

**WORK ORDER | 21-665**

Work Order Date: 04-OCT-2022 | Revised Date: 16-SEP-2022

**Vychodoslovensky Onkologicky Ustav, a.s.****CLINIGEN**

This Work Order, effective as of the last signature date below, and is between Clinigen Clinical Supplies Management SA, a Belgium corporation, with its primary place of business at Watson & Crick Hill, Rue Granbonpre 11, B-1435 Mont-Saint-Guibert, Belgium ("Clinigen Clinigen CSM SA SA"), and Vychodoslovensky Onkologicky Ustav, a.s., a company registered in Slovakia with company number 36 603 350, VAT id: SK2022124159, whose registered office is situated at Rastislavova 43, 41 91, Kosice, Slovakia ("Client").

**Key Assumptions****Protocol Number & Title:** AD ASTRA (Androgen Deprivation with Apalutamide and Stereotactic Radiotherapy); IIS Study | WO 21-665**Study Drug(s):** Apalutamide 60mg 120ct bottles | assume use of current inventory | storage and distribution at 15°C / 25°C**Expected Work Order Duration:** ~72 months**Number of Patients:** n/a**Number of Sites:** 1 | assume (5) total shipments**List of countries and/or regions in which the study will be conducted:** Slovakia**Languages required for clinical trial materials (CTM) labels:** Slovakian**Services details:**

1. Apalutamide 60mg 120ct bottles currently at Clinigen CSM SA facility

**Number and/or configuration of supplies to package and label or dispense:**

1. Package and label (~900) Apalutamide 60mg 120ct kits; each kit containing (1) Apalutamide 60mg 120ct bottle. Assume (1) label per bottle, (1) label and (2) tamper seals per kit in (5) packaging runs.

*All requests for signature need to be issued to the following mail address [cs-requests@clinigengroup.com](mailto:cs-requests@clinigengroup.com)*

**Resources and Cost Estimates****Project Cost (Based on Key Assumptions)**

	Receipt	Unit	Qty	Rate	Total
AM F2 05	Receipt fee at 15°C / 25°C	batch	4	€ 157.08	€ 628.32
	Receipt Fees Total				€ 628.32

	Packaging and Labeling	Unit	Qty	Rate	Total
AP M1 05	Design packaging documentation	fee	5	€ 875.16	€ 4,375.80
AP M8 05	Review batch documentation by QA/QC	fee	5	€ 330.48	€ 1,652.40
AP M1 10	Packaging room charge and completion of batch documentation	run	5	€ 574.26	€ 2,871.30
AP M8 15	Batch release certification by QP after production	batch	5	€ 659.94	€ 3,299.70
AP M5 18	Label proof generation	proof	2	€ 265.20	€ 530.40
AP M5 20	Label printing and review				
	carton & bottle labels	label	1,800	€ 1.26	€ 2,268.00
AP M5 05	Secondary Packaging				
	Apalutamide 60mg kits	kit	900	€ 8.00	€ 7,200.00
	Total Packaging and Labeling Fees				€ 22,197.60

Fees may apply for all non-stock labels; amounts incurred will be billed. Clinigen CSM SA reserves the right to outsource label printing and label proofs via a qualified vendor.

	Management Fees	Unit	Qty	Rate	Total
AC B2 05	Project set-up fee	project	1	€ 5,122.92	€ 5,122.92
AC B5 20	Project management	hour	144	€ 131.58	€ 18,947.52
	Management Fees Total				€ 24,070.44

\*Additional project management hours will be billed out at €131,58 per hour.

