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Janus Clinical Trials Repository (CTR) An Update

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DISCLAIMER

The views expressed in this presentation are those of the speaker and not necessarily those of the Food and Drug Administration ...

Outline

- Background
 - History of the Janus CTR
- Current State
- Looking Ahead
- Janus CTR “Look and Feel”

Background

FDA has the largest repository in the **world** of subject-level clinical trial data

- But data are largely unstructured, poorly accessible, multiple formats
 - Akin to a **data land-fill** rather than a modern, data repository
 - Tremendous opportunity to improve our scientific knowledge about medical products, and the science of medical product development
- 
- FDA Science Board Report (2007) – “FDA Science and Mission at Risk”
 - “The FDA must invest in the development of large-scale, sustainable data sharing infrastructures that can support clinical trials and pharmacovigilance...”
(page K-11 Recommendation 4)

What is Janus CTR?

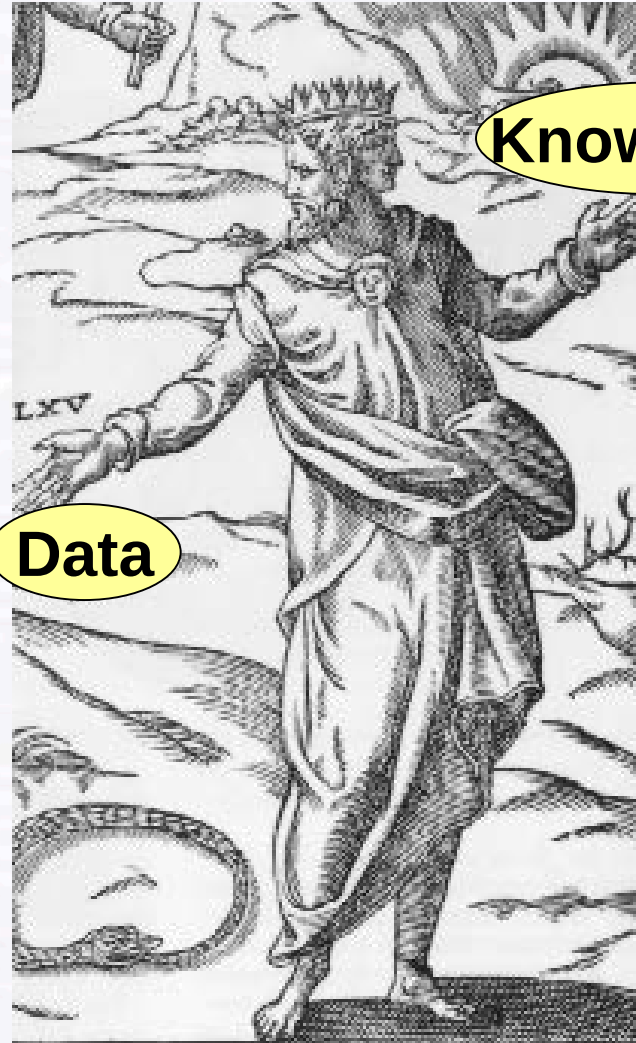
- Replace **data land-fill** with a ...
- Modern **data warehouse** to improve CDER's management and analysis of clinical trial data
- CTR is a standards-based infrastructure that supports the receipt, validation, storage, easy access and analysis of study data
- CTR intends to ...
 - Enhance scientific computing
 - Improve scientific knowledge
 - Inform regulatory decisions
 - Improve public health and patient safety

What is Janus?

