**Appendix A: Clinical Investigation Plan Synopsis Template**

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| Clinical Investigation Synopsis (Template) | |
| Title | [enter text here] |
| Short title | [enter text here] |
| Lay title, if applicable | [enter text here] |
| CIP number, version, and date | [enter text here] |
| EUDAMED Single Reference Number (SRN) or CIV-ID, if previously assigned | [enter text here] |
| CI modification number, if applicable | [enter text here] |
| Sponsor name and address | [enter text here] |
| Participating Location(s) and country(ies) | [enter text here] |
| Name of Investigational Device | [enter text here] |
| Clinical investigation Purpose and Background   * Rationale for CI * Background of device and condition * Current standard of care | [enter text here] |
| Name of Comparator, if applicable | [enter text here] |
| Clinical development stage | [enter text here] |
| Design of the clinical investigation | [enter text here] |
| Objectives | [enter text here] |
| Primary endpoints | [enter text here] |
| Secondary endpoints | [enter text here] |
| Safety endpoints | [enter text here] |
| Exploratory / Other endpoints and outcomes | [enter text here] |
| Description of participants / study population | [enter text here] |
| Inclusion criteria | [enter text here] |
| Exclusion criteria | [enter text here] |
| Sample size | [enter text here] |
| Duration and follow up of the clinical investigation | [enter text here] |
| Statistical considerations | [enter text here] |
|  |  |

Note: For combination studies, more details may be relevant, such as EU number of the clinical trial, name and description of investigational medicinal product or CIV-ID/SRN of performance study of an in vitro diagnostic device.