PV Data Management

Magnus Wallberg

Uppsala, May 22, 2013



the UPPSALA MONITORING CENTRE

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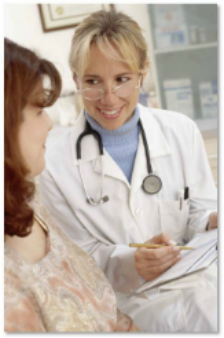
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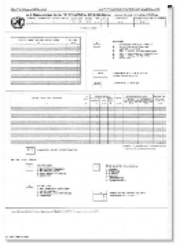


the UPPSALA MONITORING CENTRE

It all starts with the patient

The patient talks to her physician that fills out a case report on paper form that is sent to the Authority





The case report arrives at the authority...



... where it is piled up!

ADAC

Report of Suspected Adverse Drug Reaction including Birth Defects

224289

*(**Note:** Identities of Reporter, Patient and Institution will remain **Confidential**)*

Patient *(Initials or Record # only)*	Age	Sex	Weight	Height
[redacted] 05 DEC 2006	55	M	80	168

Adverse Reaction Description: DESC Date of Onset of Reaction: 29/11/06

PATIENT WITH A NON ST ELEVATION MI HAD DIAGNOSTIC ANGIOGRAM SHOWING SEVERE STENOSIS IN LAD. THE SAME DAY HAD PCI to LAD DURING WHICH EXPERIENCED PROFOUND AND SUSTAINED hypotension NOT BELIEVED with ARAMINE 6mg (several 0.5mg boluses) AND IABP. IMPROVED AFTER HYDROCORTISONE 200mg + PHENERGAN GIVEN. ??ALERGIC REACTION to CONTRAST (ISOVUE 370)

All Drug Therapy Prior to Reaction Asterisk Suspected Drug(s) *(please use trade names)*	Daily Dosage and Route	Date Begun	Date Stopped	Reason for Use
ASPIRIN	300mg O	29/11/06	—	NSTEMI
clopidogrel	300mg LOADING DOSE	29/11/06	—	NSTEMI
TEMAZEPAM	10mg	29/11/06		SEDATION
TIROFIBAN	IV BOLUS THEN INFUSION	29/11/06	29/11/06	NSTEMI
MIDAZOLAM	2mg IV	29/11/06	29/11/06	SEDATION
OMNIPAQUE	90 ml IC	29/11/06	29/11/06	ANGIOGRAM
ISOVUE 370		29/11/06	29/11/06	ANGIOGRAM

Treatment *(of reaction)*: ARAMINE, HYDROCORTISONE PHENERGAN

Outcome: Recovered ☒ Not Yet Recovered ☐ Unknown ☐ Fatal ☐ Date of Death / /

Sequelae: No ☒ Yes ☐ *(describe)* MYOCARDIAL INFARCTION

Comments *(eg. relevant history, allergies, previous exposure to this drug)*:

NO KNOWN ALERGIES before the episode. HAD ANGIOGRAM IN ANOTHER HOSPITAL. then PCI SAME DAY. REACTION DURING PCI.

POSS

Reporting Doctor, Pharmacist, etc:

Name: [redacted]

Address: [redacted]

Signature [redacted] 30/11/06

The case report arrives at the authority...



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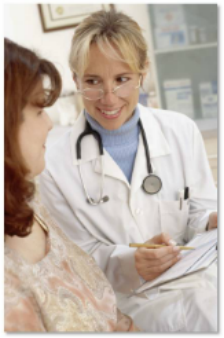

PROVINCE : MIDLANDS
DISTRICT : KWEKWE SHURUGWI
H1N1 VACCINE FORMS
COMPLETED FORMS : 2532 + 190
PROVINCE : HARARE
DISTRICT : NORTHERN, WESTERN, SOUTHERN
H1N1 VACCINE FORMS
COMPLETED : 3527
PROVINCE : MASVINGO
DISTRICT : CHIREDZI
H1N1 VACCINE FORMS
COMPLETED FORMS : 2600
PROVINCE : MIDLANDS
DISTRICT : SHURUGWI
H1N1 VACCINE FORMS
COMPLETED FORMS : 3097
PROVINCE : MASH. WEST
DISTRICT : KARIBA
H1N1 VACCINE FORMS
COMPLETED FORMS : 4190
PROVINCE : MASH EAST
DISTRICT : CHIMANIMANI
COMPLETED FORMS : 4000
H1N1 VACCINE FORMS
PROVINCE : MASH. CENT
DISTRICT :
H1N1 VACCINE FORMS
COMPLETED : 4-200
PROVINCE : MANICALAND
DISTRICT :
COMPLETED : 4100
H1N1 VACCINE FORMS
PROVINCE : HARARE
DISTRICT : WESTERN
H1N1 VACCINES FORMS
4600
PROVINCE : MANICALAND
DISTRICT :
H1N1 VACCINE FORMS
COMPLETED FORMS : 4-100
PROVINCE : MASH EAST
DISTRICT : MUTOKO
H1N1 VACCINE FORMS
COMPLETED : 3095
PROVINCE : HARARE
DISTRICT : DZIVARASEKWA
H1N1 VACCINE FORMS
COMPLETED : 2190
PROVINCE : MASH. WEST
DISTRICT : KADOMA
H1N1 VACCINE FORMS
COMPLETED : 4200
PROVINCE : MASVINGO
DISTRICT : ZAKA
H1N1 VACCINE FORM
COMPLETED : 4069 FORMS
PROVINCE : HARARE
DISTRICT : HIGHFIELD, MATAPOS
H1N1 VACCINE FORMS
COMPLETED : 3050 + 523
PROVINCE : MASVINGO
DISTRICT : CHIVI
H1N1 VACCINE FORMS
COMPLETED : 4209 FORMS
PROVINCE : MIDLANDS
DISTRICT : GWERU
H1N1 VACCINE FORMS
COMPLETED : 4050 FORMS
PROVINCE : MANICALAND
DISTRICT :
H1N1 VACCINE FORMS
COMPLETED FORMS : 11700
PROVINCE : MASVINGO
DISTRICT : CHIREDZI
H1N1 VACCINE FORMS
COMPLETED FORMS : 4760
PROVINCE : MAT NORTH
DISTRICT : BULUWAYO
H1N1 VACCINE FORMS
COMPLETED : 4920
PROVINCE : CHITUNGWIZA
DISTRICT : ST MARY'S
H1N1 VACCINE FORMS
COMPLETED FORMS : 3676
PROVINCE : MASH. EAST
DISTRICT : MARONDERA
H1N1 VACCINE FORMS
COMPLETED FORMS : 4300
PROVINCE : MASH. WEST
DISTRICT : CHEGUTU
H1N1 VACCINE FORMS
COMPLETED FORMS : 3700
PROVINCE : MASH. EAST
DISTRICT : MARONDERA, CHIKOMBA, MUDZI, MUTOKO, TAKAWIRA
H1N1 VACCINE FORMS
COMPLETED FORMS : 4000
PROVINCE : MIDLANDS
DISTRICT : GOKWE NORTH
H1N1 VACCINE FORMS
COMPLETED & ENTERED FORMS : 4080 (EXCEL)
PROVINCE : MIDLANDS
DISTRICT : SHURUGWI
H1N1 VACCINE FORMS
COMPLETED & ENTERED FORMS : 4100 (EXCEL)
PROVINCE : MIDLANDS
DISTRICT : KWEKWE SHURUGWI
H1N1 VACCINE FORMS
COMPLETED FORMS : 4000
PROVINCE : HARARE
DISTRICT : HARARE SOUTHERN (EMBAKWE)
H1N1 VACCINE FORMS
COMPLETED FORMS : 4200
PROVINCE : MAT. SOUTH
DISTRICT :
H1N1 VACCINE FORMS
COMPLETED FORMS : 2700+ 1340
PROVINCE : MASH. EAST
DISTRICT : SEKE
H1N1 VACCINE FORMS
COMPLETED FORMS : 4500
PROVINCE : MASVINGO
DISTRICT : 40
COMPLETED FORMS : 4035
H1N1 FORMS COMPLETED
HARARE EAST H1N1 VACCINES FORMS 2168
MASVINGO CENTRAL H1N1 VACCINES COMPLETED FORMS 5500 FORMS
HARARE WESTERN H1N1 VACCINES FORMS
PRESV : MAT NORTH
DIST : [illegible] VACCINE FORMS
COMPLETE 3028 + 885

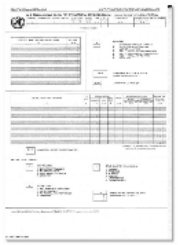
Pigeon Hole Method



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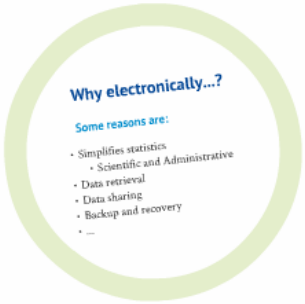




The case report arrives at the authority...



... where it is piled up!



We need to store our data electronically to manage it effectively

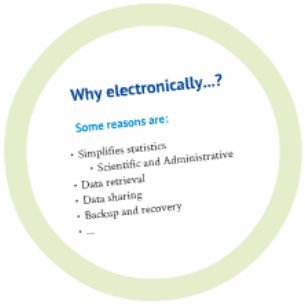
To store the data electronically is probably self evident for most of us...

...but not how!

Why electronically...?

Some reasons are:

- Simplifies statistics
  - Scientific and Administrative
- Data retrieval
- Data sharing
- Backup and recovery
- ...



We need to store our data electronically to manage it effectively

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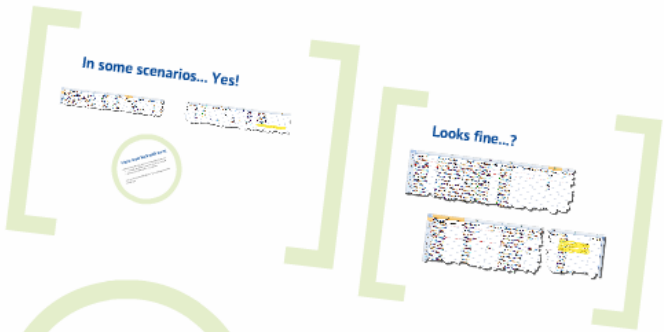
...but not how!

To store the data electronically is probably self evident for most of us...

...but not how!

What about using Excel...

Excel often comes up as the most obvious solution when structuring data... let us look at some of the pros and cons!

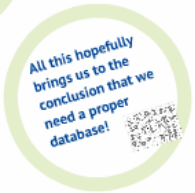




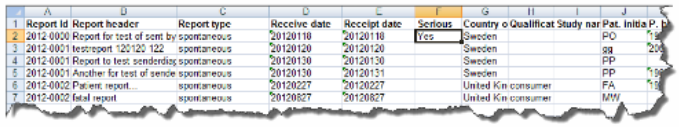




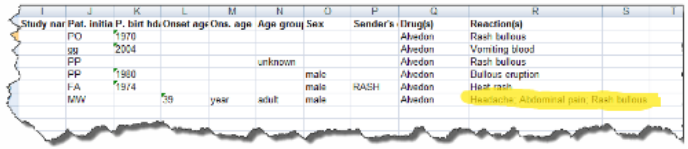




In some scenarios… Yes!



	A	B	C	D	E	F	G	H	I	J	K
1	Report Id	Report header	Report type	Receive date	Receipt date	Serious	Country o	Qualificat	Study nar	Pat. initia	P. b
2	2012-0000	Report for test of sent by	spontaneous	20120118	20120118	Yes	Sweden			PO	19
3	2012-0001	testreport 120120 122	spontaneous	20120120	20120120		Sweden			SB	200
4	2012-0001	Report to test senderdisp	spontaneous	20120130	20120130		Sweden			PP	
5	2012-0001	Another for test of sende	spontaneous	20120130	20120131		Sweden			PP	198
6	2012-0002	Patient, report…	spontaneous	20120227	20120227		United Kin	consumer		FA	19
7	2012-0002	fatal report	spontaneous	20120827	20120827		United Kin	consumer		MW	

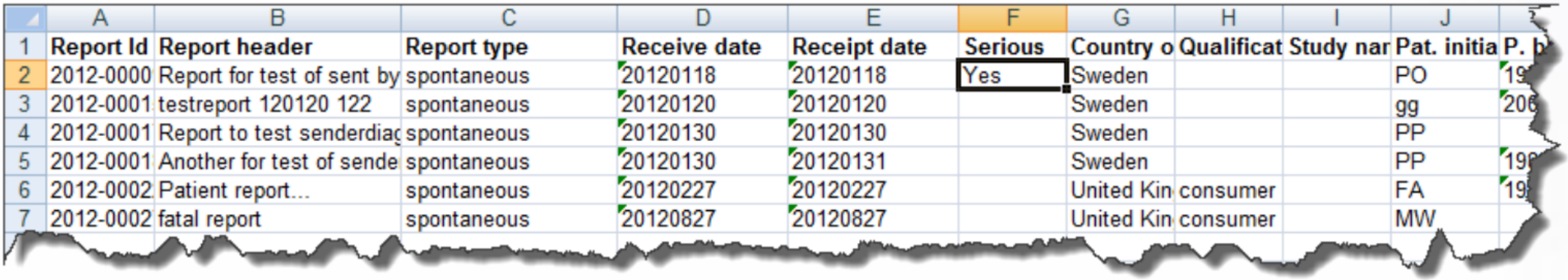


	I	J	K	L	M	N	O	P	Q	R	S	T
	Study nar	Pat. initia	P. birt hd	Onset age	Ons. age	Age grou	Sex	Sender's	Drug(s)	Reaction(s)		
		PO	1970						Alvedon	Rash bullous		
		SB	2004						Alvedon	Vomiting blood		
		PP				unknown			Alvedon	Rash bullous		
		PP	1980				male		Alvedon	Bullous eruption		
		FA	1974				male	RASH	Alvedon	Heat rash		
		MW		39	year	adult	male		Alvedon	Headache, Abdominal pain, Rash bullous		

