



Overview of the Identification of Medicinal Products (IDMP) Standards

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Outline of Talk

- Need for IDMP
- History of the IDMP
- Elements of the IDMP



Decision Making and Information

- Life is uncertain with limited predictability (The Black Swan)
- Definite information favored over indefinite information (Ellsberg Principle)
- Rational decisions usually lead to better outcomes than irrational decisions
- Most decisions are based on imperfect information (knowledge constrains; time constraints)
- Better information will often lead to better decision making
 - Rational ignorance (cost of gathering information perceived to be too great for benefit)
- Organized and integrated information is usually better information



Organizing Information

- FDA has the most important repository of human biological and product data but limited integration.
 - Submission process
 - Paper
 - PDF's
 - Organizational
 - Different Centers
 - Different Contractors
 - Institutional and Business Processes
- Costly Duplication of Systems and Effort
 - Companies and the Agency



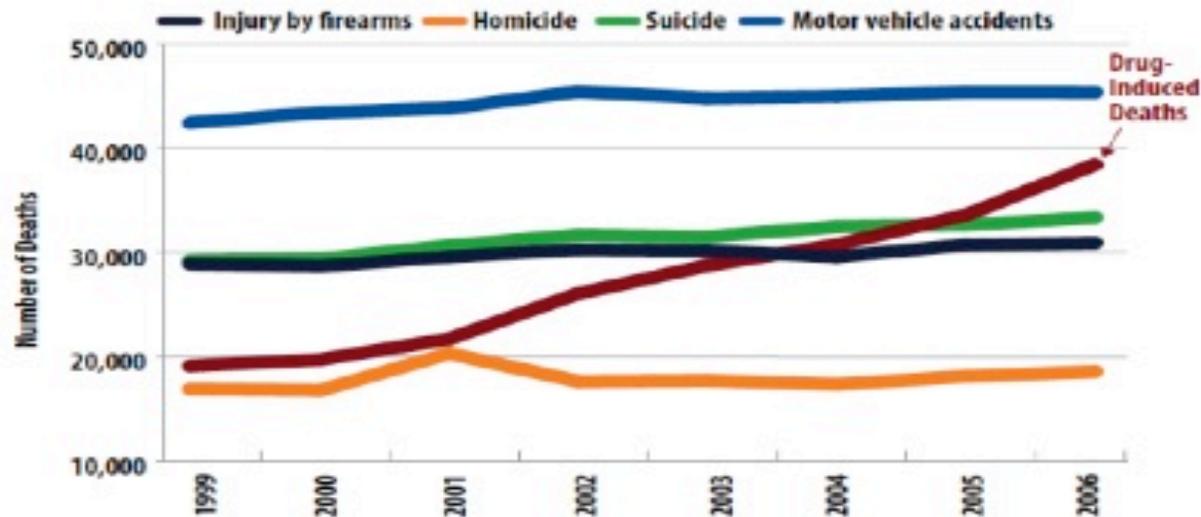
IDMP Background

- **Incidence of Adverse Drug Reactions in Hospitalized Patients: A Meta-analysis of Prospective Studies, Lazarou, et al *JAMA*. 1998;279(15):1200-1205.**
 - Stated over 100000 deaths of hospitalized patients were due to adverse drug reactions.
- **To Err Is Human: Building a Safer Health System, Institute of Medicine 1999 IOM**
 - Stated that there were 44000 to 98000 preventable deaths due to medical in the hospital
- **To Err is Human – To Delay is Deadly 2009 Consumers Union <http://safepatientproject.org/safepatientproject.org/pdf/safepatientproject.org-ToDelaysIsDeadly.pdf>**
 - Ten years later, a million lives lost, billions of dollars wasted



