

Data & Technology Strategy



U.S. FOOD & DRUG
ADMINISTRATION

Ram Iyer, Chief Data Officer

At a glance...



U.S. Food and Drug Administration

At a glance...



FDA-regulated products
account for about
20 cents of every
dollar spent by U.S.
consumers
(\$2.8 Trillion)

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\$5.9B FY2020 budget
provided by federal
government (55%) and
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Over 17,686 FTEs

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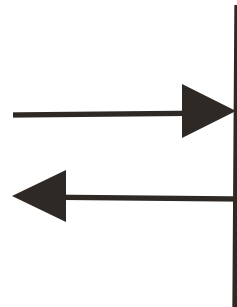
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At a glance...



\$2.5T imports and
\$1.6T exports of:

- Animal Food
- Biologics
- Drugs
- Human Food
- Cosmetics
- Medical Devices
- Tobacco



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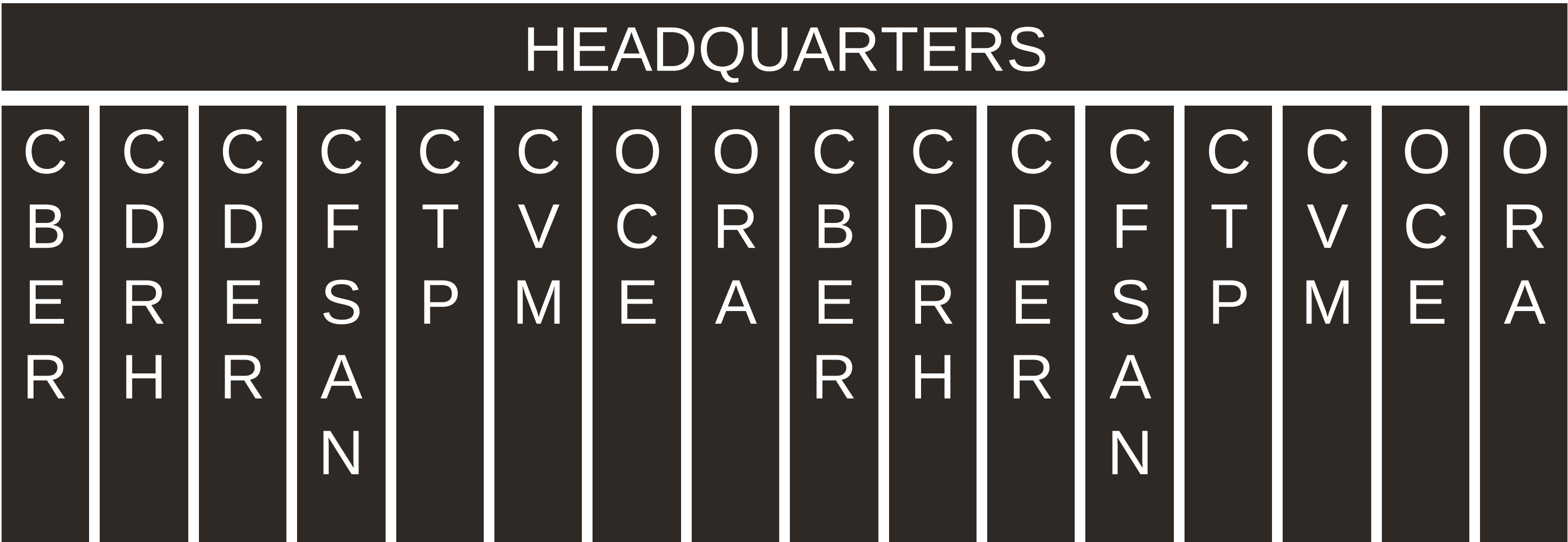
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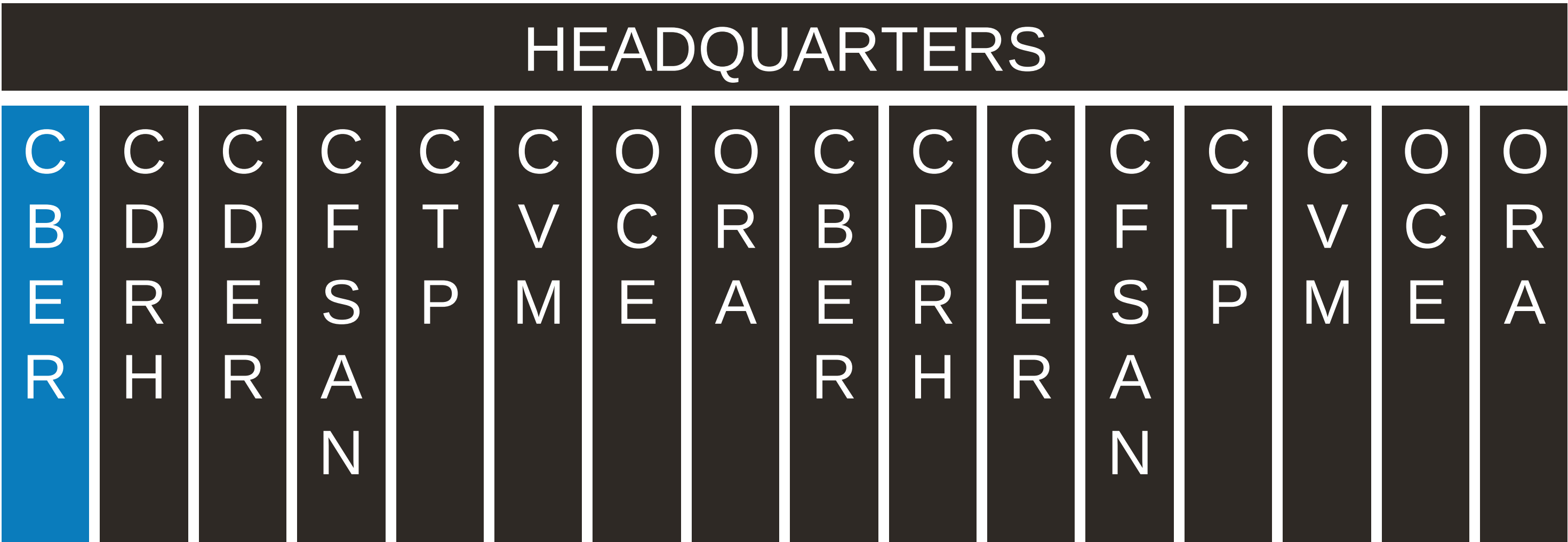
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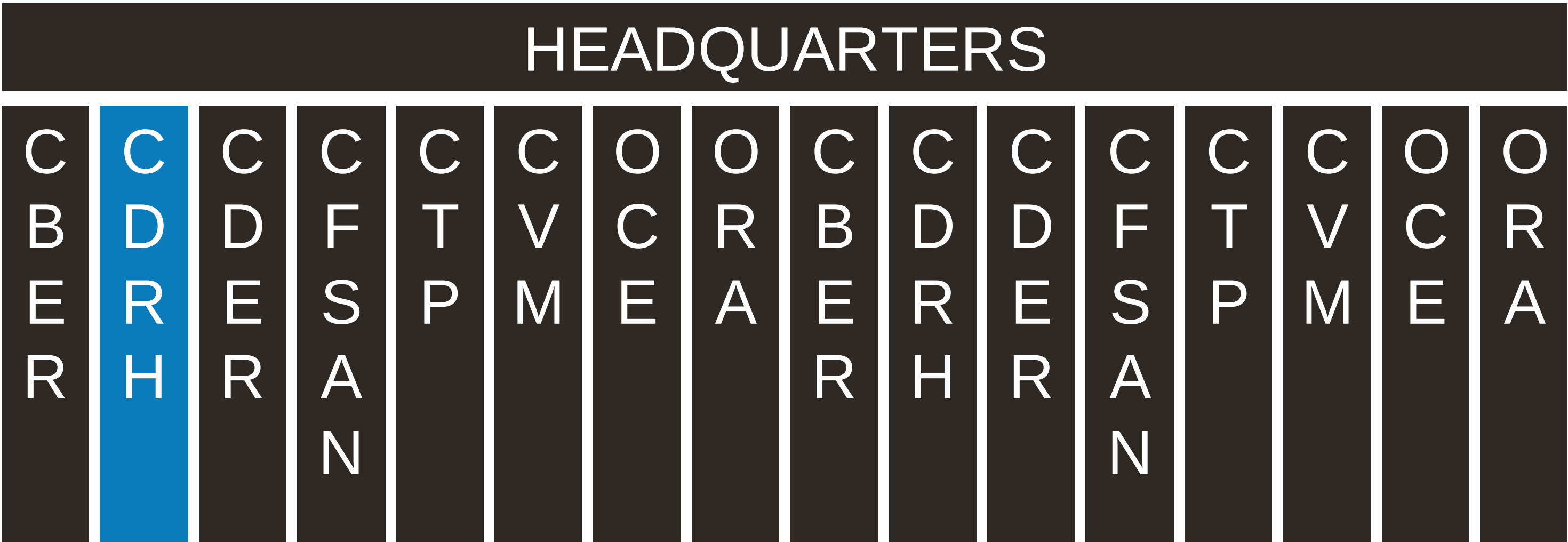
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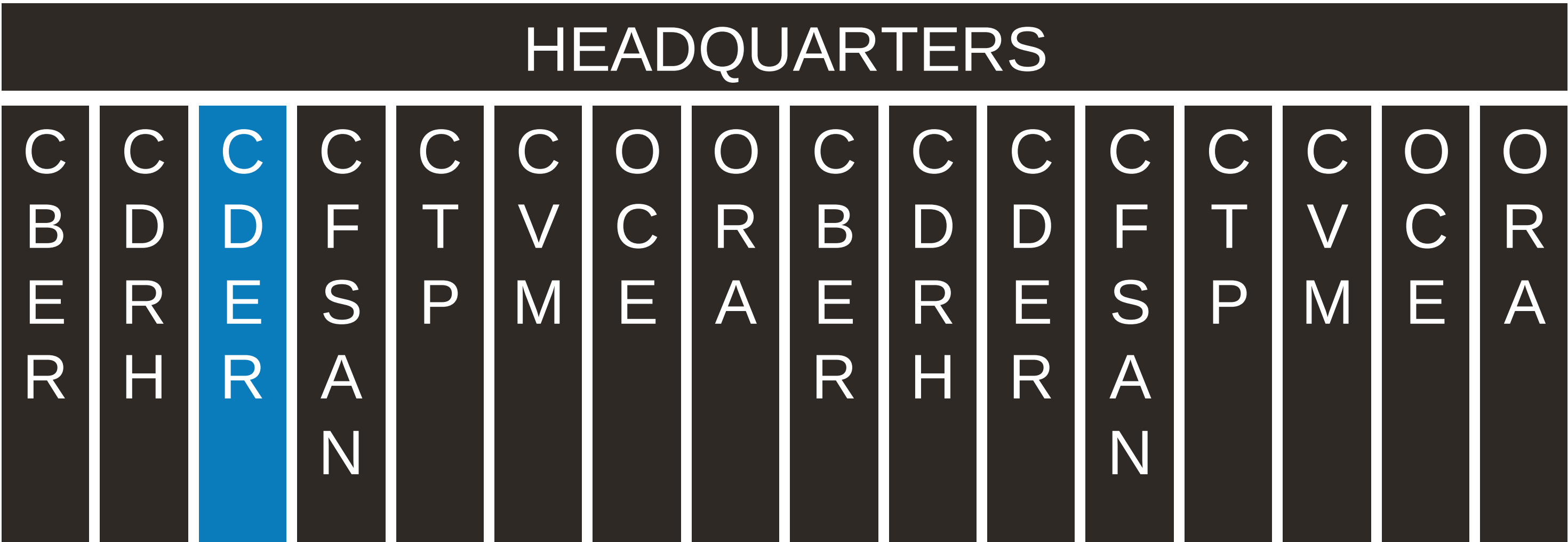
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COVID Revealed

