FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

Strategies for Premarket Approval (PMA) Success

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Outline

- Product definition
  - Device, Indication, Claims
- Testing expectations
- Early interactions with FDA
  - Development of testing expectations and strategy
- Managing change
- Premarket submission content
- What to expect during the review
- The Long View

Summary

- Tell your story!
- Preparation
  - eSTAR, guidance, standards, approval / clearance precedent
- Communication

Product Definition

- Product Definition can include:
  - Device
    - What is it?
    - How is it made?
    - Primary mechanism of action?
  - Indications
  - Claims
    - Talk to your marketing department!
    - Do you want to say it is better?
    - Do you want to say it is safer?
    - Do you need a particular claim to support reimbursement?

Indications for Use

- Target patient population?
  - Pediatrics, adults, or ….
- Extent of disease state?
  - Occasional, permanent, or ….
- How it is used
  - Surgical, transcatheter, or ….
- Clinical benefit to the patient?
  - Reduction, elimination, or …..
- Diagnostic vs “Tool”

Testing Expectations

- Comprehensive risk assessment
- Risk mitigation plan
- Device evaluation
  - Bench testing
  - Animal testing
  - Clinical testing

Submission Type

- **510(k):** Substantial Equivalence
  - Traditional
  - Special
  - Abbreviated safety & performance

- **De Novo:** General controls alone, or general and special controls, provide a reasonable assurance of safety and effectiveness

- **HDE:** Safety and probable benefit for <8,000 subject per year

- **PMA:** PMA controls + general and special controls to assure reasonable assurance of safety and effectiveness
  - Original
  - Modular
  - PMA Supplement

Breakthrough Devices Program & Safer Technologies Program (STeP)

- Intended to provide patients and health care providers with timely access to innovative devices
- Expedite the development, assessment, and review of certain devices that meet the program eligibility criteria
- Breakthrough:
  - For devices that provide for **more effective** treatment or diagnosis of **life-threatening or irreversibly debilitating diseases or conditions**
- STeP:
  - For devices reasonably expected to **significantly improve the safety** of currently available treatments or diagnostics that target an underlying disease or condition associated **with morbidities and mortalities less serious than those eligible for the Breakthrough Devices Program**
- Questions: BreakthroughDevicesProgram@fda.hhs.gov, SaferTechnologiesProgram@fda.hhs.gov

Early Interactions with FDA

BEFORE PRE-MARKET STUDIES ARE CONDUCTED:

– Q-Submission:
  - Tell us about your device and your general strategy and get our thoughts
  - Discuss complex pre-clinical testing: MR evaluation, drug testing, chronic performance
  - Ask questions about test protocol before testing; Very helpful for animal study work where it is critical to do it right the first time.
  - Not a pre-review of the submission!

– 513(g) – Request for classification determination

Guidance "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program" at https://www.fda.gov/media/114034/download

Early Interactions with FDA

Pre-Submission to Support an IDE:

- Device and target indication
- Study design / Sample size
- Endpoints / Definitions

IDE to Marketing Application Issues

- Make sure your requested sample size accounts for worst case attrition
- Audit sites frequently to minimize deviations or missed data
- Consider consenting patients for long-term follow-up (post-approval option)
- Be aware of “Future Concerns” and address them early

Managing Change

DURING THE IDE

- Changes to the device design
- Changes to suppliers
- Changes to manufacturing
- Protocol changes

Another Pre-Submission?

