The 5Ts
A Framework to Support Inclusion of Older Adults in Research

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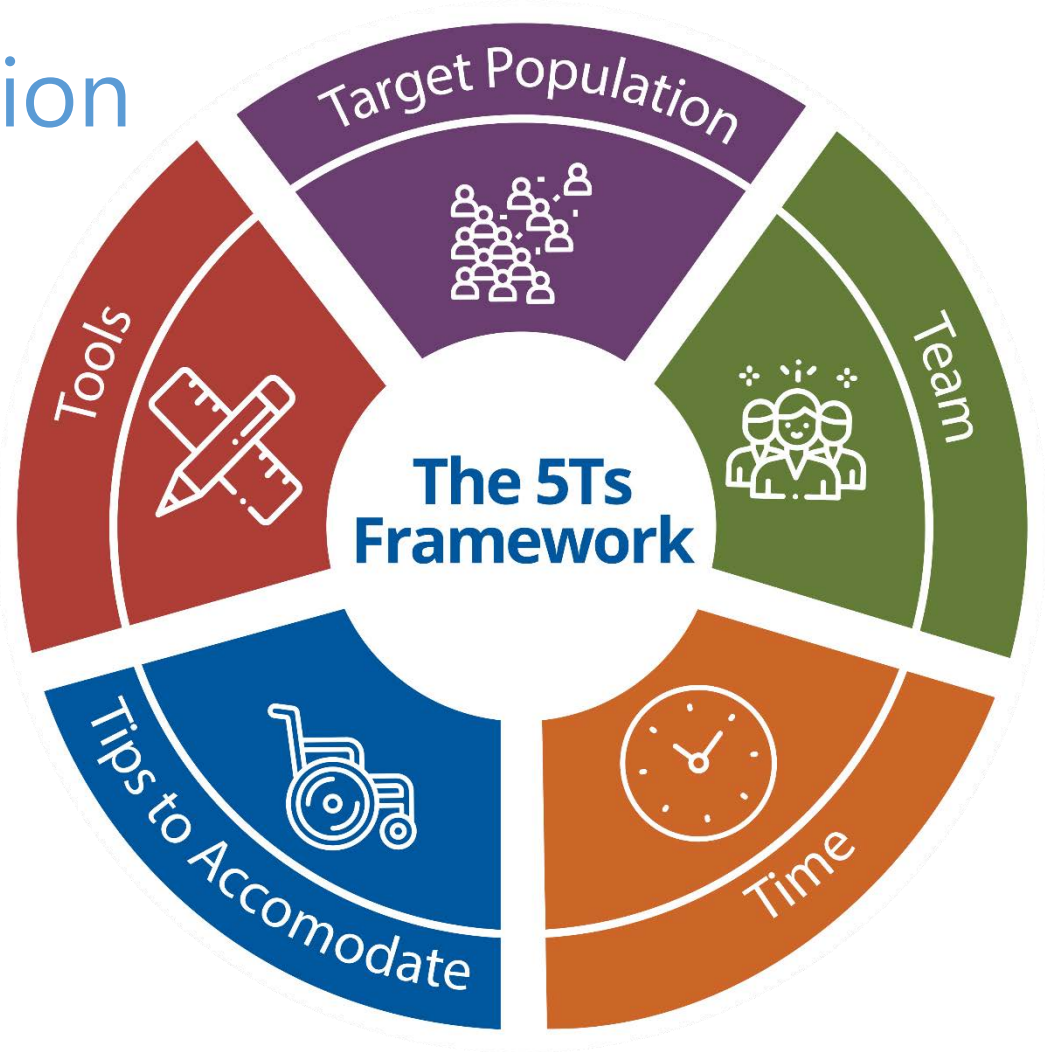


