DONGSUN CAO

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OBJECTIVE:

Seeking for a challenging position as a Statistical Programmer/Biostatistician/Data Scientist to use my excellent academic achievements and experience in Biostatistics, Genomics, Biology, and SAS programming skills

QULATIFICATION:

- 10+ yrs. of experience in the field of clinical trials
- Strong experience in data science in **Clinical Trials and Risk-Based Monitoring**
- Experience in administrative databases such as MarketScan/Truven
- Hands on experience data standards and familiarity with regulatory requirements
- Strong experience in creating **Analysis datasets, Tables, Listings, and Graphs**
- Strong leadership ability to create, maintain and define strategies to improve the efficiency of running a clinical trial work effectively in a quality-focused environment
- Strong knowledge of Biostatistics
- Extensive experience in SAS BASE, SAS MACROS, SAS/STAT, SAS/ACCESS, SAS/GRAPH, SAS-SQL, SAS ODS, GTL in Windows and UNIX environments
- Proficiency in **JMP scripting language (JSL**) and **R**
- Excellent organizational skills, time management, and ability to meet established deadlines
- Experience in creating datasets and table programming for **ISE** (Integrated Summary of Efficacy) and **ISS** (Integrated Summary of Safety) submissions to the FDA
- Ability to work independently, effectively, and collegially and demonstrated high-level critical and analytical thinking skills;
- Excellent verbal and written communication skills
- Strong motivation for excellence

EDUCATION:

Ph.D in Biology|Genetics, 2002
The University of Iowa, Iowa City, IA 52246

B.S. in Genetics 1987
Beijing Agricultural University
Beijing, China

CERTIFICATE:

SAS Certified Base programmer for SAS 9.1

SAS Certified Advanced programmer for SAS 9.1

R – Mango Solutions

JMP Software: Introduction to the JMP Scripting Language, SAS

Advanced R Markdown - R Studio

SKILLS PROFILE:

Statistical, SAS and Computer Skills

- Linear Regression
- Categorical Data analysis
- Survival Analysis
- Experimental Design
- Multivariate Analysis
- **Proficiency in SAS (SAS/BASE, SAS/GRAPH, SAS/STAT, GTL, MACRO, Proc SQL, ODS), R, JMP, JMP Clinical, VBA**

Computer Skills

- Database handling
- High proficiency on MS, scientific graphic and desk publishing software
- HTML, CSS, Java Script
- C, Java, SQL, PERL
- Qlik Sense

THERAPEUTIC EXPERIENCES:

Cardiovascular

- Cardiovascular - Heart Failure, AF

Oncology

- Oncology - Lung Cancer
- Oncology - Acute Myeloid Leukemia Cancer
- Oncology - Malignant Tumors Cancer

Infectious Diseases

- AIDS

Immunology/Inflammation

- Influenza H5N1
- Rheumatoid arthritis
- Psoriatic arthritis

Endocrine/Metabolic

- Diabetes Mellitus

Psychiatry

- ADHD

CNS

- Epilepsy

STATISTICAL COURSES AND TRAINING SESSIONS:

- **Statistical Experimental Design** I, II,
- **Intermediate Statistics** (BIOS 162, UNC)
- **Linear Regression** (BIOS 163, UNC)
- **Statistics Consulting** (BIOS 341, UNC)
- **Categorical Data Analysis** (BIOS 165, UNC)

- **Statistical Inference I & II** (BIOS 161, UNC, Audit)
- **Base SAS and Advanced SAS programming** (SAS Institute, Cary, NC)
- **GeneSpring** (Workshop, UNC),
- R – Mango Solutions
- JMP Software: Introduction to the JMP Scripting Language, SAS
- Advanced R Markdown - R Studio

PROFESSIONAL EXPERIENCES:

2017.4- Present **Principal Statistical Programmer, UCB Biosciences Inc.**

- Work as a lead programmer in phase III trials for submission in US and Asian countries.
- Works closely with study team to assure quality data and deliverables
- Ensures standards at a drug program level, integrates data across multiple studies or drug programs
- Review CRF to ensure consistency with protocol and adequacy to collect the data to meet the objectives defined in the statistical section of the protocol.
- Review CRF annotations and SDTM data specifications
- Develop ADaM specifications and creates derived-analysis datasets.
- Executes statistical analyses specified in the protocol or the Statistical Analysis Plan (SAP).
- Write SAS programs to generate tables, listings, and figures and analysis datasets.
- Performs all SAS programming required for clinical trial analysis and reporting, and various other programming tasks
- Work as lead statistical programmer in Site selection and Risk-based Monitoring (RBM). Assist in developing risk monitoring plan and Identify and develop the key risk indicators in monitoring site performance
- Developed clinical trial monitoring visualization tools using JMP Scripting Language (JSL) for customized analysis and visualization of RBM data for cross-departmental use in statistical Data Monitoring.
- Developed applications using R (Shiny) for customized analysis and visualization of clinical data. Use Kappa test to monitor the agreement between multiple raters at different levels. Use cluster analysis to detect multiple enrollments

2013.6- 2017.3 **Senior Statistical Programmer, UCB Biosciences Inc.**

- Work as a lead programmer in phase III trials for submission in US and Asian countries.
- Works closely with study team to assure quality data and deliverables
- Ensures standards at a drug program level, integrates data across multiple studies or drug programs
- Review CRF to ensure consistency with protocol and adequacy to collect the data to meet the objectives defined in the statistical section of the protocol.
- Review CRF annotations and SDTM data specifications

- Develop ADaM specifications and creates derived-analysis datasets.
- Executes statistical analyses specified in the protocol or the Statistical Analysis Plan (SAP).
- Write SAS programs to generate tables, listings, and figures and analysis datasets.
- Performs all SAS programming required for clinical trial analysis and reporting, and various other programming tasks
- Builds successful relationships and seamless interfaces at the protocol/project team level. Provides timely and effective communication to the programming and statistics leads
- Create submission-related documents – DDD.xml and SDTM/ADaM Review guides for FDA
- Support on epidemiological studies using large health administrative databases such as MarketScan/Truven
- Work as statistical programmer to assist in Site selection and Risk-based Monitoring (RBM)
- Develop application interface using JMP Scripting Language (JSL) for customized analysis of RBM data

2011.9- 2013.5 **Statistical Programmer, UCB Biosciences Inc.**

- Work as a lead programmer in phase III trials for submission in US.
- Ensures standards at a drug program level, integrates data across multiple studies or drug programs
- Review CRF to ensure consistency with protocol and adequacy to collect the data to meet the objectives defined in the statistical section of the protocol.
- Review CRF annotations and SDTM data specifications
- Develop ADaM specifications and creates derived-analysis datasets.
- Executes statistical analyses specified in the protocol or the Statistical Analysis Plan (SAP).
- Write SAS programs to generate tables, listings, and figures and analysis datasets.
- Performs all SAS programming required for clinical trial analysis and reporting, and various other programming tasks
- Builds successful relationships and seamless interfaces at the protocol/project team level. Provides timely and effective communication to the programming and statistics leads
- Create submission-related documents – DDD.xml and SDTM/ADaM review guides for FDA

2009.5- 2011.9 **Senior Statistical Programmer, ICON PLC.**

- Work as a lead programmer in various clinical trials to program, validate, maintain, and document statistical analysis programs for clinical trials on the basis of the Statistical Analysis Plan and of other trial documents (Protocol, CRF) following standard operating procedures (SOP) and working instructions.

- Ensure that datasets, tables, figures, listings, and statistical outputs are produced in an efficient manner and with high quality, following standards where applicable.
- Develop specifications of analysis datasets (ADaM) according to the SAP and mock ups.
- Support and oversight of statistical programming resources for timely delivery of all statistical programming deliverables.
- Mentor other statistical programmers as designated.

2008.5- 2009.5 **Statistical Programmer II, Kendle International, Inc.**

- Work as a lead programmer in various clinical project (Phase I to Phase III) to develop and manage programs for use in generating mapping datasets (SDTM), analysis datasets(ADaM), summary and analysis tables, data listings, and figures;
- Manage budget and timelines for projects to ensure deadlines are met and project hours stay within projected Budget.
- Assists in the preparation of submissions of electronic data (e.g., SAS® data sets) to regulatory agencies.
- Contribute strategic initiative by developing Job aid for CDISC and ADaM Standards.
- Mentoring for junior programmers.

