Memorial Sloan Kettering Cancer Center

Demystifying the Clinical Trial

Date October 27 2017

Presenters:
Allison Hyde RN, BSN, Clinical Trial Nurse
Mary Elizabeth Davis RN, MSN, AOCNS Clinical Nurse Specialist

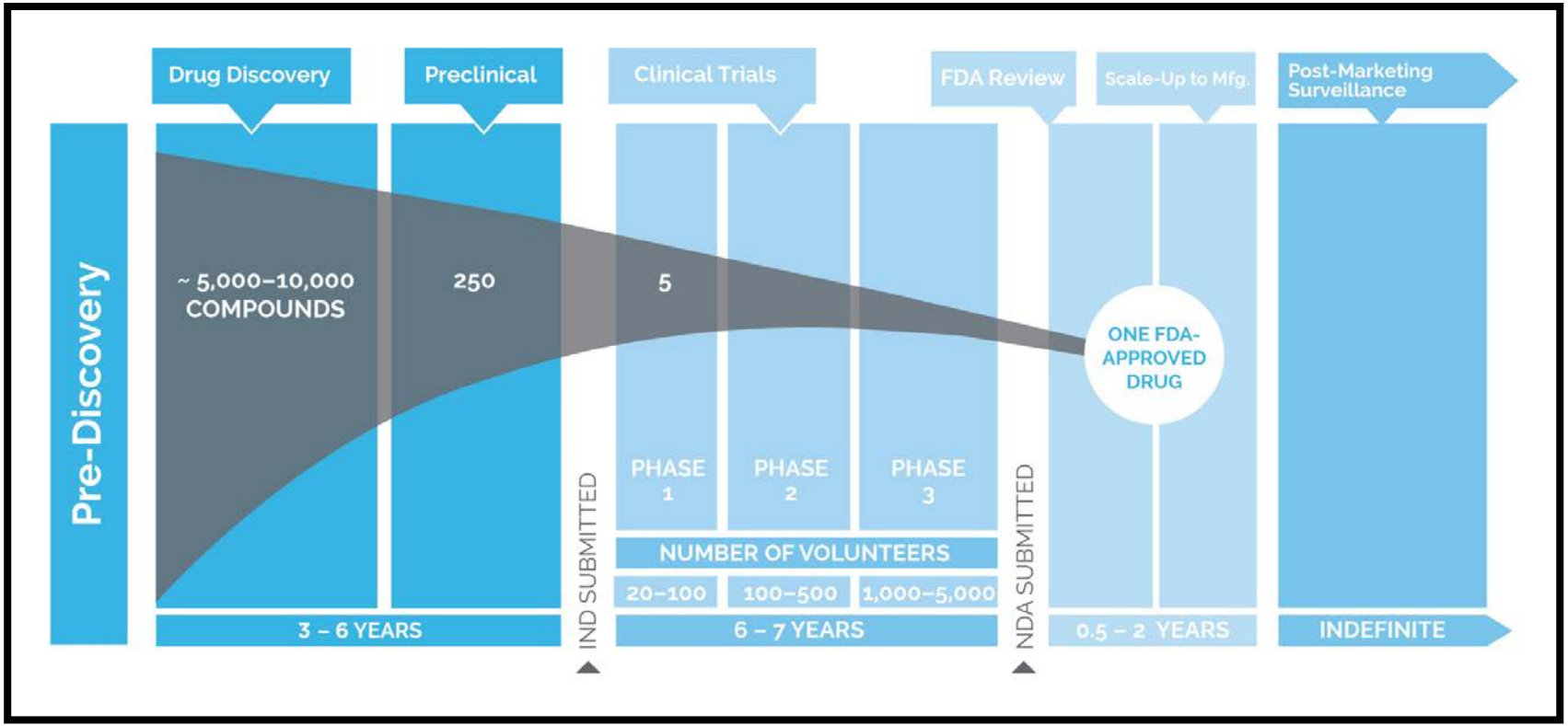
Phases of a Clinical Trial

Phase I : Is it safe?

