Dear supplier:

We would like to inform you that we have made updates to our terms and conditions regarding purchase orders. These changes are part of our ongoing efforts to simplify and streamline our operations and ensure that our business relationships are clear and mutually beneficial.

The details and new clauses will be attached to our purchase orders for your reference. The purpose of this change is to automate contracts for transactions below USD $15,000.00 (fifteen thousand dollars). In the event that our interactions exceed that amount, we will proceed to execute specific service contracts (in the applicable services) that support us in regulating the details of our business relationship. In this case, such service contract will prevail over the clauses attached to the purchase order.

This attached clause contains scenarios for the different types of services that Novartis contracts with its business partners, and therefore, in order to avoid any confusion, the clause itself details the assumptions under which each scenario is applicable to the service in question.

We greatly value our partnership and look forward to continuing to work together successfully. If you have any questions or concerns about the changes, please do not hesitate to contact our purchasing team at proveedores.latam@novartis.com. We are committed to providing you with information and clarity.

We appreciate your understanding and continued support, as well as our business partnership.

Sincerely yours,

Procurement Novartis

Adhesion Contract

1. The Parties
1.1 As "Novartis": Novartis Farmacéutica S.A. de C.V.
1.2 As "Supplier": That natural or legal person specified in the Purchase Order in charge of the supply of products and/or the provision of services to Novartis.

2. Object
Under this Agreement, Supplier agrees to deliver to Novartis or any of its affiliates or subsidiaries as agreed upon, the materials, goods, products and/or services specified in the Purchase Order at the place, date, terms, conditions and prices stated in the Purchase Order (the "Subject Matter"). In this sense, this Agreement is an integral part of the Purchase Order.

3. Acceptance:
This Agreement and its respective Purchase Order shall be considered binding upon the occurrence of any of the following events: a) the Purchase Order has been accepted by the Supplier (as indicated in clause 4.3 of this Agreement), b) by the delivery or supply of the items covered by the Purchase Order, c) by the commencement of work and/or service or manufacture of the items indicated in the Purchase Order.

Purchase orders
4.1 The parties hereby agree that Novartis shall prepare the Purchase Order based on the quotation or estimate previously submitted by Supplier.
4.2 The Purchase Order will be sent by Novartis to the Supplier by e-mail.
4.3 The Supplier shall have a period of 2 (two) calendar days from the sending of the Purchase Order to express its opinion on the Purchase Order. If the Supplier does not express its opinion within this period or if the Supplier's Acceptance is updated, expressly or tacitly, as indicated in clause 3, the Purchase Order and this Agreement shall become binding on the Parties.

5. Price and payment conditions
5.1 The price and other commercial terms specified in the Purchase Order ("Price") are final (exclusive of taxes, if any) and binding, including any and all costs necessary for the supply of the product and/or the provision of the service that is the subject of the Purchase Order. Supplier warrants that no additional costs of any kind will be incurred that are not approved in advance by Novartis. Supplier may only increase/decrease the "Price" based on governmental regulations that may affect it, subject to prior verification and approval by Novartis of such causes (exchange rate, price controls, etc.). Novartis shall have 30 days, once the request is submitted by Supplier, to authorize or terminate this Order. Notwithstanding the foregoing, Supplier shall provide the basis of calculation for pricing the materials or services.
5.2 All costs relating to the transportation and delivery of the product and/or the provision of the service by the Supplier, at the address indicated by Novartis, are also included in the Price.
5.3 The Price shall be paid in accordance with the time and conditions described in the Purchase Order. The invoice shall be sent to Novartis or uploaded to the system indicated by Novartis no later than 2 (two) business days from the date of issuance.
5.4 In the event of delay by Supplier in sending the invoice, in breach of the term stipulated in clause 5.3 above, the payment of the Price by Novartis shall be automatically delayed by the number of days equivalent to the corresponding delay in sending the invoice, without any increase in the Price, update of interest or application of any penalty or fine to Novartis.
5.5 The price indicated in the Purchase Order does not include Value Added Tax (VAT).
5.6 Supplier shall submit its Digital Tax Receipts by Internet (CFDI) as well as the Payment Receipt Complements under the terms and conditions previously indicated by Novartis and as indicated by the tax legislation in force. A copy of the purchase order must be attached to the invoice. Invoices that do not comply with the required information will not be received. No department within Novartis outside Novartis Accounts Payable may receive invoices.
5.7 Regarding the payment schedule Novartis has a policy of paying suppliers once a week, having a fixed payment schedule that is issued and published at the beginning of the year; the Supplier may request a copy of this schedule.

6. Delivery, transport and execution
6.1 The term of delivery of the product or provision of the service is the one indicated in the Purchase Order. Deliveries shall be made at the times and in the quantities determined in the Purchase Order, or in accordance with the requirements made to Supplier by Novartis. Partial deliveries will not be accepted. If Supplier fails to make deliveries or to provide service at the agreed time, all damages suffered by Novartis, any additional transportation costs, or any other additional costs to meet Novartis' requirements, shall be borne by Supplier.
6.2 Supplier shall immediately notify Novartis in writing of any forecast delay in the delivery of a product or the provision of a service.
6.3 The possible acceptance by Novartis of the shipment of the product or provision of services, outside the time period set forth in the Purchase Order, shall in no way be deemed to be a waiver of any right to damages that Novartis may claim by virtue of such delay.
6.4 All documents related to the product and/or service provided by Supplier, where applicable, such as good manufacturing practices in the pharmaceutical industry (Current Good Manufacturing Practices - "cGMP"), must be provided to Novartis at the time of delivery of the product and/or provision of the service by Supplier. Each individual delivery shall be governed by applicable law.
6.5 If Novartis detects, during the audit process provided for in Clause 16 below, Supplier's failure to comply with Clause 6.4 above, Supplier shall be subject to the payment of a penalty, to be defined by Novartis.
6.6 Novartis may specify the Carrier and/or method of transportation, Supplier shall process the shipping documents and establish the route for the movement of the goods from the LAB point. Supplier shall comply with the Carrier requirements established by HSSEQ, Road Transport which include, but are not limited to: means of transportation, assignment of a carrier on schedules for loading and unloading.
6.7 The Supplier shall bear the costs of packing, freight, coils, packaging, containers, transportation and insurance, as well as the costs incurred by Novartis for any return, correction or recovery of the product and/or provision of the service that, due to production and/or execution deficiencies, transport damage, inadequate packaging, among others, is not, at Novartis' discretion, in perfect condition for use.
6.8 The Supplier shall bear all risks of transportation and preservation of the product, until actual delivery and/or performance of the service to Novartis.
6.9 The Supplier undertakes to ensure that the product indicated in the Purchase Order arrives at the point of delivery free of damage and defects and in accordance with the requirements of the carrier.
6.10 Novartis shall not be responsible for excess shipments, which shall be returned to Supplier, who shall reimburse Novartis for all shipping, handling, sorting and transportation charges incurred for such shipments. In certain cases and at the discretion of Novartis, an acceptance tolerance of 5% or $5,000.00 maximum will be allowed.
6.11 If Supplier fails to comply with all delivery requirements contained in the Purchase Order and Contract, Novartis shall have the right to demand the same delivery by express service or air shipment and Supplier shall reimburse Novartis for any costs occasioned by such transportation unless Supplier's failure is due to an act of God or force majeure.
6.12 When it has been specified in the purchase order that deliveries are to be made in accordance with detailed schedules, the Supplier shall not manufacture, assemble or purchase more than the materials necessary to comply with these schedules, on the understanding that if it violates this indication it shall assume any liability arising therefrom.
6.13 Supplier grants Novartis the right at any time to specify the carrier and/or method of transportation to be used to deliver all or part of the material/products covered by this order. Any changes made by Novartis in the method specified shall be subject to equitable settlement by the Supplier and Novartis as set forth in the Changes clause.
6.14 Supplier may not assign or transfer its obligations for the performance of this Agreement and Purchase Order unless it has the prior written consent of Novartis.

7. Inspection
Novartis shall have the right to inspect and approve all materials, special tooling, items and quality of work and service, at all times and places. Supplier shall provide and maintain an adequate inspection system covering materials, manufacturing methods, special tooling and/or the performance of the service. Supplier shall maintain at Novartis' disposal a record of inspections made of all work and materials during the performance of the subject matter of this Contract and Purchase Order.

8. Warranty and Insurance

8.1 Supplier warrants that the materials, products or services covered by this Contract will be supplied in accordance with the specifications and quality requested by Novartis and that the same are manufactured with good material and workmanship and are free from defects. Supplier further warrants that any item, material, product or services supplied under this Contract and Purchase Order will meet the qualities necessary to adequately fulfill the purpose for which it is intended. Supplier agrees to defend, indemnify and hold Novartis harmless from any and all third party claims and complaints resulting from breaches of the above warranty.
8.2 Supplier agrees to allow Novartis at all times access to its documentation evidencing that Supplier has covered the risks that its business or the material goods subject to this Contract or the tooling supplied by Novartis or any goods thereof, may incur in the performance of this Contract. Supplier expressly agrees that all risks, total or partial loss of such goods shall be borne solely by Supplier until such goods are delivered to Novartis at the place indicated by Novartis. Supplier further agrees to indemnify and protect Novartis against any loss, claim or damage that Novartis itself or any third party may suffer as a result of the defective performance of the goods or services.

9. Refusals and Cancellations

9.1 In the event that any item, material, product or service provided is defective in material or workmanship or is otherwise not in conformity with the purchase order, Novartis shall have the right, at its sole discretion, to refuse delivery or request Supplier to make the necessary correction. In the latter case all expenses involved in the correction shall be borne solely by Supplier. The correction shall be made by Supplier immediately upon request by Novartis.
9.2 Novartis may cancel the performance of the subject matter of this Contract and Purchase Order, at any time either in whole or in part, by giving written notice to Supplier of such cancellation. Supplier shall suspend work on the date and to the extent specified in the notice and shall immediately notify Novartis of the quantities of items or material

in stock as of such date. Supplier shall comply with Novartis' instructions regarding the protection, transfer and disposition of title and possession of such items and material. In this respect Supplier waives the provisions of the final part of Art. 2635 of the Civil Code applicable in Mexico City and/or its correlatives in the other States of the Mexican Republic, in which case Novartis shall pay exclusively to Supplier the cost of the items in process.

10. Assignment of rights by the supplier

10.1 The Agreement will not be assignable without the prior written consent of the other Party, which consent may not be unreasonably withheld. Any attempted assignment in contravention of this Clause will be null and void. Notwithstanding the foregoing, Novartis will have the right, at its sole discretion, without requiring Third Party's further written consent (which Third Party confirms has been given pursuant hereto), to:

10.1.1. assign the Agreement and/or any rights and obligations pertaining thereto (including any part thereof) to any of its Affiliates; and

10.1.2. assign the Agreement, and/or any rights and obligations pertaining thereto (including any part thereof), in connection with and to the extent related to, any and all forms of divestment and investment (including but not limited to, merger, de-merger, consolidation, reorganization, share sale, asset sale, joint-venture, etc.).

For the avoidance of doubt, any (permitted) assignee will assume all obligations and rights of its assignor under this Agreement (or related to the assigned portion in case of a partial assignment).

10.2 In the event that:

10.2.1 An Affiliate receiving goods/services/deliverables no longer meets the definition of an Affiliate due to any and all forms of divestment (including but not limited to, merger, de-merger, reorganization, share sale, asset sale, joint-venture, etc.) ("**Former Affiliate**"); or

10.2.2 an asset related to a Novartis business is transferred and/or sold to a third party buyer ("**Buyer**"),

Upon request of Novartis, Third Party will continue and herewith consents to provide the relevant goods/services/deliverables to such Former Affiliate or Buyer after the date such entity ceases to be an Affiliate or an asset is transferred to a Buyer, for a period requested by Novartis in accordance with Novartis' respective transitional service or other commitments. The goods/services/deliverables provided to such Former Affiliate or Buyer will be provided in accordance with the then current terms and conditions of this Agreement.

11. Ownership, exclusivity and confidentiality

11.1 Ownership of the product/goods covered by this Agreement shall be transferred to Novartis exclusively and unconditionally, irrespective of the amount paid. In this regard, any possibility of modification or extension of the reservation of title shall be deemed to be terminated upon transfer of ownership to Novartis and/or upon acceptance of this Agreement and Purchase Order (whichever occurs first). The ownership of each design or drawing, tools, materials or equipment that by virtue of the object of this Agreement is necessary to supply to Supplier, shall always correspond to Novartis and it shall be understood that Novartis delivers it as a gratuitous bailment.

11.2 Materials, technical specifications, drawings, designs, samples, samples, descriptions, plans, tools, materials, equipment or other indications sent to Supplier by Novartis shall be used exclusively for the performance of the subject matter of this contract and Purchase Order , and shall not be used in any application for third parties, nor for any processing, mixing or blending of materials performed by Supplier on behalf of Novartis except in accordance with its direct instructions.

11.3 The Novartis goods referred to in the preceding clause, while in the possession or control of Supplier, shall be kept in good condition, at the risk and responsibility of Supplier, who in case of loss shall cover their cost to Novartis immediately. Novartis may at any time dispose of the referenced goods and Supplier shall deliver them to Novartis immediately upon request. The same provision shall apply for services related to intellectual property, such as writings, editions, photographs, designs, layouts, modeling, images and the like, which have been commissioned by Novartis, in accordance with the Intellectual Property clause.

11.4 Any diminution in the value of the Product subject to the Purchase Order or any loss to Novartis due to Supplier's failure to comply with the obligation set forth in Clause 11.3 above shall incur the liability set forth in Clause 14 below.

11.5 Supplier, its employees and agents agree to maintain the confidentiality of this Agreement and Purchase Order, as well as all information transmitted and/or made available to Supplier by Novartis arising from the performance of the service that is the subject of this Agreement, including, but not limited to, any and all oral and/or written information of a technical, operational, commercial, legal, know-how, business plans, techniques and accumulated experience, documents, contracts, papers, documents, studies, opinions, research, formulas, samples or products of Novartis, which shall be deemed confidential, restricted and proprietary to Novartis ("Confidential Information").

11.6 Supplier also agrees to use the Confidential Information solely for the purpose of fulfilling the purpose of this Agreement and Purchase Order.

11.7 No information shall be taken as Confidential Information which is publicly available or which has lawfully come to the knowledge of the Supplier prior to the receipt of such information by Novartis.

11.8 Upon fulfillment of the subject matter of this Agreement and Purchase Order, if requested by Novartis, Supplier shall immediately return any Confidential Information and destroy any copies thereof.

12. Data Privacy

12.1 The terms used in this clause shall have the following meaning:

a) "Data" means Novartis Confidential Information to be made available to Supplier for processing by or on behalf of Novartis pursuant to this Agreement and Purchase Order;

b) "Personal Information" or "Personal Data" means any information (as defined by current and applicable Mexican law) related to a person that identifies him or her or makes him or her identifiable; including, without limitation, information found in electronic and/or physical media, such as name, home address, business address, email address, age, gender, family information, profession, education, professional affiliations, salary data, credit card data, among others.

12.2 Supplier's Obligations:

a) Supplier shall not access (including remote access), copy, use or otherwise process Personal Information or Personal Data for any purpose other than as expressly necessary for the provision of the services subject to this Agreement and Purchase Order. Supplier shall ensure that all of its obligations in connection with the processing of Personal Information or Personal Data arising under this Agreement and Purchase Order shall apply to its employees and representatives in accordance with applicable laws.

b) Supplier shall process the Data on behalf of Novartis only at the express instruction of Novartis and shall process such data exclusively for the purposes set forth in this Agreement and Purchase Order and/or as expressly indicated by Novartis. Likewise, Supplier agrees to be aware of the conditions of data processing, which can be found in the Novartis Privacy Notice which can be consulted at the following link https://www.novartis.com/mx-es/aviso-de-privacidad

c) When Supplier is required to disclose any Personal Information, Confidential Information, Personal Data or Data it has obtained under this Agreement and Purchase Order due to the request of competent authority, Novartis shall be immediately notified of this request and shall always obtain its consent to any such disclosure.

d) The Supplier shall guarantee the strict confidentiality of the Data and/or Personal Information and/or Data to which it has had access during the performance of the services now contracted and not to transmit or disclose in any way such Data and/or Personal Information and/or Data to third parties.

e) Supplier and its subcontractors if applicable (see clause 13 "No Subcontracting") shall comply with all obligations related to the Security of Novartis Data and/or Personal Information to which they have access, and shall adopt and implement all technical and organizational measures to adequately protect the Data and Personal Information against any change, use and disclosure other than accidental or unlawful loss or destruction.

f) Supplier and its subcontractors (if applicable) shall, at Novartis' request or upon termination of this Agreement and Purchase Order, destroy and/or return to Novartis (at Novartis' decision) all Personal Information and/or Data collected, stored and processed within the scope of this Agreement and Purchase Order, as well as all materials or documents generated or used by Supplier in the performance of the services in which there is any proprietary information of Novartis.

g) Supplier shall immediately inform Novartis of any incident or breach of security measures for Personal Information or Data and Supplier shall cooperate with Novartis in the resolution of such breaches, including data recovery or any other form of remediation.

h) Supplier shall indemnify Novartis for any loss, damage or claim arising from any breach of its obligations under this Agreement and Purchase Order relating to the processing or implementation of technical and security measures relating to the collection, storage and processing of data and/or Personal Information.

i) Novartis reserves the right to audit or inspect Supplier's operations in relation to measures to protect personal data and the security of data collected, stored and processed upon at least 15 (fifteen) days prior written notice to Supplier.

j) If Supplier notifies Novartis of any failure or breach of data security or privacy measures, Novartis shall have the right to conduct an audit of Supplier's facilities and procedures upon 24 (twenty-four) hours prior notice.

k) If the Supplier has any doubts about the processing of the information, it must immediately clarify them with Novartis.

l) When this Agreement includes the activities described in the following concepts: Commissions for transactions related to Real Estate. Services and goods related to health. Services and goods related to security. Acquisition of hardware. Cell phones and smart phones. Hardware maintenance. Software license - Perpetual. Software license - Subscription. Software license - Maintenance. Software as a Service (SaaS). Platform as a service (PaaS). Infrastructure as a service - IaaS. End-user services (Help-desk, MPS, printers, etc.) Application, security and project services. Technological infrastructure services. Data and analytics platforms and services and emerging technology. AI, ML and automation. Web, mobile and interactive services. Digital therapeutics, SAMD and biosensors. Data links or lines - Fixed data. Telephony and conferencing, PSTN Voice/IPT. Mobile voice and data. Creative agency services. Media Contracting. General media. Patient support program. Home nursing support program. Direct marketing program. Reimbursement, co-pay and diagnostic programs. C&C - Virtual, streaming, production/staging, AV, mobile applications. Medical education and content. Consulting - Business and Management. Audit services. Business tax services. Insurance Services (not related to benefits). Litigation and Legal Transactions. General Legal Services. IP legal services (filing of applications). Translation services. Document management services. Training and development services. Talent attraction services (e.g. head hunter). Global mobility. Employee relocation services. Services related to compensation and benefits programs. Insurance services related to benefits. Sales service organizations (Field Force). Clinical supervision. Data management. Drug safety and epidemiology. IRT (IVRS). Patient contact services. Supplies and equipment for clinical trial sites. Manufacture of tablets or capsules (solids). Manufacture of creams or gels and/or semi-solids. Manufacture of syrups, solutions and/or liquids Manufacture of injectables. Manufacturing devices. Packaging. Manufacture of DS Biologics (API). Contract manufacturing of DP&FDF biologics. Manufacture of Aerosols. Manufacture of patches,

transdermal therapeutic systems and oral films. Manufacture of other dosage forms. Manufacture of cell and gene therapy intermediates. Manufacture of cell and gene therapy products. Manufacturing services. Pumps. Manufacturing; ESO API; pharmacologic substance; ESO manufacturing and chemical intermediates; the Additional Information Security Requirements Annex identified in **Annex H** of this Contract will be applicable to them.

