Safeguarding the Science: Best Practices for Investigational Drug Documentation and Management

SWOG QA Webinar

June 30, 2026

Presented by:

- **Joyce Lee, PharmD, BCOP, BCPS,** Chair, SWOG Pharmaceutical Science Committee Clinical Pharmacist Specialist, Oncology/IDS, UC Davis Comprehensive Cancer Center, Sacramento, CA
- **Vy Bui, PharmD, BCPS, CCRP,** SWOG Drug Information Subcommittee Chair

Agenda

Joyce Lee, PharmD, BCOP, BCPS, Chair, SWOG Pharmaceutical Science Committee, Clinical Pharmacist Specialist, Oncology/IDS, UC Davis Comprehensive Cancer Center:

- **Investigational Drug Accountability and IND Maintenance**
  - Investigational Drug Management and AURORA

Vy Bui, PharmD, BCPS, CCRP, SWOG Drug Information Subcommittee Chair:

- **Patient Adherence with Oral Anticancer Medications**
  - Adherence in the Literature: Chronic Myeloid Leukemia
  - Adherence in the Literature: Breast Cancer

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  - **Attend the entire educational activity and then complete and submit the post-activity evaluation via the Survey Monkey link that will be provided via WebEx chat message at the end of the webinar.**
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The maximum number of hours awarded for this Continuing Nursing Education (CNE) activity is 1 contact hour.

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Investigational Drug Accountability and IND Maintenance

Joyce Lee, PharmD, BCOP, BCPS

Chair, SWOG Pharmaceutical Science Committee

Clinical Pharmacist Specialist, Oncology/IDS

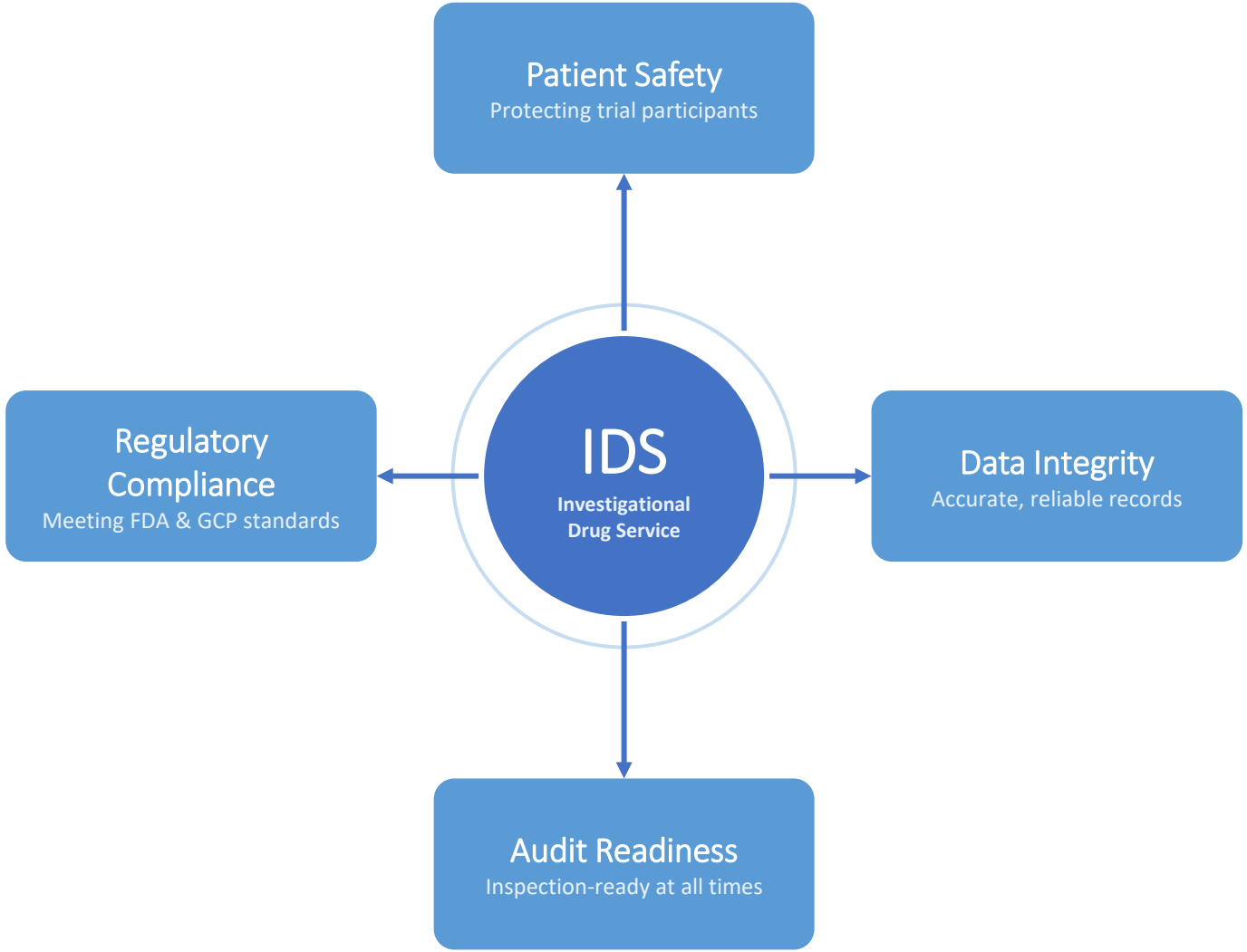
UC Davis Comprehensive Cancer Center

Sacramento, CA

Learning Objectives

- Describe the importance of investigational drug accountability.
- Explain how non-compliance impacts research outcomes.
- Perform IND maintenance activities within AURORA.
- Complete required accountability documentation.
- Verify investigator CTEP registration requirements prior to dispensing

Why Investigational Drug Accountability Matters

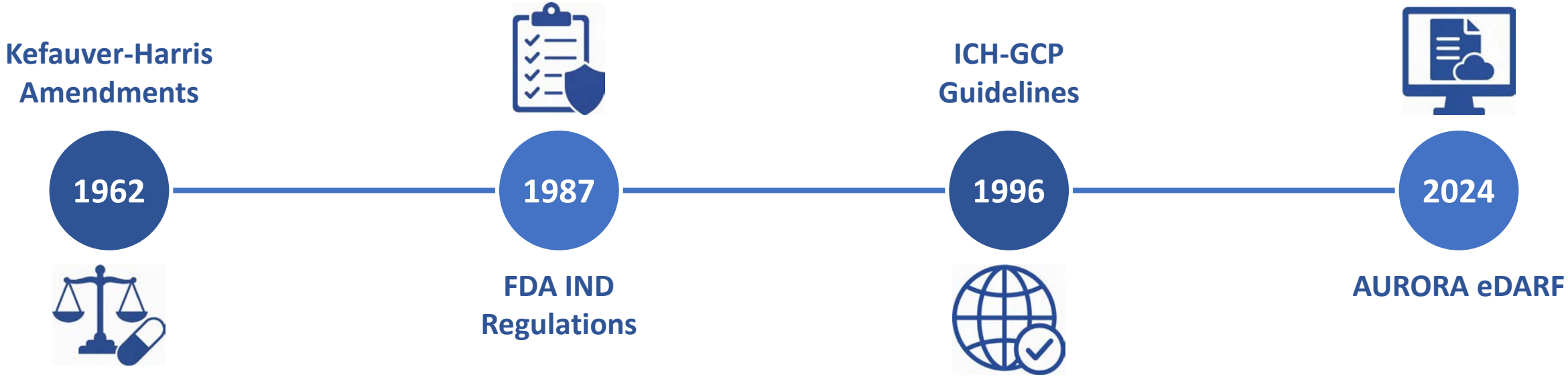


Why It Matters

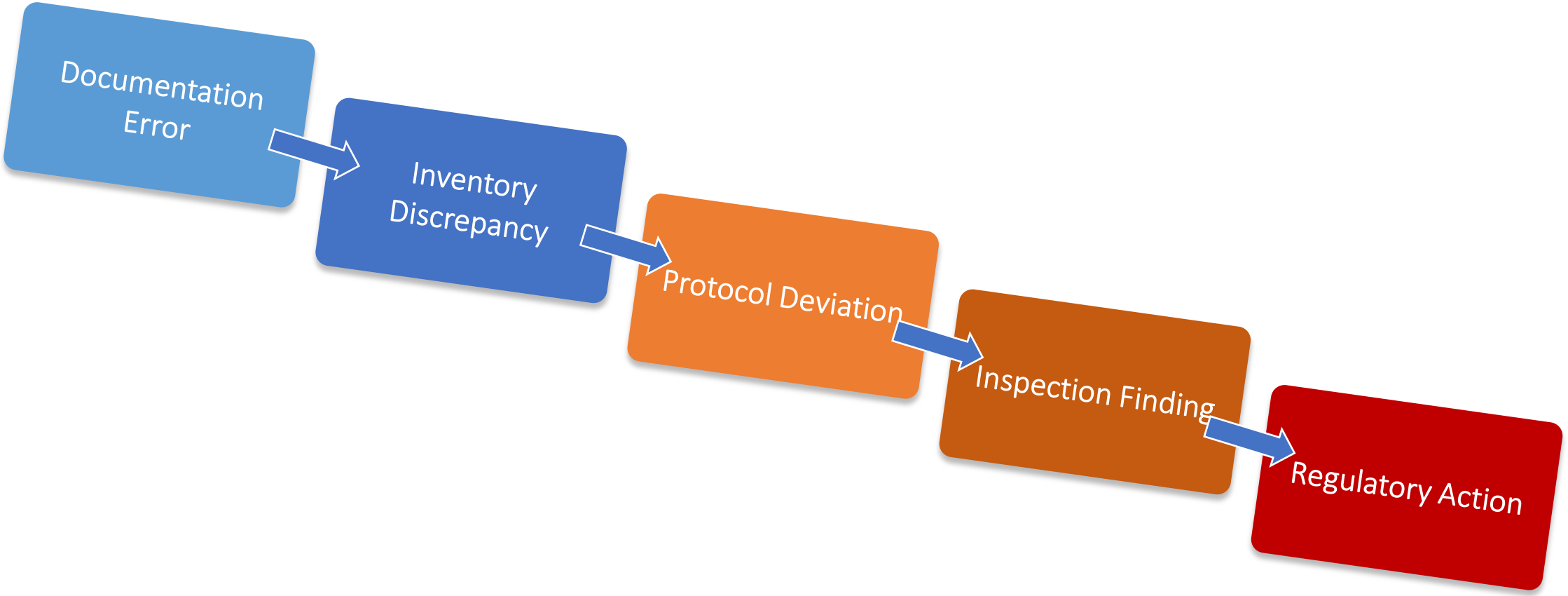
Investigational drug accountability is critical for:

- **Patient safety**
- **Protection of study integrity**
- **Regulatory compliance**
- **Prevention of diversion or misuse**
- **Reliable study outcomes**

