

**NORD**<sup>®</sup>  
National Organization  
for Rare Disorders

# NOTHING ABOUT US, WITHOUT US

Jonathan Jackson, PhD  
Director, CARE Research Center



**The incidence of patient availability sharply decreases when a clinical trial begins and returns to its original level as soon as the trial is completed.**

—Lasagna's Law



## WHY SHOULD I CARE ABOUT RECRUITMENT?

- Many registries fail to meet enrollment
- Even if they don't, enrollment is
  - › Super slow
  - › Super homogeneous or
  - › Way over budget
- We often unknowingly build in barriers to participation
- Federal agencies require that you care about this, and they're getting stricter
  - › Even if you don't have enough people to conduct statistical analysis
  - › The rise of the "valid analysis"
- Drugs, biologics, devices and pathophysiology may differ based on diverse groups



## WHY SHOULD I CARE ABOUT RECRUITMENT?

- 1 in 5 FDA approvals differ in exposure/response as a function of race and ethnicity (Ramamoorthy et al., 2015)
- Representation issues are particularly acute in advanced medical sciences (Jackson et al., 2016; Landry et al., 2018)
- Selection and survival biases skew estimates of causal factors (Mayeda et al 2018; Weuve et al., 2015)
- Recruitment to rare disease registries/ platforms is slow and tends to favor privileged populations (Johnson et al., 2014; Dwyer et al., 2021)
- What happens if we don't recruit diversely?



# WHAT DOES RECRUITMENT TO CLINICAL TRIALS LOOK LIKE?

**Table 1. Percent Participation in Clinical Trials by Subpopulation\* for New Molecular Entities and Therapeutic Biologics Approved in 2020**

	WOMEN	WHITE	BLACK or AFRICAN AMERICAN	ASIAN	HISPANIC	AGE 65 AND OLDER	UNITED STATES
AVERAGE	56%	75%	8%	6%	11%	30%	54%
Est US pop	50.8%	76.5%	13.4%	5.9%	18.3%	16.0%	
Median DTS	55%	78%	3%	5%	8%	11.5%	36%



# WHY CAN'T WE RECRUIT DIVERSE POPULATIONS?



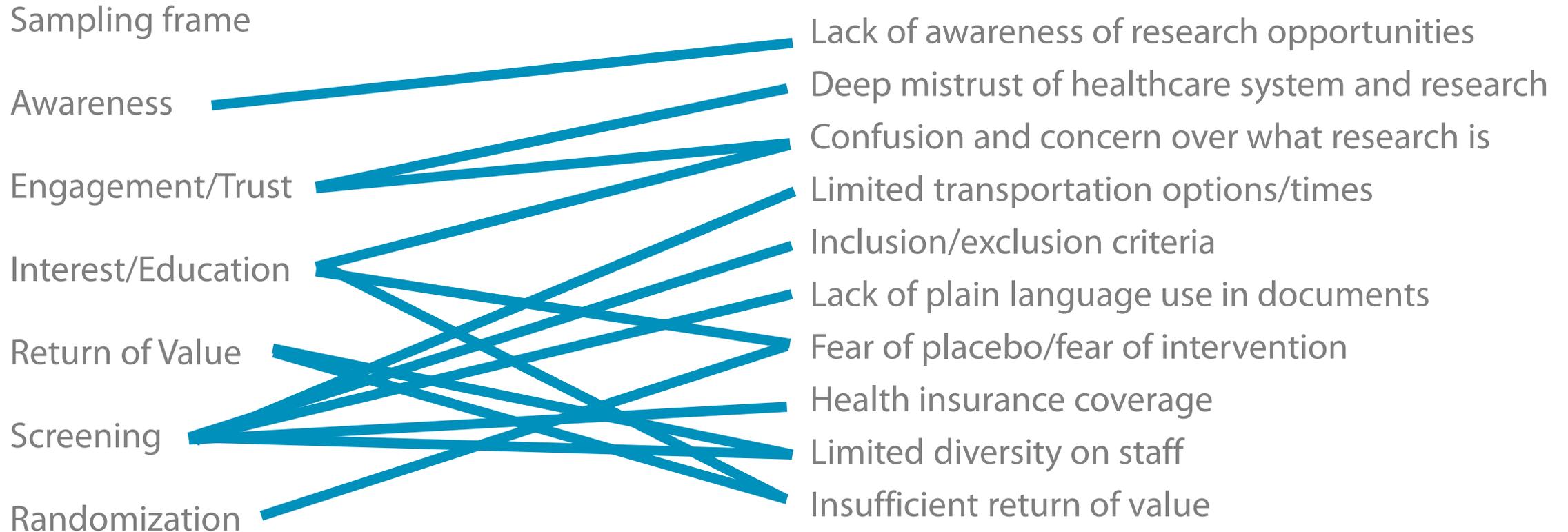
1. Lack of awareness of research opportunities
2. Deep mistrust of healthcare system and research studies
3. Confusion and concern over what research is
4. Limited transportation options/times
5. Inclusion/exclusion criteria (e.g., lumbar puncture, study partner)
6. Lack of plain language use in documents
7. Fear of placebo/fear of intervention
8. Health insurance coverage
9. Limited diversity on staff
10. Insufficient return of value

