



Procedures for Developing a Collaborative Patient Database to Assess Feasibility and Facilitate Planning and Implementation of Multicenter Clinical Trials

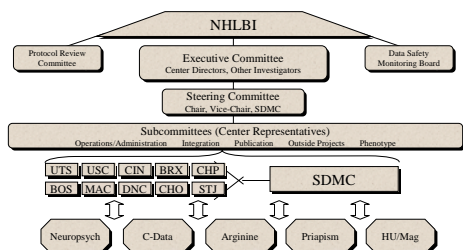


Susan Lief, Alice Lail, Ronald W. Helms, Comprehensive Sickle Cell Centers Clinical Trials Consortium
Rho, Inc., Chapel Hill, NC

1. Introduction

Collaborative efforts among multiple medical centers are often necessary to address important clinical questions. The current NHLBI Comprehensive Sickle Cell Centers Program consists of 10 Centers and a Statistics and Data Management Center (SDMC), and supports collaborative multi-center clinical trials research focused on improved treatments for sickle cell disease. A multi-center diagnostic and clinical database is being developed to facilitate study feasibility, evaluation, trial design, planning and implementation.

2. CSCC Organization



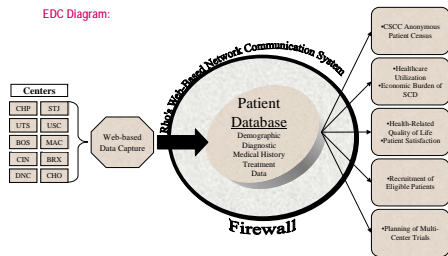
3. Purpose

Provide:

- a complete list of the CSCC patient population
- an information base for designing clinical studies (sizes of specific subgroups, etc.)
- means for identification of individuals eligible for specific studies
- basic HROOL and healthcare utilization data for a large number of individuals with SCD
- means for exploration of relationship between patient characteristics and Sickle Cell-related events

4. Electronic Data Capture (EDC)

A web-based EDC system will be used to obtain the data. With this system, the clinic's coordinator uses an internet browser to key in data into electronic case report forms. Univariate data validation tests are performed as the data are keyed. At the end of each "page," data are submitted to Rho's secure web server using SSL and stored in the study's database. At any time site personnel may log in to the system, review and correct previously entered data, key additional data or lock records to prevent further modifications.



5. Patient Enrollment

Subject enrollment planned to coincide with medical visits only, would not allow development of a sufficiently large database before the end of the current funding period. Therefore, centers will be provided technical assistance and financial support to plan and conduct a mass recruitment effort to enroll, obtain informed consent, conduct medical interviews and collect HROOL from a large number of eligible patients at one time. The recruitment campaign may be conducted at holiday events, health fairs, by phone or in any manner appropriate for that center.

6. Data Collection Process

Enrollment can occur at a special study visit OR at the time of a clinical interaction

- Data forms used at a special study visit include Enrollment, Medical History (Parts I & II), HROOL
- Data forms used during clinical visits include Enrollment, Medical History (Parts I & II) Encounter, and HROOL

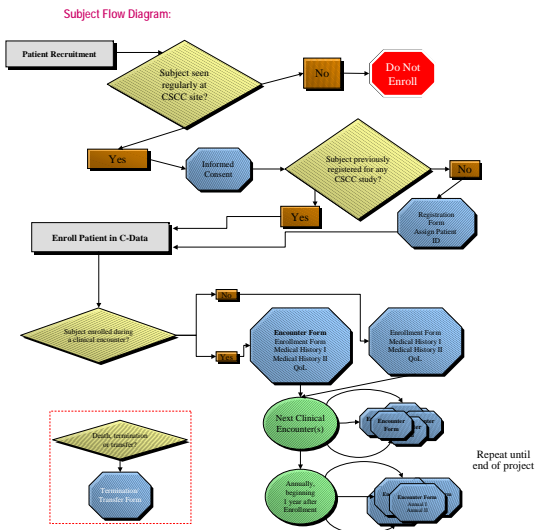
Medical History Part I clinical data are obtained via chart review, Part II demographic data are obtained via patient interview. HROOL data are obtained via self-administered survey, preferably at enrollment, or at a subsequent well visit. Encounter data are obtained at all in-person encounters, and include date, type and reason for encounter

Post-Enrollment data are obtained for all in-person encounters between participants and care providers.

