



## Curriculum Vitae

### Personal information **Joerg Zinserling**

#### Work experience

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1. Employer: Federal Institute for Drugs and Medical Devices/ Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)
  - Start date: 03 2009
  - End date:
  - Position: Biostatistician
  - Activities: Biostatistical assessment, consulting for design of clinical trials and research questions in national Scientific Advice procedures (>200), assessment of pharmacokinetics and pharmacodynamics, author of articles in peer\_reviewed scientific journals (>50), peer\_reviewer for journals listed in PubMed, member of Methodology Working Party at EMA, member of the Scientific Advice Working Party at EMA
  - Country: Germany
2. Employer: University of Bonn, University Clinic, Department of Anesthesiology and Intensive Care Medicine
  - Start date: 041996
  - End date: 022009
  - Position: Scientific assistant
  - Activities: Biostatistical assessment and design of clinical trials, design and assessment of pharmacokinetic studies, conduction of scientific studies in pharmacokinetics, radiology, lung physiology, gas exchange and respiratory care, participation in international cooperation projects with Clinical Physiology, University of Uppsala, Sweden, peer\_review for national research organizations, author of >30 articles in peer\_reviewed scientific journals, peer\_reviewer for journals listed in PubMed, peer\_reviewer for FWF (Austria)
  - Country: Germany
3. Employer: University of Göttingen, University Clinic, Department of Anesthesiology, Intensive Care and Emergency Medicine
  - Start date: 101988
  - End date: 031996
  - Position: Scientific assistant
  - Activities: Biostatistical assessment and design of clinical trials, conduction of scientific studies on respiratory mechanics, lung volume measurement, gas exchange, author of articles in peer\_reviewed scientific journals
  - Country: Germany

#### Education and training

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1. Subject: University of Bonn
  - Start date: 04 1996
  - End date: 02 2009
  - Qualification: PhD/ Dr. rer. nat.
  - Organisation: Physics, Interdisciplinary doctorate (Physics in Medicine), Biostatistics, Mathematics
  - Country: Germany
2. Subject: University of Göttingen, Germany
  - Start date: 101987
  - End date: 011995
  - Qualification: MSc Physics/ Dipl. Phys.
  - Organisation: Physics, Mathematics
  - Country: Germany

#### Additional information

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##### Publications

Aarum S, Popp C, Hunter A, Skvarc M, Reischl I, Zander H, Zinserling J, van Leeuwen P, Sutcliff J, Chesworth T, Kapeller E, Emmendoerffer A, Gravanis I, Bouygués C, Vincenzi C, Berntgen M. Multistakeholder scientific advice for medicinal products used in combination with a medical device or a companion diagnostic in the EU-summary of a Focus group discussion. *Front Med (Lausanne)*. 2025 Jul 10;12:1593644. doi: 10.3389/fmed.2025.1593644

Huber C, Zinserling J, Benda N, Vetter T, Rueckbeil M. Methodological Insights on Biomarker-Based Patient Selection: A Review of Scientific Advice Procedures at the European Medicines Agency. *Clin Pharmacol Ther*. 2025 Jan 18. doi: 10.1002/cpt.3558

Schaefer R, Donaldson L, Leus M, Osakwe CE, Chimukangara B, Dalal S, Duerr A, Gao F, Glidden DV, Grinsztejn B, Justman J, Kumwenda G, Laeyendecker O, Lee HY, Maldarelli F, Mayer KH, Murray J, Parekh BS, Rice B, Robertson MN, Saito S, Vannappagari V, Warren M, Zeballos D, Zinserling J, Miller V. Promising results of HIV prevention trials highlight the benefits of collaboration in global health: The perspective of the Forum HIV Recency Assay Working Group. *PLOS Glob Public Health* 2024 Oct 24;4(10). doi: 10.1371/journal.pgph.0003878

Benjamin Hofner, Elina Asikanius, Wolfgang Jacquet, Theodor Framke, Katrien Oude Rengerink, Lukas Aguirre Dávila, Maria Grünewald, Florian Klinglmüller, Martin Posch, Finbarr P. Leacy, Thomas Lang, Armin Koch, Jörg Zinserling and Kit Roes (2023) Vaccine Development during a Pandemic: General Lessons for Clinical Trial Design, *Statistics in Biopharmaceutical Research*, DOI: [10.1080/19466315.2023.2211538](https://doi.org/10.1080/19466315.2023.2211538)

Parkin N, Gao F, Grebe E, Cutrell A, Das M, Donnell D, Duerr A, Glidden DV, Hughes JP, Murray J, Robertson MN, Zinserling J, Lau J, Miller V; Forum for Collaborative Research Recency Assay Working Group. Facilitating Next\_Generation Pre\_Exposure Prophylaxis Clinical Trials Using HIV Recent Infection Assays: A Consensus Statement from the Forum HIV Prevention Trial Design Project. *Clin Pharmacol Ther.* 2022 Dec 22. doi: 10.1002/cpt.2830

Muders T, Luepschen H, Meier T, Reske A, Zinserling J, Kreyer S, Pikkemaat R, Maripu E, Leonhardt S, Hedenstierna G, Putensen C, Wrigge H. Individualized positive end-expiratory pressure and regional gas exchange in porcine lung injury. *Anesthesiology* 2020 Feb Epub. doi: <https://doi.org/10.1097/ALN.0000000000003151>

Leuchs AK, Brandt A, Zinserling J, Benda N. Disentangling estimands and the intention-to-treat principle. *Pharm Stat.* 2017 Jan;16(1):12-19. doi: 10.1002/pst.1791. Epub 2016 Dec

Schmidt T, Brodesser A, Schnitzler N, Gruger T, Brandenburg K, Zinserling J, Zundorf, J CD66b overexpression and loss of C5a receptors as surface markers for Staphylococcus aureus-induced neutrophil dysfunction. *PLoS One.* 2015 Jul 15;10(7):e0132703. doi: 10.1371/journal.pone.0132703. eCollection 2015.

Leuchs AK, Zinserling J, Brandt A, Wirtz D, Benda N Choosing Appropriate Estimands in Clinical Trials, Therapeutic Innovation and Regulatory Science. DOI: 10.1177/2168479014567317. Epub 2015 Feb 17.

Helms HJ, Benda N, Zinserling J, Kneib T, Friede T. Spline-based procedures for dose-finding studies with active control. *Stat Med.* 2015 Jan 30;34(2):232-48. doi: 10.1002/sim.6320. Epub 2014 Oct 16.

Cortes-Blanco A, Prieto-Yerro C, Martinez-Lazaro R, Zamora J, Jimenez-Huete A, Haberkamp M, Pohly J, Enzmann H, Zinserling J, Strassmann V, Broich K. Florbetapir (18F) for brain amyloid positron emission tomography: highlights on the European marketing approval. *Alzheimers Dement.* 2014 Oct;10(5 Suppl):S395-9. doi: 10.1016/j.jalz.2013.09.007. Epub 2014 Jan 10.

Kreyer S, Muders T, Luepschen H, Kricklies C, Linden K, Tolba R, Varelmann D, Zinserling J, Putensen C, Wrigge H. Pumpless extracorporeal CO<sub>2</sub> removal restores normocapnia and is associated with less regional perfusion in experimental acute lung injury. *Acta Anaesthesiol Scand.* 2014 Jan;58(1):52-60. doi: 10.1111/aas.12217. Epub 2013 Nov 7.

Leuchs AK, Zinserling J, Schlosser-Weber G, Berres M, Neuhauser M, Benda N. Estimation of the treatment effect in the presence of non-compliance and missing data. *Stat Med.* 2014 Jan 30 (33). doi: 10.1002/sim.5924. Epub 2013 Jul 22.

Kreyer S, Muders T, Luepschen H, Kricklies C, Linden K, Soehle M, Zinserling J, Putensen C, Wrigge H. The effect of pumpless extracorporeal CO<sub>2</sub> removal on regional perfusion of the brain in experimental acute lung injury. *J Neurosurg Anesthesiol.* 2013 Jul;25(3):324-9. doi: 10.1111/aas.12217. Epub 2013 Nov 7.

Schmidt T, Zundorf J, Gruger T, Brandenburg K, Reinert AL, Zinserling J, Witte W, Schnitzler N. Phenotyping of Staphylococcus aureus reveals a new virulent ST398 lineage. *Clin Microbiol Infect.* 2013 Mar;19(3):279-85. doi: 10.1111/j.1469-0691.2012.03775.x. Epub 2012 Feb 23.

Schmidt T, Zundorf J, Gruger T, Brandenburg K, Reinert AL, Zinserling J, Schnitzler N. CD66b overexpression and homotypic aggregation of human peripheral blood neutrophils after activation by a gram-positive stimulus. *J Leukoc Biol.* 2012 May;91(5):791-802. Epub 2012 Feb 8.

Muders T, Luepschen H, Zinserling J, Greschus S, Fimmers R, Guenther U, Buchwald M, Grigutsch D, Leonhardt S, Putensen C, Wrigge H. Tidal recruitment assessed by electrical impedance tomography and computed tomography in a porcine model of lung injury. *Crit Care Med.* 2012 Mar;40(3):903-11.

Guenther U, Wrigge H, Theuerkauf N, Boettcher MF, Wensing G, Zinserling J, Putensen C, Hoeft A. Repinotan, a Selective 5-HT<sub>1A</sub>-R-Agonist, Antagonizes Morphine-Induced Ventilatory Depression in Anesthetized Rats. *Anesth Analg.* 2010 111(4):901-907.

Kreyer S, Putensen C, Berg A, Soehle M, Muders T, Wrigge H, Zinserling J, Hering R. Effects of Spontaneous Breathing During Airway Pressure Release Ventilation on Cerebral and Spinal Cord Perfusion in Experimental Acute Lung Injury. *J Neurosurg Anesthesiol.* 2010 22(4):323-9

Ellerkmann RK, Soehle M, Riese G, Zinserling J, Wirz S, Hoeft A, Bruhn J. The Entropy Module and Bispectral Index as guidance for propofol-remifentanyl anaesthesia in combination with regional anaesthesia compared with a standard clinical practice group. *Anaesth Intensive Care.* 2010 38(1):159-66

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experimental lung injury: a randomized controlled trial. *Crit Care*. 2008; 12: R135.

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Wrigge H, Zinserling J, Neumann P, Muders T, Magnusson A, Putensen C, Hedenstierna G. Spontaneous breathing with airway pressure release ventilation favors ventilation in dependent lung regions and counters cyclic alveolar collapse in oleic-acid-induced lung injury: a randomized controlled computed tomography trial. *Crit Care*. 2005; 9: R780-R789.

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Zinserling J, Wrigge H, Neumann P, Muders T, Magnusson A, Hedenstierna G, Putensen C. Methodologic aspects of attenuation distributions from static and dynamic thoracic CT techniques in experimental acute lung injury. *Chest*. 2005; 128: 2963-70.

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Neumann P, Wrigge H, Zinserling J, Hinz J, Maripuu E, Andersson LG, Putensen C, Hedenstierna G. Spontaneous breathing affects the spatial ventilation and perfusion distribution during mechanical ventilatory support. *Crit Care Med*. 2005; 33: 1090-5.

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Wrigge H, Uhlig U, Zinserling J, Behrends-Callsen E, Ottersbach G, Fischer M, Uhlig S, Putensen C. The effects of different ventilatory settings on pulmonary and systemic inflammatory responses during major surgery. *Anesth.Analg*. 2004; 98: 775-81

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Wrigge H, Zinserling J, Neumann P, Defosse J, Magnusson A, Putensen C, Hedenstierna G. Spontaneous breathing improves lung aeration in oleic acid-induced lung injury. *Anesthesiology*. 2003; 99: 376-84.

Wrigge H, Varelmann D, Zinserling J, Hering R, Kuhlen R, Putensen C. [Proportional assist ventilation combined with automatic tube compensation. A promising concept of augmented spontaneous breathing?]. *Anaesthesist*. 2003; 52: 341-8.

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Hering R, Peters D, Zinserling J, Wrigge H, von ST, Putensen C. Effects of spontaneous breathing during airway pressure release ventilation on renal perfusion and function in patients with acute lung injury. *Intensive Care Med*. 2002; 28: 1426-33.

Stuber F, Wrigge H, Schroeder S, Wetegrove S, Zinserling J, Hoefft A, Putensen C. Kinetic and reversibility of mechanical ventilation-associated pulmonary and systemic inflammatory response in patients with acute lung injury. *Intensive Care Med*. 2002; 28: 834-41.

Hering R, Vorwerk R, Wrigge H, Zinserling J, Schroder S, von ST, Hoefft A, Putensen C. Prone positioning, systemic hemodynamics, hepatic indocyanine green kinetics, and gastric intramucosal energy balance in patients with acute lung injury. *Intensive Care Med*. 2002; 28: 53-8.

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Hering R, Wrigge H, Vorwerk R, Brensing KA, Schroder S, Zinserling J, Hoeft A, Spiegel TV, Putensen C. The effects of prone positioning on intraabdominal pressure and cardiovascular and renal function in patients with acute lung injury. *Anesth.Analg.* 2001; 92: 1226-31.

Wrigge H, Zinserling J, Stuber F, von ST, Hering R, Wetegrove S, Hoeft A, Putensen C. Effects of mechanical ventilation on release of cytokines into systemic circulation in patients with normal pulmonary function. *Anesthesiology.* 2000; 93: 1413-7.

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Rehberg B, Bouillon T, Zinserling J, Hoeft A. Comparative pharmacodynamic modeling of the electroencephalography-slowing effect of isoflurane, sevoflurane, and desflurane. *Anesthesiology.* 1999; 91: 397-405.

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Wrigge H, Sydow M, Zinserling J, Neumann P, Hinz J, Burchardi H. Determination of functional residual capacity (FRC) by multibreath nitrogen washout in a lung model and in mechanically ventilated patients. Accuracy depends on continuous dynamic compensation for changes of gas sampling delay time. *Intensive Care Med.* 1998; 24: 487-93.

Neumann P, Zinserling J, Haase C, Sydow M, Burchardi H. Evaluation of respiratory inductive plethysmography in controlled ventilation: measurement of tidal volume and PEEP-induced changes of end-expiratory lung volume. *Chest.* 1998; 113: 443-51.

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Sydow M, Bristow F, Zinserling J, Allen SJ. Variation of nitric oxide concentration during inspiration. *Crit Care Med.* 1997; 25: 365-71.

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Sydow M, Thies K, Engel J, Golisch W, Buscher H, Zinserling J, Burchardi H. [Variation in inspiratory gas flow in pressure support ventilation. The effect on respiratory mechanics and respiratory work]. *Anaesthesist.* 1996; 45: 1051-8.

Sydow M, Golisch W, Buscher H, Zinserling J, Crozier TA, Burchardi H. Effect of low-level PEEP on inspiratory work of breathing in intubated patients, both with healthy lungs and with COPD. *Intensive Care Med.* 1995; 21: 887-95.

Sydow M, Denecke T, Zinserling J, Zielmann S, Crozier TA, Burchardi H. [Determination of intrinsic PEEP during mechanical ventilation. Validation of a new optional method of measurement provided by the EVITA mechanical ventilator]. *Anaesthesist.* 1994; 43: 115-20.

Sydow M, Burchardi H, Zinserling J, Crozier TA, Denecke T, Zielmann S. Intrinsic PEEP determined by static pressure-volume curves--application of a novel automated occlusion method. *Intensive Care Med.* 1993; 19: 166-71.

Sydow M, Burchardi H, Zinserling J, Ische H, Crozier TA, Weyland W. Improved determination of static compliance by automated single volume steps in ventilated patients. *Intensive Care Med.* 1991; 17: 108-14.

## Projects

## Memberships

Member of the International Biometric Society, German region, Member of the Methodology Working Party of the Committee for Medicinal Products for Human Use (CHMP) at EMA, Member of the Scientific Advice Working Party of the Committee for Medicinal Products for Human Use (CHMP) at EMA

## Other Relevant Information