This project has received funding from the European Union's Horizon 2020 research and innovation programme under the Grant Agreement No. 826353.

HORIZON 2020
The Framework Programme for Research and Innovation

Project acronym: DigitalHealthEurope
Grant Agreement Number: 826353
Project full title: Support to a Digital Health and Care Innovation initiative in the context of Digital Single Market strategy
Call identifier: SC1-HCC-05-2018

Cloud Technology in Health Data Use – Insights from Horizon 2020 Projects

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1 Introduction and methodology

This report explores the potential of cloud technology for the European Health Data Space (EHDS), based on analyses of relevant projects and initiatives.

According to the official definition of cloud technology by the National Institute of Standards and Technology, cloud computing is a model for enabling ubiquitous, convenient, on-demand network access to a shared pool of configurable computing resources (e.g., networks, servers, storage, applications and services) that can be rapidly provisioned and released with minimal management effort or service provider interaction. [1]

This aspect of ubiquity and sharing was emphasised in a 2015 report on the Use of Cloud Computing in Health by the Joint Action to Support the eHealth Network (JASEHN). The JASEHN report points out that cloud is not a singular entity but can take on several different forms. It also stipulates that there was a certain level of reluctance to apply this kind of technology in health data contexts.[2]

This report is prepared for DG CNECT by the DigitalHealthEurope[3] (DHE) project. It presents an analysis of Horizon 2020 projects co-funded by DG CNECT, and details of lessons learnt and implications of applying cloud technologies to support the envisaged EHDS.

Methodology: The project methodology involved a database search and ensuing analysis of relevant content. A search of two European databases - CORDIS[4] and the Innovative Medicines Initiative (IMI)[5] - conducted to identify promising cloud technology projects within the healthcare domain. The search yielded 277 resulting projects, of which more than half (174) were considered potentially relevant. Additionally, DHE consortium members and staff in DG CNECT were consulted for recommendations on projects as they were assumed to have expert knowledge on the topic. The analysis was focused on (but not limited to) those projects funded by DG CNECT Units H.3[6] and G.1[7], as well as those initiatives recommended by DHE consortium members and DG CNECT contacts. As a result, 86 projects were mapped following critical data points focussing on different technological, organisational and disease-specific aspects. Consequently, a shortlist was established following two criteria:

1. Funding by EC Units H.3 or G.1 (exception: one IMI co-funded project)
2. Recommendation of the project by DG CNECT and/or consortium and/or invited experts.

The shortlist of projects examined more thoroughly for the purpose of this report included 19 projects. In particular, a roundtable was hosted with 15 recognised experts and stakeholders in the domain of cloud technology in healthcare. They corroborated the findings of this research task and furthered a discussion around its implications for the EHDS. Several of these experts are leading European initiatives expected to yield relevant additional and future insights into how cloud technologies are applied (See Annex A).

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[1] See https://www.nist.gov/news-events/news/2011/10/final-version-nist-cloud-computing-definition-published.

[2] See https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20151123_co06_02_en.pdf.

[3] See https://digitalhealtheurope.eu/.

[4] See https://cordis.europa.eu/projects/en

[5] See https://www.imi.europa.eu/projects-results

[6] Unit H.3 focuses on eHealth, Well-Being and Ageing. See https://ec.europa.eu/digital-single-market/en/content/ehealth-well-being-and-ageing-unit-h3

[7] Unit G.1 focuses on Data Policy and Innovation. See https://ec.europa.eu/digital-single-market/en/content/data-policy-and-innovation-unit-g1

2 Overall landscape analysis

Current cloud-related projects suggest an interesting though challenging landscape. The projects analysed are diverse in terms of the types of topics they cover and the amount of information publicly available on them. Among the 19 preliminary shortlisted projects, 15 were still running and some did not yet have any published deliverables. The four projects which have already ended are C3-Cloud, MyHealth–MyData, E2Data and ProAct (see references further in this section and in Annex B). The insights into the cloud in this report are primarily based on this shortlist. When classifying the projects according to keywords in the projects' objectives and official websites, three general patterns emerged along the lines of 1) Architecture aspects, 2) Technological aspects, 3) Specific services deployed on cloud.

The overall analysis of the projects was influenced by the fact that cloud technology has become ubiquitous, to a point where the concept of cloud is often not mentioned anymore by name. Thus, there needs to be a closer look taken at the applications that were used. The grouping, which follows, into the three analysis categories, and the topics treated under these headings, are often fluid and should not be perceived as having rigid borders. Likewise, a sub-section on cross-cutting or transversal aspects targets issues that do not fit rigidly into one category.

