in Stars.



DMASC emails the LAO to notify them that the protocol amendment has been implemented in Stars, and is ready to open for enrollment once the accruing LAOs and AOs are ready.



The LAO sends the CIRB- and DCP-approved protocol amendment to the accruing LAOs and AOs.



The LAO works with the accruing LAO or AO to ensure that all requirements for accruing LAO or AO protocol amendment activation are met as per the [CP-CTNet Accruing LAO and AO Activation Checklist for LAOs](#).



The LAO emails DMASC to confirm that the accruing LAO or AO has met all protocol amendment activation requirements as per the [CP-CTNet Accruing LAO and AO Activation Checklist for LAOs](#).



DMASC activates the accruing LAO or AO to the protocol amendment in the Protocol Approval module in Stars.



DMASC sends a *Confirmation of Site Activation to Protocol Amendment* email to indicate that the accruing LAO or AO is officially open to accrual to the protocol amendment in Stars. This email is sent to the LAO, the accruing LAO or AO, the DCP Study Team, and the DCP Regulatory Contractor. **Note:** The accruing LAO or AO is not activated to the protocol amendment until they receive the *Confirmation of Site Activation to Protocol Amendment* email from DMASC.



The LAO and accruing LAO or AO file the *Confirmation of Site Activation to Protocol Amendment* email in their electronic or paper essential records binder for the study.

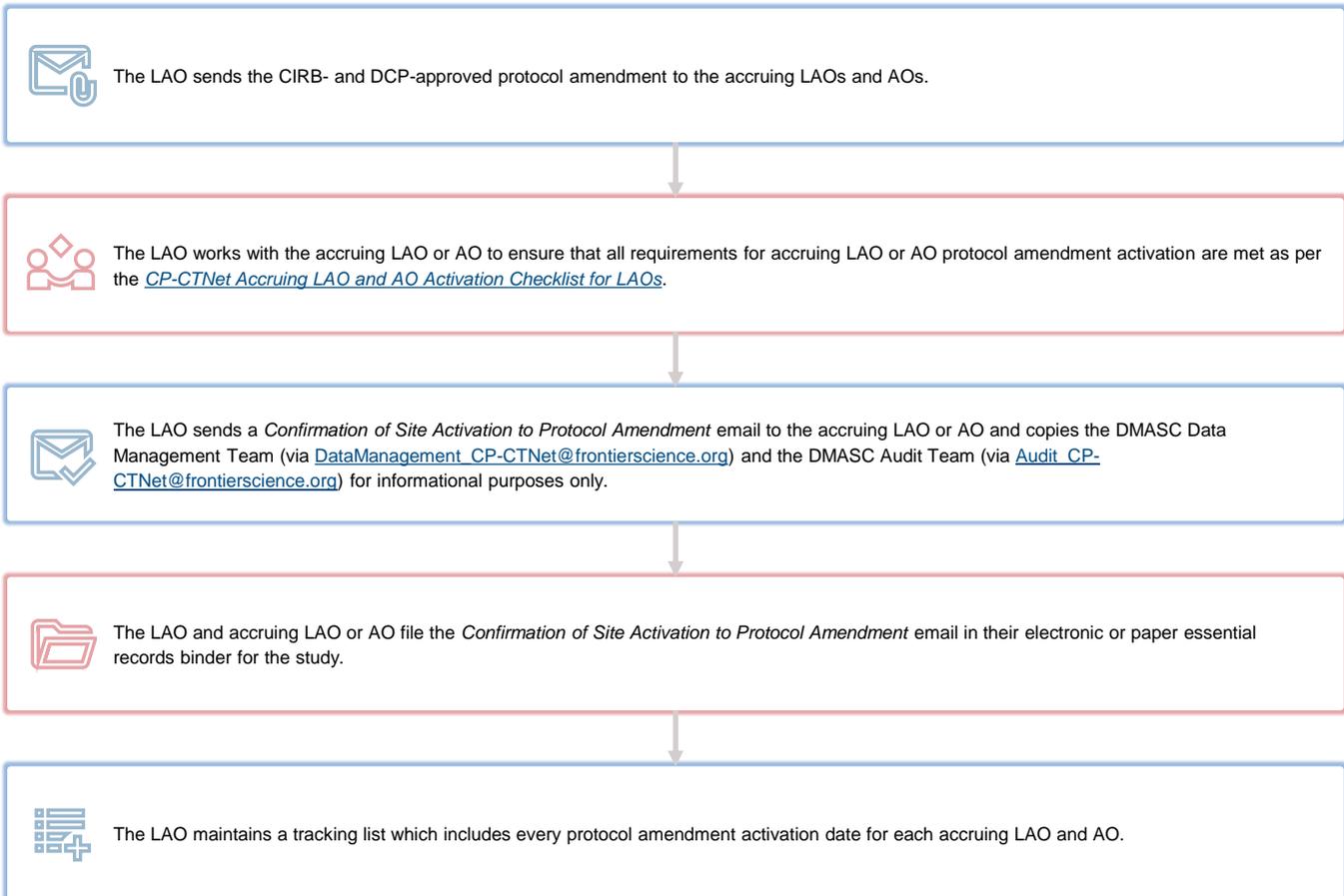


The LAO maintains a tracking list which includes every protocol amendment activation date for each accruing LAO and AO.

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## Accruing LAO or AO Activation to a Protocol Amendment Approved When a Study is Closed to Accrual

Depending on the nature of the protocol amendment, all the steps involved in the initial activation of an accruing LAO or AO may not need to be followed when activating an accruing LAO or AO to a protocol amendment when a study is closed to accrual. This infographic provides an overview of the steps to activate an accruing LAO or AO to a protocol amendment that is approved when a study is closed to accrual. **Note:** DMASC implements the CIRB- and DCP-approved protocol amendment in Medidata Rave (if needed) concurrently with the steps below. However, the protocol amendment is not implemented in Stars when the study is closed to accrual.



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