



E1.2.1 - Handbook for use and exchange of health records within the ICTUSnet framework

Manuel d'utilisation et echange des donnees de registres de sante dans le cadre du projet ICTUSnet

WP1 - DEVELOPMENT OF REGIONAL REGISTRIES AND ICTUSNET PLATFORM

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Document summarizing the criteria and recommendations for the use of data in health registries and the exchange of these and their results.

Livre indiquant les critères et recommandations pour l'utilisation des données dans des registres de santé et l'échange de ceux-ci et leurs résultats.

Revision history

Version	Date	Comments	Partner
1	30/11/2018	Creation of the document, collecting the inputs provided by the partners.	CHUM
1.1	29/01/2019	Preparation of the document for submission within the progress report	EASB
1.2	31/03/2021	Finalization of the document with the last input	CHUM
1.3	12/04/2021	Addendum with IAS comment	CHUM

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ABBREVIATIONS AND ACRONYMS

AQuAS	Agència de Qualitat i Avaluació Sanitàries de Catalunya
ARSN	Administração Regional de Saúde do Norte, I.P.
CEI-IB	Ethical Committee of Research of the Balearic Islands
CHUM	Centre hospitalier Universitaire de Montpellier
CHUT	Centre Hospitalier Universitaire de Toulouse
CICAT	Registry of “Codi Ictus Catalunya”
EC	European Commission
EEA	European Economic Area
EU	European Union
FMS	Navarrabiomed- Fundación Miguel Servet
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
IACS	Instituto Aragonés de Ciencias de la Salud
ICTUSnet	Acronym of the Project <i>“Excellence network for the development and implementation of innovative models for Ictus integrated attention.”</i>
IdISBa	Fundación Instituto de Investigación Sanitaria Illes Balears
PADRIIS	Public Data Analysis for Health Research and Innovation Program
BIGAN	BIGAN platform is a data infrastructure implemented to reuse any kind of existing data for planning, quality management and health research in Aragon.

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EXECUTIVE SUMMARY

ICTUSnet project aims to foster the development of stroke registries in different south-western European regions. Data from these regional registries will be incorporated in the ICTUSnet registry, a central repository to allow interregional benchmarking and stroke care quality assessment.

This document describes legal and regulatory requirements in each country to set up all the regional registries of the ICTUSnet project, and good practices to collect and transfer in secured the data to ICTUSnet registry. The collection and the transfer of the data within the project is governed by agreement between partners:

- 1) Consortium Agreement; the object of the Agreement is to establish the recommendation on intellectual property, result and publication
- 2) Collaboration Agreement; the object of the Agreement is to establish the conditions of the assignment of anonymised data to AQuAS, transmitted by the partners.

1. Regulatory and ethical framework

1.1. European regulation

ICTUSnet project involving human collection data, so this research will be handled in compliance with European Regulation:

- The Charter of Fundamental Rights of the EU (2000/c 364/01)
- the Activities does not involve the processing of personal data (only anonymized data), the project will not be governed by the Regulation (EU) 2016/679 of the European Parliament and of the Council, of April 27, 2016, (hereinafter, "GDPR")

A Glossary with definitions included in the text of GDPR that may be relevant for the purpose of this document are included in **Annex 2**.

The ICTUSnet project will also respect the Helsinki Declaration in its latest version and the Nuremberg Code (1947) addressing volunteer consent and proper acting.

1.2. National regulation

ICTUSnet registry will be completed by the compilation of data from the different regions. ICTUSnet registry will comply with regional and national regulation and law.

The information presented in this section has been compiled during the last quarter of 2018 and revised in March 2021 by the different clinical partners working in ICTUSnet Project, though a questionnaire set up by CHUM and reviewed by AQuAS. The questionnaire is included as **Annex 1** of this deliverable. Partners have involved in the discussion of these topics their legal and ethical contacts of reference at institutional and/or regional level.

Further information about the description of each of the regional registries can be found in Deliverable D1.3.2.