2.1 Architecture aspects

A cloud infrastructure is the combination of hardware and software that enables the five essential characteristics of cloud computing.[8] The EHDS aims at providing an interoperable cloud infrastructure for health data exchange, and some insights can be gained from the analysed projects in this regard. Chiefly, the architecture refers to federated infrastructures.

Federated infrastructure models (federation of data repositories under an overarching governance and interoperability layer) seem to emerge as a new paradigm for sharing personally identifiable health data. One example is **European Health Data & Evidence Network (EHDEN)**[9], which José Luís Oliveira (Aveiro University) presented during the roundtable. The project aims at harmonising more than 100 million anonymised health records into an OMOP (Observational Medical Outcomes Partnership) Common Data Model. Therefore, it employs a federated network, where the analysis is "brought to the data" rather than creating a central repository. **Beyond 1M Genomes**[10] aims at establishing a cross-border federated network of national genome collections, encompassing data quality and exchange standards, access protocols and more. **FeatureCloud**[11] employs a federated machine learning approach to enable privacy-preserving data mining – running federated applications. Each of these applications can output data for the next application to be processed. A highly secure, federated and large-scale European cancer imaging platform is being built by the project **EuCanImage**[12]**.** The roundtable experts also suggested considering the architecture of GaiaX[13] and its documents surrounding technical infrastructure.

This approach was also mirrored during the expert roundtable, as cloud technologies were perceived as a **technical architecture to ultimately connect repositories**. Nevertheless, the

[8] On-demand self service, broad network access, resource pooling, rapid elasticity, measured service.

[9] See https://ehden.eu/.

[10] See https://b1mg-project.eu/.

[11] See https://featurecloud.eu/.

[12] See https://eucanimage.eu

[13] https://www.data-infrastructure.eu/GAIAX/Navigation/EN/Home/home.html.

roundtable experts highlighted that infrastructure should not be constructed for the sole sake of building architecture but also to consider what specific **applications** it will deploy. Regarding the actors involved in building the architecture, two basic conditions for an EHDS infrastructure were named:

1. Ensure different **guarantees** regarding the supply/service provided by the infrastructure supplier (e.g., service level agreement(s), continuity of service, cybersecurity, option of subcontracting).
2. Establish the **governance** of the information within the infrastructure (e.g., access, edit and communication rules, etc.).

Moreover, the roundtable experts highlighted the importance of distinguishing between the requirements for infrastructure and requirements for applications as services. This would also encompass issues such as interoperability.

2.2 Technological aspects

The JASEHN report names possible technological aims a health care authority might have of a cloud solution: reliable hosting of systems and applications, be freed of low-level technical maintenance to focus on their core business, flexibility to react to changing demands and minimisation of vendor lock-in.[14] These four goals might also be relevant for the EHDS technical structure.

The kinds of technological issues which emerged during the analysis of projects in 2021 were: blockchain, cybersecurity and data security, encryption, anonymisation, interoperability, artificial intelligence (AI) and machine learning, and big data.

In the landscape of analysed projects, cloud technology builds the basis for several technological methods. **FeatureCloud** uses **blockchain** to manage patient rights and ensure that records are fixed to allow privacy-preserving data mining. **CUREX**[15] creates a platform that will allow healthcare professionals to assess and reduce their cybersecurity and privacy risks. These strategies encompass a private blockchain infrastructure, ensuring the integrity of the risk assessment process and of all data transactions between multiple stakeholders. However, it should be evaluated with care how the use of blockchain in general can hinder data contributors' "right to be forgotten".

The topic of **cybersecurity** was singled out as being of utmost importance, both in the roundtable and in numerous projects. Moreover, during the EC EHDS Roadmap Public Consultation, several contributors have voiced security concerns over the use of a public cloud. Given that public clouds are multi-access environments, it can be considered problematic to host sensitive personal data on them. An alternative recommendation would be to keep the EHDS physically separated from all other EU data spaces.[16] [17] [18] **PANACEA**[19] aims to deliver **people-centric cybersecurity** in health care, leveraging the advantages of cloud technology. They put forward a Solution Toolkit for this aim, encompassing four technological tools (for risk

[14] https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20151123_co06_02_en.pdf.

[15] See https://curex-project.eu/.

[16] See https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12663-Digital-health-data-and-services-the-European-health-data-space/F1567735.

