Third Party (3P) Premarket Review Program

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When being the third wheel can actually be a good thing

https://i.pinimg.com/originals/19/1d/f7/191df76356903675c5fff142cc95cf9f.jpg

Presentation Outline

1. General Information
2. 3P Review Workflow
3. MDUFA IV Commitments

I. GENERAL INFORMATION

Introduction to the 3P review program

The 3P Review Program will save you and FDA time and money

- Option of using accredited, non-federal organizations to review 510(k)s for low and moderate risk devices
- Better allocation of FDA's resources
- More rapid marketing clearance decisions
- FDA review timeline = **30 DAYS**

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The 3P Review Program was formally established By FDAMA

- **Third Party Review Pilot Program** for 510(k) submissions of selected medical devices [August 1, 1996]

- **Food and Drug Administration Modernization Act (FDAMA)** codified and expanded the pilot program by establishing section 523 of the Act [November 21, 1997]

The 3P Review Program was granted further authority through FDASIA and FDARA

- **Food and Drug Administration Safety and Innovation Act (FDASIA)** established criteria to accredit, reaccredit, and deny reaccreditation of 3P Review Organizations [July 9, 2012]

- **Food and Drug Administration Reauthorization Act (FDARA)** changed statutory requirements in determining 3P eligibility of class I and class II devices and incorporates MDUFA IV commitments [August 18, 2017]

3P Review Organizations cannot review all device types

- No Class III devices
- No Class II devices that:
  - Are permanently implantable
  - Are life sustaining/supporting, or
  - Require clinical data in 510(k)s
- No 510(k)s that requires multi-Center review (e.g. 510(k) for combination products, consulting reviews outside of CDRH, etc.)

http://peaceworks-coaching.com/wp-content/uploads/2015/08/NO.png

We have previously cleared IVD devices through the 3P Review Program

- **JOY**: Automated Cell-Locating Device
  - 21 CFR 864.5260 - Automated Cell-Locating Device
  - Hematology Panel

https://www.moleculardevices.com/sites/default/files/styles/gallery_xlarge/public/instruments/gallery/ImageXpressPicoLeft-lo.jpg?itok=LIMthTu2

FDARA opens up more IVD device types to 3P by allowing certain kinds of clinical data

Before FDARA

§ 360m. Accredited persons

(a) In general

(3) Certain devices

(A) In general

An accredited person may not be used to perform a review of—

(i) a class III device;

(ii) a class II device which is intended to be permanently implantable or life sustaining or life supporting; or

(iii) a class II device which requires clinical data in the report submitted under section 360(k) of this title for the device, except that the number of class II devices to which the Secretary applies this clause for a year, less the number of such reports to which clauses (i) and (ii) apply, may not exceed 6 percent of the number that is equal to the total number of reports submitted to the Secretary under such section for such year less the number of such reports to which such clauses apply for such year.

