KEY POINTS OF A SYSTEMATIC REVIEW

RCT

Evi Nagler

Vice Chair, European Renal Best Practice

Conflict of interest

- Vice Chair, European Renal Best Practice

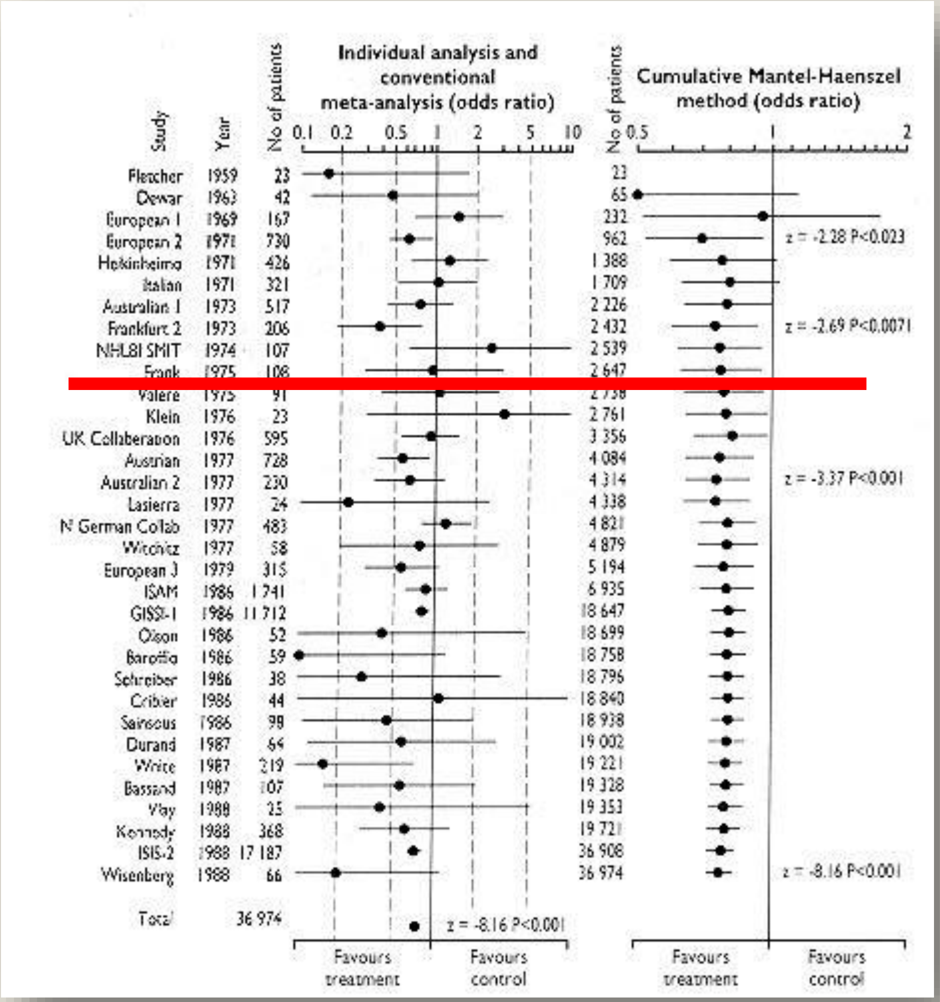
Systematic review

Narrative review

Mulrow et al. *BMJ*; 1994: 597-599

Systematic review

IV Streptokinase



Mulrow et al. *BMJ*; 1994: 597-599

What are these standardized methods?

PICO

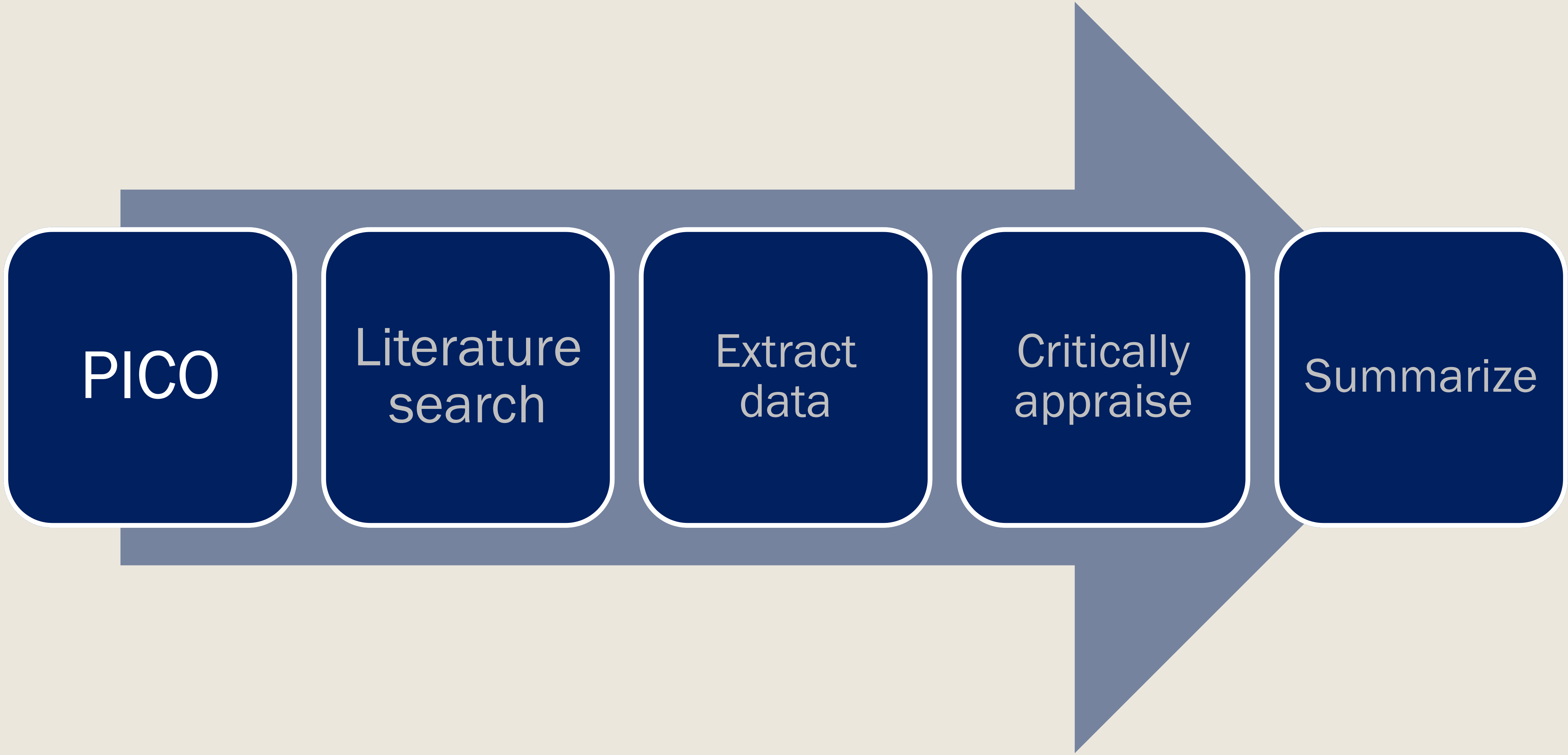
Literature search

Extract data

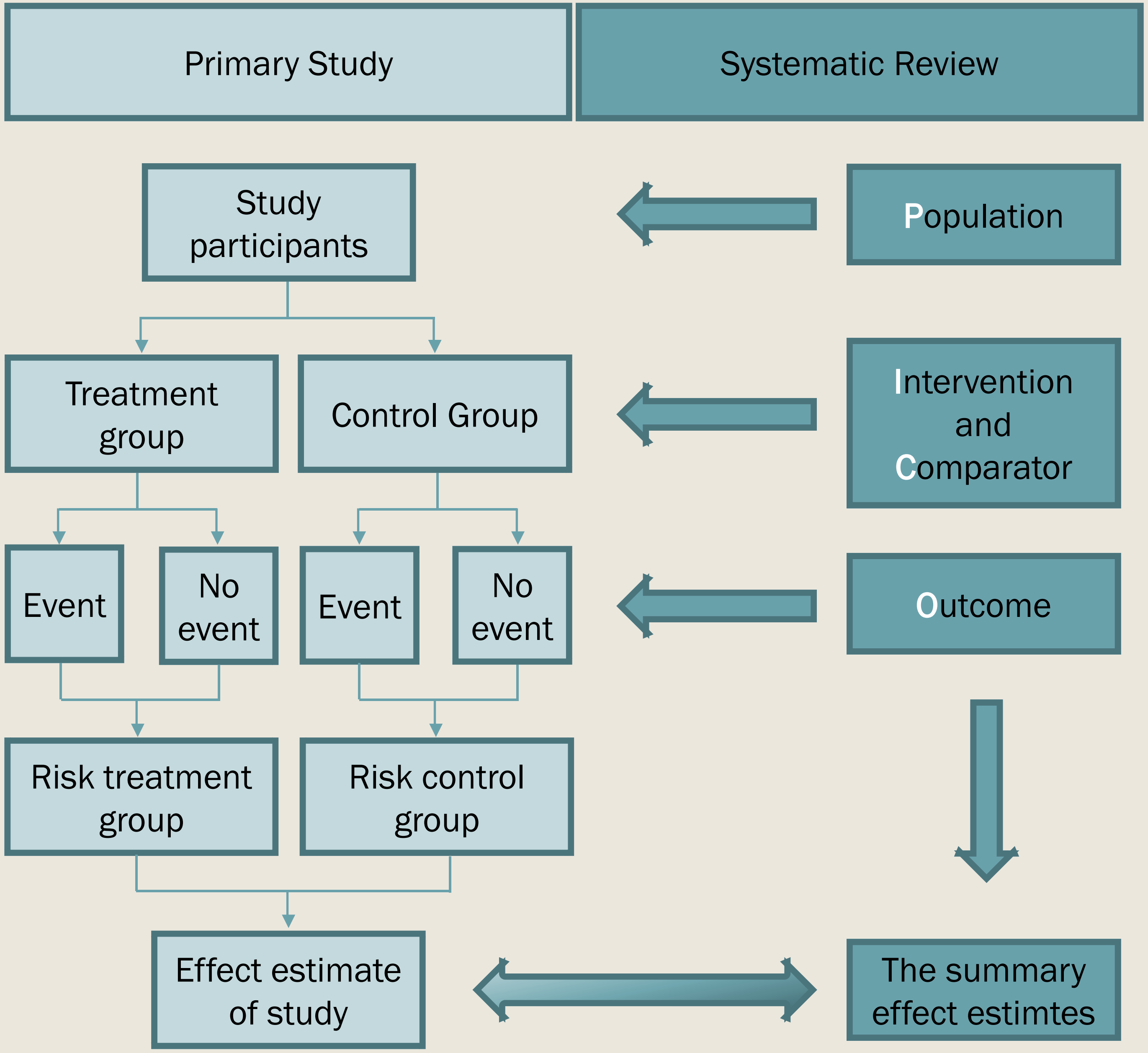
Critically appraise

Summarize

What are these standardized methods?

