U.S. FOOD & DRUG ADMINISTRATION

NDA at the FDA

Milena Lolic, MD, MS
Professional Affairs and Stakeholder Engagement

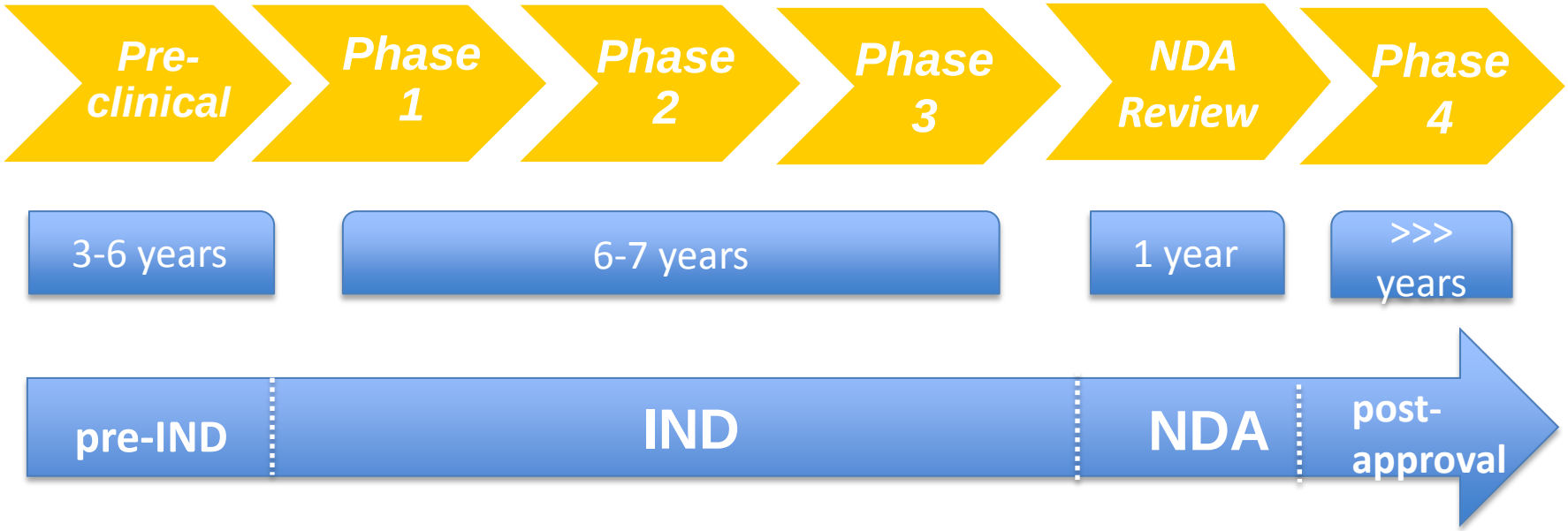
Agenda

- Before NDA : Brief overview of the drug development
- NDA at FDA: terminology and timelines
- NDA at FDA: review conduct
- Post NDA review
  - approval data
  - public information

