## Regulatory Strategy 101 Catalyze

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## Agenda

Regulatory Strategy

Your Questions



## **Experience**

- Over a decade @FDA (Former Deputy Division Director)
- Expertise: SaMD, Cardiovascular, Ophthalmology, General Hospital, Infection Control, Dental, Anesthesia, Respiratory
- Vice President Regulatory Affairs / Quality Assurance @Danaher (Fortune 150 Company)
- Lecturer @UCLA
- Advisor @NIH





## Regulatory Strategy

Arena (FDA? EU?)

Vehicle(s) (Applications, Good Manufacturing Practices)

Staging (Timeline)

Differentiation (Consultant? FTE?)

Economic Logic (Speed to market)



### **Considerations**

- Device landscape
- Specific problem(s)
- Timing engagement w/ stakeholders
- Economic logic (Use of Funds)
- Talent management



### **Problems**

- Is my regulation correct? 510(k)? DeNovo?
- How long will it <u>really</u> take to gain clearance?
- How many patients do I <u>really</u> need?
- How do I prepare for an FDA meeting?



### **Poll: What is Your Problem?**

- 1. I want to know the right FDA application
- 2. I want to know the time it will take to get my application authorized/cleared/granted/approved
- 3. I want to know the clinical study I need to do



## Regulatory Risk Classes & Data

Class	Risk	Example	Description/Data Requirements
I	Low	Band Aid	No FDA Application Good Manufacturing Practices
II	Moderate	Prescription Digital Therapeutic	Application Horizontal and Vertical Guidance and Test Standards Bench and/or Animal Clinical <1,000 patients
III	High	Pacemakers	Life Sustaining or Supporting Bench, Animal and Clinical Clinical 400 - 1,200



## **510(k) vs PMA**

### 510(k) **1-3MM**

- 1-2 years
- <70 pt study

#### PMA **3-25MM**

- 2.5-3.5 years
- >100 pt study
- Consultants => FTEs by year 3



## Regulatory Path (Timeline) Digital Health Solution

Preclinical and Pre-Submission(s)	Pivotal Clinical Study	Submission Review
<ol> <li>Regulatory Strategy</li> <li>Clinical Strategy</li> <li>Verification</li> </ol>	<ol> <li>&gt;500 pts</li> <li>Multi-Site</li> <li>Geographic Diversity</li> <li>Patient Population</li> </ol>	<ol> <li>Breakthrough         Designation?     </li> <li>Reanalysis of data</li> <li>Post Market Data</li> </ol>

Diversity



Collection

Regulatory Intelligence/Landscape

Where can we get information about our product and predicates?





### **Product and Predicate Resources**

- Guidance Document Search
- <u>Product Classification</u>
   <u>Database</u> (TPLC Report)
- Product Classification Key Word Search
- CDRH Device Advice

- Competitor(s) websites
- Pubmed
- Consultants
- Recalls Database Search
- Warning Letter Search



## Digital Health Landscape

#### 2017: 21st Century Cures **Mobile Medical Applications** Deciding When to Submit a Guidance for Industry, FDA Reviewers oftware Change to an General Wellness: and Compliance on **Guidance for Industr** sting Device Policy for Low Risk Devices and Drug Administr Guidance for Industry and nce for Industry and **Off-The-Shelf Software Use** Food and Drug Administration Staff g Administration Staff Document issued on February ly 29, 2016. AFT GUIDANCE in Medical Devices This draft guidance document is being distributed for comment purposes only. Medical Device Data Systems, Medical Document issued on August 8, 2016. **Image Storage Devices, and Medical** Document issued on: September 9, 1999 Guidance for the Convent of **Image Communications Devices** Content of Premarket Submissions for Management of Cybersecurity in Premarket Submissions for Softwar **Medical Devices** Guidance for Industry and Food and **Contained in Medical Devices Drug Administration Staff** Guidance for Industry and Food and **Drug Administration Staff** Document issued on: May 11, 2005 Document Issued on: October 2, 2014 **Clinical and Patient Decision Support Changes to Existing Medical Software Human Factors Studies and Related** Policies Resulting from Section 3060 of Software **Clinical Study Considerations in** the 21st Century Cures Act **Draft Guidance for Industry and Food Combination Product Design and Draft Guidance for Industry and** and Drug Administration Staff **Development** Food and Drug Administration Staff DRAFT GUIDANCE February 2016 DRAFT GUIDANCE This guidance document is being distributed for comment purposes only. This draft guidance document is being distributed for comment purposes only. Document issued on: December 8, 2017 Document issued on December 8, 2017.



**Timing Engagement** 

Should we start talking to FDA now?





## Should we start talking to FDA now?

#### Yes if:

- Want to clarify pathway
- Have questions on testing needs
- Want to clarify product code
- Have the time

#### Risks

- Time for FDA feedback (~60 Days)
- Unfocused discussion (Requirement creep)



### **Clinical Considerations**

- Endpoints
- Biostatistician
- Cash to execute on testing
- 12-24 months

**CRO** 

US data / OUS data



## Should we start talking to an ISO 13485 Contract Manufacturer Now?

#### Yes if:

- Not a wellness device
- Plan to launch in EU

#### Risks

- Cash burn
- Skill to evaluate



**Meeting Framework** 

How do I prepare?





## Best practices & Mistakes to avoid

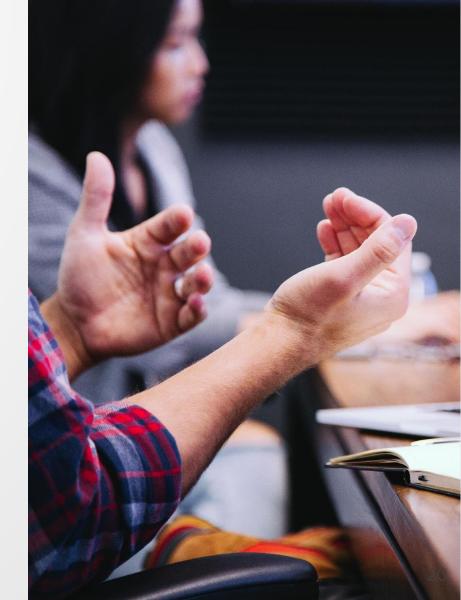
- Minimize the page count (e.g. max 25)
- Ensure time for discussion
- Drive follow up actions/decisions
- Have a good notetaker for minutes

- Build enough time to analyze and respond to FDA written feedback before meeting
- Know the deciders in the room
- Evaluate who should attend from the company



## **Control the Narrative**

How best to communicate your story in the submission





# How best to communicate your story in the FDA submission

- Consistent
- Concise
- Complete
- Direct them to information
- Provide rationale (e.g. Why you have test data on multiple product versions?)



Submission Response Plan

What should I expect during the process?





## How best to communicate with FDA during the review process. What to expect?

- Refuse to Accept
- Quick email or phone call for clarification
- Prepare for requests with quick turnaround time (e.g. < 48 hours)</li>
- Interactive vs. Hold letter

- "4 Part Harmony" deficiencies
  - What was provided
  - Why the information provided is not sufficient
  - What additional information is needed
  - Why the requested additional information is needed



## Communication Maintenance

What are best practices for maintaining communications?





# What are best practices for maintaining communications?

#### Basics

- Understand why
- Answer the question directly and succinctly

- Retell past interactions
- Make the information easy to find



## **Discussion**

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