13. No subcontracting

Third Party is not entitled to sublicense or subcontract any of its obligations under the Agreement without the prior written consent of Novartis. By entering into the Agreement, Third Party warrants and represents to Novartis that it has implemented a reasonable and appropriate due diligence process to assess any potential subcontractor, and that such due diligence process has been applied to the sublicensee/subcontractor being the subject of the request to Novartis without any negative findings. In the event that Novartis approves any such request:

a) Third Party will remain fully liable for the acts/or omissions of the approved subcontractor and for any breach or non-performance of the Agreement;

b) Third Party will include in its subcontracts, with any subcontractor approved pursuant to the Agreement, obligations which are consistent with the relevant obligations from the Agreement;

c)Third Party will be exclusively responsible for all costs associated with any such sublicense or subcontract arrangement.

d)Furthermore, Third Party undertakes to put in place and maintain for the duration of the Agreement an ongoing monitoring program of any approved subcontractors. In the event where an alert arises as part of the monitoring process, Third Party will notify Novartis in writing as soon as possible and in any event no later than seven (7) days of the alert having arisen.

14. Non-compliance, quality, inspection obligations.

14.1 In the event of defects, hidden defects or non-compliance with the provisions of the Contract or Purchase Order and/or specifications, standards, drawings, samples, descriptions or other indications as to the quality or propriety of the product and/or service provided by Supplier, all rights and remedies available to Novartis in its favor shall be governed by applicable Mexican law. In this regard, Supplier shall be liable to pay damages to Novartis for any breach of this Agreement or Purchase Order, defects or hidden faults.

14.2 Supplier represents and warrants that the product and/or service covered by this Agreement and Purchase Order and/or all products and materials used for the provision of the service contracted by Novartis are free from any defects and shall take into account all specifications, standards, drawings, samples, descriptions or other indications given by Novartis. Supplier warrants that the importation, storage, sale and conventional use of such products shall not infringe any patent or intellectual property right of any third party.

14.3 Supplier shall comply with all legislation, rule and/or regulation applicable to the subject matter of this Contract and Purchase Order.

14.4 The Supplier agrees that Novartis will be responsible for carrying out its inspection process (sampling inspection) which will include visual inspection, delivery document inspection and quality control inspection.

14.5 Supplier represents that the products/goods and/or services covered by this Agreement are free from defects and/or hidden defects. If Novartis identifies any defect and/or hidden defect in the product subject of this Contract and Purchase Order, Supplier shall be liable under the terms outlined in clause 14.6 below.

14.6 In the event Supplier fails to comply with any of its obligations set forth in this Agreement and Purchase Order it shall be subject to payment of liquidated damages to Novartis.

15. Additional obligations of the supplier

15.1 Third-party risk management

15.1.1. Novartis promotes the corporate and environmental values of the United Nations Global Compact to its third party suppliers and uses its influence to the extent possible to promote their adoption. Suppliers are obliged to comply with the Novartis Third Party Code (and any updates thereto that may be published), as well as with other Novartis policies and guidelines which can be found at https://www.novartis.com/esg/reporting/codes-policies-and-guidelines and https://www.novartis.com/supplier-portal.

15.1.2 Supplier shall familiarize itself with Novartis' Third Party Standards and shall provide all information required by Novartis regarding its practices: Labor Rights, Health, Safety, Security, Environment, Animal Welfare, Anti-Corruption, Unfair Competition, Data Privacy and Information Protection, Responsible Minerals, GMP Quality, Trade Sanctions and Export Control in the required form. Novartis (or third party specialists), will have sufficient and appropriate access to audit compliance with these third party standards.

15.1.3. Supplier shall use its best efforts to remedy identified instances of non-compliance and shall inform Novartis of the progress of these instances, when necessary. At Novartis' sole discretion, Supplier's failure to comply with these Standards of Conduct shall give Novartis the right to terminate the business relationship of this contract and Purchase Order, without Supplier being entitled to payment of any compensation, penalty or indemnity. Supplier confirms having read and understood all Novartis third party rules.

Likewise, the Supplier undertakes to:

a) Provide Novartis with the information/documentation reasonably requested in order to enable verification of compliance with the Novartis Third Party Code in the manner requested;

b) Rectify identified non-compliances with the Novartis Third Party Code and other policies and guidelines (where rectification is possible) and report on the progress of such rectifications when requested by Novartis;

c)Ensure that when Third Parties (Affiliates) and/or subcontractors/agents of Supplier and its (Affiliates) have been approved (if applicable) by Novartis to provide the (goods/services/deliverables), that such Third Parties also comply with all obligations described in this Agreement and in accordance with the Novartis Third Party Code and other Novartis policies and guidelines.

Supplier acknowledges and agrees that the Novartis Supplier Code/Third Party Code forms an integral part of this Agreement and understands that failure (by itself or its approved Third Parties) to comply with these standards and/or by obstructing/refusing Novartis' audit rights as set forth in the Novartis Supplier Code/Third Party Code constitutes a material breach of this Agreement, giving Novartis the right to terminate the Agreement only upon notice and without the need for judicial declaration.

15.2. Anti-Corruption and Anti-Bribery

The Supplier accepts and acknowledges that the present Contract contains obligations imposed in the local and federal Anti-Bribery legislations, for which it is obliged to the following:

15.2.1 Compliance with the Law:

a) Supplier, Third Party (Novartis Approved) affiliates, partners or legal representatives shall not promise, offer, pay, cause to be paid, accept payment or induce any payment or take any action that may be considered a bribe;

b) Comply with national legislation and regulations, including those related to bribery and corruption, particularly the General Law of Administrative Responsibilities in force and the National Anticorruption System in Mexico, as well as correlative applicable local legislation and/or even foreign legislation such as the US Foreign Corrupt Practices Act or the UK Bribery Act, among others that have international jurisdiction and application;

c) Comply with the standards of the Pharmaceutical Industry in Mexico;

d) Comply with all policies and guidelines received from Novartis with respect to Supplier's activities under this Agreement. In the event that Novartis adopts additional guidelines or policies with respect to Supplier's activities and/or operations applicable to the Contract Novartis shall provide Supplier with a copy and thereafter such guidelines and/or policies shall apply, if any, which upon communication shall form an integral part hereof. Supplier hereby acknowledges receipt and understanding of the applicable policies and guidelines referred to herein.

e) Fulfill its obligations under this Agreement, observing high standards of business ethics and personal integrity.

f) Supplier shall be responsible for training all of its personnel (including authorized contractors) involved in the performance of the stated activities in anti-bribery training and applicable anti-corruption policies and regulations (hereinafter referred to as "Anti-Corruption Training"), at Supplier's expense. Unless Novartis requests to conduct the training otherwise. Such "Anti-Corruption Training" shall include, at a minimum, the provisions of applicable bribery and corruption legislation and shall take place prior to the provision of services or business or contractual relationship with Novartis. Supplier shall ensure that new personnel (including authorized contractors), who will subsequently provide services to Novartis, receive "Anti-Corruption Training".

g) Novartis shall have the right, upon request, to provide (directly or through its affiliates or contractors) the "Anti-Corruption Training". If Supplier receives such a request, Supplier agrees to cooperate fully with Novartis to enable such training to be conducted, including providing reasonable and necessary access for such purpose to its facilities and employees involved in providing services to Novartis.

h) Upon Novartis' request and in compliance with the personal data protection regulation applicable in Mexico, Supplier shall promptly provide copies of the training material and the training attendance list (which shall include the name and qualification of the participant). The Supplier informs Novartis that it has informed the data subjects about the present communication of data, in accordance with its privacy notice, which the Supplier undertakes to forward to its Novartis contact point, as well as having obtained their consent to communicate the personal data of the data subject.

i) Upon request, Supplier shall provide Novartis with a letter of confirmation of compliance (hereinafter referred to as "Confirmation of Compliance"). The format of the Confirmation of Compliance shall be provided by Novartis to Supplier. If requested, the Confirmation of Compliance shall be delivered during the first quarter of the year following the calendar year to which it refers. If "Supplier" fails to provide the duly completed Compliance Confirmation, it shall be deemed a material breach hereunder and Novartis shall be entitled to terminate it in accordance with the termination and rescission clause of this Agreement.

Novartis hereby, in compliance with local and federal legislation, makes available to Supplier an email address of the Novartis Compliance Office to report any kind of present, past and future conflict of interest that affects, favors or impedes the business relationship with Novartis speak.up@novartis.com. A conflict of interest is understood as when the personal interests of a decision-maker influence or have the capacity to influence, either in a real or apparent way, financial, commercial or corporate decision making, and therefore the Supplier undertakes to invite its collaborators who make decisions in its company to report any conflict of interest that may arise. Novartis also informs the Supplier of a communication portal for the purpose of reporting any malicious, misleading or fraudulent activity that may involve any Novartis employee during the term of the business relationship. Any employee may call 001-855-366-2458, as well as speak.up@novartis.com where any complaint will be attended.

Likewise, the Supplier undertakes to comply with the provisions of Annex E of this Contract.

Supplier certifies that the information provided in the "Third Party Questionnaire", published prior to the execution of the subject matter of this Agreement and Purchase Order, is applicable, accurate and complete. Supplier shall inform Novartis in writing of: (i) any material change to the information provided in the "Third Party Questionnaire"; and (ii) any Material Change in Supplier's Structure, in both cases as soon as practicable after the material change occurs. Supplier understands that a Material Change in Supplier's Structure will mean a change in control/shareholders. "Control", means, ownership directly or indirectly of more than 50%.

15.2.3. Supplier's failure to comply with any of the obligations set forth in this clause shall be deemed a material breach of this Agreement and, therefore, Novartis shall be entitled to terminate this Agreement without the need for a court declaration.

15.3. Compliance and non-existence of an employment relationship

15.3.1. In the event that services are rendered or work is performed within Novartis facilities, Supplier shall comply with all safety rules and instructions indicated by Novartis, as well as with the applicable legislation.

15.3.2. Supplier shall ensure that all its employees performing work on Novartis premises are properly trained, identified by a badge and uniformed with Supplier's name. Supplier shall further ensure that its employees use all personal protective equipment required by applicable law, which must be provided by Supplier.

For all services rendered, the Supplier undertakes to maintain only regular registered employees, in accordance with the conditions provided for by the applicable labor provisions.

15.3.3. Supplier shall replace, immediately, all of its employees that Novartis deems unsuitable for the services, at Novartis' sole discretion, without the need for any justification.

15.3.4. No employment relationship or liability is established under this Purchase Order by Novartis with Supplier's personnel responsible for the supply of products and/or the provision of services under this Agreement. In this sense, all payments and/or dues of such personnel, whether labor, social security, tax, or any other applicable, shall be borne exclusively by Supplier as the sole responsible party and employer.

15.3.5. If Supplier's employees, contractors or agents file against Novartis a claim and/or lawsuit of a labor or any other nature as well as any other judicial action or extrajudicial proceeding, Supplier is obligated to hold Novartis harmless, assuming all liability arising from such possible proceedings, including full payment of all amounts to which Novartis may be condemned, including, but not limited to the amounts established by the Court or Tribunal, but also to all judicial and extrajudicial fees and charges, under penalty that by failing to do so, Novartis shall be entitled to terminate this Agreement without the need for judicial declaration, as well as to require Supplier to pay an indemnity equivalent to the amount for which Novartis was condemned being this amount updated with the applicable legal increases, fines and/or surcharges. Supplier is considered the sole and exclusive employer of its employees, and therefore agrees to hold Novartis harmless in the event of any claim and/or lawsuit.

15.3.6. The Supplier in the event that it is a health professional, declares, for all purposes, that this agreement shall in no way exert any influence or impair its independence with respect to the exercise of its activities and professional capacity.

16. Right to audit and file retention

16.1 Third Party will, and will ensure that its Personnel will, keep and maintain complete, appropriate and accurate Records in accordance with the Records Retention Period. Without limiting Third Party´s information security obligations under the Agreement, Third Party will maintain at its own expense all Records in secure and suitable facilities and ensure such facilities (and associated Records stored at such facilities) are (in the context of an audit) readily accessible to Novartis (and/or its appointed auditor) during the Records Retention Period.

16.2 For the purpose of ensuring Third Party`s compliance with the Agreement and to confirm all Relevant Payments, Third Party agrees and will ensure that its Personnel agree (where necessary) that Novartis (and/or its appointed auditor) will have the right, at any time upon reasonable prior notice from Novartis, during the term of the Agreement and for one year thereafter (except as otherwise specified in the Agreement) to audit and have access to: (i) all Records; (ii)Third Party´s compliance/anti-corruption program; (iii) any and all premises/facilities, networks, data processing and/or records retrieval systems owned, used or controlled by Third Party relating to or connected with the Agreement; and (iv)any other information that Novartis and/or its appointed auditor reasonably considers necessary for the proper performance of their auditing duties. The audit and access rights referenced under this Clause, include without limitation the right to conduct face to face and/or on-line interviews with Third Party Personnel, the right to access and review (in both soft and hard copy) any and all internal polices, internal audit reports, SOPs, procedures, guidelines, and/or other internal documentation of Third Party (including, without limitation, documentation with third parties relating to the audit scope and Third Party`s corporate structure), respective evidences and proofs and all written explanations provided by Third Party to confirm its compliance with the provisions of the Agreement and Relevant Payments. Any audit (and related data collection activities) shall be carried out in compliance with applicable laws.

16.3 Novartis may appoint an auditor to perform the audit referenced in the clause above, and, if so, the appointed auditor will be subject to appropriate confidentiality obligations in relation to its review of Third Party`s Confidential Information. Upon written notice (simple email to be sufficient) by Novartis that it wishes to conduct an audit, Third Party will promptly provide full cooperation and comply with the requirements of this Clause.

16.4 Each Party shall bear its own costs and expenses of any audit conducted pursuant to this Clause.

16.5 Following an audit, Novartis may discuss its/or its appointed auditor´s findings with Third Party. Third Party will, acting reasonably and without undue delay, put forward a plan (including a timetable to implement and complete the plan) to address any concerns37 identified in the audit (a "**Remediation Plan**") for Novartis' review and will reasonably consider Novartis' recommendations (if any) in such Remediation Plan. Notwithstanding any recommendations provided by Novartis to Third Party, Third Party will remain responsible for the implementation of such Remediation Plan and acknowledges and agrees that it places reliance on such recommendations at its own risk and any decisions or consequences of such decisions relating to, or the implementation of, such recommendations are within the discretion and sole responsibility of the Third Party. Third Party will comply with the steps to be taken in the Remediation Plan and will take all other necessary steps to remedy its failure and subsequently comply with its obligations at no additional cost or expense to Novartis.

16.6 Nothing in this Clause requires Third Party to provide information on profits, margins, overheads or costs of capital (other than in relation to pass-through costs or any charges calculated on a cost-plus basis) for the purposes of an audit.38

16.7 To the extent that Third Party demonstrates that access to certain areas of its facilities/premises would cause a breach of its confidentiality undertakings to its other customers, Third Party may (instead of providing access to such certain areas) put in place reasonable workarounds to enable Novartis and/or its appointed auditor to have access to resources and information reasonably required in order to carry out the audit. In respect of Records, Third Party shall not refuse to provide access to a Record based on its confidentiality status.

16.8 Any failure by Supplier to comply with the provisions of this Clause shall be deemed a breach of the Contract, entitling Novartis to terminate the Contract without the need for a court declaration.

Records means all data, information, text, drawings, books, records (including without limitation financial and training records), expense reports, documents or other materials of Third Party recorded in any form (including those created for and on behalf of Third Party by its Personnel) relating to or connected with the Agreement and/or the performance of all its obligations under the Agreement (including without limitation obligations relating to payments made by Novartis to Third Party). For this purpose, Records does **not** include any data, information, text, drawings, books, records, documents or other materials which are the subject of legal privilege (whether legal professional privilege or litigation privilege, or their equivalent in other jurisdictions).

Records Retention Period means the period for which each of the Records must be maintained, i.e. until the date which is the latest of: (a) the date which is the earliest date specified by applicable laws/regulations/accounting standards in respect of each Record; (b) the date of expiry/termination of the Agreement (or the applicable related agreement issued thereunder) plus ten years; (c) the date that the Parties agree that all matters arising from or in connection with the Agreement or that Record have been finally concluded; or (d) the date when that Record is no longer required to be stored under Novartis' records retention policy as notified to Third Party from time to time.

