HybridHeart

Deliverable 6.3

Initial Data Management Plan (DMP)

Project acronym	HybridHeart
Project number	767195
Project title	HybridHeart
Beneficiary responsible for the deliverable	AMC
Deliverable author(s)	Dara Pabittei - AMC
Deliverable version number	1.0
Actual delivery date	30-04-2018
Dissemination level	Public

Change log Initial DMP

Version	Date	Author	Reason for change
0.1	10-04-2018	Dara Pabittei - AMC	Initial draft
0.2	25-04-2018	Dara Pabittei - AMC	2nd draft according to comments and addition from dr. J. Kluin, dr. B. Overvelde, A. Wutte, and dr. R. de Miranda Azevedo
0.3	28-04-2018	Dara Pabittei - AMC	3rd draft adjusted based on the comments of dr. J. Kluin
0.4	30-04-2018	Dara Pabittei - AMC	4th draft adjusted based on comments and addition of Prof. Bouten, dr. Overvelde and mr, Wutte
1.0	30-04-2018	Dara Pabittei - AMC	Final draft adjusted based on the comments and addition of dr. R. de Miranda Azevedo

Release Approval DMP

Version	Date	Name & organization	Role
Version 1.0	30-04-2018	Jolanda Kluin – AMC	Project Coordinator

Executive summary

This deliverable provides the initial data management plan (DMP) of the HybridHeart consortium. This DMP outlines how the research data will be collected during the project, as well as how is it going to be published and available for reuse following the FAIR guiding principles for data management. This DMP is made according to the template provided by the European Comission ("Horizon 2020"). This DMP is intended to be dynamically written, and therefore it will be adjusted during the course of the project when necessary

Project summary

The HybridHeart consortium envisions to develop and bring to the clinic a soft biocompatible artificial organs. These will consist of a soft robotics shell with actuators ('artificial muscles') and sensors, enabling completely natural motion. The inner lining and structures will be made by in situ tissue engineering (TE), ensuring biocompatibility of blood-contacting surfaces.

As the first step, the consortium will develop the HybridHeart, which can completely replace a patient's heart in a procedure similar to a heart transplant, to provide a cure for heart failure, which affects ~23 million people worldwide. Currently, patients with end-stage heart failure either receive a heart transplant, if available, or long-term mechanical circulatory support, which causes severe complications. To achieve the ambitious goal of providing a permanent cure for these patients, the participants will, in parallel, develop the components of the HybridHeart: 1) a soft elastomeric robotics shell containing actuators and sensors, 2) scaffolds for in situ TE of inner lining, valves and vessels and 3) a wireless energy transfer system. These components together will form the full HybridHeart, which will be soft, adaptable, wireless and fully bio- and hemocompatible. Both functionality as well as biocompatibility of the HybridHeart will be shown in a Proof-of-Principle study in the chronic sheep model at the end of the project.

The HybridHeart project will be carried out by an interdisciplinary group of (academic) researchers and high-tech SMEs, with experience in cardiac surgery, TE, soft robotics and engineering. The technology underlying the Hybrid Heart is applicable to a range of soft robotics-based artificial organs, including the bowel, lung, or muscle structures (limbs). Replacing an entire organ with bioinspired robotic elements, TE biocompatible surfaces, artificial sensors, and an external power source allows for an off-the-shelf therapy for patients with organ failure.

The HybridHeart consortium will generate and collect data for the development and validation of the artificial heart in accordance with the general data protection regulation (Regulation (EU) 2016/679).The Hybrid Heart consortium will push the development of these newly emerging technologies forward and uniquely combine soft robotics, **in situ** TE leading and transcutaneous energy transfer to generate the first biocompatible, soft actuated heart. This project will deliver Proof-of-Principle for full **in vivo** cardiac functionality of the artificial Hybrid Heart in large animals.

Data management plan

1. Data summary

1.1. Objectives of data collection

During this 5-year project, the consortium will combine a unique set of complementary technologies to design the HybridHeart and provide Proof-of-Principle for full cardiac functionality *in vivo*. After implantation, the Hybrid Heart will consist of a soft elastomeric matrix with actuators and sensors, a wireless transcutaneous energy transfer (TET) system, with *in situ* tissue engineered heart valves, vessels and inner lining

Table 1 provides the specific objectives of each of the work packages (WP), summary, and format of the data that will be generated.

