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., Sandoz (China) Pharmaceutical 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 Third Party 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、山德士(中国)制药有限公司)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、作为其第三方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 Novartis' Professional Practices Policy ("P3 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 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.

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, 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 is within the scope of POP group 1 or group 2, ensure that it will comply with the provisions of Novartis Patient Oriented Program (POP) as set out in Appendix E;

(12) 12)if the Service is within the scope of SML and/or DEA, 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 Novartis Global Anti-Bribery 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.

若诺华专业互动政策（“P3 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 P3 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”）、“药物不良反应”（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）是指在患者或临床试验受试者进行某种药品给药后出现的不良医学事件，但该事件不一定与该药物治疗有因果关系。因此，不良事件可能是与使用药品存在时间关联的任何不利和非预期体征（例如异常实验室结果）、症状或疾病，无论是否与所用药品有关。
药物不良反应（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、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/数字参与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) 若有项目在诺华面向患者项目第 1 组或第 2 组的范围，供应商应确保其遵守**附件 E** 所列的诺华面向患者项目的规定；

(12) 若有项目在诺华社交媒体倾听项目和/或数字参与资产项目的范围，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，包括但不限于诺华全球反贿赂政策(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 Third Party 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，作为其第三方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 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诺华全球反贿赂政策中规定的标准，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 the Anti-bribery 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反贿赂政策，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 **Third Party Risk Management**. Novartis has put in place a Third Party Risk Management framework which is aimed at promoting the societal and environmental values of the United Nations Global Compact with specific third parties that Novartis deals with.

In connection with the above, 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.

第三方风险管理：诺华已制定了一套第三方风险管理机制，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. Execution and delivery of the Transaction Documents constitutes the representation by each party hereto that the individuals identified have been notified of and have consented to, the transfer, storage, and processing of such personal data, as described in this paragraph.
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，确认交易文件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描述的方式被传输、存储或处理。

20.15 **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。

Appendix A - MINIMUM INFORMATION SECURITY CONTROLS FOR SUPPLIER

附件 A - 对供应商的最低信息安全控制

1. GOVERNANCE AND COMPLIANCE 管控与合规

- Supplier shall implement and maintain an information security program, consistent with security industry practice and standards, 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.
  供应商应实施和维护符合安全行业惯例和标准的信息安全规划，以保护系统和网络基础设施，以及数据的保密性、完整性、可用性和可恢复性，至少应符合本文件的规定。
- Supplier shall ensure that it has nominated an appropriate individual to hold accountability on behalf of Supplier for ensuring technical and organizational compliance with information security controls.
  供应商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。
- Supplier's information security program must include a governance framework with supporting risk management policies that will enable and support risk management.
  供应商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

- Supplier 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.
  供应商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 IT 系统，及这些 IT 系统涉中支持诺华服务的任何形式的数据。
- Supplier shall ensure that its disaster recovery plans are periodically tested and updated to ensure they are up-to-date and effective.
  供应商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。
- Supplier shall ensure that technologies and processes used for data backup and recovery are regularly tested and have sufficient protection against any disruptive cyber-attacks.
  供应商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 handling and storage of data shall be established by Supplier to protect data from unauthorized disclosure or misuse.
  处理和存储数据的流程应由供应商建立，以保护数据免受未经授权的泄露或滥用。
- Supplier shall ensure media is disposed of securely and safely when no longer required, using formal procedures with proper documentation.
  供应商应应确保当不再需要时，使用正式程序和适当的文件，以安全的方式安全处理介质。
- Supplier shall ensure that system documentation is protected against unauthorized access.
  供应商应确保系统文档不受未经授权的访问。

4. EXCHANGE OF DATA 数据交换

- Supplier 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.
  供应商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保密性、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

- Supplier 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.
  供应商必须有一个访问控制策略，以确保只有有业务需求并得到批准的授权用户才能访问诺华数据。
- Supplier 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.
  供应商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

- Supplier must have developed and implemented policy on use of cryptographic controls for appropriate protection of data, whilst ensuring compliance with applicable statutory, regulatory and contractual requirements.

供应商必须制定并实施关于使用加密控制以适当保护数据的政策，同时确保符合适用的法律、法规和合同要求。

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

- Supplier shall ensure that networks under Supplier'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.
  供应商应确保供应商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。

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

- Supplier shall ensure that all its Workers, contractors and agents are aware of information security threats and concerns, their responsibilities and liabilities, and are equipped to support organizational security policy in the course of their work
  供应商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关切、他们的职责和责任，并在其工作过程中支持组织的安全政策。
- Supplier shall ensure that, all Workers, contractors and agents shall receive appropriate information security and data protection awareness training.
  供应商将确保，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。
- Supplier will ensure that 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.
  供应商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。

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

- Supplier shall ensure that the appropriate information security perimeters and entry controls are in place to prevent unauthorized physical access, damage and interference to Supplier's premises and data including all end user devices.
  供应商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、损坏和干扰供应商的营业场所和数据，包括所有最终用户设备。
- Supplier shall ensure that equipment is properly inventoried and maintained to ensure its continued information security.
  供应商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。

10. PROTECTION OF ORGANIZATIONAL RECORDS 保护组织记录

- Supplier shall ensure their information security program includes policies that cover data retention and data destruction consistent with security industry practice.
  供应商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。
- Supplier shall ensure appropriate controls are implemented to prevent the loss, destruction, or falsification of records during their retention period.
  供应商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。
- Supplier agrees that upon the request of Novartis or as otherwise required by law, it shall dispose (e.g. erase, destroy or render uninterpretable) all Novartis data that Supplier, its affiliates or subcontractors hold (excluding any and all copies of the Novartis data residing on Supplier's standard backup media, providing that such backup media are secured according to recognized and then-current data privacy practice and security industry practice). Supplier 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.
  供应商同意，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）供应商、其关联公司或分包商持有的所有诺华数据（不包括存在于供应商标准备份介质中的诺华数据的任何和所有副本，前提是该备份介质是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的）。应诺华要求，供应商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。诺华公司有权在处置诺华公司的数据之前，以诺华公司规定的形式和时间范围接收其数据的副本。
- Where requested by Novartis, Supplier shall certify in writing that these actions have been completed.
  如果诺华要求，供应商应书面证明这些行动已经完成。
- The following shall be considered as exceptions to this disposal requirement:
  - Supplier 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 Supplier to keep archived for legal hold or other comparable purposes
  - Where Novartis has agreed in writing with Supplier 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：
- 供应商必须为法律或监管目的将诺华数据存档；一旦法定保存期到期，诺华的这些数据将被删除
- 诺华为合法持有或其他可比目的要求供应商存档的诺华数据
- 如果诺华已与供应商书面同意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，

此类特定要求将适用。

11. TECHNICAL VULNERABILITY MANAGEMENT 技术漏洞管理

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

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

- Supplier 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.
  供应商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。
- Supplier 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，供应商将及时通知诺华。

13. MONITORING 监控

- Supplier must monitor its environment to detect and respond to information security incidents or other unauthorized activities.
  供应商必须监控其环境，以检测和响应信息安全事件或其他未经授权的活动。
- Supplier shall ensure audit controls are implemented within the Supplier environment under Supplier's control to enable independent audits/testing of appropriate audit data on operational systems while minimizing the risk of disruption to processes.
  供应商应确保在供应商控制下的供应商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。

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

- Supplier 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.
  供应商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恢复所有变更失败的回滚程序。

15. HARMFUL CODE PREVENTION 有害代码防范

- Supplier shall develop policies to manage the risks associated with the malicious use of harmful code and implement anti-malware defenses.
  供应商应制定策略来管理与恶意使用有害代码相关的风险，并实施反恶意软件防御。

Appendix B

NOVARTIS ANTI-BRIBERY POLICY

附件 B

诺华全球反贿赂政策

Effective: November 1st, 2020

生效日期：2020 年 11 月 1 日

Version ERC 100.V6. EN

版本 ERC 100.V6.简体中文

1. Introduction 介绍

1.1 Purpose 目的

Our Code of Ethics states that we do not bribe anyone. This Policy sets forth the respective principles and rules and how they must be implemented.

我们的道德准则规定，不得贿赂任何人。 该政策规定了原则和法规以及如何确保其实施。

1.2 Scope and Applicability 范围与适用性

This Policy addresses a variety of contexts in which bribery issues may arise. Other aspects of business ethics and corruption, including conflicts of interest and passive bribery (e.g. receipt of a bribe) as well as insider trading, are regulated separately.

