



**REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH**

Lebanon Clinical Trials Registry (LBCTR)

PUBLIC & APPLICANT USER GUIDE

August 2019



**REPUBLIC OF LEBANON
MINISTRY OF PUBLIC HEALTH**

TABLE OF CONTENTS



Introduction	2
Overview	2
Registering to the LBCTR and becoming an applicant.....	3
Registering a new applicant user	3
Logging on to the LBCTR as an Applicant.....	4
Managing my trials	5
Trial statues in the LBCTR	5
Registering a new clinical trial.....	6
Trial attachments.....	7
Trial results.....	7
Reviewing Administrator messages.....	8
Withdrawing a trial version	8
Downloading a trial version.....	9
Trial versions (Audit trail).....	9
How it works.....	9
User profile and password changing	10
Contact us and messaging	10
Frequently Asked Questions	11
What is a clinical trial?	11
What is the Lebanon Clinical Trials Registry?.....	11
What is the purpose of the LBCTR and why is it important?	11
Why do I need to register my trial and submit the results to the LBCTR?.....	12
Who funds the LBCTR?.....	12
Is there a charge for registering studies with the LBCTR?.....	12
My study is not yet approved by a human-subjects review board, can I register it with the LBCTR?.....	12
When will the registration number for my study be assigned?.....	13
Can I register a study after it has started, has been closed to recruitment, or has been completed? (Retrospectively)	13
What is time needed for a study to be reviewed and published at LBCTR.....	13
Annex-Tips and Description of Items to be filed in Registry.....	14

Introduction

The objective of this document is to provide an overview description as well as basic guidelines to the public and registered “applicant” users of the Lebanon Clinical Trials Registry website.

This document contains instructions on how to:

- View and search for published trials using the “Simple” and “Advanced” search functions.
- Register a new “Applicant” user.
- Register a new clinical trial application on the website.
- Review previously created trials’ applications and follow up on the applied ones that are still in process or under review.
- Modify an already existing trial application.
- Withdraw a trial before Publishing.
- View previous version(s) of a given trial, (i.e.: History versions)

As well as describe the process flow of any given clinical trial application from creation to getting the feedback and end result from the Lebanese MoPH’s reviewing committee(s)/Registry Administrator.

Overview

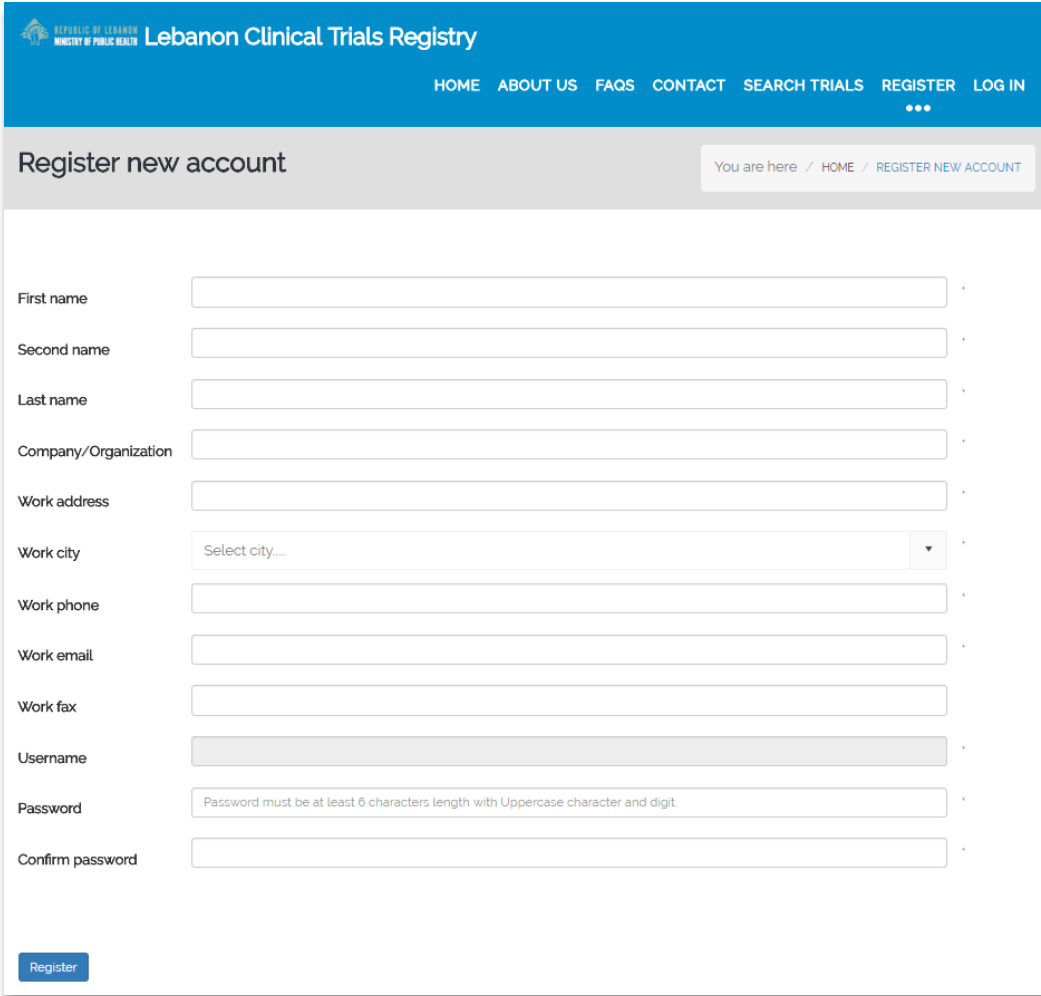
The Lebanon Clinical Trials Registry (LBCTR) is officially announced a primary registry where organizations and individuals can register their trials and in turn is serving as a data provider to the World Health Organization – International Clinical Trials Registry Platform (WHO ICTRP).

