

## APPLICATION SW DEVELOPMENT AGREEMENT

concluded in compliance with Section 1746, paragraph 2 of Act No 89/2012 Coll., the Civil Code, as amended (hereinafter referred to as the “**CC**”)

by and between:

**Czech Republic – State Institute for Drug Control**, an organisational unit of the state

Identification no. (IČ): 00023817

With its registered office at: Šrobárova 48, 100 41, Praha 10

Represented by: MUDr. Tomáš Boráň, Director

Bank details, account no.: 623101/0710

(hereinafter referred to as the “**Contract Giver**”)

and

**Iorenz Archiv-Systeme GmbH**

Identification no. (IČ): 045 238 242 18

VAT Identification no. (DIČ): DE114182772

With its registered address at: Eschborner Landstr. 75, 60489 Frankfurt, Germany

Represented by: XXX

Bank details, account no.: XXX

(hereinafter referred to as the “**Provider**”)

(the Contract Giver and the Provider being further also collectively referred to as the “**Contracting Parties**”)

### Preamble

The Contract Giver concludes this Application SW Development Agreement (hereinafter referred to as the “**Agreement**”) with the Provider as the selected contract acceptor:

### **Article 1.**

#### **Subject-Matter and Purpose of the Agreement**

1.01 Under this Agreement, the Provider undertakes to provide the Contract Giver with services consisting of the development of a software tool for work with documentation in the eCTD and NeeS formats (hereinafter referred to as “Application SW”), procured under a licence agreement concluded on the basis of contract award under tender

procedure VZ52/2015 "Implementation of the eCTD tool in the State Institute for Drug Control", for the period of 3 years of the entry into effect of this Agreement. The services consisting of the development of Application SW as referred to under the previous sentence shall be further referred to hereunder as the "Services". The Services shall be provided within the scope of 100 man-days (1 man-day shall mean 8 man-hours) throughout the entire term of this Agreement and shall include the following:

- Application SW modifications as required by the Contract Giver, which shall mean, in particular (but not exclusively), modifications of the individual configuration of the Application SW or an analysis and development of new functionalities of the Application SW;
- The provision of consultations by the Provider's specialists on the usage of the Application SW and implementation of Application SW user and administrator training.

- 1.02 The Services shall be executed by the Provider on the basis of individual orders placed by the Contract Giver and confirmed by the Provider. The individual orders placed by the Contract Giver shall be submitted by the Contract Giver's authorised person referred to under paragraph 14.01 in writing by e-mail or via a helpdesk application. Thereafter, the Provider shall establish and send from the e-mail address of their authorised person referred to under paragraph 14.01 to the e-mail address of the Contract Giver's authorised person referred to under paragraph 14.01 the anticipated scope of the Services according to the order in hours and the timeline for their provision (delivery). The Contract Giver shall then, by means of an e-mail sent from the e-mail address of their authorised person referred to under paragraph 14.01 to the e-mail address of the authorised person of the Provider referred to under paragraph 14.01, confirm the Services within the scope of the respective order, their volume in hours, and the timeline for their provision (delivery). As of this moment, the obligation of the execution of the order shall be considered binding for both Parties. The output of the execution of each order may be, in case of modifications to Application SW, deployed in production environment only following an approval of the Contract Giver's authorised person referred to under paragraph 14.01. Any outputs of execution of each order must be submitted by the Provider to the Contract Giver for acceptance. A written Acceptance Protocol shall be drafted on this fact and signed by the authorised persons of both Contracting Parties referred to under paragraph 14.01, which shall serve as a confirmation of the acceptance of the output of execution of the respective order without any objections.
- 1.03 The Contract Giver undertakes to pay the Provider the agreed price for the Services provided in compliance with this Agreement.
- 1.04 The purpose of this Agreement is to safeguard the development and a fully operable condition of the Application SW necessary for the fulfilment of the powers entrusted upon the Contract Giver by law.

## **Article 2.**

### **Rights and Obligations of the Provider**

- 2.01 The Provider shall be delivering the Services as set forth hereunder upon their own liability and shall be providing any economic, material as well as human components in a manner allowing to fulfil the purpose of this Agreement.

