Privacy Policy

The EU H2020 medical research project: HarmonicSS

"HARMONIzation and integrative analysis of regional, national and international Cohorts on primary Sjögren's Syndrome (pSS) towards improved stratification, treatment and health policy making"

Version of 4 March 2019

The HarmonicSS project invites to participate in the study to improve medical research into the Primary Sjögren's Syndrome (pSS). This document describes the project and informs about the scope and purposes of research, and also the rights granted to research participants as data subjects under Chapter III of the EU General Data Protection Regulation 2016/679 (GDPR).

The Project:

HarmonicSS is a medical research project entitled: *"HARMONIzation and integrative analysis of regional, national and international Cohorts on primary Sjögren's Syndrome (pSS) towards improved stratification, treatment and health policy making".*

The HarmonicSS vision is to create an International Network and Alliance of partners and cohorts, entrusted with the mission of addressing the unmet needs in primary Sjogren Syndrome; working together to create and maintain a platform with open standards and tools, designed to enable secure storage, governance, analytics, access control and controlled sharing of information at multiple levels along with methods to make results of analyses and outcomes comparable across centers and sustainable through Rheumatology scientific associations.

This project has received funding from the European's Union Horizon 2020 Research and Innovation Programme under Grant Agreement No 731944 and from the Swiss State Secretariat for Education, Research and Innovation SERI under grant agreement 16.0210. The HARMONICSS project officially started on 1st of January 2017 with the planned lifetime of 42 months.

The partners to the HarmonicSS project who jointly process clinical data and determine the purposes and means of processing are joint controllers in the meaning of Article 26 (1) GDPR. The framework conditions for the processing of clinical data, both as data protection obligations of the partners within the project are governed by the Data Protection Agreement, Version 3.7, of August 2018 (a joint controllers´ agreement in the meaning of Article 26 (1) GDPR). The essence of this agreement both as information to data subjects according to Article 13 and/or 14 GDPR, as applicable, are provided as follows:

Information to data subjects according to Article 13 and/or 14 GDPR, as applicable:

(a) the identity and the contact details of the controller

The following partner institutions, both as third parties involved into the project according to the rules of the HarmonicSS EC Grant Agreement (EC-GA) are responsible for the data processing as joint controllers:

ETHNIKO KAI KAPODISTRIAKO PANEPISTIMIO ATHINON (University of Athens),

PANEPISTIMIO IOANNINON,

TECHNOLOGICAL EDUCATIONAL INSTITUTE OF CRETE,

ETHNIKO KENTRO EREVNAS KAI TECHNOLOGIKIS ANAPTYXIS,

UNIVERSITA DEGLI STUDI DI UDINE,

UNIVERSITA DI PISA,

UNIVERSITA DEGLI STUDI DI PERUGIA,

UNIVERSITA DEGLI STUDI DELL'AQUILA,

UNIVERSITA DEGLI STUDI DI ROMA LA SAPIENZA,

SCUOLA SUPERIORE DI STUDI UNIVERSITARI E DI PERFEZIONAMENTO SANT'ANNA,

MEDIZINISCHE HOCHSCHULE HANNOVER,

CHARITE - UNIVERSITAETSMEDIZIN BERLIN,

FRAUNHOFER-GESELLSCHAFT ZUR FOERDERUNG DER ANGEWANDTEN FORSCHUNG E.V.,

THE UNIVERSITY OF BIRMINGHAM,

QUEEN MARY UNIVERSITY OF LONDON,

UNIVERSITY OF NEWCASTLE UPON TYNE,

CONSORCI INSTITUT D'INVESTIGACIONS BIOMEDIQUES AUGUST PI I SUNYER,

UNIVERSITE DE BRETAGNE OCCIDENTALE,

UNIVERSITY REGIONAL HOSPITAL CENTRE OF BREST (CENTRE HOSPITALIER RÉGIONAL UNIVERSITAIRE DE BREST - CHRU),

UNIVERSITE PARIS-SUD,

ASSISTANCE PUBLIQUE - HÔPITAUX DE PARIS (AP-HP),

HAROKOPIO UNIVERSITY (HAROKOPIO),

UPPSALA UNIVERSITET,

ACADEMISCH ZIEKENHUIS GRONINGEN,

UNIVERSITAIR MEDISCH CENTRUM UTRECHT,

STICHTING NEDERLANDS INSTITUUT VOOR ONDERZOEK VAN DE GEZONDHEIDSZORG,

UNIVERSITETET I BERGEN,

UNIVERSITE LIBRE DE BRUXELLES,

BioIRC d.o.o. Kragujevac,

Oklahoma Medical Research Foundation,

For further information and contact details of the partner institutions of the HarmonicSS Consortium please visit project website at: https://www.harmonicss.eu/consortium/

(b) the contact details of the data protection officer, where applicable

For contact details of the data protection officers, where applicable, please visit homepages of the partner institutions indicated along with official names at: https://www.harmonicss.eu/consortium/

(c) the purposes of the processing as well as the legal basis for the processing

The purpose of medical research in HarmonicSS is to explore the particularities of primary Sjögren's Syndrome (pSS) from multiple perspectives (inter alia genetics, biomarkers, serology, histology, etc.) and to address unmet pSS needs. The HarmonicSS project aims to create a research infrastructure to facilitate research into primary Sjogren's Syndrome (pSS). To this end, a computing platform consisting of software tools, together with a secure data repository for pooling pSS patient data is being developed. This platform is designed to be used by scientists and doctors from universities, hospitals, other research and clinical institutions as well as some collaborating partners engaged in the HarmonicSS project. By examining and analyzing the data in different ways, the researchers intend to learn more about pSS, what causes it and potential ways of treating it. As part of this, it is also planned to develop a tool for selecting patients from the integrative cohort for conducting multinational clinical trials for new pSS

treatments. Patients potentially eligible to participate in the clinical trials will be pooled based on a set of eligibility criteria as of numbers of potential subjects; no names of individual patients will be returned.

Where the clinical data is collected for research in the project and the processing of such data is necessary for achieving the project needs, the clinical partners obtain as a rule informed consent of the patient allowing the use of (de-identified) data for pSS research in the project. Where retrospective clinical data (already collected by the clinics in primary care and/or clinical trials) is necessary for research in HarmonicSS, the processing of such data takes place on the lawful basis, either provided by the GDPR, in particular, Article 9 (2) (j) in combination with appropriate safeguards according to Article 89 (1), or the national law. According to Article 5 (1) (b) GDPR, the secondary processing of personal data for scientific research shall, in accordance with Article 89 (1), not be considered to be incompatible with the initial purposes.

For the purposes of research in HarmonicSS, the clinical data will be securely pseudonymised, with the name and other identifying information removed and replaced by a unique identification code. The key linking the code to the personal information is/will be retained by the own clinic and not transferred to the project. Indeed, the HarmonicSS project is committed in all circumstances to respecting patients' confidentiality and privacy, as well as European and national privacy and data protection legislation.

The clinical data will be provided for analysis in HarmonicSS in a securely pseudonymous form: this means the medical information will be stripped of any personal details that could identify a patient (including name, address, date of birth, etc.); those details are instead replaced by a secure, unique identification code. This code is the only means of linking a patient to the data or samples. The reasons why re-linking may be needed are: (1) to verify the data against medical record of a patient if there is reason to suspect an error in data transfer; (2) to invite potential candidates to take part in suitable future research or clinical trials; (3) to contact a patient if in the course of the research there is a finding of clinical and scientific validity that may be important for the treatment of a given patient; (4) to identify data and/or samples of patients who withdraw from the study. In these cases, the only party able to link the code back to a patient is the medical partner that holds original record of a patient.

