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2021 ANNUAL REPORT





7,000

**DISTINCT RARE DISEASES
EXIST TODAY**



**1 in 10
AMERICANS
30 million
IN USA**

400 million

**GLOBALLY ARE AFFECTED
BY RARE DISEASE**



**RARE DISEASES
IMPACT MORE
PEOPLE THAN
CANCER & AIDS
COMBINED**



65%

**OF RARE DISEASES ARE
ASSOCIATED WITH A
REDUCED LIFESPAN**



95%

**OF ALL RARE DISEASES DO
NOT HAVE A SINGLE FDA
APPROVED DRUG
TREATMENT**

Data courtesy of Global Genes

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THANK YOU ALL PARTICIPANTS IN OUR STUDIES!



During our historic VCP Scientific Conference in September 2021, numerous presentations from pre-clinical researchers were presented on the functional understanding of VCP. During one of the last presentations, one of the researchers commented, "perhaps we shouldn't be talking about all the things that VCP does, but rather what VCP doesn't do?" Everyone laughed, but the comment smacked me in the face of how little is still understood about what the valosin-containing protein regulates and facilitates within our bodies and how to best address our disease gene mutation.

As a patient myself, I understand the urgency for speed in research. Our goal at Cure VCP Disease remains to let the scientists do their work, and be available to encourage and provide resources to optimize their work. We hosted the VCP Scientific Conference for this exact reason, to

encourage the sharing of knowledge about VCP and collaboration among the research community. We are driving collaborations between institutions and industry as well as pressing scientific studies faster.

Nowhere was that more evident than our groundbreaking VCP Natural History Study with Nationwide Children's Hospital in Columbus, Ohio. Once the contract was signed, in less than one month, we were up and running with patients enrolled and traveling to Columbus. We have already entered the sixth month measurement period for that study and though the study has another six months to go, we are already learning unique things about the progression of VCP disease.

We didn't stop there though! A big topic in the rare disease community is sensitivity of measures in clinical trials. We would hate to see a therapeutic work, but not be able to measure the effectiveness in a rapid enough timeframe. That is why we have partnered with Casimir, a company started by concerned parents of Duchenne Muscular Dystrophy patients. With their leadership, we have started a second study that will run in parallel with the Nationwide Study to learn even more about the progression of VCP disease as well as compare and contrast the measures' outcomes and observations between the two studies.

We were also excited that our successful work was recognized by the Chan Zuckerberg Institute's Rare As One Project. In November, it was announced that we would receive a funding grant of \$600,000, over a 3-year period to support Cure VCP Disease in the advancement of an international, patient-led collaborative research network in VCP disease. We are excited for big things in 2022!

With Hope,



Nathan Peck



Lindsay Alfano, PI at Nationwide with Nathan Peck

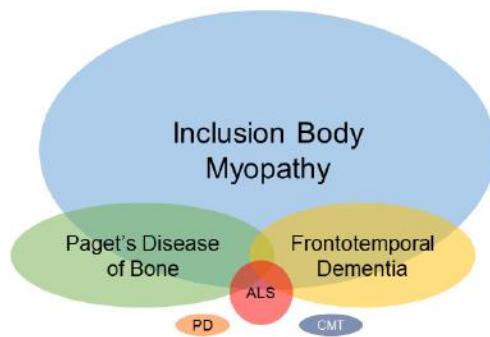


Meeting for dinner with University of California, Irvine research team

ABOUT CURE VCP DISEASE

This annual report aims to share some of our significant accomplishments for Cure VCP Disease in 2021. During a continued global pandemic, we have had an active and productive year towards driving collaborative research, increasing patient identification, and providing educational opportunities for the VCP disease community.

ABOUT VCP DISEASE



ALS - amyotrophic lateral sclerosis
CMT - Charcot-Marie-Tooth disease
PD - Parkinson's disease

VCP (Valosin containing protein, p97 gene) disease is a rare genetic mutation affecting 500-2,000 patients globally. Also known as IBMPFD and MSP1, the disease is autosomal dominant (meaning that a patient has a 50% chance of passing to offspring), adult-onset and can affect any combination of a patient's muscular, nervous and skeletal systems. Symptoms usually present in a patient's late 30's to early 40's. The disease is fatal and no treatments exist for the muscular and nervous system diseases.

