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| ***Table 3.1a Timing of the different Work Packages and their components (Gantt Chart)*** | | | | | | | | | | | | | | | | |
| **WPs/Tasks** | **YEAR 1** | | | | **YEAR 2** | | | | **YEAR 3** | | | | **YEAR 4** | | | |
| **WP1 – *The INPUT-HEART phenomapping platform*** | **Q1** | **Q2** | **Q3** | **Q4** | **Q1** | **Q2** | **Q3** | **Q4** | **Q1** | **Q2** | **Q3** | **Q4** | **Q1** | **Q2** | **Q3** | **Q4** |
| **Task 1.1**: Composing a database inventory |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Task 1.2**: Conceptual harmonisation of the available databases |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Task 1.3**: Completeness of the databases and communication of the federated learning procedure |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Task 1.4**: A blueprint for a phenomapping platform |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **WP2 - *Cardiac imaging phenomapping for early cardiovascular risk prediction*** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Task 2.1:** Software for standardizing the extraction and analysis of cardiac motion/deformation data |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Task 2.2:** Assessment of cardiac spatiotemporal motion/deformation abnormalities using the big population data |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Task 2.3:** Machine learning approaches for precision cardiac phenomaps |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Task 2.4:**  Deep phenotyping through personalized mechanistic modeling of cardiovascular physiology |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **WP3 –** ***Circulating biomarkers (proteomics) for the early detection of heart disease and risk stratification*** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Task 3.1:** Sample transfer to Olink Proteomics AB, Uppsala, Sweden |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Task 3.2:** Measurements of circulating biomarkers using PEA platform in the discovery and validation cohorts |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Task 3.3:** Integration of biomarkers profile and predictive modelling |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Task 3.4:** Developing a custom multiplex platform |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **WP4 - *Machine learning for CV risk stratification and outcome prediction*** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Task 4.1:** Exploratory phase |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Task 4.2:**  Pre-processing of the available training data |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Task 4.3:**  Selection of machine learning models |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Task 4.4:**  Design of the experimental procedure, implementation of the algorithms and model comparisons |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Task 4.5:**  Joint risk modelling |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Task 4.6:**  Models diagnostics and improving of code of the final machine learning |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

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| **WPs/Tasks** | **YEAR 1** | | | | **YEAR 2** | | | | **YEAR 3** | | | | **YEAR 4** | | | |
| **WP5 – *Development of technological platform*** | **Q1** | **Q2** | **Q3** | **Q4** | **Q1** | **Q2** | **Q3** | **Q4** | **Q1** | **Q2** | **Q3** | **Q4** | **Q1** | **Q2** | **Q3** | **Q4** |
| **Task 5.1:** Initialization phase |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Task 5.2:** Development of research application including testing and deployment phases |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Task 5.3:** Development of the server |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Task 5.4:** Development of clinical application including testing and deployment phases |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **WP6 – *Validation of the INPUT-HEART exercise and physical activity intervention*** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Task 6.1:** Evaluation strategy and demonstration plan |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Task 6.2:** System demonstration and piloting |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Task 6.3:** Overall validation of the INPUT-HEART exercise intervention |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Task 6.4:** Data acquisition |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **WP7 – *Machine learning and mechanistic modelling for identifying the most optimal exercise program characteristics*** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Task 7.1.** Refining, enriching and optimizing the DSS |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Task 7.2.** Healthcare provider and patient dashboards |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Task 7.3:** Identification of a standardized method for quantification of personal exercise |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Task 7.4:** Mechanistic modelling of phenotypic plasticity in response to exercise intervention |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Task 7.5:** Machine learning algorithms to predict adherence and efficacy based on combined physiological, demographic and psychosocial aspects of the individual |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **WP8 – *Dissemination and communication*** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Task 8.1:** Preparation of dissemination, exploitation and communication plans |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Task 8.2:** Creation and maintenance of an INPUT-HEART website |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Task 8.3:** Dissemination of results to the scientific community |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Task 8.4:** Organization and coordination of outreach activities |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Task 8.5:** Providing training within the consortium and beyond |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **WP9 – *Management and Ethics*** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Task 9.1:** Project administration, communication and innovation management, resource monitoring |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Task 9.2:** Financial and progress reports |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Task 9.3:** Management of Intellectual Property Rights (IPR) |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **Task 9.4:** Ethical and legal issues |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

