Safety Requirements Appendix

Safety Requirements for Market Research Programs

This Safety Requirements for Market Research Programs Appendix ("**Appendix**") supplements (and is not intended, and shall not be interpreted, to limit the terms of the Agreement) and is governed by the terms and conditions of the Agreement to which it is attached. Any defined terms not otherwise defined herein shall have the meanings set forth in the Agreement. The term Amgen as used herein shall mean the Amgen entity identified in the Agreement, or as applicable, the Order governing the Services to which this Appendix applies.

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[Amendments to this template are not permitted, except where indicated - REMOVE THIS INSTRUCTION PRIOR TO FINALIZATION]

1. Definitions

a. Adverse Event

An Adverse Event (AE) is any untoward medical occurrence in a patient administered an Amgen product and which is not necessarily caused by the Amgen product. An AE can therefore be any unfavorable and unintended sign (i.e. an abnormal laboratory finding), symptom, or disease temporally associated with the use of an Amgen product, combination product, or medical device, whether or not considered related to the product.

This includes:

- Any clinically significant worsening of a pre-existing condition;
- An AE that has been associated with the discontinuation of the use of a product

b. Other Safety Findings

Other Safety Findings (OSFs) include the following, regardless of whether they are associated with an AE and they must be reported to Amgen:

- Use of an Amgen product while pregnant and/or breast feeding (includes pregnancies in women whose sexual partner took, or is taking, an Amgen product)
- Medication Errors (accidental or intentional)
- Overdose
- Underdose
- Misuse
- Abuse
- Addiction
- Transmission of an infectious agent
- Accidental Exposure

- Occupational Exposure
- Lack or loss of therapeutic effect/efficacy
- Missed dose
- Reports of patient “death” after exposure to an Amgen’s product
- Off label use of an Amgen product

c. Product Complaints

Any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a drug, combination product, or device after it is released for distribution to market or clinic by either Amgen or by distributors or partners for whom Amgen manufactures the material. This includes all components distributed with the drug, such as packaging, drug containers, delivery system, labelling, and inserts.

d. Reportable Event

A “Reportable Event” is an Adverse Event (AE), Other Safety Finding, (OSF), or a Product Complaint (PC). All Reportable Events must be submitted to Amgen regardless of whether or not they are stated to be related to, or caused by, an Amgen product, combination product or device.

e. Date of Awareness

Date of awareness is defined as the earliest date that the Provider, or any persons contracted by the Provider, receives information that constitutes a Reportable Event (i.e., the earliest date the fax, email, mail or telephone call is received by Provider or person contracted by the Provider). For the purpose of Amgen regulatory reporting, the date of awareness (day zero) must be captured by the Provider and transferred to Amgen with the Reportable Event.

f. Legislation

Amgen as the Marketing Authorization Holder is responsible for regulatory and legal obligations related to Adverse Event reporting to (a) protect the health and safety of patients and (b) continually assess the safety of Amgen’s products and devices. To enable compliance with applicable regulations, Provider conducting business on Amgen’s behalf, must comply with all applicable laws and regulations (including Good Pharmacovigilance Practices – GVP modules) related to Adverse Event reporting as set forth in this Appendix.

2. Reporting Procedures

a. Identification and Reporting

A Reportable Event must be identified and reported by the Provider from all potential sources that result from exchange of information with participants, or their HCP. The Provider is required to systematically review all potential sources of Reportable Events relevant to the project. Examples of potential sources of Reportable Events include, but are not limited to, results of online or paper questionnaires, returned mail, email or text message responses, face to face or telephone interviews, customer satisfaction surveys, call center recordings, call center notes, websites, portals and digital media.

With respect to each Reportable Event, the Provider must (a) collect all necessary information for the Reportable Event in accordance with the requirements set forth in this Appendix (**see section 2e**), (b) explain to the project participants, the importance of capturing and sending Reportable Event data to Amgen, (c) seek to obtain each participant's consent to enable Amgen to follow up with the participant and or, as appropriate, the participant's HCP (**see section 2f**).

b. Transmission of Reportable Events to Amgen

Project-specific Reporting Form will be provided to Provider by the designated contact in Amgen's commercial organization (the "Amgen Contact"). Upon becoming aware of a Reportable Event, the Provider must complete Reporting Form provided and transmit it to Amgen using email or fax contact information provided on the Reporting Form.

Please note: If a project was exempt from Safety review, the Provider will not be issued with any project-specific forms and any potentially Reportable Events must then be sent to Amgen Safety per the guidance located in the link:

For US and Canada: https://wwwext.amgen.com/products/global-patient-safety/adverse-event-reporting/

For all other counties/regions:
[Amgen LSO insert relevant country link as appropriate – ***remove this instruction***]

It will be communicated to the Provider at the project set-up if the project is exempt from Safety review.

c. Reporting timeframe

All Reportable Events MUST be reported to Amgen within one (1) business day of the Provider (or any persons contracted by the Provider) awareness, (**see section 1e**). Provider, or any persons contracted by the Provider, must have processes, staff and training in place such that they can ensure the identification of a Reportable Event in a timely manner. If the situation arises that a Reportable Event is submitted late (>1 business day after awareness), a reason for the late submission must be provided by the Provider along with the late submission. Amgen will request this information as part of ongoing monitoring and compliance activities.

d. Reconciliation of Reportable Events

In order to confirm successful transfer of Reportable Events from the Provider to Amgen, reconciliation is conducted. Only "Safety reviewed" projects will be subject to reconciliation process. The Provider will be notified by Amgen contact, prior to project initiation, if a project is exempt from Safety review. Amgen contact will provide the Provider with a project-specific Reconciliation Form when applicable.

Project-specific Reconciliation Form will be used by Provider, or any persons contracted by the Provider, to provide Amgen Safety with a list of all Reportable Events submitted to Amgen during fielding (i.e. all Reportable Events previously submitted as individual reports) or confirmation that no Reportable Events were

generated for the project. Provider, or any persons contracted by the Provider, will submit completed Reconciliation Form to Amgen Safety at the end of each project (within 2 weeks of completion of field work). Following receipt of the list(s), Amgen will notify the Provider, within seven (7) business days, of any discrepancies (i.e. missing reports), which will require the Provider to retransmit such Reportable Events to Amgen.

e. Information Collected

Reportable Events must be transmitted to Amgen regardless of the amount of information available. For each Reportable Event, the Provider, or any persons contracted by the Provider, must seek to obtain the following key elements in compliance with the applicable Privacy Laws (please refer to Privacy and Data Protection Schedule attached to the Agreement):

- Patient - An actual (i.e. not hypothetical) patient, who can be identified by the Provider. Patient identifiers may include, as permitted by applicable Privacy Laws, a patient's name, initials, date of birth, age, gender or patient identification number
- Product - Details regarding the Amgen medicinal product, combination product or device, together with the Lot number and serial number
- Reporter - An identifiable reporting source (i.e. patient, caregiver, HCP)
- Event - Details regarding the Reportable Event

For each Reportable Event, Provider will capture as much information as is available and retain sufficient information to allow for successful reconciliation of Reportable Events (i.e. Amgen drug name, date report was submitted to Amgen, Vendor Reference ID, patient initials or other legally permissible identifiers).

f. Follow Up

With respect to each Reportable Event, the Provider must inform the participant that the information provided will be shared with Amgen and the relevant health authorities. In addition, Provider must seek to obtain the participant's consent, enabling Amgen to follow up directly with them or, as appropriate, the patient's HCP, regarding the Reportable Event. If the participant refuses to consent to such follow up, such refusal must be documented and transmitted to Amgen when the Reportable Event is reported.

g. Privacy and Data Protection

Without limiting Provider's obligations under the Privacy and Data Protection Schedule, Provider acknowledges and agrees that with respect to the collection of European Personal Information for a Reportable Event, Provider shall be deemed a "processor" (as such term is defined in the GDPR) of Personal Information relating to such Reportable Event.

Before or at the time that Personal Information is collected for a Reportable Event, Provider shall, to the extent required by applicable Privacy Laws, ensure that the participant receives a privacy notice (such notice to be in accordance with applicable Privacy Laws and any written instruction provided by Amgen).

3. Program Administration and Execution

a. Training

Amgen will provide training materials which communicate the safety requirements set forth in this Appendix to the Provider. The Provider is responsible for ensuring all individuals supporting the conduct of Provider's activities (or any persons contracted by the Provider) are trained using the Amgen-provided training materials. Individual Provider personnel must complete the training before rendering services on any Amgen project and must complete refresher training at least annually thereafter.

b. Written procedures

Provider must have written procedures in place, that are version controlled and dated, to support adherence to requirements set forth in this Appendix. The following include but are not limited to, identification and reporting of Reportable Events to Amgen, internal Quality Control and monitoring of performance measures, training plan, business continuity plan and disaster recovery plan.

c. Records Maintenance

The Provider is responsible for maintaining all records pertaining to the administration and execution of the project (including records of any persons contracted by the Provider) for a period of at least five (5) years to show compliance with the requirements set forth in this Appendix. This includes documents such as, staff CVs (resumes), original Reporting Forms along with Reportable Event source documents (**see Section 2a**).

d. Audits and Inspections

Without limiting Amgen's audit rights under the Agreement, upon provision of prior written notice to the Provider, the Provider will allow access to its premises, systems, personnel and records by Amgen, its agents and its representatives for the purpose of assessing the Provider's compliance with the Agreement. Such assessments may take the form of monitoring visits by Amgen personnel or formal audits by Amgen internal or external auditors, as deemed necessary by Amgen.

The Provider will cooperate with Amgen in the conduct of any such monitoring visits and audits. When applicable, following a monitoring visit or audit, Amgen may request data and records pertaining to the capture of Reportable Events for further review and assessment. Provider agrees to disclose necessary records pertaining to the Provider's staff supporting the conduct of the project (including any persons contracted by the Provider) such as CVs (resumes), training records, organizational charts etc. to Amgen, showing compliance with the requirements set forth in this safety Appendix.

The Provider also agrees to fully cooperate with any inspection of the Provider by a health authority that is related to Provider's administration and execution of the project. In the event of any such health authority inspection, the Provider will notify Amgen in writing within one (1) business day upon receiving notice of such inspection or, if no notice is given by the health authority, upon commencement of the inspection.