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TITLE: Building a Community to Advance Research for Patients with Acral Melanoma

PRINCIPAL INVESTIGATOR: Joan Levy, PhD

CONTRACTING ORGANIZATION: Melanoma Research Alliance, Washington, DC

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REPORT DOCUMENTATION PAGE

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14. ABSTRACT Acral melanoma (AM) is a rare subtype of melanoma accounting for approximately 2-3% of melanoma cases in the US, with a higher proportion of cases in populations with darker skin. AM is generally diagnosed at more advanced stages of the disease and typically is not as responsive to the treatments that have been approved for melanoma over the past decade. Therefore, more research and data are needed to comprehensively address the complexity and distinct characteristics of this disease. To address this, the Melanoma Research Alliance launched RARE, the first direct-to-patient registry for those with AM and mucosal melanoma (MM), as well as non-acral cutaneous melanoma as a comparator arm. Participants complete surveys on topics including demographics, disease and treatment history, genetics & biomarker testing, health & lifestyle, and quality of life and upload medical reports. The aims of this study are to: 1) Populate the RARE registry with datasets that accurately represent the racial and ethnic distribution of AM patients in the US; 2) Build a clinically annotated biospecimen repository of samples from AM RARE participants and distribute tissues to researchers; and 3) Create RARE data portals that allow the dissemination of integrated patient-reported, clinical, and 'omics analyses to the research community in a reasonable timeframe. At this point the RARE registry has 137 patients enrolled including 35 AM participants. Our current efforts are focused on building the diverse AM community of RARE participants and opening the associated biorepository for collection of samples.						
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TABLE OF CONTENTS

	<u>Page</u>
1. Introduction	4
2. Keywords	4
3. Accomplishments	4
4. Impact	13
5. Changes/Problems	14
6. Products	16
7. Participants & Other Collaborating Organizations	18
8. Special Reporting Requirements	21
9. Appendices	22

1. INTRODUCTION:

Acral melanoma (AM) is a rare subtype of melanoma accounting for approximately 2-3% of melanoma cases in the US, with a higher proportion of cases in populations with darker skin. Patients with AM are often diagnosed with advanced disease and have poorer prognoses. We hypothesize that the complete molecular landscape of AM and any race-related differences are understudied and there are existing barriers to AM awareness and healthcare, which delay diagnosis and increase adverse outcomes. To find better treatments and improve management of this understudied melanoma subtype, the Melanoma Research Alliance (MRA) launched RARE, the first direct-to-patient registry for those patients with AM as well as another rare melanoma subtype, mucosal melanoma (MM). Participants in RARE fill out different surveys describing their journey with the disease (participant-reported data) and can also upload medical reports to provide additional clinically abstracted data. The aims of the project include: 1) Populating the RARE registry with datasets that accurately represent the racial and ethnic distribution of AM patients in the US; 2) Building a clinically annotated biospecimen repository of samples from AM RARE participants to distribute tissues to researchers; and 3) Creating RARE data portals that allow the dissemination of integrated participant-reported, clinical, and 'omics analyses to the research community in a reasonable timeframe. To populate the RARE registry with a representative AM population, patients will be recruited through collaborations with large academic medical centers that have affiliate community-based hospitals, as well as through targeted partnerships with state registries with known diverse populations of melanoma. Participants will be consented to donate tissue with samples banked at the RARE biorepository. Researchers will gain access to tissue through an approval process to perform "omic studies and will be required to submit data from molecular analyses to the RARE registry public databases that will also integrate participant-reported and clinically abstracted datasets. Building a community of patients representing the diversity of AM, along with providing researchers and clinicians with compiled datasets, will facilitate and accelerate hypothesis-generating research around healthcare disparity and barriers as well as better define the molecular characteristics of this understudied melanoma subtype.

2. KEYWORDS:

melanoma, rare melanomas, acral melanoma, mucosal melanoma, cutaneous melanoma; biospecimen repository, tissue samples; data portals; participant-reported; clinically annotated

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Specific Aim 1: Populate the RARE registry with datasets that accurately represent the racial and ethnic distribution of Acral Melanoma (AM) patients in the US.

