

Unplanned Disruptions in Clinical Trials

An Ingram Olkin Forum Series
brought to you by the
National Institute of Statistical Sciences
Starting July 21 & 28, 2020

Nancy Flournoy, Chair, Committee on Ingram Olkin Forums

Ingram Olkin Forums: Statistics Serving Society



IOF Focus: A current societal issue that might benefit from attention from the statistical community.

GOALS:

Bring innovations in statistical methodology and data science into **new research and public policy collaborations**,

Work to accelerate the development of innovative approaches that **impact societal problems**.

Provide statisticians with an understanding of the **societal problems** and stimulate their interest.

Develop **statistical action items** to better inform public policy and to generate reliable evidence to mitigate the problem.

Facilitate **new collaborations** among statisticians and those working to understand and mitigate the problem.

History of Ingram Olkin Forums

Gun Violence (Inaugural IOF 2019)

Emerging Data Sources

Gun Violence Trends

Policing Gun Violence

Assessing Gun Violence Risks and Evaluating Initiatives

Police Shootings.

JSM Invited Panel, Monday 8/3 at 1:00 pm. Activity number 117.

Watch For:

Opioids

AI Ethics & Algorithm Bias

Unplanned Clinical Trial Disruptions: This IOF is a series

July 21 & 28

Perspective from Government Agencies

After JSM

Estimand Issues and Missing Data

Adaptive Designs:

- Group Sequential Designs;
- Sample Size Re-estimation

Perspective from Government Agencies II

July 28 Next Week, Same time, Same Place

Lilly Yue,

Deputy Director, Division of Biostatistics, FDA

G. David Williamson,

Director, Office of Science,

National Center for Environmental Health, CDC

Aldana Rosso,

Senior Adviser in Biostatistics, Danish Medicines Agency,
European Medicines Agency (EMA)

S3 Forums are to be participatory.

A survey will be sent out after the two sessions (July 21 & 28) on government perspectives of unplanned clinical trial disruptions.

Interest in the following sessions in this series will be solicited, and participant screening may result.

Participants are encouraged to request a role such as discussant, moderator, recorder or note taker.

After invited talks, participants will be assigned to small discussion groups in breakout rooms, regrouping for reporting, syntheses, and writing.

Enjoy this Ingram Olkin Forum Series on Unplanned Disruptions in Clinical Trials

On behalf of the Organizing Committee:

- **Jonathan Bartlett**, University of Bath
- ***Adam Lane**, University of Cincinnati
- **Nancy Flournoy**, University of Missouri
- **Chris Jennison**, University of Bath
- **Assaf Oron**, Institute for Disease Modeling
- ***Sergey Tarima**, Medical College of Wisconsin

*Representing the Organizing Committee on the Panel today, organizing Q/A.

Perspective from Government Agencies

Today: July 21

Nancy L. Geller,

Director of Biostatistics Research, NHLBI

Dean Follmann,

Chief, Biostatistics Research Branch, NIAID

Lisa McShane,

Associate Director, Div. of Cancer Treatment & Diagnosis;
Chief, Biometric Research Program NCI

Discussion with Q/A Following