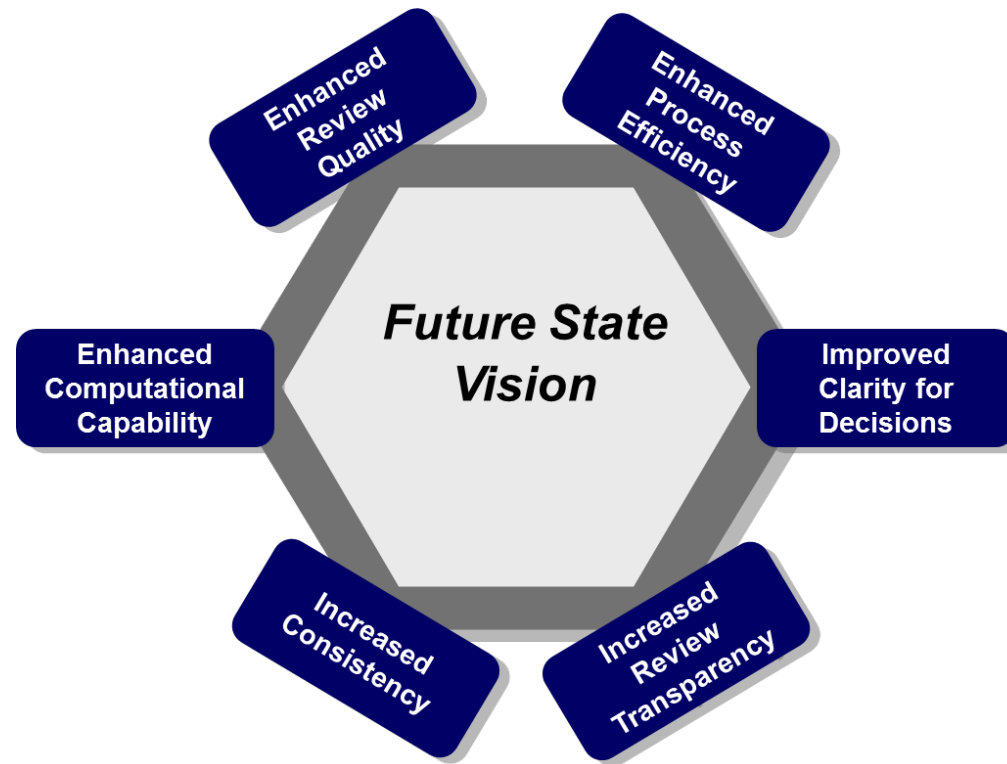


The Path of CSS Collaboration in CDER-- *Reflecting on Progress Over a Decade...*

ShaAvhrée Buckman-Garner, MD, PhD
Director, Office of Translational Sciences
Center for Drug Evaluation and Research

Dr. Janet Woodcock's Vision in 2008....



