

## Terms and Conditions for the Subscription to SafetyEasy (The Software Package)

These Terms and Conditions (T&C) apply to Your Subscription with EXTEDO to the Software Package SafetyEasy and shall constitute a binding agreement contract between You and EXTEDO. EXTEDO GmbH shall resell the Software Package to the Customer and the Customer shall pay for the Services in accordance with (i) the current Terms for the subscription to the Software Package, (ii) the [Terms and Conditions of the Service Provider](#) that are deemed incorporated by reference to the present Terms and Conditions, and (iii) upcoming specific Order Forms, (all together, the “Agreement”). Those documents and their respective Appendices shall govern the subscription between You and EXTEDO and the subsequent delivery of the Software Package to the exclusion of any other terms or conditions proposed by the Customer.

By subscribing to the Software Package and accessing and using the databases therein, you agree and accept the Agreement.

The following terms shall be understood as defined:

“Reseller” means EXTEDO GmbH, Einsteinstraße 30, 85521 Ottobrunn, Germany.

“Service Provider” means AB CUBE, SARL, 83 Avenue Philippe-Auguste, 75011 Paris, France

“Databases” means SafetyEasy PV, SafetyEasy MD, SafetyEasy MI, COSMETHICS, developed by the Service Provider.

“Software Package” means the databases SafetyEasy PV, SafetyEasy MD, SafetyEasy MI, COSMETHICS on a SaaS mode with web access performed and delivered by the Service Provider, and the services offered on a subscription by the Reseller. Software Package shall also mean the iTAP tool on a SaaS mode, whenever You subscribe to it independently. The Software Package includes the Basic Services hereby detailed under Section 1 of these Terms and Conditions. The specific Order shall include to which extent those services will be rendered by either the Reseller or the Service Provider.

“Additional Services” means services requested by the Customer (such as consulting services) and excluded from the Software Package. It can be ordered as a supplementary service to the Software Package.

“Customer” or “You” means the company, legal entity, or individuals providing professional services who subscribe to the Software Package. Only Companies as defined in Section 14 of the German Civil Code (BGB) and professional services providers must be understood as Customer according to these Terms and Conditions.

“User” shall mean the access rights per Customer for which the Customer is fully responsible to ensure the proper use in accordance with these Terms and Conditions and Service Provider’s T&C. You, as

the Customer, must ensure that the Users comply with all the obligations set out by the Service Provider therein.

“Customer Data” means all the information that is uploaded by You or an employee of You or inserted into the Database upon subscription to the Software Package. It includes the information contained in the case(s) and therefore may include personal data.

“Subscription” means the digital service of enrollment to the Software Package, for a pre-defined period of time and based on the payment of a subscription fee.

“Order Form” means the request by the Customer in written form when subscribing to the Software Package.

“Case” means every entry on the Database for pharmacovigilance purposes. This might include (but is not limited to) the ICSR (Individual Case Safety Report) or SUSAR (Suspected Unexpected Serious Adverse Reaction). The subscription fee shall be based on the number of cases that Customer decides to purchase.

## **1. Subscription to the Software Package**

EXTEDO entitles you with a subscription to the Databases and services of the Software Package for a limited period of time and according to a price defined on your Order Form.

Your subscription to the Software Package shall include the following services:

- Right to access and use the Databases as SaaS mode. This service is performed and delivered by the Service Provider AB CUBE.
- Full access to 100% of the Database(s) functionalities
- Access to the Database and Test environment
- Access for an unlimited number of users
- Maintenance and updates services after second level support.
- Support and access to validation documentation accessible to Key User(s)
- Hosting services for the database: provided by the third-party service provider of the Service Provider
- Maintenance services: by the Service Provider
- Updating services due to changes in the applicable legislation: performed by the Service Provider
- Support services: First, Second and Third level support. Support can be provided by either the Reseller or the Service Provider.
- Validation and user documentation (by the Service Provider)

Additional Services are excluded of the Software Package. Those Additional Services may include (among others) consulting services related to migration, configuration, training or validation.

You are aware and agree that Reseller may refer part of the services above mentioned to its partners in certain geographical regions.