After FDARA

21 U.S. Code § 360m - Accredited persons

(a) IN GENERAL

(3) CERTAIN DEVICES

(A) In general An accredited person may not be used to perform a review of—

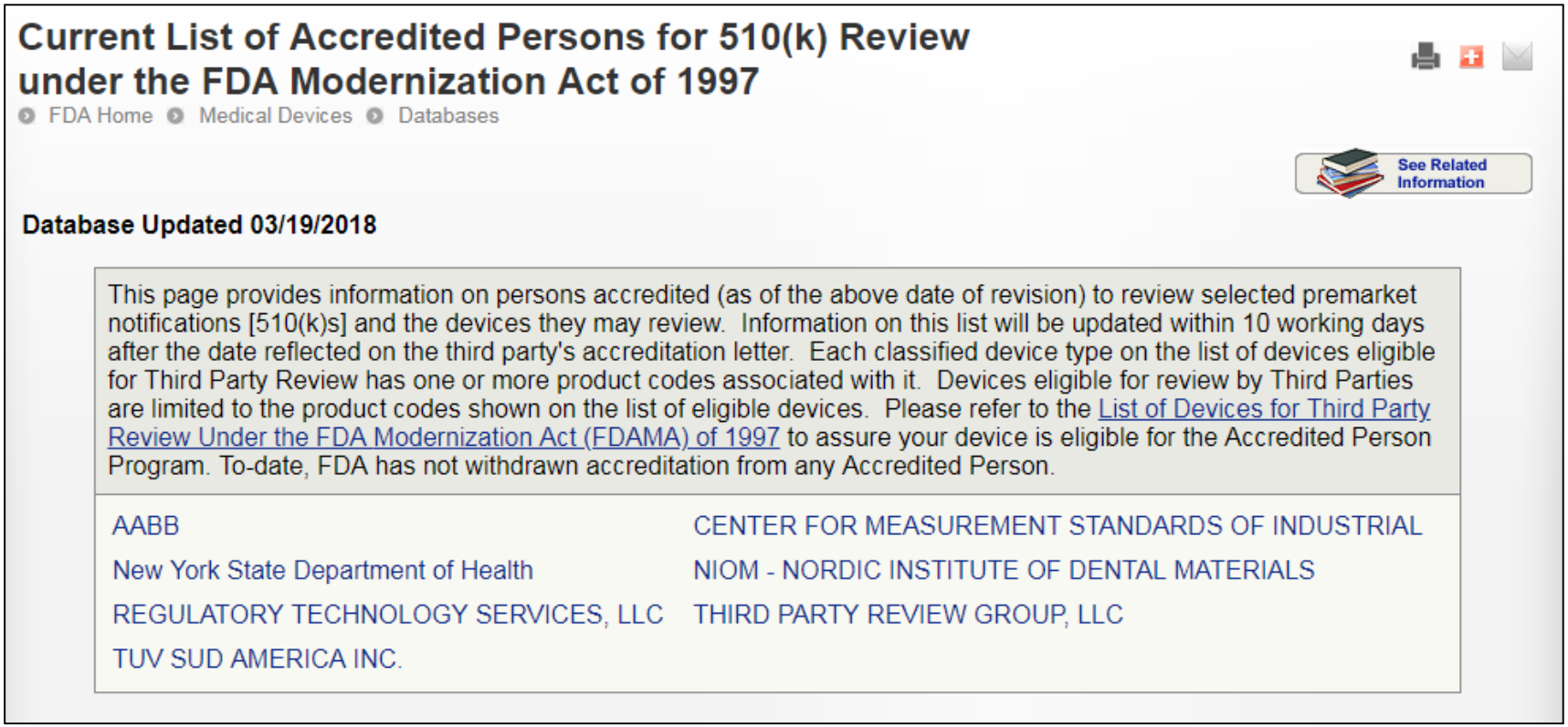
(i) a class III device;

(ii) a device classified under section 360c(f)(2) of this title or designated under section 360e–3 (d)
[1] of this title;

(iii) a device that is intended to be permanently implantable, life sustaining, or life supporting, unless otherwise determined by the Secretary in accordance with subparagraph (B)(i)(II) and listed as eligible for review under subparagraph (B)(iii); or

(iv) a device that is of a type, or subset of a type, listed as not eligible for review under subparagraph (B)(iii).

The 3P website provides a list of accredited 3P Review Organizations



Current List of Accredited Persons for 510(k) Review under the FDA Modernization Act of 1997

FDA Home › Medical Devices › Databases

See Related Information

Database Updated 03/19/2018

This page provides information on persons accredited (as of the above date of revision) to review selected premarket notifications [510(k)s] and the devices they may review. Information on this list will be updated within 10 working days after the date reflected on the third party's accreditation letter. Each classified device type on the list of devices eligible for Third Party Review has one or more product codes associated with it. Devices eligible for review by Third Parties are limited to the product codes shown on the list of eligible devices. Please refer to the List of Devices for Third Party Review Under the FDA Modernization Act (FDAMA) of 1997 to assure your device is eligible for the Accredited Person Program. To-date, FDA has not withdrawn accreditation from any Accredited Person.

AABB	CENTER FOR MEASUREMENT STANDARDS OF INDUSTRIAL
New York State Department of Health	NIOM - NORDIC INSTITUTE OF DENTAL MATERIALS
REGULATORY TECHNOLOGY SERVICES, LLC	THIRD PARTY REVIEW GROUP, LLC
TUV SUD AMERICA INC.	

