



# **Coding Organizations in Pharmaceutical Industry Survey Results**

- **Background**
- **Survey Results**
  - **General Coding Approach/Coding Targets**
  - **Technical Coding Environment**
  - **Version Control/Legacy Data**
- **Summary**
- **Conclusions**



## ➤ **Background**

## ➤ **Survey Results**

- **General Coding Approach/Coding Targets**

- **Technical Coding Environment**

- **Version Control/Legacy Data**

## ➤ **Summary**

## ➤ **Conclusions**

- **The Master Thesis with the topic *‘Management of a global coding organisation in the pharmaceutical industry’* describes the Bayer centralised coding approach and the management of the central coding group**
- **In order to compare this approach with coding organisations of other pharmaceutical companies a survey was initiated**

- **Survey was sent out via Zoomerang to member companies of the EU and US MedDRA User Groups and as a paper version to the special interest group ‘Coding and Dictionaries’ at the Association for Clinical Data Management (ACDM)**



- **Background**

- **Survey Results**

- **General Coding Approach/Coding Targets**

- **Technical Coding Environment**

- **Version Control/Legacy Data**

- **Summary**

- **Conclusions**

- **Of the companies approached, 37 participated in the survey**
- **Not all questions of the survey led to conclusive answers and could be considered for the evaluation:**
  - **Coding turnaround times per coder and auto-coding efficiency only revealed in a few instances (confidentiality aspects?)**
  - **Answers provided in free text (e.g. QC processes) inappropriate for analysis based on diversity and complexity**



- **Background**

- **Survey Results**

  - **General Coding Approach/Coding Targets**

  - **Technical Coding Environment**

  - **Version Control/Legacy Data**

- **Summary**

- **Conclusions**

- **Participants were asked to state their business areas and size of their respective organisation:**
- **Total of 21 pharmaceutical companies, 9 biotech companies and 7 CROs responded**
- **Size of their organisation was indicated as small in 3, as medium in 9 and as large in 7 instances**

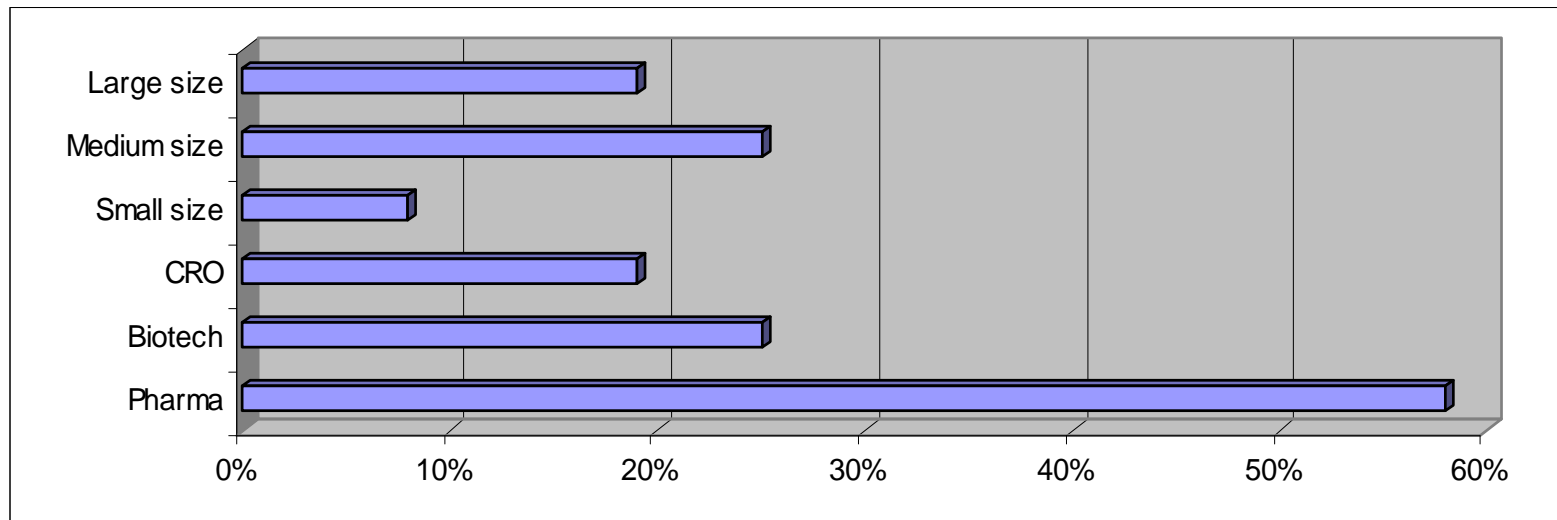


Figure 1: Business area of responders to the survey (N = 37) and company sizes (N = 19)