	Storage	Unit	Qty	Rate	Total
AS J2 10	Storage Fee at 15°C / 25°C   assume 3 locations per month * 72 months	medium location	216	€ 42.84	€ 9,253.44
	Estimated Storage Fees Total				€ 9,253.44

	Distribution	Unit	Qty	Rate	Total
AU N8 05	Shipment tracking & tracing	shipment	5	€ 26.52	€ 132.60
AU Q2 05	Distribution processing fee at 15°C / 25°C	shipment	5	€ 157.08	€ 785.40
AU Q2 10	Pick & Pack fee at 15°C / 25°C with individual identification	unit	900	€ 0.14	€ 126.00
AU Q2 15	Pick & Pack fee at 15°C / 25°C without individual identification	unit	0	€ 0.14	€ 0.00
AU Q1 10	Expedited distribution request fee (Clinigen CSM SA will make a good faith effort to process all expedited shipment requests)	shipment	0	€ 93.64	€ 0.00
	Shipping Material				
AU W2 05	Carton shipping box single use +15-25°C	carton box	12	€ 0.00	€ 0.00
AU W2 55	Temperature monitoring device (without T° exportable data)	logger	12	€ 31.62	€ 379.44
	Distribution fees Total				€ 1,423.44

	Destruction   Non-Dedicated Destruction	Unit	Qty	Rate	Total
AW V8 20	Destruction handling fee	fee	1	€ 732.36	€ 732.36
AW V8 05	Destruction box	box	1	€ 157.08	€ 157.08
	<b>Destruction Fees Total</b>				<b>€ 889.44</b>

Disclaimer: Unused materials may include, but are not limited to: IMPs, ancillary supplies, labels, packaging and labeling supplies. Non-dedicated destruction means we are destroying on a shared project basis. Clinigen CSM SA can arrange for dedicated destruction upon request, additional fees will apply. This service is for destruction only, returns and/or reconciliation services are available upon request, additional fees will apply.

	Estimated Pass-through	Unit	Qty	Rate	Total
AY U2 05	Transport				
	Courier shipping expenses	estimate	1	€ 1,200.00	€ 1,200.00
AY W5 10	Packaging and labeling components				
	Packaging and labeling components (e.g. cartons, inserts, etc.)	estimate	1	€ 2,300.00	€ 2,300.00
AY Z9 05	Other				
	Language translation	estimate	1	€ 300.00	€ 300.00
	<b>Pass-through Fees Total</b>				<b>€ 3,800.00</b>

Estimates provided are approximate; amounts incurred will be billed. Expenses will be billed with a 5% administration fee except for drug sourcing, ancillary supply sourcing, and depot services provided by Clinigen which will incur no administration fee.

## Summary of Project Budget

Receipt Fees	€ 628.32
Packaging and Labeling Fees	€ 22,197.60
Management Fees	€ 24,070.44
Storage Fees	€ 9,253.44
Distribution Fees	€ 1,423.44
Destruction Fees	€ 889.44
<b>Estimated Services Budget</b>	<b>€ 58,462.68</b>
Estimated Pass-Through Costs	€ 3,800.00
<b>Project Budget</b>	<b>€ 62,262.68</b>

## 1. SERVICES

A. Clinigen CSM SA shall provide to Client the services ("Services") described in this Work Order. In performing the Services, Clinigen CSM SA shall comply with (1) any applicable study protocol, (2) this agreement, (3) the written instructions of Client, (4) all applicable professional standards, (5) Current Good Manufacturing Practices regulations, and (6) all other applicable laws and regulations.

B. Client acknowledges that the Services specified in this agreement constitute the only obligations transferred to Clinigen CSM SA by Client.

C. Affiliates of Clinigen CSM SA may perform Services under this agreement. The terms of this agreement shall apply to any Clinigen CSM SA Affiliate performing Services under this agreement as though that Affiliate were Clinigen CSM SA. In this agreement, "Affiliate" means any entity which Controls, is Controlled by, or is under common Control of a party, and those entities which establish that shared Control with a party following the date of this agreement. In this agreement, "Control" means the ability to direct the affairs of an entity through the ownership of at least 50 percent of the voting securities or other ownership interest of that entity.

