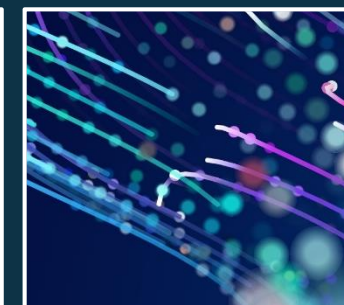
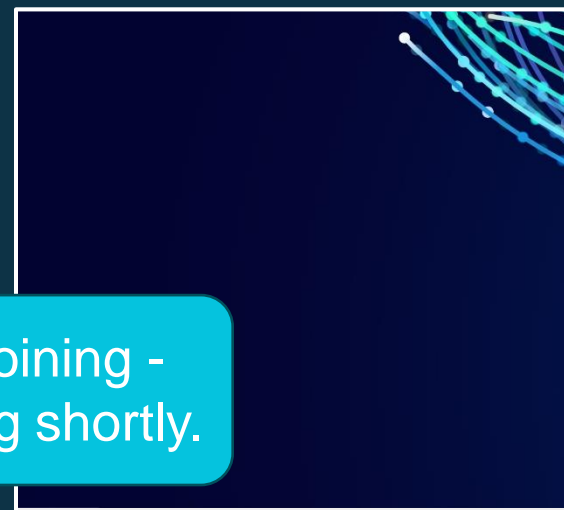




Insider Client Training Session: Issue Management – 24.1

Lisa Clough

January 9, 2025



Thank you for joining -
we will be starting shortly.

Agenda

1

Overview of
Issues within
elluminate

2

Suggested
workflows

3

Unlicensed
Users and
Issues

4

Best Practices
for Issue
Management



Overview of Issues

- Issues provide a way to communicate with Licensed or Unlicensed illuminate users within your illuminate environment
- Ask questions, request queries, ask for clarifications, request input...
- Streamlined and collaborative
- Remain within illuminate



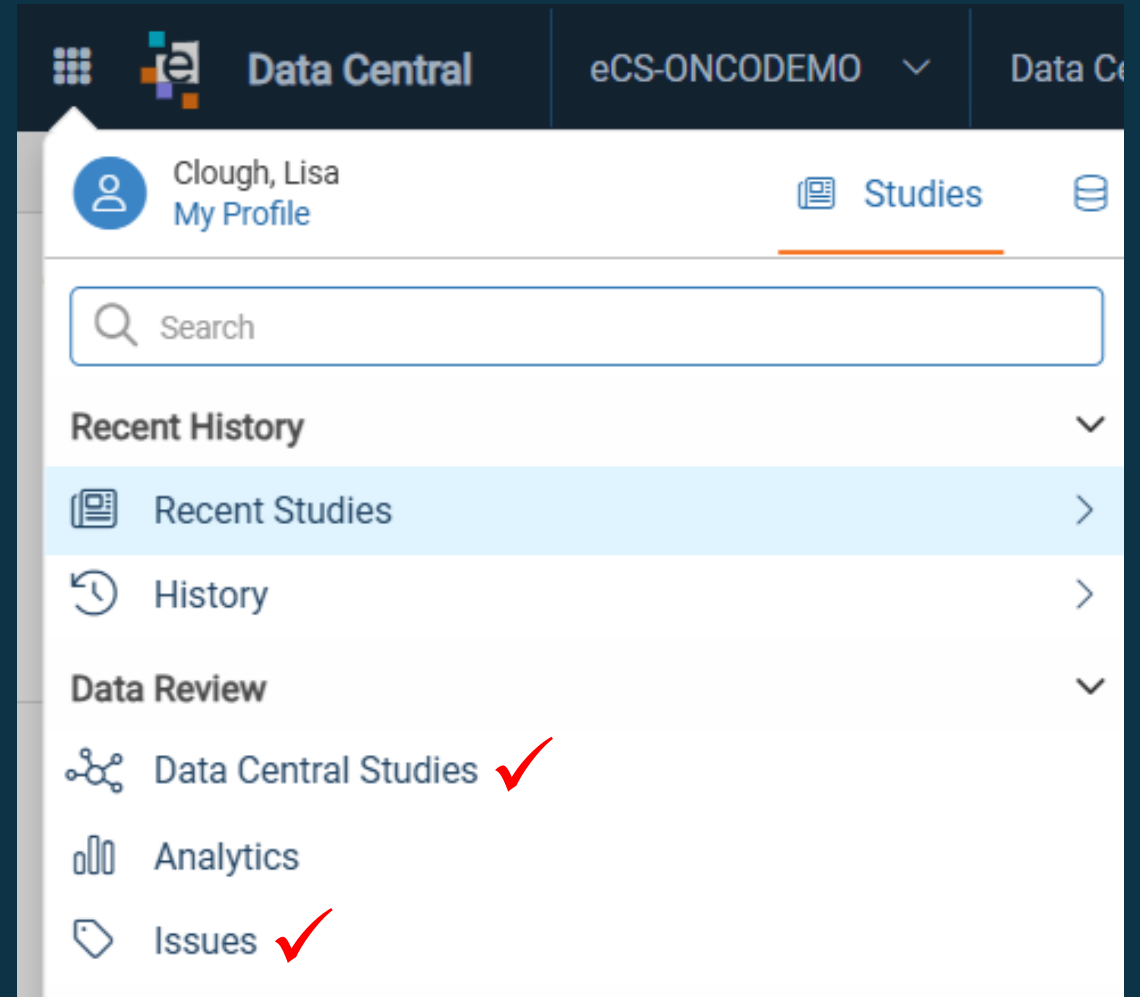
Where can I Create Issues?

