

EHDS
Community of Practice
for Secondary Use

Working Arrangements

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Acronyms and abbreviations

TERM	DESCRIPTION
CAs	Competent Authorities
CoP	Community of Practice
CSA	Coordination and support actions
DBC	Digital Business Capabilities
EHDS	European Health Data Space
EHDS2	Secondary use of health data in the EHDS
EHDS2 CA CoP	Community of Practice of Competent Authorities for secondary use of health data in scope of the EHDS2
HDAB	Health Data Access Body
HealthData@EU	Cross-border infrastructure, proposed by the EHDS regulation, to facilitate the secondary use of health data
JA	Joint Action
MS	Member State
TEHDAS & TEHDAS 2	Joint actions supporting the design (TEHDAS 2021 to 2023) and implementation (TEHDAS 2 2024 to 2026) of the EHDS regulation aspects related to secondary use of health data.

1 Executive Summary

To prepare for the implementation of the future regulation on the European Health Data Space (EHDS), Member States (MSs) have started establishing Health Data Access Bodies (HDABs) or improve and adapt already existing national bodies that could act as an HDAB. MSs that have applied for EU4Health Direct Grants for setting up HDABs highlighted the need for a common platform where they could share best practices, raise issues and concerns, and strengthen collaboration for setting up and run their HDABs. To fulfil this need, MSs decided to create a Community of Practice (CoP).

These working arrangements document is the foundation of this CoP which is composed of competent authorities and affiliated entities from EU MSs and EEA countries involved in establishing the HDABs and responsible for the secondary use of health data.

This document presents the mission and objectives of the CoP, its organisation, including description of roles and responsibilities, relevant stakeholders and procedures, the roadmap of the CoP actions, detailing different plans for the CoP, including meetings, work and subgroups and a toolbox, describing a set of tools to support its effective functioning.

Some of the main objectives of the CoP are to ensure a common understanding of the different aspects of the future EHDS regulation, enable an exchange of information on national laws, plans and strategies and to create a community that can support the definition of specifications, build common procedures, foster harmonisation, and improve interoperability. Moreover, the CoP aims to increase capacity building, identify and anticipate implementation challenges and share solutions on how to overcome them.

As presented in the document, the CoP will be composed of a General Assembly, a Steering Board and subgroups which will support MSs in defining, implementing, and operating the HDABs, their business capabilities and EHDS2 provisions. It is important to highlight that the CoP will also be the bridge between competent authorities and other stakeholders and relevant ongoing initiatives that support the development and operation of such digital business capabilities. The CoP will be supported by the secretariat and the solution providers.

Finally, these working arrangements document also presents the workplan of the CoP for 2024 with the topics that should be addressed, and the outcomes and deliverables that should be achieved in the first year. It provides details on the proposed work to be achieved by each Subgroup and the support needed by the secretariat.

2 Introduction

The EHDS2 competent authorities' Community of Practice (CoP) is composed of the competent authorities and affiliated entities, from EU Member States and EEA countries, involved in establishing the Health Data Access Bodies (HDABs) and responsible for the secondary use of health data within the European Health Data Space (EHDS) in their respective Member States, including holders of the direct grants for setting up HDABs.

This document has been prepared with the explicit purpose of strengthening the endeavours of this CoP. While each Competent Authority (CA) meticulously designs a national roadmap and establishes its national Health Data Access Body (HDAB), there is a unanimous recognition that collective, coordinated efforts can yield substantial benefits.

This CoP is the next step in the discussions held during the preparation of applications for the direct grants to set up HDABs, during which MS expressed their will to create a community to discuss and share best practices regarding HDABs.

The CoP is created, at the moment of adoption of these working arrangements, by agreement between the competent authorities and participation is on a voluntary basis. The CoP can be dissolved by competent authorities' agreement, when they feel that there is no added value in having it.

The genesis of this CoP lies in the recognition of the potential synergies that can be harnessed, the wealth of knowledge that can be shared, the identification of common issues that can emerge in the European context, and the prospect of streamlining the establishment of HDABs to increase alignment and cost-effectiveness. It stands as a testament to the collaborative commitment to navigate the complexities of secondary use of health data in the scope of the European Health Data Space.

This document includes:

- **Mission and objectives** of the CoP.
- **Organisation** of the CoP, including description of roles and responsibilities, relevant stakeholders and procedures.
- **Roadmap** of the CoP actions, detailing different plans for the community of practice, including meetings, work and subgroups.
- **Toolbox**, describing a set of tools to support the effective functioning of the CoP.

3 Mission and Objectives

Our mission is to foster collaboration and knowledge sharing among Competent Authorities and Affiliated Entities involved in establishing the HDABs and responsible for the secondary use of health data within the European Health Data Space (EHDS).

