GENERAL TERMS AND CONDITIONS

一般条款和条件

1. Transaction Documents 交易文件

1.1 An entire agreement between Novartis and Supplier with respect to any specific transaction shall be comprised of one or more of the following documents (collectively, the "Transaction Documents" and each a "Transaction Document"), and any inconsistency among the Transaction Documents with respect to such specific transaction shall be resolved by giving precedence in the order of the following documents unless otherwise specifically provided in the Transaction Documents:

(a) Any specific long-term or one-off contract or agreement governing the provision of services/products or other collaborations (the "Contract");
(b) These General Terms and Conditions;
(c) Purchase Order; and
(d) Other documents (if necessary) (e.g., Work Order/Statement of Work).

诺华与供应商之间就某个特定交易的全部协议应包括下列一个或多个文件（统称为"交易文件"，每一个文件称为一份"交易文件"），若该等特定交易的交易文件间有任何不一致之处，则除非交易文件另有明确约定，交易文件的优先等级应以以下次序降序排列：

(a) 与提供服务/产品或其他合作有关的任何特定的长期或一次性合同或协议（"合同"）；
(b) 本一般条款和条件;
(c) 采购订单；和
(d) 其他文件（如有）（例如工作订单/工作说明书）。

1.2 Supplier hereby acknowledges and agrees that in the event that both (x) a Purchase Order and (y) a Contract will be entered into between Novartis and Supplier, Supplier shall not start to fulfil any of its obligations or incur any cost unless and until (x) the Purchase Order has been issued by Novartis to Supplier, and (y) the Contract has been duly singed by both parties.

供应商承认和同意若（x）采购订单，和（y）合同 将均被诺华和供应商签署，则除非直至（x）诺华已向供应商下达采购订单，且（y）双方已正式签署了合同，供应商不应开始履行其任何义务或产生任何费用。

1.3 Supplier hereby further acknowledges and agrees that if it, within three (3) days after a Purchase Order has been sent by Novartis to an email account specified by Supplier in writing earlier, does not inform Novartis in writing that it does not agree to any term under such Purchase Order, Supplier shall be deemed as having agreed to and been bound by such Purchase Order issued by Novartis.

供应商在此确认并同意，如果供应商在诺华通过其之前书面提供的邮箱账号向其发送采购订单之后的三天之内，没有书面通知诺华其不同意采购订单中的任何条款，供应商将被视为已经同意并且愿意接受该采购订单。

1.4 Supplier agrees and confirms that the Affiliates of Novartis (including but not limited to Beijing Novartis Pharma Co., Ltd., Shanghai Novartis Trading Ltd., China Novartis Institutes for Bio-Medical Research Co., Ltd., Suzhou Novartis Technical Development Co., Ltd., Novartis Medical Technology (Zhejiang) Co., Ltd.) shall have the right to issue Work Order(s) to Supplier based on the terms under the Transaction Documents, and Supplier shall not reject such Work Orders unless Supplier has any legal ground. Unless otherwise agreed by Supplier and any Affiliate of Novartis, upon effectiveness of the Work Order(s) between Supplier and any such Affiliate of Novartis, the terms hereunder shall automatically be incorporated into and apply to such Work Orders. In case Supplier breaches any provisions under such Work Order(s), Supplier shall assume default liabilities and pay liquidated damages or other compensation to such Affiliate of Novartis directly.

For purpose of clarification, any agreement or Work Order between Supplier and Novartis or any Affiliate of Novartis is an independent agreement, and the entity which enters into the agreement or the Work Order with Supplier shall independently perform the obligations and pay service fees to Supplier pursuant to the terms and conditions thereunder. In no event shall Novartis or any of its Affiliates assume any joint liability with respect to any obligations under any agreement or Work Order that is executed by another Affiliate.

In these Transaction Documents, the term "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 Transaction Documents, 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 Supplier has received from Novartis or Novartis Personnel as part of its External Partner Risk Management processes at any time and any updates of such questionnaires.

供应商确认，诺华集团下属在华企业及在华企业分支机构(包括但不限于北京诺华制药有限公司、上海诺华贸易有限公司、诺华(中国)生物医学研究有限公司、苏州诺华医药科技研发有限公司、诺华医药科技（浙江）有限公司等)有权按照交易文件约定的条款及条件内容向供应商发出采购要约或要约邀请，供应商无正当理由不得拒绝接受诺华附属公司的前

述采购要约或要约邀请；且一旦诺华附属公司和供应商之间就此所签订的个别订单生效，则交易文件的条款应自动适用于该等订单；如供应商未按照交易文件履行前述生效的订单的，则供应商需向诺华附属公司直接承担违约赔偿责任。为避免歧义，该等个别协议或订单构成供应商和诺华或诺华附属公司之间独立的合同法律关系，诺华或诺华附属公司基于该等个别订单而各自独立地对供应商享有合同权利及承担合同义务。在任何情况下均不应视为诺华和诺华附属公司相互间需共同对供应商承担任何连带责任。

在交易文件中，“关联方”或“关联公司”或“附属公司”是指在任何时候直接或间接控制任何一方、受任何一方控制或与任何一方同受另一方控制的任何公司、合伙企业或其他实体，包括作为子公司、母公司或控股公司，或如适用，仅在联盟活动的情况下的联盟伙伴。“控制”是指拥有 50%或以上的已发行股本/股权，作为任何合伙企业的普通合伙人的地位，或一方控制或有权控制一家公司或其他实体的董事会或同等管理机构或有能力促使他人指导一家公司或其他实体的管理或政策的任何其他安排。“人员”或“员工”是指在一方及其关联公司履行交易文件项下任何义务的情况下，其各自的雇员/工人、董事、管理人员、被许可人、分包商和代理人。“第三方调查问卷” 是指供应商在任何时候从诺华或诺华人员处收到的、作为其外部合作伙伴风险管理流程的一部分的任何与合规主题（包括但不限于反贿赂合规）相关的第三方调查问卷，以及该等调查问卷的任何更新。

2. Delivery and Inspection 交付和检验

Supplier shall deliver the goods or perform the services ordered under the relevant Transaction Documents to/at Novartis facility (or other designated Novartis location) set forth in the Transaction Documents or as otherwise conveyed in writing by Novartis to Supplier (“Delivery Point”). Goods delivered under the Transaction Documents shall be subject to inspection and testing at the Delivery Point (or, if purchased for export, at the ultimate destination abroad). All or any part of the order may be returned at Supplier's expense if found within a reasonable time from the date of Novartis's inspection and testing to be defective or not in accordance with the Transaction Documents. Acceptance of all or part of the goods, or payment therefore, or failure to notify Supplier promptly, shall not waive nor affect Novartis’s right to cancel all or any part of the Purchase Order, return all or part of goods, seek liquidated damages or indemnification based on Supplier's warranties or agreements of indemnity, or any other remedies Novartis may have pursuant to the Transaction Documents and the applicable People’s Republic of China laws and regulations. Supplier shall bear the cost of inspecting and testing of goods which are rejected.
供应商应向/在交易文件指定的诺华地点或诺华书面另行通知的其它地点（简称“交付地点”）向诺华交付货物或提供服务。交易文件下的交付的产品须在交付地点（如果是基于出口目的的采购，则在最终的国外目的地）进行检验和检测。如果诺华在自检验和检测之日起的合理期限内发现货物有缺陷或与交易文件不符，则诺华有权决定退还全部或部分的货物，因此产生的费用由供应商承担。诺华接受全部或部分货物，或因此而付款，或未能及时通知供应商，并不意味着诺华放弃、亦不会影响诺华的如下权利：全部或部分地撤销采购订单的权利； 退回全部或部分货物的权利；基于供应商承诺或赔偿约定进行索赔的权利；以及其他诺华根据适用的中华人民共和国的法律法规应享有的救济。供应商应自行承担被拒收货物的检验检测费用。

3. Title and Risk of Loss 所有权和灭失风险

Title and risk of loss to goods delivered to Novartis pursuant to the Transaction Documents shall be transferred to Novartis at the Delivery Point after the goods have passed inspection process and been accepted by Novartis.
根据交易文件交付的产品之所有权和灭失风险应在产品运抵交付地点且经诺华验收合格和接受后转移至诺华。

4. Time of Essence, Cancellation 时间至关重要；撤销

Novartis may cancel all or any part of the Purchase Order(s) or may refuse to accept (and in the case of goods, may choose to return) any goods or services ordered hereunder if Supplier fails to deliver the goods or services within the time specified in the Transaction Documents (time being of the essence hereof), or fails to deliver all or any part of the goods or services in accordance with the terms under the Transaction Documents. Acceptance of part of the goods and services shall not oblige Novartis to accept later shipments of goods or performance of services, nor affect Novartis’s right to return goods already accepted.
如果供应商未能按照交易文件规定的时间交付产品或提供服务（时间对于交易文件下的产品交付/服务提供至关重要），或未能按照交易文件的规定交付产品或提供服务，则诺华有权撤销全部或部分采购订单，或拒收任何产品或服务（包括在标的是货物情况下可选择退货）。接受部分产品或服务，并不意味着诺华有义务后续继续接受产品或服务，其亦不影响诺华退还已接受产品的权利。

In the event Supplier fails to meet the delivery schedule under the Purchase Order, Novartis shall have the right to, without prejudice to its other remedies available, deduct from the Purchase Order price the liquidated damages as specified below: (i) for the first week of delay, if Supplier is able to provide an acceptable reason, no liquidated damages will be payable by Supplier; (ii) starting from the second week of delay, Supplier will need to pay liquidated damages to Novartis at the amount of 5% of total price under the relevant Purchase Order(s) per week, unless such delay is caused by a Force Majeure event, and (iii) if Supplier fails to deliver the goods/services within four (4) weeks after the due date or any other grace period agreed by both parties, without prejudice to any other rights Novartis may have (including but not limited to the right to collect liquidated damages), Novartis shall have the right to (x) terminate the related Transaction Documents in whole or in part, (y) refuse to accept any subsequent delivery of goods/services which Supplier attempts to deliver; and/or (z) recover from Supplier any expenditure reasonably incurred by Novartis in obtaining the

goods/services in substitution from another supplier and claim damages for any additional costs, losses or expenses incurred by Novartis which are in any way attributable to Supplier's failure to deliver the goods/services on the due date.
若供应商未能依据采购订单约定的时间交付服务/产品，则诺华有权（在不影响其他救济的情况下）根据以下标准从采购订单下的应付帐款中扣除违约金：(i)在迟延履行的第一周内，若供应商能提供合理的理由，供应商无需承担任何违约金；(ii)自迟延履行的第二周起，每迟延一周，供应商应向诺华支付相关订单金额的 5%作为违约金，除非该等迟延履行是由于不可抗力事件所导致的；和(iii)若供应商在约定的交付日期后的四(4)周（或双方约定的其他宽限期）内仍未能交付产品/提供服务的，则在不影响诺华享有的任何其他权利（包括但不限于收取违约金的权利）的前提下，诺华有权(x)终止全部或部分的相关交易文件；(y)拒绝接受供应商事后试图提供的产品/服务；和/或(z)要求供应商承担诺华为从其他供应商处取得替代的产品/服务而合理产生的任何费用，并要求供应商赔偿诺华因供应商未能按时提供产品/服务而产生的任何额外成本、损失或费用。

5. Supply of Goods/Services 产品/服务的提供

When performing the obligations under the Transaction Documents, the following provisions shall apply in addition to other applicable provisions under the Transaction Documents:
在履行交易文件要求的义务时，除了交易文件下的其他适用条款之外，以下条款也应当适用：

(a) Any obligation performed thereunder is in Supplier's capacity as an independent contractor and Supplier shall be solely responsible for and have control over the means, methods, techniques, and sequences of the services/goods. Neither Supplier nor its employee, agent, or representative is the employee of Novartis, and Supplier retains the exclusive right to hire, discipline, evaluate and terminate its own employees and to set their hours, wages and terms and conditions of employment. Supplier is not entitled to, and will not, receive from Novartis any insurance coverage, pension, investment saving plan contribution or other benefits provided, by or on behalf of Novartis to its employees, agents or representatives. Supplier agrees that neither itself nor its employee, agent or representative will claim to be an employee of Novartis for any purpose, and that any such claim will constitute a breach of the related Transaction Documents.
交易文件项下的任何义务应由供应商作为一个独立的供应商来履行。供应商应全权负责和控制服务/产品的手段，方法，技术和顺序。供应商或其雇员、代理人或代表都不是诺华的员工。供应商保留雇用、处罚、评估和解雇其雇员，以及设定其工作时间、工资以及雇佣条款和条件的排他性权利。供应商无权，也不会收到来自诺华的任何保险、养老金、投资储蓄计划或者由诺华或代表诺华提供给其雇员的任何其他福利。供应商同意，其以及其任何雇员、代理人或代表均不会为任何目的声称其是诺华的员工，并且同意任何该等声称均将构成对相关交易文件的违反。

(b) Supplier shall, at its sole expense, obtain, keep in force, and comply with, any and all permits, licenses, qualifications and approvals (collectively, "Permits") required under any applicable laws and regulations with respect to the services/goods provided thereunder, including, but not limited to, any and all immigration documents, visas, clearances and the like necessary and appropriate for the lawful rendition of the provisions of services/goods thereunder.
供应商应自担费用，获得并符合所提供的服务/产品相关法律法规要求的所有许可证、执照、资质和批准（统称"许可证"）并保持其效力，包括但不限于，任何所有的移民文件、签证、清关等交易文件项下的服务/产品相关法律条款要求的必要文件。

(c) (i) All inventions and discoveries made and/or developed by Supplier or one or more of its employees, agents and/or representatives, alone or together with one or more others, as a result of the performance of obligations under the Transaction Documents (collectively "Inventions"), and any patents on any Inventions(s), shall be the sole and exclusive property of Novartis, and Supplier hereby assigns, grants and conveys, and agrees to assign, grant and convey and to require its employees, agents and representatives to assign, grant and convey, to Novartis all right, title and interest in and to any Inventions and any such patents and to execute all documents reasonably deemed necessary or desirable by Novartis to perfect it sole and exclusive ownership of such Inventions and patents. Without Novartis's prior written consent, neither Supplier nor one or more of its employees, agents and/or representatives, alone or together with one or more others, shall file any patent applications on any Inventions. As used in these General Terms and Conditions, the term "Inventions" includes patentable and un-patentable inventions and discoveries, and the term "patents" includes both China and foreign patents, extensions thereof, reissues thereof, re-examination certificates issued therefore and supplemental protection certificates based thereon, and applications for all of the foregoing.
由供应商或其一个或多个雇员、代理人和/或代表单独或共同因提供交易文件下的服务而做出和/或开发的所有发明或发现（统称为"发明"），以及任何发明的任何专利，均为诺华独有且排他的财产。供应商特此向诺华转让、授予和移交，并同意该等转让、授予和移交，且要求其雇员、代理人和代表向诺华转让、授予和移交这些发明及其专利的所有权利、所有权和利益，并应签署诺华为实现其对该等发明及专利的独有且排他的所有权而被合理认为是必须或者要求的文件。未经诺华书面许可， 无论是供应商还是其一个或多个雇员、代理人或代表，均无权单独或共同就任何发明递交任何专利权申请。在本采购订单中，"发明"一词的含义包括可获得专利的和不可获得专利的发明或发现；"专利"一词的含义包括中国专利和外国专利，以及基于上述专利的延期、再颁发、复审证书、补充专利保护证书，以及对上述证书的全部申请。

(ii) All works, including, but not limited to, information, materials, documents, software code or programs (together with any related documentation), research results, designs and plans falling outside the scope of Inventions prepared and/or created as a result of the performance of obligations pursuant to the Transaction

Documents (collectively the “Works”) shall be the sole property of Novartis, and Novartis does and shall own all right, title and interest in all such Works. Supplier hereby assigns, grants and coveys, and agrees to assign, grant and convey and to require its employees, agents and representatives to assign, grant and convey to Novartis all right, title and interest in and to any intellectual property rights, including any copyrights, trademarks and service marks, in each such Work. The foregoing intellectual property rights include, but are not limited to, (i) all rights to register, or to renew any registration(s) for, such intellectual property rights, (ii) all causes of action related to such intellectual property rights and (iii) any and all moral rights, so-called droits morale and rights of attribution. Supplier hereby agrees to execute, and to require its employees, agents and representatives to execute, all documents reasonably deemed necessary or desirable by Novartis to perfect its ownership of such Works and any intellectual property rights in such Works. Without the written consent of Novartis, Supplier will not attempt to register any Work, or any part thereof, at any applicable registration offices in China, or any foreign counterpart of any of these offices. As used in these General Terms and Conditions, terms such as “copyrights”, “trademarks” and “service marks” include both China and foreign copy rights, trademarks and service marks, respectively, and applications therefore.
因提供交易文件下的服务而准备或者完成的所有发明之外的作品，包括但不限于信息、材料、文件、软件代码或程序（以及相关参考资料）、调研成果、设计及图纸（统称为“作品”），均为诺华的专有财产，诺华拥有这些作品的所有权利、所有权和利益。供应商特此向诺华转让、授予和移交，并同意该等转让、授予和移交，且要求其雇员、代理人和代表向诺华转让、授予和移交这些知识产权的所有权利、名称和利益，包括版权、商标权和服务商标。上文中所提及的知识产权，包括但不仅限于(i)该等知识产权的申请权、注册权和展期权；(ii)与该知识产权相关的权利主张的支持依据，以及(iii)与知识产权相关的人身权。供应商应签署并应要求其雇员、代理人或代表签署诺华为实现其对该等作品的所有权以及任何知识产权而被合理认为是必须的或者要求的文件。未经诺华书面允许，供应商不得试图在任何境内或境外机构注册上述作品或其部分权利。在本一般条款和条件中，“版权”、“商标权”、“服务商标”等词根据上下文的需要均分别代表中国和外国的版权、商标权、服务商标以及其申请。

(iii) Notwithstanding the above provisions, the Supplier’s intellectual property rights that existed before the effective date or not created and/or developed in accordance with the Transaction Documents after the effective date are still owned by the Supplier ("Supplier Intellectual Property Rights"). If the deliverables or services provided by the Supplier require the use of the Supplier’s intellectual property rights, the Supplier hereby grants Novartis a permanent, non-exclusive, worldwide, free, and sublicensable license to use, and Novartis is only licensed to unrestricted use of the deliverables or services under the Transaction Documents to use the Supplier’s intellectual property rights in the foregoing deliverables or services.
尽管有上述规定，供应商在生效日前已经存在的知识产权，或者在生效日之后并非根据交易文件创设和/或开发的知识产权仍归供应商所有（“供应商知识产权”）。如供应商提供的交付成果或服务需要使用供应商知识产权，供应商在此授予诺华一项永久的、非独占的、世界范围的、免费的、可再许可的许可使用权，许可诺华仅在不受限制地使用交易文件项下的交付成果或服务的范围内使用前述交付成果或服务中的供应商知识产权。

(iv) If the deliverables or services provided by the Supplier contain any third-party intellectual property rights, the Supplier shall ensure that: (1) the use of such third-party intellectual property rights has been fully authorized and the deliverables or services provided does not infringe the intellectual property rights of any third party; (2) Novartis obtains the same license as Section 5(c)(iv) for such third party intellectual property rights. Otherwise, the Supplier shall compensate Novartis for all losses (including but not limited to litigation/arbitration fees and legal fees) suffered by any third party claiming intellectual property infringement.
如供应商提供的交付成果或服务中包含任何第三方知识产权的，供应商应确保：（1）其对该等第三方知识产权的使用已经获得了充分的授权，其提供的交付成果或服务不侵犯任何第三方的知识产权；（2）诺华就该等第三方知识产权获得与第 5(c)(iv)条同等的许可。否则，供应商应赔偿诺华因任何第三方主张知识产权侵权而遭受的所有损失（包括但不限于诉讼/仲裁费和律师费）。

(v) Unless expressly stipulated in the Transaction Documents, the Transaction Documents do not grant any right in the existing intellectual property rights of either party to the other.
除非交易文件明确约定，交易文件不授予任何一方另一方既有知识产权中的任何权利。

(d) Novartis retains the exclusive ownership interest in all tools, patterns, moulds, printing plates, drawing, plans, prints materials (including, without limitation, all graphics and files), information, software, hardware, and any other equipment that Novartis may supply to Supplier in the course of Supplier's performance of the obligations thereunder, and Supplier acknowledges Novartis's exclusive ownership interest in the foregoing and agrees not to contest such interest. Supplier may use the foregoing only to provide the services/goods thereunder, and shall carefully keep the foregoing and maintain them in good operating condition at all times. Novartis shall have the right to, by notifying Supplier in writing, take back any and all the above-mentioned tools, patterns, moulds, printing plates, drawing, plans, prints materials, information, software, hardware, and any other equipment.
在供应商履行义务的过程中，诺华对所有的由诺华提供给供应商的器具、工具、模具、打印板、制图、规划、材料（包括但不限于所有的图表和文件）、信息、软件、硬件及任何其他设备享有专有所有权。供应商承认诺华的上述专有所有权，并承诺不就该等权利主张利益。供应商仅可将上述财产用于提供服务/产品，且应妥善保管和维护上述财产并使其始终处于良好的工作状态。诺华应有权，在书面通知供应商的情况下，收回任何和所有的上述器具、工具、模具、打印板、制图、规划、材料、信息、软件、硬件及任何其他设备。

(e) As a condition precedent to any payment, Supplier will furnish waivers or release of contractors' rights to file mechanic's liens against the work, materials, articles or equipment. Supplier promises to keep said property free and clear of all liens for materials and labor incident to the obligations thereunder. Supplier also waives its right to assert any lien on its own behalf and shall include in all contracts with subcontractors, labourers, and materialmen a clause containing similar provisions. In the event any lien is attached after final payment is made by Novartis pursuant to the Transaction Documents, Supplier shall refund to Novartis all expenses incurred by Novartis in discharging such liens. Novartis shall have the right, at Novartis's option, to remove any such lien by making payment to the claiming party without verifying the truthfulness and validity of the lien. All such payment shall be charged to Supplier or treated as setoff against payment payable to Supplier by Novartis.
作为任何付款的先决条件，供应商将放弃或解除其对工作、材料、物品或设备享有的留置权。供应商承诺保证上述财产无任何权利负担，并解除所有与履行本一般条款和条件项下的义务有关的材料和劳动力的留置权。供应商也放弃代表自身主张任何留置权的权利，并将在所有与分包商、工人、材料商签订的合同中包含类似的条款。如果诺华根据交易文件进行最后付款之后上述财产仍附有任何权利负担，供应商应退还给诺华为解除该权利负担而产生的所有费用。诺华有权选择通过支付给留置权人相关费用解除留置权，而不核实该留置权的真实性和有效性。以上所有费用将向供应商收取或抵销诺华对供应商的付款。

6. Price and Payment 价格和付款

6.1 If no price is specified on the Purchase Order or any other Transaction Documents, the goods and/or services furnished thereunder shall be billed at the price last quoted to Novartis, or at the prevailing market price, whichever is lower.
如果在采购订单或任何其他交易文件中未载明价格，则本一般条款和条件下提供的产品和/或服务应以给诺华的最后报价或者以通行的市场价格计价，以价格较低者为准。

6.2 Novartis will only reimburse those out-of-pocket expenses that are reasonable, necessary and expressly authorized under the relevant Transaction Documents or otherwise approved by Novartis in writing. All such expenses shall be billed at actual cost and must be supported by the verified true and accurate invoices, receipts or other appropriate documentation requested by Novartis. Otherwise, Novartis shall have the right to refuse to make any payment.
诺华仅报销那些合理、必要以及在有关交易文件中明确授权或者诺华书面批准的自付费用。 所有这些费用应按实际开销计费，并必须提供经核实的真实和准确的发票、收据或诺华要求的其他相关文件。否则，诺华有权拒绝支付任何款项。

6.3 Unless otherwise provided under the Transaction Documents, no charge will be allowed for packing, boxing, cartage or insurance, and Supplier shall prepay and assume all shipping charges. Unless otherwise agreed in writing by both parties through an order or other means, the service fee shall include all costs, remuneration, and expenses. Novartis is not obliged to pay any additional fees for the services provided by the Supplier under the Transaction Documents (including relevant orders) in addition to the service fee (including but not limited to the additional costs incurred by the Supplier due to delayed performance or correction of any service defects and the costs incurred by the time of the Supplier's personnel, etc.).
除非在交易文件中另有规定，供应商不应要求诺华承担任何包装、打包、搬运或保险费用，供应商应预付和承担所有运费。除非双方通过订单或者其他方式另行书面同意，服务费应包括所有成本、报酬、费用，诺华无义务在服务费之外就供应商根据交易文件（包括适用的订单）提供的服务额外支付任何费用（包括但不限于供应商因迟延履行或纠正任何服务缺陷而产生的额外费用以及供应商人员的在途时间所产生的费用等）。

6.4 Supplier shall send the invoice to Novartis after the services/goods have been delivered to the satisfaction of Novartis, which invoice shall cover the value of the goods delivered or service provided. Unless Novartis has any question or comment on the services/goods rendered by Supplier or the invoice issued by Supplier, relevant payment due shall be released within ninety (90) days or any longer payment period as specified under the relevant Statement of Work or Purchase Order(s) (whichever period is longer) after Novartis has received (x) the verified true and accurate invoice issued by Supplier, and (y) the written confirmation from Appendix D "Novartis Settlement Sheet" of these General Terms and Conditions (that goods/services have been received by Novartis and have passed Novartis's inspection and testing).
供应商应该在向诺华交付令其满意的服务/产品之后，向诺华寄送发票。该发票应当体现所交付产品或服务的价值。除非诺华对供应商提供的服务/产品或者供应商开具的发票有任何问题或意见，诺华应当在收到以下文件的 90 天之内或按照适用的工作说明书或采购订单中载明的更长的付款周期（以较长付款周期为准）向供应商支付相关价款：(x)供应商开具的已经验证的真实准确的发票，和(y)本一般条款和条件附件 D"诺华结算单"（确认已收到该产品/服务，且该产品/服务已经通过诺华检查和验收）。

6.5 The finance department of Novartis will only accept the invoice that is issued after the delivered goods/provided services have passed the inspection and testing of Novartis. Any invoice issued before the actual delivery date of the goods/services will be refused and returned by Novartis.
诺华财务部仅接受在交付的产品或者提供的服务通过诺华的检查和验收之后开具的发票。任何在产品/服务交付之前开具的发票均将会被诺华拒绝或者退回。

6.6 Novartis has the right to decline the payment, if the Purchase Order value is not equal to the invoice value or the good receipt value or the Novartis Settlement Sheet value.
如果采购订单价值与发票金额或者收据金额或者诺华结算单金额不符，诺华有权拒绝付款。

6.7 If Novartis has received and accepted the goods/services provided by Supplier, but does not receive the invoice issued by Supplier (including the invoice for instalment or partial payment) within thirty (30) days after the goods/services have been received and accepted, Novartis shall have the right to claim Supplier against any financial losses (if any) suffered by Novartis therefrom.
如果诺华收到且接受了供应商提供的产品/服务，但是在收到以及接受产品/服务后 30 天之内没有收到供应商开具的发票（包括分期付款或者部分付款的发票），诺华有权要求供应商支付诺华因此遭受的任何财务损失（如有）。

6.8 If it is the first time for Supplier to provide the services/goods to Novartis, Supplier shall provide the Business License or the registration certificate with similar nature, the Tax Registration Certificate (if any), or any other qualification license and documents requested by Novartis to the procurement department of Novartis. Each of such documents shall be affixed with the company chop of Supplier and be provided to Novartis via both email and facsimile. Otherwise, Novartis shall not be liable for any delay or failure of payment arising therefrom.
对于第一次向诺华提供产品/服务的供应商，供应商须按要求向诺华采购部提交《营业执照》或类似的注册登记文件、《税务登记证》(如有)、相关"资质证书"、以及任何其他诺华要求的文件。任何该等文件均需加盖供应商公章并以邮件和传真的方式向诺华提供。否则，诺华对由此引起的付款迟延不承担任何责任。

7. Confidentiality 保密

When performing the obligations under the Transaction Documents, Supplier may have access to private or confidential information of Novartis, including, but not limited to, technical information, sales, cost and other unpublished financial information, product and business information, marketing data and plans and trade secrets ("Confidential Information"). Supplier acknowledges and agrees that the Transaction Documents themselves, the Works, Inventions, and all knowledge related to Novartis that Supplier may gain from its performance of the obligations under the Transaction Documents shall be deemed Confidential Information owned by Novartis. Supplier agrees that: (i) all Confidential Information shall remain the exclusive property of Novartis; (ii) it shall maintain, and shall use prudent methods, but in no event less than commercially reasonable efforts, to cause its employees (and, if approved pursuant to the applicable Transaction Documents, its sub-contractors and agents) to maintain the confidentiality and secrecy of the Confidential Information; (iii) it shall not, and shall use prudent methods to ensure that its employees, subcontractors and agents do not, copy, publish, disclose to any third parties or use (other than pursuant to the terms hereof) the Confidential Information; and (iv) it shall return or destroy all copies of Confidential Information upon request of Novartis, and promptly certify in writing as to such destruction having occurred. The obligation of non-disclosure by Supplier shall not apply where the Supplier is required to disclose Confidential Information pursuant to judicial process, court order or administrative request, provided that Supplier has notified Novartis sufficiently in advance of any such disclosure so as to allow Novartis to seek a protective measure. Supplier shall keep Confidential Information confidential pursuant to the provisions under Appendix A hereto.
在履行交易文件规定的义务之时，供应商可能接触诺华的隐私或者保密信息，包括但不限于技术信息、销售、成本以及其他未公开的财务信息、产品及业务信息、市场数据以及计划和商业秘密（统称"保密信息"）。 供应商承认并且同意交易文件本身、作品、发明以及供应商从履行交易文件义务的过程中可能获得所有与诺华有关的讯息将被视为诺华拥有的保密信息。供应商同意 (i) 所有保密信息均为诺华的专有财产；(ii) 其应保持并采用谨慎的方法，但在任何情况下，不低于商业上的合理努力，确保其员工（如果适用的交易文件批准，其分包商和代理商）保持保密信息的保密性； (iii) 其应使用谨慎方法确保其员工、分包商以及代理商不会复制、出版、向任一第三方披露或者（未按照交易文件条款规定）使用保密信息； (iv) 按照诺华要求，归还或者销毁所有保密信息复印件，及时提供销毁的书面声明。供应商不披露的义务将不适用于根据司法程序、法院命令或行政要求必须披露的保密信息。 这种情况下，供应商应事先通知诺华该等披露，以便其能够寻求保护措施。供应商应根据附件 A 的标准保护保密信息。

8. Compliance with the Law and Policies 法律和政策合规

Supplier hereby represents and warrants that:
供应商兹此陈述并保证：

(a) In exercising its rights and performing its obligations under the Transaction Documents, Supplier will (and will ensure that its Personnel will):
  (1) not promise, offer, pay, cause to pay, accept payment or induce payment or take any action that could be considered a bribe;
  (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);
  (3) comply with industry standards;
  (4) comply with all policies and guidelines (and any updates to the same) referenced or included in the Transaction Documents or otherwise provided in written form (including electronically) during the term of the Transaction Documents by Novartis to Supplier; and
  (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.