[17] See https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12663-Digital-health-data-and-services-the-European-health-data-space/F1567608.

[18] See https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12663-Digital-health-data-and-services-the-European-health-data-space/F1436593.

[19] See https://www.panacearesearch.eu/.

assessment and mitigation, secure information sharing, security by design as well as certification, identification and authentication) and three organisational tools (for training and education, resilience governance, and secure behaviour nudging). The expert roundtable hinted at some relevant recent publications on cybersecurity[8] [9] [10] and identified the **heterogeneity of data security measures among countries** as a significant challenge. **BigMedilytics**[20] is a big data project which works across population health, industrialisation of health care services, and oncology. The goal is to establish secure and privacy-preserving cross-border and cross-organisation big data architecture for healthcare. For this aim, it is developing a Big Data Healthcare Analytics Blueprint (defining platforms and components), enabling secure collaborative innovation. However, despite the project's start in 2018, little information is available on how this blueprint contains.

Encryption mechanisms were cited in the roundtable as a vital technical feature that needs to be closely studied for the EHDS. Encryption primarily fosters security and will render data unintelligible to non-authorised users. However, despite the importance of this concept, few projects include this topic explicitly. **ASCLEPIOS**[21] is especially interesting in this regard, using modern cryptographic approaches to create a cloud-based digital health framework protecting users' privacy and preventing attacks. Symmetric Searchable Encryption is used as the primary mechanism in the project to store data from a client in a cloud, allowing search over encrypted data. In this method, encrypted data from a client is hosted by a third party who does not have the key to read the data. Only the data owner who holds the key can decrypt the data. The same principle is applied in **InteropEHRate**, where only encrypted data is stored on the cloud without sharing the encryption key with the cloud provider. In case of emergencies, healthcare organisations can acquire the key directly from the patient to decrypt the information and provide their aid to the patient.

Another key aspect is **anonymisation.** Anonymisation fosters confidentiality of data while still allowing data to be processable (e.g., for aggregation purposes). **FeatureCloud** puts forward a security-by-design approach in which all data leaving the data holders' premises are anonymised. To achieve this, FeatureCloud utilises a cloud-AI infrastructure only exchanging learned model representations which are anonymous by default. In **EHDEN,** the use of a federated query on a distributed network of local health records, rendering aggregate (and not individual) data level results, does not make a specific anonymisation technique necessary. In **InteropEHRate**, the health data is collected on the mobile devices of the patients. A specific portion of the data is anonymised directly on the patient's device before sharing it with specific research studies that the patient decided to contribute to.

Regarding **interoperability,** the experts in the roundtable highlighted the importance of considering this subject from the point of view of the data and applications rather than from a merely technical infrastructure perspective. This is particularly relevant within the context of health data use. From a researcher's perspective, however, the challenge is to ensure interoperability of cloud technologies between different systems to allow the unhampered pursuit of research questions. **C3-Cloud**[22] used an interoperability middleware allowing seamless integration with existing information systems, thus enabling fusion of multimodal patient and provider data. A significant number of projects also focusses on the interoperability of EHRs (**InteropEHRate, Smart4Health, x-eHealth**), as discussed throughout the course of this report. Semantic interoperability is further elaborated on in chapter 2.2.1.

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20 https://www.bigmedilytics.eu/.

21 See https://www.asclepios-project.eu/.

22 See https://c3-cloud.eu/.

AI and machine learning tools are employed on the cloud by several projects. **ProCAncer-I**[23] specialises in developing AI models for prostate cancer. The project will design, develop and sustain a cloud-based, secure AI European Image Infrastructure to discriminate indolent (slow-growing) from aggressive disease. The project creates advanced AI models based on novel ensemble learning methodologies, leading to vendor-specific and -neutral AI models for addressing eight prostate cancer clinical scenarios. Moreover, it defines a roadmap for AI model certification, interacting with regulatory authorities, thus contributing to validate the effectiveness of AI-based models for clinical decision making. An initiative able to provide relevant insights, especially for AI use in rare diseases, is **IndividualizedPaediatricCure**[24] **(iPC)**. The project is combining knowledgebase, machine-learning and mechanistic models to predict optimal personalised therapies for paediatric cancer. Options are tested in silico (by means of computer modelling or computer simulation) with an avatar simulating the characteristics of each patient. Specific tasks performed during the project include the application of data mining methods to discover novel patterns in paediatric leukaemia, machine learning methods to improve image-based cancer diagnostics or the use of proteogenomic data to predict the response of cancer cells to drug treatment. **INTERVENE**[25] is developing an AI-enabled federated data analysis platform to test new tools for disease prevention, diagnosis and personalised treatment through usage of the first United States of America-European pool of genomics and health data.