Learning Objectives

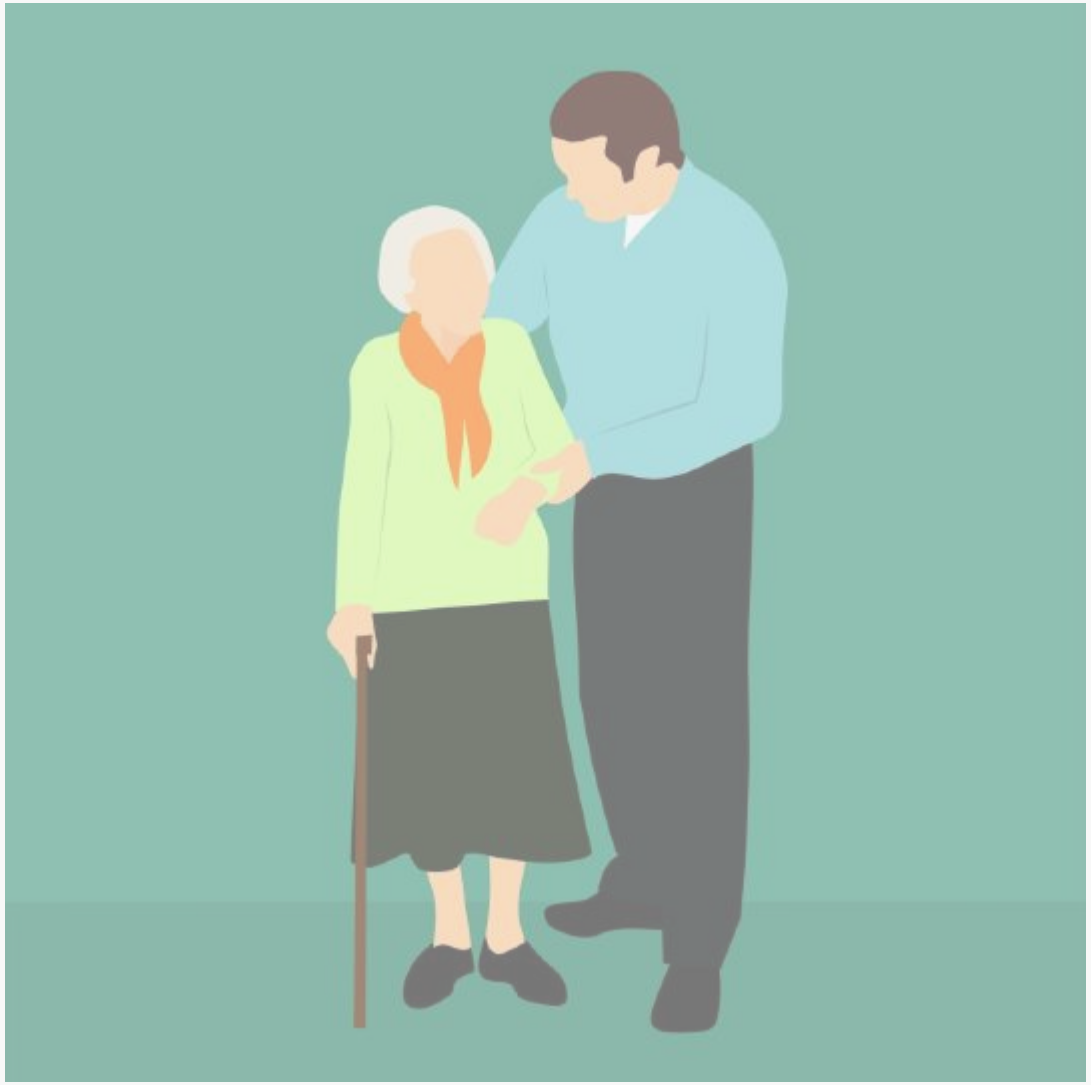
By the end of this session, you should be able to:

- ✓Discuss case examples related to recruiting older adults
- ✓Recognize the scope of the problem (why) and how the 5Ts were developed
- ✓Define the 5Ts
- ✓Identify ways to apply the 5Ts to your study

Case: Mrs. B

Mrs. B is an 83 year old retired school administrator. She has a medical history that includes knee arthritis, age-related macular degeneration (vision loss), high blood pressure, and osteoporosis. Her daughter accompanies her to clinic visits.

Mrs. B's primary care doctor's office is part of a large medical center conducting clinical research. She may be eligible for a clinical trial for a new medication.



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Mrs. B's primary care doctor's office is part of a large medical center conducting clinical research. She may be eligible for a clinical trial for a new medication.

- What barriers to participation might she face?
- What challenges might our research staff have enrolling her?
- Why might she want to participate? or Why not?
- What else would be helpful to know about Mrs. B?
- Should older adults like Mrs. B even be included in research studies?

New York Times Headlines

The Clinical Trial is Open. The Elderly Need Not Apply.

Older Adults May be Left Out of Some COVID-19 Trials

THE NEW OLD AGE column by Paula Span

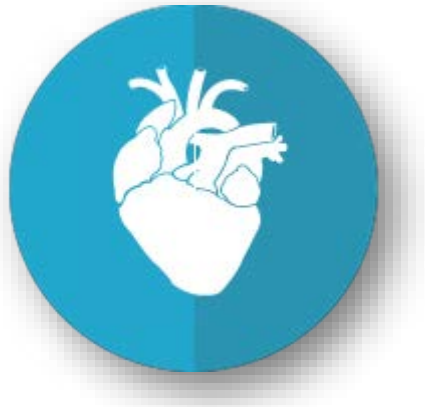
Problem

What is the scope of the problem and why is there concern?

