



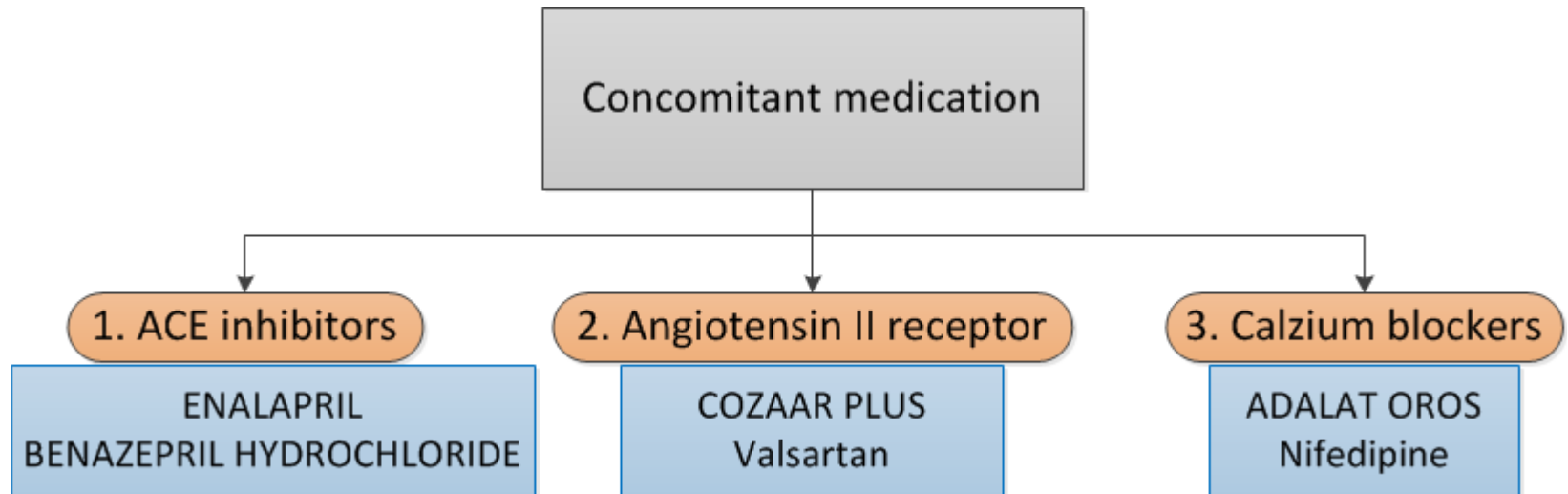
Science For A Better Life

Drug Groupings and Workflow Options for the Processing and Review of Concomitant Medication Data

PhUSE Annual Conference - Brussels

14th October 2013 - Heiko Baermann

Why Drug Groupings?



