Enhancing the Collection and Availability of Demographic Subgroup Data

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Overview

- What are Drug Snapshots?
- Why are Drug Snapshots necessary?
- What is included in Drug Snapshots?
- How are Drug Snapshots different than the Package Insert?
- What is the timeline for publishing Snapshots?
- What are key findings?
- What are the latest updates?

Snapshots Brief History

- 2014: Pilot Program
- January 1, 2015: Snapshot written for every New Molecular Entity (NME) and Original Biologic approved
- Permanent program
- Goal to publish 30 days after approval
- Does not apply to previously approved drugs

Purpose of Drug Snapshots

- Provide Information to the public about who participated in the clinical trials for NMEs and original biologics
- Also includes information on study design, results of efficacy and safety studies, and whether there were observed differences in efficacy and side effects among sex, race, and age subgroups

DRUG TRIALS SNAPSHOTS

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Drugs

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Drug Approvals and Databases

- Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book)
- Bioresearch Monitoring Information System (BMIS)
- Clinical Investigator Inspection List (CLIIL)
- Dissolution Methods Database
- Drug Establishments Current Registration Site
- **Drug Trials Snapshots**
- Drugs@FDA Database
- FDA Adverse Event Reporting System (FAERS)

Drug Trials Snapshots

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Sign Up for Email Updates about Drug Trials Snapshots

WHAT IS THE PURPOSE OF DRUG TRIALS SNAPSHOTS?

Drug Trials Snapshots provide consumers with information about who participated in clinical trials that supported the FDA approval of new drugs. The information provided in these Snapshots also highlights whether there were any differences in the benefits and side effects among sex, race and age groups. Drug Trials Snapshots is part of an overall FDA effort to make demographic data more available and transparent.

HOW TO USE SNAPSHOTS:

Each Snapshot includes contains information about the drug in a question and answer format. At the end of each section of the Snapshot, there is a shaded bar with the words “MORE INFO”. Click the “MORE INFO” bar for more technical and detailed content. At the bottom of each Snapshot, there is a link to the drug’s Package Insert as well as the medical review.

fda.gov/drugtrialssnapshot

Drug	Active Ingredient	Date of FDA Approval	What is it Approved For	Package Insert
ADDYI	flibanserin	August 18, 2015	Treatment of acquired, generalized hypoactive sexual desire disorder (HSDD) in premenopausal women	Addyi
ARISTADA	aripiprazole laurixil	October 5, 2015	Treatment of schizophrenia	Aristada
AVYCAZ	ceftazidime-avibactam	February 25, 2015	Treatment of complicated urinary tract infection (abbreviated as cUTI)	Avycaz
AVYCAZ	ceftazidime-avibactam	February 25, 2015	Treatment of complicated intra-abdominal infection (abbreviated as cIAI)	Avycaz
CHOLBAM	cholic acid	March 17, 2015	For treatment of bile acid synthesis disorders due to single enzyme defects	Cholbam
CHOLBAM	cholic acid	March 17, 2015	For treatment of peroxisomal disorders, including Zellweger spectrum disorders	Cholbam
CORLANOR	ivabradine	April 15, 2015	To reduce hospitalization from worsening heart failure.	Corlanor
COSENTYX	secukinumab	January 21, 2015	Treatment of moderate to severe plaque psoriasis in adults who do not respond well to medication applied directly to the skin	Cosentyx
COTELLIC	(cobimetinib)	November 10, 2015	Part of combination treatment for multiple myeloma	Cotellic
CRESEMBA	isavuconazonium sulfate	March 6, 2015	Treatment of invasive mucormycosis	Cresemba

Snapshots Audience

- Consumers
- Physicians, Statisticians, anyone who is interested in the data and analyses
  - (MORE INFO)

Snapshots are not a drug label

Snapshots

- Intended for public
- Consumer-friendly language
- Focus on subgroup data and analysis
- Links to FDA reviews
- 30 days after drug approval

