



**U.S. FOOD & DRUG  
ADMINISTRATION**

# DIGITAL TRANSFORMATION SYMPOSIUM

# 2023

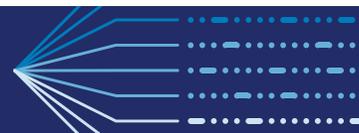
Hosted by FDA's Office of Digital Transformation



# How to do Business with FDA

**Mahesh Choksi**

**Director, Division of Acquisition Innovation  
Office of Digital Transformation (ODT)**

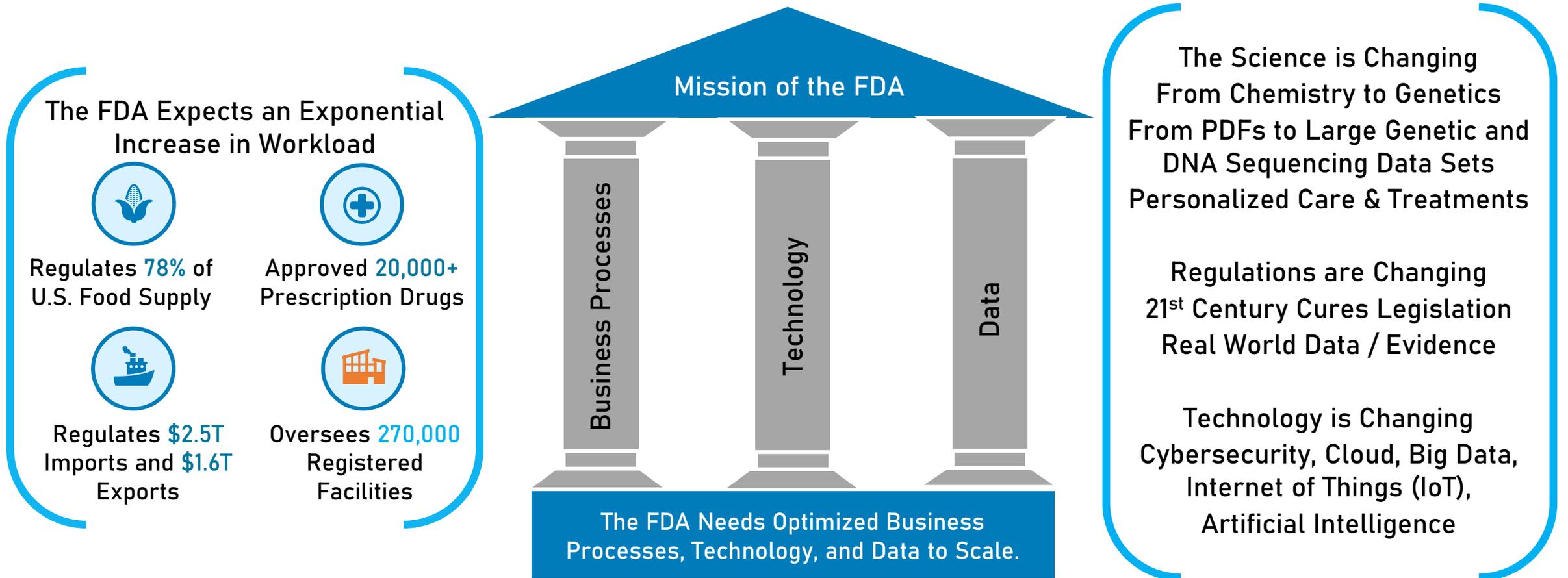


# Agenda – How to do Business with FDA?

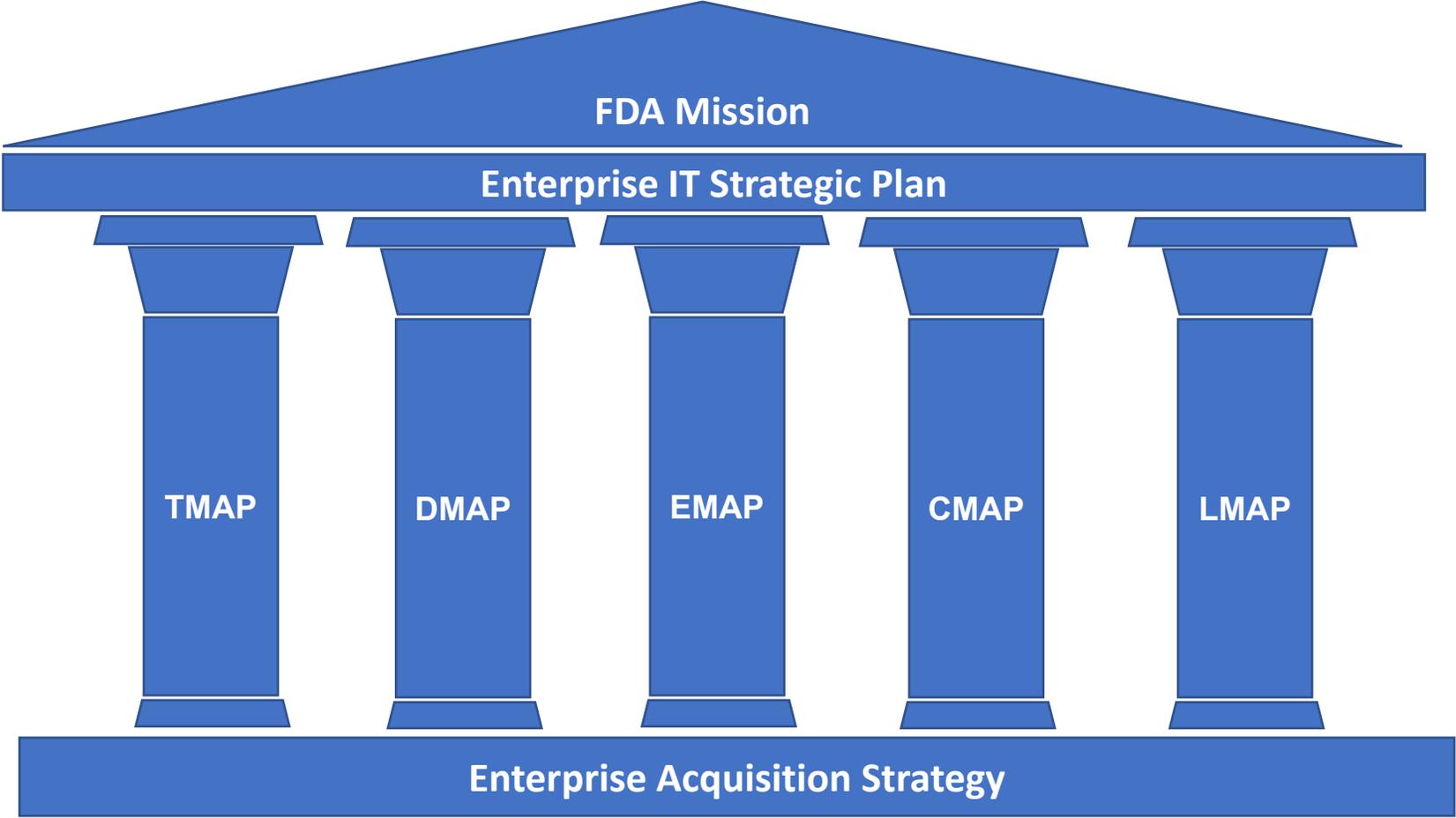
- Know your customer
- Understand expectations
- Innovative Acquisition Solutions
- Socioeconomic goals
- Resources for Acquisitions
- Analyzing Opportunities
- Strategies for Success



# Know your customer - FDA



# Pillars of FDA IT Strategic Plan



# Major Acquisition Themes

Business focused

#One FDA

Value based acquisitions

Budget informed decisions

Partnership

ODT Symposium 2024

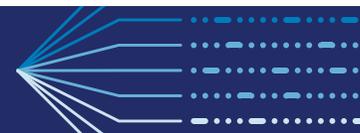
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FDA - ODT

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# Expectations: Good IT is a Team Sport

- IT Solutions are business focus, consolidated, cloud based, efficient, and secured.
- FDA and Contractors have to function well for the FDA to benefit.
- Deliver value added results.



# Expectations: What does great IT look like?

## Matured, Modernized IT Operations

Well defined service levels delivering quality operations.

Focus on service optimization.

## Financial Management

Business priorities aligned with IT spend aligned in supporting business outcomes.



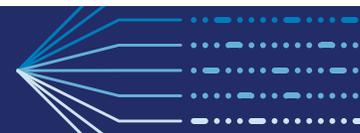
## Planning and Alignment

Strategic & operating plans coordinated across FDA and contractors.

