

Melanie Poulin-Costello

A Biostatistician with over 20 years of drug development experience across 3 major companies. My career goals stem from a passion for having an impact on others: staff, colleagues, leaders, stakeholders. I am most satisfied when staff succeed, overcome obstacles, and try new things.

Work Experience

Roche

Director Biostatistics

June 2017 to present

Cross-TA Manager

Oncology Biostatistics oversight for skin/rare diseases (LASR)

Mississauga Biostatistics Site Head

Senior¹ Statistical Scientist – oncology (Alectinib)

July 2016 to June 2017

Amgen

2007 to 2016

Senior Manager, Biostatistics – various therapeutic areas

Country Study Statistician with Health Technology Assessment focus

Managed team of consultants

Bayer

1999 to 2007

Senior Statistician – various therapeutic areas

Global Statistical Project Leader for Nexavar© in oncology

University of Toronto, Dalla Lana School of Public Health

2019 to present

Adjunct Professor, Biostatistics

English Teacher in China; Statistics Consultant for BC Ministry of Forests;

1993 - 1999

Teaching Statistics (UVic, Humber College); stay-at-home Mother

People-related experience and skills

- Successfully coaching, mentoring and managing biostatisticians across various diseases, molecules, skills sets and levels of experience
- Sponsored Biostatistics focus area of People and Culture
- Co-lead for People and Product Leader Success Work Product Team
- Career Coach for Biometrics Evolution
- Grew Mississauga Biostatistics site from 8 to >40 statisticians (PD, NCB, xRED, USMA)
- Hiring patient reported outcome scientists, statistical programming analysts, student interns
- Successfully coached staff from does-not-meet-expectations and multiple performance challenges to exceeding expectations and improved performance
- Managed consultants and CRO staff in multiple, concurrent projects
- Led cross-functional and cross-regional project teams for clinical trials, Health Technology Assessment and internal process improvements (eg SREP automation)
- Strategically balanced corporate needs and goals with development objectives
- Organized fun, social events for staff locally and globally (eg Random Virtual Chats)
- Listened when staff had difficulties, and worked together to identify and implement solutions
- Advocated for good mental health practices
- Networking to connect people and teams together to identify synergies and efficiencies in projects

¹ This job is now re-leveled to *Principal Statistical Scientist*

Project-related experience and skills

- Authored many protocols, statistical analysis plans and clinical study reports for clinical trials Phases 1 – 4 across multiple therapeutic areas
- Reviewer of Clinical Development Plans, protocols, regulatory documents, templates, SOPs and guidance documents
- Analyzed and published clinical trial and observational research results in peer reviewed journals
- Presented explanations of statistical concepts as training and in discussion such that non-statisticians enjoyed
- Demonstrated statistical competence, tact and patience in protocol development and results dissemination
- Strategically navigated complexities of TransCelerate Data Sharing initiative within Roche and with external partners (lead for TransCelerate's Operations and Governance subteam)
- Worked with Data Monitoring Committees, Contract Research Organizations, Advisory Boards, Investigator Initiated Studies
- Positively liaised and networked between medical experts, Global Development Leaders, physicians and statisticians
- Participated in strategic conversations and written communication with peers, stakeholders, TransCelerate, investigators, Health Canada, EFPIA, and academic statisticians
- Often engaged various audiences as a confident public speaker
- Successfully led organization of events (eg Biostatistics Manager's Meeting with Chris Hadfield 2019; External Controls Where Next 2020)
- Experienced in various analysis techniques including time to event analyses, multivariable regression methods, missing data methods

Education

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| Master's of Science in Statistics , University of Victoria
<i>Thesis: People-caused Forest Fire Prediction</i> | 1993 |
| Bachelor of Mathematics , University of Waterloo
<i>Major: Joint Honours Computer Science and Statistics.</i> | 1990 |

Recent Relevant Professional Development:

- Coaches Rising Summit, 2020
- Kinesis Leadership Circle Profile, 2020
- Agile Training 2020
- Myers Briggs Type Indicator, 2016 (INFP)

Professional Associations

- PSI – Statisticians in the Pharmaceutical Industry 2019 - present
- Statistical Society of Canada
 - Professional Statistician (PStat #009) from Statistical Society of Canada
- Secretary of The Applied Biostatistics Association (TABA) of Greater Toronto 2001-2006

Other Interests

- Painting and drawing
- Cycling, canoeing, hiking