# Standard Operating Procedures for Medical History (screening, baseline, and follow-up)

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# Standard Operating Procedures for Medical History (screening, baseline, and follow-up)

## PURPOSE

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| This standard operating procedure (SOP) describes the procedures for taking the medical history of subjects in the endTB Clinical Trials. |

## SCOPE

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| This SOP applies to the activity of taking the medical history by health care providers at sites monitored by the endTB Clinical Trials. |

## RESPONSIBLE FUNCTIONS

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| **Function** | **Activities** |
| **Site Principal Investigator (site-PI)** | * Supports the site clinical investigator in ensuring that the medical history collection is performed according to the study protocol |
| **Site clinical investigator (Site-CI)** | * Initiate patient contact * Gather information related to the patient’s medical history * Record the information on the source document, sign, and date it |

## DEFINITIONS and ABBREVIATIONS:

**Medical History:** A structured assessment between the patient and the medical provider, for the purpose of generating a comprehensive picture of a patient’s health and health problems. It should include an assessment of the patient’s general health status, their current and previous health problems, current and previous medical treatment, lifestyle factors and risks, and their family’s health.

## PROCEDURE

### Materials

1. Source document

### Take the medical history

The structure of the medical history taking differs according to whether it is taken at screening, at baseline, or during follow-up (interval medical history).

#### Screening medical history

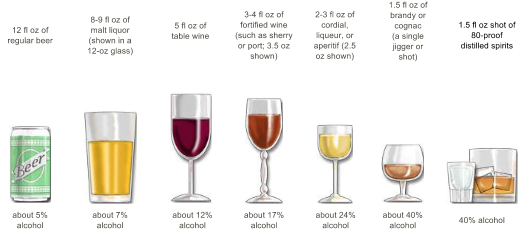
1. Ask the patient about past tuberculosis treatments in the following manner:
   * + Has the patient ever been diagnosed with tuberculosis in the past?
     + If YES, when (month and year)?
     + Has the patient ever been treated for tuberculosis in the past?
     + If YES, what was the start date of each treatment (or estimate month and year if patient does not know exact date)
     + Were the tuberculosis treatments for drug-susceptible tuberculosis or for drug-resistant tuberculosis (including MDR-TB or XDR-TB)? What was the outcome of each treatment (outcomes should be noted as cured, completed, failed, default, unknown)?
     + Ask which anti-tuberculosis drugs were used, when they were started, how long they lasted. If the patient does not remember the names go through the list of possible anti-tuberculosis drugs with the patient to see if they can identify any drugs they have taken (see Appendix 1 list of anti-tuberculosis drugs).
     + Ask about treatment observance.
2. Review the following illnesses with the patient and indicate if the patient ever had any of these specific conditions. If the answer is yes, collect the date of appearance and, for chronic conditions, ask if the illness is currently ongoing.

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| Confirmed HIV serostatus (ask if the patient has ever been tested for HIV and if he/she is willing to share the results). If HIV-positive ask for date of the positive test, recent CD4 count and HIV viral load (if available), and antiretroviral treatment history (which antiretroviral drugs were used, when they were started, how long they lasted). |
| Diabetes (type I or II) |
| Chronic renal insufficiency |
| Liver cirrhosis |
| Chronic obstructive pulmonary disease |
| Cancer |
| Heart disease or atherosclerotic disease, in particular:   * Long QT syndrome * Arrhythmic cardiac disease * Heart failure * Ischemic heart disease * Stroke |
| Syncopal episodes |
| Confirmed Hepatitis B |
| Confirmed Hepatitis C |
| Depression |
| Other psychiatric illness |
| Seizure disorder (chronic) |
| Past tuberculosis-related surgery, in particular:   * Lobectomy * Pneumonectomy * Pleural decortication |
| Past non tuberculosis-related surgery |
| Other pre-existing diseases |

1. Ask if the patient has a history of allergy or hypersensitivity to any drugs, and if yes collect the name of the drug/s.
2. Perform a concomitant medicine evaluation by gathering information about any concomitant medication/s (including anti-tuberculosis drugs) that the patient is currently taking or has taken during the last 30 days and consider for wash-out period and/or replacement of medicine/s if needed, according to **SOP-019-CT** ***Concomitant medications***.
3. Gather information about the patient’s family history, including:
   * Health of their parents.
     + Determine the causes and age of death (if applicable).
   * Health of any siblings and children.
   * Family history of medical problems or events (i.e. diabetes, cardiac events, cancer, etc.), in particular of Long QT Syndrome .
   * Genetic conditions within the family – kidney disease, etc.
   * Health of their spouse or partner (if applicable).
   * Ask if any close contacts (people living in the same household or people spending greater than 4 hours per week in the same space) have tuberculosis or symptoms of tuberculosis (cough, fever, night sweats, or weight loss).
   * Ask if anyone in the household has HIV (explain that individuals with HIV are at high risk for tuberculosis and that all answers are kept strictly confidential).

#### Baseline medical history

1. Ask the patient about any change in their medical history (concurrent illnesses, allergies, family history) since the screening visit.
2. Perform a concomitant medicine review by gathering information about any concomitant medication/s that the patient is currently taking or has taken since the screening visit, according to **SOP** **SP-019-CT** ***Concomitant medications***.
3. Gather information about the patient’s personal and social history, including:
   * The patient’s background and lifestyle, including exercise, nutrition, and overall well-being.
   * Smoking and alcohol habits.
     + - Any history of previous smoking? If YES, how many pack years. Pack years are a way to measure the amount a person has smoked over a long period of time, calculated by multiplying the number of packs of cigarettes smoked per day by the number of years the person has smoked (i.e. 1 pack year is equal to smoking 1 pack per day for 1 year, or 2 packs per day for half a year)
       - Any history of alcohol intake? If YES, number of standard alcoholic drinks per week. A standard drink is any drink that contains about 14 grams of pure alcohol (about 0.6 fluid ounces or 1.2 tablespoons). Below are standard drink equivalents as well as the number of standard drinks in different container sizes for each beverage.



* + Use of illegal substances such as cannabis, cocaine, etc.
    - Use of injecting and non-injecting drugs within the past year
  + Living situation, including if they have a stable home, and who they live with
    - Has the patient been homeless within the past year?
  + Occupation and job security
    - Has the patient been unemployed within the past year?
  + Social or financial problems
  + Food security issues (is there ever not enough food in the house, and if so how often).

#### Interval (follow-up) medical history

1. Ask the patient about any change in their medical history (concurrent illnesses, allergies, family health) since the last study visit.
2. Perform a concomitant medicine review by gathering information about any concomitant medication/s that the patient is currently taking or has taken since the last visit, according to **SOP** **SP-019-CT** ***Concomitant medications***.

### End the consultation

1. When you are satisfied that you have completed the history-taking, tell the patient you have covered everything you need.
2. Check that the patient has nothing more to add.
3. Summarize the information and check that it is complete and accurate.
4. Thank the patient.

### Document information for the patient’s record

1. Record the information on the source document.
2. Sign and date the source document.

## REFERENCES

* University College London Medical School. *Guide To History Taking And Examination*. Division of Medical Education, 2012. Web. 12 May 2016.
* "History Taking OSCE Station Guide". *OSCE Skills*. N.p., 2013. Web. 12 May 2016.

## SUPPORTING DOCUMENTS

## SOP SP-019-CT Concomitant medications (endTB Site Study Documents)

## APPENDIX

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| **Number** | **Title** |
| A1 | SP-010-CT\_A1- List of anti-tuberculosis drugs |