



EUPATI Code of Conduct and Ethical Framework

June 2020

Introduction

The European Patients' Academy on Therapeutic Innovation (EUPATI) is a pan-European project implemented as a public-private partnership by a collaborative multi-stakeholder consortium from the pharmaceutical industry, academia, not-for-profit, and patient organisations, all with a strong track record in medicine, patient engagement and education, and several of which have not previously worked together.

EUPATI builds on the strength of having a diverse group of stakeholders from different stages and perspectives of the medicines development process. The expertise and insights from EUPATI consortium partners, network members and external advisors was supported by qualitative and quantitative research as well as a systematic literature review conducted by EUPATI prior to content production.

List of contributors to EUPATI can be found at www.eupati.eu.

Scope

The Code of Conduct outlines the working culture and spirit of “assumed good intent” within EUPATI, while the Ethical Framework outlines the ethical ground rules.

This document applies to all EUPATI partners and all those involved in carrying out work for EUPATI. For the purpose of this document, they will be referred throughout as “contributors”.

Adherence

In addition to ensuring that they respect national legal requirements, all contributors are required to confirm in writing that they have read and understood and adhere to both, EUPATI Code of Conduct and Ethical Framework.

Code of Conduct

1. Rational

The Code of Conduct is based on the conviction that

- A strong partnership between partners of a collaborative multi-stakeholder project is likely to generate benefits for all parties involved.
- The integrity, credibility and independence of all involved contributors, as well as the constraints and obligations under which all contributors operate, should be respected at all times.
- A partnership in which the integrity and credibility of all parties concerned are upheld should be underpinned by core principles and values.
- The perspective of patients is unique in nature and therefore should be valued as specialist knowledge and complementary to knowledge of other experts, academia, industry, regulators and HTA bodies.

2. Principles

○ Mutual Respect

All contributors act in accordance with the principles of mutual respect. This implies that all contributors' competences, capabilities, working culture and environment shall be taken into account, understood and respected.

○ Trust

All contributors work together in a spirit of mutual trust and assumed good intent. This is underpinned by openness and clarity of communication, and genuinely shared efforts and responsibilities to contribute to common goals, although the methodology and rationale may differ across the partnership.

○ Reliability and Responsibility

All contributors commit to adhere to the partnership agreement and to rely on each other in order to achieve the EUPATI goals.

To evaluate the progress based on goals, objectives and terms agreed by all contributors at the beginning of the collaboration, the EUPATI Board conducts an annual review of the partnership.

In the event of conflict or dispute between contributors, it will be addressed by the EUPATI Board, which attempts to resolve it collectively, reflecting the spirit and principles of this code of conduct.

○ Transparency

All contributors agree to open, honest, fair and transparent communication between each other and to public at large. This includes:

- Clarity about each partner's roles and responsibilities;
- Being open about the constraints under which each party is operating;

- Publicly disclosing any other personal and institutional relationships and collaborations that might influence the partnership, as described in the section [Ethical Framework](#);
- Acknowledging each partner's role and contributions when reporting on the outcomes that resulted from the partnership;
- Showing that the resources contributed by each party to the partnership have been used appropriately as described in the partnership agreement;
- Any activity jointly undertaken with a patient organisation should operate within their constitution, articles and codes of practice;
- Contributors' independence should not be compromised or perceived as being compromised because of collaboration with fellow partners;
- No partner should seek to gain competitive advantage/or use confidential information from the partnership for its own gain.
- Adhering to the EUPATI Foundation reporting rules concerning project strategies, decision making rules, procedures, progress and outcomes as well as by ensuring regular status communication in different media, publications and in face-to-face opportunities.

- **Accountability**

All contributors are accountable for their work and should agree on the ways in which they will report back to their members, colleagues, partners and general public about their collaboration.

- **Proprietary material**

- Use of EUPATI material

Ownership and intellectual property rights of materials produced in the collaboration should be agreed upon upfront.

The terms for the use of the EUPATI name, brand and / or logo by any partner must be discussed ex ante.

- Use of other material

Patent protection rules for all material collected for EUPATI purposes is respected.

- Acknowledgement

The terms for acknowledgement of any resources, product, material and / or any other outcomes developed in the framework of the collaboration should be discussed before and an agreement is reached on how the contributors individually and collectively acknowledge them.

- **Public Disclosure**

All contributors share the responsibility of dissemination of results of the collaboration, which should be made publically available during and beyond the lifetime of the collaboration to create maximum value for the whole community.

