The administration of large collaborative, multi-institutional, multi-faceted projects is complex. The CTSA grant recipient institutions must be flexible to an ever-changing structure that increases exponentially in scope. For top-tier research to take place, the researchers must be supported with top-tier research administration. The three CTSA programs represented here are demonstrating that when we collaborate, everyone wins.

CTSA Programs

CTSA services are available for every phase of clinical and translational research projects. The cores and programs under the CTSA offer support for investigators at each phase of the clinical and translational research process:

CTSA Programs

Impact on Research Administration National Initiatives

The CTSA program encourages collaboration across CTSA institutions nationwide. These collaborations can often lead to regulatory and administrative burden which may result in a delay of studies. To address these challenges, CTSA programs create a framework for obtaining multiple IRB approvals for multisite studies. NCATS supported a single institutional IRB (SMART IRB) platform for Multi-site clinical studies through the CTSA program. SMART IRB is a platform designed to ease common challenges and burdens associated with initiating multisite research and provide a roadmap for institutions to implement the NIH Single IRB Review process. Through a flexible master IRB agreement, standard operating procedures, and complementary tools and resources, SMART IRB supports and encourages collaboration and harmonization across the nation while ensuring a high level of protection for research participants. To date, SMART IRB has 152 participating institutions, including all 64 CTSA hubs.

The goal of the CTSA sponsored initiative is to increase the speed of study initiation of multi-site clinical trials by providing a pre-agreed upon template. The position of the ACTA is straightforward and incorporates needs of both the Industry Sponsor and the Institution. More than 50 organizations representing over 225 sites have agreed that the terms of the ACTA are acceptable. Outreach has begun to initiate pilots, and 5 pilot studies are currently active.

Multi-Institutional Funding

The CTSA’s multi-institutional partnerships not only require the use of standard subcontracts, but other mechanisms to fund the appropriate multi-institutional efforts. The CTSA’s along with being award recipients of NCATS, also act as awarding agencies, operating multiple pilot project programs. When internal pilot funds are awarded from one institution to another, it can create challenges. Sometimes the awarded institution is asked to use their own match funds for the award, other times collaboration between the institutional central offices is necessary. In other cases, the award recipients may be community partners who need guidance on the rules and regulations of the funding.

Account/Subaccount Structure

For one CTSA award, multiple accounts and subaccounts are used in order to connect the funding to the applicable program. The CTSA’s operate multiple programs that act in the same way as a Division, but are generally not set up formally in that way. This requires account and subaccount naming convention and mapping, not only so the research administrators can easily recall the accounts and their corresponding programs, but also to enable internal financial reporting over the life of the grant.

CTSA Nationwide

To reduce the long time between scientific discoveries becoming health benefits, the National Center for Advancing Translational Sciences created an innovative national network of more than 50 medical research centers that work together to speed the translational research process. Currently, it is estimated that it takes an average of 17 years for only 14% of new scientific discoveries to enter day-to-day clinical practice. The CTSA Program was created to enhance the efficiency of the translational research enterprise. The CTSA hubs located and regionally catalyze innovation in training and research resources.

References

3. Contact: http://www.indiana.edu
5. https://www.ara4us.org/
7. Wolfram Syndrome Syndrome (WS) is a rare, autosomal recessive disorder characterized by juvenile diabetes, optic nerve atrophy, deafness, and each is caused by a single gene defect due to mutations in the Wolframin gene. The link to diabetes is not understood. Dr. Fujihiko Urano received NCATS support to study the development and regulation of pancreatic beta cells, which secrete insulin, and to study the effect of mutations in Wolframin on early brain development, accompanied with impairments in gait and balance and identified Calpain-2, a Ca2+ dependent protease implicated in ER stress-mediated and amyloid-mediated neuronal and beta cell death. Dr. Urano received a SMART IRB Award for “Dose Escalation Studies for Dantrolene in Mouse and PSC Models of WS” and an ICTS JTI award to prepare regulatory documents for "Phase 2 Clinical Trial for Dantrolene in Patients with Wolfram Syndrome (IND 133459)". A Phase 1 Safety and Tolerability Trial in pediatric, and adult WS patients was initiated and the FDA approved dantrolene sodium in WS treatment. To date, 3 patients have been enrolled in the Dantrolene Clinical Trial.

CTSA Programs

Examples of CTSA Program Support at WU, IU, and NWU

• Informatics
• Biostatistics
• Clinical Interactions
• Genetics and Genomics
• Summer internships
• NRSA Training Grant (TL1)
• Institutional Career Awards Program

CTSA Services:

• Governance/Administration
• Clinical support
• Pilot Funding
• Evaluation and Continuation
• Quality and Efficiency

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