



Technology Demonstrator Call 2019 under the DIH-HERO Innovation Action

Applicant guide

Please note that this applicant guide may be used for information purposes only. The information given in this guide may be subject to changes. This document is subject to revision. Please visit www.dih-hero.eu to ensure that you have the latest version. Proposals will have to be submitted using the online application form provided at www.dih-hero.eu

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1. About DIH-HERO

The European healthcare market is expected to grow from about \$2080 billion in 2016 to about \$2125 billion in 2020. Europe has numerous global healthcare equipment suppliers and the sector has a massive potential for robotic applications. Technologically Europe has a lot to offer, but the wide-scale adoption of robotic technology in the healthcare sector is at this moment limited, yet promising. Although, it can be observed that the entrance threshold declines robot technology is getting cheaper, and the number of robotics engineers who graduate from universities doubles every three years, it is also true that many innovations often do not reach the market.

The major objective of the DIH-HERO project (Digital Innovation Hubs in Healthcare Robotics) is to establish a broad-based pan-European network of Digital Innovation Hubs specialized in Healthcare Robotics. The network will focus on providing services which connect business and healthcare stakeholders in developing innovative products and services for the healthcare market. It will establish channels between healthcare and technology providers that reduce barriers to adoption and create strong mutual understanding between robotics technology innovators and healthcare professionals. Each hub partner is aimed to deliver both technical and medical expertise to the consortium through their pre-existing operational relationships with hospitals and healthcare facilities. This initiative unites expertise in business development, access to finance and innovation to robotics technology and healthcare expertise in a network of hubs that will connect and stimulate robotics innovation in all aspects of healthcare. DIH-HERO is built on concrete plans to sustain the network beyond the time span of the project and to provide a long-term network for innovators in healthcare. The network of Digital Innovation Hubs created and supported by DIH-HERO will ensure that robotics innovation in healthcare is accelerated, that SME can develop global reach and that the advantages of robotics-based healthcare can be propagated across Europe.

The current applicant guide is meant to provide detailed information concerning the DIH-HERO Technology Demonstrator Call (TD) 2019. This call is planned to be open for proposal submission from the 1st of October 2019 until the 31st of December 2019, 23:59 CET.

2. General Description of the Technology Demonstrator Call (TD) call

2.1 Purpose of TD call

The Technology Demonstrator call is meant to accelerate the development of Healthcare Robotics by demonstrating the feasibility of new, innovative and enhanced robotic solutions in healthcare application domains. By offering financial support of max. €100.000 per Technology Demonstrator, the DIH-HERO network is aimed to improve and broaden the uptake of robotics solutions and increase future investments in robotics in healthcare. DIH-HERO strives for a minimum of at least 2 awarded TD projects per application domain (see page 4 for the application domains) per call.

2.2 Who can apply?

Only legal entities being **SMEs or “slightly larger companies”** and operating in the healthcare and/ or robotics sector within the [EU and its associated countries \(EEA\)](#) are eligible for FSTP funding. This means that only **SMEs** that fulfill the criteria of the general SME definition stated in article 2 of the annex to Recommendation 2003/361 EC are allowed to apply for the TDs. These criteria can be summarized as follows:

“To count as an SME, your organization must be engaged in an economic activity and must have:

- fewer than 250 employees
- and
- an annual turnover of no more than €50 million and/or a balance sheet of no more than €43 million

Furthermore, the term **“slightly larger companies”** can be defined as follows:

“To count as a “slightly larger company”, your organisation must be engaged in an economic activity and must have:

- fewer than 500 employees
and
- an annual turnover of no more than €100 million.