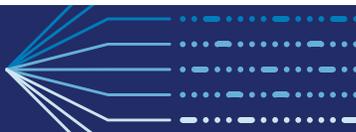
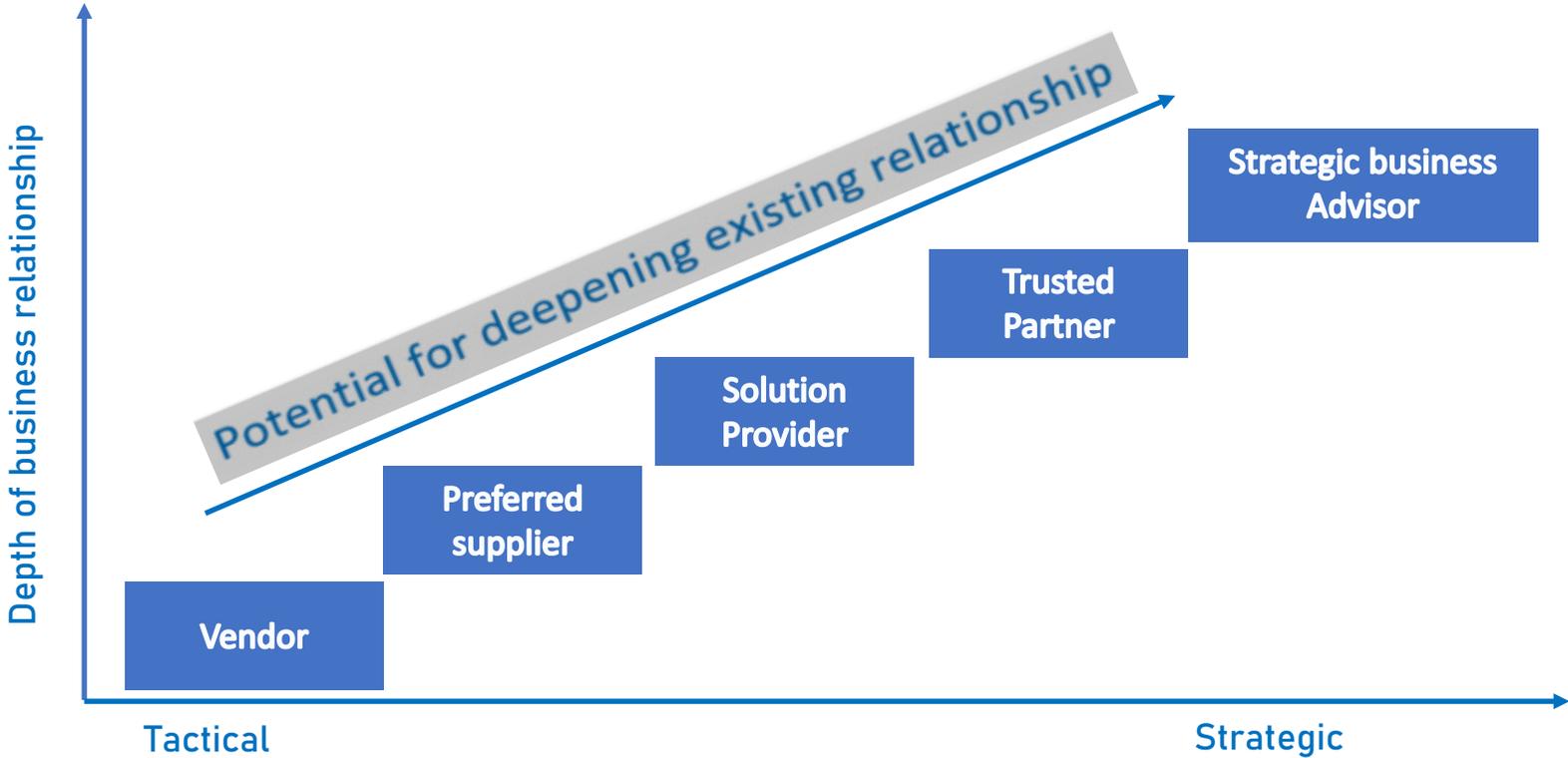
## Governance

Well-organized IT and data governance empowering strategic and tactical decisions.

