General Terms and Conditions and Licence Terms (GTC & LT)

Allgemeine Geschäfts- und Lizenzbedingungen (AGLB)

Version 2.0, valid from 02 November 2026

regarding web application “Orca”

IMPORTANT – PLEASE READ CAREFULLY: BY CREATING AN ACCOUNT OR BY UTILIZING THE APPLICATION YOU AGREE TO BE BOUND BY THESE GTC & LT. IF YOU USE THE APPLICATION, OR IF YOU CLICK “I AGREE” OR TAKE ANY OTHER AFFIRMATIVE ACTION INDICATING YOUR ACCEPTANCE OF THIS GTC & LT, YOU HAVE AGREED TO THESE TERMS. IF YOU ARE AN AGENT OR EMPLOYEE OF THE INTENDED SUBSCRIBER OR USER, YOU INDIVIDUALLY REPRESENT AND WARRANT TO DKF THAT YOU ARE AUTHORIZED TO BIND THAT PARTY TO THIS GTC & LT. IF YOU DO NOT AGREE TO THIS GTC & LT, THEN YOU ARE NOT AUTHORIZED TO USE THE APPLICATION.

These are the GENERAL TERMS AND CONDITIONS AND LICENCE TERMS (GTC & LT) for the Service Orca, between the University Hospital Basel, Department of Clinical Research, Switzerland (“DKF”) and your company or research group (“Client”).

1 Area of Application

These GTC & LT shall apply to all contracts entered into by DKF with clients on the subject of providing the Service Orca. Deviating contrasting or supplementary GTC & LT of the Client shall not apply and shall be deemed as not incorporated into the contract, unless their application is agreed to explicitly and in writing.

2 Defined Terms

2.1 “Application”

is the web Application Orca (“Application”) offered to the Client over the internet that includes certain functionalities as further disclosed to the Client. For instance, the Application can be used to establish a quality management system (QMS). Within the Application, various types of documents and records, such as SOPs, CVs, Job Descriptions Training Logs can be managed. The Application is located at the domain **.dkfbasel.ch** and includes all modifications, customizations, enhancements, revisions, updates, upgrades and documentation that are required to keep the Application constantly in the state of the art required for its purpose and that DKF shall make available periodically. Applications do not include interfaces to other non-DKF software programs.

2.2 “Controller”

means the entity which determines the purposes and means of the processing of personal data as defined in the applicable Data Protection Laws and Regulations.

2.3 “Data Protection Laws and Regulations”

means all applicable data protection laws and regulations

2.4 “Contract”

means the document signed by both parties setting forth prices and quantity of user fees for software licenses for the Application and required storage space.

2.5 “Processor”

means the entity which processes personal data on behalf of the Controller as defined in the applicable Data Protection Laws and Regulations.

2.6 “User”

refers to each employee, consultant, client or other agent of Client who accesses the Application on Client’s behalf or invitation.

3 Term

The term of this GTC & LT shall become effective on the “start date of use” as indicated in the Contract and shall continue to be in force until the last day of the termination period as set out in section “Termination”. The GTC & LT are valid for a fixed term as described in the Contract, unless terminated or renewed earlier by the parties as specified. If the DKF commenced work for Client prior to the commencement date of this GTC & LT, all provisions of this GTC & LT shall apply to such activities, including but not limited to Section “Intellectual Property”, Section “Confidentiality”, and Section “Payments”. Unless agreed differently, the chargeable use of the Application starts after a three months test period.

4 Intellectual Property

4.1 License

Subject to this GTC & LT, DKF hereby grants to Client a non-exclusive, revocable, non-sublicensable, non-transferable, license to access and use the Application and any and all work products resulting from consulting services provided hereunder solely for its internal business operations by the number of Users for which Client has paid. Client is solely responsible for providing all telecommunications, computer and other equipment necessary for accessing the Application. DKF retains the right, in its sole discretion and upon three day’s prior written notice to Client, to restrict or terminate access to the Application by Client and/or particular Users if Client and/or its Users materially breach Section of “Intellectual Property” of this GTC & LT, or through use of the Application that violates any applicable federal, state, local or international laws or regulations, or if DKF reasonably believes it necessary to preserve the security, integrity or accessibility of the Application or DKF's network.

