**Collaboration Agreement**
between a patient advocate and
a pharmaceutical company

**Reference agreement “Collaboration Agreement” draft version 1.1 (17 December 2019)**
This is a reference agreement, specific for Collaboration Agreements, that should be adapted according to the needs of the users. It is based on the “Guiding Principles on Reasonable Agreements between Patient Advocates and Pharmaceutical Companies”, provided by the WECAN project on “Reasonable Legal Agreements between Patient Advocates and Pharmaceutical Companies”, for the most recent version and more information about the guiding principles, please visit [www.wecanadvocate.eu/rapp](http://www.wecanadvocate.eu/rapp)

**COLLABORATION AGREEMENT**

**BETWEEN**:

(1) Company name incl. legal form, a company organized and registered under the laws of insert country with registered office at insert address and registered with the insert register under number insert company registration number, duly represented by insert name, insert role/function,

Hereafter referred to as the "**Company**";

AND:

(2) insert name, residentat insert address and country;

 Hereafter referred to as the "**Partner**";

The Company and the Partner are hereafter jointly referred to as "**Parties**" and individually as "**Party**".

[In case the contractual party is the patient organisation]

(1) Company name incl. legal form, a company organized and registered under the laws of insert country with registered office at insert address and registered with the insert register under number insert company registration number, duly represented by insert name, insert role/function,

Hereafter referred to as the "**Company**";

AND:

(2) [Name of the patient organization], a company organized and registered under the laws of insert country with registered office at insert address and registered with the insert register under number insert company registration number, duly represented by insert name, insert role/function,

 Hereafter referred to as the "**Partner**";

**WHEREAS:**

The Company is an international pharmaceutical company active in the field of research and development of pharmaceuticals and medicinal products.

The Partner is a patient advocate, who has a comprehensive expertise and experience in the field of health and patient advocacy, e.g., as an individual patient, career, patient advocate, patient organization representative or patient expert.

The Parties wish to collaborate in order to co-create [insert a short description of the project], as further defined under Appendix 1. Both Parties have unique assets and strengths that complement each other in this Project.

It is specified that the Company respects the mission, autonomy and independence of the Partner and any patient organisation associated with and does not seek to exert any improper influence on their objectives, activities or decisions.

**NOW, THEREFORE IT IS AGREED AS FOLLOWS:**

1. **Definitions**

**Affiliate**: any company, organization, subsidiary or other business entity that is formally attached to, legally connected to the Company or indirectly controlling, controlled by or under common control with a Party to this Agreement. “Control” shall mean the power to directly or indirectly, appoint a majority of the directors, or to otherwise direct or cause the direction of the management or polices of such company or entity whether through shared ownership, by contract or otherwise.

**Confidential Information**: all non-public and business-related information, such as, but not limited to commercially sensitive information, strategic plans or processes, unpublished scientific data, planned public campaigns or policy actions, draft project plans or concepts, written or oral, disclosed or made available to either Party, directly or indirectly, by or on behalf of one Party or its Affiliates (in the case of the Company) through any means of communication or observation.

**Contribution:** Assets, such as inter alia, funds, resources, know how brought by the Partner or the Company in order to deliver the Project as set out under Appendix 1.

**Project**: the services and deliverables that the Parties commit to deliver, in a collaborative effort, as set out under Appendix 1.