Major Task 1: Finalize the RARE registry platform, develop patient recruitment materials, and secure ethics approvals (95%)

Major Task 2: General Launch of Registry and Patient Recruitment (75%)

Major Task 3: Geo-Targeted Patient Recruitment (10%)

Major Task 4: Ongoing Participant engagement (80%)

Major Task 5: Plans for international expansion (Initial discussions with Mexico and Brasil but no formal plans)

Specific Aim 2: Build a clinically annotated biospecimen repository of samples from AM RARE participants and distribute tissues to researchers in return for derivative ‘omics data to be included in the cBio Cancer Genomics Portal (cBioPortal).

Major Task 1: Develop RARE melanoma biorepository- (40%)

Major Task 2: Assemble and structure RARE Melanoma Tissue Disbursement Committee (Not started)

Major Task 3: Disseminate and promote the biorepository and access to samples (Not started)

Specific Aim 3: Create RARE data portals that allow the dissemination of integrated participant-reported, clinical, and ‘omics analyses to the research community in a reasonable timeframe.

Major Task 1: Create the RARE Melanoma Research Portal (10%)

Major Task 2: Host datasets from RARE Melanoma Research Portal integrated with corresponding molecular analyses of tissue samples on the cBioPortal (Not started)

Major Task 3: Disseminate and promote the use of the two portals (Not started)

What was accomplished under these goals?

Specific Aim 1: Populate the RARE registry with datasets that accurately represent the racial and ethnic distribution of Acral Melanoma (AM) patients in the US.

Major Task 1: Finalize the RARE registry platform, develop patient recruitment materials, and secure ethics approvals

Subtask 1: Finalize registrational set of survey questions, treatment and quality of life profiles for participant reported data with vendor:

- Set of 8 surveys collecting: 1) general patient characteristics and demographics; 2) disease history; 3) inherited genetics and tumor biomarkers; 4) disease monitoring; 5) overall health and lifestyle; 6) quality of life (QOL); and 7) treatment overview; and 8) treatment timeline have been finalized by a patient and medical advisory committee. They have been uploaded

in the RARE registry web portal open-source platform (from a dedicated private cloud operating in a HIPAA-compliant hosting center) provided by our vendor, Ordinal Data. This enabled our first “soft launch” of the RARE registry in October 2022 and a more widespread launch in May 2023 during Melanoma Awareness month.

Subtask 2: Finalize case report forms to collect abstracted clinical and genomic information with Oversight Committee medical advisors; finalize Standard Operating Procedures (SOPs) to abstract clinical data from medical reports.

- Clinical and genomic data to be abstracted have been identified with input from the Oversight Committee of medical advisors and will be confirmed with them at a RARE medical advisory committee meeting scheduled in the late Q3/early Q4 timeframe of 2023.
- A cloud-based HIPAA compliant management platform has been identified to store the abstracted information. We are working on SOPs to abstract clinical data from medical reports. This has been slightly delayed and set as a lower priority due to the limited number of medical reports that have been uploaded onto participant dashboards. To increase the number, email reminders are sent to encourage RARE registry participants to complete surveys and upload medical reports. A demonstration of how to upload medical reports was part of our first RARE webinar targeted to participants and the general public held on August 23, 2023. This webinar is now publicly available enduring material on the MRA YouTube channel.

Subtask 3: Develop general patient recruitment materials including press release, patient stories/blogs, postcards, 1-page summary, Frequently Asked Questions and social media posts

- General recruitment material has been developed and IRB approved.

Subtask 4: Finalize IRB/HRPO (OHRO) protocols and submit for review

- IRB approval of the RARE registry protocol/consent has been secured which includes 300 acral melanoma patients. This protocol covers collection of patient-reported and clinically abstracted data from acral, mucosal and cutaneous melanoma patients. The consent (now v3.0) was amended to address requested revisions from OHRO and approved by the North Star Review Board.
- After review of the IRB approved RARE Registry Protocol (v1.0) and consent (v3.0) the USAMRDC OHARO OHRO approved this no greater than minimal risk study for the enrollment of 300 subjects with acral melanoma to the registry.

Subtask 5: MRA staff complete HIPAA training and certification

- MRA staff having the ability to access identifiable data as RARE registry administrators have completed training in Human Subject Research.