本政策规制贿赂问题可能发生的不同情况。商业道德和腐败的其他方面（包括利益冲突、收受 贿赂之类的被动贿赂和内幕交易）则单独进行规范。

This Policy contains Novartis global standards. In some countries, more stringent applicable laws, regulations or industry codes supersede the principles set out in this Policy. Divisions and local Novartis organizations may also establish more restrictive practices.

本政策包含诺华全球标准。如果某些国家的适用法律、法规或行业准则更加严格，则可取代本政策中规定的原则。

各部门和本地诺华组织机构也可以建立更具有限制性的实践规范。

This Policy is effective as of November 1, 2020, and must be adopted by all Novartis affiliates. It replaces the existing version of the Anti-Bribery Policy dated February 1, 2020.

该政策自 2020 年 11 月 1 日起生效，并且必须由所有诺华子公司采用。 它将取代现有的 2020 年 2 月 1 日的反贿赂政策。

2. Principles and Rules 原则和规定

2.1 Basic Rules 基本规定

Principles and Rules 原则和规定

Associates must not bribe and they must not use intermediaries, such as agents, consultants, advisers, distributors or any other business partners to commit acts of bribery.

诺华员工不得贿赂，也不得使用中介（如代理、咨询顾问、顾问、经销商或任何其他商业伙伴）实施贿赂行为。

Novartis does not distinguish between public officials and private persons so far as bribery is concerned: bribery is not tolerated, regardless of the status of the recipient.

就贿赂而言，诺华不会区别对待公职人员和私营组织人员：无论接收人是何种身份，都不容许贿赂。

Always ask yourself before offering, giving, or promising anything of value to any person if what you are considering could be viewed as having an illegitimate purpose. If the answer is yes, you must not proceed.

向任何人提供、给予或承诺任何有价物之前，始终询问自己正在考虑的行为是否会被视为具有 非法目的。如果答案是肯定的，则不得进行。

If you are in any doubt, consult a legal or compliance representative before proceeding.

如果您有任何疑问，请在进行之前咨询法律或合规代表。

Definitions 定义

Bribery means offering, giving or promising (or authorizing someone to offer, give, or promise) an improper benefit, directly or indirectly, with the intention of influencing or rewarding the behavior of someone to obtain or retain a commercial advantage.

贿赂是指提供、给予或承诺（或授权某人提供、给予或承诺）不当利益，旨在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。

Bribery can take a variety of forms – offering or giving money or anything else of value. In fact, even common business practices or social activities, such as the provision of gifts and hospitality, can constitute bribes in some circumstances.

贿赂可以通过多种形式，包括提供或给予金钱或者其他任何有价物。实际上，即使常规商业行 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。

Situations when Associates receive, agree to receive, request or accept a financial benefit or anything else of value are regulated by the Conflicts of Interest Policy.

《利益冲突政策》对员工接收、同意接收、要求或接受财物利益或任何其他有价物的情形进行 了相关规定。

References 参考

• Novartis Anti-Bribery Third Party Guideline《诺华反贿赂第三方指南》

• Novartis Conflicts of Interest Policy《诺华利益冲突政策》

2.2 Gifts, Hospitality, and Entertainment 礼品、招待和娱乐

Principles and Rules 原则和规定

Gifts, hospitality, and entertainment must be modest, reasonable and infrequent so far as any individual recipient is concerned.

就任何接收个人而言，礼品、招待和娱乐务必适度、合理且不可过于频繁。

Gifts, hospitality, and entertainment must never be promised, offered, or provided with the intent of causing the recipient to do something favoring Novartis, to reward such behavior, or to refrain from doing something disadvantaging Novartis.

承诺、提供或给予礼品、招待和娱乐绝不能旨在使接收人做出有利于诺华的事情，或对这种行为进行回馈，或旨在使接收人避免做出不利于诺华的事情。

Gifts of any kind including personal gifts, cultural acknowledgements or promotional aids etc., whether branded or unbranded, must not be provided to Healthcare Professionals (HCPs) or their family members.

任何种类的礼物，包括个人礼物、风俗礼节物品或推广辅助用品等，不论是否标示品牌，均不得向医疗卫生专业人士 (HCP) 或其家庭成员提供。

Cash and gifts that are cash equivalent (e.g., shopping coupons) must never be given.

绝不能给予现金和与现金等价的礼品（例如购物券）。

Do not provide entertainment to any participant to Novartis business meetings, congresses or comparable events, unless the entertainment is an appropriate and incidental part of such events. Do not pay for any side or extended trips.

切勿向诺华商务会议、大会或类似活动的任何参与者提供娱乐活动，除非其为此类活动适当且 附带的一部分。切勿为任何顺带的或延长的旅行支付费用。

Do not pay for the entertainment, hospitality, or travel costs of anyone who accompanies an invitee to a Novartis business meeting, congress, or comparable event. In situations where an invitee is unable to travel alone (e.g., patients or minors), travel costs for an accompanying person (e.g., caregiver) can be paid for provided that the rationale for this support is legitimate, documented, and considers applicable data privacy requirements.

请勿为诺华商务会议、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）的情况下，可以支付随从人员（例如护理人员） 的差旅费用，前提是提供这种支持的理由要合法、经文档备案记录并且考虑了适用的数据 隐私要求。

Before giving a gift or providing hospitality or entertainment to anyone, consider whether the reputation of Novartis, yourself, or the recipient is likely to be damaged if news of the gift, hospitality, or entertainment appeared on the front page of a newspaper. If this would embarrass either Novartis or the recipient, do not proceed.

给予任何人礼品或者提供招待或娱乐活动之前，请考虑一下如果礼品、招待或娱乐出现在报纸 首页上是否可能有损诺华、您自己或者接收人的名誉。如果会给诺华或接收人带来麻烦，请勿 进行。

Definitions 定义

Gifts are benefits of any kind given to someone as a sign of appreciation or friendship without expectation of receiving anything in return. They include 'courtesy gifts', which are small gifts given at culturally recognized occasions (e.g., weddings, funerals) or special times of the year (e.g., Christmas, New Year).

礼品是指给予某人任何形式的利益，作为答谢或友谊的表示，而不期望接收任何回报。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。

Hospitality generally includes refreshments, meals, and accommodation.

招待通常包括茶点、餐饮和住宿。

Entertainment generally includes attendance at plays, concerts, and sports events.

娱乐通常包括观看戏剧、音乐会和体育活动。

References 参考

- Principles & Practices for professionals (P3) 专业互动政策指南(P3)

2.3 Grants, Donations and Sponsorship 捐助、捐赠和赞助

Principles and Rules 原则和规定

Novartis may provide funding or other support to external organizations. This includes grants, donations and sponsorships which are governed by the P3 Policy and P3 External Funding Guideline.

诺华可以向外部组织提供资金或其他支持。其中包括受《P3 政策》和《P3 对外资助指南》管理的捐助、捐赠和赞助。

References 参考

- Principles & practices for professionals (P3) 专业互动政策指南(P3)
- Novartis Global P3 Guideline on External Funding《关于对外资助的诺华全球 P3 指南》
- Management Authorization Levels, also known as MALs《管理授权级别》，即 MAL

2.4 Rules Relating to Public Officials 公职人员相关的规定

Principles and Rules 原则和规定

Novartis does not distinguish between public officials and employees of private sector organizations so far as bribery is concerned; however, it is important to recognize that public officials are often subject to rules and restrictions that do not apply to persons who operate in the private sector.

就贿赂而言，诺华不会区别对待公职人员和私营组织的雇员，但是需要了解公职人员通常遵守 的规定和约束不适用于在私营组织中工作的个人，这一点很重要。

Any relationship with public officials must be in strict compliance with the rules and regulations to which they are subject (i.e., any applicable rules or regulations in the particular country relating to public officials or that have been imposed by their employer) and any benefit conveyed to a public official must be fully transparent, properly documented, and accounted for.