- Pre-Submission before marketing application NOT required, but useful if:
  - New / Novel device designs
  - Significantly new testing methodology
  - Questions about data from clinical trial

- Consider Timing
  - Can be concurrent with clinical trial
  - Allow enough time for FDA review

Premarket Submission: e-Copy, eSTAR, and CDRH Portal

- **eCopy:**
  - eCopy requirements outlined in guidance at: https://www.fda.gov/media/83522/download
  - If using eCopy, recommend using eCopy Validation module: https://www.fda.gov/medical-devices/how-study-and-market-your-device/ecopy-program-medical-device-submissions

- **eSTAR:** Interactive .pdf for 510(k) and De Novo. Mandatory for 510(k) beginning 10/1/2023 and De Novos beginning 10/1/2025
  https://www.fda.gov/medical-devices/how-study-and-market-your-device/estar-program

- **CDRH Portal:** progress tracker and online submission for specific submissions https://www.fda.gov/medical-devices/industry-medical-devices/send-and-track-medical-device-premarket-submissions-online-cdrh-portal

Premarket Submission Content

- Table of Contents
- Page numbers
  - (yes, even for digital formats)
- Divide submission by review area
  - Administrative, bench testing , animal testing, clinical testing, etc.
- Pre-Submission, IDE, & communication history
- Device, protocol change history
- IDE advisories; “considerations” from IDE letters
- Most recent versions of protocols
- Where applicable, review “refuse to accept” guidance documents for minimum content requirements

Important Submission Considerations

- Review all relevant guidance documents (cross-cutting and device-specific) and applicable standards
- Be upfront
  - The submitted evidence is rarely perfect, clearly identify issues and present justifications for acceptability
- Be in touch
  - With the lead reviewer; lead reviewer should be primary contact unless other arrangements are made with consulting reviewers
- Be responsive
  - Answer our questions when you say you will
  - If you don't understand a question, call/email and ask

Summary of MDUFA Performance Goals

Submission Type	Action	FDA Review Days	Percent of Submissions to Meet FDA Days					
			M4 FY22	FY23	FY24	FY25	FY26	FY27
510(k)s	Substantive Interaction	60	95%	[---------- 95% ----------]				
	Decision	90	95%	[---------- 95% ----------]				
De Novos	Decision	150	70%	70%	70%	70%	70 – 80%*	70 – 80%*
Original PMAs & Panel-Track Supplements	Substantive Interaction	90	95%	[---------- 95% ----------]				
	Decision if No Panel	180	90%	[---------- 90% ----------]				
	Decision With Panel	320	90%	[---------- 90% ----------]				
180-Day PMA Supplements	Substantive Interaction	90	95%	[---------- 95% ----------]				
	Decision	180	95%	[---------- 95% ----------]				
Real-Time PMA Supplements	Decision	90	95%	[---------- 95% ----------]				
Pre-Submissions	Written Feedback	70 or 5d prior to meeting	1,950	[---------- 90%*---------]				
CLIA Waiver by Applications	Substantive Interaction	90	90%	[---------- 90% ----------]				
	Dual CLIA / 510(k)	180	90%	[---------- 90% ----------]				
	Decision if No Panel	150	90%	[---------- 90% ----------]				
	Decision With Panel	320	90%	[---------- 90% ----------]				

*Goals may be adjusted based on volume and/or previous years performance

During the Review

- Be prepared
  - Have your team ready to answer questions; have copies of the submission and any previously submitted info (i.e., Q-Sub, IDE) available
- Plan for the possibility of a submission issue request (SIR):
  - Obtain clarification on identified deficiencies
  - Through the Q-Submission program

During the Review

- Be ready to interact on labeling
  - Have your decision makers available for quick turnaround
  - Marketing: Don’t go to the printer with draft labeling the week after the submission is sent to FDA

