



Miami Cancer
Institute

BAPTIST HEALTH SOUTH FLORIDA



SYLVESTER
COMPREHENSIVE CANCER CENTER

UNIVERSITY OF MIAMI HEALTH SYSTEM

Empowering Research with Excelling and Expanding Pharmacy Services



TGH Tampa
General
Hospital.

CANCER
INSTITUTE

Presentation Objectives

1

Describe the increasing training needs and specialization opportunities of research pharmacists.

2

Discuss opportunities for oncology pharmacists to expand research.

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

Research Pharmacist Training and Specialization



Regulations and Requirements

Federal, State, and Local Pharmacy Laws

- Code of Federal Regulations
- USP 795, 797, 800 Standards

Health Care Organization Accreditation

- The Joint Commission
- DNV (Det Norske Veritas)

CITI Program Training

International Conference on Harmonisation (ICH)

- E6. Good Clinical Practice (GCP)
- Q7. Good Manufacturing Practice (GMP)



Investigational Drug Service Best Practice Recommendations



Year	Organization	Guidance/Recommendation
2014	Hematology/Oncology Pharmacy Association (HOPA)	Investigational Drug Service Best Practice Standard
2018	American Society of Health-System Pharmacists (ASHP)	Guidelines for the Management of Investigational Drug Products
2021	National Comprehensive Cancer Network (NCCN)	Investigational Drug Service Consensus Recommendations



National Comprehensive
Cancer Network®



Training Resources

Post-Graduate Training

- Investigational Drugs and Research Pharmacy Residency Programs
 - PGY1/2 Combined
 - PGY2 Specialty

ASHP Professional Certificate

- Investigational Drug Services
 - Pharmacy processes, regulatory requirements, documentation, and clinical research study management



Investigational Drugs and Research Pharmacy Residency Programs

Operational Services

- Cleanroom Competency
- Inventory Management
 - Ordering and Receipt
 - Dispensation
 - Final Disposition
 - Environmental Monitoring
- Protocol-specific Training
- Pharmacy Fee Schedules
- Feasibility Committee
- Regulatory Compliance

Clinical Services

- Eligibility Review and Monitoring
 - Drug Interaction
 - Toxicity Management
- Outpatient Counseling
- Drug Information
- Informatics Build and Validation
- Subject Matter Expertise Review
 - Investigator-Initiated Trials
 - Scientific Merit Review Committees



