PURCHASE ORDER TERMS & CONDITIONS

This purchase order is placed subject to the terms, conditions, specifications, and instructions stated herein and on any attachments or schedules hereto and in any documents referencing this purchase order (collectively the Order). "Seller" or "Vendor" shall mean the individual or company providing goods and/or services hereunder including its employees, Affiliates, agents and subcontractors. This Order is an offer to purchase and Seller will be held to have accepted this Order upon the earliest of (a) five business days after Buyer sends the Order to Seller unless Seller expressly rejects the Order in writing during that period, (b) Seller sends an invoice to Buyer related to this Order, or (c) Seller begins to perform any service or delivers any goods specified in this Order

"Buyer" shall mean Sanofi US services Inc. as well as any Affiliate of Buyer. As used herein, "Affiliate(s)" shall mean any person or entity directly or indirectly controlling, controlled by, or under common control with Buyer, and for this purpose, "control", "controlling" and "controlled by" shall mean the ownership and control of more than fifty percent (50%) of the outstanding voting securities or interest in capital or profits, or the right to direct or control the management or affairs of any person or entity.

Any Affiliate is entitled to use the services, findings, reports, deliverables and/or goods provided under this Order to the same extent as any Affiliate identified in the Order

- 1. GOVERNING DOCUMENTS/ENTIRE AGREEMENT. Acceptance of this Order is limited to the express terms of this Order. Buyer hereby objects to and rejects any proposal for additional or different terms or any attempt by Seller to vary any of the terms of this Order, including, without limitation, all preprinted or other terms and conditions of any invoice or acknowledgement submitted by Seller, and any such additional or different terms or variances shall be deemed material. Any other such proposal or attempt shall not operate as a rejection, but this offer shall be deemed accepted by Seller without regard thereto. Any terms and conditions contained in Seller's proposal, invoice, acknowledgment, or other writing, shall be null and void. Notwithstanding the foregoing, if a fully executed written agreement (whether services Agreement, Purchase Agreement, Lease Agreement, or the like) between Buyer and Seller is in full force and effect with respect to the subject matter referenced herein, then the terms of such agreement shall govern and the terms and conditions of this Order shall be inapplicable
- 2. PRICE AND PAYMENT. Items shipped and services performed pursuant to this Order shall be billed only at the prices reflected hereon or as otherwise expressly approved in writing in advance by Buyer. If no price is reflected, goods and services shall be billed at the price last paid by Buyer or quoted by Seller for such item or service, as applicable, or at such other price for which Seller has obtained Buyer's written approval prior to shipment of goods or performance of services, as applicable. The price specified herein, unless otherwise expressly stated, includes: (i) all taxes and duties of any kind that Seller is required to pay with respect to the goods or services (including any applicable custom duties) Unless otherwise specified in this Order or any attachment hereto, Seller shall submit an invoice for the entire amount upon the completion of all services and/or provision of all goods/deliverables. Buyer shall remit payment within the period specified in this Order of an invoice from Seller that complies with the requirements of this Order. Buyer shall be entitled at all times to deduct any amount that is owed by Seller to Buyer (or any Affiliate) under this Order or any other agreement from any outstanding fees owed by Buyer (or any Affiliate of Buyer) to Seller under this Order or any other agreement.
- 3. **ORDER CHANGES**. Prior to shipment of goods or the performance of services, as applicable, Buyer may make the following changes, by providing Seller with a written change order issued by an authorized representative:
- A. specifications for items;
- B. method of shipment, packing or performance;
- C. place, time or manner of delivery or performance; or
- D. quantities.

If Buyer makes any of the foregoing changes, Buyer and Seller shall agree in writing to an equitable adjustment in price.

- 4. **TERMINATION FOR CAUSE.** Seller shall have the right to withhold all payments hereunder and terminate this Order without penalty if Seller:
- fails to deliver goods or services within the time specified herein or as otherwise agreed by Buyer in writing;
- B. fails to replace or correct defective goods or services pursuant to the warranties described in Section 9 below in a timely manner;
- C. fails to perform any material provision of this Order;
- D. fails to proceed with performance of this Order in a timely fashion to the extent that this Order or any part hereof cannot be completed within the time specified herein or as otherwise agreed by Buyer; or
- E. becomes bankrupt or insolvent or makes an assignment for the benefit of creditors.

