Enhancing Drug Accountability and Medication Safety for Research Subjects

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Department of Pharmacy

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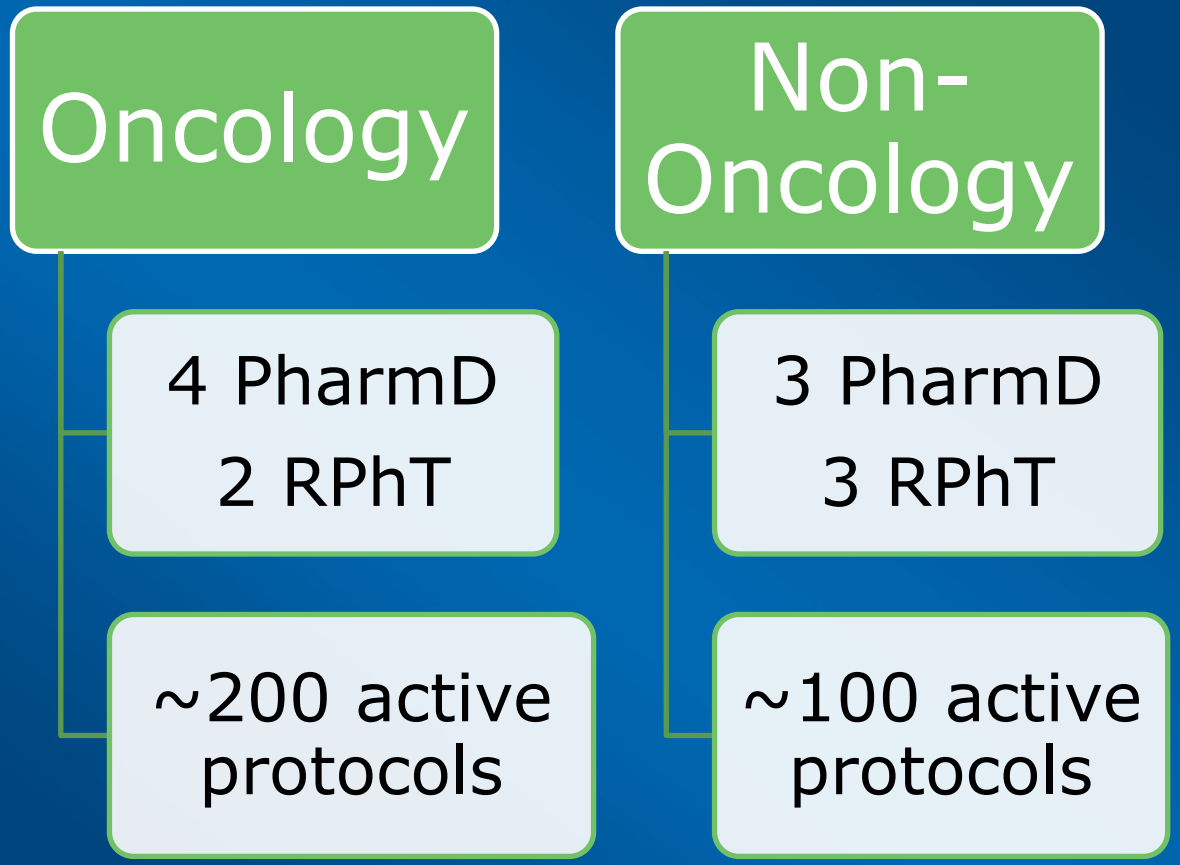
MEDICINE *of* THE HIGHEST ORDER

UR MEDICINE

Objectives

1. Overview of IDS operations
2. Enhancing medication safety
3. IDS budget considerations
4. ClickIRB and OnCore submissions
5. FDA inspection readiness

Oversight and Structure



What is an Investigational Drug Service?

The IDS is charged with ensuring that the handling, storage, labeling, distribution, and inventory maintenance of investigational products are in compliance with Good Clinical Practices (GCP), Federal and State regulations, The Joint Commission (TJC) Standards, as well as per the recommendations of the American Society of Health-System Pharmacists (ASHP) and the Hematology Oncology Pharmacy Association (HOPA).

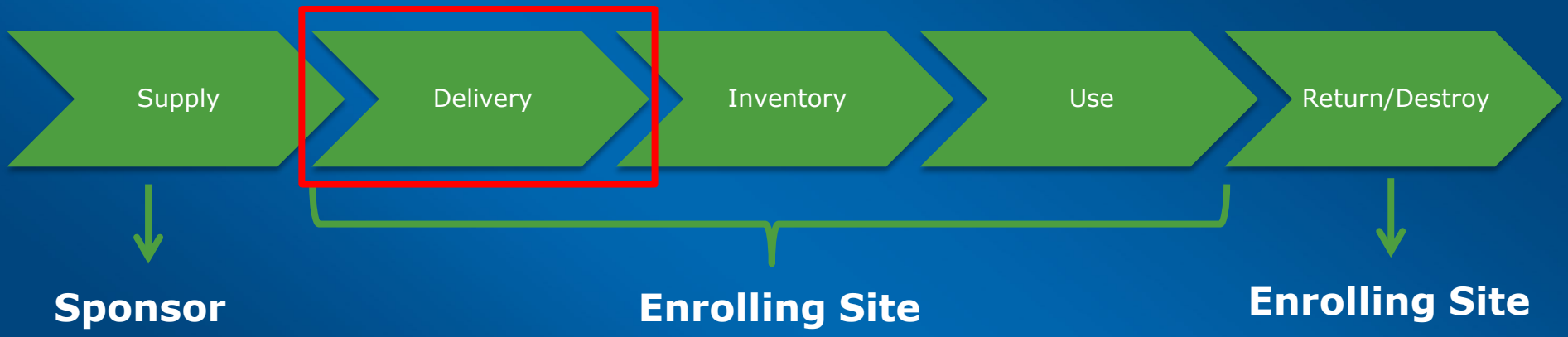
Drug "Lifecycle"


