# **Service Terms and Conditions**

Version: 1.3.0 Effective date: May 24th, 2018

This document establishes the online contracting conditions of ShareCRF (the "Contract") between INETSYS SL ("Inetsys"), a Spanish company, with NIF B82722224, with registered office at C/ Chile, 4. Edificio 2. Planta baja, oficina 13. 28290 Las Rozas de Madrid, Spain, registered in the Mercantile Register of Madrid, Volume 15.609, Book 0, folio 151, section 8, Page M-262792 and the entity that accepts the terms stipulated in this document ("Subscriber").

This Contract will be valid as of the date on which you check the box for the acceptance of these General Contracting Conditions. If you accept the Contract on behalf of your company or another entity, you represent and warrant that (i) you have sufficient legal authority to bind your company or such entity to these terms and conditions, that (ii) you have read and understood the present Agreement and that (iii) you accept the said Agreement on behalf of the party which you represent.

If you do not have the necessary legal authority to accept the said binding, do not check the acceptance box to accept these General Contracting Conditions and do not continue with the contracting of the Services. This Agreement governs the access to the Services (as defined further below) on the part of the Subscriber and the use they make of the same.

#### **Definitions**

It will be understood by:

- a. User: the natural or legal person who, freely and voluntarily, accesses the platform, irrespective of whether or not they use the services and tools offered there.
- b. **Registered User**: the natural or legal person, of legal age according to the Spanish legislation that enrols or registers in the Platform.
- c. **Subscriber**: any Registered User who has created a Study through the Platform.
- d. **Guest**: any Registered User who has been invited by a Subscriber to participate in a study.

It is possible that the same natural or legal person fits into several of the definitions previously provided. Thus, an Internet user who has created a study through the Platform will be a Subscriber, due to having created a study, but they will also be a Registered User, as that is necessary in order to be a Subscriber and, also, a User, by the mere fact of accessing the Platform.

#### 1. Parties

## 1.1. Inetsys

Inetsys, S.L. (hereafter, Inetsys), with NIF B82722224 and address at C / Chile, 4. Edificio 2. Planta baja, oficina 13. 28290 Las Rozas de Madrid (Madrid), manager of the website accessible through the URL https://www.sharecrf.com (hereafter, ShareCRF or the Platform, indistinctly), an Internet platform primarily intended to allow for the storage and management of information related to clinical trials and/or medical studies.

#### 1.2. The Subscriber

According to the definition provided in the Preliminary Stipulation of these Conditions. Likewise, the Subscriber shall be the one who must comply with the economic obligations of these Conditions relating to Inetsys.

Inetsys reserves the right to verify that the Subscriber meets the characteristics required to be in accordance with the provisions of the Preliminary stipulation and, if that is not the case, to refuse to provide the service.

#### 2. Object and acceptance

The purpose of these Conditions is to regulate the use by the Subscriber of the services offered by Inetsys on ShareCRF, and its performance on the part of Inetsys, in exchange for the anticipated consideration.

Certain characteristics of the services, such as the price or the duration thereof, will vary depending on the options selected by the Subscriber and will be those to which the Subscriber will keep subscribed to ShareCRF at any time.

For the purposes of these Conditions, the said characteristics will be referred to, hereafter, as Particular Conditions.

It will be understood that, by marking the corresponding consent verification box, the Subscriber accepts these General Contracting Conditions. The Particular Conditions selected by the Subscriber at any time will be understood as having been accepted by their mere modification and acceptance by active conduct, that is, by continuing to use ShareCRF once the changes have been communicated.

#### 3. The Services

The services to be provided by Inetsys consist of the provision of a series of tools for carrying out one (1) clinical trial or medical study and the management of all the information collected.

