Case Report Form Clinic
Biomarker evaluation study – AF_01_P08800-00
Version 07MAR19

Place barcode label here

Clinic name: _____ *Participant ID: FIND 00104__ __/__ __ __ __*

Case Report Form – Clinic

ELIGIBILITY

1.	Age between 2 and 17 years old	❑YES	❑NO
2.	Temperature of ≥ 38°C (oral or ear)/temperature of ≥ 37.5°C (axillary or skin) at initial evaluation or within 6 hours of arrival to the hospital or history of fever within 7 days.	❑YES	❑NO
3.	Less than 7 days of symptoms	❑YES	❑NO
4.	Participant has no severe/life threatening illness*	❑YES	❑NO
5.	Availability for a follow-up visit, if required	❑YES	❑NO

** based on clinician assessment or the presence of any general signs of critical illness as defined by WHO guidelines (for children: extensive vomiting, active seizure or recent history of seizures, altered mentation, inability to feed, or any of the severe IMNCI classifications; for adults: impending airway obstruction, central cyanosis, severe respiratory distress, feeble pulse, active seizure or recent history of seizures, or unconsciousness)*

STUDY INCLUSION

6.	Based on the answers above is the participant eligible for the study?#	❑YES	❑NO	
7.	Did the parent consent for the child to participate in the study?	❑YES	❑NO	
8.	Did the adolescent (13-17 years old) give an assent to participate in the study?	❑YES	❑NO	❑N/A

 # to be eligible, answers to Q1 to Q8 should all be "yes"

DEMOGRAPHIC INFORMATION

9.	Date of enrolment:	__ __(dd)/__ __(mm)/__ __ __ __(yyyy)				
10.	Sex:	❑Male	❑Female			
11.	Place of enrolment:	❑OPD	❑Inpatient	❑Health Center		
12.	Date of birth:	__ __(dd)/__ __(mm)/__ __ __ __(yyyy)			Age (years)	
13.	Is the participant pregnant ***N/A for male***	❑ Yes	❑ No	❑N/A		

**Offer test if requested*

CLINICAL HISTORY

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Tick all symptoms present as a part of current episode and estimate duration for each.

	SYMPTOMS	RESPONSE			DURATION (in days)		
14.	Duration of illness				☐☐		
15.	Fever (days)	❑YES	❑NO		☐☐		
16.	Redness of the eyes	❑YES	❑NO		☐☐		
17.	Eye discharge	❑YES	❑NO		☐☐		
18.	Sore Throat	❑YES	❑NO	❑UNKNOWN	☐☐		
19.	Ear discharge	❑YES	❑NO		☐☐		
20.	Swelling behind the ear	❑YES	❑NO		☐☐		
21.	Sneezing and rhinorrhoea	❑YES	❑NO		☐☐		
22.	Postnasal drip	❑YES	❑NO		☐☐		
23.	Cough	❑YES	❑NO		❑<2 weeks	❑<2 months	❑≥2 months
24.	Chest pain	❑YES	❑NO	❑Unknown	❑<2 weeks	❑<2 months	❑≥2 months
25.	Diarrhoea	❑YES	❑NO		☐☐		
26.	Vomiting	❑YES	❑NO		☐☐		
27.	Pain while swallowing	❑YES	❑NO	❑UNKNOWN	☐☐		
28.	Abdominal pain	❑YES	❑NO	❑UNKNOWN	☐☐		
29.	Dysuria	❑YES	❑NO	❑UNKNOWN	☐☐		
30.	Urinary frequency or urgency	❑YES	❑NO	❑UNKNOWN	☐☐		
31.	Rash	❑YES	❑NO		☐☐		
32.	Headache	❑YES	❑NO	❑UNKNOWN	☐☐		
33.	Neck stiffness	❑YES	❑NO	❑UNKNOWN	☐☐		
34.	Photophobia	❑YES	❑NO	❑UNKNOWN	☐☐		
35.	Joint pain or swelling	❑YES	❑NO	❑UNKNOWN	☐☐		
36.	Other (please specify)	❑YES	❑NO				
37.	_____				☐☐		
38.	_____				☐☐		

all yes must have duration

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TREATMENT HISTORY

39.	Has the participant taken antibiotics? ❑YES ❑NO ❑Don't know	If Yes:	40. Treatment start date: __ __/__ __/__ __ __ __ ❑Don't know 41. Treatment end date: __ __/__ __/__ __ __ __ ❑Don't know
42.	Has the participant taken antipyretics ❑YES ❑NO ❑Don't know	If yes	43. Treatment start date: __ __/__ __/__ __ __ __ ❑Don't know 44. Treatment end date: __ __/__ __/__ __ __ __ ❑Don't know
45.	Has the participant taken any other treatment? ❑YES ❑NO ❑Don't know	46. If Yes (tick one or several): ❑Antimalarial ❑Antipyretic ❑Other, specify:	