1. **Purpose of the collaboration**
	1. The Partners shall collaborate in order to deliver the Project as set out under Appendix 1.
	2. The content of the Project may be amended by mutual written agreement between the Parties.
	3. The Parties agree that the Company and the Partner delegate to the persons identified under Appendix 1 who has/have the required expertise, the performance of the Project.
2. **Contributions of both parties**
	1. As its Contribution, the Company agrees to fund the Project costs in accordance with the terms of Contribution described under Appendix 1 (the "**Project Costs**").
	2. The Company will also reimburse for all reasonable business-related travel expenses incurred in relation to the performance of the Agreement in accordance with the expenses policy set out in Appendix 2, if such costs occur and are approved by the Company.
	3. The abovementioned Project Costs and expenses are considered net of Value Added Tax ("VAT"). The Company will additionally cover VAT and other taxes, if legally required. Partner shall be responsible for all other taxes and/or any social security charges, as applicable, related to the Project Costs, unless otherwise agreed between the Parties or stipulated otherwise in the applicable law.
	4. As its Contribution, the Partner will provide its resources, expertise, knowledge, and staff as described in Appendix 1. The work time of the Partner will be covered by the Project Costs.
	5. The Parties acknowledge that the Project Costs are reasonable and aligned with the prices requested by professionals on the market for similar professional services taking into account all the contributing factors such as, inter alia, individual expertise and training, complexity of tasks, responsiveness and country of origin, as well as the total time invested (work time and preparatory time) into the Project by the Partner and comply with the industry, regulatory, and ethical guidelines as well as with the European Federation of Pharmaceutical Industries and Associations (EFPIA) “Working Together with Patients” principles, and the relevant national codes of practices applicable to the pharmaceutical industry.
	6. The Company will ensure transparency of the investments made as Project Costs in accordance with the applicable local and international laws, regulations and Codes of Conduct, in particular the European Federation of Pharmaceutical Industries and Associations (EFPIA) “Code of Practice”, and the relevant national codes of practices applicable to the pharmaceutical industry. This may involve the publication on its website or the communication to third parties of the payments made under this Agreement, including Project Costs and expenses of the Partner which the Company has covered.
3. **Independence and conflict of interest**
	1. The Agreement does not create any relationship of agency or employment or joint ventures between the Parties. The Partner shall exercise its activities under the Agreement as an independent collaborator.
	2. The Parties acknowledge that the Project Costs shall never constitute in any way an inducement to, or reward for, recommending or taking any decisions favourable or promotional to any products or services of the Company or its Affiliates, or have any influence on the content of any materials authored by or on behalf of the Partner.
	3. In case the Partner is writing, speaking or acting in public concerning the Project as set out in Appendix 1, the Partner must declare that it is collaborating with the Company whenever disclosure is required or deemed appropriate by both Parties.
	4. The Parties confirm that the Agreement is concluded independently from any business transactions and decisions in relation with the supply or purchase of goods or other services related to the Company.
4. **Term and termination**
	1. This Agreement comes into force upon signature by the Parties and shall remain in effect for the duration of the Project as set out in Appendix 1, unless terminated earlier in accordance with the terms of this Agreement.
	2. Both Parties shall have the right to terminate this Agreement without cause upon thirty (30) days’ prior written notice to the other Party.
5. **Confidentiality**
	1. The Parties undertake and agree to keep secret and confidential all Confidential Information, Confidential Information may be further specified in Appendix 1.
	2. Both Parties agree to make reasonable efforts to mark their documents and data as confidential. In case of lack of marking, or in case of orally disclosed information, the receiving Party should make reasonable efforts to clarify with the disclosing Party whether the information is confidential or not.
	3. Any disclosure of Confidential Information to third parties requires prior written consent of the disclosing Party, except for additional persons specified in Appendix 1. The Partner needs to ensure these persons follow the confidentiality rules of this Agreement.
	4. The obligations and limitations set forth herein regarding the Confidential Information shall not apply to information which is:

(i) in the public domain other than by a breach of this Agreement on the part of the receiving Party; or

(ii) rightfully received from a third party which has the right and transmits it to the receiving Party without breaching any obligation of confidentiality; or

(iii) rightfully known to the receiving Party without breaching any limitation on use or disclosure prior to receipt of the same from the disclosing Party, as shown by the records of the receiving Party; or

(iv) generally made available to third parties by the disclosing Party without any restriction concerning use or disclosure; or

(v) required to be disclosed by law or by a court of competent jurisdiction or by the rules or regulations of an applicable governmental or taxation or regulatory body or authority to whose jurisdiction the receiving Party is subject.

