ENCePP Code of Conduct Qualitative Survey

Fields marked with * are mandatory.

Introduction

Background

The **European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP)** is a network coordinated by the European Medicines Agency (EMA) responsible for the scientific evaluation, supervision and safety monitoring of medicines in the European Union. The members of this network are public institutions and contract research organisations (CRO) involved in **research in pharmacoepidemiology and pharmacovigilance**. Research interests are not restricted to the **safety of medicines** but may include the **benefits and risks of medicines**, **disease epidemiology** and **drug utilisation**. ENCePP aims to strengthen the monitoring of the benefit-risk balance of medicinal products in Europe.

A “Code of Conduct” is an agreement on rules of behaviour for a group or organisation promoting the implementation of best practice standards. The **ENCePP Code of Conduct** (the Code) has been developed to promote and support **scientific independence** and **transparency** throughout the pharmacoepidemiology and pharmacovigilance research process and, consequently, to strengthen the confidence of the general public, scientific community and all stakeholders in the integrity and value of the research. The Code sets out **rules and principles for non-interventional post-authorisation studies**, namely those conducted after a medicinal product has been approved for marketing.

The latest **revision 4** of the Code adopted by the ENCePP Steering Group in March 2018 aims to clarify and support the practical implementation of the Code's provisions. It addresses the need to avoid research being influenced by commercial, financial or institutional interests of study funders where there is potential to threaten scientific independence. It proposes strategies to separate the power and influence of study funders from researchers’ responsibilities for scientific integrity. The Code also addresses potential personal interests of researchers.

The latest version of the Code (and related documents) can be found here.

A summary of the main changes of revision 4 can be found here.

Purpose of the survey

The aim of this survey is to evaluate how this new version of the Code is understood by potential users and beneficiaries and how it will be applied. For this purpose, we seek feedback from persons who

- fund, conduct or use research for clinical or regulatory decision-making, or for policy development or evaluation;
- are interested in the quality of studies evaluating healthcare services (relatives of patients, or consumers at large);
- are patients or consumers whose data are used in research or whose health is influenced by study results.

We identified you as a member of one of these groups and we would be grateful if you could assist us by answering the survey.
This short survey, based on 5 items, will take only a few minutes to complete.

Privacy Statement
By participating in this survey, your submission will be assessed by EMA. However, EMA does not collect and store your personal details.

Data protection notice
For more information about the processing of personal data by EMA, please read the data protection notice attached.

Thank you for your response by 15 June 2018.

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Data_Protection_Notice_ENCePP_Code_of_Conduct_Survey.pdf

Question Section 1: Demographic information

* **1-A Please select the category of respondent you belong to** *(tick appropriate button).*

- ○ Patient / consumer organisation representative
- ○ Pharmaceutical industry
- ○ Researcher (academic, contract research organisation, other type of research professional not employed by pharmaceutical industry)
- ○ Healthcare professional (clinician, pharmacist, nurse, other healthcare provider)
- ○ Public health body or regulator

* **1-B How would you rate your level of knowledge about observational post-authorisation studies** *(tick appropriate button)***?**

- Very limited knowledge
- Limited knowledge
- Average knowledge
- Fairly good knowledge
- Expert

* **1-C Please select your country of residence.**

- Afghanistan
- Albania
- Algeria
- Andorra
- Angola
- Antigua and Barbuda
- Argentina
- Armenia
- Australia
- Austria
- Azerbaijan
- Bahamas
- Bahrain
- Bangladesh
- Barbados
- Belarus
- Belgium
- Belize
- Benin
- Bhutan
- Bolivia
- Bosnia and Herzegovina
- Botswana
- Brazil
- Brunei Darussalam
- Bulgaria
- Burkina Faso
- Burundi
- Côte D'Ivoire
- Cabo Verde
- Cambodia
- Cameroon
- Canada
- Central African Republic
- Chad
- Chile
- China