- ✓ Chronic disease increases at older age
- ✓ Older adults often not included in research
- ✓ Research not relevant to the patients who need it the most

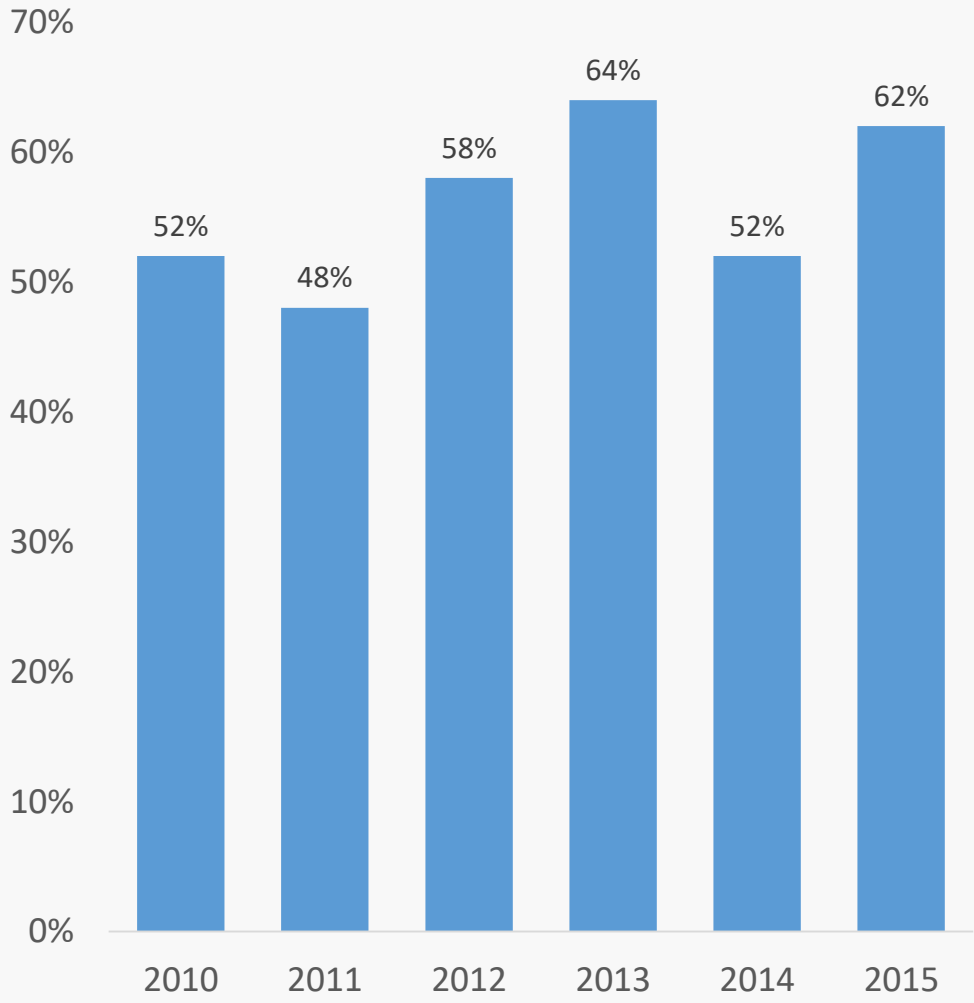
Example 1

Ischemic heart disease drug trials



- 50% of trials have upper age limit
- 40% of patients hospitalized with myocardial infarction are ≥75 years old
- 12% of trial patients are ≥75 years old

Percentage of trials with an upper age limit



Bourgeois et al. J Am Geriatr Soc. 2017

Example 2

Type 2 Diabetes

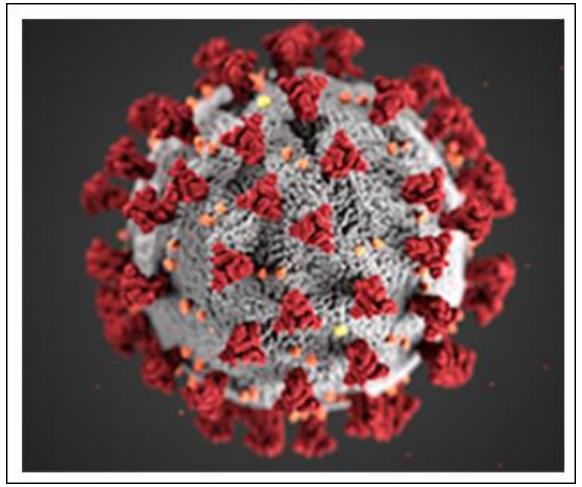
- 77% have exclusion criteria based on comorbidity
- 66% have upper age cut off
- Often do not justify these exclusions

Percentage of Trials with Exclusion Criteria that Disproportionately Affect Older adults (n=440 trials)	
Comorbidity	77%
Upper age limit	66%
Polypharmacy	30%
Cognitive impairment	18%
Short life expectancy	9%
Physical limitations	8%

Cruz-Jentoft et al. J Am Geriatr Soc. 2013

Example 3

COVID-19



- All vaccine trials have exclusions that would limit inclusion of older adults
- Older adults account for 80% of COVID-19 deaths

61% of vaccine trials had an upper age limit for study inclusion

Upper age limit	Number of vaccine trials
≥ 55 years	3
≥ 60 years	4
≥ 65 years	1
≥ 70 years	0
≥ 75 years	1
≥ 80 years	2
No age exclusion	7

Heflin BKI et al. JAMA Internal Medicine. 2020

New NIH Policy: age cutoffs not allowed

"It is the policy of NIH that all ages, including children and **<u>older adults</u>**, must be included in **<u>all</u>** human subjects research, conducted or supported by the NIH, unless there are scientific or ethical reasons not to include them."