- Data Central
- Analytics
- SCE
- ODR
- RBQM
- Specifications



Where can I Manage Issues?

- Data Central (Data Central and RBQM Issues)
- Issues (all Issues)
 - Default filter of Issues assigned to you with a status of Open



Issue Fields

- Auto-populated fields
- Priority
- Assign To
- Due By
- Visit ID
- Issue Text
- Send Notification
- Receive Notifications

Create Issue

Type	Record
Subject	0026-017
Data Store	eCS_ONCODEMO_ExceptionListings
Site ID	0009
Domain	AEDrugWithdrawn
Field	LocationOID
Value	0009
Critical Field	N

Priority:

Assign To: User Role User Group

* User:

* Due By:

Visit ID:

* Issue Text:

Send Notification to the User/Role/User Group Receive notifications for these changes

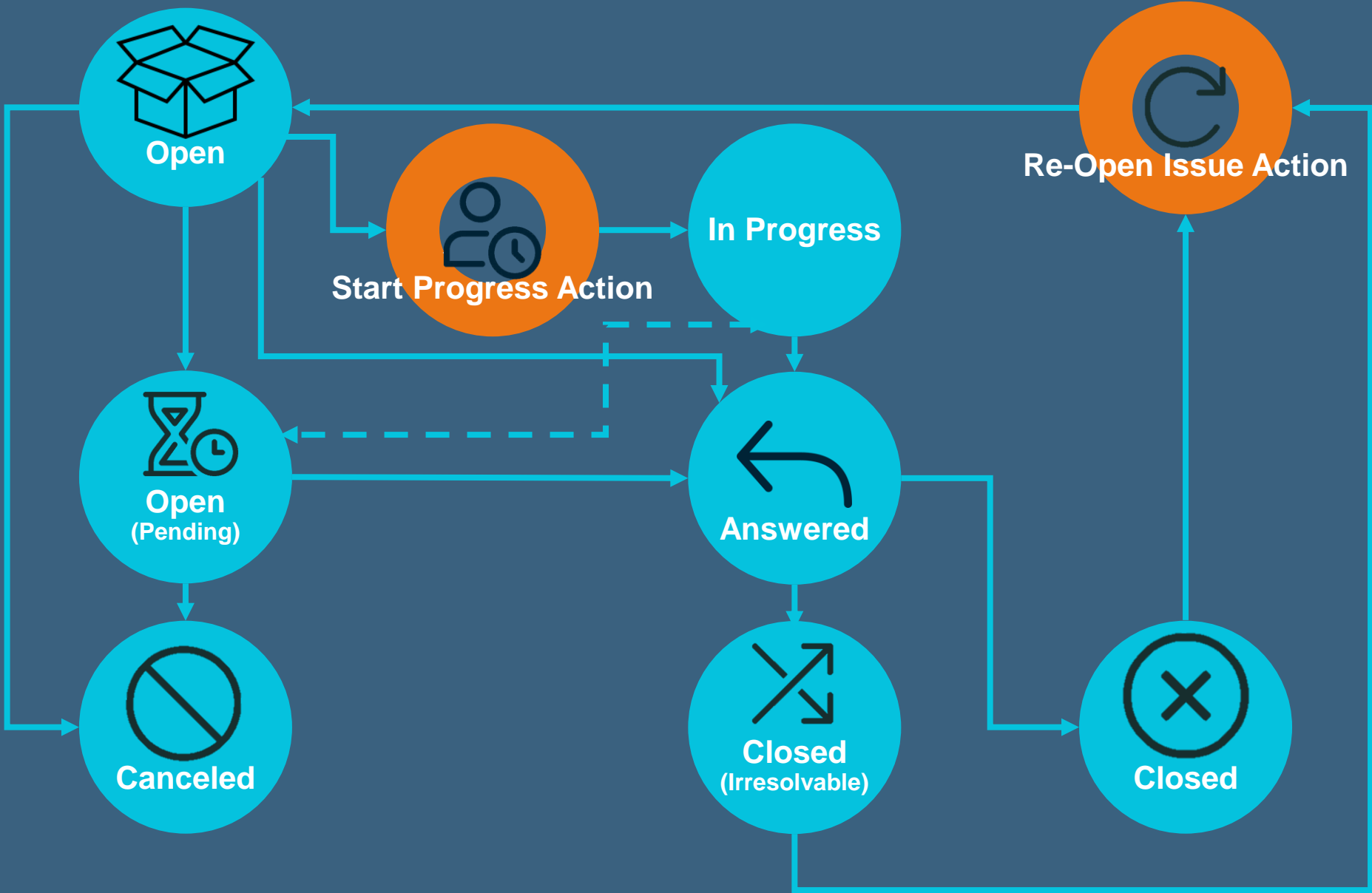


User Types






Type	Definition	Use Cases / Examples
User: Licensed User	An individual with a licensed elluminate account.	A new record issue requires the input of a specific individual user of elluminate, so the data reviewer selects that user from the picklist of licensed individuals in the “Assign to user” list.
Or Unlicensed User	An individual without an elluminate account, but who has ownership over trial-related activities.	A Data Manager observes that an external data file from a lab vendor is missing results for a required test and creates a domain issue for the point of contact at the lab to resolve.
Role: Data Central Reviewer Role	Licensed users assigned to a specific areas of responsibility for data review (e.g. Data Manager, Medical Coders, Medical Data Reviewers, etc.).	A data reviewer notices that a subject’s ALT values have stayed elevated for the past three study visits and no associated AE has been entered. S/he creates a record issue and assigns it to the Medical Data Reviewer role to investigate.
User Group	A collection of system privileges assigned to licensed users based on required elluminate usage.	An anomaly is observed in a subject’s lab values. The data reviewer assigns an issue to the Safety user group (composed of medical monitors and clinical scientists) for investigation.



Issues: Open to Closed or Canceled







Issue Statuses

Status	Icon	Definition	Use Cases / Examples
Open		The initial state of a newly created issue.	N/A