## **2. Basic Services: Acceptance of Service Provider’s T&C to access and use the Databases and related services.**

The access and use to the Databases shall be carried out by the Service Provider. The Service Provider will grant you with the access and usage rights to the Database, hosting, maintenance and updates.

By using and accessing the above products and services You agree and accept the [Service Provider's Terms & Conditions](#) which are added by reference to the present T&C. You shall therefore read and agree to the conditions before subscribing the Software Package.

### **3. Subscription term. Cancellation**

**Term.** The term of each subscription shall be specified in the Order Form. EXTEDO offers a subscription term for a minimum period of twelve (12) months. The subscription term shall be renewed automatically in the same conditions if no notice of termination (in written form) is addressed to EXTEDO.

**Cancellation of the subscription.** You can cancel your subscription to the Software Package without stating a reason by sending a notice of termination at least three months before the expiration of the subscription term. The cancellation of the subscription will imply the termination of the access and usage rights to the Software Package and related services by the Service Provider.

EXTEDO and You are entitled to cancel Your subscription at any time if any party fails to comply with any of the obligations set out under these Terms and Conditions or the Terms and Conditions of the Service Provider and fails to cure the breach within 30 days after notification.

**Returning of Customer Data with the cancellation.** You shall be solely responsible for exporting the data until the end of the subscription term.

### **4. Subscription fees. Payment**

**Subscription Fee.** The remuneration fee for the subscription to the Software Package will be described in the specific Order. The fee will be adjusted on the number of Cases that You add to Your Subscription and actually entered into the Databases. If You exceed the number of Cases during Your term of Subscription, You will be automatically charged for the higher tier segment of price.

**Billing period.** The billing cycle is set up on a yearly basis or on the basis equivalent to the subscription term. Additional Services will be scheduled on a separate Order Form. EXTEDO reserves the right to change the billing process at any time.

**Payment method:** Payment against invoice. EXTEDO will invoice You no more than forty-five (45) days during the beginning of the subscription term and each subsequent Billing Period and other times during the subscription term when fees are payable. All amounts invoiced are due and payable within thirty (30) days from the date of the invoice, unless otherwise specified in the Order Form.

All payment obligations are non-cancelable, and all amounts paid are non-refundable. All fees are due and payable in advance throughout the subscription term. If You are an EXTEDO Partner that purchases on behalf of a client, you agree to be responsible for the Order Form and to guarantee payment of all fees.

**Additional Services.** With regard to any Additional Services not explicitly mentioned in these Terms and Conditions or the respective documentation, You and EXTEDO will agree in advance on the scope of services and the remuneration fee. These services shall be ordered and paid separately.

Taxes. All fees under this section shall be understood excluding VAT and any other withholding taxes. Upon EXTEDO's request, you will provide EXTEDO with the VAT registration number under which You are registered in Your member state.

## **5. Data Protection and Customer Data**

### Data Protection

EXTEDO as Controller. EXTEDO will manage the customer relationship between you and EXTEDO as our customer. You can have access at any time to information on how we process your personal data through our [Privacy Notice available on our website](#).

EXTEDO as Processor. By using the Software Package, You may upload and submit your Customer Data into the Databases. You acknowledge and accept that the Service Provider will access, store, structure, organize or process by any means described under Article 4 of the General Data Protection Regulation (GDPR) your Customer Data on the basis of its Terms and Conditions. You acknowledge your role as Controller of such processing and accept that either The Service Provider or EXTEDO will process such data on your behalf. In that case, the provisions laid down under Appendix 1, 2, 3 of the [Service Provider's Terms & Conditions](#) will apply.

In the same role of Processor, EXTEDO might access your Customer Data when providing 1st and 2nd level support upon your request and/or any other services requested in advance. An additional [Data Processing Agreement](#) for the fulfilment of the conditions set up under Article 28 (3) GDPR must govern that processing activity. You agree and consent that EXTEDO has access to your Customer Data exclusively for the performance of the tasks assigned by You.

