

# 2022 Update of TG5 (Design)

- Aim: Provide accessible and accurate guidance on the design of observational studies
- Through: TG5 studies and collaborative studies

# TG5 Members

Name	Affiliation	Interests
Suzanne Cadarette (Co-Chair)	University of Toronto	Pharmacoepidemiology
Gary Collins	University of Oxford	Prognostic modeling; EQUATOR
Mitchell Gail (Co-Chair)	National Cancer Institute, USA	Epi design/analysis; absolute risk
Thomas Lumley	University of Auckland	Sampling, two-phase designs, etc
Paola Rebora	University of Milano-Bicocca	Two-phase designs, survival methods, etc
Peggy Sekula	University of Freiburg	Prognostic modeling; kidney disease
Neus Valveny	TFS Health Sciences, Barcelona	Clinical studies, rare adverse events, etc.
Elisabeth Williamson	London School of Hygiene and Tropical Medicine	Electronic Health Records; propensity

New members

# Papers

Gail MH, Altman DG, Cadarette SM, Collins G, Evans SJ, Sekula P, Williamson E, Woodward M. **Design choices for observational studies** of the effect of exposure on disease incidence. *BMJ Open*. 2019 Dec 9;9(12):e031031. doi:10.1136/bmjopen-2019-031031. PubMed PMID: 31822541.

Gail MH, Cadarette S. Strengthening analytical thinking for observational studies (STRATOS): Introducing the design topic group (TG5). *Biometric Bulletin*. 2019; 36 (2); 12-13.

Georg Heinze, Anne-Laure Boulesteix, Daniela Dunkler, Mitchell H. Gail, Katherine J. Lee, Ben van Calster, Michael Wallace, Willi Sauerbrei. **STRengthening Analytical Thinking for Observational Studies (STRATOS): Guidance for analysts with limited statistical knowledge**. *Biometric Bulletin* (in press)

Lola Étiévant and Mitchell H. Gail. Inference for relative hazard and covariate-specific pure risk estimated from stratified and unstratified case-cohort data (submitted)

## **In progress**

Peggy Sekula, Inga Steinbrenner, Ulla T. Schultheiss, Neus Valveny, Peola Rebora, Richard Riley, Gary Collins, Willi F. Sauerbrei, Mitchell H. Gail for topic group 5 of the STRATOS Initiative. **Design Aspects for Prognostic Factor Studies**

# Projects in Development or in Prospect

- Design and analysis of study of the effect of chronic medical exposure on risk of dichotomous outcome. E.g. Risk of hip fracture in patients receiving drugs for type II diabetes. Led by Suzanne Cadarette
- Design and analysis of outcomes based on electronic health records. Elizabeth Williamson, Paola Rebora, Suzanne Cadarette and Neus Valveny. Paola is interested in two-phase sampling as a component, a topic of interest to Thomas Lumley and Mitchell. Led by ???
- Design and analysis of studies to detect rare adverse outcomes, such as Guillain-Barré Syndrome following vaccination. Led by Neus Valveny.
- Level 1 paper on sample size calculations for observational studies. Led by Neus Valveny.

# Other TG5 Activities

- Teleconferences x 3
- Website development Suzanne Cadarette
- Participation in panels or other groups
  - Publications panel Mitchell Gail
  - Steering Committee Mitchell Gail
- Presentations and meetings
  - Paola Rebora is on the Planning Committee for the ISCB meeting in Milan in August, 2023. She will also attend.

# Promoting Leadership of TG5 Projects

- Find projects led by TG5 members in the course of their regular duties and try to encourage TG5 participation
- Regular TG5 discussions to develop a TG5 research agenda and look for TG5 members to lead
- Collaborations with other TGs

END