# LEUCONNECT PLATFORM GENERAL TERMS OF USE

**Use of the Platform is subject to prior acceptance of these General Terms of Use.**

## 1. Legal Notice

### PLATFORM PUBLISHER

The **European Association against Leukodystrophies (ELA)** whose registered office is located at 2 rue Mi-les-Vignes – CS 61024 – 54521 LAXOU cedex – FRANCE.

Telephone: +33 (0)3 83 30 93 34
Fax: +33 (0)3 83 30 00 68
Email: contact@leuconnect.com

**Publication Director**: **Pascal Prin**.

**Editorial Director**: **Jean-François Dhainaut**.

### CERTIFIED HEALTH HOSTING SERVICE

The company ALMERYS (hereinafter "**ALMERYS**"), simplified joint stock company with a capital of 40,000 euros, registered at the Trade and Companies Register in Clermont-Ferrand under registration n° 432 701 639, whose registered office is located at 46, rue du Ressort, 63967 CLERMONT-FERRAND cedex 9 – FRANCE.

Telephone: +33 (0)4 73 74 58 90
Fax: +33 (0)4 73 74 58 29
Email: almerys@almerys.com

## 2. Purpose and definitions

The purpose of these General Terms of Use is to provide a framework for the use of the Platform by Users. They serve to define the respective rights and obligations of the Platform Users and the Publisher.

THE PLATFORM IS NOT AN E-CRF. USERS ARE RESPONSIBLE FOR ANY USE OF THIS PLATFORM DURING A STUDY IN WHICH THEY ARE PARTICIPATING, AS ARE THE SPONSORS AND HEALTH PROFESSIONALS IN CHARGE OF IMPLEMENTING THE STUDY IN QUESTION. THE PUBLISHER IS NEITHER RESPONSIBLE FOR THE STUDY NOR ABLE TO CONTROL ANY OPERATIONS AND ACTIONS PERFORMED BY USERS VIA THE PLATFORM.

These General Terms of Use are accepted on the same day as:

- The information and consent form (e-cohort Consent),

- The digital signature of the general terms of use (GTU digital signature).

The terms defined below shall have the meaning and scope accorded by the acceptance and performance of these General Terms of Use.

"**Content**" refers to all texts, images, videos, tools and, more broadly, any component of the Platform.

"**Control panel**" refers to the interface to which the e-cohort Subject User has access within his/her Personal space and includes his/her calendar, questionnaires, list of proposed Studies, Studies in progress, notification centre, messaging services, and accessible areas that vary according to whether or not s/he is participating in a Study.

"**Data controller**" refers to ELA, responsible for collecting and processing personal data relating to the User during access and use of the Platform within the meaning of law n° 78-17 of 6 January 1978 pertaining to information technology, data bases and civil liberties ("known as the Data Protection Act").

"**ELA Administrator**" refers to the duly authorised ELA staff member charged with offering Studies to e-cohort Subject Users who have granted their prior consent to this end, or with transferring up on their electronic applications to Study coordinating investigators if their profile either wholly or in part meets the inclusion criteria of the Study in question.

"**GTU**" refers to these General Terms of Use of the Platform, its Services and its Content.

"**Investigator**" refers to the natural person responsible for carrying out/coordinating a Study and for following up on e-cohort Subjects involved in said Study, who thereby benefits from use of Platform services and content, in particular during the stages of pre-screening and review of e-cohort Subject files.

"**Patient file**" refers to all the information provided by the e-cohort Subject User within his/her Personal account.

"**Personal account**" refers to the account created by the e-cohort Subject User enabling him/her to access his private and secure space, as part of the use of the Services and Content of the Platform.

"**Personal space**" refers to the e-cohort Subject User's private and secure space when using all Platform Services and Content.

"**Platform**" refers to the web space published by ELA, accessible at the web address www.leuconnect.com, dedicated to leukodystrophy patients and their relatives, with the particular purpose of bringing together people who might be willing to take part in Studies within this therapeutic field.

"**Public space**" refers to the public space that any User may access within the Platform;

"**Publisher**" refers to ELA, which publishes the Platform within the meaning of law n° 2004-575 of 21 June 2004 on confidence in the digital economy (known as "law LCEN");

"**Services**" refers to all services offered by the Publisher on the Platform to enable Users to participate in Studies.

“**Sponsor**” refers to the natural or legal person leading the Study and thereby benefitting from Platform services and content in order to carry out and monitor a Study under his sole responsibility. Under no circumstance is the Publisher responsible for the Study, including when the Sponsor uses the Platform under his sole responsibility.

“**Studies**” refers to the studies relating to the services made available on the Platform, including:

- ❖ **Any research involving human subjects**:
  - Any **intervention** study involving **patient intervention that falls outside the remit of routine care**[1].
  - Any **intervention** study involving **only minimal risks and constraints**[2].
  - Any **non-intervention** study involving **no risk or constraint and involving actions routinely performed or (health) products routinely used**[3].
- ❖ **Any research not involving human subjects**, including but not limited to any study, assessment, practice analysis, care or preventative activity.

“**Users**” refers to any leukodystrophy patient, or any of his/her relatives, who accesses the Platform, its Services and Content:

- “**Subject”** refers to any leukodystrophy patient, or any of his/her relatives, who accesses the Platform’s Public space.

- “**E-cohort Subject**” refers to:
  - Any Subject who has access to all the Platform Services and Content subsequent to the creation of a Personal account, and who has specifically consented to become an “e-cohort Subject”.
  - Any healthy Subject who is a “case-control” and who, following the creation of a Personal account, accesses the reduced Platform Services and Content (“My administrative profile”) which under no circumstances allows for the collection and processing of health/medical data, and who has specifically consented to become an “e-cohort Subject”.

## 3. Contractual documents

These GTUs form the full extent of the agreement between the User and the Publisher with respect to use of the Platform, its Services and its Content along with:

- The information and consent form (e-cohort Consent)
- The general terms of use digital signature (GTU digital signature).

In the event that any of the provisions of these GTUs shall be deemed invalid by a competent tribunal the invalidity of said provision shall not affect the validity of any other provision of these terms.

The waiver of any one provision of these GTUs shall not be deemed to represent a permanent waiver of this provision or any other provision of these GTUs.