4.2 Ownership

DKF retains all rights not expressly granted to Client in this GTC & LT. Client acknowledges and agrees that, except as specifically set forth in this GTC & LT or in a Contract, DKF retains all rights, title and interest in and to the Application, including without limitation copyrights, patent rights, trademarks and trade names, and trade secrets.

4.3 Restrictions on Use

Except as otherwise specifically permitted under this GTC & LT, Client shall not, nor will Client permit any third party to (i) copy, modify, distribute, sell, assign, pledge, sublicense, lease, loan, time-share, rent, outsource, deliver or otherwise transfer the Application or any of its components to any third party in whole or in part, provided that Client may copy DKF's documentation as needed for use by its Users; (ii) derive or attempt to derive or discover the source code of any portion of the Application by any means; (iii) reverse engineer, decompile, disassemble, or translate the Application or any part thereof; (iv) upload, post, mail, publish, transmit or distribute in any way the Application or its components. Client may not access the Application for purposes of monitoring its availability, performance or functionality, or for any other benchmarking or competitive purpose, except as specifically agreed upon by the parties.

4.4 No Trademark License

No license, right or interest in the trademarks, trade names or service mark of either party or its licensor is granted hereunder, except as either party may agree in writing.

5 Confidentiality

5.1 Confidential Information

By virtue of this GTC & LT, either party may come into contact with the other party's non-public or proprietary information ("Confidential Information"). Confidential Information shall include, without limitation, any information or materials supplied to, obtained by or observed by either party or its employees, agents, consultants or subcontractors including proprietary software, source code documents, financial information, documentation, data, benchmark tests, specifications, customers, marketing strategies, business practices and any other proprietary information supplied to one party by the other and identified as proprietary or confidential, user identification and passwords, and account information. Client content created by or stored in the Application is considered Confidential Information. Each party shall hold the Confidential Information of the other party in strict confidence and not disclose the Confidential Information to third parties nor use for any purpose not authorized herein, nor permit access to Confidential Information, except to those of its employees or authorized representatives having a need to know and who are bound by confidentiality obligations at least as restrictive as those contained herein. Upon learning of any unauthorized use or disclosure of a disclosing party's Confidential Information, the other party shall immediately notify the disclosing party and reasonably assist the other party in remediating or mitigating any potential damage. If a party believes that there has been unauthorized use of Confidential Information, it shall have the right, in addition to any other remedies available to it, to seek injunctive relief to enjoin such acts, it being specifically acknowledged by the parties that any other remedies are inadequate.

5.2 Exceptions

The above restrictions of Section "Confidential Information" shall not apply to: (i) information that becomes, through no act or fault of the party receiving the Confidential Information, publicly known or generally known in the relevant industry; (ii) information received from a third party not obligated under a confidentiality agreement with the party disclosing the Confidential Information ("Disclosing Party"); (iii) information independently developed by either party without use of or reference to the Confidential Information; (iv) information required to be disclosed by law or court or governmental agency order, provided the party gives prompt notice of such requirement to the other party.

5.3 Ownership and Return of Confidential Information

All Confidential Information shall remain the property of the disclosing party; including Client content. Upon written request of the disclosing party, the other party shall promptly return to the disclosing party all documents and other tangible materials representing the disclosing party's Confidential Information, together with all copies, in whole or in part, thereof; at disclosing party's expense. After termination, DKF shall have no obligation to maintain or provide any Client content and shall, unless legally prohibited, thereafter delete all Client content in DKF's systems or otherwise in DKF's possession or control within a reasonable timeframe. It is the sole obligation of the Client to ensure that it possesses the necessary back-up copies, etc. of the Client content that it desires to retain when the agreement is terminated.

6 Additional Terms

6.1 User Overages

If at any point during the term, Client wants to activate additional User(s) totaling more than the number specified in the Contract, the additional User(s) shall be ordered by Client and will be treated as new Users and may be subject to additional fees applied by DKF. Such additional Users shall also be added to a renewal term, if applicable (as defined in Section "Renewal"). If applicable, the maximum amount of storage will be defined in the Contract. If Client does not order additional licenses for new Users but uses storage or adds additional Users in excess of agreed and ordered number of Users or storage in a Contract, excess usage and storage (i.e. above the subscribed levels) will be calculated and charged retroactively with an additional excess usage fee provided by DKF and applied by DKF from time to time. The number of User subscriptions purchased cannot be decreased during the term stated in the relevant Contract.