- 5. TERMINATION FOR CONVENIENCE. Buyer may terminate this Order in whole or in part for its convenience upon written notice to Seller. Upon receipt of notice, Seller will terminate all work in progress and advise Buyer of the value of work completed and non-cancelable materials purchased prior to receipt of such notice. Buyer will pay Seller a pro-rata share of the price set forth in this Order for work completed prior to the termination date and for reasonable non-cancelable materials that cannot be allocated to other work. Such payments shall be determined in accordance with generally accepted accounting principles, less value received by Seller for items used or resold by Seller. Buyer shall not be liable for the cost of defective, dam- aged, or destroyed work or materials nor shall Buyer be responsible for costs and expenses incurred by Seller after receipt of notice of termination from Buyer. In no event will payments made under this Section 5 exceed the aggregate Order price less payments made and expenses incurred by Buyer and adjustments allowed in settlement of termination of the Order. In the event this Order is terminated by Buyer as provided herein, payment of the fees and charges stipulated in this Section 5 shall constitute Seller's exclusive remedy.
- 6. SHIPMENT. Delivery and shipment of goods and deliverables, including the return of Buyer equipment repaired or calibrated at an off-site facility, shall be made pursuant to shipping instructions and in the timeframes stipulated in the face of this Order. Seller acknowledges and agrees that time is of the essence with respect to the delivery of goods and/or performance of services hereunder.
- A. Seller shall box, crate and package all items, as necessary, in accordance with good commercial practice and applicable law including GMP requirements, without charge to Buyer, unless otherwise specified in this Order.
- B. An itemized packing list shall be enclosed with all shipments to Buyer. Buyer's count will be accepted as final and conclusive on shipments not accompanied by a packing list.
- C.Whenever possible, Seller shall ship items from one lot only and in original containers
- D. Each container must clearly be identified by: Buyer's Purchase Order Number, item number, manufacturer's lot number, net contents and tare weight.
- E. Bills of Lading shall indicate: Buyer's Purchase Order Number, net weights, number of containers/lots, date of shipping, address of consignor/consignee, and name of Seller.
- F. Direct shipments by parties other than Seller may not be made without prior Approval of Buyer.
- G. Buyer assumes no responsibility for goods shipped without Buyer's Purchase Order having been issued. Unless otherwise indicated on the front page of this Order, all deliveries will be considered Duty Delivery Paid (Incoterms 2000), at the Buyer's "ship to" address indicated on the front page of this Order.
- H.For shipments of medicines, drugs and chemicals where Buyer is responsible for freight of more than 120 lbs., shipments should be released Per Pro MC 972 Class 60,000 of National Motor Freight Classification. Failure to comply will result in Buyer deducting any difference in freight charges from the applicable invoice.
- I. Time is of the essence of this Order. The Products shall be delivered on the date specified on the front of this Order. Buyer shall only accept deliveries at the delivery location Monday thru Friday between 9:00 am and 5:00 p.m. Failure to complete delivery of items or rendering of services by the time promised shall constitute sufficient cause for termination pursuant to Section 4 hereof. Delivery in accordance with this Order does not constitute acceptance by Buyer under this Order.
- 7. INVOICES. Seller will submit invoices in a single copy, only in electronic format through the invoice reception channel(s) as defined under https://suppliers.sanofi.com/invoicing for the invoiced Buyer entity at the invoice issue date. Submitted electronic invoices shall include all elements as defined for the invoiced Buyer entity at the invoice issue date under https://suppliers.sanofi.com/invoicing, including applicable legal and tax requirements (e.g. description of the delivered goods/services etc.). Only electronic documents received through preferred channels represent valid original invoices. Invoices sent through other channels (e.g. paper) or that do not include all the elements referred to above will not be processed. Uncompliant invoices may be returned to the Seller per email."
- 8. INSPECTION. Goods and services purchased hereunder shall be subject to Buyer's inspection and testing to the maximum extent practicable at all times and places, including during manufacture or performance, and in any event prior to final acceptance. Final inspection and acceptance by Buyer shall occur after delivery of goods or performance of services or as otherwise indicated in this Order. Buyer's inspection and acceptance shall not relieve Seller from responsibility for latent defects or warranty obligations. SELLER SHALL NOT REPLACE REJECTED GOODS OR SERVICES WITHOUT THE WRITTEN CONSENT OF BUYER. Buyer may return rejected goods, at Seller's expense, for a prompt replacement without additional charge to Buyer or a full refund of any fees previously paid for such non-conforming services. Payment of invoices or portions thereof reflecting charges for pending or rejected goods or services may be deferred without liability or loss of discount to Buyer. Title to the goods shall not pass from Seller to Buyer until Buyers final acceptance of the goods. Seller assumes all risk of loss of or damage to the goods (or any part thereof) prior to the acceptance thereof (and following any revocation of such acceptance) by Buyer.

9. WARRANTIES. In addition to any other express or implied warranties (none of which are hereby disclaimed), Seller hereby represents and warrants the following:

A. all goods and services furnished pursuant to this Order shall be free from defects in design, workmanship and materials, and shall comply with the terms of this Order and any drawings, samples, specifications and other descriptions incorporated herein; Seller has the facilities, personnel, experience and expertise sufficient in quality and quantity to perform this Order and agrees that it will perform all services pursuant to this Order in a good and workman like consistent with highest industry standards and in conformance with the requirements of this Order; if Seller performs services on Buyer's premises, Seller shall comply with the applicable environmental, security and safety rules and regulations of the particular location where the services are to be performed, and Buyer agrees that said environmental, security and safety rules and regulations shall be made available to Seller upon request; Seller shall ensure its compliance with the quality requirements outlined below in the performance of its obligations under this Order; when applicable to the services or goods supplied under this Order, Seller shall maintain an effective and compliant Quality Management System (QMS):

- B. all goods furnished hereunder shall be of merchantable quality and fit and safe for Buyer's purpose;
- C. use or sale by Buyer of goods or services furnished hereunder will not infringe any third party claims of any patent, trademark or copyright, or other intellectual property rights; Seller warrants that performance of services under this Order will not violate any proprietary rights of any third party, including, without limitation, confidential relationships, patent and copyright rights, and will be performed in accordance with applicable laws and regulations, including, but not limited to, the Economic Espionage Act of 1996 (18 U.S.C. Sections 1831-1839);
- D. all goods and services covered by this Order shall meet or exceed the safety Standards established and promulgated under the Occupational Safety and Health Act and its regulations in effect or proposed as of the date of this Order;
- E. all goods and services provided hereunder shall be manufactured, packaged, labeled, shipped and/or performed, as applicable, in accordance with all federal, state and local laws and regulations and any goods shipped hereunder are not adulterated or misbranded as those terms are defined in the Food, Drug and Cosmetic Act, nor are they misbranded hazardous substances as that term is defined in the Hazardous Substances Act:
- F. all chemical substances sold, whether individually or as a part of a mixture or mixtures, including impurities, were not manufactured, processed or distributed in commerce in violation of Section 5 or 6 of the Toxic Substances Control Act (the "TSCA"), a rule or order under Section 5 or 6 of the TSCA, or an order issued in an action brought under Section 5 or 7 of the TSCA; and
- G. as of the delivery date, software and any revision(s) thereto will not contain any computer virus or code that could be otherwise hostile, damaging or disabling to Buyer's existing information systems;
- H. Seller shall deliver good and marketable title to all goods furnished pursuant to this Order, including, without limitation, the media, articles, materials, drawings, data, information and other tangible and intangible property, and the design, delivery, installation, inspection, testing, expediting and maintenance and all related activities, specified as items, or required to furnish items, ordered by this Order;
- I. Seller is free to enter into and fully perform this Order and has obtained any and all grants of authority necessary to do so from its Board of Directors or otherwise; and
- J. all accreditations disclosed to Buyer in writing shall be in place and in good standing with respect to any Products and services provided hereunder.

