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UBORA

Euro-African Open Biomedical Engineering e-Platform
for Innovation through Education

Project title	Euro-African Open Biomedical Engineering e-Platform for Innovation through Education
Project acronym	UBORA
Project number	731053

Document title	**DATA MANAGEMENT PLAN**
Document reference	D5.2
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Abstract	This document is to be used as guideline for helping develop an adequate strategy and a set of procedures for the correct management of data used within the project and shared via the UBORA e-infrastructure.
Version	V1
Report availability	Public
Date	V1: 26-07-2017

Project funded by H2020 Programme from the European Commission

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1 Executive summary

Document: **"Deliverable 5.2–Data management plan"** is aimed at providing partners with a guideline for helping develop an adequate strategy and a set of procedures for the correct management of data used within the project and shared via the UBORA e-infrastructure. This Deliverable is part of Work Package 5: "Dissemination and exploitation", as a clear and straightforward management of generated data is fundamental for the effective exploitation of the biomedical solutions generated within UBORA and for promoting our impact in the future of the biomedical industry, which according to UBORA's foundations should be open and accessible for all.

In this context, special concerns regarding the generation, use and sharing of data arise and a data management plan is needed. This will also help to facilitate communication and networking with relevant stakeholders, including: physicians, patients and their associations, policy makers, regulatory bodies, national health systems, whose involvement is essential for the long-term viability of our approach, if we are to change the paradigm of biomedical product development. Linked to the above-mentioned sustainability of the project, generating social and economic value are both relevant issues and this leads us to intellectual property rights, licensing options and other concerns regarding the usability of the generated data, once shared via the UBORA e-infrastructure (or e-platform). Additional ethical aspects, privacy issues and security procedures are also part of the global strategy and need to be considered for optimum data management.

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2   Building a data management plan for UBORA in the context of H2020

The EU funded **"UBORA: Euro-African Open Biomedical Engineering e-Platform for Innovation through Education"** project (as part of Horizon 2020 Research and Innovation Programme within the INFRASUPP: Support to policy and international cooperation call) aims at creating an **e-Infrastructure, UBORA**, for open source co-design of new solutions to face the current and future healthcare challenges of Europe and Africa, by exploiting networking, knowledge on rapid prototyping of new ideas and sharing of safety criteria and performance data. The e-infrastructure is implemented to foster advances in education and the development of innovative solutions in Biomedical Engineering (BME), both of which are flywheels for emerging and developed economies. It is conceived as a virtual platform for generating, exchanging, improving and implementing creative ideas in Biomedical Engineering underpinned by a solid safety assessment framework. Besides the provision of resources with designs, blueprints and support on safety assessment and harmonization, specific sections for needs identification, project management, repositories and fund raising are also foreseen.

The project is composed of six work packages (WPs) including research and innovation activities linked to: the development of the UBORA e-infrastructure (WP1); to the promotion and development of innovative biomedical design projects (WP2), which will help to validate and supply the aforementioned e-infrastructure with real cases of study; to the implementation of African and European summer schools (WP3 & WP4) and to the dissemination and exploitation of results (WP5), all of which is managed (WP6) in accordance with the information provided in the Consortium and Grant Agreements.

The main objective of **"WP 5 - Dissemination and Exploitation"** is: to disseminate and exploit the results generated in UBORA in the most efficient way, in order to guarantee the sustainability of the UBORA e-Infrastructure as an organ for innovative and advanced design, but also networking and capacity building, in the field of BME and promotion of harmonized regulations for biomedical devices. To this end, the activities listed below are relevant:

- extensive dissemination and communication through traditional media and newer social media channels;
- involvement of other active institutions in BME capacity building;
- facilitating communication, networking, identification and involvement of National Policy Makers and Regulatory Bodies, Professional Bodies, and Hospitals;
- management of the processes for the capture and the protection of open copyright and licensing.

Considering that promoting open-access to our project's results is a fundamental part of the overall strategy towards building the future of "collaborative & accessible" for all BME and that the complexity of the medical projects entails the use of several different data and formats, there is a need for establishing a correct data management plan (DMP), which is the main objective of present document. This is in line with current Horizon 2020 pilots on open research data, with the promotion by the EU Commission of open-access dissemination of research and with the general views of the United Nations Global Development Goals, in which global partnerships play a special role, as happens within UBORA.

This DMP, with the modifications that shall be incorporated upon current versions, will be important for tracking the data produced during UBORA and, perhaps even more importantly, for setting the quality standards and procedures for sharing, using and licensing data by using the UBORA e-infrastructure and for promoting its sustainability, well beyond the temporal framework of the project. The DMP is written following guidelines provided by the EU and other references cited towards the end of the document.