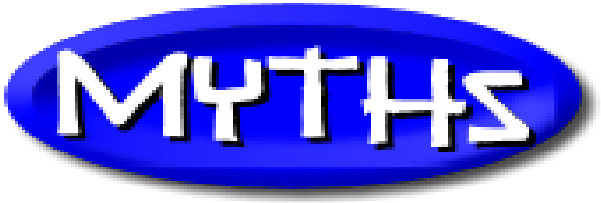
Phase II : Does it work?

Phase III : Does it work better?

Phase IV: Are there long term side effects?



Applied clinicaltrials.com

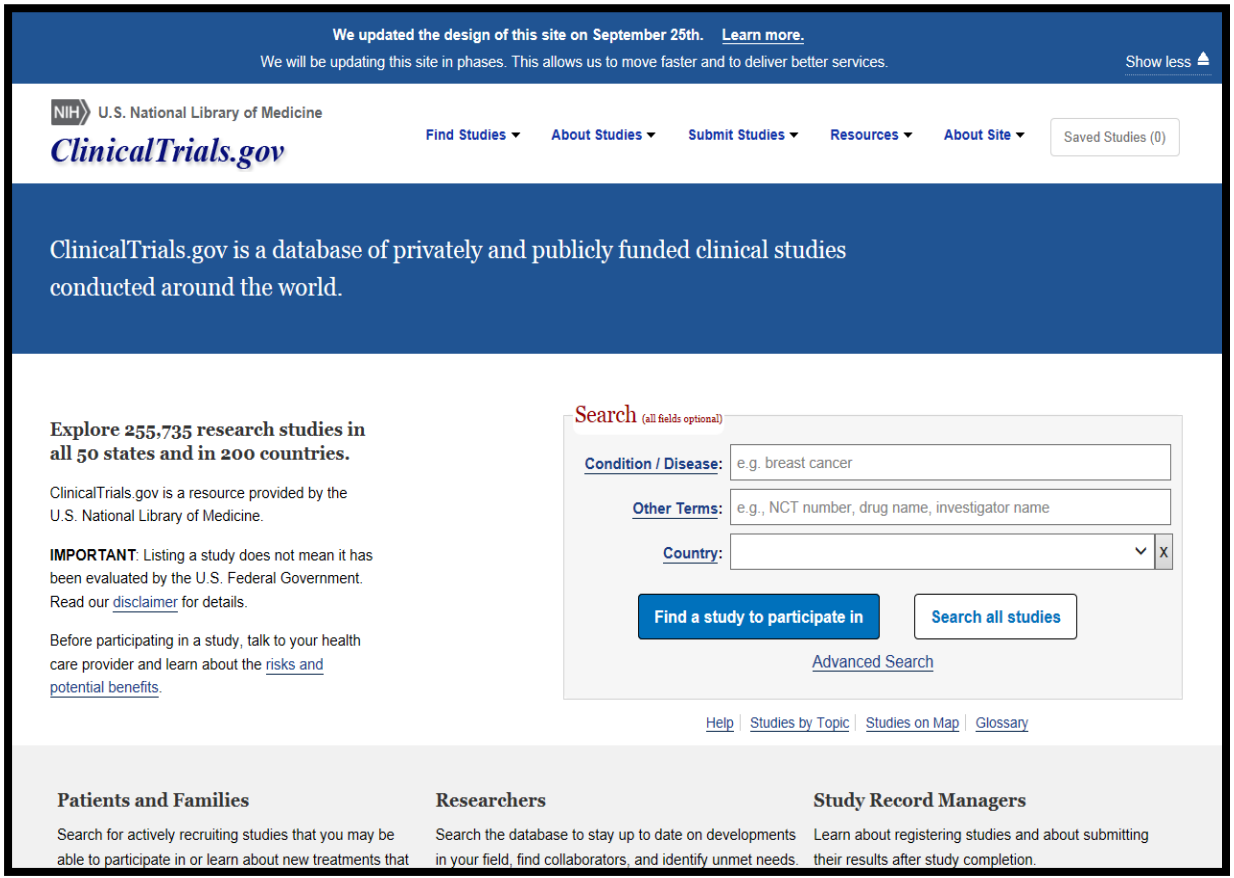


- The Guinea Pig
- The Placebo
- Cost of Care
- The Last Ditch Treatment

Who Conducts a Clinical trial?