2007.3- 2008.5 **Statistical Programmer II, PRA International, Inc.**

- Work as a team lead to ensure the success of the analysis programming aspects of the project;
- Ensure that the tables, listings, and figures that require analysis programming as described in the analysis plan have been produced and quality-controlled;
- communicate key issues to the programming team members;
- attend all relevant project team meetings and review all documentation associated with a project in order to keep abreast of developing project issues;
- meet project time lines and milestones that have been set and ensure that any concerns regarding these time lines are brought to the attention of the project team;
- communicate analysis programming issues to the team when they may affect other team members.

2005, 3- 2007.4 **Research Associate**, Center for Environmental Medicine, Asthma and Lung Biology, University of North Carolina at Chapel Hill Research

- Provide statistical programming support of analysis datasets, Perform and communicate statistical issues/results to the project team for the clinical trial in

both written and verbal form. Conduct research in the genomic area and Perform microarray data analysis in lung biology.

2002, 10 -2005.3 **Research Associate,** Carolina Cardiovascular Biology Center
University of North Carolina at Chapel Hill

- Conduct research in cardiovascular research area such muscle and heart development, and signal transduction pathway (for detail, see my publications).

PRESENTATIONS:

Development of a Risk-Based Monitoring (RBM) Visualization Application Interface using JMP Scripting Language (JSL). PhUSE 2019

Using JMP Scripting Language (JSL) to create an application interface for automated analysis of LAB data in clinical trial. PharmaSUG 2018

Use of R Shiny and Interactive Leaflet Maps to Evaluate Observer Agreement for Data Integrity at Country, Site, and Subject Level. UCB, 2018

A Shiny Application: Use of Cluster Analysis to Detect Multiple Enrollments of Patients. UCB 2018

Automation of Comparing ODS RTF outputs in Batch using VBA and SAS ®. PharmaSUG 2012

Statistical Analysis of Adverse Events in Randomized Clinical Trials Using SAS. PharmaSUG 2011

SELECTED PUBLICATIONS:

Dongsun Cao, Use of R Shiny and Interactive Leaflet Maps to Evaluate Observer Agreement for Data Integrity at Country, Site, and Subject Levels. Submitted to the PhUSE 2019

Dongsun Cao, Development of a Risk- Based Monitoring (RBM) Visualization Application Interface using JMP Scripting Language (JSL). Submitted to the PhUSE 2019

Using JMP Scripting Language (JSL) to create an application interface for automated analysis of LAB data in clinical trial. PharmaSUG 2018

Man Li, Nan Wang , Hui-Qin Gong, Wei-Zong Li, Xing-Hua Liao, Xiao-Long Yang, Hong-Peng He, **Dong-Sun Cao**, Tong-Cun Zhang 2015. Ca^{2+} signal-induced cardiomyocyte hypertrophy through activation of myocardin. Gene 557(1): 43–51**.**

Xing-Hua Liao, Nan Wang, Dong-Wei Zhao, De-Liang Zheng, Li Zheng, Wen-Jing Xing, Hao Zhou, **Dong-Sun Cao**, Tong-Cun Zhang 2014**.** NF-κB (p65) negatively regulates myocardin-induced cardiomyocyte hypertrophy through multiple mechanisms. Cellular Signalling *26(12): 2738–2748.*

Dongsun Cao, Chunbo Wang, Ruhang Tang, Huaqun Chen, Zheng Zhang, Mariko Tatsuguchi, Da-Zhi Wang 2012. Acetylation of myocardin is required for the activation of cardiac and smooth muscle genes, Journal of Biological Chemistry 287(46): 38495–38504.

Dongsun Cao 2012 Automation of Comparing ODS RTF outputs in Batch using VBA and SAS ®. PharmaSUG 2012.

Dongsun Cao, Xiaomin He, 2011, Statistical Analysis of Adverse Events in Randomized Clinical Trials Using SAS. PharmaSUG 2011.

Jun Zhou, Xing-Hua Liao, Chenyu Wu, Junyan Rui Xiao, Cailian Cheng, Nan Wang, Dongsun Cao, Tong-Cun Zhang 2011, The synergistic effects of cytomegalovirus IE2 and myocardin on cardiomyocyte hypertrophy. FEBS Letter 585:1082-1088.

