

VAC_04 - Adverse event profile of ChAdOx1 nCoV-19 vaccine (AZD1222) in Brazil: Comparison between Bio-Manguinhos/Fiocruz post-marketing surveillance database and clinical trials

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Introduction: Since March 2021, ChAdOx1 nCoV-19, the covid-19 vaccine produced by Bio-Manguinhos/Fiocruz, has been authorized in Brazil and is used in mass immunization campaigns with more than 120 million doses applied in the country.

Objective: The aim of this study was to characterize the Brazilian post-marketing safety profile of the vaccine compared with the pre-registry safety information. In Phase III clinical trials, the most identified non-serious AEFI were pain and tenderness at the injection site, headache, fatigue, myalgia, malaise, fever, chills, and nausea.

Methodology: It was proposed a retrospective descriptive analysis of Bio-Manguinhos/Fiocruz pharmacovigilance database. The absolute and relative frequencies of AEFI reported between March and December 2021 were included in the study. The assessment was conducted to verify the profile of the reported adverse events (AEFI) and compare with pre-registry information.

Results: During the period of analysis, we received 114.129 AEFI, being 109.992 non-serious (96,3%). The majority of events were received in our online form (95,4%) and were non-health professional reports (111.009 non-HCP). Regarding the age of the person that presented the AEFI, most cases were in people 60 years old or less (81,3%). The top ten reported AEFI were pyrexia (13,9%), headache (12,2%), pain at injection site (11,4%), chills (10,9%), myalgia (10,1%), fatigue (8,5%) malaise (7,5%), arthralgia (5,7%), nausea (4,5%), tenderness (4,1%), induration at injection site (3,3%), edema at injection site (2,4%) and erythema at injection site (1,2%). These events account for 95,6% of all adverse events received in the period and all are listed in the product label as common or very common. One adverse event of special interest that was first reported in post-marketing use was the vaccine-induced thrombotic thrombocytopenia (VITT). We received in this period a total of 40 reports of suspected VITT and we are closely monitoring the scenario in Brazil.

Conclusion: Our study showed that the vast majority of the AEFI reported to Bio-Manguinhos/Fiocruz in the post-marketing period were non-serious and comparable to the findings of the Phase III trials. The study also showed no new emerging trends in serious AEFI besides VITT. Although this is a descriptive study and the findings cannot be extrapolated to a populational level, it shows a safety profile that matches literature and PV data from other countries.

Keywords: Recombinant COVID-19 vaccine; Adverse events