ECOS

Navigating ECOS

(Ethics and Compliance Online System)

Compliance Module

- **Principal Investigator Self-Assessment Form (PISAF)**

National Healthcare Group
Adding years of healthy life

SingHealth
Defining Tomorrow's Medicine

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- What notifications there are

For Research Office (RO)

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1) Purpose of the Module

The PISAF is a self-assessment tool to be completed by the PI. The PI will self-assess on study processes (e.g., study conduct and informed consent).

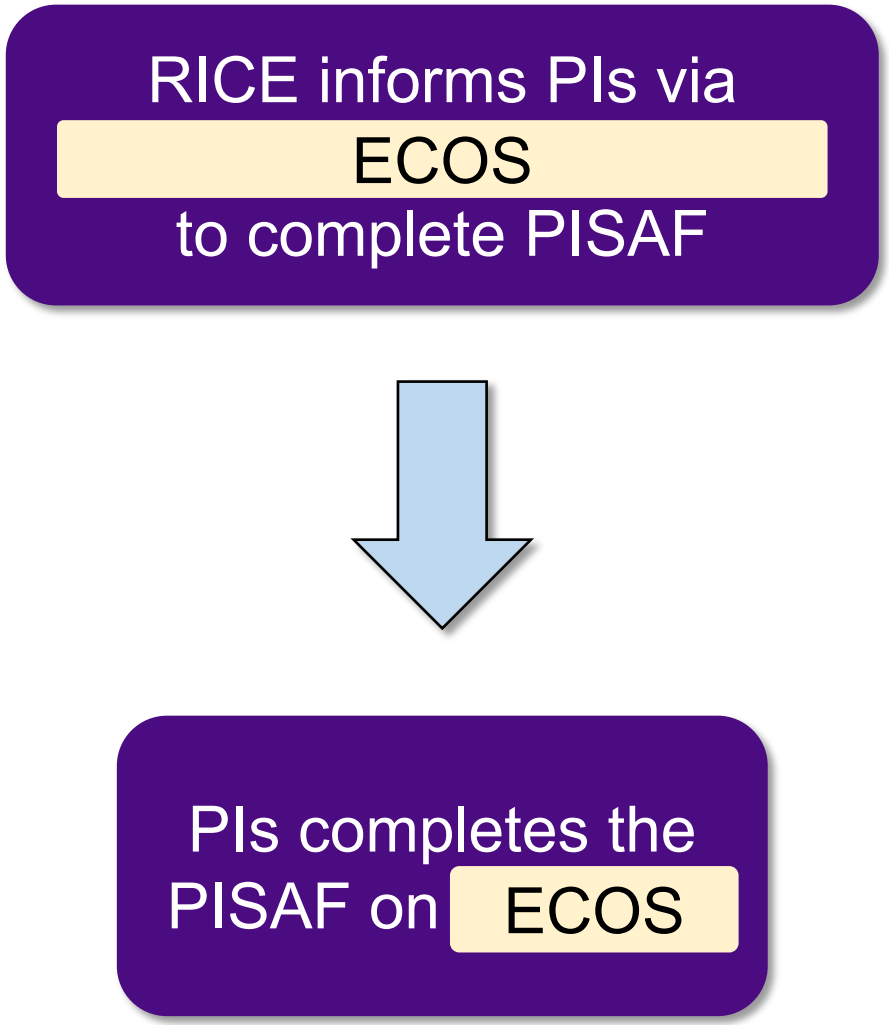
1. **Annual** completion for IRB approved studies:
    - CIRB & DSRB approved studies for **all** study classifications (i.e., HBR, Clinical Trials, others)
    - To be completed for **SingHealth sites only** (i.e., Submission will be done **at the site level (not study)** for SingHealth sites)
    - Sites where SingHealth is providing RI oversight for HBRA studies
    - **Excludes** industry sponsored, HSA-regulated Clinical Trials
    - **Excludes** other healthcare clusters (non-SingHealth PIs) for multi-site studies

PISAF will not be triggered in ECOS

2. PISAF may be triggered at other timepoints for specific studies (TBC)

Submission period: Jan 2025 to 14 Feb 2025, 23:59

2) ECOS Workflow

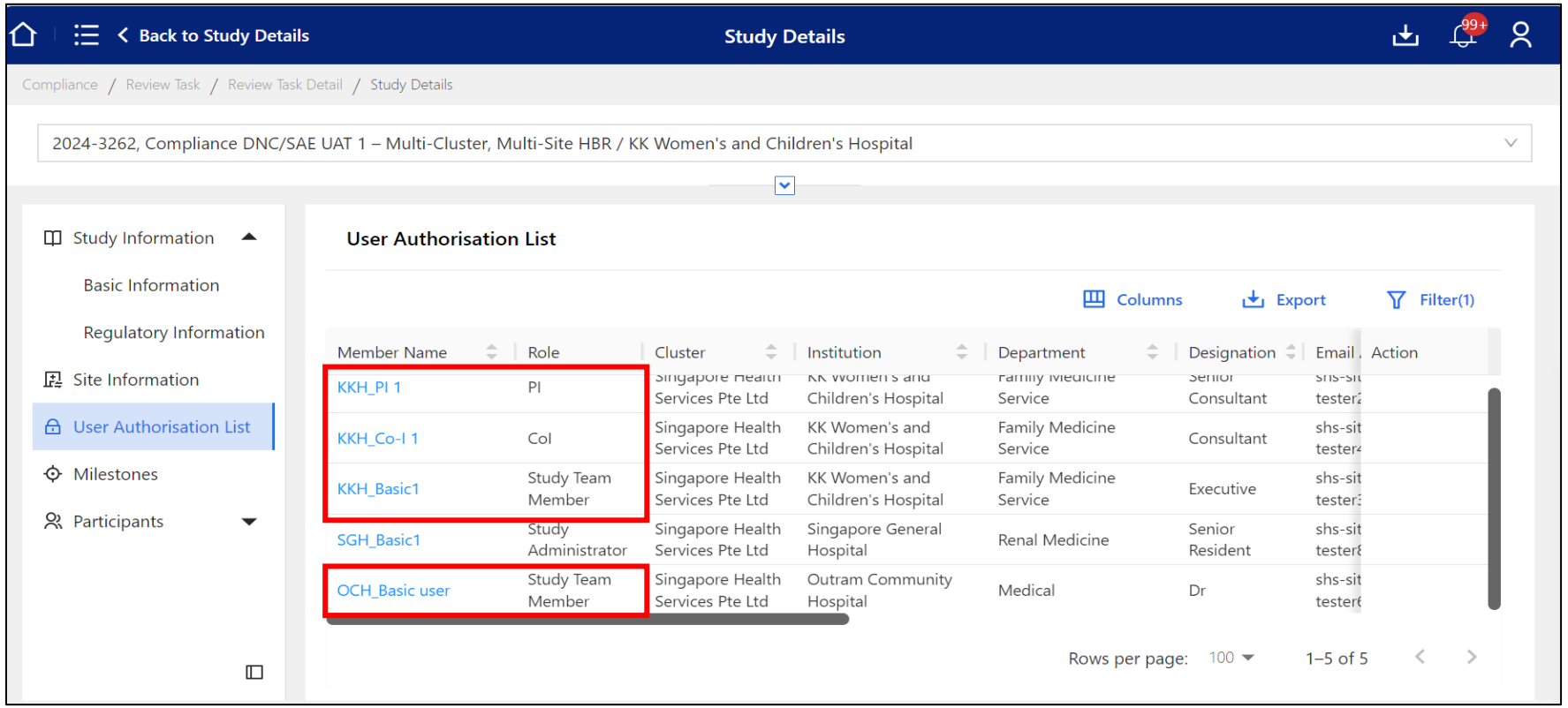


3) Module User Roles

User Roles	Level	Functions
PI / Site-PI	Site-specific	• Receive email and system notification on pending tasks. • Submit the PISAF.
Co-I & Study Team Member(s)	Site-specific	• Receive email and system notification on pending tasks. • Able to draft the PISAF.
PISAF Reviewer	SingHealth Cluster	• Reviews the PISAF.
Research Office	Institution	• View all tasks for its respective institution(s). • View and download reports on the PISAF task statuses and responses submitted.

