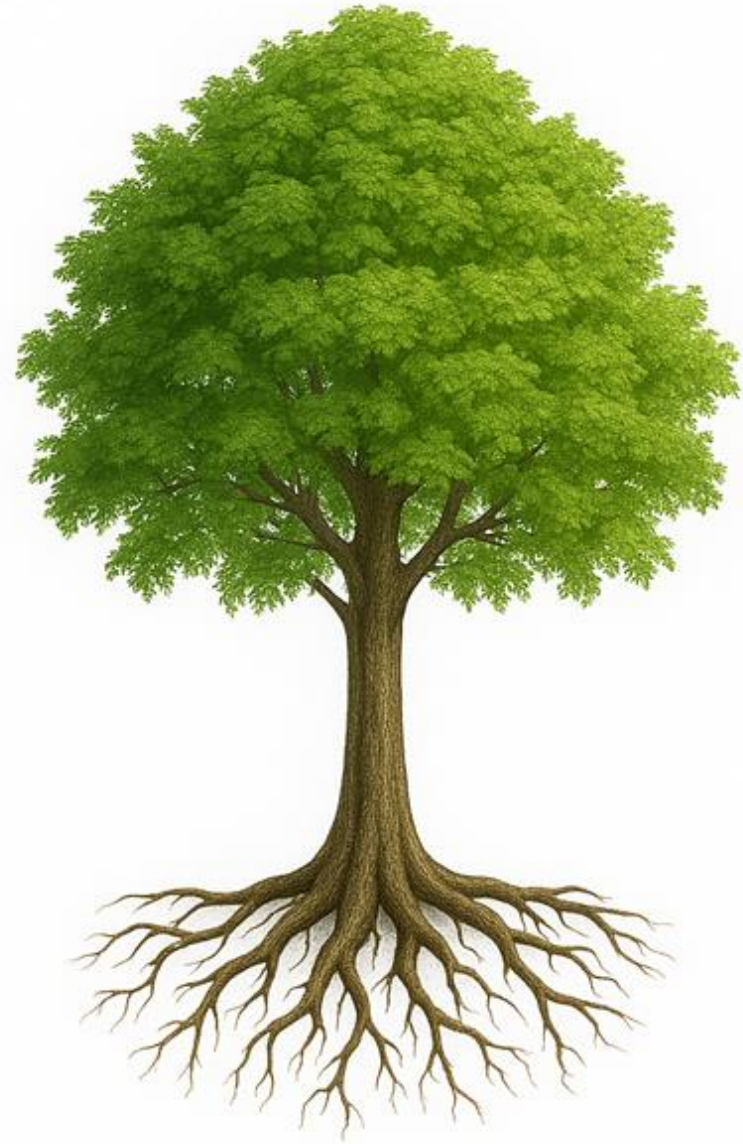# From local chapters to global guidelines: A journey of collaborative progress

Frank Bretz (Novartis)
Basel – October 16, 2025
Acknowledgment: Dominik Heinzmann

Roadmap

- Global impact

- Regional platforms

- Local seeds

The mechanics of local impact

- Small rooms, plenty discussions, high trust

- Springboard to sustainable networks

- Experimenting in safe spaces before scaling up

- Local seminar topics maturing into recurring themes

- Early signals that methods could travel

Community roots and early leadership

ROeS

The first public steps

Austro-Swiss Region of the International Biometric Society

- 1999: 'Longitudinal analysis in clinical research,' ROeS Seminar ... ...

