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Project No.: 825429 SocketSense

SOCKET:SENSE
A TAILORED FIT OF THE FUTURE

Advanced sensor-based design and development of wearable prosthetic socket for amputees

Start date of project: 2019-01-01 Duration: 36+12 months

Deliverable D7.4 :
Open access summary report

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Content

Executive Summary

In this report, we summarize the management and status of open access publications and open access datasets of the SocketSense project. To collect partners' opinions on open access issues, we sent three questionnaires to all partners, namely, open access publication questionnaire, open research data pilot questionnaire, and data repository questionnaire. To facilitate open access data management in the project, a data management committee was formed with representatives from partners.

Overall, there are 16 publications which are open to the public while 5 of them are Gold open archiving (Final print archiving using the publisher's infrastructure) and 11 of them are Green open archiving (Pre-/Post-print or Final print open archiving with possibly fee and embargo). We have also collected 16 dataset managing tables from partners. With a standard format, these tables present how these data are stored and at which level they are open access to the public, etc.

Chapter 1 Open Access Publication

This chapter contains two subsections, namely, Open Access Publication Questionnaire and Open Access Publication from outlook to summary.

1.1 Open Access Publication Questionnaire

1.1.1 Questionnaire

The Open Access Publication Questionnaire can be found in Appendix A. It was intended to facilitate the creation of a baseline on opinions regarding open access publication from partners.

It was answered by Josephine Charnley (LussTech), Begum Zeybek (TWI and Teesside University Healthcare Innovation Centre), Freygarður Þorsteinsson (Össur), Klas Brinkfeldt (RISE), Joe Millar (South Tees NHS Hospital), Andrew Pomazanskyi (Nuromedia), Cristina Suárez Mejías and Paula Algarin (Servicio Andaluz de Salud), and Fredrik Asplund and Zhonghai Lu (KTH Royal Institute of Technology).

1.1.1.1 No Opinion

Among the project's partners two were not aiming to conduct independent research, namely Lusstech and Össur. To the extent that any publications will be written by these partners within SocketSense, they would work with and according to the guidelines followed by other partners in the project. (Considering, of course, any issues with Intellectual Property Rights as they arise.)

1.1.1.2 Institutional Policies or Strategies

Several of the project partners have institutional policies, or policies frequently enforced by external entities, for open access publication.

- KTH: https://www.kth.se/en/biblioteket/publicera-analysera/vagledning-for-publicering
- TWI and Teesside University Healthcare Innovation Centre: https://www.tees.ac.uk/sections/research/portal.cfm
- National Institute for Health Research (United Kingdom) policy: https://www.nihr.ac.uk/documents/nihr-open-access-policy/12251

1.1.1.3 Favoured Types

When enforced, mainly by funding programmes such as Horizon 2020, **Green** and **Gold** open access are acceptable and targeted.

1.1.1.4 Institutional Support

Among the project partners only KTH Royal Institute of Technology offers **financial** support for open access publication, although South Tees NHS Hospital also offers guidance and facilitates the identification of external funds for this purpose.

1.1.1.5 Obstacles, Specifically Obstacles Related to the SocketSense Project

Apart from costs and the need to carefully handle Intellectual Property Rights, no obstacles to open access publication are anticipated by the project partners.

1.1.2 Questionnaire Responses

1.1.2.1 Responses from partners

The responses were collected in 2019 for the first version, and some responses are updated in 2022 by partners. The final version of responses to questionnaires can be found in Appendix B.

1.2 Open Access Publication

1.2.1 Open Access Publication Outlook

Open access publication is essentially about open archiving. **Open archiving** is that a published paper can (a) in some version, (b) at some time and (c) somewhere be accessed by others without them paying. In other words, "some kind of open access" is allowed for the publication **audience**.

However, publishers can limit open archiving:

- The author(s) might have to pay for open archiving.
- The version allowed for open archiving can be a pre-print (pre review), a post-print (post review) or the final (typeset) version.
- The open archiving might be subject to an embargo period.
- The archiving itself might have to be carried out by the author, i.e. this archiving might not be automatic.

A colour scheme is used to differentiate between some common types of archiving:

- White: No open archiving
- Yellow: Pre-print open archiving (possibly fee and embargo)
- Blue: Post-print or Final print open archiving (possibly fee and embargo)
- Green: Pre-/Post-print or Final print open archiving (possibly fee and embargo)
- Gold: Final print archiving using the publisher's infrastructure

1.2.2 Targeted Journals

The open access options associated with the journals targeted by the SocketSense project are listed in Table 1.

Table 1 Targeted Journals

Journal Name	White	Yellow	Blue	Green	Gold
MDPI Sensors journal					Authors can pay for open access (MDPI).
MDPI, Applied Sciences, Special Issue "New Trends in Robotics, Automation and Mechatronics"					Authors can pay for open access (MDPI).
2022 IEEE Biomedical Circuits and Systems				IEEE is a green publisher. Version provided by IEEE (Post-print).	

Conference (BioCAS)				IEEE embargo period is 24 months.	
International Society of Biomechanics (ISB) Annual Conference, 2021					Open access to public.
24th EUROMICRO Conference on Digital System Design (DSD)				IEEE is a green publisher. Version provided by IEEE (Post-print). IEEE embargo period is 24 months.	
15th International Conference on Biomedical Electronics and Devices					SciTePress, open access to public.
IEEE Robotics and automation				IEEE is a green publisher. Version provided by IEEE (Post-print). IEEE embargo period is 24 months.	Authors can pay for open access (IEEE).
British Journal of Surgery		Very unclear rules.			Authors can pay for open access (Wiley).
The European Journal of Vascular and Endovascular Surgery				No embargo period on personal web site. Otherwise, embargo period is 12 months.	Authors can pay for open access (Elsevier).
Journal of Vascular Surgery				No embargo period on personal web site. Otherwise, embargo period is 12 months.	Authors can pay for open access (Elsevier).

1.2.3 Considerations Related to the Targeted Journals

Considering the open access options related to the targeted journals, the project partners will:

- Start with considering the journals that offer Green access.
- Follow up on access to additional funding for paid Gold access.
- Make sure to archive papers on the authors' personal web site to shorten the embargo period, when the publisher allows this option.
- Self-archive papers after the embargo period has ended.

1.2.4 Open Access Publication Results

Table 1 lists publications produced in the SocketSense project. In summary, 5 journal papers are Gold open archiving. Two master theses, a whitepaper, and 10 conference papers are Green open archiving.

We would also note that the project has proposed a special issue accepted in the Open Access journal *MDPI Sensors*. Guest Editors are from KTH Royal Institute of Technology and RISE. More details are available at:
https://www.mdpi.com/journal/sensors/special_issues/prosthetics

Table 1 Publication Summary

Main Author(s)	Contributor(s)	Title	Type of publication	Status	Name of journal / magazine / event	Date of publication	Relevant page	DOI	URL	Comment	Access Type (Gold/Green/Blue/Yellow)
LussTech	IVF	Whitepaper - Sensors	Whitepaper	Published	Zenodo & SocketSense website	Nov 2020			Link		Green
KTH (Ahmed Moustafa, Johan Danmo)		Master Thesis: Wearable sensors in prosthetic socket	Master Thesis	Published	KTH Diva Portal	2019			Link		Green
KTH (Suranjan Ram Ottikkutti)		Master Thesis: Effective Optimization of Deployment for Wearable Sensors in Transfemoral Prosthesis	Master Thesis	Published	KTH Diva Portal	2020			Link		Green
TWI		Fuzzy-logic Inference System for Transfemoral	Conference publication	Accepted	International Society of Biomechanics	2021			Link	Oral presentation	Green

		Socket Rectification			(ISB) Annual Conference, 2021					https://isbweb.org/news/isb-now/181-december-2021/792-isb-2021-book-of-abstracts https://isbweb.org/activities/congresses	
TU	SAS	Biomechanical response of residual limb: combining shear-wave elastography and finite element analysis	Conference publication	Accepted	International Society of Biomechanics (ISB) Annual Conference, 2021	2021			Link	Oral presentation	Green
TU	SAS	Ultrasound investigation of muscle size and muscle properties in transfemoral amputees	Conference publication	Accepted	International Society of Biomechanics (ISB) Annual Conference, 2021	2021			Link	Poster presentation	Green
KTH		Evaluation of Time Series Clustering on	Conference publication	Accepted	24th EUROMICRO Conference on	11/10/2021	pp. 187-191	https://doi.org/10.1109/DSD5383	Link	This paper was the one rejected by CF and	Green

		Embedded Sensor Platform			Digital System Design (DSD)			2.2021 .00038		resubmitted to DSD. Oral presentation.	
Össur	KTH/TU	A scoping review of pressure measurements in prosthetic sockets of transfemoral amputees during ambulation: key considerations for sensor design	Journal paper	Accepted	MDPI Sensors journal	23/07/2021		https:/ /doi.or g/10.3 390/s2 11550 16	Link	Open access, Impact factor: 3.576	Gold
LussT ech	IVF	Development of Prototype Low Cost QTSS™ Wearable Flexible more Envirofriendly Pressure, Shear and Friction sensors for dynamic Prosthetic Fit Monitoring	Journal paper	Accepted	MDPI Sensors journal	28/05/2021		https:/ /doi.or g/10.3 390/s2 11137 64	Link	Open access, Impact factor: 3.576	Gold
TWI	KTH	A Sensor-based Decision Support System for Transfemoral Socket Rectification	Journal paper	Accepted	MDPI Sensors Journal	28/05/2021		https:/ /doi.or g/10.3 390/s2 11137 43	Link	Open access, Impact factor: 3.576	Gold