Finally, **Big Data** is specifically addressed by some projects, mainly in the context of making secondary use of real-world data. **E2Data**[26] is developing a new Big Data software paradigm, taking a cross-layer approach to allow communication between the four key layers of Big Data deployments: application, Big Data software, scheduler/cloud provider, and execution run time. Though not a dedicated health project, one of the four use cases is health-related, focusing on predicting re-hospitalisation. **BigMedilytics** extracts Big Data practices from its twelve pilots in population health and chronic disease, oncology and industrialisation of healthcare services.

2.2.1 Specific services deployed on cloud

A key insight of the expert roundtable was the need to distinguish between requirements for infrastructure and requirements for applications as services.

Experts proposed that the focus should be on identifying the services that are relevant to be cloud-based rather than which kind of cloud solution should be utilised.

The shortlisted projects provide some examples of applications that can productively be deployed on the cloud. They include semantic interoperability, terminology harmonisation, identity-management-as-a-service, federated analysis-as-a-service, and integrated care. A further seven services were mentioned in the expert roundtable but were not explored in detail either on that occasion or in this report.

As mentioned before, special attention should be paid to **semantic interoperability**, not only the syntactic point of view (see page 7). **PhArA-ON**[27] targets semantic interoperability between different applications by analysing the compatibility among widely used platforms and partner

[23] See https://www.procancer-i.eu/.

[24] See https://ipc-project.eu.

[25] See https://www.interveneproject.eu.

[26] See https://e2data.eu.

[27] See https://www.pharaon.eu.

solutions. The project develops platforms for the ageing population reaching beyond health, which it aims to integrate with existing systems related to mobility, smart cities and energy.

Harmonisation of terminology on meta-level has emerged as an important and feasible goal. It is important to consider that the challenge of harmonising multiple data sources through interoperability, semantic interoperability and harmonisation of data is not limited to cloud as a deployment architecture. Rather, terminology harmonisation should be studied more broadly in terms of how it is handled in further related EC-co-funded projects, beyond the scope of this report (e.g., the support action ASSESS CT[28]). However, of the shortlisted projects, only two refer to this topic. In **InteropEHRate** the importance of a common terminology across stakeholders became evident. In the project's emergency protocol, patient's health data are retrieved from the so-called S-EHR cloud and translated into the terminology and language of the respective country to enable a safe diagnosis and treatment. A common European approach towards terminology services, albeit difficult to implement, would simplify the adoption and evolution of EU protocols for cross-border health data exchange. Consequently, terminology services could be exploited by producers of health-related mobile apps for citizens, healthcare professionals and researchers, the Member States and EU organisations. For instance, InteropEHRate prototyped and recommended to adopt an EU-specific standard communication protocol, based on common terminologies, allowing citizens to download their health data in a structured and machine-readable format. Such protocol could be based on FHIR (as a transport mechanism for the data), eIDAS (as a means of identification of the individual), and the International Patient Summary (for structured content of the health data).

A technically more specified solution can be observed in **C3-Cloud**, which developed an integrated terminology server utilising semantic functions to enable the analysis of multimodal data and clinical rules. It used FHIR Terminology Service[29] specification for this purpose.[30]It was further suggested that the adoption of common terminologies is not sufficient. It is also necessary to adopt common data formats that rely on the common terminologies (e.g., common data profiles). A streamlined European approach towards data profile services could provide clarification on the latest versions of both terminologies and data formats to be adopted for cross-border health data exchange. EU Member States should share common services that publish, in machine-readable formats, and allows to query all official FHIR profiles and implementation guides officially adopted by the EU.

One service identified by the experts to be successfully employed on the cloud is **identity management-as-a-service,** which is above all addressed by the three sets of protocols in **InteropEHRate**. For instance, in the emergency protocol, the health care provider obtains a key to decrypt patient's health data from a QR-Code which the patient brings with them. The possession of the decryption key is not sufficient to access the patient's information. Authority of the healthcare provider to download the encrypted information is checked by the so-called S-EHR Cloud via a certification authority service. This service is complementary to identity services. This topic is linked to **multi-stakeholder access**, which, apart from InteropEHRate providing protocols for patients, healthcare providers and researchers, is also taken up by **EHDEN.** The project provides an EU-wide structure for the analysis of real-world data for patients, healthcare providers, governments, regulators, small and medium-sized enterprises, pharmaceutical industry, academia and payers. However, there is scant information available on how this access management is implemented.