- **Responsibilities for coding of data originating from clinical studies versus those from Drug Safety:**
- **Majority of companies, i.e. about 59% (N=21), responded that they employ separate groups for coding of data from clinical trials and those from DS**
- **Centralised, cross-functional coding approach only being used by 10 companies (28%)**

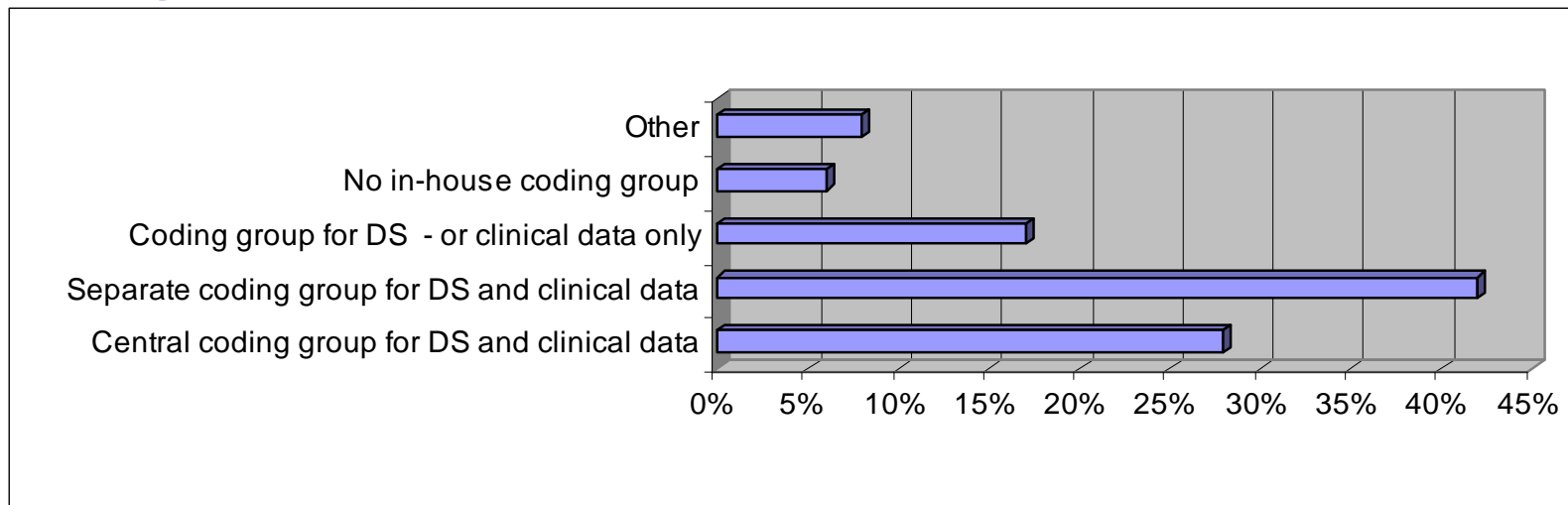


Figure 2: Do you have a centralised coding organisation that codes both, data from clinical studies as well as Drug Safety (DS) data? (N = 36)

- Number of FTEs and the ratio between internal and external resources was addressed:
- Based on size of companies, resource needs reached up to 50 internal FTEs with no external coding support and 20 FTEs with additional 11 external Coders