Whether you count as an SME or slightly larger company may depend on how you count your workforce, turnover or balance sheet. Please note that you must take into account any relationships you have with other enterprises. Depending on the category in which your enterprise fits, you may then need to add some, or all of the data. For more details: Regulation 2003/361/EC – see "Annex" for a full definition of an SME.” (European Commission, 2019)

2.3 Type of activity qualifying for financial support and major application domains

The major aim of the Technology Demonstrator project is to demonstrate a working solution addressing a specific clinical healthcare problem in one of the following major application domains in Healthcare robotics:

- Diagnostic Robotics
- Interventional Robotics
- Rehabilitation Robotics
- Robotics supporting patients
- Robotics supporting healthcare professionals

In addition, proposals must clearly state the clinical relevance of and demand for this solution, have a clear linkage to the end-user and should make use of the expertise / services of the DIH-HERO network.

2.4 How to build the project consortium

The project consortium must at least consist of 2 parties from 2 different EU/EEA countries:

Either

2 SMEs or slightly larger companies from 2 different EU/EEA countries

Or

1 SME or slightly larger company and 1 end-user (e.g. a hospital) from 2 different EU/EEA countries

Please note that when a consortium consists of other parties than SMEs only the SMEs will receive funding.

2.5 Conflict of interest

DIH-HERO core partners cannot receive any financial support from the FSTP calls provided under the current innovation action. Applicants cannot include DIH-HERO core partners in their consortia. DIH-HERO core partners cannot receive any financial support from the FSTP calls.

2.6 Duration, start and end date of the TD

The maximum Technology Demonstrator duration is 9 months. The TD should start at the first day of the following month after entry into force of the TD funding agreement.

3. Eligibility

3.1 General eligibility criteria

All of the following eligibility criteria will have to be fulfilled for a TD project to be funded:

1. Third parties receiving financial support must be a legal entity, being an SME or slightly bigger companies from EU / EEA countries;
2. At least two parties must be involved (either two SME's or slightly larger companies from two different EU/EEA countries, or one SME or slightly larger company and one end user (e.g. hospital) two from 2 different EU/EEA countries);
3. The proposal must clearly state the relevant clinical demand for the intended robotic solution including a clear linkage to end-users;
4. The proposal must address expertise and/or services of the DIH-HERO network;
5. The proposal must fit to the call text;
6. A third party may not receive more than 300k FSTP for the entire action duration;
7. Proposal must be written in English and submitted via the portal before the deadline;
8. There must be no conflicts of interests with consortium partners.
9. Third parties receiving financial support should be financially healthy (they have to sign a declaration of no financial problems).

3.2 Eligible cost categories

Costs incurred in the following cost categories will be regarded as being eligible for reimbursement according to EC guidelines:

- Direct personnel costs;
- Other services and goods
 - Direct travel and subsistence costs;
 - Equipment
 - Consumables
- Direct costs of subcontracting;

4. Payment terms and reimbursement rates

The payment structure will be for the Technology Demonstrator projects is defined as follows:

- 70% of the payment will be released at contract signature and
- 30% after the final report has been submitted and approved.

The reimbursement rate for the eligible costs incurred is 100%.

3. The application process

3.1 Proposal preparation

3.1.1 Proposal language

Any proposal for the technology demonstrator call under the innovation action DIH-HERO will have to be prepared and submitted in English language. Proposals prepared in another language will not be taken into consideration.

3.1.2 Proposal contents

Any Technology Demonstrator proposal should at least contain the following information (see also Annex I TD proposal template):

1. Administrative Data

- Contact Data will be collected from all the Technology Demonstrator consortium partners
- TD Key Data such as:
 - Full title of the TD;
 - short name of the TD;
 - Brief description (Short Abstract of approx. 6 lines)
 - Duration (max. 9 months)
 - Statement on legal agreement describing the rights and duties of each party to be negotiated among TD consortium partners), and
 - Statement on the TD announcement for publication.