Regulatory Bodies Overseeing IDS
ASHP Residency, Board of Pharmacy, USP 797, JCHAO, USP 800, DEA, FDA, NIH, Sponsors
Clinical Research Organization
Vestigo Verify™
EMR
Interface & Dispense Transactions
Interactive Response Technology
Inventory Receipt Dispensing Documentation
Vestigo®
IV Preparation
Dispense Labels & Transactions
Temperature Monitoring System
Temperature Excursion Documentation
Storage Automation Carousel/Cabinets
Inventory Transactions
Clinical Trial Management System
CTMS Interfaces
Clinical Trial Office
Protocol Information

Vestigo Accountability System

- Vestigo is considered the IDS's sole source of documentation for investigational drug accountability
  - Receipt, Dispensing, & Returns/Destruction
  - Quality Assurance – routine monitoring and audit
  - Document management
    - Study specific (i.e. pt. forms, IRT assignment emails, shipment invoices)
    - Site level (i.e. master temperature logs, SOPs, training)
- Billing operations

Drug "Lifecycle"



Shipment QA/QC

ID	Drug	Lot No.	Item No.	Expire Date	Txn Qty.	Available QOH	Unit	Location	Date/Time	Txn Type
80941	PLACEBO cards	D485441	1483257	29 Feb 2024	1.000	1	VIAL	NonOnc Cabinets	08 Dec 2022 13:15	RECEIVE

