



Curriculum Vitae

Personal information **Andreas Bonertz**

Work experience

1. Employer: Paul-Ehrlich-Institut
 - Start date: 2011
 - End date:
 - Position: Head of Section Clinical Trials

Current Activities:

- Coordination of all regulatory issues regarding clinical trials in accordance with Regulation (EU) No. 536/2014
 - Initial applications
 - Follow-up procedures (e.g. Substantial Modifications, Add MS)
 - Scientific Advice
- Member of the Rheumatology and Immunology Working Party (RIWP)
- Member of the Clinical Trial Coordination Group (CTCG)

Previous Work Experience:

- Coordination of all regulatory issues regarding test and therapeutic allergens for in vivo use in applications for marketing authorization (national, MRP/DCP/CP), clinical trials, scientific advice and follow-up procedures
- Quality assessment in applications for marketing authorization (national, MRP/DCP/CP), clinical trials, scientific advice and follow-up procedures
 - Country: Germany
- 2. Employer: German Cancer Research Center / National Center for Tumor Diseases
 - Start date: 2010
 - End date: 2011
 - Position: Scientist
 - Activities: Cell culture, blood and serum diagnostic, cell_based mediator_release_assays (mast cell and regulatory T cell interactions), ELISpot analysis, ELISA, SDS-Pages, Immunoblotting, PCR, flow_cytometry, histology, animal models; Clinical studies and IND-procedures
 - Country: Germany
- 3. Employer: Feinberg School of Medicine, Northwestern University
 - Start date: 2009
 - End date: 2009
 - Position: Scientist
 - Activities:
 - Country: United States

Education and training

1. Subject: German Cancer Research Center
 - Start date: 2007
 - End date: 2010
 - Qualification: PhD
 - Organisation:
 - Country: Germany
2. Subject: Massachusetts Institute of Technology
 - Start date: 2004
 - End date: 2005
 - Qualification: University Training
 - Organisation:
 - Country: United States
3. Subject: University of Heidelberg
 - Start date: 2001
 - End date: 2007
 - Qualification: Master of Science, Bachelor of Science
 - Organisation:
 - Country: Germany

Additional information

Publications

- Bonertz A, Draï C, Castelnovo T, Hartenstein D, Kaul S, Mitrevski M, Zubeldia JM. European Medicines Agency (EMA) commentary on EMA/CHMP Guideline on allergen products development for immunotherapy and allergy diagnosis in moderate to low-sized study populations. Br J Clin Pharmacol. 2025 May;91(5):1293-1296. doi: 10.1002/bcp.70048. Epub 2025 Mar 24.
- Schultz-Heienbrock R, Baumann S, Böhm R, Bonertz A, Breithaupt-Groegler K, Buckpesch-Heberer U, Coenen M, Erb-Zohar K, Faisst N, Grass G, Höchel J, Kovar A, Muehlenbroich A, Rengelshausen J, Riedel C,

