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## *SMART-TRIAL License agreement v3*

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### **1. Introduction**

**DISCLAIMER: NOTICE THAT THE ENGLISH VERSION OF THE LICENSE TERMS IS A TRANSLATED VERSION. THEREFORE, THE DANISH LICENSE TERMS GOVERN THE ENGLISH VERSION IN ALL CASES. IN THE CASE OF MISENTERPRETATION OR CONFUSION REGARDING THE LICENSE TERMS, PLEASE CONTACT MEDEI APS.**

**SEE DANISH VERSION ON [https://www.smart-trial.co/licenseagreement\\_dk.pdf](https://www.smart-trial.co/licenseagreement_dk.pdf)**

The present License Agreement determines the terms and conditions governing licensing of SMART-TRIAL online products, distributed by MEDEI ApS, Svendborgvej 5, 9220 Aalborg Øst. Additional services bought by Licensor from Licensee are automatically included in the present License Agreement, unless a separate agreement is in place for such services.

#### **1.1 Definition**

The present License Agreement uses the following definitions:

“License” The Parties’ agreement on the Licensed, as it appears from the order confirmation, created upon entering the agreement.

“Licensor” MEDEI ApS

“Licensee” The Customer which has entered an agreement with Licensor on the supply of the Licensed.

“Users” Anyone who has access to the Licensed product, including employees, students and other users.

“the Solution” Those of Licensor’s online products covered by the license agreement, which Licensee pays a license fee for, and is subject to these license terms.

“The License” Licensees right to use the Solution, which he achieves by accepting the License Agreement, receiving the order confirmation, and paying the license fee, see paragraph 2.1.

“License Terms” The present license terms and appendix hereto, as well as any subsequent additions or amendments hereto, including price changes.

## **2. Extent of License rights**

### **2.1 Users right to use the Solution**

Upon acceptance of the License Terms and payment of the License fee, the Licensee achieves a limited, non-transferable and non-exclusive right to use the Licensed and any subsequent updates of the Licensed in accordance with the License Terms.

The user rights only allow the Licensee to use the Solution in relation to the normal use of structuring and planning a clinical trial as well as collect, store, and export clinical data from patients/trial subjects. The Solution can also be used for Licensee's collection of sensitive personal information, for example in relation to patient recruitment.

Information and data, which make up all of or a part of the Solution used by Licensee, shall not be used in or for business purposes which compete with Licensor.

The Solution or parts hereof can under no circumstances be disclosed or otherwise be made available to third parties.

Unless otherwise expressly provided, the Licensee may not and must not allow any third party in any way to alter the Solution or other materials delivered/supplied by Licensor.

### **2.2 Technical requirements for use of the Solution.**

Licensee is responsible for providing and installing the necessary browser software for presentation of the Solution. Licensee is recognizing that the usage of the Solution is dependent on the Licensees choice of browser software. Licensee can obtain information of which browser software can be used to display the Solution through contacting Licensor. Licensor is entitled without notice to change its software with the effect that Licensee needs to obtain and install a new browser software. Licensee is also responsible for connecting to Licensor's server and reestablishing and maintaining such a connection.

### **2.3 Compliance with License Terms**

Licensee is committed to ensuring that Licensee's Users are informed about and comply with the License Terms, and respect Licensor's intellectual property rights, hereunder copyright. Licensor is entitled at any time to review Licensee's usage of the Solution in order to ensure that the License Terms are complied with. Licensee must in that context ensure that Licensor gains access to Licensee's physical environment and third party software, which Licensor needs to ensure the compliance with the License Terms.

## **2.4 Right of Cancellation and refund**

Licensee acknowledges that any rights of cancellation and refunds end when the Solution is activated. Licensee therefore agrees that the right of cancellation only can be exercised until the time when the Solution is activated. A Licensee, who is not a customer, has no rights of cancellation.

## **3. Exercising the usage rights**

The usage rights are accessed via a personal password in combination with an e-mail or text message verification.

### **3.1 Access via personal password**

Entitled to use the Solution is only the User(s) that Licensor under the License Terms stated in the present License Agreement have created a personal user profile with a personal password. A User may only login to the Solution from a single device (e.g. PC, tablet, phone) at a time.

Licensee and its User(s) shall not allow third parties to access the Solution through online services, internet, intranet or otherwise, as Licensee and its users are not allowed to inform third parties of their personal login information.