**In 2023, FDA awarded more than \$580 Million to Small Businesses!**



# Expectations: Strategic Partnership



# Expectations: Key Governance Principals



Benefits from economies of scale

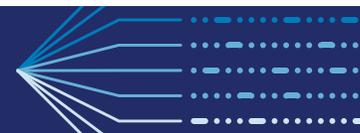
- OneFDA vision and ecosystem
- Common license management, procurement, contract and vendor management

Adopt Standard Industry Framework

- Align with TBM model for financial transparency
- ITIL for IT processes

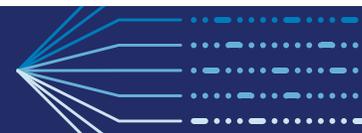
Governance across all ODT contracts

- Vendor Management
- Standard languages across all contracts
  - eSTAR reporting
  - Place of performance
  - O&M cost reduction
  - Cloud migration



# Innovative Acquisition Solutions

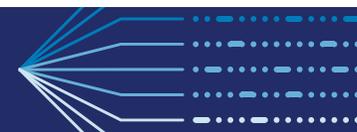
- Procurement Innovation
  - The Procurement Innovation Lab (PIL) is a DHS framework aimed at experimenting with innovative acquisition techniques across the DHS enterprise.
  - FDA extensively uses the PIL method for IT contracts so understand, learn, and be ready for the PIL acquisition method for the next contracting action. More details at <https://www.dhs.gov/pil>
  - HHS recently launched Strategic Acquisition Innovation Lab (SAIL) using artificial intelligence to quickly bring insights to aspects of acquisition work such as market research; removing barriers for new companies to enter the HHS marketplace; and re-engineering our processes to cut acquisition lead times
- Government-wide Category Management
  - learn and understand direction of governmentwide acquisitions <https://d2d.gsa.gov/report/public-category-management-dashboards-analytics>



# FDA Socioeconomic Goals

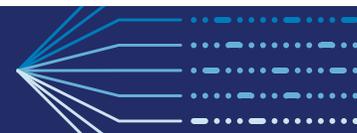
Small Business Award Categories	FY Goal (FY15-21)	FY16	FY17	FY18	FY19	FY20	FY21	FY 22 Goal (new)	FY22	FY23
Small Businesses	38%	48.5%	39.64%	36.8%	39.06%	40.09%	34.33%	37.09%	33.49%	38.02%
Small Disadvantaged Businesses	5.0%	27.9%	24.31%	25.0%	27.14%	26.96%	23.84%	25.20%	23.96%	25.84%
Women-Owned Small Businesses	5.0%	17.8%	14.22%	14.1%	14.13%	12.68%	10.33%	11.99%	11.01%	11.58%
HubZone Businesses	3.0%	2.0%	1.40%	1.8%	2.75%	4.09%	3.81%	4.94%	4.48%	4.99%
Service-Disabled Veteran Owned	3.0%	4.9%	3.42%	3.4%	2.81%	3.91%	2.29%	3.80%	3.22%	3.70%