- Schug B, Sudhop T, Warnke A, Ziegele B. Designing integrated early-phase protocols to reduce substantial modifications, including considerations for patient cohorts - a multi-stakeholder consensus view for a practical approach in Germany. *Front Pharmacol*. 2026 Jan 26
- Zimmer J, Bonertz A, Kaul S, Vieths S. Introduction of General Chapters on standard methods for allergen quantification in the European Pharmacopoeia. *Allergy*. 2023 Apr;78(4):923-927. doi: 10.1111/all.15631. Epub 2023 Jan 6.
 - Bonertz A, Tripathi A, Zimmer J, Reeb C, Kaul S, Bridgewater J, Rabin RL, Slater JE, Vieths S. A regulator's view on AIT clinical trials in the United States and Europe: Why successful studies fail to support licensure. *J Allergy Clin Immunol*. 2022 Mar;149(3):812-818.
 - Bonertz A, Mahler V, Vieths S. New guidance on the regulation of allergen products: key aspects and outcomes. *Curr Opin Allergy Clin Immunol*. 2020 Dec;20(6):624-630.
 - Ge Y, Böhm HH, Rathinasamy A, Xydia M, Hu X, Pincha M, Umansky L, Breyer C, Hillier M, Bonertz A, Sevko A, Domschke C, Schuetz F, Frebel H, Dettling S, Herold-Mende C, Reissfelder C, Weitz J, Umansky V, Beckhove P. Tumor-Specific Regulatory T Cells from the Bone Marrow Orchestrate Antitumor Immunity in Breast Cancer. *Cancer Immunol Res*. 2019 Dec;7(12):1998-2012.
 - Bonertz A, Roberts G, Slater JE, Bridgewater J, Rabin RL, Hoefnagel M, Timon M, Pini C, Pfaar O, Sheikh A, Ryan D, Akdis C, Goldstein J, Poulsen LK, van Ree R, Rhyner C, Barber D, Palomares O, Sheikh A, Pawankar R, Hamerlijnk D, Klimek L, Agache I, Angier E, Casale T, Fernandez_Rivas M, Halken S, Jutel M, Lau S, Pajno G, Sturm G, Varga EM, Gerth van Wijk R, Bonini S, Muraro A, Vieths S. Allergen manufacturing and quality aspects for allergen immunotherapy in Europe and the United States: An analysis from the EAACI AIT Guidelines Project. *Allergy*. 2018 Apr;73(4):816-826. _ Zimmer J, Bonertz A, Vieths S. Quality requirements for allergen extracts and allergoids for allergen immunotherapy. *Allergol Immunopathol (Madr)*. 2017 Dec;45 Suppl 1:4-11. doi: 10.1016/j.aller.2017.09.002. Epub 2017 Nov 9. Review.
 - Bonertz A, Roberts GC, Hoefnagel M, Timon M, Slater JE, Rabin RL, Bridgewater J, Pini C, Pfaar O, Akdis C, Goldstein J, Poulsen LK, van Ree R, Rhyner C, Barber D, Palomares O, Sheikh A, Pawankar R, Hamerlijnk D, Klimek L, Agache I, Angier E, Casale T, Fernandez_Rivas M, Halken S, Jutel M, Lau S, Pajno G, Sturm G, Varga EM, Gerth van Wijk R, Bonini S, Muraro A, Vieths S. Challenges in the implementation of EAACI guidelines on allergen immunotherapy: A global perspective on the regulation of allergen products. *Allergy*. 2018 Jan;73(1):64-76.
 - Blatner NR, Mulcahy MF, Dennis KL, Scholtens D, Bentrem DJ, Phillips JD, Ham S, Sandall BP, Khan MW, Mahvi DM, Halverson AL, Stryker SJ, Boller AM, Singal A, Sneed RK, Sarraj B, Ansari MJ, Oft M, Iwakura Y, Zhou L, Bonertz A, Beckhove P, Gounari F, Khazaie K. Expression of ROR γ t Marks a Pathogenic Regulatory T Cell Subset in Human Colon Cancer. *Sci Transl Med*. 2012 Dec 12;4(164):164ra159.
 - Timke C, Winnenthal HS, Klug F, Roeder FF, Bonertz A, Reissfelder C, Rochet N, Koch M, Tjaden C, Buechler MW, Debus J, Werner J, Beckhove P, Weitz J, Huber PE. Randomized controlled phase I/II study to investigate immune stimulatory effects by low dose radiotherapy in primarily operable pancreatic cancer. *BMC Cancer*. 2011 Apr 13;11:134.
 - Khazaie K, Blatner NR, Khan MW, Gounari F, Dennis K, Bonertz A, Tsai FN, Strouch MJ, Cheon E, Phillips JD, Beckhove P, Bentrem DJ. The significant role of mast cells in cancer. *Cancer Metastasis Rev*. 2011 Mar;30(1):45-60. Review.
 - Blatner NR, Bonertz A, Beckhove P, Cheon EC, Krantz SB, Strouch M, Weitz J, Koch M, Halverson AL, Bentrem DJ, Khazaie K. In colorectal cancer mast cells contribute to systemic regulatory T_{cell} dysfunction. *Proc Natl Acad Sci U S A*. 2010 Apr 6;107(14):6430-5. Epub 2010 Mar 22. Erratum in: *Proc Natl Acad Sci U S A*. 2010 Jul 6;107(27):12405. _ Schmitz Winnenthal H, Pietsch DH, Schimmack S, Bonertz A, Udonta F, Ge Y, Galindo L, Specht S, Volk C, Zraggen K, Koch M, Büchler MW, Weitz J, Beckhove P. Chronic pancreatitis is associated with disease-specific regulatory T_{cell} responses. *Gastroenterology*. 2010 Mar;138(3):1178-88.
 - Bonertz A, Weitz J, Pietsch DH, Rahbari NN, Schlude C, Ge Y, Juenger S, Vlodavsky I, Khazaie K, Jaeger D, Reissfelder C, Antolovic D, Aigner M, Koch M, Beckhove P. Antigen-specific Tregs control T cell responses against a limited repertoire of tumor antigens in patients with colorectal carcinoma. *J Clin Invest*. 2009 Nov;119(11):3311-21.
 - Khazaie K, Bonertz A, Beckhove P. Current developments with peptide-based human tumor vaccines. *Curr Opin Oncol*. 2009 Nov;21(6):524-30. Review. _ Nummer D, Suri Payer E, Schmitz Winnenthal H, Bonertz A, Galindo L, Antolovich D, Koch M, Büchler M, Weitz J, Schirmacher V, Beckhove P. Role of tumor endothelium in CD4⁺ CD25⁺ regulatory T cell infiltration of human pancreatic carcinoma. *J Natl Cancer Inst*. 2007 Aug 1;99(15):1188-99.

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