The Name

Janus n : (Roman mythology)

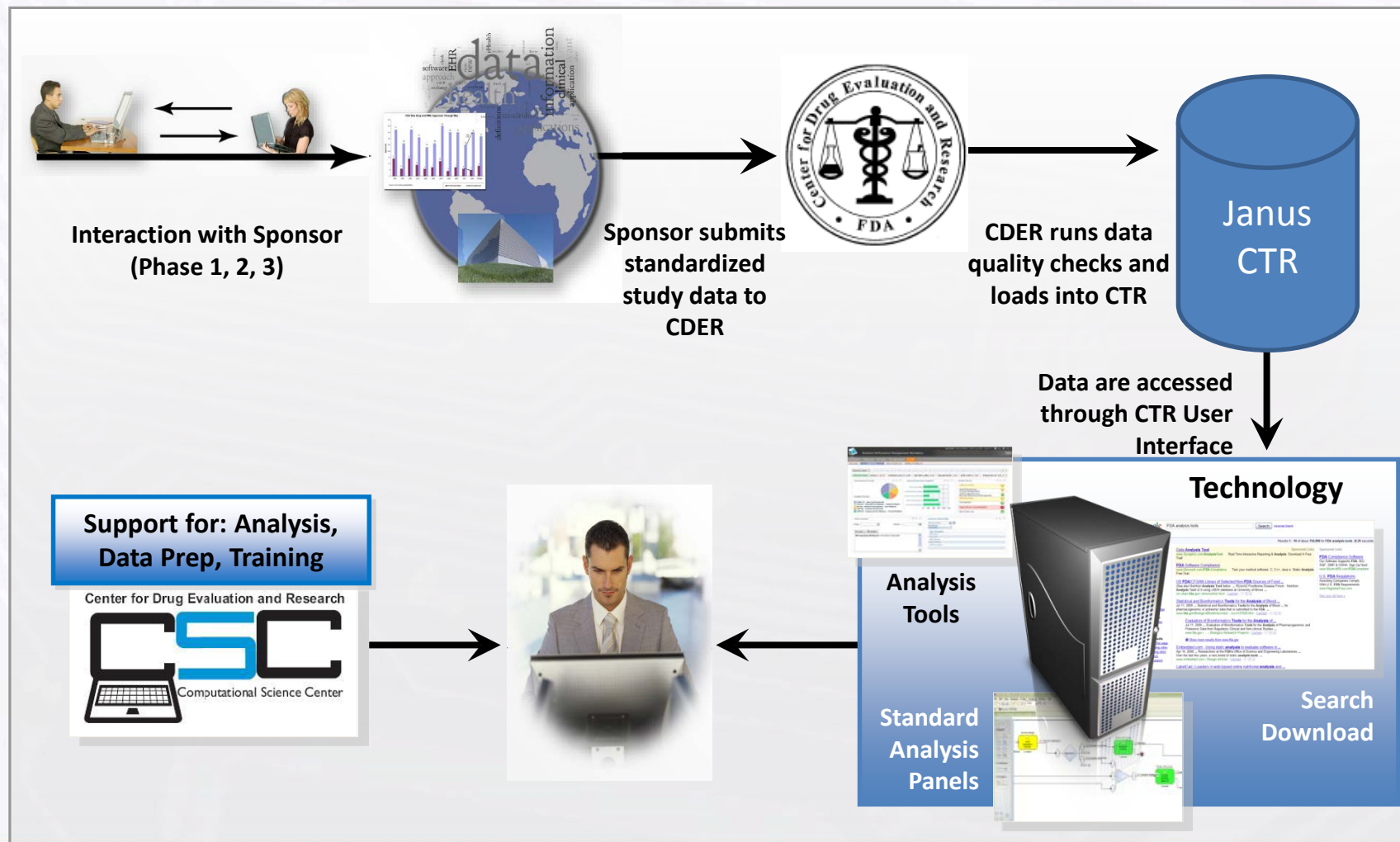
the Roman god of doorways, passages and beginnings; is depicted with two faces on opposite sides of his head, one looking towards the past and the other looking towards the future.