与公职人员的所有来往必须严格遵守公职人员应遵守的规定和法规（例如特定国家所适用的公职人员相关的规定或法规或者雇主所施行的规定或法规），而且所有向公职人员提供的利益都必须完全透明、适当记录并予以解释。

Definitions 定义

The term 'public official' has been extensively interpreted by regulators and includes

监管者对术语“公职人员”进行了广泛解释，其含义包括：

• Any elected or appointed officer or employee of a government or government department, government agency, or of a company owned or partially owned by a government
政府或政府部门、政府机关、或政府所有/部分所有的企业中选举或指派的官员或雇员

•Any elected or appointed officers or employees of public international organizations, such as the United Nations
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

• Any person acting in an official capacity for or on behalf of a government or a government department, government agency, or of a public international organization
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

• Politicians and candidates for a political office
政治人物和政治职务候选人

• Any other person who is considered to be a public official according to applicable laws, regulations and industry codes
任何根据适用法律、法规和行业准则被认定为公职人员的人

Medical and scientific personnel qualify as public officials when they work at a hospital, clinic, university or other similar facility owned or partially owned by a government.

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公职人员。

In some countries, doctors, pharmacists, clinical trials investigators, and nurses are public officials irrespective of whether they are working at a government institution.

在一些国家中，医生、药剂师、临床试验研究员以及护士都是公职人员，无论他们是否是在为 政府机构工作。

2.5 Political Contributions 政治捐助

Principles and Rules 原则和规定

Novartis may only make political contributions where these are part of the political culture in a country and aim to help build sustainable healthcare systems for the benefit of patients. For instance, Novartis may seek to support candidates, committees, or other organizations that are committed to economic growth, recognize the importance of healthcare innovation, or patient access to therapies.

诺华仅在将政治捐助视为政治文化组成部分的国家，和以帮助建立可持续的医疗卫生系统，为患者谋求福祉为目标的情况下进行政治捐助。

例如，诺华可能会寻求支持承诺经济发展、认同医疗保健创新或患者治疗可及性的重要意义的候选人、委员会或其他组织。

Political contributions must never be made with the expectation of a direct or immediate return for Novartis.

绝不通过政治捐助期望直接或立即给予诺华回报。

Political contributions must meet all of the following requirements:

政治捐助必须满足以下所有要求：

• Compliant with applicable laws, regulations, and industry codes
遵守适用的法律、法规和行业准则

• Covered by a separate budget position, approved in the ordinary budget process 设有独立的预算空间、通过正常预算流程审批

• Approved in advance by the relevant Novartis Country President, or his/her designee

事先获得相关诺华所在国家总裁或其指定人员的批准

Definitions 定义

Political contributions are monetary or non-monetary (commonly referred to as "in-kind" contributions, which include uses of resources, facilities, etc.) contributions to support political parties, politicians or political initiatives.

政治捐助是指以货币形式或非货币形式（通常称为"实物"捐助，其中包括使用资源、设施等）的捐助来支持政党、政府官员或政治提案。

2.6 Lobbying

Principles and Rules 原则和规定

Novartis engages in lobbying activities to provide policy makers with data and insights to enable widely informed decision-making conducive to improving patient outcomes and sustainable business.

诺华参与 Lobbying 活动的目的是为政策制定者提供数据和见解，让决策基于对情况的广泛了解而制定，从而有助于提高患者获益和业务可持续性。

Lobbying should not be misused for any corrupt or illegal purposes, or to improperly influence any decision. Relevant functions (e.g., Public & Government Affairs) provide guidance on how lobbying should be conducted based on the values of transparency, honesty and integrity.

Lobbying 不得为任何腐败或非法之目的而滥用，或对任何决策产生不正当的影响。相关职能部门（例如公共事务和政府事务部门）根据透明、正直、诚信的价值标准，为应该如何进行 Lobbying 提供指南。

Definitions 定义

'Lobbying' describes interactions with policy makers and other external stakeholders with the intent to represent Novartis' perspective in the policy making process. Active contribution to policy making is an integral part of the democratic process and a legitimate activity as it enables the representation of different societal interests.

"Lobbying"是指在制定政策过程中，代表诺华观点与政策制定者以及其他外部利益相关方进行的互动活动。对政策制定的积极贡献是民主程序中不可分割的一部分，也是一种合法的活 动，因为它能让不同的社会利益群体表达观点。

References 参考

- Code of Ethics《道德准则》
- Novartis Responsible Lobbying Guideline《诺华负责任 lobbying 指南》
- Novartis Anti-Bribery Third Party Guideline《诺华反贿赂第三方指南》

2.7 Facilitation Payments 通融费

Principles and Rules 原则和规定

Novartis prohibits facilitation payments, irrespective of whether local law permits facilitation payments.

无论当地法律是否允许，诺华禁止使用通融费。

Definitions 定义

Facilitation payments are payments to public officials to expedite the performance of duties of a non-discretionary nature. These payments are intended to influence only the timing of the public officials' actions (e.g., payments to expedite the issuance of a visa or clearing goods through customs), but not their outcome.

通融费是指支付给公职人员用于加快履行非自由决定性质的职责。这些费用意图是仅影响公职 人员的履行时间（例如付款以便加快签证发放或海关清货），而不影响最后结果。

2.8 Third Parties 第三方

Principles and Rules 原则和规定

Novartis must only engage Third Parties if all of the following requirements are met:

仅在满足以下所有要求的情况下，诺华才能与第三方来往：

• There is a legitimate need for the services or the goods that they provide
对第三方提供的服务或货物有合法需求

• The services and goods are priced at no more than market value
其服务及货物定价不高于市场价格

• The Third Party is suitable from an anti-bribery perspective after assessment in a robust Due Diligence process
经过严格的尽职调查流程评估之后，第三方符合反贿赂的相关要求

• There is a written contract or other written document with a similar legal effect (e.g., Purchase Order)
具备书面协议以及其他具有类似法律效力的书面文件（例如采购单）

The receipt of services or goods must be documented and in line with the requirements stipulated in Section 2.10 of this Policy.

接收第三方服务或货物时必须进行记录并且必须符合本政策第 2.10 条规定的要求。

Engagement of Third Parties – including healthcare professionals – must never be used to create an incentive, or to reward or to secure any improper business advantage for Novartis.

与第三方（包括医疗卫生专业人员）的来往绝不能用来为诺华激励、回馈或确保任何不当业务利益。

Definitions 定义

A Third Party is any natural person or legal entity with whom Novartis interacts and who poses, due to the nature of their business, a particular level of bribery risk. Novartis affiliates and Associates are not considered Third Parties in this Policy.

第三方是指与诺华往来的、因其业务性质而具有特定程度贿赂风险的自然人或法人实体。在本政策中诺华关联机构和员工不属于第三方范围。

References 参考

• Novartis Anti-Bribery Third Party Guideline《诺华反贿赂第三方指南》

2.9 New Business and Joint Ventures 新业务和联合经营

Principles and Rules 原则和规定

Before entering into an agreement for new business or entering into a joint venture, adequate anti-bribery due diligence must be completed. In addition, a remediation plan should be developed and implemented to address identified issues.

签订新业务协议或进行联合经营之前必须完成充分的反贿赂尽职调查。除此之外，应该制定和 实施相关纠正计划以解决发现的问题。

Definitions 定义

New business means any transaction involving the takeover or acquisition of all or any part of a third party or business, or the merger of a Novartis business with another company or business.

新业务是指涉及所有或部分第三方或第三方业务的接管或收购的交易，或指诺华业务与其他公 司或业务的合并。

Joint venture means any type of joint agreement or arrangement between Novartis and one or more third parties to own and operate an enterprise as a separate business for the mutual benefit of Novartis and the third party or parties.

联合经营是指为了诺华和一个或多个第三方的共同利益，诺华与一个或多个第三方之间签订的任何形式的联合协议或安排，从而以独立业务的方式来拥有和运营一家企业。

2.10 Books and Records/Internal Controls 帐簿和记录/内部控制

Principles and Rules 原则和规定

Novartis must prepare and maintain books and records that accurately and in reasonable detail document the source and use of Novartis revenues and assets.

诺华必须准备并维护准确且合理地详细记录诺华收入和资产来源及使用情况的帐簿和记录。

'Off-the-books' accounts and false or deceptive entries in Novartis books and records are strictly prohibited. All financial transactions must be documented, regularly reviewed and properly accounted for in the books and records of the relevant Novartis entity.

"帐外"账目以及诺华帐簿和记录中的错误或虚假条目都必须严格禁止。所有财务交易都必须记录在册、定期检查并在相关诺华实体的帐簿和记录中适当说明。

All relevant financial controls and approval procedures must be followed.

