SPEAKout

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Including the Elderly in Clinical Trials:

A Challenge for the Ages, Solutions for Today

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If someone came to you with an "unprecedented" challenge "without parallel in human history," would you step aside or would you rise to meet it? That is how the United Nations has described the growth of the aging population and its predicted impact on many facets of life, including healthcare. By 2050, the global population aged 60 or older is estimated to triple, reaching nearly 2 billion. In the United States, about 10,000 Americans turn 65 every day.

Champions of patient care should be concerned not only with whether people are living longer but also with whether they are living well. By opening the avenues of discovery for potentially new therapies, clinical trials are essential to those systems that can enhance quality of life for older adults.

What's the Issue?

The highest burden of chronic disease is among older adults, for whom heart disease, cancer, and respiratory disease are reported as the leading causes of death. However, older adults are often excluded from participating in clinical trials, with seemingly arbitrary age cutoffs built into the enrollment criteria.

When geriatric care providers make medical decisions based on data derived from trials limited to younger adults, the problem of risk–benefit guesswork arises. That's because an older patient may respond differently from a younger patient to the same drug because of the older patient's age-related physiologic changes and comorbid chronic conditions and other medications (polypharmacy). So, in the absence of sound evidence to support prescribing decisions, the door is often left open for potentially inappropriate or harmful drug use by older adults, which increases their risk of adverse drug-drug and drug-disease events and, consequently, morbidity, death, and increased healthcare costs.

Overcoming the Exclusion Drivers

There are many obstacles that have driven the exclusion of older adults in clinical trials, but they may not be impassable with the proper planning and creative approach.

Medical complexity

The risk of adverse events leading to study withdrawal or death may be higher among older adults because of polypharmacy and comorbidity. Reduced life expectancy may also complicate protocol design.

How to overcome it: The FDA has provided guidance on this issue (available at http://bit.ly/2c1DIKv). Here are a few of their suggestions:

- Discuss the need for geriatric data during drug development and in the marketing application submission
- Discuss a plan to collect postmarketing data of geriatric patients if enrollment efforts are unsuccessful

Lack of access and support

Many older adults may not have transportation to get to and from study visits. They may also lack other physical resources, such as at-home caregiver support, which is needed to comply with a protocol.

How to overcome it: Site staff in a trial can empower caregivers by communicating with them early and often about the requirements of the trial and discuss any barriers that may affect their loved one's ability to complete the trial. Site staff can also connect participants and their caregivers with local transportation services. (See a list at www.disability.gov/can-get-help-finding-ride.)

Inadequate education

It is essential that trial participants of all ages clearly understand an informed consent form. This form can be overwhelming and confusing to even young and otherwise healthy people. In addition, vision and thought-processing abilities tend to decline with age and may be more impaired in older patients who have cognitive disorders or diseases.

How to overcome it: All recruitment and retention materials must be written and designed to meet the unique health literacy needs of older adults. Here are a just few ways to do so:

- Emphasize the "need to know" points
- Use culture-specific, age-appropriate examples or analogies
- Ensure the material's design is free of clutter and uses large text and high-contrast colors
- Present content logically and used bulleted lists

From a trial's design to its conclusion, it's critical to identify the potential limitations and plan ahead for solutions so that geriatric patients may be better represented in clinical trials. Remember, nearly 2 billion people will be at least 60 years old in 2050. To industry leaders, this number should be a call to action—both to seize an important market opportunity and to meet urgent therapeutic needs.

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