In particular, the tools that Inetsys makes available to any Subscriber cover, in broad terms:

- a. Capture of electronic data for clinical and similar trials.
- b. Design of the variables that one wishes to be captured.
- c. Intuitive interface for the entry and validation of data.
- d. Data audit system that allows for complete traceability of any modification of the data.
- e. System of queries over the collected data
- f. Export of collected data.
- g. Import of data by means of file.
- h. Invite any Internet user to participate in clinical trials, either including relevant information or personal information.
- i. Generate user profiles, with different permissions and functions, in order to assign them, afterwards, to the users invited to participate in the trial.
- j. Test environment that allows validating the changes in the design of the variables that one wishes to be captured.

The tools and features available to the Subscriber on ShareCRF will depend on the plan you select.

The first thirty (30) days from the creation of the study will be free for the Subscriber and the latter will have access to the tools and functionalities that Inetsys offers on ShareCRF in the context of the broadest plan.

Once the said trial period has elapsed, the Subscriber must select the characteristics of the service (Particular Conditions) that are of interest to them

through the options enabled for this purpose on the Platform. Otherwise, it will be understood that the Subscriber does not wish to continue with the service, and its relationship with Inetsys is terminated with respect to the study created and the present General Conditions of Contract shall be rendered null and void.

The study and all associated information included on ShareCRF by the Subscriber and by any Guest to the study will be blocked; The Subscriber will have to have exported the information that is of interest prior to the end of the trial period.

In principle, after the trial period, Inetsys does not limit the possibility for Registered Users to generate a new study, taking advantage of the corresponding trial period for the same. However, if Inetsys detects that a Registered User may be abusing the trial period offered by Inetsys with each study created, it may limit or block the User's access to the Platform.

After the trial period, the duration and characteristics of the services will be those selected by the Subscriber on the Platform, from among the possibilities offered there at any time.

If the Subscriber, during the term of an ongoing period, modifies the subscription frequency, the new subscription fee less the pro-rata fee for the previous period being utilised would be charged at the time of the change.

If the Subscriber does not change the length of the period of the subscription and only changes the plan associated with the subscription changes:

- a. To a lower plan, a credit in favour of the Subscriber would be generated for the amount proportional to the remaining time to complete the subscription period from the moment when the Subscriber modified the plan and the difference between the previous plan and the new plan chosen. The said credit is not refundable but may be exchanged by the Subscriber in the future, with respect to the same study with which it was generated, to improve the contracted plan or for the renewal of the current subscription period.
- b. To a superior plan, as long as the automatic collection system allows it, the proportional amount would be charged to the remaining time to complete the subscription period from the moment when the Subscriber modified the plan and the difference between the previous plan and the new plan chosen. If the automatic collection system does not allow the

transfer described above, a credit in favour of Inetsys is generated for the above amount, and it will be charged in the following subscription period.

# 4. Contracting process

The contracting process is as follows:

- a. The Registered User must access ShareCRF and click on the button designed to create a study.
- b. You must then enter the information that may be required for the purposes of the study, and, after accepting these General Contract Conditions, generate the study.
- c. Once this is done, Inetsys will confirm the acceptance of these Conditions by the Client.
- d. From this moment, except in the event of force majeure, the service must be made available through ShareCRF.
- e. Before the end of the trial period, the Subscriber must choose the characteristics of the service as provided above and, depending on the frequency selected, allow for the collection of the corresponding amounts by Inetsys.
- f. In that event, Inetsys will send the corresponding invoices to the Subscriber. By accepting these Conditions, the Subscriber agrees to receive an invoice electronically. At any time this can be objected to by writing to info@sharecrf.com. In this case, Inetsys will send you a paper invoice to the address you have indicated.

## 5. Pricing policy

During the trial period, the enjoyment of the service will be free of charge.

Once the trial period has elapsed, the price will be that which corresponds to the duration and the plan selected by the Subscriber at any moment in the corresponding section of ShareCRF, which will be considered as Particular Conditions for the purposes of these General Contracting Conditions. These subscription requests and their changes will be recorded by Inetsys and will constitute proof of their acceptance.

While these Conditions remain valid, any change by the Subscriber of the temporary conditions or a change of the selected plan may result in additional charges or credits in favour of the Subscriber as provided in Stipulation 3 above.