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[1] Research referred to in para. 1 of article L. 1121-1 of the Public Health Code (CSP); article R.1121-1 CSP

[2] Directory determined by the order of 2 December 2016 determining the directory of studies referred to in para. 2 of article L. 1121-1 CSP

[3] Research referred to in para. 3 of article L. 1121-1 CSP; article R.1121-2 CSP

## 4. Effective date

### 4.1. For Subject Users

Access to the Platform and its use by any Subject User is subject to these GTUs, all laws applying to Internet usage and, more generally, all applicable laws.

Navigation within the Platform's Public space without the creation of a Personal account implies the Subject User's acceptance of these GTUs.

### 4.2. For e-cohort Subject Users

These GTUs come into full force for e-cohort Subject Users on the day that they are accepted by checking the acceptance box for these GTUs on the Personal account creation page.

The e-cohort Subject User grants his/her consent by activating a check box that is linked to a proof of acceptance.

The GTUs shall remain effective for the full duration of the period that the e-cohort Subject User continues his/her registration.

Termination of registration shall take effect either on the day deregistration is requested by the e-cohort Subject User or on the day the Publisher terminates registration as per the conditions outlined in these GTUs.

## 5. Description of the Application, its Services and Content

The platform is a digital space offering Services accessible via the web address www.leuconnect.com.

Its principal purpose is to create and moderate an e-cohort of Subjects who have expressed an interest in participating in Studies with Sponsors.

**The Services that are accessed through the Platform do not include the implementation of Studies. Their only purpose is to bring together individuals who may be interested in participating in such Studies and to offer Services to this end.**

**CONSEQUENTLY,** THE USER RECOGNISES THAT THE PLATFORM IS NOT AN E-CRF. USERS ARE RESPONSIBLE FOR ANY USE OF THIS PLATFORM DURING A STUDY IN WHICH THEY ARE PARTICIPATING, AS ARE THE SPONSORS AND HEALTH PROFESSIONALS IN CHARGE OF CARRYING OUT THE STUDY IN QUESTION. THE PUBLISHER IS NEITHER RESPONSIBLE FOR THE STUDY NOR ABLE TO CONTROL ANY OPERATIONS AND ACTIONS PERFORMED BY USERS VIA THE PLATFORM.

The Platform offers Subject Users the following Services:

- The diffusion of information and content on leukodystrophies and on the Studies
- An introduction to the bodies, Sponsors and Investigators carrying out Studies.

## 6. Services/headings/functions and associated caveats

### 6.1. Information content

The Platform contains areas in which the Subject User is offered a range of medical/field information concerning leukodystrophies.

Within the Public space, the Subject User has particular access to the following content:

- The "Leukodystrophies" section, offering access to **information and content relating to leukodystrophies**;
- The "**news**" section, which keeps the User up to date with information relating to leukodystrophy events and the Studies;
- A **FAQ** section;

Within the Personal space, the e-cohort Subject User also has access to information **newsletters**.

The User is advised that the Platform Content provides information on the current state of knowledge on leukodystrophy as well as news about the Studies.

All information is provided as texts and photographs.

CAVEAT: IN GENERAL, THE INFORMATION PROVIDED TENDS TO BE SCIENTIFICALLY ACCURATE, RELIABLE AND RELEVANT AT THE TIME OF PUBLICATION.

NEVERTHELESS, TAKING INTO ACCOUNT SCIENTIFIC AND MEDICAL DEVELOPMENTS, USERS ARE ADVISED THAT ANY INFORMATION PROVIDED IS NEITHER COMPLETE NOR EXHAUSTIVE AND MAY NOT BE SYSTEMATICALLY UPDATED.

DESPITE THE CARE TAKEN WHEN PROCESSING INFORMATION, THE PUBLISHER CANNOT BE HELD RESPONSIBLE FOR ANY ERRORS OR OMMISSIONS TO THE INFORMATION SHARED ON THE PLATFORM. THE PUBLISHER CANNOT BE HELD RESPONSIBLE FOR HOW THE INFORMATION SHARED ON THE PLATFORM IS INTERPRETED, NOR FOR ANY CONSEQUENCES RESULTING FROM ITS USE.

THUS, THE USER ACKNOWLEDGES THAT THE PLATFORM CONTENT NEITHER DIRECTLY OR INDIRECTLY CONSTITUTES A MEDICAL CONSULTATION, WHICH S/HE MUST UNDER NO CIRCUMSTANCES NEGLECT TO SEEK. INFORMATION IS PROVIDED SOLELY FOR REFERENCE PURPOSES AND IS NOT PERSONALLY TAILORED TO THE USER'S STATE OF HEALTH. IT SHALL IN NO WAY REPLACE THE FULL AND PERSONAL INTERVENTION OF A HEALTH PROFESSIONAL.

IN PARTICULAR, THE USER ACKNOWLEDGES THAT THE PLATFORM UNDER NO CIRCUMSTANCES OFFERS ACCESS TO A THERAPEUTIC EDUCATIONAL PROGRAMME, DIAGNOSTIC CARE OR ANY OTHER TYPE OF MEDICAL CARE THAT REQUIRES SKILLS THAT ARE SOLELY THE PRESERVE OF HEALTH PROFESSIONALS.

S/HE IS SOLELY RESPONSIBLE FOR THE USE OF ANY INFORMATION PROVIDED THROUGH THE PLATFORM, FOR ANY DECISION TAKEN AND FOR ANY ACTION PURSUED, BASED ON INFORMATION CONTAINED WITHIN THE PLATFORM.

INFORMATION SYSTEMS THAT ARE MADE ACCESSIBLE WITHIN THE PLATFORM SHALL BE USED IN COMPLIANCE WITH THE PLATFORM'S METHODS OF USE, ITS CONTENT AND ITS FUNCTIONS.

Within the Public space, the User is also able to access details on **future Studies or Studies that are open for recruitment**, including:

- A Study's state of progress (recruitment in progress or complete, study in progress or complete);
- A summary of the Study, its objectives, its status, the testing site;
- An "apply to take part in this study" tab.

CAVEAT: THE USER IS ADVISED THAT IN THE EVENT THAT S/HE DOES NOT HAVE A PERSONAL ACCOUNT, S/HE WILL BE INVITED TO CREATE ONE SO THAT S/HE IS ABLE TO APPLY TO TAKE PART IN STUDIES.

ONLY E-COHORT SUBJECT USERS ARE ABLE TO APPLY TO TAKE PART IN STUDIES.

THE USER IS NOTIFIED THAT S/HE WILL PROVIDE SENSITIVE DATA WITHIN HIS/HER PERSONAL SPACE, WHICH SHALL REMAIN ENTIRELY UNDER HIS/HER CONTROL, USE AND RESPONSIBILITY, AND THAT THIS SHALL REQUIRE HIM/HER TO ENSURE THAT THIRD PARTIES CANNOT ACCESS HIS/HER USER ACCOUNT.