The LBCTR public website consists of two main areas; **Public users’** area, and the **Applicant users’** area. The public area is accessible for any visitor of the website, where they can review and obtain different information about the LBCTR and its contents as well as answers for the most popular questions they may have about the LBCTR; what it is, who is responsible for it, how does it work, and how to be an applicant and publish trials. All users are also able to review the publicly published trials as well as search for a specific or a group of trials using the “Simple” and/or the “Advanced” search capabilities available on the website.

Registering to the LBCTR and becoming an applicant

Registering a new applicant user

If you want to register a clinical trial in Lebanon and have your trial published online on the LBCTR, you will first need to have a registered **Applicant** user. To do so, go to the “Register” page on the main menu and fill-in all the mandatory fields, then finally submit the form to the website Administrator for approval and activation of the newly created account.



The screenshot shows the 'Register new account' page on the Lebanon Clinical Trials Registry website. The page has a blue header with the logo and navigation links: HOME, ABOUT US, FAQs, CONTACT, SEARCH TRIALS, REGISTER, and LOG IN. Below the header, the page title is 'Register new account' and there is a breadcrumb trail: 'You are here / HOME / REGISTER NEW ACCOUNT'. The form contains the following fields:

- First name
- Second name
- Last name
- Company/Organization
- Work address
- Work city (dropdown menu with 'Select city...' text)
- Work phone
- Work email
- Work fax
- Username
- Password (with a note: 'Password must be at least 6 characters length with Uppercase character and digit')
- Confirm password

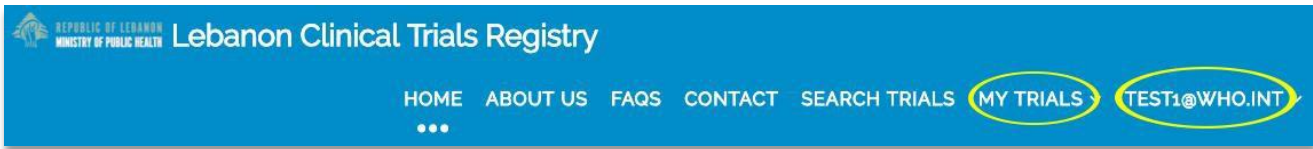
A blue 'Register' button is located at the bottom left of the form.

Upon submission, the user creation request goes to the website Admin, who will review and vet the applicant information. The Admin may get in touch with you either by phone or email to get additional information before approving the account creation.

Once the Admin approves and activates the account, you will receive an email informing you that your Applicant account has been approved, after which you will be able to use it to log in to the LBCTR website and: create a new trial application, review and/or update previously created application(s), and perform other functions as described and explained in details later on in this document.

Logging on to the LBCTR as an Applicant

After you successfully log-in to the website, two new items will appear in the main menu at the top of the page: **My Trials** and a User-specific menu showing your username, which in this document we will call **test1@who.int**.



The **My Trials** menu item contains links to the **View my trials** and the **Create new trial** pages.

View my trials page contains a list of all the trials that you created using your applicant user, and you may view the details of any of them by clicking on a trial's *Primary Registry Identifying Number*. On that page you may also click on the **Create new trial** button to start a new clinical trial application.

You may also go directly to that page by clicking on the **Create new trial** link under **My Trials** submenu item.



The **test1@who.int** menu item contains links to **My profile**, **Change password**, and **Log off**. My profile is where you may view and update you information except for the “Username” field which cannot be changed after being set the very first time during registration.

The page also contains a link to change your password where the you would need to enter the current (old) password, enter the new password and confirm it, then finally save the changes.

You may also go directly to the Change password page by clicking on the **Change password** link on the submenu item.

Managing my trials

This section is where you will find your previously created trials applications and their current statuses, create new trial applications, modify the existing ones, and review the history / previous version(s) of your trials (if applicable).

Trial statuses in the LBCTR

There are **six** trial statuses in the LBCTR, and each trial must have its status set to one of them at any given time. The LBCTR Admin is responsible for changing trials' statuses according to the trial information entered by the applicant (e.g. completion of the information and any needed explanation, level of details, clarity and understandability of the information provided, ...) and after that the feedback returned from the reviewing committee(s) for interventional studies that involves the importation of pharmaceutical products, medical devices or herbal supplements.

Trial statuses are: **Draft**, **Submitted**, **In process**, **Returned for comments**, **Approved**, and **Rejected**.

NOTE

A trial is published online on the LBCTR website for the public access only after the reviewing committee/Registry Administrator has approved it and the LBCTR Admin has changed its status to **Approved**.

NOTE

After submitting a trial, that trial gets locked and can no longer be modified until the LBCTR Admin unlocks it, enabling the applicant to make modifications to it once again.

NOTE

If a trial application gets rejected, the application form will remain locked and the applicant will not be able to make any modifications to it. The applicant may create and submit a new trial application.

Registering a new clinical trial

This is where you may create and submit new trials. The page consists of fourteen expandable sections, each of them containing a group of related fields and with a title representing the scope of those fields.

On top of the sections, you will find a link to a PDF document about tips and descriptions of the items to be filled. See in Annex at end of this guide.

[Click here to view the tips and fields' descriptions](#)

Main Information
Secondary Identifying Numbers
Sources of Monetary or Material Support
Secondary Sponsors
Contact for Public/Scientific Queries
Centers/Hospitals Involved in the Study
Ethics Review
Countries of Recruitment
Health Conditions or Problems Studied
Interventions
Primary Outcomes
Key Secondary Outcomes
Trial Attachments
Trial Results (this section is filled later)

**A trial cannot be deleted once it has been registered and/or published.*

**Trial results section should be filled within a year of the trial closure date.*

**Not all retrospective registrations will be acceptable unless the justification provided is reasonable.*

I consent to publishing what was written in the fields only.


Some of the sections contain dynamic tables where you may add as much rows you need in order to include all the necessary information. For example, if a trial has two secondary sponsors, then they both have to be entered. You may do so by first expanding the **Secondary Sponsors** section, then clicking on the **Add records +** button which will add a new row to the table containing the necessary field(s) (in this case it is only the name of the sponsor).

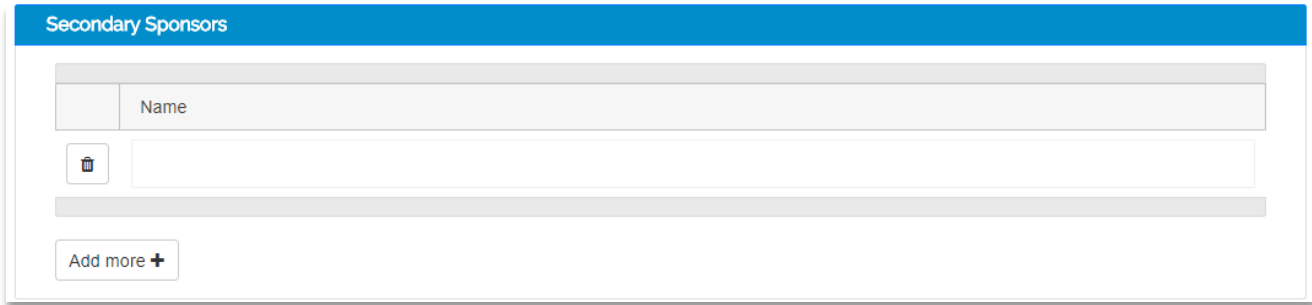
Each section should be saved before moving to the next section.

