FDA JumpStart and DataFit

Enabling the 21st Century Review Process

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PINNACLE 21

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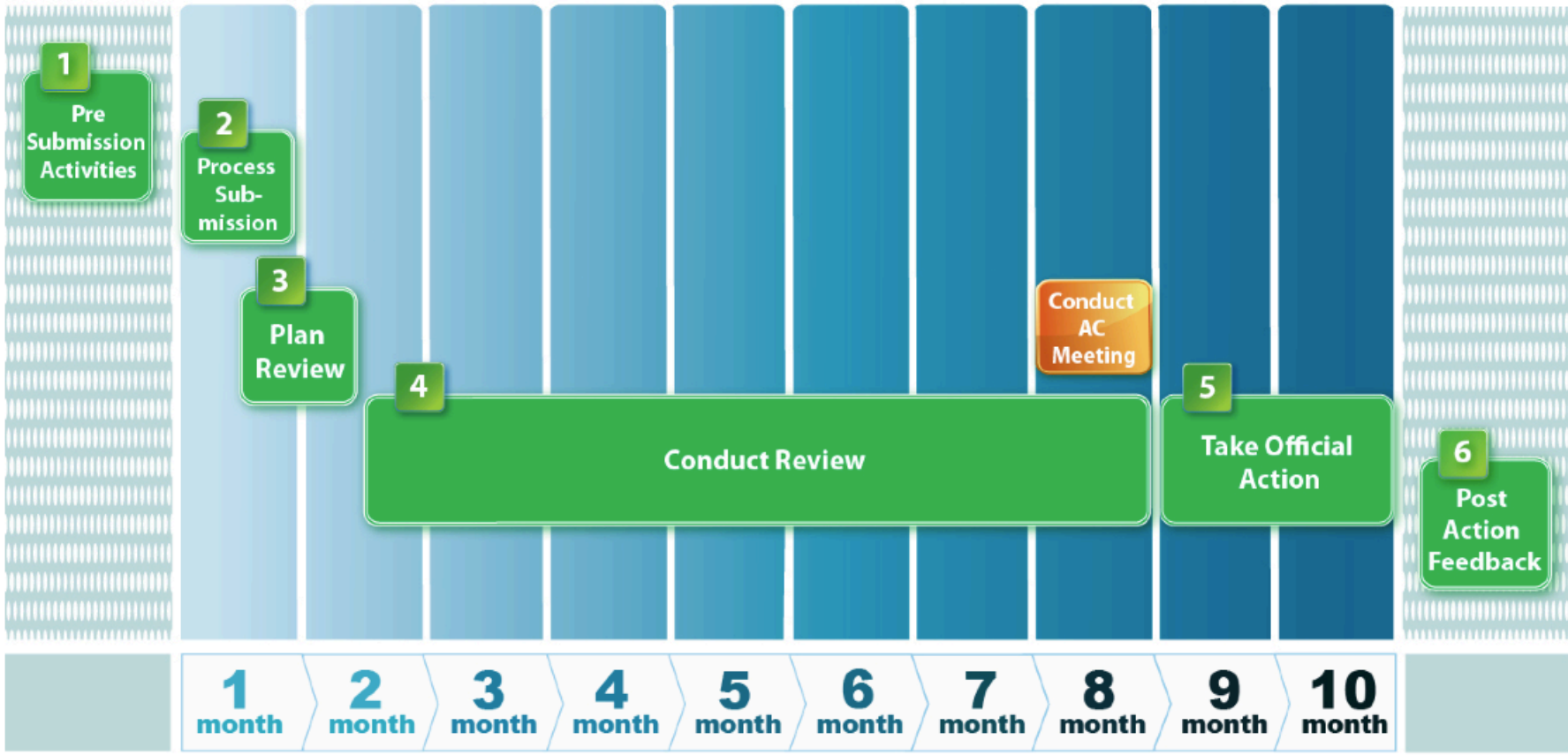
Disclaimer

