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 of Results status for the study
Name of Company: GlaxoSmithKline
Study No: 204889 (EudraCT#2016-000290-20)
Product: GSK3536851A; SB257049
Title: Phase IIb randomized, open-label, controlled, multi-center study of the efficacy, safety and immunogenicity of GSK Biologicals' candidate malaria vaccine RTS,S/AS01E evaluating schedules with or without fractional doses, early Dose 4 and yearly doses, in children 5-17 months of age living in sub-Saharan Africa (Malaria-094).
Phase: IIB
Study Period: This study is ongoing with an anticipated end date of 15 Dec 2022. Study start was on 28-Sep-2017.
Centers: 2
Number of Subjects: 1500
Statement on results availability: Malaria-094 is no longer in scope of Article 46 of the European Union Paediatric Regulation (EC No. 1901/2006, as amended). The study is evaluating GSK's candidate malaria vaccine RTS,S/AS01E, which received an EMA positive Scientific Opinion following application in accordance with Article 58 of Regulation (EC) No. 726/2004. The study was initially in scope of Article 46 because GSK was the marketing authorization holder of the vaccine Rabipur used as a control in this study. Since July 2021, all EU/EEA marketing authorizations for Rabipur have been transferred to Bavarian Nordic. Therefore, GSK has no obligations under Article 46. GSK will continue to fulfil remaining disclosure obligations for its candidate malaria vaccine RTS,S/AS01E on Clinicaltrials.gov and GSK registers as required by current regulation and company policy.