- Since 2002: ROeS Board member

- 2006-2007: ROeS President
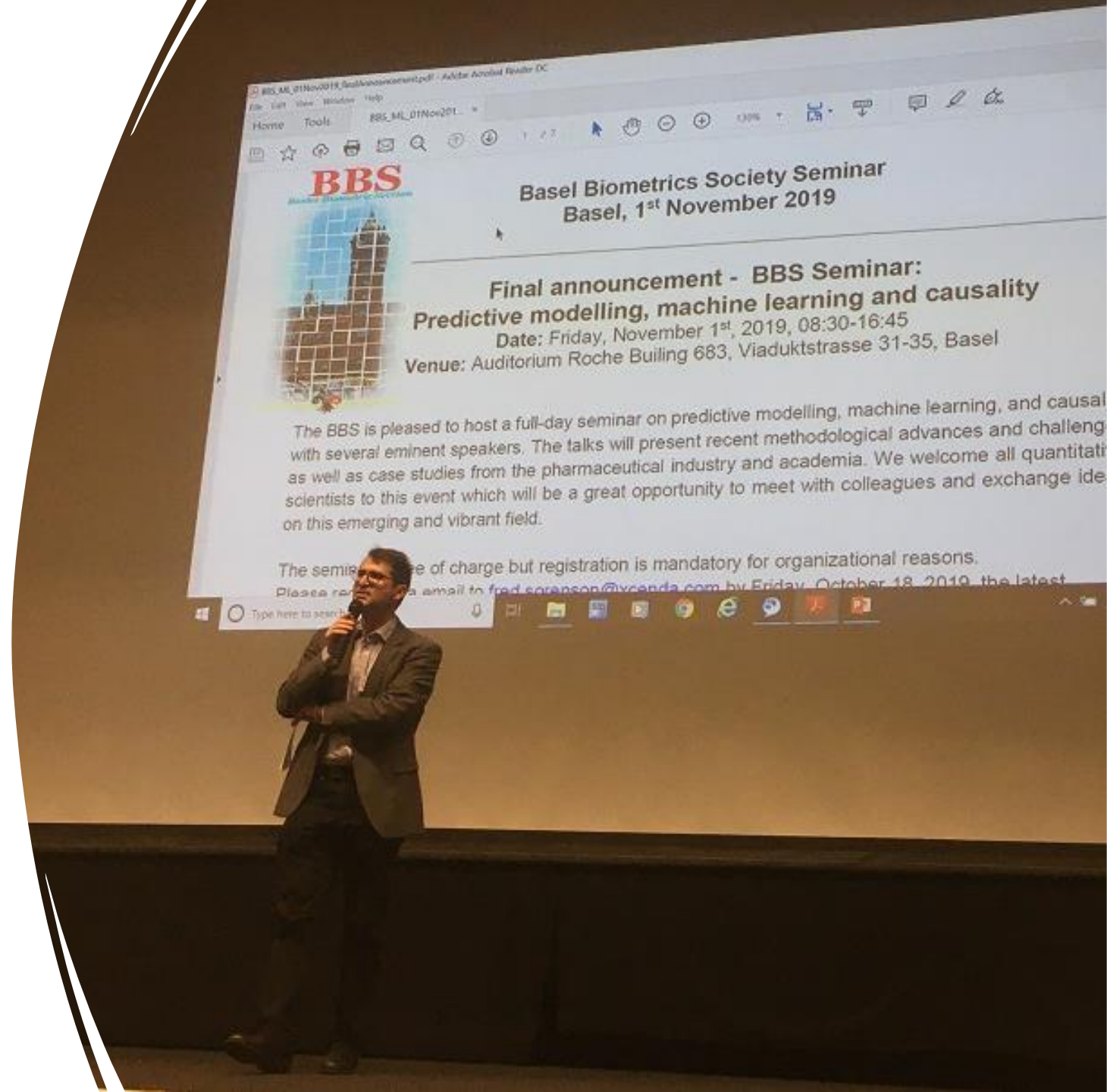
Tuesday, 28 September 1999

9:00 - 12:15	**Session 3:Generalised Estimating Equations (GEE) in Epidemiology and Clinical Research** Chair: U. Ackermann-Liebrich, University Basel
9:00	K. Y. Liang, Johns Hopkins University, Baltimore: GEE: Theoretical background and Biomedical Applications
10:00	J. Schwartz, Harvard University, Boston: GEE- and Mixed Models in Environmental Epidemiology
10:40	Coffee break
11:10	C. Schindler, University Basel: Application of GEE in Epidemiological Diary Studies
11:40	H. U. Burger, Hoffmann–La Roche AG, Basel: Longitudinal Analysis in Clinical Research

BBS
Building a home base

Basel Biometric Society & Section of the ROeS

- 2000: '*Missing values in clinical development*,' BBS Spring Seminar ... ...