3) Module User Roles

- Information of site-specific Study Team Members (STMs) are taken from the CRMS Module – User Authorisation List (UAL).
- **Site-specific PI, Co-I and STMs** can complete the PISAF. **There is no function for the Study Administrator and Study Sponsor in the Compliance Module.**



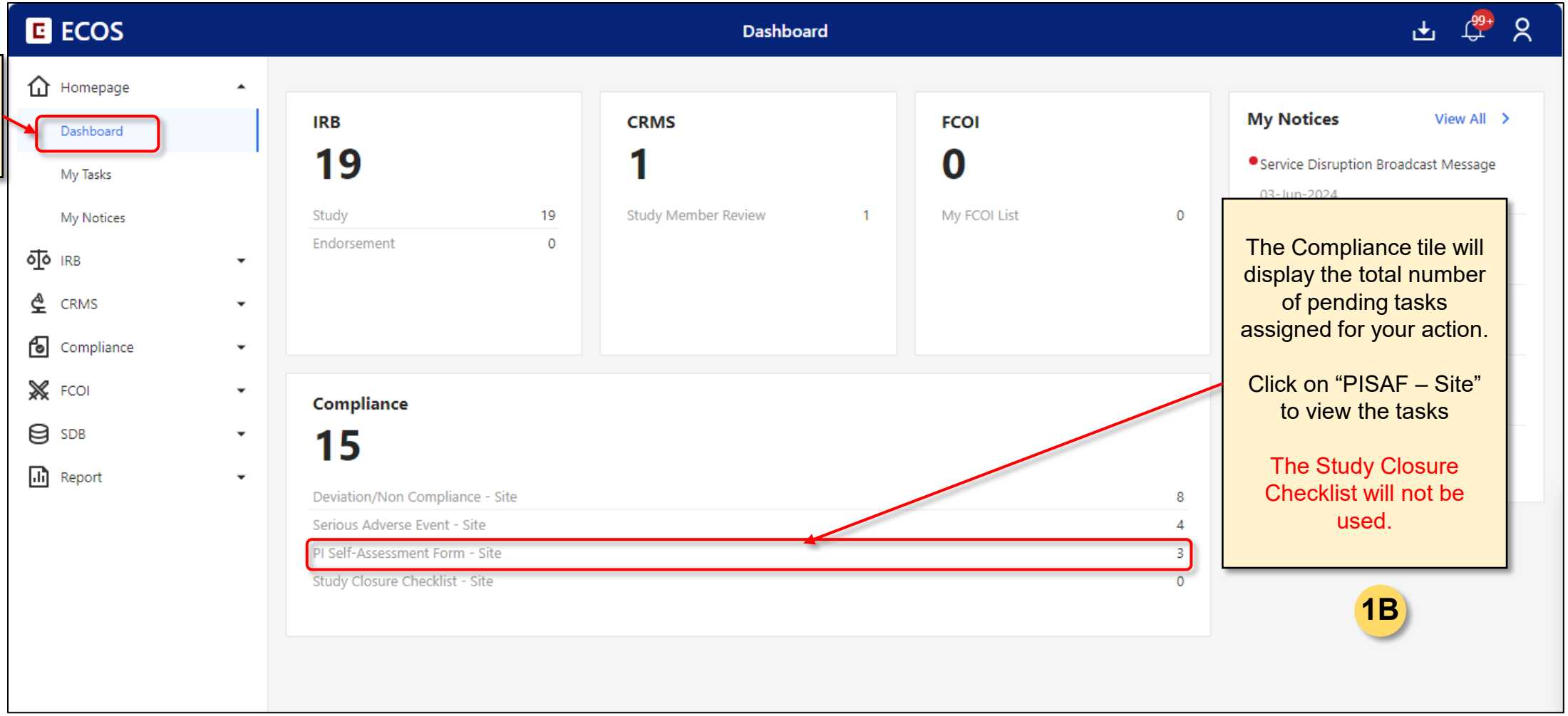
Please add the Study Team Member(s) in CRMS UAL if this has not been done.

4) Navigating the Module: When will you receive a task?

You will receive a task when:	Task Status
a) There is a PISAF for you to complete.	• Pending

4) Navigating the Module: Where to find your tasks?

To find pending tasks **assigned for your action**, there are 2 ways:



1A Click on 'Dashboard', under 'Homepage'

The Compliance tile will display the total number of pending tasks assigned for your action.

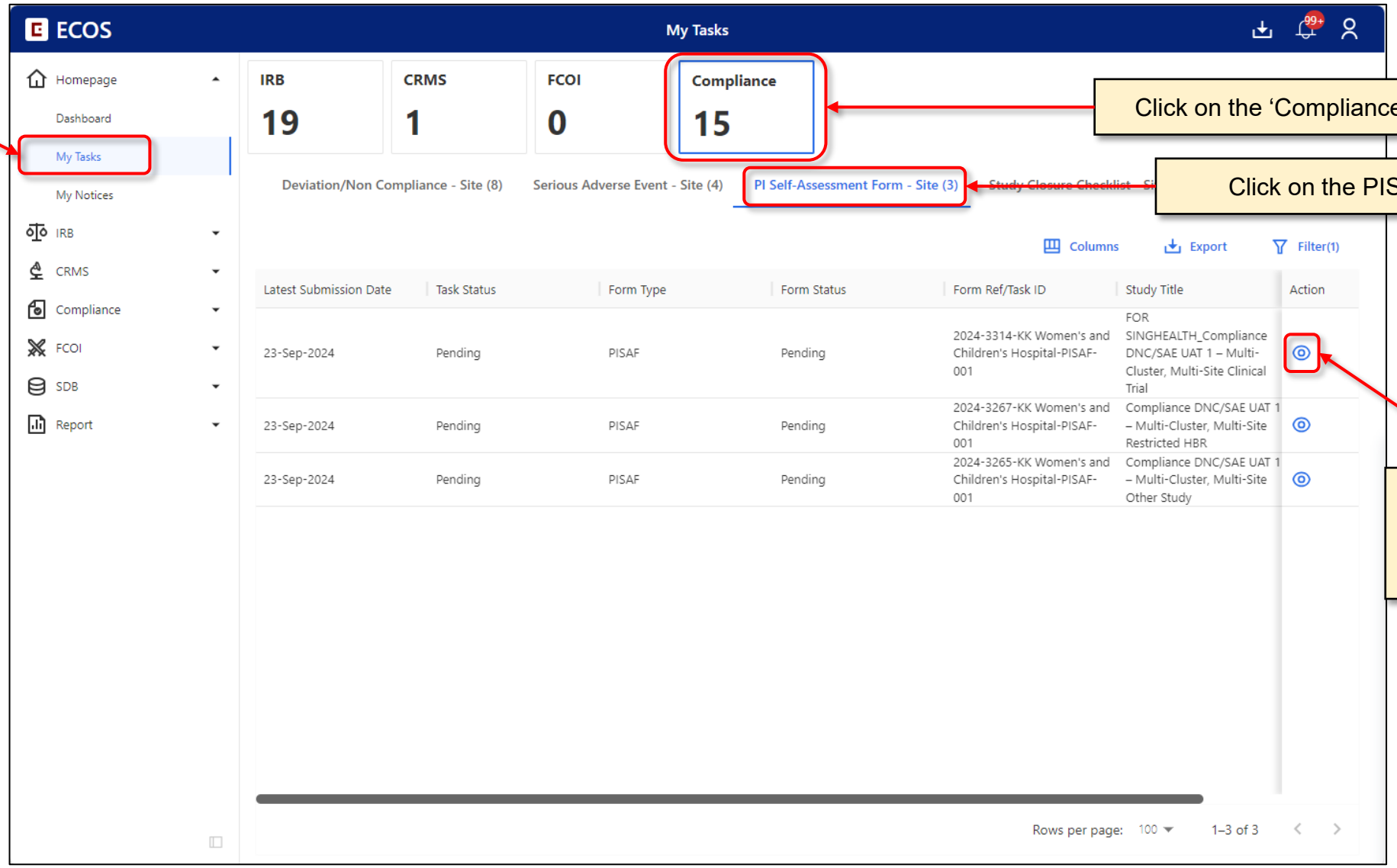
Click on "PISAF – Site" to view the tasks

The Study Closure Checklist will not be used.