Seller's obligations under all such warranties shall survive and be unaffected by any inspection, testing, acceptance and use. All such warranties shall run to Buyer, Buyer's Affiliates, and their respective successors, assigns and customers, and to users and consumers of, and others affected by, the goods or services. Upon request of Buyer, Seller agrees promptly to replace or repair any goods or services not conforming to this Order or to any warranty set forth in this Order, without any expense (including transportation expense) to Buyer. In the event of Seller's failure promptly to repair or replace such goods or services, Buyer, after reasonable notice to Seller, may repair or replace such goods or services and charge Seller for all costs incurred by Buyer in doing so

10. INDEMNIFICATION. Seller shall indemnify, defend and hold harmless Buyer, its Affiliates, and all of their respective officers, directors, agents, sub licensees, employees, subcontractors or other representatives from and against any and all claims, suits, demands, losses, liabilities, fines, damages, costs or fees (including reasonable attorneys' fees) (collectively "Claims")arising out of or relating to: (a) Seller's breach of this Order (including without limitation its representations and warranties hereunder); (b) the goods or services provided hereunder; or (c) Seller's negligence, recklessness, or wilful misconduct, including but not limited to a violation of applicable law, rule, regulation

Seller shall, at its own expense, defend, indemnify and hold harmless any Buyer, its Affiliates and/or their respective officers, directors, employees, contractors, agents, representatives, successors, assigns, customers or licensees for any alleged infringement of any United States or foreign patent, trademark, copyright or other proprietary right arising from the sale or use of any goods or services, and Buyer may be represented by and actively participate through its own counsel in any such suit or proceedings. Seller shall indemnify and hold harmless Buyer and such other parties from any Claims arising therefrom or in connection therewith. In case any goods or services, or any part or use thereof, is held to constitute an infringement, Seller shall, at its own expense, either procure for Buyer the right to continue using such goods or services or part thereof, or replace the same with a substantially equal but non-infringing goods or services meeting the requirements of this Order. In the event Seller does not or cannot

procure such rights, or replace such goods or services, Seller shall promptly refund to Buyer all payments made under this Order.

11. CONFIDENTIAL INFORMATION. Seller acknowledges that any and all data,

- documents, material or information of any type whatsoever, in whatever form or medium, whether or not marked as "confidential" and/or "proprietary", , including without limitation, designs, blueprints, specifications, engineering data for production, or product know-how, which is learned, created by, disclosed to or becomes known by Seller in connection with goods or services provided under this Order shall be considered confidential information of Buyer (collectively, "Confidential Information"), unless otherwise agreed to in writing by Buyer, and shall be kept strictly confidential by Seller. Seller shall: (A) not disclose such Confidential Information to any third party, except to agents and representatives who need to know in order to perform services or deliver goods under this Order and have signed confidentiality agreements with no less restrictive covenants; (B) use Confidential Information only to perform services or deliver goods hereunder; (C) not knowingly export or re-export, directly or indirectly, any Confidential Information received hereunder in violation of any government regulations, including 15 CFR Part 379 of regulations of the office of Export Administration; (D) upon termination or expiration of this Agreement, destroy or return to Buyer, at Buyer's option, all tangible Confidential Information in its possession and in the possession of any agents and representatives; and (E) protect Confidential Information received from disclosure with at least that degree of care used by Seller in dealing with its own confidential information and shall take reasonable steps to minimize the risk of an unauthorized disclosure of Confidential Information. Any unauthorized disclosure of confidential information shall cause Buyer irreparable harm leaving it without an adequate remedy at law and that any breach or threatened breach by Seller shall entitle Buyer to seek injunctive relief, in addition to any other legal or equitable remedies available to it, in any court of competent jurisdiction without the posting of bond or other surety with the court.
- 12. PROPRIETARY RIGHTS. With the exception of off-the-shelf software which may be provided under this Order (such software being provided under a perpetual, worldwide, irrevocable, fully paid-up, royalty-free, nonexclusive, nontransferable license to Buyer for its own internal business use), all deliverables provided or created under this Order shall be the sole and exclusive property of Buyer or any of its Affiliates ("Buyer Property") and shall be considered "works made for hire". Seller furthermore agrees that any invention, improvement or discovery (whether or not patentable) which is conceived or reduced to practice by Seller or any affiliate, employee, agent or representative of Seller in connection with goods or services provided under this Order (collectively, "Inventions"), shall be the sole property of Buyer or any of its Affiliates, and shall be treated as Confidential Information. Seller shall fully disclose to Buyer all Inventions conceived or reduced to practice by Seller or any affiliate, employee, agent or representative of Seller. Seller hereby assigns and conveys to Buyer or any of its Affiliates, at no cost to Buyer, Seller's entire right, title and interest to any and all resulting Inventions. Upon completion of performance of this Order, Seller shall deliver to Buyer all information relating to any such Invention. As for any hardware or equipment that is purchased by Buyer hereunder, title to such hardware or equipment is transferred to Buyer upon acceptance. Seller shall assist Buyer in all reasonable ways (at Buyer's expense and request) in protecting and securing Buyer Property and Buyer Inventions, including but not limited to applying for patents, copyrights or other rights therein and (iii) execute, deliver such documents as may be required to carry out the provisions of 11(ii) herein. Seller shall use Buyer Property only in compliance with all applicable federal, state and local laws and regulations. Seller will promptly return or destroy Buyer Property at Buyer's request. Seller shall and shall cause its Affiliates, employees, agents and/or representatives, as applicable, to sign all appropriate documents necessary or convenient to enable Buyer to acquire title to Inventions and to file and process applications for patents related to any Inventions.
- 13. SELLER'S RIGHTS IN PRE-EXISTING DATA AND INFORMATION. Seller shall retain title to any pre-existing Seller- developed information of any nature used in performance of services hereunder. Seller hereby grants to Buyer and is Affiliates a perpetual, worldwide, irrevocable, fully paid-up, royalty-free, nonexclusive, nontransferable license to duplicate, modify and use such information for Buyer's own internal business purposes.
- 14. INSURANCE. Prior to providing goods and/or services under this Order, Seller shall procure and maintain at its own expense and shall cause its vendors, representatives and agents, as applicable, to procure and maintain, at their own expense, insurance in accordance with the risks/limits listed below, as deemed necessary by Buyer. Such insurance shall be maintained until the services are completed and/or the goods are delivered, as applicable. Upon Buyer's request, Seller shall provide to Buyer an original certificate indicating the coverage limits set forth below which shall be signed by the insurance carrier (the "Certificate"). Buyer and its Affiliates shall be additional insureds under said policy and Buyer's and/or its Affiliates' name along with address must be shown as a "Certificate Holder." Seller's insurance policies and Seller will not permit such insurance to be reduced, expired, or cancelled without reasonable prior written notice to Buyer. The name of the insurance company must be shown for each line of insurance as well as policy numbers, limits and effective dates. Seller shall procure the following insurance:
 - A. workers' compensation insurance in statutory limits for state(s) in which the work is to be performed;
 - B. commercial general liability insurance (including Contractual Liability, Bodily Injury, Property Damage and Personal Injury) with annual limits of at least \$3,000,000 per occurrence and in the aggregate;
 - C. automobile liability (Bodily Injury and Property Damage) insurance with annual limits of at least \$1,000,000 per occurrence;
 - D. employer's liability insurance with annual limits of at least \$1,000,000 per occurrence;

