

## PUBLICATIONS

### Refereed Papers (peer-reviewed)

- *Fatigue and health-related quality of life in relapsing-remitting multiple sclerosis after 2 years glatiramer acetate treatment are predicted by changes at 6 months: an observational multi-center study (2014)*,  
P.J. Jongen, D. Lehnick, J. Koeman, S. Frequin, D. Heersema, B. Kornips, A. Schyns-Soeterboek, L.H. Visser, P. Schiphof, A. Valkenburg, J. Hiel;  
Journal of Neurology, DOI: 10.1007/s00415-014-7363-2
- *Pharmacokinetic Interaction Between Simvastatin and Fenofibrate With Staggered and Simultaneous Dosing: Does It Matter (2014)*,  
A. Winsemius, J.C. Ansquer, M. Olbrich, P. van Amsterdam, P. Aubonnet, K. Beckmann, S. Driessen, H. van Assche, G. Piskol, D. Lehnick, K. Mihara;  
Journal of Clinical Pharmacology, DOI: 10.1002/jcph.291
- *Adherence to monthly online self-assessments for short-term monitoring: a 1-year study in relapsing-remitting multiple sclerosis patients after start of disease-modifying treatment (2013)*,  
P.J. Jongen, E. Sanders, C. Zwanikken, J. Koeman, L.H. Visser, P. Koopmans, D. Lehnick;  
Patient Preference and Adherence, Vol. 2013:7, pp. 293-300
- *Health-related quality of life in relapsing remitting multiple sclerosis patients after one year of treatment with glatiramer acetate: a prospective, observational, international, and multi-centre-study (2010)*,  
P.J. Jongen, D. Lehnick, H. Carton, E.A.C.M. Sanders, P. Seelldrayers, S. Frederikson, M. Andersson, J. Speck;  
Health and Quality of Life Outcomes 2010, 8:133, pp.1-7
- *Minimized Estradiol Absorption with Ultra Low Dose 10 µg 17β-Estradiol Vaginal Tablets (2010)*,  
M. Eugster-Hausmann, J. Waitzinger, D. Lehnick;  
Climacteric, Vol 13(3), pp. 219-227
- *Acute Pancreatitis: Does Gender Matter? (2001)*,  
P.G. Lankisch, C. Assmus, D. Lehnick, P. Maisonneuve, A.B. Lowenfels;  
Digestive Diseases and Sciences, Vol. 46(11), pp. 2470-2474
- *Do We Need a Computed Tomography Examination in All Patients with Acute Pancreatitis within 72h after Admission to Hospital for the Detection of Pancreatic Necrosis? (2001)*,  
P.G. Lankisch, K. Struckmann, C. Assmus, D. Lehnick, P. Maisonneuve, A.B. Lowenfels;  
Scandinavian Journal of Gastroenterology, Vol. 36, pp.432-436
- *Unintentional Weight Loss: Diagnosis and Prognosis. The First Prospective Follow-up Study from a Secondary Referral Centre (2001)*,  
P.G. Lankisch, M. Gerzmann, J.-F. Gerzmann, D. Lehnick;  
Journal of Internal Medicine, Vol. 249, pp. 41-46
- *Does Gastroscopy Induce Myocardial Ischemia in Patients With Coronary Heart Disease? (2000)*,  
J. Schenck, C.-H. Müller, H. Lübbers, R. Mahlke, D. Lehnick, P.G. Lankisch;  
Endoscopy, Vol. 32(5), pp. 373-376

