**Step 1: Identify the study design**

What is being compared?

- Treatment only, no control group for comparison
- Treatment vs placebo
- Drug acts on one drug or placebo
- Different doses of the same drug

How similar were the groups of people in each treatment arm?

Ideally, the ONLY thing that’s different between the groups is the treatment that the people get. Getting the best results this way is called randomization.

How large was the study?

Larger studies better represent the populations and show how likely differences in outcomes are real, while small studies may show biased results. At the start of a study, researchers use statistics to determine how many people they need to achieve the most certain outcome.

Who knew which patients received which treatment?

Subjects’ and researchers’ behavior can influence outcomes if they know who is receiving the treatment. Placebo treatments (i.e. pills or injections that look like the real drug, but contain no active drug) are typically used to keep everyone blinded.

**Step 2: Assess how well the study was analyzed**

What outcomes were measured to determine treatment effectiveness?

Outcomes to be measured are determined before a study begins and should not change during the study. Objective outcomes are more reliable to measure, but subjective outcomes can be just as valid.

How many patients remained in the study? What happens next?

When more people drop out of a particular group of the study, this indicates something was wrong with that group (e.g. pills or injections that look like the real drug, but contain no active drug) are typically used to keep everyone blinded.

<table>
<thead>
<tr>
<th>Outcome measure</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vital signs</td>
<td>How a patient feels.</td>
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What's wrong here? The controls are mostly elderly and female subjects. Age and sex often affect disease outcomes, so it would be hard to determine whether a safe and effective treatment.

Even if approved, sometimes a treatment may not work in the real world because of how the drug is taken, or different patient populations. As an example of when subjective outcomes are important: if patients feel a drug gives them hope, they may be more likely to take it. This may not be due to the treatment, but rather to the placebo effect.

**What happens next?**

- If there were no differences, the standard of care remains the same.
- If there were differences, the new treatment is used.
- If the study followed up to this point, researchers compare how patients did with and without the treatment. Researchers may design a repeat clinical trial to study interesting outcomes that were observed in the original study (but not directly tested), or change the sample size, or population.

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**Analysis:**

- **Drug combo:**
  - One drug + placebo
  - One drug + another drug
  - One drug + placebo, double-blinded
  - One drug + another drug, double-blinded

- **Control Treatment:**
  - Control, single-blind
  - Treatment only, placebo, single-blind
  - Placebo, double-blinded

- **Trial starts to assess:**
  - Short-term effects: first 2 months
  - Long-term effects: entire study

- **FDA evaluates for approval:**
  - Approval required before a drug can be used in the real world
  - Approval tested only one drug in severe cases

- **Phase 4:**
  - Clinical trials to study interesting outcomes that were observed in the original study (but not directly tested)
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**Diagram:**

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