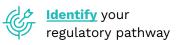
Checklist for Pre-Submission Meeting Preparation



Pre-Submissions are voluntary and the most common type of <u>Q-Submission Program</u>. Pre-Submissions provide an opportunity for innovators and organization to receive guidance from FDA teams "prior" to an intended formal FDA application (i.e. 510(k), Premarket Approval (PMA), etc.) for a digital health product. If you are not familiar with the Pre-Submission Process, learn more about it <u>here</u> or check out <u>DiMe's guide</u>.

FDA	Pre-Submission Package I Preparation Checklist				
	Cover letter				
	Center for Devices and Radiological Health (CDRH) premarket review submission cover sheet (<u>Form FDA 3514</u>)				
	Table of contents				
	Detailed product description				
	Proposed intended use/indications for use				
	Summary of previous discussions or submissions regarding the same device				
	Overview of product development				
	Specific questions for FDA feedback				
	Preferred method of receiving FDA feedback				
	Meeting format, preferred dates and times, and planned attendees				
	Audiovisual equipment needs, if meeting or teleconference is requested				
FDA	Pre-Submission Meeting Preparation Checklist				
	Complete the RTA (Refuse to Accept) checklist				
	Complete list of relevant test guidance, standards, or documentation				
	Draft 1-3 targeted questions that may include:				
	 Information provided and its interpretation 				
	 Direct questions to the FDA (ideally with yes/no responses) 				
_	 Explanation of why the question is posed 				
	Ensure consistency for the intended use, indications for use, product description, and product claims throughout the documents and the meeting				
	Identify internal organization's attendees and key expertise required for the meeting (note: the agenda, expected outcomes, and questions drive the attendee list)				
	Identify and bring in key external subject matter expert(s) for thought leadership				
	Draft a slide presentation (<15 slides)				
	Draft an agenda with expected outcome(s)				
	Identify an individual to take notes				
	Schedule a preparatory meeting(s)				
	Schedule a Day 70 meeting to review FDA written feedback				

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	Access DiMe's Digital H	ealth Regulatory Pathway Resou	rces	
	Follow up with action steps fr	om the meeting		
	Research the scientific and prattendees	ofessional backgrounds of the	e FDA r	neeting
	Draft a best and worst case till feedback)	neline and cost estimate (ba	sed on	FDA







<u>Interact</u> with regulators