

**Learnings from a
Multistakeholder Estimands
Project: A White Paper Journey**

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**BASE CAMP:
GATHERING OUR
RESOURCES**

Base Camp



“The mountains are calling – and I must go.”

John Muir

Estimands Framework ICH E9 (R1)

Clarity in Clinical Trials

- Defines treatment effects, standardizing trial result interpretation.

Industry Challenges

Theory vs Practice

- The gap between concepts and applications presents major hurdles.

Consistency

- Variability leads to reporting and submission inconsistencies.



Launch and Collaboration

Initiation

- Started **March 2022** by the PHUSE Optimizing the Use of Data Standards working group.

Teamwork

- Brings together experts, agencies, and working groups for shared estimands understanding.



ACCLIMATE: ADJUSTING TO NEW HEIGHTS

Acclimate



“Adventure awaits where the mountains meet the sky.”

White Paper Creation & Feedback Integration

Content Development

- Craft a white paper summarizing project insights and guidance on the estimands framework.

Stakeholder Feedback

- Incorporate diverse stakeholder feedback to ensure industry relevance.

Enhancing Estimands Implementation

Strategy Refinements

- Document strategies and address challenges in estimand application.

Practical Guidance

- Provide actionable advice for estimands implementation.



Collaboration & Insight Sharing

Industry Collaboration

- Foster cross-functional teamwork and industry dialogue to improve estimands understanding.

Valuable Lessons

- Share key learnings and insights for broad industry application.

FIRST ASCENT: FINDING OUR PACE



First Ascent



“The joy of reaching the top is worth every step of the climb.”

Developing Common Language Around Estimands

- **Challenge:** Addressing conflicting definitions and standardization.
- **Solution:** Engage in discussions and reference multiple sources clearly.



Volunteer Engagement

- **Challenge:** Maintaining team engagement throughout the project.
- **Solution:** Identify leads and keep core teams involved.

MIDWAY CHECKPOINT: ASSESSING OUR PROGRESS



Midway Checkpoint



“Difficult roads often lead to beautiful destinations.”

Regulatory Feedback Timing and Processing:

- **Challenge:** Regulatory feedback and conflicting guidance from agencies.
- **Solution:** Proactively reach out for input and choose less contentious examples.



Incorporating Feedback from Other Working Groups:

- **Challenge:** Need for awareness of similar groups and standards.
- **Solution:** Organize meetings to reach consensus early.

**SUMMIT PUSH:
DIGGING DEEP ABOVE
THE TREE LINE**



Summit Push



“Every mountain top is within reach if you just keep climbing.”

Barry Finlay

Conflicting Feedback From SMEs

- **Challenge:** Navigating conflicting opinions from experienced SMEs.
- **Solution:** Prioritize insights from trusted industry relationships.



Volunteer Engagement

- **Challenge:** Maintaining team engagement throughout the project.
- **Solution:** Leads keep core teams involved.

SUMMIT: TAKE IN THE VIEW



Summit



“The best view comes after the hardest climb.”

Team Member Testimonials

- “Working on this project has been an *invaluable learning experience*, especially in creating case studies. I’ve *deepened my understanding* of key concepts, enhancing my skills as a statistician. This experience has also allowed me to *apply and communicate complex concepts effectively*.”



- “Participating in this project has been a *truly rewarding experience*. The collaboration across diverse roles and companies brought about a *multitude of learnings* and *fresh perspectives* and provided opportunities to connect with others that typically isn’t possible in my day job”.

**DESCENT:
REFLECTING ON
THE WAY DOWN**



Descent



“The mountains are not in our way; they are our way.”

Descending & Reflecting: Insights Gained

- Precision in **Scope** is crucial.
- Clear **Roles & Expectations** enhance engagement.
- Seamless **Communication** is essential.



Descending & Reflecting: Achievements Unlocked

- **Organized Meetings** keep focus.
- **Diverse Perspectives** fuel creativity.
- **Feedback Loops** refine our work.
- **Community** keeps us united.

CELEBRATION AT BASE CAMP



Celebration



“Mountains are the silent storytellers of our journeys.”

Honoring Our Collective Journey

- Celebrating our achievements and insights.
- Acknowledging every team member's contribution.
- United, we've reached new heights.
- Inspired for future challenges.



A photograph of two people climbing a rocky mountain. A man in a yellow jacket and white helmet is helping a woman in a red jacket and red beanie up a rock. They are both wearing backpacks. The background is a cloudy sky. The text 'THANK YOU FOR JOINING OUR CLIMB' is overlaid on the right side of the image in a bold, dark green font.

**THANK YOU FOR
JOINING OUR
CLIMB**