PAST MEDICAL HISTORY

47.	Does the participant have a chronic disease: ❑YES ❑NO ❑ Don't know	48. If Yes (tick one or several): ❑DM ❑HIV ❑TB ❑Other chronic diseases, specify:

if all yes must have follow up questions answered

VACCINATION HISTORY

49.	Has the participant been vaccinated according to EPI?	❑Completed vaccination	❑Partially vaccinated
		❑ Not vaccinated	❑Don't know

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PHYSICAL EXAMINATION

VITAL SIGNS

50. **GENERAL APPEARANCE** ***all questions must have response recorded***

- ❑ Not ill — *Healthy and strong impression throughout examination*
- ❑ Moderately ill — *Some impairment of activities, mostly self-sufficient but clearly symptomatic*
- ❑ Acutely ill — *Unable to carry out usual activities, visibly distressed, high fever, prostrated*
- ❑ Chronically ill — *Prominent facial bones (for adults), Emaciated with bone and skin appearance*

51.	Temperature (°C)	❑ Axillary ❑ Oral ❑ Ear ❑ Skin
52.	Respiratory rate (per minute)	
53.	Pulse rate (per minute)	
54.	Blood pressure (mmHg)	_____

ANTHROPOMETRY

55.	Weight (Kg)	
56.	Height (cm)	
57.	Mid upper arm circumference (cm) *(optional)*	
58.	Peripheral signs of malnutrition *(tick one or several)*	❑No signs ❑Hair colour change ❑Oedema ❑Skin lesions

SYSTEMIC EXAMINATION		If Yes, tick one or several:		
59. ***HEENT***	❑Yes ❑No	❑Pharyngeal erythema ❑Pharyngeal enlargement ❑Conjunctival exudate	❑Conjunctival redness ❑Pain and swelling around teeth	
60. ***Lungs***	❑Yes ❑No	❑ Fast breathing ❑ Decreased air entry ❑Retractions	❑Dullness ❑Crepitation ❑Chest in drawing	❑Other, Specify:
61. ***Heart***	❑Yes ❑No	❑Tachycardia	❑Ejection murmur	❑Other, Specify:
62. ***Abdomen***	❑Yes ❑No	❑Tenderness ❑Hepatomegaly	❑Splenomegaly ❑Fluid Collection	❑Other, specify:
63. ***Genitourinary***	❑Yes ❑No	❑Costovertebral angle tenderness	❑Other, specify:	
64. ***Nervous System***	❑Yes ❑No	❑Positive meningeal signs ❑Focal neurologic deficit	❑Other, Specify:	

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65. ***Integumentary***	❑Yes ❑No	❑Maculopapular ❑Cellulitis/abscess >5mm ❑Other, specify: ❑Impetigo ❑Dermatovesicular rash
66. ***Lymphadenopathy***	❑Yes ❑No	If yes, specify location: _____ size:_____ mm
67. ***Joint Swelling***	❑Yes ❑No	If yes, specify location: _____
68. ***Other findings***	❑Yes ❑No	❑ If yes, specify:_____

If yes follow up questions must be answered

RAPID TESTS

69. Strep A RDT with Ths002	❑Positive ❑ Negative ❑Invalid ❑N/A
70. Malaria RDT	❑Pf positive ❑Pan positive ❑ Negative ❑Invalid
71. CRP/Malaria RDT	❑Pf positive ❑Pan positive ❑ Negative ❑Invalid ❑CRP positive ❑ CRP Negative ❑ CRP Invalid

