

Jointly sponsored/coprovided by the Annenberg Center for Health Sciences at Eisenhower and Clinical Care Options, LLC



**ANNENBERG CENTER
FOR HEALTH SCIENCES**
AT EISENHOWER

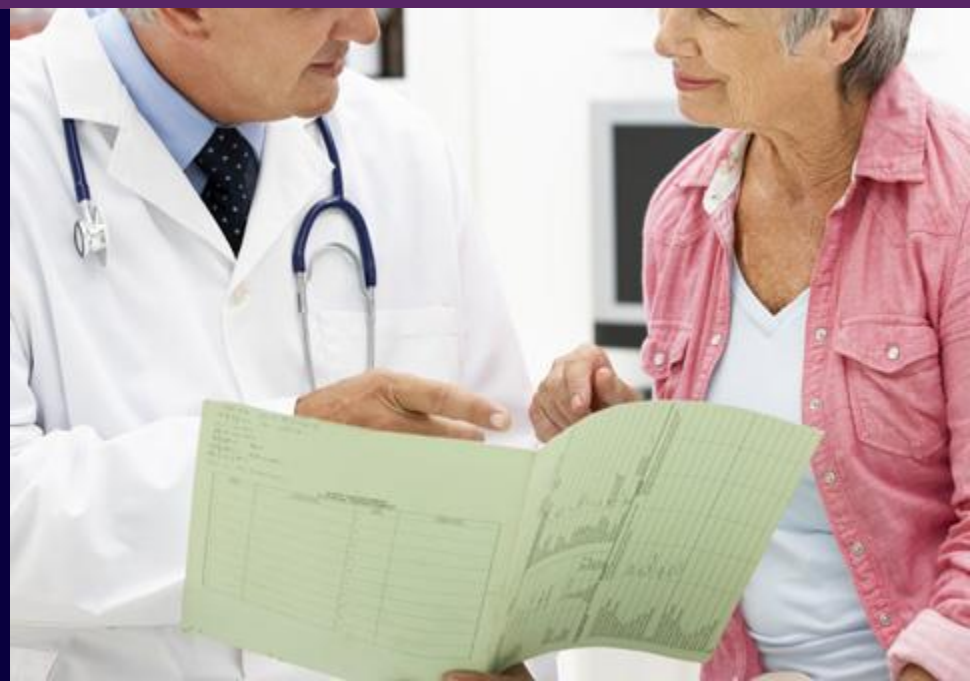
in association with



CLINICAL CARE OPTIONS®
ONCOLOGY

Navigating Malignant Melanoma: A Unique Physician, Nurse, and Patient Seminar Series