- 2.02 For the duration of the provision of Services and activities hereunder, the Provider undertakes to provide these Services and activities in the highest quality practicable and undertakes to proceed with due professional care, having regard to the interests of the Contract Giver.
- 2.03 The Provider undertakes to observe the instructions of the Contract Giver. The Provider shall be obliged to forthwith notify the Contract Giver of any circumstances identified by the former during their operation hereunder which could affect the provision of the Services hereunder or the issuance of instructions of the Contract Giver or changes thereto. The Provider shall always alert the Contract Giver of any inadvisable instructions, where applicable; should the Contract Giver, despite being alerted by the Provider, insist on the fulfilment of their instructions, the Provider shall be, to the extent appropriate, exempted from liability for possible irregularities in the performance provably arising from the execution of such inadvisable instructions.
- 2.04 The Provider undertakes to submit to the Contract Giver, without undue delay following the conclusion of this Agreement, a list of persons who shall be involved in the provision of Services hereunder. The list shall be compiled for the purposes of safeguarding access to the Contract Giver's facilities. Persons on the list shall be identified by their first name and surname and identification of their employer (or contractor, where a status other than employment is concerned). The Provider shall be obliged to provide this list of persons to the Contract Giver with these persons' explicit consent with their personal data processing by the Contract Giver for the purposes of providing them with access to the Contract Giver's facilities and for the purposes of providing them with access to the relevant parts of the Contract Giver's information system. Should the Provider fail to meet this obligation, they shall bear full responsibility stipulated by legal regulations governing personal data protection. The Contract Giver undertakes to process these personal data solely for the purposes of execution of the Services and in compliance with legal regulations governing personal data protection until the consent is withdrawn in writing. The Provider shall be obliged to agree in advance with the Contract Giver the specific working hours and time of movement of persons providing the Services hereunder within the premises of the Contract Giver, of which a protocol confirmed by the signatures of the authorised persons shall be executed. Should any personnel changes arise, the Provider shall be obliged to provide an updated list of persons to the Contract Giver without any delay.
- 2.05 The Provider shall be obliged to attend meetings summoned by the Contract Giver, which concern the provision of Services as set forth by this Agreement. Unless specified otherwise, on the part of the Provider, such meetings shall be always attended by the person authorised to act on behalf of the Provider in matters of performance under this Agreement referred to under paragraph 14.01.
- 2.06 In the performance of this Agreement, the Provider undertakes to cooperate with experts appointed by the Contract Giver, so as to achieve the purpose hereof.
- 2.07 The Provider confirms that as of the date of signature of this Agreement, they have concluded an insurance policy covering liability insurance for damages arising from their business operation for the minimum amount of 5,000,000,- CZK (in words: five million Czech crowns) with a co-payment not exceeding 10 %, and that they shall maintain the validity of this insurance policy for the term hereof and, furthermore, for the minimum of 6 months following termination of activities hereunder. Upon Contract Giver's request, the Provider shall be obliged to present the insurance policy or the insurance certificate of the respective insurance company.

- 2.08 In the provision of services hereunder, the Provider undertakes to observe any necessary precautions to prevent possible damage affecting the property of the Contract Giver or the health of the Contract Giver's employees.

### **Article 3.**

#### **Rights and Obligations of the Contract Giver**

- 3.01 The Contract Giver shall be obliged to provide the Provider with complete, truthful and straightforward information necessary for the provision of the Services hereunder, unless the nature of such information implies that it should be safeguarded by the Provider themselves as part of the performance of this Agreement.
- 3.02 The Contract Giver shall be obliged to create proper conditions for the provision of the Services hereunder by the Provider and, during the term of this Agreement, render necessary cooperation to the Provider where the Provider justifiably requests such cooperation. This concerns, in particular, hand-over of documents and other information essential for the provision of the Services, and provision of access into the Contract Giver's premises. A Provider's request for cooperation must be executed in writing and addressed to the Contract Giver's authorised person referred to hereunder. The request must be submitted in such good time so as to be able to reasonably/realistically expect the provision of the requested cooperation at the given time with a view to the Contract Giver's operating hours and the scope of the requested cooperation (e.g. the scope of required documentation or activity).
- 3.03 The Contract Giver shall be authorised to establish the time of the provision of Services in their premises in accordance with the Contract Giver's needs.
- 3.04 The Contract Giver shall be authorised to require the attendance of any representative of the Provider at meetings and the Provider undertakes to safeguard the attendance of such representative at the meetings.

### **Article 4.**

#### **The Price of the Services**

- 4.01 The Contracting Parties have agreed that the price of Services provided properly and in due time as set forth by this Agreement shall be 2,500,- CZK ex. VAT, i.e. 3,025,- CZK incl. VAT per each man-hour of Service provision.
- 4.02 This price shall be the maximum permissible and not-to-exceed price and shall include also any and all costs of the Provider associated with the provision of the Services within the scope of this Agreement.
- 4.03 Should, during the term of this Agreement (i.e. following its conclusion), the VAT rate be subjected to a change (i.e. increased or decreased), the Provider shall be obliged to reflect this change when charging (invoicing) the price of the Services, i.e. to reduce or increase the price by the amount of the change in the VAT.

