

Southern Research Enables Fortune 500 Pharmaceutical Company to Rapidly File IND Application



BACKGROUND/OVERVIEW:

Seasonal flu (influenza A and B viruses) accounts for approximately 20,000 deaths per year in the United States alone. However, there are other influenza virus strains that pose a serious threat to animal health, food security, and human health—including the Highly Pathogenic Avian Influenza Virus (HPAIV). Even though wild aquatic birds are the natural host reservoir for all influenza strains, HPAIV (H5 and H7 subtypes) have exhibited ability to overcome host range restrictions with the potential to cause zoonotic disease in other species. We are currently experiencing a global pandemic of avian flu, which has killed millions of birds around the world—even penguins in Antarctica. Avian flu has been linked to mammalian animal deaths across continents—sea lions and seals in South America, dolphins in Florida, and polar bears in Alaska. In the instances where poultry flocks are infected, they are often culled in attempts to eliminate the potential spread of the disease impacting food security and prices.

To avoid potential large-scale outbreak among the human population (comparable to SARS-CoV-2), research labs and companies are working to develop the next generation of efficacious vaccines, prophylactics, and therapeutics to treat influenza viruses.

Southern Research (SR) is at the forefront of influenza research and has a pandemic preparedness plan in place to be mission-ready for the next influenza outbreak. Our IDR team has influenza SMEs, a virus bank of emerging influenza strains, multiple established animal models and assays at the ready as part of our pandemic preparedness plan.

THE CHALLENGE:

A Fortune 500 pharmaceutical company approached SR about testing a prophylactic molecule in reducing or preventing influenza infection in the ferret model. For this specific study, the client was looking to assess their target molecule against the more deadly HPAI Select Agent H5N1 strain. In their search, they were seeking an experienced CRO that could effectively test the efficacy of their lead candidate in a HPAI challenge model. The major CRO requirements for consideration of this project:

- Influenza Expertise
- A/BSL-3 with Tier 1 Select Agent laboratory capabilities.
- Highest level of animal care and welfare possible.
- Experience with IV infusion technique(s) in ferrets.
- Established influenza animal models and gold standard assays.

THE SOLUTION:

SR experts felt they could confidently and capably conduct this study to generate quality data to help support this client's efforts to meet regulatory requirements for IND filing or BLA licensure. In fact, they felt SR was uniquely positioned to fulfill the need for several reasons:

1. SR is a full-service CRO with Tier 1 Select Agent A/BSL-3 laboratories with influenza SMEs and operational expertise. In addition, SR has a dedicated team of Study Directors (SDs) who are subject matter experts in virology, animal studies, and immunology.
2. SR takes pride in its AAALAC-accredited, USDA-registered, and OLAW/PHS Assurance for animal care and welfare. SR maintains a highly trained and AAALAC certified animal care staff. The client's evaluations of SR's animal care came back with the highest rating for animal welfare. The client had in-depth discussions with SR's veterinary staff and SDs that focused on the animal model, the challenge virus, and the details of the study protocol.
3. The study required IV infusion, and the client voiced some major concerns. SR veterinary staff showed demonstration videos of the procedure to the client team, and SR's scientific staff advised on dosing and assays to evaluate the efficacy of the study.

SR's project management team expertly arranged for meetings between all stakeholders. Upon contract signature, a dedicated Project/Study Team was assigned, which was composed of a Study Director, Project Manager, and Project Coordinator. The team worked diligently together with internal Operational Core Service teams to ensure effective and efficient execution of the project. From study initiation to final report and closeout of the study, the SR team partnered closely with the client, thereby gaining more trust.



RESULTS:

The study was performed with a Tier 1 Select Agent under A/BSL-3 conditions to evaluate the efficacy of a prophylactic at different dose levels in the ferret HPAI challenge model. While the study was ongoing, the FDA provided feedback to the client, and SR accommodated all recommended changes with minimal turnaround times thanks to the dedicated efforts of the Project Team. The client was briefed throughout the challenge phase of study with real-time data. The SR team provided data in a format that enabled the client to make internal go/no-go decisions to accelerate the planning of their next steps and studies. In addition, the transparent, real-time communication of data allowed the client's team to communicate the results to stakeholders and present data to team members in internal meetings during the study. This project has resulted in a sustained partnership, establishing SR as a trusted CRO partner.