Historical and Regulatory Framework



Non-Compliance



Potential Consequences of Non-Compliance

Patient Level

- Medication errors
- Safety concerns

Study Level

- Compromised data integrity
- Invalid endpoints

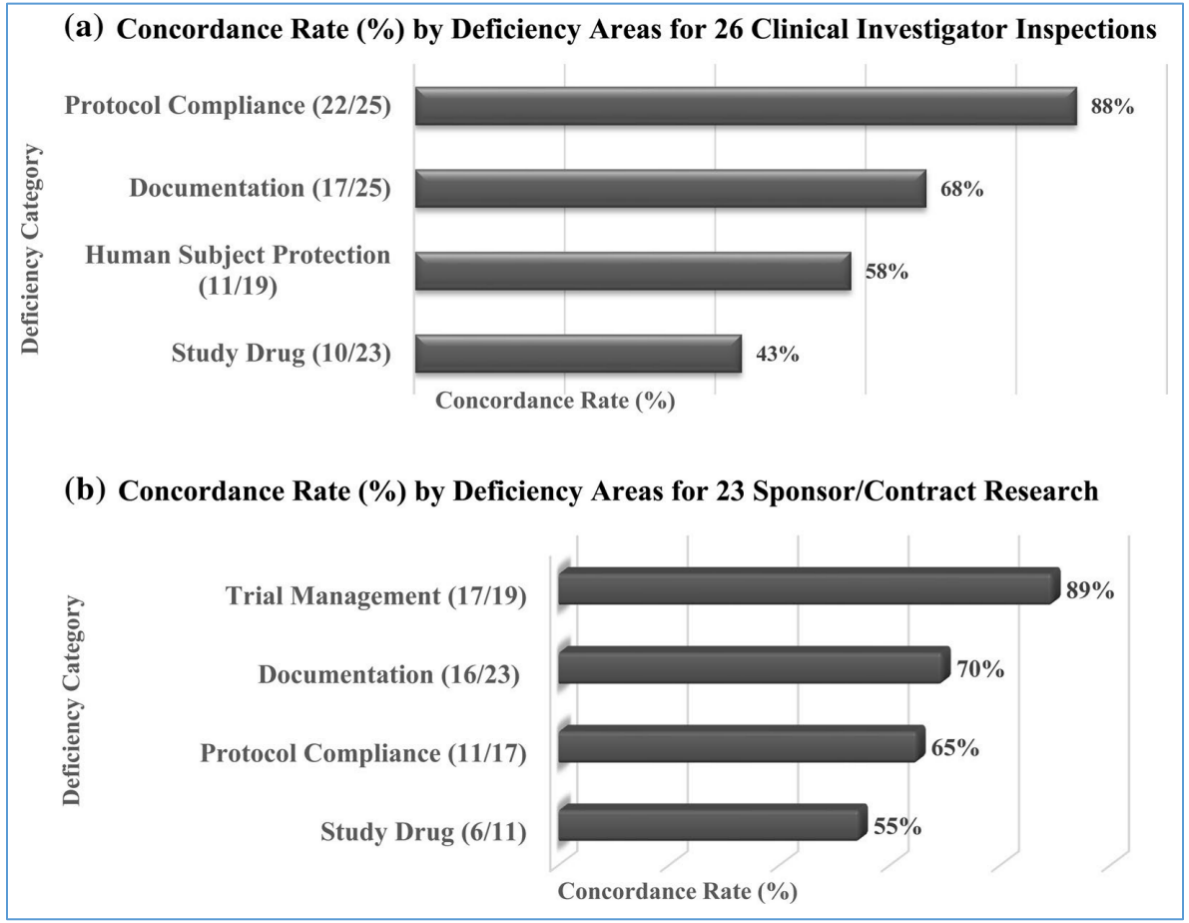
Institutional Level

- Audit findings
- CAPAs
- Regulatory sanctions

Common Audit Findings

Top Findings Include:

- Incomplete documentation
- Protocol deviations
- Inadequate accountability records
- Missing delegation documentation
- Inadequate oversight



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Question #1

Which of the following is the MOST common root cause of investigational drug accountability findings during inspections?

A. Temperature excursion

B. Drug theft

C. Documentation deficiencies

D. Incorrect storage location

Question #1 - Answer

Which of the following is the MOST common root cause of investigational drug accountability findings during inspections?

