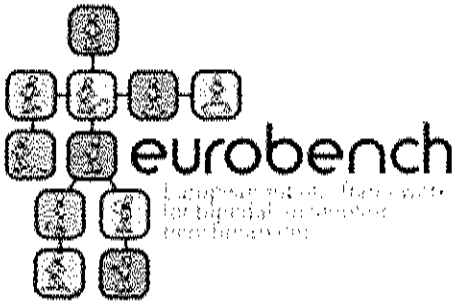

EUROPEAN ROBOTIC FRAMEWORK FOR BIPEDAL LOCOMOTION BENCHMARKING

- EUROBENCH -

Sub-projects Grant Agreement

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 779963.

Index

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 779963.

Contracting parties

Today 19 of February 2019,

PKF ATTEST INNCOME S.L., a for-profit private company organized under the laws of Spain, established in Calle Orense, 81 Planta 7, 28020, Madrid, with VAT nr ESB87239489, duly represented by María Prieto, legal representative.

hereinafter referred as the "Budget Holder"

AGENCIA ESTATAL CONSEJO SUPERIOR DE INVESTIGACIONES CIENTIFICAS (CSIC), a public research organization organized under the laws of Spain, established in C/ Serrano 117, 28006, Madrid, Spain, with VAT nr ESQ2818002D, duly represented by Professor Jesús Marco de Lucas, Vice President for Scientific and Technical Research

hereinafter referred as the "EUROBENCH Coordinator"

hereinafter collectively the Budget Holder and the EUROBENCH Coordinator referred as the "Contractor"

Of the one part, and

Fondazione Santa Lucia , a private law company organized under the laws of Italy established in Via Ardeatina n. 306, 00179 Rome , with VAT nr 05692831000 , duly represented by Maria Adriana Amadio, National ID Number AV3006797 President, Fondazione Santa Lucia ,acting as Sub-project coordinator,

University of Rome Tor Vergata Centro di Biomedicina Spaziale, a public University organized under the laws of Italy, established inVia Montpellier 1 00133 Rome, with VAT nr 02133971008, duly represented by Prof. Francesco Lacquaniti, National ID Number 804738, director,

Università degli Studi di Messina, a public University organized under the laws of Italy, established P.zza Pugliatti, 1 98122 Messina with VAT nr 00724160833, duly represented by Prof. Salvatore Cuzzocrea ,National ID Number AX 1916361, Rector,

hereinafter referred as the "Beneficiaries"

of the other part

Hereinafter collectively referred as the "Contracting Parties"

HAVE AGREED to the following terms and conditions including those in the following Annexes, which form an integral part of this Sub-grant agreement (hereinafter referred as the "Contract")

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 779963.

General Provisions

The European Commission (hereinafter referred as the "EC") and the EUROBENCH Consortium, coordinated by AGENCIA ESTATAL CONSEJO SUPERIOR DE INVESTIGACIONES CIENTIFICAS (CSIC), have signed the Grant Agreement no 779963 for the implementation of the EUropean ROBotic framework for bipedal locomotion bENCHmarking (EUROBENCH) within the framework of the European Union's Horizon 2020 research and innovation programme, H2020-ICT-2016-2017.

The EUROBENCH project provides financial support, in accordance with the conditions set out in the Grant Agreement no 779963, to Third Parties willing to:

- Contribute to the Development of the Framework (EUROBENCH FSTP-1 Open Call): To design and develop specific test benches or benchmarking routines to be integrated into the EUROBENCH framework.
- Validate the Framework (EUROBENCH FSTP-2 Open Call): Use the framework to test the performance of different kinds of robots.

The EUROBENCH FSTP-1 Open Call was closed on 31st October 2018 and the Evaluation and Selection of Proposals has been completed at the moment of the signature of this Contract, following the rules set out in the Guide for Applicants (link to the Guide for Applicants included in Annex 1) and D7.1 - FSTP Procedure Manual, property of the EUROBENCH Consortium.

This Contract aims at defining the framework of rights and obligations of the Contracting Parties under the Sub-project PEPATO, a performance indicators of spatiotemporal Patterns of the spinal muscle coordination Output during walking with an exoskeleton selected for funding under the FSTP-1 Open Call.

The Budget Holder has been appointed in the Grant Agreement signed with the EUROBENCH Coordinator and the European Commission as the responsible of transferring the funds from the EUROBENCH Coordinator to the Beneficiaries.

The Beneficiaries have received the favourable resolution by the evaluators and the Steering Committee of EUROBENCH and therefore is entitled to receive funding and services according to the terms and conditions set out under the Contract.

Article 1 - Entry into force of the contract and Termination

This Contract shall enter into force on the day of its signature by the last Contracting Party. The termination of the Contract will be subject to the terms and conditions set out in the Guide for Applicants (link to the Guide for Applicants included in Annex 1) taking into account the following provisions:

- M1:M12 → After the signature of the Grant Agreement, the Development phase will start and last 12 months.
- M13-M14 → A 2-month reporting and technical assessment period will take place after the end of the Development Phase.
- M14-M20 → Third Parties that received a positive evaluation on the Development phase will have less than 6 months to integrate their outcomes into the EUROBENCH Software and/or Facilities
- M20-M34 → The integration is completed and Third Parties are just committed to provide technical support during the FSTP-2 development (Until December 31, 2021) in case the outcome generated by the sub-project is not working properly, impeding its use during the EUROBENCH Framework Validation under FSTP-2 Open Call.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 779963.

Article 2 - Obligations and Responsibilities of the Beneficiaries

The obligations and responsibilities are defined in detail in the Annex 1 - Guide for Applicants.

The Beneficiaries shall develop a benchmarking solution according to the Sub-Project as set out in Annex 2 – Sub-project Description of Work.

Each Sub-project will be assigned to a coach, part of the EUROBENCH Consortium staff. Beneficiaries will maintain communication with their coach on periodic basis (to be agreed with the coach), in order to allow the sustainable development of the Sub-project.

The Beneficiaries will be provided with a 3-monthly report template (1-2 pages max.) that will have to send to the EUROBENCH Consortium (by email to fstp@eurobench2020.eu) and their own coach every 3 months from the beginning of the project (within 10 days from the end of each 3-month period), in order to allow deviations control and mitigation measures to be applied if needed.

Additionally, the Beneficiaries shall take every necessary precaution to avoid any risk of conflict of interest relating to economic interests, political or national affinities, family or emotional ties or any other interests liable to influence the impartial and objective performance of the Sub-project.

Article 3 - Breach of Contractual obligations

In the event the Contractor identifies that the Beneficiaries:

i) Breached their obligations under the Contract.
ii) Stopped to carry out their business object of this Contract and therefore are not able or willing to continue the Sub-project.
iii) Are engaged in a bankrupt or receivership process.

The Contractor will give written notice requiring that such breach to be remedied within 30 days.

In case the Beneficiaries have not brought remedies from the notice, the Contractor may decide to terminate the contract unilaterally.

Moreover, in the event the breach of the contractual obligations has not been remedied in the given time, the Contractor may request the Beneficiaries the refund of the payments made to date.

Article 4 - Price and Financial provisions

4.1 Maximum financial contribution

The maximum financial contribution to be granted to the Beneficiaries is **one hundred and fifty thousand euros (EUR 150.000,00)** distributed among beneficiaries according to the budget breakdown set out in Annex 2 – Sub-project Description of Work.

4.2 Distribution of the financial contribution

The financial contribution to be granted to the Beneficiaries shall be calculated and distributed in accordance with the provisions set in Annex 1 - Guide for Applicants.

In any case, the financial grant to be paid will always be subject to:

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 779963.

- A favourable resolution by the EUROBENCH Steering Committee responsible for assessing the Sub-project in each of the stages (see Article 5.2)
- The availability of funds in INNCOME bank account transferred by the EUROBENCH Coordinator, CSIC, during the relevant payment period.
- The prior writing notice to the Sub-project Coordinator of the date and amount to be transferred to its bank account (Annex 3 - Bank account information form), giving the relevant references.
- As established in Annex 1 – Guide for Applicants, payments will be made to the Sub-project Coordinator by the Budget Holder. In particular:
    - The Budget Holder reserves the right to withhold the payments in case the Beneficiaries do not fulfil with its obligations and tasks as per this contract and annexes.
    - Banking and transaction costs related to the handling of any financial resources made available to the Beneficiaries by the Contractor shall be covered by the Beneficiaries.

Payments will be released no later than thirty (30) natural days after the notification by the Budget Holder.

4.3 Payments schedule

The payment schedule is directly linked to the relevant phase of the Sub-project as per the point 7 of the Annex 1 - Guide for Applicants.

Payments along the Sub-project duration will be transferred to the Sub-project Coordinator. All payments will be made in euro.

Payments to the coordinator will discharge the EUROBENCH Consortium from its payment obligation. The coordinator must distribute the payments between the beneficiaries (partners of the Sub-project) without unjustified delay.

The payment per phase will be disbursed once all work related to specific phase has received positive assessment.

Phase 0 - Pre-financing

Third parties will receive pre-financing of 60% of their respective total funding amount (First Round Payments).

Phase 1 - Development

At the end of this phase, the Coordinator of each Sub-project will have 1 month to submit a Technical Report, which should include:

- A description of the activities carried out by the beneficiaries.
- A detailed technical description of the outcomes and the necessary procedures for their integration.
- A description of the degree of achievement of project objectives and any deviation from them.
- An Ethics Report as described in Article 7

Specific templates for technical reporting will be prepared and published by the EUROBENCH Consortium. The EUROBENCH Consortium will assess the Technical Report in a period of 1 month. If the evaluation succeeds, the Development Phase will be considered completed and the second phase (namely Integration) will start.