1B

4) Navigating the Module: Where to find your tasks?

To find pending tasks **assigned for your action**, there are 2 ways:



2A Click on 'My Tasks'

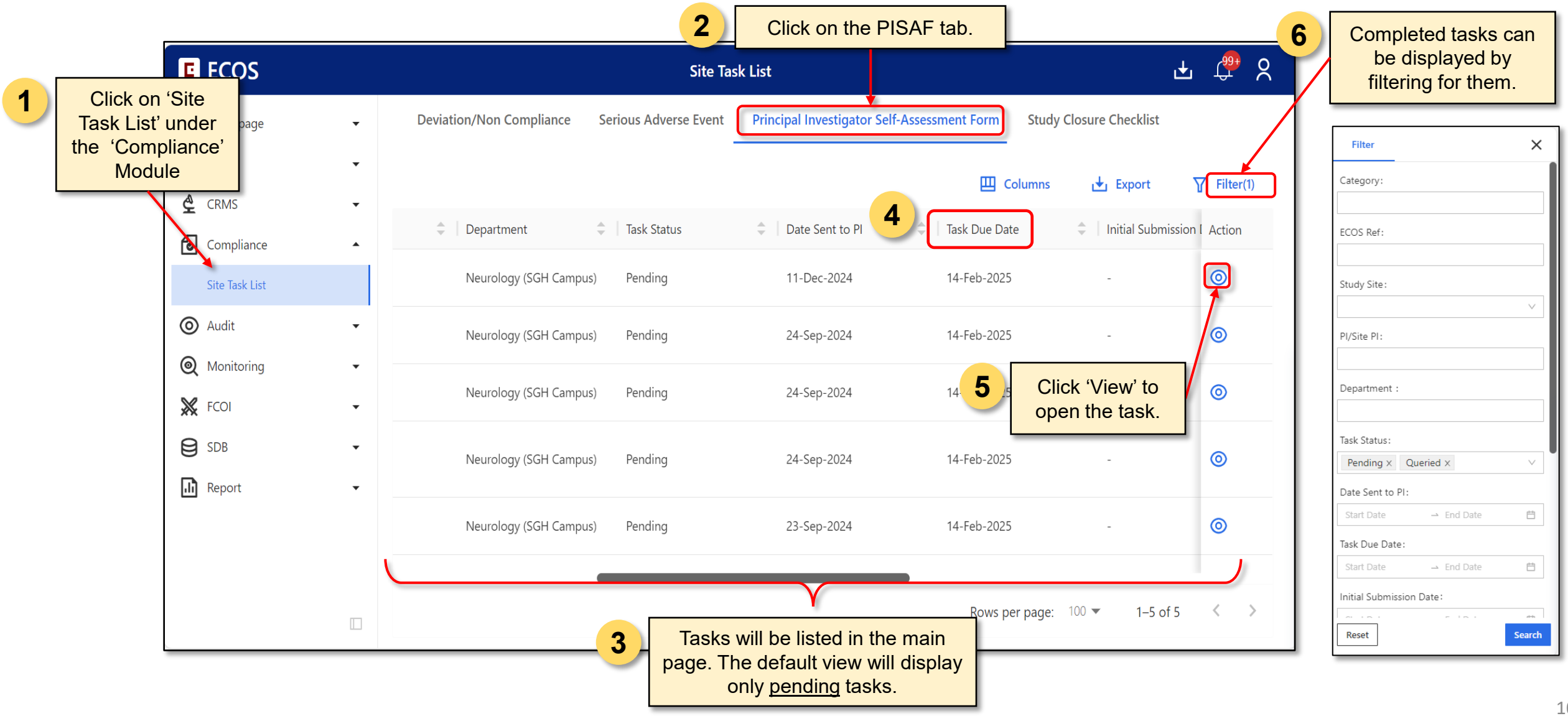
Click on the 'Compliance' tile. 2B

Click on the PISAF tab. 2C

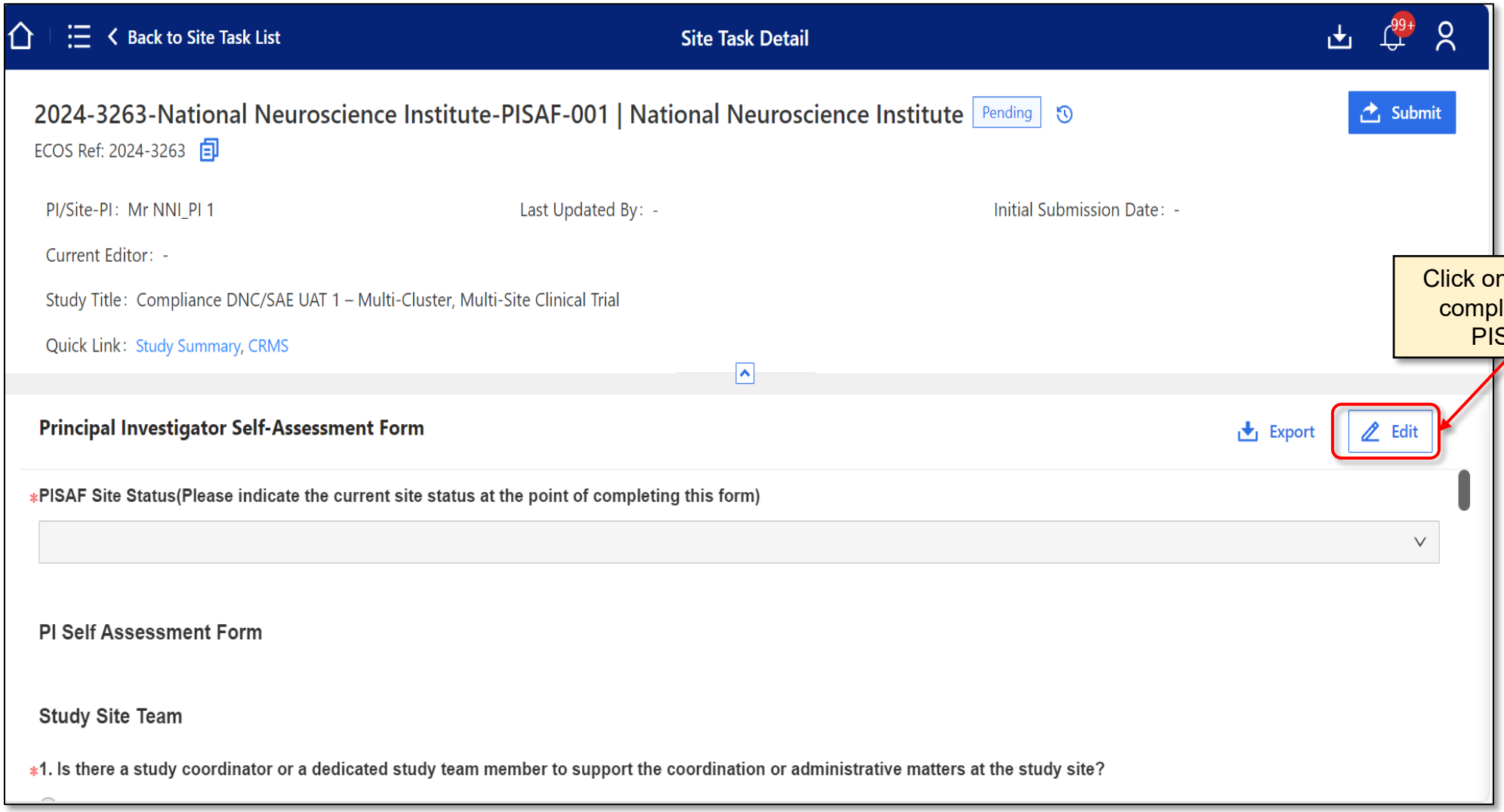
Click 'View' to see the task details. 3

4) Navigating the Module: Where to find your tasks?

