The 510(k) Program: Overview and Program Updates

FDA Small Business Regulatory Education for Industry (REdI)

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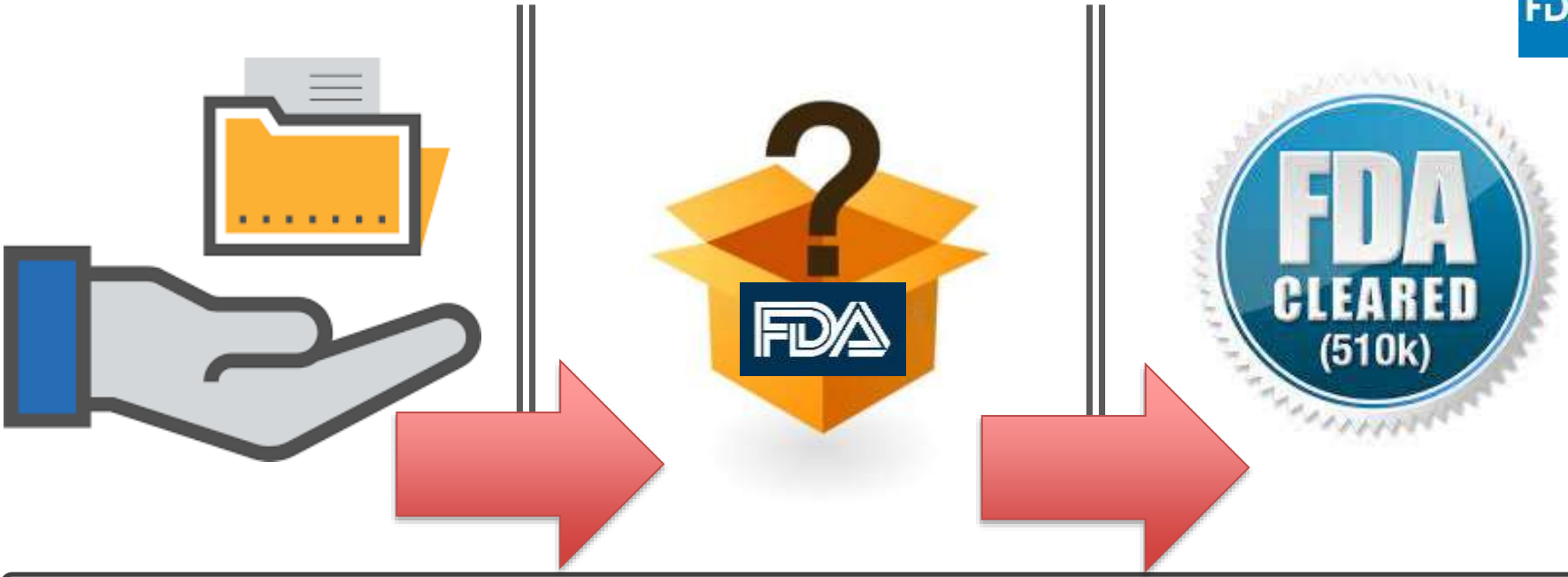


