Pediatric Blood Sampling

BME66 SPR'23 Hamida, Tracy, Fatimah, Fariha

Hamida, Tracy, Fatimah, Fariha Wed, 2/22/2023 Project Start: Feb 20, 2023 Feb 27, 2023 Mar 6, 2023 Mar 13, 2023 Mar 20, 2023 Mar 27, 2023 Apr 3, 2023 Apr 10, 2023 1 Display Week: 20 21 22 23 24 25 26 27 28 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 PROGRESS Item# Phase 1 Establish User Needs 1 Product description Fariha, Tracy, Fatima, Hamida 50% 2/22/23 2/25/23 Known user requirements Tracy, Fariha, Fatima 70% 2/25/23 2/27/23 3 Market 100% 3/3/23 Hamida 2/27/23 4 project cost estimate none 0% 3/3/23 3/8/23 5 Regulatory path none 0% 2/26/23 2/28/23 6 Phase 1 Design Review Fariha, Tracy 100% Phase 2 Design Input, Specification and Plan **Product Design Specification** Fatima 30% 2/27/23 3/3/23 3/1/23 3/6/23 Product Development Plan 0% Design Inputs Fatima, Tracy, Fariha, Hamida 40% 3/6/23 3/9/23 Concept Sketches 3/6/23 3/8/23 Phase 2 Design Review 3/6/23 3/9/23 50% Fariha, Tracy, Hamida, Fatima 2/18/23 2/23/23 User needs Phase 3 Design Process, Design Output Documented Design Reviews 3/9/23 3/14/23 Device Drawings 3/19/23 3/15/23 Specifications, Bill of Materials (X-revision) 3/20/23 3/25/23 Manufacturing and Inspection Procedures 3/26/23 3/30/23 Product Labeling 3/20/23 3/24/23 Product Labeling Product Packaging Technical File (if required) Regulatory Documentation Design Verification, Testing 10 Input/Output Verification 11 Risk Management Plan 12 Design Device Material specifications 14 Simulated Use 15 Clinical Evaluation Inspection Records (First Article Acceptance) 17 Validations Required (list) Process Device 19 Phase 3 Design Review 20

		Display Week:	1		Feb 20, 2023	Feb 27, 2023	Mar 6, 2023	Mar 13, 2023	Mar 20, 2023	Mar 27, 2023	Apr 3, 2023	Apr 10, 2023
Item#	TASK ASSIGN		START	END	20 21 22 23 24 25 26	27 28 1 2 3 4 5	M T W T F S S	M T W T F S S		27 28 29 30 31 1 2 M T W T F S S	3 4 5 6 7 8 9 M T W T F S S	10 11 12 13 14 15 16 M T W T F S S
item#	Phase 4 Design Transfer											
1	Risk Management Report		date	date								
2	Complete Design Transfer Form		date	date								
3	Specifications released at rev 0 w/change notice		date	date								
4	Summary of change from rev X to rev 0		date	date								
5	Validations											
6	Release and Distribution of Technical File (if required)											
7	Notification of Notified Body (if required)											
8	Phase 4 Design Review		date	date								
	Insert new rows ABOVE this one											