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)

• 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?

• 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)
### 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

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<tr>
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<th>WOMEN</th>
<th>WHITE</th>
<th>BLACK or AFRICAN AMERICAN</th>
<th>ASIAN</th>
<th>HISPANIC</th>
<th>AGE 65 AND OLDER</th>
<th>UNITED STATES</th>
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<tr>
<td><strong>AVERAGE</strong></td>
<td>56%</td>
<td>75%</td>
<td>8%</td>
<td>6%</td>
<td>11%</td>
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<td>50.8%</td>
<td>76.5%</td>
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<td>13.4%</td>
<td>5.9%</td>
<td>18.3%</td>
<td>16.0%</td>
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Median DTS

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<td>55%</td>
<td>78%</td>
<td></td>
<td>3%</td>
<td>5%</td>
<td>8%</td>
<td>11.5%</td>
<td>36%</td>
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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
- Ejogu 2011 | The Gerontologist
- George 2004 | Am J Public Health
- Gilmore-Bykovskyi 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

Sampling frame
Awareness
Engagement/Trust
Interest/Education
Return of Value
Screening
Randomization

Lack of awareness of research opportunities
Deep mistrust of healthcare system and research
Confusion and concern over what research is
Limited transportation options/times
Inclusion/exclusion criteria
Lack of plain language use in documents
Fear of placebo/fear of intervention
Health insurance coverage
Limited diversity on staff
Insufficient return of value
DIVERSE INCLUSION AS A WORKFLOW SOLUTION

Sampling Frame
Awareness
Engagement/Trust
Interest/Education
Return of Value
Study Design
Randomization
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 15 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
617-543-0123

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

Recruiting Research Participants

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.

What? 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: you will be paid $15 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 848-372-3817.

For more information, please visit our website at www.chinesehealthaging.org

This study is conducted under the direction of Dr. XinQi Dong, Happy Sun, Distinguished Professor of Population Health Sciences, Rutgers University.

Version 1: October 1, 2018
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
LETS 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.