- Colombia
- Comoros
- Congo
- Costa Rica
- Croatia
- Cuba
- Cyprus
- Czech Republic
- Democratic Republic of the Congo
- Denmark
- Djibouti
- Dominica
- Dominican Republic
- Ecuador
- Egypt
- El Salvador
- Equatorial Guinea
- Eritrea
- Estonia
- Ethiopia
- Fiji
- Finland
- France
- Gabon
- Gambia
- Georgia
- Germany
- Ghana
- Greece
- Grenada
- Guatemala
- Guinea
- Guinea Bissau
- Guyana
- Haiti
- Honduras
- Hungary
- Iceland
- India
- Indonesia
- Iran
- Iraq
- Ireland
- Israel
- Italy
- Jamaica

- Japan
- Jordan
- Kazakhstan
- Kenya
- Kiribati
- Kuwait
- Kyrgyzstan
- Laos
- Latvia
- Lebanon
- Lesotho
- Liberia
- Libya
- Liechtenstein
- Lithuania
- Luxembourg
- Madagascar
- Malawi
- Malaysia
- Maldives
- Mali
- Malta
- Marshall Islands
- Mauritania
- Mauritius
- Mexico
- Micronesia
- Monaco
- Mongolia
- Montenegro
- Morocco
- Mozambique
- Myanmar
- Namibia
- Nauru
- Nepal
- Netherlands
- New Zealand
- Nicaragua
- Niger
- Nigeria
- North Korea
- Norway
- Oman
- Pakistan
- Palau

- Panama
- Papua New Guinea
- Paraguay
- Peru
- Philippines
- Poland
- Portugal
- Qatar
- Republic of Moldova
- Romania
- Russian Federation
- Rwanda
- Saint Kitts and Nevis
- Saint Lucia
- Saint Vincent and the Grenadines
- Samoa
- San Marino
- Sao Tome and Principe
- Saudi Arabia
- Senegal
- Serbia
- Seychelles
- Sierra Leone
- Singapore
- Slovakia
- Slovenia
- Solomon Islands
- Somalia
- South Africa
- South Korea
- South Sudan
- Spain
- Sri Lanka
- Sudan
- Suriname
- Swaziland
- Sweden
- Switzerland
- Syrian Arab Republic
- Tajikistan
- Tanzania
- Thailand
- The former Yugoslav Republic of Macedonia
- Timor-Leste
- Togo
- Tonga

- Trinidad and Tobago
- Tunisia
- Turkey
- Turkmenistan
- Tuvalu
- Uganda
- Ukraine
- United Arab Emirates
- United Kingdom
- United States of America
- Uruguay
- Uzbekistan
- Vanuatu
- Venezuela
- Viet Nam
- Yemen
- Zambia
- Zimbabwe

Points to consider

- Please provide your own personal opinion and not the perspective of the group you belong to.
- Comments are optional and explicitly invited if you want to nuance your opinion.
- The ENCePP Code of Conduct is referred to as “the Code” in the following questions.

Question Section 2: Importance of scientific independence and transparency in specific contexts

* **2: Applying the Code would be beneficial for the following types of studies** (*select all the answers reflecting your perspective*):

- Studies **imposed as a condition** by regulatory bodies for getting (or maintaining) a marketing authorisation of a medicinal product.
- Studies **required by regulatory bodies** to be part of the medicinal product’s risk management plan (e.g. to investigate a safety concern or evaluate the effectiveness of risk minimisation activities).
- Studies **initiated/conducted voluntarily by a pharmaceutical company** (i.e. not imposed or required) for the generation of observational data (e.g. drug utilisation, gathering safety data, effectiveness in usual clinical practice, healthcare costs, better understanding of the natural history of a disease, etc.).
- Studies **initiated/conducted voluntarily by academic researchers** (i.e. not imposed or required) and **using external funding** for generation of observational data (e.g. drug utilisation, effectiveness in usual clinical practice, healthcare use, better understanding of the natural history of a disease, etc.).
- Studies **initiated/funded by health policy makers** for generation of observational data (e.g. evaluate the effectiveness of a vaccination program).
- Studies **initiated/conducted by patient advocacy groups** and **using external funding** (e.g. pharmaceutical company, European Union funded research grants).
- Other specific studies (please describe in comments).
-

All types of studies (regardless of whether imposed, required or voluntarily conducted) if results are intended to be **used for any societal decision on a medicinal product** including pricing and reimbursement or influencing healthcare policies. Please specify the types of studies in comments below.

