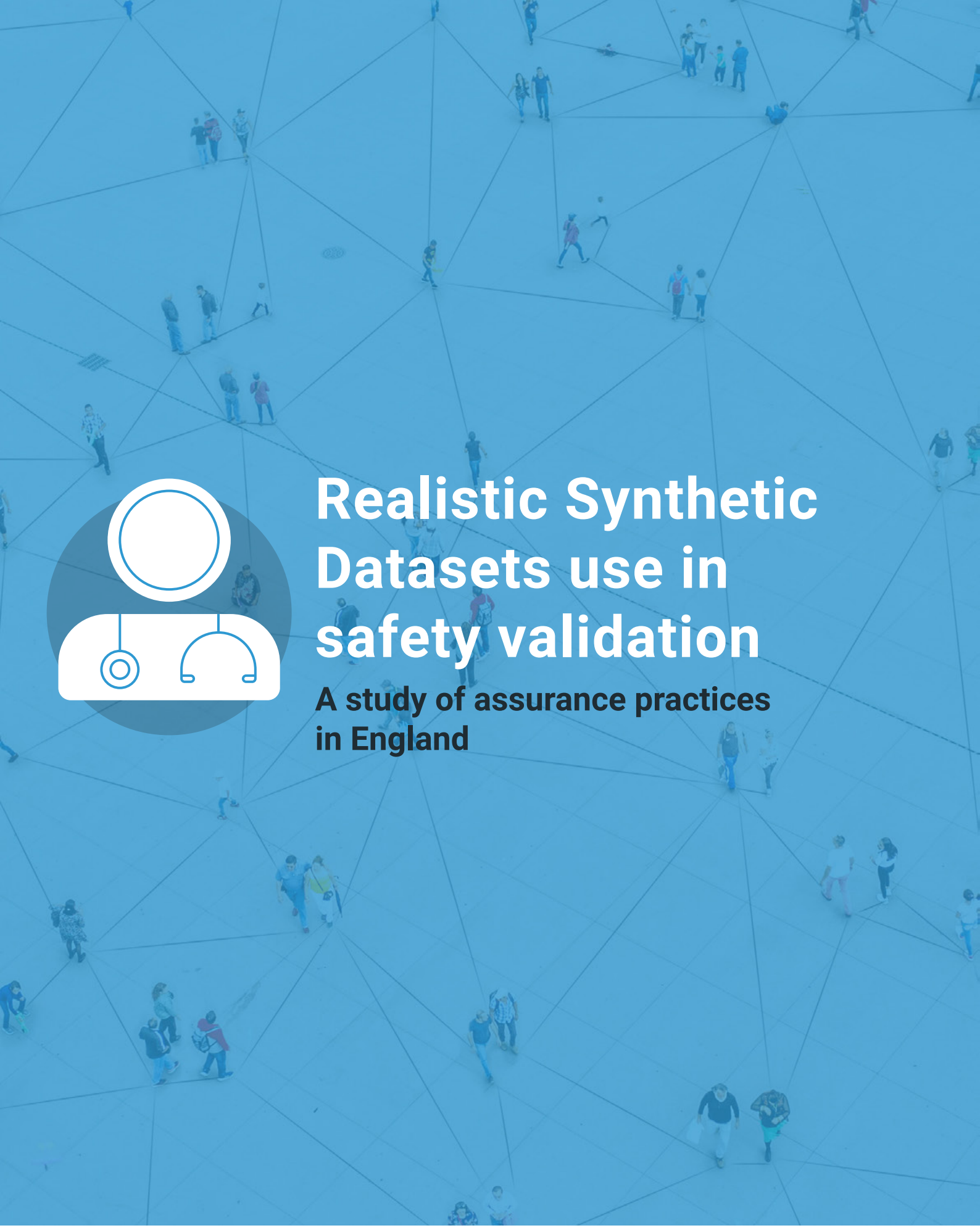

Realistic Synthetic Datasets use in safety validation

A study of assurance practices in England

ETHOS

Realistic Synthetic Datasets use in safety validation

This document discusses the development of a safety justification for an app using synthetic data as a proof of concept project. It identifies the evidence required for assurances that uses synthetic data, for example clinical decision support systems. This was part of the research drawn from a project looking at the early requirements for regulations, with software as a medical device.

Increasing numbers of intelligent healthcare applications are developed by analysing big data, on which they are trained. It is necessary to assure that such applications will be safe for patients; this entails validation against datasets. But datasets cannot be shared easily, due to privacy and consent issues, often delaying innovation. Realistic Synthetic Datasets (RSDs), equivalent to the real datasets, are a solution to this.

A link to the full paper is here:

pubmed.ncbi.nlm.nih.gov/32604594/

RDS use is providing a promising approach, for validation and safety assurance of intelligent healthcare applications.

This will overcome barriers relating to the use of real datasets due to privacy concerns, enabling development of applications that may increase patient benefit.

The paper presented an outline for the justification of such an application, validated specifically with an RSD, allowing the RSD developers to understand the implications of assurance on the data generation process. The framework allowed identification of design and validation requirements, for an RSD generation method, in a proof of concept project.

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