Checklist for Pre-Submission Meeting Preparation

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