Prevalence and impact of SARS-CoV-2 infection on maternal and infant health in African populations: protocol of a multi-centre prospective cohort study (MA-CoV project)

Supplementary material

Figueroa-Romero A, *et al. BMJ Open* 2023; 13:e067083. doi: 10.1136/bmjopen-2022-067083

File 1: Informed Consent of study

"Prevalence and impact of SARS-CoV-2 infection on maternal and infant health in African populations (MA-CoV)"

Introduction

The burden of COVID-19 is still unknown since access to diagnostic tests has been limited and therefore reserved for patients with severe disease and/or high-risk groups. In the African region, the number of reported cases is spreading and it is likely that vulnerable populations such as pregnant women and their foetuses will be directly and/or indirectly affected in the context of fragile health systems. It is important to understand the possible effects of COVID-19 on the health of pregnant and infants living in these regions to develop specific prevention measures.

Purpose and procedures of this study

The information coming from this MA-CoV study will help to understand the effects of the pandemic virus in African pregnant women. If you agree to be in the MA-CoV study, you will have a test done at the ***first antenatal care visit and in follow up visits*** in case you have symptoms or signs suggestive of COVID-19.

About the COVID-19 test

The test is a procedure called nasopharyngeal (NP) swab. The NP swab involves placing a swab (like a very long Q-tip) in your nose to collect cells and secretions. The swab will go into your nasal cavity, above the roof of your mouth. In some cases, the swab may only go into the nostril. The swab will be sent to a laboratory for testing to see if you are infected with COVID-19. The results of the COVID-19 testing will be made available to you, together with sufficient information to understand what the results mean. In case you are found to be infected, you will receive treatment free of charge and information regarding isolation and transmission prevention measures to be put in place at your home.

What happens during the study?

If you agree to be in this study, your first visit will continue today, after you read, discuss, and sign or put thumbprint on this form. You will be asked to come back to the clinic monthly before delivery. In addition, you must agree to deliver your baby at the study facility rather than at home.

If you agree to be in this study:

- We will first ask you some questions about yourself and your health
- We will ask you to give information on where you live and how to keep in contact with you
- A study clinician will examine you and will check your pregnancy status
- You will also be asked to give a venous blood sample at the first visit for tests of your blood (malaria and COVID-19 virus antibodies)
- In case you will be unwell with malaria or other infection, you will have additional blood tests done and if needed you will be given medicine and asked to come back here as scheduled by study staff
- You and your baby will receive a unique identification number (ID) and identification study card, which you will be requested to present to the study staff at every visit
- At delivery you will be visited during in the labour ward and you and your new-born baby will be examined by the study personnel.
- In addition to venous blood being collected from you, also a sample of cord blood will be taken to analyse the presence of COVID-19 virus antibodies
- A piece of placenta will be examined at the study laboratory and also tested for COVID-19 virus
- You must agree to deliver at the health facility but in case you deliver at home, the study staff will visit you as soon as possible but not later than one week after delivery and will ask you questions about your delivery and about health of your infant. At this visit you and your infant will be examined by the study personnel. Blood sample will be taken from you for tests of malaria
- We will ask you to provide us with a small sample of breastmilk (3 ml, less than a teaspoon) within three days and one month after your infant's birth to investigate if the virus can be found in maternal milk.
- When your baby is born, your child will be followed up until he/she is 1 month old
- You will be asked to come back with your new-born to the study clinic around 1 month after delivery to exam your baby and see if your baby is growing well

Other COVID-19 analyses and samples
We will also analyse the presence of the virus (which is called SARS-CoV-2) in the blood and placental samples that will be collected from you at enrolment and at the end of pregnancy. In case you are found to be infected with the COVID-19 virus, your infant will also be tested with a NP swab at birth. Also, if she/he presents with symptoms or signs suggestive of COVID-19 during her/his first month of life, she/he will have a test done and will receive the indicated treatment.

Alternatives to joining the MA-CoV study
If you choose not to participate in this study you will receive standard ANC care as before.

Risks or discomforts *(mother and infant)*
You might feel slight discomfort when we take nasopharyngeal swabs or venous blood samples at enrolment and delivery. There will be no other risks.

Benefits to you and your infant
By participating in the study, you may get better diagnosis of COVID-19 and other diseases such as malaria because of increased number of tests done. You and your baby will be regularly seen by clinical staff and in case of any symptoms or abnormal test results you and your baby will be either treated here or referred to another clinic for medical care.

Figueroa-Romero A, *et al. BMJ Open* 2023; 13:e067083. doi: 10.1136/bmjopen-2022-067083

STATEMENT of CONSENT AND SIGNATURE

Participant approval:
The consent form has been explained to me and I agree to take part in the MA-CoV study. I understand that I am free to choose to be in this activity and that saying "No" will not affect the treatment I get in this clinic, now and in future.
NOTE: You are not giving up any of your legal rights by signing this informed consent document.