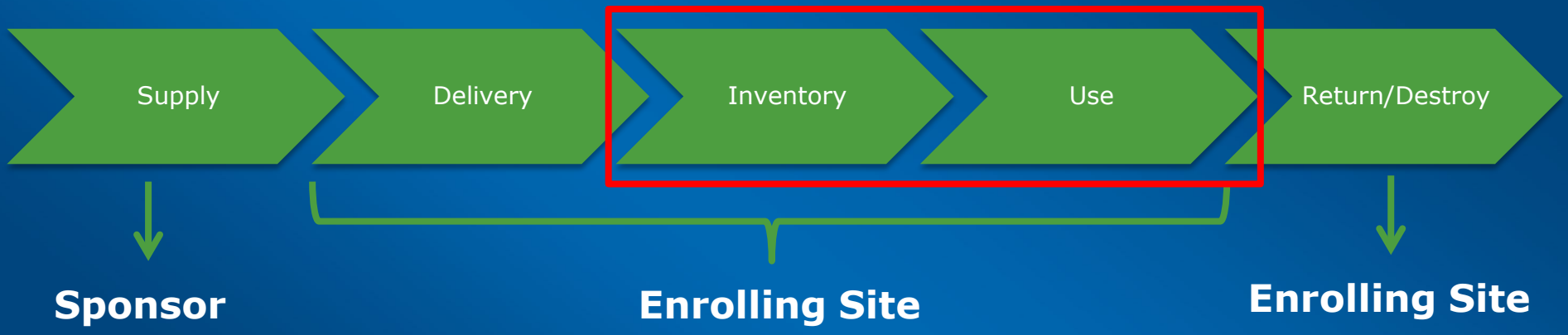
Vestigo

Quality Check Status Report

Transaction ID	Drug Description	Location Description	Lot Number	Item Number	Supplier	Transaction Quantity	QOH	Unit	Protocol Number	Transaction Type	Transaction Date/Time	Transaction User	Review Status	Review User	Review Date/Time
80410	R07046015, 500mg/2.78ml vial	NonOnc Fridge #2	1175719		Roche	42	42	VIAL	BP39529 | R07046015 (PRX002) | P614	RECEIVE	30 Nov 2022 14:06:55		Confirmed		01 Dec 2022 13:56:36
80406	Moderna Bivalent COVID-19 Vaccine	NonOnc - 20 Freezer	019H22A		EMINENT Services Corporation	1	2.5	ML	DAIT ACV01 | Covid-19 | P740	RECEIVE	30 Nov 2022 14:02:57		Rejected		01 Dec 2022 14:15:42
80407	Pfizer-BioNTech Bivalent COVID-19 Vaccine GRAY CAP	NonOnc UL Freezer	GJ6738		EMINENT Services Corporation	1	1.8	ML	DAIT ACV01 | Covid-19 | P740	RECEIVE	30 Nov 2022 14:02:58		Rejected		01 Dec 2022 14:15:42
80481	400mg packet	NonOnc Fridge #2	CKKMV		AMO Pharma Limited	6	8	KIT	AMO-02-MD-2-004 | Tideglusib | P812	RECEIVE	01 Dec 2022 14:35:10		Confirmed		01 Dec 2022 15:23:54
80482	600mg packet	NonOnc Fridge #2	CKKMW		AMO Pharma Limited	6	8	KIT	AMO-02-MD-2-004 | Tideglusib | P812	RECEIVE	01 Dec 2022 14:35:10		Confirmed		01 Dec 2022 15:23:54
80416	Staccato Alprazolam 2mg Inhaler	NonOnc Safe	341229	100225	UCB Biopharma SRL	1	1	INHALER	EP0165 | P842	RECEIVE	30 Nov 2022 15:23:53		Confirmed		01 Dec 2022 15:28:28
80417	TRAINER Staccato Alprazolam Placebo	NonOnc Safe	335948	314092	UCB Biopharma SRL	1	1	INHALER	EP0165 | P842	RECEIVE	30 Nov 2022 15:27:01		Confirmed		01 Dec 2022 15:28:28
80476	MTAU9937A open label	NonOnc Fridge #3	1170634		Genentech	5	5	VIAL	GN40040 | Lauriet | P397	RECEIVE	01 Dec 2022 14:16:29		Confirmed		01 Dec 2022 15:29:17
80523	PLACEBO cards	NonOnc Cabinets	D485441	1351056	Other	1	1	VIAL	17737 | Trailblaze-ALZ2, donanemab | P675	RECEIVE	02 Dec 2022 12:47:49		Confirmed		02 Dec 2022 14:36:42
80524	PLACEBO cards	NonOnc Cabinets	D485441	1383562	Other	1	1	VIAL	17737 | Trailblaze-ALZ2, donanemab | P675	RECEIVE	02 Dec 2022 12:47:50		Confirmed		02 Dec 2022 14:36:42
80525	PLACEBO cards	NonOnc Cabinets	D485441	1407176	Other	1	1	VIAL	17737 | Trailblaze-ALZ2, donanemab | P675	RECEIVE	02 Dec 2022 12:47:50		Confirmed		02 Dec 2022 14:36:42
80526	PLACEBO cards	NonOnc Cabinets	D485441	1521293	Other	1	1	VIAL	17737 | Trailblaze-ALZ2, donanemab | P675	RECEIVE	02 Dec 2022 12:47:50		Confirmed		02 Dec 2022 14:36:42

80982	Open Label 40mg	73488.19	228410	28 Feb 2023	1.000	1	BOTL	NonOnc Cabinets	08 Dec 2022 14:02	RECEIVE

Drug "Lifecycle"



Inventory Monitoring

Asset Name: PHARM_SMH_WCCIDS6_FRZ
Asset ID: CMT-119PHID-006

National Institutes of Health
National Cancer Institute

Division of Cancer Treatment and Diagnosis
Cancer Therapy Evaluation Program

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Investigational Agent Accountability Record

CONTROL RECORD

Name of Institution:	NCI Protocol No.:
University of Rochester Medical Center - Non-Oncology IDS (NY167)	A031704
Agent Name:	**Dose Form and Strength:**
Nivolumab 100 mg/10 mL VIals	100 mg/10 mL vials
Protocol Title:	**Dispensing Area:**
Immunotherapy With Nivolumab and Ipilimumab Followed by Nivolumab or Nivolumab With Cabozantinib for Patients With Advanced Kidney Cancer, The PDIGREE Study	Onc Fridge A
Investigator Name:	**CTEP Investigator ID.:**
Dr. Deepak Sahasrabudhe	14683

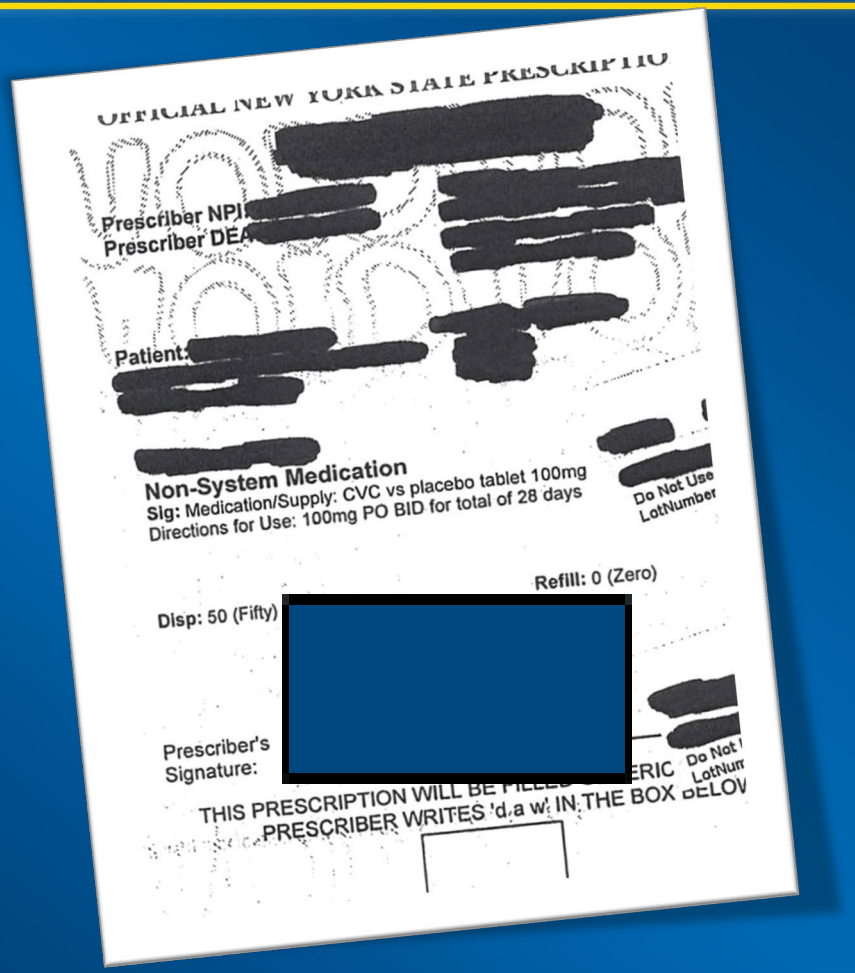
Line No.	Date	Patient's Initials	Patient's ID No.	Dose	Quantity Dispensed or Received	Balance Forward Balance	Manufacturer and Lot No.	Recorder's Initials
66	14 Nov 2022	Cycle Count			0 VIAL	12 / 12		CTraynor 14 Nov 2022 14:35:27

