Third Party Review: FDA Perspective

October 11, 2018

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Agenda:

1. Overview of 3rd Party Review Program

2. MSK IMPACT: A Regulatory Case Study

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1. Overview of 3rd Party Review Program

2. MSK IMPACT: A Regulatory Case Study

The Third Party Program exists to improve public health

The program improves public health by saving you and FDA time and resources

- Option of using accredited, non-federal 3rd Party Review Organizations (“3PROs”) to review 510(k)s for low and moderate risk devices
- Better allocation of FDA’s resources
- More rapid marketing clearance decisions
- FDA review in **30 Days**

FDA committed to revitalize the program in MDUFA IV…

Strengthen Accreditation

Make 3PRO Performance More Transparent

Give 3PROs the Information They Need

Share a Plan to Improve the Program

Assess Quality

Publish Draft Guidance

Participate in the Independent Assessment

…and FDA is delivering on that commitment

Strengthen Accreditation

Make 3PRO Performance More Transparent

Piloted

Give 3PROs the Information They Need

Share a Plan to Improve the Program

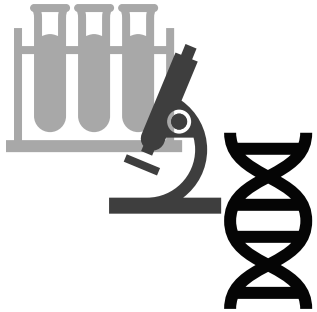
Piloting

Assess Quality

Publish Draft Guidance

Participate in the Independent Assessment

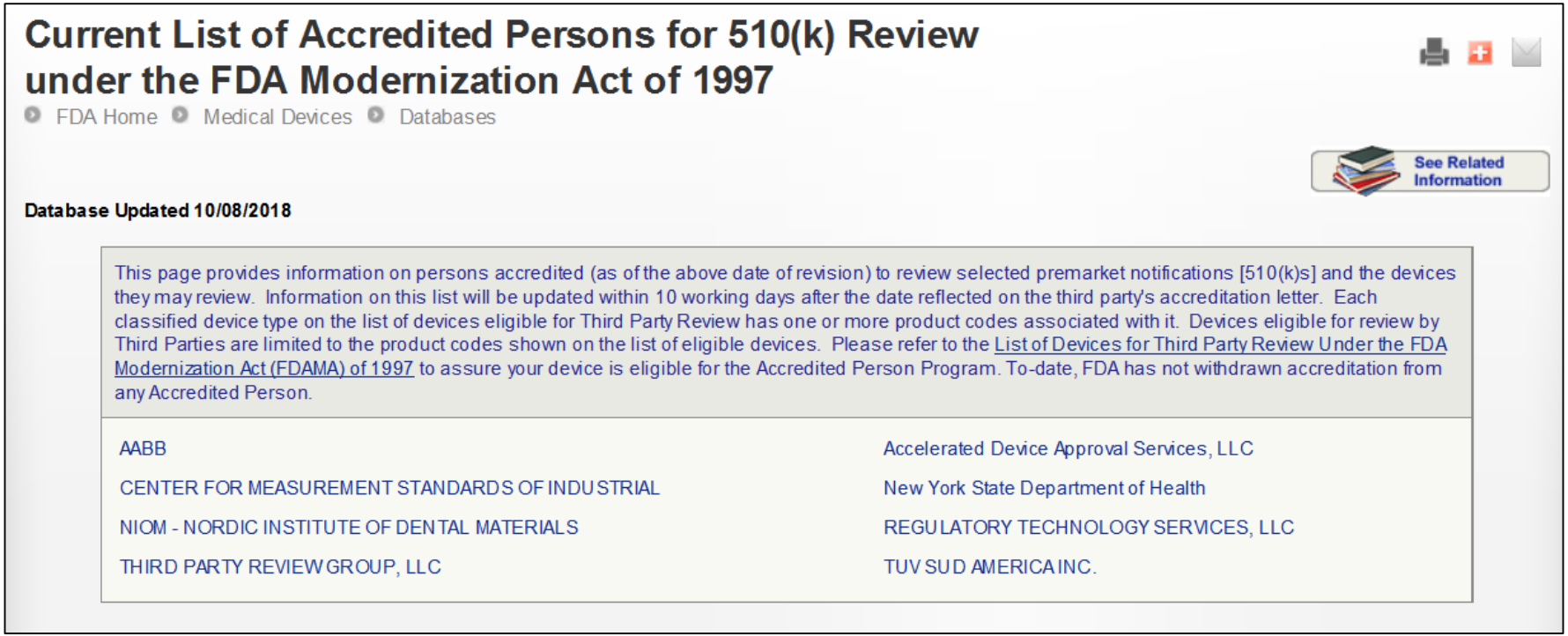
MDUFA IV commitments specifically target the program at diagnostics



- New statutory criteria expand the use of clinical data in the 3P Program
  - Intend to make many diagnostics product codes eligible
- 3PROs were trained on case studies based on redacted, cleared 510(k) decision memorandums for 3P eligible product codes with a focus on diagnostics. More training is in the works.