2. Description of the TD

The description should at least contain the following parts, which also serve as the primary proposal evaluation criteria:

Excellence (weight 30%) (max. 2 Pages)

- Ambition of the proposed experiment
- Innovative nature of the technologies, products or services offered
- Soundness of the technical approach
- Novel use of value chains inside and outside healthcare

Impact (weight 40%) (max. 2 Pages)

- Market opportunity and market readiness level
- Commercial Strategy and Scalability (generation of new business)
- Healthcare Impact (value added, service quality and outcome improvement)
- Economic impact (e.g. cost saving and job transformation, skill enhancement etc.)
- Development of business model and funding plan
- Contribution to and adoption of standards
- Contribution to EU wide adoption of Robotics in Healthcare

Implementation (weight 30%) (max. 2 Pages)

- End User involvement and alignment with proposal

- Team capabilities and management capacity of action
- Resource utilisation and efficiency

3. TD Budget estimation

4. Questions for statistical purposes

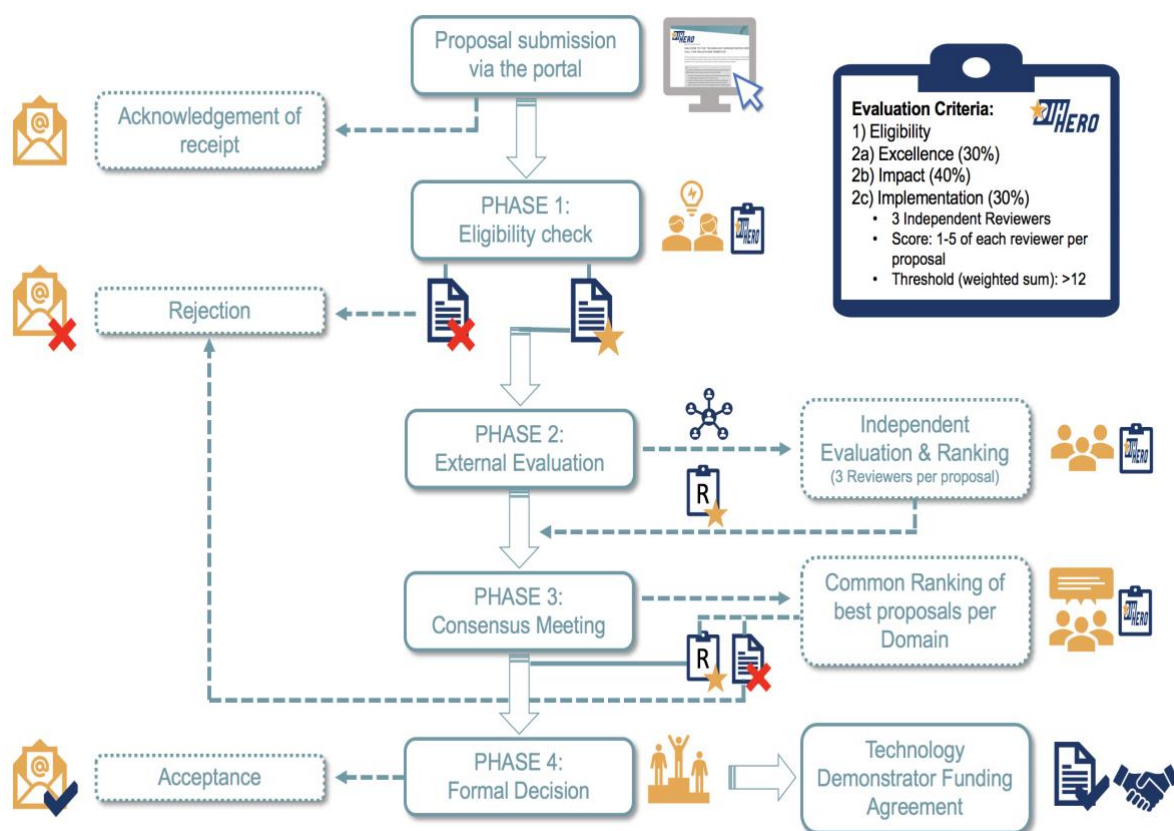
3.2 Proposal submission

Eligible proposals are to be submitted via the DIH-HERO online portal <http://dih-hero.eu>. Generally, proposals submitted by any other means will not be taken into consideration. However, to ensure the accessibility of the submission form to anyone it is in exceptional cases also possible to download the submission form and send it to dih-healthcare@utwente.nl. Once the proposal has been submitted it can be edited or updated by logging in to the portal. A legal entity is only allowed to submit one proposal per call. In case more than one proposal is submitted by one entity, only the first proposal submitted will be taken into consideration. The submission platform will allow the applicant to download the complete proposal for reference.

