



U.S. Food and Drug Administration
Protecting and Promoting Public Health

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Substance Identifiers to Organize Scientific Data

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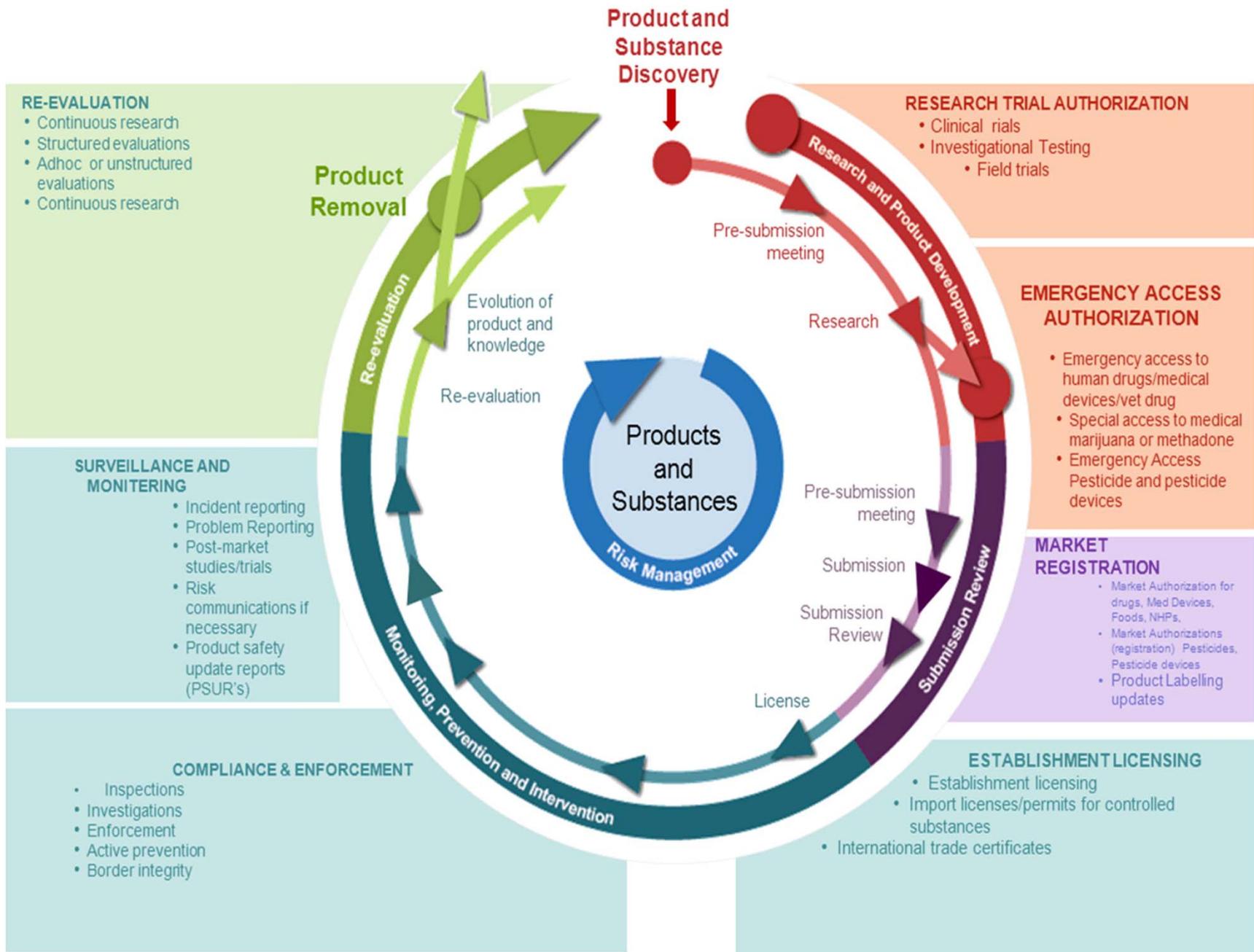
Disclaimer

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 or the Department of Health and Human Services.



Organizing Information

- FDA has the most important repository of biological, clinical and product data but limited integration.
- Decisions are based on available information
 - Information that is not organized is often not available
- Submission process
 - Paper
 - PDF's
- Organizational
 - Different Centers
 - Different Contractors
 - Business Processes
- Fielded data is much easier to organize than non-fielded data
- Fielded with controlled vocabulary is even better
- Codes are sometimes better than names





Scientific and Regulatory Information

- Not Mutually Exclusive
- Good Regulatory Practices are Scientifically Based
- Good Clinical Practice Should Be Scientifically Based
- Regulatory agencies do not regulate clinical practice
- Health is a very complex equation based on a number of interrelated factors and many of the factors are substances.
 - Individual Health = Genetics(+*/-)/pigenetics (+*/-) Environmental Exposures (Pathogens, Chemicals) (+*/-) Injuries (+*/-) Age (+*/-) Diet (+*/-) Drugs (+*/-) Culture(+*/-)Habits
- Tremendous advances against infectious diseases
- Recent Advances against Cancer
- Medicine particularly for aged is becoming very complex
- It may becoming too complex for physicians to manage
- Better Organized Information may eventually lead to Better Health
- Precision Medicine



Global Drug Regulatory Landscape

- Substandard and Adulterated Products
- Drug Use Increasing Globally
- Epidemic of Adverse Events
 - Drug Use is increasing
 - Polypharmacy (Over 1/3 of Americans over 65 years old take 5 or more medications)
- Chronic Diseases (HIV, Diabetes, IBD, Depression)
- US over 700,000 Emergency Room Visits, 100,000 hospitalizations due to drug adverse events
 - <http://psnet.ahrq.gov/primer.aspx?primerID=23>
- US over 100,000 deaths per year?
 - Vioxx, Oxycontin
- Europe over 197,000 deaths due to ADRs?
- General Belief 60-80% of Adverse Events are preventable



Global Drug Regulatory Landscape

- Panama Diethylene Glycol 2006-2007
 - Cough Syrup (Prepared by Government)
 - 365-600 deaths
 - Chinese Manufacturer (TD glycerine)
 - Spanish Manufacturer (Glycerine)
- Nigeria (2008-2009)
- Africa Substandard HIV and Malaria Medicines
- USP has a database

Path of Fake Avastin

The fake Avastin traveled through a series of overseas suppliers before reaching the Canada Drugs' network. Companies controlled by Canada Drugs procured the counterfeit cancer medicine, marketed it to U.S. doctors, and shipped it through a contractor in Tennessee, court records and business documents show. Doctors identified by the FDA as the network's customers were warned that they may have bought the fake Avastin.



