

Issues Relating to Decision Making / Implementation and Data Monitoring Committees in Adaptive Design Trials

Organizers / Moderators:

Paul Gallo, Novartis

Bram Zuckerman, FDA

PhRMA Adaptive Design Workshop

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Introduction

Adaptive designs clearly will require review of accruing data, and for different purposes than those associated with other types of monitoring with which we have more familiarity.

- What challenges need to be addressed / overcome if these designs are to be implemented in a manner which maintains integrity and interpretability of trial results?
- Who should be involved in interim data review for adaptive trial decision making and implementation?
- How should processes differ from those used in other types of monitoring settings?

Participants / session organization

Presenters

Paul Gallo
Novartis

Ning Li
FDA

Richard Kuntz
Medtronic

Bram Zuckerman
FDA

Panelists

David DeMets, *University of Wisconsin*

Susan Ellenberg, *University of Pennsylvania*

Stuart Pocock, *University College London*

Presenters will raise specific issues / questions for consideration by the panelists.