CURE VCP DISEASE MISSION (EST. 2018)

Cure VCP Disease, Inc. was formed in 2018 to cure diseases related to valosin-containing protein (VCP) associated multisystem proteinopathy (MSP), also known as IBMPFD (Inclusion Body Myopathy, Early Onset Paget's Disease of Bone and Frontotemporal Dementia). The disease can affect any combination of a patient's muscles, bones, and brain. The specific objectives of our organization are to:

- provide global education and awareness of VCP disease;
- develop and maintain a global patient registry of VCP disease patients;
- develop and maintain a fundraising vehicle;
- collaborate with other global organizations and groups;
- sponsor, fund, host and participate in events and activities that promote efforts to advance treatments and cures for VCP disease.

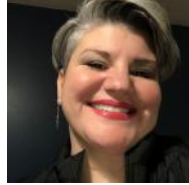
We are entirely volunteer-led and count on patients, care partners, family, friends, and the generous time of scientists and researchers to advance our mission.

Board of Directors



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Nathan Peck
Americus, Georgia



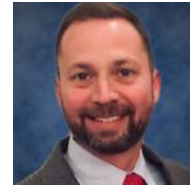
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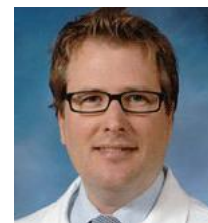
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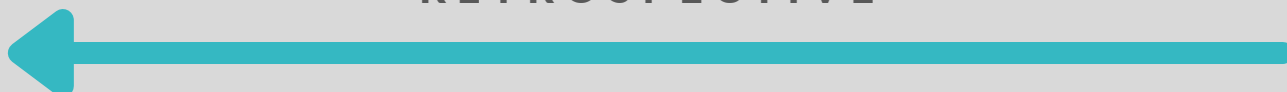
WHY PARTICIPATE IN NATURAL HISTORY STUDIES?



Having a way to measure the effectiveness of future drugs is essential for future drug development. Natural history studies facilitate better disease understanding and develop a pathway for a cure.

TYPES OF NATURAL HISTORY STUDIES

RETROSPECTIVE



Retrospective studies look backwards at patients' medical histories.



Patients' medical record collection

- Free to patients
- Free to researchers

PROSPECTIVE



Prospective studies aim to understand the progression of the disease and are normally conducted over a period of 12 to 36 months.



Annual patient reported outcome measures

- Started in 2018
- Global
- Free to patients
- Free to researchers



Muscular outcome measures

- Using validated measures
- 12-month study
- In-clinic & remote
- Global
- Free to patients



Muscular outcome measures

- 12-month study
- Remote only
- USA only
- Free to patients



ENROLLED VCP DISEASE PATIENTS

47

ELIGIBLE COUNTRIES



ABOUT ALLSTRIPES

AllStripes is a healthcare technology company dedicated to unlocking new treatments for people with rare diseases. AllStripes has developed a technology platform that generates regulatory-ready evidence to accelerate rare disease research and drug development, as well as a patient application that empowers patients and families to securely participate in treatment research online and benefit from their own medical data.

In 2021, AllStripes became a Public Benefit Corporation (PBC), with a stated purpose to drive forward research for the rare disease community and create technology to break down research silos. A PBC is a company that weighs social good in its business decision-making.

AllStripes Demographic Reports

VCP Demographics

Summer 2021

45 research activated patients

Data is from the AllStripes VCP research cohort of 45. This information is self-reported, including diagnosis.

Sex & age

Male 45% (20)
Female 56% (25)

56% are female

Of the 45 VCP patients, 56% or 25 patients are female.

The VCP cohort spans a wide age range (~39 to >70 years) with the most patients falling in the 60-64 years old range. The median age is 55 years and the mean age is 54.7 years.

Race & ethnicity

78% White (35)
71% Non-Hispanic (42)

The VCP cohort is composed of mostly white and non-hispanic patients.

Regional distribution

98% from the U.S.

79% in metropolitan regions

Most (98%) of the VCP cohort resides in the United States. These patients are distributed throughout the U.S. with the greatest presence in the Midwest. Throughout the U.S., the cohort predominantly resides in metropolitan areas of more than 50,000 residents (79%).

