Using routine data for trials and parallel sample collection studies – the GBS3 – iGBS model

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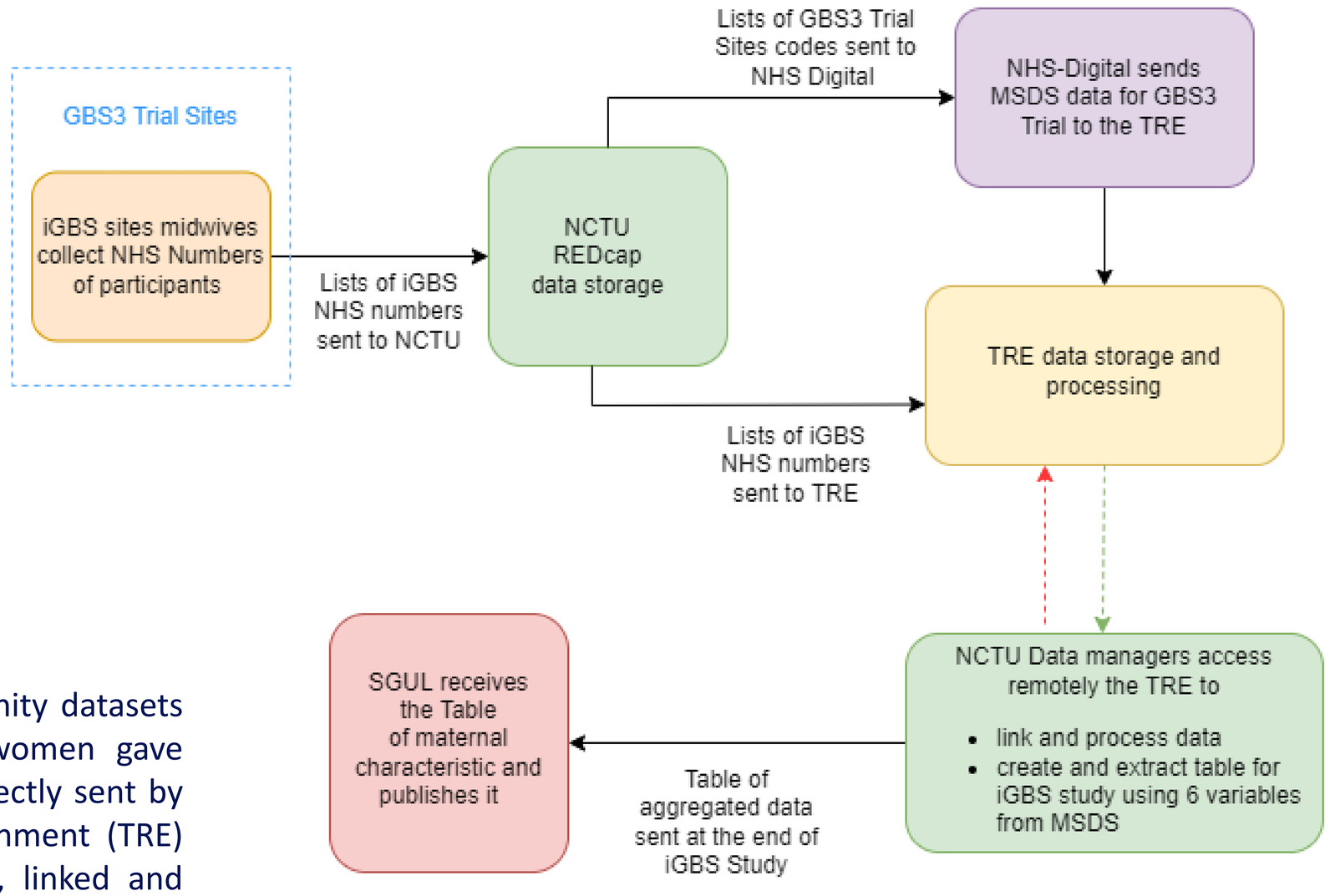
Background

The GBS3 Trial (ISRCTN49639731) assesses whether universal testing of pregnant women for Group B Streptococcus colonisation reduces early-onset neonatal sepsis, compared to the current UK risk-factor based strategy. Approximately 320,000 pregnant women from 80 maternity units in England, Scotland and Wales are needed for this cluster randomised trial. GBS3 provides a platform for collection of umbilical cord blood samples for a parallel study, iGBS (NCT04735419), to determine a serocorrelate of protection for future GBS vaccine studies. GBS3 and iGBS have different sponsors but require similar descriptive data. We describe a model where data can be shared between studies to avoid parallel requests to routine data providers and unnecessary transfer of personal identifiable information.

Methods

Nottingham Clinical Trials Unit (NCTU) has obtained the approval for GBS3 to use routinely collected health data without consent from the Confidentiality Advisory Group for England and Wales, and the Scottish equivalent. iGBS study, coordinated by St George's University of London (SGUL), has obtained a favourable ethics opinion for oral consent to collect cord blood. To define the GBS3 trial population and obtain descriptive data, e.g. ethnicity or gestational age at birth, GBS3 is requesting the Maternity Service Dataset (MSDS) from NHS Digital for England and Scottish and Welsh equivalents. iGBS study requires descriptive data of their population (a subset of the GBS3 population) which will also enable accrual data to be submitted for the Clinical Research Network portfolio.



The GBS3 trial population is defined from maternity datasets through participating hospitals' codes where women gave birth within the trial time window. All data is directly sent by the data provider to a Trusted Research Environment (TRE) where is safely stored and remotely processed, linked and analysed by designated analysts. Maternity units will provide the GBS3 team with personal identifiers for women consenting for iGBS study, who will be extracted from the maternity datasets within the TRE. Aggregate data will be tabulated for the iGBS sponsor. A data sharing agreement between the sponsors is in place.

Relevance and impact

Our approach overcomes some of the limitations of the traditional individual and manual approach, enabling a large study at lower cost. We have avoided duplication of the process for a parallel sample collection, reducing research waste.

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