

Trial Design Module

Part 1:

Types of Clinical Trials

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Clinical Research (CR)

- Patient-oriented research
 - Mechanisms of human disease,
 - Therapeutic interventions,
 - Clinical trials, or
 - Development of new technologies
- Epidemiologic and behavioral studies
- Outcomes and health services research
- CR studies:
 - Observational
 - Interventional

Clinical Trial (CT)

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

NIH Definition October 23, 2014

Types of Clinical Trials



Prevention Trials

- Evaluate better ways to prevent disease in people who have never had the disease
 - Prevent a disease from returning
- 2 types of trials:
 - Action studies – “do something”
 - Agent studies – “take something”

Screening Trials

- Assess or examine methods of identifying a condition (or risk factors for a condition) in people who are not yet known to have the condition (or risk factor)
- Tools:
 - Tissue sampling/procurement
 - Laboratory tests, including genetic testing
 - Imaging tests
 - Physical exams
 - History, including family hx (pedigree)

Diagnostic Trials

- Discover better tests or procedures for diagnosing a particular disease or condition
- Tools:
 - Imaging tests
 - Laboratory tests

Supportive Care/QOL Trials

- Explore ways to improve comfort and the quality of life for individuals with a chronic illness
- Focus on subjects AND families or caregivers

Treatment Trials

- New intervention
- New combination of drugs
 - Approved + investigational
 - Investigational + investigational
- New approaches to:
 - Surgery
 - Radiation therapy
- New approaches to combination therapies
- Psychotherapy
