Code of Conduct

Code of Conduct for all stakeholders involved in patient engagement activities within medicines development.

Background/Rationale

There is no European or international legislation defining the rules for patient engagement in medicines' lifecycle activities. Guidelines and recommendations exist covering different aspects and conditions of the collaboration between patients, sponsors, ethics committees, competent authorities or HTA bodies. However, an overarching Code of Conduct, facilitating patient engagement in practical terms, common values, ethical principles and rules for the collaborating partners is missing. Substantiated by the project's own gap analysis, PARADIGM aims to close this identified gap by developing this Code of Conduct to be applied by all stakeholders involved in patient engagement activities within medicines development.

Objective

This Code of Conduct is intended to be a stand-alone document that highlights, summarises and refers to the key patient engagement principles, rules and recommendations for collaboration presented in the different PARADIGM documents in the Toolbox in a comprehensive, understandable format.
Fact Sheets summarising the content of the different documents can be found in the Annex of this Code of Conduct. It should be read in conjunction with these.

Summary of the content

This code of conduct contains sections on the following topics:

- Ethical Principles for Patient Engagement in the Life Cycle of a Medicine
- Contractual Framework
- Competing Interests, Conflict of Interest, and Conflict

Management
- Intellectual Property, Confidentiality and Data Protection
- Access to Information and Transparency
- Accessibility of Patient Engagement Opportunities
- Representativeness
- Competencies and Capacity Building
- Adherence to the Code of Conduct
- References
- Annex 1: Fact Sheets of PARADIGM Documents

Key messages

This Code of Conduct describes the essentials for meaningful collaboration of all stakeholders involved in patient engagement activities within medicines development.

Adherence to this Code of Conduct is essential to ensure an open and fruitful interaction of engaging partners with patients and their representatives.

All stakeholders of the patient engagement community should voluntarily integrate the rules of this Code of Conduct into their collaborations and insist on observance, especially in cases of non-compliance.

Methodology

The following steps were taken in preparation of the “Code of Conduct for all stakeholders involved in patient engagement activities within medicines development” which had already been identified in the project agreement as a need to be addressed:

In late 2018:	preparatory work for the early development process

January 2019:	main partners of T4.2 representatives each of WP2 and PFMD, agreed the material to be developed
March 2019:	WP4 workshop in Berlin, including patient advocates, representatives from patient organisations, industry, academia, HTA bodies, NGOs and SMEs. Breakout groups per topic, decided on content to be developed in the known gap areas, actions and deadlines for delivery of materials were agreed, working group (WG) established, leads assigned and members of T4.2 invited to join the WG as authors or reviewers
April 2019:	Start “early development work”
July 2019:	First draft available (through iterative co-authoring/review by authoring group and WG reviewers)
September 2019:	Gap subsequently also identified by WP2 gap analysis under ‘Legal and ethical considerations’, informing on several key elements.
April 2020:	Advanced draft available for WP4 internal review, incorporating WP2 gap analysis
May 2020:	Revised draft, incorporating comments for consortium and PILG consultation
June 2020:	Final draft for public consultation.
July 2020:	Public consultation and presentation at the PEOF

All feedback received throughout the consultation rounds was addressed and consolidated. This was supported by the editorial team who worked to ensure consistency across the outputs.

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