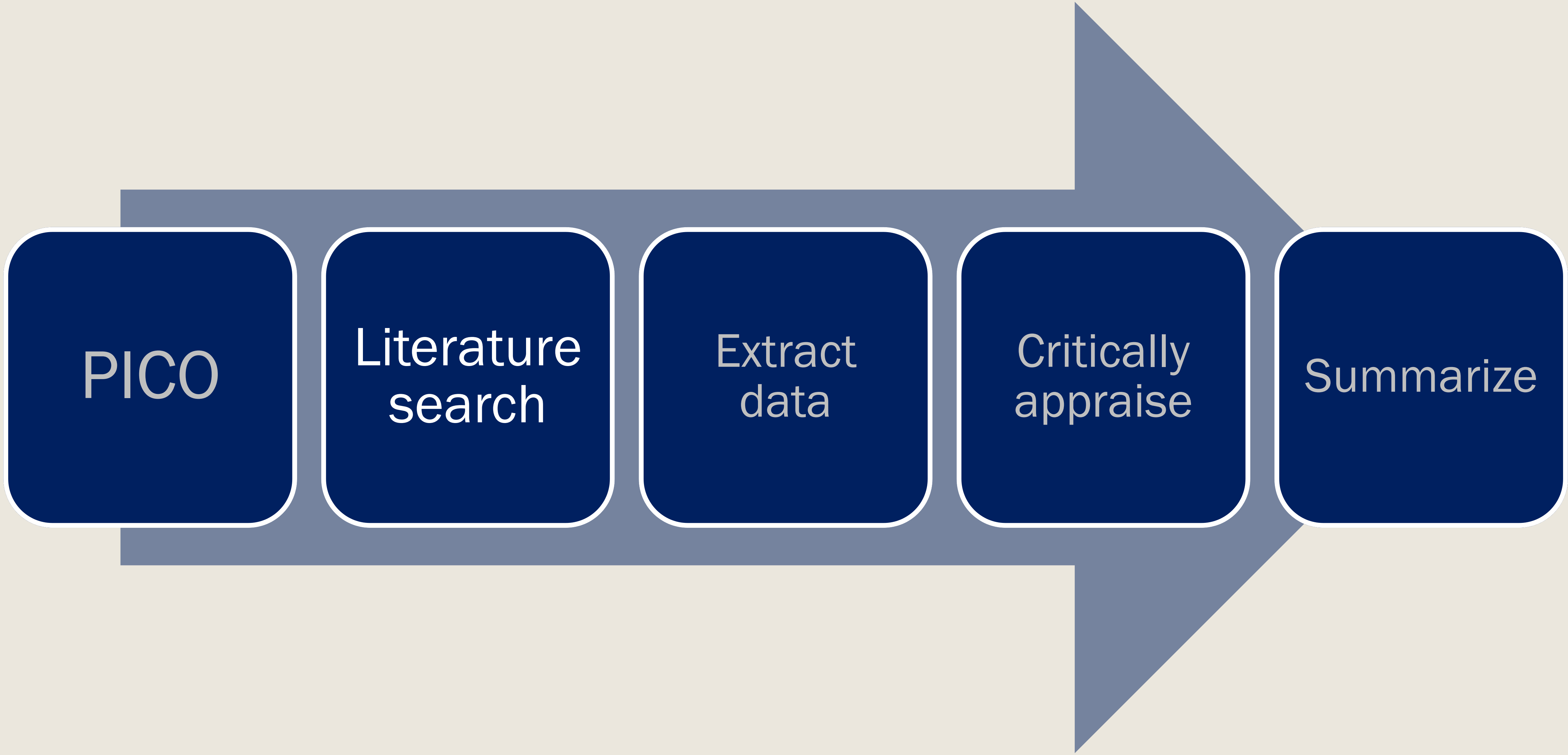


Why PICO ?

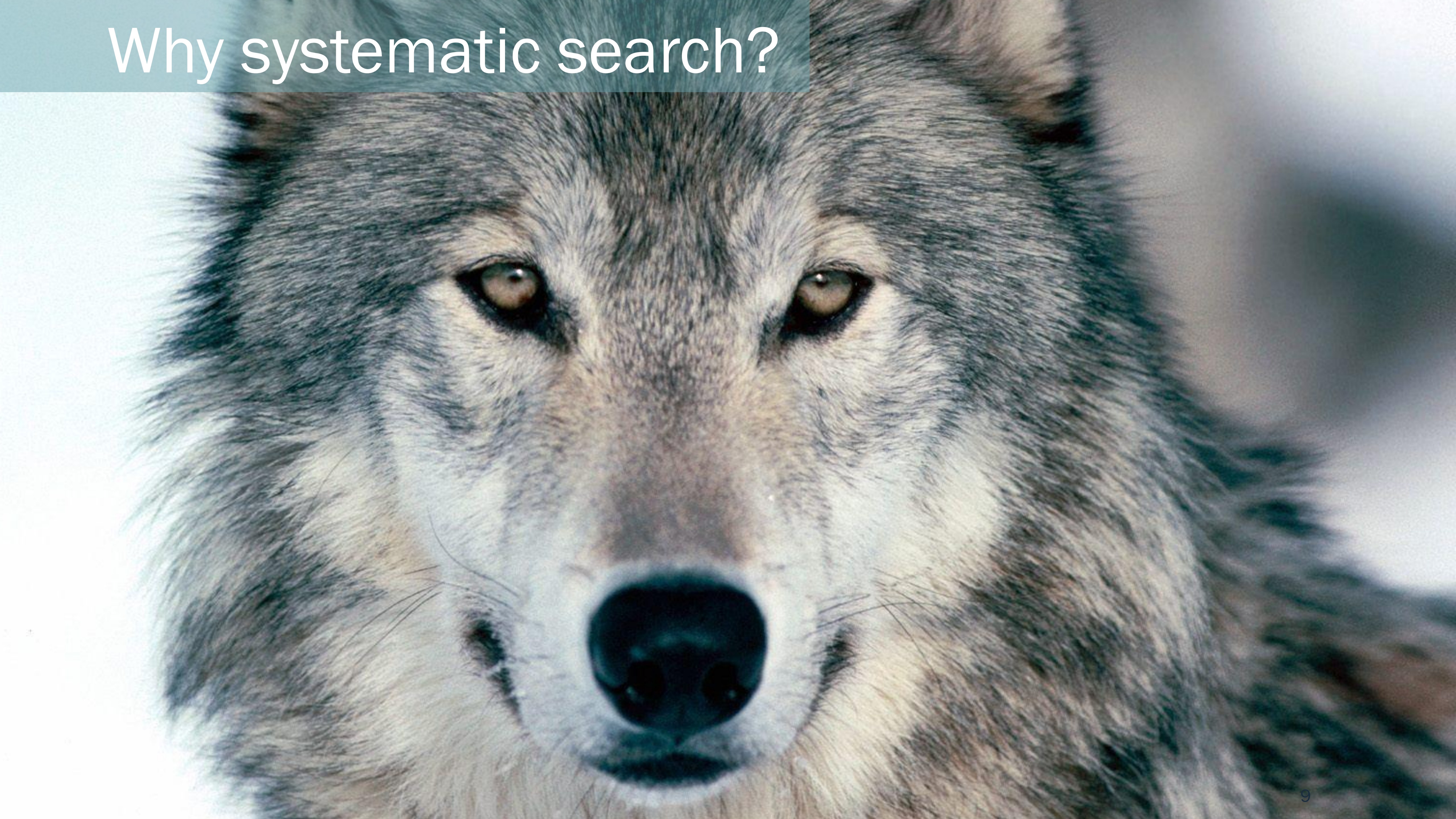


Prisma. J Clin Epidemiol; 2009: 1006-1012

What are these standardized methods?



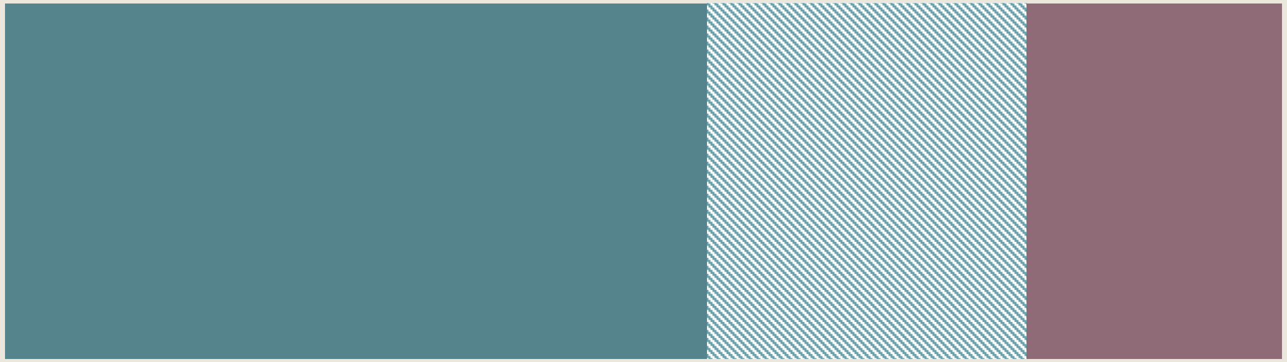
Why systematic search?



Why systematic search?

Why systematic search?

Medline



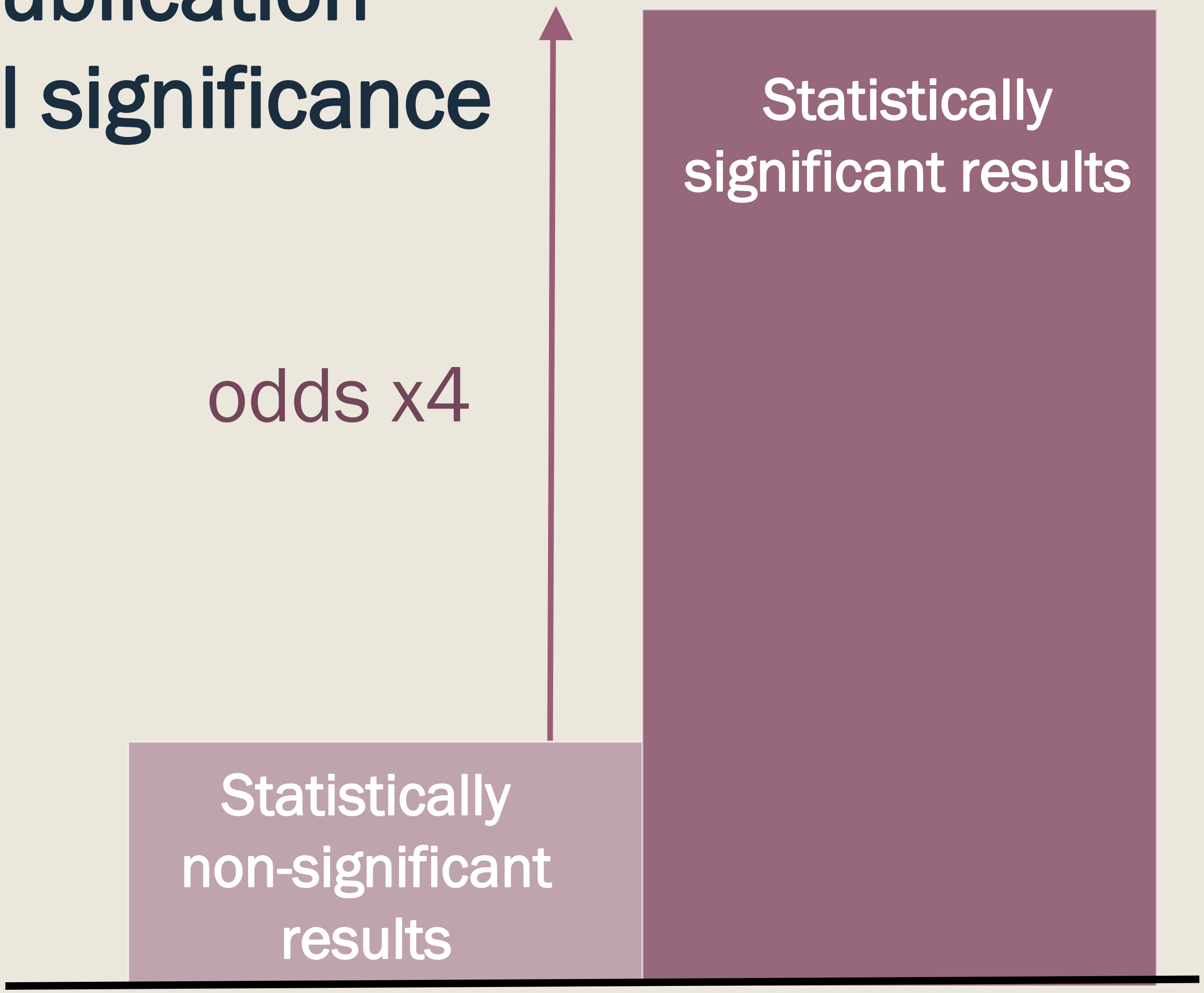
55 – 80% identified

20% missed

Hopewell et al. *CDSR*; 2007:18

Why systematic search?