If Licensee is a company, public or private institution, organization, etc. Licensee may not disclose other staff than Users, who have created a personal user profile with a personal password, access to The License via online services, internet or intranet, likewise, Licensee cannot disclose his personal password to other staff or users.

## **4. Updates and amendments to the Solution**

Licensor has rights to regularly update and amend the Solution when Licensor deems it necessary. Such an update or amendment do not restrict or provide changes in Licensee's obligations to Licensor. Furthermore, such updates or amendments to the Solution do not provide Licensee with a right to claim breach of contract against Licensor.

Licensor is also entitled to make changes to the functionality of the Solution, including removal and or changes in functions, which Licensor deems necessary to provide the best possible service to its customers. Only Licensor determines the functionalities, which meet this requirement. Such changes in the functionality of the Solution entails no restrictions or changes in the Licensee's obligations to Licensor, such as any changes of the Solutions do not give Licensee a right to claim breach of contract against Licensor.

## **5. Rights**

## **5.1 Rights to the Solution**

Licensor, or a third party from whom Licensor derives its rights, has copyright and every other right to the Solution including html-code, text, images, or other elements, which Licensee might gain access to through SMART-TRIAL. The copyright also includes any physical materials, including user manuals and training materials provided by Licensor to Licensee. Licensee shall respect Licensor's rights and Licensee is responsible without amount limitation for infringement of these rights, including unauthorized disclosure of the Solution with third parties.

Licensee shall not break or modify any security mechanisms, including access codes. If it is necessary to reset the access code, this shall be done through the integrated reset-password functionality in SMART-TRIAL. Licensee may not alter or remove entries in the Solution on rights, conditions, trademarks, product information or the like.

## **6. Payment for the Solution**

### **6.1 License fee**

License fee of EUR 899,00 excl. VAT is paid per month in advance where Licensor bills once a month.

The purchase of a monthly subscription allows MEDEI to charge EUR 899,00 excl. VAT on the first bank day after the expiry of the present subscription period, until the Licensee or the Licensor terminates the subscription.

### **6.3 Payment**

Licensor's collection of payment occurs upon activation of the Solution (start study), but not later than 14 days from Licensee's purchase.

If the Licensee fails to make payment within the specified period for payment on the outstanding amount, an interest rate shall be added in accordance with the Danish Interest Act.

Licensor reserves, in addition to rights under section 12, paragraph 3, the right to temporarily disable access to the Solution, if the Licensor does not receive timely payment of license fee from the Licensee. Licensee is not entitled to a refund of the license fee as a result of lack of access to the Licensed when closing the access to the Solution was due to Licensee's non-payment of license fee.

## **7. Fault rectification**

The Solution is licensed as-is without warranty of any kind. Licensor does therefore not guarantee that the Solution and its connection/communication with the Licensee will be uninterrupted and error

free. Licensor makes continuous testing of the Solution but cannot rule out the possibility that the Solution, as any software that is made available online, contains errors and discrepancies. Such errors do not provide Licensee with a right to claim breach of contract against Licensor or give Licensee rights to obtain amendments from Licensor. Licensor strives to ensure that all errors and discrepancies in the Solution are addressed, but does not warrant that any error and inappropriateness will be corrected.

## **8. Support**

### **8.1 E-mail support**

Licensee is entitled to support by e-mail from Licensor. The support is only given in relation to the Solution and not to interaction with Licensee's computer equipment, browser, applications, applications, etc. Licensee is only entitled to receive support in Licensor's normal business hours, at any time seen from Licensor's website.

Furthermore, Licensee is encouraged to seek help from SMART-TRIALS official help page: [help.smart-trial.co](http://help.smart-trial.co)

## **9. Liability and compensation**

Licensor is responsible for product damage in accordance with the provisions of the Danish Product Responsibility Act (Produktansvarsloven), which cannot be derogated from upon agreement, but disclaims product liability on any other basis.

Licensor shall not be liable to Licensee for any indirect or consequential damages arising from the Solution, including operating losses, loss of anticipated profit, loss and/or damage of data, loss of goodwill as well as all other forms of consequential damages. Here within can Licensor, never be held liable for errors in Licensees research, which are a result of an error/defect in the Solution.

Licensor is not responsible for losses that might arise as a result of Licensee's inability to use the Solution, regardless of the cause hereof and regardless of Licensor previously being advised of the possibility of such as loss.

