

AZIENDA OSPEDALIERO UNIVERSITARIA MEYER

Delibera del Direttore Generale n. 550 del 30-11-2022

Proposta n. 1089 del 2022

Oggetto: AFFIDAMENTO DIRETTO AI SENSI DELL'ART ALL'ART. 1 C.2 LETT. A) DEL D.L. N. 76/2020 E S.M.I. DELLA FORNITURA DEL SERVIZIO DI GESTIONE DEI DATI PER IL PROGETTO DENOMINATO "FAIRVASC - BUILDING REGISTRY INTEROPERABILITY TO INFORM CLINICAL CARE" - APPROVAZIONE DELL'ACCORDO CON THE EUROPEAN INSTITUTE FOR INNOVATION THROUGH HEALTH DATA (I-HD) – CIG Z7638753D4

Dirigente: FERRIGNO MARIANGELA

Struttura Dirigente: RESPONSABILE AFFARI GENERALI E SVILUPPO

AZIENDA OSPEDALIERO UNIVERSITARIA MEYER
(Art. 33 L.R.T. 24 febbraio 2005 n. 40)
I.R.C.C.S. Istituto di Ricovero e Cura a Carattere Scientifico
(Decreto Ministero della Salute del 02.08.2022)
Viale Pieraccini, 24 - 50139 FIRENZE
C.F. P.Iva 02175680483

DELIBERAZIONE DEL DIRETTORE GENERALE

Oggetto	Progetto
Contenuto	AFFIDAMENTO DIRETTO AI SENSI DELL'ART ALL'ART. 1 C.2 LETT. A) DEL D.L. N. 76/2020 E S.M.I. DELLA FORNITURA DEL SERVIZIO DI GESTIONE DEI DATI PER IL PROGETTO DENOMINATO "FAIRVASC - BUILDING REGISTRY INTEROPERABILITY TO INFORM CLINICAL CARE" - APPROVAZIONE DELL'ACCORDO CON THE EUROPEAN INSTITUTE FOR INNOVATION THROUGH HEALTH DATA (I-HD) – CIG Z7638753D4

Area Tecnico Amm.va	AREA TECNICO AMMINISTRATIVA
Coord. Area Tecnico Amm.va	BINI CARLA
Struttura	AFFARI GENERALI E SVILUPPO
Direttore della Struttura	MARIANGELA FERRIGNO
Responsabile del procedimento	ALESSIO FABBIANO
Immediatamente Esecutiva	NO

Spesa prevista	Conto Economico	Codice Conto	Anno Bilancio
12.000,00	Altri servizi non sanitari da privato	4202411060	2022

Estremi relativi ai principali documenti contenuti nel fascicolo		
Allegato	N° di pag.	Oggetto
1	12	Data Management Consultancy Service Agreement



IL DIRETTORE GENERALE

Dr. Alberto Zanobini

(D.P.G.R.T. n. 99 del 30 luglio 2020)

Visto il D. Lgs.vo 30.12.1992 n. 502 e sue successive modifiche ed integrazioni e la L. R. Toscana n. 40 del 24.02.2005 e s.m.i. di disciplina del Servizio Sanitario Regionale;

Dato atto che:

- con deliberazione del Direttore Generale n. 54 del 01.02.2021 è stato approvato il nuovo Atto Aziendale dell'A.O.U. Meyer, ai sensi dell'art. 6 del Protocollo d'intesa del 22.04.2002 fra Regione Toscana e Università degli Studi di Firenze, Siena e Pisa, con decorrenza dal 01.02.2021;
- con deliberazione del Direttore Generale n. 55 del 01.02.2021 sono stati assunti i primi provvedimenti attuativi in relazione alla conferma/riassetto delle strutture complesse e semplici dotate di autonomia ed al conferimento dei relativi incarichi di direzione;
- con deliberazione del Direttore Generale n. 56 del 01.02.2021 sono state assunte determinazioni attuative del nuovo Atto aziendale in relazione alla conferma/riassetto delle strutture Dipartimentali e/o a valenza dipartimentale, delle Aree Funzionali Omogenee, dell'Area Servizi dell'Ospedale, dell'Area dei Diritti del Bambino, dell'Area Tecnico Amministrativa ed al conferimento di relativi incarichi di direzione;
- con successiva deliberazione del Direttore Generale n. 92 del 15.02.2021 si è provveduto ad assumere ulteriori disposizioni attuative relative all'organizzazione dell'A.O.U. Meyer in ordine alle Strutture semplici Intrasoc, Unità Professionali, Uffici e Incarichi professionali;
- con deliberazione del Direttore Generale n. 443 del 23.09.2022 l'A.O.U. Meyer ha disposto la presa d'atto del Decreto del Ministero della Salute del 02.08.2022, pubblicato nella Gazzetta Ufficiale n. 200 del 27.08.2022, con cui l'Azienda Ospedaliero Universitaria Meyer è stata riconosciuta Istituto di Ricovero e Cura a Carattere Scientifico (I.R.C.C.S.), per la disciplina di pediatria;

