

# Overview of AURORA for Site Users

*The dawn of a new era in NCI Pharmaceutical Management Branch (PMB) agent inventory management*

# Learning Objectives

- Understand how AURORA is integrated with CTEP Clinical Oncology Research Enterprise (CORE) CTMS Applications to streamline NCI clinical trial conduct
- Identify at least two benefits of AURORA that will aid clinical trial sites in their record-keeping processes
- Recognize that some process workflows at clinical trial sites will change to incorporate the new functionality in AURORA
- Understand when use of AURORA is required

# Important Note

❖ AURORA consists of several modules, including:

1. Agent Ordering and review of order status (replaces OAOP)
2. Access to PMB provided documents (stock recovery notices, IB, and MSDS)
3. Creation and Maintenance of the PSD (Primary Shipping Designee) shipping addresses and Primary Ordering Designees
4. Enhanced communication tools to connect with PMB
5. Creation and maintenance of electronic NCI Investigational Agent (Drug) Accountability Records (eDARF) and associated inventory management practices

**When we talk about AURORA, it is not just eDARFs.**

# Frequently Asked Questions

- ❖ AURORA FAQs – PMB will develop and post online a list of FAQs for AURORA
  1. AURORA Implementation Plan FAQ – For compliance on NCI-sponsored clinical trials using PMB-supplied agents
  2. General FAQs

**First requirement: Transition from OAOP to AURORA** in approx. early August 2022.

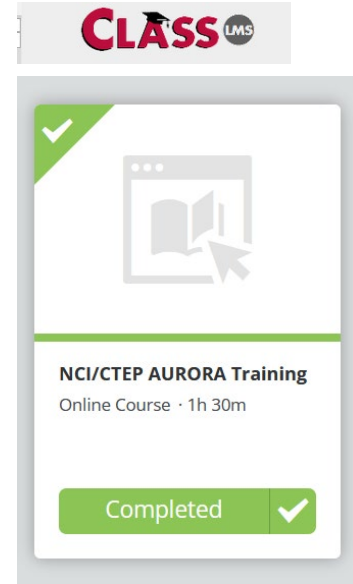
- eDARFs will be released several weeks later *but use is not required yet.*
- **No changes needed** – the same people with access to OAOP will have access to AURORA (same access to agent ordering and review of order status, access to stock recovery notices, IB, MSDS – based on your role)
- **New enhancements** – multiple shipping addresses! Many satellite dispensing areas can become control locations.

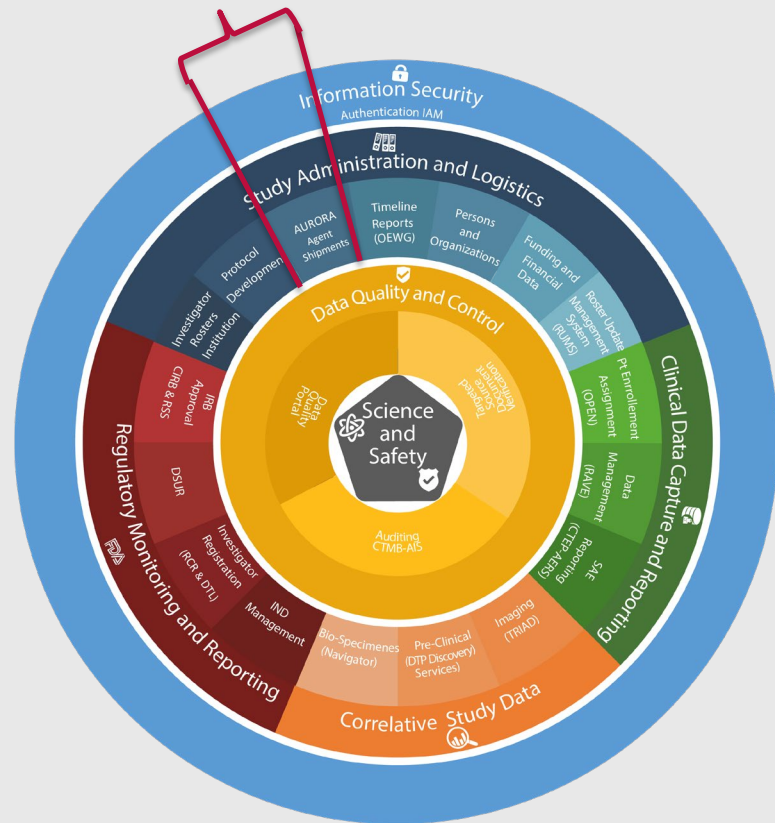
# NCI-CTEP AURORA Training Online Course

## ❖ AURORA Training Videos in CLASS (<https://classlms.org>)

1. There will be an initial series of training videos available on the CLASS website and registered A/AP/NPIVR/IVR with an active CTEP IAM user account will be invited by email to access the videos at any time.
2. Many of your questions can be answered by watching these videos or by using the Help button within AURORA.
3. Please review these before contacting PMB.
4. They are arranged in the recommended order but can be watched in any order.

Requirement date: Completion of this course is not required to access AURORA yet but will be required at a future date. Completion is electronically documented by CLASS so the certificate of completion is for your records only.





# AURORA Introduction

# What is AURORA?

AURORA is the NCI's innovative and centralized agent inventory management system

What is changing?

- Agent inventory management system is centralized at PMB and sites
- Agent ordering and accountability tasks are electronic and paperless
- Communication tools between PMB and sites are enhanced

What is not changing?

- Access to investigational agents and requirement for site inventory management
- Support of agent inventory management activities
- High-quality level customer service from PMB

# Goals of Building AURORA

- Consolidates PMB's outdated inventory management system and activities with clinical trial sites' inventory management activities
- Applies to all NCI-sponsored clinical trials using PMB-supplied agents
- Provides consistent record-keeping processes and oversight across 2000+ clinical trial sites within NCI's clinical trial networks, including international trial sites
- Provides accessibility to sponsor-required documentation
- Integration with CORE applications like IAM, RCR, RSS, START, OPEN, CTMB's Audit Information System



# High Level Benefits of AURORA

- Elimination of all paper records = no lost papers
- Improved sponsor and site compliance with regulatory requirements= system validation throughout trial conduct reduces audit and inspection findings
- Prevention of medication dispensing errors and common accountability errors = improved patient care
- PMB-determined agent expiration dates are populated on the eDARF = no missing stock notifications