Selected references:

Bendixen 2016 | Clin Ther  
Bonevski 2014 | BMC Med Res Method  
Dunbar 2019 | Ped Neur  
Ejiogu 2011 | The Gerontologist  
George 2004 | Am J Public Health  
Gilmore-Bykovskiy 2019 | Alz & Dem: TRCI  
Gul & Ali 2009 | J Clin Nursing  
Howell 2020 | Alz & Dem  
Indorewalla 2021 | J Alz Dis  
Oh 2015 | PLoS Medicine  
Otado 2015 | Clin Trans Sci  
Probstfield & Frye 2011 | JAMA  
Robinson & Trochim 2007 | Ethn Health

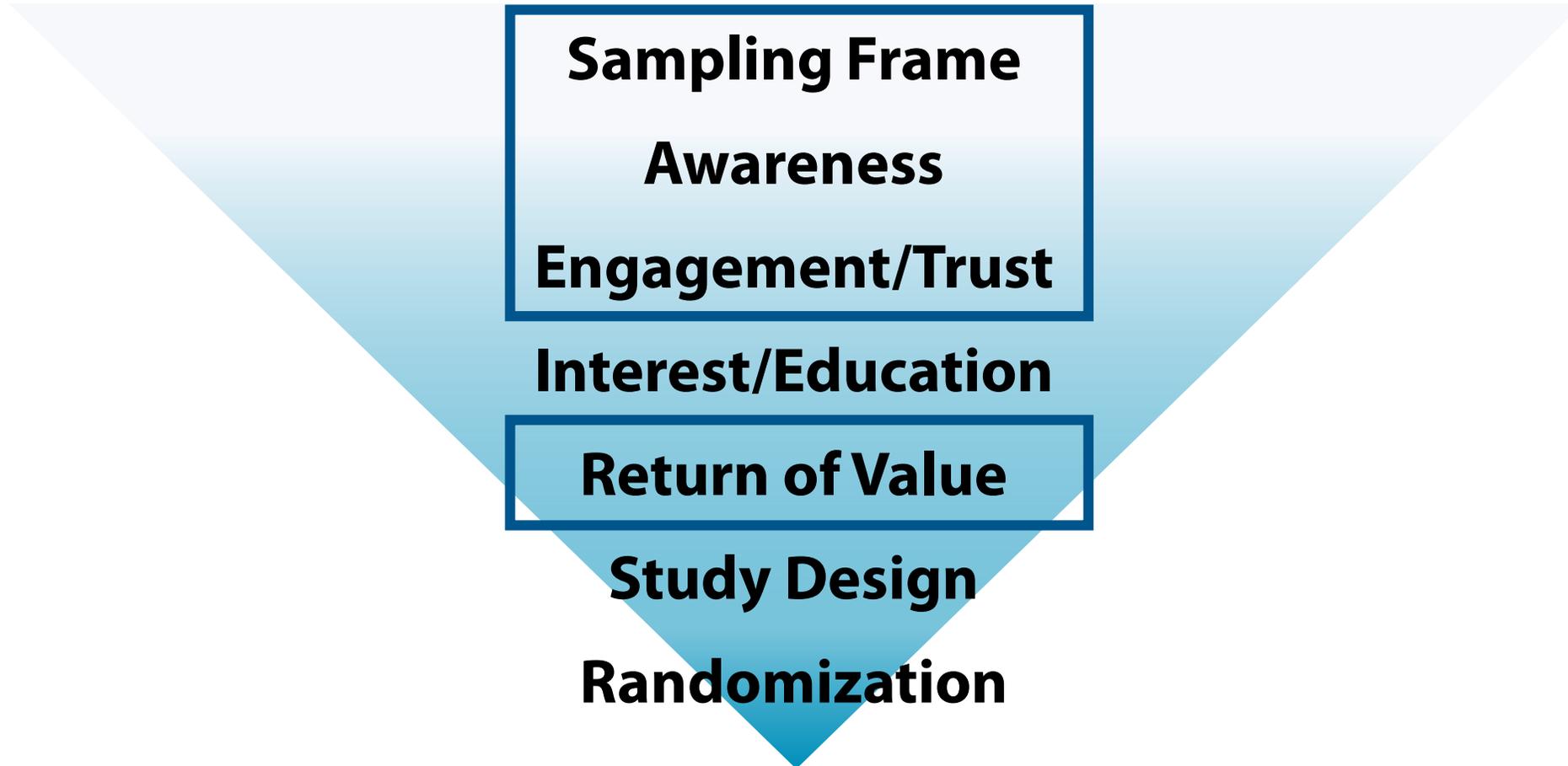


# DIVERSE INCLUSION AS A WORKFLOW SOLUTION





# DIVERSE INCLUSION AS A WORKFLOW SOLUTION





## LET'S THINK ABOUT THE SAMPLING FRAME

1. Clearly define your catchment area – who do you *want* to reach?
2. If you're enriching for underserved patients, make sure they're around
3. Think about risk factors for disease and make sure your registry is accessible for populations at high risk
4. Assume a very low reach for recruitment (on the order of 0.05% of those reached, which will be lower if you're recruiting from a marginalized group)
5. These plans will help you decide what recruitment tools to use



## LET'S THINK ABOUT RAISING AWARENESS

1. Remember that you (and most people who know you) are deeply weird
2. Think about registry design – what's the return of value for the patient?
3. Based on sampling frame, pick a method of raising awareness
4. Decide whether you're advertising to patients, families and/or clinicians
5. Pick a tool for advertising, based on sampling frame and above answers (e.g., traditional media, digital/social media, flyers, word of mouth, clinical champions, ambassadors, community outreach, advocacy organizations)
6. Keep your messaging simple – most research flyers are ignored outright
7. If you build it, they usually won't come; go to where your patients are



# LET'S THINK ABOUT RAISING AWARENESS



## DO YOU HAVE STIFF KNEES OR JOINT PAIN?

You may have **knee osteoarthritis**. Massachusetts General Hospital is looking for adults between 45 and 80 years old who have **knee osteoarthritis**. With your help, we want to learn more about a new medication.



**You will receive:**

- Reimbursement for travel expenses
- Study-related care, exams, and investigational medication at no cost.
- Recognition of Completion Award.

**You will be asked to:**

- Be a part of 11 separate, in-clinic visits.
- Answer surveys and wear a fitness watch between visits.

**FIND OUT MORE BY CALLING OR EMAILING NAME:**  
[study@mgh.harvard.edu](mailto:study@mgh.harvard.edu)  
617-643-0123



Rutgers University's  
Institute for Health, Health Care Policy and  
Aging Research

