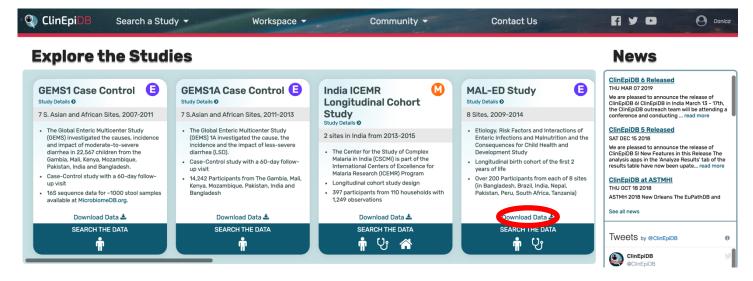
Reviewing MAL-ED study details on the "Data Set page"

This exercise will introduce you to the "Data Set page", where you can find study procedures, methodologies, Case Report Forms (the forms used for data collection), data dictionaries, key study personnel, associated publications, and other information associated with each study. It is always a good idea to explore the information of the Data Set page before you start exploring the data to make sure you understand the study design.

Reviewing study details on the Data Set page

1. Under the "Explore the Studies" section on the homepage, there are separate "Cards" that contain general information (study design, dates, sites, outcomes of interest, and numbers of participants) about each study. Cards that are greyed out indicate studies we are currently working to load onto the site; data from these studies will be available in the near future. You can scroll through to view all of the study cards. How many sites have data loaded onto ClinEpiDB from the MAL-ED study¹?

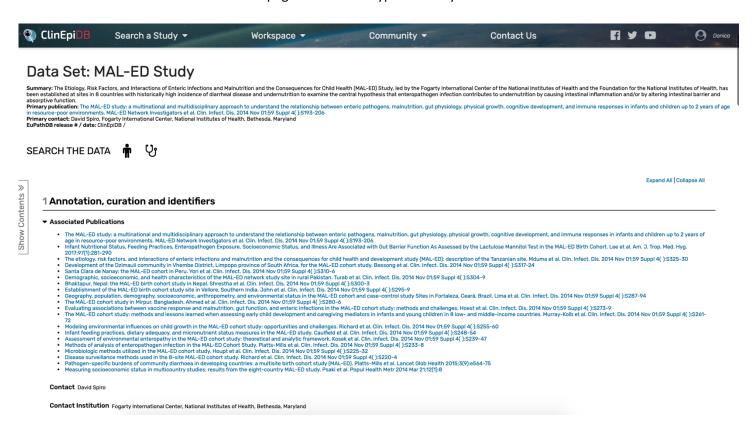


2. Click on "Study Details" on the MAL-ED card to open the MAL-ED Data Set page. The MAL-ED Data Set page is where will find more information about the study description, design, associated publications, investigators, and contact information for the MAL-ED study.



¹ MAL-ED data from 8 sites (Bangladesh, Brazil, India, Nepal, Pakistan, Peru, South Africa, and Tanzania) are available on ClinEpiDB.

3. Scroll down the MAL-ED Data Set page to see what types of study details are available.



- 4. See if you can use the information on the MAL-ED Data Set page to answer the following questions:
 - Question 1: At what ages were participants enrolled in the MAL-ED study?
 - Question 2: At what ages were blood samples collected from study participants?
 - Question 3: Where can you find the Case Report Forms used in the MAL-ED study?

Answers:

• Question 1: Participants were enrolled within the first 17 days of life.

Methodology, Study Design Details: In contrast to cross-sectional and case-control studies, the MAL-ED study was designed as a observational study that used a prospective longitudinal design to directly address a complex system of exposures and health outcomes in children born and living in eight culturally and geographically diverse resource-constrained communities in low and middle income countries. Children were enrolled within the first 17 days of life and were visited twice weekly through to 24 months of age to collect data as represented in the figure below. Each site recruited more than 200 children over a 24-month time period – targeting a smooth and constant monthly enrolment across this time frame – to assess seasonal effects of exposures. Details of the study design and descriptions of data and sample collection have been published (Clinical Infectious Diseases, vol. 59, suppl. #4, November, 2014).

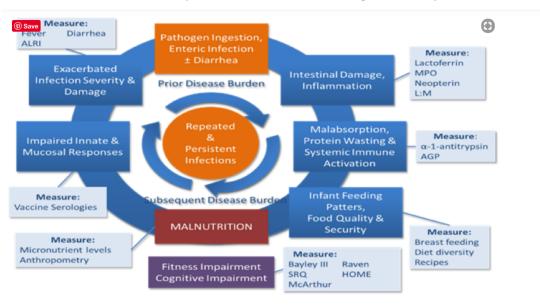
Subjects were enrolled after signed informed consent was obtained according to appropriate procedures agreed to for this project. All sites used a common standardized protocol that was developed and agreed to by study investigators, and was reviewed and approved by national, local and organizational review boards, as appropriate and required, for each collaborating institution.

The aim of the MAL-ED study is to improve scientific understanding of the complex interrelationships among enteropathogen infection, dietary intake, nutritional status, gut physiology, growth, immune function and vaccine response, and cognitive development. The timing of data and sample collection and the assessments determined are shown here.

• Question 2: Blood was collected from study participants at 7, 15, and 24 months of age.



• **Question 3:** Scroll down to the "Case Report Forms and Data Dictionaries" section. There, you can find a link to download the "Case report form codebook". The original case report forms are contained in this download file.



Developing appropriate interventions designed to break this "vicious cycle of poverty" is a long term goal. It is anticipated that knowledge derived from MAL-ED will help the public health community to better engineer prevention strategies and interventions that are envisioned to minimize those factors that contribute to lost lifetime potential.

Publications from the project can be found by clicking here: PubMed Search for MAL-ED

case Report Forms and Data Dictionaries

<u>Case report form codebook</u> - The ordebook for each case report form is included as a separate sheet
Analytic dataset codebook
Analytic dataset is included as a separate sheet