ACT Consortium

Safety Data Collection Tools for Non-Clinicians

Training Manual

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Available at: www.actconsortium.org/safetydatacollectiontools
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Introduction

Pharmacovigilance systems in most countries are weak, but this is particularly the case in limited-resource settings. As part of a larger project to collect safety data from studies conducted by the ACT Consortium, work was undertaken to develop tools which could be used by studies of different design, to facilitate and strengthen capacity for collecting safety data.

Patients exposed to medicinal products are at risk of ‘side effects’ or adverse reactions (see definitions below). Detecting and monitoring patients who experience adverse reactions is essential so that we are able to determine who is at risk and ensure patients who experience them are managed appropriately. This should be undertaken in both study and ‘real life’ settings. It is common practice to collect data on all adverse events that are experienced by patients after being administered a medicinal product; this data is then reviewed to determine if there is any possibility of the medicine causing the event.

In an attempt to standardise safety data collection across the studies within the ACT Consortium, tools for use by clinicians were developed, containing all the essential data elements required to enable meaningful safety data analysis. However, a common component throughout many of the studies was the use of non-clinicians and lower-level health workers to provide healthcare. Conventional safety data collection forms are challenging for these groups of people to complete; however, as healthcare providers, it is important that they have the expertise and appropriate tools to detect and report on adverse events. A second set of tools, specifically designed for non-clinicians was therefore developed\(^1\). These latter tools have a pictorial design to make the process of data collection an interactive experience between the data collector and the patient/caregiver. There is no requirement for the data collector to have a detailed knowledge of adverse events or their detection, meaning they are suitable for all cadres of staff within the healthcare setting.

The tools were developed to meet the needs of different study designs - figure 1 outlines the final set of data collection tools. Whilst the majority of forms are defined by a specific study design, the Serious Adverse Event (SAE) form is a stand-alone data collection form which should be used by a study clinician or senior investigator to report all SAEs, as defined by ICH GCP\(^2\) guidelines. If a clinician detects a SAE, form G can be completed instantly. In the case of non-clinicians, there is a field in each form to enable the data collector to identify SAEs, and a prompt to advise immediate referral to a clinician, senior investigator or appropriate healthcare facilities. When developing study Standard Operating Procedures (SOPs), it is important to clearly define how SAEs should be handled.
Introduction

Figure 1 Study design and safety data collection tools

Whilst passive/spontaneous reporting forms can be used in many different study designs, they also have an important role in ‘real-life’ where treatment is used in a large population. In these situations, patients who have been administered a medicine for any reason should be advised to report back if they experience any new or worsening symptoms, and the passive reporting forms used to capture the data.

Definitions

Adverse Event (AE): any untoward medical occurrence in a patient or clinical trial subject administered a medicinal product and which does not necessarily have a causal relationship with this treatment.

Adverse Drug Reaction (ADR): for new medicinal products or its new usages - any untoward or unintended response to a medicinal product which occurs at any dose; for marketed medicinal products - any untoward or unintended response to a medicinal product which occurs at doses...
Introduction

normally used for prophylaxis, diagnosis or therapy of disease or modification of physiological function. For it to be considered a reaction, there has to be at least a reasonable possibility that there is a relationship between the event and product.

**Treatment-Emergent Adverse Event (TEAE):** any event not present prior to initiation of the treatment or any event already present that worsens in either intensity or frequency following exposure to the treatment.

**Serious Adverse Event (SAE):** an event that at any dose: 1. Results in death, 2. Is life-threatening, 3. Requires hospitalisation or causes a prolongation of hospitalisation, 4. Results in persistent or significant disability/incapacity, or 5. Is a congenital anomaly/birth defect.

**Non-Clinician Reporters:** personnel responsible for collecting safety data from a population who have been administered a medicinal product. These personnel are not expected to have any formal medical training.

**How to use this manual**

Each section of this training manual refers to one of the individual non-clinician\(^a\) forms presented in figure 1. Each section starts with a detailed step-by-step guide to completing the individual fields of the form. This is followed by an ‘at-a-glance’ guide to completing the form with the key points highlighted, designed to be taken to the field and used as a prompt whilst data collection is ongoing. All sections have been written so that they can be read independently depending on which type of form is required.

All forms are available from the ACT Consortium website for download in both word and pdf format.

**Which form do I need?**

Here is a brief summary of each form which can be used to determine which is the most appropriate for your needs.

**Form A – Prospective active data collection**

Form A is designed to be used by non-clinicians as part of a prospectively designed study/programme. Patients are administered a medicinal product and initial information is collected at this time. The patient is then followed up at a later day and asked about their experience (symptoms) since taking the medicinal product. The data collected is then reviewed to determine if an adverse event was experienced and if so, further detailed reporting is undertaken.

**Form C – Retrospective active data collection**

Form C is designed to be used by non-clinicians as part of a retrospectively designed study/programme. Patients are followed up a few days after receiving a medicinal product and asked about their experience (symptoms) since receiving the medicinal product. The data is then reviewed to determine if an adverse event was experienced and if so, further detailed reporting is undertaken.

\(^a\) A training manual for the clinician reporting forms will be available to download separately from the ACT Consortium website.
Introduction

Form E – Passive spontaneous data collection

Form E is designed to enable non-clinicians to collect safety data which is being spontaneously reported by the patient or the patients caregiver. Patients are not actively being followed up and asked for their experiences after being administered a medicinal product, but rather the non-clinician has determined some other way that a possible adverse reaction has been experienced (for example, the patient may have volunteered the information or sought treatment for the reaction).

All non-clinician forms are available in adult and child versions.
Form A

Prospective Active Data Collection
Form A

Form A is designed to be used by non-clinicians as part of a prospectively designed study/programme. Patients are administered a medicinal product (termed the ‘study drug’ below) and initial information is collected at this time. The patient is then followed up at a later day and asked about their experience (symptoms) since taking the medicinal product.

Form A is available in adult and child versions.

Detailed Guide

Part A – to be completed at the time of the initial visit to the health facility, with all patients who receive treatment and consent to being interviewed. The patient/caregiver should be involved in the completion of this section, using health facility/patient-held records where necessary.

### Show the picture story to the respondent. Use the story to explain why you are filling in the form with them. Invite questions

Ensure the patient/caregiver can see the form at all times throughout the data collection process. Show them the picture story and discuss it with the patient/caregiver. Make sure they understand and are comfortable with the information being collected before proceeding.

#### 1.1 Reporter ID

#### 1.2 Reporter Contact

Enter contact details for the reporter, such as a telephone number or email address.

#### 1.3 Reporter Job Title

#### 1.4 Report Number

A unique identifiable reference number for this report (the suffix ‘/A’ represents part A of the report).

#### 1.5 Date Part A Completed

#### 2.1 Patient ID

#### 2.2 Age (yrs)

#### 2.3 Weight (kg) if known

#### 2.4 Height (cm) if known

#### 2.5 Sex M/F

#### 2.6 Pregnant? Y/N (omitted in the child form) If applicable.

#### 2.6.1 If Y, ___ months

Enter number of months pregnant, if known.

#### 3.1 Symptoms before being prescribed the study drug

Ask the patient/caregiver to describe all symptoms that occurred at the beginning of this illness episode, which led to them seeking treatment.

#### 3.2 Diagnosis

Record the diagnosis as reported by the patient/caregiver. If they are unsure of the diagnosis, use any available records to determine if a diagnosis was made and record it here.

#### 3.3 Confirmed by:

In cases being treated for malaria, tick whether diagnosis was confirmed by Rapid Diagnostic Test or Blood Slide, if applicable. In non-malaria cases, this section can be removed.

#### 4.1 Did the patient/caregiver try any treatment for these symptoms before attending the health facility?

Ask about all drugs taken in the two weeks prior to the visit.

#### 4.1.1 If yes, what did the patient take?

List treatment as reported by the patient/caregiver (brand or generic names). Where possible, include information on doses, start dates and course lengths.
4.2 Did the patient/caregiver use any traditional remedies for this illness? If yes, give details if known

Ask about all remedies taken in the two weeks prior to the visit. Where possible, record the names of the remedies and any information on doses, start dates and course lengths.