  在行使交易文件规定的权利并履行其中规定的义务的过程中，供应商将（并确保其人员将）：
  (1) 不得承诺、提供、支付、促使支付、接受支付或诱使支付，或采取任何可能被视为贿赂的行动；
  (2) 遵循所有适用的法律和法规，包括与反贿赂和反腐败相关的法律（例如但不限于美国反海外腐败法和英国反贿赂法案）；

(3) 遵守行业标准；
(4) 在交易文件有效期内，遵守诺华以书面形式（包括电子方式）提供与交易文件有关的所有政策和指南以及对这些政策和指南的更新；且
(5) 确保其拥有适当且有效的道德、风险、合规组织以及促进道德商业实践的系统或政策（包括其规模、经营范围和业务活动的性质）。

(b) The Supplier shall comply with all requirements of the Doing Business Ethically - The Novartis Anti-Bribery and Professional Practices Policy ("DBE Policy" which can be viewed and downloaded from https://www.novartis.com/esg/reporting/codes-policies-and-guidelines) as updated from time to time to the extent such requirements are applicable to the Services/Products being provided by the Supplier hereunder. Without limitation, the Supplier shall：

(1) it shall perform its duties under the Transaction Documents in compliance with all applicable laws, regulations, ordinances and rules, including but not limited to those applicable laws described under sub-sections (a) above, and the provisions in relation to anti-bribery in the Criminal Law, Anti-Unfair Competition Law, the Provisional Regulations on the Prohibition of Commercial Bribery and Foreign Corruption Practices Act of USA, etc.;
(2) not promise, offer, pay, cause to pay, accept payment or induce payment or take any action that could be considered a bribe;
(3) abide by the industry codes of conducts of RDPAC (China Association of Enterprises with Foreign Investment R&D-Based Pharmaceutical Association Committee) (see http://cnadmin.rdpac.org/upload/upload_file/1575297067.pdf) when performing the duties under the Transaction Documents (including but not limited to (x) not to provide or to offer HCPs (Healthcare Professionals) with any cash or cash equivalents that could have an inappropriate influence on HCP's decision to prescribe, dispense, recommend, purchase, supply or administer products, and (y) any interaction with HCPs should serve the ultimate purpose of improving patient care and/or practice of medicines);
(4) ensure any promotional, non-promotional or internal use only content prepared by the Supplier for Novartis' benefit are pre-approved in advance under Novartis procedures as required before any dissemination or publication;
(5) ensure any giveaways, cultural acknowledgments, medical utility items and all events, activities or interactions organized by Supplier for the purpose of the Services are pre-approved in advance under Novartis procedures as required;
(6) ensure that Novartis' involvement is transparent and disclosed in accordance with applicable laws and Novartis procedures as required;
(7) comply with the Novartis travel policy and maximum reimbursement policies on meals, expenses, travel and fees for any healthcare professionals, healthcare institutions or other third parties engaged, contracted or paid by Supplier for the purpose of the Services;
(8) ensure any benefits, fees, expenses paid or provided to healthcare professionals, healthcare institutions or other third parties on behalf of Novartis, are fair market value and not any form of inappropriate inducement to prescribe, supply, administer, recommend or buy Novartis' products;
(9) ensure that it has obtained all necessary employer, industry association and government approvals to pay any fees or expenses to healthcare professionals, healthcare institutions or other third parties by the Supplier for the purpose of the Services;
(10) Supplier shall comply with the following obligations in relation to vigilance:

i） Supplier 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.

ii） Based on the nature of the Services, Supplier 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.

iii） The definitions of terms defined below such as "Adverse Event" (or "AE"), "Adverse Drug Reaction" (or "ADR") and special situations (as further explained in this Clause 8(b)(10)) 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 Novartis product (i.e. a medicine and/or a medical device) that does not necessarily have to have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (e.g., abnormal laboratory finding), symptom or disease that is temporally associated with the use of a Novartis product (i.e. a medicine and/or a medical device), whether or not it has a causal relationship with such product.

An Adverse Drug Reaction (ADR) is 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.

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.

Supplier will forward all Adverse Event (AE) reports, reports on special situations (i.e. overdose, abuse, misuse, off-label use which are associated with Adverse Event (AE) or pregnancy or breast-feeding (with or without an adverse outcome) or off-label use in pediatrics, rebound effect, drug dependance, drug addiction, occupational or accidental exposure, suspected transmission of infectious agents, lack of efficacy, pregnancy, lactation, withdrawal syndrome, disease progression and aggravation, treatment non-compliance, medication errors, interactions), technical complaints involving potential AEs and for devices in addition device deficiencies, malfunctions, user errors or medical complaints, that Supplier 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 by Supplier or its Personnel.

Supplier shall request the reporter to give permission to provide its contact information to Novartis to facilitate follow-up on the report if needed.

iv） The obligations contained in this Clause 8(b)(10) 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).

v） All reporting in accordance with this Clause 8(b)(10) shall be made by Supplier 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.report.novartis.com/, as may be directed by Novartis.

Novartis may change the above website details provided the Supplier is given notice in writing of such change.

Supplier hereby agrees to maintain all Records for the applicable Records Retention Period as defined in the Master Services Agreement or General Terms and Conditions.

vi） The Parties hereby agree that the obligations in this Clause 8(b)(10) 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 8(b)(10);

(11) if the Service falls into the scope of Novartis POP group 1 or group 2, the Supplier and its employees shall comply with the standard vigilance contractual provisions of Novartis Patient Oriented Program (POP) group 1 and group 2 under Appendix E; if the Service falls into the scope of Novartis POP group 3, the Supplier and its employees shall comply with the *AE Reporting Clause* under Appendix E;

(12) if the Service falls into the scope of SML and/or DEA (or falls into the scope of DEA and Novartis POP group 3 at the same time), ensure that it will comply with the pharmacovigilance provisions of Social Media Listening (SML) Program and/or Digital Engagement Assets (DEA) Program as set out Appendix F;

(13) for non-interventional circumstances, the Supplier shall within the validity of the Transaction Documents ensure itself and/or its subcontractors completely and continuously terminate the social media interactive functions, including but not limited to voice, text, photos, etc and any form of comments or other interactive features;

(14) comply with all policies and guidelines provided to it by Novartis in relation to the Supplier's activities under the Transaction Documents, including but not limited to the Doing Business Ethically - The Novartis Anti-Bribery and Professional Practices Policy (see Appendix B). In the event that Novartis issues additional guidelines or policies (or updates to existing guidelines or policies) in relation to the Supplier's activities under the Transaction Documents, Novartis will provide the Supplier with a copy and the Supplier will duly comply with such guidelines and policies thereafter. The Supplier hereby confirms that it has read and understood all Novartis' policies and guidelines provided to it; and

(15) ensure that it has obtained all necessary privacy and intellectual property consents for individuals to participate and for Supplier to provide the required Services (including the data, deliverables, personal data) in accordance with Novartis' intended use.

若《赢之有道-诺华反贿赂与专业互动政策》（"DBE 政策"，包括其不时更新的版本，可通过以下链接查阅和下载(https://www.novartis.com/esg/reporting/codes-policies-and-guidelines)）适用于供应商在交易文件下下提供的服务/产品，则供应商应遵守 DBE 政策下的所有要求，包括但不限于：

(1) 供应商应当以符合适用的法律、法规、条例和规则的方式履行交易文件中要求的职责，包括但不限于上述第(a)款所述适用的法律、与刑法反贿赂相关的规定、反不正当竞争法、禁止商业贿赂行为的暂行规定以及美国反海外腐败法等；

(2) 不得承诺、提供、支付或让人支付、收受款项或诱导付款或采取任何可被视为贿赂之行动；

(3) 在履行交易文件要求的职责时应当遵守 RDPAC(中国外商投资企业协会药品研制和开发行业委员会)的相关行业行为规范(见 http://cnadmin.rdpac.org/upload/upload_file/1575297067.pdf)，(包括但是不限于

(x)不向 HCPs(医疗卫生专业人士)提供任何现金或者对 HCP 在处方、分配、推荐、购买、供应或管理产品方面有任何不良影响的现金等价物，以及(y)与 HCP 的任何互动都应当秉承以提高患者护理和/或药物治疗为最终目的；

(4) 供应商应确保其为诺华权益而准备的任何推广、非推广或仅供内部使用的资料内容在其对外散播或出版前均已根据诺华的政策获得事先批准；

(5) 供应商应确保其为提供服务而组织安排的风俗礼品、医用物品及所有活动、安排或互动均已根据诺华的政策获得事先批准；

(6) 供应商应确保诺华的参与是公开透明的，且已根据适用法律和诺华政策予以披露；

(7) 对于供应商就其为提供服务之目的而聘请、缔约或产生支付义务的医疗卫生专业人士、医疗卫生机构或其他第三方，其应遵守诺华差旅政策，且相关费用的报销金额不得超过诺华有关餐饮、费用、差旅或服务费的最高限额；

(8) 供应商应确保其代表诺华向医疗卫生专业人士、医疗卫生机构或其他第三方提供或支付的任何利益、费用、金额均符合市场公允价值，且不构在处方、供应、管理、推荐或购买诺华产品方面的任何不当诱导；

(9) 供应商应确保其已获得用人单位、行业协会和政府机构的所有必要的批准从而得以为提供服务之目的向医疗卫生专业人士、医疗卫生机构或其他第三方支付任何费用或款项；

(10) 供应商应履行以下警戒相关义务:

i) 供应商承认诺华和/或其关联公司（以下简称“诺华集团”）作为本协议所述区域内医药产品/医疗器械的注册持有人或生产商应履行特定警戒义务，以满足全球适用的监管规则和指南。

ii) 根据服务的性质，供应商及其工作人员可能会与诺华集团公司为注册持有者或生产商的产品的患者、处方者、医生或其他消费者联系。

iii) 下列术语的定义如“不良事件”（或“AE”）、“药品不良反应”（或“ADR”）和特殊情况（见在本条款 8(b)(10)中的进一步解释）符合欧盟和全球指南（指令 2001/83/EC；ICH 指南 E2A 和 E2D），并应适用于本协议。

不良事件（AE）是使用诺华产品（即药品和/或医疗器械）的患者或临床试验受试者发生的任何不利医学事件，它并不一定与该产品有因果关系。因此，AE 可以是在时间上与使用诺华产品（即药品和/或医疗器械）有关联的任何不利的和非预期的体征（例如：实验室结果异常）、症状或疾病，无论其是否与该产品有因果关系。

药品不良反应（ADR）是指药品的有害和非预期反应。在这种情况下，反应是指药品与不良事件之间至少具有合理因果关系的可能性。

在本协议中，上述定义中的药品也应适用于医疗器械。

如果提供/履行服务的区域内的地方法律、法规和/或指南对于 AE/ADR 具有更广泛的含义，则在本协议中，这些表述应具有更广泛的含义。

供应商将在 24 小时内 将供应商或其工作人员从服务提供/交付区域收到的与诺华集团产品/医疗器械相关的所有不良事件（AE）报告、特殊情况（即用药过量、滥用、故意误用、超说明书使用伴不良事件、伴妊娠或哺乳或用于未被批准的儿童、症状反弹、药物依赖、药物成瘾、职业或意外暴露、通过药物治疗传播感染性疾病、缺乏疗效、妊娠期暴露、哺乳期暴露、戒断反应/症状、疾病进展和加重、治疗不合规伴 AE、意外获益、用药错误、相互作用）、涉及潜在不良事件的技术投诉以及器械缺陷、故障、用户错误或医疗投诉的报告（以下统称为“警戒报告”）作为源文件转发给诺华。

供应商应要求报告者允许向诺华提供其联系信息，以便在需要时对报告进行跟进。

iv) 本第 8(b)(10)条所规定的义务应在本协议终止后一（1）年内存续，但记录保留相关义务除外（记录保留期限应在所有相关记录保留期限到期前存续）。

v) 根据本第 8(b)(10)条规定进行的所有报告应由供应商通过本协议随附的特定国家不良事件表进行或由诺华另行提供，且如未随附或提供，按诺华公司指示，通过以下网站进行报告：https://www.report.novartis.com/。

诺华可变更上述网站的详细信息，前提是供应商收到了此类变更的书面通知。

供应商在此同意在相关记录保留期内保留所有记录。（记录及记录保留期定义见双方签订的主协议或一般条款与条件）。

vi) 双方在此同意，本第 8(b)(10)条中的义务适用于双方未约定更详细/具体警戒义务的所有服务（比如，在 POP、社交媒体倾听/数字化互动资产项目相关服务背景下的义务）。如果双方就特定服务约定了更为详细的/具体的警戒义务，则后者应适用于该等特定服务，而非本第 8(b)(10)条规定的义务。

(11) 若有项目属于诺华面向患者项目第 1 组或第 2 组的范围时，供应商及其雇员应当遵守**附件 E** 中的 POP 第 1 组和 POP 第 2 组面向患者项目的标准警戒合同条款；若有项目属于诺华面向患者项目第 3 组的范围时，供应商及其雇员应当遵守**附件 E** 中的 *AE 报告条款*;

(12) 若有项目属于诺华社交媒体倾听项目和/或数字化活动资产（或同时属于数字化互动资产和诺华面向患者项目第 3 组）的范围时，供应商应确保其遵守**附件 F** 所列的关于社交媒体倾听项目和/或数字化互动项目的药物警戒条款;

(13) 若无互动情形，供应商应当确保在协议有效期内其自身和/或其第三方分包商完全、持续地关闭该等社交媒体的互动功能，包括但不限于语音、文字、照片等任何形式的评论或其他互动功能；
(14) 在交易文件涉及的相关活动中，供应商应当遵守诺华提供的所有政策和准则，包括但不限于《赢之有道-诺华反贿赂与专业互动政策》(见附件 B)。若诺华就供应商在交易文件下的活动发布任何其他准则或政策（或对现有准则或政策有任何更新），诺华将向供应商提供一份副本，且供应商应在此后遵守该等准则和政策。供应商兹此确认已阅读并理解所有诺华向其提供的政策和准则；和
(15) 供应商应确保其已根据诺华拟定的用途就相关个人的参与以及其提供所需服务（包括数据、产出和个人信息）获得了所有必须的隐私或知识产权同意函。

(c) all goods manufactured, packaged, labelled, licensed, tested, certified, inspected or delivered under the Transaction Documents have been or will be produced, packaged, labelled, sold and delivered in accordance with all applicable laws, treaties, codes, licenses, rules, binding requirements and regulations, including, by way of example, all laws and regulations relating to health, safety, employment, transportation, hazardous materials, toxic substances, environments, serial and identification numbers, labelling and country of origin/destination and custom requirements;
所有按照交易文件需要生产、包装、标记、许可、测试、认证、检查或交付的商品已经或将按照所有适用的法律、条约、法规、许可证、规则、约束性要求和法规（包括例如所有与健康、安全、就业、运输、危险材料、有毒物质、环境、序列号和识别码、标签和国家的原产地/目的地以及海关要求相关的法律和法规）进行生产、包装、标签、销售和交付。

(d) Supplier agrees to execute and/or furnish to Novartis as requested, all certifications, guaranties and other documents regarding compliance with laws and regulations;
供应商同意按照诺华的要求签署和/或提供与符合法律法规有关的所有认证、担保以及其他文件。

(e) it shall provide the services/goods (x) in a timely and professional manner, consistent with applicable industry standards and practices, (y) in conformance with that level of care and skill exercised by other professionals in similar circumstances but in any event no less than reasonable care and skill; and (z) with high ethical and moral business and personal integrity standards;
供应商应当(x)在符合适用的行业标准和操作实践的情况下以及时和专业的方式提供服务/产品；(y) 以其他专业人员在类似情况下所能达到的专业和技术水平提供服务/产品；但在任何情况下，都不低于合理的专业和技术水平；和(z)以高尚的道德和个人诚信标准提供产品/服务。

(f) Supplier presently, and will remain, during the term of the Transaction Documents and any extension thereof, free from any commitments or conflicts of interest that would prevent Supplier from performing its obligations to Novartis. In the course of rendering the services or providing the goods, Supplier will not violate and has not violated any prior confidentiality agreement, employment contract or any other duty owed to any other third party; and
在交易文件有效期以及延展期内，供应商目前并将继续不受限制地其向诺华履行义务，而不会被任何承诺或利益冲突所制约或阻碍。在提供服务或提供产品的过程中，供应商不会违反，并不曾违反任何在先的保密协议、劳动合同或任何向第三方所负的义务；以及

(g) all goods to be delivered under the Transaction Documents will be of merchantable quality, free from any latent or patent defects in design, materials or workmanship, will conform to Novartis's specifications, descriptions and samples, will conform to the requirements of the Transaction Documents and will be safe for their intended use, and no goods manufactured, packaged, labelled, licensed, tested, certified, inspected or delivered under the applicable Purchase Order, is, as of the date of shipment are fake or with low quality.
所有交易文件下交付的商品将符合商品质量要求，在设计、材料或工艺方面无任何潜在的或明显的瑕疵，将符合诺华的规格、描述和样品要求、满足交易文件要求、并能够安全使用于既定目的。根据适用的采购订单生产、包装、标记、许可、测试、认证、检查或交付的商品截止装运日期时没有任何赝品和劣质品。

9. Assessment, Notification of Organizational Changes 评估，组织变更通知

9.1 Supplier acknowledges and agrees that Novartis may require Supplier to complete, as part of its External Partner Risk Management processes, a Questionnaire for Third Parties. Supplier 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 Transaction Documents). Supplier warrants and represents that the information provided in any Questionnaire for Third Parties (whether provided before or during the Transaction Documents, including updates to the same) is accurate and complete (and such information shall be treated as being part of the Transaction Documents).
供应商承认并同意诺华可能会要求供应商完成第三方调查问卷，作为其外部合作伙伴风险管理流程的一部分。供应商将自费与诺华和/或诺华人员充分合作，按照合理的指示完成并交还任何第三方调查问卷（以及在协议期限内要求的任何更新）。供应商保证并声明在任何第三方调查问卷中提供的信息（无论是在协议之前或期间提供，包括对其更新）是准确和完整的（并且此类信息应被视为交易文件的一部分）。

9.2 Supplier 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 Supplier or person who Controls Supplier or there is a change to the membership

of the executive body of Supplier. For example, a change to the executive management of Supplier (e.g., CEO, N-1 to CEO), in both cases as soon as reasonably practicable after the relevant change occurs.
供应商将书面通知诺华：(i) 第三方调查问卷所提供信息的任何重大变更；和 (ii) 供应商的控制权或控制供应商的人发生任何变化，或供应商执行机构的成员发生变化。例如，在相关变更发生后合理可行的情况下尽快对供应商的执行管理层（例如，CEO，N-1 到 CEO）进行变更。

9.3 This Clause 9 applies to Supplier only, and not to any subcontractor engaged by it in accordance with the terms of the Transaction Documents.
第 9 条仅适用于供应商，不适用于其根据协议条款聘用的任何分包商。

10. Records Retention and Audit 记录保留和审计

10.1 Supplier 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 Supplier's information security obligations under the Transaction Documents, Supplier 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.
供应商将，以及确保其人员将按照记录保留期限保存和维护完整、适当和准确的记录。在不限制交易文件项下供应商的信息安全义务的情况下，供应商应自费将所有记录保存在安全和合适的设施中，并确保在记录保留期内，诺华（和/或其指定的审计人员）在审计时有权访问此类设施以及存储在此类设施中的相关记录。

10.2 For the purpose of ensuring Supplier's compliance with the Transaction Documents and to confirm all Relevant Payments, Supplier 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 Transaction Documents and for five years thereafter (except as otherwise specified in the Transaction Documents) to audit and have access to: (i) all Records; (ii) Supplier's compliance/anti-corruption program; (iii) any and all premises/facilities, networks, data processing and/or records retrieval systems owned, used or controlled by Supplier relating to or connected with the Transaction Documents; 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 Supplier 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 Supplier (including, without limitation, documentation with third parties relating to the audit scope and Supplier's corporate structure), respective evidences and proofs and all written explanations provided by Supplier to confirm its compliance with the provisions of the Transaction Documents and Relevant Payments. Any audit (and related data collection activities) shall be carried out in compliance with applicable laws.
为确保供应商遵守交易文件及确认所有相关款项（定义如下），在交易文件期限内和此后五（5）年内（协议中另有规定的除外），供应商同意并将确保其人员同意（在必要时）诺华（和/或其指定的审计人员）将有权在任何时候发出合理的事先通知，以审计和访问：（i）所有记录；(ii) 供应商的合规/反贿赂计划；(iii) 供应商拥有、使用或控制与交易文件相关的所有场所/设施、网络、数据处理和/或记录检索系统；以及(iv) 诺华和/或其指定的审计师合理地履行其审计职责所必需的任何其他信息。本条款下提及的审计和访问权包括但不限于与供应商人员进行面对面和/或在线访谈的权利，访问和审查供应商内部政策（电子或纸质版）、内部审计报告、标准操作程序要求（“SOPs”）、程序、指南和/或其他内部文件（包括但不限于在审计范围内的材料和供应商公司结构）、证据、证明以及供应商提供以确认其遵守协议和相关付款规定的所有书面解释。任何审计（及相关数据收集活动）均应按照适用法律进行。

10.3 Novartis may appoint an auditor to perform the audit referenced in Clause 10.2 above, and, if so, the appointed auditor will be subject to appropriate confidentiality obligations in relation to its review of Supplier's Confidential Information. Upon written notice (simple email to be sufficient) by Novartis that it wishes to conduct an audit, Supplier will promptly provide full cooperation and comply with the requirements of this Clause.
诺华可指定审计师进行上述第 10.2 条中提及的审计，且在该等情况下，受指定的审计师在审查供应商保密信息时应遵守相关保密义务。根据诺华向供应商发出的有关审计书面通知（包括电子邮件），供应商应立即全力予以配合并遵守本条款约定要求。

10.4 Each party shall bear its own costs and expenses of any audit conducted pursuant to this Clause.
各方应自行承担根据本条款进行的任何审计的成本和费用。

10.5 Following an audit, Novartis may discuss its/or its appointed auditor's findings with Supplier. Supplier will, acting reasonably and without undue delay, put forward a plan (including a timetable to implement and complete the plan) to address any concerns 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 Supplier, Supplier 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 Supplier. Supplier 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.
审计完成后，诺华可能会与供应商讨论其/或其指定审计人员的调查结果。供应商将合理且无不当拖延地提出计划（包括实施和完成计划的时间表），以解决审计中发现的任何问题（“补救计划”）供诺华审阅，并将合理考虑诺华对此类补救计划的建议（如有）。尽管诺华向供应商提供了任何建议，但供应商仍负责实施此类补救计划，并确认且同意就其依赖此类建议

做出的任何决定或实施后果自负风险，此类建议由供应商自行决定是否接受并承担责任。供应商将遵守补救计划列明的措施，并将采取所有其他必要措施进行补救，并随后继续履行其义务，诺华不承担任何额外成本或费用。

10.6 Nothing in this Clause requires Supplier 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.
本条款中的任何内容均不要求供应商出于审计目的提供有关利润、利润率、管理费用或资本成本的信息（与转嫁成本或任何以成本加成为基础的费用计算有关的信息除外）。

10.7 To the extent that Supplier demonstrates that access to certain areas of its facilities/premises would cause a breach of its confidentiality undertakings to its other customers, Supplier 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, Supplier shall not refuse to provide access to a Record based on its confidentiality status.
如果供应商证明访问其设施/场所的某些区域会导致违反其对其他客户的保密承诺，供应商可以采取合理的变通办法（而不是提供对这些特定区域的访问），以使诺华和/或其指定的审计人员能够获得审计所需的资源和信息以进行审计。对于该类记录，供应商不得以其处于保密状态而拒绝提供对该类记录的访问。

Records means all data, information, text, drawings, books, records (including without limitation financial and training records), expense reports, documents or other materials of Supplier recorded in any form (including those created for and on behalf of Supplier by its Personnel) relating to or connected with the Transaction Documents and/or the performance of all its obligations under the Transaction Documents (including without limitation obligations relating to payments made by Novartis to Supplier). 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).
记录是指以与交易文件有关的任何形式记录或为履行交易文件项下的所有义务（包括但不限于诺华付款义务等）而形成的供应商的所有数据、信息、文本、图纸、账簿、记录（包括但不限于财务和培训记录）、费用报告、文件或其他材料（包括由供应商及其关联方创建和/或代表供应商创建的材料）。为此目的，记录不包括任何受法律特权（无论是法律专业特权或诉讼特权，或其他司法管辖区的同等权利）保护的数据、信息、文本、图纸、账簿、记录、文件或其他信息。

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 Transaction Documents (or the applicable related Transaction Documents issued thereunder) plus ten years; (c) the date that the parties agree that all matters arising from or in connection with the Transaction Documents 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 Supplier from time to time.
记录保留期是指必须保留每份记录的期限，即直至以下日期的最晚日期： (a) 适用法律/法规/会计准则对每份记录指定的最早日期；(b) 交易文件及其相关协议到期/终止后十（10）年； (c) 双方同意由交易文件或该记录引起或与之相关的所有事项最终完成的日期； (d) 根据诺华不时书面告知的记录保留期限。

Relevant Payments means any and all payments made: (i) by Novartis to Supplier; or (ii) made by Supplier, either for and on behalf of Novartis, or on its own account, and in each case, directly relating to the obligations of Supplier under the Transaction Documents.
相关付款是指以下任何及所有付款：(i) 诺华向供应商支付的款项；或 (ii) 由供应商为诺华并代表诺华或以自己的名义作出，并且在每种情况下，与供应商在交易文件项下的义务直接相关。

11. Anti-Bribery Training 反贿赂培训

11.1 Subject to Novartis requesting otherwise, Supplier will be responsible for training all of its Personnel (including approved contractors) engaged in performing the activities set forth in these Transaction Documents 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 the standards provided by Doing Business Ethically - The Novartis Anti-Bribery and Professional Practices Policy and shall take place prior to the performance of Services for Novartis. Supplier will ensure that the AB Training is performed for any new personnel (including approved contractors) that Supplier later wishes to engage to provide the Services to Novartis. Supplier 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 Supplier 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 Supplier premises (directly or via its Personnel) the AB Training (or any part thereof). If Supplier 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 Traning, providing all reasonable and necessary access for such purpose to Supplier premises and relevant Personnel engaged to provide Services to Novartis.