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

New and longstanding 3PROs want your business & are targeting diagnostics



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

FDA Home › Medical Devices › Databases

See Related Information

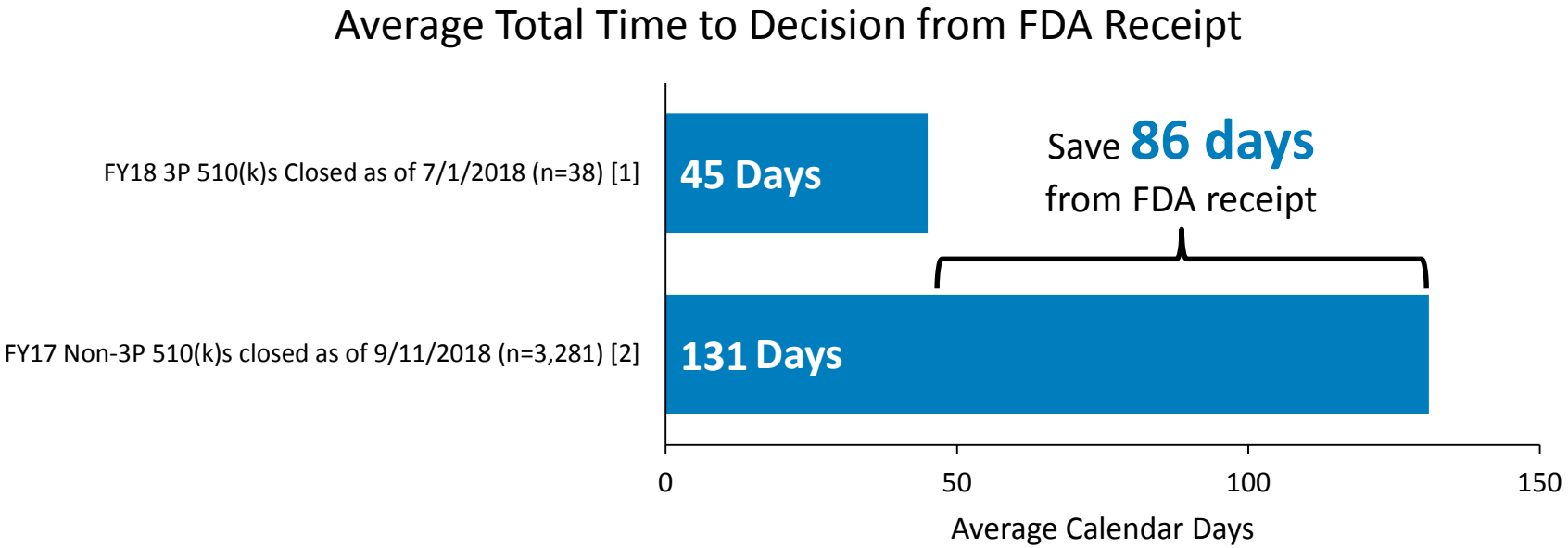
Database Updated 10/08/2018

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	Accelerated Device Approval Services, LLC
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.

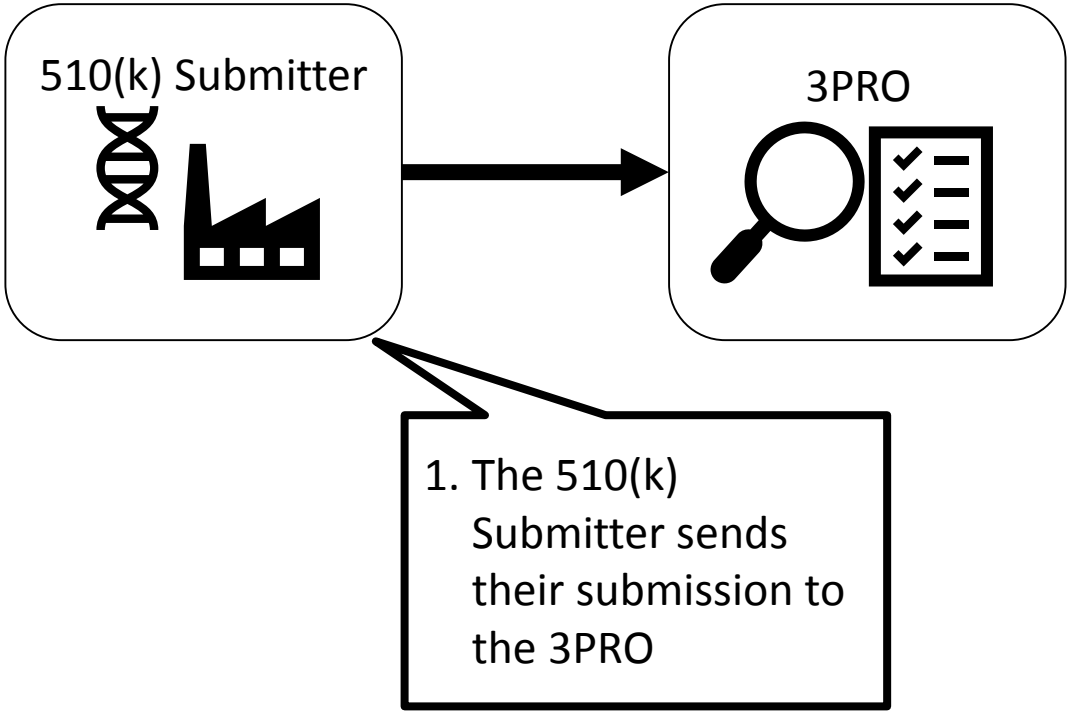
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfThirdParty/Accredit.cfm