4.3 Does the patient take any medicines regularly (e.g. for diabetes, family planning, ARVs, TB medicine, epilepsy, etc)?

Ask about any treatment the patient may take regularly, such as those for concurrent medical conditions (e.g. HIV, TB etc).

4.3.1 If yes, what does the patient take?

List treatment as reported by the patient/caregiver (brand or generic names). Where possible, include information on doses, start dates and course lengths.

4.4 Does the patient use any traditional remedies regularly? If yes, give details if known

Ask about any remedies the patient may take regularly, such as those for concurrent medical conditions (e.g. HIV, TB etc). Where possible, record the names of the remedies and any information on doses, start dates and course length.

5 Medicines prescribed at this visit (from records)

Using the information available at the health facility, record the following details of all medicines prescribed at this visit – name of drug, dose, frequency, start date, number of days prescribed.

Part B – to be completed with the patient/caregiver at the follow-up visit.

1.1 Fieldworker ID

The person collecting the information in part B may be different to the person who collected the data in part A.

1.2 Fieldworker Contact

Enter contact details for the fieldworker, such as a telephone number or email address.

1.3 Report Number

Enter the report number, as specified in section A (the suffix is now ‘/B’ to represent part B of the report).

2.1 Date of follow-up

2.2 Type of follow-up

2.3 Follow up with:

Specify whether the patient themselves is providing the information, or a representative for the patient (i.e. the caregiver if the patient is a child). If it is a representative for the patient, specify their relationship (i.e. parent, caregiver etc).

2.4.1 If the patient is not present at the follow-up visit today, please tick this box

2.4.2 If you know why the patient is unavailable, please specify

2.4.3 If the patient is in hospital or has died, please record by ticking the appropriate box and contact the senior investigator immediately

This is a serious adverse event (SAE). It is important that SAEs are identified as soon as possible and are notified to the relevant person in accordance with study procedures immediately.

3 Ask the patient/caregiver: Did you/your child take any study drug?

If the patient/caregiver admits that they did not take any study drug, no further information needs to be provided. Even if the patient only took one dose, continue completing the form.

4 Show the picture story to the respondent. Use the story to remind the patient/caregiver why

Ensure the patient/caregiver can see the form at all times throughout the data collection process. Show them the picture story and discuss it with the patient/caregiver. Make sure they
<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.1</td>
<td>Now I would like to ask you about your/your child’s health in the last ___ days since you/your child was prescribed the study drug. Starting from the day you went to the _____ can you tell me the drugs and herbs you/your child took each day, and any symptoms old or new each day. I will record these in this diary. Complete the diary with the patient/caregiver – explain to them how the data is going to be captured and ensure they can view the diary at all times. If possible, allow them to direct you as to where the information should go. Information on drugs/herbs/traditional remedies taken at any time during the follow up period should be entered in the top row. Information on all symptoms experienced by the patient during the follow up period, whether old or new, should be recorded in the bottom row. All drugs/herbs/traditional remedies taken should be included, regardless of whether they were obtained from the study health facility or elsewhere. The information should reflect how the drugs were taken, which may differ from how they were prescribed. Using the time of day at the top as a guide, position the drug in the diary at the approximate time it was taken (i.e. morning, midday or night time). Enter the dose as a superscript number near the drug entry. Complete for all doses and drugs taken. Use section 5.2 to add any additional comments such as strengths of drugs, or as a key for any abbreviations used. In the bottom row of the diary, list all symptoms experienced by the patient throughout the follow up period, including those on day 1 (which resulted in seeking treatment). As with the drugs, position the symptom at the approximate time of day to illustrate when the symptom started. Using arrows, indicate when the symptom stopped, or specify ‘ongoing’ if appropriate. If a symptom worsens, indicate this in the diary also.</td>
</tr>
<tr>
<td>5.2</td>
<td>Additional comments Section for additional comments such as details of drug strengths, key for abbreviations used or any other details that do not fit into the diary section.</td>
</tr>
<tr>
<td>6</td>
<td>Diary checklist for fieldworker Use this checklist as a guide to ensure you have completed all information.</td>
</tr>
<tr>
<td>7</td>
<td>Have there been any new or worsening symptoms in this follow up period? Review the diary once complete, to determine if there have been any symptoms that started, or worsened, after treatment was taken. If there are no new or worsening symptoms, data collection can stop at this point. If a new or worsening symptom has been identified, continue. Please see appendix 1 for further information on identifying new and worsening symptoms. If in doubt, continue.</td>
</tr>
<tr>
<td>8</td>
<td>Using the information you have recorded in the diary, fill in the first column and complete the table by asking the patient/caregiver: Copy all drugs from the diary into the first column of the table. For each drug, ask the patient/caregiver: 1. Where did they get the drug from (i.e. health facility, drug shop etc). 2. Have they used the drug/herb before? 3. If so, have they had any problems with the drug/herb before (and describe the problem if yes)? 4. Would you use this drug/herb again, and if not, why? These questions will give a picture of whether the patient has experienced a similar problem before (for example, whether you are filling in the form with them. Invite questions. understand and are comfortable with the information being collected before proceeding.</td>
</tr>
</tbody>
</table>
they always vomit after taking a particular drug) and whether they associate the problem with the drug (for example, if they say no they wouldn’t use the drug again, it implies they think it is causing the problem).

9 Ask the patient/caregiver how they are feeling now

10 Were you/your child admitted to a health facility during the follow up period? If yes, contact the senior investigator for follow up

| 10 Were you/your child admitted to a health facility during the follow up period? If yes, contact the senior investigator for follow up |
| This is a SAE. As per section 2.4.3 above, it is important that all cases of hospitalisation are identified and reported quickly, to ensure the patient undergoes more detailed follow up. |

11 Field worker action. If referred contact senior investigator for follow up

| 11 Field worker action. If referred contact senior investigator for follow up |
| If the fieldworker feels the patient requires further medical attention for any reason (i.e. they are not recovering or there is a concerning new symptom) they should document the action they have advised the patient/caregiver and details of the referral. Fieldworkers should be offered training on identifying symptoms of concern and when to refer. They should be able to contact senior members of the team if in doubt. |

12 Fieldworker comments, further information

| 12 Fieldworker comments, further information |
| Any information not already included in the form should be documented here. |

### Part C – to be completed by the safety officer.

This section of the form can be completed retrospectively after the follow up visit is complete. It should be completed as soon as possible after the visit, so that any potential safety issues are detected in a timely manner. If there were no worsening or new symptoms detected, this section does not need to be completed; however, all forms should be reviewed by the safety officer to ensure no potential adverse events have been missed.

| 1.1 Reporter ID |
| Enter the name of the safety officer who is completing part C. |

| 1.2 Reporter Contact |
| Enter contact details for the reporter, such as a telephone number or email address. |

| 1.3 Report Number |
| Enter the report number, as specified in part A and B (the suffix is now ‘/C’ to represent part C of the report). |

| 2 All medicines and herbs taken at any time during follow up |
| From the diary and question 8, complete this table with the following information: Name of all drugs/herbs taken in the follow up period, dose, frequency, date started, date stopped (or continuing), comments. |

| 3 Describe new symptoms or worsening symptoms occurring during follow up |
| From the diary and the rest of part B, complete the following information for the new or worsening symptom only – description, date started, date stopped (or continuing), outcome (see key on form), serious Y/N (the case is considered serious if the patient died, was hospitalised, or required referral). If the case is considered serious, the SAE form should be completed by the safety officer and more detailed follow up should be undertaken if possible. |
Quick Guide

Part A (pre-treatment) – this section is completed on day 1 with all patients who have been prescribed treatment.