Looking Inside the FDA black box

Learning Objectives

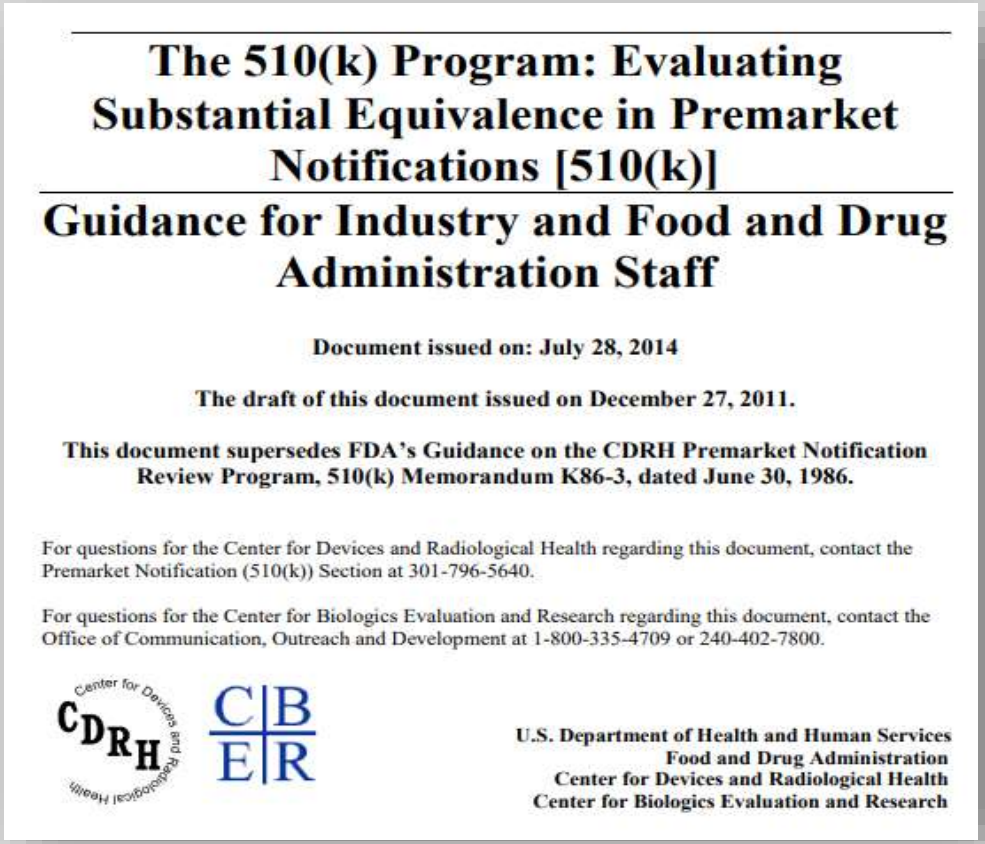
Describe the 510(k) Review Process

Discuss how to interact with FDA during the Review

Identify what's new: policies & pilots

The 510(k) Review Process:

What to expect
When to expect it



The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]

Guidance for Industry and Food and Drug Administration Staff

Document issued on: July 28, 2014

The draft of this document issued on December 27, 2011.

This document supersedes FDA's Guidance on the CDRH Premarket Notification Review Program, 510(k) Memorandum K86-3, dated June 30, 1986.

For questions for the Center for Devices and Radiological Health regarding this document, contact the Premarket Notification (510(k)) Section at 301-796-5640.

For questions for the Center for Biologics Evaluation and Research regarding this document, contact the Office of Communication, Outreach and Development at 1-800-335-4709 or 240-402-7800.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

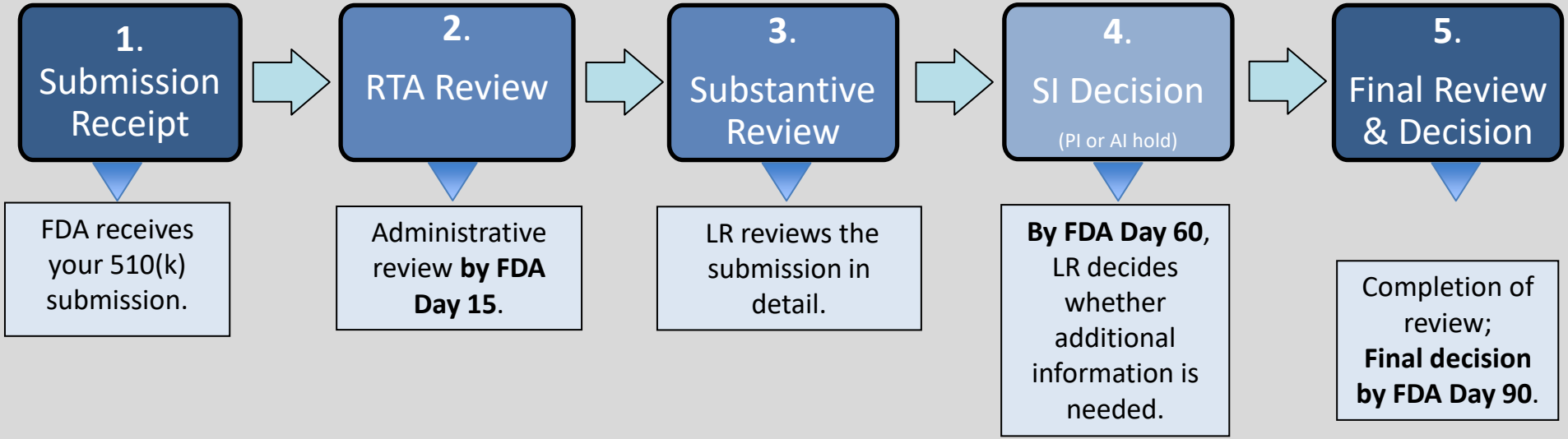
Guidance Scope

- 510(k) Decision Making Process
- 510(k) Review Standard
  - Predicate Device
  - Intended Use
  - Technological Characteristics
  - Additional Information Requests

Also check for device-specific guidance & X-cutting guidance docs

- e.g., Contact Lenses guidance
- e.g., Sterility Guidance, Biocompatibility Guidance

