2021 SCIENTIFIC RETREAT

Advancing Melanoma Research in Times of Uncertainty

Highlights from the 2021 MRA Scientific Retreat

Melanoma Research Alliance

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Letter from Chief Science Officer and Senior Director, Scientific Program

Marc Hurlbert, PhD

Kristen L. Mueller, PhD

Each year, MRA takes great pleasure bringing together the melanoma research community in Washington, DC for three days of learning, conversation, and collaboration. But in 2021, due to the ongoing COVID-19 pandemic, MRA had to take a different approach. We knew bringing the community together was more important than ever, and so for the first time in our history, MRA held its annual Scientific Retreat virtually from February 22-24, 2021.

With more than 500 registered attendees, 2021 marked the largest Scientific Retreat in MRA's history. For three days, leading researchers and clinicians from the United States and abroad, as well as senior leadership from non-profit foundations, government agencies, industry, philanthropists and other like-minded organizations gathered virtually to listen to scientific lectures and panel discussions, participate in topic-focused, small-group networking sessions, and visit virtual posters. Attendees also heard firsthand from individuals personally affected by melanoma about how grateful they are for all the advancements in treatment over the past decade and how critical it is to keep the momentum going, even in the time of COVID-19.

Scientific lectures covered a variety of topics at the leading edge of melanoma research, including novel influences on melanoma formation and progression, promising new immunotherapy drug targets to overcome treatment resistance, strategies to mitigate immune-related side effects, and the latest research and approaches for detecting melanoma early, before it spreads. A moderated panel discussion, which featured speakers from the U.S. Food and Drug Administration, the National Cancer Institute, and a large academic hospital highlighted how the COVID-19 pandemic has impacted melanoma screening and care. The panel also explored new directions in treatment strategies for patients with rare melanoma subtypes like acral, mucosal, and uveal melanoma.

Beyond the scientific sessions, the Retreat featured 38 small group networking sessions focused on topics related to melanoma prevention, detection, treatment, and survivorship, among others. Thirty-five MRA awardees presented posters across two sessions providing designated times where Retreat participants could meet with the presenters virtually to discuss the work. Finally, researchers and clinicians gathered with representatives from industry and government to discuss the current state of companion diagnostics and biomarker development for melanoma.
MRA is delighted to be able to provide a platform for sharing important research advancements and to host such critical discussions. These are vital steps towards spurring the next wave of progress so that fewer and fewer individuals will experience suffering and death due to melanoma.

Marc Hurlbert, PhD
Chief Science Officer

Kristen L. Mueller, PhD
Senior Director, Scientific Program

The Melanoma Research Community Meets the Moment

Each year, the annual MRA Scientific Retreat brings hundreds of people from across the melanoma research ecosystem together to exchange ideas, report on scientific progress, celebrate achievements, and mourn the losses. In these ways, the 2021 Retreat was no different.

However, just as 2020 — and COVID-19 — changed all facets of life, including how we work, how our children go to school, and how we see and interact with our loved ones, the 2021 Retreat couldn't be more different than those that came before it. For the first time in its history, out of necessity for the health and safety of all attendees, MRA's annual gathering was held virtually.

This year — instead of flocking to Washington, DC — participants donned headsets, huddled over computers, and carefully carved out space from their daily schedules to participate. The rigor of the scientific talks and poster sessions, opportunities for meaningful networking, and willingness to report on pre-publication work was exactly what you'd expect from

For the first time in history, MRA's annual gathering was held virtually.

an MRA event. And, without the confines of a hotel ballroom, participation flourished, almost doubling to more than 500 people — bringing even more people into the MRA community.

Participants heard from 17 patients and advocates throughout the retreat who — through the power of their stories — offered encouragement, gratitude, and reinforced the urgent need for more research, more treatments, and more hope.

Keith Tolley thanked participants for allowing him to live to see the birth of two grandchildren, the marriage of his oldest son, and to celebrate many birthdays and holidays with his family. "As a surviving stage 4 melanoma patient, I am a beneficiary of the incredible discoveries that you continue to make and the tireless work you continue to do. Because of your relentless pursuit of a cure, I have great hope that I may yet still live to see more of these special events."

Christine Garrison spoke of her daughter Rebecca who succumbed to melanoma in 2011. "She lived for seven good years after her diagnosis. During this time, you were here lifeline. She always looked to you for a lifeline when her current treatment was failing. You came through for her many times. I know today that you are the lifeline for countless others. Thank you on behalf of us all for working hard to bring us ever more 'Plan B's' and hope for a cure."

With these searing words still fresh in their mind, participants started each day of the MRA Retreat: Meeting the moment and advancing melanoma research in truly unprecedented times.

> "Because of your relentless pursuit of a cure, I have great hope that I may yet still live to see more of these special events."
>
> **KEITH TOLLEY, MELANOMA SURVIVOR**

Christine Garrison addresses all attendees during a pre-recorded video: "Thank you on behalf of us all for working hard to bring us ever more 'Plan B's' and hope for a cure."

Melanoma Screening Challenges and Controversies

In recent years, the number of new technologies dermatologists use for screening moles has expanded. In many cases, this has improved the ability of clinicians to detect a melanoma that arises on the skin at its earliest stages, when it is more amenable to being cured. These technologies include three-dimensional whole-body imaging done at a doctor's office, a method of skin-surface microscopy called dermoscopy, an innovative way to spy on moles at the microscopic level without a biopsy, and a non-invasive technique for delving into the telltale genetic changes that might indicate a mole's shift to malignancy.

