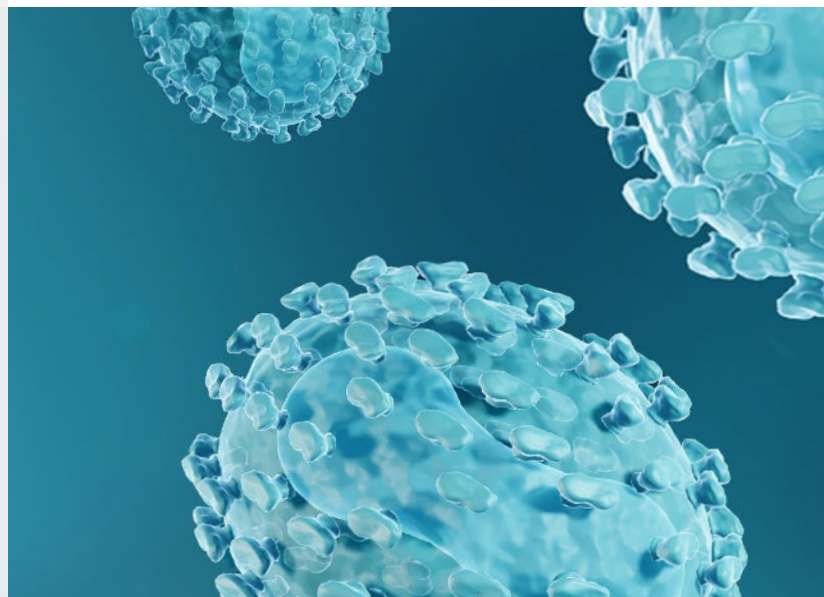


Southern Research Enables Accelerated Timeline for Pharmaceutical Company's Therapeutics for Monkeypox Virus



BACKGROUND/OVERVIEW:

Monkeypox virus (MPXV), the causative agent of mpox disease, is a member of the genus orthopoxvirus, which includes variola virus (VARV)—the causative agent of smallpox. Mpox is a re-emerging viral disease that frequently manifests as a self-limiting infection with symptoms including fever, headache, fatigue, lymphadenopathy, and skin lesions. Although mpox in humans is considered less severe than disease associated with smallpox, fatality rates of up to 10% have been reported with outbreaks caused by the virulent central African clade I MPXV. Per the Center for Disease Control and Prevention (CDC), the National Notifiable Disease Surveillance System reported an outbreak of mpox disease in the year of 2022 that led to more than 93,497 cases worldwide spanning 118 countries—many (7) of which have not been previously considered to be mpox endemic. Although MPXV was known to be predominantly endemic in West and Central Africa, recent large-scale human-to-human transmission caused the World Health Organization to declare it a public health emergency of international concern. In addition, some of the strains of MPXV are select agents which have the potential to pose a severe

threat to public health and safety as well as incite concern for bioterrorism. Currently, there is a very limited number and supply of vaccines that can protect humans against mpox disease—hence further therapeutic interventions are required. Many research laboratories (academic and non-academic) throughout the globe are working to develop vaccines and therapeutic agents against MPXV. Southern Research (SR) is supporting the mission readiness to counter emerging viral infections as part of our pandemic preparedness plan.

THE CHALLENGE:

A medium-sized pharmaceutical company approached Southern Research (SR) to test the efficacy of their therapeutic molecules against highly pathogenic MPXV, Zaire strain in non-human primates (NHPs). Because of the select agent nature of this pathogen, the sponsors required a Titer-1 Biological Safety Level-3 (BSL-3) facility with an approved select agent program to conduct experiments on NHPs. In addition to that, the project also required subject matter experts (SMEs) with high-level expertise in virology, immunology, and animal models—especially NHPs. The sponsor also required

visualization of the whole animal challenge procedures, which involved intra-venous infusion of MPXV as well as intra-venous infusion of their therapeutic agent in real-time from the BSL-3 laboratory that has restricted access. The sponsor also wanted to evaluate the toxicity of their therapeutic molecule and to conduct the pharmacokinetic study at the same time. The sponsors evaluated multiple contract research organizations but could not find a suitable partner due to their unique challenges in the scope of work.

THE SOLUTION:

SR has teams that specialize in screening, testing, and AI-driven optimization of small molecules *in vitro* as well as testing the efficacy of candidates (both vaccines and therapeutics) in animal models (including both small and large animals) against multiple viruses, including select agents like MPXV. Many pharmaceutical companies do not have the infrastructure and skilled personnel to test vaccine efficacy against wild type monkeypox viruses. Also, there are currently very few CROs who have these unique infrastructures and capabilities that can support efficacy testing of vaccines and therapeutics in BSL-3 laboratories as well as toxicity studies in small and large animals against select agents. The sponsor evaluated SR's capabilities and was impressed with the dedicated team of Study Directors (SDs), Project Managers (PMs), highly skilled technicians, scientists performing *in vivo* procedures, veterinary staff, and anatomic pathologists. The study required slow IV infusion, and the clients were seeking the highest testing quality. SR's scientific staff advised on study design including dosing and assays to evaluate the efficacy of the therapeutic agent. The business team arranged meetings with all stakeholders involved. Through honest discussion and continued updates from the SDs and PMs, the study moved smoothly from contract signature to protocol development to animal arrival. The client continued to gain trust in SR's client-focused approach and ability to individual studies based on clients' needs.



RESULTS:

These studies were performed under BSL-3 conditions evaluating the efficacy of a therapeutic agent (monoclonal antibody) against highly pathogenic MPXV, Zaire strain challenge in NHPs. SR's *in vivo* team members showed videos of the challenge procedure as well as the slow IV infusion of the therapeutics. The clients were briefed throughout the in-life part of the study with real-time data. This study was very successful, and the sponsor was very pleased with the service they received at SR. The open real-time communication of data allowed the client team to present the results to stakeholders and team members in their internal meetings. The continuous real-time updates from the dedicated SR team allowed the client to accelerate the planning of their next steps and new studies.