### 6.2. Notifications

Notifications may be sent to an e-cohort Subject User. They are alerts in the form of message banners that appear within the e-cohort Subject User's Personal space.

Notifications are sent along with an email to inform the e-cohort Subject user that s/he has received a notification in her/his Personal space; for example, in connection to a file or to a Study's progress.

Messages may be sent under the following circumstances:

- To inform the Subject that a connection to a family member has been accepted
- To invite the Subject to consent to an e-cohort
- To advise the e-cohort Subject that s/he has been selected to take part in a Study and is requested to provide his/her consent to this end
- To provide the Subject with a reminder for a scheduled event
- To invite the e-cohort Subject to complete a new questionnaire
- To advise the e-cohort Subject that s/he has received a new request to complete a questionnaire.

CAVEAT: THIS FUNCTION CAN ONLY BE ACCESSED ONCE THE E-COHORT SUBJECT USER HAS COMPLETED THE AUTHENTICATION PROCESS FROM WITHIN HIS/HER PERSONAL SPACE.

### 6.3. Secure messaging

This function allows two e-cohort Subject Users to exchange messages, once each e-cohort Subject User has agreed to be contacted by another e-cohort Subject User.

This involves providing a pseudonym, age and disease information, which will be listed in the messaging service's contact list, and enables the User to post comments.

Users may also receive messages sent by ELA Administrators through the secure messaging system, and, within the framework of their participation in a Study, they may also be sent messages by Sponsors, Investigators, or any other person acting on their behalf, who have access to the Platform for the purposes of managing and monitoring a Study's progress.

CAVEAT: THIS FUNCTION CAN ONLY BE ACCESSED ONCE THE E-COHORT SUBJECT USER HAS COMPLETED THE AUTHENTICATION PROCESS FROM HIS/HER PERSONAL SPACE.

UNDER NO CIRCUMSTANCES DOES THIS ALLOW FOR THE E-COHORT SUBJECT USER TO BE IDENTIFIED BY OTHER E-COHORT SUBJECT USERS.

### 6.4. "My profile"

Within his/her Personal space, the e-cohort Subject User is able to enter information in order to build a profile on the basis of which s/he may be offered a Study subsequent to:

- **A pre-screening phase:** a list of Subjects who may be interested in taking part in a Study is created, either by ELA administrators or digitally, using a set of criteria (age, sex, pathology) drawn from the form initially completed by the e-cohort Subject User.

- **An invitation to take part in a Study from a Sponsor,** on condition that the e-cohort Subject User has agreed for his/her data to be shared with the Study Sponsor and that s/he has agreed to potentially be contacted by the Sponsor; the Sponsor has no direct access to any identifying information.

- **A screening/enrolment phase** established by the Investigator.

CAVEAT: THE E-COHORT SUBJECT USER IS ADVISED THAT ANY STUDY ON WHICH S/HE IS ENROLLED IS CARRIED OUT UNDER THE SOLE RESPONSIBILITY OF THE SPONSOR CONCERNED AS WELL AS THAT OF THE HEALTH PROFESSIONALS COMPLETING THE STUDY, EACH WITH RESPECT TO THE AREA THAT CONCERNS HIM/HER. THE PUBLISHER IS IN NO WAY RESPONSIBLE FOR THE STUDY, INCLUDING WHEN THE SPONSOR USES THE PLATFORM TO IMPLEMENT AND MONITOR THE STUDY UNDER HIS OWN RESPONSIBILITY.

The e-cohort Subject User is advised s/he may at any time amend the details in his/her profile.

The e-cohort Subject User is advised that:

- prior to being offered participation in a Study,
- with respect to an electronic application to take part in a study sent through the field "*Take part in this research*",

The ELA Administrator shall verify that his/her profile matches some or all of the inclusion and exclusion criteria of the Study in question.

CAVEATS: THE E-COHORT SUBJECT USER IS ADVISED THAT ANY INFORMATION THAT S/HE PROVIDES SHALL REMAIN UNDER HIS/HER COMPLETE CONTROL, USE AND RESPONSIBILITY. THE PUBLISHER SHALL IN NO WAY VERIFY THE CONSISTENCY OR RELEVANCE OF THE SCIENTIFIC, MEDICAL OR HEALTH DATA ENTERED BY THE E-COHORT SUBJECT USER. IT IS UP TO THE E-COHORT SUBJECT USER TO CONSULT WITH COMPETENT HEALTHCARE PROFESSIONALS BEFORE TAKING ANY DECISION OR ACTION.

FURTHER, IN VIEW OF THE SENSITIVE NATURE OF HEALTH DATA THAT MAY BE PROVIDED WITHIN HIS/HER SPACE DEDICATED TO HIS PROFILE, THE E-COHORT SUBJECT USER IS ADVISED OF THE NEED TO PREVENT THIRD PARTY ACCESS TO HIS/HER USER ACCOUNT. THE USER IS RESPONSIBLE FOR TAKING ALL NECESSARY SECURITY MEASURES TO ENSURE THAT ACCESS TO HIS/HER USER ACCOUNT IS PROTECTED.

FINALLY, THE E-COHORT SUBJECT USER IS ADVISED THAT ACCESS TO HIS/HER FILE BY ANY ELA ADMINISTRATOR AND ANY COORDINATING INVESTIGATOR IS CARRIED OUT FOLLOWING STRONG AUTHENTICATION PROCEDURES AND SUBJECT TO HIS/HER EXPRESS PRIOR CONSENT.

The data forming the basis of the e-cohort Subject User profile are classified according to the criteria outlined below, subject to the general caveats mentioned above and specific caveats, where applicable.

### 6.4.1. “Administrative profile”

The e-cohort Subject User shall provide identifying information (name, address, family relationships).

S/he chooses how to receive his/her authentication OTP, One Time Password, (by email or SMS), and indicates his/her preference regarding post mortem preservation of his/her data, which is subject to his/her express permission being granted.

CAVEAT: THE E-COHORT SUBJECT USER IS ADVISED THAT HIS/HER EXPRESS CONSENT TO HIS/HER DATA BEING PRESERVED POST MORTEM FOR THE PURPOSES OF SCIENTIFIC STUDY IS GRANTED FROM THE “ADMINSTRATIVE PROFILE” PAGE.

