Collaboration Agreement between a patient advocate and a pharmaceutical company

** Patient advocate is an individual or representative of a patient organisation that gives a voice to patients on healthcare related issues and looks out for the best interests of an individual or group of patients. Other terminology that might also be used is "patient representative" or "patient advisor" though the meaning might slightly differ. EUPATI defines "Patient Advocates" as persons who have the insight and experience in supporting a larger population of patients living with a specific disease. They may or may not be affiliated with an organisation. (Source: EUPATI)*

Reference agreement "Collaboration Agreement" version 1.2 (16 June 2020)

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

What is this Agreement about?

This is a standard Collaboration Agreement between a pharmaceutical company and a patient advocate[1]. This Agreement defines the terms and conditions of the collaboration and covers topics like confidentiality, intellectual property, copyright, data protection, compensation and other responsibilities of both parties.

What does the Agreement include?

The first part of the Agreement (i.e. sections "Between" and "Whereas" page 2) provides the contact details of the pharmaceutical company and of the patient advocate, and a definition of both. It sets the principle that the Company will respect the independence of the patient advocate in regards to his/her decisions and activities or those of the patient organisation (if the patient is affiliated with or works for a patient organisation).

- ❑ Make sure that your personal details are correct and that you are happy with the way you are described as a patient advocate in the text.

Then, the Agreement is divided into a total of 13 sections and 3 appendices which provide details of what has been agreed on.

- ❑ Please note that the specific details of what is expected from you, timeframes, fees and expenses are included in the appendices.

Sections 1 to 13 in a nutshell:

1. **Definitions**: This section provides definitions of some key concepts.

2. **Services**: This section outlines the purpose of the collaboration between patient advocate and company which is to work together to deliver the agreed on 'project'.

For more information about the principle of "confidentiality" you can also read section 3 of the Guiding Principles document.

3. **Contributions of both parties:** This section provides details on the contributions of both patient advocate and company including project costs and reimbursements by the company and resources, knowledge, etc by the patient advocate.
    - ❑ Make sure that you are happy with the outlined project costs and your listed contributions to the project that are further explained in Appendix 1.

For more information about the principle of "financial compensation and reimbursement of expenses" you can also read section 8 of the Guiding Principles document.

4. **Independence and conflict of interest:** This section is about the independence of the patient advocate from the company and defines his/her involvement as an "independent contractor". It explains that the company will respect and not influence the decisions of the patient advocate. In particular, the payment of a fee to the patient advocate for his/her involvement in the activities, should not influence his/her decisions in this involvement. The patient advocate is expected to declare, where appropriate, that he/she is involved in the activities.

For more information about the principle of "independence and conflict of interest" you can also read section 10 of the Guiding Principles document.

5. **Term and termination:** This section relates to the timeframe of the agreement between the company and patient advocate in the context of the activities. The exact times where the agreement comes into force and finishes are established in Appendix 1 Section 1 (Term). It provides information of how

[1] Although this reference contract is described between a pharmaceutical and patient advocate, it could also be modified to fit collaborations between medical device companies and the patient community, including patient organisations. This contract version here is for the collaboration in a project where the patient organisation and its representative take over particular tasks to be handled under their own responsibility – in contrast to the consultancy contract.

the agreement can be terminated before the time established in Appendix 1 and the necessary notice period for this.

6. **Confidentiality**: This section is about the information which will be shared between the patient advocate and the company and which will be considered as "confidential" and therefore, should not be disclosed to other people. It also contains details of the situations where confidentiality would not apply. The specific people and obligations for confidentiality are provided in Appendix 1 section IV.

For more information about the principle of "confidentiality" you can also read section 3 of the Guiding Principles document.

7. **Recording of the meetings:** This section is about the use of recordings in meetings that are made for the purposes of compiling minutes or a report of the meetings.

For more information about the principle of "recording of meeting" you can also read section 5 of the Guiding Principles document.

8. **Intellectual Property rights:** This section is about the protection of 'creations of the mind' which have both a moral and commercial value. It details clauses on copyright, external use, and sole or joint ownership of intellectual property rights on materials, data, and products developed. Please refer to Appendix 1 for more details on this.

For more information about the principle of "intellectual property rights" you can also read section 4 of the Guiding Principles document.

9. **Liability**: This section is about the legal responsibility of the patient advocate for his/her involvement with the company and explains in which situations a patient advocate could be legally responsible and to what amount of money.

For more information about the principle of "indemnification, remedies and conflict resolution" you can also read section 7 of the Guiding Principles document.

10. **Data protection** (Europe only): This section is about the personal data held by or relating to either party (patient/patient advocate and company) that may be exchanged during the time of the agreement. It outlines who is liable for the use of the data and how the data should be handled and used to ensure its protection.

