Project no. 826278

SERUMS

Research & Innovation Action (RIA)

SECURING MEDICAL DATA IN SMART-PATIENT HEALTHCARE SYSTEMS

Report on Technical Roadmap for SERUMS Technology

D7.7

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Responsible Institution: FCRB
Editor and editor's address: Julio Burgos (jburgos@clinic.cat)
Partners Contributing: ACC, ZMC, USTAN

Approved by:
Reviewers: Marios Belk (UCY)
Vladimir Janjic (UD)
Technical Manager: Juliana Bowles

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RE	Restricted to a group specified by the consortium (including the Commission Services)	
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SERUMS Consortium

Partner 1	**University of St Andrews (USTAN)**
Contact Person	Name: Juliana Bowles Email: jkfb@st-andrews.ac.uk
Partner 2	**Zuyderland Medisch Centrum (ZMC)**
Contact Person	Name: Larissa Haen-Jansen Email: la.jansen@zuyderland.nl
Partner 3	**Accenture B.V. (ACC)**
Contact Person	Name: Bram Elshof Email: bram.elshof@accenture.com
Partner 4	**IBM Israel Science & Technology Ltd. (IBM)**
Contact Person	Name: Michael Vinov Email: vinov@il.ibm.com
Partner 5	**Sopra-Steria (SOPRA)**
Contact Person	Name: Andre Vermeulen Email: andreas.vermeulen@soprasteria.com
Partner 6	**Université Catholique de Louvain (UCL)**
Contact Person	Name: Axel Legay Email: axel.legay@uclouvian.be
Partner 7	**Software Competence Centre Hagenberg (SCCH)**
Contact Person	Name: Michael Roßbory Email: michael.rossbory@scch.at
Partner 8	**University of Cyprus (UCY)**
Contact Person	Name: Andreas Pitsillides Email: andreas.pitsillides@ucy.ac.cy
Partner 9	**Fundació Clínic per a la Recerca Biomèdica (FCRB)**
Contact Person	Name: Santiago Iriso Email: siriso@clinic.cat
Partner 10	**University of Dundee (UD)**
Contact Person	Name: Vladimir Janjic Email: VJanjic001@dundee.ac.uk

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1. Executive Summary

To deliver high-quality healthcare, it has become increasingly important to share confidential and personal medical data among healthcare providers. However, in the current situation (medical landscape/infrastructure) it is difficult to share medical data with hospitals across countries. Currently, data sources are siloed and not integrated. SERUMS solution includes enhanced authentication and trust mechanisms that ensure only caregivers authorized by the patients can access (parts of) the personal medical data. Integrated data systems to enable secure and protective data sharing across countries and caregivers. This deliverable, D7.7, reports on a technical roadmap for SERUMS technology. This roadmap will consider new and emerging developments in security, deep-learning, data lakes, blockchains, cloud computing, etc. as they relate to the processing and sharing of medical data. It will highlight possible future applications of the SERUMS technology and indicate the further work needed to bring the SERUMS technologies to market gathered by all consortium partners. Chapter 1 introduces the SERUMS consortium.

In chapter 2, the methods and timelines are elaborated on. Work package 7 started with the preparation of the future roadmap in June 2021, after which several steps were taken, such as sessions to gather and validate input. During these sessions, the technical partners provided input from the market and connected improvements to the developments in the field. In addition, input was gathered during Proof of Concept (PoC) 2 and 3, by stakeholders such as patients, IT personnel, and medical personnel.

In total, 17 ideas for improvement were gathered, that are displayed in chapter 3. The topics were divided into five categories: blockchain, data lake, authentication, integration and other. These 17 proposed improvements were plotted on a matrix, according to their estimated benefit and effort, in chapter 4. Using the matrix, 11 improvements were selected. Out of the total of 17, six improvements were prioritized since they are fundamental for deploying the SERUMS system in the real world. Together with five others, these will be included in our future roadmap, addressed in chapter 5.

Two scenarios for development were recognized, either developing by the SERUMS consortium or by partnering with existing organisations/platforms/networks that can be considered experts in the field. As aforementioned, the four first-named suggested improvements need to be in place first, before the other proposed improvements can be done. This can either be done through self-development or via partnering with existing companies. That should be defined during market research. According to our specialists at end-user locations, a stand-alone system is hard to sell. Most hospitals prefer systems that work via an API and can work with existing systems. Therefore, it is important to look at what is happening in the market and partner with existing organisations if possible. When partnering with organisations that are already proficient in these solutions, the SERUMS solution can focus on the developments with an innovative character, such as the Flexpass graphical accessibility. These developments can ensure that SERUMS have the right to exist in the fast-growing market for safe and secure data exchange.