Phase 2 - Integration

Third Parties that received a positive evaluation on the Development phase will have less than 6 months to integrate their outcomes into the EUROBENCH Software and/or Facilities. In particular:

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- Testbeds and devices should be brought to the corresponding EUROBENCH Facility(ies), be installed and tested with at least one of the bipedal robotic prototypes available in the facility(ies).
- Benchmarking routines should be fully integrated in the EUROBENCH Software and tested with the reference input-output data provided together with the code.
- Experimental datasets should be integrated in the EUROBENCH Database and tested with at least one of the benchmarking routines available.

After successful integration, Third Parties will be made eligible for receiving the remaining payment (40%) ("Second Round Payments") of the EUROBENCH fund. However, due to project funds retained by EC, Third Parties will only receive a 25% (reaching the 85% of the requested contribution). The final 15% of the Sub-project funding will be released only after the EC transfers the final funding to the EUROBENCH consortium in 2021.

The Beneficiaries are entitled to receive exclusively those payments allocated to each specific phase of the Sub-project provided that the conditions under Article 4.2 are met.

Article 5 – Liability

The Contractor cannot be held liable for any acts or omissions of the Beneficiaries in relation to this Contract.

Moreover, the Contractors cannot be held liable if a beneficiary or third party involved in the action causes damage to another beneficiary or third-party. The Beneficiary shall bear sole responsibility for ensuring that their acts within the framework of this Contract do not infringe third parties' rights.

The Beneficiaries aggregate liability towards the Contractors shall be limited to once the Beneficiaries share of the total costs of the Project.

5.1 Conflict of interest

The Beneficiaries must take all the measures to prevent any situation where the impartial and objective implementation of the Sub-project is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest ('conflict of interests'). Also, it must formally notify to the EUROBENCH Consortium, without delay, any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation. The EUROBENCH Consortium may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline. If the Beneficiaries breach any of their obligations, the sub-contract, Grant Agreement with the Beneficiaries, may be automatically terminated.

5.2 Technical Reporting

If the technical report, delivered in M13 for its assessment, reflects that the project tasks have not been (either totally or partially) developed will cause the technical report to be re-evaluated during the integration phase together with the applicant. If this last review doesn't succeed, the integration phase will be considered unsuccessful and the second round of payments won't take place and could take the form of recovery. The amount of this recovery, if applicable, that will not exceed the pre-financing, will depend on the degree of development of the tasks described in Annex 2 – Description of Work.

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Article 6 - Confidentiality

6.1 Principles

With respect to all information of whatever nature or form as is disclosed between the Contracting Parties in connection with the Sub-project and identified in writing as confidential, the terms of this Article shall apply.

6.2 Obligations

The Contracting Parties agree that such information is communicated on a confidential basis and its disclosure may be prejudicial to the owner of the information, and undertakes that:

i) it will not, during the term of the Sub-project and for a period of four (4) years from the expiration date of the Sub-project, use any such information for any purpose other than in accordance with the terms of the Contract.

ii) it will, during the term of the Sub-project and for a period of four (4) years from the expiration date of the Sub-project, treat the same as (and to procure that the same be kept) confidential provided always that such agreement and undertaking shall not extend to any information which the receiving Party can show:

- was, at the time of disclosure to the Subcontractor, published or otherwise generally available to the public; or
- has, after disclosure to either of the Contracting Parties, been published or become generally available to the public otherwise than through any act or omission on the part of the receiving Party; or
- was already in the possession of the Contracting Parties, without any restrictions on disclosure, at the time of disclosure to the Party; or
- was rightfully acquired from others without any undertaking of confidentiality; or
- is subsequently independently developed by the Contracting Parties without use of the information provided by the disclosing party;
- previous written consent for publication or disclosure from the other party

The Commission and/or the Contractors may disclose confidential information to its staff, other EU institutions and bodies. It may disclose confidential information to third parties, if:

(a) this is necessary to implement the Agreement or safeguard the EU's financial interests and

(b) the recipients of the information are bound by an obligation of confidentiality

In case of breach of the confidential rules hereinabove set, the Contracting Party breaching the confidentiality will remain solely liable towards possible claims.

Article 7 – Research involving human subjects and Protection of personal data

In order to comply with national and European legislation, Third Parties will have to include as part of their Technical Report in M13 of the Sub-project, an Ethics Report including:

1. Copies of the ethics reports submitted to the corresponding local ethical committee(s), which should include: i) a description of the procedures and criteria that will be used to identify/recruit research participants, ii) a description of procedures that will be implemented for data collection, storage, protection and destruction of personal data
2. Copies of ethics approvals for the research with humans obtained by the local ethical committee(s).
3. Eventual additional consent to the secondary use of the data needs to be acquired or permission needs to be obtained from the owners of the data set.

For this, Annex 4 – EUROBENCH's Ethics Deliverables give Beneficiaries access to confidential information property of the EUROBENCH Consortium (D9.1 and D9.2).

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Article 8 - Intellectual property rights and ownership

Neither this Agreement nor the performance by either of the Parties of its duties hereunder shall operate to convey, license or otherwise transfer from one Party to the other any patent, know-how, trade secrets or other intellectual property rights. The copyright, property and any other rights in any document or material supplied under this Agreement shall, in the absence of any express provision to the contrary thereon, remain with the disclosing Party.

The Parties agree that the intellectual property rights created by the Beneficiaries in the course of performing this Agreement (including without limitation any copyrights, trademarks or logos registered or not, patents and proprietary technology), shall belong to the Beneficiaries.

Despite beneficiaries will own the intellectual property of the results, they should allow the integration of the generated prototypes in the EUROBENCH Framework (facilities and/or software) for the subsequent validation during FSTP-2 and after the project end on royalty-free. The EUROBENCH consortium may study and define potential agreements with Third Parties whose outcomes will have been successfully validated, if this is considered necessary to ensure further exploitation and sustainability as part of the EUROBENCH facilities and software.

Article 9 - Force Majeure

"Force Majeure" shall mean, any unforeseeable exceptional situation or event beyond the Contracting Parties control, which prevents either of them from fulfilling any of their obligations under the Agreement, which was not attributable to error or negligence on their part. Any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure, as well as labour disputes, strikes or financial difficulties cannot be invoked as force majeure.

The Contracting Parties shall take the necessary measures to limit any damage due to force majeure. They shall do their best to resume the implementation of the action as soon as possible.

No Contracting Party shall be considered to be in breach of its obligations and tasks if such breach is caused by Force Majeure. A Contracting Party will notify the other Contracting Party of any Force Majeure as soon as possible. In case the Beneficiary is not able to overcome the consequences of Force Majeure within thirty calendar (30) days after such notification, the Contractor will decide accordingly including the termination of the Contract.

Article 10 - Information and communication

10.1 Information and communication towards the EC

The Beneficiaries shall, throughout the duration of the Sub-project, take appropriate measures to engage with the public and the media about the Sub-project and **to highlight the financial support of the EC and the EUROBENCH project**. Unless the EC or the contractor request otherwise, any publicity, including at a conference or seminar or any type of information or promotional material (brochure, leaflet, poster, presentation etc.), must specify that the Sub-project has received funding from the EC and the EUROBENCH project, therefore displaying EU's and EUROBENCH's logo on all printed and digital material, including websites and press releases and including the following text:

- For communication activities: "This project has received funding from the European Union's Horizon 2020 research and innovation programme, via an Open Call issued and executed under Project EUROBENCH (grant agreement Nº 779963)".
- For infrastructure, equipment and major results: "This [infrastructure][equipment][insert type of result] is part of a project that has received funding from the European Union's Horizon 2020

research and innovation programme, via an Open Call issued and executed under Project EUROBENCH (grant agreement Nº 779963)".

When displayed in association with a logo, the European emblem should be given appropriate prominence. This obligation to use the European emblem in respect of projects to which the EC contributes implies no right of exclusive use. It is subject to general third-party use restrictions which do not permit the appropriation of the emblem, or of any similar trademark or logo, whether by registration or by any other means. Under these conditions, the Beneficiaries are exempted from the obligation to obtain prior permission from the EC to use the emblem.

Any publicity made by the Beneficiaries in respect of the Sub-project, in whatever form and on or by whatever medium, must specify that it reflects only the author's views and that the EC and the EUROBENCH Project are not liable for any use that may be made of the information contained therein.

The EC and INNCOME, on behalf of the EUROBENCH Project, shall be authorised to publish, in whatever form and on or by whatever medium, the following information:

- the name of the Beneficiaries
- contact address of the Beneficiaries
- the general purpose of the Sub-project (publishable summary)
- the amount of the financial contribution foreseen for the Sub-project;
- after the final payment, the amount and rate of the financial contribution accepted by the EUROBENCH Project;
- the estimated amount and rate of the financial contribution foreseen for the Beneficiaries.
- the geographic location of the activities carried out;
- any publishable report, picture or audio-visual or web material provided, as non-confidential, to the EUROBENCH Project in the framework of the Sub-project (technical reports are excluded, since they are confidential and can be access only by the EUROBENCH Consortium and the EC).

The Beneficiaries shall ensure that all necessary authorisations for such publication have been obtained and that the publication of the information does not infringe any rights of third parties.

Upon a duly substantiated request by the Contractor on behalf of the Beneficiaries, the EC may agree to forego such publicity if disclosure of the information indicated above would risk compromising the beneficiaries' security, academic or commercial interests.

