Office of Internal Audit

UT Southwestern Medical Center

Clinical Trials Billing Audit

Internal Audit Report 18:02

October 12, 2018

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Executive Summary

Background

Clinical research is medical research that involves people who volunteer to participate in carefully conducted studies that ultimately uncover better ways to treat, prevent, diagnose, and understand human diseases. The UT Southwestern Medical Center (Medical Center) clinical research program supports the Medical Center mission to “promote health and a healthy society that enables achievement of full human potential,” via the Discover pillar “Research that solves for unmet needs by finding better treatments, cures, and prevention with a commitment to ensuring real-world application.” The Associate Dean of Clinical Research was appointed in the spring of this year with the responsibility to grow clinical research, increase collaboration with partner institutions and develop an infrastructure for ensuring clinical research administrative and billing processes are in compliance with policies, procedures and regulations.

Types of Clinical Research

Clinical Trials

In a clinical trial, participants receive specific interventions according to the research plan or protocol created by the investigators. These interventions might be medical products, such as drugs or devices; procedures; or changes to participants' behavior, such as diet. Clinical trials might compare a new medical approach to a standard one that is already available, a placebo that contains no active ingredients, or no intervention. Some clinical trials compare two or more interventions that are already available.

Observational Studies

In an observational study, investigators assess health outcomes in groups of participants according to a research plan or protocol. Participants might receive interventions (which can include medical products such as drugs or devices) or undergo procedures as part of their routine medical care, but participants are not assigned to specific interventions by the investigator (as in a clinical trial). For example, investigators might observe a group of older adults to learn more about the effects of different lifestyles on cardiac health.

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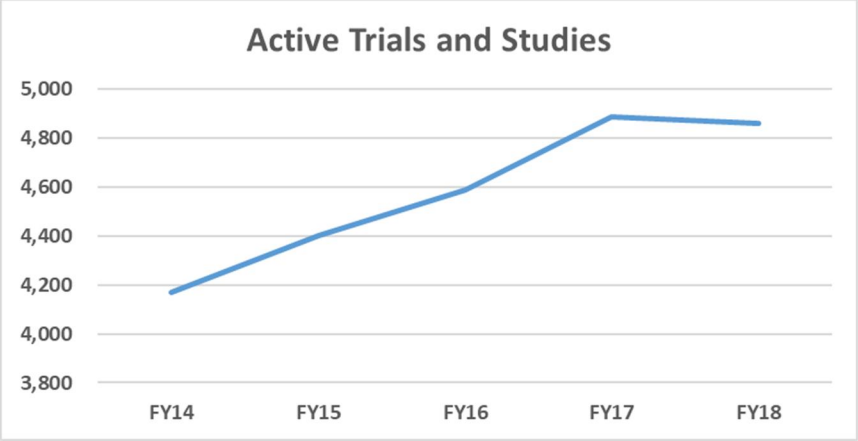
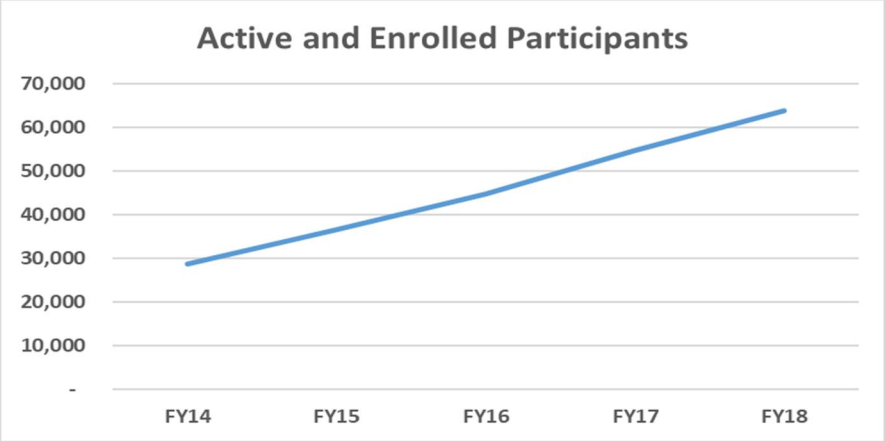


The graph above represents the number of all active trials and studies in operation during FY2014 through FY2018. The number of studies has steadily increased from 4,200 in FY2014 to 4,850 in FY2018.