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| **Work package number** | **9** | | **Lead beneficiary** | | | | ***KU Leuven*** | | |
| **Work package title** | ***Management and Ethics*** | | | | | | | | |
| **Participant number** | **P1** | P2 | | P3 | P4 | P5 | P6 | P7 | P8 |
| **Short name of participant** | **KU Leuven** | NTNU | | UiT | UDC | LIU | Data Spartan | AUTH | UNINA |
| **Person months per participant:** | **18** | 2 | | 2 | 6 | 1 | 1 | 1 |  |
| **Start month** | 01 | | | | **End month** | 48 | | | |

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| **Objectives**  The objectives of the WP9 will include:   * Efficient communication between partners and with the European Commission; * Co-ordination of technical activities according to the work plan; * Effective control of project resources (budget); * Management of IPR and innovation management; * Quality management; * Provide expertise and advices regarding the Ethical Legal and Social Implications (ELSI).   WP9 will aim efficient and productive control of the INPUT-HEART project from administrative and technical point of view. Administrative management will promise the internal (inside consortium) and external (with EC) communication, the timely control of progress work, the quality of project deliverables and the efficient financial resource handling. Technical management is responsible for the deliverance of high quality and innovative results inside project’s time constraints and specified budget.  International, EU and National regulations will be considered in relation to the use of health data and human biological samples for research purpose in order to first, ensure the availability of the biological resources (data and samples) to the scientific community, secondly to raise awareness on the rules to apply and, thirdly, to *propose relevant ELSI management tools* to the partners to the project for a practical implementation. |

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| **Description of work**  **Task 9.1 Project administration, internal communication and innovation management and resource monitoring**  The Project Coordinator will make sure that all resources foreseen for the project realisation are available to the project partners. She will ensure effective communication between partners and will track all the costs related to the project.  With regard to the technical management, the following steps are foreseen: (i) coordination of activities as described in the work plan; (ii) monitoring of the quality of planned research performed by the INPUT-HEART partners; (iii) risk management through appropriate mitigation measures; (iv) *SWOT analysis* and innovation management; (v) implementation of the strategies and decisions of the General Assembly with regard to work plan implication.  Implementation of the administrative management plan will include (i) organisation of the regular meetings including General Assembly and Steering Scientific Committee meetings; (ii) following implementation of the main principles described in the Consortium Agreement; (iii) administrative support to partners and Work Package Teams activities.  Participants: **KU Leuven,** input from all partners  **Task 9.2 Financial and progress reports**  This task involves: (i) regular communication with the European Commission; and (ii) consolidation of annual technical and financial reports, as specified in the contract with the Commission. These reports will be prepared at month 18, 36 and 48 (at the end of the project).  Participants: **KU Leuven,** input from all partners  **Task 9.3 Management of Intellectual Property Rights (IPR)**  After evaluation of the results obtained in INPUT-HEART, the diagnostic/prediction precision-based platform is foreseen to be developed within the project. Dissemination and valorisation of this novel diagnostics platform is a Common Project Objective. Important elements of IPR such as confidentiality, joint ownership policies, and access rights will be specified in the Consortium Agreement which will be signed at the start of the project. The IPR that each partner holds before entering the project and that a partner needs to include and to which access rights need to be granted for implementation of the project, will be identified in annex to the Consortium Agreement. During the duration of the project and for a period of four years thereafter, the partners shall consider as confidential any data which is identified as confidential by the disclosing beneficiary.  Proactive monitoring of project’s outputs to ensure protection and exploitation the results generated by the consortium. Screening for patentable intellectual property will be executed at regular basis. An IPR expert from the *Leuven Research and Development* will advise the Project Coordinator (employee of KU Leuven) on the related issues. A voting procedure with respect to IPR regulations will be defined in the Consortium Agreement. The General Assembly will appoint an exploitation manager within the consortium to review project’s outputs that needs to be protected and will take the appropriate actions if applicable. The generated data may first enter patenting procedures, or will be directly forwarded to dissemination. IPR and dissemination is a complex procedure within INPUT-HEART, since innovation will most likely be realized by partners involving sample collections potentially themselves carrying IPR restrictions. A report of the management of the IPR and exploitation plan of the results will be included as deliverable to the periodic report. This plan will detail the results generated and the strategy for its protection and use.  Participants: **KU Leuven**  **Task 9.4 Ethical and legal issues**  The WP will work on the ethico-legal compliance of the project proposal as a first collaborative task with all the partners. This task aims roadmap related actions from the partners for ensuring ethico-legal compliance. The Task 9.4 will also establish of a flow chart for data and samples for the project and attached legal documentation.  During the course of the project, the *Project Monitoring Committee* will ensure proper handling of personal, lifestyle, social-economic, genetic and health-related data; oversee rules for access to INPUT-HEART resources; and ensure compliance with privacy. It will also collect and evaluate existing informed consents. The Ethical Issues related to the project are detailed in the *Technical Annex,* *Section 5*.  Participants: **KU Leuven** |