Then and Now

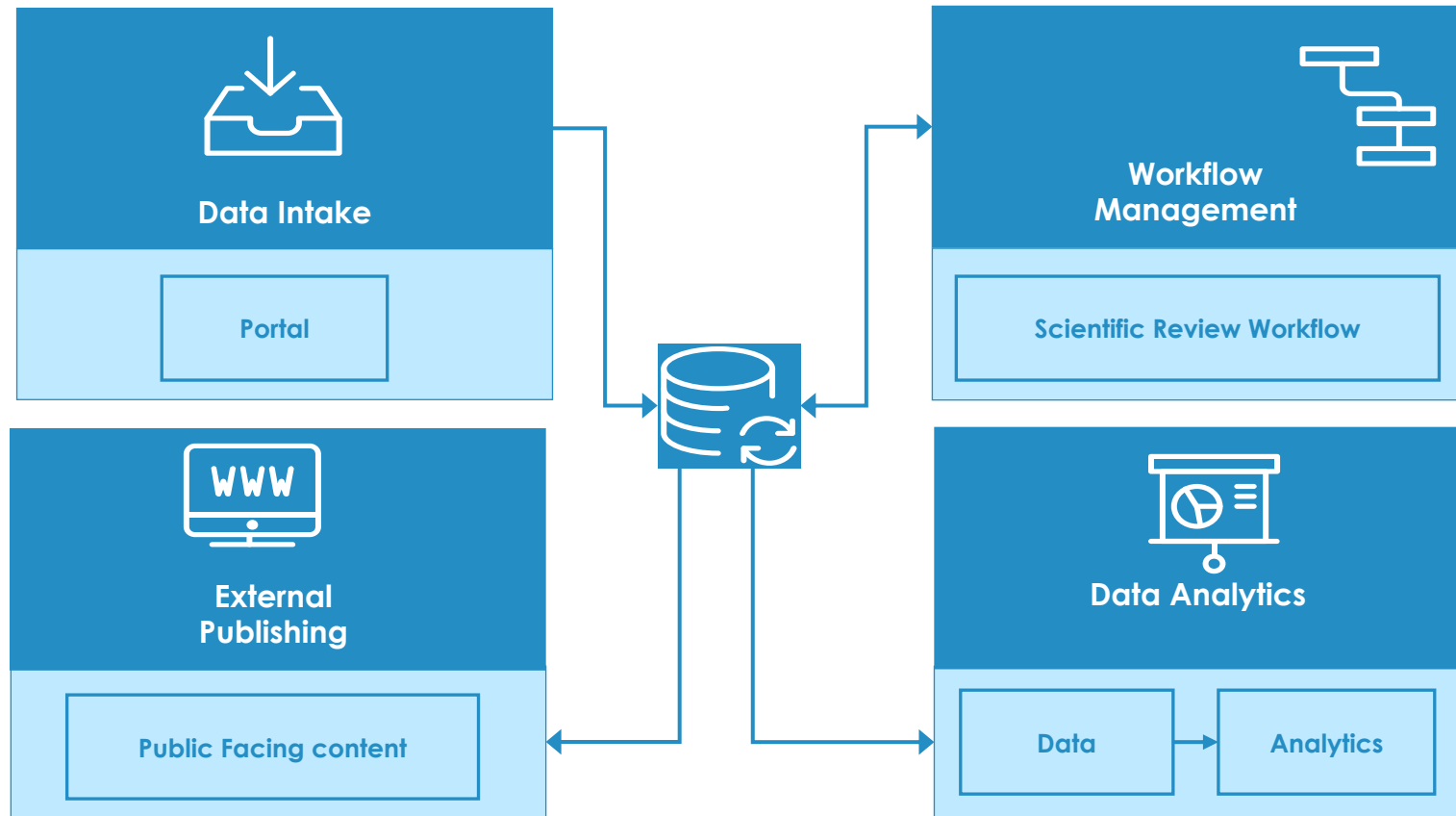
2012:

- Computational Science Center was a virtual entity with a coalition of the willing
- Focus was on visibility of the need for data standards
- Emphasis on outlining governance, staffing, handling standards-based submissions, infrastructure
- Training
- Outreach
- Focus on Tools Development/Support
- Adding Expertise
- Vision of Future State

