



**Miami Cancer
Institute**

BAPTIST HEALTH SOUTH FLORIDA



UNIVERSITY OF MIAMI HEALTH SYSTEM



Oncology Investigational Drug Services (IDS)

Advancement of Quality and
Efficiency Initiatives

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Presentation Objectives

1

Define IDS and describe individual site practice models.

2

Describe the role and function of research pharmacists at each site.

3

Describe how research pharmacists support patient enrollment, eligibility review, and Cycle 1 Day 1 dispensation.

4

Describe processes and/or resources implemented at sites to support research between central and satellite locations.

The **Investigational Drug Service** is the institution's resource for investigational medication management and accountability, regulatory compliance, financial services, and any pharmacy-related services to support clinical trials protocols.

Miami Cancer Institute (MCI) Investigational Drug Service



MCI Pharmacy: Ambulatory (primary) + Inpatient

- Research patients seen across 1 inpatient and 3 outpatient locations

Office of Clinical Research

- 193 Therapeutic Trials
- 52 Non-Therapeutic Trials
- 73 Retrospective Studies

MCI IDS Pharmacy Staffing

- Director + Manager
- IDS Supervisor
- 4 Research Pharmacists
- 2 Research Technicians



H. Lee Moffitt Cancer Center & Research Institute



- NCI Designated – Inpatient Hospital + Ambulatory
- ~ 250 beds + 3 Ambulatory Satellite Campuses
- Surgical Hospital (July 2023)
- Dedicated IDS: MCC + MKC Satellite



- 400 + studies (oncology)



- Pharmacy Practice Model clinical/operations
- Staffing
 - Manager
 - Supervisor
 - 7 IDS Clinical Pharmacists
 - 4 IDS Clinical Specialists
 - 5 Pharmacy Technician Specialists
 - 1 Purchasing Agent



University of Miami Hospital and Clinics (UMHC) IDS Pharmacy Overview

UHMC: Hospital and Non-Hospital Locations

- 3 Hospital Locations + 9 Sylvester Comprehensive Satellite Sites

IDS Pharmacy Workload

- Current Active Protocols: **500+**
- Current Active Drugs: **1291** inventory line items

IDS Staffing Model

- Pharmacy Director
- 5 Clinical Pharmacists
- 7 Full-time + 2 Per Diem Research Pharmacists
- 7 Pharmacy Technicians