Rise in Drug-Induced Deaths, 1999-2006

Figure 11. Drug-Induced Deaths Have Almost Doubled in the Last Decade

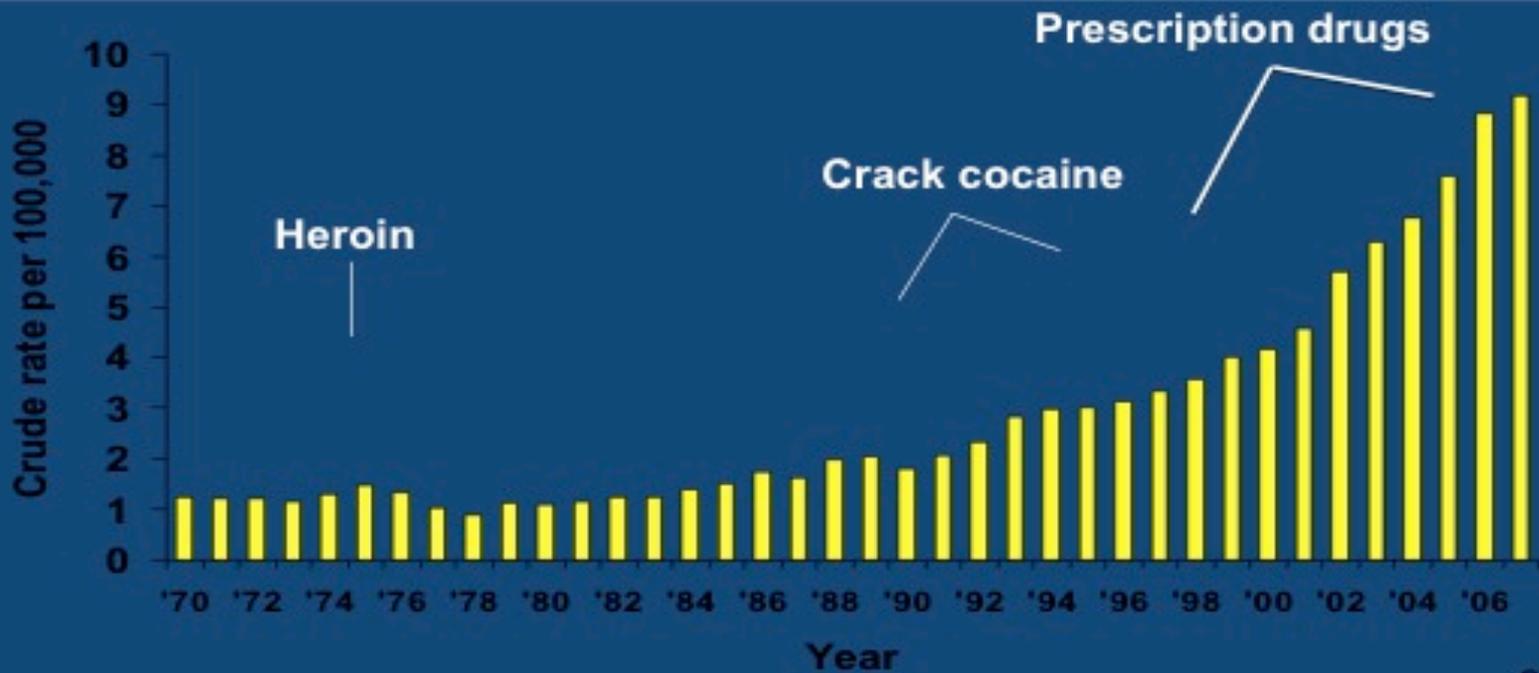


Causes of death attributable to drugs include accidental or intentional poisonings by drugs, drug psychoses, drug dependence, and nondependent use of drugs. Drug-induced causes exclude accidents, homicides, and other causes indirectly related to drug use. Not all cause categories are mutually exclusive.

Source: National Center for Health Statistics/CDC, *National Vital Statistics Report, Deaths: Final Data for 2006* (April 2009).



Epidemics of unintentional drug overdose deaths in the United States, 1970-2007





IDMP Background

- Reformulated Oxycodone Product Appears To Reduce Abuse and Misuse
 - American Pain Society Meeting 2012
- Heparin package changes (Dennis Quaid)





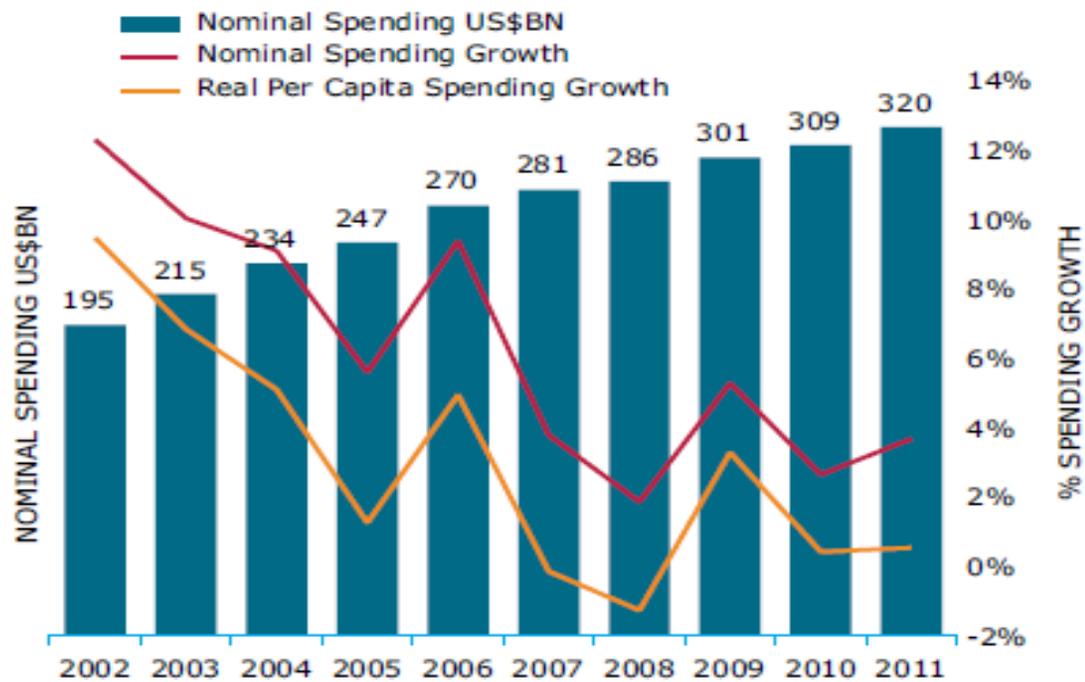
Top Therapeutic Classes by Prescriptions

DISPENSED PRESCRIPTIONS MN	2007	2008	2009	2010	2011
Total US Market	3,825	3,866	3,949	3,993	4,024
1 Antidepressants	237	241	247	254	264
2 Lipid Regulators	233	242	254	260	260
3 Narcotic Analgesics	231	239	241	244	238
4 Antidiabetics	165	166	169	172	173
5 Ace Inhibitors (Plain & Combo)	159	163	166	168	164
6 Beta Blockers (Plain & Combo)	162	164	163	162	161
7 Respiratory Agents	147	147	152	153	153
8 Anti-Ulcerants	134	139	146	147	150
9 Diuretics	137	135	132	131	128
10 Anti-Epileptics	102	110	116	122	128
11 Tranquillizers	98	101	104	108	111
12 Thyroid Preparations	103	104	105	107	110
13 Calcium Antagonists (Plain & Combo)	87	90	93	96	98
14 Antirheumatic Non-Steroid	90	91	92	93	97
15 Hormonal Contraceptives	94	94	93	91	90
16 Angiotensin II Inhibitors	83	86	85	84	86
17 Broad Spectrum Penicillins	77	74	77	76	77
18 Macrolides & Similar Type Antibiotics	63	66	69	67	69
19 Hypnotics & Sedatives	58	60	63	63	63
20 Vitamins & Minerals	60	59	58	58	60

