National Deafness and Other Communication Disorders Advisory Council Clinical Trials Working Group Report and Recommendations

Introduction

The National Institute on Deafness and Other Communication Disorders (NIDCD), part of the National Institutes of Health (NIH), relies on its Clinical Trials (CT) Section to support clinical trials for the development of therapies and interventions across the NIDCD mission areas of hearing, balance, taste, smell, voice, speech, and language. Across these mission areas, the CT Section drafts relevant funding opportunities for publication and guides investigators to them, hosts workshops and conferences, manages CT website content, and represents NIDCD on various NIH committees. The section also provides crucial oversight of CTs warranting close monitoring, based on whether they require oversight from the U.S. Food and Drug Administration (FDA) and/or have higher levels of complexity, safety risk, potential impact, or fiscal investment from NIDCD. These grants are time- and resource-intensive because of the need to manage complex budgets, track protocol and consent development, monitor regulatory compliance, assess participant safety, track study progress, process payments, prepare financial reports, and coordinate among investigators, sponsors, finance offices, and regulatory bodies throughout the life cycle of each clinical trial. These responsibilities require specialized expertise and sustained administrative effort to ensure compliance, financial accuracy, and successful project execution.

An issue of concern is the dwindling portfolio of funded CTs as existing trials reach completion and fewer funded awards enter the pipeline. This decline also comes as NIH confronts budget cuts and administrative reorganization. NIDCD therefore faces a crucial need to identify programs and infrastructure that would best benefit the NIDCD CT program, and resources to prioritize for the greatest possible impact.

In response to this need, the Director of NIDCD established the CT Working Group (WG) of the National Deafness and Other Communication Disorders Advisory Council (NDCDAC) from a group of extramural scientists with expertise developed from current or previous NIDCD CT funding. The NDCDAC charged the WG with determining:

1) Whether NIDCD is optimally fulfilling the needs of the research community in terms of training and supporting investigators with planned and ongoing CTs,
2) Whether the institute is using available CT resources optimally, and
3) What the optimal structure and composition of the NIDCD CT Section would be.

This report provides a summary of the WG's broad-based review of NIDCD-funded CTs. The WG has also issued recommendations centered around:

1) Identifying challenges that NIDCD CT investigators face in the application, planning, and implementation phases of their studies;
2) Identifying gaps and improvements to support and help the NIDCD CT community succeed;
3) Helping investigators successfully complete clinical trials practice and follow policies; and
4) Increasing the pool of CT applicants.

CT WG Process

The WG first conducted a field scan of CT Section activities, responsibilities, and strengths, followed by an examination of areas of need for investigators conducting NIDCD-funded CTs. This information was synthesized from a series of interviews with NIH staff members and extramural investigators with CT experience. Interviews focused on assessing needs and fulfillment, leveraging and prioritizing resources, optimizing structure and composition, strategic planning, and managing conflicts of interest for NIH staff. The WG also released a request for information (RFI) — NOT-DC-26-026 — to gather written responses on NIDCD CT strengths and areas of opportunity from additional stakeholders in the extramural community. The findings from these interviews and written RFI responses are summarized in this report.

Summary of Input

In general, the summary is organized by how often interviewees provided similar input on both strengths and challenges, from most frequent to least frequent. Challenges are also organized along a spectrum, from system-level issues to those specific to NIDCD.

Strengths

An Experienced Team with a Collaborative, Supportive Culture: Staff in the NIDCD CT Section have extensive CT knowledge and expertise developed by an exceptionally long duration of service at NIH, at other federal agencies, and in the private sector. Extramural interviewees cited leveraging the section's expertise throughout CT protocol development and credited the section with elevating protocol quality. Interviewees also noted that for a unit within a small institute, the NIDCD CT Section covers a broad portfolio of CT studies, including devices, drugs, and dietary and behavioral interventions across all the mission areas of the institute.

The expertise and the availability of the CT Section were especially helpful to some interviewees who experienced disruptions to their studies. One interviewee reported difficulty meeting recruitment for a study during the COVID-19 pandemic. The CT Section established monthly meetings to ensure the study met its recruitment goals and provided additional consultation on budget and timeline adjustments.

