

# AZIENDA OSPEDALIERO UNIVERSITARIA MEYER

## Delibera del Direttore Generale n. 29 del 20-01-2023

Proposta n. 48 del 2023

Oggetto: PRESA D'ATTO DELLA STIPULAZIONE DELL'ACCORDO DI FINANZIAMENTO E COLLABORAZIONE CON IL FINNISH INNOVATION FUND SITRA PER IL PROGETTO "DATA COLLABORATION RULEBOOK FOR EUROPEAN CHILDREN'S HOSPITALS"

Dirigente: MCGREEVY KATHLEEN

Struttura Dirigente: RESP. MEYER CHILDREN'S RESEARCH INSTITUTE

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

<b>Oggetto</b>	Progetto
<b>Contenuto</b>	PRESA D'ATTO DELLA STIPULAZIONE DELL'ACCORDO DI FINANZIAMENTO E COLLABORAZIONE CON IL FINNISH INNOVATION FUND SITRA PER IL PROGETTO "DATA COLLABORATION RULEBOOK FOR EUROPEAN CHILDREN'S HOSPITALS"

<b>Area Tecnico Amm.va</b>	AREA TECNICO AMMINISTRATIVA
<b>Coord. Area Tecnico Amm.va</b>	BINI CARLA
<b>Struttura</b>	MEYER CHILDREN'S RESEARCH INSTITUTE
<b>Direttore della Struttura</b>	MCGREEVY KATHLEEN
<b>Responsabile del procedimento</b>	ALESSIO FABBIANO
<b>Immediatamente Esecutiva</b>	NO

Spesa prevista	Conto Economico	Codice Conto	Anno Bilancio
€14.242,00	CONTRIBUTI DA SOGGETTI PRIVATI	4101300000	2023

Estremi relativi ai principali documenti contenuti nel fascicolo		
Allegato	N° di pag.	Oggetto
1	20	Financing and Collaboration 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 Direttore Operativo del Meyer Children's Research Institute, Dr.ssa Kathleen McGreevy, la quale attesta la regolarità amministrativa e la legittimità dell'atto;

### **Ricordato:**

- che l'AOU Meyer partecipa attivamente in plurime reti internazionali attivando rapporti con realtà pediatriche di eccellenza e sviluppando opportunità di partnership in progetti internazionali al fine, tra l'altro, di arricchire le conoscenze cliniche e scientifiche in pediatria, contribuire alla ricerca scientifica internazionale e all'innovazione e acquisire le migliori pratiche a beneficio dell'ospedale e dei piccoli pazienti;
- che, nell'intento di sviluppare progetti di partnership internazionali, l'AOU Meyer è membro fondatore della European Children's Hospital Organization (ECHO), un network di ospedali pediatrici europei che collaborano sia in ambito di assistenza sanitaria sia nella promozione di soluzioni attraverso l'innovazione, la ricerca e la formazione;

**Atteso** che nell'ambito della rete ECHO, l'AOU Meyer è stata coinvolta dall'Helsinki University Hospital, membro del medesimo network, in una proposta di progetto denominata "*Data collaboration rulebook for European Children's Hospitals*", il cui scopo è di sviluppare un programma collaborativo tra i



partners di progetto (oltre all'AOU Meyer, HUS Helsinki University Hospital, ERASMUS Sophia Children's Hospital, GOSH Great Ormond Street Hospital, HSJD Hospital Sant Joan de Déu e BKUS Children's Clinical University Hospital of Latvia) inteso a creare una governance comune sui dati sanitari tra gli ospedali della rete ECHO mediante un set di norme atte a consentire a questi di avviare una collaborazione più ampia nello scambio di dati per finalità di analisi degli stessi e di ricerca scientifica, in ottemperanza agli standard regolatori richiesti dalla normativa europea sulla protezione dei dati personali;

**Posto** che il suddetto progetto ha ricevuto un finanziamento da parte di The Finnish Innovation Fund SITRA, un fondo pubblico indipendente secondo l'ordinamento finlandese che, tra i propri ambiti di intervento, promuove progetti per lo sviluppo di sistemi di trattamento equo dei dati personali, secondo i principi ispiratori dell'Unione Europea in tema di trattamento di dati personali;

**Evidenziata** l'importanza crescente che i dati sanitari ricoprono per la ricerca scientifica e l'innovazione, con ricadute per la cura in sanità, soprattutto se possono essere oggetto di valutazione e confronto tra partner impegnati nella ricerca scientifica e nell'assistenza in pediatria;

**Rilevata** l'importanza che il progetto proposto da HUS riveste nell'incentivare la collaborazione tra ospedali pediatrici europei per la condivisione di regole, soluzioni tecniche e politiche dei dati che consentano una più efficace gestione di dati nel settore della ricerca e dell'innovazione transnazionale, secondo i valori e la normativa applicabile nell'Unione Europea;

**Considerato** che SITRA ha proposto un Accordo di finanziamento e collaborazione per l'implementazione del progetto che prevede a favore dell'AOU Meyer per le attività che saranno espletate nell'ambito del progetto medesimo un contributo di € 14.242,00, il 75% del costo complessivo del progetto pari ad € 18.990,00, il cui 25% pari a € 4.748 è coperto in termini di ore/persona lavorate nel progetto;

**Dato atto** che, per ragioni inerenti all'autorizzazione del finanziamento da parte di SITRA, è stato necessario sottoscrivere in tempi brevi il suddetto Accordo;

**Puntualizzato** che il progetto di cui trattasi ricade sotto la responsabilità del Meyer Children's Research Institute che è deputato, tra le proprie finalità, anche a promuovere progetti di ricerca favorendo collaborazioni con partner stranieri;

**Ritenuto** pertanto di prendere atto della stipulazione dell'Accordo di finanziamento e collaborazione con SITRA per la realizzazione del progetto di cui trattasi, allegato N. 1 al presente atto a formarne parte integrante e sostanziale, per la disciplina delle condizioni normative, economiche ed operative del progetto medesimo;

