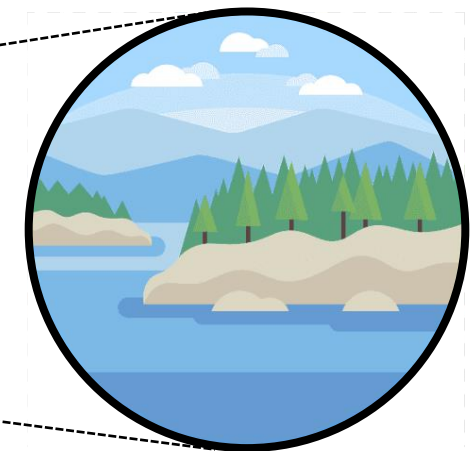


Diversity in Pediatric ^{and patient} Research: Academic [^] Perspective

Susan M. Abdel-Rahman, Pharm.D., M.A.

Chief Scientific Officer, Health Data Synthesis Institute



Disclosures

Active or Recently Concluded Consulting Activities:

- Abbott Laboratories
- Advantage Silver Dental Arrest, LLC
- World Health Organization
- Duke University/Pediatric Trials Network
- Indiana University/MPRINT Hub
- University of Arkansas for Medical Sciences
- Children's Mercy Hospital
- Pediatric Eye Disease Investigator Group
- Pediatric Praziquantel Consortium

Children on ‘*Clinical Trials*’

n=55 children 6 to 19 yr, 2-24 months post-study participation

Why did you participate in the study?

Help other children/advance science	41%
Compensation/incentives	31%
Thought it would be fun	13%
Try something completely different	11%

What was the best thing about being in the study?

It was fun/good experience	47%
Quality of care/interaction	15%
Compensation/incentives	14%
Helping other kids and/or science	11%
Food was good	8%

- ✓ *Express their altruism*
- ✓ *Experience novel opportunities*
- ✓ *Engage with the HC system in a different way*

Children on ‘*Diversity in Clinical Trials*’



Abby



Rhiannon



Ed



Kenneth



Imaan

Is it important that research includes a diverse group of children like you?

- ✓ *Equity*
- ✓ *Justice*
- ✓ *Inclusivity*

Children on ‘*Diversity in Clinical Trials*’



Abby



Rhiannon



Ed



Kenneth



Imaan

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- ✓ *Inclusivity*



Children on ‘*Diversity in Clinical Trials*’



Abby



Rhiannon



Ed



Kenneth



Imaan

What do you think of when you hear the term diversity?

- ✓ Age
- ✓ Race
- ✓ Gender
- ✓ Ethnicity
- ✓ Geography
- ✓ Culture
- ✓ Religion
- ✓ Education level
- ✓ Sexual orientation
- ✓ Co-morbidities
- ✓ Organ impairment
- ✓ Environment
- ✓ Socioeconomics
- ✓ Genetics

Relevance of the Academic Perspective

 U.S. National Library of Medicine

ClinicalTrials.gov

**Interventional, Phase I/II trials
Recruiting/Enrolling (0-17 yr)
Industry Funded (U.S.)
May 2023**

Studies	440
Sites	8770
Academia Term Count (duplicates removed)	6937 79%

Diversity Drivers in Academic-Led Pediatric Trials

One Hundred Third Congress
of the
United States of America

AT THE FIRST SESSION

*Begun and held at the City of Washington on Tuesday,
the fifth day of January, one thousand nine hundred and ninety-three*

An Act

To amend the Public Health Service Act to revise and extend the programs of the National Institutes of Health, and for other purposes.

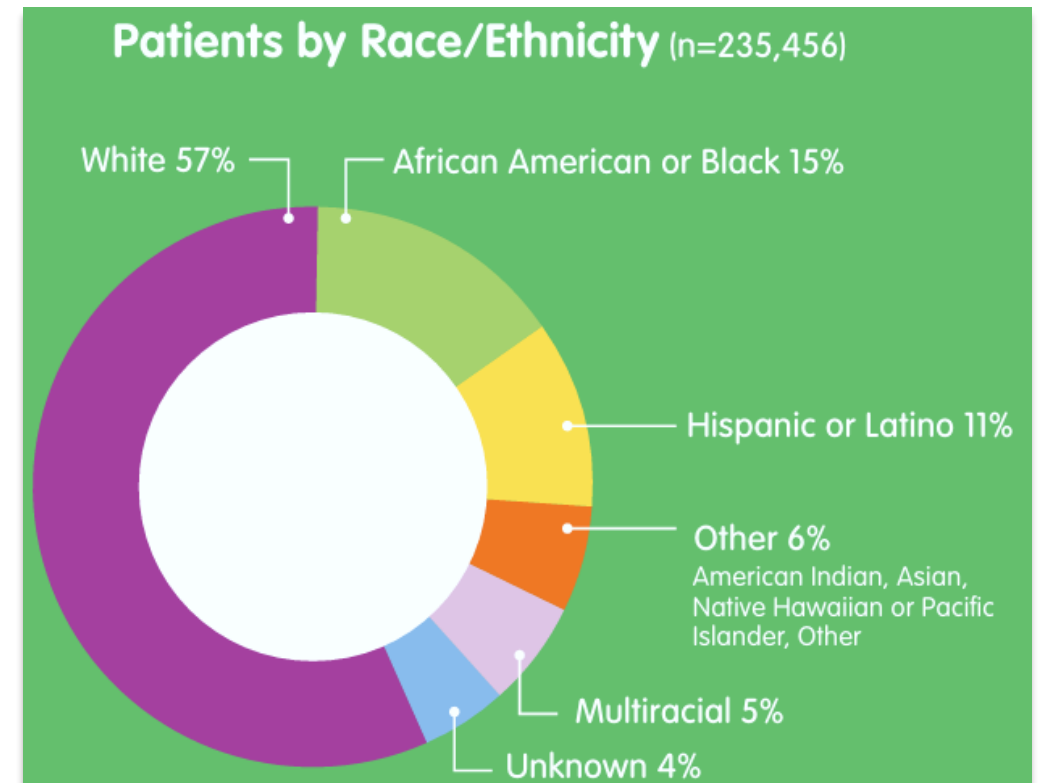
Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