Another "sea change" in melanoma detection presented by Allan Halpern of Memorial Sloan Kettering at the 2021 MRA Scientific Retreat is the shift to digital health and the use of artificial intelligence (AI) to interpret pictures of moles. In one study, this technology has improved to the point where it exceeds the accuracy of dermatologists in detecting malignant moles. "The algorithms continue to outperform humans so there's no question that

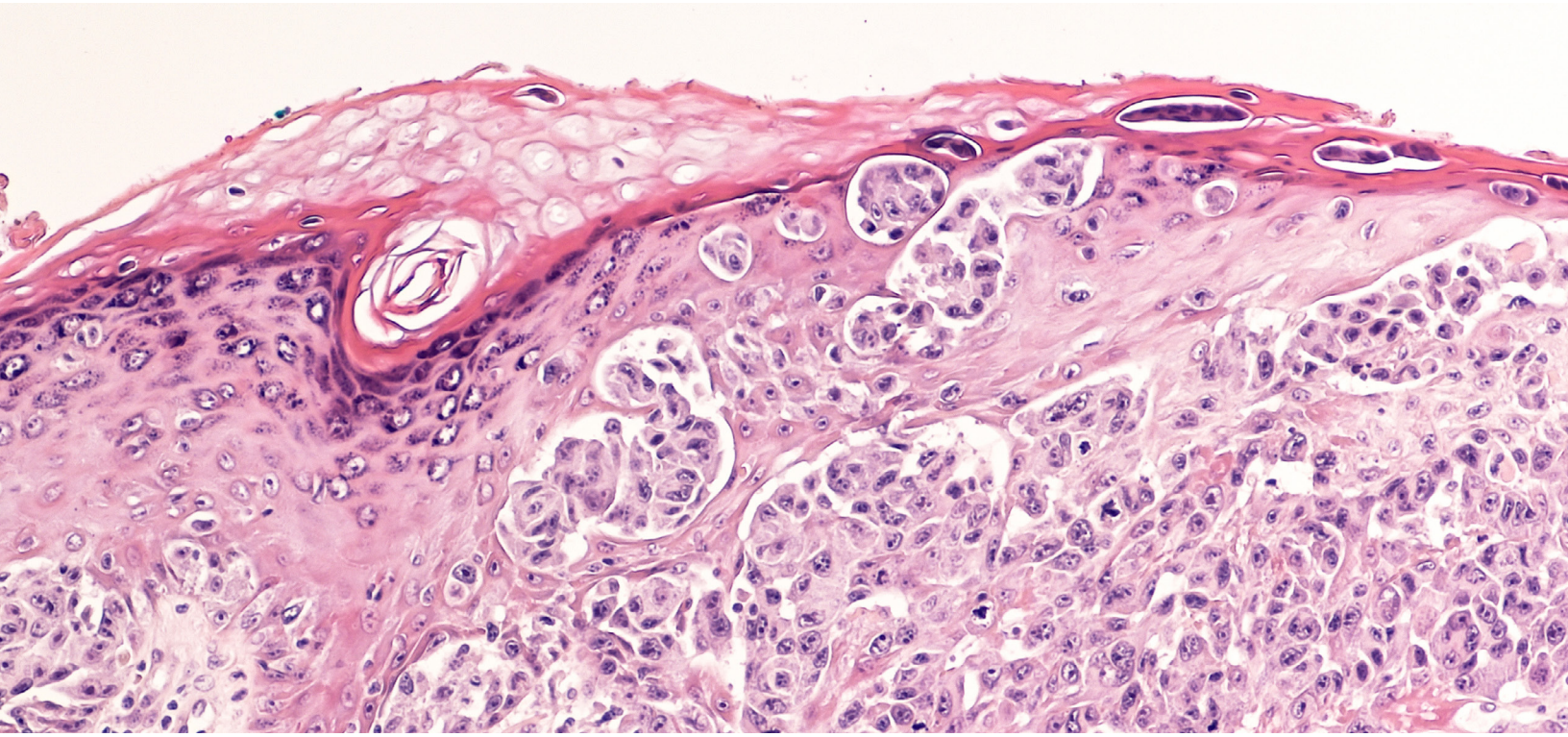
New technologies have enabled dermatologists to improve quality of care, but what are the risks?

technology and AI will continue to play an increasing role in early detection of melanoma," Halpern said. AI is also beginning to be used in cellphone apps in Europe to enable people to monitor their own moles by submitting pictures they take of them at a single or at multiple points in time. Software in the apps analyzes the pictures and alerts users if their moles have suspicious findings or changes requiring a more detailed look by a provider. These apps will eventually help people better assess their own moles in-between visits to the dermatologist.

These advances are worth celebrating as they have the potential to save lives, but Halpern cautions that "these technological advances we are very excited about have the risk of promoting overdiagnosis." Potential melanoma overdiagnosis has become a "hot topic" as a recent study indicates it already is a concern. This study, published in the New England Journal of Medicine, points out while melanoma incidence has increased by a factor of six compared to 40 years ago, this increase in cases has not been accompanied by an expected equal rise in melanoma deaths. Deaths have largely remained stable except for a recent decrease due to improved melanoma treatments.

This suggests that melanoma is being over diagnosed such that more benign, dormant stages of melanoma are being detected that may not ever have developed into deadly malignancies, or that mole changes are inaccurately diagnosed as melanoma, the study authors claim. They point out that over the past decade or two, physicians have been more inclined to biopsy suspected moles at their smaller, thinner stages when they are more ambiguous and likely to be misinterpreted.

Further compounding the risk of overdiagnosis is that pathologists have lowered the threshold for what they label melanoma, one study found, perhaps due to the tendency to err on the side of caution. The end result is that many patients are having unnecessary biopsies, resulting in greater medical costs, inconvenience, and discomfort to the patient, especially if there are functional or cosmetic complications resulting from the biopsies. Unneeded biopsies also cause undue psychological stress on patients and their loved ones as the fear of cancer looms large as they wait for test results.



Session moderator Ken Hsu and Allan Halpern in discussion.

The risk of overdiagnosis is timely because the United States Preventive Services Task Force is about to update its recommendations for skin cancer screening. In the past, this task force found inadequate evidence to suggest the need for widespread screening for melanoma, and instead recommended it only be considered for high-risk groups, such as those with a family or personal history of melanoma, or those who have a large number of moles, or atypical moles.

