

## Master Service Agreement

Version 1.4

This Master Service Agreement (“Agreement”) governs client’s (hereinafter referred to as “Client”) use of the Castor Services and applies to any and all agreements between Client and Ciwit B.V., a private company with limited liability, with its registered office at Fred. Roeskestraat 115, 1076 EE, Amsterdam, The Netherlands and registered with the Dutch Chamber of Commerce under file number 54723655 (hereinafter referred to as “Castor”),

Castor and Client may hereinafter together be referred to as “**Parties**” and individually referred to as a “**Party**”.

In consideration of the mutual covenants and promises set forth herein, and other valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows

### 1. Definitions.

The capitalized terms in this Agreement have the meaning set out below, unless a different meaning is assigned elsewhere in this Agreement, Service Order or in an Annex.

- 1.1. “**Account**” means an account with the Services, enabling the Client or an Authorized User to access and use the Services in connection with any Study or Studies conducted and processed using the Services.
- 1.2. “**Access Credentials**” means any username, identification number, password, license or security key, security token, PIN, or other security code, method, technology, or device used, alone or in combination, to verify an individual’s identity and authorization to access and use the Services.
- 1.3. “**Authorized Users**” means Client (if the Client is an individual using the Services) or Client’s employees, consultants, contractors, partners and agents who are authorized by Client to access and use the Services using the requisite Accounts and/or Access Credentials issued to Client by Castor or by using those Accounts and/or Access Credentials issued to an authorized third party by Client via Client’s Account.
- 1.4. “**Beta Services**” means products, data cuts, pilots, services, integrations, exports or other features that Castor makes available to Client to try at Client’s option, at no additional charge, and are designated as beta, limited release, preview or other similar description.
- 1.5. “**Billing Period**” means the billing period mentioned in this Agreement or Service Order.
- 1.6. “**Billing Code**” means the code that allows Client to have full access to the Services and will be provided by Castor to Client within twentyfour (24) hours after the Effective Date.
- 1.7. “**Castor Materials**” means the Services, documentation, and Castor Systems and any and all other information, data, documents, materials, works, and other content, devices, methods, processes, hardware, software, and other technologies and inventions, including any deliverables, technical or functional

descriptions, requirements, plans, or reports, that are developed, provided or used by Castor or any of its subcontractors in connection with the Services or otherwise comprise or relate to the Services or Castor Systems. Castor Materials shall also include any information, data, or other content derived from Castor's monitoring of Client's access to or use of the Services, but shall not include Client Data.

- 1.8. **"Castor Systems"** means the information technology infrastructure used by or on behalf of Castor in performing the Services, including all computers, software, hardware, databases, electronic systems (including database management systems), and networks, whether operated directly by Castor or through the use of third party services.
- 1.9. **"Client Data"** means information, data, and other content, in any form or medium, that is collected, downloaded, or otherwise received, directly or indirectly from Client, or an Authorized User by or through the Services or that incorporates or is derived from the Processing of such information, data, or content by or through the Services, including Medical Research Data. For the avoidance of doubt, Client Data does not include any information reflecting the access or use of the Services by or on behalf of Client or any Authorized User.
- 1.10. **"Duration"** means for each line item included in a Service Order the number of months that a Service will be made available to Client, commencing on the Start Date as per Section 1.18.
- 1.11. **"FDA"** means the United States Food and Drug Administration.
- 1.12. **"Intellectual Property Rights"** means any and all registered and unregistered rights granted, applied for, or otherwise now or hereafter in existence under or related to any patent, copyright, trademark, trade secret, database protection, or other intellectual property rights laws, and all similar or equivalent rights or forms of protection, in any part of the world.
- 1.13. **"Law"** means any statute, law, ordinance, regulation, rule, code, order, constitution, treaty, common law, judgment, decree, or other requirement of any federal, state, local, or foreign government or political subdivision thereof, or any arbitrator, court, or tribunal of competent jurisdiction.
- 1.14. **"Medical Research Data"** means any Client Data that could be considered sensitive personal data within the meaning of Article 9 of the GDPR.
- 1.15. **"Pass Through Costs"** mean any third-party costs incurred by Castor on behalf of Client in connection with the provision of the Services as explicitly mentioned in the Service Order. The costs may include, but are not limited to, third-party software licenses, translation fees, scale license fees, technical support, and other necessary external expenses.
- 1.16. **"Running Study"** means a Study that (a) is currently set to 'live' or (b) which had previously been set to 'live' and is no longer set to 'live' but has shown activity - including but not limited to data collection, data alteration and study design changes - in the last 30 days, unless otherwise agreed upon.
- 1.17. **"Service(s)"** means the service(s) Castor made available to Client as agreed upon between Parties, which may include providing one or more of the services, including but not limited to the services mentioned hereunder, as well as services reasonably related thereto:

- a. **"Castor Connect"** means Castor's mobile application that allows for survey invitations to be completed by study participants on their mobile device.
  - b. **"Castor eConsent"** means Castor's cloud-based software for asking and managing consent given by study participants;
  - c. **"Castor EDC/CDMS"** means Castor's cloud-based electronic data capture software.
- 1.18. **"Start Date"** means for each line item of a Service Order: (i) the earlier of the Start Date indicated on the Service Order or (ii) the date of first usage of the Billing Code by Client, whichever occurs first. Usage includes, but is not limited to: (a) performing study build activities; (b) setting a Study live (i.e. making it a Running Study); and (c) entering the Billing Code to remove any system limitations.
- 1.19. **"Study"** means the (clinical) study or studies conducted by the Client using the Services.

## 2. Nature and scope of this Agreement

- 2.1. Client will pay Castor the fees as stated in one or more Service Orders, and subject to payment of the stated fees and the conditions laid down in the Agreement or Service Order, Castor grants Client the right to use and to access the Services.
- 2.2. The following documents form an integral part of this Agreement. The following ranking will apply in the event of inconsistencies between the provisions of this Agreement or any Annexes thereto unless stated otherwise:
- I. the Service Order (and any additional Service Orders);
  - II. this Agreement;
  - III. any other Annex.

## 3. Notices

- 3.1. The Parties designate the following people as their main contact person for any communications regarding this Agreement and the Services:
- |                           |                                      |
|---------------------------|--------------------------------------|
| Castor:                   | Client:                              |
| Ciwit B.V.                | Client's address and email address   |
| Attn: Legal Department    | to be used for notice purposes shall |
| Fred. Roeskestraat 115    | be the billing address and primary   |
| 1076 EE Amsterdam         | contact's email address contained    |
| legalnotice@castoredc.com | within the Service Order, unless     |
|                           | otherwise agreed upon.               |

Notice may be made electronically if both parties have specified email addresses above. Otherwise, except as elsewhere specified in this Agreement, all notices shall be in writing and shall be given or made by delivery in person, by courier service, or by certified mail (postage prepaid, return receipt requested) to the respective Party at the above address or at such other address as a Party may hereafter notify the other Party. Written notice will be effective as follows: (a) as of the date actually delivered if sent by a recognized commercial express delivery service that uses delivery tracking technology; (b) four business days

after the date actually deposited with certified or registered mail; or (c) as of the date actually delivered if delivered by personal courier to the above mentioned address of the recipient during normal business hours. For email notice, if receipt has been electronically confirmed or if a duplicate copy is contemporaneously provided by another notice methodology set forth in this section, email notice will be effective as of the date emailed or (if transmitted and received on a non-business day) on the first business day following transmission, whichever is earlier.

#### **4. Service Order**

- 4.1. Castor offers its Services electronically via its website (castoredc.com) or a Service Order indicating which Services Castor offers to provide and which fees will be owed. A Service Order is free of obligation until signed by the Client and written Service Orders are valid for 14 days after dispatch, unless otherwise indicated in the Service Order.
- 4.2. By accepting Castor's Services via Castor's website, Client is agreeing to the terms and conditions of this Agreement. Client shall receive an invoice from Castor setting out Client's payment obligations.
- 4.3. Castor may also make an offer to the Client via its Services (e.g. enabling Client to purchase certain additional Modules through Castor's Services). The prices stated in the Service Order or on Castor's website are valid from the moment they are displayed, unless it concerns a clear programming or typing error.
- 4.4. If the Client does not explicitly indicate that it accepts the Service Order, but nevertheless agrees to it or creates the impression that Castor performs activities that are covered by the description of the Services, the Service Order will be deemed to have been accepted. This also applies in the event the Client requests Castor to perform certain activities without awaiting a Service Order.
- 4.5. If the Services of Castor is based on information provided by the Client and (prior to or during the Agreement) this information proves to be incorrect or incomplete, Castor is entitled to change its fees, Service Order and/or the terms of the Agreement accordingly.