AllStripes would like to thank **Cure VCP Disease, Inc.** for their partnership in growing this research community. AllStripes would also like to thank the patients, families and caregivers who have generously contributed data.

Questions? If you have questions about VCP cohort analysis, please reach out to the AllStripes Research Team at research@allstripes.com.

Investigating IBM and VCP Patient Characteristics in Rural and Urban areas using the AllStripes Research Real-World Data Platform

Nelson Pace, SM, PhD, Charlene Fernandez, BS, Nancy Yu, BA, BS, Kristina Cotter, MS, PhD, CGC
AllStripes Research, San Francisco, CA. partner@allstripes.com

Introduction

Patients with rare diseases face multiple barriers to care, including availability of developed therapies and distance to care for clinical specialists and clinical trials. Real-world data (RWD), i.e. data collected outside of clinical trial research, can be used to understand patient population characteristics and geographic distributions. RWD may help enable equitable care and provide research opportunities. We used a RWD platform to explore key demographic and geographic characteristics of patients from two rare indications: inclusion body myositis (IBM) and mutations of the sodium-coupling protein gene known as VCP. IBM is a rare condition that causes muscle weakness and degeneration in certain areas of the body. VCP disease, which primarily manifests as Inclusion Body Myopathy associated with Paget disease of bone and Frontotemporal Dementia (IBMPFD), is a genetic condition that can affect the muscles, bones, brain, and nerves.

Here, we demonstrate that a rare disease RWD platform can be used to investigate the distribution of patients in the United States across rural and urban areas.

Methods

Figure 1: AllStripes RWD Platform Workflow

Figure 2: IBM and VCP Geographic Distribution

This work was performed in compliance with HIPAA-Capacitated Genes (WGS) (IBM). A broad, umbrella consent was developed to allow for the identified data from medical records to be used in natural history research.

Results

One hundred eighteen IBM patients and 45 VCP patients had consented to provide data to the AllStripes Research platform. Among IBM patients, 80% were male and 34% female, and 48% of VCP patients were male and 55% female. The median age of diagnosis was 53 years for IBM (range 25-83) and 51 years for VCP (range 20-72).

Figure 2: IBM and VCP Geographic Distribution

Across the U.S., 16, 25, 22, and 34% of IBM patients reside in the Northeast, South, Midwest, and West regions of the United States, respectively. 1, 25, 31, and 23% of VCP patients reside in the Northeast, South, Midwest, and West regions, respectively. The majority of IBM and VCP patients resided in urban areas. Of the IBM patients, only 10% (n=18) live in rural areas. Similarly, of the VCP patients, only 20% (n=9) live in a rural area. This is similar to the national trend among all U.S. residents where 19.3% live in rural areas. Among IBM patients, urban residence was associated with younger age at diagnosis (p=0.032), but this was not observed among VCP patients (p=0.956).

Conclusions

To our knowledge this is the first study to investigate the distribution of IBM and VCP patients in the United States across rural and urban areas. Most patients lived in urban areas and are distributed proportionally and similarly to the general United States population. While the majority of patients live in urban areas, most rare disease patients tend to live long distances from clinical trial sites, as has been shown in prior research. This suggests that opportunities to participate in clinical trials may be limited for rare disease patients. RWD offers the opportunity to identify patient geography and care patterns to aid in understanding how to optimize rare disease patient care.

Future work will use the AllStripes RWD platform to explore access to care and research across additional rare diseases in our research portfolio. As our platform also allows for abstraction and structuring of data from medical records to inform natural history, treatment outcomes, and healthcare utilization studies, future work will also explore other factors related to time of diagnosis.

Limitations

Due to the nature of IBM and VCP, this study was limited to a small sample size. Convenience sampling method was used via patients signing up on the AllStripes Research platform and should not be considered a representative sample of all IBM and VCP patients. This study focuses on patient location at the time of sign up in the same or their location at time of diagnosis.

Acknowledgements

AllStripes would like to thank the Myositis Support and Understanding and Cure VCP Disease, Inc. for assistance in recruitment. AllStripes would also like to thank the patients who have generously contributed data to make this study possible.

MSU Myositis Support and Understanding
CURE VCP DISEASE, INC.