"Most of us agree we need to do a better job focusing our screening and public education efforts on the segment of society at greatest risk of dying from melanoma," Halpern said. But he pointed out there are some subgroups with a greater risk of dying from melanoma, such as men older than 50 years of age. Such high-risk groups should probably receive additional efforts in early detection.

Halpern noted children and people with skin of color have the least risk of dying from melanoma and so probably shouldn't undergo routine screening unless they are known to have a specific risk. He also called for improving the specificity of AI and other new technologies currently being deployed to diagnose melanoma by training and testing them with images of benign lesions across all racial, ethnic and age groups.

To counter overdiagnosis of melanoma, Halpern suggested doing more watchful waiting of ambiguous macular (flat) moles and refraining from performing a biopsy unless they show concerning changes over time. He pointed out that watchful waiting is already done for early stages of prostate and papillary thyroid cancer to counter the prevalent overdiagnosis of these cancers. Finally, Halpern called on researchers to continue to develop molecular

> "We need to do a better job focusing our screening and public education efforts on the segment of society at greatest risk of dying from melanoma."
>
> ALLAN HALPERN

A dermatologist using a dermatoscope.

markers that can more accurately distinguish between benign and malignant moles, as a current lack of such markers makes diagnosis of early melanoma subjective and somewhat imprecise.

Researchers, and private companies alike, are making important progress towards developing non-invasive techniques to determine if a biopsy is needed. While a dermatoscope, a handheld device that uses bright light and magnification to allow a dermatologist to view deeper layers of the skin, has been aiding the naked eye in detection for decades, more definitive non-invasive techniques are under development to help better diagnose abnormal lesions in a timely manner. Such tools include full body photography, reflectance confocal microscopy, electrical impedance spectroscopy, optical coherence tomography (OCT), fluorescence photography, non-invasive gene expression profiling, and high-frequency ultrasound.

One example of a non-invasive gene test that can help doctors and patients decide whether or not to biopsy a suspicious skin lesion is the Dermtech Pigmented Lesion Assay (PLA). The PLA is performed by your doctor by adhering an adhesive patch to the skin that collects a small sample to measure whether two genes, PRAME and LINC00518, are expressed at high levels. The PLA adhesive patch is then mailed to the diagnostic lab for testing, which can take up to 3 to 5 days, before results are returned to the doctor. Gene expression changes in PRAME and LINC can be detectable before physical changes to the skin lesion are visible. If one, or both, genes are highly expressed, the doctor can use this genomic information to determine if a biopsy is warranted.

Collectively, these diagnostic tools, when coupled with watchful waiting and AI, will help reduce overdiagnosis of melanoma.

The Next Frontier of Combination Immunotherapy

Maximizing the Benefits & Reducing Harms

Every general knows that the best way to successfully win a war is to deploy multiple weapons with different targets. This strategy was first used in cancer to conquer childhood leukemias with combination chemotherapy and now is being put to the test in melanoma by combining multiple checkpoint inhibitors, as well as combining checkpoint inhibitors with targeted BRAF and MEK inhibition or other agents. At MRA's 2021 Scientific Retreat, several researchers reported from such innovative frontlines. They recounted the current thinking on combination therapy for melanoma and ways to enhance the anti-tumor immune response using promising new immune targets, as well as strategies aimed at modulating the gut microbiome.

2019 Nobel Laureate William Kaelin, Jr.

During his MRA Scientific Retreat opening keynote lecture, 2019 Nobel Laureate William Kaelin, Jr., of Dana-Farber Cancer Institute, pointed out that many melanoma patients treated with BRAF/MEK targeted therapy initially respond, only to relapse later due to drug resistance. This resistance

Session moderator Stefani Spranger and John Wilson in discussion.

stems from combining drugs that block the same target or multiple targets in the same cellular signaling pathway. This not only increases the risk of toxic reactions, but also revs up the evolutionary pressure for tumor cells to escape the effects of these drugs. Such pressure prompts molecular changes inside tumor cells that enable them to elude the effects of these drugs. Underlining the challenge clinicians and researchers face in fighting melanoma and other cancers with such drugs, Kaelin said, "If you strike at the king, you must kill him."

To overcome such resistance, Kaelin suggested combining drugs with distinct and independent mechanisms of action. That way, "There is a low probability of any one [tumor] cell being resistant to three non-cross-resistant drugs. The trick is to make the math work for and not against you so you can potentially win," Kaelin said.

This approach has already proven effective for kidney cancer, Kaelin noted, and is starting to be applied to melanoma. For example, early-stage trials targeting BRAF/MEK inhibition with CDK4/6 inhibitors. "Hopefully we can someday look back at kidney cancer and melanoma and be able to say that with the development of combinations, we were able to find cures for these diseases," Kaelin concluded.

Using "Smart" Technologies to Boost Anti-Tumor Immunity

To foster more effective combination immunotherapies, a number of researchers are focusing on aspects of the immune system that work independently from those targeted by currently approved melanoma checkpoint inhibitors, such as ipilimumab, nivolumab, and pembrolizumab. Up to 50% of patients do not durably respond to these therapies, and researchers believe that by targeting additional pathways involved in an anti-tumor immune response, such combination therapy will become more effective in the long term to more patients.

One MRA-funded researcher, John Wilson of Vanderbilt University, is designing innovative nanotechnology to access a new and previously unreachable immune target within the cell. Currently approved immunotherapies use antibodies that target molecules called receptors that stick out from the surface of a cell. These receptors easily come into contact with medications circulating in the bloodstream. It is much more difficult, if not impossible, for antibodies and many other promising drug candidates to penetrate cell membranes, and access the molecules within them. These molecules include a "growing arsenal of promising intracellular therapeutic targets that have enormous potential, but require a strategy to provide open access to them," pointed out Wilson.