1.2.1. Spain

1.2.1.1. Catalonia

In Catalonia, the CICAT registry prospectively collects data from all code stroke cases in Catalonia. It is a government-mandated, region-wide registry that is part of the health administrative datasets in Catalonia and is routinely filled in by neurologists and stroke physicians as part of the daily clinical practice. Data from CICAT will feed ICTUSnet registry. The CICAT registry is safeguarded by AQuAS (Agency for Health Quality and Assessment of Catalonia), which is also responsible for routine statistical exploitation of data. All data in the CICAT registry comply with ethical and legal requirements stated by the Public Data Analysis for Health Research and Innovation Program (PADRIS) of Catalonia.

1.2.1.2. Navarra

The Navarra Stroke Registry is on a development phase, this registry will prospectively collect data from all code stroke cases in Navarra. It is a government-mandated, region wide registry feeded by the health administrative datasets in Navarra. The Navarra Stroke registry will be is safeguarded by Osansunbidea-Sanitary Information Service from Navarra Public Health System, which is also responsible for routine statistical exploitation of data. All data in the Navarra Stroke Registry comply with ethical and legal requirements from General Data Protection Regulation (GDPR).

1.2.1.3. Aragon

In Aragon, the extraction of data for the ICTUSnet registry is done by IACS through the Aragón Regional Health Authority BIGAN platform. An approval of the ethical and legal committee of Aragon has been obtained January 15th 2020. **Annex 4**

1.2.1.4. Balearic island

In Balearic Island, a regional registry has been adapted for data collection from the hospital records. It is a hospital based- registry that covers all the regional cases of EVT and, in this case, it is also considered a regional registry that is integrated into the Hospital's electronic medical record application. The registry will be routinely filled in by neurologists and neurology residents as part of their daily work.

It complies with the requirements of the Spanish data protection Agency and was authorized by the Security department of the Office of Information and Communications Technologies of the Balearic Islands Health Service.

Since it had been approved by the Ethical and Legal committee of Aragon, only the notification to the Ethical Committee of Research of the Balearic Islands (CEI-IB) was necessary (see [annex 5](#)).

1.2.2. Portugal

The Northern Regional Health Administration Stroke Registry is on a development phase, with a prospective registry of the ischemic stroke cases submitted to endovascular treatment in the North of Portugal. It is a government-mandated, region wide registry filled with data communicated by partner hospitals located in the North of Portugal. All data in the Northern Regional Health Administration Stroke Registry comply with ethical and legal requirements from General Data Protection Regulation (GDPR).

1.2.3. France

French registry is implemented by prospective data. The registry has been approved by ethical comity and French competent authority. The registry comply with French regulation ('Loi n°2012-300 du 5/03/2012 relating to research involving the human person (Loi Jardé) and their application decrees (Décret N°2016-1537 du 16/11/2016 relating to research involving the human person, Décret n° 2017-884 du 9/05/2017 amending certain regulations relating to research involving the human person), the French laws of bioethics, 'Law processing, files and freedoms N°78-17 du 6/01/1978, the declaration of Helsinki, the GDPR and Law No. 2018-493 of 20/06/2018 on the protection of personal information). Patient will be informed by the physician, with regards to the nature and scope of the study.

2. Patient data collection

The approach regarding the strategy to incorporate the data from the regional registries to the ICTUSnet registry has been discussed during the second ICTUSnet Consortium meeting and in the bi-

weekly teleconferences held by the ICTUSnet Steering Committee and the Coordination Team during the first months of the project. As mentioned above, partners have involved in the discussion of these topics their legal and ethical contacts of reference at institutional and/or regional level.

More information are available in the deliverable 1.3.1 and 1.4.1

2.1. Data protection and management in each region registry

Study subject confidentiality and welfare will always be maintained as the highest priority. All work involving data collection of human information- electronic or otherwise -, including genetic privacy and data protection, will comply with the EU General Data Protection Regulation (GDPR). In accordance of Good Clinical Practice (GCP), the data of all patients included will be recorded in each regional registry that must enable safe storage and processing to ensure the privacy of participants.

