



## Checklist of the ENCePP Code of Conduct

The purpose of this checklist is to emphasize the key elements of the ENCePP Code of Conduct that are relevant at the time of study start. The act of completing this checklist confirms that the study complies – at the time of submission - with the core principles of the Code.

The checklist must be completed<sup>1</sup> by the (primary) lead investigator of the study who should:

- Tick all boxes of each section thereby confirming compliance of the study with the Code's core principles and respective provisions for implementation. In case of sub-sections (e.g. 2.A. and 2.B.), tick all boxes of the sub-section that applies to the study.
- If applicable, provide additional information as requested.
- Sign the checklist.

*The undersigned declares upon honour the following answers on behalf of the organisation that he/she represents. Signature should be by the (primary) lead investigator.*

1. General	Check
The study has been designed in line with the Code's core principles of <ul style="list-style-type: none"> <li>• scientific independence (see Chapter 3.1 of the Code), and</li> <li>• transparency (see Chapter 3.2 of the Code).</li> </ul>	<input checked="" type="checkbox"/> <input checked="" type="checkbox"/>
2. Research contract	Check
2.A. Studies financed purely from one's own general resources (100% self-funded)	
A declaration on the use of one's own general resources, making clear references to the study and the (primary) lead investigator and being signed by (an) authorised representative(s) of the participating study entity/ies is available.	<input type="checkbox"/>
2.B. Studies receiving financing from external sources	
A research contract between the (primary) lead investigator and/or the coordinating study entity and the study funder has been concluded prior to study start.	<input checked="" type="checkbox"/>
The contract includes the following information:	

<sup>1</sup> Complete the Checklist on screen, then print and scan a signed and stamped (if applicable) copy.

- The main objectives and a brief description of the intended methods of the research as well as a clear assignment of tasks and responsibilities.
- The procedure for achieving agreement on the study protocol as well as the involvement of the funder (and regulatory authority if applicable) in the development of the protocol.
- The amount of the financial support and the payment scheme.
- Conditions for access to the study data.
- Ownership of intellectual property rights arising from the study
- A communication strategy for the scheduled interim (if applicable) and final results.

### 2.B.1 Studies financed entirely from public funding schemes

A reference to the Code is included in relevant parts of the project proposal or equivalent documents<sup>2</sup> in such a way that acceptance of the project proposal or equivalent document by the funding body constitutes agreement to adhere to the provisions of the Code including the requirement for unrestricted freedom of the investigator to publish.

### 2.B.2 Studies not financed from public sources

The statement "The parties to this agreement and individuals acting on their behalf hereby commit to adhere to the rules of the ENCePP Code of Conduct in their entirety" is included in the research contract and the latest version of the Code at the time of the signature of the contract is annexed;

OR

where this is not possible, a separate agreement with the funder has been concluded that clearly references the particular study, includes the above statement on adherence to the Code and states that this adherence with the relevant version of the Code is an additional requirement to those in the (clearly referenced) research contract.

## 3. Registration of studies

Check

The study has been/will be registered<sup>3</sup> in the EU PAS Register<sup>®</sup> before its start.

## 4. Study protocol

Check

A full study protocol<sup>4</sup> has been developed before study start.

<sup>2</sup> Any document that includes a description of the study to be funded and that has been endorsed or is otherwise recognised by the funding body.

<sup>3</sup> A study is deemed registered in the EU PAS Register<sup>®</sup> once the application has been approved by the ENCePP Secretariat.

<sup>4</sup> For the purpose of the Code of Conduct, a *full* study protocol is a version of the protocol which includes enough detail in order to answer all questions in the *ENCePP Checklist for Study Protocols*, available at [http://www.encepp.eu/standards\\_and\\_guidances/checkListProtocols.shtml](http://www.encepp.eu/standards_and_guidances/checkListProtocols.shtml).

The latest version of the full study protocol is uploaded to the EU PAS Register <sup>5</sup> .	<input checked="" type="checkbox"/>
A system is in place to allow for documentation of changes to the original version of the study protocol in a traceable and auditable way.	<input checked="" type="checkbox"/>
Information on all parties involved in the writing and adoption of the protocol including a brief description of their contribution is being made publicly available.	<input checked="" type="checkbox"/>
A detailed statistical analysis plan is described and included in or annexed to the study protocol.	<input checked="" type="checkbox"/>
<b>5. Intellectual property rights and sharing of data</b>	<b>Check</b>
A system has been put in place in order to record the data collected and processed in the study in a way that allows corroboration of published results.	<input checked="" type="checkbox"/>
A detailed description of how raw data were transformed into the data set for analysis will be available at the end of the study.	<input checked="" type="checkbox"/>
All possible steps to provide for audits by competent authorities will be taken.	<input checked="" type="checkbox"/>
Appropriate plans and agreements, if necessary, are being or have been made to respond to requests for data sharing in line with the <i>Implementation Guidance on Sharing of Study Data</i> (Annex 4).	<input checked="" type="checkbox"/>
A procedure for access to the analytical data is described in, or annexed to, the study protocol including the degree to which data can be shared and, if access is restricted, a justification why access is limited.	<input checked="" type="checkbox"/>
Please indicate the page number in the study protocol: <b>Section 11.3</b>	
<b>6. Declaration of interest</b>	<b>Check</b>
Declarations of interests of the core team members involved in the conduct of the study are documented and be made public (including members of the study steering group or committee, if established).	<input checked="" type="checkbox"/>
All persons with a financial, commercial or institutional interest in a particular outcome of the study are excluded from participation in any study activity which could influence the results or interpretation thereof in a particular direction.	<input checked="" type="checkbox"/>