510(k) Process Overview



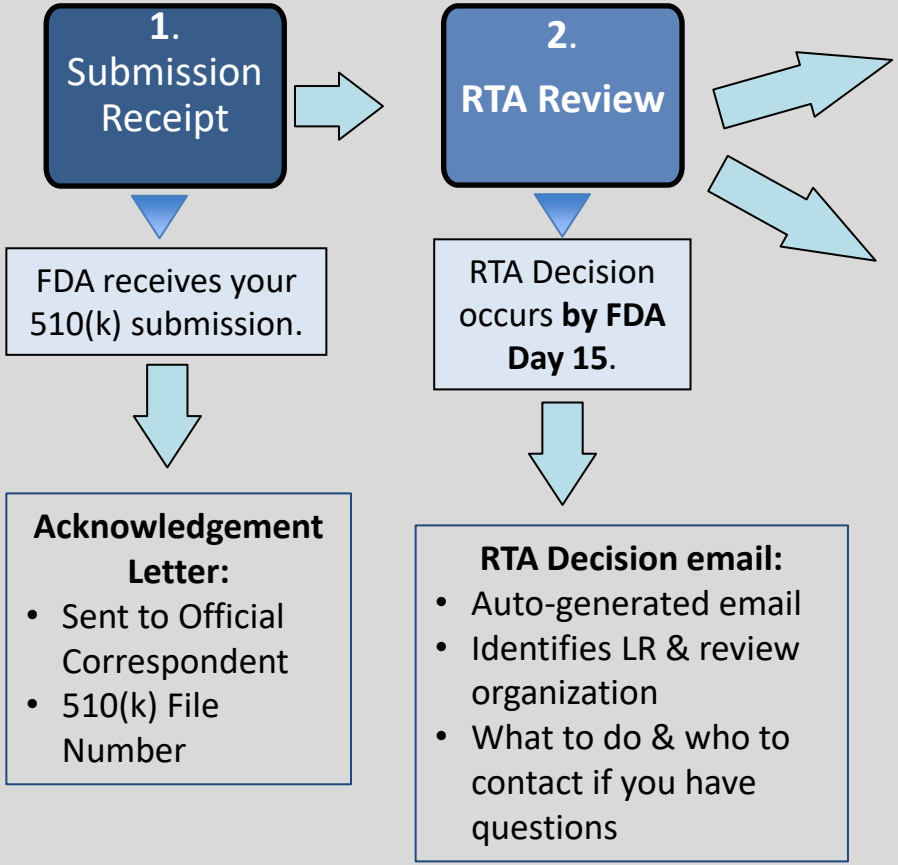
Acronyms:
RTA = Refuse to Accept
LR = Lead Reviewer
SI = Substantive Interaction
PI = Proceed Interactively
AI = Additional Information

"FDA and Industry Actions on Premarket Notification (510k(k)) Submissions: Effect on FDA Review Clock and Goals" Guidance For Industry and FDA Staff

Interacting with FDA during the 510(k) Review:

- Ways to Interact at each review milestone
- Resources and Tips

RTA Review Overview



RTA Accept:

- FDA review clock continues
- Substantive Review Begins
- LR may request information interactively

RTA Not Accepted:

- FDA review clock stops
- Submitter receives completed checklist
- Submitter responds w/ missing info w/in calendar 180d
- RTA review conducted again

[Refuse to Accept Policy for 510(k)s: Guidance for Industry and FDA Staff]

Tips for Responding to RTA

- Include the reviewer's checklist & include page/section numbers where response can be found
- Provide a rationale for why a missing item is not relevant

- Resubmit all prior information
- Make changes to the device or indications

RTA Addendum

What Is An Observation?

Issue noted during administrative review that doesn't determine acceptability of submission, but would result in a deficiency during substantive review

(Examples: Missing a necessary performance test, or results from a performance test appear deficient)

