

ASH Research Collaborative Sickle Cell Disease (SCD) Clinical Trials Network (CTN)

Frequently Asked Questions (FAQs)

1. Q: What is the ASH Research Collaborative? Is ASH involved in the CTN?

A: The ASH Research Collaborative (ASH RC) is a 501(c)3 established by the American Society of Hematology in 2018 to foster collaborative partnerships to accelerate progress in hematology, with the goal of improving the lives of people affected by blood diseases. At the foundation of the [ASH Research Collaborative is its Data Hub](#), a technology platform that facilitates the exchange of information by aggregating research-grade data on hematologic diseases in a central place for the purposes of scientific inquiry. One of the first research initiatives of the ASH RC is a Sickle Cell Disease (SCD) Clinical Trials Network (“Network”), launched in 2018 to optimize the conduct of clinical trials research in SCD. ASH founded and funded the ASH Research Collaborative (ASH RC) as a part of the family of non-profits that ASH has formed for specific missions.

2. Q: What is the application process for the Network?

A: The application process is multistep. The first step is to complete the Letter of Intent (LOI), which is a 5-page application document. A site selection subcommittee will review the completed LOI’s and invite qualified applicants to compete in a competitive RFP process. Applicants that are competitive in their response to the RFP will have a site visit.

3. Q: What is the difference between the letter of intent (LOI) and the full proposal in response to the RFP?

A: The LOI is like a CV/resume, a detailed story of your past qualifications to participate in the Network. The response to the RFP must include a detailed plan of how the site will execute research, engage the community, meet enrollment benchmarks, etc.

4. Q: Who is eligible to apply?

A: Many different types of institutions are eligible to apply, including: academic medical centers, community hospitals, outpatient medical practices with research facilities, health research institutions, and integrated health care and research consortiums.

Institutions may submit (an) application(s) if they have any of the following characteristics:

- For-profit organizations
- Non-profit organizations
- Public or private institutions, such as universities, colleges, hospitals, and laboratories
- Community-based and faith-based organizations

Foreign institutions are not eligible to apply at this time. We will be working on a time frame to potentially add foreign institutions.

5. Q: Once an applicant is selected to be part of the Network, what is the ongoing evaluation process?

A: There is an assessment report due every year, and a bi-annual evaluation and site visit which determine whether an institution will remain in the Network.

6. Q: What is the difference between the ASH RC Data Hub and the Network?

A: The [Data Hub](#) is a repository of clinical, biological, and patient-reported data designed to facilitate research and improvements in the diagnosis and treatments of hematologic diseases, which will be accessible to researchers and clinicians. The Network is a system of clinical trial sites researching SCD. ****Note, to qualify as a participant in the Network, you must agree to contribute data to the ASH RC Data Hub.**

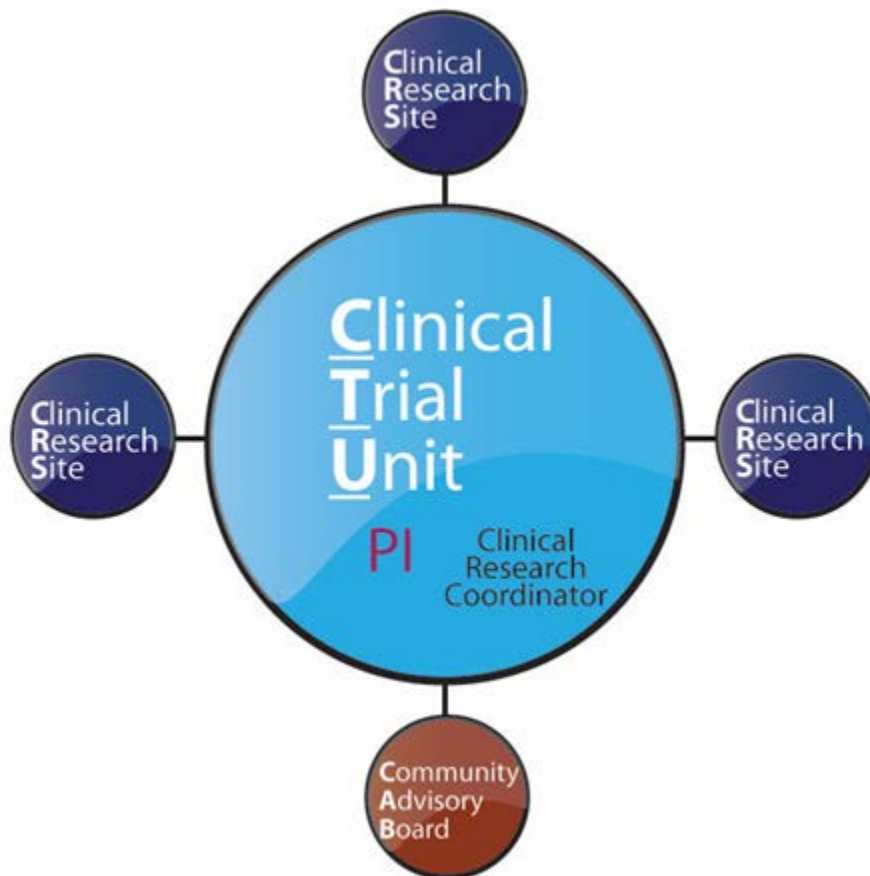


Figure 1 Clinical Trials Network Hub and Spoke Model: Clinical Trial Unit, Clinical Research Sites, and Community Advisory Board

7. Q: What is a Clinical Trial Unit (CTU)?

A: A CTU serves as the applicant organization responding to the LOI and RFP and is the lead clinical trial site providing the scientific and administrative expertise, as well as the infrastructure to support the CTN.

8. Q: What are the selection criteria for the Clinical Trial Units (CTU)?

A: Each submission will be evaluated on the basis of the applicant's proven track record of successfully conducting clinical trials at a clinical research site, experience with engaging the patient population, and experience successfully enrolling participants in clinical trials. The experience of the personnel at the proposed site/consortium will also be considered, along with the site's infrastructure to support a successful clinical trial, agreement to comply with a single IRB model, and agreement to submit data to the ASH RC Data Hub.

9. Q: What is a Clinical Research Site (CRS)?

A: A CRS is a site that is part of a CTU with a specific location with appropriate, identified and characterized potential trial participants, where clinical trial participant recruitment, retention, protocol management, and other clinical research activities are conducted. A CRS can be a hospital, outpatient clinic, community health center, private practice, or local health department clinic.

10. Q: How many Clinical Research Sites (CRS) does an application need?

A: Each application should include an adequate number of CRS(s) needed to provide access to research for those individuals living with SCD in their region, ensuring that research participants do not have to travel excessive amounts to participate in studies. As a result of regional differences in SCD care the number of CRS(s) may vary based on the location of the applicant CTU.

11. Q: What is a clinical research coordinator (CRC)?

A: A Clinical Research Coordinator (CRC) is a person responsible for conducting clinical trials using good clinical practice (GCP) under the auspices of a Principal Investigator (PI). Oftentimes, a CRC is a nurse, but that is not a requirement.

12. Q: Can institutions form a consortium with other major academic centers, community hospitals, and private practices?

A: Yes, it is strongly encouraged that major academic centers are in the same city or region to consider forming a consortium, and to submit a single application. In a consortium there will still need to be a lead institution that will be the Clinical Trial Unit (CTU) and the other sites in the consortium will be Clinical Research Sites (CRS).

13. Q: Will the Network fund research?

A: No. The Network will not be providing any grants or other direct funding for research. It will, however, be active in advocating for third-party funding for research that is a priority to the SCD patient community and the Network CTU's or CRS's.