The graph above represents the number of active and enrolled participants in research studies during FY2014 through FY2018. The number of active research participants in studies has increased from 30,000 in FY2014, reaching its highest of 64,000 active research participants in FY2018.

The following system applications are used to manage clinical research operations:

- **eIRB** – Contains documented approved clinical trial protocols. Researchers utilize smart forms and details relevant to the specific nature of research projects and develop and transmit protocols electronically to the Institutional Review Board (IRB) for review and approval.
- **Velos** – Is the primary system used for information on clinical research studies and subjects enrolled in the studies. When clinical studies are approved by the IRB, notification of approval is transmitted to Velos. When patients consent to participate in a study, they are registered with the study in Velos. A Velos to Epic interface flags the clinical trial participants in Epic and allows differentiation of research-related care from those provided as standard-of-care.
- **Epic** – Is the electronic medical record and billing system. Integration between the Velos and Epic systems allow users to perform tracking of studies for setup, approvals, flag study participants, and properly review and identify clinical research charges. The Epic scheduling (ADT) module allows patient visits to be manually flagged as research-related, which in turn allows segregation of charges into research vs, standard-of-care at UTSW facilities and physician services. Charges for research related physician services performed at Parkland

Memorial Hospital System, Children's Medical Center, and UTSW hospitals and outpatient facilities should be identified as research by UTSW Epic system which requires a research flag at the performing site.

Scope and Objectives

The Office of Internal Audit coordinated with the Office of Compliance to complete the Clinical Trials Billing audit. This is a risk based audit and part of the fiscal year 2018 Audit Plan. Audit procedures included interviews with stakeholders, review of policies and procedures and other documentation, substantive testing, and data analytics. The audit scope included research activities during the period of September 1, 2017 to July 31, 2018. Overall objectives for the review include assessing the effectiveness and efficiency of operations and programs over the internal controls that ensure achievement of objectives, compliance with key regulations and institutional policies and procedures, safeguarding of assets, and accuracy of reporting.

Specifically, the objectives are assessing the key controls in place for the following:

Office of Internal Audit:

- Accurate charge capture and segregation of charges for clinical research accounts.
- Accurate billing and invoicing to sponsors.
- Evaluation of work queues utilized to manage clinical research related charges.

We conducted our examination according to guidelines set forth by the Institute of Internal Auditors' International Standards for the Professional Practice of Internal Auditing.

Office of Compliance:

- Coverage analysis adherence based on the established protocol.
- Accurate and timely scheduling of clinical research patients based on study enrollment.
- Accurate billing and invoicing.

Results will be provided separately to management.

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Conclusion

Although the newly created position, Associate Dean of Clinical Research, was filled earlier this year and progress has been made towards creating a comprehensive clinical research infrastructure, the Associate Dean will need the cooperation and commitment of all key stakeholders (Principal Investigators, Research Coordinators, Information Resources, Sponsored Programs Administration, Department and Revenue Cycle management). These stakeholders will need to assist the Associate Dean in creating a governance committee to develop policies and procedures, clarify roles and responsibilities and establish proper tracking and monitoring of clinical trial activities to ensure accuracy of clinical research billing and compliance with policies and regulations. Administrative clinical trial processes related to research billing are at present decentralized across the Medical Center, which increases risk of billing inaccuracies.

