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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** |
|  |  |  |  |