


MedDRA in a CRO's World - Challenges and Experiences

Petra Barth


Lead Safety Manager

PRA International, Mannheim, Germany

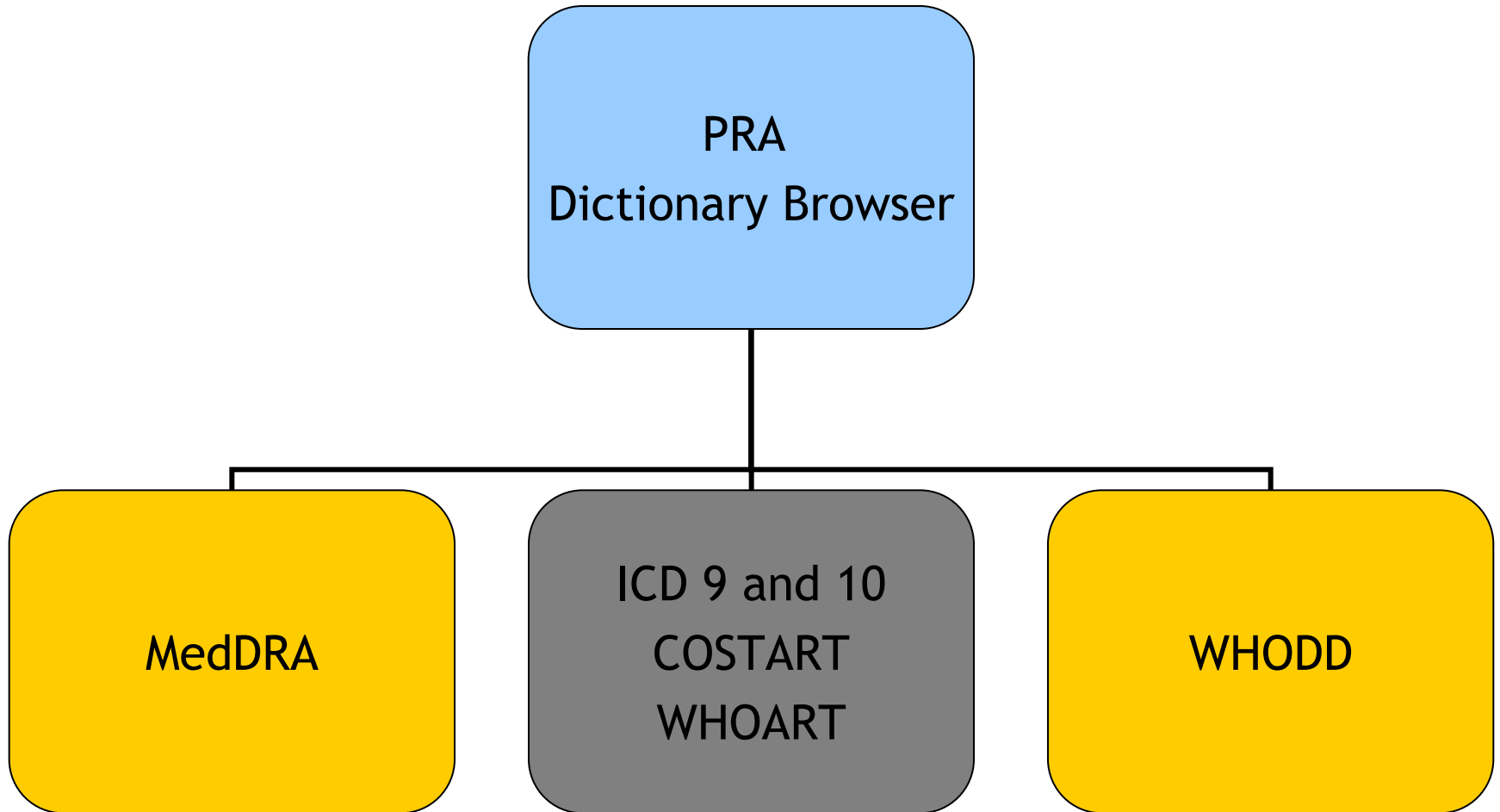
Monte Carlo March 11th, 2010

- PRA and its Tools
 - CRO specific Challenges
 - PRA's experiences
 - Coding and Data Quality
 - Trends and Development
 - Use of MSSO Services
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PRA and its Tools

