



French Gaia-X Hub

## **POSITION PAPER**

*GT Health*

v.0.9

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## *GT Health*

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## 1 VISION, AMBITIONS AND OBJECTIVES

The European Union has set its first principles on the single market that seeks to guarantee the free movement of goods, people, capitals and services. Data is the 5th pillar of these freedoms and needs to be supported as it marks the next steps in ensuring the European position in a global market. In an ever-evolving world where new actors emerge every day, reinforcing the unity and sovereignty of European citizens on key issues cannot be understated. Health data is a sensitive topic for European citizens, as well as a strategic asset for governing bodies to understand and protect their population. However, due to a lack of transparency and education about what are these data and their rules of usage, it crystalizes the public debate on ethical breaches and misusages. However, both public and private sectors data users abide to strict ethical rules and use these data to further medical knowledge for the greater community. Our four main goals are:

- maintaining European sovereignty on health data,
- creating trust in personal healthcare data usage, guaranteeing transparency and compliance towards EU and local regulations
- improving care provided to patients with big data and AI technologies,
- focusing healthcare and health pathways on patients' outcomes and real-world evidence.

For France in particular, the objective is to become one of the leading countries in health data access and utilization, in order to improve healthcare systems and the care provided to patients by leveraging European data. The more access we have to European data, the more we will be able to design suitable products that answer European ambitions and population needs. It is one of the prerequisites for precision medicine. Furthermore, this will increase attractiveness for European clinical trials. It is therefore fundamental that France and other European countries can get access to adequate means of facing those challenges against worldwide competition. Leveraging existing data, defining high quality usage models, and creating a real politic for data collection and harmonization will permit the creation of one of the highest quality repositories of health data in the world. By developing a fully transparent catalogue that defines each source of healthcare data (including a high-level definition, origin of data, size of the sample, accessible variables, authorized usage and a clear access path with a single point of contact for each within a defined timeline) transparency would be improved and a framework in which citizens are able to understand how their data might be used would be defined clearly.



## 2 USE CASES

### PRIORITY ONE USE CASE DESCRIPTIONS BRINGING SHORT-TERM VALUE

#### 1. Transparency of data for a holistic understandable epidemic dynamic for every citizen

##### Description:

Create a web platform which collects health, social and economic data and cross-references it to display relevant information regarding different situations such as the COVID-19 pandemic for example. The AI would be applied to forecast the situation and different scenarios in order to allow informed response decisions to be made.

##### Solution:

A pilot regarding the local COVID situation already exists but should be extended to other diseases or social challenges. This tool permits a holistic vision of a situation and the taking of decisions based on data and projections.

##### Problem solved:

The COVID pandemic is a good example of how difficult it is to get a holistic view to understand a dynamic situation whatever it might be: obesity, muscular skeleton disorders, seasonal flu, burn out... This platform associated with AI should be a very useful tool in so many cases.

##### Partner ecosystem:

Grand EST French Area has already developed and deploy the COVID pilot. Key partnership with French border countries, such as Germany as a first step, will permit to start quickly to extend this tool to other countries.

##### Main technology/GAIA-X components:

GAIA-X could be the central platform to pick up the different data sources and feed the model needed to handle emerging diseases and epidemics.

##### Concrete benefits:

- Ability to provide a data-driven management of health crisis
- Time saved in data collection, analyzing and treatment giving back this time to all stakeholders that are currently responsible for these actions
- Rapid understanding and mapping of tricky situations in order to make sensible decisions
- Transparency required by European Citizens to understand and accept the decisions which are applied to them. this is fully aligned with the responsible research and innovation paradigm promoted by European Commission



## 2. Image Archiving and Sharing for Medical Professionals and the Citizen

### Description:

Solution implements the sharing of medical images across a healthcare enterprise and with the citizen, based on an IHE (Integrating the Healthcare Enterprise) profiles known as Cross Enterprise Document Sharing for Images (XDS-i) and Cross Community Access (XCA). This profile is one component of the larger IHE XDS interoperability profile that describes how to establish true interoperability across healthcare enterprises when exchanging patient information. The result is an approach to cross-enterprise image sharing that brings the right data to the right people at the right time, to support the care process for individual patients as well as the collection of medical images for secondary use.

The same method should be applied with the pathology images, required the digitalization of the activities, which meet the same challenges: share and archive. The care management will take into account of different source of data and image, specifically in oncology. The facility of access and sharing is key to improve and change this aspect.