For more information about the principle of "data protection" you can also read section 6 of the Guiding Principles document.

11. **Anti-bribery compliance:** This section is about the patient advocate and the company having to comply with existing anti-bribery laws and codes. It explains the type of conduct and ways of ensuring that the patient advocate can do so and who to proceed with if there is any breach or reasons to believe there may be a breach.

12. **Entire agreement:** This section is about the entirety of the agreement between the patient advocate and company and contains details about the replacement of any and all previous oral or written agreements. It also details that any changes to the agreement need to be agreed on by both parties and made in writing.

13. **Disputes:** This section is about any disputes (disagreements) that may come up in connection to the Agreement that cannot be settled appropriately between the parties. It details that the agreement is to be governed by the laws of the relevant country and how mediation works in cases of disputes.

The agreement starts below

COLLABORATION 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, resident at 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 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 "**Partner**";

WHEREAS:

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

1)

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, carer, patient advocate, patient organisation representative or patient expert.

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

2)

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.

1) This sentence justifies why we are entering into an agreement with this specific patient advocate i.e. because they have expertise and experience in a specific field.

In this context, this means that the person who will be involved as a patient advocate in the collaboration should have the relevant experience and expertise.

2) This means that the company does not aim to apply improper or inappropriate influence. In this context, it means that the Company will not influence the patient advocate's decisions or activities or those of the organisation the patient advocate is affiliated with.

NOW, THEREFORE IT IS AGREED AS FOLLOWS:

1. Definitions

Affiliate: any company, organisation, subsidiary[1] 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 policies 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,[2] funds, resources, know how brought by the Partner or the Company in order to deliver the Project as set out in Appendix 1.

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

*1) **Subsidiary** in this context would mean a company, corporation, or limited liability company that is a separate legal entity owned and/or controlled by another company that can have local and national branches.*

*2) **Inter alia** = This means "Among other things". Used to say that there are other things involved apart from the one you are mentioning.*

2.	**Purpose of the collaboration**
2.1	The Partners shall collaborate in order to deliver the Project as set out in Appendix 1.
2.2	The content of the Project may be amended by mutual written agreement between the Parties.
2.3	The Parties agree that the Company and the Partner delegate to the persons identified in Appendix 1 who has/have the required expertise, the performance of the Project.

This means that the person(s) who will be carrying out the activities for the Project have been agreed between the Company and the Patient Organisation and are named in Appendix 1

3. Contributions of both parties

3.1 As its Contribution, the Company agrees to fund the Project costs in accordance with the terms of Contribution described in Appendix 1 (the "**Project Costs**").

1)

3.2 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.

3.3 The above mentioned Project Costs and expenses are considered net of Value Added Tax ("VAT"). The Company will additionally cover VAT and other taxes, if legally required. The 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.

2)

3.4 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.

3.5 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, 3) 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.

4)

3.6 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.

*1) **reasonable** = Reasonable expenditure is usually taken as expenditure which is necessary to fulfil the contract (without being excessive). It may vary by contractor, so if you need further clarity on this in the context of the specific contract, you should discuss it in advance with the other party (see Annex 2 - Expense policy for more comments). Although circumstances will differ from situation to situation, as a general rule of thumb "reasonable" travel expenses include (1) air or train fare; (2) related additional transportation costs, such as taxis to and from the airport or from your hotel to and from the designated venue; and (3) hotel accommodations when an overnight stay is required.*

*2) **Staff** means the employees of a company/organisation, so this will not apply if the Partner is an individual.*

*3) **inter alia** = This means "Among other things"*

4) This provision is intended to inform the Partner that the Company can disclose the amounts paid under this Agreement. The objective is to inform the Partner, the obligation belongs to the Company.

4.	**Independence and conflict of interest**
4.1	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.
4.2	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.
4.3	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.
4.4	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.

*1) **Agency** - Refers to a person or entity that has the power to act on behalf of another person or entity, in other words, a relationship where one party has the legal authority to act in place of another (for example, a sales representative who has the authority to sign a sales contract on behalf of his/her company). This means that the patient advocate who is involved in the collaboration is considered an "independent contractor" e.g. the person is contracted just for the task described in the Agreement and this does not involve other types of relationship between the Company and the patient advocate (such as employment, partnership etc.)*

***A relationship of agency** always involves an agent and a principal. A principal is a party who gives legal authority to another to act on his or her behalf. The agent is obligated to act in the best interests of the principal because the agent's actions will create legal obligations for the principal.*

*2) **Joint venture** = A commercial activity undertaken jointly by two or more parties which otherwise retain their distinct identities*

*3) **Declare** In this context "declare" means that, when presenting or referring to the project in public, the patient will need to formally disclose their collaboration with the Company*

5.	**Term and termination**
5.1	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.
5.2	Both Parties shall have the right to terminate this Agreement without cause upon thirty (30) days' prior written notice to the other Party.