6.2 Support

DKF shall use commercially reasonable efforts to correct errors (a material failure of the Application to function in accordance with its documentation and functionalities) or provide a reasonable workaround. Client shall provide access, information and support to assist DKF in the process of resolving any error. This is Client's sole and exclusive remedy for errors.

6.3 Security

The Service Level Terms and Conditions sets out commercially reasonable measures to ensure that the security of the Application meets the functionalities and the required state of the art as set out in section "Application". Client is responsible for the security of all User names and passwords granted to it, for the security of the systems used to access the Application and for its Users' compliance with this GTC & LT.

6.4 Sensitive Information

Client acknowledges that the Application is intended for processing of pseudonymized health information from participants of clinical trials, but not for credit card numbers, financial account numbers, or other similarly-sensitive personal information, and Client assumes all risk arising from use of any such sensitive information with the Application, including the risk of any inadvertent disclosure or unauthorized access thereto.

6.5 Processing of Personal Data

Client shall when considered to be the Controller, in its use of the Application, process personal data in accordance with the requirements of relevant Data Protection Laws and Regulations. Client shall in such event have the sole responsibility for the accuracy, quality, and legality of personal data and the means by which Client acquired personal data.
If DKF is considered to be a personal data Processor to Client, DKF shall fulfill its obligations as a Processor in accordance with relevant Data Protection Laws and Regulations, and will furthermore accept such assignment based on the instructions, terms and conditions in a “data processing agreement” (see further below).

6.6 Client’s responsibility

The Client is responsible for ensuring that his password and user ID are not accessible to third parties. When entering his registration data, the Client must ensure that it cannot be spied on by third parties. If the Client suspects that someone has unauthorized access to these data or that they are being used without authorization, he must change the password immediately and contact DKF. DKF recommends that the Client always keeps his devices up to date and that he locks his devices with a code so that they are better protected in the event of theft, for example. Due to the sensitivity of the data, DKF recommends further that the Client always logs out manually after completing the request. Risks arising from the lack of maintenance of the Client's systems and software are borne entirely by the Client. DKF accepts no liability for misuse.

7 Disclaimer of Warranty

The Application, access thereto, and any services provided hereunder are provided on an “as is” basis, and DKF: (a) does not make, and hereby expressly disclaim, any and all warranties, representations or conditions, whether express, implied, statutory or otherwise, including but not limited to warranties of merchantability, fitness for a particular purpose, and any warranties arising from course of dealing, usage, or trade practice; (b) does not warrant that access to the Application will be uninterrupted, error-free, or secure, or that any information, software, or other material accessible through the Application is free of viruses (although DKF represents that it will use commercially reasonable efforts to avoid viruses and other harmful contents or components); (c) shall in no event be liable to Client or anyone else for any inaccuracy, error or omission in, or loss, injury or damage (including loss of data) caused in whole or in part by, or failures, delays or interruptions of the Application.

8 Liability

8.1 Direct Damages

Except for the obligations to indemnify the other party under Section “Indemnification”, or for any breach of its nondisclosure obligations (Section “Confidentiality”), neither party is, as far as this is legally permissible, liable for any damages hereunder. The parties' liability for damages caused by intentional or grossly negligent conduct is reserved. Limitation and exclusion of liability apply both to contractual and non-contractual or quasi-contractual claims.

8.2 Consequential Damages

Except for breaches of sections “Intellectual Property” or “Confidentiality”, in no event shall Client, DKF, or DKF’s suppliers be liable for any indirect, incidental, special, consequential or punitive damages, including without limitation damages for loss of profits, data or use, incurred by either party or any third party, whether in an action in contract or tort, even if the other party has been advised of the possibility

of such damages, provided however, the foregoing shall not be construed to limit either party's obligations as set forth in Section "Indemnification"; provided further however, that in the event Client has demonstrably granted access to the Application to non-authorized users, DKF shall be entitled to recover the full amount of any license fees that would relate to such users but not to any damages or indemnifications.

9 Indemnification

9.1 General Indemnity

Subject to section "Liability", each party ("Indemnitor") shall defend and indemnify the other party, its employees, officers, directors and agents ("Indemnitee") against all damages for bodily injury, death, or damage to real property, solely caused by the Indemnitor in the course of performing the services hereunder, provided that: (i) the Indemnitor receives prompt written notice of the claim from the Indemnitee under this Section; (ii) the Indemnitor has the right to control the defense of such claim and any related settlement negotiations, and; (iii) the Indemnitee provides to the Indemnitor, with the assistance, information and authority necessary to perform the Indemnitor's obligations under this Section. The liability hereunder shall be excluded or reduced, as the case may be, if and to the extent the Indemnitee has successfully recovered from any third person, including, but not limited to an insurer, costs, expenses, compensation for such claim, or such claim results from, or has been increased by, a failure of Indemnitee to mitigate losses in accordance with the principles of the applicable laws.

