TIPS FOR WORKING WITH THE FDA/OIVD

510(k) Workshop
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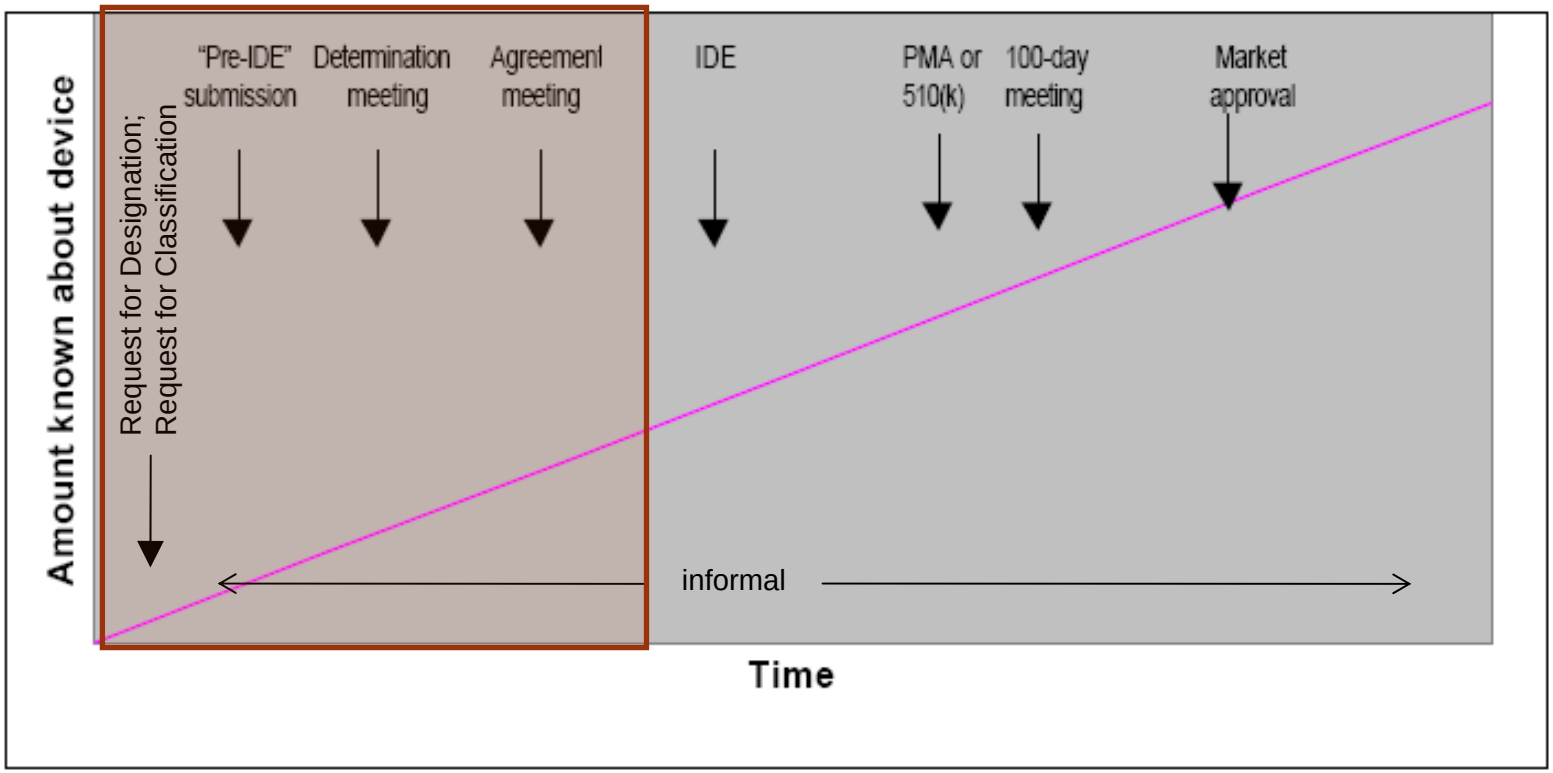
TOPICS

- Interaction Opportunities and how to handle each
- Preparing a Submission
- The why's and how's of Meetings with the FDA
- What works and what doesn't

