

[Press Release]

LSK Global PS to Conduct Global Phase III Trial of Sinovac's COVID-19 Vaccine Candidate

- **The phase III global clinical trial of the COVID-19 vaccine candidate will involve about 4,200 front healthcare workers in Dhaka, Bangladesh.**
- **The large phase III trial is a non-contact trial designed to be managed remotely instead of using a conventional face-to-face approach.**

[September 1, 2020] LSK Global Pharma Services Co., Ltd. (LSK Global PS), a leading contract research organization (CRO) in Korea, announced today that it would be conducting a phase III clinical trial of "PiCoVacc", a COVID-19 vaccine candidate being developed by China's Sinovac Biotech, in Bangladesh.

This clinical trial will involve about 4,200 frontline healthcare workers at 7 hospitals in Dhaka, Bangladesh. Bangladesh has the second highest number of COVID-19 cases in Asia, with more than 300,000 confirmed cases so far.¹ The seven hospitals chosen as clinical sites have focused on treating COVID-19 patients, leading to high rates of infection among health workers and further making it difficult to respond to the virus. To reduce secondary infections in healthcare workers and prevent the spread of COVID-19 effectively, therefore, the participants of the trial will include doctors and nurses working at the hospitals.

In addition, due to concerns over COVID-19, the trial will be managed remotely with non-contact interventions instead of taking the traditional site-centered approach. Procedures including pre-tests, informed consent and administration of the vaccine are carried out face-to-face while online tools and an ePRO solution will be used for additional informed consent and reporting of the health conditions of the participants. Clinical data will be sent directly to LSK Global PS's database and monitored remotely without investigators having to visit the site through the use of an e-source data management tool.

The advantage of non-contact clinical trials is that a high-quality patient-centered clinical trial can be conducted with reduced cost and time. In industrialized countries, therefore, non-contact trials are now conducted often and have increasingly become established as the "new normal" in the age of the COVID-19 pandemic. To respond to the changing landscape, LSK Global PS has also prepared for remote clinical trials for years.

LSK Global PS has adopted Target Health's eSource system for remote management of clinical trials and more recently in July this year, deployed Veeva Systems' eTMF, CTMS and

SiteVault Free for remote monitoring. Being the first Korean CRO to be fully equipped with solutions for non-contact clinical trials, the company is now confident about conducting many parts of the large phase III clinical trial in Bangladesh remotely, a first for Korea.

"We are so honored and humbled to conduct a large global phase III clinical trial as countries around the world continue to grapple with the rising number of confirmed cases and deaths amid the prolonged COVID-19 pandemic," said Young-Jack Lee, CEO, LSK Global PS. "We have prepared ourselves for non-contact clinical trials for years to reflect the changing clinical trial environment and believe that we are in good shape to complete this clinical trial successfully."

LSK Global PS is already conducting three clinical trials of COVID-19 vaccine candidates and one of COVID-19 treatment and is also working on two additional vaccine trials.

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¹ Trends in COVID-19 outbreak in Korea, and cases in other countries, COVID-19 website, the Korean Centers for Disease Control and Prevention
http://ncov.mohw.go.kr/bdBoardList_Real.do?brdId=1&brdGubun=14&ncvContSeq=&contSeq=&board_id=&gubun=, Last accessed on 31st Aug