Defined terms shall have the meanings set forth in the purchase order terms:

- **PHARMACOVIGILANCE TERMS**

"**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.

"**Incident**" (in the context of medical devices) shall mean any malfunction or deterioration in the characteristics 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.

**"Pharmacovigilance"** or **"PV"** shall mean medicinal products vigilance, as well as Cosmetovigilance, Nutrivigilance, and Device Vigilance as applicable to Products as defined below.

**"Pharmacovigilance Data"** or **"PV Data"** shall mean any Adverse Event (Serious or not), any incident (Serious or not), 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; 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.

**"Product(s**)" shall mean all the products that are in scope of the outsourced activity and those other products, which PROVIDER is aware are owned, manufactured, or commercialized by CLIENT or Affiliated Companies, including medicinal products, devices, cosmetics and food supplements.

**"Product Complaint" or "PC", "Product Technical Complaint" or "PTC"** refers to any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, efficacy 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.

**"Serious" (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.

"**Serious incident**" **(in the context of medical device)** 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.

- **MARKET RESEARCH ACTIVITY TERMS**

**"Active Social Media Listening"** shall mean a prospective analysis for which PROVIDER sits in or joins 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 on-line community developed by PROVIDER for CLIENT use is considered as an active social media listening project.

**"Customized Primary Market Research" (PMR)** shall mean research projects for which the information and data collected, analyzed and interpreted are proprietary to CLIENT. There are two (2) types of customized PMR:

• External customized PMR refers to research produced by MR services providers and funded by CLIENT at the request of CLIENT

• Internal customized PMR, also called "Do it Yourself (DIY)" refers to research conducted by Sanofi employees, under the responsibility of MR project lead using the DIY platform acquired by Sanofi from DIY platform providers.

**"Passive Social Media Listening"** shall mean a retrospective analysis of pre-existing social media content for which PROVIDER at the request of CLIENT will trawl the internet using key word searches/machine learning and retrieve data under the form of aggregated/trending reports. No possibility for individual consent or follow-up.

**"Syndicated Primary Market Research" (PMR)** shall mean research using pre-existing aggregated information and/or data collected by PROVIDER and purchased by multiple subscribers, and not specifically conducted or collected at the request of CLIENT or SANOFI's Affiliated Companies. There are two (2) types of Syndicated PMR:

• Non-customized syndicated PMR means that PROVIDER does not enable CLIENT to modify the pre-existing questionnaire nor add any customized questions to their questionnaire

• Customized syndicated PMR means that PROVIDER enables CLIENT to modify the pre-existing questionnaire by adding customized questions to their questionnaire

**"Syndicated Secondary Market Research" (SMR):** shall mean research using pre-existing aggregated data collected by secondary data provider and sold to multiple subscribers, and not specifically conducted or collected at the request of CLIENT or Affiliated Companies. Secondary data analyses 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.

## 1. PHARMACOVIGILANCE MONITORING AND REPORTING

### SYNDICATED SECONDARY MARKET RESEARCH (SMR):

PV Data outlined in Syndicated Secondary Market Research (SMR)data, Non-customized Syndicated PMR or Passive Social Media Listening are subject to surveillance by CLIENT for potential safety issues in accordance with, for example legal requirements and Sanofi group policy on analyses of pre-existing data.

Consequently, in case CLIENT suspects that any PV Data relating to any Products is required for safety signal analysis, CLIENT may request such PV Data and any further information relevant to such data from PROVIDER, to be provided to CLIENT within a reasonable period, so as to enable CLIENT to meet its legal and policy requirements.

**CUSTOMIZED PRIMARY MARKET RESEARCH**

This section applies to Customized PMR, Customized syndicated PMR and Active Social Media Listening but does not apply for Syndicated Secondary Market Research

a) During the course of performing the Services PROVIDER and its subcontractors shall monitor, every fieldwork day, the information collected in order to identify PV Data.

b) If during the course of performing the Services PROVIDER or its sub-contractors collect or receive any PV Data associated with Product(s) they shall report this to the CLIENT's Pharmacovigilance department ("CLIENT PV") within one (1) business day of receipt of such data, either by

   i) completing the electronic form and submitting the PV Data via the Sanofi Adverse Event Intake Portal (''PV Portal''). In cases where the PV Portal is unavailable, the PV Data Reporting form is used, and submitted to CLIENT via email as per section ii) below or by

   ii) completing the [PV Data Reporting Form] provided by CLIENT at the outset of [the Services/each project]; and sending the [PV Data Reporting Form] by email to the appropriate generic email address(es) provided by CLIENT at the outset of [the Services/each project].

   CLIENT and PROVIDER will agree on the reporting mechanism applicable to each project.

