Project**: SEAWave**

OEI - Requirement No. 1

Work Package: WP12

Deliverable: D12.1

Deliverable No.: D44

Project Details

Project name	SEAWave
Grant number	101057622
Start Date	01 Jun 2022
Duration	36 months
Scientific coordinator	Prof. T. Samaras, Aristotle University of Thessaloniki (AUTH)

Deliverable Details

Deliverable related number	D12.1
Deliverable No.	D44
Deliverable name	OEI - Requirement No. 1
Work Package number	WP12
Work Package name	Ethics requirements
Editors	Prof. T. Samaras
Distribution	Sensitive
Version	1
Draft/final	Final
Keywords	biological experiments, ethical issues, 5G NR FR2 exposure, electromagnetic radiation, skin cancer, artificial intelligence

Contents

1 Ethical issues in biomedical research

1.1 Necessity of biological experiments

The effects of exposure to electromagnetic radiation in the frequency range of 5G NR FR1 (<6 GHz) have been extensively studied in the last thirty years; because of its deep penetration in the body, its effects have been studied for several tissues. In 5G NR FR2 (>24GHz), i.e., for millimetre waves, the two most exposed human organs are the skin and the eye, due to the small penetration depth of electromagnetic radiation in this frequency range. The effects of millimetre waves on the eye have already been investigated with experimental studies on rabbits and non-human primates, as well as computational simulations with validated models for the rabbit and human eye. On the contrary, the effects of the electromagnetic radiation in the NR FR2 range (millimetre waves) on the human skin are underexamined and unknown to a large extent, even though the skin is the largest organ and an important physical and immunological barrier against physical exposure agents, mechanical insults, chemical substances, and pathogens (bacteria, viruses, parasites, etc.). Moreover, the skin has a high cellular turnover in result of the insults to which it is exposed, which is correlated with an increased risk of DNA mutations. These DNA mutations drive cellular transformation leading to skin cancer in both females and males. In fact, skin cancers comprise the largest percentage of all cancers coming from a single organ.

In order to assess the carcinogenicity of an agent it is important to integrate knowledge coming from all lines of evidence (*in vitro*, animal, human and epidemiological studies) as suggested by many risk assessment committees, including IARC. Unfortunately, the existing approaches of organ-on-a-chip (OoC) and synthetic skin cannot capture the complexity of the organ in terms of cell type multiplicity, embedded structures, and vascularization. Moreover, these approaches cannot mimic skin conditions that predispose patients to cancer initiation or promotion. Therefore, experimentation with biological material is necessary to collect results from all lines of evidence to fill the knowledge gap on the potential of millimetre waves to initiate or promote cancer in the skin. Although, this is the main health endpoint of the SEAWave, other biological and adverse health effects will also be studied in parallel when possible using the same biological material.

1.2 In vitro study

1.2.1 Partners involved

- Fraunhofer Institute for Toxicology and Experimental Medicine (ITEM)

ITEM is highly experienced in culturing cells and tissues of both animal and human origin, with a special cell culture unit, operating under Standard Operating Procedures (SOPs), with detailed

daily protocols of culture management (including cell types, culture step and disposal). All existing cell lines at ITEM are recorded in regularly updated special lists, giving information like name of the cell line, biosafety level, species, organ/cell type, origin, date of receipt, place of storage and disposal. All copies of relevant documents on cell-tissue types, provider, import licenses (if applicable) within the SEAWave project will be kept on file in a dedicated folder according to ITEM routines.

1.2.2 Study information

In vitro work will focus on the investigation of normal human skin. For this purpose, human skin cells/skin cell lines are of utmost importance as in-vitro cell models and cannot be replaced by animal cells. To be able to get meaningful results from the investigations on potential 5G-induced changes in the epigenetic, transcriptomic and miRNA landscapes of normal skin cells and also from testing of the aneugenic potential and the telomere length, it is necessary to use normal, non-transformed human skin cells, i.e., normal human epidermal keratinocytes (NHEK) and normal human epidermal melanocytes (NHEM). Immortalized cell lines are not appropriate for the above testing purposes, because cell transformation can lead to markedly altered epigenetic, transcriptomic and miRNA landscapes, telomere length and, sometimes, also changes in chromosome number. Skin tumor cell lines are even less appropriate than immortalized cells, because skin tumors represent the final disease state of interest and cannot depict early events on the way to tumor development. However, different melanoma cell lines will be purchased and used as reference for the worst-case disease state to be compared to the 5G-exposed normal skin cells.

