Research Portal User Manual

Sponsor

Table of Contents

Contents

Introduction

The Ministry of Public Health's role is to create a clear vision for the nation's health direction, set goals and objectives for the country, design policies to achieve the vision, protect the public's health, ensure high quality health research, and monitor and evaluate progress towards achieving those objectives.

A key function of MoPH is oversight research and supporting researchers to ensure that standards are met and performance targets achieved.

In implementation of these technical plans, this document contains the details about the process of accessing the Research web portal as a Sponsor.

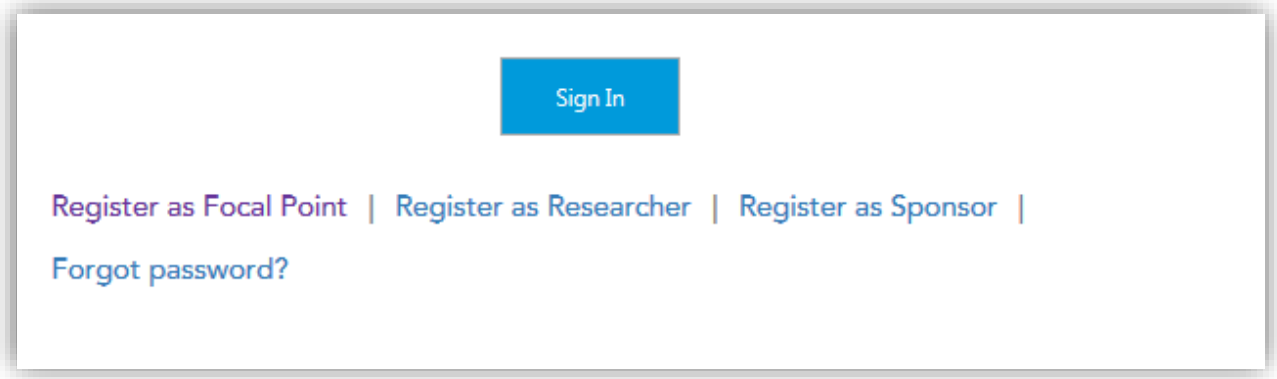
Application access

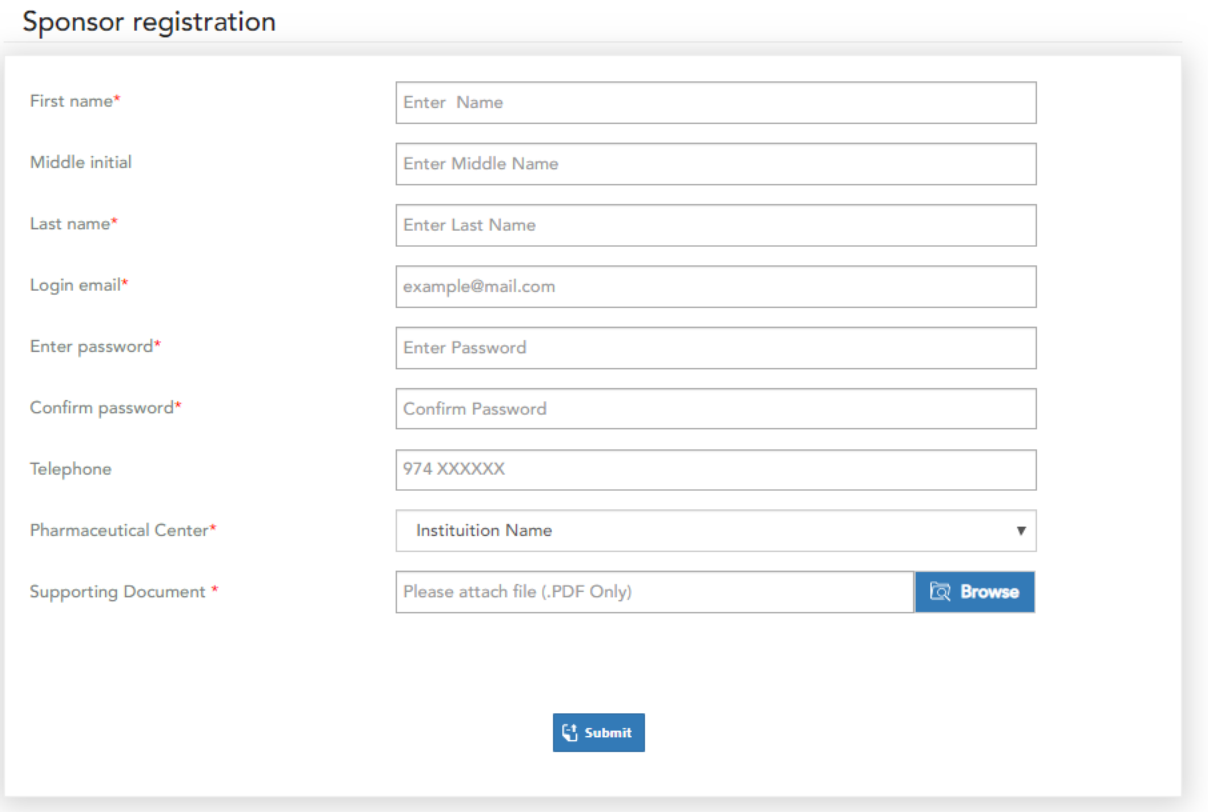
Research Department - MoPH Website

Research Department - MoPH Portal

User registration & Accesses

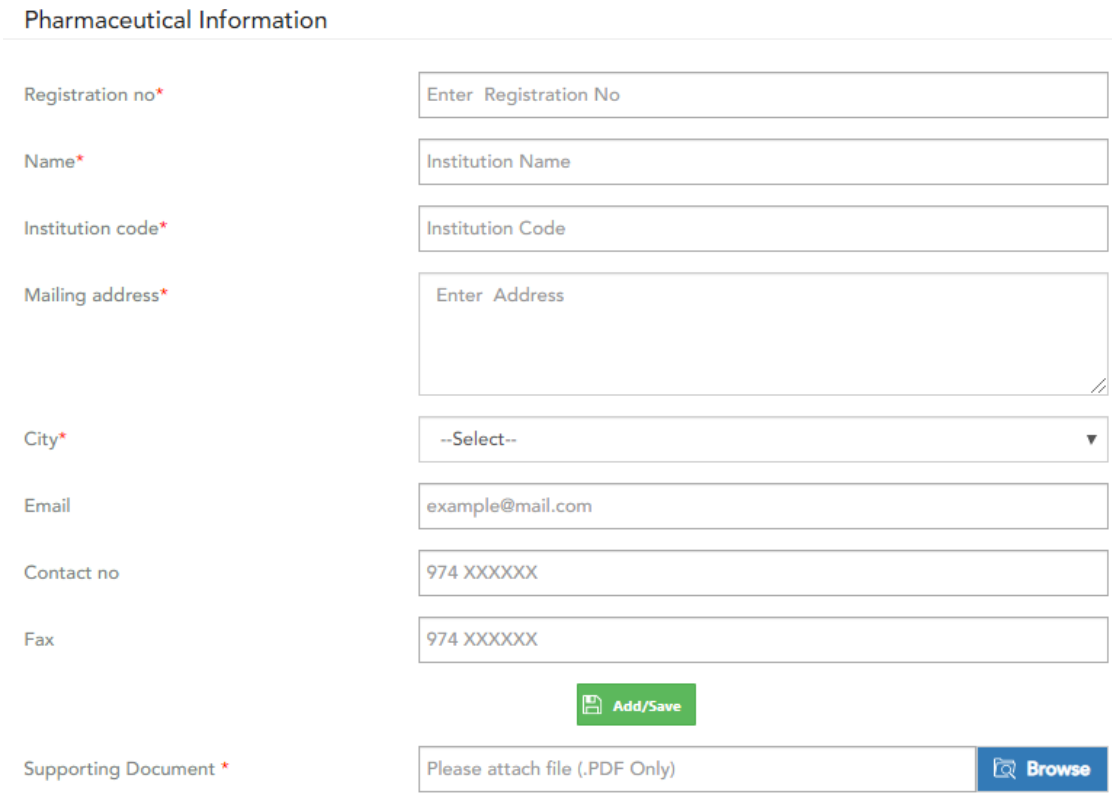
1. For registering as Sponsor click on “Register as Sponsor”



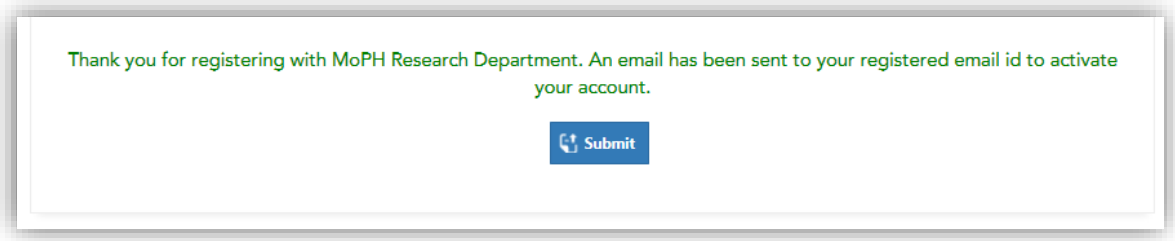


Enter all the mandatory details and upload supporting/authorization letter from your institution supporting your role.

