A The Role of Digital Health Technologies in Drug Development – *A Workshop*

Discussion Tool

Background: This discussion tool is intended to help workshop participants organize their thoughts about the opportunities and challenges for integrating digital health technologies throughout the drug research and development (R&D) lifecycle. Participants are asked to consider the following workshop objectives:

- Highlight critical barriers or 'pain points' along the drug R&D lifecycle for which digital health technologies may be uniquely suited to address;
- Consider lessons learned from currently validated digital health technology applications that could be generalizable for newer digital health technologies;
- Consider opportunities to enable the practical application of digital health technologies for improving drug development (e.g. sharing best practices for the validation and use of digital health technologies, harmonizing guidelines across sectors);
- Consider strategies to determine the evidentiary criteria for selecting digital health technologies that are fit for purpose in drug development (e.g. examining existing frameworks);
- Discuss privacy, ethical, and regulatory issues related to the use of digital health technologies.

Instructions: The following table is organized by session topic (rows) and workshop objectives (columns). If time permits, please review and consider prepopulating the table in advance of the workshop. You are welcome to seek input from colleagues within your organization as well. The discussion tool will not be collected at the workshop, but you are highly encouraged to share your thoughts during the workshop discussions.

Workshop Sessions	Workshop Objectives				
	Barriers or 'pain points' that could be addressed by digital health technologies	**Generalizable lessons learned/use cases from currently validated digital health applications**	**Best practices for the practical application of digital health technologies**	**Strategies to determine the evidentiary criteria for selecting digital health technologies that are fit for purpose**	**Privacy, ethical, and regulatory considerations**
Session I: Digital Tools for Characterizing Disease • **Deep Phenotyping and Exploratory Research** • **Disease Detection and Stratification** • **Continuous Monitoring of Disease Progression**		• Lessons learned: • Use case(s)			• Privacy Considerations: • Ethical Considerations • Regulatory Considerations
Session II: Digital Tools for Recruitment and Safety Trials • **Identifying and Recruiting Participants** • **Measuring Safety and Pharmacokinetics**		• Lessons learned: • Use case(s)			• Privacy Considerations: • Ethical Considerations • Regulatory Considerations

Workshop Sessions	Workshop Objectives				
	Barriers or 'pain points' that could be addressed by digital health technologies	**Generalizable lessons learned/use cases from currently validated digital health applications**	**Best practices for the practical application of digital health technologies**	**Strategies to determine the evidentiary criteria for selecting digital health technologies that are fit for purpose**	**Privacy, ethical, and regulatory considerations**
Session III: Digital Tools for Pivotal Trials • **Measuring Efficacy and Clinical Outcomes** • **Using Digital Health Measures to Facilitate Interpretation of Clinical Trial Data**		• Lessons learned: • Use case(s)			• Privacy Considerations: • Ethical Considerations • Regulatory Considerations
Session IV: Digital Health Tools for Post-registration Surveillance • **Post-registration Safety Surveillance** • **Patient Adherence in Real-World Settings** • **Deployment of Digital Health Solutions in Health Systems** • **Digital Health Formulary**		• Lessons learned: • Use case(s)			• Privacy Considerations: • Ethical Considerations • Regulatory Considerations