### Enter name of person completing form (1.1)

### If possible, include all drugs (4.1) and traditional remedies (4.2) taken in the two weeks prior to the visit. When recording drugs/remedies, record the names as reported (brand or generic) and include information on doses, start dates & course lengths, if known (4.1)

### List all drugs that have been prescribed at the time of visiting the health facility on the day of completing this form (5)

### Enter contact details of the person completing the form, such as a telephone number or email address (1.2)

### A unique identifiable reference number for this report (1.4)

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**Form A - Prospective Active Data Collection**

**Active ADVe (Adult) - this section is completed on day 1 with all patients who have been prescribed treatment**

**Report Form (Prospective) - Part A (Pre-Treatment)**

<table>
<thead>
<tr>
<th>1.1 Reporter ID</th>
<th>1.2 Reporter Name</th>
<th>1.3 Reporter Job Title</th>
<th>1.4 Reporter Number</th>
<th>1.5 Date Part A Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1CD12</td>
<td>Zina Amagi</td>
<td>Fieldworker</td>
<td>001</td>
<td>01 JAN 14</td>
</tr>
</tbody>
</table>

**2. Patient ID**

<table>
<thead>
<tr>
<th>2.1 Patient ID</th>
<th>2.2 Age (yr)</th>
<th>2.3 Weight (kg)</th>
<th>2.4 Height (cm)</th>
<th>2.5 Sex</th>
<th>2.6 Pregnant? (Y/N)</th>
<th>2.6.1 If Y, No of months</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1CD12</td>
<td>23</td>
<td>56</td>
<td>163</td>
<td>M</td>
<td>N</td>
<td>N</td>
</tr>
</tbody>
</table>

**3. Presenting Problem**

<table>
<thead>
<tr>
<th>3.1 Symptoms before being prescribed (Study Drug):</th>
<th>3.2 Diagnosis</th>
<th>3.3 Confirmed by: Rapid Test?</th>
<th>3.4 Malaria Blood Slide?</th>
</tr>
</thead>
<tbody>
<tr>
<td>FEVER, NAUSEA, TIREDNESS</td>
<td>MALARIA</td>
<td>[ ] Yes [ ] No</td>
<td>[ ] Yes [ ] No</td>
</tr>
</tbody>
</table>

**4. Medication History**

<table>
<thead>
<tr>
<th>4.1 Did the patient try any treatment for these symptoms before attending the health facility?</th>
<th>4.2 Did the patient use any traditional remedies for this illness?</th>
<th>4.3 If yes, what does the patient take? (Names of drugs and doses if known)</th>
<th>4.4 Does the patient use any traditional remedies regularly?</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ] Yes [ ] No</td>
<td>[ ] Yes [ ] No</td>
<td>[ ] Yes [ ] No</td>
<td>[ ] Yes [ ] No</td>
</tr>
</tbody>
</table>

**5. Medicines Prescribed at this Visit (from record)**

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dose (e.g. 2 tabs, 1 cap, 1g, 500mg, 3 ml, 1 tsp)</th>
<th>Frequency (e.g. once daily, twice daily)</th>
<th>Start Date (DD/MM/YYYY)</th>
<th>Number of days prescribed</th>
</tr>
</thead>
<tbody>
<tr>
<td>PARACETAMOL</td>
<td>2 TABS X 4/day since 26 DEC 13</td>
<td></td>
<td>01/01/2014</td>
<td>5</td>
</tr>
<tr>
<td>TRIZIVIR</td>
<td>1 TAB DAILY</td>
<td></td>
<td>01/01/2014</td>
<td>30</td>
</tr>
</tbody>
</table>

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**Page 2 of 7**
### Part B (follow up) – this section is completed with the patient/patient representative at follow up

**ACTIVE ADVERSE EVENT REPORT FORM (PROSPECTIVE) – PART B1 (FOLLOW-UP)**

<table>
<thead>
<tr>
<th>1.1 Field Worker ID</th>
<th>2.1 Follow-up Visit: Date of Follow-up (DD/MM/YYYY)</th>
<th>2.2 Type of follow-up: Attendance at clinic, Visit at home, Other Specify</th>
</tr>
</thead>
<tbody>
<tr>
<td>[redacted]</td>
<td>5th July 2014</td>
<td>[redacted]</td>
</tr>
</tbody>
</table>

**2. FOLLOW-UP VISIT**

- **Type of follow-up**: Visit at home

**NOTES TO FIELD WORKER:**

- If the patient is not present at the follow-up visit today, please tick this box and state the reason.
- If you know why the patient is unavailable, please specify.
- If the patient is in hospital or has died, please record by ticking the relevant box and contact the senior investigator immediately.

**3. Ask the patient:**

- **Did you take any [insert name of study drug]?** Yes, No
- **Reasons for taking the study drug:** (if NO - STOP)

**4. Show the picture story to the respondent. Use the story to remind the patient why you are filling in the form with them. Invite questions. Discuss with the patient:**

- The man takes medicine for malaria
- The man is being sick. This may or may not be due to the drug
- The reporter fills this form with the man

**Why we are filling in this form:**

- We are trying to find out people’s experiences with using [Study Drug]
- I would like you to tell me what happened before and after you took [Study Drug]
- I would like us to fill this form in together

If the participant never took any of the study drug, no further information is required (3)

There should be procedures in place detailing the action that should be taken if the patient has been admitted to hospital or has passed away (2.4.3)
Day 1 = the day the study drug was first taken.

5.1 Now I would like to ask you to tell your health in the last 4 days since you were prescribed [Study Drug]. Starting from the day you went to the clinic, you can tell me the drugs and herbs you took each day, and any symptoms old or new, each day. I will record these in this diary:

Day 1 = the day the study drug was first taken.

In this row, show ALL drugs taken by the patient and each dose each day.

Include ALL drugs, herbs, traditional remedies etc used by the patient throughout the follow up period, including the study drug. If drug names are abbreviated, enter the abbreviations used in section 5.2. Entries should be positioned in the box to represent the time of day they were taken. The dose taken should be included (in this example, as a superscript figure representing the number of tablets taken).

In this row, describe ALL symptoms, and unusual events experienced by the patient each day.

Include ALL symptoms experienced by the participant throughout the follow up period, including those that were present at the initial visit (at day 1). If a symptom worsened, this should be captured. Position the symptom in the box to represent the time it commenced, and use arrows to demonstrate how long they were present for. Indicate if ongoing at time of follow up visit.

5.2 Additional comments

Use additional comments section to provide details of drug strengths, key for abbreviations used or any other details that do not fit into the diary section (5.2).

Use the diary to determine if any symptoms started or worsened after the study drug was taken. If yes, continue completing the form. If no, stop. If in doubt, continue (7).
<table>
<thead>
<tr>
<th>All drugs and herbs detailed in the diary should be listed in section 8.1. The patient/patients representative should then be asked the questions 8.1.1 to 8.1.4 for each drug</th>
</tr>
</thead>
<tbody>
<tr>
<td>There should be procedures in place detailing the action that should be taken if the patient has been admitted to hospital (10)                                                                egovt/other entities.</td>
</tr>
<tr>
<td>Use this section for any additional information not included above (12)</td>
</tr>
</tbody>
</table>

### ACTIVE ADVERSE EVENT REPORT FORM – PART B2

8. Using the information you have recorded in the diary, fill in the first column, and complete the table by asking the patient:

<table>
<thead>
<tr>
<th>8.1 Name of each drug and herb used</th>
<th>8.1.1 Where did you get this drug or herb from?</th>
<th>8.1.2 Have you used this drug or herb before? (Yes/No; Patient unsure)</th>
<th>8.1.3 Have you had problems with this drug or herb before? (Yes/No); If Y, please describe</th>
<th>8.1.4 Would you use this drug or herb again? (Yes/No); If no, why not?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. COBRA TEK</td>
<td>CLINIC</td>
<td>YES</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>2. PANA DOG</td>
<td>CLINIC</td>
<td>YES</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>3. MULTIVITAMIN</td>
<td>CLINIC</td>
<td>YES</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>4. PILLITON</td>
<td>SHOP</td>
<td>YES</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>5.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