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| **Deliverables**  **D9.1:** Flow chart for data and samples exchanges in INPUT-HEART and attached legal documentation (M03).  A report describing the details of the exchanges performed within the project and presenting contractual documents to be used for ensuring ethical/legal compliance, traceability and sustainability of the database and the biobank.  **D9.2** Privacy and data protection policy for the INPUT-HEART integrated database (M06).  A report presenting the policy and governance mechanisms set up for managing data access and uses of the data made available through the database.  **D9.3:** Ethical approval for the multicentre Clinical Intervention Study (M12);  **D9.4** Annual reports to General Assembly on work plan progress, *SWOT analyses*, updated implementation plans, financial justifications and projections (M12, M24, M36 and M48).  **D9.5** Report of using newly generated data to generate *new* IPR and innovation management (M12 – M48). |

**Table 3.1b: List of work packages**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Work package No** | **Work Package Title** | **Lead Participant No** | **Lead Participant Short Name** | **Person-Months** | **Start Month** | **End month** |
| 1 | ***The INPUT-HEART phenomapping platform*** | 1 | ***KU Leuven*** | XX | 01 | 45 |
| 2 | ***Cardiac imaging phenomapping for early risk prediction*** | 2 | ***NTNU*** | XX | 01 | 48 |
| 3 | ***Circulating biomarkers (proteomics) for the early detection of heart disease and risk stratification*** | 5 | ***KU Leuven*** | XX | 01 | 45 |
| 4 | ***Machine learning for risk stratification and outcome prediction*** | 4 | ***UDC*** | XX | 03 | 48 |
| 5 | ***Development of technological platform*** | 1 | ***KU Leuven*** | XX | 01 | 45 |
| 6 | ***Hybrid exercise intervention study*** | 1 | ***KU Leuven  (Department of Rehabilitation Sciences)*** | XX | 01 | 45 |
| 7 | ***Machine learning and mechanistic modelling for identifying the most optimal exercise program characteristics*** | 2 | ***NTNU*** | XX | 04 | 48 |
| 8 | ***Dissemination, exploitation and communication*** | 6 | ***UNINA*** | XX | 07 | 48 |
| 9 | ***Management and Ethics*** | 1 | ***KU Leuven*** | XX | 01 | 48 |
|  |  |  | Total person- months | **XXX** |  |  |

**Table 3.1c: List of Deliverables**

## 3.2 Management structure, milestones and procedures

INPUT-HEART involves 8 beneficiaries (3 research units joining forces at ***KU Leuven;*** 2 at ***NTNU;*** 2 at ***UiT;*** 2 at ***UDC;*** 2 at ***AUTH***) in interdisciplinary research. The important principle of management structure of INPUT-HEART will be formulated in the Consortium Agreement. The agreement will be signed between the participants to specify the project governance, the internal organization of the consortium, the management of the project, and any other critical aspects of the project like the management of intellectual property and access rights to results and liability and confidentiality arrangements within INPUT-HEART.