#### **5. Grant and Intellectual Property Rights**

- 5.1. Subject to payment of the agreed upon fees by Client, Castor will use commercially reasonable efforts to provide Client a non-exclusive, non-transferable right to use of the Services within the term and scope of this Agreement, as further set forth in each Service Order.
- 5.2. Nothing in this Agreement is intended to transfer any Intellectual Property Rights from one Party to the other. All Intellectual Property Rights and other rights to the Client Data will expressly continue to be vested in Client and/or its licensors. Because of the nature of the Services, Castor may process such Client Data to perform its obligations under this Agreement or as otherwise permitted by this Agreement, which includes without limitation: providing the Services, storing the Client Data on Castor Systems, making backups of the Client Data, providing Client with support and/or suggestions regarding other Castor

services. Client grants Castor a limited license to Client Data solely as necessary to provide the Services to Client.

- 5.3. All Intellectual Property Rights to the Castor Materials (e.g. source codes, documentation, websites and promotional materials), will expressly continue to be vested in Castor and/or its licensors.
- 5.4. Without prior written approval of Castor, Client will not: (i) modify, duplicate, create derivative works from, disclose and/or reproduce all or any part of the Castor Materials, (ii) sublicense the Services to third parties or otherwise permit any third party to use the Services, (iii) reverse engineer, decompile, disassemble, or otherwise attempt to derive the source code of the software used to provide the Services, (iv) register domain names, brands, trademarks or Google AdWords search terms (keywords) that are similar or identical to any mark in respect of which Castor can exercise Intellectual Property Rights (e.g. the name "*Castor EDC*"), (v) circumvent or attempt to circumvent any methods employed by Castor to control access to the components, features or functions of the Services, or to prevent unauthorized use of the Services; (vi) use or otherwise exploit the Services for any purpose, commercial or otherwise, other than the intended purpose; or (vii) use the Services for purposes of competitive analysis or the development of a competing software product.
- 5.5. Castor may implement technical measures to protect the Services against unlawful use and/or against use in a manner or for purposes other than as agreed between the Parties.
- 5.6. Client may not remove, render illegible, hide or change notifications or announcements concerning Castor's Intellectual Property Rights.
- 5.7. Unless agreed upon otherwise in this Agreement or any Annex thereto, Castor is not obligated to provide Client with any source code regarding the Services.
- 5.8. Client grants Castor a royalty-free, worldwide, irrevocable, transferable, perpetual license to use and incorporate into the Services any suggestions, enhancement, requests, or other feedback provided by Client, including Authorized Users, relating to the operation of the Services.
- 5.9. Client hereby irrevocably grants all such rights and permissions in or relating to Client Data (including Client's anonymized data) as is necessary to Castor, to exercise Castor's rights and perform Castor's obligations hereunder. The Client Data (including Client's anonymized data) may be used by Castor in order to provide the Services, including to improve and further develop its Services.

## **6. Providing the Services**

- 6.1. Castor will use commercially reasonable efforts to provide Client with its Services as described in the Service Order(s). Castor will use its best efforts to keep its Services compatible with the latest version of the following web browsers: Microsoft Edge, Safari, Mozilla Firefox and Google Chrome.
- 6.2. The Services shall only be accessed and used by Authorized Users. Only an Authorized User with the Client's domain name (Accounts registered with an email address ending with Client's domain name) can initiate a Study. Client shall be responsible for the approval and issuance of additional Accounts to third parties and controlling against unauthorized access by users, and for

- maintaining the confidentiality of Access Credentials and other account information. Castor is not responsible for any harm caused by the malfeasance of individuals who were not authorized to have access to the Services but who were able to gain access solely because Accounts or Access Credentials were not terminated on a timely basis in Client's local identity management infrastructure or Client's local computers.
- 6.3. Castor will use commercially reasonable efforts to enable Client to use the Services in accordance with the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use's Guideline for Good Clinical Practice and the FDA's Guidance for Industry – Electronic Source Data in Clinical Investigations (version of September 2013).
  - 6.4. Castor will at all times comply with all applicable laws and industry standards in the performance of its obligations under this Agreement and shall obtain all rights and licenses required from third parties to operate, use, license and provide the Services, and otherwise perform its obligations under this Agreement.
  - 6.5. Client shall: (a) have sole responsibility for the accuracy, quality, and legality of all Client Data; (b) preserve and maintain the login credentials for the access to, or use of the Software and Services and notify Castor promptly of any such unauthorized access or use caused from the failure to preserve and maintain such login credentials; (c) be responsible for obtaining appropriate consent and conduct proper ethics review for any Study and shall produce documentation of such consent or review at Castor's request, (d) be responsible for complying with applicable legislation and regulations while making use of the Services; and (e) ensure its Studies comply with the relevant legislation and regulations regarding medical research. Client shall not: (i) use the Services in violation of applicable laws; (ii) in connection with the Services, send or store infringing, obscene, threatening, or otherwise unlawful or tortious material, including material that violates privacy rights; (iii) send or store malicious code in connection with the Services; (iv) interfere with or disrupt performance of the Services or the data contained therein; or (v) attempt to gain access to the Services or its related systems or networks in a manner not set forth in the Castor Materials. Client shall be liable for the acts and omissions of all Authorized Users and Client Affiliates relating to this Agreement.
  - 6.6. Castor is constantly improving its Services and may alter its Services from time to time. This means that, without additional costs, Client may use new and updated versions of the Service as made available by Castor. Because Castor's Services are provided as a standard online service, it is not possible to delay or not implement new and updated versions of the Services specifically for Client.
  - 6.7. If so demanded for a proper performance of the Services, Castor may retain third parties to perform certain activities. Castor is and remains the responsible Party towards Client.
  - 6.8. If Client or anyone using the Services pursuant to this Agreement (e.g. Authorized Users), uses the Services in violation of applicable Law, Castor will have the right to deny or limit access of such Client or users to the Services. Client is responsible for all conduct of Authorized Users using the Services.



- 6.9. Castor is entitled to archive any inactive Study or Studies that Client has created within the Services. In any case a Study is considered 'inactive' when Client has not performed any activity within that specific Study on the Services over the course of six (6) months. Castor will send Client a notification before archiving the Study, including a fifteen (15) day term for Client to cancel the archiving process.
- 6.10. If Client wants to continue an archived Study and/or view the captured data within an archived Study, then Client must request that Castor restore such Study from its archive, which may incur an additional fee.
- 6.11. The service levels for Castor EDC/CDMS, Castor eConsent and Castor Connect are specified on Castor's website ([www.castoredc.com/sla](http://www.castoredc.com/sla)).

## **7. Beta Services and Artificial Intelligence**

- 7.1. Castor may make Beta Services and related documentation available to Client. Client may choose to try such Beta Services in its sole discretion and in accordance with the documentation. Beta Services are intended for evaluation purposes only, are not fully supported by this Agreement, and may be subject to additional terms.
- 7.2. Beta Services are not considered Services under this Agreement, but all restrictions, reservation of rights, Client's obligations concerning the Services, and rights granted by Client to Castor regarding Client Data will apply equally to Client's use of Beta Services. Castor may discontinue Beta Services at any time in its sole discretion and may never make them generally available, unless otherwise agreed by the Parties.
- 7.3. Client's use of Beta Services shall expire on either (a) the date a version of such Beta Services becomes generally available as Services without the applicable Beta Services designation; or (b) the date that Castor discontinues such Beta Services.
- 7.4. Beta Services are provided "AS IS" and Castor will have no liability for any harm or damage arising out of Beta Services used in a production setting, unless explicitly agreed between Parties.
- 7.5. The Services might include artificial intelligence (hereinafter: AI System). In that case, the following provisions will apply:
  - I. Given the nature of AI-generated results of the AI System, in addition to the measures taken by Castor, it is Client's responsibility to carefully check whether the results generated with the AI System infringe the rights of third parties, and in case of doubt, Client shall (i) notify Castor and (ii) make all necessary adjustments to remove the infringing character.
  - II. Client is, based on the documentation provided by Castor, itself responsible for assessing whether, and to what extent, human intervention is necessary for the use of the AI System and/or the results generated with the AI System.
  - III. The Parties agree that no Intellectual Property Rights, in the broadest sense of the word, accrue to the results generated with the AI System. Should - contrary to this principle - any Intellectual Property Rights

nevertheless arise to the results generated with the AI System, such right the result concern shall at all times accrue to Castor and Client shall only acquire a license to use, on the understanding that Client acknowledges and agrees that the nature of results generated with an AI System means that similar results can be generated and used by other parties and Client can therefore not claim exclusivity with regard to a result generated by the AI System.