9. Ask the patient about how they are feeling now: How are you feeling now (current status)?

- Recovered fully □
- Getting better □
- One or more symptoms not improving or worsening □ (please describe) ____________________________________________________________

10. Were you admitted to a health facility during the follow up period? (period since being prescribed [Study Drug])

- Yes □ No □
- If Yes, where? ____________________________
- On which date _/_/____ (DD/MM/YYYY)

If YES Contact Senior investigator for follow-up

11. Field Worker Action

- None □
- Referred □

If referred - Give details __________________________________________

If Referred Contact Senior Investigator for follow-up

12. Field worker comments, further information

You have now completed your interview with the patient; please thank them for their time.
**Safety Data Collection Tools for Non-Clinicians – Training Manual**

**Form A - Prospective Active Data Collection**

**ACTIVE ADVERSE EVENT REPORT FORM PART C**

<table>
<thead>
<tr>
<th>1.1 Reporter ID</th>
<th>1.2 Reporter Contact</th>
<th>1.3 Report Number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0777 654 321</td>
<td></td>
</tr>
</tbody>
</table>

**2. ALL MEDICINES AND HERBS TAKEN AT ANY TIME DURING FOLLOW-UP PERIOD**

<table>
<thead>
<tr>
<th>2.1 NAME OF DRUG OR HERB</th>
<th>2.1.1 DOSE (e.g. 2 tablets; one capsule; 20mg; 1g; 5ml; 1 tsp)</th>
<th>2.1.2 FREQUENCY (e.g. once only, one daily, twice daily, when required)</th>
<th>2.1.3 DATE STARTED (DD/MM/YYYY)</th>
<th>2.1.4 DATE STOPPED (DD/MM/YYYY)</th>
<th>OR CONTINUING?</th>
<th>2.1.5 COMMENTS (E.g. missed doses, did not complete prescribed course)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. CO-ARTEM</td>
<td>4 TABS</td>
<td>Twice DAILY</td>
<td>01/1 JAN 2014</td>
<td>03/1 JAN 2014</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>2. PANADOL</td>
<td>2 TABS</td>
<td>Four TIMES DAILY</td>
<td>01/1 JAN 2014</td>
<td>02/1 JAN 2014</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>3. MULTIVITAMIN</td>
<td>2 TABS</td>
<td>DAILY</td>
<td>01/1 JAN 2014</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>4. ARITON</td>
<td>1 TAB</td>
<td>Twice DAILY</td>
<td>02/1 JAN 2014</td>
<td></td>
<td>X</td>
<td>TAKEN AFTER RASH (RASH)</td>
</tr>
</tbody>
</table>

**3. DESCRIBE NEW SYMPTOMS OR WORSENING SYMPTOMS OCCURRING DURING FOLLOW-UP PERIOD**

<table>
<thead>
<tr>
<th>3.1 DESCRIPTION OF NEW OR WORSENING SYMPTOM</th>
<th>3.1.1 DATE SYMPTOM STARTED (DD/MM/YYYY)</th>
<th>3.1.2 DATE SYMPTOM STOPPED (DD/MM/YYYY)</th>
<th>OR CONTINUING?</th>
<th>3.1.3 OUTCOME* (A-D):</th>
<th>3.1.4 SERIOUS?? Y/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. RASH</td>
<td>02/1 JAN 2013</td>
<td>.../.../...</td>
<td></td>
<td></td>
<td>N</td>
</tr>
<tr>
<td>2.</td>
<td>.../.../...</td>
<td>.../.../...</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>.../.../...</td>
<td>.../.../...</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*OUTCOME: A: RECOVERED; B: RECOVERING (GETTING BETTER); C: NOT RECOVERED (PROBLEM REMAINS); D: DEATH

**SERIOUS: Y IF: 1. DEATH; 2. ADMITTED TO HOSPITAL; 3. REQUIRED REFERRAL – IF YES – SENIOR INVESTIGATOR TO REPORT AS SERIOUS ADVERSE EVENT (ON FORM C) AS PER GCP REQUIREMENTS*
Form C

Retrospective Active Data Collection
Form C

Form C is designed to be used by non-clinicians as part of a retrospectively designed study/programme. Patients are followed up a few days after receiving a medicinal product (termed ‘study drug’ below) and asked about their experience (symptoms) since receiving the medicinal product. As this will be the first encounter with the patient, any available records should be used to assist in recording the details of what was prescribed during the initial visit to the health facility (for example, clinic records, drug shop records, patient records etc).

Form C is available in adult and child versions.

Detailed Guide

Part A – to be completed using the available records at the time of follow-up for all patients who received treatment.

<table>
<thead>
<tr>
<th>1.1 Fieldworker ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.2 Fieldworker Contact</td>
</tr>
<tr>
<td>Enter contact details for the fieldworker, such as a telephone number or email address.</td>
</tr>
<tr>
<td>1.3 Report Number</td>
</tr>
<tr>
<td>A unique identifiable reference number for this report.</td>
</tr>
<tr>
<td>2.1 Patient ID</td>
</tr>
<tr>
<td>2.2 Presenting symptoms</td>
</tr>
<tr>
<td>If reported in the available record, list all symptoms that the patient had, prior to receiving treatment.</td>
</tr>
<tr>
<td>2.3 Diagnosis</td>
</tr>
<tr>
<td>Record the diagnosis as reported in the record, if available.</td>
</tr>
<tr>
<td>2.4 Confirmed by Test?:</td>
</tr>
<tr>
<td>In cases being treated for malaria, tick whether diagnosis was confirmed by Rapid Diagnostic Test or Blood Slide, if applicable. In non-malaria cases, this section can be removed.</td>
</tr>
<tr>
<td>3.1 Medicines prescribed at this visit (from records)</td>
</tr>
<tr>
<td>Using the records available, record the following details of all medicines prescribed at the initial visit – name of drug, dose, frequency, start date, number of days prescribed.</td>
</tr>
<tr>
<td>3.2 Source of prescribed medicines information</td>
</tr>
<tr>
<td>Indicate the source used to gather the above information.</td>
</tr>
</tbody>
</table>

4.1 Date of follow-up

4.2 Type of follow-up

4.3 Follow up with:

Specify whether the patient themselves is providing the information, or a representative for the patient (i.e. the caregiver if the patient is a child). If it is a representative, specify their relationship to the patient (i.e. parent, caregiver etc).

4.4.1 If the patient is not present at the follow-up visit today, please tick this box

4.4.2 If you know why the patient is unavailable, please specify

4.4.3 If the patient is in hospital or has died, please record by ticking the appropriate box and contact the senior investigator immediately

This is a serious adverse event (SAE). It is important that SAEs are identified as soon as possible and are notified to the relevant person in accordance with study procedures immediately.
### Part B – to be completed with the patient/caregiver

