Barrier

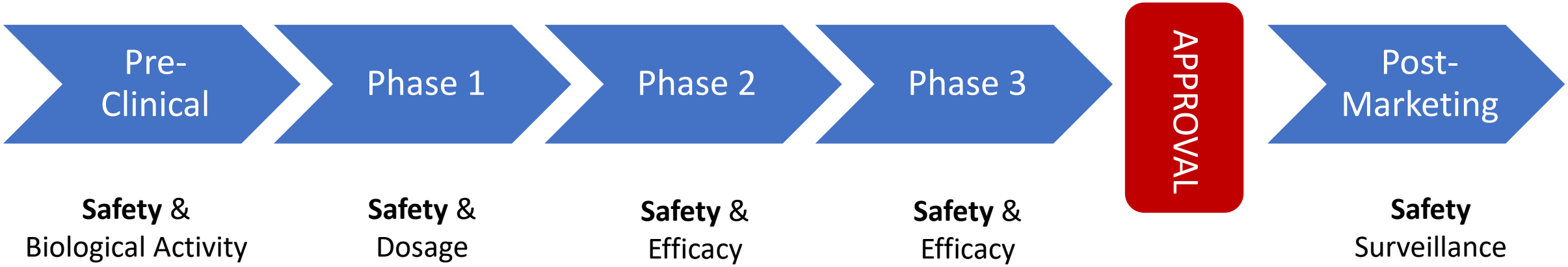
Providers are reluctant to enroll older adults because they are concerned for risk of increased toxicity

A potential solution

Establish pre- and post-marketing studies that embed aging as a focus in the lifecycle of drug development

Providers are more willing to put older (and frail) patients on pre- and post-marketing trials that are specifically designed for this special [high-risk] group

An aging focus in the lifecycle of FDA-regulated products



Potential Strategies to Minimize Risk and Improve Safety Data for Geriatric Patient

- Pre-clinical safety data to understand drug impact on aging biology (beyond chronological age)

- Parallel (ancillary) older adult-specific cohort
- Extended (expansion) older adult-specific cohort
- Concurrent differential dosing studies in older adults

- Registry (e.g., NMRI)
- Single-arm, open-label