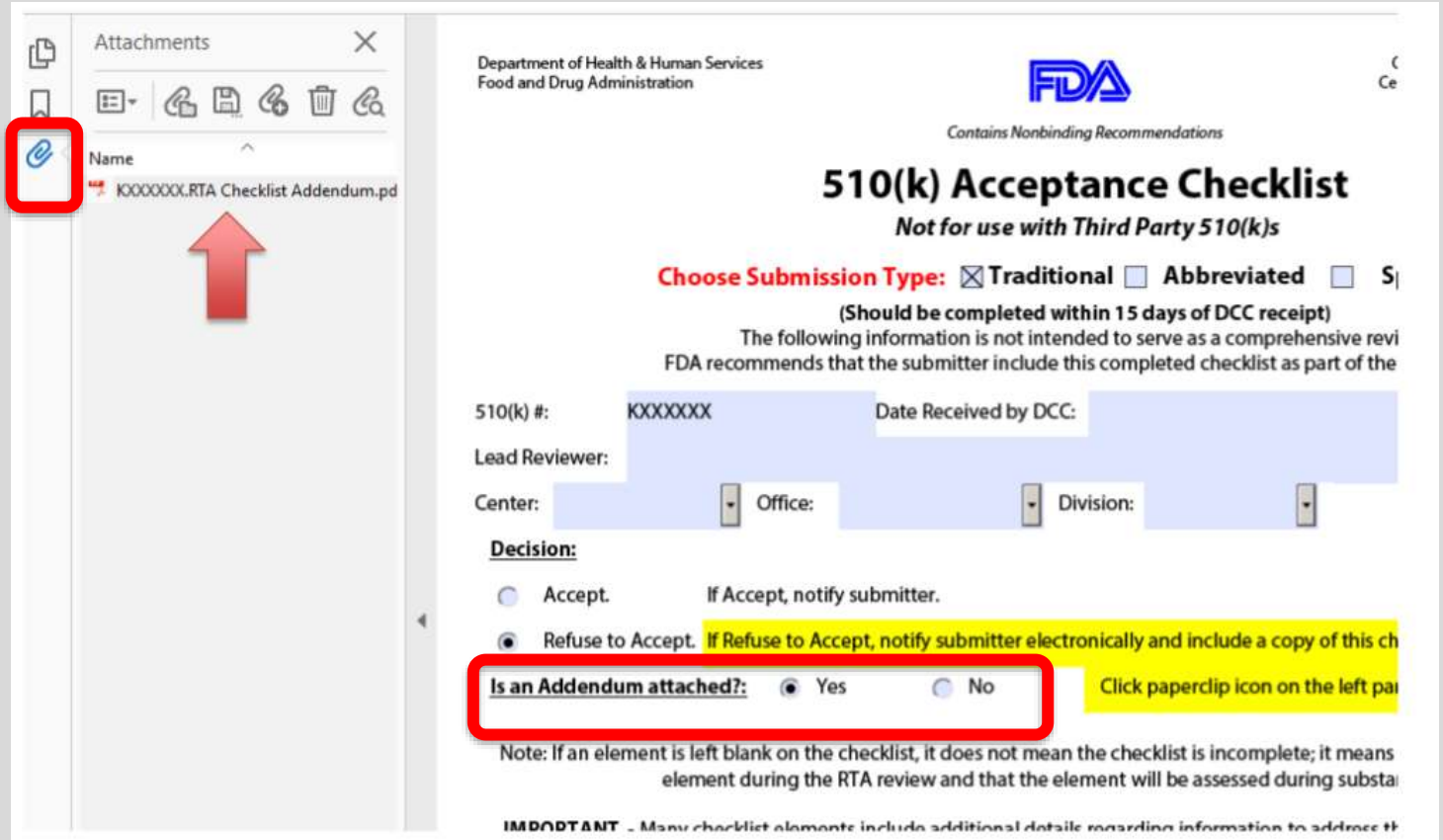
What It Is

- Early notification of "observations" made during initial RTA review
- An opportunity to address issues likely to arise during substantive review

What It is Not

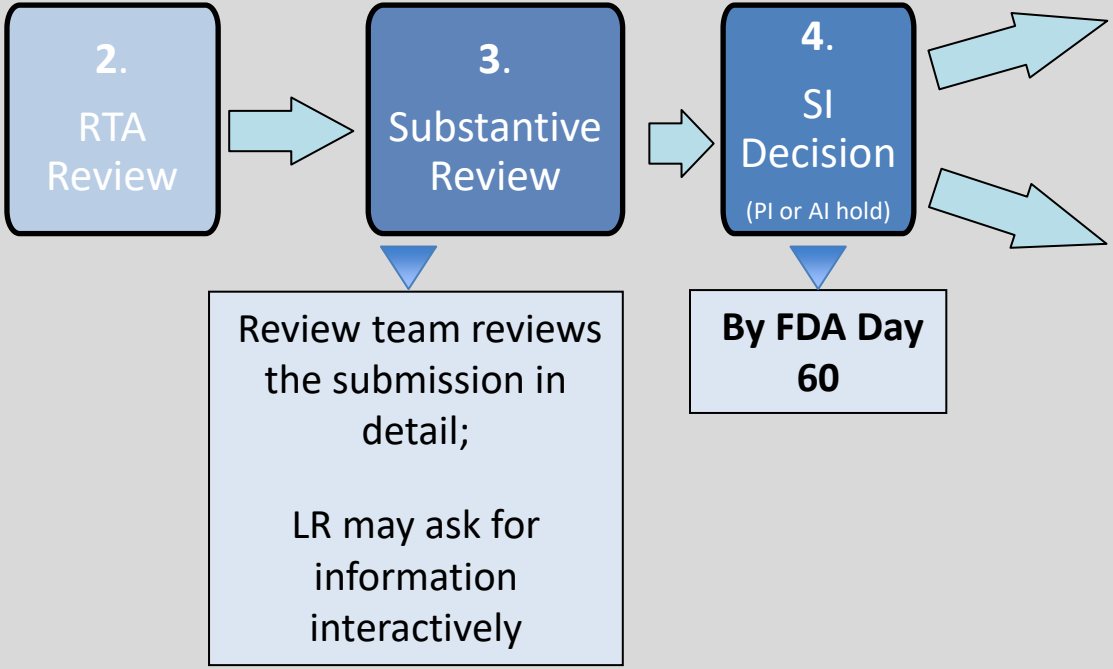
- Substantive review of submission
- Does not replace an additional information hold
- An official request for additional information
- A delay in RTA review or decision

RTA Addendum: Where to Find it, What to Do



- Must respond to missing RTA items
- Optional response to addendum items

Substantive Review Overview



PI: Proceed Interactively

- FDA review clock continues
- LR may request information interactively

OR

AI Hold: Request for Additional Information

- FDA review pauses
- Industry clock begins (180d)
- Must respond to all deficiencies
  - provide requested info
  - provide alternative with rational

Day-10 Call

Description: You can request a call with FDA that occurs within ten (10) days after issuance of an AI letter. The purpose of the call is to address clarification questions pertaining to the deficiencies in the letter.

