



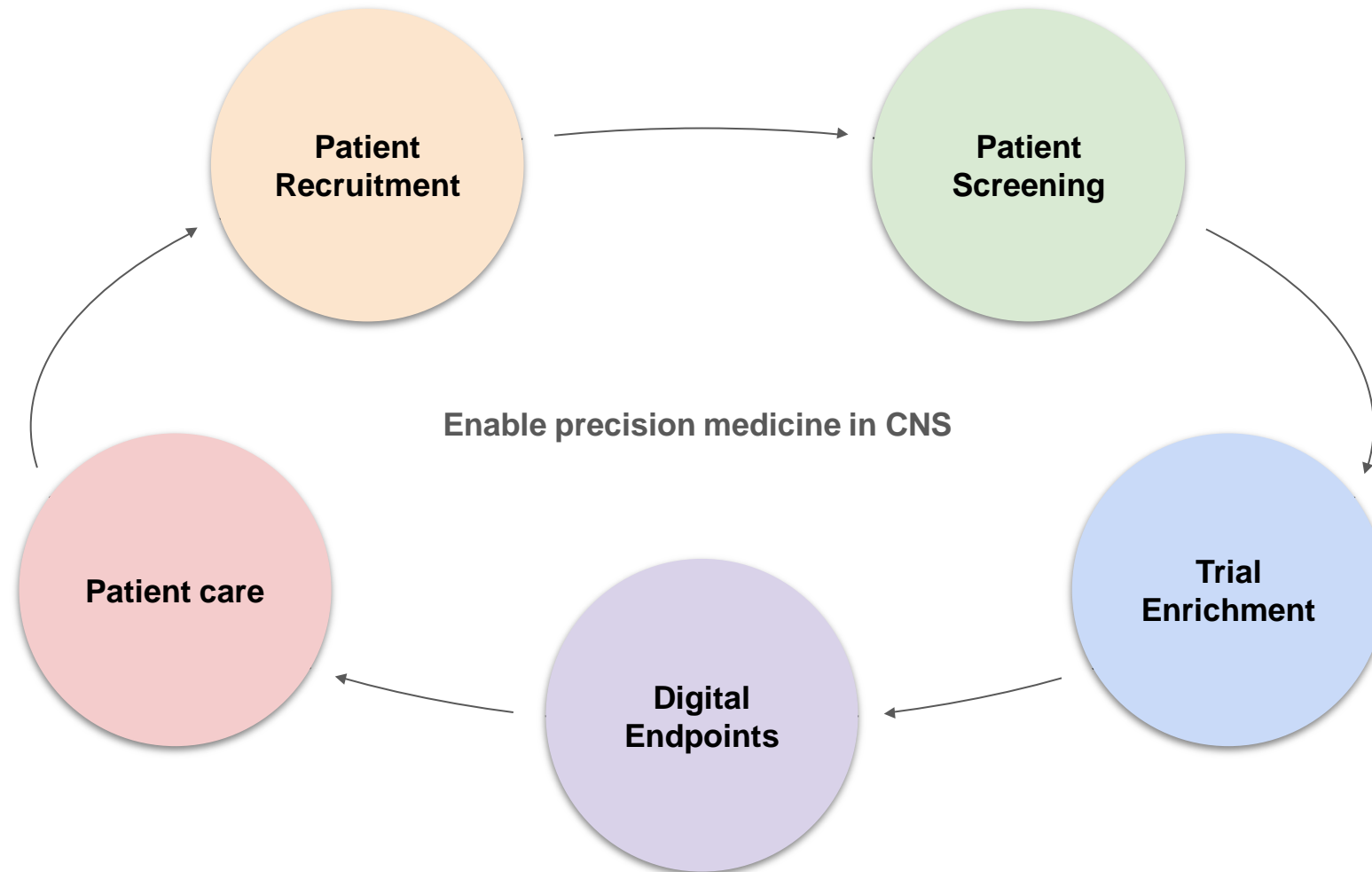
Digital Phenotyping in Clinical Trials: The Path Ahead

Chairs:

Anzar Abbas, PhD

Uma Vaidyanathan, PhD

Broadening the conversation around digital health measures



Summary of Presentations

	Recruitment / Trial Enrichment	Digital Endpoints	Patient Care
<u>Seth</u> : Automated Speech Analysis	X	X	X
<u>Adam</u> : Resting EEG	X	X	X
<u>Isaac</u> : Large Language Models	X	X	X
<u>Brian</u> : EEG platform for real world data collection	X	X	X

Why digital tools?

- Lack of effective treatments due to heterogeneity & comorbidity
- Non-invasive and increased convenience for participants
- Real time measurement and trajectories of symptoms
- Growing body of scientific evidence
- Can be used for multiple indications
- Scalability

Design Considerations

- Ease of use of software/tool
- Age affects on use of tool/device
- Evidence base
- Population of interest
- Clinician in the loop?

Regulatory perspective

- Contact FDA early
 - Define target population and indication for use
 - Safety & effectiveness criteria
 - Clearly specified outcomes
 - Special programs such as Medical Device Development Tools (MDDT), and Biomarker Qualification Program

Thanks for your time!