A. Temperature excursion

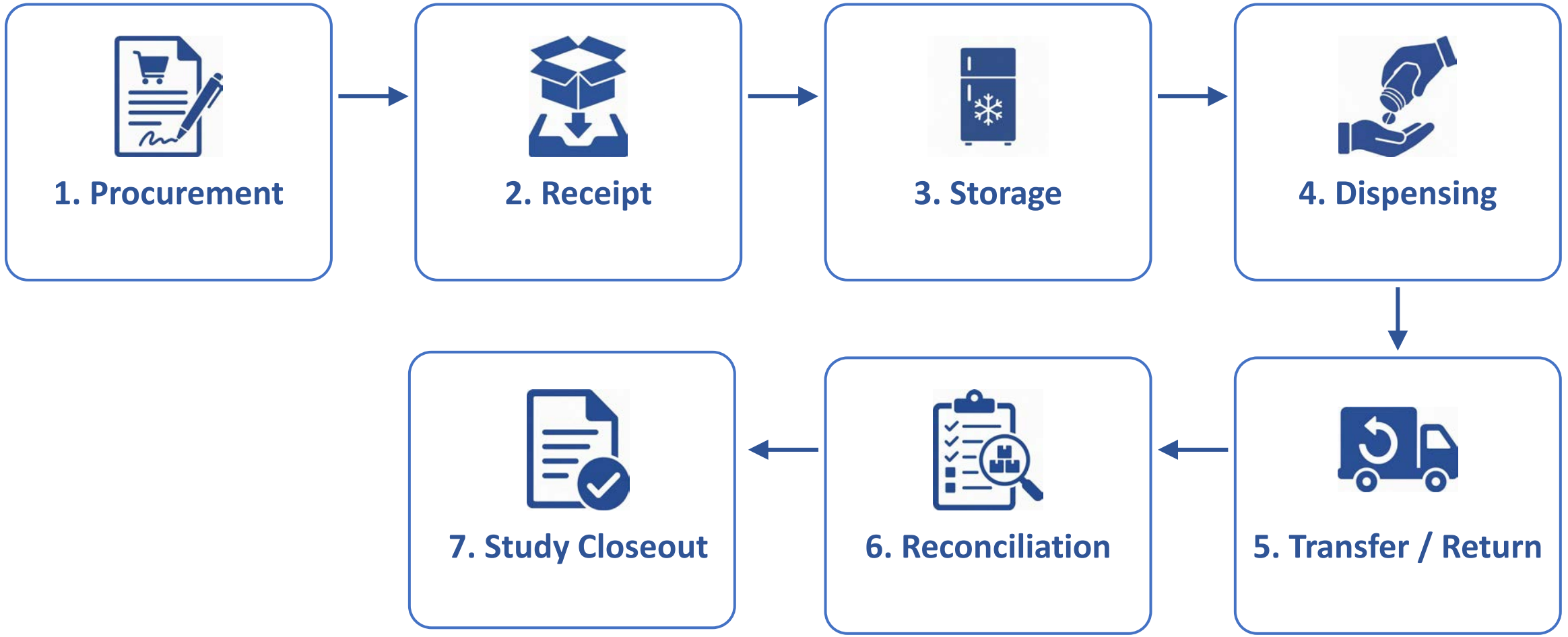
B. Drug theft

C. Documentation deficiencies

D. Incorrect storage location

Investigational Drug Management and AURORA

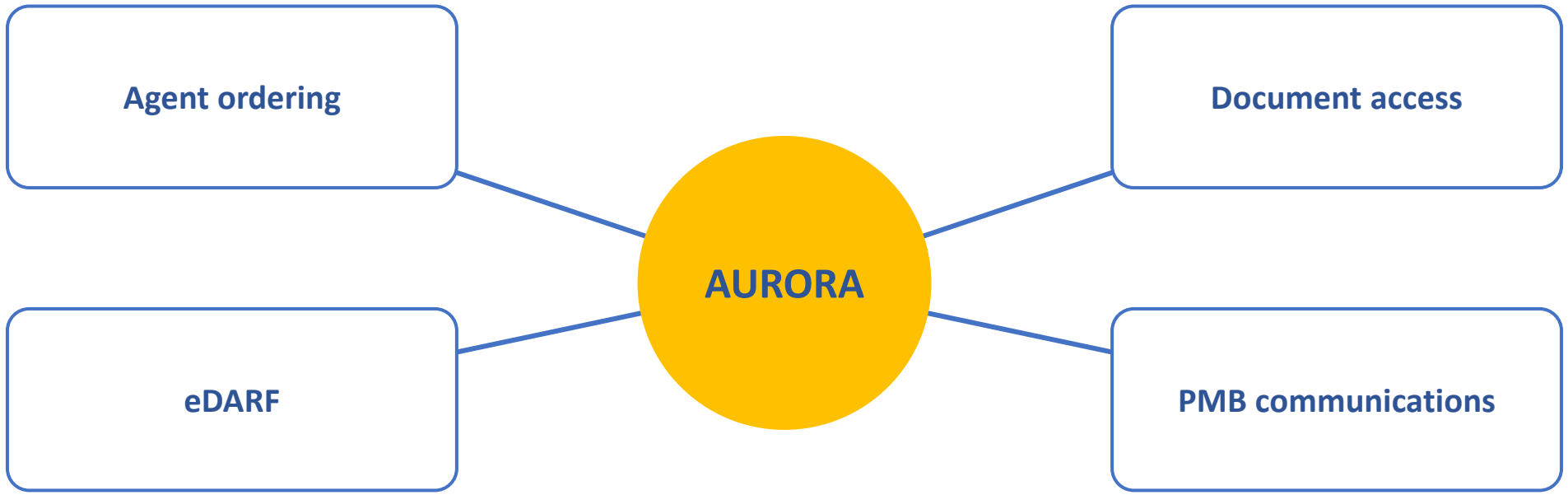
Investigational Drug Lifecycle



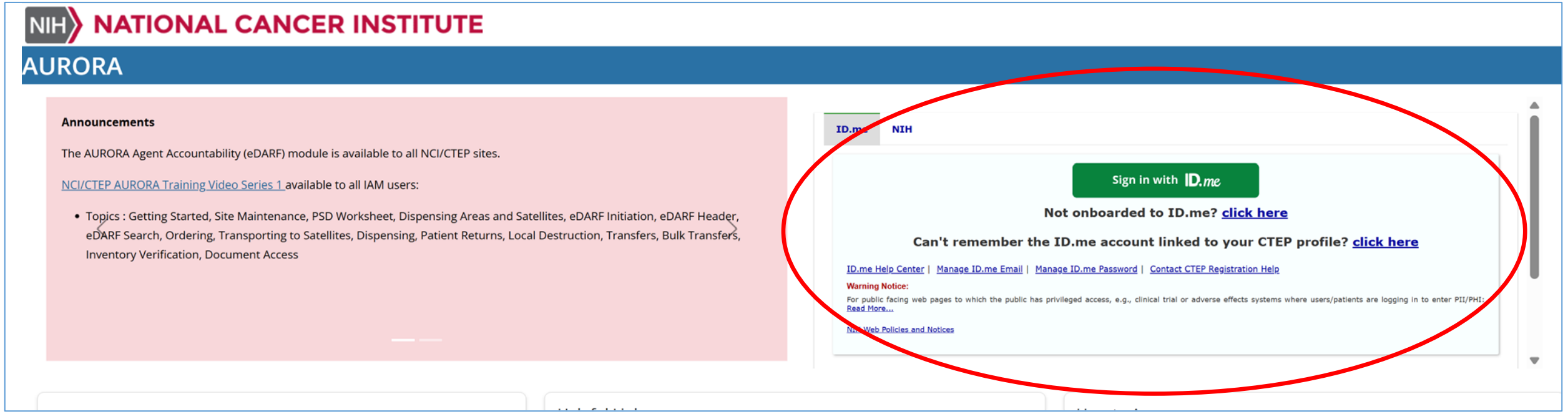
AURORA

NCI's centralized electronic inventory management system

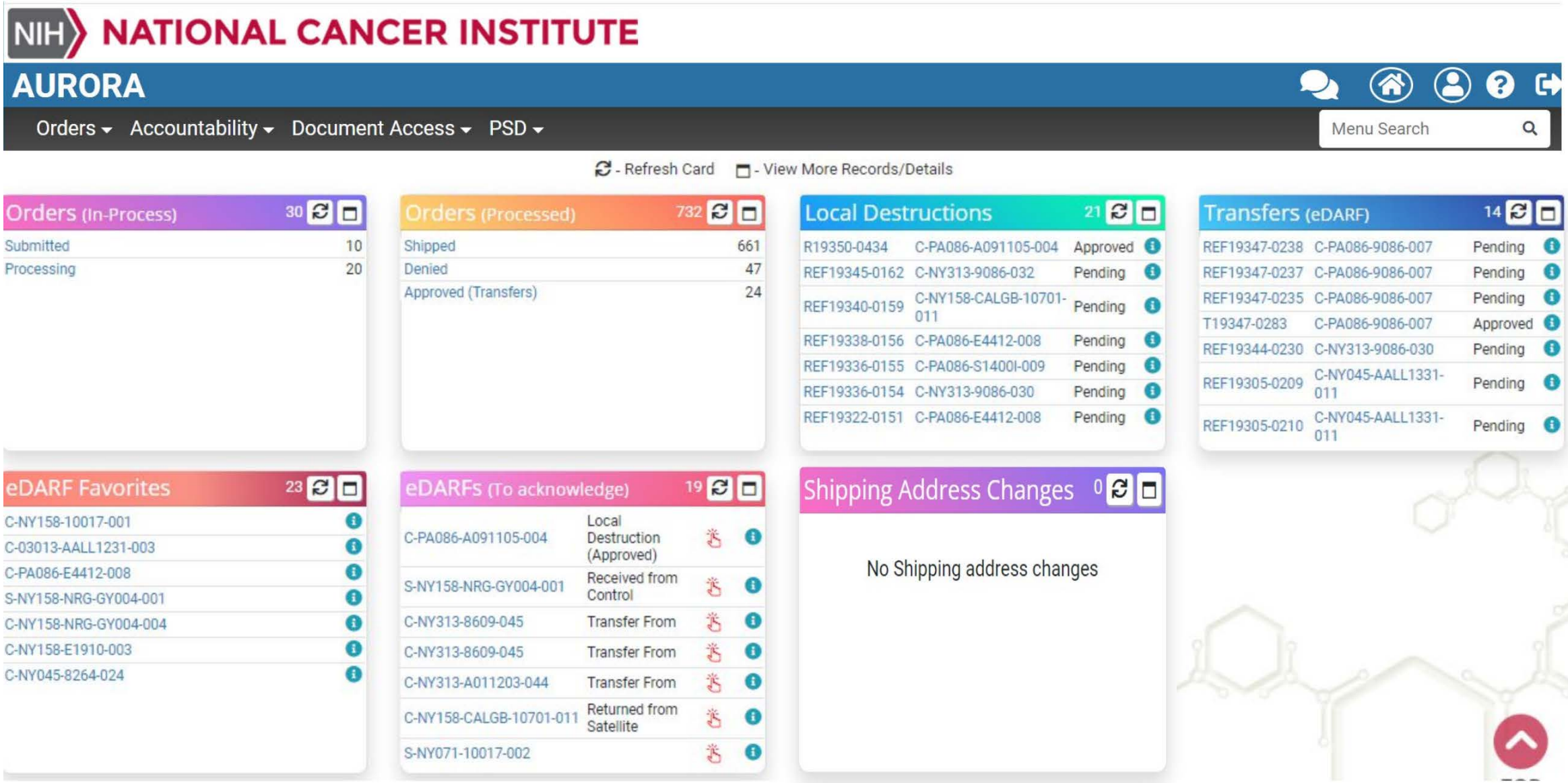
AURORA can provide electronic accountability tracking across the entire investigational drug lifecycle



AURORA



https://ctepcore.nci.nih.gov/aurora/login

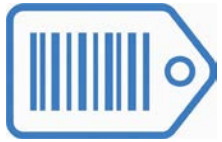


https://dctd.cancer.gov/research/ctep-trials/for-sites/agent-management/aurora-overview.pdf

Drug Receipt Responsibilities

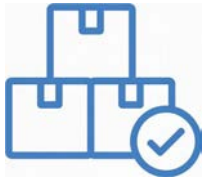
Verify shipment contents

Confirm protocol assignment



Verify lot number

Verify expiration date



Confirm quantity received

Document receipt promptly

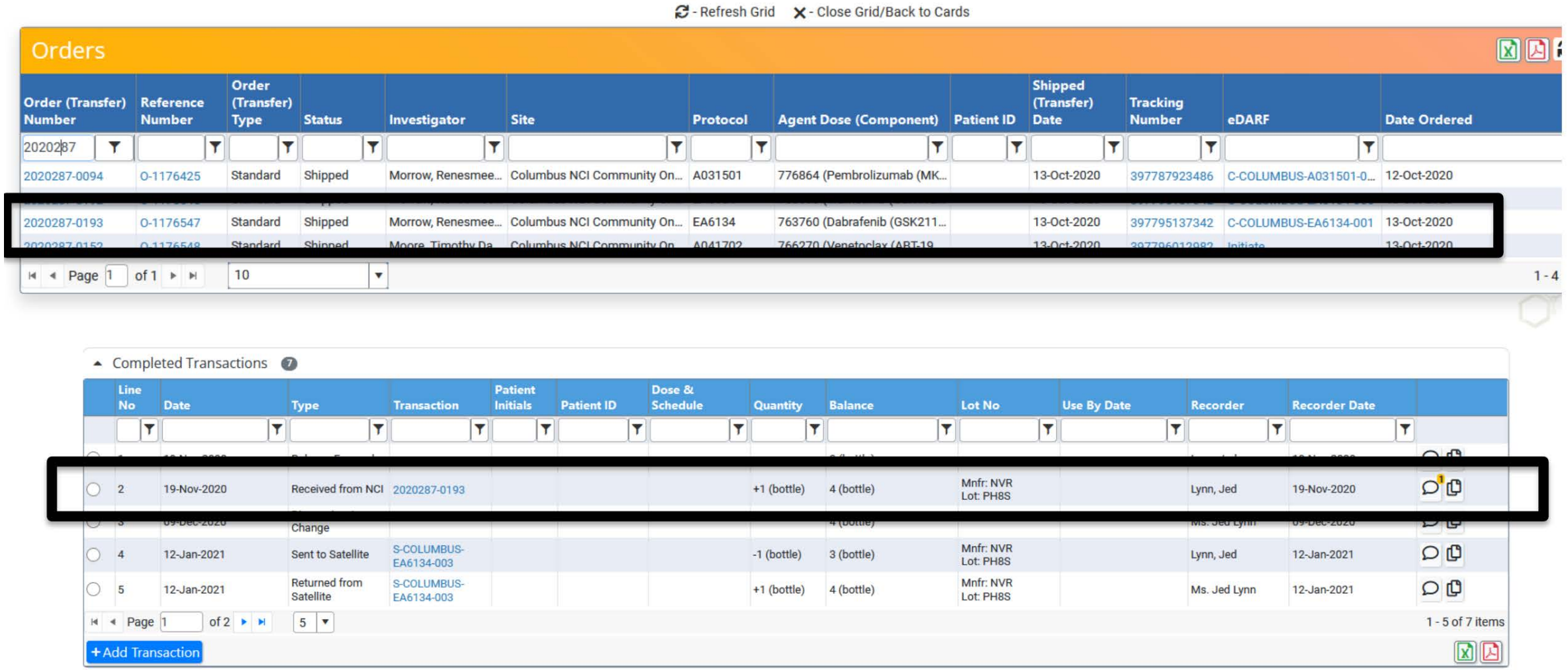
Drug Receipt Documentation

- **Date received**
- **Quantity received**
- **Lot number**
- **Expiration/re-test date (if available)**
- **Receiver initials**
- **Shipping discrepancies**

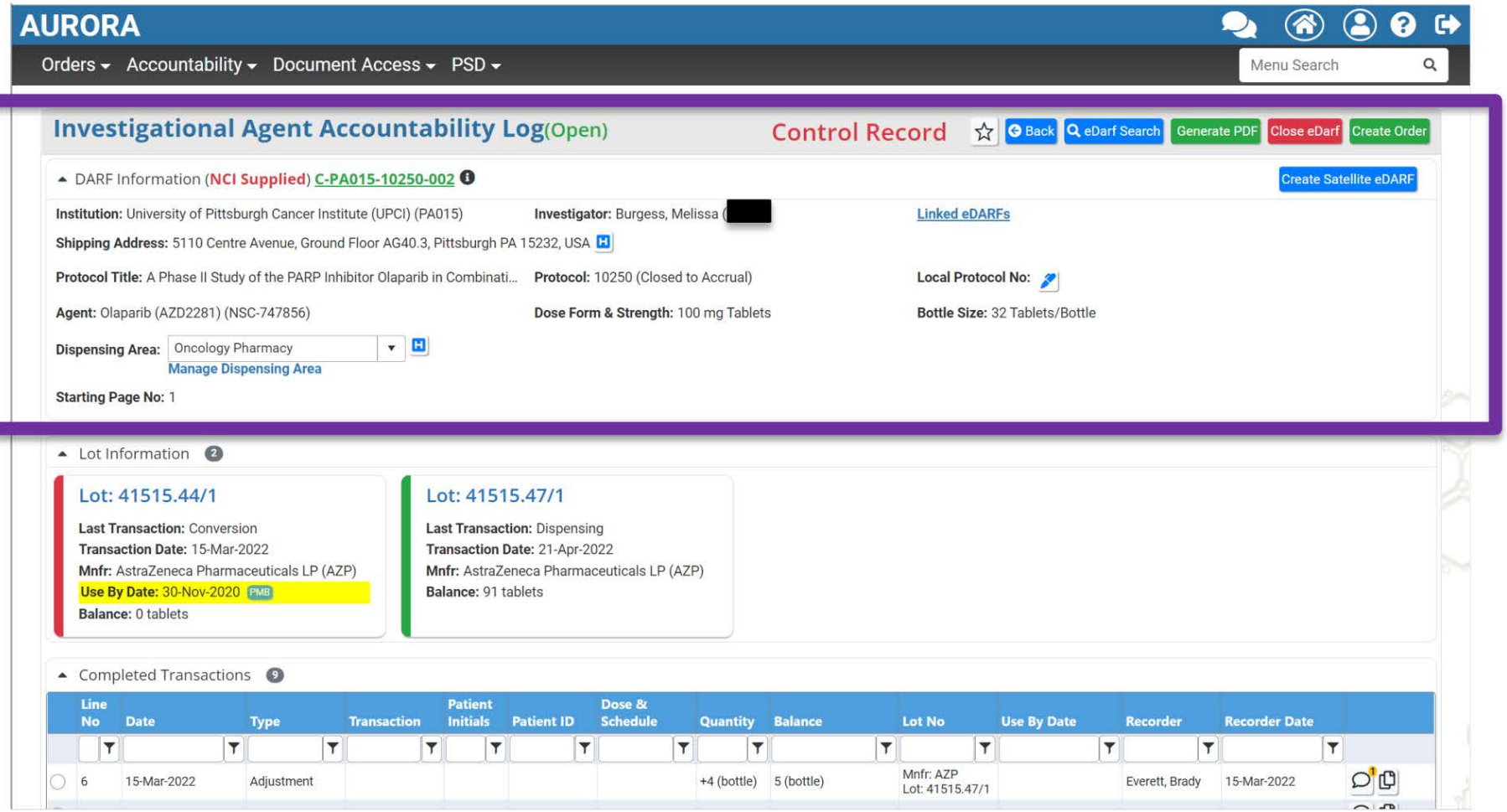
Common Findings

- **Wrong lot number entered**
- **Missing expiration date**
- **Delayed entry into AURORA**