The general purpose of the project management is the strategic control of each work package, implying coordination of the different project activities and implementation of quality control mechanisms with appropriate project standards. Project management activities include:

* Coordination of the technical and research activities of the project at the consortium level;
* Overall legal, contractual, ethical, financial and administrative management;
* Preparing, updating and managing the consortium agreement between partners;
* Setting-up secure online collaboration tools for project management, collaboration between partners and document management;
* Preparation of reports for the European Commission;
* Supervising the promotion of gender equality in the project;
* Managing IPR, exploitation and dissemination.

The project management core consists of the interacting layers as indicated in the chart (*Figure 8*) by the following bodies: Project leadership by the ***KU Leuven,*** General Assembly and Steering Scientific Committee. This management structure has been chosen for an effective project implementation and monitoring in regard to the project objective, number of partners and WPs.



***Figure 8****:* *The INPUT-HEART management structure*

***3.2.1 Project leadership***

*The Project Coordinator* (Prof Tatiana Kuznetsova, ***KU Leuven***) will be responsible for the scientific, financial and administrative coordination of the whole consortium. This includes reports on progress, cost statements, and taking care of rapid information and communication between partners. She will be in charge of the everyday operational functioning of INPUT-HEART including supervision of the recruitment campaign in accordance with the principles of the "Code of Conduct for the recruitment of researchers". In particular, clear and transparent procedures, equal opportunity in terms of nationality and gender will be ensured. The Coordinator will also insure the funds transfers between the European Commission (EC) and the partners and permanent communication with the EC representative during the whole length of the project. Yearly, the coordinator will give account of the financial and scientific status of the consortium based on continuously updated and ordered scientific and financial records as agreed in the Consortium Agreement. The responsibility of the Project Coordinator together with the leader of the Management Office will be to circulate the agenda of the meeting as well as draft the meeting minutes.

The Project Coordinator will be supported by scientific and administrative staff members of the involved KU Leuven departments (Technical Annex, KU Leuven partner information) including *KU Leuven Research & Development* (LRD). LRD is the knowledge and technology transfer office of the ***KU Leuven*** Association. LRD is dedicated to building bridges between science and industry and to transferring knowledge and technologies to the marketplace. Within LRD, Sofie Heroes will advise the Project Coordinator and the Management Team on the financial management of INPUT-HEART. Moreover, together with the Project Coordinator, Drs Adina Dumitru ***(UDC)*** and Mara Gabriela Diaconu (***NTNU***) which have extensive experience in the EU project management will provide support for the management tasks listed above.

***3.2.2 General Assembly*** (GA) is the highest decision-making and arbitration body for any issue concerning the proper implementation of the project. Chaired by the Project Coordination, the GA will include one PI of each participating institution with one vote in the decision-making process. GA will meet at the beginning (month 1) to define strategies, to fix all the administrative procedures, to set up the main rules of management and recruitment and to decide on the starting allocation of funds according to the tasks of each partner. During the life of the project the GA will meet annually and will communicate through e-tools (audio and video-conferences) if a decision is required on important and urgent issues.

The GA will take decisions on the issues related to IPR, ethics, exploitation, budget allocation and consortium action plan and its modifications. In case of no unanimous consensus on specific issues, the decision-making rule will be 2/3 of voting representatives. In case of particularly complex or difficult issues (especially in the field of IPR and Ethics) the GA may request assistance of external experts, who will provide suggestions but will not take part in the decision-making process. The GA will validate all annual progress and financial reports.

