

## SAP CDC4G : Clarifications and corrections

### 1. Clarifications

SAP version 8, published ISRCTN 41918550	Matter	Clarification
4.4 Baseline patient characteristics 4.4.4 GDM group HbA1C at first visit	In study protocol paper (SPP) HbA1c is stated as an outcome. In the SAP, HbA1c is used as a baseline characteristic.	HbA1c test is not an outcome and is only registered for women with GDM needing medical treatment.
5.1 Outcome definition	Change of secondary maternal and neonatal outcomes in SAP from the pre-defined outcomes in study protocol paper.	The decision to change secondary outcome variables for main analyses was carefully evaluated by steering group and justified based on new publications after study protocol was published (1).

### 2. Corrections

SAP version 8	Corrections	Justification for change
5.1.4.2 Neonatal outcomes	5.1.4.2 Neonatal outcomes added <ul style="list-style-type: none"> <li>Gestational length (days)</li> <li>SGA &lt;2SD</li> <li>Birthweight (g)</li> </ul>	Gestational length (days) and weight (g) added for comparison in pre-post group. SGA <2SD was added due to its clinical use in Sweden.

1. Egan AM, Bogdanet D, Griffin TP, Kgosidialwa O, Cervar-Zivkovic M, Dempsey E, et al. A core outcome set for studies of gestational diabetes mellitus prevention and treatment. Diabetologia 2020;63(6):1120-7.