Utah CTSI: The Road Forward
Agenda

- CTSI Overview and CCTS Successes to Date
- Need for a CTSI at the University of Utah
- Planning Process to Date
The Utah CTSI

The mission of the Utah CTSI is to increase the efficiency and effectiveness of discoveries to improve human health.

The Utah CTSI provides infrastructure and intellectual collaboration for clinical and translational researchers. It supports and convenes members from across the Intermountain West to:

1. Conduct innovative research across the translational spectrum,
2. Develop and test new methods and processes for translational science,
3. Design and deliver innovative services to support the research community,
4. Train the next generation of clinical and translational investigators and workforce,
5. Increase the efficiency and effectiveness of researchers to support discoveries that improve human health, and
6. Support research that is effective, efficient, reproducible, and compliant.

The mechanisms for accomplishing these objectives are through the expertise provided by its Cores and Services, numerous Workforce Development initiatives, and the collective power and resources housed in a Clinical Research Support Office.
CTSI Components and Missions

Cores and Services

• Study Design and Analysis,
• Clinical Service Delivery,
• Community Collaboration and Engagement Team,
  • Research participant advocate**
• Biomedical Informatics,
• Precision Medicine,
• Community Practice Engagement, and
• Program Evaluation.

Mission: (1) To design, develop and disseminate novel methods to advance translational science & (2) To provide CTSI members with expertise and essential services for high-quality translational science.

Workforce Development

• KL2
• TLI
• Masters of Science in Clinical Investigation***
• Speed collaboration
• Pilot programs
• K-Club
• R01 writing groups
• Research professional community*
• What is…? Team Science for pre/post docs*
• VPCAT**

Mission: (1) To provide professional development to the University translational science community, (2) To develop, execute, and evaluate innovative programs that grow novel collaborations and target key points during the research career, & (3) To facilitate faculty, student, and staff success at key stages in their careers.

CRSO*

• Epic Research
• Oncore Clinical Trials Management
• Business Development
  • Matchmaking with PIs locally
  • Establishing new collaborations
• Navigation for clinical research processes
• Protocol development
• Convene to:
  • Develop research SOPs
  • Standardize budget rates
  • Support contract negotiation and billing
• Quality Assurance (Monitors/Compliance/FDA)**
  • Research ethics consultation
• IND/IDE Support
• Pre-Award Grant support

Mission: (1) Serve as the hub for clinical research at the University of Utah. (2) Provide the navigation, tools, and services to support clinical research across the translational spectrum.

*Start-up with CTSI
**Collaborative partner
***Through School of Medicine
Primary & Dependent Awards (Total Direct & Indirect Costs)
Operating Budget

- Current CCTS has an operating budget of approximately $8M
  - The CTSA Award is $3.7M annually
  - All CTSA Awards have a cost-sharing agreement with the awarded institution. The SVPHS commits $2.7M annually
  - Additional funding comes from gifts and tuition return from the MSCI
- Transitioning from a center grant to an Institute will make the Utah CTSI eligible for indirects on the grants submitted and housed under its ORG, giving further stability and ensuring sustainability.
Cores and Services Utilization
CCTS Pilot Successes

• 47 pilots awarded between 2012 – 2019
  • Total funds spent: $1,385,000 (~$30,000/pilot)
• 17 pilots with $19,172,884 in subsequent funding
  • Overall ROI of 1,284%
• 71 publications
Membership

The Utah CTSI will have 3 types of affiliations

• Members
  o Individuals with faculty appointments at the U of U (including adjunct appointments)

• Associate Members
  o Faculty from the U, other Institutions or Community Members

• Student Members
  o Undergraduate and Graduate Students and Postgraduate Trainees
Need for an Institute
The creation of the University of Utah CTSI increases national visibility and brings the University of Utah on par with its PAC 12 peers and national peers.

**AAU**

- Of the 61 peer domestic institutions in the AAU, 51 have CTSA Awards or are affiliated with a collaborative CTSA. The University of Utah CCTS is one of 4/51 AAU peer institutions that are not designated institutes on their campuses.

**PAC 12**

- Of the funded CTSAs in the PAC 12, University of Utah’s CTSA award is the only one without a formal institute structure.