Billing accuracy is dependent on the proper setup of the clinical trials, identification of research patients and the research related procedures at time of service, and the proper review of charges by clinical departments. The revenue cycle should function efficiently to bill charges appropriately as either routine e.g. standard of care or research. Current UTSW system tools lack the functionality needed to improve research billing accuracy. The greatest and immediate opportunities relate to implementation of automated tools currently available in Velos and Epic that are not currently being utilized. This would reduce manual intervention for review of charges along with billing errors and delays. Along with system enhancements, training, updated policies and procedures should be in place with ongoing monitoring to ensure appropriate practices are followed.

Included in the table below is a summary of the observations and risk levels. See Appendix A for Risk Rating Classifications and Definitions.

Priority (0)	High (2)	Medium (3)	Low (0)	Total (5)

The key improvement opportunities risk-ranked as high and medium are summarized below.

- **#1 Implement Policies and Develop Standard Operating Procedures To Achieve Accurate Clinical Research Charge Capture And Segregation Efforts -** Policies and standard operating procedures need to be developed or updated in the immediate future to ensure consistent, complete and compliant clinical research billing activities followed by ongoing monitoring of key risk areas.

- **#2 Enhance System Capabilities to Improve Clinical Research Processes Impacting Billing Accuracy –** There are automated tools currently available in Velos and Epic that have not been implemented for tracking clinical visits and segregating charges. Manual review of research related charges increases risks of inaccurate and untimely invoicing and billing.

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- **#3 Assign Accountability and Implement Monitoring Of Research Billing Related Activities -** Professional study billing accounts are not centrally monitored and each department is responsible for billing and collecting from payors. Untimely monitoring of accounts receivables results in account write offs and loss of collections. Adjustments to study guarantor accounts reduce cash flow to fund further clinical research projects.

- **#4 Clearly Define Roles and Responsibilities for Clinical Research Staff and Principal Investigators** - Clinical trials roles and responsibilities have not been clearly defined and job descriptions do not define key job requirements. Without clearly defined roles and responsibilities, clinical trial billing activities can be inaccurate or errors may not be identified in a timely manner.

- **#5 Review and Assign Accountability for Clinical Research Work Queue and Establish Monitoring Processes -** Work queues may be assigned to individuals lacking training or access to appropriate documentation such as the Clinical Trial Coverage Analysis (CTCA). Some work queues lack ownership and there is limited monitoring of unbilled charges within the work queues resulting in lost revenue.

Management has plans to address the issues identified in the report and in some cases have already implemented corrective actions. These responses, along with additional details for the key improvement opportunities listed above and other lower risk observations are listed in the Detailed Observations and Action Plans Matrix (Matrix) section of this report.

We would like to take the opportunity to thank the departments and individuals included in this audit for the courtesies extended to us and for their cooperation during our review.

Sincerely,

Valla F. Wilson, Associate Vice President for Internal Audit, Chief Audit Executive

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Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
Risk Rating: High **1. Implement Policies and Develop Standard Operating Procedures To Achieve Accurate Clinical Research Charge Capture And Segregation Efforts** Many of the existing policies and procedures governing clinical research activities are outdated and do not reflect recent regulatory requirements. Additional policies need to be developed. Key requirements should be clear so that practices are performed consistently to ensure complete and compliant clinical research activities. Monitoring activities are not reflected in current procedures to ensure adequate internal controls for completeness of clinical trials activities and clinical research billing accuracy. With the current decentralized state of clinical trial processes, the need for a strong central governance structure is critical to monitor compliance with the standard operating procedures.	1. Create a governance committee to guide policy development and define monitoring activities to hold individuals accountable. 2. Expand current clinical research policies and procedures and identify specific policies and procedures to be created or updated. 3. Implement a comprehensive education and training program as it relates to clinical research. Establish training requirements to ensure appropriate clinical research system and process training is done for all those with clinical research responsibilities. 4. Develop monitoring processes for key risk areas to ensure compliance with policies and procedures and identify any additional training needs.	**Management Action Plans:** 1. A multi-disciplinary governance committee is being formed with the intent to set policy and ensure accountability. This Committee will assign subject matter experts to key work groups to set/revise policies and define monitoring activities to ensure expected actions are occurring as intended. 2. Utilizing key workgroups modify current /create clinical research policies and create standard operating procedures to guide day to day activities. 3. Establish a comprehensive education program, define training requirements and monitor completion of training. On an annual basis, ensure refresher training is provided and completed. 4. Utilizing the key workgroups, develop monitoring processes to ensure compliance with policies and procedures. **Action Plan Owners:** Associate Dean, Clinical Research Associate Vice President, Revenue Cycle Operations Vice Provost and Senior Associate Dean for Education, Academic Administration

