Requesting Continued Access to the RDCRN Operational Environment Cloud Platform

Contact

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This opportunity provides investigative teams funded under the Rare Diseases Clinical Research Consortia (RDCRC) for the Rare Diseases Clinical Research Network (RDCRN) (U54 Clinical Trial Optional) (RFA-TR-18-020) continued access to the RDCRN Operational Environment cloud platform. Any research activities conducted within the RDCRN Operational Environment must stay within the scope of the most recent parent grant. This RDCRN Alumni Site includes all databases active during each team's tenure as an RDCRC and the ongoing use of network tools. The RDCRN Data Management and Coordinating Center (RFA-TR-24-021) will handle only security management, account management and data storage. Any custom development, setup or data management requirements will be the responsibility of the alumni.

Purpose

The primary goals of the RDCRN Alumni Site are to:

- Foster Collaboration: Create an environment that enables RDCRN alumni to continue functioning as a collaborative group.
- Ensure Data Access: Maintain RDCRN alumni's access to the data collected during their time in the RDCRN.
- Provide Analytical Tools: Equip RDCRN alumni investigators with tools for effective data analysis.

Overview

This opportunity does not provide budgetary support for the proposed activities; however, successful alumni will gain access to RDCRN Data Management and Coordinating Center (DMCC) resources and the data collected by the specified consortium. Alumni are expected to demonstrate their expertise and resources to operate independently within the RDCRN Operational Environment (e.g., institutional support, patient advocacy group support, industry support as needed). Furthermore, successful alumni must show they have the appropriate governance in place to manage the existing RDCRC and the capacity to sign any agreements, including Data Use Agreements or Memoranda of Understanding, established by NCATS. Participants must obtain participant consent and utilize a single IRB consistent with NIH's Single IRB Policy, as outlined in NOT-OD-16-094, for any protocols involving human subjects research.

The DMCC will provide successful alumni with detailed rules of engagement and program expectations. Alumni are expected to maintain transparency in their activities and meet semiannually with the DMCC team. Additionally, alumni will be required to incorporate the RDCRN's platform and operational procedures into their plans and work collaboratively within the DMCC environment, establishing internal policies for effective cooperation.

The DMCC will remain available for consultation on such issues as troubleshooting new accounts or addressing administrative or technical challenges beyond the consortium staff's expertise. However, consortium members, having received training prior to the end of the parent grant, are expected to have acquired sufficient expertise to manage tasks like REDCap projects independently and to have financial support for any expenses required.

Eligible Alumni
As described in NOT-TR-25-012, investigative teams funded under the RDCRC for the RDCRN (U54 Clinical Trial Optional) (RFA-TR-18-020) may request continued access to the RDCRN Alumni Site when funding ends. Requests are due by Sept. 30, 2025.

The project lead must have been officially named as key personnel as identified in the most recent Research Performance Progress Report of the parent consortium awarded under RFA-TR-18-020. The project lead may have been officially named as key personnel in any of the cores or research studies within the consortium.

Request Process
Eligible alumni should address the following points in their request for continued access. Requests should be clear and concise — no longer than 10 pages. Requests should be emailed by the Authorized Organizational Representative to the contact listed above.

- Describe the primary goals and objectives of the investigative team.
- Describe how the investigative team will benefit from using current resources within the DMCC.
- Identify the project lead for the investigative team and outline the management structure, including roles and responsibilities of team members.
- Describe in detail the capacity of the investigative team to independently manage the tools and resources available within the DMCC.
- Identify who will oversee specific ongoing projects, including any involving human subjects, and how and by whom the Institutional Review Board will be managed.
- Confirm that any data generated will comply with NIH data sharing policies.
- Identify if independent resources are available to support the proposed work within the DMCC environment.
- Describe how the investigative team plans to interact with the DMCC.

When the request has been processed, an onboarding package will be provided by the DMCC.

Confidentiality
The information contained in a request will be protected by NIH from unauthorized disclosure.