### **Article 5.**

#### **Invoicing and Payment Terms and Conditions**

- 5.01 The Contract Giver shall pay the price set forth under paragraph 4.01 hereof to the Provider on the basis of an invoice issued by the Provider following the execution of the Services performed on the basis of a specific order placed by the Contract Giver. The invoice shall be always issued following the completion and delivery of the output of the execution of each order, i.e. following the acceptance of the output of the execution of each order without any objections by means of the Acceptance Protocol referred to under paragraph 1.1(a). A copy of the Acceptance Protocol signed by both Contracting Parties as referred to under paragraph 1.02, certifying the acceptance of the output of the execution of the respective order without objections, must form an attachment to the invoice.
- 5.02 The invoices must contain all of the particulars of a tax and accounting document stipulated by Act No 235/2004 Coll., on VAT, and by Act No 563/1991 Coll., on Accounting, as amended. Should a submitted invoice fail to contain the particulars prescribed by the acts or by this Agreement, the Contract Giver shall be authorised to return it to the Provider prior to the invoice due date, specifying the reason for its return. In such a case, a new maturity period shall apply, starting on the date of issue of the corrected invoice.
- 5.03 The invoice maturity period shall be 30 calendar days of the date of issue and the Provider shall be obliged to deliver each invoice to the Contract Giver no later than within 3 working days of the date of issue. The Contracting Parties have agreed that the liability to pay the invoice shall be met on the date when the relevant amount to be credited to the Provider's account is debited from the Contract Giver's account.
- 5.04 Should the Contract Giver be in default in respect of their payments hereunder, they shall be obliged to pay the Provider a default interest on the unpaid overdue amount in the rate established by the relevant legal regulations.
- 5.05 The Provider is aware of their own financial costs associated with the performance of the subject-matter of the Agreement, and in the course of Service provision shall not request any financial remuneration above the scope of the agreed terms and conditions governing the payment of the price as referred to under Article 5 hereof.

## **Article 6.**

### **Place of Performance, Obligation to Compensate Damages**

- 6.01 The Contracting Parties have agreed that the place of Service provision shall be the registered office of the Contract Giver and the registered office of the Provider.
- 6.02 The Services and activities hereunder may be provided also in a remote mode, via electronic communication networks (as referred to under Act No 127/2005 Coll., on Electronic Communications), if practicable with regard to the nature of the performance to be provided.
- 6.03 The Provider shall be obliged to compensate the Contract Giver in full for any damage caused to the Contract Giver due to a breach of any obligation stipulated by this Agreement. The provision of Section 2050 of the CC shall not apply.

## **Article 7.**

### **Provider's Subcontracting**

- 7.01 The Provider shall be obliged to deliver performance under this Agreement solely through their own employees.

## **Article 8.**

### **Protection of Confidential Information**

- 8.01 The Provider shall be obliged to maintain confidentiality of all facts learnt thereby in the performance of this Agreement which are not intended for publication by a legal regulation or which are not publicly known. Furthermore, the Provider undertakes not to enable any person to be able to disclose confidential information to unauthorised third parties, unless this Agreement stipulates otherwise. The Provider shall be obliged to handle the information provided thereto by the Contract Giver or obtained thereby in association with the fulfilment of their obligations hereunder as confidential information.
- 8.02 For the purposes of this Agreement, the following shall not be considered confidential information:
- (a) Information which has become publicly available to the public in ways other than being disclosed by the Provider;
  - (b) Information obtained by the Provider from sources other than the Contract Giver, which is marked as public by the person providing it.
- 8.03 The Provider undertakes to use confidential information solely for the purposes of meeting their obligations implied by this Agreement. Furthermore, the Provider undertakes that neither the Provider nor any other person being acquainted by the Provider with confidential information in compliance with this Agreement shall disclose it to third parties, except for cases:
- (a) concerning disclosure of confidential information to persons for whom access to this information is essential with respect to the fulfilment of the Provider's obligations implied by this Agreement;
  - (b) concerning disclosure of confidential information with a prior written approval of the Contract Giver;
  - (c) stipulated by a generally binding legal regulation or where such obligation is imposed by a final and legal ruling of a competent authority issued on the basis of its lawful authority. The Provider shall be obliged to evidence such fact upon the Contract Giver's request without unnecessary delay.
- 8.04 The Provider, moreover, undertakes to safeguard also the protection of confidential information against its illegal obtaining by third parties. Should the Provider reasonably suspect that confidential materials have been illegally disclosed (obtained), they shall be obliged to forthwith notify the Contract Giver to this effect.
- 8.05 The Provider shall be obliged to return, without unnecessary delay, any materials and objects taken over from the Contract Giver or on behalf of the latter during the performance of this Agreement without unnecessary delay following the termination of this Agreement. The Provider shall be obliged to remove confidential information stored in electronic format no later than upon the expiry of the period of their mandatory archival, where such legal obligation applies to the Provider.
- 8.06 The obligation to protect confidential information shall remain in effect also after the termination of this Agreement.
- 8.07 The Provider undertakes to bind all of their staff involved in the provision of the Services for the Contract Giver with this confidentiality obligation without unnecessary delay.

