

lukefostvedt

curriculum vitae

about

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Pfizer, Inc.
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employment

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

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. **abrocitinib (PF-04965842)**: a JAK1 inhibitor for the treatment of moderate to severe atopic dermatitis (planned August 2020 submission)
- PMx lead overseeing modeling and simulation deliverables.
- author of the PK/PD analysis of the Eczema Area and Severity Index (EASI) and Investigator's Global Assessment

report.

- author of the meta-analysis of the NCA parameters to assess dose proportionality and pharmacogenomic effects.

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. **Metabolism, excretion and pharmacokinetics of lorlatinib (PF-06463922) and evaluation of the impact of radiolabel position and other factors on comparability of data across two ADME studies**
Stypinski, D., Fostvedt, L., Lam, J., Vaz, A., Johnson, T.R., Boerma, J., Pithavala, Y.
Journal of Clinical Pharmacology, (accepted), 2020
DOI: <https://doi.org/10.1002/jcph.1621>
2. **Pharmacokinetic and pharmacodynamic modeling to support the re-approval of gemtuzumab ozogamicin**
Fostvedt, L.K., Hibma, J.E., Masters, J.C., Vandendries E, Ruiz-Garcia, A.
Clinical Pharmacology and Therapeutics, Volume 106, Number 5, 2019.
DOI: 10.1002/cpt.1500
3. **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. DOI: 10.1208/s12248-018-0202-0
4. **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 DOI: 10.1002/sce.21341
5. **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., Liau, K., Ananthkrishnan, R., Boni, J., Laird, A.D., Fostvedt, L., Kantarjian, H.M, Advani, A.S.,
Blood Advances, 2017, 1:1167-1180 DOI: 10.1182/bloodadvances.2016001925
6. **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
7. **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 DOI: 10.1080/09332480.2010.10739817
8. **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

manuscripts under review

1. **Dose selection using tumor inhibition modeling of dacomitinib in first line non small cell lung cancer patients**
Fostvedt, L.K., Nickens, D.J., Tan, Weiwei
submitted to Clinical Pharmacology and Therapeutics

2. **Exposure response modeling of the effect of glasdegib on cardiac repolarization in cancer patients.**
Fostvedt, LK., Shaik, N., Martinelli, G., Wagner, A., Ruiz-Garcia, A.
submitted to Cancer Chemotherapy and Pharmacology

manuscripts in development

1. **PK/PD modeling of the effect of lorlatinib on PR prolongation in cancer patients**
Fostvedt, LK., James, L., Pithavala, YK. *planned for 2020*
2. **PK/PD Modeling of EASI scores using a zero-inflated beta regression with abrocitinib.**
Fostvedt, LK, Valdez, H, Wojciechowski, J, Rojo, R, Wang, X, Malhotra, B. Nicholas, T. *planned for 2020*
3. **PK/PD Modeling of Thrombocytopenia for abrocitinib.**
Wojciechowski, J, Fostvedt, LK, Valdez, H, Rojo, R, Wang, X, Malhotra, B. Nicholas, T. *planned for 2020*
4. **The effect of CYP2C19 and CYP2C9 Allele variants on abrocitinib PK.**
Fostvedt, LK, Dowty, M, Johnson, J, Wang, X, Malhotra, B. Nicholas, T. *planned for 2020*
5. **Multi-level quantile regression: a bayesian approach**
Fostvedt, LK., Shelley, M. *in preparation*
6. **A multi-level mediation model evaluating the effect of teacher fidelity on student's critical thinking scores.**
Hand B, Shelley MC, Laugerman M, Fostvedt L, Therrien W.
planned to submit to Educational and Psychological Measurement

presentations

1. **Zero-inflated beta regression exposure-response modeling of the Eczema Area and Severity Index for patients taking abrocitinib**
Fostvedt, LK., Wojciechowski, J., Wang, X, Malhotra, B., Valdez, H., Rojo, R., Nicholas, TJ.
American Conference on Pharmacometrics. 2020, Denver, CO.
2. **Development of a Tumor Growth Inhibition Model for Dacomitinib in Patients with EGFR-Mutant Non-Small Cell Lung Cancer**
Nicken, DJ. Fostvedt, LK., Tan, W.
American Conference on Pharmacometrics. 2020, Denver, CO.
3. **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
4. **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
5. **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.
6. **From Here....Anywhere: What might the future hold after Redlands.**
University of Redlands, 2017. Presentation at my alma mater to current math and physics majors.
7. **The pharmaceutical industry's polyamorous relationship with R**
Fostvedt, LK.
Enterprise Applications of the R Language, 2017, San Francisco, CA
8. **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

9. **Using R to improve compliance in clinical trials**
Fostvedt, LK.
UseR! Conference, 2015, Aalborg, Denmark
10. **Data imputation in multi-level quantile regression**
Fostvedt, LK., Shelley, M.
Joint Statistical Meetings, 2014, Boston, USA, paper to be presented
11. **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
12. **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
13. **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
14. **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
15. **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
16. **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
17. **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
18. **An Example of Performance Analysis for Network Community Detection**
Fostvedt, LK., Nordman, D., Wilson, A.
Joint Statistical Meetings, 2010, Vancouver, B.C., Canada
19. **Post-Election Audit Project**
Fostvedt, LK., Hobbs, J., Pintar, A., Rockoff, D., Kim, E., Griffiths, R.
Survey Working Group, Iowa State Univ., 2009
20. **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. **Steering Committee Member, Joint ASA and ISO-P Special Interest Group on Statistics and Pharmacometrics (SxP), 2019-present**

- SIG representative for the ACoP11 scientific programming review committee

2. **Vice President of Professional Affairs, San Diego Chapter of the ASA, 2015-2019**

- 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

3. **Articles Reviewed**

- **Journal of Veterinary Dentistry**
Editorial Board, Official statistics reviewer
Reviewed 8 articles
- **Journal of Pharmacology and Toxicology**
Reviewed 1 article

professional memberships

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

awards

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|------|---|------------------------|
| 2014 | Data Visualization Contest (Track 1: 1st Place) | UseR! 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. Subject Matter Expert within the department for R, LaTeX, and general model script debugging.
3. 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.