Accountability: Agent Receipt from NCI



Accountability: eDARF Header



https://dctd.cancer.gov/research/ctep-trials/for-sites/agent-management/aurora-overview.pdf

Inventory Maintenance

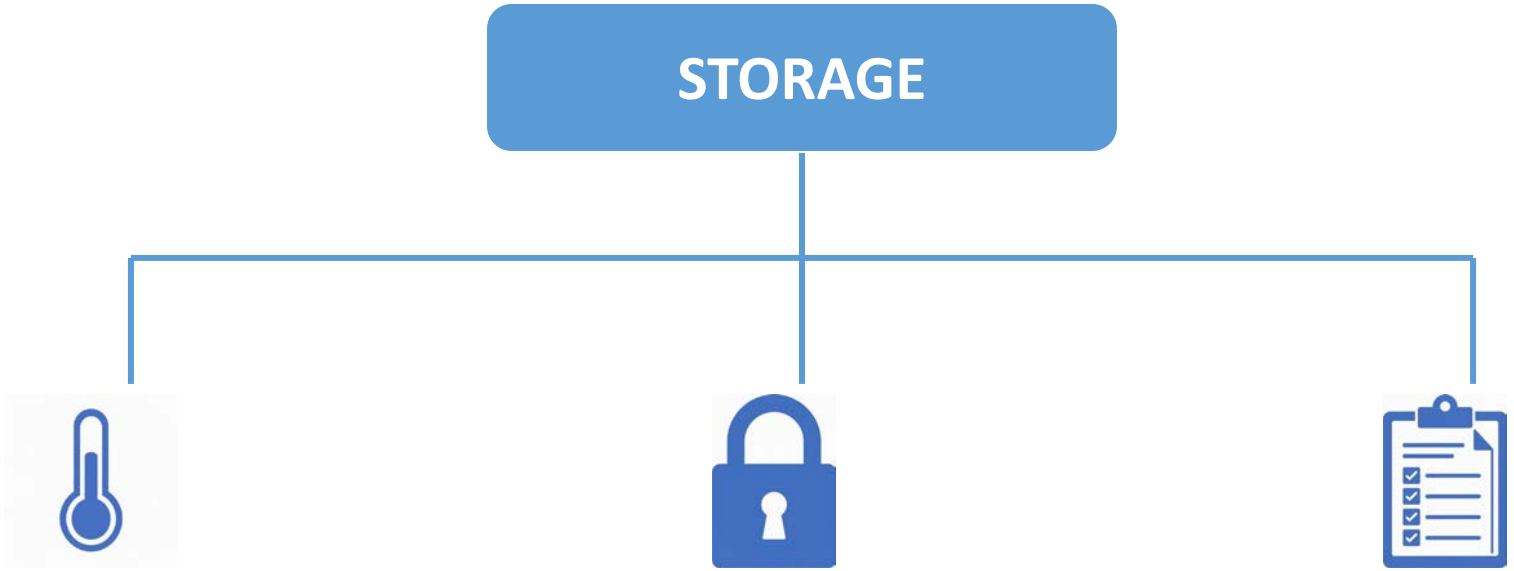
Routine Activities

- **Inventory review and reconciliation**
- **Expiration monitoring**
- **Lot tracking**
- **Discrepancy investigation**

Best Practice

Perform real-time documentation whenever possible

Storage Requirements



- **Temperature monitoring**

- **Restricted access**
- **Separation from commercial inventory**

- **Temperature logs**
- **Excursion management**

Transfer and Returns

Transfers

- Maintain chain of custody
- Document source and destination
- Verify inventory reconciliation

Returns

- Sponsor authorization
- Documentation of quantity and lot
- Destruction records if applicable

Documentation Requirements:

Date • Quantity • Lot number • Recipient/destination

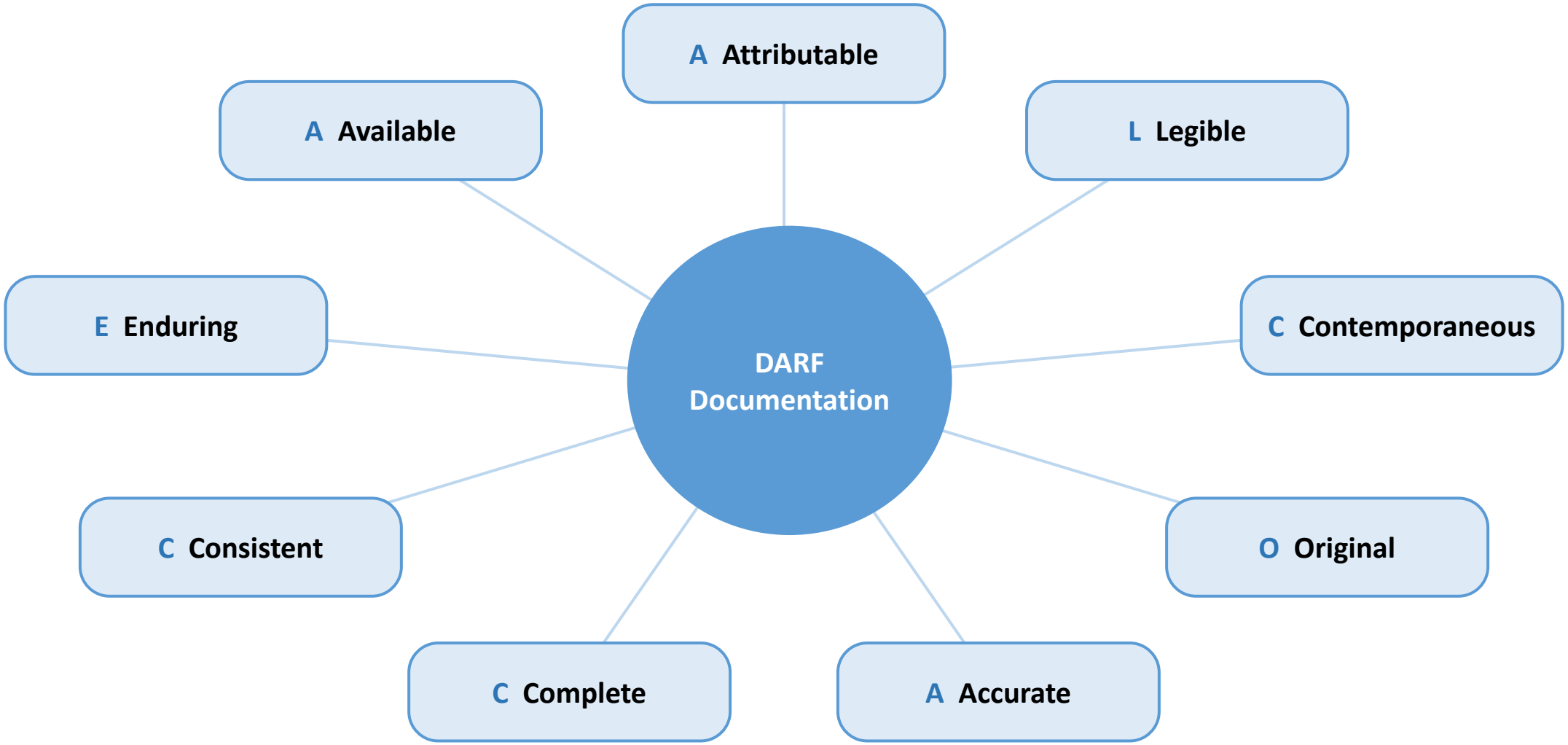
Inventory Reconciliation

	Beginning Inventory
+	**Receipts**
−	**Dispensed**
−	**Returned**
−	**Destroyed**
=	**Current Inventory**

The Key Question

Can every unit of investigational drug be accounted for?

DARF Documentation Principles “ALCOA+”



AURORA Best Practices

NCI Recommendations

- ✓ Document transactions promptly
- ✓ Use appropriate DARF transaction types
- ✓ Verify lot numbers before saving
- ✓ Reconcile inventory routinely
- ✓ Investigate discrepancies immediately
- ✓ Maintain audit readiness at all times

Question #2

A DARF shows:

Beginning Inventory = 20 bottles

Received = 10 bottles

Dispensed = 15 bottles

Transferred = 2 bottles

Destroyed = 1 bottle

What should the current inventory be?

A. 10

B. 11

C. 12

D. 13

Question #2 Answer

A DARF shows:

Beginning Inventory = 20 bottles

Received = 10 bottles

Dispensed = 15 bottles

Transferred = 2 bottles

Destroyed = 1 bottle

What should the current inventory be?