Drug Development

https://www.youtube.com/watch?v=JVNDgfCT1pg

Timeline of Drug Development



NDA at FDA

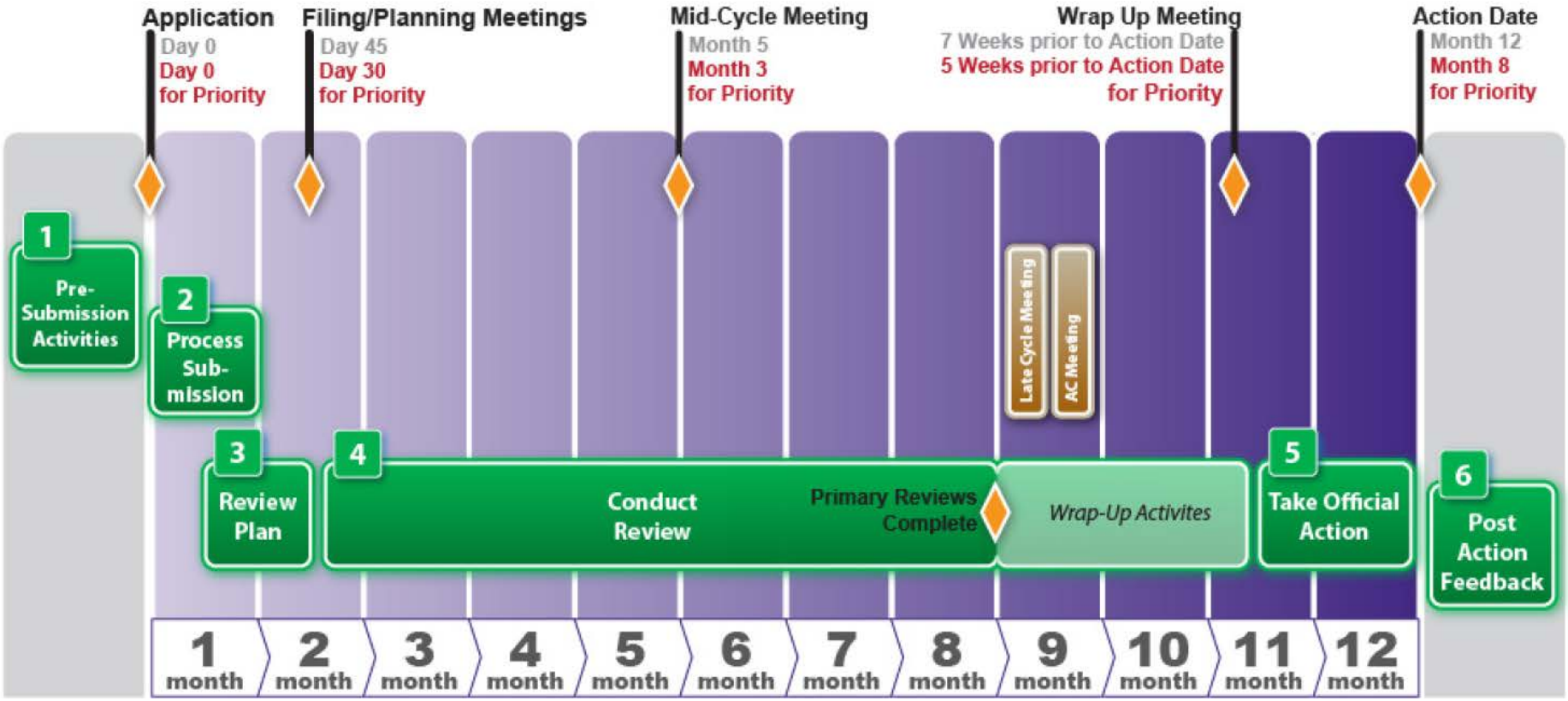
Designations and Reviews

- Fast Track*
- Orphan Drug
- Breakthrough*
- Standard
- Priority*
- Rolling

Accelerated Approval*

* types of expedited programs

NDA Review Timeline



Agenda

- Before NDA: Brief overview of the drug development
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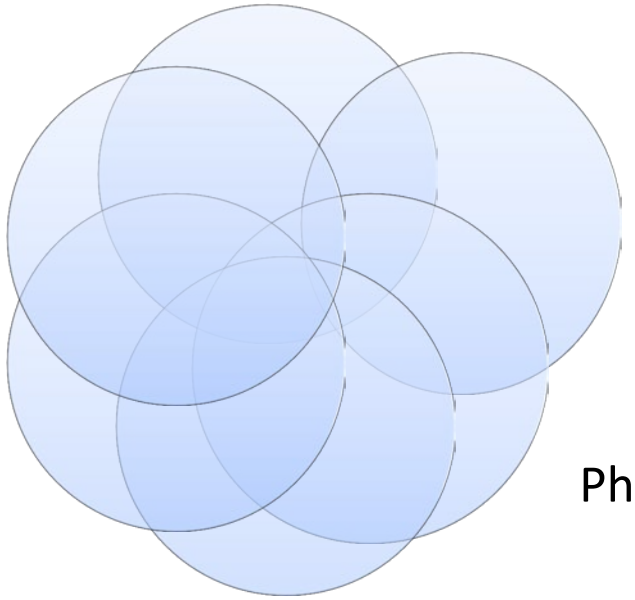
- NDA at FDA: review conduct
- Post NDA review
  - approval data
  - public information