Su proposta del Responsabile della S.O.C Affari Generali e Sviluppo, Dr.ssa Mariangela Ferrigno, la quale attesta la regolarità amministrativa e la legittimità dell'atto;

Visto l'art. 1 c. 2 lett. a) del D.L. 76/2020, convertito con modificazioni dalla L. 11 settembre 2020, n. 120 e successive modifiche (disciplina sostitutiva dell'art 36 c. 2 del d.lgs. 50 /2016 fino al 30/06/2023), che consente l'affidamento diretto di contratti aventi ad oggetto forniture e servizi aventi valore inferiore ad €139.000,00, anche senza previa consultazione di due o più operatori economici, fermo restando il rispetto dei principi di cui all'articolo 30 del codice dei contratti pubblici di cui al decreto legislativo 18 aprile 2016, n. 50;

Richiamate le Linee Guida n. 4, attuative del nuovo Codice degli appalti, approvate dall'ANAC con deliberazione n. 1097 del 26/10/2016 e successivi aggiornamenti, relative alle "Procedure per l'affidamento dei contratti pubblici di importo inferiore alle soglie di rilevanza comunitaria, alle indagini di mercato e formazione e gestione degli elenchi di operatori economici";

Visto il Regolamento Aziendale per l'acquisizione di lavori, forniture e servizi di importo inferiore alle soglie di rilevanza comunitaria approvato con Deliberazione D.G. n. 619 del 08.11.2019;

Visto l'art. 3 della legge n. 136/2010, in materia di tracciabilità dei flussi finanziari;

Rilevato che alla data odierna non sono attive convenzioni Consip di cui all'art. 26, comma 1, della L. n. 488/1999 e s.m.i., aventi ad oggetto una fornitura comparabile con quella oggetto del presente affidamento, e che quest'ultimo non rientra nelle categorie merceologiche di cui all'art. 1 comma 7 del D.L. 95/2012, convertito in Legge 135/2012 e, pertanto, non è soggetto alla disciplina ivi prescritta;

Ricordato che con Delibera del Direttore Generale n. 316 del 17.07.2020 questa Azienda ha autorizzato l'esecuzione del progetto denominato "FAIRVASC - building registry interoperability to inform clinical care", finanziato nell'ambito del Programma Comune Europeo sulle Malattie Rare (European Joint Programme on Rare Diseases EJP RD) e che con la stessa Delibera sono stati approvati la Description of Action e il Consortium Agreement sottoscritto con i partner di progetto;

Premesso che l'AOU Meyer è il Coordinatore, sotto la responsabilità del Prof. Augusto Vaglio, del progetto FAIRVASC e che, nello svolgere tale ruolo, riceve il sostegno economico della Regione Toscana in qualità di autorità finanziatrice;

Atteso che il progetto FAIRVASC consiste nella combinazione di database regionali e nazionali di una pluralità di istituzioni appartenenti a diversi paesi europei in modo da consentire, mediante la disponibilità di una più ampia quantità di dati riuniti in un unico dataset, una più solida comprensione delle vasculiti e incoraggiare altresì forme di ricerca più mirate per pervenire ad un eventuale trattamento e ad una cura appropriata;

Considerato che nel Consortium Agreement è fatto riferimento alla necessità del supporto di un sub-contrante qualificato in "tutte le materie concernenti la gestione dei dati, la protezione dei dati, la privacy e l'etica", secondo il contributo finanziario messo a disposizione da ciascun partner del progetto, in accordo con i termini finanziari dettagliati nella Description of Action;

Specificato che ciascun partner del progetto FAIRVASC contribuisce, con contratti bilaterali, al finanziamento delle attività esplicitate al punto precedente e nei limiti delle risorse finanziarie messe a disposizione di ciascun partner dalle rispettive autorità finanziatrici per il progetto di cui trattasi;

Vista la relazione del Prof. Augusto Vaglio del 15.06.2021, agli atti, con cui viene individuato, in ragione dell'esperienza e dell'expertise specifiche, The European Institute for Innovation Through Health Data (i-HD), un istituto senza scopo di lucro con sede in C. Heymanslaan 10, 9000 Gent, Belgio, quale sub-contrante per l'esecuzione di una serie di servizi concernenti l'amministrazione e il trattamento dei dati che confluiscono nel progetto FAIRVASC e, nello specifico, la valutazione della qualità dei dati, la revisione della completezza e dell'accuratezza dei dati, la protezione e la gestione dei dati del progetto anche con riferimento alla normativa europea applicabile al trattamento e alla protezione dei dati, la definizione del quadro normativo del progetto per la condivisione di dati, per le politiche di accesso e per i requisiti regolatori di gestione delle responsabilità nel trattamento dei dati;

