Norwegian Medical Products Agency

Session 3

OPTIMIZE EVIDENCE GENERATION AND PATIENT ACCESS WITH INNOVATIVE CANCER TRIALS (METHODOLOGY)

It works doesn’t mean I should buy it

CDDF; Challenges, Advances, and Open Questions in Global Cancer Drug Development and Clinical Trials
3-5 February 2025

Anja Schiel, PhD, NOMA

2025, a new era begins…..

- Approval ≠ Access

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- Clinical trial = Regulator

Efficacy (**B/R**)

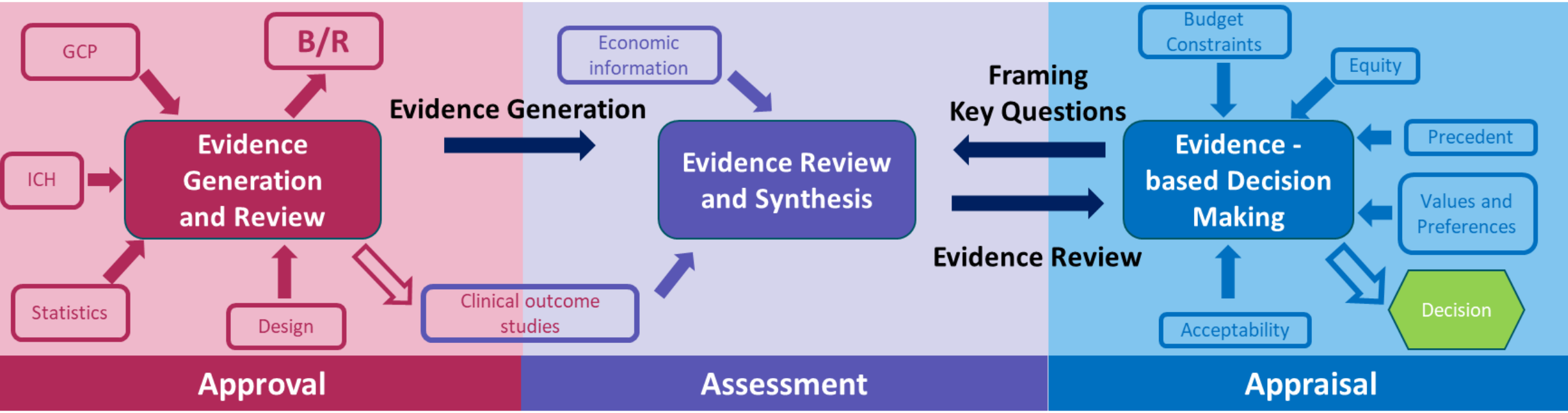
- Does it work in experimental setting
- Population selected
- Placebo or a selected comparator

- Real world = HTA

Relative Effectiveness (**C/E**)

