

Service Agreement: E-SURE **ECDC EHR-AMR specific contract no6**

Between:

Epiconcept SAS, Authorized Capital of 150 000 Euros, under statutory registration number B403 931 553 and intra-community VAT number FR55-403931553, with a registered address at 27, rue Titon 75011 PARIS (FRANCE), represented by Guillaume JEANNEROD, Chief Executive Officer.

Hereinafter referred to as **Epiconcept**,

and

The National Institute of Public Health with a registered address at Srobarova 49/48

100 00 Prague 10 represented by Barbora Mackova, MD, MHA.

Hereinafter referred to as “**the Partner Institute**”.

PREAMBLE


Whereas, Epiconcept was designated by ECDC as the holder of the tender OJ/2021/PHF/12625 “Design and implementation of multinational surveillance systems using routinely collected electronic health records in EU/EEA” and the Specific Contract n° 6 ECD.16697 ID240241/27429 under the Framework Contract n° ECDC/2022/003.


The ECDC project “Design and implementation of multinational surveillance systems using routinely collected electronic health records in EU/EEA” is coordinated by Epiconcept and involves Partner Institutes from EU member states. The Partner Institutes sites agree to conduct the activity in 2024/25.

The Specific Contract implementing Framework Contract no. ECDC/2022/003 between ECDC and Epiconcept takes precedence over this Agreement.

In case of any inconsistency between this Agreement and the ECDC contracts, the provisions of the contract signed between ECDC and Epiconcept shall prevail.

A copy of the Specific Contract is included in the Annex II of the current Agreement.

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Consequently, Epiconcept and the Partner Institute have decided to enter in this Agreement in order to define the working relationships between Epiconcept and the Partner institute that will conduct the activities according to the ECDC Specific Contracts. The following has been agreed upon:

Art.1 – Object

The subject of the present agreement is to carry out the activities within the Specific Contract n°6 ECD.16697 ID240241/27429 implementing the Framework Contract ECDC/2022/003 “*Design and implementation of multinational surveillance systems using routinely collected electronic health records in EU/EEA*”.

The present agreement also defines the obligations of the Partner Institute to fulfil this goal regarding to the ECDC’s contracts.

Art.2 - Assignment of the partner institute /Scope of work*

The role of the partner Institute is to:

- Participate (and eventually present) in both trilateral and multilateral technical meetings.
- Review and support updating the generic protocol.
- Update the country-specific protocol according to the updates on the generic protocol
- Prepare for and implement the country protocol
- If needed and agreed during the development of the project, when feasible, participate in developing a statistical analysis plan (SAP) or/and scripts to implement the generic and/or the country protocol .
- If previously agreed during the development of the project, host and organise (together with the consortium) a site visit of members of the consortium (+/- ECDC staff).
- Provide information, orally during the meetings or by filling tables or questionnaires, describing the epidemiological situation in the sites/countries and the advances and challenges on implementing the EHR-BSI surveillance.
- To prepare an annual surveillance report which, according to the status of the project, may include an update on progress in implementing the country-specific protocol and country results.
- Provide support to prepare and review an annual report, a draft manuscript, and, if needed and agreed during the development of the project, congress presentations.

Over the duration of the contract, the partner institute will commit to:

- Participate (and eventually present) and provide support in up to two multilateral meetings
- Participate (and provide information from the site related to the project) in at least one trilateral meeting.
- Provide support in reviewing the generic protocol and annexes (e.g., an SAP or a generic script)

- Update, plan and (if possible) keep implementation of the country-specific protocol , and if available, the SAP to country/site (November 24)
- Submit an annual surveillance report which, according to the status of the project, may include an update on implementing the country-specific protocol and country results (January 25)
- Provide support to prepare and review an annual report, a draft manuscript, and, if needed and agreed during the development of the project, or congress presentations
- If needed and agreed during the development of the project, participate and support organising a site-specific visit

Art.3 - Duration

The agreement shall enter into force on 7 May 2024. The duration of the tasks shall not exceed 06 March 2025.

Art. 4 - Fees

In consideration of the provision of the service performed in accordance with the terms of this agreement and upon receipt of the suitable deliverables and the corresponding invoice, Epiconcept shall pay to the Partner Institute, the amount detailed below which shall be inclusive of applicable VAT. However, such payment is to be conditional upon payment having been received by Epiconcept from ECDC.