KTH		A Mechatronics-Twin Framework based on Stewart Platform for Effective Exploration of Operational Behaviors of Prosthetic Sockets with Amputees	Conference publication	Accepted	15th International Conference on Biomedical Electronics and Devices	2022	pp. 74-83	https://doi.org/10.5220/0010838600003123	Link	Oral presentation	Green
KTH	Össur	Redundancy Reduction for Sensor Deployment in Prosthetic Socket: A Case Study.	Journal paper	Accepted	MDPI Sensors Journal	19/04/2022		https://doi.org/10.3390/s22093103	Link	Open access, Impact factor: 3.576	Gold
Ossur	LussTech	Simultaneous intra-socket shear and pressure measurements of a transfemoral amputee during dynamic and static activities: a feasibility study	Conference publication	Accepted	OTWorld 2022	2022			Link	ePoster	Green
Ossur	IVF	A toolbox for bi-directional conversions between 3D prosthetic socket	Conference publication	Accepted	OTWorld 2022	2022			Link	Oral presentation	Green

		stress measurements and its representations in 2D									
KTH	TWI	Analyzing Dynamic Operational Conditions of Limb Prosthetic Sockets with A Mechatronics-Twin Framework	Journal paper	Accepted	MDPI, Applied Sciences, Special Issue "New Trends in Robotics, Automation and Mechatronics"	19/01/2022		https://doi.org/10.3390/app12030986	Link	Open access, Impact factor: 2.679 We were invited to submit a paper.	Gold
KTH	All partners	Wearable pressure sensing for lower limb amputees	Conference publication	Accepted	2022 IEEE Biomedical Circuits and Systems Conference (BioCAS)	13/10/2022	pp. 105-109	https://doi.org/10.1109/biocas54905.2022.9948616	Link	Oral presentation	Green

This table presents the details of 16 publications. In conclusion, five papers are Gold open archiving and fully open access to public. Four papers are published on MDPI Sensors Journal, and one paper is published on MDPI Applied Sciences Journal.

Overall, eight conference papers are Green open archiving. There are three conference papers published on International Society of Biomechanics (ISB) Annual Conference 2021, two papers published on OTWorld 2022, one paper published on 24th EUROMICRO Conference on Digital System Design (DSD), one paper published on 2022 IEEE Biomedical Circuits and Systems Conference (BioCAS), and one paper published on 15th International Conference on Biomedical Electronics and Devices.

Two master theses and a Whitepaper are Green open archiving on Zenodo and KTH Publication Database DiVA, which contains publications produced by the university's researchers and students.

Chapter 2 Open Research Data Pilot

This chapter describes first the data gathering and analysis of the SocketSense project within the Open Research Data Pilot. As such, it also defines the Data Management Plan for the project. Then it presents the open research data from management to summary.

2.1 Questionnaire and Data Management Plan

The Open Research Data Pilot questionnaire can be found in Appendix C. It was answered by Josephine Charnley (LussTech), Begum Zeybek (TWI and Teesside University Healthcare Innovation Centre), Freygarður Þorsteinsson (Össur), Klas Brinkfeldt (RISE), Joe Millar (South Tees NHS Hospital), Andrew Pomazanskyi (Nuromedia), Cristina Suárez Mejías (Servicio Andaluz de Salud), and Yizhi Chen, Fredrik Asplund, and Zhonghai Lu (KTH Royal Institute of Technology).

2.1.1 Data Management Plan

This subsection summarises the feedback on the Open Research Data Pilot into a Data Management Plan for SocketSense. We specifically note that the project partners have identified the need for a data management committee.

2.1.1.1 Data Summary

Various data are generated through the SocketSense project. Clinical trial data suitable for sharing within the Open Research Data Pilot will primarily be gathered during the WP6 trials. The data gathered will:

- include anatomical data (scanning the patients' leg for dimensions and 3D shape information)
- come from biomechanical QTSS sensors (shear and pressure readings for data processing algorithms, AI and socket design algorithms)
- come from shear wave elastography (muscle tissue stiffness for finite element model simulations and data processing algorithms)
- include patient comfort data (for data processing algorithms, AI and socket design algorithms)
- include demographic information (age, height, weight)
- include permitted medical history

The data will be gathered with the participants' consent both directly from the participants and from their medical records. It is expected that this data could be of interest to researchers involved in future studies in the area of prosthetics.

2.1.1.2 FAIR Data – Making Data Findable

The project partners involved in generating the open research data will:

- Provide descriptive metadata.
- Provide rights metadata.
- Provide technical metadata.
- Use standard naming conventions already in the data collection forms.

2.1.1.3 FAIR Data – Making Data Openly Accessible

Subsets of data that are needed to validate results in scientific publications will be made openly available, but only for certain types of use and certain type of users. As an example, due to hospital policy the data will only be shared for research and education

purposes, and only until 5 years after the project ends. Those accessing the data will thus be identified as they agree to the terms and conditions of using the data before access.

Structured metadata will be published and made freely accessible to allow others to understand what research data exists, how it can be accessed, and why, when and how it was generated.

The open research data and associated metadata will be deposited in a repository.

2.1.1.4 FAIR Data – Making Data Interoperable

The SocketSense partners will try to use standard data and metadata to make the open research data interoperable.

2.1.1.5 FAIR Data – Clarifying Licenses

The licensing option is flexible, but the intention is that the data will be free of use and re-use under the defined terms and conditions.

2.1.1.6 FAIR Data – Resource Allocation

The main anticipated costs are the staff salary and associated resources for developing the metadata. It is difficult to quantify a figure.

During the project's lifetime the costs associated with the Open Research Data Pilot will be covered by the project. After the project ends, Teesside University Healthcare Innovation Centre will cover associated costs related to their data sets. Other project partners still need to investigate how to cover costs after the project ends.

Those responsible for the open research data in the project partners' organisations are:

- Teesside University Healthcare Innovation Centre – Begum Zeybek and Zulf Ali
- South Tees NHS Hospital –Sharon Brown
- Servicio Andaluz de Salud – Cristina Suárez Mejías

2.1.1.7 FAIR Data – Data Security

All project partners have policies and measures in place for securely storing data. The need to keep data appropriately secure against damage, unauthorised access, amendment or deletion, with precautions taken appropriate to its confidentiality and sensitivity, is well understood. This for instance means that:

- Personal Data will be collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes.
- Personal Data will be adequate, relevant and limited to what is necessary in relation to the processing purpose.
- Personal Data will be accurate and, where necessary, kept up to date.
- Personal Data will be kept in a form, which permits identification of subjects for no longer than is necessary for the processing purpose.
- Personal Data will be processed securely and in a manner that protects against unauthorised or unlawful processing, loss, destruction or damage.

Such considerations will weigh heavily as regards which data is shared as open research data by the project partners. These considerations will also weigh heavily in the decision on which repository will be used for sharing the open research data.

2.1.1.8 FAIR Data – Ethical Aspects

Project partners will obtain participants' informed consent before proceeding with any use of data.

Obviously, there are legal, ethical and commercial constraints on release of research data, which require project partners' policies and practices to ensure that these constraints are considered at all stages in the research process. However, we do not expect any issues within SocketSense that cannot be handled based on the project partners experience and already active precautions regarding these matters.

2.1.1.9 FAIR Data – Other Issues

No other issues related to open research data have been identified by the project partners.

2.2 Responses to Open Research Data Pilot questionnaire

We collected responses to open research data pilot questionnaire from all partners. The responses were firstly collected in 2019, and some of them are updated several times during 2019-2022. The final version can be found in Appendix D.

2.3 Open Access Data Management and Summary

2.3.1 Data Management Committee

The Data Management Committee (DMC) includes 7 partners which are TWI, LussTech, STH, KTH, Nuromedia, Össur, TU.

Details of data management committee can be found in Appendix G.

2.3.2 The Data Repository Questionnaire

We collected the answers to the following three questions for each partner:

A. Repository: Each partner shall summarize which repositories they (and your community) commonly use? Is the repository open access or limited by institutional use, etc.?

B. Which license option? We may need to choose a default licensing option.

C. Cost coverage: Please tell us how you will cover any costs for providing open research data after the project ends.

The responses to the data repository questionnaire, which are answered by partners, can be found in Appendix E.

2.3.3 Open Access Dataset Information

We collected the information including open access dataset description, partners activities and responsibilities, estimated data size, purpose use of the data analysis, data access policy, data storage position and lifetime.

We present the data managing tables from partners in Appendix F.

2.3.4 The Open Access Data Summary

We have created an open access data summary in **Zenodo** (https://zenodo.org/record/7400478#.Y5c859LMIUE), which contains all the open access publications and open access datasets.

Appendix A: Open Access Publication Questionnaire

1. Are there any institutional policy or strategy regarding open access publication of research papers by your university, company or organization? If so, please provide a reference.
2. Is your organization encouraging open access publication of research papers? If so, which type of open access is encouraged (Yellow/Blue/Green/Gold)?
3. Is there any institutional support (for instance funding) for open access publication of research papers by your university, company or organization? If so, please provide details.
4. Are there any foreseeable obstacles to open access publication of research papers by your university, company or organization?
5. Are there any foreseeable obstacles to open access publication of research papers by your university, company or organization specifically related to the SocketSense project?