**Date, Time
Location**



This program is supported by educational grants from



Bristol-Myers Squibb

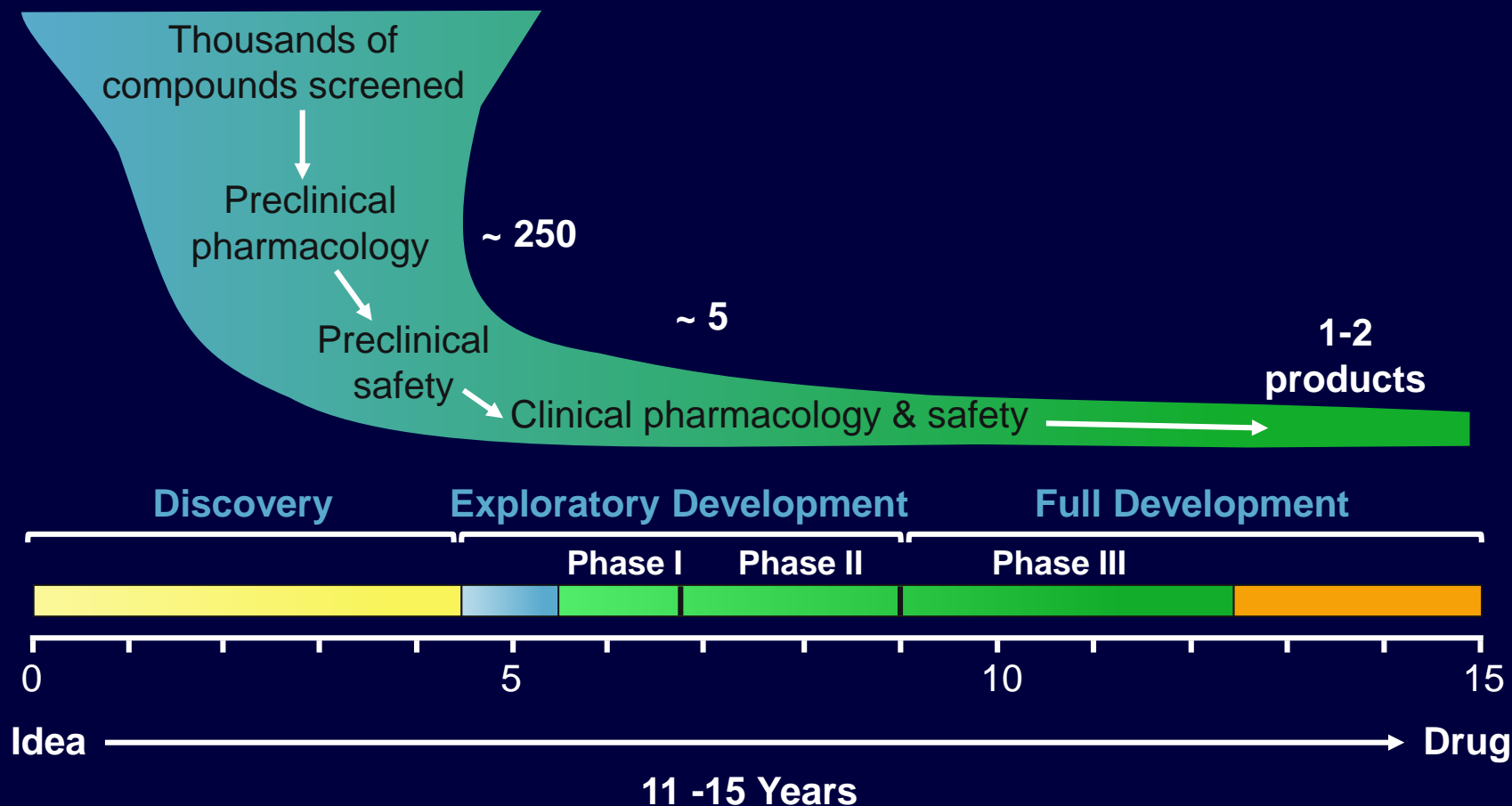


PROMETHEUS®
Therapeutics & Diagnostics

Understanding and Improving Clinical Trial Conduct



The Drug Development Process: 10-15 Years



Drug Development Is Lengthy, but Can We Speed It Up by Choosing the Right Patients?



- Disease genetics – choosing the best targets
- Target variability – better understanding of clinical targets
- Selecting responders – genetics-based selection of the optimal population
- Pharmacogenetics – predicting efficacy and safety

The Ethics of Clinical Trials

- Why are the patient eligibility criteria so strict? Why can't any patient be treated on a trial?
- What are acceptable endpoints for drug approval and why do we have them? Can't all patients cross over when they're on a randomized trial?
- Why are placebo arms used in some trials?
- How does the patient know that the doctor doesn't have a conflict of interest?
- How do patients know if their oncologist is working on the pharmaceutical company's behalf?