- ☐ **All studies** regardless of the use of their results. Scientific independence and transparency should be ensured **systematically**.
- ☐ I am not convinced applying the Code would add value to any type of study.
- ☐ I do not know.

* **2: Applying the Code would be beneficial for the following types of studies** (*select all the answers reflecting your perspective*):

- ☐ Studies of **effectiveness of medicines in usual clinical practice**, with the potential of expanding or restricting access to medicines.
- ☐ Studies of **safety of medicines**.
- ☐ All types of studies if **study results are intended to be used for any official decision on a medicinal product** (including pricing and reimbursement or influencing healthcare policies).
- ☐ All types of studies if the **study is funded by a pharmaceutical company**.
- ☐ All types of studies if the **study is funded by a public health body**.
- ☐ Other studies (please describe in comments).
- ☐ **All studies** regardless of the use of their results. Scientific independence and transparency should be ensured **systematically**.
- ☐ I am not convinced applying the Code would add value to any type of study.
- ☐ I do not know.

Comments:

500 character(s) maximum

Question Section 3: The Code - clarity and feasibility

* **3: The principles and rules of the Code (as further explained in the summary of revision 4) seem to me** *(tick appropriate button)*:

- ○ Easy to understand and easy to implement in practice.
- ○ Easy to understand but difficult to implement in practice.
- ○ Difficult to understand and difficult to implement in practice.
- ○ I am not expert enough to provide any perspective about this.

Comments:

500 character(s) maximum

The Code has been developed to promote and support **scientific independence** and **transparency** throughout the pharmacoepidemiology and pharmacovigilance research process and, consequently, **to strengthen the confidence of the general public, scientific community and all stakeholders in the integrity and value of the research**. The Code sets out rules and principles for non-interventional post-authorisation studies, namely those conducted after a medicinal product has been approved for marketing.

3.1: Do you understand what is meant by the principle of scientific independence and transparency (as further explained in the summary of revision 4) in a study** *(tick appropriate button)?**

- Yes definitely.
- Yes likely.
- Average.
- Not really.
- Not at all.

Comments:

500 character(s) maximum

3.2: Do you find the principle of scientific independence and transparency important** *(tick appropriate button)?**

- Yes definitely.
- Yes likely.
- Average.
- Not really.
- Not at all.

Comments:

500 character(s) maximum

Question Section 4: Trust in study results

4: Studies applying the Code would reinforce my trust in the study results** *(tick appropriate button).**

- Yes definitely.
- Yes likely.
- Average.
- Not really.
- Not at all.

Comments:

500 character(s) maximum

Question Section 5: Personal engagement in a study compliant with the Code versus a non-compliant study

***5: Studies applying the Code would stimulate my participation in the study as study subject** *(tick appropriate button)*.**

- Yes definitely.
- Yes likely.
- Average.
- Not really.
- Not at all.

***5: Studies applying the Code would stimulate my funding of the study** *(tick appropriate button)*.**

- Yes definitely.
- Yes likely.
- Average.
- Not really.
- Not at all.

***5: Studies applying the Code would stimulate my participation as researcher in the study** *(tick appropriate button)*.**

- Yes definitely.
- Yes likely.
- Average.
- Not really.
- Not at all.

***5: Studies applying the Code would stimulate my participation as investigator in the study** *(tick appropriate button)*.**

- Yes definitely.
- Yes likely.
- Average.
- Not really.
- Not at all.

***5: I would foster the use of the Code for my own research or research commissioned by my institution** *(tick appropriate button)*.**

- Yes definitely.
- Yes likely.
- Average.

- Not really.
- Not at all.

Comments:

500 character(s) maximum

Question Section 6: Complementary guidance

*** 6: How do you perceive the Code in context of other guidelines such as ADVANCE, ISPE GPP, ICMJE Recommendations, etc.** *(tick appropriate button)* **?**

- A useful complementary guideline filling gaps in other guidelines.
- The Code seems to me overlapping with other guidelines, thus may generate confusion.
- The Code seems to me a stand-alone guideline.
- Other perspectives (please describe in comments).
- I do not know other guidelines enough to provide any perspective about this.

Comments:

500 character(s) maximum