Any credits in favour of the Subscriber shall in no event entitle the Subscriber to recover the amount paid but may be used by them to improve the plan or the duration selected at any time with respect to the study to which they refer. Otherwise, the credit will be imputable to the renewal of the current period. Such amounts cannot be imputable to another study, and in no case will they be returned by Inetsys in the event that the Subscriber wishes to terminate the study and terminate these Conditions.

All prices are fixed by Inetsys and are shown in EUROS but do not include any applicable taxes that should be, if applicable, paid by the Subscriber. Inetsys cannot determine in advance the taxes that will be applicable since it will depend on whether or not the Subscriber is a consumer or user and the place from which the subscriber contracts. Once the Subscriber has entered this information in the appropriate form, the Subscriber will be shown the information related to the taxes that must be paid. It is possible that promotions, discounts, etc. are offered. Such circumstances will be duly informed to the Subscriber, as well as any applicable conditions in this event.

## 6. Obligations

#### 6.1. Under these Conditions, Inetsys is obligated to:

- a. Put their best efforts in the performance of the tasks appropriate and necessary for the provision of the services to the Subscriber.
- b. Comply with any other obligations contained in these General Contract Conditions or in any other conditions that may become applicable.

#### 6.2. By virtue of these Conditions, the Subscriber undertakes to:

- a. Pay, in due time and form, the corresponding amounts, including taxes, charges and any other costs specified during the contracting process.
- b. Respond authentically and accurately with whatever data that they have been provided in order to formalise the contract.
- c. Assume the responsibility flowing from not fulfilling the conditions that Inetsys requires them to meet to hold the status of Subscriber.
- d. Obtain the consent of the recipients of the invitations to register on ShareCRF which the Subscriber sends through the Platform or by external means to send them or to invite a third party to register as a Registered User of the Platform, and assume the responsibilities that flow

- from any incorrect treatment of their personal data or the non-consensual submission of commercial information by electronic means.
- e. Inform the Registered Users whom the Subscriber has invited to participate in a trial of the terms and conditions applicable and of the processing of their personal data, in compliance with any legislation that is applicable, and urging them to expressly accept them to the extent that is necessary or appropriate.
- f. Refrain from uploading data or information onto the Platform that violates the exclusive rights or the honour and personal and family privacy of third parties and/or breaches the regulations on intellectual property, industrial property, honour and protection of personal data.

  Any information that identifies or allows the identification of a natural
  - Any information that identifies or allows the identification of a natural person uploaded onto the Platform by the Subscriber must be uploaded after having informed the person to whom the reference is made and with their consent, in accordance with the provisions of the legislation on data protection.
  - With the acceptance of these General Conditions of Contract, the Client assumes any responsibility flowing from the information stored on and managed through the Platform, exempting Inetsys, who in no case controls or verifies its content and legality, from any responsibility, by limiting its function to the provision of a data hosting and storage service.
- g. Fulfil any other obligations included in these Conditions or in any other conditions that may become applicable and assume any liability arising from any breach, leaving Inetsys completely indemnified.
- h. in general, act in good faith and in a fair manner towards Inetsys and Registered Users of ShareCRF.
- i. Refrain from using the data and personal information of the Users to which they have access under these Conditions for purposes other than those provided herein, without having informed them in advance and without having obtained their consent. In particular, by way of example, refrain from using such information to offer advertising or commercial information.

#### 7. Data Protection

ShareCRF allows the Subscriber of the study in the platform to define what type of data they would like to collect in the case report form created through our service. This data, in addition with other data related with the management of the study configure what we define as Client's Data. The Client's data is property and responsibility of the Subscriber of the study. The Subscriber of the study is

responsible for the treatment of this data according to the General Data Protection Regulation (UE 2016/679). ShareCRF does not know much about the type of data collected in each study and is in charge of processing the data according to the General Data Protection Regulation (UE 2016/679). ShareCRF platform allows Subscriber to manage the data collected from their studies autonomously, allowing them to fulfil the obligations they acquire according to the type of data collected in front of the interested parties.