## **8. Backups and support**

- 8.1. Castor will make a backup of the Client Data in Castor EDC/CDMS, Castor Connect at least two times per day. Castor will make a backup of the Client Data in Castor eConsent at least one time per day. After one month, Castor will keep one version per month available. Upon request of the Client and in emergency situations, Castor is authorized and will use its best efforts to restore such backup. Restoring a backup on request of the Client will be subject to an additional fee, unless such restore is necessary because of a failure caused by Castor.
- 8.2. Castor will make an online manual available on how to use Castor's Services. Additional support may be requested by the Client through Castor's website, where Client will also be able to submit support tickets. Direct support may be available as specified on [www.castoredc.com/sla](http://www.castoredc.com/sla).

## **9. Payment conditions**

- 9.1. Client is obliged to pay for the provision of the Services. The fees to be paid by the Client are stated in one or more Service Orders. If Client purchases (additional) Services via Castor's website, then the fees are stated on Castor's website. All prices are in euros and exclusive of VAT.
- 9.2. If Client has received a discount under certain conditions and the conditions to such discount are no longer satisfied, Castor may in its sole discretion revoke such discount effective upon the date such conditions were no longer satisfied, and send Client an additional invoice for such interim period.
- 9.3. Client agrees to electronic invoicing by Castor. Invoices will be sent in PDF or another suitable format to the relevant billing contact designated by Client in the Service Order. If so instructed by Castor, Client will pay the due fees to an affiliate of Castor.
- 9.4. Upon Client's signature of a Service Order, Client shall be invoiced for all One-Time Costs and the Recurring Fees for the first Billing Period. The Billing Period shall be on an annual basis, unless a different Billing Period is stated on the Service Order. Subsequent recurring invoices will be sent on the anniversary date of the Start Date, corresponding to the agreed Billing Period in the Service Order.
- 9.5. Pass Through Costs shall be invoiced to Client at cost, with a reasonable administrative processing fee of 3% to be applied to cover transaction and handling costs, unless otherwise agreed in writing in the Service Order. For the avoidance of doubt, Client will always pre-approve the Pass Through Costs in writing and shall not be unreasonably withheld or delayed.



- 9.6. In the event that the Billing Period is shorter than the remaining Duration of a line item of the Service Order, the remaining, not previously invoiced fees of such a line item shall be invoiced in accordance with Section 9.4.
- 9.7. In case the number of Running Studies or other limitations set out in a line item of the Service Order are exceeded, Castor will send Client an invoice to cover any additional costs which shall be based on the fees agreed upon by Client in the applicable Service Order. Test studies are not counted towards the Running Studies total.
- 9.8. Castor invoices have a payment term of thirty (30) days after the invoice date, unless a different payment term is stated on the Service Order. Client is obliged to pay invoices within the stated payment term without deduction or set-off.
- 9.9. In the event payment is not made on time, Castor will send a reminder with a payment term of fourteen (14) days. If Client does not pay within the aforementioned fourteen (14) days, Client will be in default by operation of law without requiring any notice of default. Castor will have the right as of that moment to:
  - I. limit its Services, for example by restricting access to the Service and/or suspending the Service completely or temporarily;
  - II. refer the amount owed by Client for debt collection or start proceedings to collect the amounts owed itself, in which cases Client will be obliged to pay, in addition to the amount owed and the ten (10) percent of interest due, full compensation of both judicial and extrajudicial collection costs, including costs charged by lawyers, bailiffs and debt-collection agencies; and
  - III. terminate this Agreement in whole or in part.
- 9.10. Claims for payment accelerate and are immediately due and payable if Client is insolvent, declared bankrupt, applies for a suspension of payments, a general attachment is levied against Client's assets, or if Client enters liquidation, administration, or is dissolved.
- 9.11. If the Client considers an invoice to be incorrect, the Client shall provide written notice of its objections in reasonable written detail to Castor within fifteen (15) days after the invoice date. The payment obligation will continue to exist at all times. Any amount paid in excess by Client will be set off by means of a credit to a future invoice.
- 9.12. Any deviations from the payment conditions as stipulated in this Agreement, shall be agreed upon between Parties in the Service Order.

## **10. Confidentiality**

- 10.1. The Parties will observe confidentiality concerning all information received from the other Party when such information is marked as confidential, when the disclosing Party has informed the receiving Party beforehand about the confidential nature of the information to be shared, or when the receiving Party should know from context that the information is confidential. The content of this Agreement shall be considered confidential information. Parties will also impose an equivalent obligation of confidentiality on their employees and on the third parties engaged by them in the performance of this Agreement.

- 10.2. The obligations of confidentiality hereunder shall not apply to the extent that the receiving Party can demonstrate that the relevant information is required to be disclosed by: (i) Law; (ii) any regulatory authority to which the relevant Party is subject or submits; or (iii) any court of competent jurisdiction. Insofar as allowed by applicable Law, each Party will promptly inform the other Party when they receive a request from a third party to disclose certain confidential information of the other Party, so that the other Party may seek legal redress against such disclosure.
- 10.3. The obligation to treat confidential information as confidential will not be applicable:
- I. if the recipient of such information can prove that this information was obtained from sources available to the general public such as newspapers, patent databases or informative websites;
  - II. if the recipient of such information can prove that this information was received from a third party without this party being in default towards either Party arising from a confidentiality clause by distributing the information to the recipient;
  - III. if the recipient of such information can prove that this information was already in possession of the recipient prior to the date on which it was issued or made available by the other Party;
  - IV. insofar as a Party reasonably shares the confidential information with an external legal or tax advisor, provided that such external advisors are also contractually bound to confidentiality regarding the shared information.

## **11. Processing of Client Data and Medical Research Data**

- 11.1. With regards to certain Services, Client will be able to choose in which geographical area its Client Data will be hosted (please visit [this link](#) for more information about the different servers).
- 11.2. The Client specifies the objectives and means of the processing of Client Data under this Agreement. Insofar required by applicable Law, the Client shall request Castor to agree upon additional privacy related terms. The Parties will then discuss such requests in good faith.
- 11.3. The Client shall notify Castor of the purposes of the processing to the extent not already specified in this Agreement. Insofar required by applicable Law, the Client shall ensure that the Parties are familiar with the categories of Client Data to be processed by Castor and the categories of data subjects from which the Client Data is processed.
- 11.4. Medical Research Data will be hosted by Castor in the geographical area chosen by Client. However, use of certain functionalities within the Services may result in the processing of Medical Research Data in other countries. In the event the Client chooses to make use of such functionalities, Castor is permitted to transfer the corresponding Medical Research Data to third countries. On request of the Client, Castor will inform the Client about which functionalities result in the processing of Client Data in countries outside of the country chosen by Client.

- 11.5. Castor is authorized to engage third parties (sub-processors) in the execution of this Agreement in accordance with the terms of the Data Processing Agreement.

## **12. Security**

- 12.1. Castor will take appropriate technical and organizational measures with respect to the processing of the Client Data against loss or against any form of unlawful processing (such as unauthorized disclosure, damage, alteration or transfer of Client Data). These measures will provide a suitable level of protection, taking into account the state of technology, the costs of implementation, the risks associated with the processing and the nature of the information to be protected.
- 12.2. During the term of this Agreement, Castor will be ISO 27001 certified. Castor will provide proof of certification on request of the Client. Furthermore, Castor shall at least take the security measures as mentioned in its security statement, which is available at: <https://castoredc.com/security-statement>. If additional or other specific security measures or certifications are required in order to process any data, then Client must inform Castor hereof.
- 12.3. The Parties acknowledge that technology is constantly improving, therefore Castor may change the technical and organizational measures (and its security statement) from time to time. Castor endeavors to only update the technical and organizational measures (and its security statement) for the better, taking into account Section 12.1, innovations in the field of information security and the user experience. In the event of changes to the implemented technical and organizational measures, Castor will use its best efforts to update the aforementioned security statement as soon as possible.
- 12.4. Castor will use its best efforts to inform the Client of a breach of Client Data as soon as reasonably possible in accordance with the terms of the Data Processing Agreement. If applicable Laws so dictate, Castor will cooperate with the process of informing all relevant authorities and data subjects of the breach. However, the Client will remain responsible for reporting the breach to the authorities in an appropriate and timely manner insofar applicable Law so dictates.

## **13. Audits and assistance**

- 13.1. The Client has the right, at Client's sole expense, to perform an independent audit bound by confidentiality to confirm Castor's compliance with its obligations under this Agreement.
- 13.2. An audit may only be undertaken once biennially and shall take no more than two business days. Upon mutual agreement, an audit may be undertaken more than once biennially if there are well-founded specific grounds for suspecting a data breach or non-compliance with the terms of this Agreement.
- 13.3. The Client shall inform Castor of the audit at least one month before the audit shall take place.
- 13.4. Castor shall cooperate with the audit and provide all information reasonably relevant for the audit, including supporting data such as system logs, and

employees, as promptly as possible. Any expenses (e.g. employee costs) that Castor incurs to cooperate with the audit, shall be borne by the Client.

