

lukefostvedt

curriculum vitae

about

Updated March 2019
Pfizer, Inc.
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employment

2019-	Pfizer, Inc. - Associate Director Clinical Pharmacology / Pharmacometrics Global Product Development	La Jolla, CA
2014-2018	Pfizer, Inc. - Manager Clinical Pharmacology - Oncology Global Product Development	La Jolla, CA

education

2014	PhD Statistics	Iowa State University
2010	MS Statistics	Iowa State University
2008	BS Mathematics	University of Redlands

approved drugs

1. **DAURISMO® (glasdegib):** acute myeloid leukemia
- authored the PK-QTc analysis report included in the NDA
2. **LORBRENA® (lorlatinib):** ALK-positive non small cell lung cancer
- authored the QTc/PR analysis report included in the NDA
- Clinician for the mass balance study B7461004.
3. **VIZIMPRO® (dacomitinib):** EGFR-mutant non small cell lung cancer
- authored the Adverse Event PK/PD exposure response analysis report included in the NDA
- authored a PK/PD exposure response analysis report on the tumor size over time using a tumor growth inhibition model
- authored a PK/PD exposure response analysis report modeling the occurrence of dose-altering AEs and the effect of a 30 mg QD versus a 45 mg QD dosing regimen on tumor size
4. **MYLOTARG® (gemtuzumab ozogamicin):** CD33-positive acute myeloid leukemia
- authored a PK/PD exposure response analysis of safety and efficacy report included in the BLA
5. **BAVENCIO® (avelumab):** Merkel cell carcinoma
- authored a PK/PD exposure response analysis report on efficacy (OR, PFS, and OS) included in the BLA
6. **BESPONSA® (inotuzumab ozogamicin):** CD22-positive acute lymphatic leukemia
- author a PK/PD exposure response analysis evaluating efficacy and safety. Not included in the BLA

current submission work

1. **PF-04965842 (JAK1 inhibitor):** moderate to severe atopic dermatitis (planned July 2020 submission)
- PMx lead overseeing modeling and simulation deliverables.
- author of the PK/PD analysis of the Eczema Area and Severity Index (EASI) report.

2. **PF-06651600 (JAK3 inhibitor)**: moderate to severe alopecia areata
- supporting the modeling and simulation activities.

clinical trial roles

1. **Clinical Pharmacology Lead** (May 16' - Feb 19'): Study B7461006: A Phase 3 study comparing the efficacy of lorlatinib to crizotinib in treatment naive ALK-positive non small cell lung cancer.
Status: Fully Enrolled in February 2019. ClinicalTrials.gov Identifier: NCT03052608
2. **Clinican**: Study B7461004: Single-dose study of [¹⁴C] lorlatinib (PF-06463922) metabolism In healthy male volunteers.
Status: Completed and Reported. ClinicalTrials.gov Identifier: NCT02564562

publications

1. **Pharmacokinetic and pharmacodynamic modeling to support the re-approval of gemtuzumab ozogamicin**
Fostvedt, LK., Hibma, JE., Masters, JC., Vandendries E, Ruiz-Garcia, A.
Clinical Pharmacology and Therapeutics, 2019, *accepted*
2. **PharmTeX: a LaTeX-Based Open-Source Platform for Automated Reporting Workflow**,
Rasmussen CH, Smith MK, Ito K, Sundararajan V, Magnusson MO, Jonsson EN, Fostvedt L, Burger P, McFadyen L, Tensfeldt TG, Nicholas T.
The AAPS journal. 2018 May 1;20(3):52.
3. **Improving critical thinking growth for disadvantaged groups within elementary school science: A randomized controlled trial using the Science Writing Heuristic approach.**
Hand B, Shelley MC, Laugerman M, Fostvedt L, Therrien W.
Science Education, Volume 102, n4:693-710, July 2018
4. **Inotuzumab ozogamicin in adults with relapsed or refractory CD22-positive acute lymphoblastic leukemia: a phase 1/2 study**
DeAngelo, D.J., Stock, W., Stein, A.S., Shustov, A., Liedtke, M., Schiffer, C.A., Vandendries, E., Liao, K., Ananthkrishnan, R., Boni, J., Laird, A.D., Fostvedt, L., Kantarjian, H.M, Advani, A.S.,
Blood Advances, 2017, 1:1167-1180
5. **Why do simple algorithms for triangle enumeration work in the real world?**
Berry, J., Fostvedt, L., Nordman, D., Phillips, C., Seshadhri C., and Wilson, A.
Internet Mathematics, 11:6, 555-571, DOI: 10.1080/15427951.2015.1037030
6. **Fixed-Cost Versus Fixed-Risk Post-Election Audits in Iowa**
Hobbs, J., Fostvedt, L., Pintar, A., Rockoff, D., Kim, E., Griffiths, R.,
Chance, Volume 23, Issue 3, 2010
7. **Asymptotic results for configuration model random graphs with arbitrary degree distributions**
Fostvedt, L., Nordman, D., Wilson, A.
Tech. Rep. 2010-09, Iowa State University Department of Statistics Preprint, 2010