Licensors liability for loss or damage shall in no event exceed an amount equivalent to the license fee that Licensee has payed to Licensor in the license period during which the damage may have occurred.

Licensor disclaims any liability for loss or damage attributable to Licensee's own connection to Licensor's services, including lack of connectivity, system crashes, etc. This also applies to Licensee's other computer equipment, browser software, etc.

Licensor disclaims any responsibility for seeking informed consent to the processing of personal data by Licensee's patients/research subjects, and related tasks.

Licensee's breach of terms gives Licensor rights, in addition to fees for incorrect/unauthorized use of the Solution, to claim compensation in accordance with Danish Law.

## **10. Force majeure**

Neither Party shall, in relation to the present License Agreement, be held responsible for the other Party in respect to matters which are beyond the Party's control and which the Party could not have taken into account when accepting the License Agreement and could not have avoided or overcome. These matters include but are not limited to strike or other workforce related complications, over which the Parties have no control, fire, war, riot, mobilization or unforeseen military calls, monetary restrictions, lack of transport, lockouts, limit of products, restriction of assets, shortcomings in delivery, virus in the Solution, or delays from sub-contractors.

## **11. Transfer of rights**

Licensee cannot, without Licensor's written consent, assign its rights and liabilities under the License Terms to a third party.

## **12. Duration, termination, and cancellation**

The license agreement runs until either party terminates the agreement. Termination may happen at any time, but no later than 14 days before expiry of the current subscription period. The termination takes effect from the next subscription period. When Licensee has concluded his study his subscription is ended, as long as Licensee uses the "Delete Study" or "Cancel subscription" functionality in the Solution.

Furthermore, termination has to occur via e-mail to [support@smart-trial.co](mailto:support@smart-trial.co)

Licensor is entitled without notice to terminate the license agreement if Licensee fails to comply with the License Terms.

In the absence of payment, including absence during automatic renewal of subscription, Licensor reserves the right to immediately suspend Licensee's access to the Solution, including Licensee's possibility of accessing/viewing/exporting data. Licensee gains access to the Solution upon payment of arrears. Licensor will inform Licensee of a non-payment and requests such payment through e-mail. Licensee will continue to have access to invoice information and personal information via the Solution.

Licensor shall be entitled, without notice, to immediately terminate the License Agreement in the case that Licensee's use of the Solution exercises a disproportionate burden on Licensor's service compared to Licensor's expectation upon entrance of the License Agreement. Licensee is in such a case entitled to be refunded the excess prepaid license fees for the remainder of that in section 6. mentioned 1 or 12 months' period.

### **13. Changes to License Terms**

Licensor may at any time change the License Terms, including making price changes. However, such amendments shall be notified to the Licensee at least 14 days before expiry of the current subscription period. Licensor's notice must contain and specify the changes. Any changes in License Terms, including price changes, take effect from the next subscription period.

If Licensee does not wish to be bound by the revised License Terms, Licensee shall, in writing, and within 14 days before the expiry of the current subscription period inform Licensor that the revised License Terms cannot be accepted. The License Agreement is subsequently deemed terminated by Licensor's notification of change in the License Terms in accordance with the License Agreement's section 12 paragraph 1.

If the Licensee has not informed Licensor within 14 days before the expiry of the current subscription period that the changes in the License terms cannot be accepted, the License Agreement is deemed accepted and continues in accordance with the new License Terms.

### **14. Information Processing**

Licensor will in relation to the Solution collect and process information about Licensee, its Users', and their use of the Solution. Furthermore, Licensor will process personal information, including data on personal businesses, which Users might enter into Licensor's systems.

Licensor does not collect informed consent from patients/research subjects on behalf of Licensee or its Users, in regards to sensitive personal and/or health information, which Licensee or its Users might collect/obtain. It is emphasized that the Licensor shall only be considered a data processor (Databehandler) in accordance to the Danish Act on sensitive personal information (Persondataloven) §3, paragraph. 5, and that Licensee in this context is considered data Responsible (Dataansvarlig) under the Danish Act on sensitive personal information (Persondataloven) §3, paragraph. 4.

Licensor shall take appropriate technical and organizational security measures to protect data from accidental or illegal/unlawful destruction, loss, or alteration and against that, they come to the knowledge of unauthorized persons, are abused or otherwise processed unlawfully in regards to the Danish Act on sensitive personal information (Persondataloven).