70-71 must be done for all patients

CHEST X-RAY

72.	Chest X-Ray performed	❑YES ❑NO ❑N/A		
73.	Date :	__ __(dd)/__ __(mm)/__ __ __ __(yyyy)		
74.	Normal	❑YES ❑NO		
75.	Localization of abnormality (optional) *(tick one or several)*	❑Left upper zone ❑Right upper zone ❑Diffuse	❑Left mid zone ❑Right mid zone	❑Left lower zone ❑Right lower zone
76.	Picture (optional) *(tick one or several)*	❑Infiltrate consolidation ❑Mediastinal/hilar lymphadenopathy	❑Cavitary lesion ❑Micronodules (Miliary)	❑Tuberculoma ❑Pleural effusion
77.	Principal conclusion: *(tick one only)*	❑Bacterial pneumonia likely ❑Other: _____	❑Pneumonia or atypical TB	❑Pneumonia unlikely, TB likely

If yes for question 72, 73-77 must be completed

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PRESUMED DIAGNOSIS TREATMENT

78. Presumed diagnosis by the clinician: *(tick one only)*	❑ Bacterial infection ❑ Viral infection ❑ Malarial infection ❑ Parasitic infection ❑ Multiple infection ❑ Don't know		❑ Non-infectious illness, specify: ❑ Other, specify:
79. Hospitalization?	❑ Yes	❑No	❑Don't know
80. Treatment Prescribed:	❑ Yes	❑No	❑Don't know

81. If Yes, specify treatment: *(tick one or several)*

If Antibiotics, tick the box:

❑Penicillin
❑Cloxacillin
❑Ampicillin
❑Amoxi/clavulan
❑Ceftriaxon
❑Gentamycin
❑Doxycyclin
❑Ciprofloxacin
❑Chloramphenicol
❑Clindamycin
❑Erythromycin
❑Cotrimoxazole
❑Azithomycin
❑Tetracyclin
❑Cefoxitin

❑ Supportive care
❑ Antimalarial, specify:
❑ Antiviral, specify:
❑ Other, specify:

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82.	Withdrawal or early exclusion from study	❑ Yes ❑No If Yes, specify reason:

Comments: _____

_____

Investigator's Signature: _____ Date completion: __ __/__ __/__ __ __ __

First data entry: _____ Date completion: __ __/__ __/__ __ __ __

Second data entry: _____ _____ Date completion: __ __/__ __/__ __ __ __

❑ **Copy CRF sent** Date: __ __/__ __/__ __ __ __

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Participant ID: FIND 00104 __ __/__ __ __ __

Investigator initials_____

Patient Age in years_____ Sample volume collected EDTA_____

Clinical laboratory CRF enrolment visit

Investigator: Please "standard panel" will be run for all participants
Transporter: Please check all documents and confirm receipt of samples as requested
Lab scientist: 1. Please tick/note the results at the appropriate place.

INVESTIGATOR REQUEST		**TRANSPORTATION CHECK**	**BARCODE**	
STANDARD PANEL	☒	**1 EDTA tube**	**ED WB COL002**	☐
NO FOCUS PANEL	☐	**Same EDTA tube**		

2. If patient is HIV+ve by RDT add NO FOCUS panel RDT testing

Laboratory tests	**Result**
HIV RDT*** If HIV $^{+ve}$ complete NO FOCUS panel RDTs**	❑Positive ❑ Negative ❑Invalid
Malaria Microscopy results **reader 1** Reader _____	❑Positive ❑Pf ❑Po ❑PM ❑Negative Density____para/µL
	❑Positive ❑Pf ❑Po ❑PM ❑Negative Density____para/µL
Malaria Microscopy results **reader 2** Reader _____	❑Positive ❑Pf ❑Po ❑PM ❑Negative Density____para/µL
	❑Positive ❑Pf ❑Po ❑PM ❑Negative Density____para/µL
Malaria Microscopy results **reader 3** Reader _____	❑Positive ❑Pf ❑Po ❑PM ❑Negative Density____para/µL
	❑Positive ❑Pf ❑Po ❑PM ❑Negative Density____para/µL
Haematology full blood count	WBC(x10^3/µL):_____ Hct(%):____ LY(%):____NEU(%)____ (*optional*):_____
NO FOCUS if HIV +ve ☐	
No focus panel	❑Done ❑Not done
Cryptococcus	❑Positive ❑ Negative ❑Invalid
Syphilis	❑Positive ❑ Negative ❑Invalid

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Participant ID: FIND 00104 __ __/__ __ __ __

