Translation of MIK-APM-KI-Checkliste

AI Governance and Ethics Framework - Checklist

Checklist as an attachment to the project application for an AI system

The text below is a translation of the original German document and is provided for the convenience of the reader. For the binding text, please consult the original at https://www.mik.uk-erlangen.de/aktuelles/nachrichten/detail/regelung-zur-nutzung-von-ki-anwendungen-am-uker/.

Project title:	
Applicant, field:	
Type of AI system according to the AI Governance and Ethics Framework of UKER	☐ AI system for use in clinical care (medical device) ☐ AI systems for use in research projects Application where it has an impact on patient care

1 Usage scenario and scientific evaluation

1.1 Brief description of the planned usage scenario, including the user group affected and any planned integration with other UKER IT applications

☐ I hereby confirm that in the usage scenario described, the AI system is used exactly as intended by the manufacturer.

☐ The usage scenario described does not correspond 100% to the intended purpose described by the manufacturer/developer, because ... (please explain below)

1.2 Publication(s)/documentation used to assess the trustworthiness of the AI system

1.3 Autonomy of the AI system (please note Art. 14 EU AI Act)

☐ The AI system results in direct intervention in patient care without a human being able to verify the system's decision (100% autonomy).

☐ The output of the AI system is always evaluated by a human, so that it is possible to modify the result before a corresponding care process for a patient (no autonomy).

☐ In certain situations, the use of the AI system may result in autonomous intervention in the care of a patient (without a human being able to verify the system's decision) (partial autonomy);
In this case, please describe the potential autonomous action and explain why you believe the associated risk to the patient is acceptable.

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1.4 Risk of discrimination against patient groups

☐ I hereby confirm that I have reviewed the available literature/documentation and verified that the use of this AI system does not pose a risk of bias in the AI system's decisions based on the data used to develop it, which could lead to discrimination against individual patient groups.

1.5 Verification of the data used for training/developing the AI system

☐ I hereby confirm, based on the available literature/documentation, that I have verified that the data used for the training/development of the AI system are representative for the patients to be treated at the UKER.

2 Planned implementation process (including training of users)
(please note Art. 13 EU AI Act)

Please describe briefly the training measures you have planned to train future users of the AI system, not only in the use of the system, but also in relation to the specific risks that may be associated with the use of this AI system.

3 In case of the usage of an AI system in research projects and an impact on patient care

☐ A study protocol has been drawn up for the planned use of the AI system in a research context, submitted to the Ethics Committee of FAU Erlangen-Nürnberg and approved by it.

4 Reporting obligations (please note Art. 12 EU AI Act)

☐ I am aware of the requirements regarding the reporting obligations of AI systems in accordance with Art. 12 EU AI Act. These will be complied with in the AI system to be introduced. We will verify the log files generated by the AI system at regular intervals to ensure the trustworthiness and quality of the AI system throughout its entire life cycle.

5 Miscellaneous

Place, date and signature of the applicant

Note: The European AI Regulation (EU AI Regulation, EU AI Act) of June, 13 2024, was published in the Official Journal of the European Union on July, 12 2024.
https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=CELEX:32024R1689.
This is the final version of the text, which entered into force on August, 1 2024.