

## VAC\_17 - Pharmacovigilance Committee for COVID-19 vaccine (ChAdOx1-S [recombinant]) and its contribution for an effective benefit-risk assessment

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**Introduction:** An increased number of adverse events following immunization (AEFI) reports are expected during mass vaccination campaigns, since general population and surveillance teams are more attentive of its importance. Considering this current situation, the need to implement additional strategies for an effective benefit-risk assessment of the covid-19 vaccine produced by Bio-Manguinhos/Fiocruz arose. One of the actions initiated by the Clinical Advisory Unit was the establishment of a Pharmacovigilance Committee for COVID-19 vaccine (ChAdOx1-S [recombinant]) to discuss rare and serious reports of AEFI.

**Objective:** Describe the contributions of the Pharmacovigilance Committee for COVID-19 vaccine (ChAdOx1-S [recombinant]).

**Methodology:** A descriptive narrative essay on the Pharmacovigilance Committee for COVID-19 vaccine (ChAdOx1-S [recombinant]) was proposed.

**Results:** The Pharmacovigilance Committee for COVID-19 vaccine (ChAdOx1-S [recombinant]) brought together AstraZeneca Brazil, Bio-Manguinhos/Fiocruz and *ad hoc* specialists in April 2021. As the discussions progressed, National Immunization Program (NIP), National Regulatory Agency (NRA), and local AEFI surveillance representatives joined the group until December 2021. Virtual meetings were carried out to review and discuss selected AEFI for causality assessment. The group has been strengthened with the emergence of Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT) cases, a very rare AEFI with viral vector platform vaccines. There were 27 meetings in the period, where 50 individual case safety reports (ICSR) were discussed, including 32 suspected ICSR of VITT. The committee supported the implementation of PF4-antibodies detection by enzyme-linked immunosorbent assay (ELISA) at the State Institute of Hematology of Rio de Janeiro (Hemorio). This laboratory test for the diagnosis of VITT was previously unavailable in the Brazilian Public Health System (SUS). Furthermore, the group collaborated in the development of a standardized guide for the diagnosis and management of the disease, and carried out educational medical activities to increase awareness regarding this AEFI. This work also supported the publication of a NIP technical document containing recommendations and guidelines for the investigation of post-vaccination VITT in Brazil.

**Conclusion:** Continuous dynamic thinking and fast proactivity in the detection, assessment, understanding, prevention and communication of AEFI can contribute to interrupt rumors and raise confidence on the immunization program consolidated over decades.

**Keywords:** COVID-19 vaccine (ChAdOx1-S [recombinant]); Pharmacovigilance; Vaccine-Induced Immune Thrombotic Thrombocytopenia