Press release
June 24

Significant advancements and a fifteen-month extension for the RBDCOV Project

The European Commission has granted a fifteen-month extension to continue with the RBDCOV Project. So far, 240 volunteers have been recruited within all the centres set to join adolescents' clinical trial (named HH3) to test the efficacy, tolerability, and safety of the BIMERVAX® COVID-19 vaccine in adolescents aged 12 to 17.

Extension of the RBDCOV Project

The European Commission has granted a fifteen-month extension to the RBDCOV project, shifting the completion date from May 31, 2024, to August 31, 2025. This change will allow to achieve the expected number of volunteers to complete the clinical trials and meet the project's goal to investigate the efficacy, tolerability, and safety of the BIMERVAX® COVID-19 vaccine in children and adolescents.

The vaccine, developed by the pharmaceutical company HIPRA, received approval from the European Medicines Agency (EMA) last year as a booster in people aged 16 years and above previously vaccinated with two doses of COVID-19 mRNA vaccine.

Progress with the Study with Adolescents Aged 12 to 17

The HH-3 trial, launched in May 2023, has been focusing on determining whether BIMERVAX® booster dose safe in adolescents aged 12 to under 18 and to confirm if this booster dose increases the immune response (defences) against COVID-19.
The number of volunteers has steadily grown, with over 200 adolescents now taking part in this study. To reach the target of 300 volunteers, **two new Primary Care Centres (CAP) - CAP de Peralada in Girona and CAP de Centelles in Barcelona –** have been added in the clinical trial.

What's Next: Study with Children Aged 5 to 11

After the HH-3 study is completed and data from the 300 participants are analysed, a study with another paediatric group will be conducted. Due to the promising initial results of the HH-3 study, an authorisation request has been submitted to the EMA to conduct the HH-6 study with children aged 5 to under 12.
The first part of the HH-6 study will involve exploring different dosages ("dose-finding") to evaluate and determine the optimal dose of the vaccine that balances efficacy and safety considerations, maximising therapeutic benefits while minimising side effects.
The second part of the study, examining the ability of the vaccine to elicit an immune response ("immunogenicity") over a year-long period is seeking to confirm the positive preliminary results observed in adolescents among children aged 5 to 11. These immunobinding studies will allow extrapolation and comparison of vaccine effectiveness data between the two groups.

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Results in Adults living with Immunocompromising Conditions

In earlier phases of the RBDCOV project, the BIMERVAX® vaccine was tested in adults with immune systems potentially less responsive to vaccines. This study included 240 volunteers with immunocompromising conditions, such as individuals who have received a kidney transplant or have chronic kidney disease, people on a dialysis programme, people living with primary immunodeficiencies, people with HIV and individuals with an autoimmune disease undergoing treatment with rituximab (a medication used to treat certain autoimmune diseases and blood cancer).

Vaccination Centres: study with adolescents aged 12 to 17 (HH3)

Parents or guardians of minors interested in participating in this study can contact the research team via email or phone:

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