Chance of publication by statistical significance



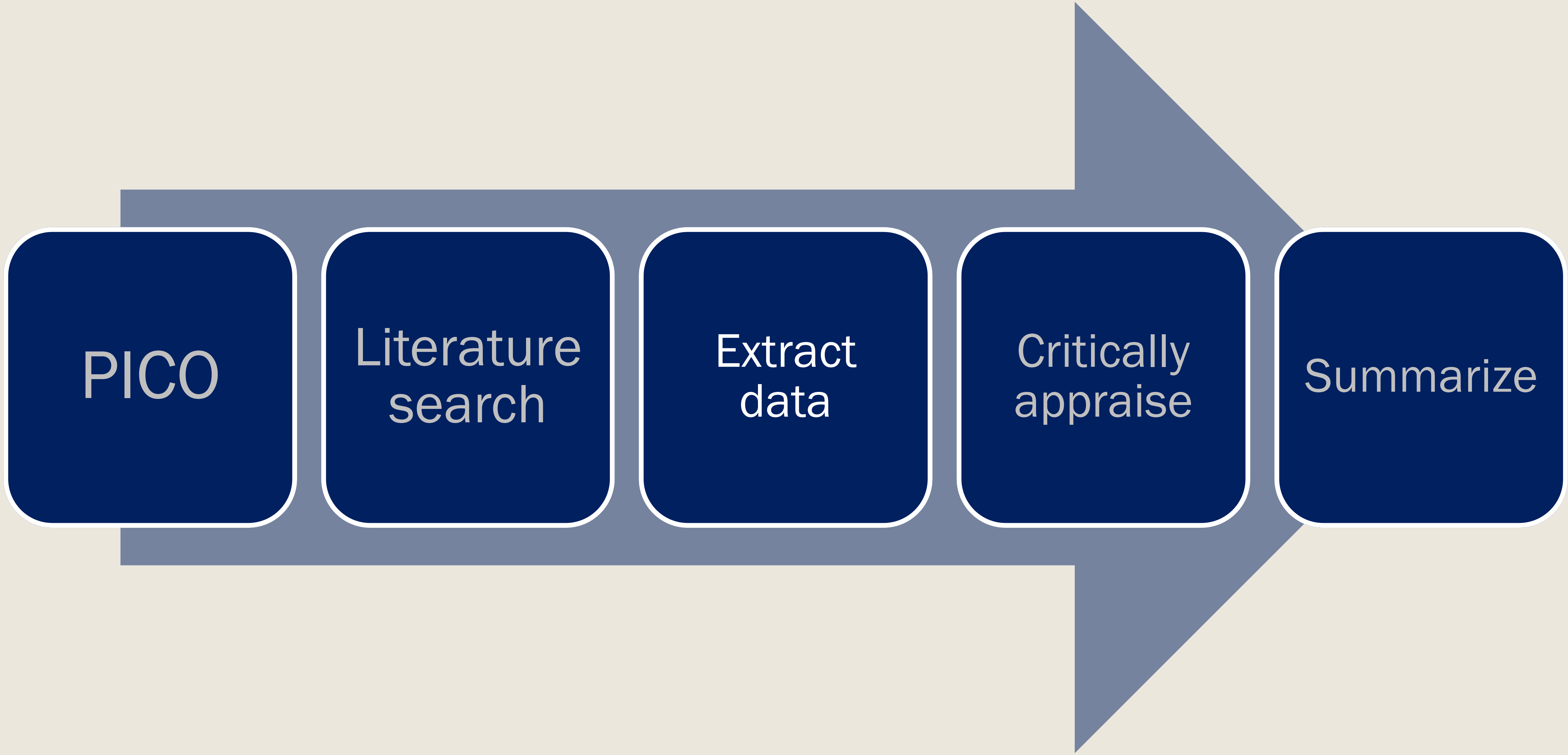
Hopewell et al. *CDSR*; 2009:21

Why study selection process?

IN

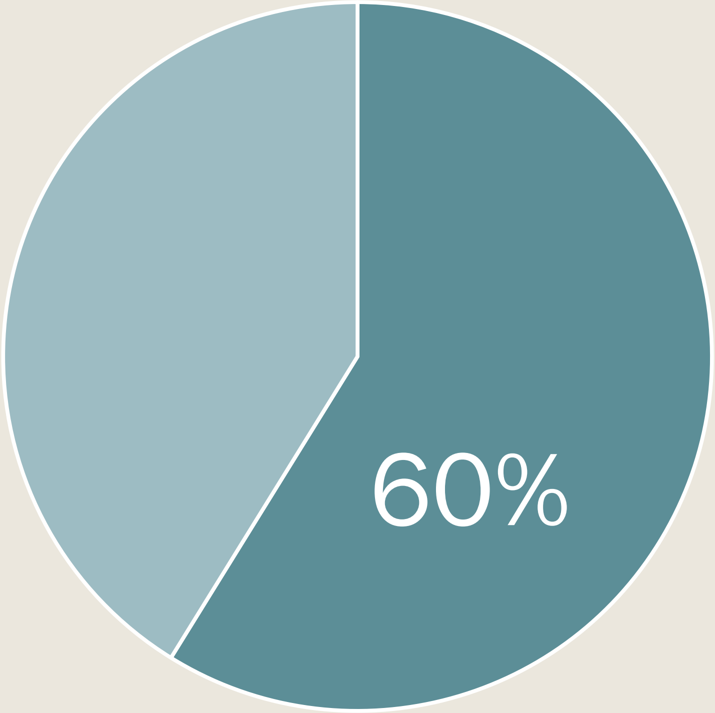
Out

What are these standardized methods?



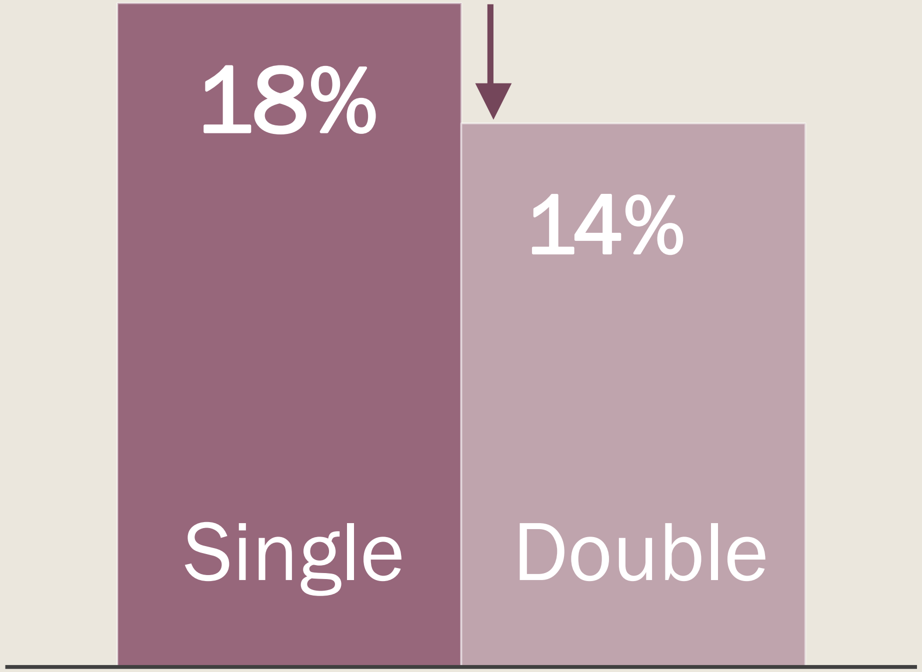
Why systematic data extraction by two?

Errors in published Systematic Reviews



Jones et al. *J Clin Epidemiol*; 2005: 741-742

Errors by type of data extraction



Buscemi et al. *J Clin Epidemiol*; 2006: 697-731

What are these standardized methods?

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Critically appraise

Summarize

Why critically appraise?

Bad design

Who needs stairs when you can fall?

Bad communication

Ahh, I knew we forgot something

Useless

Beautiful design, allas...

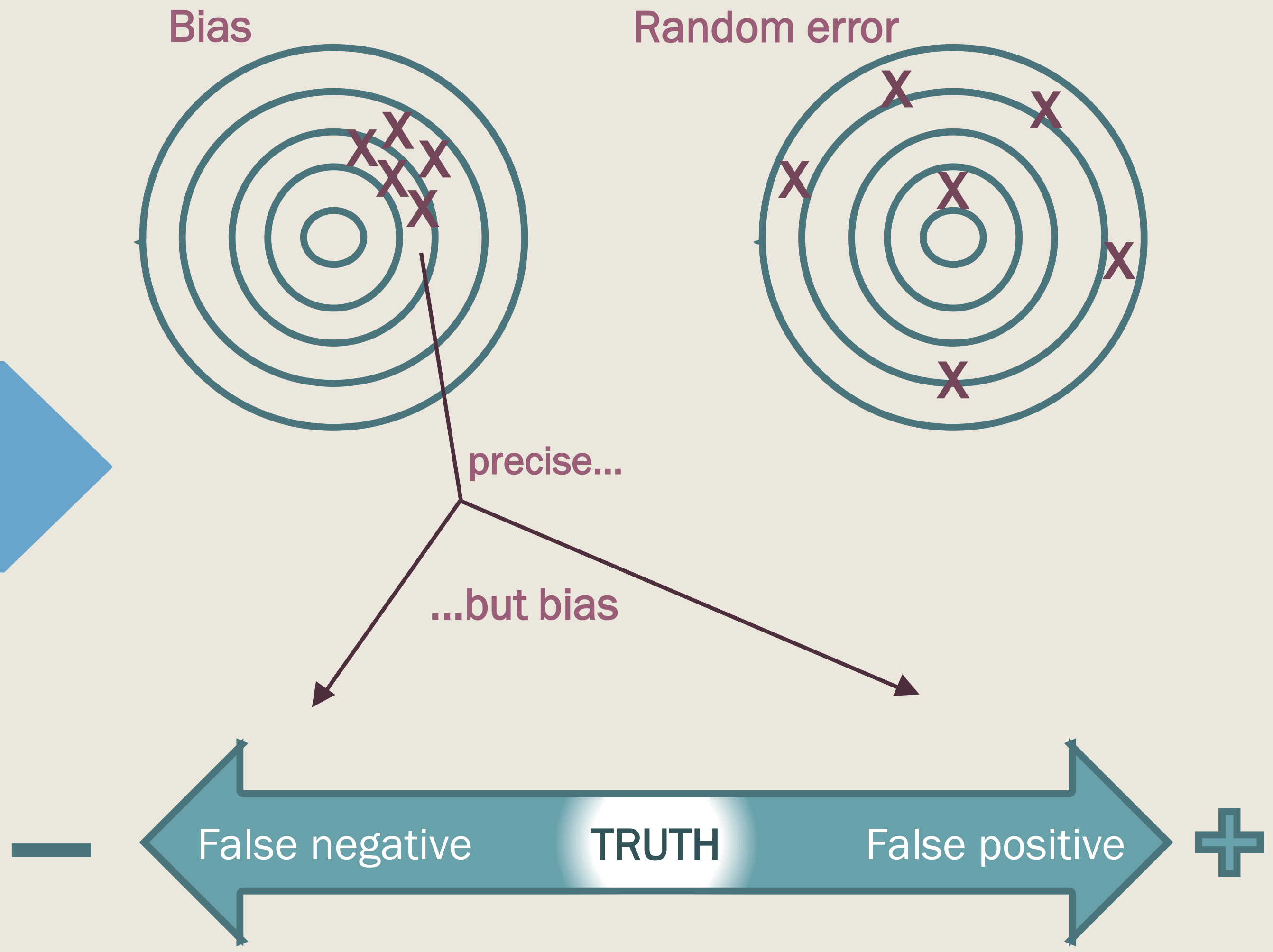
What is a critical appraisal?

