

<u>Title:</u> Standard Operating Procedure (SOP) for History Taking

Diagnosis of neglected tropical diseases (NTDs) in patients with persisting digestive disorders (≥2 weeks) in Côte d'Ivoire, Indonesia, Mali and Nepal.

1. Scope and application

This SOP applies to all patients included in the digestive syndrome study. It describes the procedure of history taking on demographic data and disease course.

2. Responsibilities

Function	Activities		
Country Principal	- Organization of the training of the site investigators regarding the history		
Investigator	taking		
	- Control of the adequate CRF filling according to this SOP		
Site Principal	Performance of history taking of all enrolled patients according to this		
Investigator	SOP		
	- Data registration according to this SOP		
	- Supervision of the adequate history taking		
Site Investigator	- Performance of comprehensive and standardized history taking of all		
	enrolled patients according to this SOP		
	- Registration of initial clinical data and follow-up data according to this		
	SOP		
Monitor	- Verification that history taking and follow-up of enrolled patients are		
	performed according to this SOP		
	- Verification that Good Clinical Practices are respected		
	- Verification that the CRF is adequately filled		

3. Material

Table / desk, chairs, blouse, towels, trash can, calendar, black pen, paper CRF.

4. Procedure

- 1. Check identity:
 - Gender
 - Birth date <u>or</u> Age in years
 - Place of residence (village / district)
- 2. Ask to specify:
 - Medical history (resolved health problems relevant to mention such as appendectomy): briefly describe and notify end date.
 - Ongoing medical problems (active disease with ongoing treatment such as diabetes) other than digestive disorders: briefly describe and notify start date and current treatment.
 - Antecedent of allergy to drug or other product.
- 3. Clinical evaluation of current symptoms:
 - Verify systematically the presence, absence (or « unknown »), during the clinical examination, of all symptoms mentioned in the CRF and specify the characteristics whenever requested (type, frequency, intensity, localization, diffusion, duration, ...).

N.B. If the question « week » or « day » is not applicable, fill "0" (zero) in the specific item.

4. Evaluation of concomitant treatment:

- Ask whether the participant has received drugs for the current illness (persistent digestive disorder) and if yes whether the treatment is still ongoing or not. Fill the treatment form with drugs already taken or ongoing for the PERSISTENT DIGESTIVE DISORDERS.
- Verify systematically the presence, absence (or « unknown »), during the clinical assessment, of the recent exposure (< 4 weeks before the onset of illness) to specific events mentioned in the CRF.

5. Document History

Revision	
SOP-WP2-CLIN-11 V1.1-03Dec2013	Initial version by Moussa Sacko and colleagues in Mali
SOP-WP2-CLIN-11 V2.1-09Dec2013	Review by Emmanuel Bottieau
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Name and function	Date	Signature			
Auteur					
Moussa Sacko and colleagues	03.12.2013	Chombo			
Revu par					
Emmanuel Bottieau	09.12.2013	Bothear			
Approuvé par					
Ninon Horié	19.05.2014				