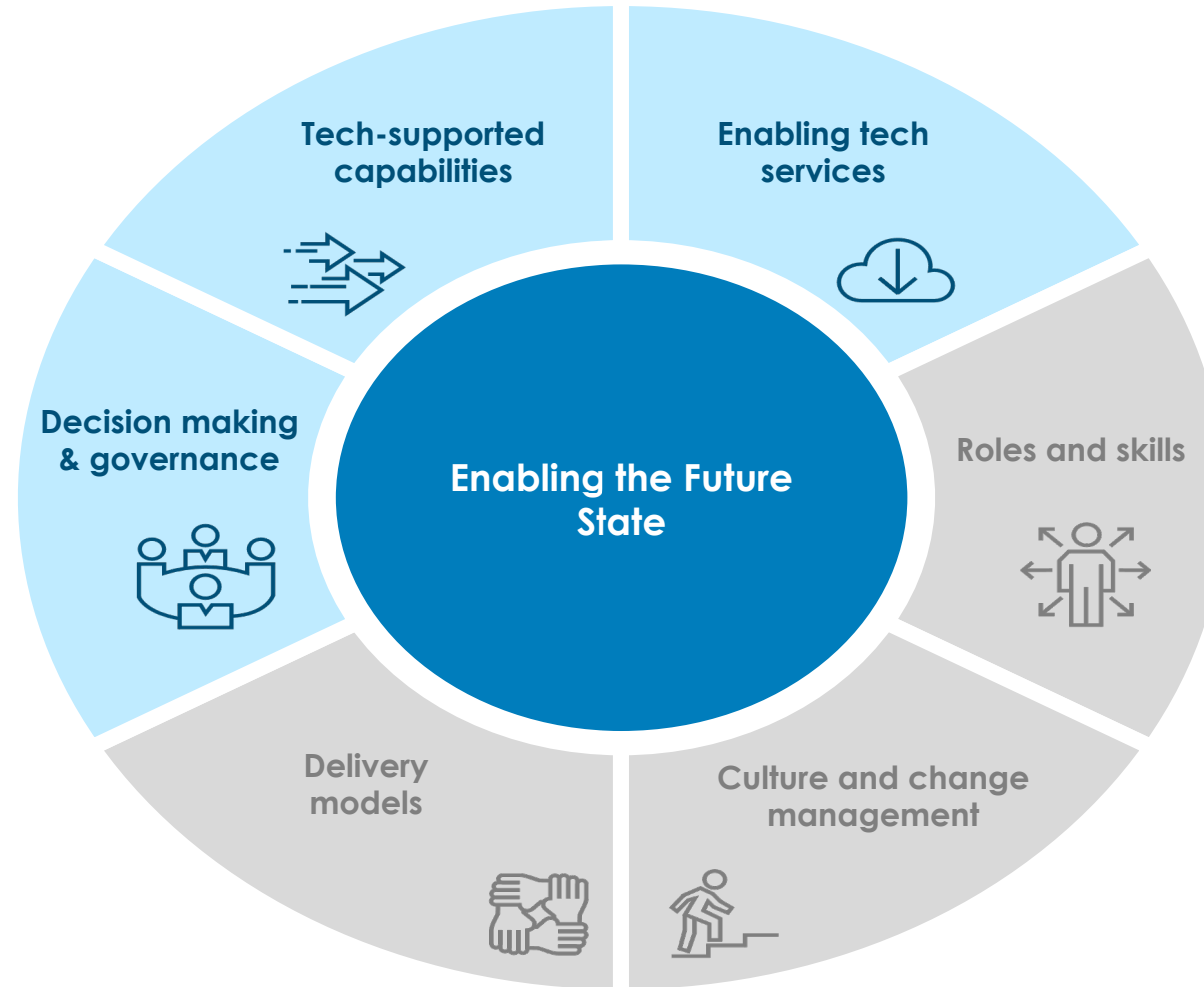
Present:

- Increased use of standardized data in regulatory submissions
- OCS Data Quality/Fitness Assessments
- Increased use of tools engaging standardized data to support regulatory review
- Increased collaboration (internal and external)
- More guidance, implementation guides, technical guides, validator rules...
- Data Standards Catalog (V 7.2)
- CBER-CDER Data Standards Strategy
- FDA Data Modernization Action Plan
- More governance structures
- More training
- More hands-on support for review staff (OCS Service Desk)
- Enhancing data science expertise
- Supporting Innovation (CDER Innovation Board)