To provide that access, Wilson's lab, which has expertise in chemistry, materials science, and immune-engineering, designed smart nanoparticles (NPs) that mimic the way some viruses enter cells. The researchers designed NPs so they are engulfed by the cell membrane of tumor and immune cells. And, once inside these membranes, a change in acidity triggers the NPs to release their active drug component, where it binds with its target. When loaded with a drug cargo that can stimulate the immune system, the NPs trigger molecular signaling that causes immune cells to activate and expand in number, so that they infiltrate into and kill tumor cells.

Wilson found that their approach resulted in significant therapeutic benefit in multiple mouse models, and that his NPs greatly enhanced anti-tumor immune responses when combined with checkpoint immunotherapy. This experimental combination inflamed a previously dormant immune response to the tumors, significantly boosting complete response rates in a mouse model of melanoma and increasing survival without causing any serious side effects. Wilson also coupled his NP technology to personalized cancer vaccines aimed at stimulating an anti-tumor immune response. The particles were small enough that they easily penetrated cells in the lymph nodes, where they enhanced the immune response there, and showed good efficacy in a mouse model of melanoma when combined with checkpoint immunotherapy. "Our smart NPs offer a platform for cancer vaccine delivery and have a number of other potential advantages as a drug carrier platform that we are actively exploring," Wilson concluded.

The Scoop is in the Poop

Perhaps, a less technical solution to improving responses to checkpoint inhibitors may be to alter the microbes in our gut, Jennifer Wargo of University of Texas MD Anderson Cancer Center reported. She noted these microbes, and the foreign proteins they produce, stimulate the immune system to better kill tumors. She found that the more diverse gut microbes are in a patient, including those with melanoma, the better their response to checkpoint immunotherapy. Having certain types of microbes in the gut were also linked to better responses in melanoma patients treated with checkpoint immunotherapy. "The scoop is in the poop," she said, adding, "You are what you eat!"

But even those patients with favorable microbes in their gut responded better to treatment when they were also on a high fiber diet. "It's not enough to have a good microbiome signature, but you also have to feed it the right things," Wargo stressed. She found that eating a high-fiber diet was

"It's not enough to have a good microbiome signature, but you also have to feed it the right things."

JENNIFER WARGO

linked to greater progression-free survival in melanoma patients treated with checkpoint immunotherapy. Mouse studies then suggested that the greater responses and survival seen in patients with a high fiber diet was due to heightened activation of immune cells. This boost in immune activity can happen in a remarkably short period of time in response to changes in diet. Wargo is currently working with other investigators at MD Anderson Cancer Center (Dr. Jennifer McQuade and Dr. Carrie Daniel-MacDougall) to interrogate the impact of dietary intervention with fiber and other strategies in patients with melanoma (NCT03950635).

Building on Wargo's findings, researchers recently experimented with transplanting stool from melanoma patients who responded to checkpoint immunotherapy into patients with metastatic melanoma in which the treatment was unsuccessful — a treatment called fecal microbiome transplantation (FMT). Wargo collaborated in one study in which clinical responses were observed in three of ten patients treated with FMT followed by anti-PD1 immunotherapy. In another study published at the same time, six of 15 patients derived clinical benefit. These results suggest that FMTs may modulate the gut microbiota in such a way as to allow patients who previously did not respond to benefit from checkpoint immunotherapy.

FMTs might also reduce certain side effects, what researchers call adverse reactions, to checkpoint immunotherapies. When patients undergoing immunotherapy developed the all-too common side effect colitis, and were treated with FMTs from healthy donors, the colitis resolved, even though it previously did not respond to steroids or other drugs intended to suppress it, Wargo reported.

Given the role that microbes play in shaping the response to cancer immunotherapies, Wargo worried that antibiotics might hamper that response. Her collaborator Dr. Laurence Zitvogel found that to be true for a number of lung cancer patients given antibiotics prior to being treated. "Those patients receiving antibiotics had dramatically worse response to therapy and worse survival," Wargo said. She is pursuing a clinical study to further examine these preliminary results.

"There's still a tremendous amount to be learned, but the future is looking quite bright," Wargo concluded.

"Hopefully we can someday look back at kidney cancer and melanoma and be able to say that with the development of combinations, we were able to find cures for these diseases."

WILLIAM KAELIN, JR.

Averting and Treating Immune-related Adverse Events Associated with Checkpoint Immunotherapies

The first ever immune checkpoint inhibitor was approved by the Food & Drug Administration (FDA) in 2011 with an indication for treating metastatic melanoma. That approval was built upon ground-breaking research by Jim Allison, MRA Scientific Advisory Panel member and 2018 Nobel Laureate. Since then, additional immune checkpoint therapies have been approved for melanoma. Indeed, checkpoint inhibitors have not only dramatically improved health outcomes in melanoma, but are now being used to treat over a **dozen different cancers**.

Checkpoint inhibitors are therapies that empower the immune system to kill cancer cells. FDA-approved checkpoint immunotherapies block specific proteins on both immune cells (PD1, CTLA4) and sometimes the tumor (PDL1) that normally act as "off" switches for the immune system. This then releases the breaks on immune cells, allowing them to kill tumor cells. While this approach has yielded dramatic results in resolving numerous cancers, sometimes immune-related adverse events (irAE) can also occur as a result of the immune system attacking healthy tissues. Such autoimmune reactions can hamper patients' quality of life, can limit the effectiveness of the treatments by requiring treatment discontinuation, and in rare instances can be fatal.

To help overcome this challenge, MRA has issued a number of research grants, including some in partnership with the **American Cancer Society** (ACS) and the **Society for Immunotherapy of Cancer** (SITC), to support an array of approaches. Some are exploring what causes these severe adverse reactions and treatments that might prevent or reverse them. Others are devising new experimental drugs that have the same tumor-killing effects as approved therapies, but without the

autoimmune side effects. Another group is searching for molecular markers that can predict which patients are more likely to develop adverse reactions to currently approved immunotherapies, which would help doctors select the best possible treatment for each patient. These investigators reported on their exciting findings at the MRA 2021 Scientific Retreat.

