Fondazione Regionale per la Ricerca Biomedica

DECRETO NR. 114 del 30/10/2024

OGGETTO: BANDO ERAPERMED JJTC 2021 – EROGAZIONE DELLA RATA PER LA SECONDA ANNUALITÀ AL POLITECNICO DI MILANO DEL PROGETTO ERAPERMED2021-062 "PERSONALISED PROGNOSTICS AND DIAGNOSTICS FOR IMPROVED DECISION SUPPORT IN CARDIOVASCULAR DISEASES (ACRONIMO PERCARD)" - CUP D43C22000030002

L'atto si compone di 25 pagine
di cui 20 pagine di allegati

Fondazione Regionale per la Ricerca Biomedica

IL DIRETTORE GENERALE DELLA FONDAZIONE REGIONALE PER LA RICERCA BIOMEDICA

DATO ATTO CHE:

- il Politecnico di Milano (di seguito "Beneficiario"), Partner Nr. 1 del progetto dal titolo "Personalised Prognostics and Diagnostics for Improved Decision Support in Cardiovascular Diseases", Acronimo PerCard, ID 062, Responsabile Scientifico Prof. Luca Mainardi, è risultato ammesso a finanziamento nell'ambito del programma europeo ERA PerMed JTC 2021 per un importo complessivo pari a **€ 185.600,00**;
- la "*Dichiarazione di svolgimento di attività non economica ai sensi delle norme in materia di aiuti di Stato*" inviata a FRRB, a mezzo PEC, in data 21.12.2021 (Prot. nr. 20210335E) e la "*Dichiarazione di accettazione del contributo*" inviata in data 23.12.2021 (Prot. nr. 20210346E);
- secondo quanto stabilito dall'Articolo 8.1 della Convenzione sopracitata, l'erogazione al Beneficiario sarà effettuata da FRRB secondo le seguenti modalità:
- "*due tranche successive entro 60 giorni dalla presentazione della prima e della seconda rendicontazione annuale, previa accettazione della documentazione ricevuta da parte di FRRB. L'importo del contributo sarà calcolato in base ai costi eleggibili effettivamente rendicontati da ciascun Beneficiario*";

CONSIDERATO CHE:

- in data 23.12.2021 il Beneficiario ha comunicato sulla Dichiarazione di accettazione contributo a firma del Legale Rappresentante inviata via PEC (Prot. 20210346E), la data di inizio del Progetto, concordata con il Partenariato transnazionale, fissata al **1° febbraio 2022**;
- In data 04.03.2022 con è stato autorizzato da parte di FRRB (Prot. 20220118U) il pagamento della rata di anticipo pari a **55.680,00€** corrispondente al 30% del finanziamento totale (185.600,0€);
- dopo la prima annualità il Politecnico di Milano ha rendicontato 22.501,26€ (meno di quanto erogato con l'anticipo)
- In data 05.05.2023 con decreto nr. 13 è stato autorizzato il pagamento della prima

rata del contributo pari a **€ 22.477,21**

DATO ATTO ALTRESI' CHE:

- in data 11.04.2024 è pervenuta dal Beneficiario (via posta ordinaria), la documentazione relativa al secondo anno di attività – periodo 01.02.2023 – 31.01.20234- del progetto PerCard, richiesta da FRRB con mail del 18.01.2024;
- in data 01.07.2024 il Direttore Generale di FRRB ha comunicato al Beneficiario (PEC Prot. 20240231U) l'esito positivo dell'istruttoria di verifica della rendicontazione economica pervenuta richiedendo, al contempo, l'invio della richiesta di erogazione;

VERIFICATA la regolarità contributiva dell'ente assegnatario del contributo – Politecnico di Milano – tramite invio del DURC da parte dello stesso (**Allegato 4**)**;**

VISTI:

- la scheda di rendicontazione economica (*Financial report*) contenente il dettaglio dei costi sostenuti dal Beneficiario nel corso del secondo anno di attività *(Reporting Period 01.02.2023 – 31.01.2024)* (**Allegato 1**);
- la richiesta di erogazione della seconda rata pervenuta in data 05.07.2024 (PEC Prot. 20240231E) per un importo complessivo pari a **€ 5.170,55**, corrispondente ai costi rendicontati e ritenuti ammissibili da FRRB nel secondo anno di attività (**Allegato 2**);
- il Codice Unico di Progetto (CUP) D43C22000030002, generato dal Beneficiario in fase di avvio del progetto;
- il report scientifico annuale inviato dal Coordinatore di progetto al Segretariato della call ERA PerMed JTC 2021 e trasmesso a FRRB in data 11.04.2024 (PEC Prot. Prot. n. 20240132E) che riporta lo stato di avanzamento scientifico del progetto transnazionale (**Allegato 3**);

RICHIAMATI:

- la DGR nr. IX/2401 del 26.10.2011 con la quale la Regione Lombardia ha costituito la "Fondazione Regionale per la Ricerca Biomedica" (di seguito "FRRB"), il cui scopo statutario è quello di promuovere la ricerca scientifica e sanitaria nel settore delle Scienze della Vita;