- Data forms used at post-enrollment visits include Encounter, and on a yearly basis Annual (Parts I & II)

Encounter data forms include date, type and reason(s) for encounter, and when appropriate, dates of hospital admission/discharge and discharge diagnoses. Annual Form Part I clinical data are obtained once each year via chart review, Part II demographic data via patient interview at a clinical visit. Annual Form Part I & II formats are similar to Medical History Form, to allow continuity but no overlap in time period.

Termination/Transfer data forms are used to obtain information if a participant dies, terminates care at a study site or transfers to another facility for treatment at any time during the study period.



7. Communication

The SDMC will establish and maintain a C-Data area of the CSCC website to facilitate ongoing day-to-day communication between the SDMC, Center data coordinators, Steering Committee and Patient Database subcommittee, and the National Heart, Lung, and Blood Institute (NHLBI) Project Office regarding all aspects of the C-Data Project. The C-Data area of the website will provide features currently available on the general CSCC site, with access to the following:

- C-Data Project goals and objectives, SOPs, the Manual of Procedures, contact information for center coordinators, other center personnel and SDMC project staff.
- C-data subcommittee materials including in-person and conference call meeting schedules, agendas, and minutes.
- C-Data project training materials, protocols, case report forms, calendars, and consent and authorization materials.

8. Next Steps

- Finalize Electronic Data Capture System
- Conduct initial and periodic study coordinator training
- Finalize templates for informed consent materials and distribute to Centers
- Finalize C-Data budget
- Develop format and mechanism for DMSB reporting
- Coordinate informed consent review process with NHLBI
- Approve sites for study initiation
- Begin subject enrollment
- Plan and initiate data monitoring activities

9. SDMC Roles

- Facilitate/assist in protocol development
- Coordinate preparation of study materials
- Coordinate central and on-site training for clinical site staff
- Monitor recruitment and accrual of study participants
- Oversee data collection, data management, quality control and analysis
- Collaborate in the preparation of scientific reports and publications
- Act as liaison between the PI and the PRC, DMSB, and study sites
- Prepare technical and administrative reports for PRC, DMSB, and other groups

10. Participating Centers

- | | |
|--|---|
| Ronald L. Nagel, MD
Bronx Comprehensive Sickle Cell Center | Cage S. Johnson, MD
University of Southern California
Comprehensive Sickle Cell Center |
| Marilyn Telen, MD
Duke-UNC Comprehensive Sickle Cell Center | Martin Steinberg, MD
Boston Medical Center
Comprehensive Sickle Cell Center |
| Kwaku Ohene-Frempong, MD
Chilens Hospital of Philadelphia
Comprehensive Sickle Cell Center | Winfred Wang, MD
St. Jude Children's Research Hospital
Comprehensive Sickle Cell Center |
| Elliott Vichinsky, MD
Northern California Comprehensive Sickle Cell Center | Clinton H. Joiner, MD, PhD
Cincinnati Comprehensive Sickle Cell Center |
| Marie J. Stuart, MD
Marian Anderson Sickle Cell Anemia Care and Research Center | George Buchanan, MD
Southwestern Comprehensive Sickle Cell Center |

C-Data Protocol Development Committee members are Samir Ballas, MD, George Buchanan, MD, Carlton Dampier, MD, Ronald W. Helms, PhD, Edward Howard, Cage Johnson, MD, Karen Kesler, PhD, Alice Lail, MPH, Susan Lief, PhD, Kwaku Ohene-Frempong, MD, Win Wang, MD, and Zora Rogers, MD.
For more information contact Susan Lief (slief@rhworld.com) or Alice Lail (alail@rhworld.com)
Funding provided by National Heart, Lung, and Blood Institute 5U4HL0 70587-2