

What Do the CTSA Network Principal Investigators Aspire to Build Today?

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Two of the most visible efforts to address the “translational gaps” in moving biomedical research forward and the “lagging” efficiency of our clinical research infrastructure by the National Institutes of Health (NIH) was the creation of the network of 60 or so Clinical and Translational Science Awards (CTSAs) to establish “integrated homes” across academic medical centers, and establishing the National Center for Advancing Translational Sciences (NCATS). In July of this year, NIH also sponsored a report by the Institute of Medicine (IOM) of the National Academies of Sciences which outlined a series of recommendations to further refine the goals of the CTSA program to better realize its full potential. Each of these is an important and laudable step in an ever-increasing effort to build the right national infrastructure that can translate the impact of scientific advances into improved human health.

However, it is equally important that these “top-down” restructuring processes are also supplemented by appropriate “bottom-up” efforts from investigators, grantees, and trainees at these academic medical centers. The Association for Clinical and Translational Sciences (ACTS), the professional organization that represents not only the CTSAs, but many non-CTSA academic medical centers, clinical and translational training programs, and patient-oriented researchers, provides just such a platform for the ground-level stakeholders to provide input into this process of national transformation through its policy statements, feedback from individual members, and public lobbying. In early Spring of this year, ACTS conducted a survey of the CTSA principal investigator (PI) group, responded to by 49 PIs, which asked for the most important short-term (i.e., which could be undertaken in a year) initiatives the CTSA consortium should be undertaking to impact clinical and translational research. Based on the results of this survey, ACTS then conducted a one-day facilitated retreat in Washington, DC, that was attended by 45 CTSA PIs or their representatives, translational researchers, as well as some of the ACTS Board members to further refine these thoughts. Described below are the recommendations from this meeting, which summarizes what the CTSA leadership group is thinking nationally. While this effort predated the IOM report, and was parallel to many NIH work groups, it is also remarkable how well these conclusions fit with the NIH and IOM vision. The PI group was also convinced that not only all of the 61 CTSAs but most research-oriented academic centers should be asked to participate in the vision.

Focus on Future Translational Researchers

Four key interest areas are targeted under this mission by the PIs. First step is to create a community for the career development awardees (e.g., KL2, K23, K08 scholars) across institutions to network, share, and provide peer mentoring. The second recommendation is to build on the wealth of educational practices already in place by sharing established courses materials,

curriculum, and virtual courses. It is estimated that hundreds of online courses exist already, but a number of roadblocks exist in permissions, fees, etc., which can be addressed by the consortium. Third, recognizing the need for flexibility and alternative career paths, they recommend designing novel, modular career paths (such as moving from academics to industry) and training people for the emerging job markets. Finally, the PIs recommend starting a pipeline at the high school level to generate interest in biomedical careers and translational sciences early.

Facilitate Multisite Collaborations

Here, the priority recommendation is to focus on smaller sized collaborations (e.g., regional networks) that have a comprehensive platform for rapid study startups (e.g., shared clinical trials, Institutional Review Board). It is suggested that successful models and tools (e.g., contract forms, intellectual property sharing documents, etc.) be further promoted and shared. The number two priority is to develop a rare disease network for CTSAs that is based on existing resources within each centers' electronic health records. This could involve developing a list of interested local champions and investigator pools for these projects, as well as having a fund of money available to the CTSAs for multicenter trials. The CTSA consortium members can create a rare disease repository/catalog through a central repository (e.g., the coordinating center) and make it available to the investigators across the country or the globe.

Expedite Preclinical Discoveries into Human Studies

Under this concept, the first recommendation is to work with the preclinical divisions of NCATS and other NIH centers and institutes to develop an accessible library of drugs, compounds, high-throughput screens and model systems, and create tools to make such data available to investigators. The second recommendation was to establish a translational pipeline of resources that catalog both (1) the sequential drug discovery processes for unique targets that a clinical investigator may be looking for, and (2) a stepwise guidance required for human drug development for translational/basic science inventors.

Begin to Coordinate Informatics Infrastructure

The primary recommendation is to develop methods to access some aspects of the electronic health records (anonymized data sets; consented disease cohorts) for research purposes in small networks of five to six CTSAs regionally. While regulatory challenges exist for large-scale sharing of data, tools and technologies can create specific registries and shared phenotypic data to enable researchers to collaborate within smaller regional networks.

Although all the CTSA PIs were highly enthusiastic about building a national infrastructure, they also recognize that an equally important responsibility for them is to transform their

local institutions and cultures for any of these ideas to flourish. They formulated the following statement expressing this sentiment: “All CTSA’s should ideally have capacity across the entire T1–T4 spectrum with sufficient resources to make their core capacities significant and meaningful. However, most CTSA’s will not have sufficient strengths in all areas, and thus, each CTSA should select one or more areas of special strength for greater

investment of their CTSA funds to yield larger benefits locally, and for the CTSA Consortium more broadly. Enhancing consortia activities is very important but this is only feasible if all CTSA’s are strong at their own institution, and are able to contribute both by usual participation and by bringing special strengths to the Consortium.” As the president of ACTS, I find this balance of local and national missions perfect. **CTS**