D. Client shall promptly send Clinigen CSM SA all materials and information in Client's control (1) that are necessary for Clinigen CSM SA to perform the Services, and (2) regarding any known or potential hazards associated with the use of any Client-Supplied Materials. Clinigen CSM SA is not liable to Client and will not be deemed to be in breach of this agreement for any errors, delays, or other consequences arising from the failure of Client to send those materials or that information. Client acknowledges that, if the materials or information provided to Clinigen CSM SA regarding the Client-Supplied Materials materially differ from the Client-Supplied Materials actually provided or if the classification of those Client-Supplied Materials changes, Clinigen CSM SA may, at its option, modify the pricing for Services involving those Client-Supplied Materials or, upon notice to Client, stop performance of the Services. If Client materially delays or suspends performance of the Services, Clinigen CSM SA may reallocate personnel, resources, or both from the Services. Clinigen CSM SA will not be liable to Client for any subsequent delay related to that reallocation.

## 2. CHANGE ORDERS

A. If either party becomes aware of a Material change that could affect the expected budget or scope of Services under this agreement, that party shall promptly discuss that change with the other party. In this agreement, "Material" means important enough to merit attention from a reasonable person.

B. Either party can initiate a change order ("Change Order") if a Material change that affects the expected budget or scope of Services under this agreement occurs or is expected to occur. When finalized, a Change Order will modify this agreement to the extent set forth in the Change Order. Each party shall negotiate in good faith when considering a Change Order.

C. If Client and Clinigen CSM SA are unable to finalize a Change Order, Clinigen CSM SA may begin performance of the Services without that finalized Change Order, on the condition that Client first provides Clinigen CSM SA with written approval to begin those Services and written approval of the rates at which Clinigen CSM SA will perform those Services. If Clinigen CSM SA begins performance of those Services without that finalized Change Order, (1) the terms of this agreement will apply to the provision of those Services as though those Services were performed under a finalized Change Order, and (2) Clinigen CSM SA and Client shall continue to promptly negotiate the finalization of that Change Order in good faith.

## 3. PAYMENT TERMS

A. Clinigen CSM SA shall submit to Client a monthly invoice describing the Services performed and, if applicable, the pass through costs incurred during that month. Client agrees that Clinigen CSM SA shall invoice applicable set-up fees upon execution of this Work Order. Clinigen CSM SA shall also invoice monthly fees to Client for the duration of the project until the latest of: (a) completion of services, (b) delivery of finished CTM or (c) destruction of all CTM. Client shall pay the undisputed portion of each invoice no later than 30 days from the invoice date. Client shall bear the cost of any transaction fees associated with payment.

B. Client shall notify Clinigen CSM SA no later than 30 days from the invoice date if it disputes all or part of an invoice. Client hereby waives the right to dispute any invoice not disputed within that period.

C. Without limiting the other rights or remedies of Clinigen CSM SA, Client shall pay Clinigen CSM SA interest on all payment amounts that are undisputed and overdue at a rate of 1.5% per month. This interest will first accrue at the beginning of the 31st day following the invoice date.

D. If any undisputed payment from Client is overdue by more than 30 days, Clinigen CSM SA may stop performance of any or all Services, on the condition that Clinigen CSM SA first notifies Client in writing of its intent to stop performance and provides Client five days following receipt of that notice to pay the overdue invoices.

- E. Client is liable to Clinigen CSM SA for all reasonable costs of collection of undisputed payments, including all legal fees and other expenses, whether or not Clinigen CSM SA files a suit for collection.
- F. Client acknowledges that Clinigen CSM SA shall invoice client and Client shall provide advance payment to Clinigen CSM SA for sourced materials and/or outsourced services.
- G. Client acknowledges that Clinigen CSM SA reserves the right to modify pricing in case of change in applicable local regulation, price modifications from its suppliers, and annual indexation for studies lasting more than twelve months.
- H. Unless noted otherwise, Client acknowledges that all fees, pass-through expenses and other sums set out in this Work Order are stated exclusive of any Value Added Tax (VAT) or similar tax, which if applicable, shall be payable in addition to the sum in question at the rate in force under the relevant law.
- I. All customs duties, charges and/or taxes incurred by Clinigen CSM SA in relation to Client shipments which cannot be reclaimed by Clinigen CSM SA or passed on to the relevant Client will be charged by Clinigen CSM SA to the Client and the Client will pay the same in accordance with the payment terms set out in this Work Order.