- 13.5. The findings resulting from the audit conducted will be assessed by the Parties in mutual consultation and, following on from this, may or may not be implemented by one of the Parties or by both Parties together.
- 13.6. Castor shall assist the Client in complying with its obligations pursuant to articles 32 to 36 of the GDPR (if any), taking into account the nature of processing and the information available to Castor. Reasonable expenses (e.g. employee costs) that Castor incurs in relation to such assistance will be reimbursed by Client.

## **14. Liability**

- 14.1. Castor's liability for direct damages sustained by the Client as a result of an attributable failure on the part of Castor to comply with its obligations under the Agreement, or on any grounds whatsoever, per event or series of related events, is limited to an amount that is equal to two (2) times the compensation (exclusive of VAT) paid by the Client to Castor during the twelve (12) months prior to the event that caused damage.
- 14.2. Direct damages only include: (1) reasonable expenses incurred by Client to determine the cause and extent of the damage; (2) reasonable expenses made by Client to repair or resolve Castor's shortcoming(s), unless the shortcoming(s) cannot be attributed to Castor; and (3) reasonable expenses incurred by Client to prevent or limit damages, insofar Client can prove these expenses have actually led to limitation of damages.
- 14.3. Liability on the part of either party for any other forms of damages, such as indirect or consequential loss, damage to or loss of other data, data stored on Castor's equipment, or damage resulting from business interruption is excluded.
- 14.4. Limitations of liability in this Agreement are not applicable in case damage is the consequence of wilful misconduct or gross negligence.
- 14.5. Liability on the part of Castor for an attributable failure to comply with this Agreement only arises if Client provides Castor proper notice of default in writing without delay, while providing Castor a reasonable term to remedy the failure, and Castor remains in default as regards compliance with its obligations after that term as well.
- 14.6. Castor shall act as a procurement facilitator for Pass Through Costs and assume no liability for the performance, quality, or availability of third-party services or products procured as part of the Pass Through Costs. Client acknowledges that all warranties, service levels, and liability concerning Pass Through Costs shall be subject to the terms of the respective third-party providers.

## **15. Force majeure**

- 15.1. Neither Party shall be in breach of this Agreement if it is prevented from carrying out its obligations under this Agreement as a result of a cause that is beyond its reasonable control (*force majeure*).
- 15.2. Force majeure includes in particular (but without limitation): domestic disturbances, mobilization, war, transportation blocks, strikes, network attacks

such as SYN (synchronous) floods or (distributed) denial of service attacks, ransomware attacks, business interruptions, supply stagnation, epidemic or pandemic, fires, floods, import and export obstructions, and internet failures or third party hosting failures.

15.3. Each Party has the right to suspend compliance with its obligations under this Agreement during the period of force majeure. If this period exceeds ninety days, each Party will have the right to terminate this Agreement without compensation to the other Party.

15.4. In the event Castor has already complied in part with an obligation under the Agreement at the time the situation of force majeure arises or will be able to comply with this obligation during this period of force majeure, Castor will have the right to separately invoice the part that has already been complied with or that will be complied with. The Client will be obliged to pay this invoice

## **16. Term and termination**

16.1. The effective date of this Agreement is the moment Castor receives notification of acceptance by the Client or upon Client's signature of a Service Order, unless a different commencement date has been agreed in mutual consultation ("Effective Date").

16.2. The Agreement is concluded for an initial term of three (3) years. After the initial term of three (3) years, this Agreement will be automatically extended for one (1) year terms unless terminated by either Party. Each Party must give the other party notice of termination six (6) months prior to the end of then-current the term.

16.3. Any Service Order that remains active upon termination of this Agreement shall continue in effect for the Duration specified within the Service Order or, if unspecified, for as long as the Client actively uses the Services in accordance with the terms of this Agreement and/or the Service Order. The provisions of this Agreement shall govern and apply to each active Service Order for the entirety of its term.

16.4. Each Party has the right to terminate this Agreement with immediate effect without being obliged to pay compensation in any way if:

- I. the other Party has failed to comply with its obligations under this Agreement and such failure, where capable of remedy, has not been remedied within a reasonable time after having received a notice of default;
- II. the other Party has a receiver, administrative receiver or similar officer appointed in respect of the whole or any substantial part of its assets, or an order is made or a resolution is passed for its winding up or a petition is presented for the appointment of a trustee, an administrator or similar officer to it, or it enters into any form of insolvency proceedings including bankruptcy under the United States Bankruptcy Code or an assignment for the benefit of creditors, or is unable to pay its debts or certifies that it is unable to pay its debts, or it makes or enters into any arrangement or compromise with any of its creditors, or if an analogous event to any of the foregoing occurs.

- 16.5. Unless otherwise agreed upon between Parties, if the Study is still considered a Running Study after the Duration as stated in a Service Order, such Service Order shall automatically renew for successive one month periods ("Automatic Monthly Extension"), until the Study no longer is a Running Study or unless either Party gives the other Party written notice of non-renewal at least thirty (30) days prior to the expiration of the then-current term. Upon an Automatic Monthly Extension, Castor shall be allowed to increase its prices by fifteen (15) percent. Client will receive an automated email at least thirty (30) days before the end of the Duration, to notify Client of a possible upcoming Automatic Monthly Extension and to offer Client the opportunity to extend the Services.
- 16.6. In the event of termination of a Service Order for any reason, Client shall remain liable for all Pass Through Costs incurred and any non-cancelable commitments made by Castor on behalf of Client prior to the termination date.

## **17. Changes to this Agreement**

- 17.1. Castor has the right to change these terms and/or the Agreement, provided it announces the proposed changes to the Client at least thirty (30) days in advance.
- 17.2. During the aforementioned 30-day period, the Client is entitled to object to the proposed changes. Should the Client object to the changes, Castor will reconsider and withdraw the changes if it considers the objection well-founded. If Castor does not receive any objections from the Client within the aforementioned term and Client keeps using the Service, then the changes are considered to be accepted by the Client.
- 17.3. However, if Castor implements the changes despite the Client's objection, the Client will have the right to terminate the Agreement as of the moment the changes enter into effect. Changes of minor importance or changes resulting from new legislation can be implemented at any time, without the Client having the right to terminate the Agreement.

## **18. Indemnification**

- 18.1. Unless prohibited by applicable Law, Client will defend and indemnify Castor against any claims by third parties to the extent that the claims arise from Client's use of the Services by any Authorized User and from all possible claims relating to the violation of any applicable legislation and regulations.
- 18.2. Castor will defend and shall indemnify Client from all possible claims relating to the violation of any applicable legislation and regulations.
- 18.3. This Indemnification Section will not apply if the underlying claim arises from the indemnified party's breach of this Agreement, modifications to the Services by the Client, any combination of the Services with materials or software not provided by the indemnifying party, or use of non-current or unsupported versions of the Services.

## **19. Representations and Warranties**



- 19.1. Each Party represents and warrants to the other Party that it has the power and authority to execute and deliver this Agreement and has taken all necessary corporate action to authorize the execution and delivery of this Agreement.
- 19.2. Client warrants that proper consent has been obtained for all Client Data.

## **20. Exit**

Upon any expiration or termination of this Agreement, except as expressly otherwise provided in the Agreement, all rights, licenses, consents, and authorizations granted by Castor to the Client hereunder will immediately terminate, taking into account the following:

- I. Client and Castor shall in good faith discuss what must be done with the Client Data stored within the Castor EDC/CDMS. Client may export the Client Data using the tools available in the Services. Client may at any time and free of charge, export the Client Data using Castor EDC/CDMS's exporting tool in Excel, CSV or SPSS format for captured Data and XML format for Study structure and metadata. Audit logs containing data entry logs are not included in such export. However, if the Client requests support in exporting such data, Castor may offer this service to the Client for a reasonable fee ("Exporting Services"). For Exporting Services, Castor will disclose the Client data by delivering the Study structure including metadata, Study Data and audit trail of all Client's Studies.
- II. If so instructed by Client, Castor shall erase Client Data from Castor EDC/CDMS (excluding backups, archives, and disaster recovery systems until such data is deleted in the ordinary course of business).
- III. If Castor does not receive instructions from Client, then Castor may retain and/or archive Client Data pursuant to the Guideline for Good Clinical Practice and taking into account the confidentiality obligations in this Agreement. In such case Castor shall only delete the Client Data captured by the Client after having informed Client via email about Castor's intention to delete such Client Data and providing the Client a ninety day period to make other arrangements with Castor. When Client has stored Data using the "Large File Storage" upload functionality, then additional costs may be charged for retaining and/or archiving such large files after a Study ends. In such case Castor will contact Client to agree upon additional charges.