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
		Target Completion Dates: 1. November 30, 2018 2. February 28, 2019 3. February 28, 2019 4. March 31, 2019

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
Risk Rating: High **2. Enhance System Capabilities to Improve Clinical Research Administrative and Billing Accuracy** System enhancements to Velos and Epic are essential for capturing clinical trials data accurately and reducing manual processes, thereby reducing risk of errors and omissions. Changes in Velos are needed to increase flagging and critical data transmission to Epic. Key system enhancements in Epic would ensure proper identification and flagging of clinical trial services, while decreasing the number of charges that would need to be manually reviewed, decreasing the risk of charges being inaccurately billed to sponsors or payors. The following are automated system tools are not currently in place: · Study calendar in Epic to ensure professional visits related to clinical research are flagged at the time of scheduling to ensure charges are appropriately classified as research and not incorrectly billed to the patient's payor as standard of care. · Velos is not consistently used to identify studies with performance site approvals and lacks controls to prevent patients from being enrolled in studies prior to approval on Velos.	1. Implement available system enhancements for Velos and Epic. As possible, system enhancements should be implemented immediately. 2. Update Velos study and clinical trial patient data system rules to ensure data required for clinical trials billing is accurate and complete when sent to Epic. Velos should be enhanced to include system functionalities that are currently not available. 3. Ensure eIRB and Epic interfaces identified in the system enhancement plan are implemented and complete transmission of data is complete and accurate. 4. Assign accountability for ensuring all system enhancements are implemented and tested to document improvement in clinical trial research billing processes and that billing errors have been reduced.	**Management Action Plans:** 1. In coordination with AIS, define system enhancement requirements and priorities for implementation. 2. Update Velos to currently available version and monitor implementation of system enhancements defined in plan above. Continue to evaluate feasibility of moving to new CTMS to further improve functionality. 3. Implement eIRB and Epic interfaces as defined in the system enhancement plan, including data validation testing to verify data integrity. 4. In coordination with AIS and IR leadership, define accountable resources for performing validation testing and implementing system enhancements. **Action Plan Owners:** Associate Dean, Clinical Research Assistant Vice President, Academic Information Systems Assistant Vice President and Chief Information Officer, University Hospitals Vice Provost and Senior Associate Dean for Education, Academic Administration Director Electronic Medical Records, Academic and Research

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
· A validation rule is not in place in Velos to ensure a patient's medical record number (MRN) matches the MRN in Epic to ensure that the Epic flag is placed on the correct patient's MRN. · There are no rules in Velos to prompt registration with key regulatory agencies and ensure this information is interfaced to Epic to facilitate accurate and timely billing.		**Target Completion Dates:** 1. November 30, 2018 2. December 31, 2018, with additional completion dates as defined in the system implementation plan 3. February 28, 2019 4. November 30, 2018