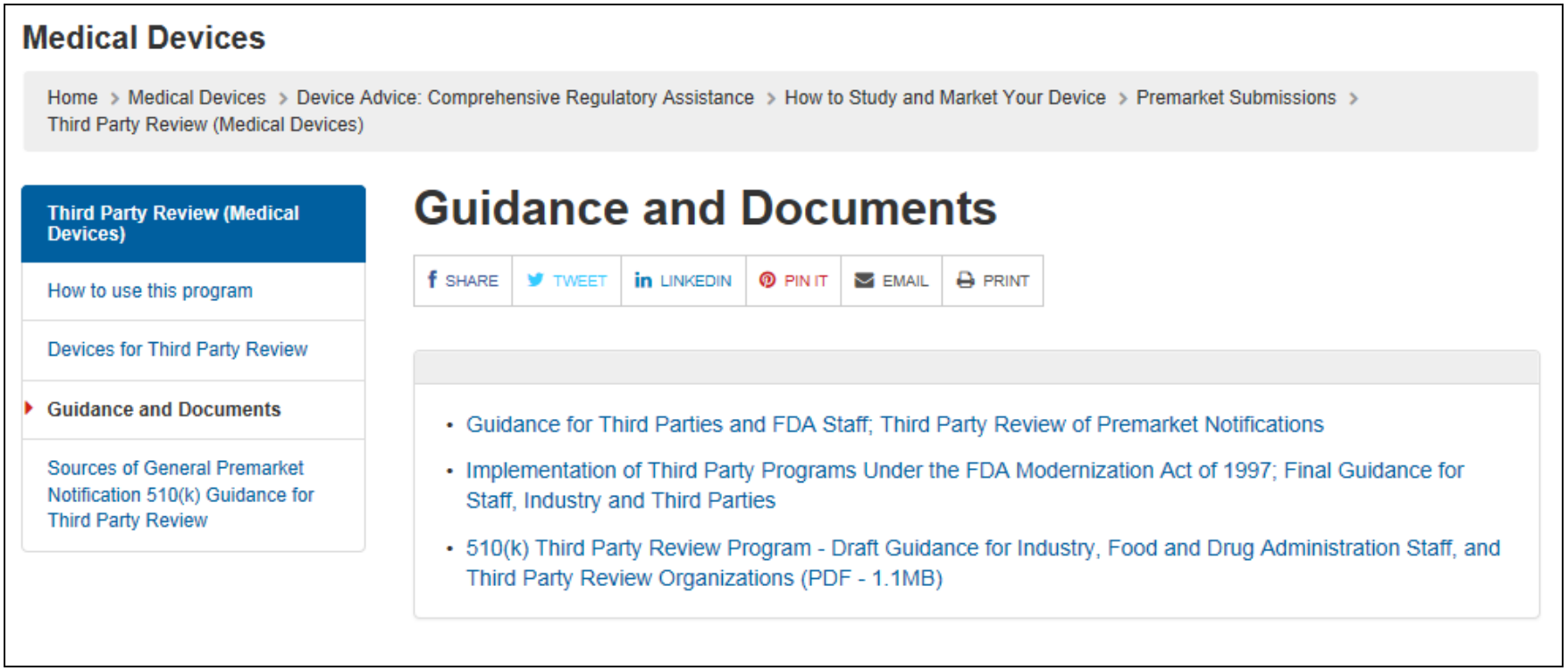
FDA has multiple websites to check device eligibility in the 3P Review Program

1. List of Devices for Third Party Review: https://www.acessdata.fda.gov/scripts/cdrh/cfdocs/cfThirdParty/current.cfm

2. Product Classification Database: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm

3. Current List of Accredited Persons for 510(k) Review: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfthirdparty/accredit.cfm

The 3P guidance documents provide more detailed information

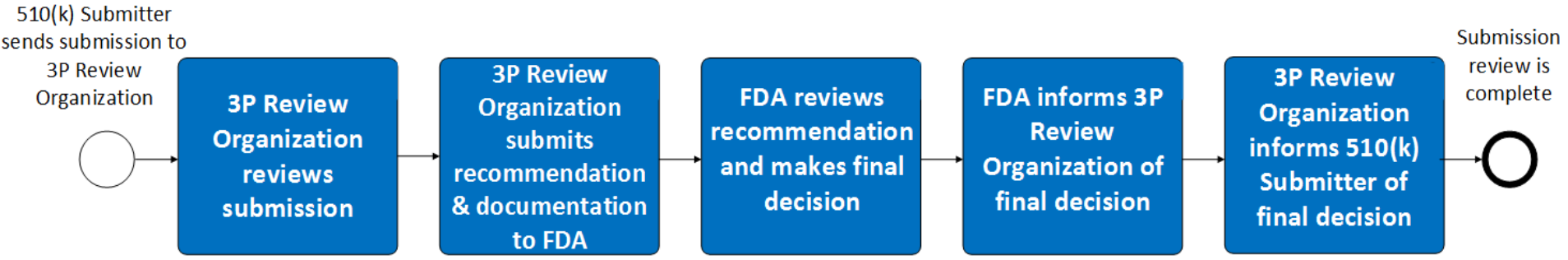


http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ThirdParyReview/ucm123993.htm

