## Computer projects:

Each student or group of students defines a research question. Lab sessions will primarily be used for discussions about the projects, in order to stimulate reflection on issues related to clinical trial design, conduct and interpretation. However, work might need to be carried out between the laboratory sessions.

If you have your own project (can be non-clinical trial related), that is fine. If not you can choose the Type 2 diabetes problem. You will need to perform the following tasks:

1. Design a study,
2. Write a protocol (cf. below)
3. Obtain the data
4. Analyze the data,
5. Draw conclusions
6. Report the work

The study protocol: After the objectives and design of a clinical study have been determined, these issues should be documented in the Study Protocol. The Study Protocol is a document containing instructions for all the parties involved in the clinical trial. You can use the simplified template provided. Suggestions of sections that might be included in the Study Protocol can be found below. You can find information in e.g. clinicaltrials.gov. Performing the study can mean many things e.g. simulating some data or simulating the end result directly.

- Introduction (brief description of the problem and treatment regimen(s))
- Objectives and purposes of the study
- Study duration
- Statistical considerations
- Number of subjects based on a sample size calculation
- Subject selection criteria:
    - Inclusion criteria
    - Exclusion criteria
- Methodology:
    - Study Plan
    - Study schedule
    - Study Visits
    - Study Assessments / Procedures
    - Definition of efficacy endpoints
    - Treatment cycles
- Safety Reporting
    - Adverse events (AEs)
    - Serious adverse events (SAEs)
    - Abnormal laboratory test values
    - Abnormal values of other safety parameters
    - Withdrawal from the Study
- Clinical laboratory parameters
- Other safety parameters
- Concomitant medications