Structured Pre-Implementation Framework: The CT Section has designed and disseminated a detailed pre-implementation framework with milestones for investigators to follow prior to enrolling participants in their CT protocol. The section recommends that framework milestones be completed within 9 months of the Notice of Award. The framework provides an overview of requirements around developing protocols; gaining approvals; establishing data safety and monitoring board oversight; completing CT registration; developing plans for safety monitoring, data management, recruitment, and retention; conducting site initiation activities; and establishing intervention availability.

The framework is designed to systematically ensure the development and implementation of a well-designed CT that can be successfully completed in a timely fashion and yield high-quality science that can inform future clinical practice. Interviewees noted that this structured approach has been cited as a best practice asset.

Partnerships for Additional Support: NIH staff have noted that NIDCD-funded investigators frequently use services provided by the Trial Innovation Network (TIN) supported by the National Center for Advancing Translational Sciences (NCATS). The TIN is built within NCATS' Clinical and Translational Science Awards (CTSA) Program. The network provides consultation services free of charge to aid CT design. NIH staff note that these consultation services could be scaled for even broader use. The Recruitment Innovation Centers (RICs) within the CTSA Program also have access to more than 93 million patients, and that access could be leveraged for study enrollment.

One interviewee voiced appreciation for the CT Section connecting them to NCATS, which provided valuable support during an ongoing drug development trial. When the interviewee faced unexpected complications with the study's drug supply, NCATS handled preclinical work reformulating the drug, showing bioequivalence, and minimizing unanticipated operational costs.

Challenges

Lack of Data on Enrollment Shortfalls: A consistent challenge across NIH is the struggle for CTs to meet their enrollment targets. For example, analysis of the CT portfolio at the National Institute of Mental Health (NIMH) has shown that the majority of 1,200 trials never reach 75% of their accrual goals. NIDCD likely faces a similar issue. However, the institute does not have systematic internal data on CT study performance. Interviewees also commented that there is a lack of support to assist underperforming studies.

Limited CT Section Staff and Resources: While recognizing the CT Section's extensive expertise, interviewees pointed out that the team is under-resourced: The section has one full-time medical officer (MO), one MO vacancy, two part-time staff members, and one volunteer consultant. The CT Section has also received extra support from contract research organizations (CROs) that provide administrative, technical, and logistical support. However, contractor funding has been dramatically reduced. Interviewees indicated that the CRO support could be

valuable in augmenting expertise, but they also raised concerns about whether CROs understand how NIH operates, what can and cannot be asked of investigators, and what the obligations of the institutional review board (IRB) are. The CT Section also faces turnover and a lack of stability in personnel, further worsening the staffing gap. Interviewees said that the staff turnover likely contributed to delayed responses and mixed messaging. This challenge affects enrollment and several other issues raised in this section.

Research Areas Outpacing NIDCD Capacity: With a small team, investigators in certain research areas report needing expertise beyond what is available at NIDCD. Notable areas include technology and device research, drug discovery, and field-specific knowledge about smell and taste. As referenced above, these knowledge gaps can be filled by existing partnerships, notably with NCATS. However, these gaps in knowledge have at times led to significant delays in studies. Interviewees said that limited subject matter expertise created a fundamental disconnect between the investigator team and the CT Section that was especially apparent during critical periods such as study launch.

Inadequate Training Infrastructure for Current and Future CT Applicants: Interviewees wished for a structured, accessible training pathway for both trainees and investigators interested in conducting CTs. Similarly, interviewees felt that there was no clear career path to becoming a CT specialist within NIDCD's research fields. They did not feel that there were training structures embedded in T32, R25, or K award mechanisms. Although NIH does offer an introductory course on CTs, interviewees reported that this course focuses more on background context for CTs instead of practical preparation for the operational challenges of running a trial. Those who reported success in running their first CTs credited that success to more experienced colleagues and mentors, given that they did not receive formal CT training themselves.

Thin CT-Facing Websites and Resources: Interviewees felt that NIDCD's web presence on CT guidance was sparse compared with that of other institutions. Those with CT experience at other institutes or agencies appreciated having resources that included toolboxes, boot camps, standardized templates, and step-by-step guides to help investigators plan and prepare their CT applications.

Lengthy Review Processes with Excessive Administrative Burden: Interviewees reported facing delays of up to 1 year before enrollment began, after FDA and IRB approvals were in place. These delays came from lengthy review processes with administrative oversight that interviewees found to be excessive, redundant, and confusing. Interviewees reported delays due to multiple rounds of post-award protocol review, inconsistent feedback, and proliferating documentation requirements. Interviewees also reported being put in difficult positions when the CT Section modified parts of the peer-reviewed study design without providing clear scientific or operational justification, creating confusion over the hierarchy of authority in the CT review and oversight process.