We aim to connect these authorities with various initiatives such as Joint Actions, Coordination Support Actions and European projects (e.g. TEHDAS2, EHDS2Pilot, QUANTUM) and with relevant national projects for EHDS implementation.

Our focus is to improve preparedness for EHDS regulatory requirements, promoting the harmonisation of procedures, while optimising the efficient use of resources. The main objectives of the CoP are summarised in the table below:

OBJECTIVES	DESCRIPTION
Support the establishment of Health Data Access Bodies	Facilitate the establishment and strengthening of HDABs, by creating a platform for cooperation on guidance and to ensure a common understanding of the different aspects of the future EHDS regulation by all parties. This includes building a common understanding and alignment on the profile of Competent Authorities that can exercise the role of HDABs, as well as their tasks and obligations among others.
Strengthen cooperation inside and outside the Community of Practice	Create a bridge (facilitating dialogue, understanding and collaboration) between the CoP members and with the broader ecosystem of stakeholders in secondary use of health data (see section 4.2).
Establish a platform for sharing information and aligning strategies	Establish a collaborative platform to exchange information, including national laws, plans and strategies, with the aim to enhance comprehension, follow progress, and improve alignment among Member States (MS) for effective implementation of the future EHDS2.
Sharing of technical knowledge and expertise	Establish a community of national experts able to support each other in the process of designing, piloting and deploying the different digital business capabilities necessary to establish the HDAB. This community can, among others, support the definition of specifications and requirements, technical implementation, piloting and troubleshooting possible issues, as well as share best practices and solutions.
Streamline Solutions and promote the 3Rs principle – Reduce, Reuse and Recycle	Create a community capable of identifying and anticipating implementation challenges and focused on sharing solutions. This involves mapping of processes, tools, projects, initiatives, etc. Solutions will preferably be drawn from lessons learnt and will give priority to cost-effective options such as “open source” or alternative software licences, use of central services, and twinning activities, among others. This approach also aims to reduce the costs associated with establishing HDABs at national scale through collaborative efforts and sharing of resources.
To increase capacity building	Identify and cultivate new competencies and skills, knowledge and tools that can support the establishment of HDABs at national level. This includes the design and delivery of training programs, providing resources, and facilitating expert-led discussions, also in collaboration with the appointed solution provider for EHDS2 Capacity Building. The aim is to provide Competent Authorities with the tools and knowledge they need to advance the preparedness for secondary use of health data and manage the HDABs.
Foster harmonisation, standardisation and interoperability	Facilitate the exchange of ideas, experiences, and best practices to build common procedures for the harmonised functioning of HDABs, promoting standardised approaches to this end, based on the outputs of relevant projects/initiatives (in section 4.2). Furthermore, promote alignment to reinforce harmonisation, standardisation and interoperability that are essential for the successful implementation of EHDS, including the alignment between EHDS1 and 2.
Strategies for disseminating results	Plan and design a comprehensive strategy to effectively disseminate the results / knowledge achieved, using a variety of channels such as media, publications, workshops. This objective aims to maximise the impact of the achievements, by promoting awareness, engagement, and utilisation of outcomes within relevant stakeholder communities.

4 Organisation

4.1 Roles and Responsibilities

The roles and responsibilities of the EHDS2 CAs CoP are depicted in the following picture and described in more detail in the table below.

