

Address: Route de Bellegarde 36; 1284 Chancy/Geneva; Switzerland
Phone: [+ 41] (0)79/ 83 83 856 (cell) / (0)22/ 756 06 44 (landline)
Email: info@totzke-scientific.com
Website: <http://www.totzke-scientific.com>
Born: July 6th 1965 in Cologne
Citizenship: German

Work Experience

Since July 2011 Co-founder and Owner, Healthcare Consultant
TOTZKE & DREHER SCIENTIFIC SA, Geneva, Switzerland

November 2008 – June 2011 Freelance Healthcare Consultant and Writer
TOTZKE SCIENTIFIC Writing, Medical Affairs & Communication, Geneva, Switzerland

Areas of expertise: Consultancy on regulatory and publication strategies; writing of clinical documents for Regulatory Affairs (study protocols, reports, Module 2 of Common Technical Documents; life cycle management: switch and repricing applications) and Medical Communication (peer review journal publications)

June 2009 – March 2011 employed by
Merck Serono SA, Geneva, Switzerland (Global Clinical Development Unit Rheumatology)

July 2010 – March 2011: Associate Director
April 2010 – June 2010: Senior Clinical Research Scientist
June 2009 – March 2010: Clinical Research Scientist

Key accountabilities: Conceptualizing and supporting Phase I-III clinical trials in osteoarthritis and cartilage injury in accordance with Clinical Development Plans; Acting as Clinical Trial Director (e.g. [NCT01066871](#)); preparation/review of submission activities (e.g. briefing books, IND, IMPD, and IB); presentation at scientific advice meetings; supporting early development projects; contributing to due diligence assessments of in-licensing opportunities; supporting communication and alignment between non-clinical research and clinical development; authoring global SOPs on the creation of Clinical Development Plans, Study Concept Sheets, and Protocols.

October 2004 – October 2008 employed at
HPM Healthcare Project Management SA, Geneva, Switzerland

January 2005 – October 2008: Head of Medical Writing (4 direct reports)
& Management board member

Key accountabilities: Building up the Medical Writing department, leadership and management of the team, including responsibility for profit and loss; bidding; scientific consultancy; statistical analysis; publication management; supervision of key projects (>40 CTD and >20 publication projects); participation in HPM's strategy planning.

October – December 2004: Project Manager Medical Writing

Key accountabilities: Reviewing, editing and writing documents in compliance with GxP and guidelines for competent authorities (e.g., CTDs, Clinical Expert Reports/Statements (CER/CES), trial protocols and reports, Risk Management Plans, IMPDs, Safety Reports; narratives and causality assessments) as well as for the public domain (manuscripts for peer-reviewed journals, registries/websites; investigator and marketing brochures).

April 1999 – September 2004 employed at
MDS Pharma Services Central Laboratory, Hamburg, Germany

June 2001 – September 2004: Scientific Director (11 direct reports)

Key accountabilities: Set-up of new analytical techniques according to GLP-, NCCLS-, and FDA-guidelines: check of feasibility, capacities, profitability; supervision of the validation; data analysis; writing of Validation/Analytical Reports and SOPs; scientific support to internal departments and to clients (technical information on methods; medical/clinical significance of lab tests and results); member of the global scientific committee on the harmonisation of analysis procedures.

April 2000 – May 2001: Senior Project Manager (4 direct reports)

April 1999 – March 2000: Project Manager (1 direct report)

Key accountabilities: Set-up, supervision and management of all central lab actions in a clinical trial according to GCP, the study protocol and sponsor's requirements: set-up of the database; writing of in- and external instruction documents as well as design of the blood collection kits for investigators; presentations of study specific procedures on investigator meetings; supervision of the delivery of lab material to and the pick-up of samples from the investigators, medical review and release of lab results, coordination of affiliate laboratories in South America, South Africa, Australia, and Asia.

Research Experience

December 1998 - February 1999 Postdoctoral Research Associate
Institute of Zoology, Dept. Ethology, University of Vienna, Austria (Prof. Dr. J. Dittami)

Research topics: Behavioural changes before and during onset of different variants of spongiform encephalopathy (BSE; CJD) in Rhesus monkeys (EU-project in collaboration with *G. Eder*, Immuno AG Vienna, *A. Aguzzi*, Zürich, and *J. Collinge*, London). Winter ecology of birds in reed beds; control mechanisms of winter fattening in bearded tits (in collaboration with *F. Bairlein* (Wilhelmshaven)).

