

# Research Portal User Manual

## Sponsor

# Table of Contents

---

## Contents

Introduction .....	2
Application access.....	2
User registration & Accesses .....	2
1. For registering as Sponsor click on “Register as Sponsor” .....	2
2. User Login after email verification - .....	5
3. Forgot password .....	5
Menu access .....	6
4. Register Clinical trial.....	7
5. Serious Adverse Event.....	7
Technical Support - .....	24

## 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.

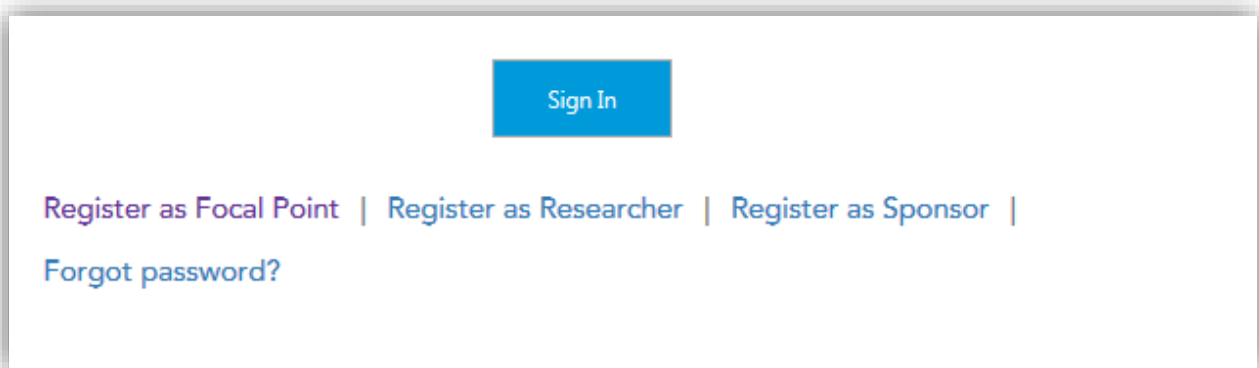
## Application access

[Research Department - MoPH Website](#)

[Research Department - MoPH Portal](#)

## User registration & Accesses

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



### Sponsor registration

First name*	<input type="text" value="Enter Name"/>
Middle initial	<input type="text" value="Enter Middle Name"/>
Last name*	<input type="text" value="Enter Last Name"/>
Login email*	<input type="text" value="example@mail.com"/>
Enter password*	<input type="password" value="Enter Password"/>
Confirm password*	<input type="password" value="Confirm Password"/>
Telephone	<input type="text" value="974 XXXXXX"/>
Pharmaceutical Center*	<input type="text" value="Institution Name"/>
Supporting Document *	<input type="text" value="Please attach file (.PDF Only)"/> <input type="button" value="Browse"/>

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, please select others and provide details about the pharmaceutical center**

### Pharmaceutical Information

Registration no*	<input type="text" value="Enter Registration No"/>
Name*	<input type="text" value="Institution Name"/>
Institution code*	<input type="text" value="Institution Code"/>
Mailing address*	<input type="text" value="Enter Address"/>
City*	<input type="text" value="--Select--"/>
Email	<input type="text" value="example@mail.com"/>
Contact no	<input type="text" value="974 XXXXXX"/>
Fax	<input type="text" value="974 XXXXXX"/>
	<input type="button" value="Add/Save"/>
Supporting Document *	<input type="text" value="Please attach file (.PDF Only)"/> <input type="button" value="Browse"/>