Appendix B: Responses to Open Access Publication Questionnaire

B.1 LussTech

1. Are there any institutional policy or strategy regarding open access publication of research papers by your university? If so, please provide a reference.

LussTech is a commercial entity and therefore we do not generally publish research papers although we are occasionally involved with some. We are not generally generating any research data though.

2. Is your organization encouraging open access publication of research papers? If so, which type of open access is encouraged (Yellow/Blue/Green/Gold)?

N/A. No formal policy.

3. Is there any institutional support (for instance funding) for open access publication of research papers by your university? If so, please provide details.

N/A. No.

4. Are there any foreseeable obstacles to open access publication of research papers by your university?

IPR considerations as a commercial entity.

5. Are there any foreseeable obstacles to open access publication of research papers by your university specifically related to the SocketSense project?

Only IPR considerations as a commercial entity.

B.2 Teesside University

1. Are there any institutional policy or strategy regarding open access publication of research papers by your university, company or organization? If so, please provide a reference.

There is no formal organisational policy. There is a national policy which applies to NIHR-funded research: https://www.nihr.ac.uk/documents/nihr-open-access-policy/12251

2. Is your organization encouraging open access publication of research papers? If so, which type of open access is encouraged (Yellow/Blue/Green/Gold)?

Yes, we encourage open access. There is no specific organizational policy on which type of 'open access' is encouraged.

3. Is there any institutional support (for instance funding) for open access publication of research papers by your university, company or organization? If so, please provide details.

We offer guidance and can endeavor to find external funding, but there is no internal organizational funding.

4. Are there any foreseeable obstacles to open access publication of research papers by your university, company or organization?

No.

5. Are there any foreseeable obstacles to open access publication of research papers by your university, company or organization specifically related to the SocketSense project?

If there is already funding in place then no issues are anticipated.

B.3 KTH Royal Institute of Technology

1. Are there any institutional policy or strategy regarding open access publication of research papers by your university, company or organization? If so, please provide a reference.

Yes, it can be found here: https://www.kth.se/en/biblioteket/publicera-analysera/vagledning-for-publicering.

2. Is your organization encouraging open access publication of research papers? If so, which type of open access is encouraged (Yellow/Blue/Green/Gold)?

Yes, KTH encourages open access publication in Green and/or Gold path.

3. Is there any institutional support (for instance funding) for open access publication of research papers by your university, company or organization? If so, please provide details.

Yes, KTH covers costs. Details are here: https://www.kth.se/en/biblioteket/publicera-analysera/vagledning-for-publicering/publicera-open-access-vi-betalar-1.859196

4. Are there any foreseeable obstacles to open access publication of research papers by your university, company or organization?

No.

5. Are there any foreseeable obstacles to open access publication of research papers by your university, company or organization specifically related to the SocketSense project?

No.

B.4 Össur

1. Are there any institutional policy or strategy regarding open access publication of research papers by your university, company or organization? If so, please provide a reference.

There is no formal policy concerning open access publications but our policy towards publications in general is that protection of IPR should be considered before publishing.

2. Is your organization encouraging open access publication of research papers? If so, which type of open access is encouraged (Yellow/Blue/Green/Gold)?

No formal policy on this.

3. Is there any institutional support (for instance funding) for open access publication of research papers by your university, company or organization? If so, please provide details.

No.

4. Are there any foreseeable obstacles to open access publication of research papers by your university, company or organization?

Only IPR considerations, see reply to question 1.

5. Are there any foreseeable obstacles to open access publication of research papers by your university, company or organization specifically related to the SocketSense project?

Only IPR considerations, see reply to question 1.

B.5 RISE IVF

1. Are there any institutional policy or strategy regarding open access publication of research papers by your university, company or organization? If so, please provide a reference.

No.

2. Is your organization encouraging open access publication of research papers? If so, which type of open access is encouraged (Yellow/Blue/Green/Gold)?

Not really, Green or Gold are usually encouraged because of EU-project requirements.

3. Is there any institutional support (for instance funding) for open access publication of research papers by your university, company or organization? If so, please provide details.

No, this have to come from the project funding.

4. Are there any foreseeable obstacles to open access publication of research papers by your university, company or organization?

Not apart from the extra cost.

5. Are there any foreseeable obstacles to open access publication of research papers by your university, company or organization specifically related to the SocketSense project?

No.

B.6 SAS (Servicio Andaluz de Salud)

1. Are there any institutional policy or strategy regarding open access publication of research papers by your university, company or organization? If so, please provide a reference.

No, but we are leading FAIR4Health research project, so we are guided by its principles. FAIR4Health research project receives support from the European Commission (Research Executive Agency) under grant agreement No. 824666 – resources from H2020 Framework Programme.

2. Is your organization encouraging open access publication of research papers? If so, which type of open access is encouraged (Yellow/Blue/Green/Gold)?

No.

3. Is there any institutional support (for instance funding) for open access publication of research papers by your university? If so, please provide details.

No.

4. Are there any foreseeable obstacles to open access publication of research papers by your university?

No.

5. Are there any foreseeable obstacles to open access publication of research papers by your university specifically related to the SocketSense project?

No.

Appendix C: Open Research Data Pilot Questionnaire

The questions below are from Annex 1 of the Data Management section of the H2020 Online Manual (see https://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/open-access-data-management/data-management_en.htm).

1. Data Summary

What is the purpose of the data collection/generation and its relation to the objectives of the project?

What types and formats of data will the project generate/collect?

Will you re-use any existing data and how?

What is the origin of the data?

What is the expected size of the data?

To whom might it be useful ('data utility')?

2. FAIR data

- Making data findable, including provisions for metadata

Are the data produced and/or used in the project discoverable with metadata, identifiable and locatable by means of a standard identification mechanism (e.g. persistent and unique identifiers such as Digital Object Identifiers)?

What naming conventions do you follow?

Will search keywords be provided that optimize possibilities for re-use?

Do you provide clear version numbers?

What metadata will be created? In case metadata standards do not exist in your discipline, please outline what type of metadata will be created and how.

- Making data openly accessible

Which data produced and/or used in the project will be made openly available as the default? If certain datasets cannot be shared (or need to be shared under restrictions), explain why, clearly separating legal and contractual reasons from voluntary restrictions.

Note that in multi-beneficiary projects it is also possible for specific beneficiaries to keep their data closed if relevant provisions are made in the consortium agreement and are in line with the reasons for opting out.

How will the data be made accessible (e.g. by deposition in a repository)?

What methods or software tools are needed to access the data?

Is documentation about the software needed to access the data included?

Is it possible to include the relevant software (e.g. in open source code)?

Where will the data and associated metadata, documentation and code be deposited? Preference should be given to certified repositories which support open access where possible.

Have you explored appropriate arrangements with the identified repository?

If there are restrictions on use, how will access be provided?

Is there a need for a data access committee?

Are there well described conditions for access (i.e. a machine readable license)?

How will the identity of the person accessing the data be ascertained?

- Making data interoperable

Are the data produced in the project interoperable, that is allowing data exchange and re-use between researchers, institutions, organisations, countries, etc. (i.e. adhering to standards for formats, as much as possible compliant with available (open) software applications, and in particular facilitating re-combinations with different datasets from different origins)?

What data and metadata vocabularies, standards or methodologies will you follow to make your data interoperable?

Will you be using standard vocabularies for all data types present in your data set, to allow inter-disciplinary interoperability?

In case it is unavoidable that you use uncommon or generate project specific ontologies or vocabularies, will you provide mappings to more commonly used ontologies?

- Increase data re-use (through clarifying licences)

How will the data be licensed to permit the widest re-use possible?

When will the data be made available for re-use? If an embargo is sought to give time to publish or seek patents, specify why and how long this will apply, bearing in mind that research data should be made available as soon as possible.

Are the data produced and/or used in the project useable by third parties, in particular after the end of the project? If the re-use of some data is restricted, explain why.

How long is it intended that the data remains re-usable?

Are data quality assurance processes described?

Further to the FAIR principles, DMPs should also address:

3. Allocation of resources

What are the costs for making data FAIR in your project?

How will these be covered? Note that costs related to open access to research data are eligible as part of the Horizon 2020 grant (if compliant with the Grant Agreement conditions).

Who will be responsible for data management in your project?

Are the resources for long term preservation discussed (costs and potential value, who decides and how what data will be kept and for how long)?

4. Data security

What provisions are in place for data security (including data recovery as well as secure storage and transfer of sensitive data)?

Is the data safely stored in certified repositories for long term preservation and curation?

5. Ethical aspects

Are there any ethical or legal issues that can have an impact on data sharing? These can also be discussed in the context of the ethics review. If relevant, include references to ethics deliverables and ethics chapter in the Description of the Action (DoA).

Is informed consent for data sharing and long term preservation included in questionnaires dealing with personal data?

6. Other issues

Do you make use of other national/funder/sectorial/departmental procedures for data management? If yes, which ones?

Appendix D: Responses to Open Research Data Pilot Questionnaire

D.1 LussTech

Responses:

LussTech is not collecting or generating any research data.