Centralization of Resources

Central Hub

Trial Activation – Drug Onboarding

Informatics Build

Billing

Protocol Compliance

Drug Procurement

Staff Education

Trial Maintenance

Regulatory Compliance

Drug Information

Research Committees

On-Site Staff

Trial Activation

Required Trainings and Education

Trial Maintenance

Drug Accountability and Inventory Management

Ordering, Receipt, Storage, Disposition

Dispensation

Cycle Counts

Temperature Excursions

Order Verification and Compounding

Drug Counseling



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

IN PURSUIT OF *YOUR CURE*.™

Diana Reyes, PharmD, MHA
Director of Pharmacy
Investigational Drug Services



A Cancer Center Designated by the
National Cancer Institute

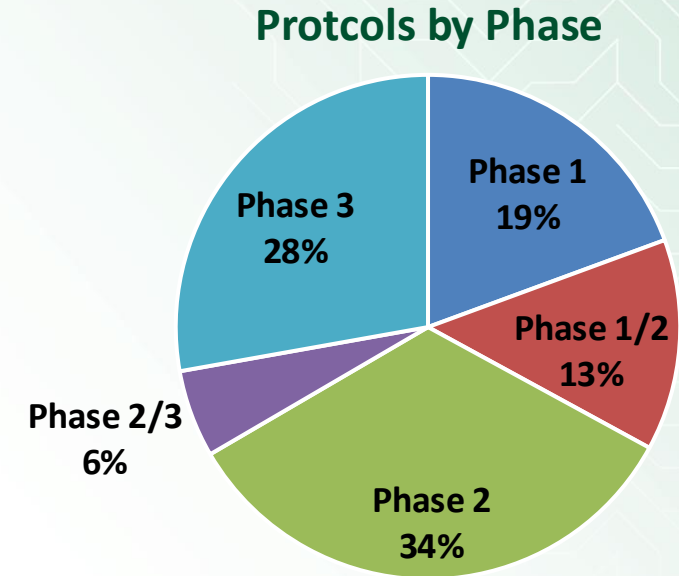
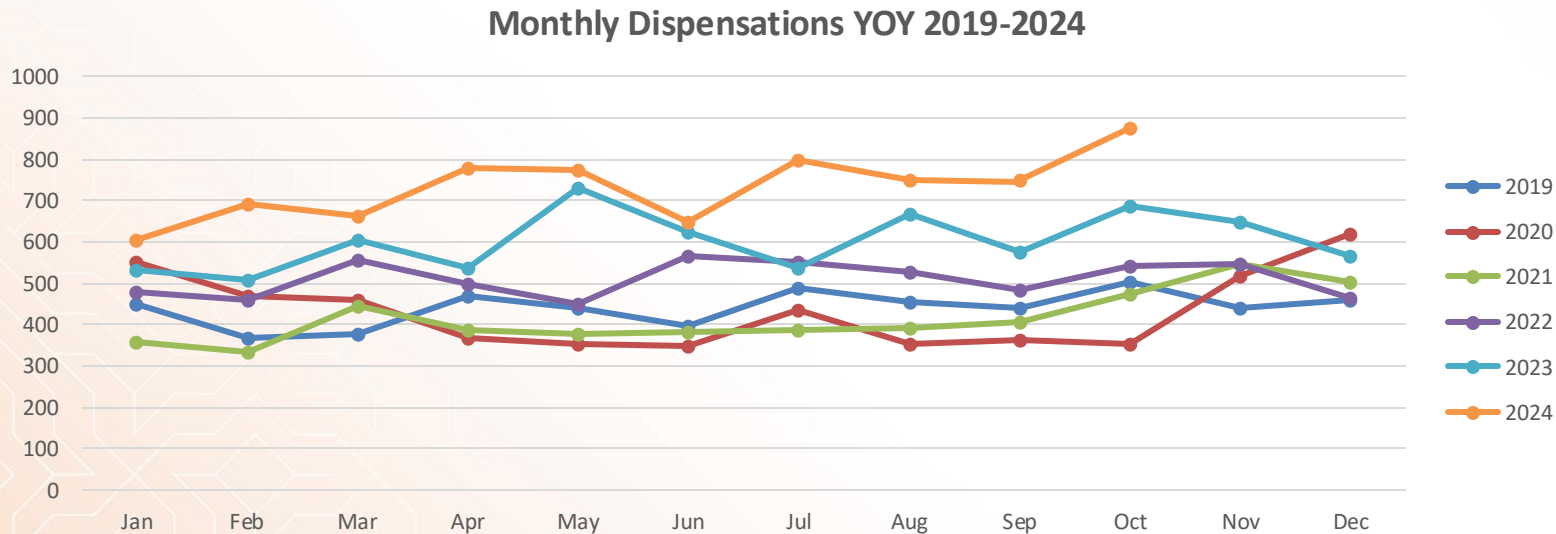
Objectives:

- Review investigational drug services growth in metrics over time
- Expanding clinical research services across a multi-site health system
- Understand specialized clinical pharmacist roles in clinical research
- Considerations for expanding to multiple IDS pharmacy locations

Investigational Drug Services (IDS) Pharmacy Overview

IDS Pharmacy Workload

- Current Active Protocols: **471**
- Current Active Drugs: **1245** inventory line items
- Current Fiscal Year (Jun 24 – Oct 24)
 - Average monthly IP dispensations: **765**
 - Average monthly subjects: **742**



Investigational Drug Services (IDS) Pharmacy Scope

University of Miami Hospital and Clinics:

3 Hospital Locations on UHealth / Miller School of Medicine Campus:



UHealth Tower



Sylvester Comprehensive Cancer Center



Bascom Palmer Eye Institute

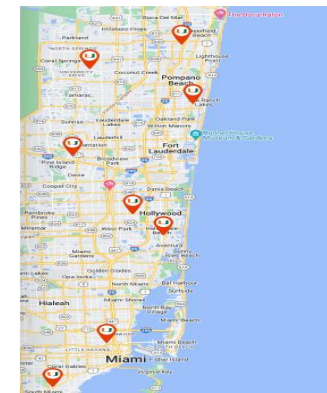
9 Sylvester Comprehensive Cancer Satellite Sites:

Miami-Dade County:

- Kendall
- Lennar
- Doral
- Aventura

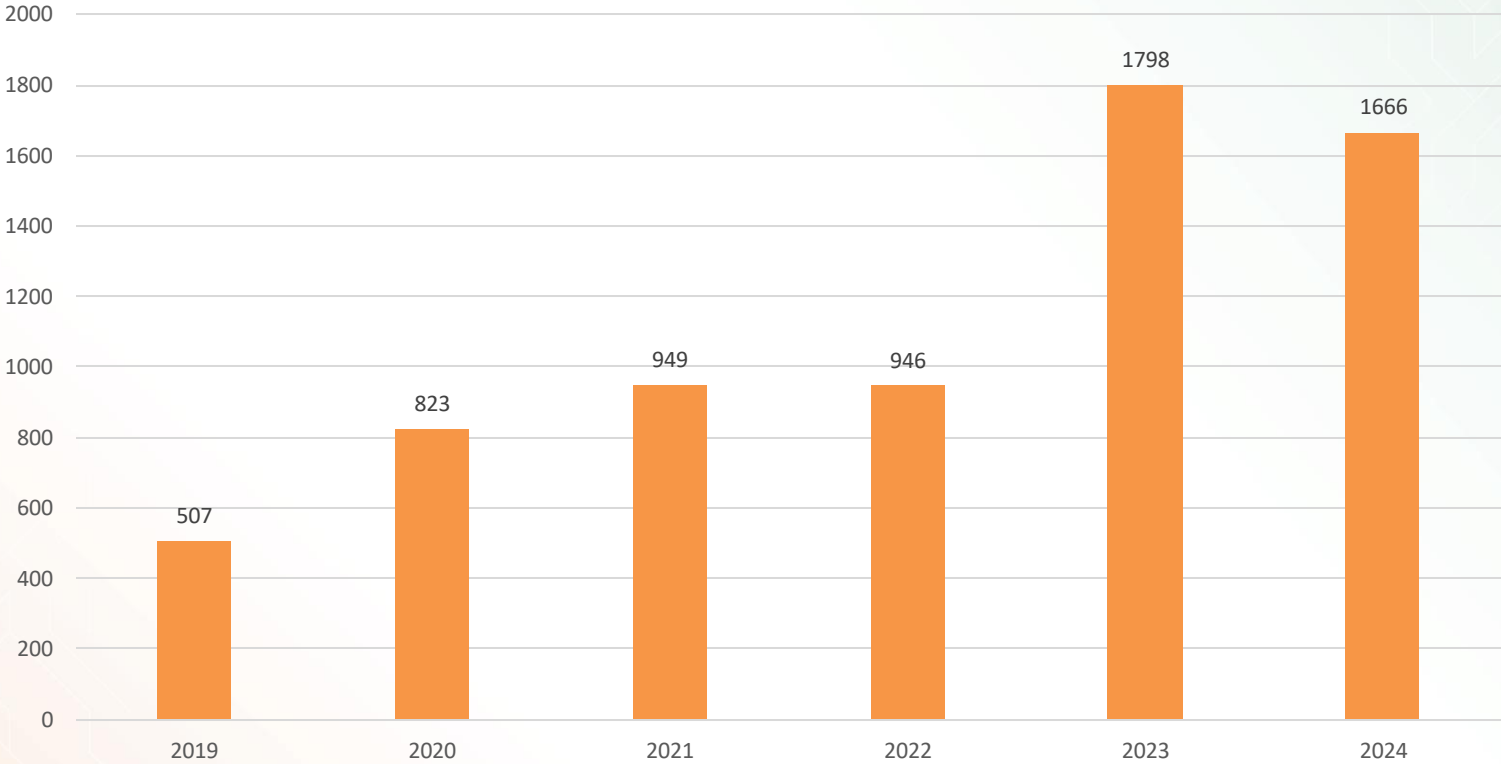
Broward County:

- Hollywood
- Plantation
- Coral Springs
- Deerfield Beach
- Fort Lauderdale



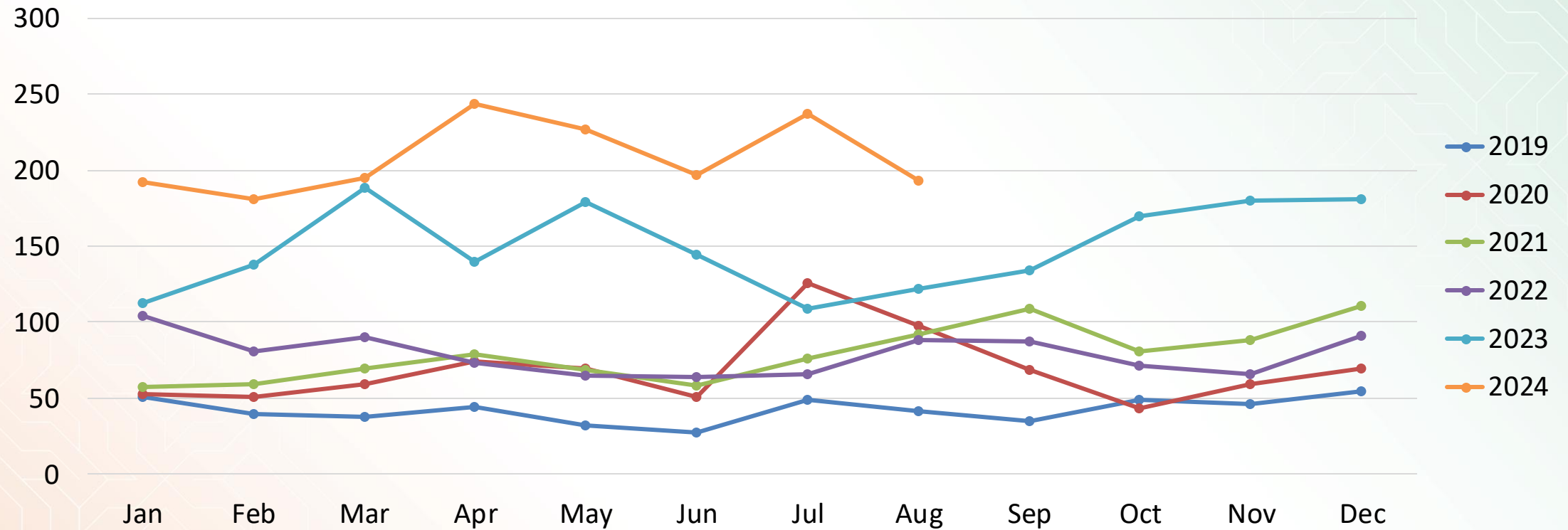
IDS Pharmacy Satellite Expansion

Investigational Drug Satellite Dispensations



IDS Pharmacy Satellite Expansion

Satellite Dispensations YOY 2019-2024



Investigational Drug Services (IDS) Pharmacy Staff Growth

2020 IDS Staffing Model (12 FT / 0 PD):

1 Pharmacy Director

1 Clinical Pharmacist:

- Phase 1 Site Disease Group / Leukemia

5 Full Time Research Pharmacists:

- Production / Dispensing
- Study Startup / Protocol Maintenance
- Regulatory

5 Pharmacy Technicians:

- Dispensing
- Inventory Mgmt
- IV Admixture

2024 IDS Staffing Model (31 FT / 3 PD):

Pharmacy Director

Pharmacy Manager

Pharmacy Buyer

6 Clinical Pharmacists:

- Phase 1 Site Disease Group / Leukemia / GU
- Multiple Myeloma / GYO / Sarcoma
- UMHC / SCCC Satellites / Breast / Thoracic
- Clinical Informatics
- Lymphoma
- Inpatient Services

12 Full Time Research Pharmacists:

- 1 x Inpatient Services
- 4 x Ambulatory Production / Dispensing
- 3 x Protocol Maintenance / Study Startup / Regulatory

2 PD Research Pharmacists

12 Pharmacy Technicians: Dispensing, Inventory Mgmt., Regulatory, Inpatient, Administrative & Billing

1 PD Pharmacy Technician



2020

2024

Specialized IDS Roles: Site Disease Group Clinical Pharmacists

- Liaison among investigators, study team, nursing and the Investigational Drug Services (IDS) Pharmacy in directing and interpreting the appropriate use of investigational products (IP)
- Collaborate with site disease group (SDG) interdisciplinary research team members in an ambulatory clinic setting and serve as a resource for protocol compliance
- Assist with providing malignancy-tailored supportive care recommendations (i.e., tumor lysis syndrome and anti-microbial prophylaxis)
- Counsel new start patients receiving IV or PO Investigational Medications +/- SOC treatment

