Fondazione Regionale per la Ricerca Biomedica

DECRETO NR. 141 del 12/12/2024

OGGETTO: BANDO ERAPERMED JOINT TRANSNATIONAL CALL FOR PROPOSALS 2021 – EROGAZIONE IN FAVORE DELL'ISTITUTO EUROPEO DI ONCOLOGIA IRCCS COORDINATORE DEL PROGETTO "IMAGENE" (ERAPERMED 2021-071) - CUP J47G21000020002.

L'atto si compone di 29 pagine
di cui 24 pagine di allegati

Fondazione Regionale per la Ricerca Biomedica

IL DIRETTORE GENERALE DELLA FONDAZIONE REGIONALE PER LA RICERCA BIOMEDICA

PREMESSO CHE:

- l'Istituto Europeo di Oncologia IRCCS (di seguito "Beneficiario"), Coordinatore del progetto dal titolo "*Epigenomic and machine learning models to predict pancreatic cancer: development of a new algorithm to integrate clinical, omics, DNA methylation biomarkers and environmental data for early detection of pancreatic cancer in high-risk individuals*", Acronimo IMAGene, ERAPERMED2021-071, Responsabile Scientifico Dr.ssa Serena Oliveri, è risultato ammesso a finanziamento nell'ambito del programma europeo ERA PerMed JTC 2021 per un importo complessivo pari a € 281.800,00;
- il Beneficiario ha inviato, a FRRB, a mezzo PEC, in data 21.12.2021 (Prot. nr. 20210336E) la "*Dichiarazione di svolgimento di attività non economica ai sensi delle norme in materia di aiuti di Stato*" e la "*Dichiarazione di accettazione del contributo*";
- con la DGR n. XI/3476 del 05.08.2020 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 JTC 2021;

CONSIDERATO CHE:

- in data 01.04.2022 ha avuto avvio il progetto Acronimo IMAGene (ERAPERMED2021-071), per una durata di 36 mesi, come comunicato dal Responsabile Scientifico (PEC Prot. nr. 20220042E del 22.02.2022) e riportato nella Convenzione stipulata tra FRRB e l'Istituto Europeo di Oncologia IRCCS;
- in data 02.07.2024 il beneficiario ha chiesto una proroga senza costi aggiuntivi (PEC Prot. nr. 20240230E), concessa da FRRB, che porta la data di fine progetto al 30.09.2025;
- il Beneficiario, in fase di avvio progetto, ha comunicato la rinuncia all'anticipo con comunicazione del 03.05.2022 (PEC Prot. nr. 20220153E);
- 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*";

DATO ATTO CHE:

- in data 03.06.2024 è pervenuta dal Beneficiario (PEC Prot. nr. 20240201E), la documentazione relativa al secondo anno di attività – periodo 01.04.2023 – 31.03.2024 - del progetto IMAGene;
- in data 07.11.2024 FRRB ha comunicato al Beneficiario (PEC Prot. nr. 20240399U) l'esito positivo dell'istruttoria di verifica della rendicontazione economica pervenuta richiedendo, al contempo, l'invio della richiesta di erogazione e della dichiarazione sulla ritenuta del 4%;

PRESO ATTO CHE il Responsabile dell'Area Amministrativa, Dr. Marco Trincavelli, ha verificato che lo stanziamento di € 101.981,91 è finanziariamente sostenibile al capitolo di spesa 20.15.5031, rientrante nei bandi previsti nel Piano di Azione FRRB relativo all'esercizio 2020, approvato da Regione Lombardia con DGR n. XI/3476 del 05/08/2020 e incassato da FRRB in data 09/11/2020;

VERIFICATA la regolarità contributiva dell'ente assegnatario del contributo – Istituto Europeo di Oncologia IRCCS – tramite acquisizione d'ufficio del DURC da parte di FRRB;

CONSIDERATO ALTRESI' CHE:

- all'art. 8.3 della Convenzione sopracitata si precisa che:
  - "*Nel caso di soggetti privati, l'erogazione del contributo sarà subordinata […] all'ottenimento, per il tramite della Banca Dati Nazionale Antimafia, della documentazione antimafia (solo nel caso di contributi superiori a € 150.000,00) nei modi e nei termini di cui all'Art. 92 D. Lgs. 159/2011 e* successive modifiche;
- in attuazione a tale articolo FRRB ha per il tramite della Banca Dati Nazionale Antimafia (BDNA), in relazione al Beneficiario, la seguente richiesta di informazione antimafia:

- protocollo nr. PR_MIUTG_Ingresso_0349972_20241105 del 05.11.2024 per l'Istituto Europeo di Oncologia IRCCS con sede legale in Milano via Filodrammatici nr. 10;

- alla data odierna, trascorso il termine minimo di 30 giorni dall'invio della nuova richiesta di informazione antimafia relativa al soggetto privato lombardo assegnatario di un contributo superiore a € 150.000,00 nell'ambito del progetto europeo IMAGene, FRRB è in attesa del nulla osta da parte della competente Prefettura;
- ai sensi dell'art. 92 comma 3 del D. Lgs. 159/2011 i contributi, i finanziamenti, le agevolazioni e le altre erogazioni possono essere corrisposti sotto *condizione risolutiva* e l'amministrazione interessata può revocare le autorizzazioni e le concessioni o recedere dai contratti, fatto salvo il pagamento del valore delle opere già eseguite ed il rimborso delle spese sostenute per l'esecuzione del rimanente, nei limiti delle utilità conseguite. Le facoltà di revoca e di recesso si applicano anche quando gli elementi relativi a tentativi di infiltrazione mafiosa siano accertati successivamente alla stipula del contratto, alla concessione dei lavori o all'autorizzazione del subcontratto;

VISTI:

- 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. XII/1670 del 28.12.2023 con la quale è stato approvato lo schema di Accordo di collaborazione tra FRRB e Regione Lombardia;
- La DDG n° XII/64 del 27.03.2023 avente ad oggetto: "Determinazioni in ordine alla Designazione del Direttore Generale della Fondazione Regionale per la Ricerca Biomedica (FRRB)" e la Deliberazione del Consiglio di amministrazione di FRRB del 31/03/2023 che ha nominato la Dott.ssa Veronica Comi quale Direttore Generale;

Fondazione Regionale per la Ricerca Biomedica

RICHIAMATI:

- il Regolamento (UE) nr. 1291/2013 del Parlamento Europeo e del Consiglio dell'11.12.2013 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 23.07.2021 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 dell'Istituto Europeo di Oncologia IRCCS con sede legale in Milano, via Filodrammatici nr. 10, di una rata pari a € 101.981,91 corrispondente alle spese sostenute e considerate eleggibili da FRRB a conclusione delle attività relative alla prima annualità del progetto Acronimo IMAGene (ERAPERMED2021-071) di cui € 4.079,28 che FRRB verserà all'erario a titolo di ritenuta del 4%;
2. di provvedere alla pubblicazione del presente Decreto sul sito web di FRRB, a cura del Responsabile del procedimento ai sensi della Legge 241/1990, Dott.ssa Giulia Maria Rossignolo.