If you agree circle YES

Volunteer's Name (print)	Volunteer's Signature or Thumbprint (if cannot write)	Date
Volunteer's Legal Guardian or Representative (as per country policy) (print)	Legal Guardian's Signature	Date
Witness's Name (if participant illiterate) (print)	Witness's Signature	Date

I have explained the purpose of this study to the volunteer. To the best of my knowledge, she understands the purpose, procedures, risks and benefits of this study.

Investigator/Designee Name (print)	Investigator/Designee Signature	Date

NOTE: This consent form with original signatures must be retained on file by the principal investigator. A copy must be given to the volunteer. If the woman refuses to take her copy of the consent with her, she states so below and signs and dates her decline statement.

Figueroa-Romero A, *et al. BMJ Open* 2023; 13:e067083. doi: 10.1136/bmjopen-2022-067083

File 2: Study case report forms

ISGlobal Barcelona Institute for Global Health MA-COV Maternal health and COVID-19	**ID** MACOC- |__|-|__|__|__|__| Site Code Subject Number **Participant's initials** |__|__| |__| 1. 2. Family name

Prevalence and impact of SARS-CoV-2 infection on maternal and infant health in African populations (MA-CoV)

Project Acronym	MA-CoV

eCRF book ID MA-CoV
Version: v.3.1
Date: 28th April 2022

BIRTH

Newborn visit

Ma-COV **Event: Birth - Newborn visit**	**ID** MACOC|__|-|__|__|__|__| Site Code Subject Nº **Participant's initials** |__|__| |__| 1. 2. Family name **Date of the visit** |__|__|- |__|__|__|-|__|__|__|__| Day Month Year	

	INCLUSION CRITERIA CHECK	
1	Mother's ID	MACOW|__|-|__|__|__|__| Site Code Subject Nº
2	Date of birth	|__|__| - |__|__|__| - |__|__|__|__| Day Month Year
3	Sex	Masculine ☐ Feminine ☐
	MEDICAL HISTORY AND PHYSICAL EXAMINATION AT BIRTH	
4	Weight (g)	|__|__|__|__|__|__|
5	Length (cm)	|__|__|.|__|
6	Head circumference (cm)	|__|__|.|__|
7	Axillary temperature (ºC)	|__|__|.|__|
8	Congenital abnormalities?	Yes ☐ No ☐
	8.1. Face and head	Normal ☐ Abnormal ☐ Unknown ☐
	8.2. Limbs	Normal ☐ Abnormal ☐ Unknown ☐
	8.3. Chest	Normal ☐ Abnormal ☐ Unknown ☐
	8.4. Spine	Normal ☐ Abnormal ☐ Unknown ☐
	8.5. Abdomen	Normal ☐ Abnormal ☐ Unknown ☐
	8.6. Genitalia	Normal ☐ Abnormal ☐ Unknown ☐
	8.7. Other abnormalities	Yes ☐ No ☐
	8.7.1. If yes, describe	_____

If necessary, fill in the comments section

9	Does the child need admission to the hospital for any problem? *If the answer is yes please fill in an AE form*	Yes ☐ No ☐
10	10.1. Neuromuscular maturity	10.1.1 Posture score |__| 10.1.2 Square window |__| 10.1.3 Arm recoil |__| 10.1.4 Popliteal angle |__| 10.1.5 Scarf sign |__| 10.1.6 Heel to ear |__|
	Ballard test: 10.2. Physical maturity	10.2.1 Skin |__| 10.2.2 Lanugo |__| 10.2.3 Plantar surfasse |__| 10.2.4 Breast |__| 10.2.5 Eye-Ear |__| 10.2.6 Geniyals |__|
	THROAT SWAB **IF THE MOTHER'S PCR HAS BEEN POSITIVE AT PREGNANCY, PLEASE FILL IN THE FOLLOWING QUESTIONS**	
11	Was a throab swab for COVID-19 collected from the newborn?	Yes ☐ No ☐
12	IF yes, indicate the SARS-CoV-2 PCR result If positive, fill/update the Adverse Event Form	Positive ☐ Negative ☐
13	Was a rapid antigen test for COVID-19 performed?	Yes ☐ No ☐
14	IF yes, indicate the COVID-19 rapid antigen test result If Positive, fill/update the Adverse Event Form	Positive ☐ Negative ☐
	HIV PROPHYLAXIS **IF THE MOTHER TESTED POSITIVE FOR HIV**	
15	Has the newborn been given an ARV drug for HIV prophylaxis? *If yes, please fill out the Medication Form*	Yes ☐ No ☐

	COMMENTS (OPTIONAL)
1	_____
2	_____
3	_____
4	_____
5	_____
6	_____
7	_____
8	_____

BIRTH

Newborn laboratory results

MA-CoV **Event: Newborn laboratory results**	**ID** MACOC|__|-|__|__|__|__| Site Code Subject Nº **Participant's initials** |__|__| |__| 1. 2. Family name **Date of the visit** |__|__|- |__|__|__|-|__|__|__|__| Day Month Year	

	SARS-CoV-2 PCR LAB RESULTS (baseline) – *if a nasopharyngeal swab was collected*	
1	Date of the sample	|__|__|- |__|__|__|-|__|__|__|__| Day Month Year
2	SARS-CoV-2 PCR test result *If positive, fill/update the Adverse Event Form*	Positive ☐ Negative ☐
3	Ct value	|__|__|
4	SARS-CoV-2 Viral load	|__|__|__|__|__|__| copies/mL

COMMENTS (OPTIONAL)

1 _____

2 _____

3 _____

4 _____

5 _____

6 _____

7 _____

8 _____

POST-PARTUM VISIT

1 month after birth

Newborn questionnaire

MA-CoV **Event: Newborn laboratory results**	**ID** MACOC|__|-|__|__|__|__| Site Code Subject Nº **Participant's initials** |__|__| |__| 1. 2. Family name **Date of the visit** |__|__|- |__|__|__|-|__|__|__|__| Day Month Year	

	ATTENDANCE TO SCHEDULED VISIT	
1	Did the infant attend the scheduled visit to the health facility?	Yes ☐ No ☐
	1.1 *If the answer is no, please specify*	Migration ☐ Not found ☐ Absent ☐ Death ☐ Refused ☐ Other ☐ _____
	MEDICAL HISTORY AND PHYSICAL EXAMINATION	
2	Weight (g)	|__|__|__|__|__|
3	Length (cm)	|__|__|.|__|
4	MUAC (cm)	|__|__|.|__|
5	Head circumference (cm)	|__|__|.|__|
6	Axillary temperature (ºC)	|__|__|.|__|
7	Does the infant have a congenital abnormality not previously diagnosed?	Yes ☐ No ☐
8	Has the infant been admitted to the hospital since the last visit?	Yes ☐ No ☐
	COVID INFECTION SUSPICION INQUIRY OF SIGNS AND SYMPTOMS DURING THE FIRST MONTH OF LIFE	
9	Cough?	Yes ☐ No ☐
10	Fever? (Tª ≥ 37,5 ºC)	Yes ☐ No ☐
11	Shortness of breath?	Yes ☐ No ☐
12	Rhinorrhea?	Yes ☐ No ☐
13	Does the participant's legal guardian report fever during the last 24 hours?	Yes ☐ No ☐
	If Temp ≥ 37,5 ºC or the answer is YES for any of the questions, collect a throat swab for COVID-19	
14	Was a throat swab for COVID-19 collected? *If yes, please complete SARS-CoV-2 PCR lab results in the Laboratory Results Form*	Yes ☐ No ☐
15	Was a rapid antigen test for COVID-19 performed?	Yes ☐ No ☐
16	If yes, indicate the COVID-19 rapid antigen test result *If Positive, fill/update the Adverse Event Form*	Positive ☐ Negative ☐

	NUTRITION	
17	Is the woman breastfeeding the infant?	Yes ☐ No ☐
	17.1 If yes, please specify when breastfeeding started	Less than an hour after birth ☐ Between 1 and 12 hours after birth ☐ Between 12 and 24 hours after birth ☐ More than 24 hours after birth ☐
18	During the first month of life, did the infant receive other foods or beverages apart from breast milk?	Yes ☐ No ☐
	18.1 If yes, please specify which foods or beverages he/she received	*Water* ☐ *Juice* ☐ Other type of milk ☐ *Vegetables* ☐ *Fruit* ☐ *Sweets or sugar* ☐ *Traditional herbs* ☐ *Rice or cereals* ☐ *Other* ☐ Please specify: _____
19	Yesterday, did the infant receive other foods or beverages apart from breast milk?	Yes ☐ No ☐
	19.1 If yes, please specify which foods or beverages he/she received	*Water* ☐ *Juice* ☐ Other type of milk ☐ *Vegetables* ☐ *Fruit* ☐ *Sweets or sugar* ☐ *Traditional herbs* ☐ *Rice or cereals* ☐ *Other* ☐ Please specify: _____
	PSYCHOMOTOR DEVELOPMENT ASSESSMENT	
20	Was the psychomotor development assessed?	Yes ☐ No ☐
21	Gross motor skills	
	21.1 Does the infant move the 4 extremities symmetrically?	Yes ☐ No ☐
	21.2 Muscle tone	Normal ☐ Abnormal ☐
22	Fine motor skills Does the infant follow objects?	Yes ☐ No ☐
23	Language / audition Does the infant respond to sounds?	Yes ☐ No ☐
24	Social skills Does the infant respond to smiles?	Yes ☐ No ☐

	COMMENTS (OPTIONAL)
1	_____
2	_____
3	_____
4	_____

POST-PARTUM

1 month after birth

Newborn laboratory results

MA-CoV NCT03671109 **Event: Laboratory results Newborn**	**ID** MACOC|__|-|__|__|__|__| Site Code Subject Nº **Participant's initials** |__|__| |__| 1. 2. Family name **Date of the visit** |__|__|- |__|__|__|-|__|__|__|__| Day Month Year	

	SARS-CoV-2 PCR LAB RESULTS (1 month after birth)	
1	Date of the sample	|__|__|- |__|__|__|-|__|__|__|__| Day Month Year
2	SARS-CoV-2 PCR test result *If positive, fill/update the Adverse Event Form*	Positive ☐ Negative ☐
3	Ct value	|__|__|
4	SARS-CoV-2 Viral load	|__|__|__|__|__|__| copies/mL
	HIV PCR LAB RESULTS – *if a HIV PCR was done*	
5	Was an HIV PCR done?	Yes ☐ No ☐
5.1	*If yes,* Date of the sample	|__|__|- |__|__|__|-|__|__|__|__|
5.2	HIV PCR test result *If positive, fill/update the Adverse Event Form*	Positive ☐ Negative ☐

	COMMENTS (OPTIONAL)
1	_____
2	_____
3	_____
4	_____
5	_____
6	_____
7	_____
8	_____

STUDY COMPLETION FORM

STUDY COMPLETION FORM MA-CoV **Event: Study completion form Newborn**	**ID** MACOC|__|-|__|__|__|__| Site Code Subject Nº **Participant's initials** |__|__| |__| 1. 2. Family name **Date of the visit** |__|__|- |__|__|__|-|__|__|__|__| Day Month Year	

	STUDY COMPLETION	
1	Date of last contact?	|__|__| - |__|__|__| - |__|__|__|__| Day Month Year
2	Did the newborn complete the study? *2.1 If the answer is no, please provide all relevant information related to reason for premature discontinuation*	Yes ☐ No ☐ Death ☐ Serious health outcome ☐ Consent withdrawal ☐ Migration ☐ Lost to follow up ☐ Other ☐ Specify: _____
3	Date of participant's study completion	|__|__| - |__|__|__| - |__|__|__|__| Day Month Year
4	I have reviewed and found all data pertaining to this participant to be complete and accurate Printed Investigator's name _____	|__|__| - |__|__|__| - |__|__|__|__| Day Month Year

Please provide all relevant information related to reason for premature study discontinuation including contributory factors in the comments section

COMMENTS (OPTIONAL)	
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	

ADVERSE EVENTS FORM

MA-CoV	ID MACOC|__|-|__|__|__|__| Site Code Subject Nº	Participant's initials |__|__| |__| 1. 2. Family name	

Severity: **1** Mild (Grade 1): Awareness of sign or symptom easily tolerated, **2** Moderate (Grade 2): Discomfort enough to cause interference with usual activity, **3** Severe (Grade 3): Incapacitating with inability to work or perform usual activity, **4** Life-threatening (Grade 4): Patient at risk of death at the time of the event, or Event Results in death, or Requires hospitalization or prolongation of existing hospitalization, or Results in persistent or significant disability or incapacity or Consists of a congenital anomaly or birth defect

Outcome: 1-Completely recovered, 2-Not yet completely recovered, 3-Deterioration, 4-Permanent damage, 5-Death, 6-Ongoing, 7-Unknown

Action Taken: 1-No action taken, , 2-Concomitant medication given, 3-Non-drug therapy given, 4-Hospitalization/Hospitalization prolonged

	ADVERSE EVENT #		
1	A. Name / Description |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|	B. Start date |__|__| |__|__|__||__|__|__|__| Day Month Year	C. End date |__|__| |__|__|__||__|__|__|__| ☐ Ongoing Month Year
2	A. Severity ☐ 1 ☐ 2 ☐ 3 ☐ 4	B. Outcome ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7	C. Action taken ☐ 1 ☐ 2 ☐ 3 ☐ 4
3	Is this AE Serious? ☐NO ☐YES		
	ADVERSE EVENT #		
1	A. Name / Description |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|	B. Start date |__|__| |__|__|__||__|__|__|__| Day Month Year	C. End date |__|__| |__|__|__||__|__|__|__| ☐ Ongoing Month Year
2	A. Severity ☐ 1 ☐ 2 ☐ 3 ☐ 4	B. Outcome ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7	C. Action taken ☐ 1 ☐ 2 ☐ 3 ☐ 4
3	Is this AE Serious? ☐NO ☐YES		
	ADVERSE EVENT #		
1	A. Name / Description |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|	B. Start date |__|__| |__|__|__||__|__|__|__| Day Month Year	C. End date |__|__| |__|__|__||__|__|__|__| ☐ Ongoing Month Year
2	A. Severity ☐ 1 ☐ 2 ☐ 3 ☐ 4	B. Outcome ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7	C. Action taken ☐ 1 ☐ 2 ☐ 3 ☐ 4
3	Is this AE Serious? ☐NO ☐YES		

MEDICATION FORMS

MA-CoV **Medication forms**	**ID** MACOC|__|-|__|__|__|__| Site Code Subject Nº	**Participant's initials** |__|__| |__| 1. 2. Family name	

	Medication #1			
1	A. Medication/ Non-drug therapy |__|__|__|__|__|__|__|__|__|__|	B. Dosage |__|__|__|__|__|__|	C. Start date |__|__| |__|__|__||__|__|__|__| Day Month Year	D. End date |__|__| |__|__|__||__|__|__|__| ☐ Ongoing Day Month Year
2	A. Reason to take it _____	B. Is an AE the cause of taking it? ☐YES (fill an AE form) ☐NO, the cause started prior to recruitment		
	Medication #2			
1	A. Medication/ Non-drug therapy |__|__|__|__|__|__|__|__|__|__|	B. Dosage |__|__|__|__|__|__|	C. Start date |__|__| |__|__|__||__|__|__|__| Day Month Year	D. End date |__|__| |__|__|__||__|__|__|__| ☐ Ongoing Day Month Year
2	A. Reason to take it _____	B. Is an AE the cause of taking it? ☐YES (fill an AE form) ☐NO, the cause started prior to recruitment		
	Medication #3			
1	Medication/ Non-drug therapy |__|__|__|__|__|__|__|__|__|__|	B. Dosage |__|__|__|__|__|__|	C. Start date |__|__| |__|__|__||__|__|__|__| Day Month Year	D. End date |__|__| |__|__|__||__|__|__|__| ☐ Ongoing Day Month Year
2	A. Reason to take it _____	B. Is an AE the cause of taking it? ☐YES (fill an AE form) ☐NO, the cause started prior to recruitment		
	Medication #4			
1	A. Medication/ Non-drug therapy |__|__|__|__|__|__|__|__|__|__|	B. Dosage |__|__|__|__|__|__|	C. Start date |__|__| |__|__|__||__|__|__|__| Day Month Year	D. End date |__|__| |__|__|__||__|__|__|__| ☐ Ongoing Day Month Year
2	A. Reason to take it _____	B. Is an AE the cause of taking it? ☐YES (fill an AE form) ☐NO, the cause started prior to recruitment		

ISGlobal Barcelona Institute for Global Health MA-COV Maternal health and COVID-19	**ID** MACOC- |__|-|__|__|__|__| Site Code Subject Number **Participant's initials** |__|__| |__| 1. 2. Family name

Prevalence and impact of SARS-CoV-2 infection on maternal and infant health in African populations (MA-CoV)

Project Acronym	MA-CoV

eCRF book ID MA-CoV
Version: v.3.1
Date: 28th April 2022

BIRTH

Newborn visit

Ma-COV **Event: Birth - Newborn visit**	**ID** MACOC|__|-|__|__|__|__| Site Code Subject Nº **Participant's initials** |__|__| |__| 1. 2. Family name **Date of the visit** |__|__|- |__|__|__|-|__|__|__|__| Day Month Year	

	INCLUSION CRITERIA CHECK	
1	Mother's ID	MACOW|__|-|__|__|__|__| Site Code Subject Nº
2	Date of birth	|__|__| - |__|__|__| - |__|__|__|__| Day Month Year
3	Sex	Masculine ☐ Feminine ☐
	MEDICAL HISTORY AND PHYSICAL EXAMINATION AT BIRTH	
4	Weight (g)	|__|__|__|__|__|__|
5	Length (cm)	|__|__|.|__|
6	Head circumference (cm)	|__|__|.|__|
7	Axillary temperature (ºC)	|__|__|.|__|
8	Congenital abnormalities?	Yes ☐ No ☐
	8.1. Face and head	Normal ☐ Abnormal ☐ Unknown ☐
	8.2. Limbs	Normal ☐ Abnormal ☐ Unknown ☐
	8.3. Chest	Normal ☐ Abnormal ☐ Unknown ☐
	8.4. Spine	Normal ☐ Abnormal ☐ Unknown ☐
	8.5. Abdomen	Normal ☐ Abnormal ☐ Unknown ☐
	8.6. Genitalia	Normal ☐ Abnormal ☐ Unknown ☐
	8.7. Other abnormalities	Yes ☐ No ☐
	8.7.1. If yes, describe	_____