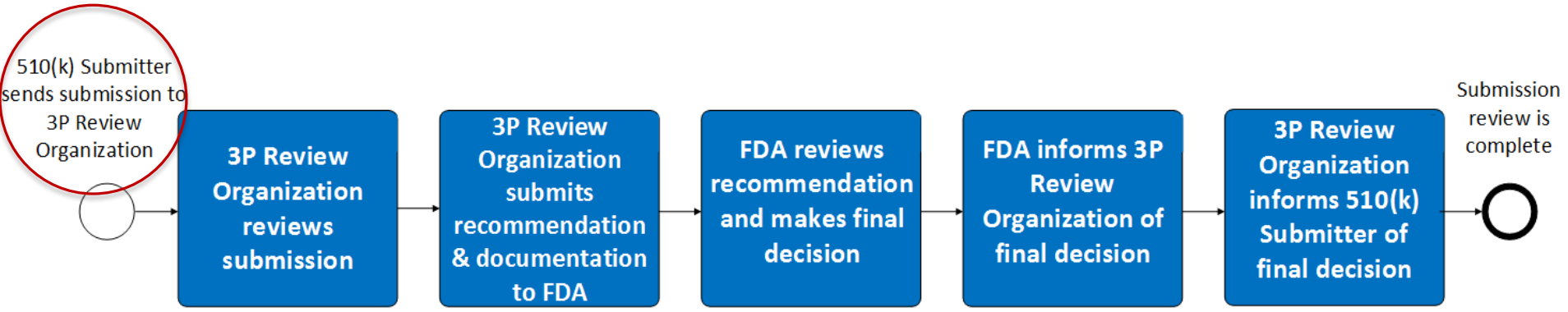
II. REVIEW WORKFLOW

Overview of workflow process of third party review organization.