2.2. Data transfer

Before the data transfer, directly identifiable data's will either be replaced by random codes or removed and temporal data will be shuffled by each partner will replace name by a RANDOM code, in compliance with all applicable law. And AQUAS will assign new RANDOM codes to the anonymized data transmitted by each partner. All the conditions of the assignment of anonymised data to AQUAS, transmitted by the partners are described in the Collaboration Agreement. **Annex 3**

An automatized process (**web service**) will allow the transfer microdata from the regional or hospital registries to the ICTUSnet central dataset for which **interoperability standards** should be agreed on before (Deliverable 1.3.1).

Considering the last approach suggested by AQUAS, each regional partner should be considered the **Data controller**, and will be responsible for the anonymization of the data of their registries that will be later incorporated in the ICTUSnet registry. The data of each patient will be anonymized before the transfer to the ICTUSnet registry without name, birth date, nor with patients' regional ID code. Therefore, once the data is anonymized, it is not considered as '**personal data**' but as '**anonymous information**' (See definitions in **Annex 2**) and the data will be considered as data from stroke 'episodes', instead of data from stroke 'patients'.

Any data transfer will be done using secure connection. Technical and methodological practicalities of the transfer of data from regional registries to the ICTUSnet registry are detailed in deliverables 1.3.1 and 1.4.1

2.1. Data protection and management of ICTUSnet registry

Following the current approach AQUAS will be considered the **Data Processor**, and will be in charge of

the maintenance of the database of the ICTUSnet registry. In addition to the anonymization implemented by the data controllers, the approach presented by AQuAS a second anonymization process that will assign to each stroke episode received a new random ID. Thus, it will be impossible to link the data in the ICTUSnet registry with the regional registries and track the case.

Technical and methodological practicalities of the storage and management of data incorporated from regional registries into the ICTUSnet registry are detailed in deliverable 1.4.1, 1.4.2. and 1.4.3.

3. Agreements covering data incorporation to ICTUSnet registry

The following agreements are already in place for ICTUSnet, establish the general conditions of implementation of the project:

- **Grant Agreement** (i.e. '*Acuerdo de concesión*' in the original wording in Spanish): signed between the Managing Authority of the INTERREG Sudoe Programme and AQuAS as main beneficiary of the ICTUSnet Project representing the Consortium.

In addition, the Consortium will issue a set of Agreements that will deal in more detail with the data management and processing between the partners (controllers) and AQuAS (processor):

- **Consortium Agreement:** document aimed to complement the Collaboration agreement, with further details and recommendation on intellectual property, result and publication.
- **Collaboration Agreement:** document defining the responsibilities of each Data Controller and Data Processor in the framework of the ICTUSnet registry. **Annex 3**

On the whole, the three documents listed above will cover a range of standard points:

- **Governance and coordination**

This sets out the role and responsibility of the project leaders. The section will define and explain the role of bodies such as coordinating committees and administrative function, the development of an adequate coordination plan.

- **Publication and Confidentiality**

The ability to publish results that are of scientific interest is an essential consideration.

The partners may choose to establish mechanisms by which sensitive results can be taken outside the sensitive context, thereby permitting publication. Inclusion of confidential information belonging to the other parties will require prior written approval, but there should also be a general expectation that this will not be withheld without good justification.

- **Access rights to background information**

The availability of background information and knowledge is a key consideration in selecting the partners. Consequently, it is important to agree what access rights will exist, and ensure that these are sufficient to allow the project to proceed satisfactorily and to permit results to be put to the intended use. Conditions and restrictions must be defined prior to entering the agreement, to the extent that these are known after reasonable enquiry. Each party should know the circumstances in which its own technologies were developed or acquired, the history of its own patents and the fields of its own technologies, so that it can warrant that it is entitled to grant a licence on the contemplated use and that to its knowledge it is not aware of potential infringement of third party rights other than disclosed.

- **Intellectual property**

The usual situation is each party will take steps to protect its own inventions at its own discretion. The parties should consider who will be responsible for defending patents and pursuing infringements.