- Since 2009: BBS Board member

- 2016-2023: BBS President

The mechanics of regional impact

- Local energy finding regional structure

- Shared questions converging into working groups

- Recurring workshops turning into trusted meeting points

- Early alignment across interest groups

- Continuity through people moving between networks

Scaling up through collaboration and shared purpose

CEN
Stitching regions together

Central European Network

Conference President / Chair or Organizing Committee member:

- 2008: Munich

- 2011: Zurich

- 2017: Vienna

- 2023: Basel

EFSPI
From Basel to Europe, and back

**European Federation of Statisticans
in Pharmaceutical Industry**

- 2011-2023: EFSPI Council member

- 2018-2019: EFSPI President

- 2016-2025: Founder and local organizer of
  the EFSPI Regulatory Statistics Workshop

Asterix
Not the Gaulish warrior

Advances in Small Trials dEsign for Regulatory Innovation and eXcellence

- EU-funded research project (FP7)

- 2014-2017: Advisory Board member

At the scientific frontier

Biometrical Journal

RESEARCH ARTICLE | 🔒 Full Access

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Hans Ulrich Burger ✉, Tom Van de Casteele, Khadija Rerhou Rantell, P... Markus Abt,
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NKC Get it! ☑

Members of the group are Anna Berglind (Astra-Zeneca), Annette Saute... (Lundbeck), Dmitry Tanetov (Hoffmann-La Roche), Fabian Model (Dena... Jansson (Lundbeck), Hans Ulrich Burger (Hoffmann-La Roche), Khadija ... Macpherson (Lilly), Markus Abt (Hoffmann-La Roche), Nikolaos Sfikas (N... (Genentech), Pilar Lim (Jansen), Rima Izem (Novartis), and Tom Van De ...

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The use of external ... be recommended?

Hans Ulrich Burger ✉, Christoph Gerlinger, Chris Harbron, Armin Koch, Martin Posch, Justine Roch... Anja Schiel

First published: 27 April 2021 | https://doi.org/10.1002/pst.2120 | Citations: 58

NKC Get it! ☑

Funding information: Springworks Therapeutics Inc; Global Alliance for TB Drug Development no... organization; EFPIA and Children's Tumor Foundation; European Union's Horizon 2020 research an... innovation programme; Innovative Medicines Initiative 2 Joint Undertaking, Grant/Award Number: ...

Pharmaceutical St...
The Journal of Applied Statistics in the Pharmaceutical Industry

Viewpoint | 🔒 Full Acces...

European Fede... Industry's posit...

Christine Fletcher ✉, Stef... on behalf of the EFSPI

First published: 18 October 2013 | https://doi.org/10.1002/pst.1603 | Citations: 8

Chapter 9
Applying the Estimand Framework: Case Studies in Neuroscience

Hans Ulrich Burger, Nikolaos Sfikas, Baldur Magnusson, Mette Krog Josiassen, Peter Quarg, Annabelle Monnet, Judith Anzures-Cabrera, Nima Shariati, and Paul Delmar

Abstract Neuroscience is a heterogeneous therapeutic area with many different facets and challenges. Different types of endpoints are utilized in neuroscience, and many different problems arise, especially with intercurrent events and missing data. The estimand framework is, therefore, helpful in many neuroscience indications, as it allows a structured approach to address such challenges. This chapter focuses on several typical neuroscience indications, including multiple sclerosis (MS), pain and migraine, Parkinson's disease (PD), and Alzheimer's disease (AD). It discusses and explains typical challenges arising in these heterogeneous diseases and, for each one, lays out a path forward based on the estimand framework. As expected, the strategies for addressing intercurrent events are the central focus and will be specifically discussed. A treatment policy strategy is frequently proposed and justifiable but not always. There are also examples where a composite variable strategy, a hypothetical strategy, or even a principal stratum strategy seems reasonable.