3   UBORA data management plan

A central objective of UBORA is to build an e-infrastructure (the UBORA e-infrastructure or e-platform) for supporting the collaborative design of biomedical devices and the open-access to the generated biomedical solutions. During the project, the e-infrastructure will be continuously loaded with innovative biomedical solutions, generated, during a first stage, among the project partners, and during the last stage of the project by invited external users, with the support of special features included in the platform for helping with project management and information sharing, so as to validate its usability and to detect and correct possible flaws, in a continuous improvement cycle.

The potential teaching-learning applications of the UBORA e-infrastructure have to be also considered, as a key issue towards the future of biomedical engineering. Indeed, one of the objectives is to make it more collaborative and accessible for all, to support the most passionate students in their path to becoming biomedical engineers and to make them aware of the benefits of international collaboration and understand the potential of engineering professionals acting globally for making a change. To this end, a couple of medical device design competitions, both ending with a design school, are planned within UBORA (Nairobi 2017 and Pisa 2018). The teaching-learning materials developed will be shared, in an open-access scheme, via the e-infrastructure, which will also support the development of students' projects, which in the end will also be uploaded to the e-infrastructure.

Along the project, progressively increasingly broader accessibility rights will be granted to external potential stakeholders (colleagues, students, physicians, policy makers, patients and their associations, …) for using the e-infrastructure, so as to support dissemination tasks. Opening the e-infrastructure will make the medical industry, the medical professional and the policy makers aware of the potentials and benefits of resorting to UBORA for addressing global health concerns in a collaborative and open-access way. At the end of the project, the e-infrastructure will be ready for supporting the construction of an open and collaborative future for BME and medical practice, hopefully with a worldwide impact beyond the initial EU-African collaboration, which is starting to generate very relevant synergies (see: http://ubora-biomedical.org).

All these circumstances require a global plan of action for managing the generated data and the related metadata, in a way which results comfortable for the IP creators (mainly those having proposals or ideas to share), before, during and after the generation of the innovative medical devices, and for the potential users (mainly those having needs to be addressed). The plan has to take into account the complexity of systematic product development and the special considerations of acting in the medical field, which lead to:

i) interactions among professionals with different backgrounds (and ways of communication);

ii) wider sets and types of data and formats used within the projects; and

iii) additional concerns in terms of patient privacy & safety and data security.

Working collaboratively and following open schemes adds uncertainties linked to protection of intellectual property, sharing of information, licensing of solutions and usability rights of the developed devices, which need to be addressed.

These aspects are covered in the following sections, which constitute the basic core of this first version of the UBORA DMP for adequately exploiting all the potentials of the UBORA e-infrastructure and of the so-enabled possibilities of collaboration.

4 Description of data and metadata

4.1 Data summary

This subsection describes the data and metadata used both within the UBORA project, mainly connected to communication among partners and with the EU, and within the UBORA e-infrastructure, as linked to the collaborative development of medical devices shared via the developed platform. The additional complexity and of the data and metadata linked to the UBORA e-infrastructure and its relevance to the future of BME warrants careful and detailed planning, as advanced in the Executive Summary.

Data shared during the UBORA project among partners: The data shared during the daily management of UBORA project include:

- Minutes and presentations from the meetings. Typically PDF files named: Date_WP-x_Description.pdf and PowerPoint files named: Date_WP-x_Description.ppt
- Reports, evaluation sheets and summarizing figures of the design competitions and design schools. Typically PDF files named: Date_WP-x_Design-Competition-y/Design-School-z_Description.pdf and Excel datasheets named: Date_WP-x_Design-Competition-y/Design-School-z_Description.xlsx
- Other documents (i.e. articles, communications, reports…). Typically PDF files named: Date_WP-x_Description.pdf and PowerPoint files named: Date_WP-x_Description.ppt

Data developed within and shared with the help of the UBORA e-infrastructure: The data developed in a collaboratively with the help of the UBORA e-infrastructure and shared following open-access schemes include:

- Data from UBORA's partners and participants in the design schools and competitions registered in the trial versions of the UBORA e-infrastructure. These include personal data registered in a formulary enabled within the e-infrastructure, as first step for accessing the information available and for designing medical devices taking advantage of the programmed collaborative features. Data include: Name, surname, (which in fact can be aliases for privacy or test purposes), contact email, short personal bio and photo.
- Documents and images helping to explain the different development steps of the projects under development. Typically PDF files named: Date_Code-of-device-or-medical-field_Description_ID.pdf or Date_Code-of-device-or-medical-field_Description_ID.jpg/png/tiff. For the code of device or medical field see Section 3.2.1. Regarding the ID, it may well happen that UBORA provides several solutions or alternatives for the same problem. Such projects, focused on the same type of device will be identified with a number based on chronological implementation.
- Blueprints or reproductions of technical sketches, technical drawings, engineering designs and computer-aided design / engineering / manufacturing files needed for adequate exchange of geometrical information and related flawless prototyping or manufacturing tasks. Typically a set of varied CAD-CAE-CAM files named: Date_Code-of-device-or-medical-field_Description_ID.xxx. These may also include initial design inputs, such as DICOM files from medical images, which will be handled confidentially and eliminating potentially private information (see Section 4).