Grant submission	Progress report
Plan for including individuals across the lifespan	Provide data on age at enrollment for all participants

Solution

Identify barriers to inclusion

Support investigators and research staff

- Grant planning
- IRB and protocol development
- Recruitment and retention

Develop a framework that can be shared across studies

Not “one size fits all”

We listened to Investigators

Elicited experiences and feedback from research investigators outside of aging research

Main findings:

1. Lack of knowledge about age-related issues
2. Prioritize enrollment targets
3. Focused on one disease at a time

"We are not sensitive to the issues of aging"

"Being in a clinical trial is a big commitment"

"We could make special allowances if older age is *really* important – otherwise just don't include them"

"Is there a framework for thinking about older adults in research?"

We listened to Research staff

Elicited experiences and feedback from research coordinators

Main findings:

1. Positive and enthusiastic about a framework
2. Need to tailor delivery of framework

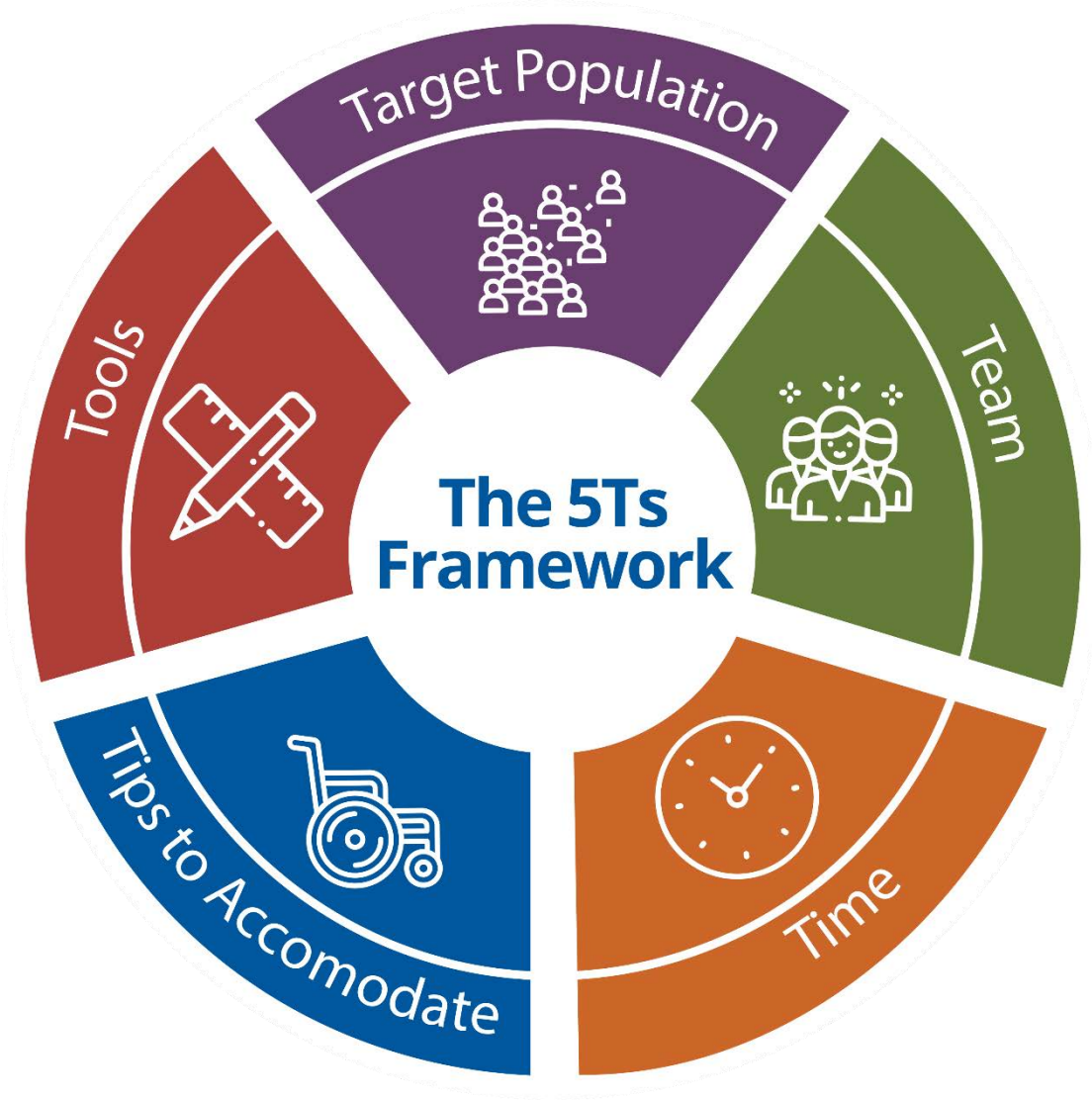
We listened to Older adults

Elicited experiences and feedback from adults ≥ 70 years old

Main findings:

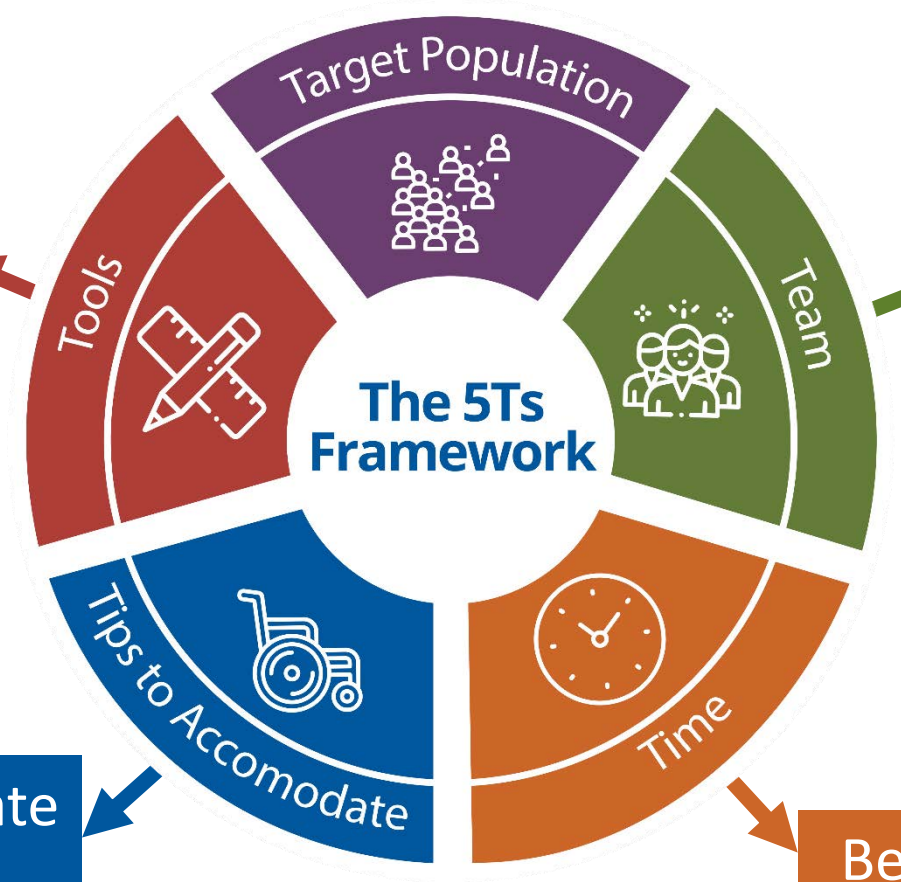
Older adults

1. Are **motivated** by personal reasons
2. Assess the **inconvenience** based on personal context


Target Population
Team
Time
Tips to Accomodate
Tools
The 5Ts Framework

Know about the “at risk” or “real-world” population

Use helpful aids and study materials and measure outcomes that are important to older adults

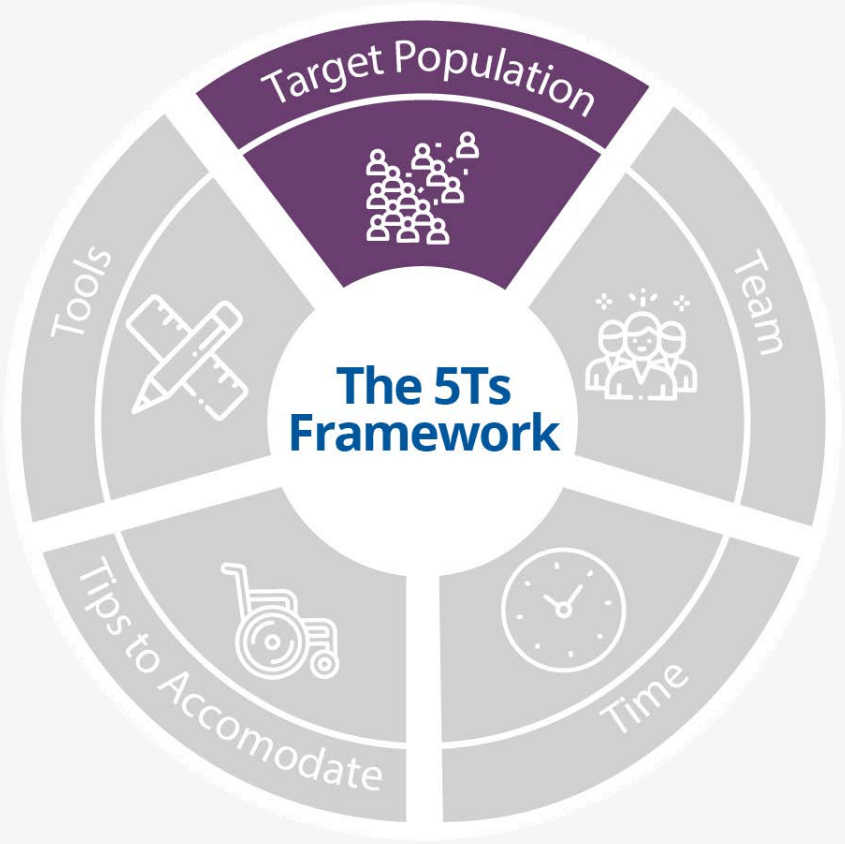


Build and train teams that know about older adults

Follow practical tips to facilitate recruitment, retention, and meaningful participation

