



American Cancer Society-Melanoma Research Alliance Request for Applications:

Understanding, Preventing and Managing Immunotherapy-Related Adverse Events (irAEs) Associated With Checkpoint Inhibition for Melanoma and Other Cancers

Joe Cotter ACS Research Constituent Engagement Manager Kristen Mueller, PhD MRA Scientific Program Director

MRA Snapshot

Founded in 2007, now largest private funder of melanoma research

- > Our mission is to eliminate melanoma suffering and death
- MRA has awarded over \$101M for 266 projects at over 100 institutions in 15 countries; typically award ~\$8-10M/year
- Leveraged an additional \$101M from matched grants (foundations, institutions and companies) and follow-on research funding
- > 100% of donations to MRA support melanoma research
 - Founders' gift covers MRA operating expenses
 - External support for Scientific Retreat & Patient Education



ACS Snapshot

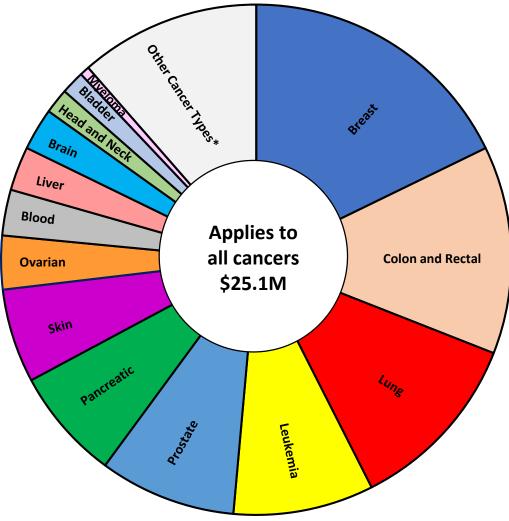
- Fund the most innovative cancer research with a primary focus on beginning investigators.
- Widest possible spectrum of basic, translational and applied cancer research.

Address critical needs in health professional training.

2017 Funding by Selected Cancer Types

Total Awarded: \$94.8M

Breast Cancer Colon and Rectal Cancer Lung Cancer Leukemia Prostate Cancer Pancreatic Cancer Skin Cancer Ovarian Cancer Blood Cancer Brain Tumor Liver Cancer Head and Neck Cancer Bladder Cancer Myeloma Other Cancer Types* \$12.4 million \$ 9.2 million \$ 8.1 million \$ 6.2 million \$ 6.0 million \$ 4.9 million \$ 4.1 million \$ 2.4 million \$ 2.0 million \$ 1.9 million \$ 1.9 million \$ 1.1 million \$ 1.0 million \$ 0.43 million \$ 8.0 million



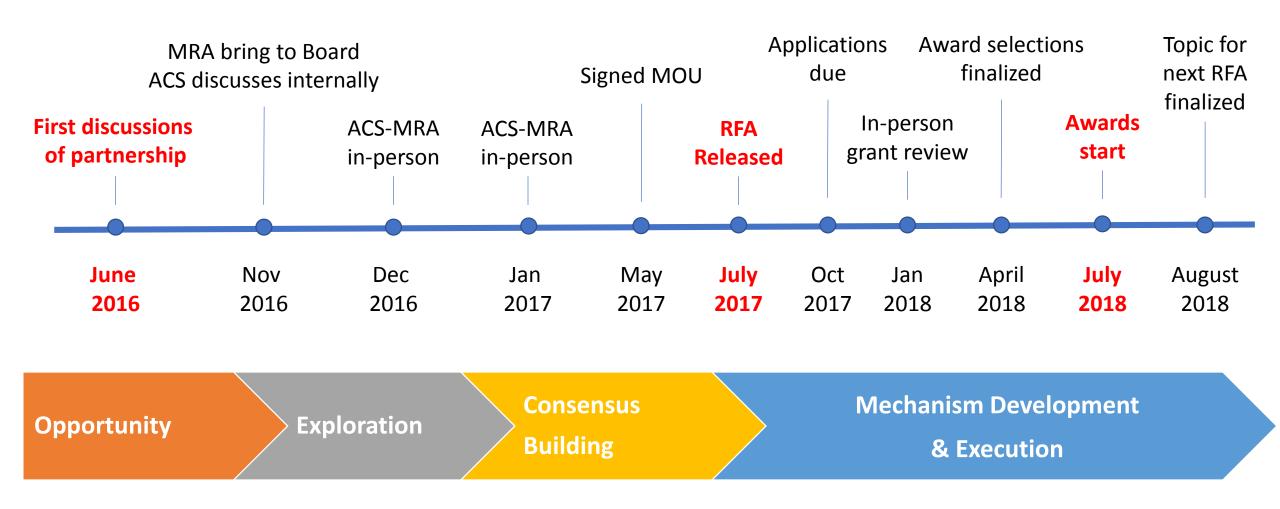
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Select RFAs to address understudied areas in cancer.