#### 4. TERM AND TERMINATION

- A. Unless earlier terminated as provided in this agreement, the term of this agreement is from the date of this agreement to the completion of Services under this agreement.
- B. Either party may terminate this agreement or a Change Order without cause and without court intervention upon 90 days notice to the other party.
- C. Either party may terminate this agreement or a Change Order without court intervention immediately upon notice if (1) the other party commits a Material breach of this agreement, or that Change Order, and (2) the party notifies the other party of that Material breach, and (3) that Material breach remains uncured for 30 days following receipt of that notification.
- D. Either party may terminate this agreement or a Change Order without court intervention immediately upon notice to the other party if the other party (1) becomes insolvent, (2) is dissolved or liquidated, (3) makes a general assignment for the benefit of its creditors, (4) files or has filed against it a petition for bankruptcy, or (5) has a receiver appointed for a substantial part of its assets.
- E. If either party terminates this agreement or a Change Order, Clinigen CSM SA shall cooperate with Client to provide an orderly conclusion of the Services and Client shall pay Clinigen CSM SA for (1) all costs and fees due as of the date of termination and (2) the approved costs related to an orderly conclusion of the Services
- F. The following sections will survive termination of this agreement: sections 5F, 6, 7, 8, 9, 10, 11, 12, 13, 20, 22, 23, 24, 25, and 26.

#### 5. CONFIDENTIAL INFORMATION

- A. In this agreement, "Client-Supplied Materials" means (1) the subset of Confidential Information that is provided to Clinigen CSM SA by or on behalf of Client, and (2) materials purchased in connection with the Services by or on behalf of Clinigen CSM SA.
- B. In this agreement, "**Confidential Information**" means (1) all information disclosed and materials provided, in any form, to the Receiving Party by or on behalf of the Disclosing Party, and (2) all information and materials that the Receiving Party derives or generates, in any form, from the information provided or materials disclosed by the Disclosing Party. Confidential Information does not include information or materials that the Receiving Party can show by written evidence:
- i. was or becomes generally known to the public through no wrongful act of the Receiving Party;
  - ii. was in the lawful possession of the Receiving Party before it received the information or materials from the Disclosing Party;
  - iii. becomes known to the Receiving Party through a third person that had the legal right to disclose or provide the information or materials; or
  - iv. was independently developed by the Receiving Party without reference to or reliance on the information or materials.
- C. In this agreement, "Clinigen CSM SA Know How" means (1) the subset of Confidential Information that is provided to Client by or on behalf of Clinigen CSM SA, and (2) any information, materials, or intellectual property rights that Clinigen CSM SA independently developed before or during the term of this agreement without reference to or reliance on the Client-Supplied Materials.
- D. In this agreement, "**Disclosing Party**" means the party disclosing the information or providing the materials.
- E. In this agreement, "**Purpose**" means the use of the Confidential Information to (1) determine whether to contract for Services under this agreement, or (2) conduct the Services under this agreement.
- F. In this agreement, "**Receiving Party**" means the party receiving the information or materials.
- G. In this agreement "**Representatives**" means the Affiliates of a party and the officers, directors, employees, consultants, and agents of that party and its Affiliates.
- H. The Receiving Party shall limit disclosure and provision of the Confidential Information to only those of its Representatives that have a need to know the Confidential Information to perform their duties and who are bound to protect the Confidential Information by terms at least as strict as those contained in this agreement. The Receiving Party shall use the Confidential Information only for the Purpose and shall not use the Confidential Information for its own benefit or for the benefit of another.
- I. The Receiving Party shall use the same degree of care to protect the Confidential Information of the Disclosing Party as it uses to protect its own information or materials of a similar nature, but shall not use less than a reasonable degree of care. The Receiving Party is liable to the Disclosing Party for any disclosure or use of the Confidential Information that breaches this agreement by it or its Representatives.
- J. The Receiving Party shall promptly notify the Disclosing Party of any actual or suspected violation of the confidentiality obligations under this agreement and shall take all reasonable steps requested by the Disclosing Party to prevent, control, or remedy that violation.
- K. The restrictions on the disclosure and use of the Confidential Information by the Receiving Party do not apply with respect to Confidential Information that the Receiving Party is required to disclose to comply with a judicial proceeding, applicable law, or government regulations. If the Receiving Party is so required to disclose the Confidential Information of the Disclosing Party, the Receiving Party shall, to the extent permitted, notify the Disclosing Party of the disclosure and take all reasonable actions to cooperate with the Disclosing Party to minimize the disclosure.
- L. The restrictions on the disclosure and use of the Confidential Information will survive for seven years following the date of termination of this agreement.

