



## **Enrollment Workshop**

Dr Aaron Mangold  
Dr Prateek Gandiga  
Scott Jones

02 March, 2024

# We have made great progress with screening and enrollment

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## The path to reaching full study enrollment

- More than 70% of our active sites in Mexico, Chile, Argentina, United States and Canada have enrolled at least 1 patient, with quite a few of our sites enrolling 3 or more.
- We acknowledge the challenge in identifying eligible patients and want to offer two different approaches from our two high-enrolling sites on how to boost recruitment at your site over the upcoming weeks.
- We are excited to support your site enroll your final subjects as we near 100% enrollment in the next 2 to 3 months.

As of Feb 29, 2024	
Enrolled	155
In Screening	30
Scheduled for Screening	22
<b>Subtotal</b>	<b>207</b>

# Discussing two approaches to successful recruitment

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Two of our high-enrollers present their advice to identify eligible candidates

## Dr Aaron Mangold



Associate Professor, Dermatology  
Medical Director, Clinical Trials Office  
Mayo Clinic, Scottsdale, Arizona, USA

## Dr Prateek Gandiga



Associate Professor, Senior Physician  
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# VALOR DERMATOMYOSITIS PATIENT RECRUITMENT

BEST PRACTICES

**Aaron Mangold MD FAAD**  
Associate Professor of Dermatology  
Medical Director, Clinical Trials Office  
Associate Medical Director, Development  
Mayo Clinic Arizona

US Investigator Meeting  
Miami, FL



# OUR TEAM



**Brett Renner**  
Clinical Research  
Coordinator



**Samantha Zunich**  
Physician Assistant



**Samantha Devlin**  
Associate Clinical  
Research Coordinator



**Miranda Yousif**  
Research Fellow



**Shams Nassir**  
Research Fellow

# LEARNING OBJECTIVE

- Screening – an exhaustive search across the institution for potential patients
- Thoughtful approach to pt screening
- Continual re-review of patient databases

# WE TAKE A BROAD APPROACH TO IDENTIFYING PATIENTS

- DM patients are rare, and eligible patients even rarer
- A thorough, institution-wide database search will help to avoid missing potentially eligible patients – 1 or 2 patients makes a big difference!
- Perform an institution-wide review of DM patients
  - We use Mayo Data Explorer (MDE), a clinical database search tool to generate an initial list of potential subjects
  - Our team then performs further chart review to ensure subjects meet minimum criteria (age, BMI, diagnosis history, cancer diagnoses)
  - Clinicians review indeterminate cases
- Speak to patient's primary providers
  - Determine if patient would be a good fit culturally and clinically

# WE TAKE A BROAD APPROACH TO IDENTIFYING PATIENTS

## Mayo Data Explorer

### Broad Criteria

- Age 18-75
- BMI < 40
- DM diagnosis
- No active cancer

## CT Team

### Review list of pts for

- History of DM symptoms (skin and muscle)
- Other relevant diagnoses
- Current medications (is a washout needed?)

## Providers

### Discuss candidates

- Review current symptoms
- Discuss medication changes if necessary
- Would pt be a good fit?
- Initial outreach to gauge pt interest



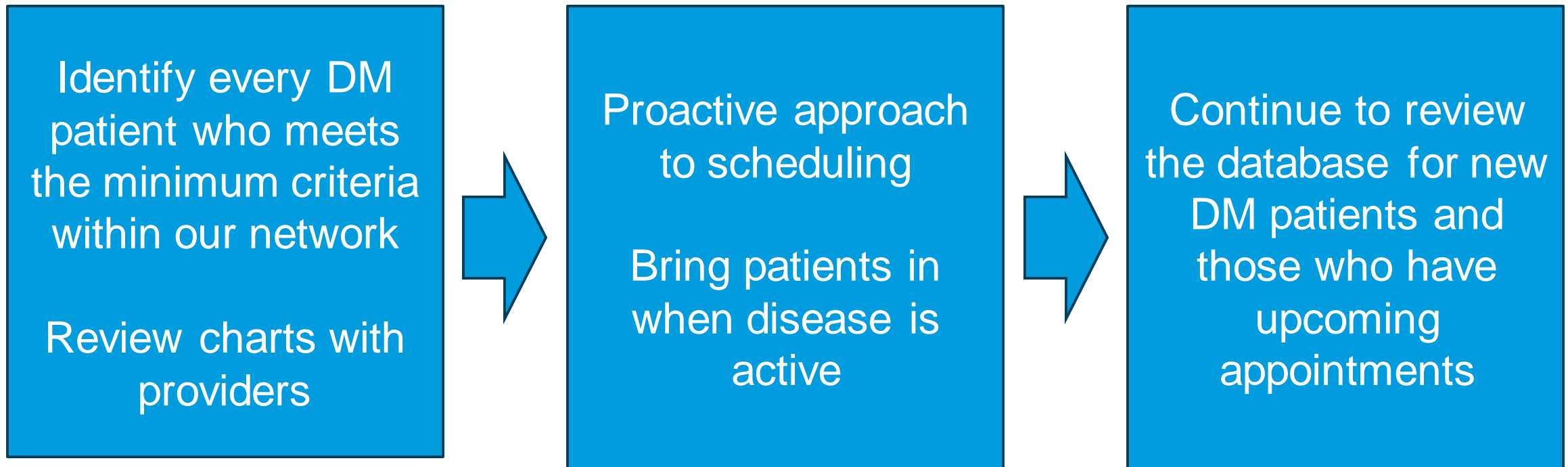
# SCHEDULING PATIENTS AS EARLY AS POSSIBLE

