

Unidos hablamos de...  
United, Let's talk about...

**United, Let's talk about....**  
Patient-Centered Asthma Studies

**Thursday, November 4, 2021**  
4:30 PM Eastern Time

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### Agenda

- Welcome and Introductions
- COVID-19 Update
- Patient-Centered Outcomes Research and the PREPARE Study
- What is Patient-Centered Outcomes Research
- Hear about patient experiences with research and why they became patient advisors



**Objectives:**

- Describe the impact asthma has on the Hispanic/Latino community
- Discuss the role that patients can play in advancing the treatment of asthma
- Identify ways you can engage in research

**Moderator**  
Tonya W. Inders,  
CEO and President  
Allergy & Asthma Network

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COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (JHU)

Last updated on 11/4/2021, 9:22 AM

	Total Cases	Total Deaths	Total Positive Cases Administered
<b>US</b>	<b>248,282,374</b>	<b>5,025,636</b>	<b>7,147,317,573</b>
<b>China</b>	<b>11,746,391</b>	<b>194,894</b>	<b>690,046,090</b>

**Deaths by Country/Region/Sovereignty**

Country/Region/Sovereignty	28 Day Count	28 Day Deaths	28 Day Positive Cases Administered
<b>US</b>	28 Day: 2,172,663   41,121	Total: 5,025,636   194,894	
<b>United Kingdom</b>	28 Day: 4,974,325   3,913	Total: 21,638,235   147,609	
<b>Russia</b>	28 Day: 945,441   28,777	Total: 1,821,121   23,714	
<b>Turkey</b>	28 Day: 793,171   15,925	Total: 1,811,101   71,284	
<b>Ukraine</b>	28 Day: 622,201   112,279	Total: 1,664,677   74,617	
<b>India</b>	28 Day: 432,211   19,796	Total: 6,321,838   149,652	
<b>Germany</b>			

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### Guest Speakers



**Elliot Israel, MD**  
Asthma Specialist  
Principal Investigator  
PREPARE Study



**Margie Lorenzi**  
Asthma Patient  
Research Patient  
Advisor/Partner



**Courtney Clyatt, MA**  
PCORI  
Senior Program Officer



**Alex Colón Moya**  
Asthma Patient  
Research Patient  
Advisor/Partner

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Patient Centered Outcomes  
Research (PCOR) and the  
PREPARE Study

Elliot Israel, MD  
Asthma Specialist  
Principal Investigator  
PREPARE Study

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Elliot.....

Why are you interested in studying asthma in the Hispanic/Latinx population?

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Polling Question #1

If you have **asthma**, how many times have you gone to an emergency room or urgent care for your asthma?

- 1) 0
- 2) 1
- 3) 2
- 4) 3
- 5) 4
- 6) 5 or more

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Polling Question #2

If you have **asthma**, how many times have you been hospitalized for your asthma in the past year?

- 1) 0
- 2) 1
- 3) 2
- 4) 3
- 5) 4
- 6) 5 or more

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**Polling Question #3**  
**Asthma Impact Question 1**

Asthma happens in Hispanic/Latinx at what rate compared to Caucasians?

- 1) The same
- 2) 35% higher
- 3) 50% higher
- 4) 100% higher

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**Polling Question #4**  
**Asthma Impact Question 2**

Hispanic/Latinx are how many times more likely to go to the emergency room or be hospitalized for asthma than Caucasians?

- 1) The same
- 2) 2 times
- 3) 5 times

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**Polling Questions #5**  
**Asthma Impact Question 3**

The death rate of Puerto Rican's with asthma compared to Caucasians:

- 1) No difference, both the same
- 2) 25% higher
- 3) 50% higher
- 4) 75-200%

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**BACKGROUND**

- Asthma prevalence is 100% higher in Hispanic/Latinx (H/L) and 35% higher in African American/Blacks (AA/B) than Caucasians
- Both H/Ls and AA/Bs have double the rates of asthma related emergency room visits and hospitalizations as Caucasians and 50% higher rates of re-hospitalization
- Puerto Rican's experience 75% - 200% higher death rate due to asthma as Caucasians
- This has been difficult to improve

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### Why do we do medical research?