- Corporate Headquarters
- Supplier
- Marketing
- Not in Canada Drugs' network
- In Canada Drugs' network

Number of medical practices warned by the FDA that they may have bought the fake Avastin



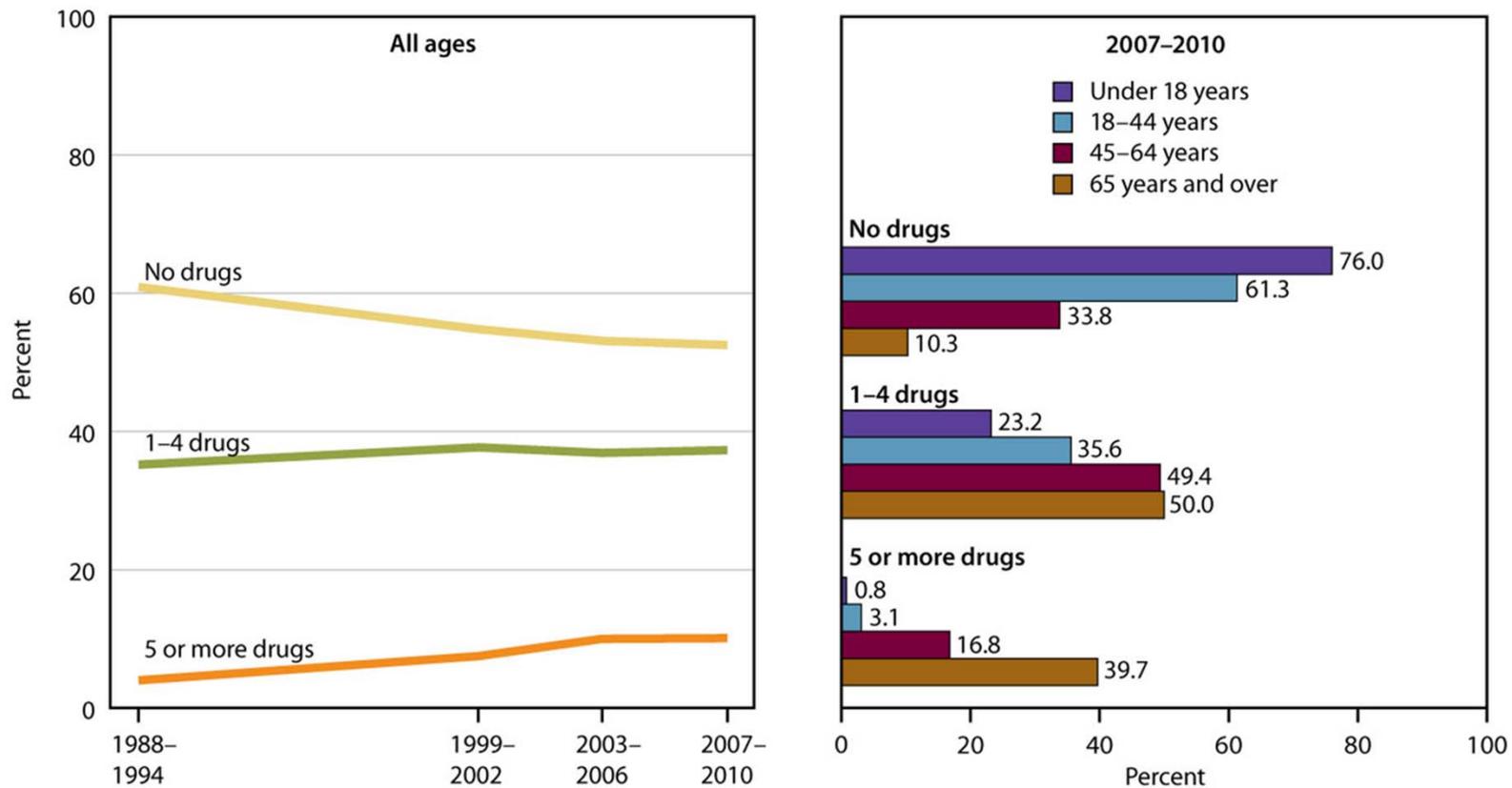
SOURCE: Weaver and Whalen, 2012.

Barbados

IOM Report: Countering the Problem of Falsified and Substandard Drugs. 2013
http://www.nap.edu/catalog.php?record_id=18272