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

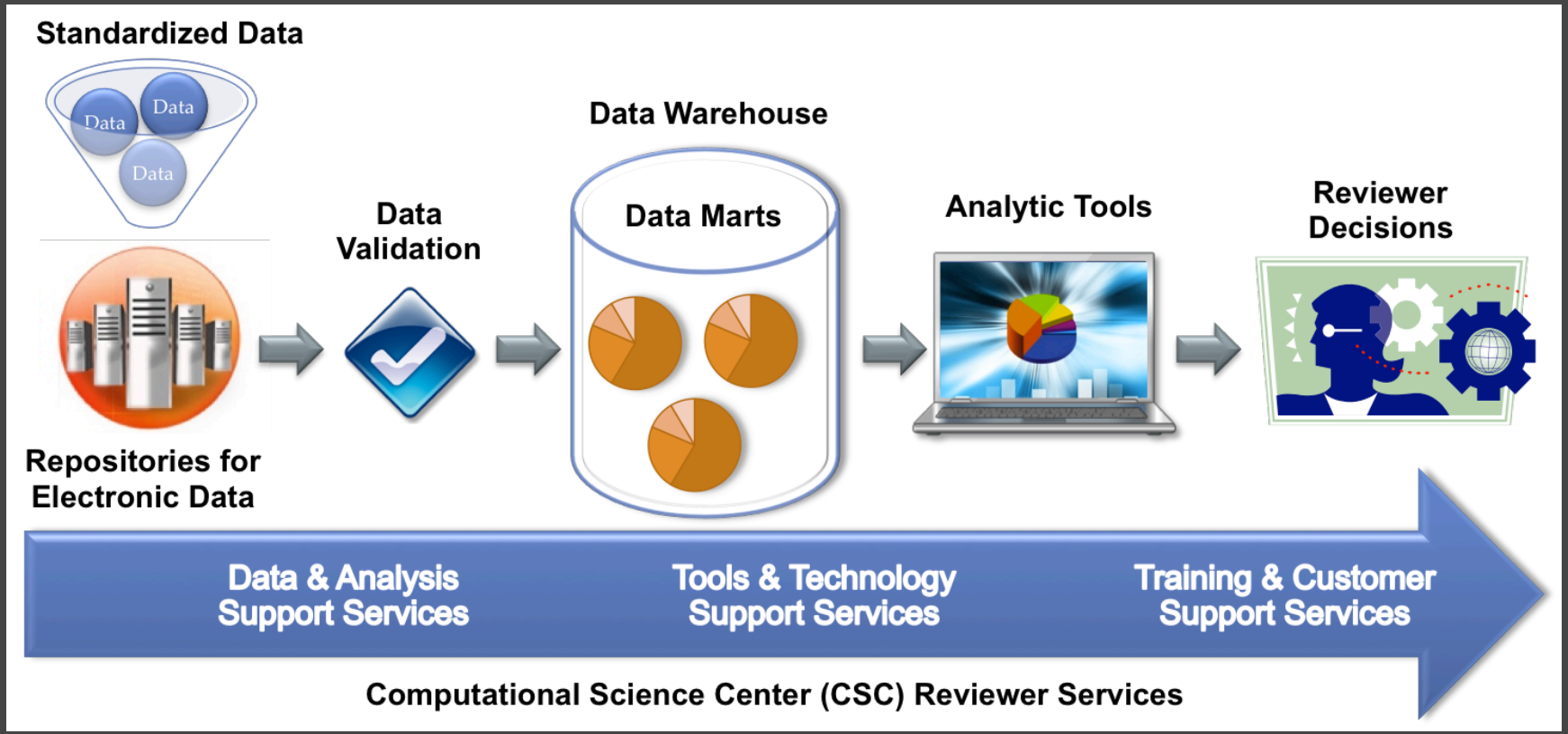
- Easier access to important resources
- Less time spent trying to analyze data
- More "think" time
- Increase ability to explore study data
- Better data visualization