- 8.08 The Contract Giver shall be authorised to publish this Agreement or parts hereof as well as information pertaining to its performance at any time during the term hereof and after its termination, which the Provider takes account of and agrees with.

## **Article 9.**

### **Contractual Penalties**

- 9.01 In case the Provider breaches any of the obligations stipulated by Article 7 hereof, they shall be obliged to pay to the Contract Giver a contractual penalty in the amount of 100,000,- CZK for each individual breach.
- 9.02 In case the Provider breaches any of the obligations stipulated by Article 8 hereof, they shall be obliged to pay to the Contract Giver a contractual penalty in the amount of 100,000,- CZK for each individual breach.
- 9.03 Should the provider be in delay with the provision of the Services against the timeline specified in the order placed by the Contract Giver, the Provider shall pay the Contract Giver a contractual penalty in the amount of 5,000,- CZK for each started day in delay.
- 9.04 The payment of the contractual penalty shall not release the Provider from the obligation to deliver the agreed performance hereunder to the Contract Giver or from the obligation to compensate the respective non-material damage or material damage suffered by the Contract Giver due to the breach of the obligation to which the contractual penalty relates. The provision of Section 2050 of the CC shall not apply.

## **Article 10.**

### **Term of the Agreement**

- 10.01 This Agreement is concluded for the period of 3 years of the coming into effect hereof.
- 10.02 This Agreement shall expire and become invalid also prior to the period referred to under the previous paragraph:
- a) upon the utilisation of 100 man-days of provided Services;
  - b) by notice of termination;
  - c) by the Provider's loss of authorisation to carry out activities necessary for the provision of the Services;
  - d) by a written agreement of the Contracting Parties.
- 10.03 In case of Agreement termination, any of the covenants of the Contracting Parties pertaining to the Provider's liability for damages, entitlement to contractual penalty, and protection of confidential information shall survive the Agreement.

## **Article 11.**

### **Notice of Termination and Withdrawal from Agreement**

- 11.01 Either of the Contracting Parties may terminate the Agreement in full or partially. The Contract Giver shall be entitled to terminate the Agreement without giving any reason, whereas the notice period for the Contract Giver shall be 6 months and shall commence

on the day following immediately the date of provable delivery of the notice to the other Contracting Party. The Provider shall be entitled to terminate the Agreement only on grounds of the Contract Giver's default in payment of an invoice issued by the Provider following performance, i.e. following proper and timely provision of the Services hereunder; the default on the part of the Contract Giver must be more than 60 days. The notice period for the Provider shall be 6 months and it shall commence on the day following immediately the date of provable delivery of the notice to the other Contracting Party. A proper delivery of the notice shall be considered its delivery via a postal service provider, courier, or its delivery to the data mailbox of the other Contracting Party.

- 11.02 Following receipt of the notice referred to under the previous paragraph, the Provider shall be obliged to continue their activities hereunder until the expiry of the notice period, unless instructed otherwise in writing by the Contract Giver. Concurrently, the Provider shall be obliged to alert the Contract Giver of measures necessary to prevent any immediate damage that the Contract Giver might suffer due to failure to complete a particular activity.
- 11.03A Contracting Party shall be entitled to withdraw from this Agreement without unnecessary delay in case the other Contracting Party substantially breaches this Agreement as referred to under Section 2002 of the CC.
- 11.04 The Contracting Party shall be obliged to notify the other Contracting Party of the former's withdrawal from the Agreement by means of a written notice of withdrawal. The notice must clearly define the grounds regarded by the Contracting Party as constituting a substantial breach of the Agreement, including a reference to the specific contractual obligation being breached.
- 11.05 Withdrawal from Agreement shall be effective as of the delivery of a written notice of withdrawal to the other Contracting Party, unless a deferred effect of the withdrawal is implied by the content of the withdrawal. A proper delivery of the notice of withdrawal from the Agreement shall be considered its delivery via a postal service provider, a courier, or its delivery to the data mailbox of the other Contracting Party.
- 11.06 The withdrawal from the Agreement shall be without prejudice to the provisions regarding protection of information, dispute settlement, securing of receivables of either of the Contracting Parties, compensation of damages, and provisions regarding those rights and obligations the nature of which implies that they should survive the Agreement following withdrawal from the Agreement (these concern, in particular, the obligation to make payments for performance provided prior to the withdrawal from the Agreement).

