

## **TEHDAS WP7, Milestone 7.2**

# **Report on EHDS services users' expectations**

**Accepted in the Project Steering Group on 26 October 2021**

Jaakko Lähteenmäki, VTT Technical Research Centre of Finland

Juha Pajula, VTT Technical Research Centre of Finland

Juan Gonzalez-Garcia, IACS Aragon Health Sciences Institute

Carlos Telleria, IACS Aragon Health Sciences Institute

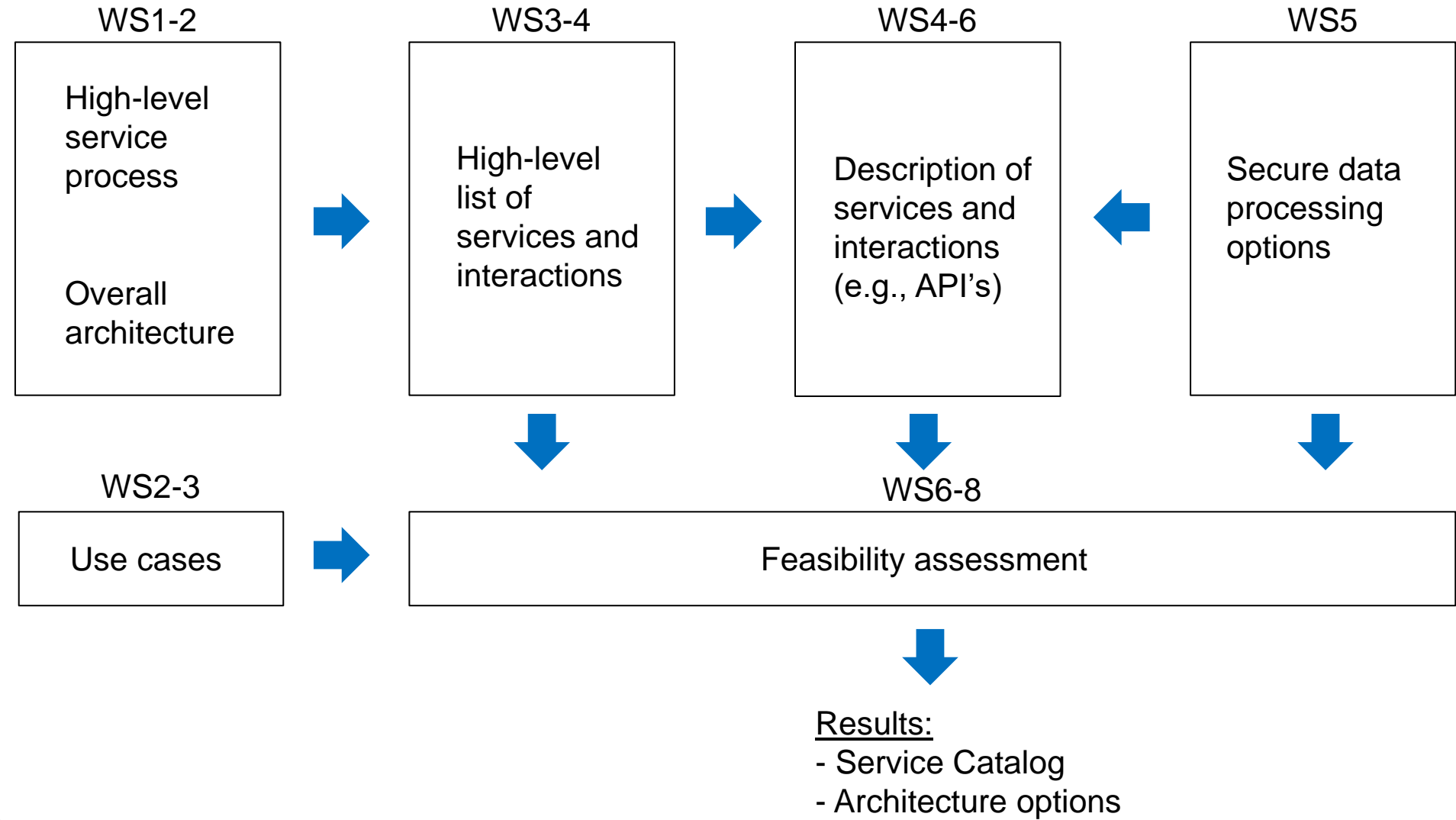


# Objective

- Collect expectations and needs of potential EHDS service users via a series of interactive workshops participated by external experts (workpackage permanent advisory group, WPAG)