必须遵守所有相关财务控制和审批流程。

The retention and archive of Novartis records must be consistent with Novartis standards and tax and other applicable laws and regulations.

诺华记录的保管和归档都必须遵守诺华的标准、税务以及其他适用法律和法规。

Definitions 定义

Books and records include accounts, invoices, correspondence, papers, CDs, tapes, memoranda and any other document or transcribed information of any type.

帐簿和记录包括账目、发票、往来通信、纸质文档、CD、磁带、备忘录以及所有其他文档或 任何类型的转抄信息。

References 参考

• Management Authorization Levels, also known as MALs《管理授权级别》，即 MAL

• Novartis Financial Controls Manual《诺华财务控制手册》

• Novartis Accounting Manual《诺华会计手册》

3. Implementation 实施

3.1 Training 培训

Associates must familiarize themselves with this Policy. Associates must be trained per the Novartis-wide compliance training curriculum. Local Novartis organizations may define additional training requirements.

员工必须熟悉本政策。员工必须根据适用于整个诺华的合规培训课程体系进行培训。本地诺华 组织机构可以定义额外的培训要求。

Training requirements for Third Parties are defined by the *Anti-Bribery Third Party Guideline* in conjunction with the *Training for Third Parties and External Service Providers Framework Guideline*.
对第三方的培训要求由《反贿赂第三方指南》和《第三方和外部服务供应商培训框架指南》共同定义。

3.2 Reporting Potential Misconduct/Non-Retaliation 报告潜在不当行为/反报复

Any Associate with knowledge of suspected misconduct must report his or her suspicion promptly in accordance with the SpeakUp Office process.

任何了解到疑似不当行为的员工必须根据 SpeakUp 办公室流程立即进行报告。

Associates who report potential misconduct in good faith or who provide information or otherwise assist in any inquiry or investigation of potential misconduct will be protected against retaliation.

出于善意地报告潜在不当行为，在任何潜在不当行为的质询或调查中提供信息或以其他方式提供协助的员工都将得到保护，避免遭到报复。

3.3 Breach of this Policy 违反此政策

Breaches of this Policy will not be tolerated and may lead to disciplinary and other actions up to and including termination of employment.

任何员工不得违反此政策，否则可能面临纪律处分，直至解除劳动合同。

3.4 Responsibilities and Implementation 责任和执行

It is the responsibility of every Novartis manager to implement this Policy within his or her area of functional responsibility, lead by example, and provide guidance to the Associates reporting to him or her. Novartis managers must also seek to structure incentives and conduct performance assessments accordingly.

每位诺华经理都有责任在其职能职责范围内执行本政策、以身作则并指导向其报告的员工。 诺华经理还必须寻求激励机制并相应地进行绩效评估。

All Associates are responsible for adhering to the principles and rules set out in this Policy.

所有员工都有责任遵守本政策中制定的原则和规定。

The owner of this Anti-Bribery Policy is Ethics, Risk & Compliance.

本《反贿赂政策》的所有者为道德、风险与合规部。

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_202.112.23.pc

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收，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 for Patient Oriented Program (POP) External Service Provider (ESP) and Health Care Professional (HCP) Contracts

附件 E

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/Health Care Professional 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 covering Novartis programs to support patient care, market research or to gain insights from patients/HCPs. These programs involve a Novartis product or disease area, where Novartis or a third party on behalf of Novartis is interacting with program participants e.g. patients, caregivers, HCPs or payers. This umbrella term excludes Novartis sponsored clinical studies/trials.

POP 是诺华的一个涵盖性术语，涵盖诺华支持患者关护、市场调研或从患者/HCP 处收集观念见解的项目。这些项目涉及诺华的产品或相关的疾病领域，其中诺华或代表诺华的第三方正在与项目参与者（例如患者、护理者、HCP 或付款者）进行互动。此涵盖性术语不包括诺华申办的临床研究/试验。

Support patient care is for the purposes of the POP Vigilance Contract Provisions defined as: providing additional education; training on the use of the product to patient or HCP; providing supplemental care to the patient or arranging financial assistance for patients. It may typically be described as patient support programs (**PSPs**) and patient access/assistance programs (**PAPs**), using different local terminologies.

出于 POP 警戒合同条款的目的，支持患者关护定义为：提供额外的教育；对患者或 HCP 进行产品使用培训；向患者提供额外的关护或为患者安排经济援助。在不同的当地术语中，通常描述为患者支持项目（**PSP**）和患者援助项目（**PAP**）。

All the above programs are classified by Novartis as set out in the table below.

所有上述项目均由诺华进行分类，如下表所示。

Table 1: POP Classification 表 1：POP 分类

	Group 1 第1组	**Group 2 第2组**	**Group 3 第3组**
Common attributes **共有属性**	○ Programs to support patient care, market research or to gain insights from patients/HCPs 支持患者关护、市场调研或向患者/HCP收集观念见解的项目 ○ Involving Novartis product or disease area of interest 涉及诺华产品或相关的疾病领域(disease area of interest) ○ Novartis or 3rd party on behalf of Novartis is interacting with program participants e.g. patients, caregivers, HCPs or payers 诺华或代表诺华的第三方与项目参与者进行互动，例如患者、护理者、HCP或付款者 ○ The above is not a routine external interaction 以上不是常规的外部互动活动		
Unique attributes **特有属性**	○ Main purpose is **to** support patient care 主要目的是支持患者关护 ○ Program Involves a Novartis approved product(s) or disease area(s) where Novartis has approved product(s) 项目涉及诺华批准的产品或诺华已批准产品的疾病领域 ○ Information received and collected on the use of a Novartis approved product on efficacy/safety/tolerability 接收并收集对于使用诺华的已批准上市产品的有效性/安全性/耐受性的信息	○ Main purpose is for market research or to gain insights from patients / HCPs 主要目的是进行市场调研或收集患者/HCP的观念见解 ○ Program contains questions related to Novartis approved product(s) 项目包含与诺华的已批准上市的产品相关的问题 ○ Information requested and primary data collected on the use of a Novartis approved product on efficacy/safety/tolerability 要求收集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	○ Any other programs not fitting in Group 1 or Group 2 任何不适合第1组或第2组的其他项目

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

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）是指在患者或临床试验受试者进行某种药品给药后出现的不良医学事件，但该事件不一定与该药物治疗有因果关系。因此，不良事件可能是与使用药品存在时间关联的任何不利和非预期体征（例如异常实验室结果）、症状或疾病，无论是否与所用药品有关。

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、医疗器械事件）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/Health Care Professional is notified during a POP shall be transferred by External Service Provider/Health Care Professional to the Novartis Patient Safety function within twenty-four (24) hours[1] of notification.

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 [2]，将其转交至诺华患者安全部门。

External Service Provider/Health Care Professional is required to reference or cross-check the relevant Novartis product list (e.g. Integrated Product List (IPL)) 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相关的诺华产品列表（如整合的产品列表（IPL）），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/Health Care Professional will notify Novartis by either using Novartis online AE reporting tool or e-mail / fax using a Novartis Adverse Event Report Form (as further specified in the Novartis POP AE Training) to report

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[1] 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.

[2] 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。

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

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[3] 诺华 POP AE 培训[4]

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

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，必须完成每年一次的刷新培训。关于诺华的产品、培训、不良事件识别和报告，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刷新培训）。

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

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/Health Care Professional 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。

[3] Training requirements are only for active ESP/HCPs in POP (not for ESPs/HCPs which are qualified but not actively engaged).
[4] 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）。

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

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

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

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/Health Care Professional 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

Applicable to External Service Providers only (not Health Care Professionals). External Service Provider hereby acknowledges and agrees that all information and responses provided to Novartis as part of the Supplier Quality Assessment (SQA) process shall be considered as an integral part of the Agreement, and that such information and responses provided are complete and accurate. Novartis will have the right during the term of the Agreement to require the reperformance of the SQA and/or for the External Service Provider/Health Care Professional to provide updates to the SQA and External Service Provider/Health Care Professional will co-operate fully in the reperformance of the SQA and providing updates requested by Novartis.

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完整、准确。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。

Applicable to External Service Providers only (not Health Care Professionals). 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.