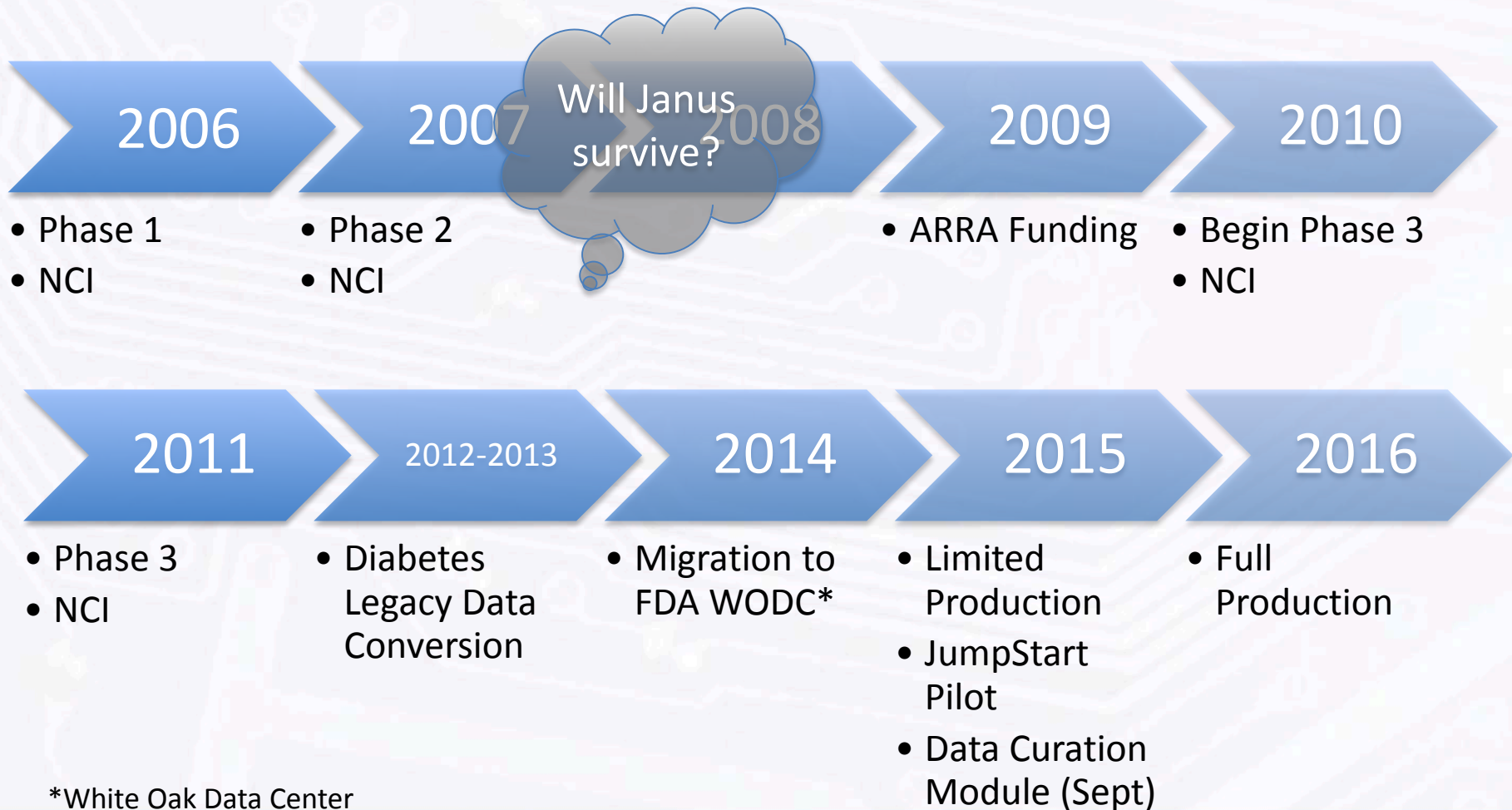
Knowledge

Data

Janus CTR Conceptual Overview



Janus CTR Milestones



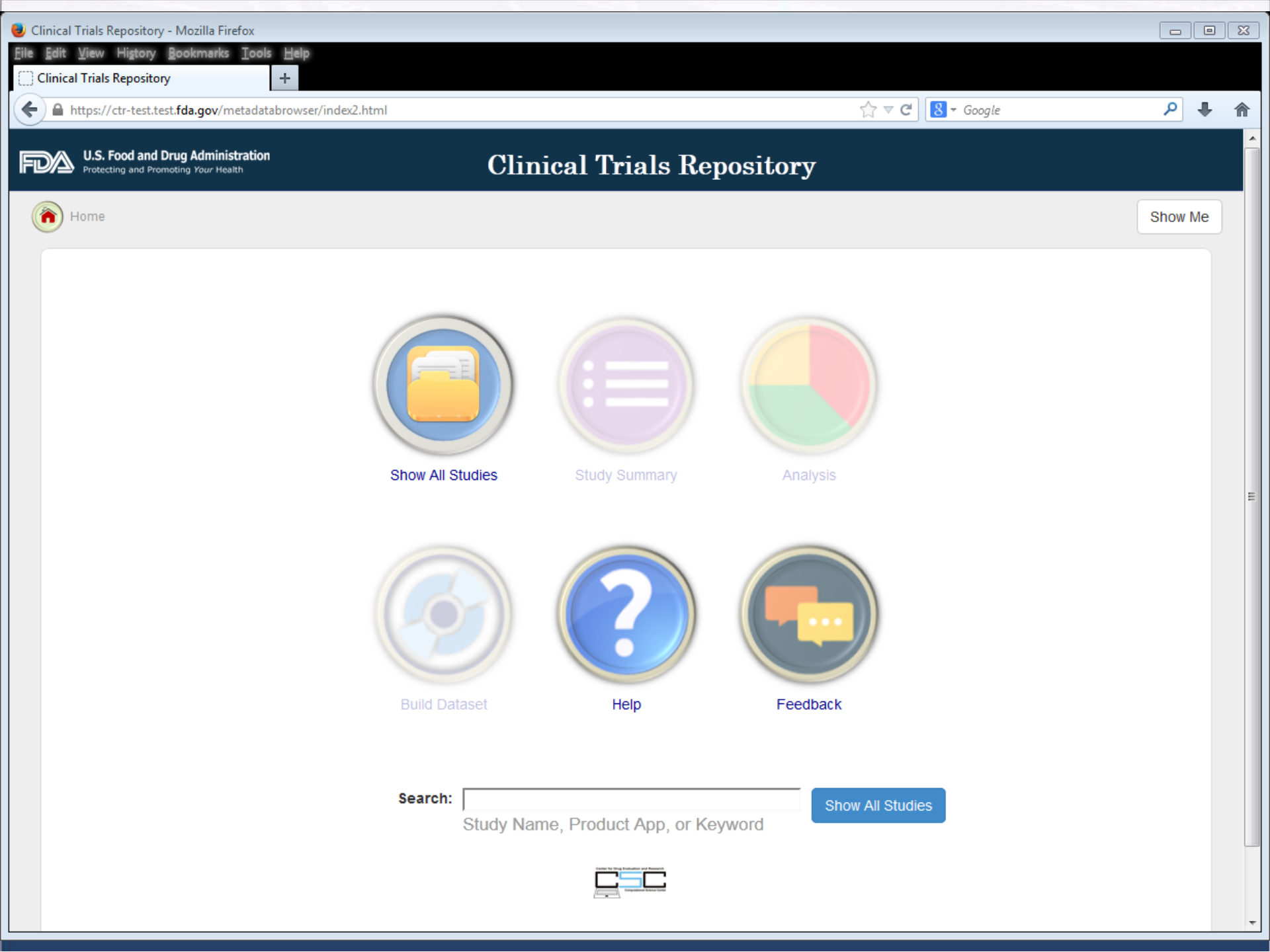
Current State

- Janus CTR is operational at the White Oak Data Center (WODC) as of January 2015
- CTR contains, as of mid March 2015:
 - Production Environment – 61 studies
 - Test Environment – 19 studies
 - Numbers steadily increasing

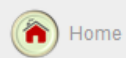
CTR “Look and Feel”

Web-based User Interface

- Evolving as user preferences/feedback are collected
- Study Browser – search studies
- Download “analysis-friendly” datasets
 - Demographics and treatment assignment info in each record
 - Numeric dates with level of precision noted (e.g. “time unknown”)
 - Suppqual information merged with parent domain
 - Units converted to U.S. conventional units
 - Full MedDRA hierarchy added to all MedDRA Preferred Terms
- Query Builder – build custom datasets to answer specific scientific, research, public health questions, especially across multiple studies
- Standard Analysis Panels (demographics, adverse events, hepatic laboratory data, etc.)