Relevant Payments means any and all payments made: (i) by Novartis to Third Party; or (ii) made by Third Party, either for and on behalf of Novartis, or on its own account, and in each case, directly relating to the obligations of Third Party under the Agreement.

17. Intellectual Property

17.1 All creative, printed, filmed material, texts and correspondence relating to the Services provided by Supplier to Novartis shall be the exclusive property of Novartis and shall be made available to Novartis, within Supplier's normal business hours and upon written request by the reviewer, duly approved by the Novartis representative.

It is understood between the Parties that any work, intellectual creation and/or material element derived from the provision and/or execution of the Services object of the present Contract that is created and/or elaborated by the supplier and/or by its employees, factors and/or dependents, and/or authorized third party suppliers, subordinate personnel under the orders of the supplier and/or by the technical personnel that in its case was contracted directly or indirectly by the supplier for the execution of the object of the present Contract, shall be considered as commissioned works in terms of the provisions of Article 83 of the Federal Copyright Law, for which reason Novartis shall enjoy exclusive ownership of the economic rights and those rights provided for in the aforementioned article, with the understanding that Novartis may make use of such works, intellectual creations and/or material elements in the manner that best suits its interests, declaring Supplier under oath that such works, intellectual creations and/or material elements are original and original works, for which reason they do not affect the rights of third parties.

The works, intellectual creations and/or material elements indicated in the preceding paragraph may be registered directly by Novartis or by the persons that Novartis freely designates before the National Copyright Institute, the Mexican Institute of Industrial Property or before any other national or foreign authority, without requiring the consent or any other type of additional authorization by the Supplier and/or by its employees, factors and/or dependents, subordinate personnel under the orders of the Supplier and/or by the technical personnel that have been hired either directly or indirectly by the Supplier for the execution of the object of this Contract.

Consequently, the Supplier undertakes, if necessary, to sign and/or provide Novartis with the necessary documentation no later than five working days following the date on which it is requested, in order for Novartis to obtain the registration and/or registration of the intellectual and industrial rights derived from the works, intellectual creations and/or material elements resulting from the execution of the Services, before any national or foreign authority or institute.

Likewise, Supplier undertakes to execute with all its employees, factors and/or dependents, subordinate personnel under the Supplier's orders and/or with the technical personnel that may be hired directly or indirectly by Supplier for the execution of the object of this Contract and Purchase Order, all contracts, agreements and other legal documents that may be necessary in order that the works, intellectual creations and/or

material elements that they may have created and/or developed are considered as works commissioned by Novartis in terms of Article 83 of the Federal Copyright Law, intellectual creations and/or material elements created and/or developed by them shall be considered as works commissioned by Novartis in terms of Article 83 of the Federal Copyright Law, as well as that such contracts, agreements and/or legal documents shall provide that Novartis shall consequently be the exclusive owner of the economic rights and of those rights provided for in the aforementioned Article 83 of the Federal Copyright Law; the express mention of its authorization for the omission of its credit in such works, intellectual creations and/or material elements when these refer to advertisements or publicity, as well as the express authorization for Novartis to make the modifications, changes, adaptations, additions and deletions that it considers necessary to the works, intellectual creations and/or material elements that result as a consequence of the provision and/or execution of the object of this Contract and Purchase Order in order to allow the best exploitation of the same.
In addition, Supplier undertakes that all contracts, agreements and other legal documents that in terms of the preceding paragraph must be executed with all its employees, factors and/or dependents, subordinate personnel under the Supplier's orders and/or with the technical personnel that may be hired directly or indirectly by Supplier for the performance of the object of this Agreement shall provide that they are obliged to sign any documentation that may be necessary within five working days following the day in which they have been requested to do so, in order for Novartis to obtain the registration and/or registration of the intellectual and industrial rights derived from the works, intellectual creations and/or material elements resulting from its participation in the performance of the Services, before any national or foreign authority or institute.
Therefore, in the event that Novartis receives or is involved in any lawsuit or claim from any third party or authority related to the rights and obligations provided under this clause and other provisions of this Agreement, Supplier agrees to indemnify Novartis by covering the reasonable legal fees and expenses resulting therefrom, in addition to any damages caused. The foregoing is without prejudice to any rights that Novartis may exercise under this Agreement and applicable law.
17.2 Supplier warrants that the importation, storage, sale or use of the items, goods or material covered by this Agreement does not infringe or contribute to the infringement of any patent, trademark, industrial design, rights or trade names, whereby Supplier agrees to hold Novartis harmless from any claim that may be brought against it or its customers and shall pay the costs, damages and expenses incurred if such a claim occurs.
Any inventions, trade secrets, ideas or original works of authorship ("the Works") that Supplier's personnel conceive, develop, discover or perform, in whole or in part, in the performance of the Service shall belong exclusively to Novartis and all Works shall be deemed to be "works for hire" (*trabajos por encargo)* or "for remuneration" *(por remunerado)* under the Federal Copyright Law. If any Work is determined not to constitute "work for hire" (*trabajos por encargo)* or "for remuneration" *(por remunerado)*, or if any rights in the Work do not vest in "Novartis" as a work for hire, "Supplier" hereby irrevocably assigns and transfers to Novartis, to the fullest extent permitted by law, free of royalty, all rights, including those of an economic nature, title and interest in the Work, including all copyrights, patents, trade secret rights and other intellectual property rights in or relating to the Work.
Any inventions, trade secrets, ideas or original works of authorship ("the Works") that Supplier's personnel conceive, develop, discover or perform, in whole or in part, in the performance of the Service shall belong to Novartis and Supplier and shall be royalty-free. Each Party may exploit it in its business and at no time shall any confidential information of the other Party be disclosed, subject to the confidentiality clause.
17.3 Each of the Parties is the owner of its own registered trademarks, distinctive signs, patents, industrial secrets and other forms of protection contemplated in the Federal Law for the Protection of Industrial Property and other applicable provisions. This Agreement in no way grants a license in favor of any of the Parties for the use or exploitation of the industrial property of the other, for which reason there must be express consent in writing and granted in accordance with the formalities required by the applicable Law.
Except for the foregoing, the Parties recognize the copyrights with respect to the previously existing materials and those that may be generated as a result of the performance of the object of this Agreement, in accordance with the provisions of the Federal Copyright Law.

18 No conflict of interest
18.1. The Supplier declares that the present Contract and its respective Purchase Order do not involve any conflict of interest in accordance with the applicable legislation.
18.2 Supplier declares and warrants that it or its employees does not have a relationship with the public service and that are not employed in governmental enterprises, state-owned enterprises, public agencies or bodies, including government-controlled medical or healthcare institutions, whose position or performance permits any undue influence or promotion of Novartis business, primarily related to public tenders and/or purchasing.
18.3. If Supplier has held, within the last 6 (six) months and/or holds or will hold a public office in the manner described in the preceding clause, Supplier shall immediately inform Novartis. In the event of failure to do so, Novartis may terminate this agreement at its sole discretion and by simple written notice without the need for a court declaration.
If the event described in the preceding paragraph occurs Novartis shall have the power to terminate the Agreement immediately without the need for a judicial declaration and by simple written notice.
If obligations already assumed by Supplier towards third parties make it impossible to immediately terminate this Agreement and Purchase Order, Supplier shall immediately notify the department responsible for its employment with the governmental entity of the existence of this Agreement and Purchase Order with Novartis.
18.4. If the provision of services is subject to professional regulations/certifications requiring the approval of a professional organization/association and/or public entity, it shall be Supplier's responsibility to ensure that such approval is obtained prior to providing any of the contracted services. Upon Novartis' request, Supplier shall provide written evidence of such approvals obtained.
18.5 Supplier shall take all necessary measures to prevent its employees, representatives, agents or intermediaries, either directly or indirectly, from paying or offering gifts, commissions, loans, privileges or other special attention to employees, representatives, agents or intermediaries of Novartis, as well as to their relatives. Likewise, Supplier undertakes to contribute to the maintenance of Novartis' Conflict of Interest policy, whereby Supplier shall provide Novartis with information on employees, directors or shareholders of Supplier who also have an interest in Novartis' business, whether as officers, employees, agents, contractors, consultants or in any other way. This information shall be kept up to date.

19. Changes
Novartis may at any time upon written notice, make changes/updates with respect to designs or specifications, method of packaging or shipment and goods the use of which Novartis grants to Supplier. If any change causes an increase or decrease in the cost or in the time specified for performance or delivery of all or part of the work it may be authorized by a Notice of Change in the Purchase Order issued by Novartis and signed by both parties.

20 Early termination and rescission
20.1. Novartis (if it is in its best interest) may terminate this Agreement with immediate effect and without liability and without the need for a court declaration, by written notice to Supplier.
20.2 Novartis may terminate this Agreement with its respective purchase order if Supplier fails to deliver the materials, objects and/or products, fails to perform the services within the specified time, fails to comply with any of the conditions and obligations at its expense contained herein In this event Novartis shall be free to choose any of the following options:
(a) Request that the materials, products, goods, property, equipment and/or services referred to in this Contract be manufactured at the Supplier's expense.
b) Request from the Supplier the forced execution of the object of this Contract and the payment of damages.
c)Terminate this contract and the purchase order without the need for a court declaration and upon written notice only with immediate effect in addition to the restitution of the amounts Novartis has paid to Supplier plus payment of damages.
Likewise, Novartis may terminate this Agreement with its respective purchase order at any time with immediate effect, by written notice to Supplier in cases of (i) violation by Supplier of the clauses relating to compliance with legislation and/or intellectual property rights;(ii) change of Control of Supplier; and (iii) that Supplier initiates the procedure tending to its declaration of bankruptcy.

21. General Provisions
21.1. The failure of a Party to timely request performance of any of the provisions or rights set forth in this Agreement shall not be deemed a waiver of such provisions, nor shall it constitute a novation or in any way affect the future exercise of such right.
21.2. Each provision of this Agreement shall be construed as valid under applicable law. In the event that any provision is deemed void or ineffective, the validity or effectiveness of the remaining provisions shall not be affected and shall remain in full force and effect and, in such event, there shall be a substitution of the void or ineffective provision with one that in accordance with applicable law shall permit the performance of the subject matter of this Agreement.
21.3. The present Contract constitutes the only valid agreement between the contracting parties, superimposing all previous discussions, documents and/or agreements (verbal or written) between the Parties in relation to the Object of the present Contract also indicated in the Purchase Order. The Supplier accepts that this Contract is independent of any other previously celebrated, in this sense, the Parties agree to be governed exclusively by the clauses of the present Contract in what refers to the purchase order; unless something different is indicated in a later document duly signed by both Parties. Therefore, in case there is any later Contract in relation to the object of the Purchase Order that is celebrated between the Parties, such Contract shall prevail over the present one.
21.4 The Parties agree that Novartis' liability that may arise from this Agreement shall be limited to the amount specified in the Purchase Order.
21.5 In case of discrepancy, the Spanish version of this Agreement will prevail.

22. Government and safety regulations
Supplier shall comply with all governmental and safety regulations regarding hazardous, restricted and toxic materials; as well as environmental, electrical and electromagnetic regulations applicable in the countries of manufacture and sale of the materials subject to this Contract, as well as with all occupational safety and health requirements stated or required by Novartis.

23. Acts of God and force majeure
None of the Parties shall be liable for breach of its obligations included in the present Contract in the event of an act of God or force majeure. In the event of an act of God or force majeure that partially or totally prevents the execution of this Contract, the same

may be terminated by any of the Parties by means of written notice, within 5 (five) calendar days following the occurrence of such circumstance, and the Parties shall be obliged to make adjustments as to the payment for the work performed, when applicable. This order is subject to modification or cancellation by Novartis in the event of fire, accidents, strikes, legal restrictions and other acts of God or force majeure beyond the control of Novartis, without any liability to Novartis.

24 Pharmacovigilance

The Supplier undertakes to send via e-mail to farmaco.vigilanciamx@novartis.com the "Notification of Contact Data" form indicated in **Annex G** duly completed.

The Supplier undertakes to carry out the activities described in the general pharmacovigilance clause indicated in **Annex A** of this Contract, when the service includes the activities described in the following concepts: Health-related services and goods. Data and analytics and emerging technology platforms and services. AI, ML and automation services. Creative agency services. Public relations; corporate communications. Medical communications. Media services fees. Media services. Direct marketing program. Reimbursement, co-payment and diagnostic programs. Health economics, access and pricing. Scientific literature and educational articles. Medical Education - Content. Business and Management Consulting. Translation Services. Intercompany operational services. Contracting for the realization of consulting projects, agencies (marketing or research), IT engineering or scientific consulting through a Statement of Work. Contract sales services (Field Force). Medical writing. Drug safety and epidemiology. Regulatory documentation and preparation. Services including media campaigns (TV, radio, print, web), call center, study material, brochures, facility support, management, patient outreach campaigns. Generation of evidence / retrospective studies. Scientific and/or Medical Consulting. Evidence generation/prospective studies, full/Multi CRO services (including or not including data purchase and data analysis) NIS/RWE/SUD/ Secondary data Scope of SOP703992. Multiplicity /NIS/IS/IS/Primary Data Scope of SOP7039924. Multi-full primary data/NIS - NOT in scope of SOP7039924. Multi-full NIS/RWE/SUD/Secondary data-NOT included in scopeSOP7039924. Cardiology and Respiratory Services. Clinical consulting, regulatory toxicology and pathology. Technical development. Academic collaborations and consulting.

The Supplier agrees to perform the activities described in the pharmacovigilance distribution clause indicated in **Annex B** when the contract includes the activities described in the following items: Distribution/Wholesale Services

The Supplier agrees to carry out the activities described in the Pharmacovigilance Digital Engagement Assets (DEA) clause indicated in **Annex C** when the contract includes a digital tool with the possibility of interaction and/or entry of safety information and whose activities are described in the following concepts: Creative Agency Services, Public Relations; corporate communication, Media Services Fees, Media Services Contracting, Direct Marketing Programs.

The Supplier agrees to perform the activities described in the Pharmacovigilance Patient Oriented Programs (POP) clause indicated in **Annex D** when the contract includes POPs activities described in the following items: Patient Support Program, Home Nursing Support Program, Reimbursement, Co-payment and Diagnostic Programs, Primary Market Studies, Secondary Market Studies, Promotional Services (In & Out store).

25 Jurisdiction and applicable law

In the event of any discrepancy regarding the interpretation, performance and enforceability of this Agreement and its respective Purchase Order, the Parties expressly submit to the applicable laws and the competent courts of Mexico City, expressly waiving any other jurisdiction that by reason of their present or future domicile may correspond to them.

ANNEX A

Whenever "third party" is mentioned, it should be understood that it refers to the "Supplier".

Adverse Event Reports / Device Incident / Special Scenario.

In accordance with the national regulations that govern topics of Pharmacovigilance and Technovigilance, Third Party have the duty to implement the necessary measures to comply with the current regulations in order to carry out the notification of any safety information from any medicine, vaccine or medical device.

If the Third Party is aware of an Adverse Event/Incident/Special Scenario on a patient consuming any Novartis product it is committed to reporting it to the Patient Safety Department within the following twenty-four (24) hours or the following business day of becoming aware of it, for Novartis to notify the National Centre of Pharmacovigilance (CNFV), or the Acknowledgement of receipt provided by the CNFV to the Third Party if it has made the notification directly. Third Party is committed to reporting all Adverse Events/Incidents/Special Scenarios regardless of the causation assessment of the Third Party or the person who reports it to Patient Safety of Novartis through of the following contacts:

- Email: farmaco.vigilanciamx@novartis.com
- Phone number: +52 55 8877 5390
- PVI: www.novartis.com/report
- Fax number: +52 55 5628 6787

For the purpose of this clause, an **Adverse Event** is any undesirable medical occurrence that may occur in a patient or clinical trial subject of research during the clinical investigation stage of a drug or vaccine but does not necessarily have a relationship causal with the treatment. An AE can therefore be any unfavorable or unintended sign (for example, an abnormal laboratory finding), symptom or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

A **Device Incident** is defined by the local regulation as any occurrence related with the use of a medical device.

In addition, all special scenario cases described below are also reportable to the Pharmacovigilance department even if they do not have a related Adverse Event / Device Incident:

Drugs

1. Exposure during pregnancy (via mother / father)
2. Exposure during breast-feeding
3. Off label use
4. Occupational Exposure / Accidental
5. Lack of efficacy
6. Technical Complaints (Events related to the quality of the drug / device)
7. Beneficial effects unexpected
8. Medication errors (eg. includes but are not limited to: incorrect route of administration, incorrect drug administration rate / inappropriate dose schedule (frequency) / wrong technique in drug usage process / wrong drug administered / accidental exposure / Administration of incorrect drug / prescribing and dispensing errors)
9. Interactions (other medicinal products, food, beverage, device)
10. Disease progression and aggravation
11. Overdose/Abuse
12. Intentional misuse
13. Withdrawal and Rebound symptoms
14. Addiction / Dependency drug
15. Transmission of infectious disease via medication
16. Treatment non-compliance with AE

Devices only

1. Intentional Misuse.
2. Theft
3. Falsification/Counterfiet

The data for a full report Adverse Event Reports / Device Incident / Special Scenario are:

- Patient
- Novartis Product
- Adverse Event / Device Incident / Special Scenario
- Reporter

However, if **at least** the following information is available, the report still being incomplete must be notified to Novartis

- Novartis Product
- Adverse Event / Device Incident / Special Scenario

Third Party is under commitment to provide Novartis with all appropriate health and/or personnel information necessary to record and report Adverse Events/Incidents and/or Special Scenario in accordance with laws and applicable regulations.

ANNEX B

Pharmacovigilance Obligations

1.1 Where any pharmacovigilance obligations are contained in the Main Business Agreement, in the event and to the extent of any inconsistency, the terms of this Exhibit or Clause will prevail in relation to pharmacovigilance matters.

1.2 The DISTRIBUTOR acknowledges that Novartis AG, as Marketing Authorization Holder (MAH) and Novartis Farmaceutica as the legal representative, for the products in the territory has certain pharmacovigilance obligations in order to meet applicable regulatory rules and guidelines worldwide.

