

End User Licence Agreement for PV-247 Pharmacovigilance Software and Service

Version 4
30 March 2016

IMPORTANT: PLEASE READ THIS LICENCE AGREEMENT CAREFULLY BEFORE USING THE SOFTWARE OR SERVICE.

Your Use of the Software or Service indicates your acceptance of this licence and that you agree to be bound by and comply with all of its terms. If you do not agree to the terms of this Agreement, do not Use the Software or Service.

1. DEFINITIONS

- (a) "Account" means your company and all of its registered Users with the right to Use the Service;
- (b) "Assured" means Assured Information Systems Ltd;
- (c) "Date of Registration" means the date when an Account is first created for use by You;
- (d) "Fees" means those fees set out in Schedule A;
- (e) "Proprietary Rights" means all property in the Software and rights to patents, trade marks, service marks, trade names, inventions, trade secrets, copyright, moral rights, rights in a design, know-how, confidential information and all or any other intellectual property rights whether or not registered relating to the origin, manufacture, programming, operating and/or servicing of the Software, the Service and any related enhancements or modifications;
- (f) "Service" means the provision of access via the Website to the Software on a server provided by and maintained by Assured;
- (g) "Software" means any version of any program in the PV-247 pharmacovigilance software suite supplied by Assured, and may also include documentation, associated media, printed materials, and online and electronic documentation;
- (h) "Software Package" means the combination of Software functionality and maximum activity levels permitted. Each Software Package attracts an individual Fee as defined in Schedule A;
- (i) "Use" means in relation to the Software or Service, to run the Software from the Website;
- (j) "User" means an identifiable person whose name has been registered within the Account and whose purpose is to run the Service and Software;
- (k) "Website" means the website operated by Assured via which You can access the Software;
- (l) "You" means any user of the Software and Service for the Account.

2. LICENSED USERS

You may use the Software and Service for a period of up to 30 days from the Date of Registration of your Account without any charges invoiced either in advance or retrospectively by Assured.

The licence granted to you permits you to register any number of Users within your Account who may use the Service and Software from the Date of Registration until termination of this Agreement.

You will be in breach of this Agreement if any person other than a registered User uses the Software.

After 30 calendar days of Use, You must either cease to access the Service, in which case this Agreement terminates,

or

your use will be chargeable as a production account based on the Software Package selected during registration. Costs will accrue from the thirtieth (30th) calendar day after the Date of Registration.

3. OWNERSHIP

Assured retains all Proprietary Rights in and to the Software and all copies thereof. All rights not specifically granted in these Terms and Conditions, including Federal and International Copyrights, are reserved by Assured. This evaluation license gives You limited license to use the Software. The Software is protected by copyright and other intellectual property laws and by international treaties. You acknowledge that the Proprietary Rights in the Software belong to Assured and You will not dispute such ownership.

4. SERVICES PROVIDED BY ASSURED

Assured will:

- (a) provide an internet connection point (Website) with, as a minimum, a broadband connection such that the Service is available to You;
- (b) make best endeavours to deliver the Service with a planned availability target of 98% for a 24 hours per day, seven days per week period, subject to reduction due to planned maintenance, equipment failure, services failure and an event of Force Majeure;
- (c) provide secure password management as follows: enforced, regular password change which also controls password format and prevents re-cycling of previous passwords;
- (d) provide virus protection as follows : Assured will regularly screen the Software and the Website with the latest proprietary virus checking software;
- (e) backup data as follows: daily back up of all data to suitable media with off-site storage;
- (f) operate a database transactional logging system such that all database changes are recorded on dual disks.
- (g) Ensure that a suitable alternative server is provided in the event of catastrophic failure of the Service such that the Service is made available within a maximum of 2 working days.

Assured shall make best endeavours to operate the Service in compliance with expected regulatory and quality standards.

Assured shall as soon as practicable after its availability for release, update the Software with any update or improvement to the Software.

Assured will use its reasonable endeavours to develop and maintain the functionality of the Software in line with published regulatory reporting formats for those reporting formats available in the current release of the Software.

Assured will maintain the currency of reference dictionaries in line with regulatory requirements.

Assured shall during normal UK office hours (9 a.m. to 5.30 p.m. Monday to Friday excluding UK Bank Holidays) and during normal USA office hours (8 a.m. to 5.00 p.m. ET Monday to Friday excluding US Public Holidays) provide Client with advice by email or a web forum as to the Use of the Software.

