ABSTRACT: 2019 ELAM Institutional Action Project

Project Title: The Utah Clinical and Translational Science Institute (CTSI)

Name and Institution: Rachel Hess, MD, MS; University of Utah

Collaborators and Mentors: CTSI working group includes: Susan Kranz (Administration), Maureen Murtaugh (Education), Julio Facelli (Informatics), Matt Rondina (Precision Medicine), Louisa Stark (Community Engagement), and Lauren Budinger (Governance); Clinical Research working group includes Mike Dean (Associate Dean for Clinical Research) and Erin Rothwell (AVPR Compliance); and Senior University Administration including: Willard Dere (CCTS co-Director and AVPR HS), Andy Wyrich (VPR), and Michael Good (SVP HS).

Topic Category: Research

Background, Significance of project: The University of Utah clinical and translational infrastructure lags behind the basic science infrastructure, is decentralized, and lacks core facilities to support clinical and translational science including data acquisition and management; clinical trials management support for contracting, billing, and monitoring; and transition of researchers from mentored to independent funding. This project will move the Utah Center for Clinical and Translational Science from an organization formed for and around a grant to one that is integral to the research mission of the University of Utah, the State of Utah, and the Intermountain Region.

Purpose/Objectives: To establish the Utah Clinical and Translational Science Institute—a hub for T0 to T5 translational science, including robust data, training, and clinical trials infrastructure embedded within our Intermountain West community and partners.

Methods/Approach/Evaluation Strategy: We have taken a multi-pronged approach to the Utah CTSI. We have convened working groups to (1) develop the institute's structure and governance, (2) improve clinical research infrastructure, and (3) review our recharge model. Each working group meets regularly and has engaged in landscape reviews of the structures and processes at other institutions. We are using this information to apply best practices in our development. Future evaluation will include successful establishment of institute, user satisfaction, increased funding, and sustainable infrastructure.

Outcomes/Results:

- (1) CTSI work group: 60% of all CTSAs are University-recognized Institutes. We are meeting with Departmental and Divisional leadership to socialize the institute and preparing documents to go through the University governance process. We have established K-to-R groups to improve transition to independence among junior faculty
- (2) Clinical Research working group: We are moving forward with unifying the current infrastructure balkanized within departments to the planned CTSI. We are working through budget implications and finalizing decisions regarding clinical trials management software and infrastructure such as Epic Research.
- (3) Recharge models: Our experience with recharge centers has exposed places that it works well (funded grants) and places that it does not (preparatory to research). We are working on budget stability with University leadership.

Discussion/Conclusion with Statement of Impact/Potential Impact: The Utah CTSI is on a path of development that will ensure that clinical and translational science is financially and institutionally sustainable in order to support high quality science that impacts the health of populations and increases the reputation of the institution. These efforts are already being recognized with increased presence on external advisory boards and membership on the CTSA national steering committee.

Utah Clinical and Translational Science Institute (CTSI)

Rachel Hess, MD, MS Associate Dean for Clinical & Translational Science, Chief, Division of Health System Innovation & Research

Collaborators: CTSI working group (Susan Krantz, Maureen Murtaugh, Julio Facelli, Louisa Stark, Lauren Budinger); Clinical Research Committee (Michael Dean, Erin Rothwell); Vice President for Research (Andy Wyrich); Senior Vice President for Health Science Office (Michael Good, Will Dere)

