InteropEHRate

EHR in people's hands across Europe

ARCHITECTURE, PROTOCOLS AND API's

MID-TERM PUBLIC WORKSHOP

21 OCTOBER 2020

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 826106

INTEROPEHRATE RESEARCH DATA SHARING [RDS] PROTOCOL

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CHALLENGES OF CROSS-BORDER RESEARCH

The heterogeneity problem: every EU country its own

- language;
- data representation standards and conventions;
- privacy laws and privacy/security policies (even with the GDPR);
- IT infrastructure.

The data collection problem:

- prospective studies: patients need to visit a research centre regularly;
- retrospective studies: patient data is retrieved from central DBs, based on general prior consent.

THE INTEROPEHRATE SOLUTION

Research data are collected directly from citizens' smartphones, residing in multiple countries, in a secure and anonymous manner, following explicit consent by the citizen.

The heterogeneity problem is addressed by:

- the Interoperability Profile (the adoption of FHIR and other healthcare standards);
- data conversion and translation services and tools.

The data collection problem is addressed by the S-EHR:

- citizens can give or revoke consent on a per-study basis;
- they can share data remotely.

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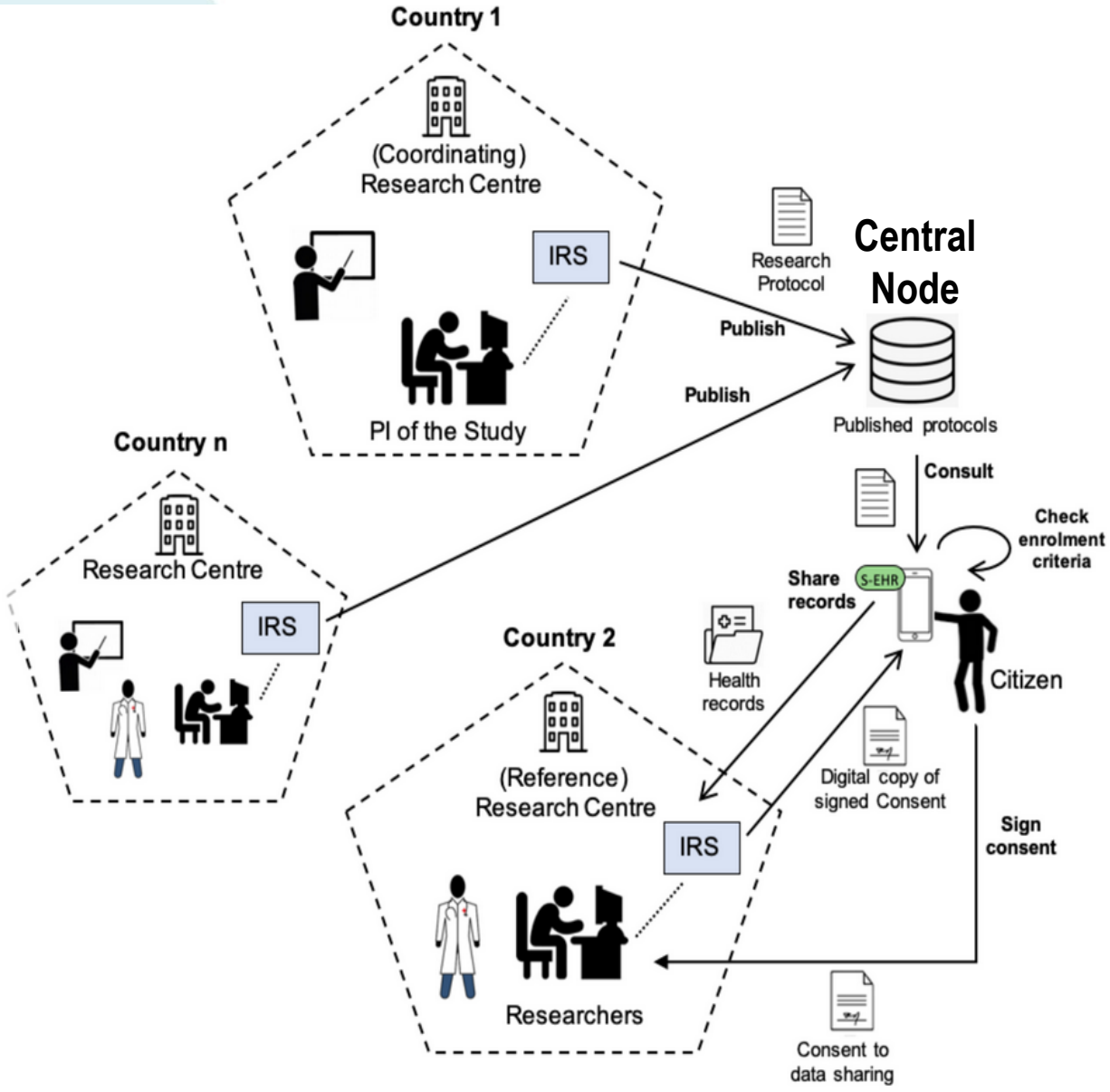
Primed by
EC Innovation Radar 2020

