Participating in a Clinical Trial

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Presentation Overview

The following topics will be discussed during the presentation:

- What is a clinical trial?
- What is a clinical trial volunteer?
- What are the phases of clinical trials?
- What is informed consent?
- How do I find out about clinical trials?

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Clinical Trial Overview

A **clinical trial** involves research using human volunteers (also called participants) that is intended to add to medical knowledge.

Human subjects are individuals who are participants in research. A subject may be either a healthy human or a patient.

Sources:
Food and Drug Administration (FDA) CFR - Code of Federal Regulations Title 21
Clinicaltrials.gov https://www.clinicaltrials.gov

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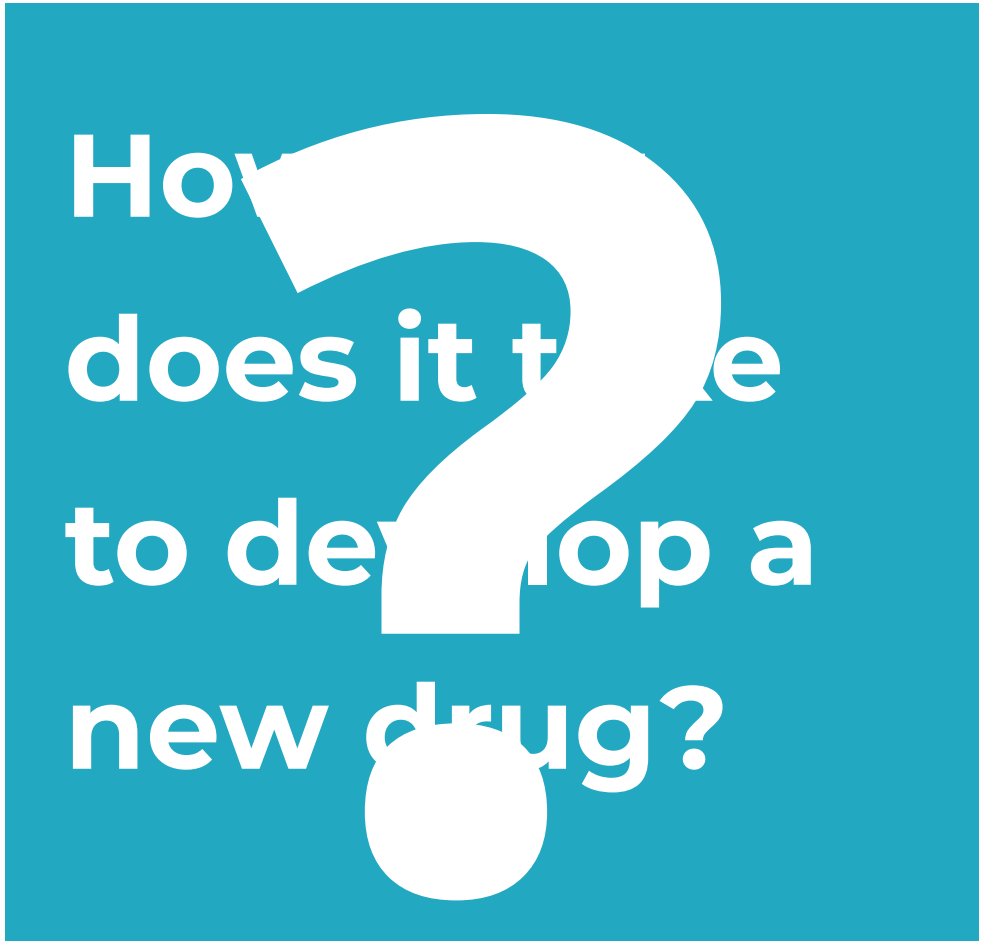
Interactive Polling Question