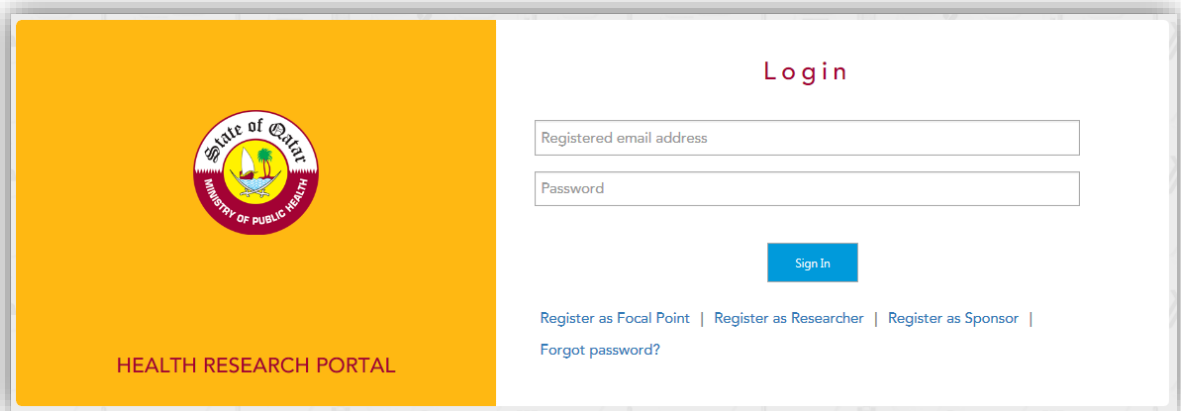
Click submit after entering all the details

Thank you for registering with MoPH Research Department. An email has been sent to your registered email id to activate your account.

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 -



HEALTH RESEARCH PORTAL

State of Qatar  
MINISTRY OF PUBLIC HEALTH

### Login

Registered email address

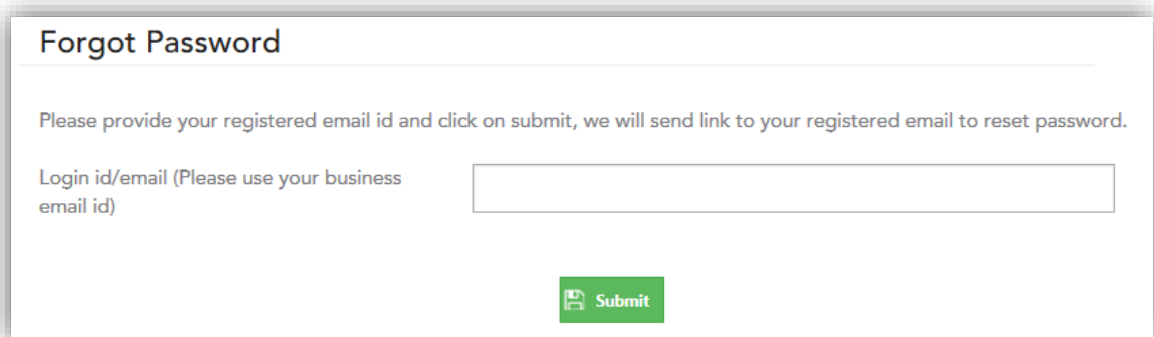
Password

Sign In

Register as Focal Point | Register as Researcher | Register as Sponsor |  
Forgot password?

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

## 3. Forgot password



### Forgot Password

Please provide your registered email id and click on submit, we will send link to your registered email to reset password.


Login id/email (Please use your business email id)

Submit

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

## MoPH Research Portal Reset Password ▶ Inbox x

research@moph.gov.qa

 to me ▾

Dear User,

[Please click here to reset password.](#)

Best regards,

Enter new password and click submit button.

### Reset your account password

Please enter new password*	<input type="password"/>
Please confirm new password*	<input type="password"/>
<input type="submit" value="Submit"/>	

### Menu access

After successful login as Researcher navigate into landing page.

Welcome ! Sponcer SP , you have logged as Sponsor

The image shows two side-by-side interactive tiles. The left tile is titled 'Register Clinical Trial' and contains the text 'View / register / submit clinical trial' and a blue button labeled 'Click to access'. The right tile is titled 'Serious Adverse Event' and contains the text 'Report serious adverse event destails' and a blue button labeled 'Click to access'.