<table>
<thead>
<tr>
<th><strong>1. Ask the patient/caregiver: Did you/your child take any study drug?</strong></th>
<th>If the patient/caregiver admits that they did not take any study drug, no further information needs to be provided. Even if the patient only took one dose, continue completing the form.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2. Show the picture story to the respondent. Use the story to remind the patient/caregiver why you are filling in the form with them. Inv</strong></td>
<td>Ensure the patient/caregiver can see the form at all times throughout the data collection process. Show them the picture story and discuss it with the patient/caregiver. Make sure they understand and are comfortable with the information being collected before proceeding.</td>
</tr>
<tr>
<td><strong>3.1 Patient ID</strong></td>
<td></td>
</tr>
<tr>
<td><strong>3.2 Age (yrs)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>3.3 Weight (kg) if known</strong></td>
<td></td>
</tr>
<tr>
<td><strong>3.4 Height (cm) if known</strong></td>
<td></td>
</tr>
<tr>
<td><strong>3.5 Sex M/F</strong></td>
<td></td>
</tr>
<tr>
<td><strong>3.6 Pregnant? Y/N (omitted in the child form)</strong></td>
<td>If applicable.</td>
</tr>
<tr>
<td><strong>3.6.1 If Y, ____months</strong></td>
<td>Enter number of months pregnant, if known.</td>
</tr>
<tr>
<td><strong>4.1 Symptoms before being prescribed the study drug</strong></td>
<td>Ask the patient/caregiver to describe all symptoms that occurred at the beginning of this illness episode, which led to them seeking treatment.</td>
</tr>
<tr>
<td><strong>5.1 Did the patient/caregiver try any treatment for these symptoms before attending the health facility?</strong></td>
<td>Ask about all drugs taken in the two weeks prior to the visit to the health facility.</td>
</tr>
<tr>
<td><strong>5.1.1 If yes, what did the patient take?</strong></td>
<td>List treatment as reported by the patient/caregiver (brand or generic names). Where possible, include information on doses, start dates and course lengths.</td>
</tr>
<tr>
<td><strong>5.2 Did the patient/caregiver use any traditional remedies for this illness? If yes, give details if known</strong></td>
<td>Ask about all remedies taken in the two weeks prior to the visit. Where possible, record the names of the remedies and any information on doses, start dates and course lengths.</td>
</tr>
<tr>
<td><strong>5.3 Does the patient/your child take any medicines regularly (e.g. for diabetes, family planning, ARVs, TB medicine, epilepsy, etc)?</strong></td>
<td>Ask about any treatment the patient may take regularly, such as those for concurrent medical conditions (e.g. HIV, TB etc).</td>
</tr>
<tr>
<td><strong>5.3.1 If yes, what does the patient take?</strong></td>
<td>List treatment as reported by the patient/caregiver (brand or generic names). Where possible, include information on doses, start dates and course lengths.</td>
</tr>
<tr>
<td><strong>5.4 Does the patient use any traditional remedies regularly? If yes, give details if known</strong></td>
<td>Ask about any remedies the patient may take regularly, such as those for concurrent medical conditions (e.g. HIV, TB etc). Where possible, record the names of the remedies and any information on doses, start dates and course lengths.</td>
</tr>
<tr>
<td><strong>6.1 Now I would like to ask you about you/your child’s health in the last ____ days since you were prescribed the study drug. Starting from the day you went to the _____ can you tell me the drugs and herbs you/your child took each day, and any symptoms old or</strong></td>
<td>Complete the diary with the patient/caregiver – explain to them how the data is going to be captured and ensure they can view the diary at all times. If possible, allow them to direct you as to where the information should go. Information on drugs/herbs/traditional remedies taken at any time during the follow up period should be entered in the top row. Information on all symptoms experienced by</td>
</tr>
</tbody>
</table>
new each day. I will record these in this diary

the patient during the follow up period, whether old or new, should be recorded in the bottom row. All drugs/herbs/traditional remedies taken should be included, regardless of whether they were obtained from the study health facility or elsewhere. The information should reflect how the drugs were taken, which may differ from how they were prescribed.

Using the time of day at the top as a guide, position the drug in the diary at the approximate time it was taken (i.e. morning, midday or night time). Enter the dose as a superscript number near the drug entry. Complete for all doses and drugs taken. Use section 6.2 to add any additional comments such as strengths of drugs, or as a key for any abbreviations used.

In the bottom row of the diary, list all symptoms experienced by the patient throughout the follow up period, including those on day 1 (which resulted in seeking treatment). As with the drugs, position the symptom at the approximate time of day to illustrate when the symptom started. Using arrows, indicate when the symptom stopped, or specify ‘ongoing’ if appropriate. If a symptom worsens, indicate this in the diary also.

6.2 Additional comments
Section for additional comments such as details of drug strengths, key for abbreviations used or any other details that do not fit into the diary section.

7 Diary checklist for fieldworker
Use this checklist as a guide to ensure you have completed all information.

8 Have there been any new or worsening symptoms in this follow up period?
Review the diary once complete, to determine if there have been any symptoms that started, or worsened, after treatment was taken. If there are no new or worsening symptoms, data collection can stop at this point. If a new or worsening symptom has been identified, continue. Please see appendix 1 for further information on identifying new and worsening symptoms. If in doubt, continue.

9 Using the information you have recorded in the diary, fill in the first column and complete the table by asking the patient/caregiver:
Copy all drugs from the diary into the first column of the table. For each drug, ask the patient/caregiver:
1. Where did they get the drug from (i.e. health facility, drug shop etc).
2. Have they used the drug/herb before?
3. If so, have they had any problems with the drug/herb before (and describe the problem if yes)?
4. Would you use this drug/herb again, and if not, why?
These questions will give a picture of whether the patient has experienced a similar problem before (for example, whether they always vomit after taking a particular drug) and whether they associate the problem with the drug (for example, if they say no they wouldn’t use the drug again, it implies they think it is causing the problem).

10 Ask the patient/caregiver how
### 11 Were you/your child admitted to a health facility during the follow up period? If yes, contact the senior investigator for follow up

This is a SAE. As per section 4.4.3 above, it is important that all cases of hospitalisation are identified and reported quickly, to ensure the patient undergoes more detailed follow up.

### 12 Field worker action. If referred contact senior investigator for follow up

If the fieldworker feels the patient requires further medical attention for any reason (i.e. they are not recovering or there is a concerning new symptom) they should document the action they have advised the patient/caregiver and details of the referral. Fieldworkers should be offered training on identifying symptoms of concern and when to refer. They should be able to contact more senior members of the team if in doubt.

### 13 Fieldworker comments, further information

Any information not already included in the form should be documented here.

---

**Part C – to be completed by the safety officer.**

This section of the form can be completed retrospectively after the follow up visit is complete. It should be completed as soon as possible after the visit, so that any potential issues are detected in a timely manner. If there were no worsening or new symptoms detected, this section does not need to be completed; however, all forms should be reviewed by the safety officer to ensure no potential adverse events have been missed.

1. **1.1 Reporter ID**
   Enter the name of the safety officer who is completing part C.

2. **1.2 Reporter Contact**
   Enter contact details for the reporter, such as a telephone number or email address.

3. **1.3 Report Number**
   Enter the report number, as specified in part A (the suffix ‘/C’ indicates that this is part C of the report).

4. **2 All medicines and herbs taken at any time during follow up**
   From the diary and question 9, complete this table with the following information: Name of all drugs/herbs taken in the follow up period, dose, frequency, date started, date stopped (or continuing), comments.

5. **3 Describe new symptoms or worsening symptoms occurring during follow up**
   From the diary and the rest of part B, complete the following information for the new or worsening symptom only – description, date started, date stopped (or continuing), outcome (see key on form), serious Y/N (the case is considered serious if the patient died, was hospitalised, or required referral). If the case is considered serious, the SAE form should be completed by the safety officer and more detailed follow up should be undertaken if possible.
**Form C - Retrospective Active Data Collection**

**Quick Guide**

**ACTIVE ADVERSE EVENT REPORTING FORM - ADULT (Retrospective)**

**Fieldworker Details**

1.1 Fieldworker ID

1.2 Fieldworker Contact

1.3 Report Number

**Part A & B – to be completed at the time of follow-up for all patients who received treatment**

**Enter name of person completing form (1.1)**

**Enter contact details of the person completing the form, such as a telephone number or email address (1.2)**

**A unique identifiable reference number for this report (1.3)**

**List drug names as reported (brand or generic) and include information on drug doses, start dates & course lengths, if known (3)**

**There should be procedures in place detailing the action that should be taken if the patient has been admitted to hospital or has passed away (4.4.3)**

**Part A – COMPLETE PATIENT DETAILS FROM REGISTER / CLINICAL RECORD INCLUDING DRUGS PRESCRIBED**

<table>
<thead>
<tr>
<th>2.1 Patient ID</th>
<th>2.2 Presenting symptoms</th>
<th>2.3 Diagnosis</th>
<th>2.4 Confirmed by Test?</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABCD 12</td>
<td>FEVER, NAUSEA, TINGNESS</td>
<td>MALARIAN</td>
<td>Rapid Diagnostic Test (RDT)? Yes [ ] No [ ] N/A [ ]</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Malaria Blood Slide? Yes [ ] No [ ] N/A [ ]</td>
</tr>
</tbody>
</table>