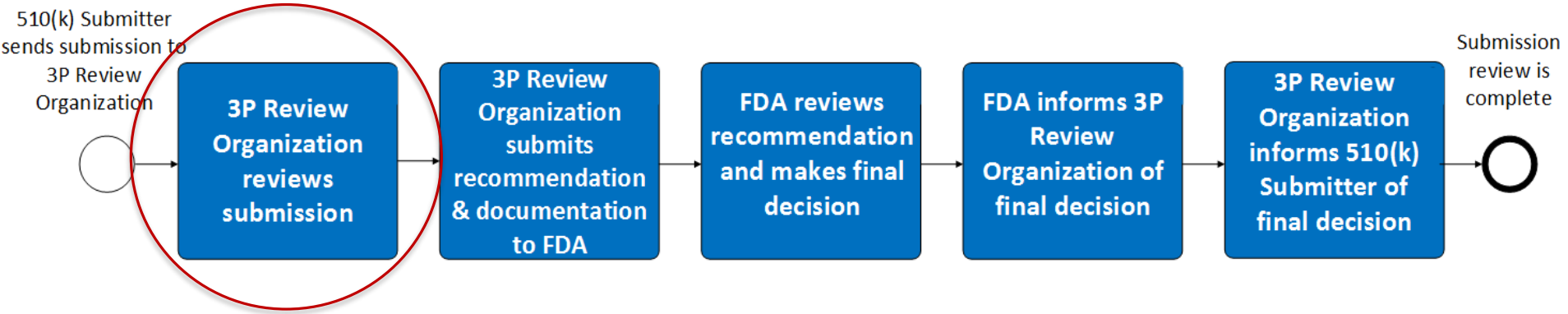
Overview of 3P Paradigm



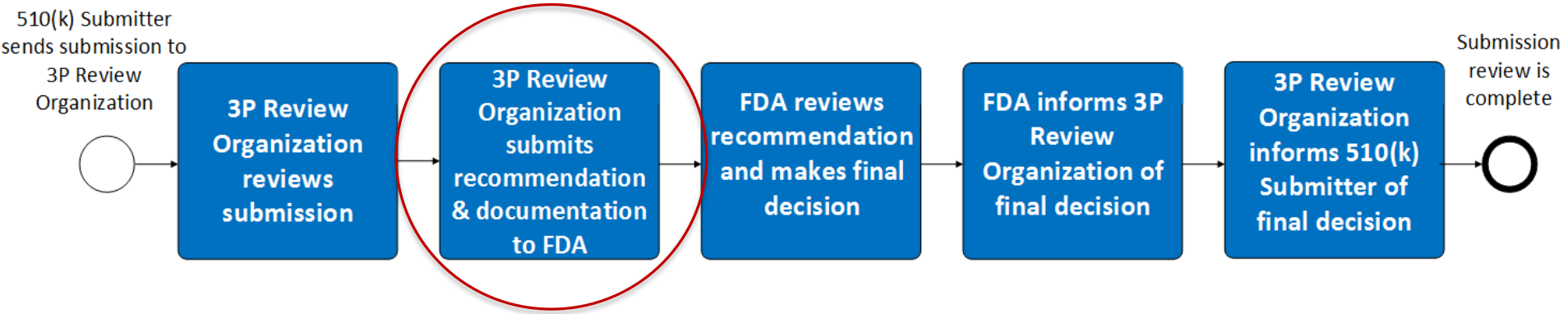
510(k) Submitter chooses to send a submission to 3P Review Organization (3PRO)



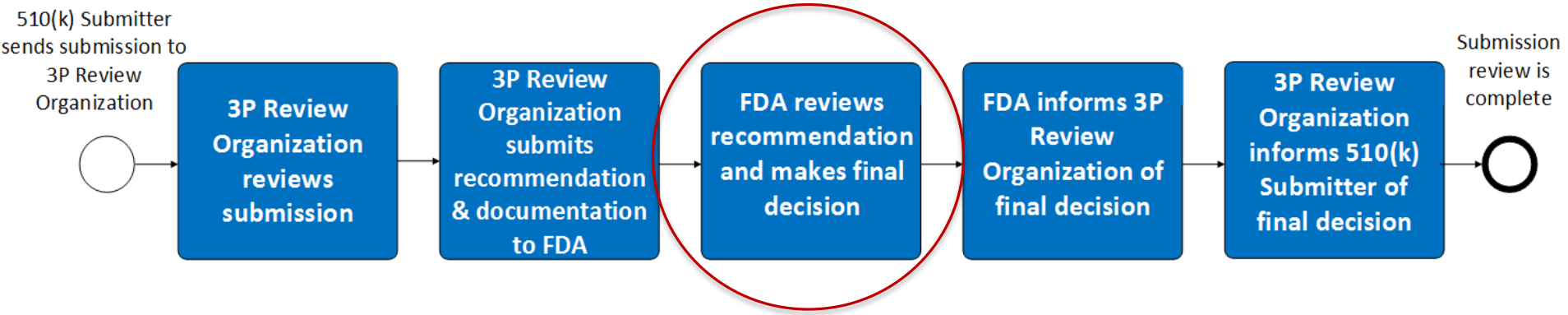
3PRO reviews submission



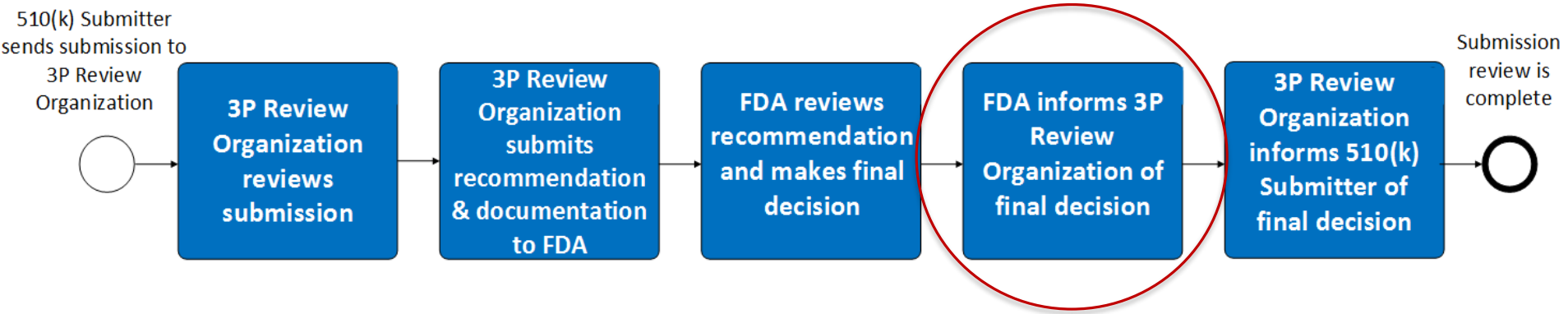
3PRO submits recommendation, review memo and associated documentation to FDA



