ANNEX 5
HEALTHCARE COMPLIANCE

1.1 General: Where the Services relate to healthcare and/or pharmaceutical market research, the Vendor represents, warrants, and covenants to Ipsos ("**Ipsos or the "Client**") that it shall:

(a) adhere to all applicable market research and pharmaceutical industry codes of conduct, guidelines and best practices including, but not limited to EPHMRA's Code of Conduct and Adverse Event Reporting Guidelines, BHBIA's Legal and Ethical Guidelines and Guidance on Reporting Adverse Events, as they apply to the Services being provided under this Agreement;

(b) ensure that each person assigned to perform the Services has the appropriate level of expertise, training and where applicable certificates necessary to perform such Services; and,

(c) provide copies of training certificates to Client on request.

1.2 Adverse Event Reporting:

(a) An "**Adverse Event"** or **"AE"** is any untoward medical occurrence in any patient, clinical investigation subject or other individual who is administered a drug or any other pharmaceutical or medicinal product, whether or not such occurrence has a causal relationship with, or is related to such drug or product, including, but not limited to, any unfavorable or unintended sign (including, for example, any abnormal laboratory finding), symptom, or disease temporally associated with the use of such a drug or product.

In the context of the Agreement, AE is to be considered an umbrella term that encompasses multiple issues such as adverse events, adverse reactions, product complaints, and special reporting situations.

By way of example and without limitation, the following events are considered Adverse Events, each case of which must be reported by Vendor in line with the obligations set out in clause 1.2(b):

- Side effects (with or without causal link)
- Lack of efficacy
- Disease progression or aggravation
- Abnormal test findings
- Unexpected therapeutic reaction / unexpected benefit
- Drug exposure during pregnancy (via the mother or father, with or without outcome)
- Drug use during lactation or breastfeeding
- Overdose (intentional or unintentional)
- Abuse
- Misuse
- Withdrawal or rebound symptoms
- Medication error (dispensing errors / maladministration)
- Drug-drug, drug-food, drug-beverage interactions
- Product quality or technical complaint (with or without AE)
- Device related incidents
- Suspected counterfeit medicine
- Off-label use
- Occupational exposure / accidental exposure
- Compassionate use (expanded access)
- Suspected transmission of an infectious agent
- Death / hospitalization

For a more detailed list of Adverse Events and criteria for reporting, the Vendor shall refer to the guidelines/trainings document issued by the Client for each project as provided by Client, where applicable.

(b) While providing any Services relating to healthcare and/or pharmaceutical market research, the Vendor warrants that it will report any AE to Client or, if required by Client, directly to the end-user client's ("**End Client**") Drug Safety department within one business day or any other timeframe as required by the End Client. If Client wishes for Vendor to notify their End Client directly, Client will provide Vendor with the contact information. Vendor must always keep Client in copy for any such communication. All individual Adverse Events will be reported using a specific AE reporting form of the pharmaceutical company or as provided by Client. To ensure compliance, the Vendor shall:

i. prior to the start of any project, liaise with Client to agree on the details of the Adverse Event reporting procedure for each such project;
ii. ensure that these obligations are communicated to, and complied with by, its personnel, including employees and subcontractors;
iii. train all Vendor personnel, including employees and subcontractors, assigned to Client projects on Adverse Event reporting prior to the beginning of any applicable project, such training materials and/or relevant information will be provided to the Vendor by Client;
iv. document all Adverse Event training activities including the topic of the training, trainer name (if applicable), date of training and the name and signature for each trainee;
v. file all original copies of such training documentation at the Vendor site, and provide copies to Client prior to the beginning of any applicable project;
vi. ensure Vendor has the rights to share training records with Client for all Vendor personnel and subcontractors, prior to providing such documentation to Client;
vii. for projects conducted with respondents within the United Kingdom, Vendor shall also adhere to the BHBIA/ABPI Adverse Event Guidelines for Market Research;
viii. prior to the interview or questionnaire administration, inform all research participants that any Adverse Event identified during the course of the study will be reported to Client or, if required by Client, directly to the End Client's Drug Safety department within the agreed timeframe and, subject to research participant's informed consent where legally permitted, that Client may contact them for additional information regarding the Adverse Event;
ix. with the exception of research participants in any country where seeking consent to waive anonymity is prohibited, include a suitably worded consent question seeking research participant's consent to the disclosure of their name and contact details with any Adverse Event report made to Client or, if required by Client, directly to the End Client's Drug Safety department;
x. in those countries where seeking consent to waive anonymity is prohibited, in the event of an Adverse Event being identified, seek research participant consent to be re-contacted either by Vendor or Client on behalf of the End Client;
xi. inform all research participants that regardless of any consent given in relation to reporting Adverse Events, all responses not related to any Adverse Events will be treated in the strictest of confidence in accordance with standard Market Research Codes of Conduct. Client will provide the Vendor with the disclaimer paragraph to be used in every project for this purpose.
xii. monitor all respondent responses in order to identify potential Adverse Events, special situations and product complaints;
xiii. complete the reporting form with all available and relevant information;
xiv. assign an ID for each reportable AE (as standard, for Quant projects use Respondent ID and for Qualitative projects use interview reference number or respondent ID as used to label each participant);
xv. validate content of completed reporting form prior to submission for
  a) completeness of information, and
  b) integrity of information;
xvi. relay all Adverse Event and other relevant information to Client or, if required by Client, directly to the End Client's Drug Safety department within one business day or any other timeframe as required by the Client of an Adverse Event being identified or of an Adverse Event being mentioned by a respondent;
xvii. where applicable, ensure to obtain confirmation of receipt by Client or by End Client within one (1) business day; if Vendor does not receive such confirmation, Vendor must contact designated point of contact to determine if the report was received. Vendor will maintain a record of the confirmation;
xviii. cooperate with Client and the End Client in case any follow ups with research participants are necessary;
xix. cooperate with Client in implementing any additional or amended Adverse Event reporting requirements required to comply with the Client's contractual requirements set out in the Agreement or Work Order or otherwise agreed to in writing.