A. 10

B. 11

C. 12 *(Answer: 20 + 10 – 15 – 2 – 1 = 12 bottles)*

D. 13

Research Pharmacist Onboarding

CTEP Registration Requirements

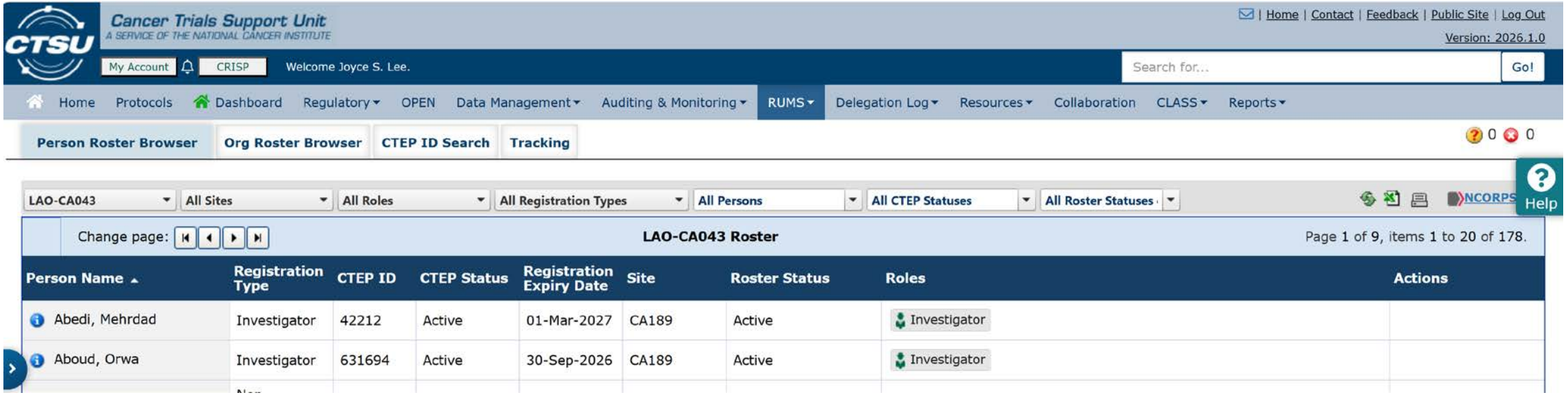
NCI-sponsored studies require investigators to maintain:

- Active CTEP registration
- Appropriate protocol authorization
- Current delegation status

Why it matters:

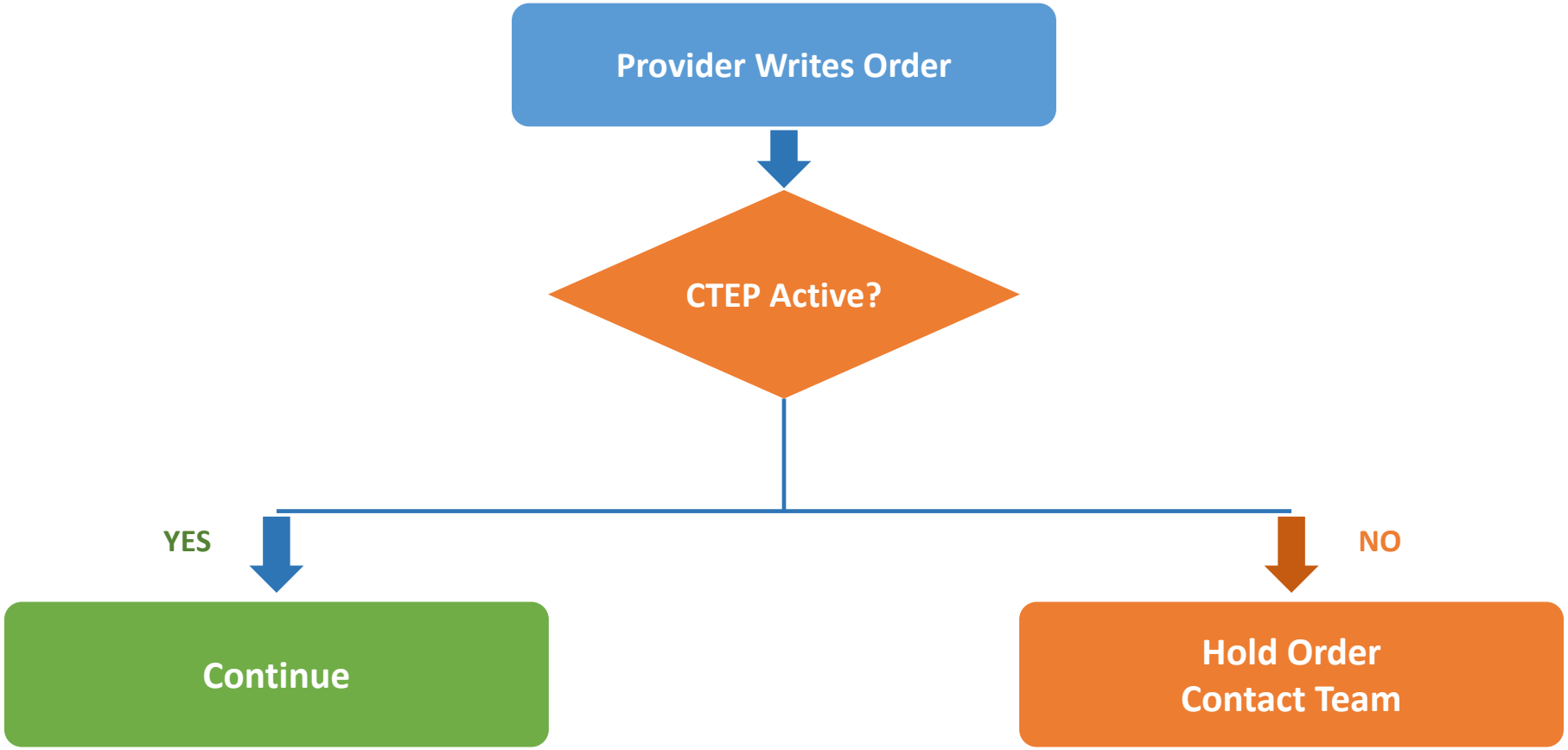
- Only qualified and authorized investigators may prescribe investigational agents.

Roster Update Management System (RUMS)



https://ctsu.cancer.gov

Verifying Prescriber Status Before Dispensing



Prior to Dispensing

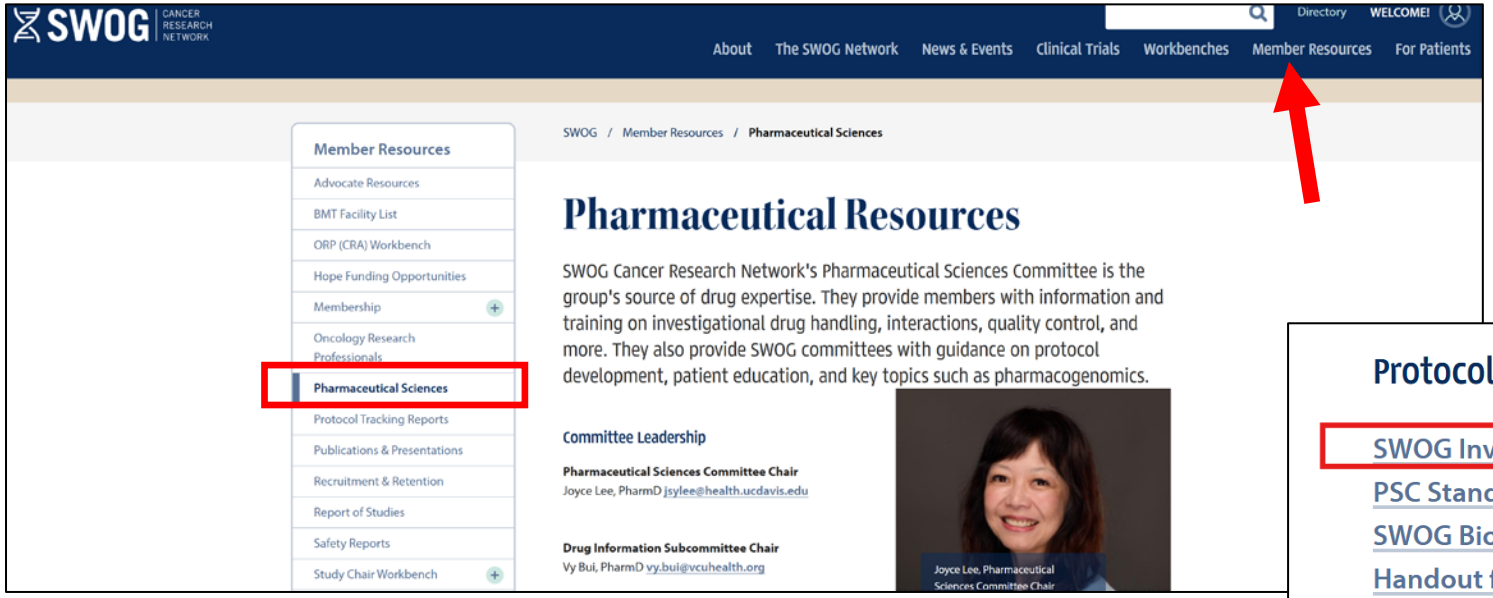
Confirm each item before dispensing study drug

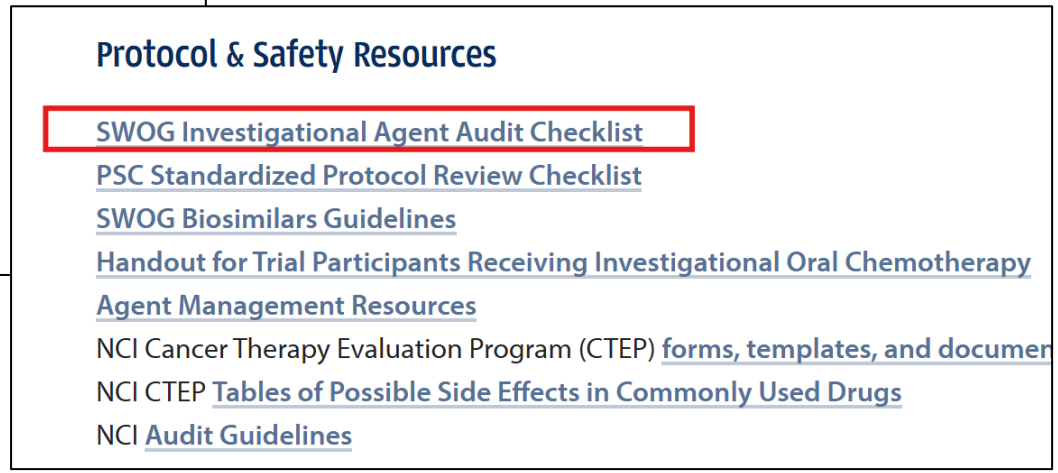
- ✓ **Valid treatment order**
- ✓ **Active protocol**
- ✓ **Eligible participant**
- ✓ **Authorized investigator**
- ✓ **Active CTEP registration**
- ✓ **Drug available and accountable**

Key Takeaways

- Every investigational product must be traceable from receipt to final disposition.
- Accountability protects patients, studies, investigators, and institutions
- Accountability is not a separate activity—it is embedded in every investigational drug transaction.

SWOG Investigational Audit Checklist





https://www.swog.org/sites/default/files/docs/2025-09/Audit%20Checklist_revised%2009-30-2025.pdf

INVESTIGATIONAL AGENT AUDIT CHECKLIST

Drug name(s): _____

Protocol #_____ **Protocol Version** _____

Audit Interval _____

Study coordinator/data manager: _____

Lead Pharmacist (if applicable): _____

Date of Last Audit (if applicable): _____

Accountability records:

___ Electronic records

___ Paper records

___ Mixed records (paper and electronic)

NOTE! This checklist is intended to be used for preparation of the site for audit and should not be shared with the auditor(s).

Step 1: Preparation of file and site (place a √ or indicate NA)

_____ Gather the investigational agent/drug file, Investigational Product (IP) logs, prescriptions, notebook (if used) and other records (including satellite records if applicable) to present to auditor since last audit (if applicable).

_____ If study is closed, obtain closed file.

_____ Sort drug receipts in chronological order.

_____ Sort return/destruction forms in chronological order.

_____ Sort transfer forms in chronological order.

_____ Sort Central and Satellite accountability records by location and date.

_____ Sort all other records by date (e.g., randomization information, worksheets).

_____ Organize prescriptions and paper orders (if applicable) by patient last name in alphabetical order or by subject number from smallest to largest then in chronological order.

