COLLECTION OF COST DATA

1. PURPOSE

This document describes the process by which DeWorm3 study staff collect and compile financial cost data. The primary objective of collecting cost data is to systematically identify, measure, and value resources required for implementation of biannual community-wide mass drug administration (MDA) for soil transmitted helminths (STH) and targeted MDA for STH (the standard of care) as deployed in the DeWorm3 trial sites.

2. INTENDED USER

The intended users of this SOP are the implementation science (IS) point person, trial coordinator, study staff maintaining financial records and the costing point persons compiling costs at each site into the costing tool.

3. RESPONSIBILITIES

All DeWorm3 study staff responsible for collection of cost data should understand and follow this SOP. It is the responsibility of the site's Principal Investigator (PI) to ensure that all study staff comply with this SOP.

It is the responsibility of the site PI to ensure that the Economic Support Unit (ESU) and the site designated costing point person have full access to the trial's financial reporting data. It is also the responsibility of the site PI to liaise with the Ministry of Health (MoH) and/or Education (MoE) and partners, depending on the implementing agency coordinating the country standard of care, to enable DeWorm3 access to relevant financial records and reports. It is the responsibility of the study team to ensure that resources used are recorded and appropriately maintained in a manner compatible with the costing tool. It is the responsibility of the costing point person to fully compile and complete the cost data collection instruments within agreed upon timelines. It is the responsibility of the ESU to train, guide, and assist the costing point person at sites in collecting cost data throughout implementation of the trial.

4. DEFINITIONS

4.1 **Intervention arm:** The group of clusters (n=20 per site) and corresponding population who will receive bi-annual community-wide MDA for three years across the DeWorm3 trial.

4.2 **Control arm:** The group of clusters (n=20 per site) and corresponding population who will receive targeted MDA of pre-school-age children (pre-SAC) and SAC in accordance with national Ministry of Health guidelines for three years across the DeWorm3 trial.

4.3 **Activity:** Throughout the DeWorm3 trial a variety of activities will be implemented to plan for, deliver, and evaluate STH MDA. Activities evaluated under this SOP are detailed in Table 1

4.4 **Sub-activity:** Each activity in turn is divided into sub-activities that represent specific steps or functions necessary to implement the activity. For example "Pre-MDA community sensitization" is a sub-activity within the "MDA" activity.

4.5 **Activities to be costed**: The DeWorm3 collection of cost data covers activities related to planning, implementation and monitoring and evaluating STH MDA in the trial's intervention and control arms (Table1); it excludes costs related to IS activities that would not be implemented by an STH program outside of a clinical trial setting.

4.6 **Running costs**: Resources essential to setting up and running day-to-day operations of the trial. These inputs are employed in a range of trial activities, are retained for the duration of the trial, and, often, represent a one-time investment (i.e. start-up, capital).

4.7 **Activity costs:** Resources essential to implementation of specific activities. These resources are acquired for implementation of a specific activity, are used-up once the activity is concluded, and often represent recurrent purchases (i.e. commodities, diagnostics, CDDs).

4.8 **Cost line item:** Specific resource (micro-input) used to implement activities (i.e. Albendazole, site PI, motorcycle, etc.).

Table 1 List of DeWorm3 activities to be costed

#	Activity	Implementation year (Y)	Implemented by	
			Intervention	Control
1	Pre-trial Sensitization	Y1	DeWorm3	DeWorm3
2	Baseline Census	Y1	DeWorm3 or partner	DeWorm3 or partner
3	Baseline School Facility Survey	Y1	DeWorm3	DeWorm3
4	Cross-Sectional Survey 1 + Longitudinal Monitoring Survey 1	Y1	DeWorm3	DeWorm3
5	Community-wide MDA in intervention arm	Y1-3	DeWorm3	NA
6	Coverage survey in intervention arm	Y1-3	DeWorm3	NA
7	School-age-targeted MDA in intervention and control arms	Y1-3	DeWorm3	MoH and/or DeWorm3
8	Coverage survey in intervention and control arms	Y1-3	DeWorm3	DeWorm3
9	School Facility Survey update	Y2-5	DeWorm3	DeWorm3
10	Census update	Y2-5	DeWorm3	DeWorm3
11	Cross-sectional survey 2 + Longitudinal monitoring survey 4 (6 months following the final round of MDA)	Y4	DeWorm3	DeWorm3
12	Cross-sectional survey 3 + Longitudinal monitoring survey 5 (24 months following the final round of MDA)	Y5	DeWorm3	DeWorm3
13	Annual review meetings	Y1-5	DeWorm3	DeWorm3

MoH= Ministry of Health; NA= Not Applicable

5. REQUIRED MATERIALS

5.1 DeWorm3 Costing Tool.
5.2 DeWorm3 Costing Tool User Guide.
5.3 DeWorm3 STH control program questionnaire.

6. PROCEDURE

6.1. Preparation for collection of cost data

a. The site PI should sign a Project Agreement or similar with the local authorities and partnering agencies that deliver STH control interventions in the country to ensure that cost data relevant to the standard of care are accessible to DeWorm3. These agreements should outline the data points needed from the control program, the dates

the data are needed by, and the agreed upon contact person with whom the DeWorm3 team can follow-up with in order to access the data.

