This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement Nº 101017331

D8.1 ODIN Webinar Series on "Data protection and health"

Deliverable No.	D8.1	Due Date	30/June/2021
Description	This deliverable describes the webinar series on "Data protection and health" that the ODIN project will organize to mainstream the topic within the consortium and engage relevant stakeholders.		
Type	Report	Dissemination Level	PU
Work Package No.	WP8	Work Package Title	Legal, Ethical and Standardization Aspects for Sustainability
Version	1.0	Status	Final

Authors

Name and surname	Partner name	e-mail
Pasquale Annicchino	UDGA	pannicchino@udgalliance.org
Stea-Maria Miteva	UDGA	smiteva@udgalliance.org

History

Date	Version	Change
04/04/2021	0.1	Initial table of content
27/04/2021	0.2	Introduction to the webinar series
18/5/2021	0.3	Titles and descriptions of the webinars
15/6/2021	0.4	Finalization of the description of the webinars
27/9/2021	0.5	Internal Review
20/10/2021	0.6	Addressing internally received feedback received
27/10/2021	1.0	Update of webinar series plan following coordination with ODIN Management, introduction of

Key data

Keywords	Data protection; e-health; webinar series
Lead Editor	Pasquale Annicchino
Internal Reviewer(s)	Cristina Melero, Giuseppe Fico, Dimitris Fotiadis

Abstract

This report describes the plan for the ODIN Webinar Series on "Data protection and health". The series has been planned in the first months of the project to be synchronized and coordinated with the general ODIN webinar series. It considers previous and ongoing research experiences upon which ODIN will build its know-how and facilitate the transfer of knowledge. The current report offers the titles and the description of the webinars. All the details will be communicated also through the ODIN website and other communication channels.

Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation, or both.

Table of contents

1 Introduction

The deployment of e-health technologies involves the processing of a high quantity of personal and non-personal data. Internet of Things (IoT) and Artificial Intelligence (AI) contribute to make more complex the compliance with the different processing operations and call for a mainstreaming of the impact of the role of data processing in the context of e-health. In line with the ODIN vision according to which evidence-based medicine revolutionized medicine with data driven procedures, so data-driven management can revolutionise hospital management. This is particularly timely taking into consideration the EU4Health programme that will run from 2021 to 2027. This series will build the know-how of the project and of the researchers involved in the project also by involving previous and ongoing research projects to facilitate the exchange of know-how and level up ODIN to the state of the art in the field. The series will also shape the internal discussions on the directions and development of possible tools within the project.

2 The structure of the series

2.1 Coordination with the general ODIN webinar series

The webinar series in "*Data protection and health*" will be coordinated with the ODIN management team and will be fully integrated in the context of the project. The series will introduce the researchers of the projects and external stakeholders to the relevance of the topic "data protection and health" by building on the experience of previous and ongoing research projects and initiatives. The series will investigate the current and forthcoming legal framework as a prerequisite for innovation sustainability for the market. It will discuss, among others, the following topics:

- Artificial intelligence in healthcare;
- Big Data in hospital environments;
- Collaborative robotics, smart care environments with regards to data processing and privacy;
- Certification of data processing in the e-health sector;
- Other topics of relevance which might be identified in the context of the WP8 or other WP activities

The webinar series will usually follow a common template:

- One moderator from ODIN WP8
- One or two speakers to address the topic
- Q&A
- Conclusion

The interventions from the speaker(s) will address: 1. State of the art – 2. Vision for the future in the field – 3. ODIN's contribution to the transition

2.2 Involvement of previous and ongoing research experiences and projects

In order to design and plan this series we have established relationships with previous and ongoing research initiatives which have developed tools and solutions in the context of the field "data protection and e-health". This will enable the creation of synergies with other research and innovation projects and the creation of a solid know-how for ODIN researchers. Furthermore, we are exploring potential endorsement through the Privacy Symposium, an international multi-stakeholder conference for professionals in data protection taking place in Venice from April 5th to April 7th 2022, organised by the European Centre for Certification and Privacy (ECCP), and supported by ODIN's consortium member Mandat International (MI).

3 Program of the ODIN webinar series on "Data protection and health"

This section offers a tentative list of the ODIN webinar series on "Data protection and health". Titles and description of each webinar has been agreed with the different ongoing and previous research initiatives which have expressed their interest and willingness to contribute to the series. In the first phase of the design of the initiative we have had bilateral calls with the partners to introduce them to the ODIN goals and initiatives and agree on the title and the content of their contribution. To effectively consider any possible unexpected circumstances, which may hinder the proper execution of the webinars, we rely on an official confirmation by the presenters no later than one month before the due date of the respective webinar, so that we can contact back-up speakers. In the second phase we will agree with the presenting partners on a date for the webinar and identify the relevant speakers. The webinars on "Data protection and health" will be held bi-monthly on the second Wednesday of the respective month, from 13:00 to 15:00 CEST. The webinar series will officially start in December 2021 and continue through the end of the project. According to the preferred level of dissemination, the webinars and all the relevant information will be communicated through the ODIN communication channels either only with the project's partners or beyond the scope of the consortium.

3.1 Titles and tentative calendar of the webinar series

1. Webinar 1: Introduction to data protection and e-health and to the webinar series (in collaboration with Activage) (*8 December 2021*), proposed speaker: Sofia Segkouli – CERTH-ITI.
2. Webinar 2: The role of standardization and certification in data protection and e-health (in collaboration with Europrivacy and Medtronic) (*9 February 2022*), proposed speaker: Cristina Melero – Medtronic.
3. Webinar 3: Innovation in e-health: the role of personal data (in collaboration with the European Institute for Innovation through health data) (*12 April 2022*), proposed speaker: Dipak Kaltra - European Institute for Innovation through Health Data (i~HD).
4. Webinar 4: The European Health Data Space and the Digital Strategy (in collaboration with ETHEL) (*14 June 2022*), speaker: proposed speaker Luc Nicholas – European Health Telematics Association (EHTEL).
5. Webinar 5: The use of AI in the context of healthcare: an analysis from the PANELFIT's experience (in collaboration with PANELFIT) (*9 August 2022*), proposed speaker: Iñigo de Miguel – University of the Basque Country (EHU).
6. Webinar 6: The Protego Project: Development of a data protection tool to reduce cybersecurity risk in hospital and care centers (in collaboration with PROTEGO) (*11 October 2022*), proposed speaker: Dave Singlee – KU Leuven.
7. Webinar 7: The Curex project: data security and privacy in the health sector (in collaboration with Curex) (*13 December 2022*), speaker: TBD.

8. Webinar 8: PANACEA Project: a sociotechnical approach to cybersecurity in healthcare context (in collaboration with PANACEA) (*14 February 2023*), proposed speaker: Pasquale Annicchino.
9. Webinar 9: Final webinar with participation of ODIN partners for shared reflections on the series (*11 April 2023*), presented by UDGA.

Should the WP8 encounter the availability of other research initiatives to contribute to the series other webinars will be added upon agreement of the management team. The planned activities are subject to speaker availability and might be reorganized or rescheduled prior to the event. Webinar organizers will take appropriate actions to mitigate any affectation to the webinar series and to ensure webinars are properly advertised to maximize attendee participation. Additional webinars may be organized in conjunction with the Privacy Symposium.

3.2 Description of the content of each webinar

In this section we offer a description of each webinar with the topics as agreed with the partner organizations. The exact date of the webinar and the name of the speakers will be communicated through the ODIN communication channels.

3.2.1 Introduction to data protection and health

E-Health personalized monitoring inevitably provides direct and indirect benefits to a wide range of stakeholders where main beneficiaries are the patients with various chronic and non-chronic diseases. A plethora of emerging technologies, apps and devices provides health information services for self-awareness and assessment of health and well-being parameters. Personalized e-health targets currently accurate, prescriptive, and preventive healthcare data. This early preventive and precision approach is critical for clinicians and healthcare personnel as it effectively supports the detection and treatment of illnesses enabling the reduction of corresponding healthcare costs.

Nonetheless, data concerning health information is related to individuals' most intimate aspect and right. From the ethics lens, when it comes to 'sensitive data' additional concerns and protection is required especially taking into consideration diverse factors such as the context of data processing, the technologies used and the contents of data. Moreover, concerns are raised from trade-offs considerations such as computing costs related to data security and filtering. Past evidence–based experience highlighted that managing sensitive data at large-scale pilot operations in the context of IoT ecosystems presents major challenges as well as the use of AR/VR and AI technologies, devices and apps.