1.3 Novartis may delegate all or parts of its pharmacovigilance obligations under this Exhibit or Clause to one or more Novartis Affiliates.

1.4 The obligations contained in this Exhibit or Clause will survive the termination or expiry of the Main Business Agreement and will continue in full force and effect until expiry date of the supplied product(s) in the Mexican territory.

1.5 The Parties agree to review this Exhibit or Clause at least at three (3) yearly intervals and/or earlier in response to a major revision to Applicable Standards or according to business needs.

1.6 The definitions of terms used in this Exhibit or Clause such as "Adverse Event" (or "AE"), "Adverse Drug Reaction" (or "ADR") and "Special Scenarios" as further explained in Section 1.7 below) are intended to be in accordance with applicable EU and worldwide regulations and guidelines (including without limitation Directive 2001/83/EC; ICH guidelines E2A and E2D) and local PV guidelines. Where local laws, regulations and/or guidelines in Mexico have a wider meaning for AE/ADR, these expressions shall be given the wider meaning for the purpose of this Exhibit or Clause.

1.7 The DISTRIBUTOR will forward all notifications that they receive relating to or in connection with the product(s) from Mexico concerning Adverse Events (AE) and/or special scenarios such as:

- laboratory findings outside the published reference range (without symptoms)
- drug-drug or drug-food interactions (with or without symptoms),
- kinetic interactions in which the only effect is a change in drug plasma concentrations,
- transmission of infectious disease via medication,
- lack of efficacy or lack of expected therapeutic effect (as defined in product label),
- pregnancy exposure (with or without outcome)
- drug use during lactation,
- treatment non- compliance where the patient did not take the medication as prescribed intentionally i.e., overdose, drug abuse and misuse (with or without symptoms), drug dependance/addiction
- medication errors (e.g., accidental exposure, occupational exposure, dispensing/prescribing errors, or drug maladministration (with or without symptoms),
- disease aggravation and disease progression (with or without symptoms),
- withdrawal reaction/syndrome and rebound effect
- unexpected beneficial effect (i.e., beneficial effect that is not related to the indication for which the product was given)
- off-label use (including off label use in paediatrics and including with or without AE).

(together "PV Reports") to Novartis as source documents within twenty-four (24) hours or at the latest by the next Business Day (BD) following the date of the DISTRIBUTOR's receipt. This shall include AEs and/or special scenarios reported with technical complaints.

1.8 PV Reports will be sent in accordance with the table below (refer Section 1.9) via online AE reporting tool, e-mail (with appropriate confidentiality classification and protection applied), or by fax as contingency. Date of the first receipt by the original recipient of any PV Report must be recorded on each report sent. PV Report receipt will be confirmed by Novartis within two (2) Business Days. In the absence of confirmation, DISTRIBUTOR will resend the PV Report until receipt is confirmed.

1.9 All reporting in accordance with this Exhibit or Clause shall be made by the DISTRIBUTOR (or its personnel) to the below Novartis contact person or contact point.

The DISTRIBUTOR shall nominate a primary and secondary PV contact person and notify these details to Novartis. Each Party may change its contact information by notifying the other Party in writing of such change becoming effective. These changes do not require any formal update of this PVA, Exhibit or Clause.

Contact details	NOVARTIS	DISTRIBUTOR
PV Reports exchange	E-mail: farmaco.vigilanciamx@novartis.com Online AE reporting tool: www.novartis.com/report Tel.: 55 8877 5390	Contact provided in accordance with clause 24 of the Contract.
Primary PV contact	Name: **Ana Karen Avila Alvarado** Title: Country Patient Safety Head Address: Av. Insurgentes Sur #2475, Tizapan San Angel, Barrio Loreto Alcaldía Álvaro Obregón, C.P. 01090 Ciudad de México T: 55 8877 4802	Contact provided in accordance with clause 24 of the Contract.

	M: 55 5418 9165 Email: ana.avila_alvarado@novartis.com	
Secondary PV Contact	Name: **Karla Iliana Martínez** Title: Patient Safety Group Manager Address: Av. Insurgentes Sur #2475, Tizapan San Angel, Barrio Loreto Alcaldía Álvaro Obregón, C.P. 01090 Ciudad de México T: 55 8877 4807 M: 55 4345 6854 Email: karla_iliana.martinez@novartis.com	Contact provided in accordance with clause 24 of the Contract.
Reconciliation and general PV inquiries	farmaco.vigilanciamx@novartis.com	Contact provided in accordance with clause 24 of the Contract.

1.10 Novartis shall provide quarterly a list of all exchanged PV Reports to DISTRIBUTOR for reconciliation. In the event that no reports were received in a particular period, a notification will be sent to the other Party indicating zero (0) reports were received for that period. In the situation where the DISTRIBUTOR has not received any PV Reports in the past twelve (12) months for legitimate reasons, the reconciliation frequency may be changed from quarterly to yearly for as long as the DISTRIBUTOR receives no further PV Reports. Thereafter, should DISTRIBUTOR receive a PV Report, the frequency will return to quarterly. The DISTRIBUTOR will provide any PV Reports notified by Novartis as missing within one (1) business day of the request.

1.11 Follow-up of PV Reports shall be performed by Novartis. In case the reporter did not agree to his contact information being revealed to Novartis the DISTRIBUTOR shall directly contact the reporter for obtaining relevant follow-up information (including but not limited to targeted follow up questionnaires from RMP and non-RMP commitments) as indicated by Novartis.

1.12 Technical complaints without any AEs and/or special scenarios pertaining to product quality issues only, are ruled by the Main Business Agreement and/or Quality Agreement between the Parties.

1.13 Novartis as the MAH is responsible for the implementation of the primary Risk Management Plan (RMP) in the territory.

1.14 Patient Oriented Programs have a probability of generating PV Reports (for example in market research, Patient Support Programs, Health Care Professional (HCP)/nurse education programs, HCP injections support programs, customer call center with sub-service providers or compliance reminder services (sms-reminder, customer call). The DISTRIBUTOR shall not initiate or facilitate any Patient Oriented Programs relating to the Products without the prior written consent of Novartis, which may be withheld at complete discretion. The DISTRIBUTOR must confirm in writing prior to program start that Novartis quality standards are established and during the conduct of the program adequate PV monitoring activities will be implemented.

1.15 Digital Engagement (DE) Activities, such as but not limited to, external facing Digital Engagement Assets (DEAs) engaging with an audience (e.g., patients, Health Care Professionals etc.) for business purposes and Social Media Listening (SML) activities have the probability of generating PV reports (e.g., websites with commenting functionalities, chat bots, free-text-fields etc.). The DISTRIBUTOR shall not initiate or facilitate any DE Activity relating to the Products without the prior written consent of Novartis, which maybe be withheld at Novartis complete discretion. The DISTRIBUTOR must confirm in writing prior to DE activity start that Novartis quality standards are established and that during the conduct of the DE activity adequate PV monitoring activities will be implemented.

1.16 Novartis as the MAH of the product(s) in Mexico shall be responsible for all other pharmacovigilance obligations of the MAH, including communication with the Health Authority. These obligations include submission of all domestic Individual Case Safety Reports (ICSR) to Local Health Authority, monitoring the overall safety of the Product, communicating safety concerns, and taking appropriate measures for patient safety. The DISTRIBUTOR will provide Novartis with any reasonable assistance Novartis might require.

1.17 Each Party shall collect, use, and disclose personal data which may be included in the PV Reports governed by this Agreement in compliance with all applicable laws, including those relating to privacy and data protection. Each Party shall be responsible for complying with all the necessary transparency and lawfulness requirements under applicable data protection laws and shall implement all reasonable physical, technical, and administrative safeguards to protect personal data from loss, misuse, and unauthorised access, disclosure, alteration, or destruction. Each Party shall provide the other Party with commercially reasonable assistance in complying with all applicable requirements of the applicable data protection laws relating to the shared personal data.

1.18 PV information (including but not limited to source documents) shall be kept by the DISTRIBUTOR for at least 10 years after the exhibit or clause expires or for a period required by applicable laws and regulations, whichever is longer.

1.19 The DISTRIBUTOR must ensure all its employees providing the activities described in this exhibit or clause are trained in PV Reporting and PV Reports exchange procedures prior to commencing any activities in relation to this exhibit or clause. Training must be given according to the most recent version of the Novartis Patient Safety Adverse Event Reporting training materials, which will be provided by Novartis to the DISTRIBUTOR on an annual basis. Annual refresher training should be performed for the duration of the agreement. The DISTRIBUTOR agrees to provide documentation of completion of training to Novartis within mutually agreed timelines.

1.20 The DISTRIBUTOR agrees to promptly communicate any non-compliance with the requirements in this exhibit or clause to Novartis and commits to correct the issues in collaboration with Novartis within mutually agreed timelines.

1.21 Novartis shall have the right to audit the DISTRIBUTOR in respect to the obligations of the DISTRIBUTOR under this exhibit or clause upon reasonable advance notice. Findings/observations from such audit will have to be addressed by a CAPA plan. The Parties will collaborate in case of a regulatory inspection.

1.22 The Parties agree that in case a separate Pharmacovigilance Agreement will be signed at any time, such validly executed Pharmacovigilance Agreement will prevail over this exhibit or clause.

GLOSSARY

"Adverse Drug Reaction" (ADR) means a response to a medicinal product which is noxious and unintended. Response in this context means that a causal relationship between a medicinal product and an Adverse Event is at least a reasonable possibility. Adverse reactions may arise from use of the product within or outside of the terms of the marketing authorisation or from occupational exposure. Conditions of use outside the marketing authorisation include overdose, misuse, abuse and medication errors.

"Adverse Event" (AE) means any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and that does not necessarily have a causal relationship with this treatment. An adverse event can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether related to the medicinal (investigational) product.
"Applicable Standards" means any of the following to the extent the applicable person is subject thereto: (a) supra-national, federal, national, state, municipal or local statute, law, ordinance, directive, regulation, rule, code, Order, guidelines or other requirement or rule of law or legal process (including common law); (b) any rule or requirement of any national securities exchange, or (c) any rule or requirement of a Regulatory Authority or agency responsible for the grant of approval, clearance, qualification, licensing or permitting of any aspect of research, development, manufacture, or commercialisation of the Products, including without limitation the following: ICH E2A and ICH E2C Guidelines, US 21 CFR, Directive 2010/84/EU, Regulation (EU) No 1235/2010, Commission Implementing Regulation No 520/2012 of 19 June 2012 (further described in EU GVP), CT Regulation (EU) No 536/2014, etc.
"Territory" shall mean the country/countries where the product(s) are intended to be sold to the end users under a marketing authorization, as such country/countries are specified in the MBA.
"**NOVARTIS AFFILIATE**" shall mean any company within the Novartis group, the ultimate owner or controller of which is Novartis AG, a company incorporated in accordance with Swiss laws, with its registered offices at Lichtstrasse 35, 4056 Basel, Switzerland.
"External facing Digital Engagement Assets" shall mean Digital Engagement Assets (DEA) deployed or accessible outside of the DISTRIBUTOR network (e.g. outside the DISTRIBUTOR Intranet, not on the DISTRIBUTOR internal app store etc.).
"Social Media Listening programs" shall mean the involvement, gathering and analyzing of user generated content from non-DISTRIBUTOR owned DEAs (such as social media communities, forums, blogs etc.) with the support of a specialized Social Media Listening (SML) tool or program for business purposes as well as listening performed manually or with the support of a specialized SML tool or program in closed or secret groups.

"Special Scenarios" shall mean:

- laboratory findings outside the published reference range (without symptoms)
- drug-drug or drug-food interactions (with or without symptoms),
- kinetic interactions in which the only effect is a change in drug plasma concentrations,
- transmission of infectious disease via medication,
- lack of efficacy or lack of expected therapeutic effect (as defined in product label),
- pregnancy exposure (with or without outcome)
- drug use during lactation,
- treatment non- compliance where the patient did not take the medication as prescribed intentionally i.e., overdose, drug abuse and misuse (with or without symptoms), drug dependance/addiction.
- medication errors (e.g., accidental exposure, occupational exposure, dispensing/prescribing errors, or drug maladministration (with or without symptoms),
- disease aggravation and disease progression (with or without symptoms),
- withdrawal reaction/syndrome and rebound effect.
- unexpected beneficial effect (i.e., beneficial effect that is not related to the indication for which the product was given)
- off-label use (including off label use in paediatrics and including with or without AE)

"Patient Oriented Programs" (POPs) means the Novartis umbrella term covering Novartis programs to support patient care, market research or to gain insights from patients/HCPs. These programs involve a Novartis product or disease area of interest, where Novartis or 3rd party on behalf of Novartis is interacting with program participants e.g., patients, caregivers, Healthcare Professional (HCP) or payers. This umbrella term excludes Novartis sponsored clinical studies/trials. Support patient care is defined within Novartis as: providing additional education; training on the use of the product to patient or HCP; providing supplemental care to the patient or arranging for financial assistance for patients. It may typically be described as patient support programs (PSPs) and patient access/assistance programs (PAPs), using different local terminologies.

"Technical Complaint" (also known as "Quality Complaint") means any verbal, written or electronic expression (including those coming through social media platforms) of dissatisfaction with a medicinal product after it is released for local commercialization, distribution or use in the Territory, including for Clinical Investigations, in relation to its identity, quality, stability, durability, usability, reliability, safety, effectiveness, or performance. The report could be made by a patient, pharmacist, health professional or any third party performing further operations on the product. This may include:

a) any quality defect and/or effectiveness (including lack of efficacy),
b) any defect related to containers and outer packages,
c) any defect related to labeling and package insert,
d) any counterfeit, falsified or tampering incidents,
e) any bacteriological contamination or significant chemical, physical or other change or deterioration in the medical product.

"Marketing Authorisation Holder" (MAH) means the Party named on the Marketing Authorisation for a specific product in a particular country.

ANNEX C

Social Media Listening program and Digital Engagement Asset standard vigilance contractual provisions

Whenever "ESP" is mentioned, it should be understood that it refers to the "Supplier".

1. Purpose

The purpose of the provisions set out below is to define Pharmacovigilance (PV) contractual requirements which External Service Providers (**ESPs**) planning to complete of any vigilance activities for SML program and/or DEA must comply with. These provisions are otherwise referred to as the "SML program and DEA Vigilance Contract Provisions" and form an integral part of the Agreement. Unless prohibited by applicable laws or GxPs, reference to "written" or "in writing" in these SML program and DEA Vigilance Contract Provisions includes (without limitation) a reference to email communications.

2. Scope

These SML program and DEA Vigilance Contract Provisions apply to digital initiatives as defined below when involving an ESP in the conduct of the vigilance activities:

- Social Media Listening (SML) programs and
- External facing Digital Engagement Assets (DEAs) where Novartis is engaging with an audience (e.g., patients, Health Care Professional etc.) for business purposes including distribution platforms for mobile applications and DEAs part of a Patient Oriented Program (POP) Group 3 as follows:
    - Novartis owned DEAs allowing users to comment both publicly and privately via the DEA engagement functionalities, including distribution platforms for mobile applications and when these DEAs are part of POP Group 3. These are also referred to as "Novartis owned DEAs with both publicly available and private/direct user engagement functionalities".
    - Novartis owned DEAs allowing users to comment only publicly via the DEA engagement functionalities including distribution platforms for mobile applications and when these DEAs are part of POP Group 3. These are also referred to as "Novartis owned DEAs with only publicly available user engagement functionalities".
    - Novartis owned DEAs allowing users to comment only privately via the DEA engagement functionalities including when these DEAs are part of POP Group 3. These are also referred to as "Novartis owned DEAs with only private/direct user engagement functionalities".
    - Third-Party owned DEAs allowing users to comment at least publicly via the DEA engagement functionalities including when these DEAs are part of POP Group 3. These are also referred to as "Third-Party owned DEAs with at least publicly available user engagement functionalities".

3. Definition of Social Media Listening programs

Social Media Listening is the process of identifying, gathering, and assessing what is being said about an industry, company, individuals, products or brands on the Internet leveraging legally or publicly available data sources. Social Media Listening can be performed manually or with the support of a specialized SML tool. Listening performed manually or with the support of a specialized SML tool in closed or secret social media groups/communities must always be registered.

Examples of SML programs include:

- Analyzing user-generated content on social media accounts such as "X" formerly known as Twitter to determine sentiment
- Conducting keyword-based queries by aggregating and analyzing all conversations related to a particular topic (e.g., around a particular disease area)
- Listening to and analyzing conversations between specific stakeholder groups (e.g., Healthcare Professionals) to optimize current communication and marketing strategies.

4. Definition of Digital Engagement Assets

- **Digital Engagement Asset**: it is a digital means of enabling interactions with audiences – providing at least one of the following functionalities:
    - posting of content or sharing content by Novartis/ESP/Third party
    - possibility of receiving user generated content
    - receiving private message from users

  Examples of DEAs: websites, social media pages/groups, discussion forms such as blogs / forums, collaboration platforms, applications (apps) including mobile apps, Instant Messaging (IM), Short Messaging System (SMS), augmented reality apps, virtual reality apps, skills (Alexa) etc.
- **Third-Party owned DEA**: It is a DEA that is owned by a Third-Party (e.g., clinical research organization, patient organization, healthcare citizen journalist, blogger, celebrity, influencer, hospital sites) **and** where:

- Novartis either has ownership, control, or influence on the content (i.e., has editorial, preview, or review privilege), **and** has a contract/agreement with the Third-Party about the use and publication of the content in place **OR**
- Novartis engages a Third-Party to act on behalf of Novartis in a digital engagement (without any control or influence on content), **and** has a contract/agreement with the Third-Party about the scope of digital engagement activities in place

- **Novartis owned DEA:** DEA created or managed by Novartis or on behalf of Novartis. Accountability for such asset lies with Novartis. DEA that is created or managed by an ESP on behalf of Novartis also fall under this category.

  This also includes:

  - Executive Committee of Novartis and Board of Directors members who use their personal DEAs to speak on behalf of the company,
  - DEAs belonging to a Novartis associate (e.g., CPO Heads, Function Heads) which are managed by Novartis or ESP teams.