To view posters, go to: <https://www.curevcp.org/allstripes> and scroll down to posters



NATIONWIDE CHILDREN'S HOSPITAL NATURAL HISTORY STUDY - IN-CLINIC & REMOTE

PROJECT GOAL

To study diagnosed VCP patients and understand the type and rate of degradation over a 12-month period. Evaluate if conducting measures remotely shows any a statistical difference than by conducting measures in-clinic.

Patient advocacy collaboration in a remote natural history study for valosin-containing protein (VCP) associated multisystem proteinopathy (MSP)

Nathan Peck¹, Sujata Patel¹, Allison Peck³,
Maureen Hart¹, Lindsay Alfano²
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²Nationwide Children's Hospital, USA



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MOTIVATION: Prospective longitudinal natural history is urgently needed to establish clinical trial readiness for the ultra-rare VCP disease population.

AIM 1: Define the natural history of VCP disease

AIM 2: Validate data collected via remote versus in-person clinic methods.

AIM 3: Identify any divergent disease trajectories

METHODS

1. Partnered with Alfano Lab at Nationwide Children's Hospital to design and conduct functional measures study
2. Conducted phase 1 study with 5 diverse patients using tele-health methods
3. Integrated learnings and patient feedback into phase 2 protocol design

PATIENT ADVOCACY ROLE

1. Provided patient perspective in study design
2. Advertised study in the patient community
3. Assembled remote patient kits to standardize equipment for measurement
4. Provided patient prep and technology training meeting for remote study
5. Provided study funding and travel stipends to participants for travel to Columbus, OH

SPRING 2021 RESULTS

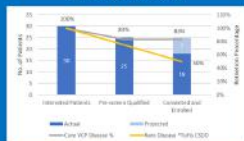
- Patient recruitment began at IRB approval
- Baseline remote & in-clinic visits launched 3 weeks from start
- Exceeded patient enrollment goal at 8 weeks
- Exploring expansion of study using remote only

Successful collaboration between researchers and patient advocacy results in:

1. Effective Study Design
2. Integrated Patient Perspectives
3. Efficient Patient Recruitment and Study Startup

For remote & in-clinic natural history study of rare disease

PATIENT RECRUITMENT



PATIENT ENROLLMENT DETAILS (as of May 28, 2021)

No. of Patients	Further Enrollment Details
18	Consented and enrolled
7	Consent meeting scheduled
1	Pending scheduling
2	Not interested or didn't qualify
2	Unable to travel

STUDY DESIGN & MILESTONES



PHASE 1
AUG 2020 – NOV 2020

- Design – 2 months
- Study visits – 1 month
- Analysis – 1 month

PHASE 2: Design
DEC 2020 – MAR 2021

- Contract and IRB approval – 3 months

PHASE 2: Launch & Enrollment
MAR 2021 – MAY 2021

- First five patients pre-qualified – 1 week
- First patient baselined – 3 weeks
- Enrollment goal reached – 8 weeks
- All baseline visits to be completed by July or August

Phenotypes of VCP associated multisystem proteinopathy (MSP)



Study Measures

UPPER EXTREMITY:

- Performance of Upper Limb 2.0 (PUL)
- Hand Grip Dynamometry
- Nine-Hole Peg Test
- ACTIVE WSV (in-clinic only)

LOWER EXTREMITY:

- North Star Assessment for limb-girdle type dystrophies (NSAD)
- Timed Up & Go (TUG)
- 100-meter walk (in-clinic only)
- 4-stair climb (in-clinic only)

SPIROMETRY:

- Forced Vital Capacity (FVC)
- Forced Expiratory Volume in 1 sec (FEV1)
- MIP/MEP (in-clinic only)

PATIENT REPORTED OUTCOMES:

- IBM-FRS
- Rasch Overall ALS Disability Scale (ROADS)
- PROMIS assessments
- Global Impression of disease severity
- Communicative Participation Item Bank
- Speech Handicap Index
- EAT-10



Poster presented at Global Genes Rare Drug Development Symposium and NORD Rare Diseases and Orphan Products Breakthrough Summit. To zoom poster, go to:
<https://bit.ly/2021naturalhistoryposter>

OUTCOMES

- Cure VCP Disease is providing travel stipends to help participants with travel to Columbus, Ohio for the in-clinic study.
- We have now opened the study to remote only VCP patients to encourage higher participation.
- Results will be published within 12 months upon the conclusion of the study in July 2022.