## High Level Benefits of AURORA, continued

- AURORA's record retention supports straight-forward pharmacy monitoring and auditing = reduced # pharmacy findings on audit
- Electronic access for pharmacy monitoring and auditing = improves compliance by allowing central and remote auditing
- Efficient inventory management and accountability record storage and retention = push button reports on demand
- Streamlined communication between trial sites and PMB = reduced email volume

# Process Workflows

*Getting Started in AURORA*

# Process Workflow: Logging into AURORA

Welcome to the National Cancer Institute's **AURORA** system. AURORA is the NCI's innovative and centralized agent inventory management system. AURORA is available for the electronic submission of agent requests for NCI sponsored trials, review of agent order request status, access to agent stock recovery notices, access to Investigator Brochures, access to Material Safety Data Sheets, maintenance of Primary Shipping Designee shipping addresses and ordering designees, and creation and maintenance of electronic Drug Accountability Record Forms and associated inventory management practices. The system, in combination with other NCI Clinical Oncology Research Enterprise (CORE) applications, provides consistent record-keeping processes and oversight across clinical trial sites, improves sponsor and site compliance with regulatory requirements and streamlines sponsor and site communications.

An IAM account is required to access AURORA. Click **Request New Account** to obtain this account or click [here](#) to check on your IAM account status.

**CTEP-IAM** ID.me NIH

Username

Password

**Sign In** **Reset**

[Forgot Password?](#) | [Reset Password?](#) | [Annual Registration](#) | [Request New Account](#) | [Help Center](#)

**Warning Notice:**  
For public facing web pages to which the public has privileged access, e.g., clinical trial or adverse effects systems where users/patients are logging in to enter PII/PHI: [Read More...](#)

[NIH Web Policies and Notices](#)

## System Requirements

- Chrome or Firefox only
- 21 CFR Part 11 compliant

## Site user requirements

- Active user account and password

## Remember:

- Access is based on user role
- 15-minute timeout warning for inactivity
- Saving work creates official sponsor records
- Module-specific help links throughout

# Site Setup

- ❖ AURORA Training Videos in CLASS (<https://classlms.org>) and FAQs (PMB website)
  1. Please review before accessing AURORA. The Getting Started video is the first of the series and FAQs will be available after the Q&A session.
  2. How do I get access to AURORA (see FAQs)? Active user account/password vs. RCR Registration Type vs. User Roles

The AURORA eDARF module will be available to everyone several weeks after the OAOP transition but the eDARF module is not required to use yet.

- AURORA Implementation Plan FAQ will be updated as timelines develop.
- Future enhancements under consideration are:
  - Inclusion of NCI funded clinical trials with non-PMB supplied agents
  - Integration with other electronic DARF systems.

# Process Workflow: AURORA Dashboard

NIH NATIONAL CANCER INSTITUTE

AURORA

Orders ▾ Accountability ▾ Document Access ▾ PSD ▾



Menu Search

- Refresh Card - View More Records/Details

Orders (In-Process) 30	
Submitted	10
Processing	20

Orders (Processed) 732	
Shipped	661
Denied	47
Approved (Transfers)	24

Local Destructions 21			
R19350-0434	C-PA086-A091105-004	Approved	
REF19345-0162	C-NY313-9086-032	Pending	
REF19340-0159	C-NY158-CALGB-10701-011	Pending	
REF19338-0156	C-PA086-E4412-008	Pending	
REF19336-0155	C-PA086-S14001-009	Pending	
REF19336-0154	C-NY313-9086-030	Pending	
REF19322-0151	C-PA086-E4412-008	Pending	

Transfers (eDARF) 14			
REF19347-0238	C-PA086-9086-007	Pending	
REF19347-0237	C-PA086-9086-007	Pending	
REF19347-0235	C-PA086-9086-007	Pending	
T19347-0283	C-PA086-9086-007	Approved	
REF19344-0230	C-NY313-9086-030	Pending	
REF19305-0209	C-NY045-AALL1331-011	Pending	
REF19305-0210	C-NY045-AALL1331-011	Pending	

eDARF Favorites 23	
C-NY158-10017-001	
C-03013-AALL1231-003	
C-PA086-E4412-008	
S-NY158-NRG-GY004-001	
C-NY158-NRG-GY004-004	
C-NY158-E1910-003	
C-NY045-8264-024	

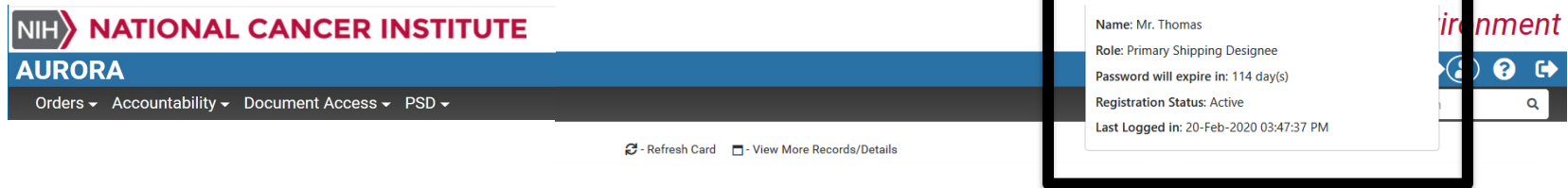
eDARFs (To acknowledge) 19			
C-PA086-A091105-004	Local Destruction (Approved)		
S-NY158-NRG-GY004-001	Received from Control		
C-NY313-8609-045	Transfer From		
C-NY313-8609-045	Transfer From		
C-NY313-A011203-044	Transfer From		
C-NY158-CALGB-10701-011	Returned from Satellite		
S-NY071-10017-002			