10.2 Information and communication among the Contracting Parties

Any notice to be given under this Contract shall be in writing to the addresses and recipients listed below:

- If communications include hard copies of the required documents, any notice to be given under this Contract shall be to the addresses and recipients listed in the Contracting Parties information or, otherwise, to the addresses indicated by the EUROBENCH Consortium via e-mail.
- E-mail communications from the EUROBENCH Consortium to Beneficiaries: communications, of any type, will be addressed to the Sub-project Coordinator's PI indicated in Annex 2 – Description of Work and, when needed, to other partner's PI indicated in the same document.
- E-mail communications from Beneficiaries to the EUROBENCH Consortium: The Sub-project coordinator's PI, indicated in Annex 2 – Description of Work, will be the only responsible for the communication from Beneficiaries to the EUROBENCH Consortium. If the beneficiary(ies) starts the communication, it should address the e-mail to an assigned Sub-project coach and/or the address fstp@eurobench2020.eu, depending on their needs. If the beneficiary(ies) answers to a previous message from the EUROBENCH Consortium, it should answer to the remittent (either the EUROBENCH coordinator, budget holder or an assigned Sub-project coach), always keeping the address fstp@eurobench2020.eu copied.


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Any change of persons or contact details shall be notified immediately to the Contractor. The address list shall be accessible to all concerned.

Article 11 - Financial audits and controls

The beneficiaries will ensure that the Commission, the European Court of Auditors (ECA) and the European Anti-Fraud Office (OLAF) have the right to exercise their powers of control on documents, information, even stored on electronic media, or on the final recipient's premises according to the General Annex K of the Horizon 2020 Work Programme. The beneficiaries must also ensure that the Commission has the right to make an evaluation of the impact of the action measured against the objective of the work program.

The beneficiaries must for a period of four years after the payment of the balance keep adequate records and other supporting documentation to prove the proper technical implementation of the action. They must make them available upon request or in the context of checks, reviews, audits or investigations. If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement, the beneficiaries must keep the records and other supporting documentation until the end of these procedures. The beneficiaries must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The Commission or/and Contractors may accept nonoriginal documents if it considers that they offer a comparable level of assurance Records and other supporting documentation on the scientific and technical implementation of the action must be in line with the accepted standards in the respective field. The beneficiaries do not need to keep record about the costs actually incurred for implementing the action.

Article 12 - Language

This Consortium Agreement is drawn up in **English**, language which shall govern all documents, notices, meetings and processes relative thereto.

Article 13 - Amendments

Amendments or changes to this Contract shall be made in writing and signed by the duly authorised representative of the Contracting Parties.

Nevertheless, in the event the EC modifies the conditions, the Contractor will amend the Contract accordingly.

Article 14 - Applicable Law

This Contract shall be construed in accordance with and governed by the laws of Spain.

Article 15 - Settlement of disputes

If the Contracting Parties are unable to resolve a dispute amicably, such dispute will be finally settled under the Courts of the City of Madrid.


This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 779963.

AS WITNESS:

The Contracting Parties have caused this Contract to be duly signed by the undersigned authorized representatives **copies,** one for each party, the day and year first above written:

For CSIC

Mr Jesús Marco de Lucas

Vice President for Scientific and Technical Research

Signature

Done at [illegible] on [illegible]/201[illegible]

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 779963.

For Fondazione Santa
Ms. Maria Adriana Amadio
President, Fondazione Santa Lucia
Signature

Done at Rome on 11.03./2019..

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 779963.

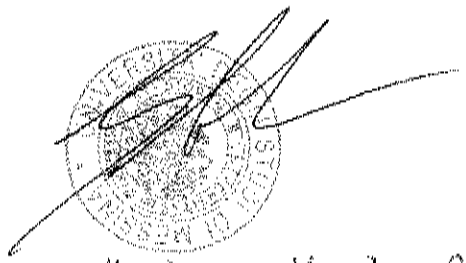
For University of Rome Tor Vergata Centro di Biomedicina SpazialeMr
Prof. Francesco Lacquaniti
Director
Signature

CENTRO DI BIO-MEDICINA SPAZIALE
Il Direttore
(Prof. Francesco Lacquaniti)

Done at Rome on 12/3/2019

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 779963.

For Università degli Studi di Messina
Prof. Salvatore Cuzzocrea
Rector
Signature



Done at Messina on 11/03/2019

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 779963.

Annexes

Annex 1. Guide for Applicants

Find the complete Guide for Applicants in the following link:
http://eurobench2020.eu/wp-content/uploads/2019/02/FSTP-1-Guide-for-Applicants_feb19.pdf
and considered it annexed to this contract.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 779963.

Annex 2. Sub-project Description of Work

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 779963.

H2020-779963 EUROBENCH
FSTP-1 Proposal

PErformance indicators of spatiotemporal PATterns of the spinal muscle coordination Output during walking with an exoskeleton (PEPATO)

History of changes:

1. Based on the recommendations and discussion following the review process of our proposal, we performed the following amendments to the proposal:
we indicated the minimum number of elderly subjects that we will register over 12 months and the equipment to be used for these recordings (TASK 3, page 4), as well as the related issues for recruitment of elderly participants in the risk analysis section (section 3.4, page 9).

2. Key Performance Indicators and achievements at month 12 of the sub-project:
- Ethics Committee approval will be obtained at FSL and at least 10 elderly healthy subjects (>65 yrs) will be recorded.
- the reference database for performance indicators will be provided for the two groups of adults, young (previously recorded data) and elderly (that will be recorded during 12 months)
- integrated software will be provided in Matlab, in open source with access to Matlab code, that allows automatic calculation of performance scores for evaluating the spinal locomotor output based on multi-muscle activity patterns (see performance indicators for TASK 2 and 3).
- a User's manual will be provided describing the steps for installing and running the software and the mathematics behind it with references to relevant scientific literature.

PErformance indicators of spatiotemporal PATterns of the spinal muscle coordination Output during walking with an exoskeleton (PEPATO)

Table 1 - Sub-project partners

Partners No	Partner organization name	PIC number	Country
1 (Coordinator)	Fondazione Santa Lucia (FSL)	999583449	Italy
2	Università degli Studi di Roma Tor Vergata (UTOV)	999844864	Italy
3	Università degli Studi di Messina (UniMe)	999662601	Italy

In the context of the EUROBENCH goals of developing benchmarking metrics and algorithms that allow automatic calculation of performance scores based on recorded data, we propose a unified benchmarking software for evaluating the spinal locomotor output based on multi-muscle activity patterns and providing performance measures closely related to the control strategy for adaptation of human walking with an *exoskeleton*.

The proposed benchmarking software will provide performance indicators of 'muscle coordination' based on pre-processed EMG signals. The goal is to evaluate changes in the functional and structural organization of the spinal locomotor output that can be mapped into muscle synergies and spinal maps of motor pool activity during walking with an exoskeleton. The final neural locomotor output is represented by the spatiotemporal modulation of motoneuron (MN) activity, which can be assessed by decomposing the coordinated muscle activation profiles into a small set of common factors, and by mapping the activity patterns from a large number of simultaneously recorded muscles onto the anatomical rostrocaudal location of the MN pools in the spinal cord, thus looking backward from the periphery to the CNS and to the central motor programming.

The PEPATO sub-project will consist of three main tasks. The first two tasks aim at developing software for automatic generation of two main groups of outcome indicators for evaluating muscle coordination during walking in the exoskeleton (*muscle synergies* [TASK 1] and *spinal maps* [TASK 2]), while the third task [TASK 3] will provide the reference database and reference performance indicators for normal walking of neurologically intact individuals.

1. Innovation (max. 2 pages)

1.1. Benchmarking problem.

Various indicators of gait performance in the exoskeleton can be used based on kinematic/kinetic measurements, such as max speed, travelled distance, range of angular motion, joint torques, symmetry of lower limb movements, cognitive effort, etc. While such variables provide general characteristics of gait performance, however, only limited conclusions can be made about the neural control strategies based on these characteristics. Furthermore, some kinematic or kinetic parameters are a consequence of the control implemented on the exoskeleton. Therefore, standard indicators based on kinematics variables have limitations and need to be complemented by performance measures of muscle coordination and control strategy such as those proposed in our sub-project.

In recent years, many researchers put significant efforts into understanding and assessing the functional state of the spinal locomotor circuits in humans[1]. The many classes of spinal interneurons can be seen as functional units representing different levels of muscle synergies, parts of movements or even more integral motor behavior[2]. Thus, the principles that the CNS uses to govern hundreds of muscles to control whole-body movements include a modular organization of the neuronal networks[3–5]. In particular, functional and structural changes at the spinal cord level induced by exoskeleton assisted walking can be mapped into muscle synergies and spinal maps of MN activity, as a means to look backward from the periphery to the central motor programming. A knowledge about what happens at the spinal output level is critical for both gait and motor function evaluation and rehabilitation.

1.2. Outcomes proposed.

The general scheme of the EMG data processing for walking in the exoskeleton is illustrated in Figure 1.