- E. umbrella liability insurance with annual limits of at least \$5,000,000 which coverage shall include excess limits for automobile, commercial general liability and employer's liability;
- F. professional liability and errors and omissions (if applicable) insurance with annual limits of at least \$1,000,000 per occurrence; and
- G. fidelity bond insurance (if applicable) with annual limits of at least \$1,000,000 million per loss which coverage shall include dishonesty, robbery, theft and forgery on premises and in transit
- 15. LIMITATION OF LIABILITY. IN NO EVENT SHALL BUYER BE LIABLE TO SELLER, SELLER'S AFFILIATES, OR ANY THIRD PARTY FOR ANY INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE, EXEMPLARY OR CONSEQUENTIAL DAMAGES ARISING OUT OF, OR IN CONNECTION W ITH, THIS ORDER, WHETHER OR NOT BUYER WAS ADVISED OF THE POSSIBILITY OF SUCH DAMAGE. BUYERS' AND ITS AFFILIATES' LIABILITY ON ANY CLAIM OF ANY KIND FOR ANY LOSS OR DAMAGE ARISING OUT OF OR IN CONNECTION WITH THIS ORDER OR FROM THE PERFORMANCE OR BREACH THEREOF SHALL IN NO CASE EXCEED THE PRICE ALLOCABLE TO THE PRODUCT OR SERVICE UPON, OR IN CONNECTION WITH, WHICH SUCH CLAIM IS BASED. BUYER SHALL NOT BE LIABLE FOR PENALTIES OF ANY KIND.
- **16. PUBLICITY.** Seller shall not, without the written consent of Buyer in each instance: (A) use the name, trade name, trademark, trade device, service mark, symbol or any abbreviation, contraction or simulation thereof of Buyer or its Affiliates in any advertisement or publication; or (B) represent, directly or indirectly, that any goods or any service provided by Seller has been approved or endorsed by Buyer or any of its Affiliates.

17. REGULATORY REQUIREMENTS.

- A. Seller shall comply with all foreign and United States federal, state and local laws and regulations applicable to it and the goods or services provided under this Order including without limitation those laws and regulations regarding
- (i) the manufacture, testing, distribution, sale, and/or promotion of pharmaceutical products and medical devices and (ii) required permits, licenses, filings, certifications, and other approvals required by the FDA or any similar state or local or foreign law or regulation.
- B. Seller represents and certifies that neither it nor any person or entity employed or engaged by Seller, including without limitation its officers, directors, employees, or agents who provide services in connection with this Agreement (collectively "Personnel") are currently: (1) excluded, debarred, suspended or otherwise ineligible to participate in federal health care programs as defined in 42 U.S.C. Sec. 1320a-7b or from federal procurement or non-procurement activities as defined in Executive Order 12689 (collectively "Ineligible"); or (2) debarred pursuant to the Generic Drug Enforcement Act of 1992, 21 U.S.C. Sec. 335 (a), as amended, or any similar state law or regulation (collectively "Debarred") or (3) convicted of a criminal offense that falls within the ambit of 42 U.S.C. Sec 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible ("Convicted").

Seller represents and certifies that it will not utilize any Ineligible, Debarred, or Convicted Personnel to provide any services hereunder. If Seller becomes Ineligible, Debarred or Convicted during the term of this Agreement, Seller will notify the Buyer promptly, and in any event no later than ten (10) business days after receiving notification of the Ineligibility, Debarment, or Conviction. Upon receipt of such notice, or if Buyer becomes aware of any existing or threatened Ineligibility, Debarment, or Conviction, Buyer shall have the right to terminate this Order and reserve all rights.