Chunbo Wang[1], **Dongsun Cao[1],** Qing Wang and Da-Zhi Wang 2011, Synergistic activation of cardiac genes by Myocardin and Tbx5. PLoS ONE, Aug 29, 2011.

Dongsun Cao, Philip A Bromberg, and James M Samet. **2010.** Diesel Particle-induced Transcription Expression of P21 Involves Activation of EGFR, SRC and STAT3. **Am. J. Respir. Cell Mol. Biol. 42:** 88-95

Chen JF, Wang S, Wu Q, **Dongsun Cao**, Nguyen T, Chen Y, Wang DZ., **2008**. Myocardin marks the earliest cardiac gene expression and plays an important role in heart development**. Anat Rec (Hoboken).** 291(10):1200-11.

Weidong Wu, Silbajoris RA, **Dongsun Cao,** Bromberg PA, Zhang Q, Peden DB, Samet JM., **2008**. Regulation of cyclooxygenase-2 expression by cAMP response element and mRNA stability in a human airway epithelial cell line exposed to zinc. **Toxicol Appl Pharmacol.** 231(2):260-6.

Dongsun Cao, Philips Bromberg, and James Samet, **2007**. COX-2 expression induced by diesel particles involves chromatin modification and degradation of HDAC1. **Am J Respir. Cell Mol Biol.** 37(2):232-9.

Dongsun Cao, Tamra Tal, Phil Bromberg, Lee graves, William Reed, and Jim Samet **2006**, Oxidative stress mediate Diesel exhaust particle induced phosphorylation of Stat3 through EGFR and Src in pulmonary epithelial cells. **Am J. Physiol**. 292:L422-L429.

Yu-Mee Kim, **Dongsun Cao,** William Reed, Weidong Wu, Robert Sibajoris, Illona Jasper, Philips Bromberg, and James M. Samet. 2006 Zn(2+)-induced NF-kappaB-Dependent transcriptional activity involves site-specific p65/RelA phosphorylation., **Cell**

Signal, 19:538-546.

Weibin Xing, Tong-cun Zhang, **Dongsun Cao**, Zhigao Wang, Christopher L Antos, Shijie Li, Yibin Wang, Eric Olson, Dazhi Wang. 2006, Myocardin induces cardiomyocytes hypertrophy. **Circulation Research** 98: 1089-1097.

Dongsun Cao, ZhigaoWang, Chun-li Zhang Jiyeon Oh, Weibin Xing, Shijie Li, James A Richardson, Dazhi Wang and Eric N Olson (2005) Modulation of smooth muscle gene expression by association of histone acetyltransferase and deacetylase with myocardin, **Molecular and Cell Biology** 25: 364-376.

Ping Qiu, Raquel Ritchie, Zhiyao Fu, **Dongsun Cao**, Jerry Cumming, Joseph M. Miano, DaZhi Wang, Hui J. Li and Li Li. 2005, Myocardin enhances Smad3-Mediated transforming growth factor-β1 signaling in a CarG box-independent manner, **Circulation Research** 97: 983-991.

Thomas Callis, **Dongsun Cao,** Dazhi Wang 2005, Bone morphogenetic protein (BMP) signaling modulates Myocardin transcriptions of cardiac genes. **Circulation Research**, 97: 992-1000.

Arthur E. Frankel, Philip D. Hall, **Dongsun Cao**, Tie Fu Liu, Marlena Moors, Kimberley A. Cohen, Andrew M. Thorburn, and Robert J. Kreitman (2004) GM-CSF Receptor Targeted Therapy of Human Leukemia, in Cytotoxins and Immunotoxins for Cancer Therapy: Clinical Applications. Ed Kawakami, Koji. CRC - TAYLOR & FRANCIS Publisher

Dongsun Cao, John E Froehlich, Hui Zhang, and Chi-Lien Cheng (2003) The chlorate-resistant and photomorphogenesis defective mutant *cr88* encodes a chloroplast–targeted HSP90. **Plant J**. 33:107-118.