5. Adverse Events

Adverse Event (AE) is any untoward medical occurrence in a patient or clinical-trial subject administered a medicinal product and which does not necessarily have to have a causal relationship with this treatment. An AE can therefore be any unfavourable and unintended sign (e.g., an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

In addition, all special scenarios and other reportable situations, including but not limited to technical complaints, medical device incidents, as described in the applicable Novartis global, and where relevant local, SML program or DEA AE training, must be notified to appropriate Novartis Department (e.g., Patient Safety, Quality Assurance etc.).

For the purpose of the SML program and DEA Vigilance Contract Provisions, adverse events, special scenarios and other reportable situations are collectively referred as "AEs" in this agreement.

6. Transfer of Safety Information

Any and all safety information meeting the minimum 2 Safety Data Elements (SDE) of an AE associated with the use/mention of a Novartis product (i.e., human medicinal product and/or medical device; including generic or brand name), regardless of causality or seriousness assessment, product labelling/or reporter type identified by the ESP during monitoring* of an SML program/DEA must be transferred by the ESP to the appropriate Novartis Department (e.g. Patient Safety, Quality Assurance etc.) within maximum twenty-four (24) hours[1] of

- Identification for SML programs,
- Posting for Novartis owned and Third-party owned DEAs with at least publicly available user engagement functionalities
- Review for Novartis owned DEAs with only private/direct user engagement functionalities which cannot be turned off/disabled for the whole time the DEA is live
- Monitoring for distribution platforms of Novartis owned DEAs with at least publicly available user engagement functionalities.

External Service Provider is required to follow monitoring requirements as detailed in the applicable Novartis global, and where relevant local, SML program or DEA AE training. External Service Provider is required to reference or cross-check the relevant Novartis product list (e.g., integrated product list and medical device list etc.) to identify relevant Novartis products (i.e., human medicinal product and/or medical device; including generic or brand name) to assist its monitoring and transfer obligations.

External Service Provider will notify Novartis by either using Novartis online AE reporting tool or e-mail/fax using a Novartis Adverse Event Report Form (as further set forth in in the applicable Novartis global, and where relevant local, SML program or DEA AE Training) to transfer the safety information to appropriate Novartis Department (e.g., Patient Safety, Quality Assurance etc.). Each report will include information that it is originating from a Novartis SML program/DEA (including specifying the SML program/DEA name and ID).

External Service Provider shall provide Novartis with any and all appropriate personal health information necessary for Novartis to record and report safety information in accordance with applicable law and regulations

[1]Where permissible by local law, if any safety information meeting the minimum 2 SDE is received during weekends, national holidays or outside of Friday business hours and office is closed on Saturday and Sunday, it is sufficient if the safety information is transferred latest by the next business day.

7 Novartis SML program and DEA AE Trainings

Novartis global, and where relevant local, SML program or DEA AE training must be completed by the External Service Provider and its Personnel (including new workers) directly involved in the monitoring of SML program/DEA, prior to initiation of the SML program/DEA, as annual refresher for ongoing SML programs/DEAs, whenever the training material is updated and prior to its effective date, using a language the ESP and its Personnel can understand and via an e-learning platform provided by Global Novartis PS. External Service Provider shall work with Novartis to ensure that the training is completed in a timely manner.

The AE training must be completed as follows:

- For Global and Multiple countries SML programs and DEAs: The Global AE training for SML program/DEA must be completed.

- For Local SML programs and DEAs: Whenever available the Local SML program/DEA AE training, must be completed. If a Local training is not available the Global AE training for SML program/DEA must be completed.

External Service Provider hereby confirms that it has received prior to entering into the SML program/DEA specific contract with Novartis a copy of in the applicable Novartis global, and where relevant local, SML program or DEA AE Training materials and acknowledges and agrees that the content (including any requirements and obligations applicable to the External Service Provider contained therein) and any updates to the same communicated by Novartis in writing during the term of the Agreement shall form an integral part of the Agreement.

At the request of Novartis in the event of any SML program/DEA training materials update External Service Provider and its Personnel must complete the training on the updated version in accordance with any completion timelines specified by Novartis.

External Service Provider must document the training and archive training records of all involved Personnel. All training materials and documentation must be made available to Novartis upon request.

Where permitted by law and subject to the terms of the Agreement regarding subcontracting, should External Service Provider subcontract any of the Services relating to the SML program/DEA, the same obligations regarding Novartis SML program/DEA AE Training as defined in this Section 7 have to be followed. It is the responsibility of External Service Provider to provide Novartis global, and where relevant local, SML program or DEA AE training to its subcontractors. Only an External Service Provider Personnel trained on the training material shall provide such training and must use the same training material he/she was trained on. Training documentation must be archived, and training material and training documentation must be made available to Novartis upon request.

It is the responsibility of External Service Provider to ensure subcontractor's compliance with the SML programs and DEAs Vigilance Contract Provisions.

8. SML programs and DEA important dates and information

External Service Provider must provide SML program/DEA owner and Novartis Patient Safety with the following dates within maximum 2 working days (i.e., excluding weekends) of occurrence: SML program/DEA actual start and closure dates and SML program/DEA monitoring start and end dates. Definitions of these dates are provided in table below.

Upon **Third-Party owned** DEA actual closure date, External Service Provider must provide Novartis Patient Safety with monitoring documentation using the monitoring form.

Definition	**SML program**	**Novartis owned DEA**	**Third-Party owned DEA**
Date of actual launch and start of monitoring	Date when first listening activities are initiated by the Novartis/ESP team	First date that the DEA is accessible/visible to the public	Date of posting of first Novartis content on the Third Party owned DEA
Date of actual closure and end of monitoring	Date when Novartis/ESP team performing the listening no longer analyzes/access the posts/data	First date the Novartis owned DEA is no longer accessible/visible to the public	Date when last Novartis content has been monitored (i.e., for 60 days after posting or until commenting is not possible anymore whichever occurs first)

9. Source Data

Vigilance source documents/data (or sometimes referred as source records/source data) refers to the raw and original data shared by users for DEAs (e.g., websites, social media channels etc.), and to the raw and original data collected from various social media platforms and online sources for SML programs. For SML programs source data is obtained through monitoring and analyzing conversations, mentions, posts, and interactions related to specific keywords, topics, brands, products, or events on social media channels (here referenced as "Source Documents/Data").

Examples of source documents/data for DEAs include but are not limited to: data entered by users on contact forms/surveys for websites, post interactions (e.g., data on likes, shares, comments, and other engagements with social media posts), messages and chat logs (e.g., conversations with users that took place through direct messages or chat features) for Social Media channels.

Examples of source documents/data for SML programs include but are not limited to: (a) social media posts (e.g., public posts made on platforms such as Facebook, Instagram, LinkedIn, YouTube, Reddit, and others) including text, images, videos, and other media shared by users, (b) **mentions and hashtags** (e.g., mentions of specific keywords, brand names, product names, and hashtags relevant to the topic of interest), (c) comments and replies (e.g., conversations in the form of comments and replies to posts on social media etc.).

In addition, in all cases, the outputs generated from any system (e.g., PVI tool; this is an online tool to report safety information meeting the minimum 2 SDE electronically to Novartis Patient Safety) used as first point of data collection/transfer will be considered as Source Document/Data too.

10. Source Data Verification – Applicable to DEAs only

Source Data Verification (SDV) is a review of a sample of the Source Documents/Data available on the DEAs subjected to SDV which is completed for each External Service Provider involved in DEA vigilance activities to determine if the External Service Provider conducting the monitoring of the DEAs, has properly identified and transferred to Novartis **all and any** safety information meeting the minimum 2 SDE of an AE associated with the use/mention of a Novartis product (i.e., human medicinal product and/or medical device; including generic or brand name). Source data verification is completed on a quarterly basis with 1st calendar quarter starting on 01st February of the year.

External Service Provider must provide Source Data **within maximum six (6) weeks** of the last day of the SDV quarter as set forth in the Novartis AE training for DEAs. Source data verification is not applicable to DEA distribution platforms. External Service Provider should document the results of these activities and make them available for Novartis review upon request. If Novartis assessed SDV as failed, Novartis may in its sole discretion request support from ESP to complete Corrective Action and Preventive Action (CAPA) plan. External Service Provider will be responsible for ensuring CAPA is completed as per timelines communication by Novartis and all associated costs and expenses incurred in carrying out such actions will be the responsibility of ESP.

Novartis will have the right to review Source Documents/Data records for the purpose of determining External Service Provider's compliance and accuracy in safety information monitoring and transfer.

In the case of any identified non-compliance/actions linked to audit observations/inspection findings or deviations related transfer of safety information, at the request of Novartis, External Service Provider hereby agrees to fully cooperate and assist Novartis in performing SDV on an ad-hoc basis.

Without prejudice to Novartis' audit rights, Novartis will have during the term of the Agreement and until expiry of any applicable archiving/retention period the right to access/inspect the Source Documents/Data (including the right of entry to relevant External Service Provider's (or their subcontractor/supplier) premises to the extent necessary to exercise such right) in order to ensure Novartis can comply with all regulatory and internal requirements relating to vigilance. In the case of any such access/inspection (including without limitation as part of SDV), the External Service Provider will follow a principle of data minimization where required by local law or this Agreement, including through anonymization/redaction of relevant Source Documents/Data to hide/obscure any personally identifiable information.

11. Corrective Action and Preventive Action, Audit, and Inspection

In case of non-compliance with the requirements of the SML program and DEA Vigilance Contract Provisions, External Service Provider commits to promptly communicate these deviations to Novartis, discuss corrective and preventive actions to be taken with Novartis and correct the issues within the relevant mutually agreed timelines (the Parties acting reasonably and in good faith). External Service Provider must document, track and close/complete any CAPA put in place internally including without limitation those put in place following input from Novartis. External Service Provider must notify Novartis of progress on open CAPA completion on a periodic basis and when completed, or as requested by Novartis.

In respect of each SML program/DEA, for the term of the relevant Agreement relating to the specific SML program/DEA and **for two (2) years following expiration or termination of the same**, Novartis, or its designated third party auditor, will have the right, to audit (whether on-site or paper based) External Service Provider's (or its agents or subcontractors) processes, procedures and training, including records, data, documentation, Source Documents/Data with respect to safety information meeting the minimum 2 SDE. External Service Provider commits to correcting issues from audit observations within the mutually agreed timelines (the Parties acting reasonably and in good faith) and promptly communicating the actions to Novartis. The Parties agree that where the Agreement contains more extensive audit and remediation rights than the audit/remediation rights set out above, the more extensive audit/remediation rights set out in the Agreement will equally apply here, subject to observing the minimum requirements set out above in terms of the duration and scope of any audit/remediation right in the context of the SML program and DEA Vigilance Contract Provisions.

In the event of Novartis legal matters, including civil litigation and governmental investigations, or any governmental inspection or audit, External Service Provider hereby agrees that it will fully cooperate as requested. In addition, the External Service Provider hereby agrees to allow domestic and international health authorities to inspect their vigilance operations as necessary for Novartis to maintain registration in the countries where the Novartis product is marketed.

12. **Archiving** External Service Provider must also create and archive documents/records such as transferred safety information and forms sent to Novartis during the provision of the Services, as well as internal standard operating procedures (SOPs) for its safety information transfer procedures and any SML program/DEA related document including but not limited to Source Documents/Data and maintain them, where permitted by local law, **for a minimum period of five (5) years**, or if a longer period is required by local law, for such longer period (in each case, measured from SML program/DEA closure). Such documents/records will be subject to audit. For the purposes of this paragraph, reference to local law in the case of jurisdictions with federal and state laws, refers to the prevailing/controlling local law (be it federal or state), and where both federal and state laws have equal application, the stricter retention standard will be applied where permitted by such local laws.

After the end of any applicable archiving/retention period, as regards the destruction of documents/records containing personal data/information which are subject to a data processing agreement (or equivalent) between the Parties (including as part of the Agreement), the provisions of the relevant data processing agreement will apply.

The archiving and retention requirements under the SML program and DEA Vigilance Contract Provisions may be more extensive than those set out in the Agreement. In case of any conflict between the provisions of the Agreement and the SML program and DEA Vigilance Contract Provisions, to the extent permitted by law, the requirements of the SML program and DEA Vigilance Contract Provisions (if stricter) will apply.

13. Amendments and Organizational Changes

Novartis reserves the right to amend the SML program and DEA Vigilance Contract Provisions at any time if a requirement is imposed upon by an authority or, in its sole clinical discretion, such amendment is necessary for patient safety. Upon written notice from Novartis of any such amendment, External Service Provider will comply immediately (or such other time period specified by Novartis) and any failure to comply will be deemed as a [material] breach of the Agreement.

In the event of any changes relating to External Service Provider including, but not limited to: organization name change, service capabilities or operations, the External Service Provider must without undue delay inform Novartis in writing about such changes.

14. Contacts

The ESP shall nominate an Account Manager and share its contact details (name, address, phone, email) with Novartis, where not provided below, promptly following signature of the Agreement.

The initial Account Manager details for the ESP are as follows: (complete annex G "**Notification of Contact Data"** of this document)

The Account Manager shall have:

- Oversight of all Novartis SML programs/DEAs and
- Be the main contact for any questions related to the SML programs/DEAs

Novartis local contact for reporting purposes] The initial Novartis local contact for reporting purposes is as follows: through the following website www.novartis.com/report or at farmaco.vigilanciamx@novartis.com

ANNEX D

Whenever "External Service Provider and/or Health Care Professionals " is mentioned, it should be understood that it refers to the "Supplier".

Patient Oriented Program standard vigilance contractual provisions for POP Group 1 and POP Group 2

1. Purpose

The purpose of the provisions set out below is to define Pharmacovigilance (PV) and Medical Device Vigilance (MDV) contractual requirements (for ease of reference together referred to as "Vigilance" requirements) which External Service Providers (**ESPs**) and/or Health Care Professionals (**HCPs**) in connection with the planning and execution of Patient Oriented Program (**POP**) are required to comply with. These provisions are otherwise referred to as the "**POP Vigilance Contract Provisions**" and form an integral part of the Agreement. Unless prohibited by applicable laws or GxPs, reference to "written" or "in writing" in these POP Vigilance Contract Provisions includes (without limitation) a reference to email communications.

2. Scope

These POP Vigilance Contract Provisions apply to all Group 1 and Group 2 Patient Oriented Programs (as defined below) conducted by ESPs or HCPs for and/or on behalf of Novartis.

Definition of POP

POP is a Novartis umbrella term for non-promotional Novartis programs which meet **all** the following criteria:

1. Involve a Novartis approved product **or** disease area of interest.
2. Novartis **or** a third-party on behalf of Novartis is interacting with programs participants, such as patients, caregivers, healthcare professionals (HCPs) and payers.
3. Program to either support patient care, conduct primary market research or gain insights categorized respectively as:

- **Patient Support Program (PSP)** refers to programs created to educate a patient or caregiver about disease, medication, administration and / or to support access, diagnosis, usage, adherence to medicinal products, and improve the overall patient healthcare outcome. These holistic models may include services that touch on patient activation, financial assistance, non-financial assistance, and/or adherence.
- **Primary Market Research (PMR)** refers to activities involving systematic original data generation, collection, and analysis following a formal design and methodology e.g., sample size, honorarium. It is carried out to meet a defined business need and rationale, documented in a formal report.
- **Insights Collection** refers to activities involving original data generation and collection that do not follow a formal design and methodology typical of PMR activities e.g., Novartis survey distributed to HCPs.

POP excludes Novartis sponsored clinical studies / trials, managed access programs (MAPs) and routine external interactions (unless the interaction involves organized data collections including surveys of patients or healthcare professionals, or information gathering on efficacy or patient compliance).

Routine external interactions, between Novartis employees and external people (e.g., as part of Ad-Board, Medical Scientific Liaison (MSL), Sales Force interactions and/or Patient Engagement interactions with patients) refer to regular communication or engagement that occurs as part of normal business operations or daily activities. It typically involves standard procedures, established protocols, or recurring interactions that are expected and do not deviate significantly from the usual course of business.

All the above programs are classified by Novartis as set out in the table below (all unique attributes must be met for the group to apply).

Table 1: POP Classification

	Group 1	Group 2	Group 3
Unique Attributes	○ Main purpose is to support patient care. ○ Program involves Novartis approved product(s). ○ Information received and/or collected on the use of a Novartis approved product on efficacy/safety/tolerability	○ Main purpose is for market research or to gain insights from patients/HCPs. ○ Program contains questions related to Novartis approved product(s). ○ Information requested and primary data collected on the use of a Novartis approved product on efficacy/safety/tolerability	○ Any POP programs that do not fit into Group 1 or Group 2.

For each POP, Novartis will confirm with [External Service Provider/Health Care Professional] before the start of the relevant POP, whether the POP is a Group 1 or 2; this can be confirmed in the Agreement, the Statement of Work or otherwise communicated by Novartis in writing to the [External Service Provider/Health Care Professional].

3. Adverse Events

Adverse Event (AE) is any untoward medical occurrence in a patient or clinical-trial subject administered a medicinal product and which does not necessarily have to have a causal relationship with this treatment. An adverse event can therefore be any unfavourable and unintended sign (e.g. an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

In addition, all special scenarios and other reportable situations, including but not limited to technical complaints, medical device incidents, as described in the Novartis POP AE training, must be notified to Novartis Patient Safety function.

For the purpose of the POP Vigilance Contract Provisions, adverse events, special scenarios and other reportable situations are collectively referred as "AEs" in this agreement.

4. Adverse Event Reporting

Any and all AEs relating to the use of a Novartis product(s), regardless of causality or seriousness assessment, product labelling and/or reporter type, of which the [External Service Provider/Health Care Professional] is notified during a POP shall be transferred by [External Service Provider/Health Care Professional] to the Novartis Patient Safety function within twenty-four (24) hours[1] of notification and as further set forth in the Novartis POP AE Training.

[External Service Provider/Health Care Professional] is required to reference or cross-check the relevant Novartis product list, as provided by Novartis, to identify relevant Novartis products to assist its reporting obligations: This is not required for POPs where POP participants' or patients' therapy is a Novartis drug or associated with a specific Novartis therapy.

