



Deliverable D5.1

Report on coordination and outreach

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1. Executive Summary

The deliverable describes actions taken to organise Pillar II for *communication* between the partners, as well as *outreach* about results, like the software solutions for secure genomic data service deployment in the distributed 1+MG nodes.

By the deadline we have

- Established recurrent GDI Pillar II Meetings for both monthly formal progress monitoring and weekly consultation for interaction and questions to the Pillar II leadership. Individual Work Packages and Tasks also have set up their individual regular meetings.
- Created Dynamic Pillar II Documentation page: a navigation point linking useful information for easier discovery for partners.
- Released the GDI Starter Kit^{1,2} in June 2023 - a software collection produced by Pillar II to give an example for service deployment. It is made available as open source on Github.
- Established a plan for bi-annual Pillar II Workshops to advance the technical roadmap and build capacities by connecting European experts. The 1st workshop was held in Sweden in February 2023 and the 2nd workshop will be held in October 2023 in Rome, Italy.
- Coordinated with WP3 to drive the deployment of the Starter Kit by five Vanguard nodes³

Advancement of the technical roadmap is enabled by

- *Work Package leads* who report progress on WP3, WP4, WP5 and WP6.
- *National (technical) coordinators* who report advancement of service deployment in their country.
- *Product owners* who are responsible for developing individual software components for the GDI Starter Kit.
- *Vanguard nodes* that provide pioneering service deployment and share their practical expertise in the European setting.
- A *Risk Assessment* process to support secure operations

¹ <https://docs.google.com/document/d/1jVqFba6iUUyZTj-Tts3L4fnHDs46bJ1McM-PuDE4uSo/edit?usp=sharing>

² <https://github.com/GenomicDataInfrastructure/>

³ <https://doi.org/10.5281/zenodo.8074286>





2. Contribution towards project outcomes

With this deliverable, the project has reached or the deliverable has contributed to the following project outcomes:

	Contributed
<p>Outcome 1</p> <p>Secure federated infrastructure and data governance needed to enable sustainable and secure cross border linkage of genomic data sets in compliance with the relevant and agreed legal, ethical, quality and interoperability requirements and standards based on the progress achieved by the 1+MG initiative.</p>	Yes
<p>Outcome 2</p> <p>Platform performing distributed analysis of genetic/genomic data and any linked clinical/phenotypic information; it should be based on the principle of federated access to data sources, include a federated/multi party authorisation and authentication system, and enable application of appropriate secure multi-party and/or high-end computing, AI and simulation techniques and resources.</p>	Yes
<p>Outcome 3</p> <p>Clear description of the roles and responsibilities related to personal data and privacy protection, for humans and computers, applicable during project lifetime and after its finalisation.</p>	No
<p>Outcome 4</p> <p>Business model including an uptake strategy explaining the motivation, patient incentives and conditions for all stakeholders at the different levels (national, European, global) to support the GDI towards its sustainability, including data controllers, patients, citizens, data users, service providers (e.g., IT and biotech companies), healthcare systems and public authorities at large.</p>	No
<p>Outcome 5</p>	No



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<p>Sustained coordination mechanism for the GDI and for the GoE multi-country project launched in the context of the 1+MG initiative.</p>	
<p>Outcome 6</p> <p>Communication strategy – to be designed and implemented at the European and national levels.</p>	<p>No</p>
<p>Outcome 7</p> <p>Capacity building measures necessary to ensure the establishment, sustainable operation, and successful uptake of the infrastructure.</p>	<p>Yes</p>
<p>Outcome 8</p> <p>Financial support to the relevant stakeholders to enable extension, upgrade, creation and/or physical connection of further data sources beyond the project consortium or to implement the communication strategy and for capacity-building.</p>	<p>No</p>



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3. Methods

The aim of WP5 is to facilitate the progress of each of the nodes in the federated infrastructure through the three defined stages of maturity, and to realise this, WP5 has three tasks: 1) technical coordination through the onboarding, deployment and operational stages, 2) providing training and knowledge transfer, and 3) performing outreach to stakeholders (including citizens in collaboration with Pillar I) and other associated organisations, infrastructures, and projects. Technical workshops and training help the nodes with the progression through the maturity levels. Work targets are based on the recommendations from the 1+MG initiative and the B1MG project.