NDA Review

Clinical

Labeling

Statistics



Toxicology

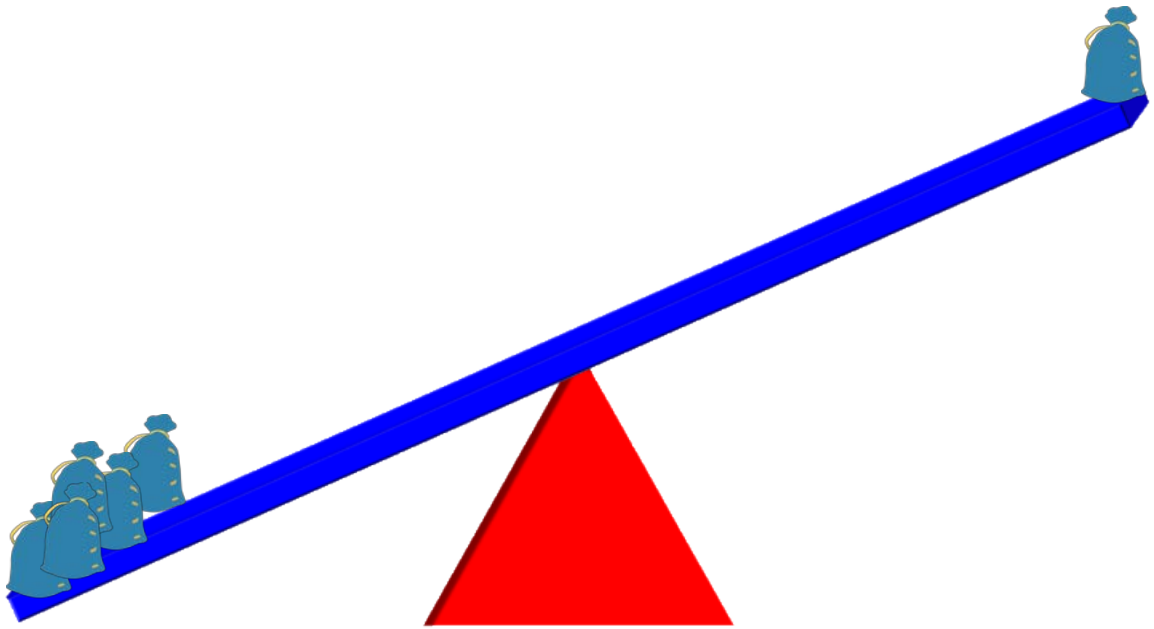
Pharmacology

Chemistry

Consults: PRO, OC, QT, DRISK, DMEPA, OPDP, PeRC, PREA, CDRH

NDA Review

Benefit-Risk Framework



ask THE EXPERT

NDA Review Decision

Approval

- drug name
- labeling
- promotional material
- manufacturing facilities

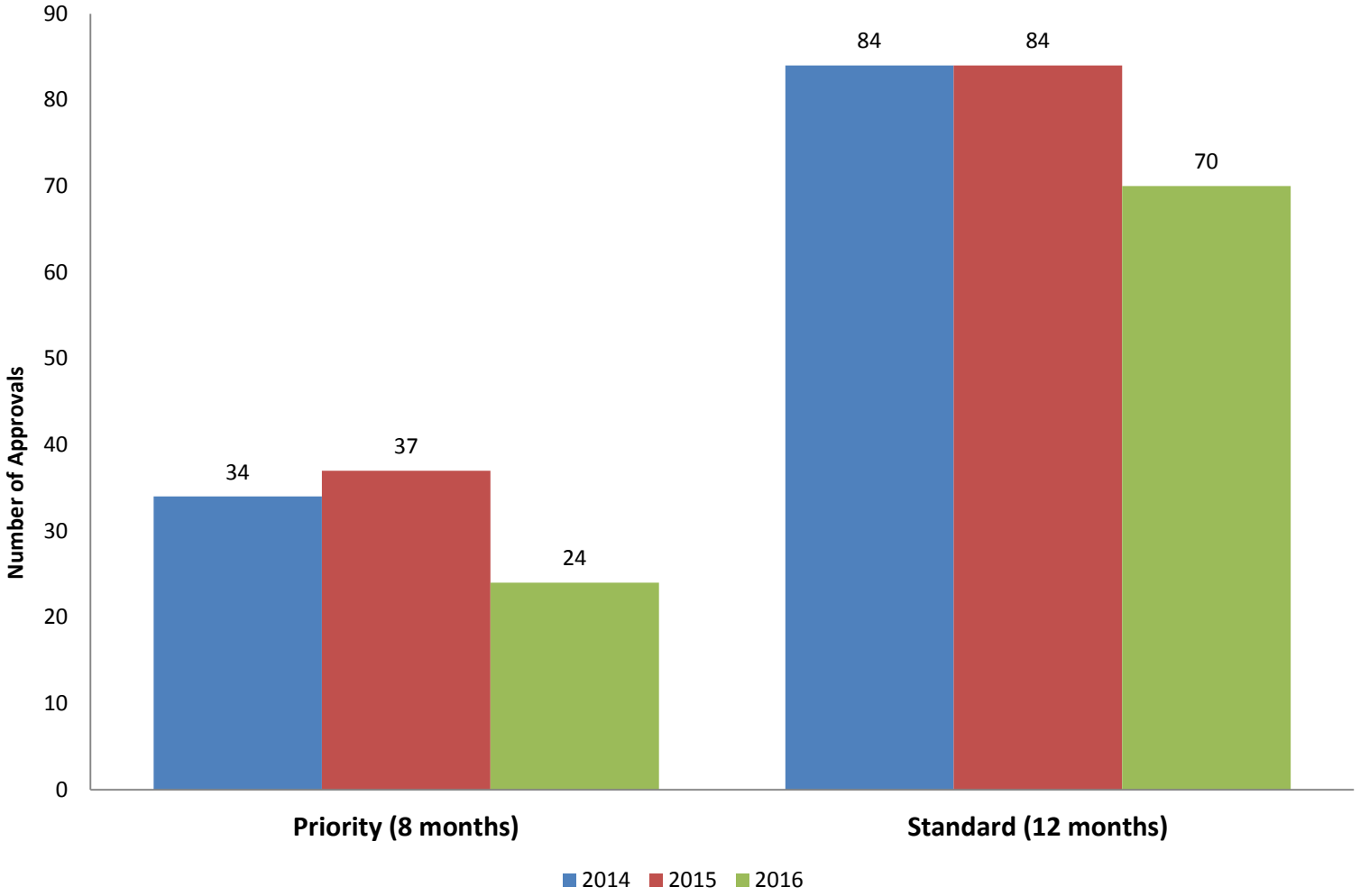