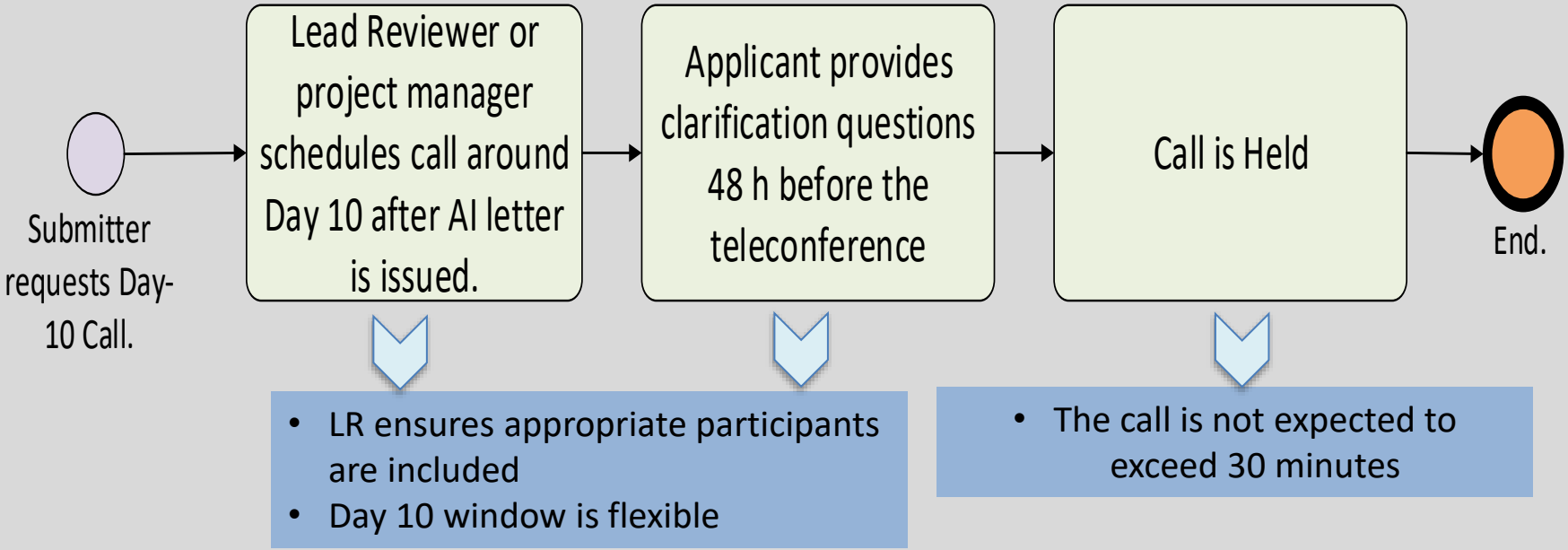
What It Is

- Teleconference
- Confirmation that submitter understands deficiencies in the letter
- Can be used to determine whether a Submission Issue Request is needed.

What It Is Not

- Review of additional information provided by submitter
- Discussion of issues unrelated to deficiencies in the AI letter
- A Submission Issue Request meeting

Day-10 Call: Process Flow



Least Burdensome (LB) Flag

Description: You feel that deficiency(s) do not adhere to the least burdensome principles and request a discussion and review with a manager

What It Is

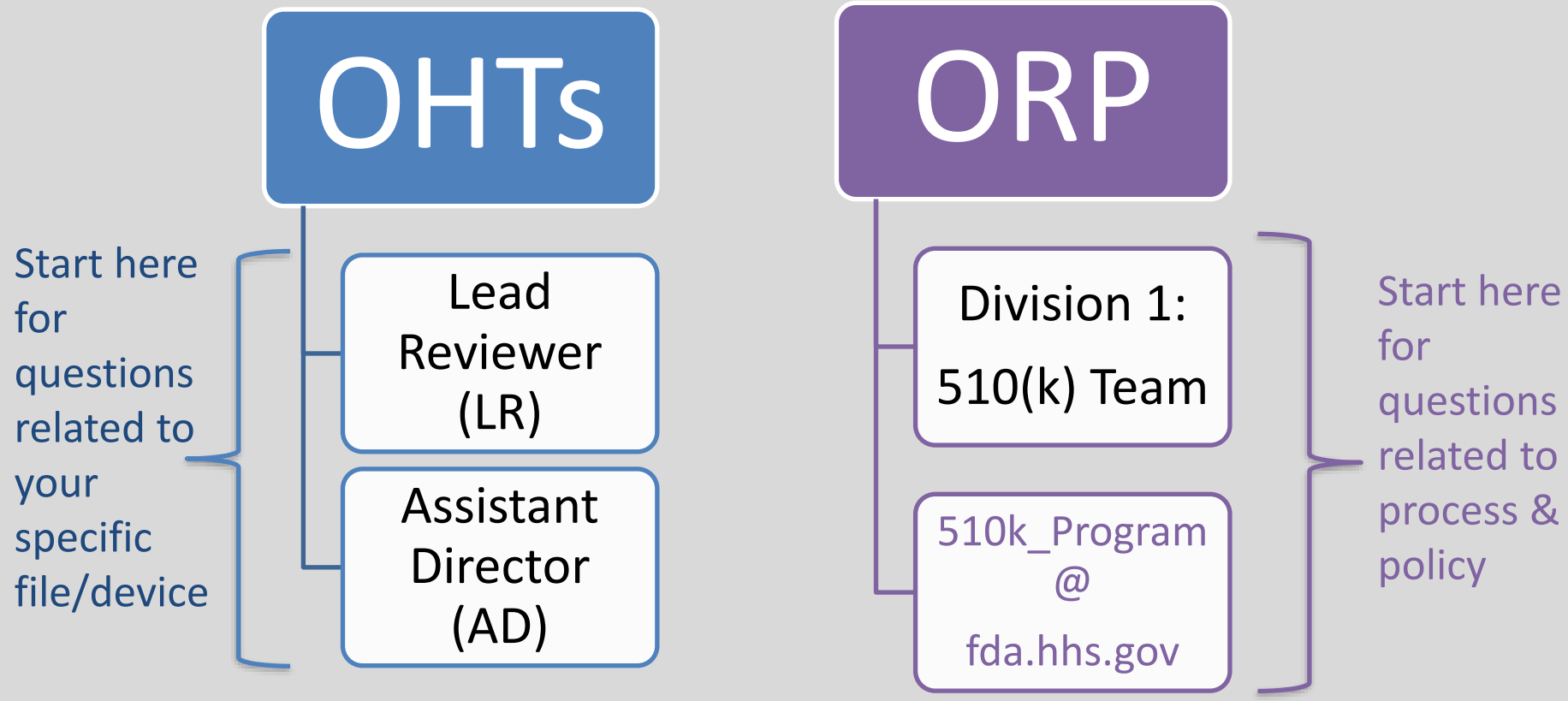
- Opportunity to address LB discrepancies in an AI letter
- Opportunity for submitters to address situations when they feel they are being held to a different standard