Table 1. Summary of HybridHeart WPs

Objectives	WP	Partners	Data summary	Format of data
Optimize in situ tissue engineering	1	TU/e, AMOLF, SSSA	Experimental / Modeling / simulation	Protocols (.docx), chemical structure descriptions, raw data (excel, .tiff) and final images (.tiff) from experiments will be stored. To minimize the datasets from computational modeling only (matlab or abaqus) computer scripts will be stored.
Develop soft robotic heart actuators, sensors and matrix	2	AMOLF, SSSA	Computational / Experimental.	To minimize the size of the data, computational data will be stored as computer scripts (.m and .py files) Experimental data will be collected from a set of commercial and in house setups (.csv), including pictures (.tiff, .JPEG) and movies (.mov)
Develop transcutaneous energy transfer	3	DMT	Programming (software data) Hardware	The generated data will be in (.m), (.c) and altium formats. The expected volume of the data will be between 500 mB – 1 GB

Integrate tissue-engineered & soft tissue robotics material	4	AMC, TU/e, AMOLF, Xeltis, DMT	Functional parameters (Cardiac output (CO), pressure gradient (ΔP), blood pressures (BP), etc) High speed images of the valve movement MRI images Immunohistochemistry and histology specimens	To maximize data interoperability, functional parameters will collect tabular data stored as comma-separated values (.csv), excel (.xls) and SPSS (.sav) format. High speed camera images: (.mov) and (.tiff)
Provide proof-of-concept in relevant in vivo model	5	AMC, TU/e, Amolf, SSSA, DMT	Functional parameters (CO, ΔP, BP, etc) Blood sample analysis Echocardiography images Immunohistochemistry and histology specimens	Functional parameters & blood sample analysis parameters: tabular data in (.csv), (.xls), or (.sav) formats. Echocardiography images (.tiff) Histology and immunohistochemistry (.tiff)

1.2. Re-using existing data

The partners in the HybridHeart consortium have previously gained experience in their respected fields of research and therefore will together lead to successful development of a soft actuated biocompatible heart. We have explored the potential of reusable data but at this stage, we see no potential of re-using the existing data, however this will be further discussed along the course of the project.

1.3. The expected size of the data

The expected size of the data generated in WP 2 is 200 GB, whereas WP 3 expects to generate approximately 400 MB data. The other WPs and partners cannot yet predict the size of the data. This information will be updated in the subsequent version of DMP.

1.4. The data utility

The HybridHeart Proof-of-Principle established in this project will set a baseline for the feasibility of novel artificial motile organ development based on soft robotics technology combined with TE and wireless energy transfer to follow. As such, this project will change the future of organ replacement, using the latest advancement and new applications of soft robotics and TE technologies, which will cause a foundational shift in transplantation research and medicine with unlimited availability of safe, biocompatible and off-the-shelf solutions for all patients.

The consortium envision that the data will be useful for the following stakeholders:

Target audience	Essential stakeholders
Medical community	Cardiologists, cardiac surgeons, researchers in the field of TE, professional organizations such as the European Society of Cardiology, TERMIS.
Soft robotics community	Researchers and scientific organizations, such as IEEE Robotics & Automation Society, and Technical Committees on Soft Robotics.
Medical device companies	Companies interested in novel types of artificial organs, such as Medtronic, Heartware, Syncardia, Carmat, Thoratex, St Jude Medical.
Patient advocacy groups	Patient organizations such as the European Heart Network and national organizations.
Regulatory bodies	Notified bodies.
Healthcare payers	Health insurance companies at national level.
General public	Governments, standardization institutes (OECD, ISO), press.