D.2 Teesside University

1. Data Summary

- What is the purpose of the data collection/generation and its relation to the objectives of the project?

Data will be collected from WP6 trial participants to (1) provide 'benchmarking' data on lower limb function and (2) to assess the reliability and efficacy of the socket sense technology.

- What types and formats of data will the project generate/collect?

It is anticipated that demographic information (age, height, weight), medical history and questionnaire responses will be collected.

- Will you re-use any existing data and how?

Identifiable personal data will be collected from trial participants. However personal data will not be shared outside of the hospital except where this is needed for the research analysis (e.g. a person's age for instance will need to be provided). This data will be attached to a unique study ID and will only be provided with the person's informed consent.

- What is the origin of the data?

The origin of the data will either be information directly provided by the participants (and recorded in data collection forms) or obtained from medical records with the participant's consent (a Research Nurse or Data Officer employed by our organization would collect this data).

- What is the expected size of the data?

There will be data from approximately 150 participants in total

To whom might it be useful ('data utility')?

The benchmarking data from the first phase of the trial could be useful be other researchers in the future.

2. FAIR data

Making data findable, including provisions for metadata

- Are the data produced and/or used in the project discoverable with metadata, identifiable and locatable by means of a standard identification mechanism (e.g. persistent and unique identifiers such as Digital Object Identifiers)?

- What naming conventions do you follow?

Will search keywords be provided that optimize possibilities for re-use?

- Do you provide clear version numbers?
- What metadata will be created? In case metadata standards do not exist in your discipline, please outline what type of metadata will be created and how.

Making data openly accessible

- Which data produced and/or used in the project will be made openly available as the default? If certain datasets cannot be shared (or need to be shared under restrictions), explain why clearly separating legal and contractual reasons from voluntary restrictions.
- Note that in multi-beneficiary projects it is also possible for specific beneficiaries to keep their data closed if relevant provisions are made in the consortium agreement and are in line with the reasons for opting out.
- How will the data be made accessible (e.g. by deposition in a repository)?
- What methods or software tools are needed to access the data?
- Is documentation about the software needed to access the data included?
- Is it possible to include the relevant software (e.g. in open source code)?
- Where will the data and associated metadata, documentation and code be deposited? Preference should be given to certified repositories which support open access where possible.
- Have you explored appropriate arrangements with the identified repository?
- If there are restrictions on use, how will access be provided?
- Is there a need for a data access committee?
- Are there well described conditions for access (i.e. a machine readable license)?
- How will the identity of the person accessing the data be ascertained?
- Making data interoperable
- Are the data produced in the project interoperable, that is allowing data exchange and re-use between researchers, institutions, organizations, countries, etc. (i.e. adhering to standards for formats, as much as possible compliant with available (open) software applications, and in particular facilitating re-combinations with different datasets from different origins)?
- What data and metadata vocabularies, standards or methodologies will you follow to make your data interoperable?
- Will you be using standard vocabularies for all data types present in your data set, to allow inter-disciplinary interoperability?
- In case it is unavoidable that you use uncommon or generate project specific ontologies or vocabularies, will you provide mappings to more commonly used ontologies?

- Increase data re-use (through clarifying licenses)
- How will the data be licensed to permit the widest re-use possible?
- When will the data be made available for re-use? If an embargo is sought to give time to publish or seek patents, specify why and how long this will apply, bearing in mind that research data should be made available as soon as possible.
- Are the data produced and/or used in the project usable by third parties, in particular after the end of the project? If the re-use of some data is restricted, explain why.
- How long is it intended that the data remains re-usable?
- Are data quality assurance processes described?

Responses to all questions above:

My expectation is that we would obtain participants' consent for the benchmarking data from the first phase of the trial (i.e. where we will collect elastomeric measurements on lower limb function) to be included in the formal publication in de-identified form – but this point still needs to be discussed with the project partners, as this data could then theoretically be used by third parties.

We would endeavor to use standard naming conventions in the data collection forms and to follow 'FAIR' principles.

3. Allocation of resources

- What are the costs for making data FAIR in your project? How will these be covered? Note that costs related to open access to research data are eligible as part of the Horizon 2020 grant (if compliant with the Grant Agreement conditions).

The main anticipated cost would be the staff time and resources in developing the metadata. It is difficult to quantify a figure given the ongoing work on developing the trial, but we would feedback if there were any concerns.

- Who will be responsible for data management in your project? Are the resources for long term preservation discussed (costs and potential value, who decides and how what data will be kept and for how long)?

We plan to assign a data officer at our organization to oversee the research data collection.

4. Data security

- What provisions are in place for data security (including data recovery as well as secure storage and transfer of sensitive data)?

We are required to record and use data securely in adherence with GCP, 'GDPR' and the 'research policy framework' (https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/; Principle 14 refers to 'Respect for Privacy').

There is already restricted confidential access to NHS medical records.

- Is the data safely stored in certified repositories for long term preservation and curation?

We would mandate that any new data collection forms are stored securely by our employees using the Trust's secure server, only transferred using an encrypted method ('NHS.net' or 'redcap' database) and archived at the organization's secure facility when the project completes.

5. Ethical aspects

- Are there any ethical or legal issues that can have an impact on data sharing? These can also be discussed in the context of the ethics review. If relevant, include references to ethics deliverables and ethics chapter in the Description of the Action (DoA).

We have experience of successfully applying for research approvals and setting up data protection arrangements, so we do not anticipate any ethical issues.

- Is informed consent for data sharing and long term preservation included in questionnaires dealing with personal data?

We will obtain participants' informed consent before proceeding with the planned use of data.

6. Other issues

- Do you make use of other national/funder/sectorial/departmental procedures for data management? If yes, which ones?

No other issues identified to highlight.

D.3 KTH Royal Institute of Technology

1. Data Summary

- What is the purpose of the data collection/generation and its relation to the objectives of the project?

KTH will generate and keep the data within SocketSense project in related working packages. The data include electronics design, sensor data, etc.

- What types and formats of data will the project generate/collect?

Codes, sensor data in tables and text files, electronics designs (schematic, layout, etc.), documents.

- Will you re-use any existing data and how?

KTH may utilize open access data following their corresponding licenses.

- What is the origin of the data?

Created by KTH or generated by partners using KTH developed equipment during the project activities.

- What is the expected size of the data?

>100 MB.

- To whom might it be useful ('data utility')?

Within the project partners, and in future to the external researchers interested in the SocketSense project.

2. FAIR data

❖ Making data findable, including provisions for metadata

- Are the data produced and/or used in the project discoverable with metadata, identifiable and locatable by means of a standard identification mechanism (e.g. persistent and unique identifiers such as Digital Object Identifiers)?

No

- What naming conventions do you follow?

We use standard naming convention following the partners' agreements.

- Will search keywords be provided that optimize possibilities for re-use?

N/A

- Do you provide clear version numbers?

For the KTH developed codes, we have version control by Git.

- What metadata will be created? In case metadata standards do not exist in your discipline, please outline what type of metadata will be created and how.

N/A

❖ Making data openly accessible

- Which data produced and/or used in the project will be made openly available as the default? If certain datasets cannot be shared (or need to be shared under restrictions), explain why, clearly separating legal and contractual reasons from voluntary restrictions.

Note that in multi-beneficiary projects it is also possible for specific beneficiaries to keep their data closed if relevant provisions are made in the consortium agreement and are in line with the reasons for opting out.

The publication related data will be accessible according to the publisher's policy. Other data will follow the SocketSense data management committee.

- How will the data be made accessible (e.g. by deposition in a repository)?

KTH may store data in shared folder on cloud.

- What methods or software tools are needed to access the data?

N/A

- Is documentation about the software needed to access the data included?

Yes, a readme file will be provided.

- Is it possible to include the relevant software (e.g. in open source code)?

Following the SocketSense data management rules.

- Where will the data and associated metadata, documentation and code be deposited? Preference should be given to certified repositories which support open access where possible.

Github and other open access service providers.

- Have you explored appropriate arrangements with the identified repository?

N/A

- If there are restrictions on use, how will access be provided?

Following the SocketSense data management rules.

- Is there a need for a data access committee?

Yes.

- Are there well described conditions for access (i.e. a machine readable license)?

Following the SocketSense data management rules.

- How will the identity of the person accessing the data be ascertained?

N/A

❖ Making data interoperable

- Are the data produced in the project interoperable, that is allowing data exchange and re-use between researchers, institutions, organisations, countries, etc. (i.e. adhering to standards for formats, as much as possible compliant with available (open) software applications, and in particular facilitating re-combinations with different datasets from different origins)?

N/A

- What data and metadata vocabularies, standards or methodologies will you follow to make your data interoperable?

N/A

- Will you be using standard vocabularies for all data types present in your data set, to allow inter-disciplinary interoperability?

N/A

- In case it is unavoidable that you use uncommon or generate project specific ontologies or vocabularies, will you provide mappings to more commonly used ontologies?

N/A

❖ Increase data re-use (through clarifying licences)

- How will the data be licensed to permit the widest re-use possible?

Following the SocketSense data management rules.

- When will the data be made available for re-use? If an embargo is sought to give time to publish or seek patents, specify why and how long this will apply, bearing in mind

that research data should be made available as soon as possible. Following the SocketSense data management rules.