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

View / register / submit clinical trial

Register / submit clinical trial

Saved/Submitted applications							
#	Reference no.	Study Phase	Investigational product	Description	Submitted on	Status	Action
1	CT-2019-0009	phase I	Yes	Observational	14/03/2019	Under Process	Comment
2	CT-2019-0010	phase I	Yes	Observational	19/03/2019	Saved	Edit Comment
3	CT-2019-0004	phase I	Yes	Observational	23/02/2019	Sentback	Edit Comment
4	CT-2019-0016	phase I	Yes	Observational	16/06/2019	Under Process	Comment
5	CT-2019-0011	phase I	Yes	Observational	27/03/2019	Sentback	Edit Comment

Completed applications							
No applications available							

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

### Clinical trial general information

Before proceeding with the on-line application, the approval by both local registered Ethics committees, Data and Safety Monitoring Boards of the affiliated study sites (when applicable), is required. The Sponsor or the Principal investigator are requested to register all the clinical trial on the registration portal of the MOPH.

The review time is different according to the following:

Category A application: include multi-center clinical studies that have been approved by the FDA-USA, the EMA-European Commission or other regulatory agencies (in the UK, Switzerland, Australia, Canada, Germany, South Africa, Japan). Category A application's permission is usually faster than Category B. The review is usually done within four to six weeks.

Category B applications: include Clinical trials with no approval from the above regulatory bodies. These trials are reviewed on a case-by-case basis. Category B application's review is usually done within six to eight weeks.

In all applications, a support letter initiated by MOPH is required in order for the clinical trials to start.



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

A clinical trial is a prospective biomedical or behavioral research study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions such as: drugs, treatments, devices, or new ways of using known drugs, treatments, or device.

Is the clinical research, to be reported, defined as a clinical trial (as per criteria mentioned above)?\*  Yes  No



### 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 device or 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 different\*  Yes  No

Marketed drug

- Indication(s) and clinical use is different
- Target patient population(s) is different
- Route (s) of administration is different
- Dosage regimen(s) is different

Institution



Provide the required information click on “next arrow”

1. Study identification, status, description and keywords

Fields with \* are mandatory

ClinicalTrials.gov Identifier	<input type="text" value="CT-001-2019"/>
Brief Title*	<input type="text" value="Human Anatomy"/>
Acronym*	<input type="text" value="HMNA"/>
Overall Recruitment Status*	<input type="text" value="Recruiting"/>
Study expected start date(mm/dd/yyyy)*	<input type="text" value="8/8/2019"/>
Expected completion date(mm/dd/yyyy)*	<input type="text" value="8/10/2019"/>
Actual completion date(mm/dd/yyyy)	<input type="text"/>
Brief Summary*	<input type="text" value="Brief Summary about the clinical trial"/>
Detailed Description*	<input type="text" value="Detailed Description about the clinical trial"/>
Primary Disease or Condition Being Studied in the Trial or the Focus of the Study*	<input type="text" value="Primary Disease or Condition Being Studied in the Trial or the Focus of the Study"/>
Keywords*	<input type="text" value="Primary Disease"/>

← →

## 2. Sponsor Details

Fields with \* are mandatory

Name of organization*	<input type="text" value="Name of organization"/>
Name of the person to contact*	<input type="text" value="Name of the person to contact"/>
Address*	<input type="text" value="Address of organization"/>
Post code	<input type="text"/>
Telephone number*	<input type="text" value="97411224455"/>
Fax number	<input type="text"/>
Email*	<input type="text" value="organizationofficial@mail.com"/>

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

Name of organization	<input type="text" value="Name of organization"/>
Name of the person to contact	<input type="text" value="Name of the person to contact"/>
Address	<input type="text" value="Address of organization"/>
Telephone number	<input type="text" value="97411224455"/>
Fax number	<input type="text"/>
Email	<input type="text"/>
Status of the sponson	<input type="text" value="--Select--"/>
Source of financing if other than the sponsor	<input type="text"/>

