REGIS Clinical Trial Decision Tree and Head of Department (HOD) Upload: July Release Notes

It has been identified that there is a discrepancy in the interpretation of the World Health Organisation (WHO) definition of a Clinical Trial. To assist in a common understanding of the definition, the NSW Health CTMS team have developed a series of questions to assist applicants during project registration to correctly identify when a study is a clinical trial and when the study should be entered into the NSW (or SWSLHD) Clinical Trial Management System (CTMS).

This document will take you through the additional questions that will be asked within the Project Registration form, SSA form, the classifications that will be created based on those responses to the additional questions and a newly created system generated CTMS tag that have been introduced to make identification and tracking of clinical trials easier in REGIS. **Note:** This is not a retrospective change.

Research governance offices will now also be able to manage and change their own HODs for departments and units related to their organisation and sites.

Release date for these changes is scheduled for Wednesday 17 July 2024.

Clinical Trial Decision Tree

Enhancement: Additional questions have been created within the Project Registration form at Part B to assist with correctly categorising clinical trials and based on responses in Part B, an additional question will be generated within the SSA form at Part A.

Classifications will also be created based on responses to these additional questions. A CTMS tag has also been created to easily identify studies that are expected to be entered into the NSW CTMS.

How will this affect the Researcher: Based on certain responses, researchers will notice additional questions have been added to the Project Registration form under Part B: Project Details and to the SSA form under Part A: Project-Wide Information.

Project Registration: Additional questions will populate, based on responses provided in Part B3 and B4.

B3.1 – B3.2: A new question has been created, B3.1 that asks whether the study is being conducted through a public hospital or public health site in NSW, ACT or TAS and will generate another question if B3.1 is answered Yes. The newly generated question B3.2 will asking if participants are prospectively assigned.

B3.1 Is this study being conducted through a Public Hospital or Public Health Site in NSW, ACT or TAS? *

(●) Yes ( ) No

B3.2 Are participants prospectively assigned? *

The term "prospectively assigned" refers to a pre-defined process (e.g., randomisation) specified in the protocol that stipulates the assignment of research subjects (individually or in clusters) to one or more arms (e.g., intervention, placebo, or other control).

( ) Yes ( ) No

B3.2 – B3.3: A further additional question, B3.3, will generate if B3.2 is answered Yes, asking if participants are assigned to one or more interventions.

B3.3 Are participants assigned to one or more Interventions? *

An intervention refers to any introduced change in procedure, treatment, or care that is being assessed for effectiveness or safety. These interventions include but are not limited to; drugs, devices, exercise, mental health, nutrition, diagnosis, biologicals and surgery.

Yes No

If Yes is selected for B3.3, a yellow warning box appears advising that the study meets the WHO & NCTGF definition of a clinical trial and should be submitted as a clinical trial. Question B4, Study Type, will automatically populate Clinical Trial when this question is answered Yes.

This study appears to meet the WHO & NCTGF definition of a clinical trial and should be submitted as a Clinical Trial.

If No is selected, a yellow warning box appears advising that this study does not meet the WHO definition of a clinical trial and to select the appropriate Study type at question B4.

This study **does not** meet the WHO definition of a clinical trial please select the appropriate Study type at B4.

B4a: When the study type is Clinical Trial, an additional question will now appear, B4a, which asks if individual NSW public hospital patients are receiving the intervention.

B4 Study type *

Clinical trial

B4a Are individual **NSW** public hospital patients receiving the intervention? *

Yes No

If Yes is selected, a yellow warning box appears advising that the study must be entered into the NSW Health CTMS whilst noting that South Western Sydney Local Health District use their own CTMS, so sites in this district are not required to use the NSW Health CTMS. If No is selected, no warning box appears.

This study must be entered into the NSW Health CTMS (more info).
Please note South Western Sydney Local Health District are using their own CTMS and this must be entered in the local SWSLHD CTMS not the NSW Health CTMS.

