Session III: The Era of COVID-19 and Beyond

Drug Research & Development for Adults
Across the Older Age Span

A NASEM Virtual Workshop August 6, 2020

Moderated by

Deborah Collyar

President

Patient Advocates in Research

The Era of COVID-19 and Beyond

- Outreach & networking strategies
 Jonathan Tobin, Clinical Directors Network and
 The Rockefeller University Center for Clinical & Translational Science
- 2. Barbershop-based outreach programs
 Ciantel Adair Blyler, Cedars-Sinai Medical Center
- **3. Patient perspective**Susan Strong, Heart Valve Voice
- 4. Caregiver perspective
 Laurel Pracht, NCI Symptom Control & HRQOL Steering Committee
- **5. Education: older adults + healthcare practitioners**Steven Rothschild, Rush Medical College

- Explore methodologies to study pharmacology for older adult populations
- Explore ways to
 engage 65+ people,
 including 80+ year olds
- Generate evidence to best optimize treatment for older adults

The "everyone" of 65+ year old patients...

Marathon runners

Regular exercise

Mobility issues

Cognitive issues

Assisted living

Nursing home

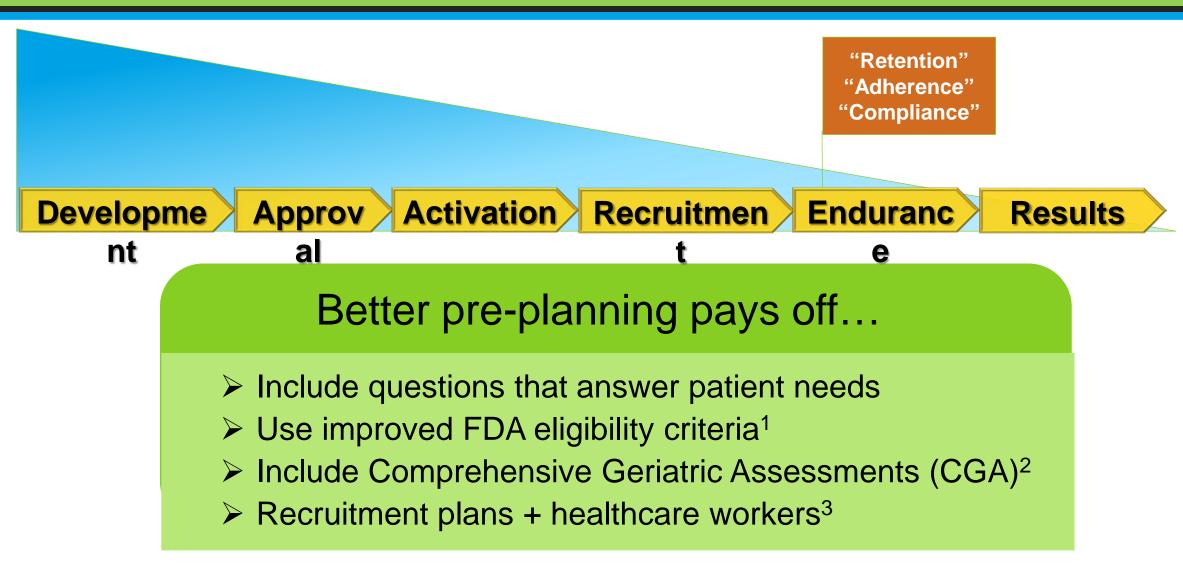
Why exclude so many from...

- Clinical trials + treatment options?
- > Who is 'responsible' to show benefit? To include patients?

Time to create a "healthy aging" program!

Connect research + pilots + initiatives + community + PEOPLE

How to incorporate older adults into clinical trials?



¹ https://www.raps.org/news-and-articles/news-articles/2020/7/fda-finalizes-guidance-on-broader-cancer-trial-eli

²https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6693722/ ³ http://bit.ly/2Pfiv4E

Different approaches for product lifecycle

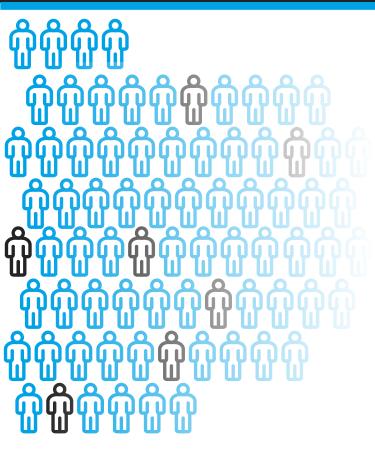
Developme Trials + RWD Results Planning Launch Access
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Incorporate better tools

- ➤ Physical settings: COVID-19 changes
- > Training needs: all kinds
- Enabling services
- ➤ Health literacy a MUST!

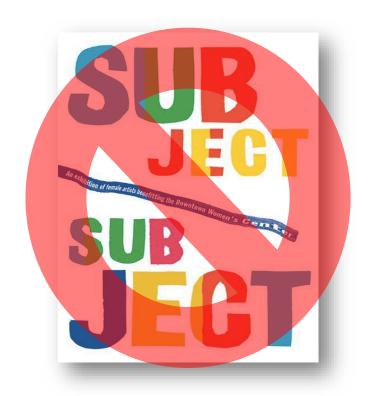
Remember, please stop blaming patients

e.g., "failing" or "response" and "non-responders"