- la DGR n. XI/5786 del 21.12.2021 con la quale è stato approvato il nuovo Statuto di FRRB;
- la DGR n. XI/1016 del 17.12.2018 con la quale è stato approvato lo schema di Accordo di collaborazione tra FRRB e la Direzione Generale Welfare di Regione Lombardia;
- la DGR n. XI/3476 del 05.08.2020 con la quale è stato approvato il Piano d'Azione 2020 che prevede, al suo interno, l'allocazione fino ad un massimo di euro 1.500.000,00 per la partecipazione di FRRB al bando internazionale ERA PerMed Joint Transnational Call (JTC) 2021;

VISTI ALTRESI':

- il Regolamento (UE) nr. 1291/2013 del Parlamento Europeo e del Consiglio dell'11 dicembre 2013 che istituisce il Programma Quadro di Ricerca e Innovazione (2014-2020) "*Horizon 2020*" quale strumento di finanziamento della ricerca scientifica e dell'innovazione per progetti di ricerca o azioni volte all'innovazione scientifica e tecnologica che portino un significativo impatto sulla vita dei cittadini europei;
- il Grant Agreement nr. 779282 firmato il 21.11.2017 tra la Commissione Europea ed un partenariato internazionale coordinato dall'Instituto de Salud Carlos III e composto da 32 enti provenienti da 23 paesi con il quale è stato approvato il progetto "*ERA-Net Cofund in Personalised Medicine — ERA PerMed";*
- la Comunicazione della Commissione Europea nr. 2014/C 198/01 "Disciplina degli aiuti di Stato a favore di ricerca, sviluppo e innovazione";
- il Regolamento UE nr. 2021/1237 della Commissione del 23 luglio 2021 che ha modificato il Regolamento UE nr. 651/2014 che dichiara alcune categorie di aiuti compatibili con il mercato interno in applicazione degli articoli 107 e 108 del Trattato;

DECRETA

per i motivi espressi in premessa, parte integrante del presente provvedimento:

1. di autorizzare l'erogazione in favore del Politecnico di Milano con sede legale in Milano, Piazza Leonardo da Vinci nr. 32, di un importo pari a **€ 5.170,55**

corrispondente alle spese sostenute e considerate eleggibili da FRRB a conclusione delle attività relative alla seconda annualità del progetto dal titolo "*Personalised Prognostics and Diagnostics for Improved Decision Support in Cardiovascular Diseases*", Acronimo PerCard (ERAPERMED2021-062), Responsabile Scientifico Prof. Luca Mainardi;

2. di riservarsi la revoca del presente provvedimento ai sensi dell'art. 92 comma 3 del D. Lgs. 159/2011.

IL DIRETTORE GENERALE
Veronica Comi

Veronica
Comi
30.10.2024
13:32:03
GMT+02:00

Fondazione Regionale per la Ricerca Biomedica

COST STATEMENT

Rev.0 del 31/10/2022

EU PROJECT (please select)	ERAPERMED
JTC	2021
PROJECT ID	ERAPERMED2021-062
PROJECT TITLE AND ACRONYM	Personalised Prognostics and Diagnostics for Improved Decision Support in Cardiovascular Diseases - PerCard
LOMBARDY BENEFICIARY	Politecnico di Milano - Dipartimento di Elettronica, Informazione e Bioingegneria
NAME OF PRINCIPAL INVESTIGATOR	Prof. Luca Mainardi
CUP NUMBER	D43C22000030002
REPORTING PERIOD (FROM-TO)	01/02/23 - 31/01/24
YEAR (please select)	2
IS VAT RECOVERABLE? (YES/NO)	NO

COST CATEGORIES	TOTAL BUDGET	REPORTING PERIOD 1	REPORTING PERIOD 2	REPORTING PERIOD 3	TOTAL COST STATEMENT	DEVIATION FROM ORIGINAL BUDGET
TOTAL PERSONNEL COSTS	*€ 75.000,00*	*€ 16.319,03*	*€ 27.616,82*	*€ 0,00*	€ 43.935,85	€ 31.064,15
CONSUMABLES	*€ 0,00*	*€ 0,00*	*€ 0,00*	*€ 0,00*	€ 0,00	€ 0,00
EQUIPMENT (LEASING OR ON HIRE)	*€ 24.000,00*	*€ 0,00*	*€ 2.994,08*	*€ 0,00*	€ 2.994,08	€ 21.005,92
TRAVEL & ACCOMODATION	*€ 15.000,00*	*€ 2.432,02*	*€ 1.007,63*	*€ 0,00*	€ 3.439,65	€ 11.560,35
PUBLICATIONS	*€ 0,00*	*€ 0,00*	*€ 0,00*	*€ 0,00*	€ 0,00	€ 0,00
OTHER DIRECT COSTS	*€ 36.500,00*	*€ 0,00*	*€ 338,80*	*€ 0,00*	€ 338,80	€ 36.161,20
SUBTOTAL	**€ 150.500,00**	**€ 18.751,05**	**€ 31.957,33**	**€ 0,00**	**€ 50.708,38**	€ 99.791,62
OVERHEADS	*€ 30.100,00*	*€ 3.750,21*	*€ 6.391,47*	*€ 0,00*	*€ 10.141,68*	€ 19.958,32
SUBCONTRACTING COSTS	*€ 5.000,00*	*€ 0,00*	*€ 0,00*	*€ 0,00*	*€ 0,00*	€ 5.000,00
TOTAL REQUESTED BUDGET	**€ 185.600,00**	**€ 22.501,26**	**€ 38.348,79**	**€ 0,00**	**€ 60.850,05**	**€ 124.749,95**