FDA review of 3P 510(k)s is fast, and we're making it faster

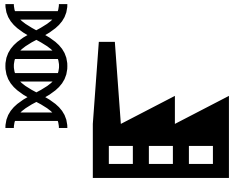


[1] https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/UCM613892.pdf, p. 14
[2] https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM620391.pdf, p. 192

3P Review Process Overview:
The 3PRO acts as a trusted intermediary between the submitter and FDA

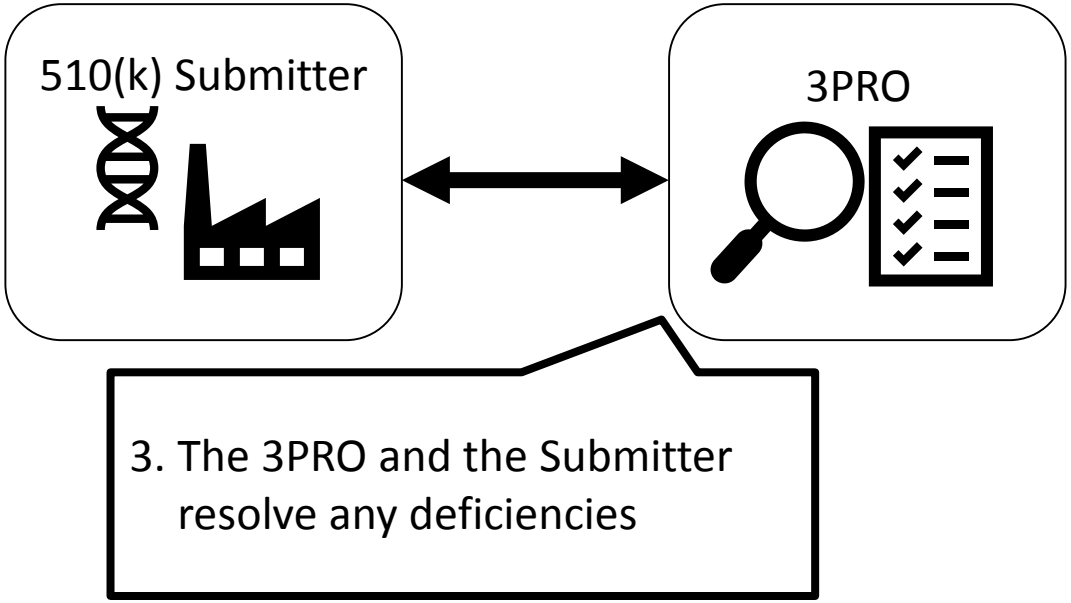

510(k) Submitter
3PRO
1. The 510(k) Submitter sends their submission to the 3PRO

510(k) Submitter

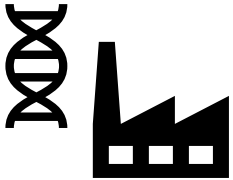


3PRO

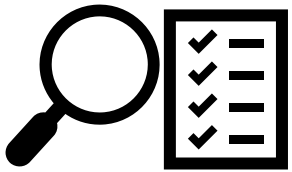
2. The 3PRO reviews the submission