Agenda

- Brief overview of the drug development
- NDA at FDA: terminology and timelines
- NDA at FDA: review conduct
- NDA post FDA review:
  - more data
  - approval data
  - public review information

Post NDA Review

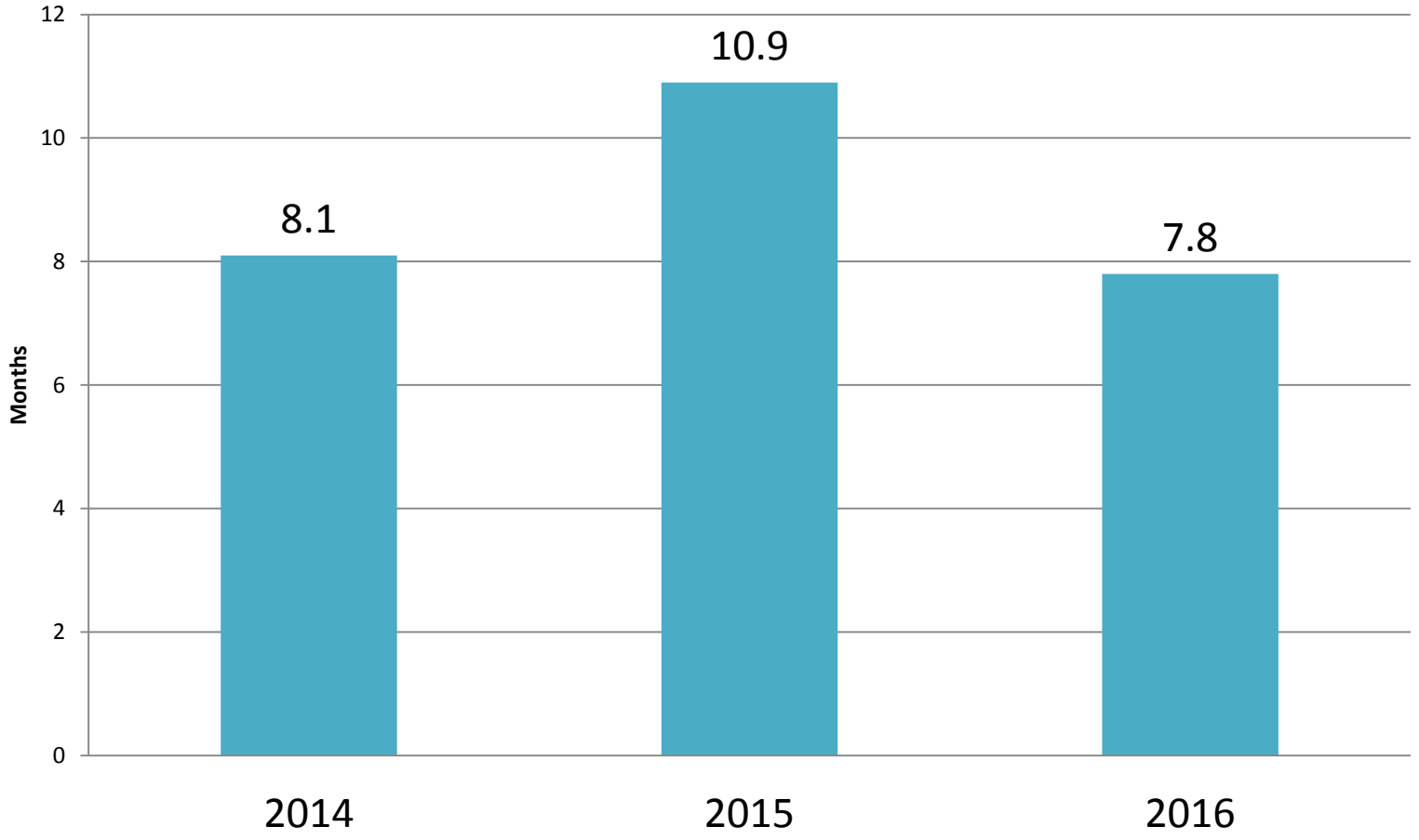
- FDA asks for more data
- Company expends development program
- Company/FDA follow drug safety