9.2 Intellectual Property Indemnity

If a third party makes a claim against Client that the Application directly infringes any patent, copyright, or trademark or misappropriates any trade secret ("IP Claim"), DKF will: (i) defend Client against the IP Claim at DKF's costs and expenses, and (ii) pay all costs, damages and expenses (including reasonable legal fees finally awarded against Client by a court of competent jurisdiction or agreed to in a written settlement agreement signed by DKF or by Client with prior written consent to DKF arising out of such IP Claim; provided that: (i) Client promptly notifies DKF in writing no later than thirty (30) days after Client's receipt of notification of a potential IP Claim; (ii) DKF may assume sole control of the defense of such IP Claim and all related settlement negotiations; (iii) Client provides DKF, at DKF's request and expense, with the assistance, information and authority necessary to perform DKF's obligations under this Section; and (iv) Client has not compromised or settled the IP Claim without DKF's prior written consent.

9.3 Limitation

Notwithstanding the foregoing, DKF shall have no liability for any claim of infringement based on: (i) the use of a superseded or altered release of the Application if the infringement would have been avoided by the use of a current unaltered release of the Application; (ii) an inadmissible modification of the Application; (iii) the use of the Application with third party software not provided by DKF; (iv) use of the Application other than in accordance with the documentation and this GTC & LT; or, (v) any materials or information provided to DKF by Client and Client content, for which Client shall be solely responsible. If the Application is held to infringe or is believed by DKF to infringe, DKF shall have the option, at its expense, to either replace or modify the Application to be non-infringing, or to obtain for Client a license in order to remedy the infringement and to continue using the Application in a non-infringing manner. If it is not commercially reasonable to perform either of the foregoing options, then DKF may terminate the Application license and refund any fees paid for the future use of the infringing Application. This section states DKF's entire liability and Client's exclusive remedy for any claim of infringement.

10 Fees and Payments

All fees and amounts due to DKF, including travel expenses, shall be set forth in one or more Contracts. All fees are payable in the currency set forth in the applicable Contract. Unless stated otherwise herein, all fees and amounts are non-refundable, and do not include any applicable taxes, which are the sole responsibility of the Client (except for taxes based on DKF's net income). All payments, if invoiced, are due within thirty (30) days from the date of invoice. All payments not made within such thirty (30) day period shall be delinquent. DKF may, in its sole discretion, immediately terminate the applicable Contracts, and Client's access to the Application with no further liability to Client. Notwithstanding the above, DKF may for each renewal period of the agreement increase its fees upon written agreement with Client. Client is provided with a written notice of the new pricing and fees not less than 90 days prior to the applicable Renewal Term.

11 Personnel

DKF personnel physically located at Client's facilities, ("On-Site"), shall comply with all reasonable workplace standards and policies of which Client notifies DKF in writing. While On-Site, DKF will have reasonable access to use Client's facilities that are necessary to perform the services and Client will provide reasonable working space to DKF. DKF and its personnel undertake to comply with the Client's instructions and regulations applicable to such On-Site.

12 Renewal

Unless Client has given DKF written notice of its desire not to renew the license or the Contract sixty (60) days prior to the end of the then-current term, a new term will automatically renew for another 12 months.

13 Termination

13.1 General

When the Processing activities end, DKF shall terminate the Client product account and delete any access to the system by Client and Users, and if applicable, at the choice of the Client, return or destroy all documents, processing and utilization results, and data sets related to the license agreement DKF have come into its possession, in a legally compliant manner. The same applies to any and all connected test, waste, redundant and discarded material. All customer data is deleted at the most 30 days following the date of termination as set out in this section. Servers/backups of content are deleted 90 days after such date. Written assurance of deletion or destruction of any Client information will be provided upon request.

