Project 3:

Read and present the clinical trial of Fluge et al (2019). Re-analyze the data focusing on the primary outcome (variable "Response"), using the intention-to-treat analysis and <u>focusing patients with a disease onset triggered by an infection</u>. The treatment groups under comparison are placebo and rituximab (values 0 and 1 of variable "treatment_group", respectively). Construct an appropriate statistical model for the primary outcome using the following covariates:

- "Age" – in years;
- "Sex" - 1 (female) and 2 (male).
- "Infection_trigger" – whether disease started with an infection (0 – no, 1 – yes, NA - unknown);
- "Disease_duration" - disease duration in years with the following categories: 1 – 2-5 years, 2 – 6-9, 3 – >10;
- "Body mass index" – you should create this variable from variables "height" (in cm) and "weight" (in kg);
- "Center" - Treatment center (it should be considered as a factor, not as numeric).

Quantify the proportion of individuals who complied with the treatment protocol exactly in each treatment group (see the corresponding data on Figure 1). Quantify the statistical uncertainty associated with this proportion in each treatment group. Compare that proportion between the two treatment groups using a statistical test. Draw your conclusions.

Reference:

Fluge Ø, Rekeland IG, Lien K, et al. B-Lymphocyte Depletion in Patients With Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: A Randomized, Double-Blind, Placebo-Controlled Trial. Ann Intern Med. 2019;170(9):585-593. doi:10.7326/M18-1451