NDA/BLA Approval Data



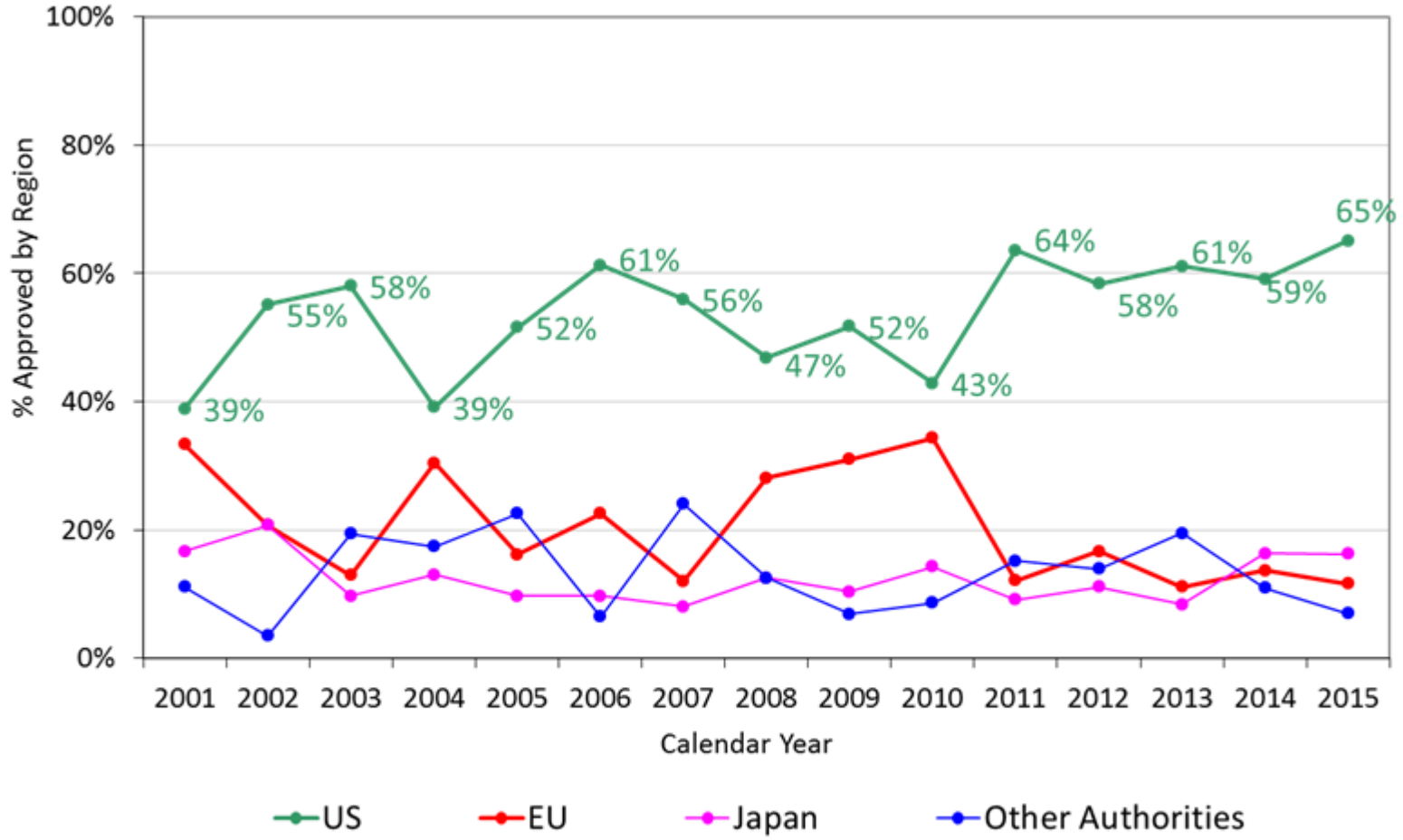
CDER approvals database

Overall Median Time to Approval



Global Drug Approvals

New Active Substances -First