

**Agreement between National Authorities or National Organisations responsible for
National Contact Points for eHealth on the Criteria required for the participation in
Cross-Border eHealth Information Services**

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Glossary of abbreviations and definitions

CBeHIS	Cross-Border eHealth Information Services that are processed via NCPeH for the purpose of cross-border healthcare, as they were agreed by the eHN (Patient Summary for unscheduled care; ePrescriptions and eDispensations) and as they will be agreed by the eHN in the future
Contracting Party	National Authority or National Organisation responsible for NCPeH in a Member State of the EU or EFTA that has signed this Agreement
Country A	Member State of affiliation according to Art. 3 (c) of Directive 2011/24/EU
Country B	Member State of treatment according to Art. 3 (d) of Directive 2011/24/EU
Cross-border healthcare	Term as defined in Art. 3 (a) and (e) of Directive 2011/24/EU
EFTA	European Free Trade Association
eHDSI	eHealth Digital Service Infrastructure enabling the provision of CBeHIS via NCPeH as Generic Services under the responsibility of the Contracting Parties and Core Services as described in the documents that are referred to in the Annex
eHN	eHealth Network according to Article 14 of Directive 2011/24/EU
EU	European Union
Governing Body	eHN or another body agreed by the eHN
Healthcare provider	Term as defined in Art. 3 (g) of Directive 2011/24/EU
Health professional	Term as defined in Art. 3 (f) of Directive 2011/24/EU
National Authority or National Organisation responsible for NCPeH	Ministry responsible for eHealth, or an organisation at a lower level that has the original or delegated competence of either operating the NCPeH and/or signing this Agreement, or an Authority at an even higher level than the Ministry responsible for eHealth (e.g. Government as collegial organ) as required by the national laws and procedures of a Contracting Party. In any case, the link between the respective Contracting Party and its National Authority as Member of the eHN must always remain established
NCPeH	National Contact Point for eHealth, acting as organisational and technical gateway for the provision of CBeHIS

Chapter I

General objective and scope

Clause I.1

(1) The eHealth Network (eHN) set up under Article 14 of Directive 2011/24/EU is the main political and strategic Governance Body for eHealth in Europe, connecting the National Authorities responsible for National Contact Points for eHealth (NCPeH). The eHN has the mandate to establish an European Interoperability Framework for Cross-Border eHealth Information Services (CBeHIS) with a view to achieving a high level of trust and security, enhancing continuity of care and ensuring access to safe and high-quality healthcare.

(2) Whereas organisational, semantic and technical interoperability have been worked upon by the eHN, the establishment of an overall interoperability framework remains needed for the achievement of the objectives under Directive 2011/24/EU, notably Articles 11 and 14 thereof. This requires an even closer cooperation among the Contracting Parties by way of displaying the legal criteria laid down in EU law and the Contracting Parties' national laws to be adhered to for the purpose of providing CBeHIS.

(3) This Agreement materializes the commitment of the Contracting Parties to fulfil all the criteria required for the participation in CBeHIS. The details of specifications for the implementation and organisation of these requirements are described in the binding documents that are referred to in the Annex. The elaboration of these documents follows a progressive approach through different stages, as described in the documents that are referred to in the Annex, in order to achieve a sustainable framework.

(4) This Agreement thus describes the criteria for the processing of personal data concerning health for the purpose of cross-border healthcare according to Directive 2011/24/EU by means of the CBeHIS.

Clause I.2

(1) Ensuring continuity of cross-border healthcare depends on transmission of personal data concerning patients' health. These personal data should flow from one Contracting Party to another, while at the same time the fundamental rights of the patients shall be safeguarded.

(2) This requires that each Contracting Party of a Country A provides the patient with adequate, correct and up to date information about the transmission of his or her personal data to a Contracting Party of a Country B, together with ensuring the secure transmission of the data to this Contracting Party of a Country B.

(3) Each Contracting Party of a Country B shall ensure secure receipt of this data and provide the appropriate level of protection when data is processed, in conformity with national law and Union provisions on the protection of personal data, in particular Regulation 2016/679/EU¹, and also ensure the secure transmission of data to the Contracting Party of a Country A.

Clause I.3

(1) Contracting Parties to this Agreement may be the National Authorities or National Organisations responsible for NCPeH in Member States of the EU and EFTA.

(2) All National Authorities or National Organisations are free to choose whether to participate in the signature of this voluntary Agreement, depending on which CBeHIS they wish to offer as a Contracting Party of a Country A and/or Country B.