The budget is distributed as follows:

This sum will only be achieved if site participants submit both deliverables associated with the project:

• Surveillance protocol	24,000 €
• Annual report	14,000 €
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TOTAL	38,000 €

The maximum budget available is:

Payment following the submission of deliverables – following the approval and payment by ECDC (April 2025)	38,000 EUR
TOTAL	38,000 EUR

Art. 5 - Payment

- The total amount indicated is a maximum. In addition to the price, no other reimbursable costs are foreseen.
- The Partner Institute will be paid the amount after submission of deliverables and upon receipt of the form (in Annex I) filled out or upon receipt of a relevant invoice.
- Each invoice issued by the Partner Institute shall describe in reasonable detail the matters to which the invoice relates.
- Payment will be done by means of an international bank transfer onto the beneficiary's account after Epiconcept has received the corresponding funds from ECDC.

- The Partner Institute is aware of the article 191 'Principle of non-cumulative award and prohibition of double funding' – under the Financial Regulation of the European Union, applicable to the project.

Invoicing information to be established to:

EPICONCEPT SAS
27 rue Titon - 75011 Paris – France

Art. 6 – Data processing

The Partner Institute shall establish the purposes and means of processing the Data collected on its own account. It shall be solely responsible for this processing under its national Data Protection law and under Regulation (EU) 2016/679 of 27 April 2016, known as the General Data Protection Regulation (GDPR) and in accordance with Annex IV (Data Processing Agreement).

Without prejudice to the stipulations below, the Partner Institute consequently declares that it shall take responsibility for the prior studies, measures and authorisations required by the abovementioned Law or European Regulation, or any other specific regulation.

Data collected may be submitted to ECDC reporting platforms (e.g. TESSy) where personal information is protected to current standards (<https://www.ecdc.europa.eu/en/personal-data-protection>).

The aim of the EHR-based BSI surveillance project is to support countries to implement BSI surveillance and submit data to ECDC when data sharing procedures are agreed and ethics and data protection approvals are in place.

Art. 7 - Audit

In case of ECDC's audit, auditors shall be empowered to audit the documents held by the natural or legal persons receiving payments from the budget of the European Communities from the date of execution of this agreement up to five years after the final payment.

Art. 8 - Responsibilities

Any communication relating to the contract or to its implementation shall be made in writing to the person listed below.

Contact for technical aspects:

[Redacted]

Contact for administrative and financial aspects:

[Redacted]

Contact for GDPR DPO aspects:

[Redacted]

Art. 9 – Confidentiality

The parties undertake to treat in the strictest confidentiality, make appropriate use of and not to disclose to third parties any information or documents which are linked to performance of the Agreement. For all matters, and including any confidentiality matters, the ECDC Specific Contract prevails.

Art. 10 – Pre-existing rights

The Partner Institute warrants that the results are free of rights or claims from creators or from any third parties for any use the ECDC may envisage and declare that the results do not contain any pre-existing rights to the results or parts of the results or to pre-existing materials as defined in the present contract.

Art. 11 – Publication

The Partner Institute is responsible for the Partner Institute communication. As such, they can publish and present the Partner Institute specific results data collected by the Partner Institute. Before publication, the Partner Institute should inform ECDC (routine outputs produced are not concerned).

Publications (peer reviewed papers and conference communications) by the Partner Institute that include data collected through this tender will acknowledge that part/all of the study was funded through the project. The appropriate wording of that acknowledgment will be checked with the ECDC project manager before manuscript/publication submission.

All publications presenting the results of the pooled data from this project will be published only after written approval from ECDC, unless the data has entered the public domain or has otherwise been made publicly available by ECDC. All manuscripts will be submitted to a peer-reviewed journal with open access.

Authorship will comply with the International Committee of Medical Journal Editors.

Art. 12 – Applicable law and settlement of disputes

The agreement shall be governed by French Law. Any dispute between the parties resulting from interpretation or application of the present agreement for which a friendly settlement cannot be reached shall be brought before the Paris (France) competent court within 3 months following the occurrence of the dispute.

Annexes

Annex I - RECEIPT FORM

Annex II - SPECIFIC CONTRACT No 6 ECD.16697 ID240241/27429 implementing activities to the Framework Contract n° ECDC/2022/003

Annex III - Data Processing Agreement

Drawn up on 15 May 2024

For Epiconcept
P/o Guillaume JEANNEROD
Valérie NANCEY

For the partner institute

ANNEX I: RECEIPT FORM

Ref.: **E-sure EHR-BSI/AMR Specific Contract No. 6 ECD.16697 ID240241/27429 implementing activities to the Framework Contract n° ECDC/2022/003.**


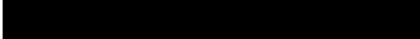
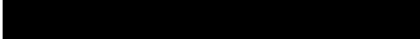
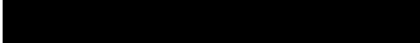
Partner Institute: The National Institute of Public Health
Srobarova 49/48
100 00 Prague 10
Czech Republic

Contacts: 

