REGIS Comms – Tuesday 18 May

Hello All,

In this issue (9):

In this issue:

- Metrics – what is causing calculation errors
- Applications not appearing on reports and dashboards – issue identified and fixed (see attached)
- Certificate of Currency milestone – RGO needs to update due date (see attached)
- Researcher Training – Feedback
- Research Office Training – next session reminder
- Future Release – 26 May tentative date
- Configuration and form changes – from 19 May
- Research Office Contribution – noting yet.....

Metrics

Metrics are calculated using an algorithm which relies on status changes occurring in an orderly fashion. The delay in producing the 2021 Q1 Metrics Report is partially down to significant quality checks which have been required due to an increase in anomalous metric results. A closer look at these results have revealed that a number of offices are making manual changes to the flow of applications which is causing the system to trip. **Please do not make manual changes**. REGIS is designed to allow the flow of an application to be captured automatically. If you process an application wholly in REGIS (which you should) there are very few reasons why you would need to make a manual status change. However, we can see that some users are employing this technique where they shouldn't and it is causing the calculations to produce a result which is often much higher than it otherwise would be if it were processed normally.

If you are not sure about when a manual change should be made, please contact the REGIS team.

If there is a consistent system issue or reason for making manual changes you should discuss this with your User Group member who will log this as an issue to follow up or as an enhancement request.

User Group members can log issues or enhancement requests here

Applications not appearing in Dashboards and Reports

Issue: Research Offices have reported instances of applications not appearing in the dashboard or in reports.

Outcome: Research Offices are manually adding attachments to approval/authorisation emails that exceed 10MB and the emails are not being sent. Emails being sent is the critical measure/filter for reports, dashboards and metrics.

Outgoing emails that have over 10mb of manual attachments will not be sent.

Action Required: Research Offices should upload any signed contracts into the Related Documents section of the STE Application and then select them to appear in the authorisation email link.

See Attached (below): How to upload singed contracts into the Related Document Section

Certificate of Currency due date – RGO needs to manually update when authorising

Issue: Researchers have reported that the Certificate of Currency milestone is due the day after the study is authorised.

Background/Current functionality: A Certificate of Currency milestone is automatically created in the STE project when a Commercially or Collaboratively Sponsored Clinical Trial (identified through classifications) is authorised.

The milestone is created on the first STE when it is authorised and is given a due date of the day AFTER authorisation.

Due to the variability of when a Certificate of Currency (CoC) expires the system is currently not automating the correct the due date.

Action Required: The Research Office needs to manually update the CoC milestone due date after authorisng the study.

If the CoC is valid for the entire study, the milestone can be deleted as the CoC will not need to be submitted again.

If the CoC has not created it is because it has been created on another STE, you do not need to create a new milestone.

See Attached (below): How to update the due date of the CoC milestone

Researcher Training – feedback to date.
Since registrations opened in February, we have had over 695 people register their interest and the 10 cycles filled, within a week!

The first cycle of Researcher training was held last week and the feedback has been very positive so far. Attendees have indicated that after the sessions they feel more confident using REGIS, have enjoyed how informative the sessions have been, how REGIS has gotten more user friendly and has more help options.

We also received some feedback around the inconsistency with what they are being shown in the training versus what they are being told by their Research Office, i.e. Some applicants are being told not to upload .zipfiles as REGIS does not allow .zipfiles to be opened or that applicants need to

upload the Ethics approved amendment documents when Ethics exists in REGIS for Site amendments.

Please note REGIS does allow for .zip files to be uploaded, if you are experiencing issues opening .zip files please let us know so we can investigate if this is a REGIS issue or local IT issue.

Upcoming Research Office Education Sessions

Research Office REGIS online training will be held every two months. The next session will be held in June, see agenda and dates below. We encourage any new staff to attend these sessions and anyone wishing for a refresher course.

A link to register will be included in the next REGU/REGIS newsletter.