Major draw back with Excel

Excel in its mostly used format has one row/case report
- Can use several but that mean that data is duplicated
- Sorting can not be done in a simple way

So… moving repeatable rows to a separate sheet might be the solution



	A	B	C	D	E	F	G	H	I	J	
1	**Report Id**	**Report header**	**Report type**	**Receive date**	**Receipt date**	**Serious**	**Country o**	**Qualificat**	**Study nar**	**Pat. initia**	**P. b**
2	2012-0000	Report for test of sent by	spontaneous	20120118	20120118	Yes	Sweden			PO	19
3	2012-0001	testreport 120120 122	spontaneous	20120120	20120120		Sweden			gg	206
4	2012-0001	Report to test senderdiag	spontaneous	20120130	20120130		Sweden			PP	
5	2012-0001	Another for test of sende	spontaneous	20120130	20120131		Sweden			PP	19
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I	J	K	L	M	N	O	P	Q	R	S	T
Study nar	Pat. initia	P. birt hd	Onset age	Ons. age	Age grou	Sex	Sender's	Drug(s)	Reaction(s)		
	PO	1970						Alvedon	Rash bullous		
	gg	2004						Alvedon	Vomiting blood		
	PP				unknown			Alvedon	Rash bullous		
	PP	1980				male		Alvedon	Bullous eruption		
	FA	1974				male	RASH	Alvedon	Heat rash		
	MW		39	year	adult	male		Alvedon	Headache; Abdominal pain; Rash bullous		

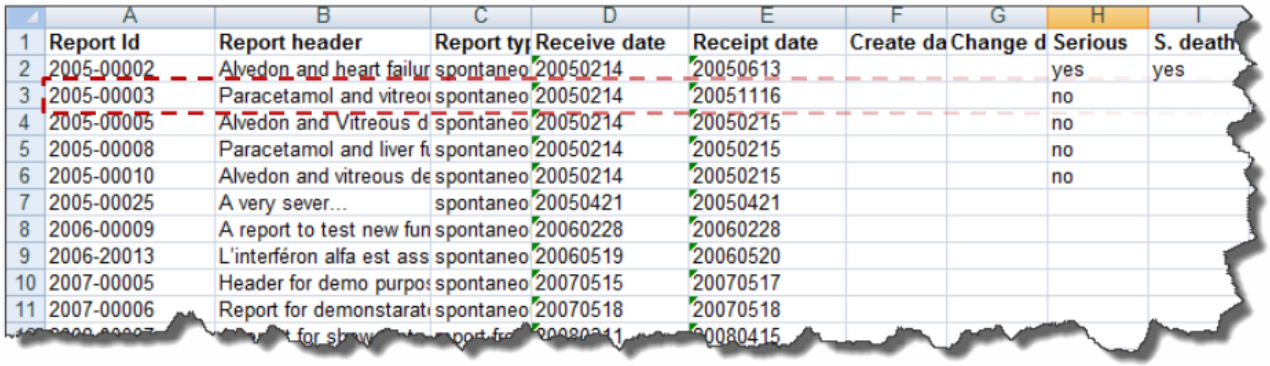
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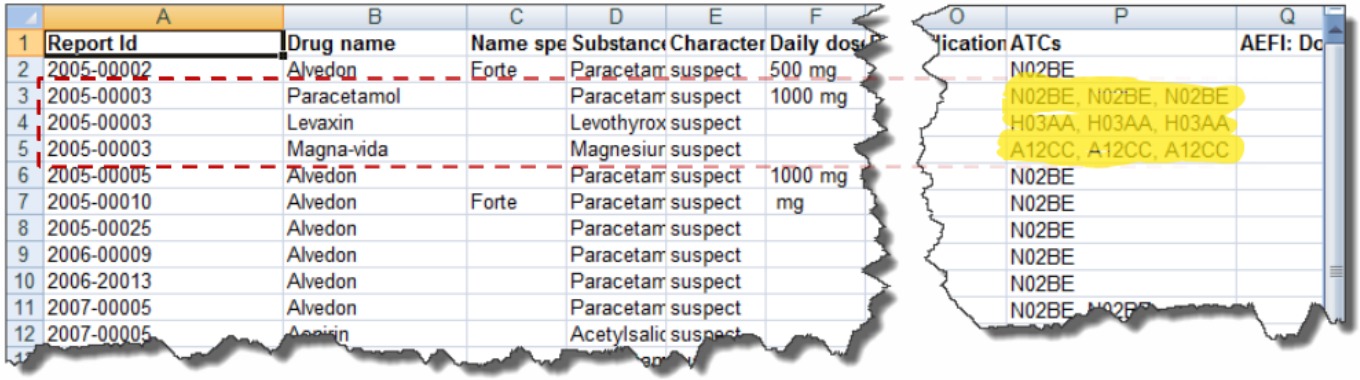
- Can use several but that mean that data is duplicated
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So... moving repeatable rows to a separate sheet might be the solution

Looks fine…?



	A	B	C	D	E	F	G	H	I
1	Report Id	Report header	Report ty	Receive date	Receipt date	Create da	Change d	Serious	S. death
2	2005-00002	Alvedon and heart failur	spontaneo	20050214	20050613			yes	yes
3	2005-00003	Paracetamol and vitreo	spontaneo	20050214	20051116			no	
4	2005-00005	Alvedon and Vitreous d	spontaneo	20050214	20050215			no	
5	2005-00008	Paracetamol and liver f	spontaneo	20050214	20050215			no	
6	2005-00010	Alvedon and vitreous de	spontaneo	20050214	20050215			no	
7	2005-00025	A very sever…	spontaneo	20050421	20050421				
8	2006-00009	A report to test new fun	spontaneo	20060228	20060228				
9	2006-20013	L'interféron alfa est ass	spontaneo	20060519	20060520				
10	2007-00005	Header for demo purpos	spontaneo	20070515	20070517				
11	2007-00006	Report for demonstarat	spontaneo	20070518	20070518				
		for sh	port fr		0080415				



	A	B	C	D	E	F	O	P	Q
1	Report Id	Drug name	Name spe	Substanc	Character	Daily dos	lication	ATCs	AEFI: Do
2	2005-00002	Alvedon	Forte	Paracetam	suspect	500 mg		N02BE	
3	2005-00003	Paracetamol		Paracetam	suspect	1000 mg		N02BE, N02BE, N02BE	
4	2005-00003	Levaxin		Levothyrox	suspect			H03AA, H03AA, H03AA	
5	2005-00003	Magna-vida		Magnesiur	suspect			A12CC, A12CC, A12CC	
6	2005-00005	Alvedon		Paracetam	suspect	1000 mg		N02BE	
7	2005-00010	Alvedon	Forte	Paracetam	suspect	mg		N02BE	
8	2005-00025	Alvedon		Paracetam	suspect			N02BE	
9	2006-00009	Alvedon		Paracetam	suspect			N02BE	
10	2006-20013	Alvedon		Paracetam	suspect			N02BE	
11	2007-00005	Alvedon		Paracetam	suspect			N02BE	
12	2007-00005	Aspirin		Acetylsalic	suspect			N02BE	

So...

Excel is not an entirely bad solution to store data!

- It is good when filtering and sorting data and it may be very good at presenting figures in graphs, charts and bars!
- Macros and functions can be powerful in working with the data, for example calculating values



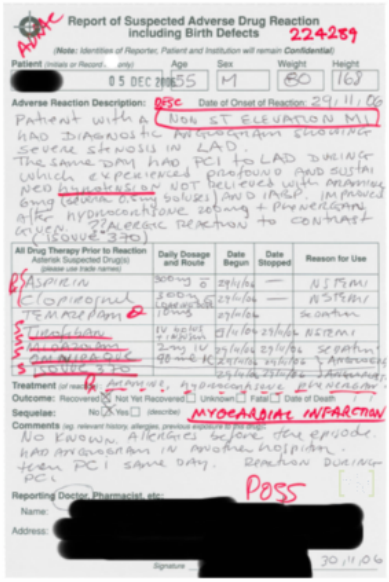


But as soon as the data is getting more complex Excel quickly becomes very hard to maintain...

The big problem in PV...

case reports ARE complex!!

Let us look at a case report in detail...



Report of Suspected Adverse Drug Reaction including Birth Defects 224289

(Note: Identities of Reporter, Patient and Institution will remain Confidential)

Patient (Initials or Record... only) [redacted] 05 DEC 2005 55 | Age | Sex M | Weight 80 | Height 168

Adverse Reaction Description: OESC Date of Onset of Reaction: 29/11/06

Patient with a NON ST ELEVATION MI had DIAGNOSTIC ANGIOGRAM 2006 SEVERE STENOSIS IN LAD. The same DAY had PCI to LAD DURING which experienced PROFOUND AND SUSTAINED hypotension NOT believed with MORPHINE 6mg (10ml 0.6mg SOLUTION) AND IMAGE. IMPROVED after HYDROCORTISONE 200mg + PROMETHAZINE GIVEN. 2ND ALLERGIC REACTION TO CONTRAST (ISOVUE-370)

All Drug Therapy Prior to Reaction Asterisk Suspected Drug(s) (please use trade names)	Daily Dosage and Route	Date Begun	Date Stopped	Reason for Use
ASPIRIN	300mg O	29/11/06	—	NSTEMI
CLOPIDOGREL	300mg O	29/11/06	—	NSTEMI
TEMAZEPAM	10MG	29/11/06		SEDATION
[illegible]	IV [illegible]	29/11/06	29/11/06	NSTEMI
[illegible]	2mg IV	29/11/06	29/11/06	SEDATION
[illegible]	90 ml IC	29/11/06	29/11/06	ANGIOGRAM
[illegible]	370	29/11/06	29/11/06	ANGIOGRAM

Treatment (of reaction): MORPHINE, HYDROCORTISONE, PROMETHAZINE

Outcome: Recovered [X] Not Yet Recovered [ ] Unknown [ ] Fatal [ ] Date of Death [ ]

Sequelae: No [X] Yes [ ] (describe) MYOCARDIAL INFARCTION

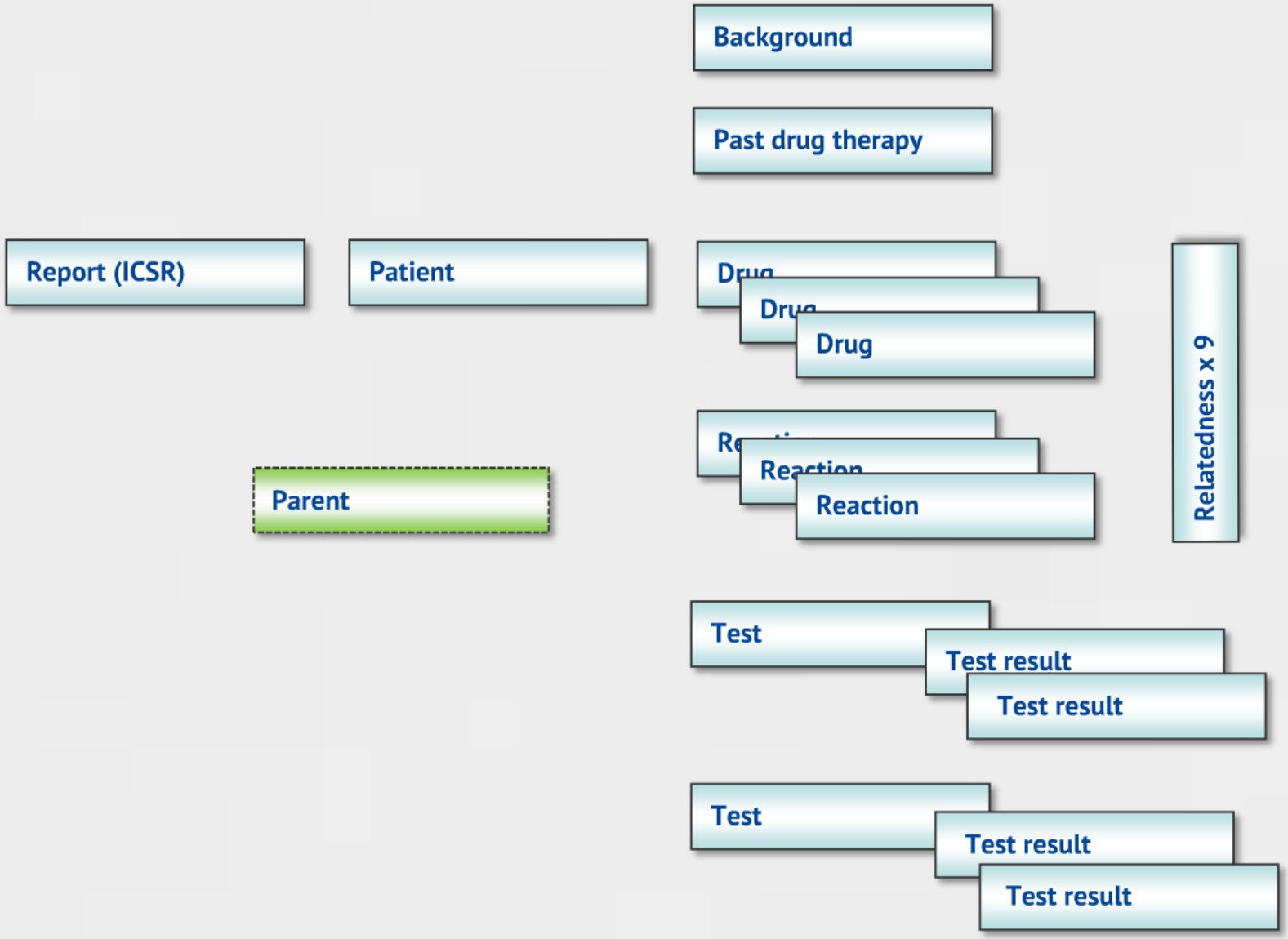
Comments (eg. relevant history, allergies, previous exposure to this drug): NO KNOWN ALLERGIES BEFORE THIS EPISODE. HAD ANGIOGRAM IN ANOTHER HOSPITAL. TEAM PCI SAME DAY. REACTION DURING PCI.