On the last page of the Project Registration form, yellow warning boxes will appear, based on responses provided at questions B3.1 – B3.3, advising the study meets the WHO & NCTGF definition of a clinical trial and should be submitted as a clinical trial. If clinical trial has already been selected at question B4, then no action is required and the study must be entered into the NSW Health Clinical Trial Management System (CTMS) or local SWSLHD CTMS as appropriate to the study.

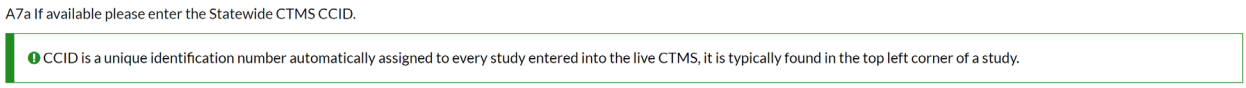
Based on the responses at questions B3.1 - B3.3, this study meets the WHO & NCTGF definition of a clinical trial and should be submitted as a clinical trial. If B4 is clinical trial, no further action is required.

This study must be entered into the NSW Health Clinical Trial Management System (read more about CTMS here) or local SWSLHD CTMS, as appropriate to the study.

SSA: An additional question has been added in Part A which will only appear if the application has a CTMS classification of Yes.

When the application has a CTMS classification of Yes, question A7a asks "If available please enter the Statewide CTMS CCID".

The additional questions that appear on the form during completion, will also appear on the output form (e.g. pdf).

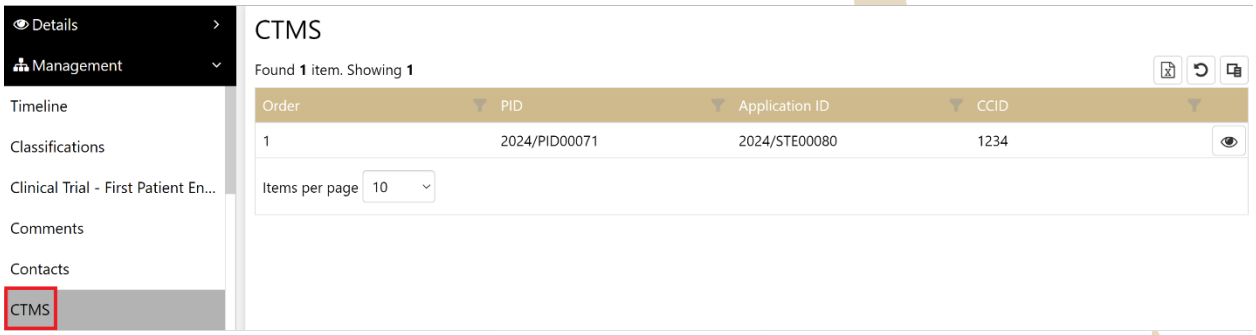


How will this affect the RO: Research offices will notice additional classifications and a new system generated tag for studies that are categorised as clinical trials, in accordance with the World Health Organisation (WHO) definition.

Upon initial submission of an STE application, a system generated 'CTMS' tag will automatically appear on the STE, where the review pathway and ETH approved tags currently appear.