ShareCRF has developed all the technical and organizational systems and measures possible, established for the regulations on the protection of personal data to prevent loss, misuse, alteration, unauthorized access and theft of personal data provided by the user or visitor.

The ShareCRF servers are hosted within the European Union, in the infrastructure owned by Amazon Web Services, guaranteeing high-security standards (both physical security of the facilities, backup copies, security of the network and the services of storage).

# 8. Order of treatment according the General Data Protection Regulation (UE 2016/679)

#### 8.1. Inetsys as processing manager

The personal data that the Registered Users provide when participating in a clinical trial or medical study created or managed by the Subscriber or the data entered by the Subscriber themselves in relation to a trial or study will be the responsibility of the Subscriber, with Inetsys being understood as a mere person in charge of the processing according to the provisions below. The same applies to the personal information that the Subscriber may upload onto the Platform and to any other personal data that may be processed by Inetsys as a consequence of the provision of services to the Subscriber.

#### 8.2. Processing and confidentiality

Inetsys will only process such data in accordance with the instructions of the Subscriber and for the provision of the contracted services and will not apply them or use them for purposes other than those described in these Conditions, nor will they communicate them, even for their conservation, to other persons, unless such assignment has been previously and expressly authorised by the Subscriber. Inetsys undertakes to keep secret any data to

which it may have access in connection with the provision of any service to the Subscriber.

#### 8.3. Subcontracts

The performance of certain services of ShareCRf.com may require the subcontracting by Inetsys of certain services to other companies. The Subscriber authorises Inetsys to subcontract to third parties the provision of any service that involves the processing of personal data within its responsibility. Any third party subcontractor may be substituted in its obligations by other service providers without the need for authorisation from or prior notice to the Subscriber, by decision of Inetsys. However, Inetsys will notify the Subscriber of any incorporation or replacement and will ensure that these providers comply with the same obligations on data protection as Inetsys.

## 8.4. Security measures

Inetsys undertakes to implement technical and organisational security measures, appropriate to the level of the data to be processed, responsibility of the Subscriber, in order to guarantee the security of the data responsibility of the Subscriber and to prevent its alteration, loss, unauthorised processing or access.

In connection with the above, Inetsys will create backup copies of the information and will work to allow for the recovery of lost data In the event of failure or error in the systems. The retrieval of information that has been deleted by a Subscriber or by an employee or user of the data thereof is not susceptible to be recovered, although Inetsys offers a payment information retrieval service, as provided in the following stipulation.

#### 8.5. Destruction of data

At any time the Subscriber may require Inetsys to completely eliminate the information related to a clinical study, in which case it will no longer be accessible and will be totally irrecoverable for the Subscriber. To make this request, the Subscriber must send Inetsys an email to that effect directed to info@sharecrf.com

# 8.4. Communication and transparency with the data responsible

In the functions of treatment manager Inetsys is committed to:

- When the affected persons exercise their rights included in the data protection regulations, inform the responsible party as soon as possible, together with any other information that may be relevant.
- In the event that Inetsys is aware that there has been a violation of data security that constitutes a risk to rights and freedoms, it will notify the data responsible without undue delay.
- Make available to the person responsible all the necessary information
  to demonstrate compliance with our obligations, as well as our
  availability for the performance of audits or inspections carried out by
  the person in charge or another auditor authorized by them and could
  not be more than one every twelve months.

#### 9. Information retrieval service

When the Subscriber wishes, as provided in the previous stipulation, to retrieve information in relation to a study removed from the Inetsys systems, they must write to Inetsys at the email address info@sharecrf.com indicating the information they want to recover and the last date on which the deleted information still existed. To contract this service it is essential that the Subscriber has provided the details of a bank card in the payment section of their profile on ShareCRF.

Inetsys will respond to the Subscriber with the cost of retrieving the information, the performance deadlines and other service features. If the Subscriber agrees, they must confirm that to Inetsys. Once confirmed, Inetsys will proceed to collect the corresponding amount and recover the information within a maximum period of two working days (as applicable in the city of Madrid), sending the Subscriber an email confirming the recovery once it has been carried out and sending the corresponding invoice in electronic format. The Subscriber agrees to receive an electronic invoice by accepting these Conditions. The Subscriber can withdraw the said consent by writing to that effect to info@sharecrf.com.