Launches by Region 2001 – 2015



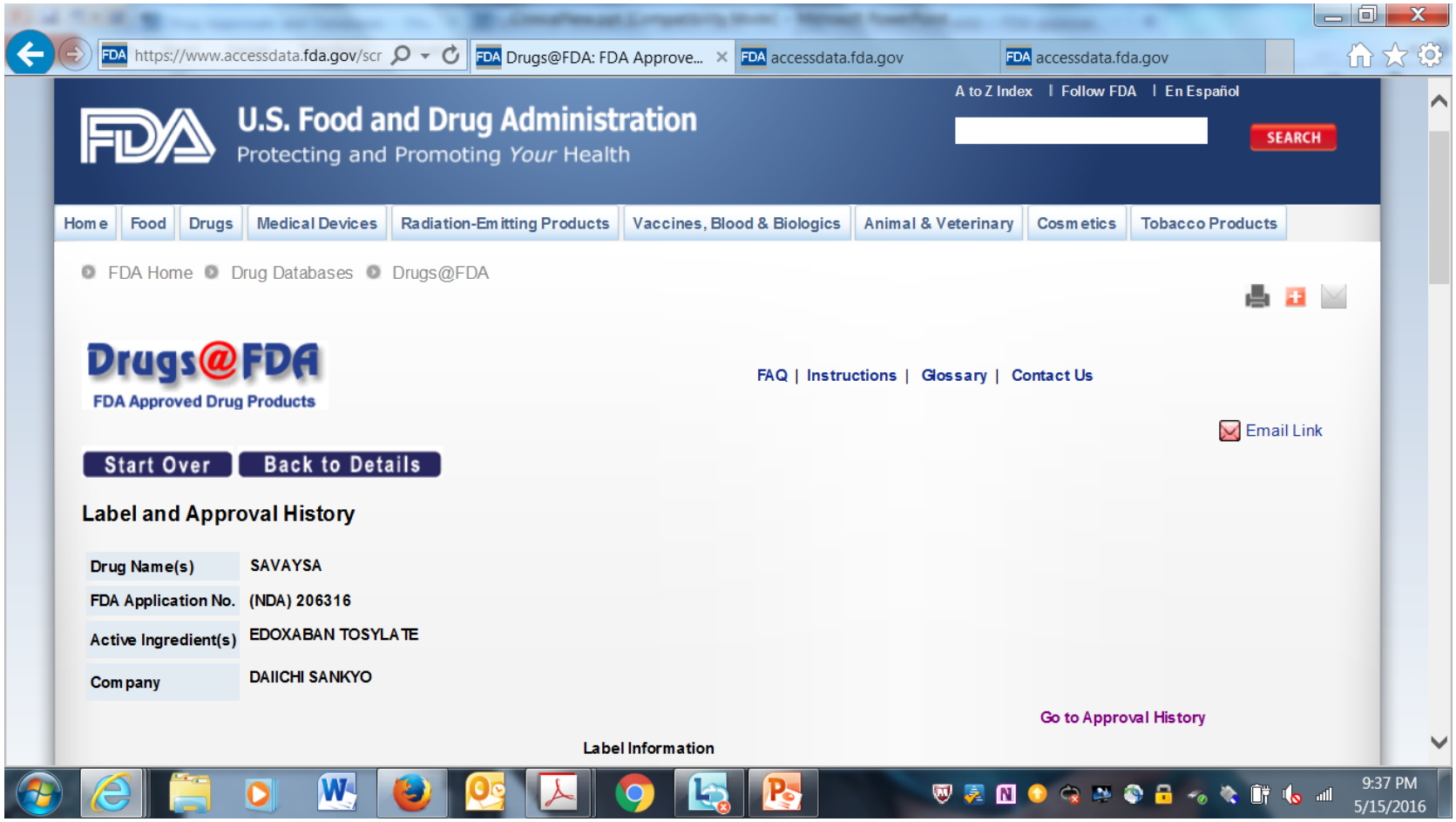
Source: *Scrip Magazine* (2001 - 2006), *Pharmaprojects/Citeline* **Pharma R&D Annual Review** (2007 - 2016)