2. Introduction

2.1. Role of the deliverable

SERUMS aims to increase the efficiency of healthcare systems in Europe while ensuring patient safety and the privacy of sensitive health data using innovative techniques that will increase resilience to cyber-attacks and promote trust in the safe and secure operation of the system. To meet this challenge, SERUMS developed and implemented innovative methods, tools, and technologies (e.g., Blockchain, Data Lake, Data Fabrication, Privacy Preserving Analytics, Personalised User Authentication Schemes) addressing the need for cybersecurity in hospitals including remote care and home-care settings. In this document, the next steps to improve the system are elaborated on and a timeline for executing these improvements is created

2.2. Relationship to other SERUMS Deliverables

In *Figure 1*, the cohesion between deliverables in the consortium can be seen. Deliverable D7.7 is part of the fifth task of work package 7. The tasks of work package 7 are:

1. Setting up requirements and Success Metrics
2. Develop use case applications that will be used to evaluate the SERUMS technology in a realistic setting.
3. Prepare and execute successful proofs-of-concept and pilots
4. Evaluate the SERUMS tools and technologies against the overall project requirements and success criteria
5. Use the outcomes of T7.4 to undertake road mapping activities that are aimed at situating future SERUMS technologies in the context of emerging technological developments in secure and safe sharing of data and advanced data analytics for medical data, and in broadening the long-term impact of the SERUMS project.

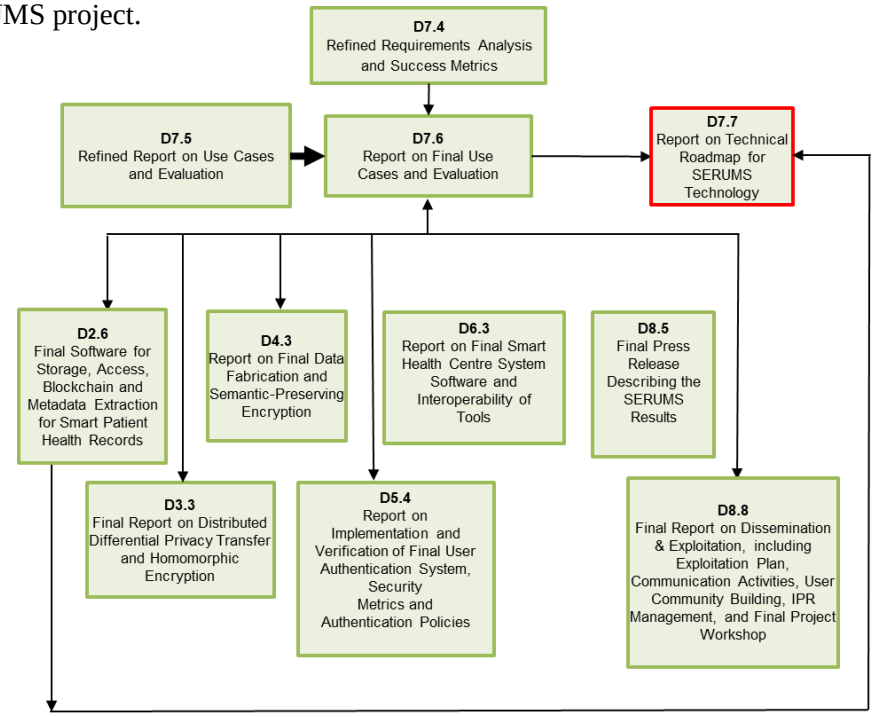

Figure 1. Visual that shows the relations between deliverables

This deliverable will consider new and emerging developments in security, deep-learning, data lakes, blockchains, cloud computing, user authentication and identity management, etc. as they relate to the processing and sharing of medical data. It will highlight possible future applications of the SERUMS technology and indicate the further work needed to bring the SERUMS technologies to market gathered by all consortium partners. In the figure above, the cohesion between D7.7 and the other deliverables can be seen. Therefore, the goal of this deliverable is to:

- Serve as guidance for future improvements and integrations for SERUMS technologies.
- Analyse the possible connection with other projects.
- Use all the feedback from D7.3, D7.5, and D7.6 to highlight possible future applications of the SERUMS technology and indicate the further work that needs to be done to bring the SERUMS technologies to market.

3. Methods and timelines

Several steps were taken to prepare deliverable D7.7. First information was gathered, then analysed and ultimately the actions were written. The timelines are shown in *Figure 2*.