### 3. Investigator Details

Fields with \* are mandatory

**Principal Investigator**

Name*	<input type="text" value="Name of Principal Investigator"/>
Organization*	<input type="text" value="Principal Investigator Organization"/>
Address	<input type="text" value="Principal Investigator Organization Address"/>
Telephone Number*	<input type="text" value="97411224433"/>
Fax Number	<input type="text"/>
Email*	<input type="text" value="pioffical@mail.com"/>

**Co-Investigator**

Name	<input type="text" value="Name of Co-Investigator"/>
Organization	<input type="text" value="Co-Investigator Organization"/>
Address	<input type="text" value="Co-Investigator Address"/>
Telephone number	<input type="text" value="97411224433"/>
Fax number	<input type="text"/>
Email	<input type="text" value="cdpioffical@mail.com"/>

#### 4. Investigational Product Information

Fields with \* are mandatory

Investigational product information

Trade name\*

United state adopted name ( USAN )

IP has marketing authorization in other countries  Yes  No

Country

Record added successfully.!

Trade name	USAN	Country	Action
Investigational product trade name	USANAME	Puerto Rico	<input type="button" value="Delete"/>



## 5 . Study Design

Fields with \* are mandatory

Interventional Study Design*	<input type="text" value="Interventional Study Design"/>
Primary purpose*	<input type="checkbox"/> Treatment <input checked="" type="checkbox"/> Prevention <input type="checkbox"/> Diagnostic <input type="checkbox"/> Supportive Care <input type="checkbox"/> Screening <input type="checkbox"/> Health Services Research <input type="checkbox"/> Basic Science <input type="checkbox"/> Device Feasibility
Additional Primary purpose (if any)	<input type="text"/>
Interventional Study Model*	<input type="checkbox"/> Single Group <input type="checkbox"/> Parallel <input checked="" type="checkbox"/> Crossover <input type="checkbox"/> Factorial <input checked="" type="checkbox"/> Sequential
Model Description*	<input type="text" value="Model Description"/>
Number of Arms*	<input type="text" value="4"/>
Is Masking ?*	<input type="text" value="No"/>
Allocation*	<input checked="" type="radio"/> N/A (not applicable) <input type="radio"/> Randomized <input type="radio"/> Nonrandomized
No of participant*	<input type="text" value="45"/>

## 6 . Arms, Groups and Interventions

**Fields with \* are mandatory**

Arm Information\*

Arm Title

Arm Type  Experimental  Active Comparator  
 Placebo Comparator  Sham Comparator

Additional Arm Type (if any)

Arm Description\*

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)\*

Other Interventions Name(s)\*

Interventions Description\*

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\*

Description\*

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\*

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

Minimum Age\*

Unit Of Time\*

Maximum Age\*

Unit Of Time\*

Eligibility Criteria

## 9. Study Contact Person and Facility Information

Fields with \* are mandatory

User type\*

The name or title, toll-free telephone number and email address of a person to whom questions concerning enrollment at any location of the study can be addressed

First name\*

Middle initial

Last name\*

Title\*


Email\*

Telephone\*

Fax

Position\*



Highest degree\*

 Add/update

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

Data added successfully

 Add/update

User type	Name	Position	E-mail address	Action
Central Contact Person	Ccp First Name Ccp Last Name	Senior	ccp-official@mail.com	 Edit  Delete

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

## 9. Study Contact Person and Facility Information

Fields with \* are mandatory

User type\* Overall Study Officials ▼

Person(s) responsible for the overall scientific leadership of the protocol, including study principal investigator. Include the following information

First name\* OSO first name

Middle initial Middle initial

Last name\* OSO last name

Title\* Mr ▼

Email\* oso-offical@mail.com

Telephone\* 974112233445

Fax 974 XXXXXX





Role\*  Study Chair  Study Director  Study Principal Investigator

Highest degree\* MD, Ph.D. ▼

Click on “Add/update” to add the details

Data added successfully

 Add/update

User type	Name	Position	E-mail address	Action
Central Contact Person	Ccp First Name Ccp Last Name	Senior	ccp-official@mail.com	 Edit  Delete
Overall Study Officials	Oso First Name Oso Last Name	Study Director	oso-offical@mail.com	 Edit  Delete

