



Study Collaboration Delivers Agility and Results During the COVID-19 Pandemic

Veristat Supports HIPRA’s COVID-19 Vaccine Program to Address Ongoing Global Needs, Culminating in Marketing Authorization of BIMERVAX®

HIPRA, a European multinational pharmaceutical company, engaged Veristat to support several international studies to test the efficacy, tolerability, and safety of its RBD dimer recombinant protein vaccine, branded as BIMERVAX®, against SARS-CoV-2. Having specialized in veterinary vaccines over its 50 years, HIPRA relied on Veristat’s extensive human vaccine experience to help the company swiftly progress through its clinical trials.

Veristat and HIPRA collaborated to demonstrate the benefits of BIMERVAX® in adult populations which included immunocompromised adults as part of the RBDCOV Project. HIPRA engaged Veristat across clinical studies, encompassing the planning and implementation of the pertinent scientific, operational, and biometrics aspects of the clinical trials.

Study Demographics



Indication:
COVID-19



**Phase II–III
Multi-Center
EU Study**
(Spain, Italy, Turkey)



Primary Services Provided

- Project Management
- Clinical Monitoring
- Medical Monitoring
- Biostatistics & Programming
- Data Management
- Medical Writing



Challenging projects with tight timelines and fast-moving working environments as experienced with the HIPRA project require exceptional teamwork across internal teams and excellent communication so that each of us can deliver on-demand. This approach facilitated such a huge achievement. I am proud to work with such a dynamic and experienced team and congratulate HIPRA on the marketing authorization of BIMERVAX®!”

—Principal Data Manager, Veristat

SOLUTION

Comprehensive Support of End-to-End Study Requirements

Throughout the trials, the Veristat team worked diligently to:

- Devise a series of check-ins and communication tools to ensure that every stakeholder had the needed visibility into the trials and their status to support strong operational efficiency and informed decisions
- Successfully accelerate the site start-up process
- Enact bold steps to overcome the study's stringent inclusion and exclusion criteria and avoid delays and support those sites challenged by slow recruitment
- Produce priority top-line results to the EMA in two weeks as a result of Veristat experts working collaboratively on the front lines of data management, biostatistics, medical affairs, and medical writing
- Provide requested clinical data to the sponsor to answer EMA questions as part of the rollover submission program to support gaining full authorization in Europe
- Veristat's Data Management and Clinical Database Programming team underwent frequent data cleaning processes to ensure clean data was made available for EMA submissions as part of the rollover review process. The team is especially proud of our achievements for HIPRA in the RBDCOV project, having designed, developed, and deployed an EDC database which took an impressive 10–30 days from design start to full deployment
- Contribute to the design of the pediatric program for the submission of the PIP (Pediatric Investigational Plan), for which study the Veristat team is poised to support as part of the RBDCOV project

IMPACT

Stepping up to Address the Impact of COVID-19 with Authorization from EMA

HIPRA received marketing authorization from the EMA for BIMERVAX® on 30 March 2023.

Creating a positive, productive work environment was pivotal in our ability to overcome the intensive challenges brought forward in the development of a COVID-19 vaccine, including the speed of events that required Veristat's immediate, yet accurate responses.

Veristat is proud to support HIPRA in the clinical trials for this new vaccine to protect society, including those more vulnerable.



Contact Veristat Today

At Veristat, we have scientific-minded experts ready to advance your vaccine through the regulatory hurdles, recruitment challenges, and approval process to safely bring vaccines to market, having supported 160+ vaccine projects to date.

To learn more about Veristat or how we can assist you in determining if our expertise meets your needs, reach out to us today.

www.veristat.com