PERSONNEL COSTS

Please refer to the JTC guidelines for the eligibility of personnel costs

NAME	POSITION	CONTRACT TYPE	PERIOD (FROM - TO)	EURO AMOUNT
GARCIA ISLA GUADALUPE	Assegnista di ricerca	Assegno di ricerca	01/2/23-15/07/23	13.808,41
GARCIA ISLA GUADALUPE	Assegnista di ricerca	Assegno di ricerca	16/7/23-31/12/23	13.808,41
			TOTAL € AMOUNT	**27.616,82**

CONSUMABLES

Please refer to the JTC guidelines for the eligibility of costs

NAME	ITEM DESCRIPTION	INVOICE NR.	INVOICE DATE	PAYMENT DATE	EURO AMOUNT
				TOTAL € AMOUNT	**0,00**

EQUIPMENT (LEASING OR ON HIRE)

NAME	ITEM DESCRIPTION	INVOICE NR.	INVOICE DATE	EURO AMOUNT	% OF USE OF THE EQUIPMENT FOR PROJECT'S PURPOSES	AMORTISATION MONTHS	EURO AMOUNT
Top Tech SRLS	ZBOOK FURY 16 G9 modello 62U85EA - RdA 82958	45/PA	23/03/23	2.740,12 €	100%	48,00	556,02 €
Carto Copy Service srl	Memoria di massa Creator P100X 12VTF-105 - RdA 82835	634/P	05/04/23	3.679,08 €	100%	48,00	702,09 €
Finbuc SRL	ProOne 440 G9 Core i7-12700T 16GB 512GB SSD Wi-Fi 6 Win 11 Pro DG 3yw - RdA 82959	001932FE	19/04/23	2.092,30 €	100%	48,00	1.679,07 €
Bsistemi SPA a socio unico	PRECISION 5680 MOBILE WORKSTATION CTO - RdA 95055	9/PA	19/01/24	4.477,40 €	100%	48,00	56,90 €
						TOTAL € AMOUNT	2.994,08

TRAVEL AND ACCOMODATION

Max 10% of direct costs

NAME	REASON FOR TRAVELING	DESTINATION	PERIOD (FROM - TO)	EURO AMOUNT
LUCA MAINARDI	Project meeting	LUDWIGSBURG	12/10/2023-13/10/2023	595,52
GARCIA ISLA GUADALUPE	Project meeting	LUDWIGSBURG	12/10/2023-13/10/2023	412,11
			TOTAL € AMOUNT	1.007,63

PUBLICATIONS

max 5% of direct costs

NAME	DESCRIPTION	INVOICE NR.	INVOICE DATE	EURO AMOUNT
			TOTAL € AMOUNT	0,00

OTHER DIRECT COSTS

Please refer to the JTC guidelines for the eligibility of costs

NAME	ITEM DESCRIPTION	INVOICE NR.	INVOICE DATE	PAYMENT DATE	EURO AMOUNT
IL MONELLO SRL	Catering	30	31/01/23	27/02/2023	338,80
				TOTAL € AMOUNT	338,80

SUBCONTRACTING

Max 20% of direct costs

NAME	PROCEDURE APPLIED	DESCRIPTION (provide details on service duration)	INVOICE NR.	INVOICE DATE	EURO AMOUNT
				TOTAL € AMOUNT	0,00

I declare that all the documentation listed in this table is archived at the Beneficiary premises and available in case of financial audits.

Name of the Beneficiary Legal Representative

Signature of the Beneficiary Legal Representative

Firmato digitalmente da:SERGIO MATTEO SAVARESI
Organizzazione: POLITECNICO DI MILANO/80057930150

Date, Place and Stamp:

RICHIESTA EROGAZIONE CONTRIBUTO
DICHIARAZIONE SOSTITUTIVA DI ATTO NOTORIO
(D.P.R. 445/2000)

Spett.le
Fondazione Regionale per
la Ricerca Biomedica
P.za Città di Lombardia 1
20124 Milano

PEC: fondazioneregionalericercabiomedica@pec.it

OGGETTO: Richiesta di erogazione contributo relativo al progetto ERAPERMED2021-062 (acronimo "PERCARD")

TITOLO PROGETTO: Personalised Prognostics and Diagnostics for Improved Decision Support in Cardiovascular Diseases

RESPONSABILE SCIENTIFICO: Prof. Luca Mainardi

CODICE CUP: D43C22000030002

Il sottoscritto Sergio Matteo Savaresi

Nato a [redacted] il [redacted]

Residente a [redacted]

[redacted]

In qualità di Rappresentante Legale dell'EntePolitecnico di Milano - DEIB, partecipante al progetto in oggetto

con sede legale in comune di Milano

CAP 20133 Piazza Leonardo da Vinci nr. 32 prov. MI

CODICE FISCALE 80057930150 PARTITA IVA 04376620151

POLITECNICO
MILANO 1863

INDIRIZZO E-MAIL
PEC: pecdeib@cert.polimi.it

CHIEDE

l'erogazione della seconda rata (dopo il secondo anno di progetto)

pari a € 5.170,55

Le coordinate per il versamento sono le seguenti:

Banca: Banca Popolare di Sondrio

Indirizzo: Agenzia n.21 Via Bonardi 4 - 20133 Milano

Codice IBAN: IT55W0569601620000001720X92

Cordiali saluti,

Milano, data della firma digitale

Firmato digitalmente
da:SERGIO MATTEO
SAVARESI
Organizzazione:
POLITECNICO DI
MILANO/80057930150

Joint Transnational Call for Proposals (2021) for

"Multidisciplinary Research Projects on Personalised Medicine – DEVELOPMENT OF CLINICAL SUPPORT TOOLS FOR PERSONALISED MEDICINE IMPLEMENTATION"

2nd Annual Report

1. General information

Project title	Personalised Prognostics and Diagnostics for Improved Decision Support in Cardiovascular Diseases
Project acronym	PerCard
Project duration (months)	36
Starting date	1.1.2022
Period covered by the report:	01/01/2023 – 31/12/2023
Periodic report:	2nd
Project website and social media accounts	https://projects.tuni.fi/percard/

2. Project Consortium

Coordinator (Partner 1):

Affiliation, Address:	Tampere University (TUNI), Kalevantie 4, 33100 Tampere
Country:	Finland
Name of Principal Investigator:	Mark van Gils
E-Mail:	mark.vangils@tuni.fi
Phone:	+358 50 4066610
Type of institution (academic, clinical, industrial)	academic
Funding Organisation:	Research Council of Finland

Project Partners:

Partner no.	Affiliation	Country	Name of Principal Investigator	Type of partner (academic, clinical, industrial)
2	Politecnico di Milano (POLIMI)	Italy	Luca Mainardi	academic
3	Centro Cardiologico Monzino (CCM)	Italy	Claudio Tondo	clinical
4	Protestant University of Applied Sciences Ludwigsburg (PUL)	Germany	Kirsten Brukamp	academic

There were no changes in the project team during the reporting period.

3. Publishable summary of the context and overall objectives of the projec

PerCard explores the value of combining integrated heterogeneous data sources with AI/ML to increase the validity of risk assessment for cardiovascular disease in different populations. The consortium develops specialised models for populations as well as mitigates the issue of gender-bias in existing risk assessment methods. Emphasis is put on methods that are easily transferable from research to practice and accessible and affordable for the wider population.

PerCard develops and uses new data analysis methods (AI, ML, signal processing, including ensemble classifiers and multi-modal approaches) to develop more powerful risk assessment methods that are accurate, robust, and explainable. The project provides advancements especially in the field of explainable AI and AI for time-series analysis. PerCard delivers an integrated decision support system for understandable personalised risk/prognosis assessment of morbidity and mortality in cardiovascular settings and tests this robustly in retrospective and prospective settings. End-users are involved throughout the entire research, development and validation process. ELSA considerations, including gender, accessibility to all, ethics of AI and decision support are an inherent part of the project.

To capitalise on earlier investments and speed up development, PerCard re-uses large retrospective databases to start with (Finland, Italy). PerCard uses robust validation methods to guarantee generalisability, combining independent test sets as well as prospective test data collection as truly independent reference.

To succeed, PerCard brings together an international interdisciplinary consortium of top-level partners: Tampere University (TUNI, co-ordinator, data analysis and link to Finnish clinical research), Polytechnic University of Milan (POLIMI, data analysis), Centro Cardiologico Monzino (CCM, clinical research), and Protestant University of Applied Sciences Ludwigsburg, Germany (PUL, ELSA considerations).

4. General overview of the objectives and deliverables for the period covered

Objectives/Deliverables			
No.	***Title***	***Partner in charge***	***Short Description***
D1.2	Harmonised retrospective data catalogue completed and available to consortium	**TUNI**	Shifted from period 1 due to using more suitable and valuable database (KARDIO/MADDEC) than originally planned. Different datasets in Finland and Italy were investigated and assessed in relation to the defined use cases. A catalogue listing the different contents and formats of the combined databases is created.
D1.3	Results of cross-validation on retrospective data of the AI/ML methods	**TUNI**	AI/ML methods developed in WP2 were trained and tested using retrospective data, in first instance from CCM. Work is continuing also in year 3 with further use cases and inclusion of wider retrospective data.
T1.3	Prospective data collection	**CCM**	Prospective data collection at CCM has started in early 2023 and is continuing.
D2.1	Definition of needs/opportunities for AI-based decision support	**POLIMI**	Shifted from period 1 due to making it a publication. A literature overview, to which all partners participated, was performed to

	algorithms in prognostics & diagnostics for CVD.		identify current limitations and opportunities, for AI-based decision support in CVD.
D2.2	Open software library for AI-based time-series feature extraction.	**POLIMI**	Combining all algorithms developed in WP2 that concern signal analysis. Ongoing task, ECG data (some of it in paper form) to be digitized before finalizing this task.
D3.2	Decision Support Software Tool - initial	**TUNI**	First version of the software tool, implementing the principle of the first chosen use case was presented to the consortium in August 2023. After this, further development continued
D4.2	ELSA recommendations for PerCard		Shifted from year 1 due to delayed start of partner PUL. Summary of the different workshop's recommendations finalised during year 2
D4.3	Qualitative research results.	**PUL**	Shifted due to delayed start of partner PUL. Preparation of work (interviews, forum discussions with different stakeholders) to be performed in the beginning of year 3.

