

The study listed may include approved and non-approved uses, formulations or treatment regimens. The results reported in any single study may not reflect the overall results obtained on studies of a product. Before prescribing any product mentioned in this Register, healthcare professionals should consult prescribing information for the product approved in their country.

Statement on cancellation before enrollment of the study and results availability- 217354 (RSV MAT-039)	
Name of Company: GlaxoSmithKline	
Study No: 217354 (EudraCT# 2021-004003-41)	
Product: GSK3888550A	
Title: A study to evaluate the safety and immune response to an unadjuvanted RSV maternal vaccine in healthy non-pregnant females from 9 to 49 years of age.	
Phase: III	
Study Period: NA	
Centres: None in EU/ EEA; 2 centres in US	
Number of Subjects: 9 enrolled in US	
Publications: NA	
<p>Statement on cancellation before enrollment of the study and results availability: There was no enrollment in the EU country planned (Spain) for this study. Therefore, the study was cancelled before enrollment in the EU, while the study was completed in the US for the 9 enrolled subjects.</p> <p>This study is no longer in scope of Article 46 of the European Union Pediatric Regulation (EC No. 1901/2006, as amended) as the only pediatric participant enrolled in this study received the investigational RSV Maternal vaccine but not the Boostrix vaccine (marketed in EU) planned to be administered in the study and following the company's decision to stop further enrollment and vaccination, no pediatric data on Boostrix were collected from this study.</p> <p>As the study continues to be a part of the Pediatric Investigational Plan (PIP) in the EU, GSK will continue to fulfil remaining disclosure obligations for its candidate RSV MAT vaccine on Clinicaltrials.gov, GSK and EU clinical trials registers as required by current regulation and company policy.</p>	