Mon Wed Fri Sun Tue Thu Sat Mon Wed Fri Sun Tue Thu Sat Mon Wed

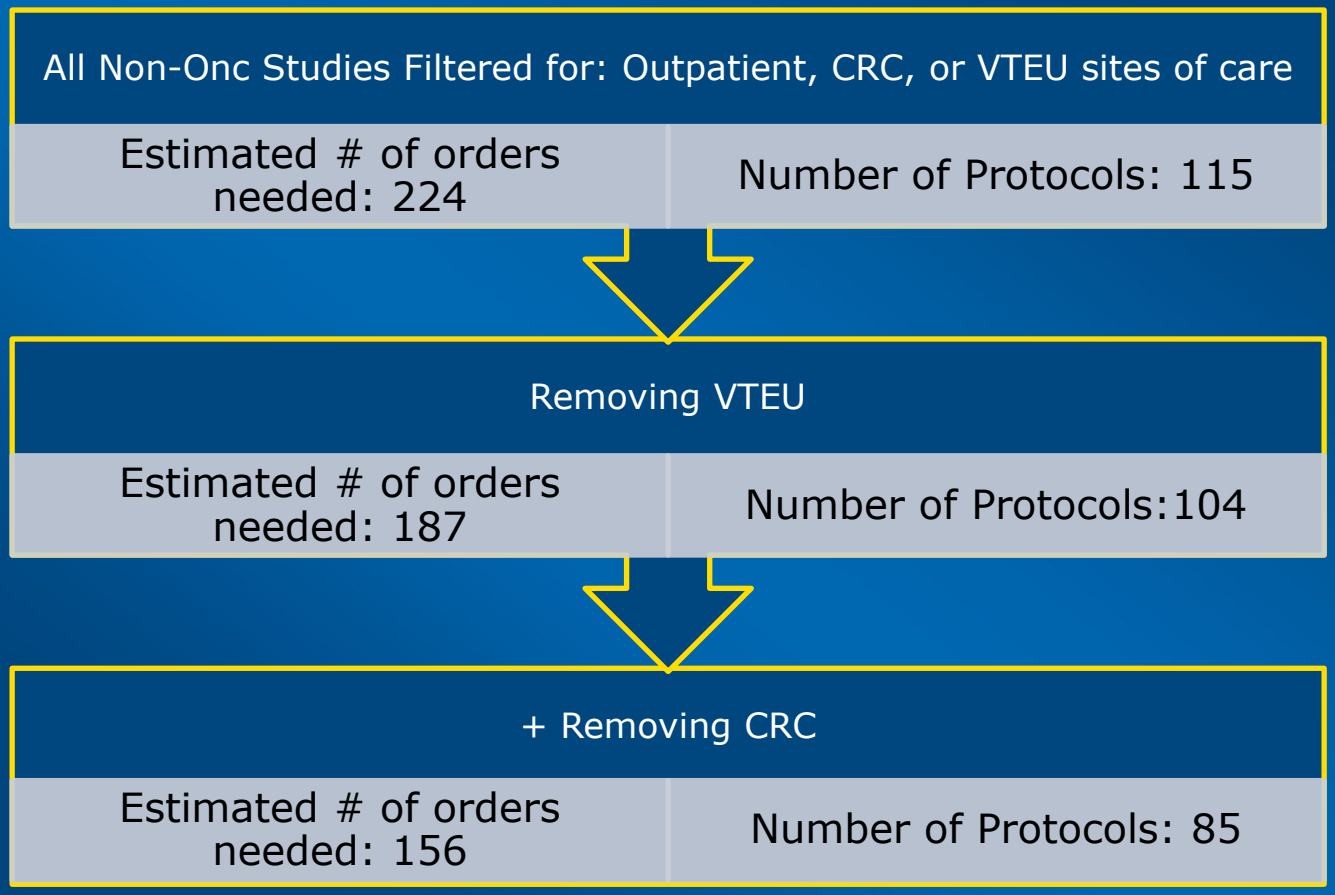
A Safe URMC Medication System: Non-Research