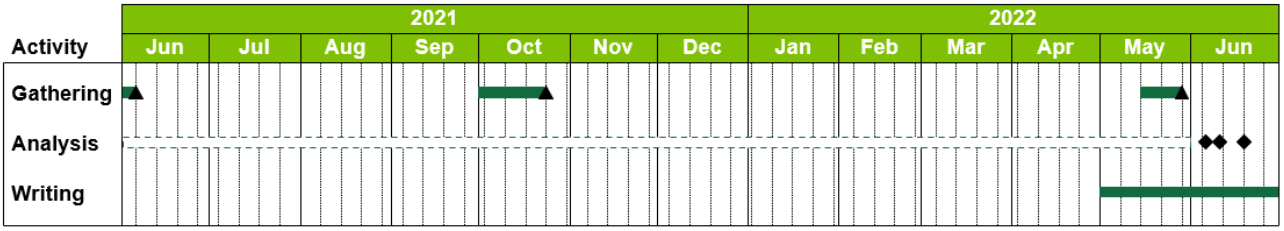

Figure 2. Visual showing the timelines for preparing deliverable 7.7

The first step was the *gathering phase.* Our main priority was to gather information with different stakeholders over time to be sure that all possible improvements were included. Therefore, the gathering started after Proof of Concept 2 in June 2021. FCRB retrieved feedback from technical partners, during organised sessions (▲). The Proof of Concepts were used to gather insights from both the medical personnel, IT professionals, and patients. Thereby, possible improvements and innovations in the field were discussed. In addition, feedback from the EU review committee was included.

Second, the input from technical partners, reviews, and PoCs was discussed during the three organized future roadmap sessions. During these meetings, the possible improvements were plotted on a benefit-effort matrix after discussion with all present technical partners**.**

Last, based on the benefit-effort matrix, short-term and long-term actions were defined. These actions are compared with developments in the field, resulting in a roadmap with concrete suggested steps for the upcoming three years.

The findings were validated by the technical partners and end users in three sessions (♦):

- Session 1: validate benefit-effort ratio
- Session 2: validate chosen improvements
- Session 3: validate roadmap timelines

4. Proposed improvements

Starting from June 2021, the 17 suggested improvements among the different technologies of the SERUMS platform were gathered. All improvements are divided into different technologies (Blockchain, Data Lake, Authentication, Integration and Other) and are displayed *Table 1*. In the appendix, from page 17, the exact content of the improvements and the associated efforts and benefits are elaborated on.

Technology	Number	Improvement
Blockchain	1	Designated doctors
	2	Share with others
	3	Automated rule Recovery
	4	Blockchain conflicting rules
Data lake	5	Uniformise tags
	6	Internationalisation
Authentication	7	Graphical password
	8	Geolocation login tracking
	9	Flexpass Graphical Accessibility
	10	Authentication Configuration
Integration	11	QR code implementation
	12	Emergency Button
	13	Delegated rule creation
	14	Access Rules Improvements
	15	Treatment related data
Other	16	Hosting across multiple locations
	17	Production Deployment

Table 1. Proposed improvements divided into different technologies

4.1. Proposed scenarios of development

For the development of the mentioned improvements, we see two scenarios, namely a bottom-up approach and a top-down approach. With the bottom-up approach, the proposed improvements will be developed by the SERUMS team. When choosing a top-down approach, SERUMS will partner with organisations/platforms/networks that have expertise in the mentioned subject. Further research must define what scenario fits best per the proposed improvement.

On the one hand, in the scenario of using a bottom-up approach, the proposed improvements will be developed by the SERUMS consortium. This approach might be best suited in the case of solutions that are not developed by other organisations, platforms, or networks yet. In addition, this approach might be best suited in the case of the development of SERUMS unique selling points.

On the other hand, when using a top-down approach, developments will be developed by organisations, platforms, or networks with expertise in the specific subject. This approach might be best suited in case of improvements that are already expertise areas of technology companies in the field or when improvements require complex technologies or might bring ethical discussions. Per improvement, it is necessary to consider which scenario fits best.

5. Future roadmap

In the following chapter, the proposed improvements are transformed into the future roadmap.

First, the 17 proposed improvements were plotted on the matrix below according to the estimated benefit and effort of the specific improvements. Then the improvements were selected based on their benefit-effort ratio, as can be seen in *Figure 3*. In addition, the fundamental functionalities needed to be developed first. As can be seen in the matrix, of the total of 17 improvements, six are fundamental, five are selected, and six improvements are not selected to be included in the future roadmap. In the following paragraphs, these choices will be elaborated on.