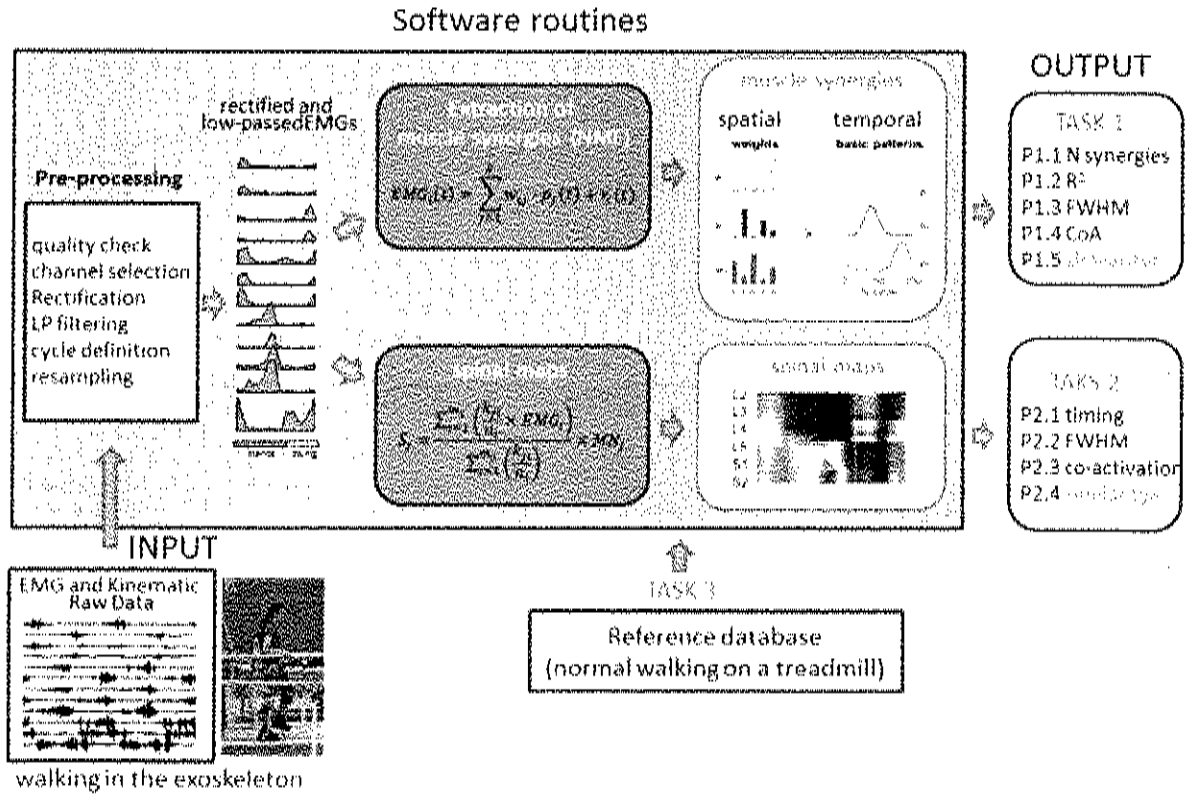


Figure 1. Input, output and main elements of the data processing chain.

PROTOCOL:

Walking on a treadmill in the exoskeleton at 3 speeds (slow, normal, fast) and recording 10 consecutive gait cycles.

INPUT:

- lower limb kinematics: ankle, hip and fifth metatarsal joint markers and knee angle in order to automatically perform a segmentation of gait cycles,

- 12 EMGs of the lower limb: gastrocnemius medialis (MG), gastrocnemius lateralis (LG), tibialis anterior (TA), peroneus longus (PL), soleus (SOL), rectus femoris (RF), vastus medialis (VM), vastus lateralis (VL), semitendinosus (ST), biceps femoris (long head, BF), tensor fascia latae (TFL) and gluteus medius (GM).

OUTPUT:

The following 2 main groups (TASK 1 and TASK 2) of performance indicators of the spinal muscle coordination output will be automatically generated using the above-mentioned input.

TASK 1 (*muscle synergies*) will evaluate both spatial (*muscle weightings*) and temporal (*basic patterns*) components of muscle modules (EMGs will be normalized to its maximum value across speed conditions):

- P1.1 the number of muscle synergies (using the 'best linear fit' method based on the percent of variance accounted for, VAF).
- P1.2 reconstruction quality (R^2) of EMG patterns from the reference muscle synergies.
- P1.3 FWHM (full width at half maximum) - duration estimate of basic patterns.
- P1.4 centre-of-activity (CoA) of basic patterns.
- P1.5 the degree of similarity with the reference group based on the best-matching scalar product of both muscle weightings and basic patterns (normalized to the Euclidean norm).

TASK 2 (*spinal maps*):

- P2.1 timing of the main loci of MN activity: timing of maximum activation of sacral (S1+S2) and upper lumbar (L3+L4) motor pools.
- P2.2 FWHM of activation of sacral and upper lumbar spinal motor pools.
- P2.3 co-activation index of sacral and upper lumbar motor pools.
- P2.4 the degree of similarity (correlation) of activation of sacral and lumbar motor pools with respect to the reference group.

TASK 3 will consist of data acquisition and analysis to obtain the reference performance indicators for comparing muscle coordination output (P1.5 and P2.4 indicators) with that of neurologically intact individuals during normal walking without an exoskeleton on a treadmill. In particular, since the differences related to the operator's age have been observed[6], we will provide a reference database for the two groups of adults, young (previously recorded data) and elderly (>65 yrs, they will be recorded over 12 months). The Ethics Committee approval will be obtained and at least 10 elderly adults will be recorded during walking using the VICON motion optoelectronic capture system for kinematics and wireless surface electromyographic (Delsys Trigno) system for recording of lower limb muscle activity.

The rationale for the proposed performance indicators (Fig. 1) is the following. First, muscle synergies during walking with the exoskeleton (performance indicators for TASK 1) demonstrate significant changes in both synergy weights and synergy temporal activations with increasing exoskeleton work and torque in unimpaired individuals[7]; the centre-of-activity also shows significant changes[8] along with a non-linear scaling and reorganization of EMG activity[8–10]. Second, specific changes in the modular organization of muscle patterns (TASK 1) occur after neurological lesions[11–13]. Patients often exhibit decreased neuromuscular complexity (P1.1-2 indicators) during gait[11,14], demonstrate impaired muscle synergies and temporal activation patterns (P1.3-5 indicators)[11–13,15] and may increase neuromuscular motor module consistency following rehabilitation[16]. Spinal functional topography (TASK 2) can be assessed by mapping multi-muscle EMG patterns onto the rostrocaudal location of the spinal MN pools and provides important information about pattern generator output during locomotion in terms of segmental control rather than in terms of individual muscle control[17]. Widening of spinal segmental output (P2.2 indicator) and alterations in the relative activation timing of sacral and lumbar motor pools (P2.1 indicator) represent important physiological markers of pathological gaits[18–21] and age-related changes[6,15,22].

1.3. Innovation of the outcomes.

Decoding the spinal locomotor output and assessment of the spatiotemporal EMG patterns, as indicators of motor function, have become an essential tool for investigating the function of pattern generation networks in the spinal cord [4,5,7,18,23–25]. Also, considerable changes in the muscle coordination output might occur with body unloading and during walking in the exoskeleton[7–10]. An abnormal spatiotemporal integration of activity in specific spinal

segments may result in a risk for failure or abnormalities in gait recovery [18,19]. There is also a differential involvement of spinal motoneuronal and interneuronal circuits in different locomotor tasks [19,26]. Therefore, this new information and corresponding benchmarking performance indicators are much needed in the context of locomotor adaptation and impairments, evaluating the effect of exercise while walking in the exoskeleton and spinal plasticity.

2. Integration in the EUROBENCH framework (max. 1 page)

2.1. The OPTION of the EUROBENCH framework that our proposal is applying for.

OPTION 1 "Developing a benchmarking solution for one specific benchmarking scenario": Walking on Treadmills (see Table 1 of the Guide for applicants). The proposed benchmarking software will provide performance indicators of 'muscle coordination' based on pre-processed EMG signals (see Table 4 with the list of relevant performance indicators in the Guide for applicants for FSTP-1 Open Call). Protocol - walking on a treadmill.

The software can be used also in other scenarios (directly for all indicators that do not depend on reference data and collecting reference data on the additional scenarios for indicators that depend on reference data).

2.2. Expected level of TRL and previous achievements.

The expected level of readiness (TRL) – 7 (integrated pilot system demonstrated): software is at planned operational system level and the final design is virtually complete after completing the FSTP-1 stage. The validation of software for an automatic generation of performance indicators during walking in the exoskeleton will be performed by the EUROBENCH partners at the FSTP-2 stage (validation of the benchmarking framework).

We have an extensive expertise in evaluating muscle modules in both normal and pathological gait and adaptation of muscle activity patterns and control of wearable exoskeletons[4,8,13,18-20,22,23,25,27,28]. A number of experiments that we previously performed, including walking in the exoskeleton and using various body weight support systems, have provided important observations and validated a number of important components of the methodology necessary to evaluate the muscle coordination output outlined in this proposal[8,15,18,23,27].

An assessment of the modular organization of the muscle patterns has also been recently developed in the context of 3 European robotics projects (in which we were PIs) related to the EUROBENCH framework:

MINDWALKER (Mind controlled orthosis and VR training environment for walk empowering), EU FP7 ICT program, grant #247959 (2010-13). The purpose of this project was to conceive a system empowering lower limbs disabled people with walking abilities that let them perform their usual daily activities in the most autonomous manner. It addressed 3 main different fields of expertise: BCI technologies, Virtual Reality and Exoskeleton Mechatronics/Control. In particular, we evaluated a non-linear reorganization of muscle coordination patterns and used a real-time EMG-based control of stepping in the exoskeleton in healthy and spinal cord injury individuals.

AMARSi (Adaptive Modular Architecture for Rich Motor Skills), EU FP7 ICT program, grant #248311 (2010-14). The AMARSi project aimed at a qualitative jump toward biological richness of robotic motor skills. A number of innovative scientific concepts and interdisciplinary research methods were implemented 1) to make robots much more versatile than today, and 2) to achieve the naturalness and compliance of their motor behaviour making them blend into the everyday routines of human society. In this project, the analysis of muscle synergies has been performed for locomotor and reaching movements, resulting in more than 15 publications on this topic.

CogIMon (Cognitive Compliant Interaction in Motion), EU H2020 large-scale robotics project, ICT-23-2014, grant #644727 (2015-19). The CogIMon project aims at a step-change in human-robot interaction toward the systemic integration of robust, dependable interaction capabilities for teams of humans and compliant robots, in particular the compliant humanoid COMAN. In this project we evaluated various human-human and human-robot interactions during walking with hand contact, including an evaluation of the neural coupling between cervical and lumbosacral pattern generation circuitries ("quadrupedal" arm-leg coordination) by analysing EMG activity, muscle coordination patterns and corresponding temporal muscle synergies and their clustering.

