

# **Best practices for ATC coding - from CRF design to authority submission**

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# Outline

- Why best practices?
- Best practice: "ATC coding"
  - Methodology
- CRF-design
- Authority submission

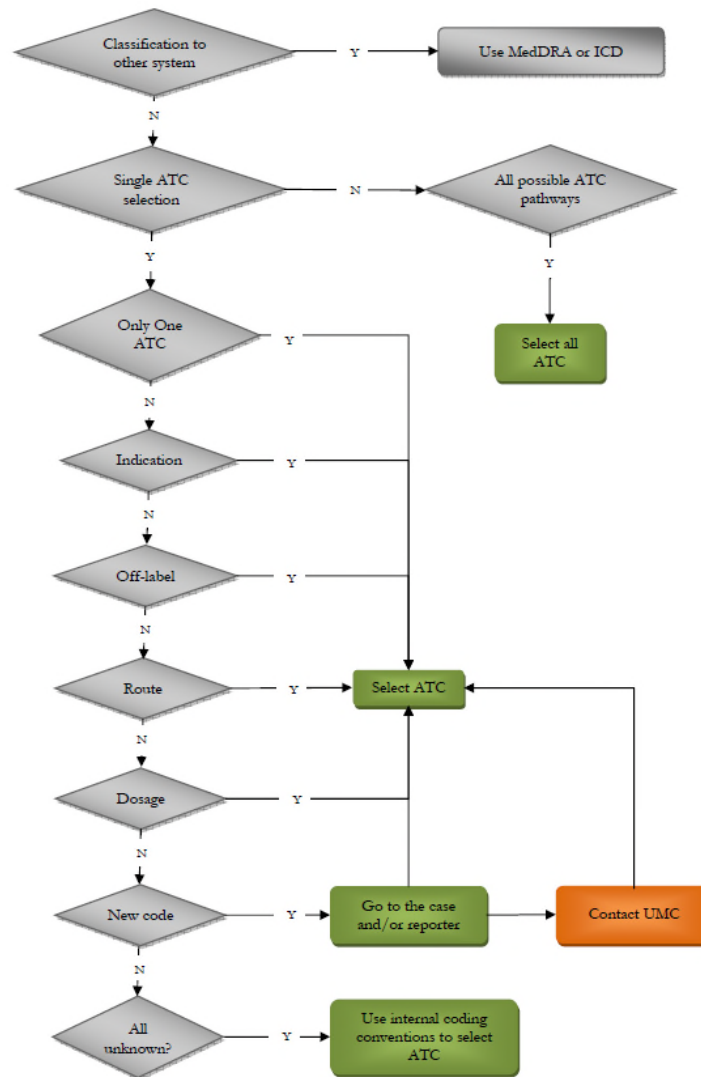
# Why Best Practices?

- Coding conventions are important for
  - Coding accuracy
  - Consistency
  - Efficiency
  - Reduce number of queries
- The Best Practices assist in creation of internal coding conventions
- The Best practices contribute to common conventions across industry

# Available Best Practices

- Non-unique names
- Missing Drugs
- Medication classification
- Next: upversioning

# Best practice procedures



# **MEDICATION CLASSIFICATION (ATC CODING)**

# Focus:

## Four (recommended) methods

1. All possible ATC pathway
2. Single ATC selection
3. Classification to system other than ATC
4. No classification

# Single ATC selection



a. Only one ATC code available?

Choose the available ATC code

## b. Is indication available?

Product Name: **Acetylsalicylic acid**

Medicinal Product ID: **1066**

Drug Code: **00002701001**

ATC code(s): **A01AD Other agents for local oral treatment *official***

**B01AC Platelet aggregation inhibitors excl. heparin *official***

**M02AC Preparations with salicylic acid derivatives**

**N02BA Salicylic acid and derivatives *official***

Local pain  
(mouth)

Stroke  
prevention

Inflammation

Pain

## c. Is route of administration available?

Product Name:

**Aciclovir**

Medicinal Product ID:

**32485**

Drug Code:

**00587301001**

Topical

Systemic

ATC code(s):

D06BB Antivirals *official*

J05AB Nucleosides and nucleotides excl. reverse transcriptase inhibitors *official*

S01AD Antivirals *official*

Ophthalmic

## d. Is dosage available?

Product Name:

**Finasteride**

Medicinal Product ID:

**43876**

Drug Code:

**01130001001**

ATC code(s):

D11AX Other dermatologicals *official*

G04CB Testosterone-5-alpha reductase inhibitors *official*

1 mg/day

5 mg/day

# All possible ATC pathway

Always choose all available ATC codes, either automatically if possible, or manually.

