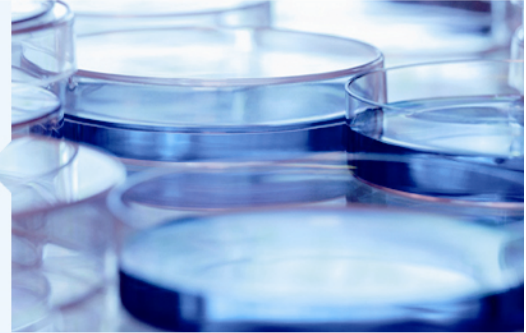


Trends and Innovations in Clinical Trial Statistics

April 21-23, 2014

Sheraton Imperial Hotel and Convention Center, Durham, North Carolina

*Co-organized by Center for Statistics in Drug Development at Quintiles and
Department of Statistics at North Carolina State University*



You are invited to attend the Trends and Innovations in Clinical Trial Statistics conference, a forum where presenters and panelists will discuss the current trends, innovation, and needs in clinical trial statistics.

The conference is aimed at a broad audience of statisticians and scientists involved in the design and analysis of clinical trials. It will feature presentations by biostatistics experts from regulatory agencies, biopharmaceutical industry, and academia on key topics in clinical trial statistics.

Keynote Speakers

Dennis Gillings, CBE, PhD

Executive Chairman, Quintiles

Lisa LaVange, PhD

Director of the Office of Biostatistics in the Office of Translational Sciences
Center for Drug Evaluation and Research, US Food and Drug Administration

Anastasios (Butch) Tsiatis, PhD

Gertrude Cox Distinguished Professor, Statistics Department, North Carolina State University

Conference Chairs

Marie Davidian, PhD

2013 President, American Statistical Association

William Neal Reynolds Professor, Department of Statistics, North Carolina State University

Alex Dmitrienko, PhD

Executive Director, Center for Statistics in Drug Development, Quintiles

Olga Marchenko, PhD

Vice President, Head of Center for Statistics in Drug Development, Quintiles

Organizing Committee

Marie Davidian, PhD

2013 President, American Statistical Association

William Neal Reynolds Professor, Department of Statistics, North Carolina State University

Alex Dmitrienko, PhD

Executive Director, Center for Statistics in Drug Development, Quintiles

Gary Koch, PhD

Professor, Department of Biostatistics, University of North Carolina at Chapel Hill

Olga Marchenko, PhD

Vice President, Head of Center for Statistics in Drug Development, Quintiles

José Pinheiro, PhD

Senior Director, Model-Based Drug Development, Janssen Research & Development

Martin Posch, PhD

Professor and Head of the Section of Medical Statistics at the Medical University of Vienna

Stephen Ruberg, PhD

Distinguished Research Fellow, Eli Lilly

Matilde Sanchez-Kam, PhD

Senior Director, Biostatistics and Data Management, Arena Pharmaceuticals

Frank Shen, PhD

Divisional Vice President, Data and Statistical Sciences, Global Pharmaceutical R&D, AbbVie

Névine Zariffa, M.Math.

Vice President, Biometrics and Information Science, AstraZeneca

DAY ONE: Monday, April 21, 2014

Pre-conference Short Courses:

- **Personalized Medicine and Dynamic Treatment Regimes:**
8a.m. –12 p.m. at Royal Room
Marie Davidian, PhD
2013 President, American Statistical Association
William Neal Reynolds Professor, Department of Statistics, North Carolina State University
Anastasios (Butch) Tsiatis, PhD
Gertrude Cox Distinguished Professor, Statistics Department, North Carolina State University
- **Advanced Methods in Oncology**
8a.m. –12 p.m. at Crown Room
Jason Fine, PhD
Professor, Department of Biostatistics, University of North Carolina at Chapel Hill
Anastasia Ivanova, PhD
Associate Professor, Department of Biostatistics, University of North Carolina at Chapel Hill
Olga Marchenko, PhD
Vice President, Head of Center for Statistics in Drug Development, Quintiles
- **Missing Data:**
1p.m. – 5p.m. at Bull Durham Room
Sonia Davis, PhD
Director, Collaborative Studies Coordinating Center
Professor of the Practice, Department of Biostatistics, University of North Carolina at Chapel Hill
Michael O'Kelly, PhD
Senior Director, Center for Statistics in Drug Development, Quintiles
- **Subgroup Identification and Analysis:**
1p.m. – 5 p.m. at Royal Room
Alex Dmitrienko, PhD
Executive Director, Center for Statistics in Drug Development, Quintiles
Eric Laber, PhD
Assistant Professor, Statistics Department, North Carolina State University
Ilya Lipkovich, PhD
Senior Director, Center for Statistics in Drug Development, Quintiles