[External Service Provider/Health Care Professional] will notify Novartis by either using Novartis online AE reporting tool or e-mail / fax using a Novartis Adverse Event Report Form (as further specified in the Novartis POP AE Training) to report the event to Novartis Patient Safety function. Each report will include information that it is originated from a Novartis POP (including specifying the Program name and Program ID).

[External Service Provider/Health Care Professional] shall provide Novartis Patient Safety function with any and all appropriate personal health information necessary for Novartis to record and report AEs in accordance with applicable law and regulations.

5. Novartis POP AE Training[2]

Novartis POP AE training must be completed by the [External Service Provider/Health Care Professional] and its Personnel (including new workers) directly involved in the POP, prior to starting any fieldwork or contacting with the participant; then refresher training on annual basis must be completed. In relation to adverse event identification and reporting, Novartis shall provide AE training either via a virtual meeting or via a e-learning platform to [External Service Provider/Health Care Professional] Personnel identified as being directly involved in the POP. [External Service Provider/Health Care Professional] shall work with Novartis to ensure that the training is conducted in a timely manner. After receiving Novartis AE training in a train-the-trainer session (and not via e-learning platform), the trained Personnel of the [External Service Provider/Health Care Professional] may provide training (including the initial training and the annual refresher training) to its Personnel.

[External Service Provider/Health Care Professional] hereby confirms that it has received prior to entering into the POP specific contract with Novartis a copy of the applicable Novartis POP AE Training materials (**POP Training Materials**) and acknowledges and agrees that the content of the POP Training Materials (including any requirements and obligations applicable to the [External Service Provider/Health Care Professional] contained therein) and any updates to the same communicated by Novartis in writing during the term of the Agreement shall form an integral part of the Agreement.

At the request of Novartis in the event of any POP Training Materials update, [External Service Provider/Health Care Professional] and its Personnel must complete training on the updated version in accordance with any completion timelines specified by Novartis.

[External Service Provider/Health Care Professional] must document the training and archive training records of all involved Personnel. All training material and documentation must be made available to Novartis upon request.

Before the First Participant First Contact (**FPFC**) date for any new POP, [External Service Provider/Health Care Professional] must send to Novartis a written AE training attestation (Novartis reserves the right to specify the format of such attestation) that all [External Service Provider/Health Care Professional] Personnel identified by the [External Service Provider/Health Care Professional] as being involved in the provision of the POP, have been trained on Novartis AE reporting as required under the POP Vigilance Contract Provisions.

Where permitted by law and subject to the terms of the Agreement regarding subcontracting, should [External Service Provider/Health Care Professional] subcontract any of the Services relating to the POP, the same obligations regarding Novartis POP AE Training as defined in the paragraph above, must be followed. It is the responsibility of [External Service Provider/Health Care Professional] to provide Novartis POP AE training to its subcontractors. Only a(n) [External Service Provider/Health Care Professional] Personnel trained on the training material (as per the train-the-trainer process outlined above) shall provide such training and must use the same training material he/she was trained on. Training documentation must be archived, and training material and training documentation must be made available to Novartis upon request.

It is the responsibility of [External Service Provider/Health Care Professional] to ensure subcontractor´s compliance with the POP Vigilance Contract Provisions.

6. Supplier Quality Assessment and Commencement of Services

[External Service Provider] hereby acknowledges and agrees that all information and responses provided to Novartis as part of the Supplier Quality Assessment (SQA) process shall be considered as an integral part of the Agreement, and that such information and responses provided are complete and accurate. Novartis will have the right during the term of the Agreement to require the reperformance of the SQA and/or for the [External Service Provider/Health Care Professional] to provide updates to the SQA and [External Service Provider/Health Care Professional] will co-operate fully in the reperformance of the SQA and providing updates requested by Novartis.

Furthermore, [External Service Provider] will pro-actively inform Novartis in writing of any change in operations relating to the POP relevant services that could have an impact on any existing Novartis qualification and, following such notification, a risk assessment or re-qualification of the [External Service Provider] as a POP service provider will be required. [External Service Provider] will reasonably co-operate (at its own expense) with Novartis in respect of any (re)qualification.

[External Service Provider] hereby acknowledges and agrees that it is not permitted to start the Services in connection with any specific POP unless and until it has received written confirmation from Novartis that it has been successfully qualified (from a Novartis internal perspective) to perform the Services relating to POPs.

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[1] Where permissible by local law, if any AE is received during weekends or national holidays, it is sufficient if the AE is reported by the next business day.

[2] Training requirements are only for active ESP/HCPs in POP (not for ESPs/HCPs which are qualified but not actively engaged).

[External Service Provider/Health Care Professional] will not start fieldwork or contact participants unless and until it has received written notification from Novartis expressly requesting it to do so.

[External Service Provider/Health Care Professional] will report the FPFC date and the Last Participant Last Contact (**LPLC**) date in writing within two (2) business days to Novartis of the applicable dates occurring.

[External Service Provider/Health Care Professional] is required to follow Good Documentation Practices during documentation of POP activities performed for and/on behalf of Novartis.

7. Adverse Event Reconciliation (AER)

AER is a mandatory quantitative Pharmacovigilance quality control for programs falling into POP Group 1 and Group 2 to confirm that all the identified AEs and other reportable scenarios have been transferred to and received by Novartis Patient Safety within 24 hours. AER is scheduled based on actual FPFC and LPLC dates.

At the written request of Novartis, [External Service Provider/Health Care Professional] agrees to cooperate and assist Novartis with periodic (at least every 3 months) internal reconciliation efforts to ensure consistency between those AEs reported by [External Service Provider/Health Care Professional] during a designated timeframe and those recorded by Novartis as per timeline indicated below.

AERs (including the initial AER) to be performed during the POP should cover a measurement period of no longer than three (3) months from (and including) the FPFC date, with the final AER measurement period ending on (and including) the actual LPLC date. The last AER must be conducted after the final contact with the last participant of the relevant POP. All AERs must be documented using the applicable Novartis forms and sent to Novartis within two (2) weeks from the AER Scheduled Due Date. For the purposes of these POP Vigilance Contract Provisions, reference to "**AER Scheduled Due Date**" shall mean: (i) for the initial AER reconciliation, the date falling at the end of the period chosen by Novartis as the measurement period for the initial AER; (ii) for AER reconciliations thereafter, the dates that occur on every anniversary of the date in (i) above; and (iii) for the final AER reconciliation, the LPLC date.

In the case of any identified non-compliance/actions linked to audit observations/inspection findings or deviations related to AE reporting, at the request of Novartis, [External Service Provider/Health Care Professional] hereby agrees to fully cooperate and assist Novartis in performing AER on an ad-hoc basis.

8. Source Documents

Source documents/data (or sometimes referred as source records/source data) are any and all types of records or supporting materials where the interactions between the [External Service Provider/Health Care Professional] and the POP participants is documented. Examples of source documents/data include but are not limited to: online surveys, recorded discussions, fax receipts, letters, database entries (i.e. Customer Relationship Management (CRM) system), documented interaction with patients or HCPs, digital apps with the ability to record an interaction, records of telephone / video calls, paper records, notes, questionnaires, e-mails, SMS and AE reporting forms if the event was recorded directly on the form during conversation with participants.

Prior to the commencement of each Group 1 POP (i.e., prior to FPFC), specific source documents/data for the POP should be clearly defined in the Agreement, Statement of Work or otherwise agreed in writing between Novartis and the [External Service Provider/Health Care Professional]. Reference to "**Source Documents/Data**" in the remaining provisions below shall, in the context of each Group 1 POP, refer to the specific source documents/data types identified in the applicable [Statement of Work/Agreement] for the Group 1 POP. In addition, in all cases, the output generated from any app/system (e.g. PVI tool; this is an online tool to report AEs electronically to Novartis Patient Safety) used as first point of data collection/report will be considered as Source Documents/Data too.

9. Source Data Verification (SDV) – applicable to Group 1 POPs only

SDV is a mandatory qualitative Pharmacovigilance quality control for programs falling into POP Group 1. During SDV the source data as contractually defined for the program is reviewed to confirm that all AEs and other reportable scenarios have been identified, transferred completely and accurately, and received by Novartis Patient Safety. SDV is scheduled based on the actual FPFC and LPLC dates. Novartis or a third party acting on behalf of Novartis, will conduct an initial SDV three (3) months after the FPFC date. Further SDVs after the initial SDV may be carried out by Novartis or a third party acting on behalf of Novartis at Novartis' discretion. [External Service Provider/Health Care Professional] should provide access to Novartis to the necessary source data (or a copy of it with written/signed/dated confirmation it is a true and accurate representation of the source data) to conduct the SDV. At a minimum, [External Service Provider/Health Care Professional] will conduct an SDV one (1) year after the initial SDV and yearly thereafter, and again at the conclusion of the relevant POP.

The amount of Source Documents/Data being checked should be agreed with Novartis depending on the number of interactions expected for the POP as per the requirements in the POP Training Materials. [External Service Provider/Health Care Professional] should provide an attestation of this activity and a high-level summary of the results to Novartis Patient Safety function within a six (6) week time period from the SDV Scheduled Due Date. For the purposes of these POP Vigilance Contract Provisions, reference to "**SDV Scheduled Due Date**" shall mean: (i) for the initial SDV, the date that occurs three (3) months after the FPFC date; (ii) for SDVs thereafter, the dates that occur every year after the date in (i) above; and (iii) for the final SDV, the LPLC date.

[External Service Provider/Health Care Professional] should document the results of these activities and make them available for Novartis review upon request. During the SDV if any non-transferred AEs are identified, Novartis may in its sole discretion require/request a full review of Source Documents/Data for all SDV Interactions and [External Service Provider/Health Care Professional] will be responsible for ensuring the full review is carried out as per timelines communicated by Novartis, and all associated costs and expenses incurred in carrying out such review will be the responsibility of [External Service Provider/Health Care Professional].

Novartis will have the right to review Source Documents/Data records for the purpose of determining [External Service Provider/Health Care Professional]'s compliance and accuracy in AE gathering and reporting.

In the case of any identified non-compliance/ actions linked to audit observations/ inspection findings or deviations related to AE reporting, at the request of Novartis, [External Service Provider/Health Care Professional] hereby agrees to fully cooperate and assist Novartis in performing SDV on an ad-hoc basis. Notwithstanding that this Section 10 is stated to apply only to Group 1 POPs, the requirement to carry out SDV on an ad-hoc basis (at the request of Novartis) will also apply to Group 2 POPs.

Without prejudice to Novartis' audit rights, Novartis will have during the term of the Agreement and until expiry of any applicable archiving/ retention period the right to access/ inspect the Source Documents/Data (including the right of entry to relevant [External Service Provider/Health Care Professional]'s (or their subcontractor/supplier) premises to the extent necessary to exercise such right) in order to ensure Novartis can comply with all regulatory and internal requirements relating to vigilance. In the case of any such access/ inspection (including without limitation as part of SDV), the [External Service Provider/Health Care Professional] will follow a principle of data minimisation where required by local law or this Agreement, including through anonymization/ redaction of relevant Source Documents/ Data to hide/ obscure any personally identifiable information.

10. Corrective Action and Preventive Action, Audits and Inspections

In case of non-compliance with the requirements of the POP Vigilance Contract Provisions, [External Service Provider/Health Care Professional] commits to promptly communicating these deviations to Novartis and correct the issues within the relevant mutually agreed timelines (the Parties acting reasonably and in good faith). [External Service Provider/Health Care Professional] must document, track and close/complete any Corrective Action and Preventive Action (CAPA) put in place internally including without limitation those put in place following input from Novartis. [External Service Provider/Health Care Professional] must notify Novartis of progress on open CAPA completion on a periodic basis and when completed, or as requested by Novartis.

In respect of each POP, for the term of the relevant Agreement relating to the specific POP and for two (2) years following expiration or termination of the same, Novartis, or its designated third party auditor, will have the right, to audit (whether on-site or paper based) [External Service Provider/Health Care Professional]'s (or its agents or subcontractors) processes, procedures and training, including records, data, documentation, Source Documents/Data with respect to AEs in relation of use of Novartis product(s). [External Service Provider/Health Care Professional] commits to correcting issues from audit observations within the mutually agreed timelines (the Parties acting reasonably and in good faith) and promptly communicating the actions to Novartis. The Parties agree that where the Agreement contains more extensive audit and remediation rights than the audit/remediation rights set out above, the more extensive audit/remediation rights set out in the Agreement will equally apply here, subject to observing the minimum requirements set out above in terms of the duration and scope of any audit/remediation right in the context of the POP Vigilance Contract Provisions.

In the event of Novartis legal matters, including civil litigation and governmental investigations, or any governmental inspection or audit, [External Service Provider/Health Care Professional] hereby agrees that it will fully cooperate as requested. In addition, the [External Service Provider/Health Care Professional] hereby agrees to allow domestic and international health authorities to inspect their vigilance operations as necessary for Novartis to maintain registration in the countries where the Novartis product is marketed.

11. Archiving

[External Service Provider/Health Care Professional] must also create and archive documents/records such as AE reports and forms sent to Novartis during the provision of the Services, as well as internal standard operating procedures (SOPs) for its AE reporting procedures and any POP related document including but not limited to Source Documents/Data from the interaction with participants and maintain them, where permitted by local law, for a minimum period of five (5) years, or if a longer period is required by local law, for such longer period (in each case, measured from POP closure). Such documents/records will be subject to audit. For the purposes of this paragraph, reference to local law in the case of jurisdictions with federal and state laws, refers to the prevailing/controlling local law (be it federal or state), and where both federal and state laws have equal application, the stricter retention standard will be applied where permitted by such local laws.

After the end of any applicable archiving/retention period, as regards the destruction of documents/records containing personal data/information which are subject to a data processing agreement (or equivalent) between the Parties (including as part of the Agreement), the provisions of the relevant data processing agreement will apply.

The archiving and retention requirements under the POP Vigilance Contract Provisions may be more extensive than those set out in the Agreement. In case of any conflict between the provisions of the Agreement and the POP Vigilance Contract Provisions, to the extent permitted by law, the requirements of the POP Vigilance Contract Provisions (if stricter) will apply.

12. Amendments and Organizational Changes

Novartis reserves the right to amend the POP Vigilance Contract Provisions at any time if a requirement is imposed upon by an authority or, in its sole clinical discretion, such amendment is necessary for patient safety. Upon written notice from Novartis of any such amendment, [External Service Provider/Health Care Professional] will comply immediately (or such other time period specified by Novartis) and any failure to comply will be deemed as a [material] breach of the Agreement.

In the event of any changes relating to [External Service Provider/Health Care Professional] including, but not limited to: organization name change, service capabilities or operations, the [External Service Provider/Health Care Professional] must, without undue delay, inform Novartis in writing about such changes.

13. Contacts

The ESP shall nominate an Account Manager and share its contact details (name, address, phone, email) with Novartis, where not provided below, promptly following signature of the Agreement.

The initial Account Manager details for the ESP are as follows:

Name: Contact provided in accordance with clause 24 of the Contract.

Email: Contact provided in accordance with clause 24 of the Contract.

Tel: Contact provided in accordance with clause 24 of the Contract.

The Account Manager shall have:

- Oversight of all Novartis POP projects and

- Be the main contact for any questions related to the POP projects

The initial Novartis local contact for reporting purposes is as follows: farmaco.vigilanciamx@novartis.com

Group 3 POP AE Reporting Clause for incorporation into the ESP/HCP Services Agreement[3]

1. Vigilance obligations

[External Service Provider/Health Care Professional] shall comply with the following obligations in relation to vigilance:

1.1. [External Service Provider/Health Care Professional] acknowledges that [Novartis] and/or its Affiliates ("**[Novartis] Group**"), as registration holder or manufacturer of medicinal products/medical devices in territories potentially covered by this Agreement has certain vigilance obligations in order to meet applicable regulatory rules and guidelines worldwide.

1.2. Based on the nature of the [Services], [External Service Provider/Health Care Professional] and its Personnel, may have contact with patients, prescribers, physicians or other consumers on a product where a [Novartis] Group company is registration holder or manufacturer.

1.3. The definitions of terms defined below such as "**Adverse Event**" (or "**AE**") and special situations (as further explained in Table 1) are in accordance with EU and worldwide guidelines (Directive 2001/83/EC; ICH guidelines E2A and E2D) and shall apply to this Agreement.

*An **Adverse Event (AE)** is any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product and which does not necessarily have a causal relationship with this treatment. An adverse event can therefore be any unfavourable and unintended sign (e.g. an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.*

For the purpose of this Agreement, reference to medicinal product in the above definitions shall also apply to medical devices.

Where local laws, regulations and/or guidelines in the territory where the [Services] are provided/delivered have a wider meaning for AE/ADR, these expressions shall be given the wider meaning for the purpose of this Agreement.

[External Service Provider/Health Care Professional] will forward all Adverse Event (AE) reports and special scenarios and other reportable situations defined in Table 1 that [External Service Provider/Health Care Professional] or its Personnel receive relating to or in connection with a [Novartis] Group product/medical device from the territory where the [Services] are provided/delivered (together "**Vigilance Reports**") to [Novartis] as source documents within **24 hours** or at the latest by the **next business day** following the date of receipt, where permissible by law (if any AE is received during weekends or national holidays) by [External Service Provider/Health Care Professional] or its Personnel.

[External Service Provider/Health Care Professional] shall request the reporter to give permission to provide its contact information to [Novartis] to facilitate follow-up on the report if needed.

1.4. Follow-up of Vigilance Reports shall be performed by [Novartis] or by the [External Service Provider/Health Care Professional], if the reporter provides the permission to follow up to the [External Service Provider/Health Care Professional] exclusively.

1.5. [External Service Provider/Health Care Professional] is required to reference or cross-check the relevant Novartis product list, as provided by Novartis, to identify relevant Novartis products to assist its reporting obligations: This is not required for POPs where POP participants' or patients' therapy is a Novartis drug or associated with a specific Novartis therapy.

1.6. The obligations contained in this Clause 1 will survive for one (1) year beyond the termination of the Agreement except those relating to Records retention (which will survive until the expiry of all relevant Records Retention Periods).