Both NHEK and NHEM cells (from adult, juvenile or neonatal donors) and melanoma cell lines will be obtained from commercial providers or cell repositories, which comply with high ethical standards, like

- ThermoFisher Scientific (https://corporate.thermofisher.com/content/tfcorpsite/us/en/index/corporate-social-responsibility/operations/governance-and-ethics.html)
- PromoCell (https://promocell.com/about-us/compliance/), or
- ECACC (https://www.culturecollections.org.uk/technical/ethical-considerations-for-cell-lines.aspx).

The planned cell models can be obtained commercially from diverse companies, together with all relevant information regarding identity, characteristics, culture method, specifications, handling and safety. The final decision on the cell types to be used and the provider will be made considering both the ethical compliance statements, availability of respective cell batches over a certain time period, appropriate characterization of the cells and the availability of comprehensive information on cell culture conditions. It is not planned to isolate human cells by own means during the course of the project.

1.3 In vivo (animal) study

1.3.1 Partners involved

- Italian National Agency for New Technologies, Energy and Sustainable Economic Development (ENEA)

In vivo (animal) experimentation will be carried out by ENEA according to the requirements of Directive 2010/63/EU concerning the protection of animals used for experimental and other scientific purposes. Italian legislation is defined in the "Decreto Legislativo" n. 26, 4 March 2014.

The overall study has already been approved by the Institutional Animal Care and Use Committee at the submission phase of the project: "IACUC members considered the project well-designed and in line with all regulations protecting animals used for research purposes." New protocols that may need to be used during the activities, and that have not yet been approved, will be submitted to the corresponding committee for animal use, for evaluation, discussion and approval prior their use during this project. Once this has been completed, a revised project license will be submitted to the Italian Ministry of Health for authorization to carry out the work.

1.3.2 Study information

The aim of the *in vivo* test is to provide information about cancer risks associated with prolonged 5G NR FR2 exposure. All the biological processes under evaluation are complex and can be influenced by multiple factors and, as such, cannot be fully reproduced *in vitro*.

At ENEA animal house, Ptch1+/- and Car-S mice will be whole body exposed to 5G NR FR2 radiation and sacrificed at different post-irradiation time points. Different methodological approaches (RT - (real time) - PCR, histology, immunohistochemistry) will be used to evaluate changes in specific target tissues. Results will be compared with those occurring in age-matched sham-exposed mice. Ptch1+/- mice are genetically modified due to a deletion in one copy of Patched1 gene and they are a well-characterized mouse model. Deregulation of the Shh pathway is sufficient to sustain abnormal cell proliferation in the skin basal layer and also results in morphological and functional defects in the lens and in the dentate gyrus of hippocampus. At ENEA, all people involved in the project are well trained to manage and recognize all pathological signs occurring during an animal's life according to the 3R principle. CarS mice are a mouse line obtained at ENEA by 10 consecutive generations of bidirectional selective breeding to two-stage skin carcinogenesis. Contrary to Ptch1+/- mice, they don't show pain, suffering or distress during their lifespan.

The 3Rs principle will be addressed as specified in the following:

- *Replace*: Currently, no validated alternative methods can replace the *in vivo* procedures scheduled for the project, due to the complexity of the biological system (skin) under evaluation.
- *Reduce*: Groups of 60 Ptch1+/- and 30 CarS mice of both sexes will be used for each

irradiation schedule, as this number has been previously shown to be adequate to detect significant variations over the background for all selected endpoints. The same number of animals has been already employed in several radiobiological studies performed at ENEA. Also, calculations of statistical power were performed, and the group size for different treatment groups was selected to reach a power of 80% to detect the expected effect size.

- *Refine*: The handling procedures will keep as low as possible pain, distress and other harmful factors threatening animal welfare. Exposure to 5G NR FR2 is expected to cause possible distress but not physical pain in the animals, so analgesia or anesthesia will not be used. Indeed, animals will be exposed in their cages in a freely moving condition. Cages will be allocated in specific exposure chambers with regulated light cycle, water, and food *ad libitum*. Animals will be inspected daily for signs of distress during the exposure period. Death is not a selected endpoint, and animals will be euthanized at completion of the experiment to collect tissues for the analyses. Animals will be sacrificed by CO_2 asphyxiation.