Challenges for Patients Thinking of Participating in Clinical Trials

- Many patients are not aware of available clinical trials
 - Only 2% of adults participate in cancer clinical trials
- Many trials call for biopsies and other tests not generally required for “standard-of-care” treatment
- There are extra visits, paperwork, and insurance hurdles to overcome
- Many patients think that once they are enrolled in a trial, all costs of every kind are paid for by the trial—not true!
- Patients think they are guinea pigs
- Informed consents are long, onerous, and complex for patients to digest

Challenges for Clinicians Who Are Participating in Clinical Trials

- Many patients think that they can be assigned to receive placebos or be in a “no treatment” group in all trials
- For the clinician, the process of informed consent is lengthy and takes a lot of time—investigational physicians cannot see the volume of patients that private doctors do
- Some community physicians may hesitate to refer to a clinical trial because of the relationship they build with the patient, a relationship that they believe best serves the interests of both parties
- Many community physicians are simply unaware of the availability of trials for their patients with cancer

Improving the Conduct of Clinical Trials

- “Breakthrough” therapies
 - An opportunity for therapies with clear/early effects in unmet need setting to be approved without phase III trials
- Support and advocacy of patients is an important factor to speed this process

Overcoming Barriers to Optimal Melanoma Care

A Discussion for Patients and Clinicians



Examples of Communication Barriers

- For the Patient
 - Fear
 - Don't want to look like they don't understand
 - Feel rushed
 - Trying to be strong
- For the Clinician
 - Time pressure
 - Distractions
 - Focus on physical aspects rather than the complete patient

Others?

How do you address these communication challenges?

Patient Concerns on Treatment

- BRAF Mutations
 - I'm BRAF negative. What does this mean for me?
 - I'm BRAF positive. Shouldn't I start with a BRAF inhibitor?
- Clinical trials
 - I don't want to be a guinea pig!
 - I don't want a placebo!
 - How do I choose among the available clinical trials?
- Side effects
 - When should I call?

Patient Concerns on Treatment

- What if I don't live near a premier melanoma care center?
 - Can I get the latest treatment options?
 - How do the experts work together with local clinicians to ensure high quality care?

Clinician Concerns With Patients on Treatment

- What should I tell my patient if they want to start a family?
- What can my patients do to help reduce symptoms related to either the disease or its treatment?
- How do I know if my patients are telling me everything I need to know?
- What other questions should I be asking my patients?

Doctors and Patients Teaming up for Success

- Insurance challenges
 - What are your options if your insurance does not cover participation in a clinical trial?
 - Your insurance only covers 80% of oral medications, and you cannot afford the remaining 20%. Are there programs to provide assistance?
 - You responded to ipilimumab when it was first given, but now melanoma is progressing again a year later and your insurance does not want to pay for ipilimumab again
 - Be proactive when it comes to appealing insurance decisions

What Can We Do To Improve Care?

- Be very vigilant about reporting adverse effects to the physician—set up lines of communication at the start
- Remember that a clinical trial is not for everyone
- A trial is a transaction—you give something and get something in return: you give time, effort, and possible increase of adverse effects, but get more provider attention and the best, cutting-edge care available for your disease
- Push your physician to look into trials at local referral centers and regional cancer centers
- Be proactive—go to ClinicalTrials.gov to look for trials

Other Needs of Patients With Melanoma: An Important Discussion

- Patients may experience symptoms of stress
 - Anxiety, depression, insomnia, isolation
 - ~ 30% of patients experience substantial levels of psychological distress indicative of a need for clinical intervention
 - Risk factors: female, young, lower education level, visible location of disease
 - Impact of diagnosis on family/friends, career; financial concerns
 - Ask the patient about his/her support system (family, friends, church, etc) and refer to appropriate support group, social worker, or psychiatrist
- Quality-of-life concerns and discussions
 - Actively involving the patient in managing his/her adverse effects
 - Dating, family planning (fertility, egg/sperm banking), survivorship

What Can We Do To Improve Care?

- Become involved in organizations that advocate for better melanoma education, care, and research
 - Melanoma Research Foundation (MRF)
 - <http://www.melanoma.org>
 - AIM at Melanoma Foundation (AIM)
 - <http://www.aimatmelanoma.org>
 - Melanoma Research Alliance (MRA)
 - <http://www.curemelanoma.org>