## ANNEX 2 EXAMPLE OF MARKET RESEARCH CONTRACT CLAUSE WORDING RELATING TO AE/PC/SRS REPORTING REQUIREMENTS.

**Note:** This example does not include any clauses related to Data Protection. You should ensure that your contract includes appropriate clauses relating to Data Protection legislation.

**In this example Clause the following terms are used with the following definitions. You should expect such definitions to change in accordance with the terms used in your specific market research agreement.**

**Service Provider** means the market research agency providing the market research services on behalf of the Client;

**Client** means that company that has commissioned the market research.

**Adverse Event** for medicines means any untoward medical occurrence in a patient or clinical trial subject administered a medicine 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 temporarily associated with the use of a medicine, whether or not considered related to the medicine.’

Adverse events may be associated with medical devices too. In this case, ‘adverse event’ means any untoward medical occurrence, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons, whether or not related to the device.

**Product Complaint** means any alleged failure of a medicine or medical device, including identity, durability, reliability, safety, efficacy or performance. It is specific to the medicine or medical device itself or its packaging, as opposed to its effect on the patient, including but not limited to:

* Damaged or missing tablets
* Incorrect strength, marking or colour of tablets
* Damaged packaging
* A label that cannot be read
* A liquid that should be clear but is cloudy or contains unexpected particles
* A bent needle
* A broken syringe
* A missing patient information leaflet
* The identification of a potentially counterfeit medicine or medical device
* A malfunction of the device

**Special Reporting Situation** means any of the following situations:

* Exposure through a parent i.e. medicine exposure to a foetus in utero (whether the foetus is exposed because the mother took the product during pregnancy or transmission from semen following the father’s exposure to the product)
* Use of a medicine or medical device during pregnancy or breastfeeding
* Reports of overdose, abuse, misuse
* Lack of therapeutic efficacy including suspected use of counterfeit/falsified medicines/tampering
* Medication errors (including dispensing errors, accidental exposure, maladministration etc.)
* Unapproved, or off-label use of a medicine or device i.e. intentional medical use that doesn’t comply with the authorised product information (including off-label use in children or the elderly)
* Withdrawal syndrome

A company may also indicate to the MRA that it considers the following to be an SRS and the MRA should make sure it understands exactly how the company defines this:

* Unexpected therapeutic benefit (the pre-existing condition improved)

Please also send the MAH/Certificate Holder any information received relating to these safety situations:

* Medicine or medicine-food interactions
* Suspected transmission of an infectious agent
* Occupational and environmental exposure (as a result of a professional or non-professional occupation)

**Project** means [**INSERT BRIEF PROJECT DESCRIPTION**]

**Clause [\*] – Adverse Event Reporting.**

1. If during the course of planning, performing or reporting on the research, the Service Provider is informed of any Adverse Event, Product Complaint or Special Reporting Situation (“***Reportable Event***”), relating to any of the Client’s medicines or medical devices, the Service Provider should use the adverse event reporting form attached as Appendix [\*] of this Agreement to report the same to the Client.
   1. Completed event reporting forms should be stored by the Service Provider for a period of [\*] or such other period as may be agreed between the parties, taking into account the requirements of the Data Protection Act 2018 and any other applicable legislation.
   2. At the lapse of the period referred to in Clause 1(a) above, the parties will agree the appropriate method of destruction and/or deletion of the adverse event reporting forms.
2. In forwarding to the Client information about Reportable Events, the Service Provider shall at all times take into account the requirements of the Data Protection Act 2018 and all other requirements set out in Clause [\*] of this Agreement.
3. The Client shall determine whether the Reportable Event is required to be added to the Client’s safety register.
4. The Service Provider shall provide a summary of all Reportable Events forwarded to the Client on a [**INSERT APPLICABLE INTERVAL**] basis.
5. The Service Provider will ensure that all of its employees, agents and representatives, including any sub-contractors, have undertaken pharmacovigilance training to a standard acceptable to the Client.

1. Notwithstanding the generality of Clause 5, the Service Provider shall provide up to date certificates of competency for all of its employees, agents and representatives, including any sub-contractors, working on the Project, in relation to pharmacovigilance reporting.