Previous software developments.

We will develop a standalone application in Matlab using object-oriented programming. While we do not have specific experience with producing commercial software, we have extensive experience with in-house development of complete software packages in Matlab for EMG pre-processing, muscle synergy and spinal map extraction, data visualization that have been used by many lab members. Moreover, we have collaborated in several projects where we have integrated our code in shared libraries. In addition, the University of Messina will involve an engineer with experience in software development.

3. Implementation (max. 3 pages)

3.1. Main activities.

Table 2 – Gantt distribution – Sub-project phases

Project Activities	Months																			
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
	DEVELOPMENT												Reporting		INTEGRATION					
configuration design/management and prototyping of software architecture to meet technical and operational requirements	x	x																		
reference database (TASK 3)	x	x	x	x	x	x	x	x	x	x										
pre-processing routines (Fig. 1) development	x	x	x	x	x	x														
incorporation of 'muscle synergies' routines (TASK 1)				x	x	x	x	x												
incorporation of 'spinal maps' routines (TASK 2)				x	x	x	x	x												
integration of software routines (Task 1, 2 and 3)									x	x	x	x								
preparation of documentation											x	x								
reporting													x	x						
software deliverable															x					
user experience feedback																x	x	x	x	
testing with exoskeleton data of the EUROBENCH partners, potential final adjustments of the quality check pre-processing (Fig. 1)																x	x	x	x	
final integration																			x	x

3.2. Background of the partners and their specific responsibilities.

All partners have an extensive experience in investigating the principles of spinal muscle coordination reflected in numerous publications in peer reviewed journals (including Science, Nat Neurosci, Brain, J Physiol, Neuron, J Neurosci, J Neurophysiol, Neuroscientist, etc.) and participation in collaborative European robotics projects (MINDWALKER, AMARSi, CogIMon).

As for international collaborations related to the EUROBENCH sub-project (in addition to the above-mentioned EU projects), we have recently organized two Research Topics of Frontiers related to modularity in motor control (https://www.frontiersin.org/articles/10.3389/fncom.2015.00126/full) and the biologically inspired control of wearable robots (https://www.frontiersin.org/research-topics/5601/neural-prostheses-for-locomotion).

Specific responsibilities for main activities:
TASK 1: UniMe
TASK 2: UTOV
TASK 3: FSL

While the different activities (TASK 1, TASK 2 and TASK 3) will be carried out by specific partners, all partners will closely collaborate throughout the project to provide a unified benchmarking software for evaluating the spinal locomotor output based on multi-muscle activity patterns and generating the proposed performance outcome indicators.

KEY PERSONNEL:

Partner 1 (FSL, coordinator): Yury Ivanenko, PhD
Dr. Ivanenko is the Head of the Gait Laboratory at the Department of Neuromotor Physiology at Fondazione Santa Lucia and will be responsible for the overall coordination of the sub-project. He is an expert in investigating normal and pathological human gait, its adaptation during walking in the exoskeleton or under various body weight support conditions and will also be responsible for assisting proper recordings, performing the analyses and providing the reference performance indicators (TASK 3). His role will be to start-up and supervise assembling software of the three main parts of the sub-project, preparing the reports and supporting the EUROBENCH Team during the validation phase.

Partner 2 (UTOV): Francesco Lacquaniti, Prof, MD, Specialist in Neurology
Francesco Lacquaniti is full Professor of Physiology of the Faculty of Medicine and Surgery and the Director of the Center of Space BioMedicine at the University of Rome Tor Vergata. He will be responsible for characterization of functional changes in spinal motor output and providing performance indicators for the (TASK 2). He will maintain collegial relationships with all members of the study team who will participate in developing a unified benchmarking software for evaluating the spinal locomotor output to ensure the success of the project.

Partner 3 (UniMe): Andrea d'Avella, Prof, PhD
Prof d'Avella is an expert for investigating the modular organization of the motor system, he is full professor at the University of Messina and will support data analysis and characterization of muscle synergies during gait (TASK 1). He will participate in monthly consensus conferences and contribute to the preparation of reports, final integration and supporting the EUROBENCH Team during the validation phase.

The research team will meet monthly (either by skype or using domestic travels between the partners) to keep abreast of the status of all activities, programming and data analysis.

3.3. Expected costs.

Table 3 - Effort - Personnel Expenses

Partners	Average PM Cost	PM Development (months 1-12)	PM Integration (months 15-20)	Total PM	Total Personnel Cost
FSL	2.4k€	12PM	3PM	15PM	36k€
UTOV	2.75k€	12PM	2PM	14PM	38.5k€
UniMe	2.75k€	12PM	2PM	14PM	38.5k€

Table 4 - Other direct costs

Partners	Travel	Consumables	Justification (travel and consumables expenses)
FSL	1.5k€	2.5k€	travels to the EUROBENCH consortium (validation phase), domestic travels between partners, EMG electrodes (consumables)
UTOV	1.5k€	-	travels to the EUROBENCH consortium (validation phase)
UniMe	1.5k€	-	travels to the EUROBENCH consortium (validation phase)

Table 5 - Total budget

Item	FSL	UTOV	UniMe	Total
Personnel	36k€	38.5k€	38.5k€	113k€
Consumables	2.5k€	-	-	2.5k€
Travel	1.5k€	1.5k€	1.5k€	4.5k€
Overheads (25%)	10k€	10k€	10k€	30k€
Total budget	50k€	50k€	50k€	150k€
Requested contribution*	50k€	50k€	50k€	150k€

** <=100k€/partner; <=300k€ per sub-project*

3.4. Risk analysis.

Risk	Likelihood	Severity	Contingency action
Recruitment of non-compliant elderly participants	medium	medium	We will have to recruit a larger number of participants than the target set so as to be able to screen them medically and test their ability to comply with the protocol
Low sensibility of indicators	low	medium	This drawback will be tackled applying additional analyses to identify new possible indicators from EMGs
Noise in the EMG channels	medium	low	Pre-processing will check for signal quality and will provide warning allowing to exclude up to 2 channels
Instrumentation constraints (missing channels)	medium	low	Pre-processing will check for EMG channel presence and will provide warning allowing to exclude up to 2 channels

The need to deal with elderly participants poses some delicate issues, including thorough anamnesis and physical examination to ascertain their fitness. Moreover preliminary tests will be necessary to verify the compliance of elderly participants in protocols involving treadmill walking.

Low sensitivity of indicators can be related to non-significant differences in the proposed performance indicators when comparing with the normal walking or different types of the exoskeletons. However, the previous studies on neurologically intact individuals walking in the exoskeleton demonstrated such differences[7,8], as well as the differences in the spinal locomotor output are highly expected for patients[11–13,15]. It is also worth stressing that TASK 3 will provide reference database/values for normal walking, rather than walking in an exoskeleton, for two reasons: first, in order to make no preference for one exoskeleton with respect to another one, and, second and more important, in order to evaluate the naturalness or similarities of the neural control strategy of walking in the exoskeleton with respect to normal walking since an abnormal spatiotemporal integration of spinal motor activity may result in a risk for failure or abnormalities in gait recovery.

Quality check of the EMG channels (see Fig. 1, data pre-processing) will be evaluated on the potential presence of noise, warning will be provided and up to two channels will be excluded. Our previous studies evaluated a sensitivity of the spinal locomotor output to the number of recorded muscles[22].

Instrumental constraints (missing channels) may be related to the difficulties in placing EMG electrodes on some muscles (e.g., TFL and GM) while walking in some types of the exoskeletons.

3.5. Potential gender differences.

TASK 3 will provide reference values, including potential gender differences.

4. Exploitation (max. 2 pages)

4.1. The added value of the proposed outcome to a potential user of the EUROBENCH framework.

The proposed outcomes will provide important information about changes in the neural control strategy and spinal locomotor output during walking in the exoskeleton, that will complement other performance indicators.

Even though some algorithms, such as NNMF, have been used for synergy extractions by a large number of international groups, the interpretation and comparison of results also depend on small differences in application of the same basic methodology, and variability across groups in the results obtained when performing the same analysis has been observed. The units of this subproject (FSL, UTOV and UniMe) are leaders in the investigation of the modular organization of the neural control of movement and human gait, in particular. Therefore, our expertise would allow the development of a software, with a corresponding User's manual, that will define the best practice when muscle synergies and spinal mapping are investigated. This manual will allow all users, also with no expertise in the assessment of spinal muscle coordination pattern, to test their exoskeleton according to a consisten methodology and to have a reliablen index on how the exoskeleton perturbs the operator's control strategy and affects/improves the spinal muscle coordination output in patients.

4.2. The potential of the proposed outcomes to create new market opportunities.

The proposed performance outcomes for evaluating changes in the neural control strategy based on the evaluation of muscle coordination patterns during walking in the exoskeleton will allow to perform the tests in any laboratory settings and compare the results with various exoskeletons.

In addition to medical applications for gait assistance and rehabilitation in patients, exoskeletons are being developed also for other applications for healthy subjects (military, industry, agriculture, etc.). Since, the market opportunities may be related to broad application of the exoskeletons and to people who develop exoskeletons and want to test them. Our methodology can be incorporated as an integral part of testing protocols that will allow to test lower limb exoskeletons developed for various purposes and will provide indexes, which determine the variation of the spinal locomotor output during walking in such exoskeletons with respect to reference values.

4.3. Feedback from potential users.
Evaluation of the neural control strategies using the proposed performance indicators during walking with the exoskeleton will be performed at the FSTP-2 stage and the feedback from the users of the EUROBENCH consortium will be provided.