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Biometrical Journal
Three regions, four countries

An official journal of the International Biometric Society (IBS)

- Since 2017-2025: Associate editor
- Since 2025: Editor

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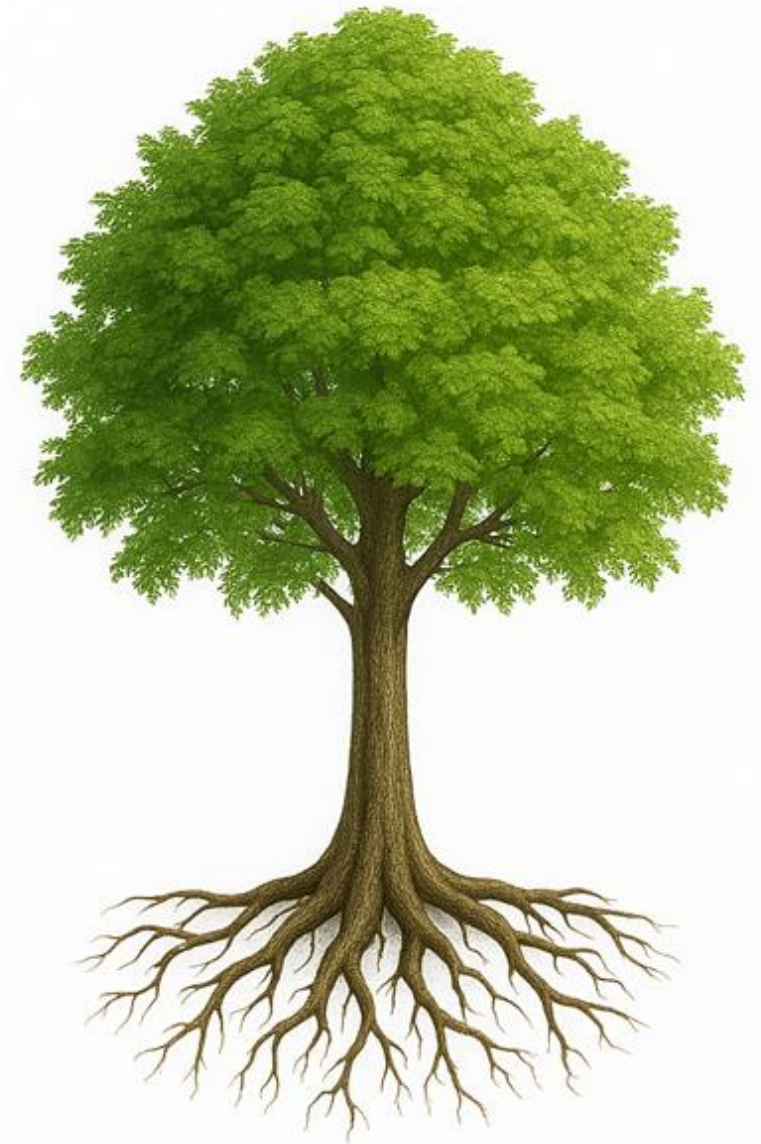| HOME | ABOUT ∨ | AUTHORS ∨ | BROWSE ∨ | VIRTUAL ISSUES |

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The mechanics of global impact