Description of service

Payment following the submission of the final report – following the approval and payment by ECDC (April 2025)	38,000 EUR
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Bank details:

Name of the bank: Ceska narodni banka
Account name: National Institute of Public Health
Account number: 
(Code) 
SWIFT Code: (BIC) 
IBAN number: 

Date, stamp and signature

ANNEX II: Copy of Specific Contract No. 6 ECD.16697 ID240241/27429 implementing activities to the Framework Contract n° ECDC/2022/003

ECDC NORMAL



SPECIFIC CONTRACT

No 6 ECD.16697 ID240241/27429

implementing framework contract No ECDC/2022/003

1. The European Centre for Disease Prevention and Control (referred to as "the Centre" or 'the contracting authority') represented for the purposes of signing this specific contract by Andrea Ammon, Director,

and

2. E-Sure Consortium, composed of

Epiconcept SAS
Main registration number: 40393155300032
27 Rue Titon
75011 Paris
France
VAT registration number: FR55403931553

appointed as the leader of the group by the members of the group that submitted the joint tender

and

Statens Serum Institut (SSI)
Main registration number: DK 46 83 74 28
Artillerivej 5
2300 Copenhagen
Denmark
VAT registration number: DK 46 83 74 28

and

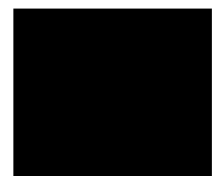
Instituto Nacional De Saúde Doutor Ricardo Jorge, I.P (INSA)
Main registration number: DL 413/71
Avenida Padre Cruz
1649 P.O.BOX 016 Lisboa
Portugal
VAT registration number: 501427511

and



Stichting Nederlands Instituut Voor Onderzoek Van De Gezondheidszorg (NIVEL)
Main registration number: 41181331
Otterstraat 118
3513CR Utrecht
Netherlands
VAT registration number: NL 0070.77.191.B.01

(collectively 'the contractor'), represented for the purposes of the signature of this framework contract by Valérie Nancey, CFO, Epiconcept SAS.



HAVE AGREED

ARTICLE 1 SUBJECT MATTER

- 1.1 This specific contract implements framework contract (FWC) No ECDC/2022/003, signed by the parties on 16/06/2022, and its amendments.
- 1.2 In accordance with the provisions set out in the FWC and in this specific contract and its annexes, which form an integral part of it, the contractor must provide the following services: services specified in Annex I.

ARTICLE 2 ENTRY INTO FORCE AND DURATION

- 2.1 This specific contract enters into force on 29/04/2024 or on the date on which the last party signs it, whichever is later.
- 2.2 The provision of the services starts from the date of entry into force of this specific contract.
- 2.3 The provision of the services must not exceed 10 months. The parties may extend the duration by written agreement before it elapses and before expiry of the FWC.

ARTICLE 3 PRICE

- 3.1 The price payable under this specific contract excluding reimbursement of expenses is EUR 742,262.51 (seven hundred and forty-two thousand two hundred sixty-two euros and fifty-one cents).
- 3.2 Reimbursement of expenses is not applicable to this specific contract.

ARTICLE 4 INTERIM PAYMENTS

- 4.1 In accordance with Article I.6 of the FWC, the contractor shall submit an invoice via *e-prior* for one or more interim payments. The contractor may submit an invoice equal to the price of any combination of the deliverables listed in the section II of the request for services (Annex I), but not exceeding 70% of the total value of the specific contract.
- 4.2. In accordance with Article I.6, the invoice shall be accompanied, inter alia, by deliverable results approved by ECDC.

ARTICLE 5 PAYMENT OF THE BALANCE

- 5.1 In accordance with Article I.6 of the FWC, the contractor shall submit an invoice via *e-prior* for the payment of the balance, upon provision of the final deliverables, approved by ECDC.
- 5.2. In accordance with Article I.6, the invoice shall be accompanied, inter alia, by final deliverable results.



Annexes

Annex I - Request for service RS/2024/PHF/240241 of 26/03/2024.

Annex II - Contractor's specific tender of 08/04/2024.

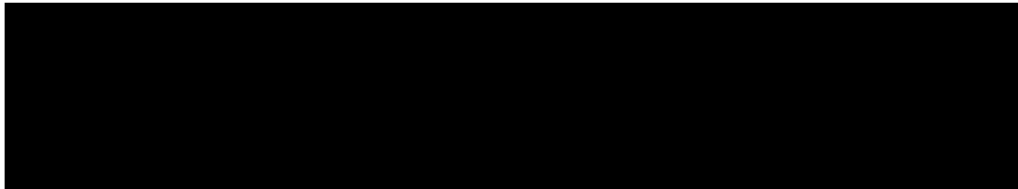
Signatures

For the contractor,

Valérie Nancey, CFO, Epiconcept SAS

For the contracting authority,

Andrea Ammon, Director



signature: _____
Done at Paris, date 2 May 2024

signature: _____
Done at Solna, date _____

In duplicate in English.