***3.2.3 Executive Board*** (EB) will consist of the Work Package Leaders and scientific experts with an outstanding knowledge in the major fields of research in INPUT-HEART. They will coordinate and monitor scientific and technological issues and events of the project. EB will (i) ensure that the results reached in each WP are integrated and shared among partners, (ii) will propose decisions and (iii) will report on the scientific progress of the project to the General Assembly. EB will prepare the agenda of the GA meetings. EB will meet on a regular basis, in person very 12 months and virtually every 3 months. Their meeting will be linked to the project review meetings.

***3.2.4 The Work Package Teams (WPT)*** are groups of partners focusing on one set of correlated tasks in the project. Each WPT is led by Work Package Leader. Within the WPT, clearly identified task leaders are assigned to each specific collaborative task listed in the WP. The WP Leaders have already been defined (see following table). They are responsible for the overall follow-up of the concerned Work Package and will ensure an efficient communication within the WPT. The role of the Work Package Leader will be:

* to take day to day decisions on the technical level, where needed after consultation with the Project Coordinator;
* to present scientific and financial progress reports on the advancement of the WPs;
* to make proposals on the allocation of WP tasks;
* to draft and validate project deliverables of the WP to be submitted to the European Commission;
* to identify potential risk within the WP;
* to inform the GA and SSC of any other difficulty arising in connection with the WP.

The WPT meetings will be held depending on developing needs during the course of the project and might have the format of a teleconference, but may also be organised alongside the GA meetings. The members of the WPT will be defined during the Kick-Off meeting.

|  |  |  |
| --- | --- | --- |
| **WP** | **WP Leader** | **Partner** |
| **WP1** | Prof Tatiana Kuznetsova | **KU Leuven** (P1) |
| **WP2** | Prof | **NTNU** (P2) |
| **WP3** | Prof | **LIU** (P5) |
| **WP4** | Prof Amparo Alonso-Betanzos | **UDC** (P4) |
| **WP5** | Prof | **KU Leuven** (P1)/ **Data Spartan** (P6) |
| **WP6** | Prof Veronique Cornelissen | **KU Leuven** (P1) |
| **WP7** | Prof Ulrik Wisloff | **NTNU** (P2) |
| **WP8** | Prof Giovanni de Simone | **CIRIAPA** (P8) |
| **WP9** | Prof Tatiana Kuznetsova | **KU Leuven** (P1) |

***3.2.5 Project Monitoring Committee*** This Committee will be created to check the quality of the tasks considering the state of the art and will be vigilant in regards with the ethical agreement providing to the relevant partners and subcontractors, and will promote gender equality during the project especially for the recruitment of PhD students and early stage researchers. This Unit will be composed of the Scientific Coordinator, the Medical Doctors acting in population cohorts and registry and one external adviser. Important mission of Monitoring Committee will be related to the Ethical regulation and data management.

***3.2.6 Advisory board.*** The consortium will seek advice from independent external internationally renowned external experts from research fields of epidemiology, computer and statistical modelling, cardiology and Social Science. The External Advisory Board will offer strategic ethical and scientific guidance to the project and facilitate access to additional relevant organisations and stakeholders committees. At this moment … already accepted this assignment (Additional Technical Annex, Letter of support). PAI Health? .

*…*

***3.2.7 Conflict resolution.*** In case of minor conflicts and delays in the project implementation (no longer than 2 months), decisions involving each WP will be taken by the WP Leader with the approval of Project Coordinator and after communication to the whole Network. If the *conflict concerns scientific issues* and it cannot be resolved in this way, the Coordinator will summon an extraordinary session of the Steering Scientific Committee which will issue an opinion. The opinion then will be transferred to the General Assembly for vote, Coordinator having an additional casting vote if necessary. In case where the *conflict involves ethics, IPR, financial or legal issues* the Coordinator will summon an extraordinary meeting of the General Assembly. On this meeting each partner will be invited to be seconded by a relevant expert or officer from its institution. These guests will only have an advisory role and will not be allowed to vote.