**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 dare atto della stipulazione dell'Accordo di finanziamento e collaborazione con SITRA per la realizzazione del progetto "Data collaboration rulebook for European Children's Hospitals" che, allegato N. 1 al presente atto, ne forma parte integrante e sostanziale.
2. Di precisare che il progetto, del valore complessivo di €18.990,00, è finanziato per il 75% da SITRA (€ 14.242,00) e che il restante 25%, per un importo complessivo di euro 4.748,00, è coperto dall'AOU Meyer in termini di ore/persona lavorate nel progetto medesimo.
3. Di dare atto che il progetto sarà gestito con l'apertura di un codice aziendale acquisito al bilancio 2023, conto di ricavo n. 4101300000, su cui graveranno tutte le imputazioni di spesa;
4. 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)

## Financing and Collaboration Agreement (hereinafter "Agreement")

### 1 Parties

**Sitra**, the Finnish Innovation Fund (hereinafter referred to as "Sitra")  
Itämerenkatu 11–13 (PL 160), 00181 Helsinki, Finland  
Business ID: 0202132-3

**Meyer Children's Hospital** (Azienda Ospedaliero-Universitaria Meyer, hereinafter referred to as "the Partner")  
VIALE GAETANO PIERACCINI 24, FIRENZE, 50139, ITALY  
Business ID: IT02175680483 (VAT number)

Sitra and the Partner shall hereinafter also be referred to as a "Party" and together as "Parties".

### 2 Background and Purpose of the Project

Project's working title is "*Data collaboration rulebook for European Children's Hospitals*" and in the project the ECHO consortium will work with Sitra's "Fair data Economy Rulebook" template and start building a data collaboration governance framework for ECHO hospitals (hereinafter referred to as "the Project").

As described in the Project Plan, the Partner is a member of the applicant consortium whose common Project Sitra shall finance.

The funding granted under this Agreement relates to financing decision number 470404 and may be used solely to the costs mentioned in the project plan and incurred by the Partner during the implementation of the Project, and which are defined in Sitra's Funding Project's Monitoring and Cost Annex, attached as [appendix 1A](#). The Project budget estimation is presented in [appendix 1B](#).

The aims, objectives and the manner of execution of the Project are specified in the project plan (hereinafter referred to as "the Project Plan"), attached as [appendix 2](#).

For the avoidance of doubt, Sitra acts as the financier of the Project and does not purchase any services from Partner under this Agreement.

The Partner represents and warrants that the information given in the Project Plan and the budget estimation is accurate and gives a true and fair view of the Project and its implementation.

The Partner shall be responsible for implementing the Project in accordance with this Agreement.

### 3 Period of the Project

The Period of the Project is 1.12.2022 – 31.5.2023. The Final Administrative Report of the Project, detailed in section 7.1 of the agreement, shall be delivered to Sitra by June 2023 at the latest.

#### 4 Project Responsible

The Person responsible for the implementation of the Project shall be Kathleen McGreevy employed by the Partner ("Project Responsible").

#### 5 Management and Supervision of the Project

The Project shall be managed and supervised by specialist Elina Drakvik from Sitra.

The Partner and Project Responsible are obliged to take into account Sitra's comments on the Project. Sitra and the Partner may further define the Project Plan as the Project progresses by their unanimous decision.

#### 6 Financing and Payments

Sitra shall finance the Project in accordance with the budget estimation presented in the appendix 1B at maximum the total amount of EUR 14 242.

Furthermore, the value of the advisory work EUR 2084 shall be considered as Sitra's financing to the Project.

In accordance with applicable law, VAT shall not be collected and paid for financing services.

The Partner shall record the Project costs separately in the Partners accounting and maintain and keep this separate record, so that the amount and basis of the costs can be verified later, if necessary. In addition, the Partner shall report to Sitra regarding the Project and the actual costs incurred in it in accordance with appendices 1 A and 1 B.

The Partner shall provide Sitra with all information regarding the use of the funding granted under this Agreement as requested by Sitra. Sitra has the right to audit the use of the funding using a third-party auditor, to the extent Sitra deems it necessary.

Sitra shall finance the Project in two separate instalments against the Partner's invoices, which have been approved by Sitra, as follows:

1. instalment      EUR 7 121      at latest 15.12.2022, provided that:

- this Agreement has been signed by both Parties, and
- the plan mentioned in section 8 of this agreement to be agreed with experts of 1001 Lakes Oy has been made.

2. instalment      EUR 7 121      at latest 30.6.2023, provided that:

- The Project has been fully completed in accordance with the Project Plan, the plan made with 1001 Lakes Oy and the terms of

this Agreement, the costs incurred in the Project have been reported to Sitra in accordance with appendices 1A and 1B and Sitra has accepted the Cost Statement Reports,

- The Final Administrative Report, detailed in section 7.1, has been delivered to Sitra and Sitra has accepted it.

Sitra's funding equals 75 % of the Project budget estimation.  
Partner's own contribution for the Project equals 25 % of the Project's budget estimation.

In the event that the actual Project costs are less than estimated as per the budget, Sitra's funding shall be adjusted accordingly.

The Partner commits to refund Sitra's funding if the Project does not materialize. Should the Project be implemented on a smaller scale than planned, the sum returned to Sitra should be in proportion to the level of implementation of the Project.

## **7 Deliverables and Intellectual Property Rights**

### **7.1 Deliverables**

**Deliverables** (hereinafter "the Deliverables") include all new materials and outputs created in connection with the Project, including but not limited to, any and all, methods, solutions, devices and other tangible assets and materials regardless of whether they may be protected under any immaterial property law or under a non-disclosure agreement, surveys, reports, information, conclusions, observations, experience, best practises and other written material as well as pictures and photographs.

