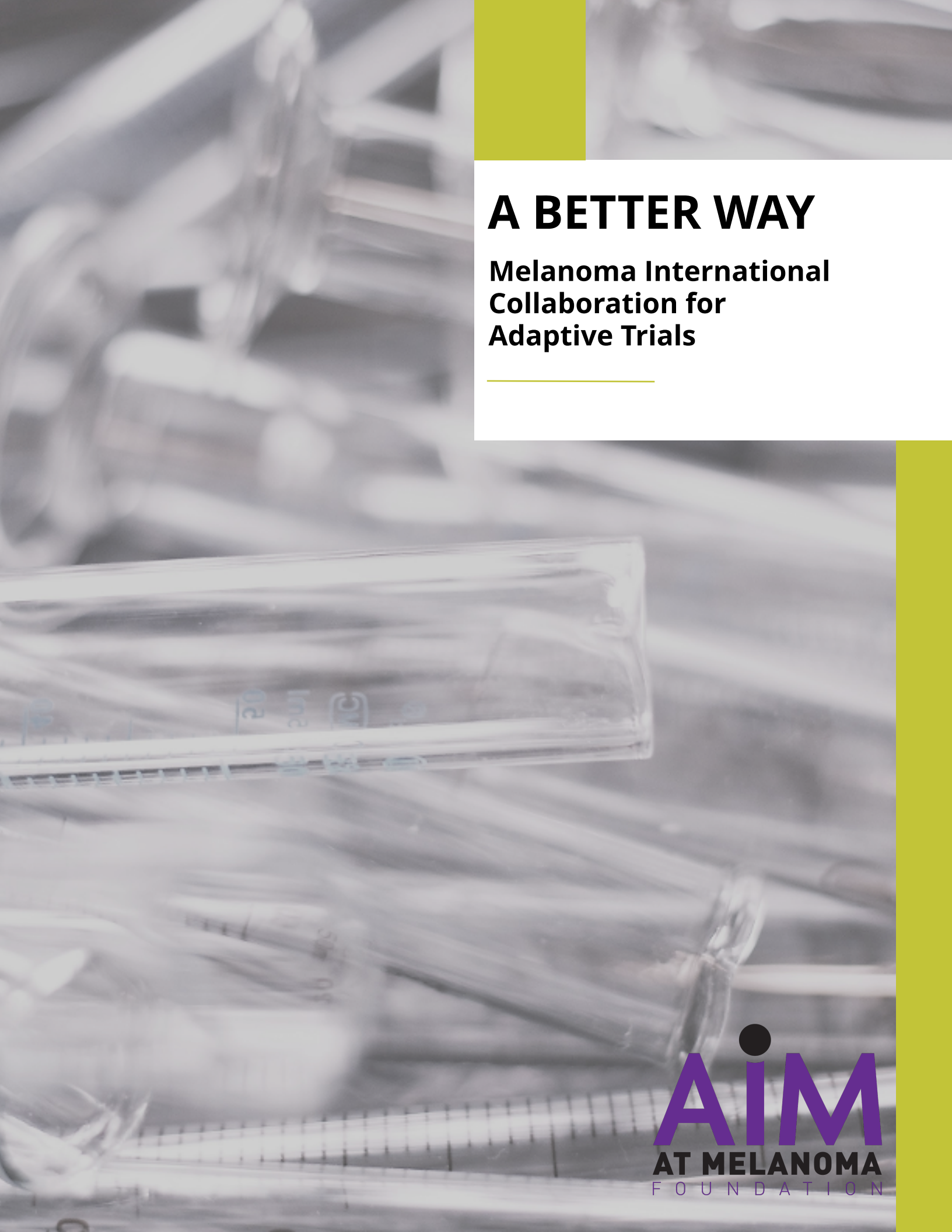


A BETTER WAY

Melanoma International Collaboration for Adaptive Trials

AiM AT MELANOMA FOUNDATION

"One of the most promising ways to make drug development more efficient—while enabling providers and patients to get better information about how a new medicine works—is by developing the science around innovative approaches to the design of clinical trials."