Cross-dependency

Data's broad value

Structure and processes

Core duties persist during crisis

Technology Modernization Action Plan



TMAP launched
September 2019 to
close the gap
between emerging
technologies and
policies, and the
patients who stand
to benefit from them.

**Modernize technical
infrastructure**

**Enhance ability to develop
technical products**

**Work with stakeholders
toward interoperability**

Data Modernization Action Plan

The FDA logo, consisting of the letters "FDA" in white, bold, sans-serif font, set against a dark gray square background.

**DMAP launched
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Data Practices

Defines reusable framework for the curation, use and compliant sharing of key data

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and Talent

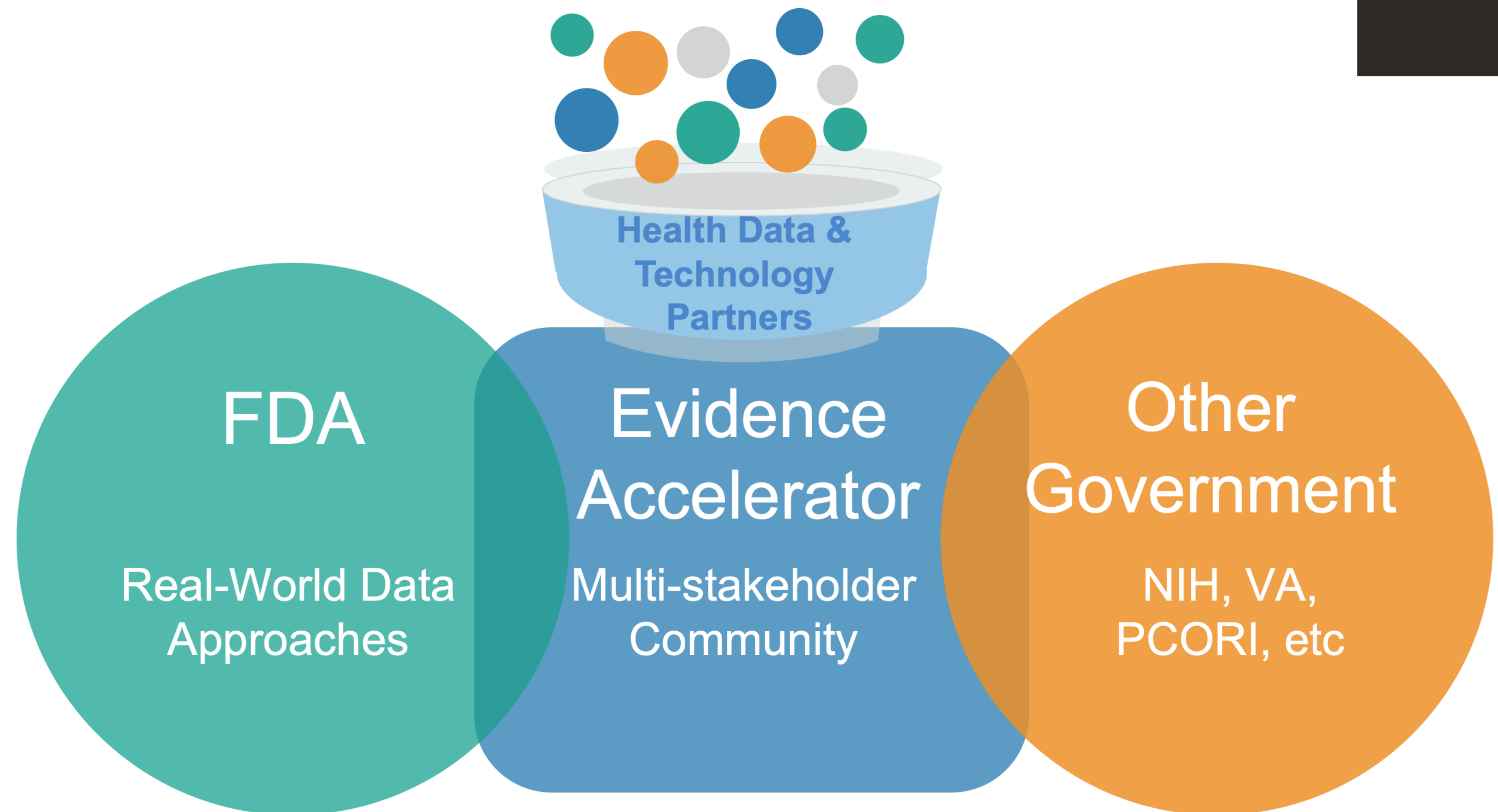
Develop internal capabilities and external partnerships to meet the demand for data skills