Shipping Address Changes 0

No Shipping address changes

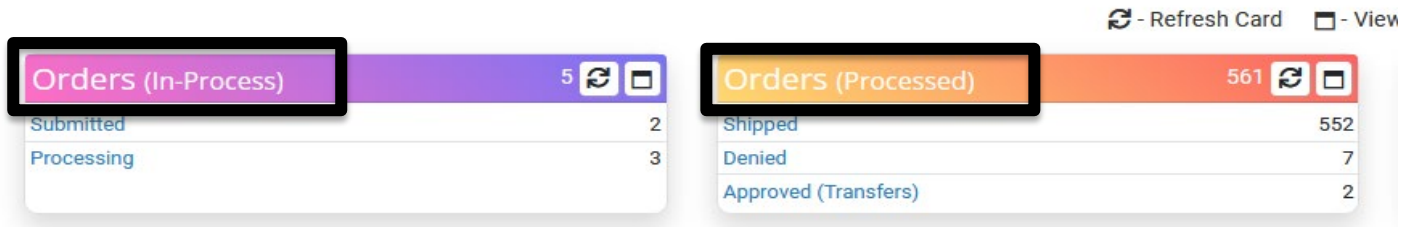
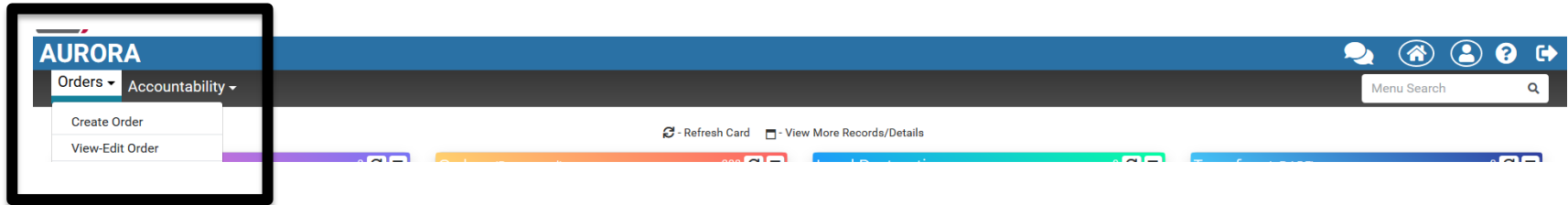


# Process Workflow: Tool Bar



# Accountability: Agent Ordering

- Orders are created from the tool bar link or from the eDARF with similar order parameters as OAOP
- Dashboard cards are convenient for tracking for Orders (in process) and Orders (Processed)





# Agent Ordering and Document Access

## Create Order

Investigator and Protocol Information

CTEP Person ID and Name \* <sup>1</sup>  
 Dr. Taral Pate (Active) Registration Status: Active Registration Type: Investigator

Select the CTEP Person

Ordering Designee: Ms. Jed Lynn Designee Role: Investigator to Primary Shipping Des

Protocol \*  
 E4A03 Protocol Title: A Randomized Phase III Study of CC-

Select the Protocol

Order Type: Standard Protocol Status: Closed to Accrual

[Policy and Guidelines for Investigational Agent Ordering](#) <sup>1</sup>

Shipping Address Details

Institution: Columbus NCI Community Oncology Research Program (COLUMBUS)

C/O: Lynn, Jec

Phone:

Email: sheree@ctis1columbusccop.org

Internal Office:

Street1: 1335 Dublin Road

Street2: Suite 124-A

City: Columbus State/Province: OH - Ohio

Zip Code: 43215 Country: USA

Patient Information

Number of patients undergoing treatment on the selected protocol \*

Order Line Items <sup>1</sup>

Actions	Agent Name - Strength - Unit - Form - Concentration - Fill Volume - Fill Unit * <sup>1</sup>	Current Inventory * <sup>1</sup>	Ordered Quantity * <sup>1</sup>	Package Description
	703813 - Lenalidomide (CC-5013) - 25 mg Capsules			

1 - 1 of 1 items

Order Details

Date Needed \*  Comments:

Courier Information

URGENT SHIPMENTS MUST BE ACCOMPANIED BY AN EXPRESS COURIER ACCOUNT NUMBER

[Select Courier Profile](#)  Save Courier Profile

Courier Name:  Courier Account Number:  Courier Reference Number:

## AURORA

Orders ▾ Document Access ▾ Accountability ▾ PSD ▾

- Investigator Brochures
- MSDS Documents
- Stock Recovery Documents

### Search

Search investigators

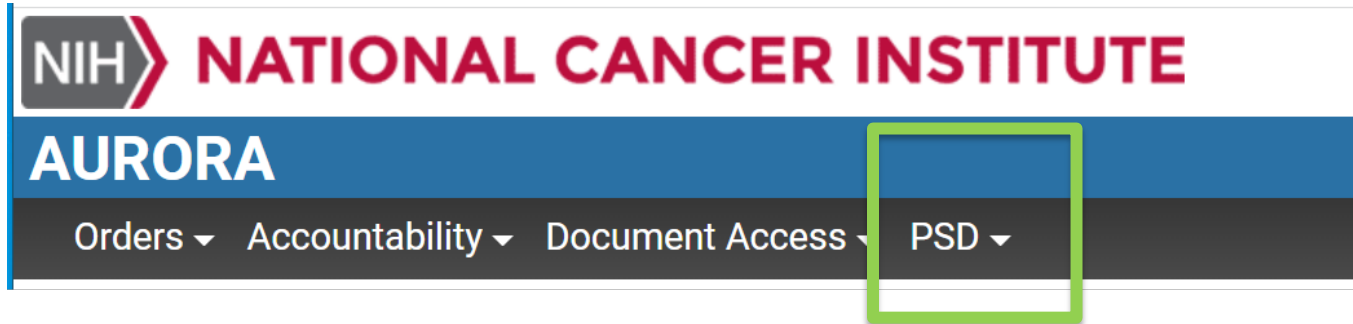
NCI Investigator Number

Investigator Last Name

Get Info

Reset

# Flexibility: Primary Shipping Designee (PSD) Worksheet



- PSD accesses the worksheet from the toolbar
- PSD address can be set up or revised as trial site's needs change
- Revised shipping address may trigger bulk transfers
- PODs are added or removed as needed

# Process Workflow: Site Maintenance

**Site Maintenance**



Control Sites

CTEP ID	Name	Organization Status	Type	Address Status	Shipping Address
PA015	University of Pittsburgh Cancer Institute (UPCI)	Active	Cancer Center	Active	5110 Centre Avenue, Ground Floor AG40.3, Pittsburgh PA 15232, USA
PA015	University of Pittsburgh Cancer Institute (UPCI)	Active	Cancer Center	Inactive	William Cooper Ambulatory Care Pavilion-Hillman Cancer Ctr, 5115 Centre Avenue, Ground Floor AG40.3, Pittsburgh PA 15232-1305, USA
PA015	University of Pittsburgh Cancer Institute (UPCI)	Active	Cancer Center	Inactive	Second Floor Pharmacy Room A210.50, Pittsburgh PA 15232-1305, USA
PA015	University of Pittsburgh Cancer Institute (UPCI)	Active	Cancer Center	Inactive	5115 Centre Avenue, Ground Floor AG40.3, Pittsburgh PA 15232, USA

1 - 4 of 4 items

Control Dispensing Area **Satellites**



+ Add

Actions	CTEP ID *	Name *	Type *	Status *	Status Date *	User Added	Date Added
 	PA011	UPMC-Magee Womens Hospital	ITN	Active	08-Jan-2021	Ms. Jordana Marie Tang	08-Jan-2021

