

A collaboration with industry members



OBJECTIVES

Evaluate digital measures in key therapeutic areas

Identify evidence gaps

Formulate regulatory strategy for acceptance of endpoint



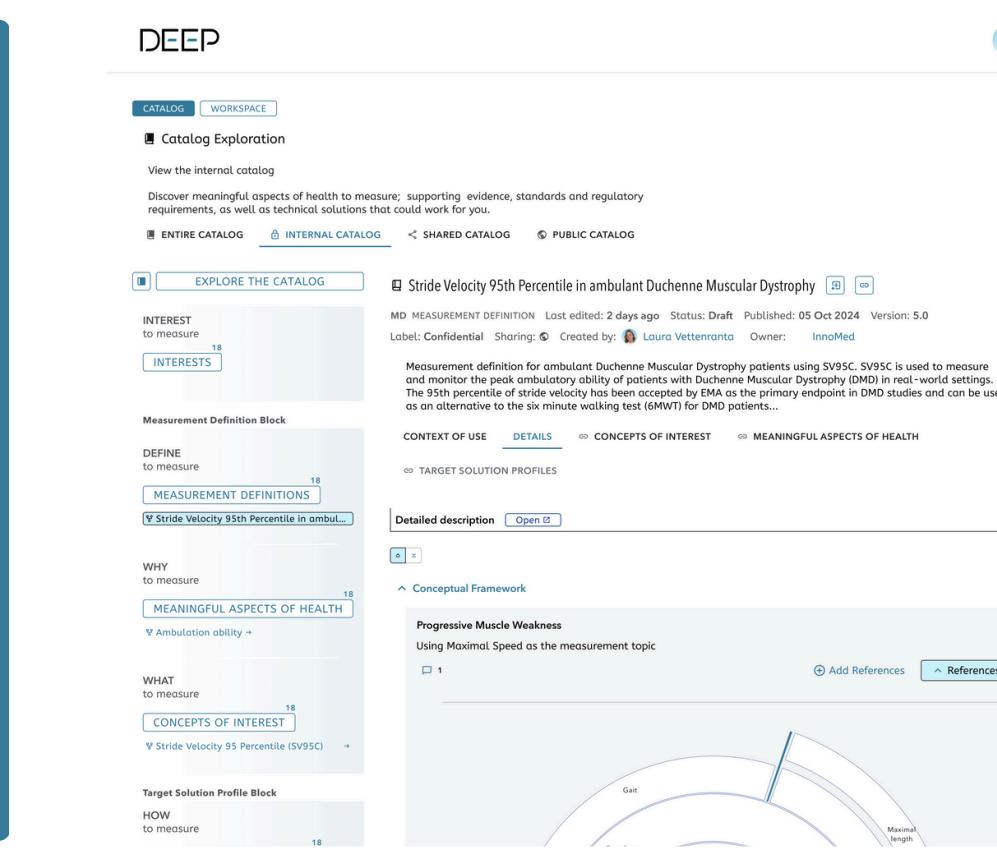
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METHOD

1
Combine insights from academia, public-private partnerships and public sources.
Leverage IHI's IKAA incentive to help industry partners advance research further.

