

Randomized trials

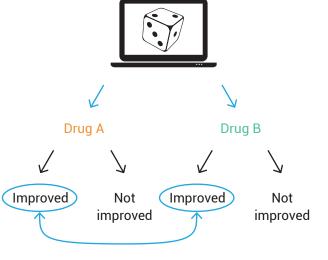
Historical controls

Comparison of data from patients who received a new drug with data from patients who have received an old drug in the past.

Received **Beceived** old drug new drug Group B Group A Now Review of State of patient ≠ the art data records acquisition

Randomization

Treatment is allocated by chance with no possibility of human influence.



Comparabilty of data:

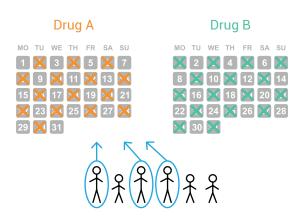
Data quality for the time when the old drug was used will probably be inferior compared to the quality of data in the period when the new drug was applied.

There will be differences between groups relating to changes over time (e.g., treatment, health care system, resources, environmental factors). When testing the effects of different drugs in humans the goal is to test them in groups that are as comparable as possible.

Why is comparability of groups so important? If there is no true randomization, treatment groups might differ significantly and that difference may influence end points.

Non-random allocation

One way of allocating non-randomly is by allocating treatment by the day of the month on which patients were admitted to the hospital.



"Pseudo-randomization":

Doctor's preconceived convictions about the effectiveness of a certain drug can influence allocation which will lead to groups not being comparable.

