

## GENERAL TERMS AND CONDITIONS OF BUSINESS

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### GENERAL

- (1) The following General Terms and Conditions of Business and Sale constitute an integral part of the contractual agreements concluded between Pharmtrace and the Client. Unless agreed otherwise, all offers, deliveries and services are based exclusively on these Terms and Conditions of Business.
- (2) Pharmtrace does not recognize any terms of the Client conflicting with these Terms and Conditions, even if Pharmtrace does not expressly raise objections to such terms in specific cases.
- (3) These Terms and Conditions of Business shall also be part of any contractual agreements within the framework of existing business relations with the Client, even if Pharmtrace does not separately refer to their inclusion.

### CONCLUSION AND CONTENT OF CONTRACT

- (1) All offers of Pharmtrace are without obligation and not binding unless stated otherwise. All contractual agreements pertaining to Pharmtrace's services and all ancillary agreements and subsequent changes are subject to Pharmtrace's confirmation in writing to become valid. However, an order from the Client shall be deemed to have been accepted even in the absence of written confirmation, if Pharmtrace carries it out within an acceptance period of not more than 30 days.
- (2) Contents and extent of the obligation to perform services result from mutual written declarations. The services agreed upon shall be the subject matter of the agreement. Under no circumstances shall the order extend to a procedure leading to a certain test result. Specifications concerning the services to be supplied shall not be fully authoritative. The right to make changes customary in the performance of research and trials is reserved provided that such changes or improvements do not impair the purpose stated in the contract.

### TERMS OF SERVICES

- (1) Unless specifically agreed otherwise, the times and dates of performance of services shall be deemed to be only approximate.
- (2) Without prejudice to Pharmtrace's rights arising from the Client's default, the dates and periods of performance shall be extended by the time the Client fails to meet its commitments under contractual or statutory provisions.
- (3) In case of force majeure and in the event of other circumstances which could not be foreseen at the time the contract was concluded (e.g., operational breakdowns of any kind, difficulties in obtaining materials or energy, labour disturbances or labour disputes of any kind, accidents, failure of utilities, disease, measures taken or decisions made by authorities or IRB/IEC's, or other such occurrences), for which Pharmtrace is not responsible and which substantially hinder or render impossible the performance of services, Pharmtrace shall be entitled to withdraw from the contract, if the circumstances are not of temporary character. In the case of temporary circumstances, the dates and periods of performance shall be extended or prolonged by the duration of the circumstances plus a reasonable startup time. If, owing to the delay, the Client cannot be reasonably expected to accept the services, Client can withdraw from the order by making a declaration in writing to this effect and sending it to Pharmtrace without delay. No claims for damages shall be allowed in the cases mentioned in the foregoing. But in every case, Pharmtrace is obligated to notify the Client without delay of the unavailability of services.
- (4) The Client shall be entitled to test results obtained during the course of services and the right to use them only when full payment has been received.
- (5) Any rights concerning inventions and results shall be subject to a separate agreement. In no event shall the Client, without the former written consent of Pharmtrace, make use of Pharmtrace's own inventions, patents, know-how or any other forms of Intellectual Property which are in possession of Pharmtrace before, during or after the performance of services.
- (6) Either party shall notify the other party of any circumstances or events that might endanger the performance of the services agreed upon.

### CLIENT'S OBLIGATIONS

- (1) Unless agreed otherwise, the Client shall provide Pharmtrace, in a timely fashion and free of charge, with all information, documents, materials and investigational products needed for any services.
- (2) The Client will inform Pharmtrace in advance of any risks inherent to investigational products, materials or any other item delivered under individual agreements. Client shall determine for the investigational product(s) acceptable storage temperature, storage conditions, storage times, reconstitution fluids and procedures and devices for product infusion and shall inform all involved parties of these determinations. In case of special risks, Client will indicate the special conditions by either labelling the respective items accordingly or inserting references in the accompanying letter. The Client is responsible for the ongoing safety evaluation of the investigational product(s) and should promptly notify all involved parties of findings that could affect adversely the safety of subjects, impact the conduct of services, or alter the approval/favourable opinion of the IRB/IEC's to continue any agreed upon services.

### OBLIGATIONS OF PHARMTRACE

- (1) Pharmtrace shall execute all services with scientific diligence and in accordance with the laws of the countries where the services are performed. Pharmtrace will adhere to the protocol and, if applicable, to guidelines and procedures, agreed upon with the client. Pharmtrace ensures that the protection of data will be safeguarded.
- (2) Client shall be entitled to audits and inspections which may take place at any time provided that the Client has given Pharmtrace sufficient notice in advance.

### PRICES AND TERMS OF PAYMENT

- (1) Pricing for the agreed services shall be based on the relevant price lists as amended from time to time, unless Client-specific prices have been agreed. Additional or special services shall be billed separately.
- (2) If not agreed otherwise, the following terms of payment shall apply:
  - 20% of the sum of order upon placement of the order
  - 30% at the beginning of the clinical part
  - 40% after termination of the clinical part

10% after handing over the final study report.

