

TERMS AND CONDITIONS FOR INVESTIGATOR INITIATED STUDIES

1. PURPOSE & SCOPE

PMPSA put in place a wide IIS Program for Sponsor-Institution(s), interested in receiving a support from Philip Morris Products S.A. (“PMPSA”) for the conduct of an independent Investigator Initiated Study (“IIS”).

These Terms and Conditions (“T&Cs”) set out the principles and requirements that govern PMPSA’s support related to IIS in addition to the provisions included into the Investigator Initiated Study Agreement to be signed by Sponsor-Institution and PMPSA in case PMPSA accepts to granting Support following a Sponsor-Institution’s request.

These T&Cs detail how PMPSA will evaluate, approve and follow-up on any request for Support for IIS. Participation of the Sponsor-Institution in PMPSA IIS Program is contingent and subject on the acceptance of the T&Cs. By submitting the INVESTIGATOR INITIATED STUDIES CONCEPT PROPOSAL (“Concept Proposal”) form, the Sponsor-Institution confirms that it has read, understood and accepted the T&C.

Sponsor-Institution through its personnel (“User”) is free to browse the <https://www.pmiscience.com/en/research/investigator-initiated-studies> (“IIS Website”), have access to and use it, subject to the Terms of Use of PMIScience.com included therein and all applicable laws. By accessing and browsing the IIS Website, Sponsor-Institution accepts, without limitation the T&Cs. PMPSA reserves the right to modify, limit or discontinue – in full or in part and without prior notice – its IIS Program at any time.

2. RESPONSIBILITY

Users of IIS Website must comply with all applicable laws and regulations.

The content of the IIS Website is protected under applicable laws, including copyright and trademark laws. All images and text are owned by or licensed to Philip Morris International (“PMI”) and, except as provided within these T&Cs, may not be downloaded, distributed, stored, reused, reposted, modified, or otherwise used without the express written permission of PMI or one of its affiliates. PMI neither warrants nor represents that use of material displayed on the IIS Website will not infringe the rights of third parties.

The User can print a copy of these T&Cs for its own personal, non-commercial use, provided it also retains all copyright and other proprietary notices contained in the materials or as specified on the IIS Website. The further use, re-use, copying, distribution, redistribution, modification, publication, or re-posting of or to any part of this IIS Website (including the text, images, audio, and video) is strictly prohibited and nothing contained on this IIS Website should be construed as granting, by implication, estoppel, or otherwise, any license or right to use any PMI and/or PMPSA intellectual property right (including, but not limited to any patent, trademark, trade name, copyright or trade secret).

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In case of any questions PMPSA IIS program leader(s) will be available providing guidance on the PMPSA IIS Program and can be reached via e-mail at the following address: iis.pmi@pmi.com.

3. INVESTIGATOR-INITIATED STUDIES

3.1. General Principles

3.1.1. By submitting a Concept Proposal form, Sponsor-Institution will:

3.1.1.1. Agree with T&Cs, understand that ownership of the content of the Concept Proposal form submitted remains with the Sponsor-Institution and to the extent the Concept Proposal form contains material that is owned by a third party, Sponsor-Institution warrants that it has obtained all necessary licenses and consents required for the use of those materials;

3.1.1.2. Understand that PMPSA will keep confidential all information received by the Concept Proposal form and additional information provided during the application process, until the end of the evaluation process;

3.1.1.3. Unless differently stated in these T&Cs, understands that Sponsor-Institution(s) have no right arising from the submission other than having (i) its Concept Proposal evaluated by PMPSA, (ii) information handled according to applicable law, and (iii) feedback given with reference to the Concept Proposal;

3.1.1.4. Understand that PMPSA reserves the right to refuse reviewing any Concept Proposal that does not comply with these T&Cs, it is not sufficiently documented, or otherwise it appears libelous, incomprehensible or insubstantial.

3.1.2. The Sponsor-Institution is an independent institution that directly and/or through one of its investigators requests support from PMPSA. IIS are studies where PMPSA is not the sponsor but only provides financial support and/or product and related documentation for the conduct of the study ("Support"). T&Cs which specifically apply to one type of Support are detailed in the appendices.