IMS Health, National Prescription Audit, Dec 2011



Spending & Growth 2002-2011



Source: IMS Health, National Sales Perspectives, Dec 2011



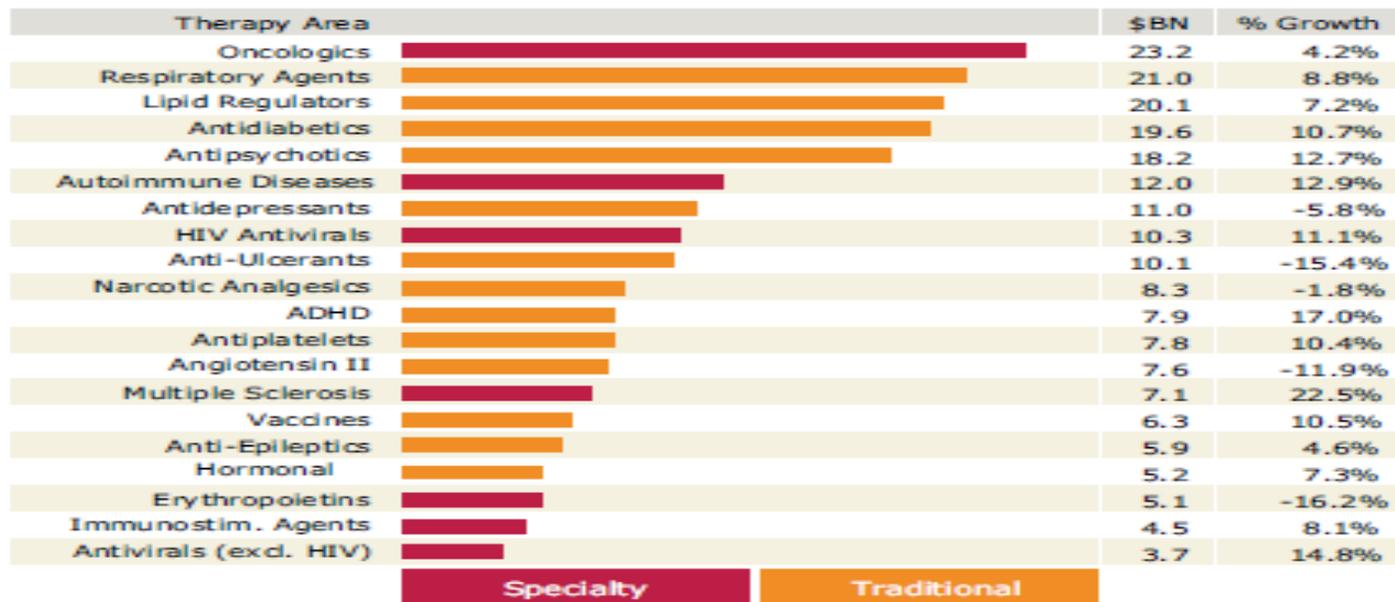
Normalized Prescriptions & Change

Patient Age	% Change	Normalized TRx Per 1,000 Population
80+	-3.4%	36,715
70-79	-1.8%	28,755
65-69	-4.3%	20,830
60-64	-1.9%	22,212
50-59	-0.3%	19,791
26-49	-1.8%	8,246
19-25	2.0%	4,165
0-18	-0.8%	3,407
Total	-1.1%	11,331

Source: IMS Health, Vector One: National (VONA), Dec 2011; U.S. Census Bureau



Spending in Leading Therapy Areas

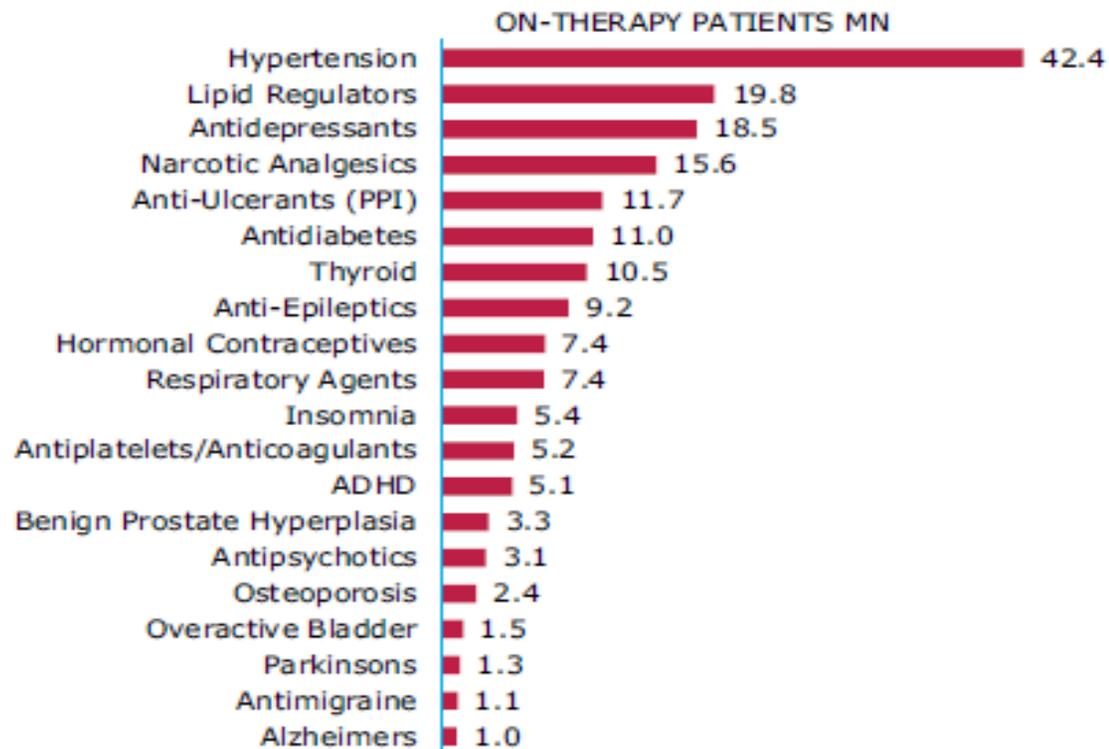


Source: IMS Health, National Sales Perspectives, Dec 2011

erythropoietin spending falling from \$6.1Bn to \$5.1Bn, in 2011, due to volume declines.