Fair accessibility of results to different communities in a fully transparent mode should be guaranteed. By communities are understood any of the following:

- different linguistic groups
- groups of persons with different levels of health literacy
- groups of persons with particular physical limitations
- groups of persons having different access to technologies, in particular computer and internet access, etc.
- groups of persons having different access to healthcare provision

It is deemed unethical to withhold the publication of any results of research, on whether the results are positive, negative or inconclusive.

- **Sustainability**

All contributors explore opportunities for a sustainable and long-term relationship, beyond the lifetime of the collaboration.

Ethical Framework

1. Rational

The Ethical Framework is based on the convictions that:

- A strong partnership between contributors of a collaborative multi-stakeholder consortium is likely to generate benefits for all parties involved in their attempts to accelerate the new treatment options.
- The integrity, credibility and independence of all involved contributors, as well as the constraints and obligations under which all contributors operate, should be respected at all times.
- A partnership in which the integrity and credibility of all parties concerned are upheld should be underpinned by core principles and values.
- The perspective of patients is unique in nature and therefore should be valued as specialist knowledge and complementary to knowledge of other experts, academia, industry, regulators and HTA bodies.
- The perspective of patients is frequently represented by patient organisations which integrate the experience of their members and disseminate this combined knowledge to help improve the disease conditions and quality of life of their members. Incorporating this patient expertise into the clinical development process will lead to clinical research and treatments that are more adapted to the real needs of patients.

2. EUPATI Ethics Panel

The core remit of the EUPATI Ethics Panel, appointed by the EUPATI Secretariat, is to provide the infrastructure and access to the required intelligence and genuine expertise in ethics and law as pertains to the medicines development processes and patient advocacy.

It advises all parties involved in EUPATI on ethical aspects, including conflicts of interest.

3. Principles

The Ethical Framework sets additional principles to the ones outlined in the section of the [Code of Conduct](#).

- **Non-maleficence:**

No physical, social or psychological harm to all those involved in the EUPATI project, particularly when vulnerable by virtue of age, social status, disability or medical condition. Decisions that primarily protect the health and well-being of patients and also advance medical knowledge for the scientific and wider public benefit are taken. No financial gains or other material benefits from this project for contributors, their families or friends

- **Equality:** all participants are treated as equals by not being biased

- **Independence, objectivity and neutrality**

Independence in selection of training / education / information material, objectivity and neutrality in its adaptation to the different patient audiences' needs, in dissemination and in allocation of resources for production and dissemination is ensured.

- **Integrity**– of behavior, processes, activities. Falsification or misrepresentation of evidence, data, findings or conclusions are avoided.

- **Declaration of Conflicts of Interest**

Conflicts of interest may arise when an individual's personal, business, economic, occupational or professional interests or loyalties conflict with the interests of EUPATI, in the course of their EUPATI activities (e.g. writing or reviewing content, taking editorial decisions, etc.) and / or EUPATI's principles on transparency, objectivity and independence.

Therefore, public declaration and management of potential conflicts of interest are of major importance. All contributors involved in EUPATI annually complete and update their disclosure, which includes their professional and non-professional activities and affiliations, which are made available to the governing bodies of EUPATI.

Identified potential conflicts of interest are reported to the EUPATI Board for resolution.

- **Anonymity and privacy:**

All activities are conducted in compliance with the Charter of fundamental rights of the European Union, in particular with its articles 7 (Respect for private and family life) and 8 (Protection of personal data). EUPATI handles all personal data in line with the European General Data Protection Regulation (GDPR). Identities and project records are kept confidential, with appropriate data protection measures, whether or not an explicit pledge has been given.

Participants are made aware that they are entitled to reject particular forms of data-gathering (e.g., use of devices such as tape-recorders and video cameras) but that it is not always possible to conceal identities completely, and that anonymity can sometimes be compromised unintentionally.

- **Consent:**

Elements of EUPATI activities constitute social research. Written consent from participants is gained and individuals' rights are respected, as below:

- Informed: given in possession and understanding of all information related to EUPATI;
- Voluntary: given freely and not as a result of coercive pressure (real or perceived);

- Competent: given by an able person who, by virtue of age, maturity and mental stability, is capable of making a free and considered choice;
- Well understood: what the research is about, why it is being conducted, who it is being conducted for and who is funding it, what the purpose of the study is and what will happen to the results, where the results will appear and who is likely to have access to them, what will be expected of them if they agree to participate and how long their participation will take, what anonymity and confidentiality mean in practice and that they can withdraw at any time or decide not to participate.