- Are the data produced and/or used in the project useable by third parties, in particular after the end of the project? If the re-use of some data is restricted, explain why. Following the SocketSense data management rules.
- How long is it intended that the data remains re-usable?

N/A

- Are data quality assurance processes described?

N/A

Further to the FAIR principles, DMPs should also address:

3. Allocation of resources

- What are the costs for making data FAIR in your project?

N/A

- How will these be covered? Note that costs related to open access to research data are eligible as part of the Horizon 2020 grant (if compliant with the Grant Agreement conditions).

N/A

- Who will be responsible for data management in your project?

KTH researchers within SocketSense project will be responsible for KTH generated data.

- Are the resources for long term preservation discussed (costs and potential value, who decides and how what data will be kept and for how long)?

Following the SocketSense data management rules.

4. Data security

- What provisions are in place for data security (including data recovery as well as secure storage and transfer of sensitive data)?

The open access data repository providers.

- Is the data safely stored in certified repositories for long term preservation and curation?
- Yes.

5. Ethical aspects

- Are there any ethical or legal issues that can have an impact on data sharing? These can also be discussed in the context of the ethics review. If relevant, include references to ethics deliverables and ethics chapter in the Description of the Action (DoA).

N/A

- Is informed consent for data sharing and long term preservation included in questionnaires dealing with personal data?

N/A

6. Other issues

- Do you make use of other national/funder/sectorial/departmental procedures for data management? If yes, which ones?

N/A

D.4 Össur

Not available (Ossur only answered the open access publication part).

D.5 RISE

1. Data Summary

- What is the purpose of the data collection/generation and its relation to the objectives of the project?

Compare different sensor materials and evaluate best sensor design.

- What types and formats of data will the project generate/collect?

Various formats from document files (Word, Ppt, Excel, ...) to parameter settings and internal data storage in the test set-up and machines.

- Will you re-use any existing data and how?

Not planned

- What is the origin of the data?

Internal, functional- and calibration test data generated in the sensor development.

- What is the expected size of the data?

>1 GB

- To whom might it be useful ('data utility')?

No one we can think of apart from (some of) the project partners.

2. FAIR data

❖ Making data findable, including provisions for metadata

- Are the data produced and/or used in the project discoverable with metadata, identifiable and locatable by means of a standard identification mechanism (e.g. persistent and unique identifiers such as Digital Object Identifiers)?

No

What naming conventions do you follow?

We use an internal naming convention to specify sensor ID, measurement number, …etc.

Will search keywords be provided that optimize possibilities for re-use?

N/A

Do you provide clear version numbers?

N/A

What metadata will be created? In case metadata standards do not exist in your discipline, please outline what type of metadata will be created and how.

N/A

❖ Making data openly accessible

- Which data produced and/or used in the project will be made openly available as the default? If certain datasets cannot be shared (or need to be shared under restrictions), explain why, clearly separating legal and contractual reasons from voluntary restrictions.

Note that in multi-beneficiary projects it is also possible for specific beneficiaries to keep their data closed if relevant provisions are made in the consortium agreement and are in line with the reasons for opting out.

None since it is only internal development data which could also be part of the IP created in the project.

- How will the data be made accessible (e.g. by deposition in a repository)?

N/A

- What methods or software tools are needed to access the data?

N/A

- Is documentation about the software needed to access the data included?

N/A

- Is it possible to include the relevant software (e.g. in open source code)?

N/A

- Where will the data and associated metadata, documentation and code be deposited? Preference should be given to certified repositories which support open access where possible.

N/A

- Have you explored appropriate arrangements with the identified repository?

N/A

- If there are restrictions on use, how will access be provided?

N/A

- Is there a need for a data access committee?

No

- Are there well described conditions for access (i.e. a machine readable license)?

N/A

- How will the identity of the person accessing the data be ascertained?

N/A

❖ Making data interoperable

- Are the data produced in the project interoperable, that is allowing data exchange and re-use between researchers, institutions, organizations, countries, etc. (i.e. adhering to standards for formats, as much as possible compliant with available (open) software applications, and in particular facilitating re-combinations with different datasets from different origins)?

N/A

- What data and metadata vocabularies, standards or methodologies will you follow to make your data interoperable?

N/A

- Will you be using standard vocabularies for all data types present in your data set, to allow inter-disciplinary interoperability?

N/A

- In case it is unavoidable that you use uncommon or generate project specific ontologies or vocabularies, will you provide mappings to more commonly used ontologies?

No (only internal data)

❖ Increase data re-use (through clarifying licenses)

- How will the data be licensed to permit the widest re-use possible?

N/A

- When will the data be made available for re-use? If an embargo is sought to give time to publish or seek patents, specify why and how long this will apply, bearing in mind that research data should be made available as soon as possible.

N/A

- Are the data produced and/or used in the project useable by third parties, in particular after the end of the project? If the re-use of some data is restricted, explain why.

No, the development data will belong to project partners only.

- How long is it intended that the data remains re-usable?

N/A

- Are data quality assurance processes described?

N/A

Further to the FAIR principles, DMPs should also address:

3. Allocation of resources

- What are the costs for making data FAIR in your project?

N/A (existing internal data storage is used. It will not be made FAIR for our generated data.)

- How will these be covered?

Note that costs related to open access to research data are eligible as part of the Horizon 2020 grant (if compliant with the Grant Agreement conditions).

- Who will be responsible for data management in your project?

Individual researchers and the IT department.

- Are the resources for long term preservation discussed (costs and potential value, who decides and how what data will be kept and for how long)?

The test data will be stored at RISE IVF for a minimum of 5 years.

4. Data security

- What provisions are in place for data security (including data recovery as well as secure storage and transfer of sensitive data)? RISE IVF internal storage behind company firewall.

Is the data safely stored in certified repositories for long term preservation and curation? Yes.

5. Ethical aspects

- Are there any ethical or legal issues that can have an impact on data sharing? These can also be discussed in the context of the ethics review. If relevant, include references to ethics deliverables and ethics chapter in the Description of the Action (DoA).

N/A for the sensor development data

- Is informed consent for data sharing and long term preservation included in questionnaires dealing with personal data?

N/A

6. Other issues

Do you make use of other national/funder/sectorial/departmental procedures for data management? If yes, which ones?

N/A

D.6 SAS (Servicio Andaluz de Salud)

- 1. What is the purpose of the data collection/generation and its relation to the objectives of the project?

As mentioned by Teesside University:

- Anatomical data (scanning the patient's leg for dimensions and 3D shape information), biomechanical QTSS sensors (shear and pressure readings for data processing algorithms, AI and socket design algorithms), shear wave elastography (muscle tissue stiffness for finite element model simulations and data processing algorithms), patient comfort data (for data processing algorithms, AI and socket design algorithms).

- Personal Data will be collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes.

- Personal Data will be adequate, relevant and limited to what is necessary in relation to the processing purpose.

- Personal Data will be accurate and, where necessary, kept up to date.

- Personal Data will be kept in a form which permits identification of subjects for no longer than is necessary for the processing purpose.

- Personal Data will be processed securely and in a manner that protects against unauthorised or unlawful processing, loss, destruction or damage.

- 2. What types and formats of data will the project generate/collect?

3D biomodel, radiological images, anatomical data (measurements), biomechanical QTSS sensors (shear and pressure readings), shear wave elastography (muscle tissue stiffness), patient comfort data (qualitative questionnaire).

- 3. Will you re-use any existing data and how?

No

- 4. What is the origin of the data?

3D biomodel, radiological images, anatomical data (healthy and amputee participants) biomechanical QTSS sensors (healthy and amputee participants), shear wave elastography (healthy and amputee participants), patient comfort data (healthy and amputee participants)

- 5. What is the expected size of the data?

1-250 mb (approximately)

- 6. To whom might it be useful ('data utility')?

Researchers

2. FAIR data

❖ Making data findable, including provisions for metadata

- 1. Are the data produced and/or used in the project discoverable with metadata, identifiable and locatable by means of a standard identification mechanism (e.g. persistent and unique identifiers such as Digital Object Identifiers)?

Yes, metadata will include use of a robust digital object identifier (For example as available through the OSF).

- What naming conventions do you follow?

As mentioned by Teesside University: follow the usual convention.

● Will search keywords be provided that optimize possibilities for re-use?

Yes

● Do you provide clear version numbers?

Yes

● What metadata will be created? In case metadata standards do not exist in your discipline, please outline what type of metadata will be created and how.

As mentioned by Teesside University; biomodels, descriptive metadata, rights metadata and technical metadata. Published research papers will also include a short statement describing how and on what terms any supporting research data may be accessed.

❖ Making data openly accessible

● Which data produced and/or used in the project will be made openly available as the default? If certain datasets cannot be shared (or need to be shared under restrictions), explain why, clearly separating legal and contractual reasons from voluntary restrictions.

Note that in multi-beneficiary projects it is also possible for specific beneficiaries to keep their data closed if relevant provisions are made in the consortium agreement and are in line with the reasons for opting out.

As mentioned by Teesside University; subset of data needed to validate results in scientific publications will be made openly available – only for certain types of use and certain type of users. Structured metadata will be published and made freely accessible which will sufficiently allow others to understand what research data exists, why, when and how it was generated, and how to access it.

Except radiological information (as patients need to provide the consent)

● How will the data be made accessible (e.g. by deposition in a repository)?