NDA post-APPROVAL

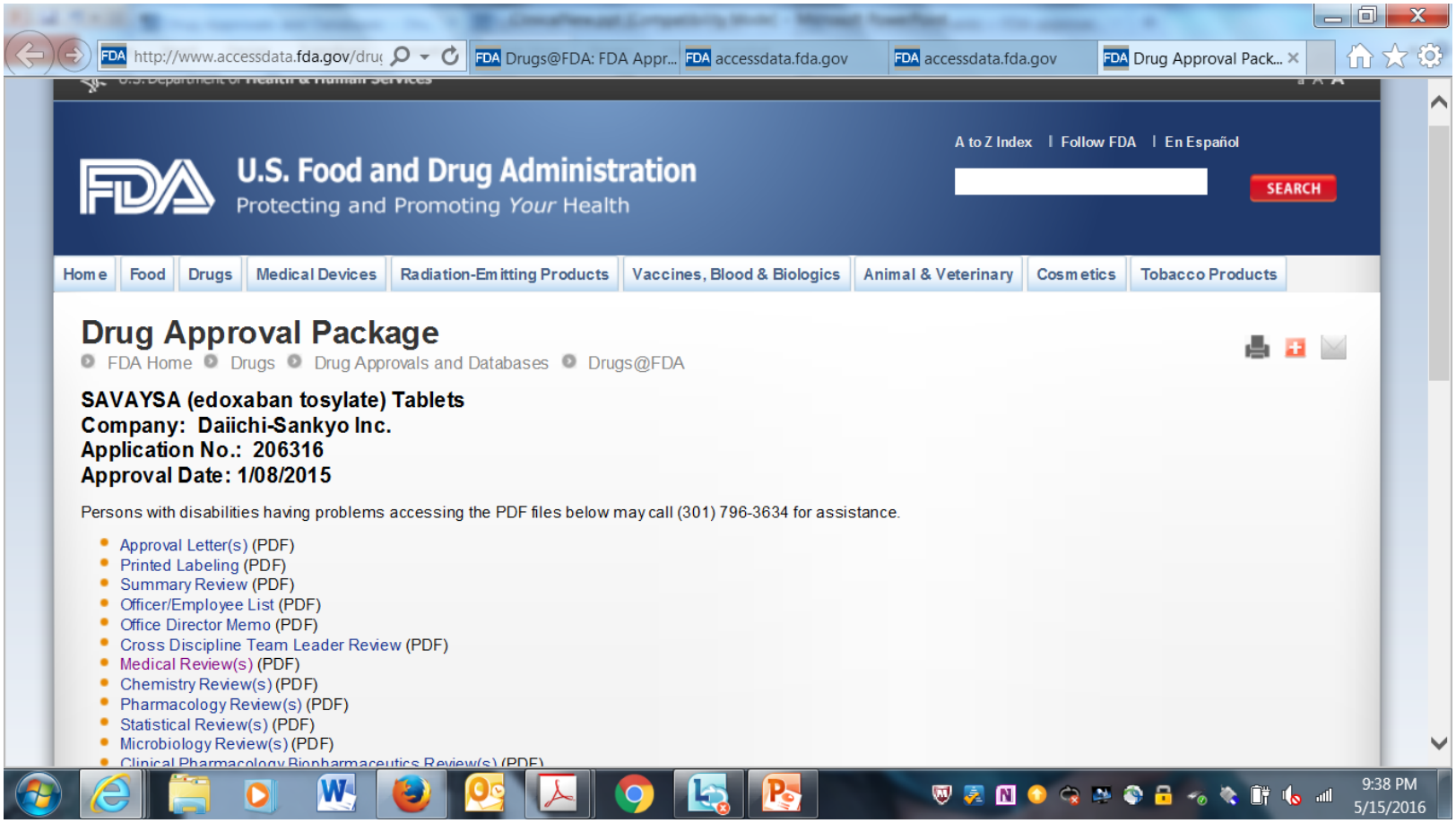
Public review information

- Press release
- FDA reviews and Prescribing Information (Drugs@FDA)
- Drug Trial Snapshots

Accessing FDA Reviews



Accessing FDA Reviews



Drug Trials Snapshots

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Sign Up for Email Updates about Drug Trials Snapshots

WHAT IS THE PURPOSE OF DRUG TRIALS SNAPSHOTS?

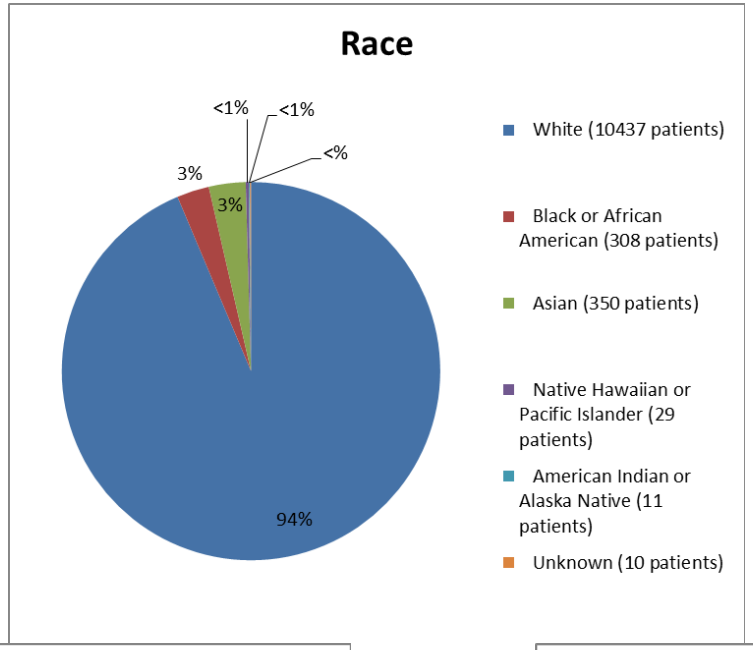
Drug Trials Snapshots provide consumers with information about who participated in clinical trials that supported the FDA approval of new drugs. The information provided in these Snapshots also highlights whether there were any differences in the benefits and side effects among sex, race and age groups.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