除非诺华另行要求，否则供应商应自费对所有参与执行交易文件的新进和原有人员（包括经批准的承包商）进行反贿赂培训（"反贿赂培训"）。反贿赂培训至少应包括适用的反贿赂和反腐败法律之条文内容以及《赢之有道-诺华反贿赂与专业互动政策》中规定的标准，并且该反贿赂培训应在供应商及其人员执行交易文件之前进行。供应商将确保所有反贿赂培训均由合格的培训师提供，并提供符合本条款要求的培训材料。

诺华有权：（i）要求供应商促使其人员通过诺华（直接或通过其关联公司或分包商）提供的培训模块在线进行反贿赂培训；或 (ii) 要求在供应商的场地直接或通过其关联公司/分包商提供反贿赂培训（或反贿赂培训的任何一部分）。如果供应商收到任何此类请求，则其特此同意自担费用与诺华全力合作以进行反贿赂培训，包括在现场进行反贿赂培训的情况下，提供所有合理必要的进入供应商工作场所的途径并安排相关人员为诺华提供必要的协助/服务。

11.2 In the case of Supplier engaging a subcontractor in accordance with the terms of the Transaction Documents, Supplier shall remain directly responsible for ensuring compliance with the above training obligations.
如果供应商根据交易文件条款聘用分包商，供应商仍应确保分包商遵守上述培训义务。

12. AB Policy Remediation 反贿赂政策补救

12.1 In certain cases, Novartis may request Supplier to undertake an online Code of Conduct module developed by Novartis ("CoC Module"). As part of this CoC Module, Novartis requires Supplier 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). Supplier 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.
在某些情况下，诺华可能会要求供应商采用由诺华开发的在线行为准则模块（"CoC 模块"）。作为此 CoC 模块的一部分，诺华要求供应商独立制定新的行为准则或更新其现行的行为准则，该准则应当包含反贿赂条款，并以适用的国际标准（例如联合国开发计划署的标准）为模型。供应商将自费与诺华全面合作完成 CoC 模块，并将以合理、无不当拖延和善意的方式执行因完成 CoC 模块而产生任何行为准则政策整改要求。

12.2 During any pre-contract or post-contract signature due diligence performed by Novartis (or its Personnel), Novartis may identify gaps in Supplier's anti-bribery compliance programme ("AB Compliance Process Gaps"). Where such AB Compliance Process Gaps are identified, Novartis may request that Supplier put forward a remediation plan to cover such AB Compliance Process Gaps and the parties agree that Clause 10.5 shall apply, mutatis mutandis, to the preparation of such remediation plan.
在诺华签署合同前后的尽职调查期间，诺华可能会发现供应商反贿赂合规计划中的差距（"反贿赂合规流程漏洞"）。如果发现此类反贿赂合规流程漏洞，诺华可要求供应商提出涵盖该等反贿赂合规流程漏洞的整改计划，并且双方同意第 10.5 条的规定在细节上作适当修正后应适用于该等整改计划的制定。

13. Annual Compliance Confirmation 年度合规确认书

13.1 Supplier 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 **Appendix G** or any materially equivalent updated form notified to Supplier 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 Supplier 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 Supplier, 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"), Supplier 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.
供应商将应诺华（或其人员）的要求，在每个报告期向诺华提供（或让授权的关联公司或代表其）以附件 G 所附表格或诺华或其人员不时通知供应商的任何实质性等效的更新表格正式完成的年度合规确认书（每一份"年度合规确认书"）。诺华可以选择指示其人员代表其收集每份年度合规确认书，供应商将出于此类目的与诺华人员合作（并促使其授权附属公司代表其就年度合规确认书进行合作）。如果供应商或其关联公司与诺华/诺华关联公司签订了多份未到期的合同，并且该等合同要求提供年度合规确认书（每份均为"现有合同"），供应商可提供（或由其经正式授权代表其行事的一家关联公司提供）涵盖多个现有合同的年度合规确认书。除非诺华（或其人员）另有指示，否则年度合规确认书应在相关报告期结束后三 (3) 个月内提交。

13.2 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 17.3, Supplier 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.
仅就本条款而言，"报告期"在每种情况下均指十二个月的期间，即从诺华（或其人员）在年度合规确认书请求中指定的日期开始的第一个报告期以及从第一个报告期周年日开始的每个后续报告期。就第 17.3 条而言，如果合规确认书在到期超过 30（三十）日未提交年度合规确认书将视为重大违约。

13.3 The obligation to provide an Annual Compliance Confirmation applies to Supplier (and not to is subcontractors, provided that the Annual Compliance Confirmation of Supplier shall cover the performance/compliance of Supplier and its Personnel).
提供年度合规确认书的义务仅适用于供应商（不包括分包商，前提是供应商的年度合规确认书应涵盖供应商及其人员的履行情况/合规）。

14. Indemnity 赔偿

14.1 Supplier shall indemnify, defend and hold Novartis and its affiliates (including their respective officers, directors, employees, contractors and agents) harmless from and against any and all third party claims, demands, causes of action, damages, liabilities, losses, costs and expenses (including reasonable attorneys' and experts' fees), penalties, and compensatory, multiple, exemplary, and punitive damages (collectively, the "Claims"), arising out of, or resulting from (a) the negligence or wilful misconduct of Supplier and/or its Representatives in the performance of any of its duties under the Transaction Documents (for the purpose of this Section the term "Representatives" includes the Supplier's employees, subcontractors, agents, or assignees (including Supplier's employees and subcontractors)), (b) from the breach by Supplier or its Representatives of any of its warranties, representations or obligations under the Transaction Documents, (c) failure of Supplier or its Representatives to comply with any applicable government requirements or laws, or (d) any assertion that the Services infringe or misappropriate any intellectual property right or other right of any third party; all except to the extent that such Claims were caused by the gross negligence or wilful misconduct of Novartis.
供应商应赔偿、保护和确保诺华和其附属公司(包括其各自的管理层、董事、雇员、承包商和代理)免遭任何由以下行为直接或间接引起的第三方索赔、要求、诉讼请求、损失、责任、损害、成本和费用(包括合理的律师和专家的费用)、罚款、以及补偿性、多重性、示范性和惩罚性赔偿(统称"索赔")：(a)供应商和/或其代表在履行交易文件的义务时的疏忽或故意的不当行为 (本条款中的代表包括供应商的雇员、分包商、代理商或受托人(包括供应商的员工和分包商))；(b)供应商或其代表违反交易文件下任何保证、陈述或义务；(c)供应商或其代表未能遵守任何适用的政府要求或法律；或(d)被指服务侵犯或盗用任何第三方的知识产权；除非这样的索赔是由诺华的严重过失或故意的不当行为导致的。

14.2 Novartis shall give Supplier written notice of any Claims. Supplier shall be entitled to select counsel of its own choosing and shall bear all of the costs for the defense of the Claims. Novartis shall be entitled to participate in the defense and settlement of any Claims and reserves the right to retain counsel at its sole cost and expense. Supplier shall not (a) enter into a settlement of any Claims asserted against Novartis, or (b) agree to any remediation in connection with any release or threatened release for which Novartis may be primarily, jointly, or secondarily responsible however, whensoever and wheresoever occurring, without the written approval of Novartis. Supplier shall reasonably and timely inform Novartis of the progress of defense and potential settlement of any Claims and any required remediation. Novartis shall be entitled, if it so chooses, to assume the defense and settlement of any Claims brought against Novartis with counsel of its own choosing at its own expense.
诺华将书面通知供应商第三方索赔事宜。供应商有权选择自己的律师，并承担所有索赔的辩护费用。诺华有权参与任何索赔的辩护与和解，并保留自行承担费用聘请律师的权利。没有诺华的书面同意，供应商不得(a)达成任何针对诺华的索赔和解，或(b)就无论何时何处发生的，诺华可能承担主要、共同或者次要责任的事件，达成补偿协议。供应商应合理并及时告知诺华索赔的辩护进程和潜在的和解方案以及任何被要求的补偿。诺华有权（如果选择该方式），自己承担费用选择律师进行索赔的辩护以及和解。

14.3 EXCEPT WITH RESPECT TO INDEMNITY OBLIGATIONS, BREACH OF CONFIDENTIALITY OBLIGATIONS, OR THE GROSS NEGLIGENCE OR WILLFUL MISCONDUCT OF A PARTY, IN NO EVENT SHALL EITHER PARTY BE LIABLE FOR ANY SPECIAL, INDIRECT, CONSEQUENTIAL, EXEMPLARY OR INCIDENTAL DAMAGES ARISING OUT OF OR RELATING TO THE TRANSACTION DOCUMENTS, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.
除有关赔偿义务、违反保密义务或者重大过失或故意不当行为，在任何情况下，任何一方都不对任何由交易文件产生的或由其引起的特殊性、间接性、结果性、示范性或附带性损害承担责任，即使该方已被告知此类损害的可能性。

15. Insurance 保险

Upon request of Novartis, Supplier shall procure insurance as requested by Novartis and provide reasonable evidence of its insurance.
若诺华要求，供应商应购买诺华要求的保险并向诺华提供购买保险的合理凭证。

16. Tax 税务

Unless otherwise provided under the Transaction Documents, Supplier shall be solely responsible for any applicable taxes associated with payments made to Supplier pursuant to the Transaction Documents. Supplier shall indemnify Novartis for any liability that Novartis may face as a result of Supplier's failure to pay any such taxes. Novartis shall be liable only for those taxes imposed on a purchaser of services/goods by operation of law.
除非交易文件另有明确约定，对于诺华根据交易文件向供应商付款而产生的所有相关税赋，应由供应商完全独立承担。若供应商未能遵守上述约定承担税款而导致诺华承担任何责任，供应商应予以补偿。诺华仅承担根据适用法律作为服务/产品采购方而需承担的税款。

17. Termination 终止

17.1 Notwithstanding anything to the contrary contained in the other Transaction Documents, the Transaction Documents and any Work Order/Statement of Work issued thereunder may be terminated by Novartis without cause upon not less than thirty (30) or fewer (if so provided in the other Transaction Documents) days' written notice to Supplier. For services performed or goods delivered prior to the effective date of termination, Supplier shall be entitled to be compensated pro rata (including reimbursement for authorized expenses) for all services executed or goods delivered in a satisfactory manner and in accordance with the Transaction Documents and any applicable Work Order/Statement of Work. Otherwise, Novartis is not liable for breach of contract or compensation.

不论其他交易文件是否有相反约定，诺华可以在任何情况下提前至少三十（30）天或提前更短的期限（若其他交易文件中有相关约定）书面通知供应商终止交易文件和任何出具的工作订单/工作说明书，而无须给出任何原因。对于终止日期之前已提供的服务或已交付的产品，若该等服务/产品是根据交易文件及任何相关的工作订单/工作说明书以令诺华满意的方式提供的，则供应商有权按比例获得报酬（包括报销被批准费用）。除此以外，诺华无需承担违约或赔偿责任。

17.2 In the event that (a) either party becomes insolvent or is unable to pay its debts, or a petition in bankruptcy or for reorganization is filed by or against it, or a receiver is appointed of the whole or any substantial portion of its property; or (b) either party is in material breach of its obligations hereunder, which breach (if curable), remains uncured for thirty (30) days following receipt of written notice from the other specifying the breach, then the other party shall have the right to terminate the Transaction Documents and any Work Order/Statement of Work issued thereunder by written notice of such election.
如果(a)任何一方无力偿债或无法偿还其债务，或针对其破产或重组的申请已提起，或其财产的全部或实质部分已被任命接管人；或(b)任何一方严重违反其在本一般条款和条件下应尽的职责，且该等违反（如果可改正）在违约方收到另一方书面通知该等违反后的三十（30）天内仍未改正的，则另一方有权通过书面通知终止交易文件和任何已签发的工作订单/工作说明书。

17.3 Supplier agrees that, its failure to comply with:

i） the standards and requirements set out in the Third Party Code;
ii） any other requirements set out in clauses 20.13;
iii） any of the following clauses of the Transaction Documents: clauses 8(a), 9, 20.1, 20.2, 10, 11, 12 and/or 13; or
iv） its obstructing/refusing Novartis' audit rights as stated in the Third Party Code

shall constitute a material breach of the Transaction Documents and entitle Novartis (without limiting any other rights of Novartis) to immediately terminate the Transaction Documents by written notice without compensation.

供应商同意，如其未能遵守：

i) 诺华第三方准则中规定的标准和要求；
ii) 第 20.13 条规定的任何其他要求；
iii) 交易文件的以下条款：第 8(a)、9、20.1、20.2、10、11、12 和/或 13 条；或者
iv) 阻碍或拒绝第三方准则中规定的诺华审计权

将构成对交易文件的重大违约，并且诺华有权以书面通知的形式立即终止交易文件而无需支付任何赔偿（不限制诺华的任何其他权利）。

17.4 Furthermore, no matter whether Novartis terminates the Transaction Documents or not, Supplier shall be obligated to pay Novartis liquidated damages equalling to 20% of the total contract value hereunder for each material breach of the Transaction Documents. If the liquidated damages are not enough to cover the damages suffered by Novartis, Supplier shall further compensate the shortfall. In any termination event, the parties will cooperate to discontinue the services provision/goods supply in the most cost-effective manner possible.
此外，无论诺华是否终止交易文件，供应商应就每次严重违反交易文件的行为向诺华支付交易文件下合同总价值之 20%的金额作为违约金。若违约金不足以补偿诺华所遭受的损失，供应商应进一步补偿。若交易文件因任何原因被终止，双方应合作以成本最低的方式终止服务的提供/产品的供给。

17.5 Upon the termination of a Transaction Document, Supplier shall immediately return, and shall cause each employee, agent, subcontractor or other related contractor, to immediately return to Novartis any and all Novartis Information, works, and materials received from Novartis for the performance of Supplier's obligations under such Transaction Document.
交易文件终止时，供应商应立即自行并促使其每位员工、代理、分包商或其他相关供应商立即返还为履行交易文件下供应商的义务而从诺华收到的任何和所有的诺华信息、作品以及资料。

17.6 Termination of any Transaction Document shall be without prejudice to any claim or right of action of either party against the other party.
任何交易文件的终止不妨碍一方对另一方行使任何索赔或采取法律行动的权利。

18. Force Majeure 不可抗力

Neither party shall be liable for any failure or delay in performance under any Transaction Document (except for indemnity obligations) to the extent said failures or delays are proximately caused by causes beyond that party's reasonable control and occurring without its fault or negligence. Strikes, lock-outs and other labour related disputes shall not be regarded as an event beyond a party's reasonable control. The parties will meet and confer in good faith to determine the best solution to limit the consequences of any force majeure event. Notwithstanding the foregoing, to the extent that a force majeure event continues for a period in excess of three (3) months from the occurrence of such event, either party may terminate the related Transaction Document upon immediate written notice.
如果由于超出一方合理控制的事件而使得其未能履行或迟延履行任何交易文件下的义务（赔偿义务除外），且该一方没有任何疏忽或过失，则该方无须为该等未能履行或迟延履行承担任何责任（赔偿义务除外）。罢工、停工和其他劳资纠纷不得被视为是超出了当事人合理控制范围的事件。对于不可抗力事件，双方将真诚地协商以确定尽可能降低不可抗力事件影响的最

佳方案。尽管如此，若某一不可抗力事件自其发生之日起持续时间超过了三(3)个月，则任何一方可立即书面通知终止相关交易文件。

19. No Publicity 不宣传

Neither party nor their agents shall use the name, insignia, symbol, trademark, trade name or logotype of the other party or any of their affiliates (or any abbreviation or adaptation thereof) in any press release or other promotional material, or otherwise disclose the fact that it is a party to any Transaction Document (except to its affiliates and advisors), or make any other disclosure or statement effecting same without the other party's prior written consent unless such disclosure is required by applicable law or judicial order.
未经另一方事先书面同意，任何一方或其代理人不应当在任何新闻稿或其他宣传材料中使用另一方及其附属公司的名称、徽记、标志、商标、商号或标识（或其任何缩写或改写），或以其他方式披露其是参与交易文件一方的这一事实（向其附属公司或顾问披露的除外），或作出可达到相同效果的任何其他披露或陈述，除非这种披露是所适用的法律或司法判决要求的。

20. Miscellaneous 其他

20.1 **Subcontracting, Due Diligence and Monitoring.** Supplier is not entitled to sublicense or subcontract any of its obligations under the Transaction Documents without the prior written consent of Novartis. By entering into the Transaction Documents, Supplier warrants and represents to Novartis that it has implemented a reasonable and appropriate due diligence process to assess any potential sublicensee/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) Supplier will remain fully liable for the acts/or omissions of the approved sublicensee/subcontractor and for any breach or non-performance of the Transaction Documents;
(b) Supplier will include in its subcontracts, with any subcontractor approved pursuant to the Transaction Documents, obligations which are consistent with the relevant obligations from the Transaction Documents; and
(c) Supplier will be exclusively responsible for all costs associated with any such sublicense or subcontract arrangement.

Furthermore, Supplier undertakes to put in place and maintain for the duration of the Transaction Documents an ongoing monitoring program of any approved subcontractors. In the event where an alert arises as part of the monitoring process, Supplier will notify Novartis in writing as soon as possible and in any event no later than seven (7) days of the alert having arisen.
分包、尽职调查和监控。未经诺华事先书面同意，供应商不得使用任何分包商、代理商/代理人、或者其它第三方（“第三方”）履行交易文件项下的义务。供应商确保其已实施合理和适当的尽职调查程序来评估任何潜在的第三方，且没有任何负面调查结果。即使诺华同意供应商使用第三方履行交易文件项下的义务：
(a) 供应商将对经批准的分许可人/分包商的作为/或不作为以及对违约行为或不履行承担全部责任；
(b)供应商将在其与根据交易文件批准的任何分包商的分包合同中包含与交易文件相关一致的义务；和
(c) 供应商应自行承担与任何此类分许可或分包安排相关的所有费用和成本。

此外，供应商承诺在协议有效期内制定并维持对任何经批准的分包商的持续监督计划。如果在监督过程中出现任何警报事项，供应商将于 7 天内以书面形式通知诺华。

20.2 **No Assignment.** These Transaction Documents 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 Supplier's further written consent (which Supplier confirms has been given pursuant hereto), to:
(a) assign these Transaction Documents and/or any rights and obligations pertaining thereto (including any part thereof) to any of its Affiliates; and
(b) assign these Transaction Documents, 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 these Transaction Documents (or related to the assigned portion in case of a partial assignment).

In the event that:
(a) an Affiliate receiving Services 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
(b) an asset related to a Novartis business is transferred and/or sold to a third party buyer ("Buyer"),
upon request of Novartis, Supplier will continue and herewith consents to provide the relevant Services 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 Services provided to such Former Affiliate or Buyer will be provided in accordance with the then current terms and conditions of these Transaction Documents.

不得转让。未经另一方事先书面同意（无正当理由不得拒绝该等同意），交易文件不得转让。任何试图违反本条款的转让均无效。
尽管有上述规定，诺华有权自行决定，无需供应商进一步书面同意（供应商已根据交易文件确认）的情况下：
a) 将交易文件和/或关于交易文件的任何权利和义务（包括其任何部分）转让给其任何关联公司；和
b) 就任何和所有形式的撤资和投资（包括但不限于兼并、分拆、合并、重组、股份出售、资产出售、合资等）以及相关的范围内，转让交易文件和/或交易文件相关的任何权利和义务（包括其中的任何部分）。

为避免疑义，任何（获准）受让人将承担其转让人在交易文件项下的所有义务和权利（或在部分转让的情况下涉及被转让部分）。
如果：
a) 由于任何及所有形式的撤资（包括但不限于合并、分拆、重组、股份出售、资产出售、合资等），接受服务的附属公司不再符合附属公司的定义（“前附属公司”）；或
b) 转让和/或出售与诺华业务相关的资产给第三方买方（“买方”），
经诺华要求，在该等前附属公司或买方不再是附属公司或资产转让给买方之日后，在诺华要求的期限内，供应商将根据诺华各自的过渡服务或其他承诺，继续并遵守交易文件同意向该等前附属公司或买方提供相关服务。 向该等前附属公司或买方提供的服务将根据交易文件届时的条款和条件提供。

20.3 Novartis is committed to operate in compliance with all applicable export controls and trade sanction rules promulgated and amended by foreign authorities, to the extent that is permitted by the local laws and regulations in China.
诺华致力于合规运营，在中国当地法律、法规允许的范围内，诺华将遵循国外机关发布和修订的、所有可适用的出口管制及贸易制裁规则。

20.4 **Applicable law, Dispute Resolution.** The Transaction Documents shall be construed by and enforced in accordance with the laws of the People's Republic of China without regard to its principles of conflicts of law. The parties hereto agree to furnish any dispute in relation to the Transaction Documents to Shanghai International Arbitration Center ("SHIAC") to be settled by arbitration in Shanghai in accordance with its then current arbitration rules. The arbitral award of SHIAC shall be final and binding upon both parties.

适用法律，争议解决。交易文件应由中华人民共和国的法律管辖并予以解释，但排除其对冲突法原则的适用。双方兹此同意，有关交易文件的任何争议应提交上海国际仲裁中心（“SHIAC”），根据其届时有效的仲裁规则在上海予以仲裁。SHIAC 的仲裁裁决是终局的，对双方当事人均有约束力。

20.5 **Access/Badging.** The performance of the Transaction Documents may require Supplier to be granted access to Novartis premises. For those engagements, Novartis shall grant Supplier's employees reasonable access to its premises for the sole purpose of performing its obligations under the Transaction Documents. Novartis shall issue identification badges or access cards for entry to Novartis' premises during performance of the Transaction Documents. Badges and access cards remain the property of Novartis. While on Novartis' premises, badges must be worn in plain sight at all times. Supplier shall promptly report any missing badges or access cards to Novartis, and Supplier shall return all badges and access cards to Novartis upon completion of the services/duties or upon Novartis' request. Supplier shall require its employees to comply with all instructions given by Novartis employees or security personnel, and any other restrictions that may be imposed upon them by Novartis. Novartis reserves the right to deny access to its facilities or remove from its premises, any individual who does not comply with Novartis' rules, regulations and policies.
访问/门禁卡。交易文件的履行可能会要求供应商被授权访问诺华场所。对于该等事宜，诺华应授予供应商的员工仅以履行交易文件义务为唯一目的、合理访问其经营场所的权限。在交易文件执行期间，诺华应向供应商发放身份牌或通行门禁卡以进入诺华场所。身份牌和通行卡始终是诺华的财产。在诺华的经营场所内，身份牌必须在任何时候均佩戴在显著的位置。供应商应及时报告诺华任何丢失的身份牌或通行卡，且供应商应在服务/职责履行完毕后或在诺华要求时，将所有身份牌和通行卡交还给诺华。供应商应要求其雇员遵守诺华员工或保安人员的指令，以及由诺华发出的任何其他限制。诺华有权拒绝任何不符合诺华之规定、规章和政策的个人进入其场所或者责令其离开诺华场所。

20.6 **Survival of Terms.** Any provision of these General Terms and Conditions that by its general nature and operation imposes or contemplates continuing obligation, including but not limited to the provisions pertaining to of (Confidentiality), (Intellectual Property), (Indemnity), (Insurance), (Termination), (Tax), (No Publicity), (Compliance with the Law and Policies) and (Miscellaneous), shall remain in force and effect notwithstanding the termination or expiration of the Transaction Documents.
持续有效。本一般条款和条件下任何根据其自身属性需持续履行义务的条款应在交易文件终止或到期后持续有效，该等条款包括但不限于“保密条款”、“知识产权条款”、“赔偿条款”、“保险条款”、“终止条款”、“税务条款”、“不宣传条款” 、“法律和政策合规”和“其他条款”。

20.7 **Entire Agreement.** The Transaction Documents represent the entire agreement and understanding between the parties relating to the subject matter, and shall supersede all documents and verbal consents or understandings (if any) given or made between the parties prior to the date of the applicable Transaction Documents. The terms under the Transaction Documents may only be amended or modified in writing signed by both parties. All Appendixes and Addendums to any Transaction Document shall form an integral part of the Transaction Documents.
完整协议。交易文件是双方之间就主题事宜达成的全部协议和谅解，并且其将取代双方之间在相关交易文件签署日期之前达成或取得的所有书面和口头的共识或谅解（如有）。交易文件的条款只能通过双方签署书面文件的方式进行修改或调整。交易文件的所有附录和附件均是交易文件不可分割的组成部分。

20.8 **Waiver.** The failure of a party to insist upon strict adherence to any term of the Transaction Documents on any occasion shall not be considered a waiver or deprive that party of the right to insist upon strict adherence to that term or any other term of the Transaction Documents. Any waiver must be in writing and signed by the party making the waiver. The invalidity or unenforceability of any term or provision of any Transaction Document shall not affect the validity or enforceability of any other term or provision thereof.
弃权。一方没有要求严格遵守交易文件中的任何条款不应视为该方放弃或剥夺该方坚持要求严格遵守该条款或交易文件下的任何其他条款的权利。任何弃权必须以书面形式由弃权的一方签署。任何交易文件中的任何条款或规定的无效或无法执行，不影响其他任何条款或规定的有效性和可执行性。

20.9 **Ethical Business Conduct 道德的商业行为**

- By executing these General Terms and Conditions, the Supplier agrees to conduct all business contemplated herein in a manner which is consistent with both applicable local law and good business ethics. The Supplier agrees to comply with, and not to take any action which would be subject to penalty under all laws, rules and regulations applicable to any applicable Transaction Document, including without limitation the Foreign Corrupt Practices Act, the UK Bribery Act as well as the applicable OECD Guidelines on Anti-bribery insofar that those acts are in line with local law. Any violation of this Section shall be deemed a material breach of the Transaction Documents, providing cause for termination pursuant to the Transaction Documents;
通过签署本一般条款和条件，供应商同意以与适用的当地法律和良好的商业道德相一致的方式开展所有业务。供应商同意遵守任何相关交易文件所适用的所有法律、法规和规章，且不会采取可能违反该等适用法律、法规和规章的任何行动，该等法律、法规和规章包括但不限于美国反海外腐败法、英国反贿赂法以及相关的反贿赂经合组织准则（若该等法案符合当地法律）。对本条的任何违反均将被视为实质性违反交易文件，且守约方可据此终止交易文件;

- Novartis promotes and protects the rights defined in the Universal Declaration of Human Rights of the United Nations within sphere of influence. Novartis does not tolerate human rights abuses within business operations. Supplier shall implement the same and not employ any “under aged” employee, use forced labor and/or engage in any other forms of exploitation labor;
诺华在其影响范围内，促进和保护在联合国世界人权宣言中规定的权利。诺华在其商业运作中不允许任何侵犯人权的行为。供应商应执行相同的标准，且不得雇佣任何“未达到年龄”的员工，使用强迫劳动力和/或从事任何其他形式的劳动剥削;

- Novartis also promotes sound practices under its Corporate Health, Safety and Environment (HSE) Policy. The health and safety of employees and the protection of the environment are major concerns. Novartis considers these topics vital to the success of the business and do not compromise them for economic or productivity gains. Supplier shall implement the same and ensure that all work places are suitably equipped and free from any recognized hazards which are liable to cause death, injury or illness; and
诺华亦推广符合企业健康、安全和环境（HSE）政策的良好实践。员工的健康和安全以及环境保护始终是重中之重。诺华认为该等事宜对企业的成功至关重要，且不会为了追求经济价值或生产力而弱化对其之重视。供应商应执行相同的标准，保证其各工作场所均配备适当的装备，而使其员工远离任何已知的可能引起死亡、伤害或疾病的危害因素; 和

- Supplier agrees to adhere to the Novartis Code of Ethics and Doing Business Ethically - The Novartis Anti-Bribery and Professional Practices Policy, which can be found at https://www.novartis.com/esg/reporting/codes-policies-and-guidelines
供应商同意遵守诺华道德准则和《赢之有道-诺华反贿赂与专业互动政策》，该等政策可以在以下网址查找 https://www.novartis.com/esg/reporting/codes-policies-and-guidelines

20.10 **Quality.** If required under the applicable Novartis quality policies and procedures, the parties to the Transaction Documents will enter into a satisfactory Quality Agreement. Supplier and Novartis quality personnel will cooperate in the drafting and execution of such Quality Agreement. The inability of the parties to agree upon a Quality Agreement will be grounds for termination of the related Transaction Documents. If the subject matter of the Transaction Documents is related to any controlled good, product or service, Supplier will allow a representative from Novartis, upon reasonable advance written notice, to audit and inspect their operations. Supplier will immediately notify Novartis of any inspections by health authorities.
质量。如果诺华相关的质量政策和程序有相应要求，交易文件各方将签署一份另各方满意的质量协议。供应商和诺华质量人员将合作起草和执行该质量协议。若当事人不能就质量协议达成一致，相关方可终止相关交易文件。如果交易文件的标的物与任何需要控制的商品、产品或者服务有关，供应商应允许诺华代表，在合理的事先书面通知的情况下审核和检查其操作运营。就任何卫生部门的检查，供应商应立即通知诺华。

20.11 **Notice.** Any notice required or permitted to be given by the applicable Transaction Documents shall be in writing and shall be deemed to have been properly served if delivered by hand or overnight courier with tracking capabilities, addressed as notified by the other party in writing.
通知。相关交易文件下的任何通知均应以书面形式作出。如果该等通知是向另一方书面通知的地址亲自递送，或通过可追踪的隔夜快递发出，则其将被视为已适当作出。

20.12 **Severability.** In the event any provision of any Transaction Document is held to be illegal, invalid or unenforceable, such provision shall be limited or eliminated to the minimum extent necessary so that the Transaction Documents otherwise remains in full force and effect.
可分割性。如果任何交易文件下的任何条款被裁定为非法、无效或不可执行，该等条款仅在必要和最低的程度内被视为已删除或相应修改，交易文件的其他条款和条件仍具有完全的效力。

20.13 **External Partner Risk Management**. Novartis has put in place an External Partner 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, the Supplier will:

- 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 (the Supplier may request a copy free of charge from Novartis);
- 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;
- 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;
- ensure that where Supplier Affiliates and/or subcontractors/agents of Supplier and its Affiliates have been pre-approved by Novartis (in accordance with these Transaction Documents) to provide the goods/services/deliverables, that such third parties also comply with the above requirements relating to the Third Party Code; and
- 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 Transaction Documents). Supplier warrants and represents that the information provided in any Questionnaire for Third Parties (whether provided before or during the Transaction Documents, including updates to the same) is accurate and complete (and such information shall be treated as being part of the Transaction Documents). For the avoidance of doubt, this subparagraph applies to Supplier only, and not to any subcontractor engaged by it in accordance with the terms of the Transaction Documents.

Supplier acknowledges and agrees that the Third Party Code forms an integral part of the Transaction Documents.

外部合作伙伴风险管理：诺华已制定了一套外部合作伙伴风险管理机制，以期向与诺华有合作关系的特定第三方实体推广联合国全球契约中的社会和环境价值。

基于此，供应商应当：

- 遵守“第三方准则”的各项要求（以及之后公布的更新版本）。“诺华第三方准则”可通过以下链接查阅和下载(https://www.novartis.com/esg/reporting/codes-policies-and-guidelines)。供应商亦可要求诺华向其提供一份免费的“第三方准则”；
- 根据第三方准则第 12.6 条的要求，应诺华的合理要求向诺华和/或其人员提供相关的信息和文件，以供诺华验证供应商是否遵循了“第三方准则”；
- 如有被认定为不符合“第三方准则”的行为，供应商必须尽力改正（如果可以改正）并按要求向诺华和/或其人员报告整改的进展；
- 确保供应商关联公司和/或供应商及其关联公司的分包商/代理人已获得诺华（根据交易文件）的预先批准以提供货物/服务/可交付成果，此类第三方也遵守上述与诺华第三方准则相关的要求；和
- 在诺华要求的情况下，自费与诺华和诺华人员充分合作，按照合理的指示填写和交还任何第三方调查问卷（以及在协议期限内要求的任何更新）。供应商保证并声明在任何第三方调查问卷中提供的信息（无论是在协议之前或期间提供，包括对其更新）是准确和完整的（并且此类信息应被视为协议的一部分）。为免疑义，本项仅适用于供应商，不适用于其根据协议条款聘用的任何分包商。

供应商兹此同意并确认第三方准则是交易文件不可分割的组成部分。

20.14 **Data Privacy.** If the Transaction Documents include collecting and processing of personal data, meaning all kinds of information related to identified or identifiable natural persons recorded by electronic or other means, both parties agree to comply with all applicable laws or regulations governing personal data protection (“Data Protection Laws”), to conduct their own personal information collecting and processing activities, and independently assume legal and compliance responsibilities. To the extent the Transaction Documents will include the processing of personal data falling within the scope of Data Protection Laws, by Suppliers for or on behalf of Novartis, the terms of Appendix C (“Data Protection Requirements”) shall apply. Supplier shall strictly comply with these Transaction Documents and all requirements in applicable Data Protection Laws when collecting, processing or managing the personal information.
隐私保护。如果交易文件涉及收集和处理个人信息，即以电子或者其他方式记录的与已识别或者可识别的自然人有关的各种信息，双方均应严格遵守适用的个人信息保护相关的法律法规（“数据保护法”）进行各自的个人信息收集和处理活动，并各自独立承担法律和合规责任。如果交易文件涉及供应商为诺华或代表诺华处理数据保护法范围内的个人信息，则附件 C（“个人信息保护要求”）适用。供应商在收集、处理或管理个人信息时，应严格遵守交易文件以及适用的数据保护法的所有要求。

The Transaction Documents may contain personal data such as name, signature, bank account details (if any) and contact information etc. that identifies or describes one or more individuals. The Transaction Documents may be transferred to, stored or otherwise processed in or other countries that have privacy and data protection laws that differ from those where the Transaction Document is executed or where the individual(s) resides. The personal data disclosed hereunder will be used for the purposes of administration and enforcement of the Transaction Documents, future interactions or the dispute resolution. The execution and delivery of the Transaction Documents will constitute a statement by each party hereto. Supplier shall acknowledge that those individuals whose information was disclosed during the execution and performance of the Transaction Documents have been notified, and those individuals executing Appendix I attached hereto agree that such personal information may be transferred, stored or processed in a manner described in this paragraph and Appendix I.

交易文件可能含有个人信息，例如可识别或描述一名或多名个人的姓名、签名、银行账号信息（如有）和联系方式等。交易文件有可能被传输、存储或处理于与交易文件签署地或签字人所在地有着不同数据保护法律的其他国家。交易文件下披露的个人信息将被用作管理和执行交易文件、未来沟通联系或双方纠纷解决之目的。交易文件的签署和交付将构成每一方的声明，供应商应确认交易文件签署和履行过程中被披露的个人均已被通知且同意该等个人信息可以按照本条及附件 I 描述的方式被传输、存储或处理。

20.15 **Sanctions and export control compliance**. Supplier agrees to sign Appendix H and comply with all relevant regulations, including but not limited to EU regulations, US Export Administration Regulations, UK Export Control Orders, Swiss Federal Act on the Implementation of International Sanctions, Swiss Ordinance on the Export, Import and Transit of Dual Use Goods, Specific Military Goods and Strategic Goods, Swiss Ukraine Ordinance, and the trade and economic sanctions imposed by the EU, UK and US (if applicable).

制裁和出口管制合规。供应商同意签署附件 H 并遵守所有相关法规， 包括但不限于欧盟法规，美国出口管理条例，英国出口管制令，瑞士联邦实施国际制裁法，瑞士两用物品、特定军事物品和战略物品的进出口和过境条例，瑞士乌克兰法令和欧英美实施的贸易和经济制裁（如适用）。

20.16 **Environmental Sustainability Criteria.** Supplier shall comply with the environmental sustainability criteria provided by Appendix J.