> *Other cancer types include: adrenalcortical, anal, bone, cervical, endometrial, esophageal, eye, gallbladder, gastrointestinal tract, hodgkin lymphoma, kaposi's sarcoma, kidney, laryngeal, nasal cavity and paranasal sinus, nervous system, neuroblastoma, non-hodgkin lymphoma, penile, respiratory system, sarcoma (soft tissue), small intestine, stomach, thyroid, urinary system, and vaginal.

Partnership and Program Development: Overview of the Collaboration



ACS- MRA RFA: Understanding, Preventing and Managing Immunotherapy-related Adverse Events (irAEs) associated with Checkpoint Inhibition for Melanoma and Other Cancers

- Focus of the RFA: Prevention, early detection, reduction and/or management of life-altering and/or outcome-limiting side-effects of checkpoint inhibitor therapy.
- **Critical gap in management of irAEs** is early identification of which patients are at greatest risk for various irAEs, which patient features are indicative of irAEs, severity and the time course of clinical manifestation, severity of irAE and if prevention strategies can limit side-effects without diminishing efficacy.
- **Overall impact** : Scientific merit, the translation nature of the proposed research and the degree to which the research has rapid clinical benefit.
- Total Investment : \$2 million

ACS and MRA each contributed \$1 million to support one Multidisciplinary Team and

5 Pilot Awards, able to raise an additional \$500,000 from BMS to support this RFP

Types of Awards

<u>Pilots x 5</u>

Budget: \$200,000

Term: 2 years

Eligibility: US institutions only, must hold independent faculty appointment at not-for-profit institutions

Award Aim: Potential for future funding

Multidisciplinary Teams x 1

Budget: \$1,000,000

Term: 3 years

Eligibility: US institutions only, must hold independent faculty appointment at not-for-profit institutions

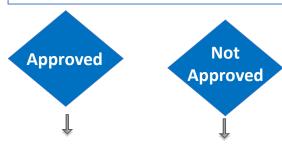
Team must include Lead PI, Team Principal & Team Investigator

Application process included LOI step

Award Aim: Potential for knowledge transfer





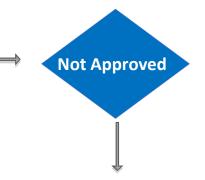


- Review process complete
- Notification by Program Director of outcome (April 1st)
- If approved, grant initiated (July 1st)

- Notification of successful LOI (9/1)
- Submission of application by 10/16 Pilot and 10/31 Team

Application assigned to a Peer Review Committee for review (November)

Review by ACS Peer Review Committees inclusive of MRA reviewers (January)



Review process complete

 Notification by Program Director of outcome (Feb/March)

Peer Review Outcome

Peer Review Committees	Pilots	Teams
Clinical Cancer Research, Nutrition, and Epidemiology	7	2
Cancer Control and Prevention: Health Policy and Health Services Research	7	2
Leukemia, Immunology and Blood Cell Development	9	3
Totals	23	7
Number Rated Outstanding	3	2

Peer Review Outcome

Team Awards	Award Title
David Gerber, UT Southwestern	Genetic and Phenotypic Biomarkers to Predict Immune-Related Adverse Events
Kai Wucherpfennig, Dana-Farber Cancer Institute	Discovery of Therapeutic Approaches for Ipilimumab- associated Colitis

Pilot Awards	Award Title
Suephy Chen, Emory	Understanding Cutaneous Immunotherapy-related Adverse Events in Melanoma
Bianca Santomasso, Memorial Sloan Kettering	Clinical Features and Biomarkers of Immunotherapy Neurologic Toxicity
Betina Yanez, Northwestern University	Development of OncoLink: A Web-Based irAE Monitoring Platform

Compromise is Key

- A minimum of 50% of the focus of the award needed to be on melanoma
- ACS oversaw the peer review process
 - Included MRA reviewers
 - LOI selection done by telecon
 - Proposals spread across 3 committees
- Indirects paid by ACS only
- Each organization manages awards separately
- Collaborated on Progress Report Template
- Will carry out joint site visits/gathering(s) of grantees

Key Takeaways

- Timing is important
- Select an area within each partner's priorities
- Regular and open communication, persistence may be needed
- Shared decision making
- Liaison from each partner to carry-out workplan
- Share each organization's policies and approval process
- Co-branding
- Flexibility

Key Takeaways, continued

Pros

- Great way to leverage additional \$\$ towards scientific priorities, expand knowledge base by broadening the disease scope
- Expands the network of researchers for an organization
- Opportunities to learn from how other funders do things
- Patients and donors have an expectation that funders should work together to further R&D

<u>Cons</u>

- Time consuming
- Compromise required
- May not always be successful