IL DIRETTORE GENERALE
Veronica Comi

Veronica
Comi
12.12.2024
13:07:54
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	071		
PROJECT TITLE AND ACRONYM	Epigenomic and machine learning models to predict pancreatic cancer: development of a new algorithm to integrate clinical, omics, DNA methylation biomarkers and environmental data for early detection of pancreatic cancer in high-risk individuals" (IMAGene).		
LOMBARDY BENEFICIARY	Istituto Europeo di Oncologia		
NAME OF PRINCIPAL INVESTIGATOR	Serena Oliveri		
CUP NUMBER	J47G21000020002		
REPORTING PERIOD (FROM-TO)	01/04/2023 - 31/03/2024	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	*€ 96.000,00*	*€ 24.098,99*	*€ 32.596,00*	*€ 0,00*	€ 56.694,99	€ 39.305,01
CONSUMABLES	*€ 17.387,00*	*€ 58,80*	*€ 11.583,84*	*€ 0,00*	€ 11.642,64	€ 5.744,36
EQUIPMENT (LEASING OR ON HIRE)	*€ 0,00*	*€ 0,00*	*€ 0,00*	*€ 0,00*	€ 0,00	€ 0,00
TRAVEL & ACCOMODATION	*€ 6.073,17*	*€ 3.526,04*	*€ 1.419,48*	*€ 0,00*	€ 4.945,52	€ 1.127,65
PUBLICATIONS	*€ 6.000,00*	*€ 0,00*	*€ 0,00*	*€ 0,00*	€ 0,00	€ 6.000,00
OTHER DIRECT COSTS	*€ 80.839,00*	*€ 0,00*	*€ 39.385,61*	*€ 0,00*	€ 39.385,61	€ 41.453,39
SUBTOTAL	**€ 206.299,17**	**€ 27.683,83**	**€ 84.984,92**	**€ 0,00**	**€ 112.668,76**	€ 93.630,41
OVERHEADS	*€ 41.259,83*	*€ 5.536,77*	*€ 16.996,98*	*€ 0,00*	*€ 22.533,75*	€ 18.726,08
SUBCONTRACTING COSTS	*€ 34.241,00*	*€ 0,00*	*€ 0,00*	*€ 0,00*	*€ 0,00*	€ 34.241,00
TOTAL REQUESTED BUDGET	**€ 281.800,00**	**€ 33.220,60**	**€ 101.981,91**	**€ 0,00**	**€ 135.202,51**	**€ 146.597,50**

PERSONNEL COSTS

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

NAME	POSITION	CONTRACT TYPE	PERIOD (FROM - TO)	EURO AMOUNT
Giulia Ongaro	Post-doctoral Fellow	Fellowship	01/08/23-31/03/24	15.714,25
Clizia Cincidda	Post-doctoral Fellow	Fellowship	01/08/23-31/03/24	16.881,75
			TOTAL € AMOUNT	**32.596,00**

CONSUMABLES

Please refer to the JTC guidelines for the eligibility of costs

NAME	ITEM DESCRIPTION	INVOICE NR.	INVOICE DATE	PAYMENT DATE	EURO AMOUNT
Illumina Italy Srl	Trusight Hereditary Cancer Enrich Oligo	7080039129	45062	26/07/2023	635,75
Illumina Italy Srl	Miseq V2 Micro	7080043098	45237	19/01/2024	3.397,46
Illumina Italy Srl	Miseq Reagent Nano Kit V2 500 Cycles	7080043098	45237	19/01/2024	3.607,03
Illumina Italy Srl	Miseq Reagent Kit V3 (600 Cycles)	7080043581	45252	29/01/2024	3.943,60
				TOTAL € AMOUNT	**11.583,84**

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
							0,00
							0,00
							0,00
						TOTAL € AMOUNT	**0,00**

TRAVEL AND ACCOMODATION

Max 10% of direct costs

NAME	REASON FOR TRAVELING	DESTINATION	PERIOD (FROM - TO)	EURO AMOUNT
Serena Oliveri	24th IPOS World Congress of Psycho-Oncology	Milan	01/09-03/09/2023	742,23
Summers Paul Eugene	Scientific Collaboration/meeting performed at partner site	Toulouse	22/06-23/06/2023	677,25
			TOTAL € AMOUNT	**1.419,48**

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W www.ieo.it

RICHIESTA EROGAZIONE CONTRIBUTO

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

Spett.le
Fondazione Regionale
per la Ricerca Biomedica
Via T. Taramelli, 12
20124 Milano

PEC: fondazioneregionalericercabiomedica@pec.it

OGGETTO: Richiesta erogazione contributo seconda rata
TITOLO PROGETTO: ***Epigenomic and machine learning models to predict pancreatic cancer: development of a new algorithm to integrate clinical, omics, DNA methylation biomarkers and environmental data for early detection of pancreatic cancer in high-risk individuals (IMAGene)***
RESPONSABILE SCIENTIFICO: ***Dr.ssa Serena Oliveri***
CODICE CUP: J47G21000020002

Il sottoscritto: Mauro Melis
nato a: [redacted], il [redacted]
codice fiscale: [redacted]

domiciliato per la carica in Milano (MI) - CAP 20121 - Via Filodrammatici nr.10

in qualità di Legale Rappresentante dell'Ente Istituto Europeo di Oncologia, partecipante al progetto in oggetto

con sede legale in Milano (MI) – CAP 20121 Via Filodrammatici nr. 10
CODICE FISCALE/PARTITA IVA: 08691440153