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

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

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**）。

Furthermore, External Service Provider/Health Care Professional 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/Health Care Professional as a POP service provider will be required. External Service Provider/Health Care Professional will reasonably co-operate (at its own expense) with Novartis in respect of any (re)qualification.

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/Health Care Professional 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 quality control measure to ensure that during the POP all AEs are captured and reported to Novartis Patient Safety function within 24 hours. AER is scheduled based on actual FPFC and LPLC dates.

AER 是一项强制性的质量控制措施，以确保 POP 项目期间的所有 AE 均于 24 小时内记录和上报至诺华患者安全部门。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/Health Care Professional agrees to cooperate and assist Novartis with periodic (at least every 3 months) internal reconciliation efforts to ensure consistency between those AEs reported by External Service Provider/Health Care Professional during a designated timeframe and those recorded by Novartis as per timeline indicated below.

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/Health Care Professional 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/Health Care Professional and the POP participants is documented. Examples of source documents/data include but are not limited to: online surveys, recorded discussions, fax receipts, letters, database entries (i.e. Customer Relationship Management (CRM) system), documented interaction with patients or HCPs, digital apps with the ability to record an interaction, telephone recordings, video recordings, 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、电话记录、视频记录、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/Health Care Professional. Reference to "**Source Documents/Data**" in the remaining provisions below shall, in the context of each Group 1 POP, refer to the specific source documents/data types identified in the applicable Statement of Work/Agreement for the Group 1 POP. In addition, in all cases, the output generated from any app/system (e.g. PVI tool; this is an online tool to report AEs electronically to Novartis Patient Safety) used as first point of data collection/report will be considered as Source Documents/Data too.

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。

NO.	Lists of the source documents 源文件列表
1	
2	

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 review of a random sample of Source Documents/Data to determine whether an AE is present, identified and reported to Novartis completely and accurately. 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). At a minimum, External Service Provider/Health Care Professional will conduct an SDV one (1) year after the initial SDV and yearly thereafter, and again at the conclusion of the relevant POP.

SDV 是指针对源文件/数据的随机样本进行的一次核查，以判断 AE 是否存在、是否被识别以及完整准确地上报至诺华。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/Health Care Professional should provide an attestation of this activity and a high level summary of the results to Novartis Patient Safety function within a six (6) week time period from the SDV Scheduled Due Date. For the purposes of these POP Vigilance Contract Provisions, reference to "**SDV Scheduled Due Date**" shall mean: (i) for the initial SDV, the date that occurs three (3) months after the FPFC date; (ii) for SDVs thereafter, the dates that occur every year after the date in (i) above; and (iii) for the final SDV, the LPLC date.

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

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/Health Care Professional'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/Health Care Professional hereby agrees to fully cooperate and assist Novartis in performing SDV on an ad-hoc basis. Notwithstanding that this Section 10 is stated to apply only to Group 1 POPs, the requirement to carry out SDV on an ad-hoc basis (at the request of Novartis) will also apply to Group 2 POPs.

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

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

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/Health Care Professional's (or its agents or subcontractors) processes, procedures and training, including records, data, documentation, Source Documents/Data with respect to AEs in relation of use of Novartis product(s). External Service Provider/Health Care Professional commits to correcting issues from audit observations within the mutually agreed timelines (the Parties acting reasonably and in good faith) and promptly communicating the actions to Novartis. The Parties agree that where the Agreement contains more extensive audit and remediation rights than the audit/remediation rights set out above, the more extensive audit/remediation rights set out in the Agreement will equally apply here, subject to observing the minimum requirements set out above in terms of the duration and scope of any audit/remediation right in the context of the POP Vigilance Contract Provisions.

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/Health Care Professional hereby agrees that it will fully cooperate as requested. In addition, the External Service Provider/Health Care Professional hereby agrees to allow domestic and international health authorities to inspect their vigilance operations as necessary for Novartis to maintain registration in the countries where the Novartis product is marketed.

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

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，凡提及司法管辖区内的当地法律，系指现行/控制的法律法规，如果法律、行政法规或地方性法规同等适用，则将在法律允许的情况下应用更严格的保留标准。

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。

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/Health Care Professional will comply immediately (or such other time period specified by Novartis) and any failure to comply will be deemed as a material breach of the Agreement, and Novartis reserves the right to immediately terminate this Agreement and Statement of Work.

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，诺华有权立即解除本协议及工作说明书。

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

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: 该项目经理的职责：

- Oversight of all Novartis POP projects and

  监管所有诺华 POP 项目，并

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

drugsafety.china@novartis.com

报告时，诺华最初当地联络人如下：

drugsafety.china@novartis.com

Appendix F
STANDARD VIGILANCE PROVISIONS FOR SOCIAL MEDIA LISTENING PROGRAMS AND DIGITAL ENGAGEMENT ASSETS
附件 F
社交媒体倾听项目和数字参与资产的警戒条款

1. Monitoring for Adverse Events 不良事件监测

a) Monitoring requirements for SML programs: SML 项目的监测要求：

SML programs must be monitored for the presence of Adverse Events (AEs)[#] associated with the use/mention of a Novartis product (i.e., human medicinal product and/or medical device) as detailed below:

必须监测 SML 项目中是否存在与诺华产品（即人类医药产品和/或医疗器械）的使用/提及相关的不良事件（AEs）#，详情如下：

All individual posts[*] from a SML program activity **manually reviewed** by Novartis associate/Third-Party associate working on behalf of Novartis must be monitored at the time of the manual review for the presence of both AEs meeting the 4 safety data elements and AEs meeting the minimum 2 safety data elements[#]. The AE manufacturer receipt date is the date of manual review of individual posts[*] (refer to below definition) by a Novartis associate/Third-Party associate working on behalf of Novartis.

由诺华员工/代表诺华的第三方的员工手动审查的 SML 项目，其活动中的所有单个帖子*必须在手动审查时监测是否存在符合 4 个安全数据元素的不良事件和符合至少 2 个安全数据元素#的不良事件。不良事件生产商接收日期是诺华员工/代表诺华的第三方的员工对单个帖子*（见下文定义）进行人工审核的日期。

[*]**Individual post:** Individual original information published by a user on the internet that can be reviewed directly on internet (e.g., on websites, SM, online forums, blogs, closed-secret groups) or indirectly from the listening activity (e.g., user posts displayed in SML dashboards or presented in summary SML reports)"

*单个帖子：用户在互联网上发布的单个原始信息，可在互联网上直接查看（例如，在网站、SM、在线论坛、博客、封闭秘密小组上）或通过倾听活动间接查看（例如，SML 仪表板中显示的用户帖子或在 SML 摘要报告中呈现的用户帖子 ）。

[#]Refer to Section 7 for definitions. #定义见第 7 节。

b) Monitoring requirements for DEAs: DEA 的监测要求：

All external facing DEAs (Novartis owned and Third-Party owned) with Enabled Engagement Functionalities[#] as well as distribution platforms for Novartis owned external facing DEAs with Enabled Engagement Functionalities must be monitored for the presence of AEs associated with the use/mention of a Novartis product (i.e., human medicinal product and/or medical device) as detailed below. 必须监测所有对外的启用参与功能#的 DEA（诺华的和第三方的）以及对外的启用参与功能的诺华的 DEA 的发布平台是否存在与使用/提及诺华产品（即人用医药产品和/或医疗器械）相关的不良事件，详情如下。

