

Table 2. Comparing SPIRIT-AI, CONSORT-AI and DECIDE-AI.

|  | <b>SPIRIT-AI</b>   | <b>CONSORT-AI</b>  | <b>DECIDE-AI</b>  |
|--|--|--|---|
| <b>Extension of existing guideline</b> | Yes  | Yes  | No  |
| <b>Stage of intended use</b>           | Late clinical trial (phase III)<br>Comparative prospective<br>evaluation | Late clinical trial (phase III)<br>Comparative prospective<br>evaluation | Early clinical trial<br>(phase I and II)                |
| <b>Study design</b>                    | Clinical trial protocol  | Randomised controlled trial  | Any   |
| <b>Key focus</b>                       | Standardisation of reporting   | Standardisation of reporting   | Assessing clinical utility,<br>safety and human factors |

CONSORT-AI: Consolidated Standards of Reporting Trials–Artificial Intelligence; DECIDE-AI: Developmental and Exploratory Clinical Investigations of Decision Support Systems Drive by Artificial Intelligence; SPIRIT-AI: Standard Protocol Items: Recommendations for Interventional Trials–Artificial Intelligence