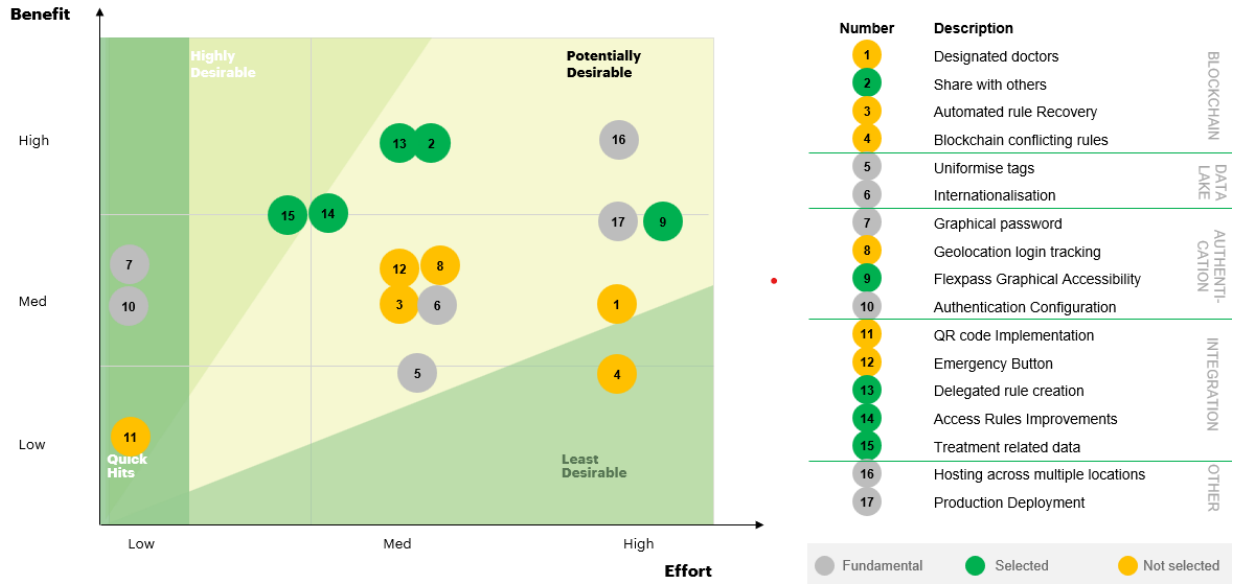

Figure 3. The benefit-effort matrix

5.1. Fundamentals

There were 17 ideas for improvement gathered by the technical experts' part of the SERUMS consortium. Since the roadmap includes the follow-up steps that can be executed in the next 3 years, not all 17 ideas can be included in the final roadmap. Therefore, decisions regarding the urgency and importance were made. The improvements that are most urgent to implement are the ideas necessary to develop a system that can operate in the real world.

Number	Description
5	Uniformise tags
6	Internationalisation
7	Graphical Password
10	Authentication Configuration
16	Hosting across multiple locations
17	Production deployment

Table 2. Improvements fundamental for deploying the serums system

Both 'uniformise tags' and 'internationalisation' are necessary functionalities to be able to exchange data between different countries that speak different languages and have different legislations. Since international data exchange is one of the main aimed functionalities of the SERUMS' system, this is important to integrate in the system, before going into production.

The ‘graphical password’ and ‘authentication configuration' improvements bring relatively fast value to the end-user. In addition, since both improvements focus on the security of the system, these improvements are fundamental for further use of the system and should be developed before production deployment.

To share data internationally, uniform tags should be implemented. With the right tags in place, and a system that can translate this structured data, the fundamentals for international data sharing are in place. Although, 'uniformise tags' is scaled as medium effort, since finding tags that can be used in different countries might be challenging. In addition, this is connected to the translation of data from one language to another. In this proposed improvement, only structured data is in-scope. It is expected that the effort for translating structured data is medium. However, to translate nonstructured data, more research is necessary. Currently, this is out-of-scope, but partnering with organisations that are experts in this field, might help the SERUMS platform to the next level.

In addition, both ‘hosting across multiple locations’ and ‘production deployment’ are fundamental for the possible use and growth of the SERUMS system. Currently, data is centralised in the FRACAS. The design of the SERUMS system has already incorporated the decentralising of the data lake. This is necessary to deploy the platform in different locations for decentralisation purposes and the network is needed so each location can communicate with each other.

All four topics are important to implement and there are already organisations in the field that have developed advanced technologies regarding these topics. Therefore, it is recommended to execute market analysis and define with existing partners what the pros and cons are for working together. According to our specialists at end-user locations, a stand-alone system is hard to sell. Most hospitals prefer systems that work via an API and can work with existing systems. Therefore, it is important to look at what is happening in the market and partner with existing organisations if possible.

5.2. Selected improvements

Besides the four ideas that are fundamental for allowing the SERUMS system to work in a real environment, multiple additional ideas were gathered to improve the SERUMS systems. Five of these ideas on security, privacy, usability, or improving our market opportunity had the best benefit/effort ratio and will be included in the roadmap for the upcoming 3 years. These improvements can be seen in *Table 3*.