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

CDER Computational Science Center

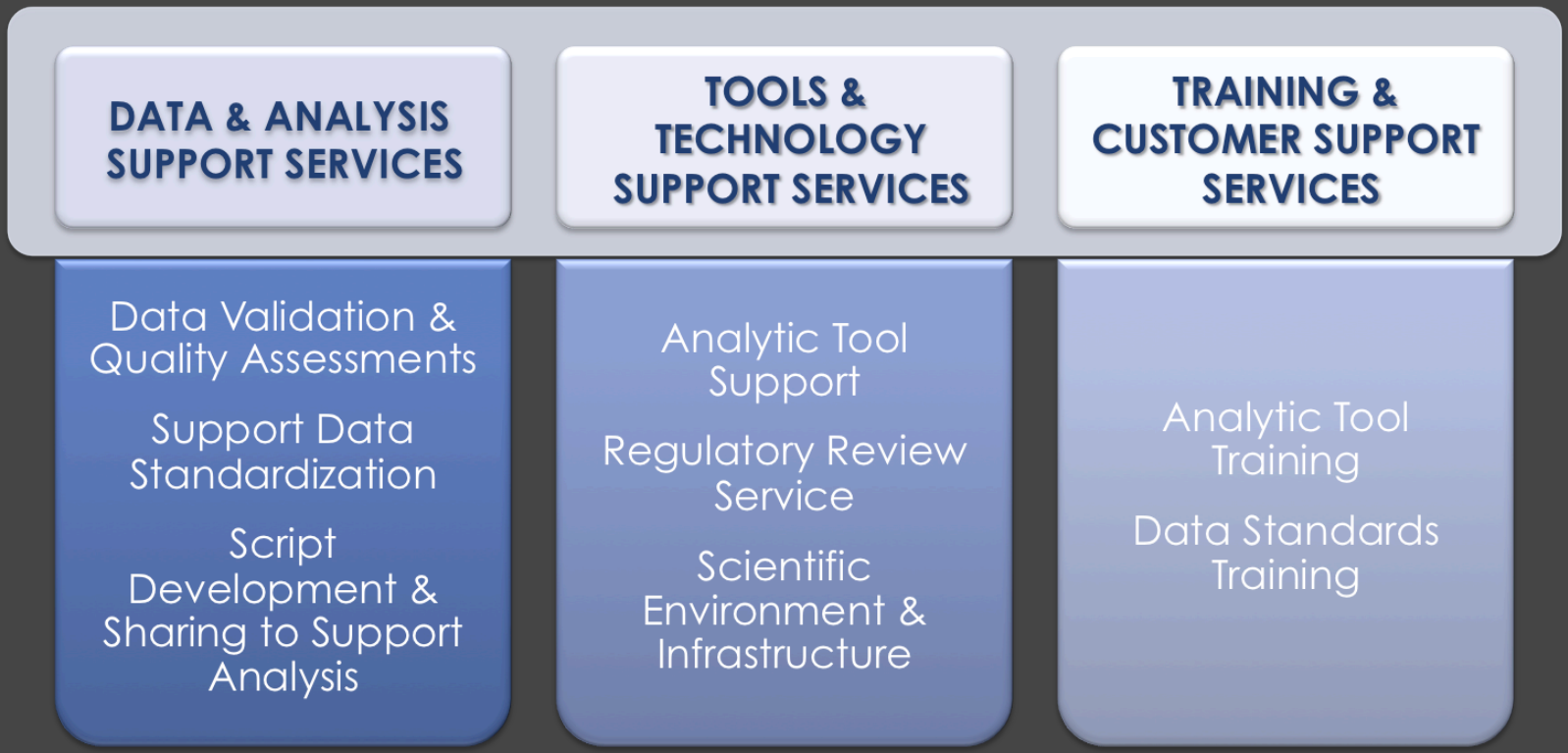
Established to develop the core infrastructure and services to provide high-quality quantitative analysis of information on product safety, effectiveness, and quality.

Intersection of data, tools and technology



Source: Lilliam Rosario, Ph.D., PhUSE Computational Science Symposium, 2014

CSC Reviewer Services



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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

Source: Lilliam Rosario, Ph.D., PhUSE Computational Science Symposium, 2014

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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