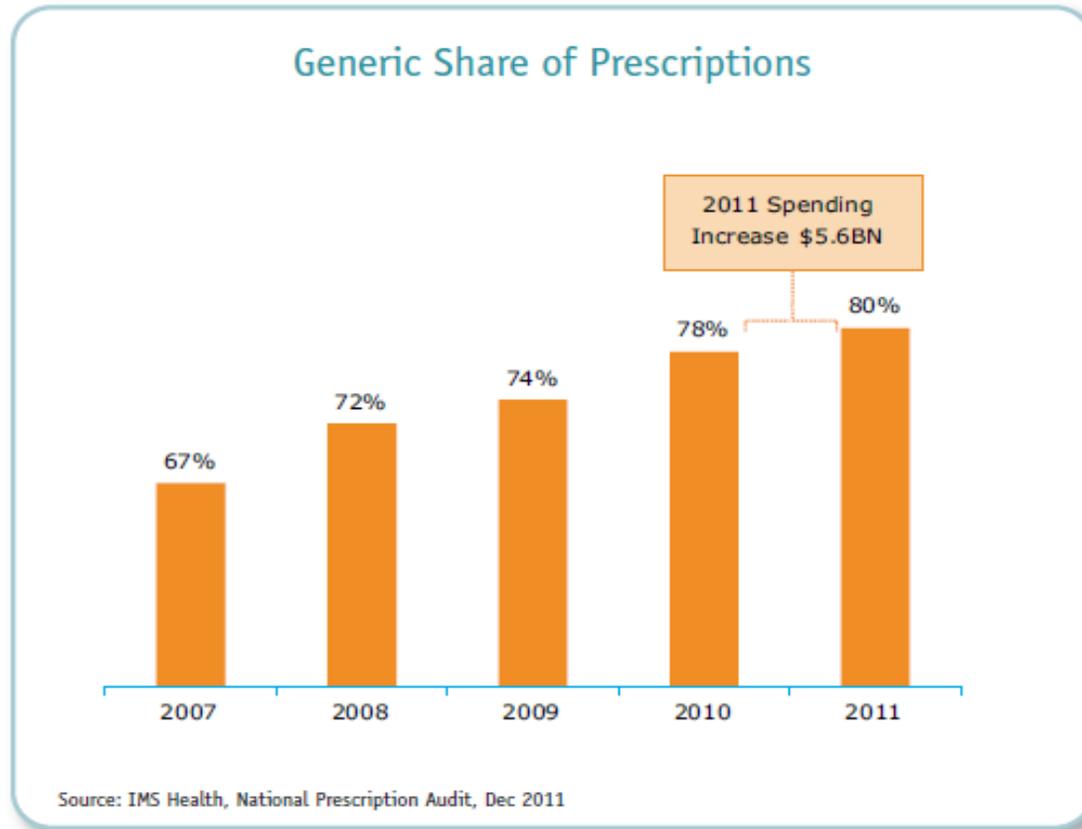
Treated Patients in Selected Therapies



Source: IMS Health, LifeLink, Dec 2011



80% Percent of Prescriptions are Generic



Generics now make up 27% of total spending.



DIRECT HEALTHCARE PROFESSIONAL COMMUNICATIONS IN EUROPE

January 2013

[Xagrid](#) - Increased risk of cardiovascular adverse events when using Xagrid (25 January 2013)

[Tredaptive](#) - Treatment with Tredaptive should be discontinued (23 January 2013)

[Gilenya](#) - Altered recommendations Gilenya (22 January 2013)

[Angiox](#) - Dosing regimens for Angiox need to be followed carefully (15 January 2013)

[Tredaptive](#) - Re-evaluation of efficacy and risks of Tredaptive (10 January 2013)

[Pradaxa](#) - New contraindication for Pradaxa (4 January 2013)



History of IDMP Project

- Initially an ICH project under the ICH M5 group (2003)
- Five official ISO standards (2012)
- HL-7 Messaging Model under development in ICH
- Consistent with the HL-7 common product model
- IDMP Complete Implementation by 2016



Need for IDMP

- Regulatory Needs
 - Pharmacovigilance and Pharmacoepidemiology
 - Safety
 - Polypharmacy (Patient over 75 years take on average of 11 medications)
 - Medication Errors
 - Drug-Drug interactions
 - Personalized Medicine
 - Drug-Food Interactions
 - Quality
 - Global Supply Chain
 - Drug Shortages



Need for IDMP

- Clinical and Research Needs
 - Track Substances from Bench to Bedside
 - Company Codes Change over the Course of Development
 - Difficult to Find All Clinical Trials on a Given Substance
 - Mine EHR to Improve Drug Utilization
 - Mine Data to Provide New Uses For Drugs
 - Tie Drugs to Targets and Genotype