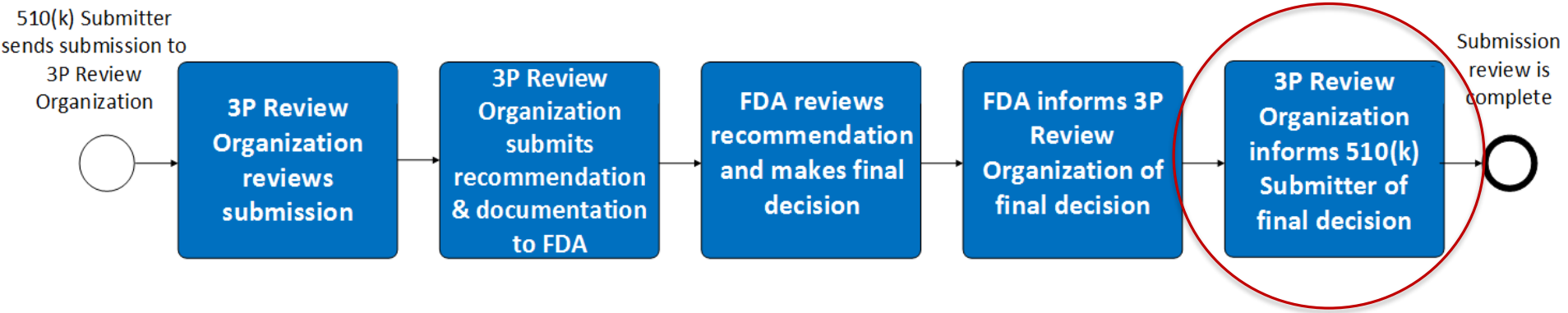
FDA reviews recommendation and makes final decision



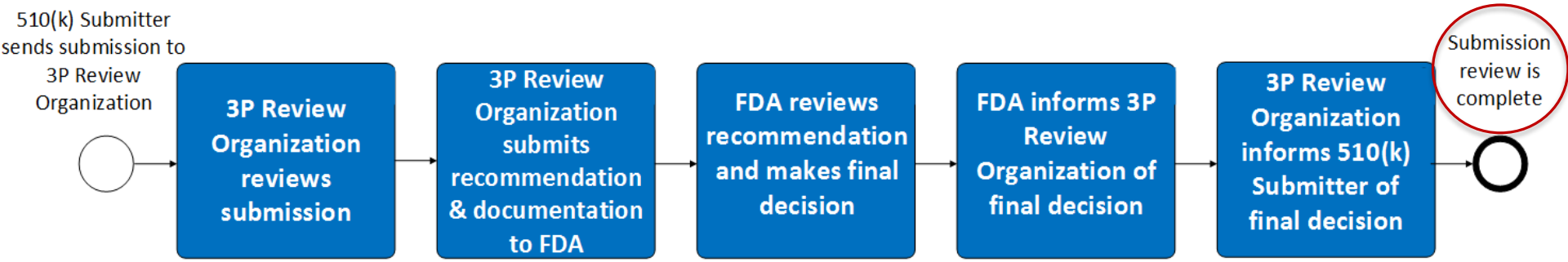
FDA informs 3PRO of final decision



3PRO informs 510(k) Submitter of final decision



3P submission review is complete



FDA can request additional information before making a final decision

- If additional information is needed to determine a clearance decision, FDA will contact the 3PRO with **deficiencies**.
- When a submission is placed on hold, 3PRO and 510(k) submitter have **180 days** to provide a supplemental response.
- After 3PRO submits *recommendation* to FDA, the agency makes the **final decision** and informs 3PRO.

All communication goes through the 3PRO

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https://thumb9.shutterstock.com/display_pic_with_logo/3747080/346652762/stock-vector-conference-icon-people-sitting-at-the-table-346652762.jpg

Sharing information upfront can streamline the review process

- 510(k) submitter has to grant permission to share all submissions related to the device in question with 3PRO
  - Unsuccessful marketing applications, pre-submissions, etc.
  - Provide submission numbers

- 510(k) submitter can request for 3PRO to be present at pre-submission meetings

III. MDUFA IV COMMITMENTS

MDUFA IV (M4) commitments strengthen the 3P Review Program

E. Third Party Review

The Agency will take the following actions to improve the Third Party Review program with a goal of eliminating routine re-review by FDA of Third Party reviews:

1. Strengthen the process for accreditation of Third Parties.
    a. Provide training for Third Parties seeking accreditation by FDA. This training shall include the opportunity for Third Parties to have access to redacted review memos and other information as appropriate.
    b. When FDA's expectations for a particular device type change, FDA will have in place a process to convey this information to the Third Parties and to industry.
2. By the end of FY 2018, establish a plan for eliminating routine re-review by FDA of Third Party reviews and implement plan within 12 months.
3. Implement a program to audit reviews conducted by accredited Third Parties.
    a. Provide tailored re-training to accredited Third Parties based on the results of audits.
4. By the end of FY 2018, issue draft guidance outlining criteria for reaccreditation of 3rd Parties and the suspension or withdrawal of accreditation of a Third Party. FDA will issue final guidance within 12 months of the conclusion of the public comment period.
5. Publish performance of individual accredited Third Parties with at least five completed submissions on the web (e.g., rate of NSE, average number of holds, average time to SE).
6. Require the independent assessment of the Third Party Review Program to evaluate efficiency including the circumstances when FDA re-reviews were conducted; and to suggest process improvements.

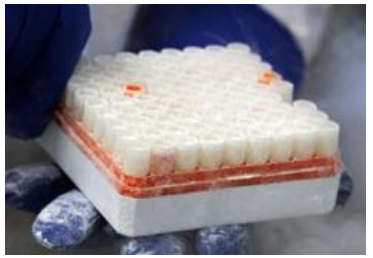
The Agency will seek greater authority to tailor the program. Specifically, FDA intends to expand the scope of the program to some product codes that require clinical data and to remove product codes from eligibility when appropriate, such as if/when safety signals arise.

As resources permit, FDA will identify pilot device areas to be the specific focus of an effort where FDA would work with willing industry partners to ensure that information allowing for high quality Third Party reviews could be made available to provide a proof of concept in certain device areas and enable the development of a broader successful program.

MDUFA IV commitments specifically target and encourage the successful use of the 3P Program for IVD devices

- New statutory requirements expands the use of clinical data in the 3P Program

  ↑ number of IVD devices eligible for 3P review



- 3PROs were trained on case studies based on redacted, cleared 510(k) decision memorandums for 3P eligible product codes in October 2017 with a focus on IVD devices. More training to come.

Magnesium Test	Varicella-Zoster Virus Test	Next Generation Sequencing Test
Fibrinogen Test	Vitamin D Test	Ultrasound Systems

http://academicdepartments.musc.edu/sebin/x/w/STspecimenvialsInset300.jpg

Training program will be device-specific and posted to fda.gov

Training sessions will be:

- led by subject matter experts
- focused on how to review and document a particular product area
- posted to fda.gov website to provide consistent training and open access to current and new 3PROs

FDA will issue draft guidance on factors used to determine 3P eligibility

§360m. Accredited persons

(a) In general

(3) Certain devices

(B) Designation for review

The Secretary shall-

(i) issue draft guidance on the factors the Secretary will use in determining whether a class I or class II device type, or subset of such device types, is eligible for review by an accredited person, including-