3.1.3. Each IIS Concept Proposal should be evaluated by a pre-established and centralized PMPSA dedicated committee to ensure (i) the Concept Proposal is in line with PMPSA's strategy and research area of interest; (ii) scientific merit and robustness of such Concept Proposal that could advance scientific/ medical knowledge; (iii) Sponsor-Institution's qualifications and expertise and (iv) the Concept Proposal's budget is reasonable and justified (fair market value) in relation to the study protocol requirements. PMPSA dedicated committee members should be individuals qualified to make these scientific assessments.

3.1.4. The outcome of the IIS shall have the prospect to be published in a peer reviewed journal by the Sponsor/Institution.

3.1.5. Any and all IIS shall be separate and absolutely not linked with any promotion and marketing activity of PMPSA products. No employee and/or consultant of PMPSA shall not be involved in the requests, handling, or provision of IIS applications or help in the preparation, review, or evaluation of IIS applications for IIS Support, or otherwise attempt to influence the decision to grant a Support

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by PMPSA. If a commercial employee or consultant of PMPSA (i.e., Marketing & Sales force) receives a request to support an IIS, such person should refer the request to the appropriate scientific contact within PMPSA who can be reached via iis.pmi@pmi.com.

3.1.6. While PMPSA may communicate its general areas of scientific interest, each Concept Proposal request must be unsolicited.

3.1.7. The details of IIS Support must be set out in a written IIS agreement compliant with these T&Cs.

3.2. IIS Support

3.2.1. PMPSA shall base its decision to provide a Support to an IIS solely based on the above-mentioned evaluation criteria as set forth in section 3.1 above.

3.2.2. IIS Support shall not be offered or provided with the intent to, either directly or indirectly, influence or encourage Sponsor-Institution to recommend PMPSA's products.

3.2.3. IIS Support shall not be used in any way to pay for a recipient's ordinary operating expenses (i.e., expenses of activities that the recipient is already required to perform or customarily performs) or support research that has already occurred or not subject matter of the Concept Proposal form.

3.2.4. The ISS research activities' and the use of PMPSA's Support must be appropriately documented in detail and roles and responsibilities clearly defined, to substantiate appropriate quality standards of the research activities. The agreed Support shall be linked with pre-defined quality milestones and shall only be provided if these milestones are achieved.

3.2.5. PMPSA shall not seek, directly or indirectly, to influence the content or the outcome of the IIS. However, PMPSA may negotiate appropriately condition in the IIS agreement with the Sponsor-Institution granting PMPSA and PMI the rights to refer to or submit the results of the research in support of regulatory filings of PMPSA and /or PMI products.

3.3. Sponsor-Institution

3.3.1. Sponsor Institution(s) include institutions, organizations or associations that conduct research with a proven track record in the subject matter of the Concept Proposal. Any misrepresentation of Sponsor-Institution(s) credentials will result in the immediate withdrawal of PMPSA Support.

3.3.2. The Sponsor-Institution must agree with the following contractual obligations:

3.3.2.1. Submission to the PMPSA IIS program leader(s) of periodic progress and safety reports; and

3.3.2.2. At the conclusion of the IIS, a written final study report which summarizes all relevant data will be completed and forwarded to PMPSA, before any publication. This final study report will be provided to PMPSA for informational purposes only

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and in order to allow PMPSA to protect PMPSA's confidential information eventually included therein. PMPSA will have no right to amend this final study report.

3.4. Study Execution

- 3.4.1. PMPSA will not be responsible for the execution of the IIS, including regulatory approvals or requirements. The Sponsor-Institution accepts and acknowledges that it is solely responsible for the initiation, conduct and management of the IIS and that it carries out the IIS entirely independently from PMPSA. PMPSA shall not be responsible in any manner whatsoever for the initiation, conduct or management of the study or for any use of the product in the study and Sponsor-Institution shall not indicate to any third party (including without limitation, any study subject, regulatory authority, or ethics committee), that PMPSA is in any manner responsible for the study.
- 3.4.2. Sponsor-Institution acknowledges that PMPSA shall have no liability (whether by indemnity or otherwise) to the Sponsor-Institution or to any employee or subject or agent of the Sponsor-Institution in connection with the conduct of the study.
- 3.4.3. Sponsor-Institution shall provide periodic progress updates and safety reports to PMPSA to ensure that study objectives and the agreed milestones are being met.
- 3.4.4. PMPSA reserves the right to reconsider its support if the research described in final study plan/protocol will be substantially changed from what is in the approved Concept Proposal form.