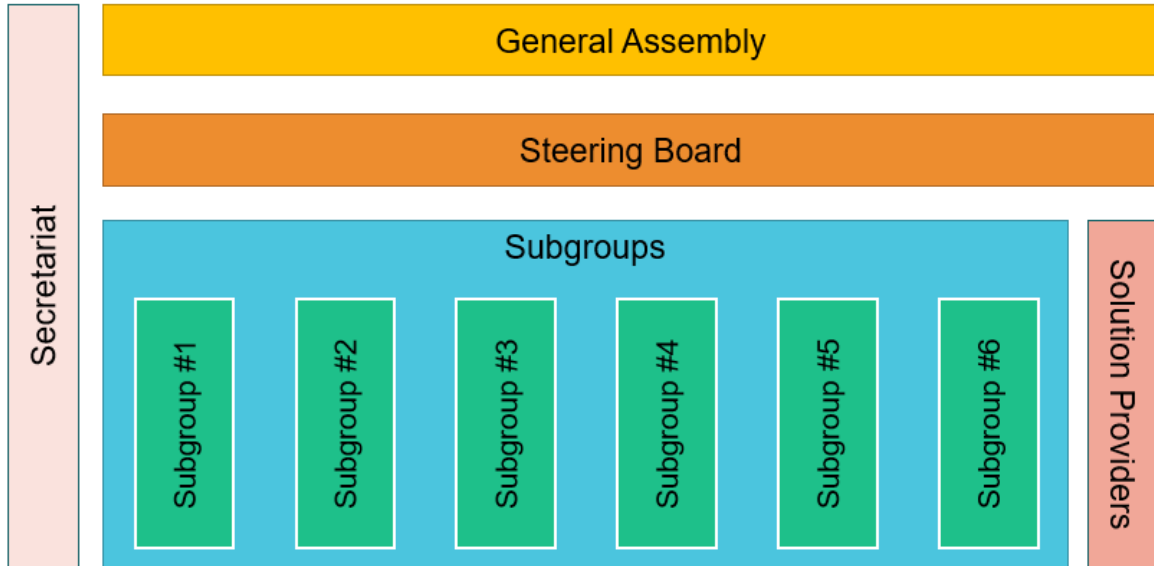


Figure 1. Overview of roles and responsibilities of the different bodies, subgroups, and players of the EHDS2 CAs CoP

The EHDS2 CAs CoP is organised in the following way:

UNIT	DESCRIPTION	RESPONSIBILITIES
General Assembly	<p>This unit is composed of 1 representative of each CA. If there are more than 1 CA per country, one should be designated as Coordinator.</p> <p>For voting purposes, only the Coordinator CA (per country) will be in the position to cast a vote.</p> <p>This unit is Co-Chaired by 1 Chair selected from the country's representatives and 1 Chair from the European Commission. There is also 1 Rapporteur from the countries' representatives. The Chair from the country's representatives rotates every 12 months to ensure equal opportunities and duties for every country.</p> <p>The General Assembly has 3 prominent roles:</p> <ul style="list-style-type: none"> - Previous Chair - Current Chair - Next chair (rapporteur) 	<p>Define the strategic vision, mission and objectives of the EHDS2 CoP, including alignment with EHDS1.</p> <p>Adopt the annual work plan for the EHDS2 CoP.</p> <p>Decide on creating subgroups.</p> <p>Decide on the creation and scope of deliverables by the CoP as well as their publication, including guidelines and best practices.</p> <p>Serve as the focal point in bringing together relevant initiatives working on EHDS.</p> <p>Define the rotation sequence of the General Assembly chairs.</p> <p>Define the rotation sequence of the Steering Board chairs.</p>

	<p>At the end of each rotation, the current chair will become the previous chair and the rapporteur will become the current chair. A new rapporteur should be appointed.</p> <p>This unit meets every 6 months, preferably in a face-2-face setting.</p>	<p>Approve a Risk Management plan related to the functioning of the CoP.</p>
<p>Steering Board</p>	<p>This unit is composed of:</p> <ul style="list-style-type: none"> - 1 Chair and 1 Rapporteur of the Steering Board. - 1 Chair and 1 Rapporteur for each Subgroup - 1 representative from each Solution Provider <p>The chair and rapporteur position should rotate every 6 months. The steering board could suggest to the General Assembly to endorse the continuation of its mandate for another 6 months.</p> <p>The steering board has 3 prominent roles:</p> <ul style="list-style-type: none"> - Previous Chair - Current Chair - Next chair (rapporteur) <p>This unit meets every month, preferably in online setting.</p> <p>For each Subgroup and solution provider, a representative should report back on the work conducted</p>	<p>Assess and prepare recommendations regarding the creation of subgroups.</p> <p>Coordinate the work of the subgroups.</p> <p>Prepare the annual work plan for the EHDS2 CoP.</p> <p>Provide quality assurance and prepare recommendations regarding the creation and scope of deliverables and their publication.</p> <p>Prepare a Risk Management Plan (including the assessment of risks, the maintenance of risk log, the adoption of mitigation measures) with the support of the subgroups and propose it to the GA for approval.</p> <p>Monitor the implementation of the common baseline plan for progression at the national level (based on a common format approved by the GA) and check periodically for updates with the support of the subgroups.</p> <p>Progress Monitoring.</p>

