Navigating the Journey from Digital Health Technologies to Meaningful Patient Outcomes

Virtual Mini Bootcamp

Pre-Bootcamp Reading

- Background Reading on Alzheimer's Disease (for Bootcamp Exercises):
  - https://www.nia.nih.gov/health/alzheimers
- Exhibit 1:

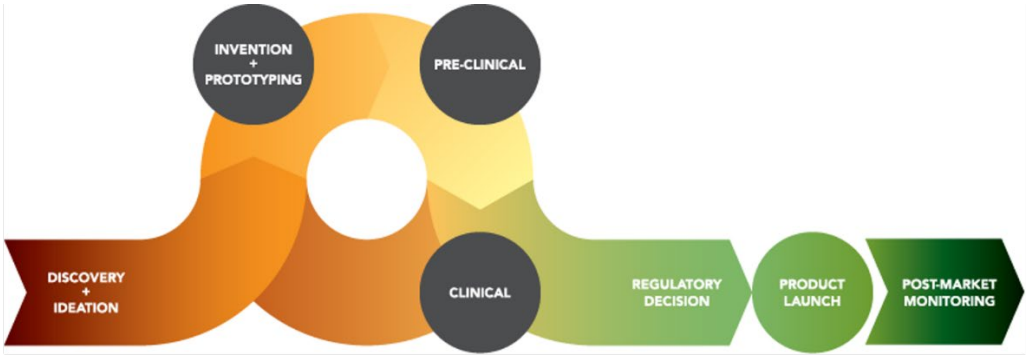

Exhibit 1: Patient Input Across the Medical Device Total Product Life Cycle

Ahead of the bootcamp, please consider points in the digital health technology (DHT) development lifecycle where patient input can be helpful. References and resources that may be helpful are included below.

Bootcamp Glossary

- BEST (Biomarkers, EndpointS, and other Tools) Resource: https://www.ncbi.nlm.nih.gov/books/NBK338448/

Bootcamp References / Resources

DIGITAL HEALTH TECHNOLOGIES

- Computerized Systems Used in Clinical Investigations: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/computerized-systems-used-clinical-investigations
- Electronic Source Data in Clinical Investigations: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/electronic-source-data-clinical-investigations
- Part 11, Electronic Records; Electronic Signatures - Scope and Application: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application
- Use of Electronic Informed Consent in Clinical Investigations – Questions and Answers: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-electronic-informed-consent-clinical-investigations-questions-and-answers
- Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/changes-existing-medical-software-policies-resulting-section-3060-21st-century-cures-act
- Policy for Device Software Functions and Mobile Medical Applications: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications
- General Wellness: Policy for Low Risk Devices: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices
- Off-The-Shelf Software Use in Medical Devices: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/shelf-software-use-medical-devices
- Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-data-systems-medical-image-storage-devices-and-medical-image-communications-devices
- Qualification of Medical Device Development Tools: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/qualification-medical-device-development-tools
- Device Determination Inbox (Informal Device Determination): DeviceDetermination@fda.hhs.gov
- Digital Health Inbox (Digital Health Policy Questions): digitalhealth@fda.hhs.gov
- Division of Industry and Consumer Education (General Questions): DICE@fda.hhs.gov, 1(800) 638-2041

- Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program

- FDA and Industry Procedures for Section 513(g) Requests for Information under the Federal Food, Drug, and Cosmetic Act: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-procedures-section-513g-requests-information-under-federal-food-drug-and-cosmetic

- Digital Health: https://www.fda.gov/medical-devices/digital-health

- Device Advice: Comprehensive Regulatory Assistance: https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance

- MedTech Strategist Article on Regulatory Legos: https://static1.squarespace.com/static/5a787b5b32601ebcc98b403c/t/5e5ec5b5ef71681f623e8eb8/1583269316110/Shuren+MP+Oct+2019+UL.pdf

- IMDRF: Software as a Medical Device: Clinical Evaluation: http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-170921-samd-n41-clinical-evaluation_1.pdf

PATIENT ENGAGEMENT

- Patient Engagement: https://www.fda.gov/about-fda/center-devices-and-radiological-health/cdrh-patient-engagement

- Patient Engagement Advisory Committee (PEAC): https://www.fda.gov/about-fda/cdrh-patient-engagement/cdrh-patient-engagement-advisory-committee

- Patient & Caregiver Connection: https://www.fda.gov/about-fda/cdrh-patient-engagement/cdrh-patient-and-caregiver-connection

- Patient Engagement in Medical Device Clinical Studies - Draft Guidance: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-engagement-design-and-conduct-medical-device-clinical-investigations

- FASTER CURES: https://milkeninstitute.org/programs/engaging-patients-in-research

- CTTI: https://ctti-clinicaltrials.org/our-work/patient-engagement/patients-groups-clinical-trials/

- PCORI: https://www.pcori.org/engagement/value-engagement

PATIENT PREFERENCE INFORMATION (PPI)

- Patient Preference Information – Voluntary Submission, Review in PMAs, HDE Applications, and De Novo Requests and Inclusion in Decision Summaries and Device Labeling: https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM446680.pdf

- CDRH Patient Preference Website: https://www.fda.gov/about-fda/cdrh-patient-engagement/patient-preference-information-ppi-medical-device-decision-making

- MDIC Patient-Centered Benefit Risk Project: A Framework for Incorporating Information on Patient Preferences Regarding Benefit and Risk into Regulatory Assessments of New Medical Technology: https://mdic.org/resource/patient-centered-benefit-risk-pcbr-framework/

- Patient Preference Methods Workshop December 2017: Benz, H.L., Lee, T., Tsai, J. et al. Advancing the Use of Patient Preference Information as Scientific Evidence in Medical Product Evaluation: A Summary Report of the Patient Preference Workshop. Patient 12, 553–557 (2019). Recordings and Transcripts available online

- MDICx Webinar Series (From stories to evidence: Quantitative Patient Preference Information to inform product-development and regulatory reviews): http://mdic.org/mdicx/

- van Overbeeke, E et al., "Factors and Situations Influencing the Value of Patient Preference Studies Along the Medical Product Lifecycle: A Literature Review", Drug Discov Today. 2019 Jan;24(1):57-68. doi: 10.1016/j.drudis.2018.09.015. https://pubmed.ncbi.nlm.nih.gov/30266656

CLINICAL OUTCOME ASSESSMENTS (COA)

- Medical Device Development Tool (MDDT) Program: http://www.fda.gov/MedicalDevices/ScienceandResearch/MedicalDeviceDevelopmentToolsMDDT/default.htm

- Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-reported-outcome-measures-use-medical-product-development-support-labeling-claims

- CDRH COA Website (includes PRO Report, Case Studies, Compendium): https://www.fda.gov/about-fda/cdrh-patient-science-and-engagement-program/clinical-outcome-assessments-coas-medical-device-decision-making

- FDA Patient Focused Drug Development Guidance Series[1]: https://www.fda.gov/drugs/development-approval-process-drugs/fda-patient-focused-drug-development-guidance-series-enhancing-incorporation-patients-voice-medical

- FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-public-health-emergency

- Walton, M. et al., "Considerations for Development of an evidence dossier to support the use of mobile sensor technology for clinical outcome assessments in clinical trials", Contemporary Clinical Trials. 2020 April; 91:105962. https://doi.org/10.1016/j.cct.2020.105962

[1] Please note that not all the guidances mentioned are final guidances and not all the final guidances listed are policies that apply to CDRH. As such, they may not be fully implemented as FDA policy or CDRH policy. However, COAs are often developed for use in various medical products so these documents may also be helpful for your awareness.