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| Clinical Trial Registry Form | Foundation University Islamabad |
| Name Principal Investigator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Supervisor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Head of the Department: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |

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| Organization's Unique Protocol ID: |  |
| **\*** Brief Title: | [Special Characters](https://register.clinicaltrials.gov/prs/html/prs-users-guide.html#specialChar)     |
| [**\***] Acronym:(if any)    | If specified, will be included at end of Brief Title in parentheses. |
| **\*** Study Type: |    Interventional   (or clinical trial) — participants assigned to intervention(s) based on a protocol   Observational   participants **not** assigned to intervention(s) based on a protocol; typically in context of routine care   Expanded Access   availability of an experimental drug or device outside of a clinical trial protocol |
| Record Verification Date: | Month:          Year:  |
| **\*** Overall Recruitment Status: |        Before selecting Suspended, Terminated or Withdrawn see the [Overall Recruitment Status definition](https://register.clinicaltrials.gov/prs/html/definitions.html#OverallStatus). |
|  | Tip: Day is not required for Anticipated dates. |
| **\*** § Study Start Date: | Month:          Day:   Year:   Type:        Date study is open for recruitment (Anticipated) or date first participant is enrolled (Actual). |
| **\*** Primary Completion Date: | Month:          Day:   Year:   Type:        Final data collection date for primary outcome measure. |
| **\*** § Study Completion Date: | Month:          Day:   Year:   Type:        Final data collection date for study. |
| **\*** Responsible Party: |            Select **Sponsor** unless the Principal Investigator has been designated as Responsible Party or the Principal Investigator is the Sponsor. |
| **\*** Sponsor: | Primary organization conducting study and associated data analysis (not necessarily a funding source). |
| Collaborators: |

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Organization(s) providing support: funding, design, implementation, data analysis or reporting.Required by International Committee of Medical Journal Editors (ICMJE) and World Health Organization (WHO)Enter **only the organization name**. |
| **\*** § U.S. FDA-regulated Drug: |        Studying one or more U.S. FDA-regulated drug or biologic products? |
| **\*** § U.S. FDA-regulated Device: |        Studying one or more U.S. FDA-regulated device products?

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| Unapproved/Uncleared Device: |        Studying at least one device product that is not yet approved or cleared by the U.S. FDA for any use? If "Yes" and this is a FDAAA 801 applicable clinical trial (ACT), the study record will not be posted on ClinicalTrials.gov unless posting is authorized. |
| Pediatric Postmarket Surveillance: |        Required only if this **study** is a pediatric postmarket surveillance of a device product ordered by the U.S. FDA. |

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| **\*** U.S. FDA IND/IDE:(Not public)  |        Studying drug/device product with U.S. FDA Investigational New Drug (IND) Application or Investigational Device Exemption (IDE)?

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| FDA Center: |        Formerly IND/IDE Grantor |
| IND/IDE Number: |  |
| IND Serial Number: | 4 digit number entered on the U.S. FDA IND application, Form 1571, if any. |

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| [**\***] Availability of Expanded Access: |        Will any non-protocol access to the investigational drug, biologic or device be provided? [[About Expanded Access records](https://register.clinicaltrials.gov/prs/html/about_expanded_access.html)]

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| Expanded Access Record: | ClinicalTrials.gov identifier (NCT number) for the associated Expanded Access record |

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| **\*** Human Subjects Protection Review: |

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| Board Status: |         |
| The following information is required if the study meets each of these criteria: not required to be registered under 42 CFR Part 11, not funded in whole or in part by the U.S. government, and is not conducted under an IND or IDE. [This information is not made public.] |
| Board Name: |  |
| Board Affiliation: |  |
| Board Contact: |

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| Phone: |  Extension:  |
| Email: |  |
| Address: |  |

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| Data Monitoring Committee: |         |
| Plan to Share IPD: |        Indicate if there is a plan to make individual participant data (IPD) available to other researchers. |
| FDA Regulated Intervention: |         |
| **\*** Brief Summary: | [Special Characters](https://register.clinicaltrials.gov/prs/html/prs-users-guide.html#specialChar)     |
| Detailed Description: | Avoid duplicating information that will be entered elsewhere, such as Eligibility Criteria or Outcome Measures. |
| **\*** Conditions or Focus of Study: |       [Search MeSH](https://www.nlm.nih.gov/mesh/MBrowser.html), the National Library of Medicine's Medical Subject Headings, for valid condition terms. |
| Keywords: |  |

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| **\*** Study Type: | Interventional |
| **\*** § Primary Purpose: |         |
| **\*** Study Phase: |        Use "N/A" for trials that do not involve drug or biologic products. |
| **\*** § Interventional Study Model: |         |
| Model Description: |  |
| **\*** § Number of Arms: |  |
| **\*** § Masking: | ParticipantCare ProviderInvestigatorOutcomes AssessorNo MaskingCheck all roles that are masked or check No Masking. |
| Masking Description: |  |
| **\*** § Allocation: |        Select N/A for single-arm studies. |
| **\*** § Enrollment: | Number of Subjects:   Type:         |

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| **\*** Arm Title: | Formerly Arm Label. Brief, descriptive label to be used as row or column heading in tables. |
| **\*** Arm Type: |          |
| [**\***] Arm Description: | Describe the intervention(s) to be administered.For drugs use generic name and include dosage form, dosage, frequency and duration. |
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| **\*** Arm Title: |  |
| **\*** Arm Type: |          |
| [**\***] Arm Description: |  |
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| **\*** Arm Type: |          |
| [**\***] Arm Description: |  |
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| Interventions: |

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| **\*** Intervention Type: |                 |
| **\*** Intervention Name: | For a drug, use generic name if established.Use the same name as in the associated Arm/Group Description(s). |
| [**\***] Other Intervention Names:(if any)    |  Include brand names, serial numbers and code names to improve search results on the ClinicalTrials.gov web site. |
| **\*** § Intervention Description: | Do not repeat information already included in arm/group descriptions. |
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| **\*** Primary Outcome Measure: |

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|  *Outcome 1* |
| Title: |  |
| Description: |  |
| Time Frame: |  |
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| [**\***] Secondary Outcome Measures:(if any)    |   |
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| Other Pre-specified Outcomes: |   |
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| Other Pre-specified Outcomes: |   |
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| **\*** Sex: |        Biological sex of eligible participants. |
| [**\***] Gender Based: |        If applicable, indicate if participant eligibility is based on self-representation of gender identity.

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| **\*** Age Limits: | Minimum:                      Maximum:                 |
| **\*** § Accepts Healthy Volunteers: |               |
| **\*** Eligibility Criteria: | [Special Characters](https://register.clinicaltrials.gov/prs/html/prs-users-guide.html#specialChar)     |

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| **\*** Central Contact Person: | First Name:    MI:    Last Name:  Degree: Phone:  Ext:  Email: Either Central Contact or Facility Contacts are required.The individual's official title may be substituted for Last Name (leave First Name, MI and Degree blank). |
| Central Contact Backup: | First Name:    MI:    Last Name:  Degree: Phone:  Ext:  Email:  |
| Overall Study Officials: |  |

Citations:    Links:    Available Study Data/Documents:  