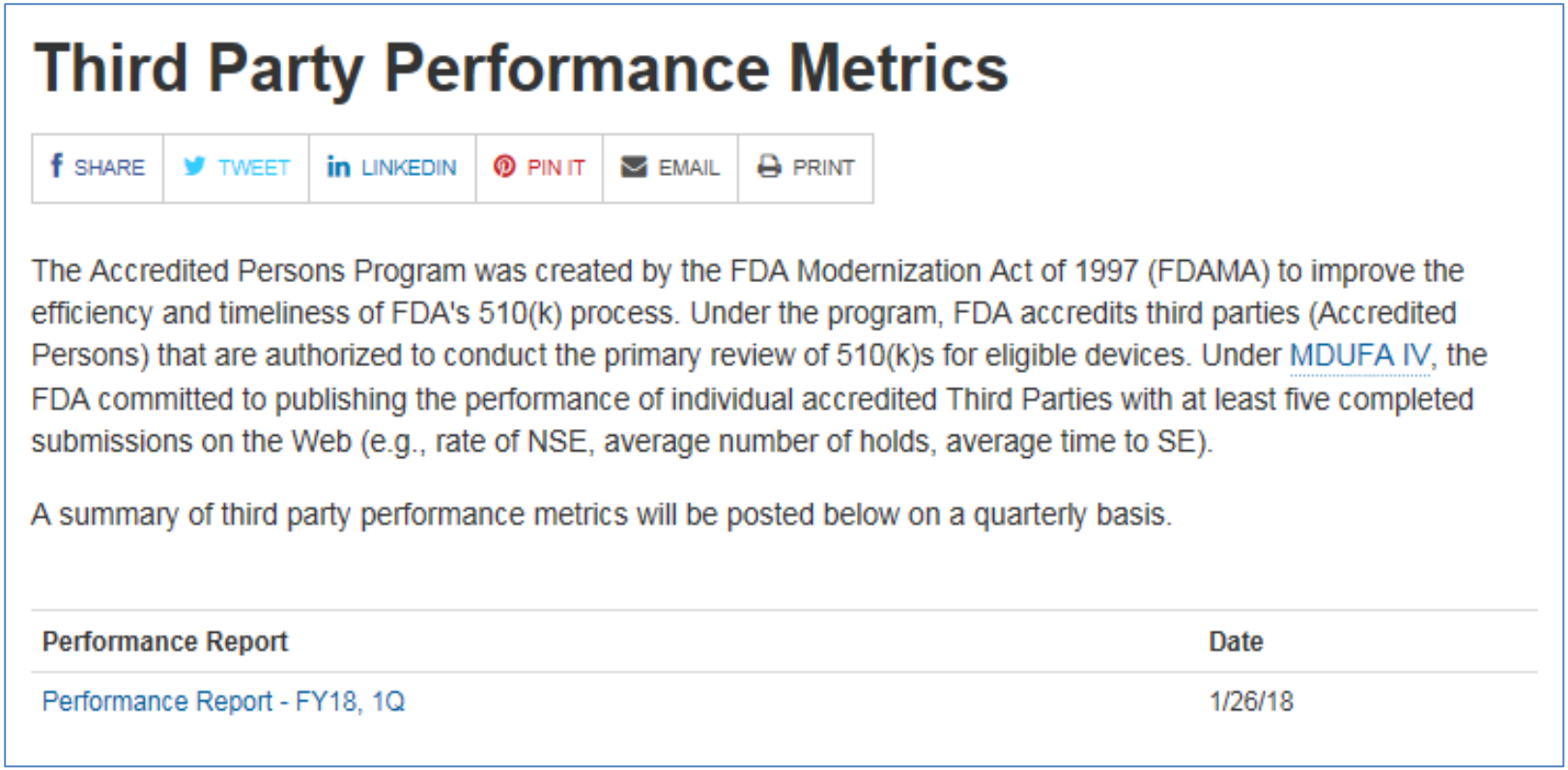
(I) the risk of the device type, or subset of such device type; and

(II) whether the device type, or subset of such device type, is permanently implantable, life sustaining, or life supporting, and whether there is a detailed public health justification for permitting the review by an accredited person of such device type or subset;

(ii) not later than 24 months after the date on which the Secretary issues such draft guidance, finalize such guidance; and

(iii) beginning on the date such guidance is finalized, designate and post on the internet website of the Food and Drug Administration, an updated list of class I and class II device types, or subsets of such device types, and the Secretary's determination with respect to whether each such device type, or subset of a device type, is eligible or not eligible for review by an accredited person under this section based on the factors described in clause (i).

Performance reports with metrics for individual 3PRO are published on the 3P website



Third Party Performance Metrics

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The Accredited Persons Program was created by the FDA Modernization Act of 1997 (FDAMA) to improve the efficiency and timeliness of FDA's 510(k) process. Under the program, FDA accredits third parties (Accredited Persons) that are authorized to conduct the primary review of 510(k)s for eligible devices. Under MDUFA IV, the FDA committed to publishing the performance of individual accredited Third Parties with at least five completed submissions on the Web (e.g., rate of NSE, average number of holds, average time to SE).

A summary of third party performance metrics will be posted below on a quarterly basis.

Performance Report	Date
Performance Report - FY18, 1Q	1/26/18

The 3P program is another 510(k) regulatory pathway for eligible devices

- For eligible devices, a 510(k) submitter can opt to submit their 510(k) submission through an accredited Third Party Review Organization
  - List of Accredited Persons can be found in the following link: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfthirdparty/accredit.cfm

- Please visit the FDA Third Party website for more information: https://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/thirdparyreview/default.htm

https://www.colourbox.com/image/inviting-people-to-join-the-team-business-team-joining-hands-concept-on-white-background-image-5737089

If you have any questions, please email 3P510K@fda.hhs.gov


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