The Deliverables do not include such materials and intellectual property rights acquired by a Party in connection with this Project, which are used under a third-party licence, or which are otherwise subject to the limitations of a third-party.

**Immaterial property rights** means all new immaterial property rights created in connection with the Project, including but not limited to, any and all patents, utility models, trademarks, copyright, right to integrated circuit design, copyright of design and knowledge protected by non-disclosure agreement and applications related to immaterial property rights.

**Background Material** (hereinafter "the Background material") includes all materials and outputs created before the Project or outside the scope of this Project; regardless of the creator; including but not limited to, any surveys, reports, information, conclusions, observations, experience, best practises and other written material as well as pictures and photographs and regardless of whether they are protected or able to be protected with intellectual property rights, e.g. copyright, patent or confidentiality. The Background material is not part of the Deliverables.

If a Party or a third-party discloses Background material to the other Party for the execution of this Project, the intellectual property rights and other rights to such



Background material shall remain the exclusive property of the disclosing Party. The disclosed Background material shall solely be used for the purpose of executing this Project.

**The Final Administrative Report of the Project** (hereinafter "the Final Administrative Report") means a report detailing the content, execution, the Partner's insights and experiences, results and impact of the Project. The Final Administrative Report shall be composed by the Partner in accordance with further instructions provided by Sitra in writing, e.g. by email.

For the sake of clarity, it is noted that the Final Administrative Report must not include any trade secrets of the organizations participating in the Project.

The Final Administrative Report is not part of the Deliverables.

**Deliverable Results** means all Deliverables and Immaterial property rights

## **7.2 Intellectual Property Rights of the Deliverables and the Final Report**

Title to the Deliverable Results shall be vested to the Partner, unless otherwise agreed in this Agreement.

### **Publication of the Deliverable Results**

The Partner shall publish separately defined part of the Deliverable Results after the completion of the Project on the website of the Partner. Sitra has also right to publish the Deliverable Results on the website of Sitra.

All possible trade secrets shall be excluded from the Deliverable Results to be published.

### **License of Sitra to use the Deliverable Results**

The Partner hereby grants Sitra a free, unlimited, non-exclusive and non-restricted user right. Sitra may assign or transfer the user right specified in this clause or grant sub-licenses under such a user right to third parties unless otherwise agreed in this agreement in order to spread the knowledge and best practises included in the Deliverable Results with the exception of any trade secrets that may be included in the Deliverable Results.

The Partner represents and warrants that the Deliverable Results do not infringe upon any intellectual property rights or other rights of third parties. The Partner shall, at its own expense, defend, indemnify and hold Sitra harmless against any and all costs resulting from claims and actions alleging that the Deliverables Results infringe upon any intellectual property rights of a third party, provided that Sitra has used the Deliverable Results in accordance with this Agreement. The Partner shall pay all damages awarded in a trial agreed to be paid to a third party if Sitra has acted in accordance with the foregoing.

### **Rights pertaining to the Final Administrative Report**

The Partner hereby grants and transfers the Final Administrative Report and copyright and other intellectual property rights thereto to Sitra with full title at the moment they are formed. For the sake of clarity, it is noted that the transfer of the rights pertaining to the Final Administrative Report grants Sitra the right to use, copy, share, publish and modify the Final Administrative Report in both written and

digital form in Finland or as a translation outside of Finland, and a right to forward the rights to a third party. Therefore, Sitra has the right to forward information contained in the Final Administrative Report to third parties or grant licences thereto.

The Partner represents and warrants, and shall be responsible for ensuring, that the Project Responsible and other persons involved in the implementation of the Project, assign all rights to the Final Administrative Report to the Partner. The Partner shall be fully responsible for compensating such persons for the assignment of rights to the Final Administrative Report, at its own expense. In addition, the Partner represents and warrants that the Final Administrative Report does not infringe upon any intellectual property rights or other rights of third parties.

The Partner shall, at its own expense, defend, indemnify and hold Sitra harmless against any and all costs resulting from claims and actions alleging that the Final Administrative Report infringes upon any intellectual property rights of a third party, provided that Sitra has used the Final Administrative Report in accordance with this Agreement. The Partner shall pay all damages awarded in a trial agreed to be paid to a third party if Sitra has acted in accordance with the foregoing.

For the avoidance of doubt, the payments under Section 6 of this Agreement shall be deemed to include compensation for the title granted to Sitra under this Agreement. The payments shall be the sole compensation payable by Sitra to the Partner in connection with this Agreement. Sitra shall in no event be liable to pay, reimburse or compensate the Partner for any other costs, expenses or payments for its performance under this Agreement.

The Partner is responsible for covering all costs related to any payments made to any possible third parties participating in any way in carrying out the Project.

## **8 Duties and Responsibilities of the Partner**

The Partner is responsible for diligent and professional implementation and overall management of the Project in accordance with this agreement and all appendices.

The main phases of the Project are described in the Project Plan.

Together with the other members of the consortium, the Partner commits oneself to a plan which will be defined together with experts of 1001 Lakes Oy (plan includes, for example, preliminary assignments and necessary meetings 1–2 times a month). The progress of the work is planned in cooperation so that it serves both the purpose of the utilisation of data and the consortium's own goals and needs.

The Partner is responsible for reporting the costs and expenses according to the appendices 1A and 1B.

The Partner represents and warrants that the funding provided by Sitra is solely used for the purpose of achieving the Project's goals and for the costs described in the Project Plan.

### **Public Procurement**

Sitra is a contracting authority as described in the Finnish Act on Public Contracts and Concessions (*Laki julkisista hankinnoista ja käyttöoikeussopimuksista 1937/2016*) (hereinafter "Act"). The Partner represents and warrants, notwithstanding Section 18. Governing Law and Dispute Settlement, that all its procurements carried out with the financing hereto from any third parties and all

financial disbursements paid thereto shall be conducted in accordance with the appropriate and applicable EU- and national public procurement rules and legislation as well as in accordance with its internal and international trade obligations pertaining to the Partner.

