

## General Terms & Conditions for RAYLYTICs SaaS platform and Professional Services

in the following also: "agreement"

### Preface

RAYLYTIC develops software that automates medical data collection and analysis tasks. Related services include the development of radiographic and clinical trial- and testing protocols, the conduct of medical image analysis, data management and statistical data processing.

Both parties wish to work together in utilizing the UNITY platform and/or to conduct clinical studies. In the latter case, the CUSTOMER acts as capital provider for the clinical study (sponsor). Physicians and other staff providing care and treatment to a patient are referred to as investigator(s), lead investigator, site(s) or in the following generally CONTRIBUTOR(S). RAYLYTIC acts as SaaS platform provider for data collection, analysis and imaging core lab services. RAYLYTIC may also provide professional support and consulting services for the CUSTOMER.

### 1. Services

As CUSTOMER reasonably directs, RAYLYTIC shall perform the activities as set forth in one or several quotation(s), collaboration agreements, master service agreements with subsequent work orders or other contractual agreements. In performance of the services, RAYLYTIC shall comply with all applicable US, European and German regulations, guidelines, and rules governing federal and state healthcare programs, including, but not limited to regulations concerning data protection and privacy, compliance regulations, anti-kickback-regulations, as well as with CUSTOMER's policies while on its premises.

### 2. Compensation

In consideration for RAYLYTIC's performance of the services, CUSTOMER shall pay RAYLYTIC the amount set forth in quotations provided by RAYLYTIC. The quotations and optionally any service descriptions define the deliverables and services provided by RAYLYTIC. A quotation becomes contractually binding to both parties once CUSTOMER returns a quotation to RAYLYTIC, signed by an authorized officer of the CUSTOMER.

CUSTOMER shall also pay RAYLYTIC for all reasonable and necessary out-of-pocket expenses incurred by RAYLYTIC in performing the services (upon presentation of appropriate receipts), including costs of travel, food and lodging (where applicable).

Travel-time is billed at 50% of the hourly consultancy rate. Transportation means: a) train: first class; b) flights: up to five hours duration economy or economy + class, above business; c) rental car: as incurred or d) 0.50€/km driven for private car usage.

Prices stated in any quote are valid for the period stated or for a maximum of two years, whichever is shorter, starting from the issue-date of the quote. RAYLYTIC reserves the right to adjust prices thereafter to adapt to changes in underlying costs and inflation. Unless otherwise stated in the quotation, RAYLYTIC will increase prices at 4.5% annually, starting 2 years from the date of contracting. Quoted prices may change at any time and RAYLYTIC will be bound to the stated prices only if the quote has been accepted in writing and returned within the period of validity. If a study is rescheduled by more than 6 months, RAYLYTIC will charge a retainer fee of 1% of the quoted total amount to cover costs associated with keeping personnel available and trained.

The parties agree that any services requested in addition to the agreed quote shall fall under the same terms, conditions and compensation schedule as outlined in the quote and this agreement. Additional services agreed to in writing will be considered approved if CUSTOMER does not cancel or object within two (2) weeks of RAYLYTIC's written order confirmation or RAYLYTIC's conduct of the requested service.

### 3. Payment Terms

Unless otherwise agreed, both parties agree to the following general payment terms:

- RAYLYTIC will provide monthly invoices. Invoicing may be skipped if the amount due is less than EUR 2.000. Invoices generally reflect the services performed and license fees due for the specified period.
- RAYLYTIC reserves the right to request payment in full once it can be reasonably demonstrated that the final deliverables are prepared and ready to be transferred to CUSTOMER.

RAYLYTIC will prepare an invoice for each of the payments due according to the terms outlined and agreed in 3) above and send the invoice electronically to CUSTOMER via PDF / email. CUSTOMER will verify the correctness of the invoice and transfer the amount due within 15 calendar-days to the following RAYLYTIC bank account:

For transfers in **EUR** (SEPA wire)

Account holder: RAYLYTIC GmbH  
IBAN: DE80 1203 0000 1059 0392 61  
SWIFT/BIC: BYLADEM1001

Bank name and address:

DKB  
Taubenstr. 7-9  
10117 Berlin  
Germany

For transfers in **USD**, from a bank **within the US**

Account holder: RAYLYTIC GmbH  
ACH and Wire routing number: 084009519  
Account Number: 9600000000054027

Bank name and address:

Wise  
30 W. 26th Street, Sixth Floor  
New York NY 10010  
United States

For transfers in **USD**, from a bank **outside the US**

Account holder: RAYLYTIC GmbH  
Routing number: 026073150  
SWIFT/BIC: CMFGUS33  
Account Number: 8310213605

Bank name and address:

Wise  
30 W. 26th Street, Sixth Floor  
New York NY 10010  
United States

### 4. Term and Termination

This agreement shall be effective upon the date of execution of a contract where RAYLYTIC is to provide their SaaS platform or professional services and continue for a period of three (3) years or for the duration of the planned study, whichever is the longer period. Either party may terminate this agreement immediately upon the breach of a material provision of this agreement by the other party. Termination or expiration of this agreement shall not affect any rights or obligations which have accrued prior thereto or in connection therewith. A termination of the agreement does not entitle the CUSTOMER to receive a refund of any prior payment. The CUSTOMER may download any results, images or other data submitted to or generated by RAYLYTIC "as is" at any time prior to termination via the UNITY platform. After termination, the CUSTOMER will lose access to the data and RAYLYTIC will delete the data from the platform, except where the data is required to provide legal evidence or a competent authority ordered RAYLYTIC not to delete data.

### 5. Confidential Information

During the term of this agreement and for a period of five (5) years thereafter, RAYLYTIC shall not disclose confidential information except as permitted in this agreement or as approved in writing by CUSTOMER. Confidential information shall include all information concerning CUSTOMER and the services disclosed to RAYLYTIC by or on behalf of CUSTOMER, or developed as a result of RAYLYTIC's performance of the services, except any portion thereof which:

- is known to RAYLYTIC on a non-confidential basis before receipt thereof under this agreement, as evidenced by RAYLYTIC's written records;
- is disclosed to RAYLYTIC after acceptance of this agreement by a third party having a right to make such disclosure in a non-confidential manner; or
- is or becomes part of the public domain through no fault of RAYLYTIC.

RAYLYTIC shall not disclose to CUSTOMER any information which is confidential and/or proprietary to a third party without first obtaining the written consent of both such third party and CUSTOMER. Upon the earlier of completion of the services or termination or expiration of this agreement, RAYLYTIC shall

destroy or return to CUSTOMER all confidential information, data and materials provided to RAYLYTIC by CUSTOMER, or created for CUSTOMER by RAYLYTIC as a result of the services, as requested by CUSTOMER.

CUSTOMER shall not disclose any information to a third party on which RAYLYTIC has an interest to keep it confidential and/or proprietary. This includes in particular, but is not limited to, RAYLYTIC's service offering, service details, service cost, RAYLYTIC's proprietary technology, documentation of RAYLYTIC's quality or IT systems, software validation documentation, IP, guidelines and process descriptions and similar documents furnished by RAYLYTIC and provided to CUSTOMER.

A violation of above confidentiality understanding by either party allows the other party to claim compensation for the incurred damage and to request immediate remediation of the situation, as deemed appropriate by the party whose confidentiality interests have been compromised.

Nothing shall be construed to restrict either party from disclosing the other party's confidential information as required by law or court order or other governmental order, provided in each case the party being requested to make such disclosure shall thoroughly validate the legitimacy of the request, timely inform the other party and use all reasonable efforts to limit the disclosure and maintain the confidentiality of such confidential information to the maximum extent possible. In addition, the party requested to make such disclosure shall permit the other party to attempt to limit such disclosure by appropriate legal means.

RAYLYTIC acknowledges that, as part of its services to CUSTOMER, it may receive patient health information ("PHI"), which shall be automatically considered confidential information, regardless of how marked or provided. In addition to all other restrictions on confidential information, RAYLYTIC will:

- (a) not disclose the PHI, except as expressly authorized under this agreement or as otherwise required by law;
- (b) use appropriate safeguards to prevent the disclosure of the PHI;
- (c) report to CUSTOMER and any authorities, if required by law, any disclosure of the PHI in a manner not provided for by this agreement;
- (d) ensure that any employee or agent to which it provides all or any portions of the PHI agrees to the same restrictions and conditions that apply to the PHI hereunder;
- (e) not make any effort to identify, or use or disclose the PHI in any manner that identifies the individual patient to whom the PHI pertains; and
- (f) not contact any of those individual patients to whom the PHI pertains.

#### 6. Presentations, Publications and Publicity

RAYLYTIC shall not present or publish, nor submit for publication, any work resulting from the services without CUSTOMER's prior written approval.

#### 7. Representation and Warranties

Each party represents and warrants that:

- (a) neither this agreement, nor any payment hereunder, is in exchange for any explicit or implicit agreement or understanding that RAYLYTIC prescribes, recommends, uses or purchases any products of CUSTOMER or otherwise arranges therefore,
- (b) the total payment for the services represents the fair market value for the services and has not been determined in any manner that takes into account the volume or value of any referrals or business between RAYLYTIC and CUSTOMER.