Common file types and formats which will be used and exchanged via the UBORA e-infrastructure are included in Annex A.2, which will be updated along the project and will serve to provide users of the platform with a list of commonly accepted files for improved interoperability. The following subsections deal in more detail with specific aspects of the data and metadata of the UBORA e-infrastructure.

Regarding the question "What do I do with my data?", which should be considered in any data management strategy, in our case both taking account the possible role of partners as project members and as users of the UBORA e-infrastructure, a schematic diagram for their management, following "FAIR" principles (see Section 3.2) is included below:
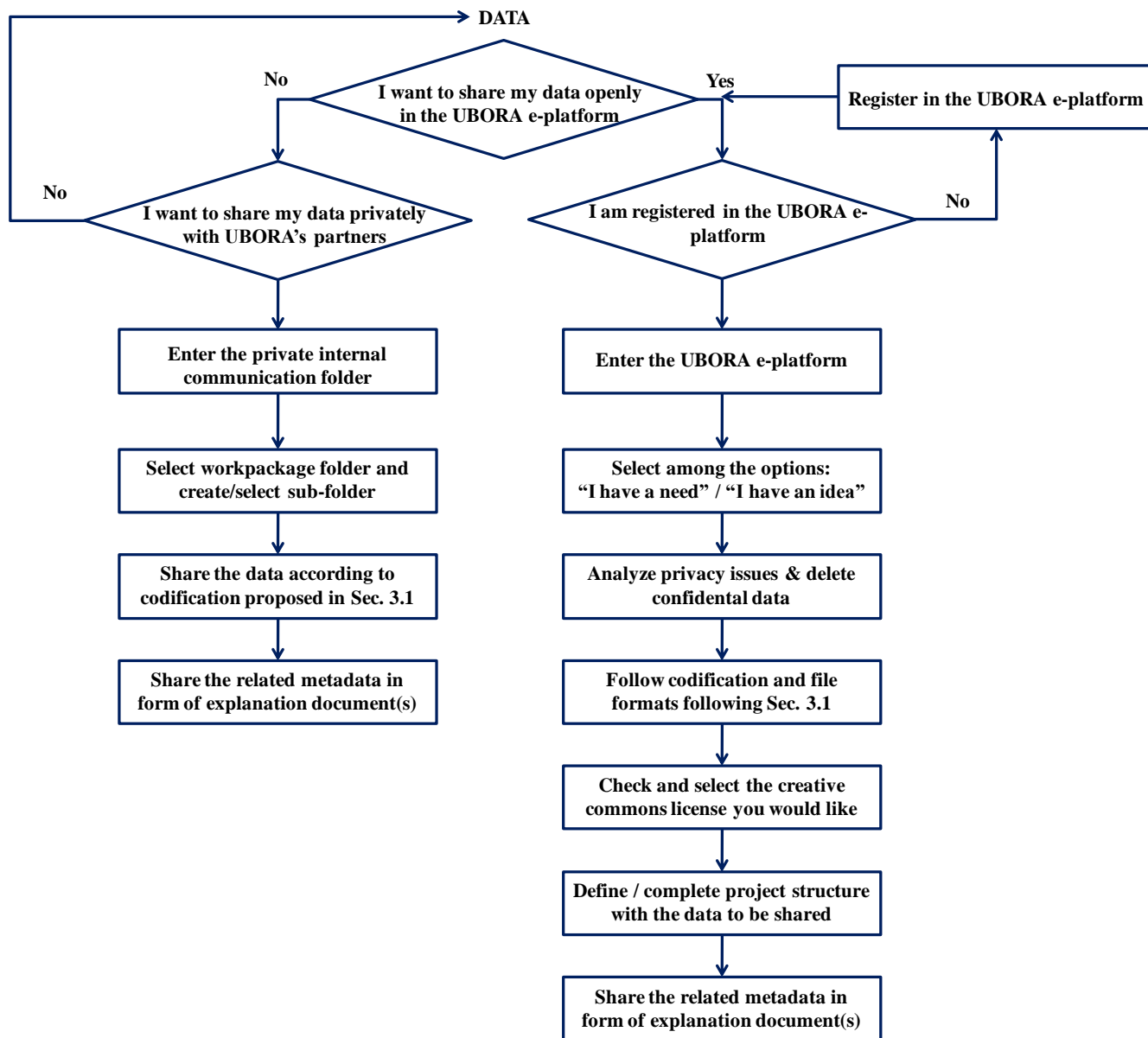
Figure 1: Simplified flow chart for managing and sharing the documents generated within UBORA, both for communication purposes with partners and for starting to fill the UBORA e-infrastructure with innovative biomedical device projects developed in a collaborative way