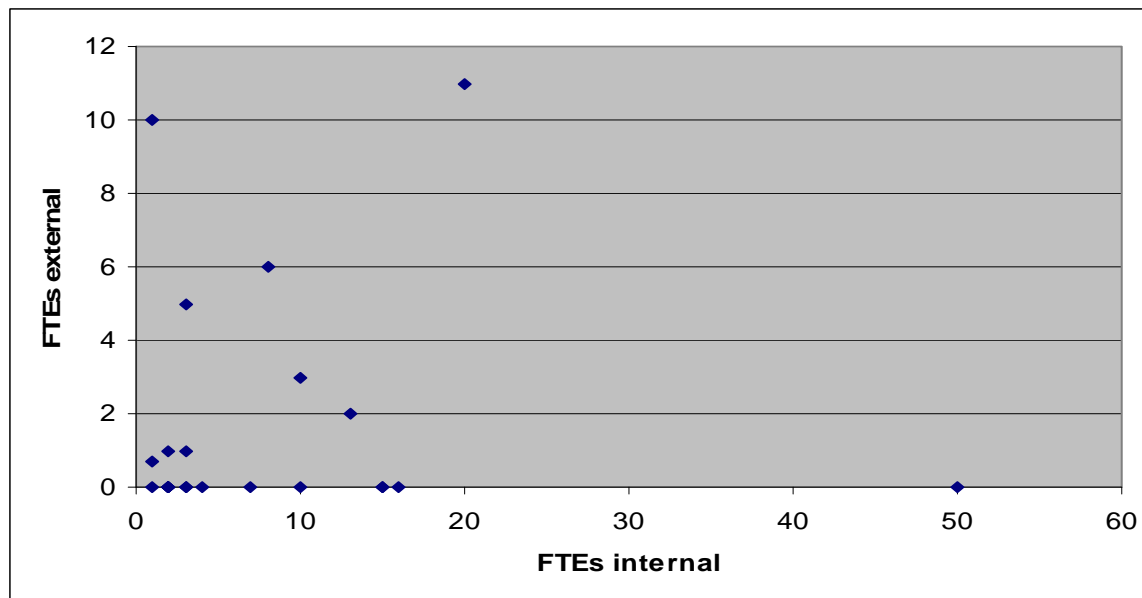


Figure 3: Internal and external FTEs assigned to coding tasks per company (N = 24)

- **Specification of tasks within clinical studies:**
- **Main focus is on phase I to phase IV trials – only small percentage of responders are responsible for coding non-interventional studies**

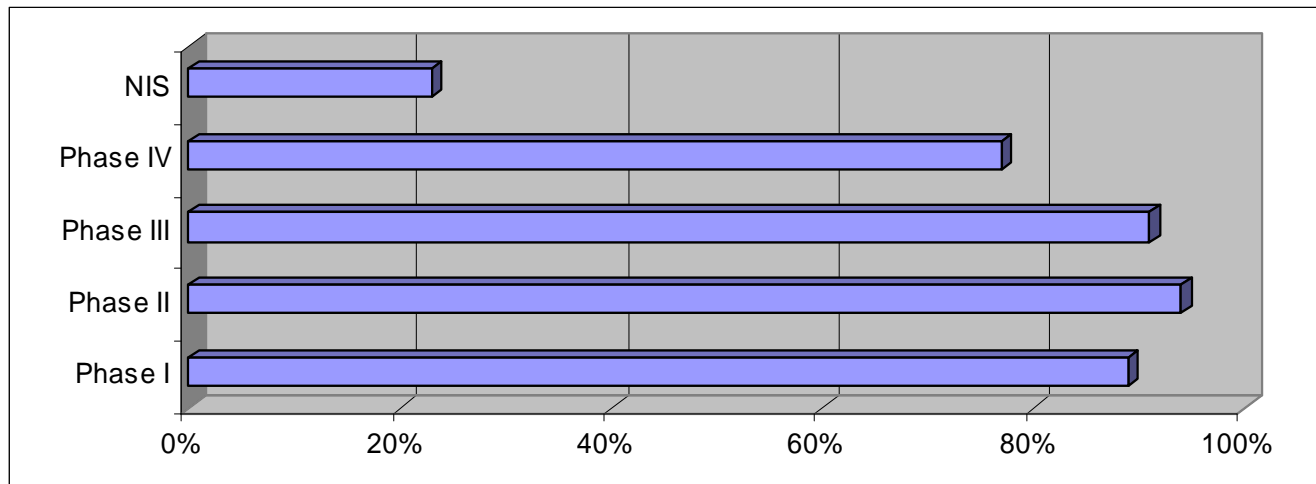


Figure 4: Responsibility for coding of studies in different phases of clinical development or with different scope (N = 34)

- **Half of the companies perform coding on a unique level in clinical trials (N=36)**
- **Coding targets in clinical studies:**

