

Christoph Glasmacher

Biometrics and SAS-Programming for Clinical Research

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My offer to you

Reliable and flexible contract services in biometry and SAS-programming based on a comprehensive range of skills and more than eight years of experience in renowned full-service CROs.

Profile and previous positions

Experienced freelancer in biometry and SAS-programming.

Previous senior biometrician at the full-service CROs *Pharmalog Institut für klinische Forschung GmbH* and *medicomp Gesellschaft für Versuchsplanung & Datenanalyse mbH* in Munich.

Graduate psychologist with more than eight years of professional experience as a biometrician in clinical contract research and additionally two and a half years as scientific assistant in academic psychology and psychotherapy research.

Experience in planning (including study design, sample size estimation and writing of statistical analysis plans), analysing and reporting of clinical studies of phase II to IV.

Familiarity with legal requirements and major EMA und FDA guidelines.

Experience in innovative and complex statistical methods such as adaptive designs, bioequivalence, non-inferiority and pharmacokinetics.

Very good skills in statistical software (e.g. SAS, PASS, nQuery and ADDPLAN).

Merits from recent projects and positions

as freelancer
(since 11/2014)

Biosimilar phase III-study (FDA- and EMA-submission):

Supervision, coordination and quality control of responsible CRO during final analyses.

Oncology - Integrated Safety Summary (FDA-submission):

SAS-Programmer for CDISC-ADaM-database

Freelance-biometrician und SAS-Programmer for medium sized CROs

as employee
(before 11/2014)

Reorganization of SAS-programming workflows and implementation of a comprehensive system of validated macros for standardised production of statistical appendices to clinical study reports.

Supervision of the implementation of CDISC-ADaM.

Leadership of a small biometrical team.

Curriculum Vitae

Professional experience

- since 11/2014 *Christoph Glasmacher – Biometrics and SAS-Programming for Clinical Research, Munich, Germany*
Freelance-biometrician and SAS-programmer, contracted by Pharmaceutical Producers and CROs
- 01/2012-10/2014 *Pharmalog Institut für klinische Forschung GmbH, Munich, Germany*
Senior biometrician, responsible for biometrical planning, analysing and reporting of clinical trials.
- 07/2007-11/2011 *medicomp Gesellschaft für Versuchsplanung & Datenanalyse mbH, Munich, Germany*
Deputy head of biometrics and data management.
- 05/2006-11/2011
Biometrician, responsible for biometrical planning, analysing and reporting of clinical trials.
- 06/2005-01/2006 *Rheinische Friedrich-Wilhelms-Universität, Bonn, Germany*
Scientific assistant responsible for statistical analyses of studies and for methodological consultancy of colleagues.
- 06-11/2004 *Christoph-Dornier-Foundation for Clinical Psychology at the Technical University of Braunschweig, Germany*
Scholarship holder and psychotherapeutic and scientific tasks in the outpatients' department of the foundation.
- 01/2003-05/2004 *Psychiatric Services of the University of Bern, Switzerland*
Scientific assistant at the department of *Dynamical Systems and Medical Care Research* responsible for the statistical analyses of scientific projects.

University education

- 10/1993-07/2002 Psychology at the *University of Saarland (Saarbrücken, Germany)*
Degree: Graduate Psychologist (Diplom-Psychologe)
Øgrade: 1,5 (*sehr gut*; UK: *lower first class* / US: *A-*)
Main focus: Research methods and clinical psychology

Studies abroad

- 01/1996-01/1997 Psychology and statistics at the *University Stockholm, Sweden*

Special qualifications

- Clinical research and biometrics
Study planning (including sample size planning, clinical study protocol)
Analysis (including statistical analysis plan, SAS-programming, clinical study report)
Data management (including data entry, data validation plan)
Experience with various study types (phase II, III, IV and NIS)
Experience with various study designs (adaptive designs, bioequivalence, non-inferiority, pharmacokinetics)
- Other research
Clinical psychology and psychiatry
Psychometry, especially questionnaire development
Survey research, especially market and opinion polls
- Computer
Statistics: SAS, PASS, nQuery, ADDPLAN, RANCODE, SQL
Standard-software: MS-Office, Adobe Acrobat
Operation systems: MS-Windows, Mac OS X
- Languages
German (native language)
Swedish (very good written and spoken, one year abroad)
English (very good written and spoken)
French (basic knowledge)
- General
Experience in leading small teams
Experience in consultancy and support of customers