- System wide IT solutions
  - Integrated system (eR[illegible]) (physician order entry)
  - Point of care bar code a[illegible]istration
- Phar[illegible]ist role
- Smart infusio[illegible]mps
- Dispe[illegible]ng automation
- IV compounding [illegible]omation

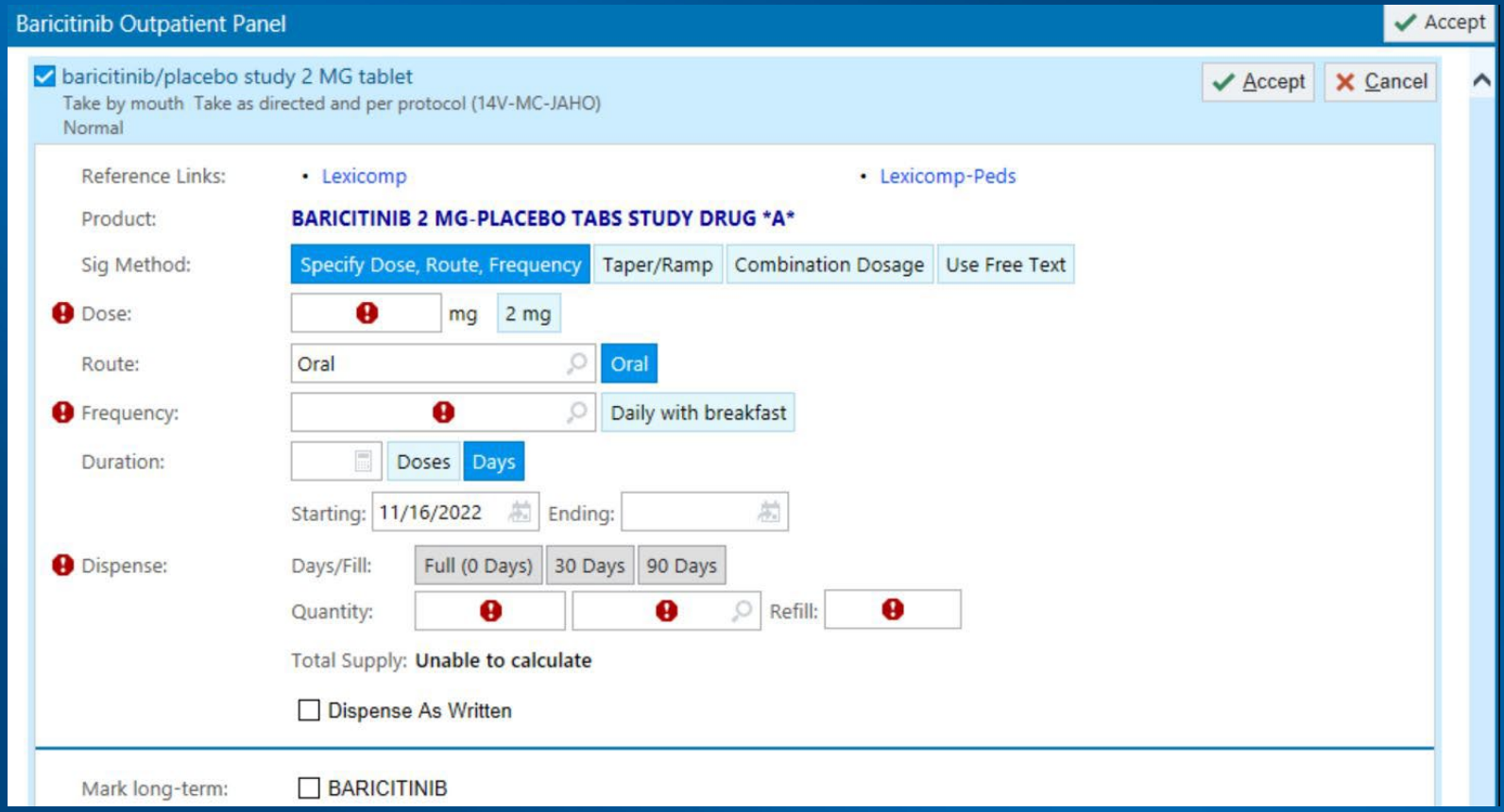
"Outpatient" ordering



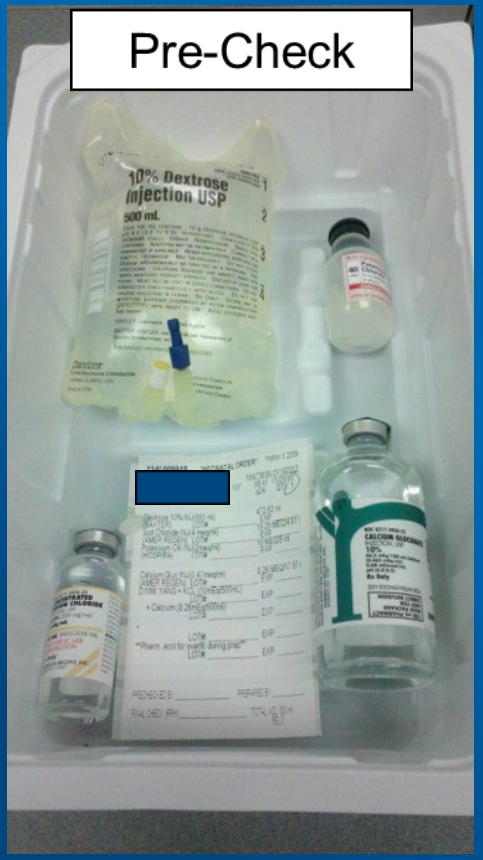
Scope of outpatient order builds needed in eRecord