13.2 Termination for Breach

If either party materially breaches the GTC & LT and such breach is not cured within thirty (30) days after written notice is given to the breaching party, then the other party may, by giving written notice of forty-five (45) days to the breaching party, terminate the applicable Contract as of the end of such forty-five (45) day period or such later date as is specified in such notice of termination or as agreed otherwise among the parties. Each party may terminate this GTC & LT for cause if the other party becomes the subject of a petition of bankruptcy or other proceeding relating to insolvency, receivership, liquidation, or assignment for the benefit of creditors.

13.3 Effect of Termination

Upon termination due to Client's uncured breach, Client shall pay all amounts due to DKF under all Contracts and shall not be entitled to a refund for any amounts already paid.

13.4 Survival

Those provisions of sections "Confidentiality", "Liability", "Indemnification", "Fees and Payments", "Renewal", "Termination", and "Miscellaneous" shall survive termination or expiration of the GTC & LT.

14 Service Level Term and Conditions

14.1 Definition of Availability

Provided that Client remains current in its payment obligations to DKF, Client shall have the right to and DKF shall have the obligation to perform the availability provisions set forth herein.

"Availability" or "Available" means Client is able to log in to the Application. "Unavailable" or "Unavailability" means Client is unable to log in to the Application, subject to the following subsections.

14.2 Scheduled Downtime

The Application may be inaccessible to Client during scheduled downtime, which will be notified to Client in writing sufficiently in advance. Scheduled downtime may occur for less than two (2) hours. Scheduled downtime shall not be considered times when the Application is unavailable.

14.3 Exceptions to "Unavailability"

In addition to scheduled downtime, any period in which Client is unable to use the Application due to the conduct of Client or any circumstances outside of the control of DKF or its third party providers, including but not limited to the following, shall not be considered times when the Application is Unavailable: (i) A failure or malfunction resulting from scripts, data, applications, equipment, or services provided and/or performed by Client; (ii) Outages initiated by DKF or its third party providers at the request or direction of Client for maintenance, back up, or other purposes; (iii) Outages occurring as a result of any actions or omissions taken by DKF or its third party providers at the request or direction of Client; (iv) Outages resulting from Client's equipment and/or third party equipment not within the sole control of DKF; (v) Events resulting from an interruption or shut down of the Application due to circumstances reasonably believed by DKF to be a significant threat to the normal operation of the Application, the facility from which the Application is provided, or access to or integrity of Client content (e.g., a hacker or a virus attack); (vi) Outages due to system administration, commands, file transfers performed by Client representatives; (vii) Other activities Client directs, denial of service attacks, natural disasters, changes resulting from government, political, or other regulatory actions or court orders, strikes or labor disputes, acts of civil disobedience, acts of war, and other force majeure items; (viii) Client's negligence or breach of its material obligations as set out in this GTC & LT; (ix) Lack of availability or untimely response time of Client to respond to incidents that require its participation for source identification and/or resolution.

14.4 Target System Availability

The "Target System Availability Level" is the Application availability level that DKF plans to meet or exceed during each quarter. The "Application Availability Level" is the number of hours during a particular period that the Application was Available to Client, excluding scheduled downtime (as defined

above), divided by the total number of hours during such period (as measured at the end of such period). The target Application Availability Level is 99% in any calendar quarter.

14.5 Service Credits and Termination

In the event that in a given year the Application Availability Level falls below 98%, DKF will provide service credits as described in the table below.

Application Availability Level	≤ 80%	> 80% - < 98%
Remedy (% of annual fee)	20	10

14.6 Sole and Exclusive Remedies

Subject to the body of these General Terms and Conditions, the service credits described in this section shall be Client's sole and exclusive remedy and DKF's sole and exclusive liability for any breach of the obligations.

15 Additional General Terms and Conditions if DKF acts as (Data) Processor

Data is loaded into DKF database as metadata for the identification and selection of resources for assignment to the work that is managed in the product. Processing activities comprises hosting, including offsite backup, disaster recovery redundant storage, and customer support. All data including personal data and identifiable information (PII) of Users is provided by the Client to the product.

The undertaking of the contractually agreed Processing of PII shall be carried out in accordance with this GTC & LT within Switzerland. The provisions shall apply to all services of data processing provided by DKF (hereinafter Processor) on behalf of the Client (hereinafter Controller) and in accordance with any privacy regulation the parties are subject to, which the Processor performs.

15.1 Scope of Processing Activities

Processor will process PII by hosting, and store project-related information in the product throughout the interface.