If necessary, fill in the comments section

9	Does the child need admission to the hospital for any problem? *If the answer is yes please fill in an AE form*	Yes ☐ No ☐
10	10.1. Neuromuscular maturity	10.1.1 Posture score |__| 10.1.2 Square window |__| 10.1.3 Arm recoil |__| 10.1.4 Popliteal angle |__| 10.1.5 Scarf sign |__| 10.1.6 Heel to ear |__|
	Ballard test: 10.2. Physical maturity	10.2.1 Skin |__| 10.2.2 Lanugo |__| 10.2.3 Plantar surfasse |__| 10.2.4 Breast |__| 10.2.5 Eye-Ear |__| 10.2.6 Geniyals |__|
	THROAT SWAB **IF THE MOTHER'S PCR HAS BEEN POSITIVE AT PREGNANCY, PLEASE FILL IN THE FOLLOWING QUESTIONS**	
11	Was a throab swab for COVID-19 collected from the newborn?	Yes ☐ No ☐
12	IF yes, indicate the SARS-CoV-2 PCR result If positive, fill/update the Adverse Event Form	Positive ☐ Negative ☐
13	Was a rapid antigen test for COVID-19 performed?	Yes ☐ No ☐
14	IF yes, indicate the COVID-19 rapid antigen test result If Positive, fill/update the Adverse Event Form	Positive ☐ Negative ☐
	HIV PROPHYLAXIS **IF THE MOTHER TESTED POSITIVE FOR HIV**	
15	Has the newborn been given an ARV drug for HIV prophylaxis? *If yes, please fill out the Medication Form*	Yes ☐ No ☐

	COMMENTS (OPTIONAL)
1	_____
2	_____
3	_____
4	_____
5	_____
6	_____
7	_____
8	_____

BIRTH

Newborn laboratory results

MA-CoV **Event: Newborn laboratory results**	**ID** MACOC|__|-|__|__|__|__| Site Code Subject Nº **Participant's initials** |__|__| |__| 1. 2. Family name **Date of the visit** |__|__|- |__|__|__|-|__|__|__|__| Day Month Year	

	SARS-CoV-2 PCR LAB RESULTS (baseline) – *if a nasopharyngeal swab was collected*	
1	Date of the sample	|__|__|- |__|__|__|-|__|__|__|__| Day Month Year
2	SARS-CoV-2 PCR test result *If positive, fill/update the Adverse Event Form*	Positive ☐ Negative ☐
3	Ct value	|__|__|
4	SARS-CoV-2 Viral load	|__|__|__|__|__|__| copies/mL

COMMENTS (OPTIONAL)

1 _____

2 _____

3 _____

4 _____

5 _____

6 _____

7 _____

8 _____

POST-PARTUM VISIT

1 month after birth

Newborn questionnaire

MA-CoV **Event: Newborn laboratory results**	**ID** MACOC|__|-|__|__|__|__| Site Code Subject Nº **Participant's initials** |__|__| |__| 1. 2. Family name **Date of the visit** |__|__|- |__|__|__|-|__|__|__|__| Day Month Year	

	ATTENDANCE TO SCHEDULED VISIT		
1	Did the infant attend the scheduled visit to the health facility?	Yes ☐	No ☐
	1.1 *If the answer is no, please specify*	Migration ☐ Not found ☐ Absent ☐ Death ☐ Refused ☐ Other ☐ _____	
	MEDICAL HISTORY AND PHYSICAL EXAMINATION		
2	Weight (g)	|__|__|__|__|__|	
3	Length (cm)	|__|__|.|__|	
4	MUAC (cm)	|__|__|.|__|	
5	Head circumference (cm)	|__|__|.|__|	
6	Axillary temperature (ºC)	|__|__|.|__|	
7	Does the infant have a congenital abnormality not previously diagnosed?	Yes ☐	No ☐
8	Has the infant been admitted to the hospital since the last visit?	Yes ☐	No ☐
	COVID INFECTION SUSPICION INQUIRY OF SIGNS AND SYMPTOMS DURING THE FIRST MONTH OF LIFE		
9	Cough?	Yes ☐	No ☐
10	Fever? (Tª ≥ 37,5 ºC)	Yes ☐	No ☐
11	Shortness of breath?	Yes ☐	No ☐
12	Rhinorrhea?	Yes ☐	No ☐
13	Does the participant's legal guardian report fever during the last 24 hours?	Yes ☐	No ☐
	If Temp ≥ 37,5 ºC or the answer is YES for any of the questions, collect a throat swab for COVID-19		
14	Was a throat swab for COVID-19 collected? *If yes, please complete SARS-CoV-2 PCR lab results in the Laboratory Results Form*	Yes ☐	No ☐
15	Was a rapid antigen test for COVID-19 performed?	Yes ☐	No ☐
16	If yes, indicate the COVID-19 rapid antigen test result *If Positive, fill/update the Adverse Event Form*	Positive ☐	Negative ☐