- Relies on local energy and regional structures

- Accumulated practice becomes codified

- Working across regions to align, not compete

- Stewardship replacing ownership

- Connecting existing structures into a visible global network

A global citizen – one of a kind

ICH
From practice to principles

International Council of Harmonisation

- Since 2019: ICH E20 Expert Working Group member
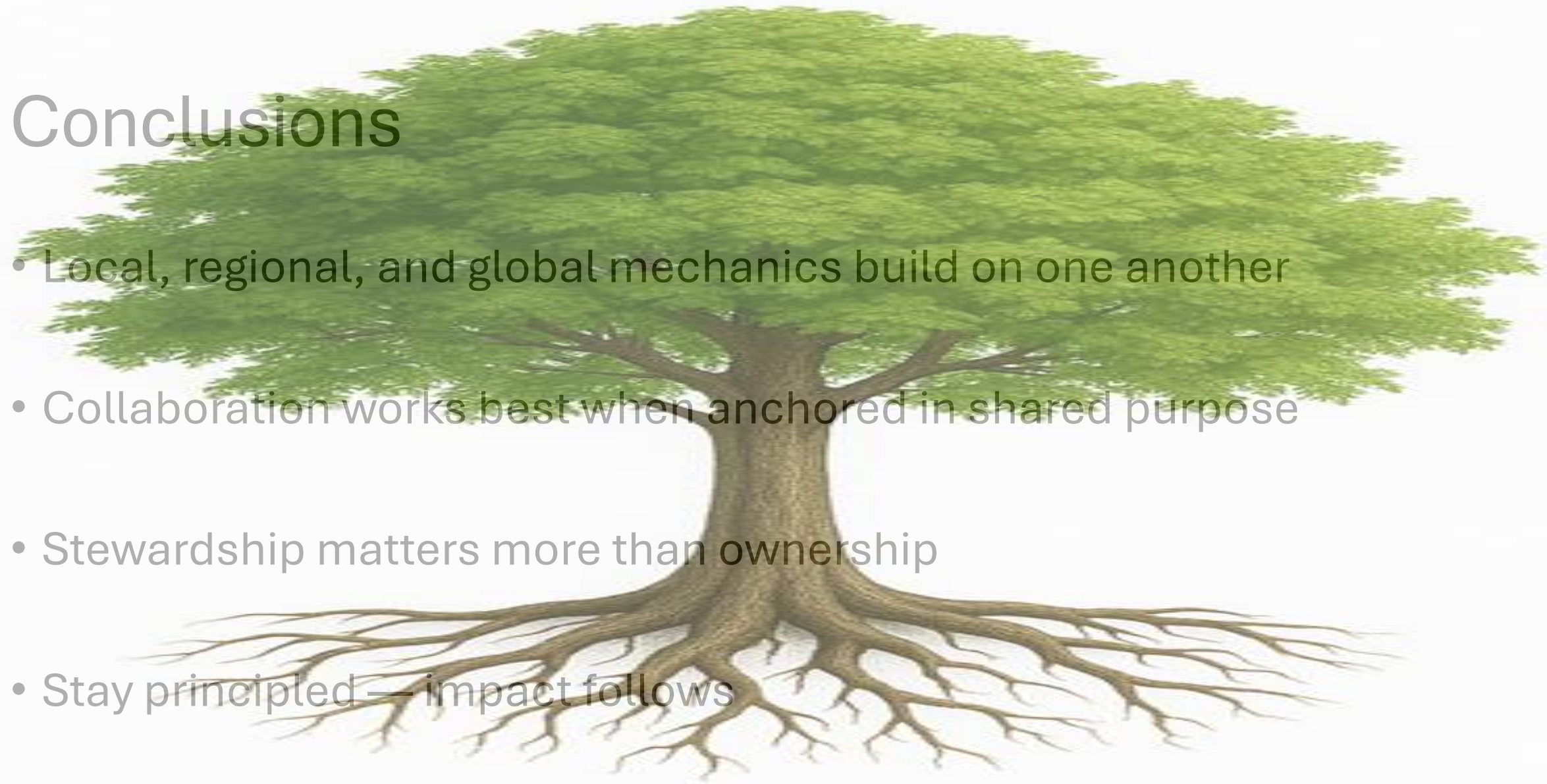
IBC2028
More to come

International Biometric Conference

- Local Organizing Committe chair

Conclusions

- Local, regional, and global mechanics build on one another

- Collaboration works best when anchored in shared purpose

- Stewardship matters more than ownership

- Stay principled — impact follows

- The reward: seeing ideas take root and grow

Thank you