What It Is Not

- An Appeal Meeting
- Change to 180 Response deadline

The Least Burdensome Provisions: Concept and Principles Guidance for Industry and FDA (February, 2019)

Resources: where to go and when



CDRH online Management Directory

What would you do?

I think one of the deficiencies asked is not relevant for my device. The best practice is…

1. Email the CDRH Ombudsman & the OHT Director to get their opinion
2. Email the LR and ask for a 10d call to clarify the rationale for the deficiency. I can escalate and throw the LB Flag if I still disagree
3. Respond to the deficiency with the requested info

Knowledge Check

If your submission is not accepted for review (RTA reject), you will always receive the checklist and the RTA addendum

1. True
2. False

What's new in 510(k)

New Program

- Safety and Performance Based Pathway

Pilots

- ASCA
- eSTAR
- Customer Collaboration Portal

www.fda.gov/medical-devices/premarket-notification-510k/510k-program-pilots

Safety and Performance (S&P) Based Pathway

What is it?

New voluntary 510(k) pathway:

- For well understood Class II devices that meet specified performance criteria
- Performance criteria outlined in Guidance Document

What's the Same?

- 510(k) MDUFA user fee and eCopy requirements
- Review Process and Timelines
- No change to the SE decision making matrix

S&P Pathway: Why Should I Use It?

- Each device guidance outlines necessary performance tests
  - Takes guess work out of applicable performance testing
  - Creates more efficient review
  - Opportunity for industry to provide input

More info www.fda.gov/medical-devices/premarket-notification-510k/safety-and-performance-based-pathway

Accreditation Scheme for Conformity Assessment (ASCA) Pilot

What is it?

- Voluntary program
- Partnership with FDA, industry, and test facilities
- Leverages recognized consensus standards to streamline device premarket review
- Enhances FDA's confidence in test methods and results

Why use it?

- Decreases need for additional information related to conformance with a standard
- Promotes consistency, predictability, and efficiency in medical device review
- Least burdensome approach to conformity assessment
- Patients have access to safe, effective, and high-quality medical devices

ASCA Pilot Web page: www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca

QUIK and eSTAR Pilots

"Quik" Review Pilot

Quality in 510(k) Review Pilot

- eSubmitter for certain devices
- Pilot ended May 2021
- Outcomes of Pilot:
  - Produced well organized submissions
  - Facilitated efficient review
  - Some features incorporated into eSTAR

eSTAR Pilot

eSTAR Pilot Program

- Started February 2020
- Voluntary use; for any device
- Submission Preparation Tool
  - Dynamic PDF template
    - Guided submission preparation
    - Complements the SMART review template used by review staff
- Still need to submit eCopy via DCC
- No RTA review; technical hold if not filled out correctly