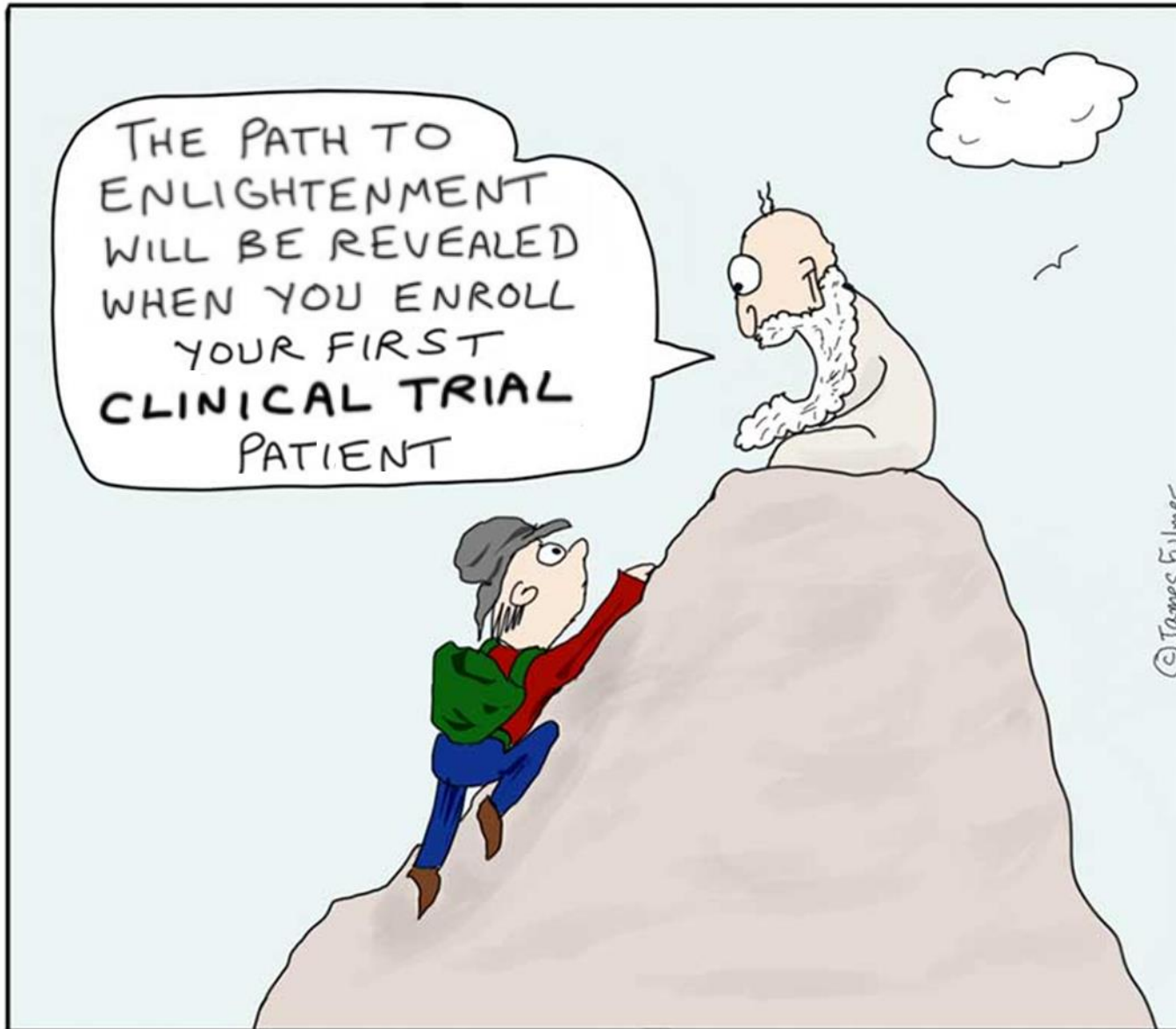
(a) SHORT TITLE.—This Act may be cited as the “National Institutes of Health Revitalization Act of 1993”.

The goal of NIH's inclusion policy is not to endorse or enforce quotas for proportional representation...

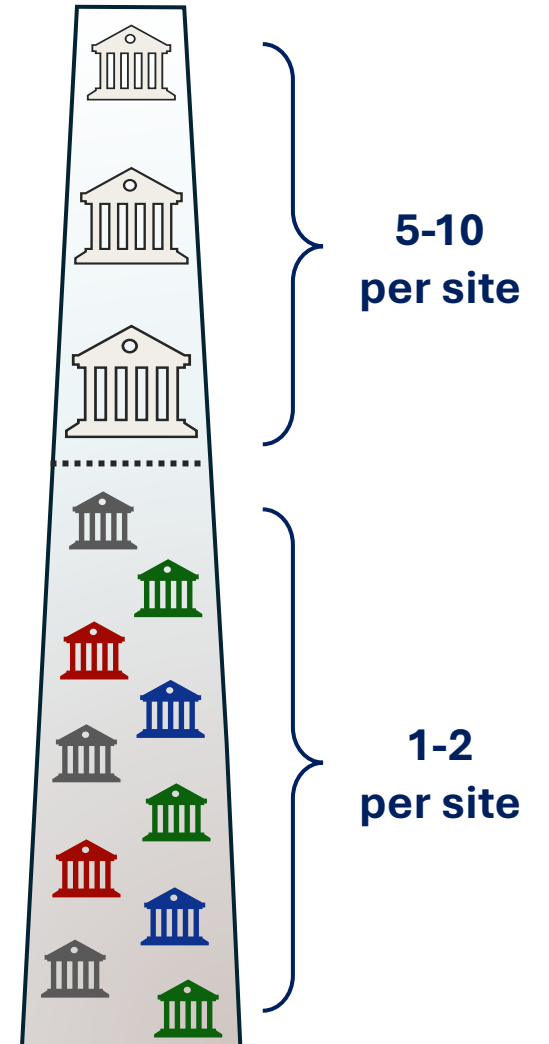
Diversity Drivers in Academic-Led Pediatric Trials



Diversity Drivers in Academic-Led Pediatric Trials



Enrollment Goal:




R/E Diversity in Academic-Led Pediatric Trials

ARTICLES | MAY 01 2021

PEDIATRICS[®]

OFFICIAL JOURNAL OF THE AMERICAN ACADEMY OF PEDIATRICS

Racial and Ethnic Diversity in Studies Funded Under the Best Pharmaceuticals for Children Act

Susan M. Abdel-Rahman, PharmD ; Ian M. Paul, MD, MSc; Chi Hornik, PharmD; Janice E. Sullivan, MD; Kelly Wade, MD, PhD; Paula Delmore, RN, MSN; Gaurav Sharma, PhD; Daniel K. Benjamin, MD, PhD, MPH; Kanecia O. Zimmerman, MD

n= 34 studies (2008 – 2020)