   If another method of PV Data transmission is required, this is communicated in writing by CLIENT to PROVIDER. When PV Data are associated with a PC, the data should be notified to both relevant CLIENT PV and relevant PC contact.

c) PROVIDER must ensure the successful transmission of the PV Data to CLIENT PV by confirming the acknowledgement of receipt (e.g., for PV Data submitted via email, this would include a return acknowledgement of receipt email; for PV Data submitted via the PV Portal, this includes a Portal identification number). In case PROVIDER does not receive such acknowledgment, PROVIDER should re-send the report and contact CLIENT PV to ensure receipt as soon as possible and no later than one (1) business day. PROVIDER must maintain acknowledgements of receipt and keep them all on file.

d) PROVIDER shall comply with all regulatory requirements applicable to the collection and reporting of PV Data in relation to the Services and shall assist CLIENT PV in complying with such regulatory requirements.

   This shall include, but not be limited to, providing information requested by CLIENT PV to fulfil its Pharmacovigilance obligations.

e) At the outset of each project, PROVIDER shall obtain the consent of any participating individuals (such as healthcare professionals, patients, or consumers) to their contact details being communicated to CLIENT which, if the individual reports any PV Data, enters into contact for further information and follow-up. PROVIDER shall keep copies of such consents according to the

record retention provisions below. If an individual does not consent to their contact details being communicated to CLIENT, they may still participate in the market research. In such cases, PROVIDER makes every effort to re-contact the individual, within the limits of applicable privacy regulations, on CLIENT's behalf, in order to retrieve as much information as possible to facilitate PV reporting requirements.

f) For the avoidance of doubt, payments made to [healthcare professionals / HCPs] [check defined terms of the Agreement] in connection with double-blind market research are not subject to transparency reporting, even if the [healthcare professional / HCP] discloses his or her identity for the purposes of reporting PV Data to CLIENT in connection with the market research. Similarly, any follow-up with the [healthcare professional / HCP] regarding such PV reports will not un-blind the research for transparency reporting purposes.

g) Breach by the PROVIDER of any of the provisions of the Agreement shall entitle the CLIENT to terminate this Agreement for cause with immediate effect.

## 2. PV COMPLIANCE AUDIT AND INSPECTION

a) For the avoidance of doubt this section supersedes any other audit or inspection provision set forth in the Agreement as far as Pharmacovigilance is concerned.

b) CLIENT has the right to audit PROVIDER's records to assess PROVIDER's compliance with the relevant provisions of the Agreement (including this appendix) and with any applicable laws. Such audit is either a documentary or physical audit, and is performed during office hours, upon reasonable prior notice, either by CLIENT's internal auditors or by a third-party auditor designated by CLIENT. Any audit(s) may not impact the confidentiality or integrity of services that PROVIDER provides to its clients. The audit(s) is carried out subject to the obligations of confidentiality set out in the Agreement and as a result, PROVIDER and/or its subcontractors are not allowed to request any specific confidentiality disclosure agreement to the auditors for the performance of the audit(s).

c) PROVIDER agrees to provide CLIENT and its auditors with supervised access to relevant systems, documentation, and individuals for the purposes of conducting the audit. Such audit may be conducted at the request of CLIENT:

   i. on an ad-hoc basis however not more than once (1) a year (upon a prior notice of four (4) to six (6) weeks for a routine audit ("Routine Audit").

   ii. in case of any actual or reasonably suspected lack of compliance by PROVIDER or PROVIDERS's subcontractors with any of their Pharmacovigilance obligations, any breach of the terms and conditions of the Agreement and/or of the applicable laws or regulations (For Cause Audit). In such a case, CLIENT informs PROVIDER not less than fourteen (14) calendar days for a "For Cause Audit", which is not subject to any frequency limitations.

d) PROVIDER shall be granted a summary report of the audit and provides a response for each finding. PROVIDER takes and causes its subcontractor(s) (if applicable) to take all appropriate measures to implement any corrective and preventive action (CAPA) identified during audits without prejudice to CLIENT's

rights and remedies pursuant to the Agreement and/or applicable laws. Any failure to remedy a non-compliance identified during the audit shall be deemed a breach of PROVIDER's obligations. CLIENT shall be allowed to review the audit report and is authorized, without any prior formalities, to freely disclose the results of such audit to any of SANOFI's Affiliated Company which shall be bound by the same obligations of confidentiality.

e) PROVIDER shall permit and will cause its subcontractor(s) to permit any inspection of its and their processes, documents, and premises by or on behalf of regulatory authorities and shall have and cause its subcontractor(s) to have the resources available to address the requests of all inspectors, irrespective of which site or Affiliated Company of SANOFI is concerned by the inspection. In the event PROVIDER is aware of a regulatory authority inspection related to the Agreement or if PROVIDER undergoes a regulatory inspection, PROVIDER immediately informs CLIENT of the inspection and scope. Documents maintained by PROVIDER must be 'inspection-ready' and PROVIDER shall cause its subcontractor(s) to do the same. PROVIDER shall not charge CLIENT for its time associated with assisting the authorities during such inspections.

f) Results of any such inspection are to be considered PROVIDER's Confidential Information and are only disclosed for the purposes of ensuring compliance with the Agreement. Unless required by law, regulation, court order, or the order of another similar governmental agency, such Confidential Information is not disclosed to other companies or made public without the prior written consent of PROVIDER.