b. A cost costing point person should be designated before any of the trial activities are started; ideally in the planning stages of the trial.

c. The site PI, trial coordinator, and costing point person should set a date for the ESU site visit. This visit should to take place prior to the baseline census.

d. The costing point person and other individuals responsible for maintaining costs should start preparing for the costing activities prior to the ESU in-country visit

    i. All study staff involved in activity costing such as the costing point person should read the DeWorm3 Study Protocol and SOPs for the activities to be costed (Table1)

    ii. The cost collection point person should familiarize him/herself with the DeWorm3 costing tool and study the accompanying user guide.

e. The ESU will visit the country on the dates agreed upon with the country team.

f. If desired by the site, the ESU staff will provide further sensitization to country partners (i.e. MoH or MoE) on the aims of economic evaluation along the DeWorm3 trial and use of country data to estimate cost of the standard of care delivered in the DeWorm3 control clusters.

g. The ESU staff will train the costing point person and other study staff involved in activity costing on the methods for costing of health interventions, and use of the Costing Tool.

h. The ESU staff and the costing point person will initiate the collection and compilation of cost data by evaluating the site's running costs (first round of cost data collection).

6.2. Overview of collection and maintenance of cost data

a. Collection and maintenance of cost data will be ongoing throughout the duration of the trial (five years, including three years of MDA and two years of surveillance).

b. The STH MDA-related activities (Table 1) evaluated in the DeWorm3 trial are implemented by the DeWorm3 project and country STH control program (i.e. MoH and/or MoE). A different strategy for collection of cost data will be pursued depending on the implementing agency.

6.3. Collection of cost data from DeWorm3 project

a. Collection of cost data from DeWorm3 project will be conducted with the DeWorm3 Costing Tool (referred to as the Tool thereafter). The Tool is pre-filled by the ESU with core inputs; it explicitly identifies resource attributes on which data should be collected. Guidance on filling out the Tool including explanation of entry fields are detailed in the User Guide.

b. The first round of cost data collection will be conducted during the ESU site visit; during this round *Running costs* will be assessed.

c. All subsequent data collection rounds will assess *Activity costs* and will be initiated upon completion of an activity of interest completed when sites initiate any of the activities listed in Table 1.

d. The following steps should be followed during each round of cost data collection:

    i. Each round of data collection should start with the costing point person identifying the key staff responsible for the implementation of the trial activity being costed.

ii. Together with the key staff identified above, the costing point person should validate and update the corresponding pre-filled activities, sub-activities, and line items in the costing tool. Line items could be added or removed to ensure that the scope of the operational resources used by the trial is adequately captured by the Tool.

iii. Together with the key staff identified above, the costing point person should identify and assemble relevant financial reports (i.e. expense reports, invoices, receipts, etc.) and other data sources to populate respective entries in the Tool. The user guide suggests sources of data that might be helpful in populating respective Tool entries.

iv. For each activity line item, the costing point person should enter information on the quantity, price, and resource attributes, as outlined in the Tool. Where these data cannot be extracted directly from receipts, payroll logs or other routine financial reporting sources the costing point person should consult the User Guide on how to obtain an estimate of requested quantity(ies).

v. For each activity line item entry in the Tool the costing point person should indicate sources of data (i.e. receipt, log book, etc.).

vi. The costing point person should evaluate Tool entries for consistency using check lists in the user guide.

vii. The costing point person should review the data entered with the key staff responsible for the activity costed and staff that contributed data to the respective sections of the Tool to ensure that these inputs were entered accurately into the Tool.

6.4. Collection of cost data from sources external to the DeWorm3 trial (i.e. MoH, MoE, etc.)

a. Collection of cost data on country standard-of-care STH MDA will be conducted at the end of the MDA implementation by the national program. The costing point person is to follow-up with the program following completion of MDA in the DeWorm3 control clusters to agree on an appropriate timeline for collection of cost data. Cost data will be collected at the lowest administrative level available (i.e. village or district congruent with DeWorm3 control clusters).

b. Steps in the collection of cost data from the STH control program are outlined below:

i. The costing point person should meet with country STH control program staff to fill-out the STH control program questionnaire; the questionnaire collects information regarding the standard of care (school-age targeted MDA for STH) and information specific to implementation of the campaign in the DeWorm3 control clusters.

ii. For each line item entry in the STH control program questionnaire the costing point person should document sources of data.

iii. The costing point person should review the final STH control programme questionnaire with STH programme staff to ensure that the final entries accurately reflect data provided by the implementing partners.

iv. At the same time or during a follow-up meeting, the costing point person should secure financial reporting documents from the country STH control program related to the standard of care (school-age targeted MDA for STH). The specific financial documents required will have been outlined in the Agreement (see 6.1.)