OIVD INTERACTION OPPORTUNITIES – PRE-SUBMISSION



FDA Guidance: "Early Collaboration Meetings Under the FDA Modernization Act (FDAMA); Final Guidance for Industry and for CDRH Staff ", Issued 2/28/01

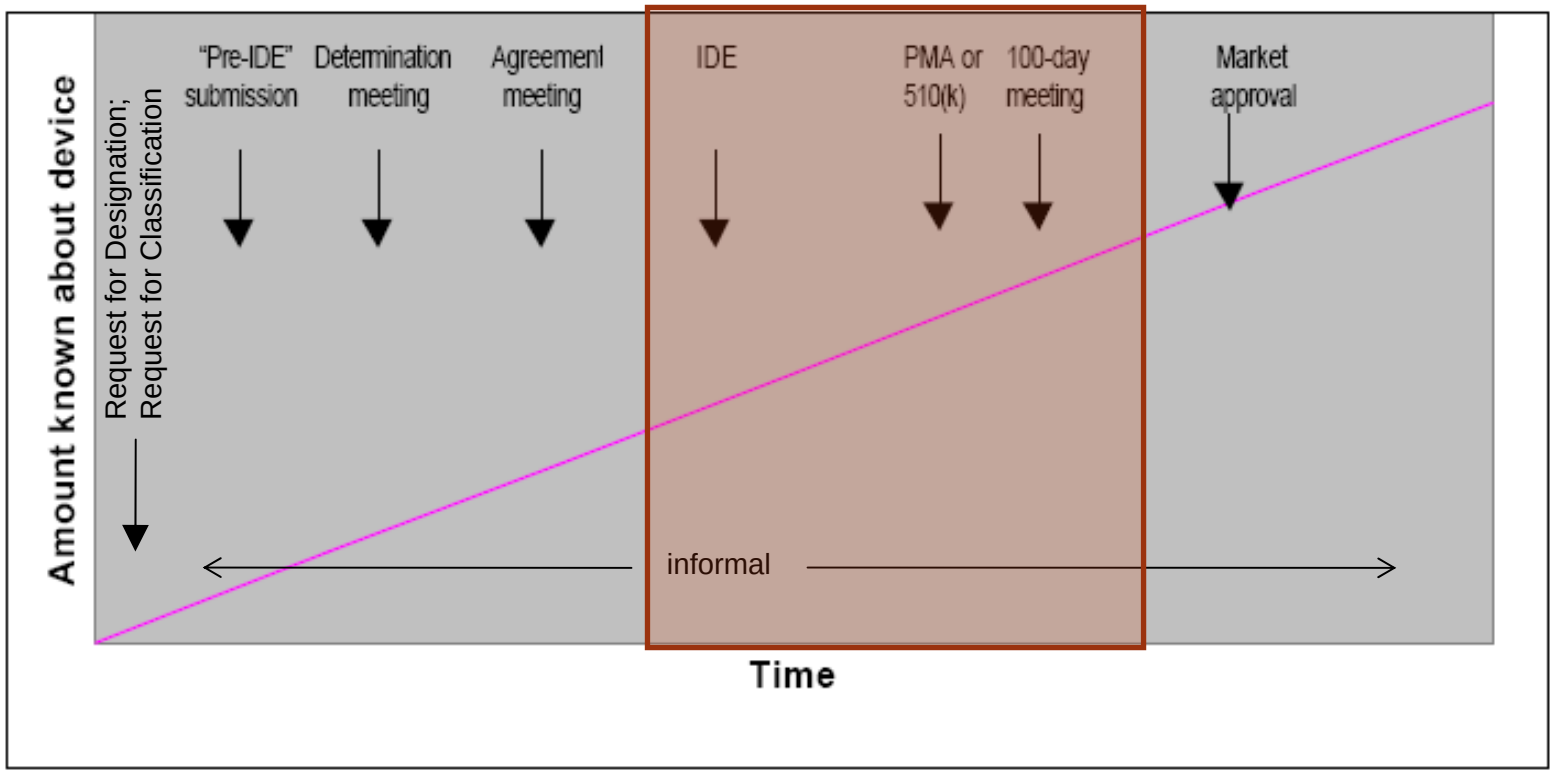
FORMAL INTERACTIONS – PRE-SUBMISSION

- 513(g) – Request for Classification
  - Identify product's regulatory status and classification before you invest time and resources
  - No specified format:
    - Detailed description of product
    - Potential predicate devices
  - Decision made by Division responsible for review
  - User Fee

FORMAL INTERACTIONS – PRE-SUBMISSION (cont.)

