Information Needed for the MedTech & Digital Health Innovation Study

Before starting the survey, please acquire the following information on cost, dates, and time to complete the milestones below. Some regulatory and clinical milestones may not apply, depending on the product.

Product Information:

1. Product Name: _____
2. Regulatory Filing Number (e.g., K123456 for 510(k) or P123456 for PMA): _____
3. Regulatory Pathway – US only (e.g. 510(k), PMA, De Novo) _____
4. Risk Class (e.g. I, II, III) _____
5. Medical Panel (e.g. Cardiovascular, Neurology, etc.) _____
6. Special Programs or Designations (e.g. Breakthrough, Pre-Cert, etc.) _____

Regulatory Milestone Dates for US FDA, EU CE Mark, Japan PMDA, and China NMPA:

7. Date of first contact with regulatory authority (e.g., FDA, CE Mark, PMDA, NMPA): _____
8. Date of regulatory submission for product: _____
9. Date of regulatory decision / approval: _____
10. Date of commercialization: _____

Reimbursement Information (US Only):

1. Did a reimbursement code exist at time of regulatory approval? _____
2. How is the product reimbursed? (e.g. Medicare, Medicaid, Private, Self-Pay) _____
3. If reimbursed, does the product receive partial or full reimbursement? _____

Company Information:

1. Company Name: _____
2. Business Unit Name (if applicable): _____
3. Organization Size (# employees): _____
4. Company Revenue (2020): _____

Funding and Time to Regulatory Clearance / Approval

1. Total funding from concept to regulatory clearance/approval ($M USD) _____
2. Total time from concept to regulatory clearance/approval (Months) _____

Average Burn Rate and Time to Complete Development Milestones

Event	Description	Duration (Months)	Monthly Burn Rate ($M USD)
R&D	R&D Start & Completion *(e.g., concept development, prototyping, benchtop & preclinical studies)*		
Clinical Unit Development	Pre-clinical development of product for use in clinical setting (e.g., clinical testing and clinical workflow integration)		
Process to Obtain IDE	Process of obtaining IDE		
FIH / Feasibility Study	First in Human (FIH) and Feasibility Study		
Pivotal Study	Start of Patient Enrollment to Study Completion Date.		
	Total period of Patient Follow-up, from Study Completion Date to Follow-up completion		
Process to Obtain Regulatory Approval	Total time period from regulation application submission to decision and approval received		
Post-Approval Activities	Post Approval Study (PAS)		
	Post Market Surveillance Study (PMS)		
Process of Obtaining Reimbursement	Total period and cost from time of regulatory approval to time of first level of reimbursement achieved.		

This study is strictly an independent research study led by the University of California Los Angeles. The investigators have no conflicts of interest to disclose. Individual company data will not be released to any regulatory bodies or entities. Study results will be published in aggregate for the benefit of advancing innovation in medical technology and digital health. This research has been certified as exempt from IRB review per 45 CFR 46.104 category 2 (IRB#20-001604).