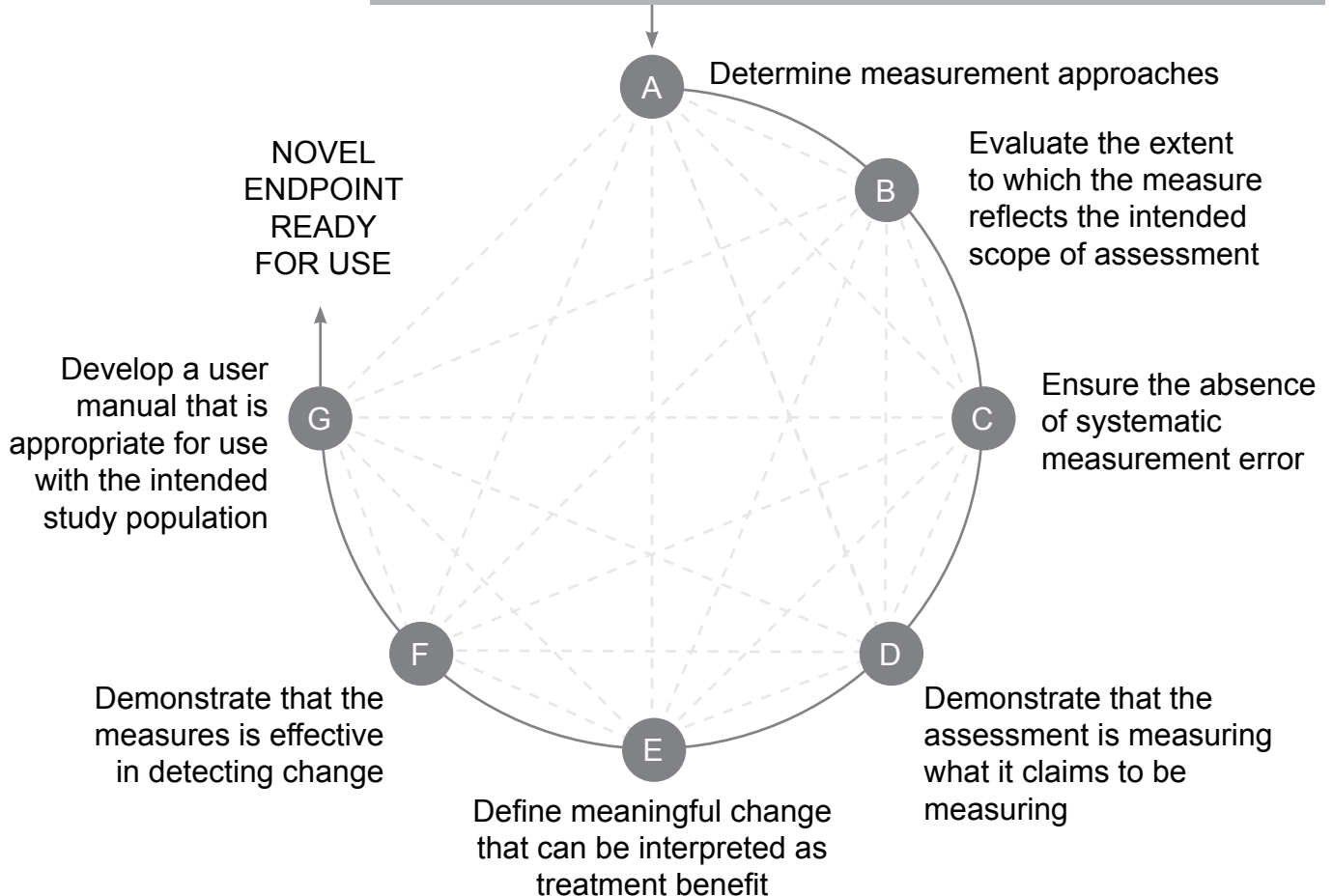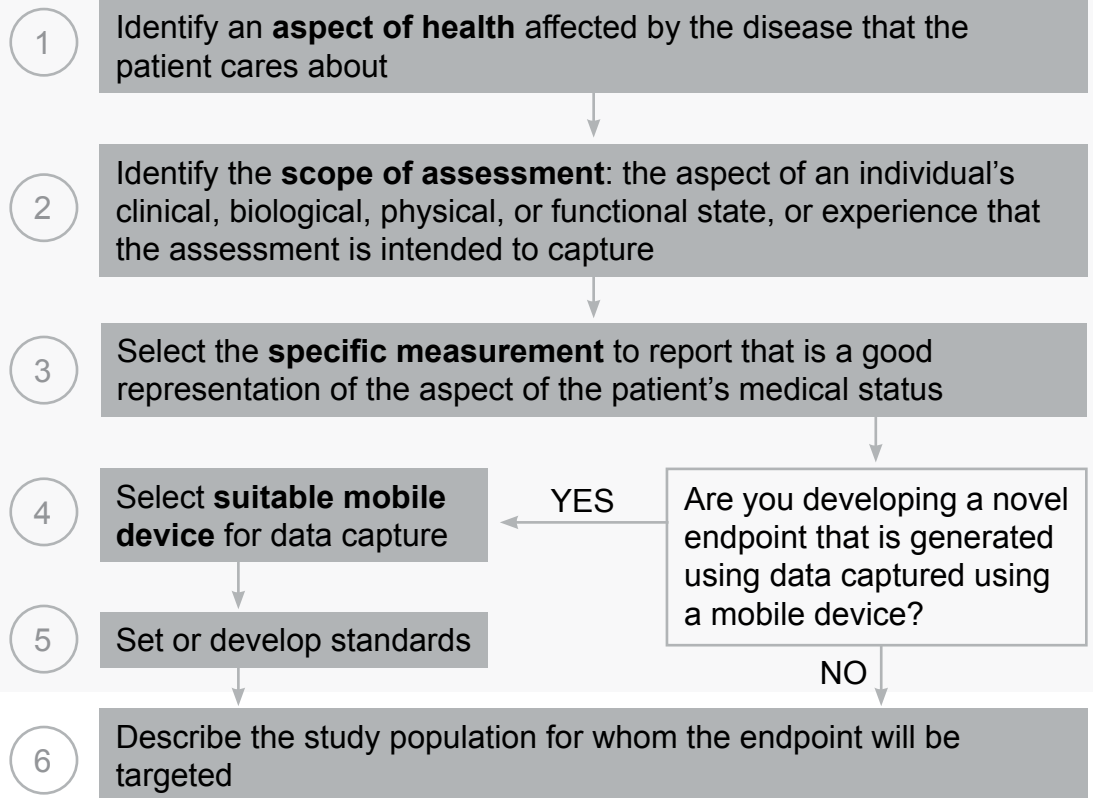# FLOWCHART OF STEPS FOR NOVEL ENDPOINT DEVELOPMENT