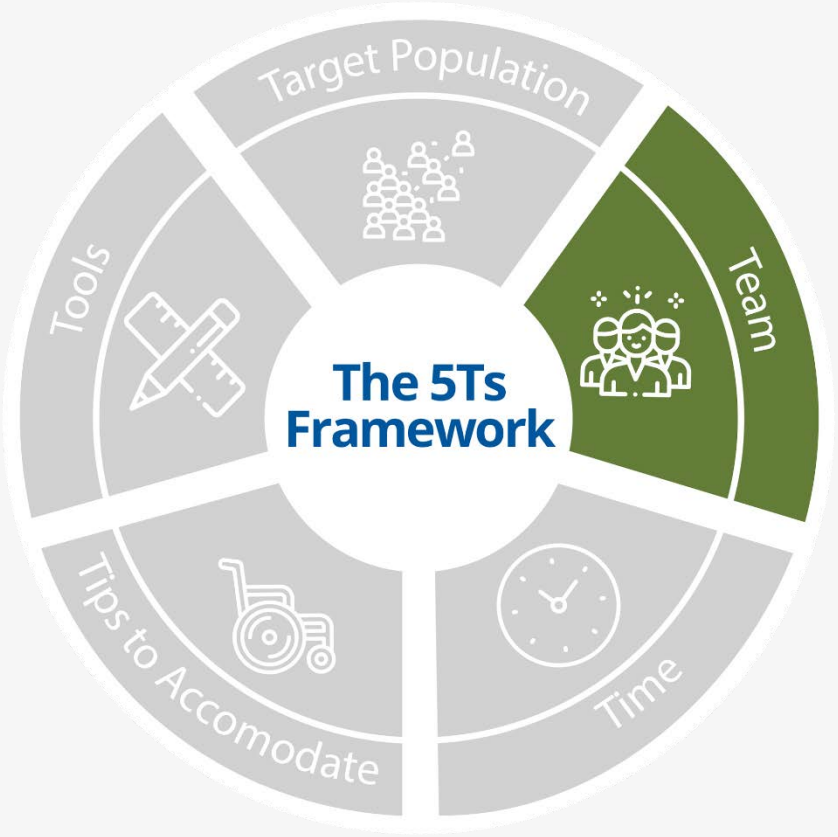
Be flexible, set the right pace, and limit time requirements

Target population



- Avoid exclusion criteria that limit study generalizability
- Provide a justification for upper age cut-offs or exclusion criteria that affect older adults
- Know the prevalence and incidence of the studied condition in older adults
- Know the demographics of the target population and geographic area with regards to average age, age range, gender, race, and ethnicity
- Estimate the prevalence of sensory, functional, and cognitive limitations in the target population
- Estimate the prevalence of common, co-occurring chronic conditions in the target population
- Recognize the range of cultural and religious beliefs and preferred languages of members of the target population
- Understand common motivations for research participation including personal relevance of the study focus
- Understand concerns about participating in research among members of the target population

Team



- Engage experts in aging research at all stages of the study and to serve on safety monitoring boards
- Assemble study teams with experience and skills interacting with older participants at all study stages including recruitment, enrollment, data and specimen collection, or intervention delivery
- Train team members to recognize and accommodate age-related sensory, functional, and cognitive limitations
- Build culturally competent and inclusive research teams that include members of the target community
- Involve participants, their family, their caregivers, or their community advocates as active members of the team
- Engage participants' health care providers, when appropriate, to allow them to advise their patients about study participation

Time

Be flexible with timing

- Be understanding that it may take longer to schedule follow-up visits as participants often require assistance from others for transportation and scheduling
- Allocate time for study staff to provide updates, reschedule missed visits, obtain missing study measures or devices and connect with participants who have had an acute health event requiring hospitalization or post-acute care in a skilled nursing facility