Shortly after proposal submission, an automatically generated acknowledgement of receipt will be sent to the applicant's email address. Please note that this acknowledgement of receipt does not imply that the proposal has been accepted as eligible for evaluation. A survey may be conducted during the course of the project among all applicants.

3.3 Proposal evaluation and selection

3.3.1. The different reviewing and evaluation phases



- Phase 1: Eligibility check (approx. 2 weeks)

Basic eligibility check according to the eligibility criteria stated in section 3.

- Phase 2: External Review (approx. 1 month)

The FSTP team will engage experts for evaluating the proposals, and ensure that they are independent from the organisations involved in the DIH-HERO consortium and from any proposer. Each proposal will be reviewed by three independent reviewers. Each evaluator will rank the application by a score from 0 to 5 for each criterion, administered in an Individual Evaluation Report. The final score will be calculated as the sum of the individual assessments provided by the Evaluators. The default threshold for individual criteria (Excellence, Impact and Implementation) is 3. The default overall threshold (the weighted sum of the three individual scores) is 12.

- Phase 3: Consensus (approx. 2 weeks)

All Individual Evaluation Reports will be combined and discussed on a consensus meeting where all reviewers will be present. The outcome of the evaluation will be a ranked list of all proposals, based on the scores obtained by each proposal and the final discussions of the reviewers at the consensus meeting.

- Phase 4: Ranking (approx. 1 week)

According to available and requested budget proposal will be selected for awarding. First the two highest ranked proposals per robotics in healthcare application domain (as defined in the call criteria) are selected. Second all proposals are selected based on their ranking on the entire ranked list of proposals.

4. Ethics

The Research activities in Horizon 2020, and hence in DIH-HERO, shall respect fundamental ethical principles, particularly those outlined in “The European Code of Conduct for Research Integrity”. Personal data must be protected and processed in compliance with the applicable EU and national law on data protection (including authorisations or notification requirements), under Regulation No 45/2001 for the purposes of implementing, managing and monitoring the TD or protecting the financial interests of the EU (including checks, reviews, audits and investigations). This regulation is from the European Parliament and the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.01.2001, p. 1). Ethical issues might refer to research with respect to e.g. humans, protection and processing of personal data, animals, environmental protection, and safety, etc. If any ethical issues apply to the TD prior to its starting date, they must be addressed in the TD proposal. On request, additional information on ethical aspects will be provided by the applicants, allowing DIH-HERO to perform an ethics review. If any ethical issues arise during the TD run time, they must be immediately communicated to DIH-HERO by sending an email to: dih-healthcare@utwente.nl A checklist summarizes any potential ethical issues that a TD proposal could raise and gives guidance on how the issues should be briefly described and how measures should be implemented.

5.. Contracting

Once an applicant has been awarded funding for a technology demonstrator, a funding agreement will be signed between the awarded SME and the coordinator of the DIH-HERO innovation action, representing the DIH-HERO consortium members.

6. TD Monitoring and Reporting

The reporting will take place via the DIH-HERO portal. The midterm and final reports will be produced by third parties will be evaluated by a review team consisting of the assigned Innovation Coach plus 2 Innovation Coaches of other projects.

7. Possibility for participation in the different DIH-HERO open calls

SMEs and slightly larger companies also have the possibility to participate in different DIH-HERO open calls to apply for financial support for technology demonstrators as well as technology transfer experiments during the course of the DIH-HERO innovation action. However, the maximum possible financial support for any SME or slightly larger company is limited to €300,000. In addition, the applicant is not allowed to hand-in multiple proposals within the different Digital Innovation Hubs Projects Trinity, DIH2 and RIMA. Proposals may be cross-checked in this regard.