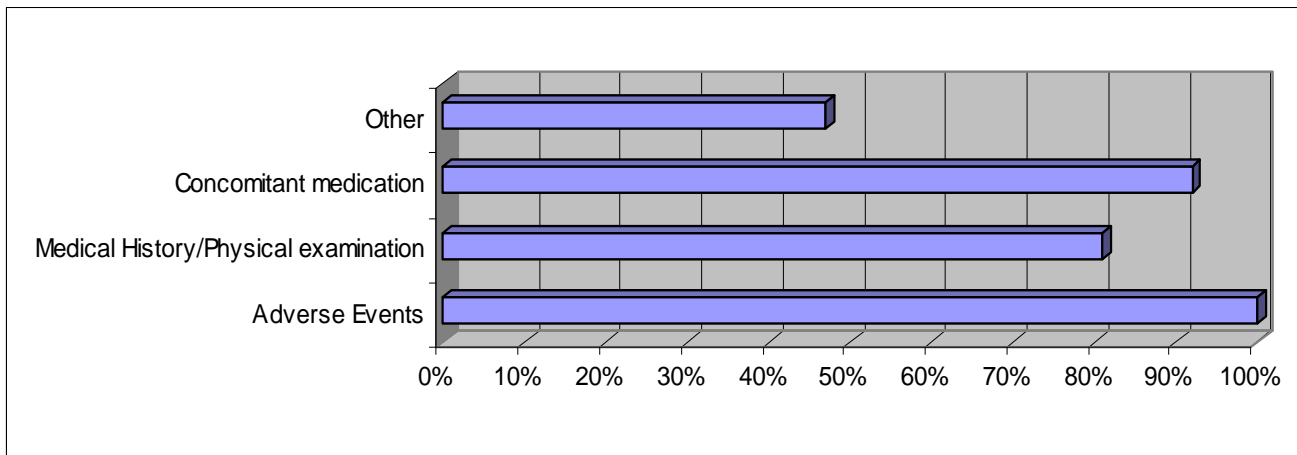


Figure 5: In clinical studies, which data do you code? (N = 36)

- **Coding targets in Drug Safety:**
- **Surprisingly the extent of coding is smaller than in clinical studies**

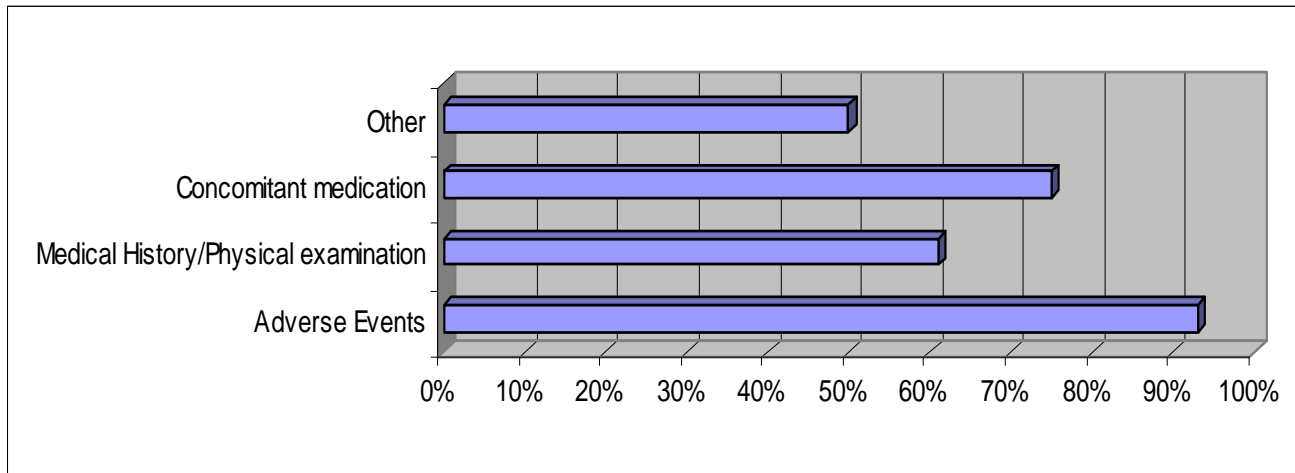


Figure 6: In Drug Safety, which data do you code? (N = 26)

- **Coding thesauri employed in clinical studies and Drug Safety:**
- **MedDRA is implemented in all companies**
- **WHO-DD in its various versions and formats is implemented by nearly all companies**