## **21. Severability**

If any provision of this Agreement (or Annexes) proves invalid, such will not impair the validity of the entire Agreement. The Parties to this Agreement will furthermore adopt (a) new provision(s) by way of replacement, which implement(s) the intention of the original provision as much as legally possible.

## **22. Entire Agreement**

- 22.1. This Agreement, and any documents referred to in it, constitute the whole Agreement between the Parties and supersede any previous arrangement,

understanding or Agreement between them relating to the subject matter they cover.

- 22.2. Each of the Parties acknowledges and agrees that in entering into this Agreement it does not rely on any undertaking, promise, assurance, statement, representation, warranty or understanding (whether in writing or not) of any person (whether Party to this Agreement or not) relating to the subject matter of this Agreement, other than as expressly set out in this Agreement.

## 23. Assignment

- 23.1. Changes to management or the legal form of Castor will not affect this Agreement.
- 23.2. This Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred, by Client without the consent of Castor, which may not be unreasonably withheld, conditioned or delayed. Notwithstanding the foregoing, either Party may, without the other Party's consent, assign this Agreement and its rights and obligations hereunder in whole or in part in connection with a Change of Control on the condition that the Assignee shall assume all obligations of its assignor under this Agreement. Any permitted assignee shall assume all obligations of its assignor under this Agreement. This Agreement is binding upon the permitted successors and assigns of the Parties. Any attempted assignment not in accordance with this section shall be void. This Agreement is binding upon the permitted successors and assigns of the Parties. **"Change of Control"** means the sale of all or substantially all the assets of such party; any merger, consolidation or acquisition of such party with, by or into another corporation, entity or person; or any direct or indirect change in the beneficial ownership of more than fifty percent (50%) of the voting capital stock of a such party in one or more related transaction, including without limitation a Change of Control of any entity which controls fifty percent (50%) or more of the voting capital stock of such party.

## 24. Governing Law and jurisdiction

The Agreement, including the Annexes, is governed by Dutch law. Unless the rules of mandatory law provide otherwise, all disputes that may arise pursuant to the Agreement will be submitted to the competent Dutch court in the Amsterdam court district.

## 25. Miscellaneous

- 25.1. Castor is entitled to use Client's tradename, trademark, logo and the general agreement description as a reference on its website and in other promotional materials of Castor.
- 25.2. Section, annex and paragraph headings shall not affect the interpretation of this Agreement.
- 25.3. A reference to 'in writing' or 'written' also includes e-mail.
- 25.4. **Third Party Beneficiaries:** The Parties do not confer any rights or remedies upon any person other than the Parties to this Agreement and their respective successors and permitted assigns.

- 25.5. **No Partnership or Agency:** nothing in this Agreement is intended to or shall operate to create a partnership between the Parties, or authorize either Party to act as agent for the other, and neither Party shall have the authority to act in the name or on behalf of or otherwise to bind the other in any way (including, but not limited to, the making of any representation or warranty, the assumption of any obligation or liability and the exercise of any right or power).
- 25.6. **Waiver:** a waiver of any right under this Agreement is only effective if it is in writing and it applies only to the Party to whom the waiver is addressed and to the circumstances for which it is given.

## Annex 1:

### DATA PROCESSING AGREEMENT

#### PREAMBLE

Both Parties, as identified in the Agreement above, have entered into an Agreement where Castor (the "Processor") is responsible for the provision of the Services for the Client (the "Controller"). Based on this Agreement, Processor will obtain personal data from Controller.

#### WHEREAS

- the Controller collects and holds personal data of various parties;
- the Controller wishes to make use of the Services and have the Processor perform certain types of processing of personal data for the purposes of providing the Services;
- the Processor and the Controller have signed an Agreement, by which the Processor will provide Services on behalf of the Controller;
- the Controller is hereby deemed to be the responsible Party within the meaning of Article 4(7) of the GDPR;
- the Processor is hereby deemed to be the processor within the meaning of Article 4(8) of the GDPR;
- the Parties, having regard to Article 28(3) of the GDPR, wish to lay down their rights and duties in writing in this Data Processing Agreement ("DPA"),

The Parties hereby agree as follows:

#### 1. Definitions

The terminology used in this DPA, such as "processing" and "personal data", have the meaning as defined in the GDPR. Capitalized terms in this DPA have the meaning ascribed to them in the Agreement or in the following list. The singular includes the plural and vice versa.

- 1.1. **EU Data Protection Laws:** shall mean the General Data Protection Regulation (EU) 2016/679 protecting the fundamental rights and freedoms of individuals and in particular their right to privacy with respect to the processing of personal data applicable to the Controller and the Processor, and additional rules and implementations of EU data protection laid down in European member state law.
- 1.2. **Medical Research Data:** any Client Data that could be considered sensitive personal data within the meaning of Article 9 of the GDPR.
- 1.3. **Module:** specific modules within Processor which make certain functionalities possible and that can be used by the Controller.
- 1.4. **Personal Data Breach:** a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise processed as described in Article 4 paragraph (12) GDPR.
- 1.5. **Study:** the clinical study or studies that are conducted by the Controller and for which Processor is used by the Controller.

## **2. Processing objectives**

- 2.1. The Controller wishes to use Processor to conduct Studies and have the Processor process personal data on its behalf. In relation to the aforementioned, Processor undertakes to process personal data within the scope of providing the services specified in the Agreement and improving those services and the user experience, taking into account the conditions set forth in this DPA.
- 2.2. Only the Controller is permitted to specify the objectives and means of the processing of personal data under this DPA. The Controller shall notify the Processor of the purposes of the processing to the extent not already specified in this DPA.
- 2.3. The Controller makes sure that the categories of personal data to be processed by the Processor and the categories of data subjects from which the personal data is processed, are mentioned in Section 11 below.
- 2.4. All rights pertaining to the personal data that is processed under this DPA shall remain with the Controller or the data subjects.
- 2.5. The Controller represents and warrants that it has a valid legal basis to process the relevant personal data and to engage the Processor in relation to such processing of personal data. Furthermore, the Controller represents and warrants that the processing by the Processor is not unlawful and does not infringe any rights of a third party. In this context, the Controller indemnifies the Processor of all claims and actions of third parties related to the unlawful processing of personal data.
- 2.6. The Controller represents and warrants that it itself is compliant with the EU Data Protection Laws.

## **3. Obligations of Processor**

- 3.1. With regard to the processing of personal data mentioned in the previous section, the Processor will use its best efforts to ensure compliance with EU Data Protection Laws.
- 3.2. On request of the Controller and within a reasonable time thereof, the Processor shall furnish the Controller with details regarding the measures it has adopted to comply with its obligations under this DPA.
- 3.3. The Processor's obligations arising under the terms of this DPA apply also to whomsoever processes the personal data under the Processor's instructions such as employees.
- 3.4. In case applicable privacy legislation requires a Data Protection Impact Assessment or a prior consultation with a supervisory authority to be conducted before the intended processing under the Agreement and this DPA may be carried out, then the Processor shall provide the Controller with assistance to the extent necessary and reasonable. The Processor may charge reasonable costs for the aforementioned assistance.

## **4. Transfer of personal data**

- 4.1. The Processor may process the personal data in countries within the European Union. Processing of personal data in countries outside the European Union is only allowed when the legal requirements for such processing have been fulfilled.

- 4.2. Notwithstanding the previous paragraph, Medical Research Data will exclusively be processed by the Processor in the country chosen by Controller. However, to be able to offer certain Modules, the Processor may engage third parties or subcontractors that process Medical Research Data in other countries. In the event the Controller chooses to make use of these Modules, the Processor is permitted to transfer the corresponding Medical Research Data to third countries, with due consideration of EU Data Protection Laws. On request of the Controller, the Processor will inform the Controller about which Modules result in the processing of Medical Research Data in countries outside of the country chosen by the Controller.
- 4.3. Notwithstanding the previous paragraphs, Medical Research Data will exclusively be stored by the Processor in the country chosen by the Controller.
- 4.4. On request, the Processor will inform the Controller about the countries in which the relevant personal data is processed.
- 4.5. Within the framework of the Agreement and this DPA, the Processor is hereby authorised by Controller to engage third parties (sub-processors) as specified under Appendix 1. On request of the Controller, the Processor shall inform the Controller about which sub-processors are engaged by the Processor. The Processor shall inform the Controller about any planned change in the used sub-processors, in which case the Controller has the right to object (in writing, within two weeks and supported by arguments) to the proposed change in sub-processors.
- 4.6. Should the Controller object to such change, then the Parties will jointly endeavour to find a reasonable solution. If Parties cannot come to a solution, then the Processor is allowed to make the planned change in the used sub-processors.
- 4.7. Insofar relevant, the Processor undertakes to bind the engaged sub-processors to substantially the same obligations as the Processor is bound to under this DPA.

