

Not Just Another Estimands Talk: Practical Strategies for Cross-Functional Engagement to Ensure Meaningful, Fit for Purpose Estimands

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Estimands: Uptake,
Application &
Communication

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Are estimands difficult?

OR

**Are we just bad at explaining
them and why they matter?**

Who is **mainly** responsible for estimands in your study teams?

1

The Lead
Statistician

2

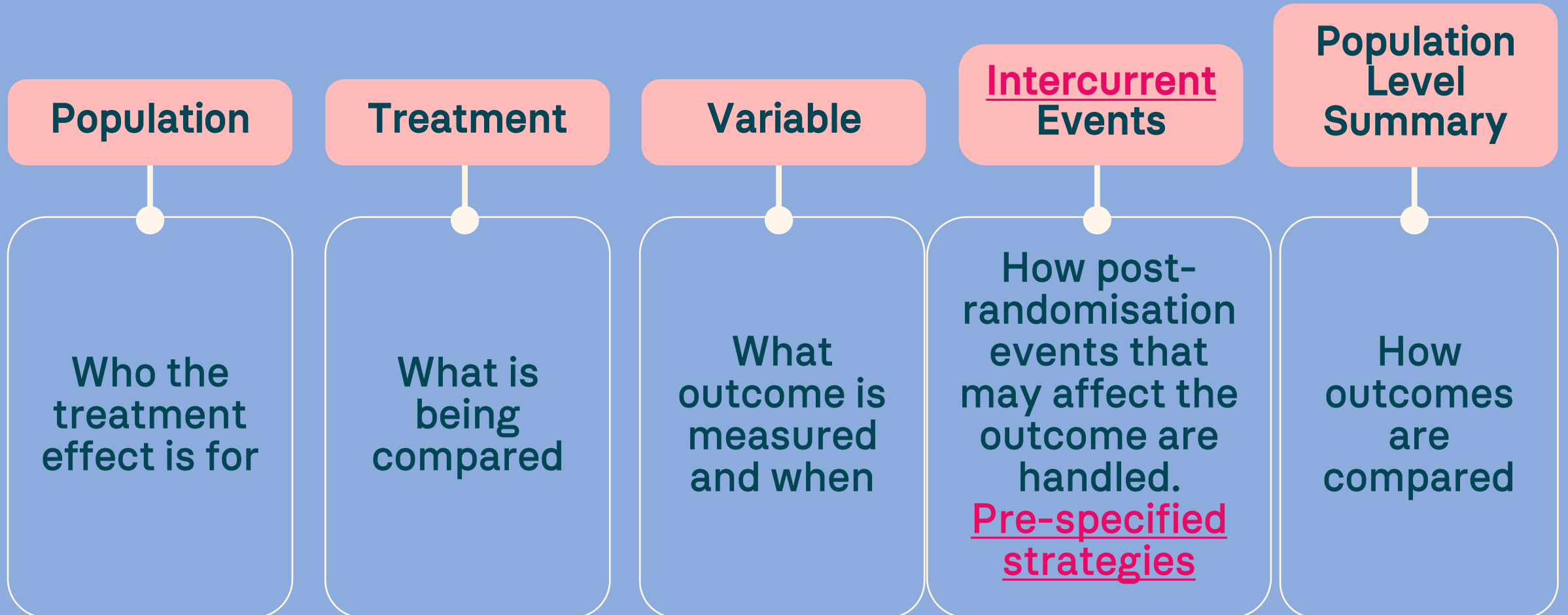
The Clinical
Lead

3

A collaboration
between Clinical
and Statistics

Estimand Definition

An estimand is a precise description of the treatment effect reflecting the clinical question posed by a given clinical trial objective (ICH E9 R1)



A stylized graphic of a hand with fingers pointing towards the top right, rendered in shades of pink and magenta. The hand is positioned in the upper right quadrant of the slide.

A Framework for Better Communication of Estimands

Tips & Strategies

A Framework for Better Communication

Tip 1

Start with the **clinical question**, not the estimand framework



Don't introduce
“estimands” or the
framework first



Start with the
decision(s)/clinical
question(s) the study
is meant to support

“

At the end of this study, what do we want
to be able to say about this treatment?

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Tip 2

Reduce jargon, introduce structure later



Describe Ideas First.
Introduce formal terminology only once the idea is understood



If jargon is unavoidable, explain it in one plain sentence



Treat the five attributes as your internal checklist, not the agenda



Use clear natural language

“

Let's first agree what outcome matters and how interruptions should be interpreted – I can map that onto the estimands framework afterwards

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Tip 3

Ask questions before proposing solutions



Use **open** questions



Let clinicians articulate the estimand without using the word



Don't present a fully formed estimand and then ask for sign-off rather than input

“

If two patients respond but one needed a dose reduction, do you see those responses as equivalent or not?

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Tip 4

Anchor to familiar clinical thinking



Use clinical reasoning clinicians already apply every day (e.g. biomarker subgroups, treatment sequencing, and response interpretation) before mapping these onto estimand components



Frame estimands in terms of interpretation, not methodology

“

Are we interested in all patients, or only the biomarker-positive subgroup?

A Framework for Better Communication

Tip 5

Use intercurrent events as conversation starters, not technical hurdles



Discuss in terms of real-world scenarios first (e.g. treatment discontinuation, rescue medication...)



Normalise uncertainty & deviations
Treat intercurrent events as expected clinical reality and remove any sense of “failure” or awkwardness

“

Dose interruptions and discontinuations are part of how this drug will be used – the analysis shouldn’t pretend they don’t exist.