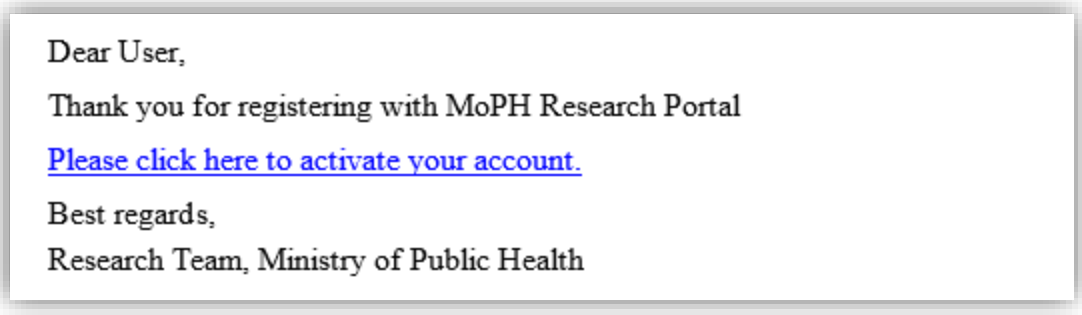
Note: if your Pharmaceutical Center is not listed in the dropdown list, pleaser select others and provide details about the pharmaceutical center



Click submit after entering all the details



You will receive an email verification on your registered email within few minutes.

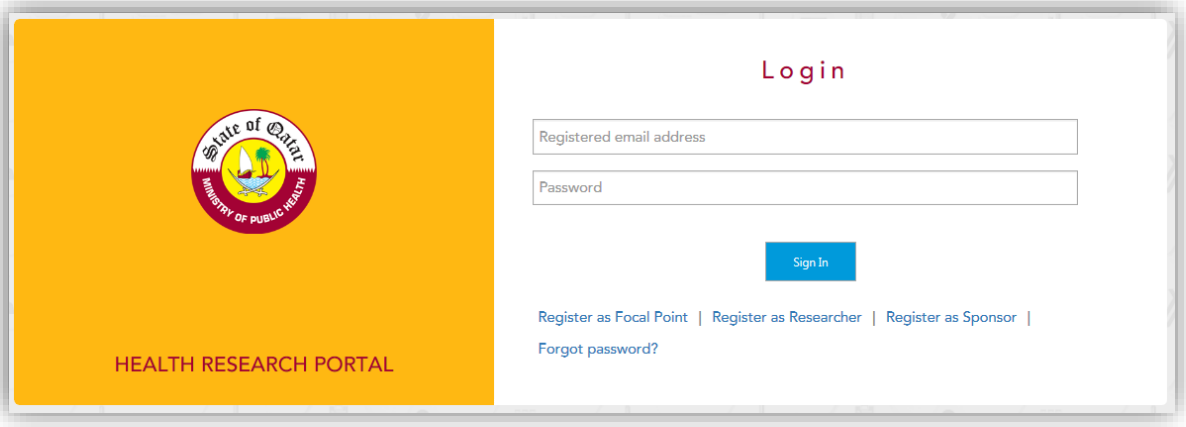

Dear User,

Thank you for registering with MoPH Research Portal

Please click here to activate your account.

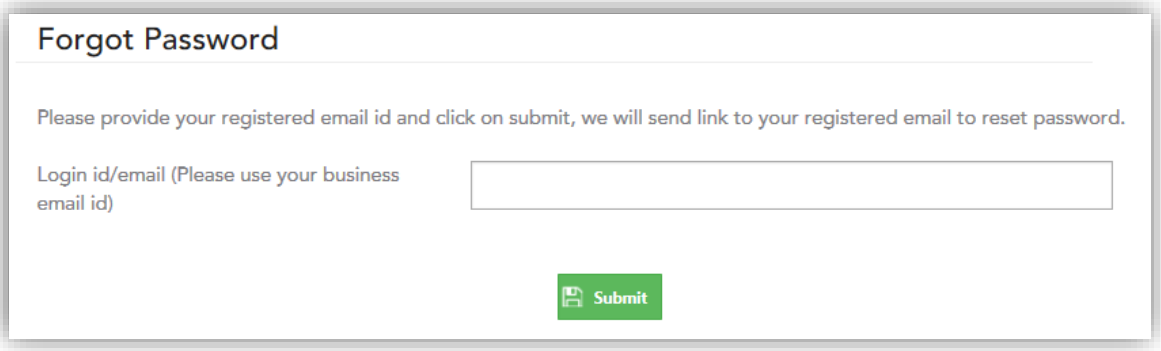
Best regards,
Research Team, Ministry of Public Health

2. User Login after email verification -

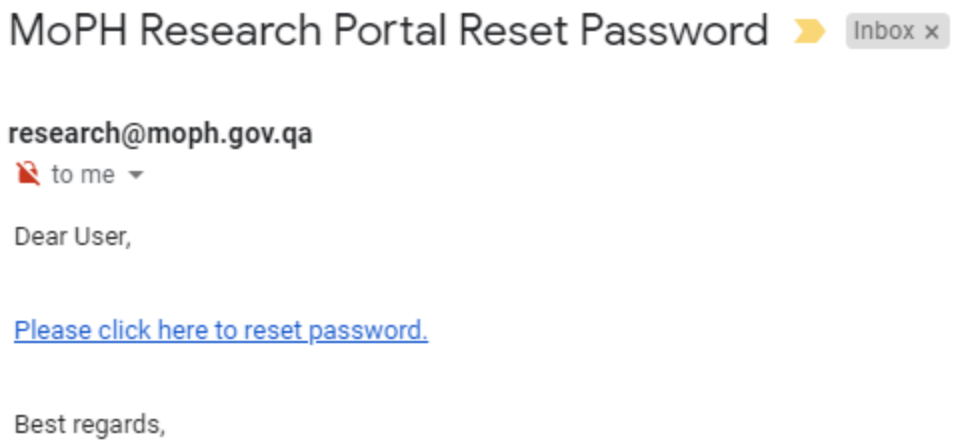


For registered users -enter registered email and password for Sign In to system.

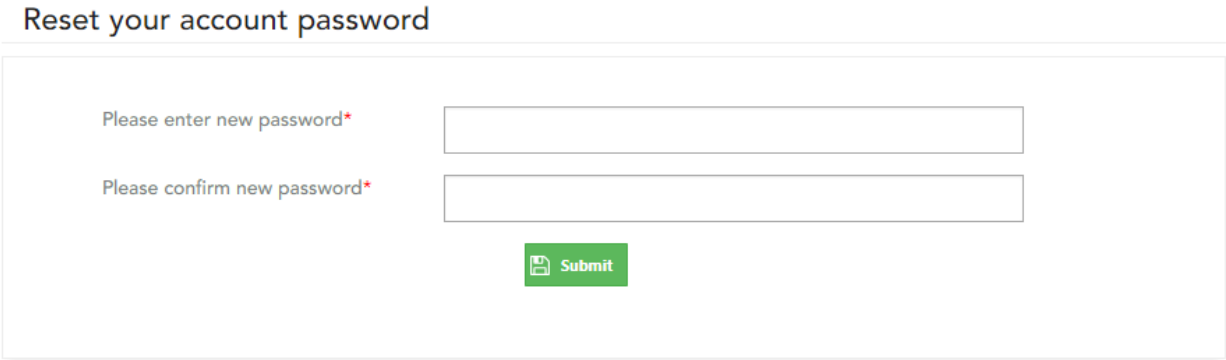
3. Forgot password



Enter registered email id and ‘click’ submit, user will get email for reset password.

