

# Estimands in Oncology Safety Task Force



The Pharmaceutical Industry Working Group on Estimands in Oncology in collaboration with PHUSE has started a Safety Task Force on estimands in safety, focusing on oncology. The Task Force will formulate recommendations regarding formulation and use of safety estimands in oncology clinical trials as well as identifying applications of estimands principles to help improve general safety reporting. Recommendations will include trial design, data collection, and analysis issues and ways to integrate clinical, statistical, operations, and data management aspects of study design and execution cooperatively. Key task force activities will include a dive into literature on the subject, formulation of recommendations, development of white papers, and preparation of journal manuscripts and conference presentations.

For more information, please contact Jonathan Siegel at [Jonathan.siegel@bayer.com](mailto:Jonathan.siegel@bayer.com). For information on the Pharmaceutical Industry Working Group on Estimands in Oncology, please visit [www.oncoestimand.com](http://www.oncoestimand.com) or contact Working Group co-chairs, Degtyarev Evgeny at [evgeny.degtyarev@novartis.com](mailto:evgeny.degtyarev@novartis.com) or Kaspar Rufibach at [kaspar.rufibach@roche.com](mailto:kaspar.rufibach@roche.com).

## Bibliography

Assessing Adverse Events in Clinical Trials During the Era of the COVID-19 Pandemic

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Siegel JM, Weber HJ., Englert S. The Role of Occlusion: Potential Extension of the ICH E9 (R1) Addendum on Estimands and Sensitivity Analysis for Time-to-Event Oncology Studies (2022b). Submitted.:

Hofner, B. Safety analyses: The Cinderella of Biostatistics? A Regulatory Perspective. EFSPi Statistics Leaders Meeting 2020.

Collopy, M. Challenges of Safety and Dual Benefit Risk Estimands. BIOP 2019.

Torres, C. Safety Estimands: A Regulatory Perspective. BIOP 2019.

PHUSE White Paper - Analyses & Displays Associated with Adverse Events: Focus on Adverse Events in Phase 2-4 Clinical Trials and Integrated Summary

PHUSE White Paper - Analysis and Displays Associated with Safety Topics of Interest- Focus on Phase II to IV Clinical Trial

PHUSE Computational Science Symposium 2020 - Planning and Interpreting Safety Analyses for Integrated Summaries Workshop

Nilsson, M., Crowe, B., Anglin, G., et al. (2020). Clinical Trial Drug Safety Assessment for Studies and Submissions Impacted by COVID-19. *Statistics in Biopharmaceutical Research*, 12:4, 498–505. <https://www.tandfonline.com/doi/full/10.1080/19466315.2020.1804444>.