By deposition in a repository

● What methods or software tools are needed to access the data?

Word processor and spreadsheet

● Is documentation about the software needed to access the data included?

No

● Is it possible to include the relevant software (e.g. in open source code)?

Not needed

● Where will the data and associated metadata, documentation and code be deposited? Preference should be given to certified repositories which support open access where possible.

Data will be located inside the hospital facilities with restrictive access for privacy police. Metadata and digital archives could be located in OSF.

● Have you explored appropriate arrangements with the identified repository?

No

● If there are restrictions on use, how will access be provided?

As mentioned by Teesside University; restricted for research and education purpose only, not commercial. Data in common format (text, excel, etc.) for easy access.

● Is there a need for a data access committee?

Yes

● Are there well described conditions for access (i.e. a machine readable license)?

No

● How will the identity of the person accessing the data be ascertained?

They must agree to terms and conditions

❖ Making data interoperable

● Are the data produced in the project interoperable, that is allowing data exchange and re-use between researchers, institutions, organisations, countries, etc. (i.e. adhering to standards for formats, as much as possible compliant with available (open) software applications, and in particular facilitating re-combinations with different datasets from different origins)?

Yes

● What data and metadata vocabularies, standards or methodologies will you follow to make your data interoperable?

Pending to be defined

● Will you be using standard vocabularies for all data types present in your data set, to allow inter-disciplinary interoperability?

Yes

● In case it is unavoidable that you use uncommon or generate project specific ontologies or vocabularies, will you provide mappings to more commonly used ontologies?

Pending to be defined

❖ Increase data re-use (through clarifying licences)

● How will the data be licensed to permit the widest re-use possible?

Free of use and re-use under the defined terms and conditions

● When will the data be made available for re-use? If an embargo is sought to give time to publish or seek patents, specify why and how long this will apply, bearing in mind that research data should be made available as soon as possible.

Yes

● Are the data produced and/or used in the project useable by third parties, in particular after the end of the project? If the re-use of some data is restricted, explain why.

No

● How long is it intended that the data remains re-usable?

According to the hospital policy: 5 years after project completion

● Are data quality assurance processes described?

No

Further to the FAIR principles, DMPs should also address:

3. Allocation of resources

● What are the costs for making data FAIR in your project?

Not clear at the moment

● How will these be covered? Note that costs related to open access to research data are eligible as part of the Horizon 2020 grant (if compliant with the Grant Agreement conditions).

The cost will be covered by the project budget. After project completion, the cost will be needed to be discussed.

● Who will be responsible for data management in your project?

Cristina Suárez Mejías

● Are the resources for long term preservation discussed (costs and potential value, who decides and how what data will be kept and for how long)?

No

4. Data security

● What provisions are in place for data security (including data recovery as well as secure storage and transfer of sensitive data)?

As mentioned by Teesside University; Personal Data must always be kept appropriately secure against damage or unauthorised access, amendment or deletion, with precautions taken appropriate to its confidentiality and sensitivity.

● Is the data safely stored in certified repositories for long term preservation and curation?

In our case, all consortium use Box system and Onedrive. Other alternative is OSF (which is being used in other projects) but this is a decision of the coordinator.

5. Ethical aspects

● Are there any ethical or legal issues that can have an impact on data sharing?

These can also be discussed in the context of the ethics review. If relevant, include references to ethics deliverables and ethics chapter in the Description of the Action (DoA).

As mentioned by Teesside University; there are legal, ethical and commercial constraints on release of research data. To ensure that the research process (including the collaborative research process) is not damaged by inappropriate release of data, research organisation policies and practices should ensure that these constraints are considered at all stages in the research process.

● Is informed consent for data sharing and long term preservation included in questionnaires dealing with personal data?

Yes

6. Other issues

● Do you make use of other national/funder/sectorial/departmental procedures for data management? If yes, which ones?

No

Appendix E: The Data Repository Questionnaire

Three questions for each partner:

A. Repository: Each partner shall summarize which repositories they (and your community) commonly use? Is the repository open access or limited by institutional use, etc.?

B. Which license option? We may need to choose a default licensing option.

C. Cost coverage: Please tell us how you will cover any costs for providing open research data after the project ends.

Answers from partners:

KTH:

A. Repository: Code at Github, open access. Paper at arXiv, open access

B. License option: CC-BY NC

C. Cost coverage: Free, no cost.

STH:

A. Repository: STH indicates that they will record the clinical trial details using nenc.reda.org.uk (regional database with limited access to R&D offices, no patient data) and with the organization's Information Governance department (study details only, no patient data). On a national level, they will record info using National Institute for Health Research (e.g. Open Data Platform at odp.nihr.ac.uk which has closed access to NHS R&D's, no patient data) and the NHS Health Research Authority website (public access but once again with limited study details, no patient data). They would seek an 'open access' publication on completion of the project (which would include de-identified research data set) but otherwise not aware of any patient data repositories they would routinely use.

B. License option: Not aware of any organizational issues or specific requirements.

C. Cost coverage: Use direct grant research income normally to cover publication costs.

Nuromedia:

A. Repository: Nuromedia indicates to use a repository limited for company use.

B. License option: Nuromedia suggests the permissive free software license Apache 2.0

C. Cost coverage: As a software developer they do not own or generate any data. It is only stored on their services for research purposes. Open research data is defined by the data owner (e.g. partner who sends us the data for visualization, storing)

Össur:

A. Repository: Data sharing is not common in the company, in some cases info about studies is provided at clinicaltrials.gov but no actual data sharing. We do not foresee to create data in Socketsense that will be shared.

B. License option: they will support the DMC suggestion.

C. Cost coverage: No information about cost.

TWI:

A. Repository: Right now in TWI-Hellas (and for SocketSense work) they use the bitbucket repository. In the future they plan to do that using open-source (Apache 2.0 or 3-clause BSD license) and they will host it in Github. This will happen after they publish papers whose work is included in the repository.

B. License option: CC BY-NC is OK for the time being. If plan to go commercially later then it would be better to use CC BY or even CC BY-ND. In general if go for commercialization then the license cannot have the NC.

C. Cost coverage: To be defined, and they expect to host the data in a public repository dedicated for research data, which is free of charge.

LussTech:

A. Repository: They do not use any repositories and do not foresee creating any data in the SocketSense project that will be shared.

B. License option: Leave to the DMC.

C. Cost coverage: No information about cost.

RISE IVF:

A. Repository: RISE IVF AB uses only internal data repository and do not plan to share any of the development data from the sensor development outside of the project as this will prevent IP and exploitation of new sensor designs.

B. License option: No opinion, leave it up to others to decide.

C. Cost coverage: Not applicable as we do not have any open research data to share.

SAS:

A. Repository: In VRUH (Virgen del Rocío University Hospital) they use:
- Healthcare data. Electronic Health Record (EHR) called Diraya, with an Oracle database. Limited to institutional use.
- Research data. A research platform called ITC-Bio, with a PostgreSQL database. Limited to institutional use.
- Research data regarding specific research projects. If it's necessary, in the context of research project, we could install too research software in our technical infrastructure. Limited to institutional use, if the data must be shared with the consortium, the data could be downloaded and shared previous anonymization.

B. License option: License for the data, or license for the software?

C. Cost coverage: To evaluate if they could cover the cost or not, they need to know details regarding the research software must be installed in the context of SocketSense.

TU:

A. Repository: We are implementing a repository for research datasets, which will sit alongside TeesRep as the output repository on the Research Portal. This will require TU researchers to deposit their datasets with Mendeley Data, and they will then show on their Portal profile page. The datasets will be open access unless revented by commercial considerations, for example, in which case an embargo would be agreed with the relevant partners.

B. License option: Agree with decision of the consortium. This would allow others to adapt and build upon the data for non-commercial purposes, as long as they attributed the original dataset to you and the wider project team. If someone uses the data, they can choose to licence their resulting dataset on different terms.

C. Cost coverage: The costs will be covered by the University in terms of the support provided by the Library and RIS, and our subscription to Mendeley Data as our repository.