- To understand a particular concern about human health such as what can be done to minimize asthma deaths in Hispanic/Latinx by
- Developing a scientific plan to:
  - Collect data/information
  - Analyze and figure out what the data mean
  - Distribute the findings to those who are impacted:
    - Patients
    - Communities
    - Healthcare providers
    - Healthcare policy makers
    - Payers

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### Polling Question #6

#### How much do you trust researchers?

- 1) A lot
- 2) A little
- 3) Not very much
- 4) Not at all

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### Different types of clinical research

- **Observational**
  - Nothing is changed, the researchers observe the effect of something the people have in common such as taking Vitamin E to see if there is an effect on heart disease
- **Experimental – Randomized Control Trial**
  - People are assigned to one or more groups by chance (by the roll of the dice)
    - One group receives an intervention such as Vitamin E and the others get a placebo (looks like a Vitamin E pill, but is not)

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### Which research type is better?

- Observational studies have biases that may give you the wrong answers

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### Vitamin E

- Many observational studies suggest that people who took Vitamin E had lower rates of heart disease

**BUT**

**people who take Vitamin E might be different than those who don't**

- Maybe they watch their diet more
- Maybe they exercise more
- Maybe they are more conscious about their health

Maybe there are other differences we don't understand as to why somebody may be a taker of Vitamin E

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### Randomized trial of Vitamin E

- Patients were assigned to Vitamin E or a fake pill by the flip of a coin
- NO benefit on heart disease

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### Different ways to help asthma research

- Being a research subject enrolling into a study or,
- Becoming a patient partner if you have asthma or care for someone with asthma – advising the researchers, becoming part of the team

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### Polling Question #7

Would you be willing to be a research subject in an asthma study?

- 1) Yes
- 2) No
- 3) Not sure
- 4) Depends on whether my doctor thought it was a good idea or not
- 5) Depends on whether my family thought it was a good idea or not

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PeRson EmPOwered Asthma Relief  
PREPARE study



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Background

- Adherence to daily inhaled corticosteroid (ICS) use is generally poor
- In controlled studies, empowering patients to use their ICS each time they use their Albuterol, **Patient-Activated Reliever-Triggered Inhaled CorticoSteroid (PARTICS)** reduces exacerbations by almost fifty percent as compared to daily use of ICS
  - Why? When a patient uses albuterol for an asthma attack s/he is opening airways in the lungs. We are asking to also use ICS which decreases inflammation in the lungs

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**PREPARE Research Question**

- Does **PARTICS** work in a real life (uncontrolled) research study? In patient populations that bear an increased burden of asthma (**Hispanic/Latinx (HIL) and African American/Black (AA/B)**) can instructing patients to use their ICS each time they use their rescue (Albuterol) improve outcomes of importance to patients, providers, and the health care system?

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Main outcome of interest

- **Exacerbations:** Asthma event with increased symptoms resulting in need for steroids (oral, shot or intravenous) or asthma related hospitalization.
  - Can a patient empowered strategy (PARTICS) decrease the number of exacerbations per year?