Dongsun Cao, Yun Lin and Chi-lien Cheng, 2000, Genetic interactions between the chlorate-resistant mutant *cr88* and the photomorphogenic mutants *cop1* and *hy5*. **Plant Cell** 12:199-210.

TEACHING EXPERIENCES:

1997-2002: Principle Biology II, Teaching Assistant

Selected Clinical Trial experience

Oncology: A Phase 2, Open-label, Randomized Clinical Trial of Skin Toxicity Treatment in Subjects Receiving Second-line FOLFIRI or Irinotecan Only Chemotherapy Concomitantly with Panitumumab.

Oncology: A Multi-center, Open-label, Randomized, Phase 2 Clinical Trial Evaluating Safety and Efficacy of FOLFIRI with Either Panitumumab or Bevacizumab as Second-line Treatment in Subjects with Metastatic Colorectal Cancer.

Oncology: Phase I Drug Interaction Evaluation of xxx and Ethanol in Healthy Subjects Open Label, Dose Escalation Trial of Oral PXD101 in Patients with Advanced Solid Tumors.

Oncology: A Multicenter, Open-Label, Noncomparative Phase 1 Clinical and Pharmacokinetic Study of Oral XXX in Patients with Advanced Cancer.

Oncology: A Phase 1/2, Open-Label, Multiple-Dose Study of the Safety, Tolerability, and Pharmacokinetics of xxx in Metastatic, Androgen-Independent Prostate Cancer Subjects.

Oncology: A multicenter open label dose–escalation phase 1 study of xxx-441 and oral Hedgehog signaling pathway inhibitor, in adult patient with advanced non-hematologic malignancies.

Cardiology: Phase II, A Clinical Investigation of Radiofrequency Ablation for the Treatment of Atrial Fibrillation Using the High-Density Mesh Bard Ablation System (Phase II).

Pain: A Phase 3, Multicenter, Randomized, Placebo-controlled, Parallel-group, Double-blind Study to Evaluate the Efficacy, Tolerability, Safety, and Pharmacokinetics of xxx in Patients Undergoing Primary Unilateral Total Knee Arthroplasty.

Pain: A Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel-group Study to Evaluate Efficacy, Safety, Tolerability, and Pharmacokinetics of a Single Intraoperative Localized Instillation of xxx in Patients Undergoing Primary Unilateral Total Hip Arthroplasty.

Ophthalmology: An 8-Week, Multicenter, Masked, Randomized Trial (with an 18-Week Masked Extension) to Assess the Safety and Efficacy of 700 μg and 350 μg Dexamethasone Posterior Segment Drug Delivery System (DEX PS DDS) Applicator System Compared with Sham DEX PS DDS Applicator System in the Treatment of Non-Infectious Ocular Inflammation of the Posterior Segment in Patients with Intermediate or Posterior Uveitis.

Endocrine/Metabolic: A Randomized, Double-Masked Placebo-Controlled, Multicenter, Phase 2 Study to Evaluate the Safety and Renal Efficacy of xxx in Patients with Diabetic Kidney Disease due to Type 1 or Type 2 Diabetes.

Infections/Parasitic Disease: A Two-Part Placebo-Controlled Evaluation of the Safety and Immunogenicity of an A/Indonesia/5/05 Recombinant Hemagglutinin Influenza H5N1 Vaccine with and without Glucopyranosyl Lipid A (GLA-SE) in Healthy Adults 18-49.

Infections/Parasitic Disease: A Phase 2a Randomized, Double Blind, Placebo Controlled Trial to Evaluate the Safety and Immunogenicity of a Trivalent Seasonal Influenza Virus-Like Particle (VLP) Vaccine (recombinant) in Healthy Adults,

Endocrine/Metabolic: An open-label, dose –escalation, phase 1 study of the oral formulation of MLN 708 administered weekly in adult patient with relapsed or refractory light change (AL) Amyloidosis who require further treatment.

Nervous System: A historical –control, multi- center, double–blind randomized study to assess the efficacy and safety of conversion to Lacosamide 400 mg/day Monotherapy in subjects with partial –onset seizures.

Nervous System: A multicenter, open-label, extension trial to assess the long-term use of Lacosamide monotherapy and safety of Lacosamide monotherapy and Adjunctive therapy in subjects with Partial –onset seizure.