Major Task 2: General Launch of Registry and Patient Recruitment

Subtask 1: Soft Launch: MRA will soft launch the Registry to our own internal networks of patients (e-mail list, online discussion community). Fix any bugs or correct system

- Soft launch of RARE Registry began in October 2022 to an internal network of patients. The ability to consent and complete surveys were found to be all intact.

Subtask 2: General Launch: Full marketing campaign for first 365 days – includes all marketing content (social media, press release, media tour, and blogs)

- Two RARE Registry patient advisors (and one medical advisor) were speakers during the 2023 Annual Patient Forum in March. This allowed them significant stage time to highlight the RARE Registry to the entire MRA patient community. This was followed with the initiation of a full marketing campaign in the Spring 2023 to support the broader launch of RARE prior to May’s melanoma awareness month. Additional marketing content includes the following:
 - MRA regularly shares information – at a minimum of three times per week – about the RARE Registry through its social media platforms. MRA reaches over 250,000 people each month through social media, the largest reach within the melanoma community.
 - The RARE Registry was integrated into all of MRA’s Melanoma Awareness months activations, including two community webinars, social media, and in-person events.
 - A landing page was added to the MRA website (www.curemelanoma.org) touting the RARE Registry. This allowed us to also integrate the registry into our existing Google Ad Grant which helps drive traffic to www.raremelanoma.org when Google users search for relevant keywords and phrases.
 - Story featuring the RARE registry entitled ‘*Supporting Equitable Cancer Research – Development of the RARE® Registry*’ on CDMRP website during National Black Family Cancer Awareness Week posted on June 13, 2023.
 - A press release announcing the RARE Registry and the enrollment of its first 100 participants was released on July 10, 2023. The statement was picked up by 389 outlets and has an estimated reach of 239 million people.
 - MRA’s Chief Executive Officer, Dr. Marc Hurlbert and RARE Registry patient advisor Amy Jardon were interviewed by Today.com for an article about acral melanomas and the RARE Registry. The article was read by an estimated 20.4 million people.
 - Newly expanded informational pages for acral, mucosal, uveal, and cutaneous melanoma were added to the MRA website. Each page provides tailored information about each subtype and includes information about the RARE Registry.
 - On August 23, 2023 MRA held the first RARE Registry Quarterly Update for registry participants and the greater community to share de-identified information about registry participants, overview new features, and outline our future plans.

Subtask 3: Translate consent and all marketing material into Spanish (MRA will assume costs of translation)

- Initially we felt that translations of the consent, surveys, and marketing material would suffice to do outreach to the Hispanic community in the US. Through discussions with clinicians and our medical advisory board we now feel a better approach is to translate the entire public facing rare registry website, e-consent, and participant dashboards including surveys, educational information and visualization tools to see emerging data. Our platform will provide an easy English/Spanish switch between the two languages. Our goal is to use a Google Translate tool for a broad and quick translation into Spanish. With MRA assuming the costs, we will then hire a medical student, fellow, or clinician fluent in Spanish to fine tune the translation and ensure that it is correct and makes sense medically. Even though this

is delaying the timeline for completion we feel an entire RARE website and dashboard in Spanish will recruit and engage more of the Hispanic community in the RARE registry in the long run as well as be useful when we do outreach to Spanish-speaking countries. This comprehensive translation approach is critical to reach one of the major goals of this study -- populate the RARE registry with datasets that accurately represent the racial and ethnic distribution of acral melanoma patients in the US.

Major Task 3: Geo-Targeted Patient Recruitment

Progress towards **Subtasks 1 and 2** include working with specific state cancer registries for distribution of RARE information to acral melanoma patients and outreach to several major cancer centers in targeted geographies:

- At the MRA annual Retreat, networking roundtables are held on different topics and Retreat attendees can participate in a subject area of their choice. At the 2023 Retreat earlier this year, the RARE registry was the most well attended networking roundtable out of 19 different topic choices. At this networking roundtable, over 20 researchers, clinicians and patient advocates gathered and discussed the status of the RARE registry and any challenges being encountered. At this roundtable the MRA learned that cancer and clinical community centers would require their own IRB approval to be able to distribute information on RARE to their patients and would not be able to use the material approved by North Star Review Board. This was recognized as a major challenge as it slowed down the process of working with institutions to disseminate RARE information. To overcome this challenge, we are working with a few of our sites to gain insight on types of informational material that would lead to a rapid approval from their institutional IRBs. We will work with our marketing contractor to create this outreach material especially targeting specific AM patient populations very quickly for submission to institutional IRBs.
- We have started outreach to providers for underserved acral melanoma patient populations to identify the collateral needs of the partner sites. We are currently focused in the New York area working with Montefiore Hospital in the Bronx and Weill Cornell Medicine in Manhattan. Discussions with the lead dermatologist and melanoma medical oncologist at Montefiore revealed 80% of their melanoma patients are either African American or Hispanic and they see a substantial number of acral melanoma patients each year. Weill Cornell Medicine has satellite hospitals in Queens and Brooklyn which include a more diverse population of acral melanoma patients. Strategies on the best way to engage the different patient populations including in person working groups are being discussed with the medical personnel at the two New York Hospitals and will be fleshed out more in the fall of 2023.

Subtask 3: Analyze the first 50 registered participants for gender, geographic, and racial/ethnic diversity. Adjust targeted marketing plan as needed.

- Currently there are 35 registered acral melanoma participants in RARE. We anticipate the number of patients to increase as our patient advocates help us do more advertising through social media through their Facebook group and our first webinar on RARE held in August becomes more disseminated. Analyzed data from the first set of acral melanoma RARE participants demonstrate that:
 - The gender distribution is 58% female and 42% male.

- Participants are from 12 US states and from 3 additional English-speaking countries.
- The racial distribution is 99% Caucasian.
- The majority have been diagnosed with acral melanoma on the soles of their feet.
- The majority were diagnosed with regional disease (melanoma at the primary site that has spread to nearby skin and lymph nodes).
- The top three common symptoms were bleeding, non-healing wounds and ulceration.

Major Task 4: Ongoing Participant engagement

Subtask 1: Assist participants in completing surveys started but not completed; ensure smooth patient experience; answer questions, track and resolve complaints and technical issues

- We created a system through the registry platform to email participants reminders to finish any surveys that have not been completed and begin ones that have not been started. These emails also include a reminder to upload medical reports. Through our dedicated RARE registry email (rare@curemelanoma.org) which is tracked daily during the work week we have answered questions from our participants. There have been no complaints or technical issues from participants to report.

Subtask 2: Participant engagement via ongoing data insights, 2 patient webinars on rare melanoma, 2 *Ask the Expert* segments, and 1 session at MRA annual Patient Forum

- As mentioned above two RARE Registry patient advisors (and one medical advisor) were speakers during the 2023 Annual Patient Forum in March. This allowed them significant stage time to highlight the RARE Registry to the entire MRA patient community. Two webinars on rare melanoma were held during Melanoma Awareness month in May and the first RARE Registry Quarterly Update for registry participants and the greater community to share de-identified information about registry participants, overview new features, and outline our future plans was held in August.
- We also added two features on the participant dashboard (homepage) that we expect will help participant engagement. The first is ‘Data Insights which graphically show cumulative emerging data from the RARE registry based on responses from participants. We started with 4 different insight pages including data from the demographics and diagnosis journey surveys and one page on responses to questions specific for acral melanoma and the other for mucosal melanoma. The second feature is called ‘How I Compare’ which will allow participants to see how their responses compare to the total responses for a given question. By returning de-identified data to participants, we are ensuring that participants feel that they are actively involved in generating valuable data for researchers to use and help advance discoveries in the field for acral and mucosal melanoma patients. The MRA views the RARE registry as a partnership between participants and the research community.

Subtask 3: Ongoing monitoring and engagement of Melanoma>Exchange acral community

- MRA’s Melanoma>Exchange is an online community and message board dedicated to those touched by melanoma. The community has grown to nearly 7,500 members and is a dedicated space for members to ask questions and discuss all things melanoma related.

Within the umbrella of the Melanoma>Exchange are various sub-categories where specific topics can be discussed – including acral melanoma. Acral community topics in the Melanoma>Exchange are being monitored and addressed on an ongoing basis. From monitoring the Melanoma>Exchange, we can use trends that we observe to help inform us on the types of resources/information our community would benefit from.