510(k) Submitter
3PRO
3. The 3PRO and the Submitter resolve any deficiencies

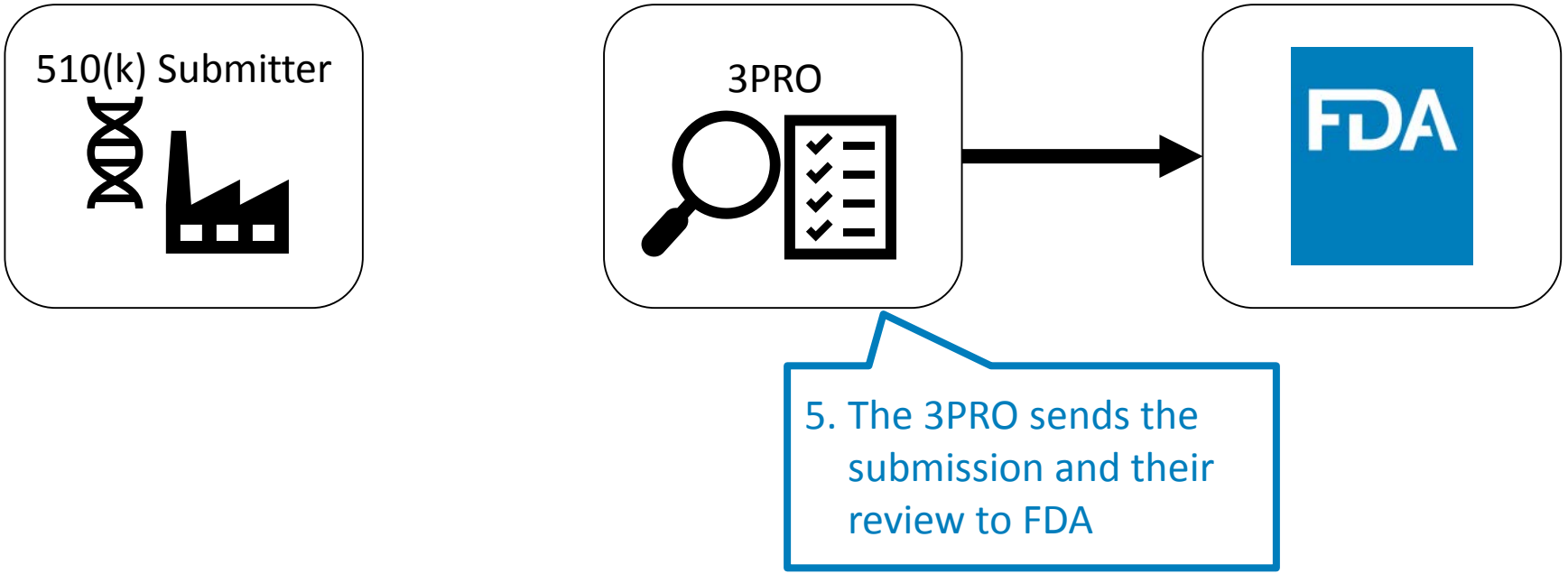
510(k) Submitter



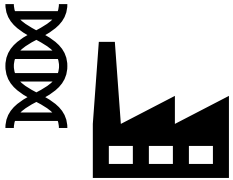
3PRO



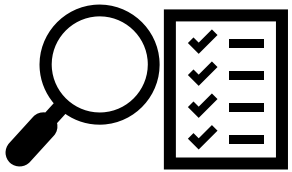
4. The 3PRO finalizes and documents their recommendation


510(k) Submitter
3PRO
FDA
5. The 3PRO sends the submission and their review to FDA

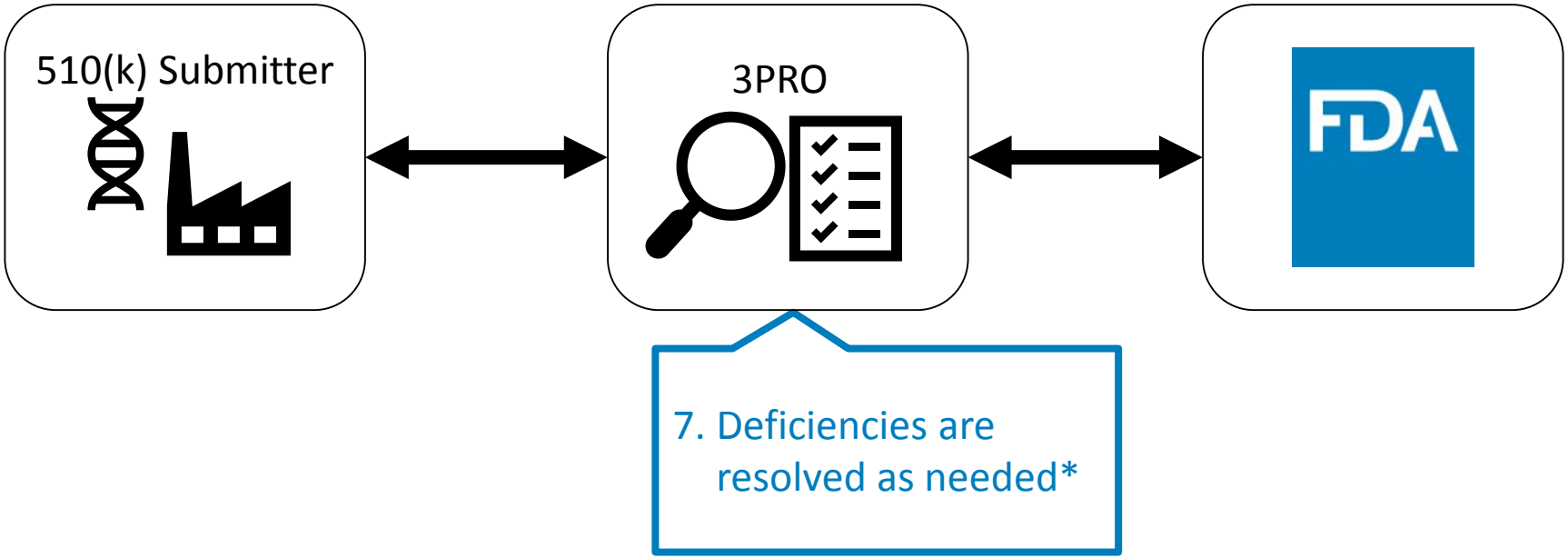
510(k) Submitter



3PRO



6. FDA reviews the 3PRO's memo and recommendation



* Shouldn't be needed


510(k) Submitter
3PRO
FDA
8. FDA finalizes and communicates its decision through the 3PRO

