Request for Consultant Services Proposal (RFP)

Solicitation Title:	Clinical Trials Associate Consultant
Solicitation Number:	FY26-IDCRC-01
Submit Questions and Proposal to:	Charlene Jones (CJones@fhi360.org)
Date of Issue of RFP:	Monday, 15 June 2026
Date Questions from Supplier Due:	Monday, 22 June 2026
Date Answers due from FHI 360:	Wednesday, 24 June 2026
Date Proposal Due:	Monday 29 June 2026
Approximate Timeframe Consultant Agreement Issued to Successful Candidate(s):	Late July

Method of Submittal:
Respond via e-mail with attached document in MS Word / pdf format. Pricing should be provided in Excel format unless otherwise specified.
Quote Validity:
The Consultant agrees to hold the prices in its offer firm for **30 days** from the date specified for the receipt of offers unless another time is specified in the addendum of the RFP.

Background

The Infectious Disease Clinical Research Consortium (IDCRC) is an NIH award to support the planning and implementation of clinical research that addresses the scientific priorities of NIAID in evaluating vaccines, other preventive biologics, therapeutics, diagnostics, including prognostics and predictive markers, and devices or the treatment and prevention of infectious diseases.

FHI 360 has partnered with Emory University to participate in leadership activities and serve as the Protocol Management Center for IDCRC driven research, leading study development and implementation funded by the Division of Microbiology and Infectious Diseases of the U.S. National Institute of Allergy and Infectious Diseases.

Scope of Work

The purpose of this consultancy is to onboard a clinical trial associate, CTA, to perform clinical research closeout activities for four multi-site clinical research studies with senior research staff for the IDCRC. The CTA will closely observe, evaluate, and report on study

closeout progress through study team call participation, study tracking, and monitoring follow up.

The primary role of the CTA II is to assist clinical research teams, specifically the FHI protocol specialist, in closeout by assisting with already shared study site closeout checklists, maintaining filing and tracking systems to coordinate essential regulatory documents for study closeout, drafting and issuing meeting minutes, and facilitating communication. All activities are performed under supervision of the assigned protocol specialist and/or senior staff.

The expected tasks and approximate level of effort of the consultant are listed below. All study acronyms are explained under the table. ***Please note that this is a full-time consultancy. It is expected to work approximately 40 hours/week and attend regular meetings with the study teams.***

Task Description	Estimated LOE
1. **Provide overall administrative support to the clinical research team, such as:** Drafting and issuing meeting minutes for study team calls, including action items and decisions under protocol specialist supervision; tracks action items to resolution. Maintaining email alias lists. Assisting in the coordination of meetings, conferences, and trainings	**ETEC:** 7 hours/month **PROMISE:** 4.5 hours/month **MAGI:** 3 hours/month **Total:** 14.5 hours/month
2. **Maintaining shared filing systems (e.g., SharePoint, MS Teams) and collecting, reviewing, and filing essential regulatory documents** in both the NIH/NIAID/DMID systems (Site Essential Regulatory Documents [SERD] system and DMID SharePoint) and with the FHI 360 filing systems (FHI 360 SharePoint and maintained study-specific electronic Trial Master File, eTMF).	**ETEC**: 2 sites; 12 hours/month **PROMISE**: 3 sites; 16 hours/month **MAGI**: 4 sites; 16 hours/month **Total:** 44 hours/month
3. **Maintaining assigned study sites closeout checklists** by working with sites and study team groups (Laboratory Operations Unit, LOU; Emmes as the Statistical and Data Coordinating Center, SDCC; etc.) to track tasks completion.	**ETEC**: 2 hours/month **PROMISE**: 2 hours/month **MAGI**: 3 hours/month **Total:** 7 hours/month
4. **Assisting assigned study sites with study monitoring activities for final Interim Monitoring Visits, IMVs and Closeout Visits, COVs** to include review of IMV and COV reports and working with sites on action items.	**ETEC**: 2 hours/month **PROMISE**: 2 hours/month **MAGI**: 4.5 hours/month