Despite the enriched relevant literature, concerning health data and ethics, privacy–related concerns some questions quoted below are still partly answered.

'Is it adequate to address trustworthiness, privacy, sensitive data protection and security through standardized tools such as organizational, regulatory and technical means?',

'Which are really the requirements of the ethical use of e-health/ medical devices, and advanced technologies in order to cope with trade-offs that emerge in a legitimate and timely manner?'

'What is the role of proper design of personalized e-health services and how ethics by design should be complemented by responsible roles' assignment, ethics' assessment procedures in order to bring the balance between personalization, privacy and trustworthiness?'.

3.2.2 The role of standardisation and certification in data protection and e-health

Certification of data processing activities can have an important role in ensuring compliance with applicable norms and creating trust among end-users. This is particularly relevant in the e-health context. Starting from the Europrivacy experience this webinar will highlight and discuss the strategic role of certification. Europrivacy is a certification scheme developed through a H2020 European research project, co-funded by the European Commission and Switzerland. It is managed by the European Centre for Certification and Privacy (ECCP) in Luxembourg and maintained by the Europrivacy International Board of Experts in data protection, with the support of partners such as the Italian Institute for Privacy, the SECAN-Lab (University of Luxembourg), and IotLab.

3.2.3 Innovation in e-health: the role of personal data

Fine-grained and close to real-time health data is of increasing importance to the development of health innovations, such as drug development, safety monitoring, medical device design and calibration, algorithm development and validation and biomarker research. The predominant data source of value to these innovation areas remains electronic health records captured in hospital and primary care settings. However, there is an increasing richness of data that is captured by people themselves through apps, wearable devices, and other monitoring solutions.

In most of these innovation areas the company or public body undertaking the research and development activity has no need or wish to identify individuals or to reconnect with them. (Requests for additional data or biological samples can normally be mediated through the data source and do not need the downstream data user to directly communicate with patients.) However, very detailed and longitudinally-linked data usually requires pseudonymisation, and for many purposes such as artificial intelligence the blurring of data through classical privacy enhancing techniques may sufficiently distort the data to make algorithm development unreliable. Federated architectures and distributed security measures like homomorphic encryption can also help to mitigate the exposure of personal data. However, it is difficult to undertake all of these innovations on data that the GDPR would regard as definitively not personal. This is more challenging still because the precise interpretation of anonymised data and the safeguarding requirements are to some extent delegated to Member States, which in turn lead a fair bit of interpretation to local data protection decision-making. This can result in heterogeneous decisions for similar requests across multiple data source sites.

On the flip side, the public is becoming increasingly aware of the importance of reusing health data for knowledge generation, such as public health intelligence during the recent pandemic, and the research that has been necessary to give us all COVID-19 vaccinations that are effective and safe. Surveys often show that if the public understands the purpose for which health data might be used for research, how it can be safeguarded and what the societal benefits are from that research, it is broadly in favour.

Europe is therefore currently challenged to find an appropriate balance between protecting citizens by safeguarding their data, and helping citizens by advancing health, care and prevention innovations. The Data Governance Act may introduce one area of middle ground, but much more work consultation is still needed to clarify how it might be put into practice operationally, and whether it is the only suitable middle ground model or one of several possibilities. Europe is also expanding the model of national or regional data access decision-making bodies, whose rules and transparency will be critical to winning public confidence in the way health data is used, whether personal or anonymised, to support research and innovation.

3.2.4 The European Health Data Space and the Digital Strategy

For many of us, the concept of European Data Space is still a very abstract one. The road is indeed long and the number of challenges to be met is important in order for the concept to become a true reality. Even if the Commission wants to progress swiftly, many have not waited for the concept to become trendy to put it to the test in specific environments and propose implementation strategies. This introductory presentation will highlight what are the main expected breakthroughs of the European Health Data Space and will briefly describe the different solutions which are promoted by different stakeholders, some privileging a fully decentralized approach while others tend to privilege a more (centrally- publicly) controlled process. Up to now the citizen-patient had no real role but he or she might become one of the first key enablers.

3.2.5 The use of AI in the context of healthcare: an analysis from the PANELFIT's experience

The use of AI mechanisms in the context of health care is one of the great hopes of personalized medicine. However, its use is subject to many controversies, which relate to the extent of its use, the information to be provided to the patient, the possibility of opposing its use, etc. In this talk, we will offer some of the essential keys to approach the subject from an ethical or legal perspective.