DAY TWO: Tuesday, April 22, 2014

7:00 AM – 8:00 AM Conference Registration and Continental Breakfast

8:00 AM – 8:15 AM Opening Remarks

Marie Davidian, PhD

2013 President, American Statistical Association

William Neal Reynolds Professor, Department of Statistics North Carolina State University

Olga Marchenko, PhD

Vice President, Head of Center for Statistics in Drug Development (CSDD), Quintiles

8:15 AM – 9:30 AM Keynote Address

Dennis Gillings, CBE, PhD

Executive Chairman, Quintiles

Lisa LaVange, PhD

Director of the Office of Biostatistics in the Office of Translational Sciences

Center for Drug Evaluation and Research (CDER), US Food and Drug Administration (FDA)

Anastasios (Butch) Tsiatis, PhD

Gertrude Cox Distinguished Professor, Statistics Department, North Carolina State University

9:30 AM – 10:30 AM Session 1: New Trends in Clinical Trials

| Session Chairs | Presenter | Panel Discussion |
|---|--|---|
| Alex Dmitrienko, PhD <i>Executive Director, CSDD, Quintiles</i> | Névine Zariffa, M.Math. <i>Vice President, Biometrics and Information Science, AstraZeneca</i> | Sara Hughes, MSc <i>Vice President, Clinical Statistics, GlaxoSmithKline</i> |
| Olga Marchenko, PhD <i>Vice President, CSDD, Quintiles</i> | | Dominic Labriola, PhD <i>Vice President, Global Biometric Sciences, Bristol-Myers Squibb</i> |
| | | Lisa LaVange, PhD <i>Director of the Office of Biostatistics, CDER, US FDA</i> |
| | | Jerry Schindler, PhD <i>Vice President, Late Development Statistics, Merck</i> |
| | | Frank Shen, PhD <i>Divisional Vice President, Data and Statistical Sciences, AbbVie</i> |
| | | Anastasios (Butch) Tsiatis, PhD <i>Gertrude Cox Distinguished Professor, Statistics Department, North Carolina State University</i> |
| | | Névine Zariffa, M.Math. <i>Vice President, Biometrics and Information Science AstraZeneca</i> |

10:30 AM – 10:45 AM Break

10:45AM – 12:00 PM Session 2: Statistical Advances in Personalized Medicine and Tailored Therapeutics

| Session Chairs | Presenters | Panel Discussion |
|---|---|---|
| Ram Suresh, PhD <i>Vice President, Head of Oncology Biometrics, GlaxoSmithKline</i> | Robert Beckman, MD <i>Executive Director, Clinical Research Oncology, Daiichi Sankyo Pharmaceutical Development</i> | Keaven Anderson, PhD <i>Executive Director, Late Development Statistics, Merck</i> |
| Michael Colopy, PhD <i>Head of Global Statistical Policies & Practices, UCB Biosciences</i> | Marie Davidian, PhD <i>William Neal Reynolds Professor, Department of Statistics, North Carolina State University</i> | Robert Beckman, MD <i>Executive Director, Clinical Research Oncology, Daiichi Sankyo Pharmaceutical Development</i> |
| | | Marie Davidian, PhD <i>William Neal Reynolds Professor, Department of Statistics, North Carolina State University</i> |
| | | Erik Pulkstenis, PhD <i>Vice President, Clinical Biostatistics and Data Management, MedImmune</i> |
| | | Ram Suresh, PhD <i>Vice President, Head of Oncology Biometrics, GlaxoSmithKline</i> |

12:00 AM – 1:00 PM Lunch

(Lunch will be provided and included in registration)

1:00 PM – 2:15 PM Session 3: Multiplicity Issues in Clinical Trials

| Session Chairs | Presenters | Panel Discussion |
|--|--|---|
| <p>Walter Offen, PhD Global Head of Statistical Innovation, Data and Statistical Sciences, AbbVie</p> | <p>Alex Dmitrienko, PhD Executive Director, CSDD, Quintiles</p> | <p>Alex Dmitrienko, PhD Executive Director, CSDD, Quintiles</p> |
| <p>Michael O'Kelly, PhD Senior Director CSDD, Quintiles</p> | <p>Gary Koch, PhD Professor, Department of Biostatistics, University of North Carolina at Chapel Hill</p> | <p>Gary Koch, PhD Professor, Department of Biostatistics University of North Carolina at Chapel Hill</p> |
| | | <p>Alok Krishen, PhD Senior Director, Biostatistics, GlaxoSmithKline</p> |
| | | <p>Walter Offen, PhD Global Head of Statistical Innovation, Data and Statistical Sciences, AbbVie</p> |
| | | <p>Abdul Sankoh, PhD Head of Biostatistics, Vertex Pharmaceuticals</p> |