If Seller's Personnel become Ineligible, Debarred or Convicted during the term of this Agreement, Seller will remove the Ineligible, Debarred, or Convicted Personnel from responsibility for, or involvement with, the services performed or goods delivered under this Agreement within five (5) business days of discovering the Ineligibility, Debarment, or Conviction.

- C. Seller shall comply with all foreign and United States federal and state antibribery laws and regulations applicable to it, including but not limited to: (i) the Anti-Kickback provisions of the Social Security Act, 42 U.S.C. § 1320a-7b, et seq., and the relevant regulations at 42 C.F.R. Part 1001 (Healthcare Fraud and Abuse Laws); and (ii) the False Claims Act, 31 U.S.C. § 3729; and (iii) the Foreign Corrupt Practices Act, 15 U.S.C. sections 78dd-1 et seq.
- D. Seller shall comply in all respects with all foreign and United States federal and state laws and regulations applicable to it relating to the confidentiality and security of individually identifiable health information and medical data, including but not limited to the Health Insurance Portability and Accountability Act of 1996 (HIPAA), and any other laws and/or regulations relating to the maintenance, use, transmission or other activity concerning patient records and confidentiality of personal and medical data in whatever form and medium.
- E. Buyer is an equal opportunity employer and federal contractor or subcontractor. Consequently, the parties agree that, as applicable, they will abide by the requirements of 41 CFR 60-1.4(a), 41 CFR 60-300.5(a) and 41 CFR 60-741.5(a) and that these laws are incorporated herein by reference. These regulations prohibit discrimination against qualified individuals based on their status as protected veterans or individuals with disabilities, and prohibit discrimination against all individuals based on their race, color, religion, sex, sexual orientation, gender identity or national origin. These regulations require that covered prime contractors and subcontractors take affirmative action to employ and advance in employment individuals without regard to race, color, religion, sex, sexual orientation, gender identity, national origin, protected veteran status or disability. The parties also agree that, as applicable, they will abide by the requirements of Executive Order 13496 (29 CFR Part 471, Appendix A to Subpart A), relating to the notice of employee rights under federal labor laws

- F. C-TPAT. Seller acknowledges that Buyer is participating in the Customs Trade Partnership Against Terrorism program ("C-TPAT Program") with the United States Government Customs & Border Protection, the general security recommendations for which are described at http://www/cpb/gov/xp/cgov/import/. In addition, Seller may request a copy of buyers Minimum Security Requirements developed in connection with the C-TPAT Program. The C-TPAT Program applies to Seller if Seller is a foreign entity that is not an affiliate of Buyer and is located outside the U.S., with which Buyer contracts or trades directly, and that manufactures, processes, assembles, evaluates, warehouse, packs, unpacks, transports or distributes Buyer's assets into the U.S. Seller Agrees that if the Program applies to Seller under the above definition, it will use its best efforts to develop and implement security procedures that compliment and support Buyer's participation in the C-TPAT program in all material respects. Breach of Seller's obligations under this Section 17 shall be grounds for immediate termination hereunder in Buyer's sole discretion.
- **17A.** Pharmacovigilance Monitoring and Reporting. To the extent any services provided to Buyer under this Order consist of "Secondary" or "Syndicated PMR" (as defined below) market research, as determined by Buyer in its sole discretion, then the terms and conditions of this Section 17A shall apply:
- A. Definitions. <u>Active social Media Listening</u> refers to a prospective analysis for which a Customer employee(s) and/or MR services providers sit in or join specific social forums to hear what is being discussed. In this situation there might be direct interactions with patients / public. Chat forum discussion done with an online community developed by a MR services provider for Sanofi use is considered as an active social media listening project.

Adverse Event or AE shall mean any untoward medical occurrence in a patient who takes or uses a product, and which does not necessarily have a causal relationship with that product. An Adverse Event can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease, temporally associated with the use of such a product, whether or not considered related to that product.

<u>Customized PMR</u> refers to research conducted by a Vendor at the request of the Customer or its Affiliates that provides clear objectives to provider in charge of elaborating the most appropriate mean/method to address questions which focus on a disease, condition, or a complication; or is intended to better understand the market environment, competitor companies, competitor products, products in development, product performance or for which the objectives and scope may include any possible mention and / or administration of a product identified by the Vendor as a product currently marketed by the Sanofi group of companies in any country worldwide.

<u>Incident</u> (in the context of medical devices) shall mean any malfunction or deterioration in the characteristics and / or performance of a medical device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side effect.

<u>Passive Social Media Listening</u> refers to a retrospective analysis of social media pre-existing content trawled in mass by a Vendor at the request of the Customer or its Affiliates using key word searches/machine learning and retrieving data under the form of aggregated/trending reports.

<u>Pharmacovigilance or PV</u> is taken to include the concepts of Cosmetovigilance, Nutrivigilance, and Device Vigilance as applicable to the Product(s) covered by this Agreement.

<u>Pharmacovigilance Data or PV Data</u> shall mean any Adverse Event (Serious or not), any incident, or any of the following special situations (with or without Adverse Events): any report of misuse; any medication error; any off-label use (intentional use outside the labelled indication); any overdose (intentional or not); any drug abuse, dependence, addiction, (withdrawal syndrome); any lack of efficacy; any drug exposure during pregnancy or child exposure during breastfeeding or conception (whether from the male or female); any occupational exposure (unintentional exposure during work); accidental exposure; unexpected therapeutic benefit; any suspected transmission of infectious agents; and / or suspected drug interactions involving active ingredients or their metabolites. Where a PTC arises in conjunction with an AE, such complaints are subject to the reporting obligations applicable to PV Data herein.