Indirizzi email:
PEC: grantsofficeieo@pec.it
indirizzo email "operativo": servizio.grantsoffice@ieo.it (per comunicazioni amministrative relative al progetto)

CHIEDE

l'erogazione della seconda rata pari a € 101.981,91.=

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Le coordinate per il versamento sono le seguenti:

- Banca: Banca Popolare di Sondrio
- Agenzia: Sede di Milano
- IBAN: IT66 F056 9601 6000 0000 9429 X53

Cordiali saluti,

Milano, 7 novembre 2024

F.to DIGITALMENTE
DAL LEGALE RAPPRESENTANTE
(ai sensi dell'Art. 24 del DLgs n. 82/2005)

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MODELLO DICHIARAZIONE RITENUTA 4%*

Il Sottoscritto Mauro Melis
nato a [redacted]
il [redacted]
Cod. Fiscale [redacted]

domiciliato per la carica in via Filodrammatici, 10 – 20122 Milano

in qualità di rappresentante legale dell'ente: Istituto Europeo di Oncologia
P. IVA/codice fiscale: 08691440153

consapevole che le dichiarazioni mendaci sono punite penalmente ai sensi dell'art. 76 del D.P.R. 28 dicembre 2000, n. 445, e che codesta Amministrazione effettuerà controlli, anche a campione, sulle dichiarazioni rese

DICHIARA

che, ai fini dell'applicazione della ritenuta del 4% prevista dal secondo comma dell'art. 28 del D.P.R. 29 settembre 1973, n. 600, il contributo oggetto della richiesta a cui viene allegata la presente dichiarazione è da considerarsi come segue: (1)

SOLO PER ENTI COMMERCIALI

X L'ente beneficiario svolge attività commerciale in via esclusiva o principale; **(soggetto a ritenuta)**

SOLO PER ENTI NON COMMERCIALI

☐ L'ente beneficiario, pur non svolgendo attività commerciale in via esclusiva o principale, destina il contributo alla riduzione di oneri gestionali o alla copertura di disavanzi di gestione cui concorrono entrate derivanti da attività di natura commerciale; **(soggetto a ritenuta; nel caso di quota di finanziamento/cofinanziamento U.E., tale quota non è soggetta a ritenuta)**

☐ Il contributo è destinato unicamente alla copertura di spese o di disavanzi alla cui formazione concorrono solo entrate di carattere istituzionale; (2) **(non soggetto a ritenuta)**

☐ L'ente beneficiario è un'organizzazione non lucrativa di utilità sociale – ONLUS – (organizzazione iscritta nel registro provinciale di volontariato, cooperativa sociale, ecc., di cui all'art. 10, D. Lgs. n. 460/97); (3) **(non soggetto a ritenuta)**

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IN GENERALE

☐ Il contributo viene dichiarato esente dalla ritenuta medesima in virtù di un'espressa deroga ai *sensi della legge* _____*;* (4) **(non soggetto a ritenuta)**

Il sottoscritto dichiara, altresì, che provvederà a comunicare tempestivamente eventuali variazioni che dovessero intervenire a modificare la presente dichiarazione, ivi comprese, in particolare, quelle previste dall'art. 149 del D.P.R. 22 dicembre 1986, n. 917 (in rif. alla perdita della qualifica di ente non commerciale).

Milano, 7 novembre 2024

Firma

_____

***Allegare fotocopia della Carta di Identità o di un documento equipollente.**

(1) apporre una crocetta sul punto interessato
(2) rif. art. 143, comma 1 D.P.R. 22 dicembre 1986, n. 917; le entrate derivano esclusivamente da contributi dei soci o degli Enti Pubblici e comunque, anche nel caso in cui ci fossero entrate di altro genere di natura commerciale, queste ultime vengono gestite con contabilità separata rispetto a quella istituzionale per la quale si richiede il contributo (art. 144, co. 2 D.P.R. 917/86)
(3) rif. art. 16 D.Lgs 460/97.
(4) indicare gli estremi della disposizione normativa.

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INFORMATIVA IN MATERIA DI TRATTAMENTO DEI DATI PERSONALI
ai sensi degli artt. 13 e 14 del Regolamento (UE) 2016/679 (GDPR)
"Modulo raccolta dati Dichiarazione Ritenuta 4%

INFORMATIVA SULLA PRIVACY

1. **Titolare del trattamento e DPO** Titolare del trattamento dei dati personali è la Fondazione Regionale per la Ricerca Biomedica, avente sede legale in Milano, Piazza Città di Lombardia nr. 1 con sedi operative in Milano, Via Torquato Taramelli nr. 12 e in Bruxelles (BE), Casa della Lombardia nr. 2, Place du Champ de Mars - Tel. 02/67650166, e-mail info@frrb.it, PEC fondazioneregionalericercabiomedica@pec.it, sito web www.frrb.it.
Al fine di meglio tutelare gli Interessati, nonché in ossequio al dettato normativo, il Titolare ha nominato un proprio DPO, Data Protection Officer (nella traduzione italiana "RPD, Responsabile della protezione dei dati personali") nella figura del Dottor Ivano Pecis, contattabile scrivendo alla mail privacy@frrb.it o alla PEC dpo.frrb@pec.it.

2. Finalità, Basi giuridiche e tipologia di Dati trattati FRRB tratta i dati personali esclusivamente per le finalità e in ragione delle basi giuridiche di seguito indicate: i dati personali da Lei forniti sono necessari per gli adempimenti previsti per legge ed in particolare al fine garantire il trattamento dei dati presenti e previsti nel modello "Dichiarazione ritenuta 4%".

3. **Autorizzati e Responsabili del trattamento** I dati personali sono trattati da personale dipendente di FRRB, previamente autorizzato al trattamento e appositamente istruito e formato. I dati personali possono essere trattati anche da soggetti esterni, formalmente nominati dal Titolare del Trattamento quali Responsabili del trattamento ai sensi dell'art. 28 GDPR, appartenenti alle seguenti categorie: società che erogano servizi tecnico/informatici; società che erogano servizi di comunicazioni telematiche e, in particolar modo, di posta elettronica; società che erogano servizi di gestione e conservazione documentale; soggetti cui la FRRB ha affidato lo svolgimento dell'istruttoria di ammissibilità/ricevibilità della domanda.