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### PREPARE research patient population

- 19 US sites
  - Primary care and asthma specialty clinics
- 1200 patients, 600 AA/B and 600 H/L
  - Adults 18-75
  - Uncontrolled asthma
- 300 AA/B, 300 H/L – Assigned to PARTICS
- 300 AA/B, 300H/L – Assigned to Usual Care

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### Research Patient follow up

- Patients are seen in person once, then followed for 15 months by monthly survey
- Last patient finished the study in April 2021 – analysis has begun to determine if PARTICS decreases the yearly number of exacerbations

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### PREPARE Study research team

- Typically research is conducted by trained researchers
- PREPARE is different: we include patient partners who work with the team

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### Why Involve Patients/Caregivers as advisors in Research

- Brings important views from people who will be impacted by the study results including what the research question should be
- Connects lived experience together with the research question
- Keeps research staff grounded
- Contributes to dissemination process & education of general public and/or relevant patient populations

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### PREPARE Patient Partner/advisor population

- H/L and AA/B Patient Partners/Advisors who are asthma patients or caregivers
  - 9 H/L – 3 Spanish speaking only
  - 7 AA/B
- Conference calls weekly at the beginning of the study – then at least once a month – continue 5 years later
  - Each month one in English and one in Spanish with the same information
- Involved in every aspect of our work
  - Study question, developing wording and education tools for patients

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### Changes made because of Patient Partner input

- Wording of instructions
- Shortened monthly survey (7-10 minutes)
- Giving patients a choice of how to answer the monthly survey: online, by phone interview or by mail
- Instructional videos depicting patients like them
- \$20 payment for each survey completed
- Patients who fill out surveys within 6 days of receiving a reminder are entered into a raffle to win one of 3 monthly \$150 prizes
- One click to answer the monthly survey

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### IMPACT

- Enrolled 598 H/L and 603 AA/B – sometimes difficult populations to enroll
- Consistent 90%+ survey return rate at 15 months – *this is very unusual*
- Low drop out rate – 17/1201
- 84% of the patients assigned to using ICS with Albuterol (PARTICS) report adhering to using ICS with Albuterol all or most of the time over 15 months

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### Polling Question #8

Would you be willing to be a patient partner/advisor for an asthma study?

- 1) Yes
- 2) No
- 3) Not sure
- 4) Depends on whether my doctor thought it was a good idea or not
- 5) Depends on whether my family thought it was a good idea or not

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Margie will share her story about her experience with asthma and research



Margie Lorenzi

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What Is PCOR?  
And How Can You Get Involved?



Courtney Clyatt  
Senior Program Officer

November 4, 2021



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Who PCORI Is and  
What We Do



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Patient-Centered Outcomes Research Institute (PCORI)




- An independent research institute authorized by Congress in 2010 and governed by a 21-member Board
- Funds comparative clinical effectiveness research (CER) that engages patients and other stakeholders throughout the research process
- Seeks answers to real-world questions about what works best for patients based on their circumstances and concerns
- Helps people make informed healthcare decisions, and improves healthcare delivery and outcomes, by producing and promoting high-integrity, evidence-based information

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**How Is Our Work Different?** pcori

- We focus on answering questions most important to patients and those who care for them.
- We aim to produce evidence that can be easily applied in real-world settings.
- We engage patients, caregivers, clinicians, insurers, employers, and other stakeholders throughout the research process.
- This makes it more likely we'll get the research questions right and the study results will be useful and taken up in practice.



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**What is different about PCOR**



Focuses on research topics, questions, and **outcomes most important to patients** and those who care for them.



Works closely with a **range of healthcare stakeholders**—including patients, caregivers, scientists, clinicians, health systems, and insurers—to guide our research funding.



Requires that **patients be engaged** in the research we fund, not as subjects but as partners who help determine what to study and how.

CSHPatWORK

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**Patient-Centered Outcomes Research (PCOR)** pcori

**PCOR is a relatively new form of CER that....**

- Considers patients' needs and preferences, and the outcomes most important to them
- Investigates what works, for whom, under what circumstances
- Helps patients and other healthcare stakeholders make better-informed decisions about health and healthcare options



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**Pays Particular Attention to** pcori

- Conditions that heavily burden patients, families, and/or the healthcare system
- Chronic or multiple conditions
- Rare and understudied conditions
- Conditions with varied outcomes across subpopulations