Number	Description
2	Share with others
9	Flexpass graphical accessibility
13	Delegated rule creation
14	Access rules improvements
15	Treatment related data

Table 3. Chosen improvements for the future roadmap

The improvements ‘access rule improvements’, ‘treatment-related data’, ‘delegated rule creation’, and ‘share with others’ were selected to be included on the future roadmap based on their benefit-effort ratio. The improvement ‘Flexpass graphical accessibility’ is included on our roadmap, based on the high value it might bring to the end-user. In addition, this feature of the SERUMS system is one of its unique selling points and improving that functionality might enhance the market value of the SERUMS system and increase its usability and accessibility for all of Europe’s citizens. For all selected improvements, further research should indicate which of the two scenarios, bottom-up or top-down, best suits the development of the improvement. Six improvements were not included to be part of the three-year future roadmap based on their benefit-effort ratio or the value that they might bring to the end-user. As a remark, this does not mean that these improvements do not need to be implemented. Developments in the field might alter the needs of the end-user or might simplify the implementation of certain improvements. Therefore, it is important to include market research when developing the system.

5.3. Future roadmap

Below, in *Figure 4*, the proposed roadmap for the next three years is displayed. As aforementioned, the four first-named suggested improvements need to be in place first, before the other proposed improvements can be done. This can either be done through self-development or via partnering with existing companies. That should be defined during market research. As discussed previously, connecting with an existing partner has been the preferred option, as a stand-alone solution is hard to sell to the end user organisations. In addition, it is knowledgeable to have an ongoing market research team in place since the developments in the field follow one another in quick succession. To illustrate, the European Health Data Space will condition us on how we are going to use our systems and will carry standards to the public. SERUMS would need to ensure to follow the guidelines regarding data exchange across borders (Cross-Border Directive 2011/24/EU).

The start dates are based on the estimated benefit of the proposed improvement. In addition, the topics scored with effort low are estimated on 3 months of work, low/medium on 6 months of work, medium on 9 months of work, and high on 1 year of work. Since this is an estimation, the actual time spent may vary, and more research is needed for more precise planning. In addition, the availability of enough resources is a precondition.

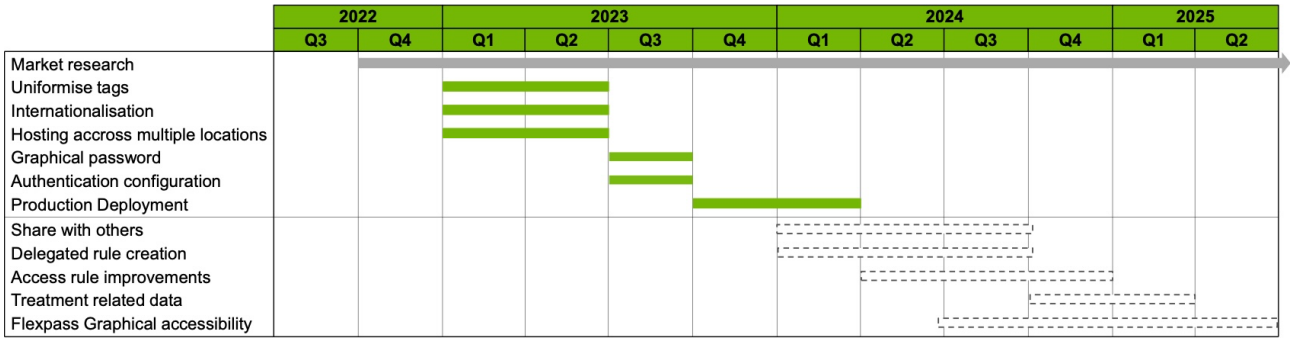

Figure 4. The advised future roadmap for the upcoming three years.

5.4. Developments in the field

Besides the urge to connect with technology partners in the field, there are also other Horizon 2020 studies executed by other consortia, that might add value to or connect with the SERUMS project. These studies can be found in Appendix 2. The outcomes of these projects might have an influence on the technical developments, proposed in the future roadmap. For example:

- SERUMS technologies could be integrated with the X-ehealth project that is developing a format for health record exchange cross-border. This might help us standardise the data and the tags associated with them.
- SERUMS can be used together with privacy-preserving tools developed within Horizon 2020. For example, the Sphinx project could help SERUMS detect cybersecurity threats. Another Horizon2020 project, focusing on cybersecurity, is CUREX that could help detect possible data breaches.
- SERUMS might connect to PoSeID-on, a blockchain solution that guarantees that Personal Identifiable Information ("PII", i.e., information related to a Data Subject, that can be used to identify directly or indirectly the person) cannot be shared without the data's subject consent. This might help with the further development of 'treatment related data' or 'share with others.

6. Conclusions

Overall, the proposed improvements show similarities with both other Horizon 2020 projects as developments in the public. This shows how high the interest of society is and how great the demand is for a way to share health data securely and quickly. Therefore, we see a future for (parts of) the SERUMS platform to add value for European citizens. As some of the other Horizon 2020 projects are not finished yet, these studies might help the SERUMS platform to perform on a higher level, or the SERUMS platform might have an impact on their development.

