

Guidelines for clinical trial protocols for interventions involving artificial intelligence: the SPIRIT-AI extension

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Scope: This document pertains to the reporting of clinical trial protocols for studies evaluating interventions that include an artificial intelligence component.

Reference: See `source/variants/spirit-ai.yml` for canonical link and provenance.

Instructions

- Use the boxes to confirm each reporting item.
- Add reviewer notes under each section as needed.

Checklist Items

- ☐ **Item 1: Title** - Indicate that the trial involves AI.
- ☐ **Item 2: Abstract** - Provide a structured summary of the protocol.

Notes

Reviewer notes

Provenance

- Source: See sidecar metadata in `source/variants/spirit-ai.yml`
- Version: 2020
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