

Data Voyagers: Navigating the Fascinating Universe of Medical Affairs Statistics

Launch & Lifecycle eSIG

Become a part of our SIG where we aim to:



Provide a platform for statisticians working in the launch and lifecycle management space to help each other in areas of pre-competitive collaboration



Shape the industry by increasing the influence of statisticians to optimize evidence generation and inform clinical practice. Showcase examples through case studies, publications, etc.



Drive scientific projects and innovation forward related to the field of Launch and Lifecycle

Randomized controlled Single Arm & Pragmatic Trials

Real-world Evidence Post Marketing Commitments

Novel Endpoints, Estimands, causal inference, external controls, generalizability, subgroups, clinical decision support



The Integrated Evidence Plan (IEP) addresses the needs of multiple stakeholders (Regulators, HTA, Clinical Practice)



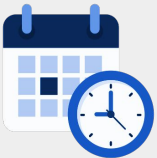
A **global document** that provides a comprehensive framework inclusive of all global evidence generation functions (e.g. regulatory, access, and affiliate activities)

Why do we need an IEP?



It defines the clinical & access evidence needed to fulfill regulatory requirements, maximize access and deliver meaningful insights to inform clinical practice.

Timing of IEP Creation:



- Starts early enough (before Ph III) to ensure evidence will be in place for regulatory, access, and commercial launch
- Reviewed regularly and updated as needed to reflect changes in context (both internal and external)

How can statisticians add value?

Become familiar with different functional stakeholders and their needs, **hone the research questions**, identify evidence **gaps**, select the right **data sources**, help with **trade-off** considerations, **reduce complexity**

Recent Publications

Dyachkova Y, Dunger-Baldauf C, Barbier N, et al. **Do You Want to Stay Single? Considerations on Single-Arm Trials in Drug Development and the Postregulatory Space.** Pharm Stat. Published online June 25, 2024. doi:10.1002/pst.2412.