4.4. Risk analysis on the forecasted functionality of the outcomes in the following 5 years after sub-project ending.
The benchmarking algorithms will be provided with a User's manual describing the steps for installing and running the software and the mathematics behind it with references to relevant scientific literature demonstrating its soundness. Due to potentially broad application of the proposed performance indicators, the software will be developed in open source with an access to Matlab code.

4.5. Regulation and maintenance to ensure full exploitation of the outcomes.
During both testing and validation phases, we will collect feedback from the EUROBENCH users and, if necessary, adjustments in the software will be performed.

4.6. Supporting the EUROBENCH Team during the whole duration of the EUROBENCH sub-project.
All three units (FSL, UTOV and UniMe) will maintain close contacts with the EUROBENCH Team during the whole duration of the EUROBENCH sub-project, including software testing with the EUROBENCH partners and the validation phase (FSTP-2).

5. Participants involved in the sub-project (max. 2 pages)

5.1. Short biosketch of the persons responsible for carrying out the proposed activities.

Yury Ivanenko, PhD. Research Director, leader of the Gait and Posture team. Dr. Yury Ivanenko obtained a M.S. in Biophysics at Moscow Physics and Technology Institute in 1982 and a Ph.D. in Biophysics in 1987 in the Motor Control Laboratory headed by Prof. Gurfinkel at the Institute for Information Transmission Problems (IITP), Russian Academy of Sciences (Moscow). He has been a lecturer in Biophysics and Biochemistry at the Ryazan Medical Institute (Russia, 1986-1991), a senior researcher at IITP, Moscow (1991-1995), and a senior fellow in the laboratory of Prof. Berthoz at the Collège de France in Paris (1995-98). He published more than 120 papers in peer-reviewed journals with an h-index 40 (Scopus). He is at Fondazione Santa Lucia since 1998. He has been PI or Co-PI in European robotics projects: MINDWALKER (STREP, FP7), AMARSi (IP, FP7), CogIMon (IL, H2020). He is the Board Director of the International Society for Posture and Gait Research (2014-2018), the member of the Editorial Board of the Experimental Brain Research and the Editor of two journals, Plos One and Frontiers in Physiology.

Francesco Lacquaniti, MD, Board in Neurology. Professor of Physiology at the University of Rome Tor Vergata, Director of the Centre of Space Bio-medicine at the same University. Prof. Francesco Lacquaniti received a Degree in Medicine and a Degree in Neurology from the Medical School of Turin University. After a post-doc in the Department of Physiology of the University of Minnesota in Minneapolis, he joined the Italian National Research Council in Milan where he has been Acting Director of IFCN till 1994. In 1994 he became full professor of Physiology at Cagliari University and, since 1997, he holds the same position at the University of Rome Tor Vergata. He authored or co-authored more than 200 articles in peer-reviewed journals with an h-index 59 (Scopus), and co-edited 3 books. He has been PI or Co-PI in several European projects, Human Frontiers Science Program, and PI of a large scale program funded by the Italian Space Agency (DCMC, 16 M€). In recognition of his work in the field of motor control, in 2012 Francesco Lacquaniti has become a member of the Academia Europaea (the Pan-European Academy of Sciences, Humanities and Letters with about 3,800 elected leading scholars), and awarded the Herlitzka prize. He is Section editor of Experimental Brain Research and member of the Editorial Board of Frontiers in Physiology.

Andrea d'Avella obtained a B.Sc. in Physics at Milan University, and a Ph.D. in Neuroscience at M.I.T. (2000) working on the modular organization of the motor system under the supervision of Emilio Bizzi. In 2003 he joined the Laboratory of Neuromotor Physiology at Fondazione Santa Lucia, Rome, Italy. Since 2015 he is Professor of Physiology in the Department of Biomedical, Dental Sciences and Morphofunctional Imaging at the University of Messina, Italy. His research is focused on investigating sensorimotor control of reaching, throwing and catching movements, muscle synergies in healthy subjects and after neurological lesions, motor adaptation. He has developed a decomposition algorithm to identify time-varying muscle synergies from multi-muscle EMG recordings and an approach using myoelectric control in a virtual environment ("virtual surgeries") to directly probe the synergistic organization of the motor system. His publications have had a significant impact (h-index: 29, 596 citations for the most cited publication on muscle synergies, Scopus). He has coordinated and participated in national and international research projects funded by the Human Frontiers Science Program Organization, the European Union, the Italian Ministries of Health and Research. He has been a member of the Board of Directors of the Society for the Neural Control of Movement from 2006 to 2015. He is a member of the Editorial Boards of the Journal of Motor Behavior, the Journal of Neurophysiology and Frontiers in Computational Neuroscience.

5.2. Previous collaborations with other partners of the sub-project.

Close collaboration between the sub-project partners (Dr. Ivanenko, Prof. Lacquaniti and Prof d'Avella) has been established for about 20 years, including more than 70 joint publications on various aspects of human gait control,

walking in the exoskeleton, multi-muscle coordination patterns and muscle synergies in both neurologically intact individuals and patients.

5.3. Infrastructure and technical equipment.

FSL. Fondazione Santa Lucia is the largest rehabilitation hospital in the center-south of Italy and a leading biomedical research center investigating a broad range of topics and approaches in neuroscience. The Gait and Posture Laboratory is integrated in the Department of Neuromotor Physiology within the Fondazione Santa Lucia of Rome. The Department of Neuromotor Physiology is leading in the investigation of normal and pathological gait and is composed of a multidisciplinary team of experts in advanced biotechnologies and highly-trained specialists in practicing state-of-the-art neurological rehabilitation. We have two testing rooms (~120 m^2 each) for investigating normal and pathological human gait. The Gait and Posture Laboratory is equipped with: multichannel (32ch) wireless surface electromyographic (Delsys Trigno, Zerowire) systems, instrumental treadmills, body weight supports systems including a patented exoskeleton system for simulating microgravity and investigating rhythmogenesis, VICON and SIMI motion optoelectronic capture systems, force plates (Kistler), multisensory (proprioceptive-vestibular-visual) stimulation techniques including a patented system for foot pressure stimulation during walking, in-shoe foot pressure measurements (Pedar, Novel gmbh) and foot pressure distribution measurement system (Tekscan walkway) for overground stepping, a patented system for measuring inter-personal interaction forces during walking, as well as advanced gait analysis (kinematics, kinetics, EMGs) software including real-time analyses (e.g., real-time EMG analysis for assessing motor patterns and using biofeedback from EMGs to control an exoskeleton during assisted gait in patients). Access to a wide variety of data acquisition and analysis software is available throughout the lab.

UTOV. The University of Rome Tor Vergata is a public research university located in Rome, Italy. Research is carried out in 27 departmental and inter-departmental research centers. The Centre of Space Biomedicine was created as an inter-faculty centre to coordinate all research activities related to space biomedicine, and has been directed by Prof. Lacquaniti since 1999. It currently coordinates several different units of research, encompassing motor control, reduced gravity simulators for investigating human gait, cardiovascular physiology and pathophysiology, exercise physiology, bone and muscle pathophysiology, endocrinology, biochemistry, neurology, neurophysiology, genetics, biotechnology, biomedical engineering, sensor engineering, telecommunications, satellite communications. Research is funded by the Italian Space Agency, European Space Agency, European Commission, University Ministry (PRIN, FIRB grants), Health Ministry, Telethon and other charities. CBMS has routinely been involved in space experiments, with cellular/molecular studies (in vitro or in vivo) and human studies (on astronauts). The Centre of Space Biomedicine is leading in using various body weight support systems for the investigation of human gait. The testing room (~120 m^2) for gait research of UTOV is equipped with an instrumental treadmill (WOODWAY), motion capture systems, wireless surface electromyographic systems, as well as advanced gait analysis (kinematics, kinetics, EMGs) software. Access to a wide variety of data acquisition and analysis software using various programming languages and statistical analysis packages is available (Matlab, LabView, C++, standard office-related software packages, Statistics, SPSS etc.).

UniMe. University of Messina (UM) has a large biomedical community working on the neuroanatomy and neurophysiology of the motor system, neural plasticity, neuromodulation, and neurorehabilitation. The laboratory led by Dr. d'Avella includes 1 biomedical engineer, 1 PhD, and 1 post-doc with expertise in human motor control, EMG recordings, muscle synergy analysis, and software development. The lab is equipped with a 16 channels wireless EMG recording system (Trigno, Delsys Inc.), a 6-axis force transducer (Delta, ATI-IA), a VR setup with stereoscopic display for myoelectric control and simulation of virtual surgeries, computer workstations for DAQ and data analysis, A/D DAQ cards. The lab has also access to a motion capture system (BTS) and a complete CAREN (Motek) system through a collaboration with the IRCCS Centro Neurolesi in Messina.

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Annex 3. Bank account information form

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 779963.

Dear applicant to EUROBENCH FSTP-1 Open Call, regarding the fulfilment of the Grant Agreement to become a beneficiary of our funding programme we need you to provide the following information:

ACCOUNT HOLDER INFORMATION:

Account Name Holder	Fondazione Santa Lucia
Holder's Address	Via Ardeatina, 306
Postcode	00179
Town/City	Roma
Country	Italy
Contact Person	direzione.amministrativa@hsantalucia.it
Telephone	0039 6 515011
Phone	Phone

BANK ACCOUNT INFORMATION:

Bank Name	Monte dei Paschi di Siena
Branch Address	Piazza Guglielmo Marconi, 7
Postcode	00144
Town/City	Roma
Country	Italy
IBAN number / Account number	IT 40 G 01030 05086 000001[illegible]
SWIFT code	PASCITM1A22

BANK STAMP + SIGNATURE OF BANK REPRESENTATIVE

DATE + SIGNATURE OF ACCOUNT HOLDER (**OBLIGATORY**)

FONDAZIONE SANTA LUCIA IRCCS
MARIA ADRIANA AMADIO

The bank stamp + signature of bank representative can be substituted by the attachment of a recent bank statement (less than 2 months).

