



Use of Synonym Lists at Grünenthal

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Topics Overview

- Company (Grünenthal and Lundbeck)
- Dictionary management infrastructure
- Synonym list concept / management
 - workflow
 - concept
 - advantages & disadvantages
- Practice Sharing – Interactive Q&A



Grünenthal – key facts



Active Substances



tramadol
hydrochloride



buprenorphine



paracetamol
+ tramadol



lidocaine



buprenorphine



tapentadol

Shareholders:

100% Wirtz family (19
shareholders)

Headquarters:

Aachen, Germany

Therapeutic Areas:

Prescription pharmaceuticals
for

- moderate pain
- severe pain

Employees:

4.900 worldwide

155

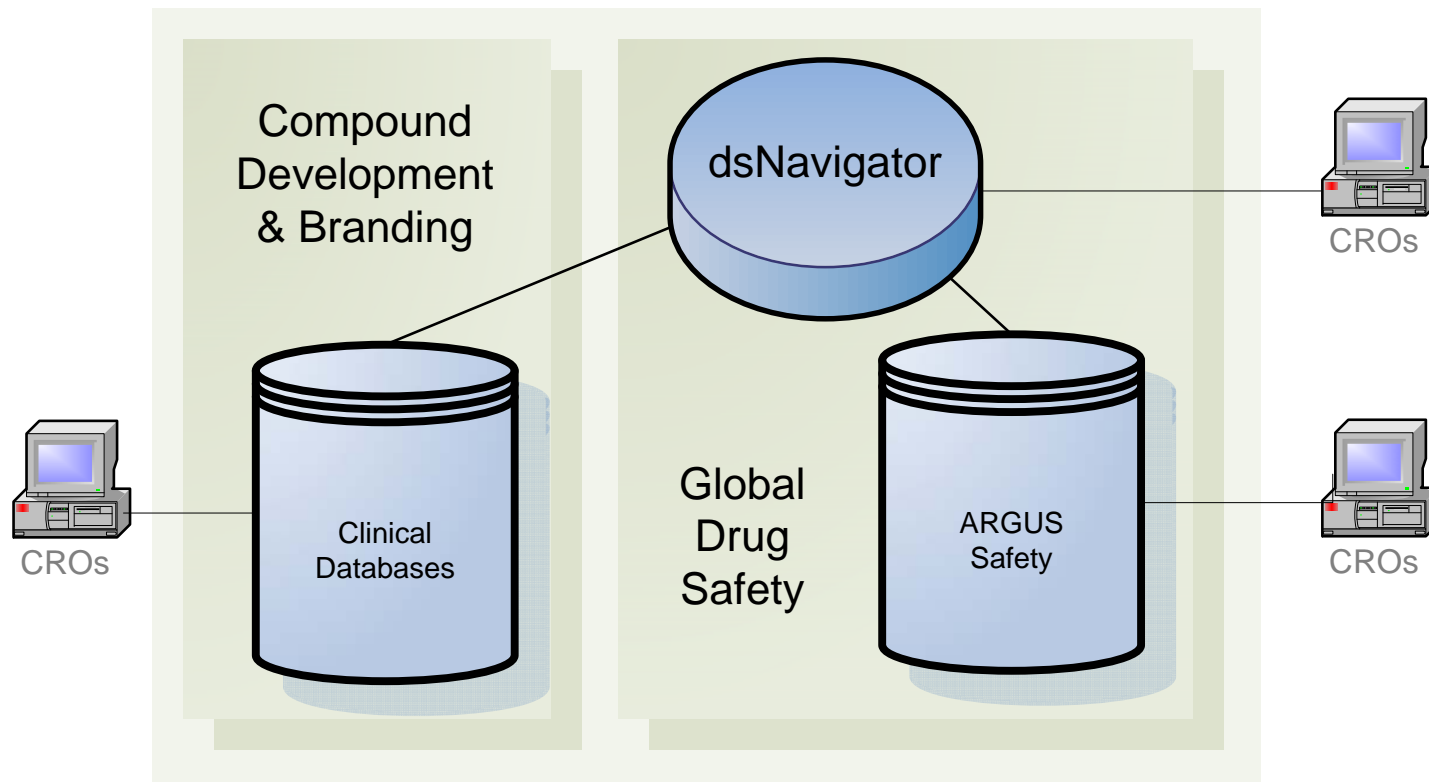
Countries in which our
products are available