1 - 1 of 1 items

Satellite Dispensing Area **Satellite Designees**

+ Add

Actions	CTEP Person ID *	Name	Registration Type	Registration Status	Status *	Status Date *	User Added	Date Added
 	[REDACTED]	Ms. Jordana Marie Tang	Associate	Active	Active	08-Jan-2021	Ms. Jordana Marie Tang	08-Jan-2021

1 - 1 of 1 items

TOP

# Process Workflow: Errors and Notifications

The image shows two screenshots of the AURORA system interface. The top screenshot displays an error notification: "Error! Dispensing Area (PHARMA201918) is currently Inactive. No Dispensing is allowed. Please select new Dispensing Area or add new one in Site Admin Maintenance." The bottom screenshot displays an info notification: "Info! Protocol Status change letter has been issued for NCI Protocol 10265 on Sep-30-2019. Please review: 10265 - 623408 (MoAb 14.18, chimeric (CH14.18)) - 09-30-19 - PRS.DOCX".

**AURORA**  
Orders ▾ Accountability ▾

**Investigational Agent Accountability Log (Open)**

▲ Notifications

**Error!**

- Dispensing Area (PHARMA201918) is currently Inactive. No Dispensing is allowed. Please select new Dispensing Area or add new one in Site Admin Maintenance.

**AURORA**  
Orders ▾ Accountability ▾

**Investigational Agent Accountability Log (Open)**

▲ Notifications

**Info!**

- Protocol Status change letter has been issued for NCI Protocol 10265 on Sep-30-2019. Please review: [10265 - 623408 \(MoAb 14.18, chimeric \(CH14.18\)\) - 09-30-19 - PRS.DOCX](#)

▲ DARF Information (NCI Supplied) [C-TN089-10265-003](#)

**Institution:** The West Clinic - Wolf River (TN089) **Investigator:** Tillmanns, Todd

**Shipping Address:** Research Pharmacy, 7945 Wolf River Boulevard, West Clinic Center, Germantown TN 38138, USA

**Protocol Title:** new protocol for 1.5.0 testing **Protocol:** 10265 (Active)

**Agent:** ABC (NSC-555666) **Dose Form & Strength:** 2 nm light Injection

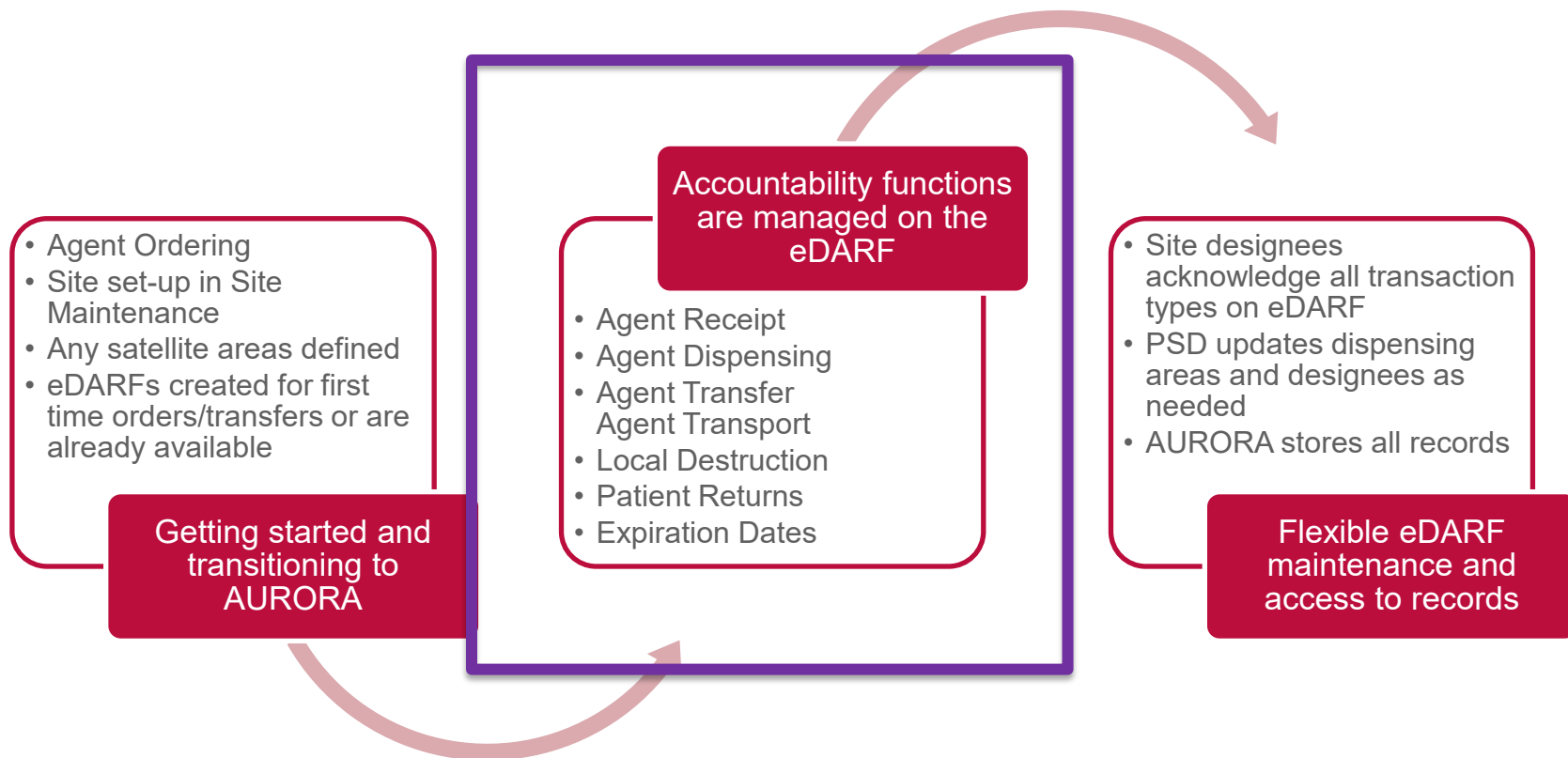
# Process Workflow: Dialog Function

The site will use this function to:


- Report temperature excursions to PMB for evaluation and receive PMB response for documentation
- Report product complaints to PMB
- Ask protocol or agent related questions
- If required, upload supporting documents in the accountability record relevant to the affected agent supply