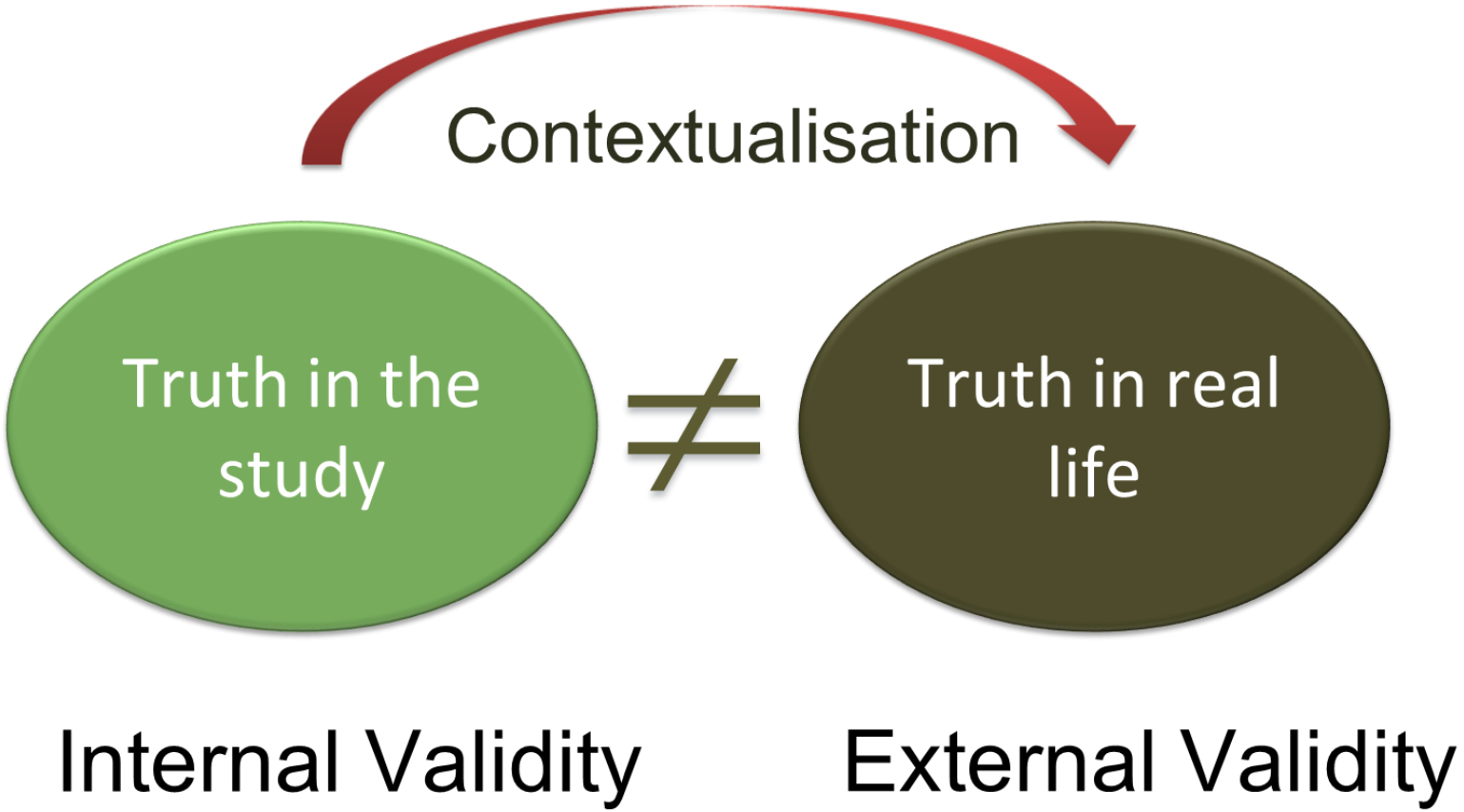
- How does it work in clinical practice
- Patients as they come
- Many alternative treatments

The Trinity



Adapted from Teutsch, S.; Berger, M. (2005) 'Evidence synthesis and evidence-based decision making: Related but distinct processes. *Medical Decision Making*, pp 487-489

Internal versus External validity

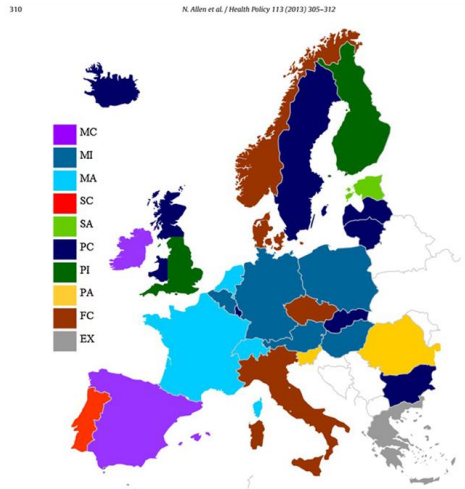


Internal versus External validity

Contextualisation

Truth in the study ≠ Truth in real life

Internal Validity External Validity



2025, a new era begins…..

I

(Legislative acts)

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(Text with EEA relevance)

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Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

November 2020
Clinical/Medical

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Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials Guidance for Industry

DRAFT GUIDANCE

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For questions regarding this draft document, contact (OCE/CDER) Lola Fashoyin-Aje, 240-402-0205, (CBER) Office of Communication, Outreach, and Development, 800-835-4709, or 240-402-8010, or CDRHClinicalEvidence@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
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Office of Minority Health and Health Equity (OMHHE)

April 2022
Clinical/Medical

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Postmarketing Approaches to Obtain Data on Populations Underrepresented in Clinical Trials for Drugs and Biological Products

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U.S. Department of Health and Human Services
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August 2023
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Real World Data/Real World Evidence (RWD/RWE)

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