S/HE IS ALSO FREE TO LEAVE THE E-COHORT AT ANY TIME.

NO HEALTH/MEDICAL DATA RELATING TO THE E-COHORT USER IS COLLECTED AT THIS STAGE.

The e-cohort Subject User may share information regarding his/her family relationships with other members.

CAVEAT: WHERE APPLICABLE, S/HE IS RESPONSIBLE FOR ANY INFORMATION RELATING TO THE COLLECTION AND PROCESSING OF PERSONAL DATA WITHIN THE PLATFORM.

The e-cohort Subject User may also send an invite to family members, who will receive a notification through the secure messaging system accessible via the Control panel.

The e-cohort Subject User will receive notification that another E-cohort User has accepted his/her invite via the secure messaging system, which can be viewed in his/her Control panel.

CAVEATS: THE PLATFORM ALLOWS THE E-COHORT SUBJECT USER TO SEND AN EMAIL TO ANOTHER FAMILY MEMBER WHEN S/HE HAS PROVIDED AN EMAIL ADDRESS AND THE NATURE OF THEIR FAMILY RELATIONSHIP.

THE USER IS REQUESTED TO CAREFULLY CHECK THE IDENTITY OF RECIPIENTS BEFORE USING THE SEND FUNCTION, WHICH S/HE DOES UNDER HIS/HER SOLE RESPONSIBILITY.

### 6.4.2. “My leukodystrophy”:

The e-cohort Subject User provides information about his/her disease under the heading “**My disease history**”:

- “My disease”: selection of pathology from pre-populated fields, current status

- "Symptoms: date, description, triggering factors
- "Diagnosis": name and location of medical centre/doctor, date symptoms first appeared.

The e-cohort Subject User may also provide all information on "Leukodystrophy family history" by showing the relationships to any family member presenting with, or having presented with, a leukodystrophy whose type and date of diagnosis can be stated.

#### 6.4.3. "My healthcare professionals"

The e-cohort Subject User may supply information about his/her medical environment and the health professionals involved in his/her care program.

CAVEATS: THE E-COHORT SUBJECT USER ENTERS HEALTHCARE PROFESSIONALS' DETAILS UNDER HIS/HER SOLE RESPONSIBILITY, AFTER HAVING INFORMED THEM OF HIS/HER INTENTION TO DO SO.

S/HE IS NOTIFIED THAT THE PLATFORM UNDER NO CIRCUMSTANCES ALLOWS FOR AN INTERVENTION BY A HEALTHCARE PROFESSIONAL, NOR ANY EXAMINATION BY HIM/HER.

#### 6.4.4. "Disease management"

As part of his/her disease management, the e-cohort Subject User is invited to enter information under the heading "**Social support**": whether s/he is aware of the various social and legal services to which s/he is entitled, whether s/he is in touch with any patient groups, any other families, has ELA membership, as applicable.

Under the heading "**Disease impact on my daily life**", the e-cohort Subject User is able to rank his/her discomfort by category (food, sleep, pain, speech, vision, hearing, memory, motor activities, ability to communicate) on a scale of 1 to 10, and may also add any relevant comments.

CAVEAT: THE FUNCTION THAT ENABLES DISEASE IMPACT TO BE EXPRESSED ON A SCALE IS IN NO WAY AN EVALUATION OR CONVERSION OF DATA PROVIDED. THIS SCALE IS NOT A MEDICAL TOOL.

The e-cohort Subject User may also detail the disease impact on his/her family unit, partner/parents, professional life, and provide information about his/her current place of residence.

CAVEAT: PLEASE NOTE THAT THE USER MUST NOT PROVIDE ANY DETAILS ABOUT HIS/HER SOCIAL SITUATION AND, IN PARTICULAR, MUST NOT PROVIDE INFORMATION REGARDING ANY SOCIAL DIFFICULTIES, WHERE APPLICABE.

#### 6.4.5. "Edit my profile"

The e-cohort Subject User is supplied with a function that enables him/her to export/edit his/her profile and s/he undertakes to take any measures necessary to securing the safety and confidentiality of his/her data when activating this function.

CAVEATS: PLEASE NOTE THAT WHERE THERE HAS BEEN A BREACH TO INTERNET SECURITY OR WHERE THE CONNECTION IS UNRELIABLE, THIS FUNCTION INVOLVES RISKS TO DATA SECURITY AND CONFIDENTIALITY.

IN SUCH AN EVENT, THE FUNCTION IS USED UNDER THE E-COHORT SUBJECT USER'S SOLE RESPONSIBILITY.

### 6.5. "My calendar"

The e-cohort Subject User is able to access an on-line calendar through the Platform's Control panel

which, in particular, provides information on events relating to protocols for the Studies on which s/he is enrolled.

This function is only available for the purposes of completing the Study, under the Sponsor's sole and exclusive responsibility, when the e-cohort Subject User is enrolled on a Study.

CAVEATS: THE PUBLISHER IS IN NO WAY RESPONSIBLE FOR THE USE OF THIS FUNCTION AS PART OF A STUDY'S IMPLEMENTATION. USE OF THIS TOOL IN THE CONTEXT OF PARTICIPATION IN A STUDY, IS UNDER THE STUDY SPONSOR'S SOLE RESPONSIBILTY.

### 6.6. "My questionnaires"

The e-cohort Subject User is able to access questionnaires through his/her Control panel.

The e-cohort Subject User will receive a notification through his/her Control panel's secure messaging system when a new questionnaire has been made available.

The e-cohort Subject User may be requested to complete pre-screening questionnaires prior to being selected to participate in a Study.

CAVEATS: THE E-COHORT SUBJECT USER IS ADVISED THAT THE DATA S/HE PROVIDES TO CREATE HIS/HER PROFILE IS USED TO DETERMINE WHETHER OR NOT S/HE IS ASKED TO TAKE PART IN A STUDY IN THE EVENT THAT HIS/HER PROFILE FULLY OR PARTLY MATCHES THE INCLUSION CRITERIA OF THE STUDY IN QUESTION.

ANY DATA IS PROVIDED UNDER HIS/HER ENTIRE CONTROL, MANAGEMENT AND RESPONSIBILITY.

THE E-COHORT SUBJECT USER IS ADVISED THAT HIS/HER DATA SHALL UNDER NO CIRCUMSTANCES BE TRANSMITTED TO SPONSORS AND COORDINATING INVESTIGATORS WITHOUT HIS/HER EXPRESS PRIOR CONSENT GRANTED AT THE TIME HIS/HER PERSONAL ACCOUNT IS CREATED (e-cohort Consent), AND AT THE TIME OF RECEIVING AN OFFER TO PARTICIPATE IN A STUDY.