The processing of information aims to provide Licensor with the opportunity to ensure that the License Terms are complied with. Furthermore, the processing of information occurs in order to ensure that Licensor can adequately analyze Licensee's use of the Solution with the intention to provide Licensee with optimal services through the Solution. Lastly, the processing of information is conducted for statistical purposes in order for further commercial development of the Solution as well as for Licensor's marketing of the Solution to Licensee.

Each User will at first login to the Solution be presented with a User's consent for treatment of his personal information, which must be accepted before the User can gain access to the Solution. The conditions of the consent can be seen in Appendix 1 in the present License Agreement.

The consent includes processing of the following information: Licensee's full name, User's initials, User's e-mail addresses, User's mobile number, staff ID, organization name, department, address, used IP addresses, login-date (year-month-day-hour-minute-seconds), as well as actions conducted by Licensee and Users in the SMART-TRIAL solution and its servers, hereunder search words, clicks, prints or copies of documents. Licensor will store collected information for at least two years and Licensee or his License User's cannot request Licensor to delete any of their data due to security measures.

Licensee and Licensee's Users can request information on which data is being processed, as well as Licensee can upon request have misleading information corrected/deleted.

Processed information will not be disclosed to third parties.

Licensor constantly updates and verifies the information to ensure the accuracy of processed information. Furthermore, Licensor ensures that processing of information occurs in a data environment that meets present safety requirements.

Licensor cannot perform a "right to be forgotten" deletion on individual study subjects/patients/participants. Licensee is in all cases responsible for performing this individually within the system itself by using delete methods (delete subjects) available.

## **15. Danish E-commerce Act disclosure requirements (E-handelsloven)**

Licensor shall comply with all disclosure obligations which law on services in the information society require, hereunder certain aspects on laws on electronic trade (e-handelsloven). In order not to complicate communication between Licensee and Licensor, the e-commerce act (e-handelsloven) §§ 10, 11, paragraph 1 and 12 are waived to the extent possible, cf. the e-commerce Acts § 13, paragraph 2.

## **16. Contractual Basis**

The entire contractual basis consists of the order confirmation and License Terms of the present License Agreement.

In the event of ambiguities, the following hierarchy between the dossiers is valid, in that the order confirmation shall prevail over the License Terms.

1. Order confirmation, or a document, which in its wording reads in its stead.
2. License Terms

## **17. Governing Law and Jurisdiction**

The present License Agreement is subject to Danish Law. Any disputes arising in connection with the License Agreement, including disputes regarding its existence or validity, shall be settled by the court of Aalborg (Byretten i Aalborg)

## **Appendix 1 to the License Terms**

Users will at first login to the Solution be presented with a User's consent for treatment of his personal information, which must be accepted before the User can gain access to the Solution. This consent is reproduced below for Licensee's information.

### **Consent for processing personal data**

I hereby declare that I have been informed, that Licensee has entered a license agreement with MEDEI ApS, Svendborgvej 5, 9220 Aalborg Øst ("Licensor"), in relation to my use of Licensor's product ("SMART-TRIAL").

In order to use SMART-TRIAL I have created a personal user profile with a personal password, which I shall use for login.

I hereby accept that Licensor collects and processes information of my use of Licensor's SMART-TRIAL.

I am informed that the processing of my information is intended to provide Licensor with the opportunity to ensure that my SMART-TRIAL License Terms, and possible employer License Terms are respected. Furthermore, I am informed that the processing of my information is intended to provide Licensor with knowledge of Licensee's use of SMART-TRIAL. Finally, I am informed that the processing is due to security- and statistical-purposes for further improvement, and commercial development of Licensor's product SMART-TRIAL.

I understand that the processing includes the following information: My full name, my initials, my e-mail address, my mobile phone number, staff ID, organization name, department, IP-addresses from where I have logged into SMART-TRIAL, timestamps of my login (year-month-date-time-minute-second), as well as all interactions I execute with SMART-TRIAL and Licensor's server(s), hereunder for example input search words, clicks on links, print outs, copying, etc. I also understand that Licensor stores such information for at least two years, and I cannot request Licensor to delete my data or user profile, due to system security measures.

I have been informed that Licensor, on my request, will inform me of which information are being processed, and Licensor will upon my request conduct corrections of any incorrect or misleading information.

I have also been informed that the information will not be disclosed to any other third party, other than my "Study collaborators" or "Study Owner".