

FDA JumpStart and DataFit

Enabling the 21st Century Review Process

Max Kanevsky

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Disclaimer

The views and opinions presented here represent those of the speaker and should not be considered to represent advice or guidance on behalf of the Food and Drug Administration.




21st Century Review Initiative

A set of performance standards to follow during drug review with the goal of making the process more organized, integrated, efficient and effective.

Dr. Woodcock's Vision for Modernizing Product Review

- › Easier access to important resources
- › Less time spent trying to analyze data
- › More “think” time
- › Increase ability to explore study data
- › Better data visualization

Source: Dr. Chuck Cooper, CDISC EU Interchange, 2013



Better Data

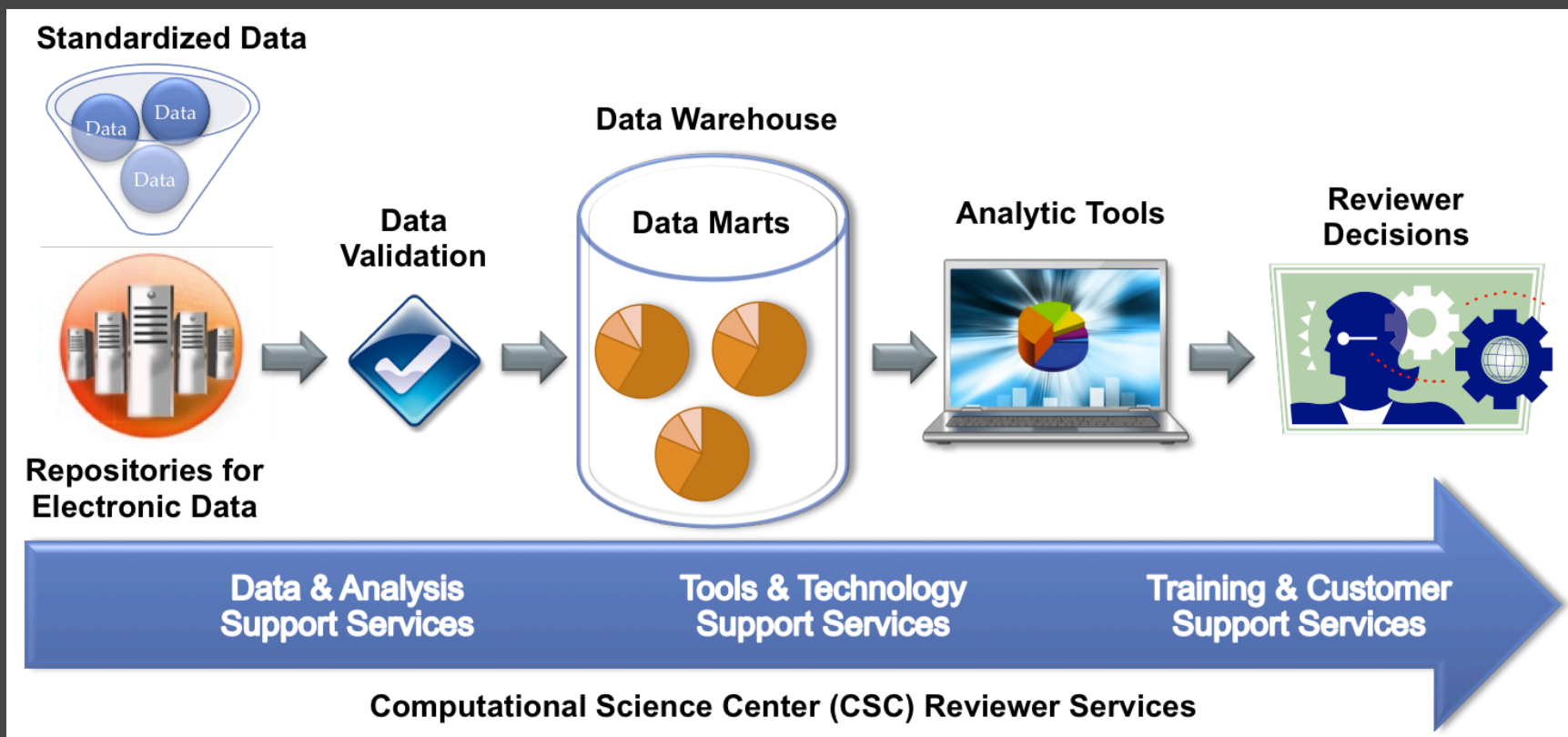
Better Tools

Better Decisions

CDER Computational Science Center

Established to develop the core infrastructure and services to provide high-quality quantitative analysis of information on product safety, effectiveness, and quality.