If disputes cannot be solved at this stage, each beneficiary is entitled to submit the dispute, controversy or claim to the sole competent courts of Brussels. The following table give an overview of the main milestones of INPUT-HEART. This table will give along the project a mean to estimate the well timing of the tasks or to adjust some task in order to correct eventual delay or to re-synchronize different tasks in order to achieve the objectives of INPUT-HEART.

***3.2.8 Innovation management***

*Internal factors (strength, weaknesses*): INPUT-HEART combines many assets to guarantee a successful outcome. Multidisciplinary cooperation along the value chain from idea to product or service is a key to stimulating innovation. INPUT-HEART will aid knowledge exchange between partners who benefit from cross-fertilisation between disciplines and from synergies of pooling resources among participants with similar research goals. The consortium set-up and the translational nature of partner expertise will stimulate scientific and technological innovation within the project. Beyond the duration of INPUT-HEART, the project will strengthen European innovation capacity through establishing long-lasting ties between project partners and facilitating future cooperation and innovation. In addition, partners will perform research and innovation at the interface of academia and industry, contributing to the translation of research outcomes into marketable products (an open service platform, a precision multiplex custom biomarker panel, etc.) and improved health care (better diagnostic algorithm for early HF stages).

With a view on the specific research direction supported through INPUT-HEART, the innovative output of the project will be an integrative diagnostic platform based on analysis of big data using machine leaning algorithms with integrated phenomics data, which might open a new chapter in preventive cardiology research. INPUT-HEART takes a jumpstart because of the high degree of phenotypes standardisation that have been already applied in the population epidemiological studies from expert epidemiological centres in Europe.

It should be underscored that the potential of applying the machine learning algorithms and digital technological platform in cardiovascular prevention has not yet been previously exploited which is a weakness.

*External factors (opportunities, threats)*: The societal challenges, research environment, recent computer and technological developments all represent opportunities for research and innovation related to prevention or delay of onset of overt cardiovascular diseases. Moreover, industrial partners (***Data Spartan Limited and Olink***) inv00olved in the developing of technological products have strong presence in the market and therefore should have a positive impact on distribution and acceptance on the new platforms developed within this project. However, the market especially related to the cardiac biomarkers is very competitive and some existing solutions are addressing, in part, the same needs as addressed here.

Also, the evidence from randomised clinical trials should be produced in order to finalise the clinical applicability and cost-effectiveness of the identified risk biomarkers and diagnostic algorithms.

*SWOT analysis:* The weaknesses that were identified in not having fully exploited machine learning algorithms and networking analysis will be addressed by establishing the present innovation project. The competitive situation will be addressed by developing a tool with open-source codes and ability of different researchers to validate this technological platform in their research environment. Moreover, by the end of the project, the UK NIHR and Rand Science of Science template (www.rand.org/randeurope/research/innovation\_policy/science-policy-research.html) will be applied to design randomised clinical trials to test diagnostic platform and stratification factors with the greatest potential impact on heart health at the lowest cost.

**Table 3.2a: List of milestones (should be completed)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **N°** | **Milestone name** | **Related WP(s)** | **Due date (in month)** | **Means of verification** |
| **M1.1** | Features inventory in each cohort and completeness of data | 1 | 06 | Released inventory for internal use |
| **M1.2** | A blueprint for a phenomapping platform | 1 | 45 | Internal report |
| **M2.1** | Validation of software tool for cardiac motion/deformation data analysis | 2 | 24 | Internal report, release the codes |
| **M2.2** | Results on statistical model of temporal/longitudinal evolutions | 2 | 45 | Internal report |
| **M2.3** |  | 2 | XX | XX |
| **M2.4** |  | 2 | XX | XX |
| **M3.1** | First proteomics measurements | 3 | 06 | Internal report |
| **M3.2** | Measurements metabolites by PEA platform concluded | 3 | 12 | Dataset |
| **M3.3** | Predictive modelling and selection of proteins for developing a multiplex custom panel | 3 | 24 | Internal report |
| **M4.1** | Obtaining the curated datasets that will be employed to develop the statistical and machine learning models | 4 | 12 | Dataset |
| **M4.2** | First results on selection of the candidate models | 4 | 24 | Internal report, release the codes |
| **M4.3** | Validation results of the trained models | 4 | 42 | Validation of codes |
| **M4.4** | Final code version of the models to be included in the open platform | 4 | 47 | Final codes released |
|  |  |  |  |  |
| **M5.1** | TP definition completion | 5 | 12 | Internal report |
| **M5.2** | TP design completion | 5 | 39 | Internal report |
| **M5.3** | TP construction completion | 5 | 46 | Software released |
| **M6.1** |  | 6 | XX |  |
| **M6.2** | Demonstration completed | 6 | XX | Internal report |
| **M6.3** | Overall assessment of the intervention completed | 6 | XX | Internal report |
| **M7.1** |  | 7 | XX |  |
| **M7.2** |  | 7 | XX |  |
| **M7.3** |  | 7 | XX |  |
| **M8.1** | INPUT-HEART Website | 8 | 03 | Website operational |
| **M8.2** | Final conference | 8 | 48 | Conference |

