**Table 1. Identified major gaps and potential solutions for new drug evaluation in older adults**

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| **Identified Gaps** | **Potential solutions** |
| Insufficient enrollment of the oldest group (e.g., over age 75 years) and those with frailty, multimorbidity as well as polypharmacy in clinical trials  Lack of accepted criteria for “representative” population for clinical trial enrollment | * Eliminate unnecessary eligibility criteria * Reduce barriers to participation * Improve perceptions of and access to drug evaluation research * Expand relevant research efforts to settings providing long-term care * Address Ethical concerns * Establish enrollment goals based on prevalence of intended indication and feasibility * Define geriatric relevant terms and conditions and preferred methods of measurement |
| Unknown effect of aging on PD and of common chronic conditions on PK and PD in older adults (e.g., multimorbidity, polypharmacy, frailty) efficacy, and safety | * Obtain clinical pharmacology data early enough to guide study design * Apply model informed approaches to guide drug development * Obtain PD data in trials, including older age pertinent outcome and safety measures for drug use and discontinuation * Conduct subgroup analyses of trial data by age and common geriatric conditions for PK, PD, effectiveness, and safety * Evaluate continuously safety and effectiveness in older adults with real-world data * Update timely drug labels to include new information throughout the product lifecycle |
| Absence of patient-centered endpoints important to older adults | Engage older adults, their caregivers, healthcare providers, especially geriatric healthcare experts, and patient advocates to identify endpoints of importance to them |