环境可持续性标准。供应商应遵守附件 J 中规定的环境可持续性标准。

20.17 **Language.** These Transaction Documents are executed both in English and Chinese. In the event of any conflict, the Chinese version shall prevail.

语言。交易文件以中英文签署。如中英文之间出现不一致，以中文文本为准。

IN WITNESS WHEREOF, the Supplier executed this agreement as follows：

以兹为证，本协议由供应商签署如下：

[FULL LEGAL SUPPLIER COMPANY NAME /供应商名称]

(Seal/盖章)

Signature/签名: _____

Printed Name/姓名: _____

Title/职务: _____

Date/日期: _____

Appendix A

MINIMUM INFORMATION SECURITY CONTROLS FOR THIRD PARTIES[1] AND【ADDITIONAL INFORMATION SECURITY REQUIREMENTS】

附件 A

对第三方的最低信息安全控制[2]及【附加信息安全要求】

1. GOVERNANCE AND COMPLIANCE 治理和合规

- Third Party shall implement and maintain an information security program, consistent with security industry practice and applicable laws and regulations, to protect the systems and network infrastructure, as well as the confidentiality, integrity, availability, and resiliency of data, at minimum, as set forth in this document and to ensure a level of security appropriate to the risk.
  第三方应实施和维护符合安全行业惯例和适用法律法规标准的信息安全规划，以保护系统和网络基础设施，以及数据的机密性、完整性、可用性和可恢复性，至少应符合本文件的规定，并确保与风险相适应的安全级别。
- Third Party shall ensure that it has nominated an appropriate individual to hold accountability on behalf of Third Party for ensuring technical and organizational compliance with information security controls.
  第三方应确保其已指定适当的个人代表其负责确保在技术和组织上遵守信息安全控制。
- Third Party's information security program must include a governance framework with supporting risk management policies that will enable and support risk management.
  第三方的信息安全规划必须包括一个治理框架，该框架具有支持风险管理的政策，能够开启和支持风险管理。

2. BUSINESS CONTINUITY 业务连续性

- Third Party shall have appropriate business continuity and disaster recovery plans to ensure timely recovery of its IT systems involved in any operation with data, in any form, supporting the services provided to Novartis, in the event of a disaster or other significant disruptive event.
  第三方应制定适当的业务连续性和灾难恢复计划，以确保在灾难或其他重大破坏性事件发生时，及时恢复其涉及任何形式的数据运营相关的、支持向诺华提供服务的 IT 系统。
- Third Party shall ensure that its disaster recovery plans are periodically tested and updated to ensure they are up-to-date and effective.
  第三方应确保其灾难恢复计划得到定期测试和更新，以确保其最新和有效性。
- Third Party shall ensure that technologies and processes used for data backup and recovery are regularly tested and have sufficient protection against any disruptive cyber-attacks.
  第三方应确保用于数据备份和恢复的技术和过程得到定期测试，并对任何破坏性网络攻击提供足够的保护。

3. MEDIA HANDLING 介质处理

- Procedures for the handling and storage of data shall be established by Third Party to protect data from unauthorized disclosure or misuse.
  处理和存储数据的流程应由第三方建立，以保护数据免受未经授权的泄露或滥用。
- Third Party shall ensure media is disposed of securely and safely when no longer required, using formal procedures with proper documentation.
  第三方应确保当不再需要时，使用正式程序和适当的文件，以安全的方式处理介质。
- Third Party shall upon termination of the contractual relationship with Novartis or upon Novartis' request return to Novartis all media and other assets provided to Third Party by Novartis.
  第三方应在与诺华终止合同关系或诺华要求时，将诺华提供给第三方的所有介质和其他资产归还给诺华。
- Third Party shall ensure that system documentation is protected against unauthorized access.
  第三方应确保系统文档不受未经授权的访问。

4. EXCHANGE OF DATA 数据交换

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[1] Capitalized expressions used in this document have the same meaning as in the latest version of the Novartis Third Party Code (available at https://www.novartis.com/esg/reporting/codes-policies-and-guidelines) unless expressly defined in the attached glossary, stated otherwise or the context requires otherwise. In this document, reference to "Third Party" or "Third Parties" is limited only to such third parties that would be classified as falling under the definition of "Suppliers" in the Novartis Third Party Code.

[2] 在本文件中使用的大写定义词与最新版本诺华第三方准则（可在 https://www.novartis.com/esg/reporting/codes-policies-and-guidelines 上查阅）中的含义相同，除非在附录定义表中有明确定义、另有说明或上下文另有要求。在本文件中，"第三方"的定义仅限于根据诺华第三方准则定义为"供应商"的第三方。

- Third Party shall maintain the confidentiality, integrity, availability and resiliency of data and systems hosting or accessing such data within its organization and within any external entity; this includes exchange agreements, physical media in transit, electronic messaging and the protection of data associated with the interconnection of business information systems.
  第三方应在其组织内和任何外部实体内维护数据和承载或访问此类数据的系统的机密性、完整性、可用性和可恢复性；这包括交换协议、运输中的物理介质、电子消息和对与业务信息系统互连有关的数据的保护。

5. ACCESS CONTROL 访问控制

- Third Party must have an access control policy that ensures that only authorized users that have a business need that is approved will have access to Novartis data.
  第三方必须有一个访问控制策略，以确保仅有业务需求并得到批准的授权用户才能访问诺华数据。
- Third Party shall review user access rights to ensure that the allocation and use of privileges are controlled and restricted where necessary and as applicable to Novartis data or any systems storing such data.
  第三方应审查用户访问权限，以确保特权的分配和使用在必要时受到控制和限制，并适用于诺华数据或存储此类数据的任何系统。

6. CRYPTOGRAPHIC CONTROL 加密控制

- Considering relevant information security risks, state of the art, security industry practice and applicable laws and regulations, Third Party shall design, implement and maintain cryptographic controls, including encryption as appropriate of Novartis data.
  考虑到相关信息安全风险、现状、安全行业惯例和适用法律法规，第三方应设计、实施和维护包括对诺华数据的适当加密在内的加密控制。

7. CONTROLLED PROCESSING AND USAGE OF ARTIFICIAL INTELLIGENCE 人工智能的受控处理和使用

- Third Party shall ensure separate processing of data collected for different purposes, e.g. multi-client capability, sandboxing, development/testing vs. production environment which is used by end-users.
  第三方应确保为不同目的收集的数据进行单独处理，例如，多客户端功能、沙箱、开发/测试与最终用户使用的生产环境。
- Third Party shall ensure that, only data which are necessary for each specific purpose of the processing are processed, by applying as appropriate data sanitization/minimization and data removal techniques.
  第三方应通过使用适当的数据清除/最小化和数据删除技术，确保仅处理每个特定处理目的所必需的数据。
- Third Party shall only use AI systems for processing Novartis´ data following prior agreement from Novartis. In such a case, Third Party shall maintain appropriate safeguards in accordance with the best industry practices (for example, prohibition of using Novartis data for training, anonymization of Novartis data, secure handling of Novartis data etc.) related to usage of such AI systems.
  第三方只能在事先与诺华达成协议后使用人工智能系统处理诺华的数据。在这种情况下，第三方应根据使用该 AI 系统相关的最佳行业惯例(例如，禁止将诺华数据用于培训、匿名化诺华数据、安全处理诺华数据等)来保持合适的安全防护。

8. COMMUNICATIONS AND NETWORK SECURITY 通讯与网络安全

- Third Party shall ensure that networks under Third Party's control are adequately managed, controlled and protected from threats and vulnerabilities, and shall maintain the confidentiality, integrity, and availability of data and prevent the unauthorized access to such systems and applications used to process data at rest or in transit.
  第三方应确保第三方控制下的网络得到充分的管理、控制和保护，免受威胁和漏洞的侵害，并应维护数据的机密性、完整性和可用性，防止未经授权对用于处理静止或传输中数据的系统和应用程序的访问。
- Third Party connecting to Novartis environment shall ensure it is capable of meeting the relevant Novartis technical standards applicable to such environment.
  第三方连接诺华环境需确保能够满足适用于该环境的相关诺华技术标准。

9. SECURITY TRAINING AND AWARENESS 安全培训和安全意识

- Third Party shall ensure that all its Workers, contractors and agents are aware of information security threats and concerns, their responsibilities, and are equipped to support organizational security policy in the course of their work.
  第三方应确保其所有工作人员、承包商和代理了解信息安全威胁和担忧、他们的责任，并在其工作过程中支持组织的安全政策。
- Third Party will ensure that, all Workers, contractors and agents shall receive appropriate information security and data protection awareness training.
  第三方将确保，所有工作人员，承包商和代理应接受适当的信息安全和数据保护意识培训。
- Third Party shall ensure that its Workers use institutional e-mail addresses (as opposed to personal email or communication platform accounts) for any correspondence containing or relating to Novartis data.
  第三方应确保其员工使用组织的电子邮件地址（而不是个人电子邮件或通信平台账户）进行任何包含诺华数据或与诺华数据有关的通信。

10. PHYSICAL AND ENVIRONMENTAL SECURITY 物理和环境安全

- Third Party shall ensure that appropriate information security perimeters and entry controls are in place to prevent unauthorized physical access, damage and interference to Third Party's premises and data including all end user devices.
  第三方应确保适当的信息安全边界和准入控制到位，以防止未经授权的物理访问，以及对第三方场所和数据，包括所有终端

用户设备的损坏和干扰。

- Third Party shall ensure that equipment is properly inventoried and maintained to ensure its continued information security.
  第三方应确保设备得到适当的清点和维护，以确保其持续的信息安全。

11. PROTECTION OF ORGANIZATIONAL RECORDS 保护组织记录

- Third Party shall ensure their information security program includes policies that cover data retention and data destruction consistent with security industry practice.
  第三方应确保其信息安全计划包括符合安全行业惯例的数据保留和数据销毁政策。
- Third Party shall ensure appropriate controls are implemented to prevent the loss, destruction, or falsification of records during their retention period, including determining whether and by whom data has been entered, accessed, modified or removed from data processing systems.
  第三方应确保实施适当的控制，以防止记录在保存期间丢失、销毁或伪造，包括确定数据是否和由谁输入、访问、修改或从数据处理系统中移除。
- Third Party agrees that upon the request of Novartis or as otherwise required by law, it shall dispose of (e.g. erase, destroy or render uninterpretable) all Novartis data that Third Party, its affiliates or subcontractors hold or manage (acknowledging that copies of the Novartis data may reside on Third Party's standard backup media that are subject to standard backup rotation scheme and are secured according to recognized and then-current data privacy practice and security industry practice). Third Party shall provide to Novartis report with appropriate level of detail on Novartis data stored on backup media upon Novartis request at no additional costs to Novartis. Novartis shall have the right to receive a copy of Novartis data in the form and within the timeframe specified by Novartis before its disposal.
  第三方同意，应诺华的要求或法律的其他要求，销毁（例如，抹去、销毁或使其无法读取）第三方、其关联公司或分包商持有或管理的所有诺华数据（认可诺华数据的副本可能存在于第三方的标准备份介质上，该等备份介质受标准备份轮换方案的约束，并根据公认的和当时现行的数据隐私惯例和安全行业惯例进行保护）。应诺华要求，第三方应向诺华提供关于存储在备份介质上的诺华数据的适当详细程度的报告，而诺华不承担额外费用。诺华有权在相应诺华数据被处置之前，以诺华规定的形式和时间范围接收其数据的副本。
- Where requested by Novartis, Third Party shall certify in writing that these actions have been completed.
  如果诺华要求，第三方应书面证明这些行动已经完成。
- The following shall be considered as exceptions to this disposal requirement:
  - Third Party must keep Novartis data on file for legal or regulatory purposes; such Novartis data shall then be removed as soon as the legal retention periods have expired
  - Novartis data which Novartis has requested Third Party to keep archived for legal hold or other comparable purposes
  - Where Novartis has agreed in writing with Third Party specific return/destruction/retention requirements in respect of certain Novartis data, in which case, such specific requirements will apply.
  以下情况应视为此处置要求的例外情况：
  - 第三方必须为法律或监管目的将诺华数据存档；一旦法定留存时间到期，该等诺华数据应被删除
  - 诺华为合法持有或其他目的要求第三方存档的诺华数据
  - 如果诺华已与第三方书面协定关于某些诺华数据的特定返还/销毁/保留要求，在这种情况下，此类特定要求适用。

12. TECHNICAL VULNERABILITY MANAGEMENT 技术漏洞管理

- Third Party shall have a vulnerability management program that monitors and maintains the information security state of the Third Party environment.
  第三方应该有一个漏洞管理程序来监控和维护第三方环境的信息安全状态。
- Third Party shall establish and maintain policies that demonstrate adequate application of updates and patch management of Third Party IT systems.
  第三方应建立和维护能够充分维护第三方 IT 系统的更新和补丁管理的政策。
- Third Party shall create and maintain hardware and software inventories and conduct regular vulnerability scans.
  第三方应建立和维护硬件和软件清单，并定期进行漏洞扫描。

13. INFORMATION SECURITY INCIDENT MANAGEMENT 信息安全事件管理

- Third Party will ensure that management responsibilities and procedures are established to ensure a quick, effective and orderly response to security incidents and to report and manage information security incidents and weaknesses including appropriate reporting.
  第三方将确保建立管理责任和程序，以确保快速、有效和有序地应对安全事件，并报告和管理信息安全事件和弱点，包括适当的汇报。
- Third Party will promptly inform Novartis in case of a security incident related to Novartis data.
  如果发生与诺华数据相关的安全事件，第三方将及时通知诺华。

14. MONITORING 监控

- Third Party must monitor its environment to detect and respond to information security incidents or other unauthorized activities.
  第三方必须监控其环境，以检测和响应信息安全事件或其他未经授权的活动。

- Third Party shall ensure audit controls are implemented within the Third Party environment under Third Party's control to enable independent audits/testing of appropriate audit data on operational systems while minimizing the risk of disruption to processes.
  第三方应确保在第三方控制下的第三方环境中实施审计控制，以便能够对运营系统的适当审计数据进行独立审计/测试，同时将流程中断的风险降至最低。

15. CONFIGURATION AND CHANGE MANAGEMENT 配置和变更管理

- Third Party shall have a change management process that ensures that the impact of changes is understood prior to rollout, includes criteria for establishing the success or failure of a change, and ensures that any roll-back procedures for failed changes are approved before changes are made.
  第三方应建立变更管理流程，以确保在实施变更之前了解变更的影响，包括确定变更成功或失败的标准，并确保在进行变更之前批准所有变更失败的回滚程序。

16. HARMFUL CODE PREVENTION 有害代码防范

- Third Party shall develop policies to manage the risks associated with the malicious use of harmful code and implement anti-malware defenses.
  第三方应制定策略来管理与有害代码恶意使用相关的风险，并实施反恶意软件防御。

Additional Information Security Requirements
附加信息安全要求

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").
这些附加信息安全要求（"AISR"）补充了本协议、诺华第三方准则（"TPC"）和诺华最低信息安全控制（"MISC"）中包含的任何其他信息安全要求。

1. Information security assessments and certifications (supplementing TPC Section 12.5)
信息安全评估和认证（补充 TPC 第 12.5 节）
   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.
   诺华或被其指定方可进行技术和/或其他评估，包括测试，以评估诺华数据和诺华环境的安全性和可恢复性。
   1.2 Third Party and its subcontractors shall maintain the following audit reports:

AUDIT REPORTS	ISSUE DATE
TO BE FILLED BY THIRD PARTY with audit reports: a) SSAE 18 SOC 2 Type II audit report and/or b) for SOX relevant also SSAE 18 SOC 1 Type II	

   第三方及其分包商应保存以下审计报告：

审计报告	发行日期
由第三方填写审计报告：a) SSAE 18 SOC 2 类型 2 审计报告和/或 b) SOX 相关的 SSAE 18 SOC1 类型 2	

   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.
   第三方应确保渗透和安全测试定期（至少每年）由经验丰富和公认的专业人员进行，并与诺华数据处理环境中的安全行业惯例一致，此类测试的结果应按要求提供给诺华。
   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.
   关于以上第 1.1-1.3 节，如果发现任何漏洞或缺陷，第三方应根据安全行业惯例制定和实施补救计划，不得无故拖延。如果第三方不遵守此要求，诺华将有权根据各自协议的终止条款终止本协议。

2. General information security requirements (supplementing MISC Section 1, 3, 5 and 6)
一般信息安全要求（补充 MISC 第 1、3、5 和 6 节）
   2.1 Third Party shall process Novartis Data in accordance with Security Industry Practice.
   第三方应按照安全行业惯例处理诺华数据。
   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.
   第三方的信息安全规划应根据以下评估定期（至少每年）审查和更新：(i)内部和外部风险；(ii)使用防御性基础设施或治理；(iii)发现、应对和减轻威胁的能力；及(iv)符合监管规定的能力。
   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.
   考虑到相关的信息安全风险，第三方应实施符合安全行业惯例的适当加密标准，如至少 NIST 800 和/或 ISO 27001。
   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.
   第三方应确保对包含诺华数据的系统、通过公共数据网络的网络访问和从第三方最终用户工作站对第三方环境（诺华数据处理的地方）的访问实施多因子认证。
   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.
   第三方只能在以下环境处理诺华数据：(a)安全的生产环境；或(b)任何其他双方同意的安全环境。
   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.
   第三方应在其服务中实施和维护符合安全行业惯例的措施，以检测、调查、补救和防止以任何方式影响诺华数据或诺华环境的任何未经授权或恶意代码的含有、安装或执行。
   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.
   第三方应监控诺华数据处理过程中涉及的任何系统的可用补丁以便及时评估、测试和安装。
   2.8 Third Party shall maintain adequate audit trails to support security audits and the detection and investigation of any Security Incident.
   第三方应保持足够的审计踪迹，以支持安全审计和任何安全事故的检测和调查。

3. Continuity Standards (supplementing TPC Section 12.9 and MISC Section 2)
连续性标准（补充 TPC 第 12.9 节和 MISC 第 2 节）
   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)

第三方应确保以下恢复时间目标(RTO)和恢复点目标(RPO)：

目标	目标的最长时间[小时]
恢复时间目标(RTO)	24 （或相关工作说明书/采购订单中另有规定）
恢复点目标（RPO）	24 （或相关工作说明书/采购订单中另有规定）

4. Novartis Environment (supplementing MISC Section 4, 7 and 8)
诺华环境（补充 MISC 第 4、7 和 8 节）

4.1 Any connection with the Novartis Environment including its parameters is subject to prior Novartis approval and Third Party's compliance with Novartis requirements and may be disconnected by Novartis at any time.
与诺华环境的任何连接，包括其参数，都要经过诺华的事先批准，第三方需遵守诺华的要求，且诺华可能随时断开连接。

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.
如果第三方人员收到：(i)诺华颁发的出入卡或类似的准入机制；(ii)诺华个性化网络接入账户；(iii)诺华设备；(iv)诺华的电子邮件账户；或(v)对诺华环境的其他类型的访问，第三方应确保该第三方人员应遵守诺华的任何适用的信息安全政策。第三方应通知诺华任何可能影响诺华的第三方人员的状态变化。第三方还应确保其可能进入包含诺华数据的第三方环境的人员将接受第三方的监控，以遵守适用的第三方信息安全政策和标准。

5. Security Incidents (supplementing MISC Section 12)
安全事故（补充 MISC 第 12 节）

5.1 Third Party shall monitor, analyze, and respond to Security Incidents.
第三方应监控、分析和应对安全事故。

5.2 Third Party shall notify Novartis without undue delay, but not later than twenty-four (24) hours after becoming aware of Security Incident.
第三方应没有不当延误地通知诺华，但不迟于知道安全事故后二十四（24）小时内。

5.3 Novartis contact for reporting Security Incident: Phone: +420 225 775 050 (backup number: +420 225 850 012), Email: soc@novartis.com.
诺华安全事故报告联系人：电话：+420 225 775 050（备份号：+420 225 850 012），电子邮件：soc@novartis.com.

5.4 Third Party shall provide contact for reporting or discussing Security Incident promptly upon Novartis request.
第三方应根据诺华的要求提供联系人，以便及时报告或讨论安全事故。

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.
第三方应在没有不当延迟的情况下，采取适当的措施，以最大限度地减少诺华数据的进一步暴露，并实施补救措施，以防止类似安全事故的再次发生。

5.6 Third Party shall report root cause and impact to Novartis Data as well as a progress of remediation actions adopted.
第三方应向诺华报告事故根本原因和对诺华数据影响，以及所采取补救措施的进展。

DEFINITIONS
定义
The definitions below apply to the capitalized terms as used in these AISR.
以下定义适用于这些 AISR 中使用的术语。

"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.
"诺华数据"指任何性质（包括个人数据和诺华机密信息）和任何形式的所有数据、信息、文件或记录，无论是在本协议日期之前还是之后存在的，无论是由第三方就向诺华提供的服务创建或处理的，还是由诺华（或代表其行事的第三方）就本协议向第三方提供的。
"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.
"诺华环境"指由诺华、诺华附属公司或诺华分包商管理或代表诺华、诺华附属公司或诺华分包商管理的任何诺华系统或基础设施，可供第三方访问。
"TPC" means the Novartis Third Party Code as referenced in the Agreement.
"TPC"指本协议中提及的诺华第三方准则。

“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.
“MISC”指诺华公共互联网上公布的诺华最低信息安全控制措施：https://www.novartis.com/esg/reporting/codes-policies-and-guidelines，构成 TPC 的一部分。
“Production Environment” means an environment where the software, products, or updates are released to operations for the intended end-users.
“生产环境”是指软件、产品或更新被发布给预定最终用户的操作的环境。
“Recovery point objective (RPO)” means how much Novartis Data can be lost without possibility of recovery.
“恢复点目标（RPO）”意味着有多少诺华数据可能丢失而没有恢复的可能性。
“Recovery time objective (RTO)” means how long the services, Novartis Data, or systems used to deliver the services, under the Agreement may be unavailable.
“恢复时间目标(RTO)”指本协议项下的服务、诺华数据或用于提供服务的系统可能不可用的时间。
“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.
“安全事故”指实际或潜在地危及诺华数据的机密性、完整性或可用性，或以其他方式危及诺华环境的信息安全的事件。
“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.
“安全行业惯例”指与第三方可比较的公司和/或处理类似信息的公司，在信息安全领域内普遍接受的相关行业标准和惯例。如国际标准化组织(ISO/IEC) ISO/IEC ISO27001、ISO/IEC 27002:2013、SSAE-18、ISAE3402、国家标准与技术研究所(NIST) NIST 800-55、开放网络应用安全项目(OWASP)构建安全网络应用指南、以及与根据本协议提供的服务相关的互联网安全中心(CIS)标准（或此类安全标准的任何普遍接受的后续标准）等各种行业标准所述。

Appendix B

NOVARTIS DOING BUSINESS ETHICALLY POLICY

附件 B

诺华全球赢之有道政策

Effective: November 1st, 2023 (Version 1.0 EN)

生效日期：2023 年 11 月 1 日 (版本 1.0 简体中文)

Version ERC 100.V6. EN

版本 ERC 100.V6.简体中文

1 简介

1.1 目的

在诺华，我们创想医药未来以改善人们的生活，延长人们的寿命，利用科学技术解决社会上一些最具挑战性的医疗卫生问题。我们的目的推动我们的价值观并定义我们的文化，我们的道德原则指导我们进行日常决策，使我们能够诚信行事并建立社会信任。

本政策按照我们的 *《道德准则》[1]* 中概述的原则和承诺制定。旨在确保我们在所有外部互动中保持高道德标准。

1.2 范围与适用性

本政策

涵盖了所有与外部利益相关者进行的，存在潜在贿赂、不当影响、不道德业务或不道德推广行为风险的互动。

该政策的内容也是我们 *手册 [2]* 的基础，手册中提供了与某些活动相关的更为详细的指导。因此，该政策应与 *手册 [2]*（美国工作实践文件）、*《反贿赂第三方指南》[3]* 和其他相关的诺华政策、标准或指南一起解读。

该政策及其 *手册 [2]* 可通过 *BeSure 等平台*以数字格式获得。所有互动都必须按照当地法律、法规和行业准则进行。如果任何当地法律、法规和行业准则比本政策中的规定更严格，则必须遵守更严格的要求。

请注意，潜在的、被视为的或实际的利益冲突以及被动贿赂（例如收受贿赂）的情况受 *《利益冲突指南》[4] 的监管*。

该政策适用于所有员工。

该政策于 **2023 年 11 月 1 日**起生效，诺华所有附属公司都必须执行。它取代了当前版本的《诺华反贿赂政策 (AB)》 和《诺华专业互动政策 (P3)》。

所有聘用第三方的诺华员工都有责任确保与第三方签订的合同包含须遵守本政策和手 *册 [2]* 相关规定的条款。

1.3 角色和责任

角色	责任
所有员工	• 在与外部利益相关者互动时必须遵守本政策并符合所有要求
经理	• 确保遵守本政策
公司 ERC	• 拥有并维护本政策

2 我们的道德准则承诺

我们对赢之有道（即以合乎道德的方式开展业务）的承诺是我们所作一切的核心。在瞬息万变的世界中，我们每个人都对我们的行为、我们的决定以及我们与利益相关者的互动负责。

正如我们的 *《道德准则》[1]* 所规定的，我们作出以下承诺，我们每个人都需要坚持：

2.1 我们不容忍任何形式的贿赂或腐败

贿赂可以以多种形式进行。即使是常规商业行为或社交活动（如提供礼品和招待），在某些情况下也可构成贿赂。

因此，我们承诺：

- 我们不会出于不当影响任何决策的目的给予、提供或承诺给予任何有价物（例如，礼物、好处、招待、付款等）。
- 我们不会使用第三方/中间商（例如，代理人，顾问）或任何其他业务合作伙伴来实施贿赂或腐败行为。
- 即使当地法律允许，我们也不会支付通融费。
- 就贿赂和腐败而言，我们不区分政府和公职人员 (GO) 以及私人：无论接收人是何种身份，都不容许贿赂和腐败。

向任何人给予、承诺或提供任何有价物之前，我们必须始终询问自己正在考虑的行为是否会被视为出于不正当的目的。**如果答案是肯定的，则不得进行。**

2.2 我们将保持高道德标准的商业行为

我们对我们的行动、决定以及我们与利益相关者的互动方式负责。我们遵守所有法律和监管要求，并遵守我们行业制定的规则。

因此，我们承诺：

- 我们以负责任、合乎道德和透明的方式与我们的利益相关者互动。
- 我们确保我们的互动有明确、真实、透明和适当的目标，旨在造福患者、医学实践和整个医疗卫生系统。
- 我们以相互尊重的态度对待我们的利益相关者，避免给他们造成任何利益冲突或造成此种印象。
- 我们会为利益相关者提供的服务确定公正、适当和客观的报酬。
- 我们会在当地法律或行业法规规定的情况下披露价值转移和诺华与相关利益相关者的互动，并持续评估在哪些情况下可以而且适宜进行额外的披露以提高透明度。
- 我们重视并尊重利益相关者的独立决策。我们保护研究期间所获得数据的完整性和有效性，并尊重和保护患者和动物的权利、安全性和福祉。
- 我们不会寻求或有意地接受任何会侵犯我们任何利益相关者的保密性和/或隐私权的信息。

3 我们的风险框架

我们的风险框架提供了一种结构化方法来管理与我们的对外互动相关的风险。该风险框架旨在帮助我们识别、评估和管理这些风险。

在我们参与任何活动或互动之前，无论是面对面、通过数字渠道还是两者结合的方式，我们都会考虑以下事项：

定义明确的目标

我们开展具有明确、透明、真实和适当目标的活动。这确保我们在整个活动中始终专注于实现预期目的。

评估风险

我们识别并评估实际的、潜在的或会被他人认为是贿赂或不当影响的风险，以及传播任何误导性信息的风险，并制定缓解措施来应对此类风险。 这确保我们仅在可以适当管理潜在风险的情况下开展活动。

适当互动

我们以合乎道德、诚信的方式行事，并遵守当地法律、法规、行业准则和内部政策。这确保我们维护信任并满足内部和外部利益相关者的期望。

监控、核对和学习

我们监控和核对我们的活动，以确保活动按照批准的方式进行，实现其预期目标，适当管理已识别的风险，并维护和保留相关的支持文件。这确保我们能够学习和应对新情况，并不断改进我们的工作方式。

4 我们的互动

当我们与不同类型的外部利益相关者互动时，例如医疗卫生专业人员 (HCP) 和医疗卫生组织 (HCO)、患者、看护人员和患者组织 (PO)、政府和公职人员 (GO)、学术和科学机构、付款人、批发商和分销商、供应商、非政府组织 (NGO)、媒体代表和社交媒体网络红人，我们承诺以负责、合乎道德、透明和专业的方式行事。

互动的基础

我们必须考虑我们活动的预期目的以及这些活动是推广性质还是非推广性质。这是为了保持非推广活动的非推广实质，并遵守非推广活动与推广活动之间的界限。

我们不会直接向患者或公众推广产品，除非当地法律或法规允许。在允许此类直接面向消费者的推广时，我们会根据适用法规负责任地进行推广。我们绝不鼓励不必要或过度使用诺华产品。

我们不会在任何非推广情况下使用带有任何推广内容的资料，以避免被看作变相推广。

信息和资料标准

我们分享准确、清晰、公正、均衡、真实且无误导性的信息。

我们仅在收到上市许可后，根据批准的药品说明书进行产品推广。

我们在推广时，仅引用被批准的药品说明书，或被科学证据证实的信息。

HCP、患者组织及其他外部利益者相关者可能会主动向我们要求获得未批准上市药物和未批准适应症信息。只有来自医学部或任何其他被授权部门的某些代表可以对这些要求做出回应提供此类信息。

互动的类型

与外部利益相关者的互动可以有多种形式。我们将这些互动分为以下三大类：

1. 聘用
2. 资助与合作
3. 礼品、样品和其他物品

4.1 聘用

我们选择与信誉良好的外部利益相关者合作，这些利益相关者具有提供所需服务的必要经验和能力。如果没有足够的履行证明，我们不会为服务付费。

我们可以直接或通过第三方聘用外部利益相关者。然而，无论我们如何聘用，我们都有责任恰当地进行互动，避免意图不当地影响我们利益相关者的决策，避免被他人认为对决策造成不当影响，或实际对决策造成不当影响的后果，包括推荐、购买、开具处方或使用我们的产品。

除了这些适用于**所有**聘用的一般要求外，某些类型的聘用可能需要考虑一些额外事项，具体如本节所述。

研究

我们仅在为了回答相关科学、卫生经济学、行为、政策或社会问题以更好地理解和加强患者关怀或任何其他相关目标时才进行研究。

我们尊重和保护患者和动物的权利、安全性和福祉，并保护所获得数据的数据完整、准确性、保密性和有效性。我们遵循适用和既定的伦理、科学、法律和监管标准，并确保我们的研究具有社会和临床价值。