upcoming manuscripts

1. **Mass balance studies to characterize the metabolism of lorlatinib**
Stypinski, D., Fostvedt, LK., Pithavala, YK., James, L., Loi, CM. *planned for 2019*
2. **Multi-level quantile regression: a bayesian approach**
Fostvedt, LK., Shelley, M. *in preparation*
3. **Dose selection using tumor inhibition modeling of dacomitinib in first line non small cell lung cancer patients**
Fostvedt, LK., Nickens, DJ. *planned for 2019*
4. **PK/PD modeling of the effect of glasdegib on QTc prolongation in cancer patients**
Fostvedt, LK., Shaik, N., Martinelli, G., Wagner, A., Ruiz-Garcia, A. *planned for 2019*

5. **PK/PD modeling of the effect of lorlatinib on PR prolongation in cancer patients**
Fostvedt, LK., Pithavala, YK. *planned for 2019*
6. **PK/PD modeling of the safety of dacomitinib in first line non small cell lung cancer patients**
Fostvedt, LK., Mebus, C., Ruiz-Garcia, A., Tan, W. *planned for 2019*

presentations

1. **Population pharmacokinetic/pharmacodynamic evaluation of the effect of glasdegib exposure on cardiac repolarization (QT interval) in cancer patients.**
Fostvedt, LK., Shaik, N., Martinelli, G., Wagner, A., Ruiz-Garcia, A.
American Association of Cancer Research Annual Meeting, Atlanta, GA, 2019
2. **Metabolism of lorlatinib: a tale of two halves**
Stypinski, D., Fostvedt, LK., Vaz, A., Lam, J., Pithavala, YK., Loi, CM.
American Society for Clinical Pharmacology and Therapeutics Annual Meeting, 2019, Washington DC
3. **A tumor growth inhibition (TGI) model for long-term tumor measurements in ALK-positive NSCLC patients on crizotinib therapy**
D’Cunha, R., Nickens, DJ., Fostvedt, LK., Tan, W.
American Conference on Pharmacometrics. 2018, San Diego, CA.
4. **The pharmaceutical industry's polyamorous relationship with R**
Fostvedt, LK.
Enterprise Applications of the R Language, 2017, San Francisco, CA
5. **Shiny_ncappc, A Shiny App for Non-Compartmental Analysis (NCA)**
Fostvedt, LK., Hibma, J, Acharya, C.
American Society for Clinical Pharmacology and Therapeutics, 2016, San Diego, CA
6. **Using R to improve compliance in clinical trials**
Fostvedt, LK.
UseR! Conference, 2015, Aalborg, Denmark
7. **Data imputation in multi-level quantile regression**
Fostvedt, LK., Shelley, M.
Joint Statistical Meetings, 2014, Boston, USA, paper to be presented
8. **A longitudinal study of the effect of a new approach to teaching science based on multivariate mixed effects models**
Fostvedt, LK., Shelley, M., Baenziger, J., Laugerman, M., Gonwa-Reeves, C., Le, D., Hand, B., Therrien, W.
Joint Statistical Meetings, 2013, Montreal, Canada
9. **An inquiry-based approach to teaching science: A multilevel mediation model**
Shelley, M., Fostvedt, LK., Baenziger, J., Laugerman, M., Gonwa-Reeves, C., Le, D., Hand, B., Therrien, W.
Joint Statistical Meetings, 2013, Montreal, Canada
10. **Are Teachers to Blame?: Two-Level Quantile Regression of Teacher Quality on Student Performance**
Fostvedt, LK., Shelley, M., Baenziger, J., Laugerman, M., Gonwa-Reeves, C., Le, D., Hand, B., Therrien, W.
American Educational Research Association Annual Meeting, 2013, San Francisco, USA
11. **Effect of the Science Writing Heuristic learning approach on Future Achievement**
Fostvedt, LK., Shelley, M., Baenziger, J., Laugerman, M., Gonwa-Reeves, C., Le, D., Hand, B., Therrien, W.
National Association for Research in Science Teaching Annual International Conference, 2013, Puerto Rico
12. **Investigation of Cornell Critical Thinking Results as Affected by Science Writing Heuristic**
Fostvedt, LK., McGill, M., Shelley, M., Baenziger, J., Hand, B., Therrien, W.
European Association for Research on Learning and Instruction: SIG18, 2012, Zürich, Switzerland
13. **Assessing the Impact of a New Science Curriculum on Under- And Over-Achieving Students**
Fostvedt, LK., Shelley, M., Baenziger, J., Hand, B., Therrien, W.
Joint Statistical Meetings, 2012, San Diego, USA