6. Confidentiality

6.1 The Parties undertake and agree to keep secret and confidential all Confidential Information, Confidential Information may be further specified in Appendix 1.

1)

6.2 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.

6.3 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.

6.4 The obligations and limitations 2) set forth herein regarding the Confidential Information shall not apply to information which is:

3)

(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 4) an applicable governmental or taxation or regulatory body or authority to whose jurisdiction the receiving Party is subject.

6.5 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. The receiving Party may be permitted to retain copies if required to demonstrate compliance with this Agreement or with legal proceedings.

*1) **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.** This means that when information is disclosed orally (e.g. as a part of a discussion or conversation) the Company or Patient Party should make reasonable efforts to explain to the other involved party if the information is confidential. In other words, it should be stipulated clearly to the respective party that the information is confidential.*

*2) **Set forth herein** means that a more detailed statement or explanation is addressed somewhere else in the document i.e. underneath in this case.*

***3) Section 6.4** - The obligations and limitations, regarding Confidential Information, described in the Agreement, shall not apply to: (i) information which is already in the public domain; (ii) information which was received by the patient from a third party which has the right to transmit it; (iii) the patient knew this information by other means before the information was disclosed to him/her by the Company and has records of this; (iv) the information is generally disclosed to third parties by the Company without any restriction concerning use or disclosure; (v) the patient has been required to disclose it by law, court or by rules and regulations of a relevant authority (e.g. governmental, taxation or regulatory).*

*4) **An applicable governmental or taxation...body =** required to be disclosed by law or by a court of competent jurisdiction or by the rules or regulation of ….a relevant governing body, taxation authority, or regulatory body.*

7. 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:

(i) is allowed by both Parties for internal purposes;

(ii) is permitted subject to the prior written consent of the other Party for any external use;

(iii) is permitted, in any case, where required for the performance, or for the verification of the performance, of the Services.

8. Intellectual Property rights

8.1 All information, data and Intellectual Property rights owned by each Party prior to this Agreement shall remain the property of that Party.

8.2 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.

8.3 In the event assignment of Intellectual Property Rights needs to be more specifically defined under applicable law, this assignment of copyright includes, without limitation:

(i) 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);
(ii) the right to publicly perform and communicate totally or partly the Services and by all means (e.g., slides, video, film, recordings, web site) ;
(iii) the right to translate totally or partly the Services in all languages;
(iv) 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;
(v) the right to claim copyright in the world for the full duration and any renewal or extensions.
(vi) This assignment of copyright is valid worldwide and for the duration of the copyright according to applicable law.

8.4 Each Party guarantee that the above Intellectual Property Rights have not been previously 1) assigned and/or licensed and that it is entirely free to be validly assigned to the other Party, without any liens, encumbrance or pledge 2) whatsoever. This means that no third-party has any rights on the Services

8.5 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.

*1) **Assigns** = gives*

*2) **Liens, encumbrance or pledge** = These are technical legal terms and in this context, they mean that there is no 3rd party who can claim that the consultant has already assigned the intellectual property to this party.*

***Pledges** are a form of security to assure that a person will repay a debt or perform an act under contract.*

***Encumbrance** is a broad term referring to any sort of claim against a property.*

***Lien** is a right which entitles a party to hold on to assets in their possession pending payment of a debt owed.*

9.	**Liability**
9.1	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 misconduct or omission. They 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 reputation etc.).
9.2	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.

9.1 *This means that, under this agreement and to the extent permitted under the law, the Consultant is not responsible for any bad consequences for the services provided, unless this is by* ***gross negligence*** *(a conscious disregard of the need to use reasonable care which results in an action that is likely to cause harm), intentional misconduct or intentional omission.*

Wilful omission *means to deliberately or knowingly failing to do or say something*

10. Data protection [For Europe only]

10.1 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.

1) 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)

10.2 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, 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.

10.3 In addition, each Party shall:

3)

(i) maintain, and procure that its employees and agents keep, Personal Data confidential in accordance with the Parties' confidentiality obligations contained in this Agreement;

(ii) 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;

(iii) 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.

(iv) 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;

(v) 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)

10.4 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)

10.5 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 their personal data they have provided as set out in Appendix 3.

*1) **Section 10.1** defines the roles and responsibilities of each party during the agreement.*
"...each party will be free to determine the lawful purpose…" = this sentence describes that the parties will have no joint liability/accountability regarding their collection, processing and use of data during the agreement, meaning that each party is liable and responsible on their own.