Dato atto che nella suddetta relazione, tra l'altro, viene evidenziato che i-HD ha sviluppato una leadership su scala globale nell'ambito del data governance, aspetto centrale nel progetto FAIRVASC, possedendo ampie competenze nel fornire supporto ai partner del progetto nella valutazione della qualità dei dati dei registri sulle vasculiti che saranno federati nel progetto e garantendo la necessaria esperienza per gli aspetti regolatori afferenti all'ambito della privacy;

Rilevato che il corrispettivo a favore di i-HD per i servizi che tale istituto renderà nell'ambito del progetto FAIRVASC così come sopra richiamati ammontano ad € 9.836,07 oltre IVA;

Rilevato che ai sensi di quanto previsto dall'art 15 c. 2 del regolamento per l'acquisizione di lavori, forniture e servizi di importo inferiore alle soglie di rilevanza comunitaria, *“l'AOU Meyer dispone verifiche in ordine ai requisiti di idoneità dei contraenti, nell'ambito delle singole procedure di affidamento, di importo uguale o superiore ad euro 20.000,00 (I.V.A. esclusa) e, per le procedure di importo inferiore ad euro 20.000,00 (i.v.a. esclusa), esclusivamente a campione. Negli affidamenti di importo inferiore ad euro 10.000,00 (i.v.a. esclusa), per ragioni di semplificazione procedurale, si può prescindere dall'effettuazione dei controlli”*;

Ritenuto, per quanto sopra espressamente evidenziato, di affidare il servizio di gestione dei dati del progetto FAIRVASC a The European Institute for Innovation Through Health Data, per un importo di € 9.836,07 oltre IVA secondo quanto disciplinato dallo schema di Accordo sul servizio di consulenza per la gestione dei dati che il suddetto istituto eseguirà per l'amministrazione dei dati del progetto sulla base del documento di Description of Action e del Consortium Agreement;

Ritenuto pertanto di stipulare l'Accordo sopra citato con The European Institute for Innovation Through Health Data per la disciplina delle condizioni normative, economiche ed operative delle attività che tale istituto svolgerà nell'ambito del progetto di cui trattasi, che, allegato N. 1 al presente atto, ne forma parte integrante e sostanziale;

Ritenuto di aver ottemperato a quanto disposto dall'articolo 32, c. 2, del Codice, poiché dal presente atto sono desumibili:

- a) il fine di pubblico interesse che con il contratto si intende perseguire;
- b) l'oggetto del contratto;
- c) il valore economico;
- d) la forma del contratto;
- e) le clausole ritenute essenziali;
- f) le modalità di scelta del contraente e le ragioni di tale scelta

Dato atto:

- che il pagamento della fornitura del servizio di cui trattasi avverrà dietro presentazione di fattura da parte di The European Institute for Innovation Through Health Data;
- che l'affidamento è individuato dal seguente codice CIG Z7638753D4;
- che la spesa è esigibile nell'anno 2022;

Considerato che il Responsabile del Procedimento, individuato ai sensi della Legge n. 241/1990 nella persona del Dr. Alessio Fabbiano sottoscrivendo l'atto attesta che lo stesso, a seguito dell'istruttoria effettuata, nella forma e nella sostanza è legittimo;

Acquisito il parere del Coordinatore dell'Area Tecnico Amministrativa, Dr.ssa Carla Bini, espresso mediante sottoscrizione del presente atto;

Vista la sottoscrizione del Direttore Sanitario e del Direttore Amministrativo, per quanto di competenza, ai sensi dell'art. 3 del Decreto Legislativo n. 229/99;

DELIBERA

Per quanto esposto in narrativa che espressamente si richiama,

1. Di incaricare con affidamento diretto, ai sensi di quanto consentito dall'art. 1 c. 2 lett. a) del D.L.76/2020, convertito con modificazioni dalla L. 11 settembre 2020, n. 120 e successive modifiche (disciplina sostitutiva dell'art 36 c. 2 del d.lgs. 50 /2016 fino al 30/06/2023), The European Institute for Innovation Through Health Data con sede in C. Heymanslaan 10, 9000 Gent, Belgio, per l'importo offerto di € 9.836,07 oltre IVA, la fornitura del servizio di gestione dei dati nell'ambito del progetto FAIRVASC, secondo quanto disciplinato dallo schema di Accordo, Allegato N. 1 al presente atto a formarne parte integrante e sostanziale.
2. Di stipulare il suddetto Accordo con The European Institute for Innovation Through Health Data.
3. Di prendere atto della relazione prodotta dal Prof. Augusto Vaglio per quanto riguarda la scelta di The European Institute for Innovation Through Health Data per le attività di gestione dei dati del progetto FAIRVASC come definite nel documento di Description of Action, nel Consortium Agreement e nell'Accordo sopra richiamato.
4. Di imputare la somma complessiva di € 12.000,00 (9.836,07 + IVA), CIG Z7638753D4 per lo svolgimento delle attività come segue:
 - Euro 12.000,00 al Bilancio 2022 PRCD Y02/4202411060/D22..... CDC 894.
5. Di dare atto che è individuato quale responsabile delle prestazioni del presente contratto per il livello di programmazione delle attività, per gli aspetti tecnico-professionali, azioni di verifica e controllo della qualità delle prestazioni erogate, il Prof. Augusto Vaglio.
6. Di dare atto altresì che si procederà alla pubblicazione prevista dall'art. 1 comma 32 della Legge n. 190/2012 nei termini previsti dalla normativa e dall'art. 37 del D.Lgs. n.33/2013.
7. Di trasmettere il presente atto al Collegio Sindacale ai sensi dell'art. 42, comma 2, della L.R.T. n. 40/2005 contemporaneamente all'inoltro all'albo di pubblicità degli atti di questa A.O.U. Meyer.