Treating Colitis Among Patients Receiving Checkpoint Immunotherapy

Kai Wucherpfennig of Dana-Farber Cancer Institute and his colleagues used their MRA-American Cancer Society Team Science award to explore what goes awry in melanoma patients who develop colitis after being treated with checkpoint inhibitors. Colitis, inflammation of the colon that causes severe diarrhea, is a common irAE affecting up to 25% of patients receiving checkpoint immunotherapy.

When Wucherpfennig compared colon tissue samples of patients who developed colitis to those being treated with the same therapies who did not develop colitis, he found key molecular differences. These changes included an increase in a protein called tumor necrosis factor (TNF) in those with colitis, suggesting that a drug already on the market that targets this factor (infliximab) might alleviate this complication. Team member Michael Dougan, of Mass

General, initiated a clinical trial that opened in August 2020 to test this possibility (NCT04305145). Wucherpfenning noted that although his findings are specific to the colitis, some of the molecular changes he observed are likely to be relevant for other irAEs affecting the skin, lungs, and other tissues that frequently interact with microbes in the environment.

The Next Generation of CTLA4 Checkpoint Immunotherapies

Pan Zheng, formerly of University of Maryland, Baltimore, and founder of the biotech companies OncoImmune and OncoC4, is hoping to avoid autoimmune side effects with next generation anti-CTLA-4 antibodies that are being

"Our findings suggest autoimmune disease is not necessarily the price for cancer immunity."

PAN ZHENG

tested in the clinic. Her studies in mice found some antibodies targeting the protein CTLA-4 were able to effectively kill melanoma tumors without triggering an autoimmune reaction, unlike the current CTLA-4 targeted therapy (ipilimumab). She and her team hope that these alternative antibodies could serve as a second generation CTLA-4 therapy and would allow patients to experience the tumor-killing effects of the therapy while minimizing the irAEs.

Zheng then investigated why this was the case and found that CTLA4 protein bound to ipilimumab was broken down in immune cells, which reduced the amount of CTLA4 expressed on the surface of these cells. In contrast, the new antibody Zheng developed maintained the level of CTLA4 on the cell surface. In the case of Zheng's antibody, this difference allowed the mice to better keep autoimmune reactions at bay. "Our findings suggest autoimmune disease is not necessarily the price for cancer immunity," Zheng said. "You can have an anti-tumor effect without immune-related adverse events." With the support of a National Cancer Institute small business innovation award, Zheng is currently testing one of these antibodies (ONC-392) in a small number of cancer patients either alone, or in combination with pembrolizumab, to determine its safety and optimal dosing for future clinical trials (**NCT04140526**).

Predicting Patients Most Likely to Develop Serious Reactions

Another approach to avoiding serious autoimmune reactions of cancer immunotherapies is to predict those patients who are more likely to develop them. MRA-SITC Young Investigator Shaheen Khan of UT Southwestern and her colleagues have discovered molecular markers that show promise for identifying these patients. Certain protein levels were increased in blood samples taken from cancer patients, including patients with melanoma, who experienced autoimmune reactions to checkpoint immunotherapy compared to those that did not. If these findings are validated in future studies, clinicians could use them to help inform treatment decisions and to identify irAEs in their earliest stages, when they may be more easily treated.

The researchers also developed mice who are prone to autoimmune disease as a model for studying irAEs, and found one of the proteins detected in cancer patients who develop autoimmune reactions was also elevated in the autoimmune-prone mice. Studies in these mice might suggest ways to prevent the autoimmune reactions from occurring in patients altogether. "We hope our findings may ultimately help customize therapy, expand the use of immunotherapy, and reduce toxicities in cancer patients," Khan noted in a poster session.

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SHAHEEN KHAN

Patients with rare melanoma subtypes (such as in the eyes) tend not to respond as well to current treatments for sun-exposed skin.

Rare Melanoma Research, Patient Registries & Clinical Trials

Despite the tremendous progress made in the last decade in treating melanoma, approximately one third of patients don't benefit from currently approved therapies. This includes the majority of people with rare forms of melanoma — melanomas that develop in the eye, nailbeds, palms, soles of the feet, and various mucosal membranes. Patients facing these subtypes tend not to respond as well to current treatments as patients with cutaneous melanomas that arise on sun-exposed skin. But as investigators continue to chip away at understanding what causes these melanomas and how they differ from UV-driven cutaneous melanomas, the hope is the better understanding they reap will be sown into improved treatments for these patients. Researchers explored both the challenges and the opportunities for research on rare melanomas at the 2021 MRA Scientific Retreat.

Approximately one-third of patients don't benefit from current therapies; this includes many patients with rare forms of melanoma.

New Insights Into the Genetics of Acral Melanoma

Keiran Smalley of H. Lee Moffitt Cancer Center and Research Institute and his MRA-funded team hope to find a genetic 'smoking gun' of what causes acral melanoma, a rare subtype of melanoma that develops on the palms, soles of feet, or under finger or toe nails, and comprises about two to three percent of all melanomas. The researchers assumed that, like many cutaneous melanomas, acral melanomas evolve from moles whose growth goes awry due to a series of specific genetic flaws. But this didn't prove to be so for most of the tissues they analyzed when the researchers genetically compared benign moles from acral sites (feet, hands) to that of acral melanoma tumors. "This surprised us because it suggests it is unlikely that acral nevi [moles] are likely to be the precursors for the majority of acral melanomas," Smalley said.

Digging deeper, they then mapped out the genetic landscapes of nine acral melanoma samples and found tremendous variability in the genetic material and the ways in which cell functions were altered. Unfortunately, no distinctive genetic signature was found among the samples that could provide a specific target for a drug that might be effective for patients with this rare melanoma. However, the researchers did find a group of genes with altered activity shared among most of the samples. The researchers also noted fewer and less active immune cells in the acral melanoma tumor samples compared to samples from cutaneous melanoma. This suggests that acral melanoma is less likely to spark an immune response and may explain why many patients with this subtype often do not respond to checkpoint immunotherapy, Smalley noted.