4. **Destinatari e Pubblicazione dei dati personali** I dati personali degli Interessati potranno essere comunicati ad altri soggetti che trattano i dati in qualità di Titolari autonomi del trattamento: potranno essere comunicati al personale interno della Fondazione o a consulenti esterni debitamente istruiti dal Titolare. in caso di contenzioso, all'Autorità giudiziaria e ai legali del Titolare.

5. Natura del conferimento dei dati Il conferimento dei dati richiesti è necessario. Il mancato conferimento (totale o parziale) non consente il corretto prosieguo dell'iter amministrativo di valutazione ed eventuale accoglimento della dichiarazione.

6. Periodo di conservazione dei dati I dati personali degli Interessati vengono conservati dalla Fondazione per un periodo di tempo massimo di 10 anni dalla data di sottoscrizione della dichiarazione, fatta salva la necessità di prolungare la conservazione dei dati sino alla definizione di eventuali contenziosi, ovvero sino alla conclusione di eventuali attività di vigilanza e controllo operate da Enti terzi.

7. Trasferimento dei dati in Paesi extra-SEE FRRB può avvalersi, anche per il tramite dei propri Responsabili del trattamento, di società di servizi di comunicazione telematica e, in particolar modo, di posta elettronica, che potrebbero collocare o far transitare i messaggi e le informazioni personali degli utenti anche in Paesi non appartenenti allo Spazio Economico Europeo (SEE) o che in tali Paesi potrebbero salvare copie di backup dei dati. Al fine di garantire un adeguato livello di protezione dei dati personali, queste società possono attuare il trasferimento solo verso Paesi (o settori di questi) che sono stati oggetto di apposite decisioni di adeguatezza adottate dalla Commissione europea, oppure sulla base di Clausole Contrattuali Standard approvate dalla Commissione stessa.

8. Diritti dell'Interessato Il Regolamento (UE) 2016/679 riconosce agli Interessati diversi diritti esercitabili contattando il Titolare o il DPO ai recapiti indicati al punto 1 della presente informativa. Tra i diritti esercitabili, purché ne ricorrano i presupposti di volta in volta previsti dalla normativa (in particolare, artt. 15 e seguenti del Regolamento) vi sono: il diritto di conoscere se la Fondazione ha in corso trattamenti di dati personali che riguardano l'Interessato e, in tal caso, di avere accesso ai dati oggetto del trattamento e alle informazioni a questo relative; il diritto alla rettifica dei dati personali inesatti che riguardano l'interessato e/o all'integrazione di quelli incompleti; il diritto alla cancellazione dei dati personali che riguardano l'interessato; il diritto alla limitazione del trattamento; il diritto di opporsi al trattamento; il diritto alla portabilità dei dati personali; il diritto di revocare il consenso in qualsiasi momento, senza che ciò pregiudichi la liceità del trattamento, basato sul consenso, effettuato prima della revoca. Per ricevere maggiori informazioni sui diritti esercitabili, ciascun Interessato può rivolgersi direttamente al Titolare o al DPO. In ogni caso, l'Interessato ha anche il diritto di presentare un formale Reclamo all'Autorità garante per la protezione dei dati personali, secondo le modalità reperibili sul sito internet www.garanteprivacy.it

PUBLICATIONS

max 5% of direct costs

NAME	DESCRIPTION	INVOICE NR.	INVOICE DATE	EURO AMOUNT
				0,00
				0,00
				0,00
			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
World Courier	Spese di spedizione campioni da Milano a Lodz	932202400964930	19/02/2024		1.966,11
Istituto Europeo di Oncologia	Prestazioni cliniche (come da autorizzazione FRRB in sede di application): n. 50 Risonanze Magnetiche MRI, con e senza contrasto, dei seguenti distretti: torace , addome inferiore e scavo pelvico, addome superiore.	Autocertificazione a firma del Legale Rappresentante	n/a		37.419,50
				TOTAL € AMOUNT	**39.385,61**

SUBCONTRACTING

Max 20% of direct costs

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

Signature of the Beneficiary Legal Representative

Date, Place and Stamp:
Milan, 24th May, 2024

ERA PerMed

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

ERA PerMed Joint Call Secretariat
The JCS is hosted by the Italian Ministry of Health (It-MoH)
Viale Ribotta, 5 Roma, ITALY
With the support of the Fondazione Regionale per la Ricerca Biomedica, (FRRB), Lombardy (Italy)
Maria Jose Ruiz Alvarez
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This project has received funding from the European Union's Horizon 2020 Research and Innovation Programme under Grant Agreement No. 779282

General information

Project title	Epigenomic and machine learning models to predict pancreatic cancer: development of a new algorithm to integrate clinical, omics, DNA methylation biomarkers and environmental data for early detection of pancreatic cancer in high-risk individuals.
Project acronym	IMAGene
Project duration (months)	**36**
Starting date	**01/04/2022**
Period covered by the report:	01/04/2023 – 31/03/2024
Periodic report:	2st year
Project website and social media accounts	imagene.ieo.eu

1. Project Consortium

Coordinator (Partner 1):

Affiliation, Address:	Istituto Europeo di Oncologia (IEO), via Adamello 16, 20139 Milan
Country:	Italy
Name of Principal Investigator:	Serena Oliveri
E-Mail:	serena.oliveri@ieo.it
Phone:	+39 02 943 72054; +393296761854
Type of institution (academic, clinical, industrial)	Private hospital, for profit organization
Funding Organisation:	FRRB, Fondazione Regionale per la Ricerca Biomedica

Project Partners:

Partner no.	Affiliation	Country	Name of Principal Investigator	Type of partner (academic, clinical, industrial)
2	Bellvitge Biomedical Research Institute (IDIBELL)	Spain	Victor Raul Moreno Aguado	Clinical
3	Pomeranian Medical University (PMU)	Poland	Tomasz Kazimierz Wojdacz	Academia

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4	The Oncology Institute "Prof Dr. Ion Chiricuta" (IOCN)	Romania	Ovidiu Balacescu	Clinical
5	Centre Hospitalier Universitaire de Toulouse (CHUT)	France	Louis Buscail	Clinical

Please indicate any changes in the project team.