1. Q1 - Reliable?
2. Q2 - Meaning?

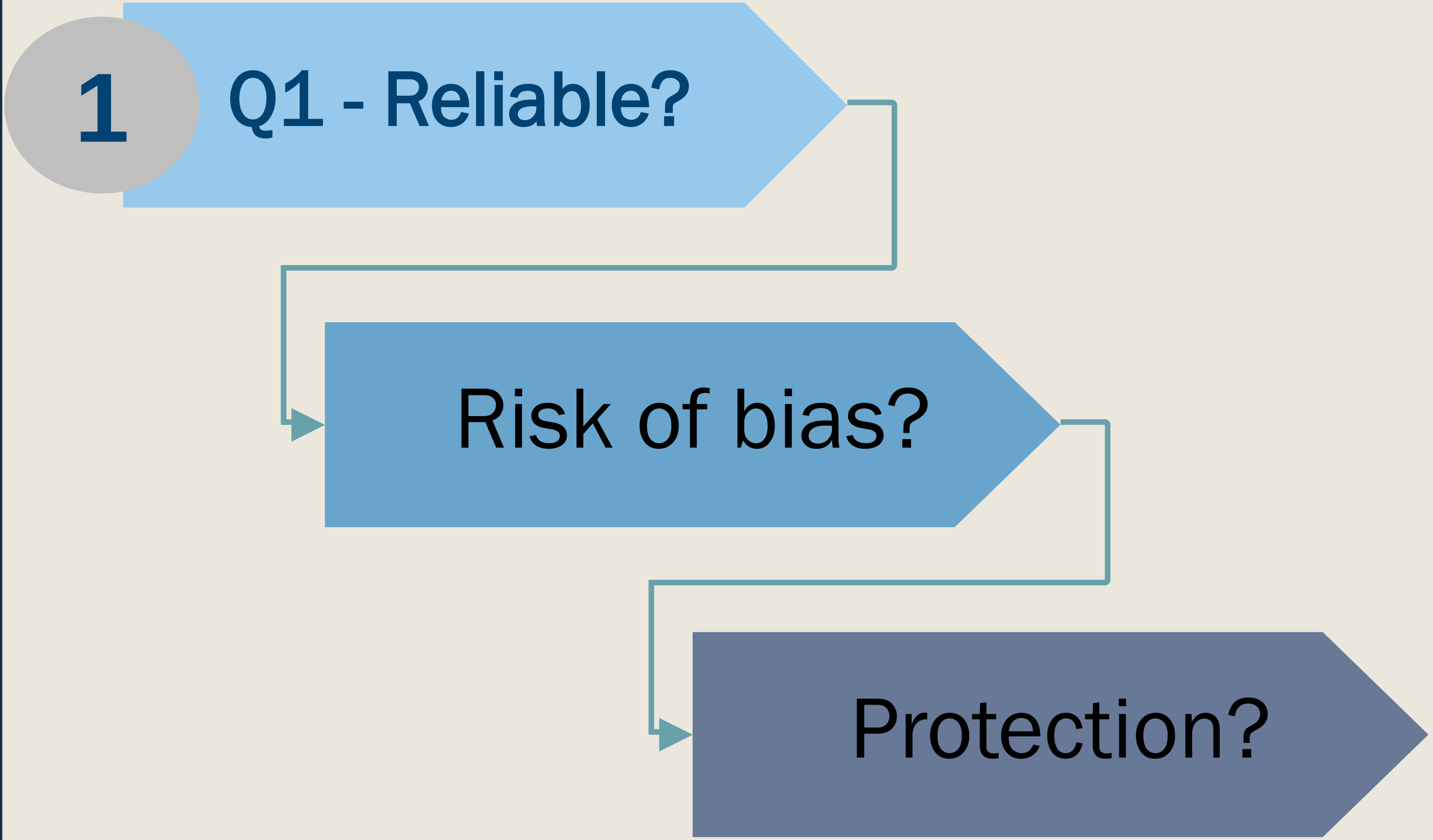
What is a critical appraisal?

1 Q1 - Reliable?

Risk of bias?



What is a critical appraisal?

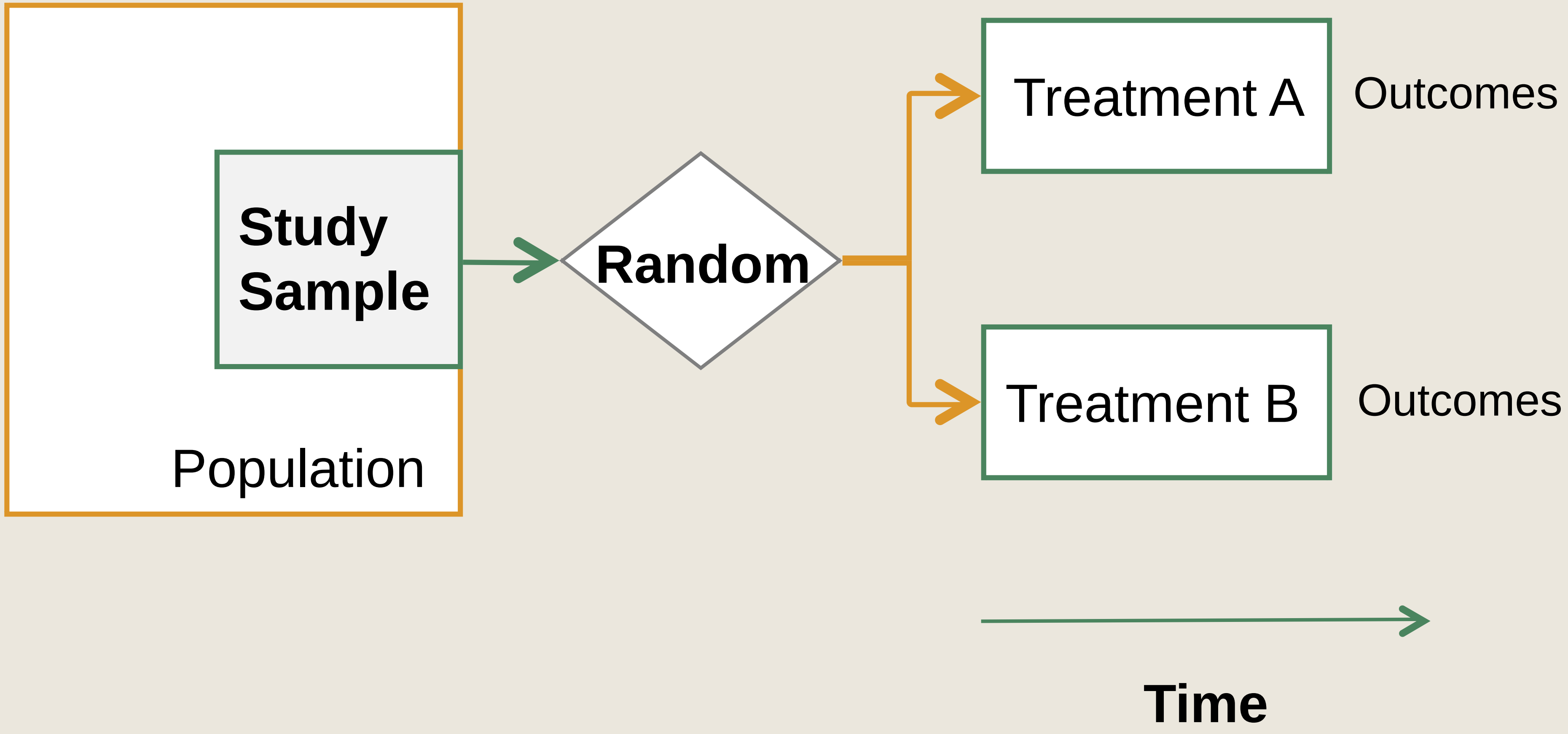


Protection - 5 Elements!