Titia de Lange of Rockefeller University, Marcin Imielinski of Weill Cornell, and their research team also found a tremendous amount of variability in the genetic landscape of the acral melanoma samples they studied. Many of these genetic alterations were due to major disruptions in genetic material, akin to typhoons creating piles of genomic wreckage, which break up the chromosomes and reattach the genes on them in new ways. These genetic disruptions are quite different from the smaller number of consistent and more pinpoint genetic changes often seen in cutaneous melanoma on sun-exposed skin. But because of the jumbling and multiplication of genetic material that often occurs after these chromosomal catastrophes, they likely trigger production of new proteins (antigens). The immune system can recognize some of

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KIERAN SMALLEY

these new tumor antigens and attack the cells that have them when stimulated by checkpoint immunotherapy, the researchers speculate. They suggest that molecular markers for these types of chromosomal disruptions, if present in patients' tumors, might indicate whether they are likely to respond to such treatments.

UV-Driven Melanomas Extend Beyond the Skin

Richard Marais of the Cancer Research UK Manchester Institute reported on a new discovery that suggests that a subgroup of mucosal melanoma patients could respond to checkpoint immunotherapies or targeted therapies. Most mucosal melanomas arise in areas of the body not exposed to the sun, so lack the telltale genetic changes caused by ultraviolet radiation (UVR) induced DNA damage that are thought to contribute to responsiveness of these melanomas to checkpoint blockade. Mucosal melanomas are also not generally considered to be eligible for BRAF plus MEK inhibitors. However, Marais has found that melanomas arising in the mucosal membrane that covers the eye and lines the inside of eyelids have the distinctive signature common to sun-induced common cutaneous melanoma. These mucosal melanomas also had a high mutation burden and a high incidence of BRAF mutations, suggesting that they are likely to respond to the therapies approved for common cutaneous melanoma. Quoting Nick Hayward's data, Marais noted that uveal melanomas arising on the iris also bear the telltale genetic signature of sun-induced DNA damage, suggesting that these melanomas may also respond to checkpoint immunotherapies.

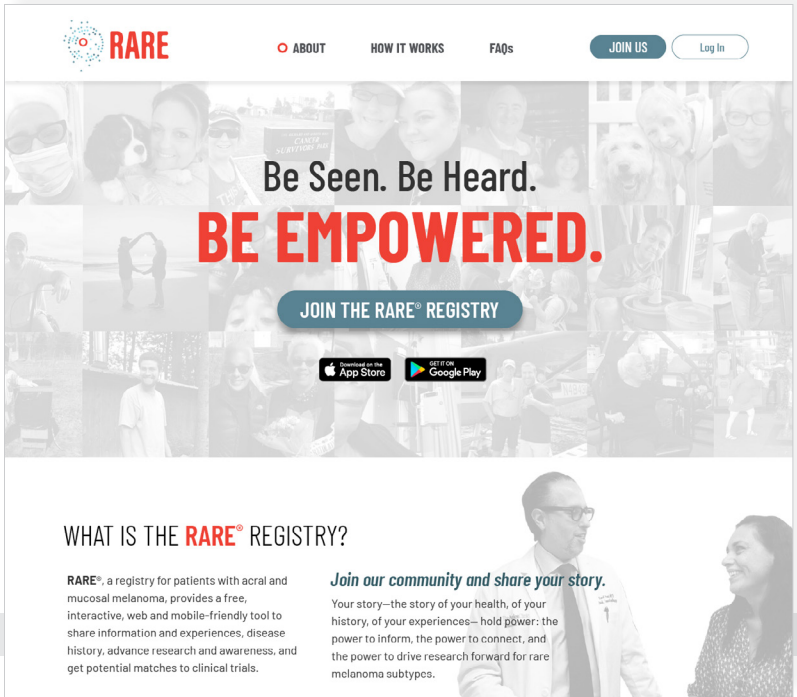
"This makes us start to think about basic concepts in how melanoma is driven," Marais said, pointing out that the data suggests that melanoma is driven by distinct processes in different parts of the body, but that UVR imprints additional events over the baseline processes to accelerate melanoma development. "We need to apply these findings to develop new treatments for rare melanomas, because responses are driven by the underlying genetics rather than by the tissue of origin" Marais noted, concluding that these findings reinforce public health messages about the importance of protecting the eyes from UVR.

Session moderator Hunter Shain with Titia de Lange and Marcin Imielinski in discussion.

Furthering Clinical Trials on Rare Melanomas

Recognizing more research is needed to fully understand rare melanomas and how best to treat them, the MRA will be launching the **RARE Registry** for patients with acral and mucosal melanoma in 2021, while the **Melanoma Research Foundation** will launch a separate registry in 2021 to focus on patient experiences with ocular melanoma. The MRA RARE Registry will provide a centralized portal for patients with mucosal or acral melanomas to enter their medical data, their risk factors for melanoma, and information about their quality of life. The registry will also collect other nonmedical information that can help inform decisions for melanoma researchers, clinicians, policymakers, and funders. Maryam Asgari of Massachusetts General Hospital and Co-Principal Investigator to MRA's registry, reported at the "No Patient Left Behind" panel discussion on the last day of the retreat. In addition, some patients whose data are part of the MRA registry will be offered a genomic analysis of their tumors free of charge. This analysis can show genetic changes during and after their treatments, which should help researchers understand why certain treatments stop working over time in some patients.