### **Economic Activities**

The Partner represents and warrants that it does not engage in any economic activity and the funding granted under this Agreement shall not be used for the purposes of its economic activities during or after the Project. The Partner is an integral part of a national health service, directly funded from State resources and provide their services free of charge on the basis of universal coverage. In accordance with section 24 of the Commission Notice on the notion of State aid (2016/C 262/01), the Partner is therefore not considered to engage in economic activity.

Should the EU's supervisory authority consider the financing granted under this agreement to include such state aid that the EU state aid regulation deems forbidden, Sitra has the right to demand the financing to be paid back to Sitra with penalty interest.

Except for procurements executed in accordance with the Act [or in accordance with national procurement regulations as agreed above in this Section 8 under "Public Procurements"] with funding granted by Sitra under this Agreement, and if part of the funding is channelled to undertakings, the Partner is responsible for ensuring the channelling of funds is market-based, as per the [applicable] EU state aid rules.

If despite the representation and warranties of the Partner, the funding is deemed to benefit the economic activities of the Partner or another entity, Sitra shall not be liable for any direct or indirect damage caused to the Partner or another entity. Funding which is incompatible with the EU state aid rules can be recovered from the Partner with interest.

### **Accessibility**

The Act on the Provision of Digital Services (*laki digitaalisten palvelujen tarjoamisesta 306/2019*) imposes obligations on Sitra. The Partner commits to ensure that the Deliverables, meet the requirements of the guidelines of accessibility attached as [appendix 3](#).

### **Compensation for Damages**

The Partner shall be independently liable for any damages it causes to Sitra, other participants of the Project or to third parties. However, the Partner shall not be liable for any indirect or consequential damage caused to Sitra in connection with this Agreement. The maximum amount of liability for damages is defined as five times the amount of financing under this Agreement, nevertheless the minimum of EUR 100 000. Limitations of liability will not be applied if the Partner has caused damage wilfully or through gross negligence, violated the terms of the Final Report / Deliverable Results agreed in section 7, violated the terms for the processing of personal data agreed in section 10, violated the confidentiality obligation agreed in section 17 or violated any intellectual property rights.

## 9 Project Communications and Right to Use as a Reference

Project communications shall be agreed between the Parties separately in writing, e.g. by email or by making a separate written plan on Project communications. With respect to Project communications, the Partner has the right to mention Sitra as the financier of the Project. However, the Partner does not have the right to use Sitra's logo. More specific details concerning Sitra's visibility in Project communications can be detailed in the communications plan, if deemed necessary.

As the financier of the Project, Sitra is entitled to visibility in all Project communications and publicity in the media and the public arena.

After the completion of the Project, the Partner may not use Sitra's name or logo as a reference in the Partner's own operations, general marketing materials or otherwise without a separate prior written consent of Sitra.

## 10 Processing of Personal Data

To the extent the Parties process personal data when fulfilling their obligations under this Agreement, they shall comply with all effective and applicable data processing and privacy protection laws. Both Parties shall be independent controllers of data (who determine the purposes and means of the processing of personal data) as defined in applicable law. The Party shall also be responsible for ensuring that the processing of personal data shall be carried out in accordance with the laws and professional data protection practice applicable to it.

In addition, the Parties commit to take appropriate technical and organisational measures to ensure safe processing of personal data. The Parties commit to ensure their processing of personal data and data security meet the requirements of data protection regulation that might enter into force after this Agreement has entered into force.

## 11 Delays

If the Partner determines that a delay will occur or is likely to occur, it shall, without delay, notify Sitra in writing of the delay. In such cases, Sitra can unilaterally alter the payment schedule agreed in Section 6 or the period of the Project agreed in Section 3 to correspond to the actual progression of the Project or can withhold payment of the instalments referred to in Section 6 entirely if the delay is significant.

Sitra also has the above-mentioned right if the implementation of the Project at any time significantly deviates from what has been agreed in the Project Plan and this Agreement. In the event the Project is delayed, or the implementation deviates from what has been agreed, Sitra and Partner can, if necessary, enter into a new Agreement on how to continue the Project and realise the financing thereof.

## 12 Assignment of the Agreement

The Partner may not wholly or partly assign its rights and obligations under this Agreement to any third party except with the prior written consent of Sitra.

The Partner may not change the Project Responsible, the project manager named in the Project Plan or any other key personnel in the Project except with the prior written consent of Sitra.

### **13 Amendments to the Agreement**

A Party may not deviate from the Project Plan in a manner that would endanger the implementation of the Project, schedule or the purpose of the Project, except with the prior written consent of the other Party. If such factors occur during the implementation of the Project, that require amending or modifying the Agreement or its appendices, a Party must inform the other Party without delay.

All amendments and/or additions to the Agreement must be agreed in writing to be valid.

### **14 Termination of the Agreement**

Sitra has the right to terminate the Agreement in the event of such a change in the circumstances or any preconditions of this Agreement that would endanger the implementation or the purpose of the Project or if the Partner has in any other way breached the Agreement and has failed to remedy such a breach within 15 days of the receipt of Sitra's written notification.

In the event of such a termination by Sitra, the Agreement shall terminate within one (1) month of the receipt of Sitra's written termination notification by the Partner.

In addition, Sitra has the right to terminate the Agreement with immediate effect if, the Partner has breached the Agreement intentionally or through gross negligence; or:

- commits a material breach of its obligations detailed in this Agreement and the Project Plan, or
- the Partner has in any other manner acted against the purpose of the Agreement, against good faith or against good business or administrative practice.

The Partner has the right to terminate this Agreement with immediate effect if Sitra neglects to make the Payments in accordance with this Agreement in the event where the Partner has fulfilled all its obligations and duties in accordance with this Agreement, or if Sitra commits a material breach of its other obligations under this Agreement.