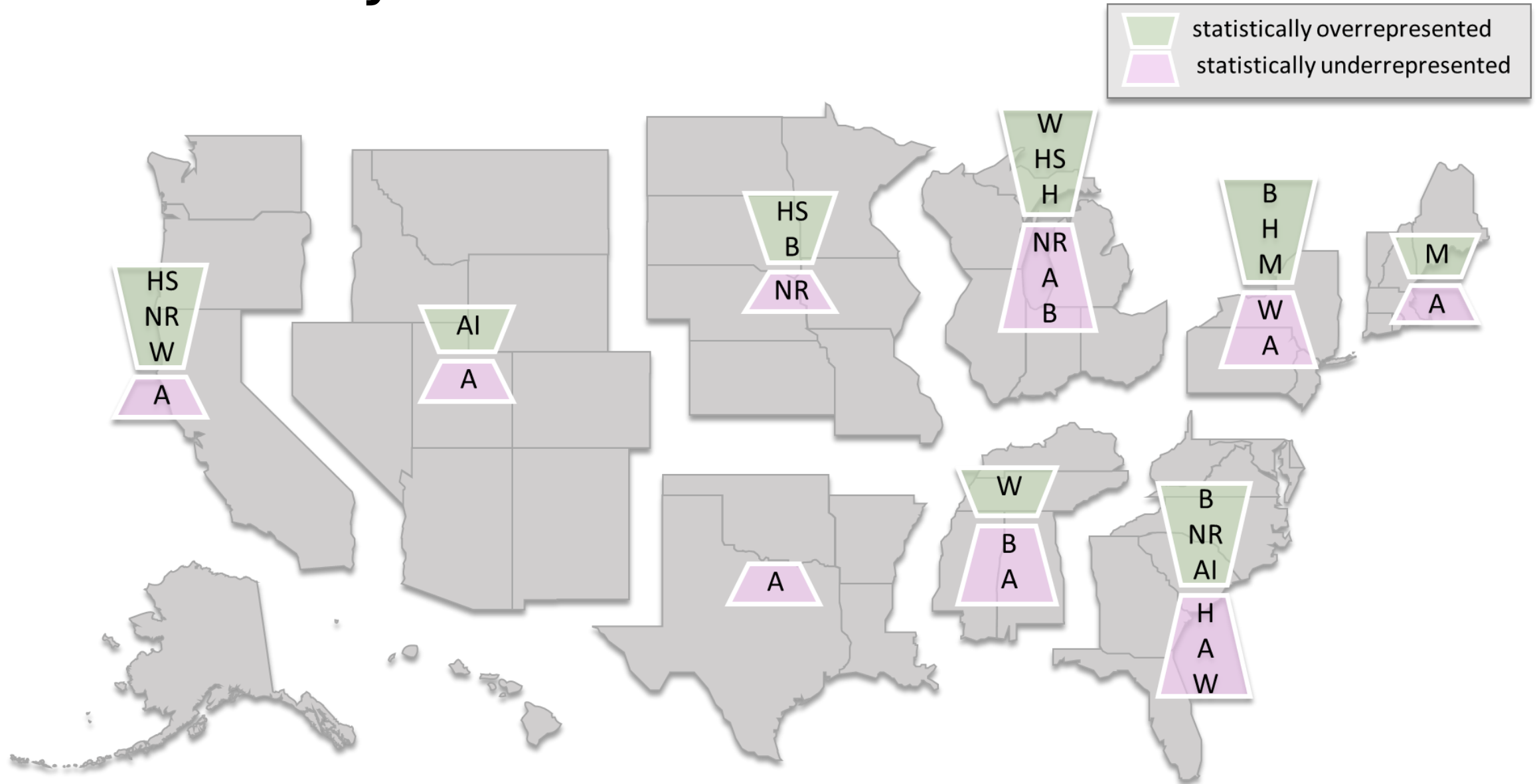
n=167 study sites

n= 10,918 participants,

n= 113 cities in 46 states

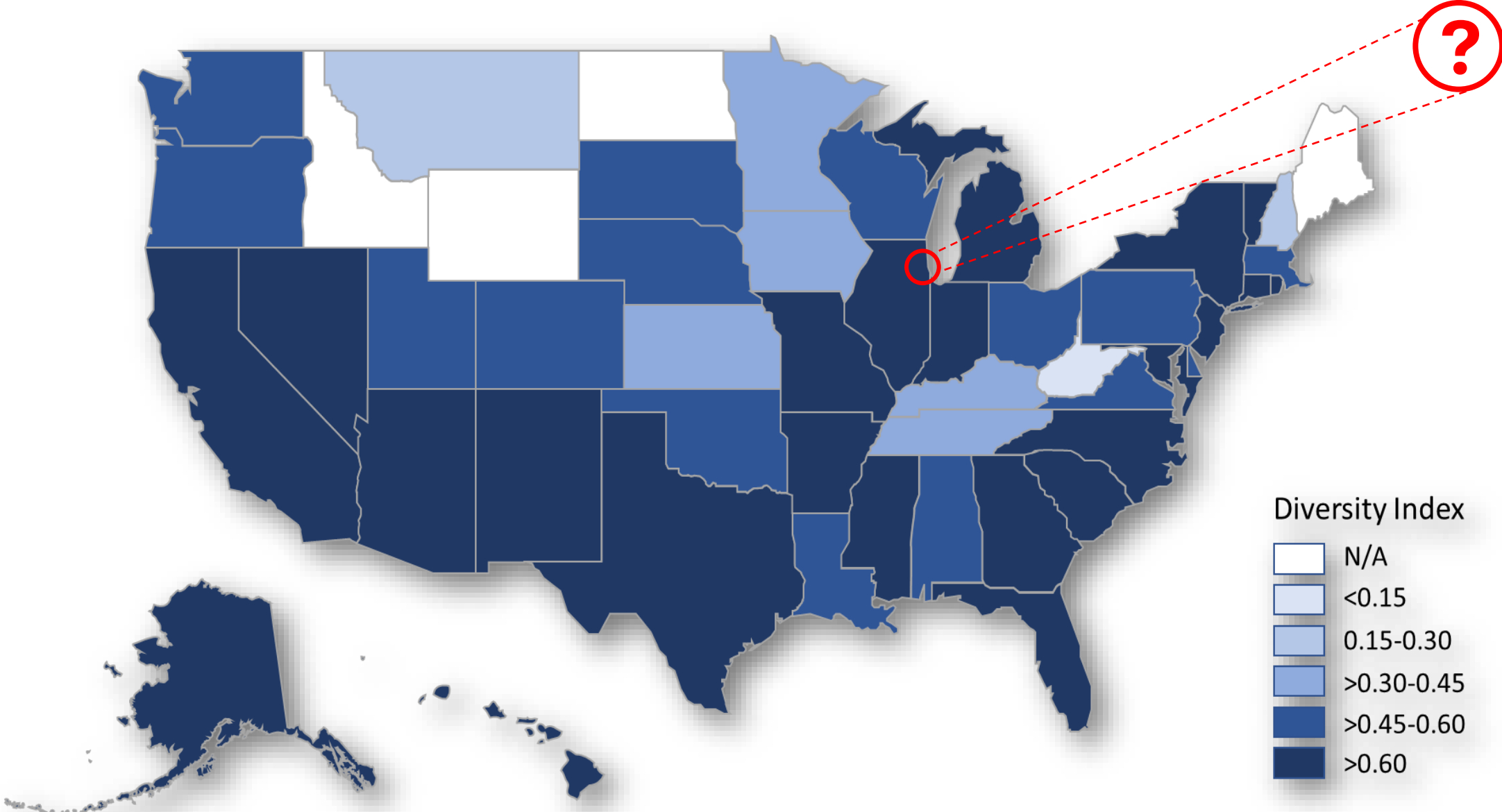
Race/Ethnicity	Expected	Observed
White	61.5%	63.1%
Black or African American	24.5%	24.6%
Multi-race, not specified	3.2%	3.7%
Asian	6.0%	2.3%
American Indian or Alaskan Native	0.5%	0.8%
Hawaiian or Pacific Islander	0.1%	0.3%
Not reported/Unknown	4.2%	5.2%
Hispanic or Latino	13.2%	15.8%