2:15 PM – 3:30 PM Session 4: Adaptive Designs in Drug Development

| Session Chairs | Presenters | Panel Discussion |
|--|--|---|
| <p>José Pinheiro, PhD Senior Director, Model-Based Drug Development, Janssen Research & Development</p> | <p>Brenda Gaydos, PhD Research Fellow, Head of Clinical Trial Optimization, Eli Lilly</p> | <p>Brenda Gaydos, PhD Research Fellow, Head of Clinical Trial Optimization, Eli Lilly</p> |
| <p>Jeff Maca, PhD Senior Director, CSDD, Quintiles</p> | <p>Estelle Russek-Cohen, PhD Director of the Division of Biostatistics, Center for Biologics Evaluation and Research (CBER), US FDA</p> | <p>Lisa LaVange, PhD Director of the Office of Biostatistics CDER, US FDA</p> |
| | | <p>Olga Marchenko, PhD Vice President, Head of CSDD, Quintiles</p> |
| | | <p>José Pinheiro, PhD Senior Director, Model-Based Drug Development (MBDD), Janssen Research & Development</p> |
| | | <p>Yili Pritchett, PhD Senior Director, Statistical Head for Infectious Disease, Immunology, Transplantation, Neuroscience and Pain Therapeutic Areas, Astellas Pharma</p> |
| | | <p>Estelle Russek-Cohen, PhD Director of the Division of Biostatistics CBER, US FDA</p> |

3:30 PM – 3:45 PM Break

(Afternoon snacks will be provided and included in registration)

3:45 PM – 5:00 PM Session 5: Data Mining and Subgroup Identification

| Session Chairs | Presenters | Panel Discussion |
|---|---|--|
| Eric Laber, PhD Assistant Professor, Statistics Department, North Carolina State University | Ilya Lipkovich, PhD Senior Director CSDD, Quintiles | Alan Hopkins, PhD Vice President, Biometrics, Theravance |
| Erik Pulkstenis, PhD Vice President, Clinical Biostatistics and Data Management, MedImmune | S. Stanley Young, PhD Assistant Director for Bioinformatics, National Institute of Statistical Sciences | Michael Kosorok, PhD W. R. Kenan, Jr. Distinguished Professor and Chair of Department of Biostatistics, University of North Carolina at Chapel Hill Eric Laber, PhD Assistant Professor, Statistics Department, North Carolina State University Ilya Lipkovich, PhD Senior Director, CSDD, Quintiles Cristiana Mayer, PhD Scientific Director, Statistical Modeling, Model- Based Drug Development, Janssen Research & Development S. Stanley Young, PhD Assistant Director for Bioinformatics, National Institute of Statistical Sciences |

5:00 PM – 5:45 PM POSTER SESSION

DAY THREE: Wednesday, April 23, 2014

7:00 AM – 8:00 AM Conference Registration and Continental Breakfast

8:00 AM – 9:15 AM Session 6: Missing Data

| Session Chairs | Presenters | Panel Discussion |
|--|---|---|
| Gary Koch, PhD <i>Professor, Department of Biostatistics, University of North Carolina at Chapel Hill</i> | Craig Mallinckrodt, PhD <i>Research Fellow, Strategy and Decision Sciences, Eli Lilly</i> | Sonia Davis, PhD <i>Director, Collaborative Studies Coordinating Center Professor of the Practice, Department of Biostatistics, University of North Carolina at Chapel Hill</i> |
| Yili Pritchett, PhD <i>Senior Director, Statistical Head for Infectious Disease, Immunology, Transplantation, Neuroscience and Pain Therapeutic Areas, Astellas Pharma</i> | Michael O'Kelly, PhD <i>Senior Director CSDD, Quintiles</i> | Gary Koch, PhD <i>Professor, Department of Biostatistics, University of North Carolina at Chapel Hill</i> |
| | | Roderick Little, PhD <i>Richard D. Remington Distinguished Professor of Biostatistics, Professor at Department of Statistics, University of Michigan, Ann Arbor</i> |
| | | Craig Mallinckrodt, PhD <i>Research Fellow, Strategy and Decision Sciences Eli Lilly</i> |
| | | Michael O'Kelly, PhD <i>Senior Director, CSDD, Quintiles</i> |

9:15 AM – 10:30 AM Session 7: Statistical Methods in Dose-Ranging Studies

| Session Chairs | Presenters | Panel Discussion |
|---|---|---|
| Seth Berry, PharmD <i>Strategic Director, CSDD, Quintiles</i> | Sergei Leonov, PhD <i>Senior Principal Scientist, AstraZeneca</i> | Seth Berry, PharmD <i>Strategic Director, CSDD, Quintiles</i> |
| Venkat Sethuraman, PhD <i>Executive Director, Global Biometric Sciences, Bristol-Myers-Squibb</i> | José Pinheiro, PhD <i>Senior Director, MBDD, Janssen Research & Development</i> | Valerii Fedorov, PhD <i>Vice President, Head of Predictive Analytics, Quintiles</i> |
| | | Weili He, PhD <i>Director, Late Development Statistics, Merck</i> |
| | | Sergei Leonov, PhD <i>Senior Principal Scientist, AstraZeneca</i> |
| | | José Pinheiro, PhD <i>Senior Director, MBDD, Janssen Research & Development</i> |
| | | Russell Reeve, PhD <i>Senior Director, CSDD, Quintiles</i> |