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
Risk Rating: Medium **3. Assign Accountability and Implement Monitoring Of Research Billing Related Activities** Study guarantor accounts contain aged amounts that have not been collected. As of August 31, 2018, total study related accounts receivable was $2M, with $1M greater than 120 days old. Inadequate monitoring of accounts receivables results in account write offs and delayed collections. In the current decentralized state, each department is responsible for billing and collecting amounts from other departments or sponsors and disagreements over amounts billed are not resolved in a timely manner. Aged items in study account accounts receivable are primarily due to: · disagreements of billing amounts between departments · budget to actual variances where professional charges may have not been budgeted.	1. Coordinate centralized billing responsibilities for clinical services performed under clinical trials. 2. Centralize invoicing to department and sponsors, combining research hospital and professional charges on to a single Epic bill. 3. Establish requirements for account adjustments, supporting documentation and required approval thresholds. 4. Assign accountability for monitoring of sponsor and department billing processes and transactions to ensure accurate and timely billing and appropriate account transactions. 5. Expand training on coverage analysis budgeting for research team members and PIs. 6. Provide training to the department chairs, including updates on responsibility for monitoring key activities within academic departments.	**Management Action Plans:** 1. Revenue Cycle and SPA leadership will develop a coordinated centralized billing plan with defined responsibilities for clinical trials billing to sponsors. 2. Coordinated centralized invoicing will be included in the plan referenced in action plan #1 above. 3. Define requirements for account adjustments for study guarantor accounts. 4. Develop schedule for reporting overdue accounts receivables and any adjustments posted to study guarantor accounts to the governance committee. 5. SPA training team to coordinate training on coverage analysis basics as well as recurring issues to all research team members. 6. Provide clinical trials program update for the department chairs describing the governance updates and highlighting their role in reinforcing these requirements at a department level.

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
		Action Plan Owners: Vice President and Chief Operating Officer, Office of Academic Affairs Associate Dean, Clinical Research Associate Vice President, Revenue Cycle Operations Assistant Vice President, Sponsored Programs Administration Financial Analysis Manager, Academic and Research **Target Completion Dates:** 1. December 31, 2018 2. December 31, 2018 3. December 31, 2018 4. December 31, 2018 5. March 31, 2019 6. March 31, 2019

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
Risk Rating: Medium **4. Clearly Define Roles and Responsibilities for Clinical Research Staff and Principal Investigators** Clinical trials roles and responsibilities are not clearly defined and job descriptions do not adequately define key requirements as they relate to research billing. In addition, requirements for clinical research training are not defined and are not monitored to ensure completion. Without clearly defined roles and responsibilities, clinical trial billing activities can be inaccurate or errors may not be identified in a timely manner. The following are examples of conflicting or missing responsibilities: · In some cases, the Clinical Research Coordinator have conflicting duties (i.e. inadequate segregation of duties) such as responsibilities for billing and also collecting amounts from sponsors. · Reconciliations of clinical research visits to approved study coverage analysis are not routinely performed to monitor accuracy of billing.	1. Update clinical research policies and standard operating procedures to define key roles and responsibilities for clinical research staff to ensure clarity and understanding of clinical research billing processes. 2. Develop monitoring processes for key risk areas to ensure compliance with research billing policies and procedures and identify any additional training needs. 3. Ensure Velos and Epic system access is aligned with defined roles and responsibilities. 4. Monitor status of clinical research training requirements for Principal Investigators and research team members.	**Management Action Plans:** 1. Standard operating procedures will be updated/developed to provide clarity in roles and responsibilities to include training requirements to improve understanding of the clinical research billing processes. 2. Key monitoring steps will be defined and responsible parties assigned. The results of the monitoring procedures will be shared with the work groups and governance committee along with action steps as needed to include training, process improvement, etc. 3. Define standardized Epic and Velos system access for Research Coordinators and research team members and update Epic and Velos access based on this standard. 4. A training plan will be developed for research team members and completion of training will be tracked and reported to the appropriate workgroup. **Action Plan Owners:** Associate Dean, Clinical Research Vice President & Chief Operating Officer, Academic Affairs Assistant Vice President, Sponsored Programs Administration

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
		Target Completion Dates: 1. December 31, 2018 2. March 31, 2019 3. January 31, 2019 4. February 28, 2019