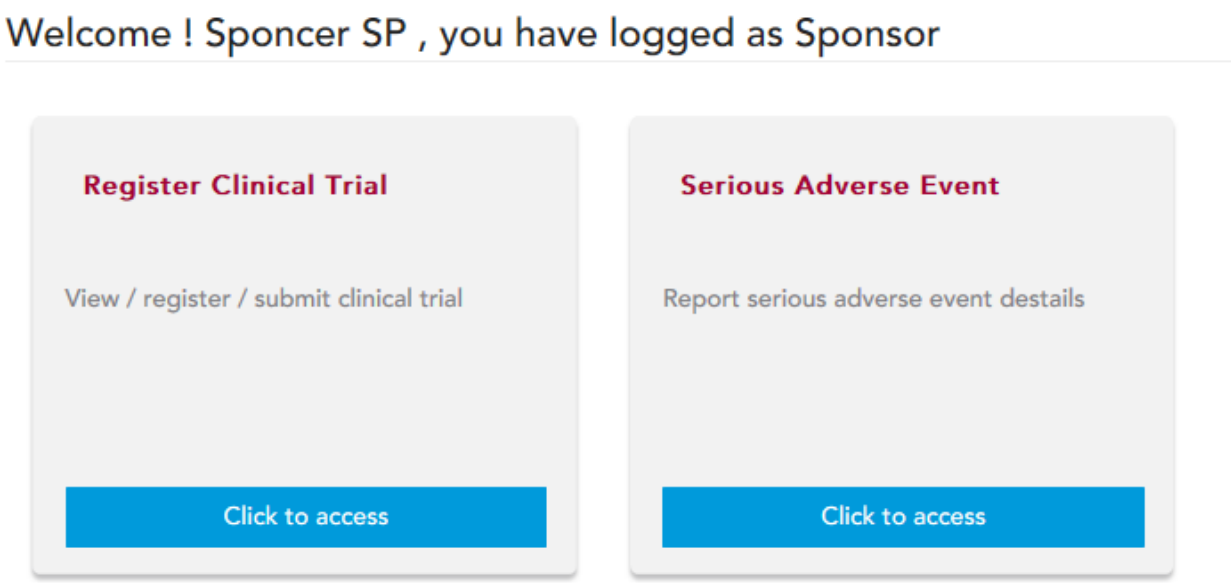


Enter new password and click submit button.



Menu access

After successful login as Researcher navigate into landing page.



Click on the respective tile to take an action, some are explaining below.

4. Register Clinical trial

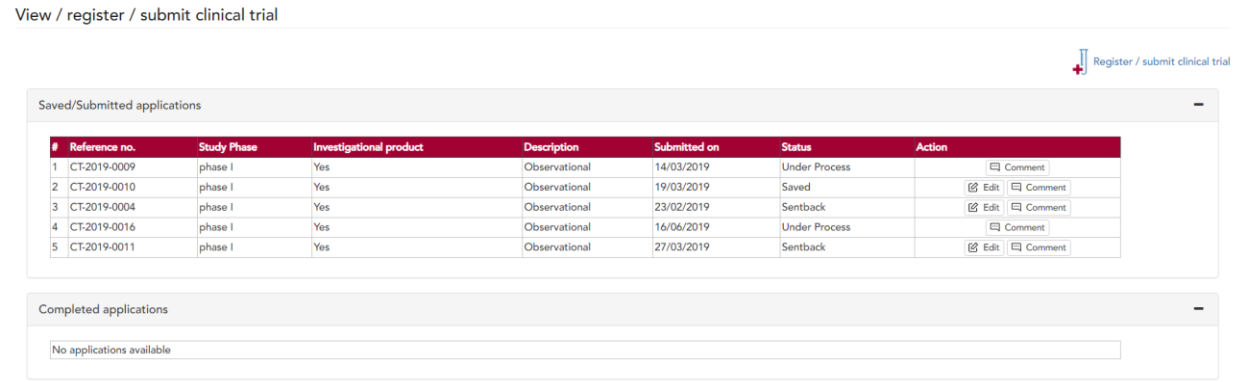
Option to submit /report clinical trial to MoPH

5. Serious Adverse Event

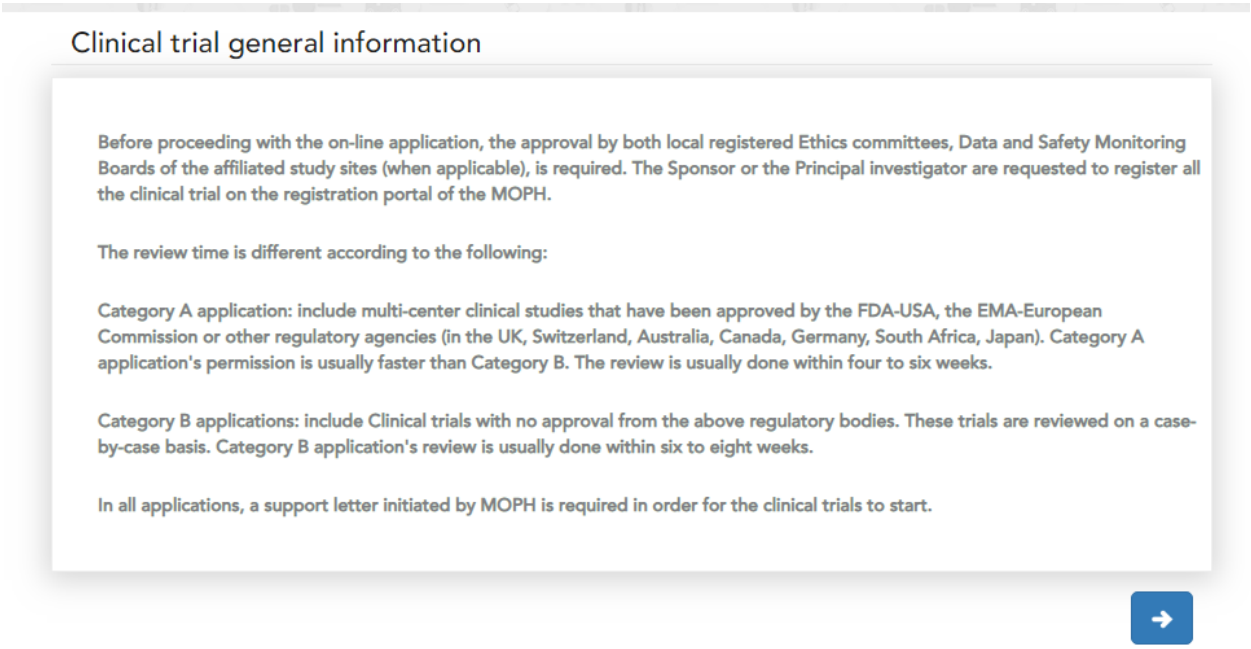
Report serious adverse event details

NOTE: From any section/any page in order to go to your home page, please click on "MoPH logo" on the header (top left section)

Register Clinical Trial

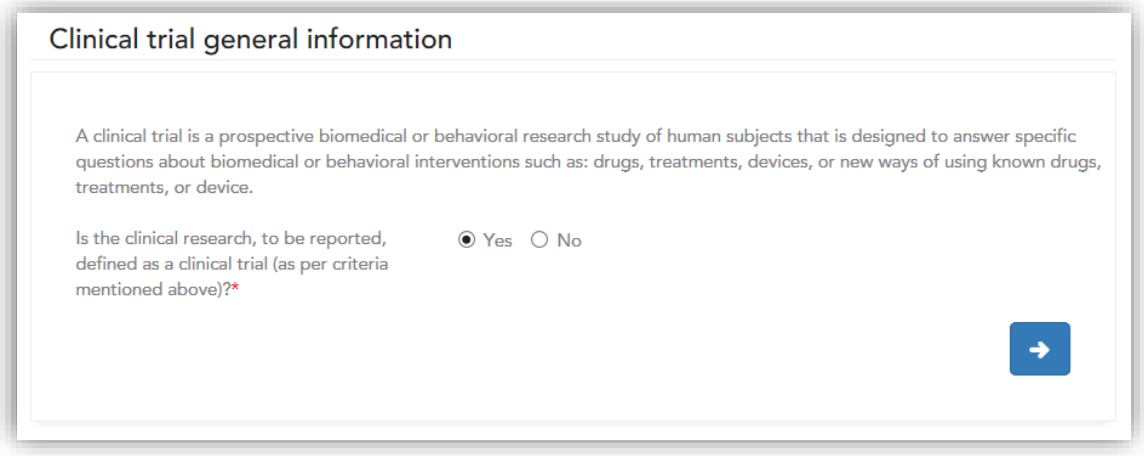


Click on “Register/Submit clinical trial” to register a new clinical trial
In order to edit a saved application, click on “Edit” on them respective row in the Saved/Submitted grid



Read the instructions carefully before proceeding.