2. Findable, Accessible, Interoperable, and Reusable (FAIR) Data

2.1. Making data findable, including provisions for metadata

Discoverability of the Data (metadata provision)

Digital object identifier will be generated for all publications, related documents (e.g. study protocol, data transfer agreements, data access policies) as well as the datasets. During the course of the project all data will be recorded in lab journals and stored digitally and locally in the secure internal drive of the consortium. We will look at www.fairsharing.org and https://bioportal.bioontology.org/ for existing databases, standards, metadata, and ontologies that can be used for type of data that will be generated in the project. If no metadata provision is available each partner will create a codebook or file explaining the variable names, calculations used to analyze the data, exact scripts for calculations used with analysis of the data, parameter settings, detailed methodology, etc. this code book will be linked to the generated data.

Naming and keywords of the data

The data will be named as follows:
WP number/Institution name/Task or deliverable number/Subtasknumber/filename/year

Example:

Keywords will also be available to ensure data discoverability, following existing standards such as the Medical Subjects Headings (MeSH) terms.

2.2. Making data openly accessible

The data that will be generated and collected for development and validation of the artificial heart is in accordance with the General Data Protection Regulation (Regulation (EU) 2016/679). All partners will own the full intellectual property (IPR) relating to their own proprietary technologies. Access to the existing IPR between the partners and terms and condition regarding ownership of IP generated in the project will be agreed upon in a prearranged consortium agreement (CA). IP generated within the project shall be disclosed in confidence to the other partners in the consortium.

When a partner wishes to commercially exploit knowledge of which (part of) the IPR is in the hands of another consortium partner, the exploiting partner will pay royalties or another appropriate form of remuneration. After protection of findings, results will be disseminated via (high-impact) peer-reviewed articles following the 'green' or 'gold' standard according to the EC Open Access policy. To ensure accessibility of the publications we will also publish the author version on partners' institutions website and/or the HybridHeart website.

Each partner/member of the consortium will make their own decision on when to open their datasets, but the data will be at latest in the public domain when a related publication a peer-reviewed journal is available. Restriction made to the open access will be voluntarily. There are no specific software tools needed to access the data (standard file formats readable in open source software will be used).

2.3. Making data interoperable

Similar to what was previously stated in section 2.1. to enhance data interoperability, we will search for existing metadata, standards, and ontologies at www.fairsharing.org and https://bioportal.bioontology.org/. This information will be updated in the next version of DMP. Somewhere during the course of the project the consortium will discuss the potential of placing the open access publications and the data set (including the associated metadata) at data repositories such as www.zenodo.org and www.re3data.org. However this will not change the obligations to protect the result, the confidentiality obligations and the security obligations.

2.4. Increase data re-use (through clarifying licenses)

We will ensure the accessibility of the published articles by either publishing it open access journal or made the author version available on our website or partners' websites. We will look into using available repositories such as www.zenodo.org to increase the discoverability of the data. During the next general assembly meeting, we will discuss the term and the extent of reusing data generated in this project. It is possible that access to certain datasets will be restricted and can only be granted upon submission of research proposal and subsequent approval from the consortium. The data produced can be of interest to other researchers in the medical, soft robotics and tissue engineering communities as well as for medical devices companies.

Each consortium members will be responsible for the quality assurance of how his or her data will be reused. Prior to submitting deliverables or publications, we will perform internal reviewer process within the consortium to ensure the quality of the data/publications.

3. Allocation of resources

The individual beneficiaries and partner organizations will be responsible for the data management of the HybridHeart project. Data generated will be stored locally in the internal server of the partner that generated and owned the data. Long term preservation: collected data will be stored for up to 10 years at each of partner organization. Costs for data storage and preservation will be estimated at a later stage by using the “Data management costing tool” provided by the UK Data Service (http://www.data-archive.ac.uk/media/247429/costingtool.pdf).

4. Data security

All generated data will be digitally and locally stored in the internal server of each partner organizations. This local storage underlie the EU roles and national rules, which will be followed and to protect the data. According to the standard protocols, the data will be regularly back-up.

5. Ethical aspects

The HybridHeart project will comply with ethical principles and if applicable international, EU and national law (in particular, EU Directive 2004/23/EC). The consortium confirms that it will follow these ethical principles regardless where the research is performed.

The consortium ensures to:

- Keep track of the material imported/exported between EU members of states and associated countries.
- Obtain the necessary accreditation/designation/authorization/licensing for using animal in research.