Start Progress (In Progress)		For Open issues, the “Start Progress” action changes the status to “In Progress” to indicate work on the issue has begun.	The In Progress status can be used to better differentiate between Open issues and issues actively under investigation by the assignee.
Move to Pending (Open)		A sub-status of Open, indicates an issue that may require additional time before it can be answered / actioned.	Use this status to set aside issues that cannot be immediately actioned or that require verification by another party to confirm they are valid issues.
Reassign*		An optional action to change the designated owner of open issues from the original assignee. This works only when reassigning in bulk.	Example reassignment rationale: The original assignee is unexpectedly out of office and closing the issue is business critical.
Answered		A short-term disposition of an issue where an issue response has been provided, but the issue is not yet closed.	The action of entering a response to the issue automatically changes the status of the issue from “Open” to “Answered.”



Issue Statuses, continued

Status	Icon	Definition	Use Cases / Examples
Closed		The final disposition of an issue that has been answered / resolved.	From the previous example, the data reviewer who raised the record issue on the CM entry of venlafaxine reviews the answer, confirms the MH is updated as stated, and changes the status of the issue to “Closed.”
Closed (Irresolvable)		An optional final disposition of an issue that has been answered, but the issue cannot satisfactorily be resolved.	Example issue/response: “Please confirm date of last dose for subject.” / “Subject was lost to follow-up.” Example rationale: “Issue is unable to be resolved since subject was lost to follow-up.”
Canceled		The final disposition of an issue that was created in error and requires no further action/answer.	Example: A data reviewer creates a domain issue instead of a record issue by mistake. The data reviewer comments that it was created in error and cancels the issue. The status of the issue changes to “Canceled.”
Re-Open (status shows as Open)		An optional action for previously closed issues requiring additional clarification or follow-up.	Example issue response: MH has been updated to include depression. Example re-open rationale: The new MH record for depression does not indicate that it’s treated with a concomitant medication.