¹ Directive 95/46/EC until 24 May 2018.

(3) Once a National Authority or National Organisation has chosen to become a Contracting Party to this Agreement, it is obliged to fulfil the criteria required herein in order to be admitted to participate in the CBeHIS according to paragraph (2).

(4) All Contracting Parties have the right to choose, in accordance with EU law and their respective national law, the method for the fulfilment of the required criteria.

Clause I.4

The eHN shall amend the Agreement according to Clause III.1.1.3 within 12 months from the adoption of the Agreement on 9 May 2017, depending on the need for such an amendment based on the evaluations and conclusions reached until then.

Chapter II

Criteria required for the participation in CBeHIS

Section 1: Legal criteria

Clause II.1.1

Data protection and security

Clause II.1.1.1

Legal basis for the cross-border processing and patient information

(1) The processing of personal data concerning health for the purpose of cross-border healthcare pursuant to Directive 2011/24/EU via CBeHIS is lawful in compliance with the conditions stated in Regulation 2016/679/EU², in particular Article 9 thereof, and national law compliant with the stated Regulation. Further processing of these data according to Article 6 paragraph 4 of Regulation 2016/679/EU³ shall be excluded.

(2) Each Contracting Party shall ensure that patients are provided with the information pursuant to Articles 13 and 14 of Regulation 2016/679/EU⁴.

Clause II.1.1.2

Identification and authentication of patients, health professionals and healthcare providers

(1) In order to enhance patient safety and privacy in cross-border healthcare, Contracting Parties shall ensure the unambiguous identification of patients, health professionals and healthcare providers, without prejudice to Regulation 2014/910/EU:

a.) Contracting Parties using electronic means of identification that are notified under Regulation 2014/910/EU and applicable to the health domain, shall adhere to this Regulation, its Implementing Acts and the documents that are referred to in the Annex.

b.) Contracting Parties using non-electronic means of identification, or using electronic means of identification not notified under Regulation 2014/910/EU, or using electronic means of identification that are notified under Regulation 2014/910/EU but not applicable to the health domain, shall adhere to the relevant documents listed in the Annex.

(2) Each Contracting Party shall ensure that it uses means of authentication that are adequate to the sensitivity of personal data concerning health according to Regulation 2014/910/EU and Regulation 2016/679/EU⁵.

Clause II.1.1.3

Authorization of health professionals

Each Contracting Party of a Country B shall ensure that for the purpose of cross-border healthcare only health professionals authorized according to its national law may have access to patients' data concerning health, without prejudice to other lawful grounds for processing under Regulation 2016/679/EU⁶.

² Directive 95/46/EC until 24 May 2018.

³ Directive 95/46/EC until 24 May 2018.

⁴ Directive 95/46/EC until 24 May 2018.

⁵ Directive 95/46/EC until 24 May 2018.

⁶ Directive 95/46/EC until 24 May 2018.

Clause II.1.2

Liability, applicable law and jurisdiction

(1) The civil liability of each designated NCPeH as Generic Services under the responsibility of the Contracting Parties is determined by the liability regime in accordance with the applicable law and competent jurisdiction.

(2) The Contracting Parties do not assume any liability for Core Services as described in the documents that are referred to in the Annex.

Section 2: Organisational criteria

Clause II.2

Processing of personal data concerning health via NCPeH

Each Contracting Party shall designate one NCPeH to act as a single communication gateway with the NCPeH designated by other Contracting Parties. In order to be admitted to participate in the CBeHIS according to the process defined under Clause III.1.2.1 of this Agreement, each Contracting Party shall ensure the compliance of its NCPeH with the criteria set forth in this Agreement, taking into account the relevant processes and criteria defined in the documents that are referred to in the Annex.

Section 3: Semantic criteria

Clause II.3

Semantic processing

(1) Each Contracting Party shall ensure semantic processing as needed for the provision of cross-border healthcare via CBeHIS.

(2) Each Contracting Party is responsible for the accuracy and integrity of semantic processing and must therefore use the most recently adopted version of the Master Value Set Catalogue and maintained national versions of these controlled vocabularies used in semantic processing.

(3) In order to be admitted to participate in the CBeHIS according to the process defined under Clause III.1.2.1 of this Agreement, each Contracting Party shall ensure the compliance of its NCPeH with the criteria set forth in this Agreement, taking into account the relevant processes and criteria defined in the documents that are referred to in the Annex.