UHealth Tower



Sylvester Comprehensive
Cancer Center



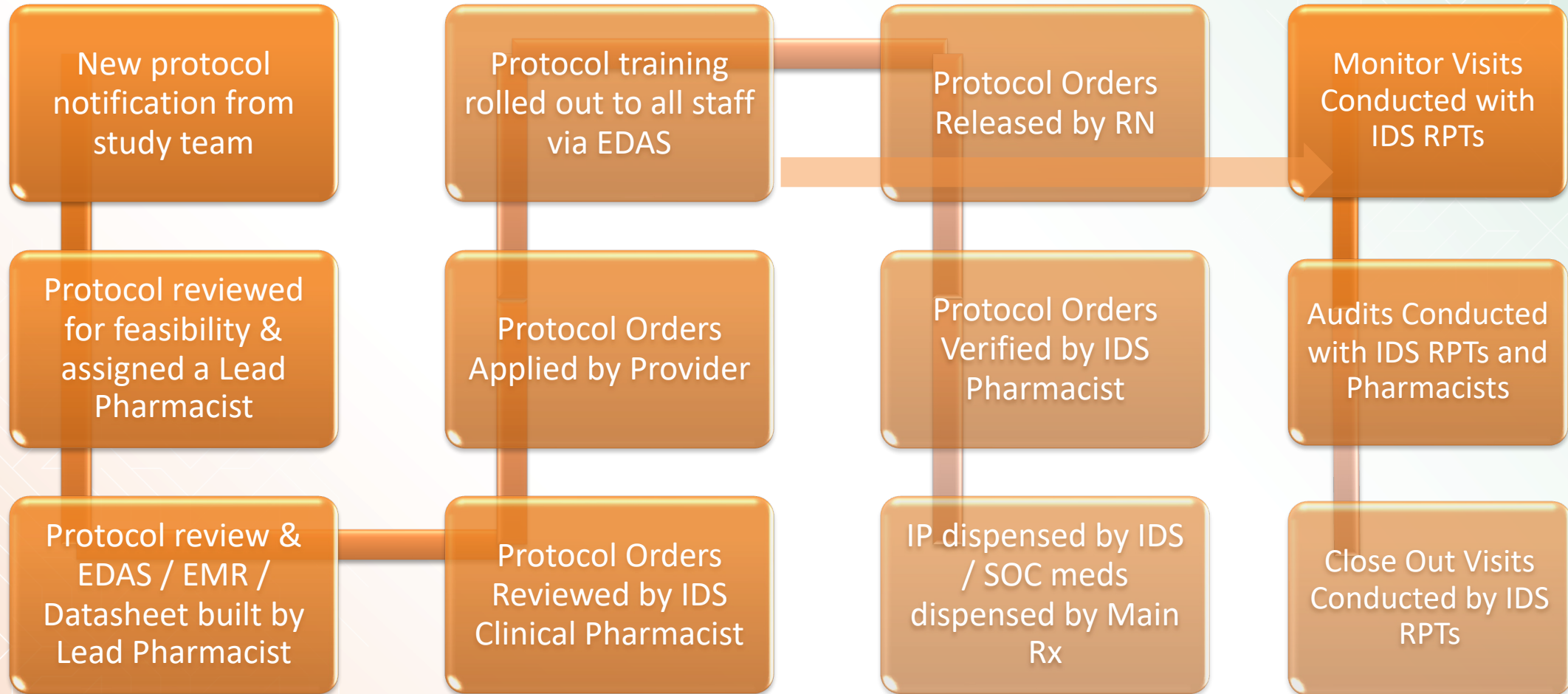
Bascom Palmer
Eye Institute



What are the roles and
functions of research
pharmacists?

UHMC IDS Pharmacy Overview

IDS Clinical Trial Process Map



UHMC IDS Pharmacy Overview

General Support Services:

H. Lee Moffitt Cancer Center - IDS Staff Roles

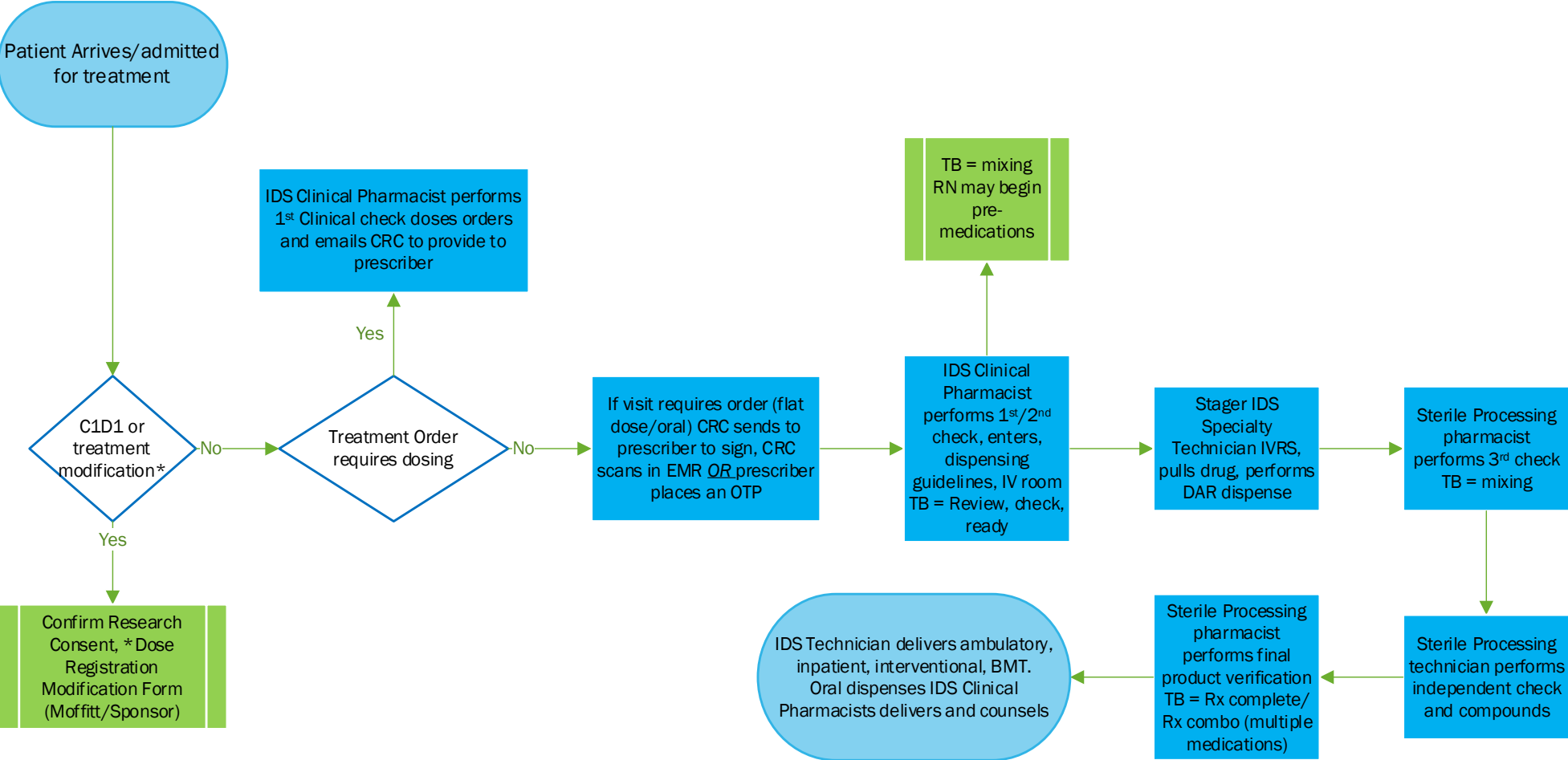


MCI IDS Pharmacy Services



How do research pharmacists support patient enrollment, eligibility review, and Cycle 1 Day 1 dispensation?

H. Lee Moffitt Ambulatory Research Patient Workflow



Clinic Tracking Board Select Profile: Default Profile

As of Tue Apr 4 2023 14:45

Pager or Phone:	All Appts:	Appt Type:	Pt Appt Tm:	Appt Time:	Check-in time:	Name:	Study Drug:	MCC #:	Pharm Status:	New Vitals:	Labs Status:	Pt Status:	CTC:	Orders:	Pharmacy Cmts:	RX:	Drug Status:	Appt Duration:
		Arrival Time Clinical Research Infusion	16:15	17:30			CPI OR PLACEBO, RUXOLITINIB	MCC21279 C3D1		9 results posted	12 of 14 orders Completed			Orders P (07:10)	NAME ALERT (07:10)			01:30

H. Lee Moffitt IDS Treatment Day Preparation



Enrollment

New patients identified through prep report
Sample IDS New Subject Prep Checklist:

- ☒ Informed Consent
- ☒ Eligibility Review
- ☒ Current Medication Review
- ☒ Research Treatment Order
- ☒ Confirm sufficient inventory
- ☒ Verify authorized prescriber
- ☒ Verify arm / dose level assignment

Medication List Review

Current medication list against protocol
exclusion & prohibited medication sections
Identify protocol DDI risks
Prohibited vs. Monitoring

Inventory Management

Complete 7-10 days out
Verify and place order



CRU IDS Daily Prep Report

(Clinical Research Unit)

Run Time: 8/8/2022 3:41:33 PM
Appt Date: 8/15/2022 to 8/15/2022

Appointment Date	Appointment Time	MRN	Patient Name	Appointment Type	MCC Protocol #/Cycle/Day	Study Drug Name	CTC Name	Orders	Labels	Inventory In Stock and In Date	IVRS	Informed Consent	Dose Registration Form	Pharmacy Comments – Free Text
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UHMC IDS Pharmacy Overview

Clinical Pharmacist Role:

■ Patient Enrollment & Screening Eligibility Reviews

- Review concomitant medications for potential prohibited therapies, drug-drug interactions, prior therapies and appropriate wash-out periods
- Provide clinical recommendations for alternatives to prohibited therapies and drug interactions
- Clinical laboratory value review for assessment of proper organ function
- Review of inclusion/exclusion criteria

■ Prior to Treatment Start

- Prior to C1D1: Add and review treatment plans, confirm dosing/scheduling, provide supportive care recommendations (i.e., hydrations / antihyperuricemics for Tumor Lysis Syndrome, anticoagulation prophylaxis)
- Confirm adequate supply of IP available in stock
- Ensure IDS staff have completed required protocol training

