THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center®

Department of Internal Audit

MDA23-112 Investigational Drug Review
March 1, 2023

Executive Summary

The Investigational Pharmacy Services department (IPS) is responsible for the administrative management of all investigational drugs used at MD Anderson. Specific operational responsibilities of this office include but are not limited to drug acquisition, inventory control, and investigational drug accountability. IPS serves as the liaison between researchers and the Division of Pharmacy in addition to ensuring pharmacy compliance with clinical trial protocol requirements[1]. The institution currently has about 1,300 active individual protocols with investigational drugs. Additionally, clinical trials at MD Anderson continues to increase with an average of 350 new protocols activated every year.

Audit Results

Internal Audit conducted a review to ensure proper safeguarding and storage of investigational drugs. Our review indicated an immediate need to expand the storage capacity of IPS's Main Pharmacy to meet the current and future needs of clinical trials. Also, we noted a need to ensure employees' safety during the receiving and handling of investigational drugs. In addition, we identified opportunities to strengthen access controls over investigational drugs, and to improve maintenance and monitoring of cold storage units to ensure proper storage conditions.

Further details are outlined in the Detailed Observations section. Less significant issues were communicated to management.

Management Summary Response:

Management agrees with the observations and recommendations and has developed action plans to be implemented on or before 6/30/2025.

Appendix A outlines the objective, scope, and methodology for the engagement.

The courtesy and cooperation extended by the personnel in Investigational Pharmacy Services are sincerely appreciated.

Sherri Magnus

Sherri Magnus, CPA, CIA, CFE, CRMA, CHIAP
Vice President & Chief Audit Officer
March 1, 2023

[1] *Source: MD Anderson SharePoint- Investigational Pharmacy Services*

DETAILED OBSERVATIONS

1. Expand Storage Capacity for Investigational Drugs — HIGH

The Code of Federal Regulations and IPS Policy requires all investigational agents to be stored at appropriate temperatures and under appropriate conditions in accordance with requirements of manufacturer and/or sponsor recommendations.

The Main IPS Pharmacy's cold storage units are currently exceeding capacity, and investigational drugs are not stored in ideal conditions. For example:

- The cold storage units containing the investigational drugs are stacked in such a way that limit appropriate airflow, increasing the risk of unit failure and drug loss.

- No backup is available for the two specialized freezers (sub-70-degree) containing sensitive and patient customized medications. Therefore, any freezer failure may cause a loss of medications that could lead to significant impact on patients' safety, institutional reputation, and financial loss.

In addition, the department recently conducted a capacity analysis of the Main IPS Pharmacy. As shown in the table below, the results indicated a need to expand the current storage capacity to cope with the rapid increase in clinical trials and ensure sustainability of operations.

	Current			Future 5 years	
Storage Condition	**Capacity**	**Inventory need**	**Difference**	**Inventory need**	**Difference**
Room Temperature	736 Protocols	658 Protocols	78	1,468 Protocols	(732)
Cold Temperature	504 Protocols	577 Protocols	(73)	1,387 Protocols	(883)

Also, the Environmental Health & Safety, Sustainability and Emergency Management (EHSSEM) completed a risk assessment for IPS Main Pharmacy on December 2019 and their report raised a concern about the limited operating space in the pharmacy.

MD Anderson's strategy is to accelerate and expand clinical trials which could increase the inventory of investigational drugs. Therefore, it is essential for IPS to have adequate capacity to store additional investigational drugs in order to provide the support needed to help the institution in executing this strategy.

Recommendation

The Division of Pharmacy should coordinate with Financial Planning and Analysis to develop and implement a plan which aligns with the institutional strategy to support clinical trials. The plan should meet current and future needs and ensure medications are properly stored according to manufacturer requirements.

Management Action Plan

Responsible Executive: Rosanna Morris
Division/Department Executive: Ryan Roux
Owner: Sapna Amin
Due Date: June 30, 2025

A. *Investigational Pharmacy interim space expansion is part of Institutional FAR 180617. This FAR has dependencies on adjacent spaces being vacated (FAR222255). It is estimated from Facilities/Project Management that construction is slated for 5/15/2024 and tentative completion of 06/30/2025. For Future, as part of the Master Facility plan, we will relocate and seek appropriate sizing in the new space/facility planned for ACB 2/3 Space planning is underway and aligns with institutional strategy for support and growth of clinical trials.*

B. *Refrigerators and Freezers: Interim Cold storage expansion was done (02/17/23) with the purchase of new refrigerators. At this time, while this will not meet the full needs of the current and planned research volumes, it will help with current decompression. Future space expansion will be part of the Facilities master planning.*

2. Maintain and Monitor Cold Storage Units — HIGH

Preventive maintenance and regular monitoring are not occurring for cold storage units in the Main IPS Pharmacy. In the last few months, IPS had several cold storage unit failures. We confirmed that Facilities Services discontinue scheduled maintenance checks of cold storage units. A refrigerator malfunction in October 2022, caused medications related to nine protocols were determined unusable, thereby potentially delaying patients' treatment. IPS estimated a total loss of $374,000 for these medications. The Division of Pharmacy Standard Operating Procedure states that a semi-annual 14-point inspection and maintenance check should be performed for cold storage.