IL DIRETTORE GENERALE
(Dr. Alberto Zanobini)

IL DIRETTORE SANITARIO
(Dr.ssa Francesca Bellini)

IL DIRETTORE AMMINISTRATIVO
(Dr. Tito Berti)

(1) MEYER CHILDREN'S UNIVERSITY HOSPITAL

AND

(2) The European Institute for Innovation Through Health Data

DATA MANAGEMENT CONSULTANCY SERVICE AGREEMENT

DATA MANAGEMENT CONSULTANCY SERVICE AGREEMENT

This Agreement, effective as of the Commencement Date, is between:

- (1) **Meyer Children's University Hospital (the "Contract giver")**, a paediatric public university hospital of the Italian public health system, with registered office in Viale Gaetano Pieraccini, 24, 50139, Florence, Italy, represented by its Managing Director and Legal representative Alberto Zanobini; and
- (2) **The European Institute for Innovation Through Health Data (the "Contract acceptor")**, a company incorporated in Belgium, with principal business location at C. Heymanslaan 10, 9000 Gent, Belgium, registered with RPR/RPM in Brussels (judicial district) under number BE0628.646.310.

Hereinafter individually a "Party" and together the "Parties".

Background:

- A. The Contract giver is the Coordinator of the project "FAIRVASC - building registry interoperability to inform clinical care" (the "Project"), funded under the "Transnational research projects to accelerate diagnosis and/or explore disease progression and mechanisms of rare diseases" of the European Joint Programme on Rare Diseases (EJP RD).
- B. The Contract giver has entered into a Consortium Agreement ("CA") with other Project partners on the basis of a Description of Action ("DoA") of the Project, in accordance with the EJP RD procedure.
- C. The Regione Toscana ("Prime Sponsor") has awarded the Contract giver a grant, through Professor Augusto Vaglio ("Principal Investigator") of the Nephrology facility of the Contract giver, to enable the participation of the Contract giver in the Project.
- D. The Contract acceptor has expertise in the fields of data management and data quality services, quality assurance services, compliance, information governance and advisory services.
- E. The Contract acceptor is aware of each of the beneficiaries of the Project partners, their roles and responsibilities, and their contributions to the Project, both before and after submission of the Project for funding by EJP RD.
- F. By virtue of the above and in compliance with the DoA and the CA, as well as on the basis of a report by the Principal Investigator concerning the choice of the company for the delivery of the project management services, the Contract giver has identified the Contract acceptor as the company uniquely well suited to support the following activities of the FAIRVASC project, as specified in the relevant work packages of the DoA and the CA, on the basis of being the sole supplier with the background knowledge of the project:
 - (1) Assisting in defining the data quality assessments that will be undertaken;
 - (2) Assisting in providing training to local registry teams and funded FAIRVASC personnel on profiling and quality-assurance work and assist in the review of the completeness and accuracy of data in each registry;
 - (3) Advising on how data are managed and protected as they are processed within the Registries and across the Consortium;

- (4) Working with the Registry Data Controllers to support them with conducting their Data Protection Impact Assessments with a project wide, high level DPIA for FAIRVASC;
 - (5) Focusing on the GDPR interplay with applicable Member State law and data needs for each clinical research question as defined by the consortium;
 - (6) Coordinating the preparation of a series of legal, access policy, accountability data management and regulatory requirements and resources for each Registry (through codes of conduct) as well as to provide a legal framework for data sharing within and beyond FAIRVASC;
 - (7) Promoting and guiding the involvement of patient representative consortium partners in the drafting of transparency materials for data subjects and the wider public; and
 - (8) Advising on the exchange of data processes between the Registries and partners as well as other ad hoc issues, including pseudonymization and anonymity for defined clinical research themes.
- G. Both the CA and the DoA provide for the delivery of data management services for the overall data management of the Project.
- H. The Contract giver wishes to engage the Contract acceptor to provide the Services (as defined hereof) in connection with the Project, all subject to the provisions of this Agreement and the CA and DoA. It is acknowledged that each of the Project partners will be entering into a separate agreement with the Contract acceptor for the provision of the Services. The costs for the Services will not be borne solely by Contract giver as Coordinator, but they will also be distributed across the Project partners, in accordance with the funding amounts specified in the DoA