* 1. After the completion of delivery of the Project, termination of this Agreement or whenever the disclosing Party requires it, the receiving Party may be asked to return and/or delete the Confidential Information. After returning and/or deleting such Confidential Information, the receiving Party will complete and sign the Appendix 4. The receiving Party may be permitted to retain copies if required to demonstrate compliance with this Agreement or with legal proceedings.
1. **Recording of the meetings**

7.1 Unless otherwise specified in writing, the Parties agree that the use of recordings, minutes and reports, of any kind and on any support, of any meeting attended by the Parties:

1. is allowed by both Parties for internal purposes;
2. is permitted subject to the prior written consent of the other Party for any external use;
3. is permitted, in any case, where required for the performance, or for the verification of the performance, of the Services.
4. **Intellectual Property rights**
	1. All information, data and Intellectual Property rights owned by each Party prior to this Agreement shall remain the property of that Party.
	2. Unless otherwise agreed between the Parties in Appendix 1, all Intellectual Property Rights on materials, data and products developed or prepared solely or jointly by the Parties in connection with the Project shall be jointly owned by the Parties. As a result, each Party will be entitled to use separately such Intellectual Property Rights on a non-exclusive world-wide, royalty-free basis, including any modifications and enhancements, subject to respecting confidentiality obligations under Article 6.
	3. In the event assignment of Intellectual Property Rights needs to be more specifically defined under applicable law, this assignment of copyright includes, without limitation:
5. the right to reproduce, copy, distribute and/or edit totally or partly the Services on all media (eg, paper, film, CD-ROM, Internet) and by all processes (e.g., photocopy, scanning, word or digital processing, recording);
6. the right to publicly perform and communicate totally or partly the Services and by all means (e.g., slides, video, film, recordings, web site) ;
7. the right to translate totally or partly the Services in all languages;
8. the right to modify by adding and/or deleting totally or partly the Services and to disclose these modified versions. These modified versions do not misrepresent the Services and/ the Partner’s intent;
9. the right to claim copyright in the world for the full duration and any renewal or extensions.
10. This assignment of copyright is valid worldwide and for the duration of the copyright according to applicable law.
	1. Each Party guarantee that the above Intellectual Property Rights have not been previously assigned and/or licensed and that it is entirely free to be validly assigned to the other Party, without any liens, encumbrance or pledge whatsoever. This means that no third-party has any rights on the Services
	2. Any external use of the other Party's name, trademark or logo requires prior written consent of the other Party. In case this prior written consent is given, the name, trademark or logo should always be used according to the guidelines of the Partner or the Company.
11. **Liability**
	1. To the extent permitted by law, the Parties shall not be held liable towards each other for the performance of their services under this Agreement, unless caused by gross negligence or wilful. It shall in no circumstances be liable for any indirect or consequential loss or damage incurred by one Party in connection with the activities contemplated in this Agreement (such as a loss of profit or damage to the reputation etc.).
	2. In any event, each Party's liability cannot exceed twice the value of the Contribution of the Partner with the exclusion of external costs. The value of the Contribution of the Partner will be defined in advance in writing by both Parties.
12. **Data protection [For Europe only]**
	1. During the term of the Agreement, in the context of delivering the Project that is the subject of this Agreement, either Party may be processing the personal data exchanged under the Agreement. The Parties acknowledge that, in relation to the processing of such personal data, each Party will be free to determine the lawful purpose and the means of such processing and therefore will act as separate data controller. In no event will this Agreement lead to a situation where the Parties can be considered joint controllers.
	2. Each Party agrees to comply with its obligations under the Regulation 2016/679 of the European Parliament and of the Council on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) and any other applicable data protection laws. In particular, each Party shall: (i) process either Party’s personal data for the purpose of (a) managing the contractual relationship; (b) complying with a legal obligation; and (c) responding to requests from a competent supervisory authority or individuals; (ii) implement and maintain appropriate technical, organizational and security measures that are necessary to protect Personal Data processed under this Agreement from any accidental, unauthorized or unlawful use, destruction, loss or damage, as well as from alteration, access or processing personal data.
	3. In addition, each Party shall:
		* + 1. maintain, and procure that its employees and agents keep, Personal Data confidential in accordance with the Parties' confidentiality obligations contained in this Agreement;
				2. notify the other Party in writing without undue delay, but no more than 48 hours after becoming aware of a personal data breach, and provide reasonable cooperation after becoming aware of a personal data breach relating to any personal data processed in the context of this Agreement;
				3. provide reasonable cooperation and assistance to the other Party and notify in writing without undue delay in relation to any request formulated by a data subject to exercise their rights to have access, correct, object or delete any Personal Data held about them in the context of the Agreement.
				4. notify the other Party in writing without undue delay and provide reasonable cooperation and assistance in the event of receipt of any request, allegation, complaint or the initiation of inspection proceedings by a competent Supervisory Authority, without undue delay for the adoption of the appropriate measures, if this affects the processing of personal data under this Agreement;
				5. save where a Party has a duty to keep the other Party’s personal data as required by the law, a competent supervisory authority and for client relationship purposes, delete or return all personal data to the other Party upon termination or expiry of this Agreement.
	4. In case that the disclosure of personal data is required for the performance of the Agreement, the Parties will provide the data subjects with an adequate privacy notice regarding said disclosure.
	5. Personal data of the Partner and of individuals representing the Company will be kept confidential. This data may only be used by the other Party if required by law or with prior written consent of the other Party.