4.2   FAIR (Findable, Accessible, Interoperable, Re-usable) data

4.2.1   Making data findable

Once the UBORA e-infrastructure is loaded with dozens of projects, towards the end of the project, it will be necessary to count with adequately implemented search mechanisms for easily reaching the medical solutions and, hence, promoting its friendly usability and its popularization as a tool medical professionals, for medical device innovators, for policy makers and for patients and patient associations. In order to make such data findable, the UBORA e-infrastructure has been designed with interactive tabs, which help to organize the generated projects and the uploaded information and data.

The projects are being currently created and organized answering the following questions:

- A) Which clinical area does your solution belong to?
- B) What kind of technology do you propose?
- C) Which clinical needs do you address?

A) For the clinical areas, a list of common Medicine specialties is used including:

From surgical fields: General surgery, ophthalmic surgery, cardiovascular surgery, colorectal surgery, neurosurgery, oral and maxillofacial surgery, oncologic surgery, orthopedic surgery, otolaryngology, plastic surgery, podiatric surgery, transplant surgery, trauma surgery, urology, vascular surgery, pediatric surgery.

From internal medicine: Angiology / vascular medicine, cardiology, critical care medicine, endocrinology, gastroenterology, geriatrics, hematology, hepatology, infectious disease, nephrology, neurology, oncology, pediatrics, pneumology / chest medicine, rheumatology, sports medicine, traumatology and orthopedics.

From diagnostic medicine: Pathology, molecular biology, diagnostic radiology, nuclear medicine, clinical neurophysiology, transfusion medicine, cellular pathology, clinical chemistry, hematology, clinical microbiology, clinical immunology.

From other major disciplines: Anesthesiology, dermatology, emergency medicine, family medicine, obstetrics and gynecology, gerontology, medical genetics, neurology, ophthalmology, pediatrics, pharmaceutical medicine, rehabilitation, psychiatry, preventive medicine, public health.

In addition, there is also the possibility of defining more specific areas by using the tab: "Other: (Describe)", giving users the possibility of personalization.

B) From the perspective of medical technologies, ideas, proposals and projects can be grouped in: In vitro diagnostic device, in vivo diagnostic device, ergonomic support, implantable device, active implantable device, monitoring device, preventive device, surgical device, laboratory equipment, other supporting equipment, mobile-based technology, e-based technology, software; other technologies (to be described by the user).

C) From the perspective of clinical needs, ideas, proposals and projects are grouped in: Prevention of pathology or disease, point-of-care diagnosis, remote or self-diagnosis, monitoring purpose, support to surgery, replacement of human tissues or organs, non-surgical therapy / administration of drugs, support to medical practice, support to laboratory practice, rehabilitation, other clinical needs (to be described by the user).

Once the fields from previous subsections A, B & C are ordered and numbered, such numbers may be used as identification coordinates for classifying the different projects according to the type of medical device being developed, to the medical area involved and to the clinical need being addressed. This classification may be also used as part of the name of the different documents involved in the project, according to the instructions provided in the data summary from Section 3.1.

There are alternative or synergistic possibilities which may need further assessments to help make the data findable (and also accessible):

D) The Global Medical Device Nomenclature (GMDN): The GMDN Agency (https://www.gmdnagency.org) is responsible for the development of a nomenclature used to identify medical devices. The main purpose of the GMDN is to provide health authorities and regulators, health care providers, manufacturers and others with a naming system that can be used to exchange medical device information and support patient safety. The GMDN was compiled by experts worldwide following ISO Standard 15225 and, for each device of the GMDN database, provides a name, a code and a brief description.

Using the GMDN for naming and classifying the projects and devices developed within UBORA and those designed collaboratively and shared through the UBORA e-infrastructure is attractive, as it would benefit from existing frameworks. However, as the GMDN Agency Ltd. is a private agency and considering the membership fees required for using the GMDN for UBORA and the e-infrastructure, some ethical issues arise. Taking account that UBORA's objectives are clearly focused on open-access and available for all medical devices, resources have to be allocated to those aspects really requiring investment. The University of Pisa is in contact with GMDN, trying to obtain their sponsorship for UBORA, which would help to make their methodology further known, thus being a win-win agreement. If no agreement is reached, the potential use of GMDN will be analyzed in term.