First, steps 1-6 should be completed sequentially in the order shown.
Then, steps A-G must be completed, but the order of execution may vary.

To ensure novel and useful endpoints are identified and adopted efficiently, CTTI recommends that these steps occur in a pre-competitive space

1. Identify an **aspect of health** affected by the disease that the patient cares about

2. Identify the **scope of assessment**: the aspect of an individual's clinical, biological, physical, or functional state, or experience that the assessment is intended to capture

3. Select the **specific measurement** to report that is a good representation of the aspect of the patient's medical status

Are you developing a novel endpoint that is generated using data captured using a mobile device?

YES →

4. Select **suitable mobile device** for data capture

5. Set or develop standards

NO

6. Describe the study population for whom the endpoint will be targeted

A — Determine measurement approaches

B — Evaluate the extent to which the measure reflects the intended scope of assessment

C — Ensure the absence of systematic measurement error

D — Demonstrate that the assessment is measuring what it claims to be measuring

E — Define meaningful change that can be interpreted as treatment benefit

F — Demonstrate that the measures is effective in detecting change

G — Develop a user manual that is appropriate for use with the intended study population

NOVEL ENDPOINT READY FOR USE

For more information, including suggested approaches and considerations for each step, see the Detailed Steps document that accompanies this flowchart. Note: Go to Table 1 for steps 1-6 and Table 2 for steps A-G.