_____ For audits that review selected patients, obtain the list of patients to be audited from the auditor or study coordinator/data manager for the study.

_____ Reserve conference room for auditors if audit is occurring on-site.

_____ For remote audits, ensure that all necessary files are scanned. These files must match the original source and/or uploaded in accordance with site regulatory SOP with consistent file nomenclature.

Step 2: Preparation of central and satellite investigational agent records.

	Y	N	N/A	Comments
Drug Acquisition				
Drug receipts are signed and dated. Shipping records maintained in the study binder/file.				
Lot number and expiration date are recorded on receipts. If expiration date is not available, "unknown" is inserted. Lot number should not be "unknown".				
Manufacturer and supplier for all IP receipts is recorded on the Drug Accountability Record Form (DARF).				
Confirm temperature device data downloaded and report printed for all receipts, if applicable.				
Drug arrival confirmed with sponsor, if applicable (with receipt of confirmation).				
Drug Accountability Record Form (DARF)-Compliance with Protocol Requirements				
For National Cancer Institute (NCI)-supplied agents, NCI DARF is utilized. For non-NCI-supplied drugs, NCI DARF, sponsor DARF, or sponsor approved DARF is used. Check protocol/study documents and communication with sponsor to ensure that correct DARF/DARF version is used (the form did not expire).				
When NCI DARFs are used, ORAL NCI Investigational Agent DARF is used for all oral drugs.				
For NCI-supplied agents, if electronic DARFs are used instead of the NCI DARF, the eDARF printout is identical to the NCI DARF.				
For NCI-supplied agents, DARFs are not lot-specific (i.e., all lots are listed on same page).				
For NCI-supplied agents, for each shipment, the investigator listed on the shipping receipt is the same as the investigator listed on the DARF, and only one investigator is listed on each DARF.				
Patient-specific DARF is used, if required by protocol.				
Separate DARF is used for each study agent or placebo and each study protocol.				
Separate DARF is used for each study agent strength and dosage form, if applicable.				
If applicable, drug assignment (with appropriate documentation) for a blinded trial complies with the procedure described in the protocol/study documents.				
Drug Accountability Record Form (DARF)-Central Location				
Recordings on the DARF are maintained in a timely manner.				
DARF header/footer is properly and completely filled out (no blanks). (e.g., drug name, strength, lot number(s), expiration date if available, page number, etc.). Drug name matches IP receipt.				
If expiration date is not available, "unknown" is inserted.				
Drug dispensing unit and strength are recorded, if applicable.				
Balance forward is completed.				
Subject initials (not name) and subject study number (not medical record number) are recorded on DARF.				
Date and quantity of drug **receipt** are correctly recorded on DARF.				
Date and quantity drug **dispensed** are correctly recorded on DARF.				
Date, quantity and lot number of drug **transported to a satellite** are correctly recorded on DARF, if applicable.				
Date, quantity and lot number of unused drug **returned from a satellite** are correctly recorded on DARF, if applicable.				

References

Bourgeois J. Procurement, Accountability and Administration of Investigational Agents. In: Manual for Oncology Clinical Research Nursing. Oncology Nursing Society; 2025.

Kay SC, Luke DG, Ramer HR. ASHP Guidelines for the Management of Investigational Drug Products. Am J Health Syst Pharm. 2018;75(8):561-573. https://doi.org/10.2146/ajhp170812

NCI DCTD. Best Practices for the AURORA Accountability eDARF. 2024. https://dctd.cancer.gov/research/ctep-trials/for-sites/agent-management/aurora-best-practices.pdf

NCI DCTD. Policy and Guidelines Documents. 2022. https://dctd.cancer.gov/research/ctep-trials/for-sites/agent-management#policy-and-guidelines-documents

Samara C, et al. Safety Surveillance During Drug Development. Adv Ther. 2023;40:2147-2185. https://doi.org/10.1007/s12325-023-02492-3

Sellers JW, et al. Descriptive Analysis of Good Clinical Practice Inspection Findings. Ther Innov Regul Sci. 2022;56:753-764. Https://doi.org/10/1007/s43441-022-00417-w

SWOG Oncology Research Professional Manual, Chapter 6. Drug Ordering and Maintenance. 2025. https://txwb.crab.org/TXWB/CRA_MANUAL/Vol1/chapter%2006_Drug%20Ordering%20and%20Maintenance.pdf

Zwart, C., Cloud, A., Kogelman, A. & Boomershine C. (2022). Implementation and evaluation of a formal investigational drug service at a community cancer center. *Journal of Hematology Oncology Pharmacy*, 12(5):256-63. Retrieved from: https://www.jhoponline.com/issue-archive/2022-issues/october-2022-vol-12-no-5/implementation-and-evaluation-of-a-formal-investigational-drug-service-at-a-community-cancer-center

Questions?

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Patient Adherence with Oral Anticancer Medications

Vy Bui, PharmD, BCPS, CCRP

SWOG Drug Information Subcommittee Chair

Learning Objectives

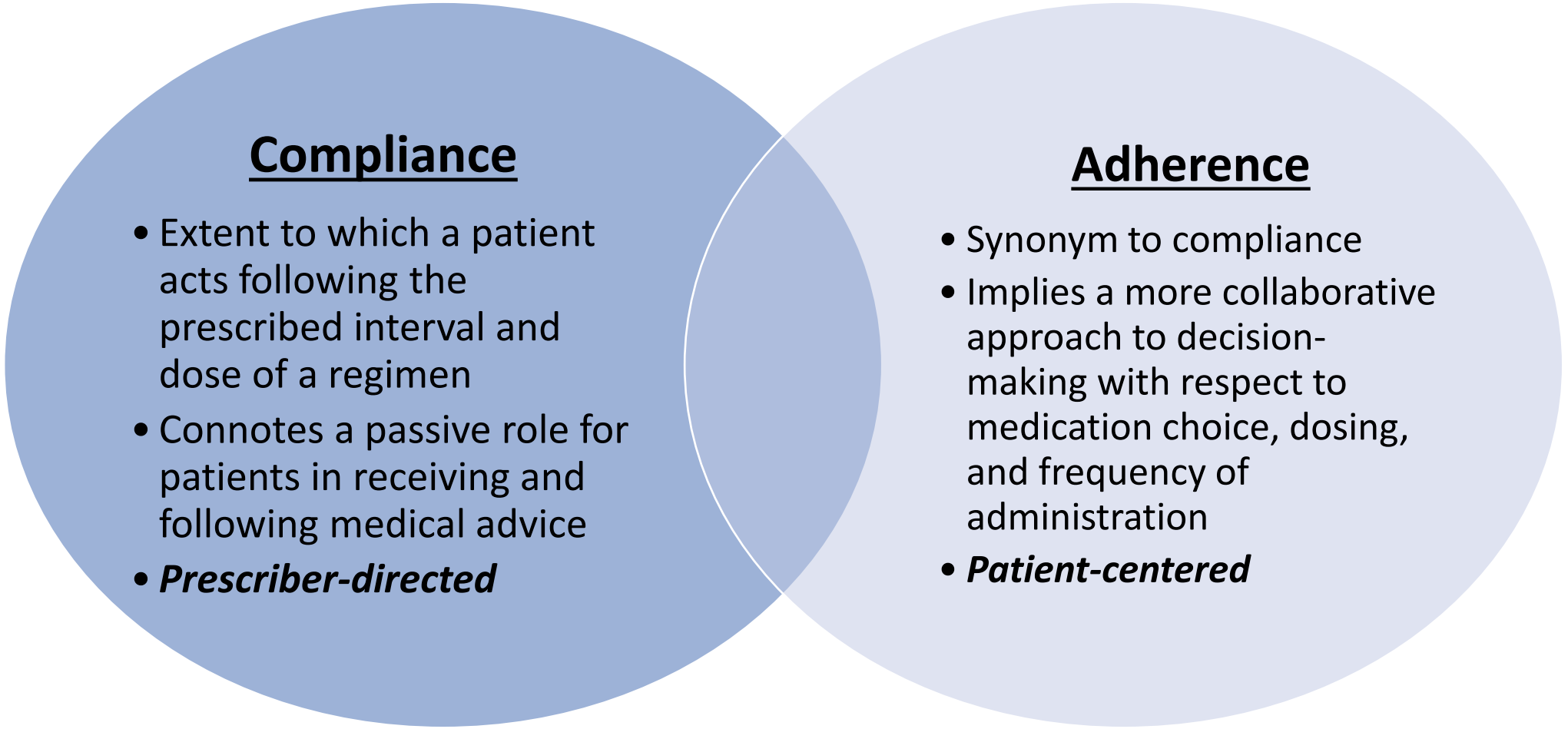
- Define patient adherence in the context of oncology clinical trials
- Identify key components of adherence tracking
- Explain the impact of patient adherence on study endpoints
- Describe clinical trial expectations for oral medication accountability and documentation

Background

- Oral anticancer medications
  - Account for 40%–50% of new cancer treatments in development
  - More responsibility on patients and caregivers for administration at home versus hospital/clinic
  - Adherence is a critical factor influencing patient outcomes and clinical trial data

US FDA, 2021.
Lasala R, *Eur J Hosp Pharm*. 2023 Nov;30(6):328-332.

Definitions



Cramer JA, *Value Health*. 2008 Jan-Feb;11(1):44-7.
Greer JA, *Oncologist*. 2016 Mar;21(3):354-76.

Adherence in Clinical Trials

- Between 16% to 100% during clinical trials
- Decreases after FDA-approval due to factors affecting access

Al-Barrak J, *Support Care Cancer*. 2013;21:2351–2357.
Levit LA, *J Clin Oncol*. 2022 Apr 1;40(10):1036-1040.
Partridge AH, J Natl Cancer Inst. 2002;94:652–661.
Mathes T, *Cancer Epidemiol*. 2014;38:214–226.
Murphy CC, *Breast Cancer Res Treat*. 2012;134:459–478

Challenges with Oral Oncology Agents

- Complex regimens and cycles
- High pill burden
- Toxicities
- Interactions with other medications, supplements, and diet
- Population-specific barriers
- Out of pocket costs

Levit LA, *J Clin Oncol*. 2022 Apr 1;40(10):1036-1040.
B.A. Given, Oncology Nursing Society Foundation, Pittsburgh, PA (December 2010)
Werneke U, (2004). *Br J Cancer* 90:408–413.

Adherence Tracking

- No gold standard for measuring adherence
- Most clinical trials measure % of prescribed doses of medication taken over a specified period of time
- 80% or higher is considered good adherence

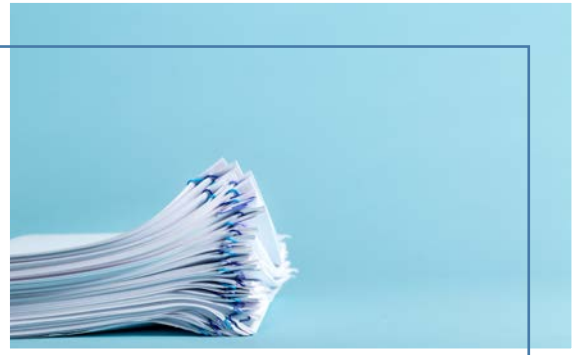
Greer JA, *Oncologist*. 2016 Mar;21(3):354-76.