Global Drug Regulatory Landscape



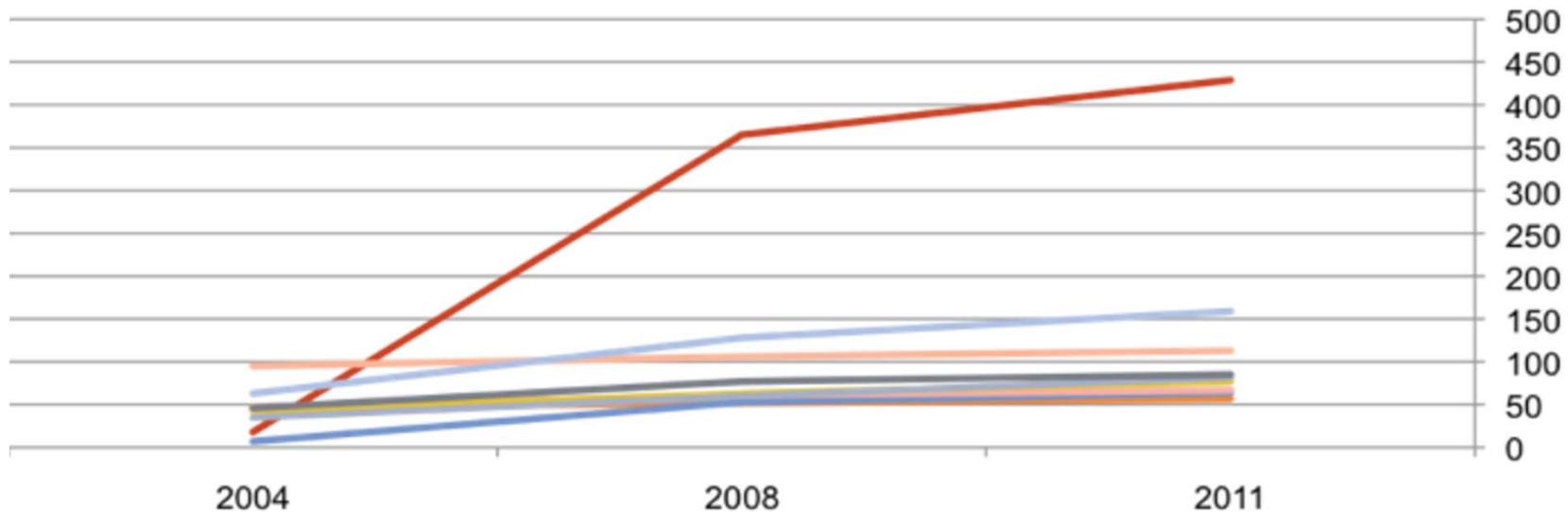
Prescription drug use in the US

NOTE: Use is in the past 30 days. Except for age group estimates, percentages are age-adjusted.
SOURCE: CDC/NCHS, Health, United States, 2013, Figure 20. Data from the National Health and Nutrition Examination Survey.



Global Drug Regulatory Landscape

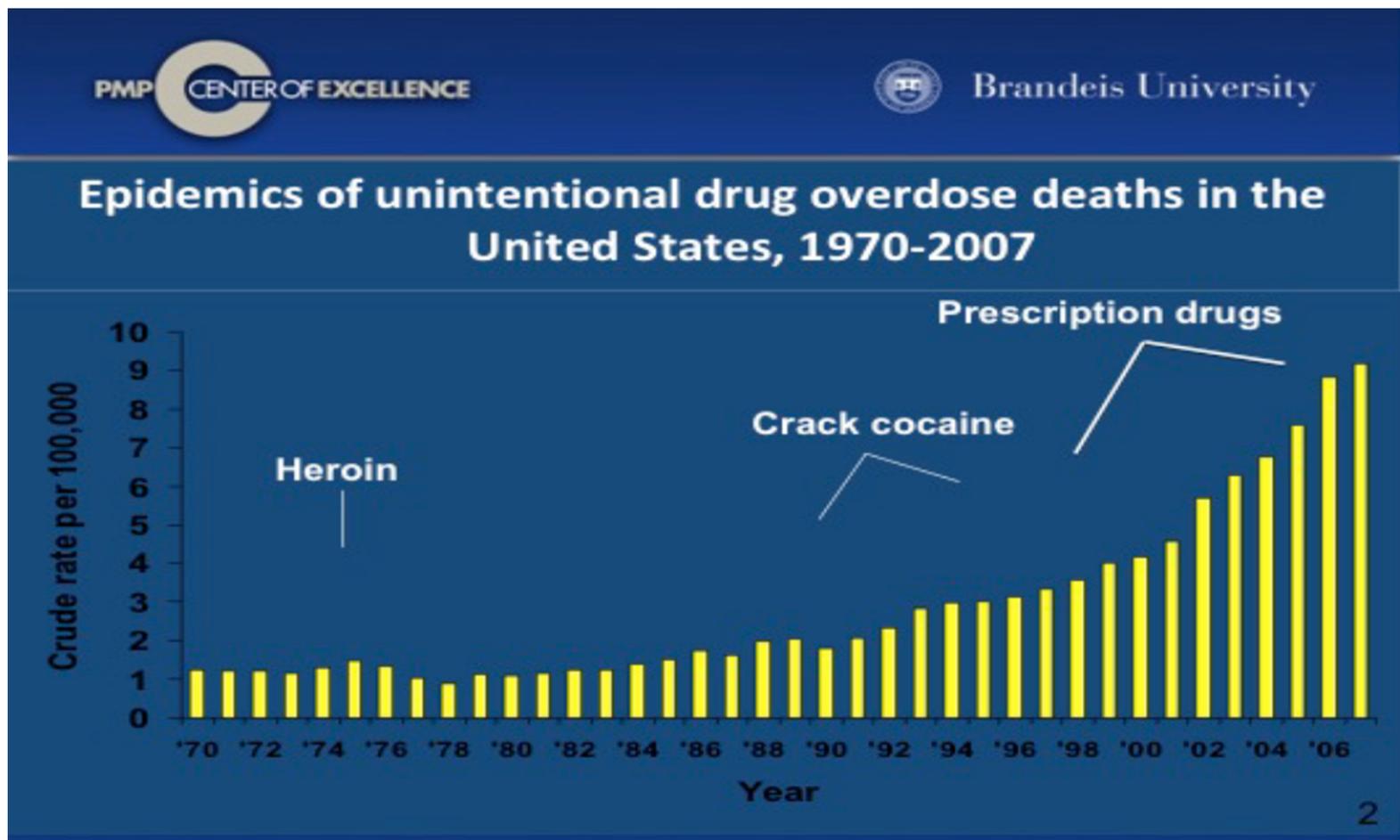
Number of adverse drug reactions reported to the MHRA



- Psychiatric disorders
- Reproductive & breast disorders
- Respiratory disorders
- Vascular disorders
- General disorders
- Pregnancy conditions
- Gastrointestinal disorders
- Skin disorders
- Nervous system disorders