Goals of IDMP Project

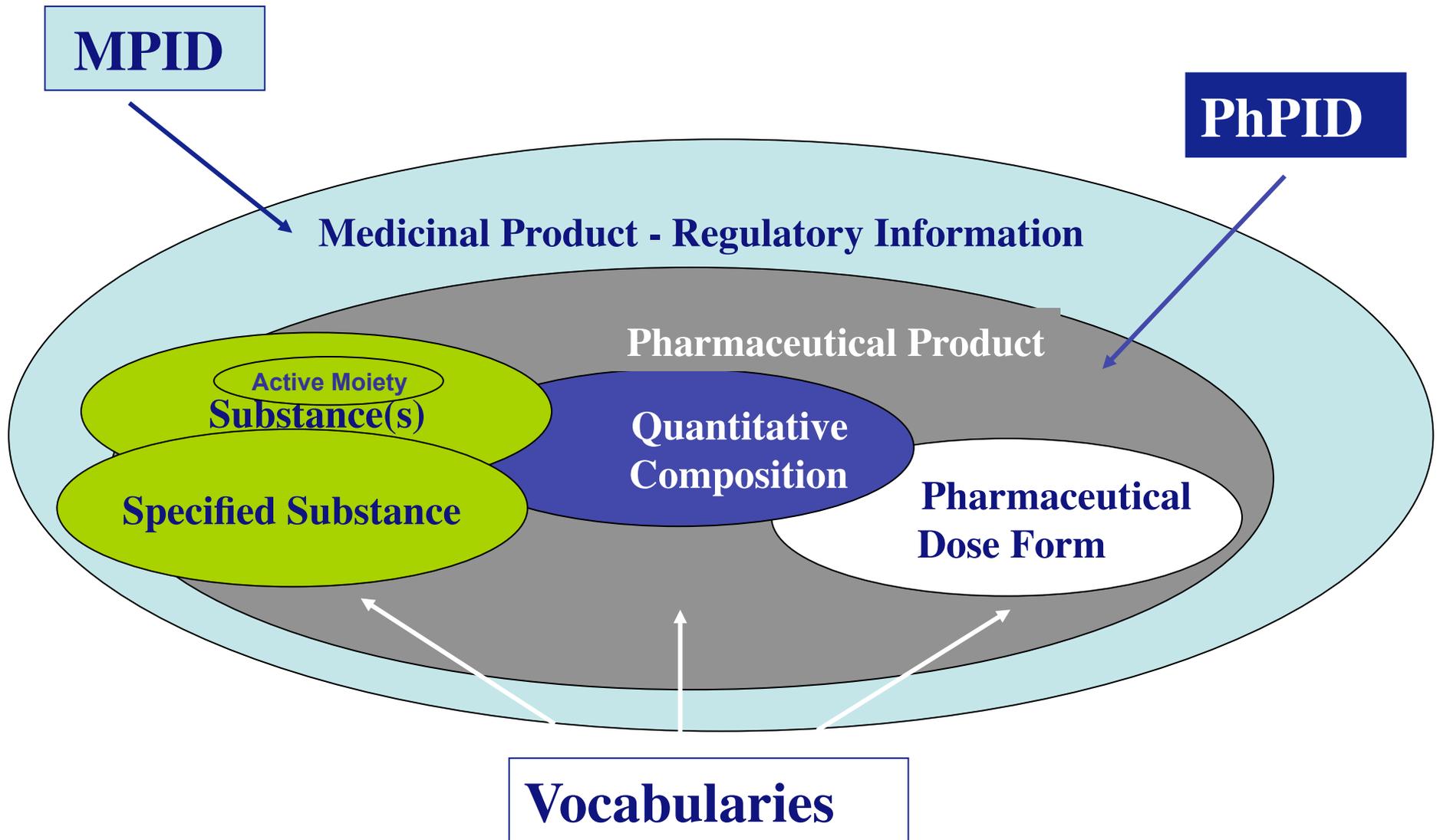
- Develop a common data structure and terminology for the description of medicinal products
 - Facilitate data exchange
 - Pharmacovigilance
 - Quality of pharmaceuticals/detect/prevent counterfeiting
 - Predict/prevent drug-drug food-drug interactions
 - Incorporation of diverse data into databases
 - Prevent drug shortages
 - Consistent review
 - Assist in mining of EHRs (Effectiveness. Safety, Better Dosing)
 - Bridge LADMER data and genomics effort



Five Interrelated IDMP Standards

- 11615 Health Informatics — Identification of Medicinal Products — Data elements and structures for the unique identification and exchange of regulated medicinal product information (Editor: Sabine Brosch EMA)
- 11616 Health informatics – Identification of Medicinal Products -Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information (Editor: Vada Perkins FDA)
- 11238 Health Informatics — Identification of Medicinal Products — Data elements and structures to uniquely identify and describe substances (Editors: Larry Callahan and Frank Switzer FDA)
- 11239 Health Informatics — Identification of Medicinal Products — Data elements and structures to uniquely identify pharmaceutical dose forms, units of presentation and routes of administration (Editor: Chris Jarvis EDQM)
- 11240 Health informatics — Identification of Medicinal Products — Data elements and structures to uniquely identify Units of Measurement (Editors: Christof Gessner and Aniello Santoro EMA)