1.7. All reporting in accordance with this Clause 1 shall be made by [External Service Provider/Health Care Professional] via the country specific Adverse Event form attached to this Agreement or otherwise provided by [Novartis], and where not attached or provided, via the following website https://www.novartis.com/report , as may be directed by Novartis.

[Novartis] may change the above website details provided the [External Service Provider/Health Care Professional] is given notice in writing of such change.

1.8. [External Service Provider/Health Care Professional] hereby agrees to maintain all Records/Source documents for the applicable Records Retention Period as per definitions below.

Source documents/data (or sometimes referred as source records/source data) are any and all types of records or supporting materials where the interactions between the [External Service Provider/Health Care Professional] and the POP participants is documented. Examples of source documents/data include but are not limited to: online surveys, recorded discussions, fax receipts, letters, database entries (i.e. Customer Relationship Management (CRM) system), documented interaction with patients or HCPs, digital apps with the ability to record an interaction, records of telephone / video calls, paper records, notes, questionnaires, e-mails, SMS and AE reporting forms if the event was recorded directly on the form during conversation with participants.

[3] Can be used not just for Group 3 POPs but also for any P3 Policy "customer" facing situation where the more detailed POP or Social Media Listening/Digital Engagement Asset vigilance contract provisions are not applicable.

Records Retention Period. External Service Provider/Health Care Professional] must archive documents/records such as AE reports and forms sent to Novartis during the provision of the Services, as well as internal standard operating procedures (SOPs) for its AE reporting procedures and any POP related document including but not limited to Source Documents/Data from the interaction with participants and maintain them, where permitted by local law, for a minimum period of five (5) years, or if a longer period is required by local law, for such longer period (in each case, measured from POP closure). Such documents/records will be subject to audit. For the purposes of this paragraph, reference to local law in the case of jurisdictions with federal and state laws, refers to the prevailing/controlling local law (be it federal or state), and where both federal and state laws have equal application, the stricter retention standard will be applied where permitted by such local laws.

After the end of any applicable archiving/retention period, as regards the destruction of documents/records containing personal data/information which are subject to a data processing agreement (or equivalent) between the Parties (including as part of the Agreement), the provisions of the relevant data processing agreement will apply.

The archiving and retention requirements under the Vigilance Obligations Clause may be more extensive than those set out in the Agreement. In case of any conflict between the provisions of the Agreement and the Vigilance Obligations Clause, to the extent permitted by law, the requirements of the Vigilance Obligations Clause (if stricter) will apply.

1.9. The Parties hereby agree that the obligations in this Clause 1 apply to all [Services] where the Parties have not agreed more detailed/specific vigilance obligations (such as in the context of POP, Social Media Listening/Digital Engagement Asset related [Services]). Where for specific [Services], the Parties have agreed more detailed/specific vigilance obligations, then the latter will apply in respect such specific [Services] instead of the obligations set out in this Clause 1.

Table 1 – Special scenarios and other reportable situations

Special scenario and other reportable situation	Definition
Abnormal laboratory finding	Any value below or above the normal range values (outside a published reference range with/without symptoms). E.g., HCP observed a decrease in the neutrophil count 1.0×10e9/L upon treating the patient with Novartis Product X.
Abuse	Persistent or sporadic intentional excessive use of a Novartis product which results in harmful physical or psychological effects to the patient. E.g.: A patient repeatedly used Novartis product X at higher dose for an intense euphoric sensation
Any symptom, disease or change in the underlying disease	E.g.: Blood pressure increased drastically in a hypertensive patient after patient started treatment with Novartis product drug X for jaw pain.
Death	Any mention of someone's death while being on a Novartis product or shortly after taking a Novartis product. Important note: Whenever death is mentioned, ensure to collect "cause of death" details during the interaction with POP participant/reporter. If cause of death is unknown, ensure to specify the same while transferring to Novartis Patient safety.
Congenital anomaly/Birth defect	Conditions existing at, and generally before birth, which are a marked deviation from the normal standard. E.g.: A female patient treated with Novartis product X during her pregnancy and gave birth to a baby with congenital heart valve anomaly or cleft lip.
Disease progression and aggravation	Worsening of the clinical condition as part of the natural history of the disease process (as expected), or acceleration of the condition beyond what was expected, with or without a lack of Novartis product effect.
Exposure during pregnancy	A female patient using a Novartis product prior to, or during a pregnancy, or a male patient who used a Novartis product prior to, or during the period of conception of his partner.
Exposure during breast feeding	A mother using a Novartis product while in the period of breast feeding.
Disability or incapacity (transient/persisting damage)	A substantial disruption of a person's ability to conduct normal life functions. e.g., a change, impairment, damage or disruption in the patient's body function/structure, physical activities and/or quality of life. E.g.: After treatment with Novartis product X, the patient developed peripheral neuropathy which led to impairment of his daily living activity (e.g., not able to walk properly).
Drug-Drug interactions & Drug-Device interactions *(with or without symptoms)*	When a medicinal product/medical device, endogenous chemical agents, or chemicals used in/resulting from diagnostic tests interacts with the Novartis product X and *affects its pharmacological activity (k*inetic interactions in which the only effect is a change in drug plasma concentrations), either desirable or undesirable.
Drug-Food interactions *(with or without symptoms)*	When components of the diet (food, beverages) affects the pharmacological activity of Novartis product X, either desirable or undesirable.
Drug dependence/ Addiction	A cluster of behavioral, cognitive, and physiological phenomena that may develop after repeated substance use.

Special scenario and other reportable situation	Definition
	Typically, these phenomena include a strong desire to take the product, impaired control over its use, persistent use despite harmful consequences, a higher priority given to product use than to other activities and obligations, increased tolerance, and a physical withdrawal reaction when product use is discontinued.
Lack of efficacy or lack of expected therapeutic effect	Lack of anticipated clinical/therapeutic benefit or response as defined in the product label *with or without worsening* of the disease/condition being treated.
Life-threatening event	Life-threatening event refers to a reaction in which the patient was at risk of death at the time of the reaction; it does not refer to a reaction that hypothetically might have caused death if more severe.
Medical Device	Any instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, software, material or other article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more specific medical purpose(s). A medical device does not achieve its primary intended action by pharmacological, immunological, or metabolic means.
Medical Device Incident	Any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect.
Medication Errors	Includes any preventable event that may cause or lead to inappropriate medication use, including unintended accidental exposure or unintended patient harm while the medication is in the control of a healthcare provider, patient, or consumer. Medication errors can occur as a result of a deficiency at different points including, from ordering the medication to the time when the patient is administered with the drug, e.g., prescribing, administering, dispensing, repackaging and monitoring.
Misuse (with or without symptoms)	Intentionally and inappropriately taking a Novartis product in a way which is not recommended in the labeling document or in terms of the marketing authorization (with or without symptoms).
Occupational exposure	An exposure to a Novartis product as a result of one's professional or non-professional occupation. This does not include the exposure to one of the ingredients during the manufacturing process before the release as finished product.
Off-label Use	Situations where a medicinal product is intentionally prescribed and used not in accordance with the authorized product information in the territory of the report. If the patient was prescribed/advised by the HCP to use the medicine not in accordance to authorized product information, then this should be treated as off-label use.
Overdose	Taking more of a Novartis product than what is the maximum recommended dose in the product information.
Hospitalization	In-patient hospitalization, either for day surgery, or minimum overnight stay, or, an existing hospitalization that is prolonged as a result of an event. ▪ E.g., A patient was placed on Novartis oncology maintenance therapy. 2 weeks later, the patient was hospitalized for cholelithiasis.
Rebound effect	An aggravated return of signs/symptoms of disease or return of original symptoms at a higher intensity or severity than that experienced previously following discontinuation of a Novartis product X treatment or development of tolerance to it.
Special Device Scenarios with or without AEs	Cases of drug-device or device-device interaction, Lack of device therapeutic effect (as defined in the product label), Device-related drug overdose, Device use error leading to medication error or impact on the patient/user (including all medication and dispensing errors and accidental drug exposure associated to the device), Device abnormal use leading to medication error or impact on the patient/user (including off-label use and intentional misuse), Drug withdrawal syndrome/reaction attributable to a device and all cases of transmission of infectious disease via device.

Special scenario and other reportable situation	Definition
Technical Complaint for Medicinal Products with or without AEs	A Technical Complaint is any verbal, electronic or written expression of dissatisfaction with a Novartis medicinal product's Identity, Quality, Stability, Reliability, Safety, Effectives, Performance or usage. This may include: any fault of the containers and outer packages, any fault of the labelling and package insert etc.
Technical Complaint for Medical Devices	Written, electronic or oral communication that alleges, deficiencies related to the identity, quality, durability, reliability, usability, safety, or performance of a medical device that has been released from the market organization's control or related to a service that affects the performance of such medical devices.
Transmission of infectious disease via medication	According to European regulations, any organism, virus or infectious particle, pathogenic or non-pathogenic, should be considered an infectious agent. Hence, any suspected transmission of an infectious agent via a Novartis product is to be reported to Novartis.
Treatment Non-Compliance with AEs	A situation where the patient did not take the medication as prescribed either voluntarily/intentionally or involuntarily/unintentionally.
Unexpected beneficial effect	Beneficial effect that is not related to the indication for which the product was given. ▪ E.g.: A diabetic patient treated with Novartis cholesterol lowering product X notices more stable blood glucose levels after start of treatment.
Withdrawal reaction syndrome	A group of symptoms of variable clustering and degree of severity that occur on cessation or reduction of use of Novartis product X that has been taken repeatedly, usually for a prolonged period and/or in high doses. The syndrome may be accompanied by signs of physiological disturbance. A withdrawal syndrome is one of the indicators of a dependence syndrome.

ANNEX E

Anti-bribery Compliance Agreement

Whenever "third party" is mentioned, it should be understood that it refers to the "Supplier".

Definitions.

- **"Affiliate"** means any company, partnership or other entity which at any time directly or indirectly controls, is controlled by or is under common control with either Party including as a subsidiary, parent or holding company, or where applicable, an alliance partner solely in the context of alliance activities.
- **"Control"** means the ownership of 50% or more of the issued share capital/equity interests, status as a general partner in any partnership, or any other arrangement whereby a Party controls or has the right to control the board of directors or equivalent governing body of a corporation or other entity, or the ability to cause the direction of the management or policies of a corporation or other entity.
- **"Personnel"** means in the context of a Party and its Affiliates performing any obligations under the Agreement, each of their respective employees/workers, directors, officers, sub-licensees, sub-contractors and agents.
- **"Questionnaire for Third Parties"** means any questionnaire for third parties relating to compliance topics including, without limitation, anti-bribery compliance that Third Party has received from Novartis or Novartis Personnel as part of its Third Party Risk Management processes at any time and any updates of such questionnaires.

1. Third Party Risk Management.

1.1 Novartis Third Party Code

1.1.1 Novartis has put in place a Third Party Risk Management framework which is aimed at promoting the societal and environmental values of the United Nations Global Compact with specific third parties that Novartis deals with. In connection with the above, Third Party will:

1.1.2 Comply with the Third Party Code (and any published updates) which can be viewed and downloaded from https://www.novartis.com/esg/reporting/codes-policies-and-guidelines (you may request a copy free of charge from Novartis);

1.1.3 Having regard to Section 12.6 of the Third Party Code, provide information/documentation on reasonable request to Novartis and/or its Personnel to allow Novartis to verify compliance with the Third Party Code in the form requested;

1.1.4 Rectify identified non-compliances with the Third Party Code (where capable of remedy) and report remediation progress to Novartis and/or its Personnel on request. As part of this remediation process, Novartis may request that Third Party put forward a Remediation Plan (as defined in Clause 5.5) to cover such identified non-compliances with the Third Party Code and the Parties agree that, in such cases, Clause 5.5. shall apply, mutatis mutandis, to the preparation of such Remediation Plan;

1.1.5 Ensure that where Third Party Affiliates and/or subcontractors/agents of Third Party and its Affiliates have been pre-approved by Novartis (in accordance with the Agreement) to provide the goods/services/deliverables, that such third parties also comply with the above requirements relating to the Third Party Code; and

1.1.6 Where required by Novartis, fully co-operate (at its own expense) with Novartis and Novartis Personnel in completing and returning, as reasonably instructed, any Questionnaire for Third Parties (and any requested updates to the same during the term of the Agreement). Third Party warrants and represents that the information provided in any Questionnaire for Third Parties (whether provided before or during the Agreement, including updates to the same) is accurate and complete (and such information shall be treated as being part of the Agreement). For the avoidance of doubt, this subparagraph applies to Third Party only, and not to any subcontractor engaged by it in accordance with the terms of the Agreement.

Third Party acknowledges and agrees that the Third Party Code forms an integral part of the Agreement.

1.2 Subcontracting, Due diligence and monitoring

See clause 13 of the Contract of Adhesion.

1.3 Termination:

Supplier agrees that, its failure to comply with:

1.3.1. the standards and requirements set out in the Third Party Code;

1.3.2. any other requirements set out in this Clause 1;

1.3.3. Any of the following Clauses of this agreement: 2, 1.2, 3, 4, 5, 6, 7 and/or 8.

1.3.4 Obstructing/refusing Novartis' audit rights as stated in the Third Party Code and Clause 5 of this Annex.

Shall constitutes a material breach of the Contract and, at Novartis's sole discretion, a 30-day cure period may be granted to comply with the foregoing without limiting any of Novartis's rights. If such corrections are not made, Novartis shall have the right (without limiting any other rights of Novartis) to immediately terminate the Contract by written notice without any indemnity, refund, or compensation and without the need for a judicial declaration.

2 **Compliance with Laws and Policies.**

2.1. In exercising its rights and performing its obligations under the Agreement, Third Party will (and will ensure that its Personnel will):

2.1.1. not promise, offer, pay, cause to pay, accept payment or induce payment or take any action that could be considered a bribe;

2.1.2. comply with all applicable laws and regulations, including those related to bribery and corruption (such as, but not limited to, the US Foreign Corrupt Practices Act, UK Bribery Act);

2.1.3. comply with industry standards;

2.1.4. comply with all policies and guidelines (and any updates to the same) referenced or included in the Agreement or otherwise provided in written form (including electronically) during the term of the Agreement by Novartis to Third Party; and

2.1.5. ensure it has an appropriate (having regard its size, scope of operations and nature of business activities) and effective ethics, risk and compliance organization and systems/policies in place designed to promote ethical business practices.

3. No assignment.

See clause 10 of the Contract of Adhesion.

4. Assessment.

4.1 Third Party acknowledges and agrees that Novartis may require Third Party to complete, as part of its Third Party Risk Management processes, a Questionnaire for Third Parties. Third Party will fully co-operate (at its own expense) with Novartis and/or Novartis Personnel in completing and returning, as reasonably instructed, any Questionnaire for Third Parties (and any requested updates to the same during the term of the Agreement). Third Party warrants and represents that the information provided in any Questionnaire for Third Parties (whether provided before or during the Agreement, including updates to the same) is accurate and complete (and such information shall be treated as being part of the Agreement).

4.2. Third Party will inform Novartis in writing of: (i) any material change to the information provided with the Questionnaire for Third Parties; and (ii) of any change of Control of Third Party or person who Controls Third Party or there is a change to the membership of the executive body of Third Party. For example, a change to the executive management of Third Party (e.g., CEO, N-1 to CEO), in both cases as soon as reasonably practicable after the relevant change occurs.

4.3. This Clause 4 applies to Third Party only, and not to any subcontractor engaged by it in accordance with the terms of the Agreement.

5. Records Retention and Audit.

See clause 16 of the adhesion contract

6. Anti-bribery training

6.1 Subject to Novartis requesting otherwise, Third Party will be responsible for training all of its Personnel (including approved contractors) engaged in performing the activities set forth in the Agreement on anti-bribery ("AB Training") at its own expense. Such training shall include at a minimum the provisions of the applicable bribery and corruption laws and shall take place prior to the performance of services for Novartis. Third Party will ensure that the AB Training is performed for any new Personnel (including approved contractors) that Third Party later wishes to engage to provide the goods/services/deliverables to Novartis. Third Party will ensure that all AB Training is delivered by an appropriately qualified trainer and with training materials which meet the requirements of this paragraph.

Novartis shall be entitled, upon request, to: (i) require Third Party procures that its Personnel will carry out the AB Training online, via a training module made available by Novartis (or its contractors/agents); or (ii) perform at Third Party premises (directly or via its Personnel) the AB Training (or any part thereof). If Third Party receives any such request, it hereby agrees to fully cooperate with Novartis (at its own expense) to enable such AB Training to be carried out, including, in the case of on-site AB Training, providing all reasonable and necessary access for such purpose to Third Party premises and relevant Personnel engaged to provide services to Novartis.

6.2 In the case of Third Party engaging a subcontractor in accordance with the terms of the Agreement, Third Party shall remain directly responsible for ensuring compliance with the above training obligations.

7. AB Policy Remediation.

7.1 In certain cases, Novartis may request Third Party to undertake an online Code of Conduct module developed by Novartis ("CoC Module"). As part of this CoC Module, Novartis requires Third Party to independently develop a new or update its existing Code of Conduct which should contain, inter alia, anti-bribery provisions and which is modelled on applicable international standards (for example, those of the United Nations Development Programme). Third Party will (at its own expense) fully co-operate with Novartis in completing the CoC Module, and will, acting reasonably, without undue delay and in good faith, carry out any Code of Conduct policy remediation requirements resulting from CoC Module completion.

7.2. During any pre-contract or post-contract signature due diligence performed by Novartis (or its Personnel), Novartis may identify gaps in Third Party`s anti-bribery compliance programme ("AB Compliance Process Gaps"). Where such AB Compliance Process Gaps are identified, Novartis may request that Third Party put forward a remediation plan to cover such AB Compliance Process Gaps and the Parties agree that Clause 5.5 shall apply, *mutatis mutandis*, to the preparation of such remediation plan.

