



NAFTNet Study Concept Proposal Outline

Title of Study:

Primary investigator (s):

Date:

Overall study hypotheses:

Objectives:

Primary objective:

Secondary objectives:

Exploratory objectives:

Study Endpoints:

Primary Endpoint:

Secondary Endpoints:

Other Endpoints:

Background and significance of problem to be studied:

Study design

- **Study population**

Inclusion criteria

Exclusion criteria

Study methods

Sample size calculation

Plans for long-term follow-up (methods and length of follow-up)

Budget

References

- 1.
- 2.
- 3.