3.2.6 The Protego project: development of a data protection tool to reduce cybersecurity risk in hospital and care centres

Health care is an essential service that uses a great deal of sensitive personal data which has a high black-market value being a lucrative target for data theft and ransomware attacks. The objective of the ProTego project is to develop tools and guidelines to help health care systems users address cybersecurity risks. The activities in the ProTego project are centred around: (1) stakeholder education and awareness, (2) risk assessment and detection, using machine learning and AI, and (3) risk mitigation by deploying advanced data protection measures. In this webinar, we will mostly focus on the latter and discuss the main research activities and results of ProTego related to data protection. These include advanced memory encryption, access control and network slicing

3.2.7 The Curex project: data security and privacy in the health sector

CUREX is a research and innovation action funded under the H2020 framework that introduces a novel, flexible and situational awareness-oriented platform designed specifically to reinforce the security of healthcare organisations. CUREX aims to protect the health data handled by hospitals from the risks that are propagated all the way from the security gaps in their IT infrastructure. To achieve this goal, cybersecurity and privacy risk assessments are being performed, while optimal recommendations for cyber risk mitigations are offered in the form of a decision support tool. The platform encompasses a suite of tools establishing trust between healthcare organisations to address the necessity of data exchange in a fully GDPR-compliant manner. Moreover, considering the human-factor, CUREX improves the cyber hygiene culture among personnel through identifying employee group-specific gaps and needs with regards to raising cybersecurity and data privacy awareness, using for this purpose a survey tool to address to the different groups (i.e., administrative, medical, IT, executive/security). The project capitalises on existing distributed ledger and health technological artifacts whose aim is to provide accountability and auditability functionalities that will increase trust among hospitals and care centres.

3.2.8 Panacea project: a sociotechnical approach to cybersecurity in healthcare context

Over the last few years, ICT, connected medical devices and related data have become mission-critical for healthcare operations, but are still poorly protected and vulnerable, also because management and staff still attach low priority to cybersecurity. Therefore, cyberattacks and incorrect staff behaviour are growing risks for business continuity, patients' safety, and data privacy.

The EU-funded PANACEA project has been based on the assumptions that cybersecurity and privacy/data protection must take care of the sociotechnical nature of the "system at risk" (ICT infrastructures, data, networked medical devices, medical doctors, nurses, administrative staff, business processes) and of the cybersecurity "defence system". The project has therefore delivered a toolkit including seven tools, providing the "defence system" with three "socio" tools and four "technical" tools.

"Socio" tools include (1) contextualized controls, organization, and ROI evaluation methods for cybersecurity risk governance, (2) educational voice-less videos to show correct behaviour, (3) a methodology to design behavioural "nudges".

"Technical" tools include software supporting (1) dynamic risk assessment and mitigation actions recommendation, (2) inter-organizational secure information sharing, (3) systems/medical devices security-by-design and certification, (4) user-friendly facial identification and authentication.

The first intervention of the webinar will describe the sociotechnical model and, after providing an overview of the "socio" tools, will focus on the cybersecurity governance organization.

The second intervention, after providing an overview of the "technical" tools, will focus on the dynamic risk assessment tool.

3.2.9 Final webinar with the participation of ODIN partners for shared reflections on the series

This webinar will discuss the contribution of the series to the development and implementation of the activities of the ODIN project. It will mobilize know-how from different relevant WPs and involve ODIN partners with interest and expertise in the field. It will also consider possible legislative developments at the EU level to discuss them and assess their impact on the ODIN project.

4 Conclusion

The webinar series on “Data protection and health” will be organized in the context of the activities of ODIN WP8 with three main objectives:

- Facilitate the transfer of know-how from previous and ongoing research projects and initiatives and equip the ODIN research team with a knowledge-base that can be utilized for the developments of ODIN’s solutions;
- Stimulate the internal discussion within ODIN in order to facilitate a better horizontal coordination between WPs and activities;
- Stimulate a data protection by design culture within ODIN.

Each webinar, whose dissemination level is indicated as public, will be recorded, and made available also to the larger public through the ODIN communication channels. Additional webinars might be organized, should the opportunity and interest arise. They will all be announced on the ODIN website and organized in the context of WP8 activities.