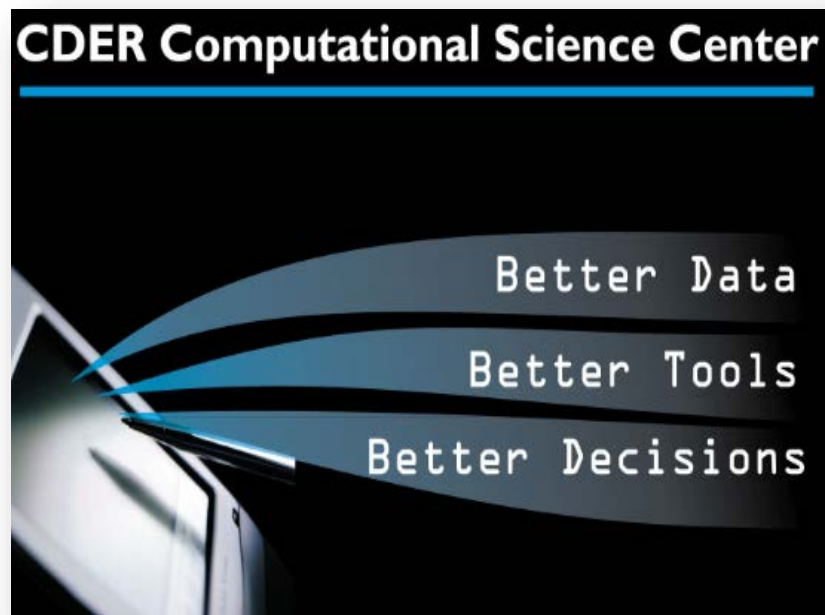




Lilliam Rosario, Ph.D.

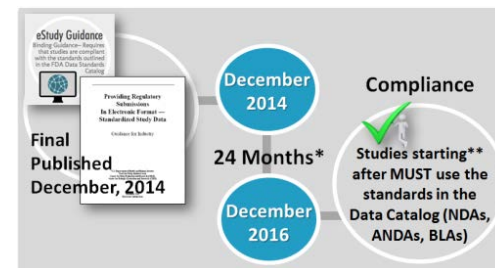
Director, Office of Computational Science
Office of Translational Science
CDER



Support CDER in **continually improving** the drug evaluation and review processes across the drug lifecycle through **innovation**, supporting the submission and use of **high quality data**, and providing access to **high-end analytical tools** and **training**.

Policy

eStudy Guidance
and Technical
Conformance
Guide



Standards

Electronic
Standardized
Study Data

FY2013, FY2014, FY2015(Q1)
Number (%) of NDAs with
Study Data Submissions in CDISC SDTM*

Fiscal Year	# of Submissions	% with CDISC SDTM
2013	223	55 %
2014	233	64 %
2015 (Q1)	66	69 %

*Source: Office of Business Informatics, CDER - One or more explicitly stated SDTM studies (or study data structure that resembled SDTM).

Technology

Janus Clinical
Trials Repository



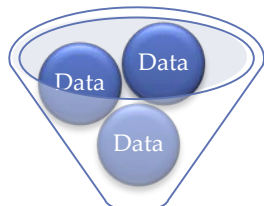
Transforming
the
Regulatory
Review
Process



Improved Access to Study Data to Support
Regulatory Decision-Making

Intersection of data, tools and technology

Standardized Data



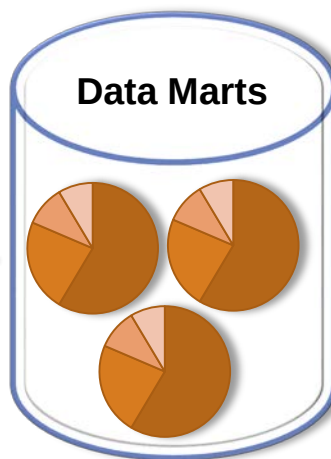
Repositories for
Electronic Data



Data
Validation



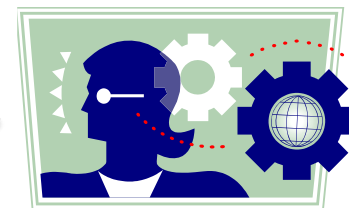
Data Warehouse



Analytic Tools



Reviewer
Decisions



Data & Analysis
Support Services

Tools & Technology
Support Services

Training & Customer
Support Services

Computational Science Center (CSC) Reviewer Services



High quality data is the key to enabling regulatory reviewers to fully utilize the Computational Science Center's tools and services **to support decision making**