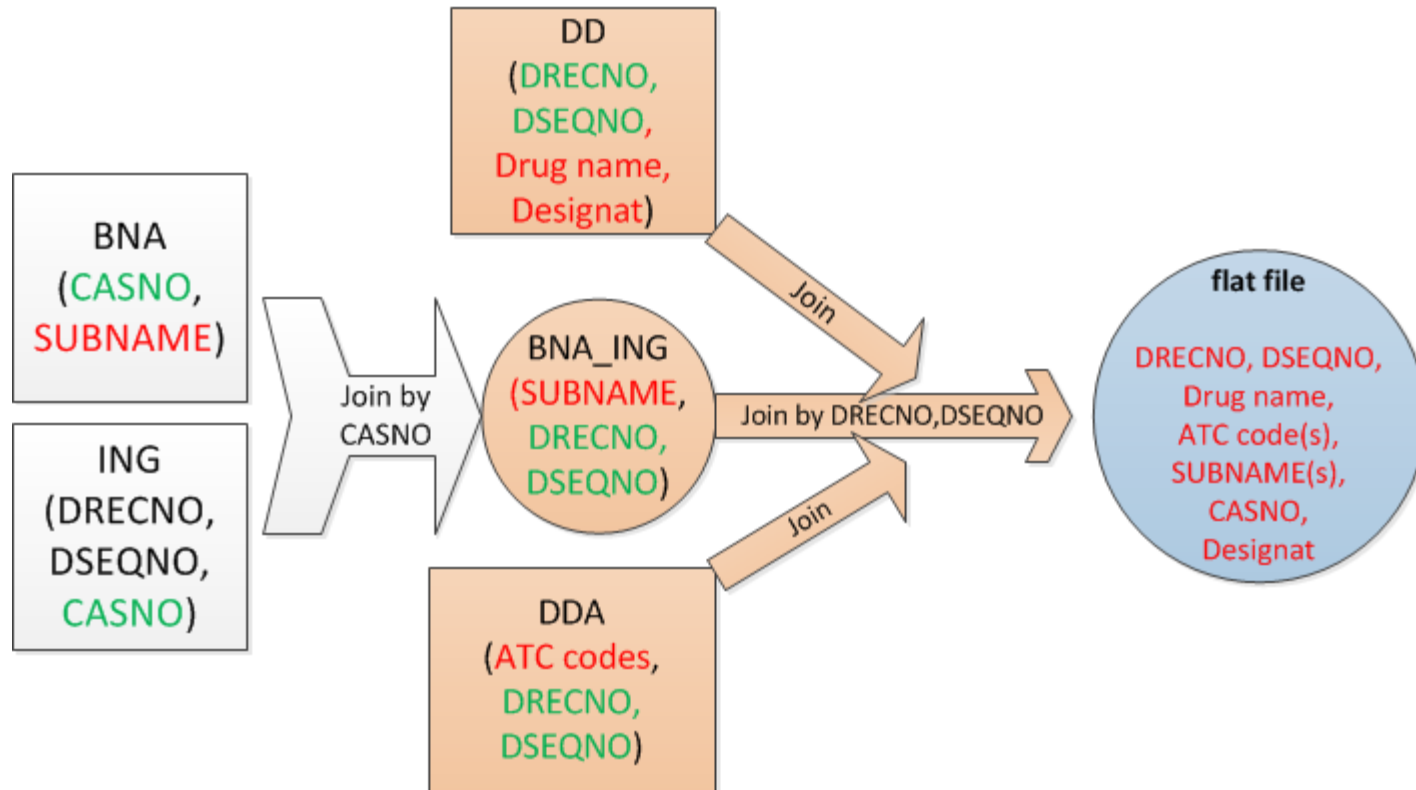
- Identify or aggregate medicines having one or more properties together (e.g. indication, chemical, pharmacodynamics)
- Support for medical review, identification of protocol deviations
- Finding of drug interactions



Bayer Drug Groupings (BDG)

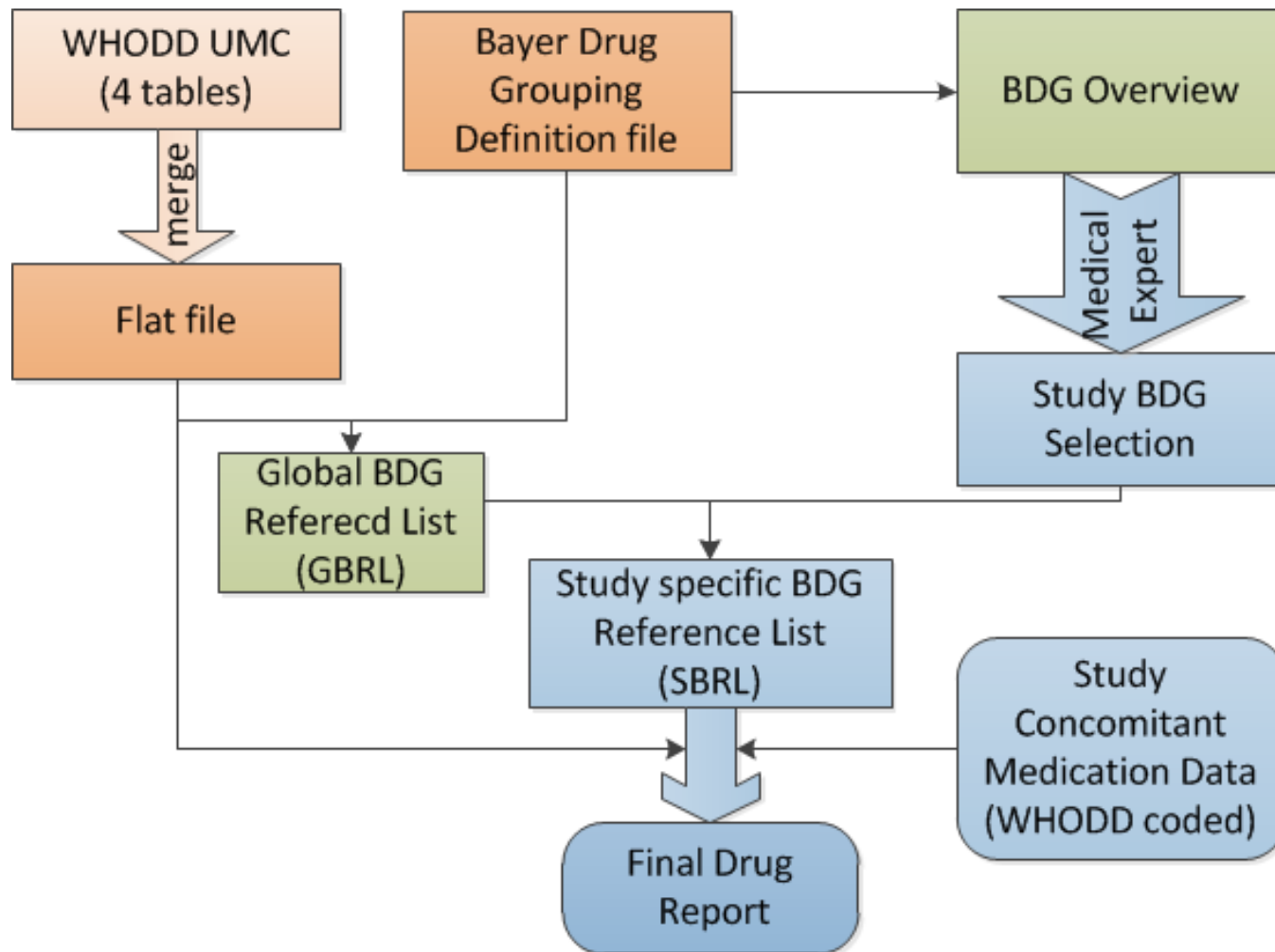
- Standardized Drug Grouping (SDG) are provided by Uppsala Monitoring Center
- If SDG is not available or ATC classification not sufficient:
 - ➔ internally developed **Bayer Drug Groupings (BDG)** based on:
 - Substance(s)
 - ATC code(s)
 - WHO-DD DRECNO(s)
 - Trade names

