

A collaboration with industry members

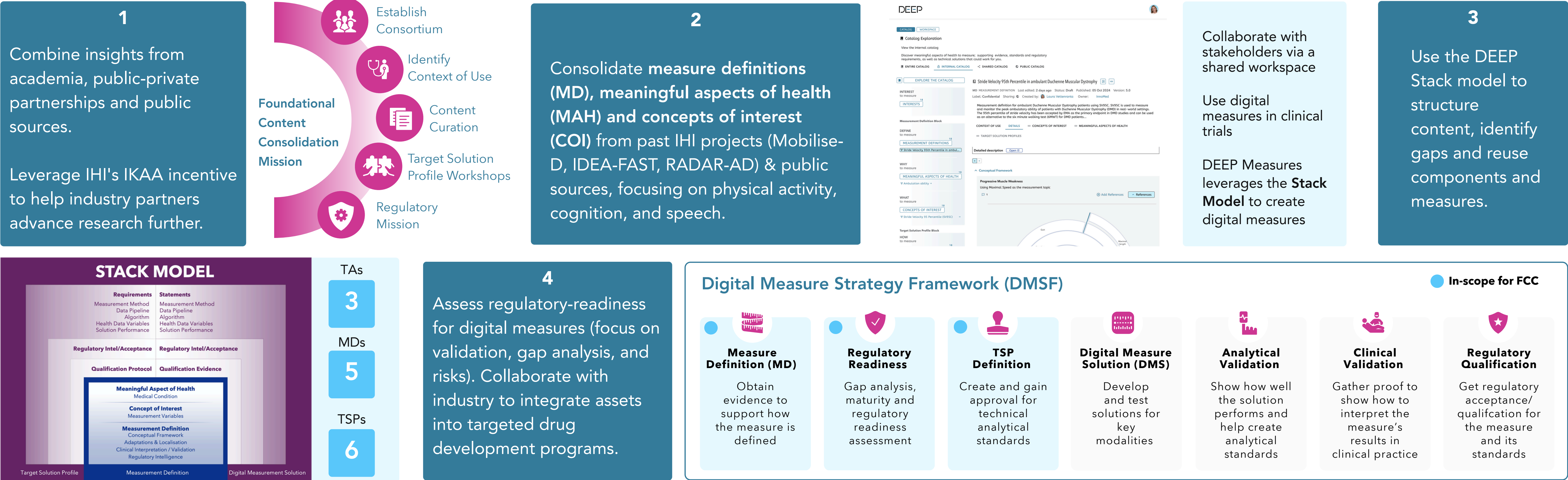


Foundational Content Consolidation (FCC) from Public-Private-Partnerships for Regulatory-Ready Digital Endpoints Across Multiple Therapeutic Areas

OBJECTIVES

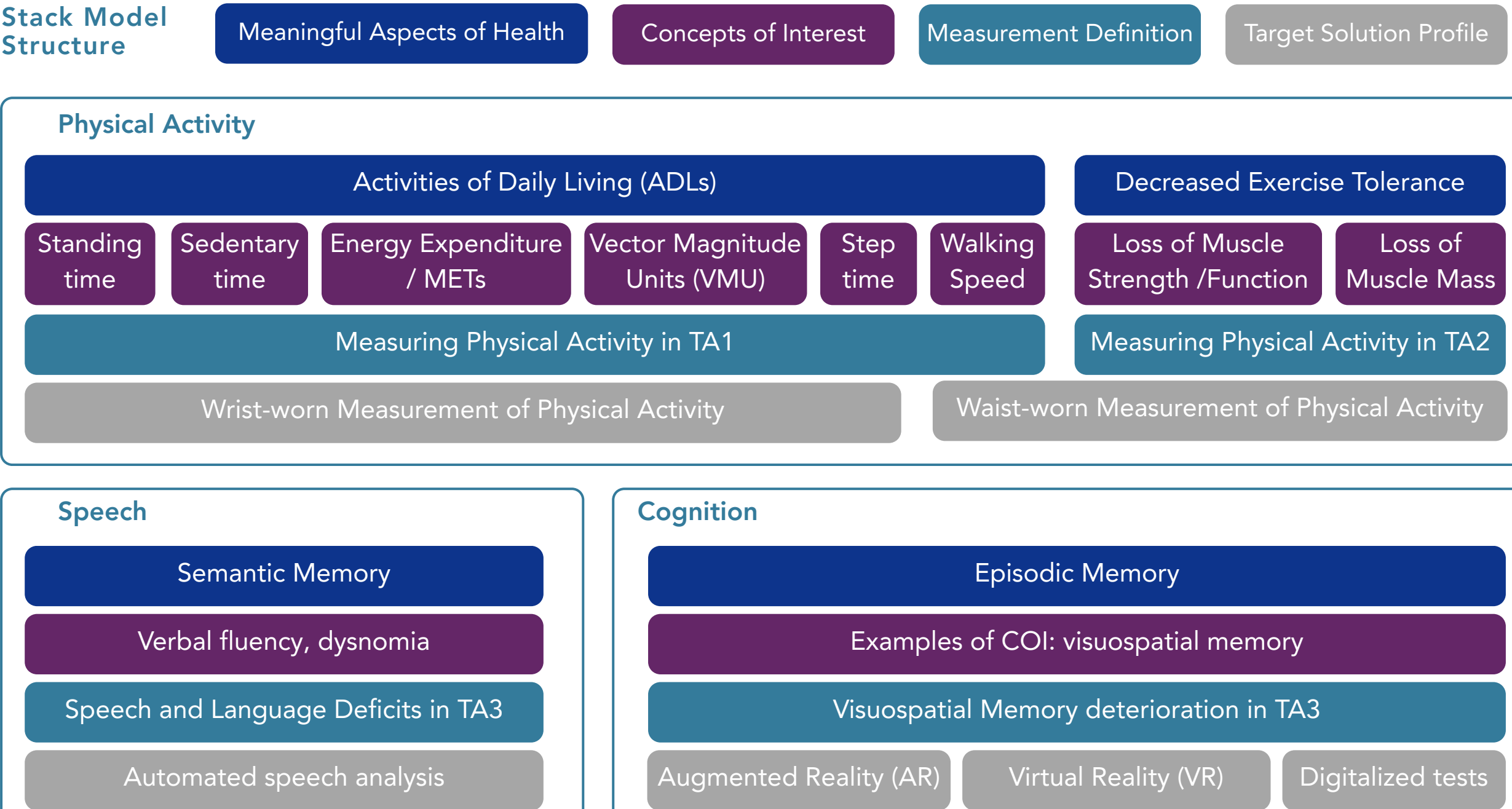
- Evaluate digital measures in key therapeutic areas
- Identify evidence gaps
- Formulate regulatory strategy for acceptance of endpoint

METHOD



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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