**In 2023, FDA awarded more than \$727 Million to Small Businesses!**

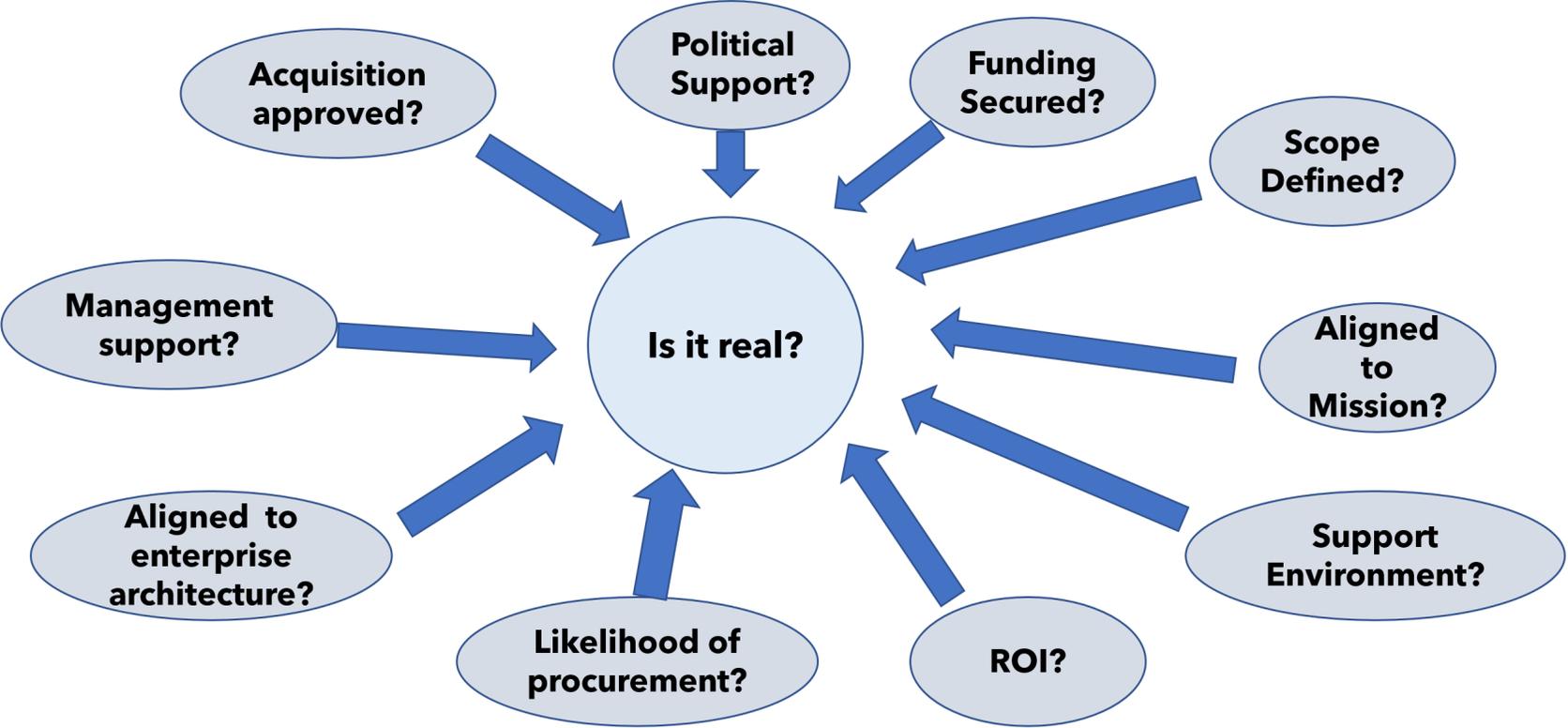


# Resources to do business with FDA

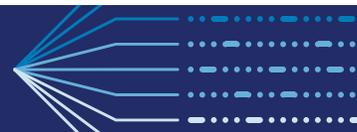
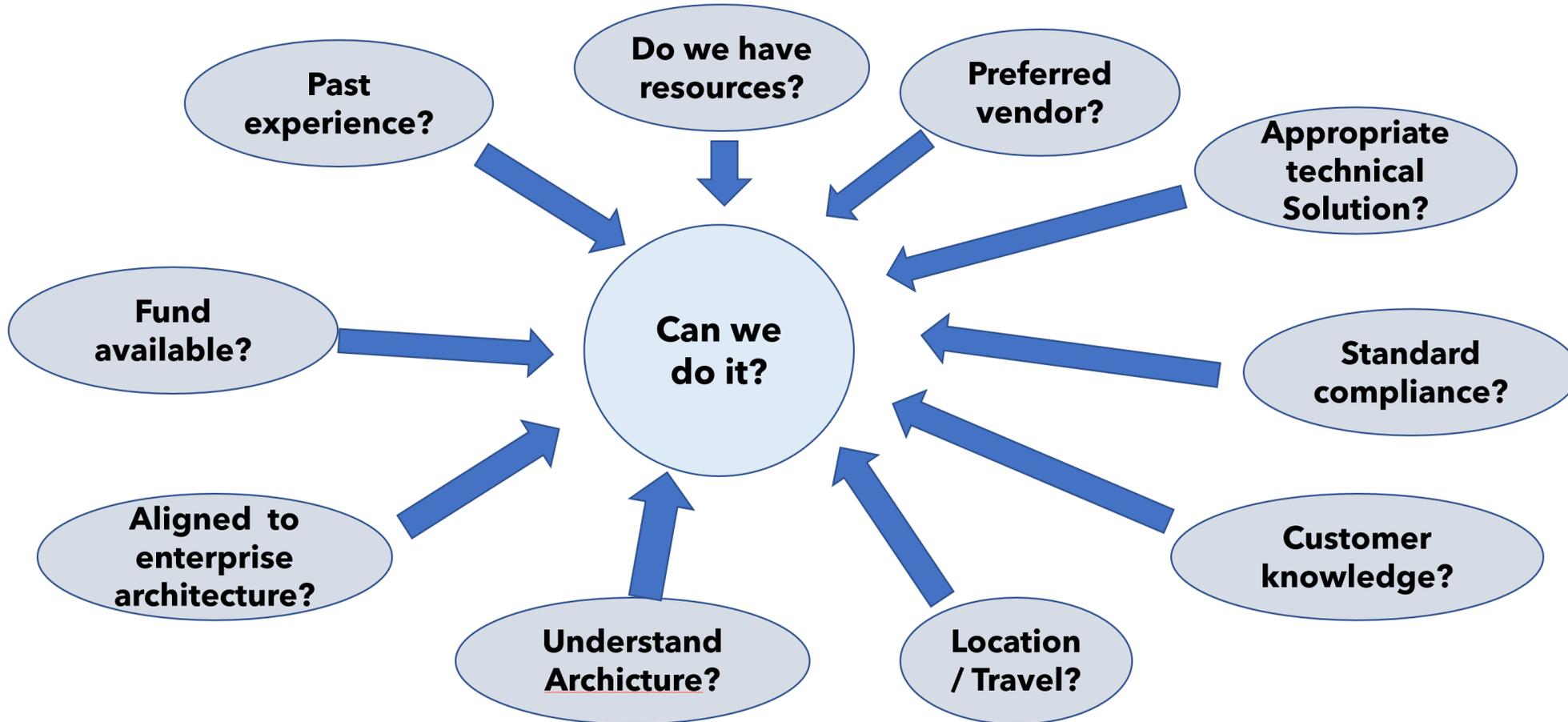
- Contact the Small Business Program Office - [www.hhs.gov/about/smallbusiness/](http://www.hhs.gov/about/smallbusiness/)
- Register and learn SBCX system <https://osdbu.hhs.gov/> of HHS OSDBU – Small business vendor resource for program office and contracting divisions. Ensure your correct NAICS codes are listed in SBCX system.
- How to do business with HHS - <https://osdbu.hhs.gov/industry/doing-business>
- Register in System for Award Management (SAM) - [www.sam.gov](http://www.sam.gov)
- Find HHS contracting opportunities at [SAM.GOV Contract Opportunities](http://SAM.GOV), which is updated constantly with each new contract listing.
- Attend agency sponsored Vendor Outreach Sessions, annual FDA IT Symposium, Trade Fairs, and Other Business Networking Events for networking and teaming opportunities
- Explore Subcontracting Opportunities