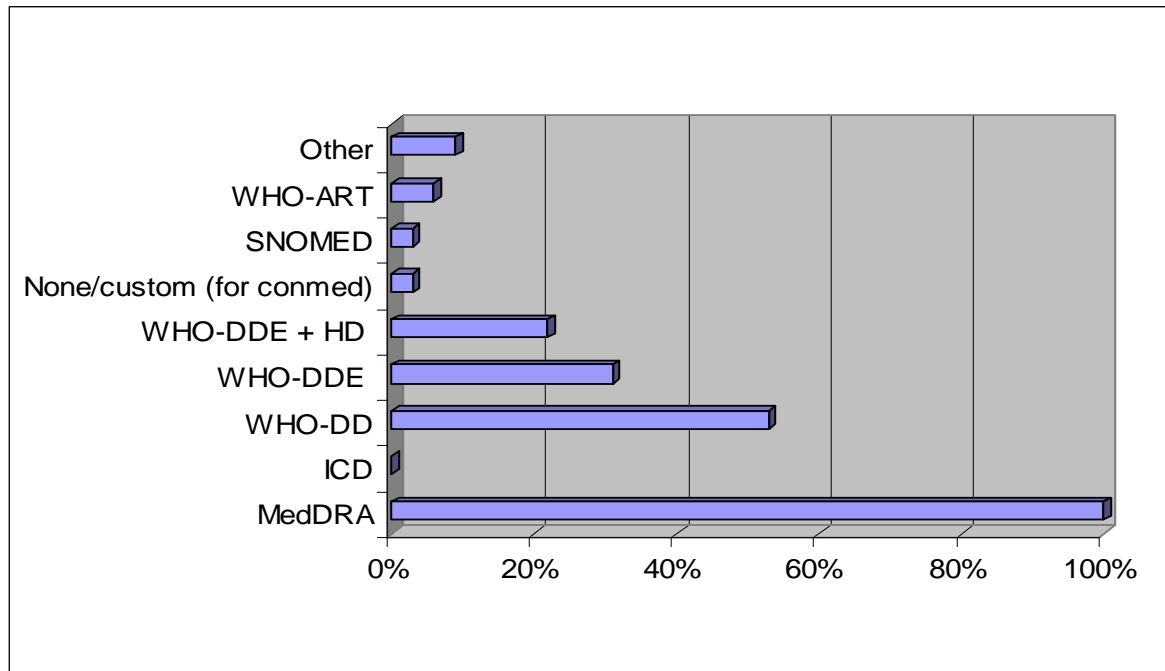


Figure 7: Which coding thesaurus do you apply (multiple responses possible)? (N = 32)

- **Cross-functional application of coding guidelines:**
- **Majority of companies use the same coding conventions in clinical studies and Drug Safety**

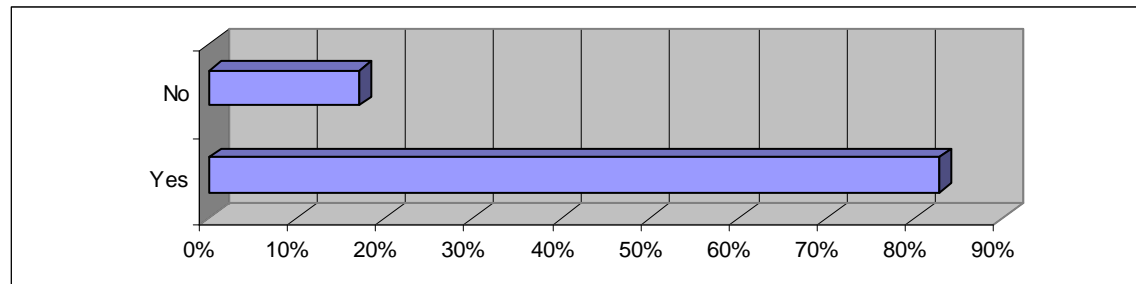


Figure 8: Do you use the same coding conventions for clinical study data and data in Drug Safety? (N = 30)

- **Use of coding conventions across therapeutic areas:**
- **Majority of companies apply the same coding conventions, irrespective of the therapeutic area**

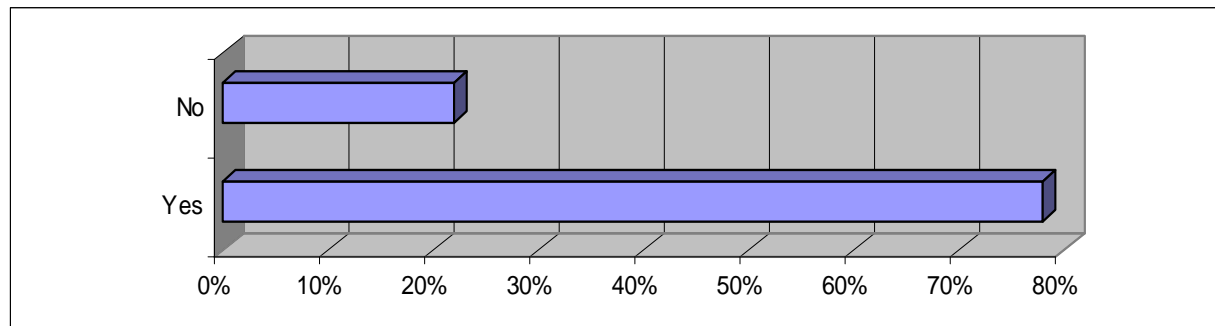


Figure 9: Do you use the same coding conventions across therapeutic areas? (N = 32)