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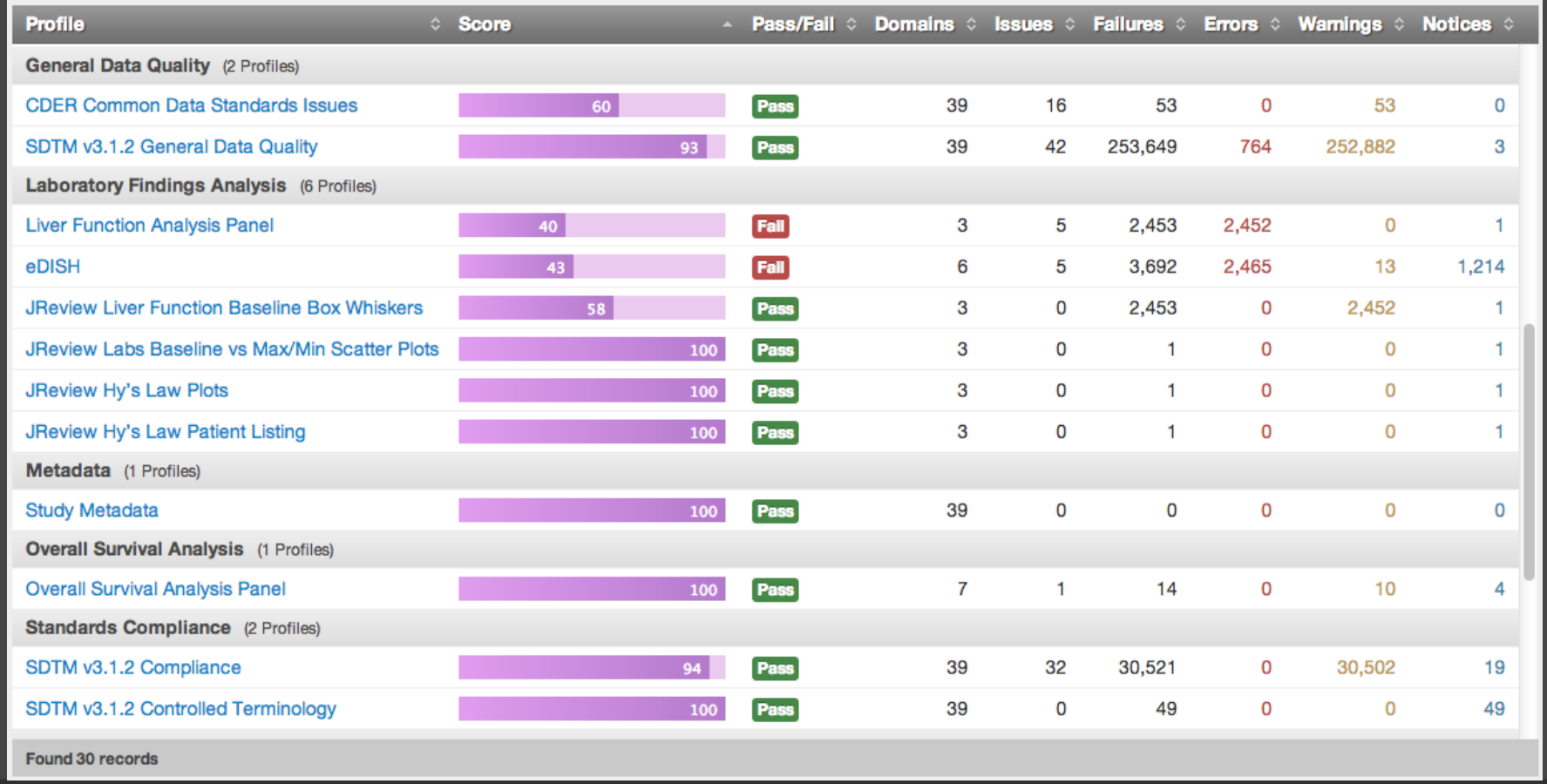
Is Study Data Useful?