Both EHDEN and InteropEHRate also exemplify how **federated analysis-as-a-service** could work. This application is linked to the structure of a federated network and is realised through

[28] See: ASSESS CT recommendations at https://assess-ct.eu/fileadmin/assess_ct/final_brochure/assessct_final_brochure.pdf.

[29] See https://www.hl7.org/fhir/terminology-service.html

[30] See https://c3-cloud.eu/wp-content/uploads/2019/06/D6.3_v1.pdf.

a series of protocols (InteropEHRate) or a common data model (InteropEHRate and EHDEN). The RDS protocol of InteropEHRate provides federated access to health data within a network that includes patients (as data providers) and research centres (as data consumers). **FeatureCloud** utilises a common platform to enable access to available data spread across different institutions for research purposes. In all these cases, the data analysis and/or matching occurs within the original data source.

Looking beyond technical applications, medical use cases related to **integrated and personalised care** can be successfully applied on the cloud. All applications mentioned in this section provide a sound basis for individualised care, which is also mirrored in the projects. The platform created by **C3-Cloud** enables the collaborative creation and execution of personalised care plans between healthcare professionals, informal carers and patients, in a challenging environment of comorbidities[31] and polypharmacy[32]. **iPC** combines artificial intelligence and in silico patient avatars to find appropriate cancer therapies for individual children. **ProAct** aims to enable multimorbid[33] patients to lead their chronic disease management. Open application programming interfaces integrate various new and existing technologies to advance "home-based" integrated care. To this aim, the project uses data aggregation and cloud platform systems.

Other service applications that were mentioned in the roundtable as useful applications for cloud, but are not evidently present in the analysed projects, are:

- Cohort discovery
- Output management
- Coordination spaces (metadata, semantic servers)
- Temporary storage spaces
- Temporary processing spaces (e.g., through the use of AI)
- Common digital health services (e.g., Platform-as-a-Service - PaaS)
- Visualisation services

2.2.2 Transversal aspects

A number of cross-cutting or transversal aspects were cited as affecting cloud computing broadly in relation to health and care data and being seen in many of the projects analysed. It is essential to study specific use cases, since the type of data to be handled in/through a cloud also determines the choice of the cloud infrastructure. The six items that arise either in the 19 shortlisted projects or in the expert discussions are Electronic Health Records, citizens' own control of health data, cloud service models, the variety of health data used, common approaches to electronic contracts, and standardised electronic consent forms.

First, Electronic health record (**EHR)** aspects relate both to a specific cloud use case and incorporate architecture and technological issues. Of the 19 shortlisted projects, four relate specifically to the EHR. It is essential to study each specific case since the type of data handled in/through a cloud also determines the choice of the cloud infrastructure. **InteropEHRate** aims to tackle the current lack of interoperability of EHR systems across the EU whilst equipping patients to manage their health data. Moreover, a protocol for secure and cross-border exchange of medical evidence will be proposed. It puts citizens at the centre of health data mediation by adopting a device-to-device standard. Citizens are empowered to authorise the exchange of their health data through **decentralised authorisation mechanisms**. This will be

[31] Comorbidity describes "the burden of illness co-existing with a particular disease of interest". See: https://academic.oup.com/eurpub/article/29/1/182/5033670.

[32] Polypharmacy refers to "the use of multiple medicines". See: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5635569/

[33] The term multimorbidity describes the "coexistence of multiple health conditions in an individual". See: https://academic.oup.com/eurpub/article/29/1/182/5033670

applied in a cross-border as well as research context. **X-eHealth** aims to build on the established European Patient Summary to facilitate the exchange of EHR in a common framework to flow alongside the care continuum and health entities across the EU. This will be achieved through a workable, interoperable, secure and cross-border exchange format, consequently highlighting the rather technical aspects of EHR integration and exploitation. Due to its recent start, no further insights are available yet.

Second, following this paradigm of patient empowerment, **MyHealth–MyData** strives to equip patients to control their data encompassed in the EHR. This is done by informing the patient about how two associated subsets of data encompassed in their EHR might reveal information they would not like to disclose publicly. Furthermore, the project pursues to enable healthcare institutions (e.g**.**, research/teaching hospitals, GPs) who are willing to engage with data analytics partners to appraise the importance of the data subsets they own[34]. **Smart4Health** finally aspires to empower citizens to manage their health data for personalised health via **a citizen-centred EHR exchange**. This will be achieved through an application allowing users to collect, manage, share and donate health-related data across the EU. In this, application, interoperability, complementarity and cooperativity with current ventures within the domain of EHR (e.g., national or local initiatives) will be considered.