FINANCIALS

TOTAL PROJECT COST FOR 35 PATIENTS

\$165,000

**FOR 12 MONTHS
(PROJECT STARTED IN MAR 2021)**

CASIMIR HOME-BASED STUDY - VCP VIDEO ASSESSMENT



PROJECT GOAL

To determine whether a VCP Video Assessment (VVA) would detect noticeable patient change over a shorter period of time than other proposed outcomes. In other words: is there a concrete advantage to pursuing this approach for trial design? This data could also be valuable for other rare diseases.

PROJECT DESIGN

Cure VCP Disease has contracted with Casimir (<https://casimirtrials.com/>) to perform a novel study to assess disease progression over time using video assessments with up to 25 VCP patients. Patients will submit videos of how they do everyday activities, like taking off a shirt or standing up from a couch. The advantage to this approach is that patients can be assessed from the comfort of their own home, and these customized measures may be more sensitive to distinct changes than other performance measures commonly used in clinical trials. A certified rater will assess each video using a customized multiple point scorecard. The VVA will take place at four time points; baseline, week 1, month 6 and month 12. Because no travel is involved to participate, burden to the patient is minimal and our home-bound patients can be included in future clinical trials. This project started in October 2021.

ABOUT CASIMIR



Casimir is a Contract Research Organization that develops novel outcomes for decentralized and hybrid trials in order to better understand disease progression and treatment benefit. Their creative protocols were vital in the approval of EXONDYS51, the first FDA-approved treatment for Duchenne Muscular Dystrophy. Because Casimir scorecards are more granular than what's quantified in traditional outcome measure scorecards, there is a possibility that more granular patient changes could be missed. Casimir designs and runs rigorous decentralized and hybrid studies designed to address the needs of regulators, payers, and patients.

FINANCIALS

TOTAL PROJECT COST FOR 25 PATIENTS

\$76,425

FOR 12 MONTHS (PROJECT STARTED IN OCT 2021)

The burden of VCP disease is severe, and there are no approved treatments for VCP disease. VCP disease is a slowly progressing disease with the typical patient losing the ability to walk 5-10 years after diagnosis. VCP disease may affect a person's muscles, nerves, bones, and brain, but the disease will present differently between patients. For these reasons, it is unknown if measured change could be detected in one year with existing validated measures for other diseases (such as ALS, inclusion body myositis, limb-girdle muscular dystrophy scales).

PROJECT GOAL

To establish a multidisciplinary care guidelines to educate the VCP clinical and patient communities for appropriate pharmacotherapies and supportive therapies. Benefits also include expediting time-to-accurate diagnosis as well as improving the quality of care for patients.

Development of a standard of care for patients with valosin-containing protein (VCP) associated multisystem proteinopathy (MSP)

Mandira Kanti, Allison Peck, Lindsay B. Allred, Sarah E. Berges, Meredith K. James, Nupur Ghoshal, Euse Hualar, Claire Hendrick, Shaobu Khan, Pradeep P. Mammen, Sujata Patel, Gerald Pfeffer, Stuart F. Rankin, Shikhar Ray, Bill Seewald, Andrew Swenson, Tahseen Musaffar, Corral West, Virginia Kromida, on behalf of the VCP Standards of Care Working Group

Development of a standard of care for patients with valosin-containing protein (VCP) associated multisystem proteinopathy (MSP)

www.curevcp.org
@Allison38600974
allison-peck-vcp

AIM 1: Establishing a multidisciplinary standard of care for appropriate pharmacotherapies and supportive therapies

AIM 2: Expediting time to accurate diagnosis
AIM 3: Identify gaps and future directions for clinical research

METHODS

1. Recruited a multidisciplinary team of 50 physicians and therapists
2. Domain teams reviewed literature, exchanged ideas, and prepared a domain consensus recommendation based on expert opinion and adjacent disease practices
3. A virtual consortium meeting was held on April 9, 2021
4. Meeting discussion points integrating into one manuscript with team member sign-off