## 5. Security

- 5.1. The Processor will use its best efforts to take appropriate technical and organisational measures with respect to the processing of the personal data against loss or against any form of unlawful processing (such as unauthorised disclosure, damage, alteration or transfer of personal data). These measures should constitute a suitable protection level, taking into account the state of technology, the costs of implementation, the risks associated with the processing and the nature of the information to be protected.
- 5.2. During the term of the Agreement, the Processor shall be ISO 27001 certified. The Processor will provide proof of certification on request of the Controller. Furthermore, the Processor shall at least take the security measures as mentioned in its security statement, which is available at:  
<https://castoredc.com/security-statement/>.
- 5.3. Parties acknowledge that technology is constantly improving, therefore the Processor is allowed to change the technical and organizational measures (and its security statement) from time to time. The Processor endeavours to only update the technical and organisational measures (and its security statement) for the better, taking into account Section 5.1, innovations in the field of information security and the user experience. In the event of changes to the implemented



technical and organisational measures, the Processor will use its best efforts to update the aforementioned security statement as soon as possible.

- 5.4. Logs and measurements from the Processor shall be deemed to be authentic, unless the Controller supplies proof to the contrary.

## **6. Duty to report**

- 6.1. The Processor will use its best efforts to inform the Controller of a Personal Data Breach as soon as possible. In any event the Processor will inform the Controller of a Personal Data Breach within 48 hours after the Processor has become aware of the Personal Data Breach.
- 6.2. If EU Data Protection Laws so dictate, the Processor will cooperate with the process of informing all relevant authorities and data subjects of the Personal Data Breach. However, the Controller will remain responsible for reporting the Personal Data Breach in an appropriate and timely manner.
- 6.3. The notification obligation includes at least the notification by the Processor to the Controller that a Personal Data Breach has occurred, as well as (i) the presumed cause of the Personal Data Breach, (ii) the consequences of the Personal Data Breach as known or expected at that time, (iii) the proposed solution to the Personal Data Breach, (iv) the (security) measures taken thus far, and (v) the designated contact who will follow-up on the notification.
- 6.4. If the Processor doesn't have all the information mentioned in the previous paragraph at its disposal, then the Processor will send the missing information as soon as possible.

## **7. Requests of data subjects**

Where a data subject submits a request to the Processor regarding his/her personal data (for example, to inspect, correct or delete the data, or to receive a copy of the data), the Processor will forward the request to the Controller and the request will then be dealt with by the Controller. The Processor may notify the data subject hereof. On request of the Controller, the Processor will provide assistance with handling such request to the extent necessary and reasonable. The Processor may charge reasonable costs for such assistance.

## **8. Confidentiality**

- 8.1. All personal data processed within the framework of this DPA by the Processor (and/or its sub-processors) on behalf of the Controller is subject to a duty of confidentiality vis-à-vis third parties. The Processor shall bind its employees and/or sub-processors, who will perform processing activities under this DPA, to an obligation of confidentiality.
- 8.2. This duty of confidentiality will not apply in the event that the Controller has expressly authorised the furnishing of such information to third parties, where the furnishing of the information to third parties is reasonably necessary in view of the nature of the instructions and the implementation of the Agreement and this DPA, or where there is a legal obligation to make the information available to a third party.

## 9. Audits

- 9.1. The Controller has the right to have audits performed by an independent third party bound by confidentiality to check Processor's compliance with this DPA.
- 9.2. An audit may only be undertaken once biennially and shall take no more than two business days. The Parties will agree in good faith the date of the audit.
- 9.3. The Processor shall cooperate with the audit and provide all information reasonably relevant for the audit, including supporting data such as system logs, and employees, as promptly as possible.
- 9.4. The costs of the audit, including the costs that the Processor has to make to cooperate with the audit, shall be borne by the Controller unless the findings from the audit indicate that Processor has been in breach of the GDPR. In that case all reasonable costs shall be borne by the Processor.
- 9.5. The findings further to the audit conducted will be assessed by the Parties in mutual consultation and, following on from this, may or may not be implemented by one of the Parties or by both Parties together.

## 10. Duration and termination

- 10.1. This DPA commences on the Effective Date and will stay in effect for as long as the Agreement is in effect. This DPA will automatically be terminated when the Agreement is terminated.
- 10.2. This DPA cannot be terminated prematurely and can only be amended with written and mutual agreement of both Parties. However, Parties both agree to amend this DPA if necessary, based on (new) privacy or data protection legislation.
- 10.3. This DPA forms an integral part of the Agreement which contains a limitation of liability and provisions with regards to jurisdiction. Such provisions are directly applicable to this DPA. In the event this DPA is terminated for any reason whatsoever, the Parties will discuss what to do with the processed data, subject to Section 16 of the Agreement.

## 11. Categories of Purpose and categories of personal data

### 11.1. Nature of the processing:

- I. Processor is providing the Controller with the software-as-a-service for electronic data capture and relevant support. It offers a platform database for the storage and management of medical research, namely electronic data capture, which may include, but not be limited to, the management of clinical studies, electronic consent, and surveys.
- II. Processor only provides the electronic data capture service on request of the Controller. How it is used, and which data is processed is up to the Controller. Parties shall process any and all personal data in line with EU Data Protection Laws. Processor only processes such data on behalf of the Controller.

### 11.2. Categories of personal data that are processed:

- I. Processor will process the following categories of personal data from the Controller exclusively in the context of the Agreement:
  - a. Identity data (last name, first name, login name).
  - b. Contact information (address, e-mail, IP address, telephone, fax).

- c. Contact information including Medical Research Data strictly for the purpose of using the survey module or Castor eConsent (e-mail, IP address, name of Study), according to 4.2 above and Appendix 1 below.
  - d. Behavioural data linked to the product of Processor and its users (e.g. user behavior, login logs, performance metrics).
- II. In addition, the Processor may process the personal data originated by the Controller. The personal data originated, entered and uploaded by the Controller will be at the Controller's sole discretion and risk. The Processor will not have access to or be able to identify what kind of personal data has been originated by the Controller and as such the Processor cannot know in advance what kind of personal data will be originated, entered and uploaded by the Controller. However, within the purpose of the performance of the Agreement, categories of personal data, including Medical Research Data originated by the Controller include the following:
  - a. Identity data (initials, date of birth, login name).
  - b. Medical and health information (such as physical and mental health, drug tests results, disabilities, family or individual health history, health records, blood type, DNA code, prescriptions, images).
  - c. Physical characteristics and findings (such as height, weight, age, gender).

#### 11.3. Categories of data subjects:

- 1. Partners, patients, and study participants of the Controller.
- 2. Employees and other staff members of the Controller, including trainees, administrators and research assistants.
- 3. Other persons whose data are processed by the Controller, such as counterparties.





#### 11.4. Purposes of the processing:


- I. The Processor shall process personal data for the purpose of fulfilling its obligations under the Agreement in relation to the Study.
- II. Controller may use Processor for the purposes listed below:
  - a. Electronic data capture system including the management of clinical research and, when using the encryption module, the contact data
  - b. Linking to Controller's internal and external sources
  - c. Extensive search and reporting possibilities
- III. On behalf of the Controller, the Processor will be storing the personal data of the Controller and thereby will be processing the personal data of the Controller, including Medical Research Data.
  - a. The Controller will be processing Data by and not limited to, the uploading, downloading, modifying, correcting and deleting personal data, including Medical Research Data.
  - b. Controller wishes to use Processor to manage and store data for its clinical study.


## Appendix 1 of DPA


### Castor Third Party Personal Data Processors

For each Castor EDC/CDMS study, the study administrator determines the data center where the data is hosted (please visit [this link](#) for more information).