Add lines as relevant.

5. Work performed during the reporting period and main results achieved so far

Please describe the work performed per WP.

WP 1	**Clinical Research and Validation**
Leading Partner: CCM	
Additional involved Partners: TUNI, POLIMI, PUL	
Planned timeline (according to GANTT chart): M1-M36	**Actual timeline: M1-M36**
Work performed, Challenges, Achievements WP1 continued its work, using the clinical use cases that were defined in the consortium in year 1 as main theme. Two groups of use cases were defined: group 1 dealing with risk assessment of adversary events (esp. atrial fibrillation) after cardiac surgery, and group 2 dealing with longer-term cardiovascular risks and mortality. For group 1, retrospective data at TUNI and CCM that was harmonised, and for this group the prospective CCM data collection has been ongoing in year 2 (forming an independent test set for the developed algorithms and software solution). Group 2 will mainly concentrate on longer-term risk prediction. From CCM, for Group 1 there is a n=1258 CABG and n=2445 post-AMI cases, and for group 2 n=1248 CABG retrospective available. Prospective data-collection matches to the post-AMI data. TUNI retrospective data matches to all 3 CCM groups, in first instance also concentrating on harmonization with the post-AMI set. Complete harmonisation of the different databases from different partners, took longer than originally foreseen due to the extra work required at TUNI side, due to the complexity of the different databases and formats in which the data were stored. However, the added value (both in large number of patients as well as the richness of recordings) fully offsets this delay. Furthermore, the different partners had access to different parts of the CCM databases already before M12, so that the work in WP2 and WP3 could commence. The prospective data collection at CCM is progressing well, with 148 patients enrolled at the	

time of writing, it is being registered at clinicaltrials.gov. Data collection will also continue through the 3rd project year to collect as many cases as possible for independent testing with good accuracy.
Has there been a deviation from the original work plan or from the original timeline? In year 1 it was decided to use Finnish Anges and KARDIO databases instead of the originally listed Young Finns and Health2000, since they were found more suitable for the selected use cases and were considerably richer in quantity and quality. This also implied more complexity, and longer duration for the harmonization work. This was a well-motivated choice made by the consortium – investing in high-quality scientific results in the long term at the less-significant trade-off of having some delay in the dates of deliverables. The prospective data collection started well. There was a minor temporary break due to staff resourcing issues at CCM in autumn 2023, but these have been resolved. Prospective data collection is continuing also in year 3, to get as many as possible cases as investment for scientifically valuable results.

WP 2	**New information discovery using AI and ML**
Leading Partner: POLIMI	
Additional involved Partners: TUNI, CCM, PUL	
Planned timeline (according to GANTT chart): M1-M36	**Actual timeline: M1-M36**
Work performed, Challenges, Achievements WP2 started in T2.1 in year 1 by defining the needs and opportunities for AI-based decision support in CVD with a systematic literature study with a thorough literature study on what is the state of the art and opportunities/requirements regarding AI/ML for cardiac risk prognosis and diagnosis. In year 2 this was compiled into a high-level scientific paper, to allow maximum dissemination and value. The paper was accepted to the journal *Computers in Biology and Medicine* February 2024. Task 2.2 has carried on with initial signal processing and biomarker extraction efforts especially on ECG, based on earlier developed methods at POLIMI. One challenge was the need to digitize paper-based ECGs from retrospective datasets. Tight co-operation with WP3 was in place, especially in the latter half of the reporting period, to transfer selected algorithms to software implementation state in WP3. In Task 2.3, Advanced AI/ML approaches and Explainable AI methods (TUNI) have been investigated to be combined with ML-classification heartbeat-classifier tools developed at POLIMI, this work will be submitted as paper to conference and results will are being incorporated in WP3's decision support solution.	
Has there been a deviation from the original work plan or from the original timeline? Deliverable 2.1, was upgraded from 'standard deliverable' to scientific paper to generate higher impact. This also meant that journal reviews and resubmissions took their time. Otherwise, the tasks have been advancing as planned. Some minor complications arose with need to digitize in the order of 200 paper-ECGs to allow further processing, as well as the fact that we mainly concentrated on CCM data as the large Finnish database was still being prepared. This implies that the D2.2 'Open-software library for time-series feature extraction" will be available in year 3. These considerations do not affect reaching the overall goal of the workpackage though. Also compensating for this, the D2.3 "Open software library for AI-based multivariable decision support in CVD" planned for year 3 is well ahead of schedule in writing. Staff change at POLIMI meant that knowledge needed to be transferred to a new researcher – this went smoothly.	