Result: An FDA-equivalent review, in less time, through a trusted intermediary

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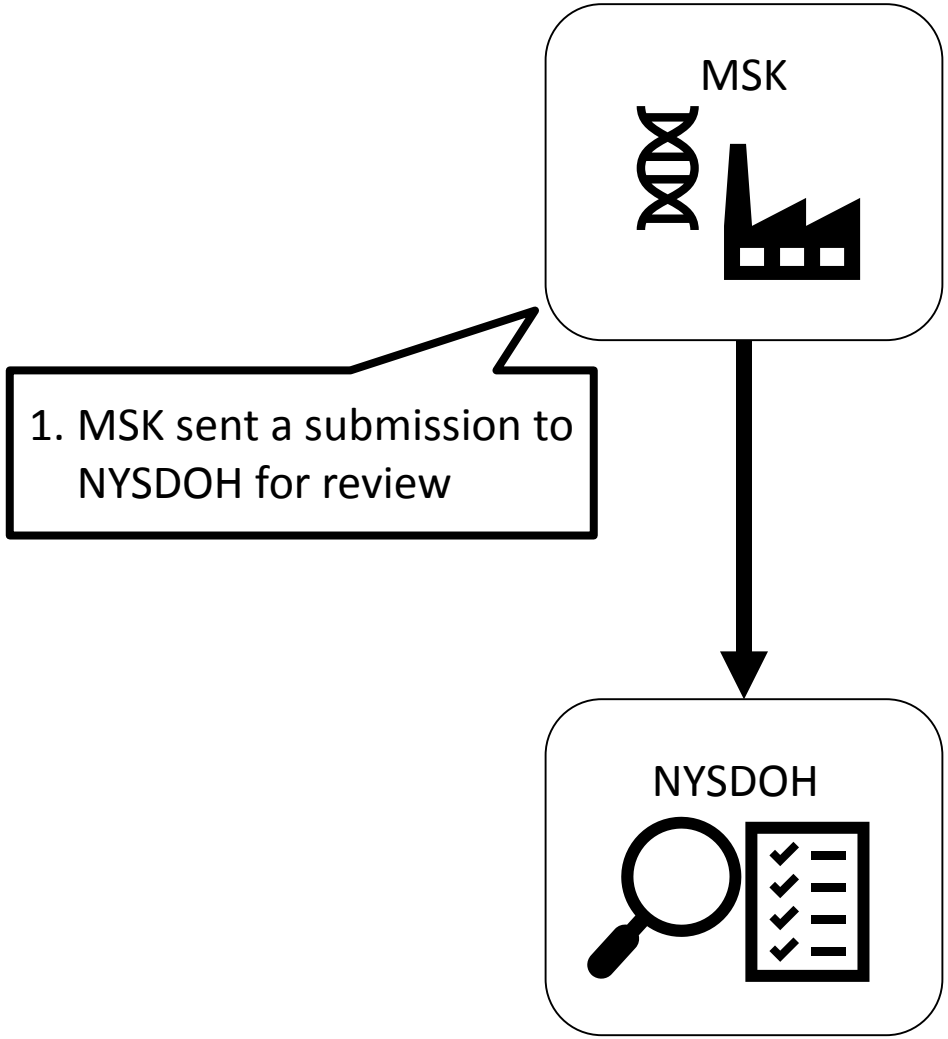
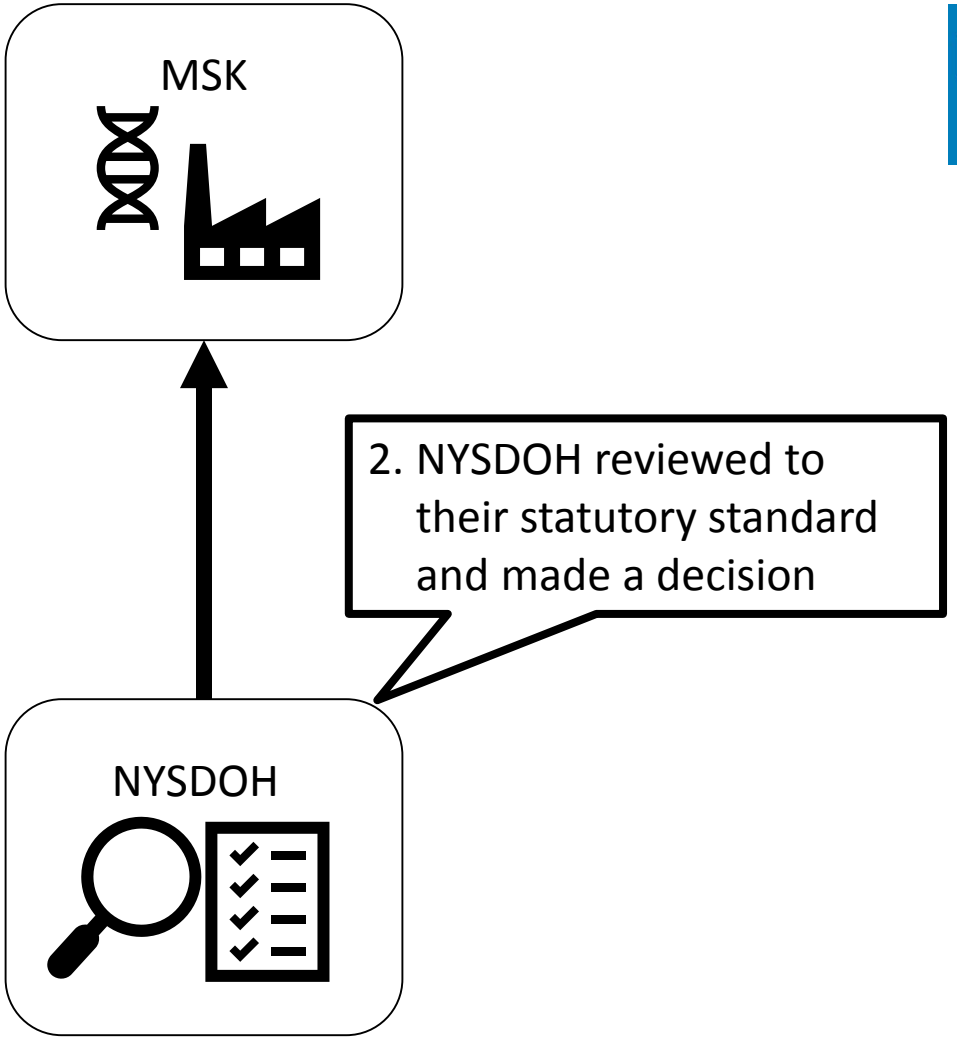
2. MSK IMPACT: A Regulatory Case Study