RED: ~10 years

BLUE: ~15 years

GREEN: ~5 years

YELLOW: ~20 years

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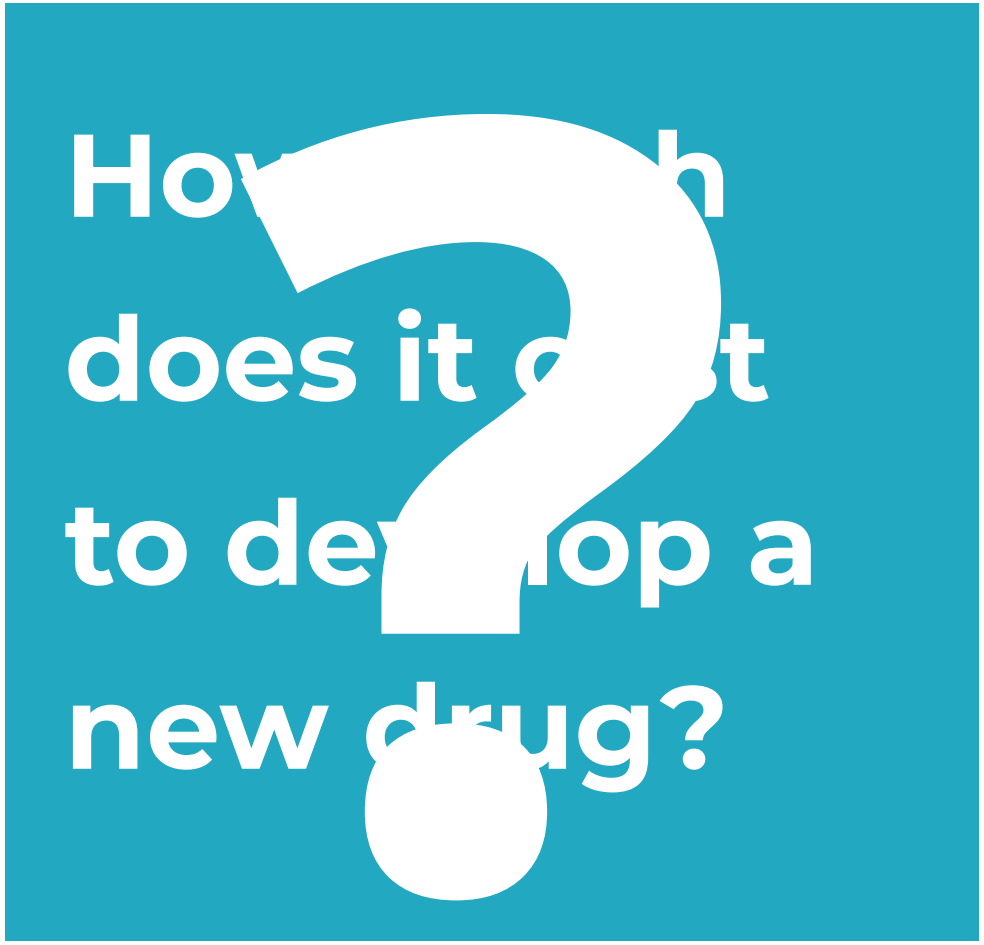
Interactive Polling Question



RED: 20 million dollars

BLUE: 85 million dollars

GREEN: 10 million dollars

YELLOW: 50 million dollars

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What are the different trial phases?

	Phase I	Phase II	Phase III	Phase IV
Purpose	Testing the safety of the drug - first testing in humans; for oncology studies not healthy volunteers	Determining whether a drug works in a broader population	Confirming how well a drug works in a large number of patients - size and scope depends on the disease prevalence	Proving a drug in the real world
Studies…	…safety of the medication or treatment	…efficacy	…safety, efficacy and dosing	…long-term effectiveness; cost effectiveness
# of participants	20-80	100-300	1,000-3,000	Thousands
Duration	Up to several months	Up to years	1-4 years	>1 year
Success rate	70%	33%	25-30%	70-90%

Basic description of different clinical trials phases (Source: CERN Foundation)

Interactive Polling Question

RED: Doctor or other healthcare professional

BLUE: From a family member or friend

GREEN: From the internet (social media, online advertisements, online patient forums)