In addition, the current development of the European Health Data Space (EHDS) points out the importance of standardization and rules considering European health data. The SERUMS consortium also sees this functionality as fundamental to the development of the SERUMS platform. Since this is an important development for the European Commission, the outcome will shape the future of the SERUMS platform and how to perform international data sharing.

Besides the developments in the public, the improvements necessary to uptake the SERUMS platform in real business or public organisations need to be executed. Our preference is to partner with existing organisations with ongoing developments towards these functionalities. Stand-alone solutions have little chance of keeping up in the market these days. When partnering with organisations that are already proficient in these solutions, the SERUMS solution can focus on the developments with an innovative character, such as the Flexpass graphical accessibility. These developments can ensure that SERUMS have the right to exist in the fast-growing market for safe and secure data exchange.

7. Appendix 1

This chapter will further explain the proposed improvements. The suggested improvements are first described as User Stories. Second, the expected benefit and efforts are elaborated on.

1. Designated Doctors
Description: As a patient, I should be able to share my data with a specific department in a hospital. Although data has been authorized by the patient, maybe the access could be overused in case of the hack to a medical stuff or the hospital admin. An intrusion detection system was proposed instead of giving hard numbers of access attempts. This improvement would achieve a layer of security in top of the Blockchain and the authentication system. **Benefit: Low/Medium** A certain amount of trust for employees with clearance must be present. Thereby, they cannot tamper with data in the blockchain, and all their access is logged. **Effort: High** Having a proper mechanism for hospital IT admin access would be a project itself. Some level of trust is required, or stuff gets expensive. Access logging is easy and readily available but preventing intrusion on this level is a whole other topic.

2. Share with others
Description: As a patient, I want to be able to share my data as part of the SERUMS registry with the desired person (family member/friend) via the same granular access rules. And give them the authorization to view my data. **Benefit: High** It would help to the patient to build a health family history data system. **Effort: Medium** Family members can be granted access within the same rules as doctors and staff if they have got a SERUMS ID. Implementation is very similar, not much needs to be changed in the blockchain, so for the blockchain component the effort is low. Also, on a regulation basis it is easy to implement. But on the integration, it is medium.

3. Automated rule recovery
Description: As a user, I want that rules can be easily and automatically restored by looking at their previous value in the blockchain. With blockchain, in the event of data being compromised, it is always possible to identify the historical values of the record. With the patient-Id/doctor-Id, combined with a timestamp of when the party is compromised, you would be able to see all transactions created related to the user. **Benefit: Medium** There needs to be a “disaster recovery” plan. **Effort: High** Having a central authority able to remove (possibly compromised) Rules opens a new vulnerability. You need many mechanisms that this central authority cannot be used with malicious intent. Having this automated, one would need to think of the condition which triggers this workflow.

4. Blockchain conflicting rules

Description: As a user of the SERUMS platform, I want clarity about which rules overrule other rules in case of conflicting rules. Currently, from the user perspective, while trying to create a rule that conflicts, a message will be shown explaining what happened and how the new rule can be added without conflict. Blockchain and data lake could have an invalid state when two rules are conflicting. In case the conflicting rule arrives at the data lake and the blockchain, an automated mechanism is necessary that will solve the rules with an optimistic approach.

Benefit: Low/ medium

Many patients means that there will be many rules. Therefore, there will be conflicts.

Effort: High

Including defining a concept, which defines the precedence, the effort would be high here.

5. Uniformise tags

Description: As an organisation, I want to be able to share information via the SERUMS system, and therefore, the data needs to be standardized and uniformised.

In the current system, the data is fetched by selecting the location and the different tags.

Benefit: Medium/low

Easily translate tags and therefore data across organisations in a common data format by using uniform tags that correspond to all use case scenarios

Effort: Medium

Requires translation to find a word for each language that can translate across for multiple languages for each tag, will take time and effort. Also needs time to decide on selecting few uniform tags for all scenarios.

6. Internationalisation

Description: As a user, I want to be able to share my data with hospitals in other countries and therefore, the SERUMS technologies should be adapted to Internationalisation standards.

The proposed changes are a) Make all the UI translated (language, number format, LTR-RTL, unit system...) b) Add translation on the data using SERUMS API by means of metadata. c) Structured data should be translated (medical reports, pdf documents) *.

* Currently, nonstructured data is out-of-scope. This needs to be included in later stages of the development or via partnering with existing organisations.

Benefit: Medium

Easy to supply documentation in a variety of languages to all medical institutions and patients. But required for the success of the SERUMS technologies.

Effort: Medium

Will require translations in addition to a method of using automatic translations of entire pdf documents. For a large amount of documentation, this will take time in addition to error-checking where the automatic translation will not provide a 100% success rate. This is extra important, considering the sensitivity of the data.