Conceptual Model





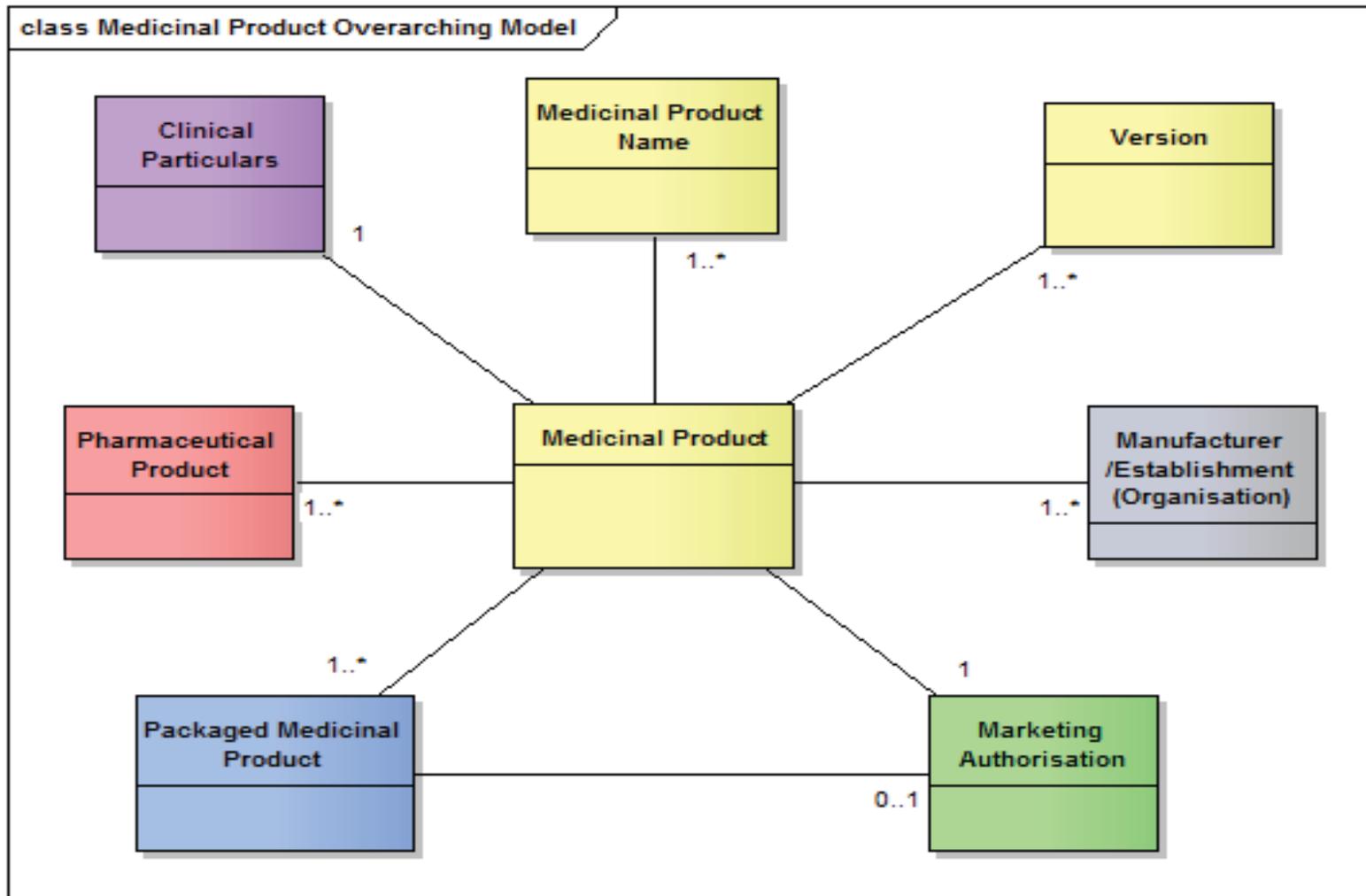
IDMP

FOUR LEVELS OF INFORMATION

- SUBSTANCE (Global Identifier)
 - SPECIFIED SUBSTANCE (Global/Regional)
 - PHARMACEUTICAL PRODUCT (Global Identifier) substance, strength, dosage form
 - MEDICINAL PRODUCT (Regional)
-
- **11238 ADDRESSES BOTH SUBSTANCES AND SPECIFIED SUBSTANCES**

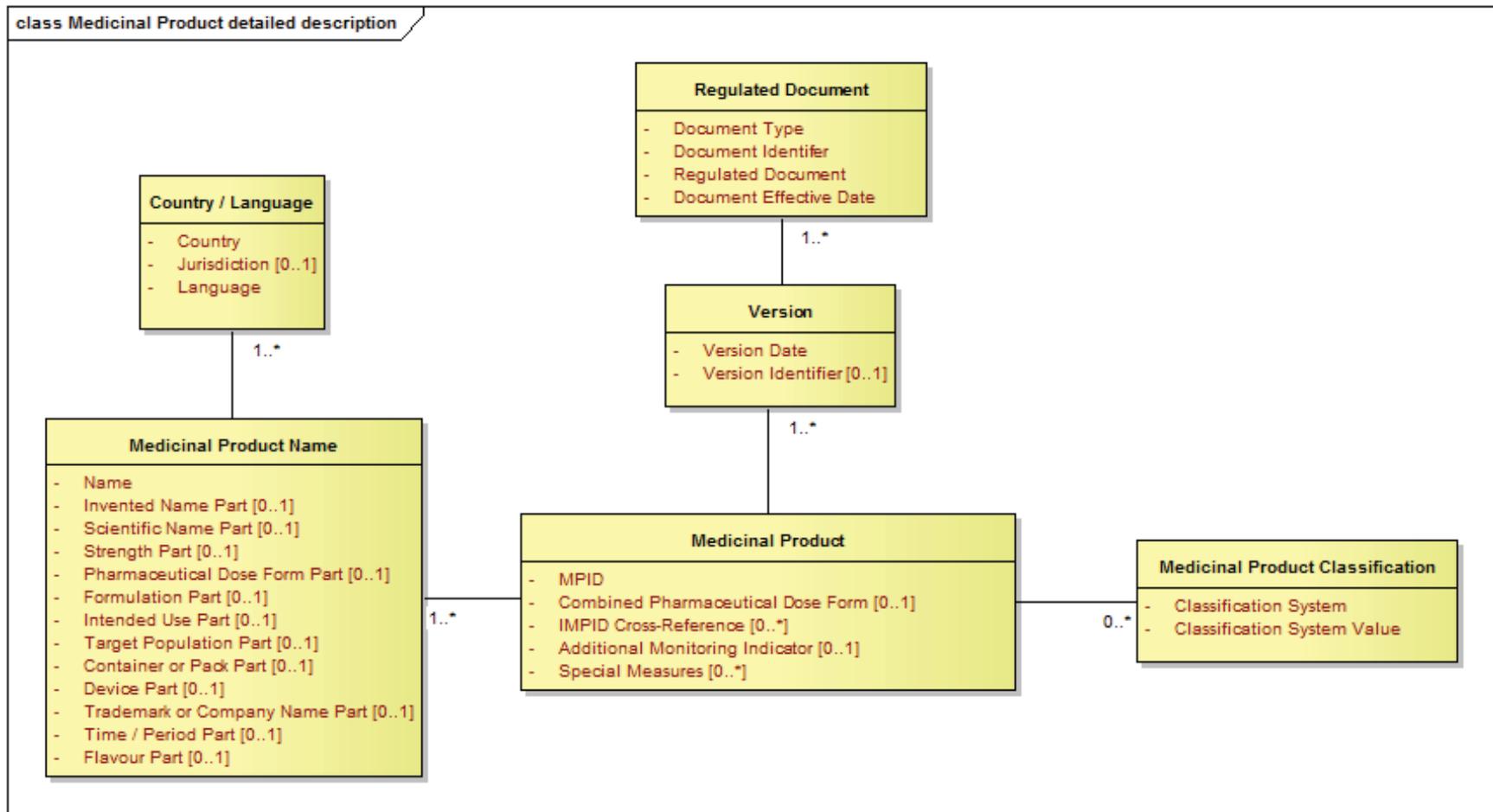


IDMP Overall Model





IDMP Detailed Medical Product





IDMP Medicinal Product

- MPID
 - US-NDC Code
 - EU number for Centrally Authorized Products
 - Netherlands RVG Code
- Combined Pharmaceutical Dose Form
 - Solvent and Powder for Injection Administered Dose Form differs from Manufactured Dose Form
- IMPID-Investigational Medicinal Product ID
- Additional Monitoring Indicator
 - Black Box or Triangle
- Special Measures
 - Phase IV Trials



IDMP Medicinal Product Name

- Name is divided into parts
 - Complete name
 - Drug XYZ® Precisehaler 200 mg for adults
 - Invented Name
 - Drug XYZ
 - Scientific Name
 - Albuterol or Albuterol Sulfate
 - Strength Part
 - 200 mg