The Parties agree as follows:

1. Definitions

1.1 *Definitions.* In this Agreement, the following words shall have the following meanings:

Affiliate	In relation to a Party, means any entity or person that Controls, is Controlled by, or is under common Control with that Party.
Claims	All demands, claims and liability (whether criminal or civil, in contract, tort, including negligence, or otherwise) for losses, damages, legal costs and other expenses of any nature whatsoever and all costs and expenses (including legal costs) incurred in connection therewith.
Commencement Date	The commencement date of this Agreement and of the Services is 1 June 2020. Notwithstanding the actual date of execution hereof, this Agreement shall be effective as of and from the Commencement Date.
Completion Date	The completion date of this Agreement and of the Services as set out in Schedule 1.
Confidential Information	All technical or commercial information that: <ul style="list-style-type: none"> (i) in respect of information provided in documentary form or by way of a model or in other tangible form, at the time of provision is marked or otherwise designated to show

	expressly or by necessary implication that it is imparted in confidence;
	(ii) in respect of information that is imparted orally, any information that the Disclosing Party or its representatives informed the Receiving or its representatives Party at the time of disclosure was imparted in confidence; and
	(iii) any copy of any of the foregoing.
Contract acceptor	The individual(s) identified in Schedule 1 who will perform the Services, or such other persons as may be appointed in accordance with Clause 2.2.
Control	Direct or indirect beneficial ownership of 50% (or, outside a Party's home territory, such lesser percentage as is the maximum, permitted level of foreign investment) or more of the share capital, stock or other participating interest carrying the right to vote or to distribution of profits of that Party, as the case may be.
Fees	The fees to be paid to the Contract acceptor by the Contract giver as set out in Schedule 2.
Foreground IP	All Intellectual Property generated by the Contract acceptor in the performance of the Services.
Intellectual Property	All intellectual property of any description including copyright, trademarks, database rights, design rights, patents, utility models, and applications for, and the right to apply for any of the foregoing items.
Project	Means the project as defined in Recital A.
Services	The services to be provided by the Contract acceptor for the Contract giver as more fully described in Schedule 1.

2. Consultancy services

- 2.1 *Services.* In consideration of the payment of the Fees by the Contract giver to the Contract acceptor, the Contract acceptor shall provide the Services to the Contract giver from the Commencement Date, all in accordance with the provisions of this Agreement and the requirements of the CA and DoA as executed by the Project partners..
- 2.2 *Contract acceptor.* The Services will be performed by the Contract acceptor. The Contract acceptor may not, at any time throughout the term of this Agreement, substitute the Contract acceptor with an alternative Contract acceptor with similar qualifications and experience without the prior written approval of the Contract giver. In the event of any such sub-Contract acceptor being appointed in accordance with the terms of this clause, the provisions of Clause 10.3 shall apply.
- 2.3 *Timetable.* Where Schedule 1 states that Services are to be performed within a specific timeframe, then the Contract acceptor shall use reasonable efforts to perform the Services by the relevant date. Where Schedule 1 does not require that Services are to be performed within a specific timeframe, then the Contract acceptor shall nonetheless use reasonable efforts to perform the Services in a timely manner.
- 2.4 *Delays.* If the Contract acceptor foresees any potential delays in the completion of the Services, the Contract acceptor will notify the Contract giver as soon as is reasonably practicable and take reasonable steps to mitigate any delay to the Completion Date.

2.5 *Reports.* The Contract acceptor will provide any required reports to the Contract giver and the CA partners at the times as required by such parties during the Project term.

2.6 *Independent Contract acceptors.* The relationship of the Contract acceptor to the Contract giver shall be that of independent Contract acceptor. This Agreement is not intended to, and does not, create any contract of employment or other legal relationship between the Contract acceptor and the Contract giver.

3. Fees

3.1 *Invoices.* The Contract acceptor shall provide the Contract giver with invoices for the Fees due to the Contract giver in accordance with the payment timeline set out in Schedule 2.

3.2 *Payment.* The Contract giver shall pay all valid invoices within thirty (30) days of receipt of an invoice.

3.3 *Expenses.* Unless otherwise stated in Schedule 2, the Fees are inclusive of all expenses reasonably incurred by the Contract acceptor in the performance of the Services.

3.4 *Currency and VAT.* All amounts stated shall be paid in Euro and Value Added Tax noted in Schedule 2 and on the invoice where applicable.

3.5 The Fees shall not exceed the amount detailed in Schedule 2 except in the case of prior written agreement between the Contract giver and the Contract acceptor.