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### Engagement: Ensuring Patient/Stakeholder Partnership

pcori

- Patients and stakeholders from across the entire healthcare enterprise are actively and meaningfully involved in the entire research process—from the development of research priorities to the dissemination and uptake of research findings.
- Patients are treated as partners in research, not just subjects.
- To achieve critical goals:
  - To influence research to be patient-centered, relevant, and useful
  - To establish trust and a sense of legitimacy in research findings
  - To encourage successful uptake and use of research results



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### Eugene Washington PCORI Engagement Award Program

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- Support projects to build a community of patients and other stakeholders equipped to participate as partners in PCOR/CER, as well as serve as channels to disseminate PCORI-funded study results
- Funding to support engagement in, and with, research, not to conduct research

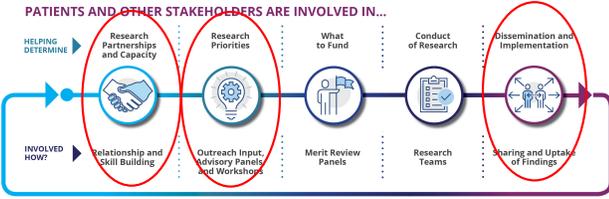


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### Engagement in Research

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PATIENTS AND OTHER STAKEHOLDERS ARE INVOLVED IN...



HELPING DETERMINE: Research Partnerships and Capacity

INVOLVED HOW?: Relationship and Skill Building

Research Priorities: Outreach Input, Advisory Panels and Workshops

What to Fund: Merit Review Panels

Conduct of Research: Research Teams

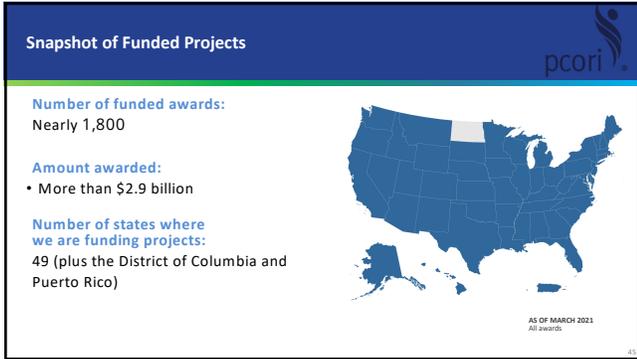
Dissemination and Implementation: Sharing and Uptake of Findings

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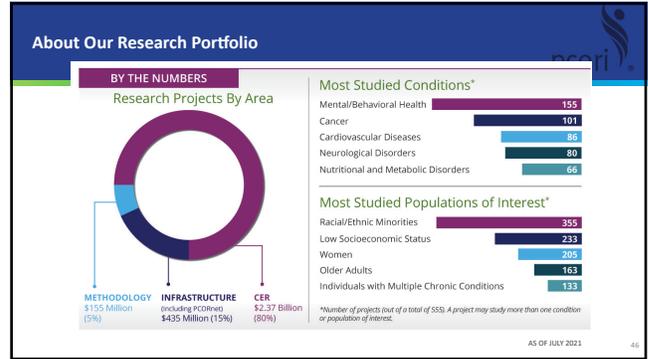
### Our Growing Research Portfolio



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### Questions that matter

**Research Addressing Questions That Matter**  
PCORI funds comparative clinical effectiveness research (CER) studies to help patients and those who care for them make better-informed decisions about their options for managing asthma.

**PATIENT**

My asthma is really bad. I'm supposed to use my inhaler every day, but I'm afraid of the side effects.

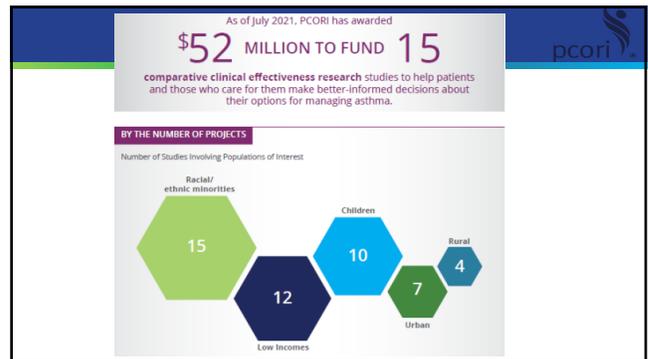
Would it work just as well if I take my medicine only when I have symptoms, rather than every day?