## **Article 12.**

### **Force Majeure**

- 12.01 The Contracting Parties shall not be liable for partial or complete failure to perform the contractual obligations due to force majeure. Force majeure shall be considered such circumstances arising after the signature hereof as a consequence of inevitable events of extraordinary nature which directly affect the performance of the subject-matter of the Agreement and which could not be anticipated prior to the conclusion of this Agreement by the Contracting Party claiming the existence of the influence (effect) of force majeure and which cannot be controlled by this concerned Contracting Party despite their best efforts.
- 12.02 In case of existence of force majeure, the timelines governing the delivery of contractual obligations shall be prolonged by the time while force majeure lasts.



- 12.03 The Contracting Party affected by force majeure shall be obliged to notify the other Contracting Party in writing about the commencement and termination of the case of force majeure without any delay, no later, however, than within 15 days. Should the Contracting Party fail to do so, they would not be able to effectively rely on force majeure.

### **Article 13.**

#### **Severability Clause**

- 13.01 Should any of the provisions of this Agreement be or become invalid, ineffective or unenforceable, the other provisions of this Agreement shall remain valid and effective. In lieu of the invalid, ineffective or unenforceable provision, the provisions of generally binding legal regulations which govern the particular aspect of the mutual relationship between the Contracting Parties shall apply. The Contracting Parties undertake to regulate their relationship by subsequent adoption of another provision which, in effect, best reflects the intention of the invalid, ineffective or unenforceable provision. Should any provision, which would otherwise be adequate in terms of completeness of the regulation of the rights and obligations, be missing from this Agreement, the Contracting Parties shall make any and all reasonable endeavours to supplement this Agreement with such a provision.

### **Article 14.**

#### **Final Provisions**

- 14.01 The authorised persons of the Contracting Parties appointed for the purposes of communication in matters pertaining to the performance hereunder shall be the following individuals (any of the below-mentioned ones):

For the Contract Giver:

XXX

XXX

For the Provider:

XXX

- 14.02 This Agreement may be amended solely by means of written, numbered, and bilaterally confirmed covenants, explicitly called "Agreement Amendment". No other records, protocols, etc. shall be considered amendments to the Agreement.
- 14.03 Should facts preventing proper performance hereof arise on the part of either of the Contracting Parties, such Contracting Party shall be obliged to forthwith notify the other Contracting Party to this effect.
- 14.04 This Agreement is executed in 2 counterparts of which each Contracting Party receives one.
- 14.05 The Contracting Parties declare that they have read the Agreement carefully and that the content hereof is clear and understandable for them. They declare that this Agreement has not been concluded in distress or under other conditions unfavourable to either Party.

14.06 The provisions of the CC or, if applicable, other effective legal regulations of the Czech Republic shall apply to all cases not specifically addressed by the arrangements hereunder.

14.07 The Provider takes account of the obligation to publish the Agreement as well as any orders placed on the basis hereof in the Registry of Agreements (hereinafter referred to as the "Registry of Agreements") in compliance with Act No 340/2015 Coll., on the Registry of Agreements, and by signing this agreement, the Provider expresses their consent with the publication of any and all data specified in the Agreement or in the orders by the Contract Giver in the Registry of Agreements established through the aforementioned Act, with the exception of personal data. The Provider explicitly declares that no data specified in this Agreement and annexes hereto constitute business secret as referred to by Section 504 of the CC.

14.08 This Agreement is adopted as of the date of signature by both Contracting Parties and comes into effect as of the date of publication in the Registry of Agreements.

In witness of the entire content of the Agreement being the expression of their true, solemn, and free will, the persons authorised to conclude this Agreement on behalf of the Contracting Parties attach their hand-written signatures.

Done in Prague on 9.12.2024

Done in Frankfurt on 20.11.2024

Contract Giver:

Provider:

.....  
MUDr. Tomáš Boráň  
State Institute for Drug Control,  
Director

.....  
XXX