# Workshop plan



# Workshops organised

- Workshop 1 (online), 18.05.2021, 40 participants
- Workshop 2 (online), 22.06.2021, 46 participants
- Workshop 3 (online), 14.09.2021, 39 participants



# Methods to collect inputs of experts

- Questionnaire on the current practices and expectations concerning secondary use of health and social data carried out before workshop 1 (29 responders)
- Interactive groupwork in WS1 to comment questionnaire results, initial architecture, service process and FAIR principles ([link](#))
- Interactive groupwork in WS2 to further refine the overall architecture and service process and to define initial use cases ([link](#))
- Interactive groupwork in WS3 to comment and define interactions between architecture entities ([link](#))

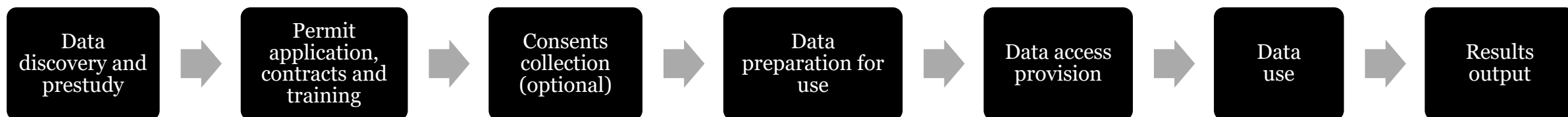


# Results summary

- Identification of the high-level service process for secondary use of health and social data (EHDS user journey)
- Identification of the overall architecture
- High-level process and overall architecture serve as a reference to support the forthcoming WPAG 7 work on EHDS services and architectures



