

## DECIDE-AI

# Post-piloting item wording amendments

V3 - 28.10.21

Item 2 and 3 were renumbered as 2a and 2b because they both address aspects of the intended use/purpose. The subsequent items were renumbered accordingly. The numbers here below refer to the new numbering.

Overall, “algorithm” was replaced by “AI system” when describing the intervention being evaluated (algorithm + supporting software + supporting hardware). This was done to make the difference between the underlying mathematical model and the actual end product evaluated clearer.

### Item 2a

Describe the target ~~ed problem and~~ medical condition (s) and problem(s), including the current standard practice, and the ~~target-intended~~ patient population (s).

Justification: improve readability and align with regulatory vocabulary.

### Item 2b

Describe the intended users rs of the ~~algorithm-AI system~~, its planned integration in the care pathway, and the potential impact, including patient outcomes, it is intendeds to have achieve.

Justification: intended use is described as a combination of information about: targeted medical condition and problem, intended patient population, intended users, use environment, mode of action. These were all broadly covered by item 2a and 2b already, expect users.

### Item 3c

Describe steps taken to familiarise the users with the ~~algorithm-AI system~~, including any training ~~received~~ provided prior to the study.

#### Item 4a

Briefly describe the ~~algorithm~~ AI system, specifying ~~its~~ the version and the type of underlying algorithm used. Describe, or provide a direct reference to, the characteristics of the patient population on which the algorithm was trained and its ~~expected~~ performance ~~from~~ in preclinical development/validation studies.

#### Item 4b

Identify the data used as inputs. Describe how the data were acquired, the process needed to enter the input data, ~~any~~ the pre-processing applied and how missing/low-quality data were handled.

Justification: all AI system will apply some sort of pre-processing, “any” is redundant.

#### Item 4c

Describe the AI system ~~algorithm~~ outputs and how they were presented to the users (an image may be useful).

#### Item 5a

Describe the settings in which the ~~algorithm~~ AI system was evaluated, ~~including which additional clinical information (i.e. not provided by the AI system) was accessible to the users to interpret or put into context the output of the AI system~~ algorithm.

Justification: We received consistent comments from the pilots that this was unclear and impracticable to report. Moreover, during clinical evaluation, information is not controlled and any type of clinical information can theoretically be accessed, so this part of the item does not bring much additional useful information.

#### Item 5b

Describe the clinical workflow/care pathway in which the AI system ~~algorithm~~ was evaluated, the timing of its use, how the final supported decision was reached and by whom.

Justification: “care pathway” seems to be more commonly used than “patient pathway”

#### Item 8

Describe whether specific methodology ~~ies~~ was were utilized toward an ethics-related goal (such as algorithmic fairness) and ~~its~~ their rationale.

Justification: clarity about ethics methodologies being applicable tools rather than an abstract concept.

### Item 9a

*Describe the baseline characteristics of the patients included in the study, and report on input data ~~availability~~ missingness.*

### Item 10a

*Report on the user exposure to the AI system ~~algorithm~~, on the number of instances the AI system ~~algorithm~~ was used, and on the users' adherence to the intended implementation.*

### Item 10b

*Report any significant changes to the clinical workflow or ~~care-patient~~ pathway caused by the AI system ~~algorithm~~.*

Justification: "care pathway" seems to be more commonly used than "patient pathway"

### Item 11

*Report any changes made to the AI system ~~algorithm~~ during the study. Report the timing of these modifications, the rationale for ~~them~~ each, and ~~any the~~ changes in outcomes observed after each of them.*

### Item 12

*Report on the user agreement with the AI system ~~algorithm~~. Describe any instances of and reasons for user variation from the AI system's ~~algorithm's~~ recommendations and, if applicable, users changing their mind based on the AI system ~~algorithm~~ recommendations.*

### Item 13a

*List any significant errors/malfunctions related to: AI system ~~algorithm~~ recommendations, supporting software/hardware, or users. Include details of: (i) rate of occurrence, (ii) apparent causes, (iii) whether they could be corrected, and (iv) any significant potential impacts on patient care.*

### Item 15

*Discuss whether the results obtained support the intended use of the AI system ~~algorithm~~ in clinical settings.*

### Item 16

*Discuss what the results indicate ~~suggest~~ about the safety profile of the AI system ~~algorithm~~.  
Discuss ~~the~~ any observed errors/malfunctions and instances of harm, their implications for  
patients care and whether/how they can be mitigated.*

### Item I

Provide a structured summary of the study. Consider including: ~~target condition and problem~~, intended use of the ~~algorithm~~ AI system, type of underlying algorithm, study setting, number of patients and users included, primary, ~~and~~ secondary, safety and human factors outcomes measured, ~~key safety endpoints, human factors evaluated~~, main results, conclusions.

Justification: target condition and problem part of the intended use.

### Item III

Provide a reference to any study protocol, study registration number, and ethics approval.

### Item VI

State how patients were involved in any aspect of: the development of the research question, the study design, and the conduct of the study ~~conduct or in the development of the research question~~.

Justification: makes it clearer that “any aspects” related to all three following concepts and reorder in chronological order of involvement. Ongoing discussion about whether it is better to use “conduct” or “execution” (see online shared E&E good research practice document).

### Item VIII

Report on the differences s in the main outcomes according to the prespecified subgroups.

### Item X

Disclose any relevant conflicts s of interest, including the source of funding for the study, the role of funders, any other roles s played by commercial companies, and ~~authors’~~ personal conflicts of interest for each of the authors.

Justification: clarify how these CoI are different from the first listed.