4. Contract acceptor's obligations

4.1 During the term of this Agreement, the Contract acceptor shall ensure that its staff and agents and any approved appointed sub-Contract acceptors:

- (a) Are suitably qualified and experienced to carry out the Services required of them; and
- (b) Shall carry out the Services with good practice and in accordance with all applicable laws, enactments, orders, regulations, statutes, byelaws, standards, codes of practice and other similar instruments; and
- (c) Shall provide all information and documentation that the Contract giver reasonably requires.

5. Intellectual Property

5.1 *Foreground IP.* All Foreground IP shall be the sole property of the Contract giver. In consideration for the Fees paid to the Contract acceptor, the Contract acceptor hereby assigns to the Contract giver all rights, title and interest in the Foreground IP generated in the course of providing the Services. The Contract acceptor shall execute any and all such documents as may be necessary to transfer title to and apply for patents or other protections for such Foreground IP. All Foreground IP shall be treated as Confidential Information and the provisions of Clause 6 shall apply. The Contract acceptor further undertakes to make no claim to ownership of any intellectual property developed or discovered during the course of the Project.

6. Confidentiality

6.1 *Confidentiality obligations.* Each Party (the "**Receiving Party**") undertakes from the Commencement Date:

- (a) to maintain as secret and confidential all Confidential Information obtained directly or indirectly from the other Party (the "**Disclosing Party**") in the course of or in anticipation of this Agreement and to respect the Disclosing Party's rights therein;

- (b) where such Confidential Information is obtained, will use such Confidential Information only for the purposes of this Agreement;
- (c) to disclose such Confidential Information only to those of its employees, Contract acceptors and sub-licensees pursuant to this Agreement (if any) to whom and to the extent that such disclosure is reasonably necessary for the purposes of this Agreement; and
- (d) to ensure that all those to whom disclosure of, or access to, such Confidential Information has been given, including its officers, directors, employees and professional advisers, comply with the provisions of this Agreement, and the Receiving Party shall be liable to the Disclosing Party for any breach of this Agreement by any of the foregoing.

6.2 *Exceptions to obligations.* The provisions of Clause 6.1 shall not apply to Confidential Information which the Receiving Party can demonstrate by reasonable, written evidence:

- (a) was, prior to its receipt by the Receiving Party from the Disclosing Party, in the possession of the Receiving Party and at its free disposal; or
- (b) is subsequently disclosed to the Receiving Party without any obligations of confidence by a third party who has not derived it directly or indirectly from the Disclosing Party; or
- (c) is independently developed by the Receiving Party by individuals who have not had any direct or indirect access to the Disclosing Party's Confidential Information; or
- (d) is or becomes generally available to the public through no act or default of the Receiving Party or its agents, employees, or Affiliates.

6.3 *Disclosure in accordance with legal obligations.* To the extent that the Receiving Party is required to disclose any of the Disclosing Party's Confidential Information by order of a court or other public body that has jurisdiction over it or under other legal obligations, such as under a *bona fide* freedom of information request, it may do so, provided that, before making such a disclosure the Receiving Party shall, unless the circumstances prohibit:

- (a) inform the Disclosing Party of the proposed disclosure as soon as possible, in any event, no later than five (5) working days after becoming aware of the proposed disclosure; and
- (b) permit the Disclosing Party to make representations (written or otherwise) in respect of the disclosure and/or confidential treatment of the Confidential Information.

6.4 *Duration of obligations.* The obligations of confidentiality and non-use set out in this Clause 6 shall survive termination of this Agreement for any reason for a period of four (4) years from the end of the Project.

7. Warranties

7.1 *No implied warranties, etc.* Each of the Parties acknowledges that, in entering into this Agreement, it does not do so in reliance on any representation, warranty or other provision except as expressly provided in this Agreement, and any conditions, warranties or other terms implied by statute or common law are excluded from this Agreement to the fullest extent permitted by law.

7.2 *Performance of the Services.* The Contract acceptor shall use its best endeavours to perform the Services and shall use a professional industry standard of care and skill in the performance of the Services which shall be delivered by the Completion Date or any other date as mutually agreed between the Parties.

8. Liability and indemnity

8.1 *Liability of the Parties.*

- (a) To the extent that either of the Parties has any liability in contract, tort (including negligence), or otherwise under or in connection with this Agreement, including any liability for breach of warranty, their liability shall be limited in accordance with the following provisions of this Clause 8.1. However, the limitations and exclusions of liability set out in this Clause 8.1 shall not apply to any indemnity against third party Claims given under Clause 8.2.
- (b) The aggregate liability of the Contract giver shall be limited to the sum equal to the total Fees paid to the Contract acceptor by the Contract giver under this Agreement.
- (c) In no circumstances shall either Party be liable for any loss, damage, costs or expenses of any nature whatsoever incurred or suffered by the other Party or its Affiliates that are (i) of an indirect, special or consequential nature; or (ii) any loss of profits, revenue, business opportunity or goodwill.
- (d) Nothing in this Agreement excludes or limits any person's liability to the extent that it may not be so excluded or limited under applicable law, including any such liability for death or personal injury caused by that person's negligence, or liability for fraud or fraudulent misrepresentation.