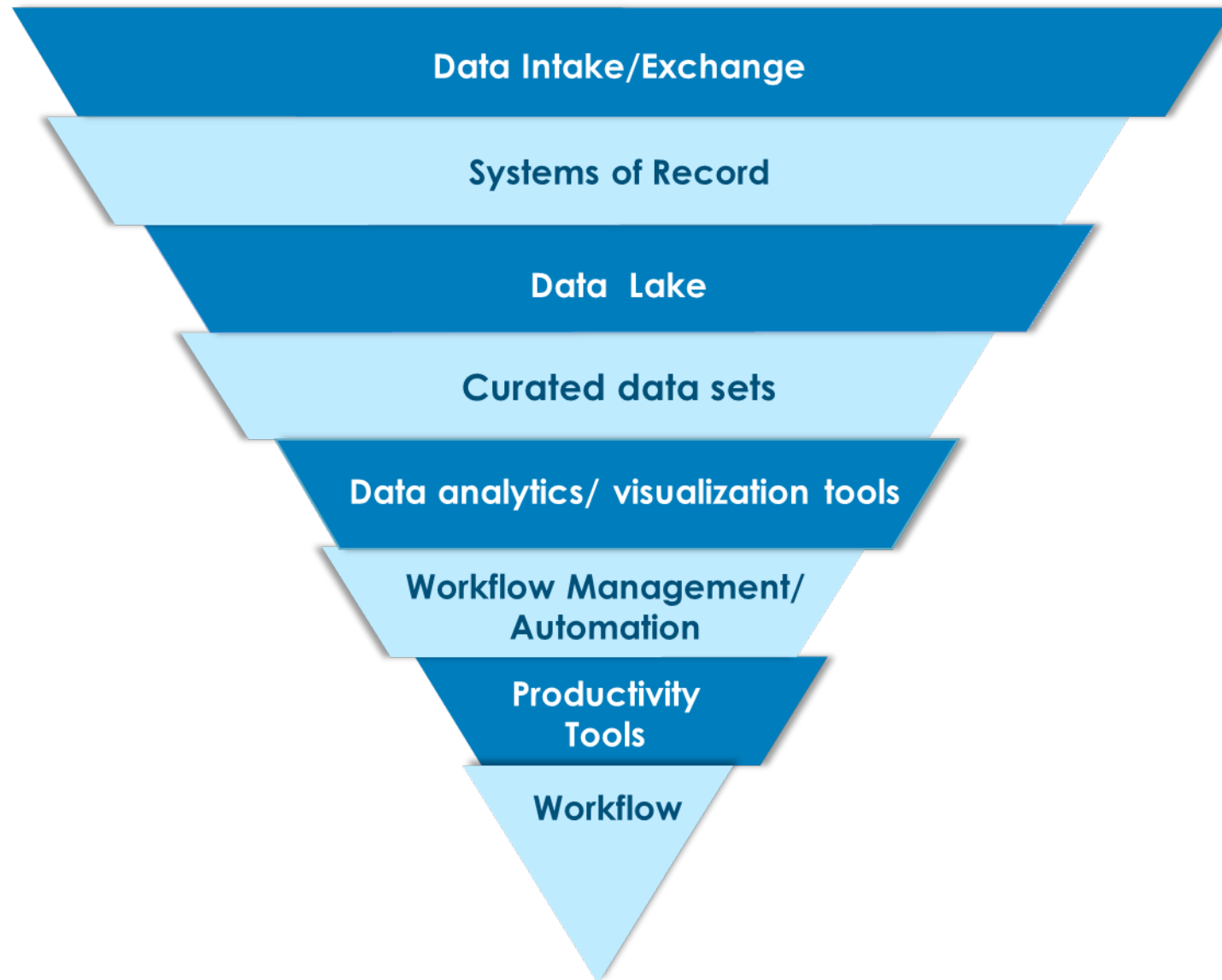
Looking at the bigger picture--Core Capabilities



Future State Building Blocks



Where Are We Headed?



**CONTINUED COLLABORATION IS INVALUABLE FOR
ENABLING OUR FUTURE STATE VISION.**

THANK YOU FOR COLLABORATING WITH US...



U.S. FOOD & DRUG
ADMINISTRATION