You acknowledge and accept that Assured reserves the right to require a minimum of four hours per month downtime for the Service, in order to provide routine maintenance. Assured shall use reasonable endeavours to

ensure that such maintenance will normally be outside of normal UK office hours (9 a.m. to 5.30 p.m. Monday to Friday). Whenever possible, Assured will notify You prior to instituting a period of downtime.

No services for implementation, installation, development, validation, training and/or support are included beyond that explicitly stated in this agreement.

5. PROHIBITIONS

You may not do any of the following:

- (a) translate, reverse engineer, decompile, disassemble, or otherwise reduce the Software to a human-perceivable form;
- (b) modify or create derivative works based on the Software;
- (c) rent, lease, sublicense or (except as permitted below) otherwise transfer rights to the Software;
- (d) distribute the Software to other persons; or
- (e) Use the Software or Service 'for hire' to third parties.

6. OBLIGATIONS

In order to Use the Software for processing pharmacovigilance related to human medical products You are obliged to obtain and keep current a subscription for the MedDRA terminology dictionary.

You must comply with all applicable laws regarding use of the Software and Service.

7. CONFIDENTIALITY AND DATA PROTECTION

Each party agrees to protect the other party's Confidential Information (other than that which is in the public domain) and not to disclose it for at least 10 years from the date of this agreement, except to such persons as may need to know it for the purposes of this Agreement.

Further, to the extent that Assured has access to information provided by You or otherwise available as a result of your using the Software or Service, Assured acknowledges and agrees that such information is highly confidential and private in nature and agrees to hold such information in the strictest of confidence, and to protect such information. Assured shall not use or disclose such information without your prior written consent unless required to do so for legal reasons in which case Assured will inform You in advance of such release.

The requirements of confidentiality shall survive the expiration, termination or cancellation of this Agreement.

Both parties shall comply with all applicable laws and regulations concerning the Software, Service and Website.

8. AUDIT PROVISIONS

During the term of this Agreement You will have the right, at your expense, upon no less than five (5) working days prior written notice and at a date and time that is mutually agreed, to audit Assured to enable You to meet your obligations under relevant laws and regulations, with specific emphasis on Assured policies, procedures, security, change control, systems and services, product handling of electronic data and records and electronic

signatures and security. Assured's commercial and financial policies, procedures and data are excluded from the scope of any audit to the maximum extent possible.

Such audit will be conducted by your personnel under obligations of confidentiality, will not interfere unreasonably with Assured's business activities, and will be conducted no more than once per two calendar years, unless You have received a request from a regulatory authority with jurisdiction over your business, or unless a previous audit has disclosed a material non-conformance to the standards required by the appropriate agencies.

All material made available during the audit may not be reproduced or copied in any form.

You may determine to conduct the audit at Assured's premises, by telephone, by paper or via the internet.

You will use information received during an audit solely for the purposes of the Agreement and will otherwise maintain the confidentiality of such information.

You agree that Assured will charge and, You will pay, for the time required by Assured staff to conduct the audit, answer auditor's questions, write or respond to an audit report and related follow up tasks at its current hourly rate for internal projects.

9. FEES

You agree to pay Assured the Fees outlined in Schedule A of this Agreement.

Unless otherwise agreed in the Schedule, payment for invoices will be made by You within 30 days from the date of invoice from Assured.

Assured shall issue to You an invoice in respect of all Fees in respect of the preceding period. This will occur on or around the 5th day of each month or quarter. The period of invoicing is at Assured's sole discretion.

All sums payable pursuant to this Agreement are exclusive of any value added or other applicable tax or duties, for which that party shall be additionally liable.

If any sum payable to Assured by You is not paid within 14 days after the due date Assured may suspend performance of its obligations and/or charge interest on a daily basis at the rate of 4% above the Bank of England Base Rate from time to time in force, compounded quarterly, from the date for payment of that sum to the date of actual payment.

Assured will revise the fee rates in Schedule A in line with industry standards once in each 12 month period with the exception that an interim change to these fee rates may be applied at Assured's discretion should the exchange rate between the US dollar and/or the Euro and the Pound Sterling vary by more than 7.5% in either direction from the rate in force at time of the previous revision. Announcement of changes to Fee rates will be provided on the Website no fewer than 30 (thirty) days before the new rates become effective. New fee rates announced in this manner will replace Schedule A of this Agreement.

10. LIMITED WARRANTY AND DISCLAIMER

Provided that You have complied with all obligations in clause 6, Assured warrants that the Software and your use of the Software does not and will not knowingly infringe the intellectual property rights of any third party.

Assured makes no other warranties of any kind in connection with third party software whether express or implied that are used as part of the Service or by You.