"Tech ready"
"Addresses needs of existing markets"

WHAT INTEROPEHRATE DELIVERS

- The **Research Data Sharing Protocol** that defines how citizens, using their S-EHR App:
  - get informed of research studies,
  - are checked for eligibility,
  - give or revoke consent on a per-study basis,
  - shared their health data anonymously.
- **Demonstrator** implementations:
  - within the S-EHR App:
    - download of research study descriptions,
    - citizen involvement (getting informed, handling consent),
    - eligibility check and data retrieval,
    - anonymisation, pseudonymisation, security mechanisms,
  - within the Research Network:
    - upload and publishing of research study descriptions,
    - reception of anonymous citizen data,
    - management of pseudonyms.

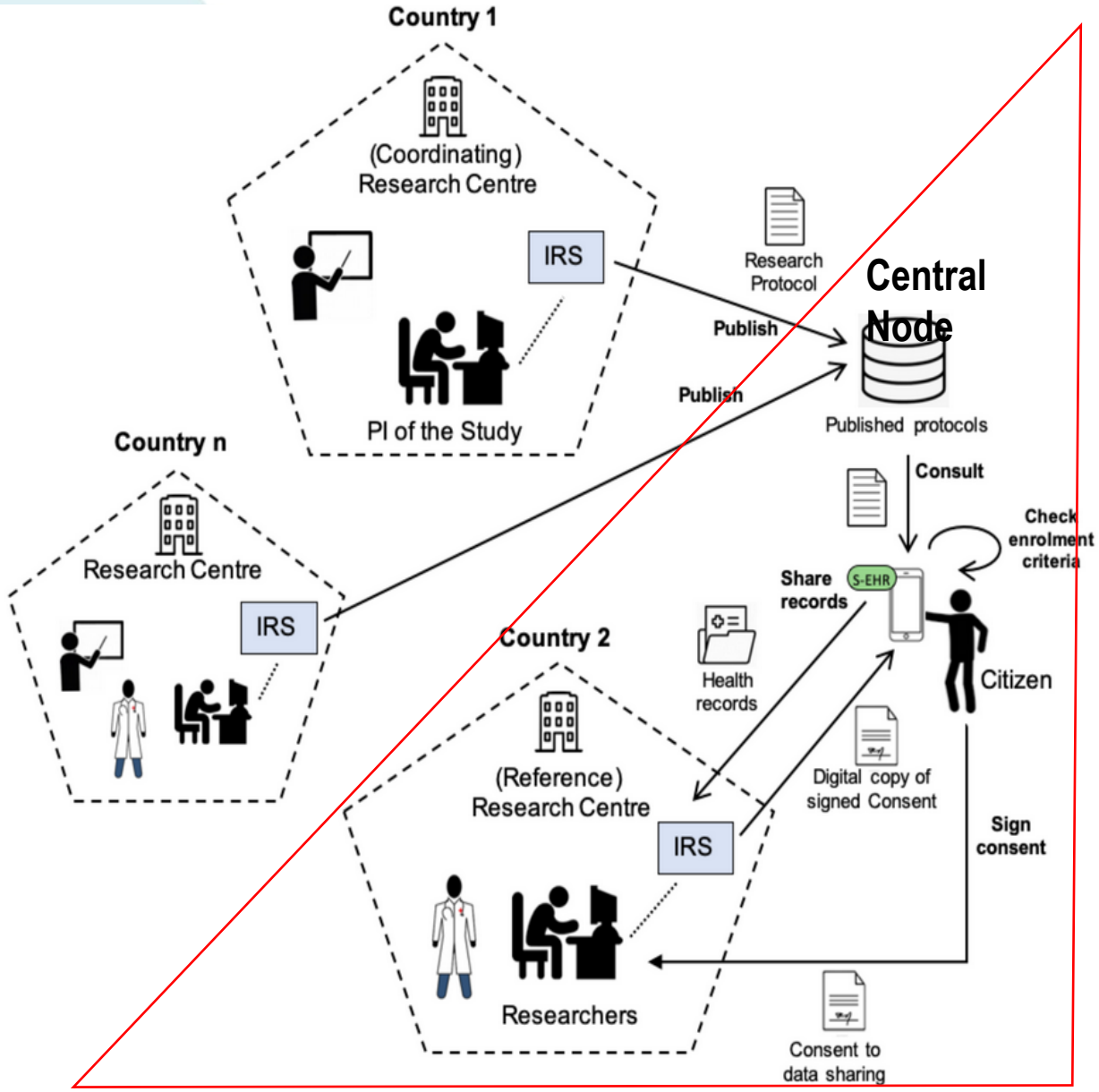


PROTOCOL SCOPE

The RDS Protocol concentrates on communication with the citizen's mobile device:

1. **OPT-IN** to notifications about future studies
2. **DOWNLOAD** of the description of new studies
3. **ENROLMENT** into a new study
4. **DATA RETRIEVAL** from the mobile device
5. **WITHDRAWAL** from a study
6. **OPT-OUT** from future studies

Other aspects of the research process (how to define a study, ethical committee, etc.) are not covered.