■ Cycle 1 Day 1

- Clinical laboratory value review for dosing criteria
- Provide education to study team/nursing staff/IDS pharmacists/patients



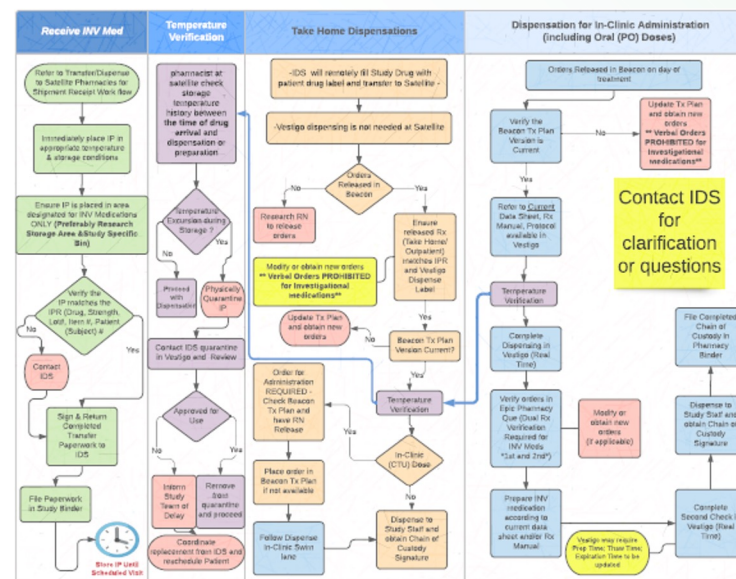
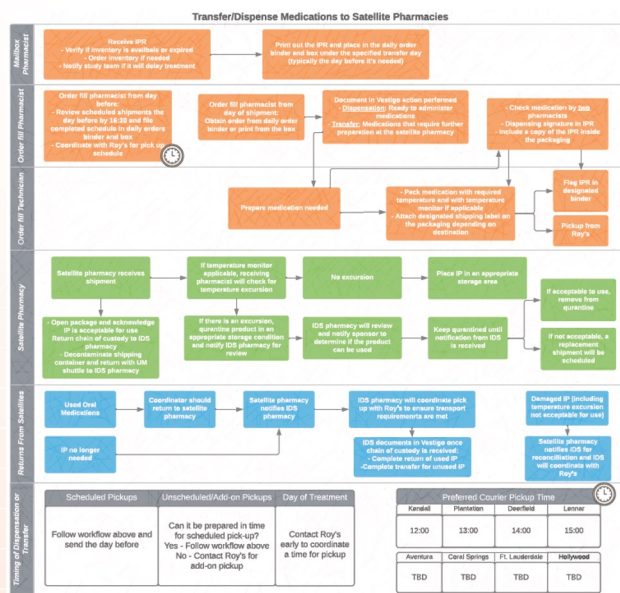
What processes and/or resources are available to support research between central and satellite locations?



Investigational Drug Services (IDS) Pharmacy Overview

Sylvester Satellite distribution workflow:

- Centralized IDS receives drug inventory and manages par/reorder levels for protocols
- IDS sends satellite pharmacies patient-specific inventory 1 business day prior as requested by study team
- Frontline pharmacists at satellites are trained to dispense in EDAS