### Solution:

Nowadays, a mixture of formats is used to share medical images (film, prints, DVD, Email, software portals, messaging services). Healthcare professionals do not have easy or quick access to medical images of a patient, especially when these were created at another clinic or enterprise. Patients/citizens do not have a single means to access their medical images, independent of the location where they were made. Researchers do not have an easy/affordable way to collect large sets of digital images for clinical trials or research.

### Problem solved:

This capability is expected to reduce the amount of unnecessary images (because a previous image was not known or not available at the point of care), to reduce costs in image handling, and to give the citizen control over their medical images and their destiny (e.g. for 2nd opinion, when switching treating physician or when traveling across Europe)."

### Partner ecosystem:

The use case involves the medical image storage and archive solutions that store the (often) large images at source. These are typically maintained by the IT organizations of clinical operations (radiology clinics, hospitals, etc.), on premise or in a cloud. Image sharing across a region requires a central infrastructure with a central document registry and a document retrieval/viewing functionality, maintained by an IT organization of a regional entity. The required IHE components are available from several IT vendors, to be implemented by an implementation team. This team works together closely with IT specialists at the local and regional entities.

### Main technology/GAIA-X components:

The ambition of this use case is to connect these image exchange infrastructures at a supra-regional or supra-national scale, deploying on the federated GAIA-X infrastructure. Existing XDS-i infrastructures are candidates for adoption as nodes of the GAIA-X infrastructure. To



realize this, Philips has volunteered to take a coordinating role between a selection of existing XDS-i infrastructures, their owners and respective suppliers, in order to realize a breakthrough in scale and availability. Other volunteers are requested to join the initiative and to extend the functionality with additional enabling capabilities (e.g. patient consent management, image de-identification, decentral image analysis services, and more). An alignment is required with the cross-border sharing of imaging on the roadmap of the European Health Data Space. This use case builds upon that initiative.

This use case relies on the IHE XDS and XCA standards. A first implementation can use existing XDS-i implementations and/or implement one or more additional XDS-i implementations and connect them to one or more patient portals. The standards exist to combine multiple XDS-i infrastructures: cross community access (XCA-i). The main tasks during implementation at scale include:

- Develop a standard deployment model of XDS-i and XCA-i components on the GAIA-X infrastructure
- Develop a standard implementation package (software/services) to support easy adoption by image storage and archive systems
- Coordinate the integration of existing XDS-i infrastructures
- Coordinate the targeted deployment of new image sharing and image storage infrastructures. The deployment requires identity and authentication management (IAM) for patients and providers, and a provider directory.

#### Concrete benefits:

- Provide an imaging component to the Electronic Health Record or Patient Health Record: the shared imaging record, in a community, region, etc.
- Effective means to contribute and access imaging documents across health enterprises, for clinical care as well as research
- Enable sharing imaging documents between radiology or surgical departments, private physicians, clinics, long term care, acute care with different clinical IT systems
- Care providers are offered the means to query and retrieve imaging documents (images and reports) of interest using the same mechanisms used to query other documents
- Provide access to images for the patient/citizen from a single overview, even when images were created at different locations
- A unified approach to support patient rights (access to images), clinical care (images at the point of care) as well as research (image collection).

### **3. Digital Health, predictive and personalized medicine**

#### Solution:

Develop tools that are able to suggest personalized care plans for patients and predict health deterioration or crises. In addition, predict the costs for patients, governments and health industries.

#### Problem solved:



This use case is to manage healthcare costs more efficiently than today by improving healthcare pathways and patient management, finally in achieving Value Based Healthcare (VBHC).

Three steps are needed: 1) Stratification of population 2) profiling of each patient accordingly to the stratification, and defining the optimal care plan 3) adjustment of care plans based on new real-time information collected by digital and connected devices or on-line questionnaires, etc.

#### Partner ecosystem:

Hospitals, National health systems, health industry, pharmaceutical industry, Biotech and IoT companies and startups (medical device manufacturers, Health IoT device providers). Accelerate the growth and success of European Health Startups. The new emergent Digital Therapeutics (DTx) market is a great opportunity for Europe.