- Novartis owned DEAs: All DEA "Public user generated content" **MUST** be monitored for the presence of both AEs meeting the 4 safety data elements and AEs meeting the minimum 2 safety data elements[#]. Monitoring **MUST** be conducted **once per business day**, for the time the DEA is live. 诺华的 DEA：必须监测所有 DEA 的"公共用户生成内容"是否存在满足 4 个安全数据元素的不良事件和满足至少 2 个安全数据元素#的不良事件。在 DEA 生效期间，必须在每个工作日进行一次监测。
- Distribution platforms of Novartis owned DEAs: All "Public user generated content" **MUST** be monitored for the presence of both AEs meeting the 4 safety data elements and AEs meeting the minimum 2 safety data elements[#]. Monitoring **MUST** be conducted **once per month**, for the time the DEA is live. 诺华的 DEA 的发布平台：必须监测所有"公共用户生成的内容"是否存在满足 4 个安全数据元素的不良事件和满足至少 2 个安全数据元素#的不良事件。在 DEA 生效期间，必须在每月进行一次监测。
- Third-Party owned DEAs: All DEA "Public user generated content" related to the Novartis "sponsored/owned" content **MUST** be monitored for the presence of both AEs meeting the 4 safety data elements and AEs meeting the minimum 2 safety data elements[#]. Monitoring **MUST** be conducted **once per business day**, for the duration of the agreement (i.e., relating to the Third-Party DEA) or 60 days after the last sponsored activity, whichever is longer (agreement duration

and date of last sponsored activity will be communicated by Novartis to ESP) 第三方的 DEA：必须监测所有 DEA 的与诺华"赞助/拥有" 内容相关的"公共用户生成的内容"是否存在满足 4 个安全数据元素的不良事件和满足至少 2 个安全数据元素#的不良事件。在协议期限内（即与第三方 DEA 相关）或最后一次赞助活动后 60 天内（以较长者为准（协议期限和最后一次资助活动的日期将由诺华告知 ESP）），必须在每个工作日进行一次监测。

#Refer to Section 7 for definitions. #定义见第 7 节。

2. **Transfer of Adverse Events 不良事件传递**

a) Transfer of AEs for SML programs: The Vendor must transfer any reported AE associated with the use/mention of a Novartis product (i.e., human medicinal product and/or medical device) to appropriate Novartis Department as follows: SML 项目的 AE 传递：供应商必须按照以下方式将与诺华产品（即人类医药产品和/或医疗器械）的使用/提及相关的任何报告的 AE 传递到恰当的诺华部门：

- **If** identified **during a business day transfer within 24 hours** of identification[3] as detailed below: 如果在工作日识别到 AE, 请在识别后的 24 小时内(3)传递，详见下文：
  - **If** identified during Friday business hours (and your office is closed during Saturday & Sunday) transfer **on the day** of identification 如果在周五工作时间内识别到 AE（并且您的办公室在周六和周日关闭），则在识别的当天工作时间内传递
  - **If** identified after business hours on Friday (and your office is closed during Saturday & Sunday) transfer latest by the **end of next business day 如果在周五工作时间后识别到 AE（并且您的办公室在周六和周日关闭），最晚在下一个工作日结束前传递**
  - **If** identified on the last day before national holidays transfer **on the day** of identification 如果在国家法定节假日前的最后一天的工作时间内识别到 AE，则在识别的当天工作时间内传递
- **If** identified on weekends/national holidays transfer latest by the **end of business day** following that of identification 如果在周末（并且您的办公室在周六和周日关闭）识别到 AE：最晚在下一个工作日结束前传递
- If AEs are identified during extended weekends and national holidays: Delivered within two calendar days of identification. 如果在延长的周末和国家法定节假日期间识别到 AE：在识别后的两个日历日内传递。

[3] Identification must occur at same time as manual review of individual posts is completed. 识别 AE 必须在完成对单个帖子的手动审查的同时进行。

b) Transfer of Adverse Events for DEAs / DEA 的不良事件传递：

- The Vendor must transfer any reported AE associated with the use/mention of a Novartis product (i.e., human medicinal product and/or medical device) to appropriate Novartis Department as follows: 供应商必须按照以下方式将与诺华产品（即人类医药产品和/或医疗器械）的使用/提及相关的任何报告的 AE 传递到恰当的诺华部门：

- Novartis owned and Third-Party owned DEAs: 诺华的和第三方的 DEA：
  - **If** posted on a business day transfer within maximum 24 hours of posting as detailed below: 如果在工作日发布，最晚在 24 小时内传递，详情如下：
    - **If** posted during Friday business hours (and your office is closed during Saturday & Sunday) transfer on the day of posting 如果在周五工作时间内发布（并且您的办公室在周六和周日关闭），则在发布当天工作时间内传递
    - **If** posted outside of Friday business hours (and your office is closed during Saturday & Sunday) transfer latest by the end of business day following that of posting 如果在星期五工作时间后发布（并且您的办公室在星期六和星期日关闭），最迟在发布后的下一个工作日结束前传递
    - **If** posted on the last day before national holidays transfer on the day of posting, 如果在国家法定节假日前的最后一天工作时间内发布，则在发布当天工作时间内传递，
  - **If** posted on weekends/national holidays transfer latest by the end of the business day following that of posting. 如果在周末发布（并且您的办公室在周六和周日关闭），则最晚在发布后的下一个工作日结束前传递。
  - If posted on extended weekends and national holidays, deliver no later than two calendar days after posting. 如果在延长的周末和国家法定节假日期间发布，则最晚在发布后的两个日历日内传递。

- Distribution platforms of Novartis owned DEAs: Transfer to appropriate Novartis Department **within maximum 24 hours** of monitoring. 诺华的 DEA 的发布平台：在监测后最多 24 小时内传递至恰当的诺华部门。

c) In all cases: 在所有情况下：

In any case transfer of AEs associated with the use/mention of a Novartis product (i.e., human medicinal product and/or medical device) must be performed as per timelines defined in the Novartis AE training for SML programs (i.e., Modules A and C)/DEAs (i.e., Modules A and B), as applicable.
在任何情况下，必须按照适用的 SML 项目诺华 AE 培训（即模块 A 和 C）/DEA 诺华 AE 培训（即模块 A 和 B）中规定的时限将与诺华产品（即人类医药产品和/或医疗器械）的使用/提及相关的 AE 传递。

The Vendor must transfer all AEs associated with the use/mention of a Novartis product (i.e., human medicinal product and/or medical device) regardless of the Vendor's or reporter's causality assessment. Vendor will notify Novartis preferably using the online AE reporting tool (PVI, Pharmacovigilance Intake) or alternatively by fax / e-mail / online using a Novartis AE Report Form to transfer the event to appropriate Novartis Department. An example of the Novartis AE Report Form is attached hereto as Exhibit 1. Copies of the Novartis AE Report Form can be requested to your PS contact. Notwithstanding anything to the contrary set forth in this Agreement, Vendor shall provide Novartis with any and all appropriate personal health information necessary for Novartis to record and report AE(s) in accordance with applicable laws and regulations. Social Media Listening programs may require transfer of AEs associated with the use/mention of a Novartis product (i.e., human medicinal product and/or medical device) in the format of Aggregate Report(s), according to guidance provided in the Novartis AE training for SML programs. An example of an Aggregate Report form is attached hereto as Exhibit 2. Aggregate Reports must be sent to the Novartis PS Department in the country where the SML program Owner is located.

供应商必须传递所有与诺华产品（即人类医药产品和/或医疗器械）的使用/提及相关的 AE，无论供应商或报告者的因果关系评估结果如何。供应商最好使用在线不良事件报告工具(PVI，药物警戒纳入系统）通知诺华，或者使用诺华不良事件报告表通过传真/电子邮件/在线通知诺华，以便将事件传递至恰当的诺华部门。诺华不良事件报告表示例见附件 1。可向您的 PS 联系人索取诺华 AE 报告表的副本。不管有任何跟本协议相反的规定，供应商应根据适用法律法规向诺华提供诺华记录和报告 AE 所需的任何及所有适当的个人健康信息。根据 SML 项目的诺华 AE 培训中提供的指南，社交媒体倾听项目可能需要以集结报告的形式传递与诺华产品（即人类医药产品和/或医疗器械）的使用/提及相关的 AE。集结报告格式示例见附件 2。集结报告必须发送至 SML 项目负责人所在国家的诺华 PS 部门。

3. Source Data Verification (SDV) for DEAs / DEA 的源数据核准（SDV）

Source Data Verification (SDV) is the vigilance quality control which must be performed for DEAs to ensure that all AEs associated with the use/mention of a Novartis product (i.e., human medicinal product and/or medical device) have been properly identified and transferred to appropriate Novartis Department within timelines as described in the Novartis AE training for DEAs. Source data verification **must** be performed for Novartis owned and Third-Party owned DEAs with Enabled Engagement Functionalities as described in the Novartis AE training for DEAs. Source data verification is not applicable to the distribution platforms of the DEAs (e.g., Google Appstore, Apple Appstore etc.).