**PUBLIC UNIVERSITIES**

- 79% of the public universities ahead of our campus in BRIMR rankings have formal institutes for their CTSA awards.
## Presidential Priorities

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<th>Develop and transfer new knowledge</th>
<th>CTSI</th>
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<td>Transformative Excellence Program: Recruit clusters of high achieving faculty in target areas of strength and societal relevance to ensure vibrant future</td>
<td>Increased speed of discovery to implementation in health care and community</td>
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<td>Increase diversity of faculty, including women in science and engineering</td>
<td>Research reproducibility</td>
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<td>Enhance graduate program quality and student support to enable recruitment and education of top talent</td>
<td>Convening for collaboration—supports the mission and sentiment of TEP</td>
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<td>Build program quality in key areas</td>
<td>Standard programing for pre and post-docs so T-Leads can focus on science</td>
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<tr>
<th>Promote student, staff, and faculty success to transform lives</th>
<th>KL2 applicants from across Utah—University for Utah</th>
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<td>Expand scholarship opportunities and strategically align scholarships with access, achievement, and completion goals</td>
<td>Opportunities for faculty, students, and staff to promote retention of faculty past the start-up phase—pilots, training, etc.</td>
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<td>Deploy data analytics and retention reporting systems to facilitate improvement in student support and services</td>
<td>Research ethics</td>
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<td>Extend UOnline to increase access to U programs and promote completion</td>
<td>Pilot funding leads to larger programs of University—PRISM, Kai</td>
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<td>Increase participation in high impact programs (deeply engaged learning opportunities)</td>
<td>Support productivity and success of junior faculty—K club, K-to-R writing groups, medical writing, graphics</td>
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<td>Enrich and expand learning communities to include honors, transfer, sophomore, and living and learning communities</td>
<td>Community of research professionals—support staff, decrease turnover, save money</td>
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<th>Engage communities to improve health and quality of life</th>
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<td>Provide transformative and innovative health care</td>
<td>Develop training to introduce communities to research to speed dissemination</td>
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<td>Enable exceptional quality patient care</td>
<td>Online/ distance curriculum</td>
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<td>Expand outreach and engagement to shape and improve the U</td>
<td>Access to clinical trials for rare diseases by increasing opportunities</td>
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<td>Engage communities in broad range of campus offerings, from arts to athletics to lifelong learning opportunities</td>
<td>Professionalism of research staff interactions with patients and community leading to improved patient satisfaction</td>
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<td>Increase access to the U through online offerings</td>
<td>Integration of research into clinical practice (e.g., through Epic, MyChart)</td>
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<td>Partner with communities to meet critical needs and enhance access to the U</td>
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<th>Ensure long-term viability of the university</th>
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<td>Improve campus infrastructure to support core operations</td>
<td>PRISM project</td>
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<td>Promote efficiency in all aspects of university operations</td>
<td>Kai Yandell project</td>
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<td>Reduce impact of the U on the environment</td>
<td>Leveraging extramural funding potential through institute designation:</td>
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<td>Ensure effective communication with stakeholders and build support for university initiative with legislative, corporate, and private partners</td>
<td>- Increase respect and opportunity, align with PAC-12</td>
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<td>Achieve an appropriate balance among affordability, access, and quality across the institution</td>
<td>Engage community members as leaders of research</td>
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<td>Engage in continuous improvement practices across the university</td>
<td>Consistent contracting</td>
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<td>Uniform representation of University in clinical trials</td>
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<td>Increased revenue from clinical trials</td>
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<td>Compliance around Medicare billing, IRB, and IRS</td>
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We Support the University

- Research Training
  - KL2
  - TL1
  - MSCI
  - NSF and NIH Grant Writing Workshops
- Research Infrastructure
  - RedCap users
  - CHPC
  - Joint hire with Philosophy and VPR for Ethics Training, etc
  - Research participant advocacy group
    - Translation and Interpretation
  - SDBC
Appropriate Growth Trajectory

- Part of the Health Sciences Strategic plan for 2020
- Increases Institutional, Philanthropic, and National visibility
- Perfect score on last renewal, NCATS will be looking for innovation, growth and commitment
- We have met our aims and are laying the foundation for our next phase
CTSI Planning Process

2019
- Occurred continuously through 2019
- CTSI Planning Committee
- CRSO Planning Subcommittee
- Membership Subcommittee
- Follow up meetings with Dr. Good

Key 2019 Milestones
- April 2019: CTSI Membership Subcommittee Convened
- August 2019: Subcommittee report out to CTSI Planning Committee
- October 2018: Meeting with Dean Kelda about CIB Priorities

Key 2020 Milestones
- January 2020: Convened Expanded CRSO Planning Subcommittee
- February 2020-May 2020: Individual Meetings with Deans and Department Chairs
- May 2020: CTSI Needs Assessment Sent to Researchers on Campus
- Continuous Engagement with Campus Leadership throughout 2020

Key 2020 Milestones
- October 2020: SOMEC Approval
- December 2020: SOM College Council Approval
- December 2020: Graduate Council
- December 2020: Academic Senate Executive Committee
- January 2021: Academic Senate
- March 2021: Board of Regents
CTSI Planning Committee