- HHS Small Business representative: Natasha Boyce, FDA Small Business Specialist, [natasha.Boyce@hhs.gov](mailto:natasha.Boyce@hhs.gov)



# Analyze Opportunities - Viability



# Analyze Opportunities - Doable?

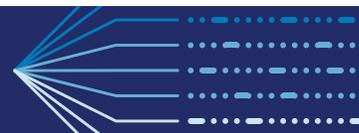


# Analyze Opportunities - Winnable?



# Strategies for Success

- Customer focus
- Be a strategic business provider and not a billing partner
- GWAC vehicles
- Learn new innovative acquisition methods and master it
- Recruit and Retain High Quality Staff and Experts
- Diversification vs. Single Focus
- Innovative and a problem solver
- Invest in Business Development
- Networking
- Utilize Teaming and Relationships





# Discussion

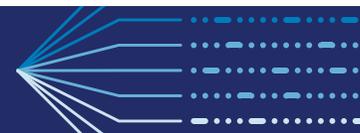


# Procurement Innovation Lab (PIL) Method for Agile Acquisition – A Fireside Chat

Monica Taylor, Senior Innovation Coach, US Department of  
Homeland Security Procurement Innovation Lab

Andrew Jernell, FDA Director, Division of IT Acquisitions

Mahesh Choksi, Director, Division of Acquisition Innovation





# Upcoming Acquisitions

**Andrew Jernell**

**FDA Director**

**Division of IT Acquisitions**