<u>Product(s)</u> shall mean all the products owned and / or manufactured and / or commercialized by the Customer or any of its Affiliates, including medicinal products, devices, cosmetics and food supplements.

<u>Product complaint, Product Technical Complaint or PTC</u> refers to any written, electronic, or oral communications that allege deficiencies related to the identity, quality, reliability, safety, durability, effectiveness, or performance of a product, device, its packaging, or any written leaflet or other information provided with such product or device, after it is released for distribution. Where a PTC is also associated with PV Data this should be notified to Customer PV in accordance with the procedure set out herein.

<u>Secondary Market Research</u> analyses, reports or data refers to pre-existing data collected 'in mass' by secondary data Vendor and purchased by multiple subscribers, and not specifically conducted or collected at the request of the Customer or its Affiliates. Examples include, but are not limited to: sales volume or value data, prescription data, promotional volume or spending value data, longitudinal patient data, aggregated or compiled meta-analysis or data

<u>Secondary/Syndicated Market Research</u> analyses, reports or data refers to preexisting data collected 'in mass' by secondary data Vendor and purchased by multiple subscribers, and not specifically conducted or collected at the request of the Customer or its Affiliates. Examples include but are not limited to: sales volume or value data, prescription data, promotional volume or spending value data, longitudinal patient data, aggregated or compiled meta-analysis or data.

<u>Serious</u> used in connection with events, reactions and experiences shall mean any untoward medical occurrence that at any dose results in, or may have resulted in, death, is immediately life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability and / or incapacity or is a congenital anomaly or birth defect.

<u>Serious</u> Incident shall mean shall mean any incident that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, (c) a serious public health threat.

Syndicated Primary Market Research (PMR) refers to pre-existing results collected in mass by a Vendor and purchased by multiple subscribers, and not specifically conducted or collected at the request of the Customer or its Affiliates. Syndicated PMR could replace in certain cases a customized PMR such as tracking, patient chart audit, customer survey, customer satisfaction. There are two types of Syndicated PMR:: Non-customized syndicated PMR means that if the Vendor does not enable the Customer to modify the pre-existing questionnaire nor add any customized questions to their questionnaire. Customized syndicated PMR means that the Vendor enables the Customer to modify the pre-existing questionnaire by adding customized questions to their questionnaire

SECONDARY OR SYNDICATED MARKET RESEARCH. PV Data outlined in Secondary market research data, syndicated PMR or passive social media listening are subject to surveillance by the Customer for potential safety issues in accordance with, for example legal requirements and Sanofi group policy on analyses of pre-existing data. Consequently, if the Customer suspects that any PV data relating to any Sanofi Products may be required for safety signal analysis, the Customer may request such PV data and any further information relevant to such data from the Vendor, to be provided to the Customer within a reasonable period, so as to enable the Customer to meet its legal and policy requirements.

17.B. **COMPETITIVE INTELLIGENCE**. To the extent any services provided to Buyer under this Order consist of competitive intelligence as determined by Buyer in its sole discretion, such services shall comply with the following:

A.. SECONDARY INTELLIGENCE GATHERING

- (i) The search for secondary sources of intelligence will be restricted to those that are deemed as being in the public domain
- those that are deemed as being in the public domain.

 (ii) At no time will staff acquire and report intelligence from documents that have been classified as confidential.
- (iii) The search for secondary sources will be confined to the Internet, physical repositories of documents (such as public, government and institutional libraries) and other places that can be legitimately accessed by the public.
- (iii) At no time will the search for documents be carried out on competitor's premises.
- (iv) Any confidential documents that are acquired inadvertently will either be returned to the originating company or destroyed
- $\mbox{(v)}$ All data presented to Buyers will conform to European Data Protection legislation.

B. PRIMARY INTELLIGENCE GATHERING

- (i) The search for primary intelligence will specifically exclude anything that can be construed as a "trade secret" within the meaning of the US Economic Espionage Act.
- (ii) No primary intelligence gathering (for example on pricing and discounts) that could place Buyers in breach of the Anti-Trust and Competition laws will be undertaken.
- (iii) No illegal methods will be used to gain intelligence. Trespass, phone tapping, bugging, hidden cameras and theft will never be carried out.
- (iv) No staff member or any associated consultant engaged for the purpose of collecting primary intelligence will misrepresent themselves to respondents. The identity of their employer will always be revealed and staff are expressly prohibited from presenting themselves as students, journalists, recruitment consultants or employees of the competitor organizations being studied.
- (v) Although the specific purpose of the enquiry may be concealed, at no time will staff tell a direct lie about the objectives of their enquiry.
- (vi) At no time will respondents be provided with any financial or other inducements in exchange for the provision of intelligence.
- (vii) Respondents will not be blackmailed or coerced into providing intelligence.
- (viii) If respondents expressly specify that information provided is confidential it will not be revealed to the Buyer.
- (ix) No intelligence that could damage the reputation or employment prospects of the respondent will be sought or passed on to Buyers.

- (x) The sources of the intelligence provided to Buyers may be identified generically but the names of respondents will be protected.
- (xi) All data provided by Buyers will be treated as confidential and will not be disclosed to third parties.
- 18. TAXES. Any sales or use taxes determined to be applicable as a result of this Order shall be the responsibility of Buyer. Seller and Buyer shall cooperate to the fullest extent allowable by law to minimize any and all sales and use, transfer or other excise taxes applicable on payments to be made by Buyer to Seller. Any and all taxes to be charged to Buyer by Seller and remitted to tax authorities by Seller on behalf of Buyer shall be separately stated on any invoices or statement of fees submitted by Seller to Buyer. All Invoices submitted to Buyer from any Seller resident, domiciled, incorporated, organized or located outside the United States (hereinafter, "Foreign Seller") must separately state amounts payable for services performed inside the United States and outside the United States. If any foreign Seller provides any services in the United States, Buyer reserves the right to withhold tax up to 30% of any payment to Foreign Seller, unless Foreign Seller demonstrates to Buyer's satisfaction that such payment is exempt from U.S. withholding tax, and where applicable, submits accurate and completed Internal Revenue Service forms to support a claim for exemption from U.S. withholding tax.