1.3.3 Study ethical approval

The ethical approval obtained from the Italian Ministry of Health is included in the Annex.

1.4 Study SEAWave-Clin

1.4.1 Partners involved

- Partner involved: Centre Hospitalier Universitaire Vaudois (CHUV)

1.4.2 Study information

The clinical trial SEAWave-Clin planned in the project involves both healthy and patient volunteers. Recruitment will be on a voluntary basis both for healthy citizens and for patients, who will receive a financial compensation. Patients recruited for the SEAWave-Clin clinical study will be dermatoporosis patients and patients with skin tumor syndromes, who will be recruited from patients treated at the CHUV. Selection of volunteers is solely based on study requirements namely age, health status, and gender. Volunteers will be provided with:

- An information document about their participation in research with information on the use of health data and samples for research purposes. This document includes information on the meaning of voluntary participation, on what happens if a participant withdraws consent, how health data and biological samples are protected, how the data can be used in the research context, whether volunteers are informed about research outcomes, and about the CHUV biobank (upon request, patients are provided with a detailed brochure about the biobank)
- A detailed consent form for the use of health data and biological samples for research purposes
- A detailed information sheet about the study context and about the study procedure

- A detailed information sheet in preparation of the biopsies, including details on the procedure, on possible complications, and on measures to be taken in case of complications.
- A detailed consent form for the participation to the clinical study to be signed for full recruitment.
- These documents have been developed under the supervision and advice of the Clinical Research Centre of the CHUV (CRC, https://www.chuv.ch/fr/crc/crc-home) and follow institutional approved standards.

The research carried out using acquired samples and data will not reveal any individual information about a volunteer's health. In rare cases, however, relevant results may be discovered, for which treatments or preventive actions are available. In this case, and following institutional guidelines, volunteers are informed. If they do not wish to receive such information, volunteers are requested to contact the Research Consent Unit at CHUV, at the address indicated at the end of the first document from the list above.

The clinical trial SEAWave-Clin will include the sampling of human tissues through biopsies on the site of exposure (upper arms and inner thighs). Biopsies (paraffin and frozen samples) will be collected one hour after treatment and 24 hours after treatment.

Standard procedures for skin biopsies will be applied:

- the skin will be disinfected with an antiseptic
- following local anaesthesia and given the need for samples of less than 6mm in diameter, skin samples will be taken with a single-use, sterile "punch"
- the skin will then be thoroughly disinfected again, and the wound will be appropriately handled

The use of sterile equipment and the application of strict and hygiene standards ensures minimal risk. The patients are followed for the healing of their wound and relevant treatments are administered in case of complications. Adverse events and severe adverse events will be reported to the authorities.

Clinical trials are closely monitored by the Clinical Research Centre of the CHUV and get permission from SwissEthics (Swiss Association of Research Ethics Committees, https://swissethics.ch). The following documents had to be submitted:

- Ready to use documents
  - Prof. Gaide's CV
  - Prof. Gaide's proof of GCP training
  - Grant agreement
  - Details for infrastructure suitability and availability location
  - Information on secure handling of biological material and personal data, storage
  - Participant information sheet and informed consent (ICF)
  - Participant compensation (ICF 10. Dédommagement)
- Pending documents

  - Synopsis of the study
  - Study plan (protocol) signed and dated
  - Monitoring plan
  - CRF information
  - Insurance
  - Staff list
  - Information on reviews of the proposal by other ethics committees or regulatory affairs
- Documents to be prepared
  - Cover letter
  - Addendum

1.4.3 Study ethical approval

The ethical approval obtained from the Cantonal Commission (of Vaud, VD) for Ethics in Human Research is included in the Annex.

2 Ethical issues in technological research

2.1 Artificial Intelligence

2.1.1 Partners involved

- Telecom Paris, Institut Polytechnique de Paris, Institute Mines-Telecom (TP-IPP)
- Aristotle University of Thessaloniki (AUTH)

2.1.2 Study information

Artificial Intelligence (AI) will be used in the project in the form of an artificial neural network to interpolate and forecast

- the electromagnetic fields (EMF) emitted by base stations, in which case *in situ* measurements and data coming from existing EMF sensors will be used to train and test the models;
- the power emitted by mobile phones, in which case the power emitted during voice calls and files uploading will be used to train and test the models.

Collection of data, training and testing of the neural network will be conducted by project engineers. No human being will directly interact with the AI application developed in this project. The application of AI in this project is not targeted to decision making, but has an informative role.

