# P8157 - Analysis of Longitudinal Data, Fall 2019
# Homework - 3
# **Due : November 26, 2012**

November 13, 2019

In the previous HWs we had part A and part B for the analytical and computational part. Now that you know how to set up the analysis and perform an analysis we combine the two parts. Below you will find two questions. In your solutions you will clearly set up the model, state the assumptions and any calculations to explain your answers. Simultaneously you will analyze the associated data.

## Question - 1

In a randomized, double-blind, parallel-group, multicenter study comparing two oral treatments (denoted A and B) for toe-nail infection (De Backer etal., 1998; also see Lesaffre and Spiessons, 2001), patients were evaluated for the degree of onycholysis (the degree of separation of the nail plate from the nail-bed) at baseline (week 0) and at weeks 4, 8, 12, 24, 36, and 48 thereafter. The onycholysis outcome variable is binary (none or mild versus moderate or severe). The binary outcome was evaluated on 294 patients comprising a total of 1908 measurements. The main objective of the analyses is to compare the effects of oral treatments A and B on changes in the probability of the binary onycholysis outcome over the duration of the study. The raw data are stored in an external file: toenail.dat Each row of the data set contains the following five variables: ID,Y,Treatment,Month,Visit. The binary onycholysis outcome variable Y is coded 0 = none or mild, 1 = moderate or severe. The categorical variable Treatment is coded 1=oral treatment A, 0=oral treatment B. The variable Month denotes the exact timing of measurements in months. The variable Visit denotes the visit number (visit numbers 1-7 correspond to scheduled visits at 0, 4, 8, 12, 24, 36, and 48 weeks).

1. Consider a random effects model with a random intercept for the log odds of moderate or severe onycholysis. Assuming linear trends and month as the time variable.

2. Provide Interpretations for the fixed effects coefficients in your model. Interpret the random effect parameter.

3. From the results of your analysis what conclusions do you draw about the effect of treatment on changes in the severity of onycholysis over time? Provide results that support your conclusions.

4. How are the interpretations different from the GEE model.

# Question - 2

The Skin Cancer Prevention Study was a randomized, double-blind, placebo-controlled clinical trial of beta carotene to prevent non-melanoma skin cancer in high-risk subjects (Greenberg et al., 1989, 1990; also see Stukel, 1993). A total of 1805 subjects were randomized to either placebo or 50 mg of beta carotene per day for 5 years. Subjects were examined once a year and biopsied if a cancer was suspected to determine the number of new skin cancers occurring since the last exam. The outcome variable is a count of the number of new skin cancers per year. The outcome was evaluated on 1683 subjects comprising a total of 7081 measurements. The main objective of the analyses is to compare the effects of beta carotene on skin cancer rates. The raw data are stored in an external file: skin.dat Each row of the data set contains the following 9 variables: ID,Center, Age, Skin, Gender, Exposure, Y, Treatment and Year.

Note: The outcome variable Y is a count of the of the number of new skin cancers per year. The categorical variable Treatment is coded 1=beta carotene, 0 =placebo. The variable Year denotes the year of follow-up. The categorical variable Gender is coded 1 male, 0 female. The categorical variable Skin denotes skin type and is coded 1 = burns, 0 otherwise. The variable Exposure is a count of the number of previous skin cancers. The variable Age is the age (in years) of each subject at randomization.

1. Set up a suitable random effects (random intercept) model for rate of skin cancers with Treatment and Year as covariates.

2. Provide Interpretations for the fixed effects coefficients in your model. Interpret the random effect parameter.

3. From the results of your analysis what conclusions do you draw about the effect of beta carotene on the rate of skin cancers? Provide results that support your conclusions.

4. Repeat the above analysis adjusting for skin type, age, and the count of the number of previous skin cancers. What conclusions do you draw about the effect of beta carotene on the adjusted rate of skin cancers?

5. How are the interpretations different from the GEE model.