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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Sponsor reference: |  | | | | REC reference: |  | | | R&D reference: |  | |
| Authors: | | |  | | | | | | | | |
| Title: | | |  | | | | | | | | |
| Intended journal: | | |  | | | | | | | | |
| Article 🞏 | | Editorial 🞏 | | Conference abstract 🞏 | | | Letter 🞏 | Book review 🞏 | | | Other 🞏 |
| Abstract: | | | | | | | | | | | |

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| --- | --- | --- | --- | --- |
|  | **Yes** | **No** | **N/A** | **Comments** |
| The analysis undertaken and reported complies with the analysis plan (eg pre-specified statistical, qualitative analysis plan) | 🞏 | 🞏 | 🞏 |  |
| The manuscript reports the results fully | 🞏 | 🞏 | 🞏 |  |
| The manuscript makes reference to any protocol amendments | 🞏 | 🞏 | 🞏 |  |
| The manuscript reports any relevant breaches | 🞏 | 🞏 | 🞏 |  |
| The manuscript addresses any safety issues | 🞏 | 🞏 | 🞏 |  |
| The manuscript addresses any key issues raised by sponsor | 🞏 | 🞏 | 🞏 |  |
| The manuscript acknowledges appropriate bodies | 🞏 | 🞏 | 🞏 |  |

**Chief Investigator (or delegate) signature/date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| **SPONSOR REVIEW** |
| **Approval** 🞏 **Full review required** 🞏 |
| **Sponsor signature/date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |