# 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**

Trials attachments has three sections; for registration, for importation purposes and related for safety reporting and amendments. Choose type of 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. 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)

Links to publications related to the study

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