The 1+MG signatory countries are expected to indicate data infrastructure capacities where to deploy new genomic data management services that are developed in coordination by WP5 in the GDI Pillar II. The national nodes may choose local physical or virtual (cloud) infrastructure, or a hybrid strategy depending on national policies for sensitive data management and funding instruments. Availability of infrastructure on to which the 1+MG/GDI node services will be deployed is a critical success factor for each 1+MG member state individually, and required also for the success of WP5 European-level coordination of technical infrastructure service deployment.

WP5 coordination provides member states information on how to build their national capacity and capabilities through documented experience of (primarily the vanguard) nodes which are ahead in the process, and by providing a European peer network for national experts. WP3, WP4 and WP5 together provide support from experience in deploying the European interoperability layers on the chosen data infrastructure. Each national node implements the required capabilities based on this experience, and adapts processes, services and emerging genomic data technologies to be congruent with national genome data strategy decisions. Over time, each node deployment will need to be dynamically adjusted to follow the 1+MG node development roadmap and the service architecture work of the Pillar II that is building on the B1MG data infrastructure proof-of-concept.

The work in WP5 especially drives forward technical interoperability between the 1+MG nodes that will be operated in each country. This technical interoperability is a prerequisite for improved semantic interoperability (see also WP8). To realise the needed technical interoperability, WP5 forms a technical network of 1+MG infrastructure experts who can train and provide knowledge and technology transfer between existing and aspiring nodes. Co-development of existing services, including dissemination of new developments and requirements of the infrastructure arising from Data Protection by Design and Default principles, will be performed across nodes. Capacities made available in each national node are key. Independent of the choices of the national nodes for deployment of physical or cloud infrastructure, WP5 coordination provides a common strategy for interoperability, as well as scalability for storage or compute or data network required in the longer term to support the proposed volume of data and number processing requests.





4. Description of work accomplished

The GDI Pillar II comprises four WPs, numbered 3 through 6. WP3 is designed to support a national node as it progresses sequentially through the three-stages of maturity - onboarding, deployment, to operational status, which are mapped to Technical Readiness Levels (TRLs), including quarterly self-assessments and monitoring of progress (by WP1), and required software development. This work is supported by WP5 and existing operational nodes. WP4 is concerned with European level operations which ensure that once national nodes are operational, they are fully interoperable with each other and that they can operate as a single unit through centrally provided services. WP5 is technical coordination, training, and outreach, while WP6 provides the data management plans for onboarding of 1+MG genomic datasets and technical implementation of data governance. Through these WPs, Pillar II will deliver, deploy, and maintain the infrastructure and services defined by the 1+MG/B1MG PoC that will provide the specifications and operational service model for federated national nodes (holders of 1+MG data), each typically deployed by a nation or region. WP5 supports the interactions between the four WPs in Pillar II as well as Pillar interactions between Pillar II and Pillars I and III. To cover the scope of this deliverable, the internal communication between the partners in the technical work packages and the outreach to others, the organisation of the technical development roadmap, and the setup of processes to guarantee secure operations of genomic data services will now each be described in more detail.

4.1 Communication Roadmap

Several meeting series with different goals and scopes have been set up by WP5 to connect Pillar II together.

4.1.1 Pillar II monthly formal meeting

First, the main binding meeting is the GDI Pillar II monthly coordination meeting. The Pillar II monthly meeting is driven by the work package and Pillar II leads. Each month, it connects software solution product owners, national deployment coordination, and discusses choices of standards. All Pillar II participants are encouraged to participate. Generally, between 40 and 55 participants are registered in the participant list of the meetings.. The meeting is considered also as an outreach event, it is open for external experts from institutes who are not directly involved in the GDI project, as well as representatives from other projects and data spaces, such as EHDS and EUCAIM.

In these monthly meetings, the *Work Package Leads* each report their progress using standard reporting templates. Voluntary summaries of activities in Pillar I and Pillar III are also solicited in the same template.