Reporting Doctor, Pharmacist, etc: POSS

Name: [redacted]

Address: [redacted]

Signature: [redacted] 30/11/06


Background
Past drug therapy
Report (ICSR)
Patient
Drug
Drug
Drug
Relatedness x 9
Reaction
Reaction
Reaction
Parent
Test
Test result
Test result
Test
Test result
Test result

Report of Suspected Adverse Drug Reaction including Birth Defects

ADRAC 224289

*(**Note:** Identities of Reporter, Patient and Institution will remain **Confidential**)*

Patient (Initials or Record No. only)	Age	Sex	Weight	Height
[redacted] 05 DEC 2006	55	M	80	168

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BS ASPIRIN	300mg O	29/11/06	—	NSTEMI
CLOPIDOGREL	300mg PO LOADING DOSE	29/11/06	—	NSTEMI
TEMAZEPAM O	10mg	29/11/06		SEDATION
S TIROFIBAN	IV BOLUS + INFUSION	29/11/06	29/11/06	NSTEMI
S MIDAZOLAM	2mg IV	29/11/06	29/11/06	SEDATION
S OMNIPAQUE	90 ml IC	29/11/06	29/11/06	ANGIOGRAM
S ISOVUE 370		29/11/06	29/11/06	ANGIOPLASTY

Treatment *(of reaction)*: ARAMINE, HYDROCORTISONE PHENERGAN

Outcome: Recovered ☒ Not Yet Recovered ☐ Unknown ☐ Fatal ☐ Date of Death / /

Sequelae: No ☒ Yes ☐ *(describe)* MYOCARDIAL INFARCTION

Comments *(eg. relevant history, allergies, previous exposure to this drug)*:

NO KNOWN ALERGIES before the episode. HAD ANGIOGRAM IN ANOTHER HOSPITAL. THEN PCI SAME DAY. REACTION DURING PCI.

POSS

Reporting Doctor, Pharmacist, etc:

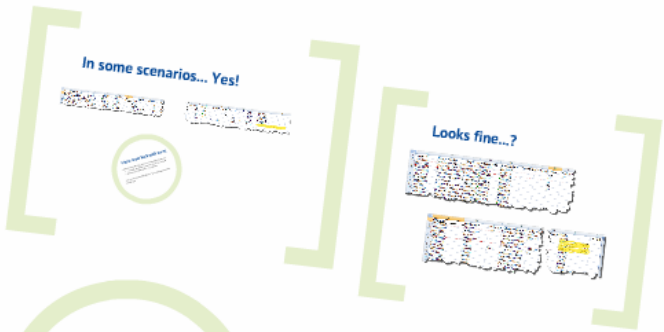
Name: [redacted]

Address: [redacted]

Signature [redacted] 30/11/06

What about using Excel...

Excel often comes up as the most obvious solution when structuring data... let us look at some of the pros and cons!

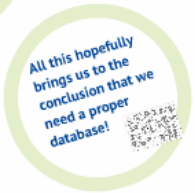










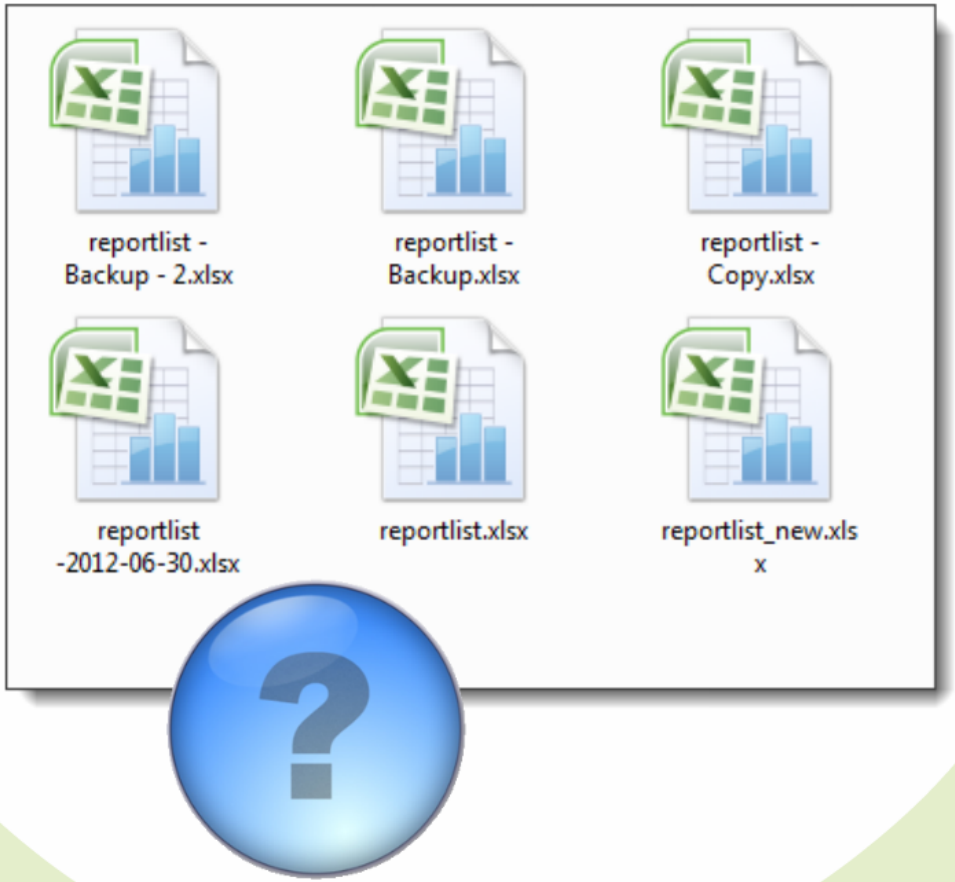


Yet another problem with Excel

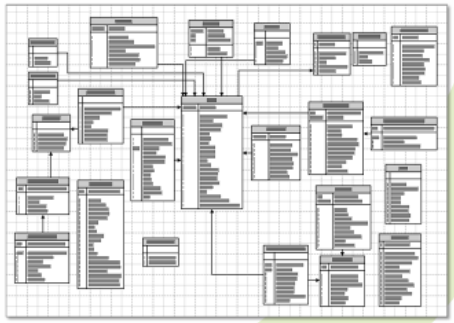
I	J	K	L	M	N	O	P	Q	R	S	T
Study nar	Pat. initia	P. birt hd	Onset age	Ons. age	Age grou	Sex	Sender's	Drug(s)	Reaction(s)		
	PO	1970						Alvedon	Rash bullous		
	gg	2004						Alvedon	Vomiting blood		
	PP				неизвестн			Alvedon	Rash bullous		
	PP	1980				мужской		Alvedon	Bullous eruption		
	FA	1974				мужской	RASH	Alvedon	Heat rash		
	MW		39	year	взрослый	мужской		Alvedon	Headache; Abdominal pain; Rash bullous		

	M	N	O	P	Q
ge	Ons. age	Age grou	Sex	Sender's	Drug(s)
					Alvedon
					Alvedon
		неизвестн			Alvedon
			мужской		Alvedon
			мужской	RASH	Alvedon
	year	взрослый	мужской		Alvedon

And more...


reportlist - Backup - 2.xlsx
reportlist - Backup.xlsx
reportlist - Copy.xlsx
reportlist -2012-06-30.xlsx
reportlist.xlsx
reportlist_new.xlsx

All this hopefully brings us to the conclusion that we need a proper database!




case
report

The PV database

The case report itself is only a small part of the minimum requirements on a PV database

WHO DDE

Sender

WHO-ART

SOC HLT PT IT

case report

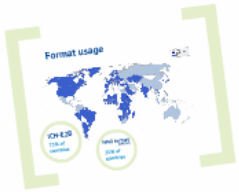
Receiver(s)

MedDRA® MSSO

Submission(s)

Reporting Formats







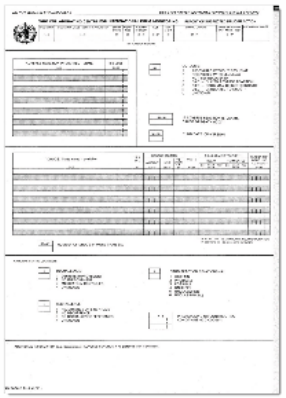


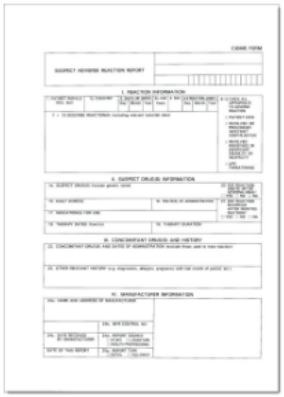


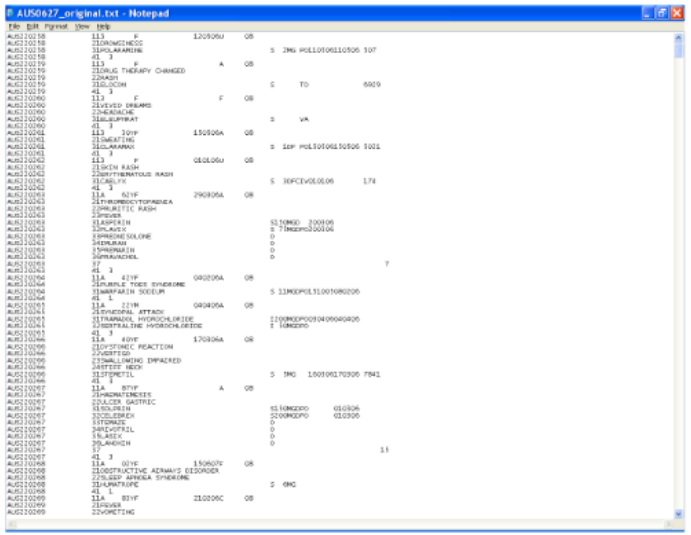


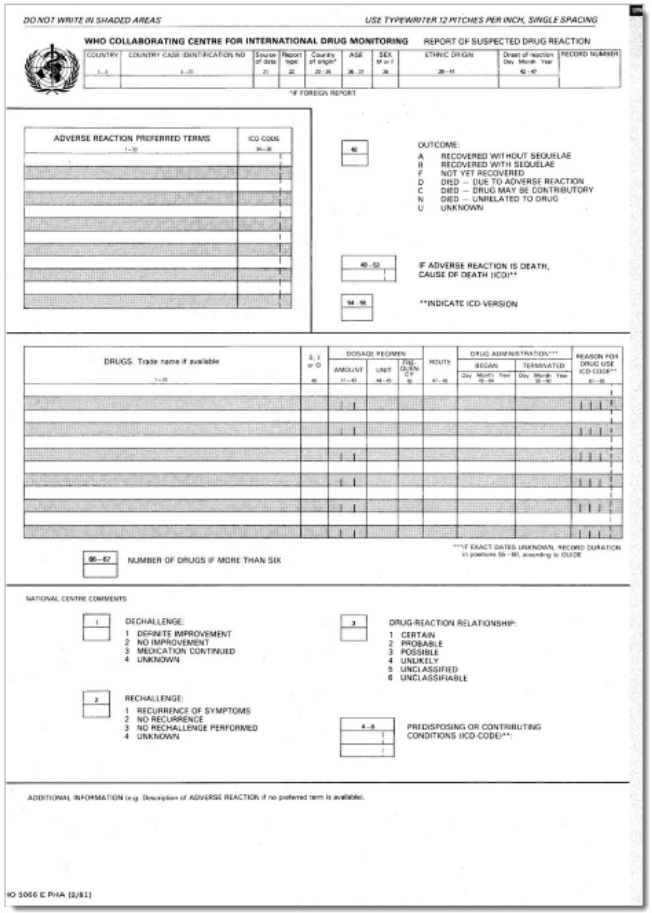
In the beginning there was darkness...

... and then came...