# Classification to system other than ATC

Use other system  
better suited for  
indications, for  
example MedDRA or  
ICD

# No classification

Classify drugs of interest when needed - not included in coding process

- Use ATC
- Use Standardised Drug Groupings
- Use Customised Drug Groupings

**Conclusion: selection of classification method affects what is needed on CRF, to reduce number of queries**



# Authority submission

# Authority submission

<b>NERVOUS SYSTEM</b>	<b>17 ( 65.4)</b>	<b>14 ( 66.7)</b>	<b>23 ( 76.7)</b>	<b>25 ( 86.2)</b>	<b>79 ( 74.5)</b>
<b>PSYCHOLEPTICS</b>	<b>7 ( 26.9)</b>	<b>9 ( 42.9)</b>	<b>17 ( 56.7)</b>	<b>14 ( 48.3)</b>	<b>47 ( 44.3)</b>
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b>	<b>2 ( 7.7)</b>	<b>4 ( 19.0)</b>	<b>6 ( 20.0)</b>	<b>6 ( 20.7)</b>	<b>18 ( 17.0)</b>
<b>ZOLPIDEN TARTRATE</b>	<b>2 ( 7.7)</b>	<b>2 ( 9.5)</b>	<b>2 ( 6.7)</b>	<b>2 ( 6.9)</b>	<b>8 ( 7.5)</b>
<b>LORAZEPAM</b>	<b>1 ( 3.8)</b>	<b>0</b>	<b>3 ( 10.0)</b>	<b>3 ( 10.3)</b>	<b>7 ( 6.6)</b>
<b>ZOPICLONE</b>	<b>1 ( 3.8)</b>	<b>1 ( 4.8)</b>	<b>3 ( 10.0)</b>	<b>1 ( 3.4)</b>	<b>6 ( 5.7)</b>
<b>ALPRAZOLAM</b>	<b>1 ( 3.8)</b>	<b>2 ( 9.5)</b>	<b>0</b>	<b>2 ( 6.9)</b>	<b>5 ( 4.7)</b>
<b>CLONAZEPAM</b>	<b>1 ( 3.8)</b>	<b>2 ( 9.5)</b>	<b>1 ( 3.3)</b>	<b>1 ( 3.4)</b>	<b>5 ( 4.7)</b>

# Authority submission

Any WHO Drug	23 (88.5)	19 (90.5)	29 (96.7)	29 (100)	100 (94.3)
IBUPROFEN	3 (11.5)	4 (19.0)	7 (23.3)	10 (34.5)	24 (22.6)
PARACETAMOL	4 (15.4)	4 (19.0)	10 (33.3)	6 (20.7)	24 (22.6)
DIPHENHYDRAMINE HYDROCHLORIDE	2 ( 7.7)	4 (19.0)	6 (20.0)	6 (20.7)	18 (17.0)
LOPERAMIDE HYDROCHLORIDE	2 ( 7.7)	2 ( 9.5)	3 (10.0)	7 (24.1)	14 (13.2)
EPOETIN ALFA	1 ( 3.8)	0	9 (30.0)	3 (10.3)	13 (12.3)
LISINAPRIL	2 ( 7.7)	3 (14.3)	3 (10.0)	5 (17.2)	13 (12.3)
MULTIVITAMINS	2 ( 7.7)	2 ( 9.5)	5 (16.7)	3 (10.3)	12 (11.3)
HYDROCORTISONE	0	1 ( 4.8)	1 ( 3.3)	8 (27.6)	10 ( 9.4)
PREPARATION H /01565701/	1 ( 3.8)	1 ( 4.8)	2 ( 6.7)	5 (17.2)	9 ( 8.5)
ACETYLSALICYLIC ACID	2 ( 7.7)	1 ( 4.8)	4 (13.3)	1 ( 3.4)	8 ( 7.5)
CETIRIZINE HYDROCHLORIDE	3 (11.5)	1 ( 4.8)	1 ( 3.3)	3 (10.3)	8 ( 7.5)
SERTRALINE HYDROCHLORIDE	1 ( 3.8)	1 ( 4.8)	3 (10.0)	3 (10.3)	8 ( 7.5)
ZOLPIDEM TARTRATE	2 ( 7.7)	2 ( 9.5)	2 ( 6.7)	2 ( 6.9)	8 ( 7.5)
DESLOMATADINE	0	1 ( 4.8)	4 (13.3)	2 ( 6.9)	7 ( 6.6)
HYDROCHLOROTHIAZIDE	1 ( 3.8)	2 ( 9.5)	2 ( 6.7)	2 ( 6.9)	7 ( 6.6)

# CDISC – SDTM

- All methods comply with SDTM standard
- CMCLAS field allows for single or multiple ATC codes
- CMCLAS field not obligatory (for concomitant medications)

# Summary

- Decide whole team together what and how it is to be analysed.
- Decide on methodology assessing pros and cons.
- Use your coders for input.
- Authorities are moving towards CDISC standard for submission – all described methods are compliant with the submission standard.

# Thank you!

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