

# The HRB-TMRN summer scholarships

## **Abstract Template**

### **Project title**

Micro-simulation based approach to power and sample size calculations for nutrient trials

### Institution

Trinity College Dublin

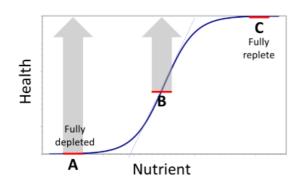
### Project details (max 250 words)

The sigmoid-shaped dose-response curve relates the health to nutrient status (Figure 1). The health benefit following supplementation depends on the individual's starting point, and the accomplished improvement in status. Standard approaches for sample size calculation in randomised controlled trials (RCTs) are insufficiently granular when significant variability exists in the population, as is often the case for nutrients due to the differences in lifestyle, diet, body size and composition, health and other. Moreover, they cannot account for a prominent intra-individual variability; e.g. there is a cyclical seasonal pattern in vitamin D status.

This project will contribute to the development of a statistical software for the R computing language. The package uses a microsimulation-based approach to estimate power and sample size for nutrient RCTs, by modelling individual nutritional trajectories and thereby allowing for significant inter-individual variation. This tool can aid in experimental design; its virtue comes by closely mimicking the complex biological processes that occur in nutrient trials. A bespoke power computation scheme is proposed, with simulation models for each part of the biological dose-effect mechanism and incorporating both the inter-individual and intra-individual variability. The functionality will be developed that enables users to explore the effects of common parameters (e.g. RR, mean nutrient status or variation in the population) on trial outcomes (power and sample size) and to visualise them with an array of graphical commands.

This interdisciplinary project between research teams in epidemiology and statistics will provide the student with exposure to clinical, statistical and computational elements of health research.

**Figure 1.** The sigmoid curve describing the relationship between health and nutrient status that is representative for most nutrients within physiological ranges. The maximum health benefit that can be achieved depends on participant's starting point.



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