DO NOT WRITE IN SHADED AREAS — USE TYPEWRITER 12 PITCHES PER INCH, SINGLE SPACING

WHO COLLABORATING CENTRE FOR INTERNATIONAL DRUG MONITORING REPORT OF SUSPECTED DRUG REACTION

COUNTRY	COUNTRY CASE IDENTIFICATION NO	Source of data	Report type	Country of origin*	AGE	SEX M or F	ETHNIC ORIGIN	Onset of reaction Day Month Year	RECORD NUMBER
1–3	4–20	21	22	23–24	25–27	28	29–41	42–47	

*IF FOREIGN REPORT

ADVERSE REACTION PREFERRED TERMS 1–30	ICD CODE 34–38

40 — OUTCOME:
A RECOVERED WITHOUT SEQUELAE
B RECOVERED WITH SEQUELAE
F NOT YET RECOVERED
D DIED — DUE TO ADVERSE REACTION
C DIED — DRUG MAY BE CONTRIBUTORY
N DIED — UNRELATED TO DRUG
U UNKNOWN

49–50 — IF ADVERSE REACTION IS DEATH, CAUSE OF DEATH (ICD)**

51 — **INDICATE ICD-VERSION

DRUGS: Trade name if available 1–29	S, I or O 46	DOSAGE REGIMEN AMOUNT 47–43	DOSAGE REGIMEN UNIT 44–45	DOSAGE REGIMEN FREQUENCY 46	ROUTE 47–48	DRUG ADMINISTRATION*** BEGAN Day Month Year 49–54	DRUG ADMINISTRATION*** TERMINATED Day Month Year 55–60	REASON FOR DRUG USE ICD CODE** 61–65

***IF EXACT DATES UNKNOWN, RECORD DURATION in positions 59–60, according to GUIDE

66–67 — NUMBER OF DRUGS IF MORE THAN SIX

NATIONAL CENTRE COMMENTS

1 — DECHALLENGE:
1 DEFINITE IMPROVEMENT
2 NO IMPROVEMENT
3 MEDICATION CONTINUED
4 UNKNOWN

2 — RECHALLENGE:
1 RECURRENCE OF SYMPTOMS
2 NO RECURRENCE
3 NO RECHALLENGE PERFORMED
4 UNKNOWN

3 — DRUG-REACTION RELATIONSHIP:
1 CERTAIN
2 PROBABLE
3 POSSIBLE
4 UNLIKELY
5 UNCLASSIFIED
6 UNCLASSIFIABLE

4–5 — PREDISPOSING OR CONTRIBUTING CONDITIONS (ICD-CODE)**:

ADDITIONAL INFORMATION (e.g. Description of ADVERSE REACTION if no preferred term is available).

IO 5066 E PHA (2/81)

CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH Day Month Year	2a. AGE Years	3. SEX	4-6 REACTION ONSET Day Month Year	8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
						☐ PATIENT DIED ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION ☐ INVOLVED PERSISTENCE OR SIGNIFICANT DISABILITY OR INCAPACITY ☐ LIFE THREATENING

7 + 13. DESCRIBE REACTION(S) (including relevant tests/lab data)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)		20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA
15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION	21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA
17. INDICATION(S) FOR USE		
18. THERAPY DATES (from/to)	19. THERAPY DURATION	

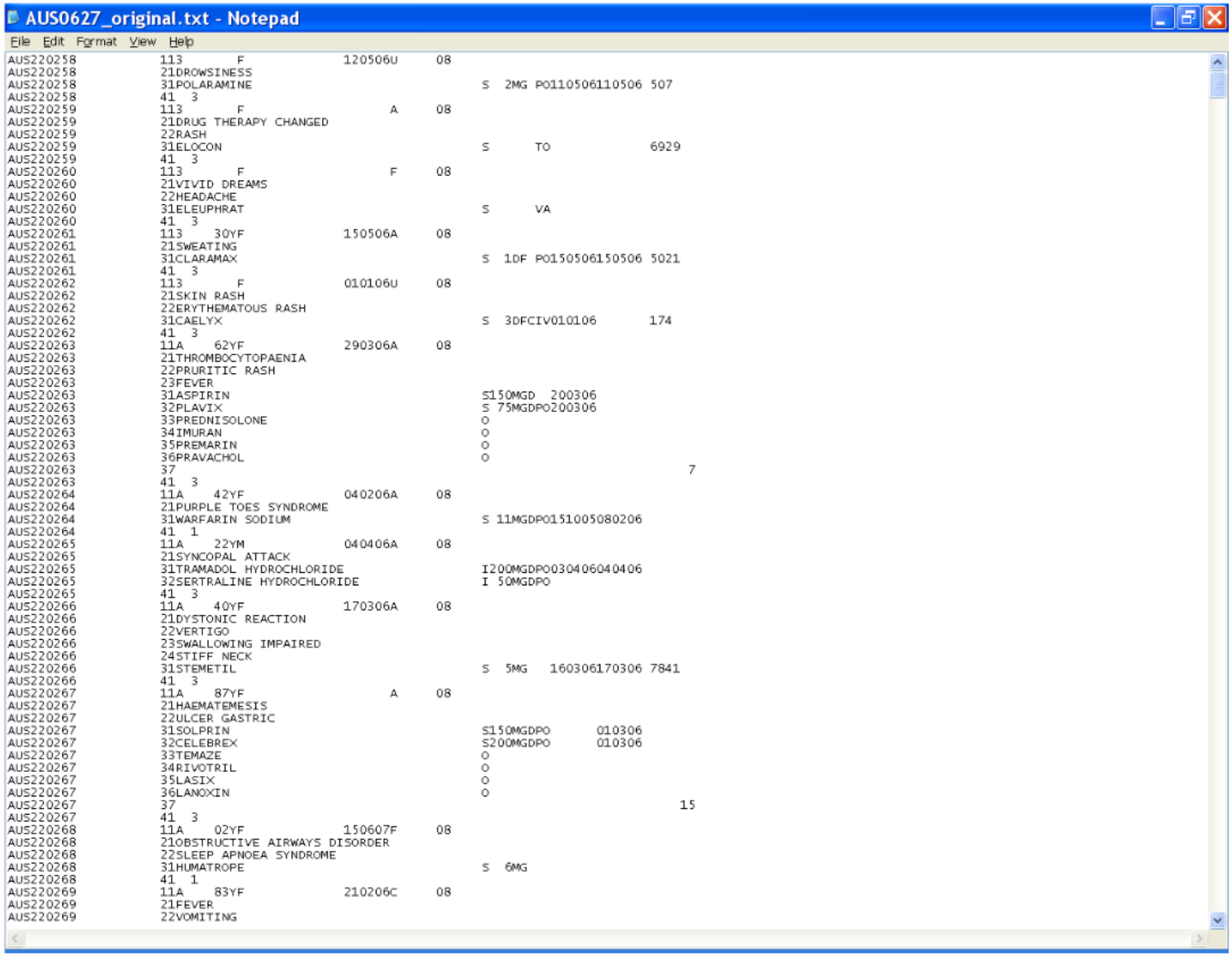
III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER	
	24b. MFR CONTROL NO.
24c. DATE RECEIVED BY MANUFACTURER	24d. REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL
DATE OF THIS REPORT	25a. REPORT TYPE ☐ INITIAL ☐ FOLLOW-UP


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File Edit Format View Help
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AUS220258 21DROWSINESS
AUS220258 31POLARAMINE S 2MG PO110506110506 507
AUS220258 41 3
AUS220259 113 F A 08
AUS220259 21DRUG THERAPY CHANGED
AUS220259 22RASH
AUS220259 31ELOCON S TO 6929
AUS220259 41 3
AUS220260 113 F F 08
AUS220260 21VIVID DREAMS
AUS220260 22HEADACHE
AUS220260 31ELEUPHRAT S VA
AUS220260 41 3
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AUS220262 113 F 010106U 08
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AUS220262 22ERYTHEMATOUS RASH
AUS220262 31CAELYX S 3DFCIV010106 174
AUS220262 41 3
AUS220263 11A 62YF 290306A 08
AUS220263 21THROMBOCYTOPAENIA
AUS220263 22PRURITIC RASH
AUS220263 23FEVER
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AUS220263 32PLAVIX S 75MGDPO200306
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AUS220263 34IMURAN O
AUS220263 35PREMARIN O
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AUS220266 24STIFF NECK
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AUS220269 22VOMITING



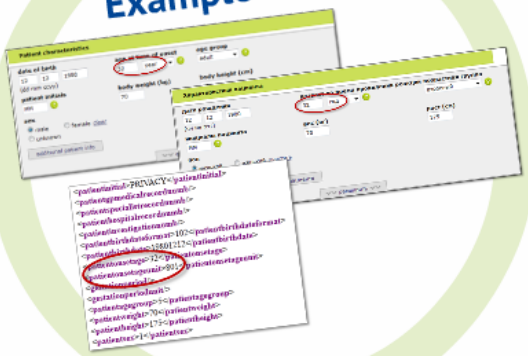
ICH-E2B standard (xml files)

Format for transferring data between databases of different structure

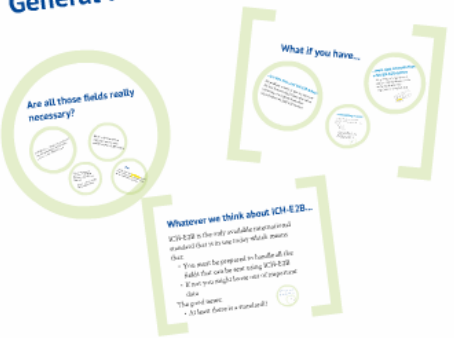
ICH;
International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use



Example



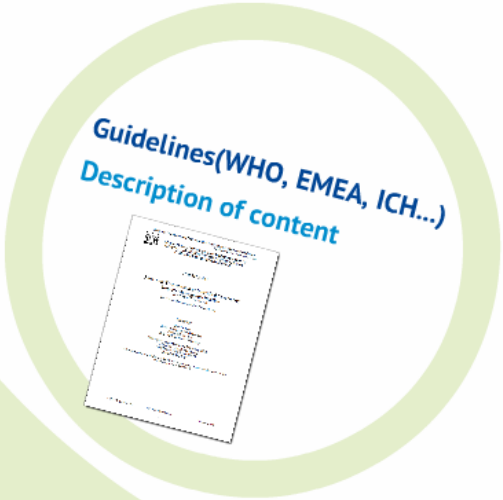
General ICH-E2B comments

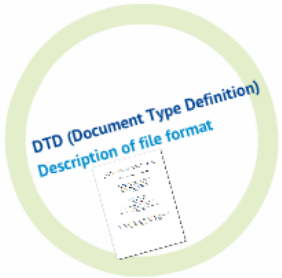


ICH-E2B standard (xml files)

Format for transferring data between databases of different structure

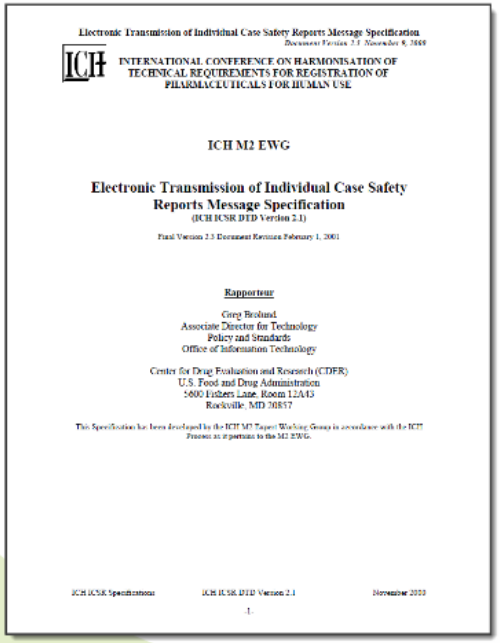
ICH;
International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use





Guidelines(WHO, EMEA, ICH...)

Description of content



Electronic Transmission of Individual Case Safety Reports Message Specification

Document Version 2.3 November 9, 2000

ICH INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

ICH M2 EWG

Electronic Transmission of Individual Case Safety Reports Message Specification

(ICH ICSR DTD Version 2.1)

Final Version 2.3 Document Revision February 1, 2001

Rapporteur

Greg Brolund
Associate Director for Technology
Policy and Standards
Office of Information Technology

Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration
5600 Fishers Lane, Room 12A43
Rockville, MD 20857

This Specification has been developed by the ICH M2 Expert Working Group in accordance with the ICH Process as it pertains to the M2 EWG.

ICH ICSR Specifications ICH ICSR DTD Version 2.1 November 2000

-1-

INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

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The gestation period at the time of exposure is captured in section B.4.k.10.

See the companion document for format specifications.

B.1.2.3 Patient age group (as per reporter)

- ***Neonate***
- ***Infant***
- ***Child***
- ***Adolescent***
- ***Adult***
- ***Elderly***

User Guidance:

The terms are not defined in this document and are intended to be used as they were reported by the primary source. This section should be completed only when the age is not provided more specifically in sections B.1.2.1 or B.1.2.2.

B.1.3 Weight (kg)

User Guidance:

The weight at the time of the event/reaction.

B.1.4 Height (cm)

B.1.5 Sex

User guidance:

See the companion document for format specifications.

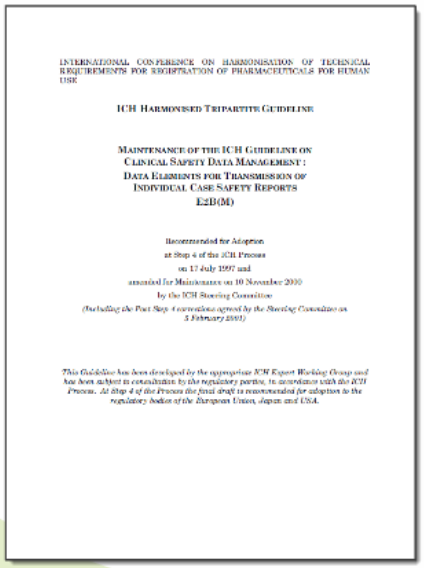
B.1.6 Last menstrual period date

User guidance:

Incomplete dates can be included, (i.e., month, and year or year only). See the companion document for

DTD (Document Type Definition)

Description of file format



INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

ICH HARMONISED TRIPARTITE GUIDELINE

MAINTENANCE OF THE ICH GUIDELINE ON CLINICAL SAFETY DATA MANAGEMENT: DATA ELEMENTS FOR TRANSMISSION OF INDIVIDUAL CASE SAFETY REPORTS E2B(M)

Recommended for Adoption
at Step 4 of the ICH Process
on 17 July 1997 and
amended for Maintenance on 10 November 2000
by the ICH Steering Committee
(Including the Post Step 4 corrections agreed by the Steering Committee on 5 February 2001)

This Guideline has been developed by the appropriate ICH Expert Working Group and has been subject to consultation by the regulatory parties, in accordance with the ICH Process. At Step 4 of the Process the final draft is recommended for adoption to the regulatory bodies of the European Union, Japan and USA.

INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

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	[illegible] observed in the fetus unit			804= 810=Trimester	
B.1.2.3	Patient age group		1N	1=Neonate 2=Infant 3=Child 4=Adolescent 5=Adult 6=Elderly	patientagegroup
B.1.3	Weight (kg)		6N		patientweight
B.1.4	Height (cm)		3N		patientheight
B.1.5	Sex		1N	ISO 5218 1=Male 2=Female	patientsex
B.1.6a	Last menstrual period date	Date format	3N	102 - Format CCYYMMDD, 610 - Format CCYY[illegible]	lastmenstrualdateformat

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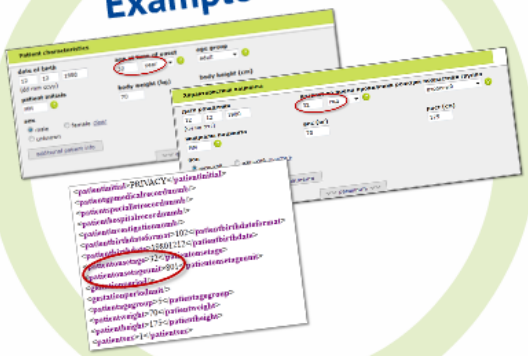
ICH-E2B standard (xml files)

Format for transferring data between databases of different structure

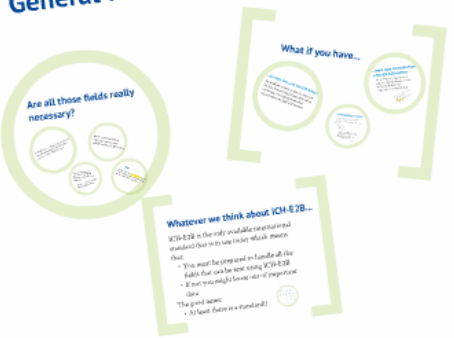
ICH;
International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use



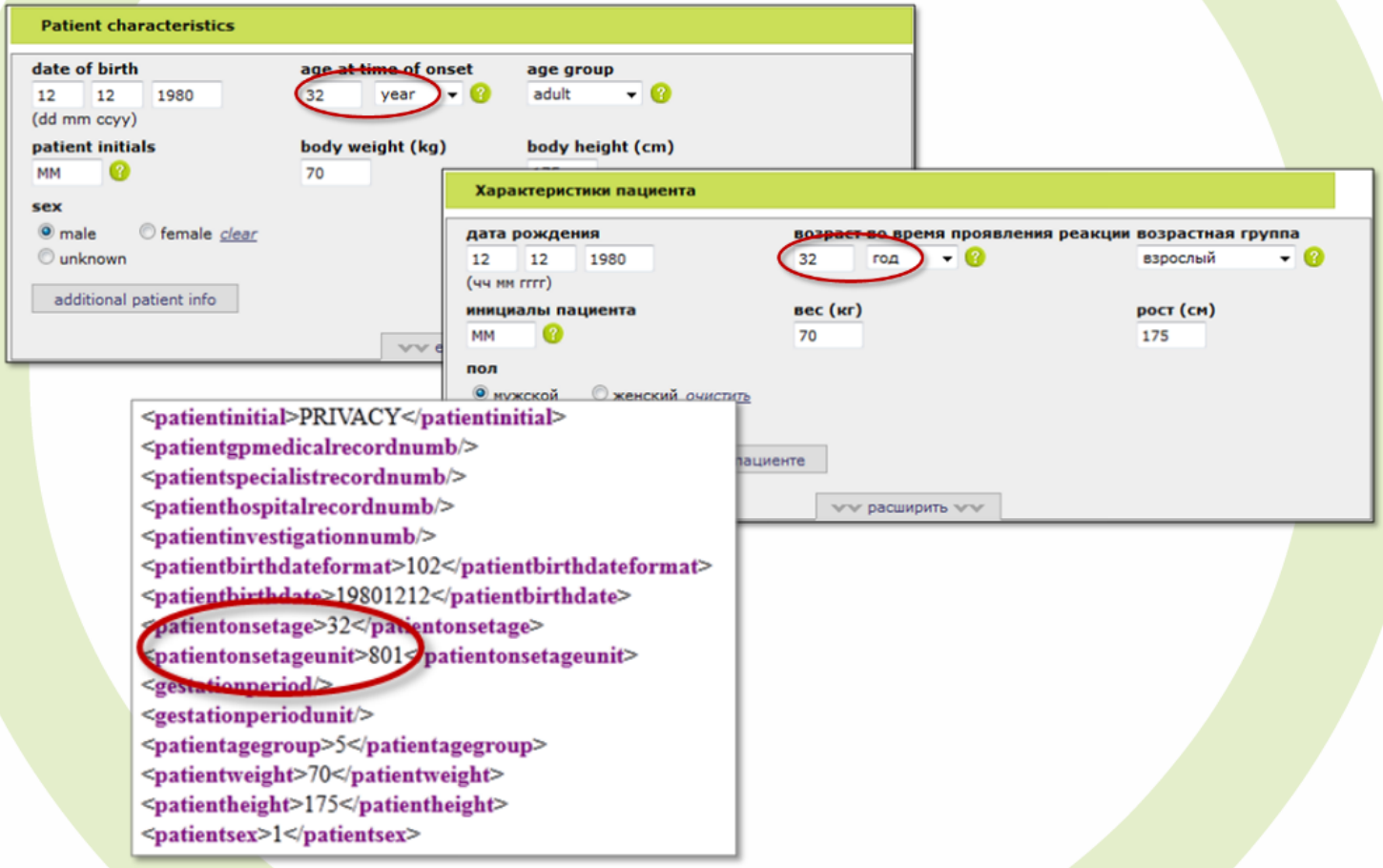
Example



General ICH-E2B comments



Example


Patient characteristics
date of birth
12 12 1980
(dd mm ccyy)
age at time of onset
32 year
age group
adult
patient initials
MM
body weight (kg)
70
body height (cm)
sex
male
female clear
unknown
additional patient info
Характеристики пациента
дата рождения
12 12 1980
(чч мм гггг)
возраст во время проявления реакции
32 год
возрастная группа
взрослый
инициалы пациента
MM
вес (кг)
70
рост (см)
175
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мужской
женский очистить
расширить
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<patientsex>1</patientsex>

General ICH-E2B comments





Whatever we think about ICH-E2B...

ICH-E2B is the only available international standard that is in use today which means that:

- You must be prepared to handle all the fields that can be sent using ICH-E2B
- If not you might loose out of important data

The good news:

- At least there is a standard!!



Are all those fields really necessary?

A CIOMS form contains only a very small part of what is available in ICH-E2B...
... and so does the WHO format

Most of the data used in analyzing case reports is available in the CIOMS format

If you only receive case reports on CIOMS/WHO format your database could reflect that

Leaving you with a simpler, less complex, database

But...

As soon as you start exchanging data with others that you do not have control over you will receive other data fields

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What if you have...

...less data than what ICH-E2B defines

No problem as long as you are aware of the fact that you might loose data when retrieving case reports from other organizations on ICH-E2B format.

...more data elements than what ICH-E2B defines

No problem as long as you are aware of that the data can not be easily shared with other organizations using ICH-E2B.

You must also be aware that when using the extra elements in analyzing the data - those elements will ONLY be available on your "own" case reports.

...mismatching lexicons

E2B defines a set of controlled vocabularies (lexicons) to use... Like:
Gender

- 1 = male
- 2 = female

As indicated before - deviating from the content may not be very problematic if you are aware of the consequences...
However - if you deviate from the predefined lexicons you might get into problems



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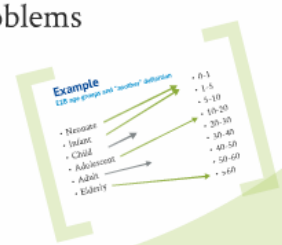
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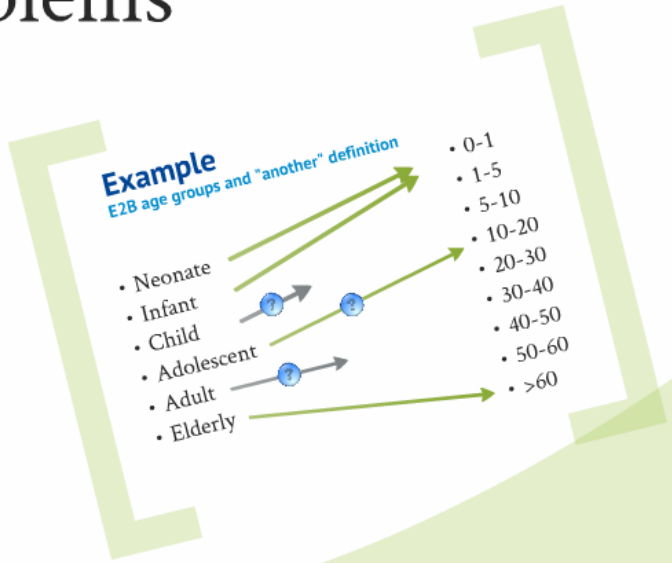
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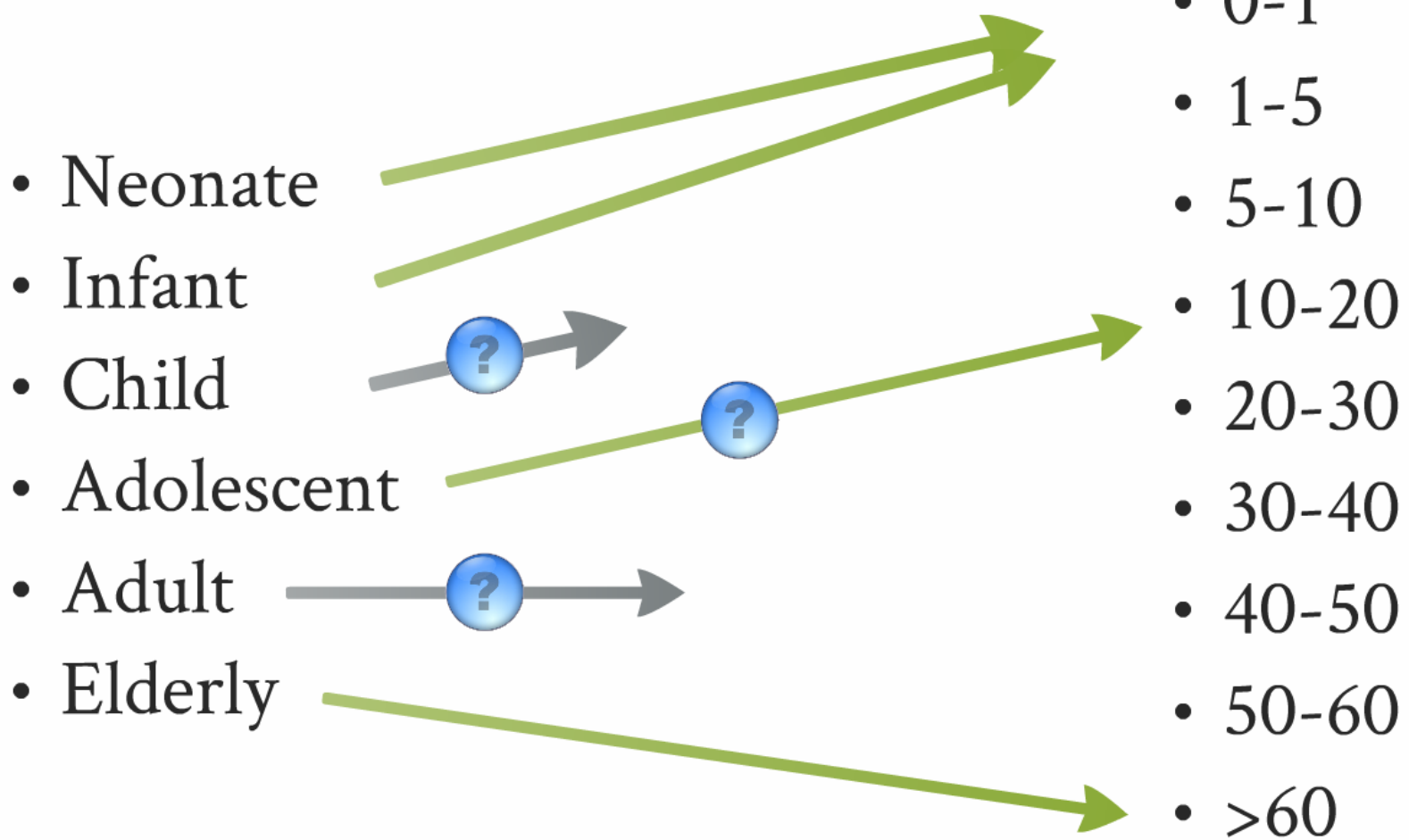
2 = female

As indicated before - deviating from the content may not be very problematic if you are aware of the consequences...
However - if you deviate from the predefined lexicons you might get into problems



Example

E2B age groups and "another" definition



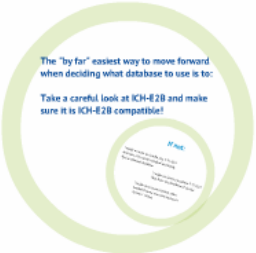
Whatever we think about ICH-E2B...