The recovery of information implies substitution of the database at the given moment by the database as it was on the date indicated, which means that the information entered between the one and the other date would be lost, and must be entered manually by the Subscriber.

## 10. Intellectual and industrial property

The Subscriber will keep all the intellectual and/or industrial property rights that it has over the contents that they enter onto the Platform, by themselves or through Registered Users that they invite to participate in trials.

Notwithstanding the above, Inetsys shall be bound, by virtue of these Conditions, to use the distinctive signs that identify the Subscriber or its products and/or services in the market in order to promote ShareCRF on the Platform itself.

# 11. Exclusion of responsibility

Inetsys shall do its best to ensure that the provision of services runs without incident, although it cannot guarantee that there will be no errors or incidents, especially of a technical nature. Inetsys will not be responsible for the consequences arising from such errors or incidents when they derive from the actions or omissions of third parties or when they could not have been foreseen by Inetsys.

Inetsys does not guarantee the utility of the services for the Subscriber.

Under no circumstances will Inetsys assume any responsibility for the consequences arising from the conduct of the Subscriber and/or Registered Users on the Platform. In particular, only by way of example, Inetsys will not be responsible for:

- a. The information provided by the Subscriber for the provision of services or for errors in the same.
- b. The information that Registered Users provide with their enrolment on the Platform or during the use of it.
- c. Infringements of exclusive rights or breach of current legislation or these Conditions by the Subscriber or by the Registered Users.
- d. The way that the Subscribers treat the Registered Users on ShareCRF and vice versa.
- e. The participation of Registered Users in clinical trials generated by the Subscriber.
- f. Any relationship arising between the Subscriber and any Registered User as a result of the use by both of ShareCRF.

Regarding the content hosted by the Subscriber on the Platform, Inetsys is considered, in accordance with article 16 of Law 34/2002, of July 11, on

Services of the Information Company and Electronic Commerce as a provider of hosting services or data storage, thus it assumes no responsibility for any activities or any information stored as a result of the Subscriber's enjoyment of the services contracted.

Inetsys does not supervise or control the content of the Subscriber. However, if for any reason Inetsys knew or had an indication that the referred information or content constitute or imply any infringement of the legislation or rights or interests of third parties (intellectual property, industrial, image rights...) or the competent authority urged Inetsys to eliminate them, Inetsys will proceed to withdraw or block them, provisionally or definitively, as appropriate.

The Subscriber declares that they make use of the services provided by Inetsys at their own risk, the activity of Inetsys being limited to the provision of a series of tools for the construction and management of electronic CRD.

In any event, the responsibility assumed by Inetsys in no case includes the loss of profit and will be limited, in each case, at most and for any reason, to the total amount received by Inetsys in consideration for the services.

## 12. Compensation

The failure by the Subscriber to comply with these Conditions or any other that may become applicable may cause harm and prejudice to Inetsys. In this sense, the Subscriber will be required to provide compensation for any damage, prejudice, loss or cost (such as attorneys' and prosecutors' fees).

Likewise, if the failure by the Subscriber gives rise to any type of claims or proceedings against Inetsys, the Subscriber should indemnify Inetsys for them, the latter being able to reclaim any expense, cost, damage or harm derived from the failures.

#### 13. Modifications

Inetsys reserves the right to make modifications of any kind to ShareCRF, whether relating to its appearance or interface, the code, in the implementation, etc.

Any change in these Conditions will be communicated by Inetsys to the Subscriber, who must accept it. Otherwise, it is understood that the Subscriber

wishes to prevent the extension of the contract in the terms provided in the following stipulation.