During a PMA Review

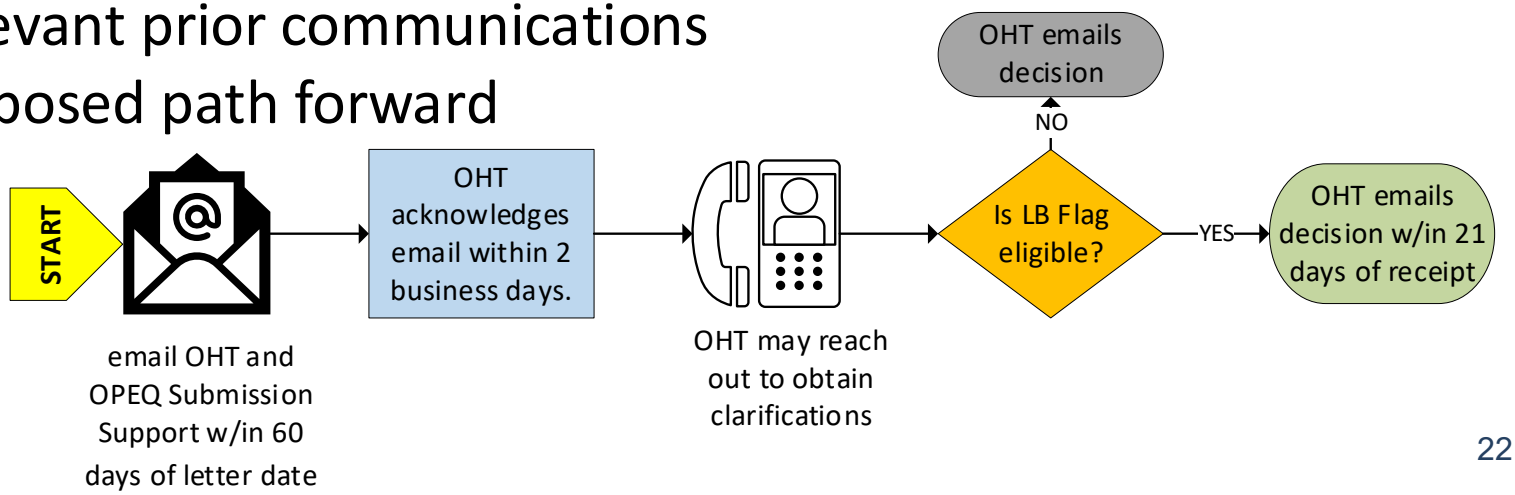
- Plan for the possibility of a Panel meeting
  - FDA will tell you as soon as we know – many times decision is driven by data in the PMA
- Be ready for inspections
- Be realistic when advising on timelines for ramp up of manufacturing facilities and distribution chains
- Work with the epidemiologist on post-approval study plans early – our goal is to approve protocol at time of PMA approval

Dealing with Additional Information Request

- Contact lead reviewer for any clarifications
  - Opportunity for “Day 10 Call”
- Address each question
  - Provide response to deficiency or detailed justification for not addressing
- Least Burdensome Flag
  - Started with 510(k): expanded to include PMA, HDE, De Novo
- Be aware of response due date!
  - Call / email LR or Program Area if uncertain
  - SIR timing does not change due date

Least Burdensome Flag

- What it is:
  - Opportunity to address LB discrepancies in a deficiency letter
  - Opportunity for submitter to address situations when they feel they are being held to a different standard
- What it is NOT:
  - An Appeal Meeting
  - Change to 180 Response deadline
- The email should include a 1-2 page summary:
  - Disagreement(s) limited to 2 topic areas
  - Relevant prior communications
  - Proposed path forward



Common Pitfalls

- Administrative Issues
- Product description insufficient or inconsistencies throughout document
  - Technical writing is important!
- Supportive data insufficient or missing without rationale
- Inadequate responses to data requests
- Prior interactions / discussions not addressed
- Poor communication

After the Review

You're Done! Now get started

- PMA
  - Annual Reports, PAS requirements, PMA supplements, 30-day notice supplements, site change supplements
- DeNovo → 510(k)
  - Must continue to meet Special Controls
- 510(k)
  - 510(k) modifications guidance
  - Software modifications guidance

Contact Information

- Division of Consumer and Industry Education
  - DICE@fda.hhs.gov
  - 1 (800) 638-2041
- OPEQ / ORP / Division of Submission Support
  301-796-5640 - OPEQSubmissionSupport@fda.hhs.gov

  Joshua Nipper, Director, Division of Submission Support
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& Devices

Thank You!

Questions?