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And help pre-empt questions from the competent authorities during their assessment of the application, i.e., allows sponsors to proactively provide the information the authorities expect to see in the CIP. While it is not legally binding, and therefore not mandatory, it should be considered best practice. Following it can help ensure a smoother process for all parties. General Expectations of the Clinical Investigation Plan The Clinical Investigation Plan (CIP) is expected to be: Detailed enough to serve as a manual for investigators conducting the clinical investigation. Allow the investigation to be conducted consistently across multiple sites and over time. Allow the Competent Authorities and Ethics Committees to assess whether the investigation was designed in such a way that any potential risks to subjects are justified when weighed against the expected clinical benefits. Allow assessment of whether the reliability and robustness of the data expected to be generated warrants the exposure of subjects to the investigational device and the procedures described in the CIP. Therefore, it is preferred that all necessary information be included in the CIP itself. If any required information must be contained in a separate document, then the CIP should summarize and reference this document. Further, the separate document(s) should be submitted together with the CIP as a single submission. Content of Each Section of Clinical Investigation Plan The MDCG guidance covers each section individually and advises on the type and level of content expected. General Introduction Identification and description of the investigational device Benefits and risks of the investigational device, clinical procedures, and clinical investigation Relevance of the clinical investigation Objectives and hypotheses Design of the clinical investigationGeneral information such as type of investigation, with rationale for choosing it, for its endpoints and for its variables as set out in the clinical evaluation planInformation on the investigational device and any comparator to be used in the clinical investigationInformation on subjects, selection criteria, size of investigation population, representativeness of investigation population in relation to target population and, if applicable, information on vulnerable subjects involved such as children, pregnant women, immune-compromised or elderly subjectsDetails of measures to be taken to minimize bias, such as randomization, and management of potential confounding factorsDescription of the clinical procedures and diagnostic methods relating to the clinical investigation and in particular highlighting any deviation from normal clinical practice Statistical design and analysis Data management Modifications of the Clinical Investigation Plan Deviations from the Clinical Investigation Plan Device accountability Statements of compliance Informed consent process Adverse events, adverse device effects and device deficiencies End, suspension, or premature termination of the clinical investigation Arrangements for subjects following participation Publication policy Technical and functional features of the device Bibliography The 21-page guidance expands on each of the above topics and subtopics. For example: Subsection 3.3.2 Risks: it is not necessary to include specific mitigations for risks that are determined to be negligible due to a low probability of occurrence and low severity of harm. However, it is expected that all possible risks are identified. This section also provides examples of how clinical investigation design can contribute to risk mitigation, e.g., the use of pre-specified stopping rules. Section 3.8 Data Management: the measures to be implemented in case of a data security breach (as required under MDR, section 4.5, chapter II, Annex XV) could be placed in this section. Or if provided in a separate document, cited in this section of the Clinical Investigation Plan. Please refer to the guidance document for a full overview of recommendations. Synopsis Template The PDF version is available as Appendix A within the MDCG guidance. A separate Word (editable) version was also provided by the MDCG, which was linked at the start of this post. Below is image of the contents for reference.

Mdr clinical investigation plan. Mdr clinical evaluation plan template. Mdr clinical evaluation plan example. Mdr post market clinical follow up plan template.