### Deletion of Customer Data

Once you notify EXTEDO of the termination of your subscription, EXTEDO nor the Service Provider will have any obligation to maintain or keep your Customer data and will therefore be deleted or destroyed, all copies or records after the effective expiration of the subscription. You shall be solely responsible for exporting the data until the end of the subscription period.

## **6. Confidential Information**

For the purposes of these T&C, confidential information means all the information disclosed either by You or EXTEDO during the delivery of the Software Package, whether orally or in writing, that is designated as confidential or that reasonably should be understood as confidential given the nature of the information or the circumstances of disclosure. Your confidential information includes the Customer Data and our confidential information includes the services that EXTEDO or the Service Provider delivers to You. This may include but is not limited to the pricing for the subscription of the databases and services, the business and marketing plans, technology and technical information, product plans and designs and/or business plans.

Confidential information does not include information that is or becomes generally known by the public without any breach of obligation owed to the disclosing party; or was known by the receiving party prior to its disclosure by the disclosing party without any breach of obligation owed to the disclosing party; or was independently developed by the receiving party.

Both, EXTEDO and Customer shall keep and maintain the confidential information in secret at all time, and do not publish, communicate, disclose or divulge the confidential information to any person, corporation or entity other than the prior approved affiliates. The confidentiality obligation shall last during the whole duration of the subscription and shall survive for a period of 2 years after termination of such subscription.

## **7. Intellectual Property**

The Customer acknowledges that both the Reseller and the Service Provider shall retain the ownership of the intellectual property rights related to the provision of the software package, including, as an example list, the source code of the databases, methodologies, processes, know how, trademarks, trade secrets and/or patents.

The Customer must agree with the Terms and Conditions of the Service Provider when using, accessing and storing any Intellectual Property Rights of the databases and any other services performed by the Service Provider.

## **8. Limitation of Liability**

Liability cap. Within the delivery of the Software Package, EXTEDO shall respond for the 1st and 2nd level support up to an amount of 2000 EUR. The liability provisions of the Service Provider under its Terms and Conditions shall apply to the rest of the services of the Software Package rendered by the Service Provider.

Force majeure event. EXTEDO shall have no liability to the Customer under these Terms and Conditions if it is prevented from, or delayed in, performing its obligations under this Agreement or from carrying on its business by acts, events, omissions or accidents beyond its reasonable control, including, without limitation, strikes, lock-outs or other industrial disputes (whether involving the workforce of the Reseller or the Service Provider or any other party), failure of a utility service transport network, malicious damage, breakdown of machinery, fire, flood, storm failure of power supply or default of suppliers or sub-contractors, including the Service Provider.

Disclaimer of damages. To the maximum extent permitted by applicable law, in no event will EXTEDO be liable for any special, incidental, indirect, exemplary, punitive, or consequential damages of any kind and however caused including, but not limited to, attorneys fees and costs, business interruption or loss of profits, business opportunities, or goodwill.

EXTEDO shall have no liability to the Customer under these Terms and Conditions if EXTEDO's performance or Service Provider's performance of its obligations are prevented or delayed by any act, omission, fault or negligence of the Customer or the Customer's agents, sub-contractors or employees, in particular due to:

- Damage to the Customer's equipment, software or telecommunications links.
- Wrongful use of the Software, including by the Customer or the Customer's clients, or non-compliance with any operating instructions given by the EXTEDO or Service Provider.
- Disclosure, unlawful or fraudulent use of the passwords or credentials for access
- Fault, negligence or omission by a third party not connected to the Reseller
- Issue by a competent authority of an order which is binding on the Reseller or the Service Provider and which may affect the subscription to the Software Package
- Total or partial loss of the material and/or data uploaded due to an error by the Customer

- Incompatibility of the Database with any of the Customer's equipment, software or telecommunications links.

## **9. Governing Law and Jurisdiction**

Regarding all legal relations resulting from these Terms and Conditions for the subscription to the Software Package, You and EXTEDO agree to apply the laws of the Federal Republic of Germany, without prejudice of further legal relationships you may enter with the SERVICE PROVIDER. The application of the United Nations Convention on Contracts for the International Sale of Goods (CISG) is hereby excluded. The place of jurisdiction for all disputes arising from and in connection with these Terms and Conditions is Munich.