Clinical Trials Repository



Home

Show Me



Show All Studies



Study Summary



Analysis



Build Dataset



Help



Feedback

Search:

Show All Studies

Study Name, Product App, or Keyword

- 
Show All Studies
- 
Study Summary
- 
Analysis
- 
Build Dataset
- 
Help
- 
Feedback

Current Search

Keyword
(None)

Refine Results

Study Parameters

Search Results

Select one or more studies to enable
Analysis and Build Dataset

Show 25 entries

Keyword:

Select	Study Name	Product App	Title	Indication
☒	Short Title	NDA	A Double-Blind, Randomized, Comparator-Controlled Study in Subjects with Type 2 Diabetes Mellitus Comparing the Effects of Progression of Coronary At	Type 2 Diabetes Mellitus
	Short Title	NDA		TYPE 2

Selected Studies

Product App: NDA0
StudyName:

Click on Analysis or Build Dataset at the top of the screen to use the Selected Study

Search

Refine Results

Study Parameters

Comparative Treatment Name

Control Type

Select Item from List

ACTIVE
COMPARATOR
NONE
PLACEBO

Current Therapy or Treatment

Description of Trial Design

Diagnosis Group

Exploratory Outcome Measure

Healthy Subject Indicator

Intervention Model

- User can search by any SDTM Trial Summary (TS) parameter
 - TS data are **critical** for CTR Search to function properly

Clinical Trials Repository - Mozilla Firefox

File Edit View History Bookmarks Tools Help

Clinical Trials Repository +

https://ctr-test.test.fda.gov/metadatabrowser/index2.html?search b Google

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Clinical Trials Repository

Select A Study NDA Study ID

Study Summary Show Me

Study Summary Trial Inclusion / Exclusion Study Protocol Study Define XML Reviewer Notes Reviewer Log

1. Descriptive Information

DESIGN	PARALLEL
Trial Title	Short Title
Trial Phase	Phase IIIb Trial
Trial Type	EFFICACY
Clinical Study Sponsor	Sponsor
Trial Length	365 Days
Randomization	Yes
Trial Blinding Schema	DOUBLE BLIND
Control Type	COMPARATOR

2. Condition

Trial Indication Type	TREATMENT
DESIGN	PARALLEL
Indication	Type 2 Diabetes Mellitus

Study Browser

Standard Analysis Panels

Standardized Analysis Parameters

Selected Studies :

Product App: NDA()

Study Name: ()

Analysis Panel: (None)

Choose an Analysis Panel:

Adverse Events

[Adverse Events Severity Analysis Panel](#)

[Adverse Events Toxicity Grade Analysis Panel](#)

Demographics

FIRRS

General

MedDRA

Standardized Analysis Parameters

Selected Studies :

Product App: NDA0

Study Name:

Analysis Panel: (None)

Choose an Analysis Panel:

Adverse Events

Demographics

FIRRS

General

[Disposition Analysis Panel](#)

[Liver Lab Panel Analysis](#)

MedDRA

Standardized Analysis Parameters

Selected Studies :

Product App: NDA

Study Name: 1

Analysis Panel: (None)

Choose an Analysis Panel:

Adverse Events

Demographics

[Demographic Analysis - For Office of Womens Health](#)

[Demographic Analysis Panel](#)

FIRRS

General

MedDRA

CTR Analysis - Mozilla Firefox

File Edit View History Bookmarks Tools Help

CTR Analysis

+

https://ctr-test.test.fda.gov/ctreports/index2.html?studies[0][productApplicationNumber]=

bnN

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Google

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Report #1: Demographic Baseline Characteristics: Overview

?