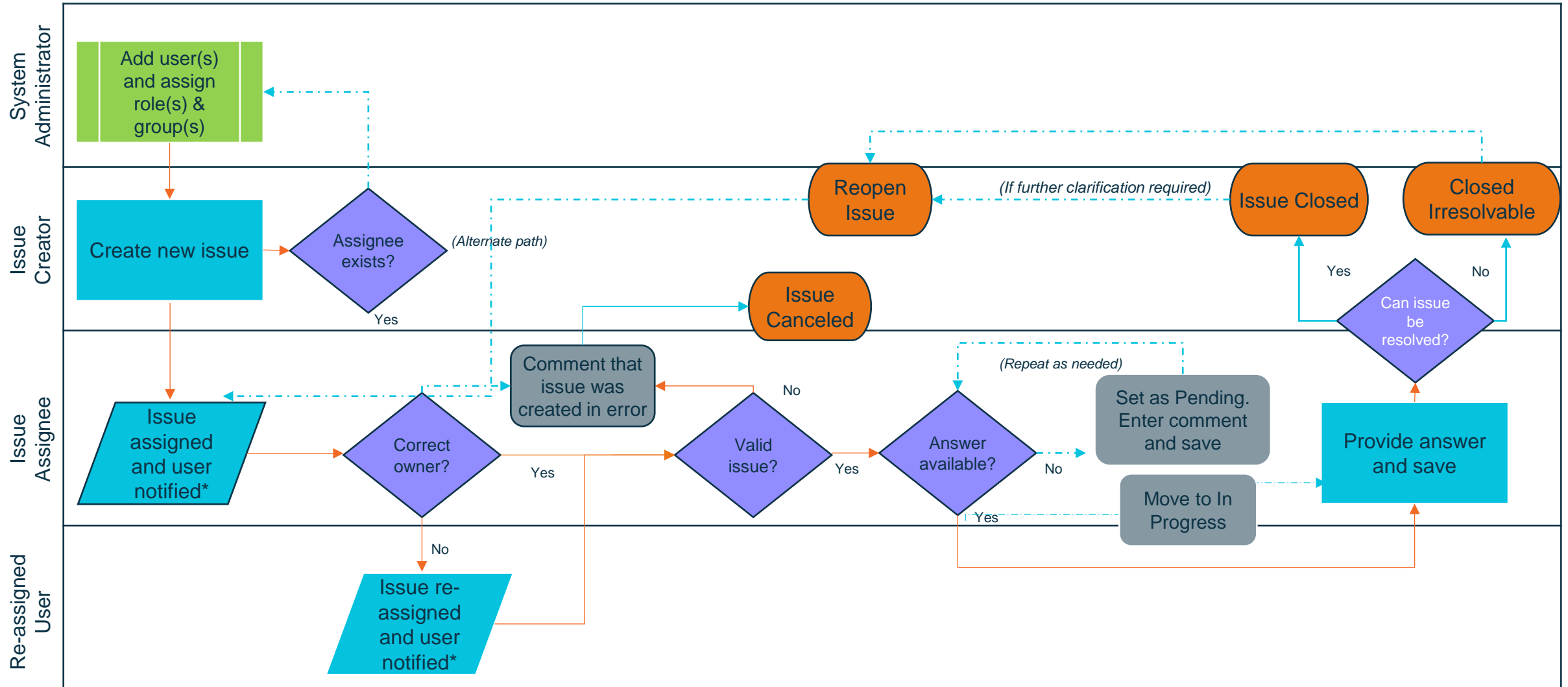




Issue Workflows

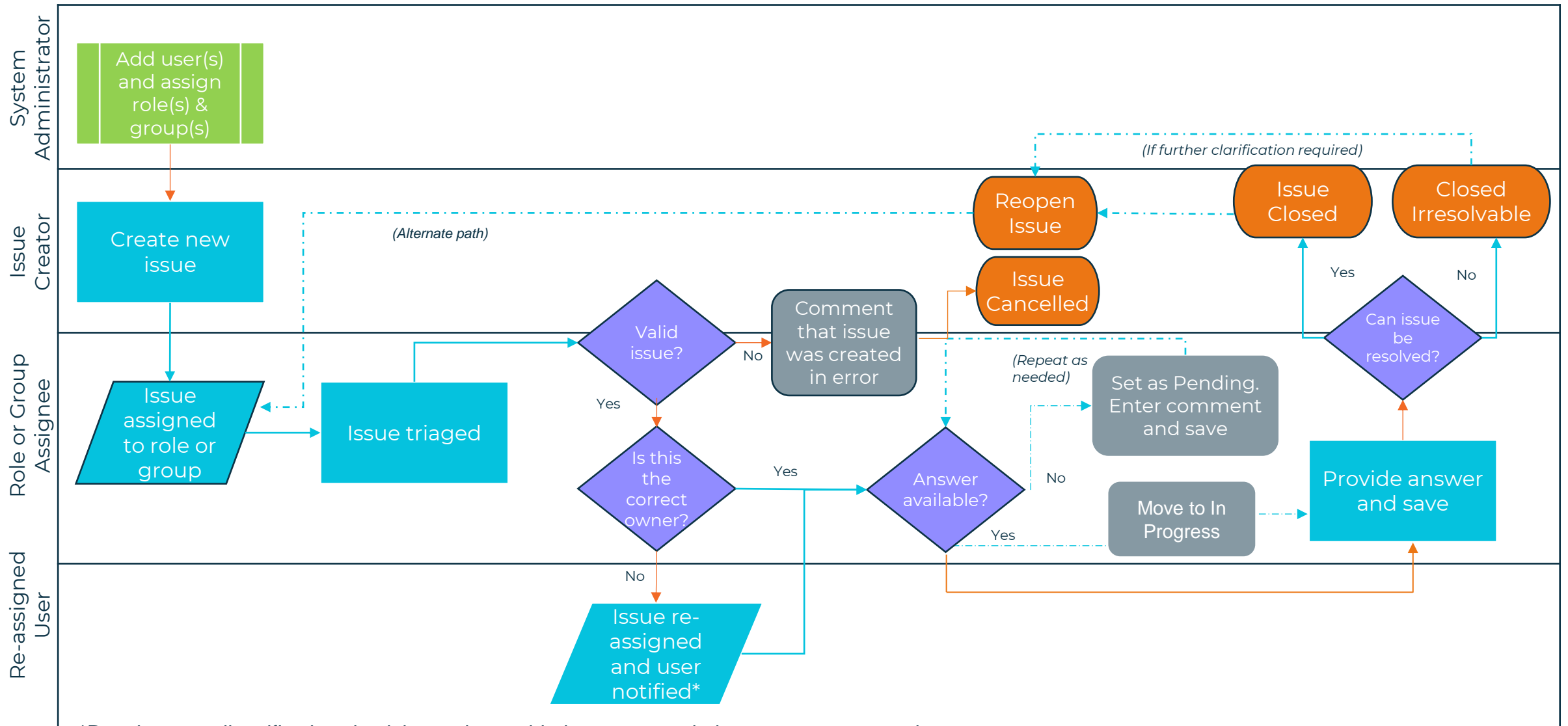


Recommended Workflow for Issue Resolution (Licensed Users)