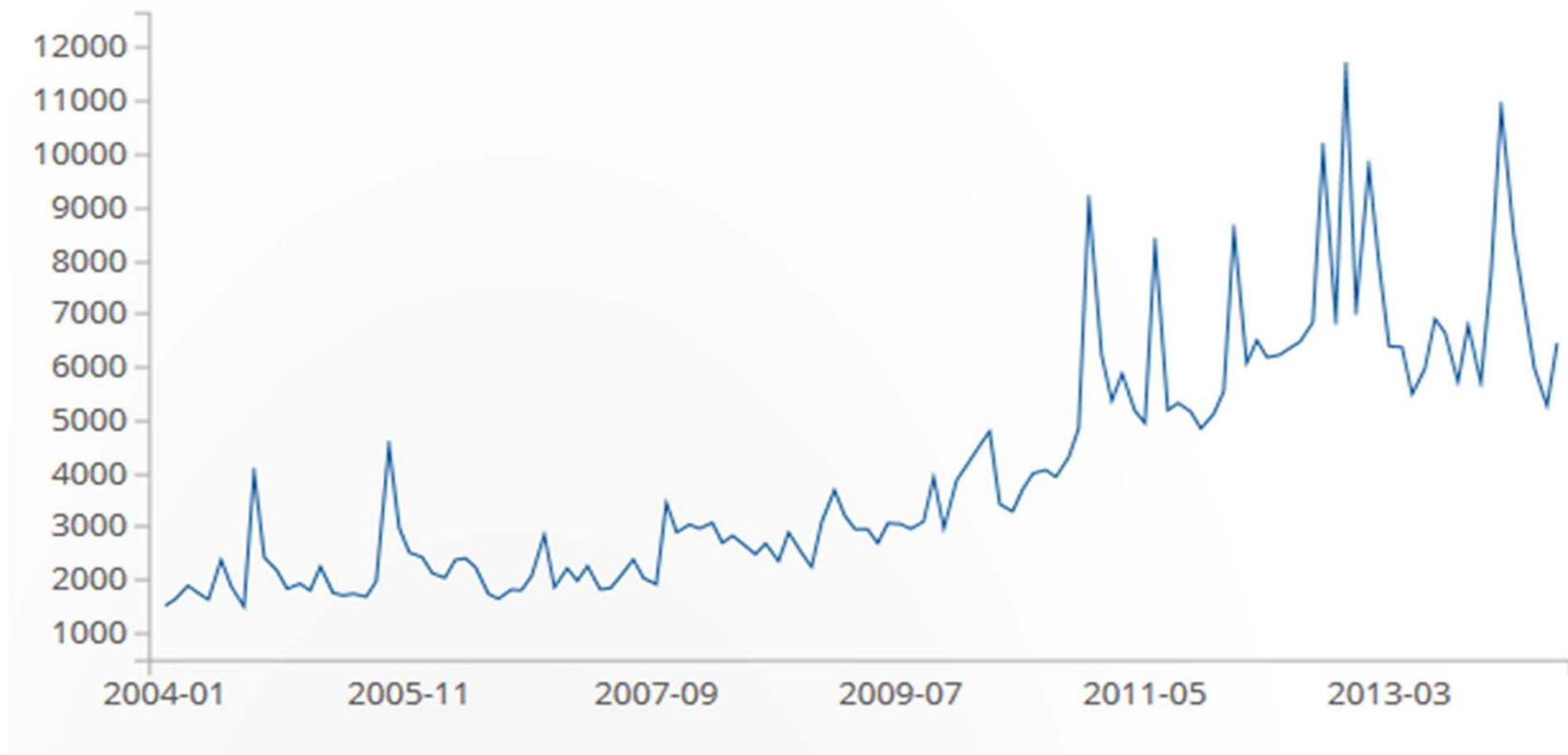


Global Drug Regulatory Landscape





Global Drug Regulatory Landscape



Deaths per month for all suspect drugs (openFDA)

[https://api.fda.gov/drug/event.json?search=receivedate:\[20040101+TO+20160101\]+AND+seriousnessdeath:1&count=receivedate](https://api.fda.gov/drug/event.json?search=receivedate:[20040101+TO+20160101]+AND+seriousnessdeath:1&count=receivedate)



Types of Data and Level

- Physical Data
 - Solubility (Specified Substance Group 1)
 - Distribution coefficient (Log D) (Substance Level)
 - Spectra
 - Mass Spectroscopy (Substance Level)
 - NMR Spectroscopy (Substance Level)
 - UV (Substance Level)
 - IR (Substance and/or Specified Substance Group1)
 - Near IR
 - Melting Point/Boiling Point (Specified Substance Group 1)
 - Flowability (Specified Substance Group 1)
 - Hardness (Specified Substance Group 1)
 - Compressibility (Specified Substance Group 1)
 - Hydration/Solvation (Substance Level)
 - Thermal Gravimetric Analysis (Substance and/or Specified Substance Group1)
 - Viscosity (Substance)



Types of Data and Level

- Toxicity Data (substance level; metabolites and impurities)
 - Acute Toxicity (LD50, LD5)
 - Chronic Toxicity
 - Genotoxicity (Ames; Cellular; Animal)
 - Developmental
 - NOAEL Level
 - Cellular
 - Animal Tox Workup (Substance Level)
- Pharmacology Data
 - Ladmer Data (Animal and Human: Product and substance level)
 - Liberation Test (Dissolution; Product)
 - Adsorption (Bioavailability; T_{max}, C_{max}, AUC, Product)
 - Distribution (V_d; Substance)
 - Metabolism (Substance)
 - Excretion (Substance)
 - Response (PD; Substance and/or product)
 - Metabolic Enzymes (Substance; substrate, inhibitor, inducer)
 - Transporter Proteins (Substance; substrate, inhibitor, inducer)
 - Target (Substance: substrate: agonist, antagonist, inhibitor, inducer)
 - Protein Binding (Substance;)
 - Off Target Interactions (Substance: substrate: agonist, antagonist, binding; inhibitor, inducer)



Types of Data and Level

- **Clinical Data**
 - Clinical Trial Data (Product)
 - Individual Patient Data
 - Summary Data
 - Safety Data (Substance and Product)
 - CDISC (STM)
 - Biomarkers
 - Special Populations
 - Outcomes

- **Product Quality Data**
 - Formulation (Substance and/or Group1 Specified Substance)
 - Impurities and degradents (substances)
 - Stability Data (product and substance)
 - Manufacturing Data (substance and product)
 - Lot data (Manufacturer, Lot Number)
 - Site Data
 - Process Data
 - Processing Material
 - Starting Materials
 - Inspection Data



SRS

- Impurities
- Metabolites
- Metabolic Enzymes
- Transporter



Substance Registration System / Ingredient Dictionary (SRSID)

CALLAHANIL
Administrator Privilege
Version 2.9.8

- Home
- Register Substance
- Register Mixture
- Register Application
- Register Product
- Search Substance
- Search Ingredient
- Lookup
- Help
- Logout

Welcome to the Substance Registration System / Ingredient Dictionary

SRSID integrates application, product and activity information available at FDA and from external reference sources for the substances present in regulated products.