Demographic Baseline Characteristics		Drug			Control			Overall	
		N=273			N=274			N=547	
		Stat	Count	%	Stat	Count	%	Stat	Count
Age Statistics	Max Years	83			83			83	
	Mean (SE) Years	59.7 (9.1)			59.9 (9.5)			59.8 (9.3)	
	Median Years	59			60			60	
	Min Years	39			36			36	
	Mode Years	63			57			62	
	Q1 Years	53			54			54	
	Q3 Years	66			66			66	
Age Group	Age 75 and Over		16	5.9		21	7.7		37
	Age between 1 year and 65 years		193	70.7		191	69.7		384
	Age between 65 and 75		64	23.4		62	22.6		126
Ethnicity	HISPANIC OR LATINO		71	26.0		63	23.0		134
	NOT HISPANIC OR LATINO		202	74.0		211	77.0		413
Race	AMERICAN INDIAN OR ALASKA NATIVE		10	3.7		3	1.1		13
	ASIAN		16	5.9		12	4.4		28
	BLACK OR AFRICAN AMERICAN		27	9.9		31	11.3		58
	WHITE		220	80.6		228	83.2		448
Sex	F		93	34.1		85	31.0		178
	M		180	65.9		189	69.0		369

Export to Excel

➔ Share

Standard Analysis Panels -- Demographics



Build Dataset from

Show Me

Selected Studies

Product App: ND

Study Name:

Variables

Standard Demographics & Treatment

Add New Column or Variable

Demographics.Unique Subject Identifier

Demographics.Subject Identifier for the Study

Demographics.Age

Demographics.Date/Time of Birth

Demographics.Sex

Domains

Add Selected

Adverse Events

Clinical Assessment

Comments

Concomitant Medications

Death Diagnosis

Demographics

Disposition

Drug Accountability

ECC

Filter

Select records where all of the following apply:

Demographics.Age is greater than " 65 "

[Add new condition]

Query Builder – Create Custom Datasets

CTR Build Dataset - Mozilla Firefox

File Edit View History Bookmarks Tools Help

CTR Build Dataset +

https://ctr-test.test.fda.gov/adhocquery/index2.html?studies[0][productApplicationNumber]= studyName Google

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Clinical Trials Repository

Build Dataset from Diabetes_Actos_01-01-TL-OP1-516: "Demographics and Treatment" Show Me

Selected

Product App:
Study Name:

Domains

- Ad
- CI
- Co
- Co
- De
- De
- Disposition
- Drug Accountability
- EGC

Create Feedback

Summary :

Context : Build Dataset

Type : --Select Type--

Severity : --Select Severity--

Detail :

Please enter a short summary of your feedback

Which aspect of the Clinical Trials Repository would you like to give feedback on?

What type of feedback is this?

How debilitating is the problem?

Enter a detailed description of your feedback. If this is a bug, please describe the steps you took to cause it to happen. Provide as much detail as possible

Ok Cancel

Feedback Form

How Does CTR Help the Reviewer?

Reviewers can...

- Locate and download clinical trial data in an “analysis-friendly” format
- Pool data across studies within an application for integrated analyses
- Execute a panel of standard analyses designed with the clinical review template in mind (e.g. demographics)
- Create custom datasets to answer specific scientific or public health questions. This Query function enables pooling data across studies, advanced filtering, and downloading the data to their desktops

CTR Operational Pilot and JumpStart

- CTR is currently in an operational pilot
 - Only “**JumpStart**” studies are being loaded
 - CTR undergoing “user acceptance testing”
- **JumpStart** is CDER’s award winning program to “jump start” the regulatory review process
- Applications are enrolled in the JumpStart program:
 - 30 marketing applications targeted for 2015
 - Pivotal trials of these applications are stored in CTR

Summary

- Janus CTR is operational at FDA
 - 2015 – Operational Pilot
 - 2016 – Full Production
- CTR is transforming how CDER manages and analyzes clinical trial data

Thank You for your attention!!



SOLDIERS AT ATTENTION.

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