To find **ALL** pending tasks **for ALL your studies**:



4) Navigating the Module: How to complete the PISAF?



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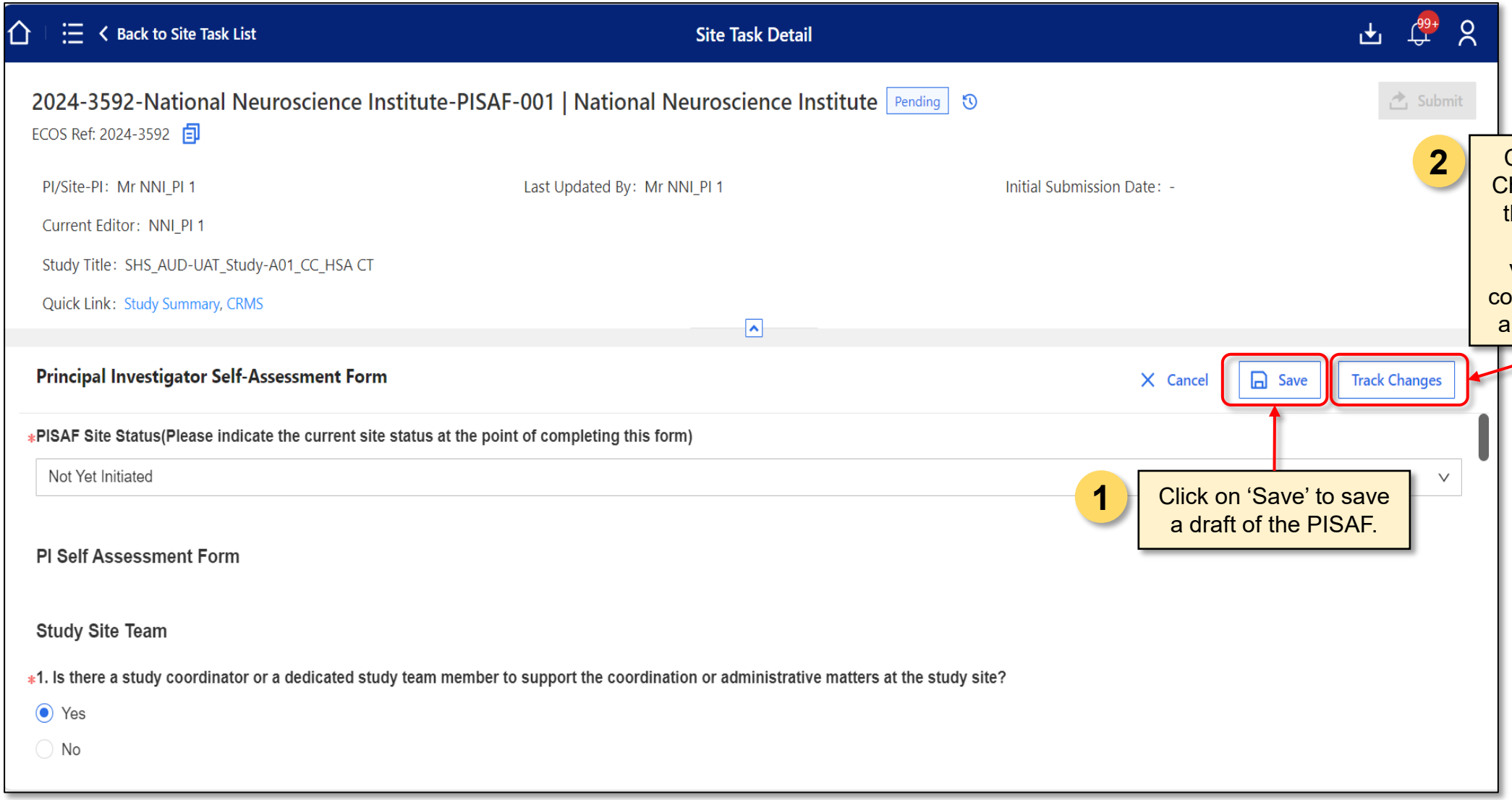