In main information section, most of the fields are mandatory and are marked with a red star.

NOTE

Once a new row is added to a dynamic table, all the contained fields must be entered.

A row can be deleted from a dynamic table by clicking the corresponding  icon.



Upon completion of the form you will have to agree to have your trial automatically published on the LBCTR website by checking the “***I consent to publishing what was written in the fields only***” checkbox.

You may, at any time, and before submitting the trial, click the **Save as draft** button to save and preserve the current state of the trial as is, in order to finish and submit it later. The draft will be saved, and you may go back to it by searching for it in the **My Trials** page.

Once a trial is submitted, you will receive a confirmation email, and the trial application status will be changed to **Submitted**. You may still open and view you submitted trial, however, you will no longer be able to modify it. As soon as the trial starts going through the reviewing process, its status will change to **In Process by Registry Administrator**, and you will receive a notification email about the updated status.

A new additional **Download as PDF** button will appear at the bottom of the **Trial details** page once a trial is submitted; this button is used to downloading a PDF formatted version of that trial.

Trial attachments

There are mandatory supporting documents that must be attached and uploaded with every trial application. The trials attachments has three sections; for registration, for importation purposes and related for safety reporting and amendments. After attaching each document; save before proceeding to attaching other documents. All files to be attached are to be kept confidential, for internal use only and not for publishing. All documents attached will be kept in history records from administrator side in case record of a study is updated.

The mandatory documents for registration are: Protocol, IRBs, Investigator brochure, Principle investigator letter, country of origin registration, and summary on product. The mandatory documents for importation (if applicable): Importation request, Invoice, Certificate of analysis, Certificate of release, Pharmacy request, and GMP certificate. Attachments fields are secured.

NOTE

Only **PDF** and **Microsoft Word (DOC, DOCX)** file types are allowed for uploading trial' attachments.

Trial results

For Trials results; they should be reported within a year of study closure date.

Reviewing Administrator messages

There might be cases where the Admin or the reviewing committee needs more information or clarification regarding a submitted trial, in that case the LBCTR Admin will change the trial's status to **Returned for comments**, you will receive an email notification, and the trial will become editable once again for you to apply the required modification(s) and/or provide the additional information according to what is stated in the Admin message. Administrator messages will be shown in a separate section that will appear at the bottom of the trial application form as shown in the following figure.

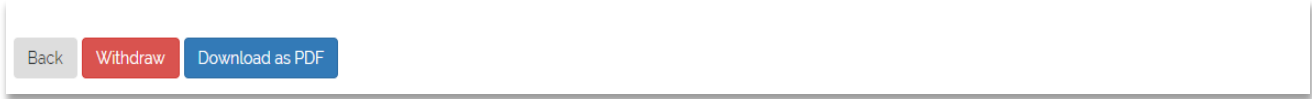
Administrator Messages	
Message	Date
This is the first message	15/05/2018
Second message	29/05/2018
Third message	12/06/2018

Withdrawing a trial version

Whenever you want to retract a trial application that has been submitted before being published; you can send the administrator a message to withdraw the record of that study. Once a record is published, it cannot be withdrawn. You can only make changes to some fields once the study is published; for example recruitment status.

Downloading a trial version

Downloading a trial is achieved by just opening any trial desired and scrolling to the bottom where there will be a blue **Download as PDF** button on the left that when clicked, it will generate a PDF formatted version of that trial and prompt the website visitor/applicant to download the generated file to their computer.



Trial versions (Audit trail)

In the LBCTR, a trial can have more than just one version at the same time; only one version will be labeled as current and published to the public access. Older versions will have a tag inside “previous version”. This versioning feature enables the LBCTR to keep previous (older) versions of any given approved (online) trial, in case the owner updates and submits the trial and it gets approved by the LBCTR Admin. When that happens, the newly approved version of the trial will take the older version’s place on the LBCTR public website, and older version will still be accessible for the public through designated buttons located within the **Trial version(s)** expandable section on the top left of the **Trial details** page.