WP 3	**Personalised CVD Decision Support in Clinical Practice**

Leading Partner: TUNI	
Additional involved Partners: POLIMI, PUL, CCM	
Planned timeline (according to GANTT chart): M1-M36	**Actual timeline:** M1-M36
Work performed, Challenges, Achievements After defining the initial version of the requirements for a Decision Support Solution in the first year, the work proceeded towards the first implementations. A workshop with clinical experts was held in January 2023 in Milan, further elaborating scenarios and user preferences for the chosen use cases. After this, the software development work was started and a first deployable proof-of-principle prototype (with 'placeholder' patient data) was discussed together with the consortium in August 2023. Towards the end of the reporting period, tight co-operation with WP2 led to the transfer of the first WP2 algorithms to the Decision Support Software tool implementation. A first functional version was available for the consortium in M26. This work is in continuous co-operation with WP4 (ELSA considerations) and WP1 (clinical input), and has been carried out with active participation from all partners.	
Has there been a deviation from the original work plan or from the original timeline? T3.2 and T3.3 started later than planned , due to the fact that they need results from WP2 first, as well as the final harmonized data from WP1. Work proceeded, in first instance using algorithms based on CCM retrospective data that was available. Widening algorithm tuning with TUNI data is happening at the start of period 3. This shift in timing, however, has no consequence for the software implementation of WP3 itself.	

WP 4	**Ethical, Legal and Societal Aspects (ELSA)**
Leading Partner: PUL	
Additional involved Partners: TUNI, POLIMI, CCM	
Planned timeline (according to GANTT chart): M1-M36	**Actual timeline:** M1-M36
Work performed, Challenges, Achievements The work concentrated on continuation of tasks, especially T4.2 (ELSA integration): in tight interaction with all partners, and in particular WP3 and WP2 - it was discussed how the different aspects regarding especially Ethical and Legal aspects play a role in Decision Support Systems for CVD. Also, the ELSA aspects have been taken up as part of the literature review in WP2. The fact that the formal approval of the German funding organisation (for WP4 leader PUL) took well until the end of the first year to be finished, caused staff recruitment delays for partner PUL. These were solved in year 2, and all the work had been done via the extra efforts of the PI of PUL, which was a major achievement. At the end of the reporting period concrete plans were advancing for the qualitative research (interview and focus group meetings) with clinicians, former patients, academics and industry representatives from Italy, Finland and Germany.	
Has there been a deviation from the original work plan or from the original timeline? Overall the timeline of WP4 had a delay due to late formal approval from the German funding organization. This delay has been largely reduced during year 2.	

WP 1	**PerCard management**
Leading Partner: TUNI	
Additional involved Partners: POLIMI, CCM, PUL	

Planned timeline (according to GANTT chart): M1-M36	Actual timeline: M1-M36 M1-M36
Work performed, Challenges, Achievements Project management (T5.1) continued throughout the year 2. Two face-to-face meetings, in Milan in January and Ludwigsburg in October, were major consortium-wide events. These were complemented by monthly/bi-monthly meetings with the different PI's as well as WP-specific meetings (See Sec 5). An Advisory Board meeting was held (M20) with participation of patient organisation and industry representatives with useful feedback that was taken to heart in the further implementation work. Further dissemination continued nationally and internationally (See Sec 9). One researcher from Polimi has been granted 'affiliated researcher staff position' to TUNI to co-operate efficiently in data-analysis in WP2, this is to be extended to also include CCM researchers. Risk tables were discussed and updated in every consortium wide meeting. Overall the progress is going well, and the atmosphere of co-operation good – all partners are contributing actively. Some deliverables were decided to be delivered to somewhat later in time (see WP discussions). This was as a well-thought out trade-off of reaching scientific significant impact vs calendar months in the original Gantt chart.	
Has there been a deviation from the original work plan or from the original timeline? As discussed, the decision to use a richer retrospective database in Finland meant more harmonization work – this resulted in a delay of the full retrospective dataset. This was not a major issue as other WP work could proceed with CCM data as start.	

6. Transnational Collaboration, Meetings and Mobility

Describe consortium meetings (physical and virtual) including more than 2 partners (date, location, purpose, results).

Participants	*Date*	*Location*	*Purpose*	*Results*
All partners	*26-27.1.2023*	*POLIMI and CCM, Milan*	*Face-to-face consortium meeting, updates and planning*	*Agreed actions for the next half year*
All partners	*14.4.2023*	*on-line*	*Update of progress in all WPs, planning of next steps*	*Agreed actions for next months*
All partners	*4.7.2023*	*on-line*	*Update of progress in all WPs, planning of next steps*	*Agreed actions for next months*
All partners	*21.8.2023*	*on-line*	*Demonstration and feedback on 1st SW prototype*	*Inputs to further development*
All partners + Advisory Board	*12.9.2023*	*on-line*	*Project progress presentation and discussion*	*Inputs for further project directions*

Joint PerCard WP2-WP3 Meeting	*4.10.2023*	*On-line*	*Plan integration of WP3 algorithm into WP3 DSS*	*Criteria and requirements for deployment defined.*
All partners	*12-13.10.2023*	*PUL, Ludwigsburg*	*Face-to-face consortium meeting, updates and planning*	*Agreed actions for the next half year*
All partners	*11.12.2023*	*on-line*	*Update of progress in all WPs, planning of next steps*	*Agreed actions for next months*
Additionally, all WPs had focussed meetings in which several partners discussed together on work topics (eg data harmonization, algorithm development, joint paper writing, SW development, ELSA considerations). They are not listed separately here, but estimated to be in the order of >20 meetings				

Please describe the benefits and the synergies of the collaboration including: any joint project or initiative, any staff exchange or cross-country recruitment, training opportunities for new staff, any obstacles to the transnational collaboration and the proposed solution (max 2,000 characters including spaces).