Screening Eligibility Review

Inclusion/exclusion criteria

Clinical Laboratory Value Assessment

Concomitant medications for potential prohibited therapies

Drug-drug interactions

Prior therapies

Wash-out periods

Specialized IDS Roles: Site Disease Group Clinical Pharmacists

Operational Services:

- Assist with implementation protocol build into electronic medical record (i.e. EPIC treatment plan) in collaboration with informatics team
- Ensure training is completed with IRB approved protocol amendments
- Drug accountability & inventory management (i.e., Vestigo)
- IP Monitoring (Temperature, Inventory Management, Documentation)

Expanding Pharmacy Services to 2nd IDS Location

Operational Staffing Considerations:

- New site hours of operation: 7 am – 5 pm

New SOC Pharmacy Services:

- Pyxis Inventory Management
- SOC IV and Chemo Dispensing (including CADD)
- High-cost Medication Inventory (Willow Cycle Counts)
- Narcotic Dispensing / Auditing
- PAP Medication Inventory & Dispensing
- Medication Area Inspections
- Segregation of Investigational IP per TJC MM Standards
- Waste Billing
- SOC Medication Procurement / Receiving
- Emergency Cart Medication Maintenance

Duplicated Non-Dispensing Pharmacy Services:

- Clean Room Disinfection & Decontamination

Duplicated Research Pharmacy Services:

- Daily Investigational Drug Shipment Receipts (*mixed send-outs and sponsor shipments*)
- Monthly Investigational Drug Temperature monitoring / documentation for equipment
- Monthly Investigational Medication Expires (*requires sponsor communication and approval*)
- Monthly Investigational Drug Inventory Cycle Counts
- Annual / bi-annual device calibration
- INV Protocol Dispensation Document Scanning

Unique Research Pharmacy Services:

- Individual Protocol Training (**600+ per employee annually**)
- IWRS/IRT System Access Request and Maintenance (**170+ unique logins + individual training per employee**)



TGH Cancer Institute

Empowering Research with Excelling and Expanding Pharmacy Services

Gene A. Wetzstein, PharmD, BCOP

Director, Supportive Care Research & Scientific Affairs



**CANCER
INSTITUTE**

SUPPORTIVE CARE RESEARCH & SCIENTIFIC AFFAIRS

Supportive Care Research

- Supportive therapies
- Implementation Science
- Real-World Evidence Generation
- Health Economics & Outcomes Research



Scientific Affairs

- Research Opportunities
- Scientific Exchanges
- Grants/ Education
- Publication Support

Practice and Scientific Industry Relations



We want the same thing

FROM CONCEPT TO PRACTICE

- “Monitoring and treatment among patients with transfusional iron overload: preliminary findings from an electronic medical records review study”¹
- “Venous thromboembolism prophylaxis in a large oncology center”²
- “Rapid Infusion Rituximab in Maintenance Therapy: Is It Feasible?”³
- “Optimizing premedications in the prevention of Bendamustine infusion-related reactions”⁴
- “Cost Comparison of PARP Inhibitors in Women with Ovarian Cancer in the US Healthcare Market”⁵
- “Case Report: immune globulin intravenous 10%, human – slra use in three young children with immune abnormalities and acute respiratory failure secondary to RSV infection”⁶

1. Pharmacotherapy 2010; 30: Abstract 106E; 2. MASCC/ISOO Symposium 2011 ; 3. Blood, Abstract 4973, 2011; 4. Cancer Control 2012; 19 (3): 245-47; 5. Journal of National Comprehensive Cancer Network 2020, Vol 18: Issue 3.5; 6. Front. Immunol., 13 September 2023 Sec. Viral Immunology Volume 14

SUMMARY

- A lot of opportunities exist in different research areas
- Identify specifically what question(s) you want to address and study
- Gauge interest and align
- Determine required resources and logistics
- Write up your proposal and budget

An aerial photograph of Tampa General Hospital, a large multi-story building with a curved facade, situated on the waterfront. The city skyline is visible in the background under a clear blue sky. The text 'THANK YOU' is overlaid in large white letters, with a yellow horizontal bar underneath it.

THANK YOU