

MSP Focus Group Risk Based Approach in Clinical Trials



Elke Stahl
MSP AG meeting
18 September 2025

MSP FG – Risk Based Approach

Members from Regulatory, Academics, Non-commercial Organisations and Commercials

- Mariagrazia Felisi (TEDDY)
- Jacques Demotes (ECRIN)
- Stéphanie Kromar (EORTC)
- Fergus Sweeney (CDDF)
- Simon Tabassome (ESC)
- Marko Skelin (ESOP)
- Mira Zuidgeest (UMC Utrecht)
- Tarec Christoffer El-Galaly
- Laura Evangelista (EANM)
- Paula Babarovic (Novartis)
- Gracy Crane (Roche)
- Nora Cascante Estepa (Miltenyi)
- Wolfgang Berdel (MedEthicsEU)
- Monique Al (CTCG/MedEthicsEU)
- Marianne Lunzer (CTCG)
- Elke Stahl (CTCG)
- Ana Zanoletty (EMA)
- Laura Pioppo (EMA)
- Ornela Ademi (EMA)

MSP FG – Risk Based Approach

- Aim
 - Support the revision of the ,recommendations on risk proportionate approach in clinical trials' working group
 - Support ACTEU Workshop on risk based approaches in clinical trials Q4/2025?
- Kick off meeting 16 Sept 25