The e-cohort Subject User may be asked to complete questionnaires relating to his/her condition as part of a study.

CAVEATS: USE OF THIS FUNCTION FOR THE PURPOSES OF CARRYING OUT A STUDY, AS WELL AS FOR THE COLLECTION AND PROCESSING OF PERSONAL DATA IS UNDER THE SOLE RESPONSIBILITY OF THE STUDY SPONSOR. THE PUBLISHER IS IN NO WAY RESPONSIBLE IN THIS REGARD.

### 6.7. "Take part in research"

The e-cohort Subject User is able to access a list of Studies in progress from his/her Control panel, including:

- The state of progress of each Study (recruitment in progress or complete, study in progress or complete, participation statistics)
- An outline of the Study, its objectives, its status, the testing venue
- An "apply for this study" tab

The e-cohort Subject User may apply online to take part in a Study by consulting the outlines describing the Studies. The inclusion/exclusion criteria are listed in read-only format.

In the event that his/her profile is kept during the pre screening stage, s/he will receive an automated notification through the secure messaging service on his/her Control panel.

His/her identifying data (contact details) are sent to the Study coordinating Investigator for the Study in question under the Sponsor's responsibility, subject to a new consent having been granted.

An e-cohort Subject User who has not been selected will be advised of this by the coordinating Investigator by means of a secure messaging notification accessible via his/her Control panel.

An e-cohort Subject User who is selected during this stage will also receive a secure messaging notification accessible via his/her Control panel, and becomes a candidate for the screening stage.

Each time a Study is launched, a request for consent to participate is sent under the Sponsor's responsibility, in compliance with the provisions of the Public Health Code, within the margins of the Platform.

CAVEAT: THE E-COHORT SUBJECT USER IS ADVISED THAT ANY STUDY ON WHICH S/HE IS CONSEQUENTLY ENROLLED IS CARRIED OUT UNDER THE SOLE RESPONSIBILITY OF THE SPONSOR IN QUESTION AND THE HEALTH PROFESSONALS INVOLVED IN CARRYING OUT THE STUDY, INDEPENDENT OF THE PLATFORM.

## 7. Terms of Platform and Personal space access and use

### 7.1. Terms of access

In the case of minors, access to the Personal space, Services and Content made available to e-cohort Subject Users is subject to authorisation by the minor's legal representative.

**Minors**

When a date of birth is entered identifying the Subject as a minor, s/he is invited to provide a list of persons holding legal responsibility on the registration page of the Personal space.

At least one legally responsible person must be provided in order to create a Personal account (surname, first name, email, relationship to Subject).

When the Personal account is created, an email is sent to each of the named legally responsible persons.

The legally responsible person/s will be able to activate the Personal account by using a link provided in the email.

The minor Subject will be unable to connect to his/her Personal account until one of the named legally responsible persons has agreed to activate the minor Subject Personal account.

Thereinafter, certain actions carried out by the minor e-cohort Subject User within his/her Personal space may result in emails being sent to his/her legal representative/s (for example, a consent request for the minor to participate in a Study).

In general, Users may only use the Platform Services and Content for the purposes outlined in these GTUs and, in particular, may not use the Platform, including Services and Content, to try to recruit clients, promote a product, service, health centre or, in general, for any advertising or promotional ends.

The Platform Services and Content are for Users' personal use and may not be used to the benefit of any company or other organisation. Commercial companies, and, in general, any organisation or entity, may not become a User and may not use the Platform without the Publisher's express permission.

Any use that violates the rights of the Publisher will result in legal action against the User.

The e-cohort Subject User acknowledges that s/he has access to a secure Personal space in his/her capacity as a patient who has expressed his/her desire to participate in Studies.

S/he undertakes not to share his/her authentication information with any third party.

The User acknowledges and agrees that s/he is solely responsible for all Internet connection charges.

### 7.2. Registering on the Personal space

The User is advised that access to the Personal space and the different Services and Content provided on the Platform is subject to the creation of a Personal account.

The **creation of a Personal account** for accessing the Platform is completely free to the User.

In general, once a Personal account has been created, the e-cohort Subject User undertakes to enter his/her identifying data under his/her sole responsibility, control and management, and undertakes to provide full, exact and up to date information, and not to usurp the identity of a third party, nor to hide or modify his/her age.

In the event that the e-cohort Subject User provides false, inaccurate, misleading, incomplete or obsolete information, the Publisher reserves the right to suspend or refuse access to all or part of the Platform, as well as to its Services and Content, without notice or liability, either temporarily or permanently.

Further, access to the Platform is subject to a procedure that secures **acceptance of the GTUs**.

Further, the e-cohort Subject User may potentially take part in an e-cohort. S/he will be specifically invited to give his/her e-cohort consent when s/he first connects to his/her Personal space (e-cohort Consent).

Having granted his/her consent to take part in an e-cohort, the e-cohort Subject User will be asked to indicate whether or not s/he suffers from a leukodystrophy.

Where applicable, the e-cohort Subject User is advised and acknowledges that use of the Services and access to Content directly or indirectly involves the collection and processing of personal health/medical data. To this effect, following the creation of his/her Personal account, the e-cohort Subject User is asked to:

- Read the information notice provided (e-cohort Consent),

- Then provide his/her informed, express, prior **consent** to the **collection and processing of personal health/medical data**.

The e-cohort Subject User's consent is granted by ticking the check box linked to a proof of acceptance.

The Platform can be accessed via any Internet enabled device.

### 7.3. Connecting to the Personal space

Each time the e-cohort Subject User connects to the Personal space s/he is authenticated by means of:

- A **login** that, by default, corresponds to the e-cohort Subject's email,

- And a strictly confidential **password** selected by the e-cohort Subject User. To comply with the required security measures, this password must be made up of at least ten characters, which shall include at least one number, one special character, one upper case letter, one lower case letter. It must be updated every six months from the first day of connection, and reuse of the five most recent passwords is not permitted. To maintain security, the User's password must not relate to him/herself or, where applicable, to the person for whom s/he is a legal representative and who uses the Platform (name, date of birth, etc.),

- An **OTP code**, a "One Time Password", is sent to the e-cohort Subject User either by email or SMS according to the e-cohort Subject's preference stated at the time the Personal account was created.