R/E Diversity in Academic-Led Pediatric Trials



A- Asian, AI- American Indian/Alaskan Native, B- Black, H- Hawaiian/Pacific Islander, HS- Hispanic, M- multiracial, NR- not reported, W- White

R/E Diversity in Academic-Led Pediatric Trials



Children on ‘*the Lack of Diversity in Clinical Trials*’



Abby



Rhiannon



Ed



Kenneth

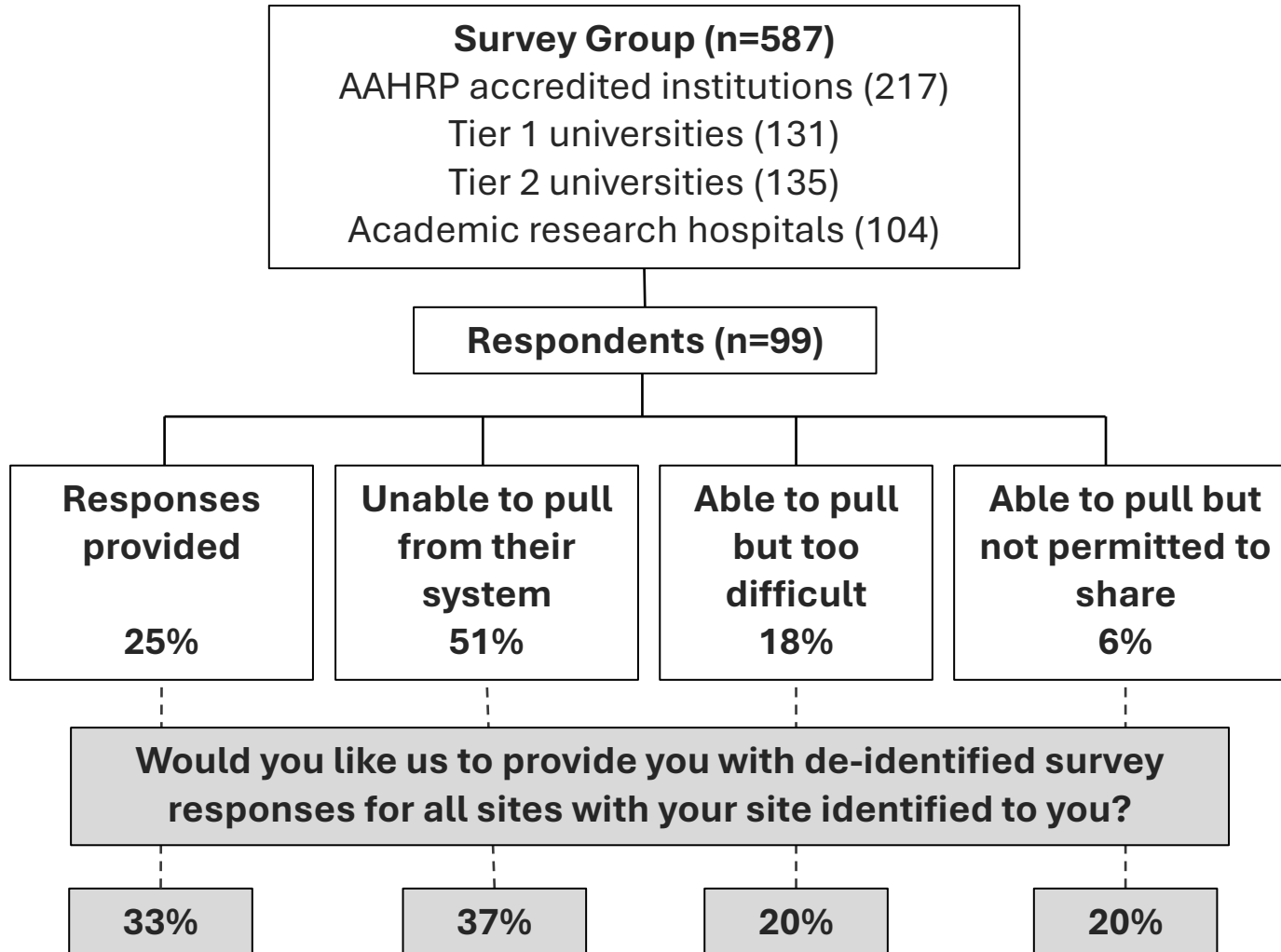


Imaan

Why do you think some studies don't include a diverse group of children?