19. INTERNATIONAL SHIPMENT REQUIREMENTS.

A. <u>Document Requirements.</u> Buyer requires the following information for all shipments originating outside the United States (excluding Puerto Rico) destined to Buyer or any Buyer affiliate in the United States:

(i) Packing List:

A packing list will be included with all shipments and must contain the following: (a) Order number; (b) product part number and description; (c) total number of boxes in shipment and corresponding merchandise enclosed; (d) quantity; and (e) final delivery address. The packing list shall be attached to the outside of the crate.

(ii) Itemized Commercial/Proforma Invoice:

The invoice must be in English and shall contain, at a minimum, the following: (a) manufacturer's complete name and address; (b) Seller's complete name and address (if different from the manufacturer); (c) a detailed and accurate description of the merchandise including part numbers, GMID, etc.; (d) quantity, including unit of measure and purchase price in the currency of purchase of each item included on the invoice; (e) Incoterms (e.g., E XW, FOB, DDP, etc.); (f) Purchase Order or Order Number; (g) Chemical Abstract services Number (CAS#) (h) International Non-Proprietary Name (INN) if available and where applicable; (i) country of origin of merchandise; (j) freight and insurance charges that are to be paid by Buyer, and are included in the cost of the materials (must be itemized separately on the invoice); (k) U.S. Harmonized Tariff Schedule to the 8th or 10th digit; and (l) the full invoice price charged to Buyer. Invoices for shipments that make up one of multiple shipments shall be made under a single Order, and the value shall be stated as the actual value of the merchandise. Nominal, fictitious or arbitrary values will not be accepted. Additional payments which will be or have been made to Seller by Buyer for items such as assists (e.g., tooling, molds, dies, materials or components provided for incorporation or manufacture of the finished products), royalties, packing, or commissions or progress payments should be separately itemized and identified on the commercial invoice.

- B. <u>Labeling/Marking.</u> All products must be clearly marked in English with their country of origin. All shipping cartons should also be marked in English with the country of origin of the product being shipped.
- C. <u>Pre-Alert (Advance Distribution of Shipping Documents.</u> Prior to the tender of the material(s) to the carrier or freight forwarder, Seller shall forward a complete set of shipping documents including the commercial invoice, packing list, bill of lading, air waybill, and if applicable Certificate of Analysis, Dangerous Goods Declaration, Participating Government Agency's required documentation and/or statements.

20. HOTEL SERVICES.

The following additional provisions apply if Seller is providing hotel and/ or meeting room accommodations.

A. Seller agrees to provide the space, services and facilities specified by Buyer in this Order. In the event Buyer terminates this Order pursuant to Section 5 above, then, in lieu of any payments specified in Section 5, Buyer willcompensate Seller based upon the following schedule:

Date of Cancellation	Percentage owed
From Acceptance of this Order to 91 days out	10%
90 days to 31 days	50%
30 days or less	75%

In the event of termination, Seller shall undertake all reasonable measures to mitigate any loss resulting from such termination. The cancellation fees shall be reduced by Seller's revenues resulting from (i) rooms resold and credited to Buyer's account on first rooms sold basis and (ii) food and beverage charges which the Seller was able to reverse, resell or re-use for other Seller events. In the event (a) the cancellation hereunder relates to a meeting function or other event and (b) Buyer or Buyer's representative re-books a replacement event within two (2) years of the original cancelled event date, then any cancellation fees owed hereunder shall be credited against the fees owed for the replacement event. The replacement event does not need to be of equal or greater size than original event.

B. If Seller accepts reservations from other pharmaceutical companies during the same reservation dates specified in this Order, Seller shall promptly notify Buyer

of such fact without identifying the name of the other company. Buyer shall have option to terminate this Order immediately without penalty or any payment under Section 5. All paid deposits will be returned to Buyer.

