OBJECTIVE

Loss of function and diminished quality of life are overarching fears for most older people. Both of these threats are hallmarks of sarcopenia as it is currently understood. At present, the U.S. Food and Drug Administration (FDA) does not have a policy on sarcopenia and there are no drugs approved for this disease. Any clinical trials for sarcopenia must demonstrate that a treatment improves how patients with the disease feel, function or survive.

Patient-reported outcome (PRO) measures are potential endpoints to support regulatory assessment of sarcopenia treatments. PROs may be most relevant to measuring improvement in ambulatory function and quality of life. The primary goal for this meeting is to highlight progress toward defining sarcopenia as a disease and advancing performance-based outcome measures (like SPPB and Gait Speed) while exploring how patient input and PRO measures specifically, may play a role in clinical trials for sarcopenia treatments.

WELCOME

8:00-8:30 a.m.  Registration and Continental Breakfast

8:30-9:00 a.m.  Welcome and Overview of the AIM Coalition
    Dan Perry, Aging in Motion Coalition

PRESENTATIONS

9:00-9:30 a.m.  Lessons from FNIH Consensus Conference on Sarcopenia and Initiative to Establish a Clinical Definition
    Maria Vassileva, Foundation for the NIH

9:30-9:40 a.m.  Q&A

9:40-10:10 a.m.  Progress on Performance-Based Measures for Sarcopenia and Role of Patient-Reported Outcomes
    Jack Guralnik, University of Maryland
10:10-10:20 a.m.  Q&A
10:20-10:50 a.m.  Principles of PRO Measure Development that Apply to Sarcopenia
                    Donald Patrick, University of Washington, Seattle
10:50-11:00 a.m.  Q&A
11:00-11:20 a.m.  Break

PANEL

11:30-12:30 p.m.  Status of PRO Development and role of PROs for Sarcopenia Treatment Trials
Discussion Leader:  Dana Sue Hardin, Eli Lilly
Suggested Panelists:  William Dale, University of Chicago
                   Jack Guralnik, University of Maryland
                   Bill Evans, GlaxoSmithKline
                   Ashley Slagle, U.S. Food and Drug Administration
                   Donald Patrick, University of Washington, Seattle

• Are there PRO measures in other diseases used to measure direct treatment benefit that are formally qualified by the FDA?
• Would a PRO measure for sarcopenia intended for use a primary endpoint in a clinical trial require qualification by FDA if it meets the criteria laid out in the Agency’s guidance on PRO measure development?
• How has patient input been incorporated into concept selection for existing PRO measures for sarcopenia?
• Has a focus on an older population presented specific challenges for PRO development and use for sarcopenia?
• How well do you feel current PRO measures like the Age-Related Muscle Loss Questionnaire, could demonstrate direct evidence of a treatment benefit?
• Should PROs for sarcopenia be used to measure treatment benefit or to supplement other primary endpoints in a trial?
• How do you feel ongoing research on sarcopenia as a disease will affect the utility of existing PRO measures as primary or supporting endpoints in sarcopenia treatment trials?

12:30-1:00 p.m.  Q&A

CLOSING

1:00-1:30 p.m.  Concluding Remarks
                   Dan Perry, Aging in Motion Coalition

* Snacks will be available during the 11:15 break and boxed lunches will be available at 12:30