Beginning and duration of the processing starts with the conclusion of the contractual relationship and ends whenever the Controller terminates the contractual relationship.

15.2 Principles of the Processing Activities

Insofar as it is included in the scope of services, the principles related to Processing activities of PII as described in the applicable privacy regulation parties are subject to, must be adhered to by the Processor through the Controllers instructions. Thereby, Processor may carry out, retain, rectify, erase or restrict the Processing of PII only on documented and prior written instructions from the Controller, unless required to do so by the applicable laws to which Processor is subject. In such a case, Processor shall inform Controller of that legal requirement before processing, unless that law prohibits such information on important grounds of public interest. Processor shall immediately inform Controller if, in its opinion, an instruction infringes the applicable data protection provisions.

15.3 Categories of Personal Data

The subject matter of the processing of PII comprise in general the following data types/categories that the Controller/users insert when using the product
✓ Personal Master Data (Key personal data, *for identification*)
✓ Contact Data (*for logging in to the system*)
✓ IP addresses (*for identification*)
✓ Pseudonymized clinical trial participant data (*as part of TMF content*)

15.4 Categories of Data Subjects

The Categories of data subjects comprise in general
✓ Controller employees
✓ Users invited to the product by Controller
✓ Authorized Agents/Contractors
✓ Contact Persons
✓ Clinical trial participants
✓ Other persons using or mentioned in the product provided

15.5 Technical and Organizational Measures (TOM's)

TOM's to be taken shall guarantee a data protection level appropriate to the risk concerning confidentiality and integrity of the Controller and Users, in accordance with availability and resilience of the systems. The state of the art, implementation costs, the nature, scope and purposes of processing as well as the probability of occurrence and the severity of the risk to the rights and freedoms of natural persons determine the actions taken into account.
Processor's TOM's comprises
✓ Internal policies and instructions to Processor's employees
✓ Internal authorization for access to data
✓ Incident Management Response Plan

The TOM's are subject to constant technical progress and further development. In this respect, it is permissible for the Processor to implement alternative adequate measures. In so doing, the security of the defined measures must not be reduced. The Processor shall periodically monitor the internal processes and the TOM's to ensure that Processing within the area of responsibility is in accordance with the requirements of applicable data protection laws and privacy for the protection of the rights of the data subject.

15.6 Confidentiality

The Processor entrusts only such employees with the processing activities who have been bound to confidentiality and have previously been informed about the data protection provisions relevant to their work. The Processor and any person acting under its authority who has access to PII, shall only process PII by specific instructions from the Controller, which includes the powers granted in this GTC & LT, unless required to do so by law.

15.7 Assistance and Information

Processor shall make available to Controller on request all information necessary to demonstrate compliance with this GTC & LT, and shall allow for and contribute to audits, including inspections, by Controller or an auditor mandated by Controller in relation to the Processing of Controller personal data by the Processors.

The Processor shall, promptly notify Controller if Processor receives a request from a Data Subject to exercise the Data Subject's right of access, right to rectification, restriction of Processing, erasure, data portability, object to the Processing, or its right not to be subject to an automated individual decision making.

Processor shall not respond to a data subject request except on the documented instructions of Controller or as required by applicable laws to which the Processor is subject, in which case Processor shall to the extent permitted by applicable laws inform Controller of that legal requirement before the Processor responds to the Data Subject Request.

The Processor shall cooperate, on request, with the Controller to demonstrate and ensure compliance with a supervisory authority in performance of its legally obliged tasks. The Controller shall be informed of any inspections and measures conducted by the supervisory authority, insofar as they relate to the agreement. This also applies if the Processor is under investigation or is party to an investigation by a competent authority in connection with infringements to any Civil or Criminal Law, or Administrative Rule or Regulation regarding Processing of PII in connection with this GTC & LT.

15.8 Data Breach Notification

Processor shall notify Controller without undue delay upon Processor or any Sub-Processor becoming aware of a personal data Breach affecting Controller personal data. Processor shall provide sufficient information to Controller to meet any obligations to report or inform Data Subjects of the personal data Breach under applicable Data Protection Laws and Regulations. Processor shall co-operate with Controller and take reasonable commercial steps as are directed by Controller to assist in the investigation, mitigation and remediation of each such personal data Breach.

15.9 Appointment of Sub-Processors

Controller acknowledges and agrees that Processor may engage Processor Affiliates or a third-party as Sub-Processors in connection with the provision of the services according to the GTC & LT.