 Microsoft Corporation	<b>Service Description</b>	<b>User Data</b>	Yes	<b>Type of DPA</b>	DPA + EU Standard Contractual Clauses
	Hosting of Castor EDC/CDMS and all medical data and/or Large File Upload or Castor eConsent data.  (Servers available in several geographical locations.)	<b>Patient Data</b>	Yes	<b>Status</b>	DPA signed
		<b>Data Location</b>	Per request of client.		
		<b>Types of data:</b> user account data, patient medical information & email addresses (encrypted), application usage information			
 Mailgun Technologies, Inc (Mailjet)	<b>Service Description</b>	<b>User Data</b>	Yes	<b>Type of DPA</b>	DPA + EU Standard Contractual Clauses
	Transactional user email for EU/UK-server, used to send out surveys to patients. ISO 27001 certified.	<b>Patient Data</b>	Only when used for surveys.	<b>Status</b>	DPA signed
		<b>Data Location</b>	BE/GER		
		<b>Types of data:</b> user account data (email, name), patient email address (for survey module use only)			
 SFDC Ireland Limited	<b>Service Description</b>	<b>User Data</b>	Yes	<b>Type of DPA</b>	DPA + EU Standard Contractual Clauses
	Customer support (helpdesk), Customer Relationship Management, triggered emails. ISO 27001 and SOC 2 Type 2 certified	<b>Patient Data</b>	No	<b>Status</b>	DPA signed
		<b>Data Location</b>	GER/FRA		
		<b>Types of data:</b> user account data (e.g. email, name), application behavior logging (e.g. new study created), study metadata			
 Highspot, Inc	<b>Service Description</b>	<b>User Data</b>	Yes	<b>Type of DPA</b>	DPA + EU Standard Contractual Clauses
	Sales enablement tool. ISO 27001 and SOC 2 Type 2 certified	<b>Patient Data</b>	No	<b>Status</b>	DPA signed
		<b>Data Location</b>	Europe		
		<b>Types of data:</b> user account data (e.g. email, name), application behavior logging (e.g. new study created), study metadata			

 <b>DATADOG</b> Datadog, Inc	<b>Service Description</b>	<b>User Data</b>	Yes	<b>Type of DPA</b>	DPA + EU Standard Contractual Clauses
	Service provider used for central log aggregation.	<b>Patient Data</b>	Yes	<b>Status</b>	DPA signed
		<b>Data Location</b>	GER		
		<b>Types of data:</b> application, infrastructure and networking logs of the Castor platform. These logs may include personal data of anyone accessing our systems (IP addresses)			


 HCL Technologies B.V.	<b>Service Description</b>	<b>User Data</b>	Yes	<b>Type of DPA</b>	DPA
	24/7 Helpdesk support services for Castor's applications end users	<b>Patient Data</b>	No	<b>Status</b>	DPA signed
		<b>Data Location</b>	GER		
		<b>Types of data:</b> user account data (e.g. email, name), study metadata			

 Stefanini NV	<b>Service Description</b>	<b>User Data</b>	Yes	<b>Type of DPA</b>	DPA
	24/7 Helpdesk support services for Castor's applications end users  If Direct To Patient (DTP) Services are purchased: Helpdesk support services for patients	<b>Patient Data</b>	No (Yes if DTP Services are purchased)	<b>Status</b>	DPA signed
		<b>Data Location</b>	Europe		
		<b>Types of data:</b> user account data (e.g. email, name), study metadata (if DTP Services are purchased) patient data			


Depending on the services purchased (e.g. specific hosting location preferences) Castor may also engage:

 <b>MANDRILL</b> Rocket Science Group (Mandrill & Mailchimp)	<b>Service Description</b>	<b>User Data</b>	Yes	<b>Type of DPA</b>	DPA + EU Standard Contractual Clauses
	Transactional user email for US-server, used to send out surveys to patients.	<b>Patient Data</b>	Only when used for surveys.	<b>Status</b>	DPA signed
		<b>Data Location</b>	US		
		<b>Types of data:</b> user account data (email, name), patient email address (for Castor EDC/CDMS's survey module use only)			


Not yet applicable. Depending on the services purchased (e.g. specific hosting location preferences) Castor may also engage:

 Twilio Inc (SendGrid)	Service Description	User Data	Yes	Type of DPA	DPA + EU Standard Contractual Clauses
	Transactional user email for US-server and Castor Standard Studies, used to send out surveys to patients. ISO 27001 and SOC 2 Type 2 certified.	Patient Data	Only when used for surveys.	Status	DPA signed
		Data Location	US		
		Types of data: user account data (email, name), patient email address (for survey module use only)			


Depending on the services purchased (e.g. Large File Upload functionality) Castor may also engage:

 Google LLC	<b>Service Description</b>	<b>User Data</b>	Yes	<b>Type of DPA</b>	DPA + EU Standard Contractual Clauses
	Hosting EDC/CDMS Large File Upload, Cloud Messaging and Key Management System and all related personal data.  (Servers available in several geographical locations.)	<b>Patient Data</b>	Yes	<b>Status</b>	DPA signed
		<b>Data Location</b>	Per request of client.		
		<b>Types of data:</b> encrypted patient information & encrypted email addresses, application usage information, device token.			


Not yet applicable. Depending on the services purchased (e.g. specific support with study building or medical coding) Castor may also engage:

 Julius Clinical research B.V.	<b>Service Description</b>	<b>User Data</b>	Yes	<b>Type of DPA</b>	DPA
	Additional consulting services. E.g. data management, statistical analysis.	<b>Patient Data</b>	Yes	<b>Status</b>	DPA signed
		<b>Data Location</b>	NL		
		<b>Types of data:</b> fully dependent on ordered services. May include user account data and patient medical information.			

Depending on the services purchased (e.g. specific support with study building or medical coding) Castor may also engage:

 Prudentia Group LLC	<b>Service Description</b>	<b>User Data</b>	Yes	<b>Type of DPA</b>	DPA + EU Standard Contractual Clauses
	Additional consulting services. E.g. medical coding.	<b>Patient Data</b>	Yes	<b>Status</b>	DPA signed
		<b>Data Location</b>	Per request of client.		
		<b>Types of data:</b> fully dependent on ordered services. May include user account data and patient medical information.			

Depending on the services purchased (e.g. Analytics Dashboard) Castor may also engage:

 Digital Ocean, LLC	<b>Service Description</b>	<b>User Data</b>	Yes	<b>Type of DPA</b>	DPA + EU Standard Contractual Clauses
	Hosting and network infrastructure of R-Shiny server	<b>Patient Data</b>	Yes	<b>Status</b>	DPA signed
		<b>Data Location</b>	EU		
		<b>Types of data (FOR USE CASTOR EDC/CDMS ANALYTICS DASHBOARD ONLY):</b> fully dependent on ordered services. May includes user account data and patient medical information, which is only accessible by the Castor EDC/CDMS authorized user and only goes through Service temporarily in transit. No data is stored on the R-shiny server			



## **Appendix 2 of DPA**

### **EU SCCs**

#### **1. SIGNATURE OF THE EU SCCs:**

Where the EU SCCs apply in accordance with Section 4 of the DPA each of the Parties is hereby deemed to have signed the EU SCCs at the relevant signature block in Annex I to the Appendix to the EU SCCs.

#### **2. MODULES**

Module Two (Controller to Processor) of the EU SCCs applies to the transfer of personal data under this DPA.

#### **3. POPULATION OF THE BODY OF THE EU SCCs**

3.1 The following applies as and where applicable to Module Two and the Clauses thereof:

- (a) The optional 'Docking Clause' in Clause 7 is not used and the body of that Clause 7 is left intentionally blank.
- (b) In Clause 9:
  - (i) OPTION 2: GENERAL WRITTEN AUTHORISATION is used. The placeholder "[Specify time period]" shall be read as "20 days". Annex III to the Appendix to the EU SCCs shall be read as containing the list of sub-processors set out in Appendix 1 of this DPA; and
  - (ii) OPTION 1: SPECIFIC PRIOR AUTHORISATION is not used and is deleted.
- (c) In Clause 11, the optional language is not used and is deleted.
- (d) In Clause 13, all square brackets are removed and all text therein is retained.
- (e) In Clause 17: OPTION 1 applies, and the Parties agree that the EU SCCs shall be governed by the law of the Netherlands in relation to any transfer of personal data originating from the EEA; and OPTION 2 is not used and that optional language is deleted.
- (f) For the purposes of Clause 18, the parties agree that any dispute arising from the EU SCCs in relation to any transfer of personal data originating from the EEA shall be resolved by the courts of Amsterdam, and Clause 18(b) is populated accordingly.

3.2 In this Paragraph 3, references to “**Clauses**” are references to the Clauses of the EU SCCs.

#### **4. POPULATION OF ANNEXES TO THE APPENDIX TO THE EU SCCs**

4.1 Annex I to the Appendix to the EU SCCs is populated with the corresponding information detailed in Section 11 of the DPA.

4.2 Part C of Annex I to the Appendix to the EU SCCs is populated as follows: “The competent supervisory authority shall be the Dutch supervisory authority”.