October 1992 – October 1998 employed at
Institute of Avian Research, Wilhelmshaven, Germany (Prof. Dr. F. Bairlein)

August 1996 – October 1998 Postdoctoral Research Associate
(DFG Ba 816/12-1)

Research topics: Control mechanisms of the migratory fattening in passerine birds; evaluation of similarities to mammalian obesity by means of glucose tolerance and hormone response tests. Collaboration with *I. Schmidt* (MPI, Bad Nauheim) on the effects of leptin on birds.

October 1992 – July 1996 Research Assistant

Research topics: Validation of heterologous immunoassays for the evaluation of hormone levels in birds (in collaboration with *A. Hübinger*, Diabetes-Forschungsinstitut, Düsseldorf); seasonal variations of blood metabolite and hormone levels in a migratory bird species (*Sylvia borin*); influence of food shortage on seasonal hyperlipemia and hyperglycemia; influence of thyroidal and pituitary effectors on fattening. Supervision of a project concerning the influence of fasting on blood composition in herring gulls (in collaboration with *O. Hüppop*, Helgoland).

November 1991 – August 1992 Research Assistant
Institute of Biochemistry, Deutsche Sporthochschule (DSHS), Cologne, Germany
(Prof. Dr. M. Donike)

Research topics: Evaluation of the relevance of pituitary hormone and creatinine concentrations in the urine of athletes for doping analysis; routine chemical preparation of urine samples preceding GC/MS analysis for the detection of steroids.

Education

2007 Diploma in ‘Pharmaceutical Medicine’, European Center of Pharmaceutical
Medicine (ECPM), University of Basle, Switzerland
1996 Dr. rer. nat. (PhD), University of Cologne, Germany
1991 Diploma in Biology (MSc), (Zoology, Botany, Biochemistry, Genetics),
University of Cologne, Germany
1987 Prediploma in Biology (BS), University of Cologne, Germany
1984 Abitur; Candidate *Stiftung des Deutschen Volkes*

Vocational Training

- *Statistics for Non-Statisticians Program*, 2009-2010, Merck Serono Global Biostatistics
- *EMWA Professional Development Program*, Foundation and Advanced Level Certificate, 2009, European Medical Writer Association (EMWA)
- *Action Leadership Program*, 2003, Niagara Institute
- *Fachkunde Strahlenschutz*, 1993, University of Hannover

Expertise/Therapeutic Areas

- Clinical Research, Pharmaceutical and Laboratory Medicine
- Good Practices (GLP, GCP, GPP)
- Biosafety: EBSA-delegate; familiar with animal experimentation under Biosafety Level (BSL) 3 and 4 conditions; certified handle radioactive isotopes
- Oncology, Osteoarthritis, Osteoporosis, Pain, Endocrinology, Diabetes, Metabolism, Nutrition, a.o. (see publication list)

Technical Skills and Personal Traits

- Languages: German (native), English (business fluent), French (fluent)
- MS Office Power user, SPSS, SigmaPlot
- Well versed in statistics and in common analytical and laboratory techniques
- ambitious and persistent (experienced marathon and ultra marathon runner and cyclist)

Teaching and Expert Experience

- Contribution to lectures at the University of Vienna
- Instruction and supervision of graduate and undergraduate students and trainees
- Referee for a number of scientific journals (*Austral Ecology*, *Canadian Journal of Zoology*, *Comparative Biochemistry & Physiology*, *Contemporary Clinical Trials*, *Functional Ecology*, *Journal of Comparative Physiology*, *Journal of Ornithology*, *Journal of Zoology*, *Zoology*)

Personal References

Available upon request.

