

Developments in early phase dose-finding trials

Sam Hinsley, Pavel Mozgunov, Andrew Hall, Matt George,
Anais Andrillon, Sandrine Micallef

16 June 2026



Agenda

- Introduction to the new early phase ESIG - *Sam Hinsley*
- Recent advances in dose-finding: an introduction - *Pavel Mozgunov*
- Designing phase I trials with backfilling to mitigate screening and treatment delays - *Andrew Hall*
- A novel method for inserting dose levels mid-trial in early phase combination studies - *Matt George*
- U-DESPE: a Bayesian Utility-based methodology for dosing regimen optimization based on Dose-Exposure, Safety, Pharmacodynamics, Efficacy in early-phase oncology trials - *Anais Andrillon & Sandrine Micallef*

Introduction to the new early phase ESIG

Sam Hinsley





About us

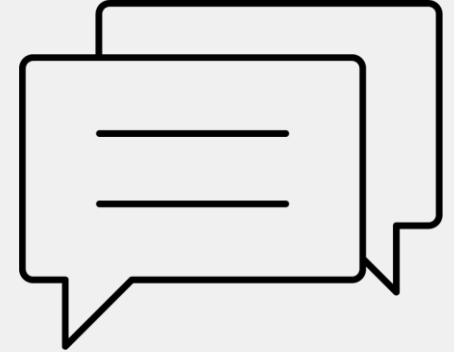
- Established January 2026
- Currently 28 members - academia, pharma, CRO & research groups
- Key aim: **“To advance the use of innovative trial methodologies to improve standards within the early phase clinical trials community and reduce substandard treatments being taken into later phase trials”**

Objectives

- Promote the use of innovative designs and statistical methodologies, where appropriate
- Improve understanding and implementation of methods within early phase trials via training, meetings and publications
- Share knowledge and real-life experiences between key stakeholders in both academia and industry
- Create space for collaboration, fostering a community of support rather than competition

Want to join?

Email: samantha.hinsley@phastar.com
marie-karelle.riviere@saryga.com



Include

- Brief sentence on your background in early phase
- Confirmation of PSI/EFSPI membership

(Max. 2 people per company)

Website: www.psiweb.org/sigs-special-interest-groups/sigs