- Global CRO (> 3,000 employees)
 - Services for all phases of clinical development (> 2,100 clinical trials in more than 60 countries on 5 continents)
 - Dictionary licenses (MedDRA 1999)
 - Dictionary Browser (1998)
 - Coding Tool (1998)
 - Centralisation of coding (2005)
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PRA's Dictionary Browser



PRA's Coding Tool

- Add-on to PRA clinical database system
- Principle: unique terms -> master table
- Functionalities:
 - ✓ master/slave protocols
 - ✓ splits
 - ✓ dictionary versioning
 - ✓ reports

PRA's Coding Tool (cont'd)

PRA Coding Tool

DASOLMESOLMCHF / DL40

Set Up

Pull New Batch

Find/Update Codes

Run Reports

Change Algorithm

Truncate Table

Purge Master

Update SOC/ATC

Exit

PRA's Coding Tool (cont'd)

PRA Coding Tool [X]

Set Up

Protocol /

| Key Description | Table Name | Verbatim Field | Dictionary | Master Protocol | ATC Code | Body System Code |
|-----------------|------------|----------------|-----------------------|-----------------|----------|------------------|
| EVENTS | AE | AEEVENT | PRAMEDDRA121_15OC | | No | Yes |
| MEDICATION | CON COL | CMNAME | PRAWHODRUG2009MAR01DD | | Yes | No |
| HISTORY | MH | MHXDESC | PRAMEDDRA121_15OC | | No | Yes |
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PRA's Coding Tool (cont'd)

PRA Coding Tool [X]

Pull New Batch

Key HISTORY

| Verbatim | Code | Translation |
|------------------------|------|-------------|
| CORANARY HEART DISEASE | | |

Record #

Dictionary

| Term | Code |
|---|----------|
| <u>Coronary artery disease aggravated</u> | 10048560 |
| Coronary artery disease aggravat. | 10048378 |
| Coronary artery disease progression | 10066521 |
| Coronary heart disease | 10068617 |
| Coronary artery disease | 10011078 |

CRO Challenges

- Different CLIENTS
 - ‘big pharma’ vs. ‘small biotech’
- Different PROJECTS
 - Data Management
 - Drug Safety
 - Data Integration
- Different DATABASE SYSTEMS

PRA's Experiences

Standard vs. Customised Dictionary

standard MedDRA

- Global acceptance including authorities
- Change requests
- Browser

client customised

- Flexibility
- Control

*alternative
company thesaurus*



PRA's Experiences (cont'd)

Splitting vs. Lumping

- diagnosis with signs/symptoms -> NO SPLIT
- provisional diagnosis with signs/symptoms -> NO SPLIT
- surgeries with underlying condition -> NO SPLIT
- equivalent terms -> SPLIT
- Vomiting due to DRUG

medical condition itself (overall approach)

vs. LLT Adverse drug reaction (exception)

