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?
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
Interactive Polling Question

How long does it take to develop a new drug?

- **RED**: ~10 years
- **BLUE**: ~15 years
- **GREEN**: ~5 years
- **YELLOW**: ~20 years
Interactive Polling Question

How much does it cost to develop a new drug?

- **RED:** 20 million dollars
- **BLUE:** 85 million dollars
- **GREEN:** 10 million dollars
- **YELLOW:** 50 million dollars
### What are the different trial phases?

<table>
<thead>
<tr>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Phase IV</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Purpose</strong></td>
<td>Testing the safety of the drug - first testing in humans; for oncology studies not healthy volunteers</td>
<td>Determining whether a drug works in a broader population</td>
<td>Confirming how well a drug works in a large number of patients - size and scope depends on the disease prevalence</td>
</tr>
<tr>
<td><strong>Studies...</strong></td>
<td>...safety of the medication or treatment</td>
<td>...efficacy</td>
<td>...safety, efficacy and dosing</td>
</tr>
<tr>
<td><strong># of participants</strong></td>
<td>20-80</td>
<td>100-300</td>
<td>1,000-3,000</td>
</tr>
<tr>
<td><strong>Duration</strong></td>
<td>Up to several months</td>
<td>Up to years</td>
<td>1-4 years</td>
</tr>
<tr>
<td><strong>Success rate</strong></td>
<td>70%</td>
<td>33%</td>
<td>25-30%</td>
</tr>
</tbody>
</table>

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

How do you find out about clinical trials?

- **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
How do people find out about clinical trials?

Sources and influencers vary depending on disease status

- **64%** ask a health professional for information or assistance in dealing with health or medical issues
- **64%** digital communications
- **20%** other sources

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!