<p>Subgroups</p>	<p>Each Subgroup is composed of:</p> <ul style="list-style-type: none"> - 1 Chair and 1 Rapporteur (who will also be members of the Steering Board). - Volunteers from the CoP, ideally representatives from all interested countries. - Experts, also those external to the CoP, if considered adequate. <p>A chairing term of 1 year is suggested to ensure equal opportunities and duties for each country.</p> <p>Each Subgroup defines its meeting frequency, preferably meets in an online setting.</p> <p>Section 5.3 presents a proposal for the establishment of specific subgroups to kickstart the work of the community.</p>	<p>Support MSs in defining, implementing, and operating the HDABs and EHDS2 provisions.</p> <p>Report to the Steering Board about the work conducted.</p> <p>Offer guidance on development and implementation.</p> <p>Mapping of MS needs and priorities, as well as existing initiatives.</p> <p>Promote plan and progress sharing, formalising collaboration requests for existing forums.</p> <p>Discuss the National implementation progress updates and the lesson learnt from sharing knowledge and best practices related to the implementation of the plan.</p> <p>Each Subgroup elects its own chair and rapporteur.</p>
<p>Secretariat</p>	<p>Provides administrative support for the EHDS2 CAs CoP units. This includes making arrangements for the meetings, support meetings conduction and follow up.</p> <p>It is expected that the Secretariat will be provided by the European Commission.</p>	<p>Support the functioning of the CoP by assisting in the organisation of meetings.</p> <p>Support subgroups in managing the fora thematic areas and consultation needs identified by the subgroups.</p> <p>Formalise communication with external entities.</p> <p>Support the dissemination activities, such as the dissemination of relevant results within the Community and outside, especially those that are considered of public interest. In addition, support the dissemination of events to relevant stakeholders when needed.</p> <p>Support the onboarding of new members, by providing the necessary access rights, as well as creating an onboarding manual to support the participation of new members.</p>
<p>Solution Providers</p>	<p>This unit include different entities responsible for providing services and supporting the EHDS2 CAs CoP units.</p>	<p>Provide services enabling capacity building initiatives, including the preparation and performance of trainings, as well as the preparation of</p>

	<p>It is expected that the Solution Provider resources will be provided by the European Commission.</p>	<p>support materials.</p> <p>Provide a EHDS2 Support Centre, including all services necessary to support the functioning of the secondary use of health data as described in the EHDS regulation.</p> <p>Provide HealthData@EU Central IT Services to enable the functioning of the HealthData@EU infrastructure.</p>
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4.2 Relevant stakeholders

The EHDS2 CAs CoP has several potentially relevant stakeholders. These include representatives from i) different projects, joint actions, European initiatives, ii) EU institutions (e.g. ECDC, EMA, Eurostat, JRC, HERA) and iii) international institutions (see section 4.3 for further details). Some of the most relevant stakeholders/initiatives from which work can be leveraged for the CoP work are listed below. This is not an exhaustive list; rather it aims to provide guidance on the currently identified pillars for CoP activities.

STAKEHOLDER	DESCRIPTION	CoP's interest
TEHDAS 1	Joint action proposing evidence-based options and recommendations for setting up the EHDS for secondary use.	Outcomes from this JA can be useful for the development of the digital business capabilities in HDABs. For example, concrete recommendations on semantic interoperability and citizens' engagement can be very useful.
TEHDAS 2	Joint action preparing the ground for and supporting the legislative developments towards the EHDS for secondary use.	Prepare guidelines and technical specifications for common aspects of the implementation of the proposed EHDS / supporting the legislative developments of EHDS2.
HealthData@EU Pilot	Pilot specific aspects of the EHDS regulation, especially the HealthData@EU infrastructure.	Learn from the pilot experience, scale up solutions, and take up specifications on digital business capabilities and deploy them at national level, such as Health DCAT-AP metadata standard for the national dataset catalogues and eDelivery.
EHDS2 Capacity Building	Provide training tools and deliver trainings to HDAB staff and EHDS2 ambassadors and provide implementation tools and monitoring dashboard for the national	Collaboration with the CoP and the national experts that will be part of the HDABs. Training and toolkits for implementation will be created for this audience.

	implementation of the 5 DBCs.	
CSA on Data Quality and Utility Label (QUANTUM)	Develop and test the implementation of the data quality and utility label foreseen within the EHDS regulation.	Assess feasibility of implementation and contribute to specifications and guidelines.
TREs (ELIXIR-led EOSC-ENTRUST)	Develop a secure processing environment for health related data.	Gather insights and advice, learn from their progress and consider the reuse of solutions.
DARWIN EU (EMA + coordination centre)	Data Analysis and Real World Interrogation Network (DARWIN EU®) delivers real-world evidence from across Europe on diseases, populations and the uses and performance of medicines. This enables EMA and national competent authorities in the European medicines regulatory network to use these data whenever needed throughout the lifecycle of a medicinal product.	Alternative way of mobilising health data for a specific purpose (regulatory), alignment with EHDS governance needed.
GDI	Develop a specific infrastructure for the sharing of genomic data.	Gather insights and advice, learn from their progress and consider the reuse of solutions.
EUCAIM	Develop a specific infrastructure for the sharing of cancer imaging data, embedded within the EHDS framework.	Gather insights and advice, learn from their progress and consider the reuse of solutions.
Uncan.eu (CSA)	Develop a concept for a cancer research data infrastructure, embedded within EHDS framework.	Gather insights and advice, learn from their progress and consider the reuse of solutions.