E) The Universal Medical Device Nomenclature System™ (UMDNS): The UMDNS, developed and copyrighted by the ECRI Institute (https://www.ecri.org/Components/UMDNSPlus/Pages/default.aspx), is another standard international nomenclature and computer coding system to manage medical devices.The nomenclature is used in applications ranging from hospital inventory and work-order controls to national agency medical device regulatory systems and from e-commerce and procurement to medical device databases.

Again, as happens with the GMDN, using the UMDNS requires permission (of ECRI in this case) and subscription, although in this case some free subscriptions may be possible.

Both GMDN and UMDNS are highlighted by WHO as the most used nomenclatures currently used, which is to be taken into account. According to WHO, 51% of 175 countries use a nomenclature system for medical devices, of which 26% use a nationally developed one. GMDN is slightly more used than UMDNS in Europe, while UMDNS is much more present than GMDN in Africa. See interactive graph:

http://gamapserver.who.int/gho/interactive_charts/health_technologies/nomenclature/atlas.html

Further contacts and debate within members of UBORA will let us decide the best alternative, either existing or self-developed or a combination of approaches.

4.2.2 Making data accessible

In the case of UBORA, the e-infrastructure (Fig. 2) developed for the collaborative design of open-source medical devices, will be the key tool for making project's data available. The platform will incorporate developed projects, publications, teaching materials and will be made open to the public for being used as reference collaborative design resource in the biomedical industry.

Considering that UBORA will turn out to be, using a metaphor, a sort of "collaborative Wikipedia of medical devices", the contents uploaded will be made available to the community, in principle resorting to different types of Creative Commons Licenses (https://creativecommons.org/).

In all cases, attribution to the designer or to the developing team has to be granted (CC BY). The UBORA project and the support of the EU must be also acknowledged following the standard formula to be included in the e-infrastructure. During the project, once the first examples are uploaded to the e-infrastructure and the usability and accessibility are addressed, we will analyse other possible additions to the basic mentioned CC BY license, including "share-alike", "non-derivatives", "non-commercial", among others, although this may well be (in the final version of the e-infrastructure) a final decision of the designer or developer, as happens in collaborative environments for sharing documents and blueprints such as: Wikimedia Commons, Thingiverse, GrabCAD, among others.

Accessibility to the platform will require registration, which the users will freely achieve by introducing basic personal and contact data, as already detailed. Users will accept following the terms of usability expressed in the "terms and conditions" section of the e-infrastructure for registration. Once registered, users will have access to the projects of innovative medical devices uploaded to UBORA and to the projects' data and metadata. Search of desired data will be supported by keywords and by the classifications of clinical areas, medical technologies and clinical needs previously detailed. Users will be responsible for the veracity of the information uploaded to UBORA (or modified within UBORA by them) and the managers of the UBORA e-infrastructure will retain the right to expel users that do not adequately use the information shared.
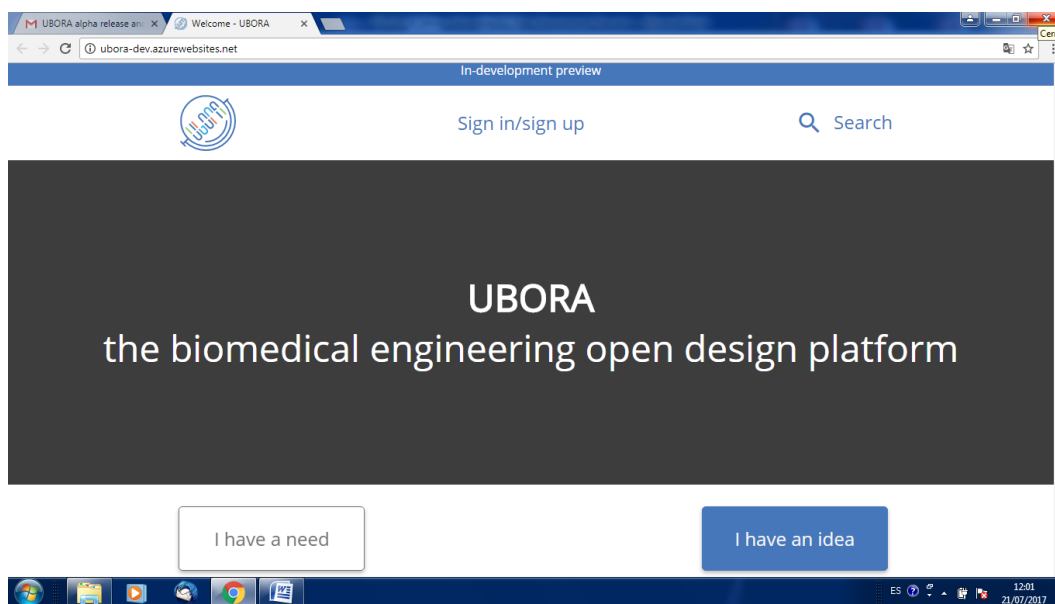
Figure 2: Portrait images of the alpha release of the UBORA e-infrastructure (http://ubora-dev.azurewebsites.net/).