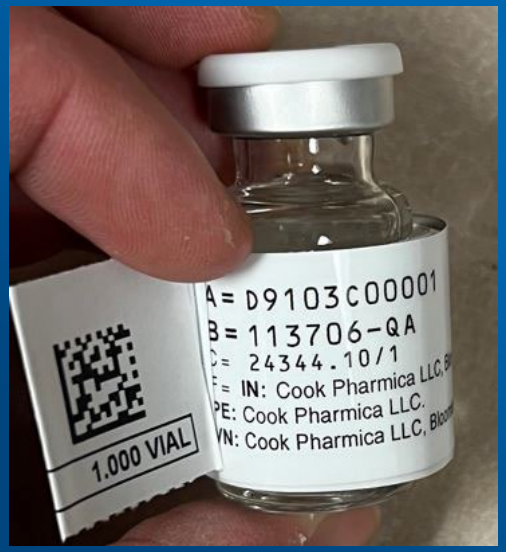
New "outpatient" order



The Highest Risk…



Dispensing automation



Bar Code Scanning

Gravimetric Analysis

Future of Medication Safety in Clinical Research

1. Integrated system (eRecord)
   - All research encounters captured in eMAR
   - Standardized physician order entry
   - Bar code medication administration
2. Sterile product production
   - Bar code scan verification
   - Digital image capture
   - Can investigational products incorporate gravimetric checks?
3. Pump integration

IDS Budget Considerations

IDS Financial Structure

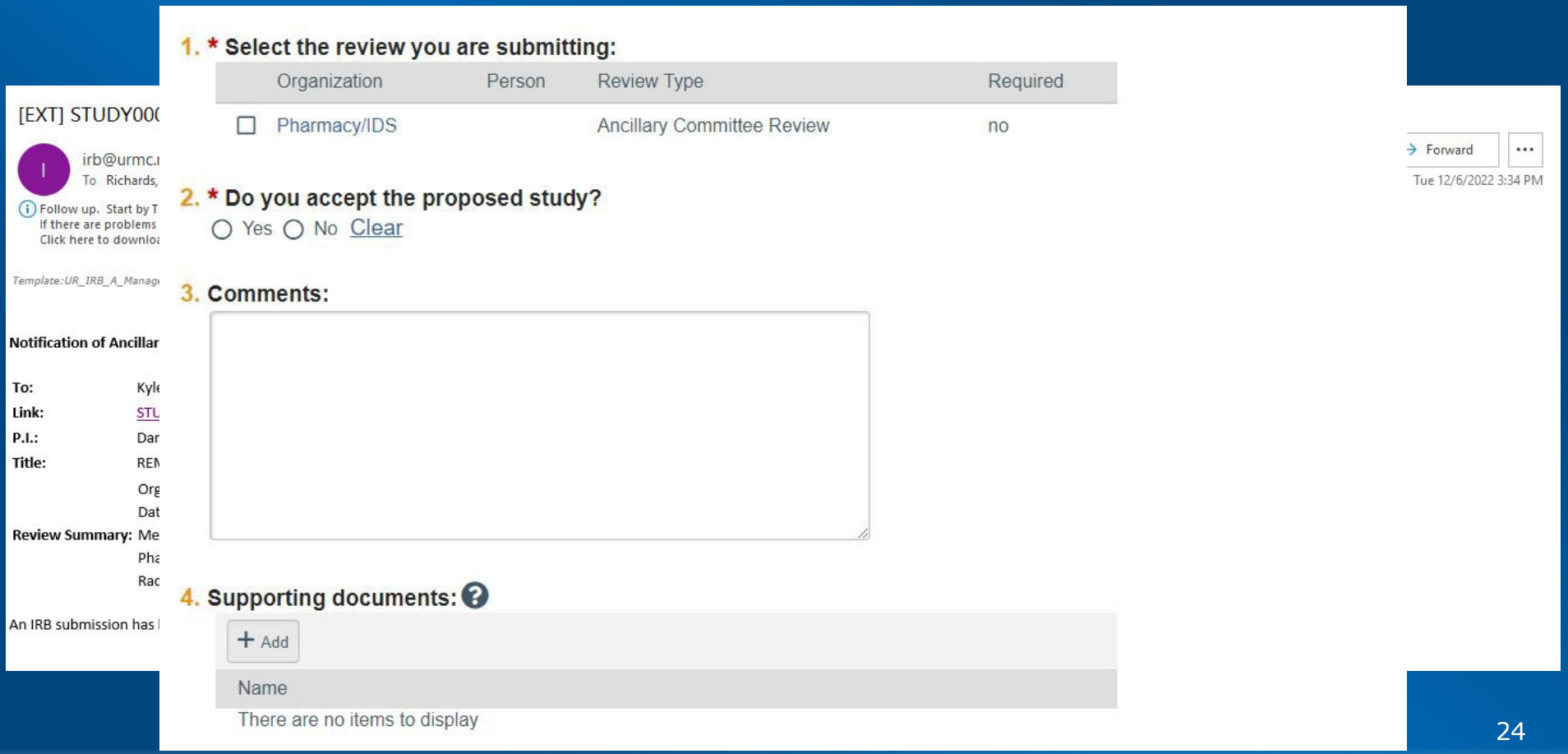
1. IDS is a "core" service center within SMD
2. Budget & Rates
   - Fee structure
     - ✓ Start up
     - ✓ Maintenance
     - ✓ Close out
     - ✓ Dispensing fees (IV dose, IM/SubQ dose, oral, etc.)