4.3 Procedures

PROCEDURE	DESCRIPTION	INPUT & OUTPUT
New Subgroup	Any member of the CoP can propose the creation of a new Subgroup. The procedure starts by submitting a request containing the reasoning for the new group. This request is assessed by the Steering Board and submitted to the General Assembly for decision.	<i>input:</i> Request submitted to the Steering Board. <i>output:</i> Decision (accept/reject request).
Adoption of document by General Assembly	When the CoP wishes to have some sort of documentation adopted by the General Assembly, it should follow a process that accounts for proper timing for commenting, consensus building (including the Steering Board assessment) leading to the adoption at	<i>input:</i> Recommendation for adoption, including document as annex. <i>output:</i> Decision (accept/reject recommendation).

	a General Assembly meeting.	
Risk management	<p>The CoP has a risk management system to identify and address risks related to the functioning of the community.</p> <p>The General Assembly approves the risk management plan.</p> <p>The Steering Board is responsible for maintaining the risk log, preparation of risk assessment by the subgroups, adopting mitigation measures, and monitoring the mitigation of risks.</p>	<p><i>input:</i> Risk Management Plan (proposed by the Steering Board and approved by the GA)</p> <p><i>output:</i> risks recognized in the subgroups/Steering Board functioning (risk assessment).</p> <p>mitigation measures (defined to manage the identified risks).</p> <p>updated risk level (after the application of mitigation measures).</p> <p>up to date risk log (to track improvements).</p>
National implementation progress updates	<p>Check, through a common approach approved by the GA, the implementations and progress provided at a national level, and national implementation plans' updates to the GA.</p> <p>Discuss, within the subgroups, lessons learnt from sharing knowledge and best practices developed at a national level following the national implementation plans.</p>	<p><i>input:</i> baseline national implementation plan and updated versions (proposed by the Steering Board using a common format and approved by the GA).</p> <p><i>output:</i> progress updates report (presented by the Steering Board to the GA).</p> <p>updated versions of the baseline national implementation plan.</p> <p>lessons learnt based on knowledge and best practices sharing.</p>
Preparation of next year work plan	<p>Considering the scarce resources of the community and strategic importance on how the available resources are allocated, there will be a structured procedure to elaborate the work plan for the next year. The work plan is a description of the CoP's priorities and actions in the coming year.</p> <p>By the end of each year, the subgroups will provide for their part a description of the next year's work plan to the Steering Board. The Steering Board will prepare the final, unified version of the next year's work plan. The work plan is accepted and elaborated by the</p>	<p><i>input:</i></p> <ol style="list-style-type: none"> 1) Preparation of the next year's work plan for the community, including the detailed plans for each Subgroup 2) Preparation of the next year's work plan in the Steering Board <p><i>output:</i></p> <ol style="list-style-type: none"> 1) The next years work plan is accepted and, in some cases, elaborated in the General Assembly

	General Assembly.	
Deciding on chairs and rapporteurs	<p>Deciding on the chair and rapporteur for the General Assembly: 12 months rotation. Can be modified by the joint decision in the General Assembly.</p> <p>Choosing the chair and rapporteur for the Steering Board: nomination / election in the General Assembly.</p> <p>Choosing the chair and rapporteur for each Subgroup: subgroups elect their own chairs and rapporteurs. The subgroups can independently decide on the rotation.</p>	<p><i>input:</i> suggestions on the nominations.</p> <p><i>output:</i> decision on the chairs and rapporteurs.</p>
General Assembly (every 6 months)	<p>The General Assembly should have at least the following points in the agenda:</p> <ol style="list-style-type: none"> 1) Chairs and rapporteurs for Steering Board and Subgroup. 2) Documents to be adopted. 3) Work plan (assessment) <ol style="list-style-type: none"> a. in the end of the year, a next year's work plan b. middle of the year, assessment of the work plan 4) Suggestions on the new subgroups (assessed by the Steering Board beforehand) (if any). 5) Updates on the risk management plan (if any). 	<p><i>input:</i> Preparation by the subgroups and assessment by the Steering Board.</p> <p><i>output:</i> Decisions in the General Assembly.</p>

5 Roadmap

5.1 Meetings plan

According to the provisions defined for the EHDS2 CAs CoP units, the following meeting plan is suggested:

MEETINGS	DESCRIPTION	Remarks
General Assembly	Meets every 6 months Preferably, in a face-2-face setting	May November
Steering Board	Meets every month Online	In the 2nd week of each month
Subgroups	Each Subgroup defines its meeting frequency Mainly online	

5.2 Work Plan for 2024

A community of practice needs a well-organised work plan as it serves as a roadmap for cooperation, coordination, and effective use of resources to achieve common goals, thus guaranteeing the community's long-term development and added value.

