Welcome to the inaugural issue of the STAR STI Update, a quarterly publication. The STAR STI CTG is committed to conducting research that will result in the prevention and control of sexually transmitted infections (STIs). In this issue, we will share updates from the first quarter of 2014, including an introduction to Coordinating Center (CC) staff, an update on concept proposals (CPs), and a featured article submitted by our readership.

Meet the Coordinating Center

The Coordinating Center (CC), based at Social & Scientific Systems, Inc. (SSS), is responsible for supporting the activities of the STAR STI CTG. Responsibilities include budget development for the project; assisting with the development of standard operating procedures; supporting the development of CPs; coordinating, processing, and supporting the scientific peer review of CPs; supporting meetings and conference calls; and maintaining the group’s Web site.

Jeffrey Klausner, M.D.—Principal Investigator (PI). Dr. Klausner is responsible for the overall governance and scientific leadership for the STAR STI CTG. He oversees research prioritization, concept and protocol development, and study implementation. Dr. Klausner is Professor of Medicine in the Division of Infectious Diseases at the David Geffen School of Medicine at the University of California, Los Angeles. He has been conducting human subjects research for more than 20 years, using investigational products in the treatment of herpes simplex virus infection, chlamydial urethritis, and prevention and treatment of syphilis.

Peter Kerndt, M.D.—Deputy Project Director. Dr. Kerndt shares the responsibility for operational decisionmaking and management of the STAR STI CTG. He holds appointments as Adjunct Professor at the University of California, Los Angeles, School of Public Health, Department of Epidemiology, and as Clinical Professor in the Department of Medicine, Division of Infectious Disease and Preventive Medicine at the University of Southern California Keck School of Medicine. Dr. Kerndt also serves on the Executive Committee of the American Sexually Transmitted Disease Association.

Gwendolyn Maddox, M.S.—Project Manager. Ms. Maddox leads the CC staff, overseeing administrative and business operations for the STAR STI CTG, including subcontracts, budgets, information management, procurement, contract logistics, and communications. She has been with SSS for more than 5 years and was previously the project director for an international research network. She has more than 21 years of experience as a manager and 19 years of experience managing organizations.

Linda Boone—Budget Analyst. Ms. Boone assists with the preparation and review of all STI budgets. She has managed protocols and the protocol site budget process, and has prepared and maintained protocol-specific laboratory, site, and comprehensive budgets for an international research network. She has been with SSS for 12 years.
Jaclyn Ellis, Ph.D.—Biostatistician. Dr. Ellis reviews the STAR STI CTG’s CPs. She has participated in the area of statistical genetic research for more than 5 years. Her past experience includes research in cardiovascular disease, chronic kidney disease, and aging. She has conducted research for the National Heart Lung and Blood Institute, Women’s Health Initiative, and Cooperative Health Research in the Region Augsburg (known as KORA—a regional research organization in Germany). She has been with SSS for 10 months.

Karen Ferebee—Newsletter Coordinator. Ms. Ferebee coordinates the STAR STI CTG’s newsletter activities on a quarterly basis, communicating directly with contributors. Ms. Ferebee has been with SSS for 10 years, where she has supported several international research networks in various capacities. She has extensive experience in word processing and technical writing. Ms. Ferebee was previously a newsletter editor for a small nonprofit organization with a readership of 15,000.

Michaela Hochmuth—Web/Management Information System (MIS) Coordinator. Ms. Hochmuth is responsible for editing, updating, and conducting requirements analyses for the STAR STI CTG Web site, the MIS, and other information systems for the group. She holds a bachelor’s degree in computer studies and worked for 3 years as the MIS and Web site coordinator for an international research network before joining the STAR STI CTG’s CC. Ms. Hochmuth has been with SSS for 4 years.

Sara McCurdy Murphy—CP Coordinator. Ms. Murphy coordinates the CP solicitation process, organizes conference calls, and drafts conference call summaries. She served as the executive committee coordinator for the operations center of a large international research network for 3 years. Before coming to SSS, Ms. McCurdy was a program coordinator for the American Society of Transplant Surgeons. She has been with SSS for 4 years.

Marius Virsilas—Budget Specialist. Mr. Virsilas develops budgets for CPs and tracks and updates the STAR STI CTG’s budget. Before joining SSS, Mr. Virsilas worked for 5 years as a senior project analyst on USAID-funded global trade and investment projects. He has been with SSS for 8 months.