IDS Home Page

University of Rochester Medical Center Dept. of Pharmacy		
Investigational Drug Services CHARGE WORKSHEET		Note: estimate only
Primary Study Drug:		PI:
Protocol Number:		Date:
NOTE: Account # needed before ANY PURCHASES (if applicable). This ESTIMATE is subject to change if actual IDS costs or sponsor requirements change. The IDS is a service center subject to Uniform Guidance and required to adjust its fees periodically to reflect the actual cost of services		
Activity		**Cost**
Start-up fee		
(fee will be charged once SIV has occurred - fao to be supplied by department)		
One time charge assessed at study initiation (with initial pharmacy bill): protocol review and set-up, training, coordination of eRecord and/or Vestigo build, registration of study with NY state per NYS class 4 researcher's license requirements (if applicable) ***(This fee will be applied once SIV has***		
Annual Maintenance fee		
(fee will be charged once first drug shipment arrives on site or at time of first commercially sourced chemotherapy verification and yearly thereafter)		
Note: Billed on annual basis upon first receipt of study drug or first commercially sourced chemotherapy verification and continuing until the official pharmacy close out visit has occurred. The initial fee will be issued upon initial study drug receipt or first commercially sourced chemotherapy verification and covers the functions listed below during the 1st year of service. The fee will thereafter be issued annually on the anniversary month. Maintenance of regulatory forms/binder, ongoing protocol review and subsequent training functions (review of amendments), continued evaluation and/or updates to eRecord treatment plans based upon amendment reviews, meetings, monitoring/auditing visits, and correspondence.		
Close-Out fee		
Note: Billed upon closure of the study, which includes study closure meeting, return/destruction of study drug(s), final reconciliation of regulatory documents, archiving of study file		
Dispensing Cost (select all that apply)		
Note: NY State law requires separate written prescriptions/orders for EACH study drug, including different doses of the same drug. The dispensing fee is PER INDIVIDUAL PRESCRIPTION OR ORDER prepared and not "per dispensing visit."		
☐ Per prescription prepared	FALSE	$ -
☐ Per standard IM/SQ dose prepared	FALSE	$ -
☐ Per standard IV dose prepared	FALSE	$ -
☐ Per inpatient day prepared (oral dosing)	FALSE	$ -
☐ Per comercially sourced chemotherapy order reviewed/verified	FALSE	$ -
Special Notations:		
Others (specify): ***FAO will need to be supplied to IDS Pharmacy by department once SIV has occurred** ***Prorated annual fees will no longer be issued** ***Fees listed on budget are subject to change to cover the cost of IDS services**		
The Investigational Drug Service and Dept. of Pharmacy require Principal Investigator (PI) approval of all IDS budgets prior to study initiation. By signing below, the PI agrees to the above budget and assumes responsibility to pay all subsequent IDS bills accordingly. Please fax the signed copy back to the IDS at 585-756-4446		
(Signature of PI)		(Date)

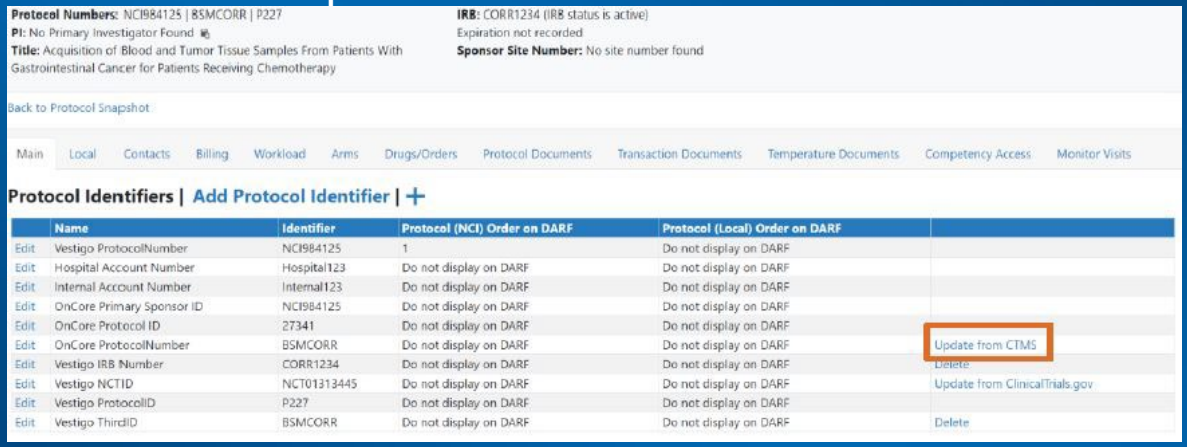
ClickIRB and OnCore

IRB Ancillary Committee



Vestigo & OnCore Interface

1. Addition of protocol via CTMS protocol number
   - *Protocol identifiers*
2. Loading contacts
3. Addition of arms
4. Enrollment and maintenance of patients