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The good news:

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The "by far" easiest way to move forward when deciding what database to use is to:

Take a careful look at ICH-E2B and make sure it is ICH-E2B compatible!



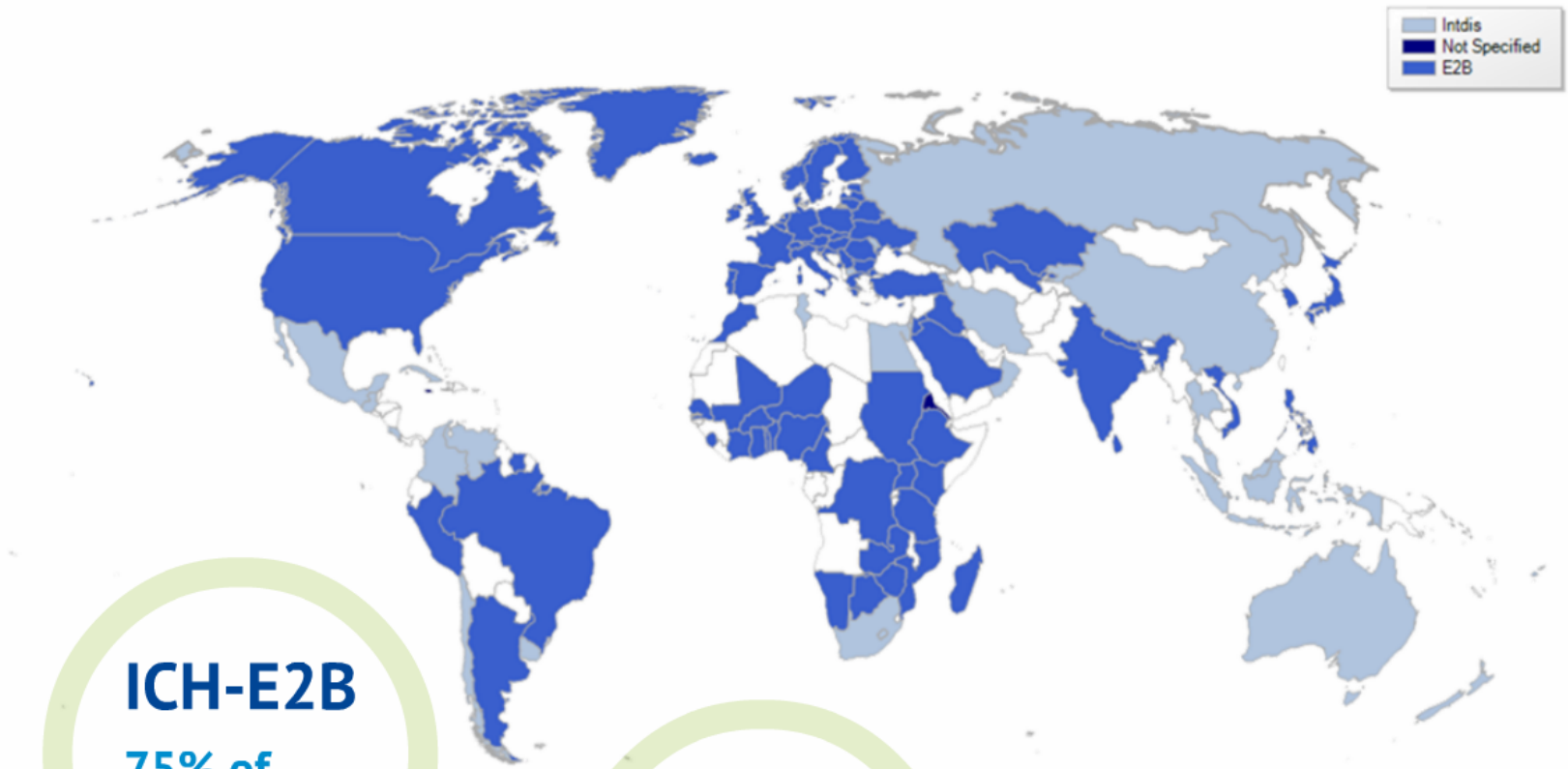
If not:

Decide on how to handle any ICH-E2B data that can not be handled seamlessly by the selected database

Decide on how to produce ICH-E2B files from the database of choice

Decide on any conversion rules needed if there are mismatches in ”lexicon” values

Format usage



ICH-E2B

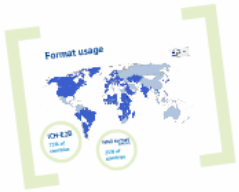
75% of countries

WHO format (INTDIS)

25% of countries

Reporting Formats













Now you might ask...
why should we care about formats?

Because patient safety is NOT a country based problem but a problem that is best addressed by world wide collaboration AND sharing of knowledge (including data)!

The PV database

The case report itself is only a small part of the minimum requirements on a PV database

WHO DDE

Sender

WHO-ART

SOC HLT PT IT

case report

Receiver(s)

MedDRA® MSSO

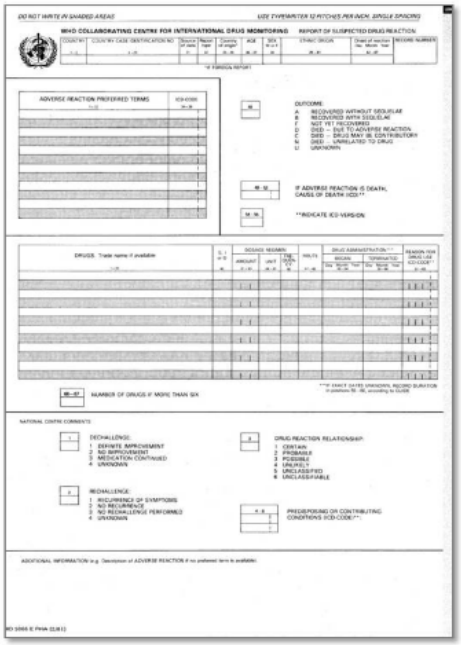
Submission(s)

An example…

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<reaction>
    <primarysourcereaction/>
    <reactionmeddraversionllt>Osteoarthritis</reactionmeddraversionllt>
    <reactionmeddrallt/>
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    <reactionmeddrapt/>
    <termhighlighted>1</termhighlighted>
    <reactionstartdateformat>203</reactionstartdateformat>
    <reactionstartdate>200801191230</reactionstartdate>
    <reactionenddateformat>102</reactionenddateformat>
    <reactionenddate>20080112</reactionenddate>
    <reactionoutcome>1</reactionoutcome>
</reaction>
<drug>
    <drugcharacterization>1</drugcharacterization>
    <medicinalproduct>Alvedon</medicinalproduct>
    <obtaindrugcountry>SE</obtaindrugcountry>
    <drugauthorizationcountry>SE</drugauthorizationcountry>
    <drugauthorizationholder>Astra</drugauthorizationholder>
</drug>
```

```
<reaction>
    <primarysourcereaction/>
    <reactionmeddraversionllt>Joint effusion</reactionmeddraversionllt>
    <reactionmeddrallt/>
    <reactionmeddraversionpt/>
    <reactionmeddrapt/>
    <termhighlighted/>
    <reactionstartdateformat>203</reactionstartdateformat>
    <reactionstartdate>20120711</reactionstartdate>
    <reactionenddateformat>102</reactionenddateformat>
    <reactionenddate>20120715</reactionenddate>
    <reactionoutcome>1</reactionoutcome>
</reaction>
<drug>
    <drugcharacterization>1</drugcharacterization>
    <medicinalproduct>Tylol</medicinalproduct>
    <obtaindrugcountry>SE</obtaindrugcountry>
    <drugauthorizationcountry>SE</drugauthorizationcountry>
    <drugauthorizationholder/>
</drug>
```

Alvedon 500 mg tablets



WHO COLLABORATING CENTRE FOR INTERNATIONAL DRUG MONITORING — REPORT OF SUSPECTED DRUG REACTION

ADVERSE REACTION PREFERRED TERMS

OUTCOME

DRUGS: Trade name if available

NUMBER OF DRUGS IF MORE THAN SIX

DECHALLENGE

DRUG-REACTION RELATIONSHIP

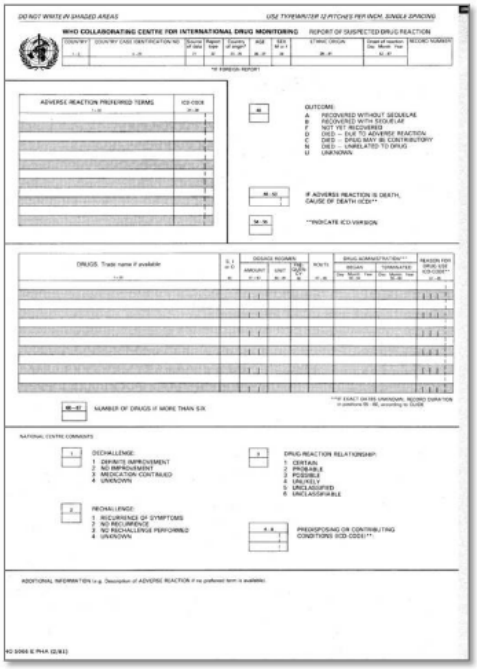
RECHALLENGE

PREDISPOSING OR CONTRIBUTING CONDITIONS

ADDITIONAL INFORMATION