MRA's soon-to-be-launched registry is being developed collaboratively with patients, researchers, and care providers. Patients and loved ones helped drive the design process and selected the research questions they wanted the registry to help answer. "We really put the patients in the driver's seat when it came to asking what do you want to know about your tumor," Asgari said. Researchers also identified gaps in the current knowledge about rare melanomas and what questions in the registry might help close those gaps, she added. Asgari noted that the two melanoma registries will be a great conduit to connect patients with rare melanomas to clinical trials. Patients are asked if they are willing to participate in such trials and researchers conducting



> "We really put the patients in the driver's seat when it came to asking *what do you want to know about your tumor?*"
>
> MARYAM ASGARI

those trials can easily find them by using the registry. The MRA registry will also be an open-access research portal for investigators who can use its data in their studies. “Once we have the data we can study, breakthroughs in treatment will follow,” Asgari stressed.

Eventually, the MRA registry will go global, enabling patients in countries in which rare melanomas are more common to contribute their data, furthering the usefulness of the registry in research and the development of new treatments for people all over the world with acral and mucosal melanomas, Asgari reported. Steven Lemery of the Food and Drug Administration (FDA), who was also on the panel discussion, stressed “As a society, we need to establish these registries to find better ways to treat and prevent these diseases.”

Ensuring patients with rare melanomas have access to clinical trials is also essential. One learning from the pandemic is that more extensive use of telehealth has increased accessibility of clinical trials to more patients. Researchers are shipping patients their investigational drugs, conducting video visits, and doing remote monitoring. These efforts enable more patients to participate in clinical trials, pointed out all the participants in the panel discussion. “Telehealth is fantastic,” said Asgari. “You can save patients having to drive in to be evaluated for things that you can now do more readily online.” Lemery added that the FDA is working with various stakeholders on ways to gather enough data that is more user friendly, so patients who live in a rural area, for example, don’t have to travel to participate in a clinical trial at a major urban center, and instead can have blood and other tests done at their local facilities or at their homes. “There’s no reason we can’t do clinical trials using telehealth to reach rural and other underserved communities,” James Doroshow of the National Cancer Institute (NCI) stressed, noting that NCI hasn’t seen any significant change in the quality of such trials or an increase in adverse side effects when they are run in this decentralized manner. “I hope the future has a more patient-friendly approach to clinical trials with more ability for patients who don’t live in a big city to enroll in them.” Lemery said.

Learn more about melanoma clinical trials and find potential matches:

CureMelanoma.org/ClinicalTrials

Clockwise from left: Elliot Sigal, Steven Lemery, Maryam Asgari, and James Doroshow on the “No Patient Left Behind” panel.

INDUSTRY ROUNDTABLE

Biomarkers: What You Need to Know

What They Are, Why They Matter, and Where They are Going

The melanoma treatment field has been rewarded recently with an abundance of riches, including several targeted therapies, checkpoint immunotherapies, and many more experimental treatments in the pipeline. But all these exciting new treatment options for patients can also create complexity and confusion about which treatments patients should receive first, when combination treatment is necessary, when to stop therapy and when to switch to a new treatment altogether. Fortunately, help is on the way in the form of biomarkers — molecular or cellular indicators for whether a patient is likely to respond or is currently responding to their therapy, or whether they are likely to have a recurrence of their cancer.

What are Biomarkers?

At the most basic level, biomarkers are objective and measurable signs that something is or is not taking place within the body. The term is literally a mashup of 'biological' and 'marker' and is used constantly in modern medicine. Put in a different way, doctors use various biomarkers to determine if your liver is working correctly, to determine if your body is responding appropriately to a medication, or a surgery is successful.

When it comes to melanoma biomarkers, we are often referring to the expression of certain proteins by tumor cells themselves or other cells in the tumor microenvironment, the presence or a specific genetic mutation, or even clinical metrics such as the size of the tumor(s) and location. But relevant biomarkers aren't only in the tumor or tumor-environment — they can also be found in other parts of the body including cell-free snippets of DNA found in the blood, or the composition of the gut microbiota. Many of these biomarkers are showing promise for aiding treatment decisions for melanoma

patients, but only one, BRAF mutation status, is currently approved by the Food and Drug Administration (FDA) to distinguish melanoma patients likely to respond to therapies targeting the BRAFV600E mutation in this gene.

How are Biomarkers Measured?

Some biomarkers, such as the size or location of a tumor are easy to measure, but others require the development of sophisticated tests that are able to measure tiny changes in the body, from specific mutations driving a tumor (such as tests designed to measure BRAF status), to the diversity of bacteria in the gut's microbiome. Keeping the development of new biomarker tests in lockstep with the advancement of new treatment options is important to help guide the use of new therapies.

For example, targeted therapies are currently FDA approved in the treatment of patients with BRAF mutant melanoma. This is great for the half of all patients with cutaneous melanoma who have the mutation, but what of the other half? What if we had no way of knowing who fit into this category without treating everyone — and then simply prayed it would work? Fortunately, researchers developed accurate and reproducible biomarker tests to determine who is likely to benefit from this treatment approach, saving patients without the BRAF mutation from a treatment that isn't likely to ever work for them.

> "There are a lot of exciting biomarkers in melanoma, but we're now looking at the gap between discovery and clinical practice."
>
> **JANICE TAUBE**

Developing biomarker tests is important because it gives clinicians information they need to make strategic treatment recommendations for their patients.

What are the Current Challenges and Where are Biomarker Tests Heading?

First and foremost, it isn't always clear what can be objectively measured — for all patients — to answer some of the most pressing questions faced by clinicians. Second, these tests must be rigorously evaluated in clinical trials before they can be widely adopted.

Current research suggests that a combination of biomarkers may be more informative than measuring a single biomarker such as BRAF status. For example, one pretreatment biomarker panel that relies on six biomarkers for tumor and immune cell features was found to be a much more powerful predictor of risk of melanoma recurrence than its individual components.

One of the more comprehensive approaches to discerning biomarkers is to do a complete genetic analysis of a patient's tumor via a process called next-generation sequencing (NGS), which is likely to be more informative than a simple genetic test, as multiple genes are now known to play major roles in melanoma. Researchers think that NGS can be useful for melanoma patients because some mutations identified with this technology may be "actionable." That is, there are approved drugs that may be aligned with specific mutations, often used to treat other forms of cancer, that may be effective in treating melanomas with these mutations.