The screenshot displays the AURORA web application interface. At the top, a blue header contains the text 'AURORA' and navigation icons. Below the header, a dark grey bar shows 'Orders' and 'Accountability' dropdown menus, along with a 'Menu Search' field. The main content area is divided into two panels. The left panel, titled 'Investigational Agent Accountability', displays details for a specific agent: 'DARF Information (NCI Supplied) C-CT037-EA9161-001', 'Institution: Smilow Cancer Center/Yale-New Haven Hospital (CT037)', 'Shipping Address: Pharmacy, 266 South Frontage Road, Eighth Floor', 'Protocol Title: A Randomized Phase III Study of the Addition of Ven...', and 'Agent: Ibrutinib (PCI-32765) (NSC-748645)'. It also includes a 'Dispensing Area' dropdown set to 'IDS' and a 'Starting Page No: 3'. The right panel, titled 'Dialog', is a modal window with a title bar and standard window controls. It contains a 'Send to' dropdown set to 'PMB', a 'Category' dropdown set to 'Dispensing', and a text input field with the placeholder 'Enter your Message here'. A green 'Post' button is located at the bottom right of the dialog. In the background, a 'Record' panel is partially visible, featuring a star icon, a 'Back' button, an 'eDarf Search' field, a 'Generate PDF' button, and a 'Create Satellite eDARF' button.

# Accountability Process Workflow



## Helpful Hints for Initiating eDARFs for the first time

- Collect your current inventory quantity and lot number information for each lot prior to initiating eDARFs (Recall that AURORA security logs you off after 15 min of inactivity and unsaved work is lost)
- Make sure information entered is accurate before saving since this creates official records in the system
- Remember that inventory information you enter will be used by AURORA to notify you of expiration notifications
- Help  is available at the top right corner of the toolbar to give step-by-step instructions
- Generally “Initiate eDARF” function is accessed on dashboard at time of agent receipt or agent transfer

# Accountability: eDARF Header

- eDARF names are unique records generated by AURORA
  - Ex: **C** or **S-NY158-EA9161-001**
- Header is auto-populated for protocols with PMB-supplied agents
  - Once set up, most eDARF header fields cannot be changed
- Add Local Protocol Number to header if desired
- Choose dispensing area from the list of areas already set up in Site Maintenance
- Errors, warnings and relevant alerts are provided above header



# Accountability: eDARF Header

AURORA

Orders ▾ Accountability ▾ Document Access ▾ PSD ▾
Menu Search

Investigational Agent Accountability Log(Open)
Control Record

▲ DARF Information (NCI Supplied) C-PA015-10250-002 1 Create Satellite eDARF

**Institution:** University of Pittsburgh Cancer Institute (UPCI) (PA015)     **Investigator:** Burgess, Melissa [REDACTED]     [Linked eDARFs](#)

**Shipping Address:** 5110 Centre Avenue, Ground Floor AG40.3, Pittsburgh PA 15232, USA

**Protocol Title:** A Phase II Study of the PARP Inhibitor Olaparib in Combinati...     **Protocol:** 10250 (Closed to Accrual)     **Local Protocol No.:**

**Agent:** Olaparib (AZD2281) (NSC-747856)     **Dose Form & Strength:** 100 mg Tablets     **Bottle Size:** 32 Tablets/Bottle

**Dispensing Area:** Oncology Pharmacy   
Manage Dispensing Area

**Starting Page No.:** 1

▲ Lot Information 2

Lot: 41515.44/1

**Last Transaction:** Conversion  
**Transaction Date:** 15-Mar-2022  
**Mnfr:** AstraZeneca Pharmaceuticals LP (AZP)  
**Use By Date:** 30-Nov-2020 PMB  
**Balance:** 0 tablets

Lot: 41515.47/1

**Last Transaction:** Dispensing  
**Transaction Date:** 21-Apr-2022  
**Mnfr:** AstraZeneca Pharmaceuticals LP (AZP)  
**Balance:** 91 tablets

▲ Completed Transactions 3

Line No	Date	Type	Transaction	Patient Initials	Patient ID	Dose & Schedule	Quantity	Balance	Lot No	Use By Date	Recorder	Recorder Date
6	15-Mar-2022	Adjustment					+4 (bottle)	5 (bottle)	Mnfr: AZP Lot: 41515.47/1		Everett, Brady	15-Mar-2022

# Accountability: Agent Receipt from NCI

🔄 - Refresh Grid   ✕ - Close Grid/Back to Cards

## Orders

Order (Transfer) Number	Reference Number	Order (Transfer) Type	Status	Investigator	Site	Protocol	Agent Dose (Component)	Patient ID	Shipped (Transfer) Date	Tracking Number	eDARF	Date Ordered
2020287												
2020287-0094	O-1176425	Standard	Shipped	Morrow, Resensee...	Columbus NCI Community On...	A031501	776864 (Pembrolizumab (MK...		13-Oct-2020	397787923486	C-COLUMBUS-A031501-0...	12-Oct-2020
2020287-0193	O-1176547	Standard	Shipped	Morrow, Resensee...	Columbus NCI Community On...	EA6134	763760 (Dabrafenib (GSK211...		13-Oct-2020	397795137342	C-COLUMBUS-EA6134-001	13-Oct-2020
2020287-0193	O-1176548	Standard	Shipped	Moore, Timothy Da...	Columbus NCI Community On...	A041702	766270 (Vogelstein ARB10...		13-Oct-2020	397796619082	C-COLUMBUS-A041702-001	13-Oct-2020

Page 1 of 1   10

### Completed Transactions 7

Line No	Date	Type	Transaction	Patient Initials	Patient ID	Dose & Schedule	Quantity	Balance	Lot No	Use By Date	Recorder	Recorder Date
2	19-Nov-2020	Received from NCI	2020287-0193				+1 (bottle)	4 (bottle)	Mnfr: NVR Lot: PH8S		Lynn, Jed	19-Nov-2020
3	09-Dec-2020	Change					4 (bottle)	4 (bottle)			Ms. Jed Lynn	09-Dec-2020
4	12-Jan-2021	Sent to Satellite	S-COLUMBUS-EA6134-003				-1 (bottle)	3 (bottle)	Mnfr: NVR Lot: PH8S		Lynn, Jed	12-Jan-2021
5	12-Jan-2021	Returned from Satellite	S-COLUMBUS-EA6134-003				+1 (bottle)	4 (bottle)	Mnfr: NVR Lot: PH8S		Ms. Jed Lynn	12-Jan-2021

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[+ Add Transaction](#)

# Accountability: Add Transaction Types from eDARF

▲ DARF Information (NCI Supplied) [C-CT037-EA3161-002](#)