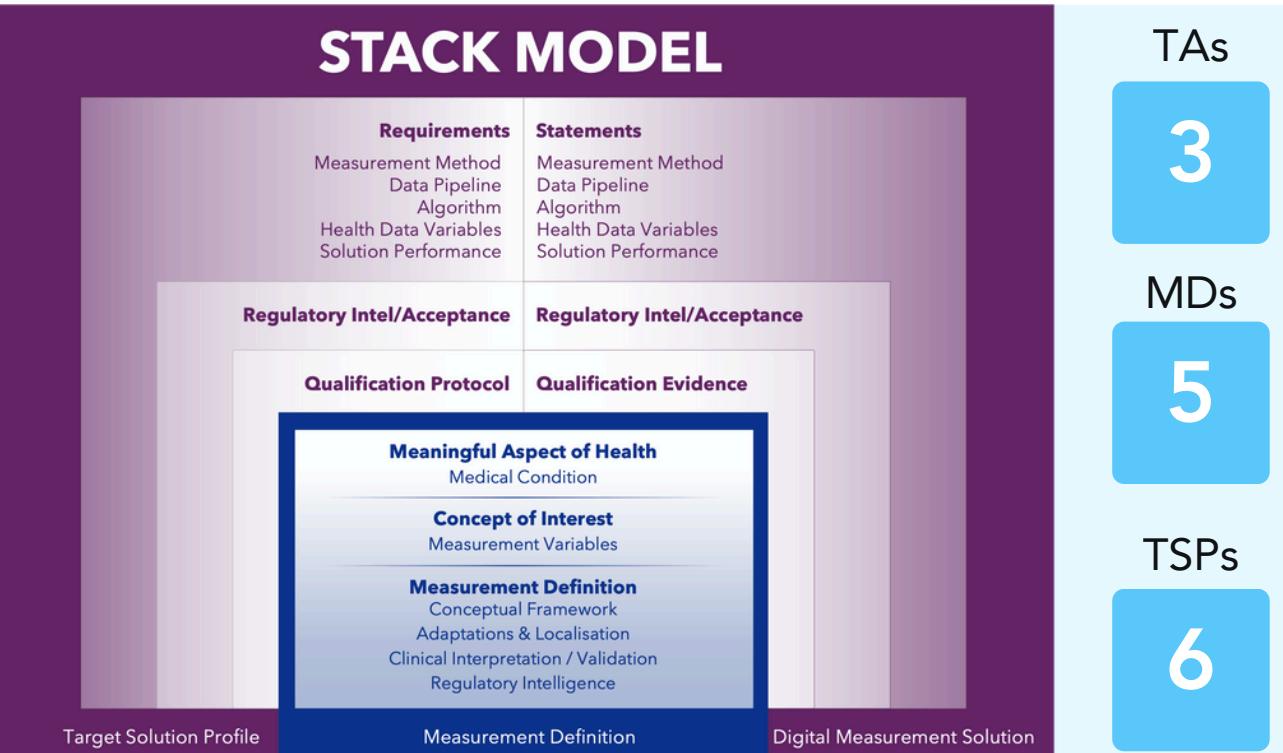


2
Consolidate measure definitions (MD), meaningful aspects of health (MAH) and concepts of interest (COI) from past IHI projects (Mobilise-D, IDEA-FAST, RADAR-AD) & public sources, focusing on physical activity, cognition, and speech.



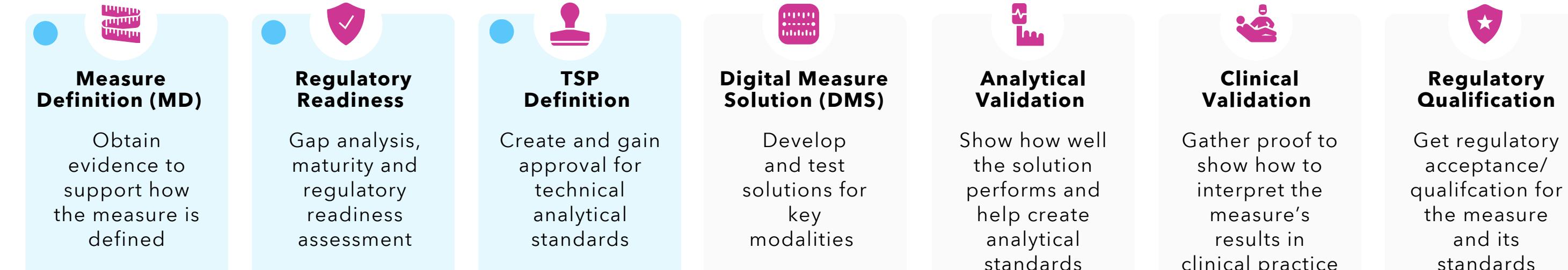
Collaborate with stakeholders via a shared workspace
Use digital measures in clinical trials
DEEP Measures leverages the **Stack Model** to create digital measures