我们确保：

- 研究对象的选择是公正的、合乎道德的，并且尊重多元化和包容性的重要原则。研究绝对不是推广性质的活动。
- 我们的研究由合格的研究人员在适当的机构/中心进行。
- 根据适用的法律法规，识别、收集、监测、适当跟进不良事件并向相关卫生当局或机构适当报告。
- 及时发表研究结果，禁止扣留或隐瞒数据。我们必须保护机密的、可取得专利的信息和/或个人信息。

专业服务

我们聘请外部利益相关者提供专业和正当的服务，包括但不限于顾问、咨询服务和演讲。

我们记录要执行的约定服务。对于有偿专业服务，在开始服务之前，服务相关方必须有已生效的且对所有相关方有约束力的书面协议。

以下外部利益相关者适用的特殊考虑事项：

- 如果 GO 有影响诺华业务的直接/实际职位，则不能聘用他们提供有偿专业服务。
- 符合 GO 定义的 HCP、科学家和学者可以提供有偿专业服务，但前提是他们以 HCP、科学家或学者的身份行事。在以这种身份行事时，他们可能会受到我们必须遵守的其他法律、法规和行业准则的约束。
- 在聘请有影响力的人提供服务时，本政策中引用/定义的所有承诺和要求均适用。这是为了避免对 HCP、患者或弱势群体产生不当影响的风险，包括数字内容可能被视为对诺华产品的不当推广的风险。

药房服务

我们可能聘用药房，利用药房资源和能力提供推广和非推广服务。我们不会通过药房服务不当影响 HCP、HCO 或患者。

活动和专业会议

我们出于科学、教育、政策、推广或其他专业目的组织活动和专业会议，或资助第三方组织的活动和专业会议。此类活动可以通过现场参会方式或虚拟方式进行。

对于诺华组织的活动和专业会议：

- 我们必须有明确和正当的目的，并且活动必须符合当地法律法规和行业准则，在有利于交流目的的场所公开透明地进行，不得被认为是奢侈或不适当的。
- 我们可能仅以茶点和/或餐点的形式款待参与者，这些款待必须适度、合理，是活动主要目的的附带内容。
- 我们不会为参加诺华商务会议、大会或类似活动的任何 HCP 提供娱乐。对于涉及除 HCP 以外的任何利益相关者的任何活动，不提供娱乐，除非娱乐是此类活动适当的、附带的一部分，并且是当地法律法规允许的。我们不会为任何顺带的或延长的旅行支付费用。
- 我们不会为诺华商务会议、大会或类似活动受邀者的随从人员支付娱乐、招待、或差旅费用。受邀者不能独自出行（例如，患者或未成年人），或必须与官方委派人员一起出行的情况下，可以支付随从人员（例如看护人员或官方委派人员）的差旅费用，前提是提供这种支持的理由要正当、有文档记录并且考虑了适用的数据隐私要求。

对于第三方组织的活动和专业会议：

- 在评估其适当性时，我们会考虑诺华自己主办的活动标准。
- 我们会书面记录为第三方组织的活动提供的任何资助支持，并应由双方确认。
- 我们不会将从第三方活动组织者处获得的任何利益传递给客户或潜在客户。

学习与教育

学习和教育的目的是提高 HCP 和 GO 的科学知识、技能和能力，以改善患者关怀、医疗实践以及患者和医疗卫生的整体结果。

如果市场上有明确的教育需求，我们可以资助参与者参加第三方活动（例如会议）。此类第三方活动可以是现场形式（国内/国际）、虚拟形式或混合形式。在可行、适当且符合教育目标的情况下，对于不担任讲者、顾问、海报展示者或不会为诺华担任其他积极角色的 HCP，我们应该考虑支持他们以虚拟形式参加。

我们不会为 HCP 的陪同人员支付相关费用或帮助其参与活动。

GO 可能会受到其他法律、法规和行业准则的限制。

公共政策参与

我们的公共政策参与活动对于与外部利益相关者（如 GO）进行建设性对话至关重要，其目的是创造和支持基于证据的解决方案，改善创新药物的可及性。

我们本着透明、诚实和诚信的价值观，出于合法目的与外部利益相关者进行互动，并确保我们的公共政策立场和预期结果对我们的利益相关者清晰明了，并有适当的文件记录。

我们以协作和公正的心态开展公共政策参与活动，旨在为我们的利益相关者提供长期价值。

我们确保我们的公共政策参与活动不会被滥用于任何腐败或非法目的，或不正当地影响任何决定。

我们根据我们的内部政策（包括*道德规范 [1]*）、适用法律、法规和行业准则披露与公共政策参与相关的费用。

定价和市场准入

我们可以与参与推荐、决定诺华产品纳入医保、或购买诺华产品的外部利益相关者进行互动。这种情况下：

- 我们确保所有讨论都是真实、准确和透明的。
- 我们根据当地法律、法规和行业准则披露与作为处方委员会成员的 HCP、科学家或学者的互动，并在我们的账簿和记录中准确、适当地记录折扣、商业返利和其他付款。
- 我们遵守适用的当地法律法规。
- 如果讨论涉及尚未在该国家或地区获得批准的产品，我们确保所有交流都是非推广性的。

如果是和 GO 进行往来互动，我们了解他们还会受到其他法律、法规和行业准则等的限制。

患者沟通

我们可能会支持患者、看护人员或患者组织或与他们互动。

当向患者或患者组织提供支持或与他们互动时，我们确保所有互动都符合道德、透明、不具有推广性质，并符合诺华的使命，同时保持患者和患者组织的独立性。

我们在书面协议中记录任何互动或支持，其中包括支持的性质、资助金额、明确的可交付成果和活动的目的。

患者支持项目 (PSP)

我们可能会在一段固定的时间内以患者支持项目的形式向患者和患者组织提供支持。这些计划可能包含财务支持、产品使用支持、一般患者支持、产品/疾病教育、诊断或这些内容的组合。

我们不得设计或使用 PSP 来鼓励开具诺华产品的处方。

如果 PSP 包括从患者收集数据，包括对计划进行反馈，则可能还适用其他法规。同样，如果 PSP 包含数字或软件部分，则数字化互动方面的管理和法规也可能适用。

根据适用的法律法规，识别、收集、监测、适当跟进不良事件并向相关卫生当局或机构适当报告。

管控式用药项目 (MAP)

如果当地法律和/或法规允许，我们可以在临床试验之外，为患有严重或危及生命的疾病或病症但没有相当的或令人满意的替代疗法的患者提供在当地未获批准或无法获得的诺华产品。仅当满足所有 MAP 标准（包括非诺华主动提供的标准）时才提供此类机会。请求必须是独立地从 HCP、HCO、医疗机构或任何其他相关的合格机构收到的。

数字健康活动

我们可能支持使用技术来帮助改善个人的健康和保健，推进诊断、疾病管理和整体医疗卫生方面的改进，以及降低医疗卫生成本，包括症状追踪器、配套应用程序和诊断工具。

我们可以通过开发数字解决方案、在第三方平台内提供内容或通过许可和/或订阅支持对此类平台的访问来实现这一点。在所有情况下，目标都是增加患者的可及性和/或减少现有的健康差距。

利用社交媒体和数字渠道

我们生活在一个"信息社会"，这个社会提供数字渠道和社交媒体作为与我们的外部利益相关者进行有关医药产品和治疗领域的传递、沟通和互动的新方式。这些渠道的使用适用 *《社交媒体准则》（数字参与平台的个人使用）[5]*，并且需要考虑和管理与使用社交媒体相关的其他风险。

使用第三方

我们仅在以下情况下聘用第三方：

- 这些第三方承诺会达到诺华的标准，例如 *《第三方准则》[6]* 中涵盖的标准。
- 其服务及货物定价不高于市场价值，除非 *《全球采购指南》[7]* 允许。
- 第三方适合未来开展的活动，并根据 *《反贿赂第三方指南》[3]* 进行了适当的尽职调查（包括反贿赂尽职调查，如适用）。
- 签订了书面协议或者其他具有类似法律效力的书面文件，例如采购订单。 *《全球采购指南》[7]* 的相关规定应适用。

4.2 资助与合作

我们可能会与信誉良好的外部利益相关者合作或向其提供资助，以改善医疗卫生、推进科学/医疗知识的进步，或支持我们生活和工作的社区，我们可能会与信誉良好的组织合作或向其提供资助。

所有类型的资助与合作都必须有明确和透明的目标，并应有文件记录。

资助

我们可能会向外部组织提供资助，以推动诺华的使命、推进科学知识的进步或支持社区。这可以以医疗卫生、慈善或企业公民资助的形式提供。

支持第三方申办的临床研究活动的资助应通过研究者发起的试验/研究 (IIT/IIR) 途径进行。

对 HCP 和第三方组织的活动的赞助受第 4.1 节"聘用"的监管。

在提供资助时，我们：

- 仅支持合法的信誉良好的组织，但绝不支持个人。
- 避免任何潜在利益冲突，并且不得使用资助获取不当利益或取悦某个资助接受方。

- 鉴于所支持活动的类型，确保任何资助均合理，并根据当地法律、法规和行业准则正确跟踪、记录、披露和说明。

合作项目

我们可能会决定与信誉良好的外部利益相关者合作，以强化医疗卫生系统并规模化使患者受益。此类合作的目标必须旨在改善患者关怀、优化患者体验或强化整体医疗卫生系统。

我们确保参与合作的各方都积极参与并为推进共同目标做出贡献，这些目标必须清晰透明。

政治捐助

我们只能在符合当地传统的国家提供政治捐助，以帮助建立可持续的医疗卫生系统、推进突破性的医疗创新或以其他方式支持诺华的正当利益。 在进行政治捐助时，我们必须遵守以下要求：

- 遵守适用的法律、法规和行业准则。
- 在专门的预算涵盖范围内，通过正常预算流程审批。
- 事先获得相关诺华所在国家总裁或其指定人员或公共事务代表的批准。
- 已对政党和接受捐助的代表进行适当的尽职调查。

专业组织的成员资格

我们可加入专业组织，包括商会和医学协会，以代表诺华进行发声。这样做时，我们确保此类成员资格：

- 符合诺华的总体使命和利益。
- 在加入任何此类组织之前，有明确的预期结果并妥善记录。
- 经所在国家/地区诺华法人实体负责人或其指定人员或代表批准。
- 遵守适用的法律法规。

我们不会出于不当影响该组织或其成员的意图加入任何组织。

加入行业协会和进行信息交流必须符合*《反垄断与公平竞争政策》[8] 的要求。*

我们绝不资助外部利益相关者成为专业组织的成员或对此进行补偿。

4.3 礼物、样品和其他物品

我们绝不会承诺、提供或给予任何有价物、以试图影响接收人做出有利于诺华的事情、或对这种行为进行回馈、或试图使接收人不做出不利于诺华的事情。

礼物、招待和娱乐

我们不向任何外部利益相关者提供现金和作为现金等价物的礼品（例如，礼品卡）。

我们不会向 HCP、HCO、PO 或患者及其家庭成员提供娱乐、任何种类的礼物，包括个人礼品、风俗礼节物品或推广辅助用品，不论是否标示品牌。我们不得将个人资金用于任何这些物品。

不鼓励向 GO、媒体和（上面未提及的）其它外部利益相关者赠送礼品。仅当满足以下所有条件时，才允许赠送小礼品表示感谢：

- 适度、合理、不频繁，并且以公开透明的方式给予，并且
- 得到当地法律、法规和任何适用于接收人的内部政策允许
- 不会提供给处于能够关于诺华业务做出决定的职位的接收人。
- 不会与接收人的职责产生冲突，或者被他人认为存在冲突
- 如果不提供此类象征性的小礼品会造成尴尬，或者被认为是对当地习俗的不尊重。

我们接受或被赠与礼品的情况受 *《利益冲突指南》[4]* 的监管。

样品

在当地法律、法规和行业准则允许的情况下，我们可以向有产品处方权的 HCP 提供诺华医药产品的免费样品，以使他们和患者熟悉产品，最终达到改善患者关怀的目的。

提供样品时：

- 我们不会提供它们作为推荐和/或开具处方、购买、供应、销售或给药诺华产品的诱因。
- 在当地法律、法规和行业准则允许的情况下，我们可以直接向患者分发非处方药 (Over The Counter, OTC) 产品样品。
- 它们必须标记为样品，以防止转售或任何其他滥用。

医用物品和教育用品

在当地法律、法规和行业准则允许的情况下，我们可以向 HCP 提供医用物品，这些物品在价值方面应适度、合理，且提供频率应是偶尔为之。

医用物品必须：

- 用于对 HCP 或患者进行直接教育，或协助患者进行治疗或管理他们的病况，以及
- 不得用来抵消正常运营成本或日常业务开支，或为 HCP 带来个人利益。
- 不得使用标示品牌的产品（无产品标识），除非品牌的标示对于患者正确使用该物品至关重要，或是遵循当地法律、法规或行业准则的要求。

书籍和订阅的价值必须合理。其他教育用品必须价值适中。

在限定的商定期限内，我们可以向 HCP 或 HCO 免费提供演示和测量器械。

我们在提供器械时，会考虑潜在的价值转移，我们会确保器械贴有适当的标签，并且在收到其用于预期用途的上市批准之前不会提供它们。

我们确保在整个测量期间，器械的所有权归属诺华，且在非测量期间不得存放在任何 HCP 或 HCO 的住所内。

5 控制

本文档的控制存储在诺华控制登记册中，网址为" *go/controlregister*"。

6 违反本政策

违反本文件将导致补救、纠正措施或纪律处分，情节严重时包括终止雇佣关系。

实际或可疑的不当行为应根据 *SpeakUp 政策 [9]* 进行报告。诺华将采取措施进行保密，并禁止对通过任何渠道善意报告可疑或实际不当行为的员工或配合不当行为调查的员工进行任何形式的报复。

7 例外情况

本政策不允许有例外情况。

8 改编

不允许对本政策进行改编。

9 定义

术语	定义
员工	诺华公司及其关联机构的员工，包括高级职员和经理，以及通过外部服务提供商雇用的任何外部员工。
贿赂	提供、给予或承诺（或授权某人提供、给予或承诺）不当利益，试图直接或间接地影响或回馈某人的行为以便获得或维持商业利益。
看护人员	帮助患者完成日常活动、进行医疗保健或帮助患者完成因疾病或残疾而无法自己进行的任何其他活动的人员。此人也可能参与或直接为患者做出医疗决策。看护人员的例子包括父母或法定监护人、配偶或伴侣、成年子女、亲属或其他朋友。
风俗礼节物品	与医学实践无关，仅表达对当地重大国家纪念日、文化或宗教节日、大型活动的庆祝与问候的小额物品（也被称为"礼节性礼品"）。
外部利益相关者	任何非诺华员工或不为诺华工作的人员，其行为可能对诺华产生影响。
通融费	支付给 GO 用于加快履行非自由决定性质的职责。这些费用的意图是仅影响政府官员的履行时间（例如付款以便加快签证发放或海关清货），而不影响最终结果。
公允市场价值 (FMV)	用以确定为在给定国家提供的服务的付款金额是否适当的方法。
礼品	礼品是指作为答谢或友谊的表示给予某人任何形式的利益，而不期望收到任何回报。其中包括"礼节性礼品"，即在文化上认可的场合（例如婚礼、葬礼）或者年度特殊时期（例如圣诞节、新年）给予的小礼品。

政府和公职人员 (GO)	任何政府或政府部门、政府机关，或由政府所有或部分所有的公司推举或委任的官员或员工。在政府所有或政府部分所有的医院、诊所、大学或其他类似机构内就职的医学和科技人员也被视为政府官员。 • 任何国际公共组织（例如联合国）中选举或指派的官员或雇员 • 任何以官方身份或代表政府或政府部门、政府机关或公共国际组织行事的人员 • 政治人物和政治职务候选人 • 根据适用法律、法规和行业准则，属于政府官员的任何其他人
医疗卫生组织 (HCO)	无论公立还是私立，任何向患者提供医疗服务，能够开药方、定购、分配、建议、购买、供给、给药、出租和使用诺华产品的法人实体（例如，公司、合伙企业或医疗卫生协会）及其所有办公人员和医疗协会或组织。
医疗卫生专业人士 (HCP)	任何医疗、牙科、药房或护理专业人员，或任何在其专业活动中可开具处方、推荐、采购、供应、销售或给药药用产品的其他人员。
研究者发起的试验/研究 (IIT/IIR)	由独立研究者或学术申办方开发和申办的具有科学和医学价值的研究。IIT 可以是在没有诺华参与的情况下进行的临床或非临床研究，IIT 申办方请求诺华对此提供资金、药品或两者。
管控式用药项目 (MAP)	向患有严重或危及生命的疾病或病症的患者提供其所在国家尚未批准或尚未获得的医疗产品的计划。
媒体代表	代表电台、电视台、报纸、新闻杂志、期刊、网站、博客或新闻机构收集和报道诺华问题的任何个人。
患者	有带病生活的亲身经历的人。他们的主要作用从主观角度上分享自己的疾病和治疗经验。
患者组织	主要代表患者及其家人和/或看护人员利益和需求的非营利机构。
患者支持项目 (PSP)	患者支持项目 (PSP) 是一个总称，用于描述旨在改善医药产品的获取、使用和依从性的计划或举措。在某些司法管辖区，当地法律可能要求仅在患者已经或打算接受诺华治疗后才提供此类计划
药房	任何有资格并在适用情况下获准推荐、给药或配发医药产品的法人实体。术语"药房"包括个体药房、连锁药房（通过法律途径或由相同的管理/所有权关联的几家个体药店，或有权签订合同并在属于不同法律实体，例如，购买集团、药店协会、特许经营店等的药店执行服务的营销服务提供者）以及注册为药房的个人。
药房服务	诺华将药房资源和/或能力用于以下目的之一的任何安排： • 向最终客户推广/宣传诺华和/或产品品牌；或者 • 购买适当的内部决策和分析所需的数据；或者 • 促进患者获得诺华产品（即药房中产品的实际提供、促进面向最终消费者的折扣活动等）。
推广	由诺华公司开展、组织或赞助的任何针对 HCP 的活动，旨在通过所有沟通方式（包括互联网）促进我们医药产品的处方开具、推荐、供应、给药或消费。
社交媒体网络红人	社交媒体网络红人是在某个行业或内容类型中建立了信誉的人，可以接触到广泛的受众并且其观点受到目标受众的积极评价。

第三方	第三方是诺华通过提供/接收商品和/或服务/活动与之互动的任何个人或法人实体。在本政策中，诺华关联机构和员工、HCP 以及 HCO 不属于第三方范围。

10 缩略语

缩略语	描述
DTC	直接面向消费者推广
FMV	公允市场价值
GO	政府或公职人员
HCO	医疗卫生组织
HCP	医疗卫生专业人士
IIR	研究者发起的研究
IIT	研究者发起的试验
MAP	管控式用药项目
PO	患者组织
PSP	患者支持项目

11 参考文件

参考编号	文档名称
1	道德准则
2	赢之有道手册
3	反贿赂第三方指南
4	利益冲突指南
5	社交媒体指南（数字互动平台的个人使用）
6	诺华第三方准则
7	《全球采购指南》
8	反垄断与公平竞争政策
9	SpeakUp 政策

Appendix C
DATA PROTECTION REQUIREMENTS
附件 C
个人信息保护要求

1. **Conflict and Survival 冲突和存续**
   1.1. This Data Protection Requirements Appendix ("**Data Protection Appendix**") is made a part of the Agreement and incorporated therein by reference. This Data Protection Appendix will survive the expiration or termination of the Agreement for as long as Personal Data is being processed by Data Processor. In the event of a conflict or inconsistency between this Data Protection Appendix and any other portion of the Agreement, this Data Protection Appendix will govern.
   本个人信息保护要求（"**数据保护附件**"）是本协议的组成部分，并通过引用纳入其中。只要数据处理方在处理本附件范围内的个人信息，本数据保护附件在本协议到期或终止后将继续有效。如果数据保护附件与协议的任何其他部分发生冲突或不一致，则本数据保护附件优先适用。

2. **Specification of the Personal Data and Processing Activities 个人信息和处理活动**
   2.1. Personal Data under this Appendix means any information related to identified or identifiable natural persons recorded by electronic or other means that is Processed directly or indirectly, by Supplier or Supplier Subcontractors on behalf of and as instructed by Novartis. This may include name or initials, home or other physical address, cell/mobile or telephone number, photograph and/or any data or information subject to Data Protection Laws.
   本附件范围内的个人信息是指供应商或供应商的分包商代表诺华并根据诺华指示，直接或间接处理的任何以电子或者其他方式记录的与已识别或者可识别的自然人有关的各种信息。这可能包括但不限于：名字或姓名首字母缩写、家庭或其他地址、手机或电话号码、个人健康信息、收入信息、照片和/或任何受数据保护法约束的其他数据或信息。
   2.2. The types of Personal Data, methods, purpose, duration, and protection measures of Processing of Personal Data, by the Supplier are defined in the Agreement.
   供应商处理个人信息的种类、处理方式、目的、期限和保护措施由本协议及/或适用的工作说明书或采购订单约定或决定。

3. **Technical and Organisational Measures 技术和组织措施**
   3.1. Supplier shall carry out Processing activities on Personal Data solely for the purpose and requirements specified in the Agreement and as instructed by Novartis. All persons who have access to Personal Data must maintain its confidentiality, the limitation of use to specific purposes, and access shall be permitted on a need-to-know basis to the extent required for the performance of Supplier's obligations. Supplier shall ensure that all persons who have access to Personal Data have received appropriate privacy and security training, which shall be updated periodically in accordance with applicable laws, regulations, and industry standards, or as otherwise requested by Novartis. Supplier shall not use or disclose any Personal Data that Supplier creates, receives, maintains, or transmits as a result of performance of Supplier's obligations, other than as expressly permitted or required by the Agreement.
   供应商应按照本协议中规定的目的和要求，并按照诺华的指示开展个人信息处理活动。所有有权访问个人信息的人员必须对数据严格保密，确保仅为特定目的使用，并且仅在履行供应商义务所需的范围内，在"需要知道"的基础上访问。供应商应确保所有有权访问个人信息的人员都已经接受适当的隐私保护和安全培训，并应根据适用的法律，法规和行业标准或按照诺华的其他要求进行定期更新。除非本协议明确允许或要求，供应商不得使用或披露其为履行供应商义务而创建，接收，维护或传输的任何个人信息。
   3.2. The Supplier shall establish the minimum technical security and organizational measures referenced in the Third Party Code together with any additional requirements, if applicable. The technical and organisational measures are subject to technical advancements and development. In this regard, it is permissible for Supplier to implement alternative adequate measures so long as the minimum defined level of security is not reduced. Substantial changes must be documented.
   供应商应制定"**诺华第三方准则**"中提及的最低技术安全和组织措施以及任何额外安全要求（如有）。技术和组织措施受到技术进步和发展的影响。在这方面，只要不降低最低定义的安全水平，供应商就可以实施替代的适当措施。供应商应有正式的流程管理和记录此类变更。
   3.3. Throughout the term of the Agreement, Supplier will maintain and monitor a comprehensive, written privacy and information security program, including data protection policies and procedures, and consistent with any privacy compliance plan established between the parties and attached hereto, that contains administrative, technical and physical safeguards designed to protect against reasonably anticipated threats to the security, confidentiality or integrity of, and the unauthorized Processing of, Personal Data. Supplier will periodically assess reasonably foreseeable risks to the security, confidentiality, integrity, and resilience of electronic, paper and other records containing Personal Data and evaluate and improve, where necessary, the effectiveness of its safeguards for limiting those internal and external risks.
   在整个协议期内，供应商需维护和监控一个全面的书面隐私和信息安全计划，包括符合本附件要求的个人信息保护政策和流程，其中包含旨在防止可合理预见的信息安全、保密或完整性以及防止未经授权的个人信息处理相关的管理、技术以及物理的防护措施。对于包含个人信息的电子、纸质和其他记录的安全性、保密性、完整性和可用性等方面可合理预见的风险，供应商应进行定期评估，并在必要时评估和改进其控制内部和外部风险的保护措施的有效性。

4. **Rectification, Restriction, Cross-Border Transfer and Erasure of Personal Data 修改、限制、跨境传输和删除个人信息**

4.1. The Supplier may not on its own authority rectify, erase or restrict the processing of Personal Data that is being processed on behalf of Novartis or transfer any Personal Data outside of China, except by written instructions from Novartis. Supplier will notify Novartis promptly (and in any event within five business days from receipt) of any communication received from a Data Subject relating to the Data Subject's rights to access, modify, correct or delete Personal Data and to comply with all instructions of Novartis in responding to such communications.
除诺华的书面指示外，供应商不得自行更改、删除或限制正在代表诺华进行的个人信息的处理或向中国境外传输本附件范围内的个人信息。如果收到来自信息主体的任何与信息主体访问、修改、更正或删除个人信息等权利相关的任何要求或投诉等，供应商应立即通知诺华（且任何情况下应在收到通知的五个工作日内），并遵守诺华回应相关要求或投诉的所有指示。

5. Quality Assurance and other Duties of Supplier 供应商的合作和其他义务

5.1. As requested by Novartis at any time, Supplier shall immediately (at least within twenty four (24) hours) provide Novartis with the contact details of Supplier's data protection officer or person responsible for personal data protection for the purposes of direct contact.
如果诺华在任何时候提出要求，供应商应立即（至少二十四（24）小时内）向诺华提供其个人信息保护专员（如法律有专员指定的强制要求）或者如前述不适用，提供负责个人信息保护的人员的联系方式，以便直接联系。

5.2. Supplier will notify Novartis in writing and as soon as practical of any request made by any government, law enforcement or regulatory agency (but no later than one (1) business day from the date of any such request) for information concerning, or access to, Personal Data, unless notification to Novartis is prohibited by Data Protection Laws or other applicable laws, rules, regulations or orders. Supplier will cooperate with Novartis in responding to such requests.
如果任何政府、执法机构或管理机构要求提供有关个人信息的相关信息或提出访问个人信息的任何要求时，供应商应以最快的速度书面形式通知诺华（但不迟于收到此类请求之日起一（1）个工作日），但数据保护法或其他适用的法律、法规或命令禁止通知诺华的除外。供应商应与诺华合作响应或回复此类要求。

5.3. Novartis shall be informed immediately of any inspections and measures conducted by the supervisory authority, insofar as they relate to the Processing of Personal Data. This also applies insofar as the Supplier is under investigation or is party to an investigation by a competent authority in connection with infringements to any civil or criminal law, or administrative rule or regulation regarding the processing of Personal Data in connection with the Agreement.
供应商应立即通知诺华关于监管机构进行的任何与个人信息处理相关的检查和措施。这也适用于供应商正在被调查中，或者作为与本协议项下处理个人信息相关的主管当局调查（包括民事侵权、刑事或者行政）的当事一方。

5.4. As requested by Novartis, Vendor shall make available to Novartis all information necessary to demonstrate compliance with this Data Protection Appendix and shall allow for and contribute to audits, including inspections, conducted by Novartis or another auditor mandated by Novartis.
如果诺华要求，供应商应向诺华提供所有必要信息和说明等以证明其符合本附件约定的要求，并应允许并协助诺华或其授权的审计人员进行审核。

6. Supplier Subcontracting 供应商分包

6.1. Subcontracting for the purpose of this Data Protection Appendix are to be understood as meaning services which relate directly to the provision of the principal obligation related to the processing of Personal Data pursuant to the Agreement. This does not include ancillary services, such as telecommunication services, postal / transport services, maintenance and user support services or the disposal of data carriers, as well as other measures to ensure the confidentiality, availability, integrity and resilience of the hardware and software of data processing equipment.
本数据保护附件的项下的分包应理解为根据本协议，与提供个人信息处理有关的主要义务直接相关的服务。这不包括辅助服务，例如电信服务，邮政/运输业务，维护和用户支持业务或数据载体处理，以及确保数据处理设备硬件和软件的机密性，可用性，完整性和恢复的其他措施。

6.2. Supplier understands and agrees that, without limitation, the confidentiality, privacy and security requirements contained in the Agreement also apply to any permitted Supplier Subcontractors, temporary employees or other third-parties who receive any Personal Data as a result of the Agreement. Supplier shall only enter into sub-contract agreements that include data protection provisions no less restrictive than the provisions set forth in this Data Protection Appendix. Upon written request by Novartis, copies of such sub-contracts shall be provided to Novartis within seven (7) business days. Novartis must be granted (a) the right to monitor and inspect Supplier Subcontractors upon reasonable notice and (b) the right to obtain information from Supplier about the substance of the sub-contract and the implementation of the data protection obligations within the sub-contract relationship, upon written request.
供应商理解并同意，本协议中包含的保密，隐私和安全要求也适用于任何基于本协议而接收任何个人信息的供应商的分包商、临时雇员或其他第三方。供应商应签订分包协议，其包含的数据保护条款不得低于本数据保护附件中规定的限制条款。在诺华提出书面要求的情况下，供应商应在七（7）个工作日内向诺华提供此类分包协议的副本。供应商应授予诺华（a）在合理的通知下监督和检查供应商的分包商的权利，以及（b）经书面要求，有权从供应商获得有关分包协议的实质内容以及分包协议内数据保护义务的实施情况。

7. Data Security Breach 数据安全事件

7.1. At any time during the processing of Personal Data, Supplier shall notify Novartis immediately of any Data Security Breach (or any data compromise, damage or loss) involving Personal Data which may affect Novartis data under this Agreement, including any breach at facilities, systems or equipment of Supplier's subcontractors. The Novartis contact for reporting Data Security Breach identified by Supplier: soc@novartis.com. Supplier agrees to assist and cooperate with Novartis concerning any disclosures to affected parties, government or regulatory agencies and with any other remedial measures requested by

Novartis or required under any law. Supplier will take such mutually agreeable steps to prevent the continuation or repetition of such Data Security Breach.
在个人信息处理过程中，如果发生任何涉及个人信息的数据安全事件或者任何数据泄露、毁损、丢失等情况可能影响本协议项下诺华相关数据（“**数据安全事件**”），包括在供应商的分包商的设施、系统或设备等发生的数据安全事件，供应商应立即通过soc@novartis.com通知诺华。供应商同意协助并与诺华合作处理任何向受影响的第三方、政府或监管机构的披露以及采取诺华或法律所要求的任何其他补救措施。供应商应采取共同同意的步骤防止此类数据安全事件持续或重复发生。

7.2. Unless otherwise required by applicable Data Protection Laws or any other law, rule, regulation or order, Supplier will make no disclosures to affected parties or any government, law enforcement or regulatory agencies concerning a Data Security Breach relating to the Personal Data except as directed by Novartis. Notwithstanding the foregoing, Supplier may contact local police in the event of a physical breach of Supplier facilities or theft of equipment or documents.
除非适用的数据保护法或任何其他法律、法规或命令另有要求，在没有诺华指令的情况下，供应商不应向受影响的第三方或任何政府、执法机构或监管机构披露与个人信息相关的数据安全事件。尽管有上述规定，供应商可能会在发生供应商设施的物理损坏或者设备或文件被盗窃的情况下与当地警方联系。

7.3. Supplier will assist and cooperate with Novartis concerning any disclosures to such parties or agencies, and with any other remedial measures requested by Novartis or required under any law, rule, regulation or order applicable to Supplier or Novartis, at Supplier's expense, including providing notice to Data Subjects of a Data Security Breach and providing any other services to such individuals.
供应商应自行承担所有费用协助并与诺华合作处理任何向相关第三方、政府或监管机构的披露以及处理诺华要求的或法律、法规或命令所要求的任何适用于供应商或诺华的其他补救措施，包括但不限于通知信息主体发生的数据安全事件，以及向这些个人提供的任何其他服务。

8. Deletion and Return of Personal Data 个人信息的删除和返还

8.1. Copies or duplicates of Personal Data shall never be created without the knowledge of Novartis, with the exception of back-up copies as far as they are necessary to ensure orderly data processing, as well as Personal Data required to meet regulatory requirements to retain data.
在诺华不知情的情况下，供应商不得创建任何个人信息的复印件或副本，但是确保数据处理所必须的备份副本或者为满足法律或监管机关数据留存要求所需的个人信息除外。

8.2. Upon termination or expiration of the Agreement, or as requested in writing by Novartis at any time, Supplier will, at its own expense and at Novartis's option: (a) promptly return all Personal Data; or (b) destroy all documents, materials, and any other media that may contain Personal Data, without retaining any portion or copy thereof. Supplier will provide Novartis with a Certificate of Destruction of Personal Data in a form acceptable to Novartis, signed by an authorized employee of Supplier who has supervised such destruction.
本协议终止或到期时，或者根据任何时候诺华的书面要求，供应商应自行承担费用并按诺华的要求：（a）及时归还所有个人信息；或（b）销毁所有可能包含个人信息的文件、资料和其他媒体，而不保留任何部分或副本。供应商应向诺华提供一份诺华接受的个人信息销毁证明，由供应商授权的监督销毁的员工签署。

9. Definition 定义

“**Personal Data**” – The definition set out in Article 2.1 of this Appendix.
“个人信息” – 定义见本附件2.1条。

“Data Protection Laws” – all laws, rules, regulations, and orders of any jurisdiction or subdivision thereof relating to the privacy, security, confidentiality and/or integrity of Personal Data that are applicable to the operations, services or products of Supplier and Novartis, including but not limited to China Cybersecurity Law and other laws and regulations governing personal data protection.
“数据保护法”–
适用于供应商或诺华的运营、服务或产品的，有关个人信息隐私、安全、保密和/或完整性相关的任何管司法辖区的法律法规，包括但不限于中国网络安全法以及其他规制个人信息保护的法律和法规。

“**Data Security Breach**” – (a) the loss, inadvertent disclosure, unauthorized access to or acquisition of or misuse of Personal Data or any media containing Personal Data; (b) the disclosure or use of Personal Data in a manner inconsistent with Data Protection Laws, the Agreement or this Data Protection Appendix; or (c) any other act or omission that negatively impacts the security, confidentiality, and/or integrity of Personal Data.
“数据安全事件” –
（a）个人信息的丢失、疏忽泄露、未经授权访问、获取或滥用，或任何含有个人信息的媒介遗失；（b）以不符合数据保护法、协议或本数据保护附件的方式披露或使用个人信息；或（c）对个人信息的安全性、保密性和/或完整性有负面影响的任何其他行为或不作为。

“**Data Subject**” – an identified or identifiable person whose Personal Data are processed, accessed, received, transmitted, deleted, or maintained by the Supplier on behalf of and under the instruction of Novartis. An identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his/her physical, physiological, mental, economic, cultural or social identity.
“信息主体” –
供应商代表诺华并在诺华指导下处理、访问、接收、传输、删除或维护的个人信息所能识别或可识别的个人。可识别的个人可能是直接或间接识别的人，特别是通过结合身份号码或者一个或多个他/她的身体、生理、精神、经济、文化或社会身份的特定因素。

"**Process, Processed, Processing**" – any handling of Personal Data by any means, including, without limitation, collecting, accessing, receiving, using, transferring, retrieving, manipulating, recording, organizing, storing, maintaining, hosting, adapting, altering, possessing, sharing, disclosing (by transmission, dissemination or otherwise making available), blocking, erasing, destroying, selling, or licensing.