4.2.3 Making data interoperable

Interoperability will be achieved by using the previously described formats and by taking account of the existing compatibilities among design programmes and files (see Annex A.2), which will be continuously updated. A support document for users of the UBORA will be prepared with description of the preferred file types (in fact an updated version of A.2). It is also important to note that each project developed within UBORA will be developed by a different team of international designers and collaborators, which will probably choose among the existing options of computer-aided design, modeling and manufacturing software, so surely the file types used within UBORA will be varied, as already advanced.

It is also necessary to highlight that the UBORA e-infrastructure will count on a group of mentors/managers, i.e. partners from the EU UBORA project motivated about the long-term viability of the e-infrastructure and colleagues with international impact in bioengineering, who will advise users of the e-infrastructure about the preferred file formats for improved interoperation.

We will resort to "international" file exchange standards, for instance .stl (standard tessellation language) in the case of files for prototyping tasks. However, it is also true that these formats may well change along the following years and be substituted by other more efficient ones, to which the files already available in the e-infrastructure will need to be adapted (see subsection 3.2.3). To cite an example, the "universal" or standard .stl, .igs, .dxf…, CAD formats are not optimal, in spite of their popularity in additive manufacturing, especially for features and geometries with a mathematical representation, as such features can be described and programmed in many cases in just a couple of code lines, while their CAD representation unnecessarily increases size and computational demand. The shift to algorithmic, rather than descriptive geometry is a key factor to promote the definition of material properties by design and to further apply knowledge-based and bioinspired materials to real products and medical devices, which in turn will lead to new file formats in forthcoming years. We will define procedures for managing these issues.

4.2.4 Making data re-usable

The medical device development projects validated in the e-infrastructure by the UBORA mentors/managers and reviewed as potentially beneficial for solving global healthcare concerns, once completed, will be archived in the protected servers of the UBORA e-infrastructure and made available to users during the whole life of the e-infrastructureor until the developer together with the team of mentors/managers of UBORA decide to replace it by a better solution or to eliminate it due to existing alternatives performing better.

Back-ups of the projects, documents and blueprints (i.e. CAD files for prototyping and relevant design-related files) will be performed monthly. Updating of relevant files will be also performed, as part of the global strategy for making the UBORA e-infrastructure technically and economically viable beyond the project's lifetime. Technical personnel will need to be devoted to the sustainability and management of the project (potentially with related costs of up to 30.000€/year in the mid-term) and to counting with secure and private hosting space (around 10.000€/year in the mid-term for 100-500 projects with a total capacity of 100TByte).
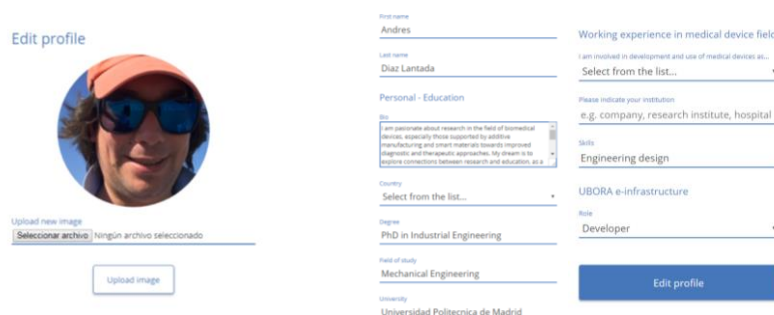
5   Ethical aspects, privacy issues and security concerns

5.1   Special ethical aspects and their management

During the EU UBORA project's lifespan, the medical devices developed will rely solely on healthy volunteers for being tested in laboratory environments, hence being "prototypes for assessment of functionality". These devices will be in most cases consequence of partners' dedication to the UBORA project or the result of students' developments within the design competitions and the design schools. No device potentially harmful for users will be tested in humans during the project. In any case, ethical approval from local ethical committees will be obtained prior to commencing the assessments, as described in Deliverable 1.1. After the project's life, in the mid- and long-term life of the UBORA e-infrastructure, UBORA managers will not be responsible for the use given to the online resources of the e-infrastructure and it will be the unique responsibility of the potential manufacturers taking inspiration on the projects available in the e-infrastructure, to fulfill pre-market approvals and to respond to potential failures of the products they decide to manufacture and commercialize. Further aspects will be discussed in next versions of this deliverable.