## 14. Duration and resolution

These Conditions come into force from the moment they are accepted by the Subscriber and their duration will be that which corresponds to the Particular Conditions at any time, automatically renewable for identical terms, unless either party communicates its intention to the contrary, at least 30 days before any of the renewals. The Subscriber may modify the duration period at any time that subsequently selected being applicable with immediate effect and being subject to automatic renewals for the same terms. In the event that the Subscriber has not selected a duration period and, in such circumstances, made a payment, the duration will be 30 days, which corresponds to the trial period that Inetsys offers.

Notwithstanding the above, the Subscriber may request the dissolution of the agreement made under these Conditions at any time, without the right to recover any amount paid, communicating it to Inetsys by an email to the address info@sharecrf.com.

Inetsys may unilaterally dissolve the agreement made under these General Conditions of Contract In the event of a situation of liquidation, either by judicial order, or by the adoption of a social agreement or, otherwise, when the business related to the provision of the service becomes economically unfeasible. This will not give the right to economic compensation of any kind.

Inetsys may also dissolve the agreement made under these conditions unilaterally in the event of serious or repeated breach by the Subscriber of the provisions of these Conditions or the applicable Particular Conditions, without the right to financial compensation of any kind and without a refund of any amount paid by the Subscriber.

Notwithstanding the above, there are obligations that, by their nature, endure, including after the contract has ended. Once the service period has finished, all the information will be available to the Subscriber for seven more days in order that the latter may resolve any outstanding issues, modify data, etc. Once the said period has elapsed, access to the study created by the Subscriber will be blocked and Inetsys will keep the corresponding data stored in the system for a period of three months from the end date of the service period. After this time,

Inetsys will completely eliminate any information related to the study stored in their systems.

#### 15. General issues

# 15.1. Safeguard and interpretation

The present General Contracting Conditions and the Particular Conditions accepted constitute a unique agreement between the Subscriber and Inetsys.

In the event of any contradiction between the provisions of these Conditions and any other conditions agreed between the parties, the terms and conditions of these Conditions will take precedence over what is provided in them unless the stipulations included in them expressly establish otherwise.

The fact that any of the parties, due to impossibility or convenience, does not require strict compliance with any of the terms of these Conditions at any given time, does not imply nor can it be interpreted as a total or partial modification of the same, nor as a waiver on their part to demand compliance in strict terms, in the future.

The declaration of nullity of any or some of the Stipulations of these Conditions by a competent authority will not prejudice the validity of the remaining ones. In such an event, the contracting parties undertake to negotiate a new stipulation in substitution of the annulled one with the greatest possible similarity with it. If a replacement becomes impossible and the stipulation is essential for these Conditions, in the opinion of the party harmed by its elimination, the latter may opt for the dissolution of the agreement concluded under the Conditions.

Any reference made in these Conditions to an article or a regulatory norm that is repealed shall be understood as made to the equivalent provision that replaces it.

#### 15.2. Assignment and delegation

The Subscriber may not assign or delegate the rights granted in these Conditions or the obligations assumed by them without the express consent of Inetsys and the entity receiving the rights and obligations that are being granted. Any assignment and/or delegation that do not have such consent will be null.

Inetsys may assign or delegate its rights and obligations contained in these Conditions totally or partially and in a completely free manner without the need for prior notice. Inetsys may also, for the purposes of any legal transaction, substitute the host of this legal relationship for anyone else.

## 15.3. Language

The language applicable to these Conditions is Spanish. If versions of the same have been offered in other languages, it has been as a courtesy, for the convenience of the Subscriber. The latter expressly accepts that they will always be governed by the Spanish version.

If there is any contradiction between what the Spanish version of these General Contracting Conditions says and what one of the translations says, in any case, the Spanish version will take precedence.

## 15.4. Legislation and jurisdiction

The relations between Inetsys and the Subscriber arising as a result of the acceptance of these Conditions will be governed by Spanish legislation and jurisdiction.

To the extent that the Subscriber does not perform the role of consumer and user in accordance with the applicable regulations, the parties will submit, expressly waiving any other jurisdiction that may apply, unless by law a different jurisdiction is determined imperatively, to the Courts and Tribunals of Majadahonda.