The collaboration has worked well. Mainly co-operation has been working by having on-line planning and feedback meetings and then all staff working at their respective locations. TUNI and POLIMI have agreed to have one POLIMI staff member as 'external TUNI staff' to allow better co-operation with data analysis and access to ICT systems in practice. This will be extended to also include CCM staff in year 3. TUNI and POLIMI participated successfully to a HEU proposal in the field of CVD risk assessment using data-driven approaches (hypertrophic cardiomyopathy), "SMASH-HCM (Stratification, Management, and Guidance of Hypertrophic Cardiomyopathy Patients using Hybrid Digital Twin Solutions)" https://www.linkedin.com/showcase/smash-hcm-project/?trk=organization_guest_main-feed-card_feed-actor-name. It will guarantee further co-development of methods started in PerCard and expansion of co-operation and network, and recruitment and employment of staff at both TUNI and POLIMI. The 10M€ project is co-ordinated by TUNI and will run 2024-2027. TUNI and PUL are together in a two-stage EU proposal on multi-source data analysis, that successfully advanced to the second stage of the HORIZON-HLTH-2024-STAYHLTH-01-05-two-stage call. The topic is data-driven solutions for diabetes and depression patients. Here we further expand the ELSA collaboration. Full proposal deadline is 11 April 2024.

7. Data Management Plan

Please describe all changes (if any) from the strategy described in the Data Management Plan (DMP) sent to the ERA PerMed Joint Call Secretariat. (Max. 2,000 characters including spaces).

With the focussing of the use case, and comparison of the exact properties of the retrospective databases in Finland and Italy, it was realised that there are more suitable alternatives for the 2 earlier envisioned databases (YoungFinns and Health 2000) –we use now the Anges data (including angiography), and in particular the MADDEC data (https://link.springer.com/chapter/10.1007/978-981-10-5122-7_278) that have a considerably richer content (both in number of subjects as well as data features), and are more compatible with the CCM retrospective, and especially prospective data. This requires updates to Sec 1.3, Types of Data, of the DMP, that will be done at the start of year 3, once all data are stable.

8. Patients Involvement

Does your project involve a patient representative/organization? yes/~~no:~~ Finnish Heart Association

What is the role(s) of the patient representative(s)/organization(s) in your project (please select all that apply)?

INVOLVEMENT (where patient representative/organization are actively involved in the research project):

☒ Involvement in identifying research priorities within the project
☒ Serving as members of the project advisory or steering committee(s)
☐ Commenting and developing patient information leaflets or other research materials
☐ Undertaking interviews with research participants
☐ Carrying out specific aspects of the research projects
☐ Other (please specify)

PARTICIPATION (where patients take part in the research study):

☒ People being recruited to a clinical trial
☒ Completing a questionnaire or participating in a focus group as part of a research study
☐ Other (please specify)

ENGAGEMENT (where information and knowledge about research is provided and disseminated):

☒ Scientific conferences/open day with debates and discussions on research where patient representative(s)/organization(s) are invited to find out about the research projects
☒ Raising awareness of the project through media such as television programmes, newspapers and social media
☒ Dissemination to patient organizations and the patient community on the findings of a study
☐ Other (please specify)

9. Peer Reviewed Articles

Only include publications after the start date of the project, ***with clear acknowledgement of ERA PerMed funding:*** *"This project was supported by [name of funding organization, or an acknowledgment as requested by your national funding organization], under the frame of ERA PerMed."*

Type of Publication*	Partner No	Publication (authors, title, journal, year, issue, pp.)	DOI	Open access (yes/no)	Confir-mation **
Article in journal	1,3,4	ACCEPTED February 2024: ECG-based data-driven solutions for diagnosis and prognosis of cardiovascular diseases: A systematic review Pedro A. Moreno-Sánchez*, Guadalupe García-Isla, Valentina D. A. Corino, Antti Vehkaoja, Kirsten Brukamp, Mark van Gils, Luca Mainardi. Computers in Biology and Medicine, 2024.		yes	☒
Publication in conference proceedings,	1	ACCEPTED February 2024: Enhancing Arrhythmia Diagnosis with Data-Driven Methods: A 12-		yes	☒

compiled in book series		Lead ECG-Based Explainable AI Model. Emmanuel C. Chukwu ~Emmanuel_C._Chukwu , Pedro A. Moreno-Sánchez. Proc Nordic Conference on Digital Health and Wireless Solutions, Oulu, May 2025, Springer Nature, 2025			

Add lines as relevant.

** Type of publication: Article in journal, Publication in conference proceedings, Books-Monographs.*

*** I, the coordinator, confirm that this publication includes content generated within our ERA PerMed project and that ERA PerMed was acknowledged as indicated above.*

10. Further Dissemination Activities

Only include publications and activities after the start date of the project.