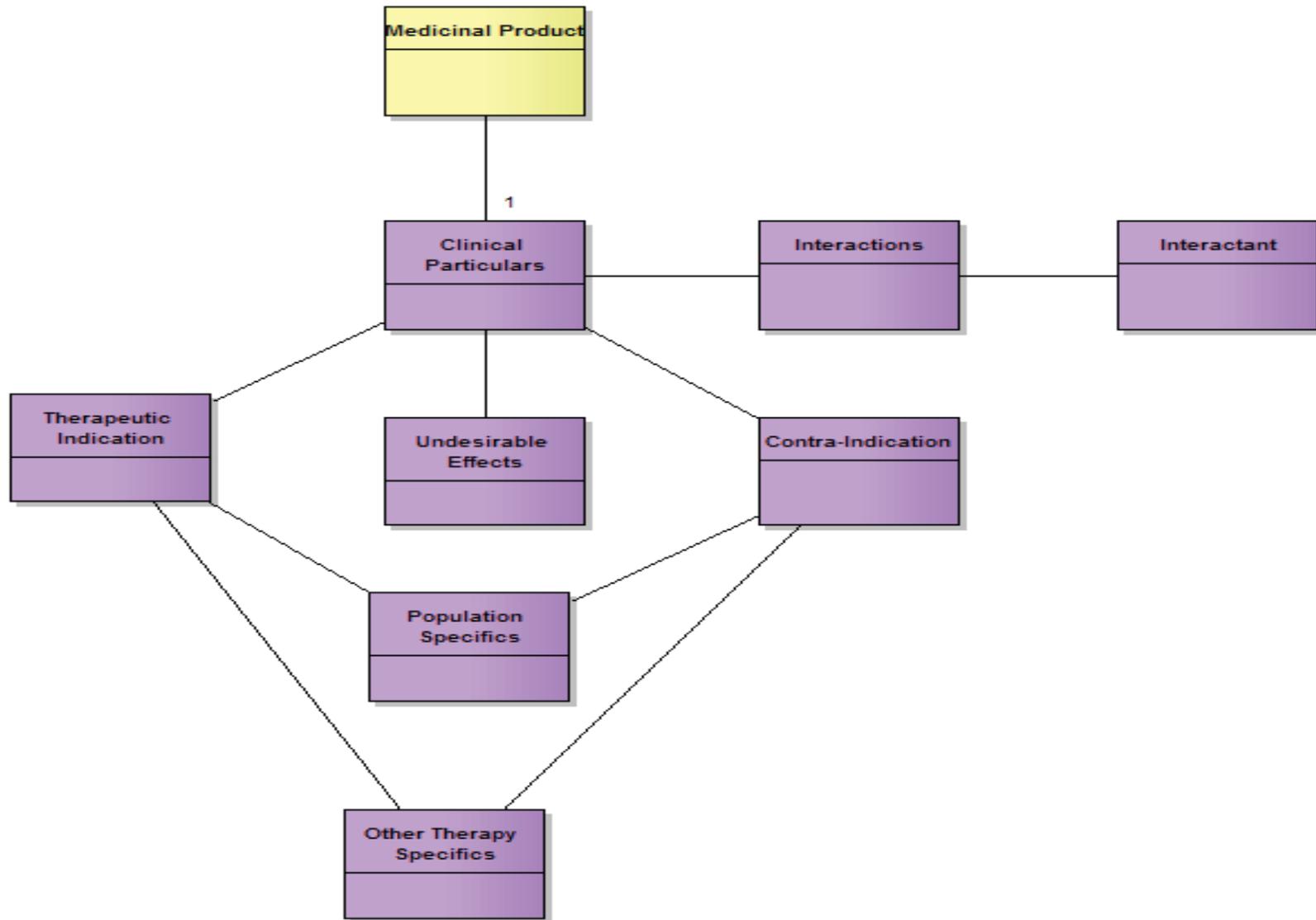


IDMP Medical Product Name

- Device Part
 - Precisehaler
- Target Population Part
 - Adults
- Formulation Part
 - “SpecialMed Sugar Free Cough Syrup”, Sugar Free is the formulation part
- Intended Use Part
 - “Drug-BI Caplets - Heartburn Relief”, Heartburn Relief