As third transversal aspect, the concept of **Cloud Service Models** is situated between architecture and areas of application. Different service models can range from Infrastructure-as-a-Service (IaaS – provider runs processing, storage and networks while client manages operating systems, data and applications) to Software-as-a-Service (SaaS - cloud provider runs the entire cloud infrastructure).[35] Between these two extremes sits the Platform-as-a-Service model (PaaS), through which programming languages, tools and/or libraries are deployed for software development or deployment. In making the choice of the cloud service model to use, the advantage of freeing the data owner from maintenance responsibilities need to be weighed against the possible lack of control of sensitive data or applications. The choice of the geographic location of a cloud provider might be strategic in this regard. For instance, the French Health Data Hub has seen controversy around being hosted on Microsoft servers, thus possibly being subject to the US Cloud Act.[36] Among the analysed projects, few explicitly state which parts of the solution are managed by the cloud provider and which are not, though it appears that a comprehensive Software-as-a-Service approach contradicts the widespread concept of a federated network. **InteropEHRate** defines communication protocols that are independent from the Cloud Service Model adopted to deploy the communicating applications. **ASCLEPIOS**' cloud service provider is using the IaaS service model and stores encrypted versions of users' data (patients, doctors, healthcare practitioners, etc.). **ProACT** employs a SaaS as well as a PaaS solution. In the SaaS solution, a cloud-based service makes available different CareApps through various access options. However, the project also follows a PaaS model, allowing developers to provide apps.[37]

On a fourth level, there is some heterogeneity regarding regarding the **kind of health data** treated through the cloud solution in the different projects, there is some heterogeneity. Apart from those explicitly related to the EHR (see above), some projects focus explicitly on comorbidity and/or multi pharmacy (**C3-Cloud, ProACT, PhArA-ON),** which is an area where a holistic analysis of health data from different sources is crucial. Other areas of focus include genomics (**INTERVENE, B1MG)**, imaging, especially in oncology **(EuCanImage, ProCAncer-I),** as well as complex in silico medicine **(iPC)** or re-hospitalisation (**E2Data).** Some projects focus on

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[34] See http://www.myhealthmydata.eu/deliverables/D8.5_Value-Estimation-Model.pdf and http://www.myhealthmydata.eu/deliverables/D7.4-Study-report.pdf.

[35] See https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20151123_co06_02_en.pdf.

[36] See https://www.lexology.com/library/detail.aspx?g=c39919b5-5101-462f-bfcd-90fb6190be09.

[37] See http://www.proact2020.eu/pdf/deliverables/D6.5.pdf.

real-world data in general, without more specification in the available information **(BigMedilytics, EHDEN).**

Fifth, in terms of expert commentary the need to define requirements for a **common approach towards electronic contracts**, including citizen's informed consent, was mentioned. **Standardised electronic consent forms** which are comprehensible would foster transparency and citizen's trust, particularly if citizens would be notified in case of violation of data protection. Apart from the consent there is a bigger transparency topic about the actual data use. Blockchain technology may be considered for such service.

3 Preliminary conclusions and recommendations

Preliminary conclusions for the EHDS relate to infrastructure choices that have stood the test, implementation of specific technical aspects, as well as insights on concrete services to be deployed on the cloud. The recommendations outlined here are preliminary and rather high level. For more detailed insights to be offered by DigitalHealthEurope, a closer look at the project deliverables is necessary.

In the realm of **architecture**, federated networks are a common approach. However, it needs to be studied to what extent **scalability limitations** exist for some areas including the **timeliness of responses**, which may be needed in seconds or less for AI data mining, and the ability to **connect small-scale data repositories** that are hosted by small organisations such as primary care offices, whose technical infrastructure may not support responding to a large number of real-time queries. In any case, the infrastructure should be tailored according to the applications that are supposed to be run on the cloud.

The analysed projects also provide examples of use of specific **technical** tools, such as blockchain, Big Data, as well as Artificial Intelligence and Machine Learning. Relatively few projects focus explicitly on **cybersecurity, encryption and anonymisation** – considering that these aspects have been particularly highlighted as important in the expert roundtable. In the projects that address these issues, the three concepts are typically closely related.