```
<reaction>
    <primarysourcereaction/>
    <reactionmeddraversionllt>Osteoarthritis</reactionmeddraversionllt>
    <reactionmeddrallt/>
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<drug>
    <drugcharacterization>1</drugcharacterization>
    <medicinalproduct>Alvedon</medicinalproduct>
    <obtaindrugcountry>SE</obtaindrugcountry>
    <drugauthorizationcountry>SE</drugauthorizationcountry>
    <drugauthorizationholder>Astra</drugauthorizationholder>
</drug>
```

Alvedon Forte



DO NOT WRITE IN SHADED AREAS

USE TYPEWRITER 12 PITCHES PER INCH, SINGLE SPACING

WHO COLLABORATING CENTRE FOR INTERNATIONAL DRUG MONITORING

REPORT OF SUSPECTED DRUG REACTION

ADVERSE REACTION PREFERRED TERMS

ICD CODE

OUTCOME:
A RECOVERED WITHOUT SEQUELAE
B RECOVERED WITH SEQUELAE
C NOT YET RECOVERED
D DIED — DUE TO ADVERSE REACTION
E DIED — DRUG MAY BE CONTRIBUTORY
N DIED — UNRELATED TO DRUG
U UNKNOWN

IF ADVERSE REACTION IS DEATH, CAUSE OF DEATH (ICD)**

**INDICATE ICD VERSION

DRUGS: Trade name if available

DOSAGE REGIMEN

AMOUNT

UNIT

DAILY DOSE

ROUTE

DRUG ADMINISTRATION**

BEGAN

TERMINATED

REASON FOR DRUG USE ICD CODE**

NUMBER OF DRUGS IF MORE THAN SIX

NATIONAL CENTRE COMMENTS

DECHALLENGE:
1 DEFINITE IMPROVEMENT
2 NO IMPROVEMENT
3 MEDICATION CONTINUED
4 UNKNOWN

DRUG-REACTION RELATIONSHIP:
1 CERTAIN
2 PROBABLE
3 POSSIBLE
4 UNLIKELY
5 UNCLASSIFIED
6 UNCLASSIFIABLE

RECHALLENGE:
1 RECURRENCE OF SYMPTOMS
2 NO RECURRENCE
3 NO RECHALLENGE PERFORMED
4 UNKNOWN

PREDISPOSING OR CONTRIBUTING CONDITIONS (ICD CODE)**

ADDITIONAL INFORMATION (e.g. Description of ADVERSE REACTION if no preferred term is available)

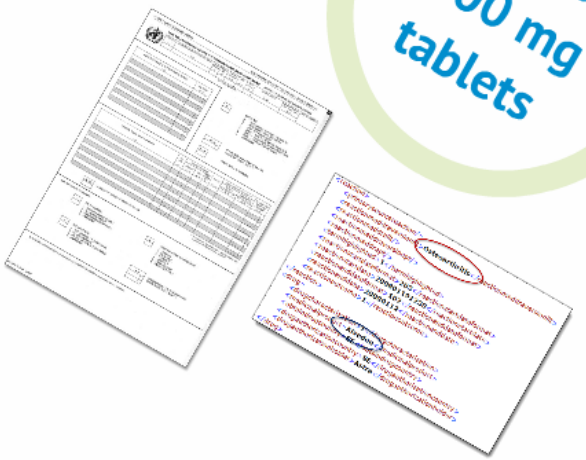
Alvedon

Alvedon 500 mg tablets

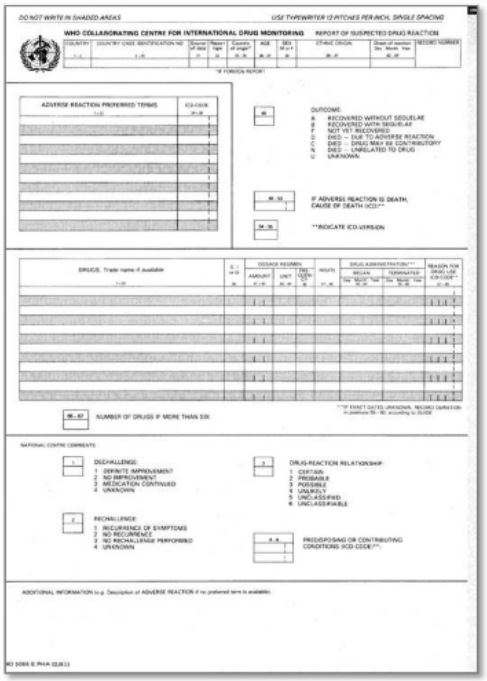
Alvedon 24 mg/ml Oral

Alvedon Forte

Parasal Supp



Parasal 250 mg tablets



DO NOT WRITE IN SHADED AREAS — USE TYPEWRITER (2 PITCHES PER INCH, SINGLE SPACING)

WHO COLLABORATING CENTRE FOR INTERNATIONAL DRUG MONITORING — REPORT OF SUSPECTED DRUG REACTION

COUNTRY | COUNTRY CASE IDENTIFICATION NO | Source of data | Report type | Date of report* | AGE | SEX | ETHNIC ORIGIN | Date of reaction: Day Month Year | RECORD NUMBER

* IF FOREIGN REPORT

ADVERSE REACTION PREFERRED TERMS | ICD-CODE

OUTCOME:
A RECOVERED WITHOUT SEQUELAE
B RECOVERED WITH SEQUELAE
F NOT YET RECOVERED
D DIED – DUE TO ADVERSE REACTION
C DIED – DRUG MAY BE CONTRIBUTORY
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U UNKNOWN

IF ADVERSE REACTION IS DEATH, CAUSE OF DEATH (ICD)**

**INDICATE ICD VERSION

DRUGS, Trade name if available | DOSAGE REGIMEN: AMOUNT | UNIT | DAILY DOSE | ROUTE | DRUG ADMINISTRATION**: BEGAN Day Month Year | TERMINATED Day Month Year | REASON FOR DRUG USE ICD-CODE**

NUMBER OF DRUGS IF MORE THAN SIX

** IF EXACT DATES UNKNOWN, RECORD DURATION in positions 59 – 60, according to GUIDE

NATIONAL CENTRE COMMENTS

DECHALLENGE:
1 DEFINITE IMPROVEMENT
2 NO IMPROVEMENT
3 MEDICATION CONTINUED
4 UNKNOWN

DRUG-REACTION RELATIONSHIP:
1 CERTAIN
2 PROBABLE
3 POSSIBLE
4 UNLIKELY
5 UNCLASSIFIED
6 UNCLASSIFIABLE

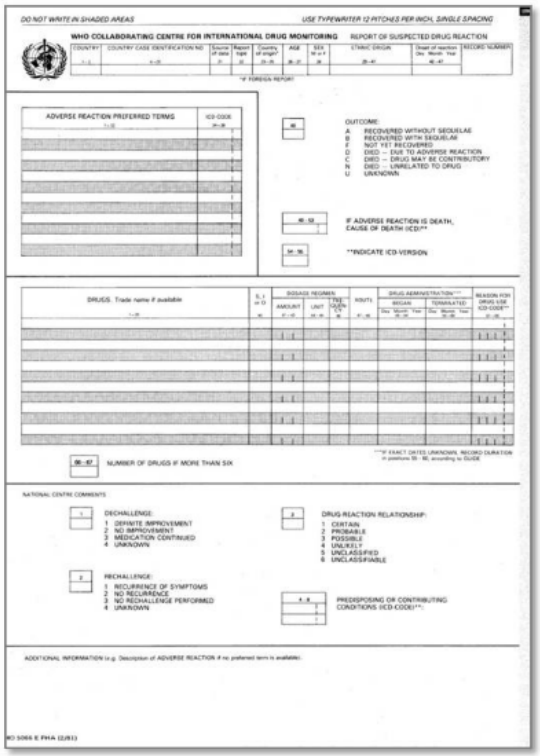
RECHALLENGE:
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2 NO RECURRENCE
3 NO RECHALLENGE PERFORMED
4 UNKNOWN

PREDISPOSING OR CONTRIBUTING CONDITIONS (ICD-CODE)**:

ADDITIONAL INFORMATION (e.g. Description of ADVERSE REACTION if no preferred term is available):

WHO 5066 E PHA (0811)

Tylol 500 mg Tablets



DO NOT WRITE IN SHADED AREAS — USE TYPEWRITER 12 PITCHES PER INCH, SINGLE SPACING

WHO COLLABORATING CENTRE FOR INTERNATIONAL DRUG MONITORING — REPORT OF SUSPECTED DRUG REACTION

COUNTRY | COUNTRY CASE IDENTIFICATION NO | Source of data | Report type | Country of origin* | AGE | SEX M or F | ETHNIC ORIGIN | Onset of reaction Day Month Year | RECORD NUMBER*

*IF FOREIGN REPORT

ADVERSE REACTION PREFERRED TERMS | ICD CODE

OUTCOME:
A RECOVERED WITHOUT SEQUELAE
B RECOVERED WITH SEQUELAE
F NOT YET RECOVERED
G DIED — DUE TO ADVERSE REACTION
C DIED — DRUG MAY BE CONTRIBUTORY
N DIED — UNRELATED TO DRUG
U UNKNOWN

IF ADVERSE REACTION IS DEATH, CAUSE OF DEATH (ICD)**

**INDICATE ICD VERSION

DRUGS. Trade name if available | DOSAGE REGIMEN: AMOUNT | UNIT | TIME CODE | ROUTE | DRUG ADMINISTRATION*** BEGAN Day Month Year | TERMINATED Day Month Year | REASON FOR DRUG USE ICD CODE**

***IF EXACT DATES UNKNOWN, RECORD DURATION in positions 59 - 66, according to GUIDE

NUMBER OF DRUGS IF MORE THAN SIX

NATIONAL CENTRE COMMENTS

DECHALLENGE:
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4 UNKNOWN

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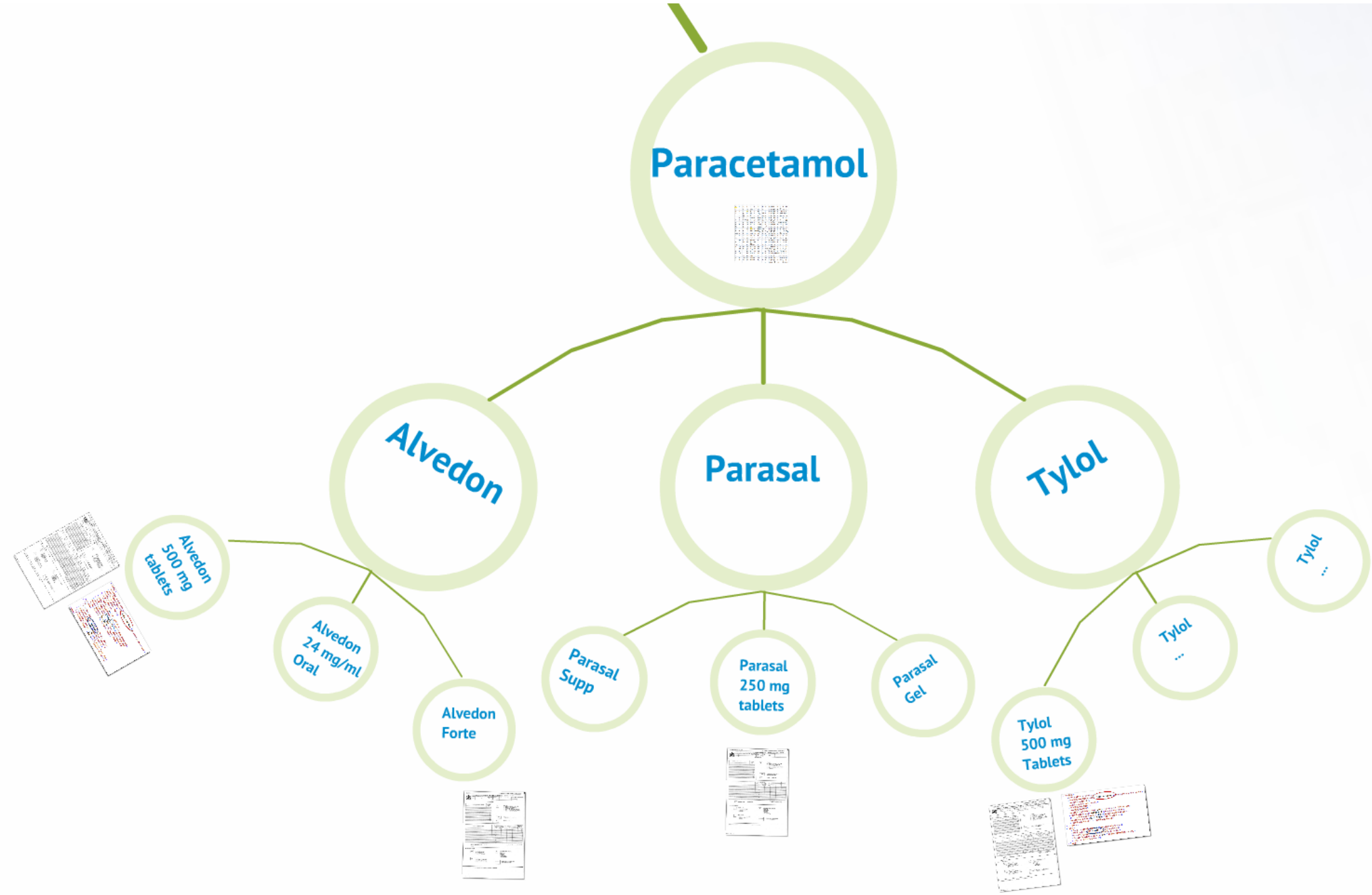
RECHALLENGE:
1 RECURRENCE OF SYMPTOMS
2 NO RECURRENCE
3 NO RECHALLENGE PERFORMED
4 UNKNOWN

PREDISPOSING OR CONTRIBUTING CONDITIONS (ICD CODE)**:

ADDITIONAL INFORMATION (e.g. Description of ADVERSE REACTION if no preferred term is available):

WO 5066 E PHA (2/81)

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<reaction>
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    <reactionmeddrallt/>
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    <reactionenddateformat>102</reactionenddateformat>
    <reactionenddate>20120715</reactionenddate>
    <reactionoutcome>1</reactionoutcome>
</reaction>
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    <drugcharacterization>1</drugcharacterization>
    <medicinalproduct>Tylol</medicinalproduct>
    <obtaindrugcountry>SE</obtaindrugcountry>
    <drugauthorizationcountry>SE</drugauthorizationcountry>
    <drugauthorizationholder/>
</drug>
```


Paracetamol
Alvedon
Alvedon 500 mg tablets
Alvedon 24 mg/ml Oral
Alvedon Forte
Parasal
Parasal Supp
Parasal 250 mg tablets
Parasal Gel
Tylol
Tylol 500 mg Tablets
Tylol ...
Tylol ...