- (3) Prices are quoted in euro (EUR) plus the current VAT.
- (4) Unless agreed otherwise, payment shall be made without deduction within 14 days of the date of the invoice. If settlement is by bills of exchange or checks, payment shall be deemed to have been made when they are cashed.
- (5) In case of default of payment by the Client, Pharmtrace is entitled to charge an interest rate 8% above the reference rate. This does not exclude asserting claims for other damages.
- (6) If after placing of an order a project has not begun or stopped early for reasons beyond Pharmtrace's control, Pharmtrace shall be entitled to account for a lump sum compensation of 20% of the remaining sum of the order in addition to already supplied performances.
- (7) The Client shall not be entitled to withhold payment on account of Client's counterclaims or to set it off against such counterclaims unless such counterclaims are uncontested or recognized by declaratory judgment.
- (8) If, after concluding the contractual agreement with the Client, circumstances become known to Pharmtrace which tend to substantially undermine confidence in Client's willingness or ability to pay, Pharmtrace is entitled, notwithstanding agreements to the contrary, to make future services contingent on advance payment or security.
- (9) If it turns out that the order for services can only be completed if Pharmtrace bears further financial expenses which were not foreseeable upon conclusion of the agreement, Pharmtrace will notify the Client without delay. After receipt of such notification, the Client shall be entitled to choose either that Pharmtrace shall continue with the execution of the order at Client's expense or to withdraw from the contract. In the case of withdrawal, Pharmtrace shall be reimbursed for its costs incurred to the date of notification of the decision to withdraw. Client shall additionally bear any drop-out costs.

### WARRANTY

- (1) Warranty by Pharmtrace is limited to the observation of scientific diligence and state-of-the-art-performance.
- (2) Pharmtrace will in no case warrant test results that are intended by the Client.
- (3) In case of defects occurring during the execution of services, Pharmtrace is obligated to remedy such defects or to supply services free from defects within a reasonable period of time. The Client shall not have the option of withdrawing from the order or reducing the initially agreed service price until the removal of defects fails or does not take place within a reasonable period.
- (4) If the reason for a defect lies in the performance of an external trial center (hospital, institute, medical practice) or any other third party possibly involved in rendering services and Pharmtrace cannot be blamed for a fault in selection or instruction of the third party, then any claims against Pharmtrace shall be excluded. Pharmtrace shall neither be responsible for the control nor the supervision of third parties. In case third party defaults lead to damages of the Client, Pharmtrace will assign all its claims against the respective third party to the Client.
- (5) Pharmtrace will in no case warrant a successful application procedure with the IRB/IEC or any other equivalent Health Authority or any specific duration for the evaluation of applications that are necessary for the performance of services.
- (6) Claims against Pharmtrace relating to defects or delays of services which have their cause in the lawful withdrawal of volunteers or patients within a study shall be excluded. In the event the study or research project has to be cancelled due to the withdrawal of study participants, Pharmtrace shall be remunerated at least for the services rendered until the cancellation of the services.
- (7) All warranty claims shall become statute-barred 12 month after delivery of the final study report or, in case of study discontinuation, 12 month after the Client acknowledged the discontinuation of services no matter the underlying reasons.

### LIABILITY

- (1) In all cases involving slight negligence, Pharmtrace is exempt from any liability for damages, in particular from liability due to breaches of duty arising from the contractual relationship and from statutory provisions, unless injury to life, limb or health of persons is concerned. Similarly, this exemption from liability does not apply to cases of breach of a substantial contractual obligation, but such liability shall be limited to compensation for typical, predictable damage. Unless agreed otherwise, any liability arising from the performance of services by Pharmtrace is limited to the value of the particular contract or agreement.
- (2) The aforementioned limitation of liability shall not apply to cases of liability without fault which are governed by law. However, it does apply in equal measure to the personal liability of our statutory and vicarious agents.
- (3) Any liability of Pharmtrace for investigational products, its manufacture, transport, storage, labelling or distribution shall be excluded. Additionally, Client will hold harmless Pharmtrace against claims or suits for injuries caused by the treatment with the investigational product.
- (4) Client is liable for the correctness of all materials and information given to Pharmtrace within the framework of a study or the performance of any other services agreed upon. Client will hold harmless Pharmtrace against damages caused by an infringement of the duty to inform and disclose risks and ensure safety of Client's investigational products, materials, compounds or any other study or service supply.

### CONCLUDING CLAUSES

- (1) The place of performance for all obligations arising from the contractual relationship and the legal venue for any disputes arising from the contractual relationship is Berlin. The legal relationships between Pharmtrace and the Client are subject exclusively to the law of the Federal Republic of Germany.
- (2) If individual provisions of the present Terms and Conditions of Business or parts thereof are or become null and void, this shall not affect the validity of the remaining portion or of the remaining provisions. It shall be deemed to have been agreed that in the place of the provision or part thereof that is null and void, that legally valid provision shall apply, which, in a legally permissible manner, comes as close as possible to the economic objective pursued with the provision that is null and void. The same applies mutatis mutandis, if the contract should prove incomplete.