StatisticALS
Statistical Consultancy
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Curriculum Vitae

Summary

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

Permanent employment history

2022-present	StatisticALS, *Statistical Consultant*
2018 – 2022	S-cubed, *Principal Statistical Consultant*
2017 – 2018	Danish Medicines Agency, *Senior Advisor Biostatistics* ● Assessment of new drug applications from initial submission to approval ● Scientific advice to companies
2015 – 2017	Leo Pharma, *Principal Statistician* ● Project statistician for 2 different products ● Involved in a variety of projects mainly within dermatology
2008 – 2015	Novo Nordisk *Principal Statistician* (2014-2015) ● Advisory Committee Meeting for Obesity ● Response to questions from FDA regarding the Obesity submission ● Publications ● Project statistician and responsible for safety summary for a diabetes product *Principal Epidemiologist* (2011-2014) ● Disease epidemiology and general epidemiology/epidemiological methods mainly within haemophilia and growth hormone ● Risk management plans ● Publications ● Mentoring of colleagues ● Supervision of master student in Statistics *Senior Epidemiologist* (2010-2011) ● Observational studies ● Database studies using CPRD *Senior Statistician* (2008-2010) ● Meta analyses ● Phase 3b study within diabetes

	• Phase 1 studies within diabetes
2006 – 2008	Department of Biostatistics, University of Copenhagen, *Assistant professor (post.doc.)* • Several research projects, among others hormonal contraception and the risk of venous thrombosis using Danish Registries • Collaboration with many clinicians from the Juliane Marie Centre, Rigshospitalet • Involved in all stages from study planning to publication
2005 – 2006	Institute of Cancer Epidemiology, Danish Cancer Society, *Statistician* • Several research projects, among others development of the incidence of childhood leukemia over time, and abortions in cancer survivors • Teaching assistant in Statistics for medical students
2004 – 2005	Department of Epidemiology, University of Copenhagen, *Assistant professor (post.doc.)* • Research project on breast cancer and mammography screening • Teaching assistant in Epidemiology for medical students
2002 – 2003	Department of Mathematics, University of Oslo, *Post.doc.* • Research in Mathematics

Consultancy history

Customer	**Tasks**
CSF-Dynamics	Input to protocol and sample size calculations
Danish Medicines Agency	Training and mentoring of their employed statisticians
Qufora	(Two contracts) Reporting of study Input to protocol and sample size calculations
Embla	Planning, conduct and reporting of statistical analyses
Vivostat	Investigate possible scenarios for stopping a study early
NeRRe Therapeutics	Member of the Data Safety Monitoring Board for a study
Lundbeck	Submission, production of all output
UNEEG	Input to protocol Perform sample size calculations based on simulations Review statistical analysis plan
Qlife	Discussions of trial design and input to protocol Sample size calculations and statistical analysis plan
ALK	(Four contracts) Input to synopsis and protocol Sample size calculation and statistical analysis plan Participate in project team, study conduct and reporting Submission Q&A Writing of statistical analysis plan template
BioPorto	Statistical advice regarding establishment and validation of cut-point for a diagnostic test aiming for FDA approval Assessment of cut-point based on available data
Leo Pharma	(Two contracts) Input to and practical implementation of statistical analyses for publications Input to setting up procedures for working with analysis requests and having appropriate QC level at all stages
Ferring	Substitute project statistician Participate in project team, study conduct Perform ad hoc analyses Prepare data for interim analysis Set up central statistical monitoring

MC2	Perform sample size calculation Provide input to protocols (phase 3) Write/provide input to statistical analysis plans Review clinical trial report

Education

1997 – 2002	Ph.D. Mathematics, University of California at Santa Barbara
1994 – 1996	M.S. Mathematics, University of Copenhagen
1991 – 1994	B. S. Mathematics and Chemistry, University of Copenhagen

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