- Primary Investigator (usually a MD)
- The research team: Doctors, Nurses and other health care clinicians, Research Study Assistants
- Clinical studies can be sponsored, or funded by various individuals/companies or organizations.

Finding a Clinical Trial



Clinical Trials.gov

Memorial Sloan Kettering Cancer Center

6 Studies found for:

Erdheim-Chester Disease | United States

List | By Topic | On Map | Search Details

Hide Filters

Download | Subscribe to RSS

Show/Hide Columns

Filters

Apply | Clear

Status

Studies:

- ☐ Not yet recruiting
- ☐ Recruiting
- ☐ Enrolling by invitation
- ☐ Active, not recruiting
- ☐ Suspended
- ☐ Terminated
- ☐ Completed
- ☐ Withdrawn
- ☐ Unknown status[†]

Expanded Access:

Eligibility Criteria

Age:

_____ years OR

Group:

- ☐ Child (birth–17)
- ☐ Adult (18–65)
- ☐ Senior (66+)

Sex:

- ◉ All
- ○ Female
- ○ Male

☐ **Accepts Healthy Volunteers**

Study Type

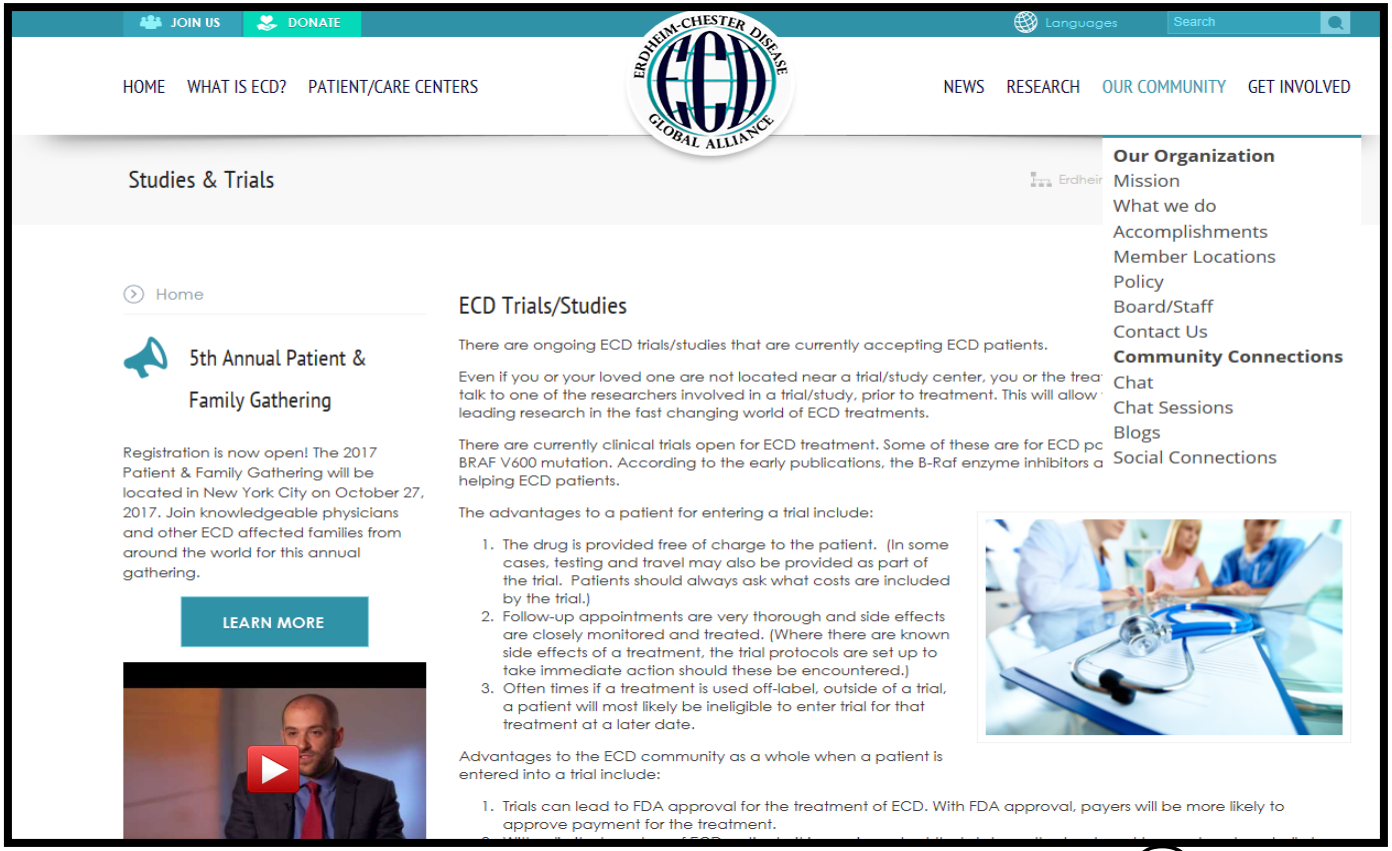
Study Results

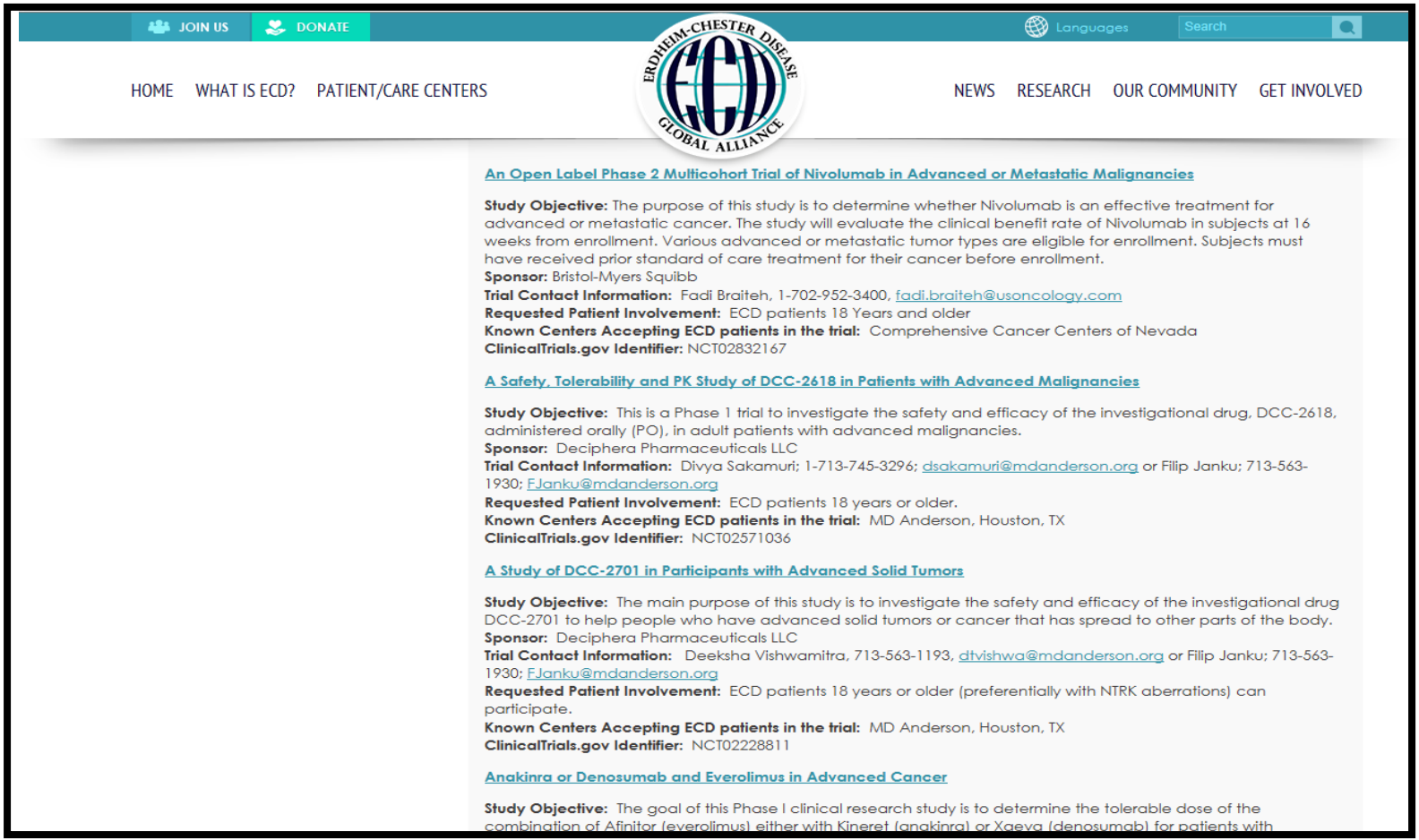
Study Phase

Row	Saved	Status	Study Title	Conditions	Interventions	Locations
