How do drugs and devices get FDA approval?

Drugs

The Gold Standard

For many years, the FDA required two clinical trials to determine if the drug is safe and effective, meaning the benefits usually outweigh the risks when used as intended.

- ✓ The clinical trials include many patients
- ✓ Patients are randomly chosen to take the drug or a placebo (or comparator drug)
- ✓ The patients do not know if they are taking the drug or a placebo. The doctors do not know which patients are taking the drug or a placebo.

In recent years, FDA increasingly approves drugs reviewed under "faster pathways" with lower standards:

- Smaller number of patients
- Some studies aren't 'double blind,' opening the door to bias in the reporting of results
- Some study results are based on "surrogate" markers like tumor shrinkage or blood pressure instead of patient health or survival

67% of cancer drugs were approved this way for 'expedited review':

- Surrogate endpoints as an outcome
- Only required to complete one clinical trial
- Required to conduct a longer-term study after approval, but little incentive to finish quickly

Devices

Low risk devices (band aids, crutches):

- No application to FDA necessary

Moderate risk devices (artificial joints, glucose monitors):

- 95% of devices are in this category
- No clinical trials to prove safety or effectiveness required
- Must show **'substantial equivalence'** to another device on the market (could be to a device that has been recalled)

High risk devices (pacemaker, artificial heart):

- 1 clinical trial to show 'reasonable' assurance of safety & efficacy
- Often have no control group, so scientists cannot always determine if the device itself is safe and effective

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