Clinicians also face the conundrum of whether to treat patients beyond surgery, as the drugs originally approved for unresectable metastatic melanoma are now approved to treat some stage 3 patients, in what is known as the adjuvant setting. Clinical trials are also looking at treating patients with even earlier stages of the disease. Physicians are treating some patients at high risk of having a melanoma recurrence before or shortly after their surgical removal of their tumor with immune and other cancer therapies, in an effort to have "no tumor left behind" even though many of those patients are likely to be cured by

surgery alone. To help navigate these challenges, clinicians need a better understanding of which patients are most likely to have a recurrence of their melanoma and thus should be subjected to the risks of the drug treatments.

"We have the challenge of colliding multiple biomarkers for multiple therapies," noted Keith Flaherty of Massachusetts General Hospital. Janice Taube, a dermatopathologist at Johns Hopkins University added, "There are a lot of exciting biomarkers in melanoma, but we're now looking at the gap between discovery and clinical practice." Taube and Flaherty were two of about two dozen representatives from industry, the FDA, and academia that the MRA brought together as part of its 2021 Scientific Retreat for a lively roundtable discussion on how to move biomarker development forward and into clinical practice so that more melanoma patients can benefit.

Taube suggested biomarkers currently in the discovery and development stages need to be tested in large clinical trials. The results of such trials can refine the guidelines for how these biomarkers are interpreted, as well as validate their reproducibility and accuracy, and their efficiency, in terms of cost and time. She pointed out unity is lacking in terms of how current biomarkers are used, with cutoff levels for specific biomarkers varying according to the institution at which they are done. She suggested developing more universal guidelines for biomarkers.

MRA's Chief Science Officer Marc Hurlbert asked whether more extensive NGS analyses should be reserved for melanoma patients not served well by current treatments. Jason Luke of the University of Pittsburgh responded "Everyone agrees that patients with advanced melanoma should have NGS and not just BRAF and that would open up greater space for these patients to participate in clinical trials." Luke suggested MRA advocate for NGS as part of the standard care for patients with advanced melanoma as a way to inspire insurers to pay for such analyses. Deborah Norton of Novartis agreed that there needs to be clarification of which melanoma patients should have NGS and when. "I think all melanoma patients need it but there is resistance to this from insurers, so a call to action on this would be helpful," she said. "Is NGS testing ready for prime time is a key point," Flaherty stressed.

What is Needed to Move the Field Forward?

Before taking new steps to move the field forward, it's important to make sure that no patients are being left behind. David Solit of Memorial Sloan Kettering Cancer Center suggested that MRA could advocate for the creation of a tiered list of biomarkers seen as standard of care for patients with melanoma, versus those used only in the framework of a clinical trial. Solit noted that insurers based their reimbursement policies on expert statements about when certain treatments or diagnostic tests should be performed, and there is a lack of an expert organization for cancer biomarkers that can make those recommendations. Norton suggested tapping the National Comprehensive Cancer Network (NCCN) to work with for expert biomarker recommendations. NCCN is a non-profit network of 30 Comprehensive Cancer Centers in the United States that publishes treatment guidelines and insurers often follow those guidelines in determining what is covered.

Taube noted there is great academic interest in developing tests that could simultaneously measure multiple biomarkers in a tumor utilizing a single technique such as histrochemistry, thus reducing the tumor sample size needed, but she is disappointed by how these innovative tests are not moving forward and into clinical practice. "How best can we partner with industry and the FDA for them?" she asked. Luke suggested MRA could consider advocating for such multiplex tests as part of standard of care for melanoma patients. Steven Lemery of the FDA added MRA could help establish standards for when patients should be re-biopsied or have blood samples to assess for biomarkers for treatment effectiveness, so as to clarify when insurers should reimburse such procedures.

"Every year biomarkers become more relevant. We have to stop talking about them and do something to drive their use in practice," Norton stressed. ○

Agenda, Participants, & Sponsors

Agenda

(All times listed are in EST)

Monday, February 22

11:00am-1:00pm	**Scientific Session 1:** Novel influences on tumorigenesis and progression
Keynote Lecture:	William Kaelin, Dana-Farber Cancer Institute
Speakers:	Titia de Lange, The Rockefeller University
	Marcin Imielinski, Weill Cornell
	Hilary Coller, University of California, Los Angeles
	David Lombard, University of Michigan: Oncogenic role of the SIRT5 deacylase in melanoma
6:30-7:30pm	**Poster Session 1**

Tuesday, February 23

9:30-10:30am	**Poster Session 2**
11:00am-1:00pm	**Scientific Session 2:** Novel immunotherapy targets and mechanisms of immune-related adverse events
Keynote Lecture:	Jennifer Wargo, University of Texas MD Anderson Cancer Center
Speakers:	Pan Zheng, University of Maryland, Baltimore
	John Wilson, Vanderbilt University
	Kai Wucherpfenning, Dana-Farber Cancer Institute: Molecular Pathways of Colon Inflammation Induced by Checkpoint Blockade
6:30-7:30pm	**Networking Roundtables Session 1**

Wednesday, February 24

9:30-10:30am	**Networking Roundtables Session 2**
11:00am-1:00pm	**Scientific Session 3:** New approaches to detecting and treating melanoma
Keynote Lecture:	Richard Marais, Cancer Research UK
Speakers:	Keiran Smalley, Moffitt Cancer Centers
	Elizabeth Patton, University of Edinburgh
	Allan Halpern, Memorial Sloan Kettering Cancer Center
1:30-2:30pm	**Moderated Panel Discussion** – No Patient Left Behind: Treating & Diagnosing Patients with Unmet Medical Needs.
Panelists:	Maryam Asgari, Massachusetts General Hospital, Steven Lemery, US Food and Drug Administration (invited), Ned Sharpless, National Cancer Institute

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