Training Cycle Agenda
Day 1: (AM/PM sessions are mandatory) AM Session: Understanding the system and settings. PM Session: Ethics and Governance Eligibility.
Day 2: Ethics session – Review and Meeting
Day 3: Ethics session – Create decisions from within a Meeting and from the Application
Day 4: Governance session – Review and Authorisation
Day 5: Governance session – Review and process Amendments, Safety Reporting and Milestone
Day 6: Optional session – Managing and updating the Head of Department List

June REGIS Training	
Pre-Training Setup: All Users	Wednesday 16 June 2021
Day 1: All Users	Monday 21 June 2021
Day 2: Ethics	Tuesday 22 June 2021
Day 3: Ethics	Wednesday 23 June 2021
Day 4: Governance	Thursday 24 June 2021
Day 5: Governance	Friday 25 June 2021
Day 6: Optional	Monday 28 June 2021

Future Releases

As part of the enhancements scheduled to be released this financial year, the following are currently being tested. Pending release date is Wednesday 26 May but may be changed. A confirmed release date will be advertised on the REGIS log in pages.

STE Decisions – More information

Issue: Currently when a more information form is submitted by an applicant (this could be from a site amendment or site safety form) the submitted documents do not automatically appear to download.

Enhancement: The system will automatically include the documents in the decision download. RGO's no longer have to manually identify and select the documents.

How will this affect the RO: RGO's will automatically be provided the output form and any attachments that were submitted with the more information form.

How will this affect the Researcher: Researchers should notice no difference.

Notification of an amendment to a research study – HREC extension

Issue: Currently a RO needs to manually create a milestone if there is a HREC extension. Many RO are not doing this. A new milestone to be auto created on extension.

Enhancement: When a HREC extension is approved additional milestones are created automatically. If 12 Months or more milestones added per rule each 12 months. If less than 12 months new milestone with new end date.

How will this affect the RO: RO will no longer need to manually create Ethics progress report milestones.

How will this affect the Researcher: Researcher will now have a milestone available for every 12 months.

ETH Application – Not approved – STE flow
(passed when decision made in decisions)

Issue: When an Ethics application has an Application Decision Not approved the decision needs to be communicate to the Sites.

Enhancement: When an Ethics application has a Not Approved decision any site applications should be "Withdrawn"

How will this affect the RO: When an ethics application is "Not Approved" the system will automatically change the status of any Site applications to Withdrawn.

How will this affect the Researcher: Researchers will see the application status of Withdrawn

ETH Application – Withdrawn – STE flow

Issue: When an Ethics application has been withdrawn this needs to be communicated to the sites and the site application needs to be locked out. Currently this is should be done manually by the reviewing HREC communicating to the sites but it is not and often the Sites continue reviewing the site application when they don't need to.

An ethics application can be withdrawn 3 ways:

- By the researcher through communication to the HREC
- By the Research Office manually changing the status
- By the system when a study has been ineligible for 60 days

Enhancement: When an ETH is withdrawn any related sites should also be withdrawn by change of status.

How will this affect the RO: When an ethics application is "Withdrawn" the system will automatically change the status of any Site applications to Withdrawn.

How will this affect the Researcher: Researchers will see the application status of Withdrawn

ETH & STE application – more information requested – no response 30 days

Issue: Research Offices want a study that has had a request for more information that has not been responded to in 60 days, to follow the same flow as when a study is made ineligible and a new version not submitted in 60 days. System withdrawn.

Enhancement: When an application (ETH or STE) has had a request for information and no response for 30 days the application should be withdrawn.

A system generated reminder will be sent to the CPI (ETH)/PI (STE) and Admin Contact at 15 and 25 days, on day 30 the system will change the status of the application to Withdrawn and send an email to notify of the action and that a new application will be required.

How will this affect the RO: No active changes to RO processing.

How will this affect the Researcher: A Researcher now has 30 calendar days to provide a response to a request for information for a new application. If a response is not provided the system will withdraw the application.

External Portal - HOD Decisions – After authorisation

Issue: Currently a Head of Department decision that has not been made remains open even after the STE recommendation is made. If a HOD decision is made after the authorisation the application status changes and causes confusion.

Enhancement: Once an STE has a recommendation by RGO decision completed any outstanding HODs cannot make a decision through the external portal.

How will this affect the RO: Nil change

How will this affect the Researcher: Nil change

External Portal - HOD Decisions – Filtering in external portal

Issue: if a HOD decision is overridden the outcome of the decision remains pending. It then sits on the HOD decision page like it's outstanding but can not be changed.

Enhancement: When HOD decision made outcome should show per the overridden outcome.

How will this affect the RO: Nil change

How will this affect the Researcher: Nil change

Internal portal – decisions

Issue: If the research office manually adds multiple HOD decisions the system only reads the first decision, this means if there is another HOD decision pending the status will change to Submitted or Information Provided even though there is still a pending decision. Status should not change until all HOD decisions have been made.