- ✓ Stagnant strategies
- ✓ Parental restrictions
- ✓ Safety concerns
- ✓ Cultural barriers
- ✓ Language barriers
- ✓ Financial constraints
- ✓ Limited communication
- ✓ Lack of awareness
- ✓ Restricted outreach
- ✓ Fears
- ✓ Misconceptions

(Missed) Opportunities - Language



When P/A/C were translated:	
1 other language	92.9%
2 other languages	4.1%
3 other languages	1.6%
4 other languages	1.1%
5+ languages	0.3%

**CMH IRB (2012)
federal/internal**

↓

exponential ↑ YOY x 3

(Missed) Opportunities - Literacy

J Immigrant Minority Health (2015) 17:1504–1508
DOI 10.1007/s10903-014-0116-6



ORIGINAL PAPER

Evaluating the Effectiveness of an Illustrated Permission/Assent Form

Susan M. Abdel-Rahman

<http://wjss.sciedupress.com>

World Journal of Social Science

Vol. 5, No. 1; 2018

Scientists, Students, and Crowds: A Collaboration to Improve Health Literacy

Susan M. Abdel-Rahman^{1*}, Nicole McClure Kurlbaum² & Stan Fernald²

Leading Article | [Published: 17 July 2019](#)

Facilitating Informed Permission/Assent/Consent in Pediatric Clinical Trials

[Susan M. Abdel-Rahman](#)

[Pediatric Drugs](#) **21**, 205–214 (2019) | [Cite this article](#)



(Missed) Opportunities - Misconceptions

Interventional Studies

Trial Type (Disease)	Non-Interventional Studies			Surgical Studies				
	Trial Type	Non-Hispanic White	All Minority Groups	Trial Type (Disease)	Non-Hispanic White Offered Enrollment	Non-Hispanic White Consent Rate	All Minority Groups Offered Enrollment	All Minority Groups Consent Rate
Drug maintenance (schizophrenia)								
Day hospital vs. inpatient (substance abuse)								
Drug trial (cardiac arrhythmia)	In-person interview	25,515		Surgery vs. medical management (angina pectoris)	2,065	37.1%	30	43.3%
Risk counseling (breast cancer)	In-person interview	1,778		Tonsillectomy vs. tonsillectomy with adenoidectomy (recurrent throat infection)	172	47.1%	15	66.7% ^a
Estrogen treatment (cardiovascular disease)	Review of child's medical chart	19,420		TPN (post-surgery malnourishment)	432	63.7%	162	74.1%
Drug trial (cancer)		46,713		Surgery vs. medical management (recurrent otitis media)	175	50.9%	37	27.0%
Drug trial (HIV infection)	4-h medical exam	1,778		PTCA vs. CABG (coronary artery disease)	793	46.3%	49	51.0%
Drug trial (HIV infection)		169	71.6%	17				
Treatment trial (alcohol abuse)		167	62.9%	n/a				
Radiation (ocular melanoma)		2,823	45.7%	15	53.3	28	50.0%	

(Missed) Opportunities - Misconceptions

ARTICLES | DECEMBER 01 2006

PEDIATRICS®

Tracking *Trichophyton tonsurans* Through a Large Urban Child Care Center: Defining Infection Prevalence and Transmission Patterns by Molecular Strain Typing 🛒

Susan M. Abdel-Rahman, PharmD; Steve Simon, PhD; Krista J. Wright, LPN; Liliane Ndjountche, MS; Andrea Gaedigk, PhD

n=446

100% participation

ARTICLES | MAY 01 2010

PEDIATRICS®

The Prevalence of Infections With *Trichophyton tonsurans* in Schoolchildren: the CAPITIS Study 🛒

Susan M. Abdel-Rahman, PharmD ✉; Nancy Farrand, RN, BSN; Eric Schuenemann, BA; Tricia K. Stering, BS; Barry Preuett, BA; Richard Magie, DO; Annette Campbell, RN, BSN

n=10,514

99.8% participation

Genetic predictors of susceptibility to cutaneous fungal infections: A pilot genome wide association study to refine a candidate gene search