#### Main tech / GAIA X component:

This project implies common requirements for European personal and health data management. It requires the merging of several databases, coming from different sources: hospitals, homes, pharmacies... Data access, lack of standards, multiplicity of partnership, non-uniformity of national health systems in EU... are difficulties that GAIA-X can help overcome. Furthermore, accessing to data in real-time to help with day-to-day care (and not only retrospective studies), may be a key differentiator for GAIA-X

Interoperability and the standards used are key. Indeed, in order to share, operate, analyze, build AI models and so on with data coming from different stakeholders all across Europe, we need to be able to connect our databases and "speak the same language". This requires having defined standards for those databases (like the HL7 / FHIR standard) and connecting them through APIs or transferring and storing them in dedicated secure centralized data lakes.

#### Concrete benefits:

Unleash the potential of AI based medicine across Europe. With that said the second benefit becomes obvious, which is the rise of European companies as worldwide competitors allow digital sovereignty. Also, this use case answer one of the main goals of GAIA-X which is to develop common requirements for a European data infrastructure.

## **4. Rare Diseases**

### Context

The French Government, French Life Science companies and French university hospitals have invested in Rare Diseases research and treatment for a long time. In 2007, they created a data bank (BNDMR, standing for "*Banque Nationale de Données Maladies Rares*"),





collecting a limited number of items per patients, including the Common Data Elements<sup>1</sup>. Indeed, the French minimal data set has inspired the European CDE.

With 700k patients, this is a largest rare disease epidemiologic cohort in the world, already serving several research purposes, in particular along epidemiology, public health, and health economics. The unified structure and data model, which included about 6 000 different rare diseases, is a precious asset. For example, it provides a National Rare Diseases Identifier (IdMR) to guarantee anonymity and interoperability with other registries on rare diseases. Different international standards and nomenclatures specify the diagnosis and other descriptors such as phenotypes (Orphanet, HPO, ICD-10) or genes (HGNC). It should be noted that CDE are the essential elements of any genomic prescription, therefore gathering them may serve a number of purposes.

### Problem solved

Some diseases are so rare that one can expect that less than 100 patients may be diagnosed for each disease throughout the whole Europe. This makes it all the more so important for physicians and researchers to know where patients are taken care of and can be contacted for integrating research programs.

### Solution

CDE should be collected and made easily accessible throughout Europe.

### Partner ecosystem

France is leading 7 of 24 of European Reference Networks (ERNs) for rare diseases. All ERNs have been granted a limited subsidy for building rare disease registries. ERNs are in turn assisted by the European Joint Program on Rare Diseases, dealing with interoperability issues and includes a FAIRification program. Separately, various Natural Language Processing (NLP) projects are conducted in various countries, and several around CDE.

### Main tech / Gaia X component

While first steps have already been undertaken in this direction, it is paramount to work on at least three additional projects to make this data collection and accessibility real over the medium term:

- a) *Gaia X should manage a European project on equipping hospitals with direct data collection forms nested into HER : In order to prevent data collection fatigue, not only web based application should be developed but preferably IT forms directly nested within electronic health records*
- b) *Gaia X could provide IT technical support on FAIRification throughout Europe as well as data science support on data valuation*
- c) *Last, also to deal with structured data collection fatigue, Gaia X could manage a European Natural Language Processing project in order to (half-)automatically fill in the CDE throughout all European hospitals*

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<sup>1</sup> [https://eu-rd-platform.jrc.ec.europa.eu/set-of-common-data-elements\\_en](https://eu-rd-platform.jrc.ec.europa.eu/set-of-common-data-elements_en)





## 5. European Health Data catalog for transparency and Innovation

### Description / Solution:

Healthcare data users are facing issues for identifying adequate data sources, as they are usually non-advertised, and must rely on a third-party vendor that limits its access due to intermediary fees which drastically increases the cost for each project, or restricts focus on specific high value services. As these intermediaries play a crucial role as they gain expertise on data, they shouldn't be the gatekeepers of data access despite their obvious added value for independent analysis generation.

European Citizens with higher visibility of existing data will then get a better understanding of the rules and limitations of usage, and potentially a central hub to use their rights to retraction of databases as per their fundamental right under GDPR guidelines.

The main idea is to create a one-stop-desk providing details and transparency on:

- Available data (content, format, topic)
- Location and ownership
- Access and governance
- Pricing
- Technical documentation and data description

The catalogue should be greater than a single list of sources, and would need to serve all actors from the health data chain:

Healthcare data producers would also find a framework to mutualize efforts for data access, foster collaboration and apply single data models (i.e. FAIR, FHIR, OMOP CDM) with the objective of achieving new discoveries and a greater number of publications in emerging fields of research where data is crucial. It will also set a transparent "marketplace" for data with adequate pricing and a single-entry point for sources that will allow users to meet their compliance requirements by avoiding payments to an undefined body.