When an e-cohort Subject User is authenticated to access his/her Personal account by means of these authentication details, this renders the e-cohort Subject User irrefutably accountable for any operations carried out while these identifiers are in use, under the conditions outlined in the "Proof of Acceptance" section of these GTUs.

That is, any operation carried out by the User through his/her Personal account by means of these authentication details shall be deemed to have been executed by the User and under his/her sole responsibility.

Thus, the User undertakes to protect the identity of these authentication details, with the understanding that the Publisher cannot be held responsible for any loss or damage arising from a failure to fulfil this obligation, and that any use of the abovementioned elements is under the User's sole responsibility.

The Personal account will be blocked following five failed login attempts.

In the event that these authentication details are lost or stolen, the User undertakes to immediately notify the Publisher at the following email address: contact@leuconnect.com.

Further, the e-cohort Subject User may at any time request that the Publisher change his/her authentication details, particularly when s/he suspects that an unauthorised third party has used them or when the Personal account has been blocked.

- In the event that the password has been misplaced or forgotten the e-cohort Subject User may himself/herself register this loss/misplacement and set a new password in line with the criteria described above.

    - In the first instance, the e-cohort Subject User will receive a dual factor OTP, which s/he must re-enter on the Platform authentication page. The first OTP is sent by SMS to his/her mobile phone, the second is sent by email.

    - Once the dual factor OTP has been successfully entered, the e-cohort Subject User will be able to reset his/her password.

- When the Personal account has been blocked following five failed login attempts.

    - Following three failed login attempts, a CAPTCHA will invite the e-cohort Subject User to enter a series of characters displayed on the screen in order to prevent any remote attacks and thereby preclude application accounts from being blocked.

Furthermore, a software tool compels the User to renew his/her password every six months, as recommended by CNIL.

Where applicable, the Publisher undertakes to notify the User that his/her password or renewal data has been comprised within a 72-hour period of this infringement having been identified. The User must then change his/her password the next time s/he connects, as recommended by CNIL.

## 8. User obligations and responsibilities

The Publisher authorises Users to view, download and print Platform Content for strictly personal and non commercial use within France and for the time that the Platform is accessible online.

Users undertake to use the Platform:

- In compliance with all laws, regulations and third party rights, in particular, intellectual property rights and image copyright.
- Fairly and in accordance with its intended purpose.

In particular, Users shall:

- Comply with all security measures as set out in the “Security” section of these GTUs.
- Use the Platform, Services and Content in compliance with the legal and regulatory provisions in force.
- Not to market Services distributed via the Platform, whether in whole or in part.

In the event of non compliance with one or more of the provisions of these GTUs, access to the Platform or the e-cohort Subject User’s Personal account may unilaterally, ipso jure and without notice be temporarily suspended or permanently blocked.

## 9. Intellectual property

### 9.1. Content and Services

Any use, reproduction, copy or dissemination of one or various elements of the Platform for anything other than personal use is prohibited.

The entire Platform, Content and Services, including but not limited to, the domain name, texts, graphic design, graphics, photographs, pictures, sounds, images, audio and video content, but also the website structure, the navigation system, the headings design and structure, their titles, whether planned or actual, is protected by intellectual property rights held or claimed by the Publisher, with the authorisation of the holders of these rights.

These Content and Services are intended exclusively for the User's personal use and information, and the User is granted private, non-collective and non-exclusive use.

In the absence of the Publisher's express and prior agreement, all copies, reproductions and uses by the User other than those listed above are prohibited, in particular:

- Any adaptation, making available to the public, whether or not requested to do so, dissemination, retransmission in any format whatsoever, sharing in a network, public communication with or without charge, of all or part of the work, services, and all elements protected under, or subject to protection under, intellectual property law as reproduced within the Platform.

- Any link, access, alteration, addition or suppression that affects the online publication's automated processing system and that modifies the publishing conditions or the editorial policy.

Any failure of the User to comply with these obligations shall constitute an infringement punishable by articles L. 335-2 et seq. of the Intellectual Property Code.

### 9.2. Data bases

In compliance with the provisions of law n° 98-536 of 1 July 1998 transposed into the Intellectual Property Code of directive 96/9 CE of 11 March 1996 governing the protection of databases, the Publisher is the producer and proprietor of all or part of the databases that make up the Platform, their structure and their content.

By accessing the Platform, the User acknowledges that the data therein are legally protected and, in compliance with the abovementioned provisions of 1 July 1998, s/he is prohibited from, in particular, extracting, reusing, saving, reproducing, representing or preserving in any format whatsoever, all or a qualitatively or quantitatively substantial part of the content of the databases within the Platform which s/he shall access, as well as the systematic or repeated extraction or reuse of qualitatively or quantitatively insubstantial parts where his/her operations manifestly exceed normal conditions of use.

### 9.3. Trademarks, distinguishing signs and logos

Unless otherwise stated, the Publisher owns all trademarks used on the Platform.

In the absence of the Publisher's express and prior agreement, any reproduction (whether in whole or in part) and any use of these trademarks, whether figurative or otherwise, owned by the Publisher, shall render the User liable to legal action.

## 10. Hypertext links

### 10.1. From the Platform

The Publisher does not verify the content and the sites linking from the Platform and is in no way responsible for the content of sites to which links are made.

Their presence in no way means that the Publisher adheres to or validates their content nor does the Publisher accept any responsibility whatsoever for the content or the use of these third party sites.

The Publisher provides the links on a purely illustrative basis, without any assessment procedure or certification of the sites in question.

Each User accesses third party sites under his/her own sole responsibility, including when the links are provided on the Platform.

### 10.2. To the Platform

Any link to the Platform requires the Publisher's express and prior permission, which may be requested at the following email address: contact@leuconnect.com.

## 11. Personal data protection

ELA is the Data controller, under Data Protection Law, for the processing of e-cohort Subject Users personal data, collected during access and use of information services, and communication and management of e-cohort data bases provided on the Platform, in compliance with declaration n°1929198 registered on 09 February 2016 with the National Commission for Data Protection and Civil Liberties (CNIL).

Subject identifying data may be collected and processed through the contact form, as notified in a statement from CNIL.

The e-cohort Subject User has been notified that by registering on his/her Personal space on the Platform, s/he has the option to join an e-cohort.

By ticking a check box, s/he gives his/her consent to join an e-cohort when s/he first connects to his/her Personal space (e-cohort Consent).

Having expressed his/her consent to join an e-cohort, the e-cohort Subject User is invited to state whether or not s/he has a leukodystrophy.