**Table 3.2b: Critical risks for implementation**

This paragraph is dedicated to a first analysis of possible risks relating to implementation, which could affect the achievement of planned results. For each risk detailed contingency plan is provided which might be implemented to properly face the out coming situation: Obviously, at this stage, this list should be considered just as a preliminary exercise which might be enriched or modified, during the following of the project activities and system development. The following table is a specific representation for Risks, mitigation actions and contingencies.

|  |  |  |
| --- | --- | --- |
| **Description of risk (indicate level of likelihood: Low/Medium/High)** | **WP(s) involved** | **Proposed risk-mitigation measures** |
| Needs of specific technical and scientific skills to fulfil the R&D effort necessary to realise the project backbone (low). | All WPs | Scientific and medical partners represent a strong alliance of leading organisations that can boast the needed competences to realise and implement this ambitious venture. |
| Technical innovation needed is beyond project capacity (low) | All WPs | Partners have been chosen to minimize the possibility of this risk as they have the full range of required skills and represent the most advanced organisations in the fields related to aims of the project. |
| Delays into the integration of the modules into the framework (medium) | All WPs | Very early definition of the integration rules and specification and strict time-planning and control from the start of the project |
| Maintaining quality of complex cardiovascular phenotypes in particularly imaging obtained by multiple observers in longitudinal studies is a challenge (medium) | WP1 and WP5 | The phenomics data and in particularly cardiac imaging data were previously collected using the highly standardised protocols in the renowned epidemiological centres in Europe. Moreover, KU Leuven will act as the central platform for quality control of cardiovascular phenotypes for epidemiological studies. |
| Follow-up studies fail to secure new usable data (low) | WP1 | SOPs are already established. |
| Low prevalence of participants with cardiac malfunction in the general population that might affect statistical power (low). | WP2-WP7 | Previously we demonstrated that the prevalence of left ventricular remodelling and dysfunction in the available cohorts cohort is about 25%. This finding was also confirmed by other population studies. Therefore, in our cohorts we have a large pool of participants at the higher risk of HF and other cardiovascular diseases. |
| The integration and processing of heterogeneous and complex information implies difficult challenges (medium) | WP1-WP7 | WP1 will particularly address the issue of phenomics data *standardisation, harmonisation and integration* at different levels. Use of the latest high-throughput techniques facilitates the integration of Big Data on *–omics*. For instance, we will use the same platform for measuring proteomics in the available population cohorts and registries patients at risk. |
| Missing data, censored data or non-usable data in some of the variables of the problem, due to several reasons, as for instance lack of measurements in some patients (high) | WP7 | Different cohorts will be used, and a considerable number of variables, participants and duration of studies are included. Statistical methods should take this into account; the possible censoring will be considered. |
| Data biased towards specific types of patients (medium) | WPX | The participants in the cohorts were recruited randomly from the general population. However, we should Include novel statistical methods that consider this circumstance: bias detection and correction methods, as statistical inference for length biased data and truncated data. |
| Problematic integration of modules with  different development stacks provided by  partners (medium). | WP5 | Conceptual agreement between all partners involved in development of machine learning algorithms (KU Leuven, UDC, NTNU, AUTH) will be reached in the beginnings of the project by month 12. |
| Federated learning will not improve models’  predictive performance (medium). | WP5 | External datasets will be obtained from partners  willing to share them. The datasets will be used  for model training on a single node. |
| Partner underperforms or leaves the consortium affecting the final project outcome (low) | WP1 | In case of partner’s resignation, pending work-load will be either re-distributed among the partners on the basis of their competencies or a replacement partner will be identified. In addition, the Consortium Agreement will foresee such situations and will de-scribe measures to be taken to prevent non-compliance to project activities. |
| Not enough participants to provide enough valid data or mix of population to give valid sample (low) | WP6 | The number of users foreseen for the pilots and validation study is at least 400. Even if valid data are collected from less users than initially planned the numbers will be sufficient guaranteeing valid sample sizes. |
| Poor quality of data to validate the results and build the models (low) | WP6-WP7 | The sites are centres of excellence in exercise physiology and have been carefully selected to ensure that there capacities are suitable for the demonstrations, pilots and larger scale validation. |
| Lack in dissemination and communication (low) | WP8 | External network will be formed with institutes of partners and a support will be provided. |