#### 6. OWNERSHIP OF CONFIDENTIAL INFORMATION

- A. The Receiving Party acknowledges that the Disclosing Party is the exclusive owner of (1) the Confidential Information disclosed, and (2) all rights in or arising from that Confidential Information. This agreement does not grant or imply any license or conveyance of those rights to the Receiving Party other than for the Purpose. If the Receiving Party creates an invention, work, or improvement using the Confidential Information of the Disclosing Party, the Receiving Party shall irrevocably assign and transfer any right, title, or interest in that invention, work, or improvement to the Disclosing Party without further consideration. At the request and expense of the Disclosing Party, the Receiving Party shall assist the Disclosing Party in acquiring and maintaining that right, title, or interest.
- B. Excluding Clinigen CSM SA Know How, any work product that results from the Services performed under this agreement is the sole property of Client. Excluding Clinigen CSM SA Know How, all intellectual property rights relating to that work product are the sole property of Client. Client may use or transfer that work product that is the property of Client or those intellectual property rights that are the property of Client for any lawful purpose, with no further payment to Clinigen CSM SA.
- C. If Client files a patent application that covers an invention resulting from or made in performance of the Services, excluding Clinigen CSM SA Know How, Clinigen CSM SA shall, at the request and expense of Client, help Client to prepare and prosecute that patent application. Clinigen CSM SA shall also execute all documents necessary for (1) the filing of that patent application, and (2) for the vesting of the patent title in Client.

## 7. STORAGE OF CONFIDENTIAL INFORMATION

- A. Clinigen CSM SA shall maintain all original study documentation for the longer of (1) the period of time required by applicable laws or regulations, or (2) five years following the termination of this agreement. At the end of that period, Clinigen CSM SA may destroy that documentation, on the condition that Clinigen CSM SA first provide Client 90 days prior notice to ensure that Client has the opportunity to request a transfer of that documentation to Client or a third party.
- B. Upon completion of the Services under this agreement, Clinigen CSM SA may destroy some or all of the Client-Supplied Materials related to those Services other than original study documentation and retain samples, on the condition that Clinigen CSM SA first provide Client 90 days prior notice to ensure that Client has the opportunity to request a transfer of those Client-Supplied Materials to Client or a third party.
- C. Clinigen CSM SA shall maintain all retain samples for one year following the expiration date of the retain sample drug product. At the end of that period, Clinigen CSM SA may destroy those retain samples, on the condition that Clinigen CSM SA first provide Client 90 days prior notice to ensure that Client has the opportunity to request a transfer of those retain samples to Client or a third party.
- D. When the Disclosing Party requests, the Receiving Party shall return to the Disclosing Party the requested Confidential Information and materials generated from the Confidential Information, except that (1) the Receiving Party may retain one copy of the Confidential Information in its confidential files to ensure compliance with this agreement, and any electronic copies that have been automatically generated as part of a routine backup, and (2) Clinigen CSM SA shall maintain all original study documentation and retain samples as described in this section.
- E. Client shall pay Clinigen CSM SA for all reasonable expenses related to the destruction or return of Client-Supplied Materials.

## 8. PUBLICITY

- A. Except as required by law, each party shall not use the name of the other party or the name of any employee of the other party in connection with any publicity without the prior written consent of the other party.
- B. Clinigen CSM SA shall not publish or present material related to the Services without the prior written consent of Client, except that Clinigen CSM SA may publish or present summary level examples of the Services without the prior written consent of Client on the condition that the summary level examples could not be used to identify Client or the nature of any Client-Supplied Materials.