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2. Publishable summary of the context and overall objectives of the project

*Please summarize the project **objectives and major achievements** using language accessible to the public (max. 2000 characters including spaces). **This abstract may be published (e.g. ERA PerMed website).***

Pancreatic cancer (PC) has the lowest survival rate of all cancers in Europe, with no early detection strategies available. 1st-degree relatives of patients with PC have at least a 2-fold increased risk of developing the disease, although it is well-known that besides family history other epidemiological risk factors predispose to PC onset. The IMAGene project will develop, calibrate and test a comprehensive Cancer Risk Prediction Algorithm (CRPA) to predict PC in high-risk (HR) asymptomatic subjects, by including multidimensional data. IMAGene will also investigate the potential for DNA methylation biomarkers to improve currently available risk indexes, and validate the feasibility of using liquid biopsies for early detection of cancer in HR individuals.

In this first phase of IMAGene (1st-year) each documented clinical, environmental, lifestyle and family history risk factor for PC have weighted within the algorithm and combined to obtain an Epidemiological Risk Score (ERS). Cancer susceptibility related to specific germline mutations has been estimated using the GWAS catalog combined into a polygenic risk score. Finally, an epigenetic risk signature was developed using publicly available DNA methylation data on patients with sporadic PC and adequate controls. The calibration of ERC/CRPA prototype in 24 sporadic PC patients is going to be finalized.

A centralized database and data repository were developed and REDCap software programmed to collect data from enrolled subjects. Psychological assessment has been established, and the potential adherence of 1st-degree relatives to IMAGene trial has been investigated. The selection and characterization of 1st-degree relatives of PC patients is ongoing, after the official IRB approval of the IMAGene protocol. Ethical guidance was provided for the informed consent and information sheet, and for properly handling the return of results. Finally, uniform WB-MRI protocol was established and standardized among the different centers.

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

Objectives/Deliverables			
No.	***Title***	***Partner in charge***	***Short Description***
WP1, *T1.1*	*Cancer Risk Prediction Algorithm development and calibration*	IDIBELL/ICO PMU IOCN	Deliverables achieved: a) The prototype algorithm CRPA for PC prediction has been developed. The weight of each risk factor have been established through an in-depth consultation of the current literature and public databases, and then translated into specific inputs of the algorithm, calculating an Epidemiological Risk Score (ERS). b) The calibration on a small sample of confirmed sporadic PC cases enrolled at ICO and IOCN has been completed.
WP1, *T1.2*	*Data management*	IDIBELL/ICO	Deliverables achieved: a) The centralized database and data repository has been developed in REDCap software and designed to be GDPR-compliant; b) All questionnaires were translated into 4 languages (according to the languages of the 4 enrolling centres) and uploaded into REDCap. c) The procedures for

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			anonymizing and collecting data were standardized across centres.
WP1, *T1.3* *T1.4*	*Selection and characterization of first-degree relatives of PC patients*	IEO, IDIBELL/ICO, IOCN, CHUT	174 Asymptomatic 1st-degree relatives of PC patients, who meet the pre-specified inclusion criteria have been enrolled and completed the visit where relevant familial, clinical, and lifestyle information have been collected and ERS calculated. Deliverables achieved: 1) Medical, psychological visits and blood sampling completed in all cancer centres; 2) Radiological findings collected and reports completed at IEO, CHUT and IOCN; 3) Genetic analysis and reports completed at IEO; 4) Completed agreement for genetic analysis among enrolling parties ICO, IOCN and CHUT with Eurofins Genoma Lab. Analysis for CHUT, ICO and IOCN at Eurofins Genoma are now ongoing; 5) Collected data were included in REDCap and in the CRPA.
WP2, *T2.1*	*DNA methylation analysis in sporadic cases and HR subjects*	PMU	Deliverables achieved: a)Completed agreements and procedures with recruiting parties and the laboratory at University of Lodz for the DNA methylation analysis; b) Completed epigenomic analysis for the calibration study c) Completed epigenomic analysis for asymptomatic 1st-degree relatives of PC patients enrolled (WP1); d) a dedicated researcher has been recruited and publicly available data for the development of first version of epigenetic risk signature have been analysed and used for the calibrated CRPA.
WP3, *T3.1*	*Implementation of uniform WB-MRI protocols & advanced Visualization/Analysis of WB-MRI*	IEO ICO IOCN CHUT	Deliverables achieved: a) A uniform protocol for the Whole Body-MRI in order to guarantee consistency between centres has been implemented. b) The software and codification applied to support sites in reporting outcomes has been validated.
T3.2	*Imaging Screening in High–Risk subjects*	IEO ICO IOCN CHUT	Deliverables achieved: a) Imaging screenings (WB-MRI) have been completed at IEO, CHUT and IOCN, and 1-year follow up have been scheduled. WB-MRI at ICO will be completed within June 2024 (Month 27); b) for each lesion, radiologists reported location, size, volume, and appearance using an adaptation of the MY-RADS reporting guidelines (PMID: 30806604). All imaging and clinical outputs were used as inputs to ERS-CRPA model optimization (WP1).
WP4, *T4.1* *T4.2*	*HR individuals' preferences, psycho-cognitive profiles and decisions.*	IEO	Deliverables achieved: a) Participants' preferences toward the procedures along with perceived individual risk, stress levels and coping strategies has been assessed through a

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			semi-structured interview at the baseline visit. All the interviews have been accurately recorded and later transcribed; b) A list of validated questionnaires and ad hoc questionnaires was established and submitted to the enrolled participants at baseline. Data collection completed on REDCap; c) Follow up questionnaires at 6 and 9 months have been implemented, translated into 4 languages and uploaded to REDCap. Data collection for follow up is ongoing. Qualitative and quantitative data analysis are now ongoing for data collected at baseline.
WP5, *T5.1*	*Provide ethical guidance for the different phases of the project*	IEO	IEO coordinated partners in the application of regional and national ethical and legal frameworks. Deliverables achieved: a) guidance for data management; b) guidance GDPR for patient recruitment, informed consent signature, and return of results, use of retrospective data and transfer and storage of biosamples.
WP5, *T5.3* *T5.4*	*I. Ethical aspects surrounding return of results.* *II. Study of ethical issues surrounding the use of epigenetics signatures as markers*	IEO CHUT IOCN IDIBELL/ICO	Semi-structured interviews with expert stakeholders have been postponed at the 3rd year of project, due to organizational difficulties. They will focus on i. how to offer a responsible process for the management of unsolicited findings and returning of results (RoR) to participants, including considerations related to the right not to know and medical benefits; ii. How to adapt the informed consent for oncological patients' relatives (healthy subjects) in case of epigenetic screening.
WP6, *T6.1*	*Cost and benefit analysis, utility analysis*	IEO, IDIBELL/ICO, IOCN, CHUT	Deliverables achieved: a) Ad hoc questions to measure direct and indirect costs afforded by participants to undergo the IMAGene screenings procedures have been implemented and standardized among centres. They have been included into REDCap and submitted together with the 6th month follow up survey (WP4).

