

Biostatistics & Epidemiology

Expertise & Resources in
Therapeutic Products Directorate and
Biologics & Genetic Therapies Directorate

Health Products and Food Branch
Direction générale des produits de santé et des aliments

Where We Are Situated

- ! Office of Science – Therapeutic Products Directorate (TPD)
- ! Centre for Biologic Research - Biologics & Genetic Therapies Directorate (BGTD)

Our Main Responsibility

Provision of Consulting Service
and Expert Advice in Biostatistics
and Epidemiology, and R&D

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Our Main Goal

To ensure that only valid and quality information are used in the risk and benefit analysis of therapeutic products, and that appropriate statistical methods are used in their analysis and interpretation

Health Products and Food Branch

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What Do We Do?

- ! Directly support the product review process
- ! Participate in the preparation of guidelines
- ! Deliver training courses in Biostatistics and Epidemiology
- ! Develop, promote and implement Risk Management models and practices
- ! Develop quantitative methods for product review

What Do We Do?

- ! Support laboratory function in the design, analysis and interpretation of experiments
- ! Provide consultation services for pre- and post-market issues
- ! Participate on key committees and working groups

Pick An Example

- ! Directly support the product review process
 - Provide expert advice on all aspects of trial design, analysis, and interpretation of results
 - Communication and correspondence with sponsor: in meetings, wording of questions to sponsor for clarification of submitted information, wording of prescription information and claims in product monographs
 - In case of dispute, reanalysis of data

Pick Another One

- ! Participate in the preparation of guidelines
 - Bioequivalence
 - Metered-dose inhalers
 - Nasal corticosteroid spray
 - Steroidal oral contraceptives

Who Do We Have?

! TPD

- 1 Senior Consulting Statistician
- 5 Biostatisticians

! BGTD

- 1 Senior Consulting Statistician
- 3 Biostatistician



Health Santé
Canada Canada

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Who Are Our Clients?

- ! Management
 - Special projects and assignments
- ! Research scientists
 - Experimental design and analysis
 - Analytical method validation
- ! Drug, biologic, and medical device evaluators
 - Clinical trials design and analysis
 - Bioequivalence
 - Pre-clinical and toxicology studies
 - Chemistry and manufacturing
- ! External - Various stakeholders