## 9. NOTICES

- A. Each party shall provide any notice or other communication to the other party that is required or permitted by this agreement in writing.
- B. Notice will only be deemed to be given under this agreement if sent to the address below by (1) personal delivery, (2) a nationally-recognized, next-day courier service, or (3) first class registered or certified mail, postage prepaid.

If to Client:  
Vychodoslovensky Onkologicky Ustav. a.s.  
Rastislavova 43  
41 91  
Kosice  
Slovakia

If to Clinigen CSM SA:  
Clinigen Clinical Supplies Management SA  
Watson & Crick Hill  
Rue Granbonpré 11  
B-1435 Mont-Saint-Guibert  
Belgium  
ATTN: Legal Department  
Tel: +32 (0)10 237 444  
Fax: +32 (0)10 470 860

- C. Notice given by personal delivery, courier service, or registered or certified mail is effective upon receipt.

## 10. INDEMNIFICATION

- A. Clinigen CSM SA shall indemnify Client and its Representatives for damages arising out of nonparty claims that Client is legally obligated to pay as a result of the death of or bodily injury to any person, or the destruction of or damage to any property, to the extent caused by the negligent act, error, or omission of Clinigen CSM SA or anyone for whom Clinigen CSM SA is legally responsible.
- B. Client shall indemnify Clinigen CSM SA and its Representatives for damages arising out of nonparty claims that Clinigen CSM SA is legally obligated to pay as a result of the death of or bodily injury to any person, or the destruction of or damage to any property, to the extent (a) caused by the negligent act, error, or omission of Client or anyone for whom Client is legally responsible, or (b) those claims arise in connection with the development, testing, use, manufacture, or commercialization of Client-Supplied Materials.

## 11. LIMITATIONS

- A. Except as expressly set forth in this agreement, Clinigen CSM SA makes no warranty, express or implied, regarding the accuracy, completeness, performance, merchantability, or fitness for a particular purpose of the Services or the results obtained from the work of Clinigen CSM SA.
- B. Each party provides all Confidential Information "as-is" and without any warranty, express or implied, regarding its accuracy, completeness, performance, merchantability, or fitness for a particular purpose.
- C. Each party and its Representatives is not liable for consequential, incidental, special, or indirect damages or lost profits, whether contractual or extra-contractual in nature, or for damages caused by acts of negligence, whether contractual or extra-contractual in nature, that are not intentional or reckless.
- D. Clinigen CSM SA is not liable, on a contractual or extra-contractual basis, for loss of or damage to Client-Supplied Materials that are not reasonably under the control of Clinigen CSM SA. Clinigen CSM SA is only responsible, on a contractual or extra-contractual basis, for that loss or damage to Client-Supplied Materials if that loss or damage results from the willful misconduct or recklessness of Clinigen CSM SA.
- E. The collective, aggregate liability of Clinigen CSM SA and its Representatives under this agreement and any Change Orders will not, on a contractual or extra-contractual basis, exceed the amount of payments actually received by Clinigen CSM SA from Client under this agreement.
- F. Except for actions brought in relation to a failure to pay money, each party shall bring any action relating to an alleged breach of this agreement or a Change Order, no later than one year after the date of the occurrence of the breach. Any action not brought within that period, other than an action brought in relation to a failure to pay money, is barred without regard to any other limitations period set forth by law or regulation.

## 12. INSURANCE

- A. Each party states that it maintains a policy or program of insurance or self-insurance sufficient to support its obligations under this agreement.

### 13. INDEPENDENT CONTRACTOR

- A. With respect to the personnel Clinigen CSM SA assigns to perform the Services, Clinigen CSM SA shall (1) provide their compensation, (2) withhold all taxes from that compensation, (3) perform all other employer-related obligations, (4) make all deductions required by law, and (5) provide all supervisory, administrative, and quality control activities.
- B. The parties intend that the personnel Clinigen CSM SA assigns to perform the Services are not and will not be deemed to be employees of Client. The parties intend that Clinigen CSM SA is an independent contractor of Client. This agreement does not create any other association between the parties.

### 14. ASSIGNMENT

- A. Each party shall not assign this agreement without the express written consent of the other party, except that either party may assign this agreement without that consent if assigned to an Affiliate or to an entity that acquires substantially all of the assets and business of the party. Any attempted assignment in violation of this section is prohibited and is of no effect.