The HarmonicSS platform will also be protected by strict organizational and technical security measures, in conformity with the EU data protection law, to guard i.a. against accidental loss, disclosure and/or unauthorized access to the data within it.

(d) the categories of personal data concerned

The clinical data used for research in HarmonicSS may include diagnosis data, clinical measurements, objective tests, laboratory, biopsies, ultrasound images, survey data, etc. This data has normally already been collected from the patients or extracted from bio-samples taken by the medical partners in course of providing clinical care and/or clinical trials. However, some of the research studies may require the clinical partners to collect more data (clinical or survey data) and/or biological samples (such as plasma, tissue, blood, serum, DNA or RNA). By collecting such data, the clinical partners would normally ask for informed consent by the patient.

(e) the recipients or categories of recipients of the personal data, if any

Only the partner institutions, who need to access and process clinical data for performing their tasks in the project, will have access to the clinical data stored in the platform. Access is granted subject to signing the Data Protection Agreement and implementation of strict security measures. All researchers processing the data from the project are bound by a confidentiality obligation and confirm that appropriate security measures are in place to keep the data safe during the duration of the research.

For a full list of the partner institutions please visit: http://harmonicss.eu/consortium/

(f) envisaged transfer of personal data to a third country or international organisation and the existence or absence of an adequacy decision by the Commission, or reference to the appropriate or suitable safeguards

Most of the research institutions, participating in the HarmonicSS project, who will access the data, are within the EU. They are all bound by strict EU rules in the way they process the data. However, apart from the EU partners, the project also includes non-EU partners, namely:

- UK (post March 2019): THE UNIVERSITY OF BIRMINGHAM (UoB), QUEEN MARY UNIVERSITY OF LONDON (QMUL), UNIVERSITY OF NEWCASTLE UPON TYNE (UNEW);
- Serbia: the BioIRC Research and Development Centre Kragujevac [http://www.bioirc.ac.rs/];
- US: Oklahoma Medical Research Foundation [www.omrf.org] and the Sjögren's Syndrome Foundation [http://www.sjogrens.org].

For a full list of partner research institutions please visit: http://harmonicss.eu/consortium/.

As the risks from processing data in and/or from these countries may be higher than in the EU, the project will transfer data to them only if there are compelling scientific grounds for this. In such cases, it will take all reasonable steps to ensure that appropriate and suitable safeguards to protect privacy of the patients are in place. In particular, the project implements standard data protection clauses adopted by the Commission pursuant to Article 46 (2) (c) GDPR as appropriate safeguards. A copy may be requested via contact form at the project website (https://www.harmonicss.eu/contact-us/) or medical institution – a party to the data transfer.

(g) the period for which the personal data will be stored, or if that is not possible, the criteria used to determine that period;

The data will be stored as part of the HarmonicSS project for the duration of the project, which started on 1 January 2017 and will last for 42 months, but in any case not longer than the final report has been accepted by the Commission (approximately a two-month final review period, until 31 August 2020). However, it is hoped to maintain the project platform for further pSS research beyond the lifetime of the project subject to adequate financial and technical support. This means the project may wish to keep the clinical data for a longer period. Important to note that any subsequent research study involving the use of patient clinical data will only be undertaken, if approved by research ethics committee and subject to the requirements by the law. Patients wishing to contribute to the ongoing pSS research beyond the project lifetime may do so by giving a separate consent.

(h) rights of data subjects

Right to request from the controller access to and rectification or restriction of processing concerning the data subject or to object to processing

In principle, the HarmonicSS project takes all reasonable measures to maintain and have the rights granted to the data subjects under Chapter III of the GDPR enforceable, to the extent that the right is applicable under the EU and/or Member State law. However, some of the rights may be subject to restrictions and/or limitations due to the complexity associated with the realization of such rights in the context of medical research.