- 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

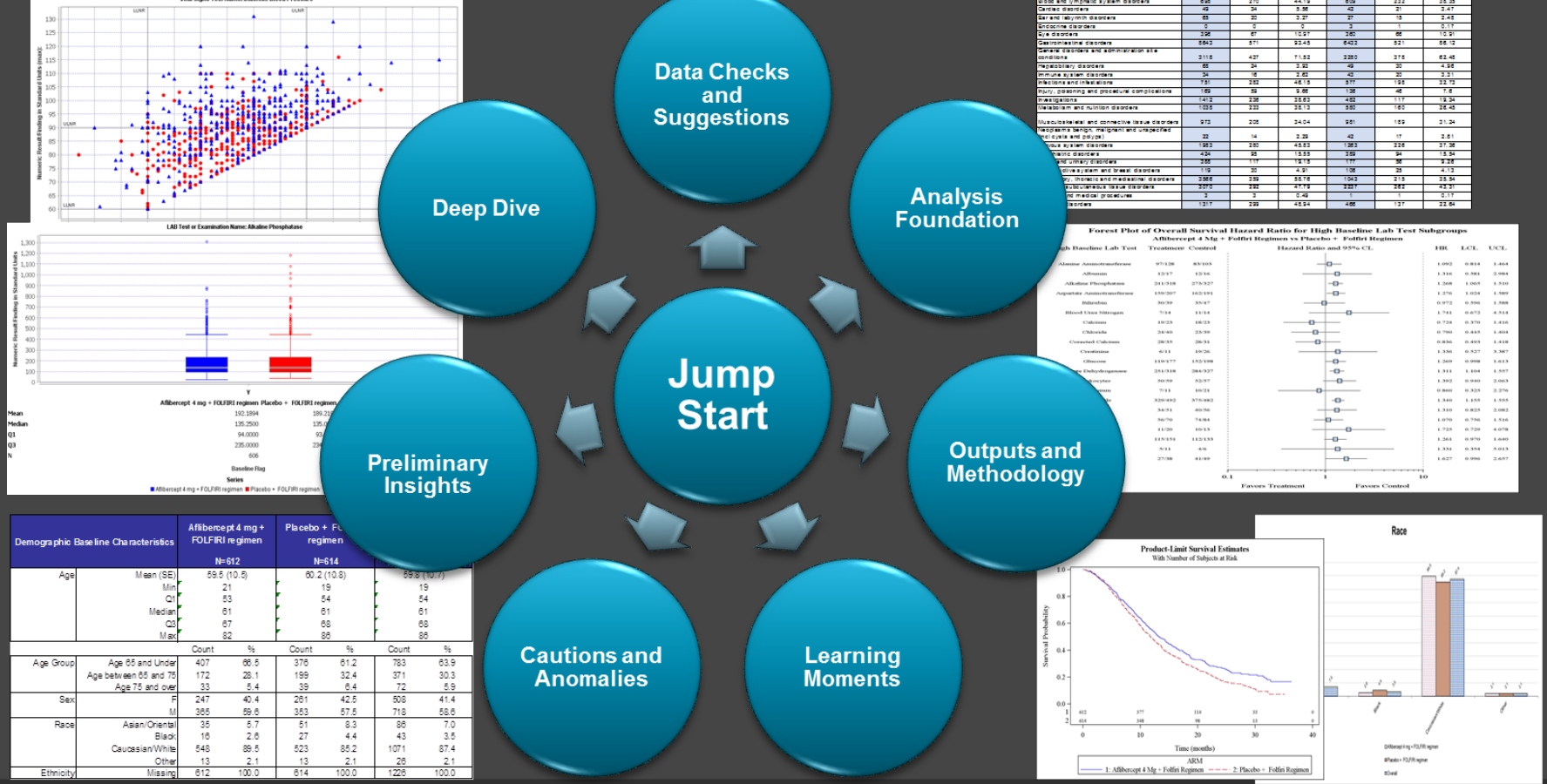
A project to improve the quality of submissions by assessing and enforcing CDISC compliance and data fitness (usefulness).

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



Demographic Baseline Characteristics		Aflibercept 4 mg + FOLFIRI regimen N=612		Placebo + FOLFIRI regimen N=614		
Age	Mean (SE)	59.5 (10.8)		60.2 (10.8)		59.8 (10.7)
	Min	21		19		19
	Q1	53		54		54
	Median	61		61		61
	Q3	67		68		68
	Max	82		86		86
		Count	%	Count	%	Count	%
Age Group	Age 65 and Under	407	66.5	376	61.2	783	63.9
	Age between 65 and 75	172	28.1	199	32.4	371	30.3
	Age 75 and over	33	5.4	39	6.4	72	5.9
Sex	F	247	40.4	261	42.5	508	41.4
	M	365	59.6	353	57.5	718	58.6
Race	Asian/Oriental	35	5.7	51	8.3	86	7.0
	Black	16	2.6	27	4.4	43	3.5
	Caucasian/White	548	89.5	523	85.2	1071	87.4
	Other	13	2.1	13	2.1	26	2.1
Ethnicity	Missing	612	100.0	614	100.0	1226	100.0

FDA JumpStart Services

A consolidated process that takes various CSC tools and technologies and applies them against submissions to “jump start” the review process.

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

FDA JumpStart wins HHS Innovates Award

The FDA's "JumpStart Drug Review" was selected for a 2014 HHS Innovates Award! This groundbreaking program was recognized as a "Secretary's Pick" by Secretary Sylvia Matthews Burwell and Deputy Secretary Bill Corr.

Questions

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