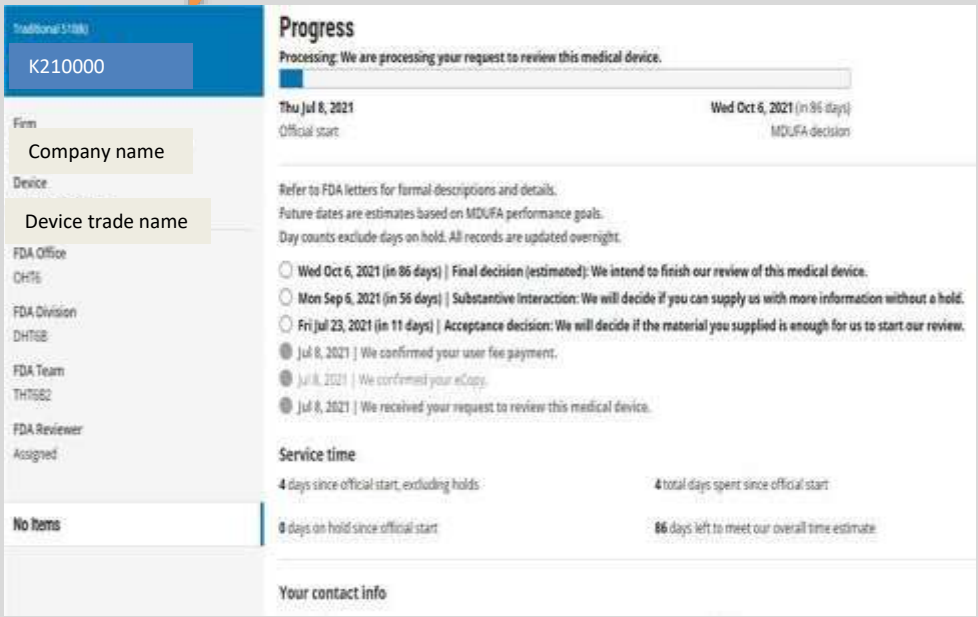
Customer Collaboration Portal Pilot

CCP Pilot

Progress Tracker Pilot

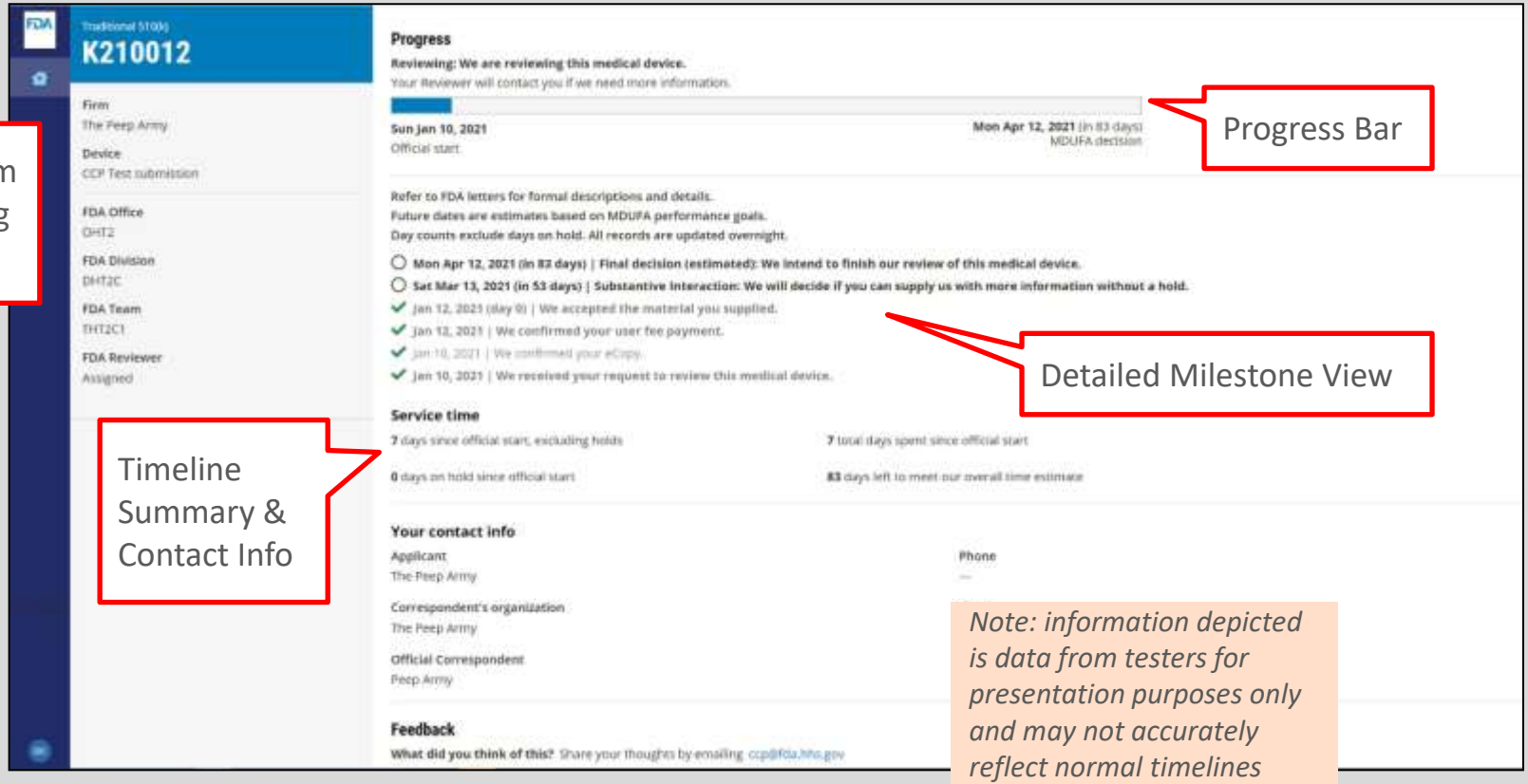
- Pilot started June 2021
  - 100 industry participants
  - [Progress Tracker Pilot web page]
  - Realtime Status updates