8. Support to applicants

For further information and questions regarding the 1st the open call for travel vouchers under the DIH-HERO innovation action, the applicable eligibility criteria and the evaluation or in case of any technical problems concerning the submission of the proposal via the online portal, please contact the project coordinator by sending an email to: dih-healthcare@utwente

When contacting the Helpdesk, please include the following:

- a. Your username, telephone number and email address;
- b. Detailed description of the specific problem
- c. If possible, screenshots of the problem.



Technology Demonstrator Call 2019 under the DIH-HERO innovation action

Please note that this proposal template may be used for information purposes only. The information given may be subject to changes. Proposals will have to be submitted using the online application form provided at www.dih-hero.eu

Appendix 1: Proposal template

Technology Demonstrator Open Call 2019 Submission Form

WELCOME TO THE TECHNOLOGY DEMONSTRATOR OPEN CALL 2019 FOR HEALTHCARE ROBOTICS!

One essential aspect for the development a pan-European network of Digital Innovation Hubs (DIHs) in Healthcare Robotics are the Technology Demonstrator Projects, aimed to accelerate the development of Healthcare Robotics by demonstrating the feasibility of new, innovative and enhanced robotic solutions in healthcare application domains.

1. Summary of eligibility criteria

To be eligible for taking part in the Technology Demonstrator Call within the DIH-HERO project all of the following criteria will have to be fulfilled:

- a. Third parties receiving financial support must be a legal entity, being an SME or slightly bigger companies from EU / EEA countries;
- b. At least two parties have to be involved (either two SME's or slightly larger companies from two different EU/EEA countries, or one SME or slightly larger company and one end user (e.g. hospital) two from 2 different EU/EEA countries;
- c. The proposal must clearly state the relevant clinical demand for the intended robotic solution including a clear linkage to end-users;
- d. The proposal must address expertise and/or services of the DIH-HERO network;
- e. The proposal must fit to the call text;
- f. A third party may not receive more than 300k FSTP for the entire action duration;
- g. Proposal must be written in English and submitted via the portal before the deadline;
- h. There must be no conflicts of interests with consortium partners.
- i. Third parties receiving financial support must be financially healthy (they have to sign a declaration of no financial problems).

If you are sure to fulfil all the criteria given above, please continue with the next section.

2. Summary of required information

The following information will be required to complete the submission form:

- Administrative Data Basic contact data of each TD project partner (e.g. full name of legal entity, type of company, company registration number, place of registration, address, company website, as well as the name, telephone number and e-mail address of the main contact person)
- Key Data of the TD Project (e.g. full title of the TD; short name of the TD; brief description (short abstract of approx. 6 lines); project duration; Statement on legal agreement describing the rights and duties of each party to be negotiated among TD consortium partners), and statement on the TD announcement for publication.
- TD Project Proposal uploaded as pdf format.
- Signed declaration of honor saved in pdf format.
- Signed declaration of informed consent for data processing saved in pdf format.
- Questions for statistical purposes.

1. Administrative Information

Please provide the general information about the project partners.

Fields marked with a () are required.*

Partner 1 (TD project coordinator)

Full name of legal entity*

Type of company*

Please state the legal form of the entity.

- We confirm that we fulfill all criteria qualifying as a SME according to the EC definition (please upload the results of the SME self-assessment test)
- We confirm that we fulfill all criteria qualifying as a slightly larger company according to the EC definition.

Company registration number*

This is the official registration number at which the company is registered in the country where it is located (e.g. chamber of commerce).

Place of registration*

PIC code

This is a 9-digit number serving as a unique identifier for organisations (legal entities) participating in EU funding programmes. If you have not participated in an EU funding programme before, please move to the next question.

