

### **Project 3**

Read and present the clinical trial of Fluge et al (2015). Describe and re-analyze the data (see Table 1 of Fluge et al for the definition of the variables) focusing on the primary outcome. Construct an appropriate statistical model where you can determine which the factors are significantly affecting the primary outcome. Quantify the proportion of individual who complied with the treatment protocol exactly. Quantify the proportion of adverse events (see subsection “Adverse Events” within the “Results” section). What is the statistical uncertainty associated with these two proportions? Given all the results, what are your (statistical) recommendations for conducting a phase III trial?

### **Reference:**

Fluge Ø, Risa K, Lunde S, et al. B-Lymphocyte Depletion in Myalgic Encephalopathy/ Chronic Fatigue Syndrome. An Open-Label Phase II Study with Rituximab Maintenance Treatment. PLoS One. 2015;10(7):e0129898. Published 2015 Jul 1. doi:10.1371/journal.pone.0129898