For the scope of these T&Cs, a "change" shall be considered "substantial" if it is likely to have a significant impact on:

- the safety or physical or mental integrity of the Study's participants, if applicable; or
- the scientific value of the study; or
- the scope, or conduct, or management of the study; or
- the quality or safety of any investigational product used in the study, if applicable.

- 3.4.5. PMPSA reserves the right to withhold Support for an IIS where in PMPSA's judgment the applicant for Support has or may be perceived to have a conflict of interest in respect of PMPSA, its affiliates or products, or the outcome of the research. Examples of such circumstances might include, without limitation significant share holdings in PMPSA; or other commercial interests in PMPSA, its products or research efforts.

3.5. Publication and Study Data

- 3.5.1. All study data and information belong exclusively to the Sponsor-Institution.
- 3.5.2. Study findings and results should be shared in order to enable a third party to repeat the study and should be made available together with any publication(s) and/or presentation materials arising from or relating to this IIS.

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If the study is clinical in nature the Sponsor/Institution makes sure that the study (including results) is registered at www.clinicaltrials.gov as per the requirements of the registry.

3.5.3.Sponsor/Institution shall provide a copy of any manuscript and final report relating to the Study results to PMPSA, before any relevant publication, allowing PMPSA to review and comment on them in order to permit PMPSA to ask for the deletion of any reference to PMPSA's confidential information and/or obtain appropriate intellectual property protection. For the sake of clarity, the results generated by Sponsor/Institution in the performance of the IIS shall not be in any way conditioned by PMPSA. Publications are under the sole responsibility of the Sponsor-Institution, they do not belong to PMPSA and must be published under Open Access and identifiable as such.

3.5.4.PMPSA's Support must be appropriately disclosed with the corresponding IIS identification number in the relevant section(s) of any publication(s) and/or presentation materials arising from or relating to the relevant IIS. PMPSA will disclose on its website the support and funding provided.

3.5.5.Sponsor-Institution should inform PMPSA within five (5) days following acceptance of publication by a journal and provide PMPSA with the appropriate publication details (name of the publication, date etc.) as well as a copy of the accepted publication for informational purposes only.

4. EVALUATION AND APPROVAL

4.1. Requests

4.1.1.PMPSA will establish and document a submission process for the evaluation of any Concept Proposal form. The request must be:

4.1.1.1. unsolicited; and

4.1.1.2. in writing and providing a detailed description of the required support, timing and budget, and any other appropriate information necessary to meet relevant accounting and records requirements.

4.2. Evaluation and Approval

4.2.1.PMPSA will evaluate each Concept Proposal form

4.2.1.1. according to criteria outlined in section 3.1.3.;

4.2.1.2. PMPSA ensures that the Sponsor/Institution is notified in writing whether their request is approved or denied and in case of approval a proper agreement shall be drafted and signed by PMPSA and Sponsor/Institution.

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5. TRANSPARENCY AND PUBLIC DISCLOSURES

5.1.1.Sponsor-Institution agrees that PMPSA may, without prior consent, publicly disclose information about Sponsor-Institution as required by applicable laws, including, but not limited to identifying Sponsor-Institution as conducting the IIS, and the amount of funding provided, and expenses covered by PMPSA. Sponsor-Institution further agrees to provide, at PMPSA's reasonable request, any information necessary for PMPSA to make such disclosure.

5.1.2.Sponsor-Institution shall comply with any requirements under applicable laws or institutional policies to obtain approval from any regulatory authorities or professional associations and any other employers or institutions prior to performing the IIS and will do so on a timely basis. Evidence of such notifications and/or approvals shall be provided to PMPSA upon request.