**Institution:** Smilow Cancer Center/Yale-New Haven Hospital (CT037)      **Investigator:** Bhatia, Aarti

**Shipping Address:** Pharmacy, 266 South Frontage Road, Eighth Floor Room 8-110, New Haven CT 06510, USA

**Protocol Title:** A Phase II/III Randomized Study of Maintenance Nivolumab Versus Observation L...      **Protocol:** EA3161 (Active)

**Agent:** Nivolumab (NSC-748726)      **Dose Form & Strength:** 100 mg Injection      **Bottle Size:** 10 mL Vial

**Dispensing Area:** IDS [Manage Dispensing Area](#)

**Starting Page No:** 4

▼ Lot Information 1

▲ Completed Transactions 1

Line No	Date	Type	Transaction	Patient Initials	Patient ID	Dose & Schedule	Quantity	Balance	Lot No	Use By Date
1	21-Feb-2020		Balance Forward					10 (vial)		

Page 1 of 1

[+ Add Transaction](#)

▲ Add Transaction

**Date \*** 21-Feb-2020

**Type \***

- Dispensing
- Adjustment
- Inventory Verification
- Request Local Destruction
- Request Transfer To

[Reset](#) [Save](#)

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Department of Health and Human Services | National Institutes of Health | National Cancer Institute | USA.gov

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## Transaction Types

- Dispensing
- Inventory adjustment
- Inventory verification
- Local Destruction
- Transfer
- Transport (if Satellite is set up)

# Accountability: Agent Dispensing in AURORA

- Patient study ID is accessible from OPEN
- Site can assign use-by dates to specific lots (but not required)
- PMB-assigned use-by date will override site's assigned date
- Agent supply configuration can be converted from container size to unit size if needed
  - Example shown converts bottles to capsules









Agent: Dabrafenib (GSK2118436B) (NSC-763760)      Dose Form & Strength: 50 mg Capsules      Bottle Size: 120 Capsules/Bottle



Dispensing Area:  

Starting Page No: 1

▼ Lot Information <sup>2</sup>

▲ Completed Transactions <sup>8</sup>

Line No	Date	Type	Transaction	Patient Initials	Patient ID	Dose & Schedule	Quantity	Balance	Lot No	Use By Date	Recorder	Recorder Date	
6	29-Jun-2021	Conversion					120 (capsules)				Lynn, Jed	29-Jun-2021	 
7	29-Jun-2021	Dispensing		AB	123456	50 mg daily	(capsules)	92 (capsules)	Lot: PHBS	30-Sep-2022 <a href="#">Site</a>	Lynn, Jed	29-Jun-2021	  
8	30-Jul-2021	Dispensing		AB	123456	50 mg daily	-28 (capsules)	64 (capsules)	Mnfr: NVR Lot: PHBS	30-Sep-2022 <a href="#">Site</a>	Lynn, Jed	30-Jul-2021	  

[+ Add Transaction](#)  

[Reset](#) [Save](#)

# Accountability: Inventory Adjustment in AURORA

Used for inventory discrepancies (comment is required)

**AURORA**

Lot Information 2

**Lot: L0605099A4**  
Last Transaction: Dispensing  
Transaction Date: 21-Feb-2020  
Mnfr: Pharmacyclics Inc (PHY)  
Balance: 2 bottle

**Lot: L0609081A1**  
Transaction Date: 21-Feb-2020  
Mnfr: Pharmacyclics Inc (PHY)  
Balance: 2 bottle

Completed Transactions 2

Line No	Date	Type	Transaction	Patient Initials	Patient ID	Dose & Schedule	Quantity	Balance	Lot No	Use By Date	Recorder	Recorder Date
1	21-Feb-2020	Balance Forward						5 (bottle)			Ferencz, Thomas Michael	21-Feb-2020
2	21-Feb-2020	Dispensing		ABC	19040	420 mg QD	-1 (bottle)	4 (bottle)	Mnfr: PHY Lot: L0605099A4		Ferencz, Thomas Michael	21-Feb-2020

Page 1 of 1

+ Add Transaction

**Add Adjustment Transaction**

Date \* 24-Feb-2020 Type \* Adjustment

Manufacturer/Lot No \* L0609081A1 Transaction Action \* Add Adjusted Quantity \* 1 bottle Use by Date dd-MMM-yyyy Attach Select files...

Comments \* was misplaced after 2/21 dispensing

Reset Save

TOP

# Accountability: Agent Verification in AURORA

AURORA supports clinical trial site procedure for inventory verification and IDS best practices. This is not a required transaction type.

Completed Transactions 8

Line No	Date	Type	Transaction	Patient Initials	Patient ID	Dose & Schedule	Quantity	Balance	Lot No	Use By Date	Recorder	Recorder Date	
1	22-Dec-2020	Balance Forward					0 (bottle)	0 (bottle)			Lynn, Jed	22-Dec-2020	
2	22-Dec-2020	Inventory Verification					0 (bottle)	0 (bottle)			Lynn, Jed	22-Dec-2020	
		Received from Control	C-COLUMBUS-EA6134-001						Mnfr: NVR Lot: PH8S				
4	12-Jan-2021	Returned to Control	C-COLUMBUS-EA6134-001				-1 (bottle)	0 (bottle)	Mnfr: NVR Lot: PH8S		Lynn, Jed	12-Jan-2021	
5	27-Apr-2021	Received from Control	C-COLUMBUS-EA6134-001				+1 (bottle)	1 (bottle)	Mnfr: NVR Lot: PH8S		Ms. Jed Lynn	27-Apr-2021	

Page 1 of 2 5

+Add Transaction

1 - 5 of 8 items

# Accountability: Local Destruction in AURORA

Local destruction request is the only agent return mechanism within AURORA eDARF module for final disposition of PMB supplied agents that are:

- Expired
- Unsuitable for use
- Cannot be transferred to another NCI trial

▲ Pending/Denied Transactions 1

Actions	Line No	Date	Type	Transaction	Reason	Quantity	Mnfr/Lot No	Recorder	Recorder Date
	1	27-Aug-2021	Request Local Destruction	REF21239-0010 (Pending)	Lot expired	-2 (bottle)	Mnfr: CLVS Lot: YXNC	Ms. Jed Lynn	27-Aug-2021