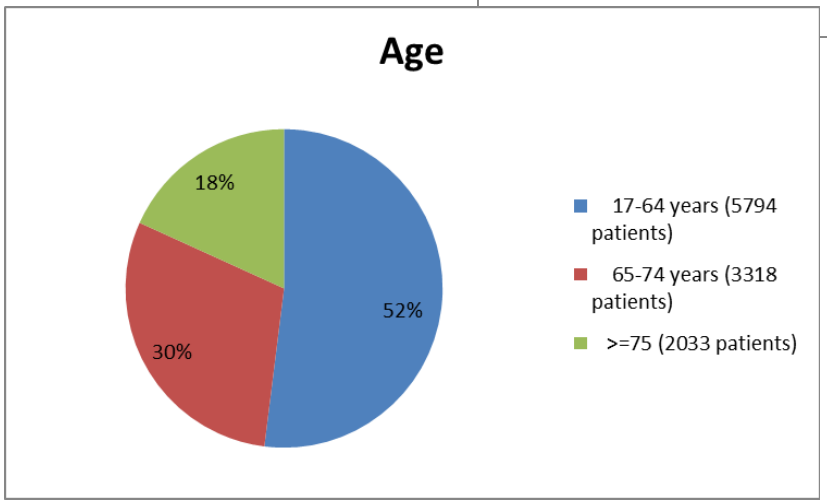
HOW TO USE SNAPSHOTS:

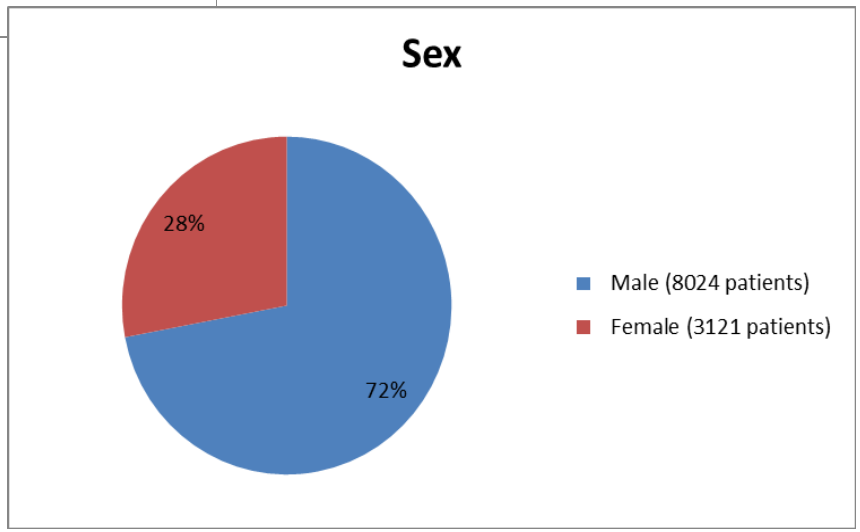
Each Snapshot contains information about the drug in a question and answer format. At the end of each section of the Snapshot, there is a shaded bar with the words "MORE INFO". Click the "MORE INFO" bar for more technical and detailed content. At the bottom of each Snapshot, there is a link to the drug's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

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
ADLYXIN	lixisenatide	July 27, 2016	Improvement of blood sugar control in adults with diabetes mellitus (DM) type 2 when used in addition to diet and exercise	Adlyxin
ALECENSA	alectinib	December 11, 2015	For the treatment of metastatic non-small cell lung cancer	Alecensa
ANTHIM	obiltoxaximab	March 18, 2016	For the treatment of inhalational anthrax	ANTHIM
ARISTADA	aripiprazole lauroxil	October 5, 2015	Treatment of schizophrenia	Aristada
AVYCAZ	ceftazidime-avibactam	February 25, 2015	Treatment of complicated intra-abdominal infection (abbreviated as cIAI)	Avycaz
AVYCAZ	ceftazidime-avibactam	February 25, 2015	Treatment of complicated urinary tract infection (abbreviated as cUTI)	Avycaz
AXUMIN	fluciclovine F 18	May 27, 2016	Detection of prostate cancer recurrence	Axumin
BRIDION	sugammadex	December 15, 2015	For the reversal of the effects of certain neuromuscular blocking agents	Bridion
BRIVIACT	brivaracetam	February 18, 2016	Treatment of partial-onset seizures	Briviact
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
CINQUAIR	reslizumab	March 23, 2016	For the treatment of a specific type of severe asthma (called eosinophilic phenotype asthma)	Cinquair
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	Cosentyx

Who Participated in the Clinical Trials?







Content of a Snapshot

- Information about who participated in the clinical trials

and

- Information about
  - trial design
  - overall drug efficacy and safety
  - differences in efficacy and safety among sex, race, and age subgroups

Public Info Comparison

	Reviews	PI	DTS
Complexity and length of the document	✓✓✓✓	✓✓✓	✓✓
Comprehensive drug information	✓✓✓✓	✓✓✓	✓✓
Rationale for approval	✓✓✓✓	✓✓	
Demographics in drug development program	✓✓✓✓	✓✓	
Demographics in pivotal trials/subgroups	✓✓✓✓	✓✓	✓✓✓
Reasons for specific subgroup representation	✓		
Consumer friendly information		✓	✓✓✓✓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