The Partner consents to the Company using his/her personal data he/she has provided as set out under Appendix 3.

1. **Anti-bribery compliance**
	1. The Parties undertake to comply with any applicable anti-bribery regulations and codes relating to anti-bribery and anti-corruption (the “Anti-Bribery Laws”), including but not limited to the US Foreign Corrupt Practices Act and the UK Bribery Act 2010. The Partner is prohibited from offering or paying directly or indirectly anything of value to a government official or any other person, entity or institution covered under the Anti-Bribery Laws in order to:
2. win or retain business for the Company;
3. improperly influence an act or decision that will benefit the Company;
4. gain an improper advantage for the Company.

Partner undertakes to keep accurate and transparent records to reflect transactions and payments. Should the Partner breach or have any reason to believe that it might have breached this section, it shall inform the Company immediately, in writing, and cooperate with the Company to investigate and document the facts.

* 1. Partner will notify Company if Partner attains a position to influence purchasing decisions of a government entity of health-care-related institution (including a hospital, health board or any other institution of a similar nature). Such purchasing decisions may relate, for instance, to tenders issued by health authorities or decisions of formulary committees of public hospitals. In case of such notification by the Partner, Company has the right to terminate this Agreement with immediate effect by written notice. Partner shall also notify the purchase decision-maker in said institution of the Partner’s financial relationship with Company before any purchasing decision is made.
1. **Entire Agreement**
	1. The Agreement constitutes the entire agreement between the Parties, and supersedes and replaces any prior or contemporaneous communications, representations or agreements between the Parties, whether express or implied, oral or written, including all previous agreements with regard to the subject matter of the Agreement, as well as all negotiations, conversations and discussions between the Parties. The Parties will therefore not be able to derive any rights from prior agreements.
	2. Any amendment to the Agreement may be made only in writing and by mutual agreement between the Parties.
2. **Disputes**
	1. This Agreement shall be governed by and construed in accordance with the laws of insert country.
	2. Any dispute arising in connection with the Agreement which cannot be settled amicably mediation shall be submitted to the exclusive jurisdiction of the courts of the country in which the defendant has its main registered office as to the Company and its main registered office as to the Partner if the Partner is acting as a legal entity or its residence in case the Partner is acting as a physical person.

|  |  |
| --- | --- |
| Signed by the PartnerSigned ……………………………………… Date ……………………….. | Signed for and on behalf of the CompanySigned ……………………………………… Date ……………………….. |

IN WITNESS WHEREOF, the Parties have signed and executed the Agreement in [insert place of signing] on [insert date of signing], in two (2) originals, each Party acknowledging receipt of a signed original.