The termination with immediate effect enters into force by the receipt of the termination notification.

### **15 Consequences of the Termination**

The Partner shall not be entitled to any compensation or damages in the event the Agreement is terminated in accordance with Section 15, except for direct damages relating to the termination when the Partner uses its right to terminate the Agreement with immediate effect.

If the Agreement is terminated in accordance with Section 15, Sitra shall pay for the part of the Project implemented by the Partner up to the date of termination in relative portion to the amount of Sitra's funding detailed in Section 6, provided that all the materials and reports and Partner's report concerning the current status of the Project are handed over to Sitra.

## 16 Confidentiality

For purposes of this Agreement, "Confidential Information" shall mean any information or documents disclosed by a Party ("Disclosing Party") to the other Party ("Receiving Party"), either directly or indirectly, in writing, orally or by inspection of tangible objects, which contain trade secrets, other comparable information of business activities or other information, ideas or concepts, which are being created as a result of the Project proprietary to the Disclosing Party or any third party that has furnished it to the Disclosing Party.

The Receiving Party having received Confidential Information shall keep such information confidential.

However, the Parties have the right to disclose information concerning this Agreement, the Partner, the amount of the funding and the Project in accordance with the Act on the Openness of Government Activities (*laki viranomaisten toiminnan julkisuudesta, 621/1999*) and applicable national/local law, excluding information considered confidential under said act or national/local law, if information is requested from Sitra under the Act or the Partner under applicable national/local law.

Notwithstanding the confidentiality provisions of this Agreement, the Parties may disclose any information associated with the financing of the Project, to the respective supervisory authorities.

## 17 Governing Law and Dispute settlement

This Agreement, and any dispute, claim or controversy arising out of or relating to this Agreement, or the breach, termination or validity thereof, are governed by and construed in accordance with the laws of Finland excluding its choice of law provisions.

Any disputes arising out of or in connection with this Agreement, shall be settled amicably through negotiations. All disputes arising out of or in connection with this Agreement which cannot be settled through amicable negotiations between the respective Parties shall be settled by the District Court of Helsinki.

## 18 Term of the Agreement

This Agreement shall enter into force and become binding on the signing date after the Agreement has been signed by both Parties.

For the sake of clarity, it is noted that the terms of this Agreement are applied to the Project and its costs from 1.12.2022, regardless of the signing date and the term of the Project detailed in Section 3.

The appendices attached to the Agreement supplement and are an integral part of the Agreement. In the event of a discrepancy between the appendices and the Agreement, the terms and conditions of the Agreement shall prevail followed by the appendices in numerical order.

The Agreement shall be binding until the Parties have fulfilled all their obligations under this Agreement. The Sections 7, 8, 9, 10, 16 and 17 of this Agreement shall survive the expiration or termination of this Agreement.

## 19 Signatures

This Agreement can be executed in one (1) or more identical copies. Delivering the signature page by email or signing the Agreement with an electronic signature service is considered equal to signing the original copy.

The Parties have signed this Agreement on the date marked on the signature page or on the date marked in the electronic signature service as the signature date.

In \_\_\_\_\_, \_\_\_\_\_ 2022

**Meyer Children's Hospital (Azienda Ospedaliero-Universitaria Meyer)**



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Alberto Zanobini, CEO  
email: [direzione.generale@meyer.it](mailto:direzione.generale@meyer.it)  
Tel.no.: +39 055 566 2280

In \_\_\_\_\_ 2022

**Sitra, the Finnish Innovation Fund**



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Kristo Lehtonen, Director

### **APPENDICES:**

Appendix 1: Funding Project's Monitoring and Cost Annex (appendix 1A) and Cost Statement Report (appendix 1B)

Appendix 2: Project Plan, 21.10.2022

Appendix 3: guidelines of accessibility for Sitra's co-operation partner

# Verification

Transaction 09222115557485287516

## Document

<p><b>470409_Financing agreement MEYER</b> Main document 10 pages <i>Initiated on 2023-01-17 08:54:36 CET (+0100) by Henna Keränen (HK2)</i> <i>Finalised on 2023-01-17 15:04:41 CET (+0100)</i></p>	<p><b>470409_Appendix 1 A Funding project's monitoring and cost annex 01042022</b> Attachment 1 4 pages Not merged with the main document <i>Attached by Henna Keränen (HK2)</i></p>
<p><b>470409_Appendix 1B Project Cost Statement 2022_MEYER</b> Attachment 2 1 page Not merged with the main document <i>Attached by Henna Keränen (HK2)</i></p>	<p><b>470409_Appendix 2 HUS Project plan - SITRA rulebook call for porposals 21102022</b> Attachment 3 2 pages Not merged with the main document <i>Attached by Henna Keränen (HK2)</i></p>
<p><b>470409_Appendix 3 Guidelines on accessibility</b> Attachment 4 1 page Not merged with the main document <i>Attached by Henna Keränen (HK2)</i></p>	

## Initiator

<p><b>Henna Keränen (HK2)</b> Sitra Company reg. no. 0202132-3 <i>henna.keranen@sitra.fi</i> +358504737499</p>
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## Signing parties

<p><b>Alberto Zanobini (AZ2)</b> Meyer Children's Hospital <i>direzione.generale@meyer.it</i> +393496054275</p> <p></p> <p><i>Signed 2023-01-17 12:19:59 CET (+0100)</i></p>	<p><b>Kristo Lehtonen (KL2)</b> Sitra <i>kristo.lehtonen@sitra.fi</i></p> <p></p> <p><i>Signed 2023-01-17 15:04:41 CET (+0100)</i></p>
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## Approving parties

<p><b>Elina Drakvik (ED2)</b> Sitra <i>Elina.drakvik@sitra.fi</i></p>	<p><b>Anu Ojala (AO2)</b> Sitra <i>Anu.ojala@sitra.fi</i></p>
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# Verification