### 15. INSPECTION AND AUDITS

- A. Clinigen CSM SA shall permit Client or its representative to audit or inspect Clinigen CSM SA's facilities, processes, and records that relate to the Services, on the condition that Client provides Clinigen CSM SA with 14 days notice and reasonable accommodation for scheduling. During any audit or inspection, Client or its representative may inspect only those facilities, processes, and records that relate to the Services. Client or its representative shall not inspect information relating to the other clients of Clinigen CSM SA.
- B. Each party shall promptly notify the other party of any government or regulatory agency audit or inspection relating to the Client-Supplied Materials.
- i. If the government or regulatory agency audit or inspection occurs at a Clinigen CSM SA facility, Clinigen CSM SA shall permit Client or its representative to observe any portion of that audit or inspection that directly and exclusively relates to the Services. Client or its representative shall not actively participate in or direct the manner in which Clinigen CSM SA conducts the audit or inspection.
- ii. Each party shall promptly provide the other party with (1) a copy of any reports or findings from that audit or inspection, and (2) a copy of any responses.
- C. Client shall pay Clinigen CSM SA for any audits or inspections by Client or its representative on a time and materials basis if (1) the frequency or length of the audits or inspections by Client or its representative exceeds that frequency or length expected from similar clients, and (2) that excess frequency or length is not the fault of Clinigen CSM SA.
- D. Client shall pay Clinigen CSM SA on a time and materials basis for all government and regulatory agency audits that occur as a direct result of performing the Services for Client on the condition that the government or regulatory inspection or audit is not the fault of Clinigen CSM SA.
- E. Clinigen CSM SA may prohibit a representative of Client from participating in an audit or inspection of Clinigen CSM SA if that representative is a competitor of Clinigen CSM SA.

### 16. DEBARMENT CERTIFICATION

- A. Each party states that it has not been debarred or convicted of a crime that could lead to debarment by any regulatory agency in any jurisdiction. If either party or any of its Representatives becomes debarred or receives notice or threat of action of debarment, that party shall promptly notify the other party.
- B. Clinigen CSM SA shall use reasonable efforts to not use the services of any nonparty to perform the Services that has been debarred or convicted of a crime that could lead to debarment by any regulatory agency in any jurisdiction. If Clinigen CSM SA receives notice of the debarment of any nonparty involved in the performance of the Services, Clinigen CSM SA shall promptly notify Client.

### 17. ANTI-CORRUPTION AND ANTI-BRIBERY

- A. Each party states that it complies with all applicable anti-corruption and anti-bribery laws. Each party shall not offer, give, or agree to give any gift or other consideration as an inducement or reward relating to the Services in violation of those laws.

### 18. FORCE MAJEURE

- A. In this agreement, "**Force Majeure Event**" means, with respect to a party, any event or circumstance, regardless of whether it was foreseeable, that (1) was not caused by that party and (2) prevents that party from performing any of its obligations under this agreement, except for an obligation to pay money, despite the reasonable efforts of that party to perform.
- B. Each party is not liable for any failure to perform under this agreement to the extent that failure to perform is due to a Force Majeure Event, on the condition that the party affected by the Force Majeure Event promptly notifies the other party in writing of (1) that Force Majeure Event, (2) its effect on performance, and (3) the expectations of that party regarding the duration of that Force Majeure Event.
- C. Either party may terminate this agreement immediately upon notice to the other party if that other party is unable to perform its obligations under this agreement for longer than 90 days after the occurrence of the Force Majeure Event.