- Register**
 - Substance and/or Ingredient
 - Mixture and/or Ingredient
- Register Application**
- Search Substances**
- Search Ingredients**
- Administration**
 - Manage Lookup Values
 - UNII Switch
- Administrator Help**

Substance | Product | Application | Clinical Trial | Adverse Event

Search for Substances

Exact Match | Substance Name | **Search**

[More Options](#)

Structure Search Mode:

- Substructure Search
- Similarity Search 80 %
- Exact Structure
- Flexmatch

[clear](#)

Search Substance Information on the FDA Substance Registration System (SRS)

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The session will expire in case of no activity on the SRSID website for more than 2 hours. Restart the session by opening a new browser window.

Substance Search Results for

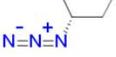
Records Found: 1

Substance ID:/ UNIT	Structure:	BDNUM:	Ingredient Name:	Application Count	Product Count	Clinical Trial Count	Adverse Event Case Count
View Details 8085 / 4B9XT59T7S View/Update		0148163AA	ZIDOVUDINE (SRS Preferred Term)	CDER Count:216 Application SRS Count:45 Total:261	Active:85 Inactive: 0	Total: 371	Total: 18077

Records Found: 1

Export Results: [Excel](#)

The session will expire in case of no activity on the SRSID website for more than 2 hours. Restart the session by opening a new browser window.



Molecular Weight: 267.24

Inchl: [\[+Expand\]](#)

CLASS:

ZIDOVUDINE
 - USP-MEDICINES COMPENDIUM
 - ZIDOVUDINE
 - ZIDOVUDINE

J05AR01
 - ATC
 - ANTIINFECTIVES FOR SYSTEMIC USE
 - ANTIVIRALS FOR SYSTEMIC USE
 - DIRECT ACTING ANTIVIRALS
 - Antivirals for treatment of HIV infections, combinations
 - zidovudine and lamivudine

J05AR04
 - ATC
 - ANTIINFECTIVES FOR SYSTEMIC USE
 - ANTIVIRALS FOR SYSTEMIC USE
 - DIRECT ACTING ANTIVIRALS
 - Antivirals for treatment of HIV infections, combinations
 - zidovudine, lamivudine and abacavir

J05AR05
 - ATC
 - ANTIINFECTIVES FOR SYSTEMIC USE
 - ANTIVIRALS FOR SYSTEMIC USE
 - DIRECT ACTING ANTIVIRALS
 - Antivirals for treatment of HIV infections, combinations
 - zidovudine, lamivudine and nevirapine

J05AF01
 - ATC
 - ANTIINFECTIVES FOR SYSTEMIC USE
 - ANTIVIRALS FOR SYSTEMIC USE
 - DIRECT ACTING ANTIVIRALS
 - Nucleoside and nucleotide reverse transcriptase inhibitors
 - zidovudine

N000009947
 - Cellular or Molecular Interactions [MoA]
 - Enzyme Interactions [MoA]

AZI	Synonym	CHEMID
BW-A-509U	Code	STN (SCIFINDER)
BW-A509U	Code	USP DICTIONARY
COMBIVIR COMPONENT ZIDOVUDINE	Synonym	DRUGS@FDA
COMPOUND S	Code	USP DICTIONARY
LAMIVUDINE/ZIDOVUDINE TEVA COMPONENT ZIDOVUDINE	Trade Name	EMA LIST
RETROVIR	Trade Name	USP DICTIONARY
THYMIDINE, 3'-AZIDO-3'-DEOXY-		USP DICTIONARY
TRIZIVIR COMPONENT ZIDOVUDINE	Trade Name	DAILYMED
ZIDOVUDINE COMPONENT OF COMBIVIR	Synonym	DRUGS@FDA
ZIDOVUDINE COMPONENT OF LAMIVUDINE/ZIDOVUDINE TEVA	Trade Name	EMA LIST
ZIDOVUDINE COMPONENT OF TRIZIVIR	Trade Name	DAILYMED
ZIDOVUDINE [EMA EPAR]	Synonym	EMA LIST
ZIDOVUDINE [EP]	Synonym	EUROPEAN PHARMACOPOEIA
ZIDOVUDINE [HSDB]	Synonym	NLM
ZIDOVUDINE [INN]	Synonym	INN
ZIDOVUDINE [JAN]	Synonym	KEGG
ZIDOVUDINE [MART.]	Synonym	MARTINDALE
ZIDOVUDINE [MI]	Synonym	MERCK INDEX
ZIDOVUDINE [ORANGE BOOK]	Synonym	ORANGE BOOK
ZIDOVUDINE [USAN]	Synonym	USP DICTIONARY
ZIDOVUDINE [USP-MC]	Synonym	USP-MC
ZIDOVUDINE [USP]	Synonym	USP/NF
ZIDOVUDINE [VANDF]	Synonym	NDF-RT
ZIDOVUDINE [WHO-DD]	Synonym	WHO DRUG DICTIONARY

[Hide Codes](#)

Code Type	Code	Data Source	Comments
BDNUM	0148163AA	SRSID	

View Reference Information - Windows Internet Explorer

http://srsid.fda.gov/9618/ePS/UpdateSubstance.do?mode=viewRefInfo&calledFrom=subResult&SUBSTANCE_ID=8085

transcriptase inhibitors
- zidovudine

N000009947
- Cellular or Molecular Interactions [MoA]
- Enzyme Interactions [MoA]
- Enzyme Inhibitors [MoA]
- Nucleic Acid Synthesis Inhibitors [MoA]
- Reverse Transcriptase Inhibitors [MoA]
- Nucleoside Reverse Transcriptase Inhibitors [MoA]

