

# Effectiveness of MDF

Area/Type: Medical R&D; Very large-scale

Sponsor/Support: WACA/OCP and OCG

Length/Project Status: 33 months; **ONGOING**



TRANSFORMATIONAL  
INVESTMENT  
CAPACITY

## Project Summary

### Problem

The current standard ready-to-use therapeutic food (RUTF) formulation may be insufficient to restore physiological and immunological resilience and may contribute to the risk of relapse. Management of severe acute malnutrition (SAM) needs new RUTF formulations to address the high risk of relapse.

### Proposed Solution

**Evaluate a new microbiome-directed food (MDF)** that aims to improve the gut microbiome and improve programmatic outcomes, including relapse, in children with uncomplicated SAM. The new milk-free product could also, in addition to the expected clinical benefits, offer an alternative to standard RUTF that can be produced with local ingredients. The randomized controlled trial **will enrol 3,678 children** aged 6 to <24 months with uncomplicated severe acute malnutrition at 4 outpatient treatment centres in Niger.



### Potential Impact

- Generates comprehensive **evidence on the clinical effectiveness** of MDF.
- Aims to **reduce child morbidity and mortality related to SAM** and improve long-term health and developmental outcomes for children in Niger and other countries with similar contexts.

### Viability

- Builds on the **learnings of a randomized acceptability trial** conducted among 128 children with acute malnutrition in Niger.
- Capitalizes on **extensive groundwork already in place**.

### Risk Mitigation

- **Applies a staged approach:** Results from an initial phase enrolling 400 of the 3,678 children will be analysed in terms of safety and efficacy before proceeding to the full trial.

### Scalability

- Aims to use study results to **inform changes to global policy and MSF protocols** that allow for adoption of an alternative RUTF formulation.
- Clarifies post-TIC ambitions including **strategic engagements for scale-up and access strategies**.