Pursuant to Article 89 (2) GDPR, where personal data are processed for scientific or historical research purposes or statistical purposes, Union or Member State law may provide for derogations from the rights referred to in Articles 15 (Right of access), 16 (Right to rectification), 18 (Right to restriction of processing) and 21 (Right to object) subject to the conditions and safeguards referred to Article 89 (1) in so far as such rights are likely to render impossible or seriously impair the achievement of the specific purposes, and such derogations are necessary for the fulfilment of those purposes.

Pursuant to Article 14 (5) (b) GDPR, where the data have not been obtained from the data subject, the obligation to provide information shall not apply if the provision of such information proves impossible or would involve a disproportionate effort, in particular for processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes, subject to the conditions and safeguards referred to in Article 89 (1) or in so far as the obligation to provide information is likely to render impossible or seriously impair the achievement of the objectives of that processing. In such cases, the project shall take appropriate measures to protect the data subject's rights and freedoms and legitimate interests, including making the information publicly available.

Right to erasure ('right to be forgotten')

The data subjects participating in the HarmonicSS project shall have the right to obtain from the controller the erasure of personal data concerning him or her without undue delay and the controller shall have the obligation to erase personal data without undue delay where one of the following grounds applies:

(a) the personal data are no longer necessary in relation to the purposes for which they were collected or otherwise processed;

(b) the data subject withdraws consent on which the processing is based according to point (a) of Article 6(1), or point (a) of Article 9(2), and where there is no other legal ground for the processing;

(c) the data subject objects to the processing pursuant to Article 21(1) and there are no overriding legitimate grounds for the processing, or the data subject objects to the processing pursuant to Article 21(2);

(d) the personal data have been unlawfully processed;

(e) the personal data have to be erased for compliance with a legal obligation in Union or Member State law to which the controller is subject.

Pursuant to Article 17 (3) (d) GDPR, the right to erasure may not apply to the extent that processing is necessary: for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89 (1) in so far as the right referred to in paragraph 1 is likely to render impossible or seriously impair the achievement of the objectives of that processing.

Right to data portability

The data subjects participating in the HarmonicSS project shall have the right to receive the personal data concerning him/her, provided to the project, in a structured, commonly used and machine-readable format and have the right to transmit those data to another controller without hindrance from the controller to which the personal data have been provided, where:

(a) the processing is based on consent pursuant to point (a) of Article 6(1) or point (a) of Article 9(2) or on a contract pursuant to point (b) of Article 6(1); and

(b) the processing is carried out by automated means.

In exercising the right to data portability, the data subject shall have the right to have the personal data transmitted directly from one controller to another, where technically feasible.

Right to withdraw consent at any time

The data subjects participating in the HarmonicSS project shall have the right to withdraw consent at any time. Prior to giving consent, the data subjects shall have been informed thereof by the respective clinical partner. It shall be as easy to withdraw as to give consent.

Right to lodge a complaint with a supervisory authority

Without prejudice to any other administrative or judicial remedy, the data subjects participating in the HarmonicSS project shall have the right to lodge a complaint with a supervisory authority, in particular in the Member State of the habitual residence, place of work or place of the alleged infringement if the data subject considers that the processing of personal data concerning him/her infringes the EU General Data Protection Regulation 2016/679.

(i) the source from which the personal data originate

The source of clinical data processed in the HarmonicSS project are the medical partners, treating and/or monitoring pSS patients who have agreed to participate in the project. These clinical partners are listed on the project website.

(j) the existence of automated decision-making, including profiling

HarmonicSS does not implement automated individual decision-making, including profiling.

(k) contact points for data subjects

According to the rules of the HarmonicSS Data Protection Agreement, clinical partners act as primary contact points to handle requests from their patients participating in the project. Irrespective of the terms of this arrangement, data subjects may exercise their rights granted under the Regulation 2016/679 in respect of and against each of the partners – joint controllers in the HarmonicSS project. For a full list of partners – joint controllers in the HarmonicSS project, please see section a) above or visit the project website at: https://www.harmonicss.eu/consortium/.