Add lines as relevant.

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

Please describe the work performed per WP.

WP 1	**Development, training and calibration of PC risk prediction algorithm (CRPA) and High-Risk individuals selection**
Leading Partner: Partner 2, IDIBELL/ICO (prof. Victor Raul Moreno Aguado)	

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Additional involved Partners: Coordinator Partner 1, IEO (dr. Serena Oliveri); Partner 3, PMU (prof. Tomasz Kazimierz Wojdacz); Partner 4, IOCN (dr. Ovidiu Balacescu); Partner 5, CHUT (Louis Buscail)	
Planned timeline (according to GANTT chart): (from M13 to M21)	**Actual timeline:** (from M13 to M21)
Work performed, Challenges, Achievements (*Max. 1,200 characters including spaces*) The main deliverable of WP1 was fully accomplished: the PC risk prediction algorithm, or CRPA has been defined, and a calibration study based on 25 patients diagnosed with pancreatic cancer has been performed. For this calibration study, patient recruitment involved two ICO-centres in Spain, and IOCN in Romania. For the main trial, asymptomatic 1st-degree relatives of PC patients, who meet the pre-specified inclusion criteria, have been selected. The calibrated CRPA is currently being prospectively tested on this cohort of subjects at High Risk of developing PC. Enrolled subjects are distributed as follows: 50 cases from the coordinator site in Italy (IEO), 49 from French partner (CHUT), 35 from Spain (ICO/IDIBELL), and 40 from Romanian partner (IOCN), reaching a total number of 174 participants, beyond those planned. This required additional Material Transfer and Service Agreements (MTAs and SAs, respectively) which were successfully signed halfway through the year 2023 by the institutions involved. For each subject case, we accomplished the full routine medical visit, psychological interview, blood sampling and the baseline radiological screening examinations using Whole-Body MRI.	
Has there been a deviation from the original work plan or from the original timeline? *If so, explain the reasons for deviation, the consequences and the proposed corrective actions. Max. 600 characters including spaces.* Partner CHUT enrolled 49 over 50 subjects planned. IOCN (Dr Ovidiu Balacescu) enrolled 40 subjects out of the planned 35, ensuring the total number foreseen in the work plan and a higher number to compensate for any dropouts. There was a delay of a few months in the completion of screening with WB-MRI in subjects enrolled at ICO (Spain), due to institutional organizational barriers. Partner 2, ICO is going to complete the radiological screening examinations within June 2024. IOCN started implementing NGS testing for the hereditary panel (Illumina-TruSight Hereditary Cancer) and applying it to identify the genetic alterations of pancreatic cancer patients (Romanian group) to be associated with the CRPA algorithm.	

WP 2	**Epigenetic analysis for risk profiling and cancer screening**
Leading Partner: Partner 3, PMU (prof. Tomasz Kazimierz Wojdacz)	
Additional involved Partners	
Planned timeline (according to GANTT chart): (from 13 to M24)	**Actual timeline:** (from M13 to M24)
Work performed, Challenges, Achievements (*Max. 1,200 characters including spaces*) PMU finalized agreements, protocols and coordinated the logistics behind samples shipments from the enrolling centres to the epigenetic analysis laboratory at the University of Lodz (Poland). Epigenetic analysis in the blood samples from the sporadic cases selected for ERS-CRPA calibration have been completed. Bioinformatical processing of publicly available data were finalized and implemented for the development of the epigenetic risk signature, contributing to the CRPA calibration. PUM worked in collaboration with partner IDIBELL to finalize the CRPA analysis and calibration PMU also coordinated the pre-processing of the blood DNA samples for HR subjects. DNA methylation results were delivered in April 2024. PMU created dataset genome wide methylation profiles of HR subjects and sporadic cases. Statistical analyses are currently underway by PUM and IDIBELL. The results will be presented at the IMAGene Mid-term meeting in Warsaw (June 4-5), and at the Clinical Epigenetics	

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International Conference CLEPIC 2024. After a thorough review of the literature and the most recent ongoing studies, PMU also determined the appropriate protocol to apply for liquid biopsy analysis, to be performed for the enrolled HR subjects at 1-year follow-up.
Has there been a deviation from the original work plan or from the original timeline? *If so, explain the reasons for deviation, the consequences and the proposed corrective actions. Max. 600 characters including spaces.* Methylation analysis were postponed (about 3 months) compared to the planned timeline, but still completed within the second year of the project. This was due to a short delay in blood collection and difficulties in organizing samples shipments with couriers. Because of difficulties in communication exchange with consultant Dr. M. Lupien and the laboratory in Canada, initially involved to conduct cfMeDIP-seq analyses as well as significant increase of the costs of the experimental work, partner responsible for the experimental part of the epigenetic screening - PUM evaluated the scientific validity of other liquid biopsy protocols suitable for the IMAGene study. After discussion, an agreement was reached with the entire consortium to proceed with the protocol previously published in Nature Communications 2018 Nov 29;9(1):5068, by Moss J et al. These analyses are now planned to be conducted in a European laboratory, yet to be determined (several laboratories are currently being consulted in Italy, Poland, Romania, and Spain), to streamline both communication and reduce shipping and analysis costs.