• Includes current CCTS faculty and staff leadership
  • Advised by workforce development, membership, and clinical research office sub-committees
• Representation from the University of Utah Academic Senate
• Representation from VPR office
• Reports to the Directors of the CCTS, Drs. Hess and Dere.
• Directors of the CCTS report to the Office of the Senior Vice President for the Health Sciences and subsequently the University President
Campus Representation on CTSI Planning Sub-Committees

- Anesthesiology
- Biomedical engineering
- Biomedical Informatics
- CCTS
- College of Nursing
- Dermatology
- Eccles Health Sciences Library
- Epidemiology
- HCI
- Human Genetics
- Internal Medicine
- Marriott Library
- Neurosciences
- OB/GYN
- Office of Quality Compliance
- Orthopedics
- Pediatrics
- Pediatrics Clinical Trials Office
- Population Health Sciences
- Psychology
- Radiology
- Social and Behavioral Sciences
- Social Work
- Surgery
- SVPHS Office
Campus Wide Faculty Engagement Plan

- Individual Meetings with each School of Medicine Department Faculty and Leadership
- Meetings with Deans of Main Campus Colleges
- Needs Assessment Survey Emailed to Faculty in May 2020
Results of Needs Assessment

- OnCore/Epic Research: 59 responses
- Assistance with grant writing: 58 responses
- QA/Internal monitoring assistance/Compliance: 58 responses
- Additional training and education for PI responsibilities & regulatory oversight or coordinator training: 57 responses
- IND/IDE (FDA support and maintenance): 55 responses
- Scientific writing support: 55 responses
- Clinical Trials Specific Contracting: 50
- Budget negotiation/post award management support: 52
- Additional training/assistance in research methods-study design, protocol development, etc: 51 responses
- DCC services and support: 47 responses
Utah CTSI Structure
The new Clinical and Translational Science Institute (CTSI) could provide additional resources outside your department/division/center. Indicate how valuable these resources would be for your personal ability to conduct clinical research.

Top 5 responses:

- QA/Monitoring
- Integration of research with EMR (OnCore/Epic Research)
- IND/IDE support
- Additional training for study staff and PI’s
- Increased contracting support
CLINICAL RESEARCH SUPPORT OFFICE
What would make conducting clinical research easier?

"Support from the University. We have such eager young surgeons that have great ideas, but there is no data support, no money for research assistants and we cannot afford the stats bills we get as a small division"

"A better method for managing the finances of industry sponsored clinical trials. What needs to be invoiced? Have invoices been sent? have they been paid? etc... "

"Monitoring is great in Pediatrics but expensive if you have yet to be funded shouldn’t be so cost prohibitive-why would the institution charge for this support? It protects the PI and the UU IRB and OSP timelines could be improved. If we want to be competitive, this needs to improve."

"Having a one-stop shop campus process/resource that's plug and play with regard to 1) inquiry and Q&A, 2) designing studies, including costs of including experts in clinical research study design and management, and 3) compliance with different types of clinical research conduct on campus for IND/IDE and regulatory issues"
What would make conducting clinical research easier?

"Provide more resources to be more uniform with things such as the creation of SOPs across the University, monitoring training and compliance within the divisions and not outsourced to other departments or areas (so we are able to maintain FDA compliance"

"A pool of trained research coordinators that one could have confidence in. Some of the CCTS resources are skin deep - they sound great on the website but turn out to be less than advertised when one inquires. It would be helpful to be quite clear about what does and does not exist"

"Additional tools for financial management in clinical trials, specifically post-award invoicing functions, connected to Epic queue work and an efficient OSP. Additionally use of a Central or Single IRB for Industry trials moving away from our local IRB that can"t turn around an amendment efficiently. Takes 8-10 weeks for amendments that are full board"

"Accessing central services for overall trial support, data management, trained research personnel, redcap support etc. Having to piece meal these critical services together is costly and a substantial barrier particularly for junior researchers without an established team"
Final Comments

"I am excited to see where this new initiative will lead. It could be a tremendous asset to expand and improve clinical research"

"For your project to be successful it must make research easier and no more expensive (ideally, less expensive) for researchers"

"Publication costs are difficult to manage. Some people may need some help there. I am essentially developing a system to build cohorts using the EDW. I see how this is going to be very valuable to others in my division who want to start on the research path, particularly with my mentorship. I would also like to be site PI for a pragmatic clinical trial. Please let me know if a good opportunity arises"

"We need a central group for budget, contract, FDA and monitor support to help Investigators"

We need this!!! The University has needed something like this to support our investigators for years!
Questions