Prescribing Information

- Intended for healthcare professionals
- Technical language
- Comprehensive resource for drug information
- Not linked to FDA reviews
- Published with drug approval

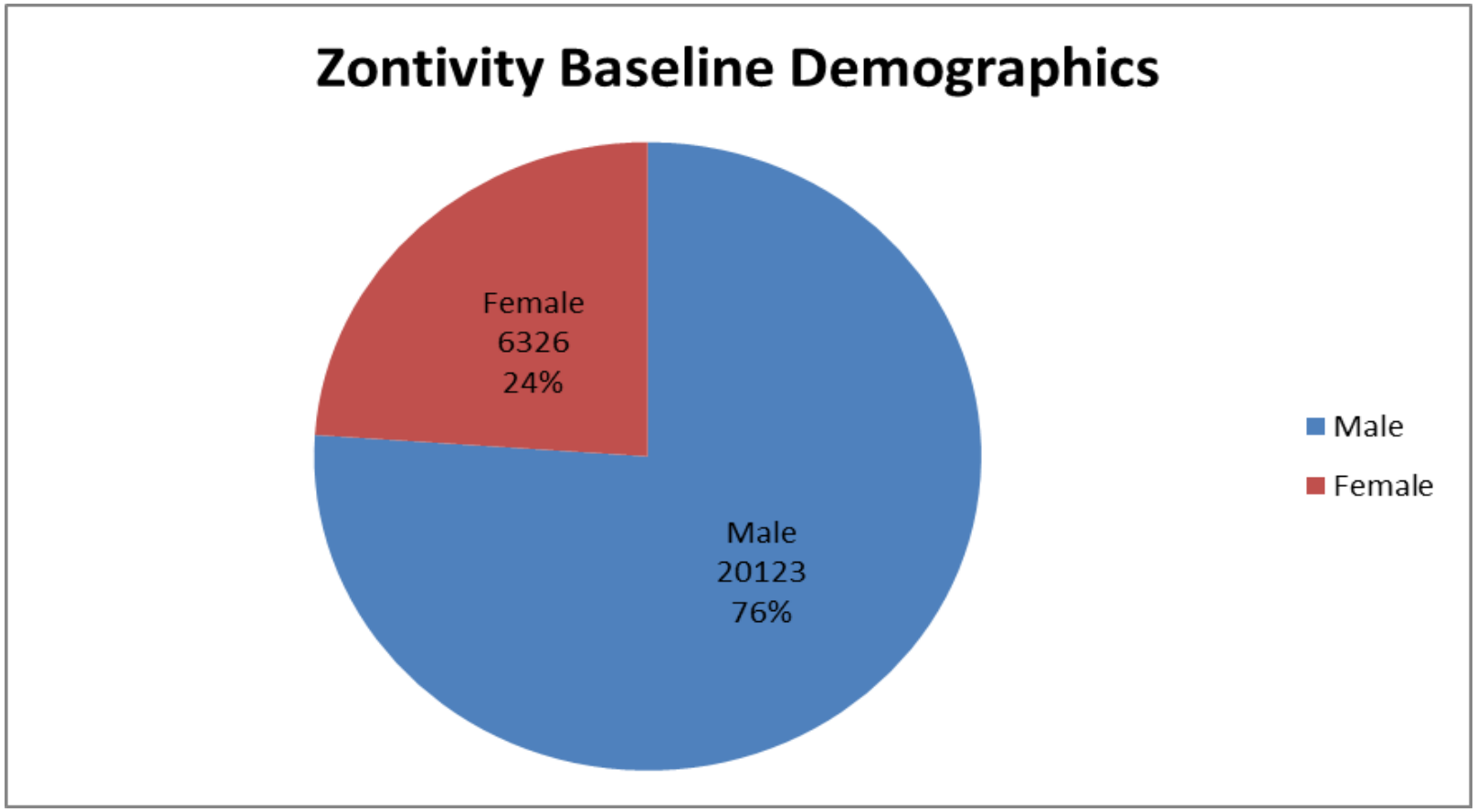
Drug Trials Snapshots

- Summary of information
  - *What is the drug for?*
  - *What are the benefits of the drug?*
  - *What are the possible side effects?*
  - *How were the clinical trials designed?*
- Demographic Information