Regarding concrete **services to be deployed on the cloud,** there seem to be solid solutions for federated analysis-as a-service, as well as in applications for integrated care. However, many unmet needs identified by the experts remain, especially in **terminology and identity management**. Considering **transversal aspects**, noteworthy frameworks are available for EHR exchange, always closely related to cybersecurity.

Finding a suitable cloud service model requires a good balancing of ease of use and autonomy. Research on why cloud technology adoption is slow in healthcare as compared to other domains highlighted that **healthcare organisations often adopt SaaS, but hardly ever PaaS or IaaS.**[38] This is in contrast to the common business context, in which all service models appear to be equally relevant to many purchasers. Apparently, healthcare poses specific requirements to PaaS and IaaS, which are not covered by general solutions on the market, thus hampering the development and adoption of cloud computing in healthcare.

From a desk analysis of the projects, it is difficult to assess the **weaknesses of certain cloud concepts** in the analysed projects. The problems in existing cloud solutions the projects aim to tackle include lack of scalability (E2Data), un- or insufficiently encrypted or protected data on the cloud (ASCLEPIOS, PANACEA, InteropEHRate), existence of data cemeteries (BigMedilytics), and insecure client-cloud and inter-cloud communication (FeatureCloud). It needs to be evaluated in interviews with the project participants, which cloud solutions have not turned out successful in practice.

Considering the abovementioned experiences, the following preliminary recommendations for an EHDS structure emerge. They are based both on the project analysis and on the expert input in the dedicated DHE roundtable.

1. **Define the concept of operation for EHDS infrastructure based on existing use cases.**

   Study meaningful examples of cloud use (e.g., the projects in this report) and use them as an inspiration for the EHDS infrastructure.

2. **Agree on approaches to terminology and identity management.**

[38] Gao F, Thiebes S, Sunyaev A. Rethinking the Meaning of Cloud Computing for Health Care: A Taxonomic Perspective and Future Research Directions. J Med Internet Res. 2018 Jul 11;20(7):e10041.

This is a more achievable goal than harmonising the data themselves.

3. **Define requirements for cybersecurity, encryption techniques and anonymisation.**

   Healthcare does not fully take advantage of existing mechanisms yet.

4. **Assess which applications (as services) are best suited to a cloud approach.**

   Examples from this report relate to terminology management, identity management, encryption, etc.

5. **Separate requirements for infrastructure from requirements for application services.**

   Especially in the realm of interoperability, there is a slightly exaggerated focus on syntax and infrastructure.

6. **Assess implications of applying federated architecture and analysis solutions.**

   This challenge aligns well with the envisioned EHDS concept since it intends to build on existing infrastructure rather than aim at centralising data. In the application of a federated architecture, it is important to ensure agility to support the incremental and evolutive integration of different data sources and data consumers.

7. **Consider the physical location of the cloud service provider.**

   Having a Europe-based provider is of strategic interest.

8. **Define rules regarding which kind of cloud solutions can be part of EHDS.**

   Especially when choosing a cloud service model (e.g., SaaS), this can have big security implications.

9. **Leverage emerging technologies by including them in an assessment process.**

   Artificial Intelligence, blockchain, big data and others are pull-factors for the uptake of cloud technology but are scarcely being used in healthcare practice currently.

10. **Build or buy the services needed to host applications on the cloud.**

    Conceptualise the envisaged services first, then commission services fit for purpose.

11. **Define requirements for a common approach towards electronic contracts, including citizen's informed consent.**

    Standardised electronic consent forms which are comprehensible would foster transparency and citizen's trust, particularly if citizens would be notified in case of violation of data protection. Blockchain technology may be considered for such service.

12. **Develop a standard communication protocol allowing citizens to download their health data in a structured and machine-readable format.**

    This proposal for a protocol is in line with the GDPR. Such protocol could be based on FHIR (as a transport mechanism for the data), eIDAS (as a means of identification of the individual), and the International Patient Summary (for structured content of the health data).

The identified Horizon 2020 projects deliver interesting insights on use cases, practices and unmet needs regarding cloud technology in health data use.

For a closer examination and more concrete recommendations in relation to cloud technology and health and care data use, it would be necessary to study the deliverables, conduct interviews and a survey with the representatives of the most relevant projects.