ANNEX 1 – Form for the collection of ethical and regulatory requirements at regional level

LEGAL ASPECTS FOR EACH REGION/ COUNTRY



REGION/ COUNTRY		Yes/ No	COMMENT
legal contact			
Data of the patient			
reuse of public health data			
prospective study			
Regulatory and ethical submission to obtain permission for REGISTER/ COHORT			
Person Protection Committee (CPP : the role is to make sure that the study is ethical and the rights of participants)			
National Competent Authority			
Data Protection Authority (Ensure that data privacy law is applied to the collection, storage, and use of personal data)			
Other			
DOCUMENT NECESSARY FOR SUBMISSION			
Clinical Study insurance			
Investigator list and CV			
Study Protocol (described the project, inclusion, exclusion criteria)			
eCRF or register file			
Synopsis			
Patient information			
Consent form			
Other			
CONTRACT NEED			
Intellectual property			
data transfer			
use of the data			
Result and Publication			

ANNEX 2 – Glossary of relevant definitions from GDPR text

For clarification purposes, definitions detailed in the **Article 4 of GDPR** are included as Annex (full text - in English - available here: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016R0679&from=EN>):

‘personal data’ means 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;

‘processing’ means any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction;

‘processor’ means a natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller;

‘controller’ means the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data; where the purposes and means of such processing are determined by Union or Member State law, the controller or the specific criteria for its nomination may be provided for by Union or Member State law;

‘data concerning health’ means personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status;

‘pseudonymisation’ means the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person;

Also, from the GDPR, ‘Preamble’:

anonymous information, namely information which does not relate to an identified or identifiable natural person or to personal data rendered anonymous in such a manner that the data subject is not or no longer identifiable.

ANNEX 3 – Template of Data Processing Agreement

Barcelona, at [...] of [...] of 2019

COLLABORATION AGREEMENT BETWEEN _____ AND AGENCIA DE QUALITAT I AVALUACIÓ SANITÀRIES DE CATALUNYA FOR THE ASSIGNMENT OF ANONYMOUS DATA IN THE FRAMEWORK OF THE ICTUSNET PROJECT (WORK PACKAGE 1)

BY AND BETWEEN

Of the first part, _____, as Controller for data at origin, with VAT no. _____ and address _____. Represented by _____, with ID no. ..., acting as ____ (hereinafter, "_____").

And of the second part, **Agència de Qualitat i Avaluació Sanitàries de Catalunya**, with NIF Q0801969-G and address Calle Roc Boronat, 81-95 2a Planta, Barcelona. Represented by Montserrat Moharra i Francés, with ID number 46049000-X, acting as Deputy Director by virtue of his appointment by the Resolution of the Minister of Health of July 30th 2020 (hereinafter, "**AQuAS**").

Hereinafter jointly referred to as "**Parties**", and separately as "**Party**". The Parties recognize mutual capacity to be bound by this COLLABORATION AGREEMENT (hereinafter, the "**Agreement**"),

WITNESSETH

- I. WHEREAS, both parties are part of the Consortium that is developing the ICTUSnet Project entitled "Network of excellence for the development and implementation of innovative models of integrated stroke care", co-financed by the Interreg Sudoe Program through the European Regional Development Fund, with code SOE2/P1/E0623, and regulated by the Concession Agreement and the Collaboration Agreement.
- II. WHEREAS, AQuAS, as leader of the Work Package 1 of ICTUSnet Project, has committed to provide _____ the following activities: reception, storage, maintenance, analysis and conservation of anonymized data (hereinafter, "**the Activities**"), to establish a centralized registry whose results will be integrated into the ICTUSnet platform, considering what is described in work package number 1 "Development of the decentralized registries and of the ICTUSnet platform" of the ICTUSnet Project, according to Annex II of the Concession Agreement.
- III. WHEREAS, these Activities are also detailed in Annex I of this Agreement in accordance to that indicated in the Concession Agreement.