WP 3	**WB-MRI & epigenetic analysis for early detection of cancer: feasibility**
Leading Partner: Coordinator Partner 1, IEO (dr. Serena Oliveri)	
Additional involved Partners: Partner 2, IDIBELL/ICO (Victor Raul Moreno Aguado), Partner 4, IOCN (dr Ovidiu Balacescu), Partner 5, CHUT (prof Louis Buscail).	
Planned timeline (according to GANTT chart): (from M1 to M32)	**Actual timeline:** (from M13 to M24)
Work performed, Challenges, Achievements (*Max. 1,200 characters including spaces*) IEO implemented a uniform WB-MRI protocol for all the enrolling cancer centers. The researcher in charge at IEO, Dr. Paul Eugene Summers, working at the Precision Imaging and Research Unit IEO, performed a remote training for radiologists directly involved in the project and site visits at each cancer center to standardize the MRI protocol and data reports, using an adaptation of the MY-RADS reporting guidelines (PMID: 30806604), among cancer centres. Imaging screening in enrolled HR subjects was performed at baseline for all subjects enrolled at IEO, IOCN and CHUT, and are going to be completed at ICO. 1-year follow up were also scheduled. For each lesion, the radiologist reported location, size, volume, and appearance using an adaptation of the MY-RADS reporting guidelines (PMID: 30806604). Partners are analysing Imaging data and correlating them with data collected for WP1 and WP2. Data were also included in REDCap and into the CRPA. All imaging and clinical outputs are used as inputs to ERS-CRPA model optimization (WP1).	
Has there been a deviation from the original work plan or from the original timeline? *If so, explain the reasons for deviation, the consequences and the proposed corrective actions. Max. 600 characters including spaces.* The ICO partner encountered organizational barriers and difficulties in scheduling participant's appointments at the cancer centre that slowed the radiological screening of enrolled subjects. Therefore, the subjects have completed all the visits and blood extraction, and are currently finalizing WB-MRIs at baseline. Completion of MRI is foreseen at month 28 (July 2024).	

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WP 4	HR individuals' preferences, psycho-cognitive profiles and decisions
Leading Partner: Coordinator Partner 1, IEO (dr. Serena Oliveri)	
Additional involved Partners: Partner 2, IDIBELL/ICO (Dr. Victor Moreno Aguado), Partner 4, IOCN (Dr. Ovidiu Balacescu), Partner 5, CHUT (prof Louis Buscail).	
Planned timeline (according to GANTT chart): (from 5 to 32)	**Actual timeline:** (from 13 to 24)

Work performed, Challenges, Achievements (*Max. 1,200 characters including spaces*)

IMAGene participants completed standardized ad-hoc questionnaires and qualitative interviews at the time of enrolment during the medical visit, to assess their preferences, perceived individual risk, biases in risk estimate, stress levels and coping strategies. In addition, health literacy, expectations, concerns, perceived utility of the procedure were assessed. Questionnaires and data are uploaded in REDCap. Interviews were recorded at IEO, ICO and CHUT, transcribed and transferred to IEO in anonymized form. Both quantitative and qualitative data collected at baseline are now being analysed. Follow up surveys at 6-month follow up are also submitted and now ongoing, using web interfaces securely linked to REDCap, to monitor the stress levels due to the participation to the trial, post-test acceptability and satisfaction with the procedures plus impact of the screening outcomes.

Has there been a deviation from the original work plan or from the original timeline? *If so, explain the reasons for deviation, the consequences and the proposed corrective actions. Max. 600 characters including spaces.*

No deviation in the work plan.

WP 5	Address the ethical, legal and social issues (ELSI)
Leading Partner: Coordinator Partner 1, IEO (dr. Serena Oliveri)	
Additional involved Partners: Coordinator teams member in charge: dr Virginia Sanchini; Partner 5, CHUT (prof Louis Buscail); Consultant: dr Heidi Howard, Lund University	
Planned timeline (according to GANTT chart): (from 1 to 36)	**Actual timeline:** (from 13 to 24)

Work performed, Challenges, Achievements (*Max. 1,200 characters including spaces*)

IEO constantly monitored partners' liaise with their legal and research coordination offices to ensure they follow ethical and legal (regional and national) frameworks to complete agreements among consortium partners and external services. In the second year, ethical guidance focused on how properly handling the return of results (RoR) of the screening procedures (genetic testing and MRI results). In particular, the ethical aspects surrounding RoR have been the focus of several regular IMAGene bi-weekly meetings. The main experimenter for the project in each cancer centre was invited to interface with the professionals involved for the management of RoR (oncologists, radiologists, geneticists), and establish, within the specific local procedures and regulations, the communication steps to follow with the patients in compliance with Good medical practice. The consortium agreed for a RoR plan to offer a responsible process for the management of unsolicited findings and RoR to participants, including considerations related to the right not to know and medical benefits. It will be revised after the planned in-depth qualitative semi-structured interviews with 15 first-degree relatives of PC patients and 15 clinicians.

Has there been a deviation from the original work plan or from the original timeline? *If so, explain the reasons for deviation, the consequences and the proposed corrective actions. Max. 600 characters including spaces.*

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Lund University, initially a partner included in the IMAGene consortium and completely dedicated to the ELSI WP, was not able to take part in the consortium due to a declared lack of funds from the Swedish funding agency SRC. Because of this huge loss, the following scientific activities have been postponed at the 3rd year of project: semi-structured interviews with expert stakeholders on i. how to offer a responsible process for the management of unsolicited findings and returning of results (RoR); ii. How to adapt the informed consent for oncological patients' relatives (healthy subjects) in case of epigenetic screening.

WP 6	**Cost and Utility Analysis, and requisites for designing large-scale studies**
Leading Partner: Coordinator Partner 1, IEO (dr. Serena Oliveri)	
Additional involved Partners: All partners	
Planned timeline (according to GANTT chart): (from 25 to 36)	**Actual timeline:** (from 6 to 12)
Work performed, Challenges, Achievements (*Max. 1,200 characters including spaces*) Starting from the 6th month follow up (see WP4), enrolled HR subjects have been invited to fill in questionnaires for the Value-Based Health Care paradigm/analysis (VBHC)[31]. Questionnaires include items related to the indirect costs (e.g. absence from work, costs for public transportation, costs for any overnight stays, and others) they faced in order to travel to the hospital and undergo the screening procedures in the trial, for performing the analysis under the. At 1-year follow up other questionnaires are planned to be submitted to participants with the same aims. The equation to integrate the indices (direct and indirect costs for the required cancer screening procedures) into a single macro indicator have been implemented, and it represents the maximum health protection achieved for each euro spent	
Has there been a deviation from the original work plan or from the original timeline? *If so, explain the reasons for deviation, the consequences and the proposed corrective actions. Max. 600 characters including spaces.* No deviation in the work plan.	