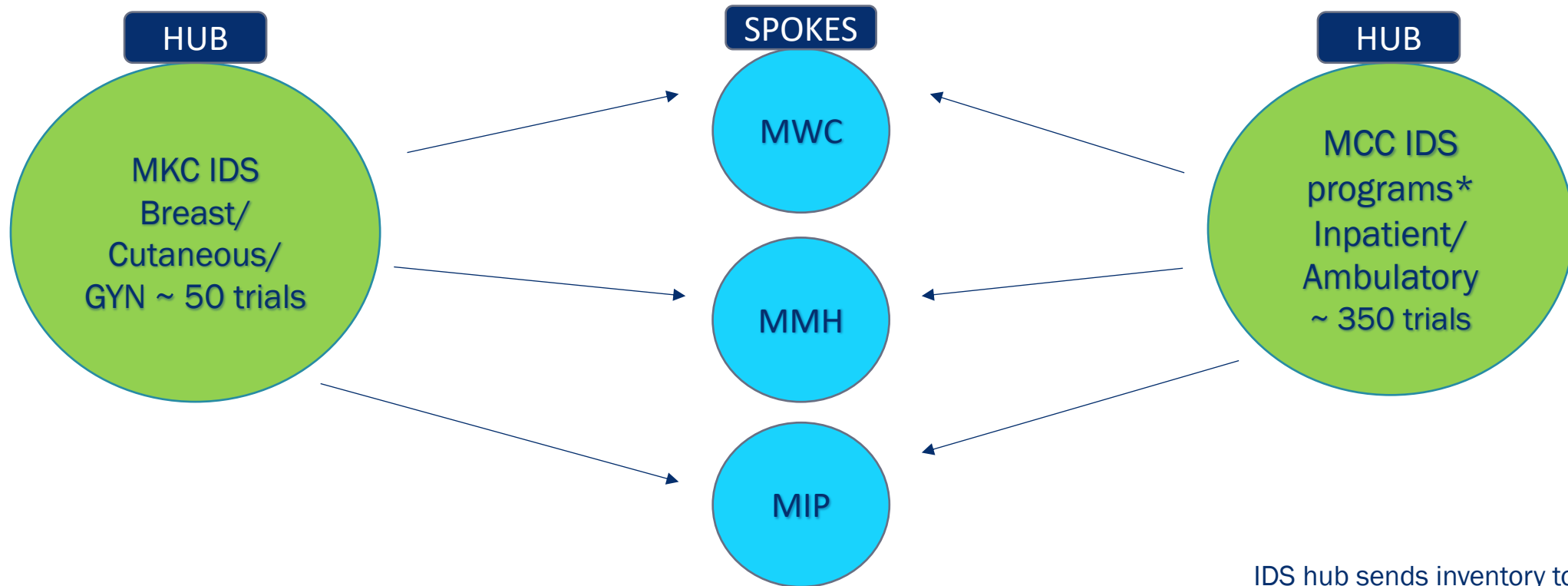
EDAS: electronic drug accountability software

IDS – Hub and Spoke Distribution Model



Current State: 2 Program Specific Hubs

Remote Work: HUB to spoke and from home



IDS hub sends inventory to satellites
*Thoracic, Sarcoma, Heme, Cellular
Immunotherapy, H&N, GU, etc