14. **Student Learning and Inquiry-Based Science Instruction: Testing Effectiveness in a Randomized Trial**
Fostvedt, LK., Shelley, M., Hand, B., Therrien, W., Gonwa-Reeves, C., Baenziger, J., Villanueva, M.
American Educational Research Association Annual Meeting, 2012, Vancouver, B.C., Canada
15. **An Example of Performance Analysis for Network Community Detection**
Fostvedt, LK., Nordman, D., Wilson, A.
Joint Statistical Meetings, 2010, Vancouver, B.C., Canada
16. **Post-Election Audit Project**
Fostvedt, LK., Hobbs, J., Pintar, A., Rockoff, D., Kim, E., Griffiths, R.
Survey Working Group, Iowa State Univ., 2009
17. **The Pros of Pro Bono Statistical Consulting**
Fostvedt, LK. - Invited Panelist
Joint Statistical Meetings, 2009, Washington D.C., USA

tutorials

1. **Ordinal Regression using R**
Lead with Tim Nicholas, Ana Ruiz, and Dana Nickens
October 21, 2018 at ACoP9, San Diego, CA
2. **Using LaTeX for Regulatory Reports**
Internal courses provided in Groton, Cambridge, and La Jolla.

service

1. **Vice President of Professional Affairs, San Diego Chapter of the ASA, 2015-present**
 - Organized a local 1-day mini-conference (3/17, keynote speaker: Jessica Utts)
 - Responsible for organizing ASA travel courses
 - Responsible for organizing seminars (Sallie Keller 6/17, Hal Stern 2/18)
 - Participated in judging local high school projects for statistics awards
2. **Steering Committee Member, Joint ASA and ISoP Special Interest Group on Statistics and Pharmacometrics (SxP), 2019-present**
3. **Articles Reviewed**
 - **Journal of Veterinary Dentistry**
Editorial Board, Official statistics reviewer
Reviewed 7 articles
 - **Journal of Pharmacology and Toxicology**
Reviewed 1 article

professional memberships

current **American Statistical Association**
current **International Society of Pharmacometrics**

awards

2014	Data Visualization Contest (Track 1: 1st Place)	UseRI Conference
2008	GlaxoSmithKline Scholar Award	Iowa State University
2008	Jebe Fellowship	Iowa State University
2004	Presidential Scholarship	University of Redlands
2004	Achievement Award	University of Redlands

miscellanea

1. Proficient with R, NONMEM, LaTeX, prior experience with C++ and SAS
2. Letter to the Editor of the New York Times: **Using a Formula to Rate Teachers**, Page A24 of the New York edition, March 14, 2011.