Professional experience during years of studies

02/2001-12/2002	Private lessons in statistics and usage of SPSS for students writing their diploma-thesis in psychology or doctoral-thesis in medicine
9/2001-2/2002	<i>Institute of Psychology at the University of Saarland, Germany</i> Student assistant for the realisation of computer-based experiments and their analysis in the project 'Processing of Personal Descriptions'
12/2000-05/2001	<i>Community Nonnweiler, 'Was geht?! e.V.' and Foundation Democracy Saarland ('Stiftung Demokratie Saarland')</i> Analysis and reporting of a survey on the child- and family-friendliness of the community of Nonnweiler (Saarland, Germany) including the presentation of results to the city council
01-06/2000	<i>German Research Institute for Artificial Intelligence (Deutsches Forschungsinstitut für Künstliche Intelligenz)</i> Student assistant for the planning, realisation and analysis of experiments on the efficiency of different teaching methods on mathematical proofs
07-09/1999 12/1999-03/2000	<i>Institute of Psychology at the University of Saarland, Germany</i> Student assistant for the planning, realisation and analysis of two evaluation studies about the quality of teaching and training of fellow students in practical evaluation research and usage of SPSS and MS-EXCEL
04-06/1999	<i>Institute of Computer Science at the University of Saarland, Germany</i> Student assistant for the planning, realisation and analysis of an evaluation study about the teaching software <i>GANIMAL</i>
09-12/1998	<i>EMNID (Opinion and Market Research) in Bielefeld, Germany</i> Internship in the departments for <i>Opinion and Social Research</i> and for <i>Media Research</i> : Mainly planning and analysis of public opinion polls
06-12/1998	<i>Ludwig-Boltzmann-Institut for Empirical Media Research, Vienna, Austria (Ludwig-Boltzmann-Institut für empirische Medienforschung)</i> Freelancer for the planning (including the approval procedure at the ministry of education) and realisation of a study about TV-news reception of teenagers
02-04/1997	<i>Institute for Scientific Film in Göttingen, Germany (Institut für den Wissenschaftlichen Film)</i> Internship during a production of an educational film

Memberships in professional associations

- International Biometrical Society, German Region, Working Group Pharmaceutical Research (Arbeitsgruppe Pharmazeutische Forschung)
- German Society for Medical Informatics, Biometry and Epidemiology (Deutsche Gesellschaft für Medizinische Informatik, Biometrie und Epidemiologie e.V., GMDS)
- German Society for Pharmaceutical Medicine (Deutsche Gesellschaft für Pharmazeutische Medizin, DGPharMed)

Trainings / congresses

Biometrics

- IMBI, Heidelberg
 - Multiple Testing and Group-sequential Designs, Heidelberg 02/2010
- SAS Institute
 - Repeated Measurement Designs (Messwiederholungsdesigns), Munich 07/2013
 - Statistic 2: ANOVA and Regression (Statistik 2: Weiterführende Techniken der Varianzanalyse und Regression), Heidelberg 01/2013
 - SAS Macro Language 1: Essentials, Munich 08/2010
 - SAS-Programming 2: Data Manipulation Techniques, Munich 06/2010
- European Statistical Forum
 - 4th Annual Conference of the European Statistical Forum: Missing Data in Clinical Trials, Amsterdam 11/2013
- Clinrex
 - CDISC-ADaM, Munich 12/2013
- Colloquium Pharmaceuticum
 - Clinical Data Management: Valid Data in Clinical Studies, Frankfurt 09/2008
- International Biometrical Society
 - Workshop on Adaptive Designs, Berlin 09/2006
 - Summer School, Sample Size Planning – Basics and new Challenges (Sommerschule, Fallzahlplanung – Grundlagen und neue Herausforderungen), Bad Herrenalb, 07/2012
 - Meetings of the Working Group Pharmaceutical Research, Nuremberg 11/2006, Munich 11/2007, Basle 11/2008, Berlin 05/2009, Ingelheim 11/2009, Hofheim 11/2012, Darmstadt 11/2013 and Munich 11/2014
- BVMA
 - Forum: Clinical Data Interchange Standards Consortium–CDISC, Munich 06/2011
- BfArM
 - Discussion on Adaptive Designs, Bonn 10/2006

Clinical research

- DGPharMed
 - Efficiency in Clinical Trials 2012, Study Endpoints and Designs: Principles, Practice, Perspectives (Effizienz in der klinische Prüfung 2012, Studienendpunkte und –designs: Prinzipien, Praxis, Perspektiven), Frankfurt 06/2012
- BVMA
 - 15th Symposium of the BVMA: The Clinical Trial – Data and Facts (Die klinische Prüfung - Daten und Fakten), Munich 11/2007
 - 20th Symposium of the BVMA: Pharmaceutical Research: ...with Patients, for Patients (Arzneimittelforschung; ...mit Patienten, für Patienten), Munich 11/2012
- BfArM
 - BfArM in dialogue: The Impact of Non-Interventional Study for the Assessment of Efficacy and Safety of Drugs, Bonn 08/2006
- Clinrex
 - GCP-Refresher: Regulatory Update / Non-interventional Studies (NIS), Munich 10/2012 and 11/2103