▲ Completed Transactions 4

Line No	Date	Type	Transaction	Patient Initials	Patient ID	Dose & Schedule	Quantity	Balance	Lot No	Use By Date	Recorder	Recorder Date
1	10-Dec-2020	Balance Forward						3 (bottle)			Lynn, Jed	10-Dec-2020
2	10-Dec-2020	Received from NCI	2020281-0031				+2 (bottle)	5 (bottle)	Mnfr: CLVS Lot: CBFCW		Lynn, Jed	10-Dec-2020
3	25-Jan-2021	Dispensing Area Change						5 (bottle)			Ms. Jed Lynn	25-Jan-2021
4	01-Aug-2021	Local Destruction	R21218-0004				-1 (bottle)	4 (bottle) Reserved: 2 (bottle)	Mnfr: CLVS Lot: YXNC		Ms. Jed Lynn	06-Aug-2021

[+ Add Transaction](#)

# Accountability: Agent Transfers in AURORA

Agent transfer requests are for reasons such as:

- Change of site PI
- Change of protocol status and/or patients are off study treatment
- Management of short-dated supplies or urgent medical need
- Blinded study patient is transferred to another site PI

Pending/Denied Transactions 1										
Actions	Line No	Date	Type	Transaction	Reason	Quantity	Mnfr/Lot No	Recorder	Recorder Date	
	3	26-Oct-2021	Request Transfer To	REF21299-0020 (Pending)	Urgent medical need	-1 (vial)	Mnfr: MSD Lot: S028160	Ms. Jed Lynn	26-Oct-2021	

Completed Transactions 5												
Line No	Date	Type	Transaction	Patient Initials	Patient ID	Dose & Schedule	Quantity	Balance	Lot No	Use By Date	Recorder	Recorder Date
2	11-Dec-2020	Transfer From	T21025-0012 C-COLUMBUS- S1418-010				+2 (vial)	5 (vial)	Mnfr: MSD Lot: S028160		Ms. Jed Lynn	06-Aug-2021
3	22-Oct-2021	Transfer To	T21295-0016 C-COLUMBUS- A031501-003				-1 (vial)	4 (vial)	Mnfr: MSD Lot: S028160		Ms. Jed Lynn	22-Oct-2021
4	26-Oct-2021	Transfer To	T21299-0017 C-COLUMBUS- A031501-003				-1 (vial)	3 (vial)	Mnfr: MSD Lot: S028160		Ms. Jed Lynn	26-Oct-2021
5	26-Oct-2021	Transfer To	T21299-0018 C-COLUMBUS- A031501-003				-1 (vial)	2 (vial) Reserved: 1 (vial)	Mnfr: MSD Lot: S028160		Ms. Jed Lynn	26-Oct-2021

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[+ Add Transaction](#)





# Accountability: Agent Transporting to Satellite

## Control Record

Completed Transactions 7











Line No	Date	Type	Transaction	Patient Initials	Patient ID	Dose & Schedule	Quantity	Balance	Lot No	Use By Date	Recorder	Recorder Date	
1	19-Nov-2020	Balance Forward						3 (bottle)			Lynn, Jed	19-Nov-2020	 
2	19-Nov-2020	Received from NCI	2020287-0193				+1 (bottle)	4 (bottle)	Mnfr: NVR Lot: PH8S		Lynn, Jed	19-Nov-2020	 
3	00-Dec-2020	Dispensing Area						4 (bottle)			Ms. Jed Lynn	00-Dec-2020	 
4	12-Jan-2021	Sent to Satellite	S-COLUMBUS- EA6134-003				-1 (bottle)	3 (bottle)	Mnfr: NVR Lot: PH8S		Lynn, Jed	12-Jan-2021	 
5	12-Jan-2021	Satellite	EA6134-003				+1 (bottle)	4 (bottle)	Lot: PH8S		Ms. Jed Lynn	12-Jan-2021	 

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+Add Transaction  

## Satellite Record

Completed Transactions 8

Line No	Date	Type	Transaction	Patient Initials	Patient ID	Dose & Schedule	Quantity	Balance	Lot No	Use By Date	Recorder	Recorder Date	
1	22-Dec-2020	Balance Forward						0 (bottle)			Lynn, Jed	22-Dec-2020	 
2	22-Dec-2020	Inventory						0 (bottle)			Lynn, Jed	22-Dec-2020	 
3	12-Jan-2021	Received from Control	C-COLUMBUS- EA6134-001				+1 (bottle)	1 (bottle)	Mnfr: NVR Lot: PH8S		Ms. Jed Lynn	12-Jan-2021	 
4	12-Jan-2021	Control	EA6134-001				-1 (bottle)	0 (bottle)	Lot: PH8S		Lynn, Jed	12-Jan-2021	 
5	27-Apr-2021	Received from Control	C-COLUMBUS- EA6134-001				+1 (bottle)	1 (bottle)	Mnfr: NVR Lot: PH8S		Ms. Jed Lynn	27-Apr-2021	 

Page 1 of 2 | 5 | 1 - 5 of 8 items

+Add Transaction  

# Clinical Trial Site Flexibilities

# Flexibility: Recording Patient Returns in AURORA

Patient return of unused agent can be recorded on the line of dispensing

- Indicated to the right of the dispensing line once completed
- Multiple returns can be documented on same dispensing line

Completed Transactions 8

Line No	Date	Type	Transaction	Patient Initials	Patient ID	Dose & Schedule	Quantity	Balance	Lot No	Use By Date	Recorder	Recorder Date
6	29-Jun-2021	Conversion						120 (capsules)			Lynn, Jed	29-Jun-2021
7	29-Jun-2021	Dispensing		AB	123456	50 mg daily	-28 (capsules)	92 (capsules)	Mnfr: NVR Lot: PH8S	30-Sep-2022 <a href="#">Site</a>	Lynn, Jed	29-Jun-2021
8	30-Jul-2021	Dispensing		AB	123456	50 mg daily	-28 (capsules)	64 (capsules)	Mnfr: NVR Lot: PH8S	30-Sep-2022 <a href="#">Site</a>	Lynn, Jed	30-Jul-2021

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+ Add Transaction

6 - 8 of 8 items

Patient Returns

Quantity Returned \*  RX #  Returned Date \*  Destruction Date

Comments

Reset Save

# Flexibility: Bulk Agent Transfers

AURORA



🔄 - Refresh Card    🗄️ - View More Records/Details

Card Title	Count	Sub-items
Orders (In-Process)	5	Submitted: 2, Processing: 3
Orders (Processed)	561	Shipped: 552, Denied: 7
Local Destructions	0	No Local Destructions requests
Transfers (eDARF)	0	No Transfer Requests
eDARF Favorites	1	C-PA015-NRG-GY009-004
Shipping Address Changes	1	PA015 PSD 3 eDARFs, 3 Investigators
eDARFs (To acknowledge)	0	No eDARF Transactions to be acknowledged
Notifications	11	2021-003 (1) Nov-08-2021 12:58 PM 2, R-21294-002-01 (1) Oct-21-2021 11:46 AM 1