- C. In the event that Seller fails to provide the facilities and services for an event as set forth herein, Seller will be required to refund any amount paid by Buyer. Seller agrees that Buyer may incur additional expenses to relocate Buyer's event. Seller shall be liable to Buyer for any increased and related costs and expenses resulting from such cancellation. Buyer shall provide to Seller itemized statements with supporting documentation of such expenses. In the event a guaranteed reservation for room accommodation cannot be honored upon arrival, the Seller will, at its sole expense provide: (i) guest accommodations for said guest at another hotel of equivalent or superior quality; (ii) daily transportation between locations.
- D. Seller and Buyer agree that the performance of this Order by either party is subject to acts of God, war, strikes, acts of terrorism, government regulations, disaster, fire, civil disorder, or other similar cause beyond the control of the parties making it inadvisable, illegal or impossible to hold the event or for Seller to provide the facility. This Order may be terminated in whole or in part without penalty for any one or more such reasons listed above, by written notice from one party to the other at any time.
- 21. **GOOD MANUFACTURING PRACTICES**. Where Seller provides goods or services for Buyer to manufacture medicinal products that require compliance with the principles and guidelines of current good manufacturing practices ("cGMP") it is the responsibility of Seller to satisfy the following additional requirements.
- A. Seller personnel shall have appropriate education, training and experience, training shall be documented and records shall be available to Buyer upon request;
- B. Seller shall follow generally recognized good documentation practices for cGMP documentation:
- C. Seller shall perform services in accordance with written standard operating procedures;
- D. Seller shall record and investigate deviations and out-of-specification results;
- E. Seller shall notify Buyer within two (2) business days of discovery of a nonconformance that where the integrity of the service or good is compromised;
- F. Seller shall provide information to Buyer in response to qualification questionnaires provided by Buyer and if requested, shall allow access to its premises and to relevant documentation to allow Buyer to assess Seller's compliance with the terms of this [Order] and cGMP and will provide prompt written responses to any findings;
- G. Seller shall maintain records of source manufacturer(s) and chain-of-custody;
- H. Seller shall notify Buyer of relevant changes impacting the goods or services provided, e.g. changes in premises where services are performed or goods are produced, key equipment used, processes or specifications. Seller shall provide a minimum of ninety (90) days' advance notice to enable Buyer to evaluate the potential impact of the change;
- Seller shall retain records relating to the goods and/or services provided to Buyer for a minimum of 7 years or for such longer period as may be required by applicable laws and regulations;
- ${\sf J.}$ Seller shall only utilize original equipment manufacturer parts when performing preventative or corrective maintenance on Buyer equipment;
- K. Seller shall utilize current NIST traceable, or equivalent, standards to perform calibration for Buyer and when calibrating equipment to be used for services to be provided to Buyer;
- L. Seller shall provide all paperwork related to performance of calibration to Buyer on the same day that work is completed for work performed at a Buyer site;
- M. Seller shall utilize standard operating procedures and status labels provided by Buyer for all work performed at a Buyer site unless otherwise agreed in writing;
- N. Seller shall document the lot number and expiration date for all applicable consumables required to perform any services; and
- O. Seller shall not remove any raw data from a Buyer site. Raw data must be provided to the Buyer prior to the Seller leaving the Buyer site.

22. PRIVACY

- A. CCPA. Seller will comply with all applicable data protection laws, including but not limited to the California Consumer Protection Act (Cal. Civ. Code 1798.100 1798.199) (the "CCPA") as applied to its sale and provision of goods and services to Buyer. All capitalized terms used in this Section that are not defined elsewhere will have the meaning given in the CCPA. Seller will provide Buyer with all assistance required for Buyer to comply with a Consumer's request under the CCPA, including deleting, providing access, or stopping the Sale of any Personal Information provided by Buyer. Seller will not Sell Personal Information provided by Buyer without providing notice to the Consumer and obtaining the Consumer's explicit permission. Further, Buyer will implement and maintain reasonable security procedures and practices appropriate to the nature of the Personal Information processed under this Agreement. These procedures and practices will include all applicable requirements described in the most recent version of the Center for Internet Security Controls. If Seller does not implement a requirement, Seller will maintain and provide to Buyer documentation describing equivalent safeguards used to protect Personal Information received from or on behalf of Buyer.
- B. GDPR/EU Regulations. If Seller handles "personal data" as defined by Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the

protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (the "GDPR"), the parties will comply at all times with the GDPR and Buyer's Data Processing Agreement ("DPA"). Buyer will make a copy of its DPA available upon request.

23. GENERAL.

- A. **Assignment.** Seller shall not, in any manner, delegate or assign its obligations, rights or interest under this Order without the prior written consent of Buyer. Buyer may assign this Order in whole or in party without the prior written consent of Seller.
- B. Buyer's Property. Materials and equipment furnished by Buyer for use by Seller in connection with this Order shall remain the property of Buyer, shall be used only in performance of this Order by Seller, shall be maintained by Seller in good condition, and shall be insured by Seller against loss, theft or damage while in Seller's custody, care and control. Upon completion of this Order, Seller shall return to Buyer or dispose of such remaining materials and equipment at Buyer's direction.
- C. Choice of Law. This Order shall be governed by and construed in accordance with (i) the laws of the State of New Jersey without regard to its conflict of laws rules or principles.
- D. Waiver. The remedies reserved herein shall be cumulative and shall be in addition to all other remedies provided in law or equity. No waiver of a breach of any provision of this Order shall constitute a waiver of any other breach or of such provision. Any waiver by either party of a breach of any provision of this Order shall not operate as, or be construed to be, a waiver of any other breach of such provision or of any breach of any other provision of this Order. Failure by either party to insist upon strict adherence to any term of this Order on one or more occasions shall not be considered a waiver or deprive such party of the right thereafter to insist upon strict adherence to that term or any other term of this Order.
- E. Entire Agreement/Amendments/Change Orders. This Order shall constitute the entire agreement between the parties with respect to the subject matter hereof. The terms of this Order may not be amended or modified other than in a writing signed by both parties. No course of dealing or course of performance between the parties shall be deemed to modify, amend or otherwise alter the terms of this Order.
- F. Buyer's Internal Policies. All work is to be performed in accordance with Buyer's internal policies and procedures that are applicable to the goods delivered or services rendered, including but not limited to:
- (i) Buyer's contractor safety policies and procedures (general and site-specific)
- (ii) Buyer's sexual harassment policies and procedures
- (iii) Buyer's Code of Ethics
- (iv) Buyer's Information Security Measures

Such policies are available upon request.

- G. Independent Contractor. Seller is an independent contractor, free of control or supervision by Buyer as to the means or manner of performing such work.
- H. **Subcontracting**. Seller must obtain Buyer's written approval prior to using subcontractors to perform work under this Order.
- I. Force Majeure. Neither party is liable for delays in performing any of the terms of this Order caused by the effects of fire, strike, war, terrorism, government restriction or prohibition, or other causes reasonably beyond its control and without its fault, but the party failing to perform shall use all reasonable efforts to resume performance of this Order as soon as feasible.
- J. **Survival.** The obligations hereunder which by their terms might apply after the completion or termination of this Order (including, without limitation, Sections 9, 10, 11, 15 and 17F shall survive such completion or termination.