"处理" –

以任何方式处理个人信息，包括但不限于收集、访问、接收、使用、转移、检索、操作、记录、组织、存储、维护、托管、改编、拥有、共享、披露（通过传输、传播或其他方式提供）、限制、删除、销毁、出售或许可。

"**Supplier**" – the performer and provider of the Services or Products under the Agreement as described thereunder.

"供应商" – 指协议第一页所述服务的执行者和提供者。

"**Supplier Subcontractor**" – any third party that assists Supplier in performing its obligations under the Agreement, including an affiliate or direct or indirect subcontractor of Supplier.

"供应商的分包商" – 协助供应商履行协议项下义务的任何第三方，包括供应商的分支机构或者直接或间接分包商。

Appendix D: Novartis Settlement Sheet
附件 D：诺华结算单

Please download and fill in the following Novartis Settlement Sheet in pdf format:
请下载并填写以下 pdf 格式的诺华结算单：

Novartis Settlement Sheet

The following is a sample and for your reference only:
以下为填写示例，仅供参考：

NOVARTIS

Novartis Settlement Sheet
诺华结算单

Mandatory Fields 必填项

Purchase Order Number 采购订单编号:	30XXXXXXXX	Invoice Amount 发票总金额:	19,970.40
Service Name 服务名称:	XX会议	Vendor Name 供应商名称:	XXXX旅行社集团有限公司
Service Start Date 服务开始日期:	20/12/2021	Service End Date 服务结束日期:	21/12/2021
Invoice Quantity 发票张数:	2	Vendor Contact Information 供应商联系人及联系方式:	张XX 189-xxxx-xxxx 或 zhangxx@xx.com
Milestone Service 分期付款:	第一期付款	Contract Number (if any) 合同编号（如有）：	XXXXXXXXX
Terms of Milestone Payment 分期付款条款:	两次分期付款条款。 第一次：在协议签署生效后60日内，支付XX费总金额的50%。即RMBXXX; 第二次：在甲方完成服务的50%或以上场次并提供相关证明文件后，诺华按照合同约定的费用支付第二笔款项。 除非诺华方同意，会议实际产生的费用总额不得超过条款第二条(a)款约定的项目经费预估总额。		

It is acceptable to attach the contract payment milestone terms in a separate page if the terms are too long.
若合同付款条款过多，可单独打印作为附件一同提交。

Expense Details 费用结算明细

No. 序号	Service Description 服务描述	Unit Price 单价	Quantity 数量	Settlement Amount 结算金额	Service End Date 服务结束日期	Notes 备注
1	住宿费	10,000.00	1.00	10,000.00	21/12/2021	
2	场租费	5,600.00	1.00	5,600.00	21/12/2021	
3	餐饮费	3,340.00	1.00	3,340.00	21/12/2021	
4						

It is acceptable to fill in a separate *Novartis Settlement Sheet* if there are too many items.
若结算内容条目过多，可额外填写一份诺华结算单一同提交。

Discount Amount 折扣金额	(100.00)	N/A
Total Amount Before Tax 税前结算总金额	18,840.00	N/A
Tax Rate 税率	6%	N/A
Total Amount After Tax(Invoice Amount) 税后结算总金额（发票总金额）	19,970.40	N/A

Novartis PO Owner Commitment
诺华采购订单负责人承诺

I verified expense details mentioned above and other related supporting documents provided. I hereby confirm those support documents are correct, valid, complete and have effected as of the sign-off date.
我已复核上述所有费用明细及已提供的其他相关支持性文件，确认其正确、有效、完整，并且截止至签署日均已真实发生。

诺华采购订单负责人职位 Title of Novartis PO Owner	XX经理
诺华采购订单负责人（电子）签字 Sign by Novartis PO Owner	
诺华采购订单负责人签字日期 Date of Signature	21/12/2021

Vendor Commitment
供应商承诺

I verified expense details mentioned above and other related supporting documents provided. I hereby confirm those support documents are correct, valid, complete and have effected as of the sign-off date.
我已复核上述所有费用明细及已提供的其他相关支持性文件，确认其正确、有效、完整，并且截止至签署日均已真实发生。

供应商职位 Title of Vendor	XX经理
供应商签字(正楷) Sign by Vendor	张XX
供应商签字日期 Date of Signature	22/12/2021
供应商盖章 Chop	

Declaration说明:

1) This *Novartis Settlement Sheet* is applicable for Novartis indirect PO.
该《诺华结算单》适用于诺华间接采购订单。
2) This *Novartis Settlement Sheet* should be signed and chopped by vendor, and signed by Novartis PO owner (e-sign/handwriting).
该《诺华结算单》必须由供应商签字盖章确认，并由诺华采购订单负责人签字确认（电子签名/手签）。
3) This *Novartis Settlement Sheet*, together with the invoice (hard copy), needs to be sent to Novartis Shanghai Invoice Process Team by vendor.
<Delivery address: Xiao Nuo, Novartis Shanghai Invoice Process Team, No.4218 Jinke Road, Pudong District, Shanghai, 201203, Tel: 400600998800-4-1>
供应商应把该《诺华结算单》原件连同发票原件，一同邮寄至诺华上海发票处理团队。
<邮寄地址：上海张江金科路4218号，诺华财务中心发票处理团队小诺欧，邮编：201203，联系电话：400600998800-4-1>
4) Other related supporting documents(e-version) should be sent to Novartis PO owner by vendor.
其他相关支持性文件（电子版）需由供应商发送给诺华采购订单负责人。

Appendix E
Pharmacovigilance Provision and Adverse Event (AE) Reporting Requirements
Pharmacovigilance Provision for Patient Oriented Program (POP) External Service Provider (ESP) and Health Care Professional (HCP) Contracts
附件 E
药物警戒条款及不良事件（AE）报告要求
面向患者项目（POP）外部供应商和医护专业人员合同中的药物警戒条款

Patient Oriented Program standard vigilance contractual provisions for POP Group 1 and POP Group 2
POP 第 1 组和 POP 第 2 组面向患者项目的标准警戒合同条款

The External Service Provider mentioned in this provision below refers to the contract party other than Novartis signing this Agreement.
以下本条款中提及的合同相对方指签署本协议的诺华以外的合同方。

1. Purpose 目的

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.
下文所列条款的目的是定义药物警戒（PV）和医疗器械警戒（MDV）合同要求（为便于参考，以下统称为“警戒”要求），与面向患者项目（**POP**）的计划和执行相关的外部服务提供者（**ESP**）和/或医疗保健专业人士（**HCP**）需要遵守。这些条款在其他情况下称为“**POP 警戒合同条款**”，并构成协议不可分割的一部分。除非适用法律或 GxP 禁止，否则在这些 POP 警戒合同条款中提及“书面”或“书面形式”包括（但不限于）电子邮件通信。

2. Scope 范围

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.
这些 POP 警戒合同条款适用于由 ESP 或 HCP 为和/或代表诺华开展的所有第 1 组和第 2 组面向患者项目（定义如下）。

3. Definition of POP POP 的定义

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 是诺华的一个涵盖性术语，涵盖符合以下所有标准的非推广性诺华项目：
1. 涉及诺华已批准的产品或关注的疾病领域。
2. 诺华或代表诺华的第三方会与项目参与者例如患者，患者看护者，医疗保健专业人士，付款者进行互动。
3. 支持患者关护、进行初级市场研究或获取观念见解项目，分别分为：
    - 患者支持项目（PSP）是指为患者或患者看护者提供有关疾病、药物、用药的教育和/或支持药品的获取、诊断、使用、依从性，以及改善患者总体医疗保健结局而创建的项目。这些项目的整体模式可能包括但不限于涉及患者激活、经济援助、非经济援助和/或依从性服务。
    - 初级市场研究（PMR）是指按照正式设计和方法（如样本量、酬金）进行的涉及系统性的原始数据生成、收集和分析的活动。它是为了满足明确的业务需求和理由而进行的，并记录在正式报告中。
    - 获取观念见解是指涉及原始数据生成和收集的活动，这些活动不遵循 PMR 活动的正式设计和方法，例如分发给 HCP 的诺华调查。

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).

POP 不包括诺华赞助的临床研究/试验、管控用药项目（MAP）和常规外部互动（除非该互动涉及有组织的数据收集，包括对患者或医疗保健专业人员的调研，或者关于疗效或患者依从性的信息收集）。
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.
诺华员工和外部人员之间的常规外部互动（例如，作为顾问委员会、医学科学联络员（MSL）、销售人员互动和/或患者参与部门与患者的互动）是指作为正常业务运营或日常活动的一部分进行的定期沟通或参与。它通常涉及标准流程、已建立的方案或预期的重复互动，并且不会显著偏离正常的业务过程。

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).
所有上述项目均由诺华进行分类，如下表所示（对应的组别必须满足所有特有属性）。

Table 1: POP Classification 表 1：POP 分类

	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.

第 1 组	第 2 组	第 3 组
特有属性	○ 主要目的是支持患者关护 ○ 项目涉及诺华批准的产品 ○ 收到的和/或收集的关于使用诺华已批准上市产品的有效性/安全性/耐受性的信息	○ 主要目的是进行市场调研或收集患者/HCP 的观念见解 ○ 项目包含与诺华的已批准上市的产品相关的问题 ○ 收集的关于使用诺华已批准上市产品的有效性/安全性/耐受性的一手数据	○ 任何不适用第 1 组或第 2 组的其他项目

For each POP, Novartis will confirm with External Service Provider 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.
对于每个 POP，诺华将在相关 POP 开始前与合同相对方确认，POP 是第 1 组还是第 2 组；这可以在协议、工作说明书 、任务订单、工作订单等中确认或诺华以书面形式与合同相对方沟通。

4. Adverse Events 不良事件

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.
不良事件（AE）是使用诺华产品（即药品和/或医疗器械）的患者或临床试验受试者发生的任何不利的医学事件，它并不一定与该产品有因果关系。因此，AE 可以是在时间上与使用诺华产品有关联的任何不利和非预期的体征（例如：实验室结果异常）、症状或疾病，无论其是否与该产品有因果关系。

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.
此外，诺华 POP AE 培训中描述的所有特殊情况和其他可上报情况（包括但不限于技术投诉、医疗器械事故）必须通知诺华患者安全部门。
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.
出于 POP 警戒合同条款的目的，本协议下将把不良事件、特殊情况和其他可上报情况统一称为“AE”。

5. Adverse Event Reporting 不良事件报告

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 is notified during a POP shall be transferred by External Service Provider to the Novartis Patient Safety function within twenty-four (24) hours[3] of notification and as further set forth in the Novartis POP AE Training.
与使用诺华产品相关的任何 AE，不论因果关系或严重性的评估如何、说明书是否载明和/或报告者类型如何， 合同相对方在 POP 项目执行期间获知的，合同相对方应在获知后二十四（24）小时内[4]，将其转交至诺华患者安全部门。

External Service Provider 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.
合同相对方需参考或检查诺华提供的相关诺华产品列表，以识别相关诺华产品，协助其履行报告义务：POP 参与者或患者的治疗是诺华药物或与特定的诺华治疗相关的 POP，则无需如此。

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 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).
合同相对方可以通过使用诺华线上 AE 报告工具或通过电子邮件/传真发送诺华不良事件报告表的方式（正如诺华 POP AE 培训中的进一步的说明）向诺华患者安全部门上报不良事件。每份报告均需要包含来自诺华 POP 的信息（包括指定项目名称和项目 ID）。

External Service Provider 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.
合同相对方应向诺华患者安全部门提供诺华根据相关法律法规记录和报告 AE 所需的任何适当的个人健康信息。

6. Novartis POP AE Training[5] 诺华 POP AE 培训[6]

Novartis POP AE training must be completed by the External Service Provider 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 Personnel identified as being directly involved in the POP. External Service Provider 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 may provide training (including the initial training and the annual refresher training) to its Personnel.
在开始任何现场工作或与参与者联系前，合同相对方及其直接参与 POP 的工作人员（包括新员工）必须完成诺华 POP AE 培训；然后，必须完成年度 AE 再培训。关于不良事件的识别和报告，诺华应通过线上会议或通过电子学习平台，向确定直接参与 POP 的合同相对方工作人员提供 AE 培训。合同相对方应与诺华合作，确保及时开展培训。在培训师培训会议上（而非通过电子学习平台）接受诺华 AE 培训后，合同相对方经过培训的人员可为其工作人员提供培训（包括初始培训和年度 AE 再培训）。

External Service Provider 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 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.
合同相对方在此确认，其在与诺华签订 POP 特定合同之前已收到适用的诺华 POP AE 培训材料（POP 培训材料）的副本，并认可和同意 POP 培训材料的内容（包括其中包含的任何适用于合同相对方的要求和义务），协议期间诺华以书面形式传达的任何更新应构成

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[3] 1) If identified AE during a business day, must transfer within 24 hours of identification, as detailed below:
- If identified AE during Friday business hours (and your office is closed during Saturday & Sunday), transfer on the day of identification.
- If identified AE after business hours on Friday (and your office is closed during Saturday & Sunday), transfer latest by the end of next business day.
- If identified AE on the last day before national holidays, transfer on the day of identification.

2) If identified AE on weekends (and your office is closed during Saturday & Sunday), transfer latest by the end of next business day following that of identification.
3) If identified AE during extended weekends and long national holidays, transfer no more than two calendar days following that of identification.

[4] 1）如果在工作日获知 AE，最晚在 24 小时内传递，详情如下：
- 如果在周五工作时间内获知 AE（并且您的办公室在周六和周日关闭），则在获知 AE 当天工作时间内传递。
- 如果在星期五工作时间后获知 AE（并且您的办公室在星期六和星期日关闭），最迟在获知 AE 后的下一个工作日结束前传递。
- 如果在国家法定节假日前的最后一天工作时间内获知 AE，则在获知 AE 当天工作时间内传递。

2）如果在周末获知 AE（并且您的办公室在周六和周日关闭），则最晚在获知 AE 后的下一个工作日结束前传递。
3）如果在延长的周末和国家法定节假日期间获知 AE，则最晚在获知 AE 后的两个日历日内传递。

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

[6] 培训要求仅适用于 POP 中的正在执行项目的 ESP/HCP（不适用符合资质但当前未执行项目的 ESP/HCP）。

协议不可分割的一部分。

At the request of Novartis in the event of any POP Training Materials update, External Service Provider and its Personnel must complete training on the updated version in accordance with any completion timelines specified by Novartis.
应诺华的要求，如果 POP 培训材料发生任何更新，合同相对方及其工作人员须根据诺华指定的时间完成更新版本的培训。

External Service Provider 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..
合同相对方必须记录涉及的所有工作人员的培训，并将培训记录归档。所有培训材料和文件须应要求提供给诺华。

Before the First Participant First Contact (**FPFC**) date for any new POP, External Service Provider 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 Personnel identified by the External Service Provider as being involved in the provision of the POP, have been trained on Novartis AE reporting as required under the POP Vigilance Contract Provisions.
在任何新 POP 的首位参与人首次接触（FPFC）日期之前，合同相对方必须向诺华发送书面的 AE 培训证明（诺华公司保留指定此类证明格式的权利），证实合同相对方确定参与 POP 的所有合同相对方工作人员已根据 POP 警戒合同条款的要求接受了诺华的 AE 报告相关培训。

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 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 to provide Novartis POP AE training to its subcontractors. Only an External Service Provider 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.
在法律允许的情况下，根据关于分包的协议条款，如果合同相对方分包与 POP 有关的任何服务，则必须遵守与诺华 POP AE 培训相关的上述相同义务。合同相对方负责向其分包商提供诺华 POP AE 培训。仅（根据上述培训师培训流程）接受过培训材料培训的合同相对方工作人员可提供此类培训，且必须使用其曾接受过培训的相同培训材料。培训记录必须归档，并且所有培训材料和文件须应要求提供给诺华。

It is the responsibility of External Service Provider to ensure subcontractor´s compliance with the POP Vigilance Contract Provisions.
合同相对方负责确保分包商遵守 POP 警戒合同条款。

7. Supplier Quality Assessment and Commencement of Services 供应商质量评估和服务开始

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 to provide updates to the SQA and External Service Provider will co-operate fully in the reperformance of the SQA and providing updates requested by Novartis.
本条仅适用于外部服务提供者（而非医疗保健专业人士）：外部服务提供者在此确认并同意，作为供应商质量评估（SQA）流程的一部分向诺华提供的所有信息和答复应视为协议不可分割的一部分，且所提供的信息和答复是完整和准确的。在协议期限内，诺华有权要求重新履行 SQA 和/或要求合同相对方提供对 SQA 的更新，合同相对方将全面配合重新履行 SQA，并提供诺华要求的更新。

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.
本条仅适用于外部服务提供者（而非医疗保健专业人士）：此外，合同相对方将主动以书面形式通知诺华任何可能会影响到当前诺华认证资质的与 POP 服务相关的操作变更，并且诺华在收到该通知后，需要对合同相对方进行风险评估或重新进行 POP 服务提供者的资格认定。合同相对方将（自费）就任何（重新）资格认定与诺华展开合理的合作。

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.
本条仅适用于外部服务提供者（而非医疗保健专业人士）：外部服务提供者在此确认并同意，除非且直至收到诺华的书面确认，其已成功获得履行与 POP 相关的服务资格（从诺华内部角度），否则，其不得就任何 POP 项目开始服务。

External Service Provider will not start fieldwork or contact participants unless and until it has received written notification from Novartis expressly requesting it to do so.
合同相对方除非且直至收到诺华明确要求其开展现场工作或联系参与者的书面通知，否则不得开始现场工作或联系参与者。

External Service Provider 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.
合同相对方将在相应日期发生后的两（2）个工作日内以书面形式向诺华报告首位参与者首次接触（FPFC）日期和末位参与者末次接触日期（LPLC）。

External Service Provider is required to follow Good Documentation Practices during documentation of POP activities performed for and/on behalf of Novartis.
在记录为和/代表诺华开展的 POP 活动期间，合同相对方要遵守良好的文件记录规范。

8. Adverse Event Reconciliation (AER) 不良事件核对（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.
AER 是 POP 第 1 组和第 2 组项目的强制性定量药物警戒质量控制，以确认所有已识别的 AE 和其他可报告的情况已在 24 小时内上报诺华患者安全部并由其接收。AER 的安排是基于实际的 FPFC 日期和 LPLC 日期。

At the written request of Novartis, External Service Provider 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 during a designated timeframe and those recorded by Novartis as per timeline indicated below.
根据诺华公司的要求，合同相对方同意与诺华公司合作并协助诺华公司定期（至少每季度一次）的内部核对工作，以确保合同相对方在指定时间段内上报的不良事件与诺华公司按照以下时间表所记录的不良事件的信息一致。

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.
在 POP 期间进行的 AER（包括初始 AER）应涵盖从 FPFC 日期起（并且包括 FPFC 日期）不超过三（3）个月的测量期，最终的 AER 测量期在实际 LPLC 日期结束（包括 LPLC 日期）。末次 AER 必须在相关 POP 项目完成最后一次接触最后一位参与者后进行。所有 AER 必须使用适用的诺华表格记录，并在 AER 规定截止日期起两（2）周内发送至诺华。在 POP 警戒合同条款中，"AER 规定截止日期"指：（i）对于初始 AER 核对，该日期为诺华选择的初始 AER 测量期结束时；（ii）对于后续的 AER 核对，为上述（i）项所述日期的每个周年日；（iii）对于最后一次 AER 核对，为 LPLC 日期。

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 hereby agrees to fully cooperate and assist Novartis in performing AER on an ad-hoc basis.
如果在稽查或审计结果中发现任何关于 AE 报告的违规或有 AE 报告相关的偏离行动，应诺华的要求，合同相对方在此同意充分配合协助诺华临时开展 AER。

9. Source Documents 源文件

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 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.
源文件/数据（或有时称为源记录/源数据）是记录合同相对方和 POP 项目参与者互动的任何类型的记录或支持材料。源文件/数据示例包括但不限于：在线调查、记录的讨论、接收的传真、信函、数据库条目（即客户关系管理（CRM）系统）、记录的与患者或 HCP 的互动、能够记录互动的数字应用程序、电话/视频通话记录、纸质记录、笔记、调查问卷、电子邮件、SMS 和 AE 报告表（与参与者交谈期间直接将 AE 事件记录在报告表中时）。

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. 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.
在第 1 组 POP 开始之前（即在 FPFC 之前），应在协议，工作说明书中明确定义 POP 的具体源文件/数据,或诺华与合同相对方另行书面约定。在各个第 1 组 POP 的背景下，下文其余条款中提及的"源文件/数据"应指第 1 组 POP 适用工作说明书/协议中确定的具体源文件/数据类型。此外，在所有情况下，任何应用程序/系统（例如 PVI 工具；这是一种在线工具，以电子方式向诺华患者安全部门报告 AE）生成的作为初始数据收集/报告的输出也将视为源文件/数据。

10. Source Data Verification (SDV) – applicable to Group 1 POPs only 源数据验证（SDV）-仅适用于第 1 组 POP

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 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 will conduct an SDV one (1) year after the initial SDV and yearly thereafter, and again at the conclusion of the relevant POP.
SDV 是 POP 第 1 组项目的强制性定性药物警戒质量控制。在 SDV 期间，对项目合同定义的源数据进行审查，以确认所有 AE 和其他可报告场景已被识别、完整准确地上报，并由诺华患者安全部接收。SDV 的安排是基于实际的 FPFC 和 LPLC 日期。诺华或代表诺华行动的第三方将在 FPFC 日期后三（3）个月进行初始 SDV。初始 SDV 后的进一步 SDV 可由诺华或代表诺华行动的第三方自行决定进行。合同相对方应向诺华提供进行 SDV 所需的源数据（或一份带有书面确认/签字/注明日期的副本，确认其为源数据的真实准确的呈现）。合同相对方将至少在初始 SDV 后一（1）年、此后每年以及在相关 POP 结束时进行 SDV。

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 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.
根据 POP 培训材料中的要求，对于需要验证的源文件/数据的数量，应基于 POP 预期的互动次数与诺华达成一致。合同相对方应在 SDV 规定截止日期起六（6）周内向诺华患者安全部门提供该活动的证明和核查结果的概括总结。在 POP 警戒合同条款中，"SDV 规定截止日期"指：（i）对于初始 SDV，该日期为 FPFC 日期后三（3）个月；（ii）对于后续的 SDV，为上述（i）项所述日期后每年的日期；以及（iii）对于最终 SDV，为 LPLC 日期。

External Service Provider 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 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.
合同相对方应记录这些活动的结果，并根据诺华的要求将其提供给诺华进行审查。在 SDV 期间，如果发现了任何未上报的 AE，诺华可自行决定要求/请求对所有 SDV 互动的源文件/数据进行全面审查，合同相对方将负责确保按照诺华传达的时间表进行全面审查，开展此类审查产生的所有相关费用和支出将由合同相对方负责。

Novartis will have the right to review Source Documents/Data records for the purpose of determining External Service Provider's compliance and accuracy in AE gathering and reporting.
诺华有权审查源文件/数据记录，以确认合同相对方在收集和上报 AE 中的合规性和准确性。

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 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.
如果在稽查或审计结果中发现任何与 AE 报告相关的违规或有 AE 报告相关的偏离行动，应诺华的要求，合同相对方在此同意充分配合协助诺华临时开展 SDV。尽管第 10 节规定仅适用于第 1 组 POP，但（根据诺华的要求）临时开展 SDV 的要求也适用于第 2 组 POP。

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 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.
在不损害诺华稽查权利的前提下，在协议期限内以及任何适当归档/保留期满前，诺华将有权访问/检查源文件/数据（包括进入相关合同相对方的（或其分包商/供应商）场所的权利，只要是有必要行使此类权利），以确保诺华可遵守与警戒相关的所有监管和内部要求。就任何此类访问/检查（包括但不限于作为 SDV 一部分的访问/检查）而言，合同相对方将遵守当地法律或本协议要求的数据最小化原则，包括通过对相关源文件/数据进行匿名化/编辑，以隐藏/掩盖任何个人可识别信息。

11. Corrective Action and Preventive Action, Audits and Inspections 纠正措施和预防措施，稽查与审计

In case of non-compliance with the requirements of the POP Vigilance Contract Provisions, External Service Provider 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 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 must notify Novartis of progress on open CAPA completion on a periodic basis and when completed, or as requested by Novartis.
当发现未遵守 POP 警戒合同条款要求的情况时，合同相对方有义务立即将这些发现上报至诺华，并在双方协定的时间内加以纠正（双方本着合理诚信的原则行事）。合同相对方必须记录、追踪和关闭/完成内部采取的任何纠正和预防措施（CAPA），包括但不限于诺华提供意见后采取的措施。合同相对方必须定期以及在完成时或根据诺华的要求通知诺华关于进行中的 CAPA 完成的进展情况。

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'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 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.
关于各个 POP，就与特定 POP 有关的相关协议条款而言，并且在该等协议到期或终止后两（2）年内，诺华或其指定的第三方稽查员将有权稽查（现场或纸质）合同相对方（或其代理商或分包商）的流程、程序和培训（包括记录、数据、文件、源文件/与使用诺华产品相关的 AE 数据）。合同相对方有义务在双方约定的时间内纠正稽查观察结果中的问题（双方本着合理诚信的原则行事）并及时向诺华传达相关措施。双方同意，如果协议包含的稽查/补救权利相比上述稽查/补救权利更为广泛，则协议中规定的更为广泛的稽查/补救权利此处同等适用，同时遵守上述 POP 警戒合同条款中规定的任何稽查/补救权的持续时间和范围方面的最低要求。

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.
对于诺华公司的法律事件，包括民事诉讼和政府调查，或任何政府审查或稽查，合同相对方在此同意按要求全力配合。此外，合同相对方在此同意允许本国和国际卫生当局根据需要审查其药物警戒活动，以便诺华在诺华产品上市国家保持登记注册状态。

12. Archiving 归档

External Service Provider 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.
合同相对方还必须创建文件/记录并归档，例如在提供服务期间发送给诺华的 AE 报告和表格，以及其 AE 上报流程的内部标准操作规程（SOP）和任何 POP 相关文件，包括但不限于来自与参与者互动的源文件/数据，并在当地法律允许的情况下将其保存至少五（5）年，或在当地法律要求保存更长时间的情况下将其保存更长时间（每种情况下，从 POP 结束时开始计算）。此类文件/记录需接受稽查。在本款中，凡提及联邦和州法律管辖的司法管辖区内的当地法律，系指现行/控制的地方法律（无论是联邦或是州），如果联邦和州法律同等适用，则将在该等地方法律允许的情况下应用更严格的保留标准。