6.5. Quality assurance and quality control

a. Upon completion the cost collection person should submit the Tool, STH program questionnaire and any financial documents obtained from the program for DeWorm3 internal review (Figure 2).

b. Following each round of cost data collection, the costing point person should submit to the site PI the completed cost data collection instruments for review.

c. The costing point person should revise the instruments based on feedback from the site PI.

d. Following the internal review, the costing point person should submit the completed Tool to the ESU (Figure 2). In the first year of the trial the completed Tool should be submitted to the ESU no later than *3 weeks following completion of the trial activity* costed. Thereafter, the Tool is submitted for review with the ESU every six months.

e. The ESU will review the data collected.

f. The costing point person should revise entries in the Tool based on feedback from the ESU.

g. Following the internal review, the costing point person should submit the completed STH control program questionnaire and program financial reporting documents to the ESU. These documents should be submitted to the ESU no later *than 3 weeks following the meeting with the STH program* where these were sourced.

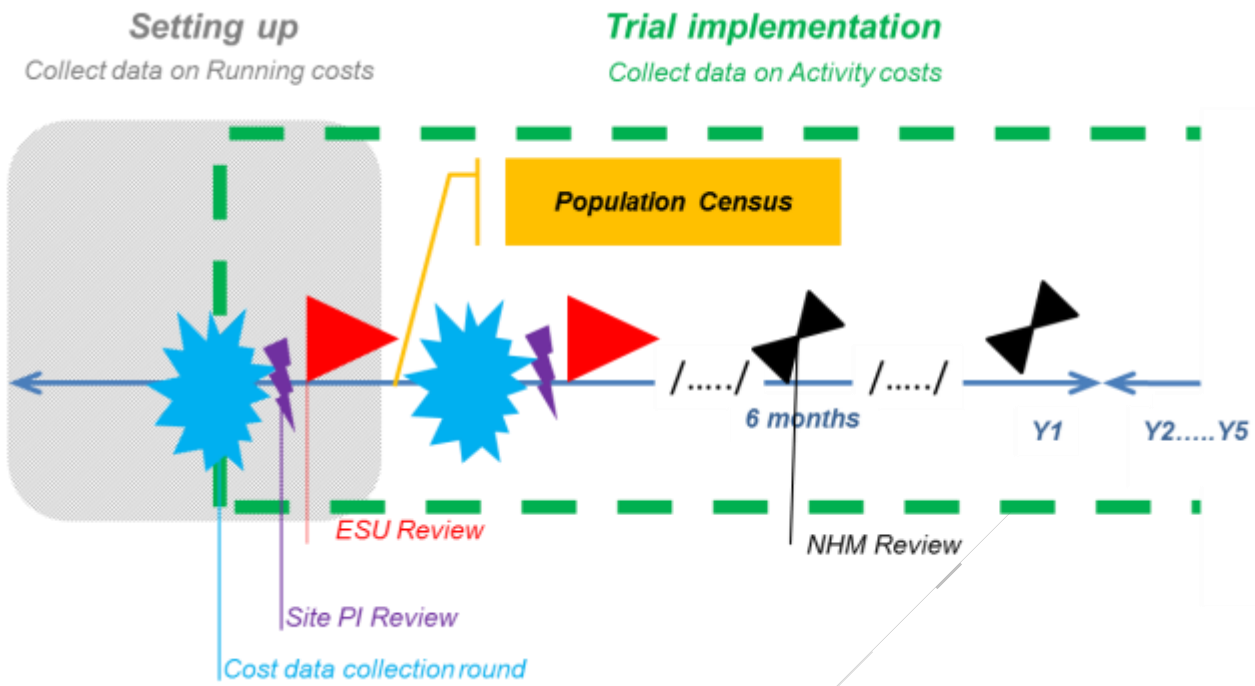
h. The ESU will review these documents and extract data necessary for estimating cost of STH MDA implementation in the control arm of the trial.

i. On request from the ESU the costing point person should follow-up with the national program to clarify questions related to the data shared by the program.

6.6. Submission of deliverables

a. *Every six months* the costing point person should submit the completed Tool, STH program questionnaire (if completed), and financial reports from the STH program (if collected) to the DeWorm3 central office at the Natural History Museum.

Figure 2 Timeline for cost collection and review of costing tool against stages of trial implementation and routine financial reporting



6.7. Changes to SOP and costing tool

a. Following the in-country site visit, the ESU may update this SOP or the costing tool in order to optimize and better tailor collection of cost data to sites.

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Approvals

I have reviewed and approve this SOP for implementation.

Principal Investigator	**Signature**	**Date**
Site Principal Investigator	**Signature**	**Date**

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SITE NAME

Read and Review Log

List of individuals who read and reviewed the SOP

Date	Name	Title	Signature*

*By signing this log, study staff confirm that they have read and understood the content of the SOP