The goal of this feature is to make it possible for the LBCTR visitors and users to observe and compare the differences made to the published trials over time.

How it works

When an applicant submits a trial application form and it eventually gets approved, this trial version then becomes the **Current** version of the trial. A current version of any trial is the version that is currently published and accessible for all the LBCTR website visitors. If this trial used to have an older version that was approved and published, that older version is then marked as a history version and will still be accessible through the **Trials version(s)** expandable section on the **Trial details** page.



The Trials version(s) section will show buttons for *each history version* (if exists), *the current version*, *the newly submitted version* (if there is one). However, the new button will appear only to the owner applicant of the trial.

User profile and password changing

This is where you may review and update your information and change your password when needed. The **Change Password** page is accessible through the link on the bottom of the **My Profile** page, or directly through the **Change Password** link on the main menu under applicant-specific menu item.

Contact us and messaging

This page consists of two parts; the first part contains information about who to contact and how, in addition to details about the physical address.

The second part is a form that the LBCTR website visitors can use to directly message the Admin regarding any feedback, support, or complaint(s) they might have.

Send Message

Name

Email

Message type

Feedback ▾
Feedback
Support
Complaint

Message

Frequently Asked Questions

What is a clinical trial?

A clinical trial is any research project that prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the cause-and-effect relationship between a health-related intervention and a health outcome. Health-related interventions are those used to modify a biomedical or health-related outcome; examples include drugs, surgical procedures, devices, behavioral treatments, educational programs, dietary interventions, quality improvement interventions, and process-of-care changes. Health outcomes are any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events.

What is the Lebanon Clinical Trials Registry?

The Lebanon Clinical Trials Registry (LBCTR) is an online registry of clinical trials being undertaken in Lebanon. The LBCTR includes trials that target humans; from the full spectrum of therapeutic areas of pharmaceuticals, surgical procedures, preventive measures, lifestyle, devices, treatment and rehabilitation strategies and complementary therapies. The LBCTR will allow registration for investigational (mandatory for some types of interventional studies) as well as observational studies (optional).

What is the purpose of the LBCTR and why is it important?

The purpose of clinical trial registration is to have transparency of research conducted in Lebanon and to prevent selective publication and selective reporting of research outcomes, to prevent unnecessary duplication of research effort, to help patients and the public know what trials are planned or ongoing into which they might want to enroll, and to help give ethics review boards considering approval of new studies a view of similar work and data relevant to the research they are considering. Thus, prospective registration is a must and should be done before the first patient enrolment. In addition, Clinical Trial registration is needed to fulfill ethical obligations to participants and the research community, help editors and others understand the context of study results, facilitate systematic reviews and other analyses of the research literature and promote more efficient allocation of research funds and aids the Ministry of Health to regulate clinical trials done in the country.

Why do I need to register my trial and submit the results to the LBCTR?

It will be required by a Ministerial Decree that will be issued by the Minister of Public Health: It will require (obligatory) responsible parties to register and submit summary results of investigational clinical trials conducted in Lebanon that involve pharmaceutical products (Phase II to IV), medical devices and genetic testing with Lebanese Clinical Trials Registry. Phase I studies will not be allowed in Lebanon. Some studies might be considered if the product will be locally manufactured (to support innovation) or if proven safety in humans (used in other diseases/conditions).

Observational studies are optional (on voluntary basis) to be registered, but highly recommended/encouraged.

Registration of clinical trials is also required for Journal Publication: The International Committee of Medical Journal Editors (ICMJE) requires trial registration as a condition of the publication of research results generated by a clinical trial. The ICMJE requires, and recommends that all medical journal editors require, registration of clinical trials in a public trials registry at or before the time of first patient enrolment as a condition of consideration for publication. Editors requesting inclusion of their journal on the ICMJE website list of publications that follow ICMJE guidance should recognize that the listing implies enforcement by the journal of ICMJE's trial registration policy. The ICMJE accepts registration in any registry that is a primary register of the WHO International Clinical Trials Registry Platform (ICTRP).