Comments: _____

Laboratory scientist name: _____ Date completion: __ __/__ __/__ __ __ __

Final data entry: _____ Date completion: __ __/__ __/__ __ __ __

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Clinic name: _____ *Participant ID: FIND 00104* __ __/__ __ __ __

Case Report Form – Follow up

Treatment History between Initial Evaluation

1. Has the participant taken antibiotics? ❑NO ❑Don't know	❑YES → If yes specify _ _ _ _ _	2. Treatment start date: __ __/__ __/__ __ __ __	❑Don't know
		3. Treatment end date: __ __/__ __/__ __ __ __	❑Don't know
		4. Participant was considered cured:	❑YES ❑NO
5. Has the participant taken any other treatment? ❑NO ❑Don't know	❑YES →	6. ❑Antimalarial ❑Antipyretic	❑Other, specify:

Follow up Clinical Assessment

7.	Has the fever gone ?	❑YES	❑NO	❑Don't know
8.	If yes to #5, how many days after initiation of treatment?	_____		
9.	Are there any additional symptoms?	❑YES	❑NO	❑Don't know
10	If yes, what is the type of symptoms? ❑ Respiratory ❑ Gastrointestinal ❑Fever without focus ❑Rash ❑ Urinary tract ❑ Arthritis ❑ Other, please specify:_____			

Final Clinical Diagnosis

11	Presumptive Diagnosis:	▪ Bacterial infection ▪ Viral infection ▪ Parasitic infection ▪ Multiple infection	❑ Non-infectious illness, specify: ❑ Other, specify: ❑ Don't know
12	Date Diagnosis (dd/mm/yyyy):	__ __/__ __/__ __ __ __	
13	Patient found:	❑ Alive ❑ Dead	Note: _____

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Clinic name: _____ *Participant ID: FIND 00104* __ __/__ __ __ __

Investigator's Signature: _____ Date completion: __ __/__ __/__ __ __ __

First data entry: _____ Date completion: __ __/__ __/__ __ __ __

Second data entry: _____ _____ Date completion: __ __/__ __/__ __ __ __

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Participant ID: FIND 00104 __ __/__ __ __ ____

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Microbiology Laboratory CRF enrolment visit

Investigator initials: _____

Investigator: Please tick/mark the required tests on the form, "standard panel" will be run for all participants.
Transporter: Please check all documents and confirm receipt of samples as requested
Lab scientist: Please confirm receipt of samples and tick/note the results at the appropriate place

INVESTIGATOR REQUEST		**TRANSPORTATION CHECK**		**BARCODE**	
STANDARD PANEL	☒	**Blood culture bottle *1**		**BCCOL001**	☐
Urine for Storage	☒	**Container**		**U001**	☐
URINARY PANEL*	☐	**Urine sample**		**UCOL001**	☐
STOOL PANEL~	☐	**Stool sample * 1 – split in parasitology**		**Patient ID only**	☐
CNS PANEL	☐	**CSF sample**		**CSF001**	☐
SKIN/JOINT/ASPIRATE	☐	**Other sample/S**		**OT**	☐
Transported by			**Received by**		

INVESTIGATOR REQUEST		**TRANSPORTATION CHECK**		**BARCODE**	
RESPIRATORY PANEL	☐	**Urine**			☐
Transported by			**Received by**		

Laboratory tests	**Results**
STANDARD PANEL	**Time and date of blood collection:** **Tubes collected:** Aerobic ❑
Blood culture	❑ Positive ❑ Negative ❑ Contamination
	If culture positive, specify Gram staining results: ❑ Gram positive ❑ Gram negative ❑ Rods ❑ Cocci ❑ No pathogen observed, ❑ Pathogen isolated Pathogen: ❑ E.coli ❑ kleb pneu ❑ Staph aur ❑ Salmonella Other: _____

DIARRHEAL PANEL	**Time and date of stool collection:**
Faeces culture	Pathogen isolated: ❑ No ❑ Yes specify_____