Intersection of data, tools and technology



CSC Reviewer Services

DATA & ANALYSIS SUPPORT SERVICES

Data Validation &
Quality Assessments

Support Data
Standardization

Script
Development &
Sharing to Support
Analysis

TOOLS & TECHNOLOGY SUPPORT SERVICES

Analytic Tool
Support

Regulatory Review
Service

Scientific
Environment &
Infrastructure

TRAINING & CUSTOMER SUPPORT SERVICES

Analytic Tool
Training

Data Standards
Training

**What is the key ingredient for
FDA to meet their goals?**

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Requiring High Quality
Standardized (CDISC) Data



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

FDA's Definition of Data Quality

- › High Quality Data is both **Compliant** and **Useful**
- › **Compliant** means the data confirms to applicable data standards
- › **Useful** means the ability of data to support the intended use

Is Study Data Useful?

- › Is data structure and content well documented?
- › Does data support the use of standard-based review tools? (e.g., JReview, MAED)
- › Can reviewers reuse common analysis? (e.g., Liver function, Hy's Law plot)
- › Are there data quality issues that could impact the review process and results?

Profile	Score	Pass/Fail	Domains	Issues	Failures	Errors	Warnings	Notices
General Data Quality (2 Profiles)								
CDER Common Data Standards Issues	60	Pass	39	16	53	0	53	0
SDTM v3.1.2 General Data Quality	93	Pass	39	42	253,649	764	252,882	3
Laboratory Findings Analysis (6 Profiles)								
Liver Function Analysis Panel	40	Fail	3	5	2,453	2,452	0	1
eDISH	43	Fail	6	5	3,692	2,465	13	1,214
JReview Liver Function Baseline Box Whiskers	58	Pass	3	0	2,453	0	2,452	1
JReview Labs Baseline vs Max/Min Scatter Plots	100	Pass	3	0	1	0	0	1
JReview Hy's Law Plots	100	Pass	3	0	1	0	0	1
JReview Hy's Law Patient Listing	100	Pass	3	0	1	0	0	1
Metadata (1 Profiles)								
Study Metadata	100	Pass	39	0	0	0	0	0
Overall Survival Analysis (1 Profiles)								
Overall Survival Analysis Panel	100	Pass	7	1	14	0	10	4
Standards Compliance (2 Profiles)								
SDTM v3.1.2 Compliance	94	Pass	39	32	30,521	0	30,502	19
SDTM v3.1.2 Controlled Terminology	100	Pass	39	0	49	0	0	49

Found 30 records

FDA DataFit Project

A project to improve the quality of submissions by assessing and enforcing CDISC compliance and data fitness (usefulness).

DataFit Objectives

- › Implement OpenCDISC Enterprise
- › Develop additional validation rules to assess if data is “fit for use” in modern review process
- › Improve the quality of submissions by
 - › Requesting sponsors to validate data against FDA rules prior to submission
 - › Explain issues that could not be resolved in Study Data Reviewer's Guide

DataFit Value

- › Automates CDISC compliance and data fitness assessment process
- › Provides results to reviewers well in advance of filing
- › Reduces uncertainty for sponsors on how to submit data and to avoid post-submission requests

JumpStart Objectives

- › Accesses and reports on whether data is fit for use
- › Automates analysis that are universal or common
- › Highlights areas that may need focus for review
- › Provides support to reviewers

Questions

Max Kanevsky

CEO of Pinnacle 21, Founder of OpenCDISC

mkanevsky@pinnacle21.net