

## Bio Farma Clinical Trials Phase Three of BUMN COVID-19 Vaccines in West Sumatra and South Sulawesi



(Left-right): Director of Padang Pariaman Hospital Dr Jasnelli MARS, President Director of Bio Farma Honesti Basyir, Kadinkes Padang Pariaman dr H Aspinuddin and Main Researcher of the Unand Medical Center Dr. . Asrawati, made a visit to the Phase 3 Clinical Test Center for the Covid 19 Vaccine BUMN, where 1700 West Sumatra volunteers participated from a total of 4,050 volunteers nationally.

(Padang Pariaman 12/7) Bio Farma held a phase three clinical trial of the BUMN Covid-19 vaccine at the Padang Pariaman Regional General Hospital, West Sumatra, Tuesday (12/7/2022). Similar activities were held simultaneously at the Binamu City Health Center, Jeneponto, South Sulawesi.

The phase three clinical trial of the BUMN Covid-19 vaccine in Padang Pariaman was directly reviewed by the President Director of Bio Farma, Honesti Basyir; Director of Finance, HR & Risk Management IGN Suharta; Senior Executive Vice President (SEVP) Bio Farma Production, Juliman; and SEVP Research and Development of Bio Farma, Adriansjah Azhari. The event was also attended by the Deputy Regent of Padang Pariaman, Rahman; Dean of the Faculty of Medicine, Andalas University (Unand) Afriwardi; Padang Pariaman Police Chief, AKBP M Qori Oktohandoko; Director of Unand Hospital, Yevri Zulfiqar; and the Head of the Padang Site Clinical Trial Team, dr. Asrawati.

In his remarks, the Deputy Regent of Padang Pariaman Rahman admitted that he was proud that his region was trusted to be the site of the third phase clinical trial of the COVID-19 vaccine for BUMN. "Alhamdulillah, Padang Pariaman is one of the clinical trial sites with the most samples," he said.

Head of the Research Team for Phase 3 Clinical Trials at the Padang Pariaman and Padang Sites, Asrawati noted that the phase three clinical trials of the BUMN Covid-19 vaccine in Padang Pariaman Regency and Padang City involved 1,725 volunteers: aged between 18-70 years, in good health, and had never exposed to the Covid-19 virus. Each volunteer will get two injections within a span of 28 days.

Asrawati explained that the phase three clinical trial of the BUMN Covid-19 vaccine had entered the second injection. The volunteers will be monitored for the next year to ensure the safety and effectiveness of the vaccine in generating immunity in the body.

When reviewing clinical trial activities in Padang Pariaman, Bio Farma President Director Honesti Basyir said the BUMN Covid-19 vaccine was a manifestation of the independence of the Indonesian nation during the pandemic, this was a milestone in the achievements of the nation's children.

According to Honesti, the BUMN Covid-19 Vaccine proves that Indonesia is able to make vaccines from upstream to downstream independently. The entire process of making the vaccine is carried out by the nation's children. He emphasized that this would not be possible without collaboration between researchers, educational institutions, industry, and the government.

“Next, Bio Farma will wait for the issuance of the EUA from the POM. Bio Farma is currently waiting for the results of the Halal audit conducted by LPPOM MUI. God willing, it meets the Halal criteria. We hope that these two certificates will appear at the end of July,” Honesti said.

Honesti said the BUMN Covid-19 vaccine will be used for the first and second doses of adult vaccines. Meanwhile, the use of the third dose of vaccine (booster) will pass clinical trials in the near future. He also hopes that in the future this vaccine can be used for primary doses and booster doses for children (aged 6-17 years).



(Left-Right): Bio Farma Operations Director M Rahman Roestan, Jeneponto District

Secretary Muhammad Arifin Nur, Dr. Dra. Lucia Rizka Andalucia, Apt, M.Pharm, MARS Director General of Pharmacy and Medical Devices, Ministry of Health, Dr. dr. Martira Maddeppungeng, Sp.A(K) Principal Investigator/Principal Researcher and Sri Harsi Teteki Director of Institutional Relations Bio Farma, held a press conference after reviewing the COVID-19 Vaccine Clinical Trial of BUMN in Jeneponto, South Sulawesi

Meanwhile, a review of the BUMN Covid-19 vaccine clinical trial in Jeneponto was carried out by Bio Farma's Director of Operations, Rahman Roestan, and Bio Farma's Director of Institutional Relations, Sri Harsi Teteki. The activity was also attended by the Regent of Jeneponto Regency, Iksan Iskandar. The clinical trial in Jeneponto was also attended by the Director General of Pharmacy and Medical Devices (Farmalkes) of the Ministry of Health (Kemenkes) Lucia Rizka Andalucia. During the review, Rizka appreciated the involvement of the community, health workers both in hospitals and health centers and the Jeneponto Regency Government in the success of phase three clinical trial of the vaccine produced by Bio Farma.

"There is one critical stage that must be passed in the manufacture of vaccines, namely the clinical trial stage to be given permission and can be used by the community," said Rizka.

Rizka hopes that this domestically produced vaccine will not only be used by the people of Indonesia but can also be exported for use abroad.

This review of the phase three clinical trial of the BUMN Covid-19 vaccine in Padang Pariaman and Jeneponto is part of the "Anniversafari", which is a series of activities to commemorate the 132-year anniversary of Bio Farma on August 6, 2022, where the Board of Executives of Bio Farma will visit work to the region to review the implementation of the COVID-19 vaccine clinical trial for BUMN and greet the BUMN Pharmaceutical team in the area. Since 2020, Bio Farma has become a Pharmaceutical BUMN Holding with Kimia Farma and Indofarma as subsidiaries.

In addition to reviewing phase three clinical trials, Bio Farma also implements a Social and Environmental Responsibility (TJSL) program. Bio Farma handed over twenty-seven sacrificial animals which were distributed in Mataram, Jeneponto, Padang Pariaman, and several other cities in Indonesia.