### 19. DISPUTE RESOLUTION

- A. If any dispute or claim arises from or related to this agreement or the relationship of the parties, the parties shall attempt to settle that dispute or claim through good faith negotiation by authorized representatives of the parties. Either party may initiate this informal dispute process by sending notice of the dispute to the other party. If the parties are unable to resolve the dispute at the end of thirty days following receipt of that notice, each party may then file a claim for arbitration.
- B. If a party files a claim for arbitration, any dispute arising out of or in connection with this agreement, including any question regarding its existence, validity, or termination, is to be referred to and finally resolved under the rules of the London Court of International Arbitration. Those rules are incorporated by reference into this clause. If the amount in dispute is less than or equal to \$250,000, the number of arbitrators will be one. If the amount in dispute is greater than \$250,000, the number of arbitrators will be three. The seat, or legal place, of the arbitration will be New York, New York, United States. The arbitral proceedings will be conducted in English.
- C. If any dispute arising out of or in connection with agreement is not able to be arbitrated, the parties consent to exclusive jurisdiction and venue of the state and federal courts sitting in the New York county, New York, United States.

### 20. REMEDIES

- A. If the Services provided by Clinigen CSM SA do not meet the agreed upon specifications or render the work product of Clinigen CSM SA unreliable or unusable to Client, Clinigen CSM SA shall, at its option, and on the condition that Client provides Clinigen CSM SA notice of that problem no later than 30 days after receipt of the Services, either (1) correct those Services without charge or (2) refund Client for those Services.

### 21. GOVERNING LAW

- A. This agreement, any claim arising from or related to this agreement, and the relationship of the parties are construed, governed, interpreted, and applied in accordance with the laws of Belgium, exclusive of its conflicts of laws provisions. The parties reject any application to this agreement of (1) the United Nations Convention on Contracts for the International Sale of Goods and (2) the 1974 Convention on the Limitation Period in the International Sale of Goods.

## 22. CONSTRUCTION OF AGREEMENT

A. The official language of this agreement, the Change Orders, and any notice or other document required by this agreement is English. If a dispute arises concerning the construction or meaning of a text, reference will only be made to the text as written in English and not to any other translation into any other language.

## 23. DATA PROTECTION

A. Client states that it (1) complies with all legal requirements regarding data protection, and (2) has received all required consents regarding the use of personal data in connection with this agreement.

B. If Clinigen CSM SA processes the personal data of a living individual on behalf of Client, Clinigen CSM SA shall (1) process that personal data only on the written instructions of Client, and (2) implement appropriate technical and organizational measures to protect that personal data against unauthorized processing, loss, damage, or destruction.

## 24. SEVERABILITY

A. If one or more provisions in this agreement is or becomes invalid or unenforceable, the parties intend that the validity and enforceability of the other provisions not be affected. The parties intend that the invalid or unenforceable provision be replaced by a provision that is valid and enforceable and that corresponds most closely to the economic intent of the parties as evidenced by the original provision.

## 25. WAIVER

A. Except as provided in this agreement, any delay of a party in enforcing its rights under this agreement or any waiver of a party as to a particular default or other matter does not constitute a waiver of the rights of that party to enforce its rights under this agreement.

## 26. ENTIRE AGREEMENT

A. This agreement constitutes the entire agreement of the parties relating to the exchange of Confidential Information between the parties and the provision of Services. This agreement supersedes and terminates all prior agreements between the parties relating to the exchange of Confidential Information between the parties and the provision of Services. The parties hereby disclaim any duties not provided for in this agreement relating to the exchange of Confidential Information between the parties and the provision of Services. This agreement may not be modified except by an agreement in writing signed by an authorized representative of each party.

B. If a provision of a Change Order conflicts with a provision in this agreement, the provision in this agreement will control, unless the provision in the Change Order expressly provides otherwise.

## 27. COUNTERPARTS AND DELIVERY

A. The parties may execute this agreement electronically and in counterparts. Each counterpart, when executed, will constitute an original and, when taken together, will constitute a single agreement.

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### Approval Signatures

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**Clinigen Clinical Supplies Management SA**

BY: \_\_\_\_\_

NAME: \_\_\_\_\_

TITLE: \_\_\_\_\_

DATE: \_\_\_\_\_

**Vychodoslovensky Onkologicky Ustav, a.s.**

BY: \_\_\_\_\_

NAME: MUDr. Tomáš Sieber, MPH      Ing. Eva Milá

TITLE: Chairman of the board of directors   Vice-chairman of the board of directors

DATE: \_\_\_\_\_