4 Annexes

4.1 Annex A: List of roundtable participants

Birgit Morlion - DG CNECT
Ceri Thompson - DG CNECT
Mirela Negrean – DG CNECT
Ronan McDonnell – Acquis Health
Danny Van Rojien - COCIR
Diane Whitehouse – EHTEL
Francesco Torelli – Engineering
Dipak Kalra - EUROREC
Zoi Kolitsi – EUROREC, empirica
Susheel Varma – HDR UK
Henrique Martins – Independent Expert
Jeremy Thorp – Independent Expert
José Luís Oliveira – University of Aveiro
Oliver Zobell – Project Management Jülich
Darragh McGeown (observer) - Acquis Health

4.2 Annex B: Shortlisted projects

Project Acronym and Title	EU Funding	Ongoing	Project Website	Cordis/IMI Factsheet
ASCLEPIOS Advanced Secure Cloud Encrypted Platform for Internationally Orchestrated Solutions in Healthcare	H.3	Yes	https://www.asclepios-project.eu/	https://cordis.europa.eu/project/id/826093
BigMedilytics Big Data for Medical Analytics	G.1	Yes	https://www.bigmedilytics.eu/	https://cordis.europa.eu/project/id/780495
B1MG Beyond 1M Genomes	H.3	Yes	https://b1mg-project.eu/	https://cordis.europa.eu/project/id/951724
C3-Cloud A Federated Collaborative Care Cure Cloud Architecture for Addressing the Needs of Multimorbidity and Managing Polypharmacy	H.3	No	https://c3-cloud.eu/	https://cordis.europa.eu/project/id/689181
CUREX Secure and Private Health Data Exchange	H.3	Yes	https://curex-project.eu/	https://cordis.europa.eu/project/id/826404

Project Acronym and Title	EU Funding	Ongoing	Project Website	Cordis/IMI Factsheet
E2DATA European Extreme Performing Big Data Stacks	G.1	No	https://e2data.eu/	https://cordis.europa.eu/project/id/780245
EHDEN European Health Data Evidence Network	N/A	Yes	https://ehden.eu/	https://www.imi.europa.eu/projects-results/project-factsheets/ehden
EuCanImagine A European Cancer Image Platform Linked to Biological and Health Data for Next-Generation Artificial Intelligence and Precision Medicine in Oncology	H.3	Yes	https://eucanimage.eu/	https://cordis.europa.eu/project/id/952103
FeatureCloud Privacy preserving federated machine learning and blockchaining for reduced cyber risks in a world of distributed healthcare	H.3	Yes	https://featurecloud.eu/	https://cordis.europa.eu/project/id/826078
IndividualizedPaediatricCure **(iPC)** Cloud-based virtual-patient models for precision paediatric oncology	H.3	Yes	https://ipc-project.eu/	https://cordis.europa.eu/project/id/826121

Project Acronym and Title	EU Funding	Ongoing	Project Website	Cordis/IMI Factsheet
InteropEHRate Interoperable EHRs at user edge	H.3	Yes	https://www.interopehrate.eu/	https://cordis.europa.eu/project/id/826106
INTERVENE International consortium for integrative genomics prediction	H.3	Yes	https://www.interveneproject.eu/	https://cordis.europa.eu/project/id/101016775
MH-MD My Health – My Data	G.1	No	http://www.myhealthmydata.eu/	https://cordis.europa.eu/project/id/732907
Panacea Platform for Automatic, Normalized Annotation and Cost-Effective Acquisition of Language Resources for Human Language Technologies	H.3	Yes	https://www.panacearesearch.eu/	https://cordis.europa.eu/project/id/826293
PHArA-ON Pilots for Healthy and Active Ageing	H.3	Yes	https://www.pharaon.eu/	https://cordis.europa.eu/project/id/857188
ProAct Integrated Technology Ecosystem for ProACTive Patient Centred Care	H.3	No	http://www.proact2020.eu/	https://cordis.europa.eu/project/id/689996

Project Acronym and Title	EU Funding	Ongoing	Project Website	Cordis/IMI Factsheet
ProCAncer-I An AI Platform integrating imaging data and models, supporting precision care through prostate cancer's continuum	H.3	Yes	https://www.procancer-i.eu/	https://cordis.europa.eu/project/id/952159
Smart4Health Citizen-centred EU-EHR exchange for personalised health	H.3	Yes	https://smart4health.eu/	https://cordis.europa.eu/project/id/826117
X-eHealth Exchanging electronic Health Records in a common framework	H.3	Yes	https://x-ehealth.eu/	https://cordis.europa.eu/project/id/951938