PATIENT ADVOCACY ROLE

1. Provided patient perspective in project scope
2. Recruited expert clinicians to participate
3. Organized communications, facilitated discussions, and hosted meetings
4. Assisted in literature review
5. Reviewed and edited the manuscript concerning patient perspective and symptoms

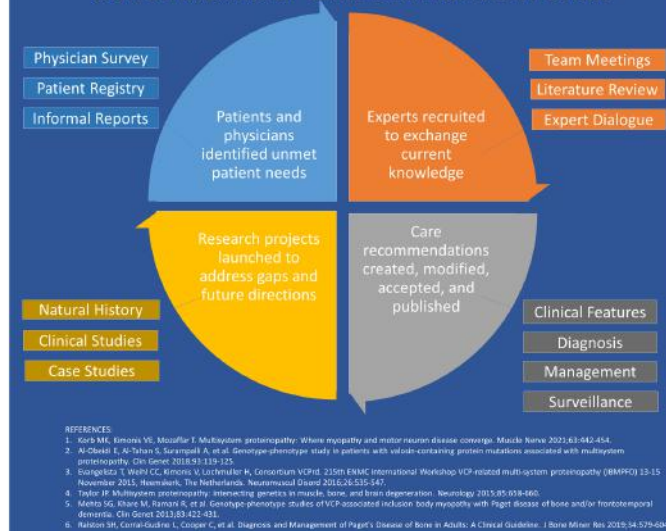
RESULTS

- Each domain team created a 2-5 page consensus guideline
- One multidisciplinary manuscript has been submitted for publication

Successful collaboration between patient advocacy and researchers for standard of care addresses unmet patient need in rare disease:

1. Delays in diagnosis and prolonged time to treatment
2. Delays in recognizing involvement of other organ systems
3. Disparate care between clinics
4. Disease development in at risk, undiagnosed family members

OUR STANDARD OF CARE DEVELOPMENT CYCLE



ABOUT VCP ASSOCIATED MSP

Rare, heterogeneous, autosomal dominant, genetic disorder affecting multiple organ systems including the muscular, skeletal, and central nervous system

PREVALENCE OF PHENOTYPES

- Inclusion Body Myopathy ~ 90%
- Paget's disease of Bone ~ 40%
- Frontotemporal dementia ~ 30%
- Respiratory dysfunction ~ 40-50%
- Amyotrophic lateral sclerosis ~10%
- Parkinson disease ~ 4%
- Alzheimer disease ~ 2%
- Spastic paraplegia ~ isolated
- Charcot Marie Tooth disease ~ isolated
- Cardiomyopathy ~ unknown
- Urinary and anal dysfunction ~ unknown

MULTIDISCIPLINARY DOMAIN TEAMS

- Genetic diagnosis
- Myopathy
- Frontotemporal dementia
- Paget's disease of bone
- ALS and CMT
- Parkinson's disease/ parkinsonism
- Cardiomyopathy
- Respiratory dysfunction
- Supportive therapies (including physical and occupational therapy, speech language pathology)
- Mental health
- Supplements and nutrition



Poster presented at NORD Rare Diseases and Orphan Products Breakthrough Summit. To zoom poster, go to: <https://bit.ly/SOCVCPPoster>

PARTICIPATING CLINICIANS

50+

PARTICIPATING COUNTRIES

7

DOMAINS ADDRESSED

10

CLINICIANS VOLUNTEERED THEIR TIME

TIME

OUTCOMES

A manuscript has been submitted to a medical journal that will reach a global medical audience. Next steps include the development of a summary patient guide that patients can provide to their doctor to increase awareness of VCP disease, expedite diagnosis, and foster better understanding of the type of care VCP disease patients require.



The VCP Scientific Conference was an international virtual meeting held on September 9-10, 2021. This multidisciplinary and collaborative conference created a forum for experts and trainees to share scientific knowledge and discuss future research directions. Hosted by Cure VCP Disease, this conference was the first VCP focused scientific meeting since the European Neuromuscular Commission (ENMC) meeting in 2015.