8.2 *Contract acceptor Indemnity.* The Contract acceptor shall indemnify the Contract giver against any and all Claims howsoever arising from or in any way connected with the Contract acceptor's activities in performing the Services.

9. Term and Termination

9.1 *Commencement and termination by expiry.* This Agreement shall come into force on the Commencement Date and, unless terminated earlier in accordance with this Clause 9, shall terminate automatically by expiry upon the Completion Date.

9.2 *No replacement Contract acceptor available.* If the Contract acceptor becomes unavailable and is unable to provide a suitable replacement to perform the Services, as mutually agreed by the Parties, then the Contract giver may terminate this Agreement by written notice to the Contract acceptor, such termination to take effect as specified in the notice.

9.3 *Early termination.* Without prejudice to any other rights of remedies, either Party may terminate this Agreement, at any time, on written notice to the other Party (the "**Other Party**"):

- (a) if the Other Party is in material breach of its obligations under this Agreement and, where the breach is capable of remedy within thirty (30) days, the Other Party has not remedied the breach within thirty (30) days of receiving written notice which specifies the breach and requires the breach to be remedied; or
- (b) if: (i) the Other Party becomes insolvent or unable to pay its debts as and when they become due; (ii) an order is made or a resolution is passed for the winding up of the Other Party (other than voluntarily for the purpose of solvent amalgamation or reconstruction); (iii) a liquidator, examiner, receiver, receiver manager, or trustee is appointed in respect of the whole or any part of the Other Party's assets or business; (iv) the Other Party makes any composition with its creditors; (v) the Other Party ceases to continue its business; or (vi) as a result of debt and/or maladministration the Other Party takes or suffers any similar or analogous action.

9.4 *Consequences of termination.* On termination of this Agreement, for any reason other than termination by the Contract giver under Clause 9.3 above, the Contract giver shall pay to the Contract acceptor any payment which was due to the Contract acceptor prior to the date of termination but which was not paid prior to termination.

10. General

- 10.1 *Force majeure.* Neither Party shall have any liability or be deemed to be in breach of this Agreement for any delays or failures in performance of this Agreement that result from circumstances beyond the reasonable control of that Party, including labour disputes involving that Party. The Party affected by such circumstances shall promptly notify the other Party in writing when such circumstances cause a delay or failure in performance and when they cease to do so.
- 10.2 *Amendments.* This Agreement may only be amended in writing signed by duly authorised representatives of the Parties.
- 10.3 *Sub-contracting.* Subject to the written authorisation of the Contract giver, the Contract acceptor may sub-contract any part of the Services. The Contract acceptor shall be responsible for the work of any sub-contractor and for such sub-contractor's compliance with the provisions of this Agreement.
- 10.4 *Assignment.* Neither Party may assign, mortgage, charge or otherwise transfer any or all of its rights and obligations under this Agreement without the prior written agreement of the other Party.
- 10.5 *Entire agreement.* This Agreement, including its Schedules, sets out the entire agreement between the Parties relating to its subject matter and supersedes all prior oral or written agreements, arrangements or understandings between them relating to such subject matter. The Parties acknowledge that they are not relying on any representation, agreement, term or condition which is not set out in this Agreement. The signature of a Party by means of an electronic signature (e.g. via AdobeSign) counts as an original signature with the same validity, enforceability and permissibility. Each Party may receive a fully signed copy of the Agreement. The transfer of this copy by e-mail or via an electronic signature system will have the same legal force and legal effect as the transfer of the original copy of the Agreement.
- 10.6 *Waiver.* No failure or delay by either Party in exercising any right, power or privilege under this Agreement shall impair the same or operate as a waiver of the same nor shall any single or partial exercise of any right, power or privilege preclude any further exercise of the same or the exercise of any other right, power or privilege. The rights and remedies provided in this Agreement are cumulative and not exclusive of any rights and remedies provided by law.
- 10.7 *Notices.* Any notice to be given under this Agreement shall be in writing and shall be sent to the contact person named below, or such other name and address as that Party may from time to time notify to the other Party in accordance with this Clause 10.7. The contact details of the Parties are as follows:

The Contract giver:

General Affairs and Development Manager
Name: Maria Concetta Lucania
Telephone: +39 0555662310
Email: mariaconcetta.lucania@meyer.it

Clinical Trial Office
Name: Alessio Fabbiano
Telephone: +39 0555662795
Email: alessio.fabbiano@meyer.it

The Contract acceptor — Representative
Mr. Geert Thienpont
Managing Director
The European Institute for Innovation Through Health Data
E-mail: geert.thienpont@i-hd.eu
Tel: + 32 9 332 34 21

10.8 *Interpretation.* In this Agreement:

- (a) the headings are used for convenience only and shall not affect its interpretation;
- (b) references to persons shall include incorporated and unincorporated persons; references to the singular include the plural and vice versa; and references to the masculine include the feminine and vice versa;
- (c) references to Clauses and Schedules mean clauses of, and schedules to, this Agreement;
- (d) references in this Agreement to termination shall include termination by expiry; and
- (e) where the word “including” is used it shall be understood as meaning “including without limitation”.