Data collected from users through targeted experiments under the second bullet point above will be handled according to data privacy standards. However, data collected by project engineers for the purpose of the project (not as individuals) and open data retrieved from online resources are not associated with private information or individuals.

The partners in charge of developing the artificial neural network take responsibility for the way the applications function. Institute Mines-Telecom is at the forefront of developments on machine learning and artificial intelligence according to the highest ethical standards.

3 Conclusions

Ethical approvals were obtained for all protocols that will be implemented in animal and human experimentation within the SEAWave project. Therefore, the research activities that will be performed are in line with ethical principles and relevant legislations.

4 Annex

4.1 Ethical approval for animal study of SEAWave (WP6)

Ministero della Salute

DIREZIONE GENERALE DELLA SANITÀ ANIMALE E DEI FARMACI VETERINARI
UFFICIO 6

ENEA - Roma
pec: enea@cert.enea.it
c.a. Dr.ssa Carmela MARINO
email: carmela.marino@enea.it
e, per conoscenza
ASL Roma 4 - Servizi Veterinari Area C
pec: dipartimento.prevenzione@pec.aslroma4.it

OGGETTO: D.lgs. 26/2014 sulla protezione degli animali utilizzati a fini scientifici.
Trasmissione autorizzazione ai sensi dell'art. 31.
Autorizzazione **n° 107/2023-PR (Risp. a prot. EE25E.24)**

Si trasmette l'autorizzazione **n° 107/2023-PR**, rilasciata ai sensi dell'art. 31 del D.lgs. 26/2014.

IL DIRETTORE DELL'UFFICIO 6
Dr. Vincenzo Ugo SANTUCCI

SANTUCCI VINCENZO UGO
2023.02.16 08:54:26
CN=SANTUCCI VINCENZO UGO
C=IT
2.5.4.4=SANTUCCI
2.5.4.42=VINCENZO UGO
RSA/2048 bits

Documento prodotto in originale informatico e firmato digitalmente ai sensi del "Codice dell'Amministrazione Digitale" (d.lgs. n. 82/2005 e ss.mm.)

Referente: G. Aleandri - g.aleandri-esterno@sanita.it

Ministero della Salute

DIREZIONE GENERALE DELLA SANITÀ ANIMALE E DEI FARMACI VETERINARI
UFFICIO 6

Autorizzazione n. **107/2023-PR**

IL DIRETTORE GENERALE

Vista la domanda di autorizzazione del progetto di ricerca **"Valutazione dell'impatto sulla salute dell'esposizione cronica ai campi elettromagnetici generati dal sistema cellulare di quinta generazione (5G) operante alle frequenze millimetriche"**, ex articolo 31 del decreto legislativo 4 marzo 2014, n. 26, acquisita con prot. EE25E.24 del 16/11/2022 ed integrazione del 31/01/2023, inoltrata dal **Centro Ricerche ENEA Casaccia, sede legale in Roma, Via Anguillarese 301**, per il tramite dell'Organismo preposto al benessere degli animali di cui all'articolo 25 del menzionato d.lgs. n. 26/2014, e finalizzata all'esecuzione di un progetto di ricerca come descritto nella documentazione allegata alla domanda;

Tenuto conto del pagamento della Tariffa D, come previsto dal decreto ministeriale 27 marzo 2019 per le attività contemplate negli articoli 20, 31, 32 e 33 del d.lgs. 4 marzo 2014, n. 26;

Visto l'articolo 31, comma 1, del d.lgs. n. 26/2014, nel quale il Ministero della salute è individuato quale autorità competente al rilascio dell'autorizzazione all'esecuzione di progetti di ricerca che prevedono l'utilizzo di animali a fini scientifici secondo le finalità di cui all'articolo 5, comma 1, in continuità con la precedente normativa di cui al decreto legislativo 27 gennaio 1992, n. 116;

Visti gli articoli 12, 13, 14, 15, 16 e 17 del succitato d.lgs. n. 26/2014, che stabiliscono le modalità di utilizzazione degli animali nelle procedure condotte a fini scientifici;

Visti gli articoli 31, 32, 34 e 35, nonché gli Allegati IV, VI, VII e IX del d.lgs. n. 26/2014, che fissano i requisiti generali per il rilascio di autorizzazione per progetti di ricerca;

