



MedDRA

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Aventis experience in recoding
Safety data with MedDRA

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Last year in Nice...

Recoding approach of Pharmacovigilance data with MedDRA

- ➔ **Introduction**
- ➔ **RPR Pharmacovigilance environment**
- ➔ **Issues faced**
- ➔ **Strategy developed**
- ➔ **Conclusion**

Pharm Vig environment

➤ Databases

- RPR: in-house DB since 1995
- HMR: ClinTrace

➤ Terminologies

- RPR: Whoart & Costart for AEs
ICD9-CM for diseases and indications
- HMR: HARTS for AEs
ICD9, ICD9-CM, ICD10 for diseases and

indications

Pharm Vig environment ctd

➤ Terminology maintenance

- RPR : internal maintenance / dictionary specialists
coding via in-house synonyms (7 500)
- HMR : internal maintenance / dictionary specialists
coding via in-house synonyms (as many as
verbatimims)

Strategy developed

➤ **RPR recoding strategy**

- all PV data, no priority
- AE : from synonym excepted when « no appropriate term » or « reaction unevaluable »
- Indication & Disease : from verbatim
- before the database transfer

➤ **HMR recoding strategy**

- all PV data, no priority
- AE, Indic & Disease : from verbatim (refer to assigned codes when needed)

Coding steps (RPR)

➤ **Coding rules**

Coding conventions (11)

- site / event
- site / cancer type

➤ **Coding level (target)**

Coding with LLT

➤ **MedDRA version**

Same version all project long

Coding steps (RPR) ctd

- **Autoencoding**

 - Algorithm (external)

 - Score from 0 to 100

- **Manual checking**

 - Manual recoding with more accurate LLT
if necessary

- **Final validation**

 - Approved or sent back for modification

Autoencoding score* (RPR)

➤ Adverse events

9 600 rows : 57%

8 100 syn. : 61%

1 500 verb. : 36%

➤ Diseases

6 500 rows : 57%

➤ Indications

8 000 rows : 44%

* : means coding not modified after autoencoding

Some difficulties... (RPR)

- **Translation issues** \mapsto go to original AE
 - burn / burning
 - facial zona
 - gastric acidity
- **Ambiguous synonyms** \mapsto define a rule
 - occlusion syndrome (intestinal obstruction)
 - congestion head (rhinitis)
- **Other**
 - 2 medical concept in 1 AE \mapsto split
 - uncodable AE \mapsto use « ill-defined disorder NOS »

Results (RPR)

➤ **Profile : BS distribution differs**

Classification of data in other SOC's

➤ **Accuracy -**

- prophylaxis for indications
- burning, cramps, edema, laceration for AEs (site)

↳ need to ask for LLT creation

Results (RPR) ctd

➤ Accuracy +

ex : EI «no appropriate term» : 177 rows / 229 AEs

73 AE with LLT « no appropriate reaction »

8 AE « ill-defined disorder NOS »

classified in 19 SOCs with MedDRA

General disorders & admin 42%

Surgical & medical proced 23%

Injury & poisoning 10%

(Other SOCs < 3% each)

Product X : Whoart BS

	% AE	Nb AE
PLATELET BLEEDING AND CLOTTING	18	2215
VASCULAR (EXTRACARDIAC) DISORDERS	14	1736
BODY AS A WHOLE-GENERAL DISORDERS	9	1157
RESPIRATORY SYSTEM DISORDERS	8	943
GASTRO-INTESTINAL SYSTEM DISORDER	6	794

(total : 12 382 AEs / 4 733 syn)

Product X : MedDRA SOCs

	% AE	Nb AE
GENERAL DISORDERS & ADMINISTRATION SITE CONDITIONS	18	2199
VASCULAR DISORDERS	17	2053
CARDIAC DISORDERS	10	1208
INVESTIGATIONS	8	1040
BLOOD & LYMPHATIC SYSTEM DISORDERS	8	956

(total : 12 382 AEs / 4 733 syn)

Whoart « Platelet bleeding & clotting »

MedDRA SOCs	n=2215
Vascular disorders	42 %
Blood and lymphatic system disorders	33 %
Investigations	11 %
Skin & subcutaneous tissue disorders	8 %
Gastrointestinal disorders	3 %
Injury and poisoning	2 %
General disorders and administrat	1 %
Other (Renal, Cardiac, Congenital, Eye, Nervous)	< 1 % each

Whoart « Vascular (extracardiac) dis. »

MedDRA SOCs	n=1736
Vascular disorders	50 %
General disorders and administration	32 %
Nervous system disorders	9 %
Surgical & medical procedures	6 %
Injury and poisoning	1 %
Other (Gastrointestinal, Skin, Hepato-biliary, Congenital, Cardiac, Investigations, Renal, Respiratory, Neoplasms)	< 1% each

Conclusion

- Project needs to be prepared for a long time
- Adapt strategy according to specificities (database, coding, data)
- Once data are converted / recoded, think ...

...MedDRA