The table below depicts the work plan proposed for 2024. Due to its nature, work plans tend to be "living documents" in which information is frequently updated to represent the latest developments and decisions. For that reason, this information should be transposed into a specific tool facilitating its maintenance.

The following deliverables will contribute to the fulfilment of the objectives proposed for the EHDS2 CAs CoP.

DELIVERABLE	DESCRIPTION (link to objective)	WHEN
Put in place the Toolbox for the community	Put in place the tools defined in the toolbox (chapter 6 of this document)	2024 Q1
Map of national implementation plans	To enable common understanding of each national implementation plan, this live registry will allow each country to share the national implementation plan. Firstly, a common format of national plans needs to be defined. This can also be used for progress update. Additionally, some of the deliverables of HDAB projects (that are of value for all MS) could be mapped and published here too.	2024 Q2
Organise a liaison event with the	To facilitate the collaboration with HealthData@EU pilot project, aiming at identifying	2024 Q1

HealthData@EU pilot project	relevant lessons learnt and reusable solutions explored	
Needs assessment report	To define which deliverables are needed within national implementation plans and to what extent they are covered by other initiatives like TEHDAS2, taking the timeline of EU initiatives into account.	2024 Q2/3
Kick-off of baseline subgroups	Organise the first meeting, establish the first chair and rapporteur for each subgroups and task forces, define the initial meeting plan and define the work plan for 2024.	2024 Q2
Plan Fora 2024	Define the planning for Fora to be organised by 2024	2024 Q2
2025 Work Plan	Define the work plan for 2025: <ul style="list-style-type: none"> - Deliverables - Meetings plan - Fora plan - Work plans (per Subgroup) 	2024 Q4

5.3 Proposed subgroups

To achieve the outlined objectives for the CoP, it is proposed the formation of distinct subgroups. However, considering the constraints posed by limited resources, each Subgroup should be meticulously crafted with a singular focus, underpinned by a clear and well-defined purpose, and accompanied by a structured work plan.

To kickstart the CoP, the suggestion is to establish the following subgroups, categorised into three specific purposes:

1. Facilitating collaborative design and development of Digital Business

Capabilities:

- *Subgroup 1 - Data Access Application systems:* Focus on designing and developing data access application systems.
- *Subgroup 2 - Health Datasets Metadata Catalogue and Data Quality and Utility:* Focus on designing and developing health datasets catalogues and contribute to data quality and utility.
- *Subgroup 3 - Secure Processing Environments:* Focus on designing and developing secure processing environments.
- *Subgroup 4 - Cross-border Gateways:* Focus on designing and developing the cross-border gateway.

2. Coordinating Deployment and Operations:

- *Subgroup 5 - Deployment and Operations:* Focus on coordinating deployment and operational aspects.

3. Stakeholders engagement:

- *Subgroup 6 - Stakeholders' Fora:* Focus on engaging with stakeholders.

SUBGROUP	DESCRIPTION	RESULTS
Digital business capabilities subgroups		
Data Access Application systems (DAAM)	<p>Aims to support MS in designing and developing data access application management systems, as MS begin to design, implement, pilot and / or go live in production.</p> <p>Support the definition of specifications and requirements, technical implementation, piloting and troubleshooting possible issues, as well as share good practices. This Subgroup should also consider multi-country requests.</p>	<ul style="list-style-type: none"> • Workplan, prioritisation and KPIs: map MS needs and priorities. • Map existing initiatives addressing the development and implementation of DAAM. • Identification of topics for stakeholder engagement. Ensure participation in relevant forum initiatives. • Benchmarking existing solutions.
Health Datasets Metadata Catalogue (HDsC) and Data Quality and Utility (DQU)	<p>Aims to support MS in designing and developing the National Datasets Catalogue (metadata catalogue), as MS begin to design, implement, pilot and / or go live in production.</p> <p>Address the quality and utility requirements, to enhance the quality of electronic health data made available through the health data access body, as well as support data holders in enhancing the data quality of dataset descriptors (metadata records) and raw data (data).</p> <p>This Subgroup might be split into two task forces: one for the HDsC and the other for the DQU component, although they should work in tandem.</p>	<ul style="list-style-type: none"> • Workplan, prioritisation and KPIs: map MS needs and priorities. • Map existing initiatives addressing the development and implementation of HDsC and DQU. • Identification of topics for stakeholder engagement. • Ensure participation in relevant forum initiatives. • Benchmarking existing solutions. • Specifications and requirements to set up a HDsC and promote data quality and utility. • Health DCAT-AP metadata standard specifications developed by the EHDS2 pilot project should be considered.
Secure Processing Environments (SPEs)	<p>Aims to support MS designing and developing Secure Processing Environments, as MS begin to design, implement, pilot and / or go live in production.</p> <p>This Subgroup will support the definition of specifications and requirements, technical implementation, piloting and troubleshooting possible issues, as well as share good practices.</p> <p>This Subgroup should also consider</p>	<ul style="list-style-type: none"> • Workplan, prioritisation and KPIs: Map of MS needs and priorities. • Map existing initiatives addressing the development and implementation of SPEs: identification of topics for stakeholder engagement should be considered; participation in relevant forum initiatives must be ensured.

