CURRICULUM VITAE - ROBERTO BUGARINI

SAN DIEGO CA, USA

Nationality: USA, Italy

TEL +1 858-230-2326

EMAIL ROBY_BUGA@YAHOO.IT

PROFESSIONAL EXPERIENCE

Pfizer - La Jolla, San Diego, CA – USA Oct, 2021 – present
Vice President Global Biostatistics

- Global Head of Biostatistics – Oncology early clinical development
- Leadership and strategic directions of the global Biostatistics platform
- Represents Biostatistics organizationally within corporate environment in order to enable successful impact on clinical development
- Managing the oncology statistical group (10-12 statisticians; locations: La Jolla- San Diego (CA), Cambridge (MA), Boulder (CO))

Pfizer - La Jolla, San Diego, CA – USA June, 2017 – Oct 2021
Executive Director Biostatistics

- Global Head of Biostatistics – Oncology early clinical development
- Coordinate all statistical activities at the asset level and clinical trial level from Dose Finding to POC
- Managing the oncology statistical group (10-12 statisticians; locations: La Jolla- San Diego (CA), Cambridge (MA), Boulder (CO))
- Leading statistical initiatives
    - Bayesian Designs: Develop strategies for combination of investigational agents. Phase 1 dose-escalation-selection for combinations.
    - Develop strategies for patient selection in phase 1 and 2 clinical trials. Phase 1 expansion cohort adaptation. Biomarker adaptive designs and adaptive randomization.
    - Immuno-oncology clinical endpoints
    - Develop sample eCRF tracking and data transfer processes for biomarker samples
    - Interaction with Regulatory Agencies (eg FDA, PMDA, EMA)

Pfizer - La Jolla, CA – USA April, 2015 – June, 2017
Snr Director Biostatistics

- Statistical support for clinical development of Immuno Oncology and Therapeutic Cancer Vaccines. Application of Decision Theory and Adaptive Design to expedite clinical development.
- Group Head (3 statisticians) immuno oncology early development statistics

Pfizer - La Jolla, CA – USA April, 2012 – April, 2015
Director Biostatistics

- Responsible for statistical aspects of clinical development plans: Early Development Oncology, Personalized Medicine, Oncology Immunotherapy and Therapeutic Vaccines.

Novartis Oncology - Cambridge, MA – USA April, 2010 – April 2012
Assoc. Director Biostatistics
Head of Biomarkers Oncology Biostatistics

- Discovery, Development and Analysis of Biomarkers in Oncology
- Provide high quality and timely statistical support to enhance the integration and impact of biomarker & imaging data on the clinical development of compounds within the oncology portfolio
- Integration of personalized medicine
- Support molecular diagnostics and "companion diagnostics" activities
- Development of SOPs and Guidelines for Biostatistics, Statistical Reporting and Data management
- Managing a team of biomarker and clinical statisticians, programmers and data managers in Oncology Translational Medicine
    - Group of 3 statisticians, 2 statistical programmers and 1 data manager.

Genomic Health, Inc - Redwood City, CA-USA June, 2007 – April, 2010
Principal Biostatistician

- Design and development of statistical methodology and study design clinical trials (Oncology – Breast Cancer).
- Statistical support for presentations and publications
- Algorithm development, Prognosis, Prediction of cancer Genes and Gene interactions with cancer treatments, Analysis of biomarkers, Flexible log cumulative hazard functions and Fractional Polynomial Regression. Evaluation, assessment and calculation of sample size and statistical power.
- Design and analysis of observational studies using survival analysis as well as clinical and genetic epidemiology methods. Case-Control and Nested Case-Control studies, Cohort Sampling, Weighting, False Discovery Rate, Supervised and Unsupervised methods with Cross-Validation.

