

lukefostvedt

curriculum vitae

about

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employment

2022-	Pfizer, Inc. - Director Clinical Pharmacology / Pharmacometrics	Phoenix, AZ
2019-2021	Pfizer, Inc. - Associate Director Clinical Pharmacology / Pharmacometrika	Cambridge, MA
2014-2018	Pfizer, Inc. - Manager Clinical Pharmacology - Oncology	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. **CIBINQO®(abrocitinib):** moderate to severe atopic dermatitis
- pharmacometrics lead for the program responsible for PMx components in the submissions and regulatory interactions worldwide.
2. **DAURISMO®(glasdegib):** acute myeloid leukemia
- authored the PK-QTc analysis report included in the NDA
3. **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.
4. **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
5. **MYLOTARG®(gemtuzumab ozogamicin):** CD33-positive acute myeloid leukemia
- authored a PK/PD exposure response analysis of safety and efficacy report included in the BLA
6. **BAVENCIO®(avelumab):** Merkel cell carcinoma
- authored a PK/PD exposure response analysis report on efficacy (OR, PFS, and OS) included in the BLA
7. **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 development/submission work

1. **etrasimod**: an oral, selective, sphingosine 1-phosphate receptor modulator.
2. **CIBINQO® (abrocitinib)**: a JAK1 inhibitor for the treatment of moderate to severe atopic dermatitis (Approved by EMA, FDA, MHRA, Swiss Health, Health Canada, PMDA,)
 - PMx lead overseeing modeling and simulation deliverables for global submissions and query responses.
 - 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.
 - author of the joint parent/metabolite population PK model report.

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. **Tumor growth inhibition modeling to support the starting dose of dacomitinib**
Fostvedt, LK., Nickens, DJ., Tan, W, Parivar, KP
Clinical Pharmacology and Therapeutics: Pharmacometrics & Systems Pharmacology, 2022, *accepted*
DOI: 10.1002/psp4.12841
2. **Population pharmacokinetic-pharmacodynamic modeling of platelet time-courses following administration of abrocitinib**
Wojciechowski, J., Malhotra, BK., Wang, X., Fostvedt, LK., Valdez, H., Nicholas, T.
accepted by British Journal of Clinical Pharmacology, 2022, DOI: 10.1111/bcp.15334
3. **Population pharmacokinetics of abrocitinib in healthy individuals and patients with psoriasis or atopic dermatitis**
Wojciechowski, J., Malhotra, BK., Wang, X., Fostvedt, LK., Valdez, H., Nicholas, T.
Clinical Pharmacokinetics, 2022, DOI: 10.1007/s40262-021-01104-z
4. **Exposure response modeling of the effect of glasdegib on cardiac repolarization in cancer patients.**
Fostvedt, L., Shaik, N., Martinelli, G., Wagner, A., Ruiz-Garcia, A.
Expert Review of Clinical Pharmacology, Volume 14, Number 9, 927-935, 2021, DOI: 10.1080/17512433.2021.1925538
5. **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.
The Journal of Clinical Pharmacology, Volume 60, Number 9, 1254-1267, 2020 DOI: 10.1002/jcph.1621
6. **Pharmacokinetic and pharmacodynamic modeling to support the re-approval of gemtuzumab ozogamicin**
Fostvedt, L., Hibma, J., Masters, J., Vandendries E, Ruiz-Garcia, A.
Clinical Pharmacology and Therapeutics, Volume 106, Number 5, 2019. DOI: 10.1002/cpt.1500
7. **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
8. **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