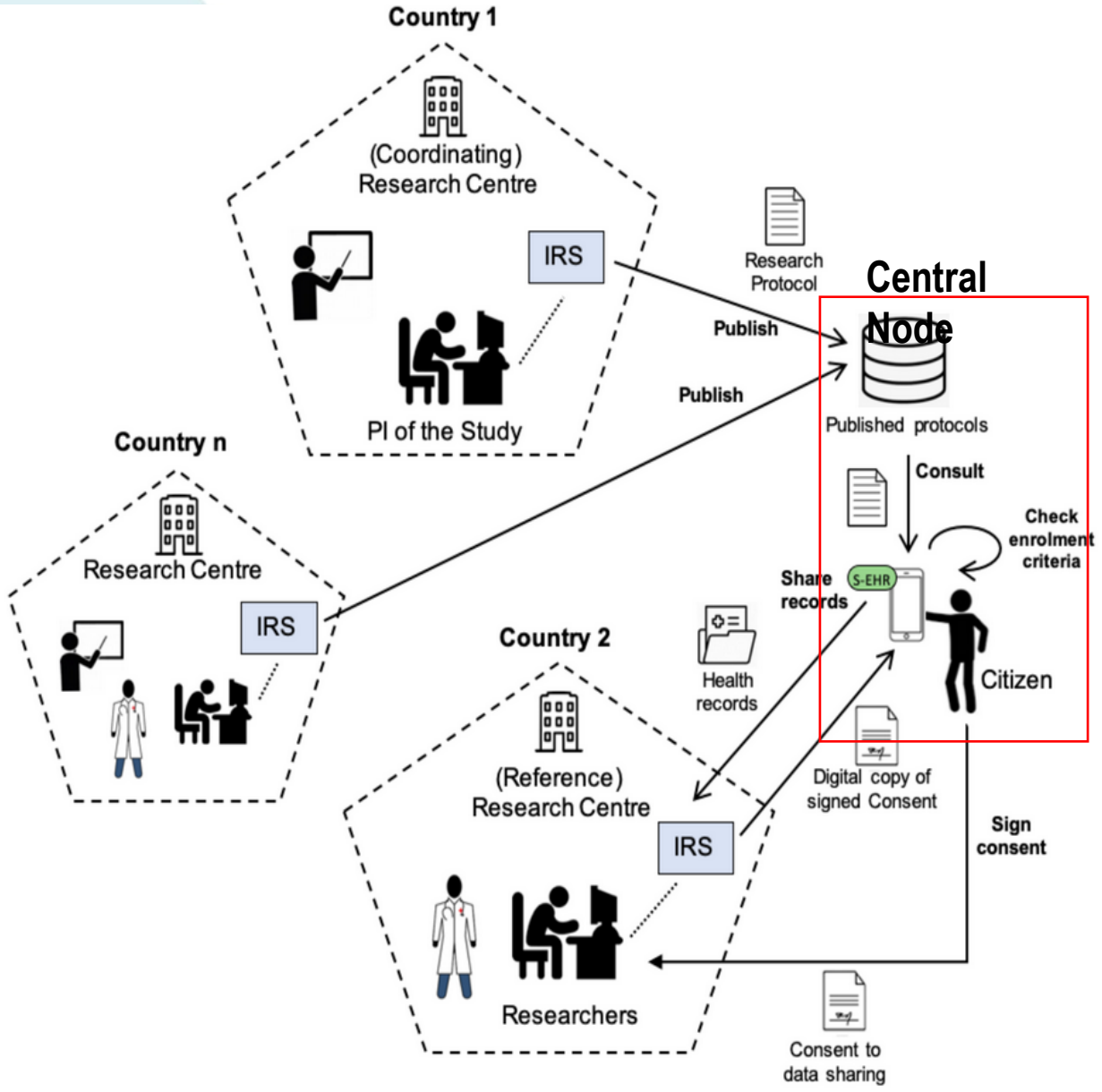


RDDI: INTERFACE FOR DOWNLOADING RESEARCH DEFINITIONS

1. The S-EHR App regularly polls the Central Node of the