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
Risk Rating: Medium **5. Review and Assign Accountability for Clinical Research Work Queue and Establish Monitoring Processes** Charges for services provided to research patients are transmitted to various work queues that are assigned to various parties in departments. Some work queues are assigned to persons lacking access to appropriate documentation to appropriately address charges in work queues and there is no centralized monitoring of work queues to ensure the charges are appropriately and timely addressed. In addition, there is a work queue referred to as the "Catch All" work queue, which contains $252K in charges greater than 60 days old for 425 patients, and is assigned to a resource in Information Resources. Persons in IR do not have clinical research knowledge or access to the coverage analysis to make appropriate determination of the charges. Aged charges are in this work queue because there is no one accountable for making sure the charges are reviewed and resolved in a timely manner. Without the appropriate persons assigned to perform work queue reviews results in risk of inaccurate and untimely billing.	1. Develop resource plan to ensure timely review of items in work queues while maximizing existing resources. 2. Determine and assign responsible party for each of the work queues. Responsible parties should have clinical research knowledge and have received training. 3. Create work queue metrics for performance expectations to ensure complete and timely review of charges in the work queues. 4. Determine appropriate reporting and monitoring responsibilities for ensuring work queues are managed appropriately.	**Management Action Plans:** 1. Revenue Cycle and SPA leadership to define resource needs for review of items in clinical research work queues, ensuring the proper individuals are assigned work queues and accountability is established. 2. Revenue Cycle leadership in coordination with SPA will provide recommendation to the governance committee on responsible parties for the clinical research related work queues, including the Catch All work queue. Ownership will be transferred based on approval of recommendation. 3. Monitoring of these work queues will be included in the overall monitoring procedures. 4. Reporting of work queue performance will be included in reporting of overall monitoring efforts. **Action Plan Owners:** Associate Vice President, Revenue Cycle Operations Vice President & Chief Operating Officer, Office of Academic Affairs Assistant Vice President, Sponsored Programs Administration

Detailed Observations and Action Plans Matrix

Observation	Recommendation	Management Response
		Target Completion Dates: 1. December 31, 2018 2. February 28, 2019 3. March 31, 2019 4. March 31, 2019

Appendix A – Risk Classifications and Definitions

As you review each observation within the Detailed Observations and Action Plans Matrix of this report, please note that we have included a color-coded depiction as to the perceived degree of risk represented by each of the observations identified during our review. The following chart is intended to provide information with respect to the applicable definitions and terms utilized as part of our risk ranking process:

	Degree of Risk and Priority of Action	
Risk Definition- The degree of risk that exists based upon the identified deficiency combined with the subsequent priority of action to be undertaken by management.	**Priority**	An issue identified by Internal Audit that, if not addressed immediately, has a high probability to directly impact achievement of a strategic or important operational objective of a UT institution or the UT System as a whole.
	High	A finding identified by Internal Audit that is considered to have a high probability of adverse effects to the UT institution either as a whole or to a significant college/school/unit level. As such, immediate action is required by management in order to address the noted concern and reduce risks to the organization.
	Medium	A finding identified by Internal Audit that is considered to have a medium probability of adverse effects to the UT institution either as a whole or to a college/school/unit level. As such, action is needed by management in order to address the noted concern and reduce the risk to a more desirable level.
	Low	A finding identified by Internal Audit that is considered to have minimal probability of adverse effects to the UT institution either as a whole or to a college/school/unit level. As such, action should be taken by management to address the noted concern and reduce risks to the organization.

It is important to note that considerable professional judgment is required in determining the overall ratings presented on the subsequent pages of this report. Accordingly, others could evaluate the results differently and draw different conclusions. It is also important to note that this report provides management with information about the condition of risks and internal controls at one point in time. Future changes in environmental factors and actions by personnel may significantly and adversely impact these risks and controls in ways that this report did not and cannot anticipate.