# High-level service process for secondary use of health and social data (“User Journey”)

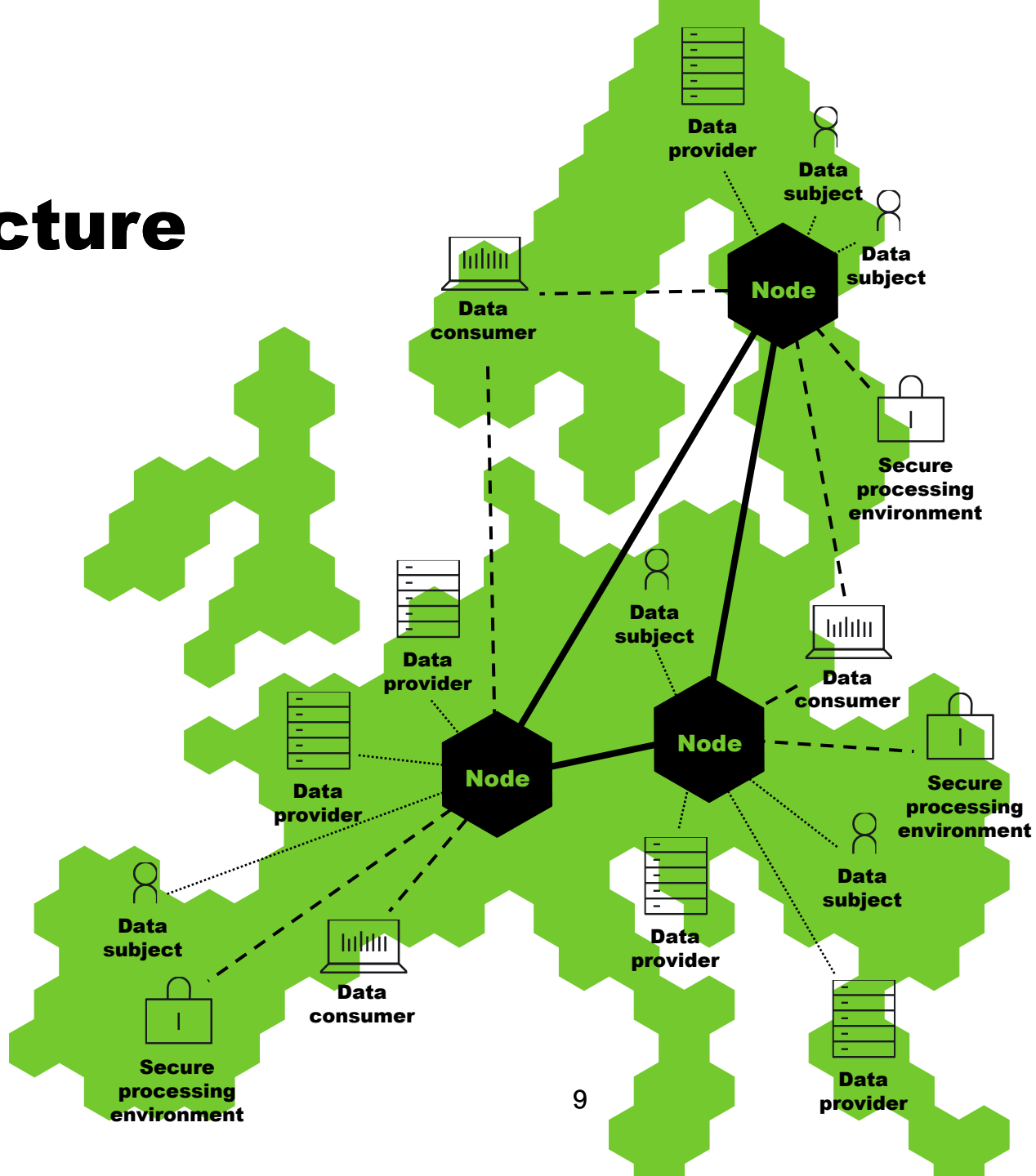


# High-level service process steps

Process step	Description
Data discovery and prestudy	Searching and finding data. Evaluating the availability of needed data types, data quality and number of subjects (available statistical power). Open service carefully designed not to leak sensitive information.
Permit application, contracts and training	Application for data access. Application processing including ethical review. Contracts specifying conditions for data use (e.g., definition of data processing environment) and training the user for responsible use of data (both e-learning and helpdesk services).
Consents collection (optional)	In case informed consent is needed, the data subjects are invited to provide their consent for the study. Note (1): this consent is related to the secondary use of the data ( <u>not</u> the consent that is required in the context of clinical trials). Note (2): the need for consent in the secondary use context varies among countries (interpretation of legislation) and use cases.
Data preparation for use	Preprocessing and other actions to make data ready for use, e.g., integration of registers (“real” or “virtual”), filtering, ensuring data quality and anonymity. Option: provision of synthetic data.
Data access provision	Three options: (1) online access to secure processing environment (in control of EHDS), (2) online access to download data to a user-controlled secure processing environment, (3) online access to upload (or choose) algorithms for data processing in a secure processing environment (in control of EHDS or original data controller).
Data use	Data analysis and processing in the scope of secondary use of health and social data.
Results output	Actions to ensure anonymity, reusability and appropriate publication of results. For example: verifying that identities of study subjects cannot be recovered; enabling results to be reproduced and verified by independent groups; archiving of results; sharing of study protocols, analysis SW and data queries. Actions to ensure personally targeted feedback, information of usage of personal data and reporting of incidental findings (as appropriate and as accepted by the data subject).



# Overall architecture



Co-funded by the Health Programme of the European Union

# Overall architecture components

Component	Description
Secure processing environment	Secure data processing environment fulfilling appropriate requirements to process sensitive personal data. Computing resources may be independent trusted computing nodes or controlled by a node, data provider (register controller) or the data consumer organisation. For example, when federated learning is enabled the computation resource is closely linked with the data provider.
Data provider	Organisation responsible of maintaining the original data. This can be any type of data provider having data resources related with the health and wellbeing of an individual. Most typically: data generated in healthcare delivery and social services processes, health and social sciences research, data extracted from biosamples (biobank data) and self-generated data (e.g., recorded by personal devices or personal health services. The “data provider” in the overall architecture may also refer to a “data partner” managing one or more original data sources under contract with their data controllers.
Node	An organisation providing processes and functions needed to enable secondary use of data as defined by the EHDS. The node provides interconnected services supporting various functions for data access (see “high-level service process”). Depending on future definitions to be made (not in the scope of WP7) there maybe one node per country or less or more. Also depending on future definitions (not in the scope of WP7) the network of nodes can be a true peer-to-peer network or there may be one master node for centralized functions.
Data consumer	Organisation using the EHDS data. For example, a public research organisation (university, university hospital, research institute), other public organisation, not-for-profit 3 <sup>rd</sup> sector organization or a private company.
Data subject	Identifiable natural person whose data is used. As identified by the GDPR, identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.