Transaction 09222115557485287516

*Approved 2023-01-17 10:40:44 CET (+0100)*

*Approved 2023-01-17 10:43:11 CET (+0100)*

This verification was issued by Scrive. Information in italics has been safely verified by Scrive. For more information/evidence about this document see the concealed attachments. Use a PDF-reader such as Adobe Reader that can show concealed attachments to view the attachments. Please observe that if the document is printed, the integrity of such printed copy cannot be verified as per the below and that a basic print-out lacks the contents of the concealed attachments. The digital signature (electronic seal) ensures that the integrity of this document, including the concealed attachments, can be proven mathematically and independently of Scrive. For your convenience Scrive also provides a service that enables you to automatically verify the document's integrity at: <https://scrive.com/verify>



Sitra

1 April 2022

## Monitoring and Cost Annex for projects funded by Sitra

### 1 General

This Monitoring and Cost Annex (“Annex”) is applied to the projects funded by Sitra, the Finnish Innovation Fund (“Sitra”).

In the funding agreement, Sitra may exceptionally agree upon costs eligible for the project also in accordance with the funding terms and conditions of another financier of the project.

Sitra requires high-quality project planning, cost accounting and reporting from the beneficiary. The beneficiary shall arrange its accounting in a way that the costs arising from the project can be itemised, their connection to the accounting records and to the project cost report can be verified. The project costs shall be monitored separately in the beneficiary’s accounting records.

This Annex describes the minimum content of project planning and reporting and defines the costs that can be covered by Sitra's funding. In addition, this Annex sets out the principles for monitoring and reporting the costs incurred during the project.

This Annex is an annex to the funding agreement concluded with Sitra.

### 2 Project plan

The project shall have a sufficiently detailed project plan, including, but not limited to, a description of the project, its objectives and outcomes pursued, timetable, resourcing, budget, other potential partners and their funding contributions, an estimate of the amount of any own contribution of the beneficiary, responsible persons, and a description of follow-up and reporting. The project plan shall be prepared by the beneficiary, in collaboration with Sitra where necessary.

The costs of the project shall be itemised in the budget by cost type in accordance with the terms and conditions of this Annex. Voluntary work shall not be included in the project costs.

### 3 Reporting of costs

The beneficiary shall report to Sitra (to the person responsible for the project) the actual costs incurred in the project as agreed in the funding agreement and in any event no later than in conjunction with the final cost report. When the final report has been approved, no further costs may be presented for the project.

Project costs are reported by using Sitra’s project cost report template. Furthermore, the beneficiary shall ensure that all reported costs comply with this Annex.

Additional information shall be submitted to Sitra upon request in case the monitoring of the project so demands. Additional information may, for example, include accounting reports.

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1 April 2022

#### 4 Audit

Sitra shall have the right to carry out an audit on the beneficiary's finances and operations related to the project, conducted by an external auditor. The beneficiary shall cooperate with the party carrying out the audit and make available free of charge all the material and information needed for the proper conduct of the audit.

If the total amount of funding granted by Sitra exceeds EUR 400,000, the beneficiary shall submit to Sitra a project-specific audit report on the use of the funding. The audit report shall be submitted to Sitra within three months of the closing of the project. The costs of the audit may be included in the costs of the project, provided that the audit does not reveal any irregularities in the execution of the project.

#### 5 Eligible costs

Sitra's funding may only be used to cover the costs under the funding agreement as presented in the project plan in accordance with this Annex. All costs must be reasonable and necessary for the execution of the project.

Eligible costs may include expenses that are:

- incurred during the duration of the project; and
- recorded in the beneficiary's accounts in accordance with the Accounting Act (1336/1997) and Decree (1339/1997) and good accounting practices.

The costs may be accepted inclusive of value added tax if the beneficiary is ultimately liable to pay the value added tax.

##### 5.1 Wages and salaries

The beneficiary shall arrange the monitoring of the working hours of the people working in the project reliably and appropriately. The working hour records for each individual working directly for the project shall be maintained at an hourly level.

Sitra's funding can only be used to cover the share of wages and salaries paid that correspond to the effective working hours allocated to the project. Effective working hours do not include paid absence from work, such as annual holidays, sick leaves, maternity, parental and paternal leaves or other indirect working hours.

Wages and salaries paid in accordance with the collective agreements and other pay provisions applicable to the beneficiary are accepted as eligible project costs. The pay costs recognised for the project shall be actual costs exclusive on any profit margin. The materials related to the working hour records shall be retained for a period of ten years following the payment of the last funding instalment for the project.

##### 5.2 Indirect costs

The breakdown of project costs into direct and indirect costs shall follow the principles generally applied in beneficiary's accounting.

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Indirect costs are allocated to the project by means of an indirect personnel cost factor and overhead cost factor. The factors used in the project shall be recorded in the project budget that is included in the project plan. Sitra approves the indirect personnel and overhead cost factors, which are calculated on the basis of beneficiary's accounting.

#### 5.2.1 Indirect personnel costs

Indirect personnel costs are allocated to the project by means of the indirect personnel cost factor. The percentage of direct wages and salaries allocated to the project is used as indirect personnel cost factor. If the beneficiary is unable to reliably calculate indirect personnel cost factor derived from its accounting, Sitra will accept a factor that is a maximum of 50 per cent of the wages and salaries of the project's effective working hours, or 30 per cent if holiday pay is not paid.

Indirect personnel costs include, but are not limited to, pay for paid absence from work, holiday pay and social security contributions, pension payments, accident and unemployment insurance premiums and other equivalent employer contributions, and refunds of such contributions.

#### 5.2.2 Overhead costs

Sitra's funding may only be used for covering the beneficiary's overhead costs if Sitra deems this justified for the execution of the project and only to the extent that they have been duly itemised in the project plan or its appendices. In this case, regarding eligible overhead costs, the provisions below concerning overhead costs shall be complied with.