3
Use the DEEP Stack model to structure content, identify gaps and reuse components and measures.



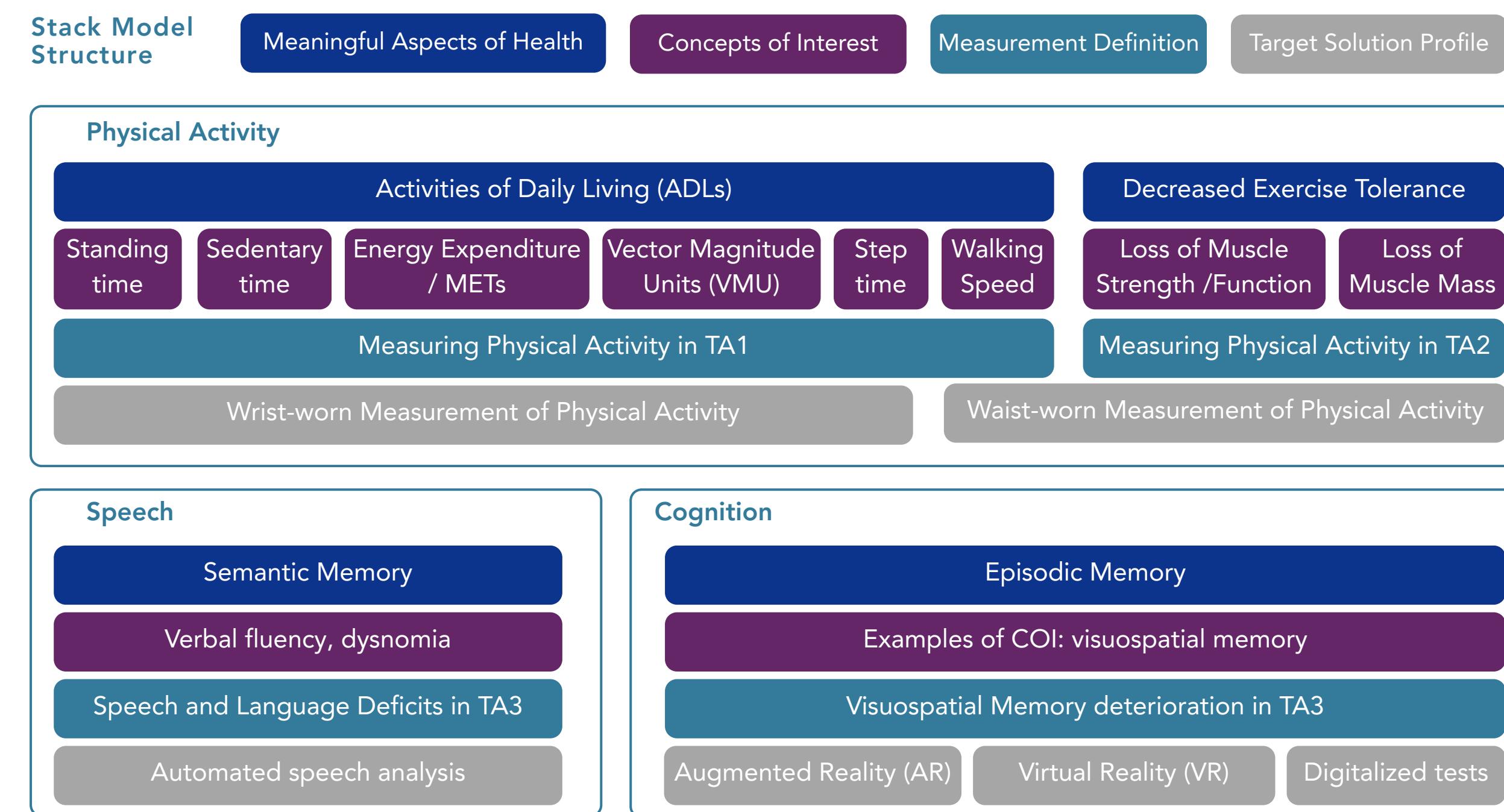
4
Assess regulatory-readiness for digital measures (focus on validation, gap analysis, and risks). Collaborate with industry to integrate assets into targeted drug development programs.

Digital Measure Strategy Framework (DMSF)



RESULTS

- Digital measures in physical activity, cognition & speech for three therapeutic areas evaluated in collaboration with Pfizer and BMS.
- Measures mapped to neurological, metabolic, and respiratory indications.
- COIs for physical activity: activities of daily living and exercise tolerance; for speech & cognition: executive function and memory.
- Developed 5 Measurement Definitions (MDs) and 6 Target Solution Profiles (TSPs).
- Successful real-time collaboration enabled by DEEP platform workspaces.
- Ongoing gap assessments will guide further evidence curation and regulatory strategy.



CONCLUSION

The FCC initiative showcases a scalable and collaborative approach to adoption of regulatory-ready digital endpoints in drug development.

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