Provide the required information in the screen, click on “next arrow icon” and the system will guide you through the application



Clinical trial general information

Fields with * are mandatory

Study phase* — phase I | phase II | phase III | phase IV

Interventional: A type of clinical trial in which participants are assigned to groups that receive one or more intervention/treatment (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the trial's protocol. Participants may receive diagnostic, therapeutic, or other types of interventions a study where the medicinal product(s) is (are) prescribed in the usual manner in accordance with the terms of the marketing authorization)

Observational: a type of clinical trial in which participants are identified as belonging to study groups and are assessed for biomedical or health outcomes. Participants may receive diagnostic, therapeutic, or other types of interventions, but the investigator does not assign participants to a specific interventions/treatment.

What is the clinical trial's type ?* — Observational | Interventional

What is the Intervention?*
- A new drug; or an approved drug used for a different indication
- Drug or combination of drug not used as per same usual care settings (route, dosage, target population, indication of use)
- A new medical deviceor approved medical device with alterate use
- A new therapeutic intervention (such as cell transplant, gene transfer etc)
- None of the above

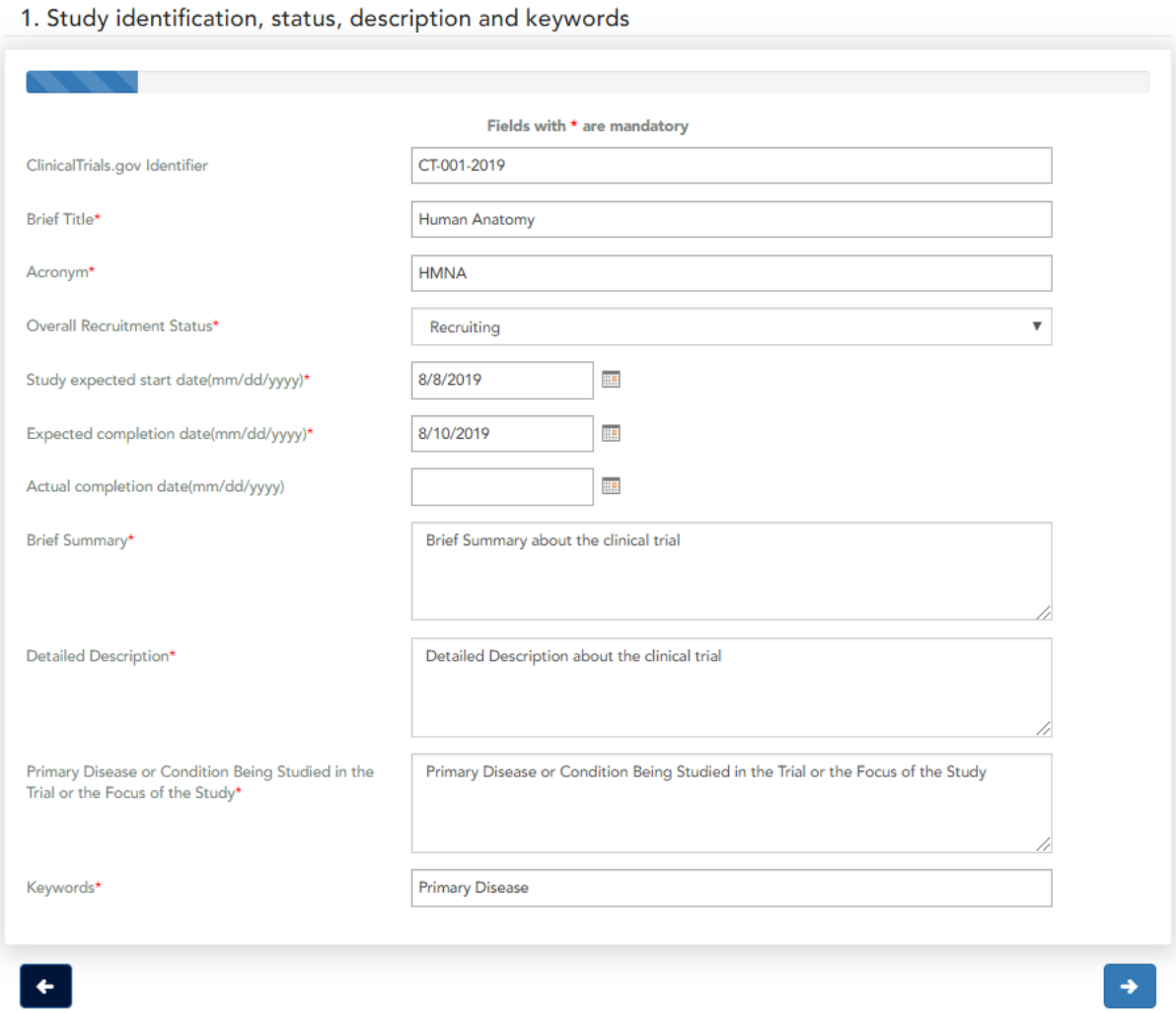
Is it a new investigational product* — Yes | No

Product already approved for use in Qatar and one of the following is diffrent* — Yes | No

Marketed drug
- [ ] Indication(s) and clinical use is different
- [x] Target patient population(s) is different
- [x] Route (s) of administration is different
- [ ] Dosage regimen(s) is different

Institution: Institution Name-Demo

Provide the required information click on “next arrow”



2. Sponsor Details

Fields with * are mandatory

Name of organization*	Name of organization
Name of the person to contact*	Name of the person to contact
Address*	Address of organization
Post code	
Telephone number*	97411224455
Fax number	
Email*	organizationofficial@mail.com

Legal representative of the sponsor in the state of Qatar (if different from the sponsor)

Name of organization	Name of organization
Name of the person to contact	Name of the person to contact
Address	Address of organization
Telephone number	97411224455
Fax number	
Email	
Status of the sponson	--Select--
Source of financing if other than the sponsor	

3. Investigator Details

Fields with * are mandatory

Principal Investigator

Name*	Name of Principal Investigator
Organization*	Principal Investigator Organization
Address	Principal Investigator Organization Address
Telephone Number*	97411224433
Fax Number	
Email*	pioffical@mail.com

Co-Investigator

Name	Name of Co-Investigator
Organization	Co-Investigator Organization
Address	Co-Investigator Address
Telephone number	97411224433
Fax number	
Email	copioffical@mail.com

4. Investigational Product Information

Fields with * are mandatory

Investigational product information

Trade name*: Enter trade name

United state adopted name (USAN): Enter United state adopted name

IP has marketing authorization in other countries: Yes / No

Country: --Select--

Record added successfully.!

Add

Trade name	USAN	Country	Action
Investigational product trade name	USANAME	Puerto Rico	Delete

5 . Study Design

Fields with * are mandatory

Interventional Study Design*	Interventional Study Design
Primary purpose*	☐ Treatment ☑ Prevention ☐ Diagnostic ☐ Supportive Care ☐ Screening ☐ Health Services Research ☐ Basic Science ☐ Device Feasibility
Additional Primary purpose (if any)	
Interventional Study Model*	☐ Single Group ☐ Parallel ☑ Crossover ☐ Factorial ☑ Sequential
Model Description*	Model Description
Number of Arms*	4
Is Masking ?*	No
Allocation*	◉ N/A (not applicable) ○ Randomized ○ Nonrandomized
No of participant*	45

6 . Arms, Groups and Interventions

Fields with * are mandatory

Arm Information*	Arm Information
Arm Title	Arm Title
Arm Type	☐ Experimental ☐ Active Comparator ☑ Placebo Comparator ☐ Sham Comparator
Additional Arm Type (if any)	
Arm Description*	Arm Description
Interventions*	Interventions
Interventions Type*	☐ Drug: Including placebo ☐ Device: Including sham ☐ Biological/Vaccine ☐ Sham Comparator ☑ Radiation ☑ Behavioral ☐ Genetic ☐ Dietary Supplement ☐ Combination Product ☐ Diagnostic Test
Additional Interventions Type (if any)	
Interventions Name(s)*	Interventions Name
Other Interventions Name(s)*	Other Interventions Name
Interventions Description*	Interventions Description
Arm or Group/Interventional Cross Reference*	Arm or Group/Interventional Cross Reference

7 . Outcome Measures

Fields with * are mandatory

It is mandatory to have one primary outcome measures, You can have multiple outcome measures under others.

