Best Practices for the AURORA Accountability eDARF

User Roles in AURORA

- Best practice: Access to eDARFs is based on individuals being assigned to be the primary shipping designee, primary ordering designee, or satellite designees, or investigators. Assess which site personnel need which AURORA functions prior to setting up the PSD worksheet, site maintenance and dispensing areas. See the chart available on our website: https://ctep.cancer.gov/branches/pmb/aurora.htm

AURORA Function	Primary Shipping Designees	Primary Ordering Designees	Control site-assigned Satellite Designees	Investigators	All Other Users
Agent Ordering	✓	✓		✓	
Document Access - IB	✓	✓	✓	✓	✓
Document Access - MSDS, stock recovery	✓	✓		✓	
View PSD worksheet	✓	✓		✓	
Create and Edit PSD worksheet	✓			✓*	
Agent Accountability	✓ Control Dispensing Area and Satellite Dispensing Area records	✓ Control Dispensing Area and Satellite Dispensing Area records	✓ Satellite Dispensing Area records only	✓	

*Only investigators serving as a primary shipping designee have the ability to create new PSD records and submit updates to current PSD records.

Adding designees/satellite designees

- Best practice: When creating control dispensing areas, satellite dispensing areas and adding satellite designees in Site Maintenance, save your changes along the way. Satellite designees do not need to be listed on the PSD Worksheet but will only have access to satellite eDARFs once assigned.

AURORA eDARFs can only be initiated for CTEP-IND trials with PMB-distributed agents

- Best practice: Identify CTEP IND trials with PMB-distributed agents ahead of activation by checking the CTSU website or alternatively checking the AURORA shipped orders grid under the Sponsor column after agents have already been ordered.

An eDARF can only be initiated one of two ways:

1. From a recent shipment (find initiate eDARF hyperlink in the shipped orders grid)
   - Best practice: Have all existing protocol inventory and lots identified so that inventory balance can be carried over during the eDARF set up.
2. From an eDARF agent transfer or agent sent to satellite (in the case of a satellite eDARF)

- Best practice: Only request an agent transfer from an existing eDARF and only transfer agent in the same units (bottles to bottles or capsules to capsules, for example). NOTE: Paper DARF to eDARF transfers will not be approved.

Starting page numbers when initiating an eDARF
- Best practice: When initiating an eDARF that carries over existing accountability information from another source (NCI paper DARF or commercial DARF), the starting page number should be the next consecutive page number. After conversion to the eDARF, paper records should be retained according to the FDA's IND regulations.
- Best practice: If the eDARF was initiated using page 1 when it was really the continuation of an existing record, add a comment or upload a note-to-file (on the first line of the eDARF) explaining the change in page numbers from your existing record.

Completing eDARFs is final
- Best practice: Only complete an eDARF when all transactions are completed, inventory is zero and no patients remain on treatment. This transaction cannot be reversed.

Multiple shipping addresses
- Best practice: To ensure the shipping address is current, check the shipping address that populates the new eDARF header. If multiple old shipping addresses are present, contact PMBAfterHours@mail.nih.gov for assistance.

Agent unit conversion
- Best practice: Whole containers can be converted into partial units during a transaction like dispensing. Once converted, it cannot be changed back to whole containers.

Agent transfer and returns
- Best practice: Request agent transfers or returns for PMB-supplied agents according to how you have been keeping accountability records. If NCI paper or commercial DARF, then request using the forms on the PMB website. If using the AURORA eDARF, request the transaction type on the eDARF and authorization will be provided electronically in AURORA.

Errors in AURORA
- Best practice: Sites are responsible for correcting or documenting eDARF errors by using the comment field, uploading a note to file, or performing an inventory adjustment as a last resort. PMB does not correct eDARF errors for sites. AURORA eDARFs are permanent records.

Audits in AURORA
- Best practice: Keep in mind that auditors do not have access to AURORA currently. Audit requirements, processes and procedures remain unchanged for sites using AURORA for agent accountability.

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