- **Use of synonym lists for coding purposes:**
- **Majority of companies introduced synonym lists in their coding process**

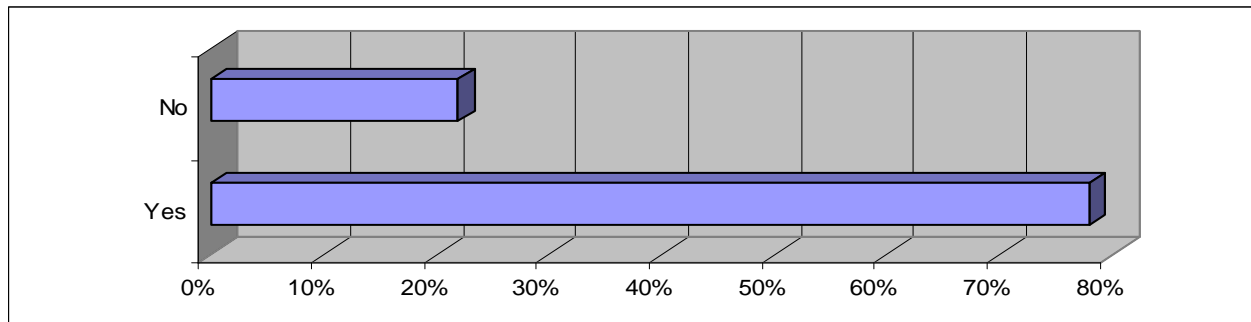


Figure 10: Do you use synonym lists for coding purposes? (N = 32)

- 
- **Background**
  - **Survey Results**
    - **General Coding Approach/Coding Targets**
    - **Technical Coding Environment**
    - **Version Control/Legacy Data**
  - **Summary**
  - **Conclusions**

- **Technical environment – applications used:**
- **Most companies utilise a customised commercial product**

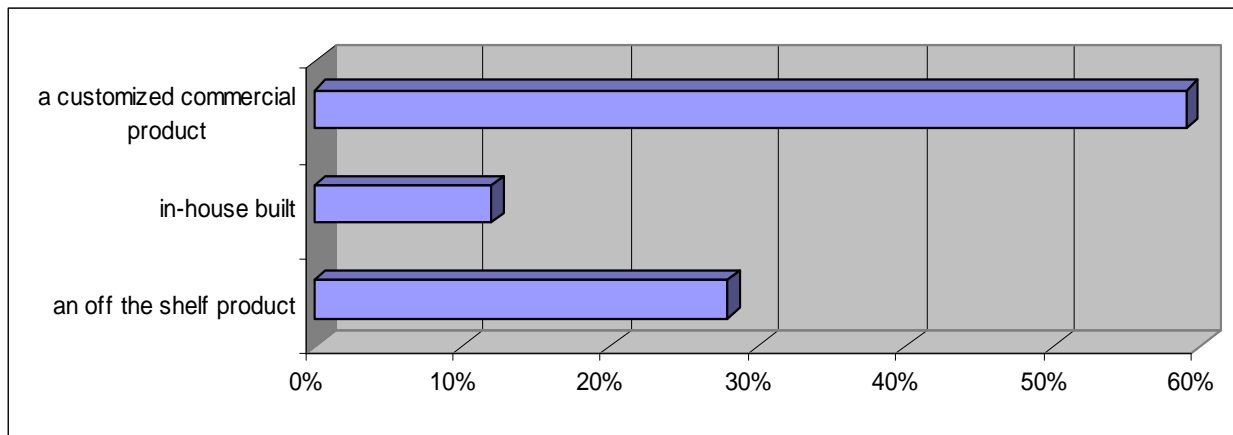


Figure 11: Is the coding application you use...(N = 32)

- **Auto-coding algorithms/auto-coding features:**
- **Vast majority of companies use an auto-coding feature and / or auto-coding algorithm during the coding process**

