Risk Assessment Model
for Digital Health Product Lifecycle

Digital Health Regulatory Pathways

DIGITAL MEDICINE SOCIETY

					
PRODUCT STAGE	**Planning & Research**	**Design**	**Testing & Validation**	**Production & Manufacturing**	**Post-Launch**
PRODUCT RISKS	Risks during this stage include a lack of market research, lack of understanding of patient needs, lack of consideration of the intended use of the product, failure to identify and include the relevant patient population, and more.	Risks during this stage include design flaws that could lead to injury or harm, lack of consideration of patient safety and usability, and failure to conduct appropriate human factors engineering studies.	Risks during this stage include risk of injury or harm during preclinical or clinical studies, lack of data to support the safety and efficacy of the product for the intended use population, and failure to meet performance specifications.	Risks during this stage include quality control issues that could lead to product failure or malfunction, supply chain disruptions that could lead to product shortages, and failure to meet manufacturing standards that could lead to unsafe products.	Risks during this stage include product recalls, adverse event reports, and failure to meet post-market surveillance requirements, which could lead to delayed identification of safety issues and increased risk to patients.
RISK ASSESSMENT	*During Design*		*During Development*		*During Post-market Use*