



Use of Synonym Lists @ Lundbeck

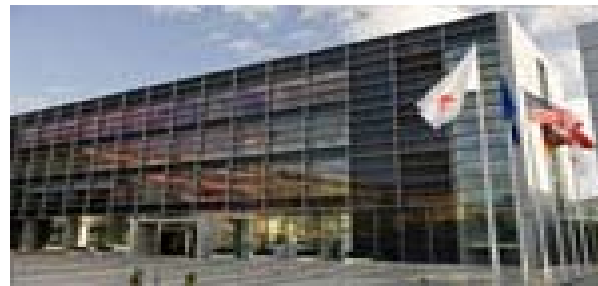
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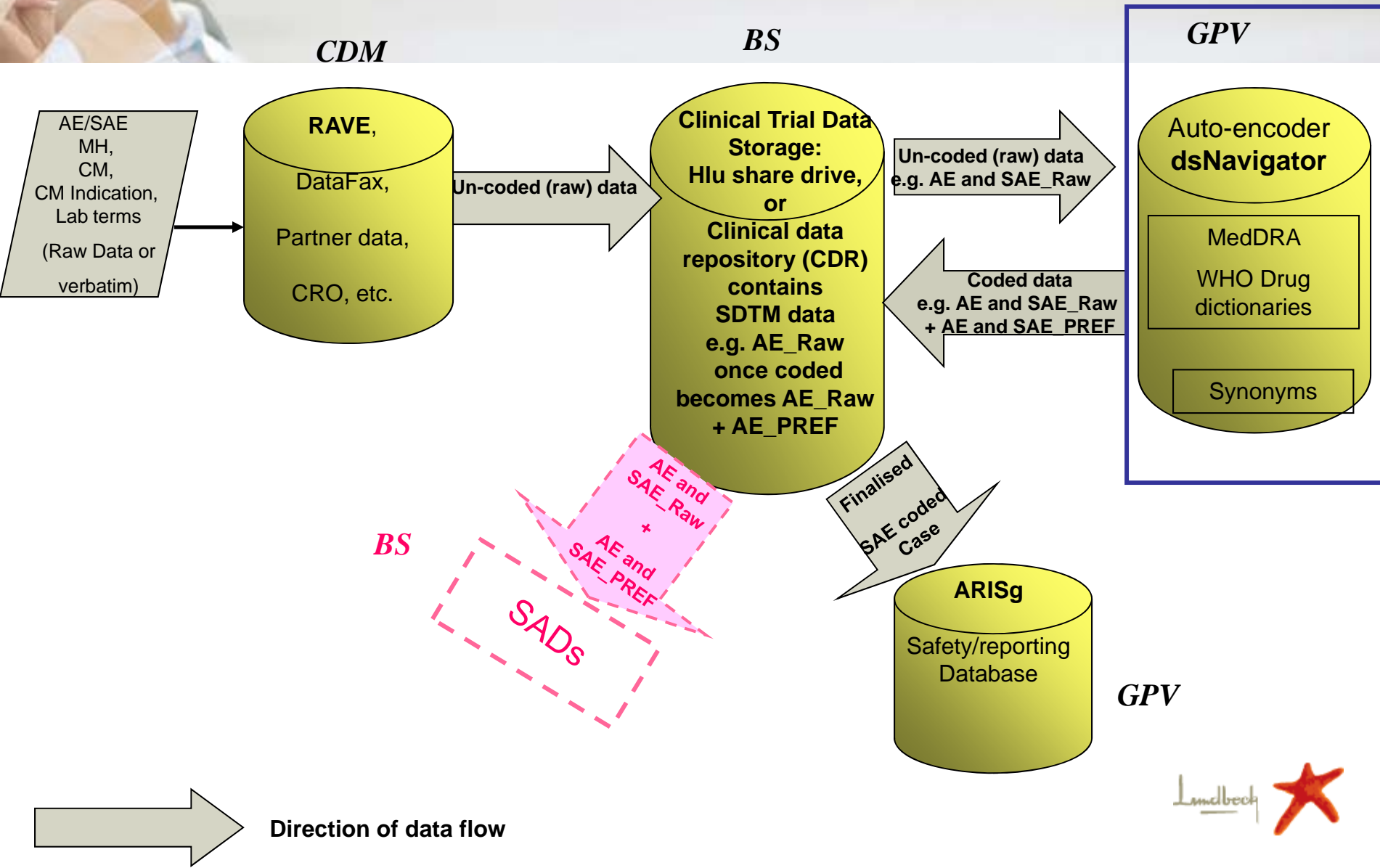
Lundbeck in brief...