**3. MEDICINES PRESCRIBED AT THIS VISIT (FROM CLINIC/SHOP RECORD OR PATIENT HELD RECORD)**

<table>
<thead>
<tr>
<th>3.1 Drug name</th>
<th>3.1.1 Dose (e.g. 2 tablets; one capsule; 20mg; 1g; 5ml; 1 tsp)</th>
<th>3.1.2 Frequency (e.g. once only, once daily, twice daily, when required)</th>
<th>3.1.3 Start Date (DD/MM/YYYY)</th>
<th>3.1.4 Number of days prescribed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. LOPINAVIR</td>
<td>4 TABS</td>
<td>TWICE DAILY</td>
<td>01/ Jan/2014</td>
<td>3</td>
</tr>
<tr>
<td>2. PANADOX</td>
<td>2 TABS</td>
<td>FOUR TIMES DAILY</td>
<td>01/ Jan/2014</td>
<td>3</td>
</tr>
<tr>
<td>3. MULTIVITAMIN</td>
<td>2 TABS</td>
<td>ONCE DAILY</td>
<td>01/ Jan/2014</td>
<td>30</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**4. FOLLOW-UP VISIT (TODAY)**

<table>
<thead>
<tr>
<th>4.1 Date of Follow-up (DD/MM/YYYY)</th>
<th>4.2 Type of follow-up</th>
<th>4.3 Follow up with:</th>
</tr>
</thead>
<tbody>
<tr>
<td>4/11/2014</td>
<td>Attendance at clinic [ ] ; Visit at home [ ] ; Other [ ]</td>
<td>Patient [ ] Patient representative [ ] , Specify __________________</td>
</tr>
</tbody>
</table>

**NOTES TO FIELD WORKER:**

4.4.1. If the patient is not present at the follow-up visit today, please tick this box [ ] . 4.4.2. If you know why the patient is unavailable, please specify __________________ . 4.4.3. If the patient is in hospital [ ] or has died [ ] please record by ticking the relevant box and CONTACT THE SENIOR INVESTIGATOR IMMEDIATELY.
If the participant never took any of the study drug, no further information is required (1)

If possible, include all drugs (5.1) and traditional remedies (5.2) taken in the **two weeks** prior to the visit. When recording drugs/remedies, record the names as reported (brand or generic) and include information on doses, start dates & course lengths, if known.
Day 1 = the day the study drug was first taken.

Include ALL drugs, herbs, traditional remedies etc used by the patient throughout the follow up period, including the study drug. If drug names are abbreviated, enter the abbreviations used in section 6.2. Entries should be positioned in the box to represent the time of day they were taken. The dose taken should be included also (in this example, as a superscript figure representing the number of tablets taken).

Include ALL symptoms experienced by the participant throughout the follow up period, including those that were present at the initial visit. If a symptom worsened, this should be captured. Position the symptom in the box to represent the time it commenced and use arrows to demonstrate how long they were ongoing for. Indicate if ongoing at time of follow up visit.

Use this checklist to ensure all available data is captured (7)

Review the diary to determine if any symptoms started or worsened after the study drug was taken. If yes, continue. If no, stop. If in doubt, continue (8)

Use additional comments section to provide details of drug strengths, key for abbreviations used or any other details that do not fit into the diary section (6.2)
All drugs and herbs detailed in the diary should be listed in section 9.1. The patient/patients representative should then be asked the questions 9.1.1 to 9.1.4 for each drug.

There should be procedures in place detailing the action that should be taken if the patient has been admitted to hospital (11).

Use this section for any additional information not included above (13).

---

### ACTIVE ADVERSE EVENT REPORT FORM – PART B3

#### 9. Using the information you have recorded in the diary, fill in the first column, and complete the table by asking the patient:

<table>
<thead>
<tr>
<th>9.1 Name of each drug and herb used</th>
<th>9.1.1 Where did you get this drug or herb from?</th>
<th>9.1.2 Have you used this drug or herb before? (Yes/No/ Patient unsure)</th>
<th>9.1.3 Have you had problems with this drug or herb before? (Yes/No); If Y, please describe</th>
<th>9.1.4 Would you use this drug or herb again? (Yes/No); If no, why not?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. COXETEM</td>
<td>CLINIC</td>
<td>YES</td>
<td>No</td>
<td>YES</td>
</tr>
<tr>
<td>2. PANASON</td>
<td>CLINIC</td>
<td>YES</td>
<td>No</td>
<td>YES</td>
</tr>
<tr>
<td>3. MULTIVITAMIN</td>
<td>CLINIC</td>
<td>YES</td>
<td>No</td>
<td>YES</td>
</tr>
<tr>
<td>4. PILITIN</td>
<td>SUPP</td>
<td>YES</td>
<td>No</td>
<td>YES</td>
</tr>
<tr>
<td>5.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### 10. Ask the patient about how they are feeling now: How are you feeling now (current status)?

Recovered fully ☐; Getting better ☐; One or more symptoms not improving or worsening ☐ (please describe) ____________________________________________________________________________________________

#### 11. Were you admitted to a health facility during the follow up period? (period since being prescribed [Study Drug])

Yes ☐ No ☐  If Y, where _____________________________

On which date __/__/____ (DD/MM/YYYY)

**If YES** Contact Senior investigator for follow-up

#### 12. Field Worker Action

None ☐ Referred ☐

If referred - Give details ____________________________________________________________________________________________

**If Referred** Contact Senior investigator for follow-up

#### 13. Field worker comments, further information

You have now completed your interview with the patient; please thank them for their time.
In the example above, rash is the only new symptom (i.e. commenced after drugs were taken).

All drugs from the diary and question 9 should be entered here (2.1)

### ACTIVE ADVERSE EVENT REPORT FORM PART C

<table>
<thead>
<tr>
<th>Patient ID:</th>
<th>ABCD 12</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 Reporter ID</td>
<td>JONAH MULUNGU</td>
</tr>
<tr>
<td>1.2 Reporter Contact</td>
<td>093 654 321</td>
</tr>
<tr>
<td>1.3 Report Number</td>
<td>001</td>
</tr>
</tbody>
</table>

### 2. ALL MEDICINES AND HERBS TAKEN AT ANY TIME DURING FOLLOW-UP PERIOD

<table>
<thead>
<tr>
<th>2.1 NAME OF DRUG OR HERB</th>
<th>2.1.1 DOSE (e.g. 2 tablets; one capsule; 20mg; 15ml; 1 tsp)</th>
<th>2.1.2 FREQUENCY (e.g. once only, daily, twice daily, when required)</th>
<th>2.1.3 DATE STARTED (DD/MM/YYYY)</th>
<th>2.1.4 DATE STOPPED (DD/MM/YYYY)</th>
<th>2.1.5 COMMENTS (E.g. missed doses, did not complete prescribed course)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. LOZARTEN</td>
<td>4 TFSS</td>
<td>TWICE DAILY</td>
<td>01/Jan/2014</td>
<td>03/Jan/2014</td>
<td></td>
</tr>
<tr>
<td>2. PANADOL</td>
<td>2 TFSS</td>
<td>FOUR TIMES DAILY</td>
<td>01/Jan/2014</td>
<td>02/Jan/2014</td>
<td></td>
</tr>
<tr>
<td>3. MULTIVITAMIN</td>
<td>2 TFSS</td>
<td>DAILY</td>
<td>01/Jan/2014</td>
<td>02/Jan/2014</td>
<td></td>
</tr>
<tr>
<td>4. PIRITON</td>
<td>1 TFSS</td>
<td>PLUS DAILY</td>
<td>02/Jan/2014</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 3. DESCRIBE NEW SYMPTOMS OR WORSENING SYMPTOMS OCCURRING DURING FOLLOW-UP PERIOD

#### 3.1 DESCRIPTION OF NEW OR WORSENING SYMPTOM

- **RASH**
  - Started: 27/Jan/2014
  - Stopped: 27/Jan/2014
  - Outcome: Recovered
  - Serious: No

- 2.
  - ..../..../....
  - ..../..../....
  - Serious: No

- 3.
  - ..../..../....
  - ..../..../....
  - Serious: No
Form E

Passive (Spontaneous) Data Collection
Form E

Form E is designed to enable non-clinicians to collect safety data which is being spontaneously reported by the patient or the patient’s caregiver. Patients are not actively being followed up and asked for their experiences after being administered a medicinal product (termed the ‘suspect drug’ below), but rather the non-clinician has determined some other way that a possible adverse reaction has been experienced (for example, the patient may have volunteered the information or sought treatment for the reaction).