- Scott Gottlieb

FDA Commissioner

The single biggest question of our time in melanoma--and in all cancer research:

What can we offer to patients who do not respond to immunotherapy?

Immunotherapy is revolutionary—no doubt. For melanoma, a disease with a single digit Stage IV survival rate only ten years ago, immunotherapy is a tantalizing breakthrough: A solid percentage of melanoma patients have seen a response.

But for the those who don't see a response—and for those whose response is not durable—the same dismal survival statistics are their reality.

For these thousands of melanoma patients for whom there is no viable treatment, we must change our approach to testing new therapies. Our current clinical trial system tests one or two drugs at a time, which may take multiple years—a slow, inefficient, and ineffective process.

To find the cure for melanoma, we must test therapies in *a global, collaborative, adaptive format*—a pioneering new model to get effective therapies to patients faster. MICAT is that format.

And because the principles of immunotherapy first identified in melanoma have been successfully applied to other cancers, we know that whatever drugs are effective in melanoma will likely be effective in other cancers.

There is a better way. **MICAT.**

AIM at Melanoma is establishing a global, collaborative, patient-centric, multi-arm clinical trial that will bring effective melanoma therapies to market faster: Melanoma International Collaboration for Adaptive Trials (MICAT)

AIM AT MELANOMA FOUNDATION

TRADITIONAL CLINICAL TRIALS

Controlled Approach, Limited Results

In traditional drug trials, new therapies are tested **one or two at a time** against the standard of care, a slow approach to finding new treatments.

Patients are randomized to the standard therapy or the new therapy, and **regardless of how they are faring**, continue with their therapy until the end of the study or, sadly, their death.

Often a study ends with the finding that the new treatment is no better than the standard approach, **a disappointing result that costs lives.**

ADAPTIVE PLATFORM TRIALS

A Better, Smarter Way

Adaptive platform trials are different in three important ways:

1. They have **multiple arms**—multiple new treatments are simultaneously compared to the standard of care or a statistical arm.

2. Adaptive trials are **biomarker driven**, allowing researchers to collect and use data that could yield personalized treatments.

3. They allow researchers to **review results as the study progresses** with the goal of reassigning patients to treatment groups that are performing better.

Adaptive platform trials lead to personalized therapies and faster answers on a drug's efficacy—and may save lives in the process.

Melanoma has not had an adaptive platform trial until now. Until MICAT.

HOW WILL IT WORK?

- **MICAT** will use an adaptive design in a modular trial process. Drug candidates will be evaluated in bio-marker defined patient subpopulations to identify the most effective drugs, drug combinations, and treatment sequences for specific melanoma sub-types in the context of standard and emerging biomarkers.

- **MICAT** will determine the probability that novel therapies will improve progression free survival. Treatments "graduating" from MICAT will be recommended for advancement, either for Phase III evaluation or potentially for additional evaluation for marketing approval within MICAT. Each recommendation will include biomarker characterization.