Vista la nota n. 6619 del 13/02/2023, con cui l'Istituto Superiore di Sanità ha comunicato l'esito positivo della valutazione tecnico-scientifica sul progetto di ricerca;

Considerato che ricorrono i requisiti stabiliti dal d.lgs. n. 26/2014 per il progetto da autorizzare;

Preso atto che il responsabile del progetto di ricerca, ai sensi dell'articolo 3, comma 1, lettera g) del d.lgs. n. 26/2014, è la **Dr.ssa Mariateresa MANCUSO**;

Considerato che **lo stabilimento utilizzatore Centro Ricerche ENEA Casaccia, sito in Roma, Via Anguillarese, 301, è autorizzato con n. 64/2001-A del 21/09/2001, ai sensi del D.lgs. 116/92**;

Visto l'articolo 4, comma 2 e l'articolo 16 del decreto legislativo 30 marzo 2001, n. 165 e successive modifiche, recanti le funzioni dei dirigenti di uffici dirigenziali;

Responsabile del procedimento: Dr. Vincenzo Ugo SANTUCCI
Referente: G. Aleandri - g.aleandri-esterno@sanita.it

AUTORIZZA

1. Il **Centro Ricerche ENEA Casaccia, sede legale in Roma, Via Anguillarese 301**, all'esecuzione del progetto di ricerca ex articolo 31 del decreto legislativo 4 marzo 2014, n. 26, in conformità a quanto indicato nella richiesta di autorizzazione citata in premessa e, in particolare, con riferimento a:

"Valutazione dell'impatto sulla salute dell'esposizione cronica ai campi elettromagnetici generati dal sistema cellulare di quinta generazione (5G) operante alle frequenze millimetriche"

e all'impiego di 280 topi in toto, come indicato al punto 10 dell'Allegato VI.

2. La **Dr.ssa Mariateresa MANCUSO** quale responsabile del progetto di ricerca, ai sensi dell'articolo 3 comma 1, lettera g) del d.lgs. n. 26/2014;

3. Il **Centro Ricerche ENEA Casaccia, sede legale in Roma, Via Anguillarese 301**, all'esecuzione del progetto di ricerca di cui al punto 1, **presso lo stabilimento utilizzatore Centro Ricerche ENEA Casaccia, sito in Roma, Via Anguillarese, 301, autorizzato con n. 64/2001-A del 21/09/2001, ai sensi del D.lgs. 116/92**.

Alla conclusione del progetto di ricerca il responsabile di cui all'articolo 3, comma 1, lettera g) del d.lgs. n. 26/2014 dovrà inviare alla scrivente Amministrazione la documentazione necessaria ai fini della valutazione retrospettiva come previsto dall'articolo 32 del citato decreto.

La presente autorizzazione ha una durata di trentasei mesi e può essere revocata secondo quanto previsto dall'articolo 31, comma 15 del d.lgs. n. 26/2014.

IL DIRETTORE GENERALE
Dott. Pierdavide LECCHINI

Documento prodotto in originale informatico e firmato digitalmente ai sensi del "Codice dell'Amministrazione Digitale" (d.lgs. n. 82/2005 e ss.mm.)

Responsabile del procedimento: Dr. Vincenzo Ugo SANTUCCI
Referente: G. Aleandri - g.aleandri-esterno@sanita.it

4.2 Ethical approval for clinical study SEAWave-Clin (WP7)

canton de vaud

COMMISSION CANTONALE
D'ÉTHIQUE DE LA RECHERCHE
SUR L'ÊTRE HUMAIN

CER-VD

Av. de Chailly 23
1012 Lausanne

Pr Olivier Gaide
CHUV – Dermatologie et vénéréologie
Avenue de Beaumont 29
1011 Lausanne

Lausanne, le 26/09/2023
Réf. JMA/ams/ac

Décision de la Commission cantonale (VD) d'éthique de la recherche sur l'être humain (CER-VD)

Project-ID	2023-00884
Titre du projet	Double-blind randomized controlled study of the effects of 5G radiation on skin
Investigateur principal	Pr Olivier Gaide
Promoteur	CHUV, Pr Olivier Gaide
Centres	Pr Olivier Gaide, CHUV - Dermatologie, Lausanne

Décision

☒ Autorisation accordée
Cette autorisation est valable pour la durée annoncée de l'étude mais au maximum pour 5 ans à compter de la date de la présente décision.