Creation of Flat file



Joining of standard WHO-DD B2 files

Bayer Drug Groupings Workflow



BDG Definition file



PARENT_BDG	BDG_NAME	SEARCHLEVEL	OPERATOR	SEARCHSTRING
Antihypertensives (subgroups)	Adrenergic receptor antagonists - Beta blocking agents	ATCCODE	EQUALS	C07
Antihypertensives (subgroups)	Centrally acting antihypertensives (adrenergic receptor agonists)	DRUGRECNO	EQUALS	900120
Antihypertensives (subgroups)	Centrally acting antihypertensives (adrenergic receptor agonists)	SUBNAME	EQUALS	Clonidine
Centrally depressant drugs excluding anesthetics	Analgesia producing opioids	SUBNAME	CONTAINS	Sufentanil
	Corticosteroids	ATCCODE	BEGINS WITH	D07

Search Level:

ATCCODE

DRUGRECNO

SUBNAME

TRADE NAME

Operator “Begins with” -> LIKE ‘search string%’

Operator “Contains” -> LIKE ‘%search string%’

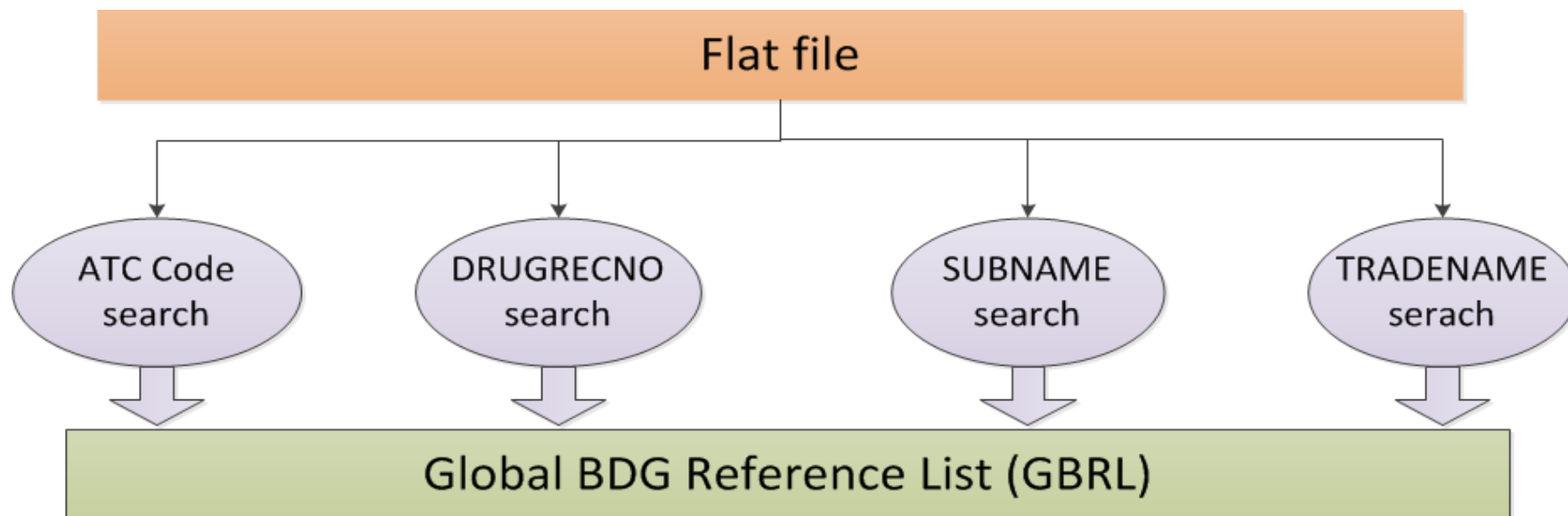
Operator “Equals” -> EQUALS ‘search string’