Notwithstanding the foregoing, for source files/data stored on the DEA for interactions with participants, for source files/data containing AEs, the retention period is at least five (5) years after the source file/data was generated; Source files/data that do not contain AEs should be stored for at least until the SDV is completed, and the SDV should be completed within the specified time limit. For other POP-related documents signed by the patient (e.g., informed consent of the patient, supporting documents such as insurance payment information) stored in the DEA, they shall still be retained in accordance with the retention time limit specified in the first paragraph of this article.
尽管有前述约定，针对存储在数字化平台[7]的与参与者互动的源文件/数据，对于含有不良事件内容的源文件/数据，保存时限至少为该源文件/数据产生之后的五（5）年；对于不含有不良事件内容的源文件/数据，至少要保存到源数据验证（SDV）完成，源数据验证（SDV）应在规定的时限内完成。对于存储在数字化平台中的其他 POP 相关的由患者签署、提交或产生的文件（例如：患者知情同意、支持性文件如保险赔付资料）仍应按照本条第一段中规定的保存时限进行保存。

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.
任何适用的归档/保存期限结束后，如果销毁的文件/记录包含受双方数据处理协议（或同等协议）（包括本协议的一部分）约束的个人数据/信息，则相关数据处理协议的规定适用。

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[7] 数字化平台包括但不限于：
- 对外/公开的网站（医疗专业人员门户网站、活动网站、直播网站等）
- 移动应用
- 微信小程序
- 社交媒体账号（如微信公众号等）
- 数字化技术（如人工智能、物联网、可穿戴设备等）
- 软件医疗器械
- 即时通讯平台

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.
POP 警戒合同条款的归档和保留要求可能比协议中规定的要求更广泛。如果协议条款与 POP 警戒合同条款之间存在任何冲突，在法律允许的范围内，POP 警戒合同条款的要求（如果更严格）将适用。

13. Amendments and Organizational Changes 修订和组织变更

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 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.
诺华保留随时修订 POP 警戒合同条款的权利，可在任何权威机构提出要求时进行修订，或根据独立的临床判断认为有必要进行此类修订以保证患者安全时进行修订。当收到诺华发出的此类修订书面通知时，合同相对方应立即遵守（或诺华指定的其他时间），任何不遵守行为将被视为严重违反本协议的行为。

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.
当合同相对方出现任何变动时，包括但不限于组织名称变更、业务能力或运营，合同相对方必须及时将这些变更以书面形式通知诺华。

14. Contacts 联络人

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.
在签署本协议后，ESP 应立即指定一位项目经理并把该人员的详细联络信息（姓名、地址、电话、电子邮箱）发送至诺华（下文未提供）。

The initial Account Manager details for the ESP are as follows: ESP 最初的项目经理详情如下：
Name 姓名：
Email 电子邮箱：
Tel 电话：

The Account Manager shall have:
- Oversight of all Novartis POP projects and
- Be the main contact for any questions related to the POP projects
该项目经理的职责：
- 监管所有诺华 POP 项目，并
- 作为任何 POP 项目相关问题的主要联络人
-

Novartis local contact for reporting purposes 用于上报目的的诺华当地联络人
The initial Novartis local contact for reporting purposes is as follows: 报告时，诺华最初当地联络人如下：
[insert contact details including email address] [插入联系方式，包括电子邮箱地址]

AE Reporting Clause
AE 报告条款

The External Service Provider mentioned in this provision below refers to the contract party other than Novartis signing this Agreement.
以下本条款中提及的合同相对方指签署本协议的诺华以外的合同方。

1. Vigilance obligations 警戒义务
External Service Provider shall comply with the following obligations in relation to vigilance:
合同相对方应履行以下警戒相关义务：

1.1 External Service Provider 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.
合同相对方承认诺华和/或其关联公司（以下简称**"诺华集团"**）作为本协议所述区域内医药产品/医疗器械的注册持有人或生产商应履行特定警戒义务，以满足全球适用的监管规则和指南。

1.2 Based on the nature of the [Services], External Service Provider 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.
根据服务的性质，合同相对方及其工作人员可能会与诺华集团公司为注册持有者或生产商的产品的患者、处方者、医生或其他消费者联系。

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.
下列术语的定义如"不良事件"（或"AE"）和特殊情况（见表 1 中的进一步解释）符合欧盟和全球指南（指令 2001/83/EC；ICH 指南 E2A 和 E2D），并应适用于本协议。

*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.*
***不良事件**（**AE**）是使用诺华产品（即药品和/或医疗器械）的患者或临床试验受试者发生的任何不利的医学事件，它并不一定与该产品有因果关系。因此，AE 可以是在时间上与使用诺华产品有关联的任何不利和非预期的体征（例如：实验室结果异常）、症状或疾病，无论其是否与该产品有因果关系。*

For the purpose of this Agreement, reference to medicinal product in the above definitions shall also apply to medical devices.
在本协议中，上述定义中的药品也应适用于医疗器械。

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.
如果提供/履行服务的区域内的地方法律、法规和/或指南对于 AE/ADR 具有更广泛的含义，则在本协议中，这些表述应具有更广泛的含义。

External Service Provider will forward all Adverse Event (AE) reports and special scenarios and other reportable situations defined in Table 1 that External Service Provider 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**[8].

[8] 1) If identified AE during a business day, must transfer within 24 hours of identification, as detailed below:
- If identified AE during Friday business hours (and your office is closed during Saturday & Sunday), transfer on the day of identification.
- If identified AE after business hours on Friday (and your office is closed during Saturday & Sunday), transfer latest by the end of next business day.
- If identified AE on the last day before national holidays, transfer on the day of identification.

2) If identified AE on weekends (and your office is closed during Saturday & Sunday), transfer latest by the end of next business day following that of identification.
3) If identified AE during extended weekends and long national holidays, transfer no more than two calendar days following that of identification.

合同相对方将在 **24 小时**内[9]将合同相对方或其工作人员从服务提供/交付区域收到的与诺华集团产品/医疗器械相关的所有不良事件（AE）、特殊情况和表 1 中定义的其他可报告情况（以下统称为**"警戒报告"**）作为源文件转发给诺华。
External Service Provider shall request the reporter to give permission to provide its contact information to [Novartis] to facilitate follow-up on the report if needed.
合同相对方应要求报告者允许向诺华提供其联系信息，以便在需要时对报告进行跟进。

1.4 Follow-up of Vigilance Reports shall be performed by [Novartis] or by the External Service Provider, if the reporter provides the permission to follow up to the External Service Provider exclusively.
警戒报告的随访应由诺华执行。或者如果报告人仅允许合同相对方对报告进行随访，则由合同相对方来执行。

1.5 External Service Provider 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.
合同相对方需要参考或交叉检查诺华提供的相关诺华产品清单，以确定相关的诺华产品，以协助其履行报告义务：POP 参与者或患者的治疗是诺华药物或与特定诺华治疗相关的 POP 项目不需要这样做。

1.6 The obligations contained in this Clause 0 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).
本第 1 条所规定的义务应在本协议终止后一（1）年内存续，但记录保留相关义务除外（记录保留期限应在所有相关记录保留期限到期前存续）。

1.7 All reporting in accordance with this Clause 1 shall be made by External Service Provider 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.
根据本第 1 条规定进行的所有报告应由合同相对方通过本协议随附的特定国家不良事件表进行或由诺华另行提供，且如未随附或提供，按诺华公司指示，通过以下网站进行报告：https://www.novartis.com/report 。
[Novartis] may change the above website details provided the External Service Provider is given notice in writing of such change.
诺华可变更上述网站的详细信息，前提是合同相对方收到了此类变更的书面通知。

1.8 External Service Provider hereby agrees to maintain all Records/Source documents for the applicable Records Retention Period as per definitions below.
合同相对方在此同意按照以下定义，在适用的记录保留期内保留所有记录/源文件。

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 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.
源文件/数据（或有时称为源记录/源数据）是记录合同相对方和 POP 参与人互动的任何类型的记录或支持材料。源文件/数据示例包括但不限于：在线调查、记录的讨论、接收的传真、信函、数据库条目（即客户关系管理（CRM）系统）、记录的与患者或 HCP 的互动、能够记录互动的数字应用程序、电话/视频通话记录、纸质记录、笔记、调查问卷、电子邮件、SMS 和 AE 报告表（与参与人交谈期间直接将事件记录在表格中时）。

Records Retention Period. External Service Provider 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

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[9] 1）如果在工作日获知 AE，最晚在 24 小时内传递，详情如下：
如果在周五工作时间内获知 AE（并且您的办公室在周六和周日关闭），则在获知 AE 当天工作时间内传递。
- 如果在星期五工作时间后获知 AE（并且您的办公室在星期六和星期日关闭），最迟在获知 AE 后的下一个工作日结束前传递。
- 如果在国家法定节假日前的最后一天工作时间内获知 AE，则在获知 AE 当天工作时间内传递。

2）如果在周末获知 AE（并且您的办公室在周六和周日关闭），则最晚在获知 AE 后的下一个工作日结束前传递。
3）如果在延长的周末和国家法定节假日期间获知 AE，则最晚在获知 AE 后的两个日历日内传递。

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.
记录保留期限。合同相对方必须存档文件/记录，如在提供服务期间发送给诺华的不良事件报告和表格，以及其不良事件报告程序的内部标准操作程序（SOP）和任何 POP 相关文件，包括但不限于与参与者互动的源文件/数据，并在当地法律允许的情况下，将其保存至少五（5）年，或者如果当地法律要求更长的期限，则保存更长的期限（在每种情况下，从 POP 关闭开始计算）。此类文件/记录将接受审计。就本段而言，在具有联邦和州法律的司法管辖区中，提及的地方法律是指现行/控制性的地方法律（无论是联邦法律还是州法律），并且在联邦和州的法律具有同等适用性的情况下，在这些地方法律允许的情况下将适用更严格的保留标准。

Notwithstanding the foregoing, for source files/data stored on the DEA for interactions with participants, for source files/data containing AEs, the retention period is at least five (5) years after the source file/data was generated; Source files/data that do not contain AEs should be stored for at least until the SDV is completed, and the SDV should be completed within the specified time limit. For other POP-related documents signed by the patient (e.g., informed consent of the patient, supporting documents such as insurance payment information) stored in the DEA, they shall still be retained in accordance with the retention time limit specified in the first paragraph of this article.
尽管有前述约定，针对**存储在数字化平台[10]的与参与者互动的源文件/数据**，对于含有不良事件内容的源文件/数据，保存时限至少为该源文件/数据产生之后的五（5）年；对于不含有不良事件内容的源文件/数据，至少要保存到源数据验证（SDV）完成，源数据验证（SDV）应在规定的时限内完成。对于存储在数字化平台中的其他 POP 相关的由患者签署、提交或产生的文件（例如：患者知情同意、支持性文件如保险赔付资料）仍应按照本条第一段中规定的保存时限进行保存。

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.
在任何适用的存档/保留期结束后，对于受双方之间的数据处理协议（或同等协议）约束的包含个人数据/信息的文件/记录的销毁（包括作为协议的一部分），相关数据处理协议的规定将适用。

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.
警惕义务条款下的存档和保留要求可能比协议中规定的更广泛。如果本协议的规定与警戒义务条款之间存在任何冲突，在法律允许的范围内，将适用警戒义务条款的要求（如果更严格）。

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.
双方在此同意，本第 1 条中的义务适用于双方未约定更详细/具体警戒义务的所有服务（比如，在 POP、社交媒体听力/数字参与资产相关服务背景下的义务）。如果双方就特定服务约定了更为详细的/具体的警戒义务，则后者应适用于该等特定服务，而非本第 1 条规定的义务。

Table 1 – Special scenarios and other reportable situations
表 2：特殊情况和其他可报告情况

Special scenario and other reportable situation **特殊情况和其他可报告情况**	Definition 定义
Abnormal laboratory finding **实验室结果异常**	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.

[10] 数字化平台包括但不限于：
- 对外/公开的网站（医疗专业人员门户网站、活动网站、直播网站等）
- 移动应用
- 微信小程序
- 社交媒体账号（如微信公众号等）
- 数字化技术（如人工智能、物联网、可穿戴设备等）
- 软件医疗器械
- 即时通讯平台

	任何参数值低于或高于正常范围值（在已发表的参考范围之外，有/无症状）。 例如：HCP 观察到患者使用诺华产品 X 后中性粒细胞计数降低为 1.0 × 10e9/L
Abuse **药物滥用**	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 持续或偶尔、故意过度使用诺华产品，并对患者的身体或心理造成有害影响。 例如：一名患者为了获得强烈欣快感而反复使用更高剂量的诺华产品 X。
Any symptom, disease or change in the underlying disease **潜在疾病的任何症状、疾病或变化**	E.g.: Blood pressure increased drastically in a hypertensive patient after patient started treatment with Novartis product drug X for jaw pain. 例如：一名高血压患者在使用诺华产品 X 治疗颌骨疼痛后血压急剧升高。
Death **死亡**	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. 任何提及某人在使用诺华产品期间或之后不久死亡的情况。 重要提示：无论何时提及死亡，请确保在与 POP 参加者/报告者互动时收集"死亡原因"的详细信息。如果死亡原因未知，确保在传递给诺华患者安全部时注明。
Congenital anomaly/Birth defect **先天性异常/出生缺陷**	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. 出生时和通常在出生前存在的与正常标准存在明显偏差的情况。 例如：一名在妊娠期间接受诺华产品 X 治疗的女性患者产下一例先天性心脏瓣膜异常或唇裂的婴儿。
Disease progression and aggravation **疾病进展和恶化**	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. 作为疾病进展自然史一部分的临床状况恶化（如预期），或病情加速超过预期，无论诺华产品是否缺乏疗效。
Exposure during pregnancy **妊娠期药物暴露**	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. 女性患者在妊娠前或妊娠期间使用诺华产品，或男性患者在其伴侣受孕前或受孕期间使用诺华产品。
Exposure during breast feeding **哺乳期药物暴露**	A mother using a Novartis product while in the period of breast feeding. 母亲在哺乳期使用诺华产品。
Disability or incapacity (transient/persisting damage) **残疾或失能（短暂/持续性损害）**	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). 极大破坏了患者进行日常生活功能的能力；如对患者的身体功能/结构、体力活动和/或生活质量造成改变、损伤、损害或破坏。 例如：在接受诺华产品 X 治疗后，患者出现周围神经病，并导致日常生活活动受损（例如：不能正常行走）。
Drug-Drug interactions & Drug-Device interactions *(with or without symptoms)* **药物-药物相互作用和药物-器械相互作用*（有或无症状）***	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. 药品/医疗器械、内源性化学制剂或诊断检测中使用/产生的化学物质与诺华产品 X 相互作用，并*影响其药理活性*（动力学相互作用，其中唯一的影响是药物血浆浓度的变化），无论是否有利。
Drug-Food interactions *(with or without symptoms)* **药物-食物相互作用*（有或无症状）***	When components of the diet (food, beverages) affects the pharmacological activity of Novartis product X, either desirable or undesirable. 当饮食成分（食物、饮料）影响诺华产品 X 的药理活性，无论是否有利。
Drug dependence/ Addiction **药物依赖/成瘾**	A cluster of behavioral, cognitive, and physiological phenomena that may develop after repeated substance use. 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. 重复使用某物质后可能出现的一组行为、认知和生理现象。 一般来说，这些现象包括强烈渴望服药、对药物使用的控制受损、在产生有害后果的情况下仍持续使用、比其他活动和义务更优先考虑药物的使用、耐受增加和停用药物时身体戒断反应。
Lack of efficacy or lack of expected therapeutic effect **缺乏疗效或缺乏预期治疗效果**	Lack of anticipated clinical/therapeutic benefit or response as defined in the product label *with or without worsening* of the disease/condition being treated. 缺乏产品说明书中定义的预期临床/治疗获益或反应，*无论是否有*正在治疗疾病/状况的*恶化*。
Life-threatening event **危及生命的事件**	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. 危及生命的事件是指患者在出现反应时有死亡的风险；并非是指假设将来发展严重时可能会导致死亡。
Medical Device **医疗器械**	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. 生产商出于一个或多个特定医疗目的，计划单独或联合用于人体的任何仪器、装置、器具、机器、用具、植入物、体外试剂、软件、材料或其他类似或相关物品。 医疗器械不能通过药理学、免疫学或代谢方式在人体内或人体上实现其主要预期作用，但可通过这些方式辅助其发挥预期功能。
Medical Device Incident **医疗器械事故**	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. 已上市的器械的特性或性能出现任何故障或退化，包括人体工学特征导致的使用错误，以及任何生产商提供的信息不足和任何不良副作用。
Medication Errors **用药错误**	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. 可能引起或导致用药不当的任何可预防事件，包括在医疗保健专业人员、患者或消费者控制药物期间的意外暴露或患者意外伤害。 用药错误可能是由于不同环节的缺陷而发生的，包括从订购药物到患者接受药物的时间，例如处方、给药、配药、重新包装和监测。
Misuse (with or without symptoms) **误用（有或无症状）**	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). 以说明书或上市许可中未推荐的方式故意和不当地使用诺华产品（有或无症状）。
Occupational exposure **职业暴露**	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. 因个人的专业或非专业职业而暴露于诺华产品。这不包括在成品放行前的生产过程中暴露于其中一种成分。
Off-label Use **超说明书使用**	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. 故意按照报告区域内的授权产品信息开处方和使用药品的情况。 如果 HCP 开处方/建议患者不按照授权产品信息用药，则应视为标示外用药。
Overdose **用药过量**	Taking more of a Novartis product than what is the maximum recommended dose in the product information. 服用的诺华产品剂量超过了产品信息中的最大推荐剂量。
Hospitalization **住院治疗**	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. 由于事件导致患者住院，无论是进行日间手术，或最短隔夜停留，还是事件导致现有住院治疗延长。 ■ 例如，一名患者接受诺华肿瘤维持治疗。2 周后，患者因胆石症住院。
Rebound effect **症状反弹**	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.

	停用诺华产品 X 治疗后或对其产生耐受性后，疾病体征/症状加重反弹，或原有症状复发的强度或严重程度高于之前。
Special Device Scenarios with or without AEs **特殊器械情况伴或不伴 AE**	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. 药物-器械或器械-器械相互作用，缺乏器械治疗效果（如产品说明书中定义的），器械相关用药过量，导致用药错误或影响患者/用户的器械使用错误（包括与器械相关的所有用药和配药错误以及意外药物暴露），导致用药错误或影响患者/用户的器械异常使用（包括超说明书使用和有意误用），器械引起的药物戒断综合征/反应，所有通过器械传播感染性疾病的病例
Technical Complaint for Medicinal Products with or without AEs **药品技术投诉伴或不伴 AE**	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. 药品技术投诉是对诺华药品不满的任何口头、电子或书面表达：标识，质量，稳定性，可靠性，安全性，有效性，性能或用途。 这可能包括：容器和外包装的任何缺陷，标签和说明书的任何缺陷
Technical Complaint for Medical Devices **医疗器械技术投诉**	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. 书面、电子或口头沟通，声称与已脱离市场组织控制的医疗器械标识，质量，耐用性，可靠性，可用性，安全性或性能有关的缺陷，或与影响诺华医疗器械性能的服务有关。
Transmission of infectious disease via medication **通过药物传播感染性疾病**	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. 根据欧洲法规，任何微生物、病毒或感染性颗粒（致病性或非致病性）均应视为感染性病原体。因此，任何感染性病原体疑似通过诺华产品传播的情况均应向诺华报告。
Treatment Non-Compliance with AEs **治疗不合规伴 AE**	A situation where the patient did not take the medication as prescribed either voluntarily/intentionally or involuntarily/unintentionally. 患者自愿/故意或非自愿/无意地不按处方使用药物的情况。
Unexpected beneficial effect **意外获益**	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. 与诺华产品治疗适应症无关的有利作用。 例如：接受诺华降胆固醇产品 X 治疗的糖尿病患者在治疗开始后观察到血糖水平更为稳定。
Withdrawal reaction syndrome **戒断反应综合征**	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. 在停止或减少使用诺华产品 X（其通常是长期和/或高剂量反复服用的）时出现的一组症状，这些症状的聚集程度和严重程度各不相同。 该综合征可能伴有生理紊乱的体征。 戒断综合征是依赖综合征的指标之一。

附件：AE 报告表:

请在获知的 24 小时内填写并发送至诺华中国患者安全部门　　Argus 编号：_____

传真号码：010-65050243, 邮件：drugsafety.china@novartis.com

不良事件报告表- 机密 (标*的内容只能由诺华员工或指定人员或授权合作伙伴填写)

☐ 首次报告* ☐ 随访报告*	诺华公司获知日期* (MRD) 日-月-年: 注：诺华公司获知日期是指诺华员工或指定人员或授权合作伙伴获知不良事件的日期

报告类型：☐ 自发报告 ☐ 文献 ☐ 面向患者项目 (项目名称_____ 项目编号_____)
☐ 数字参与资产项目/社交媒体倾听项目 (项目名称_____ 项目编号_____)

I. 患者资料 (遵守数据保密规定):

姓名拼音首字母	不良事件发生所在国	出生日期 (日/月/年)	不良事件发生时年龄/年龄组	性别	身高 (cm)	体重 (kg)	种族	患者编号 (面向患者项目)

II. 不良事件信息

不良事件	事件起始日期 (症状出现日期) (日/月/年)	事件结束日期 (日/月/年)	结果如何? REC 痊愈 SEQ 痊愈但有后遗症 IMP 改善 UNC 未变 DET 加重 FAT 致死的 UNK 不详	事件因果关系 S -可疑/相关 NS -不可疑/不相关 NA-无法评价	标明所报不良事件是否符合下列严重性标准？请标明所有符合的标准。 *(见下方说明)*	CO 严重性评估 如果严重性标准缺失/升级 (添加理由，例如基于FMA IMA 列表)

不良事件描述

*** 严重性标准 ***

☐ D. 患者因不良事件死亡 *请注明*
死亡日期: _____
死亡原因: _____
是否进行尸检? (是/否)_____ 若进行尸检，请在左侧“不良事件描述”中对结果进行简要说明。

☐ LT. 事件发生时威胁生命
不良事件发生时患者即面临死亡危险的不良事件

☐ HOSP. 导致住院或延长住院时间
入院日期: _____
出院日期: _____

☐ DI3. 导致永久的严重的伤残或器官功能损伤
对患者正常生活能力造成实质破坏，对身体功能、生理活动和或生活质量造成严重的、持续的或永久的改变、损伤和破坏。

☐ MI3. 重要医学事件
是可能使患者受到危害或者导致患者需要医学或外科干预以避免发生其他严重后果的不良事件

☐ CA. 先天异常或出生缺陷

☐ NS. 非严重

III (a). 可疑药物信息							
药品名称 (商品名或通用名。生物制品请提供商品名)	给药途径	剂型	给药方案或日剂量(单位)	治疗日期(日/月/年) 若治疗仍在持续中，则注明持续中。若无确切日期，则注明用药天数。		适应症	批号& 失效日期 (日/月/年)
				开始日期	结束日期		
III (b). 并用药品信息							
III (c). 可疑医疗器械信息							
器械名称(商品名或标签/包装印刷名)	相关药品(如与器械一起使用)& 适应症	器械使用者(医疗人员，消费者，外行使用者)	器械是否重复使用? 是/否	器械使用日期(日/月/年) 若治疗仍在持续中，则注明持续中。若无确切日期，则注明使用天数。		唯一器械编号	软件版本/序列号/批号& 有效期 (日/月/年)
				开始日期	结束日期		
III (d). 并用医疗器械信息							
III (e). 对医疗器械采取的措施 & 可疑器械所在场所：说明器械是否被更换、丢弃或未采取任何措施，以及报告时可疑器械所在场所							

IV. 药物其他信息/采取措施 *(请勾选所有合适的选项)*		
☐ 继续使用该药物	☐ 停止使用该药物 (请选择): ☐ 暂时 / ☐ 永久	☐ 减少该药物使用量
☐ 非药物治疗不良事件*	☐ 药物治疗不良事件*	☐ 其他 (请予以说明)
☐ 未进行治疗		

*若进行治疗，请予以描述:	
停用可疑药物后不良事件是否减轻? 可疑药物_____ ☐ 是 ☐ 否 ☐ 不详 ☐ 不适用 可疑药物_____ ☐ 是 ☐ 否 ☐ 不详 ☐ 不适用 可疑药物_____ ☐ 是 ☐ 否 ☐ 不详 ☐ 不适用 可疑药物_____ ☐ 是 ☐ 否 ☐ 不详 ☐ 不适用	重新使用可疑药物后不良事件是否再次发生? 可疑药物_____ ☐ 是 ☐ 否 ☐ 不详 ☐ 不适用 可疑药物_____ ☐ 是 ☐ 否 ☐ 不详 ☐ 不适用 可疑药物_____ ☐ 是 ☐ 否 ☐ 不详 ☐ 不适用 可疑药物_____ ☐ 是 ☐ 否 ☐ 不详 ☐ 不适用
该不良事件是否属于质量投诉或缺乏疗效? ☐ 是 ☐ 否	

V. 其他信息:	
相关病史包括现有或已有状况(如有可能，请提供日期):	
	风险因素: ☐ 饮酒 ☐ 过敏 ☐ 药物滥用 ☐ 抽烟 若为女性，是否处于妊娠期? ☐ 否 ☐ 是 末次月经日期: _____ 预产期:

VI. 相关的实验室检查或检查报告:			
检查项目	检查日期(日/月/年)	结果(具体明单位)	正常值

VII. 其他信息: 请提供以上内容的补充信息.

VIII. 报告者信息: 请用正楷字体填写			
报告者类型 ☐ 医疗人员 ☐ 消费者 ☐ 其他 (请注明:_____)			
姓名(名字、中间名和姓氏、后缀(如果适用)):		电话:	
职业:		传真:	
地址:		邮箱:	

报告者是否同意与其联系进行随访

☐ 是 ☐ 否 ☐ 不适用

若报告者不是治疗医师，是否同意与其治疗医师联系进行随访

☐ 是 ☐ 否 ☐ 不适用

若同意联系，请填写医师联络方式:

姓名:

电话: 邮件:

传真: 地址:

填表人: ☐医药代表☐医学信息☐医学事务☐项目专员(面向受试者项目或数字参与资产社交媒体倾听项目) ☐ 其他: _____

正楷签名: 签名: 日期(日/月/年):

诺华及其关联公司将收集、处理和分析本表格中提供的信息，以评估与使用诺华产品相关的副作用，并按照法律或法规的要求向本国监管当局，以及世界其他国家/地区的监管当局披露该信息。有关本报告的所有信息以及任何随访获得的更多的医疗详情都将符合适当的数据保护法规和措施，以保护您的个人数据。您可以通过向诺华全球隐私办公室 global.privacy_office@novartis.com 发送电子邮件来行使您的隐私权。更多详情请访问 www.novartis.com。

COs 说明(在没有任何本地数据隐私要求或此处所示要求比本地要求更严格的情况下应遵循:

- *在随访过程中，COs 应使用此不良事件表中数据隐私免责声明的本地翻译版本*
- *如果随访是通过邮件进行的，则在邮件中包括免责声明*

(注：因为免责声明已存在于本不良事件表中，如果随访是通过邮件进行的，而本不良事件表并未一起寄出，则邮件应包括免责声明)

- *如果通过电话进行随访，则必须重读免责声明*

Appendix F

SOCIAL MEDIA LISTENING PROGRAM AND DIGITAL ENGAGEMENT ASSET STANDARD VIGILANCE CONTRACTUAL PROVISIONS

附件 F

社交媒体倾听项目和数字化互动资产的标准警戒合同条款

1 Purpose 目的

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.

下文规定的条款旨在定义外部服务提供商（**ESP**）计划完成 SML 项目和/或 DEA 的任何警戒活动时必须遵守的药物警戒（PV）合同要求。这些条款也被称为"SML 项目和 DEA 警戒合同条款"，并构成协议不可分割的部分。除非适用法律或 GxP 禁止，否则在这些 SML 项目和 DEA 警戒合同条款中提及"书面"或"以书面形式"包括（但不限于）电子邮件通信。

2 Scope 范围

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".

当实施警戒活动中涉及 ESP 时，这些 SML 项目和 DEA 警戒合同条款适用于下文定义的数字化倡议：

- **社交媒体倾听（SML）项目**和
- **面向外部的数字化互动资产（DEA）**，其中诺华出于业务目的与受众（例如，患者、医护专业人员等）互动，包括移动应用程序的发布平台和面向患者项目（POP）第 3 组的 DEA 部分，如下所示：
    - **a)** **诺华的 DEA**，允许用户通过 DEA 互动功能公开和私下发表评论，包括移动应用程序的发布平台，以及当这些 DEA 成为 POP 第 3 组的一部分时。这些也被称为"具有公开可用和私人/直接用户互动功能的诺华的 DEA"。
    - **b)** **诺华的 DEA**，允许用户通过 DEA 互动功能**仅公开发表评论**，包括移动应用程序的发布平台，以及当这些 DEA 成为 POP 第 3 组的一部分时。这些也被称为"具有公开可用用户互动功能的诺华的 DEA"。
    - **c)** **诺华的 DEA**，允许用户通过 DEA 互动功能**仅私下发表评论**，包括当这些 DEA 成为 POP 第 3 组的一部分时。这些也被称为"仅具有私人/直接用户互动功能的诺华的 DEA"。
    - **d)** **第三方的 DEA**，允许用户通过 DEA 互动功能**至少公开发表评论**，包括当这些 DEA 成为 POP 第 3 组的一部分时。这些也被称为"至少具有公开可用的用户互动功能的第三方的 DEA"。

3 Definition of Social Media Listening programs 社交媒体倾听项目的定义

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.

社交媒体倾听是利用合法或公开可用的数据源，识别、收集和评估互联网上关于一个行业、公司、个人、产品或品牌的言论的过程。社交媒体倾听可以手动进行，也可以在专门的 SML 工具的支持下进行。在封闭或秘密的社交媒体小组/社区中手动进行或在专门的 SML 工具的支持下进行的倾听必须始终登记。

SML 项目的示例包括：

a) 分析社交媒体账户（如如微信、微博、抖音等）中用户生成的内容，以确定观点
b) 通过集结和分析与特定主题相关的所有对话（例如，围绕特定疾病领域），进行基于关键词的查询
c) 倾听并分析特定利益相关者群体（例如，医护专业人员）之间的对话，以优化当前的沟通和营销策略。

4 Definition of Digital Engagement Assets 数字化互动资产的定义

- **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.

- **数字化互动资产**：它是一种实现与受众互动的数字手段，至少提供以下一种功能：
  1. 诺华/ESP/第三方发布内容或共享内容
  2. 具有接收用户生成内容的可能性
  3. 接收来自用户的私人消息

  DEA 示例：网站、社交媒体页面/组、如博客/论坛的讨论形式、协作平台、应用程序（apps），包括移动应用程序、即时消息（IM）、短信系统（SMS）、增强现实应用程序、虚拟现实应用程序、技能（Alexa）等。
- **第三方的 DEA**：由第三方（例如，临床研究组织、患者组织、医疗保健公民记者、博客、名人、影响力者、医院网站）持有的 DEA **以及**：
  a) 诺华对内容拥有所有权、控制权或影响力（即拥有编辑、预览或审核特权），**并**与第三方就内容的使用和发布签订了合同/协议，**或**

b) 诺华聘请第三方代表诺华进行数字互动（不控制或影响内容），**并**与第三方就数字互动活动的范围签订了合同/协议

- **诺华的 DEA：**由诺华或代表诺华创建或管理的 DEA。这些资产的责任在于诺华。由代表诺华的 ESP 创建或管理的 DEA 也属于这一类别。

  还包括：
  - 使用个人 DEA 代表公司发言的诺华执行委员会和董事会成员的 DEA，
  - 由诺华或 ESP 团队管理的属于诺华员工（例如，CPO 负责人、职能部门负责人）的 DEA。

5 Adverse Events 不良事件

Adverse Event (AE) is any untoward medical occurrence in a patient or clinical-trial subject administered a Novartis product (i.e. a medicinal product for human use and/or a medical device) 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 Novartis product (i.e. a medicinal product for human use and/or a medical device), 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.