Subtask 4: Participant consent to release of medical records; abstract clinical and genomic information into registry case report forms

- We are working on amending the current protocol/consent to include participant consent to release medical records. We are also starting some pilot studies to determine the best way to abstract clinical and genomic information from medical records. In addition, we are contacting companies that perform these services.

Specific Aim 2: Build a clinically annotated biospecimen repository of samples from AM RARE participants and distribute tissues to researchers in return for derivative ‘omics data to be included in the cBio Cancer Genomics Portal (cBioPortal).

Major Task 1: Develop RARE melanoma biorepository

Subtask 1: Identify vendor to serve as the centralized biobank repository of patient samples with a Laboratory Management System (LIMS) to track the receipt, processing and distribution of samples; Finalize the contract.

- Through an RFP process, we have identified the partner to serve as the RARE melanoma biorepository. This partner is an academic site that has a large skin cancer biorepository mainly from melanoma patients with several hundred samples from rare melanomas including acral melanoma. Therefore, this site has extensive experience in processing of melanoma tumor samples into different derivatives, storage of the samples and distribution of the samples to outside laboratories. SOPs are already in place for receipt, storage and distribution of samples with a customized LIMS system hosted on a HIPAA compliant server to track sample and clinical information. They have a strong research program in rare melanomas and also support the importance of sharing samples and reagents within the broader research community, the latter being a driving force in creating the RARE biorepository. In July of this year, we did a site visit and met with the site PI for this project and the site’s grants and contracts contact person and we should be close to finalizing the contract shortly.

Subtask 2: Develop all SOPs for receiving, processing and distributing tissue samples

- The majority of SOPs have been established and are already in use for the existing skin cancer biorepository. We have hired a consultant (MRA separate funds) to consent patients to release their samples and arrange to have samples shipped to the biorepository. This consultant is highly experienced in performing these tasks and has worked with 4 other foundations on biorepository projects. Now that the consultancy contract has been signed we will be working together on the consenting process and developing additional SOPs to support receipt of samples from outside sites and labs.

Subtask 3: Test LIMS to ensure all samples can be tracked appropriately

- After the contract is finalized we will work on a pilot project with ‘fake’ shipments from other locations to ensure that samples can be tracked appropriately. In addition, we are creating a minimal clinical data set to be associated with the samples. Either MRA will have direct access to the site’s LIMS to enter the clinical data or a dedicated person at the site will enter this data. This is to ensure that the samples are clinically annotated in the LIMS so that they can be easily identified for tissue use requests.

Major Task 2: Assemble and structure RARE Melanoma Tissue Disbursement Committee

Subtask 1: Obtain input from Oversight Committee concerning members and governance of this committee; reach out to suggested members and form committee

Subtask 2: Set priorities and standards for acceptable tissue use research proposals with Tissue Disbursement Committee

Subtask 3: Finalize the terms of a data sharing agreement for return of research results from investigators who have access to samples

- North Star Review Board recommended that a separate protocol/consent be developed for the RARE Biorepository. Therefore, we are working with our recently identified consultant (described in Specific Aim 2/Major Task 1/Subtask 2) to write this protocol and consent. Based on the consultant’s expertise this should expedite the submission to the IRB. Once IRB approved this will require submission to OHRO for approval. Therefore, we have shifted our priorities from working on the Tissue Disbursement Committee tasks to developing the new biorepository protocol/consent, the latter being a more immediate need.

Specific Aim 3: Create RARE data portals that allow the dissemination of integrated participant-reported, clinical, and ‘omics analyses to the research community in a reasonable timeframe.

Major Task 1: Create the RARE Melanoma Research Portal

Subtask 1: Program the link of patient/participant reported data (PRD) from the RARE registry to corresponding clinical and genomic data abstracted from medical reports in an accessible portal

Subtask 2: Test the validity of the portal with the first 15 patients who have consented to the release of medical reports to ensure that the link of PRD and additional clinical data is working correctly

- There have not been enough medical reports uploaded to begin abstraction of clinical and genomic data and to set up the link between participant-reported and clinical/genomic data. We are sending out email reminders to upload medical reports and have demonstrations through our recent RARE webinar on how this can be done.

What opportunities for training and professional development has the project provided?