Countries and national coordinators report their technical progress in a standard template as well. In the meeting only highlights and observed issues from countries are usually discussed and addressed to observe time constraints.

Further agenda items are identified and prioritised and invited by Pillar II leads.

Notes of the proceedings of these meetings are taken collaboratively in a rolling minutes document, which also contains links to the templates filled by national coordinators and work package leaders.

4.1.2 Pillar II weekly free-form “coffee” meeting

Secondly, a meeting series is set up for the entire Pillar II as a *free-form coffee break* repeating weekly meeting on Mondays. These meetings do not have an agenda, but focus on topical items, successes and the upcoming week. Project participants are encouraged in this meeting to raise any issues and questions they may have to the Pillar leadership. An average of 20-25 participants take part in these meetings. For these meetings also notes are taken collaboratively in a rolling minutes document.

4.1.3 Pillar II Work package meeting series

In WP3 a separate closed meeting series has been set up in which product owners discuss progress and issues for product integration. Also, a regular meeting series has been set up to foster interactions between the product owners and the work package leaders. Notes of these meetings are taken collaboratively in a rolling notes document. These two meetings will soon be supplemented with a third informal series of deployment catchup; this will aid in the scaleup of operations in other nodes. Continued technical development is supported by WP3-led workshops (described separately below).

For WP4 a monthly meeting is set up in which each task reports progress. Each meeting also features a more in-depth presentation by one of the tasks reporting progress and issues faced. Notes of these meetings are taken collaboratively in a rolling notes document.

WP6 also set up monthly meetings where each of the Task Leads reports on progress using a standardised template. In addition, each meeting can also address a single topic relevant to data management. For example, in the early months of the project each of the use-cases in the project has been invited to present their use-case in the WP6 meeting, informing the interaction of Pillar II and Pillar III. Notes of these meetings are taken collaboratively in a rolling notes document.

As a further form of outreach, several members of Pillar II, including the Pillar leaders and the WPL of WP6 (Data Management) are systematically attending meetings in Pillar I and Pillar III to monitor the interactions between all the GDI Pillars. Similarly, Pillar I and Pillar III leads are invited to the Pillar II meetings. GDI Pillar II also needs to address the data protection and governance requirements that came from B1MG WP2, and continue to come with 1+MG WG2, to ensure the work of Pillar II conforms to all necessary legal and ethical requirements. This interaction was primarily via B1MG arranged workshops (held in Brussels in February and September 2023), but formal communication



channels between Pillar II and 1+MG WGs, such as regular meetings or email lists, need to be agreed to continue where B1MG left off, incorporating Pillar III and the coordinator.

Pillar II/WP5 also maintains an in-project page of *GDI Pillar II Key Documents* which provides mostly in-project pointers to presentations, demos and meeting agendas and notes. Links are updated to represent the most relevant content at each moment.

4.1.4 Relationships to other European-level actions and legislation

GDI is interaction with the EHDS2 via the HealthData@EU⁴ pilot project and ELIXIR to present the genomics use case for secondary use of health data, and the alignment is also detailed on the 1+MG framework website⁵, and GDI has also taken account of relevant work from TEHDAS⁶ to try and ensure alignment, and has contributed to the TEHDAS deliverable 7.2 on 'Options for the services and services architecture and infrastructure for secondary use in EHDS'⁷. As GDI outputs are open source, GDI products, and utilised standards can be used by other data spaces and infrastructures for genomic data that does not reside within the GDI, but ensure interoperability. The Pillar II monthly formal meeting is also a place where participation by EHDS and DG SANTE occurs, helping to align GDI with EHDS.

4.2 Technical Coordination Roadmap

Major coordinated technical result achieved so far is the *GDI Starter Kit* released in June 2023. Product owners for each of the identified software components of the GDI Starter Kit were nominated at the very beginning of the project. These product owners have worked together to build these components into the starter kit that has been released as a set of containers available through GitHub.