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URINARY PANEL	**Aliquot 2 tubes of 1 mL and store at -80°C (research lab), ensure collection of at least 40ml if additional tests required** **1 Urine sample** ☐	**U COL001** ☐
Urine dipstick (combu 9)	WBC: ❑Positive ❑ Negative ❑ Invalid Nitrites: ❑Positive ❑ Negative ❑ Invalid	
Urine Culture	❑ Positive ❑ Negative ❑ Contamination If positive specify pathogen isolated ❑ E.coli❑ Proteus❑ Pseudo ❑ Entero ❑ Staph ❑ Strep ❑ S.saprophyticus ❑ Other _____	
RESPIRATORY PANEL ☐	**Use urine for this panel**	
S. pneumoniae RDT (urine)	❑Positive ❑ Negative ❑Invalid	
CNS PANEL ☐	**Time and date of CSF collection:**	
CSF Examination	Grossly looks: ❑Crystal clear ❑Turbid ❑Bloody Cells (per mm3):_____ Neutrophil (%):_____ Protein:_____ mg/dL Glucose:_____ mg/dL	
Cryptococcus RDT (CSF)	❑Positive ❑ Negative ❑Invalid	
S. pneumoniae RDT (CSF)	❑Positive ❑ Negative ❑Invalid	
Gram stain	❑ Not done ❑ Pathogen observed ❑ No pathogen observed If pathogen observed *(tick one of several):* ❑ Gram neg intracellular diplococci ❑Gram pos diplococci ❑ Gram neg rods ❑ Yeast ❑ Other, specify:_____	
Culture	Pathogen isolated: ❑No ❑ ,Neis men ❑,Strep Pn ❑,Strep Aga ❑, Cypto ❑,Other ❑ specify _____	
SKIN/JOINT/ASPIRATE ☐	**Time and date of sample collection:** **Type of sample collected:**	
Gram stain	❑ Not done ❑ Pathogen observed ❑ No pathogen observed If pathogen observed *(tick one as needed):* ❑ Gram pos ❑ Gram neg ❑ Rods ❑ Cocci ❑ Yeast ❑ Other, specify:_____	
Culture	Pathogen isolated:	

Comments:_____

Laboratory scientist: _____ Date completion: __ __/__ __/__ __ __ _

Final data entry: _____ Date completion: __ __/__ __/__ __ __ __

❑ **Copy CRF released to Data** Date: __ __/__ __/__ __ __ __

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Biobank Storage

Samples for biobanking	Vol	Barcode ID	Freezer box name and number	position
Urine biobanking 1	1ml	U001	FIND Urine biobanking	
Urine biobanking 2	1ml	U002	FIND Urine biobanking	

PS: Take samples to research laboratory freezer and attach this part of the CRF to the Research CRF.

Comments: _____

Laboratory scientist: _____ Date completion: __ __/__ __/__ __ __ _

Final data entry: _____ Date completion: __ __/__ __/__ __ __ __

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Investigator initials_____

Parasitology laboratory CRF enrolment visit

Transporter: Please check all documents and confirm receipt of samples as requested, sign form
Lab scientist: Please sign form on receipt of correct samples
Tick/note the results at the appropriate place.

INVESTIGATOR REQUEST		**TRANSPORTATION CHECK**	**BARCODE**	
Stool Panel	☐	**Note: Stool sample to be split in Parasitology and sent to microbiology**	**STCOL001**	☐
Urinary Panel	☐	**Urine to be sent from microbiology laboratory (if applicable)**	**Patient ID (barcode not required)**	☐
Transported by:			**Received by:**	

DIARRHEAL PANEL	**Time and date of stool collection:**
Rotavirus/adenovirus RDT	❑Adenovirus Positive ❑Rotavirus Positive ❑ Negative ❑Invalid
Appearance of faeces	❑ Bloody ❑ Rice water ❑ Hard stool ❑ Don't know ❑ Watery ❑ Green watery ❑ Other, specify:_____
Microscopy	❑ Not done ❑ Pathogen observed ❑ No pathogen observed If pathogen observed *(tick all that apply):* ❑ Ascari lumbricoids ❑ Trichuris trichuria ❑ strongyloides species ❑ Hookworm species ❑ protozoa spp ❑ Other, specify:_____

Unary PANEL	**Time and date of stool collection:**
Microscopy	❑ Not done ❑ Pathogen confirmed ❑ No pathogen observed If other pathogen observed specify:_____

* *if suspicion of schistosomiasis*

Comments: _____

Laboratory scientist name: _____ Date completion: __ __/__ __/__ __ __ __

Final data entry: _____ Date completion: __ __/__ __/__ __ __ __

❑ **Copy CRF sent** Date: __ __/__ __/__ __ __ _