



More Than a P-Value: Understanding the Differences Between Clinical and Statistical Significance

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Who we are



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Agenda

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INTRODUCTION TO STATISTICAL AND CLINICAL SIGNIFICANCE

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STATISTICAL SIGNIFICANCE VS. CLINICAL SIGNIFICANCE

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CONCLUSION

01



Introduction

Definitions

Statistical Significance



- Whether the observed effect or relationship in a study is unlikely to have occurred due to chance.

Clinical Significance



- Whether the size of the effect or difference observed is substantial enough to have real-world implications in a clinical setting.

Assessing Statistical and Clinical Significance

Statistical Significance

- Hypothesis testing
- Confidence Intervals
- P-values
- Power analysis (adequate sample size)

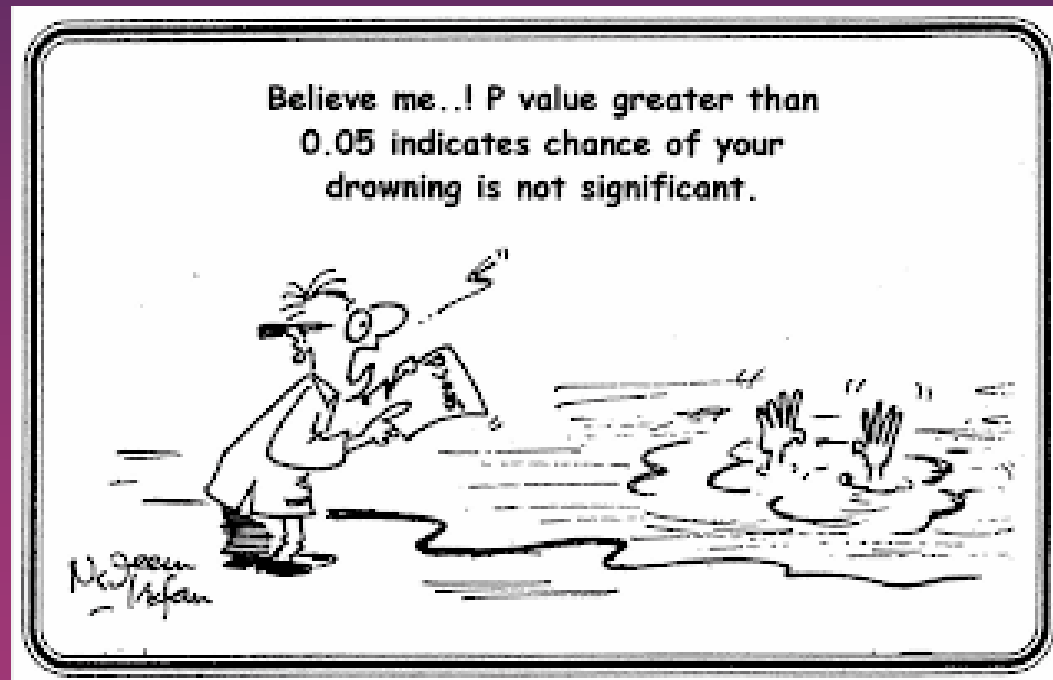


Clinical Significance

- Effect Size
- Use of Clinical Benchmarks or Minimum Clinically Important Difference (MCID)
- Real-world applicability

More Than a P-Value...

- The p-value...
 - Doesn't provide any information about clinical significance.
 - Can be very small, but that difference might not be clinically meaningful.
 - Is an arbitrary cut-point, not an absolute threshold. Scientific context is critical.