Susan M. Abdel-Rahman 👤 ✉ • Barry L. Preuett

Published: June 18, 2012 • DOI: <https://doi.org/10.1016/j.jdermsci.2012.05.003>

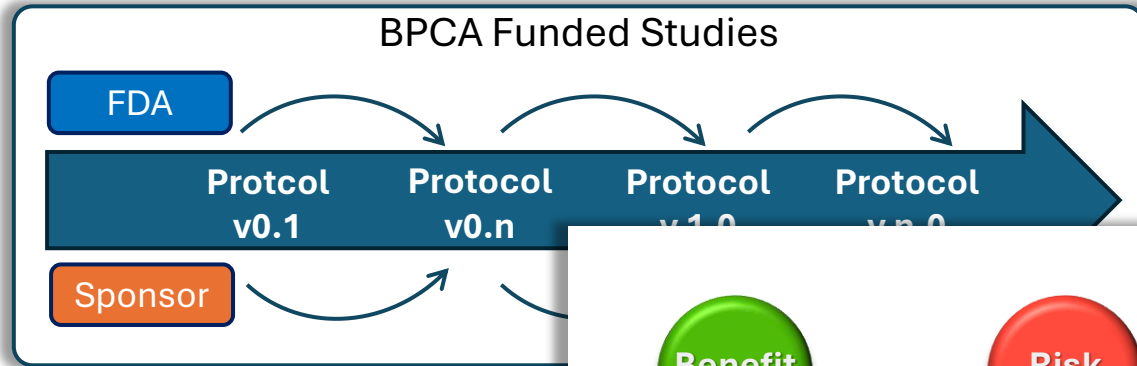
JDS
JOURNAL OF
Dermatological
Science

n=163

98.7% participation

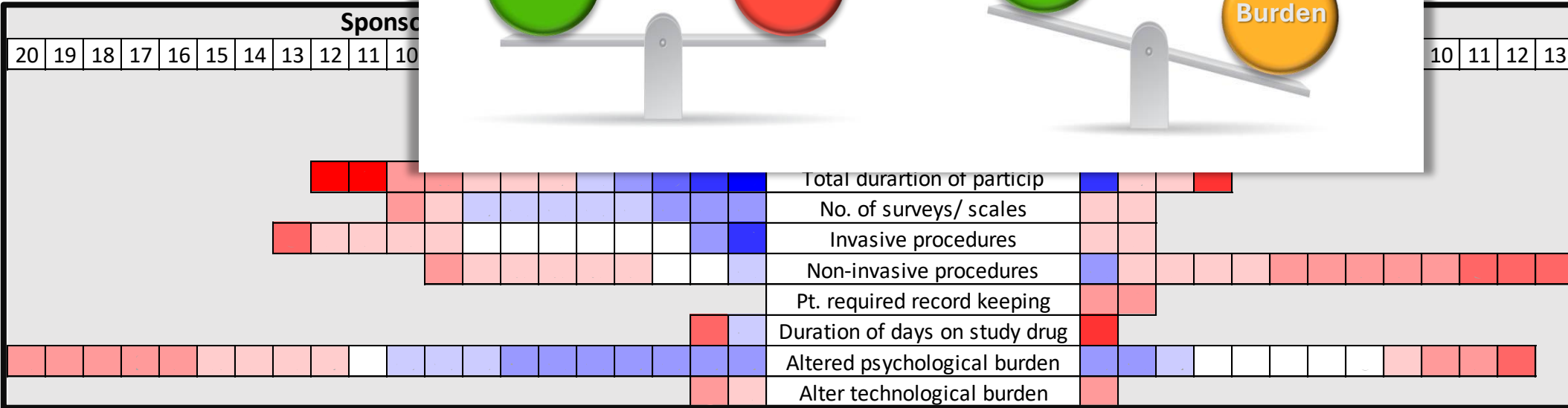
(Missed) Opportunities – Participant Burden

21 studies, 94 unique protocol versions
123 changes linked to burden

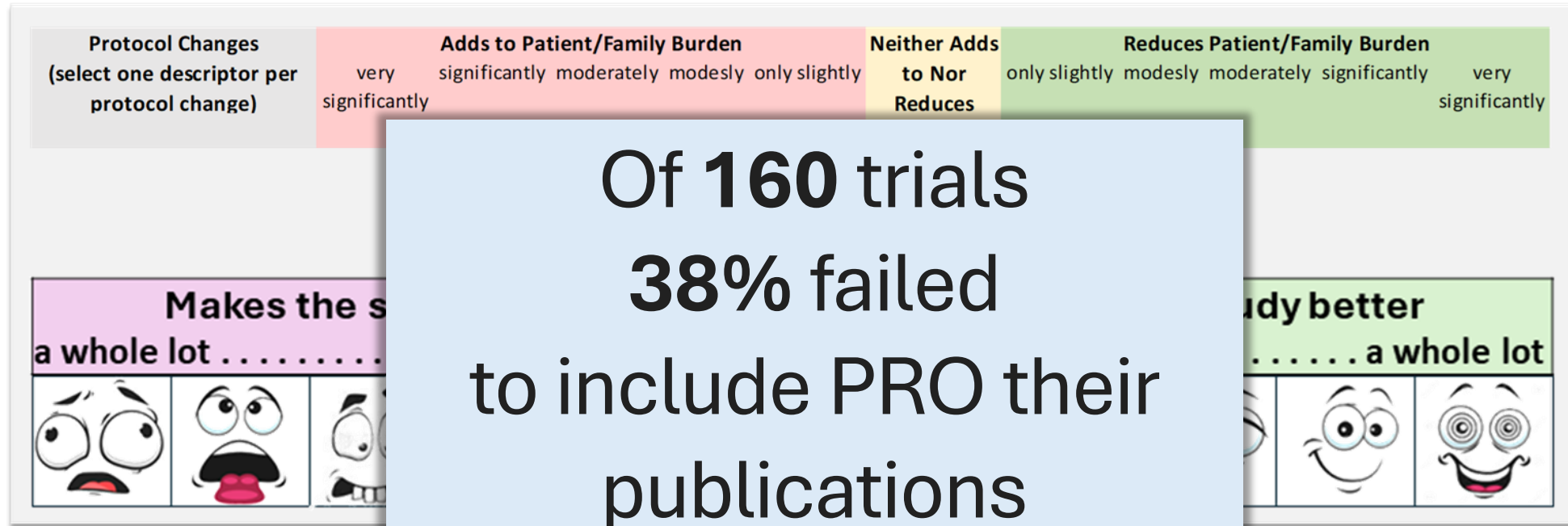


- under-/uninsured
- restricted income
- limited PTO

household



(Missed) Opportunities – Participant Burden



venous bl	
u	
fe	
bronchodilator responsiveness challenge	test how easy you can breathe 🗣️
Tanner staging	look at your private areas
electrocardiogram	place stickers on your chest to see your heartbeat ❤️

(Missed) Opportunities – System Issues

Description	Time frame	Patient Numbers	Unknown race (%)
hospital transactional database	2000-2011	91,983,358	25.3
Health claims database	2000-2016	73,992,364	26.0
academic healthcare system	2014-2015	2,338,421	59.5
national survey	1999-2011	71,916	6.4
patient satisfaction survey	2014-2015	25,308	13.7

Self-report vs. EHR	
Race/ethnicity:	
Black	70.9%
Hispanic	83.8%
White	93.8%
Language preference:	
Spanish	79.3%

(Missed) Opportunities – System Issues

Child R/E Birth Certificate vs. EHR (n=325,810)

		Hispanic					
		White	Black	As/PI	AI/AN	Multi	Other
% classified as:	White	67.6	11.2	21.0	50.3	51.8	41.9
	Black	0.3	67.1	0.2	0.6	10.6	0.5
	As/PI	0.2	0.4	44.9	0.8	12.2	0.5
	AI/AN	0.0	0.1	0.2	15.8	0.6	0.2
	Multi	0.1	1.5	1.2	1.4	1.9	0.0
	Other	17.1	4.9	6.5	14.7	10.9	41.2
	Unk	14.7	14.8	26.2	16.4	12.0	15.6