The Lebanese Clinical Trials Registry (LBCTR) is officially a primary registry where organizations and individuals can register their trials that are conducted in Lebanon and LBCTR in turn will serve as a data provider to the WHO ICTRP.

Who funds the LBCTR?

The Lebanese Ministry of Public Health.

Is there a charge for registering studies with the LBCTR?

No there is not.

My study is not yet approved by a human-subjects review board, can I register it with the LBCTR?

No you cannot.

When will the registration number for my study be assigned?

After being approved for publication.

Can I register a study after it has started, has been closed to recruitment, or has been completed? (Retrospectively)

No, it has to be registered before the recruitment of the first patient/subject. (Prospective registration).

Some retrospective registrations will be acceptable given a reasonable justification is provided.

Whats is the time needed for a study to be reviewed and published at LBCTR?

Maximum of 2 weeks

Annex

Tips and definitions for items of the registry to be filled

Main Information Section:

Most of fields are mandatory and are marked by a red star.

It includes the following fields:

- **Primary Registry Identifying Number**

Name of Primary Registry and the unique ID number assigned by the Primary Registry to this trial once a record is opened.

- **Protocol Number**

It is the international unique number of any trial.

- **MOH Registration Number**

It is given once study is submitted by hand to the ministry for importation purposes (if applicable). This number to be entered at a later stage not at opening of record, unless it is available. Tick a checkbox if the study is already registered at the MOH and date of registration in national regulatory agency should also be entered (if applicable/available).

- **Tick checkbox if the study is registered at country of origin;** where the product used in the trials is being manufactured. If not registered, justify why not. It is a requirement by the MOH to approve studies that are conducted at country of origin.

- **Type of Registration;** registration should be done before the recruitment of the first patient, thus this is considered prospective registration.

For retrospective registration a justification should be provided. Not all retrospective registration will be acceptable unless the justification is reasonable. Example; study started before the registry existed.

- **Primary Sponsor**

The individual, organization, group or other legal entity which takes responsibility for initiating, managing and/or financing a study. The Primary Sponsor is responsible for

ensuring that the trial is properly registered. The Primary Sponsor may or may not be the main funder. Primary sponsor country of origin is also required; this is where the product used (pharmaceutical, medical device, others) in the study is manufactured.

- **Public Title with Acronym (if applicable)**

Title intended for the lay public in easily understood language.

- **Scientific Title with Acronym (if applicable)**

Scientific title of the study as it appears in the protocol submitted for funding and ethical review. Include trial acronym if available. Acronym is a short abbreviation that is usually given to studies.

- **Brief Summary of Study in English & Arabic**

To give a brief in a simple language about the study objective to target lay people and patients.

- **Health Condition(s) or Problem(s) Studied**

Primary health condition(s) or problem(s) studied (e.g., depression, breast cancer, medication error). If the study is conducted in healthy human volunteers belonging to the target population of the intervention (e.g. preventive or screening interventions), enter the particular health condition(s) or problem(s) being prevented.

Another section after the main information section will require more details about the health conditions; where it is required to add name of condition, code of disease/condition based on ICD 10 to be chosen from a list, and to add keywords.

- **Intervention(s)**

For each arm of the trial record a brief intervention name plus an intervention description.

Another section after the main information section will require more details about the interventions and these include:

Intervention Name: For drugs use generic name; for other types of interventions provide a brief descriptive name.

o For investigational new drugs that do not yet have a generic name, a chemical name, company code or serial number may be used on a temporary basis. As soon as the generic name has been established, update the associated registered records accordingly.

o For non-drug intervention types, provide an intervention name with sufficient detail so that it can be distinguished from other similar interventions.

Intervention Description: Must be sufficiently detailed for it to be possible to distinguish between the arms of a study (e.g. comparison of different dosages of drug) and/or among similar interventions (e.g. comparison of multiple implantable cardiac defibrillators). For example, interventions involving drugs may include dosage form, dosage, frequency and duration.

If the intervention is one or more drugs then use the International Non-Proprietary Name for each drug if possible (not brand/trade names). For an unregistered drug, the generic name, chemical name, or company serial number is acceptable.

If the intervention consists of several separate treatments, list them all in one line separated by commas (e.g. "low-fat diet, exercise").