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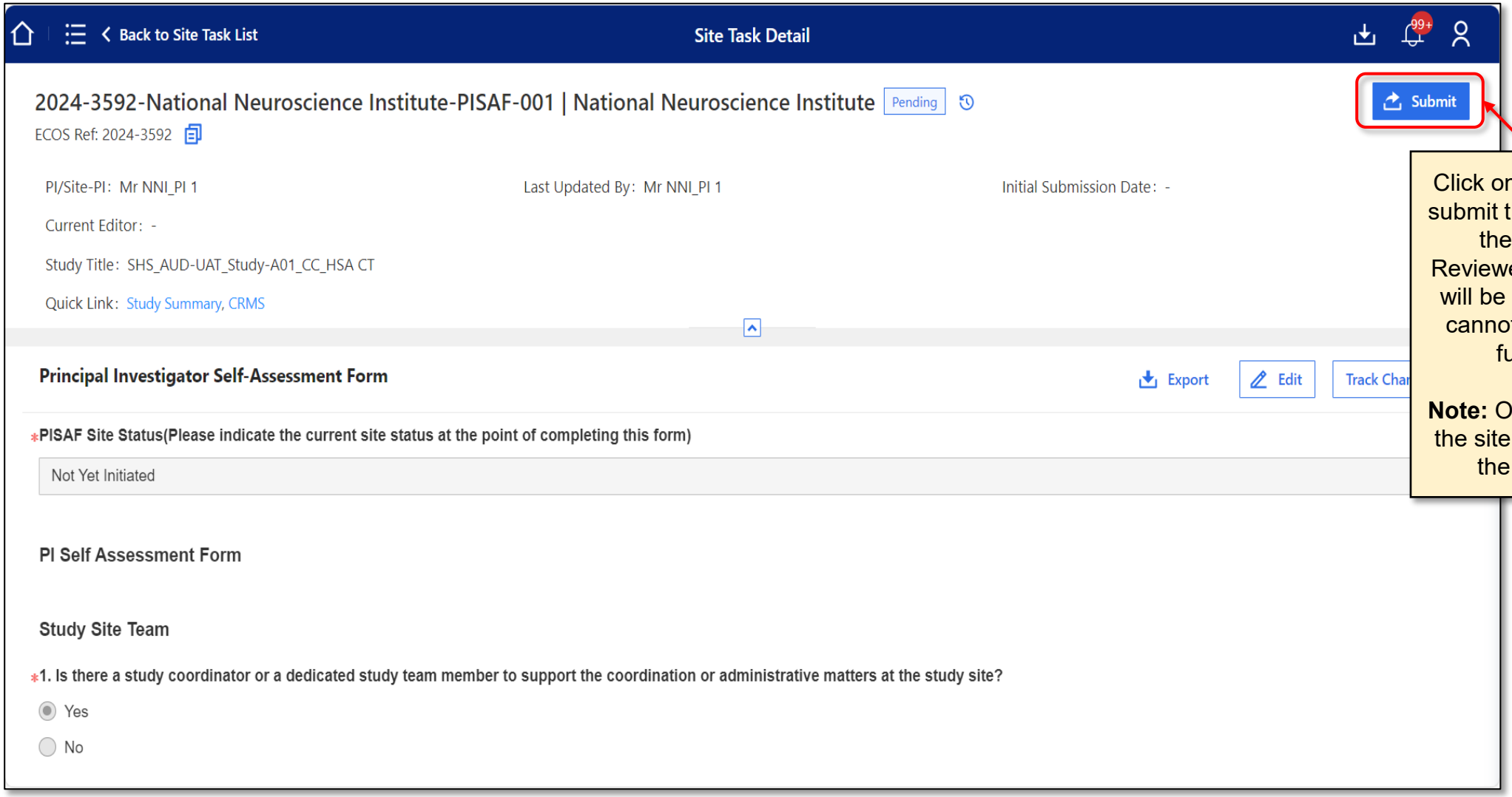
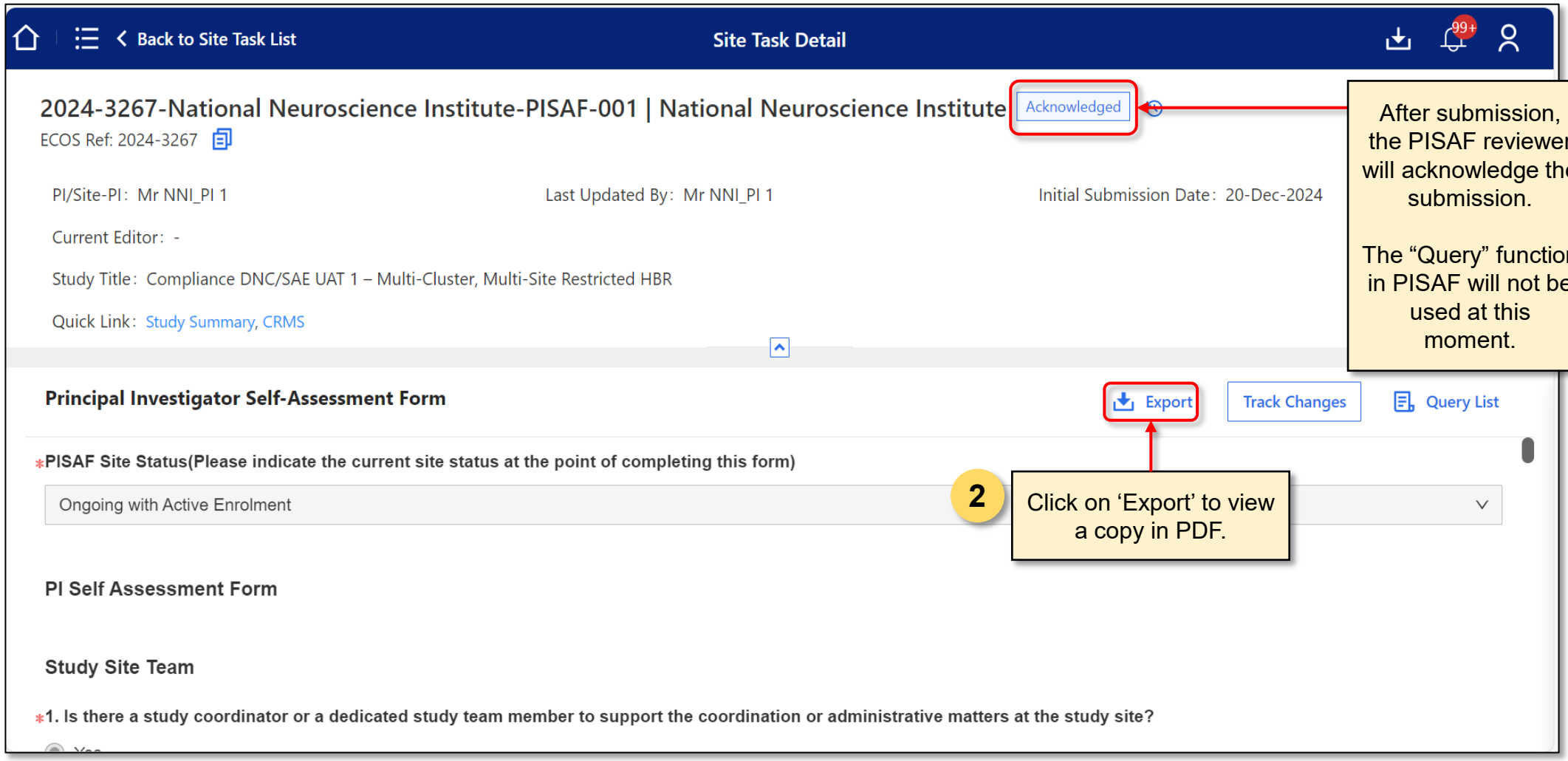


3

Click on 'Submit' to submit the PISAF to the PISAF Reviewer. The form will be locked and cannot be edited further.

Note: Only the PI of the site can submit the PISAF.

4) Navigating the Module: PISAF Acknowledged

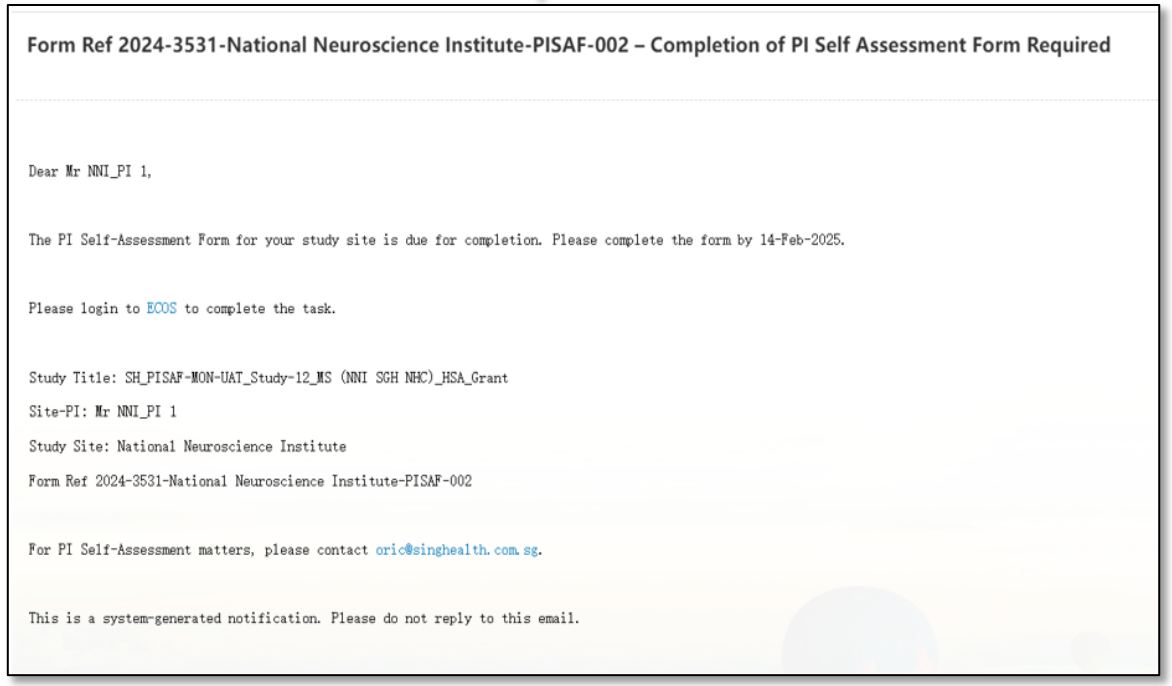


4) Navigating the Module: What notifications are there?