Address*

Street Address*

ZIP/Postal Code*

City*

Country*

Company website

Main contact person

Please provide the contact information of the person who administers the entire process. An account will be created using the provided email address.

Fields marked with a () are required.*

Name*

First*

Last*

Telephone*

Email address*

We advise you to use a functional email address that is not tied to a single person.

Partner 2:

Full name of legal entity*

Type of company*

Please state the legal form of the entity.

- We confirm that we fulfill all criteria qualifying as a SME according to the EC definition (please upload the results of the SME self-assessment test)
- We confirm that we fulfill all criteria qualifying as a slightly larger company according to the EC definition.
- We confirm that we fulfill all criteria qualifying as an end-user according to the definition.

Company registration number*

This is the official registration number at which the company is registered in the country where it is located (e.g. chamber of commerce).

Place of registration*

PIC code

This is a 9-digit number serving as a unique identifier for organisations (legal entities) participating in EU funding programmes. If you have not participated in an EU funding programme before, please move to the next question.

Address*

Street Address*

ZIP/Postal Code*

City*

Country*

Company website

Partner 3:

Full name of legal entity

Type of company

Please state the legal form of the entity.

Company registration number

This is the official registration number at which the company is registered in the country where it is located (e.g. chamber of commerce).

Place of registration

PIC code

This is a 9-digit number serving as a unique identifier for organisations (legal entities) participating in EU funding programmes. If you have not participated in an EU funding programme before, please move to the next question.

Address

Street Address

ZIP/Postal Code

City

Country

Company website

Partner 4:

Full name of legal entity

Type of company

Please state the legal form of the entity.

Company registration number

This is the official registration number at which the company is registered in the country where it is located (e.g. chamber of commerce).

Place of registration

PIC code

This is a 9-digit number serving as a unique identifier for organisations (legal entities) participating in EU funding programmes. If you have not participated in an EU funding programme before, please move to the next question.

Address

Street Address

ZIP/Postal Code

City

Country

Company website

Partner 5:

Full name of legal entity

Type of company

Please state the legal form of the entity.

Company registration number

This is the official registration number at which the company is registered in the country where it is located (e.g. chamber of commerce).

Place of registration

PIC code

This is a 9-digit number serving as a unique identifier for organisations (legal entities) participating in EU funding programmes. If you have not participated in an EU funding programme before, please move to the next question.

Address

Street Address

ZIP/Postal Code

City

Country

Company website

TD Project - Key Data

Please provide the following key information about your TD project.

Fields marked with a () are required.*

Full title of the TD project

Short name of the TD project

Brief description of the TD project (Abstract of approx. 6 lines)

Please give a short description of your TD project including the purpose and the aim of the project

Duration of the TD project

Statement concerning legal agreement to be negotiated among the TD project partners*

- The TD project partners will negotiate and sign an agreement describing all rights and duties of each party involved. If the TD will be financially supported, we will send it by email no later than one month after the TD start to: dih-healthcare@utwente.nl

- The TD project partners have already signed an agreement describing all rights and duties of each party involved. If the TD will be financially supported, we will send it by email no later than one month after the TD start to: dih-healthcare@utwente.nl

Announcement of the TD*

- The TD key data can be published after approval of the TD financial support.
- The TD brief description can be published at the end of the TD and after the delivery of the public abstract (for details see the TD funding agreement). Note: Other TD key data have to be published, as required by the EC.

5. Files

Please attach the detailed proposal, the result of the SME-Self-assessment questionnaire, the signed declaration of honour and the signed informed consent form for data processing and storage as pdf to the email you send.

- TD Proposal upload
- SME-Self assessment questionnaire (as attachment to the email)
- Signed declaration of honour
- Signed informed consent form for data processing

6. Questions for Statistical Purposes

7. Consent*

I agree to the [privacy statement](#) of DIH-HERO.

