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Introducing the Causal Inference Special Interest Group Sponsored by PSI and EFSPi

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PURPOSE

- Apply advances in causal inference methodology to address industry applications in RCT's, while considering the framework of ICH, e.g. E9(R1), and guidelines from health authorities;
- Promote a causal perspective on the data generating mechanisms in RCTs to facilitate selection of the appropriate methodology that best addresses the scientific question of interest;
- Promote careful selection of estimators for the estimand of interest;
- Promote evaluation of causal inference assumptions via sensitivity analyses;
- Foster discussion on the practical implications of non-collapsibility, accounting for baseline covariate (including marginal versus conditional estimands), selection bias, etc.

OBJECTIVES

- Create a community of best practices for the application of causal inference thinking and application;
- Propose invited sessions to the scientific conferences and invited seminars throughout the year;
- Development a white paper on the implementation and application of causal inference methodology and thinking in the analysis of RCT data;
- Publish peer-reviewed scientific manuscripts demonstrating causal inference methodologies and applications in RCTs
- Build consensus on best practices for causal inference in RCTs
- Develop tools and strategies for communicating causal concepts to non-statistical colleagues

BECOMING A MEMBER

The working group is open for all interested who are working in clinical trials and commit to actively contribute to this SIG: i.e. who are willing to contribute to prepare materials, sharing experience for exemplary use, etc. Membership is limited to at most 2 people per institution.

Applications including a brief biography and short description on motivation will be considered. Please send applications as per to Kelly Van Lanker (Kelly.VanLancker@UGent.be) and Sanne Roels (sroels4@ITS.JNJ.com)

ACTIVITIES

Upcoming Webinar

Joint PSI/EFSPi Casual Inference SIG Webinar:
Opportunities in applying a causal inference framework during the analysis of an RCT

- Tuesday, November 19th. 15:00-16:30 CET
- Location: Online via Zoom
- The event is free to both Members of PSI and Non-Members

Monthly Group Meetings

- The SIG organizes monthly group meetings to discuss various topics in causal inference.
- The goal of these meetings is to build an inclusive learning environment where we can share knowledge to bring back to our individual institutions.
- To choose the topics for the group meetings, we first conducted a survey, and members were asked to vote on the topics of interest. The poll results are presented in Table 1.

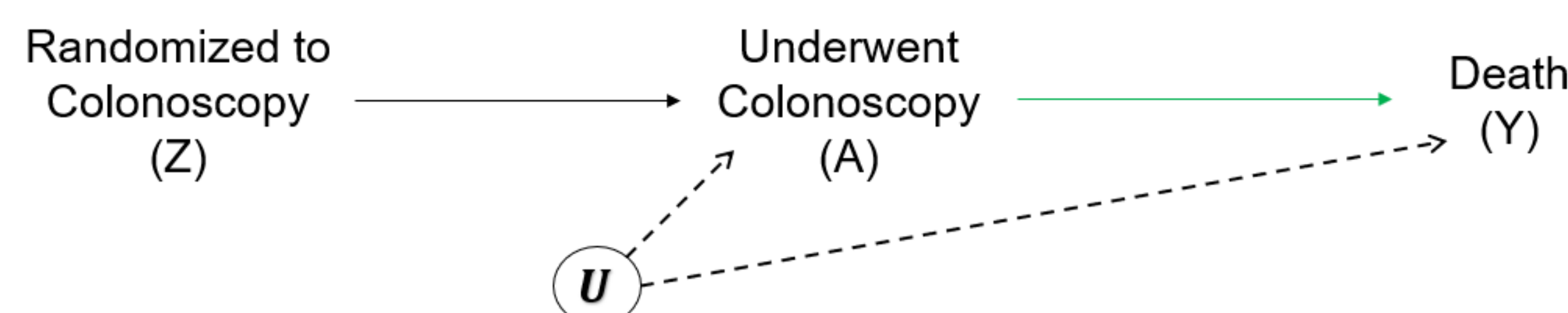
Conference and Workshop Ambitions

- EUROCIM 2025 - Ghent, Belgium
- ISCB 2025 - Basel, Switzerland
- PSI 2025

A CLINICAL TRIAL EXAMPLE

Scientific question

Does undergoing colonoscopy have a causal effect on risk of death?



Topic	Votes
Mediation analysis and its role in drug development	10
Understanding of data generating mechanism (DAG, SWIGs)	6
Analyses conditioned on post-baseline events, estimation strategies for hypothetical and principal stratum estimand and sensitivity analyses	6
Baseline covariate adjustment - marginal & conditional estimands	5
Extrapolation to other populations and questions around the degree of extrapolation / transportability	5
Sensitivity analyses for identification assumptions	2
Use of external data to clinical trials: e.g., external control arms, hybrid design	2
Alternative inferential approaches to causal inference	1
Approaches for missing (observed) data, linking to implementation in estimation	1
Estimating heterogeneous (conditional) treatment effects	1

Table 1. Voting results on potential causal topics for SIG

- Would the intention-to-treat analysis identify a causal effect? i.e., $E[Y | Z=1]$ vs. $E[Y | Z=0]$
- Would the per-protocol analysis identify a causal effect? i.e., $E[Y | Z=A=1]$ vs. $E[Y | Z=A=0]$
- Would either of these analysis answer the scientific question?

CORE LEADERSHIP TEAM



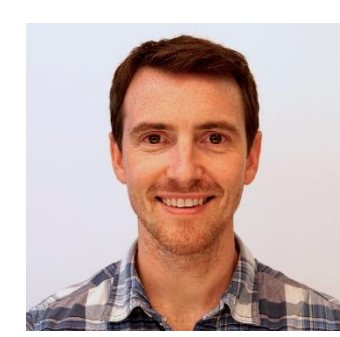
Alex Ocampo
Novartis, Switzerland
Interests: Mediation Analysis, Causal Graphs, Survival Analysis, Semiparametric Theory



Sanne Roels
Johnson & Johnson, Belgium
Interests: Covariate adjustment, Surrogate markers, Causal inference



Kelly Van Lanker
Ghent University, Belgium
Interests: Covariate Adjustment, Causal Inference, Treatment Effect Transportability



Tim Morris
University College London, UK
Interests: Missing Data & Causal Inference, Conditional vs. Marginal Estimands



Jesper Madsen
Novo Nordisk, Denmark
Interests: Mediation, Dynamic Path Analysis

SIG MEMBERS

Our new SIG welcomes those from industry, public health, academia and regulators and includes the following members:

- Yannis Jemai, Cytel, USA
- Hongseok Kim, CSL Behring
- Baldur Magnusson, UCB, CH
- Hege Michiels, Argenx, Belgium
- Simon Newsome, Novartis, CH
- Silvia Noirjean, GSK, Spain
- Jim Rogers, Metrum Research, USA
- Kasper Rufibach, Merck, CH
- Tina Sotto, J&J, Belgium

Our SIG was formed this year and is thus actively recruiting more members.

Please refer to QR code to join!