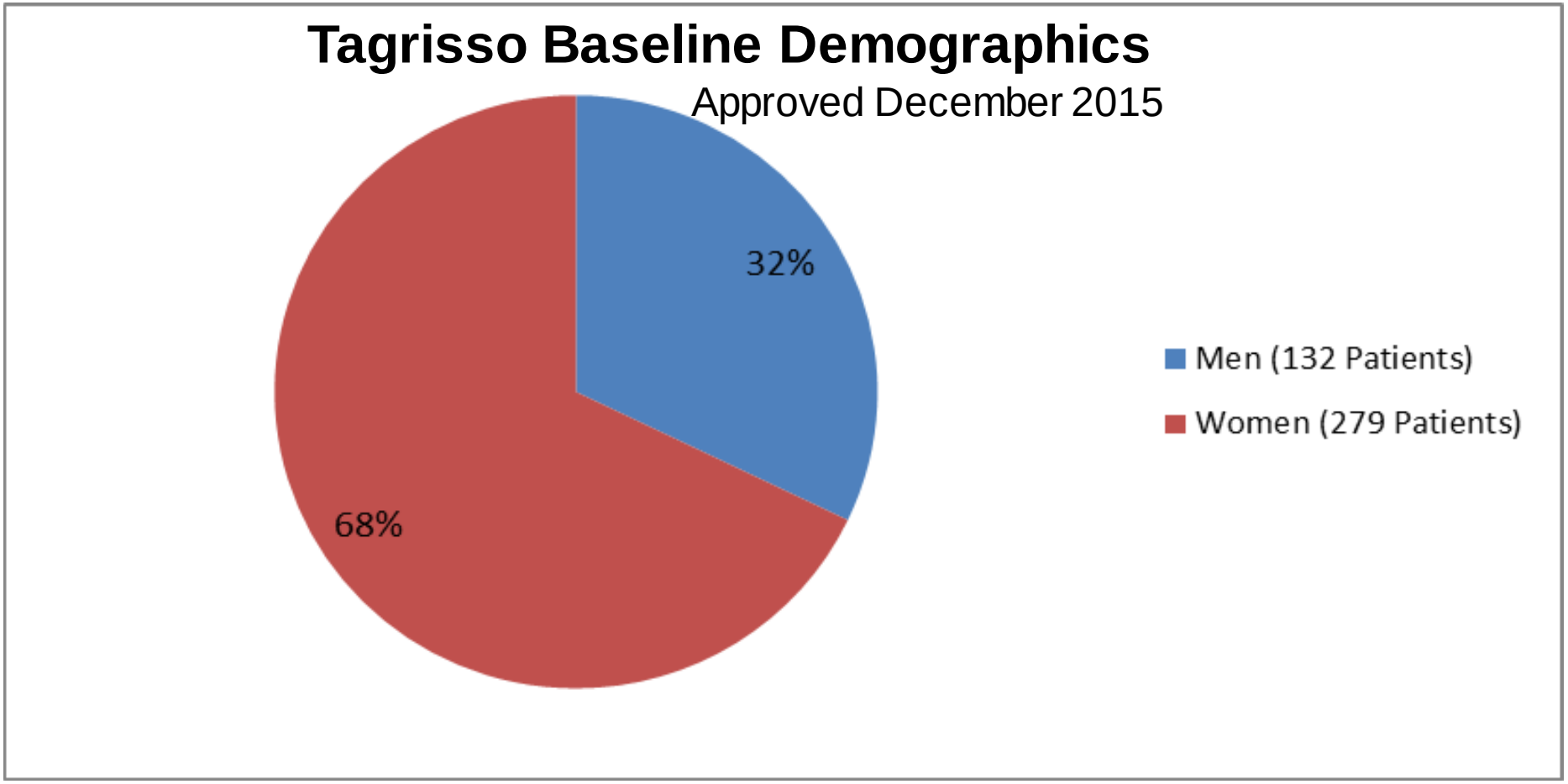
Key Snapshot Questions: Subgroups

- Who were in the clinical trials by **sex, race, and age** subgroups?
- Were there observed **differences in efficacy and safety** among sex, race, and age subgroups?