Where applicable, the e-cohort Subject User has been informed and has, by means of a check box, consented to his/her health/medical data being collected and processed in accordance with the information and consent notice (e-cohort Consent).

The e-cohort Subject User's attention is drawn to the sensitive nature of the health data s/he shares on the Personal space, which are furthermore covered by patient confidentiality.

Personal health data collected during preventive, diagnostic, care or social and medico-social follow-up activities (hereinafter called "medically sensitive data"), in the meaning of the provisions of article L.1111-8 CSP, are liable to be collected and processed during implementation of Services offered to e-cohort Subject Users via the Platform, and are hosted by a certified health hosting service to this end.

Under the Data Protection Act, the e-cohort Subject User has the right to object to his/her personal data being hosted by a third party, which s/he may exercise by contacting the ALMERYS Data Protection Officer (DPO).

The e-cohort Subject User is advised that personal data processing is carried out in order that s/he may:

- Access the Platform's Public space Services, accessible to all Subjects.
- Register with the e-cohort as an e-cohort Subject.
- Electronically submit an application to participate in a Study in progress that is published on the Personal space.
- Receive a request from an ELA Administrator to participate in Studies.

This being otherwise, the e-cohort Subject cannot create a Personal account on the Platform as made available by the Publisher, nor access Services or Content.

The Data controller may extract statistics using aggregated anonymous data produced within the Platform.

By consenting to join the e-cohort, the e-cohort Subject User agrees to be contacted by Sponsors. Nevertheless, before any personal data is transmitted, a notification is sent to the e-cohort Subject on the Platform, containing a form for obtaining consent.

Personal data is used strictly by:

- Expressly authorised ELA Administrators.
- Sponsors and Investigators, as well as any persons acting on their behalf, who are expressly authorised to receive such information by the e-cohort Subject User through his/her e-cohort consent and by receipt of an email offering participation in a Study.
- Expressly authorised ALMERYS personnel in order that they may carry out technical maintenance and certified health data hosting, in compliance with the certification conditions.

The Data controller guarantees that the User's personal data will not be transmitted to any unauthorised third party without his/her agreement.

The User is advised that, once his/her data is transmitted to a Sponsor, with his/her express authority, the Sponsor will act as data controller, under its own responsibility, for the Study it carries out.

The e-cohort Subject User is advised that his/her personal data is preserved for the duration of the contractual relationship with the Data controller and is then securely archived in the form of anonymous data, in compliance with the provisions of article 36 of the Data Protection Act and the CNIL recommendations within Deliberation n°2005-213 of 11 October 2005 relating to adoption of a recommendation regarding electronic archiving methods of personal data in the private sector ("fixed data").

Further, having granted his/her express prior consent to preserve data *post mortem* through the "administrative file" page, his/her data is liable to post mortem preservation with a view to later potential use for research purposes, subject to the conditions outlined in paragraph 3 of article 56 of the Data Protection Act.

In compliance with the Data Protection Act, the e-cohort Subject User has the right to access, correct, oppose and suppress his/her personal data, which may be exercised by applying to the ALMERYS DPO at the following address: dpo@almerys.com. The e-cohort Subject User is advised that if s/he is a minor at the time data are collected through the Platform his/her personal data will be deleted immediately upon his/her request.

Further, the e-cohort Subject User has rights relating to his/her digital death:

- The right to set general directives relating to the preservation, deletion and sharing of personal data following his/her death, which may be registered with a trusted digital repository certified by CNIL.
- The right to set specific directives relating to the processing of personal data referred to in the general directives, which may be registered with the ALMERYS DPO at the abovementioned address and that are the object of his/her specific consent to this end.

The Data Controller shall implement all necessary security measures in order to guarantee the protection and security of e-cohort Subject Users' personal data, in particular with respect to unauthorised access by third parties.

## 12. Cookies

The Platform is designed to be particularly responsive to Users. It uses cookies for this purpose.

A cookie is a small alphanumeric file deposited on the User's hard drive when s/he connects to the Platform.

The sole purpose of the cookies used in the Platform is to:

- Allow or facilitate navigation within the Platform.
- Collect statistics on Platform usage.
- Evaluate the Platform audience (frequency of visits, number of Subjects registered)

Cookies deposited during Platform use do not enable the personal identification of Users but register information relating to navigation from the User's computer to the Platform, which the Publisher may consult during the User's subsequent visits to the Platform.

Information collected is for the Publisher's exclusive use and is under no circumstances shared with third parties.

### 13. Limitation of liability

The Publisher makes every effort to ensure the operation and security of the Platform, and that any information shown on the Platform is accurate and up to date.

However, despite the care taken to provide Users with available and verified information and/or tools, the Publisher cannot guarantee the exactness, accuracy or comprehensiveness of any information made available to the User within the Platform, or its continual proper functioning and complete cyber security.

The Publisher shall not be held liable for errors, the unavailability of information and/or the presence of a virus on the Platform.

The Publisher reserves the right to at any time modify, temporarily or permanently interrupt all or part of the Platform, and this without giving prior notice to the Users. The Publisher cannot be held liable for any modification, suspension or interruption of the Platform.

The User acknowledges that s/he is solely responsible for his/her use of the Platform, its Services and Content, as well as for any decision taken and for any action carried out in relation to the Platform Services and Content.

The User is advised that any Content is strictly illustrative and is in no way a substitute for a medical consultation or clinical examination.

Consequently, the User acknowledges that the Publisher cannot be held liable for any material or immaterial damage, whether direct or indirect, whatever the cause (including any damages that may be caused as a result of the potential spread of a virus, computer fraud or Internet connectivity constraints or limitations), nor any consequences resulting from:

- Consulting the Platform, its use, any information and use of information, and Content contained therein.
- Use of Services employed via the Platform.
- Being prevented from accessing the Platform, its Services or Content, excluding direct damages resulting from gross or wilful negligence.

Thus, the Publisher shall not be held liable in the event that the Platform, its Services and Content cannot be accessed as a result of events beyond its control that could not reasonably be foreseen and whose effects could not be avoided through appropriate measures, and which prevent the performance of its obligations, in compliance with the legal definition shown in article 1278 of the Civil Code (Force Majeure event).

The performance of these GTUs shall be suspended for the duration of the Force Majeure event, unless the resulting delay justifies the User's termination of registration, and the Publisher shall make every attempt to halt the Force Majeure event or to find a solution that will enable it to perform its contractual obligations despite the Force Majeure event.

In the event that the hindrance is permanent, the User's registration shall be terminated.