4.3 Annex II of the EU SCCs is populated with the corresponding information detailed in Section 5 to the DPA.

## **Appendix 3 of the DPA**

### **UK Addendum**

#### **1. UK TRANSFER ADDENDUM**

1.1 Where relevant in accordance with Section 4 of the DPA, the EU SCCs also apply in the context of transfer of personal data originating from the UK as varied by the UK SCCs in the manner described below:

(a) Part 1 to the UK SCCs. The parties agree:

- (i) Tables 1, 2 and 3 to the UK SCCs are deemed populated with the corresponding details set out in Section 11 to the DPA and the foregoing provisions of Appendix 2 (subject to the variations effected by the UK Mandatory Clauses described in (b) below); and
- (ii) Table 4 to the UK SCCs is completed by the box labeled 'Data Exporter' being deemed to have been ticked.

(b) Part 2 to the UK SCCs. The Parties agree to be bound by the UK Mandatory Clauses of the UK SCCs.

1.2 As permitted by Section 17 of the UK Mandatory Clauses, the parties agree to the presentation of the information required by 'Part 1: Tables' of the UK SCCs in the manner set out in this Appendix 3 of the DPA; **provided that** the parties further agree that nothing in the manner of that presentation shall operate or be construed so as to reduce the Appropriate Safeguards (as defined in Section 3 of the UK Mandatory Clauses).

1.3 In relation to any transfer of personal data originating from the UK to which they apply, where the context permits and requires, any reference in the DPA to the EU SCCs, shall be read as a reference to those UK SCCs as varied in the manner set out in this Appendix 3 of the DPA.

## **Appendix 4 of the DPA**

### **Swiss Addendum**

To the extent that Swiss data protection law, in particular the Federal Act on Data Protection of 25 September 2020, applies to the processing under the EU SCCs and requires, Parties to the EU SCCs to which this addendum is attached agree that the EU SCCs shall apply as modified such that (1) all references to GDPR in the EU SCCs shall refer to applicable Swiss data protection law, (2) the term "member state" must not be interpreted in such a way as to exclude data subjects in Switzerland from the possibility of bringing legal proceedings for their rights in their place of habitual residence, (3) the term "personal data" as used in the EU SCCs shall include personal data as defined in applicable Swiss data protection law, and (4) the Swiss Federal Data Protection and Information Commissioner shall be the applicable supervisory authority.

## **Appendix 5 of DPA**

### **Jurisdiction-Specific Terms**

To the extent Processor processes personal data originating from and protected by data protection laws in one of the jurisdictions listed in Appendix 4, then the terms specified in Appendix 4 with respect to the applicable jurisdiction (“Jurisdiction-Specific Terms”) apply in addition to the terms of this DPA. In the event of any conflict or ambiguity between the Jurisdiction-Specific Terms and any other terms of this DPA, the applicable Jurisdiction-Specific Terms will take precedence, but only to the extent of the Jurisdiction-Specific Terms’ applicability to Processor.

#### **California:**

Except as described otherwise, the definitions of: “Controller” includes “Business”; “Processor” includes “Service Provider”; “data subject” includes “consumer”; “personal data” includes “personal information”; in each case as defined under CCPA.

1. For this “California” section of Appendix 4 only, “Permitted Purposes” shall include processing Business’ personal information only for the purposes described in this DPA and in accordance with Business’ documented lawful instructions as set forth in this DPA, as necessary to comply with applicable law, as otherwise agreed in writing, including, without limitation, in the Agreement, or as otherwise may be permitted for Service Providers under the CCPA.
2. Service Provider’s obligations regarding data subject requests, as described in Section 7 (Requests of data subjects) of this DPA, apply to consumer’s rights under the CCPA.
3. Notwithstanding any use restriction contained elsewhere in this DPA, Service Provider shall process Business’ Data only to perform the services as described in the Agreement, for the Permitted Purposes and/or in accordance with Business’ documented lawful instructions, except where otherwise required by applicable law.
4. Service Provider may aggregate Business’ personal information as part of performing the services specified in this DPA and the Agreement.
5. Where sub-processors process the personal data of the Business, Service Provider takes steps to ensure that such sub-processors are Service Providers under the CCPA with whom Service Provider has entered into a written contract that includes terms substantially similar to this DPA or are otherwise exempt from the CCPA’s definition of “sale”. Service Provider conducts appropriate due diligence on its sub-processors.

## Annex 2:

### CASTOR STANDARD AGREEMENT

#### PREAMBLE

Both Parties, as identified in the Agreement above, have entered into an Agreement where Castor is responsible for the provision of the Services for the Client. Based on the study criteria provided for by Client, Castor will provide the Services under the terms defined in this Castor Standard Agreement (“CSA”). The following terms will only apply to a Castor Impact Program Study and Castor Essentials Study. All capitalized terms shall have the same meaning as in the Agreement unless stated otherwise.

#### 1. Definitions

The capitalized terms in this CSA have the same meaning as set out below.

- 1.1. **“Castor Essentials Study”** means a Study that qualifies for the Castor Essentials conditions as set out on and has been purchased through the Castor website ([www.castoredc.com/castor-essentials](http://www.castoredc.com/castor-essentials)).
- 1.2. **“Castor Impact Program Study”** means a Study that qualifies for the Castor Impact Program conditions as set out on the Castor website ([www.castoredc.com/castor-impact-program](http://www.castoredc.com/castor-impact-program)) and has been approved by Castor for participation in the Castor Impact Program.
- 1.3. **“Castor Standard Study”** means either a Castor Essentials Study or Castor Impact Program Study.
- 1.4. **“Personal Data Breach”**: means a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorized disclosure of, or access to, personal data transmitted, stored or otherwise processed as described in Article 4 paragraph (12) GDPR.
- 1.5. **“Welcome Email”** means the notification confirming the purchase of the Services by the Client.

#### 2. Nature and scope of this Castor Standard Agreement

- 2.1. Castor will provide the Services to Client as long as the Castor Standard Study meets the requirements set out on the Castor website ([www.castoredc.com](http://www.castoredc.com)) by Client and this CSA.
- 2.2. By accepting the offer and terms of this CSA via the Castor website, Client is agreeing to its terms and conditions.
- 2.3. Castor will provide the Services under the conditions set out in the Agreement and CSA. In case there are any inconsistencies between the terms of this CSA and the Agreement, the terms of the CSA will prevail.
- 2.4. The service levels for Castor Standard Studies for Castor EDC/CDMS are specified on Castor’s website ([www.castoredc.com/sla](http://www.castoredc.com/sla)) and will apply to all Castor Standard Studies unless agreed upon otherwise.

#### 3. Backups and support



- 3.1. Castor will use commercially reasonable efforts to make a backup of the Client Data in Castor EDC/CDMS at least once per day. After one month, Castor will keep one version per month available. Upon request of the Client and in emergency situations, Castor is authorized and will use its best efforts to restore such backup. Restoring a backup on request of the Client will be subject to an additional fee, unless such restore is necessary because of a failure caused by Castor.

#### **4. Payment conditions**

- 4.1. Client shall be invoiced upon accepting the terms and conditions of this CSA via the Castor website.
- 4.2. Client is obliged to pay upfront for the provision of the Services as presented in the Welcome Email.
- 4.3. Castor shall reserve the right to charge Client retroactively for the Castor Standard Study in case the information provided by Client was incomplete and/or incorrect. Castor will inform the Client beforehand.
- 4.4. Castor reserves the right to increase the pricing of its Services after the initial End Date of the Castor Standard Study as indicated in the Welcome Email.

#### **5. Audit and assistance**

- 5.1. Client shall only be allowed to perform an audit per the terms of Section 13 of the Agreement and/or Section 9 of the DPA in the event that a Personal Data Breach occurred, for which Castor may be reasonably held responsible. For the avoidance of doubt, Client is not entitled to perform audits under Section 13 of the Agreement or Section 9 of the DPA if no Personal Data Breach has occurred.
- 5.2. All costs associated with the audit performed by Client - either by a third party, Client or Castor - shall be borne by Client under any condition.

#### **6. Liability**

- 6.1. Castor's liability for direct damages sustained by the Client as a result of an attributable failure on the part of Castor to comply with its obligations under the Agreement or CSA, or on any grounds whatsoever, per event or series of related events, is limited to an amount that is equal to the compensation (exclusive of VAT) paid by the Client to Castor during the twelve (12) months prior to the event that caused damage.

#### **7. Term and termination**

- 7.1. Castor may terminate the CSA immediately upon notice to Client. Client may terminate this CSA immediately upon notice if the Castor Standard Study and associated Services are provided free of charge. In any other case, Client can only terminate the CSA once the (initial) Duration of the Castor Standard Study has completed. Client needs i) to provide Castor notice at least thirty (30) days before the end of the Duration of the Castor Standard Study and ii)

set the Castor Standard Study to not-live at least thirty (30) days before the end of the Duration of the Castor Standard Study.

- 7.2. If Castor or Client terminates the CSA, Castor will reasonably assist Client to return or delete all Client Data, if requested by Client.