源数据核准(SDV) 是 DEA 必须执行的警戒质量控制，以确保与诺华产品（即人类医药产品和/或医疗器械）的使用/提及相关的所有 AE 都已得到正确识别，并在诺华针对 DEA 的 AE 培训中所述的时限内传递至恰当的诺华部门。必须对启用参与功能的所有诺华的和第三方的 DEA 进行源数据核准， 如 DEA 诺华 AE 培训中所述。源数据核准不适用于 DEA 的发布平台（例如，Google 应用商店、Apple 应用商店等）。

The Vendor will be requested to provide the source data following process detailed in Novartis AE training for DEAs, and **within maximum** six (6) weeks of the last day of the SDV review period. SDV cannot be conducted by the same person who conducted the monitoring/transfer of AEs associated with the use/mention of a Novartis product (i.e., human medicinal product and/or medical device).

供应商必须按照诺华针对 DEA 的 AE 培训中详述的流程提供源数据，并在 SDV 审核期最后一天后最多六（6）周内提供源数据。SDV 不能由监测/传递与诺华产品（即人类医药产品和/或医疗器械）的使用/提及相关的 AE 的同一人进行。

Novartis will have the right to review Vendor source data records for the purpose of determining Vendor compliance and accuracy in safety information gathering and transfer.

诺华将有权审核供应商源数据记录，以确定供应商在安全性信息收集和传递方面的合规性和准确性。

4. Adverse Event Training for SML programs and DEAs / SML 项目和 DEA 的不良事件培训

Prior to (i) the effective date of this Agreement or (ii) with the addition of a new Novartis product under this Agreement, as the case may be, and without affecting Vendor's obligations to comply with this Agreement and any applicable laws, rules or regulations with respect to AEs associated with the use/mention of a Novartis product (i.e., human medicinal product and/or medical device), Novartis or an authorized Third-party agent of Novartis shall provide Vendor employees and / or agents identified by Vendor as being involved with the Novartis products with information and training with respect to vigilance activities (e.g. AE recognition, AE transfer, completion of SDV etc.). Vendor shall ensure timely distribution of information and work with Novartis to ensure the timely conduct of such training.

在(i)本协议生效日期之前或(ii)在本协议项下添加新的诺华产品之前（视具体情况而定），并且在不影响供应商遵守本协议的义务以及与诺华产品（即人类医药产品和/或医疗器械）的使用/提及相关的 AE 相关的任何适用法律、法规或规定的情况下，诺华或诺华授权的第三方代理商应向确定与诺华产品有关的供应商员工和/或代理商提供与警戒活动有关的信息和培训（例如，AE 识别、AE 传递、完成 SDV 等）。供应商应确保及时分发信息，并与诺华协作以确保及时实施所述培训。

After such Novartis training and without limiting Vendor's obligations to hire its employees to perform the obligations of Vendor under this Agreement in accordance with the terms and conditions of this Agreement, Vendor shall ensure all employees and / or agents of Vendor involved with the Novartis products have completed proper training before they are permitted to be involved with the Novartis product(s) as follows: **at least once per annum** during the term including performing the initial training for new employees or agents hired after the date of Novartis' training as well as when training material is up-dated and before its effective date. For SML programs and DEAs all trainings shall be completed via a training platform. Vendor shall record and maintain documentation with respect to training of all such employees and agents and such information and documentation shall be available to Novartis upon request.

所述诺华培训完成后，在不限制供应商根据本协议的条款和条件雇佣其员工履行供应商在本协议项下的义务的情况下，供应商应确保供应商涉及诺华产品的所有员工和/或代理商在被允许参与诺华产品之前已经完成了如下适当的培训：在本协议期限内，每年至少一次，包括对在诺华培训日期之后雇佣的新员工或代理商进行初始培训，以及培训材料更新并在生效日期之前进行培训。对于 SML 项目和 DEA，所有培训应通过培训平台完成。供应商应记录和保存与所有此类员工和代理商培训有关的文件，且应诺华要求，此类信息和文件应提供给诺华。

Should Vendor subcontract out work to other ESPs, it is the responsibility of Vendor to ensure training has been completed by its subcontractors as per process detailed above and ensure compliance by its subcontractors with this Agreement.

如果供应商将工作分包给其他 ESP，供应商应负责确保其分包商已按照上述流程完成培训，并确保其分包商遵守本协议。

5. Record retention 记录保留

Vendor shall also create, document, and maintain for the term of the Agreement and five (5) years thereafter, records of the safety information reports and forms sent to Novartis during the term, and any SML program/DEA related document including but not limited to source data records. Such documents shall be subject to audit by Novartis as set forth below. 供应商还应在协议期限内及其后五（5）年 创建、记录和维护在协议期限内发送给诺华的安全性信息报告和表格的记录，以及任何 SML 项目/DEA 相关文件，包括但不限于源数据记录。此类文件应由诺华按照以下规定进行稽查。

6. 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 Vigilance Provisions, Vendor commits to promptly communicate these findings to Novartis and discuss corrective and preventive actions to be taken with Novartis. Vendor commits to correct such findings with mutually agreed timelines. For the term of this Agreement and **two (2) years following expiration or termination hereof**, Novartis, or its designated third party auditor who is not a competitor of Supplier and agrees to enter into an appropriate confidentiality agreement with Supplier shall have the right, upon reasonable prior advance written notice to Vendor, to inspect and audit Vendor processes, procedures and training, including records and documentation thereof, with respect to the safety information, as well as any other information, data or materials in the possession of Vendor (or its agents or subcontractors) related to AEs associated with the use/mention of a Novartis product (i.e., human medicinal product and/or medical device). Such audits may be scheduled no more frequently than once per year. Vendor shall ensure that any affiliate or agent of Vendor that may have information, data or materials related to safety information, in patients taking a Novartis product(s), or may receive such AEs, is subject to the same obligations and requirements as set forth in this section. The records, documentation, materials, and

information that are the subject matter of any such audit shall be considered Confidential Information of Vendor pursuant and subject to the provisions of this Agreement. To the extent any such audit includes findings of noncompliance with the requirements of this Agreement; Vendor commits to correct such audit findings with mutually agreed timelines and promptly communicate corrective actions taken to Novartis.

如果不符合警戒条款的要求，供应商承诺立即将这些发现传达给诺华，并与诺华讨论将采取的纠正和预防措施。供应商承诺在双方约定的时间期限内纠正该等发现。在本协议期限内以及本协议期满或终止后两（2）年内，诺华或其指定的第三方稽查员（不是供应商的竞争对手并同意与供应商签订适当的保密协议）应有权在事先合理书面通知供应商的情况下，检查和稽查供应商流程、项目和培训，包括其记录和文件，涉及安全性信息以及供应商（或其代理人或分包商）拥有的与诺华产品（即人类医药产品和/或医疗器械）的使用/提及相关的 AE 有关的任何其他信息、数据或材料。此类稽查的计划频率不得超过每年一次。供应商应确保，如果供应商的任何关联公司或代理商拥有与使用诺华产品的患者安全性信息相关的信息、数据或材料，或可能收到此类 AE，应遵守本节规定的相同义务和要求。作为任何该等稽查标的的记录、文件、材料和信息应根据本协议的规定视作供应商的机密信息。如果任何该等稽查发现不符合本协议要求；供应商承诺按照双方约定的时限内纠正此类稽查结果，并及时将采取的纠正措施传达给诺华。

Notwithstanding anything herein to the contrary, in the event Novartis reasonably believes that Vendor has breached its obligations under this Section 6 or has failed to take appropriate corrective action in response to prior audit findings, Novartis or an independent third party may perform an audit directed at the suspected breach or failure to implement correction by providing Vendor with reasonable prior advance written notice.

不管有任何跟本协议相反的规定，如果诺华有理由认为供应商违反了其在本第 6 节下的义务，或未能针对先前的稽查结果采取适当的纠正措施，则诺华或独立第三方可以通过事先合理书面通知供应商，针对疑似违反或未实施纠正措施的行为进行稽查。

If Novartis undergoes any type of governmental and/or regulatory inspection or audit, including but not limited to civil litigation related to the subject matter of this Agreement, Vendor agrees to reasonably cooperate as requested with respect to such matter. In addition, the Vendor agrees to allow domestic and international health authorities to inspect their vigilance operations as it is necessary for Novartis to maintain registration in the countries where the Novartis Product is marketed.