	NUTRITION	
17	Is the woman breastfeeding the infant?	Yes ☐ No ☐
	17.1 If yes, please specify when breastfeeding started	Less than an hour after birth ☐ Between 1 and 12 hours after birth ☐ Between 12 and 24 hours after birth ☐ More than 24 hours after birth ☐
18	During the first month of life, did the infant receive other foods or beverages apart from breast milk?	Yes ☐ No ☐
	18.1 If yes, please specify which foods or beverages he/she received	*Water* ☐ *Juice* ☐ Other type of milk ☐ *Vegetables* ☐ *Fruit* ☐ *Sweets or sugar* ☐ *Traditional herbs* ☐ *Rice or cereals* ☐ *Other* ☐ Please specify: _____
19	Yesterday, did the infant receive other foods or beverages apart from breast milk?	Yes ☐ No ☐
	19.1 If yes, please specify which foods or beverages he/she received	*Water* ☐ *Juice* ☐ Other type of milk ☐ *Vegetables* ☐ *Fruit* ☐ *Sweets or sugar* ☐ *Traditional herbs* ☐ *Rice or cereals* ☐ *Other* ☐ Please specify: _____
	PSYCHOMOTOR DEVELOPMENT ASSESSMENT	
20	Was the psychomotor development assessed?	Yes ☐ No ☐
21	Gross motor skills	
	21.1 Does the infant move the 4 extremities symmetrically?	Yes ☐ No ☐
	21.2 Muscle tone	Normal ☐ Abnormal ☐
22	Fine motor skills Does the infant follow objects?	Yes ☐ No ☐
23	Language / audition Does the infant respond to sounds?	Yes ☐ No ☐
24	Social skills Does the infant respond to smiles?	Yes ☐ No ☐

	COMMENTS (OPTIONAL)
1	_____
2	_____
3	_____
4	_____

POST-PARTUM

1 month after birth

Newborn laboratory results

MA-CoV NCT03671109 **Event: Laboratory results Newborn**	**ID** MACOC|__|-|__|__|__|__| Site Code Subject Nº **Participant's initials** |__|__| |__| 1. 2. Family name **Date of the visit** |__|__|- |__|__|__|-|__|__|__|__| Day Month Year	

	SARS-CoV-2 PCR LAB RESULTS (1 month after birth)	
1	Date of the sample	|__|__|- |__|__|__|-|__|__|__|__| Day Month Year
2	SARS-CoV-2 PCR test result *If positive, fill/update the Adverse Event Form*	Positive ☐ Negative ☐
3	Ct value	|__|__|
4	SARS-CoV-2 Viral load	|__|__|__|__|__|__| copies/mL
	HIV PCR LAB RESULTS – *if a HIV PCR was done*	
5	Was an HIV PCR done?	Yes ☐ No ☐
5.1	*If yes,* Date of the sample	|__|__|- |__|__|__|-|__|__|__|__|
5.2	HIV PCR test result *If positive, fill/update the Adverse Event Form*	Positive ☐ Negative ☐

	COMMENTS (OPTIONAL)
1	_____
2	_____
3	_____
4	_____
5	_____
6	_____
7	_____
8	_____

STUDY COMPLETION FORM

STUDY COMPLETION FORM MA-CoV **Event: Study completion form Newborn**	**ID** MACOC|__|-|__|__|__|__| Site Code Subject Nº **Participant's initials** |__|__| |__| 1. 2. Family name **Date of the visit** |__|__|- |__|__|__|-|__|__|__|__| Day Month Year	

	STUDY COMPLETION	
1	Date of last contact?	|__|__| - |__|__|__| - |__|__|__|__| Day Month Year
2	Did the newborn complete the study? *2.1 If the answer is no, please provide all relevant information related to reason for premature discontinuation*	Yes ☐ No ☐ Death ☐ Serious health outcome ☐ Consent withdrawal ☐ Migration ☐ Lost to follow up ☐ Other ☐ Specify: _____
3	Date of participant's study completion	|__|__| - |__|__|__| - |__|__|__|__| Day Month Year
4	I have reviewed and found all data pertaining to this participant to be complete and accurate Printed Investigator's name _____	|__|__| - |__|__|__| - |__|__|__|__| Day Month Year

Please provide all relevant information related to reason for premature study discontinuation including contributory factors in the comments section