- IV. WHEREAS, for the execution of the Activities, AQuAS shall process certain anonymized data referring to cases of stroke that have required endovascular treatment provided by the _____ and under its responsibility (See Annex I).
- V. WHEREAS, _____ is enabled to assign the anonymized and transformed data according to the data model and interoperability standards required in the ICTUSnet Project, to facilitate evaluation, planning and health management.
- VI. WHEREAS, in order to regulate the conditions of processing of the anonymized data, the Parties agree to regulate the confidentiality and protection of the anonymized data to be processed by AQuAS during the performance of the Activities.
- VII. For the avoidance of doubt, as the provision of Activities does not involve the processing of personal data (only anonymized data), the Agreement will not be governed by the Regulation (EU) 2016/679 of the European Parliament and of the Council, of April 27, 2016, (hereinafter, "GDPR") and *Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales* (hereinafter, "LOPDyGDD), as well as *Lei n.º 58/2019 de 8 de agosto relativa à proteção das pessoas singulares no que diz respeito ao tratamento de dados pessoais e à livre circulação desses dados*.

In accordance with the foregoing, the Parties agree that the Agreement will be governed by the following

CLAUSES

FIRST. - OBJECT

- 1.1** The object of the Agreement is to establish the conditions of the assignment of anonymized data to AQuAS, transmitted by the _____, relating to episodes of admission in hospital for stroke from 01.10.2019 that have required endovascular treatment indicated in Annex I of this Agreement, to establish a centralized registry whose results will be integrated and visualized in the ICTUSnet platform to facilitate evaluation, planning and health management within the ICTUSnet Project.
- 1.2** Furthermore, the purpose of this Agreement is to define the conditions of confidentiality under which AQuAS will carry out the use of anonymized data necessary for the correct provision of the Activities described in the Work Package 1.
- 1.3** The Activities will be provided by AQuAS in its own premises, and with its own systems, other than those of the _____.

1.4 The establishment of the registry and the platform will include the following Activities to the anonymized data transferred:

- **Reception**
- **Storage**
- **Maintenance**
- **Analysis, presentation and delivering of aggregated results**
- **Conservation**

1.5 In this sense, ____ guarantees the correct anonymization of the data provided to AQUAS within the framework of the Agreement, with ____ committing itself to follow an adequate data anonymization procedure that is duly documented. ____ states that said anonymization procedure follows the standards or procedures contained in the Guide of the Spanish Agency for Data Protection "*Orientaciones y garantías en los procedimientos de anonimización de datos personales*" with special attention to the audit of the anonymization process to ensure that at all times the system works correctly.

SECOND. – DURATION AND EXTENSION OF THE AGREEMENT

This Agreement is enforceable from the date of its signature and is valid until March 31, 2021, the expected date of completion of the ICTUSnet Project. Notwithstanding the foregoing, the Parties may extend the validity of the Agreement through one of the following options:

- a) By joint agreement of the Consortium to extend the Agreement. In this case, the extension must be reflected in a new agreement other than the present one.
- b) By express agreement between the Parties to this Agreement. In this case, the extension must also be reflected in a new agreement other than the present one or by means of an addendum. The intent of renewal must be made by prior written notice sent to the other Party with a minimum antecedence of thirty (30) days.

The above is without prejudice to the survival of all those obligations (such as the obligation to return and/or destroy the data) that, in accordance with its nature or the terms of this Agreement, shall survive its termination, as well as any other legal obligation that shall be applicable to the Parties after the termination of the Agreement.

THIRD. - PURPOSE OF THE ASSIGNMENT OF THE DATA

The anonymized data will be processed only for the purpose to carry out the provision of the Activities described in this Agreement.

AQuAS may not use the anonymized data for a purpose other than that established in this Agreement.

In case AQuAS deems necessary to carry out a processing with a different purpose other than those

established above, it will be required to request and obtain the explicit written authorization of the ____.

QUARTER. - TYPE OF DATA

The data to be processed and included by AQuAS in the ICTUSnet registry are those that correspond to the variables previously agreed upon by the ICTUSnet clinical beneficiaries (see Annex I, according to Deliverable 1.1.1 'Glossary of variables for the ICTUSnet registry' from Work Package 1).

The anonymized data set will include information about episodes, not patients. That is, each row of the ICTUSnet record will correspond to an episode of reperfusion therapy.