A Framework for Better Communication

Tip 6

Make downstream consequences explicit



Link early decisions to interpretability and utility later



Explicitly discuss how early ambiguity and/or the impact of each decision may affect final analyses and their interpretation



Consider visualisations or patient level examples to illustrate



If we don't agree this now, we may end up with a result that's hard to explain, or defend, later.

A Framework for Better Communication



More tips for communicating about intercurrent events...



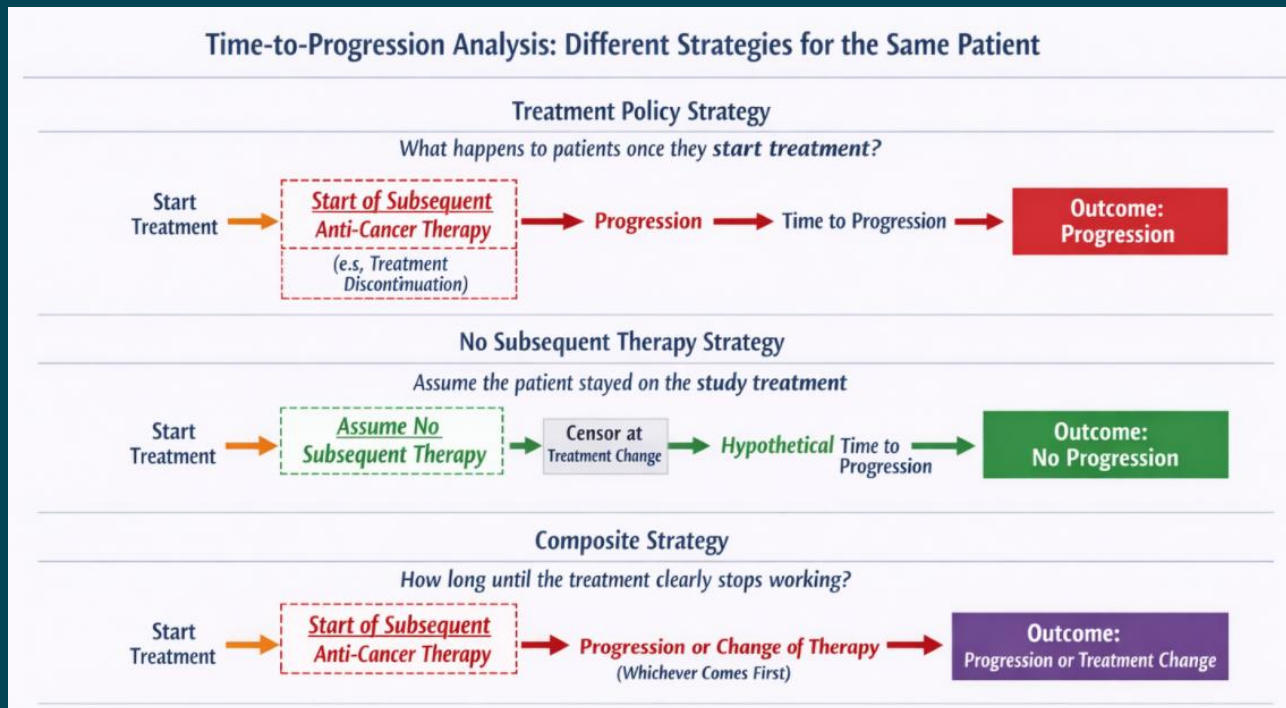
Patient-level examples



Think about useful visualisations



Simulations



A Framework for Better Communication

Tip 7

Focus on one decision at a time



Don't try to define the full estimand in one meeting



Isolate the most clinically contentious or most important element first



Avoid overloading early discussions with population, endpoint, summaries, and sensitivity all at once

“

Today, let's just agree how we want to think about treatment discontinuation, we'll come back to the rest.

A Framework for Better Communication

Tip 8

Frame estimands as collaborative



Be explicit that good estimands require clinical input and shared ownership



The statistician is a facilitator of structured decision making, not the sole decision maker



Engagement rather than deferral

A Framework for Better Communication – Summary

Lead with Clinical Intent

- Start with the clinical question, not the framework
- Anchor to reasoning clinicians already use daily

Simplify the Language

- Reduce jargon; introduce structure later
- Use real-world scenarios

Facilitate, Don't Dictate

- Ask open questions before proposing solutions
- Focus on one decision at a time

Build Shared Ownership

- Make downstream consequences explicit
- Co-create; don't just present for sign-off

Putting it into Practice

Phase III Oncology Study: Overall Survival



**Lead with
Clinical Intent**

How does our treatment affect
how long patients live

**Simplify the
Language**

Treatment switching is expected –
does it change interpretation?

**Facilitate,
Don't Dictate**

If a patient switches therapy, do we
count survival the same way?

**Build Shared
Ownership**

We need to agree on how to handle
switching now, or risk results
stakeholders can't interpret.



Putting it into Practice

Depression Study: MADRS Change from Baseline at Week 24

**Lead with
Clinical Intent**

How does this drug improve depressive symptoms?

**Simplify the
Language**

Our drug alone, or regardless of rescue meds?

**Facilitate,
Don't Dictate**

After rescue meds, is the MADRS still meaningful?

**Build Shared
Ownership**

We need to decide how to handle this now, or risk results no one trusts.



**Better estimands
start with
better conversations**

Thank you

Any Questions?

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