N0000175459
- Chemical Ingredients [Chemical/Ingredient]
- Carbohydrates [Chemical/Ingredient]
- Glycosides [Chemical/Ingredient]
- Nucleosides [Chemical/Ingredient]
- Nucleoside Analog [Chemical/Ingredient]
- Chemical Ingredients [Chemical/Ingredient]
- Chemical Classes for Pharmacologic Classification [Chemical/Ingredient]
- Analogs/Derivatives [Chemical/Ingredient]
- Nucleoside Analog [Chemical/Ingredient]
- Chemical Ingredients [Chemical/Ingredient]
- Nucleic Acids, Nucleotides, and Nucleosides [Chemical/Ingredient]
- Nucleosides [Chemical/Ingredient]
- Nucleoside Analog [Chemical/Ingredient]

N0000175462
- Established Pharmacologic Class [EPC]
- Human Immunodeficiency Virus Nucleoside Analog Reverse Transcriptase Inhibitor [EPC]

1047
- LiverTox
- Antimicrobial
- Antiviral: HIV
- Nucleoside analogue

QJ05AR01
- VATC
- ANTIVIRALS FOR SYSTEMIC USE
- DIRECT ACTING ANTIVIRALS
- Antivirals for treatment of HIV infections, combinations
- zidovudine and lamivudine

QJ05AR04
- VATC
- ANTIVIRALS FOR SYSTEMIC USE
- DIRECT ACTING ANTIVIRALS
- Antivirals for treatment of HIV infections, combinations
- zidovudine, lamivudine and abacavir

[Hide Codes](#)

Code Type	Code	Data Source	Comments
BDNUM	0148163AA	SRSID	
CAS	30516-87-1	ChemID	
EMA ASSESSMENT REPORTS	COMBIVIR (AUTHORIZED: HIV INFECTIONS)	EMA ASSESSMENT REPORTS	
EMA ASSESSMENT REPORTS	LAMIVUDINE/ZIDOVUDINE TEVA (AUTHORIZED: HIV INFECTIONS)	EMA ASSESSMENT REPORTS	
EVMPD	SUB00153MIG	EVMPD	
INN	6118	INN	
LIVERTOX	1047	LIVERTOX	
MESH UI	D015215	MESH	
NCI THESAURUS	C947	NCI THESAURUS	
NDF-RT	N000009947	NDF-RT	
NDF-RT	N0000175459	NDF-RT	
NDF-RT	N0000175462	NDF-RT	
SWISS MEDIC	15495	SWISS MEDIC	
USP-MC MONOGRAPH	ZIDOVUDINE	USP-MC MONOGRAPH	
WHO-ATC	J05AF01	WHO-ATC	
WHO-ATC	J05AR01	WHO-ATC	
WHO-ATC	J05AR04	WHO-ATC	
WHO-ATC	J05AR05	WHO-ATC	
WHO-ESSENTIAL MEDICINES LIST	6.4.2.1	WHO-ESSENTIAL MEDICINES LIST	
WHO-ESSENTIAL MEDICINES LIST	6.4.2.3 (LAM/NEV/ZID)	WHO-ESSENTIAL MEDICINES LIST	
WHO-ESSENTIAL MEDICINES LIST	6.4.2.3 (LAM/ZID)	WHO-ESSENTIAL MEDICINES LIST	
WHO-VATC	QJ05AF01	WHO-VATC	
WHO-VATC	QJ05AR01	WHO-VATC	
WHO-VATC	QJ05AR04	WHO-VATC	
WHO-VATC	QJ05AR05	WHO-VATC	
WIKIPEDIA	ABACAVIR/LAMIVUDINE/ZIDOVUDINE	WIKIPEDIA	
WIKIPEDIA	LAMIVUDINE/ZIDOVUDINE	WIKIPEDIA	

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100%

- ANTIVIRALS FOR SYSTEMIC USE
 - DIRECT ACTING ANTIVIRALS
 - Nucleoside and nucleotide reverse transcriptase inhibitors
 - zidovudine
- 6.4.2.1
 - WHO ESSENTIAL MEDICINES LIST
 - Anti-infective medicines
 - Antiviral medicines
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Showing 1 to 10 of 101 entries

Product NDC	Proprietary Name	Labeler Name	Ingredient Type	Strength Number
0054-0052 <small>View Details</small>	Zidovudine	Roxane Laboratories, Inc	Active Ingredient	.3(g)
0093-5385 <small>View Details</small>	Lamivudine and Zidovudine	Teva Pharmaceuticals USA Inc	Active Ingredient	.3(g)
0173-0107 <small>View Details</small>	RETROVIR	GlaxoSmithKline LLC	Active Ingredient	10(g)
0173-0108 <small>View Details</small>	RETROVIR	GlaxoSmithKline LLC	Active Ingredient	.1(g)
0173-0113 <small>View Details</small>	RETROVIR	GlaxoSmithKline LLC	Active Ingredient	10(g)
0173-0501 <small>View Details</small>	RETROVIR	GlaxoSmithKline LLC	Active Ingredient	.3(g)
0173-0595 <small>View Details</small>	COMBIVIR	GlaxoSmithKline LLC	Active Ingredient	.3(g)
0173-0691 <small>View Details</small>	TRIZIVIR	GlaxoSmithKline LLC	Active Ingredient	.3(g)
0378-5180 <small>View Details</small>	Lamivudine and Zidovudine	Mylan Pharmaceuticals Inc.	Active Ingredient	.3(g)
0378-6106 <small>View Details</small>	Zidovudine	Mylan Pharmaceuticals Inc.	Active Ingredient	.3(g)

Showing 1 to 10 of 101 entries

Export Results: [Excel](#)