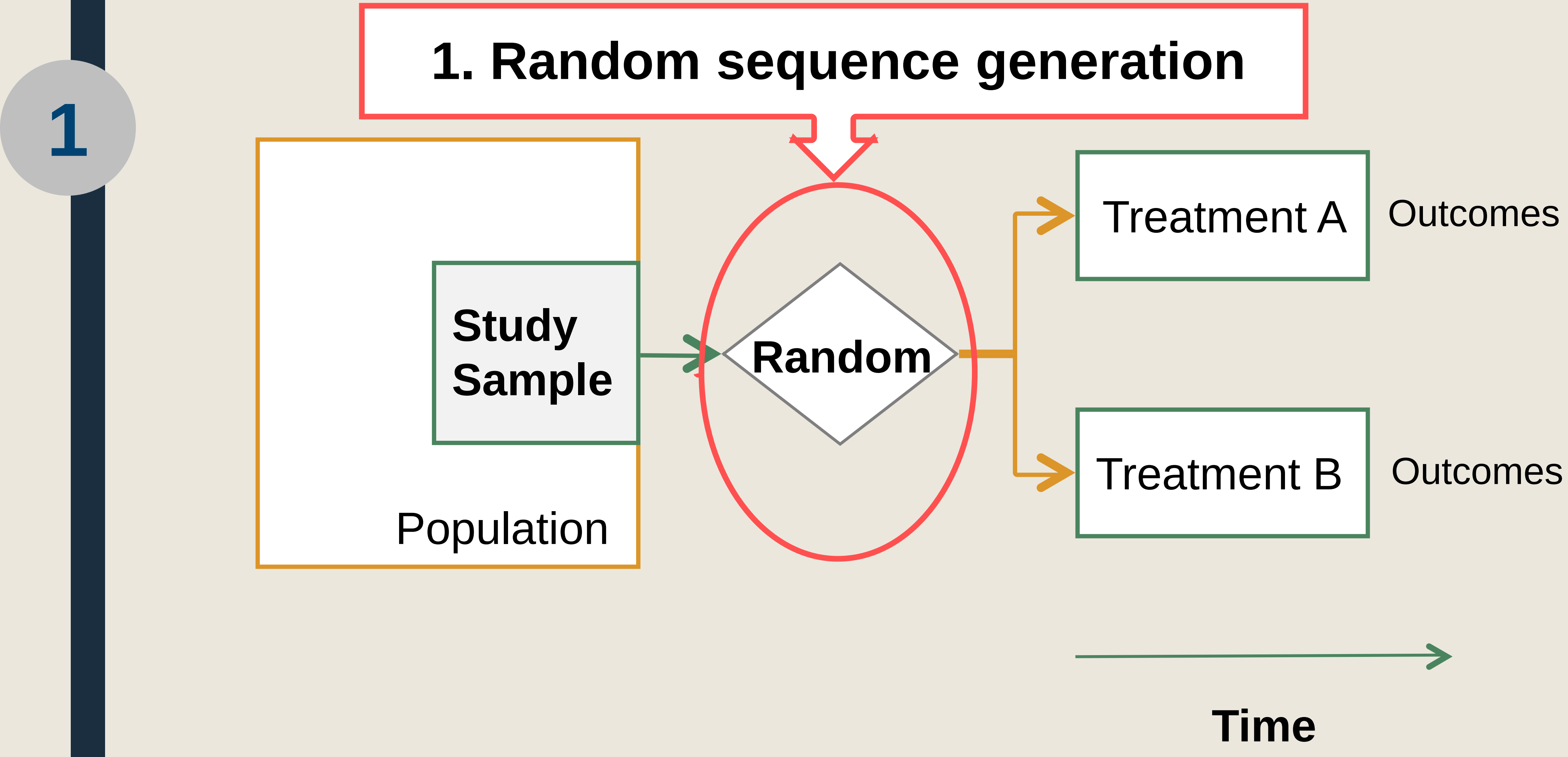
1 Random sequence generation

Protection – Random sequence

1



Protection – Random sequence



Protection – Random sequence

1 Random sequence generation

What is the goal of randomisation?

- Balancing groups for known and unknown factors that could influence their outcome
- Only difference between arms is the intervention
- Hence: difference in outcome is consequence of treatment

Protection - Random sequence

1 Random sequence generation

Good

- Random number tables
- Computer random number generator
- Coin tossing

Bad

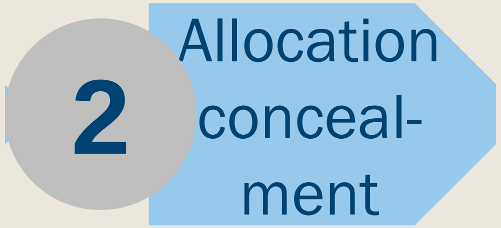
- Odd or even date of birth
- Date of admission
- Hospital record

→ Can’t be sure that the goups don’t systematically differ in some unknown factor that might have influenced the outcome!

Protection – 5 elements!

2 Allocation conceal-ment

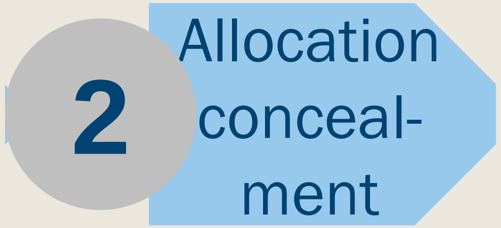
Protection – Allocation concealment



What

- Masking the treatment allocation from participants and investigators BEFORE they enter the trial

Protection – Allocation concealment



What

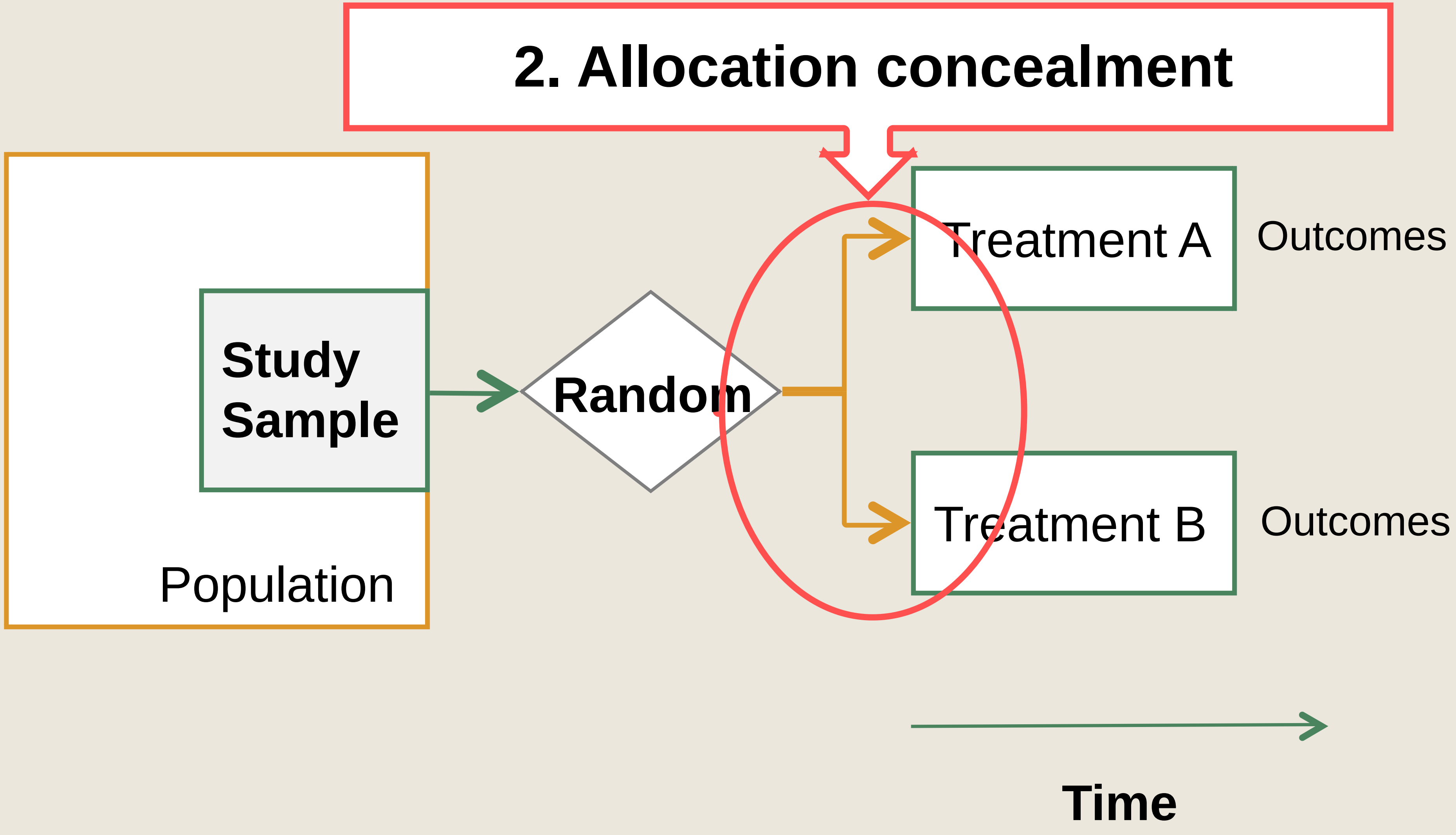
- Masking the treatment allocation from participants and investigators BEFORE they enter the trial

Goal

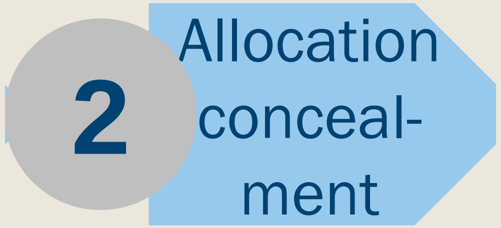
- To ensure knowledge of treatment allocation does not influence the decision
  - For patients to participate
  - For investigators to enroll

Protection – Allocation concealment

2



Protection – Allocation concealment



Good

- Central allocation (telephone, web-based after enrolment)
- Serially numbered, opaque, sealed envelopes.

Bad

- Open random allocation schedule
- Assignment envelopes without appropriate safeguards
- Not mentioning the concealment procedure

30-40 % higher treatment effect estimate

Protection – 5 elements!

3 Blinding

Protection – Blinding

3 Blinding

What

- Masking the treatment allocation to
    - Participants
    - Investigators
    - Health care providers
    - Data analists
- AFTER the randomisation procedure

Protection – Blinding

3 Blinding

What

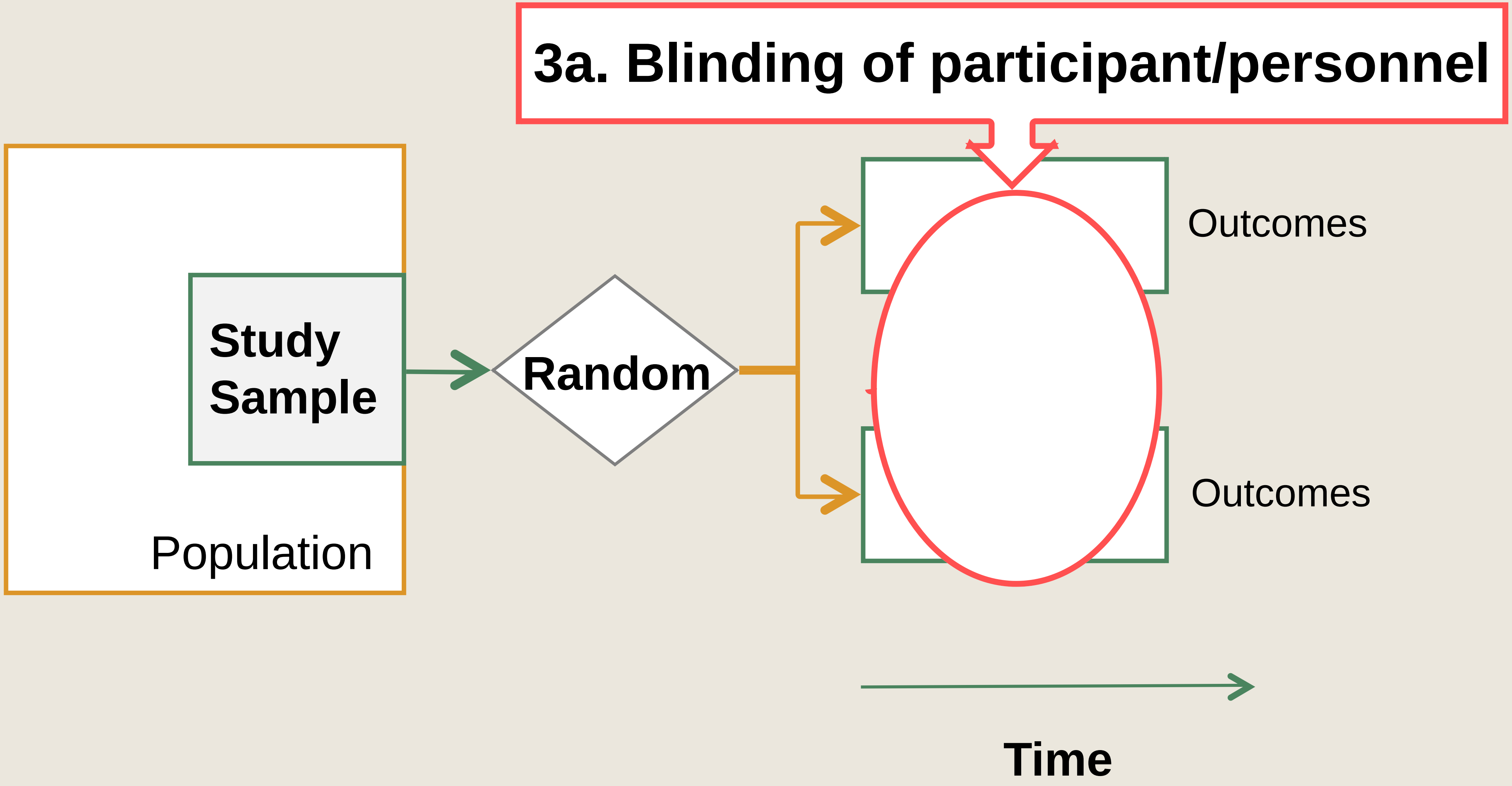
- Masking the treatment allocation to
  - Participants
  - Investigators
  - Health care providers
  - Data analists
- AFTER the randomisation procedure