<sup>5</sup> When uploading the protocol in the EU PAS Register<sup>®</sup>, it may not be immediately accessible to the public unless the (primary) lead investigator so chooses.

7. Study steering group or committee	Check
<b>7.A. Absence of a study steering group or committee</b>	
Please check here if no steering group or committee is foreseen for the study.	<input type="checkbox"/>
<b>7.B. Establishment of study steering group or committee is foreseen</b>	
No expert with a direct conflict of interest is appointed as a member.	<input checked="" type="checkbox"/>
The composition is being/will be made publicly available.	<input checked="" type="checkbox"/>
8. Publication/Reporting of studies	Check
Appropriate plans and agreements, if necessary, have been made (e.g. as part of the dissemination and communication policy) ensuring publication of results	
<ul style="list-style-type: none"> <li>including results from prematurely terminated studies.</li> </ul>	<input checked="" type="checkbox"/>
<ul style="list-style-type: none"> <li>independent of statistical significance and whether the results are positive or negative.</li> </ul>	<input checked="" type="checkbox"/>
<ul style="list-style-type: none"> <li>in form of a clear summary of the main results.</li> </ul>	<input checked="" type="checkbox"/>
<ul style="list-style-type: none"> <li>in form of an abstract uploaded to the EU PAS Register® within 3 months after the final study report. (Note that requests for delays are possible pending response to peer-review comments).</li> </ul>	<input checked="" type="checkbox"/>
<ul style="list-style-type: none"> <li>in form of a full report of all results with a scientific or public health impact without delay (taking into account relevant legal provisions in case of a suspected public health impact).</li> </ul>	<input checked="" type="checkbox"/>
<ul style="list-style-type: none"> <li>independently by the (primary) lead investigator irrespective of data ownership.</li> </ul>	<input checked="" type="checkbox"/>
<ul style="list-style-type: none"> <li>providing for the possibility of review by the study funder prior to submission – but without unjustified delay.</li> </ul>	<input checked="" type="checkbox"/>
<ul style="list-style-type: none"> <li>considering comments from the study funder and enabling the study funder to request changes to the presentation of the results to delete confidential information.</li> </ul>	<input checked="" type="checkbox"/>
<ul style="list-style-type: none"> <li>making publicly available comments of the funder.</li> </ul>	<input checked="" type="checkbox"/>
<ul style="list-style-type: none"> <li>taking into account the provisions for authorship of the Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals by the International Committee of Medical Journal Editors (ICMJE).</li> </ul>	<input checked="" type="checkbox"/>

9. Confidential information	Check
A definition of what constitutes confidential information has been agreed between the parties of the research contract.	<input checked="" type="checkbox"/>
The definition of confidential information does not consider data and results as being confidential except in relation to relevant data privacy laws.	<input type="checkbox"/>

Name of the coordinating study entity: Federal Institute for Drugs and Medical Devices

Name of (primary) lead investigator: Prof. Dr. Britta Haenisch

Date: 22/06/2023

Signature: 

Stamp (if applicable)

**Bundesinstitut für  
Arzneimittel und Medizinprodukte**  
Kurt-Georg-Kiesinger-Allee 3  
53175 Bonn

## **Amendment to the Checklist of the ENCePP Code of Conduct (European Medicines Agency)**

for the study: Development, optimisation and implementation of artificial intelligence methods for real world data analyses in regulatory decision-making and health technology assessment along the product lifecycle (Real4Reg)

5. A system has been put in place in order to record the data collected and processed in the study in a way that allows corroboration of published results.

*Amendment: The programs are kept, so results can be recreated at data authorities servers. The dataset is kept by the data authorities granting the permission to the data (see study protocols). Access to the data kept by the data authorities can be applied for at these authorities.*

5. A procedure for access to the analytical data is described in, or annexed to, the study protocol including the degree to which data can be shared and, if access is restricted, a justification why access is limited. Please indicate the page number in the study protocol

*Amendment: Access to the dataset is restricted as mentioned in the study protocols in order to comply with data protection regulations. Access can be applied for at the data authorities granting the permission (see study protocols).*

8. Appropriate plans and agreements, if necessary, have been made (e.g. as part of the dissemination and communication policy) ensuring publication of results...

*Amendment: We at Real4Reg conduct independent research, which is also independent from the funders. We do, however, appreciate scientific feedback from the funder and consider it in the publication of results if we evaluate it as scientifically sound and relevant. Naturally, we will not publish confidential information.*

22 June 2023