

# COVID-19 Response Open Call under the DIH-HERO Innovation Action

# Applicant guide

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Proposals will have to be submitted using the online application form provided at <u>www.dih-hero.eu</u>

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# 1. About DIH-HERO

Europe has numerous global healthcare equipment suppliers, and the sector has 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 focuses on providing services that connect business and healthcare stakeholders in developing innovative products and services for the healthcare market. It establishes channels between healthcare and technology providers that reduce barriers to adoption and create a strong mutual understanding between robotics technology innovators and healthcare professionals. Each hub partner is aimed to deliver both technical and medical expertise to the network 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 ofrobotics-based healthcare can be propagated across Europe.

The current applicant guide is meant to provide detailed information concerning the DIH-HERO COVID-19 Response Open Call (CR) 2021. This call is planned to be open for proposal submission from the 15th of October 2021 until the 15th of January 2022, 23:59 CET.

## 2. General Description of the COVID-19 Response call

## 2.1 Purpose of COVID-19 Response call

The COVID-19 Response call is meant to accelerate the embedding of robotic applications in healthcare-related settings and to enable the smooth deployment of new, effective robotic-based solutions. By funding up to 8 projects with a max. amount of €250.000 per COVID-19 Response project, the DIH-HERO network is aimed to stimulate technology pull from the healthcare-related settings by removing barriers and developing a clinical connection at earlier development stages boosting fast, high quality, impactful large-scale deployment of robots in clinical environments all over Europe, satisfying a current clinical demand or need. The COVID-19 special actions are focused on broad Covid-19 solutions and robotic applications related to the current situation including COVID-19 response, recovery and support in daily challenges that are still existing due to the pandemic as well as post COVID-19 challenges.

## 2.2 Type of activity qualifying for financial support and major application domains

The major aim of the COVID-19 Response project is to launch 4 project pilots in 4 different countries, embedding robotic applications in healthcare-related environments in later development stages (TRL7-8) (excl. disinfection since disinfection robots have already been funded under other European Initiatives), satisfying a current clinical demand or need related to COVID-19. The major application domains are as follows:

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 the robotic application, have a clear linkage to the end-user, and describe how the services / expertise of the DIH-HERO network will be used during the execution of the project. During the 9 months project duration the robotic application must be deployed in 4 healthcare related settings located in 4 different countries. The minimum possible deployment phase is 6 months spread over the 4 different end-users; however, the deployment period must be maximized to the extent possible.

#### 2.3 How to build the project consortium

The project consortium must at least consist of 1 SME or slightly larger company and 4 endusers (e.g. a hospital) from 4 different EU (incl. associated countries) /EEA countries.

#### Definition of an SME/ slightly larger company

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 as well as those who are operating in EEA countries 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 CRs. 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 organization 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 consider any relationships you have with other enterprises. Depending on the category in which your enterprise fits, you may thenneed to add some or all the data.

#### 2.4 Conflict of interest

DIH-HERO core partners cannot receive any financial support from the FSTP calls provided under the current innovation action. Therefore, applicants cannot include DIH-HERO core partners in their consortia. Moreover, to avoid conflicts of interest, applicants that have any financial or legal connections with one or more DIH-HERO core partners, cannot apply for financial support via the COVID-19 Response call.





#### 2.5 Duration, start and end date of the COVID-19 Response call

After the project has been awarded the funding agreement will be prepared and sent to the lead company with a request to return the signed contract within a period of 4 weeks. After signing the contract, the awarded consortia will have one preparation month before starting the project period, for which the maximum duration is 9 months. Starting earlier than a month after signing is possible, however, it should be considered that only costs within the project period can be declared.

# 3. Eligibility

## 3.1 General eligibility criteria

All the following eligibility criteria will have to be fulfilled for a COVID-19 Response project to be funded:

1. Third parties receiving financial support must be a legal entity, being an SME or slightly larger companies from EU (incl. associated countries) / EEA countries.

2. The proposal must clearly state the relevant clinical demand (added value) and the healthcare problem related to COVID-19 to be solved by the proposed robotic system and the added clinical value of the solution.