	COMMENTS (OPTIONAL)
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	

ADVERSE EVENTS FORM

MA-CoV	**ID** MACOC|__|-|__|__|__|__| Site Code Subject Nº **Participant's initials** |__|__| |__| 1. 2. Family name	

Severity: **1** Mild (Grade 1): Awareness of sign or symptom easily tolerated, **2** Moderate (Grade 2): Discomfort enough to cause interference with usual activity, **3** Severe (Grade 3): Incapacitating with inability to work or perform usual activity, **4** Life-threatening (Grade 4): Patient at risk of death at the time of the event, or Event Results in death, or Requires hospitalization or prolongation of existing hospitalization, or Results in persistent or significant disability or incapacity or Consists of a congenital anomaly or birth defect

Outcome: 1-Completely recovered, 2-Not yet completely recovered, 3-Deterioration, 4-Permanent damage, 5-Death, 6-Ongoing, 7-Unknown

Action Taken: 1-No action taken, , 2-Concomitant medication given, 3-Non-drug therapy given, 4-Hospitalization/Hospitalization prolonged

	ADVERSE EVENT #		
1	A. Name / Description |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|	B. Start date |__|__| |__|__|__||__|__|__|__| Day Month Year	C. End date |__|__| |__|__|__||__|__|__|__| ☐ Ongoing Month Year
2	A. Severity ☐ 1 ☐ 2 ☐ 3 ☐ 4	B. Outcome ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7	C. Action taken ☐ 1 ☐ 2 ☐ 3 ☐ 4
3	Is this AE Serious? ☐NO ☐YES		
	ADVERSE EVENT #		
1	A. Name / Description |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|	B. Start date |__|__| |__|__|__||__|__|__|__| Day Month Year	C. End date |__|__| |__|__|__||__|__|__|__| ☐ Ongoing Month Year
2	A. Severity ☐ 1 ☐ 2 ☐ 3 ☐ 4	B. Outcome ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7	C. Action taken ☐ 1 ☐ 2 ☐ 3 ☐ 4
3	Is this AE Serious? ☐NO ☐YES		
	ADVERSE EVENT #		
1	A. Name / Description |__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|__|	B. Start date |__|__| |__|__|__||__|__|__|__| Day Month Year	C. End date |__|__| |__|__|__||__|__|__|__| ☐ Ongoing Month Year
2	A. Severity ☐ 1 ☐ 2 ☐ 3 ☐ 4	B. Outcome ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7	C. Action taken ☐ 1 ☐ 2 ☐ 3 ☐ 4
3	Is this AE Serious? ☐NO ☐YES		

MEDICATION FORMS

MA-CoV **Medication forms**	**ID** MACOC|__|-|__|__|__|__| Site Code Subject Nº	**Participant's initials** |__|__| |__| 1. 2. Family name	

	Medication #1			
1	A. Medication/ Non-drug therapy |__|__|__|__|__|__|__|__|__|__|	B. Dosage |__|__|__|__|__|__|	C. Start date |__|__| |__|__|__||__|__|__|__| Day Month Year	D. End date |__|__| |__|__|__||__|__|__|__| ☐ Ongoing Day Month Year
2	A. Reason to take it _____	B. Is an AE the cause of taking it? ☐YES (fill an AE form) ☐NO, the cause started prior to recruitment		
	Medication #2			
1	A. Medication/ Non-drug therapy |__|__|__|__|__|__|__|__|__|__|	B. Dosage |__|__|__|__|__|__|	C. Start date |__|__| |__|__|__||__|__|__|__| Day Month Year	D. End date |__|__| |__|__|__||__|__|__|__| ☐ Ongoing Day Month Year
2	A. Reason to take it _____	B. Is an AE the cause of taking it? ☐YES (fill an AE form) ☐NO, the cause started prior to recruitment		
	Medication #3			
1	Medication/ Non-drug therapy |__|__|__|__|__|__|__|__|__|__|	B. Dosage |__|__|__|__|__|__|	C. Start date |__|__| |__|__|__||__|__|__|__| Day Month Year	D. End date |__|__| |__|__|__||__|__|__|__| ☐ Ongoing Day Month Year
2	A. Reason to take it _____	B. Is an AE the cause of taking it? ☐YES (fill an AE form) ☐NO, the cause started prior to recruitment		
	Medication #4			
1	A. Medication/ Non-drug therapy |__|__|__|__|__|__|__|__|__|__|	B. Dosage |__|__|__|__|__|__|	C. Start date |__|__| |__|__|__||__|__|__|__| Day Month Year	D. End date |__|__| |__|__|__||__|__|__|__| ☐ Ongoing Day Month Year
2	A. Reason to take it _____	B. Is an AE the cause of taking it? ☐YES (fill an AE form) ☐NO, the cause started prior to recruitment		