- Initial contact to be made by patient's provider
  - Educating the pt about the trial, and gauging their interest
- Once a patient is interested, CRCs utilize clinical/research slots
  - Encourage earlier appointments if patient's preference
- Dermatomyositis waxes and wanes
  - Critical to identify patients when their disease is eligible
  - Move quickly to assess their willingness to screen
  - Schedule screening (or pre-screening) appointments as early as patient and CT team are available

# REGULARLY REVIEW THE DATABASE FOR NEW PATIENTS

- After the initial database search, continue to review the DM patients who have upcoming appointments in the next 4-6 weeks
- New patients are added to the database regularly
  - We aim to identify these patients in advance of their next appointment
  - Discuss with the provider in advance of the pt's appt
  - CRC's on hand at ppt to answer any questions the provider or pt might have about the trial
  - If patient is interested – immediately schedule them for a screening
  - Review charts, assess eligibility across the core criteria, and reach out to potentially bring their next appointment in earlier

# WE AIM TO FIND EVERY ELIGIBLE PATIENT



# Dr Prateek Gandiga

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Associate Professor, Senior Physician  
Rheumatology, Emory University Myositis Clinic  
Atlanta, Georgia, USA

# What has helped us enroll patients

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- Finding patients within our local network
  - Passive advertising
  - Tracking potential future participants
  - Outreach to colleagues
    - Keep the message simple
  - Thank those who are helping
  - Working closely with fellows
- Expanding the search
  - Epic SlicerDicer
  - Chart reviews with CRCs
  - Using the Priovent resources to decrease the burden

# Marketing can help!



- Patients have time while waiting to see trial posters
- Goal is to catch attention
- Placed in our clinic, but also in other likely locations (eg, Dermatology, Pulmonology, etc)

# Prospecting

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- Mention clinical trial to patient at first meeting and intermittently at follow-ups
- Emphasize that it is one of our options without 'pushing'
- Bookmark patients that may benefit later

# Collaborate with colleagues

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And remember to keep it simple!

- Mention clinical trials to...
  - Colleagues in our Division
    - Mention updates during Grand Rounds and Faculty Meeting
    - Mention when we have clinics at the same time
    - Posters in the clinic's touchdown area
  - Colleagues outside of our Division
  - People who refer to me
  - When calling to coordinate about patients

The goal isn't necessarily to get into specifics, but remind them that we have trials that might benefit their DM patients

- Get the Fellows Excited
  - Learners want to be helpful
  - They travel to a LOT of different sites
  - Incentivize them to be excited
    - Feedback about why a patient might be a good fit
    - Peaching pearls
    - Opportunity to learn IMACS measures



# Getting an introduction

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- Patients are MUCH more open to discuss the trial if introduced by someone they already trust
- It can be challenging for a patient when the first contact about a trial is made by the SC/CRC with whom they have no pre-existing relationship
- Having the primary make the intro has made a HUGE difference in how receptive patients have been to considering the protocol and screening
- Believe in positive feedback (really believe in positive feedback)
  - Follow up with primary
  - Emphasize the things that they will value (ie patient benefits of protocol)

## Part 2: Expanding our search

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# What I see from my clinic list...