Dr. Rachel Fischer, post-doctoral fellow on this project, has received training in understanding the development and management of a direct to patient registry and in the development of an IRB protocol. In addition, Rachel has mentored two post-baccalaureate interns: Isabel Ryan, BS and Nicolas Starink, BS, MPH. Rachel, Isabel and Nico have participated in professional development through the Health Research Alliance and its ongoing peer ‘Registry and Biobank’ working group semi-annual meetings. This professional development has allowed for refinement of the MRA Rare Melanoma Registry and will be key in opening the RARE Biorepository (Specific Aim 2 of the proposal). Rachel attended ASCO (June 2022 and 2023) with MRA senior scientific and leadership team and had the opportunity to engage with several industry partners interested in the Rare Registry. Rachel will represent MRA and present a poster on the RARE registry at the upcoming Society for Melanoma Research International Congress (November 2023). Now that Isabel is no longer at the MRA, Nico and another intern, Viren Sehgal attend weekly science team meetings and weekly full staff meetings. As a part of each of their respective internship projects, each made a formal presentation to MRA all staff about their internship projects and progress made – both related to rare melanomas. Nico has been critical in operational aspects of the registry and analyzing data collected in response to survey answers. He has played an essential role in developing the new participant dashboard features, Data Insights and How I Compare. He is currently training Viren to assist in data analysis.

How were the results disseminated to communities of interest?

We have used a variety of marketing and outreach approaches to broadly disseminate information on the RARE Registry and initial emerging data. Details of these approaches are listed in Specific Aim 1/Major Task 2/Subtask 2

What do you plan to do during the next reporting period to accomplish the goals?

In the next reporting period we will prioritize the following activities to enhance geotargeting patient recruitment, ability to abstract clinical data and opening the RARE Biorepository:

- Translation of entire RARE website, participant dashboard, surveys and all related material into Spanish
- Development of marketing and educational material representing a diverse patient population that could be quickly IRB approved at different sites and distributed to patients. In addition to NYC sites, connect with 2-3 additional sites in other states that see a diverse patient population
- Amend RARE protocol to enable access to medical records. Identify most efficient way to abstract and store clinical data
- Finalize and receive IRB and OHRO approval of new Biorepository protocol and consent. Finalize contract with Biorepository site and have systems in place for a functioning biorepository

4. IMPACT:

What was the impact on the development of the principal discipline(s) of the project?

Nothing to report

What was the impact on other disciplines?

Nothing to report

What was the impact on technology transfer?

Nothing to report

What was the impact on society beyond science and technology?

Nothing to report

5. CHANGES/PROBLEMS:

Change in approach and reasons for change

Nothing to report.

Actual or anticipated problems or delays and actions or plans to resolve them

One major problem encountered is the need to secure IRB approval from each site that will be distributing information about RARE to their patients. We are working with several sites and our medical advisors to better understand the requirements for a more expedited IRB approval of information. Once we have a better understanding we will quickly have our marketing company develop the appropriate material for institutions to submit for IRB approval. We truly believe that enrollment will be enhanced when doctors and their staff can discuss and distribute information on RARE to their patients. We are also identifying appropriate community and foundation events that will allow distribution of our current IRB approved material.

Changes that had a significant impact on expenditures

Nothing to report

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Significant changes in use or care of human subjects

Nothing to report during this period.

Significant changes in use or care of vertebrate animals- N/A

Significant changes in use of biohazards and/or select agents

N/A

6. PRODUCTS:

- **Publications, conference papers, and presentations**

Journal publications.

Nothing to report

Books or other non-periodical, one-time publications.

Nothing to report

Other publications, conference papers and presentations.

Poster presentation at the Society for Melanoma Research International Congress in November, 2023:

Updates from RARE: A Registry for Patients with Acral and Mucosal Melanoma

Rachel A. Fischer¹, Nicholas Starink¹, Viren S. Sehgal¹, Cody Barnett¹, Maryam M. Asgari², Marc S. Hurlbert¹, Joan Levy¹

¹Melanoma Research Alliance, Washington, DC, United States; ²University of Colorado Anschutz School of Medicine, Aurora, CO, United State

Appendix A: Entire abstract (to be published just prior to meeting)

- **Website(s) or other Internet site(s)**

<https://www.youtube.com/watch?v=rYliX2nQZ1s>:

The first **RARE Registry Quarterly Webinar Update** for registry participants and the greater community to share de-identified information about registry participants, overview new features, and outline our future plans.