Section 4: Technical criteria

Clause II.4.1

Security Principles

In order to be admitted to participate in the CBeHIS according to the process defined under Clause III.1.2.1 of this Agreement, each Contracting Party shall ensure the compliance of its NCPeH with the principles of data protection by design and by default, the requirements for confidentiality, integrity, authenticity, availability, non-repudiation, encryption and other means of data security and control measures in compliance with Regulation 2014/910/EU and Regulation 2016/679/EU⁷, taking into account the relevant processes and criteria defined in the documents that are referred to in the Annex.

Clause II.4.2

Traceability, audit and non-repudiation

In order to be admitted to participate in the CBeHIS according to the process defined under Clause III.1.2.1 of this Agreement, each Contracting Party shall ensure the compliance of its NCPeH with the requirements for logs, audit trails, non-repudiation and other means of data security and control measures in compliance with Regulation 2014/910/EU and Regulation 2016/679/EU⁸, taking into account the relevant processes and criteria defined in the documents that are referred to in the Annex.

⁷ Directive 95/46/EC until 24 May 2018.

⁸ Directive 95/46/EC until 24 May 2018.

Chapter III Governance

Section 1: Governance for this Agreement

Clause III.1.1

Signature, entry into force, term and termination

Clause III.1.1.1

Signature

(1) In accordance with Clause I.3, this Agreement shall be open to the participation of National Authorities or National Organisations responsible for NCPeH in Member States of the EU and EFTA that meet the criteria required for the participation in CBeHIS as set out by this Agreement and taking into account the documents that are referred to in the Annex.

(2) The duplicate of the Agreement that is signed by the representative of the Contracting Party duly authorized according to national laws and procedures shall be provided to the Governing Body. In case the signatory is not the respective Member of the eHN, a written approval from the Ministry responsible for eHealth shall be provided. The Agreement will remain open for signature for an indefinite time. The Governing Body shall keep one signed version of the Agreement of all the Contracting Parties.

(3) The signing of this Agreement is one criterion for the admission in accordance with Clause III.1.2.1, as described in the documents that are referred to in the Annex. The signature of the Agreement by a Contracting Party means that it accepts, subject to paragraph (4), to adhere unconditionally to all legal criteria set out in this Agreement.

(4) Contracting Parties may express their consent to be bound by this Agreement subject to approval according to their national laws and procedures. This approval must be granted in order to complete the signing of this Agreement as one criterion for the admission in accordance with Clause III.1.2.1.

Clause III.1.1.2

Term and termination

(1) This Agreement shall subsist until it is either replaced by another Agreement or legislative act, or is terminated in accordance with paragraph (2).

(2) This Agreement shall be terminated if agreed in writing unanimously by the Contracting Parties.

Clause III.1.1.3

Amendment of the Agreement

(1) This Agreement may be amended only in writing. Any Contracting Party or Member of the eHN may propose amendments to this Agreement by forwarding a proposal for

amendment to the Governing Body. Upon receiving such a proposal, the Governing Body shall forward the proposal to the other Contracting Parties and Members of the eHN.

(2) The Agreement may be amended by the eHN in accordance with the procedure defined in Article 7 of the Rules of Procedures of the eHN.

Clause III.1.2

Admission, withdrawal and exclusion, dispute resolution

Clause III.1.2.1

Admission:

Each Contracting Party that has signed this Agreement shall be admitted by the eHN to participate in the CBeHIS if the compliance of its NCPeH with the criteria set forth in this Agreement is established, taking into account the relevant processes and criteria defined in the documents that are referred to in the Annex.

Clause III.1.2.2

Withdrawal, exclusion and technical suspension

(1) Contracting Parties are entitled to terminate their participation in the Agreement. Withdrawal of a Contracting Party requires a written declaration of the Contracting Party to the Governing Body with a notice period of 4 (four) months. The right to withdraw without notice period for good cause in written form shall remain unaffected. It shall constitute good cause, in particular and without limitation, if

- a) the Agreement contradicts national legislation;
- b) the continued operation would severely harm the interests of the Contracting Party.

(2) A Contracting Party may accede to the Agreement again at any time without a readmission ban after the withdrawal of that Contracting Party has become effective, according to the process defined under Clause III.1.2.1.

(3) The eHN shall exclude a Contracting Party if the Contracting Party ceases to have legal capacity or ceases to exist. The eHN may exclude a Contracting Party for good cause according to paragraph (4).

(4) The exclusion of the Contracting Party shall take immediate effect as of the date of the decision of the eHN. The Contracting Party must be notified by the eHN of the decision in writing. It shall constitute good cause, in particular and without limitation, if

- a. the continued operation of the relevant Contracting Party would harm the aim and main interests of this Agreement;
- b. a Contracting Party repeatedly infringes the provisions of this Agreement despite a written reminder by the Governing Body.