Goal

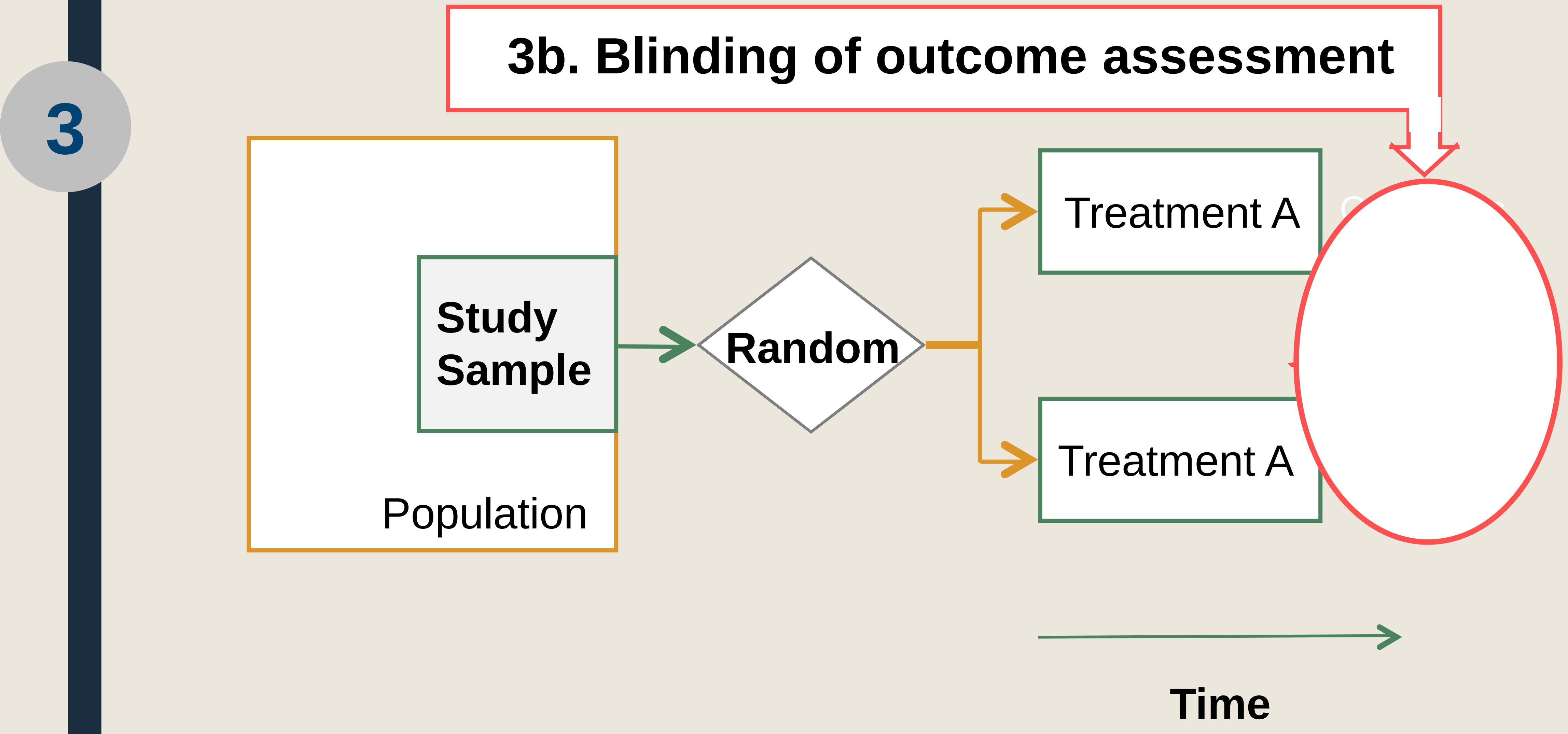
- Behaviour and perception of those involved is not influenced by knowledge of treatment

Protection – Blinding

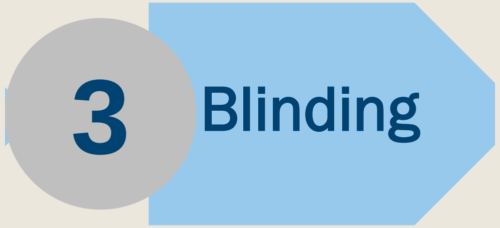
3



Protection – Blinding



Protection – Blinding



Good

- All participants and key personel blinded, unlikely to have been broken
- No blinding, but unlikely that this will have affected the outcome…

Bad

- No blinding or incomplete blinding, and outcome likely to be biased by knowledge of treatment allocation.

Protection – 5 elements!

Protection – 5 elements!

4 Follow-up

What

- What was the length of follow-up?

  Was the period long enough to observe a treatment effect?

- What was the loss to follow-up?

  ≤ 5% ok, ≤10% reasonably acceptable

  ≥ 20% screams trouble!

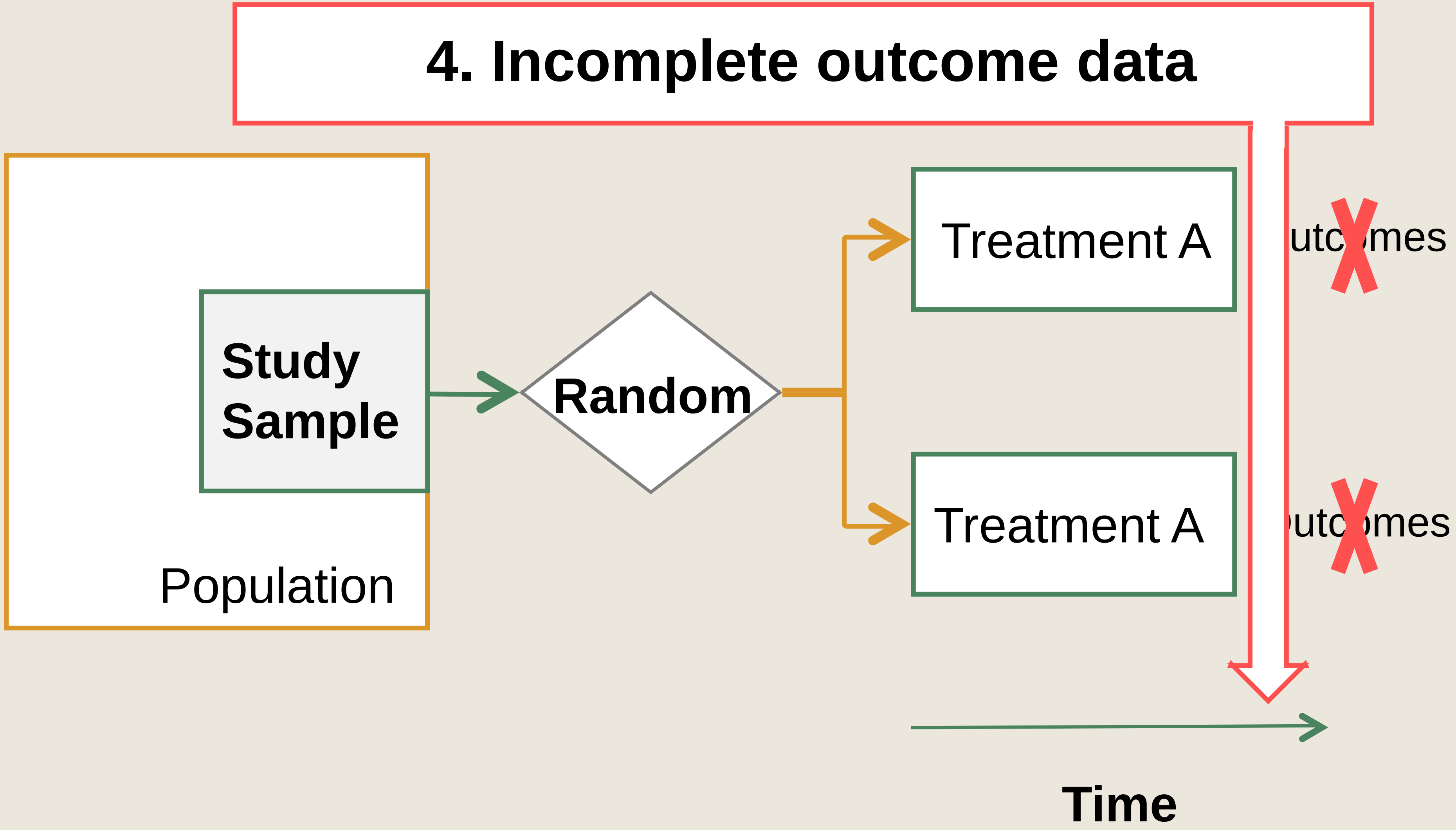
- Was the loss to follow-up evenly distributed and what were the reasons?

  Were they related to treatment side-effects?

  Was it because they moved?

Protection – Incomplete outcome data

4



Protection – Incomplete outcome data

Good

- No missing outcome data
- Missing outcome data balanced in numbers across groups, with similar reasons across groups
- ‘Intention-to-treat’ analysis

Bad

- Reason to be related to treatment and outcome, with either imbalance in numbers or reasons for missing data across intervention groups
- ‘As-treated’ analysis

Protection – 5 elements!

5

Selective reporting

Protection – 5 elements!

5 Selective reporting

What

- Only some of the expected end-points were reported

Protection – 5 elements!