5.2   Privacy issues and their management

Regarding privacy, it is UBORA's policy to respect users' privacy regarding any information that the e-infrastructure may collect. Accordingly, the privacy policy, which affects all data collected and shared through UBORA e- platform, is outlined as follows: UBORA will collect personal information by lawful and fair means and, where appropriate, with the knowledge or consent of the individual concerned (i.e. Fig. 3).Before or at the time of collecting personal information, UBORA will identify the purposes for which information is being collected. UBORA will collect and use personal information solely for fulfilling those purposes specified by us and for other ancillary purposes, unless UBORA obtains the consent of the individual concerned or as required by law. Personal data should be relevant to the purposes for which it is to be used, and, to the extent necessary for those purposes, should be accurate, complete, and up-to-date. UBORA will protect personal information by using reasonable security safeguards against loss or theft, as well as unauthorized access, disclosure, copying, use or modification. UBORA will make readily available to customers information about its practices linked to the management of personal information. UBORA will only retain personal information for as long as necessary for the fulfillment of those purposes. More specifically, in the case of files resulting from medical imaging technologies or clinical procedures, the personal information regarding patients, which does not influence the development of related medical devices, will be omitted. In cases where such information may be relevant, UBORA e-infrastructure will include a confidential area for being used only by those involved in the medical device development project(s) with permission granted by the involved patient(s).

Figure 3: Example of user's information incorporated to the profile. No sensitive data (i.e. personal ID, address, phone…) are collected and only a contact email and name, which can be an alias, are needed.

5.3   Security concerns and their management

According to the FDA, medical devices, like other computer systems, can be vulnerable to security breaches, potentially impacting the safety and effectiveness of the device. This vulnerability increases as medical devices are increasingly connected to the internet, to hospital networks, and to even other medical devices or, in some cases, patient's devices (https://www.fda.gov/MedicalDevices/DigitalHealth/ucm373213.htm). Being UBORA e-infrastructure a collaborative online resource, these security concerns are of special relevance for the long-term viability of our proposed approach and for success in managing global health issues. As explained before, UBORA will protect personal information by using reasonable security safeguards, depending on the resources allocated for private and secure hosting space, which may well reach 10.000€/year in the mid-term for 100-500 projects with a total capacity of 100TByte. The adequate provisions will be performed, once the long-term technical-economic viability is analyzed (Task 5.2 and its deliverables D5.3 *Preliminary exploitation and sustainability plan* (M9) and D5.4 *Final exploitation plan with guidelines for open licensing of designs* (M30).

6   Conclusions

Dissemination, exploitation and communication activities, performed in UBORA within WP5, are fundamental to achieve better awareness, to distribute the generated knowledge and to create novel opportunities for European and African integrated innovation in BME. In parallel to the e-infrastructure implementation for innovative and safe design, a set of guidelines have been implemented to correctly manage the data generated within the project and especially those made publicly available via UBORA. Such guidelines have been summarized here for the benefit of the project.

Consequently, the present **"Deliverable 5.2–Data management plan"** has been implemented to provide partners with a standard press release for presenting the UBORA project, its main objectives and initial steps to the press and scientific-technical community, as support to other dissemination and communication actions aimed at promoting project's impacts. This initial standard management plan, even if performed with the perspective of just six months of project running, provides a basic framework for starting with the adequate management of already generated data, which being already shared via the first test version of the UBORA e-infrastructure, which will constitute the grounds for the future of collaborative and open biomedical engineering. This text will be complemented with additional information and advices along the project's life, so as to generate a more robust and effective DMP, also supporting harmonization in the medical industry, according to the basic objectives of the project.

7   References

For preparing the data management plan:

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- Data management plan- Open researchdatapilot: Guida alla redazione, Centro Risorse per la Ricerca Multimediale (CRR-MM), Alma Mater Studiorum, Università di Bologna.
- Data Management Plan, article published in Wikipedia, the Free Encyclopedia, (last access: 14th of July, 2017).
- FDA Report on Cybersecurity: https://www.fda.gov/MedicalDevices/DigitalHealth/ucm373213.htm
- Guidelines on FAIR data management in Horizon 2020, EU Commission, Directorate-General for Research & Innovation, version 3.0, 26th July, 2016.
- Online resources: Data management plan online, Digital Curation Centre. https://dmponline.dcc.ac.uk, (last access: 14th of July, 2017).

