

Designing Clinical Trials for Older Adults

➤ What has worked

- Dedicated trials for Older Patients
 - CALGB 49907¹, MRC Focus 2², Alliance 171601
- Minimize exclusion criteria: let patient/doctor decide
- Trials for Vulnerable Patients (Dr. Mohile)

➤ What does not work

- Reminders and other unneeded sensory input

Success: A171601 Alliance

- Cooperative Group Based (PI: Sedrak - [NCT03633331](https://clinicaltrials.gov/ct2/show/study/NCT03633331))
- Question: What is the effect on function and toxicity of palbociclib and endocrine therapy in women 70 and older?
- Problem: In pivotal registration trial only 37 pts ≥ 65
- Pragmatic trial
- Funding NCI NCORP
- Accrual completed using multiple sites
- A successful prototype for other trails now ongoing.

Older Adult Relevant Endpoints

- Expansion Cohort for successful Phase III trials
 - Establish reasonable 95% CI for toxicity in 65 and older
 - Key for new agents
- Functional change
 - Incorporate the GA or relevant domains
 - Patient reported outcomes
 - Chronic Toxicity: neuropathy, fatigue
- Value: Was it worth it?