Further, Assured does not warrant that the Software and Service will meet your requirements, or that the operation of said Software and Service will be uninterrupted or error-free. The entire risk as to the results and performance of such materials is assumed by You.

Except as set forth in the foregoing limited warranty, Assured disclaims all other warranties, either express or implied, or otherwise including the warranties of merchantability and fitness for a particular purpose to the extent permitted by law. If applicable law implies any warranties with respect to the Software, all such warranties are limited in duration to thirty (30) days from the Date of Registration. No oral or written information or advice given by Assured, its dealers, distributors, agents or employees shall create a warranty or in any way increase the scope of this warranty.

11. LIMITATION OF LIABILITY

As consideration for the grant of this licence, in no event will Assured be liable for direct, indirect, special, incidental, cover, or consequential loss or damages arising out of the Use of or inability to use the Software or Service, even if advised of the possibility of such damages.

You will be exclusively responsible for your own Use of the Software, the Service and for all content supplied by You and accordingly You indemnify Assured in respect of all costs damages and expenses incurred as a result of any claims by third parties in tort or otherwise against Assured arising in any way out of the Use of any of the Software, the Service or content by You.

You acknowledge that Assured exercises no control whatsoever over the content of the information that You transmit and that it is your sole responsibility to ensure that the information and materials that You and the other users of your Account transmit and receive comply with all applicable laws and regulations.

The Parties hereby further agree that Assured does not and cannot control the flow of information to or from Assured's own network and other portions of the Internet. Such flow depends on the performance of Internet services provided or controlled by third parties outside the control of Assured whose actions or failures may impair or disrupt your connections to the Internet or parts thereof.

Assured shall not be liable for any loss of data resulting from delays, corruption of data non-deliveries, misdeliveries or service interruptions. Assured shall not be liable for any unauthorised access to Assured's or your transmission facilities or equipment or for any unauthorised access to or alteration theft or destruction of your data files programs procedures or information through accident fraudulent means or devices or any other method provided that such damage does not occur as a result of Assured's default or negligence

In all cases Assured's entire liability for remedy of all the foregoing shall be limited to the greater of the amount of fees paid by You to your Account in the six (6) months prior to the notification to Assured of such liability or £100 (One hundred pounds sterling).

12. TRANSFER

You may be able transfer all of your rights under this Agreement, provided the recipient agrees to the terms of this Agreement, registers the intent to transfer with Assured, Assured approves the transfer, and recipient pays any applicable transfer fees. Approval of any license transfer is within the sole discretion of Assured or its successors in interest.

13. TERMINATION

Your rights regarding the Software and Service under this License shall remain in effect only as long as you are in full compliance with the terms and conditions of this Licence, and shall terminate automatically if you fail to comply with any such terms or conditions and do not cure such failure within thirty (30) days of becoming aware of such failure.

This licence is effective until terminated by either party at any time.

The accounts associated with a License terminated in compliance with this agreement will be disabled and will be deleted from the System 30 days after termination.

Upon termination and written request by You, Assured will return all case data entered into a production account to You in an agreed format and subject to an administration fee to cover the cost of extracting the data from the database and sending it to you.

Termination of this Agreement will not affect any already existing rights or liabilities of either party, nor will it affect the coming into force or continuance in force of any provision of this Agreement which is expressly, or by implication, intended to come into or continue in force on or after ending this Agreement.

14. FORCE MAJEURE

Despite anything else contained in this Agreement, neither party will be liable for any delay in performing its obligations under this Agreement if that delay is caused by circumstances beyond its reasonable control (including, without limitation, any delay caused by an act or omission of the other party) and the party affected will be entitled to a reasonable extension of time for the performance of its obligations.

15. LEGAL JURISDICTION

This Agreement will be governed by and construed in accordance with English law and both parties agree to submit to the exclusive jurisdiction of the courts of England. In the event of any dispute between the Client and Assured under this Agreement, the parties will negotiate with each other in good faith in an attempt to resolve the dispute.

Schedule A : Fees

Fees are levied according to the Software Package that You selected on the Website for Use by the Account. Fees are paid annually at the rates set below.

Where an Account exceeds the maximum number of permitted cases in a twelve month period, You may either elect to upgrade the Account to the next level or pay an “additional cases” fee per case entered into the Software above the package maximum.

The basic element of charge is a single case entered into the Software. This cost is standard regardless of the type of case processed, the number of follow up reports received and entered for the case or the number of reports derived from its data.

The current table of costs for each Software package available under this licence and optional additional elements is available via the Website and forms part of this Agreement.