CURRICULUM VITAE

Name:	Dr. Dirk Lehnick
Education:	
OCT 1986 – OCT 1991	*Faculty of Economics, University of Goettingen / Germany* Diploma in Business Administration (Betriebswirtchaftslehre) Gustav Hopf award for best exam of the year Scholarship granted by the Konrad Adenauer Foundation
JUL 1997	*Faculty of Economics, University of Goettingen / Germany* PhD (Thesis in Statistics on Statistical Risk Analysis: Rate Ratios and Odds Ratios in Two- and Moredimensional Contingency Tables): summa cum laude
Professional and Work Experience:	
Since MAY 2017	*University of Lucerne / Switzerland* Head Biostatistics and Methodology CTU-CS (Clinical Trial Unit – Central Switzerland) The Clinical Trial Unit Central Switzerland (CTU-CS) has been initiated as a cooperation of the Swiss Paraplegic Centre (in Nottwil), the Lucerne Cantonal Hospital and the University of Lucerne. The aim is to establish and further develop a common institution in order to support and strengthen the existing clinical research capabilities. Consulting and resources of the CTU-CS will be available for research initiatives driven by present and future network partners as well as for externally sponsored projects.

MAY 2010 – MAR 2017

NUVISAN GmbH, Neu-Ulm / Germany,

Head of Data Science /
Director Biostatistics

Directing and supervising all biostatistical, pharmacokinetic and data-related operations

Managing internal teams in Neu-Ulm (NUVISAN) and Neuss (FOCUS, part of the NUVISAN group until DEC 2012) as well as several external service providers

Project responsibility across all relevant phases (Phase I-IV) and therapeutic areas

Evolving strategies how to develop the departments incl. implementation of state-of-the art processes (eClinical, EDC etc.), services (pharmacometrics, modelling and simulation, health economics etc.) and standards (CDISC, statistical programming, reporting etc.)

Conducting policy training and ensure employees are working in compliance with SOPs and GCP guidelines

Recognizing major departmental successes and failures and resolve accordingly

Evaluating departmental capacity needs on an ongoing basis and coordinate/delegate workload efficiently and in accordance with given timelines

Process control / process improvement (Six Sigma)

Representing department/functional area in Business Development, including reviewing proposals and participating in general capabilities and bid defense meetings

Consulting for clients regarding development programmes, study design (incl. adaptive designs), health authorities

Participation in / contribution to Scientific Advice, Steering Committee, Medical Boards, DSMB meetings

Clients located in Europe, US/Canada, Japan and India

JAN 2010 – APR 2010

STATPROC (self-employed), Hohentengen / Germany

Statistical Processing, Analysis and Consulting

Freelance / Consulting / Interim Management projects

Clients in several European countries

Statistical consulting and teaching

Supervising and performing biostatistical and

data-related activities

Consulting for clients regarding development programmes, study design (incl. adaptive designs), health authorities

Developing strategies and standards regarding Data Management, Analysis and Reporting, and cross-functional processes

Process management, policy training, auditing

Steering committees, Monitoring boards

JUN 2009 – DEC 2009

Medpace Switzerland GmbH, Zurich / Switzerland

Director of Biostatistics

Directing all operations of designated functional area, department, geographic region, or group of employees

Statistical consulting and teaching (clients and internal)

Supervising for all biostatistical and data-related activities

Coordinating functions and activities between departments to ensure contracts/projects awarded to Medpace are successfully completed

Overseeing hiring, training, and evaluation of associates

Conducting policy training and ensure employees are working in compliance with SOPs and GCP guidelines

Recognizing major departmental successes and failures and resolve accordingly

Evaluating departmental capacity needs on an ongoing basis and coordinate/delegate workload efficiently and in accordance with given timelines

Representing department/functional area in Business Development, including reviewing proposals and participating in general capabilities and bid defense meetings

Maintaining Medpace departmental SOPs to ensure they are present and appropriate

Since Medpace was at that time no longer able to commit to its intended European growth strategy, the Zurich office has been closed by end of 2009

APR 2006 – MAY 2009

AAIPharma GmbH & Co. KG, Neu-Ulm / Germany

Director Biostatistics/Pharmacokinetics/Data Analysis

Managing and supervising 10-15 statisticians, pharmacokineticists and data analysts in Germany and the United Kingdom

Global international clinical Phase II-IV trials as well as local Phase I/IIa trials (also toxicokinetic evaluation of pre-clinical trials)

50 – 100 evaluation / report projects per year

All major therapeutic areas incl. cardiology, CNS, oncology, diabetes, endocrinology, women's health, gastroenterology, dermatology, medical devices

Clients located in US/Canada, Europe and Japan

Main focus on Phase I/II, PK/PD (full service as well as stand-alone projects)

Project responsibility and supervision for all biostatistical and data-related parts and issues

Budget responsibility, contribution to proposals, bid defence, sales and marketing activities

Consulting for clients regarding development programmes, study design, health authorities

Developing strategies and standards regarding Data Management, Analysis and Reporting, Statistical Programming, Software Validation, and cross-functional processes

AUG 2003 – MAR 2006

IMFORM International Clinical Research GmbH, Darmstadt / Germany

Director Biostatistics

Managing and supervising 10-15 statisticians, pharmacokineticists and statistical programmers in Germany (headquarter) and the Czech Republic

International clinical Phase I-IV trials across more than 20 European countries

All major therapeutic areas incl. cardiology, CNS, oncology, diabetes, respiratory, rheumatology, gastroenterology, dermatology

Clients located in US/Canada, Europe and Japan

Strong focus on Phase II-IV (usually and preferably full service projects)

Project responsibility and supervision for all biostatistical parts and issues

Budget responsibility, contribution to proposals, bid defence, sales and marketing activities

Consulting for clients regarding development programmes, study design (incl. adaptive designs), health authorities

Developing strategies and standards regarding Data Management, Analysis and Reporting, Statistical Programming, Software Validation, and cross-functional processes

OCT 1997 – JUL 2003

Institute for Statistics and Econometrics, University of Goettingen

Senior Fellow (Assistant Professor), Lecturer for Statistics, Econometrics and Mathematics

Supervising teams of PhD students as well as teaching courses with up to 1000 students

Research on a huge variety of topics in Statistics, Medicine, Finance, Market Research, Customer Analytics and Marketing, Economics, Logistics, Quality Management (Six Sigma), and Criminology

Research co-operations with private companies and institutions from various branches

OCT 1997 – JUL 2003

University of Cooperative Education, Welfenakademie Vienenburg/Woeltingerode

Lecturer for Statistics

Teaching classes of students selected, employed and sponsored by private companies (banking, retail, insurance, industry and service companies)

JUN 1992 – JUL 2003

Prof. Dr. P. G. Lankisch, Municipal Clinic of Lueneburg

Statistical Co-Researcher and Statistical Consulting

APR 1997 – OCT 1997

Private University of Applied Sciences, Goettingen

Lecturer for Statistics

OCT 1991 – SEP 1997

Institute for Statistics and Econometrics, University of Goettingen

Scientific Associate

SEP 1988 – OCT 1991

Institute for Statistics and Econometrics, University of Goettingen

Student Assistant

Memberships:	IBS (International Biometric Society)
	IBS Working Groups (related to Pharmaceutical Research; representatives of pharmaceutical industry, regulatory authorities etc.)
	IHEA (International Health Economics Association)
	ENBIS (European Network for Business and Industrial Statistics)

Lucerne, May 2017