- Request for Designation
  - Know which Center(s), Office(s) will review submission
  - Know which Center(s), Office(s) will take the lead in the review
- Pre-IDE
  - Detailed product description, clinical trials plan, statistical analysis plan
  - Formal feedback from OIVD on your clinical trials plan and submission strategy
  - Non-binding

OIVD INTERACTION OPPORTUNITIES – SUBMISSION



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FORMAL INTERACTIONS – SUBMISSION (cont.)

- IDE
  - Formal approval from FDA to begin your clinical trial
  - Content defined in 21 CFR 812.20(b)
  - Most IVDs and clinical trials are exempt – 21 CFR 812.2(c)(3)
  - IVDs not exempt if results are used to determine treatment of patient during trial

FORMAL INTERACTIONS – SUBMISSION (cont.)

- 510(k)
  - Class II products
  - Traditional, Abbreviated, or Special 510(k) – choose the APPROPRIATE type
- PMA
  - Class III products
  - Traditional, Modular, PDP – choose the BEST type

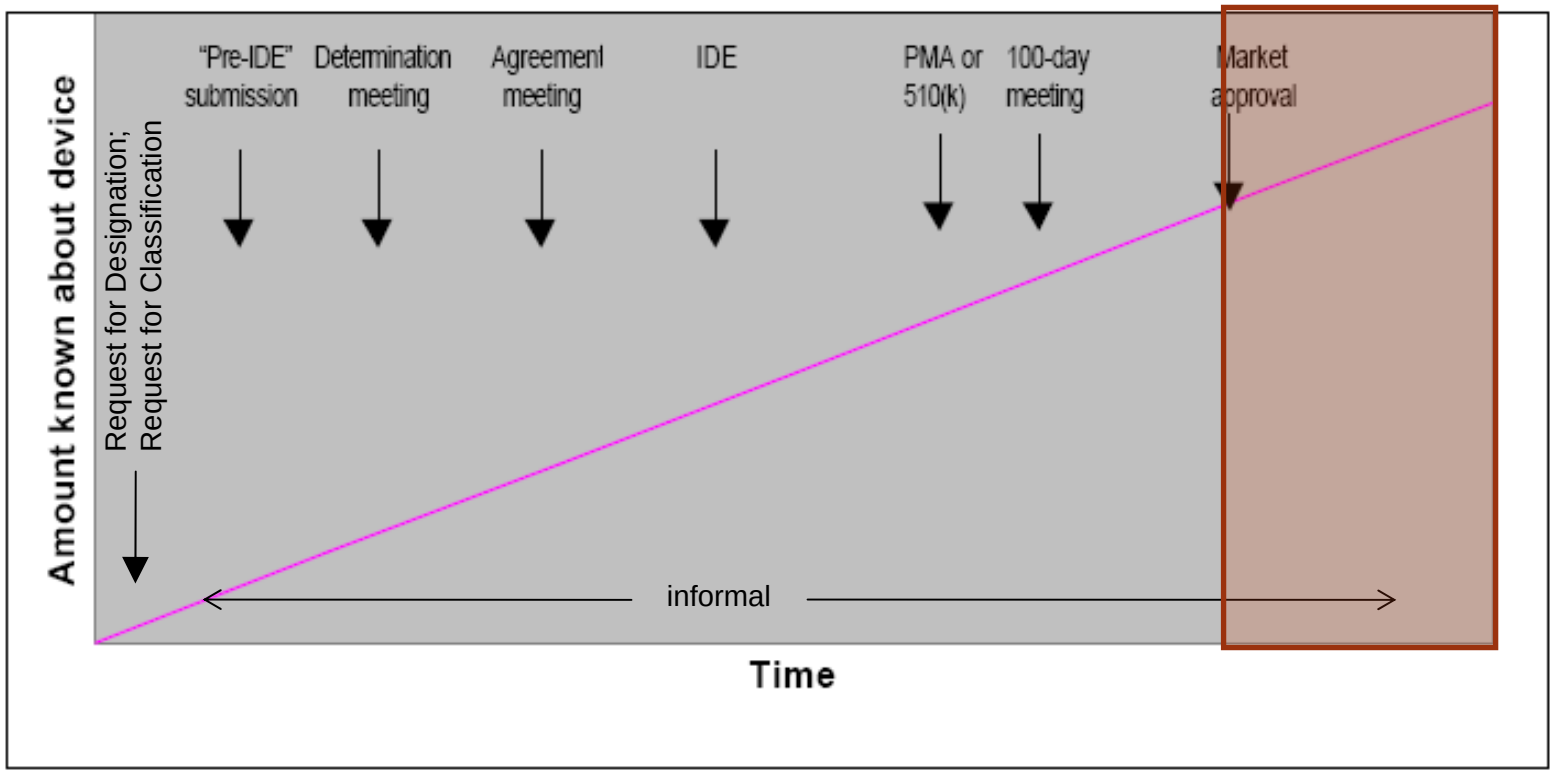
FORMAL INTERACTIONS – Don't submit yet if:

- Your trial enrollment isn't finished.
- Your participant follow-up isn't finished (unless that follow-up isn't relevant to the proposed claims).
- Your testing isn't finished.
- Your data analysis isn't completed.
- Your final data analysis doesn't support your proposed claim! (i.e. statistically significantly lower performance)

FORMAL INTERACTIONS – Submit when:

- Everything in the “Don’t submit yet if” list is completed.
- All the information, studies, data analysis, and data line listings are clearly described, neatly presented, well-organized, and logically numbered.
- Your Table of Contents is detailed and updated.
- Your document has been proofread, preferably by someone outside of the preparation group.

OIVD INTERACTION OPPORTUNITIES



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FORMAL INTERACTIONS – POST-MARKET

- Includes conditional approval follow-up, inspectional issues, product problems.
- Submit conditional approval follow-up to appropriate OIVD Division.
- Follow-up at district office for inspectional issues.
  - Respond promptly with correctional plan and timeline.
  - Provide updates at promised timepoints.
  - Contact OIVD Division if pre-market issues are questioned.

FORMAL INTERACTIONS – POST-MARKET (cont.)

- Recalls
  - Notify District Office
  - Recall Report – follow the same rules about any submission or telephone communications
- Medical Device Reports
  - Notify FDA Center
  - Write clearly and concisely
  - Provide relevant information

MEETING PREPARATIONS

- Decide what your meeting objectives are.
- Decide who should attend
  - Keep the number low!
- Prepare an agenda around your objectives.
- Plan your presentation for time allotted, leaving time for questions and discussion.
- Have your questions ready.
- Do a practice run of the presenter(s) and presentation.

MEETING PREPARATIONS (cont.) – Example Meeting Agenda

- Introductions
- Meeting Objectives
- Questions
- Product Description (overview)
- Presentation of critical information
- Discussion
- Review Questions and Answers
- Review of promised information or follow-up (e.g. meeting minutes)

DURING THE MEETING

- The Three B's:
  - Be Prompt
  - Be a Good Listener
  - Be Non-Defensive
- Have a designated note-taker
- Communicate your goals clearly, but be willing to compromise.
- Offer to follow-up on questions you can't answer; then do it!
- Stay on agenda and time

AFTER THE MEETING

- Send a letter to OIVD with the minutes and any requested information.
- Follow-up with OIVD on the minutes to ensure no miscommunications.
- Reach agreement with OIVD on next steps.
- Don’t promise what you can’t do, then do what you promised.

INFORMAL INTERACTIONS

- Telephone call; e-mail; fax
- If needed to clarify regulatory or clinical requirements for your type of product
- If you need specific information – formal interaction
- To answer FDA questions or obtain clarification to their questions during a submission review

Thank you

Judi Smith