

Frequently Asked Questions – Aurora Agent Management System

Revised: October 28, 2024

Cancer Therapy Evaluation Program, Pharmaceutical Management Branch

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Implementation plan for compliance on NCI-sponsored clinical trials using PMB-supplied agents

1. When will the Agent Accountability (eDARF) module be released?

A full rollout of the Agent Accountability (eDARF) module is planned for December 27, 2024. The eDARF module will be available to all sites after this date. Please subscribe to the [PMB Listserv](#) to receive future announcements.

2. When will the Agent Accountability (eDARF) module be required?

The date has not been determined yet. Use of the Agent Accountability (eDARF) module is voluntary at this time.



3. Will the Agent Accountability (eDARF) module in AURORA be able to integrate into other electronic DARF systems?

The feasibility of integration of AURORA with other electronic DARF systems will be evaluated. For sites utilizing other eDARF module systems, use of the NCI eDARF module will be required at some point for NCI IND-sponsored trials with PMB-supplied agents. Use of the NCI eDARF system is necessary to integrate with the entire suite of applications in the NCI Clinical Trial Management System.

Getting Started in Aurora

4. Which web browsers are compatible with AURORA?

While Chrome and Firefox are the preferred web browsers for best performance, AURORA can also be accessed through other browsers such as Microsoft Edge and Safari. However, there may be features that do not perform or display as intended.

5. Can errors or mistakes be corrected in AURORA?

AURORA is record system compliant with GCP and 21CFR Part 11. Saved transactions cannot be undone. PMB does not have the ability to correct site errors. Some errors may be resolved with a subsequent transaction or comment but please report errors to PMB via PMBAfterHours@mail.nih.gov for resolution assistance if needed.

6. Are the training videos required if only using AURORA for specific tasks?

Review of the AURORA training videos will be a prerequisite to access AURORA at some point in the future. The date has not been determined. The video(s) required to be viewed will be dictated by your user role.

Site Maintenance in AURORA

7. When is the appropriate time to perform site set up?

Site set up is the first action to be taken within AURORA Agent Accountability. No eDARF transactions can be completed in AURORA until site set up is completed.



8. Can a satellite site be converted to a control site since AURORA allows multiple shipping addresses for a single investigator?

Yes. A site currently functioning as a satellite dispensing area of a control and identified as a practice site for one or more registered investigators on the investigator's FDA Form 1572, must return any agent inventory to the control dispensing area and close out their current satellite eDARFs. The site currently functioning as a satellite dispensing area must set up a PSD, PSD shipping address and PODs in the PSD Worksheet module in AURORA. Each applicable investigator must link the newly created PSD package as a shipping address in their Agent Shipment Form in RCR and submit. Once approved, the site may submit order requests as a control dispensing area and receive agent shipments as a control dispensing area and maintain control eDARFs.

9. Can multiple shipping addresses be assigned to the same investigator?

Yes. Multiple PSD addresses corresponding to an investigator's practice sites may be identified on the investigator's Agent Shipment Form in RCR. The PSD packages (PSD, shipping address and PODs) need to be created in the AURORA PSD Worksheet module first if they do not currently exist. The correct shipping address for the investigator must be selected in AURORA at the time of agent order request submission.

Primary Shipping Designee (PSD) Worksheet in AURORA

10. Can the same PSD be assigned to multiple control sites?

Yes, the same PSD can be assigned to multiple control sites.

Local Destruction in AURORA

11. Are expiration dates for PMB-supplied agents updated automatically?

PMB assigned agent lot expiration dates will be updated in the eDARF module when a stock notification letter is issued by PMB. A site can enter a temporary expiration/use by date for any lot without a PMB assigned expiration date. Regardless of who entered the expiration date, the system prohibits dispensing



past its expiration date. Once PMB assigns an expiration date, that date cannot be changed and takes precedence over any site entered date.

12. Can PMB-supplied agents continue to be returned to the NCI Clinical Repository?

Once sites start to use the AURORA eDARF module, all agent final disposition will be performed via Local Destruction request and approval via the eDARF.

Returns to the NCI Clinical Repository will not be accepted. Sites not using AURORA eDARF will still need to return agent to the NCI Clinical Repository per the PMB Policies and Guidelines until use of AURORA eDARF is mandatory.

Agent Inventory Verification in AURORA

13. Is there a way to co-sign transactions (for example, agent receipt, sending to satellite sites, dispensing etc.)?

The co-signer/2nd reviewer may add a comment to the transaction noting verification or approval of a completed transaction if required by site processes.

Agent Ordering in AURORA

14. I am a Primary Shipping Designee or Ordering Designee for my site, why can't I place orders for PMB-supplied agents in AURORA?

Investigators, Primary Shipping Designees, and Primary Ordering Designees identified in the PSD Worksheet for a shipping address must be associated to the investigator's profile in RCR on the Agent Shipment Form to place orders for PMB-supplied agents in AURORA.

Document Access in AURORA

15. Will stock notification letters continue to be emailed to site personnel (site investigators, shipping and ordering designees)?

Yes, PMB will continue to email stock notifications of the 5 letter subtypes to appropriate site personnel: expiration, protocol status, recall, IND withdrawal, and extension of expiration.

Other AURORA Topics

16. Who should I contact if I need assistance with AURORA?

The help button on the AURORA dashboard provides step-by-step help. The NCI/CTEP AURORA Training video series in the [CLASS Learning Management System](#) also provides detailed guidance. For issues related to AURORA, please contact PMBAfterHours@mail.nih.gov. Include AURORA in the subject line.