Overhead costs are allocated to the project by means of the overhead cost factor. The overhead cost factor is the percentage of the combined sum of wages and salaries for effective working hours allocated to the project and indirect personnel costs.

The costs covered by the overhead cost factor may include, for example, costs incurred for administrative services, depreciation on machinery and equipment and the use of premises insofar as they are not treated as direct costs according to the general accounting policies applied.

#### 5.3 Travel costs

Sitra will accept as eligible travel costs the actual travel and accommodation costs incurred in connection with the execution of the project. The hours travelled shall not be included in the working hours.

Travel costs are accepted in accordance with the current regulations of the Finnish Tax Administration:

- Decision of the Finnish Tax Administration on tax-exempt allowances for business travel
- Guidelines of the Finnish Tax Administration on the compensation of commuting expenses in taxation

Sitra

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#### 5.4 Material and supplies costs

Materials and supplies purchased that are necessary for the project are accepted as eligible in accordance with the invoicing.

#### 5.5 Purchased services

Services purchased are accepted as eligible in accordance with the invoicing.

#### 5.6 Machinery and equipment

Machinery and equipment that are necessary for the execution of the project will be accepted as eligible in accordance with the invoicing if the machine or equipment is mainly used in the project. If a machine or equipment is also used in activities other than the project, the acquisition cost will be accepted as eligible to the extent that the equipment is used in the project. If the useful life of the equipment is longer than the duration of the project, the portion of the acquisition cost corresponding to the accumulated depreciation over the duration of the project will be accepted as eligible.

The acquisition cost of personal computers, mobile phones and other similar tools are indirect costs and will not be accepted as eligible project costs unless overhead costs are accepted as eligible project costs pursuant to section 5.2.2. In this case, these costs shall be included in the costs stated by means of the overhead cost factor.

#### 5.7 Other costs

Under other costs, costs that are necessary for the execution of the project and reasonable and not included in any of the above items, can be accepted as eligible in accordance with the invoicing. Other costs shall always be itemised in the project budget and reporting template.

#### 5.8 Rejection of costs

Sitra reserves the right not to accept the costs presented in the cost reporting if the relevance of the costs to the project cannot be clearly substantiated.

### PROJECT INFORMATION

Number of the Financing Agreement		Reporting period	
Name of the project			
Data collaboration rulebook for European Children's Hospitals			
Beneficiary's company name		Business ID	
Azienda Ospedaliero Universitaria Meyer		IT02175680483 (VAT number)	
Project responsible person		Phone number	
Kathleen McGreevy		+390555662644	
Email address			
<a href="mailto:kathleen.mcgreevy@meyer.it">kathleen.mcgreevy@meyer.it</a>			
Cost report contact person		Phone number	
Marina Melandri		+390555662838	
Email address			
<a href="mailto:marina.melandri@meyer.it">marina.melandri@meyer.it</a>			

### COST REPORT

The project budget is presented in column I, and the actual total costs in column J, itemized by cost types.  
 Fields marked in yellow are filled in. Green fields in column K are informative only and can be used to support reporting.  
 The actual costs of the project (column J) are always presented according to the total, from the beginning of the project to the end of reporting period.

Project budget	<b>18 990</b>
Sitra's financing (maximum) €	<b>14 242</b>
Sitra's financing share of the total costs	<b>75 %</b>

Wages and salaries	
Indirect personnel expenses	<b>9 %</b>
Overheads	<b>10 %</b>
Travel expenses	
Materials and supplies	
Machinery and equipment	
Services purchased / subcontractors	
Other expenses (please specify below):	

Project budget	Project actual costs	Previously reported costs (informative)
	(dd.mm.yyyy-dd.mm.yyyy)	(dd.mm.yyyy-dd.mm.yyyy)
12 560		
1 068	0	0
1 363	0	0
4 000		
0	0	0
<b>18 990</b>	<b>0</b>	<b>0</b>

**Total costs**

<b>Sitra's funding (based on actual costs)</b>		<b>0</b>
1. instalment	dd.mm.yyyy	
2. instalment	dd.mm.yyyy	
3. instalment	dd.mm.yyyy	
4. instalment	dd.mm.yyyy	<b>0</b>

**Additional information**

#### Date and signature

I hereby confirm that the costs reported are caused by the project and are registered in the beneficiary's accounts. The allocation of the costs to the project has been made in accordance with Sitra's Funding agreement and the Monitoring and cost annex.

\_\_\_\_\_  
Place and date

\_\_\_\_\_  
Signature

## Project: Data collaboration rulebook for European Children's Hospitals

### 1 Ecosystem vision, project partners & objectives

Privacy concerns and regulations have made sharing of health data highly complex and time-consuming for data controllers (hospitals), which severely limits access to health data. The consortium's long-term vision is to facilitate access to health data, provide tools for federated health data analysis and build services that generate sharable synthetic datasets. Then, scientific, and industrial research, SMEs and innovators can tap into rich and high-quality datasets and remain GDPR compliant.

We believe that the ethical use of sensitive data and maintaining trust between ecosystem parties require agreeing on a trust framework and governance rules to be followed by ecosystem parties. Shared rulebook with business, legal, and technical operating standards also increases transparency toward authorities (data protection boards, ethical committees etc.) and ensures that data subjects (patients) can exercise their rights. In a cross-border setting, agreeing on shared governance is not an easy task because each 1) hospital partners must follow both GDPR and their national regulation and organization policies 2) parties have unique technical infrastructure, data maturity, and administrative capacities 3) governance rules should allow scalability of the ecosystem (new partners and new services) from new regions.