(5) Immediate interim technical suspension from the CBeHIS of a Contracting Party at its own discretion or by the Governing body may be executed in case the Contracting Party or the Governing Body identifies a risk or an incident as defined under Directive 2016/1148/EU. All other Contracting Parties shall be immediately informed thereof by the respective Contracting Party suspending at its own discretion or by the Governing Body, without prejudice to any obligations under the mentioned Directive. The duration of the immediate interim technical suspension of a Contracting Party from the CBeHIS is indefinite. Technical suspension from the CBeHIS of a Contracting Party ends either

when the Governing Body decides that the Contracting Party again meets all the set criteria or the eHN decides upon the exclusion of the Contracting Party from the Agreement according to paragraph (4).

(6) As of the effective termination of participation in the Agreement, the respective Contracting Party shall no longer be entitled to any rights. Such termination shall not affect commitments entered into or liabilities incurred by the respective Contracting Party prior to such termination.

Clause III.1.2.3

Dispute Resolution

(1) Any dispute between the Contracting Parties about the interpretation of any provision of this Agreement or the documents that are referred to in the Annex shall be resolved amicably and informally, as far as possible, pursuant to this Clause.

(2) Prior to the initiation of any formal dispute resolution proceedings including litigation, the Contracting Parties shall first attempt to resolve their dispute informally, as follows:

- a. upon the written request of either Contracting Party to the other, each Contracting Party shall appoint a designated representative for the purpose of endeavouring to resolve such dispute;
- b. the designated representatives shall meet as often as either Contracting Party reasonably deems necessary in order to gather and furnish to the other all information with respect to the matter in issue which the Contracting Party believes to be appropriate in connection with its resolution. The designated representatives shall discuss the problem and negotiate with each other in good faith in an effort to resolve the dispute informally;
- c. during the course of negotiations, all reasonable requests made by either Contracting Party to the other for non-privileged information, reasonably related to the Agreement, shall be honoured in order that each of the Contracting Parties may be fully advised of the other's position; and
- d. the method of endeavouring to resolve the dispute shall be left to the discretion of the designated representatives.

(3) Neither Contracting Party shall commence formal dispute resolution proceedings including litigation, until the earlier of:

- a. at least one of the Contracting Parties' designated representatives as referred to in paragraph (2) concluding that resolution of the dispute through continued negotiation of the matter does not appear likely; or
- b. 30 (thirty) Working Days after either Contracting Party's written request under paragraph (2) has been submitted to the other Contracting Party and that other Contracting Party has failed to appoint a designated representative.

(4) If the dispute cannot be resolved by informal dispute resolution, a formal dispute resolution process will be followed.

(5) This Clause shall not constitute a waiver of either Contracting Party's right to institute formal dispute resolution proceedings including litigation in order to avoid the expiration of any applicable limitation periods.

(6) Each Contracting Party must, unless technically suspended according to Clause III.1.2.2 paragraph (5), continue performing its obligations under the Agreement while any dispute is being resolved informally, unless and until the Agreement is terminated or in accordance with the final determination of the dispute resolution procedure.

Section 2: Governance for the Annex

Clause III.2

- (1) The list of referred documents in the Annex and the documents that are referred to in the Annex may be amended by the body that has adopted the list or the respective document, or by another body that is agreed by the eHN.
- (2) Amendments of the list of referred documents in the Annex or of the documents that are referred to in the Annex shall not be considered as an amendment of the Agreement.
- (3) In case of contradiction between the Clauses of this Agreement and the provisions in the documents listed in the Annex, the Clauses of this Agreement shall prevail.

Signed in _____, on _____ in duplicate.

Annex

1. **Guidelines on Electronic exchange of health data under the Cross-Border Directive 2011/24/EU**
2. **Guideline on an Organisational Framework for eHealth National Contact Point**
3. **Recommendations on Country Guide for eHealth NCP implementation**
4. **Policy paper on how to assess Member States' overall readiness to go live**
5. **Policy Paper on assessment and decision procedures under CEF funding**
6. **eHealth-specific eID framework across-borders**
7. **Guideline on Interoperability of electronic professional registries**
8. **Governance model for the eHealth Digital Service Infrastructure during the CEF funding**
9. **The Commitment of the European Commission to deliver the Core Services for eHealth Digital Service Infrastructure**
10. **Rules of Procedures of the eHealth Network**