1	☐	Recruiting	Long-term Outcome After Vemurafenib / BRAF Inhibitors Interruption in Erdheim-chester Disease	• **Erdheim-Chester Disease**		• Memorial Sloan Kettering Cancer Center New York, New York **United States** • AP-HP, Groupe Hospitalier Pitié-Salpêtrière Paris France
2	☐	Suspended	Dabrafenib and Trametinib in People With BRAF V600E Mutation Positive Lesions in **Erdheim Chester Disease**	• BRAF V600E Mutation	• Drug: Dabrafenib Mesylate • Drug: Trametinib Dimethyl Sulfoxide	• National Institutes of Health Clinical Center, 9000 Rockville Pike Bethesda, Maryland **United States**
3	☐	Recruiting	Clinical and Basic Investigations Into **Erdheim Chester Disease**	• Myelofibrosis • Gaucher **Disease** • Pulmonary Fibrosis • (and 2 more...)		• National Institutes of Health Clinical Center, 9000 Rockville Pike Bethesda, Maryland **United States**
4	☐	Recruiting	A Study of Lenalidomide for Adult Histiocyte **Disorders**	• Langerhans Cell Histiocytosis (LCH) • Histiocytoses **Erdheim-chester Disease** • Histiocytic Sarcoma (HS)	• Drug: Lenalidomide	• Dana-Farber Cancer Institute Boston, Massachusetts **United States**