YELLOW: Other sources

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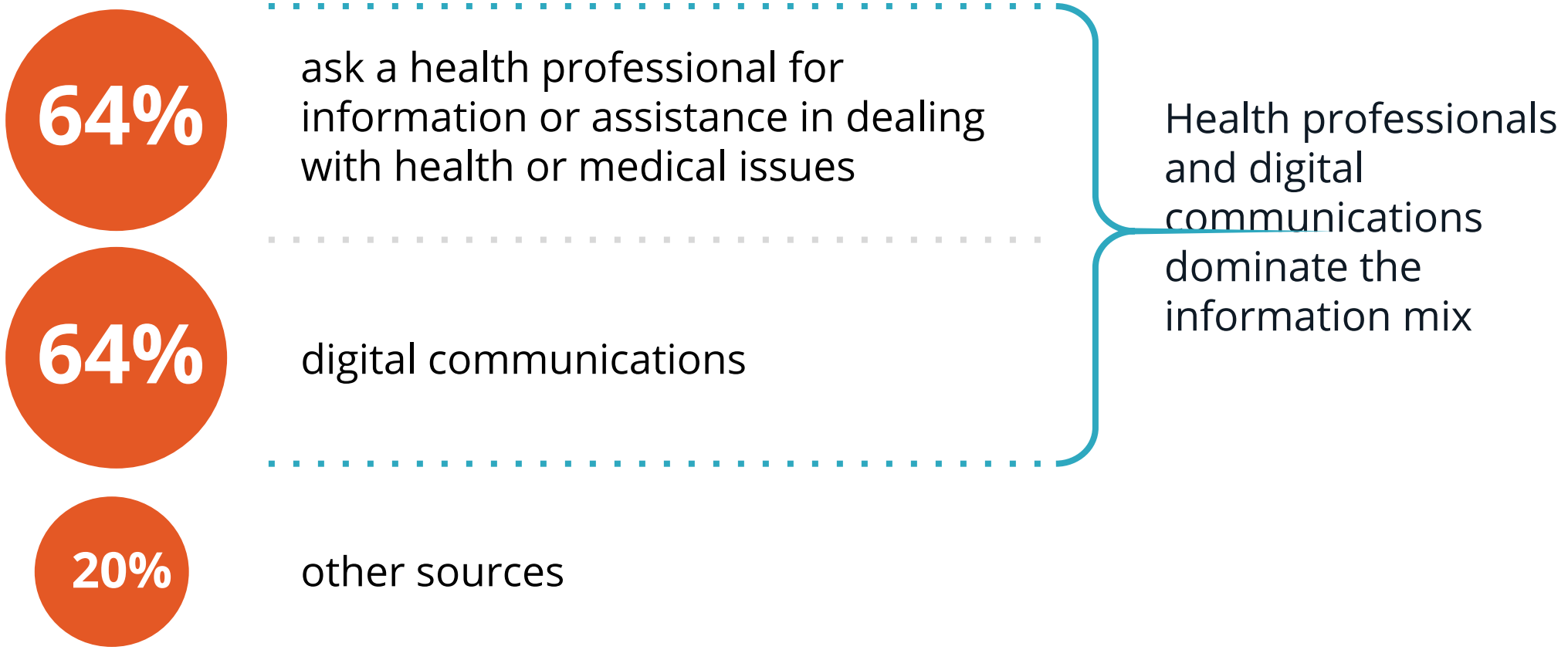
How do people find out about clinical trials?

Sources and influencers vary depending on disease status



Sample Size = 12,427, Base: All respondents Source: CISCRP 2017 Patient and Insights study Survey

What is informed consent?

- **Informed Consent** is process used by researchers to communicate to potential and enrolled participants the risks and potential benefits of participating in a clinical study.
- A patient must to agree to the study requirements and sign an **informed consent document** before starting the screening process for the study
- **You can choose to leave the study at any time**
  It is ultimately the choice of the patient to participate and continue participation in a research study. The decision to end participation in a study should involve discussions with the study physician and your own personal physician.

Clinicatrials.gov: https://clinicaltrials.gov/ct2/about-studies/glossary

Interactive Question

Blue Scenario

An informed consent document was provided to Mrs. Smith. Dr. Brown reviewed the information with Mrs. Smith and informed her that she could not change her mind about participation in the clinical trial after she signs the consent document.

Orange Scenario

An informed consent document was provided to Mrs. Smith. Dr. Brown reviewed the information with Mrs. Smith and allowed time for her to discuss the research study with her family members as well.

What questions should I ask?

Don’t be afraid to ask…

- What type of procedures or tests are required and what to do these tests involve?
- What are other treatment options and how does the study treatment compare?
- How many office visits are there and how long is each visit?
- Is hospitalization required for any visits or at any time?
- What are the known side effects?
- What there be any cost to participate ?
- Will my insurance cover any of the costs?
- How long is my involvement needed?

Questions

Thank you!