The Clinical Trials Repository brings it all together:



*Data Integration
Exploration
Analysis*

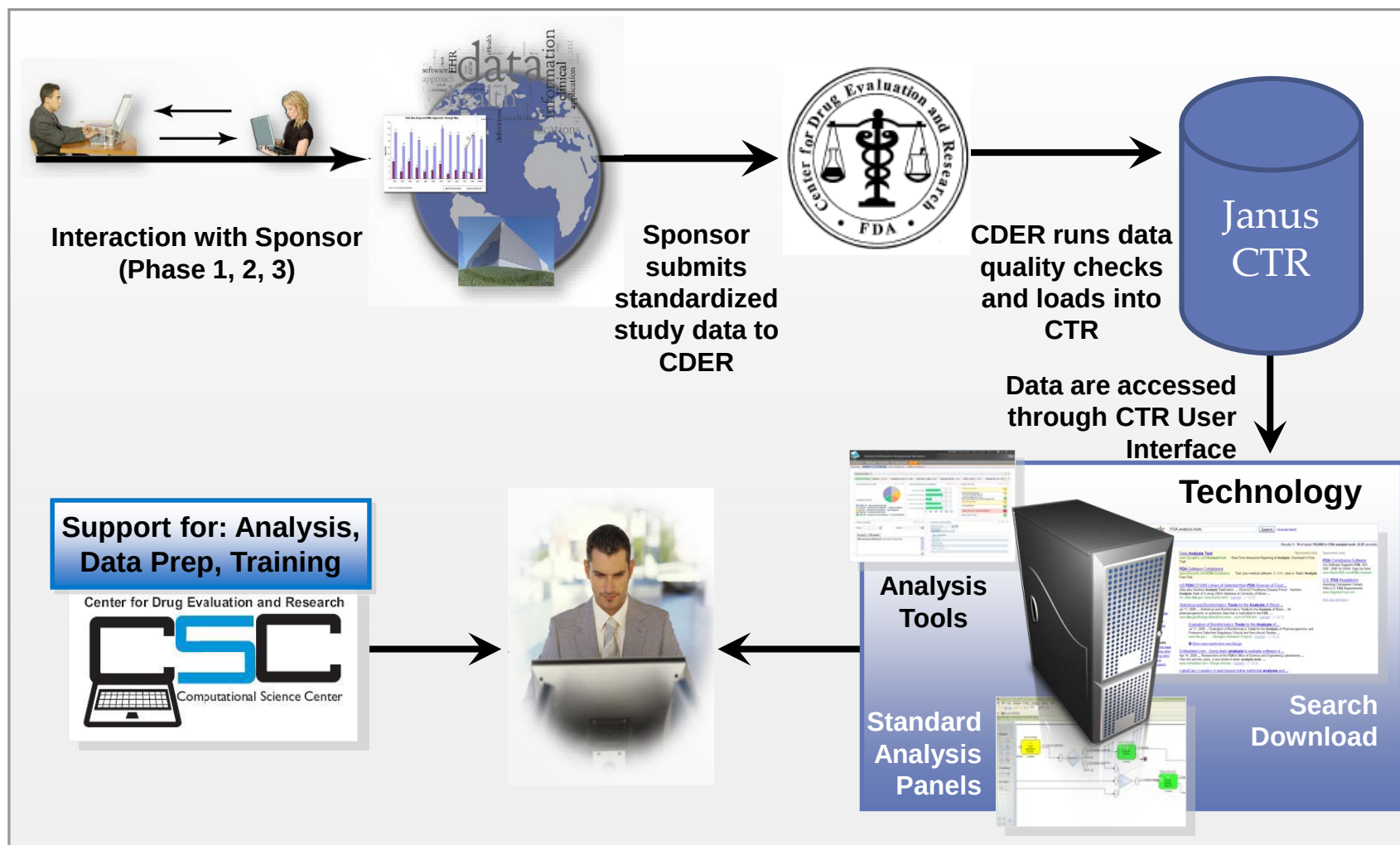
**Rigorous
Testing**

Training

Go Live

**Integrate
with
Jumpstart**

Vision for Janus CTR



CSC Reviewer Services

DATA & ANALYSIS SUPPORT SERVICES

Data Validation
and Quality
Assessments

Support Data
Standardization

Script
Development &
Sharing to Support
Analysis

TOOLS & TECHNOLOGY SUPPORT SERVICES

Analytic and
Visualization Tool
Support

JumpStart Service

Regulatory Review
Services

TRAINING & CUSTOMER SUPPORT SERVICES

Analytic Tool
Training

Data Standards
Training

Clinical Reviewer
Portal

INNOVATION