5 Selective reporting

What

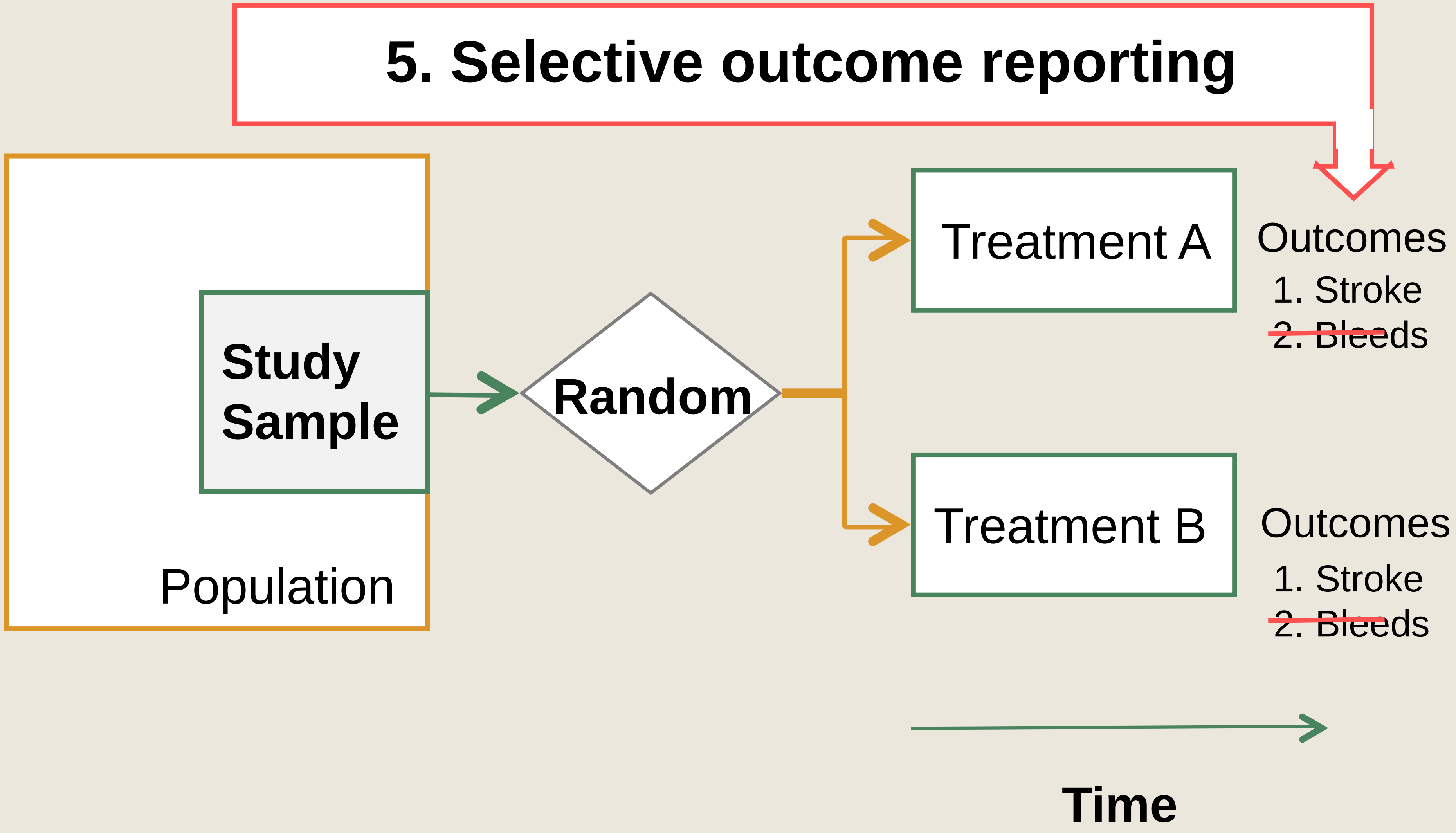
- Only some of the expected end-points were reported

Problem

- If harms or negative or statistically non-significant outcomes are not reported, the report will unfairly advantage the experimental treatment

Protection – Selective outcome reporting

5



Protection – Selective outcome reporting

5

5 Selective reporting

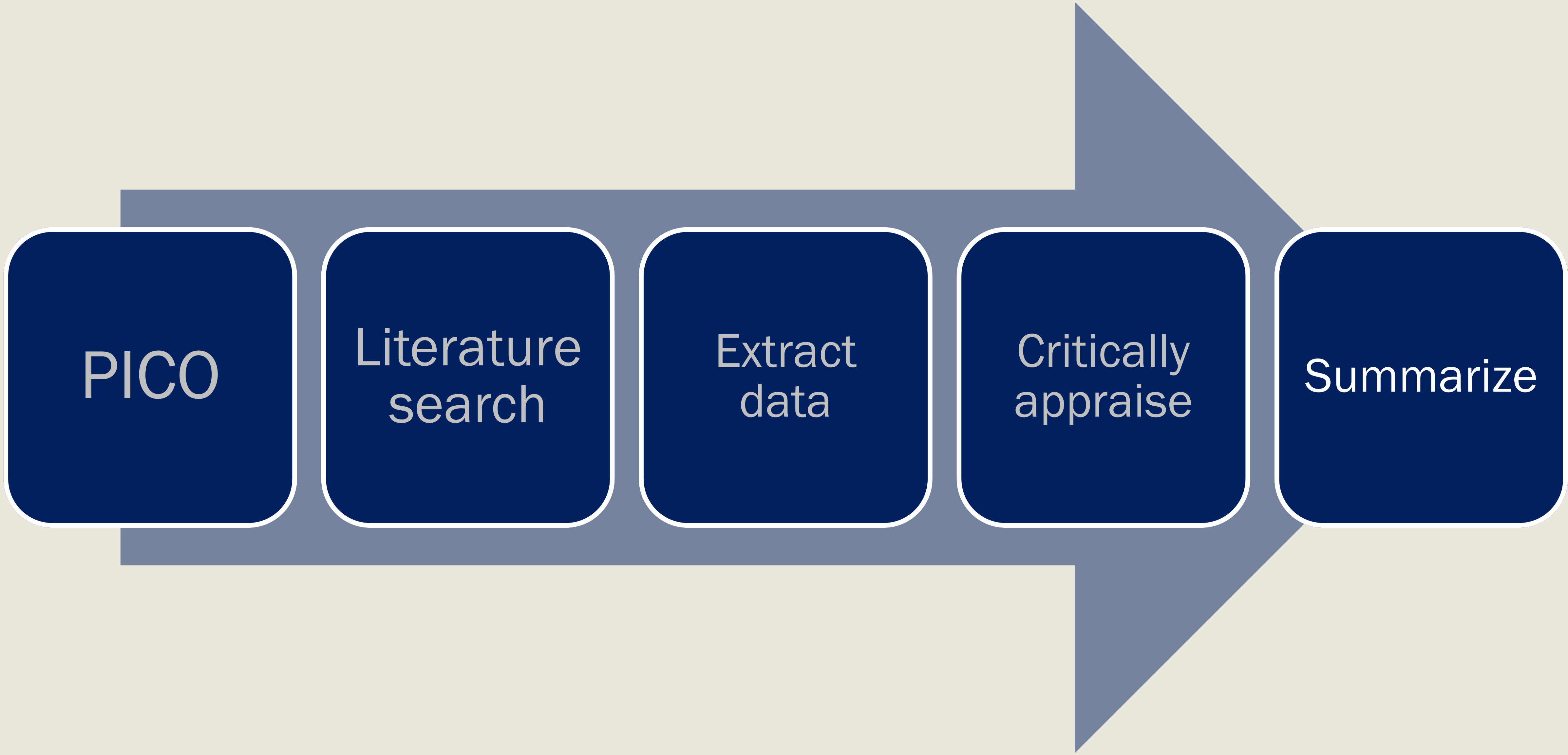
Good

- The study protocol is available and all study’s pre-specified outcomes reported
- The study protocol is not available but the published reports include all expected outcomes

Bad

- Primary outcomes reported using not pre-specified measurements or analysis methods
- Reported primary outcomes were not pre-specified
- The study report fails to include results for a key outcome that would be expected to have been reported for such a study

What are these standardized methods?



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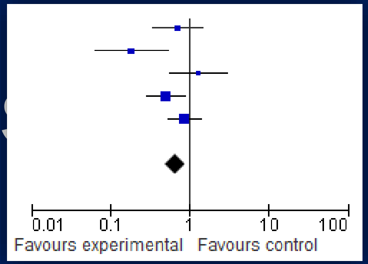
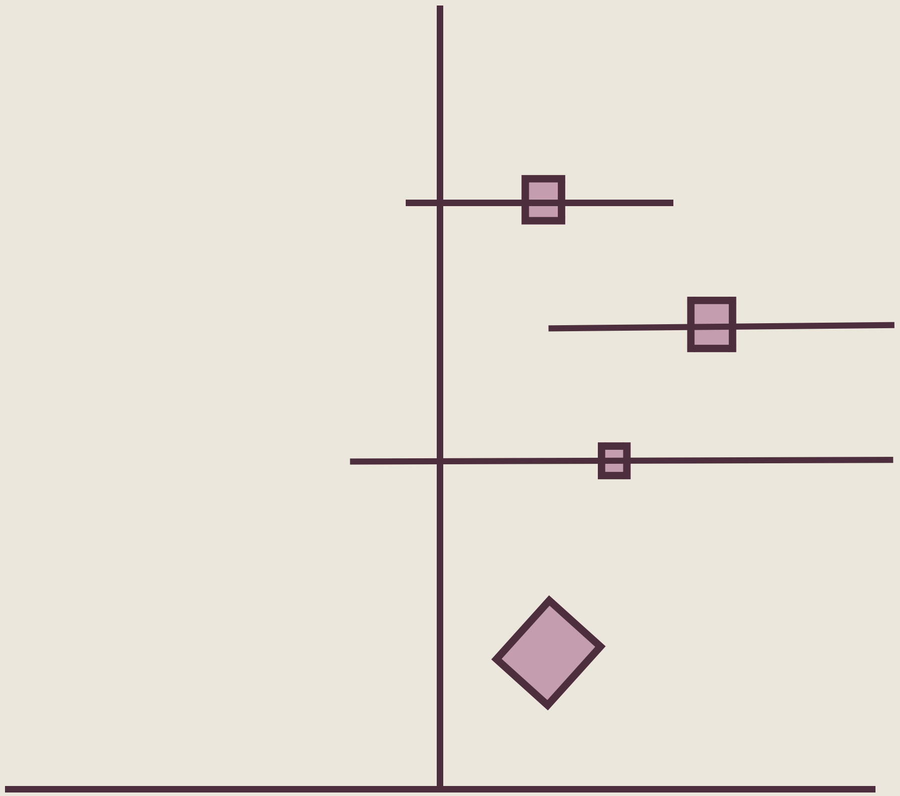