Also very early in the project, vanguard nodes were identified who have started the implementation of the five 1+MG functionalities by using components of the Starter Kit or alternatives of their own choosing. In June 2023, five of the vanguard nodes were able to demonstrate the functionalities in order to reach the first big technical milestone in the project. This was also communicated externally via a press release⁸,

GDI uses GitHub⁹ as the central repository for the products developed by GDI, and also is establishing a Zenhub instance to track and map the requirements, documentation, and SOPs developed within the project, and help track the work that is required to support the use cases, stakeholders, and other end users. This is especially important with respect to 1+MG WG2 (ELSI), to ensure that the data protection requirements are addressed and tracked.

⁴ <https://ehds2pilot.eu/>

⁵ <https://framework.onemilliongenomes.eu/ehds-data-lifecycle>

⁶ <https://tehdas.eu/>

⁷ <https://tehdas.eu/app/uploads/2023/07/tehdas-options-for-the-services-and-services-architecture-and-infrastructure.pdf>

⁸ <https://gdi.onemilliongenomes.eu/gdi-starter-kit.html>

⁹ <https://github.com/GenomicDataInfrastructure/>





4.2.1 Technical Workshops

Continued technical development is supported by Pillar II workshops. Agenda of the meetings is set according to what is timely for Pillar II and especially WP3, including service deployment and software development where gaps are identified in the existing products recommended for the infrastructure. Invitations are extended to Pillar II members, and participation is expected from project members that are working on the topics to be addressed at the workshop. Participation from all infrastructure nodes is encouraged and this is monitored throughout the registration period. The purpose of these face-to-face workshops is to streamline knowledge transfer and capacity building across Europe between experts by openly sharing best practices and working together during the lifetime of the GDI project. Workshops are intended to take place at least once a year; in the first project year two workshops were organised to cover the urgent needs of the project and early deliverables.

4.2.1.1 First workshop: Sweden

The first of the technical workshops was held in Sweden in March 2023 and supported the assembly of the Starter Kit and the process towards the first demonstration of the functionalities. The meeting had 65 participants.

4.2.1.2 Second workshop: Italy

A second workshop is planned for October 2023 in Italy to further develop the node deployments (WP3), including connection to the future user portal (WP4), scaling out the starter kit knowledge to new nodes (WP3), and refinement of the Data Management knowledge (WP6) that will help each node create and maintain a data management plan including the project-developed Standard Operating Procedures (WP3/4/5) and a Risk assessment procedure (see 4.3). Two weeks before the meeting, 93 people were registered and with this list all but one country in the project will be represented.

4.2.1.3 Third workshop: TBC

A Third workshop is planned and we are seeking a host to organise it with Pillar II leadership in 2024.

4.3 Risk Assessment Matrix

Risk assessments and security audits on all relevant GDI information assets¹⁰ within each of the national nodes, the central components (like the GDI User Portal) and federated infrastructure will be performed regularly to obtain a comprehensive view on the entire infrastructure. A Plan-do-check-act cycle is planned (frequency to be established, probably yearly) to iteratively improve the infrastructure and identify and manage risks. Pillar II will facilitate building of this process

¹⁰ A GDI information asset is defined as any data, device, tool or other component of the environment that supports information-related activities. Assets generally include hardware (e.g. servers and switches), software (e.g. applications and support systems), services and confidential information.



in collaboration with Pillar I. So far, a GDI Risk Assessment template (spreadsheet¹¹ based) has been prepared by WP5, based on a FitSM model¹², that will allow the project as a whole and the individual nodes to analyse risks and plan mitigation (control measures). Each identified potential vulnerability vector is assigned a likelihood of occurring, and an impact score. Based on the combination of likelihood and impact, each potential vulnerability is assigned a time window for mitigation. A meeting has been planned to present the risk assessment procedure (inventory, assessment, control measures), the model, who should be involved, and the proposed tool to the relevant participants. At that meeting decisions are to be taken about safe ways of collecting the information at the different nodes, and how potential vulnerabilities can be shared from nodes that have identified them to nodes that may also be affected without elevating risks or creating additional risks through public communication. This will be a process in the GDI project in the beginning, and the operational organisation running the created infrastructure as soon as possible later.