Hub to Spoke

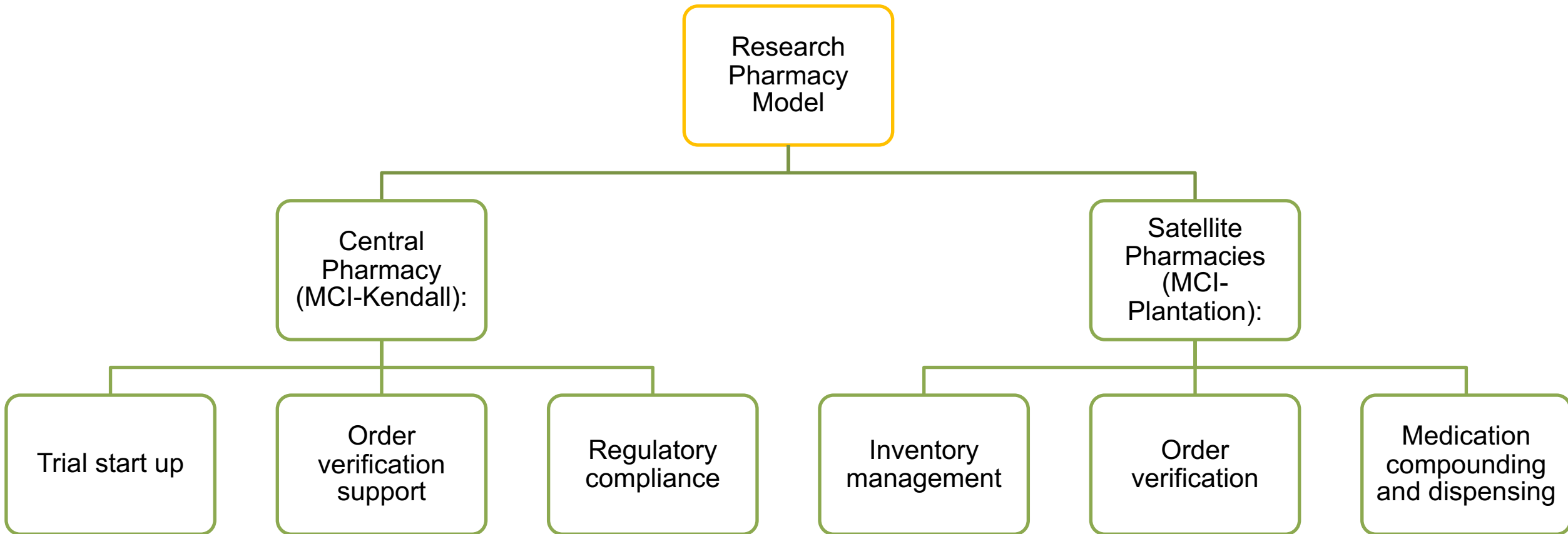


Main IDS to Satellites

- Moffitt ambulatory centers
- Hybrid model
 - Hub IDS process satellite patients remotely
- Develop study specific guidelines
- Onsite non-IDS staff roles
- Input from front-line staff
- Ensure same quality checks
- Staff training requirements
- Perform trial “runs”

Storage	-MCC
Ordering/Procurement	ECOG: Pembrolizumab *SOC: CARBOplatin + PEMEtrexed (weight based)
Receiving	Control Pharmacy MCC ships to Satellite Pharmacy.
Prior to Day of Treatment	<p>2 days before Day of Treatment</p> <p>CRC to provide orders to be dosed to SatelliteIDSPharmOrd@moffitt.org scanned subject line: MWC_MIP_20163 Sub 001 Research Med Order C3D1 Dated 10.26.2021</p> <p>ECOG trial allows drug order to be placed if a patient is in screening/registered, CRC to email Research Pharmacy</p> <p>IDS Prep:</p> <ul style="list-style-type: none"> • Confirm satellite has a SOC inventory, in prep report place estimated doses for SOC based on pt prior BSA/weight for CARBOplatin + PEMEtrexed
Drug transfer (Prior to day of treatment OR day of treatment)	<p>IDS Prep Product (Pembrolizumab invest study supply)</p> <p>Vestigo immediate transfer from Control to Satellite</p> <p>Moffitt Courier:</p> <p>Provide Interdepartmental Transfer Form Pembrolizumab: RF</p> <p>Key point: Transfer day before</p> <p>Satellite Staff:</p> <p>Upon receipt satellite staff to complete transfer form and email scanned to Satellite IDS Email and file in Satellite IDS binder</p>
Day of treatment	<p>Post Ep and labs resulting IDS remote doser to dose and email CRC to obtain signed treatment orders and scan to HIMIS</p> <p>If dose change required and insufficient drug on site: (CRC inform pt of ~45 min transit)</p> <p>IV drug: IDS will remotely perform clinical review, order/DAR entry, fill out corresponding prep card and print/send labels to satellite. (*For split visits w/signed orders day before will send completed prep card/labels with study drug)</p> <ul style="list-style-type: none"> • IDS will scan/send prep card to satellite. Satellite Rph pull corresponding vials and use the IPAD to take pictures (showing vial#/LOT/exp) and send to satelliteidspharmord@moffitt.org for IDS product check and DAR dispense • Once IDS confirms product checked Satellite Rph provides prep card, study drug and labels to IV room for compounding <ul style="list-style-type: none"> • Satellite tech/RPh will follow/sign prep card. Completed prep card scan/email satelliteidspharmord@moffitt.org to IDS and file in binder by end of day. (Control to create/maintain pt specific folder + satellite Key Point: Immediate transfer date/time prior to dispense date) <p>Dispense</p> <p>Satellite dispense to satellite infusion center for administration</p>

MCI IDS Pharmacy Services



Audience Questions

Research Pharmacist Training Opportunities

01

On-the-job training
(most common)

02

ASHP Investigational
Drug Services
Certificate Program



Investigational Drug Service and Research PGY2 Pharmacy Residency

- 12-month post-graduate formal training program to build on Pharm.D. education and prepare competent pharmacist to provide care for research participants, who understand the regulatory requirements that govern clinical research, and develop leaders in pharmacy operations required to support clinical research
- ASHP accreditation available

MCI IDR PGY2 Pharmacy Residency



Dina Dumercy McHenry,
PharmD, MBA, BCOP-
Program Director

Vivian Nguyen, PharmD,
BCPS- Program Coordinator



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