	interoperability standards in alignment with multi-country secondary data use.	<ul style="list-style-type: none"> • Benchmarking existing solutions. • Specifications and requirements to set up a SPE.
Cross-border Gateways	<p>Aims to support MS in designing and developing the cross-border gateway, as MS begin to design, implement, pilot and / or go live in production.</p> <p>This Subgroup aims to support the definition of specifications and requirements, technical implementation, piloting and troubleshooting possible issues, as well as share good practices. Support functional end-to-end testing.</p>	<ul style="list-style-type: none"> • Workplan, prioritisation and KPIs: map of MS needs and priorities. • Map existing initiatives addressing the development and implementation of HDsC and DQU. • Identification of topics for stakeholder engagement • Ensure participation in relevant forum initiatives. • Specifications and requirements to set up a Cross-border gateway.
Coordinating Deployment and Operations		
Deployment and Operations	<p>Aims to:</p> <ul style="list-style-type: none"> • support MS in setting up a HDAB. • facilitate collaboration among MS and with different stakeholders based on the needs identified in the subgroups; support MS in lowering implementation expenses by cooperation and sharing resources. • support MS in sharing their plans including sustainability and business continuity plans, and progress status. • define a KPI framework regarding the workplan of the different subgroups, as well as provide a status report. • define a service desk framework (incident classification, country-specific, cross-border-specific, personnel training, etc.). 	<ul style="list-style-type: none"> • Workplan, prioritisation and KPIs: map MS needs and priorities. • Guidelines to set up HDABs. • Mapping and analysing existing initiatives. • Identification of topics to be addressed by the forum and promoting a synergistic approach that prevents possible overlaps. • National implementation plans & progress reports, and maturity status. • KPIs framework and report. • Community service desk. • Shared licences for information systems. • Shared experts. • Connection with HealthData@EU central services. • Plan of twinning. • Implementation and pilot support. • Go live and routine operation support.
Stakeholders' engagement		

Stakeholders' Fora	<p>Aims to: Organise events to consult and engage stakeholders beyond the CoP, namely:</p> <ul style="list-style-type: none"> • EU projects and initiatives, joint actions; • External experts (e.g., from industry, universities, other sectors, which may represent different roles, such as data users, data holders). • EU institutions such as, but not limited to: ECDC, EMA, Eurostat, HERA and representatives of other data spaces. • International institutions such as, but not limited to: FDA, U.S. Department of Health & Human Services, Australian TGA, and representatives of other non-EU data spaces (e.g., Canada, Japan, China, USA, etc). 	<ul style="list-style-type: none"> • Gather perspective / viewpoints from different stakeholders' groups. • Collect insights from ongoing initiatives to trigger changes and updates on relevant requirements and specifications. • Identification of capacity building needs. • Provide knowledge on the frameworks and infrastructures existing outside EU towards highlighting the future directions for international interoperability.
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6 Toolbox

To support the effective functioning of the EHDS2 CA CoP, it is essential to establish a toolbox. The table below outlines the identified requirements, specific needs, potential solutions, and the responsible parties capable of providing them.

Additionally, the table below proposes a prioritisation of tools according to 2 deployment phases:

- Phase 1: the tools needed to start the CoP activities.
- Phase 2: the tools needed to take advantage of the full potential of the CoP activities.

NEED	REQUIREMENTS	DEPLOY. PHASE	CANDIDATE SOLUTIONS	PROVIDER
ONLINE COLLABORATION	<ul style="list-style-type: none"> - Structured Information - Jointly create and edit text - Upload documents (document registry) - Create links to other pages or online resources - Calendar of meetings - Map of national implementation plans - Templates for standard requests (i.e. change request, risk identification, Subgroup creation) 	Phase 1	Confluence	EC
VIDEOCONFERENCING	<ul style="list-style-type: none"> - Enable online meetings (audio, video and screen sharing); - Support chat functions, reactions, request the floor; 	Phase 1	Planned meeting: Webex	EC