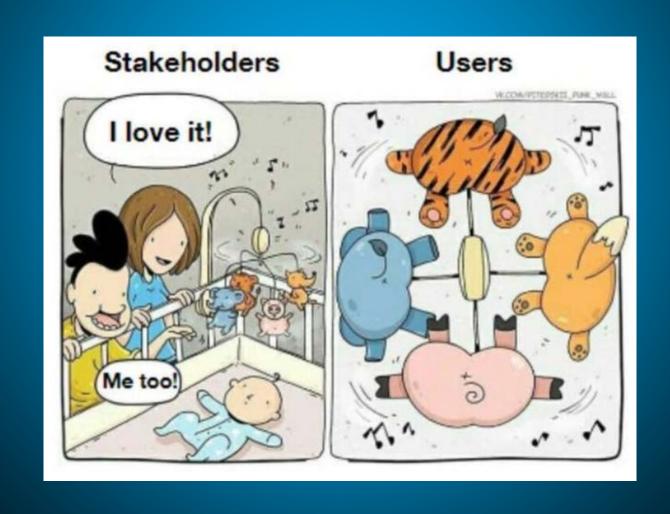
PATIENTS RESPOND TO TREATMENT

...their disease may not



Let's work together on accurate language

One final point: CONTEXT



The Era of COVID-19 and Beyond

1. Outreach & networking strategies

Jonathan Tobin

- President/CEO, Clinical Directors Network
- Senior Epidemiologist, The Rockefeller University Center for Clinical & Translational Science

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 engage 65+ people,
 including 80+ year olds
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Barbershop-based outreach programs: Case study

Ciantel Adair Blyler

- Clinical Research Pharmacist
- Cedars-Sinai Medical Center

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 engage 65+ people,
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3. Patient perspective

Susan Strong

- Director, Patient Engagement
- Heart Valve Voice

- Explore methodologies to study pharmacology for older adult populations
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 engage 65+ people,
 including 80+ year olds
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4. Caregiver perspective

Laurel Pracht

- Research Patient Advocate & Patient Representative
- NCI Symptom Control & HRQOL
 Steering Committee

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 engage 65+ people,
 including 80+ year olds
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- 5. Education: older adults+ healthcare practitioners
 - Steven Rothschild
 - Chair, Family Medicine
 - Professor, Department of Family Medicine
 - Professor, Department of Preventive Medicine
 - Rush Medical College

- Explore methodologies to study pharmacology for older adult populations
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 engage 65+ people,
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Q & A

Give people (& providers) the 4 Cs...

Clear Communication of Content in CONTEXT







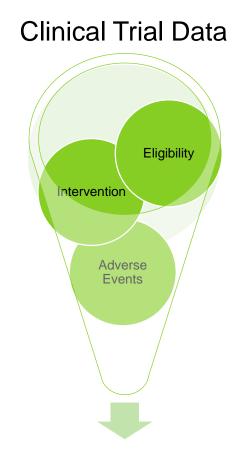


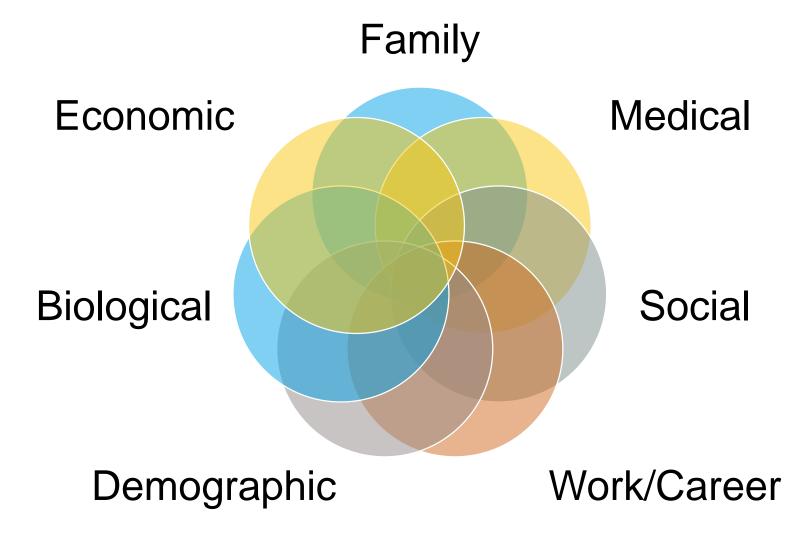
For THEM, no matter their role in health

Traditional data...

All Other 'Patient" Data

THIS is real world!





Different approaches for product lifecycle

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Incorporate better tools

- ➤ Physical settings: COVID-19 changes
- > Training needs: all kinds
- Enabling services
- ➤ Health literacy a MUST!



Panel discussion

Questions for panel

- 1. How do we start 'connecting the dots' to increase older adult participation into research (short-term)?
 - Ex: how to implement some COVID-19 changes permanently?
 - Structure + reimbursement + design + communication + empowerment + ?
 - Telehealth and help people participate through it step forward
 - Telehealth has lowered burden of entry; no travel
 - e-divide: who am I missing? Zip codes, reflection pop.
 - What things matter to patients, not A1C, etc.?
 - How to create virtual linkages & understand that each point of contact is unique and captures important info, but only 1 point.
 - Social determinants of health have to be included for the whole picture

Questions for panel

- 2. What longer-term steps are needed to create a *real* system?
 - Research: standards, initiatives, methodology, etc.
 - Health:
 - What is reasonable to push forward and how (ex. AHA & hypertension)

Questions for panel

- 3. How can we incorporate better design for older adults?
 - Ex: clinical trial endpoints, eligibility, PROs, conditional approval, etc.
 - a) Understand misaligned incentives before we can fix them

Patient Advocates In Research (PAIR)



Where research meets reality

Thank you! Keep in touch

Deborah Collyar



deborah@tumortime.com



https://collyar.wordpress.com/



www.linkedin.com/in/deborahcollyar/



@deborahcollyar



www.facebook.com/DeborahCollyarAuthor