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NCT Number	Bdnum	Title	Conditions	Sponsor
NCT00000625 <small>View Details</small>	0148163AA	A Randomized, Double-Blind Phase II/III Trial of Monotherapy vs. Combination Therapy With Nucleoside Analogs in HIV-Infected Persons With CD4 Cells of 200-500/mm ³	HIV Infections	National Institute of Allergy and Infectious Diseases (NIAID) Bristol-Myers Squibb Glaxo Wellcome
NCT00000628 <small>View Details</small>	0148163AA	A Pharmacokinetic Study of L-697,661 Alone and in Combination With Zidovudine	HIV Infections	National Institute of Allergy and Infectious Diseases (NIAID) Merck Sharp & Dohme Corp.
NCT00000629 <small>View Details</small>	0148163AA	The Effects of Valproic Acid on Zidovudine Glucuronidation and Pharmacokinetics in HIV-Infected Patients.	HIV Infections	National Institute of Allergy and Infectious Diseases (NIAID)
NCT00000637 <small>View Details</small>	0148163AA	A Randomized Comparative Trial of Zidovudine (AZT) Versus 2',3'-Dideoxyinosine (ddI) Versus AZT Plus ddI in Symptomatic HIV-Infected Children	HIV Infections	National Institute of Allergy and Infectious Diseases (NIAID) Bristol-Myers Squibb Glaxo Wellcome
NCT00000647 <small>View Details</small>	0148163AA	An Open Trial Combining Zidovudine, Interferon-alfa, and Recombinant CD4-IgG With Transplantation of Syngeneic Bone Marrow and Peripheral Blood Lymphocytes From Healthy gp160-Immunized Donors in the Treatment of Patients With HIV Infection	HIV Infections	National Institute of Allergy and Infectious Diseases (NIAID)
NCT00000649 <small>View Details</small>	0148163AA	An Open-Label, Staggered Rising Dose Cohort Study Assessing the Pharmacokinetics, Safety, and Tolerance of BI-RG-587 in Combination With Zidovudine in Patients With HIV Infection (CD4+ Cell Count < 400/mm ³)	HIV Infections	National Institute of Allergy and Infectious Diseases (NIAID) Boehringer Ingelheim Pharmaceuticals
NCT00000651 <small>View Details</small>	0148163AA	A Randomized, Double Blind, Comparative Study of Dideoxycytidine (ddC) Alone or ddC/AZT Combination Versus Zidovudine (ZDV) Alone in Patients With HIV Infection Who Have Received Prior ZDV Therapy	HIV Infections	National Institute of Allergy and Infectious Diseases (NIAID) Hoffmann-La Roche Glaxo Wellcome
NCT00000652 <small>View Details</small>	0148163AA	A Phase I Study to Evaluate the Safety and Toxicity of the Combination of Zidovudine and 2',3'-Dideoxyinosine (Didanosine) in Children With HIV Infection	HIV Infections	National Institute of Allergy and Infectious Diseases (NIAID) National Cancer Institute (NCI)
NCT00000656 <small>View Details</small>	0148163AA	A Phase I/II, Open Label Study to Evaluate the Antiviral Potential of Combining Zidovudine and Zalcitabine	HIV Infections	National Institute of Allergy and Infectious Diseases (NIAID)

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Showing 1 to 10 of 16 entries

Substance Name	Related Substance Name	Related UNII	Related Structure	Public Domain	Relationship Type
ZIDOVUDINE View Details	ZIDOVUDINE	4B9XT59T7S	Show Structure	N	ACTIVE MOIETY
ZIDOVUDINE View Details	STAVUDINE	BO9LE4QFZF	Show Structure	Y	IMPURITY - PARENT
ZIDOVUDINE View Details	3'-(3-(3-AZIDO-2,3-DIDEOXY- BETA-D-ERYTHRO- PENTOFURANOSYL))-3,6- DIHYDRO-5-METHYL-2,6- DIOXO-1(2H)-PYRIMIDINYL)-3'- DEOXYTHYMIDINE	WF6985DLTU	Show Structure	N	IMPURITY - PARENT
ZIDOVUDINE View Details	ZIDOVUDINE DIPHOSPHATE	K7ZG448VSM	Show Structure	Y	METABOLITE ACTIVE - PARENT
ZIDOVUDINE View Details	THYMIDINE, 3'-CHLORO-3'- DEOXY-	8GQZ0LXHOC	Show Structure	Y	IMPURITY - PARENT
ZIDOVUDINE View Details	3'-AMINO-3'-DEOXYTHYMIDINE	7W21M0C25B	Show Structure	Y	METABOLITE TOXIC - PARENT
ZIDOVUDINE View Details	ZIDOVUDINE GLUCURONIDE	CD09F5JM6T	Show Structure	Y	METABOLITE INACTIVE - PARENT
ZIDOVUDINE View Details	ZIDOVUDINE TRIPHOSPHATE	6RGF96R053	Show Structure	N	METABOLITE ACTIVE - PRODRUG
ZIDOVUDINE View Details	ZIDOVUDINE	4B9XT59T7S	Show Structure	Y	BASIS OF STRENGTH
ZIDOVUDINE View Details	UNSPECIFIED IMPURITY		Show Structure	Y	IMPURITY - PARENT

Showing 1 to 10 of 16 entries

Export Results: [Excel](#)

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- VATIC
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 - DIRECT ACTING ANTIVIRALS
 - Antivirals for treatment of HIV infections, combinations
 - zidovudine, lamivudine and nevirapine
- QJ05AF01
 - VATIC
 - ANTIVIRALS FOR SYSTEMIC USE
 - DIRECT ACTING ANTIVIRALS
 - Nucleoside and nucleotide reverse transcriptase inhibitors
 - zidovudine
- 6.4.2.1
 - WHO ESSENTIAL MEDICINES LIST
 - Anti-infective medicines
 - Antiviral medicines
 - Antiretrovirals
 - Nucleoside/Nucleotide reverse transcriptase inhibitors
- 6.4.2.3 (LAM/NEV/ZID)
 - WHO ESSENTIAL MEDICINES LIST
 - Anti-infective medicines
 - Antiviral medicines
 - Antiretrovirals
 - Protease inhibitors
- 6.4.2.3 (LAM/ZID)
 - WHO ESSENTIAL MEDICINES LIST
 - Anti-infective medicines
 - Antiviral medicines
 - Antiretrovirals
 - Protease inhibitors
- COMBIVIR (AUTHORIZED: HIV INFECTIONS)
 - EMA EPAR
 - DISEASES
 - MALE DISEASES OF THE URINARY AND REPRODUCTIVE SYSTEMS
 - GENITAL DISEASES, MALE
 - SEXUALLY TRANSMITTED DISEASES
 - SEXUALLY TRANSMITTED DISEASES, VIRAL
 - HIV INFECTIONS
- LAMIVUDINE/ZIDOVUDINE TEVA (AUTHORIZED: HIV INFECTIONS)
 - EMA EPAR
 - DISEASES
 - MALE DISEASES OF THE URINARY AND REPRODUCTIVE SYSTEMS
 - GENITAL DISEASES, MALE
 - SEXUALLY TRANSMITTED DISEASES
 - SEXUALLY TRANSMITTED DISEASES, VIRAL