Type of dissemination activity*	Partner No	Description	Link	Target audience**
Workshop/seminar	1	1.3.2023 Presentation at University of Twente, The Netherlands	n/a	Biomedical Technology Research community
Workshop/seminar	2	1.4.2023 Presentation of PerCard at Politecnico di Milano Open Day	n/a	Perspective Master Students and PhDs
Workshop/seminar	1	5.4.2023 Presentation of the project and its objectives as a part of a talk: "Measurement and AI methods for risk prediction and assessment of cardiac and vascular patients" at the spring seminar of Finnish Cardiovascular Research Center Tampere.	n/a	Researchers and principal investigators mainly in clinical medicine field, also biomedical engineering.
Conference	1	4.5.2023 International Conference on Welfare Technology, Seinäjoki Finland	https://sedu.fi/ecwt-conference-evidenced-the-importance-and-broadness-of-welfare-technology/?lang=en	Researchers, healthcare professionals, medical device manufacturers and service providers, students
Workshop/seminar	1	22.5.2023 Presentation at Brunel University, UK	n/a	Computer science and biomedical research community
Communication in a scientific conference	4	21.6.2023 Talk (K.B.) as well as published abstract and poster presentation: "Kirsten Brukamp, Luca Mainardi, Claudio Tondo, Mark van Gils: Personalisierte Prognostik und Diagnostik	n/a	Scientific community

		für eine verbesserte Entscheidungsunterstützung bei kardiovaskulären Erkrankungen: Künstliche Intelligenz in der Gesellschaft (PerCard-KIG)" [i.e. in English: "Kirsten Brukamp, Luca Mainardi, Claudio Tondo, Mark van Gils: Personalised Prognostics and Diagnostics for Improved Decision Support in Cardiovascular Diseases: Artificial Intelligence in Society (PerCard-KIG)"], ELSA status seminar for funding programs, Federal Ministry of Research and Education (i.e. "Bundesministerium für Bildung und Forschung" BMBF) in Germany (funding sponsor), Berlin, Germany, June 21, 2023		
Communication in a scientific conference and training program for PhD students	4	5.7.2023 Talk: "Forschung und Entwicklung für Gesundheitstechnologien im Kontext der Sozial-, Verhaltens- und Wirtschaftswissenschaften" [i.e. in English: "Research and development for health technologies in the context of social, behavioral, and business sciences"], PhD student training program at universities of applied sciences in the federal state Land Baden-Württemberg, Technical University Stuttgart, Stuttgart, Germany, July 5, 2023	n/a	Scientific community: PhD students
Communication in a scientific conference	4	20.7.2023 Talk: "Artificial Intelligence in Health Care: Empirical Data from Research and Development Projects", 16th World Congress of Bioethics WCB, Basel, Switzerland, July 20, 2022	see below (1)	Scientific community
Workshop/seminar	1	7.11.2023 Presentation for Czech Ambassador to Finland, Finland	n/a	Researchers, policy makers, government representative
Communication in a scientific conference	4	21.11.2023 Talk: "Personalised Prognostics and Diagnostics for Improved Decision Support in Cardiovascular Diseases	n/a	Scientific community

		(PerCard)", EU Research Networking Meeting, University Albstadt-Sigmaringen, Campus Sigmaringen, Sigmaringen, Germany, November 21, 2023		
Communication in a talk at a university	4	22.11.2023 Talk: "Gesundheitstechnologien und Künstliche Intelligenz für Behandlungsunterstützung und Risikoerkennung in der Medizin" [i.e. in English: "Health Technologies and Artificial Intelligence for Treatment Support and Risk Assessment in Medicine"], Kiel University, Kiel, Germany, November 22, 2022	n/a	Scientific community
Communication in multiple talks at a university	PUL	Talks in courses on (1) research methods, (2) research project development, (3) project management, (4) health care innovations, study programs in Nursing (B.A.), Social Work (B.A.), and Social Work (M.A.), Protestant University Ludwigsburg, Ludwigsburg, Germany, 2022 and 2023	see below (2)	Academic community: Bachelor's and Master's students
Workshop/seminar	1	30.11.23. Poster presentation titled “Explainable AI analysis of a prediction model for detecting premature atrial and ventricular complexes” in the research days of Faculty of Medicine and Health Technology of Tampere University. The content of the poster is part of the works performed in T2.3	n/a	Scientific and industry community from Tampere region.

Internet links:
(1) https://organizers-congress.org/frontend/index.php?page_id=7871&v=List&do=15&day=all&ses=3737#anker_session_3737 [February 20, 2024]
(2) https://www.eh-ludwigsburg.de/en/university/directory-of-persons/detail/k.brukamp [February 20, 2024]

Add lines as relevant.

** Type of publication or dissemination activity: Master/PhD/MD thesis; Communication in scientific conferences or workshops; dissemination to the general public; e.g. Organisation of a Conference/Workshop, Press Release, Exhibition, Flyers, Social media, Web-site, Communication campaign; Other (please specify).*

*** Target audience: scientific community, general public, policymakers, industry, etc.*

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Numero Protocollo	INAIL_46036383	Data richiesta	17/10/2024	Scadenza validità	14/02/2025

Denominazione/ragione sociale	POLITECNICO DI MILANO
Codice fiscale	80057930150
Sede legale	PIAZZA LEONARDO DA VINCI, 32 20133 MILANO (MI)

Con il presente Documento si dichiara che il soggetto sopra identificato RISULTA REGOLARE nei confronti di

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