Format of IDE

IDE Suggested Format

Initial IDE: Report of Prior Investigations

Under the headings below, list, by name or nature of the study, previously conducted studies of the device. Include all studies that are relevant to the proposed clinical

investigation, whether adverse or supportive.

For each unpublished study, provide an adequate summary of:

- description of study methods
- outcome data
- study conclusions relevant to
- safety and effectiveness

For animal studies, add:

- rationale for animal selection
- statistical justification for the number of animals studied

For clinical studies, add:

- rationale for subject selection
- statistical justification for the number of subjects studied

Include a copy of each report containing adverse information. If unpublished studies did not reveal any adverse information, state this.

For each published study, provide a bibliography listing and a brief narrative summary of the study conclusions. Attach a copy of each article listed. If there are no relevant studies of the device under a given heading, specify “None.”

1. **Prior Non-Clinical Investigations of the Device**
    1. **Non-clinical investigations conducted by (or under the direction of) the sponsor-investigator**
        0. **Laboratory studies**
            0. Unpublished laboratory studies
            0. Published laboratory studies
    0. **Animal studies**
        0. Unpublished animal studies
        0. Published animal studies
    0. **Compliance with Good Laboratory Practice regulations statement**
1. **Non-clinical investigations conducted by other investigators**
    0. **Laboratory studies**
    0. **Animal studies**

2. **Prior Clinical Investigations of the Device**
    2. **Clinical investigations conducted by the sponsor-investigator**
        0. **Unpublished clinical investigations**
        0. **Published clinical investigations**
        0. **Clinical investigations conducted under other IDEs held by the sponsor-investigator**

If the device being evaluated in the proposed clinical investigation has been studied under other IDEs held by the sponsor-investigator, specify this and incorporate under this section (or in a referenced Appendix), a letter from the sponsor-investigator authorizing the FDA to access information in the other IDE files.

2. **Clinical investigations conducted by other investigators**
3. **Prior Non-clinical and Clinical Investigations Conducted in Support of an Approved Marketing Application**

If the device being evaluated in the proposed clinical investigation is a commercially marketed device now being studied for a different indication,

specify this and incorporate under this section (or in a referenced Appendix), a letter from the commercial manufacturer authorizing the FDA to access the manufacturer’s PMA or 510(k) for information pertaining to the IDE.

Last updated: 26 Aug 2022

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