Interim report at 18 months for projects within clinical research

Project Reg. No VR:

Project title:

Name of main applicant

Date and registration number of ethics approval:
If ethics approval is lacking, reason/planning:

Date of registration and number in clinicaltrials.gov or corresponding:
If the study is not registered, why is this?

Number of study patients stated in full application based on power calculation:
Number of patients based on any revised power calculation:

Date of first patient included in study according to full project plan:
Date of last patient included in study according to full project plan:
Date of last patient concluded in study according to full project plan:

Total number of patients screened at 18 months:
Total number of patients included at 18 months:
Current date of first patient included in study:
Current planned date of last patient included in study:
Current planned date of last patient concluded in study:
Planned follow-up period (primary study endpoint):

Does the project follow the time plan? If NO, please state reason(s) below:

Regulatory issues?
Cause?
What measures are planned?

Difficulty recruiting personnel to the study?
Cause?
What measures are planned?

Problem with patient recruitment?
Cause?

What measures are planned?

Methodology problem or equipment problem, etc?
Cause?
What measures are planned?

Other reasons for delay?
State which
What measures are planned?

Does the project comply with the number of national/international collaboration partners in the project plan?
If NO, please state reason
What measures are planned?

Does the project company with the financial plan?
If NO, please explain and state reason

What measures are planned for adapting the study to the budget, or the budget to the study?

Other current information of importance for the implementation of the project:

Date & signature of main applicant