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“Research nurses play a vital role in ensuring clinical research studies **run smoothly** and that participants are **safe and fully informed**”



Pick A et al (2010)

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**CLINICAL RESEARCH**

- Understand health and disease
- Find **new and better ways** to:
  - ✓ Detect
  - ✓ Diagnose
  - ✓ Treat
  - ✓ Prevent disease
- Finding **new treatment** and **improving** patient care.




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## CLINICAL TRIAL

Clinical research studies involving human participants assigned to an **intervention** in which the study is designed to evaluate the effect(s) of the intervention on the participant and the effect being evaluated is a health-related **biomedical or behavioral** outcome.

(NIH, 2014)




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## CLINICAL TRIALS - PHASE I

**Tests a new biomedical intervention**

Safety and tolerability

Asses toxicity

Drug's pharmacokinetic and pharmacodynamics

First stage of testing

20-80 subjects




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## CLINICAL TRIALS - PHASE II

Therapeutic Exploratory Trial

**Efficacy** in patients (1<sup>st</sup> objective)

**Safety** Issues (2<sup>nd</sup> objective)

Optimum dose finding

IIA: Designed to assess dosing requirements

IIB: Designed to study efficacy

100-300 Subjects




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**CLINICAL TRIALS – PHASE III**

Therapeutic **confirmatory** trials  
 Determine **efficacy** of the intervention  
 Monitor adverse effects  
 Subtypes  
 Phase IIIA: sufficient and significant data.  
 Phase IIIB: Label expansion, additional safety **data**.  
**300-3000** subjects

**PARTICIPANTS NEEDED**




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**CLINICAL TRIALS – PHASE IV**

Post Marketing Studies (PMS)  
 Monitor the **effectiveness**  
 Determine behavior of drug in **real life** situations  
 Adverse effects  
 Several **thousand** volunteers with disease/condition




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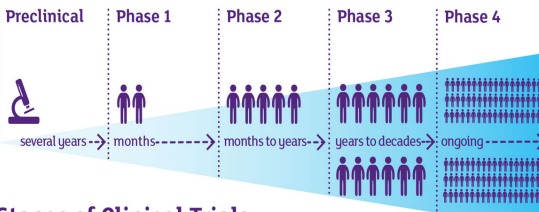
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**Stages of Clinical Trials**



<https://www.cancer.gov.au/gpmedia/693946fo-Oct17-40x1-a2d0-3c17343c17-01/phase-4-clinical-trials.jpg?width=1200&height=442&w=1200&h=442>

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### RESEARCH NURSE VS STUDY COORDINATOR

|                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                    |
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| <p><b>RESEARCH NURSE</b></p> <p>Specialty nursing practice focused on the care of research subjects and implementation of clinical research</p> <p style="text-align: right;">(Bevans et al, 2011)</p> | <p><b>STUDY COORDINATOR</b></p> <ul style="list-style-type: none"> <li>• <b>Responsibilities</b></li> <li>• <b>Certifications</b> <ul style="list-style-type: none"> <li>• Association of Clinical Research Professionals (ACRP)</li> <li>• Society of Clinical Research Associates (SOCRA)</li> </ul> </li> </ul> |
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### Skills

- Management
- Organizational skills
- Teaching
- Mentoring
- Communication





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### KEY POINTS

- Patient **ADVOCATE**, ensuring patient's safety and protection
- Understand the research **process** and **terminology**
- **Collaboration and cooperation** with other researchers and members of the multidisciplinary team is crucial




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### RESPONSIBILITIES RESEARCH CLINICAL NURSE

- Finding information about **clinical trials** for patient
- Reinforcement of the informed consent process
  - Patient and caregiver **education**
- Advocating for **ethical** care
- Administering **investigational drugs**
- Collecting **biospecimens**
- Monitoring for **side effects**

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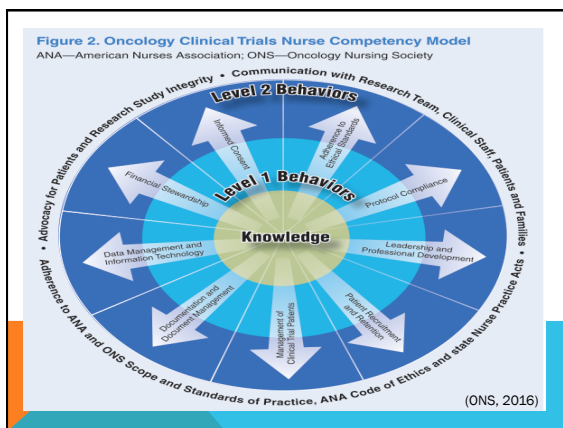
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### STUDY COORDINATOR RESPONSIBILITIES

- **Regulations and ethics**
  - Good clinical practices
- **Study approvals – IRB, biosafety**
- **Protocol – plan**
- **Clinical trial operations**




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**STUDY COORDINATOR RESPONSIBILITIES**

- **Patient recruitment**
  - Possible candidates
- **Inform consent process – Voluntariness**
- **Samples collection**
  - Laboratory processing and shipping
- **Medication administration**
- **Participants follow up – Retention**

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**STUDY COORDINATOR RESPONSIBILITIES**

- **Data collection and safety reporting**
- **Communication with sponsor**
- **Site visits**
  - Sponsor
  - Other organizations
- **Study close out**

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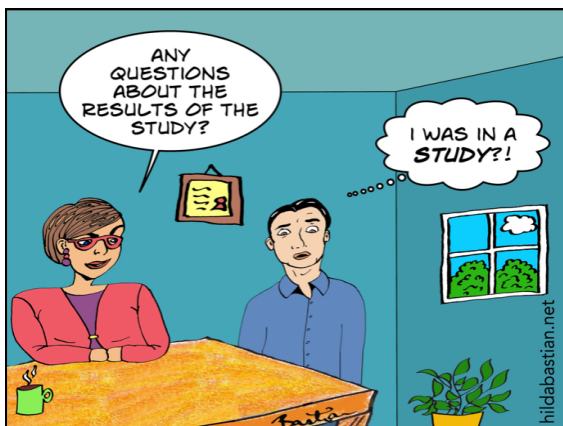
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Today's standard of  
care was yesterday's  
clinical trial.

(Ness and Royce, 2017)