8. Annual Compliance Confirmation.

8.1. Third Party will, where requested by Novartis (or its Personnel), for each Reporting Period, deliver (or have an authorized Affiliate acting for and on its behalf deliver) to Novartis a duly completed annual compliance confirmation in the form attached at **Annex F** or any materially equivalent updated form notified to Third Party from time to time by Novartis or its Personnel (each a "**Annual Compliance Confirmation**"). Novartis may, at its option, instruct its Personnel to collect each Annual Compliance Confirmation on its behalf and Third Party will co-operate (and procure that any authorized Affiliate acting on its behalf in respect of the Annual Compliance Confirmation co-operates) with any such Personnel for such purpose. Where Third Party, or its Affiliates, have multiple non-expired contractual agreements with Novartis/Novartis Affiliates which include the requirement to provide an Annual Compliance Confirmation (each an "**Existing Contract**"), Third Party may provide (or have an Affiliate, which is duly authorized to act for and on its behalf to provide) an Annual Compliance Confirmation covering more than one Existing Contract. Unless otherwise directed by Novartis (or its Personnel), the Annual Compliance Confirmation shall be delivered within three (3) months of the end of the relevant Reporting Period.

8.2. For the purposes of this Clause only, reference to "**Reporting Period**" is a reference in each case to a twelve-month period, the first reporting period commencing on the date specified by Novartis (or its Personnel) in the Annual Compliance Confirmation request and each subsequent reporting period commencing on the anniversary of the first reporting period. For the purposes of Clause 1 and the termination provisions contained therein, Third Party will only be considered to be in material breach, as far as submission of the Annual Compliance Confirmation, if the due dates are exceeded by 30 (thirty) days.

8.3. The obligation to provide an Annual Compliance Confirmation applies to Third Party (and not to is subcontractors, provided that the Annual Compliance Confirmation of Third Party shall cover the performance/compliance of Third Party and its Personnel).

ANNEX F

Annual compliance confirmation form

Whenever "third party" is mentioned, it should be understood that it refers to the "Supplier".

The Parties, as agreed in the Agreement and in Annex E "Anti-Bribery Compliance Agreement", agree that **Supplier**'s confirmation of compliance to be sent to **Novartis** shall be in the following format. The following is shown for reference purposes only; in case of applying the format collection will be done separately from this document.

--- Start of format ---

Section 1: Introduction

We are sending you this Annual Compliance Confirmation ("**ACC**") in order to assist you in complying with your contractual commitments to Novartis and its Affiliates. Going forward, you will only need to complete a single ACC for each relevant reporting period, to confirm compliance by you and, if applicable, your Affiliates, with the obligations set out in Section 2 of this ACC, as they apply to all non-expired contractual agreements you and/or your Affiliates may have with Novartis and its Affiliates ("**Existing Contracts**"). Existing Contracts only refer to those contracts with Novartis/Novartis Affiliates which already contain a commitment on you/your Affiliates to complete and return an Annual Compliance Confirmation. You do not need to report your compliance in respect of contractual agreements which do not have an existing Annual Compliance Confirmation obligation.

In Section 2, if you have complied for the Reporting Period (as defined below) with the relevant obligation(s) you should answer YES. If you have not complied, please answer NO and provide further details as requested below.

This ACC relates to the twelve-month period commencing from and including (the "**Reporting Period**").

Data Privacy Statement

To understand how we collect and process any personal information, please refer to our General Privacy Notice for Third Parties, available at: https://www.novartis.com/sites/www.novartis.com/files/general-data-privacy-notice-for-third-parties.pdf

Section 2:

Part 1: Compliance with Law & Regulations

In this Part 1, we are asking for a confirmation that you and your Affiliates have complied during the Reporting Period with all obligations contained or referenced in our Existing Contracts relating to compliance with laws, regulations (such as, but not limited to, the US Foreign Corrupt Practices Act, UK Bribery Act and your local anti-bribery law), industry codes/standards, any Novartis policies, standards and guidelines forming part of an Existing Contract and any commitments relating to anti-bribery and anti-corruption.

☐ Yes

☐ No

If no, please state the relevant law/regulation and the date since the said law/regulation has not been adhered to.

_____

If no, state whether the Business owner has been informed and how.

_____

Part 2: Subcontracting/Assignment

In this Part 2, we are asking you to confirm that you have complied during the Reporting Period with all obligations contained or referenced in our Existing Contracts relating to subcontracting, assignment or transfer of any rights or obligations under the Existing Contracts.

☐ Yes

☐ No

☐ Not applicable

If no, please state the relevant obligations and the date since the said obligation has been subcontracted/sublicensed.

_____

If no, state whether the Business owner has been informed and how.

_____

Part 3: Training

In this Part 3, we are asking you to confirm that you have complied during the Reporting Period with all obligations contained or referenced in our Existing Contracts relating to anti-bribery training (and related recording keeping) and that your staff, personnel, workers involved in the performance of the Existing Contracts have participated in your anti-bribery and anti-corruption training.

☐ Yes

☐ No

If no, reason for non-provision of training to relevant personnel

_____

Sincerely,

_____

Name : _____
Position: Legal representative
Signature: _____
Date: _____
Mail: _____
Country: _____

--- End of format ---

ANNEX G

Notification of Contact Data

Start of format

Dear Patient Safety Team

In relation to clause 24, *Pharmacovigilance*, of the adhesion agreement entered into between Novartis Farmacéutica S.A. de C.V. and [*Company Name]*, I would like to share the contact information to carry out the pharmacovigilance activities/responsibilities described in Annexes B, C and D.

Contact information	Novartis Farmacéutica S.A. de C.V.	[Company name]
PV Report Exchange	Secure e-mail: farmaco.vigilanciamx@novartis.com Online EA Notification Tool www.novartis.com/report Tel.: 55 8877 5390 Fax: 55 5628 6787 *(only in case of contingency)*	
PV primary contact	Name: **Ana Karen Avila Alvarado** Position: Country Patient Safety Head Address: Av. Insurgentes Sur #2475, Tizapan San Angel, Barrio Loreto Alcaldía Álvaro Obregón, C.P. 01090 Mexico City. T: 55 8877 4802 M: 55 5418 9165 E-mail: ana.avila_alvarado@novartis.com	Name: Position: Address: Tel: E-mail:
Secondary PV contact	Name: **Karla Iliana Martínez** Position: Patient Safety Group Manager Address: Av. Insurgentes Sur #2475, Tizapan San Angel, Barrio Loreto Alcaldía Álvaro Obregón, C.P. 01090 Mexico City. T: 55 8877 4807 M: 55 4345 6854 E-mail: karla_iliana.martinez@novartis.com	Name: Position: Address: Tel: E-mail:
PV reconciliation and general inquiries	farmaco.vigilanciamx@novartis.com	E-mail

Sincerely: [Include *Company Name]*.

End of format

ANNEX H

Additional information security requirements

Whenever "third party" is mentioned, it should be understood that it refers to the "Supplier".

These Additional Information Security Requirements ("AISR") supplement any other information security requirements contained within the Agreement, Novartis Third Party Code ("TPC") and Novartis Minimum Information Security Controls ("MISC").

1. **Information security assessments and certifications (supplementing TPC Section 12.5)**

1.1 Novartis or its nominated party may perform technical and/or other assessments including testing to evaluate security and resilience of Novartis Data and Novartis Environment.

1.2 Third Party and its subcontractors shall maintain the following security certifications and audit reports:

1	**CERTIFICATIONS/AUDIT REPORTS**	2	**ISSUE DATE**
2.	The Supplier shall email to its Novartis point of contact any safety certifications and/or audit reports it maintains, e.g., ISO27001 safety certification or SSAE 18 SOC 2 Type 2 audit report.		

1.3 Third Party shall ensure penetration and security tests are periodically (at least annually) performed by experienced and recognized professionals, and in alignment with Security Industry Practice on the environment where Novartis Data is processed and results from such tests are made available to Novartis upon request.

1.4 With respect to sections 1.1-1.3 above, if any gaps or vulnerabilities are found, Third Party shall without undue delay prepare and implement a remediation plan in accordance with the Security Industry Practice. Third Party's failure to comply with this requirement shall entitle Novartis to terminate the Agreement in accordance with respective Agreement's termination clause.

2. General information security requirements (supplementing MISC Section 1, 3, 5 and 6)

2.1 Third Party shall process Novartis Data in accordance with Security Industry Practice.

2.2 The information security program of Third Party shall be periodically (at least annually) reviewed and updated based on assessments addressing: (i) internal and external risks; (ii) use of defensive infrastructure or governance; (iii) the ability to detect, respond to, and mitigate threats; and (iv) the ability to fulfil regulatory requirements.

2.3 Considering relevant information security risks, Third Party shall implement adequate encryption standard(s) in line with Security Industry Practice, such as NIST 800 and/or ISO 27001 at minimum.

2.4 Third Party shall ensure multi factor authentication is in place for systems containing Novartis Data and for network access over a public data network and for access to Third Party environment (where Novartis Data is processed) from Third Party's end user workstations.

2.5 Third Party shall process Novartis Data only in: (a) a secure Production Environment; or (b) any other mutually agreed upon environment that is secure.

2.6 Third Party shall, in connection with its services, implement and maintain measures aligned to Security Industry Practice to detect, investigate, remediate, and prevent, the inclusion, implementation, or execution of any unauthorized or malicious code in any manner impacting Novartis Data or the Novartis Environment.

2.7 Third Party shall monitor available patches, evaluate, test, and implement them in a timely manner for any systems involved in processing of Novartis Data.

2.8 Third Party shall maintain adequate audit trails to support security audits and the detection and investigation of any Security Incident.

3. Continuity Standards (supplementing TPC Section 12.9 and MISC Section 2)

3.1 Third Party shall ensure the following Recovery Time Objective (RTO) and Recovery Point Objective (RPO):

Objective	Maximum time for an objective [in hours]
Recovery Time Objective (RTO)	24 (or as otherwise specified in the relevant Statement of Work/Purchase Order)
Recovery Point Objectives (RPO)	24 (or as otherwise specified in the relevant Statement of Work/Purchase Order)

4. Novartis Environment (supplementing MISC Section 4, 7 and 8)

4.1 Any interface, connectivity with the Novartis Environment is subject to prior Novartis approval and may be disconnected by Novartis at any time.

4.2 If Third Party personnel receives: (i) a Novartis issued badge or similar access mechanism; (ii) a personalized Novartis network access account; (iii) a Novartis device; (iv) a Novartis e-mail account; or (v) other type of access to Novartis Environment, Third Party shall ensure that such Third Party personnel shall follow any applicable information security policies of Novartis. Third Party shall notify Novartis of any changes to the status of Third Party's personnel that may affect Novartis. Third Party shall also ensure that its personnel who may access Third Party environment containing Novartis Data will be subject to Third Party´s monitoring on compliance with applicable Third Party information security policies and standards.

5. Security Incidents (supplementing MISC Section 12)

5.1 Third Party shall monitor, analyze, and respond to Security Incidents.

5.2 Third Party shall notify Novartis without undue delay, but not later than twenty-four (24) hours after becoming aware of Security Incident.

5.3 Novartis contact for reporting Security Incident: Phone: +420 225 775 050 (backup number: +420 225 850 012), Email: soc@novartis.com.

5.4 Third Party shall provide contact for reporting or discussing Security Incident promptly upon Novartis request.

5.5 Third Party shall, without undue delay, perform appropriate actions to minimize further exposure of Novartis Data and implement remediation actions to prevent a recurrence of a similar Security Incident.

5.6 Third Party shall report root cause and impact to Novartis Data as well as a progress of remediation actions adopted.

6. SOX requirements

6.1 For services supporting financial processing that needs to comply with Sarbanes-Oxley Act ("SOX") or Novartis financial controls, Third Party shall ensure such services´ information systems and related controls are assessed, at least annually, in accordance with SOX. Third Party shall be fully responsible to ensure SOX compliance and demonstrate it to Novartis. Services assessment report, such as then-current SOC 1 Type 2 or equivalent report, shall be provided to Novartis upon request. Services that shall comply with this Section shall be identified by Novartis, at its sole discretion, in the task order, SOW or in any other relevant contractual document.

DEFINITIONS [Drafting note: the definitions below should be adjusted to fit your specific contract.]

The definitions below apply to the capitalized terms as used in these AISR.

"**Novartis Data**" means all data, information, documents or records of whatever nature (including personal data and Novartis confidential information) and in whatever form and whether subsisting before or after the date of the Agreement and whether created or processed by Third Party in connection with the services provided to Novartis or provided by Novartis (or third parties acting on their behalf) to Third Party in connection with the Agreement.

"**Novartis Environment**" means any Novartis system or infrastructure managed by or on behalf of Novartis, Novartis Affiliates or Novartis sub-contractor accessible to Third Party.

"TPC" means the Novartis Third Party Code as referenced in the Agreement.

"MISC" means Novartis Minimum Information Security Controls as published on Novartis public internet: https://www.novartis.com/esg/reporting/codes-policies-and-

guidelines and which form part of TPC.

"**Production Environment**" means an environment where the software, products, or updates are released to operations for the intended end-users.

"**Recovery point objective (RPO)**" means how much Novartis Data can be lost without possibility of recovery.

"**Recovery time objective (RTO)**" means how long the services, Novartis Data, or systems used to deliver the services, under the Agreement may be unavailable.

"**Security Incident**" means an event that actually or potentially jeopardizes the confidentiality, integrity, or availability of Novartis Data, or otherwise compromises the information security of the Novartis Environment.

"**Security Industry Practice**" means relevant industry standards and practices generally accepted within the information security community, for companies comparable to the Third Party and/or companies processing comparable information, as exemplified in various industry standards such as International Organization for Standardization (ISO/IEC) ISO/IEC ISO27001, ISO/IEC 27002:2013, SSAE-18, ISAE3402, National Institute of Standards and Technology (NIST) NIST 800-55, the Open Web Application Security Project (OWASP) Guide to Building Secure Web Applications, and the Center for Internet Security (CIS) Standards (or any generally accepted successor to such security standards) relevant for the services provided under the Agreement.

--- End of format ---

ANNEX I
Environmental Sustainability Criteria ("ES")

1. Novartis Environmental Sustainability Strategy

(a) Climate: Novartis is committed to becoming a net-zero carbon company across the entire value chain by 2040.

(b) Nature: Novartis is committed to contributing to Nature Positive, that is, to "halt and reverse nature loss by 2030 against a 2020 baseline and achieve full recovery by 2050," as defined by the Nature Positive Initiative based on the 2022 Global Biodiversity Framework.

2. Novartis Environmental Sustainability Expectations

(a) Climate: The Supplier will continuously reduce its Greenhouse Gas (GHG) emissions in its own operations and across its entire value chain to meet its science-based targets established in accordance with 4(a).

In line with current best practices and recognized guidelines, such as the Science Based Targets initiative (SBTi), the Supplier is also encouraged to adopt Beyond Value Chain Mitigation (BVCM) measures to help avoid or reduce GHG emissions beyond its value chain.

(b) Water: The Supplier will seek to continuously reduce water withdrawals across its operations and avoid any impact on the quality of water in the receiving aquatic environment in accordance with local regulatory requirements.

(c) Waste: The Supplier will seek to continuously reduce waste in its operations and to adopt environmentally friendly materials for products and/or services procured by Novartis whenever possible.

(d) Supplier Engagement: The Supplier, together with its approved subcontractors/suppliers, will support the Novartis Environmental Sustainability Strategy and comply with (i) the provisions in Sections 2(a)–(c) above, (ii) any applicable law related to Environmental Sustainability, and (iii) any stipulation of the existing contract related to Environmental Sustainability.

3. Environmental Sustainability-related data collection and reporting obligations

(a) Upon request, the Supplier will grant Novartis, its Affiliates, and/or designated representatives access to assess the Supplier's performance with respect to environmental management expectations related to the products and/or services procured by Novartis.

(b) Together with the Supplier and its Affiliates, Novartis may establish a sustainability roadmap for products and/or services procured by Novartis, including agreeing to track certain Environmental Sustainability Key Performance Indicators ("Environmental Sustainability KPIs"), defining baselines, and setting milestones to monitor the Supplier's performance against the Environmental Sustainability Expectations and identify opportunities to improve the Environmental Sustainability performance of the Supplier and its Affiliates.

(c) The Supplier and its Affiliates will establish and maintain Environmental Sustainability data in accordance with relevant sustainability standards, for example the Global Reporting Initiative ("GRI"), the EU Corporate Sustainability Reporting Directive ("CSRD"), and similar, and the respective materiality assessment. The Supplier will also ensure that its suppliers and the broader supply chain follow the same standards.

(d) The Supplier and its Affiliates will establish and maintain Environmental Sustainability data specific to Novartis's product/service (Product/Service Carbon Footprint) and make it available to Novartis annually. To this end, they will follow industry frameworks, for example the Partnership for Carbon Transparency (PACT) framework developed by the World Business Council for Sustainable Development (WBCSD).

(e) The Supplier and its Affiliates will allow Novartis to communicate its Environmental Sustainability data related to products and/or services procured by Novartis and/or its Affiliates to an independent third-party platform in an anonymized manner, as necessary for external reporting, benchmarking, and audits.

4. Sustainability standards and commitments

(a) The Supplier and its Affiliates will establish and maintain public commitments related to carbon emissions, align their targets, and obtain approval for them through the Science Based Targets initiative (SBTi) (www.sciencebasedtargets.org) by the end of 2025.

(b) The Supplier and its Affiliates will make and maintain external Environmental Sustainability disclosures and reporting, either through CDP (www.cdp.net), in the form of integrated filing, or through EcoVadis (www.ecovadis.com), including the carbon module.

(c) The Supplier and its Affiliates will provide, upon request by Novartis or at the agreed frequency, relevant environmental footprint data verified by an independent third party (e.g., SGS, TUEV, Bureau Veritas, etc.).

Acknowledgement

We refer to all existing agreements between Novartis and ..... (Name of the supplier legal entity) in force ("the Agreement"). By signing this document, we intend to amend the Agreement to fully incorporate the Environmental Sustainability Criteria mentioned. ..... (Name of the supplier legal entity) of ..... (Supplier address) acknowledges receipt of the Novartis Environmental Sustainability Criteria and undertakes to comply with them. This document will be considered part of the Agreement and any future reference to the Agreement will include the Environmental Sustainability Criteria.

--- End of format ---