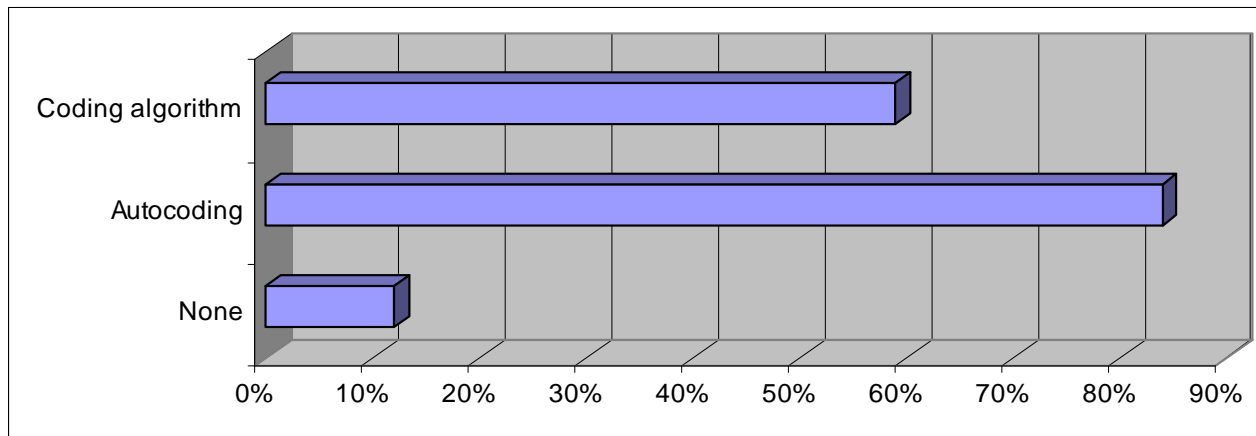


Figure 12: Do you use an auto-coder and a coding algorithm for automated coding?  
(Multiple responses possible) (N = 32)



- **Background**

- **Survey Results**

- **General Coding Approach/Coding Targets**

- **Technical Coding Environment**

- **Version Control/Legacy Data**

- **Summary**

- **Conclusions**

- **Recoding of data for ongoing clinical studies after MedDRA/WHO-DD version updates:**
- **2/3 of the companies recode data of ongoing studies after a new MedDRA/WHO-DD version has been released**

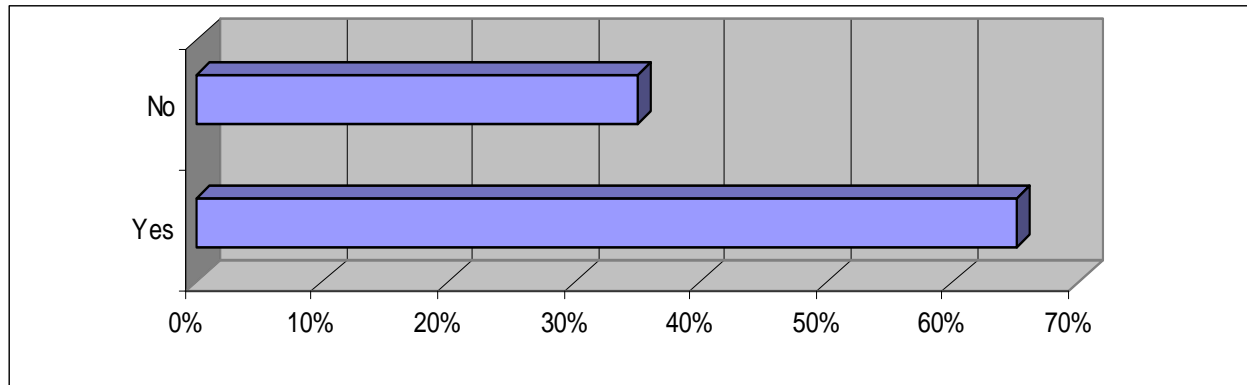


Figure 13: For ongoing studies, do you recode already coded data to the newest MedDRA and/or WHO-DD version? (N = 26)

- **Recoding of data for completed clinical studies after MedDRA/WHO-DD version updates:**
- **2/3 of the companies do not recode data for already completed studies after a new MedDRA/WHO-DD version has been released**