WP 7	**Project management**
Leading Partner: Coordinator Partner 1, IEO (dr. Serena Oliveri)	
Additional involved Partners:	
Planned timeline (according to GANTT chart): (from 1 to 36)	**Actual timeline:** (from13 to 24)
Work performed, Challenges, Achievements (*Max. 1,200 characters including spaces*) Work performed: 1. Regular bi-weekly meetings to monitor overall project progress, coordinate efforts, ensure corrective actions if needed. 2. Organization of in person Mid-term meeting and open workshop about IMAGene scientific activities and results at Warsaw (4-5 May 2024). 3. Virtual training Whole-Body MRI protocol and data reports based on MY-RADS reporting guidelines.	

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Has there been a deviation from the original work plan or from the original timeline? *If so*, *explain the reasons for deviation, the consequences and the proposed corrective actions. Max. 600 characters including spaces.*

In accordance with and on behalf of IMAGene Consortium, the Principal Investigator will ask ERA Per Med secretariat for a 6-month no cost extension (from the current end date 31st March 2025 until the new end date 30th September 2025) due to:

- organizational delays at the enrolling cancer centres in performing MRI screening of patients at baseline (T1.4 and T3.2);

- delay in samples shipment to external laboratories, and consequent completion of epigenetic analysis (WP2).

Concurrently with the request to JCS, each partner will forward the extension request to its own "National Funding Organization".

This postponement will allow the regular completion of the 1-year follow-up, data analyses, the achievement of all tasks under WP6 and dissemination through publications

Please add WPs as relevant. M = Month.

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5. 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*
Steering committee members listed in the consortium agreement.	Bi-weekly meetings since 13-04-2023 and currently scheduled every 2 weeks	Zoom	Management and Coordination of scientific activities	Minutes available
IMAGene MID-Term meeting. All researchers involved in the project (In person or connected remotely)	4th-5th June 2024	CLEPIC Congress Meeting in presence	- Assesses the fulfilment of all scientific activities and deliverables (training, management, networking, etc.); - Discussion of results obtained at baseline assessment for each WP; - Check follow-up activities and timeline.	Minutes available
Paul Eugene Summers and radiologists at Centre Hospitalier Universitaire de Toulouse	22th – 23th June 2023	Centre Hospitalier Universitaire de Toulouse, France Site-visits	WB-MRI training, sequences installation and testing	

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).

Thanks to the transnational collaboration, it has been possible to carry out a strong exchange of expertise among highly clinical professionals from different scientific areas (psychologists, radiologists, oncologists, biologists, biostatisticians, epidemiologists etc.). The synergy and availability among IMAGene partners also allowed making, during this 2st year of the project, an adjustment in the recruitment of participants (1st degree relatives of cancer patients) for the validation phase of the algorithm. Dr Paus Summers, researcher radiologist in charge at IEO, completed the site visits at CHUT and IOCN for installing the correct MRI sequences planned for the project and trained radiologist in using specific protocols and reporting results. Dr Paul Summers also finalized a vitual training for radiologist working at ICO. Finally, the constant exchange of information and expertise related to the topics and disciplines involved in IMAGene, allowed to extend the collaboration

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between the partners to other European projects, and plan the future collaboration between IMAGene partners for European applications, with an extension of the consortium itself. To date no particular obstacles have been encountered for the collaboration between partners, neither in the execution of the Tasks planned for IMAGene nor in sharing of knowledge, expertise, materials and methods for implementing scientific research.

6. 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).

No significant changes from the strategy described in the initial DMP.

7. Patients Involvement

Does your project involve a patient representative/organization? ***YES***

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)

Provide advice on participants' assessment. For this reason, a patient representative will be appropriately invited to attend major consortium meetings, and consulted by the PI as needed by the project.

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)

8. Peer Reviewed Articles

Only include publications after the start date of the project, ***with clear acknowledgement of ERAPerMed 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."*

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Type of Publication*	Partner No	Publication (authors, title, journal, year, issue, pp.)	DOI	Open access (yes/no)	Confir-mation **
					☐
					☐
					☐

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.*

Publication plan

WP number	Type of data	Title
WP1. ERS- CRPA	*Quantitative results*	*Epidemilogical risk factors and Algorithm calibration*
WP3. WB-MRI	*Quantitative results*	*WB-MRI screening results and MRI protocol at baseline*
WP3. WB-MRI & epigenetic analysis	*Quantitative results*	*WB-MRI results compared with Epigenetic profiles for subjects at high risk for Pancreatic Cancer: evidences from the IMAGene project*
WP4. Psychological Evaluation	*Qualitative results*	*What matters to first-degree relatives when they are offered preventive screening for Pancreatic Cancer? A qualitative study*
WP4. Psychological Evaluation	*Quantitative results*	*Psychological characteristic and life style habits of high-risk individuals participating in a clinical trial for early detection of pancreatic cancer (T0)*
WP4. Psychological Evaluation	*Quantitative results*	*Psychological and behavioral impacts of participating in a clinical trial for early detection of pancreatic cancer in individuals at high risk (T0-T1)*
WP1. ERS- CRPA	*Quantitative results*	*Genetic profile of patients at high risk of Pancreatic Cancer and comparison with MRI results and epigenetic profiles*

9. 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**
Web-site	1 and 2	Dedicated project web-site	https://www.imagene.ieo.eu/	General public
Social media	All	Network linkedin advertisement of		scientific community, general public

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		IMAGene scientific activities		
Communication in conference 24th IPOS World Congress of Psycho Oncology 31st August – 3rd September 2023 in Milan, Italy	1	Talk title: IMAGene. Epigenomic and machine learning models to predict Pancreatic Cancer in High Risk asymptomatic subjects		scientific community

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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ISTITUTO NAZIONALE PER L'ASSICURAZIONE CONTRO GLI INFORTUNI SUL LAVORO

Istituto Nazionale Previdenza Sociale

Durc On Line

Numero Protocollo	INAIL_46005365	Data richiesta	16/10/2024	Scadenza validità	13/02/2025

Denominazione/ragione sociale	ISTITUTO EUROPEO DI ONCOLOGIA SRL
Codice fiscale	08691440153
Sede legale	VIA FILODRAMMATICI, 10 20121 MILANO (MI)

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

I.N.P.S.

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