35

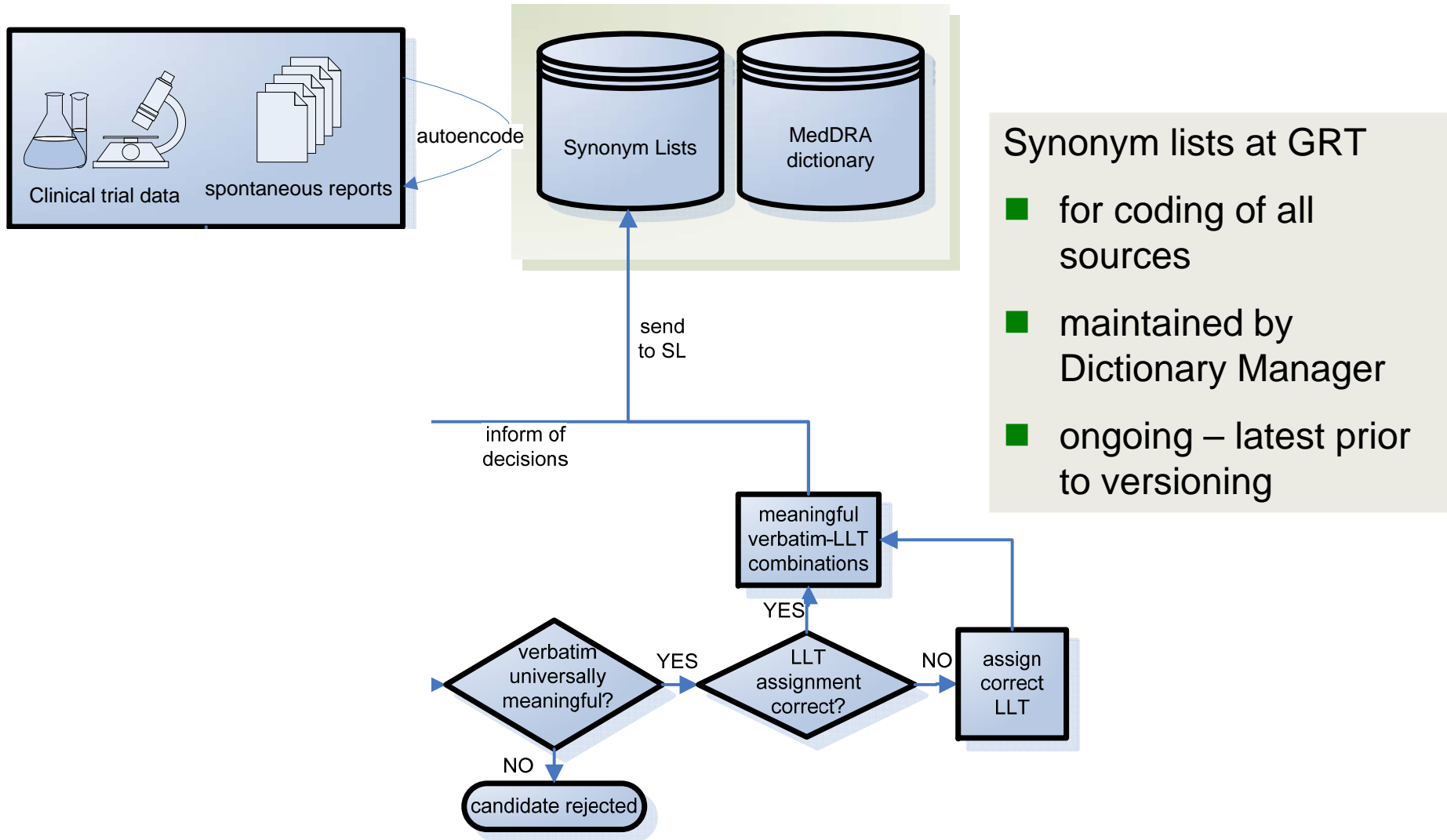
Affiliates

Coding and dictionary management system

- dsNavigator as unique platform (version 2010.01)
- Interface to safety database (Argus) and clinical databases



Synonym list workflow



Synonym lists at GRT

- for coding of all sources
- maintained by Dictionary Manager
- ongoing – latest prior to versioning

Implemented synonym lists at Grünenthal

- no product specific synonym lists in place
- different synonym lists per type of code

type of code	size of list
adverse events (AE)	24 316
medical history (MH)	15 763
indications (IND)	2 204
test names (TEST)	just implemented

Establishment & maintenance - is it worth the effort?

- Yes, because
 - coding consistency is increased
 - impact analysis during MedDRA update based on SLs
 - effort for coding & recoding activities is reduced

EXAMPLE

- pooled AEs of medical compound end of phase III (5903 unique)
- most trials coded after the implementation of synonym list
- SL increased significantly during this time

coding set	MedDRA version	direct matches
original trials	7.1 to 11.0	wide range; frequently <50%
1st pooling	11.0	76%
2nd pooling	13.0	97% (18% MedDRA, 80% SL)

why different synonym list per type of code?

- different conventions per source are in place - examples:

EXAMPLES

- AE vs MH:
 - Social circumstances not used for AEs at GRT
 - drug abuser vs. drug abuse
- MH vs IND:
 - term 'unknown' has a different meaning
 - 'loose weight' might reflect different concept
- AE vs TEST: - 'blood pressure' can be handled differently

- further increase of efficiency during coding and candidate approval

disadvantage

- slight non-meaningful differences between SLs evolve over time



Thank you!