Appendix 2: DIH-HERO Consortium Members

1. Universiteit Twente (UT)
2. Universitätsklinikum Aachen (Aachen)
3. Fraunhofer Gesellschaft zur Förderung der angewandten Forschung e.V. (FhG-IPA)
4. Commissariat à l'énergie atomique et aux énergies alternatives (CEA)
5. Scuola Superiore di Studi Universitari e Perfezionamento Sant'Anna (SSSA)
6. Politecnico di Milano (POLIMI)
7. Fondazione Istituto Italiano di Tecnologia (IIT)
8. Fundacion Tecnalia Research & Innovation (TECNALIA)
9. Deutsches Zentrum für Luft- und Raumfahrt e.V. (DLR)
10. Imperial College of Science Technology and Medicine (Imperial)
11. Teknologisk Institut (DTI)
12. Interuniversitair Micro-electronica Centrum (IMEC)
13. Elektrotehnički fakultet, Univerzitet u Beogradu (ETF)
14. Eidgenössische Technische Hochschule Zürich (ETH Zürich)
15. Fundacja Rozwoju Kardiochirurgii im. prof. Zbigniewa Religi (FRK)

Appendix 3: TRL Levels

TRL1	Scientific literature reviews and initial Market Surveys are initiated and assessed. Potential scientific application to defined problems is articulated.
TRL2	Hypothesis(es) is generated. Research plans and/or protocols are developed, peer reviewed, and approved.
TRL3	Initial proof-of-concept for device candidates is demonstrated in a limited number of laboratory models (may include animal studies).
TRL4	Proof-of-concept and safety of candidate devices/systems demonstrated in defined laboratory/animal models.
TRL5	IDE review by CDRH results in determination that the investigation may begin. For a 510(k), preliminary findings suggest the device will be substantially equivalent to a predicate device.
TRL6	Data from the initial clinical investigation demonstrate that the Class III device meets safety requirements and supports proceeding to clinical safety and effectiveness trials. For a 510(k), information and data demonstrate substantial equivalency to predicate device and support production of the final prototype and final testing in an operational environment.
TRL7	Clinical endpoints and test plans agreed to by CDRH. For a 510(k), information and data demonstrate substantial equivalency to predicate device and use in an operational environment, and support the preparation of 510(k).
TRL8	Approval of the PMA [or, as applicable, 510(k)] for device by the CDRH.
TRL9	None – continue surveillance

Appendix 4: Declaration of honour

Declaration of honour

The undersigned, hereby declares and confirms the following:

- We have read, understood and will comply with the open call details and requirements.
- All information provided in the DIH-HERO technology demonstrator proposal submitted by our entity is correct and complete.
- The information on the organisation's legal status submitted is correct (e.g. type of legal entity, in particular with respect to the SME and slightly larger company status).
- We are aware of the fact that we can withdraw the DIH-HERO technology demonstrator proposal at any time, and we will not be penalised for withdrawing.
- Our company is not in any situation, which would exclude us from receiving financial support for third parties.
- Our company is not under liquidation or in financial difficulty.
- Our company is not subject to a conflict of interest in connection with the cascade funding.
- We will inform the DIH-HERO consortium, without delay, of any situation considered a conflict of interest or which could raise a conflict of interest.
- We will process any personal data in compliance with the applicable EU and national law on data protection.

Name entity representative

Date

Signature

Appendix 5: Declaration of informed consent for data processing

Declaration of informed consent for data processing and storage

The undersigned, hereby declares and confirms the following:

- I have read and understood the open call details and requirements.
- I am aware of the fact that the contact and company details provided in the proposal submission form will be processed by the DIH-HERO consortium for the purposes of the open call for technology demonstrators under the DIH-HERO innovation action.
- I am aware of the fact that the contact and company details provided will be stored by the DIH-HERO consortium for reporting purposes to the European Commission.
- I am aware of the fact the any personal data obtained in the framework of the DIH-HERO travel voucher call will be processed in compliance with the Regulation (EU) 2016/679 General Data Protection Regulation.

Name entity representative

Date

Signature