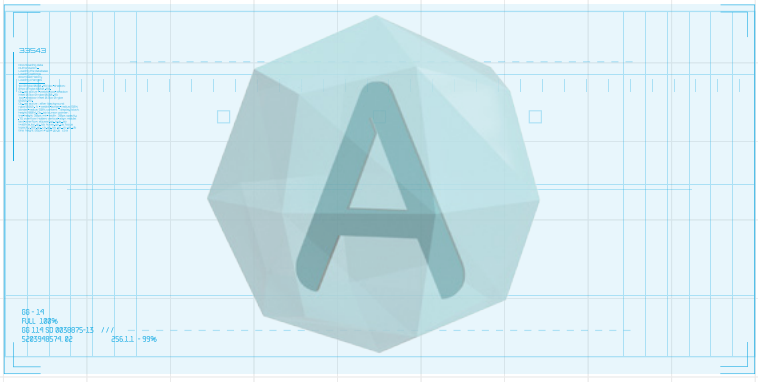
A challenge for Nubilaria: Two studies to support patients affected by COVID-19



At the beginning of the pandemic due to SARS-CoV-2, Nubilaria was required to provide support to Inmunova, an Argentine biotechnology company, for the implementation of two studies regarding its investigational treatment for moderate to severe COVID-19 disease.

Both studies were conducted in Argentina:

1. A randomized, multicentre, double-blind, placebo-controlled, adaptive Phase 2/3 clinical trial to assess the pharmacokinetics, safety and efficacy of a hyperimmune polyclonal equine serum anti-SARS-COV-2 in hospitalized adult patients with moderate and severe COVID-19.
2. A post-registration pharmacovigilance follow-up study for the monitoring of efficacy, effectiveness and safety of the hyperimmune polyclonal serum.

For the first study:

The short delivery time was the most critical factor.

The Sponsor needed to have the eCRF ready and online for Regulatory Approval by a precise date and this compelled us to a mandatory Go-Live term that allowed for no delays.

We created the eCRF and provided Randomization, Clinical Data Management services and customized Reports to monitor the study progression.

We setup the database as well as a provision of information retrieval and export tools.

We also hosted the project on a secure and validated platform.

About the second study:

The most critical factor was the configuration of a multi-player, highly complex Drug Management system capable to support the entire cycle.

We created the eCRF and the configuration of a broad and highly automatized Drug Management platform.

We setup the database as well as a provision of information retrieval and export tools, as we did for the first study. We hosted the project on a secure and validated online platform.

In addition to that, we configured the database to allow the expansion of the study to each new country within 5 working days from the formal request.

The outcomes:

Regarding the first study, the database setup began on July 1st 2020 and the eCRF Go-Live on July 17th 2020, basically there were 16 working days from the first requirements to delivery.

The data collected in the Phase 2/3 clinical trial and the results obtained showed a reduction in mortality, hospitalization in intensive care, and the requirement for mechanical ventilation.

Based on these results, the Argentine regulatory authority –National Administration of Medicines, Food and Medical Technology– approved the use of the hyperimmune serum anti-SARS-CoV-2 for the treatment of adult patients with moderate to severe COVID-19. The approval was under an emergency use authorization registry, in pandemic conditions, expanding the study of its clinical effects through an efficacy, effectiveness and safety monitoring plan during a year. In this sense, the second study in which Nubilaria has been involved in the setup of the database as well as a drug's provision of information, has allowed collecting data from more than 10,000 treated patients in a very short time span (less than a year).

This large database in now being used by Inmunova for the conduction of a Phase 4 Clinical Trial, which will support the drug's marketing authorization.