9. **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. DOI: 10.1182/bloodadvances.2016001925
10. **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
11. **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
12. **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. **A multi-level mediation model evaluating the effect of teacher fidelity on student's critical thinking scores.**
Fostvedt L, Shelley MC, Laugerman M, Hand B
revised and resubmitted to Journal of Experimental Education
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.
submitted to Clinical Pharmacology and Therapeutics: Pharmacometrics & Systems Pharmacology

manuscripts in development

1. **The Effect of CYP2C19 and CYP2C9 Allele Variants on Abrocitinib Pharmacology.**
Fostvedt, LK, Dowty, M, Johnson, J, Wang, X, Malhotra, B. Nicholas, T. *planned for 2022*

presentations

presenter in **bold**

1. **PK/PD modeling of abrocitinib exposure and peak pruritus NRS score**
Fostvedt, LK., Nicholas, T., Valdez, H., Wang, Y.
American Conference on Pharmacometrics. 2022.
2. **Population PK analysis of somatogron using a bayesian approach with informative priors.**
Pei, X., Niu, T., Fostvedt, LK.,Korth-Bradley, J.
American Conference on Pharmacometrics. 2022.
3. **ERmod: a semi-automated exposure-response (E-R) analysis and reporting tool to support decision making while increasing time and cost savings in drug development**
Irby, D., Fostvedt, LK, Nickens, DJ., Nicholas, T.
American Conference on Pharmacometrics. 2022.
4. **Integrated parent/metabolite population PK model of abrocitinib to support dose recommendations**
Fostvedt, LK., Malhotra, BK., Wang, X., Valdez, H., Nicholas, T.
American Conference on Pharmacometrics. 2021, Virtual Conference.
5. **Application of longitudinal exposure-response modelling to support dacomitinib starting dose in patients with EGFR-mutation positive NSCLC**

Fostvedt, LK., Nicken, DJ., **Tan, W.**

World Conference on Lung Cancer, 2021, Virtual Conference.

6. **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, T.
American Conference on Pharmacometrics. 2020, Virtual Conference.
7. **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, 2020, Virtual Conference.
8. **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
9. **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
10. **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.
11. **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.
12. **The pharmaceutical industry's polyamorous relationship with R**
Fostvedt, LK.
Enterprise Applications of the R Language, 2017, San Francisco, CA
13. **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
14. **Using R to improve compliance in clinical trials**
Fostvedt, LK.
UseR! Conference, 2015, Aalborg, Denmark
15. **Data imputation in multi-level quantile regression**
Fostvedt, LK., Shelley, M.
Joint Statistical Meetings, 2014, Boston, USA, paper to be presented
16. **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
17. **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
18. **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
19. **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

20. **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
21. **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
22. **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
23. **An Example of Performance Analysis for Network Community Detection**
Fostvedt, LK. Nordman, D., Wilson, A.
 Joint Statistical Meetings, 2010, Vancouver, B.C., Canada
24. **Post-Election Audit Project**
Fostvedt, LK. Hobbs, J., Pintar, A., Rockoff, D., Kim, E., Griffiths, R.
 Survey Working Group, Iowa State Univ., 2009
25. **The Pros of Pro Bono Statistical Consulting**
Fostvedt, LK. - Invited Panelist
 Joint Statistical Meetings, 2009, Washington D.C., USA

tutorials

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

service

1. **Steering Committee Member, Joint ASA and ISoP Special Interest Group on Statistics and Pharmacometrics (SxP), 2019-present**
 - Co-Chair of SxP (Statistics Chair) 2021-present
 - SIG representative for the ACoP12 and ACoP13 awards committee
 - SIG representative for the ACoP11 scientific programming review committee and awards 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 13 articles

- **Journal of Pharmacology and Toxicology**
Reviewed 1 article
- **Clinical Pharmacology and Therapeutics: Pharmacometrics & Systems Pharmacology**
Reviewed 3 articles

4. Student Mentoring

- Summer 2021 Mentor for Yuchen Wang.
Topic: PK/PD modeling using Stan vs. NONMEM. Developed a PK/PD modeling of Pruritus.
- Summer 2017 Co-mentor to Ronilda D’Cunha. Work presented at ACoP9.
Topic: Tumor Growth Inhibition Modeling using NONMEM and R.

professional memberships

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

awards

- | | | |
|------|---|------------------------|
| 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. High proficiency with R (including Shiny), NONMEM, LaTeX,
2. Subject Matter Expert within the department for R, LaTeX, and general model script debugging.