ABSTRACT: 2017 ELAM Institutional Action Project Symposium

Project Title: Expansion of a clinical trials management system: Uniting the University of Virginia School of Medicine mission, vision and values to improve clinical research

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Collaborators and Mentors: Mentors: David Wilkes MD and Margaret Shupnik PhD
Collaborators: Lori Elder RN, Catherine Reniere MA, James Harrison MD PhD, BD Kim

Background, Significance of project: A clinical trials management system (CTMS) is fundamentally a database used to maintain and manage clinical trials with respect to planning, performing and reporting functions. For the Dean’s office at the University of Virginia School of Medicine (UVA SOM), the CTMS is used to create accurate reports regarding the state of clinical research efficiently throughout the enterprise, allowing both an in-moment view of the state of clinical research across different research groups as well as appropriate resource allocation.

Currently, each clinical research group tracks research data individually and via differing methodology, with no centralized system to measure productivity at the enterprise level. Implementing an institution-wide CTMS will allow improved clinical operations decision-making, resulting in more efficient trial planning and milestone tracking via executive management dashboards and metrics reporting. Investigators will also benefit, as clinical research groups will be invited to take advantage of the CTMS, using such functionalities as: tracking subjects, tracking data entry, managing monitor visits, and facilitating invoicing and payments, among other functions.

Purpose/Objectives: The primary purpose of this project is to implement an institution-wide CTMS.

Methods/Approach:
• Poll similar institutions regarding: CTMS system used, enterprise expansion strategies, budget, personnel, and resource requirements (√July16)
• Create core group to complete justification, design time-line, and build preliminary budget (√July16)
• Present project to Dean’s cabinet for design and budget approval (√Aug16)
• Work with University procurement office to negotiate and sign contract (√signed Jan17)
• Create steering committee (√Jan17)
• Hire project manager, and begin hiring project personnel (√Jan17 and ongoing)
• Kick-off meeting (√Mar17)
• Begin roll-out with most interested research groups
• Complete roll-out with GO LIVE in 2019. Continue ongoing support of system after GO LIVE.

Outcome and Evaluation Strategy:
The overall outcome is successful implementation of the CTMS, measured by successful GO LIVE with all teams. Evaluation strategies will include measures of:
• Compliance with data entry (minimal requirements)
• Data integrity, queried via internal audit
• Researcher satisfaction, measured by survey of investigators and staff regarding implementation process and the system itself
• Accrual per protocol per month
• Ability to allocate resources, measured via dollars per patient accrued, numbers of publications, and group research portfolios

Conclusion with Statement of impact/potential impact:
Within one year of GO LIVE, the impact on UVA SOM clinical research will be: successful tracking of research productivity; appropriate and effective allocation of resources; improved utilization and efficiency of research infrastructure; improved enrollment in clinical research; increased publication of clinical research studies in high impact journals; and ultimately the successful application for a Clinical and Translational Science Award (CTSA).
Expansion of a Clinical Trials Management System: Uniting the University of Virginia School of Medicine in Mission, Vision and Values to Improve Clinical Research

Linda Duska, MD, MPH

Collaborators: Lori Elder RN, Catherine Reniere MA, James Harrison MD PhD, BD Kim

Mentors: David Wilkes MD and Margaret Shupnik PhD

Present state:
Clinical research groups track research data individually, with differing methodology. There is no centralized system to measure productivity at the enterprise level. This situation leads to inconsistent reporting and out of date information.

A clinical trials management system (CTMS) is fundamentally a database used to maintain and manage clinical trials with respect to planning, performing and reporting functions.

**Background**

- **Survey** other institutions re: CTMS system used, enterprise expansion strategies, budget, personnel, and resource requirements
- **Create** core group to complete justification, design time-line, and budget
- **Present** project to Dean’s cabinet for approval
- **Negotiate** and sign contract with University procurement
- **Create** steering committee
- **Hire** project manager
- **Kick-off** meeting
- **Begin** roll-out with most interested groups
- **Complete** roll-out with GO LIVE in 2019
- **Continue** ongoing support

**Methods/Approach**

- Survey other institutions re: CTMS system used, enterprise expansion strategies, budget, personnel, and resource requirements
- Create core group to complete justification, design time-line, and budget
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- Kick-off meeting
- Begin roll-out with most interested groups
- Complete roll-out with GO LIVE in 2019
- Continue ongoing support

**Outcomes/Evaluation**

Successful implementation of the CTMS will be measured by successful GO LIVE with all teams.
Evaluation will include measures of:
- Compliance with data entry
- Data integrity
- Researcher satisfaction, measured by survey of investigators and staff
- Accrual per protocol per month
- Ability to allocate resources, measured via dollars per patient accrued, numbers of publications, and group research portfolios

**Conclusions**

Within one year of GO LIVE, the impact on UVA SOM clinical research will be:
- Successful tracking of research productivity
- Appropriate and effective allocation of resources
- Improved utilization and efficiency of research infrastructure
- Improved enrollment in clinical research
- Increased publication of clinical research studies in high impact journals

**Ultimatley the successful application for a Clinical and Translational Science Award (CTSA)**

**Objective**

- To implement an enterprise-wide CTMS

**Future state:**
- **Real-time**, accurate reports regarding state of clinical research efficiency throughout the enterprise, allowing appropriate resource allocation
- Improved clinical operations decision-making, resulting in more efficient trial planning and milestone tracking
- Customer (investigator) satisfaction with CTMS functionality

Presented at the 2017 ELAM® Leaders Forum