Enhancement: Where multiple separate HOD decisions are created in the internal portal the system should recognise when any HOD decisions are not yet completed and not progress.

How will this affect the RO: Increased confidence that all required decisions have been made.

How will this affect the Researcher: Nil change

Site application form – adding new HOD to new version

Issue: A researcher can currently add new new/additional HODs to a new version of the application form, but the system doesn't create a new decision for the new HODs or create and send the HOD email to the new HODs.

Enhancement: When new HOD's are added to a new version of the site application form the new HODs should receive an email requesting them to make a decision. The status should show as Completed pending HOD until all HOD's have made a decision.

How will this affect the RO: Increased confidence that all required decisions notifications have been sent.

How will this affect the Researcher: Nil change

Configuration and Form updates

From Wednesday 19 May COVID questions should no longer appear on newly created forms.

How will this affect the RO: Nil changes to current procedures

How will this affect the Researcher: Researches will no longer see COVID questions.

Research Office Contribution

Got something to share? Share it here.
We have a couple of Offices with items on the bubble so watch this space!

How to upload signed contracts into the Related document section

Option 1: Where draft or unsigned versions already exist in REGIS.

Click page edit on the right hand menu

Select edit item to unlock the data details

Click the Replace file toggle to "Yes"

Click or Drag and Drop to add the signed file

Update the title so it appears exactly how you want it to appear in the approval email and click save.

The title and system version will update, you can view previous version by clicking the view document version history icon

Option 2: Where the document does not yet exist in REGIS.

Click page edit on the right hand menu
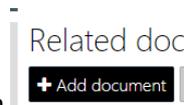
Click the "+ Add document" button

Click or Drag and Drop to add the signed file/s – you can select multiple documents at the same time.
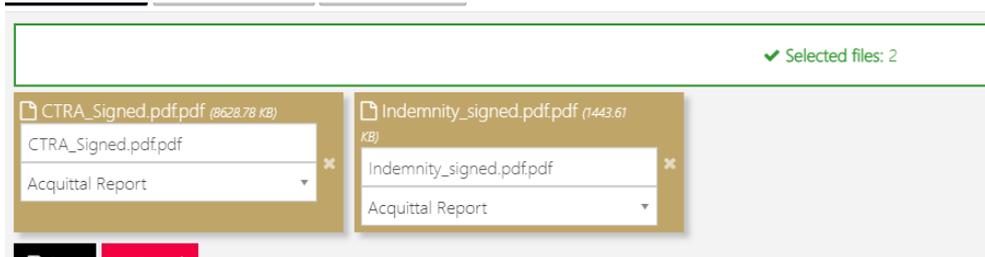
Update the title to what you want to appear in the approval letter.

Click the dropdown to update the document type, start typing to reduce the options

When all details are updated click Save.

Adding document to your letter
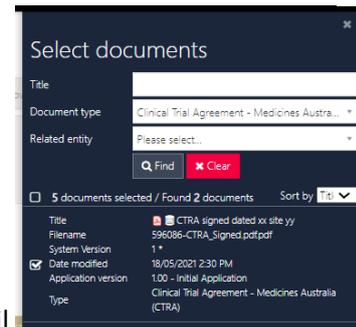
Follow the wizard to include the document/s in the approval email

You may choose to move around the dot points but you should not have to update the details as they are pulling through correctly from related documents.

The document will automatically be made available through the secure link
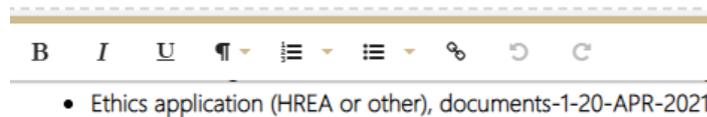
Any will be easily identified by the Researcher in the external portal.

How to update the due date of the CoC milestone

After sending the authorisation email, navigate to the STE Project, click the project icon on the right-hand menu.

- *Hint: If the authorisation email pulls through the Clinical Trial study type this should be a flag to check if a milestone is created*

Click Milestones, IF the Certificate of Currency milestone exists, click the page edit. If no milestone exists then no further action is required.
Select the Certificate of Currency Milestone.

Select 'Vary Milestone'

Navigate to 2. Change milestone date and update the 'New due date' per the expiry date of the CoC and add a reason for the change. Then navigate to the end of the wizard.

Click the send email toggle to No