Statement of Work

Title: Biological Therapeutics Product Development Subject Matter Expert Consulting Services to Support the Development of Therapeutic Biotechnology Products (Biologics)

The NINDS has a need for gene-based therapeutics development subject matter expert (SME) consultants to provide technical recommendations and advice that will support the translational development of novel therapeutics (Biologics) for NIH drug discovery and development programs. The support included in this contract will cover chemistry, manufacturing, and controls (CMC) expertise for synthetic oligonucleotides such as antisense oligonucleotides (ASO) and small interfering RNAs (siRNA)

Scope of Work

General Requirements:

Independently and not as an agent of the Government, the Contractor shall furnish all the

necessary services, qualified personnel, material, equipment, and facilities not otherwise provid ed by The Government that are needed to support NIH biologics programs, including NIH BPN programs, URGenT, and HEAL PTDP.

The Contractor shall provide this support on an ad hoc basis or while serving on NIH BPN and HEAL Lead Development Teams (LDTs) and URGENT Multi-Disciplinary Project Teams (MPTs), which include both SME consultants and NIH staff. These teams will map out a product development and clinical evaluation research strategy, including milestones, and oversee manufacturing and nonclinical study services by
Contract Manufacturing Organizations (CMOs) and Contract Research Organizations (CROs).

SME consultants will be expected to provide feedback and guidance on project milestones, development strategy, study design, and data interpretation through in-person meetings, conference calls, and email. Specific consulting responsibilities will depend on the ex pertise of the individual consultant and the needs of individual biologics projects and programs.

Consultants may be involved in multiple projects.

Specific Requirements:

The contractor shall provide consulting services in the following Performance Area(s).

Performance Area 1: Gene-based Therapy Chemistry, Manufacturing and Controls (CMC)

Subject matter experts in process development and/or analytical development of gene and oligonucleotide-based therapies, including but not limited to, ASOs, siRNAs, AAV, lentivirus, and non-viral vector therapeutic modalities. CMC consultants will be expected to provide
chemistry, manufacturing and controls expertise and contribute feedback and guidance on projects to the NIH, project Principal Investigators (PIs) and to LDT/MPT members through conference calls and by email. Additionally, CMC consultants are expected to contribute to regulatory filings (e.g., INTERACT, pre-IND, and IND submissions, among other regulatory documents that may be needed).

The role of the CMC SME consultant may include, but is not limited to, the following

responsibilities and tasks:

a. Review and comment on the adequacy of non-GMP and
   GMP manufacturing, including scale-up, analytical method development and qualification, and process development (upstream and downstream processing) approaches proposed by Principal Investigators (PIs) and CMOs
b. Provide guidance on proposed formulations and delivery methods, which may include
   complex formulations such as polymers, liposomes, and other nanoparticle

   constructs
c. Provide strategy and feedback on process development and manufacturing plans proposed by the PI team and CDMO
d. Provide feedback on therapeutic oligonucleotide sequences and
   synthesis processes proposed by the team, as applicable.
e. Provide feedback on critical quality attributes, release testing, etc.
f. Evaluate CMC data on a weekly or biweekly basis
g. Serve as the CMC expert in order to identify potential product
   manufacturing challenges and suggest strategies to address these challenges
h. Accompany NIH staff or visit, at NIH staff request, CROs and
   CMOs under supporting projects in BPN, HEAL, and URGENT.

i. Inspect facilities and discuss appropriateness of CRO/CMO proposed methodology

j. CMC consultant may be asked to evaluate the potential tractability

(including surrounding IP space) of a proposed therapeutic

k. Collaborate on design of investigative studies in support of therapeutics development projects

l. In partnership with other consultants, contractors, and the NIH staff, advise, strategically plan, and manage CMC to facilitate preclinical evaluation and safety testing, Investigational New Drug (IND) submissions, and clinical studies

m. Facilitate LDT/MPT discussions via telephone and email regarding assigned CMC efforts

n. Provide strategic guidance for the continued development and improvement of the BPN, HEAL PTDP, and URGenT biologics programs

Key Personnel:

The Contractor employee working under this award shall be considered key personnel

Key Personnel requirements are as follows:

General Requirements:

a. Demonstrated senior-level oversight of research and development efforts for gene-based or oligonucleotide therapeutics products
b. A track-record of successfully building and leading therapeutic development teams
c. A significant track
record of scientific accomplishment as evidenced by publications and/or contributions to the development of marketed products
d. Experience in team leadership, consulting, or service on strategic and advisory boards a re desired
e. Must be able to work in a virtual, cross-
functional team environment and manage competing priorities
f. Must participate actively in project team discussions
g. Must have strong interpersonal skills, attention to detail, excellent
organizational, writing, communication, presentation, and documentation skills as well as computer and software literacy

h. Broad experience across the entire biologics discovery and development process is especially desired
i. Must have experience working with multi-disciplinary teams at a senior level preferably in the biopharmaceutical industry, especially teams with members from outside organizat ions and members at various management levels

Education and Specific Work Experience

Requirements:

a. A MS, PhD, or MD in a relevant scientific discipline is preferred. If a BS or MS, must have PhD-level experience in biopharmaceutical industry.
b. Must have at least 10 years of relevant professional experience
c. Must have at least 10 years demonstrated experience in oligonucleotide/siRNA therapy product development
d. Must have at least 10 years of experience in managing or being a senior leader in t therapeutics development projects in the biopharmaceutical industry
e. SME consultants supporting the URGenT program must also have at least 5 years of experience in supporting rare and/or ultra-rare product development programs
f. Experience with biologics development for nervous system conditions is preferred but not required
g. Experience interacting with the FDA or other regulatory authorities preferred
h. Extensive understanding of FDA or other regulatory agency requirements for IND submissions and clinical trial execution (and when applicable for ultra-rare diseases) is preferred

Period of Performance:

The NIH anticipates needing 4 - 5 consultants during this time.

The total period of performance (POP) includes a one-year base period and two (2) subsequent one-year option periods. The anticipated POP dates are as follows:

Base Period: Tentative Start Date - 21 September 2026- September 2027

Option Period One**:** September 2027 – September 2028

Option Period Two**:** September 2028 – September 2029

Place of Performance:

The primary place of performance will be the Contractor site. Conference calls and email will be the primary mode of communication; however, the Contractor may be required to work
at Government facilities or the facilities of selected principal investigators on an as needed basis.

Travel:

The Contractor may be required to travel within the contiguous United States to provide the services described in this SOW. The Contractor shall make its own travel arrangements; the Government shall reimburse all reasonable travel costs up to the Government approved limits.

All travel arrangements must be made in accordance with Federal Travel Regulations in effect at the time of travel and must be approved by the Contracting Officer's Representative and authorized by the Contracting Officer prior to being finalized or invoiced.