Publications (as main author)

- Totzke U (1995): Klinisch-chemische Charakterisierung und erste Befunde zur endokrinen Regulation der zeitlichen Fettdeposition der Gartengräsmücke (*Sylvia borin*). *J. Ornithol.* **136**: 363 (Abstract).
- Totzke U (1995): Validierung heterologer Immunoassays zur Bestimmung von Hormonen des Energiestoffwechsels an Kleinvögeln. *J. Ornithol.* **136**: 363-364 (Abstract).
- Totzke U, Bairlein F, Hübinger A (1996): Variations of plasma metabolites and hormones during migratory fat deposition of the garden warbler (*Sylvia borin*). *Verh. Deutsch. Zool. Ges.* **89**:1: 191 (Abstract).
- Totzke U (1996): Klinisch-chemische Charakterisierung und Befunde zur endokrinen Regulation der zeitlichen Fettdeposition der Gartengräsmücke (*Sylvia borin*). *Dissertation Universität Köln*.
- Totzke U, Bairlein F, Hübinger A (1997): The fat deposition of migratory birds: metabolic changes as in human type-IIb-diabetes ? *Exp. Clin. Endocrinol. Diab.* **105**, Suppl. 1: 29 (Abstract).
- Totzke U, Hübinger A, Bairlein F (1997): A role for pancreatic hormones in the regulation of the autumnal fat deposition of the garden warbler (*Sylvia borin*)? *Gen. Comp. Endocrinol.* **107**: 166-171.
- Totzke U, Hübinger A, Bairlein F (1998): Metabolic and hormonal adaptations in the garden warbler (*Sylvia borin*) during the premigratory fat deposition. *Biol. Cons. Fauna* **102**: 346 (Abstract).
- Totzke U, Hübinger A, Bairlein F (1998): Glucose utilization rate and pancreatic hormone response after oral glucose loads are influenced by the migratory condition and fasting in the garden warbler (*Sylvia borin*). *J. Endocrinol.* **158**: 191-196.
- Totzke U & Bairlein F (1998): Implications of food supply and fattening in the migratory garden warbler (*Sylvia borin*). *Ostrich* **69**: 385-386 (Abstract).
- Totzke U & Bairlein F (1998): The body mass cycle of the migratory garden warbler (*Sylvia borin*) is associated with changes in plasma metabolite levels. *Comp. Biochem. Physiol.* **121A**: 127-133.
- Totzke U (1999): Grenzen der äußerlichen Depotfettmenschätzung bei Zugvögeln. *J. Ornithol.* **140**: 253 (Abstract).
- Totzke U & Bairlein F (1999): Ähnlichkeiten bei der Fettdeposition für den Zug und für den Winter? *J. Ornithol.* **140**: 244 (Abstract).
- Totzke U, Hübinger A, Korthaus G, Bairlein F (1999): Fasting increases the plasma glucagon response in the migratory garden warbler (*Sylvia borin*). *Gen. Comp. Endocrinol.* **115**: 116-121.
- Totzke U, Fenske M, Hüppop O, Raabe H, Schach N (1999): Influence of fasting on blood and plasma composition in herring gulls (*Larus argentatus*). *Physiol. Biochem. Zool.* **72**(4): 426-437.
- Totzke U, Hübinger A, Dittami J, Bairlein F (2000): The autumnal fattening of the long-distance migratory garden warbler (*Sylvia borin*) is stimulated by intermittent fasting. *J Comp Physiol B* **170**: 627-631
- Totzke U & Kuyas C (2005): Non-frozen transports of whole blood samples do not cause relevant bias for global coagulation tests in clinical trials evaluating the drug safety. *Contemp. Clin. Trials* **26**(4): 488-502.

Publications (as co-author)