Outcome measure* ○ Primary ○ Others

Title* Enter title

Description* Enter description

Time frame* Enter time frame

Add

Outcome Measures added successfully

Outcome measure	Title	Time frame	Description	Action
Primary	Primary Outcome measure	5 Months	Description	Delete

8 . Eligibility

Fields with * are mandatory

Gender Based* No: Eligibility is not based on gender

Age Limits - The minimum and maximum age of potential participants eligible for the clinical study provided in relevant unit of time

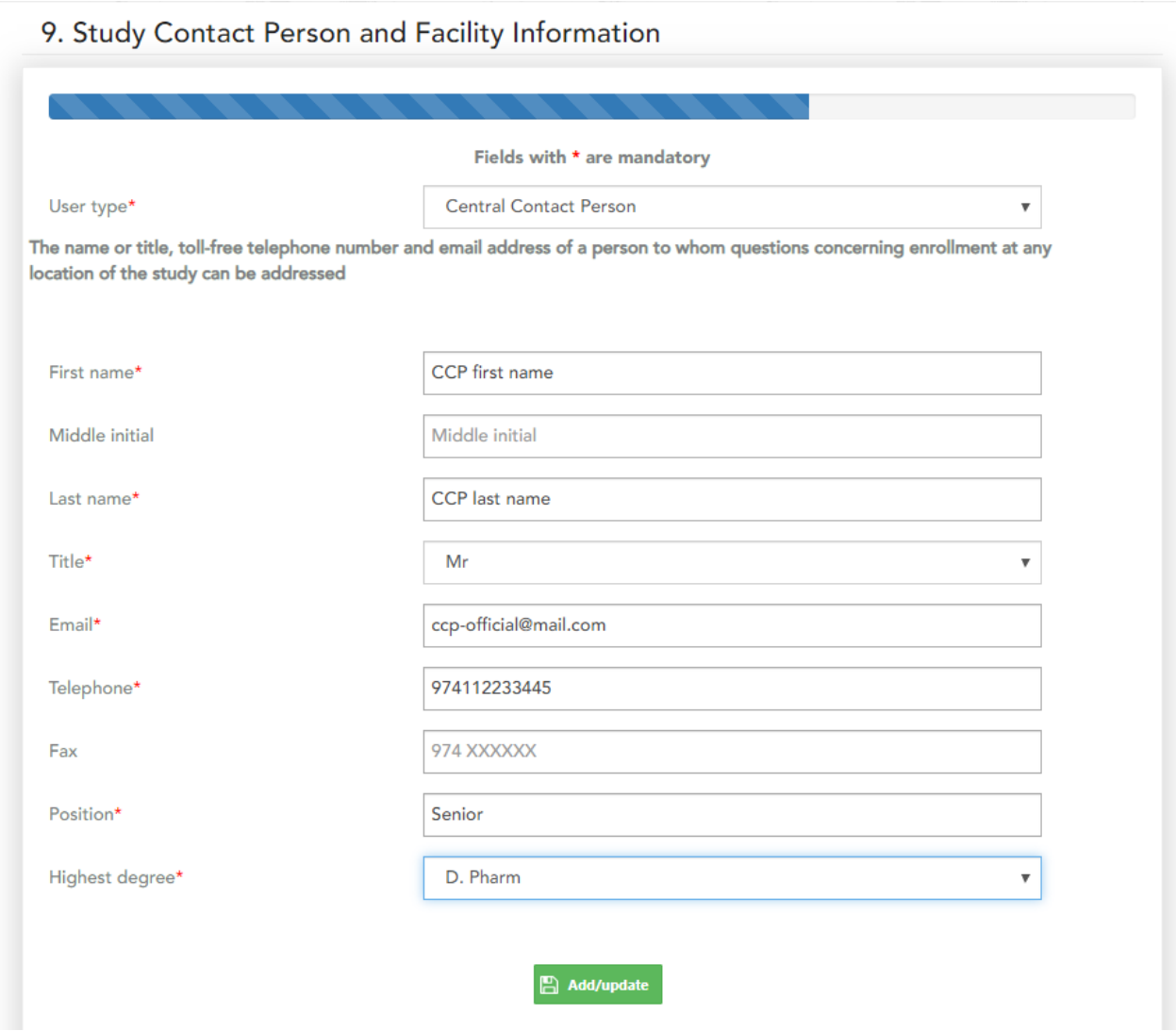
Minimum Age* 34

Unit Of Time* Months

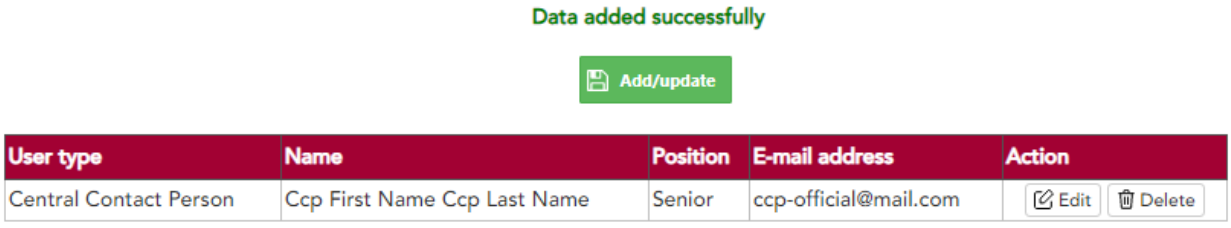
Maximum Age* 34

Unit Of Time* Years

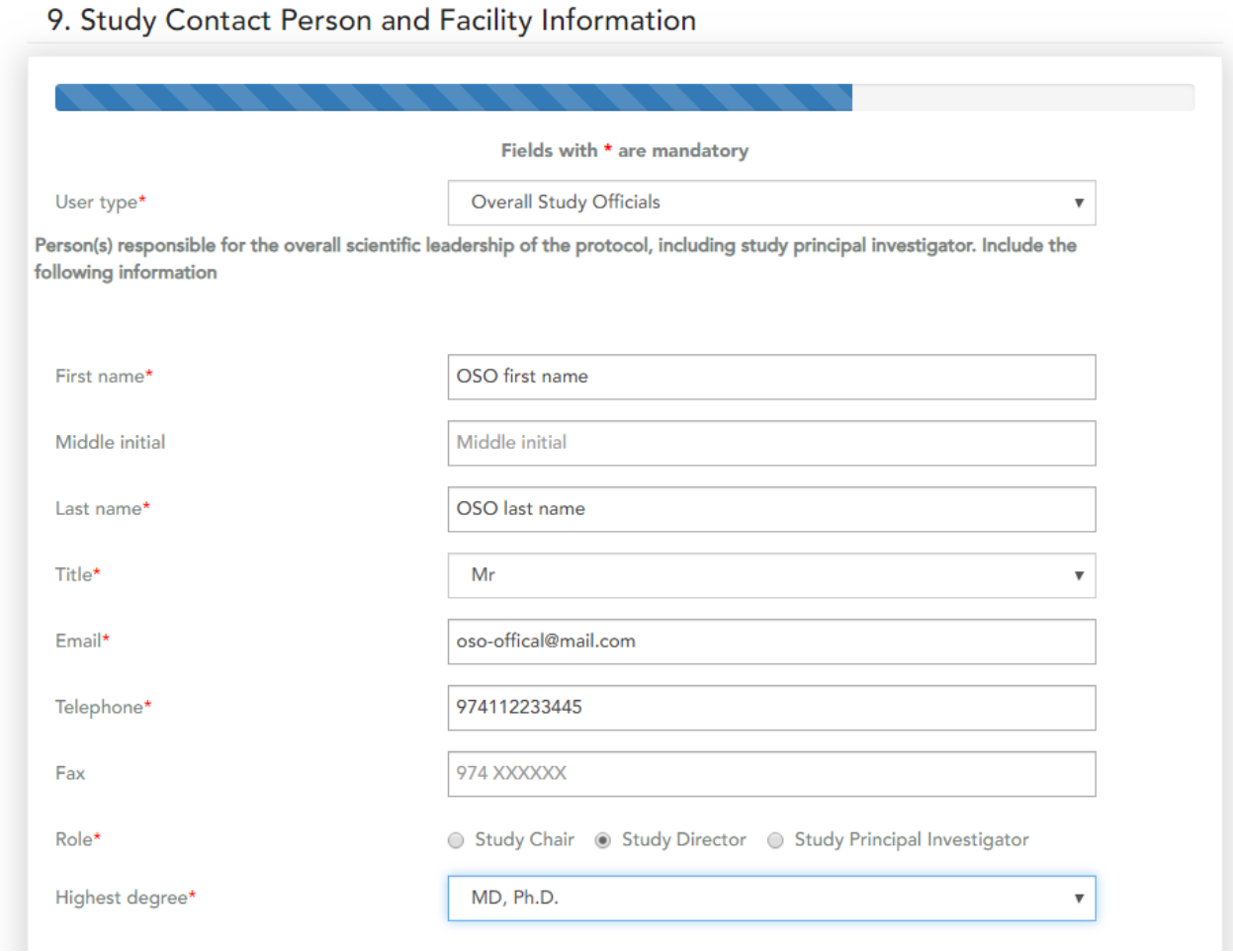
Eligibility Criteria Eligibility Criteria