(c) After the completion of each project, or at different agreed intervals, Vendor must complete a summary of all Adverse Events, special situations and product complaints that were reported. A reconciliation form will be provided by Client and must be completed regardless of the number of Adverse Events identified and reported during the project, even if the number is zero. Such form will be submitted to Client' project manager and/or to the End Client if so required.

(d) If any personal data related to reportable Adverse Events, special situations and product complaints is being exchanged by e-mail, the information must be attached to the e-mail in form of password protected files and encrypted in transit using AES 256 bit or stronger encryption.

(e) In the event the Vendor engages subcontractors to perform services related to Client projects, the Vendor shall:

i. obtain Client authorization prior to engaging any subcontractor;
ii. require fulfilment by the subcontractor of these Adverse Event reporting requirements on substantially the same terms as those outlined in this Agreement.

1.3 Storage of AEs

Vendor must retain the following information for an unlimited period or for such period as may be agreed between the parties:

i. all relevant source data;
ii. AE forms completed for every AE on every project;
iii. evidence of sending AE forms to the Client's Drug Safety department;
iv. confirmation of receipt from the End Client's Drug Safety department.

At completion of Services, Vendor shall transfer all relevant project material (including but not limited to original source data, any pharmacovigilance related material and correspondence such as those stated above in article 1.2) to Client, for Client to retain in accordance with their own requirements. The Vendor is responsible to ensure all project related material is safely received by Client.

Before any data is destroyed, Vendor must obtain authorization from Client. Client might request at that point for data to be transferred to Client for confidential longer-term storage.

1.4 Audit

Without prejudice of any other audit right provided to Ipsos herein, for the term of this Agreement and three (3) years following expiration or termination hereof, Client, its designated third-party auditor or End Client, shall have the right to audit with reasonable prior notice the supplier´s processes, procedures and training, including records, data, documentation with respect to AEs in relation to the services provided to Client.

Vendor commits to correcting issues from audit observations within the mutually agreed timelines and promptly communicating the actions to Client.

1.5 Incentive Payments for Healthcare Projects

(a) Any proposed incentive payment provided to a market research participant must be based on fair market value (FMV), in local currency and clearly identified in service letter/proposal.

Vendor must pay incentives to participants in accordance with all respective regulations in the relevant country and all Codes of Conducts applicable.

In addition, Vendor and where relevant their subcontractors must comply with the following considerations when paying incentives to participants:

i. As standard, the only payment solutions accepted by Client are by bank transfer, checks, or vouchers;
ii. Other types of incentive payments must be approved by Client and its End Clients in writing;
iii. In those cases where an exception is granted within the service letter/proposal Vendor must keep in its books all proofs of payments made to participants, such as receipt signed by participant in case of physical exchange of a voucher, and shall make them available to Client on demand;
iv. In no event will Vendor provide an additional or higher incentive to any participant than is indicated in the service letter/proposal, unless such increase has been discussed with and approved by Client in writing;
v. Vendor recognizes that payments to government employees and HCPs within certain countries and states are restricted and will abide by such restrictions.

(b) **Transparency Reporting**: Vendor shall comply with all applicable national laws, regulations, and industry guidelines in regard to transparency of incentive payments to market research participants (e.g., US Sunshine Act, Loi Bertrand and Loi Anti-Cadeaux in France, etc.).

If applicable, Vendor represents that it has procedures in place to track, document, and report payment of incentives to local authorities on behalf of Client and its End Clients.
Upon demand, Vendor shall be able to produce evidence of their compliance with applicable national laws, regulations, and industry guidelines.

On a project-by-project basis, Client might be required to report incentive payments (including any expenses paid) to its clients; in such cases, Client and Vendor will discuss and agree prior to start of the Services how to comply with such transparency reporting requirements. Vendor warrants to provide Client and its End Clients with the necessary information to comply with such requirements.