5	☐	Recruiting	Uptake and Biodistribution of 18F-fluorocholine in Histiocytic **Disorders** by PET Imaging and Biopsy Measurement	• **Erdheim-Chester Disease** • Langerhans Cell Histiocytosis • Histiocytic **Disorders**	• Radiation: F-choline PET Scan • Device: FDG-PET • Procedure: biopsy	• Memoral Sloan Kettering Cancer Center New York, New York **United States**
6	☐	Recruiting	A Study of Memory, Thinking, and Brain Imaging in Adults With Histiocytosis	• Histiocytosis	• Behavioral: Trail Making Test, Parts A & B • Behavioral: Brief Test of Attention • Behavioral: Symbol Span • (and 7 more...)	• Memoral Sloan Kettering Basking Ridge Basking Ridge, New Jersey **United States** • Memorial Sloan Kettering Monmouth Middletown, New Jersey **United States** • Memorial Sloan Kettering Cancer Center @ Suffolk Commack, New York

Memorial Sloan Kettering Cancer Center

ECD Global Alliance website





Memorial Sloan Kettering Cancer Center

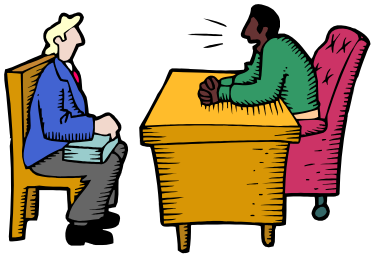
Steps of a Clinical Trial

- Discussion about Clinical Trial
- Eligibility and Screening
- Informed Consent
- Registration
- Testing
- Follow up