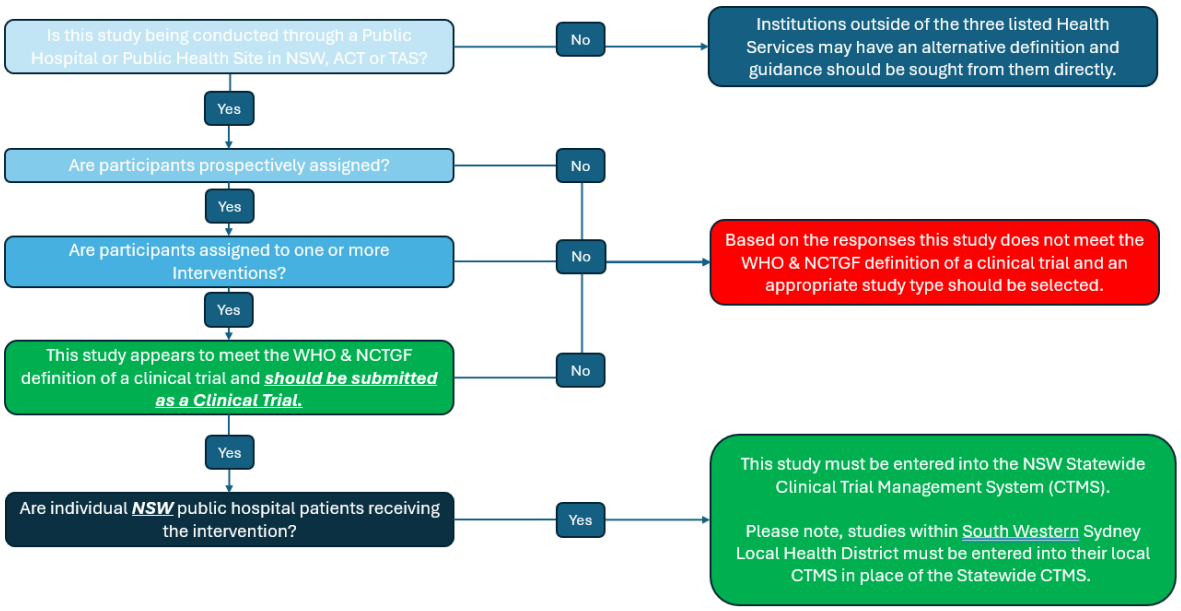
Within the Classifications of the application, a CTMS classification will now appear. This classification will automatically transfer to the Project upon authorisation

A new CTMS header in the left-hand menu of the application, under Management, has been created and will pull the PID and STE identifiers and the CCID entered into the STE.

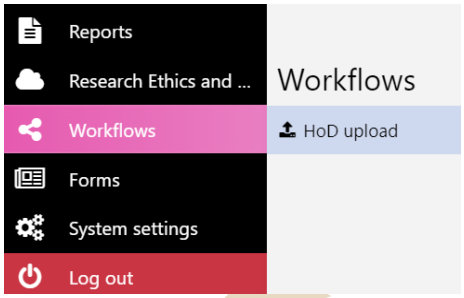


The classifications are reportable, and the REGIS team is currently investigating existing dashboards to identify where this new classification data will be available.

Clinical Trial & CTMS Decision Tree



Head of Department (HOD) Upload



Enhancement

A menu called 'Workflows' will be visible in the left-hand menu to research governance office staff members who have been given super user access. A new permission group has also been created to manage this access.

How will this affect the Researcher:

Nil Impact.

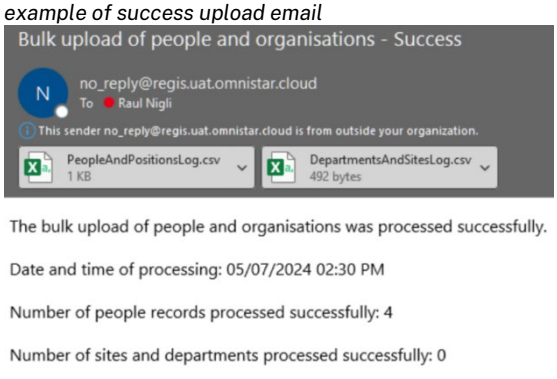
How will this affect the Research Office:

Users who have super user access will be able to see the 'Workflow' menu option and upload the Head of Department (HOD) data into REGIS, via the 'HoD upload' option.

This will enable them to upload their HOD excel spreadsheet directly into REGIS and make the relevant staff changes without having to contact the NSW eHealth REGIS team. These changes are made in real-time and go into effect immediately.

Super users will receive an email direct to them, confirming if the changes have been made or not, along with any success/error messaging. These changes are limited to HODs only, any changes to sites and departments will still need to be sent to the NSW eHealth REGIS team for approval and action.

example of success upload email



example of failure upload email