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

**Reference agreement “Consultancy Agreement” version 1.2 (16 June 2020)**
This is a reference agreement, specific for Consultancy 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)

**CONSULTANCY AGREEMENT**

**BETWEEN**:

(1) Company name incl. legal form, a company organised 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 "**Consultant**";

The Company and the Consultant 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 organised 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 organisation], an organisation 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 "**Consultant**";

**WHEREAS:**

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

The Consultant 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, carer, patient advocate, patient organisation representative or patient expert (the "Consultant").

The Company wishes to engage the services of the Consultant to provide the services set forth below, and the Consultant wishes to provide such services. The services are provided for the purpose of supporting healthcare and/or research.

It is specified that the Company respects the mission, autonomy and independence of the Consultant 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, organisation, 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.

**Fees**: the compensation paid for the services performed by the Consultant to the Company as specified in Appendix 1, exclusive of the expenses such as travel costs.

**Services**: general consultancy and advisory services provided to the Company by the Consultant as set out in Appendix 1.

1. **Services**
	1. The Consultant shall provide the Services to the Company as set out in Appendix 1.
	2. The content of the Services may be amended by mutual written agreement between the Parties.

[**Add the following provision in case the contractual party is the patient organisation**]

* 1. The Parties agree that the Patient Organisation delegates to [insert name] who has the required expertise, the performance of the Services. [Insert name] shall perform the Services in compliance with the Consultant's obligations under this Agreement.
1. **Fees and expenses**
	1. For the Services rendered under the Agreement, the Consultant shall be compensated in accordance with the terms of payment described in Appendix 1.
	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 Fees and expenses are considered net of Value Added Tax ("VAT"). The Company will additionally pay VAT as legally required. The Consultant shall be responsible for all other taxes and/or any social security charges, as applicable, related to the Fee, unless otherwise agreed between the Parties or stipulated otherwise in the applicable law.
	4. The Parties acknowledge that the Fees for the Services 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 Services by the Consultant 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.
	5. The Company will ensure transparency of the payments made to the Consultant 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 fees and expenses of the Consultant which the Company has covered.
2. **Independence and conflict of interest**
	1. The Agreement does not create any relationship of agency, or partnership or employment or joint ventures between the Parties. The Consultant shall exercise its activities under the Agreement as an independent contractor.
	2. The Parties acknowledge that the Fees 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 Consultant.
	3. Wherever disclosure is required or appropriate, the Consultant commits to declare that it is providing Services to the Company whenever it writes, speaks or acts in public about a matter that is the subject of the Agreement.
	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.
3. **Term and termination**
	1. This Agreement comes into force upon signature by the Parties and shall remain in effect for the duration of the Services 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.
4. **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 Consultant 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 Services, 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. 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 Consultant:

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, the Consultant assigns to the Company all of its Intellectual Property Rights on materials and products developed or prepared for the Company by the Consultant in connection with the Services performed hereunder. However, the Consultant shall always be free to use the general knowledge, skills and experience and any general ideas, concepts, know-how and techniques that the Consultant has acquired or used in the course of performing the Services, subject to respecting confidentiality obligations under Article 6.

The Consultant guarantees 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 Company, without any liens, encumbrance or pledge whatsoever. This means that no third-party has any rights on the Services.

* 1. Any external use by one of the Parties 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 Consultant or the Company.
1. **Liability**
	1. To the extent permitted by law, the Consultant shall not be held liable for the performance of its Services under this Agreement, unless caused by gross negligence or wilful misconduct or omission. They shall in no circumstances be liable for any indirect or consequential loss or damage incurred by the Company in connection with the activities contemplated in this Agreement (such as a loss of profit or damage to the reputation of the Company, etc.).
	2. In any event, either Party’s liability is limited to a maximum of the Fees set out in Appendix 1, excluding VAT. If no Fee was paid, the Consultant's liability is limited to the amount of all expenses paid under this Agreement.
2. **Data protection [For Europe only]**
	1. During the term of the Agreement, in the context of performing the Services that are 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:
		* + 1. 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;
				2. implement and maintain appropriate technical, organisational 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 Consultant 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 Consultant consents to the Company using their personal data they have provided as set out in 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 Consultant 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.

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

* 1. The Consultant will notify the Company if the Consultant 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 Consultant, the Company has the right to terminate this Agreement with immediate effect by written notice. The Consultant shall also notify the purchase decision-maker in said institution of the Consultant’s financial relationship with the 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. For any dispute arising in connection with the Agreement which cannot be settled amicably by 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 in case the Consultant is acting as a legal entity or of the country in which the Consultant has its residence in case the Consultant is acting as a physical person.

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| --- | --- |
| Signed by the ConsultantSigned ……………………………………… 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: Description of the Services, Financial terms and Confidentiality

Appendix 2: Expense Policy

Appendix 3: Consent form for the use of Personal Data

**Appendix 1: Description of the Services, the 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 of the assignment**

Click here to enter text.

**III. Financial terms**

Specify here the financial terms, e.g. the fixed fee or hourly rate and hours to be covered

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

[In case the Consultant refuses to be paid:]

The Parties agree that there will not be any Fees paid under the Agreement. All provisions referring to the Fees are therefore not applicable.

Invoicing conditions:

The Consultant's invoice shall be paid by bank transfer within 30 days after receipt of a valid invoice.

**IV. 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 Consultant’s condition (flights lasting more than six hours shall be in Business class);
2. Travel costs of accompanying person, in case the Consultant 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 the Consultant’s patient advocacy duty from preceding or to subsequent meetings, this shall be covered if deemed reasonable. Shared costs with other meeting organisers 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:**

The Company shall either pay the above-mentioned expenses directly or reimburse the Consultant. Where the Consultant 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. The Consultant 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 Consultant  | Clearly describe each purpose, e.g. to use Consultant's health-related data for analysis purposes | Add text here | [ ]  I agree  |