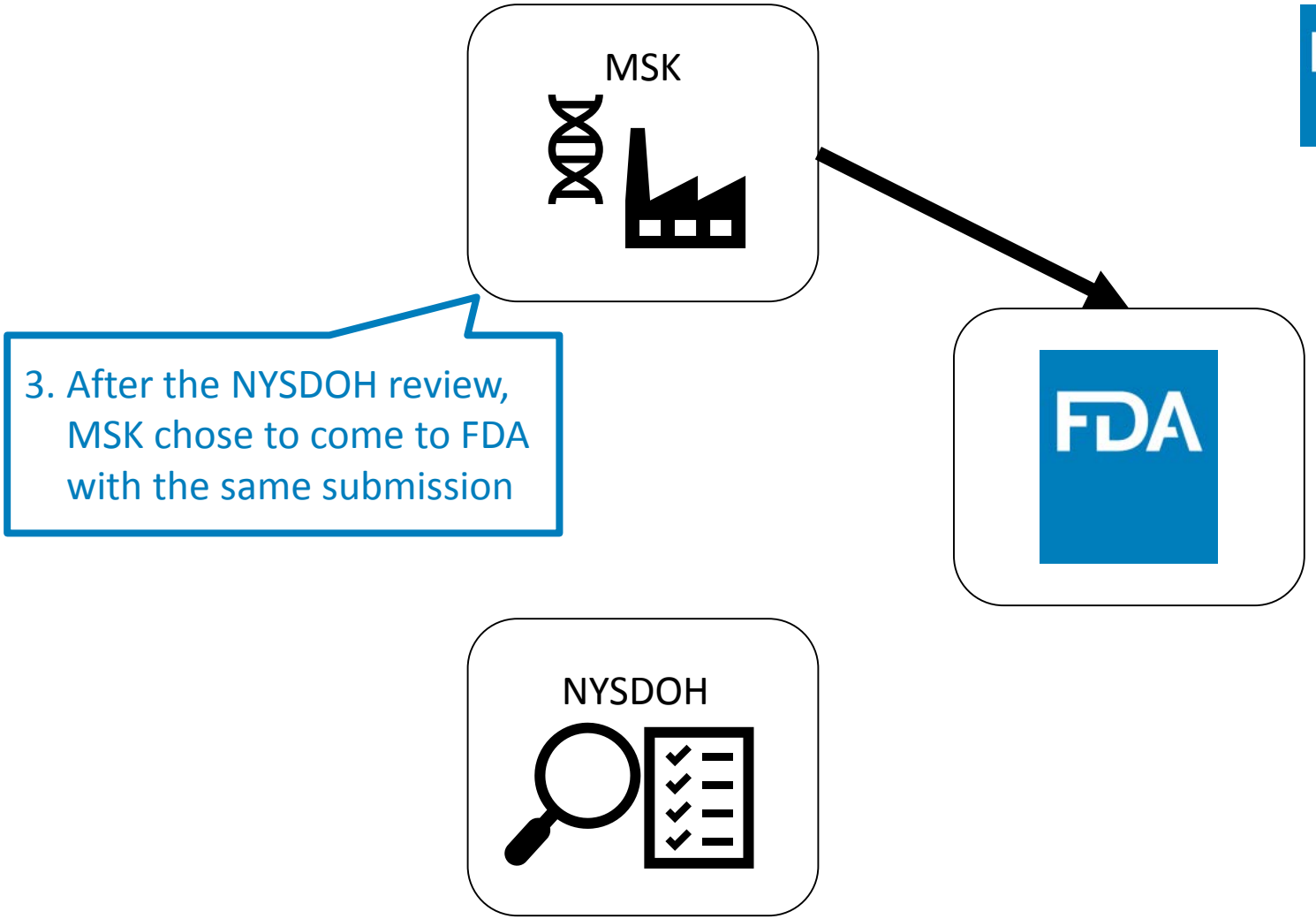
MSK IMPACT: A Regulatory Case Study

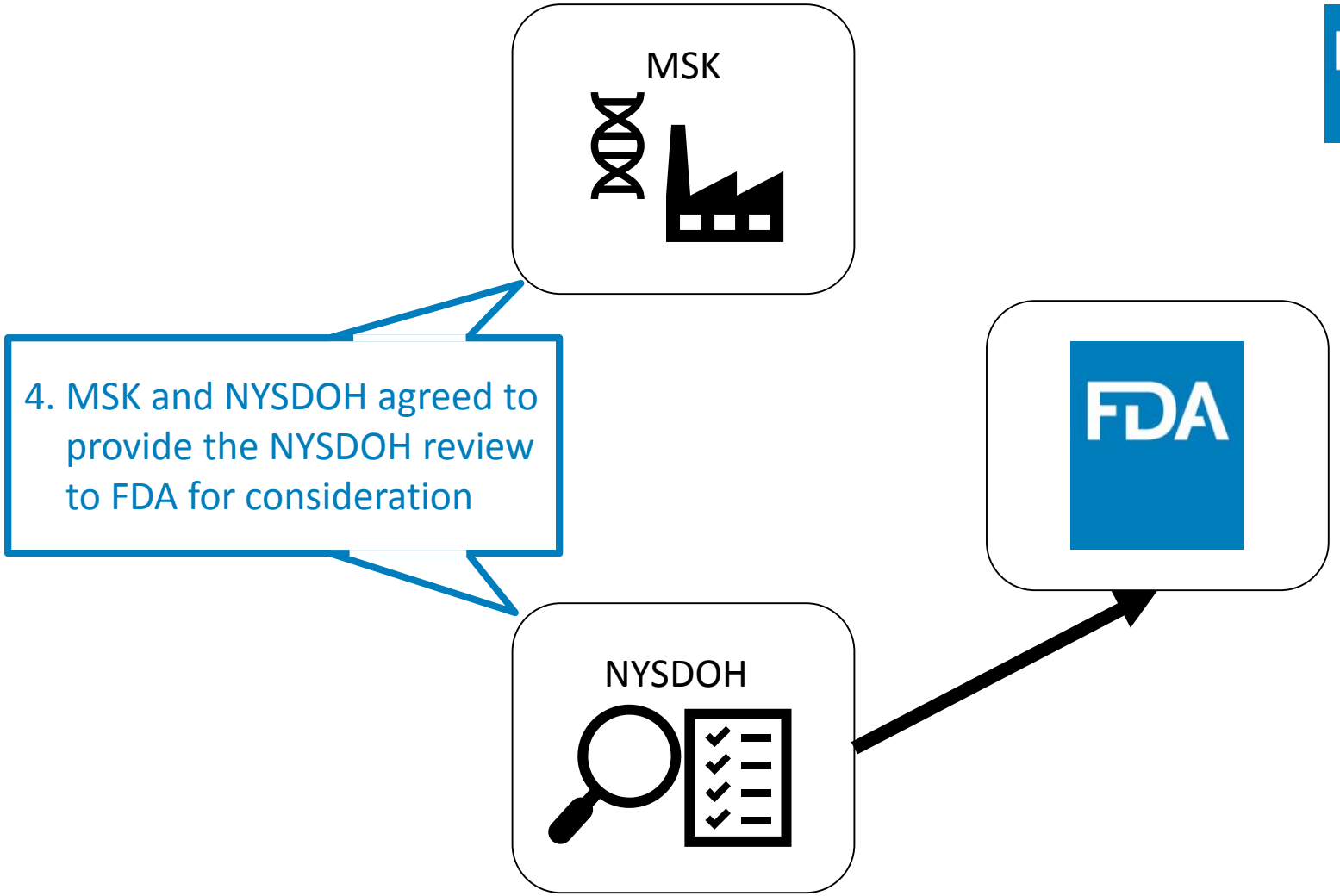
Because the MSK IMPACT De Novo was a trial run, and because all parties agreed, we blazed a new trail