Regulatory Review

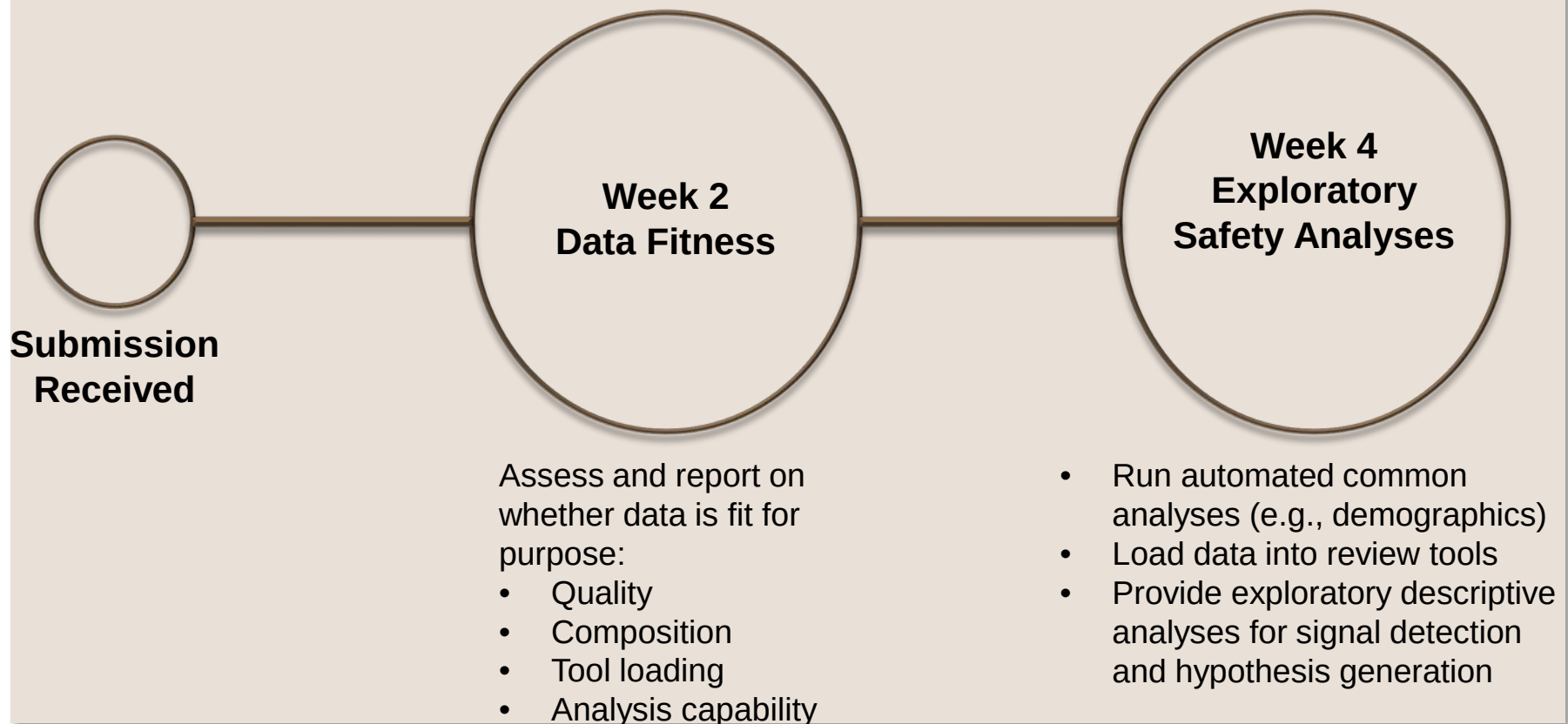
...

Applying the **Right** Tools
at the **Right** Time
for the **Right** Audience

<http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm397921.htm>

The JumpStart service has two major components focusing on data fitness and exploratory safety analyses

JumpStart Sessions



The JumpStart session is organized around the clinical review template and provides outputs to support specific sections within the review

The Line Up for JumpStart

JumpStarting the Regulatory Review Process

JumpStart Overview

Jeno Pizarro and Austin Taylor

The Review Perspective

Dr. Peter Miele and Dr. Steve Lemery