Task Description	Estimated LOE
	Total: 8.5 hours/month
5. **Communicating directly with assigned study sites** to provide assistance, collect required documents, seek site updates, consulting with protocol specialists as needed.	**ETEC**: 8 hours/month **PROMISE**: 12 hours/month **MAGI**: 8 hours/month **Total:** 28 hours/month
6. **Assist in addressing DMID 22-0019 Doxy study quality control review action items** for study sites eTMF content under the supervision of the clinical research quality specialist.	8 hours total
7. **Complete quality control review of four study sites eTMF content on DMID 22-0019** after being trained by clinical research quality specialist at a set agreed upon timeframe, prior to closing of overall study eTMF room.	8.5 hours total
8. **Complete required sponsor clinical trials training** to include eTMF, SERD, GCP, HSP, and relevant NIH/NIAID/DMID modules	15 hours total
9. **Attend internal team meetings**	4 hours/month

DMID 23-006 ETEC: A Phase 2b, Double-Blind, Placebo Controlled Trial to Evaluate the Efficacy of Intramuscularly Administered CssBA+dmLT against Moderate-severe Diarrhea in a Controlled Human Infection Model with Enterotoxigenic Escherichia coli (ETEC) Strain B7A in Healthy Adults
DMID 24-0003 PROMISE: A Prospective, Randomized, Open-label Phase 4 Study of the Immunology and Safety of Maternal RSV Vaccination (ABRYSVOTM), Infant Nirsevimab (BEYFORTUSTM) Immunization, or Both Products During the First Year of Life
DMID 19-0004 MAGI: A Phase 2 randomized, observer blind, placebo-controlled study, to assess efficacy of meningococcal Group B vaccine rMenB+OMV NZ (Bexsero, GSK) in preventing gonococcal infection
DMID 22-0019 Doxy: A Phase 4 Study of a 3-Day vs. 7-Day Regimen of Doxycycline for the Treatment of Chlamydial Infection

Location of Work: Remote; United States

Travel: N/A

Timetable and Address for Submission

Proposals are due no later than 5:00 PM EDT on Monday, June 29, 2026. Required documentation listed below must be e-mailed to Charlene Jones (CJones@fhi360.org)

Qualifications

- Associate degree or its international equivalent in clinical research, health, behavioural, life or social sciences or other related field; Bachelor's degree preferred
- 1-3 years of experience in clinical research
- Familiarity with applicable clinical research regulatory requirements (i.e., Good Clinical Practice (GCP) and International Conference on Harmonization (ICH) guidelines) is preferred
- Ability to write clearly and succinctly, able to synthesize and summarize information; must be able to accurately record meeting minutes and document action items and decisions. Knowledge of medical and laboratory terminology is preferred.
- Strong interpersonal skills and ability to communicate in a professional, clear and positive fashion
- Ability to work independently and in a cross-cultural team and geographically diverse environment
- Ability to prioritize and multitask, proactively follow-up on tasks, effectively manage time, assess, meet and/or adapt to changing priorities and deadlines effectively
- Proficiency in Microsoft Office 365 (i.e., Word, Excel, PowerPoint, Outlook, Teams)
- Demonstrated effective organizational skills
- Demonstrated strong attention to detail
- Must be able to read, write and speak fluent English

Evaluation Criteria: Proposals will be evaluated in accordance with the following criteria:

- Experience in closing out clinical trials and ability to adhere to FHI IDCRC team's work instructions, internal work instructions, and sponsors' SOPs and MOPs.
- Experience with taking and distributing meeting minutes
- Experience working with multiple databases
- Experience following file naming conventions and filing documents in alignment with internal file structures

Required Documentation: Proposals must include the following components:

- Resume/CV
- Writing samples to include team email communication and meeting minutes as feasible (copies or links)
- Cover letter stating daily rate, in USD

FHI 360 Disclaimers

- FHI 360 may perform a background check on any selected Consultant candidates.
- FHI 360 may cancel the solicitation and not award
- FHI 360 may reject any or all responses received
- Issuance of the solicitation does not constitute an award commitment by FHI 360

- FHI 360 reserves the right to disqualify any offer based on failure of the offeror to follow solicitation instructions
- FHI 360 will not compensate any offeror for responding to solicitation
- FHI 360 reserves the right to issue award based on initial evaluation of offers without further discussion
- FHI 360 may choose to award only part of the activities in the solicitation, or issue multiple awards based on the solicitation activities
- FHI 360 reserves the right to waive minor proposal deficiencies that can be corrected prior to award determination to promote competition
- FHI 360's supplier terms and conditions can be found here while our consultant terms and conditions can be found here