10:30 AM – 10:45 AM Break

10:45 AM – 12:00 PM Session 8: Analysis of Safety Data

| Session Chairs | Presenters | Panel Discussion |
|---|---|--|
| Qi Jiang, PhD <i>Executive Director, Global Biostatistical Science, Amgen</i> | Aloka Chakravarty, PhD <i>Director, Division of Biometrics VII, CDER, US FDA</i> | Bruce Binkowitz, PhD <i>Executive Director, Late Development Statistics, Merck</i> |
| Weili He, PhD <i>Director, Late Development Statistics, Merck</i> | Matilde Sanchez-Kam, PhD <i>Senior Director, Biostatistics and Data Management, Arena Pharmaceuticals</i> | Aloka Chakravarty, PhD <i>Director, Division of Biometrics VII CDER, US FDA</i> |
| | | Qi Jiang, PhD <i>Executive Director, Global Biostatistical Science, Amgen</i> |
| | | Estelle Russek-Cohen, PhD <i>Director of the Division of Biostatistics Center for Biologics Evaluation and Research (CBER), US FDA</i> |
| | | Matilde Sanchez-Kam, PhD <i>Senior Director, Biostatistics and Data Management, Arena Pharmaceuticals</i> |
| | | Venkat Sethuraman, PhD <i>Executive Director, Global Biometric Sciences, Bristol-Myers Squibb</i> |

12:00 PM – 1:00 PM Lunch

(Lunch will be provided and included in registration)

1:00 PM – 2:30 PM Session 9: Statistical Applications in Oncology Clinical Trials

| Session Chairs | Presenters | Panel Discussion |
|--|--|--|
| Jennifer Gauvin, PhD Manager, Clinical Statistics, GlaxoSmithKline | Keaven Anderson, PhD Executive Director, Late Development Statistics, Merck | Keaven Anderson, PhD Executive Director, Late Development Statistics, Merck |
| Bruce Binkowitz, PhD Executive Director, Late Development Statistics, Merck | Anastasia Ivanova, PhD Associate Professor, Department of Biostatistics, University of North Carolina at Chapel Hill | Aloka Chakravarty, PhD Director, Division of Biometrics VII CDER, US FDA Stephen George, PhD Professor of Biostatistics, Department of Biostatistics and Bioinformatics, Duke University School of Medicine Anastasia Ivanova, PhD Associate Professor, Department of Biostatistics, University of North Carolina at Chapel Hill Shannon Morris, MD PhD Senior Director, Early Development Oncology, GlaxoSmithKline Estelle Russek-Cohen, PhD Director of the Division of Biostatistics CBER, US FDA Guochen Song, PhD Strategic Director, CSDD, Quintiles |

2:30 PM – 2:45 PM Break

(Afternoon snacks will be provided and included in registration)

2:45 PM – 4:15 PM Session 10: Statistical Applications in Neuroscience Clinical Trials

| Session Chairs | Presenters | Panel Discussion |
|---|---|--|
| Michael D. Smith, PhD <i>Director, Clinical Statistics, Pfizer</i> | Sonia Davis, PhD <i>Director, Collaborative Studies Coordinating Center Professor of the Practice, Department of Biostatistics, University of North Carolina at Chapel Hill</i> | Anthony F. Abruzzini, PhD <i>Vice President, Global Strategic Drug Development, Quintiles</i> |
| Russell Reeve, PhD <i>Senior Director, Center for Statistics in Drug Development, Quintiles</i> | José Pinheiro, PhD <i>Senior Director, MBDD, Janssen Research & Development</i> | Sonia Davis, PhD <i>Director, Collaborative Studies Coordinating Center Professor of the Practice, Department of Biostatistics University of North Carolina at Chapel Hill</i> |
| | | Ilya Lipkovich, PhD <i>Senior Director, CSDD, Quintiles</i> |
| | | José Pinheiro, PhD <i>Senior Director, MBDD Janssen Research & Development</i> |
| | | Michael D. Smith, PhD <i>Director, Clinical Statistics, Pfizer</i> |
| | | Yili Pritchett, PhD <i>Senior Director, Statistical Head for Infectious Disease, Immunology, Transplantation, Neuroscience and Pain Therapeutic Areas, Astellas Pharma</i> |

4:15 PM – 4:30 PM Concluding Remarks

Alex Dmitrienko, PhD
Executive Director, Center for Statistics in Drug Development, Quintiles