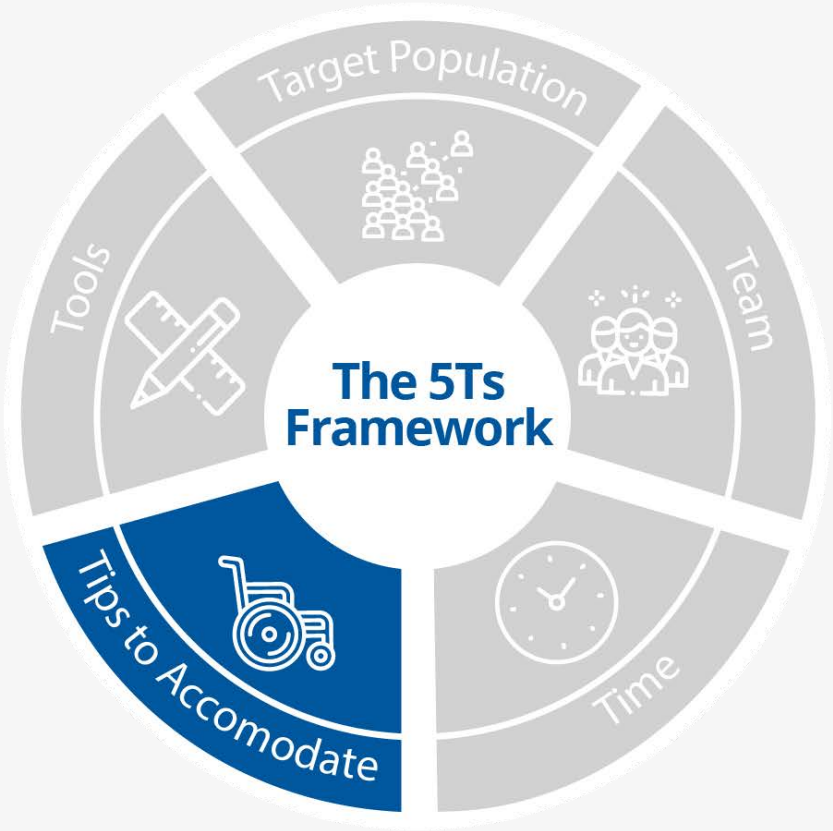
Set the right pace

- Plan for appropriate screening time and lower response rates
- Plan for initial time to educate participants about research in general before discussing the specific study procedures
- Allot enough time for decision making during the informed consent process and provide opportunities for participants to seek advice from family, caregivers, or their health care providers
- Anticipate longer study visits for some participants

Limit time requirements

- Limit the number study measures
- Use the briefest study measures when possible to reduce burden
- Avoid adding study measures that address unplanned future research questions

Tips to accommodate



__Ask__ about limitations and __Plan__ to accommodate

General tips

- Provide door-to-door transportation
- Meet participants at the entrance and escort them
- Identify study locations that are convenient for participants
- Consider caregiver needs including convenient drop off locations

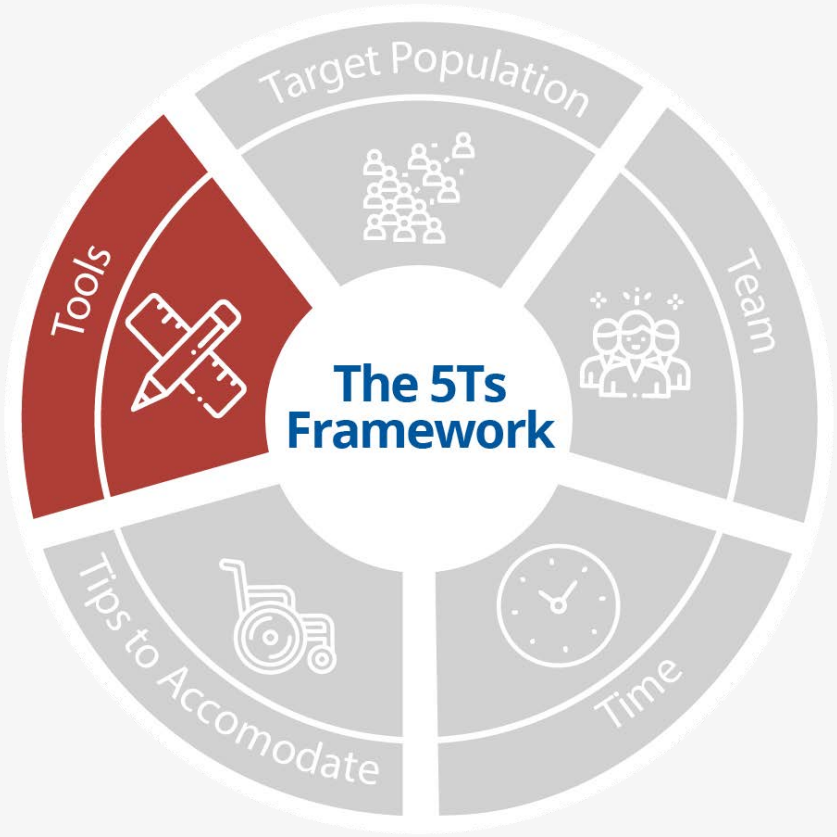
Sensory, functional, and cognitive limitations

- *Hearing*: Use a standardized hearing protocol
- *Vision*: Bring reading glasses to study visits, Use high-contrast written materials (black font/white background) and large font size
- *Mobility limitations:* Choose study locations that are close to parking, do not require stairs, or long walking distances
- *Functional limitations:* Ask about other limitations that might affect the participant's ability to complete study assessments
- *Cognitive limitations:* Recognize signs of cognitive impairment, Consider use of proxies for data collection if cognitive limitations prior to enrollment and obtain permission to contact proxies if limitations develop

Participants with chronic conditions

- Recognize and address participant concerns about how participation may impact their other health conditions
- Advise participants whether or not to take regularly prescribed medications prior to attending study visits