	<ul style="list-style-type: none"> - Enable breakout rooms; - Enable recording of meetings; 		Ad Hoc bilateral meetings: Teams OS-tools (e.g. jitsy)	
FORUM	<ul style="list-style-type: none"> - Support discussion - Allow asking and answering questions in a structured way - Allow structure and store discussion and information in topics and threads - Allow uploading files - Search function 	Phase 1	Health Policy Platform	EC
INSTANT MESSAGES	<ul style="list-style-type: none"> - Accelerate communication between peers - Allow immediate communication - Easiness of use 	Phase 2	Slack Google chat Element Rocket chat	Slack.com https://chat.google.com/ https://element.io/ https://www.rocket.chat/
PUBLISHING	<ul style="list-style-type: none"> - Make information publicly available online; 	Phase 2	Joinup ¹	EC
ISSUE TRACKING	<ul style="list-style-type: none"> - Monitor, tracking of specific tasks, issues 	Phase 2	Jira Trello	EC

Upon conclusion of the deployment of the tools indicated in Phase1, a re-assessment is recommended to determine if the needs initially identified for Phase 2 are still valid or if, based on the insights collected during the CoP activities, new or higher priority needs were identified.

6.1 User stories

TOOL	User Stories
ONLINE COLLABORATION	<p>User Story 1-Developing guidelines for the data application form</p> <p>A HDAB is going to establish their data application form for the first time. Some countries are in the same situation, others have it in progress and others already have it.</p> <p>Those members of the CoP who already have it share their data application form in the common repository.</p> <p>These members can work together on a guideline for a data application form.</p>

¹ Example of a community <https://joinup.ec.europa.eu/collection/semic-support-centre>

	<p>All this information will be archived for any CoP member who may need it in the future, rather than build it from scratch.</p>
Videoconferencing	<p>User Story 1 - Planned meetings Several CoP subgroups plan to have weekly meetings over the next few months.</p> <p>User Story 2 - Planned meetings The CoP has identified some Working Packages from different projects that have some overlapping tasks, e.g. Application forms. Continuous monitoring is required from CoP. The CoP plans a series of online meetings with the participants of those projects.</p> <p>User Story 3 - Unplanned meetings The person "A" in charge of a task goes on leave unexpectedly and only has a few hours to notify the participants, he needs to call a meeting immediately to inform. "A" schedules a meeting from their professional teams with the participants in the next 15 min.</p>
FORUM	<p>User Story 1 - Asking advice on IT resources needed to host a dataset catalogue A member of a CA who is in charge of contracting IT services for hosting the Dataset Catalogue needs an estimation of the characteristics of the hosting service. He/she opens a new thread in the forum of EHDS2 CAs CoP under the topic of Dataset Catalogue, asking for advice on the hosting needs. Members of other CAs, who have already set up the Dataset Catalogue in their country, share their experiences. In the future, other countries that set up their Dataset Catalogues refer to this thread to estimate the need of resources.</p>
INSTANT MESSAGES	<p>User Story 1 - Asking information about a meeting Country A has organised a webinar to explain the dataflow of their HDAB. A person that has recently joined the health data agency of Country B asks for the connection details of the Webinar in the instant messaging app. Another user shares the meeting details and allows the new person to follow the webinar.</p> <p>User Story 2 - Support direct communication during test procedures If needed, while performing tests that involve more than one country, the test users could take advantage of the instant messaging tool to accelerate informal communication between them.</p>
PUBLISHING	<p>User Story 1 - Publishing Guidelines issued by the CoP Following the work of a Subgroup on a specific aspect of "secondary use of health data", the CoP considers important to disseminate the knowledge on specific guidelines and best practices. The CoP uses the publishing tool to publish and make publicly available the guidelines. This publishing tool would allow for version management, so that whoever discovers a document can always be redirected to the most updated version.</p> <p>User Story 2 - Publishing of Meeting Minutes Following a Global meeting of the CoP, for sake of transparency and trust from the public opinion, it is decided to make publicly available the main discussions, conclusions and agreed next steps. The CoP uses the publishing tool to publish the meeting minutes. The publishing tool should also allow interested people to indicate their interest in receiving updates</p>

	about upcoming events.
ISSUE TRACKING	<p>User Story 1 - Delineation and progress monitoring of strategic activities The CoP defined a strategic roadmap for deployment of tools to support the CoP. This involves the deployment of 3 tools for which different status are expected: analysis, configuration, testing and operation. To monitor the progress of deployment of this tool, the CoP decides to use the issue/task tracking system.</p> <p>User Story 2 - Organise an event The CoP agreed on organising a big event bringing together several stakeholders. To plan, coordinate and monitor the progress of the arrangements necessary before, during and after the event, the CoP decided to track all necessary tasks in the issue/task tracking system.</p> <p>User Story 3 - Issue tracking on the use of a common solution Upon adopting a common software solution to fulfil a certain digital business capability, the CoP agreed on starting using the issue tracking system to document, monitor and follow up on issues resulting from the use of such a common solution.</p>