- ***Data controller** = the party that decides in the first place why and how to use the personal data*

*2) **Section 10.2.** Establishes that following the European General Data Protection Regulation (GDPR), the parties agree to observe the applicable laws and that all personal data is processed in a secure manner.*

- ***Alteration** = Making a change to [something]*

*3) **Section 10.3***

- ***Agent** in this context means that any 3rd party consultants or temporary staff within each contracting organisation (should also observe the data protection obligations within this agreement).*
- ***Data subject** is a generic legal terminology used to mean the individual(s) to whom data that is being collected during the agreement/ project relates and who can be identified.*
- ***(iv)** In the case of a request for information (sent by data protection authorities) concerning this agreement, the parties agree to notify each other of the request and cooperate to comply with the request.*
- ***(v)** If there is a legal obligation to retain the collected data, then the parties agree to comply, but if not, they should delete or return the data collected during the project.*

*4) **Section 10.4** describes that if there is a need to disclose/ share the collected data with a 3rd party as part of the project, the individuals whose data it is need to be notified/ informed.*
*5) **Section 10.5** sets the obligation for the parties to always have a written consent from the other party when collected data relating to the Speaker or to the representatives of the Company is being used for a specific purpose, unless they have to comply with a legal obligation to use data for certain purposes.*

- *The consent is collected by filling in and signing the form in Appendix 3.*

11. Anti-bribery compliance

11.1 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:

(i) win or retain business for the Company;

(ii) improperly influence an act or decision that will benefit the Company;

(iii) gain an improper advantage for the Company.

The 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.

11.2 The Partner will notify the Company if the 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, the Company has the right to terminate this Agreement with immediate effect by written notice. The Partner shall also notify the purchase decision-maker in said institution of the Partner's financial relationship with the Company before any purchasing decision is made.

Section 11 ***Anti-bribery*** *- A bribery is an attempt to make someone do something for you by offering, giving, receiving or soliciting of any item of value to influence the actions of an official, or other person, in charge of a public or legal duty*

Anything of value *refers to any good (or service provided) that has a certain benefit to the recipient that is real and that is ordinarily purchased rather than given away for free.*

12 Entire Agreement

12.1 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.

12.2 Any amendment to the Agreement may be made only in writing and by mutual agreement between the Parties.

Supersedes *means to replace something that is older. In this context it means that, for this particular Project, this Agreement replaces any previous or current agreements, communication, representations, discussions or conversations between the Company and the patient related to the Project, either in written or oral.*

Contemporaneous *= Existing or done at the same time*

13. Disputes

13.1 This Agreement shall be governed by and construed in accordance with the laws of insert country.

13.2 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 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.

Section 13.1 - ***Construed*** *= understood or interpreted*

Section 13.2 - This article specifies how and where any disputes will be determined. It assumes that in the event of a disagreement, there will first be an attempt to resolve it through mediation. If it cannot be resolved by mediation, the person (company or consultant) will need to sue in a court where the other person lives or, for a corporate entity, is registered.

Signed by the Partner	Signed for and on behalf of the Company
Signed ……	Signed ……
Date ……..	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 30th 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

In-kind contribution *is a non-monetary contribution as opposed to "in cash" (=money), for example when the service is offered by the patient free of charge (e.g. the person prefers not to be paid for his/her involvement in the Project). On the company's side, this could be for example, providing a meeting room to a patient organisation.*

Appendix 2: Expense Policy

The Company agrees to cover:

I. 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);

II. Travel costs of accompanying person, in case the Partner has a justified medical need to be accompanied by other persons;

III. In case of three-way travel or additional stayover at the meeting is required within the Partner'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 Partner. Where the 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. The 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.

*This section explains that expenses which are **reasonable** will be reimbursed/paid and provides examples of some of the types of expenses which should be considered as reasonable. This is an important issue as it means that some expenses if considered as unreasonable may not be reimbursed. Ideally this should be discussed and agreed in advance.*

Although circumstances will differ from situation to situation, as a general rule of thumb "reasonable" travel expenses include (1) air or train fare; (2) related additional transportation costs, such as taxis to and from the airport or from your hotel to and from the designated venue; and (3) hotel accommodations when an overnight stay is required.

[For Europe only:]

Appendix 3 – Consent Form for the use of Personal Data

1)

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

2)

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

This Appendix serves as a consent form that should be pre-filled by the contracting parties and signed by the individual(s) who give their consent for the pre-defined purpose.

*1) **Data subject** is a generic legal terminology used to mean the individual(s) to whom data that is being collected during the agreement/ project relates and who can be identified. In this Appendix specifically it means the patient advocate (consultant) who is giving his or her consent for the purposes described.*
2) This means that if individuals do not provide the Company with their consent, or if they have already consented, but subsequently withdraw their consent, there may be consequences for them –although they will not suffer from negative consequences. The Company seeking the individuals' consent may not be able to explain in detail the consequences of not consenting or withdrawal, besides the information already provided to the individuals.