- Bairlein F & **Totzke U** (1992): New aspects on migratory physiology of trans-Saharan passerine migrants. *Ornis Scand.* **23**: 244-250.
- Büdinger L, Neuser N, **Totzke U**, Merk HF, Hertl M (2001): Preferential usage of TCR-V β 17 by peripheral and cutaneous T cells in Nickel-induced contact dermatitis. *J. Immunol.* **167**: 6038-6044.
- Lim K & **Totzke U** (2004): Die Integration des Problem-based Learning in die Ausbildung zum Physiotherapeuten. *Z. Physiotherapeuten* **56**: 33-41.
- Dittami J, Meran I, Bairlein F, **Totzke U** (2006): Winter patterns of foraging, fat deposition and corticosterone differ between Bearded and Blue Tits: Is this an expression of egalitarian or depositic winter flocks? *J. Ornithol.* **147 suppl**: 158 (Abstract).
- Lopatka L, **Totzke U**, Schmid A, Käufeler R (2007): Die Traubensilberkerze in der Behandlung menopausaler Beschwerden – Ergebnisse einer Therapiebeobachtung mit Cimifemin[®] uno. *J. Menopause* **14(2)**: 16-21.
- Steinmetz HT, Hellmich M, Neise M, Aldaud A, Lerchenmüller C, Tsamaloukas A, Fandel F, Weiligmann C, **Totzke U**, Schmitz S (2007): Prediction of the responsiveness to treatment with erythropoiesis-stimulating factors - a prospective clinical study in patients with solid tumors. *Oncologist* **12**: 748-755.
- Haschke-Becher E, Vockenhuber M, Niedetzky P, **Totzke U**, Gabriel C (2008): A new high-throughput screening method for the detection of chronic lymphatic leukemia and myelodysplastic syndrome. *Clin Chem Lab Med* **46(1)**: 85-88.
- Steinmetz HT, **Totzke U**, Söling U, Groschek M, Mittermüller J, Schweigert M, Tesch H, Nawka S, Schmitz S, Tsamaloukas A (2008): Hemoglobin levels that trigger ESA treatment decisions for cancer associated anemia – examination of practice in Germany. *Curr Med Res Opin* **24(10)**: 2751-2756.
- Haschke-Becher E, **Totzke U**, Afazel S, Johansson T, Schwarz M, Ladurner G, Wild C (2009): Clinical decision rules for the use of liquor diagnostics in hospitalised neurology patients reduced costs without affecting clinical outcomes. *Int J Technol Assess Health Care* **25(2)**: 208-13.
- Steinmetz HT, **Totzke U**, Tsamaloukas A, Schweigert M, Mittermüller J, Nawka S, Tesch H, Groschek M, Söling U, Hellebrand E, Schmitz S (2011): A prospective observational study of anaemia management in cancer patients - results from the German Cancer Anaemia Registry. *Eur J Cancer Care* **20**: 493-502
- Isbaniah F, Wiyono WH, Yunus F, Setiawati A, **Totzke U**, Verbruggen M (2011): Echinacea along with zinc, selenium, and vitamin C to alleviate exacerbation of chronic obstructive pulmonary disease: results from a randomised controlled trial. *J Clin Pharm Therap.* [**Epub ahead of print**]
- Apprich S, Mamisch TC, Welsch GH, Stelzeneder D, Albers C, **Totzke U**, Trattng S (2011): Quantitative T2 Mapping of the patella at 3.0 Tesla is sensitive to early cartilage degeneration, but also to unloading of the knee. *Eur J Radiol* [**Epub ahead of print**]

Publications with acknowledged contributions

- Scheiffarth G, Wahls S, Ketzenberg C, Exo KM (2002): Spring migration strategies of two populations of bar-tailed godwits, *Limosa lapponica*, in the Wadden Sea: time minimizers or energy minimizers? *Oikos* **96(2)**: 346–354.
- Bairlein F (2002): How to get fat: nutritional mechanisms of seasonal fat accumulation in migratory songbirds. *Naturwissenschaften* **89(1)**: 1-10.
- Kunz I, Meier KM, Bourson A, Fisseha A, Schilling W (2008): Effects of rimonabant, a cannabinoid CB1 receptor ligand, on energy expenditure in lean rats. *Int. J. Obesity* **32(5)** 863-870.
- Haschke-Becher E, Brunser O, Cruchet S, Gotteland M, Haschke F, Bachmann C (2008): Urinary D-lactate excretion of infants receiving *Lactobacillus johnsonii* with formula. *Ann. Nutr. Metab.* **53(3-4)**:240-244
- Steinmetz T, Tsamaloukas A, Schmitz S, Wiegand J, Rohrberg R, Eggert J, Breuer F, Tessen HW, Eustermann H, Thomas L (2010): A new concept for the differential diagnosis and therapy of anaemia in cancer patients. *Support. Care Cancer* [**Epub ahead of print**]
- Apprich S, Welsch GH, Mamisch TC, Szomolanyi P, Mayerhoefer M, Pinker K, Trattng S (2010). Detection of degenerative cartilage disease: comparison of high-resolution morphological MR and quantitative T2 mapping at 3.0 Tesla. *Osteoarthritis Cartilage* **18(9)**:1211-7