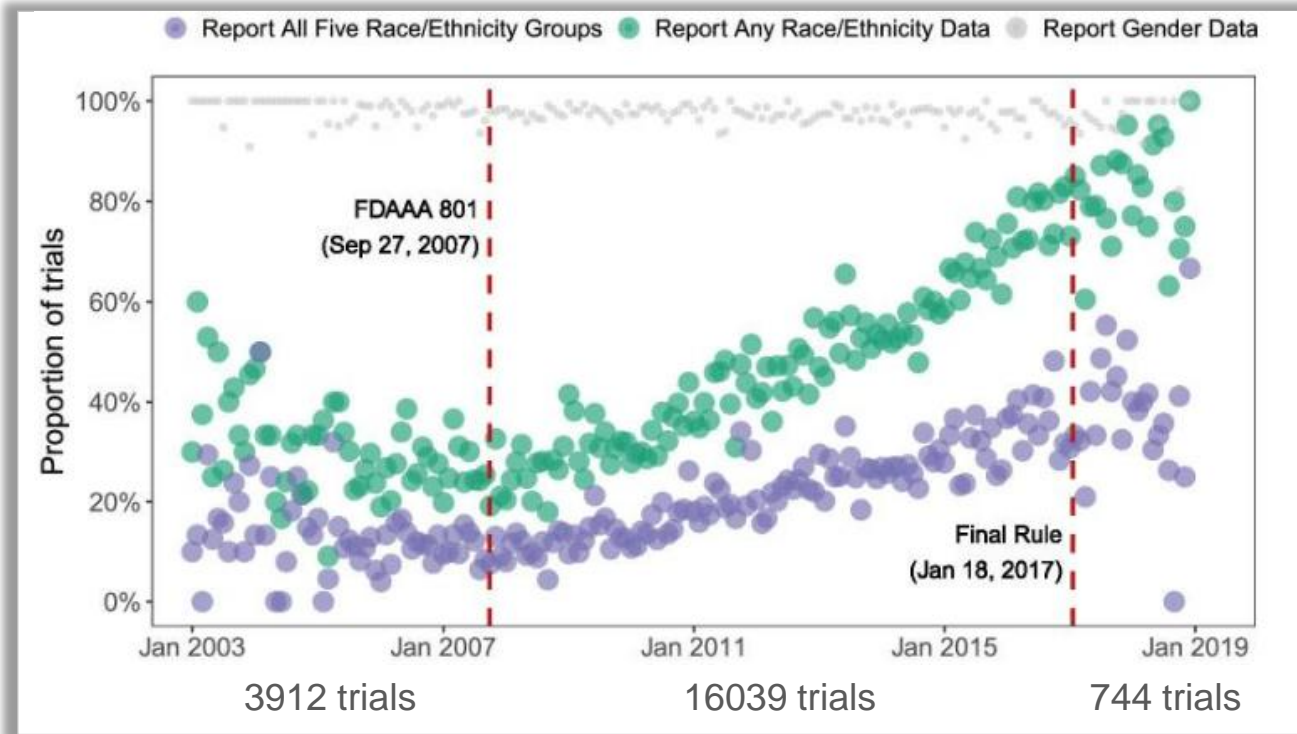
		Non-Hispanic					
		White	Black	As/PI	AI/AN	Multi	Other
% classified as:	White	84.7	3.7	10.4	24.7	39.2	7.1
	Black	0.3	67.1	0.4	3.8	11.8	0.0
	As/PI	0.7	0.3	71.5	21.3	29.2	0.0
	AI/AN	0.1	0.0	0.7	13.9	0.7	0.0
	Multi	0.2	0.9	0.7	2.1	1.9	0.0
	Other	2.0	0.9	3.0	3.5	2.8	82.1
	Unk	12.1	12.8	13.8	30.7	12.8	10.7

(Missed) Opportunities – Miscommunication

	White	Black	Hispanic	Multiracial
It is important for hospitals and clinics to collect information from patients about their race or ethnic background.				
Somewhat or strongly disagree	9%	20%	25%	6%
How concerned would you be that this information could be used to discriminate against you or other patients?				
Very concerned	19%	53%	10%	22%
It is important for hospitals and clinics to conduct studies to make sure all patients get the same high-quality care regardless of their race or ethnic background.				
Strongly agree	92%	93%	95%	100%

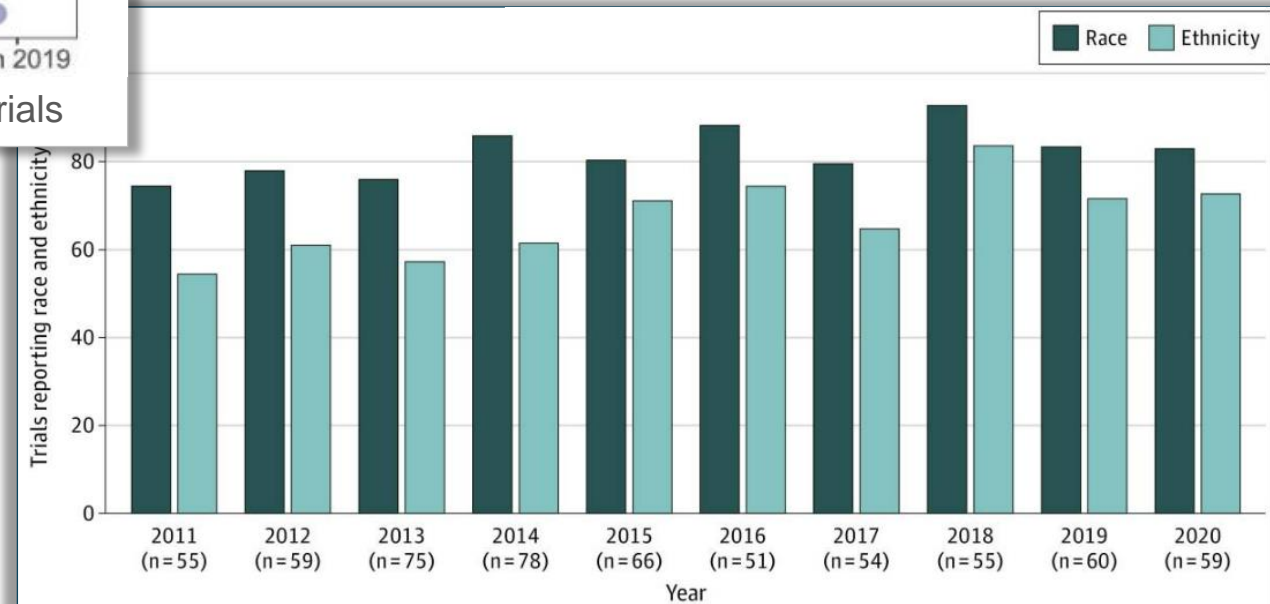
- Different interpretations of the question
- Ease of selecting a response
- Perceptions about the purpose

(Missed) Opportunities – Benchmarking



Proposed Strategies

- Prevalence percentage
- Prevalence % vs. census population
- Prevalence % vs. disease population (Participation to Prevalence ratio)
- Participation Ratio
- Diversity Index