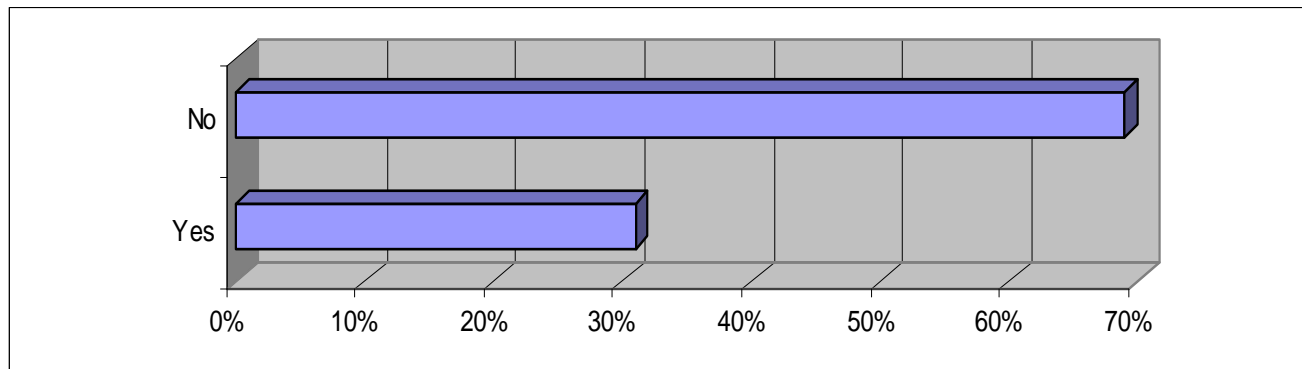


Figure 14: For legacy data, do you recode completed studies with every new version of MedDRA and/or WHO-DD? (N = 26)

- **Recoding of data in the Drug Safety database after MedDRA/WHO-DD version updates:**
- **Most companies recode the data of their Drug Safety databases to the latest versions**

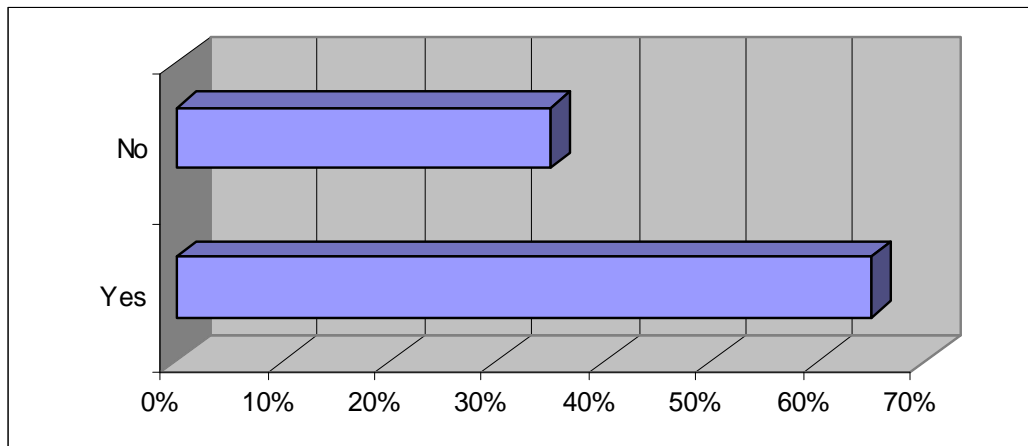


Figure 15: For the Drug Safety database, do you recode the data with every new version of MedDRA and/or WHO-DD? (N = 20)



- **Background**

- **Survey Results**

- **General Coding Approach/Coding Targets**

- **Technical Coding Environment**

- **Version Control/Legacy Data**

- **Summary**

- **Conclusions**

- **Most companies still work with separate coding groups for clinical studies and Drugs Safety or**
- **Have only one in-house coding group for either of these functions and outsource the other part**
- **Potential divergence of coding approaches is accounted for by cross-functional application of the same coding conventions and use of synonym lists**



- **Background**

- **Survey Results**

- **General Coding Approach/Coding Targets**

- **Technical Coding Environment**

- **Version Control/Legacy Data**

- **Summary**

- **Conclusions**

## Consequences of the separation of coding units:

- **Maximum flexibility and optimal accommodation of local demands, close cooperation with customers**
- **Higher resource needs, potential under-utilisation of resources, dilution of clear accountability**
- **High training and communication effort**
- **Need for more than one technical platform**
  - **Synchronisation of new dictionary versions, synonym lists and changes of the auto-coding algorithms necessary**
  - **Increase of purely administrative tasks**
  - **Decrease of the overall efficiency of the function**
- **Hinders the globally consistent application of coding standards**

## Consequences of the centralisation of the coding units:

- **Endorses global implementation, maintenance and usage of coding standards and processes**
- **Enables more efficient usage of available coding resources**
  - **Avoids overlaps/ redundancies in functions, roles and individual responsibilities**
  - **Establishes clear accountability**
- **Facilitates training and communication, supports rapid decision making and consistent transmission of decisions throughout the group**
- **Enables to build strong individual coding expertise on the basis of high coding turn-over rates**
- **Less diverse working environment for coding staff**
- **Loss of proximity to the customers**



# Discussion

**Contact Details:  
Martina.Viell@bayer.com**