Facility Information in a clinical study

Definition : for each participating facility in a clinical study, add the following information









Facility information

Unit name



Please add details about all the participating facilities

### 10 . Required Documents

Fields with \* are mandatory

Contract/Agreement with the pharmaceutical company*	Please attach file (.PDF Only)	 Browse
Contract/Agreement with a CRO (if applicable)*	Please attach file (.PDF Only)	 Browse
Clinical Trial Protocol*	Please attach file (.PDF Only)	 Browse
Investigators Brochure*	Please attach file (.PDF Only)	 Browse
Informed Consent (Arabic/English)*	Please attach file (.PDF Only)	 Browse
Available safety information*	Please attach file (.PDF Only)	 Browse
Case Report Form / All instruments for data collection*	Please attach file (.PDF Only)	 Browse
Local IRB approval Letter*	Please attach file (.PDF Only)	 Browse

If the clinical trial conducted in other countries (multicenter international trial)  Yes  No

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**

## 11 . Data Safety Monitoring Plan Information

Fields with \* are mandatory

Is DSMB required\*  Yes  No

DSMB charter\*

DSMB report after initial meeting\*

Member first name\*

Member last name\*

Degree\*

Role\*  Chair  Member  Alternate

Affiliated with the institution\*  Yes  No

Scientific\*  Yes  No

Gender\*  Female  Male

Professional specialty\*

Represented capacity\*

Curriculum Vitae(CV)\*

Gender\*  Female  Male

Professional specialty\*

Represented capacity\*

Curriculum Vitae(CV)\*


DSMB member acknowledgement and conflict of interest disclosure\*

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

Serious adverse event report

 Serious adverse event

Serious adverse event

#	Reference no.	Clinical trial	Submitted on	Status	Action
1	SAE-2019-0008		24/04/2019	Saved	 Edit    Comment
2	SAE-2019-0007		17/04/2019	Saved	 Edit    Comment
3	SAE-2019-0009		29/05/2019	Saved	 Edit    Comment
4	SAE-2019-0001		07/02/2019	Saved	 Edit    Comment

Completed applications

No applications available


### Serious adverse event

**Fields with \* are mandatory**

Clinical trial registered \*  Yes  No

Kindly report clinical trial to [research@moph.gov.qa](mailto:research@moph.gov.qa). please download clinical trial report form from below link

Download clinical trial report form [Clinical trial report form](#)



### 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

Diagnosis for study participation


Brief description of the nature of the SAE\*

 Add/save



**Fields with \* are mandatory**

Category of the SAE*	<input type="radio"/> Date of death <input type="radio"/> Congenital anomaly/birth defect <input type="radio"/> Life threatening <input type="radio"/> Required intervention to prevent permanent impairment <input type="radio"/> Hospitalization- initial or prolonged <input type="radio"/> Disability/incapacity <input type="radio"/> Other
Intervention type	<input type="radio"/> Medication or nutritional supplement (specify) <input type="radio"/> Device (specify) <input type="radio"/> Surgery (specify) <input type="radio"/> Behavioral/lifestyle (specify)
Relationship of event to intervention	<input type="radio"/> Unrelated ( clearly not related to the intervention ) <input type="radio"/> Possible ( may be related to intervention ) <input type="radio"/> Definite ( clearly related to intervention )
Was study intervention discontinued due to event	<input type="radio"/> Yes <input type="radio"/> No
What medications or other steps were taken to treat the SAE	<input type="text" value="What medications or other steps were taken to treat the SAE"/>
Type of report	<input type="radio"/> Initial <input type="radio"/> Follow-up <input type="radio"/> Final
List any relevant tests, laboratory data, and history, including preexisting medical conditions	<input type="text" value="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](mailto:rdhelpdesk@moph.gov.qa)