1

An email notification will be sent to the PI / Site PI / Co-I / STMs.

The email will contain the study title, PI/Site-PI name, study site, and form reference number. There will also be a direct link to ECOS to bring the recipient directly to the platform.



Form Ref 2024-3531-National Neuroscience Institute-PISAF-002 – Completion of PI Self Assessment Form Required

Dear Mr NNI_PI 1,

The PI Self-Assessment Form for your study site is due for completion. Please complete the form by 14-Feb-2025.

Please login to ECOS to complete the task.

Study Title: SH_PISAF-MON-UAT_Study-12_MS (NNI SGH NHC)_HSA_Grant
Site-PI: Mr NNI_PI 1
Study Site: National Neuroscience Institute
Form Ref 2024-3531-National Neuroscience Institute-PISAF-002

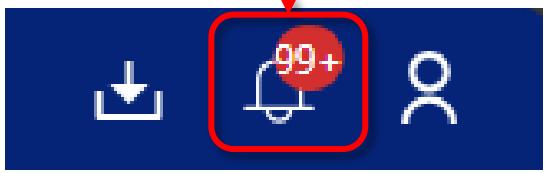
For PI Self-Assessment matters, please contact oric@singhealth.com.sg.

This is a system-generated notification. Please do not reply to this email.

2

A system notification will be sent to the PI / Site PI / Co-I / STM's user account.

It can be access via the bell icon, found on the top right corner. A bubble will indicate the number of system notifications.



3

Reminder emails will be sent every weekly (7 days).

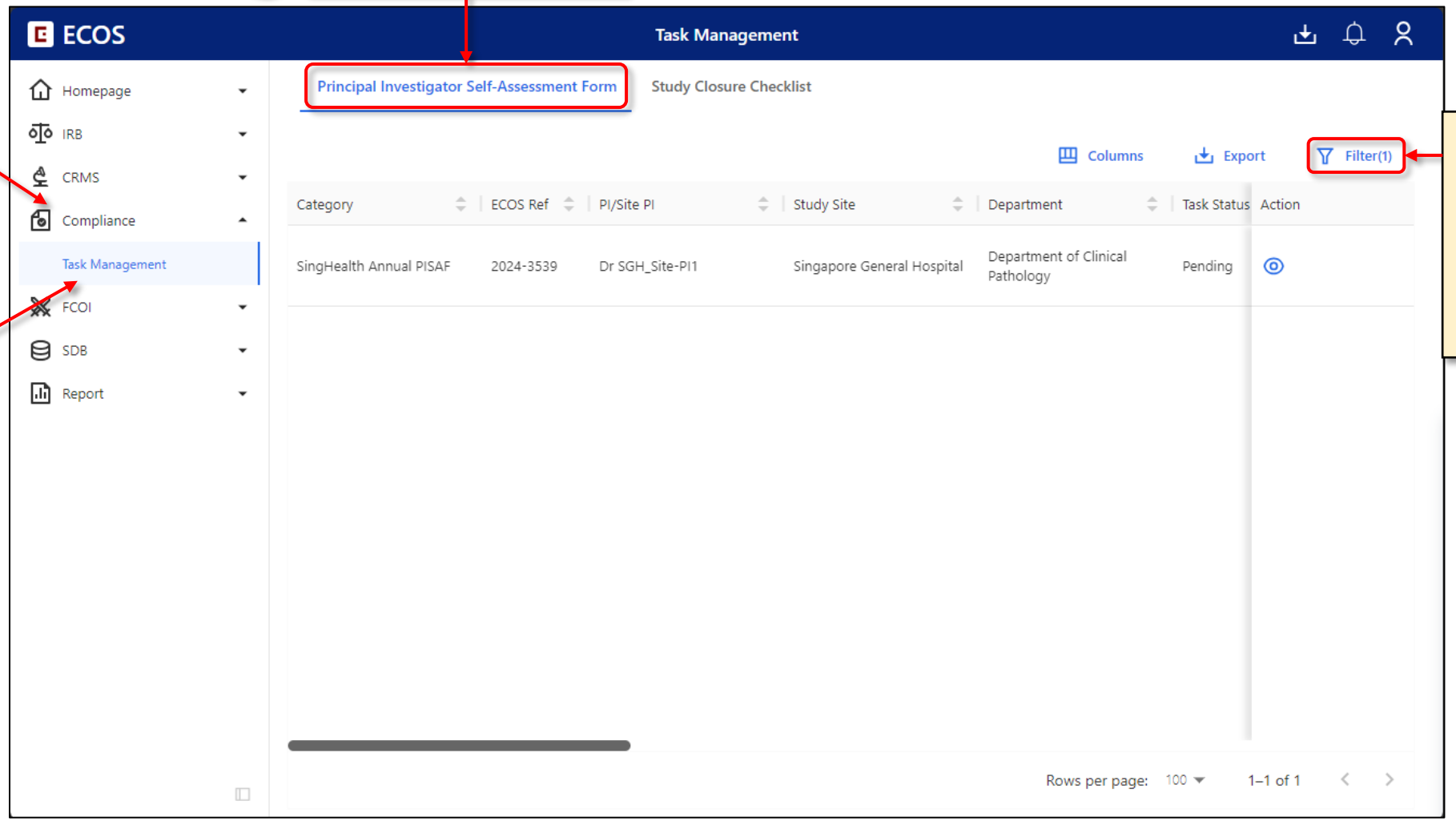
The task will auto-close if the PISAF is not submitted by 14 Feb 2025, 2359hr.

4) Navigating the Module: Where to view all tasks for the institution?

3 Click on the PISAF tab.

1 Click on the 'Compliance' module.

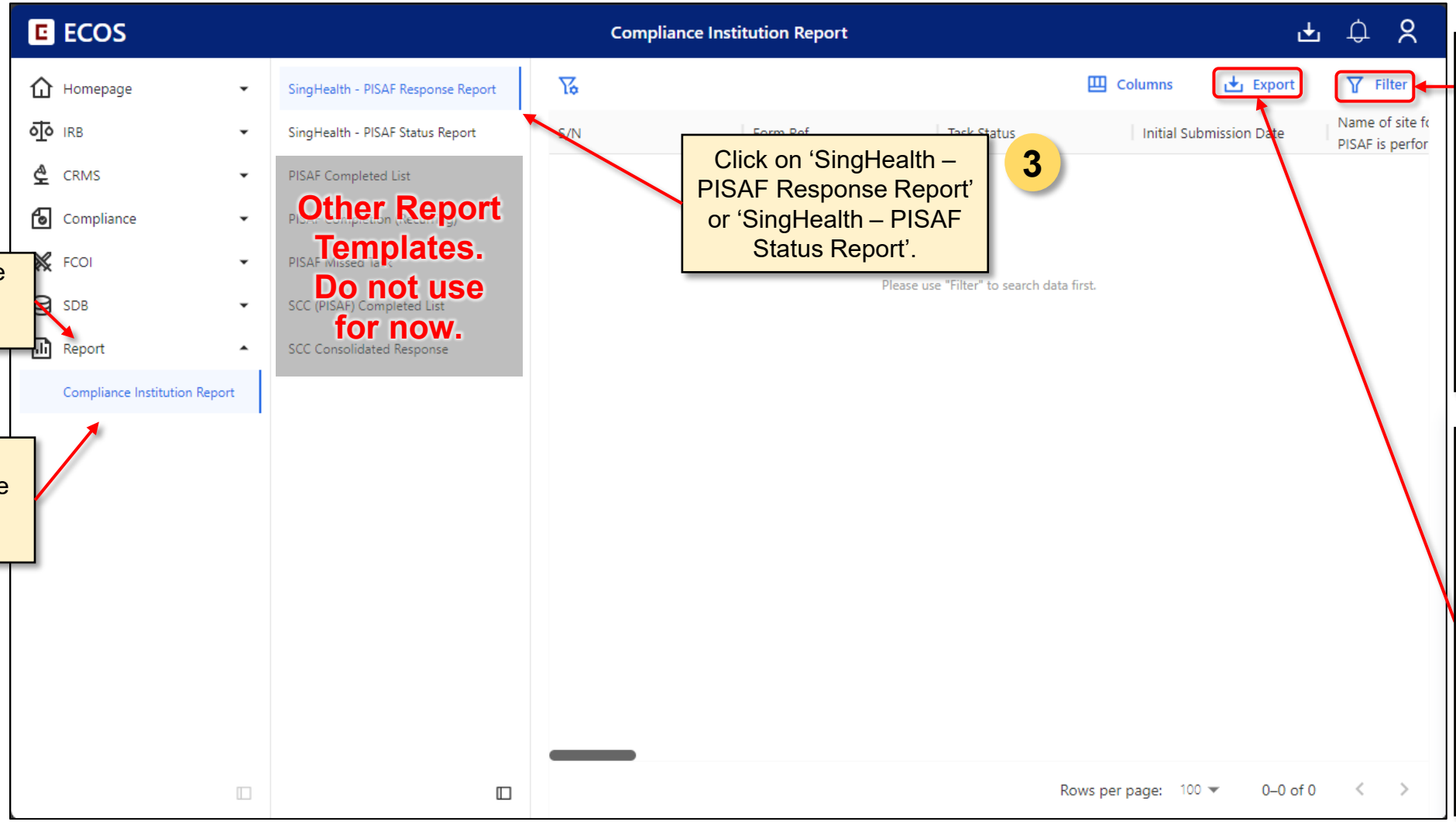
2 Click on 'Task Management'.