Interviewees identified factors that may contribute to these issues in the review process. First, larger institutes, such as the National Cancer Institute and the National Heart, Lung, and Blood Institute, have models that integrate intramural and extramural components of CT studies. However, NIDCD does not have such a model, and that difference can potentially lead to miscommunication in studies that involve both intramural and extramural study teams. Second, even though CROs are meant to support the CT Section, interviewees reported receiving inconsistent feedback from contractors reviewing their studies.

Recommendations

The NIDCD CT WG developed the following recommendations to address some of the challenges identified in this report. These recommendations are prioritized based on feasibility and potential to address challenges in training, resources, and enrollment, which were deemed high-priority areas of opportunity.

1) **Leverage consultants and domain experts strategically to streamline the review process and appropriately use limited NIDCD CT Section resources.**
   To avoid administrative burden while addressing the need for specific subject matter expertise, NIDCD should consider using consultants with scientific domain expertise in areas such as drug development, device trials, or language intervention for high-value, one-time protocol reviews. NIDCD could further streamline the review process by establishing a clear hierarchy of reviewers, which may help minimize confusion over study protocols and ultimately prevent delays to studies.

2) **Proactively integrate partnerships across NIH into the CT application process.**
   The NIH Office of Disease Prevention is developing its own infrastructure to provide CT expertise. The office will be a valuable addition to existing NIH resources, to NIDCD, and to other NIH institutes. In addition, interviewed NIH staff proposed several ways to make better use of existing CT resources within NCATS, including the use of the TIN. One option is having NCATS host NIDCD-specific workshops. Given the TIN's ability to scale its consultations, NIDCD could also consider requiring applicants to meet with TIN staff or review the network's resources before submitting a CT application. The National Institute of Diabetes and Digestive and Kidney Diseases is using the TIN in this way and could serve as a model for NIDCD. Earlier TIN and RICs involvement may also help investigators anticipate and address challenges to study enrollment.

3) **Develop a workforce pipeline for CT-capable investigators.**
   NIDCD could consider releasing a Highlighted Topic appropriate for career awards (through K mechanisms) or institutional training grants (through R25 or T32 mechanisms) focused on training for clinical trialists. New CT grant mechanisms (e.g., biphasic grant mechanisms) could also provide greater support for investigators, particularly during the planning phase of a trial. A biphasic grant would provide 1 to 2 years of support for planning and launching the

trial and then up to 5 years of CT support. This would address the concern from interviewees that too much of the grant time was spent on planning activities, leaving insufficient time to complete the trial.

4) **Develop a structured CT training ecosystem.**
   Interviewees repeatedly indicated that it should be a priority for NIDCD to begin developing resources as part of a CT training ecosystem. NIDCD could offer CT toolkits and boot camps. The institute could also host workshops at NIH and through professional society meetings. NIDCD could develop phased training for CTs for everyone from graduate students to senior faculty. Finally, the American College of Surgeons offers a postgraduate course that could serve as an adaptable training model. Although it may take time to develop these resources, creating this training ecosystem may streamline the CT application process and in turn ease burdens on the NIDCD CT Section.

Future Priorities

In addition to the recommendations for immediate consideration provided above, the NIDCD CT WG offers the following approaches to consider for future activities and priorities.

1) **Expand data infrastructure for NIDCD-specific recruitment.**
   To improve the quality of CTs, CT data, and research across the institute's mission areas, NIDCD could consider ways to improve audiometric data infrastructure. This data type is not extractable from 95% of U.S. electronic health records. Investing in common data elements embedded at CT sites could address persistent recruitment bottlenecks.

2) **Build a multisite CT network for NIDCD mission areas or partner with other institutes that already have CT networks.**
   Interviewees praised the value of disease-focused CT networks for providing resources, training, and subject matter expertise. NIDCD has tried establishing such a network with the Creating Healthcare Excellence through Education and Research (CHEER) clinical research network, but this was not deemed sustainable or considered a good use of resources. NIDCD could explore whether such infrastructure could be developed within existing resources, notably NCATS' CTSA Program.