Common Adherence Tools

Pill diaries

Pill counts

Patient interview

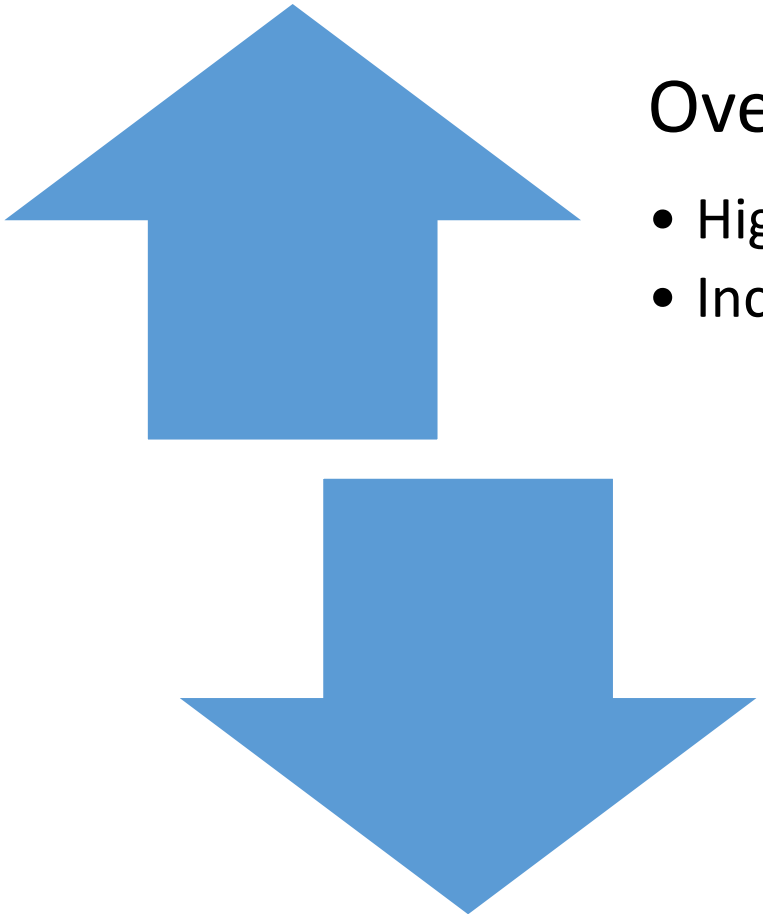


Dispensing/accountability logs

Source documentation

Greer JA, *Oncologist*. 2016 Mar;21(3):354-76.

Impact of Adherence



Over-adherence

- Higher drug metabolite exposure
- Increased toxicities

Under-adherence

- Subtherapeutic drug concentrations
- Disease progression or increased mortality risk
- Require more aggressive therapies

Cardoso E, *Clin Pharmacokinet*. 2018 Jan;57(1):1-6.
Le Saux O, *Cancer Chemother Pharmacol*. 2018 Aug;82(2):319-327.

Adherence in the Literature: Chronic Myeloid Leukemia

Noens et al 2009 (ADAGIO Study)

Background	Imatinib is highly effective for CML but requires continuous adherence. Real-world adherence and its impact on outcomes remain unclear.
Study objective	To assess prevalence of nonadherence, identify determinants, and evaluate association with treatment response
Study Design	Prospective, observational, multicenter study with 2 time points (baseline and ~90 days)

Noens et al 2009 (ADAGIO Study)

Population	Adults (≥14 years) with CML on imatinib ≥30 days
Interventions	Non-interventional; adherence measured via multiple methods (BAAS, VAS, pill count, interviews)
Outcomes	• Primary: Prevalence of nonadherence • Secondary: Determinants of nonadherence, association with treatment response

Noens et al 2009 (ADAGIO Study)

Baseline characteristics (n=169)	• Mean age: 57 years • Male: 55% • Mean adherence (pill count): 90.9%
Results	• Nonadherent patients had worse outcomes • Suboptimal response group missed more doses (23.2% vs 7.3%, p=0.005) • Nonadherence associated with age, living alone, higher dose, longer disease duration • Better adherence associated with knowledge, self-efficacy, education

Marin et al 2010

Background	Variability exists in molecular responses to imatinib in chronic myeloid leukemia (CML). Poor adherence to oral anticancer therapy may contribute significantly.
Study Objective	To determine whether adherence to imatinib correlates with molecular response in patients with chronic-phase CML
Study Design	Prospective observational single-center cohort study using microelectronic monitoring (MEMS)

Marin et al 2010

Population	Adults with chronic-phase CML on imatinib for 2+ years and in complete cytogenic response (CCyR)
Interventions	Imatinib 400 mg/day (some escalated to 600 mg) Adherence measured over 3 months using MEMS device
Outcomes	•Primary: Major molecular response (MMR) (≥3-log reduction) •Secondary: Complete molecular response (CMR), (4 log reduction)

Marin et al 2010

Baseline characteristics (n=87)	•Median age = 51 years •Male = 56% •Median adherence = 97%-98%

Results	•Adherence ≥ 90% vs <90%
	  •MMR: 94.5% vs 28.4% (p <0.001)
	  •CMR: 43.8% vs 0%
	•No MMR when adherence ≤80%
	•Lower adherence associated with adverse effects (fatigue, nausea, muscle cramps)
	•Adherence was strongest independent predictor of outcomes (RR 11.7 for MMR)

Adherence in the Literature: Breast Cancer

Eliassen et al 2023

Background	Adjuvant endocrine therapy (AET) improves outcomes in hormone receptor–positive breast cancer, but adherence is suboptimal due to side effects and long duration
Study objectives	To evaluate how AET adherence affect survival outcomes in breast cancer
Study design	Systematic review

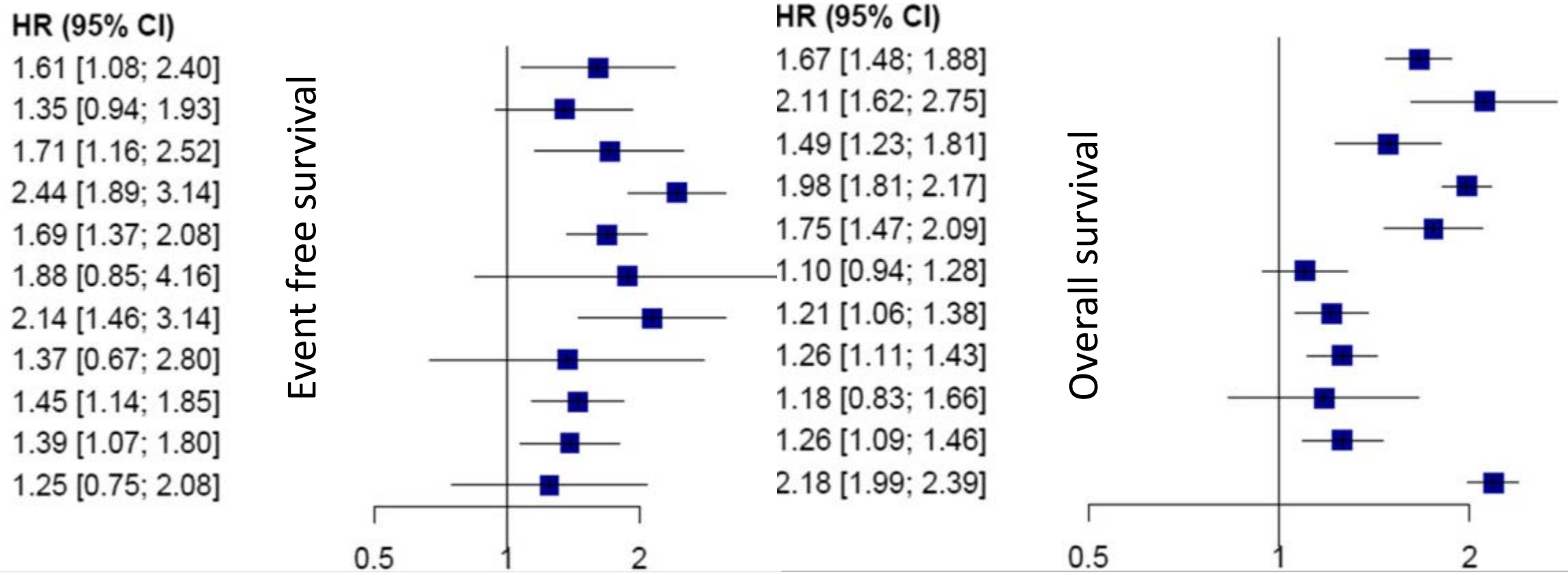
Eliassen et al 2023

Eligibility	Studies evaluating adherence to AET and outcomes (recurrence, event-free survival, overall survival) in women with early-stage, non-metastatic hormone receptor–positive breast cancer on endocrine therapy
Outcomes	• **Primary**: Event-free survival (recurrence, disease-free survival) • **Secondary**: Overall survival

Eliassen et al 2023

Results

- Event free survival: 7/10 studies showed worse outcomes with non-adherence
- Overall survival: 7/9 studies showed reduced survival



Guideline Recommendations

Hematology/Oncology Pharmacist Association Best Practices for the Management of Oral Oncolytic Therapy: Pharmacy Practice Standard

ONS Guidelines™ to Support Patient Adherence to Oral Anticancer Medications

Guideline Recommendations

Prescribe + Verify	Educate + Plan	Monitor + Support	Document + Escalate
• Confirm regimen, dose, schedule • Assess patient factors • Insurance + access coordination	• Clear patient/caregiver education • Written + verbal instructions • Side effect expectations + management plan • Adherence tools	• Routine follow-up • Assess adherence • Manage toxicity promptly • Reinforce education and motivation	• Document adherence and toxicities • Communicate with research + care team • Adherence nonadherence causes • Adjust plan as needed

References

- Al-Barrak J, Cheung WY. Adherence to imatinib therapy in gastrointestinal stromal tumors and chronic myeloid leukemia. Support Care Cancer. 2013;21:2351–2357. doi: 10.1007/s00520-013-1831-6.
- B.A. Given, C.W. Given, S. Spoelstra Intervention to improve adherence and symptoms from oral agents: final scientific report Oncology Nursing Society Foundation, Pittsburgh, PA (December 2010)
- Belcher SM, Mackler E, Muluneh B, Ginex PK, Anderson MK, Bettencourt E, et al. ONS Guidelines™ to Support Patient Adherence to Oral Anticancer Medications. Oncol Nurs Forum. 2022 Jun 17;49(4):279-295. doi: 10.1188/22.ONF.279-295. PMID: 35788731; PMCID: PMC9303042.
- Cardoso E, Csajka C, Schneider MP, Widmer N. Effect of Adherence on Pharmacokinetic/Pharmacodynamic Relationships of Oral Targeted Anticancer Drugs. Clin Pharmacokinet. 2018 Jan;57(1):1-6. doi: 10.1007/s40262-017-0571-z. PMID: 28634655.
- Cramer JA, Roy A, Burrell A, Fairchild CJ, Fuldeore MJ, Ollendorf DA, Wong PK. Medication compliance and persistence: terminology and definitions. Value Health. 2008 Jan-Feb;11(1):44-7. doi: 10.1111/j.1524-4733.2007.00213.x. PMID: 18237359.
- Eliassen FM, Blåfjelldal V, Helland T, Hjorth CF, Hølland K, Lode L, et al. Importance of endocrine treatment adherence and persistence in breast cancer survivorship: a systematic review. BMC Cancer. 2023 Jul 4;23(1):625. doi: 10.1186/s12885-023-11122-8. PMID: 37403065; PMCID: PMC10320891.