☐ Autorisation avec charges
Cette autorisation est valable pour la durée annoncée de l'étude mais au maximum pour 5 ans à compter de la date de la présente décision.

☐ En l'état, l'autorisation ne peut pas être accordée

☐ Autorisation non accordée

☐ Non entrée en matière

Remarques :

La CER-VD vous remercie pour vos réponses détaillées.

1. Votre réponse au point 2 : La date de fin à indiquer dans BAEC est la dernière visite du dernier patient. Veuillez corriger et harmoniser également avec ce qui est prévu dans le protocole (section 4.3: "The recruitment should last for a few month (September 2023 – January 2024)" et "The end of the clinical part with the last patient is expected in or before July 2024".
2. Votre réponse au point 4 : Nous avons pris note que le contrat de consortium est en cours de signature et sera soumis dans BASEC une fois dûment complété et signé. Veuillez noter qu'aucun partage de données ne pourra avoir lieu avant que la CER-VD ait approuvé le document.

Classification

☒ Essai clinique au sens de l'OClin

- ☐ de médicament
- ☐ de transplants standardisés
- ☐ avec des organismes génétiquement modifiés ou pathogènes
- ☒ autres essais cliniques au sens du chapitre 4 de l'OClin

Catégorie : B

- ☐ de dispositifs médicaux
- ☐ de thérapie génique
- ☐ de transplantation
- ☐ avec rayonnements ionisants

Procédure de décision

☐ Procédure ordinaire ☐ Procédure simplifiée ☒ Procédure présidentielle

La Commission certifie se conformer aux principes ICH GCP.

Taxes et émoluments

Déjà facturé.

Voies de recours

La présente décision peut faire l'objet d'un recours au Tribunal cantonal, Cour de droit administratif et public. L'acte de recours doit être déposé auprès du Tribunal cantonal dans les **30 jours** suivant la communication de la décision attaquée ; il doit être signé et indiquer les conclusions et motifs du recours. La décision attaquée est jointe au recours. Le cas échéant, ce dernier est accompagné de la procuration du mandataire.

Copie pour information à :

☐ OFSP

☒ Autre(s) Christine Pich, christine.pich@chuv.ch
BPR, bpr@chuv.ch

Signature

p.o. Arthur Zinn, secrétaire général
Prof. Jean-Marie Annoni
Vice-président

Annexes : -Obligations du requérant
-Signification des décisions possibles
-Liste des documents soumis les 09.05.2023, 22.05.2023, 11.07.2023 et 19.09.2023

Annexes

Obligations du requérant (promoteur ou investigateur principal) :

Soumission de documents : les documents modifiés et les nouveaux documents relatifs à l'étude/au projet de recherche sont soumis via le dossier existant. Les documents qui ne sont plus valides sont effacés et remplacés par les nouveaux. Les documents révisés doivent être soumis une fois en mode « suivi des modifications » et une fois en mode « modifications acceptées » (« track changes » et « clean »). Les documents d'information et de consentement ainsi que le protocole doivent être transmis dans un format permettant la recherche (PDF navigable) ou scannés avec une fonction OCR (Optical Character Recognition). Le cas échéant, les documents révisés sont également mis à disposition des autorités compétentes pour approbation.

Remarque : La commission d'éthique compétente examine, dans le cadre du processus d'autorisation, les feuilles d'information et déclarations de consentement dans une des langues officielles suisses: allemand, français ou italien. La commission d'éthique ne fait qu'accuser réception des feuilles d'information et déclarations de consentement écrites dans d'autres langues. Le promoteur ou la direction du projet est responsable de la traduction correcte des documents.

Obligations d'annonce : Les obligations d'annonce (p.ex. d'événements indésirables, d'interruption d'étude) et de soumission pour autorisation des modifications essentielles obligatoires s'appliquent (Ordonnances). Le rapport final est à remettre à la commission d'éthique compétente dans un délai d'une année à compter de la fin ou de l'arrêt de l'étude.

Devoir d'enregistrement : Le promoteur d'un essai clinique doit procéder à l'enregistrement dans un registre primaire reconnu par l'OMS ou dans le registre de la bibliothèque médicale nationale des Etats-Unis d'Amérique (clinicaltrials.gov) puis indiquer le numéro de l'étude sur le portail BASEC. Le transfert des données vers le Swiss National Clinical Trials Portal (SNCTP) est effectué automatiquement suite à l'autorisation de l'étude par la commission d'éthique, sous réserve de l'accord du requérant. Les données relatives à l'essai clinique figurant sur les deux registres sont accessibles au public. Swissethics publie également sur son site des informations sur chaque étude ayant reçu une autorisation, à l'exception des essais cliniques de phase I.