- **Founded by Hans Lundbeck in 1915**
- **Vision - to become a world leader in psychiatry and neurology**
- **Mission - to improve the quality of life for those suffering from psychiatric and neurological disorders**
- **Marketed products: Alzheimer's disease, depression and anxiety, epilepsy, Huntington's disease, insomnia, Parkinson's disease, and schizophrenia.**
- **Products presence in more than 100 countries**
- **Headquarter in Copenhagen, Denmark**
- **Approximately 5,900 employees in 56 countries**
- **Partnerships**






Infrastructure





Clinical Trial Coding

- Tools and data types
 - MedDRA / Desktop browser 3.0b
 - Autoencoder (dsNavigator version 3.4.2)
 - Synonym Lists (2)
 - AE, MH, Indication of CM and [Lab test name](#)
- Coding Process
 - Autoencoding
 - Manual coding
 - On-line coding approval
 - Synonym candidates: Approved_As_Synonym or Approved_Non_Synonym)
 - Final study coding approval sign-off (paper coding report) 




Synonyms Management (I)

- Component:
 - Copy of (locked and active) raw verbatim combined with dictionary terms values (LLT to SOC)
 - Global_MedDRA: >11779 (AEs)
 - Other_MedDRA: >13861 (MH, IND, [Lab tests](#))
- Purpose:
 - Auto-encoding hit rate
 - Consistency and coding conventions respect
 - Long-term time saving and cost effectiveness



Synonyms Management (II)

- Frequency:
 - Weekly – studies – candidates – approval/rejection
 - Monthly – active studies/compounds - consistency
 - Monthly – safety and clinical coding reconciliation (SAE – SUSAR)
 - 6 months – up-versioning – impact analysis (SL)
- Responsibility:
 - Coding & Dictionary Manager
 - M.D. (acting as Referee for disagreement and sign-off 6-month impact analysis) 



Synonym Lists Approvers

Coding and Dictionary Manager

- Weekly review coding of status “Approved” and “Approved With Query”
- Decision making:
 - verbatim and coding OK: candidate submission and approval (Approved_As_Synonym)
 - troublesome verbatim and/or doubtful coding: recoding proposal or M.D. consultation – rejection – (Approved_As_Synonym or Approved_Non_Synonym)
- Monthly across compounds coding consistency review: negotiation and recoding, as applicable (none so far = 5 in-house compounds)
- Up-versioning migration issues (impact analysis) – proposed solutions for synonym updates to a designated M.D. for final approval



Conclusion – Advantages and Disadvantages

- Rapid and efficient reference for coders and approvers – less disagreement
- Coding consistency throughout compounds – Integrated safety summary carried out smoothly and timely – less recoding
- Reference for approval of CRO's coding
- Ad hoc reference for coding in safety database – clinical study and safety data coding consistency: 90%
- Coding conformed with coding conventions
- Effort on close communication to coders & approver
- Negotiation skills required
- Challenge in keeping different meaning of same terms in GLOBAL_MedDRA SL vs OTHER_MedDRA SL
- Efficient resource planning during up-versioning



Sharing Your Practice

- Do you have and use synonym list(s)?
- For clinical trials and/or post-marketing?
- How are the synonyms organised?
 - one list for all types of data?
 - or different lists for different types of data?
 - global or by compound or study specific?
- Which role manage/validate synonym list(s)?