



Health Research Board  
**TMRN**  
Trials Methodology Research Network

## Project title:

**Mixed-Effects Pattern-Mixture Models for the Missing Data in the NILVAD Study**

## Institution:

**University of Limerick (UL)**

## Project details:

NILVAD study (A European multicentre double-blinded placebo-controlled phase III trial of *nilvadipine* in mild to moderate Alzheimer's disease) started on January 1, 2012. NILVAD aims to test the efficacy and safety of nilvadipine in more than 500 subjects with mild to moderate AD over a treatment period of 18 months. Male and female patients with mild to moderate AD aged between 50 and 90 with a range of medical morbidities and frailty will be included in the study. If this trial is successful, nilvadipine would represent an advance in the treatment of AD patients and would have a major impact on the health and social care costs incurred in Europe by this neurodegenerative disorder.

Missing data are a common occurrence in longitudinal studies and can have a significant effect on the conclusions that can be drawn from the data. Mixed effects models are frequently chosen for the primary analysis of clinical trial studies; however, such models require data missing at random. Pattern mixture models are methods for handling non-ignorable missing data.

The aim of this project is to apply pattern mixture methods in order to handle missing values of the NILVAD study.

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