Signification des décisions possibles

Autorisation accordée : L'étude peut commencer selon le plan de recherche accepté. Elle doit être menée dans le cadre des dispositions légales en vigueur. D'autres obligations d'autorisation (Swissmedic/OFSP) doivent être respectées.

Autorisation avec charges : L'étude peut commencer selon le plan de recherche accepté. Elle doit être menée dans le cadre des dispositions légales en vigueur. Les charges doivent être remplies dans un délai de 30 jours. Les documents modifiés seront réévalués en procédure présidentielle. D'autres obligations d'autorisation (Swissmedic / OFSP) doivent être respectées.

En l'état, l'autorisation ne peut pas être accordée : L'étude ne peut pas commencer. Prière de répondre point par point aux conditions de la commission d'éthique et de nous faire parvenir les documents révisés avec les modifications apparentes et la mention de la date de la nouvelle version.

Autorisation non accordée : L'étude ne peut pas commencer dans sa forme actuelle. Une nouvelle soumission reste possible.

Non entrée en matière : Justification, voir ci-dessus, par exemple la commission d'éthique n'est pas juridiquement compétente pour accorder une autorisation ou l'étude ne nécessite pas d'autorisation.

Liste des documents soumis

Pr Olivier Gaide, CHUV - Dermatologie, Lausanne		
nom du fichier	date du fichier	version
1. Cover Letter		
1-230914-coverletter.pdf	14/09/2023	
2. Synopsis of the study plan		
see doc/cat: **4**, page/ref: **3 / 1 Study synopsis**		
3. Participant information sheet and informed consent (ICF)		
3-230821-informed-consent-v2-1.pdf	21/08/2023	2.1
3-230821-informed-consent-v2-1-wtc.docx	21/08/2023	2.1
4. Study plan (protocol), signed and dated		
4-230821-clinicalprotocoltemplateforotherclinicaltrials-v2-1.pdf	19/09/2023	2.1
4-230821-clinicalprotocoltemplateforotherclinicaltrials-v2-1-wtc.docx	21/08/2023	2.1
4a. Monitoring plan		
230822-seawave-monitoring-plan-v1-0-sign.pdf	22/08/2023	1.0
5. CRF (Case Report Form)		
5-crf-information-v2-0-wtc.docx	11/07/2023	2.0
6. Investigator's CV, dated		
gaideo-cv-230509.pdf	09/05/2023	
7. Investigator's proof of GCP training		
gaide-trree-gcpe6r2.pdf	28/08/2019	
7-gaide-trree-swinatsuppl.pdf	15/11/2018	
8. Details on infrastructure suitability and availability at the location where the trial is executed		
8-details-infrastructure-suitability-availability-location.docx	15/05/2023	
9. Agreement between sponsor/commissioned institution / grant provider or other third parties and the investigator		
grant-agreement-101057622-seawave.pdf	23/05/2022	
10. Insurance		
see doc/cat: **4**, page/ref: **p18 (6.8)**		
11. Other documents handed over to study participants		
flyer-seawave-clin-wotc.pdf	11/07/2023	2.0
flyer-seawave-clin-wtc.pdf	11/07/2023	2.0
12. Details on nature and scope/value of compensation for participants		
The Patient Information Form (Document no. 3) contains details on compensation		
14. Information on secure handling of biological material and personal data, and in particular on the storage thereof		
see doc/cat: **4**, page/ref: **18 / 8.3 Confidentiality and coding**		
15. Information on reviews of this proposal by other Ethics Committees or Regulatory Authorities (Foreign or Swiss)		
15-information-reviews-proposal-other-ethics-committees-regulatory-authorities.pdf	27/01/2023	
39. Miscellaneous / Varia		
2023-00884-form-rep-230609.docx	11/07/2023	1.0
2023-00884-form-rep-230814.docx	19/09/2023	1.0
seawave-consortium-agreement-v2-14-final-signed-8of15.pdf	11/09/2023	1.0
t-samaras-chuv-letter-signed.pdf	24/08/2023	1.0
39-letteritis-calibration-seawave.pdf	13/03/2023	1.0
39-speag-scs108-acccertitifcate-1909.pdf	05/07/2019	1.0