Systematic review ≠ Meta-analysis

Why? To increase precision



Systematic review ≠ Meta-analysis

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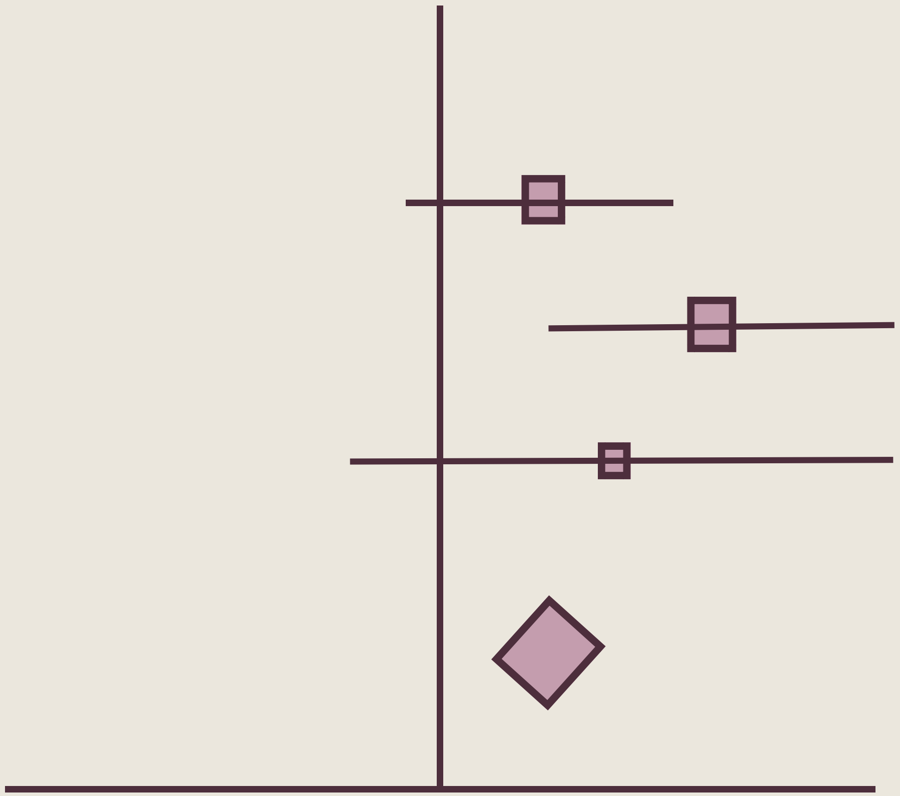
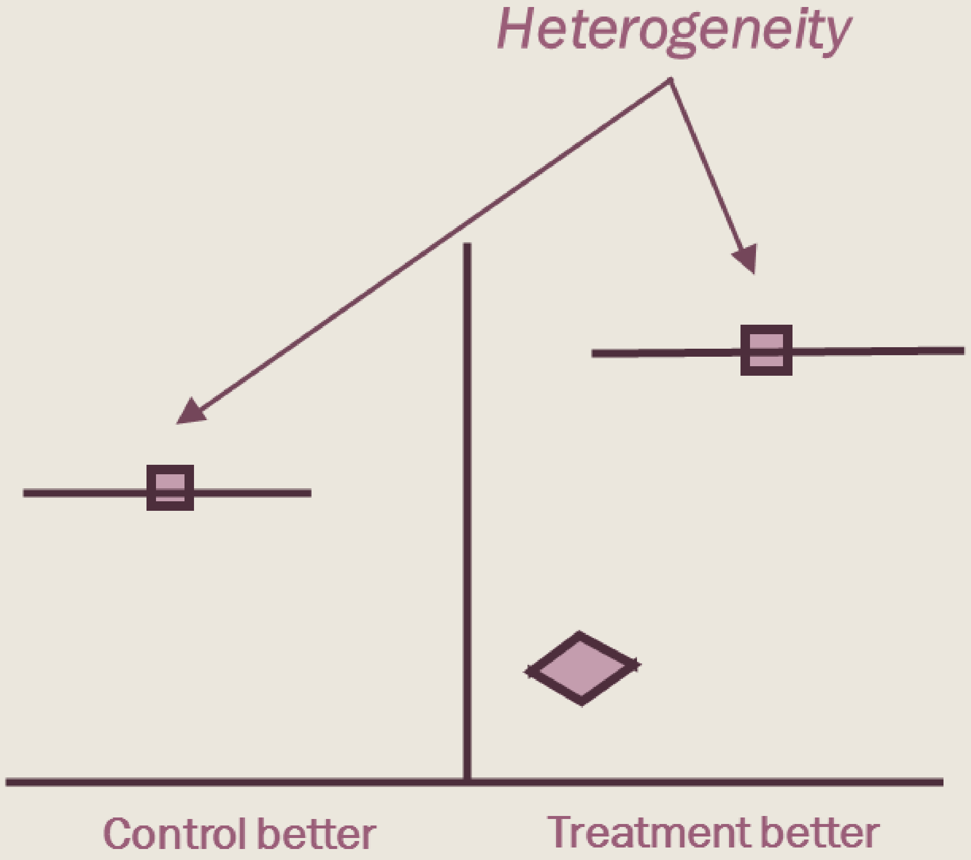


Careful : Do not compare apples and oranges…



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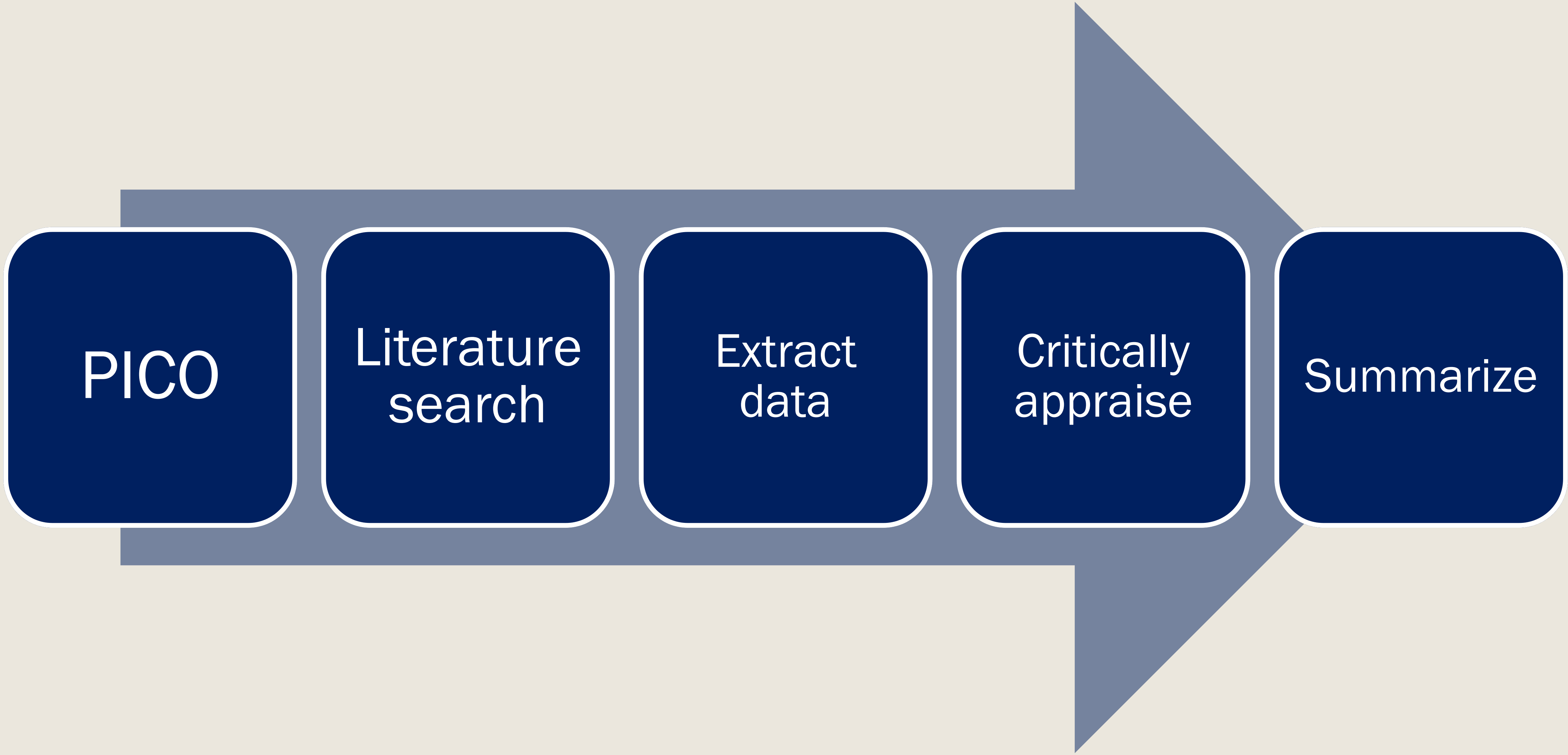

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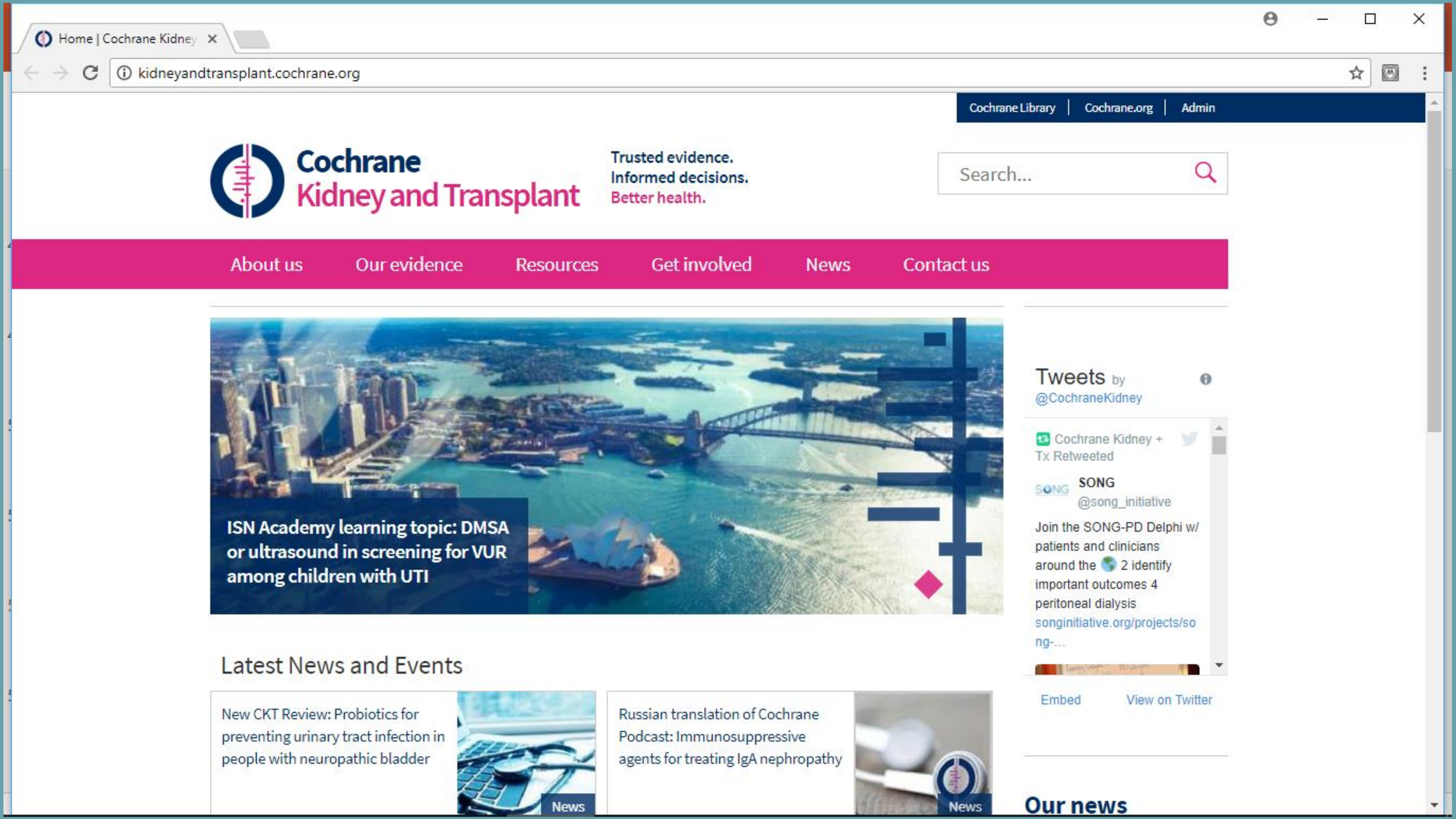
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European Renal Best Practice