3. The proposed solution must be an already existing robotic system that is in the later stages of development (TRL7-8) and deployable by the 4 healthcare end-users in 4 different countries.

4. The proposal must fit to the call text.

5. A third party may not receive more than €300k total grant funding from the DIH-HERO FSTP calls.

6. Proposal must be written in English and submitted via the portal before the deadline.

7. There must be no conflicts of interests with DIH-HERO consortium partners.

8. Third parties receiving financial support must be financially healthy (a financial declaration must be signed as a condition of the award).

#### 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
- Direct costs of subcontracting (maximum of 15% of the total estimated budget) whereas,
  - $\circ$   $\$  subcontracting must be necessary to implement the action.
  - subcontracting may cover only a limited part of the action.
  - awarding of subcontracts must be done ensuring the best value for money or, if appropriate, the lowest price principle.
  - any conflict of interests must be avoided.
- Other services and goods
  - Direct travel and subsistence cost
  - Equipment
  - Other goods and services
- Indirect costs (25% of direct personnel costs and other direct costs) (for lead SMEs/slightly larger companies only)

Please note that it is only possible to include infrastructure hardware in the budget that is needed to embed a working solution in the healthcare-related setting, as this call focuses on the deployment of a working solution. In addition, the majority if the budget must be distributed to the SME/ slightly larger companies, whereas it is allowed to allocate some budget for cost coverage to the end-users.





# 4. Payment terms and reimbursement rates

The payment structure will be for the COVID-19 Response projects is defined as follows:

- 40% of the payment will be released when the contracts with the clinical partners are signed.
- Final payment will be made based on the achievements/ finalization of the different Deployment Work Packages.

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 COVID-19 Response call under the innovation action DIH-HERO will have to be prepared and submitted in the English language. Proposals prepared in another language will not be taken into consideration.

#### 3.1.2 Proposal contents

Any COVID-19 Response proposal should at least contain the following information:

1. Administrative Data (to be filled in the online application form)

- Contact Data from all the COVID-19 Response project partners
  - COVID-19 Response Key Data such as:
    - The full title of the COVID-19 Response project;
    - The short name of the COVID-19 Response project;
    - Brief description (Short Abstract of approx. 8-12 lines)
    - Targeted application domain
    - Current TRL
    - Project Duration (max. 9 months)
    - Statement on legal agreement describing the rights and duties of each party to be negotiated among COVID-19 Response project partners), and
    - Statement on the COVID-19 Response announcement for publication.
- 2. Description of the COVID-19 Response Project

The <u>proposal template</u> provides an elaborate overview of sections that need to be present in the COVID-19 Response proposal for it to be considered. The following sections as described in the proposal template will serve as the primary evaluation criteria:

#### Excellence (weight 20%) (max. 2 Pages)

- Clear definition of the current clinical demand or need related to COVID-19 (direct COVID-19 and post-covid-19 challenges) addressed by the robotics solution is given.
- There is a clear description of the ambition for the proposed deployment.
- The soundness of the technical approach is elaborated on.
- There is a clear demonstration of the novelty and inventiveness in the proposed approach and solution.
- The applicant shows a clear understanding of the relevant current state deployment and the contribution made by the proposal to advancing it.
- The applicant shows a clear understanding of the clinical or healthcare relevance of the





proposal.

#### Impact (weight 40%) (max. 4 Pages)

- A clear description of the healthcare impact and added value of the solution and its deployment is provided.
- How successful deployment of the robot in the clinical settings can be recognised (what does success look like from the applicant's perspective?) is clearly described.
- The impact on healthcare professionals and healthcare processes is defined.
- A risk assessment of robot deployment in the proposed clinical settings and mitigations is provided.
- The potential to up-scale the solution is identified.
- There is an elaboration on the benefits to the end-user.
- There is an elaboration on the financial impact of deployment for the end-user.
- A business model and funding plan for large scale deployment is outlined.
- The necessary standards and regulatory compliance needed for successful deployment are described.
- The contribution made to the EU wide adoption of Robotics in Healthcare is explained.
- There is evidence that the robotic application proposed has not yet been deployed on a larger scale in the clinical setting (deployed in less than 2 European countries (TRL 7-8))