Protocol Numbers: NCI984125 | 85MCORR | P227
PI: No Primary Investigator Found
Title: Acquisition of Blood and Tumor Tissue Samples From Patients With Gastrointestinal Cancer for Patients Receiving Chemotherapy
IRB: CORR1234 (IRB status is active)
Expiration not recorded
Sponsor Site Number: No site number found

Back to Protocol Snapshot

Main | Local | Contacts | Billing | Workload | Arms | Drugs/Orders | Protocol Documents | Transaction Documents | Temperature Documents | Competency Access | Monitor Visits

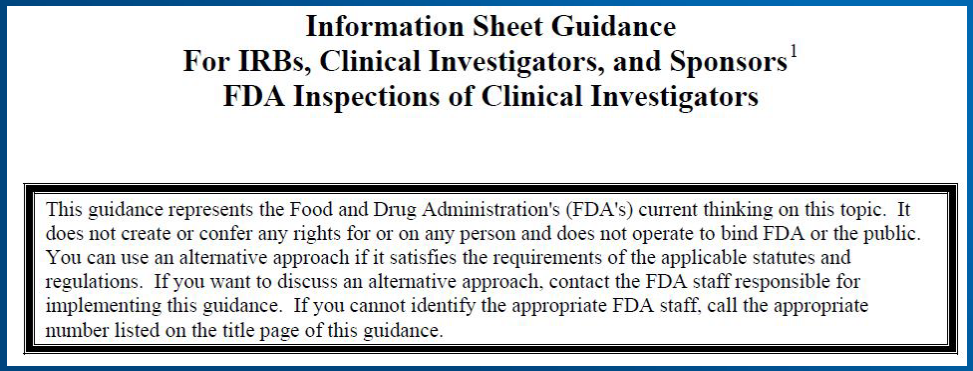
Protocol Identifiers | Add Protocol Identifier | +

	Name	Identifier	Protocol (NCI) Order on DARF	Protocol (Local) Order on DARF	
Edit	Vestigo ProtocolNumber	NCI984125	1	Do not display on DARF	
Edit	Hospital Account Number	Hospital123	Do not display on DARF	Do not display on DARF	
Edit	Internal Account Number	Internal123	Do not display on DARF	Do not display on DARF	
Edit	OnCore Primary Sponsor ID	NCI984125	Do not display on DARF	Do not display on DARF	
Edit	OnCore Protocol ID	27341	Do not display on DARF	Do not display on DARF	
Edit	OnCore ProtocolNumber	BSMCORR	Do not display on DARF	Do not display on DARF	Update from CTMS
Edit	Vestigo IRB Number	CORR1234	Do not display on DARF	Do not display on DARF	Delete
Edit	Vestigo NCTID	NCT01313445	Do not display on DARF	Do not display on DARF	Update from ClinicalTrials.gov
Edit	Vestigo ProtocolID	P227	Do not display on DARF	Do not display on DARF	
Edit	Vestigo ThirdID	BSMCORR	Do not display on DARF	Do not display on DARF	Delete

FDA Inspection Readiness

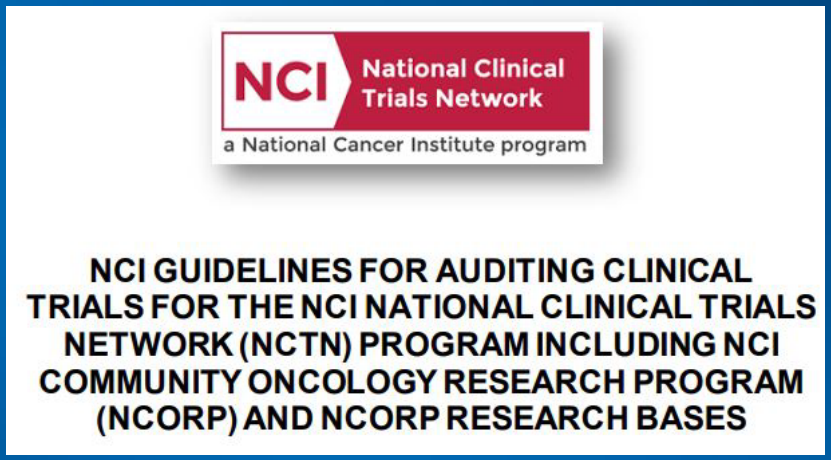
My thoughts…

- FDA inspection guidance
- NCI audit documents
- 21 CFR Part 312 Subpart D
- Audit ready system – Vestigo



Information Sheet Guidance
For IRBs, Clinical Investigators, and Sponsors[1]
FDA Inspections of Clinical Investigators

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.



NCI National Clinical Trials Network
a National Cancer Institute program

NCI GUIDELINES FOR AUDITING CLINICAL TRIALS FOR THE NCI NATIONAL CLINICAL TRIALS NETWORK (NCTN) PROGRAM INCLUDING NCI COMMUNITY ONCOLOGY RESEARCH PROGRAM (NCORP) AND NCORP RESEARCH BASES

Conclusion

IF YOU DON'T HAVE TIME TO DO IT RIGHT, WHEN WILL YOU HAVE TIME TO DO IT OVER?

– JOHN WOODEN