02

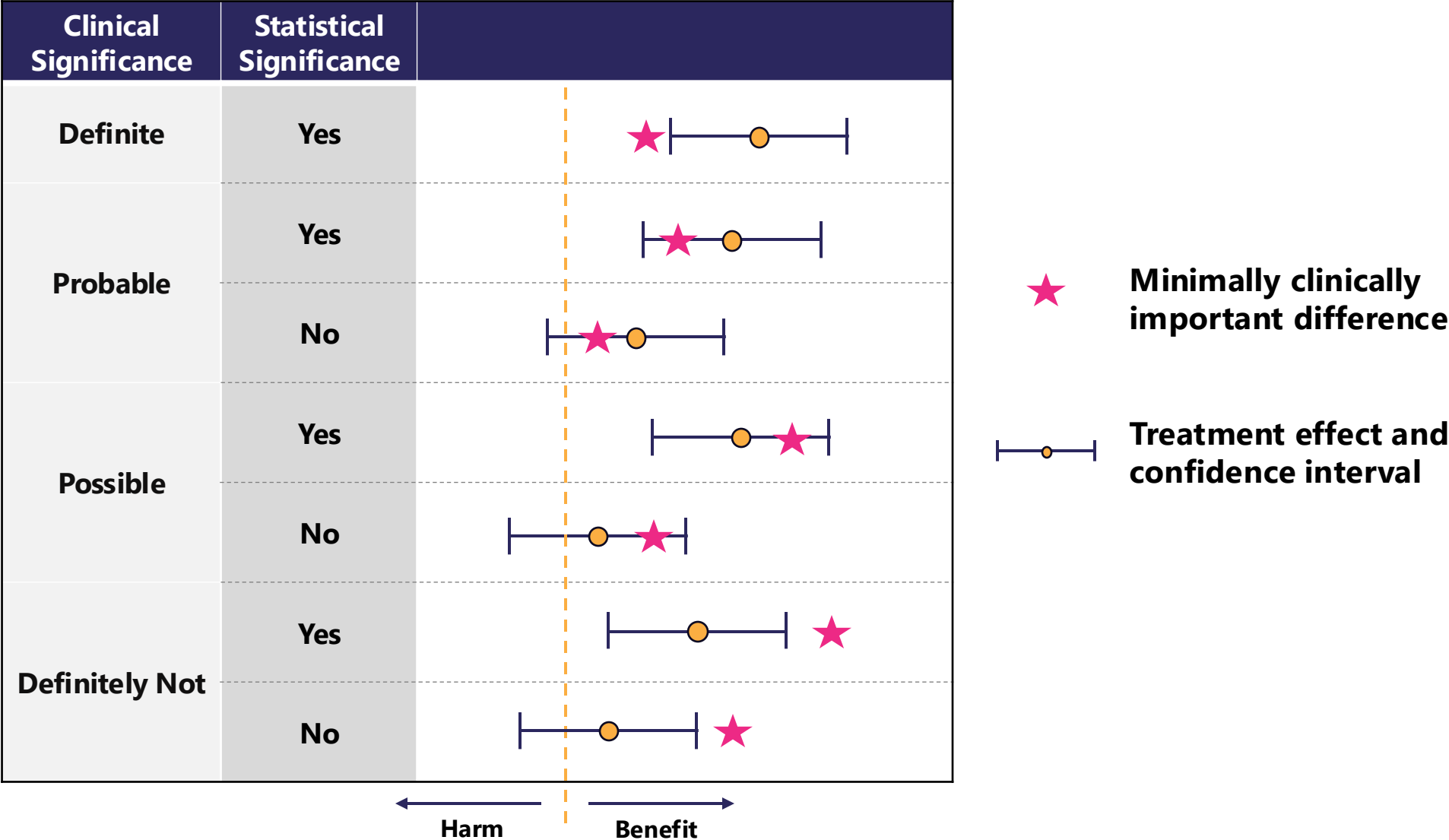


Statistical Significance vs. Clinical Significance

Statistical Significance vs Clinical Significance

		Clinically Significant	
		Yes	No
Statistically Significant	Yes	✓ Statistically and clinically reliable ✓ Typically assume the groups, outcomes, or treatments are different	✓ The effect is highly reliable, but not clinically meaningful ✓ Consider that the sample size may be too large
	No	✓ The effect is clinically useful, but not reliable ✓ Consider that the sample size may be too small	✓ Not statistically nor clinically reliable ✓ Typically assume the groups, outcomes, or treatments are not different

Statistical Significance vs Clinical Significance



03



Case Studies

CASE STUDY

Hypertension



Study Overview

Sample size: 500 participants

Intervention: New antihypertensive drug

Comparison group: Placebo

Outcome: Change in SBP after 12 weeks of treatment

Results

Treatment group: SBP reduced from 150 mmHg to 148 mmHg (a 2 mmHg reduction).