alternative split



Queries for certain records usually not accepted as

➤ **Medical History:**

study indication

➤ **Adverse Events:**

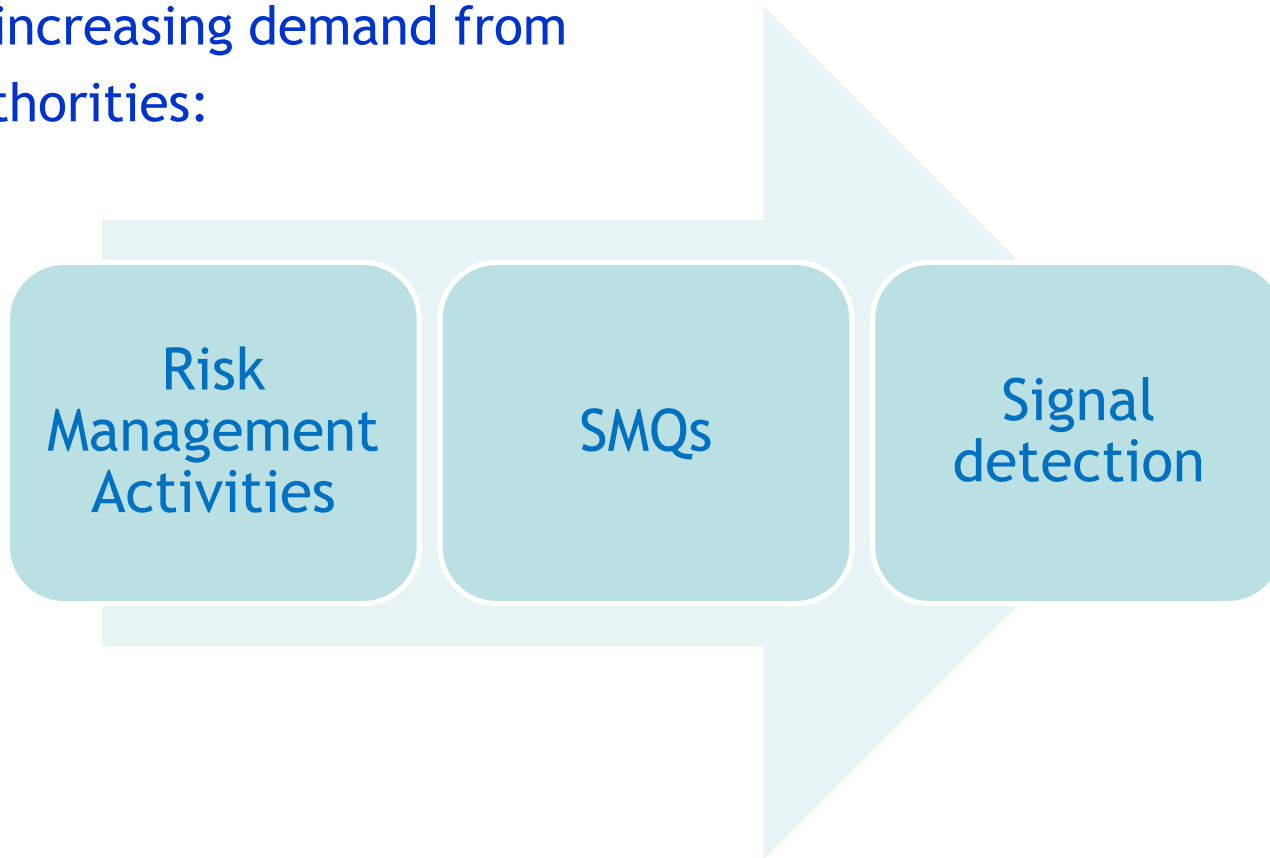
worsening of study indication, worsening of pre-existing conditions, surgeries / procedures, abnormal findings including lab values, investigations, diagnostic procedures, congenital conditions, social circumstances, provisional diagnoses, death

Data Integration

Requires close collaboration between coder and programmer with special attention on

- File structure
- Upload procedure
- Content of datasets
- Characteristics of coding tool
- Quality of previous coding
- Focus of analysis

Based on increasing demand from health authorities:



Use of MSSO Services

- **Official MedDRA Browsers**
to be used soon, but no decision yet whether web based and/or desktop browser
- **Training Sessions**
so far only little use due to limited application, added value vs. costs consideration (including travel)
- **Certified MedDRA Coder**
is it already or will it become a selling factor?

Thank You!

- Questions?
- Comments?
- Remarks?
- Ideas?
- Suggestions?