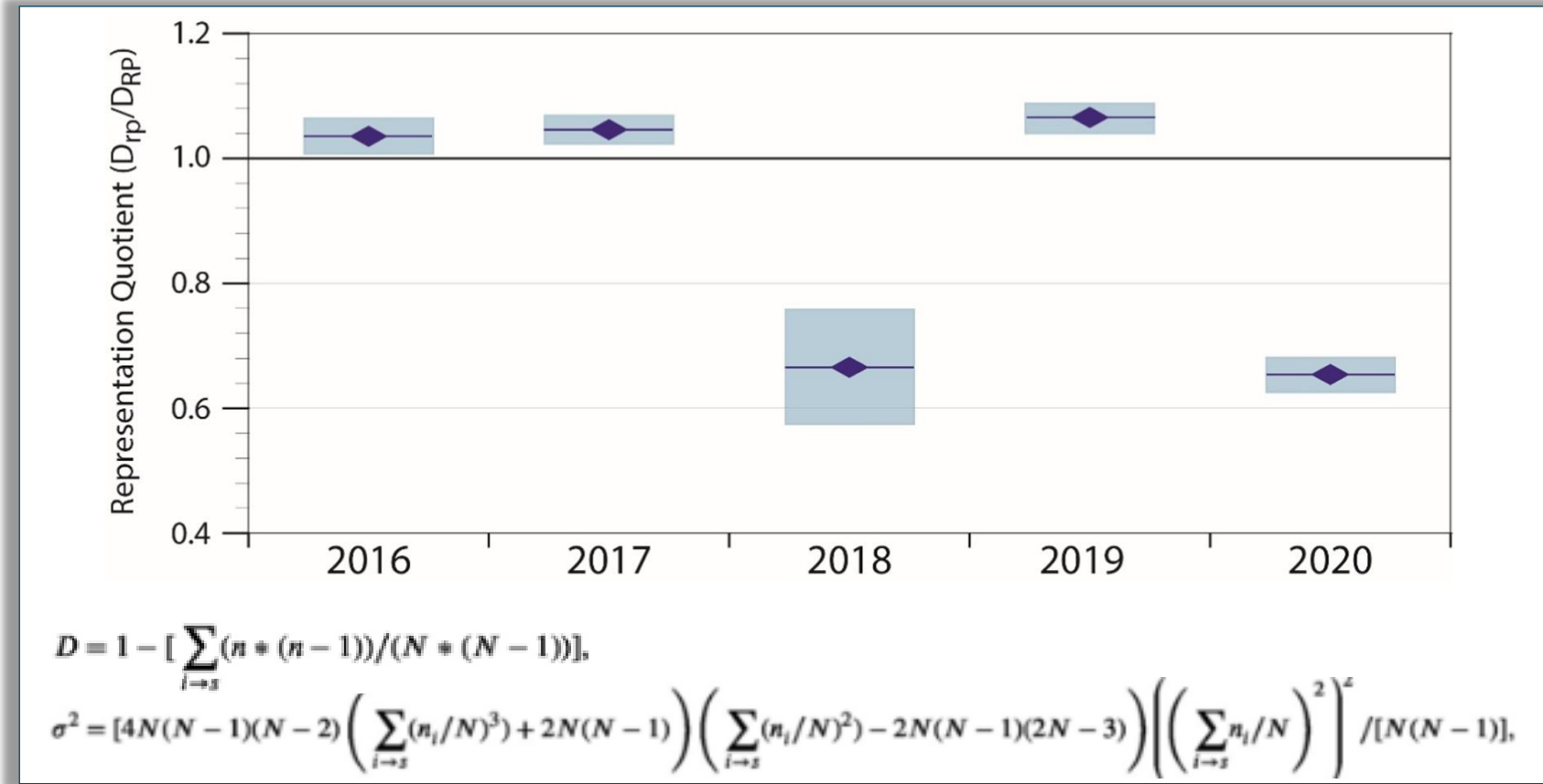


Turner BE, et al. Lancet Reg Health 2022; JAMA Pediatr. 2022;11:100252

Rees CA, et al. JAMA Pediatr. 2022;176(5):e220142

Brewster RCL, et al. Pediatrics. 2023;151(4):e2022058552

(Missed) Opportunities – Benchmarking



Impact of Benchmarking

Diversity
in
CHILDREN'S
BOOKS
2012

OUT OF 3,600 CHILDREN'S BOOKS REVIEWED BY THE CCBC IN 2012

SOURCE: FIRST BOOK INFOGRAPHIC: TINA KUGLER

Dive Children 20

Percentages of books depicting
Based on the 2015 publishing statis
Book Center. School of Educa
ccbc.education.wi

0.9%
American
Indians/
First Nations

2.4%
Latinx

DIVERSITY IN CHILDREN'S BOOKS

Percentage of books depicting character
based on the 2018 publishing stat
Cooperative Children's Book Cente
University of Wisconsin
ccbc.education.wisc.edu/bo

1%
American
Indians/
First Nations

5%
Latinx

218
BOOKS

Asia
Islan
Pacifi

2020 REPRESENTATION IN CHILDRENS PICTURE BOOKS

41% White

29% Animals

12% Black

0.001% Pacific Islander
0.008% Arab
0.15% Indigenous

9% Asian

6% Latinx

3% Disability

Children on ‘*Improving Diversity in Clinical Trials*’



Abby



Rhiannon



Ed



Kenneth



Imaan

If you were in charge of research, what would you do to make sure that studies are diverse?

- ✓ *Extraordinary effort*
- ✓ *Community outreach*
- ✓ *Relationship building*
- ✓ *Interpersonal connection*
- ✓ *Intentional site selection*
- ✓ *Reputational awareness*
- ✓ *Exercise humanity*
- ✓ *Transportation*
- ✓ *Partnering*
- ✓ *Translation*
- ✓ *Communication*

Acknowledgements



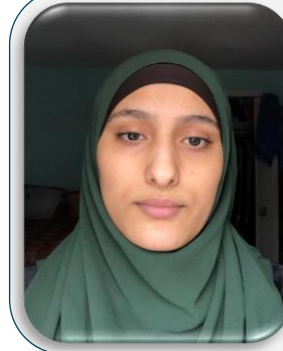
Abby

wants to enter medicine and is participating in her high school medical club to expand her experience before going to college.



Ed

was diagnosed with a critical medical condition and traveled over 5,000 miles from Africa to Italy for life saving treatment.



Imaan

passionately advocates for better medicines while balancing the rigors of a chronic health condition.



Kenneth

is wearing apparel that spotlights up and coming youth designers dedicated to supporting diversity and inclusion.



Rhiannon

is former Chair of the iCAN Young Professionals and has spoken several times before the FDA.

What would you tell researchers who think that ensuring diversity is too hard?

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