

## 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 articled 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

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 Klingmüller, 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, Gruber 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 (<sup>18</sup>F) 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. Painless 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 painless 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, Gruber T, Brandenburg K, Reiners 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, Gruber T, Brandenburg K, Reiners 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.

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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

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

Putensen C, Theuerkauf N, Zinserling J, Wrigge H, Pelosi P. Meta-analysis: ventilation strategies and outcomes of the acute respiratory distress syndrome and acute lung injury. *Ann Intern Med.* 2009 151(8):566-76

Guenther U, Manzke T, Wrigge H, Dutschmann M, Zinserling J, Putensen C, Hoeft A. The counteraction of opioid-induced ventilatory depression by the serotonin 1A-agonist 8-OH-DPAT does not antagonize antinociception in rats *in situ* and *in vivo*. *Anesth Analg.* 2009 108(4):1169-76.

Schewe JC, Komusin A, Zinserling J, Nadstawek J, Hoeft A, Hering R. Effects of spinal anaesthesia versus epidural anaesthesia for caesarean section on postoperative analgesic consumption and postoperative pain. *Eur J Anaesthesiol.* 2009; 26: 52-9.

Varelmann D, Muders T, Zinserling J, Guenther U, Magnusson A, Hedenstierna G, Putensen C, Wrigge H. Cardiorespiratory effects of spontaneous breathing in two different models of experimental lung injury: a randomized controlled trial. *Crit Care.* 2008; 12: R135.

Wrigge H, Zinserling J, Muders T, Varelmann D, Gunther U, von der Groben C, Magnusson A, Hedenstierna G, Putensen C. Electrical impedance tomography compared with thoracic computed

tomography during a slow inflation maneuver in experimental models of lung injury. Crit Care Med. 2008; 36: 903-9.

Hering R, Bolten JC, Kreyer S, Berg A, Wrigge H, Zinserling J, Putensen C. Spontaneous breathing during airway pressure release ventilation in experimental lung injury: effects on hepatic blood flow. Intensive Care Med. 2008; 34: 523-7.

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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.

Hering R, Zinserling J, Wrigge H, Varelmann D, Berg A, Kreyer S, Putensen C. Effects of spontaneous breathing during airway pressure release ventilation on respiratory work and muscle blood flow in experimental lung injury. Chest. 2005; 128: 2991-8.

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.

Varelmann D, Wrigge H, Zinserling J, Muders T, Hering R, Putensen C. Proportional assist versus pressure support ventilation in patients with acute respiratory failure: cardiorespiratory responses to artificially increased ventilatory demand. Crit Care Med. 2005; 33: 1968-75.

Wrigge H, Uhlig U, Baumgarten G, Menzenbach J, Zinserling J, Ernst M, Dromann D, Welz A, Uhlig S, Putensen C. Mechanical ventilation strategies and inflammatory responses to cardiac surgery: a prospective randomized clinical trial. Intensive Care Med. 2005; 31: 1379-87.

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

Hering R, Viehofer A, Berg A, Kreyer S, Zinserling J, Wrigge H, Putensen C. Weight loss of respiratory muscles during mechanical ventilation. Intensive Care Med. 2003; 29: 1612. 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?]. Anaesthetist. 2003; 52: 341-8.

Zinserling J, Wrigge H, Varelmann D, Hering R, Putensen C. Measurement of functional residual capacity by nitrogen washout during partial ventilatory support. Intensive Care Med. 2003; 29: 720-6. 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, Hoeft 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, Hoeft 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.

Wrigge H, Zinserling J, Hering R, Schwalfenberg N, Stuber F, von ST, Schroeder S, Hedenstierna G, Putensen C. Cardiorespiratory effects of automatic tube compensation during airway pressure release ventilation in patients with acute lung injury. Anesthesiology. 2001; 95: 382-9.

Putensen C, Zech S, Wrigge H, Zinserling J, Stuber F, von ST, Mutz N. Long-term effects of spontaneous breathing during ventilatory support in patients with acute lung injury. Am.J.Respir.Crit Care Med. 2001; 164: 43-9.

Hering R, Wrigge H, Vorwerk R, Brening 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.

Putensen C, Mutz NJ, Putensen-Himmer G, Zinserling J. Spontaneous breathing during ventilatory support improves ventilation-perfusion distributions in patients with acute respiratory distress syndrome. *Am.J.Respir.Crit Care Med*. 1999; 159: 1241-8.

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.

Sydow M, Bristow F, Zinserling J, Allen SJ. Flow-proportional administration of nitric oxide with a new delivery system: inspiratory nitric oxide concentration fluctuation during different flow conditions. *Chest*. 1997; 112: 496-504.

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

Putensen C, von ST, Hering R, Stuber F, Zinserling J. Effect of different ventilatory support modalities on the ventilation to perfusion distributions. *Acta Anaesthesiol Scand Suppl*. 1997; 111:119-22.: 119-22.

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]. *Anaesthesia*. 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]. *Anaesthesia*. 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