Therefore, any data transferred by the ____ will be rendered anonymous in such a manner that the data subjects cannot be, under any circumstances, identified or identifiable by AQuAS during the performance of the Activities.

FIFTH. – ____' OBLIGATIONS

The ____ undertakes to make available to AQuAS the anonymized data and the information necessary for their proper use for the fulfilment of the purpose of this Agreement.

Therefore, it is the obligation of the ____ to:

- a) previously anonymise any personal data to be processed by AQuAS in such a manner that the data subjects cannot be identified by AQuAS (under any circumstances);
- b) carrying-out any risk or impact assessment to evaluate the origin, nature, particularity and severity of any risk. The outcome of the assessment should be considered when determining the appropriate measures to be taken in order to demonstrate that the data has been duly anonymized selecting any technical anonymization measures;
- c) design the confidentiality chain;
- d) transmit the anonymized data for the provision of the Activities by AQuAS under the conditions established above.

SIXTH. – AQUAS' OBLIGATIONS

AQUAS undertakes to comply with the following obligations:

- a. To use the anonymized data only to carry out the Activities contemplated in this Agreement and in the Concession Agreement and in the Collaboration Agreement of the ICTUSnet Project.

- b. If the AQuAS considers that some of the instructions contravene the current law regarding data protection, specifically the REGULATION (EU) 2016/679 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) and the *Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales*, the AQuAS will inform immediately about it to the ____.
- c. To maintain strict confidentiality concerning the anonymized data, as well as to ensure that persons authorised to process the anonymized data have committed themselves to confidentiality or are under an appropriate obligation of confidentiality. This obligation will continue even after the termination of this Agreement.
- d. To apply the appropriate technical and organizational measures to guarantee a level of security appropriate to the risk. These measures will be implemented taking into account the state of the art, the costs of application, and the nature, scope, context and purposes of the processing, as well as the risks, their probability and the seriousness for the rights and freedoms of the natural persons, including, where appropriate, among others:
- the assignment of a new identifier (random and automatic) to each anonymized episode received at the destination;
 - the ability to guarantee the permanent confidentiality, integrity, availability and resilience of treatment systems and services;
 - the ability to restore availability and access to data quickly in the event of a physical or technical incident;
 - a process of regular verification, evaluation and assessment of the effectiveness of technical and organizational measures to ensure the safety of treatment.

In assessing the adequacy of the security level, particular attention shall be paid to the risks presented by the processing, in particular as a result of the destruction, loss and / or accidental and / or unlawful alteration of the anonymized data transmitted, stored and / or processed, otherwise treated, or communication and / or unauthorized access to this data.

- e. To keep under its control and custody the anonymized data accessed in relation to the development of the Activities under this Agreement. To commit not to disclose them, transfer them - or in any other way - communicate them, not even for their preservation, to persons outside to this Agreement and to the provision of the Activities object of the present Agreement, with the exception of the publications that arise from the results , in the form of aggregated data, derived from the analysis of the data.
- f. However, being anonymized data, AQuAS may hire the necessary suppliers ('Subprocessor') for the correct achievement of the purposes of the Agreement, provided that: (i) AQuAS provides

at least 30 days' prior notice of the addition or removal of any subprocessor (including details of the processing it will perform); (ii) AQuAS imposes confidentiality terms on any third-party to protect the anonymized data to the same standard provided for by this Agreement.

- g. Once the object of the Agreement ends, to store the data in the ICTUSnet registry, being available to the Parties at all times and being able to recover them, if required.
- h. To make available to the ____ all information necessary to demonstrate compliance with the obligations laid down in this Agreement.

SEVENTH. – DATA OF THE PARTIES THAT SIGN THIS AGREEMENT OUTSIDE THE ANONYMIZED DATA

The signatories parties' data included in this Agreement and those others exchanged among them to enable the provision of the Activities included in this Agreement (contact persons), will be processed by the Parties in order to allow the development, compliance and control of this Agreement, being the purpose of the processing to facilitate evaluation, planning and health management in the framework of the ICTUSnet Project, conserving the data until 31 May, 2021 and until they prescribe the possible responsibilities derived from it.