In this project, the consortium will work with Sitra's "Fair data Economy Rulebook" template and start building a data collaboration governance framework for ECHO hospitals. The work is guided by following principles:

- Finding the minimum set of governance that allows parties to start collaboration on data use
- Ensuring scalability and evolution of collaboration (new partners, new services, new activities, changes in organization's policies or regulatory requirements)
- Collaboration with minimal centralized structures and with minimal need for legal & policy harmonization between parties from different countries
- Alternative approaches for the ecosystem to sustain its operations through a viable business model

Project is executed by six member hospitals of ECHO (European Children's Hospitals Organization [www.echohospitals.org](http://www.echohospitals.org)) with the support of ECHO secretariat.

- HUS Helsinki University Hospital is Finland's largest provider of healthcare services, serving almost 2.0 million residents. The New Children's Hospital of HUS is Finland's largest hospital focused on demanding specialist pediatric medical care.
- ERASMUS Sophia Children's Hospital (Rotterdam) provides care for children with rare and complex disorders and is the largest of the seven university medical centres in the Netherlands.
- GOSH Great Ormond Street Hospital (London) is the largest pediatric hospital in the UK and delivers the widest range of specialized care, receiving over 255,000 patient visits and carries out approximately 18,800 operations a year.
- HSJD Hospital Sant Joan de Déu (Barcelona) is a private not-profit university hospital that provides top-level health care services for children and pregnant mothers. HSJD combines basic general pediatrics with specialized care for all tertiary-level pediatric pathologies.
- MEYER Azienda Ospedaliero Universitaria (Firenze) is the one of the top children's hospitals in Italy with representation of all clinical specialties. It is a highly specialized paediatric hospital and is the national reference center for complex cases.

- BKUS Children’s Clinical University Hospital of Latvia (Riga) is the only pediatric hospital in Latvia providing high quality healthcare services and currently delivering the emergency as well as the widest range of primary and secondary care services for pediatric patients.

Four of the hospitals (HUS, ERASMUS, GOSH and HSJD) are relatively advanced in their data capabilities (infrastructure and administrative) and they will lead the work as “ecosystem founding members”. Two of the participating hospitals (MEYER, BKUS) are considered “early new adopters” of the ecosystem rulebook and their role is to iteratively validate the design of the governance framework and provide feedback to the rulebook. The validation is an essential check that the rules are acceptable for new parties to join the ecosystem and that participation is possible for hospitals at varying levels of technical and administrative maturity.

## 2 Tasks and deliverables

The project has two tasks, all partners participate in both tasks.

**Task 1: Fair Data Economy Rulebook template review** from four perspectives 1) Data maturity requirements for data controllers (data harmonization, metadata, forms of data access and sharing). 2) Technical requirements (Infrastructure, APIs, standards to follow). 3) Business rules (value generation, financial rules, ecosystem services). 4) Legal rules (agreements, duties and rights of parties, liability, code of conduct, accession of new parties, terms of data use)

**Task 2: Iteratively adapting and validating the rulebook template** to meet the data collaboration needs of ECHO hospitals. The work is done with three iteration rounds, where suggestions by “founding members” are validated by the “early new adopters”.

**Deliverable (D1):** Sitra’s “Fair Data Economy rulebook” draft adaptation to the data collaboration needs of European Children’s Hospitals.

## 3 Project activities and timeline

The project starts with a kick-off meeting, includes weekly Teams-sessions and concludes with a physical / hybrid workshop (1,5 days) where project results are finalized and reviewed. The coordinator plans and prepares the meetings and engages with ECHO’s secretariat, other ECHO member hospitals, and the ECHO executive board.

Tasks & activities / Project month	M1	M2	M3	M4	M5	M6
Project coordination	*					D1
Task 1 - Fair Data Economy Rulebook template review						
Task 2 – Adapting and validating the rulebook					**	

\*) Kick-off meeting; \*\*) Physical / hybrid workshop

## 4 Resources and budget

All partners engage expert personnel to participate in the tasks (total 1 PM). In addition, HUS will provide project leadership & coordination resource with 1,5 PM. A small budget reservation (15 000€) is for external services. Travel budget is for 2 trips / 1-2 persons / partner and HUS budget includes an additional reservation of 5000 € for engaging other ECHO member hospitals. Project total budget is 159.000 €, with expected funding from Sitra 120.000€ (75% of project costs).



7.12.2020

## Guidelines on accessibility for Sitra's co-operation partners

Building the future belongs to everyone. For this reason, communications must be easy to read and understand for all our audiences. When planning and creating our digital content, it is important to consider the needs of those with impaired hearing or eyesight, dyslexia or some other functional limitation.

Sitra is bound by law to observe the [Act on the Provision of Digital Services](#) and [the Directive \(2016/2102\) on the accessibility of the websites and mobile applications of public sector bodies](#). Accessibility is part of promoting equality, and therefore we expect our partners to observe similar rules on accessible digital communications.

This means that all content created during a project or as a project outcome must comply with the criteria laid down in the above regulations. This content includes publications, blogs, videos, PowerPoint presentations, forms, websites and mobile applications.

Accessibility means that:

- All materials produced are written or spoken in clear language.
- Online materials (such as publications, blogs, PowerPoint presentations and invitation forms) should be compatible with screen-reader software (e.g. photos, graphs and charts include alternative texts) and laid out with a sufficiently large font size and appropriate colour contrasts. Red and green are not used in the same graph.
- Stream recordings are subtitled within 14 days of original release.
- A written version of all audio or video content is provided (for example, a podcast is also published as an article and all videos have subtitles excluding stream recordings that are online for less than 14 days).
- Images on social media are posted with alternative texts and videos are subtitled.
- If any project funded by Sitra creates its own website or mobile application, the development and annual running costs of which are at least 50% covered by Sitra, then this project and any associated sites or apps must also comply with the statutory accessibility criteria.

More detailed instructions on the production of materials are available at the website [saavutettavasti.fi](http://saavutettavasti.fi) provided by Celia, the national centre for accessible literature and publishing in Finland. With InDesign files, for example, the [Adobe guidelines](#) for accessible PDF files are also useful.