10.9 *Further action.* Each Party agrees to execute, acknowledge and deliver such further instruments, and do all further similar acts, as may be necessary or appropriate to carry out the purposes and intent of this Agreement.

10.10 *Announcements.* Neither Party shall make any press or other public announcement concerning any aspect of this Agreement or make any use of the name of the other Party in connection with or in consequence of this Agreement, without the prior written consent of the other Party.

10.11 *Law and jurisdiction.*

- (a) This Agreement shall be governed by and construed in accordance with the laws of Italy and each Party agrees to submit to the exclusive jurisdiction of the courts of Italy.
- (b) Notwithstanding Clause 10.110, before commencing any litigation, each Party shall consider in good faith whether it would be reasonable in the circumstances for the Parties to agree to pursue any alternative dispute resolution processes. Such alternative processes may include internal escalation procedures and/or mediation in accordance with the World Intellectual Property Organization (WIPO) mediation rules. For the avoidance of doubt, however, nothing in this Agreement shall prevent or delay a Party from seeking an interim injunction.

10.12 *Data Protection.* The Parties will abide by the General Data Protection Regulation 2016/679 and any other laws and regulations relating to the processing of personal data and privacy which apply to a Party (“**Data Protection Legislation**”). It is agreed by the Parties, that prior to the transfer of any data (whether personal, coded or anonymous) a Data Transfer Agreement (“**DTA**”) will be entered into by the Parties. Such DTA, if required, will be tailored to serve the particular Services provided under this Agreement.

Agreed by the Parties through their authorised signatories:

For and on behalf of
Meyer Children's University Hospital

For and on behalf of
***The European Institute for Innovation
Through Health Data***

Signed

Signed

Name Alberto Zanobini

Name Geert Thienpont

Title Managing Director

Title Managing Director

Date

Date 24/10/2022

Schedule 1

Service Specification

Service to be provided	<p><i>The Services will be as stated within the FAIRVASC Work Packages 1 and 2 description of the DOA, and specifically:</i></p> <p>WP 1: Registry profiling & data preparation, in order to create a set of metadata records for each registry that describe the holdings, the data quality and completeness, the access policies, the patient consent status and other relevant characteristics of that registry. It also quality-assures and selects high-quality data in each registry and anonymises it, in preparation for uplift (WP3). This lays the foundation for RDF uplift (WP3), but also provides an essential 'handbook' to the registries, for use in all future research</p> <p>WP2: Legal and Ethical, in order to capture the legal and ethical environment of each registry, patient perspectives on data sharing and re-use, and also the national and international legislation and regulations that apply to FAIRVASC. A checklist of legal and ethical points will feed into all technical work and will enhance the 'handbook' generated in WP1. Legal and ethical clearance for all FAIRVASC activities will be secured in this WP.</p> <p><i>The Contract acceptor shall also assist the Contract giver in developing ad hoc content regarding data quality, metadata specifications, data management and audit trail specifications.</i></p>
Deliverables	<i>The Contract acceptor will develop content that contributes to the FAIRVASC Work Packages 1 and 2 deliverables of the DOA.</i>
Timescale	<i>Commencement Date: 1 June 2020</i>
	<i>Completion Date: Three years from the Commencement Date or such additional period as may be agreed by the Parties in writing.</i>
Reports	<i>Provide such reports as may be required from time to time by the Contract giver.</i>
Meetings	<i>Attend such meetings as may be required from time to time by the Contract giver.</i>
Name of Contract acceptor	The European Institute for Innovation Through Health Data (I-HD) through its employees.

Schedule 2

Payment and Notices

Fees (Contract acceptor's time, Expenses etc.)	€9,836.07 Excluding VAT €2,163.93 VAT @ 22% €12,000.00 Total Including VAT
Payment timeline:	€12,000 (including VAT) after the date of last signature of this agreement
Payments	All payments will be made by the Contract giver within 30 days from receipt of a valid invoice by the Contract acceptor. Invoices are to be issued on or after the above-mentioned dates of the payment timeline.
Contract giver's address for notices:	Alessio Fabbiano Clinical Trial Office Viale G. Pieraccini 24 50139 Firenze Italy Tel: +390555662795 Email: alessio.fabbiano@meyer.it
Contract acceptor's address for notices:	Attn.: Mr. Geert Thienpont The European Institute for Innovation Through Health Data (I-HD) c/o University Hospital Gent - Building K3 – 5th Floor - Entrance 42 Unit of Medical Informatics and Statistics C. Heymanslaan 10 9000 Gent Belgium
Contract givers VAT Number:	02175680483
Contract acceptors VAT number:	BE0628.646.310