Derivation of content in Global BDG Reference List



Search results for ATC code “begins with” search

parent_bdg	bdg_name	cond	drecno	dseqno1	atccode
Antidepressants	Monoamine oxidase A inhibitors	LIKE N06AG%	006274	01	N06AG
Antidepressants	Monoamine oxidase A inhibitors	LIKE N06AG%	008045	01	N06AG
Antidepressants	Monoamine oxidase A inhibitors	LIKE N06AG%	008766	01	N06AG
Antidepressants	Monoamine oxidase A inhibitors	LIKE N06AG%	015507	01	N06AG



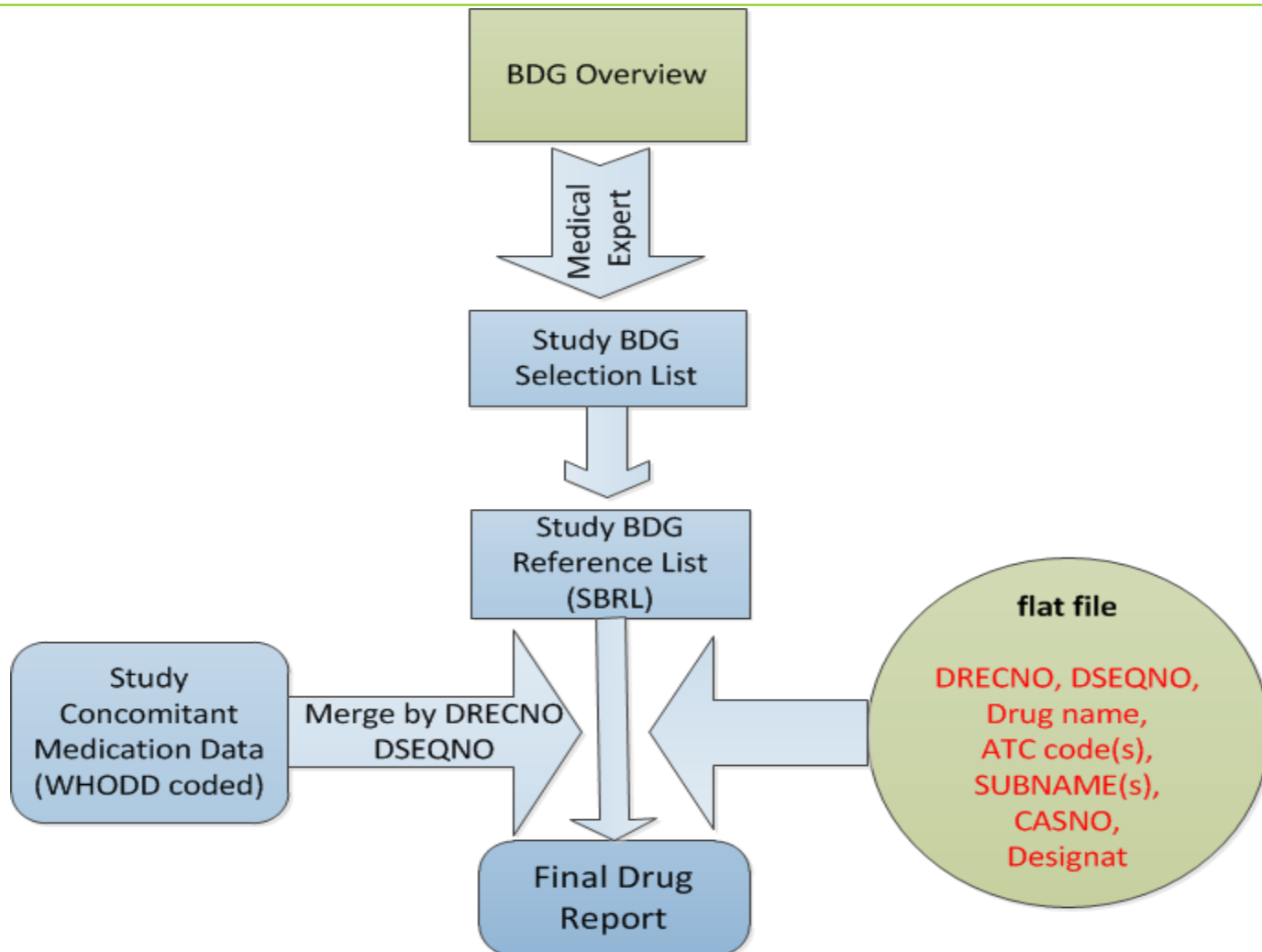
BDG- Study (Project) level

BDG's of interest for the Study (project) specific BDG

Reference list (SBRL) selected by the Medical Expert

PARENT_BDG	B_CODE	BDG_NAME	SBRL_INCLUDE
Antiarrhythmics (subgroups)	1001	Adrenergic receptor antagonists - Beta blocking agents	x
Antiarrhythmics (subgroups)	1060	Adrenergic receptor antagonists - Combined beta and alpha blocking agents	x
Antiarrhythmics (subgroups)	1002	Antiarrhythmics, class I and III	
<u>Antiarrhythmics (subgroups)</u>	1003	Anticholinergic agents used in bradycardia	x
Antiarrhythmics (subgroups)	1004	Digitalis glycosides	x
Antiarrhythmics (subgroups)	1005	Other antiarrhythmics	

BDG- Study (Project) level





BDG based tables and listings

Report example on patient level after merging Concomitant Medication data with BDG information

PARENT_BDG	BDG_NAME		DRUGNAME WHO-DD	<u>Reported drug name</u>	SUBJECT ID
Antihypertensives	ACE inhibitors		ENALAPRIL [ENALAPRIL]	ENALAPRIL	6
Antihypertensives	ACE inhibitors		BENAZEPRIL HYDROCHLORIDE	BENAZEPRIL HYDROCHLORIDE	1
Antihypertensives	Angiotensin II receptor antagonists		COZAAR PLUS	COZAAR PLUS	1
Antihypertensives	Angiotensin II receptor antagonists		VALSARTAN	Valsartan Capsules	3
Antihypertensives	Calcium blockers	channel	NIFEDIPINE	Nifedipine Controlled Release Tablet	5