European and National institutions will be able to access and compare best practices in terms of care, allowing improvement to their own practices, and base evaluations on larger samples of data that will have a higher representation of European citizen diversity.

### Problem solved:

The catalogue is only the cornerstone of a bigger vision where local, national and European bodies will be able to collaborate and set up standards for data sharing, access rules and support.

This catalogue should be primarily aimed at healthcare data, however, additional data that provides context of the patient status need to be included as well (socio-economics, demographics, meteorology etc.).

Partner ecosystem: Leveraging Health Data Hub initiative and existing French catalogue. Hospitals, National health systems, health industry, pharmaceutical industry, Biotech and IoT companies and startups (medical device manufacturers, Health IoT device providers...).



The idea is also to leverage local /regional hubs technical and regulatory expertise and network.

#### Main technology / GAIA-X components:

The catalogue must be a trusted marketplace with no direct hosting, to avoid issues of data security. However, data should be accessible through either local institution or a secured common analytic platform. To reflect the trend in federated data analytics, the catalogue must also be supportive of emerging technologies platforms (ARKHN or Health data Train) and initiatives (such as EDHEN network) to facilitate access to data in a secured way.

The data harmonization challenge is not limited to shared standards, in particular when dealing with clinical data we are facing a variety of clinical pathways (the patient journey in France is not exactly the same in Germany or elsewhere) and this has to be taken into account when aggregating data.

The catalogue would also offer services on top of centralizing all available initiatives: a standardized metadata catalog, a data quality module, etc.

#### Concrete benefits:

This catalogue would also highlight the richness of the European health data ecosystem, and therefore increase its usage by European and non-European users. This will be to the benefit of the regulatory bodies that will have regulatory submissions based on European populations, and the data producer that will be able to cover their investments to make the data accessible to a wider audience.

Participation in the catalogue must be voluntary, with an incentive to participate by providing clear benefits to data producers (either from a framework for patients to retract, or a lesser grading of trust from the regulators to incite users to use the platform rather than individual sources)

Adding to the data listing, the catalogue must also be a place where data producers can exchange best practices to foster the community and, in time, support the ones with an ambition to share data to execute their vision

### **OTHER USE CASES OF INTEREST**

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#### **6. Governance & Accessibility**

Each stakeholder (research, start-up, enterprise etc) on GAIA-X should be clearly identified and a RBAC (Role-Based Access Control) system will deliver the correct rights. A traceability system will track each action for compliance and security concerns.

A Sandbox environment will be created for data exploration if the data is not permitted to leave the GAIA-X confines. A similar example is TrinetX in the US <https://trinetx.com/>



On upload process, a part of metadata will be mandatory to permit accessibility. For example, therapeutic area or clinical trial number. Without that, the Data Catalog will be useless.

In addition, French data protection authority (CNIL) may inspire other European countries for it has created special rules or “reference methods” which allow researchers to use Real World Data without any formalism. Instead, researchers and stakeholders commit to respect all the rules for data privacy.

## 7. Genomics (mainly for Oncology & Rare diseases)

Genomic medicine is profoundly changing patient care. To ensure that everyone has access to new technologies in genomic medicine in an equitable manner throughout the country, French government has setting up a plan: the French Plan for Genomic Medicine 2025. It aims to change methods for diagnosis, prevention and treatment of patients by 2025. To address territorial issues, two platforms (300M€) have been set up: SeqOIA (<https://laboratoire-seqoia.fr/>), to cover the north and west, and Auragen, for east and south. Each platform has been designed to handle around 18,000 patients per year.

Yet, an official list of 61 prescriptions (for rare disease and cancer) allow physicists and doctor to prescribe their patients a molecular profiling. For cancers, the patient will benefit from the sequencing of the whole genome (WGS-T), whole exome (WES-T) and whole transcriptome (WTS-T) of the tumor, as well as the sequencing of the whole genome of blood sample (WGS-C); for rare diseases, the patient and its close relatives (parents, close family) while benefit from a whole genome sequencing of blood (WGS-C).

