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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| **\*** Overall Recruitment Status: | | | | | | | | | | Before selecting Suspended, Terminated or Withdrawn see the [Overall Recruitment Status definition](https://register.clinicaltrials.gov/prs/html/definitions.html#OverallStatus).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: | | |  |  | | --- | --- | |  |  |     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?   |  |  | | --- | --- | | 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. | | | |
| **\*** 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)?   |  |  | | --- | --- | | 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. | | | |
| [**\***] 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)]   |  |  | | --- | --- | | Expanded Access Record: | ClinicalTrials.gov identifier (NCT number) for the associated Expanded Access record | | | |
| **\*** Human Subjects Protection Review: | | | | | | |  |  | | --- | --- | | 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: | |  |  | | --- | --- | | Phone: | Extension: | | Email: |  | | Address: |  | | | | |
| 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: | Participant Care Provider Investigator Outcomes Assessor  No Masking  Check 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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| Interventions: | |  |  | | --- | --- | | **\*** 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: | |  | | --- | | *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.   |  | | --- | |  | |
| **\*** 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:  