Management

- ComTeam AG
 - Clear Leadership (Klar führen), Gmund 09/2013
- FORUM Institut für Management
 - Time and Self-Management (Zeit-, Selbst- und Energiemanagement), Munich 12/2013
 - Project Management in Clinical Trials (Projektmanagement in der klinische Prüfung), Munich 06/2012
- IHK München
 - Business Administration, IHK certified training (Betriebswirtschaft kompakt, Praxistraining mit IHK-Zertifikat), Munich 09-12/2010
 - Basic Knowledge Law (Basis Wissen Recht), Munich 06/2013
 - Basic Knowledge Taxes (Basis Wissen Steuern), Munich 06/2013

Scientific publications

Tromm, A., Bunganič, I., Tomsová, E., Tulassay, Z., Lukáš, M., Kykal, J., Bátorvský, M., Fixa, B., Gabalec, L., Safadi, R., Kramm, H.-J., Altorjay, I., Löhr, H., Koutroubakis, I., Bar-Meir, S., Štimac, D., Schäffeler, E., Glasmacher, C., Dilger, K., Mohrbacher, R., Greinwald, R. & International Budenofalk Study Group (2011). **Budesonide 9 mg Is at Least as Effective as Mesalamine 4.5 g in Patients With Mildly to Moderately Active Crohn's Disease.** *Gastroenterology*, 140 (2), 425-434.

Piechatzek, M., Indlekofer, F., Daamen, M., Glasmacher, C., Lieb, R., Pfister, H., Tucha, O., Lange, KW., Wittchen, H.-U. & Schütz, C. G. (2009). **Is moderate substance use associated with altered executive functioning in a population-based sample of young adults?** *Human Psychopharmacology: Clinical and Experimental*, 24 (8), 650-665.

Indlekofer, F., Piechatzek, M., Daamen, M., Glasmacher, C., Lieb, R., Pfister, H., Tucha, O., Lange, K.W., Wittchen, H.U., Schütz, C. (2009) **Reduced memory and attention performance in a population based sample of young adults with a moderate lifetime use of cannabis, ecstasy and alcohol.** *Journal of Psychopharmacology*, 23 (5) 495-509.

Glasmacher, C. & Merten, J. (2003, October). **Einfluss des mimisch affektiven Nähe-Distanzregulierungsverhaltens von Therapeuten und Patienten auf die Qualität der therapeutischen Beziehung und den Therapieerfolg.** Poster at the Congress of the Swiss Psychological Society (Kongress der Schweizerischen Gesellschaft für Psychologie), Bern.

Melis, E., Glasmacher, C., Ullrich, C. & Gerjets, P. (2001). **Automated Proof Planning for Instructional Design.** In J.D. Moore & K.Stenning (Hrsg.), *Proceedings of the 23rd Annual Conference of the Cognitive Science Society* (pp. 166-171). Mahwah, NJ: Erlbaum.

Glasmacher, C. (1999). Risse in der Mediengesellschaft. *Psychologie Heute*, 26 (6), 59-62.

Hobbies

Photography, outdoor-activities

Personal details

Born on February, 19th 1973, German citizenship

Further documents (available on request)

Professional trainings (only 2010 to 2016)

SAS – Repeated Measurement Designs
(SAS – Messwiederholungsdesigns)

SAS – Statistic 2: ANOVA and Regression
(SAS – Statistik 2: Weiterführende Techniken der Varianzanalyse und Regression)

SAS – Programming 2: Data Manipulation Techniques
(SAS – Programmierung 2: Datenmanagement im Data Step)

SAS – Makrosprache 1: Grundlagen
(SAS – Macro Language 1: Essentials)

CDISC-ADaM

Clinical Data Interchange Standards Consortium–CDISC, BVMA-Forum

4th Annual Conference of the European Statistical Forum:
Missing Data in Clinical Trials

Sommerschule, Fallzahlplanung – Grundlagen und neue Herausforderungen
(Summer School, Sample Size Planning – Basics and new Challenges)

Multiples Testen und gruppensequentielle Verfahren
(Multiple Testing and Group-sequential Designs)

Klar führen (Clear Leadership)

Zeit-, Selbst- und Energiemanagement (Time and Self-Management)

Projektmanagement in der klinische Prüfung (Project Management in Clinical Trials)

Betriebswirtschaft kompakt, Praxistraining mit IHK-Zertifikat
(Business Administration, IHK certified training)

University certificates

Universität des Saarlandes: Diplomzeugnis Psychologie

Stockholm University: Register of student records

Professional references

Pharmalog Institut für klinische Forschung GmbH

medicomp Gesellschaft für Versuchsplanung & Datenanalyse mbH

Christoph-Dornier-Stiftung für klinische Psychologie, Braunschweig

Universitäre Psychiatrische Dienste Bern

Universität des Saarlandes, Arbeitseinheit Sozialpsychologie

Deutsches Forschungszentrum für Künstliche Intelligenz, Saarbrücken

Universität des Saarlandes, Fachrichtung Psychologie

Universität des Saarlandes, Fachrichtung Informatik

TNS EMNID, Bielefeld

Institut für den Wissenschaftlichen Film, Göttingen