## 3. PV TRAINING AND TRAINING MATERIALS

a) PROVIDER ensures that all PROVIDER's employees and any consultants, contractors or sub-contractors working on the project (collectively referred to as "PROVIDER's Personnel") involved in the project have undergone pharmacovigilance training ("PV Training") to ensure compliance with regulatory requirements and CLIENT standards.

   CLIENT is responsible for developing the PV Training materials and making these available to PROVIDER through CLIENT's electronic learning management platform (LMS). Upon successful completion of the PV Training, each learner downloads the PV training certificate from the LMS. If alternative ways of PV training are needed, these are agreed upon between CLIENT and PROVIDER prior to the start of the project.

   PV Training certificates are valid for one (1) year from the date of training for each of PROVIDER's Personnel working on the project, provided that CLIENT has not made substantial changes to the PV Training materials requiring retraining, where in such event, PROVIDER ensures that its relevant Personnel is completing the updated PV Training within the timelines requested by CLIENT.

b) PROVIDER shall ensure that all its Personnel working on the project complete such PV Training

   i. prior to the initiation of each project for those who do not have a valid PV Training certificate,

ii. on an ad hoc basis for those who are newly involved in the project prior to being engaged to provide the Services or whenever substantial changes requiring re-training are made to the PV Training materials, on an annual basis for any project that is to last for more than one (1) year.

c) PROVIDER shall maintain and provide to CLIENT the PV Training certificates for all PROVIDER's Personnel engaged directly in the project. PV Training certificates are provided by PROVIDER to CLIENT via CLIENT Market Research Tool. PROVIDER shall have processes in place to ensure compliance with this requirement.

## 4. RECONCILIATION

a) Either at the completion of fieldwork or monthly if fieldwork lasts longer than one month, PROVIDER completes the status of the reconciliation within the CLIENT Market Research tool and upload a completed reconciliation template in the event PV Data were reported during the reconciliation period.

b) If any missing PV Data are identified during reconciliation CLIENT PV notifies PROVIDER. In such instances, PROVIDER shall forward to CLIENT PV the missing PV Data within one (1) business day of such notification. PROVIDER will implement appropriate corrective and preventive measures and will communicate those measures to CLIENT PV.

## 5. QUALITY CONTROL CHECKS

a) Projects involving any currently marketed product of CLIENT, utilizing certain methodologies and with a focus on the efficacy, tolerance, satisfaction, advantages/ disadvantages and/or treatment use of CLIENT Product (classified by CLIENT as Category A projects) are subject to Quality Control (QC) checks to ensure that PV Data are appropriately identified and reported. CLIENT notifies PROVIDER when the conduct of a QC check is required.

b) In the event QC checks are required the following must be completed:

i) the QC check entails performing a review on ten percent (10%) of the source documentation (call scripts, questionnaires, audio and video records etc.) for category A projects, as mentioned in section 5.a) above. If the project fields in multiple countries a review on ten percent (10%) of the source documentation should be performed in each country. This QC check must be performed by an individual who did not process the original data and who is appropriately trained on PV requirements as per the provisions related to the "PV Training". The process is required to be performed monthly, or at the end of the fieldwork if the project lasts less than one (1) month.

ii) results of the QC check are provided by PROVIDER to CLIENT PV via CLIENT Market Research tool.

iii) in the event of issues discovered by PROVIDER through the QC check, PROVIDER notifies CLIENT PV and implements appropriate corrective and preventive measures and communicates those measures to CLIENT PV.

c) In the event of any repeated non-compliance with the PV requirements, the Agreement or any identified or potential quality issues, CLIENT PV may request additional QC check measures or retrospective review activities to be performed, and PROVIDER shall complete them at PROVIDER's own cost.

## 6. RECORD RETENTION

PROVIDER shall retain all PV records, including PV Data Reporting Forms, PV training records, consent forms, reconciliation documents, QC check forms, CAPA documentation, audit and inspections reports and responses, and relevant proof of sending of such data and documents in accordance with PV requirements set out in this document, for a minimum period of three (3) years following completion of the Services, unless any other period applies under local regulatory requirements. During such period all source data and information shall be made available to CLIENT as soon as possible but no later than one (1) business day following request from CLIENT, including, but without limitation, in case of any regulatory inspection. After the end of the retention period, PROVIDER shall provide the original PV records or copies of the original PV records to CLIENT.