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| **Protocol Pre-Submission Synopsis Template** | | | |
|  | Title of the Study: |  | |
|  | Sponsor name: |  | |
|  | Investigational Product (s) |  | |
|  | Background and Rationale (Brief) |  | |
|  | Indication (s) |  | |
|  | Clinical trial Phase |  | |
|  | Trial objectives | Primary objectives:  Secondary Objectives): | |
|  | Trial Design |  | |
|  | Trial End points | Primary endpoints:  Secondary endpoints: | |
|  | Number of Participants |  | |
|  | Eligibility criteria | Inclusion criteria:  Exclusion criteria: | |
|  | Trial Site (s) |  | |
|  | Duration of the trial |  | |
|  | **Date** | **Names** | **Signature** |
|  |  |  |  |