Pubchem CID [35370](#) Pubchem

Product Application Clinical Trial Relationship **Adverse Event**

Adverse PT Adverse DME Adverse CVM

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Showing 1 to 10 of 4,187 entries

Substance Name	PT Term	Prim SOC	Case Count	PT Count	PT Count Percent	SOC Count	SOC Count Percent	In React Labels	In Boxed Warnings	Total React Labels
ZIDOVUDINE	MATERNAL EXPOSURE DURING PREGNANCY	INJURY, POISONING AND PROCEDURAL COMPLICATIONS	18077	2288	12.66	5661	31.32	0	0	53
ZIDOVUDINE	MATERNAL DRUGS AFFECTING FOETUS	INJURY, POISONING AND PROCEDURAL COMPLICATIONS	18077	2087	11.55	5661	31.32	0	0	53
ZIDOVUDINE	ANAEMIA	BLOOD AND LYMPHATIC SYSTEM DISORDERS	18077	1697	9.39	4242	23.47	53	53	53
ZIDOVUDINE	PYREXIA	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	18077	1305	7.22	4705	26.03	51	51	53
ZIDOVUDINE	VOMITING	GASTROINTESTINAL DISORDERS	18077	910	5.03	3378	18.69	51	51	53
ZIDOVUDINE	PREMATURE BABY	PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS	18077	849	4.7	3729	20.63	0	0	53
ZIDOVUDINE	CAESAREAN SECTION	SURGICAL AND MEDICAL PROCEDURES	18077	827	4.57	1207	6.68	0	0	53
ZIDOVUDINE	NAUSEA	GASTROINTESTINAL DISORDERS	18077	747	4.13	3378	18.69	52	52	53
ZIDOVUDINE	DIARRHOEA	GASTROINTESTINAL DISORDERS	18077	677	3.75	3378	18.69	52	52	53
ZIDOVUDINE	NEUTROPENIA	BLOOD AND LYMPHATIC SYSTEM	18077	642	3.55	4242	23.47	53	53	53

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HUMAN CYTOCHROME P450 3A4 View Details	IMATINIB	BKJ8M8G5HI	Show Structure	N	INHIBITOR - METABOLIC ENZYME
HUMAN CYTOCHROME P450 3A4 View Details	BEDAQUILINE	788461289Y	Show Structure	N	SUBSTRATE - METABOLIC ENZYME
HUMAN CYTOCHROME P450 3A4 View Details	WARFARIN, (R)-	09CC5J5C8A	Show Structure	N	SUBSTRATE - METABOLIC ENZYME
HUMAN CYTOCHROME P450 3A4 View Details	PALBOCICLIB	G9ZF61LE7G	Show Structure	N	SUBSTRATE - METABOLIC ENZYME
HUMAN CYTOCHROME P450 3A4 View Details	CARBAMAZEPINE	33CM23913M	Show Structure	N	SUBSTRATE - METABOLIC ENZYME
HUMAN CYTOCHROME P450 3A4 View Details	OMEPRAZOLE	KG60484QX9	Show Structure	N	SUBSTRATE - METABOLIC ENZYME
HUMAN CYTOCHROME P450 3A4 View Details	NARINGIN	N7TD9J649B	Show Structure	N	INHIBITOR - TARGET
HUMAN CYTOCHROME P450 3A4 View Details	FLUTICASON PROPIONATE	O2GMZ0LF5W	Show Structure	N	SUBSTRATE - METABOLIC ENZYME
HUMAN CYTOCHROME P450 3A4 View Details	TRAZODONE	YBK48BXK30	Show Structure	N	SUBSTRATE - METABOLIC ENZYME
HUMAN CYTOCHROME P450 3A4 View Details	DACOMITINIB ANHYDROUS	2XJX250C20	Show Structure	N	SUBSTRATE - METABOLIC ENZYME

Showing 1 to 10 of 15 entries

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Export Results: [Excel](#)

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CLASS:
 SLC22A7
 - UCSF-FDA TRANSPORTAL
 - DRUG TRANSPORTER

MGC24091	Synonym	WEB PAGE
MGC45202	Synonym	WEB PAGE
NLT	Synonym	UNIPROT
NOVEL LIVER TRANSPORTER	Synonym	UNIPROT
OAT2	Synonym	UNIPROT
ORGANIC ANION TRANSPORTER 2	Synonym	UNIPROT
SLC22A7	Synonym	UNIPROT

[Hide Codes](#)

Code Type	Code	Data Source	Comments
BDNUM	1031169AA	SRSID	
UCSF-FDA TRANSPORTAL	SLC22A7	UCSF-FDA TRANSPORTAL	

Product Application Clinical Trial **Relationship** Adverse Event

Show 10 First Previous **1** 2 3 Next Last

Showing 1 to 10 of 23 entries

Substance Name	Related Substance Name	Related UNII	Related Structure	Public Domain	Relationship Type
OAT-2 View Details	CEFAMANDOLE	5CKP8C2LLI	Show Structure	Y	INHIBITOR - TRANSPORTER
OAT-2 View Details	TRICHLORMETHIAZIDE	Q58C92TUN0	Show Structure	Y	INHIBITOR - TRANSPORTER
OAT-2 View Details	CEFOTAXIME	N2GI8B1GK7	Show Structure	Y	INHIBITOR - TRANSPORTER
OAT-2 View Details	SULINDAC	184SNS8VUH	Show Structure	Y	INHIBITOR - TRANSPORTER
OAT-2 View Details	CEFOPERAZONE	7U75I1278D	Show Structure	Y	INHIBITOR - TRANSPORTER
OAT-2 View Details	CEPHALOTHIN	R72LW146E6	Show Structure	Y	INHIBITOR - TRANSPORTER
OAT-2					