#### **StatisticALS**

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### Introduction

As a statistician with more than 20 years of experience in applied statistics, I founded StatisticALS in 2022 to work as an independent statistical consultant. I thrive on variety in my work and solving challenging problems so my aim is to have a mixture of assignments in terms of both content and duration.

# **Summary**

- 20+ years working with applied statistics
- Nine years of employment in **biostatistics** and **epidemiology** within the pharmaceutical industry (Novo Nordisk, Leo Pharma)
- Assessment of new drug applications at the Danish Medicines Agency
- Statistical consultant (Ferring, ALK, Lundbeck, and others) since 2018

## Selected Experience

#### I have worked with

- All phases of pharmaceutical clinical development including late phase observational trials and trials based on real world data/registry data.
  - Study design, sample size calculations, estimands
  - o Protocol input, statistical analysis plan, planned and post-hoc analyses
  - o Submissions, Questions and Answers, regulatory meetings
- Small early-stage biotech companies as well as large international pharmaceutical organizations within a variety of different disease areas. I also have experience within the medical device and diagnostic test areas

#### Skills

- Expert in applied statistics in a variety of settings from study planning through publication
- Knowledgeable about clinical development both from the perspective of the company and the regulator
- Extensive experience with observational studies, post approval studies, and registry studies
- Proficient in the programming language SAS