Steps of a clinical trial

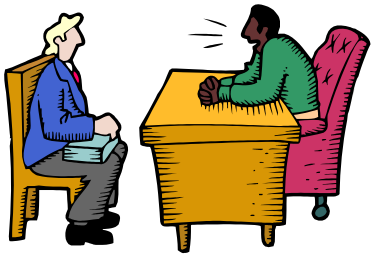
- Discussion about trial as option
- Confirm eligibility
  - Trials may have specific pathologic criteria (i.e.- BRAF mutation)
  - Lab values need to be within specific parameters
  - Past treatments may affect eligibility
  - Certain medications may exclude
  - Performance status “KPS”
- Informed consent
  - Informed Consent is a process

The Informed Consent Process



Discussion

Informed Consent Form & Research Authorization



Ongoing Information

Steps of a Clinical trial- Testing and Follow-Up

- Patient has the right to stop participation at any time and NOT affect ongoing care
- Study may include keeping side effect logs or pill diaries, extra blood tests “PK”s, imaging, or other safety measures(EKGs, eye exams)
- May include long term follow-up after completing treatment

Who pays?

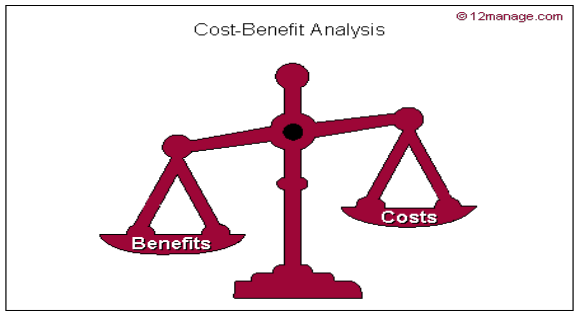
Before enrolling talk to your insurance company and sponsor of the trial.

Sponsor coverage

- Investigational agent: the drug or equipment
- Research tests required by protocol
- Additional testing required by protocol

Patient responsibility /Insurance

- Doctor visits
- Lab tests
- Established treatment for ECD
- X-rays, MRIs and other imaging tests



For more information about cost: www.cancer.gov

Is a Clinical Trial Right for Me??

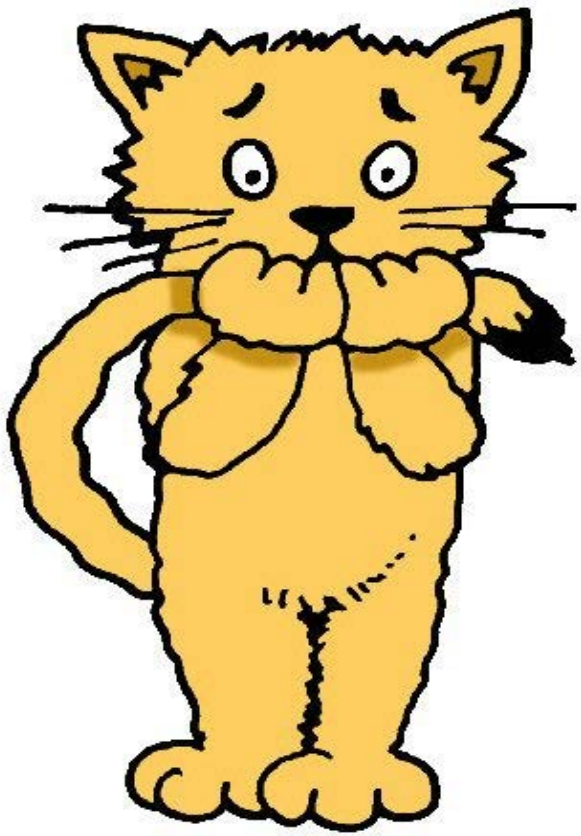
Advantages

- Access to best care possible
- Receiving treatments before widely available
- Close monitoring
- Chance to play an active role in healthcare and research
- Helping future generations

Disadvantages

- Unknown risks and side effects
- Unknown benefit
- Frequent tests and visits

Memorial Sloan Kettering
Cancer Center



Summary:

Don’t be Afraid to Ask questions!
Many of the Answers will be found in the Consent

- How does the drug work?
- How often do I have to come to the hospital/clinic?
- How long will the study last?
- What expenses will I incur?