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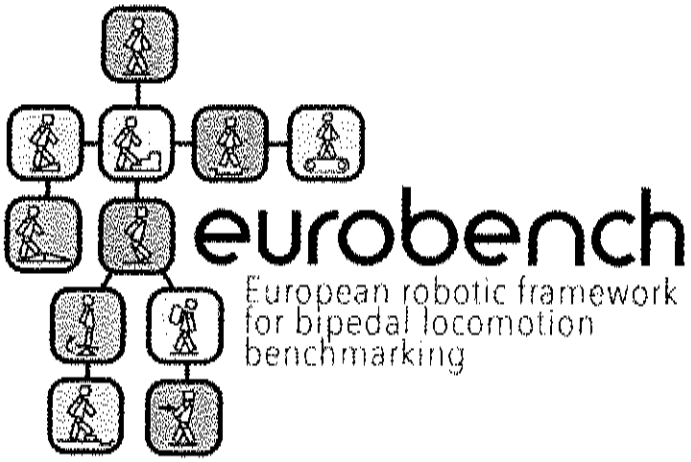
Annex 4. EUROBENCH Ethics Deliverables

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 779963.



Deliverable Title	D9.1 Ethics – Research involving human subjects
Deliverable Lead:	CSIC
Related Work Package:	WP9: Ethics
Related Task:	T9.1 Ethical plan for research involving human subjects
Author(s):	Erik Prinsen; Diego Torricelli
Dissemination Level:	Confidential
Due Submission Date:	30/06/2018
Actual Submission:	30/10/2018
Project Number	779963
Instrument:	Research and Innovation Action
Start Date of Project:	01.01.2018
Duration:	48 months

Abstract Ethical plan for research involving human subjects

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No 779963

Versioning and Contribution History

Version	Date	Modified by	Modification reason
v.01	11/07/2017	Erik Prinsen	First Version
	19/07/2018	Diego Torricelli	Revision
	02/08/2018	Erik Prinsen	Revision
v.02	03/08/2018	Diego Torricelli	Revision and second version
v.03	22/09/2018	Diego Torricelli, Sandra Correas Carrasco	Modifications in order to include this Deliverable as Annex in the Grant Agreement for Third Parties (e.g. changed the level of confidentiality to public)
v.04	24/10/2018	Diego Torricelli	Last changes after decision of not including this deliverable as Annex, due to suggestion form legal department.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No 779963

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Executive Summary

Deliverable (D) 9.1 is one of two required deliverables for work package 9 which focuses on Ethics. D9.1. focuses on ethical issues that arise from doing experiments with human beings. This deliverable is written in line with the "Horizon 2020 Programme – Guidance how to complete your ethics self-assessment" as a basis.[1] Deliverables 9.1 and 9.2 together form the ethical plan. The aim of the ethical plan is to ensure that the project complies with the ethics requirements. Both deliverables will serve as a guide for both partners of the consortium (internal partners) as well as partners that submit a proposal through one of the calls for Financial Support for Third Parties (the external partners).

[1] Available at: http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf. [Accessed July 4th 2018]

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No 779963

Description of work & main achievements

There are two main ethical issues identified at the time of submission of the EUROBENCH project: (i) ethical issues associated with performing experiments with human subjects, and (ii) ethical issues associated with the protection of personal data. This deliverable will focus on the ethical issues associated with performing experiments with human subjects while D9.2 will focus on the ethical issues associated with the protection of personal data.

The main ethical issues that were identified are displayed in Table 1.

*Issue number**	*Description*
2.1	Details on the procedures and criteria that will be used to identify/recruit research participants must be provided (inclusion/exclusion criteria).
2.9	Copies of ethics approvals for the research with humans must be submitted. Patients must be allowed to withdraw their data from the data analysis. Provide an explanation for the choice of retention period.
4.1	Copies of opinion or confirmation by the competent Institutional Data Protection Officer and/or authorization or notification by the National Data Protection Authority must be submitted.
4.3	Justification must be given in case of collection and/or processing of personal data.
4.4	Detailed information must be provided on the procedures that will be implemented for data collection, storage, protection and destruction and confirmation that they comply with national and EU legislation.
4.5	Detailed information on the informed consent procedures that will be implemented in regard to the collection, storage and protection of personal data must be submitted on request. The consortium needs to provide details on the database used of the source of the data, the procedures for data processing and data safety procedures. Eventual additional consent to the secondary use of the data needs to be acquired or permission needs to be obtained from the owners of the data set.
7.3	The applicants must ensure that appropriate health and safety procedures conforming to relevant national guidelines/legislation are followed for staff included in this project.
10.1	Details on measures to prevent misuse of research findings must be provided. Especially in relation to Third Parties participation, all ethical issues need to be cleared before validation commences.

* As stated in 779963_Annex1

In the following sections, each ethical issue will be commented upon and the measures to address each ethical issue will be stated.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No 779963

Issue 2.1: Details on the procedures and criteria that will be used to identify/recruit research participants must be provided (inclusion/exclusion criteria).

When performing experiments with human subjects, both internal and external partners will have to comply with the local, national guidelines to perform the experiments. For all partners this will mean that they will have to obtain approval from the (local) medical ethical research committee. The partners will have to write a research proposal to be able to obtain this ethical approval. In this research proposals, all partners (both internal and external) will have to provide information about the recruitment procedures and in- and exclusion criteria.

In case partners perform experiments in which there is no need for an approval from a (local) medical ethical research committee, partners will submit an ethics report to the ethics board in which details about the recruitment procedure and in- and exclusion criteria are clearly stated.

Issue 2.9: Copies of ethics approvals for the research with humans must be submitted. Patients must be allowed to withdraw their data from the data analysis. Provide an explanation for the choice of retention period.

Copies of ethics approvals of both internal and external partners will be submitted.

In case participants choose to leave a study that is performed as part of the EUROBENCH project, they will be allowed to withdraw their data from the data analysis.

The choice of long retention period is based on the fact that the processed data is available for the centralized facilities for a period that is longer than the duration of the EUROBENCH project. This is necessary for any benchmarking activities that take place after the EUROBENCH project has finished. We feel that this is necessary to allow the centralized facilities to function after the EUROBENCH project has been finalized.

Issue 4.1: Copies of opinion or confirmation by the competent Institutional Data Protection Officer and/or authorization or notification by the National Data Protection Authority must be submitted.

This information will be submitted where applicable.

Issue 4.4: Detailed information must be provided on the procedures that will be implemented for data collection, storage, protection and destruction and confirmation that they comply with national and EU legislation.

For the consortium partners or Third Parties that need to obtain approval from the (local) medical ethical research committee, the detailed information on the procedures that will be implemented for data collection, storage, protection and destruction and confirmation will be included in the research protocol that will be submitted to the ethical board during the reporting period (M13) of the sub-project. Next to this, the Grant Agreement between the EUROBENCH consortium and Third Parties

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No 779963

will include a statement that the Third Parties will have to comply with national and EU legislation. By signing the Grant Agreement, the Third Parties will confirm that they will comply to these legislations. Furthermore, Third Parties will have to release an Ethics Report (together with the Technical Report) at 12 months of the project. The Ethics Report should contain 2 sections, which correspond with (i) Human Beings, and (ii) Personal Data. These sections correspond with the EUROBENCH Deliverables 9.1 and 9.2. Finally, contractual obligations with the Third Parties will include the ethical principles of Horizon 2020, including the principles of proportionality, right to privacy, right to protection of personal data, the right to the physical and mental integrity of a person, the right to non-discrimination and the need to ensure high levels of human health protection (Article 19 Regulation (EU) 1291/2013).

All data will be encoded and only the third party data controller (which should be specified by each Third Party in the proposal), the EUROBENCH data controller (Erik Prinsen, RRD) and the project Scientific Controller (Diego Torricelli, CSIC) will have the key to re-identification. Only pseudo-anonymous data will be kept in the project database. Personal data will not be disclosed, made available to private or public agencies, traded or otherwise used for purposes, other than those specified in the proposal. No unnecessary data will be collected and measures will be taken to ensure that no data may be cross-referenced to build a more complete profile.

Issue 4.5: Detailed information on the informed consent procedures that will be implemented in regard to the collection, storage and protection of personal data must be submitted on request. The consortium needs to provide details on the database used of the source of the data, the procedures for data processing and data safety procedures. Eventual additional consent to the secondary use of the data needs to be acquired or permission needs to be obtained from the owners of the data set.

For the consortium partners or Third Parties that need to obtain approval from the (local) medical ethical research committee for the research to be conducted, the information regarding the procedures collection, storage and protection of personal data will be included in Ethics Report during the reporting period (M13) of the sub-project. In case partners do not need to obtain ethical approval, this should be also specified in the Ethics Report.

Furthermore, the EUROBENCH Consortium will provide details on the database used of the course of the data, the procedures for data processing and data safety procedures where relevant. In addition, we will also obtain additional consent to the secondary use of the data from the owners of the data set where relevant. In general, data will only be retrieved from local databases of project partners according to the ethical approval of the relevant studies and will follow the local data management and safety procedures. Additional data that is based on new hypotheses derived during the study will only be transferred once approved by the ethics committee.

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Issue 7.5: The applicants must ensure that appropriate health and safety procedures conforming to relevant national guidelines/legislation are followed for staff included in this project.