Epic Patient Lookup My Tools Clinical References SlicerDicer

### Patient Lists

Edit List Write Handoff Create Progress Note Orders

#### My Lists

▶ Anti-ZO ARS	
▶ ARS	42
▶ IBM and IBM OVERLAP	5
▶ IMNM (incl seroneg, SRP, HMGCR)	36
▶ JDM	6
▶ MDA-5	9
▶ Mi-2	4
▶ NXP-2	12
▶ OVERLAP Myositis	30
▶ RHABDO and OTHER myopathies	10
▶ SAE	
▶ SERONEG and MISC DM/PM	
▶ TIFF-g or CANCER-ASSOC	20

# ...vs what we see from a database search

Epic Patient Lookup My Tools Clinical References Remind Me Write Note Send Letter Call Patient Orders Only Refill

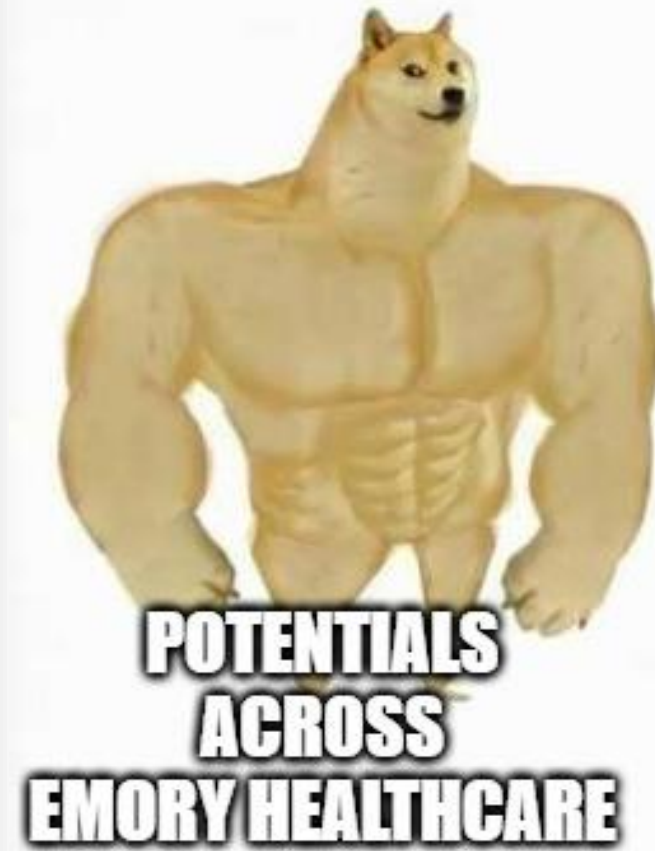
SlicerDicer X

Cogito SlicerDicer ergo sum

Number of Patients by Age in Years Range and Diagnosis... Last 6 months

	Number of Patients	
Aug 30, 2023 – Feb 29, 2024	545	
Age in Years 18 years or more an...	470	
Neoplasm	7	
C80 - malignant neoplasm	2	
Inclusion body myositis (IBM)( ICD-...	2	
Polymyositis or Juvenile	2	
Drug-induced myopathy( ICD-10-CM...	0	
None of the above	457	
BMI 14.0 or more and less than 40.0	325	

Load All

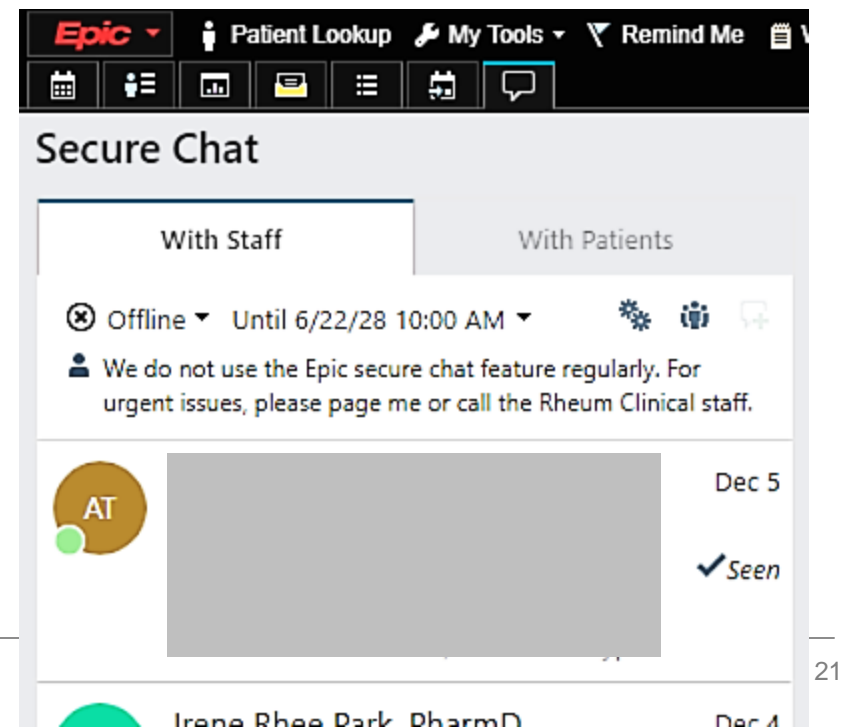
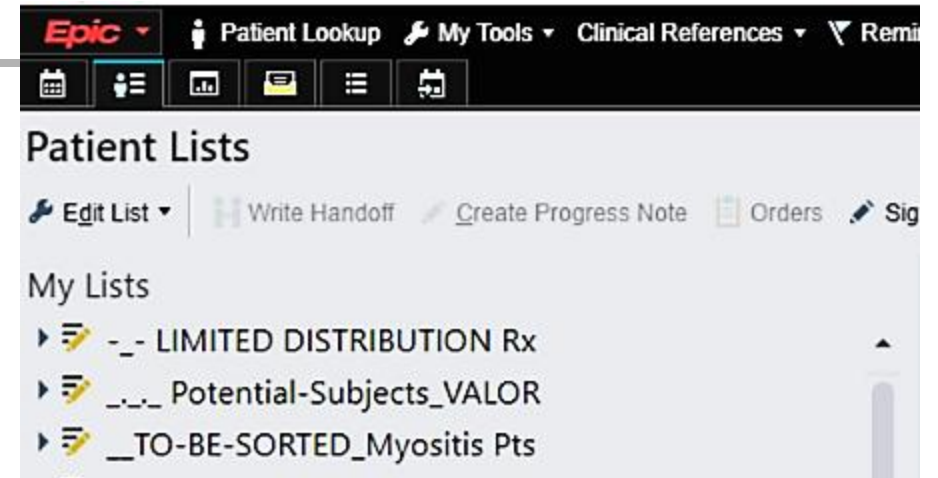