Project website and social media sites:

- http://ubora-biomedical.org
- https://www.facebook.com/UBORA-261898414244796/?ref=bookmarks
- https://twitter.com/uborabiomedical
- https://www.researchgate.net/project/UBORA-Open-Biomedical-Engineering-e-Platform-for-Innovation-through-Education

Appendix

A.1. List of acronyms

- ABEC: African Biomedical Engineering Consortium.
- CAD: Computer-aided design.
- CAE: Computer-aided engineering.
- CAM: Computer-aided manufacturing.
- CC: Creative Commons.
- EC: European Commission.
- DICOM: Digital communications in Medicine.
- DMP: Data management plan.
- FAIR: Findable, accessible, inter-operable, re-usable.
- FEM: Finite element modeling.
- GMDN: Global medical device nomenclature.
- H2020: Horizon 2020.
- IP: Intellectual property.
- STL: Standard tessellation language.
- UMDNW: Universal Medical Device Nomenclature System™.
- WP: Work package.

A.2. Common file formats to be handled within ubora and the UBORA e-infrastructure

TYPICAL FORMATS TO BE USED IN UBORA PLATFORM

Use	Software	Main File format	Compatibility with	Open Source	Free	Student license	Freemium	Typical File size (MB)
Document editing	Libre Office Writer	odt	docx	yes	yes	NA	NA	5
Document editing	MS Word	docx	pdf (limited), odt	no	no	yes	no	5
Document sharing	Adobe Acrobat	pdf		no	no	no	yes	2
Image sharing		jpg, png, tiff						
CAD	FreeCAD	FCstd		yes	yes	NA	NA	2
CAD	Sketch Up		dwg, dxf	yes	yes	NA	NA	
CAD	AutoCAD by Autodesk	dwg	stl, igs, step	no	no	yes	NA	10
CAD	Rhinoceros	3dm	stl, igs, step					
CAD & FEM	Inventor by Autodesk	ipt (parts) iam (assemblies)	stl, igs, step, dwg	no	no	yes	NA	10
CAD & FEM	Catia by Dassault	catpart (parts) catproduct (assemblies)	stl, igs, step	no	no	no	NA	10
CAD & FEM	Solidworks by Dassault	sldprt (parts) sldasm (assemblies)	stl, igs, step	no	no	no	NA	10
CAD & FEM	Solid Edge by Siemens	par (parts) asm (assemblies)	stl, igs, step, catpart, prt, dwg	no	no	no	NA	10
CAD & FEM	NX by Siemens	prt (parts) asm (assemblies)	stl, igs, step, catpart, par, dwg	no	no	yes	NA	10
CAD & FEM	Creo Elements / ProEngineer	prt (parts) asm (assemblies)	slt, igs	no	no	yes	yes	10
FEM	Ansys	db		no	no	no	yes	10-10000
FEM	Abaqus - Simulia by Dassault	abq, inp, mdl, prt, sim		no	no	no	NA	10-10000
FEM	Comsol	mph	Matlab, stl, igs, step, catpart, ipt,	no	no	no	NA	10-10000
FEM	MSC Nastran	nas, bdf, dat	stl, igs, catpart, prt,	no	no	no	NA	10-10000
FEM	Altair Hyperworks	varied	stl, fem, igs, step	no	no	no	NA	10-10000
Rendering & animation	Maya by Autodesk	iff	jpg, png, tiff, gif, mov	no	no	yes	NA	5
Rendering & animation	3DSmax by Autodesk	3ds, obj, mtl	stl, igs, step, catpart, ipt, jpg, png, tiff, gif, mov					5
Rendering & animation	Blender	blend	stl, obj, 3ds	yes	yes	yes	NA	5
Rendering & animation	Keyshot	varied	stl, igs, catpart, prt,	no	no	no	NA	5
Rendering & animation	Luxrender	varied	most rendering software	yes	yes	NA	NA	5
Rendering & animation	Cycles	varied	most rendering software	yes	yes	NA	NA	5
Rendering & animation	Kerkythea	varied	most rendering software	yes	yes	NA	NA	5
Rendering & animation	Freestyle	varied	most rendering software	yes	yes	NA	NA	5
Medical imaging reconstruction	3D Slicer	Imports dicom		yes	yes	NA	NA	100-500
Medical imaging reconstruction	ITKsnap	Imports dicom		yes	yes	NA	NA	100-500
Medical imaging reconstruction	InVesalius	Imports dicom	Conversion to stl	yes	yes	NA	NA	100-500
Medical imaging reconstruction	OsiriX	Imports dicom	Conversion to stl	yes	yes	NA	NA	100-500
Medical imaging reconstruction	MIMICS by Materialise	Imports dicom	Conversion to stl and FEM	no	no	no	no	100-500
Medical imaging reconstruction	AMIRA	Imports dicom		no	no	no	no	100-500

Acronyms: CAD - Computer-aided design; FEM - Finite element modeling
Fundamental file formats for UBORA's usability: docx, pdf, stl, igs, dicom, jpg, png, tiff, gif, mov, avi

(To be updated along the project, considering the usability of the different design, modeling and manufacturing systems and their accessibility).