不良事件（AE）是使用诺华产品（即人用医药产品和/或医疗器械）的患者或临床试验受试者发生的任何不利医学事件，它并不一定与该产品有因果关系。因此，AE 可以是在时间上与使用诺华产品（即人用医药产品和/或医疗器械）有关联的任何不利的和非预期的体征（例如：实验室结果异常）、症状或疾病，无论其是否与该产品有因果关系。

此外，所有特殊情况和其他可报告情况（包括但不限于技术投诉、医疗器械事故，如 SML 项目或 DEA 适用的诺华全球以及相关的当地 AE 培训所述）必须告知恰当的诺华部门（例如，患者安全部、质量保证部等）。

针对 SML 项目和 DEA 警戒合同条款的目的，本协议中的不良事件、特殊情况和其他可报告情况统称为"AE"。

6 Transfer of Safety Information 安全信息的传递

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 must be transferred as soon as possible and always within the following specified time:
- If the starting time occurs during Friday business hours and your office is closed on Saturdays and Sundays, it will be transferred on the same day,
- If the starting time occurs outside of Friday business hours and your office is closed on Saturdays and Sundays, it shall be transferred no later than 2 calendar days,
- If the starting time occurs during the business hours of the day before the national holiday, it shall be transferred on the same day,
- If the starting time occurs during weekend/national holiday, it shall be transferred no later than 2 calendar days.

ESP 在监测*SML 项目/DEA 期间识别到与诺华产品（即人类医药产品和/或医疗器械；包括通用或品牌名称）的使用/提及相关的 AE（即满足最低 2 个安全数据元素（SDE）的**任何和所有**安全性信息），无论因果关系、严重性评估、产品标签或报告者类型如何，必须在以下起算时间发生后最长二十四（24）小时内[1]由 ESP 传递给恰当的诺华部门（例如患者安全部、质量保证部等）：

- 对于 SML 项目，从**识别**日期起算，

- 对于至少具有公开可用的用户互动功能的诺华的和第三方的 DEA，从**发布**日期起算
- 对于仅具有私人/直接用户互动功能的诺华的 DEA（在 DEA 开启的整个时间内无法关闭/禁用用户互动功能），从**审查**日期起算
- 对于至少具有公开可用的用户互动功能的诺华的 DEA 的发布平台，从**监测**日期起算。

外部服务提供商须遵守 SML 项目或 DEA 适用的诺华全球和相关的当地 AE 培训中详述的监测要求。外部服务提供商须参考或交叉检查相关诺华产品列表（例如，整合产品列表和医疗器械列表等），以识别相关诺华产品（即人类医药产品和/或医疗器械；包括通用或品牌名称），以协助其监测和传递义务。

外部服务提供商将通过使用诺华在线不良事件报告工具或使用诺华不良事件报告表（如 SML 项目或 DEA 适用的诺华全球以及相关的当地 AE 培训中进一步规定）通过电子邮件/传真告知诺华，以将安全性信息传递给恰当的诺华部门（例如，患者安全部、质量保证部等）。每份报告将包括来自诺华 SML 项目/DEA 的信息（包括具体说明 SML 项目/DEA 名称和 ID）。

外部服务提供商应向诺华提供诺华根据适用法律法规记录和报告安全性信息所需的任何和所有适当的个人健康信息。

[1] 在当地法律允许的情况下，如果在周末、国家假日或周五非工作时间且办公室在周六和周日关闭时收到任何满足最低 2 个 SDE 的安全性信息，则需尽快传递且始终在以下规定时间内：

- 如果起算时间发生在星期五工作时间，且您的办公室在星期六和星期天不办公，在当天传递，
- 如果起算时间发生在星期五非工作时间，且您的办公室在星期六和星期天不办公，最迟不超过 2 个日历日传递，
- 如果起算时间发生在国家假期前一天工作时间，在当天传递，
- 如果起算时间发生在周末/国家假期，最迟不超过 2 个日历日传递。

7 Novartis SML program and DEA AE Trainings 诺华 SML 项目和 DEA AE 培训

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.

在启动 SML 项目/DEA 之前，直接参与 SML 项目/DEA 监测的外部服务提供商及其人员（包括新员工）必须通过诺华全球 PS 提供的电子学习平台完成 SML 项目或 DEA 的诺华全球以及相关的当地 AE 培训（使用 ESP 及其人员可以理解的语言）；针对正在进行的 SML 项目/DEA，直接参与 SML 项目/DEA 监测的外部服务提供商及其人员（包括新员工）还要完成年度 AE 再培训，以及要在 AE 培训材料更新后并在其生效日期之前完成 AE 培训。外部服务提供商应与诺华合作，以确保及时完成培训。

必须完成 AE 培训，如下所示：

- **对于全球和多个国家的 SML 项目和 DEA**：必须完成 SML 项目/DEA 的全球 AE 培训。
- **对于当地 SML 项目和 DEA**：如适用，必须完成 SML 项目/DEA 的当地 AE 培训。如果无法获得当地培训，则必须完成 SML 项目/DEA 的全球 AE 培训。

外部服务提供商特此确认，其在与诺华签订 SML 项目/DEA 特定合同之前，已收到 SML 项目或 DEA 适用的诺华全球以及当地 AE 培训材料的副本，确认并同意其内容（包括其中包含的适用于外部服务提供商的任何要求和义务）以及诺华在协议期限内以书面形式告知内容的任何更新应构成协议不可分割的部分。

如果出现任何 SML 项目/DEA 培训材料更新，应诺华的要求，外部服务提供商及其人员必须按照诺华规定的任何完成时间表完成对更新版内容的培训。

外部服务提供商必须记录所有相关人员的培训并存档培训记录。所有培训材料和文件必须在要求时提供给诺华。在法律允许的情况下，根据本协议有关分包的条款，如果外部服务提供商分包了与 SML 项目/DEA 有关的任何服务，则必须遵守本第 7 节中规定的关于诺华 SML 项目/DEA AE 培训的相同义务。外部服务提供商负责向其分包商提供 SML 项目或 DEA 诺华全球以及相关的当地 AE 培训。只有接受过培训材料培训的外部服务提供商人员才能提供此类培训，并且必须使用与他/她接受过培训的相同培训材料。培训文件必须存档，培训材料和培训文件必须在要求时提供给诺华。

外部服务提供商负责确保分包商遵守 SML 项目和 DEA 警戒合同条款。

8 SML programs and DEA important dates and information SML 项目和 DEA 重要日期和信息

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)

外部服务提供商必须在以下情形发生后最长 **2 个工作日**内（即，不包括周末）向 SML 项目/DEA 所有者和诺华患者安全部提供以下日期：SML 项目/DEA 实际开始和关闭日期以及 SML 项目/DEA 监测开始和结束日期。这些日期的定义见下表。

在**第三方的** DEA 实际关闭日期后，外部服务提供商必须使用监测表格向诺华患者安全部提供监测文件。

定义	**SML 项目**	**诺华的 DEA**	**第三方的 DEA**
实际启动和监测开始日期	诺华/ESP 团队发起首次倾听活动时的日期	公众访问/可见 DEA 的首次日期	在第三方的 DEA 上发布第一份诺华内容的日期
实际关闭和监测结束日期	诺华/进行倾听的 ESP 团队不再分析/访问帖子/数据的日期	公众不再访问/可见诺华的 DEA 的首次日期	监测诺华末次内容的日期（即，发布后 60 天或直至无法再发表评论，以先发生者为准）

9 Source Data 源数据

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.

警戒源文件/数据（或有时称为源记录/源数据）是指 DEA 用户共享的原始数据和初始数据（例如，网站、社交媒体渠道等），以及 SML 项目从各种社交媒体平台和在线来源收集的原始数据和初始数据。对于 SML 项目，通过监测和分析社交媒体渠道上与特定关键词、主题、品牌、产品或事件相关的对话、提及信息、帖子和互动来获得源数据（此处称为“源文件/数据”）。DEA 的源文件/数据示例包括但不限于：用户在网站联系表/调查中输入的数据，社交媒体渠道方面的帖子互动（例如，点赞、分享、评论和其他参与社交媒体帖子互动方面的数据）、消息和聊天记录（例如，通过直接消息或聊天功能与用户进行的对话）。

SML 项目的源文件/数据示例包括但不限于：（a）社交媒体帖子（例如，在如微信、微博、抖音和其他平台上发布的公共帖子），包括用户共享的文本、图像、视频和其他媒介，（b）提及和话题标签（例如，提及特定关键词、品牌名称、产品名称和与感兴趣主题相关的话题标签），（c）评论和回复（例如，以对社交媒体帖子的评论和回复形式的对话等）。

此外，在所有情况下，任何系统（例如，PVI 工具；这是一种在线工具，用于以电子方式向诺华患者安全部报告满足最低 2 个 SDE 的安全性信息）生成的输出结果（用作数据采集/传递的第一个时间点）也将被视为源文件/数据。

10 Source Data Verification – Applicable to DEAs only 源数据核准-仅适用于 DEA

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.

源数据核准（SDV）是对 DEA 中可用的源文件/数据样本进行的审核，该审核针对参与 DEA 警戒活动的各外部服务提供商完成，以确定进行 DEA 监测的外部服务提供商是否已正确识别并向诺华传递了与诺华产品（即人类医药产品和/或医疗器械；包括通用或品牌名称）的使用/提及相关的 AE，即满足最低 2 个 SDE 的**所有和任何**安全性信息。源数据核准按季度完成，第一个日历季度从该年的 02 月 01 日开始。

外部服务提供商必须在诺华 DEA AE 培训中规定的 SDV 审核期最后一天后**最多六（6）周内**提供源数据。源数据核准不适用于 DEA 发布平台。外部服务提供商应记录这些活动的结果，并在要求时提供给诺华进行审核。如果诺华将 SDV 评估为失败，诺华可自行决定请求 ESP 提供支持以完成纠正措施和预防措施（CAPA）计划。外部服务提供商将负责确保按照诺华沟通的时间表完成 CAPA，执行此类措施所产生的所有相关成本和费用将由 ESP 负责。

诺华将有权审核源文件/数据记录，以确定外部服务提供商在安全性信息监测和传递方面的合规性和准确性。

如果发现任何与稽查发现/检查发现或安全性信息传递相关偏差有关的不合规情况/措施，应诺华要求，外部服务提供商特此同意充分配合并协助诺华在临时需要时进行 SDV。

在不损害诺华稽查权的情况下，诺华将在协议期限内和任何适用的存档/保留期满前有权访问/检查源文件/数据（包括在行使此类权利所需的范围内进入相关外部服务提供商（或其分包商/供应商）场所的权利），以确保诺华遵守所有与警戒相关的监管和内部要求。如果进行任何此类访问/检查（包括但不限于作为 SDV 的一部分），外部服务提供商将遵循当地法律或本协议要求的数据最小化原则，包括通过匿名化/编辑相关源文件/数据来隐藏/模糊任何个人身份信息。

11 Corrective Action and Preventive Action, Audit, and Inspection 纠正和预防措施、稽查和检查

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.

如果不符合 SML 项目和 DEA 警戒合同条款的要求，外部服务提供商承诺立即将这些偏差告知诺华，与诺华讨论应采取的纠正和预防措施，并在各方约定的相关时间表内纠正问题（各方合理且诚信行事）。外部服务提供商必须记录、跟踪并关闭/完成内部实施的任何 CAPA，包括但不限于根据诺华的意见实施的 CAPA。外部服务提供商必须定期将开放 CAPA 的完成进度告知诺华，以及在完成时或按照诺华的要求进行通知。

关于各 SML 项目/DEA 而言，就关于特定 SML 项目/DEA 相关协议的期限而言，在**上述期限到期或终止后两（2）年内**，诺华或其指定的第三方稽查员将有权稽查（无论是现场稽查还是基于纸质文件稽查）外部服务提供商（或其代理人或分包商）的流程、程序和培训，包括记录、数据、文件、源文件/数据（关于满足最低 2 个 SDE 的安全性信息）。外部服务提供商承诺在各方约定的时间表内纠正稽查发现中的问题（各方合理且诚信行事），并立即将措施告知诺华。各方同意，如果本协议包含的稽查和补救权比上述规定的稽查/补救权更广泛，则本协议中规定的更广泛的稽查/补救权在此将同样适用，但应遵守上述在 SML 项目和 DEA 警戒合同条款背景下就任何稽查/补救权的持续时间和范围提出的最低要求。

如果诺华存在法律问题，包括民事诉讼和政府调查，或任何政府检查或稽查，外部服务提供商特此同意，其将根据要求充分配合。此外，外部服务提供商特此同意允许国内和国际药品监管部门检查其警戒操作，作为诺华在诺华产品上市国家保持注册的必要条件。

12 Archiving 存档

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.

外部服务提供商还必须创建并存档文件/记录，例如在提供服务期间发送给诺华的表格和传递给诺华的安全性信息，以及其安全性信息传递程序的内部标准操作规程（SOP）和任何 SML 项目/DEA 相关文件（包括但不限于源文件/数据），并在当地法律允许的情况下，将其保存**至少五（5）年**，或者如果当地法律要求更长的时间，则保存更长的时间（在每种情况下，从 SML 项目/DEA 关闭开始计算）。此类文件/记录将接受稽查。针对本段的目的，在根据联邦和州法律进行管控的管辖区要参考当地法律是指现存/占支配地位的当地法律（联邦或州），如果联邦和州法律具有同等适用性，则在当地法律允许的情况下，将采用更严格的保留标准。

在任何适用的存档/保留期结束后，对于根据各方之间的数据处理协议（或同等协议）（包括作为协议的一部分）销毁包含私人数据/信息的文件/记录，将采用相关数据处理协议中的条款。

SML 项目和 DEA 警戒合同条款下的存档和保留要求可能比协议中规定的更广泛。如果本协议条款与 SML 项目和 DEA 警戒合同条款之间存在任何冲突，在法律允许的范围内，将采用 SML 项目和 DEA 警戒合同条款（如果更严格）的要求。

13 Amendments and Organizational Changes 修订和组织变更

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.

如果机构强制要求或基于其唯一临床判断这样的修改对于患者安全行是必要的，则诺华保留随时修订 SML 项目和 DEA 警戒合同条款的权利。在收到诺华发出的任何此类修订的书面通知后，外部服务提供商将立即遵守（或诺华规定的其他时间段），任何未遵守的情况将被视为 [重大] 违反本协议。

如果发生与外部服务提供商有关的任何变更（包括但不限于：组织名称变更、服务能力或运营），外部服务提供商必须立即以书面形式将此类变更告知诺华。

14 Contacts 联系人

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.

[Optional: The initial Account Manager details for the ESP are as follows: Name:
Email:

Tel:

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

[**Optional:** Novartis local contact for reporting purposes]

The initial Novartis local contact for reporting purposes is as follows:

[insert contact details including email address]

如果下文未提供，ESP 应在协议签字后立即任命客户经理并与诺华分享其联系方式（姓名、地址、电话、电子邮箱）。

[可选：ESP 的初始客户经理联系方式如下：

姓名：电子邮箱：

电话：

客户经理应：

- 监督所有诺华 SML 项目/DEA，以及
- 作为 SML 项目/DEA 相关问题的主要联系人

[**可选：**针对报告目的的诺华当地联系人]

针对报告目的，初始诺华当地联系人如下：

[插入联系方式，包括电子邮箱地址]

Appendix G – **ANNUAL COMPLIANCE CONFIRMATION**

附件 G - 年度合规确认书

Section 1: Introduction / 第 1 节：简介

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.

我们向您发送此年度合规确认书 ("ACC") 以帮助您遵守您对诺华及其附属公司的合同承诺。今后，您只需为每个相关报告期填写一份 ACC，以确认您和您的关联公司（如适用）遵守本 ACC 第 2 节规定的义务，因为它们适用于所有您和/或您的关联公司可能与诺华及其关联公司签订的未到期合同（"现有合同"）。现有合同仅指与诺华/诺华关联公司签订的合同，其中已经包含关于您/您的关联公司完成并交还年度合规确认书的承诺。对于没有现有年度合规确认义务的合同，您无需报告您的合规情况。

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.

在第 2 节中，如果您在报告期内（定义见下文）遵守了相关义务，您应该回答"是"。如果您没有遵守，请回答"否"并按以下要求提供更多详细信息。

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

本 ACC 涉及自　年　月　日（含该日）开始的 12 个月期间（"报告期"）。

Data Privacy Statement / 数据隐私声明

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

要了解我们如何收集和处理任何个人信息，请参阅我们的第三方通用隐私声明，网址为：
https://www.novartis.com/sites/www.novartis.com/files/general-data-privacy-notice-for-third-parties.pdf

SIGNATURE / 签名：

Name of the Company / 公司名称：

Country of Registration / 注册国家：

Individual completing on behalf of COMPANY / 代表公司填写的个人:

Contact Details (email) / 联系方式（电子邮件）：

****

Section 2 / 第 2 节 :

PART 1: COMPLIANCE WITH LAW & REGULATIONS / 第 1 部分：遵守法律法规

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.

在第 1 部分中，我们要求确认您和您的关联公司在报告期内遵守了我们现有合同中包含或提及的与遵守法律、法规（例如但不限于美国反海外腐败法、英国反贿赂法和您当地的反贿赂法）、行业规范/标准、构成现有合同一部分的任何诺华政策、标准和指南以及与反贿赂和反腐败有关的任何承诺。

☐ Yes / 是

☐ No / 否

• If no, please state the relevant law/regulation and the date since the said law/regulation has not been adhered to. / 如否，请说明相关法律/法规以及该法律/法规未被遵守的日期。

_____

• If no, state whether the Business owner has been informed and how. / 如否，请说明是否已通知相关项目负责人以及如何通知。

_____

PART 2: SUBCONTRACTING/ASSIGNMENT / 第 2 部分：分包/转让

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.

在这第 2 部分中，我们要求您确认您在报告期内遵守了我们现有合同中包含或提及的与现有合同项下任何权利或义务的分包、转让或转让有关的所有义务。

☐ Yes / 是

☐ No / 否

☐ Not applicable / 不适用

• If no, please state the relevant obligations and the date since the said obligation has been subcontracted/sublicensed. / 如否，请说明相关义务以及该义务被分包/转许可的日期。

_____

• If no, state whether the Business owner has been informed and how. / 如否，请说明是否已通知相关项目负责人以及如何通知。

_____

PART 3: TRAINING / 第 3 部分：培训

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.

在第 3 部分中，我们要求您确认您在报告期内遵守了我们现有合同中包含或提及的与反贿赂培训（和相关记录保存）相关的所有义务，并且您的员工、人员、工人在履行现有合同时参加过您的反贿赂和反腐败培训。

☐ Yes / 是

☐ No/ 否

• If no, reason for non-provision of training to relevant personnel. / 如否，未向相关人员提供培训的原因

_____

附件 H - 制裁和出口管制合规认证

Appendix H- SANCTIONS AND EXPORT CONTROLS COMPLIANCE CERTIFICATION

Vendor Name: _____
Vendor Address: _____
_____
_____
Point of Contact:
_____

Export Compliance Certification

On behalf of [insert Vendor name], I hereby certify that:

- The information provided in the attached Product List is accurate and complete.
- The items in the attached Product List have not been exported, reexported or transferred in violation of any of the following laws or regulations:
    - Regulation (EU) No. 2021/821 ("EU Dual Use Regulation");
    - U.S. Export Administration Regulations ("EAR"), 15 C.F.R. Pts. 730-774;
    - UK Export Control Order 2008 (S.I. 2008/3231);
    - Swiss Federal Act on the Implementation of International Sanctions ("Embargo Act");
    - Swiss Ordinance on the Export, Import and Transit of Dual Use Goods, Specific Military Goods and Strategic Goods ("Goods Control Ordinance");
    - Swiss Ukraine Ordinance 946.231.176.72 of 22 March 2022; and
    - Trade and economic sanctions administered by the United Kingdom, the European Union, and the United States.

I certify that all of the facts contained in this certification are true and correct to the best of my knowledge. If I determine that any information or statements contained are not accurate in the future, we agree to promptly inform you of such changes.

Signature: _____ **Date:** _____
Name: _____ **Email:** _____
Title: _____ **Tel. No.:** _____

Note: This document should be signed by a senior official who works for the Vendor.

Product List

Product Name	Part Number	Manufacturer	Mfr. Country	Origin Country	Import Date	HTS Classification	Export Classification (if applicable)

Version: 20240901

附件 I- 隐私声明

尊敬的供应商联系人：

为诺华供应商管理、与您联系、服务费支付、合同和信息管理、供应商合规培训（如有）以及完成其他履行本服务协议相关事宜，诺华需要收集您的姓名、手机号码、电子邮箱、公司电话、城市、传真（如适用）。

为了实现本隐私声明下的处理目的，您提交给我公司的个人信息可能存储于诺华在中国境内和境外的相关内部信息系统（例如供应商管理系统、财务系统、合同系统等），和/或在中国境外进行处理，我们会采取符合商业上合理的技术和安全防护措施保护您个人信息的安全，并在适用数据保护法律允许的时间范围内保留您的个人信息。仅经授权的诺华员工或诺华授权代表诺华处理您个人信息的第三方（如技术服务、数据处理服务商等）在需要知道的基础上会访问和使用您的个人信息。诺华会与这些第三方采取适当的合同措施保护您的个人信息。在此，我公司郑重向您承诺，我公司将对您提供的该等信息严格保密。除非根据法律规定或应行政或司法机构要求，未经您的事先书面同意，我公司不会将您的个人信息向任何上述主体之外的其他方披露，也不会用于本隐私声明所述之外的其他任何目的。

如果您需要查询、复制、更改或删除您的个人信息，或者希望行使您的其他个人信息主体权利，或有任何相关问题、要求或投诉，请联系【填入诺华联系人(BO)邮箱】，他们会协助您进行后续处理。

鉴于诺华集团为跨国集团，为了诺华全球业务经营管理的需要，我们可能使用集团位于中国境外的应用系统进行个人信息处理。为实现本隐私声明文首所述的处理目的，在遵守适用法律法规的前提下，您向我们提供的上述信息（包括姓名、手机号码、电子邮箱、公司电话、城市、传真）将传输至我们境外的关联公司（境外关联公司名称：Novartis Pharma AG，联系方式及行权渠道为：global.privacy_office@novartis.com；关于处理方式的进一步信息请见诺华总部的隐私政策：https://www.novartis.com/privacy/privacy-policy）。

本人特此确认和同意：

☐本人已经阅读和同意诺华按照《隐私声明》中所述目的处理我的个人信息。

☐本人同意诺华按照《隐私声明》所述向中国境外传输我的个人信息。

确认签字：_____

日期：_____

Appendix J- ENVIRONMENTAL SUSTAINABILITY ("ES") CRITERIA
附件 J- 环境可持续性标准

1. Novartis ES Strategy 诺华 ES 战略

(a) Carbon neutrality: Novartis is committed to becoming carbon neutral across its value chain by 2030 with the following stipulation: All Novartis products and/or services should be carbon neutral by 2030. Additionally, Novartis has committed to become a net zero carbon emissions company across the value chain by 2040.

碳中和：诺华致力于到 2030 年前在其价值链上实现碳中和，并遵守以下规定：到 2030 年前，所有诺华产品和/或服务应实现碳中和。此外，诺华致力于到 2040 年前成为整个价值链净零碳排放的公司。

(b) Water quality: Novartis is committed to becoming water sustainable in its operations and to ensuring that manufacturing effluents have no water quality impacts on the receiving aquatic environment.

水质：诺华致力于在其运营中实现水的可持续性，并确保生产废水不会对接收的水生环境造成水质影响。

(c) Waste reduction: Novartis is committed to becoming plastic neutral by 2030 by promoting circular economy, continuously reducing waste in operations, and adopting eco-friendly materials in its products and/or services where feasible.

减废：通过促进循环经济，持续减少运营中产生的废物，并在可行的情况下在其产品和/或服务中采用环保材料，诺华致力于到 2030 年前实现塑料中和。

2. Novartis ES Expectations 诺华 ES 预期

(a) **Carbon: Supplier shall ensure that all products and/or services procured by Novartis should be carbon neutral by 2030.**

碳：到 2030 年前，供应商应确保诺华采购的所有产品和/或服务实现碳中和。

(b) Water: Supplier shall ensure water is used responsibly throughout their operations and avoid any water quality impacts on the receiving aquatic environment as per local regulatory requirements.

Supplier shall manage active pharmaceutical ingredient (API) and drug substance manufacturing effluents during the course of production of products and/or services procured by Novartis in order to avoid any water quality impacts on the receiving aquatic environment with the following stipulations:

i. Manufacturing effluents must be treated according to local regulatory requirements, and at least by either an on-site or an off-site mechanical-biological treatment.

ii. The ratio of the API load to surface water (predicted environmental concentration, PEC) to the predicted no effect concentration (PNEC) shall be below 1 (PEC/PNEC<1), with the concerned PNEC value retrieved from a scientifically sound and reliable source approved by Novartis.

iii. For API, Supplier shall demonstrate its water quality performance to Novartis through the disclosure of mass balances and/or analytical monitoring results. For a mass balance approach, conservative assumptions shall be applied.

水：供应商应确保在整个运营过程中负责任地用水，并根据当地监管要求避免对接收水生环境造成任何水质影响。

供应商应在诺华采购的产品的生产和/或服务过程中管理活性药物成分 (API) 和原料药生产废水，以避免对接收水生环境造成任何水质影响，具体规定如下：

i. 生产废水必须按照当地法规要求进行处理，至少采用现场或场外机械生物处理。

ii. 地表水的API 负荷（预测环境浓度，PEC）与预测无效应浓度 (PNEC) 之比应低于 1 (PEC/PNEC<1)，相关 PNEC 值取自诺华批准的可靠科学来源。

iii. 对于 API，供应商应通过披露质量平衡和/或分析监测结果向诺华证明其水质表现。对于质量平衡方法，应采用保守假设。

(c) Waste: Supplier shall aim to continuously reduce waste in its operations and adopt eco-friendly materials for products and/or services procured by Novartis where feasible.

废物：供应商应致力于持续减少其运营中产生的废物，并在可行的情况下为诺华采购的产品和/或服务采用环保材料。

(d) Supplier along with their approved subcontractors/suppliers shall support Novartis' ES Strategy by complying with (i) the provisions of Sections 2 (a) to (c) above, (ii) any applicable laws relating to ES and (iii) any terms in the existing contract relating to ES.

供应商及其批准的分包商/供应商应遵守 (i) 上述第 2 (a) 至 (c) 节的规定，(ii) 与 ES 相关的任何适用法律，以及 (iii) 现有合同中与 ES 相关的任何条款，从而支持诺华的 ES 战略。

3. ES Related Data Collection & Reporting Obligations ES 相关数据收集和报告义务

(a) Upon request, Supplier shall grant access to Novartis, its Affiliates and/or designated representatives for conducting assessments on Supplier's performance with regard to the ES Expectations for products and/or services procured by Novartis.

根据要求，供应商应允许诺华、其关联方和/或指定代表对供应商在诺华采购的产品和/或服务的 ES 预期方面的表现进行评估。

(b) Together with Novartis, Supplier and its Affiliates shall establish a sustainability roadmap for products and/or services procured by Novartis, including agreeing to track certain ES related Key Performance Indicators ("**ES KPIs**"), defining baselines and setting milestones in order to track Supplier's performance with regard to the ES Expectations and to identify opportunities to improve Supplier's and its Affiliates ES performance.

供应商及其关联方应与诺华一起为诺华采购的产品和/或服务制定可持续发展路线图，包括同意跟踪某些与 ES 相关的关键绩效指标（"**ES KPI**"），定义基线和设定里程碑，以跟踪供应商在 ES 预期方面的表现，并确定改进供应商及其关联方 ES 表现的机会。

(c) Supplier and its Affiliates shall establish and maintain ES data in accordance with the relevant sustainability standards e.g. Global Reporting Initiative ("GRI") and the respective materiality assessment. Supplier will also ensure same standards are followed by their suppliers and overall supply chain.

供应商及其关联方应根据相关可持续性标准，如全球报告倡议（"GRI"）和各自的重要性评估，建立和维护 ES 数据。供应商还将确保其自身的供应商和整个供应链遵循相同的标准。

(d) Supplier and its Affiliates shall establish and maintain Novartis product/service specific ES data (Product/ Service Carbon Footprint), and shall make it available to Novartis on annual basis. For this, they shall follow industry framework e.g. Partnership for Carbon Transparency (PACT) framework developed by the World Business Council for Sustainable Development (WBCSD).

供应商及其关联方应建立和维护诺华产品/服务特定的 ES 数据（产品/服务碳足迹），并每年将其提供给诺华。为此，他们应遵循行业框架，例如世界可持续发展商业理事会 (WBCSD) 制定的碳透明度伙伴关系 (PACT) 框架。

(e) Supplier and its Affiliates shall allow Novartis to report their ES related data regarding products and/or services procured by Novartis and/or its Affiliates to an independent third-party platform in an anonymized form, as may be required for the purposes of external reporting, benchmarking and auditing.

供应商及其关联方应允许诺华出于外部报告、基准测试和审计目的所需，以匿名形式向独立的第三方平台报告与诺华和/或其关联方采购的产品和/或服务有关的 ES 相关数据。

4. Sustainability Standards and Commitments for the Supply Chain 供应链的可持续性标准和承诺

(a) Supplier and its Affiliates shall establish and maintain public commitments related to carbon emissions and shall align its targets with and have them approved by the Science based targets initiative (SBTi) (www.sciencebasedtargets.org).

供应商及其关联方应建立并坚持与碳排放相关的公共承诺，并应使其目标与科学碳目标倡议 (SBTi) (www.sciencebasedtargets.org) 保持一致，并获得其批准。

(b) Supplier and its Affiliates shall establish and maintain external ES reporting and disclosures either through CDP (www.cdp.net), covering the climate change and water security modules, or through EcoVadis (www.ecovadis.com) in combination with PSCI (www.pscinitiative.org).

供应商及其关联方应通过涵盖气候变化和水安全模块的 CDP (www.cdp.net)，或通过 EcoVadis (www.ecovadis.com) 结合 PSCI (www.pscinitiative.org) 建立和维护外部 ES 报告和披露。

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

供应商及其关联方应根据诺华的要求或按照约定的频率提供经独立第三方（如 SGS、TUEV、Bureau Veritas 等）认可的相关环境足迹数据。