Research Network for new studies.

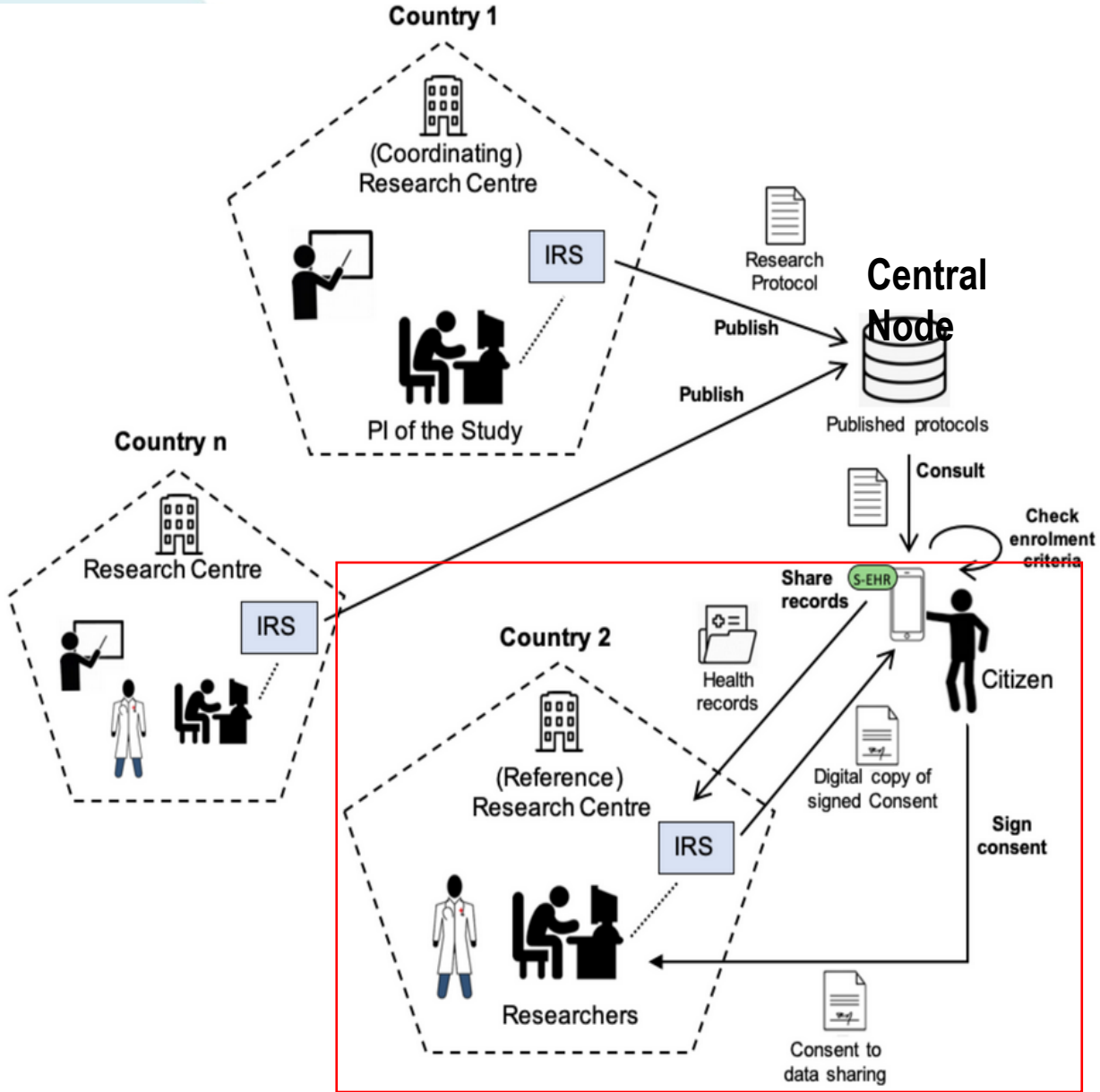
2. Digitally signed *Research Definition Documents* are automatically downloaded.