Novartis Vaccines & Diagnostics (formerly Chiron) - Emeryville, CA-USA Dec, 2005 – May, 2007
Cluster Biostatistician

Chiron Vaccines - Siena, Italy Sept, 2001 – October, 2005
Project Biostatistician

- Provide statistical input to clinical development plans
- Responsible for statistical aspects of projects, including experimental design, analysis, and presentation of data. Phase I-II-III-IV clinical trials. Superiority and non-inferiority, efficacy and safety objectives.
- Regulatory Submissions and interactions with Regulatory Agencies (e.g. BLA, IND, EOPII, Scientific Advice, EU centralized and decentralized)
- Ensure appropriate wording of the primary and secondary objectives and statistical hypotheses, statistical sample size, power calculations, and selection of statistical analysis methodology.
- Medical Affairs: collaboration with external KOL, co-author presentations and publications
- Provide technical/statistical reports on the data for review by the report writing team
- Meet with internal and external non-statistical colleagues and provide statistical consulting.
- Provide training to internal and external customers on statistical issues in biomedical research

(ISS) Italian National Institute of Public Health - Rome, Italy Apr, 1998 – Sept, 2001
Laboratory of Epidemiology and Biostatistics,
AIDS and Sexual Transmitted Diseases
Statistician

- Develop statistical analysis plans, statistical analyses and statistical reports

- Collaborate with stat analyst on defining and creating derived variables.
- Provide an active collaboration in the paper (international publications) writing process.
- Provide statistical input in Clinical Epidemiology, Quantitative Epidemiology and Genetic Epidemiology, Case-Control studies, Cohort studies
- In vitro and in vivo pre-clinical analyses and bioequivalence studies. Process validation, assay validation, and assay and bioassay development.

EDUCATION

University of Rome "La Sapienza"
Laurea in Statistics 1993-1998
Title of Degree Thesis: Estimates of Incidence of HIV Infection by Back-Calculation Models
Graduated cum laude (110/110 cum laude)

Diploma in Computer Science in "G. Vallauri" Institute of Rome 1987–1992

PROFESSIONAL COURSES ATTENDED

- Advanced Epidemiology. ISS - Rome, Italy
- Experimental Design and Analysis of Variance. ISS
- Cohort Studies: Design, Analysis and Application. ISS
- Economic Program Evaluation and Health Economy. Mediterranean School of Medical Statistics and Clinical Epidemiology - Siracusa, Italy
- Applied Survival Analysis and Mixed Models. OHIO State University - Columbus, OHIO, USA
- Missing Data Analysis. Italian Society of Biometrics- Florence, Italy
- Clinical Trials, Bioinformatics in Medicine, Pharmaco-Epidemiology, Genetic Epidemiology. Erasmus Summer Program – Rotterdam, The Netherlands
- GCP – Good Clinical Practices. Chiron – Siena, Italy
- Molecular Epidemiology and Bioinformatics – ISS – Rome, Italy
- Using SAS Proc GLM. University of Reading, UK
- Meta-analysis. University of Cambridge, UK
- Data Mining, Stanford University of California
- Executive Coaching (1 year program)

PROFESSIONAL COURSES TAUGHT

- Epidemiological Surveillance of HIV Infection and Sexual Transmitted Diseases (STD). ISS – Rome, Italy
  (Lectures on "Evaluation of Diagnostic Assays and Screening Programs")
- Statistical Methods in Epidemiology (Elementary). ISS
- Statistical Methods in Epidemiology (Advanced). ISS

- Applied Statistics in Bio-Medical Research (University of Siena – Faculty of Pharmacy – one quarter course)

LANGUAGE

- English fluent
- Italian (mother tongue)

PROGRAMMING KNOWLEDGE

Statistical Software

- SAS, Stata, IBM Modeler, R, RStudio, Pascal, Winbugs,
  BayesAdapt: BLRM dose finding, Bayesian approach for time to event data, Bayesian Adaptive Randomization (developed internally)

Reviewer of AIDS Journal (since May 2005)
Reviewer of European Journal of Cancer Care (since Jan 2006)
Reviewer of Pharmaceutical Statistics (since Nov 2016)
Reviewer of Epidemiology (since Jan 2017)

Dichiaro di essere a conoscenza che il presente curriculum vitae sarà pubblicato sul sito istituzionale dell'Ateneo, nella sezione “Amministrazione trasparente”, con le modalità e per la durata previste dal D.Lgs. 33/2013, art. 15.