#### Implementation (weight 40%) (max. 4 Pages)

- The involvement of end-users in the implementation and deployment processes is clearly explained in 4 different deployment work packages.
- The process of deployment at each end-user site is clearly explained.
- The deployment challenges are clearly identified.
- The team capabilities and management capacity needed to achieve the outcomes are explained.
- A work plan, specifying the work division among partners (incl. deliverables and milestones) has been developed.
- There is a description of the resource utilization and efficiency.
- The resources and training needed at the end-user sites for successful deployment are clearly identified.
- The approvals and consent needed to operate successfully at each of the end-user sites and the timeline to acquire them are clearly documented.
- There is a description of the management and monitoring approach used to track project and deployment progress, especially at the end-user sites.

Deployment: During the 9 months project duration the robotic application must be deployed in 4 healthcare-related settings located in 4 different countries. The minimum possible deployment phase is 6 months spread over the 4 different end-users; However, the deployment period must be maximised





to the extent possible. Each deployment trajectory must be described in a separate work package. (See also implementation criteria and <u>budget template</u>)

- 3. COVID-19 Response Estimated budget (to be uploaded in the online application form)
- 4. Declaration of Honour (signed by all project partners) (to be uploaded in the online application form)
- 5. <u>Declaration of Informed Data Consent for data processing and storage</u> (signed by all consortium partners) (to be uploaded in the online application form)
- 6. Questions for statistical purposes (included in the online application form)

#### 3.2 Proposal submission

Eligible proposals are to be submitted via the DIH-HERO online portal <u>http://dih-hero.eu</u> before the call deadline. 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. Two to three weeks before the deadline, there will be an opportunity for a basic pre-check, which is highly recommended. With this check, DIH-HERO will not in any way give feedback on the content but on the completeness of the proposal. Requests to review the completeness of a proposal after the deadline for the preliminary completeness check, will not be considered. Shortly after proposal submission, an automatically generated acknowledgment of receipt willbe sent to the applicant's email address. Please note that this acknowledgment of receipt does not imply that the proposal has been accepted as eligible for evaluation. During the project, a survey may be conducted among all applicants.

## 3.3 Proposal evaluation and selection

#### 3.3.1. The different reviewing and evaluation phases







• Phase 1: Eligibility check

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

• Phase 2: External Review

The FSTP team will engage experts for evaluating the proposals and ensure that they are independent of the organizations involved in the DIH-HERO consortium and from any proposer. Each proposal will be reviewed by three independent reviewers. Each evaluator will rank the proposal 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 10.

• Phase 3: Consensus

All Individual Evaluation Reports will be combined and discussed at 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 discussions of the reviewers at the consensus meeting.

• Phase 4: Hearings

The applicants whose proposals have been ranked under highest 20 proposals during the consensus meeting will be invited for hearings. The outcome will be a ranked list of proposals based on the hearings.

• Phase 5: Ranking

DIH-HERO is aimed to award up to 8 of the highest-ranked proposals, provided that they have a score above threshold. If a consortium is chosen to be awarded, it will only receive the requested amount as mentioned in their respective budget estimation.

## 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 to implement, manage and monitor the COVID-19 Response or protecting the financial interest 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 concerning 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 COVID-19 Response Project prior to its starting date, they must be addressed in the COVID-19 Response 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 COVID-19 Response project run time, they must be immediately communicated to DIH-HERO by sending an email to: dih-healthcare@utwente.nl





# 5. Contract

Once an applicant has been awarded funding for a COVID-19 Response Project, a funding agreement will be signed between the awarded SME/ slightly larger company and the coordinator of the DIH-HERO innovationaction, representing the DIH-HERO consortium members.

## 6. COVID-19 Response Monitoring and Reporting

The reporting will take place via the DIH-HERO portal. The midterm and final reports will be produced by third parties and will be evaluated by a review team consisting of the assigned Deployment Coach plus 2 Deployment 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 COVID-19 Response, Technology Demonstrator as well as technology transfer experiments during 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, theapplicant 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 for applicants

For further information and questions regarding the open call for COVID-19 Response 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.nl

When contacting the Helpdesk, please include the following:

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