

# How the 'Estimand Implementation Working Group' brings together statisticians and clinicians to support the estimand journey

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## DISCUSSIONS

The EFPIA / EFSPi Estimand Implementation Working Group (EIWG) is co-lead by Amel Besseghir, Chrissie Fletcher and Nanco Hefting and has regular monthly meetings to discuss and develop best practices and

recommendations to support implementation of estimands and to explore implementation in non-confirmatory trials e.g. PKPD, single-arm and non-interventional studies.

## COLLABORATIONS

**Onco Estimand**  
([www.oncoestimand.org](http://www.oncoestimand.org))

- Mission: To foster a common understanding and consistent implementation of the estimand framework in oncology clinical trials
- Liaison: Stefan Englert

**PHUSE**  
(<https://advance.phuse.global/>)

- Mission: Sharing ideas, tools and standards around data, statistical and reporting technologies regarding estimands
- Liaison: Armin Schueler

**TransCelerate**  
([www.transceleratebiopharmainc.com/assets/clinical-content-reuse-solutions](http://www.transceleratebiopharmainc.com/assets/clinical-content-reuse-solutions))

- Mission: To collaborate across the global biopharmaceutical research and development community to facilitate the implementation of estimands
- Liaison: Helle Lynggaard

## TRAININGS and WEBINARS

The training sub-team (lead by Judith Anzures-Cabrera) has released a series of webinars relevant to anyone working in clinical trials: Clinician, Regulator, Investigator, Ethics Committee, HTA Agencies, Statistician.

### ***The Estimands Academy for Trial Teams*** "Bringing estimands to *life* through case studies"

Webinar 4: Proposing Estimands from Different Perspectives

### ***The Estimands Academy for Trial Teams*** "Bringing estimands to *life* through real case studies"

Webinar 2: Estimands in Oncology - How and Why

### ***The Estimands Academy for Trial Teams*** "Bringing estimands to *life* through real case studies"

Webinar 3: Estimands from trial planning to publication in medical journals: The ETHOS trial.

### ***The Estimands Academy for Trial Teams*** "Bringing estimands to *life* through real case studies"

Webinar 1: PIONEERING estimands in Clinical Development

## All trainings are freely available through PSI's Library as 'Video-on-Demand'

Portal: <https://psiweb.org/vod/Index/> or via YouTube on the EFPIA channel

Collection: The Estimands Academy for Trial Teams



<https://psiweb.org/vod/Index/>

## PUBLICATIONS from WORKING GROUPS

- O. Keene., H. Lynggaard , S. Englert, V. Lanius, D. Wright. **Why Estimands are Needed to Define Treatment Effects in Clinical Trials.** *BMC Medicine* 21:276 (2023)
- A. Morga, NR. Latimer, M. Scott, N. Hawkins, M. Schlichting, J. Wang. **Is Intention to Treat Still the Gold Standard or Should Health Technology Assessment Agencies Embrace a Broader Estimands Framework?: Insights and Perspectives From NICE and IQWiG on the ICH E9(R1) Addendum.** *Value Health.* 2022 Sep 20:S1098-3015(22)02148-9.
- H. Lynggaard, J. Bell, C. Lösch, A. Besseghir, K.

- Rantell, V. Schoder, V. Lanius. **Principles and Recommendations for Incorporating Estimands into Clinical Study Protocol Templates.** *Trials* (2022)
- C. Fletcher, N. Hefting, M. Wright, J. Bell, J. Anzures-Cabrera, D Wright, H. Lynggaard, A. Schueler. **Marking 2-years of new thinking in clinical trials - the estimand journey.** *Ther Innov Regul Sci* 56, 637–650 (2022).
- O. N. Keene, D. Wright, A. Phillips, M. Wright. **Why ITT analysis is not always the answer for estimating treatment effects in clinical trials** (2021). *Contemporary Clinical Trials.*

Further details on the working group: [https://www.efspi.org/EFSPi/Working\\_Groups/EFSPi\\_EFPIA\\_EIWG.aspx](https://www.efspi.org/EFSPi/Working_Groups/EFSPi_EFPIA_EIWG.aspx)

## BECOME A MEMBER

The general spirit of the working group is inclusive. If you'd like to contribute in one or the other way, we propose you first reach out to your company's representative(s) (if applicable) and align within your company who is best placed to contribute.