Form E is available in adult and child versions.

Detailed Guide

Part A - to be completed with the patient/caregiver.

1.1 Fieldworker ID
1.2 Fieldworker Contact
Enter contact details for the fieldworker, such as a telephone number or email address.

1.3 Report Number
A unique identifiable reference number for this report.

2. Show the picture story to the respondent. Use the story to explain why you are filling in the form with them. Invite questions
Ensure the patient/caregiver can see the form at all times throughout the data collection process. Show them the picture story and discuss it with the patient/caregiver. Make sure they understand and are comfortable with the information being collected before proceeding.

3.1 Patient ID
3.2 Age (yrs)
3.3 Weight (kg) if known
3.4 Height (cm) if known
3.5 Sex M/F
3.6 Pregnant? Y/N (omitted from child form)
3.6.1 If Y, _____ months
Enter number of months pregnant, if known.

4.1 What is the adverse event you are reporting?
If the answer is no, than this is not an adverse event and data collection can stop at this point. However, if a pre-existing symptom worsened after starting the suspect drug, then this is an event, and data collection should continue.

5.1 Can you tell me what symptoms you had before you took the suspect drug?
Ask the patient/caregiver to describe all symptoms that occurred at the beginning of this illness episode, which led to them seeking treatment and being given the suspect drug.

5.2 Did the patient try any treatment(s) for this illness before you took suspect drug? If yes, what?
Ask about all drugs taken in the two weeks prior to the visit to the health facility. List treatment as reported by the patient/caregiver (brand or generic names). Where possible, include information on doses, start dates and course lengths.

6.1 Does the patient take any medicines or herbs regularly (e.g. for blood pressure, family planning),
Ask about any treatment the patient may take regularly, such as those for concurrent medical conditions (e.g. HIV, TB etc). Where possible, record the names of the...
Part B1 - to be completed with the patient/caregiver.

1.1 Can you tell me what happened from the first day you took the suspect drug? Complete the diary with the patient/caregiver – explain to them how the data is going to be captured and ensure they can view the diary at all times. If possible, allow them to direct you as to where the information should go. Information on drugs/herbs/traditional remedies taken at any time during the follow up period should be entered in the top row. Information on all symptoms experienced by the patient during the follow up period, whether old or new, should be reported in the bottom row. All drugs/herbs/traditional remedies taken should be included, regardless of where they were obtained from. The information should reflect how the drugs were taken, which may differ from how they were prescribed. Using the time of day at the top as a guide, position the drug in the diary at the approximate time it was taken (i.e. morning, midday or night time). Enter the dose as a superscript number near the drug entry. Complete for all doses and drugs taken. Use section 1.2 to add any additional comments such as strengths of drugs, or as a key for any abbreviations used. In the bottom row of the diary, list all symptoms experienced by the patient throughout the follow up period, including those on day 1 (which resulted in seeking treatment). As with the drugs, position the symptom at the approximate time of day to illustrate when the symptom started. Using arrows, indicate when the symptom stopped, or specify ‘ongoing’ if appropriate. If a symptom worsens, indicate this in the diary also.

1.2 Additional comments Section for additional comments such as details of drug strengths, key for abbreviations used or any other details that do not fit into the diary section.

2 Diary checklist for fieldworker Use this checklist as a guide to ensure you have completed all information.

Part B2 - to be completed with the patient/caregiver.

3 Using the information you have recorded in the diary, fill in the first column and complete the table by asking the patient/caregiver: Copy all drugs from the diary into the first column of the table. For each drug, ask the patient/caregiver: 1. Where did they get the drug from (i.e. health facility, drug shop etc) 2. Have they used the drug/herb before? 3. If so, have they had any problems with the drug/herb before (and describe the problem if yes)?
4. Would you use this drug/herb again, and if not, why? These questions will give a picture of whether the patient has experienced a similar problem before (for example, whether they always vomit after taking a particular drug) and whether they associate the problem with the drug (for example, if they say no, they wouldn’t use the drug again, it implies they think it is causing the problem).

4 Ask the patient how they are feeling now

5 Were you/your child admitted to a health facility during the follow up period? If yes, contact the senior investigator for follow up

This is a Serious Adverse Event. It is important that all cases of hospitalisation are identified and reported quickly, to ensure the patient undergoes more detailed follow up.

6 Field worker action. If referred contact senior investigator for follow up

If the fieldworker feels the patient requires further medical attention for any reason (i.e. they are not recovering or there is a concerning new symptom) they should document the action they have advised the patient/caregiver and details of the referral. Fieldworkers should be offered training on identifying symptoms of concern and when to refer. They should be able to contact more senior members of the team if in doubt.

7 Fieldworker comments, further information

Any information not already included in the form should be documented here.

Part C – to be completed by the safety officer.

This section of the form can be completed retrospectively. It should be completed as soon as possible after the patient has reported the event, so that any potential issues are detected in a timely manner.

1.1 Reporter ID

Enter the name of the safety officer who is completing part C.

1.2 Reporter Contact

Enter contact details for the reporter, such as a telephone number or email address.

1.3 Report Number

Enter the report number as specified in part A (the suffix ‘/C’ indicates that this is part C of the report).

2 All medicines and herbs taken at any time during follow up

From the diary and question 3, complete this table with the following information: Name of all drugs/herbs taken in the follow up period, dose, frequency, date started, date stopped (or continuing), comments.

3 Describe new symptoms or worsening symptoms occurring during follow up

From the diary and the rest of part B, complete the following information for the new or worsening symptom only – description, date started, date stopped (or continuing), outcome (see key on form), serious Y/N (the case is considered serious if the patient died, was hospitalised, or required referral). If the case is considered serious, the SAE form should be completed by the safety officer and more detailed follow up should be undertaken if possible.
**Quick Guide**

**Patient ID:** ABCD 12

1. **Passive ADVERSE EVENTS REPORT FORM – PART A Version**

2. **Show the picture story to the respondent. Use the story to explain why you are filling in the form with them. Invite questions.**

3. **When recording drugs/remedies, record the names as reported (brand or generic) and include information on doses, start dates & course lengths, if known (5.2, 6.1)**

4. **Safety Data Collection**

5. **Part A & B – to be completed with the patient/caregiver if they have reported an untoward event after taking a medicinal product**

6. **If possible, include all drugs and traditional remedies taken two weeks prior to the visit (5.2)**

**1.1 Enter name of person completing form**

**1.2 Enter contact details of the person completing the form, such as a telephone number or email address**

**1.3 A unique identifiable reference number for this report**

**2. Why we are filling in this form:**
- We are trying to find out people’s experiences with using [suspect drug]
- I would like you to tell me what happened to you before and after using [suspect drug]
- I would like us to fill this form together

**3. Adverse Event**

3.1 What is the adverse event you are reporting? **VOMITING**

3.2 Did you experience these symptoms after taking [suspect drug]? Yes ☐ No ☐

**I will ask you more details about this soon**

**5. Illness History**

5.1 Can you tell me what symptoms you had before you took [suspect drug]? **Fever, vomiting, tiredness**

5.2 Did you use any other treatment(s) for this illness before you took [suspect drug]? Yes ☐ No ☐ If yes, what? **PARACETAMOL 2 TABS X 4/Day Since 20 Dec 13**