## Recruiting Research Participants

**THE PINE STUDY**

**What is PINE Study?** PINE Study stands for Population Study of Chinese Elderly.

**Why?** PINE study is research being done to understand psychological and social issues that affect the general well-being of Chinese older adults.

**Who?** Rutgers University's Institute for Health, Health Care Policy and Aging Research invites Chinese older adults (aged 60 or older) and their family members/friends to participate in the study.

**When and How?** Participants will be asked to participate in a survey and/or attend a small-group discussion to share thoughts on issues relating to one's well-being in the community. The survey will take approximately 1.5 hours. The group discussion will take approximately 2 hours. You will receive \$15 upon completion of the survey. If you participate in the group discussion, you will receive \$15. You will be paid according to the following schedule if you participate again during the longitudinal phase of this study: \$20 for your first follow-up interview; \$30 for your second follow-up interview; \$40 for your third follow-up interview; \$50 for your fourth follow-up interview.

**Where?** Depending on participant's preference, the study will either take place in community centers or participant's residence.

If you or anyone you know might be interested in participating, please contact the research team at 848-932-3817.

For more information, please visit our website at [www.chinesehealthyaging.org](http://www.chinesehealthyaging.org)

This study is conducted under the direction of Dr. Xinqi Dong, Henry Rutgers Distinguished Professor of Population Health Sciences, Rutgers University

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**IRB APPROVED**

IRB ID: Pro2018001423  
Approval Date: 10/11/2018  
Expiration Date: 10/10/2019



## LET'S THINK ABOUT BUILDING ENGAGEMENT

1. Provide some return of value to prospective patients or referrers
2. Be intentional about building a community, preferably led by those living with rare disease
3. This is where it helps to have a diverse staff and study ambassadors (but you need sampling and awareness plans first)
4. Will probably need at least three touch points to move ahead
5. Help people navigate and curate information around rare disease, and keep them updated



## LET'S THINK ABOUT DELIVERING RETURN OF VALUE

1. There are often three types of value: time, money and information. Try for all three when you're designing a study.
2. A strong return of value, especially for information, will drive registry interest
3. Make sure you have a clear return of value for all stakeholder groups
4. Money isn't everything, but it isn't nothing—the same for logistical support
5. Build value at the level of families and communities
6. Make it fun to participate, or at least easy
7. If you don't know how to do any of this, then consult patients





**Of all forms of inequality, injustice  
in healthcare is the most shocking  
and inhuman.**

— Martin Luther King, Jr.

# Thank you.