Reference (2)

- Greer JA, Amoyal N, Nisotel L, Fishbein JN, MacDonald J, Stagl J, Lennes I, Temel JS, Safren SA, Pirl WF. A Systematic Review of Adherence to Oral Antineoplastic Therapies. Oncologist. 2016 Mar;21(3):354-76. doi: 10.1634/theoncologist.2015-0405. Epub 2016 Feb 26. PMID: 26921292; PMCID: PMC4786357.
- Lasala R, Santoleri F, Romagnoli A, Abrate P, Musicco F, Costantini A. Medication adherence reporting in pivotal clinical trials: overview of oral oncological drugs. Eur J Hosp Pharm. 2023 Nov;30(6):328-332. doi: 10.1136/ejhpharm-2021-002998. Epub 2022 Jan 20. PMID: 35058307; PMCID: PMC10647863.
- Le Saux O, Bourmaud A, Rioufol C, Colomban O, Guitton J, Schwiertz V, Regnier V, You B, Ranchon F, Maraval-Gaget R, Girard P, Chauvin F, Freyer G, Tod M, Henin E, Trillet-Lenoir V. Over-adherence to capecitabine: a potential safety issue in breast and colorectal cancer patients. Cancer Chemother Pharmacol. 2018 Aug;82(2):319-327. doi: 10.1007/s00280-018-3612-x. Epub 2018 Jun 15. PMID: 29948022.
- Levit LA, Arora S, Kluetz PG, Magnuson A, Rahman A, Harvey RD. Call to Action for Improving Oral Anticancer Agent Adherence. J Clin Oncol. 2022 Apr 1;40(10):1036-1040. doi: 10.1200/JCO.21.02529. Epub 2022 Jan 6. PMID: 34990218.
- Mackler E, Segal EM, Muluneh B, Jeffers K, Carmichael J. 2018 Hematology/Oncology Pharmacist Association Best Practices for the Management of Oral Oncolytic Therapy: Pharmacy Practice Standard. J Oncol Pract. 2019 Apr;15(4):e346-e355. doi: 10.1200/JOP.18.00581. Epub 2019 Mar 12. PMID: 30860937; PMCID: PMC6494244.
- Mathes T, Pieper D, Antoine S L, et al. Adherence influencing factors in patients taking oral anticancer agents: A systematic review. Cancer Epidemiol. 2014;38:214–226. doi: 10.1016/j.canep.2014.03.012.

References (3)

- Marin D, Bazeos A, Mahon FX, Eliasson L, Milojkovic D, Bua M, et al. Adherence is the critical factor for achieving molecular responses in patients with chronic myeloid leukemia who achieve complete cytogenetic responses on imatinib. J Clin Oncol. 2010 May 10;28(14):2381-8. doi: 10.1200/JCO.2009.26.3087. Epub 2010 Apr 12. PMID: 20385986; PMCID: PMC6366340.
- Murphy CC, Bartholomew LK, Carpentier MY, et al. Adherence to adjuvant hormonal therapy among breast cancer survivors in clinical practice: A systematic review. Breast Cancer Res Treat. 2012;134:459–478. doi: 10.1007/s10549-012-2114-5.
- Noens L, van Lierde MA, De Bock R, Verhoef G, Zachée P, Berneman Z, et al. Prevalence, determinants, and outcomes of nonadherence to imatinib therapy in patients with chronic myeloid leukemia: the ADAGIO study. Blood. 2009 May 28;113(22):5401-11. doi: 10.1182/blood-2008-12-196543. Epub 2009 Apr 6. PMID: 19349618.
- Partridge AH, Avorn J, Wang PS, et al. Adherence to therapy with oral antineoplastic agents. J Natl Cancer Inst. 2002;94:652–661. doi: 10.1093/jnci/94.9.652
- U.S. Food and Drug Administration. (2021). Oncology (cancer)/ hematologic malignancies approval notifications https://www.fda.gov/drugs/resources-information-approved-drugs/oncology-cancer-hematologic-malignancies-approval-notifications
- Werneke U, Earl J, Seydel C, Horn O, Crichton P, Fannon D (2004) Potential health risks of complementary alternative medicines in cancer patients. Br J Cancer 90:408–413. 10.1038/sj.bjc.6601560

Patient Case

John Doe is enrolled in ABC123 and is receiving ponatinib to be taken daily in 28-day cycles. He returns to clinic for Cycle 2.

Patient Case (continued)

John Doe's Ponatinib Pill Diary: Cycle 1

Sun	Mon	Tue	Wed	Thu	Fri	Sat
	Day 1 ✓	Day 2 ✓	Day 3 ✓	Day 4 ✓	Day 5 ✓	Day 6 ✓
Day 7 ✓	Day 8 ✓	Day 9 ✓	Day 10 ✓	Day 11 ✓	Day 12 ✓	Day 13 ✓
Day 14 ✓	Day 15 ✓	Day 16 ✓	Day 17 ✓	Day 18 ✓	Day 19 ✓	Day 20 ✓
Day 21 ✓	Day 22 ✓	Day 23 ✓	Day 24 ✓	Day 25 ✓	Day 26 ✓	Day 27 ✓
Day 28 ✓						

IDS Pharmacy Drug Accountability Records for JD

Dispensed	Returned
1 bottle	1 empty bottle returned with 8 tablets remaining

Dr. Smith's Progress Note

Returns for Cycle 2 refill. States, "I took it most days, but I skipped a few when I felt really nauseous"

Patient Case – Question #3

What is the most appropriate way to manage this situation?

A. Accept the pill diary as accurate and continue treatment without changes

B. Document non-adherence, reconcile discrepancies, and address nausea with supportive care and patient re-education

C. Ignore drug accountability since patient-reported adherence is more reliable

D. Discontinue the patient from the study due to non-adherence

E. Only update the pill count and do not modify clinical management

Patient Case – Question #- Answer

What is the most appropriate way to manage this situation?

A. Accept the pill diary as accurate and continue treatment without changes

B. Document non-adherence, reconcile discrepancies, and address nausea with supportive care and patient re-education

C. Ignore drug accountability since patient-reported adherence is more reliable

D. Discontinue the patient from the study due to non-adherence

E. Only update the pill count and do not modify clinical management

Open Forum Discussion – Questions and Answers

Post-Course Evaluation

- To receive 1.0 CEU contact hour participants must:
  - **Have attended the entire educational activity and**
  - **Complete and submit the post activity-evaluation**

Prior QA Webinars Accessible for Review

Previous Webinars and Upcoming Webinar Information is posted at:
SWOG Quality Assurance Live Webinar Series | SWOG

All enduring courses are posted via CTSU CLASS

CEU Courses:

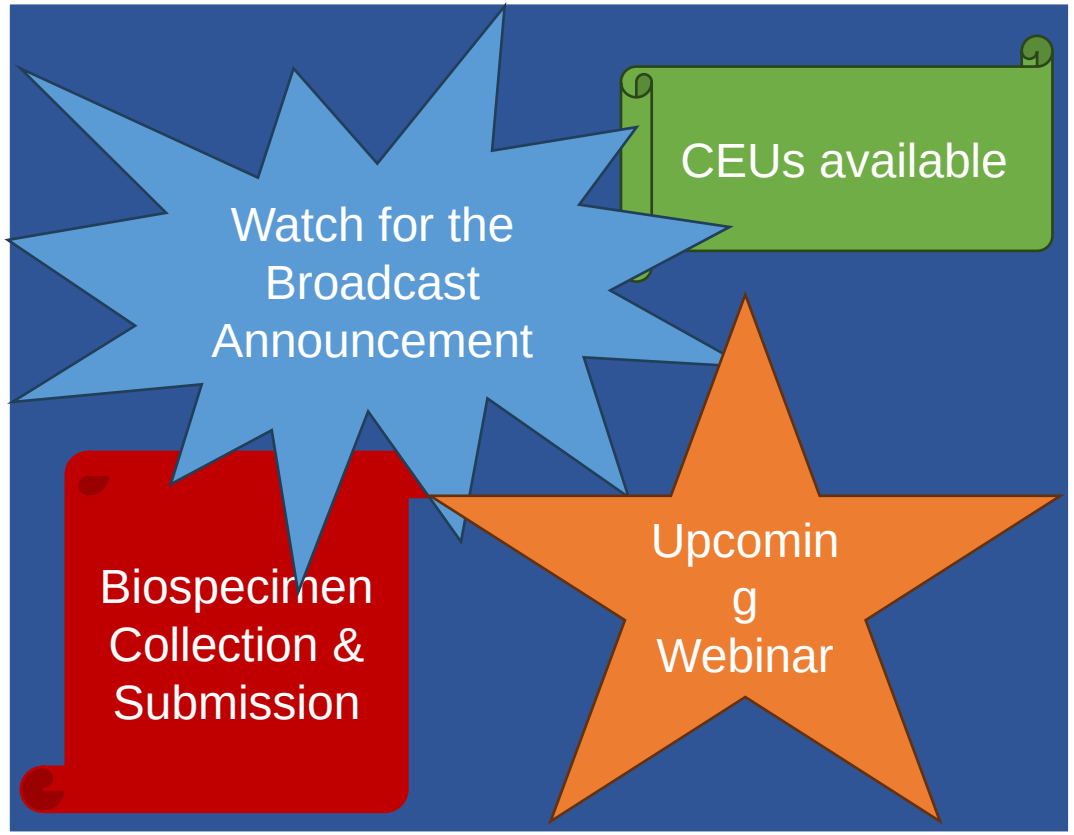
- From the Ground Up: Implementing QA at the Site Level (1 contact hour)
- Navigating Adverse Events: What's New in CTCAE v6 (1 contact hour)
- Biospecimen Collection and Submission (1 contact hour)
- Cytogenetics (1 contact hour)
- Serious Adverse Event Reporting & Updates (1 contact hour)
- Disease Assessment in Solid Tumors (1 contact hour)

CEU Courses Expiring Soon:

- Workload Prioritization in Clinical Trials
  1.5 contact hours; CEU Expiration: 9/6/26.
  Last Day to Enroll to CLASS course: 9/5/26;
  Last day to Complete for CEU credit: 9/6/26

Non-CEU Courses posted in CLASS:

- Research Protocol Deviations vs Deficiencies
- Best Practices for Informed Consent
- Adverse Event Reporting
- SWOG Audits: Preparing for Success and Audit Process
- How to Develop a CAPA Plan



Upcoming QA Live Webinar

Patient-Reported Outcomes

~Presented by: SWOG PRO Core Team:
TBD

Friday, September 11, 2026

12:00 PM Eastern Time

Registration information will be distributed via:

- SWOG Broadcast Emails
- CTSU Broadcast Emails, and
- Posted at: **SWOG Quality Assurance Live Webinar Series**

This activity will be submitted to the Georgia Nurses Association for approval to award contact hours. Georgia Nurses Association is accredited as an approver of nursing continuing professional development by the American Nurses Credentialing Center's Commission on Accreditation.

Thank you