如果诺华接受任何类型的政府和/或监管机构视察或稽查，包括但不限于与本协议标的相关的民事诉讼，供应商同意按照要求合理配合该等事项。此外，供应商同意允许国内和国际卫生当局检查其警戒操作，因为诺华有必要在诺华产品销售的国家维持注册。

Novartis reserves the right to amend this Section 6, at any time if a requirement is imposed upon it by an entity with authority or, in its sole clinical discretion, such amendment is necessary for medical safety. Upon written notice from Novartis of any such amendment, Vendor will comply immediately and any failure to comply shall be deemed a breach of this Agreement.

诺华保留在任何时候修订本第 6 节的权利，如果具有权力的实体对其提出要求，或者根据其唯一的临床判断，该修订对于医疗安全是必要的。在诺华发出任何此类修订的书面通知后，供应商将立即遵守，任何未遵守的行为将被视为违反本协议。

7. Definitions 定义

Term 术语	**Definition 定义**
Adverse Event (AE) 不良事件（AE）	For purposes of this Agreement, an **Adverse Event** is any untoward medical occurrence in a patient or clinical-trial subject administered with a Novartis product (i.e., human medicinal product and/or medical device) and which does not necessarily have to have a causal relationship with this product. An AE can therefore be any unfavorable and unintended sign (e.g., an abnormal laboratory finding), symptom, or disease temporally associated with the use of a Novartis product (i.e., human medicinal product and/or medical device), whether or not considered related to the product. 就本协议而言，不良事件是使用诺华产品（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并且不一定与该产品有因果关系的任何不良医学事件。因此，不良事件（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）存在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，无论是否与产品有关。 In addition to AEs, all special scenarios, and technical complaints must be transferred to Novartis, as described in the respective Novartis AE training (i.e., Novartis AE training for SML programs/DEAs, as applicable) that Vendor has to be aware of. 除不良事件外，所有特殊情况和技术投诉必须传递给诺华，如供应商必须了解的诺华不良事件培训（即针对 SML 项目/DEA 的诺华不良事件培训，如适用）中所述。
Digital Engagement Asset 数字参与资产	Digital Engagement Asset 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 Digital Engagement Assets include websites, social media pages/groups, discussion forms such as blogs / forums, collaboration platforms, chatbots, applications (apps) including mobile apps, instant messaging, SMS, augmented reality apps, virtual reality apps, skills (Alexa) etc. 数字参与资产（DEA）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： • 诺华/ESP/第三方发布内容或共享内容 • 具有接收用户生成内容的可能性 • 接收来自用户的私人消息 DEA 的示例包括网站、社交媒体页面/组、如博客/论坛的讨论形式、协作平台、聊天机器人、应用程序（apps），包括移动应用程序、即时消息、短信、增强现实应用程序、虚拟现实应用程序、技能（Alexa）等。

Term 术语	**Definition 定义**
Enabled Engagement Functionality 启用参与功能	• **For Novartis owned DEAs:** publicly available user commenting **with exclusion** of any information from the public space of the DEA platform (e.g., standard e-mails, contact form/button) sent to a non-public personal domain of a Novartis associate on the platform "direct Private Message" or to Novartis mailboxes/Novartis ESPs as this information is subjected to spontaneous AE reporting by the recipient • **For Third-Party owned DEAs:** all publicly available user commenting • **For distribution platforms of Novartis owned DEAs**: all publicly available user commenting • 对于诺华的 DEA：公开可用的用户评论，不包括 DEA 平台公共空间中的任何信息（例如，标准电子邮件、联系表格/按钮），发送到平台上的诺华员工的非公共个人域中的"直接私人消息"或发送到诺华邮箱/诺华 ESP 的信息，因为这些信息直接由收件人自行报告 AE · 对于第三方的 DEA：所有公开可用的用户评论 · 对于诺华的 DEA 的发布平台：所有公开可用的用户评论
Private/Direct Message 私人/直接消息	**private information** (e.g., message/response/comment/post, contact form, text messages (SMS)) with respect to a DEA, is any information that is visible to the intended recipient(s) only. For example: • Information shared by a member of the target audience or general public with Novartis only (e.g., received in Novartis official business email address/group mailbox/generic email addresses) Information shared by a member of the target audience or general public with ESP(s) working on behalf of Novartis (e.g., received in ESPs official business email address/group mailbox/generic email addresses) 与 DEA 有关的私人信息（例如，信息/回复/评论/帖子、联系方式、短信（SMS）），是指仅对目标接收者可见的任何信息。 例如： • 目标受众成员或普通公众仅与诺华共享的信息（例如，通过诺华官方业务电子邮件地址/集团邮箱/通用电子邮件地址接收的信息） 目标受众成员或普通公众与代表诺华工作的 ESP 共享的信息（例如，通过 ESP 的官方业务电子邮件地址/集团邮箱/通用电子邮件地址接收的信息）。
Publicly Available Information 公开可用的信息	**publicly available information** (e.g., message*/response/comment/post) with respect to a DEA is, any information originating from a member of the target audience or the general public that is visible to all other member(s) of the target audience/general public accessing the DEA. For example: a post or comment on the Novartis Corporate Facebook/Twitter/LinkedIn account/pages, a review published on the Appstore (e.g., Apple Appstore, Google Play store etc.) *Excluding DEA Private/Direct Messages 与 DEA 有关的公开可用的信息（例如，消息*/响应/评论/帖子）是指来自目标受众成员或公众的任何信息，而这些信息对于访问 DEA 的目标受众/公众的所有其他成员都是可见的。 例如：诺华公司 Facebook/Twitter/LinkedIn 账户/页面上的帖子或评论，Appstore 上发布的评论（例如，Apple Appstore、Google Play store 等） *不包括 DEA 私人/直接消息

Term 术语	**Definition 定义**
SML program SML 项目	A Novartis SML program involves gathering and analyzing user generated content from non-Novartis owned Digital Engagement Assets (such as social media communities, forums, blogs etc.) with the support of a specialized SML tool or program for business purposes. In addition, listening performed manually or with the support of a specialized SML tool or program in closed or secret groups must always be registered. Examples of SML programs include: _Analyzing user-generated content posted on non-Novartis owned social media accounts such as Twitter to determine sentiment _Conducting keyword-based queries on non-Novartis owned Digital Engagement Assets, aggregating and analyzing all conversations related to a particular topic (e.g., around a particular disease area) _Listening to and analyzing conversations on non-Novartis owned Digital Engagement Assets between specific stakeholder groups (e.g., HCPs) to optimize current communication and marketing strategies ▪ 诺华 SML 项目是在专门的 SML 工具或项目的支持下，从非诺华的数字参与资产(如社交媒体社区、论坛和博客等)中收集和分析用户生成的内容。 ▪ 此外，手动执行的倾听项目，或在封闭或秘密小组中，在专门的 SML 工具或项目的支持下执行的倾听项目也必须注册。 ▪ SML 项目的例子包括: ▪ 分析发布在非诺华的社交媒体账户(如 Twitter)上的用户生成的内容，以确定观点。 ▪ 对非诺华的数字参与资产进行基于关键字的查询，汇总并分析与特定主题相关的所有对话(例如，围绕一个特定疾病区域)。 - 倾听并分析在非诺华的数字参与资产上的特定利益相关群体(如 HCPs)之间的对话，以优化当前的沟通和营销策略

Attachments: 附件：
Exhibit 1: AE reporting form - Please attach your local AE reporting form
附件 1：AE 报告表-请附上您当地的 AE 报告表
Exhibit 2: Aggregate report: Please attach FRM-7025610
附件 2：集结报告：请随附 FRM-7025610

Abbreviation List 缩略语列表

AE	Adverse Event 不良事件
DEA	Digital Engagement Asset 数字参与资产
ESP	External Service Provider 外部服务提供商
FRM	Form 表格
PVI	Pharmacovigilance Intake 药物警戒纳入系统
SM	Social Media 社交媒体
SML	Social Media Listening 社交媒体倾听
SDV	Source Data Verification 源数据核准

Exhibit 1: AE Reporting Form
附件 1 ：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 未愈 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，例如医学人员认为）或无）

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耳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: _____

☐ DIS. 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。

☐ MS. 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. 相关的实验数据或检查报告:			
检查项目	**检查日期** (日/月/年)	**结果** (请标明单位)	**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（面向患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，则必须宣读免责声明*

Exhibit 2: Aggregate Report

附件 2：集结报告

FRM-7025610_5.0_EF%20的副本.xlsx

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

_____