3. The eligibility of the citizen w.r.t. the study criteria is silently checked by the S-EHR App (based on citizen consent).



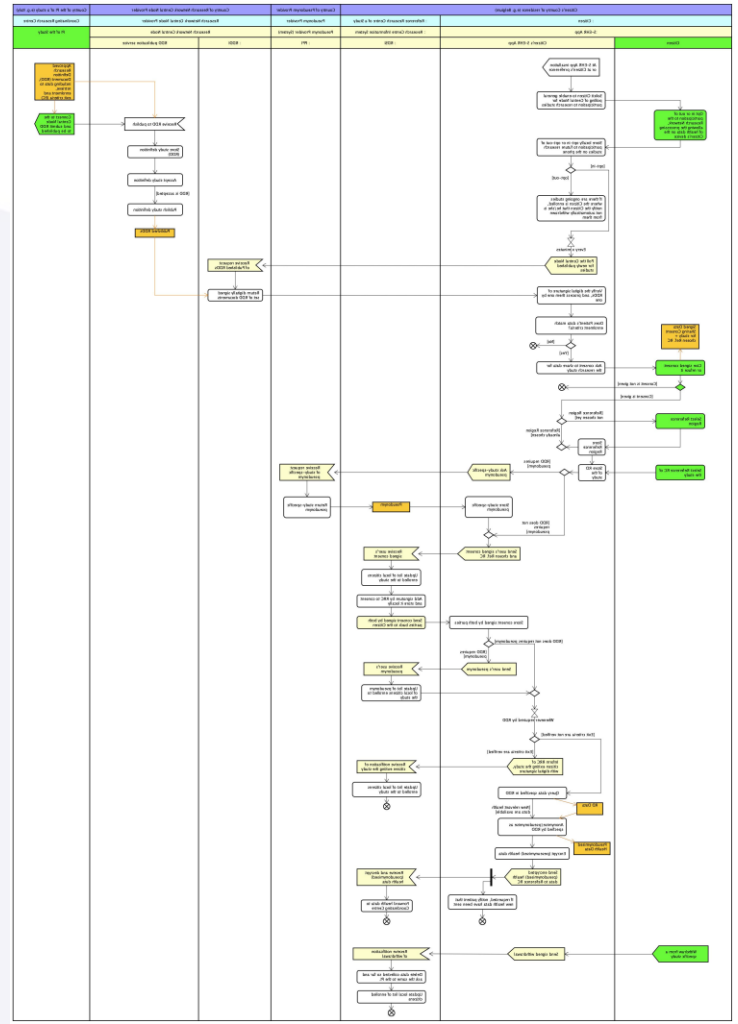
RSI: INTERFACE FOR SHARING HEALTH DATA FOR RESEARCH

1. The citizen decides whether to participate in the study and selects a *Reference Research Centre*.
2. The digitally signed consent is sent to the RRC.
3. During the study, at regular intervals defined by the RDD, relevant health data are automatically retrieved, anonymized, and sent to the RRC.
4. The citizen may withdraw from a study at any time and may opt out from research altogether.



INNOVATIVE TECHNOLOGIES

- **Adoption of the FHIR standard** enables:
  - machine-interpretable definitions of studies,
  - cross-border data retrieval;
- **Semantic mapping and conversion** enable cross-border interoperability;
- **Encryption and digital signatures** support the secure and trustable transmission of consent and data;
- **On-device pseudo/anonymisation** supports the privacy of sensitive personal data.



THANK YOU

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