A decision to promote a node to deployment or production level will be defined based on availability of processes such as these risk assessments including disaster recovery plans, TRL of a node, ELSI compliance via data protection by design and default principles, and overall sustainability of service operations, each proven in the appropriate way such as with appropriate contracts.

4.4 Outreach

Outreach is a crucial part of WP5 to bring the work of the GDI to a wider audience. Part of this process has been to establish and maintain communication channels with associated projects and organisations. Two presentations were given to the Global Alliance for Genomics and Health¹³ (GA4GH) at the GA4GH Connect meeting¹⁴ in London (19 - 21 April 2023) on the Genomic Data Infrastructure¹⁵ and the GDI as a GA4GH Implementation Forum (GIF) project. Additionally GDI was presented at the GA4GH 11th Plenary in San Francisco on September 20th 2023.

WP5 has also given input into the work of the Data Spaces Support Centre¹⁶, which aims to identify common practices and identify best practices across different data spaces within the EU. As mentioned above, WP5 has also been participating in the HealthData@EU Pilot to try and ensure that the requirements of the GDI are taken into account in the development of the EHDS (secondary use) and vice versa.

WP5 has also worked with the ELIXIR Human Data Communities and the ELIXIR Federated Human Data Community to ensure that the developments within the GDI are regularly disseminated outside of the GDI to interested communities and associated projects, such as Federated EGA¹⁷. Along with

¹¹ <https://docs.google.com/spreadsheets/d/1AA31HX-Z6iMAxDKxNQmKqfBWN5Odesrf/>

¹² <https://www.fitsm.eu/>

¹³ <https://www.ga4gh.org/>

¹⁴ <https://www.ga4gh.org/event/ga4gh-connect/>

¹⁵ <https://drive.google.com/file/d/1-miOSSXyjp-q8yvl5TEihndiZUTJ7HP4/view>

¹⁶ <https://dssc.eu/>

¹⁷ <https://ega-archive.org/federated>



the interactions with GA4GH, these processes try to ensure technical, and where possible, semantic interoperability of the GDI infrastructure with other genomic data infrastructures.

WP5 has also worked with WP4 on B1MG to ensure the B1MG roadmap aligns as much as possible with the GDI roadmap, and that all the recommendations and actions coming out of B1MG are actioned during the course of GDI. This includes monitoring and working with the deployment of the EU wide digital identity¹⁸ and SIMPL¹⁹. The eID will enable data subjects, as citizens, to monitor and control the use of their data, when this exists within the GDI, enabling increased trust of the infrastructure with EU citizens and residents. SIMPL will ensure that the different sectoral data spaces, such as Genomics, Energy, Agriculture etc are interoperable and can be interconnected.

5. Results

We have

- Established recurrent GDI Pillar II Meetings for both monthly formal progress monitoring and weekly consultation for interaction and questions to the Pillar II leadership. Individual Work packages and tasks also have set up their individual regular meetings.
- Created Dynamic Pillar II Documentation page: a navigation point linking useful information for easier discovery for partners
- Released the GDI Starter Kit^{20, 21} in June 2023 - a software package produced by Pillar II to give an example for service deployment. It is made available as open source on Github.
- Established a plan for bi-annual Pillar II Workshops to advance the technical roadmap and build capacities by connecting European experts. The 1st workshop was held in Sweden in February 2023 and the 2nd workshop will be held in October 2023 in Rome, Italy.
- Coordinated with WP3 the deployment of the Starter Kit by five Vanguard nodes²²

In order to coordinate the GDI Pillar II technical roadmap we have organised

- *Work Package Leads* reporting progress on WP3, WP4, WP5 and WP6 in meeting series
- *National (technical) coordinators* to report advancement of service deployment in their country in WP5/Pillar II monthly meeting
- *Product owners* who are responsible for developing individual software components for European integrated software package initiated by releasing the Starter Kit
- *Vanguard nodes provide* pioneering service deployment and share their expertise in the European setting.