Annex III : Data Processing Agreement

v15/09/2023

Within the Contract Agreement signed, this annex defines the Data Processing Agreement between the parties.

Definitions

Controller: a natural or legal person, public authority, agency or any other body which, alone or jointly with others, determines the purposes and means of the processing of personal data.

Processor: a natural or legal person, public authority, agency or other body which processes personal data on behalf of the Controller.

Sub-processor: a natural or legal person, public authority, agency or other body which processes personal data on behalf of the Processor.

Personal data: any information relating to an identified or identifiable natural person (data subject). An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

Sensitive personal data: personal data concerning racial or ethnic origin, political opinion, religion, belief or trade union membership, and the processing of genetic and biometric data with the aim of uniquely identifying a natural person, medical data or information concerning a natural person's sexual circumstances or sexual orientation.

Processing of personal data: any use of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, analysis, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction.

Third party: any other natural or legal person, public authority, agency or body other than the data subject, Controller, Processor, and persons who, under the direct authority of the Controller or Processor, are authorised to process personal data, including companies within the same group.

Parties : Processors, Controllers, Sub-processors involved in this contract

Data subject: identified or identifiable natural person to which the personal data can be linked.

Subject: Identified or identifiable natural person whose personal data are collected.

Role and responsibilities

The activities provided for in this Contract involve the processing of personal data for which **each Party is independent Controller for the performance of its duties.**

The Parties acknowledge that, in the course of performing their obligations under this Contract, they may process personal data of each other's contacts, such as employees, customers, suppliers, or partners. The Parties agree to comply with their respective obligations under the General Data Protection Regulation (GDPR) and any applicable national data protection laws with regard to such personal data.

Each Data Controller undertakes to comply with the provisions of Regulation (EU) 2016/679 of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (hereinafter, the "Regulation"), as well as with the provisions of the Supervisor Authority for the protection of personal data.

The Parties will only process the personal data of the contacts for the purposes of fulfilling their contractual obligations and maintaining their business relationship. The Parties will not process the personal data of the contacts for any other purpose, unless they have obtained the prior consent of the data subject or they are required by law to do so.

In particular, the Data Controllers, pursuant to art. 25 of the Regulation, undertake to put in place technical and organisational measures that guarantee an adequate level of security from the start of the processing, taking into account the state of the art and the costs of implementation, as well as the nature, purpose, context and purpose of the processing, as well as the risk of varying probability and severity for the rights and freedoms of individuals. The Parties will implement appropriate technical and organisational measures to ensure the security and confidentiality of the personal data of the contacts. The Parties will notify each other without undue delay in the event of a personal data breach that affects the other Party's data. The Parties will cooperate with each other and with the relevant supervisory authorities to resolve any issues arising from the breach and to mitigate its adverse effects.

The Parties undertake to put in place, in accordance with art. 32 of the Regulation, all the necessary guarantees in order to meet all the requirements for the protection of the rights of the persons concerned, in such a way as to preserve the confidentiality, integrity and availability of the data.

The Parties will respect the rights of the data subjects under the GDPR, such as the right to access, rectify, erase, restrict, or object to the processing of their personal data, or the right to data portability. The Parties will assist each other in responding to any requests from the data subjects exercising their rights.

The Parties will not transfer the personal data of the contacts to any third country or international organisation, unless they have ensured an adequate level of data protection in accordance with the GDPR. If a Party engages a subprocessor to process the personal data of the contacts on its behalf, it will enter into a data processing agreement with the subprocessor that includes the standard contractual clauses adopted by the European Commission or any other safeguards approved by the GDPR.

Categories of data subjects

Contacts working for the fulfilling of their duties and activities within the current contract.

Type of data to be processed

Personal data of the contacts : Name, Surname, email address.

Retention Period

The Controllers will retain the personal data as long as necessary for the execution of the contract.

Notification in case of breach of the GDPR

Each party shall notify the other immediately if they believe that the instructions are in breach of the Personal Data Legislation.

Use of subcontractors

If the Controllers use Processors to carry out the processing of personal data which is covered by this Agreement, special or general written permission shall be obtained from the Processor before such processing of personal data commences.

Security audits

The Processors may conduct security audits of the other Processors.

DPO

- Epiconcept's contact for personal data protection issues and security issues : Dalhia Khnafo - DPO & CSO - d.khnafo@epiconcept.fr
- Contact for personal data protection issues and security issues: this information will be sent to the Processor as soon as possible.