# Use your resources

## 1. Partnering with your partners

- Very quick pre-lim chart review
- Triage based on a few key features
  - Current medications
  - Medical history
  - Compliance
- Chart review at our weekly meetings
- Follow up with potentials

Bookmark patients in real-time



## Use your resources

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# Use your resources

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Ade Adeboye  
Medical Monitor



Scott Jones  
Director, Clinical Operations



Sabrina Pogrebivsky  
Manager, Clinical Operations

- Helped CRC do prelim screening, Slicer-Dicer, triaging potentials
- They REALLY know the protocol
- Often quicker to run a patient by them
- Sometimes identify a potential I wouldn't have thought of

# Use your resources

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Spoke to our local myositis chapter, followed up with interested patients in neutral way



**Taryn Smith**

Patient Evaluation Manager



# In summary

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- Passively and actively advertising
- Tracking potential future participants
- Reminding fellows, colleagues inside/outside division, collaborators
- Thanking those who are helping
- Simplifying
- Searching my list and searching EMR for people I don't see
- Using Priovent to decrease the burden

# Key features of successful recruitment strategies

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## Steps every site can take to boost recruitment at their site

1. Perform a thorough database search for patients at your institution
  - Simple criteria for Epic Slicer/Dicer or Internal Informatics search
    - Patients seen within last 2 years
    - Aged 18-75
    - BMI < 40 (or unspecified)
    - DM diagnosis (ICD.10 codes = M33.1, M33.9)
      - Exclude JDM
    - No active cancer diagnosis
  - Prioritize list based on visit date and review for:
    - History of skin and muscle disease
    - No hx of thrombosis, cancer within 5 yrs
    - Current medications, provider, symptoms
  - Discussions with Priovant to help determine the most efficient path to screening and randomization
    - Each patient is dynamic and answers may be beyond the MR

# Key features of successful recruitment strategies

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## Steps every site can take to boost recruitment at their site

2. Look for patients who are 50-75% eligible
  - Many patients require some med stabilization/washout
  - Medical history can be discussed with the MM as the details matter on determining eligibility
  - There may be situations where discussions on complex patient cases with our medical monitor can help find an opportunity to enroll a patient who may otherwise fail an initial review
3. Be proactive about outreach – when possible, contact patients before their next appointment
  - Timeline from pt identification to screening can be anywhere from 2 weeks to 3 months
  - If pts are interested, they can be brought in earlier for pre-screening
4. To best prepare a patient for screening, it is best to align with pts' current providers to determine if they are a good candidate for the trial
5. We have seen higher positive response rates when a physician makes the initial outreach. Whenever possible, we recommend that the PI or provider is the first to contact a patient about the trial

The logo for Prioivant Therapeutics features the word "prioivant" in a dark blue, lowercase, sans-serif font. A stylized graphic of two blue spheres connected by a thin line is positioned over the "io" in "prioivant". Below the main text, the word "therapeutics" is written in a smaller, light blue, lowercase, sans-serif font, with each letter spaced out.

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therapeutics