- The Leishmaniasis East Africa Platform (LEAP) group (2010): Geographical variation in the response of visceral leishmaniasis to paromomycin in East Africa: a multicentre, open-label, randomized trial. *PLoS Negl. Trop. Dis.* **26(4)** e709.
- Saupé N, Zubler V, Hodler J, Zanetti M, Mamisch TC, Pfirrmann CWA (in press): Intraarticular delayed gadolinium-enhanced mri of cartilage of the hip. When to image after direct arthrography? *Radiology*
- Parmar S, Stingl JC, Huber-Wechselberger A, Kainz A, Renner W, Langsenlehner U, Krippel P, Haschke-Becher E (submitted) The impact of the UDP-glucuronyltransferase 2B7 polymorphism on progression free survival of epirubicin-treated breast cancer patients. *J. Clin. Oncol.*
- Schmitz S, Chatsipirois D, Potthoff K, Hellebrand E, Link H (submitted): A two-day cross sectional survey suggests a paradigm change for the treatment of cancer-associated anaemia in Germany. *Support. Care Cancer*

Congresses and invited lectures

- 127th Annual Meeting *DO-G*, Wilhelmshaven, Germany, 21.-26.9.1994 (2 poster)
- 89th Annual Meeting *DZG*, Oldenburg, Germany, 27.5.-1.6.1996 (lecture)
- 41st Symposium *DGE*, Lübeck, Germany, 6.-8.5.1997 (lecture)
- *Max-Planck-Institut für Verhaltensphysiologie*, Andechs, Germany, 24.2.1997 (invited lecture)
- 1st Meeting *EOU*, Bologna, Italy, 28.-30.8.97 (poster)
- *Konrad-Lorenz-Institut für vergleichende Verhaltensforschung*, Austrian Academy of Sciences, Vienna, Austria, 17.12.1997 (invited lecture)
- 22nd *IOC*, Durban, South Africa, 17.-22.8.98 (poster)
- 131st Annual Meeting *DO-G*, Jena, Germany, 7.-11.10.1998 (1 poster, 1 lecture)
- 133rd Annual Meeting *DO-G*, Leipzig, Germany, 19.-25.9.2000 (poster)
- 14th Spring Meeting *EMWA*, Malta, 17.-21.5.2005
- 18th European Meeting *DIA*, Paris, France, March 2006
- 15th Spring Meeting *EMWA*, Lyon, France, May 2006
- 24th *IOC*, Hamburg, Germany, 13.-19.8.2006 (poster)
- 19th European Meeting *DIA*, Vienna, Austria, 26.-28.3.2007
- 9th Autumn Meeting *EMWA*, Basle, Switzerland, 1.-3.11.2007
- 20st European Meeting *DIA*, Barcelona, Spain, 3.-5.3.2008
- Annual Meeting of the German, Austrian, and Swiss Societies for Haematology and Oncology (*DGHO*, *ÖGHO*, *SGMO*, *SGH*), Vienna, Austria, 10.-14.10.2008
- 17th Spring Meeting *EMWA*, Ljubljana, Slovenia, 26.-30.5.2008
- *OARSI 2009* World Congress on Osteoarthritis, Montreal, Canada, 10.-13.9.2009
- 9th World Congress *ICRS*, Sitges/Barcelona, Spain, 26.-29.9.2010

Professional Memberships

- *ICRS*, International Cartilage Repair Society (2010 – current)
- *TIPPA*, The International Publication Planning Association (2008 – current)
- *SWAPP*, Swiss Association of Pharmaceutical Professionals (2007 – current)
- *DIA*, Drug Information Association (2006 – current)
- *EMWA*, European Medical Writer Association (2005 – current)
- *EBSA*, European Biosafety Association (2000 – 2004)
- *DO-G*, Deutsche Ornithologen-Gesellschaft (1997 – 2008)