- **Technologies or techniques**

Nothing to report

- **Inventions, patent applications, and/or licenses**

Nothing to report

- **Other Products**

Nothing to report

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Site 1: Melanoma Research Alliance

Name: Joan Levy, Ph.D.

Project Role: PI

Research Identifier: N/A

Nearest person month worked: 2.0

Contribution to the project: Dr. Levy has drafted and submitted protocol/consent to IRB and OHRO, provided guidance to the build of the RARE Registry platform and related features and led the efforts to identify a vendor/partner for the RARE Biorepository

Funding Support: MRA general funds and this award (no funds yet drawn down from CDMRP).

Name: Rachel Fischer, Ph.D.

Project role: Post-Doctoral Fellow

ORCID ID: 0000-0003-4123-800X

Nearest person month worked: 2.0

Contribution to Project: Dr. Fischer led project meetings to build the RARE Registry data portal and manages the operation of the RARE registry and project team meetings.

Funding support: MRA general funds and this award (no funds yet drawn down from CDMRP).

What individuals have worked on the project? (cont.)

Site 1: Melanoma Research Alliance

Name: Isabel Ryan, B.S.

Project role: Science Intern

ORCID ID: none

Nearest person month worked: 1.0

Contribution to Project: Ms. Ryan helped upload the IRB approved surveys into the RARE Registry platform

Funding Support: MRA general funds.

Name: Nicolas Starink, B.S., M.P.H.

Project role: Science Intern

ORCID ID: none

Nearest person month worked: 1.0

Contribution to Project: Mr. Starink helped with operational aspects of the registry, setting up the participant dashboard to include new features to engage participants and analyzing emerging data

Funding Support: MRA general funds.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to report

What other organizations were involved as partners?

Nothing to report

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS:

QUAD CHARTS:

9. APPENDICES:

Appendix A: Abstract accepted for poster presentation at Society for Melanoma Research 20th International Congress

Appendix A: Society for Melanoma Research (SMR) Abstract

Accepted for poster presentation at the SMR 20th International Congress
(Not yet published)

Authors:

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Title:

Updates from RARE: A Registry for Patients with Acral and Mucosal Melanoma

Roughly 90% of melanomas form on sun-exposed skin, while rare subtypes—such as acral and mucosal melanoma—form on parts of the body shielded from the sun. Each year, about 5,000 patients in the US are diagnosed with these subtypes. Patients facing rare melanoma subtypes are often diagnosed later and have poorer prognoses. In Oct. 2022, the Melanoma Research Alliance launched RARE, the first direct-to-patient registry for those with acral (AM) and mucosal melanoma (MM), as well as non-acral cutaneous melanoma as a comparator arm. Through RARE, participants complete surveys on topics including demographics, disease and treatment history, genetics & biomarker testing, health & lifestyle, and QoL. Participants can also upload medical reports that are used to validate participant reported data and provide additional clinical information.

Since launch, over 100 participants have enrolled in RARE. Of this cohort:

- 72.4% report a history with MM and 25% with AM; <1% cutaneous
- 69.1% are female and 30.1% male;
- 92.5% of participants report working indoors; and
- 96.2% have earned at least a high school diploma or equivalent.

Most participants (84.4%) said they were the first to identify signs or symptoms of their melanoma, while 7.8% and 5.2% of participants' doctors and family members, respectively, were first to do so. Initial insight into patient disease history showed that 52.6% and 62.5% of AM and MM patients had regional disease upon diagnosis. For participants with AM, the most common sites for primary lesion were the sole of foot (52.6%) and toenails (36.8%). For participants with MM, the most common site for the primary lesion was located in vagina/vulva (33.2%), anus (28.6%) nasal (21.4%), and sinus cavity (16.6%). Participants were first diagnosed by clinicians with a range of specialties, including surgery (19.3%), dermatology (17%), oncology (15.9%), and OB/Gyn surgery (11.4%). Over half of all participants, with both subtypes, felt their diagnosis was not made in a timely manner.

The RARE Registry gives patients with acral, mucosal, and cutaneous melanoma the opportunity to partner with researchers to address critical unanswered questions about acral and mucosal melanoma.

The registry is actively recruiting and data will be regularly analyzed and reported.