We ensure that the appropriate health and safety procedures conforming to relevant guidelines/legislation are followed for staff included in this project. This will be done according to the good clinical practice guidelines and clinical trial directive. To minimize risks, the functional capability of the technology (both Hardware and Software) will be tested several times before starting the trials, so that the participants can use a reliable and stable version of the system at any stage. For all systems that are not CE-marked, we will provide an Investigational Medical Device Dossier (IMDD) to be submitted for approval by corresponding local Medical Ethical Research Committee. This dossier will specify the device description and specifications, previous generations, labels and instructions for use, quality system for design and manufacturing of the device, manufacturing process, risk management report, product verification and validation.

Issue 10.1: Details on measures to prevent misuse of research findings must be provided. Especially in relation to Third Parties participation, all ethical issues need to be cleared before validation commences.

To be able to determine whether there is potential misuse of research finding, one is advised to answer the following questions[2]:

1. Could the materials/methods/technologies and knowledge concerned harm people, animals or the environment if modified or enhanced?
2. What would happen if they ended up in the wrong hands?
3. Could they serve any purposes other than the intended ones? If so, would that be unethical?

Materials/methods/technologies and knowledge that is concerned could potentially harm people when modified or enhanced. To minimize these risks, the functional capability of the technology (both Hardware and Software) will be tested several times before starting the trials, so that the participants can use a reliable and stable version of the system at any stage. Our development team will take all the necessary steps on testing and validation and these steps will include, for example, the technology being tried by relevant healthy individuals as part of pre-pilot testing exercises. There will also be a technical support in every country, which can be called and will solve problems as fast as possible.

The main problem with materials/methods/technologies ending up in the wrong hands is the case when they end up in the hands of a competitor of the technology that is being developed or evaluated. To minimize the risk of this, confidentiality agreements will be signed between internal partners and/or third parties where deemed relevant. Furthermore, data will be stored on secured servers that can only be accessed by authorized personnel.

We feel that the materials/methods/technologies cannot serve any purposes other than the intended ones. Therefore, no measures are taken to prevent misuse of research findings.

[2] ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf

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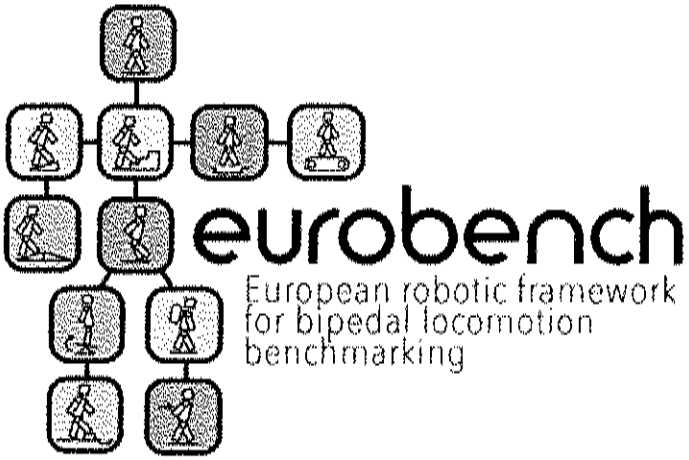
Ethics Board

The project will create an ethics board that will ensure that the internal partners as well as the third parties follows the stipulations that are laid out in this deliverable and D9.2 (ethics human data).

Deviations from the workplan

There are no deviations from the workplan.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No 779963



Deliverable Title	D9.2 Ethics – Protection of personal data
Deliverable Lead:	CSIC
Related Work Package:	WP9: Ethics
Related Task:	T9.2 Ethical plan for protection of personal data
Author(s):	Erik Prinsen; Diego Torricelli
Dissemination Level:	Confidential
Due Submission Date:	30/06/2018
Actual Submission:	30/10/2018
Project Number	779963
Instrument:	Research and Innovation Action
Start Date of Project:	01.01.2018
Duration:	48 months
Abstract	Ethical plan for research involving human subjects

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No 779963

Versioning and Contribution History

Version	Date	Modified by	Modification reason
v.01	11/07/2017	Erik Prinsen	First Version
	19/07/2018	Diego Torricelli	Revision
	02/08/2017	Erik Prinsen	Added contents from GA Part B
v.02	03/08/2018	Diego Torricelli	Revision and second version
v.03	22/09/2018	Diego Torricelli, Sandra Correas Carrasco	Modifications in order to include this Deliverable as Annex in the Grant Agreement for Third Parties (e.g. changed the level of confidentiality to public)
v.04	24/10/2018	Diego Torricelli	Last changes after decision of not including this deliverable as Annex, due to suggestion form legal department.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No 779963

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Executive Summary

Deliverable (D) 9.2 is one of two required deliverables for work package 9 which focuses on Ethics. D9.2. focuses on ethical issues associated with the protection of personal data. This deliverable is written in line with the "Horizon 2020 Programme – Guidance how to complete your ethics self-assessment" as a basis.[1] Deliverables 9.1 and 9.2 together form the ethical plan. The aim the ethical plan is to ensure that the project complies with the ethics requirements. Both deliverables will serve as a guide for both partners of the consortium (internal partners) as well as partners that submit a proposal through one of the calls for Financial Support for Third Parties (the external partners).

[1] Available at: http://ec.europa.eu/research/participants/data/ref/h2020/grants_manual/hi/ethics/h2020_hi_ethics-self-assess_en.pdf. [Accessed July 4th 2018]

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No 779963

Description of work & main achievements

There are two main ethical issues identified at the time of submission of the EUROBENCH project: (i) ethical issues associated with performing experiments with human subjects, and (ii) ethical issues associated with the protection of personal data.

This deliverable (D9.2) focuses on the ethical issues associated with the protection of personal data.

The main ethical issues that were identified are displayed in Table 1.

*Issue number**	*Description*
2.6	The applicant must clarify whether vulnerable individuals/groups will be involved. Details must be provided about the measures take to prevent the risk of enhancing vulnerability/stigmatisation of individuals/groups.
4.4	Detailed information must be provided on the procedures that will be implemented for data collection, storage, protection and destruction and confirmation that they comply with national and EU legislation.
4.5	Detailed information on the informed consent procedures that will be implemented in regard to the collection, storage and protection of personal data must be submitted on request.

* As stated in 779963_Annex1

In the following sections, each ethical issue will be commented upon and the measures to address each ethical issue will be stated.

Issue 2.6: The applicant must clarify whether vulnerable individuals/groups will be involved. Details must be provided about the measures take to prevent the risk of enhancing vulnerability/stigmatisation of individuals/groups.

No vulnerable groups/individuals will be involved[2]. All participants that will participate as part of the experiments of the EUROBENCH project will be capable of providing informed consent themselves. We will not include children. In addition, we will not include individuals that have cognitive impairments of such origin that someone other than the participant her-/himself will have to provide informed consent for participation.

Next to this, we believe that there is no risk for enhancing vulnerability/stigmatisation of enhancing vulnerability/stigmatisation of individuals/groups.

[2] The definition of vulnerable group is based on the following source: L. Peroni and A. Timmer, "Vulnerable groups: The promise of an emerging concept in European Human Rights Convention law," Int. J. Const. Law, 2013.

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Issue 4.4: Detailed information must be provided on the procedures that will be implemented for data collection, storage, protection and destruction and confirmation that they comply with national and EU legislation.

For the partners that need to obtain approval from the (local) medical ethical research committee, the detailed information on the procedures that will be implemented for data collection, storage, protection and destruction and confirmation will be included in the research protocol that will be submitted to the ethical board during the reporting period (M13) of the sub-project. Next to this, the Grant Agreement between the EUROBENCH consortium and Third Parties will include a statement that the Third Parties will have to comply with national and EU legislation. By signing the Grant Agreement, the Third Parties will confirm that they will comply to these legislations. Furthermore, Third Parties will have to release an Ethics Report (together with the Technical Report) at 12 months of the project. The Ethics Report should contain 2 sections, which correspond with (i) Human Beings, and (ii) Personal Data. These sections correspond with Deliverables 9.1 and 9.2.

All data will be encoded and only the Third Party data controller (which should be assigned by each Third Party before the execution of any data collection, and reported in the Ethics Report), the EUROBENCH data controller (Erik Prinsen, RRD) and the project Scientific Controller (Diego Torricelli, CSIC) will have the key to re-identification. Only pseudo-anonymous data will be kept in the project database. Personal data will not be disclosed, made available to private or public agencies, traded or otherwise used for purposes, other than those specified in the proposal. No unnecessary data will be collected and measures will be taken to ensure that no data may be cross-referenced to build a more complete profile.

Issue 4.5: Detailed information on the informed consent procedures that will be implemented in regard to the collection, storage and protection of personal data must be submitted on request. The consortium needs to provide details on the database used of the source of the data, the procedures for data processing and data safety procedures. Eventual additional consent to the secondary use of the data needs to be acquired or permission needs to be obtained from the owners of the data set.

For the consortium partners or Third Parties that need to obtain approval from the (local) medical ethical research committee for the research to be conducted, the information regarding the procedures collection, storage and protection of personal data should be submitted as part of the Ethics Report (in the case of Third Parties, to be submitted to the consortium at month 13 of the sub-project).

Furthermore, the EUROBENCH Consortium will provide details on the database used of the course of the data, the procedures for data processing and data safety procedures where relevant. In addition, we will also obtain additional consent to the secondary use of the data from the owners of the data set where relevant. In general, data will only be retrieved from local databases of project partners according to the ethical approval of the relevant studies and will follow the local data management and safety procedures. Additional data that is based on new hypotheses derived during the study will only be transferred once approved by the ethics committee.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No 779963

Ethics Board

The project will create an ethics board that will ensure that the internal partners as well as the Third Parties follows the stipulations that are laid out in this deliverable and D9.2 (ethics human data).

Deviations from the workplan

There are no deviations from the workplan.

This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No 779963