Driver Project: Evidence Accelerator Collaboration

FDA

The COVID-19 Evidence Accelerator is an initiative launched by the Reagan-Udall Foundation for the FDA, in collaboration with Friends of Cancer Research.

It provides a unique venue for major data organizations, government and academic researchers, and health systems to gather and design quick-turn-around queries and share their results.



Real-World Data for COVID-19

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April 2, 2021

Guidance on Evaluating Impact of Viral Mutations on COVID-19 Tests and Lessons Learned Thus Far

January 28, 2021

COVID-19 Evidence Accelerator workgroup to coordinate medication use definitions across Evidence Accelerator data partners

March 17, 2021

COVID-19 Evidence Accelerator: A parallel analysis to describe the use of Hydroxychloroquine with or without Azithromycin among hospitalized COVID-19 patients

December 20, 2020

What if we captured the spirit and urgency of Covid-19 research to cure cancer?

Driver Project: Seafood Imports AI

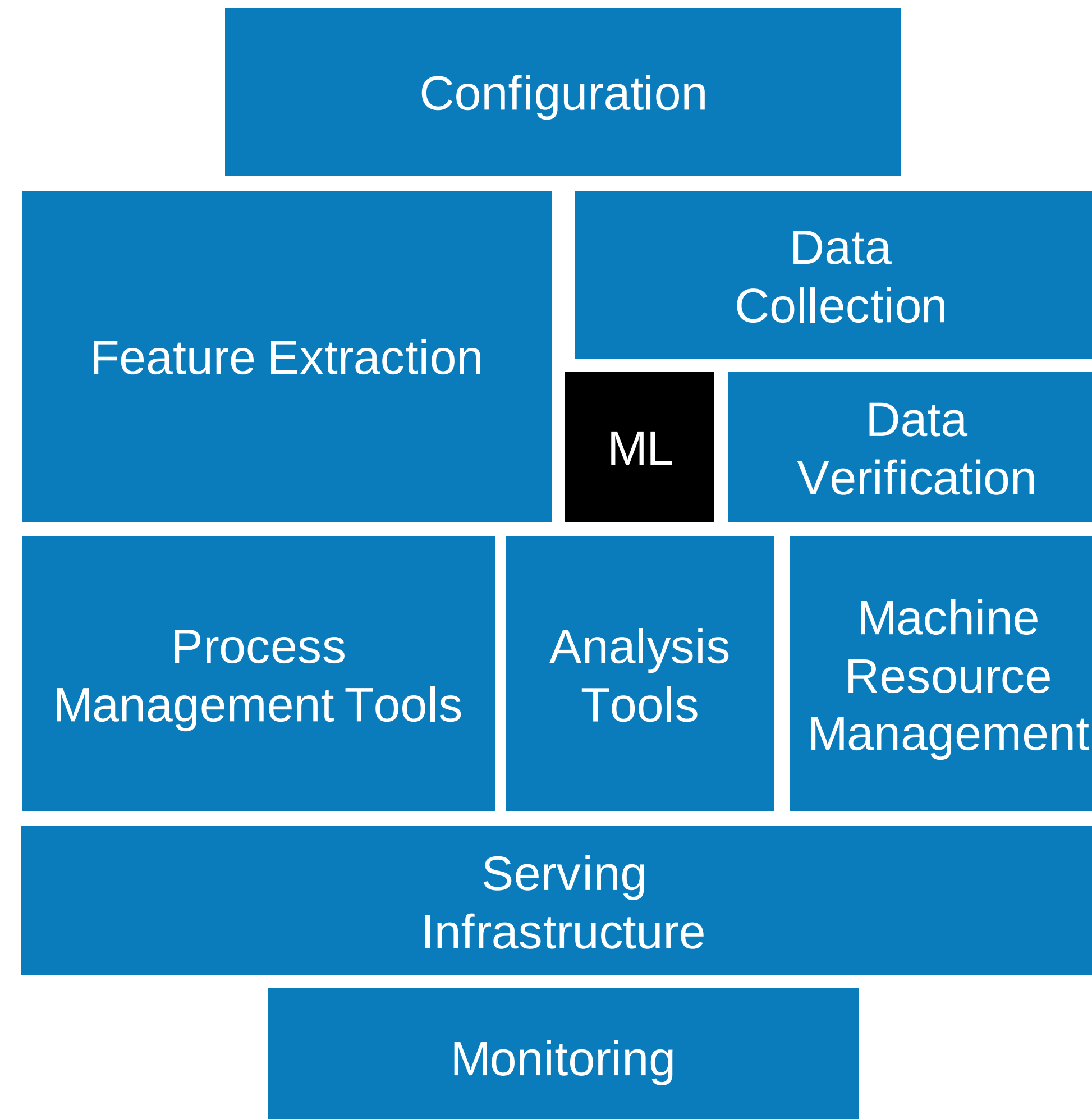
FDA

Seafood screening AI production pilot reinforced the importance of the entire data environment, especially: user experience.

Lessons learned about user trust, acceptability, and adherence prompt:

- * User-centered design
- * Portfolio approach
- * Time for development

AI Platform Playbook



Driver Project: Seafood Imports AI

FDA

August 31, 2020

Import Screening Pilot Unleashes the Power of Data and Leverages Artificial Intelligence