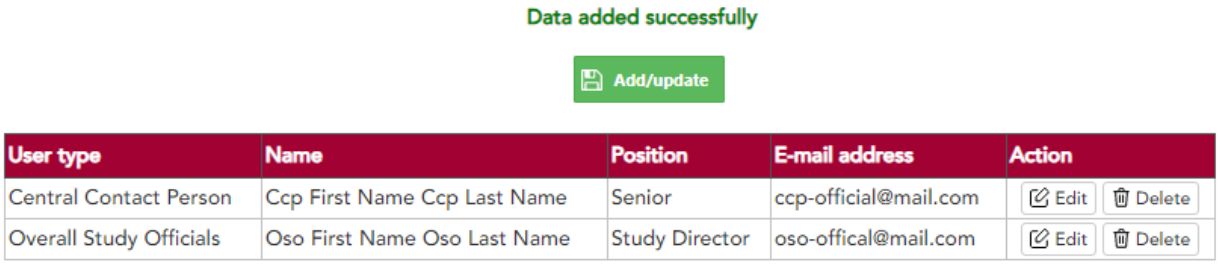
Please chose user type “Central contact person” add the details for the central contact person and click on “Add/Update”

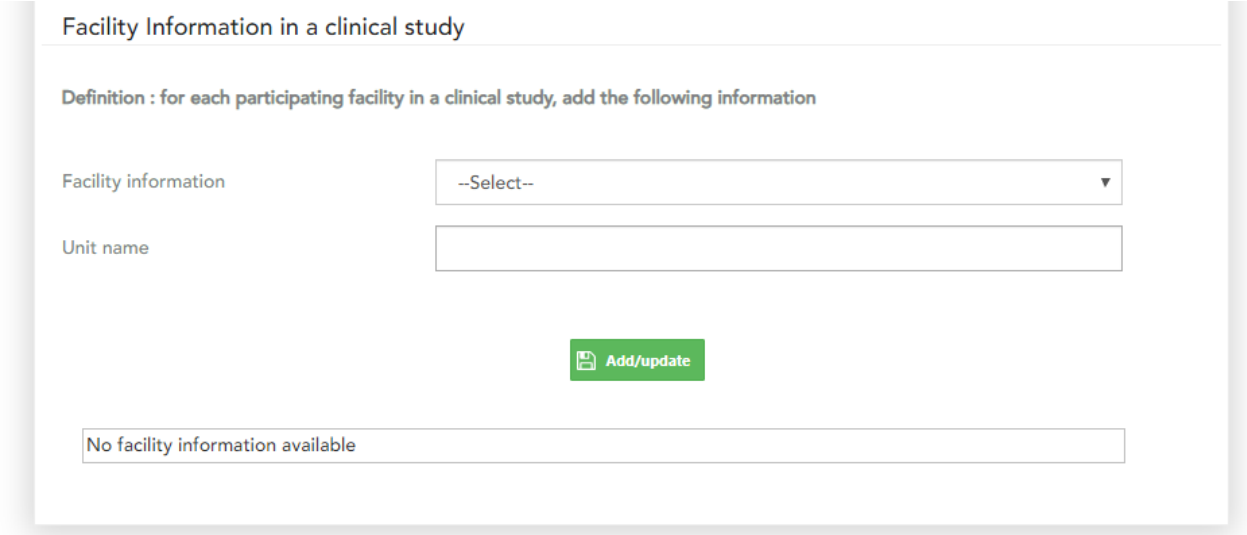


Please choose “Overall Study official” and provide information about all the study officials and their role