Appendix 1: Project details, Contribution, Financial terms and Confidentiality

Appendix 2: Expense Policy

Appendix 3: Consent form for the use of Personal Data

**Appendix 1: Project details, Contributions, Financial terms and Confidentiality**

This order is issued in accordance with the Agreement signed on Click here to enter a date by the Parties.

**I. Term**

Start date: Click here to enter a date.

Date of completion: Click here to enter a date.

**II. Description**

Details of any service, tools, products, to be delivered under the Agreement

Details of any pre-existing assets belonging to the Parties and that they agree to bring to the Project

**III. Governance**

Number of participants / identification of participants/ organisation of the meetings etc

**IV. Contributions and Financial terms**

The Contribution of the Company will consist in covering the Project Costs.

The Project Costs are detailed as follows:

Specify here the different costs of the Project title+ amount

The Contribution of the Partner will consist in the following posts:

Specify here the different resources to be provided by the Partner: title+ amount if possible (in the range of)

The work provided by the Partner will be covered by the Project Costs and will be paid to the Partner. Each 30 of the month, the Partner will issue an invoice addressed to Specify here to whom the invoice should be addressed for the work performed during the ongoing month, such invoice will be paid by bank transfer within 30 days following receipt of the invoice.

Specify here any additional payment terms

All amounts referred to in this Agreement are expressed exclusive of VAT (added if applicable).

 [In case the Partner refuses to be paid:

In-kind contributions by any partner without financial compensation should also be specified here.

**V. Confidentiality**

Specify here the third parties / names to whom the rules of disclosure of confidential information is extended, including all obligations for non-disclosure and confidentiality

**Appendix 2: Expense Policy**

**The Company agrees to cover:**

1. Reasonable travel expenses, e.g. inbound and outbound flight and/or train cost, accommodation, as well as transfer to and from the meeting venue, taking into account the specific needs, physical or mental, of the Partner’s condition (flights lasting more than six hours shall be in Business class);
2. Travel costs of accompanying person, in case Partner has a justified medical need to be accompanied by other persons;
3. In case of three-way travel or additional stayover at the meeting is required within Partner’s patient advocacy duty from preceding or to subsequent meetings, this shall be covered if deemed reasonable. Shared costs with other meeting organizers should then be considered wherever possible.

In addition, the Parties have agreed on the reimbursement of the following expenses:

Click here to enter text.

**The following terms of payment are agreed:**

Company shall either pay the above-mentioned expenses directly or reimburse Partner. Where Partner has incurred the expense directly, reimbursement will be made upon provision of satisfactory invoices/requests for payment and itemized receipts clearly detailing the nature of each expense claimed. Partner will always comply with the applicable laws, codes of practice.

The payment of expenses shall be paid by bank transfer within 30 days after receipt of the invoice.

**[For Europe only:]**

**Appendix 3 – Consent Form for the use of Personal Data**

In the context of the Agreement, the Company may use some of the personal data you (the "data subject") provided for various purposes. For some of these purposes, the Company may need to obtain your prior consent. The table below lists each of these purposes and allows you to consent (or not) to the use of your personal data by the Company for each separate purpose.

IMPORTANT: Your consent is entirely voluntarily and you are under no obligation to consent. Even if you provide us your consent, you can subsequently withdraw consent at any time (although this will not affect the lawfulness of any use of your personal data prior to such withdrawal) by

* using the provided form available on hyperlink
* notifying us in writing thereof on address
* or by e-mail e-mail address

Please note that if you do not provide us with your consent, or if you subsequently withdraw consent, we will not (no longer) be able to explain consequences of not consenting

|  |  |  |  |
| --- | --- | --- | --- |
| Data subject  | Purpose of the processing  | Types of personal data that will be processed  | Tick if you consent  |
| Clearly state which data subject's consent is sought-e.g. the Partner  | Clearly describe each purpose, e.g. to use Partner's health-related data for analysis purposes | Add text here | [ ]  I agree  |