TECHNICAL RESOURCES INTERNATIONAL, INC.

Your Partner in Clinical Research

TRI to Support the ACTIV-1 IM Study for Treating COVID-19

Bethesda, Maryland (10/19/2020): Technical Resources International, Inc. (TRI) has been awarded a contract to conduct the Randomized Master Protocol for Immune Modulators for Treating COVID-19 (ACTIV-1 IM) study under the Biomedical Advanced Research and Development Authority's (BARDA) Medical Countermeasures Clinical Studies Network, in collaboration with the National Institutes of Health (NIH). Some COVID-19 patients experience an immune response in which the immune system unleashes excessive amounts of proteins that trigger inflammation — called a "cytokine storm" — that can lead to acute respiratory distress syndrome, multiple organ failure and other life-threatening complications. ACTIV-1 IM will evaluate the safety and efficacy of three immune modulator drugs designed to restore balance to an overactive immune system.

Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) is a public-private partnership led by the NIH and coordinated by the Foundation for the National Institutes of Health (FNIH) to develop a research strategy for prioritizing and speeding development of the most promising COVID-19 vaccines and treatments. ACTIV brings together partners from government, industry, academia and non-profit organizations.

The National Center for Advancing Translational Sciences (NCATS), part of NIH, will coordinate and oversee the trial with funding support provided by BARDA, part of the HHS Office of the Assistant Secretary for Preparedness and Response, in support of the Operation Warp Speed goals. ACTIV-1 IM is expected to enroll approximately 2,100 hospitalized adults with moderate to severe COVID-19 at medical facilities in the United States and Latin America.

The ACTIV public-private partnership selected three agents for the study from a pool of over 130 immune modulators initially reviewed based on several factors including their relevance to COVID-19, strong evidence for use against inflammatory reaction and cytokine storm and availability for large-scale clinical studies. The initial agents are infliximab (REMICADE), developed by Janssen Research & Development, LLC., one of the Janssen Pharmaceutical Companies of Johnson & Johnson; abatacept (ORENCIA), developed by Bristol Myers Squibb; and Cenicriviroc (CVC), an investigational late-stage agent developed by AbbVie.

All participants in the trial will receive remdesivir, which is the current standard of care treatment of hospitalized patients with COVID-19. They will be randomly assigned to receive a placebo or one of the immune modulators as an add-on treatment. The trial will study the different combination treatment regimens with respect to illness severity, recovery speed, mortality and hospital resource utilization.

TECHNICAL RESOURCES INTERNATIONAL, INC.
6500 Rock Spring Drive, Suite 650 Bethesda, MD 20817
Ph: (301) 564-6400 Fax: (301) 897-7400 Website: www.tech-res.com

Under the BARDA contract, TRI and its subcontractors Duke Clinical Research Institute (DCRI) and Syneos Health and Fisher Bioservices will provide full-service capabilities to support the implementation of the study.

About TRI

Technical Resources International, Inc. (TRI) is a full-service contract research organization (CRO). TRI's areas of expertise include clinical trials management, clinical operations, regulatory affairs, medical writing, safety & pharmacovigilance, data management & biostatistics, data analytics and visualization, bioinformatics, quality assurance, training, communications, event planning and management, and information technology. For more than 41 years, TRI has provided support to government agencies, the private sector, and non-profit organizations. Further information is available at www.tech-res.com

TECHNICAL RESOURCES INTERNATIONAL, INC.
6500 Rock Spring Drive, Suite 650 Bethesda, MD 20817
Ph: (301) 564-6400 Fax: (301) 897-7400 Website: www.tech-res.com