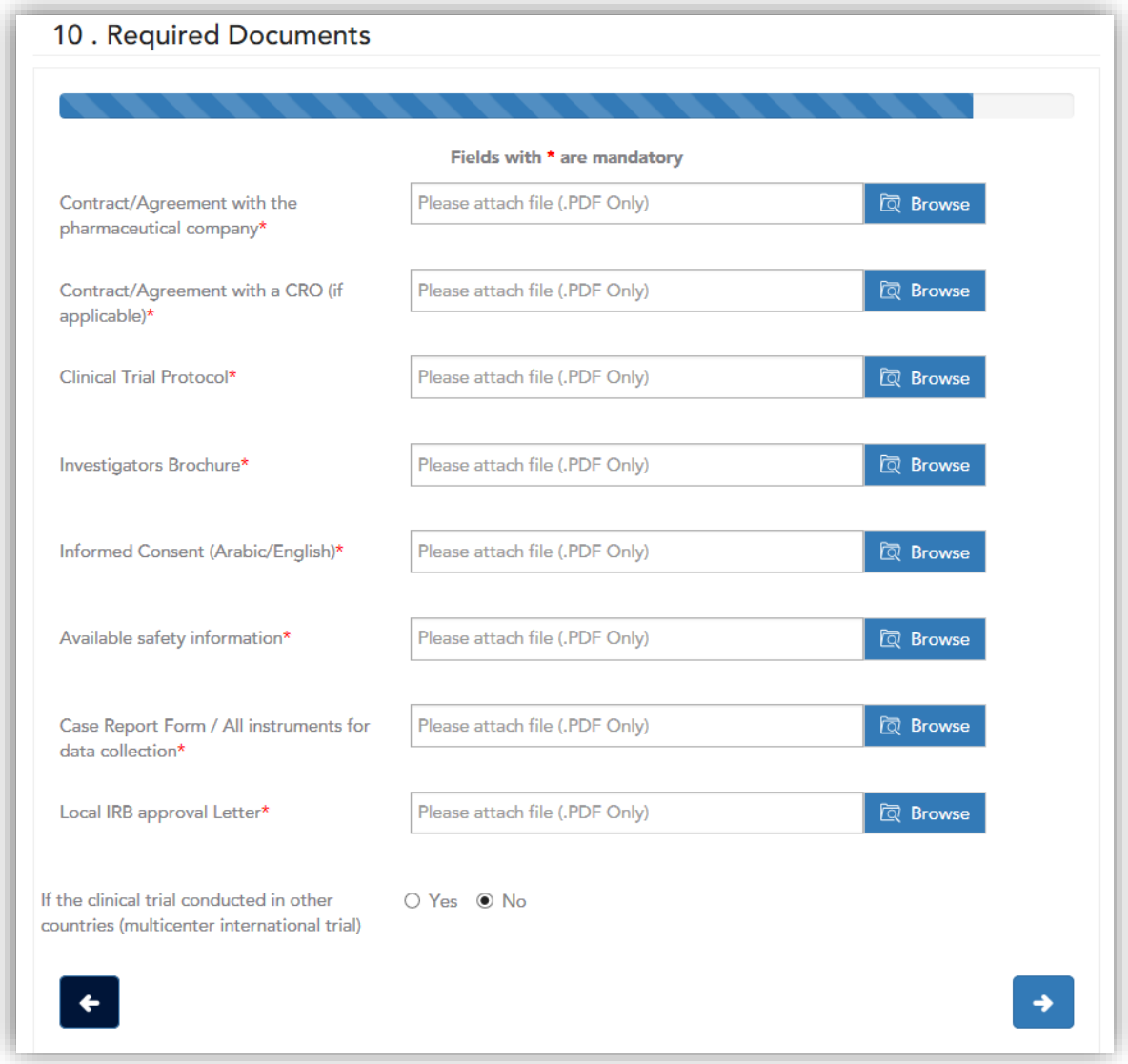


Click on “Add/update” to add the details



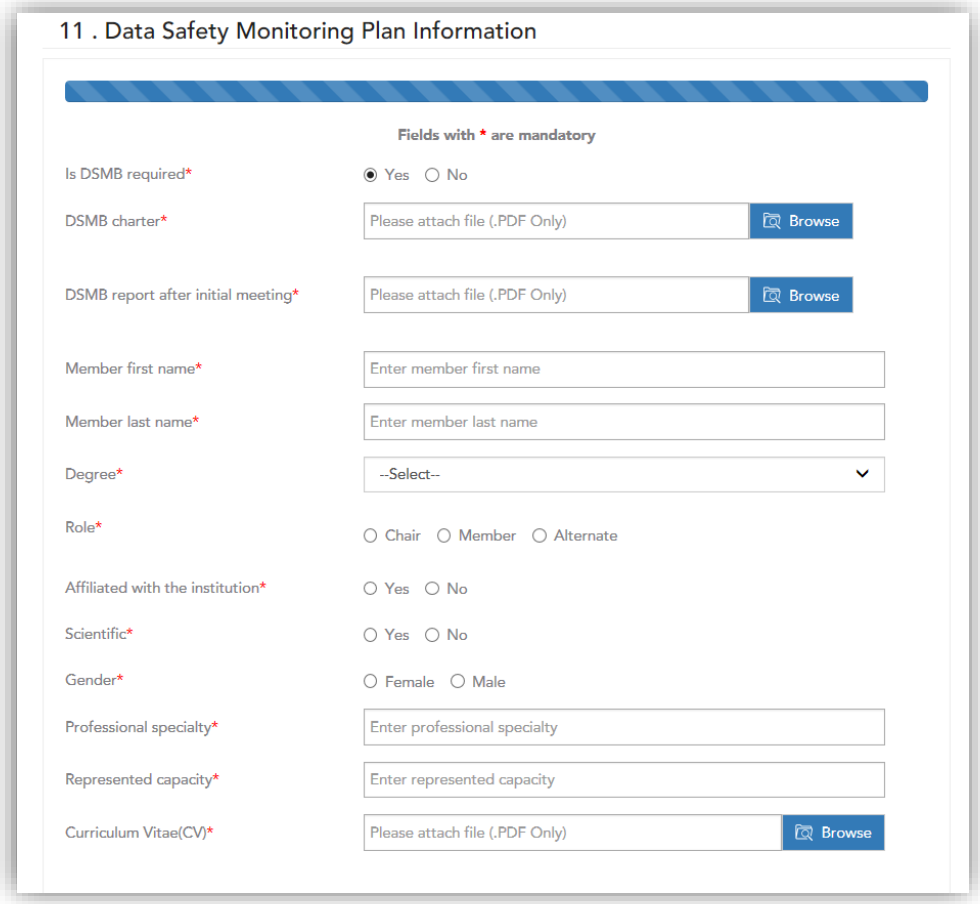


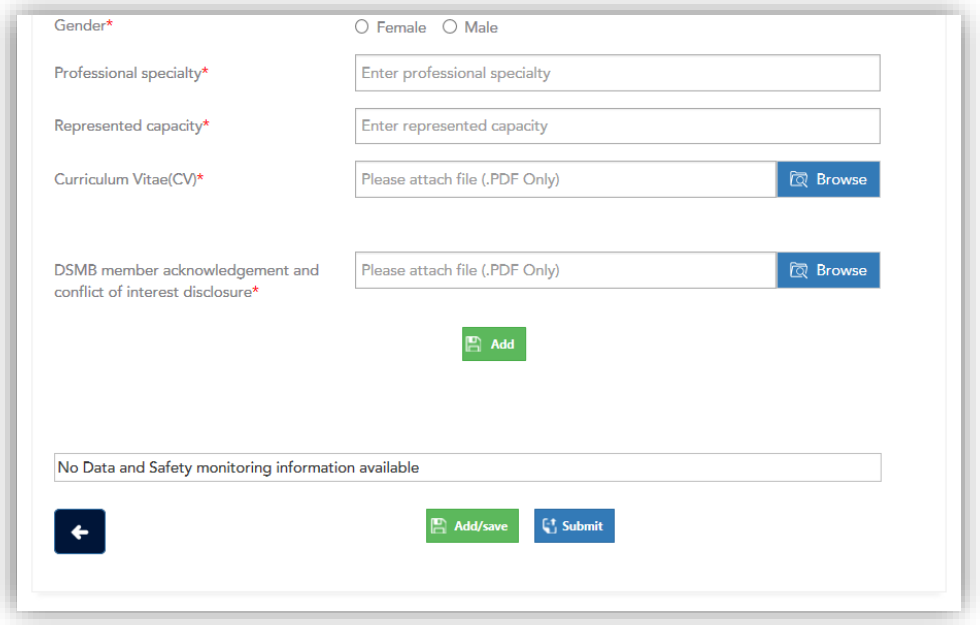
Please add details about all the participating facilities



Please make sure to attach all the required documents.

Note: if any for the requested documents is not available, please attach a supporting document/clarification for the non-availability of the required document