4 By default, pending tasks will be displayed.

Click on 'Filter' to search for a specific study.

Navigating the Module: How to generate the PISAF Reports?



1 Click on the 'Report' module.

2 Click on 'Compliance Institution Report'.

Click on 'SingHealth – PISAF Response Report' or 'SingHealth – PISAF Status Report'.

3

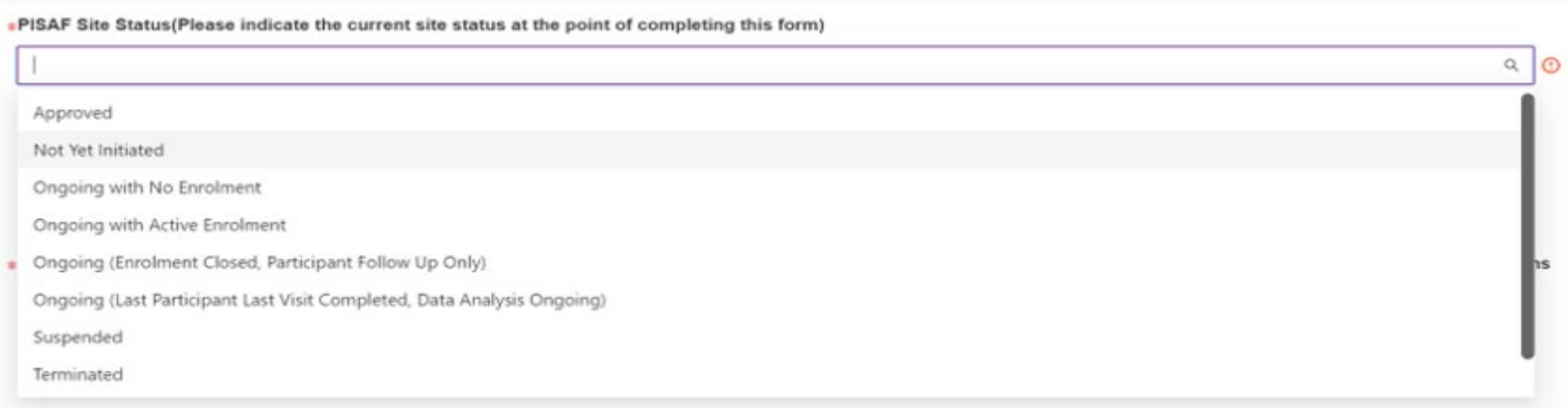
4 Click on 'Filter' and select the filter conditions to display the required data. If no filter conditions are selected, the report will display all data for the report.

5 Click on 'Export' to download the report.

It is possible to customise the columns to display and filter for specific conditions before downloading the report.

Reminder: The report will only be able to include data up to the day before the day of report generation.

PISAF – Site Status, Site Team



Study Site Team

***1. Is there a study coordinator or a dedicated study team member to support the coordination or administrative matters at the study site?**

◯ **Yes**
◯ **No**

1.1 Comments:
Please complete this section if you have responded “No” to the question above.

PISAF – Study File

Study File

*2. Does your site keep any physical file(s) containing study documents?

◯ Yes
◯ No

2.1 Please indicate the documents that are filed in your study files. If the document was not filed or not relevant for your study, please leave the checkbox blank.

☐ IRB submission documents
☐ IRB approval, renewal or acknowledgement letter/s
☐ Regulatory (i.e. MOH or HSA) submission documents
☐ Regulatory (i.e. MOH or HSA) approval documents (e.g. CTC/CTA/CTN, MOH approval for restricted HBR)
☐ Clinical Research Material Notification (CRM-N) from HSA (eg. For use of Therapeutic Products, Medicinal Products, Medical Device, CTGTP, Radiopharmaceuticals)
☐ Original signed informed consent forms signed off by the participant and person obtaining consent (and witness, if applicable)
☐ Training documentation (e.g. Certificate for CITI, HBRA, ICH-GCP or Study-specific training)
☐ Site Delegation Log signed off by the site-PI
☐ Participant Screening and Enrolment Log
☐ Participant Identification Code list
☐ Data Collection Forms/ Case Report Forms (CRF)
☐ Human Biological Materials (HBM) collection/shipping records
☐ Investigational Product (IP) dispensing/returns records
☐ Medical Device (MD) management records
☐ Serious Adverse Event or Adverse Event Tracking Log

*3. Was a study agreement(s) signed prior to the start of your study? The study agreement(s) may include Clinical Trial Agreement, Research Collaborative Agreement, Service Agreement, Project Agreement, Material Transfer Agreement, Data Sharing Agreement, etc.

◯ Yes
◯ No, a study agreement was not signed prior to the start of the study. The study agreement was signed during the conduct of the study
◯ No, the study does not require a study agreement
◯ No, I am not sure

4. Comments (Optional):
Please complete this section if you have responded “No” to any of the questions above.

PISAF – Study Specific training, Obtaining Written Informed Consent

Study-Specific Training

*5. Has study-specific training (e.g. Site initiation meeting or other relevant training) been conducted and documented for the site team members?

◯ Yes
◯ No

5.1 Please select the study-specific training topics that were covered. If the topic was not covered or not relevant for your study, please leave the checkbox blank.

☐ Eligibility criteria (Inclusion/Exclusion criteria) of the study
☐ Study design and study procedures required
☐ Randomisation Process
☐ Informed Consent Process and requirement of a witness (Note: A witness is required for studies under the scope of HBRA)
☐ Handling of Investigational Product (IP) (e.g. Dispensing and return by the participant)
☐ Handling of Medical Device
☐ Data collection process
☐ Safety Reporting
☐ For a multi-site IIT or HBRA study, Communication Plan with lead site

6. Comments (Optional):
Please complete this section if you have responded "No" to the question above.

Obtaining Written Informed Consent

*7. Has any written informed consent been obtained from study participants at this study site?
Note: Indicate "NA" if Waiver of written consent granted by the IRB or Verbal consent will be obtained.