For controlled trials, the identity of the control arm should be clear. The control intervention(s) is/are the interventions against which the study intervention is evaluated (e.g. placebo, no treatment, active control). If an active control is used, be sure to enter in the name(s) of that intervention, or enter "placebo" or "no treatment" as applicable. For each intervention, describe other intervention details as applicable (dose, duration, mode of administration, etc.).

Keywords

• **Key Inclusion and Exclusion Criteria**

Inclusion and exclusion criteria for participant selection, including age and gender. Other selection criteria may relate to clinical diagnosis and co-morbid conditions; exclusion criteria are often used to ensure patient safety.

Age maximum should not exceed 100 (to have a reasonable age set).

• Study Type

Study type consists of:

- o Type of study (interventional or observational)
- o If Interventional, specify type of intervention (choose from a list): pharmacological, surgical, behavioral treatment, educational programs, dietary intervention, quality improvement, process of care changes, preventive measures, life style changes, complementary therapies, rehabilitation strategies, devices, radiation, genetic, diagnostic, combination.
- o Then, you have to specify Trials scope (also to choose from a list): prophylaxis, therapy, safety, pharmacokinetics, dose-response, pharmacogenetic, or others.
- o Study design including:
 - Method of allocation (randomized/non-randomized/NA*) *Not Applicable
 - Masking (Open/Blinded/NA)
 - Design Control: (placebo, active, uncontrolled, historical, dose comparison, NA)
 - Purpose (Treatment, prevention, diagnostic, supportive care, screening, health services research, basic science, others)
 - Assignment (single arm, parallel, crossover or factorial, others)
- o Study Phase (if applicable)
- o Pharmaceutical Class if applicable if the study include a pharmaceutical product or more
- o Therapeutic indication of the product/procedure used within the study and therapeutic benefit of the study
- o If Interventional, and type of intervention is chosen to be pharmaceutical, additional fields will appear name if Investigational medicinal product (IMP), if IMP has marker authorization (only in Lebanon, or worldwide, both or not marketed yet) with year of authorization (if applicable). Also you need to specify the type of the IMP: (cell therapy, gene therapy, Immunological, plasma derived, radiopharmaceutical, product containing genetically modified organism, others)
- o IF study is observational, new fields will open to be filled:
 - Study Model (cohort, case-control, case-only, case-crossover, ecologic or community studies, family-based, others) with a field to explain the model of the study.
 - Time perspective (retrospective/prospective/others) and to explain the time perspective.
 - Target follow up duration and unit
 - Number of groups/cohorts

- **Biospecimen retention**

To state whether biological samples are to be retained and not, and if so, if the samples will include DNA and describe the specimens to be collected during the study.

For DNS samples collected, additional requirements might be requested following current laws and regulations.

- **Sample Size**

Sample Size consists of:

- o Number of participants that the trial plans to enroll in total.
- o Number of participants that the trial has enrolled.

- **Date of First Enrollment**

Anticipated or actual date of enrolment of the first participant.

- **Date of Study Closure**

Anticipated or actual date of closure of the study which is the expected or official study end date hat is established by the IRB closure letter.

- **Recruitment Status**

Recruitment status of this trial:

- o Pending: participants are not yet being recruited or enrolled at any site
- o Recruiting: participants are currently being recruited and enrolled
- o Suspended: there is a temporary halt in recruitment and enrolment
- o Not recruiting
- o Complete: participants are no longer being recruited or enrolled
- o Other

- **Completion date**

Date of study completion: The date on which the final data for a clinical study were collected (commonly referred to as, "last subject, last visit").

• IPD sharing statement

Statement regarding the intended sharing of de identified individual clinical trial participant-level data (IPD). Should indicate whether or not IPD will be shared, what IPD will be shared, when, by what mechanism, with whom and for what types of analyses. It consists of:

- o Plan to share IPD (Yes, No)
- o IPD sharing statement description

• Secondary Identifying Numbers

Other identifiers include:

- o The Universal Trial Number (UTN)
- o Other trial registration numbers issued by other Registries (both Primary and Partner Registries in the WHO Registry Network, and other registries)
- o Identifiers issued by funding bodies, collaborative research groups, regulatory authorities, ethics committees / institutional review boards, etc.

All secondary identifiers should have 2 elements: an identifier for the issuing authority (e.g. NCT, ISRCTN, ACTRN) plus a number.