The Parties undertake to transfer this information to the data subjects and indicate that they can exercise their rights of access, rectification, erasure, restriction of processing, data portability and object, sending their request to the address indicated in the heading of this Agreement. In any case, data subjects have the right to present a claim to the corresponding control authority if they deem it appropriate. The data subjects can contact the Data Protection Officer of the other Party at the following email addresses dpd@ticsalutsocial.cat or, respectively.

EIGHTH. - JURISDICTION AND APPLICABLE LAWS

All disputes arising out of or in connection with this Agreement, which cannot be solved amicably, shall be finally governed by current Spanish regulations. In order to resolve any discrepancy regarding the interpretation and/or execution of what is established therein, both Parties agree to submit to the jurisdiction of the Courts and Tribunals of the domicile of the defendant.

IN WITNESS WHEREOF, each Party has executed this Agreement by a duly authorized individual effective as of the signature date, signing in duplicate and on a single effect, in the place and the date contained in the header.

By the ____

By AQuAS

Signed. ____

Signed Montserrat Moharra i Frances
Deputy Director

ANNEX 4 – Approval by the Regional Ethical Committee of Aragon



Informe Dictamen Favorable

C.P. - C.I. PE19/511
15 de enero de 2020

Dña. María González Hinjos, Secretaria del CEIC Aragón (CEICA)

CERTIFICA

1º. Que el CEIC Aragón (CEICA) en su reunión del día 15/01/2020, Acta Nº 01/2020 ha evaluado la documentación referida al estudio:

Título: PLATAFORMA ICTUSNET PARA LA MEDICION OBJETIVA DEL MANEJO DEL ICTUS EN EL TERRITORIO DEPENDIENTE DE LA RED DE UNIDADES NEUROVASCULARES PARTICIPANTES EN EL PROYECTO ICTUSNET.

Investigador Principal: Enrique Bernal Delgado, Instituto Aragonés de Ciencias de la Salud

Versión protocolo: V.0.0.1 de 05-12-2019

2º. Considera que

- El proyecto se plantea siguiendo los requisitos de la Ley 14/2007, de 3 de julio, de Investigación Biomédica y su realización es pertinente.
- Se cumplen los requisitos necesarios de idoneidad del protocolo en relación con los objetivos del estudio y están justificados los riesgos y molestias previsibles para el sujeto.
- Es adecuada la utilización de los datos y se han obtenido los permisos oportunos para su utilización.
- El alcance de las compensaciones económicas previstas no interfiere con el respeto a los postulados éticos.
- La capacidad de los Investigadores y los medios disponibles son apropiados para llevar a cabo el estudio.

3º. Por lo que este CEIC emite **DICTAMEN FAVORABLE** a la realización del estudio.

Lo que firmo en Zaragoza

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por GONZÁLEZ HINJOS
MARIA - DNI 03857456B
Fecha: 2020.01.20
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María González Hinjos
Secretaria del CEIC Aragón (CEICA)

ANNEX 5 – Approval by the Ethical Committee of Research of the Balearic Islands (CEI-IB)



En fecha 10 de septiembre de 2020 se recibió en la sede del Comité de Ética de la Investigación de las Islas Baleares (CEI-IB) el estudio que se especifica a continuación para su notificación en la reunión 28/2020, del 30 de septiembre:

Nº de expediente: **IB 4345/20 PI**

Título: **PLATAFORMA ICTUSNET PARA LA MEDICION OBJETIVA DEL MANEJO DEL ICTUS EN EL TERRITORIO DEPENDIENTE DE LA RED DE UNIDADES NEUROVASCULARES PARTICIPANTES EN EL PROYECTO ICTUSNET**

Investigadora principal: Carmen Jiménez Martínez

Servicio: Neurología

Centro: Hospital Universitario Son Espases

Primer CEI evaluador: CEI Aragón (CEICA)

Palma, 18 de septiembre de 2020



Esther Cardo Jalón

Secretaria Técnica del CEI de las Islas Baleares