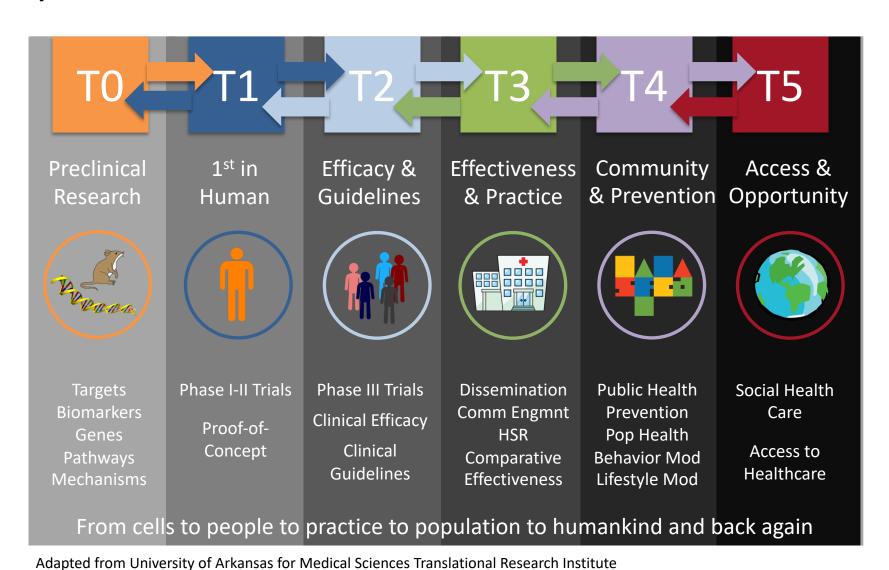
Background & Significance

Univ. of Utah clinical & translational infrastructure lags behind bench science infrastructure, is decentralized, and lacks key core facilities.

With the transition to an institute, the Utah CTSI will move from an organization formed from and around one grant to an integral part of the research mission of the University, State, and Region

Purpose/ Objective

The Utah Clinical and Translational Science Institute (CTSI)will be a hub for T0 to T5 translational science



It will provide robust infrastructure to support

- Data acquisition and management
- Clinical research support including contracting, billing, and monitoring
- Transition of researchers from mentored to independent funding

The CTSI will be embedded within our University, the State of Utah, our Intermountain West community and our regional partners

Methods/ Approach/ Evaluation Strategy

We formed work groups to

- (1) Develop the CTSI structure and governance
- (2) Improve clinical research infrastructure
- (3) Review recharge models

Each group conducted landscape review of the structures and process at other institutions, which provided data to apply best practices

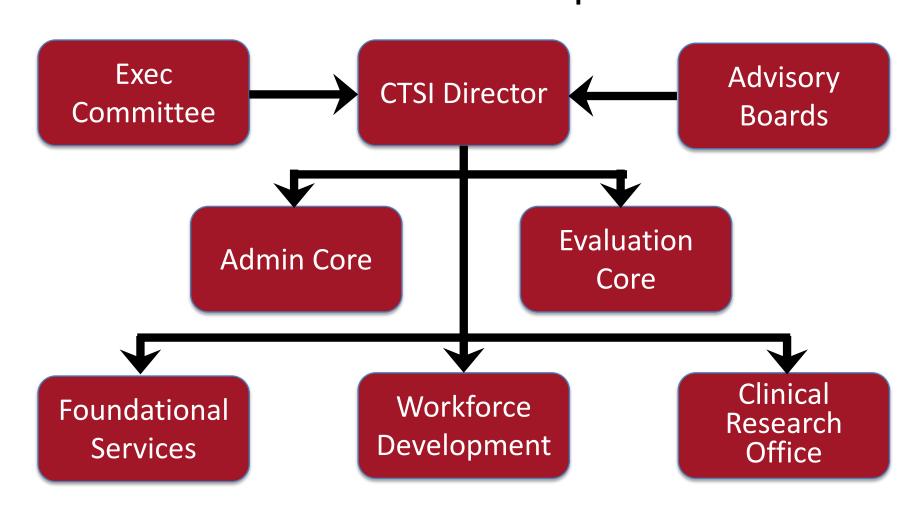
Future evaluation will continue to include

- User satisfaction
- Funding
- Sustainability of infrastructure

Outcomes/ Results

CTSI work group

- 60% of CTSAs are University-recognized Institutes
- Socialized CTSI with Univ. faculty & leadership
- Governance and membership model finalized



K-to-R groups established; implementing and disseminating best practices

Clinical Research work group

- Central clinical trials office will be part of CTSI
 - Budget negotiation
 - Site monitoring
 - Research coordinator community
 - CTMS
 - Research integration into EHR
 - Participant payment infrastructure
 - Electronic data capture

Recharge models

- Work well for funded research
- Not sustainable for unfunded projects, e.g.,
 - Preparatory to research
 - Trainee projects
- Subsidies will always be necessary
 - Ensuring equity is essential

Statement of Impact

The Utah CTSI is on a path that will ensure that clinical and translational science is financially and institutionally sustainable and supports high quality science that impacts the health of populations and increases the reputation of the institution

Next Steps

- Institutionalize collaborations with other Utah Universities
- Finalize documents for governance
- Finalize financial support model