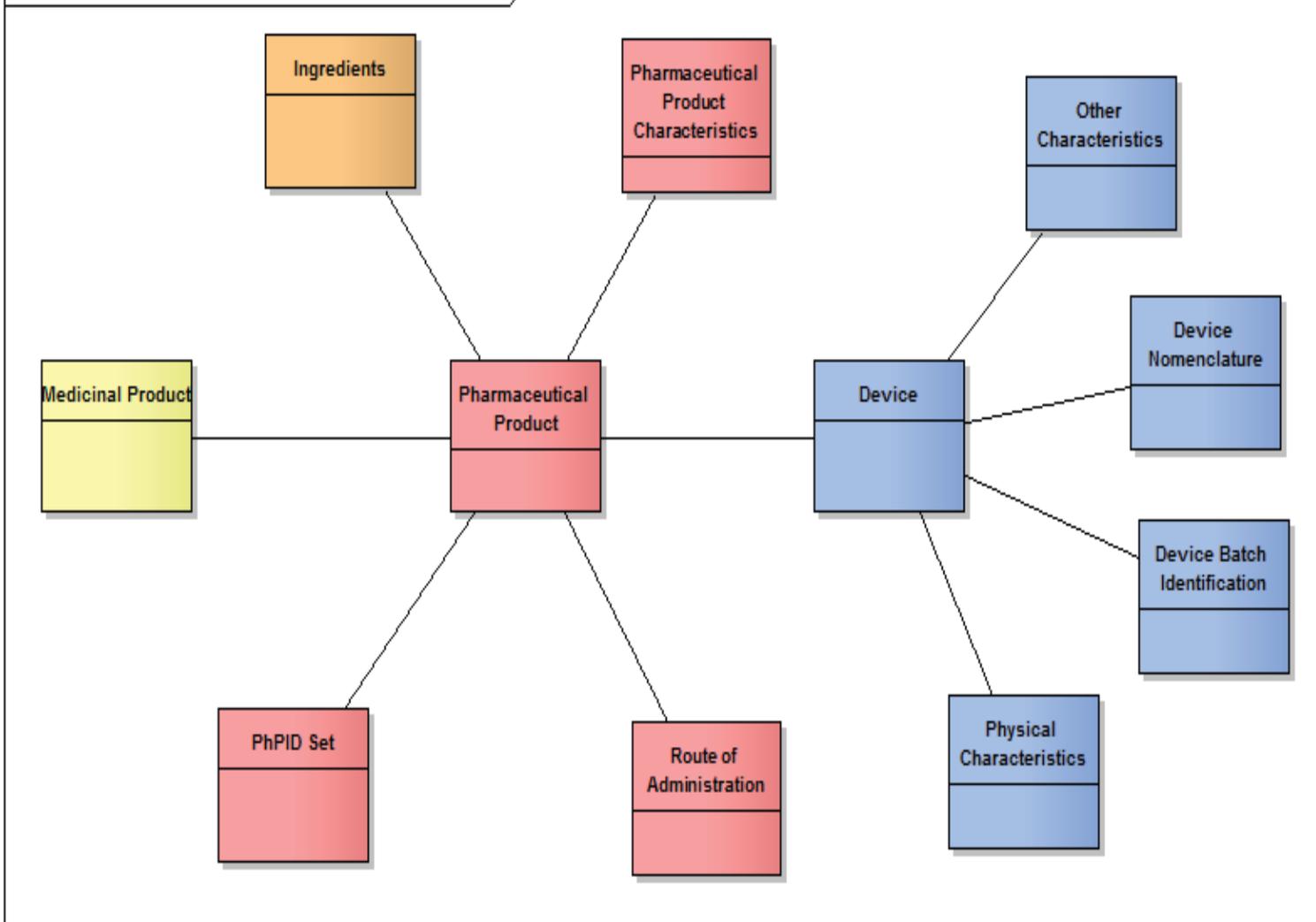


class Clinical Particulars high level





class Pharmaceutical Product & Medical Device high level





11239 Dose Form Model

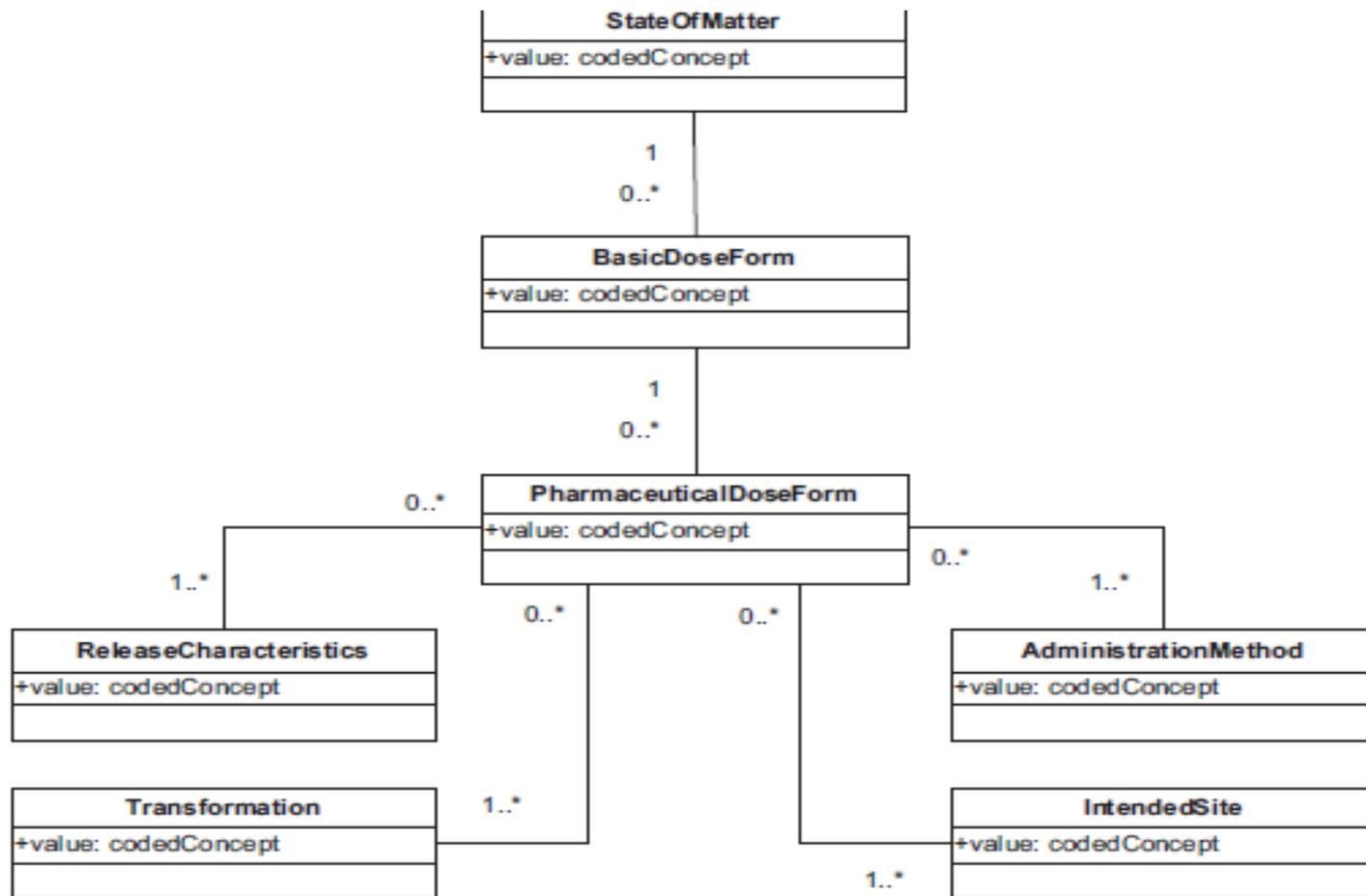


Figure 5. Conceptual diagram for the pharmaceutical dose form class.



class Ingredients & Substances detailed description