◯ Yes
◯ No
◯ NA

*7.1 Please answer the following questions (Q7.1 to 7.6) with reference to the last 2 participants that were enrolled into the study. List the last 2 participant's study number **that were enrolled** below:

*7.2 The latest version of the IRB and HSA-approved (as applicable) informed consent form (ICF) was signed by the participant at the time of written consent.

◯ Yes
◯ No

*7.3 There is documentation in the research participant's medical records and/or source document to describe the informed consent process and the research participant has voluntarily consented to the study.

◯ Yes
◯ No

*7.4 The participant has personally signed AND personally dated on the ICF.

◯ Yes
◯ No

PISAF – Database and Study Records

*7.5 If your study is regulated under HBRA, informed consent has been obtained in the presence of a witness. If your study is not regulated under HBRA or a witness has been exempted or not required, please indicate as "NA".

◯ Yes
◯ No
◯ NA

*7.6 The participants have received a copy of the signed ICF.

◯ Yes
◯ No

8. Comments (Optional):
Please complete this section if you have responded "No" to any of the questions above.

Database and Study Records

*9. The study team members have been authorised to access identifiable data for the research (e.g. SCM/Citrix, Financial/Operational portals, etc.). Please indicate NA if the study does not require access to identifiable data from hospital systems.
Important: National Electronic Health Records (NEHR) cannot be used for research!

◯ Yes
◯ No
◯ NA

*10. There are processes put in place to safeguard all confidential, proprietary and personal data/information against security breaches.

◯ Yes
◯ No
◯ I don't know

*11. Please indicate if the Clinical Research Management System (CRMS) module in Ethics and Compliance Online System (ECOS) has been completed with the 3 following information for your study site. To indicate which fields below has been completed.

☐ Milestones. For important events such as planned/actual site initiation date, first participant screened, first participant enrolled etc.
☐ Participant - Recruitment Numbers. To provide the actual recruitment number by per month
☐ Site Information. To provide site contact personnel, funding information etc.
☐ No information has been entered in CRMS for the above mentioned fields

12. Comments (Optional):

PISAF – Declaration

*Declaration

- The research study is conducted in compliance with the IRB approved protocol and applicable regulations (Human Biomedical Research Act, Health Products (Clinical Trials) Regulation or Medicines (Clinical Trials) Regulations).

- The research study is conducted in accordance with SingHealth Research Institution's (RI) or sponsor's (if applicable) policies. This includes the policy on subject's re-identification in the case of an Incidental Finding (if applicable).

- Serious adverse events (including unexpected serious adverse events), safety lapses, protocol deviation and non-compliance are reported to the IRB, regulatory authorities and relevant bodies (eg. sponsor etc) where required.

- The SingHealth PI is actively supervising the overall study conduct and shall investigate areas of concern (if any that arises). Remedial measures will be taken to close the issues.

- The study team members have provided full support and cooperation to any study monitoring or quality review request(s) by SingHealth and/or the applicable regulatory authorities.

- The information provided are true and accurate at the time of submission.

FAQ

Q1: What status of the studies will I get a notification to complete the PISAF?

A1: All studies with a status of Approved, Ongoing, Ongoing (enrollment closed, participant on follow up), Ongoing (LPLV over, analysis ongoing), Suspended will get a notification to complete the PISAF.

Q2: Who can complete and submit the PISAF?

A2: Any Study Team Member, including the Co-I and Site PI, can complete the PISAF. But only the Site PI can submit the PISAF in ECOS. The Study Team Member can help to complete the PISAF and the Site PI will review the completed form for submission in ECOS.

Q3: For my multi-site study involving SGH, CGH and KKH, do I have to complete the PISAF 3 times as it was mentioned that the PISAF is completed at site level?

A3: Yes. The PISAF is completed for each site at the site level. The responses provided for the PISAF will pertain to that particular site.

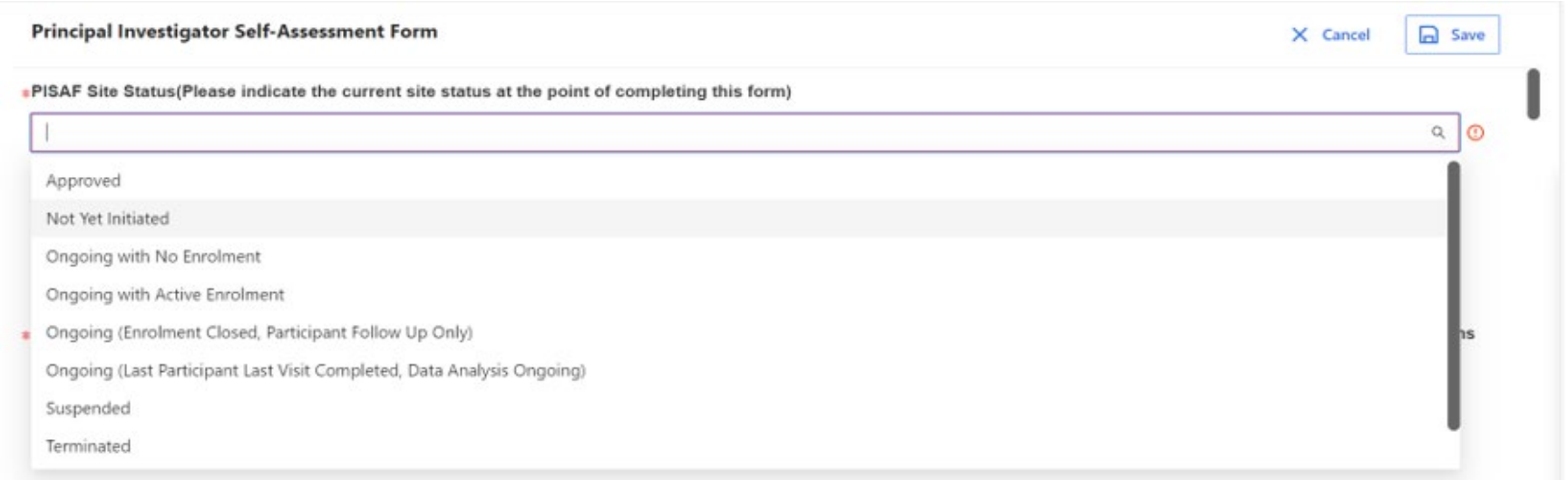
Q4. For my study, the Site PI and Co-I received the pending task to complete the PISAF in ECOS. As a CRC, I did not receive any pending task in ECOS. Why?

A4: Please check your study role defined in CRMS under User Authorisation List (UAL). **The Study Administrator will not receive any tasks for PISAF.** Only **Site-specific PI, Co-I and Study Team Members (STM)** can complete the PISAF.

FAQ

Q5: I have received the PISAF task but my study has not yet been initiated, how do I complete the PISAF?

A5: On the PISAF, there is a PISAF site status. The status can be updated here and to indicate “NA” for the questions where relevant.



Q6: I have received the PISAF task but my study site does not recruit participants, how do I complete the PISAF?

A6: You should complete the questions where relevant to your study site. It is acceptable to indicate “No” or “NA” and provide comments where necessary.

FAQ

Q7: How about for DSRB approved studies, will I need to complete the PISAF?

A7: The PISAF will have to be completed for SingHealth sites, regardless whether CIRB or DSRB approves it. For example, for a multi-site study involving NUH, TTSH and SGH where the study has been submitted to DSRB for review, the PISAF will be completed for the SGH site by the SGH site PI. The ECOS system will trigger the PISAF for the SGH site.

Need help?

- SingHealth Users

  it.helpdesk@singhealth.com.sg
  1800-666-7777

- For Non-PHI Users

  https://for.sg/ecos-support-request