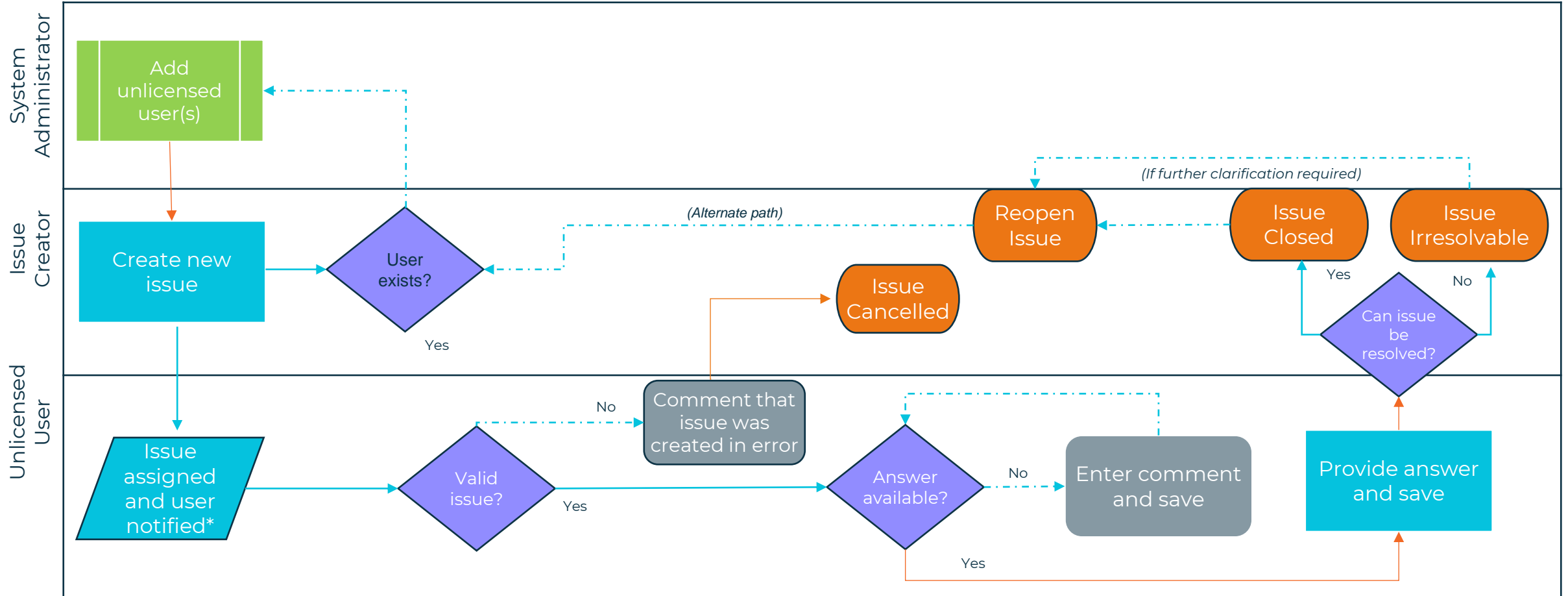
*Requires e-mail notification check box to be enabled - recommended to ensure prompt action.

Recommended Workflow for Issue Resolution (Role / Group)



*Requires e-mail notification check box to be enabled - recommended to ensure prompt action.

Recommended Workflow for Issue Resolution (Unlicensed User)



Unlicensed Users can only answer and comment in an issue.

*Requires e-mail notification check box to be enabled - recommended to ensure prompt action.



**Unlicensed Users
and Issues**



Unlicensed Users and Issues

Key Points

Unlicensed users:

- ✓ Can only see issues that have been assigned to them
- ✓ Can export the list of issues assigned to you and then import the file back into illuminate with the allowed response user and response fields filled out
- ✓ Can only answer issues
- ✗ Cannot access the data behind the issue





Best Practices

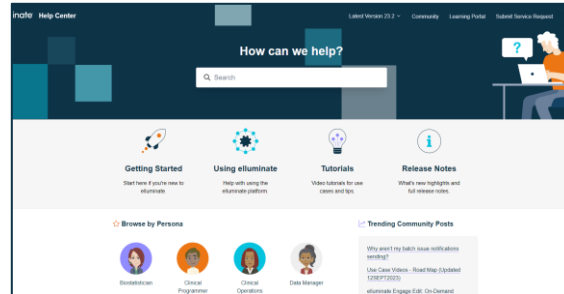


Best Practices

- When accessing the Issues module from the illuminate home page, the view defaults to a filtered list of Open issues assigned to you. Remember to remove the filters to see all issues.
- “Answered” issues should only be closed by the initiator (or designee) rather than the issue assignee.
- When assigning an issue, enable the email notification checkbox to ensure prompt action, especially for “critical” issues.
- If a conclusive answer is not currently available, set the issue status to Pending and utilize the Comments section to track actions and input.
- If an issue needs to be canceled, enter a comment relating to the rationale prior to canceling.
- Unlicensed users must first be set up by an illuminate administrator before they can be selected from the User picklist.
 - Consider adding their company as Unlicensed User so they are all grouped together.



Resources



HELP CENTER

<https://support.eclinicalsol.com/hc/en-us>

The Help Center is a comprehensive resource to find detailed articles and tutorials for elluminate features and functions, as well as new release documentation. Use Conversations to learn from the elluminate community or to ask questions.



LEARNING PORTAL

https://illuminate.learnupon.com/users/sign_in

The Learning Portal provides a full catalogue of eLearning modules covering all aspects of elluminate functionality. Users are enrolled in required-for-access training(s) and can self-enroll into other courses for expanded learning opportunities.



Questions?