Antihypertensives	Calcium blockers	channel	ADALAT OROS	ADALAT OROS	2

BDG/WHO-DD based tables & listings

Review report example after merging Concomitant Medication data with BDG information and substance name + ATC codes from the WHO-DD flat

DRUG_NAM	DRRECNM	SEQ_N01	SEQ_N02	BDG MATCH	Aspirin	NSAIDs	SUB_NAME	ATC codes
RESTAMIN KOWA [DIPHENHYDRAMINE HYDROCHLORIDE]	000004	02	071				DIPHENHYDRAMINE HYDROCHLORIDE	D04AA, N05CM, R06AA
VENA [DIPHENHYDRAMINE LAURILSULFATE]	000004	05	002				DIPHENHYDRAMINE LAURILSULFATE	D04AA, R06AA
ASPIRIN [ACETYLSALICYLIC ACID]	000027	01	004	Salicylic acid and derivatives	1	1	ACETYLSALICYLIC ACID	A01AD, B01AC, M02AC, N02BA
BAYASPIRIN	000027	01	212	Salicylic acid and derivatives	1	1	ACETYLSALICYLIC ACID	A01AD, B01AC, M02AC, N02BA
ATROPINE SULFATE	000028	02	001				ATROPINE SULFATE	A03BA, C01B, S01FA
ATROPIN	000028	02	002				ATROPINE SULFATE	A03BA, C01B, S01FA
NEOPHYLLIN	000037	01	016				AMINOPHYLLINE	R03DA
INDOMETACIN	000038	01	001	NSAIDs (excluding salicylic acid and derivatives)		1	INDOMETACIN	C01EB, M01AB, M02AA, S01BC

Conclusions

- Central maintenance of BDG definitions by Medical Dictionary Experts
- Support of project consistency
- Usage of global defined standard objects to support data/medical review (e.g. JReview) and reports
- No additional programming on study / project level required
- Avoid redundant programming and maintenance



Forward-Looking Statements

This presentation may contain forward-looking statements based on current assumptions and forecasts made by Bayer Group or subgroup management.

Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com.

The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.



Thank you for your attention!

Heiko.Baermann@bayer.com