- Future:
  - Interact with LR through portal
  - All premarket submission types



Progress Tracker: Industry View

Data pulled from internal tracking systems



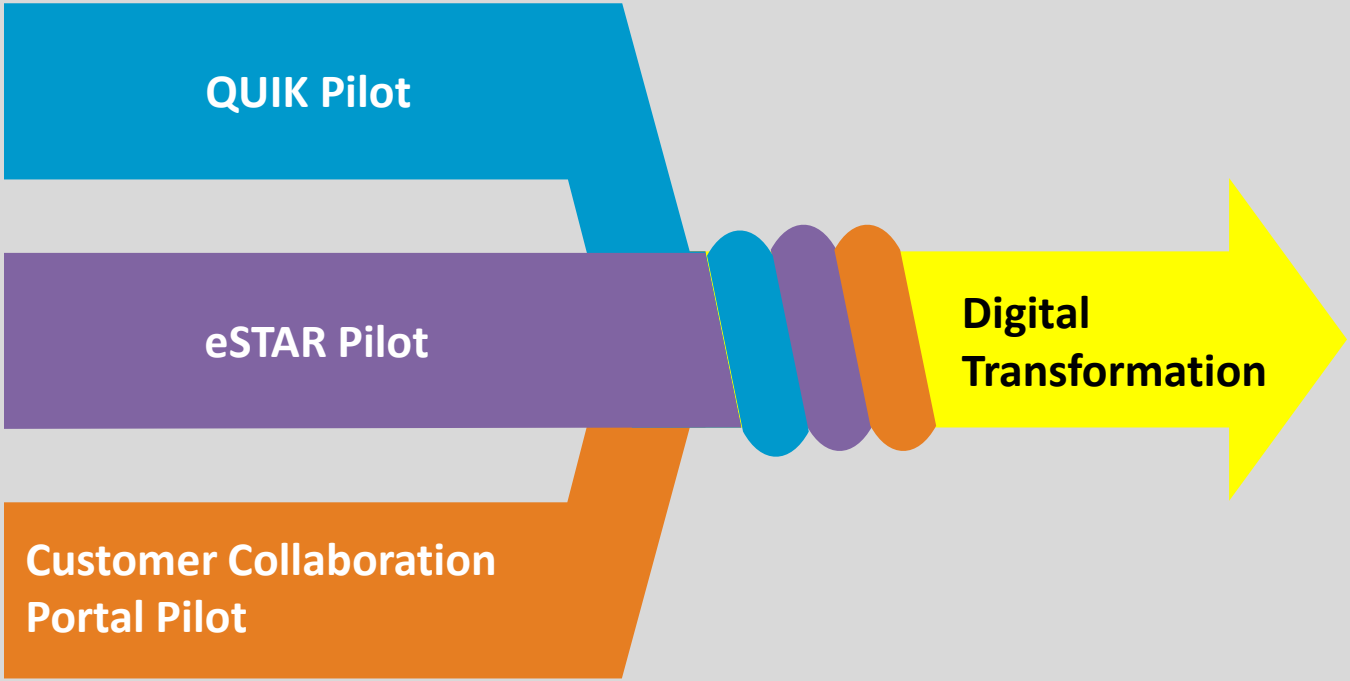
Progress Bar

Detailed Milestone View

Timeline Summary & Contact Info

Note: information depicted is data from testers for presentation purposes only and may not accurately reflect normal timelines

Digital Transformation: 510(k)



- Electronic 510(k) Submission
- Guided Submission Templates
- FDA/Industry Collaborative Portal

Resources

Slide Number	Cited Resource	URL
5	The 510(k) Program: Evaluating Substantial Equivalence	www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k
6	FDA and Industry Actions on Premarket Notification (510k(k)) Submissions: Effect on FDA Review Clock and Goals	www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-premarket-notification-510k-submissions-effect-fda-review-clock-and-goals
8	Refuse to Accept Policy for 510(k)s	www.fda.gov/regulatory-information/search-fda-guidance-documents/refuse-accept-policy-510ks
15	The Least Burdensome Provisions: Concept and Principles	www.fda.gov/regulatory-information/search-fda-guidance-documents/least-burdensome-provisions-concept-and-principles
16	CDRH Management Directory	www.fda.gov/about-fda/cdrh-offices/cdrh-management-directory-organization

Resources, cont'd

Slide Number	Cited Resource	URL
20	510(k) Pilots Web page	www.fda.gov/medical-devices/premarket-notification-510k/510k-program-pilots
22	Safety and Performance Based Pathway Program	www.fda.gov/medical-devices/premarket-notification-510k/safety-and-performance-based-pathway
23	ASCA Pilot Web page	www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca
23	ASCA Pilot program guidance	www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-pilot-program
25	Progress Tracker Pilot	www.fda.gov/medical-devices/industry-medical-devices/progress-tracker-premarket-submissions

Questions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