Under all circumstances, any Health Professional User who provides a Service shall remain entirely and exclusively responsible for any acts or decisions arising from his/her professional activity, in compliance with all legal, regulatory and ethical obligations bearing upon his/her professional activity.

## 14. Security

In general, maintaining Personal space security requires e-cohort Subject Users to:

- Conform to the security guidelines and, in particular, the rules relating to the setting and amendment of authentication details.

- Respect access management, in particular, to refrain from using another e-cohort Subject User’s authentication details, nor to seek to know this information.

- Keep authentication details strictly confidential and to not divulge these to third parties and, in general, to any third party whatsoever, regardless of his/her professional role or activities

- Notify the Publisher of any technical malfunction experienced and any anomaly discovered, as well as any intrusions.

In particular, the e-cohort Subject User must take all appropriate measures to protect his/her data and materials from contamination by a virus or any other form of attack that might be present within the Platform.

E-cohort Subject Users are advised that any technical interventions on the Platform are carried out subject to the provisions of the Data Protection Act.

E-cohort Subject Users are aware of the risks inherent to the use of telecommunications and this even when secure access is available such as on the Platform, in particular in relation to:

- Unreliability of Internet connections, notably when it comes to data transmission, where applicable.
- Continuity of access not being guaranteed to the Platform, its Services and Content
- Performance not being guaranteed in terms of the volume and speed of data transmission, where applicable, and the spread of any virus.
- Any other technical constraint that is not under the Publisher’s control and responsibility.

The Publisher shall under no circumstances be held liable for these risks and their prejudicial consequences to the e-cohort Subject User, whatever their extent.

## 15. Data amendment and recovery

### 15.1. Amendment and termination by the Publisher

The Publisher reserves the right to modify these GTUs, or the rules relating to Platform use, at any time. Each new version of these GTUs shall be placed online on the Platform and the User will be invited to accept each new version of the CGUs.

The Publisher further reserves the right to develop the Platform, its Services and Content. Technical modifications may be made without prior notice from the Publisher. Further, the Publisher reserves the right to temporarily or permanently suspend access to the Platform, immediately and without any form of compensation.

Each User accepts that the Publisher may immediately terminate his/her access to the Platform without prior or formal notice or indemnity of any kind whatsoever, in the event of any failure to comply with the obligations outlined in these GTUs or with the legislation in force.

Without limitation to the foresaid, the User's registration is particularly liable to termination in the event of:

- Breaches to or infringements of these GTUs.
- Failure to respect a legal or regulatory statute in force.
- An unauthorised connection attempt, fraudulent use of the system or the usurpation of authentication details.
- Voluntary deregistration by the User
- Technical malfunction that has erroneously led to the deactivation of the e-cohort Subject User's registration.

### 15.2. Amendments and termination by the User

Under the Data Protection Act, the User may at any time request the amendment or suppression of personal data. S/he may also shut down his User Account at any time by contacting the ALMERYS DPO at the following address: dpo@almerys.com.

### 15.3. Personal data recovery

**At the request of an e-cohort Subject User who is not involved in a Study**

- The e-cohort Subject User shall address his/her request for data recovery to the ALMERYS DPO at the following address: dpo@almerys.com. Where termination is initiated by the e-cohort Subject User and s/he withdraws his/her request for termination or s/he contests having initiated the request, s/he should simply address an email to the ALMERYS DPO to halt the termination procedure, within 60 days of the notification of termination email having been sent.

- Data are either persevered anonymously for research purposes or archived, in accordance with the e-cohort Subject User's preference.

- During the 60-day period, the e-cohort Subject User is able to download the entire content of his/her Patient file as a printable document from his/her Personal space using the export function. After this date, his/her access to the application will be deactivated.

**Following the e-cohort Subject User's death**

- Where the e-cohort Subject User has, during his/her lifetime, authorised the preservation of his/her data post mortem, his/her Patient file will be preserved in the application and his/her data will be rendered anonymous.

- Where the e-cohort Subject User has not authorised the preservation of his/her data post mortem, these will be archived.

## 16. Proof of acceptance

The computerised records preserved within the Publisher's computer system in the form of encrypted information shall be deemed to be proof of communications and the different written transmissions between Users and the Platform, and the Publisher.

The User acknowledges and accepts that, once s/he is authenticated through his/her Personal space, any expression of intent demonstrated by the use of available functions, and in particular (1) the transmission of his/her consent to his/her health data being collected and processed, and (2) the acceptance of these GTUs, is deemed an electronic signature under the provisions of articles 1366 et seq. of the Civil Code and of articles 1111-25 et seq. of the Public Health Code, and thereby establish his/her consent by demonstrating his/her acceptance.

In accordance with the provisions of articles 1366 et seq. of the Civil Code and of articles 1111-25 et seq. of the Public Health Code, the computerised records preserved under reasonable conditions of security and integrity within the Publisher's electronic file processing servers, and those of his certified health hosting service, are irrefutably deemed to be proof of tasks, exchanges and notifications carried out for the purposes of implementing Services; in particular, for the execution of an electronic signature through the use of authentication details, which are defined as and deemed to be a valid signature and proof in the meaning of the provisions abovementioned.

The preservation and archiving of information and data is carried out by means of a reliable and sustainable system in accordance with the provisions of the Civil Code and the Public Health Code abovementioned.

In consequence of which, in the absence of a clear and proven error by the Publisher or its certified health hosting service, the User may not dispute the admissibility, validity or probative value of any of the abovementioned elements provided in an electronic format or system, on the basis of any legal provision whatsoever specifying that certain documents must be written or signed in order to be valid as proof. Thus, the elements mentioned shall be valid as proof and, if the Publisher and/or its certified health hosting service produce these as proof in any litigious or other proceedings, they shall be admissible, valid and actionable in the same way and under the same conditions and with the same probative value as any other document that might be prepared, received or preserved in writing.

## 17. Applicable Law

These GTUs are governed by French law.
By using the Platform, Users from outside France expressly accept the application of French law.
Consequently, Users acknowledge that, in general, all information shared and/or exchanged on the Platform is prone to be inconsistent or inappropriate for use outside France.

In the absence of an amicable agreement being reached, any dispute relating to the Platform or its use shall be subject to a French tribunal, whatsoever the User's place of residence.

## 18. General provisions

The Publisher may at any time transfer all or part of the rights and obligations set out in these GTUs, and the Platform, to a subsidiary or to a successor.

The User is not authorised to transfer his/her agreement with the Publisher.