- Any street address, city or zip code change could trigger bulk agent transfers
- Agent transfer transactions are completed simultaneously in AURORA eDARF module
- Address change on PSD worksheet can be done at the time of relocation

# Flexibility: eDARF Search Module

- Powerful search function allows user to locate eDARFs by specific search criteria. Examples:
  - Inventory on hand by agent, protocol or investigator
  - All expiring agent inventory by date range
  - All agent/strength on hand in case urgent need for agent transfer
  - All inventory for an ordering investigator who has left the site
  - All inventory on hand when control dispensing area is re-locating and all agents need to be transferred
- Results can be exported as excel or pdf document

# Flexibility: eDARF Search for Agent/Lot

## Drug Accountability Record Search

Search Criteria

Reset

Preset Searches

- Threshold Balance Search
- Expiration Search

Advanced Search

eDARF

- Institution \*
- eDARF
- eDARF Deta

Institution

Enter Search Criteria

UPMC-Magee Womens Hospital (PA011)

University of Pittsburgh Cancer Institute (UPCI) (PA015)

## Drug Accountability Record Search

Search Criteria

- eDARF
  - eDARF
  - eDARF Details
  - Institution \*
  - Protocol
  - Investigator
  - Dispensing Area
- AGENTS (Components)
  - NSC (Component)
  - Dose
  - Bottle Size
  - Lot (PCN)
  - Manufacturer
  - Lot (PCN) Details
- PATIENTS
  - Patient
- TRANSACTIONS
  - Transaction
  - Recorded User
  - Transaction Details

Lot (PCN)

Enter Search Criteria

L0605099A4 (PHY)

Note: The search results has more records. If the record is not found in the above list, please enter the search criteria

Lot (PCN)  Search

Added Search Criteria

Expand All

- Institution
  - Smilow Cancer Center/Yale-New Haven Hospital (CT037) x
- NSC
  - Ibrutinib (PCI-32765) (NSC-748645) x
- Lot
  - Lot: L0609081A1 (PHY) x

Reset Search

# Flexibility: eDARF Search Results for Agent/Lot

**NIH NATIONAL CANCER INSTITUTE** Beta Environment

**AURORA** Menu Search

### Drug Accountability Record Search

▼ Search Criteria

2 records found, 2 records are displayed.

eDARF Search Results

eDARF Number	eDARF Type	eDARF Status	Institution	Investigator	Protocol	Patient	Agent (Component)	Dose	Dispensing Area	eDARF Balance	Last Transaction	Last Transaction Date
C-CT037-EA9161-001	CONTROL	Open	Smilow Cancer Center/Yale-New Haven Hospital (CT037)	Scott Huntington, MD	EA9161		Ibrutinib (PCI-32765) (NSC-748645)	140 mg Capsules	IDS	3 bottle	Adjustment	24-Feb-2020
C-CT037-A041702-006	CONTROL	Open	Smilow Cancer Center/Yale-New Haven Hospital (CT037)	Elan Gorshein, DO, JD, MPH, BA	A041702		Ibrutinib (PCI-32765) (NSC-748645)	140 mg Capsules	IDS	10 bottle	Balance Forward	24-Feb-2020

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# Process Workflows

*Record Retention and Site Auditing*



# Process Workflow: Record Retention

- Accountability records include:
  - Shipment records
  - eDARFs (includes receipt, dispensing, transfers, local destructions)
  - Notes to file
- All authorized personnel can access past site records even if not authorized at the time the records were created
- eDARF OMB Form Number and expiration date will still exist and print automatically and updated by PMB within AURORA. Sites will no longer need to monitor eDARF expiration for AURORA generated eDARFs.

# Process Workflow: Site Auditing

## AURORA:


- Improves site compliance with pharmacy audits
- Retains accountability records indefinitely
- Allows records to be accessible to authorized site personnel and off-site auditors
- Produces on-demand records when needed
- Accountability records can be saved and uploaded in advance of an audit or submitted for remote monitoring

# Future Enhancements Under Consideration and Resources

# Planned and Future Enhancements Under Consideration

- Management of multiple shipping addresses
- eDARF set-up for all NCI studies (including non-PMB supplied agents)
- Specialized reports on-demand
- Integration with other electronic accountability systems

# Resources for AURORA

- NCI/CTEP AURORA Training online course
- Full AURORA Overview video and slides
- PMB Frequently Asked Questions (FAQ) webpage 
- Help button on AURORA dashboard provides step-by-step help
- [PMBAfterHours@mail.nih.gov](mailto:PMBAfterHours@mail.nih.gov) – send emails with subject: AURORA
- PMB general phone: 240-276-6575

# Summary

1. First requirement is transitioning from OAOP to AURORA for drug ordering, viewing orders, accessing PMB supplied documents (approx. early August 2022)
  - No changes in the agent ordering process or individual access
  - Implementation Plan FAQ for future announcements of requirements
2. eDARFs module in AURORA available several weeks after OAOP transition
  - Use is not required by sites yet but available if desired. (See Implementation Plan FAQ)
3. Review the NCI-CTEP AURORA Training video series available in CLASS website – look for email invite soon
  - Attend the July Q&A session with any questions after viewing

Contact: [PMBAfterHours@mail.nih.gov](mailto:PMBAfterHours@mail.nih.gov) or 240-276-6575

# Acronyms

- **PMB** Pharmaceutical Management Branch
- **CORE** Clinical Oncology Research Enterprise
- **NCI** National Cancer Institute
- **CTMS** Clinical Trials Monitoring Service
- **MSDS** Material Data Safety Sheet
- **RCR** Registration and Credential Repository
- **DTL** Delegation of Task Log
- **CTEP-AERS** Cancer Therapy Evaluation Program- Adverse Event Reporting System
- **OAOP** Online Agent Order Processing application
- **RCR** Registration and Credential Repository
- **OPEN** Oncology Patient Enrollment Network
- **IAM** Identity and Access Management
- **RSS** Regulatory Support System
- **START** Study Abstraction Review & Tracking
- **CTMB** Clinical Trials Monitoring Branch
- **CFR** Code of Federal Regulations
- **POD** Primary Ordering Designee
- **IDS** Investigational Drug Service
- **PI** Principal Investigator
- **OMB** Office of Management and Budget
- **CTEP** Cancer Therapy Evaluation Program



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