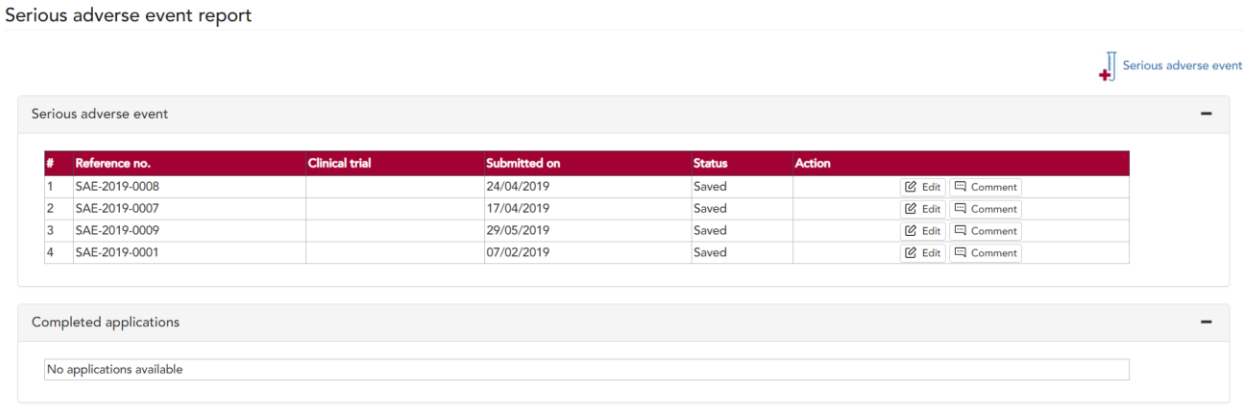


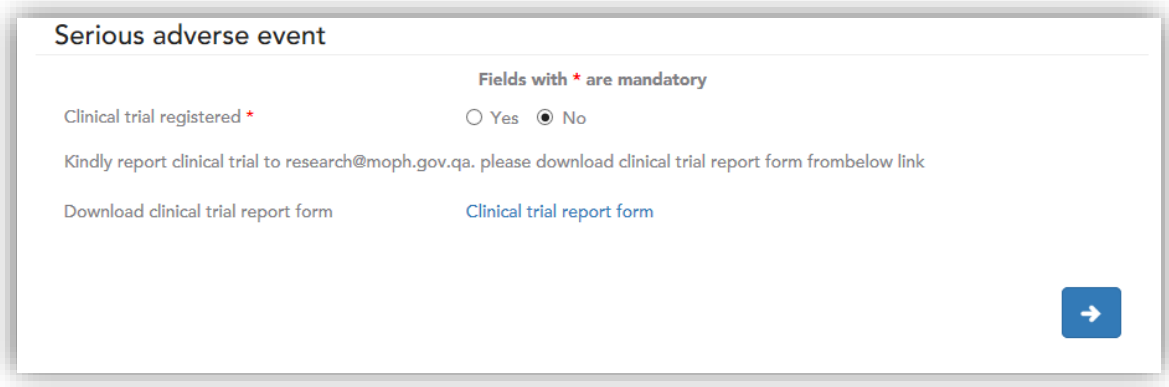


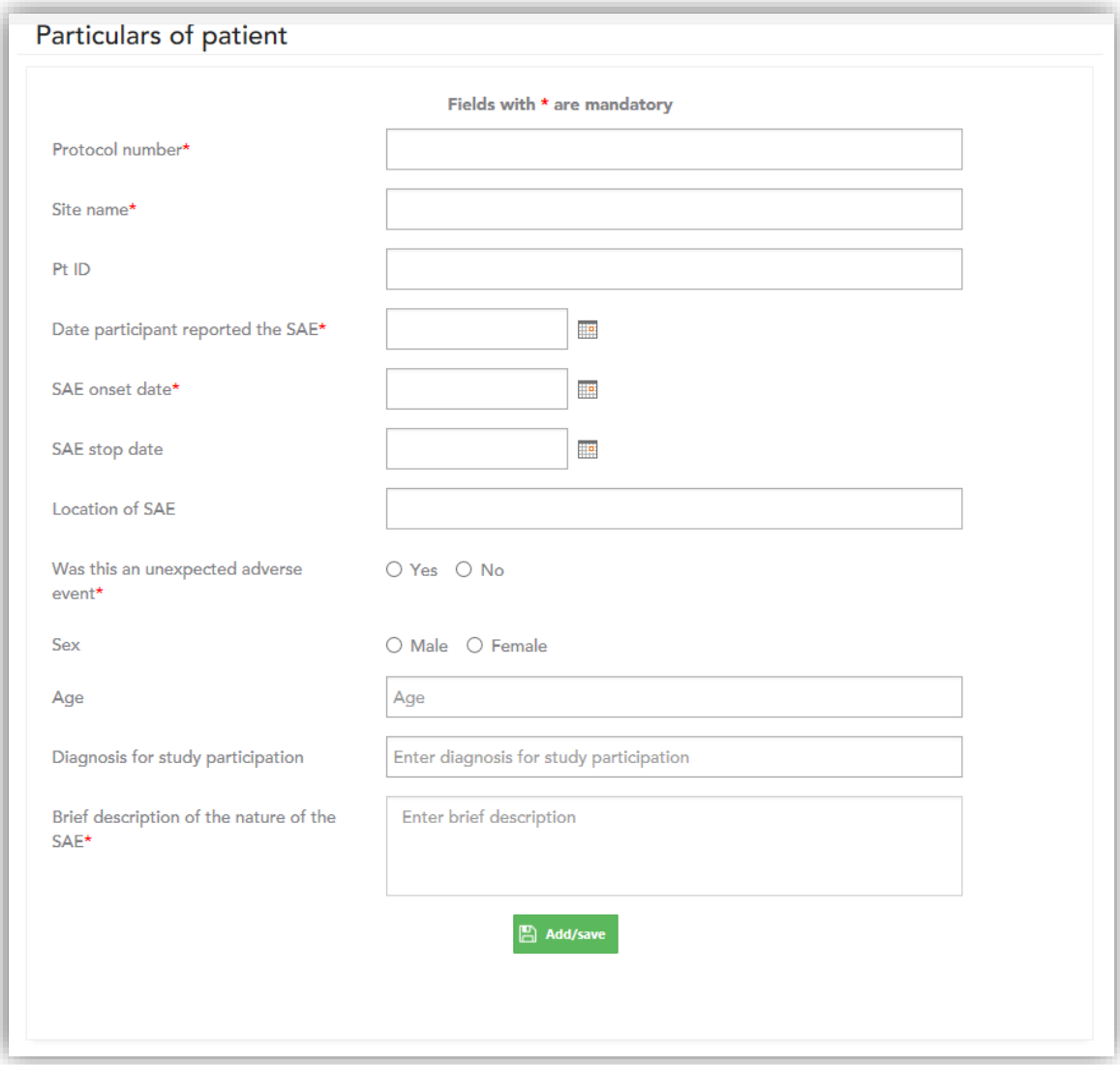
Please click on “Submit” to submit for review, click on “Add/Save” if you wish to submit later

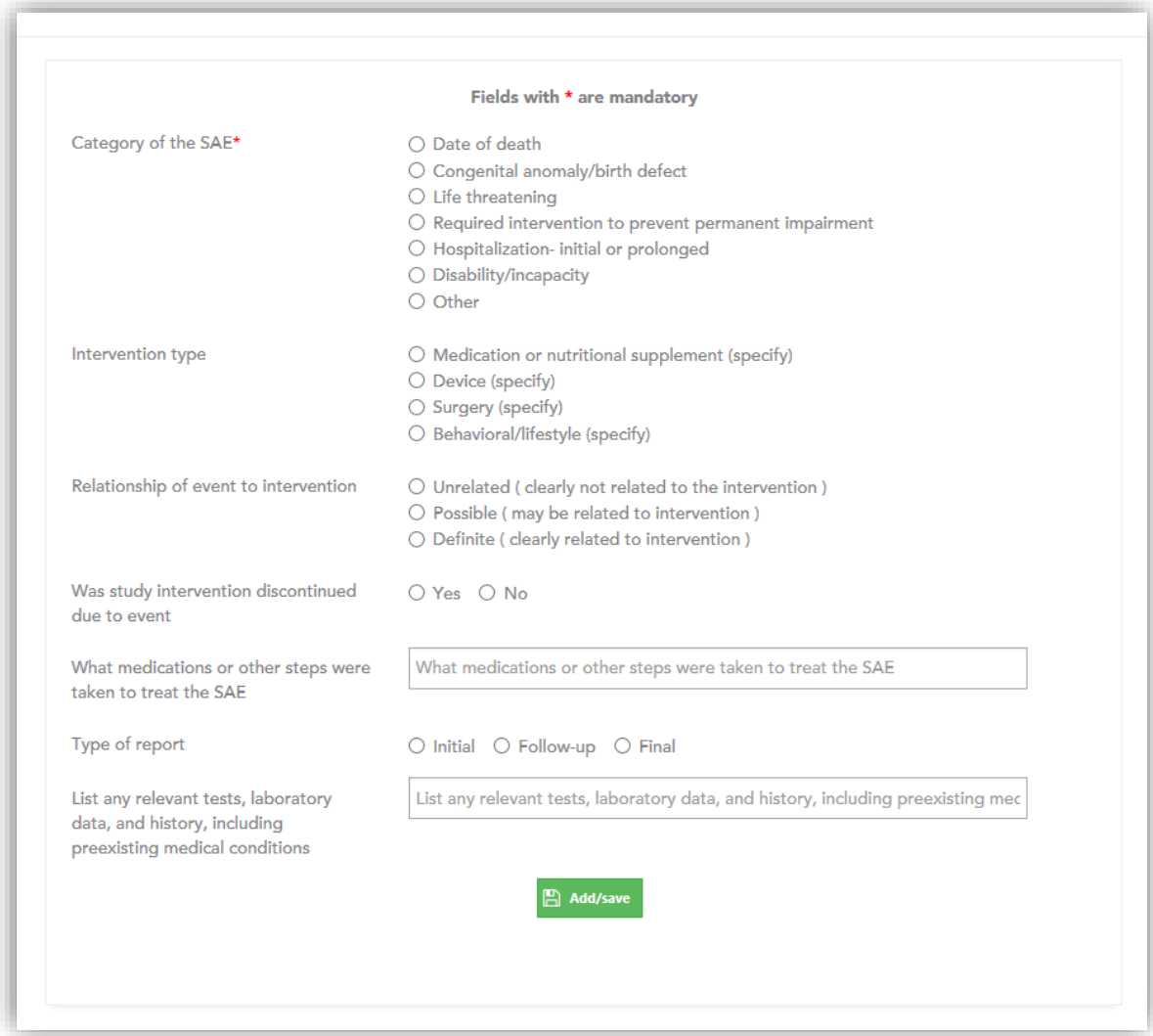
Serious adverse Event

Click on “Serious adverse event” to report a SAE






Particulars of patient
Fields with * are mandatory
Protocol number*
Site name*
Pt ID
Date participant reported the SAE*
SAE onset date*
SAE stop date
Location of SAE
Was this an unexpected adverse event*
Yes
No
Sex
Male
Female
Age
Age
Diagnosis for study participation
Enter diagnosis for study participation
Brief description of the nature of the SAE*
Enter brief description
Add/save



Fields with * are mandatory

Category of the SAE*
- Date of death
- Congenital anomaly/birth defect
- Life threatening
- Required intervention to prevent permanent impairment
- Hospitalization- initial or prolonged
- Disability/incapacity
- Other

Intervention type
- Medication or nutritional supplement (specify)
- Device (specify)
- Surgery (specify)
- Behavioral/lifestyle (specify)

Relationship of event to intervention
- Unrelated (clearly not related to the intervention)
- Possible (may be related to intervention)
- Definite (clearly related to intervention)

Was study intervention discontinued due to event: Yes No

What medications or other steps were taken to treat the SAE: What medications or other steps were taken to treat the SAE

Type of report: Initial Follow-up Final

List any relevant tests, laboratory data, and history, including preexisting medical conditions: List any relevant tests, laboratory data, and history, including preexisting mec

Add/save

Technical Support –

For any technical queries please send an email to – *rdhelpdesk@moph.gov.qa*