

## Considerations on the study of drugs and vaccines in women during the COVID-19 pandemic. The EMA perspective

Marco Cavaleri

Head of Biological Health Threats and Vaccine Strategy, EMA

During the pandemic, several clinical trials for the treatment or prevention of COVID-19 have been conducted with new or repurposed therapeutics and with investigational vaccines.

Some of these studies were large randomized controlled trials that led to the approval of new vaccines or to recommending the use of therapeutics for COVID-19.

In the context of such studies, women were generally included in a satisfactory proportion versus men. In the trials of therapeutics such as the studies conducted with remdesivir, baricitinib and dexamethasone, at least one third of the patients enrolled were women, reflecting the current proportion of COVID-19 female cases requiring hospitalization and oxygen supplementation. Interestingly, studies with immunomodulators showed some trends towards a reduced effect of the treatment in female patients compared with males, who suffer from a worse prognosis. However, other co-variables may have played a major role in explaining such difference, and more data need therefore to be collected.

With respect to vaccines, it is well known that sex is a predictor of susceptibility to specific infections and autoimmune diseases, but it can also influence the response to immunization, which is why it is appropriate to have an adequate representation of females in the clinical trials with vaccines.

Pivotal clinical trials conducted to support the approval of COVID-19 vaccines resulted in an equal enroll-

ment across gender. The overall safety and efficacy profile did not differ between males and females for all the vaccines approved. From a safety perspective, the emergent cases of thrombosis with thrombocytopenia with the two approved viral vectored vaccines were reportedly more prevalent in females than males. More data are needed to further characterize the incidence of this risk by age and gender.

Overall, during the pandemic large clinical trials to support the approval of vaccines and therapeutics included women to an adequate extent. Such effort allowed for the regulatory assessment of the safety and efficacy of vaccines and therapeutics also in females, thus further supporting their approval.

**Keywords.** Drugs, vaccines, COVID-19, women.

*Conflict of interest:* the Authors declare that they have no competing interests.

---

*Correspondence to:*

**Marco Cavaleri**

Head of Biological Health Threats and Vaccines Strategy

EMA (European Medicines Agency)

Amsterdam, The Netherlands

email: marco.cavaleri@ema.europa.eu