Sagina Wahi—Senior Health Analyst. Ms. Wahi works with the members of the STAR STI CTG Scientific Review Committee (SRC) to review and execute their consulting contractual agreements. She liaises with SSS contracts and accounting staff to manage records and reports on the status of the agreements and payments for the members. Ms. Wahi has been providing similar services and expertise to sites participating in various projects at SSS for approximately 2½ years.

**Update on Concept Proposals**

A CP is the first step in proposing a STAR STI CTG study. It is a three- to five-page outline designed to provide the information needed by the SRC and the National Institute of Allergy and Infectious Diseases (NIAID) Division of Microbiology and Infectious Diseases (DMID) to assess scientific merit, public health impact, feasibility, priority, and potential overlap with other studies—and thereby determine whether submission to DMID for potential protocol development is warranted. Elements included in the CP are:

- Rationale
- Hypothesis
- Objectives
- Design
- Intervention/treatment regimen
- Population
- Sample size
- Clinical/laboratory evaluations
- Study location
- Statistical considerations
- New and/or unique assays or technology
- Available external support or collaboration
- Anticipated ethical concerns
- Estimated cost per subject

The CP is developed by an investigator(s) and then submitted to the STAR STI CTG via the CP submission system located at https://proposals.starstictg.s-3.net. The STAR STI CTG CP Coordinator (CPC) will review the CP to ensure completion and will forward it to the STAR STI CTG PI. If the CP is not complete, the CPC will notify the proposing investigator that a completed CP must be submitted before it can undergo budget, statistical, and SRC reviews. To date, 20 CPs have been submitted for SRC review, 13 of which have been submitted to DMID for consideration.

**2013–2014 Concept Proposal Submission and Review Timeline**

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Overview of the DMID Contract Process

Social & Scientific Systems, Inc. (SSS), partnered with UCLA to form the STAR STI CTG. SSS is the prime awardee, providing administrative, financial, and clinical operations expertise. UCLA is a subcontractor, providing scientific leadership with Dr. Jeffrey Klausner as STAR STI CTG PI. This contract award is an indefinite delivery, indefinite quantity (IDIQ) of services for a fixed time period of July 2013 to July 2020. An IDIQ is used when the General Services Administration cannot determine, above a specified minimum, the precise quantities of supplies or services that the Government will require during the contract period. Work and funding are issued using task orders (TOs) by Request for Task Order Proposals (RFTOP). Each TO has a prescribed scope of work. NIAID/DMID will issue RFTOPs for each TO through a competitive process for which only IDIQ awardees can compete. For this IDIQ, three awards were issued. SSS and UCLA’s first TO award was issued in September 2013 to provide administrative, project management, and overall support of tasks and functions associated with the operations of the STAR STI CTG, including the identification, design, development, and review of CPs for all STAR STI CTG clinical research. The next RFTOP for protocol development and/or implementation is expected to be released soon.

Featured Article

Adapted from the BJOG article “Multipurpose Prevention Technologies: Maximising Positive Synergies,” by M Lusti-Narasimhan, M Merialdi, and B Holt.

The World Health Organization will collaborate with the Coalition for Advancing Multipurpose Innovations (CAMI) to edit a supplement to BJOG. The publication is anticipated in September 2014. This supplement was developed to highlight multipurpose prevention technologies (MPTs). According to the article, greater method choice results in improved method acceptance and continued use. Many agencies worldwide are directing their own research and developing safe and effective MPTs. Ultimately, improved efficiencies with MPTs result in increased protection against health risks and positively address reproductive health needs.


Announcements

• SSS will send new site surveys at the beginning of June requesting update capabilities at each site. Your prompt attention will be greatly appreciated.

• Thank you to the good folks at CAMI for contributing the featured article this month!

• Congratulations to Kimberly Page, Ph.D., M.P.H.! Dr. Page will be joining the University of New Mexico Health Sciences Center as the Chief of Division of Epidemiology, Biostatistics, and Preventive Medicine on July 1, 2014.

• The mission of the STAR STI CTG is to introduce innovation to address new challenges in sexual and reproductive health, support key clinical trials to assess the efficacy of new interventions, and produce clinical research outcomes that will contribute to human reproductive health and specifically lead to the prevention and control of STIs.

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