¹⁸ https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/europe-fit-digital-age/european-digital-identity_en

¹⁹ <https://digital-strategy.ec.europa.eu/en/news/simpl-cloud-edge-federations-and-data-spaces-made-simple-updated-august-2023>

²⁰ <https://docs.google.com/document/d/1jVqFba6iUUyZTj-Tts3L4fnHDS46bJ1McM-PuDE4uSo/edit?usp=sharing>

²¹ <https://github.com/GenomicDataInfrastructure/>

²² <https://doi.org/10.5281/zenodo.8074286>



The GDI starter Kit was presented in a dedicated workshop²³ at the ELIXIR All Hands²⁴ in Dublin on June 8th 2023 and the 1+MG special group meetings. The interaction with EHDS has resulted in the use of DCAT-AP within the GDI User Portal to ensure interoperability with the data catalogue in EHDS².

6. Discussion

An increasing number of 1+MG technical PoC services are becoming deployed in vanguard nodes. The next step is to combine the experience from individual nodes into a process to make refinements to the 1+MG PoC technical services architecture design. The process has not been started yet, the plan is to include a small group of Pillar II experts to make a draft of the architecture from 1+MG operational, "business", service and stakeholder viewpoints. This prospective blueprint of a national 1+MG node is the starting point for further discussions across GDI Pillars.

The principles of data protection by design and by default²⁵ are adopted for all architecture planning, and new software development and deployment in the project. However, the tools in the starter kit and almost all other services and tools deployed for the setup of the 1+MG infrastructure have been designed and built before the start of the GDI project. As part of the risk assessment process, an evaluation of their design and defaults is to be undertaken and GDI will implement appropriate technical and organisational measures to achieve better alignment with data protection by design and default principles.

GDI is interacting with EHDS via HealthData@EU, but the landscape around EHDS is evolving and changing, which presents a risk to GDI timelines by delaying decisions based on the EHDS. However the core GDI infrastructure is based on international open and community based standards, and as such represents the current state of the art in genomic data sharing. This means that however the different data spaces and infrastructures evolve, they should be interoperable even if they are separate. However, the optimal solution would be for the same core infrastructure to be applicable to the genomic data in each and all data spaces.

7. Conclusions & Impact

The coordination mechanisms for connecting and coordinating people across all the European partners in the technical Pillar of the project have been established.

The first major result was achieved with the publication of the GDI Starter Kit in June 2023 and demonstration at the annual ELIXIR All-Hands meeting, which has been widely communicated.²⁶ Five

²³ <https://docs.google.com/document/d/18keVeoqujEikJ2cuitOBgeWmwsPMFy1E5AbdAciyspl/edit>

²⁴ <https://elixir-events.eventscase.com/EN/elixirallhands2023/Agenda>

²⁵ <https://gdpr-info.eu/art-25-gdpr/>

²⁶ <https://gdi.onemilliongenomes.eu/gdi-starter-kit.html>



nodes quickly demonstrated the functionalities, and other nodes in the GDI network are using their experience and the results to work on their own implementations.

Meetings that have been set up in Pillar II are generally well-attended, with e.g. sometimes over 50 participants in the Pillar II meetings and 20-25 in the informal coffee meetings.. Cross-Pillar interactions are cultivated but could still be strengthened further by giving other Pillars more systematically a platform to raise their own issues. The first technical workshop had participation from all but two countries in the project, including all vanguard nodes and product owners. The workshop resulted in a common understanding about the functioning expected from the starter kit, and how the products were to be connected. Registrations for the second technical workshop show participation from all but one country in the project. Both workshops have achieved their desired reach.

Ultimate output of the collaborations is technical progress in the implementation of the nodes, which is monitored through a maturity model by WP1 and reported separately..

8. Next steps

Next high-level coordination target is aligning the data management needs in the Genome of Europe (GoE) with the emerging services from the GDI data infrastructure. Continuing iterations with ELSI data protection by design and default principles constitutes a major undertaking as well. Many of the starter products have been used in production services in individual countries, and are being applied for the 1+MG initiative ambitions in the GDI project. Discussion with the legal experts is expected to lead to refinements of the existing software to comply with the data protection principles needed to securely manage genomic data types needed in order to understand the molecular basis of the driving use cases in Pillar III, including Genome of Europe.