Disclaimer: There is no 3rd Party Review program for De Novos

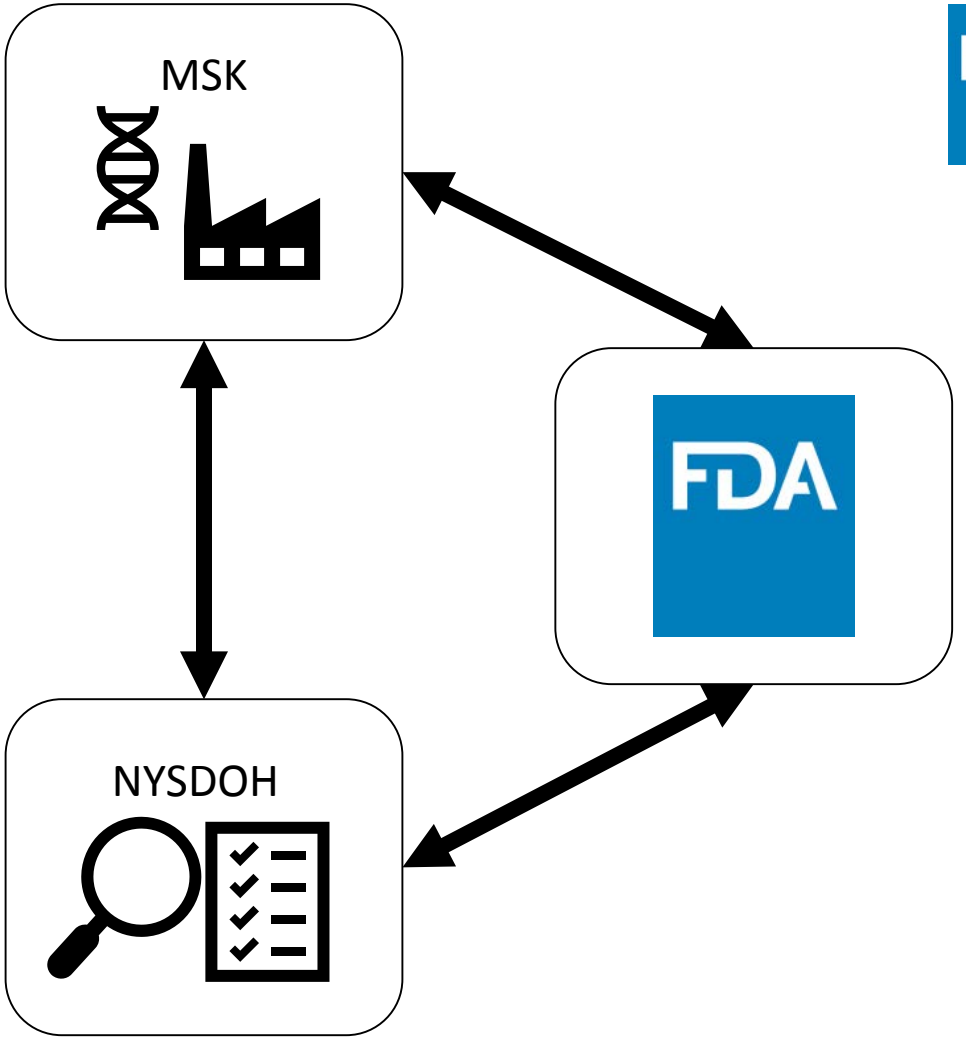

MSK
1. MSK sent a submission to NYSDOH for review
NYSDOH


MSK
2. NYSDOH reviewed to their statutory standard and made a decision
NYSDOH


MSK
FDA
3. After the NYSDOH review, MSK chose to come to FDA with the same submission
FDA
NYSDOH

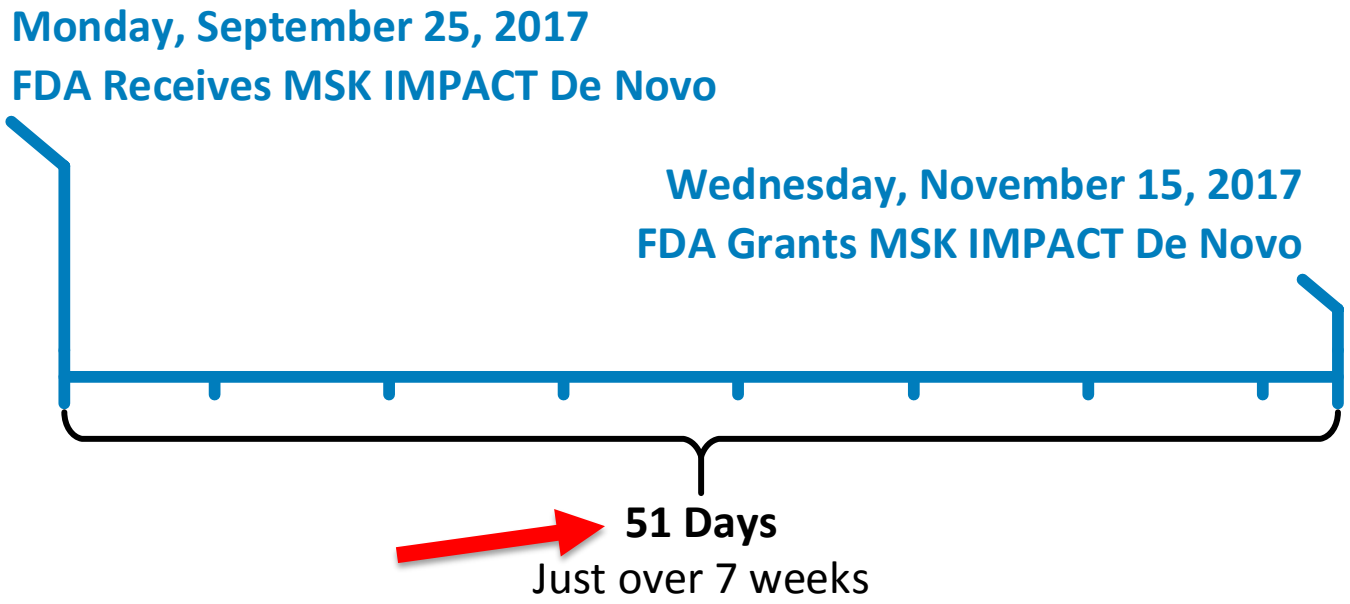

MSK
4. MSK and NYSDOH agreed to provide the NYSDOH review to FDA for consideration
NYSDOH
FDA

All parties agreed to work interactively with open lines of communication



Result: 3PRO review saved FDA time

A typical De Novo review can take 150 days, not including requests for additional information. But in this case…



Result: FDA established a 3P-eligible 510(k) pathway for tumor profiling

"…FDA worked closely with NYSDOH and MSK to help ensure that the IMPACT test is accurate, reliable and clinically meaningful. This collaboration is an excellent example of how the FDA can partner with the medical and development communities to review innovative tests as quickly as possible."

- *Jeff Shuren, MD*
  CDRH Director

Result: New pathway provides timely access to validated tumor profiling diagnostics to better inform treatment decisions for cancer patients

Questions?

3P510K@fda.hhs.gov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