RAYLYTIC warrants that:

- (a) the terms of this agreement are not inconsistent with any other contractual or legal obligations RAYLYTIC may have or with the policies of any institution with which RAYLYTIC is associated,
- (b) it is able and willing to provide the services requested by CUSTOMER and that RAYLYTIC has the experience, personnel and resources to do so in a commercially reasonable and workmanlike manner. RAYLYTIC further warrants and represents that it will provide to CUSTOMER services that, in RAYLYTIC's best professional judgment, fulfill the needs and requirements that CUSTOMER has contracted with RAYLYTIC to fill;
- (c) any services will be performed applying scientifically based, state-of-the-art knowledge and procedures, in particular GCP and GLP guidelines, under utmost objectivity and neutrality; RAYLYTIC warrants that neither internal nor external conflict(s) of interest prevent the objective conduct of the requested services;
- (d) all received data is protected against non-authorized access by employing state-of-the-art technical and organizational measures;
- (e) the safety and availability of all received data. For this, RAYLYTIC servers and data storage are geographically distributed and hosted in qualified, EU-GDPR compliant datacenters, located in Germany.
- (f) all staff affiliated with data relating to this agreement is personally obliged to medical secrecy according to §203 StGB (German book of criminal code) and aware of the personal consequences of non-compliance, including imprisonment.
- (g) RAYLYTIC maintains a 21 CFR part 820 and ISO 13485 compliant quality management system for the development of software modules utilized for medical diagnostic purposes. Software modules that process, store or access patient health information (PHI) are compliant to HIPAA and EU-GDPR regulations. Software modules that create records for use within clinical trials are compliant to 21 CFR part 11. The UNITY platform as a whole is compliant to GCP and GMP guidelines.
- (h) RAYLYTIC maintains an independently audited information security management system according to ISO 27001.
- (i) The UNITY software platform is constantly being improved. Due to the nature of web-based software, CUSTOMER will always receive the most recent released software version. CUSTOMER may have access to other versions for testing or investigational uses.
- (j) RAYLYTIC follows the continuous integration software development paradigm. Instead of mayor releases that may confront customers with substantial retraining issues, CUSTOMER will benefit from continuous, incremental updates with a release cycle between 3 and 6 weeks for the production system.
- (k) The availability of the UNITY platform is ensured through data center server hosting with redundant internet connections, data backups, emergency power supply, multi-layer physical, cyber security and access controls and other state-of-the-art emergency and cyber defense means. The availability is guaranteed at over 99.5% excluding maintenance windows (scheduled on weekends and bank holidays whenever possible).
- (l) RAYLYTIC maintains a prioritized backlog for feature requests and errors. Thorough automated and manual testing and validation means are applied to ensure data validity, traceability and consistency at all times. Possible other errors include incompatibilities with certain browsers, unavailability of certain functions, spelling errors or unavailability of the service. Based on the severity of the error, RAYLYTIC guarantees a response time of less than 5 days for the least prioritized issues, and 12h for the most severe issues.

Except as provided herein, RAYLYTIC makes no warranties, either express or implied, in connection with the services to be performed hereunder. RAYLYTIC specifically declines any implied warranties of merchantability and/or performance for a particular purpose or product in connection with the services to be rendered under this agreement. It is the CUSTOMER's responsibility to validate appropriateness and compliance of the platform for the intended use.

Except when explicitly agreed otherwise, RAYLYTIC may correct or revise analysis results at any time until a study database is locked. Reasons for revision may be the correction of errors, the application of improved analysis or QA validation methods or data cleaning procedures.

In the event of an imminent threat related to data privacy or the availability of the UNITY platform, RAYLYTIC reserves the right to temporarily shut down or disconnect the UNITY platform or related services as a last resort to minimize damage and accelerate the remediation of any risk. In such an event, RAYLYTIC shall not be liable for any damage caused by the unavailability of the system.

#### 8. Data Ownership

The ownership of the collected data is determined by country or state law and therefore may vary. It is the common understanding of the parties, that