- *No Strict Correlation Between Necrosis and Organ Failure in Acute Pancreatitis* (2000),  
P.G. Lankisch, D. Pflüchthofer, D. Lehnick;  
Pancreas, Vol. 20(3), pp. 319-322
- *Underestimation of Acute Pancreatitis: Patients with Only a Small Increase in Amylase-Lipase Levels Can Also Have or Develop Severe Acute Pancreatitis* (1999),  
P.G. Lankisch, S. Burchard-Reckert, D. Lehnick;  
GUT, Vol. 44(4), pp. 542-544
- *Presence and Extent of Extrapancreatic Fluid Collections Are Indicators of Severe Acute Pancreatitis* (1999),  
P.G. Lankisch, K. Struckmann, D. Lehnick;  
International Journal of Pancreatology, Vol. 26(3), pp. 131-136
- *Fecal Weight Determination Can Unfortunately Not Replace Unpopular and Costly Fecal Fat Estimation in the Diagnosis of Steatorrhea* (1999),  
P.G. Lankisch, M. Dröge, H. König, D. Lehnick, B. Lembcke  
International Journal of Pancreatology, Vol. 25(1), pp. 71-72
- *Acute Pancreatitis: Which Patient Is Most at Risk?* (1999),  
P.G. Lankisch, D. Pflüchthofer, D. Lehnick;  
Pancreas, Vol. 19(4), pp. 321-324
- *Which Etiology Causes the Most Severe Acute Pancreatitis?* (1999),  
P.G. Lankisch, C. Assmus, D. Pflüchthofer, K. Struckmann, D. Lehnick;  
International Journal of Pancreatology, Vol. 26(2), pp. 55-58
- *Faecal Elastase 1: Not Helpful in Diagnosing Chronic Pancreatitis Associated with Mild to Moderate Exocrine Pancreatic Insufficiency* (1998),  
P.G. Lankisch, I. Schmidt, H. König, D. Lehnick, R. Knollmann, M. Löhr, S. Liebe;  
GUT Vol. 42, No. 4, pp. 551-554
- *Morbidity and Mortality in 602 Patients with Acute Pancreatitis Seen between the Years 1980-1994* (1996),  
P.G. Lankisch, S. Burchard-Reckert, M. Petersen, D. Lehnick, C.A. Schirren, H. Köhler, F. Stöckmann, H.J. Peiper, W. Creutzfeldt  
Zeitschrift für Gastroenterologie (German Journal of Gastroenterology) 34(6), pp. 371-377
- *Diagnostic Intervals for Recognizing Celiac Disease* (1996),  
P.G. Lankisch, A. Martinez Schramm, F. Petersen, M. Dröge, D. Lehnick, B. Lembcke;  
Zeitschrift für Gastroenterologie (German Journal of Gastroenterology) 34(8), pp. 473-477
- *Etiology and Age Have Only a Limited Influence on the Course of Acute Pancreatitis* (1996),  
P.G. Lankisch, S. Burchard-Reckert, M. Petersen, D. Lehnick, C.A. Schirren, F. Stöckmann, H. Köhler;  
Pancreas, Vol. 13(4), pp. 344-349

## Monographs

- *Rate Ratios und Odds Ratios in zwei- und mehrdimensionalen Kontingenztafeln* (1998),  
D. Lehnick;  
Frankfurt, Berlin, Bern, New York, Paris, Wien.
- *Stichprobengröße bei Opferbefragungen in der Dunkelfeldforschung* (1998),  
W. Ahlborn, F. Böker, D. Lehnick;  
BKA-Forschungsreihe, Wiesbaden.

## Lecture Notes / Teaching Material (Selection)

- Hilfsblätter zu den Vorlesungen in Statistik I für Wirtschaftswissenschaftler (Skriptum),  
W. Ahlborn, D. Lehnick;  
Göttingen 2000, 298 pp.
- Hilfsblätter zu den Vorlesungen in Statistik II für Wirtschaftswissenschaftler (Skriptum),  
W. Ahlborn, D. Lehnick;  
Göttingen 2000, 325 pp.
- Hilfsblätter zur Vorlesung Ökonometrie (Skriptum), 128 pp.  
W. Ahlborn, D. Lehnick;  
Göttingen 1999
- Übungsaufgaben mit Lösungen zu Statistik I (Übungsbuch mit ausführlichen Lösungen),  
W. Ahlborn, D. Lehnick;  
Göttingen 1999, 296 pp.
- Übungsaufgaben mit Lösungen zu Statistik II (Übungsbuch mit ausführlichen Lösungen),  
W. Ahlborn, D. Lehnick;  
Göttingen 1999, 285 pp.

For approx. 20 further textbooks, lecture notes, formularies and exercise books (150 – 400 pages each) in Statistics, Mathematics and Econometrics, issued between 1991 and 2002 at the University of Goettingen, Dirk Lehnick headed the editorial teams who contributed and reviewed the corresponding modules.

## Conference Papers / Abstracts / Posters

- ECCO 2017, European Cancer Congress, 27-30 January 2017, Amsterdam, The Netherlands
  - *Demonstration of Pharmacokinetic and Pharmacodynamic Comparability in Healthy Volunteers for B12019, a Proposed Pegfilgrastim Biosimilar*,  
K. Roth, H. Wessels, B. Gastl, D. Lehnick, K. Jacob, R. Jankowsky

- 58<sup>th</sup> Annual Meeting of the American Society of Hematology (ASH), 3-6 December 2016, San Diego, California, USA
  - *Demonstration of Pharmacokinetic and Pharmacodynamic Equivalence in Healthy Volunteers for B12019, a New Proposed Pegfilgrastim Biosimilar*, K. Roth, B. Gastl, D. Lehnick, K. Jacob, R. Jankowsky; Blood, Vol. 120 (2016), p. 5079
- 28<sup>th</sup> DIA Annual EuroMeeting, 6-8 April 2016, Hamburg, Germany
  - *Clinical Development Strategies for Biosimilars – A Mid-Size Pharma Perspective*, K. Roth, D. Lehnick, R. Jankowsky
- 21<sup>st</sup> Annual Meeting of the North American Menopause Society (NAMS), 6-9 October 2010, Chicago, USA
  - *Estrogen Pharmacokinetics during Treatment with 10 mcg or 25 mcg Estradiol Vaginal Tablets in Postmenopausal Women with Vaginal Atrophy: A Randomized Clinical Trial*, J. Simon, J. Goldstein, J. Germak, D. Lehnick, M. Eugster-Hausmann (Second place prize in best poster award)
- 11<sup>th</sup> Annual Congress for Clinical Pharmacology, 22-24 October 2009, Heidelberg, Germany
  - *Conversion of azathioprine to mercaptopurine is not a function of gender type*, K. Dilger, D. Lehnick, J. Heuer; British Journal of Clinical Pharmacology, Vol. 68 Issue s1 (2009), pp. 6-59
- American Society of Reproductive Medicine, 64<sup>th</sup> Annual Meeting, 8-12 November 2008, San Francisco, USA
  - *Low estradiol plasma levels during 12 weeks therapy with ultra low dose 10 µg 17β-estradiol vaginal tablets*, M. Eugster-Hausmann, D. Lehnick; J. Waitzinger, S.E. McKendrick, E. Lang; Fertility and Sterility, Vol. 90 (2008), pp. S251-S252;
- 23<sup>rd</sup> Congress of the European Committee for the Treatment and Research in Multiple Sclerosis (ECTRIMS) and 12<sup>th</sup> Annual Conference of Rehabilitation in MS (RIMS), 11-14 October 2007, Prague, Czech Republic
  - *FOCUS Study – Fatigue and Quality of Life in Relapsing-Remitting Multiple Sclerosis Patients Using Glatiramer Acetate Improved at 6 and 12 Months of Treatment* P.J. Jongen, H. Carton, E.A.C.M. Sanders, P. Seeldrayers, S. Frederikson, M. Andersson, D. Lehnick
- Second Annual ENBIS (European Network of Industrial and Business Statistics) Conference, 23-24 September 2002, Rimini, Italy
  - *Six Sigma in the Context of Logistic Processes* D. Lehnick
  - *Assessing the Cost of Providing Quality in Inventory Systems* C. Uhlenbrock, D. Lehnick

- Annual Meeting of the American Gastroenterological Association and Digestive Disease Week 2000, 21-24 May 2000, San Diego, USA
  - *Do We Need a Computed Tomography Examination in All Patients with Acute Pancreatitis within 72h after Admission to Hospital?*,  
P.G. Lankisch, K. Struckmann, C. Assmus, D. Lehnick, P. Maisonneuve, A.B. Lowenfels;  
Gastroenterology, Vol. 118, No. 4 (2000), A162 (920)
- Annual Meeting of the American Gastroenterological Association and Digestive Disease Week 1999, 16-19 May 1999, Orlando, USA
  - *Low Ranson-/Imrie-Scores on Admission Render Contrast-Enhanced Computed Tomographies Unnecessary in Acute Pancreatitis*,  
P.G. Lankisch, K. Struckmann, C. Assmus, D. Lehnick;  
Gastroenterology, Vol. 116, No. 4 (1999), G4952
- Digestive Disease Week and 99<sup>th</sup> Annual Meeting of the American Gastroenterological Association, 16-22 May 1998, New Orleans, USA
  - *Which Etiology Causes the Most Severe Acute Pancreatitis?*,  
P.G. Lankisch, C. Assmus, D. Pflichthofer, K. Struckmann, D. Lehnick;  
Gastroenterology, Vol. 114, No. 4 (1998), A476
  - *Which Is the Critical Balthazar Score Value for Indicating Organ Failure in Acute Pancreatitis?*,  
P.G. Lankisch, D. Pflichthofer, C. Assmus, D. Lehnick;  
Gastroenterology, Vol. 114, No. 4 (1998), A477
- 8<sup>th</sup> Meeting of the International Association of Pancreatology, 13-15 July 1998, Tokyo, Japan
  - *Can Simple Fecal Weight Determination Replace Unpopular and Costly Fecal Fat Estimation in the Diagnosis of Malabsorption?*,  
M. Dröge, H. König, D. Lehnick, B. Lembcke, P.G. Lankisch  
International Journal of Pancreatology, Vol. 23 (1998), p. 218
  - *Which Etiology Causes the Most Severe Acute Pancreatitis?*,  
C. Assmus, D. Pflichthofer, K. Struckmann, D. Lehnick, P.G. Lankisch;  
International Journal of Pancreatology, Vol. 23 (1998), p. 212
  - *Underestimating Acute Pancreatitis*,  
S. Burchard-Reckert, D. Lehnick, P.G. Lankisch;  
International Journal of Pancreatology, Vol. 23 (1998), p. 213
- 30<sup>th</sup> European Pancreatic Club Meeting, 10-13 June 1998, Thessaloniki, Greece
  - *Can Simple Fecal Weight Determination Replace Unpopular and Costly Fecal Fat Estimation in the Diagnosis of Malabsorption?*,  
M. Dröge, H. König, D. Lehnick, B. Lembcke, P.G. Lankisch;  
Digestion 59 (1998), pp.244-245
  - *Which Etiology Causes the Most Severe Acute Pancreatitis?*,  
C. Assmus, D. Pflichthofer, K. Struckmann, D. Lehnick, P.G. Lankisch;  
Digestion 59 (1998), pp.232-233
  - *Which Is the Critical Balthazar Score Value for Indicating Organ Failure in Acute Pancreatitis?*,  
D. Pflichthofer, C. Assmus, P.G. Lankisch, D. Lehnick;  
Digestion 59 (1998), p.232

- 53. Jahrestagung der Deutschen Gesellschaft für Verdauungs- und Stoffwechselkrankheiten, 2-5 September 1998, Kiel, Germany
  - *Bei akuter Pankreatitis ist die Entwicklung von Organversagen und Nekrosen kein paralleler Vorgang!*,  
D. Pflüthofer, C. Assmus, P.G. Lankisch, D. Lehnick;  
Zeitschrift für Gastroenterologie (German Journal of Gastroenterology), Vol. 36 (1998), p. 695
  - *Welche Ätiologie führt zur schwersten akuten Pankreatitis (AP)?*,  
C. Assmus, D. Pflüthofer, K. Struckmann, D. Lehnick, P.G. Lankisch;  
Zeitschrift für Gastroenterologie (German Journal of Gastroenterology), Vol. 36 (1998), p. 697
  
- American Pancreatic Association 1998 Meeting, 5-6 November 1998, Chicago, USA
  - *Can Simple Fecal Weight Determination Replace Unpopular and Costly Fecal Fat Estimation in the Diagnosis of Malabsorption?*,  
M. Dröge, H. König, D. Lehnick, B. Lembcke, P.G. Lankisch;  
Pancreas, Vol. 17, No. 4 (1998), p. 431
  - *Underestimating Acute Pancreatitis*,  
S. Burchard-Reckert, D. Lehnick, P.G. Lankisch;  
Pancreas, Vol. 17, No. 4 (1998), p. 428
  
- 29<sup>th</sup> European Pancreatic Club Meeting, 9-12 July 1997, London, UK
  - *The Underestimated Acute Pancreatitis*,  
S. Burchard-Reckert, D. Lehnick, P.G. Lankisch;  
Digestion 58 (1997), Suppl. 2, (with S. Burchard-Reckert, P.G. Lankisch)
  - *Early Contrast-Enhanced Computed Tomography (CT) and Localisation of Extrapancreatic Exudation Predict the Course of Acute Pancreatitis (AP)*,  
K. Struckmann, C. Assmus, D. Lehnick, R. Becher, P.G. Lankisch;  
Digestion 58 (1997), Suppl. 2
  
- First Combined Meeting of European Pancreatic Club and the International Association of Pancreatology, 12-15 June 1996, Mannheim, Germany
  - *Is Elevated Serum Amylase Threefold the Upper Limit of Normal on Presentation Decisive for the Outcome of Acute Pancreatitis?*,  
S. Burchard-Reckert, D. Lehnick, P.G. Lankisch;  
Digestion 57 (1996), p. 220
  - *Morbidity and Mortality in Acute Pancreatitis: An Update*,  
P.G. Lankisch, S. Burchard-Reckert, M. Petersen, C.A. Schirren, H. Köhler, F. Stöckmann, H.J. Peiper, W. Creutzfeldt;  
Digestion 57 (1996), p. 243
  - *Has Contrast-Enhanced Computed Tomography Performed on Admission Any Prospective Value for the Course of Acute Pancreatitis: Results of a Prospective Study*,  
K. Struckmann, C. Assmus, D. Lehnick, R. Becher, P.G. Lankisch;  
Digestion 57 (1996), p. 267

- Digestive Disease Week and 97<sup>th</sup> Annual Meeting of the American Gastroenterological Association, 18-24 May 1996, San Francisco, USA
  - *Steatorrhea: Can We Trust Our Eyes?*,  
P.G. Lankisch, M. Dröge, S. Hofses, H. König, D. Lehnick, B. Lembcke;  
Gastroenterology, Vol. 110, No. 4 (1996), A24
  - *Is Heightened Serum Amylase Elevation on Presentation Decisive for the Outcome of Acute Pancreatitis?*,  
P.G. Lankisch, S. Burchard-Reckert, D. Lehnick;  
Gastroenterology, Vol. 110, No. 4 (1996), A408
  - *Morbidity and Mortality in Acute Pancreatitis: An Update*,  
P.G. Lankisch, S. Burchard-Reckert, M. Petersen, D. Lehnick, C.A. Schirren,  
H. Köhler, F. Stöckmann, H.J. Peiper, W. Creutzfeldt  
Gastroenterology, Vol. 110, No. 4 (1996), A409

## **Clinical Drug Development**

Since 2003, Dirk Lehnick has led Biostatistics and Data Science departments in Contract Research Organisations (CROs) and has been involved in many drug development programmes in the pharmaceutical industry.

In several hundred projects he has contributed to essential documents including Clinical Study Protocols, Clinical Study Reports (according to ICH E3), Statistical Analysis Plans, Interim Reports (e.g. statistical or pharmacokinetic reports), Dossiers, Briefing Books etc.

Due to the nature and mechanisms of commercial development of medicinal products and medical devices, including respective regulatory and economical frameworks, the vast majority of these documents are confidential and property of the sponsors (usually pharmaceutical or biotech companies).