Placebo group: SBP reduced from 150 mmHg to 149 mmHg (a 1 mmHg reduction).

Statistical result: $p = 0.01$ (indicating a statistically significant difference between the two groups).

Study Implications

A 2 mmHg reduction in SBP, while statistically significant, is likely too small to produce substantial benefits in terms of reducing cardiovascular risk or improving health outcomes in most patients.

MCID for SBP reduction: Experts typically consider a reduction of at least 5 mmHg to have a meaningful impact on long-term health outcomes, such as reducing the risk of stroke or heart attack.

CASE STUDY

Diabetes



Study Overview

Sample size: 40 participants

Intervention: New SGLT2 inhibitor (10 mg once daily)

Comparison group: Placebo

Outcome: Change in HbA1c from baseline to Week 12

Results

Treatment group: HbA1c reduction of -0.6% (Baseline: 8.1% → 7.5%).

Placebo group: HbA1c reduction of -0.3% (Baseline: 8.1% → 7.8%).

Statistical result: $p = 0.12$ (not statistically significant, likely due to small sample size).

Study Implications

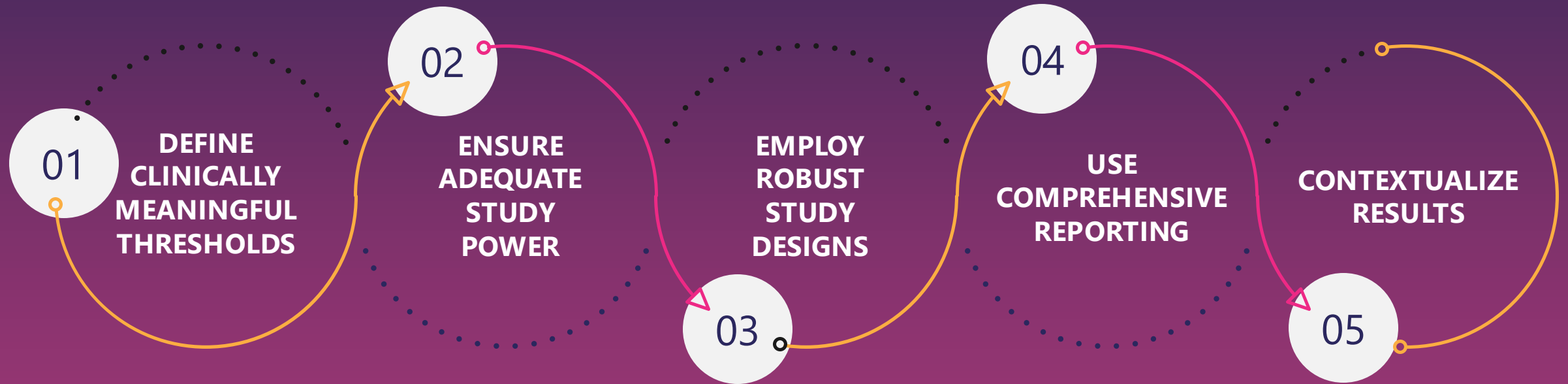
Clinical Relevance: Despite **not achieving statistical significance for HbA1c reduction**, a **0.6% decrease in just 12 weeks** is considered **clinically meaningful**, as even small reductions can lower long-term complications.

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Conclusion

Key Considerations



References

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Thank You
Questions?