- (a) Study CONTRIBUTORS (not patients) own the medical records they create from patient encounters. Patients may or may not own the data in their medical records, but, in any case, they may have a right in most states and countries to review or seek modifications of their records. As RAYLYTIC stores anonymized or pseudonymized data only, RAYLYTIC cannot and will not be able to make any data changes or disclose any data based on patients' requests. Any such requests will be handled through the study CONTRIBUTOR or study sponsor.
- (b) RAYLYTIC does not have the right to disclose any PHI records to other parties than the CONTRIBUTOR of the record or to the study sponsor. If PHI shall be disclosed to a third party, the CUSTOMER will provide evidence of an agreement between CONTRIBUTOR and CUSTOMER allowing the release of anonymized or pseudonymized PHI to the third party. Such evidence may be documented in the patient informed consent form or an agreement between the CONTRIBUTOR(s) and CUSTOMER.
- (c) CUSTOMER owns the data records collected by its CONTRIBUTORS – if permitted by applicable law – and any aggregated data and any further analysis or statistics created by RAYLYTIC, the CUSTOMER or a third party as part of this agreement, its appendices and referenced quotation(s). Any rights of publication, disclosure or use of this data belongs solely to the CUSTOMER.
- (d) RAYLYTIC owns the UNITY software platform including all modules and the database system. The database system may contain input data (including medical images and clinical data), processing information and analysis results for multiple CUSTOMERS and studies. RAYLYTIC owns the proprietary software, database system, the data records and any trained AI algorithms. CUSTOMER agrees that the contributed data records, collected images and other data become part of the whole database system. CUSTOMER grants RAYLYTIC the right to store, use and anonymize the contributed data for internal purposes such as QA, plausibility-, validation- and verification checks, accuracy assessments, technical improvements and the further development of its software.

By this agreement, CUSTOMER does not acquire any license or use-right to utilize the RAYLYTIC technologies or services other than stated in the referenced quote. If RAYLYTIC agreed to make the UNITY system accessible relating to the CUSTOMERs clinical studies as part of an executed order or collaboration agreement, CUSTOMER has access to the study records, analyses, data records and images the CUSTOMER or his CONTRIBUTORS provided data for. By specifying the duration and paying the corresponding storage and maintenance fee, CUSTOMER may request continued access to the data residing in the UNITY system, which RAYLYTIC agrees to provide for the period agreed.

CUSTOMER may export or download any data record and image collected or produced under an executed collaboration agreement for any purpose while CUSTOMER has access to the UNITY system and the data is maintained by RAYLYTIC. CUSTOMER is responsible to comply with any legal data retention obligations. RAYLYTIC has no obligation to maintain and make data accessible after CUSTOMER ceased to pay for data storage and maintenance.

9. Debarment

RAYLYTIC represents and warrants that RAYLYTIC has no knowledge of any circumstances which may affect the accuracy of the foregoing representations and warranties. RAYLYTIC further represents and warrants, that it is not aware of any proceedings or investigations of the German Federal Institute for Drugs and Medical Devices (BfArM), the US-FDA or any other debarment proceedings against RAYLYTIC or any person or entities performing services or rendering assistance relating thereto. RAYLYTIC will immediately notify CUSTOMER if RAYLYTIC becomes aware of any such circumstances during the term of this agreement.

10. Independent Contractor

RAYLYTIC's status under this agreement is that of an independent contractor, or for HIPAA considerations, of a business associate. RAYLYTIC shall not be deemed an employee, agent, partner or joint venturer of CUSTOMER for any purpose whatsoever, and RAYLYTIC shall have no authority to bind or act on behalf of CUSTOMER or vice versa.

11. Subcontracting and Medical Advisor

RAYLYTIC will subcontract certain services, such as qualitative image analysis and selected consulting services, to practicing radiologists or orthopedic surgeons who can demonstrate expert knowledge and experience for the duties assigned. Upon request, RAYLYTIC will disclose the identity and provide evidence of a radiographic reviewer's qualification by disclosing the name(s) and CV(s) of the affiliated reviewer(s). RAYLYTIC's senior medical advisor is Prof. Dr. Martin Skalej.

12. Choice of Law

This agreement shall be governed by and construed in accordance with the laws of the European Union. In case of a controversy or claim arising out of this agreement, the place of jurisdiction shall be the place of the business of the accused party.

13. License & Copyright

The software provided by RAYLYTIC for the conduct of a clinical study or data collection task is a use-license for the agreed duration of the study. The license does not include rights of ownership to the software or for use beyond the agreed duration, for reverse-engineering, copying, embedding, transferring or otherwise disclosing any part of its code into other software or to another party, except with the written approval of RAYLYTIC.

14. Non-Solicitation

During the cooperation and for a period of one year after its end, the parties undertake not to solicit or hire employees of the other. In case of violation, the hiring party shall be obliged to pay damages, the amount of which shall be determined by the respective higher annual salary of the employee at either of the parties.

15. Miscellaneous

These terms & conditions are a legally binding part of the parties' agreement for cooperation with respect to the subject matter hereof. Only the version of the terms & conditions shall apply which was current when placing the order by the customer. Any previous versions shall be superseded with respect thereto. The invalidity, in whole or in part, of any of the provisions of these terms and conditions, shall not affect the enforceability of any of the other provisions thereof. The parties agree that any invalid clauses shall be replaced by clauses conforming to applicable law while the original intent is maintained to the maximum extent allowable.

This version is effective September 13, 2023 and supersedes any previous versions for all contractual engagements executed after this date.



Frank T. Trautwein, CEO Raylytic GmbH