Appendix F: The Data Managing Tables

G.1 Teesside University

TU_DS01_Biomedical analysis data	
Data description	
Basic science study involving procedures with human participants. Including experimental measurements and tubular data.	
Partners activities and responsibilities	
Partner owner of the data; copyright holder (if applicable)	TU
Partner in charge of the data collection	TU
Partner in charge of the data analysis	WP4 partners.
Related WP(s) and task(s)	WP4
Standards	
Info about metadata (production and storage dates, places) and documentation.	Experimental measurements and tabular data.
Standards, format	Types and formats of data generated/collected Stump and socket geometry (.stl) Socket interface pressures (.txt, .csv) Muscle and fat tissue thickness (.DICOM) Muscle stiffness (.xls) Perceived socket comfort (.xls) Gait kinematics and kinetics (.c3d) Pseudonymised patient evaluation (.xls)
Estimated data size	50 GB
Data exploitation and sharing	
Purpose use of the data analysis	To be able to assist to achieve the SocketSence project objectives; a sub-study called An investigation into residual limb-socket interface pressures and their relationship with received levels of socket comfort in trans-femoral amputees" were conducted where the main research objective is to measure the pressure on residual limb-socket

	interface in different regions of the trans-femoral residuum and relate it with comfort.
Data access policy/ dissemination level	Only full analysed and published data will be made openly accessible (which will be made as a part of the publication's supplementary data). Datasets will be made available using the University's publicly accessible research data repository, https://researchdata.tees.ac.uk/
Embargo periods (if any)	An embargo will be set within the University's research data repository after which time a dataset will be made publicly available. There is also a possibility to permanently restrict access to a dataset and to require interested parties to contact the project lead to request access. The record on the University's data repository specifies the licence under which the datasets can be accessed and used. The University's default option is CC BY 4.0
Archiving and preservation (including storage and backup)	
Data storage. Where? For how long?	Datasets will be made available using the University's publicly accessible research data repository, https://researchdata.tees.ac.uk/. This is a secure cloud-based repository, and datasets are encrypted in flight and stored in a data centre with ISO 27001 accreditation. All datasets are assigned a Digital Object Identifier (DOI) as a persistent identifier and go through a moderation process within the University prior to publication. Published datasets are archived with Data Archiving and Network Services (DANS). A link to the datasets will be automatically created within each University contributor's staff profile on the institutional Research Portal and can be linked to related outputs and project records to enhance visibility. There are no additional costs associated with storage in the University repository

G.2 KTH Royal Institute of Technology

KTH_DS01_ Sensor Redundancy Reduction
Data description

The program involved in the 2022 MDPI Sensors paper “Redundancy Reduction for Sensor Deployment in Prosthetic Socket: A Case Study”. https://github.com/CRDloghorizon/SocketSense-KTH-1	
Partners activities and responsibilities	
Partner owner of the data; copyright holder (if applicable)	KTH
Partner in charge of the data collection	Össur
Partner in charge of the data analysis	KTH
Related WP(s) and task(s)	WP5
Standards	
Info about metadata (production and storage dates, places) and documentation.	Open access publication standard.
Standards, format	This data will be stored in the .py file. The data may be packaged as .zip or similar file.
Estimated data size	~30kb
Data exploitation and sharing	
Purpose use of the data analysis	Refer to paper **https://doi.org/10.3390/s22093103**
Data access policy/ dissemination level	Open access to public.
Embargo periods (if any)	No.
Archiving and preservation (including storage and backup)	
Data storage. Where? For how long?	Zenodo and Github. Permanent.

KTH_DS02_ Sensor Clustering	
Data description	
The program involved in the 2021 24th Euromicro Conference on Digital System Design paper “Evaluation of Time Series Clustering on Embedded Sensor Platform”. https://github.com/CRDloghorizon/SocketSense-KTH-1	
Partners activities and responsibilities	
Partner owner of the data; copyright holder (if applicable)	KTH
Partner in charge of the data collection	Open dataset from UCR

Partner in charge of the data analysis	KTH
Related WP(s) and task(s)	WP3
Standards	
Info about metadata (production and storage dates, places) and documentation.	Open access publication standard.
Standards, format	This data will be stored in the .py and .c file. The data may be packaged as .zip or similar file.
Estimated data size	~100kb
Data exploitation and sharing	
Purpose use of the data analysis	Refer to paper https://doi.org/10.1109/dsd53832.2021.00038
Data access policy/ dissemination level	The code is open access.
Embargo periods (if any)	No.
Archiving and preservation (including storage and backup)	
Data storage. Where? For how long?	Zenodo and Github. Permanent.

KTH_DS03_Stewart_Platform_Mock_Trials	
Data description	
Mock Trials done with Stewart platform	
Partners activities and responsibilities	
Partner owner of the data; copyright holder (if applicable)	KTH
Partner in charge of the data collection	KTH
Partner in charge of the data analysis	KTH
Related WP(s) and task(s)	WP5
Standards	
Info about metadata (production and storage dates, places) and documentation.	Open access publication standard.
Standards, format	This data regarding the curated time stamp information (excluding developmental data) will be stored in the .csv file. The data may be packaged as .zip or similar file.

Estimated data size	-
Data exploitation and sharing	
Purpose use of the data analysis	To establish a baseline for trial duration. To prepare and train researchers for trials.
Data access policy/ dissemination level	The method has been published in BIODEVICES 2022 Conference titled “A Mechatronics-twin Framework based on Stewart Platform for Effective Exploration of Operational Behaviors of Prosthetic Sockets with Amputees”. The above mentioned data is available upon request.
Embargo periods (if any)	No.
Archiving and preservation (including storage and backup)	
Data storage. Where? For how long?	Hard Drive and OneDrive. Permanent.

KTH_DS04_Biomechanical_Model	
Data description	
Biomechanical Model of Transfemoral amputee gait behaviour	
Partners activities and responsibilities	
Partner owner of the data; copyright holder (if applicable)	KTH
Partner in charge of the data collection	KTH
Partner in charge of the data analysis	KTH
Related WP(s) and task(s)	WP4
Standards	
Info about metadata (production and storage dates, places) and documentation.	Open access publication standard.
Standards, format	This data will be stored in the standard OpenSim formats. .mot, .grf, .csv, etc. The data may be packaged as .zip or similar file.
Estimated data size	~800MB
Data exploitation and sharing	
Purpose use of the data analysis	Evaluate performance of Biomechanical model in estimating socket-stump interface dynamics
Data access policy/ dissemination level	Private. Yet to be published.

Embargo periods (if any)	No.
Archiving and preservation (including storage and backup)	
Data storage. Where? For how long?	OneDrive and Hard Disk. Permanent.

KTH_DS05_Finite_Element_Analysis	
Data description	
Finite Element Analysis model and results of transfemoral amputee socket-stump interface.	
Partners activities and responsibilities	
Partner owner of the data; copyright holder (if applicable)	KTH
Partner in charge of the data collection	KTH
Partner in charge of the data analysis	KTH
Related WP(s) and task(s)	WP3
Standards	
Info about metadata (production and storage dates, places) and documentation.	Open access publication standard.
Standards, format	This data will be stored in the .txt and .csv file. The data may be packaged as .zip or similar file.
Estimated data size	~600MB
Data exploitation and sharing	
Purpose use of the data analysis	Refer to paper DOI:10.3390/s21113743
Data access policy/ dissemination level	The paper is published on MDPI Sensors.
Embargo periods (if any)	No.
Archiving and preservation (including storage and backup)	
Data storage. Where? For how long?	Hard disk and OneDrive. Permanent.

G.3 Össur

Össur_DS01_PilotStudy
Data description

For all pilot studies held at Össur premises: Pressure data (QTSS + Novel); Shear data; Gait monitor data; Video recordings; Photos; Subject feedback forms	
Partners activities and responsibilities	
Partner owner of the data; copyright holder (if applicable)	Össur
Partner in charge of the data collection	Össur
Partner in charge of the data analysis	Össur
Related WP(s) and task(s)	WP5
Standards	
Info about metadata (production and storage dates, places) and documentation.	See data description.
Standards, format	Numerical/text (e.g., .txt, .asc); videos (e.g., .mov, .mp4); photos (e.g., .jpg, .png)
Estimated data size	~10GB
Data exploitation and sharing	
Purpose use of the data analysis	Data will be useful for the consortium, and scientific community
Data access policy/ dissemination level	All data is stored within Össur's secure data management system prior to anonymisation and dissemination. Pressure, shear, and gait monitor data is open access. All other data (videos, photos, etc.) will remain confidential to the consortium partners only.
Embargo periods (if any)	Confidential data will remain closed for an unlimited period.
Archiving and preservation (including storage and backup)	
Data storage. Where? For how long?	All data is stored within Össur's secure data management system prior to anonymisation and dissemination. Pressure, shear, and gait monitor data is open access.

	All other data (videos, photos, etc.) will remain confidential to the consortium partners only.

Össur_DS02_2DResidualLimbMaps	
Data description	
2D representation of 3D scans of patients' residual limbs	
Partners activities and responsibilities	
Partner owner of the data; copyright holder (if applicable)	Össur/TU
Partner in charge of the data collection	TU
Partner in charge of the data analysis	Össur/TU
Related WP(s) and task(s)	WP4
Standards	
Info about metadata (production and storage dates, places) and documentation.	See data description.
Standards, format	Images (e.g., .svg, .png, .pdf), 3D CAD (e.g, .stl, .sldprt)
Estimated data size	500MB
Data exploitation and sharing	
Purpose use of the data analysis	Data will be useful for the consortium, and scientific community
Data access policy/ dissemination level	Open access
Embargo periods (if any)	N/A
Archiving and preservation (including storage and backup)	
Data storage. Where? For how long?	The data will be stored on the specified open-access database for the SocketSense project.