I frequently emphasize the importance of data in the U.S. Food and Drug Administration's work as a science-based regulatory agency, and the need to "unleash the power of data" through sophisticated mechanisms for collection, review and analysis so that it may become preventive, action-oriented information.

February 8, 2021

FDA Moves into Second Phase of AI Imported Seafood Pilot Program

The U.S. Food and Drug Administration has launched the second phase of its Artificial Intelligence (AI) Imported Seafood Pilot program. The pilot is scheduled to run from February 1, 2021 through July 31, 2021, and the agency does not expect any significant service interruptions to industry and seafood import processors.

The pilot is designed to enhance and improve the agency's ability to quickly and efficiently identify imported seafood products that may pose a threat to public health. This is especially important since the United States imports upwards of 94 percent of its seafood supply.

In 2019, the agency launched the first phase

Driver Project: Inspections During Crisis

FDA

FDA halted most foreign and domestic inspections during COVID-19 to mitigate the spread of the virus.

Novel tools were employed to address the growing backlog, including real-time county-level data to manage risks to FDA investigators and regulated-industry workforces.

A data-driven, risk-based approach will support this mission-critical work going forward.



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Driver Projects

Evidence Accelerator

Seafood Imports AI

Data-driven Inspections

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Large Mandate
Complex Environment
Need to Modernize
Promising Start
Bright Horizon

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