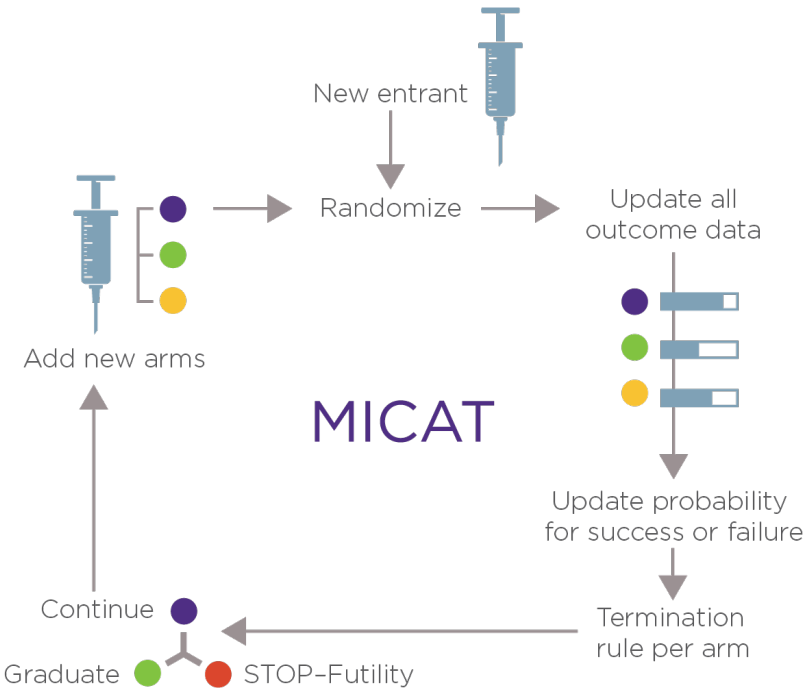
- **MICAT** offers the most efficient, informative evaluation platform to assess all classes of melanoma therapy:

  Interaction of Anti-PD-1 and Anti-CTLA4 with biomarkers

  Checkpoint inhibitors and combinations

  T-cell targeting agents and strategies

  Novel targeted agents in addition to BRAFi and MEKi combinations



HELP US FIND THE CURE

Start-up funding for an adaptive platform trial is critical.

The estimated cost for MICAT start-up is $5.5M, which includes regulatory submissions for the U.S., the E.U., and Australia and creation of:

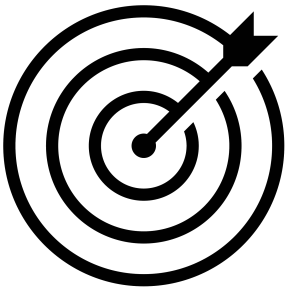
- platform design and statistical modeling
- drug forecasting system
- response adaptive randomization system

Once this initial work is complete, MICAT can welcome industry partners and open the trial. **The overall cost of this multi-year, multi-arm trial is approximately $25M.**

AIM at Melanoma and the MICAT team are seeking philanthropic support for both the initial costs and the overall study. Gifts to AIM at Melanoma, a U.S. non-profit 501(c)(3), in support of MICAT are tax-deductible to the fullest extent of the law.

Those who support MICAT will not only help find treatments for melanoma, but also advance the study of cancer biomarkers and aid the search for treatments for multiple cancers.

$2.2M	50% of total costs for 100 patients per treatment arm
$1.45M	Start-up: Study design/protocol ready
$1.35M	Start-up: Randomization and drug management systems
$512,000	Two years of operating costs



We Need Your Help. The Time is Now.

ABOUT US

Founded in 2004, AIM at Melanoma is the largest international melanoma foundation seeking the cure for melanoma.

AIM at Melanoma is dedicated to:

- ***Innovation in Melanoma Research***
  We believe that the cure for melanoma will be found more quickly by bringing together leading global researchers and funding their collaborative research. Our three paradigm-shifting global research initiatives, including MICAT, are poised to reshape the future of melanoma.

- ***Legislation, Policy & Advocacy***
  We are the respected voice of melanoma across the nation. When drugs are approved, legislation is drafted, and research is assessed, AIM is at the table, speaking loudly and clearly on behalf of patients and their families. We are trusted advisors for medical boards, government agencies, and pharmaceutical companies on critical topics that affect melanoma patients.

- ***Education & Support***
  Both in the U.S. and on a global level we provide comprehensive, easy-to-access melanoma resources to patients and health care professionals. AIM's patient, family, and caregiver support offerings—such as our *Ask a Melanoma Expert* service, which allows patients and loved ones to ask both medical and general melanoma questions, and our *Peer Connect* program, which matches newly diagnosed survivors with melanoma veterans—serve as models for other cancer foundations.

MICAT

A collaboration of world experts in melanoma and clinical trials:

- AIM at Melanoma
- IMWG (International Melanoma Working Group, an AIM initiative)
- Berry Consultants
- RA Capital
- Industry partners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