7. Graphical password

Description: As a user, I want my passwords to be safe and non-guessable.

This can be done by improving the accuracy of gestures. Ans also by implementing a sort of feedback on password strength in the creation process, for example, easy hotspots. In addition, it is required to implement an option to allow automatic password change (e.g., 2 weeks).

Benefit: Medium

The password strength meter and improvements of gesture accuracy have been implemented as part of the final version of FlexPass. Apply password change to increase security.

Effort: Low

Password change can be realized by implementing a database timestamp check.

8. Geolocation login tracking

Description: As a patient, I want to be alarmed, by for example email or text, when a suspicious login is happening. The system needs to detect suspicious consecutive locations.

Benefit: Medium

Geolocation login tracking is important to increase security.

Effort: Medium

This requires setting up an SMS server or using third-party SMS APIs for sending out SMSs to the users.

9. Flexpass Graphical Accessibility

Description: As a visually impaired patient, I want to have the possibility to make use of the SERUMS system. FlexPass primarily relies on visual elements, requiring end-users to perceive, process and recall visual information, and accordingly select certain regions on an image. For visually impaired users, an alternative is to investigate whether and how audio information (e.g., a sequence of music) could be communicated to the end-user. Another interesting direction for addressing visual accessibility issues could relate to utilizing Braille code-based images and haptics in the graphical user authentication process. Such an approach would require utilizing and/or implementing certain hardware and software technology for storing the Braille code in the FlexPass system, and end-users to read and select secret regions of the Braille code image through haptic technology.

Benefit: Medium/high

For supporting accessibility, that would imply more people could have access to the SERUMS solution.

Effort: High

This requires implementing and evaluating the suggested new paradigms and systems based on the proposed ideas.

10. Authentication Configuration

Description: As a user, I want the SERUMS system to be as secure as possible.

In a production environment, the authentication module needs to be configured, the 2-factor authentication is required (with a memory of 60 days or so). Implement an option to allow automatic password to reset.

Benefit: Medium

Allow service providers to customize their policies based on their requirements and needs

Effort: Low

Password reset can be realized by implementing a database timestamp check

11. QR code Implementation

Description: As a patient, I want easy and secure data sharing when I visit a hospital in a foreign country. This might be generated by implementing a QR code. To facilitate the task of the data exchange between the hospital and patients, a QR code is generated by the patients' system. The hospital can scan the code and will show a form to grant access to the department, some default tags, and expiration date. This is a similar approach to the covid-19 applications.

Benefit: Low

This additional functionality will increase the usability in terms of task completion efficiency and effectiveness

Effort: Low

Similar functionality is already implemented as part of SERUMS Two-Factor Authentication in which patients are pairing their devices by scanning a QR code. The front end would need to include a QR scanner as part of rule creation. There are also potential security issues, as QR codes and barcodes can be hijacked. It is important what data the QR code contains, if it is just the organisation or the department, then there is not a lot of risks. If there is personal data in there it might be a security risk.

12. Emergency Button

Description: As a patient, I want doctors to have the right amount of data available that is necessary to treat me in emergency situations.
In a situation where the patient cannot grant access to the hospital staff to his/her data (not conscient, partly disposable) the specific doctors/nurses need to be able to see a restricted version of the medical health record.
The patient allows data sharing in an emergency situation upfront and medical staff uses the emergency button if necessary. This must be logged so the patient can review who has attempted his record.

Benefit: Medium

In a hospital there are many situations where the patient cannot grant access to the SERUMS platform, this would close this gap, and let doctors have access the data.

Effort: Medium

Potential security and legal issues surround this. Work would need to be done on who would have access, and in what circumstances it can be used. At a minimum, the blockchain would need to record it as an emergency rule, so the history can be preserved.

13. Delegated rule creation

Description: As a patient, I want to be able to decide for myself if I want to give a specific doctor access to my data.
This means that patients could grant individual doctors' permission (temporally, or till the patient wants) in the system to create rules on their behalf. This permission would be a rule itself on the blockchain.
The patient should also be able to review what actions the doctor executed with this new permission.

Benefit: High

This would help patient with technical difficulties, to delegate their doctor of confidence to manage his/her rules and reduce the friction to use the access rules mechanism.

Effort: Medium

Doctors can create rules on behalf of patients; however, the patients still need to accept the rule. If the goal is to allow doctors to give access without any patient input, then there are similar issues to the emergency button. The blockchain would need to record who created the rule, and a system would need to be set up to allow other parties to set up rules on someone else's behalf.

