

Service Agreement: E-SURE **ECDC EHR-SARI specific contract no3**

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

National Institute of Public Health, with a registered address at Srobarova 48/49, 100 00 Prague, Czech Republic, represented by Barbora Mackova, M.D. director

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

PREAMBLE

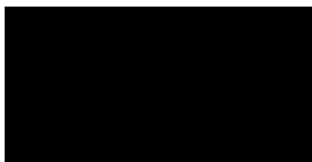
Whereas, Epiconcept was designated by ECDC as the holder of the tender OJ/2021/PHF/12625 “Design and implementation of multinational surveillance systems using routinely collected electronic health records in EU/EEA” and the Specific Contract n°3 ECD.14898 ID26495 under the Framework Contract n° ECDC/2022/003.

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 2023/24.

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.



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°3 ECD.14898 ID26495 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:

- Develop a country-specific EHR-based SARI surveillance annual report. An annual report template will be provided by Epiconcept. The report should describe obstacles and opportunities regarding technical, epidemiological, and data protection aspects, when attempting to extract, link and analyse health care data from health information systems. The country-specific annual report should include a summary in English and a statement from the national leads indicating that the report has been approved for submission to ECDC. This is to be delivered by **26 January 2024**.
- Participate in the Multilateral/Network meetings
- Participate in the Bilateral meetings
- Host a site visit upon request
- Review and validate documents as requested
- Participate in the SARI surveillance EU/EEA wide evaluation
- Participate in a scientific manuscript (optional)

Art.3 - Duration

The agreement shall enter into force on 24 May 2023. The duration of the tasks shall not exceed 23 February 2024.

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.

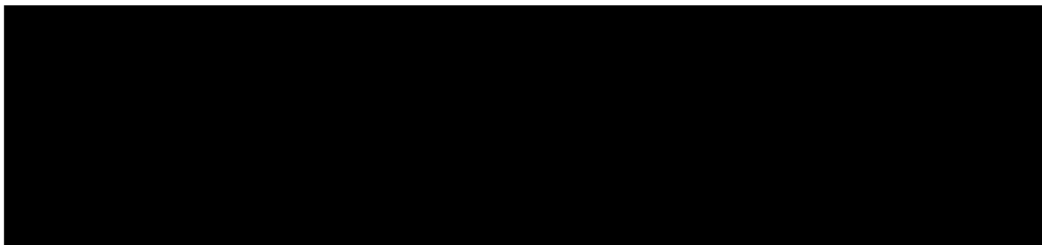
The maximum budget available is:

Payment following the submission of the requested deliverables – following the approval and payment by ECDC (March 2024)	12,000 EUR
TOTAL	12,000 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:



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).

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.

The aim of the EHR-based SARI surveillance project is to support countries to implement SARI surveillance and submit data to ECDC via TESSy when ethics and data protection approvals are in place.

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>).

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

Surveillance sites are responsible for the surveillance site communication. As such, they can publish and present the surveillance site specific results from data collected by the surveillance site. Before publication in scientific journals, the sites should inform ECDC. ECDC does not need to be informed before publication of regular national surveillance reports.

Publications in scientific journals by surveillance sites that include data collected through this tender will acknowledge that part/all of the work 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 No3 ECD.14898 ID26495 implementing activities to the Framework Contract n° ECDC/2022/003

Annex III - Data Processing Agreement

Drawn up on 27 September 2023,



For Epiconcept
P/o Guillaume JEANNEROD
Valérie NANCEY

For the partner institute

ANNEX I: RECEIPT FORM

Ref.: **E-sure EHR-SARI Specific Contract No. 3 ECD.14898 ID26495 implementing activities to the Framework Contract n° ECDC/2022/003.**



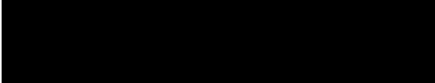
Partner Institute: National Institute of Public Health
Srobarova 48/49,
100 00 Prague,
Czech Republic

Contacts: 

Description of service

Payment following the submission of the requested deliverables – following the approval and payment by ECDC (March 2024)	12,000 EUR
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Bank details:

Name of the bank: 
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. 3 ECD.14898 ID26495 implementing activities to the Framework Contract n° ECDC/2022/003

ECDC NORMAL



SPECIFIC CONTRACT

No 3 ECD.14898 ID26495

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

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SC3 ECD.14898 ECDC/2022/003

ECDC NORMAL

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

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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.
- 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 the date on which the last party signs it.
- 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 9 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 568,200.00 (five hundred sixty-eight thousand two hundred euros).
- 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 interim payment(s). The contractor may submit an invoice equal to the price 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.

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.

SC3 ECD.14898 ECDC/2022/003

ECDC NORMAL

Annexes

Annex I - Request for service RS/2023/PHF/26495 of 11/04/2023

Annex II - Contractor's specific tender of 02/05/2023

Signatures

For the contractor,

For the contracting authority,



signature: _____
Done at Paris, date 18 May 2023

signature: _____
Done at Solna, date _____

In duplicate in English.

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A handwritten signature in black ink, consisting of stylized initials.

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.