G.4 RISE and LussTech

RISE_DS01_Sensor production and test data

Data description	
MDPI Publication by RISE and LussTech which has been paid for to be “Open Access” already - https://www.mdpi.com/1424-8220/21/11/3764 Whitepaper on Sensors by LussTech and RISE – currently on the H2020 website but we understand this is not currently classed as permanently “Open Access” so we will also deposit it in an Open Access Depository - https://www.socketsense.eu/wp-content/uploads/sites/50/2021/04/White-Paper-sensors-Nov-2020-v2.pdf	
Partners activities and responsibilities	
Partner owner of the data; copyright holder (if applicable)	RISE and LussTech
Partner in charge of the data collection	RISE and LussTech
Partner in charge of the data analysis	RISE and LussTech
Related WP(s) and task(s)	WP2
Standards	
Info about metadata (production and storage dates, places) and documentation.	See above
Standards, format	-
Estimated data size	-
Data exploitation and sharing	
Purpose use of the data analysis	Sensor functionality test..
Data access policy/ dissemination level	Open access
Embargo periods (if any)	-
Archiving and preservation (including storage and backup)	
Data storage. Where? For how long?	-

G.5 SAS

SAS_DS01_Sensor measurements
Data description
Pressure and shear measurement data are generated by testing patients who perform exercises while wearing integrated sensor strips (which are connected to the rest of the

SocketSense system) inside their own socket.	
Partners activities and responsibilities	
Partner owner of the data; copyright holder (if applicable)	SAS
Partner in charge of the data collection	SAS, Össur, KTH, TU, TWI
Partner in charge of the data analysis	TU, Össur, KTH
Related WP(s) and task(s)	WP6, WP5
Standards	
Info about metadata (production and storage dates, places) and documentation.	-
Standards, format	TXT, CSV
Estimated data size	-
Data exploitation and sharing	
Purpose use of the data analysis	Analysis of the data will provide the results of the accuracy and reliability of the pressure/shear measurements of the technology system. Data analysis will provide insight into the agreement of measurements obtained by the SocketSense system and those obtained by a commercially available socket pressure measurement system. Analysis of the data will provide insight into the functionality of the SocketSense system during static and dynamic conditions. Data analysis will provide insight into the agreement between patient-identified high pressure zone locations and SocketSense system measurements, and whether these results are affected by patients with different characteristics (tonicity, residual limb geometry, etc.). Analysis of the data will provide insight into the effectiveness of the SocketSense algorithm in advising socket alteration based on controlled modification.

	The results of the current study will form the basis for a power analysis to determine the required sample size for a future clinical trial of the technology system.
Data access policy/ dissemination level	The results and data of the project will be open to the public/scientific community, but only for scientific and educational purposes, and in compliance with the GDPR (General Data Protection Regulation)
Embargo periods (if any)	-
Archiving and preservation (including storage and backup)	
Data storage. Where? For how long?	Data stored in the secure data repository located at the Virgen del Rocío University Hospital for 10 years until it can be destroyed. https://www.sspa.juntadeandalucia.es/servicioandaluzdesalud/hhuuvr/innovacion/GIT/repo Need a password to access it (White open archiving).

SAS_DS02_Scales outcomes	
Data description	
The assessment of the sensations of pressure, pain and temperature rise experienced by the participants during the clinical trial are collected using the Borg Scale (pressure), the Visual Analogue Scale (pain) and the Visual Temperature Rise Scale (temperature rise) after the performance of each of the exercises in the clinical trial.	
Partners activities and responsibilities	
Partner owner of the data; copyright holder (if applicable)	SAS
Partner in charge of the data collection	SAS
Partner in charge of the data analysis	TU, Ossur, KTH
Related WP(s) and task(s)	WP6, WP5
Standards	
Info about metadata (production and storage dates, places) and documentation.	See data description.
Standards, format	XLS
Estimated data size	-

Data exploitation and sharing	
Purpose use of the data analysis	Data analysis will provide insight into the agreement between patient-identified high pressure zone locations and SocketSense system measurements, and whether these results are affected by patients with different characteristics (tonicity, residual limb geometry, etc.)
Data access policy/ dissemination level	The results and data of the project will be open to the public/scientific community, but only for scientific and educational purposes, and in compliance with the GDPR (General Data Protection Regulation)
Embargo periods (if any)	-
Archiving and preservation (including storage and backup)	
Data storage. Where? For how long?	Data stored in the secure data repository located at the Virgen del Rocío University Hospital for 10 years until it can be destroyed. https://www.sspa.juntadeandalucia.es/servicioandaluzdesalud/hhuuvr/innovacion/GIT/repo Need a password to access it (White open archiving).

SAS_DS03_Ultrasound and elastography images	
Data description	
Elastographic and ultrasound images are collected from the residual limb of transfemoral amputees, and from the thigh of non-amputees or from the contralateral non-amputee limb of amputees.	
Partners activities and responsibilities	
Partner owner of the data; copyright holder (if applicable)	SAS
Partner in charge of the data collection	SAS
Partner in charge of the data analysis	TU
Related WP(s) and task(s)	WP4
Standards	
Info about metadata (production and storage dates, places) and documentation.	-
Standards, format	DICOM

Estimated data size	-
Data exploitation and sharing	
Purpose use of the data analysis	Shear wave elastography has been used to measure Young's modulus of different muscles of 4 healthy subjects and 6 trans-femoral amputees with different age groups. The development of a finite element (FE) model has also been carried out for establishing the correlation between the skin pressure and mechanical properties of the residual limb.
Data access policy/ dissemination level	The results and data of the project will be open to the public/scientific community, but only for scientific and educational purposes, and in compliance with the GDPR (General Data Protection Regulation)
Embargo periods (if any)	-
Archiving and preservation (including storage and backup)	
Data storage. Where? For how long?	Data stored in the secure data repository located at the Virgen del Rocío University Hospital for 10 years until it can be destroyed. https://www.sspa.juntadeandalucia.es/servicioandaluzdesalud/hhuuvr/innovacion/GIT/repo Need a password to access it (White open archiving).

G.6 TWI

TWI_DS01_Unwrap	
Data description	
Images with UV unwrapped sockets.	
Partners activities and responsibilities	
Partner owner of the data; copyright holder (if applicable)	TWI
Partner in charge of the data collection	TWI
Partner in charge of the data analysis	TWI
Related WP(s) and task(s)	WP4 and WP5
Standards	
Info about metadata (production and storage dates, places) and documentation.	-

Standards, format	PNG
Estimated data size	10 MB
Data exploitation and sharing	
Purpose use of the data analysis	Refer to DOI: https://doi.org/10.3390/s21113743
Data access policy/ dissemination level	Open access
Embargo periods (if any)	-
Archiving and preservation (including storage and backup)	
Data storage. Where? For how long?	Hard disk and Onedrive. Permanent.

TWI_DS02_RectAlign	
Data description	
Sockets as a result of rectification and alignment.	
Partners activities and responsibilities	
Partner owner of the data; copyright holder (if applicable)	TWI
Partner in charge of the data collection	TWI
Partner in charge of the data analysis	TWI
Related WP(s) and task(s)	WP4 and WP5
Standards	
Info about metadata (production and storage dates, places) and documentation.	See above
Standards, format	STL
Estimated data size	50 MB
Data exploitation and sharing	
Purpose use of the data analysis	Refer to DOI: https://doi.org/10.3390/s21113743
Data access policy/ dissemination level	Open access
Embargo periods (if any)	-
Archiving and preservation (including storage and backup)	
Data storage. Where? For how long?	Hard disk and Onedrive. Permanent.
TWI_DS03_TemplateMatching	

Data description	
Images after running pressure template matching algorithms.	
Partners activities and responsibilities	
Partner owner of the data; copyright holder (if applicable)	TWI
Partner in charge of the data collection	TWI
Partner in charge of the data analysis	TWI
Related WP(s) and task(s)	WP4 and WP5
Standards	
Info about metadata (production and storage dates, places) and documentation.	See above
Standards, format	PNG, JPG
Estimated data size	10 MB
Data exploitation and sharing	
Purpose use of the data analysis	Refer to DOI: https://doi.org/10.3390/s21113743
Data access policy/ dissemination level	Open access
Embargo periods (if any)	-
Archiving and preservation (including storage and backup)	
Data storage. Where? For how long?	Hard disk and Onedrive. Permanent.

G.7 STH

STH_DS01_Patient data	
Data description	
Patient data (medical records and newly collected data for the clinical trials via the trial's case report forms)	
Partners activities and responsibilities	
Partner owner of the data; copyright holder (if applicable)	STH
Partner in charge of the data collection	STH
Partner in charge of the data analysis	TWI

Related WP(s) and task(s)	WP4, WP5, WP6 and WP7
Standards	
Info about metadata (production and storage dates, places) and documentation.	Adhere wherever possible to open access publication standard terminology
Standards, format	-
Estimated data size	Multiple data items (e.g., demographics, medical history and questionnaire responses) for each of the 9 UK participants
Data exploitation and sharing	
Purpose use of the data analysis	Answer the research objectives (as per the outcome measures in the clinical investigation protocol)
Data access policy/ dissemination level	Consent obtained for data to be shared with partners in consortium and used in publication – but on basis that any unnecessary (in terms of data analysis and dissemination) personal identifiable information is not included in external data transfers outside of STH
Embargo periods (if any)	Do not publicly disseminate until data analysis is fully complete with any queries resolved where possible – if there is any exception to this then obtain consortium approval
Archiving and preservation (including storage and backup)	
Data storage. Where? For how long?	7 years in secure archiving facility ('RESTORE') used by STH through sub-contract arrangement

Appendix G: The Data Management Committee

The Data Management Committee includes 7 partners:

Data Management Committee (DMC) for SocketSense	
Organization	Member
TWI	Mike Karamousadakis
LussTech	Josephine Charnley
STH	Sharon Brown
KTH	Zhonghai Lu, Wenyao Zhu, Yizhi Chen
Nuromedia	Andrew Pomazanskyi
Össur	Freygardur Thorsteinsson
TU	Begum Zeybek, Zulf Ali