14. Access Rules Improvements

Description: As a patient, I want to be able to see recent and outdated access rules easily, so some tasks would need to be done to the current system.
We want to facilitate the task of creating rules, for that there are some changes that need to be done. a) UI: The patient should be able to order by recent, filter & group the different access rules (option to hide outdated). b) Have a historic grave of all rules (including expired) that would be shown to the patient and can be used as proof that certain doctors could/couldn't have access to certain patient data, in case there is a conflict between the patient and the medical department. For this, the data lake should store the access rules, and not use the blockchain as a database. c) Have a notification system when rules are about to expire, (Email or same push notification to SERUMS the app)

Benefit: Medium/high

It would help to manage the access rules and having an historic grave could be used as a proof of who had have access or not to certain patient data.

Effort: Medium/low

Including the concept and architecture of the notification system, this is medium. Business logic to retrieve historic and expired rules is not complex.

15. Treatment related data

Description: As a patient, I only want the necessary data shared with specific doctors. For example, if I am visiting a cardiologist, I want my psychological data to be hidden.
Local and European legislation must be taken into consideration when sharing some sort of medical data such as mental health-related data. When sensible data is going to be shared there should be a mechanism of warning.

Benefit: Medium/High

Benefit is medium/high for ethical and privacy reasons.

Effort: Low/Medium

Treatments are a tag within the system that patients can apply rules to. If its specifically psychological treatments, then a new tag would need to be generated.

16. Hosting across multiple locations & Production deployment

Description: As a user, I want those changes regarding the SERUMS system can be tested before going into production across multiple locations.
In a real production environment, some changes would be needed to the SERUMS technologies so the following needs can be achieved:
Be able to deploy the SERUMS platform in different locations (web, data lake, blockchain node, authentication module) and the networks needed so each location can communicate with each other.
Facilitate the task of the deployment, with a standardized and guided method, so the location would not need local experts (Kubernetes, Blockchain, …).
Make an infrastructure that could scale to millions of users a day.

Benefit: High

This would be necessary to have the SERUMS technologies available for the market.

Effort: High

Currently, the FRACAS had limited availability. In a different situation, this would be different since another environment would be used.

8. Appendix 2

X-eHealth

The EU-funded X-eHealth project will lay the groundwork for a **practical, interoperable, secure and cross-border Electronic Health Record** exchange format, working towards the improvement of the eHealth sector. The project will promote a **faster and more sustainable EU digital transformation**: it aims to move towards a **uniform interoperable data-sharing format structure**. X-eHealth will build on the already existing Patient Summary service and lay the foundations for a common structure for medical imaging, discharge letters, laboratory results and rare diseases. **Planned final date: August 2022 (***CORDIS | European Commission*, 2022d).

CUREX

Reliable digital information and communication infrastructures are crucial for healthcare providers. In this context, the EU-funded CUREX project will make it possible for healthcare providers to assess the realistic cybersecurity and privacy risks they are exposed to and suggest mathematically optimal strategies for addressing these risks with safeguards tailored specifically for each business case and application. Specifically, CUREX is setting up a decentralised architecture enhanced with a private blockchain infrastructure that ensures the integrity of the risk assessment process and of all data transactions that occur between the diverse range of stakeholders involved. The results of this project will boost data security in various situations, from remote healthcare and patient **cross-border** mobility to data exchanges for research. **End date: March 2022 (***CORDIS | European Commission*, 2022a).

SPHINX

SPHINX aims to introduce a Universal Cyber Security Toolkit, thus **enhancing the cyber protection of Health IT Ecosystem** and **ensuring the patient data privacy and integrity**. It will also provide an automated zero-touch device and service verification toolkit that will be easily adapted or embedded on existing, medical, clinical or health available infrastructures. **End date: March 2022 (***CORDIS | European Commission*, 2022c)

PoSeID-on

PoSeID-on is aimed at developing a novel Privacy Enhancing Dashboard for personal data protection supporting the pillars of the new EU's General Data Protection Regulation (GDPR) with regards to digital security, that will be implemented within a single, integrated tool, adopting blockchain and smart contracts technology. It will provide targeted benefits for end users by enabling data protection by design and by default. Thus, the primary aim of PoSeID-on is empowering data subjects in having a concise, transparent, intelligible and ease access, as well as tracking, control and management of their personal data processed by public and private organisations, acting as data controllers and/or data providers. **End date: March 2021** *(CORDIS | European Commission*, 2022b).

9. References

CORDIS | European Commission. (2022a). CUREX- seCUre and pRivate hEalth Data eXchange. https://cordis.europa.eu/project/id/826404

CORDIS | European Commission. (2022b). PoSeID-on-Protection and Control of Secured Information by Means of a Privacy Enhanced Dashboard. https://cordis.europa.eu/project/id/786713

CORDIS | European Commission. (2022c). SPHINX-A Universal Cyber Security Toolkit for Health-Care Industry. https://cordis.europa.eu/project/id/826404

CORDIS | European Commission. (2022d). X-eHealth: eXchanging Electronic Health Records in a Commom Framework. https://cordis.europa.eu/project/id/951938