Tools



Tools for recruitment and enrollment

- Create personalized recruitment materials when possible
- Consent documents that include pictures of study tasks
- Two versions of consent – one shortened, bulleted summary for easier reference
- Postage-paid envelope to return signed consent after review at home
- Proxy consent form template
- Electronic enrollment tracking system with capability to provide periodic enrollment reports by age

Tools for data collection and follow-up

- Visual aids for demonstrating study tasks or measures
- Data collection tools that allow multiple ways to enter data – online, tablet, paper, interviewer entered
- Modified assessments for in-home use

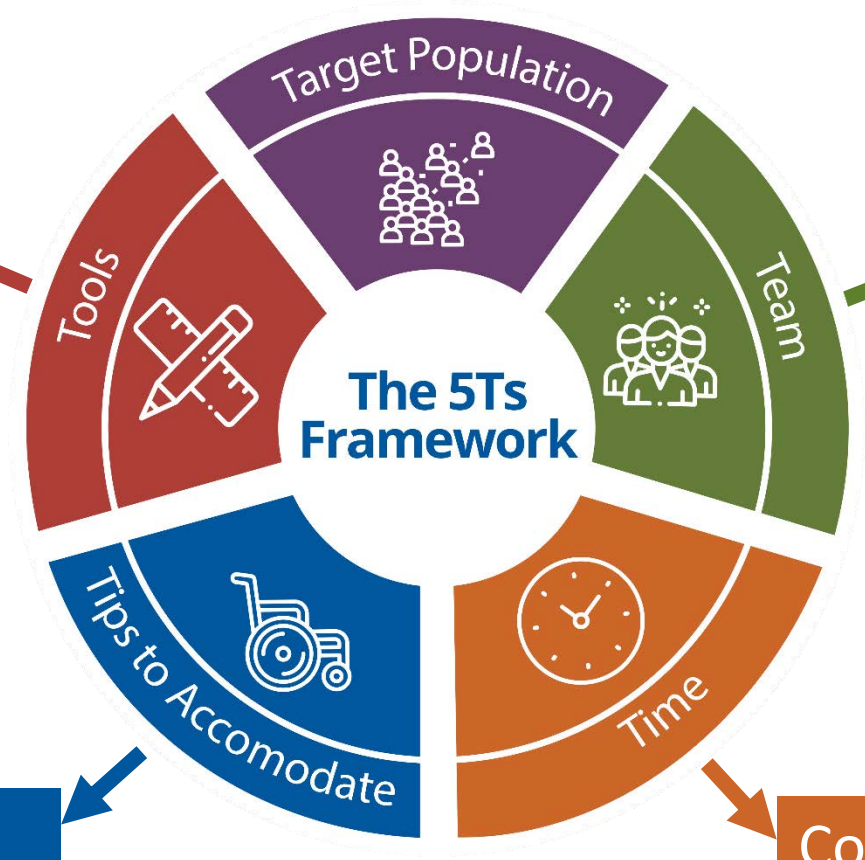
Measurement tools specific to older adults

- Choose tools that measure function, physical performance, and patient-reported outcomes as appropriate. Adapted measures for hearing and vision limitations may be necessary.

Mrs. B

Mrs. B is similar to many patients in the target population

Use a large print visual aid to explain study procedures. Measuring gait speed as secondary outcome.



Our team needs to be prepared to work with participants like Mrs. B. Mrs. B's "team" includes her daughter

Ask: Arthritis limits walking
Plan: Short distance from car to study site, wheelchair escort

Consider Mrs. B's schedule, her daughter's schedule, plan for 1 hour instead of 30 minutes

Applying the 5Ts to your study

- "One size fits all" doesn't work
- Different: study designs, locations, team members, budgets
- Each study (or study site) should review the 5Ts and consider how to tailor for their needs
- Step 1: Answer key questions (5Ts Worksheet)
- Step 2: Develop a plan to address

5T	Our plan
Target population	
Team	
Time	
Tips to accommodate	
Tools	

5T	Questions	Answer	Plan
Target population	What type of limitations (sensory, functional, etc.) may this population have? How common are they?	About 20% of our target population has hearing loss	Limit exclusions that affect those with hearing loss
Team	What team members will be interacting with older adults? What training do they need? Who else should we include in our "team"?	Clinic research staff, phone interviewer, lab technician	Train team members to maximize speech clarity Contact audiology to discuss voice amplifying devices
Time	How long will the study visits last for someone with no limitations? How long will the study last for someone with sensory or functional limitations?	Longer visits necessary for some participants	Change research staff schedule to reflect need for some longer visits
Tips to accommodate	How, when, where, and what are participants asked to do? How would limitations affect each study step?	Recruiting in-person at busy clinic office	Identify a quiet space or offer different setting Remember: **Ask** and **Plan**
Tools	How will we know if have enrolled the right number of older adults?	Not sure	Report number of older adults enrolled at monthly recruitment meetings

Summary

For research to have an impact, older adults **must be included**

Barriers to inclusion are **common**

Each study may face a **different set of challenges** and **solutions** may be different

The 5Ts Framework can help teams anticipate and address common challenges

Thank you

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