In addition, we noted nine cold storage units in the Main Pharmacy auxiliary space on the 7th floor is not hard wired with Facilities Services for temperature monitoring. Per the Investigational Pharmacy Services Policy, all refrigerators and freezers maintained within MDACC for the storage of investigational inventory shall be monitored by AeroScout and Facilities Management. Proper monitoring and are essential to reduce the risk of equipment failure and loss of investigational drugs.

Recommendation

IPS should coordinate with Facilities Services to ensure semi-annual inspections are conducted for all cold storage units. Also, all storage unit temperatures should be monitored by AeroScout and Facilities Services.

Management Action Plan

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Owner: Sapna Amin
Due Date: August 31, 2023

A. *Facilities Management is working in conjunction with the pertinent contractor for a vendor quote and timeline. The Facilities team is working with the contractor for the Building Automated System (BAS) monitoring installation. It is expected that the BAS connection be done by Aug 31st, 2023.*

B. *Facilities Management was contacted and they confirmed they perform Semi-annual inspections. Facilities management also confirmed they keep the inspection records on file electronically and PM inspection documentation can be requested from their department.*

3. Ensure Employees' Safety During Receiving of Investigational Drugs — HIGH

The receipt of investigational drugs in the Main IPS Pharmacy create unnecessary safety risk for other pharmacy employees. The current practice is to receive investigational drugs in a shared space with 33 employees' workstations. The institution considers investigational drugs as high alert medications and should be treated with extra consideration. The National Institute for Occupational Safety and Health (NIOSH) considers cancer drugs as hazardous, and working with or near hazardous drugs in health care settings may cause serious adverse health effects in workers.

Recommendation

IPS management should coordinate with Environmental Health & Safety, Sustainability and Emergency Management (EHSSEM) to evaluate and implement mitigating measures during the receiving of investigational drugs to ensure employees' safety.

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The Division of Pharmacy has completed a Risk assessment associated with Hazardous drug handling across all areas (USP800 readiness). Currently, there is staff training and competencies, appropriate PPE and supplies, to further mitigate employee risks. We recognize this is not best practice and are actively seeking facility changes in the interim to advance safety and compliance. Investigational Pharmacy interim space expansion is part of Institutional FAR 180617 and FAR 222255. It is estimated from Facilities/Project Management that construction is slated for 5/15/2024 and tentative completion of 06/30/2025.

4. Strengthen Access Controls over Investigational Drugs — MEDIUM

Current security measures at the Main IPS Pharmacy are not sufficient to protect against theft and diversion. While the pharmacy has instituted badge access to the area, as well as several security cameras within the pharmacy. However, we noted a lack of security cameras over the cold storage units. Over 33 employees have access to the investigational drugs. Except for the controlled substances, none of the other drugs are kept in a locked cabinet.

The minimum requirements of Code of Federal Regulations for storage and handling drugs requires all facilities to be equipped with a security system that provides suitable protection against theft and diversion. Having security cameras could assist in monitoring and tracking access to investigational drugs, as well as reduce the risk of drug diversion.

Recommendation

IPS Management should consider adding security cameras over the cold storage units to strengthen the access and monitoring controls over investigational drugs.

Management Action Plan

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UTPD and Security Risk and Mitigation was contacted to initiate assessment. UTPD will facilitate a review and FAR will be done for installation. Currently, there are controls in place via physical audits, sponsor/monitor audits on the trial, and secured badge access to area.

Appendix A

Objective, Scope and Methodology:

The objective of the review is to ensure proper safeguarding and storage of investigational drugs for the period of November 2022 through the present, and related periods.

Our procedures included but not limited to the following:

- Interviewed key personnel to gain an understanding of business process related to investigational drugs.
- Reviewed relevant organizational and departmental policies to understand processes within the department.
- Reviewed a sample of documents related to monitoring and safeguarding of investigational drugs.
- Reviewed Best Practices and Guidelines published by industry specific organizations.
- Reviewed the department's internal analysis on storage needs.
- Conducted onsite walkthroughs in the Main Investigational Pharmacy, an Inpatient and Outpatient Pharmacy in the main campus, Sugar Land Houston Area Location (HAL), West Houston HAL, and The Woodlands HAL.

Our internal audit was conducted in accordance with the *International Standards for the Professional Practice of Internal Auditing*. The internal audit function at MD Anderson Cancer Center is independent per the *Generally Accepted Government Auditing Standards (GAGAS)* requirements for internal auditors.

Audit Team members: Ann Lovelady, Mahmod Mrad, Anthony Buancore. Leslie McDaniel

Number of Priority Findings to be monitored by UT System: *None*

A Priority Finding is defined as "*an issue identified by an internal audit that, if not addressed timely, could directly impact achievement of a strategic or important operational objective of a UT institution or the UT System as a whole.*"