**6. Routine Medicine**

6.1 Do you take any medicines or herbs regularly? (e.g. for blood pressure, family planning, ARVs, TB medicine) Yes ☐ No ☐ If yes, Which ones? **Truvir 1 TAB TWICE DAILY**

**3.6 Pregnant? Y/N N**

**3.6.1 If Y _months**
**Form E – Passive (Spontaneous) Data Collection**

### Passive Adverse Event Report Form – Part B1

1.1 Can you tell me what happened in the first day you took [Suspect Drug]?

<table>
<thead>
<tr>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Later follow-up day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>Date</td>
<td>Date</td>
<td>Date</td>
<td>Date</td>
</tr>
<tr>
<td>WED</td>
<td>TUE</td>
<td>FRI</td>
<td>SAT</td>
<td>1/1</td>
</tr>
</tbody>
</table>

- **What drugs and herbs did you use?**
  - In this row, show ALL drugs taken by the patient and each dose each day.
  - Include ALL drugs, herbs, traditional remedies etc used by the participant throughout the follow up period, including the study drug. If drug names are abbreviated, enter the abbreviations used below. Entries should be positioned to represent the time of day they were taken. The dose taken should be included also (in this example, as a superscript figure representing the number of tablets taken).

- **What were your symptoms each day?**
  - In this row, show ALL symptoms experienced by the patient each day, including adverse events.
  - Include ALL symptoms experienced by the participant throughout the follow up period, including those that were present at the initial visit. If a symptom worsened, this should be captured. Position the symptom to represent the time of onset of the symptom, and use arrows to demonstrate how long they were ongoing for. Indicate if ongoing at time of follow up visit.

1.2 Additional Notes

- Pan = Panadol
- MV = Multivitamin Tablet

### Diary Check

- Field worker: Have you recorded, for the whole follow-up period?
  - For Drugs
    - Drugs and herbs used?
    - The doses used (where known)?
    - When the doses were taken?
  - For Symptoms
    - Described all symptoms reported by the patient?
    - When each symptom started?
    - When each symptom stopped? (or indicate if ongoing)

Use this checklist to ensure all available data is captured (2)

Use additional comments section to details of drug strengths, key for abbreviations used or any other details that do not fit into the diary section (1.2)
All drugs and herbs detailed in the diary should be listed in section 3.1.

| 1. | SHARTIM | CLINIC | YES | NO | YES |
| 2. | PAM ADOO | CLINIC | YES | NO | YES |
| 3. | MULTIVITAMIN | CLINIC | YES | NO | YES |
| 4. | | | | | |
| 5. | | | | | |
| 6. | | | | | |

There should be procedures in place detailing the action that should be taken if the patient has been admitted to hospital or has passed away (5)

Use this section for any additional information not included above (7)

Form E – Passive (Spontaneous) Data Collection

PASSIVE ADVERSE EVENT REPORT FORM – PART B2

3. Using the information you have recorded in the diary, fill in the first column, and complete the table by asking the caregiver

<table>
<thead>
<tr>
<th>3. 1 Name of each drug and herb used</th>
<th>3.1.1 Where did you get this drug or herb from?</th>
<th>3.1.2 Have you used this drug or herb before? (Yes/No/ Patient unsure)</th>
<th>3.1.3 Have you had problems with this drug or herb before? (Yes/No); If Y, please describe</th>
<th>3.1.4 Would you use this drug or herb again? (Yes/No); If no, why not?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. SHARTIM</td>
<td>CLINIC</td>
<td>YES</td>
<td>NO</td>
<td>YES</td>
</tr>
<tr>
<td>2. PAM ADOO</td>
<td>CLINIC</td>
<td>YES</td>
<td>NO</td>
<td>YES</td>
</tr>
<tr>
<td>3. MULTIVITAMIN</td>
<td>CLINIC</td>
<td>YES</td>
<td>NO</td>
<td>YES</td>
</tr>
<tr>
<td>4.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. Ask the patient about how they are feeling now: (current status)?

- Recovered fully □; Getting better □ (please describe) □
- Problem remains □ (please describe) □
- Death □ (if death report to senior investigator) □

5. Were you admitted to a health facility during the follow up period? (period since being prescribed [Suspect Drug]) □ Yes □ No □
If Y, Where ____________

If YES Contact Senior investigator for follow-up

6. Field Worker Action
- None □ Referred □
If referred – Give details ____________________________

If Referred Contact Senior investigator for follow-up

7. Field worker comments, further information

### Form E – Passive (Spontaneous) Data Collection

#### Part C - this section is for completion by the safety officer (or appropriately trained member of staff)

**PASSIVE ADVERSE EVENT REPORT FORM PART C**

<table>
<thead>
<tr>
<th>1.1 Reporter ID</th>
<th>1.2 Reporter Contact</th>
<th>1.3 Report Number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0777 634 521</td>
<td>001/C</td>
</tr>
</tbody>
</table>

#### 2. ALL MEDICINES AND HERBS TAKEN AT ANY TIME DURING FOLLOW-UP PERIOD

<table>
<thead>
<tr>
<th>2.1 NAME OF DRUG OR HERB</th>
<th>2.1.1 DOSE (e.g. 2 tablets; one capsule; 20mg; 1g; 5ml; 10ml)</th>
<th>2.1.2 FREQUENCY (e.g. once only, one daily, twice daily, when required)</th>
<th>2.1.3 DATE STARTED (DD/MM/YYYY)</th>
<th>2.1.4 DATE STOPPED (DD/MM/YYYY)</th>
<th>2.1.5 COMMENTS (e.g. missed doses, did not complete prescribed course)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. CO-PROCOL</td>
<td>4 TABS</td>
<td>TWICE DAILY</td>
<td>01/01/2014</td>
<td>03/01/2014</td>
<td>√</td>
</tr>
<tr>
<td>2. PAPA DO C</td>
<td>2 TABS</td>
<td>FOUR TIMES DAILY</td>
<td>01/01/2014</td>
<td>02/01/2014</td>
<td>√</td>
</tr>
<tr>
<td>3. MULTIVITAMIN</td>
<td>2 TABS</td>
<td>DAILY</td>
<td>01/01/2014</td>
<td>02/01/2014</td>
<td>√</td>
</tr>
<tr>
<td>4.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### 3. DESCRIBE NEW SYMPTOMS OR WORSENING SYMPTOMS OCCURRING DURING FOLLOW-UP PERIOD

<table>
<thead>
<tr>
<th>3.1 DESCRIPTION OF NEW OR WORSENING SYMPTOM</th>
<th>3.1.1 DATE SYMPTOM STARTED (DD/MM/YYYY)</th>
<th>3.1.2 DATE SYMPTOM STOPPED (DD/MM/YYYY)</th>
<th>3.1.3 OUTCOME (A-D):</th>
<th>3.1.4 SERIOUS? **</th>
</tr>
</thead>
<tbody>
<tr>
<td>VOMITING</td>
<td>02/01/2014</td>
<td>03/01/2014</td>
<td>B</td>
<td>N</td>
</tr>
<tr>
<td>2.</td>
<td>...........................................</td>
<td>...........................................</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>...........................................</td>
<td>...........................................</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

*All drugs from the diary and question 3 should be entered here (2.1)*

*In the example above, vomiting is the only worsening symptom (i.e. got worse after drugs were taken)*
References


Appendix 1 – Example diaries and identification of a new or worsening symptom (Adverse Event)

Example 1

The fever and vomiting were present before the study drug was commenced and hence are not new symptoms. The headache, on the other hand, commenced after the study drug was taken and therefore is a new symptom — AE.

Example 2

All symptoms in this case were present before the study drug was taken, and there is no indication that any of them worsened. Therefore, there were no new or worsening symptoms and data collection can stop at this point — NO AE.
Example 3

All symptoms were present before the study drug was commenced. However, the vomiting appears to have worsened – they were reported to have vomited once on day 1, but 4 times in day 2. This has occurred after the study drug was commenced. Therefore, there is a worsening symptom ➤ AE.