Relying on the biological and technical expertise of MOABI, the AP-HP bioinformatics core facility (<http://idfseqit.fr/>), that has previously developed specific tools for specific disease gene panel sequencing data analysis (around 40,000 patients per year), SeqOIA brings this expertise at the genome scale level, breaking technological boundaries (hardware and software).

Two applications have already been developed and are shared in open source:

- Spice: This application is used to handle medical prescriptions and contains clinical information of the patient
- gLeaves : This application is dedicated to biological interpretation of sequencing data. It can handle sorting and complex filtering of billions of genetic variants in seconds

Moreover, SeqOIA managed to organize the workflow of the information across all people involved within the analysis of a given sample, i.e. clinician, doctor, biologists, bioinformatician, technician.

In parallel of the clinical use of genomic data, there's some other challenges that need to be addressed in the field of research based on largest infrastructure such as Gaia X:

- Handle genomics data in the context of cohort of patients
- Ensure reliability of clinical data and genomics data and design smart algorithms in order to enhance Phenotype/Genotype analysis.



## 8. Care Pathway, home-based and hospitalized COVID-19 patients

Some GAIA-X French founding members are EMR (Electronic Health Record) system specialists. They have a unique experience of care pathways in many European countries and their common challenges. There is an opportunity to create a large sharing space with GAIA-X to improve healthcare effectiveness.

With the COVID-19 pandemic, there have been real changes in the approach to ecosystems and a new momentum around remote patient monitoring. For example, a successful initiative is Covidom <https://esante.gouv.fr/virage-numerique/talents-esante/covidom>.

Covidom created large datasets in few weeks. Above all they broke the barriers between city healthcare professionals and hospitals. Others home-based Patient Support Program from Life Science companies could enrich and benefit a GAIA-X dedicated care pathway data space.

### OTHER AREAS BEING CONSIDERED

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The following topics have also been identified as areas to be developed by the various stakeholders as data is playing a key role. Those use cases will be further developed at a later stage:

- Digital Health and Personalized Medicine focused on autoimmune, inflammatory, cancer diseases and long-COVID
- Intelligent medical devices
- Digital Pathology (oncology, immunology, rare diseases)
- Cardiology (research & real-world data)



### 3 REGULATORY TOPIC AND BUSINESS MODELS

(we refer to data for research purposes: R&D, clinical trials...)

#### SEVERAL REGULATORY ISSUES HAVE TO BE MANAGED

As a matter of fact, there will be a need in terms of regulatory and certification topics to go further regarding harmonization and convergence at Europe level and for all European countries.

The legal aspects related to data sales contract agreements are highly specific and costly. As a result, it is mandatory to establish a European framework agreement. The monetization of data must foster innovation.

It seems important to be able to guarantee the choice of cloud service providers between the different current players and the future comers in the market. A clear execution plan for the new cloud providers, including the associated services, will have to be delivered in order to give visibility for the customers. In case of migration, we need to select solutions that will facilitate it.

The different steps and processes to get certified, from research to CE Mark, need to be simplified, harmonized, quicker and transparent.

Obviously, it is essential to define the rules/laws relating to data computing, duplication, hosting locations: country, Europe, international...notion of synthetic data, and regarding the processes of anonymization, pseudo anonymization and standardization too: as an example, the notion of “Reference Methodology” in France.

Finally, the integration of blockchain solutions could be an opportunity to solve concerns on transparency, security, data management and governance, and topics related to patient registers, research purpose and genomics as well.

#### BUSINESS MODEL

##### 1. Data

We believe in a scalable “pricing” data model, based on data quality: Pseudonymization, Anonymization, annotation, segmentation, certification compliance. But the model needs to address the objectives of simplification and legibility. It will have to ensure the development of innovation in the e-health business from big, mid-size companies to startups.

This model will deliver “Pricing transparency”

The Blockchain solutions would be studied as an enabler of pricing model implementation and secure “pricing transparency”.



## 2. e-Health business

In terms of market access, we need to revisit certification and reimbursement process as we talk about e-DM and software. The current processes need to evolve as this market is highly dynamic and competitive.

In the same topics, we believe in a dedicated reimbursement of “e-Health DMs” and associated clinical applications

The question related to marketplace revenue management, SAS model, Subscription model...have to be investigated to deliver recommendations. In addition, all the different existing platforms needs to get connected and harmonized to the get benefit of Europe scale

As connectivity is one of the most critical components, 5G deployment has to be accelerated across Europe to achieve the objectives.