## 3.3 Consortium as a whole

Consortium consists of 8 allied partners from 7 European countries willing to co-operate and share of complementary and interdisciplinary technical skills and scientific and clinical expertise required for the development of INPUT-HEART project. The Consortium is formed with strong commitment to develop innovative predictive algorithms based on machine learning for precise risk stratification and management in cardiovascular medicine. These integrative computer models will allow person-tailored decision-making and planning of the optimal interventions. The description of each participating organisation done in the Section 4.1, gives evidence of their strong involvement and assignment on specific project research activities and different tasks, and show how the presence of each of them is necessary in this interdisciplinary project to assure the achievements of the objectives of the project. The multidisciplinary nature of our project is in line with the call objectives.

It is evident, from both the detailed partners description given above as well as from the indication of the typology of organisations involved, how each project participant has been carefully chosen because it brings to the project specific skills that combined with the other participants competences compose the right set of complementary capabilities necessary to pursue and reach INPUT-HEART project objectives. In this context project activities have been attributed to individual participant, taking in full account the main experiences each partner had in each specific domain relevant to INPUT-HEART. Most of the partners participated in the completed or ongoing European projects (see Section 4.1).

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Participant No \*** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** |
| cohorts of populations or patients | x | X | X |  | X |  |  | X |
| biobank | x | X | X |  |  |  |  |  |
| computer science/machine learning | X | X | X | X |  | x | X |  |
| cardiovascular modelling | X | X |  |  |  |  |  |  |
| epidemiology | X | X | X |  | X |  |  |  |
| Preventive cardiology |  |  | X |  | X |  |  | X |
| cardiac rehabilitation and exercise physiology | X | X |  |  |  |  | X | X |
| psychology |  |  |  | X |  |  |  |  |
| bioinformatics platform developer | X |  | X |  |  | X |  |  |

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## 3.4 Resources to be committed

According to the usual accounting principles, the main eligible costs of INPUT-HEART project include personnel costs, consumables, durable equipment, and travel and subsistence. The calculation of INPUT-HEART budget considers each partner’s usual accounting practice. Principles of economy (“value for money”) and efficiency served as guideline to draft the budget.

***Personnel***— INPUT-HEART partners will involve staff members, engaging both permanent employees and temporary staff, part of which will be hired specifically for the project. In estimating the necessary funding to cover salaries, each institution applied local accounting rules, considering specific costs for the personnel with given qualifications and seniority to be required for specific tasks in the project.

***Consumables, running expenses and travel***— Ten partners have allocated budget resources for consumables and all requested support for travel and participation in project meetings and workshops considering their location and the length of travel.