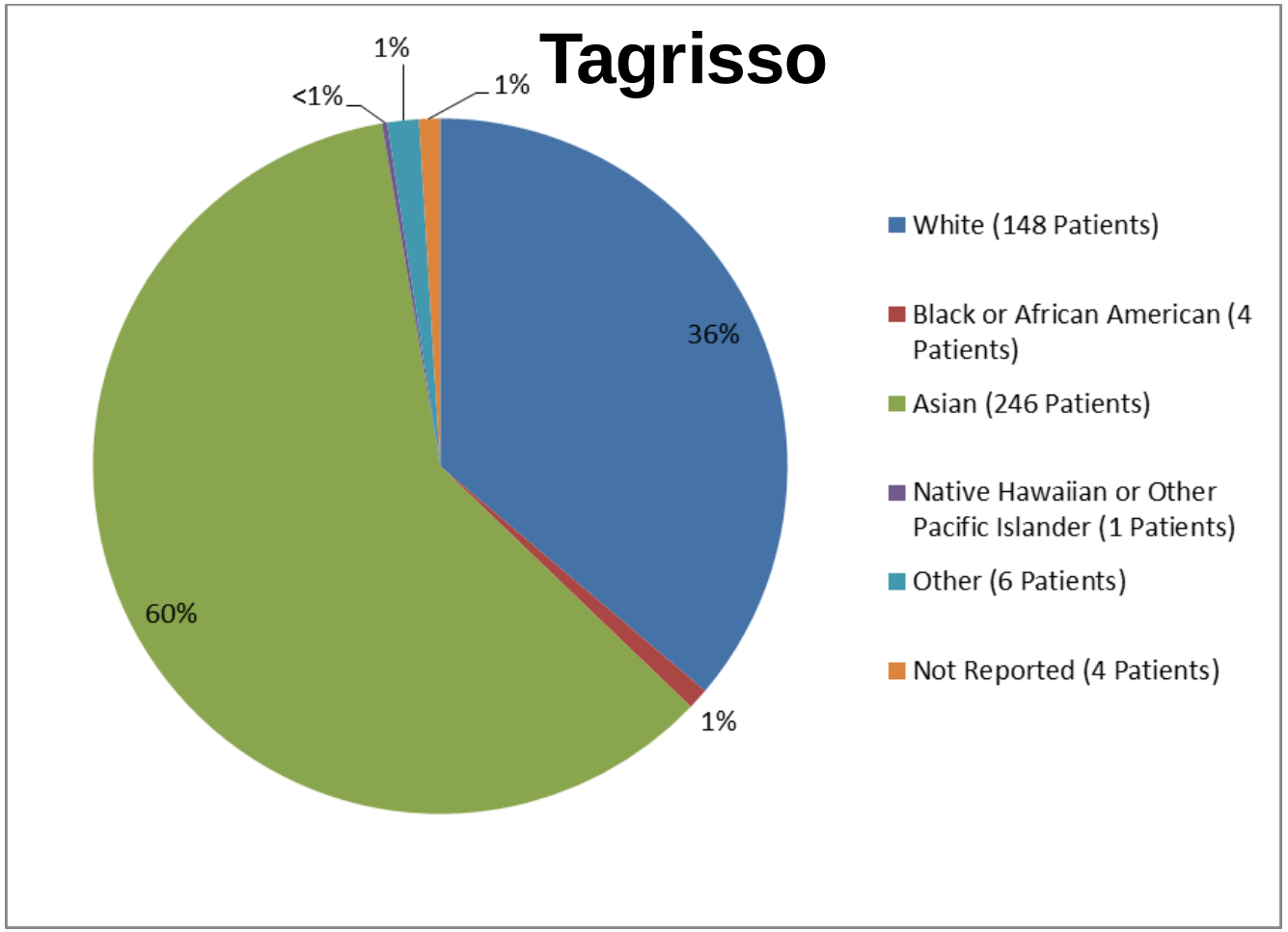
Snapshots: Sex Demographics



Snapshots: Sex Demographics



Snapshots: Racial Demographics



Snapshot Overview

	WOMEN	AFRICAN AMERICAN	ASIAN	WHITE	AGE 65 AND OLDER
AVERAGES	46%	8%	12%	76%	26%

Snapshots on Cardiovascular

BRAND NAME	INDICATION	WOMEN
UPTRAVI	Pulmonary arterial hypertension	**80%**
REPATHA	Hypercholesterolemia (HoFH)	**50%**
SAVAYSA	Reduce risk of pulmonary embolism in VTE patients	**43%**
PRALUENT	Hyperlipidemia	**40%**
SAVAYSA	Reduce the risk of stroke in a Afib patients	**38%**
KENGREAL	Blood thinner following heart procedure	**28%**
CORLANOR	Heart failure	**24%**
ENTRESTO	Heart failure	**22%**
AVERAGE		**41%**

Snapshots in Oncology

BRAND NAME	INDICATION	WOMEN	AFRICAN AMERICAN	ASIAN	WHITE	AGE 65 and OLDER
IBRANCE	Breast cancer	100%	1%	6%	90%	47%
TAGRISSO	Lung Cancer (T790M+, NSCLC)	68%	1%	60%	36%	45%
ALECENSA	Metastatic NSCLC	56%	2%	19%	74%	13%
YONDELIS	Advanced soft tissue sarcoma	52%	0%	9%	81%	N/A
LENVIMA	Thyroid cancer	49%	2%	18%	79%	40%
FARIDAK	Multiple Myeloma & other cancers	48%	5%	29%	64%	42%
DARZALEX	Multiple Myeloma	46%	10%	6%	76%	45%
NINLARO	Multiple Myeloma	43%	2%	9%	84%	58%
COTELLIC	Melanoma	42%	0%	0%	93%	27%
UNITUXIN	Neuroblastoma	40%	7%	3%	82%	N/A
EMPLICITI	Multiple Myeloma	40%	4%	10%	84%	57%
LONSURF	Advanced metastatic colorectal cancer	39%	1%	35%	58%	44%
ODOZMO	Advanced basal cell carcinoma (BCC)	37%	0%	0%	94%	54%
PORTRAZZA	Metastatic squamous non-small cell lung cancer (NSCLC)	17%	1%	8%	85%	39%

Platform for Important Questions

- Is there enough data to make conclusions about efficacy and safety for all subgroups?
- How many patients per subgroup are needed?
- When is generalizability ok?
- When differences among subgroups are seen, when are differences clinically meaningful?

Recent Activity

- Total of **57** Snapshots
- Over **123,718** people visited the site since launch of the website
- These people generated **101,447** visits to the site (some came more than once)
- The average visit lasted **2:10 minutes**
- The top 5 Snapshots visited were **Jublia, Lonsurf, Savaysa, Kybella,** and **Cosentyx**

Future Steps

- Snapshots have created more questions
- “What is the right number?”
- Duke Margolis Meeting
- Continuing to improve and streamline process for generating Snapshots

Looking Forward

- Continuing discussion on variability in response to drugs among subgroups
- Deeper understanding of when subgroup differences are plausible
- Best practices for reporting subgroup differences to the public
- Commitment to continued transparency

Questions?

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PROFESSIONAL AFFAIRS & STAKEHOLDER ENGAGEMENT

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