The Basics of Clinical Research

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Where does it begin?

- Basic Science - an understanding the disease to be treated
- Basic Research - the process of discovery within the laboratory
- When a promising compound is identified, preclinical investigations take place in animals.

Preclinical Phase

During the rigorous testing in the preclinical phase, a drug is considered successful if it is:

- absorbed into the bloodstream
- distributed to the proper site of action in the body
- metabolized efficiently and effectively
- successfully excreted from the body
- Demonstrated to be nontoxic

Phase I

Traditional first-in-human dose-finding study for a single agent

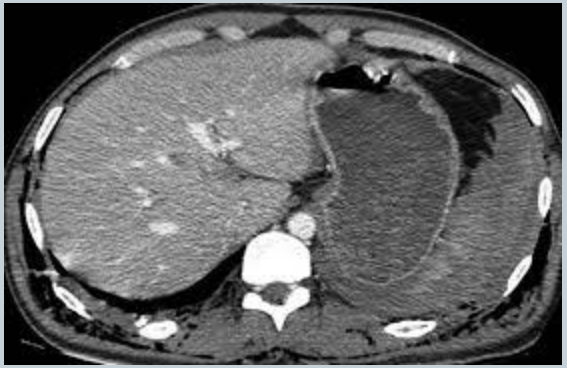
Goals:

- Evaluate the safety and tolerability
- Determine the maximum tolerated dose
- Determine dose-limiting toxicity
- Observe preliminary response

Phase II

Goals:

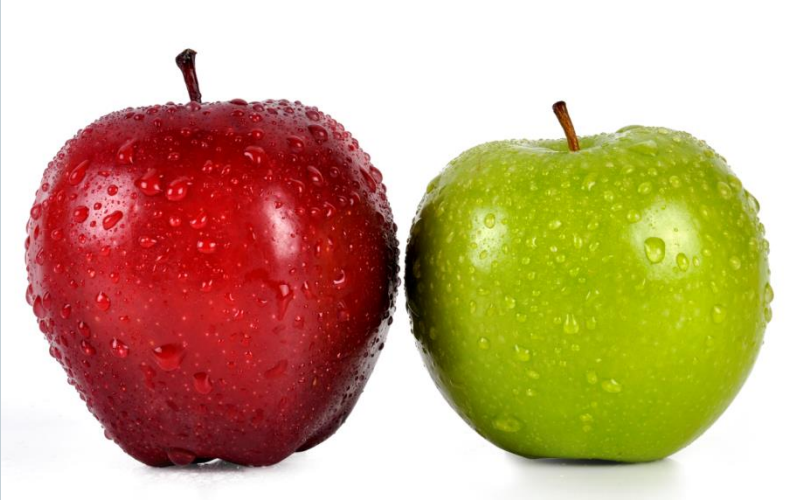
- Further define safety and toxicity
- Provide and initial assessment of efficacy
- Screening out ineffective drugs
- Identifying promising drugs



Phase III

Goals:

- Assess the efficacy of the drug or new intervention compared to the standard therapy.
- Provide further evaluation of safety.



Phase IV/Post Marketing Surveillance Trials

Drug has been approved for commercial marketing

Goals:

- Monitor for additional long-term and additional safety
- Monitor for efficacy
- Monitor for quality of life effects
- Assess drug-food reactions

Additional Information

- Before drugs can be tested in the human population they are approved by independent review boards
- Myth's about placebo
- Clinical Research Services Department

    - 535 Intervention and Non-Intervention

Implementation of a Study

- Physician introduces study
- Treatment options
- Each Study is Unique
- Clinical Research Coordinator's ensure the correct implementation of the study
- Data is gathered and inputted
- Statistician determines clinical significance
- Off to FDA for approval

Consent

It is important that you read and understand several general rules that apply to anyone that takes part in our study is:

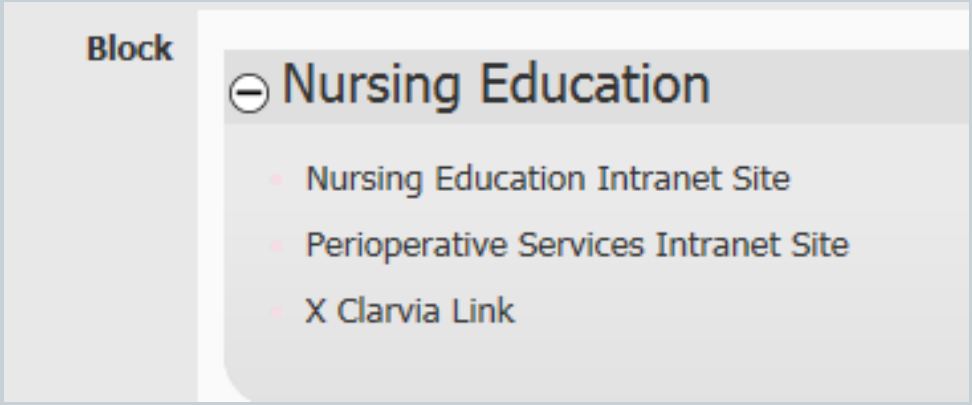
1. This study is considered research.
2. Taking part in the study is voluntary.
3. You may withdraw from the study at any time without penalty, loss of any benefits, or access to care at RPCI to which you are otherwise entitled.
4. Personal benefit may not result from taking part in the study, but knowledge may be gained that will benefit others.
5. If you decide not to take part in this study, it will not affect your care at Roswell Park Cancer Institute now or in the future.
6. If we become aware of important new findings that relate to your participation or continued participation in this study we will discuss them with you