3) **Integrate dissemination and implementation (D&I) into CT planning.**
   Although this report focuses on challenges before and during CTs, interviewees also discussed challenges CTs face at the translation stage. For future priorities, NIDCD could look to the Patient-Centered Outcomes Research Institute for examples of how to incorporate D&I plans within CT applications and embed D&I expertise into future CT networks.

4) **Issue targeted requests for applications (RFAs) to stimulate translational CT pipelines.** NIDCD could continue to demonstrate its commitment to D&I initiatives by convening a WG to assess which disorders under its mission areas currently have a viable translational path. NIDCD could then issue targeted RFAs to increase the CT applicant pool in those research areas. NIMH and the National Institute on Aging have successfully used this strategy for CTs on schizophrenia and Alzheimer's disease, respectively.

Discussion

NIDCD is committed to building and expanding CTs. Inherent to this objective is a commitment to the current and future workforce of investigators interested in applying for and conducting CTs under the institute's mission areas. These recommended actions are meant to guide such commitments.

As mentioned above, NIDCD is already conducting ongoing work toward positive change. At the May 2026 meeting, NDCDAC members approved a concept to implement a phased award mechanism for future CTs. The first phase will support investigators for 2 years as they work toward planning and preparatory milestones. Investigators will then have a traditional 5-year implementation under the second phase. The two-stage award will have a single peer review. This new funding structure is meant to better support the planning phase of CTs and enable investigators to better address challenges that frequently cause early trial failures.

NIH as a whole is also considering funding mechanisms that can better support early career investigators. NIH is exploring funding models that would allow mentored K award recipients to lead clinical trials while maintaining the award's primary focus on career development. The new award structure must provide adequate funding to properly support CTs. The award must also support investigator independence while providing adequate training in CT management. NIDCD will work to ensure that these considerations are met and that new funding policies are suitable to the institute's needs and the needs of the investigators seeking NIDCD support.

In spite of the challenges that the NIDCD CT Section faces, its strengths cannot be overstated: The experienced and dedicated team works deftly across the institute's wide mission areas. Combined with existing frameworks and partnerships, the section has routinely supported and enabled the development of scientifically rigorous CT protocols. The NIDCD CT WG has issued these recommendations with the hope that they further strengthen the section and add to its already impressive capabilities.

Implementing these recommendations, especially recommendations for future priorities, will take a significant investment of both time and resources. However, the potential benefit is clear. With these recommendations, the WG aims to facilitate the development of an efficient, effective CT pipeline that considers both trainees and investigators at every career stage, leading to greater CT engagement and a healthier CT ecosystem.

NIDCD Clinical Trials Working Group Recommendations

Strategies to Strengthen Clinical Trials at NIDCD

	1 Leverage Consultants and Domain Experts Strategically	2 Proactively Integrate Partnerships Across NIH into the CT Application Process	3 Develop a Workforce Pipeline for CT-Capable Investigators	4 Develop a Structured CT Training Ecosystem
High-Priority Recommendations	• Use consultants with scientific domain expertise for high-value, one-time protocol reviews. • Streamline and establish hierarchy within the review process.	• NIH Office of Disease Prevention • National Center for Advancing Translational Sciences (NCATS) Clinical and Translational Science Awards (CTSA) Program resources	• Offer Highlighted Topics for career awards (K mechanisms) and institutional training grants (R25 or T32). • Develop new CT grant mechanisms to support investigators, particularly during the planning phase.	• Offer CT toolkits, boot camps, and practical resources. • Host workshops at NIH and through professional society meetings. • Provide phased training from graduate school through senior faculty.
Key Benefits	**Provides necessary expertise while reducing administrative burden.**	**Earlier access to scalable resources improves study design and enrollment success.**	**Builds a sustainable pipeline of skilled investigators and strengthens trial planning.**	**Improves investigator preparedness and reduces burdens on the CT Section.**
Expected Impact on Clinical Trials	**Improved Enrollment Success** Early engagement of resources and expert guidance helps overcome recruitment barriers.	**Faster Startup Times** Streamlined reviews, targeted expertise, and better-prepared applications accelerate trial initiation.	**Higher-Quality Trials** Stronger training, resources, and expertise yield well-designed, rigorous, and reliable trials.	**Better Investigator Experience** Clear guidance, training, and accessible resources reduce confusion and administrative burden.