There is no limit to the number of secondary identifiers that can be provided.

If no secondary identifying number place Not applicable (NA).

• Source(s) of Monetary or Material Support

Major source(s) of monetary or material support for the trial (e.g. funding agency, foundation, company, institution).

• Secondary Sponsor(s)

Additional individuals, organizations or other legal persons, if any, that have agreed with the primary sponsor to take on responsibilities of sponsorship.

A secondary sponsor may have agreed to:

- o take on all the responsibilities of sponsorship jointly with the primary sponsor; or
- o form a group with the Primary Sponsor in which the responsibilities of sponsorship are allocated among the members of the group; or
- o act as Primary Sponsor's legal representative in relation to some or all of trial sites.

• Contact for Public Queries

Email address, telephone number and postal address of the contact who will respond to General queries, including information about current recruitment status.

Public queries contact should be local (i.e based in Lebanon) and not related to any pharmaceutical industry.

• Contact for Scientific Queries

There must be clearly assigned responsibility for scientific leadership to a named Principal Investigator. The PI may delegate responsibility for dealing with scientific enquiries to a scientific contact for the trial. This scientific contact will be listed in addition to the PI.

At least one contact information should be added for each field.

• Centers/Hospitals involved in the study (in Lebanon)

To add the name of the hospital/center, Principle investigator name and specialty to double check if he/she is fit for the trial scope, and if there is ethical approval (approved, not approved or Not applicable).

• Ethics Review

The ethics review process information of the trial record in the primary register database.

It consists of:

- o Name of Ethics committee that gave the approval, to be chosen from a list of authorized IRBs in Lebanon, if applicable
- o Date of approval
- o Name and contact details of Ethics committee(s)

• Countries of Recruitment

The countries from which participants will be, are intended to be or have been recruited at the time of registration. Lebanon should be included in the list.

• **Primary Outcome(s)**

Outcomes are events, variables, or experiences that are measured because it is believed that they may be influenced by the intervention.

The Primary Outcome should be the outcome used in sample size calculations, or the main outcome(s) used to determine the effects of the intervention(s). Most trials should have only one primary outcome.

For each primary outcome provide:

- o The name of the outcome (do not use abbreviations)
- o The metric or method of measurement used (be as specific as possible)
- o The timepoint(s) of primary interest

Example:

Outcome Name: Depression

Metric/method of measurement: Beck Depression Score

Timepoint: 18 weeks following end of treatment

• **Key Secondary Outcomes**

Secondary outcomes are outcomes which are of secondary interest or that are measured at timepoints of secondary interest. A secondary outcome may involve the same event, variable, or experience as the primary outcome, but measured at timepoints other than those of primary interest.

As for primary outcomes, for each secondary outcome provide:

- o The name of the outcome (do not use abbreviations)
- o The metric or method of measurement used (be as specific as possible)
- o The timepoint(s) of interest

• **Trial Attachments**

The trials attachments has three sections; for registration, for importation purposes and related for safety reporting and amendments. Choose type of the document from a list and upload, after attaching each document; save before proceeding to attaching other documents. All files to be attached are to be kept confidential, for internal use only and not for publishing. All documents attached will be kept in history records from administrator side in case record of a study is updated.

• Summary Results

It consists of:

- o Summary of results in Lebanon
- o Study results globally (if applicable)
- o Date of posting of results summaries
- o Date of the first journal publication of results
- o URL hyperlink(s) related to results and publications
- o Baseline Characteristics: Data collected at the beginning of a clinical study for all participants and for each arm or comparison group. These data include demographics, such as age and sex, and study-specific measures.
- o Participant flow: Information to document the progress and numbers of research participants through each stage of a study in a flow diagram or tabular format.
- o Adverse events: An unfavorable change in the health of a participant, including abnormal laboratory findings, and all serious adverse events and deaths that happen during a clinical study or within a certain time period after the study has ended. This change may or may not be caused by the intervention being studied.
- o Outcome measures: A table of data for each primary and secondary outcome measure and their respective measurement of precision (eg a 95% confidence interval) by arm (that is, initial assignment of participants to arms or groups) or comparison group (that is, analysis groups), including the result(s) of scientifically appropriate statistical analyses that were performed on the outcome measure data, if any.
- o URL link to protocol file(s) with version and date (if willing to share) & to publications related to study