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.

➢ Select RFAs to address understudied areas in cancer.

2017 Funding by Selected Cancer Types

Total Awarded: $94.8M

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

*Other cancer types include: adrenocortical, 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.

Applies to all cancers $25.1M
Partnership and Program Development: Overview of the Collaboration

First discussions of partnership: June 2016
- MRA bring to Board
- ACS discusses internally

ACS-MRA in-person: Nov 2016

ACS-MRA in-person: Dec 2016

Signed MOU: Jan 2017

Applications due: May 2017

RFA Released: July 2017

In-person grant review: Oct 2017

Award selections finalized: Jan 2018

Awards start: April 2018

Topic for next RFA finalized: July 2018

Opportunity Exploration Consensus Building Mechanism Development & Execution
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

**Pilots x 5**
- **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
Peer Review Flowchart for Team Award: Review of LOIs and Grant Applications

- 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)

- Notification by Program Director of outcome (Feb/March)

Not Approved

Approved for Council Review

Final Peer Review by the Council for Extramural Grants and MRA Leadership (March)

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

Not Approved

Not Approved
## Peer Review Outcome

<table>
<thead>
<tr>
<th>Peer Review Committees</th>
<th>Pilots</th>
<th>Teams</th>
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<tbody>
<tr>
<td>Clinical Cancer Research, Nutrition, and Epidemiology</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>Cancer Control and Prevention: Health Policy and Health Services Research</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>Leukemia, Immunology and Blood Cell Development</td>
<td>9</td>
<td>3</td>
</tr>
<tr>
<td><strong>Totals</strong></td>
<td><strong>23</strong></td>
<td><strong>7</strong></td>
</tr>
<tr>
<td><strong>Number Rated Outstanding</strong></td>
<td><strong>3</strong></td>
<td><strong>2</strong></td>
</tr>
<tr>
<td>Team Awards</td>
<td>Award Title</td>
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<td>---------------------------------------------</td>
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<tr>
<td>David Gerber, UT Southwestern</td>
<td>Genetic and Phenotypic Biomarkers to Predict Immune-Related Adverse Events</td>
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<tr>
<td>Kai Wucherpfennig, Dana-Farber Cancer Institute</td>
<td>Discovery of Therapeutic Approaches for Ipilimumab-associated Colitis</td>
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<tr>
<th>Pilot Awards</th>
<th>Award Title</th>
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<tr>
<td>Suephy Chen, Emory</td>
<td>Understanding Cutaneous Immunotherapy-related Adverse Events in Melanoma</td>
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<tr>
<td>Bianca Santomasso, Memorial Sloan Kettering</td>
<td>Clinical Features and Biomarkers of Immunotherapy Neurologic Toxicity</td>
</tr>
<tr>
<td>Betina Yanez, Northwestern University</td>
<td>Development of OncoLink: A Web-Based irAE Monitoring Platform</td>
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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

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