OBJECTIVES:

- Share scientific findings
- Develop young investigators
- Discuss research strategies
- Identify gaps and barriers so that therapies may be developed for VCP patients

To view all conference videos, go to: <https://bit.ly/2021vcpconferencevideos>

REGISTERED PARTICIPANTS

157

POSTER PRESENTERS

28

COUNTRIES REPRESENTED

9

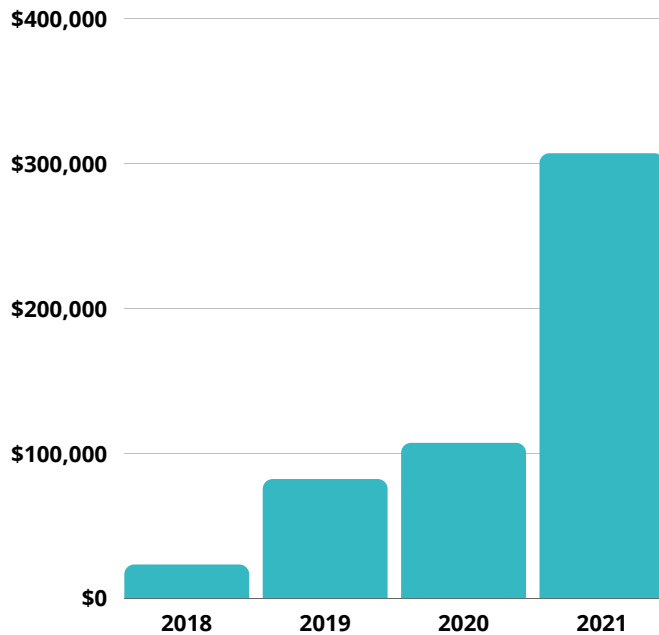
SPEAKERS

26

OUTCOMES

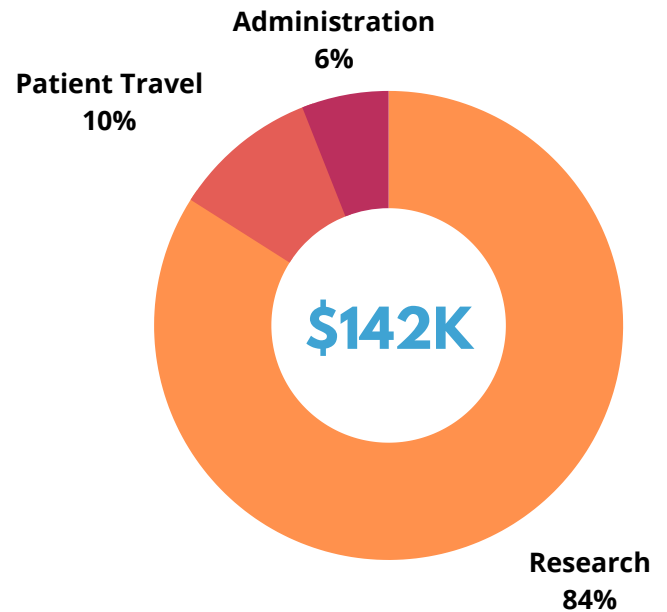
In early 2022, a summary of the VCP Scientific Conference will be published for global scientific review. This will increase awareness of VCP disease and grow engagement and involvement. Cure VCP Disease will restart monthly VCP Focus Group meetings with participants.

AMOUNT RAISED BY YEAR



2021 EXPENDITURES

Reporting as of December 21, 2021



2021 GRANTS RECEIVED

Chan
Zuckerberg
Initiative



\$200K

YEAR 1 FOR CAPACITY
BUILDING



\$5K

CONDUCTING COMMUNITY
EDUCATION OF RARE DISEASE
LEGISLATIVE EFFORTS



\$5K

COMMUNITY BUILDING

Monumental News: Cure VCP Disease was one of 20 patient-driven rare disease organizations (out of 200) selected to join the Rare As One Network. The funding grant of \$600,000, over a 3-year period, will support Cure VCP Disease in the advancement of an international, patient-led collaborative research network in VCP disease, strengthen organizational capacity, convene the community, and align patients and researchers towards shared priorities.

Read more at: <https://chanzuckerberg.com/newsroom/czi-awards-13-million-to-patient-led-organizations-advancing-rare-disease-research/>

ACCELERATING PROGRESS

TOGETHER WE CAN MAKE A DIFFERENCE

Accomplishments - 2021