**HEALTH SYSTEM ADMINISTRATOR**

Our medical center treats a substantial number of patients who have asthma.

What are the most effective strategies or combinations of strategies we can use to help improve the lives of our patients?

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**How We Engage Stakeholders**

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**Opportunities to Get Involved**

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**PCORI Ambassador Center**

About The PCORI Ambassador Program  
Get Involved  
Resources  
Who Are PCORI's Ambassadors?  
Ambassador Center

**PCORI Ambassador Program**

**About the PCORI Ambassador Program**  
Learn what the Ambassador program is and how it supports PCORI's overall mission and vision.

**Get Involved**  
Complete the program interest form to get started. New Ambassadors can learn about ways to get involved.

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**Research Fundamentals Structure**

**Learning Need Navigation Tool**

**Interactive PDF**

**Video-Based Module**

**Five Interactive Learning Modules**

- Developing Research Questions
- Designing the Research Study
- Planning Patient-Centered Consent and Study Protocols
- Sampling, Recruiting, and Retaining Study Participants
- Understanding and Sharing Research Findings

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**Resources for Engagement Practice**

1. Provide **foundational knowledge in PCOR/CER to non-scientist participants** on research and other projects, and to patient and stakeholder merit reviewers, peer reviewers, and PCORI Ambassadors.
2. Provide **training and resources to support multi-stakeholder teams** in both the engagement of patient and stakeholder partners and effectively working together (i.e., team science).

**Self-paced** and focused on **just-in-time needs** throughout the PCOR process.

Patients   Researchers   Caregivers   Providers   Insurers

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**Find Out About Other Ways to Get Involved**

- PCORI Merit Review Process
  - <https://www.pcori.org/finding-opportunities/merit-review/merit-review-process>
- PCORI Advisory Panel Openings - <https://www.pcori.org/engagement/engage-us/pcoris-advisory-panels/advisory-panel-openings>
  - Health Disparities and Delivery Research
  - Patient Engagement
  - Clinical Trials
  - Rare Disease
  - Clinical Effectiveness and Decision Science
- PCORI Peer Review Process
  - <https://www.pcori.org/research-results/peer-review/peer-review-process>
- PCORI Engagement Tools and Resources Repository
  - <https://www.pcori.org/engagement/engagement-resources/Engagement-Tool-Resource-Repository>
- Subscribe to PCORI's Newsletter
  - <https://www.pcori.org/webform/subscribe>

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**Contact Information**

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**Alex has asthma and will share his experience as a research patient. Hear how and why he became a research patient advisor/partner.**

**Alex Colón Moya**  
Asthma Patient  
Research Patient Advisor/Partner

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### Question & Answer time with our panel






**Elliot Israel, MD**  
Asthma Specialist  
Principal Investigator  
PREPARE Study

**Margie Lorenzi**  
Asthma Patient  
Research Patient  
Advisor/Partner

**Courtney Clyatt, MA**  
PCORI  
Senior Program Officer

**Alex Colon Moya**  
Asthma Patient  
Research Patient  
Advisor/Partner

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### Thank you for attending!

- Join us next month, Dec. 2, 2021 – Let's keep the conversation going!
- Sign-up to receive our free AAN Research Newsletter
- Join our Asthma Registry – help make a difference in asthma research
- Get involved with AAN patient focus groups, ad boards, research studies
- Learn how you can become an AAN Patient Advisor
- Free Access AAN asthma and COVID-19 education materials
- Participate in one of our asthma studies!

contact  
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