Checklist for Pre-Submission Meeting Preparation

Digital Health **Regulatory Pathways**

Pre-Submissions are voluntary and the most common type of Q-Submission Program. 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 here or check out DiMe's guide.

FDA Pre-Submission **Package** I Preparation Checklist

- ☐ Cover letter
- ☐ Center for Devices and Radiological Health (CDRH) premarket review submission cover sheet (Form FDA 3514)
- ☐ 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** I 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

- [ ] Draft a best and worst case timeline and cost estimate (based on FDA feedback)
- [ ] Research the scientific and professional backgrounds of the FDA meeting attendees
- [ ] Follow up with action steps from the meeting

Access DiMe's Digital Health Regulatory Pathway Resources

Identify your regulatory pathway

Build your regulatory strategy

Interact with regulators