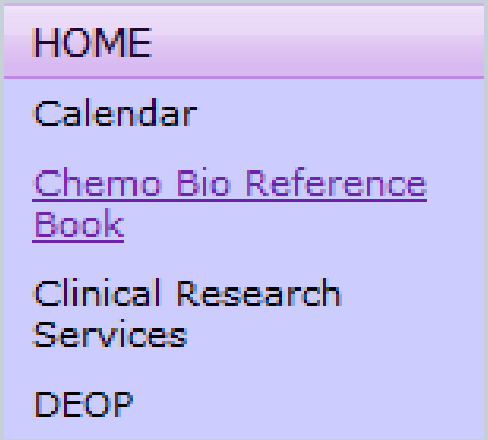
The type of study, the risks, benefits, discomforts, and other important information about this study are discussed below.

Study calendar

	Screening Phase[a]	Treatment Phase[b]					End of Treatment Phase	Follow-Up Phase I[c, u]	Follow-Up Phase II[c, u]
Patient Visit #	0 (baseline)	1	2[v]	3	4[v]	5-12	13	Q 6 months	Q 12 months
Cycle (C) 1 cycle = 28 Days	0 (baseline)	C1		C2		C3, C6, C9,C12, C15,C18,C21,C24	After C26 or early termination		
Day (D) of Cycle	-30 to 0	D1[d]	D14[v]	D1	D14[v]	D1			
Time Window (days)		+/-2	+/-2	+/-2[n]	+/-2	+/- 7[n]	30-42	+/- 35	+/-56
Informed Consent[e]	X								
Inclusion/Exclusion Criteria	X								
Medical History & Demographic Data[f]	X								
Concomitant Medications[g]	X	X		X		X	X	X[g]	X[g]
ECOG Performance Status	X	X		X		X	X		
Physical Exam/Vital Signs[h]	X	X		X		X	X		
IP Dispensing; IP and Non-IP Drug Compliance[i]		X		X		X	X		
Adverse Event Reporting[j]	X	X	X[v]	X	X[v]	X	X	X[w]	X[w]
Hematology[k]	X	X	X[v]	X	X[v]	X	X		

Where to find more information

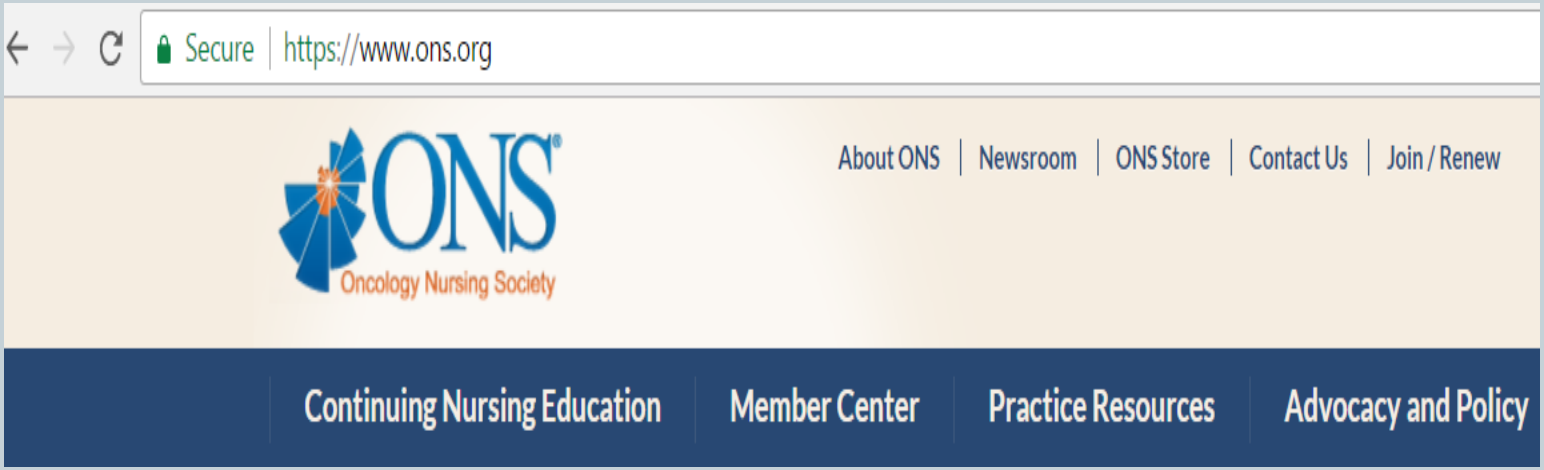




https://nursingeducation.roswellpark.org/SitePages/Clinical%20Research%20Services.aspx

CRS Protocol Instruction

ONS and Reimbursement

- Oncology Nursing Society
- Reimbursement
- 

Clinical Research