Processor shall make available to Controller the current list of Sub-Processors for the Services. Such List of Sub-Processors shall include the identities of the Sub-Processors, their country of location and details of the Processing to be undertaken.

Processor shall give Controller prior written notice of the appointment of any new Sub-Processor, including country of location and full details of the Processing to be undertaken by the Sub-Processor. Controller may object to Processor’s use of a new Sub-Processor by notifying Processor promptly in writing within thirty (30) business days after receipt of Processor’s notice.

15.10 Transfers

In the event Processor transfers PII to Sub-processors for the purpose of facilitating the Services provided, transfer must be subject to adequate transfer mechanisms, such as approved adequate level of protection. The Processing activities shall be such activities as necessary for Processor to provide the product and/or Services for Customer as described in the GTC & LT.

15.11 Deletion and return of data

Processor shall in any event thirty (30) days after the date of cessation of any Services involving the Processing of Controller personal data delete and procure the deletion of all copies of Controller personal data.

Controller may in its sole discretion by written notice to Processor within twenty (20) days of the Cessation Date require Processor to (a) return a complete copy of all Controller personal data to

Controller by secure file transfer in such format as is reasonably notified by Controller to Processor; and (b) delete and procure the deletion of all other copies of Controller personal data Processed by Processor.

16 Miscellaneous

The contractual relationship shall be construed and governed exclusively by the laws of Switzerland, without regard to its conflicts of laws, unless otherwise set forth in the relevant Contract. The United Nations Convention on the International Sale of Goods will have no application to the contractual relationship. All disputes arising out of or in relation to the contractual relationship will be brought before the competent court at Basel (City), Switzerland. In case of disputes, the Parties will consult each other before taking legal action.

DKF reserves the right to amend the terms and conditions of this GTC & LT. The Client shall be informed of such amendments by e-mail or through the information being made available on the Application's web site, which shall be notified to Client by advance e-mail as well. The Client shall be deemed to have received such notice within two (2) weeks of the notice being sent by e-mail. Where the Client does not accept the amendment, the Client shall be entitled, within thirty (30) calendar days from the date of dispatch of the e-mail to terminate the agreement with immediate effect. Where the agreement is not terminated by the Client within the aforementioned time, the Client shall be deemed to have accepted the new terms and conditions.

Neither party may assign the GTC & LT, or its rights or duties hereunder, to any third party, in whole or in part, except that it is agreed that a change of control of a party is not deemed an assignment pursuant to this section; provided, however, that DKF may terminate the contractual relationship if a change of control of Client results in that Client is controlled by competitor to DKF.

All notices under this contractual relationship shall be in writing, including e-mail. All communications shall be sent to each party's address specified in this GTC & LT and in the Contract (or such other address as such party may later specify in writing for such purpose).

The provisions of this GTC & LT are severable. If any one provision is held to be invalid, the invalid provision will be replaced by a valid clause coming closest to the invalid clause's intention. No failure or delay by a party in enforcing any right under this GTC & LT shall constitute a waiver of that right.

This GTC & LT has been prepared in the English language and the same shall be controlling in all respects. Any non-English versions of this GTC & LT are provided solely for accommodation purposes. The Contract and the GTC & LT constitute the entire contractual relationship of the parties with respect to this subject matter, and supersedes all prior and contemporaneous representations, proposals, negotiations, discussions, and agreements between the parties, whether oral or in writing, including but not limited to any agreement related to confidentiality and nondisclosure. There are no intended third-party beneficiaries under this GTC & LT.

Except for Client's obligations to make payments as set forth in this GTC & LT and each party's obligations related to confidentiality, each party shall be excused from performance for any period during which, and to the extent that, it or its subcontractor(s) is prevented from performing any obligation or service, in whole or in part, as a result of causes beyond its reasonable control and without its fault or negligence. Such acts shall include without limitation acts of God, strikes, lockouts, riots, acts of war, epidemics, governmental laws and regulations imposed after the fact, fire, communication line failures, power failures, earthquakes, floods or other natural disasters (a "Force Majeure Event"). Delays in delivery or in meeting completion dates due to Force Majeure Events shall automatically extend such dates for a period equal to the duration of such events. In the event of any conflict between the provisions in this GTC & LT and any Contract, the terms of such Contract shall prevail to the extent of any inconsistency.

Departement Klinische Forschung
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