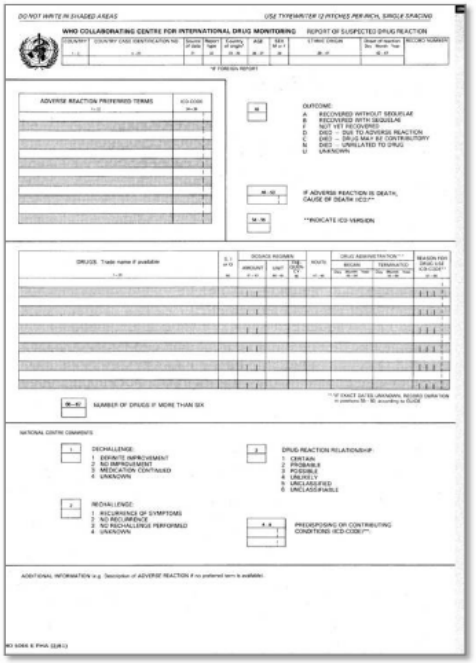
Paracetamol	Flamodol	Non aspirin	Tyladol	Neo-aspilets	Wingesic	Cetafrin	Farmadol	Alpinyl
Dymadon	Servigesic	Benalpharm	Aradol	Herron paracetam	Chemifen	Tilekin	Ekacetol	Napa
Panadol	Parafol	Dolipran	Yanil	Fepril	Tempir	Pulmol	Erphamol	Paraclear
Alvedon	Parasis	Cefalgin	Prawagesic	Rapidol	Doloket	Paracemil	Itramol	Octadon n
Tylenol	Tendamol	Paracemol	Acepol	Paralink	Acetofal	Acetamil	Paradyn	Tamol
Tempra	Navamol	Paracenol	Homisol	Rimadol	Tylenol children	Thylom	Xepamol	Reliv
Calpol	Parapyrol	Tazamol	Ramol	Parantal	Dolfenol	Sonridor	Darcemol	Actimol
Atasol	Noval	Tabcin	Zancpal	Panadol actifast	Partamol	Fenalgin	Citomol	Pehamol
Acetaminophen	Cetam	Acetamol	Kempol	Ipamol	Uphamol	Acetitol	Farsidol	Lonarid mono
Acamol	Getol	Q-pap	Nafapol	Aceval	Remedol	Tylalgin	Lanamol	Panado
Hedex	Lapain	Revanin	Parasal	Dirox	Remidol	Paracetrex	Oparel	Curpol
Ben-u-ron	Pyrapol	Stanback af	Lefin	Apotel	Milidon duplex	Analgisen	Samconal	Fibramol
Finimal	Temfal	Treupel dolo	Munapol	Placidex	Progesic	Dorsanol	Nalgesik	Sinaspril parac
Campain	Ace	Termax	Mylenol	Perfalgan	Arfen	Tyramol	Unicetamol	Fevrin
Phenacetyl	Actol	Kinderparacetamol	Paradexamol	Fensum	Analgiser	Viclor	Ifitamol	Panasorbe
Paracetol	Adcetamol	Milidon-500	Faramol	Paramin	Kalin	Paracetamol raffo 500	Alphagesic	Parsel
Panodil	Tamen	Milidon-650	Painol	Tylenol arthritis p	Mili	Paracetamol raffo ninc	Bodrex junior	Dhamol
Panamax	Depol	Milidon-120	Analpol	Acetalgin	Pritamol	Custodial	Paracetamol(b)	Kamex
Exdol	Fevac	Milidon-250	C.c.don	Geniol-p	Dynamol	Predualito	Hexalgesic	Pecet
Empracet	Tempac	Sumagesic	Estadol	Paracetamol haer	Pavidon	Dristancito	Nasamol	Bufferin c2
Pinex	At98	Duatrol	Pedrol	Dymadon p	Serimol	Paracetamol fecofar	Contratemp	Gunaceta
P.c.l.	Cetajap	Panadol osteo	Pedric	Children's tylenol	Coxan	Paracetamol raffo 650	Erlamol	Curadon
Paracet	Hepa	Momentum analgetic	Kasamol	Junior strength ty	Coxa	Para z mol cabuchi	Turpan	Calpol-6 plus
Polarfen	Getamol	Paracetamol roesch u ha	Parapol 6 plus	Junior disprin	Winamol	Paracetamol larjan	Omegrip	Pantalgin
Panadon	Qap	Paracetamol genericon	Amadol	Kinder finimal	Winmotan	Paracetamol lazar	Emturnas	Efferalgan
Cetamol	Nebs	Infalgina	Provas	Paracetamolum	Medon	Paracetamol vent-3	Kamolas	Beechams hot
Dumin	Alkaparol	Notem	Flamol	Halenol	Conflo	Reanima	Tropigesic	Anadin paracet
Dapyrin	Atopen	Sidus	Tanamol	Perdolan	Hoemal	Vick vitapyrena	Gamesic	Treuphadol
Setamol	Cetol	Sinedol	Tempol 6 plus	Acetam	Biogesic	Acetolit	Procet	Panamol
Paraco	Feva	Terol	Febrol	Duracetamol	Litamol	Multifebrin	Hufagesic	Lupocet
Paraspen	Tempil	Minofen	Paradin	Daleron	Parcemol	Nodipir	Algostase	Malgis
Datril	Tynol	Doluvit	Tymole	Calsil	Unimol	Paracetamol raffo 1 g	Pyranal	Captin
Novogesic	Pyrin	Winasorb	Painfit	Becetamol	Paximol	Mejoral para ninos	Ascofen	Zetamol
Melabon infantil	Pana	Temperal	Aksopol	Influbene	Dolomol	Mejoral	Citrapar	Tylenol childre
Gelocatil	Fea	Alpirex	Ocepol	Contra-schmerz	Jopamol	Tafirol 1 g	Febricet	Apap
Ticelgesic	Nova	Temprin	Lifmol	Etoran	Dolocet	Tabcin caliente	Nebagin	Doregrippin
Sanmol	Act	Oxigricol	Panol	Panam	4-all	Apracur antifebril	Paramosha	Medipyrin
Tachipirina	Aceta	Brontonyl	Fedramol	Pediatrix	Razimol	Paracetamol vannier	Prohodol	Nufadol
Algogen	Xcel	Dolviran nf	Delmol	Calpol sugar free	Philamol	Fada paracetamol	Pyranol	Opigesic
Apiretal	Reset	Febrim	Bamol	Tylol	Antamol	Paratral	Efferalgan maxi	Atamel
Aeknil	Atp	Andox	Wyladol	Paracetamol al	Cendol	Paracetamol lafedar	Panadol active	Ottopan
Abrol	Ispha	Tylex	Askprol	Dolo	Panda	Paracetamol northia	Antipyrol	Panadol baby
Hopadol	Knock	Sedalmerk sedalito	Vamol	Acamoli	Feverol	Paracetamol fortbentc	Omol	Analgan
Termagon	Fast	Antidol	Panafin	Perfusalgam	Grippostad heissgetra	Parageniol	Nebalgan	Lemsip

Paracetamol	Flamodol	Non aspirin	Tyladol	Neo-aspilets	Wingesic	Cetafrin	Farmadol	Alpinyl	Lofe	Apovital apoce	Anaseran	Galpamol	Entalgic	Tasenol er	Parton
Dymadon	Servigesic	Benalpharm	Aradol	Herron paracetam	Chemifen	Tilekin	Ekacetol	Napa	Alice	Feverall adult	Jabtol	Mandanol	Pyradol	Timerol er	Tymol
Panadol	Parafol	Dolipran	Yanil	Fepril	Tempir	Pulmol	Erphamol	Paraclear	Paracip	Paracetamol A	Molceden	Tixymol	Antalgic	Ensid er	Paradon
Alvedon	Parasis	Cefalgin	Prawagesic	Rapidol	Doloket	Paracemil	Itramol	Octadon n	Pyremol	Dolono	Quantalgesic	Paracets plus	Actamol	Raperon er	Voramol
Tylenol	Tendamol	Paracemol	Acepol	Paralink	Acetofal	Acetamil	Paradyn	Tamol	Medomol	Aminofen max	Moldrex	Mrs cullens	Gencetamol	Aspen-s	Parmy
Tempra	Navamol	Paracenol	Homisol	Rimadol	Tylenol children	Thylom	Xepamol	Reliv	Tyfy	Aminofen	Parace	Obimol	Empaped	Bioaset-f	Alfree
Calpol	Parapyrol	Tazamol	Ramol	Parantal	Dolfenol	Sonridor	Darcemol	Actimol	Docin	Anacin aspirin	Geran	Paracetamol aln	Noralget	Tanophen	Depyret
Atasol	Noval	Tabcin	Zancpal	Panadol actifast	Partamol	Fenalgin	Citomol	Pehamol	Paxol	Comtrex sore t	Axondol	Pyrital	Ranidol	Suspen er	Paragen
Acetaminophen	Cetam	Acetamol	Kempol	Ipamol	Uphamol	Acetitol	Farsidol	Lonarid mono	Retherma	Tylenol cold	Nektol	Paracyl	Painblok	Neuridon	Godpara
Acamol	Getol	Q-pap	Nafapol	Aceval	Remedol	Tylalgin	Lanamol	Panado	Cadpar	Elixsure fever/	Eurigesic	Para	Disprin junior	Lonarid	Fenn
Hedex	Lapain	Revanin	Parasal	Dirox	Remidol	Paracetrex	Oparel	Curpol	Welset	Feverall childr	Westamol	Pamol f	Adco-paracetar	Paraphar	Sara
Ben-u-ron	Pyrapol	Stanback af	Lefin	Apotel	Milidon duplex	Analgisen	Samconal	Fibramol	T-98	Feverall infant	Myremol	Alvedon dos	Jp paracetamol	Docpara	Daga
Finimal	Temfal	Treupel dolo	Munapol	Placidex	Progesic	Dorsanol	Nalgesik	Sinaspril paracetam	Pm	Feverall junior	Knolpyrene	Febrex	Von paracetam	Dolol-instant	Saridon
Campain	Ace	Termax	Mylenol	Perfalgan	Arfen	Tyramol	Unicetamol	Fevrin	Splendid	Tylenol childre	Calodol	Chemists own p	Micro-paraceta	Paracetamol eur	Newtamol
Phenacetyl	Actol	Kinderparacetamol	Paradexamol	Fensum	Analgiser	Viclor	Ifitamol	Panasorbe	Paralife	Komaphen	Lafayette parace	Chemists own p	Irzapyrin	Perfusalgan	Hypotem
Paracetol	Adcetamol	Milidon-500	Faramol	Paramin	Kalin	Paracetamol raffo 500	Alphagesic	Parsel	Babygesic	Kosher care pa	Retalgan	Tylenol 8 hour	Pelix	Paracetamol tev	Paragin
Panodil	Tamen	Milidon-650	Painol	Tylenol arthritis p	Mili	Paracetamol raffo ninc	Bodrex junior	Dhamol	Disprin plus	Liquiprin	Zetifen	Infant's acetami	Promol	Paralgin	Phartamol
Panamax	Depol	Milidon-120	Analpol	Acetalgin	Pritamol	Custodial	Paracetamol(b)	Kamex	Disprin parace	Mapap extra st	Parvid	Pharmacist chil	Febrinol	Cold & flu	Ceta
Exdol	Fevac	Milidon-250	C.c.don	Geniol-p	Dynamol	Predualito	Hexalgesic	Pecet	Fabrimol	No aspirin	Zydinol	Ridenol	Panaram	Parahexal	Gepamol
Empracet	Tempac	Sumagesic	Estadol	Paracetamol haer	Pavidon	Distancito	Nasamol	Bufferin c2	Paracetanal	Non-aspirin	Neo-kiddielets	Apamide	Samophen	Comfarol	Manopar
Pinex	At98	Duatrol	Pedrol	Dymadon p	Serimol	Paracetamol fecofar	Contratemp	Gunaceta	Pyrakem	Nortemp	Flurinol	Childrens panac	Kanamol	Parafizz	Parac
P.c.l.	Cetajap	Panadol osteo	Pedric	Children's tylenol	Coxan	Paracetamol raffo 650	Erlamol	Curadon	Jagcin	Apap x	Acetan	Paratab	Gabrol	Anfetol	Qualimol
Paracet	Hepa	Momentum analgetic	Kasamol	Junior strength ty	Coxa	Para z mol cabuchi	Turpan	Calpol-6 plus	Junimol	Pain relief	Focus	Milidon	Paratol	Supofen	Symol
Polarfen	Getamol	Paracetamol roesch u hi	Parapol 6 plus	Junior disprin	Winamol	Paracetamol larjan	Omegrip	Pantalgin	Lupicip	Panadol childr	Dolofen	Grippostad	Caltol	Vimergol	Hero
Panadon	Qap	Paracetamol genericon	Amadol	Kinder finimal	Winmotan	Paracetamol lazar	Emturnas	Efferalgan	Regamol	Silapap	Aceticin	Lekadol	Elkopal	Paramolan	Paramy
Cetamol	Nebs	Infalgina	Provas	Paracetamolum	Medon	Paracetamol vent-3	Kamolas	Beechams hot lemc	Amol	St.Joseph aspi	Cetafen	Panadol junior	Iphcol	Atralidon	Zeromol
Dumin	Alkaparol	Notem	Flamol	Halenol	Conflo	Reanima	Tropigesic	Anadin paracetamo	Facer	Tempra quickl	Dolan	Rivalgyl	Paramal	Katagrip	Mymol
Dapyrin	Atopen	Sidus	Tanamol	Perdolan	Hoemal	Vick vitapyrena	Gamesic	Treuphadol	Merimol	Tylenol regula	Amofen	Titralgan	Paramac	Zaramol	Doremol
Setamol	Cetol	Sinedol	Tempol 6 plus	Acetam	Biogesic	Acetolit	Procet	Panamol	Paraldim	Tylenol junior	Doloptal	Paramax	Cetalix	Efferalgan odis	Denamol
Paraco	Feva	Terol	Febrol	Duracetamol	Litamol	Multifebrin	Hufagesic	Lupocet	Pyrowok	Tylenol headac	Renur a	Apo acetamino	Tempain	Anti-gripe ascle	Singha
Paraspen	Tempil	Minofen	Paradin	Daleron	Parcemol	Nodipir	Algostase	Malgis	Pinkin	Tylenol infant	Phempro	Detsky antibol	Panadol cf	Kataprin	Tumdi
Datril	Tynol	Doluvit	Tymole	Calsil	Unimol	Paracetamol raffo 1 g	Pyranal	Captin	Fibromet	Paracetamol Bi	Pediafen plus	Ben u ron	Valadol	Noral	Typanol
Novogesic	Pyrin	Winasorb	Painfit	Becetamol	Paximol	Mejoral para ninos	Ascofen	Zetamol	Okadol	Paracetamol Bi	Kenox	Acetophen	Acetosal	Tempo	Seamol
Melabon infantil	Pana	Temperal	Aksopol	Influbene	Dolomol	Mejoral	Citrapar	Tylenol childrens	Paracon	Grippostad hei	Ondafen	Paramol	Febrisol	Sedalon	Comycin-p
Gelocatil	Fea	Alpirex	Ocepol	Contra-schmerz	Jopamol	Tafirol 1 g	Febricet	Apap	Ultragin-new	Poro	Toran	Calpol 6 plus	Pyrol	Volpan	Cotemp
Ticelgesic	Nova	Temprin	Lifmol	Etoran	Dolocet	Tabcin caliente	Nebagin	Doregrippin	Lypar	Paracetamol A	Piret	Gripex	Albapol	Parasedol	Parastar
Sanmol	Act	Oxigricol	Panol	Panam	4-all	Apracur antifebril	Paramosha	Medipyrin	Pidimol	Paracetamol E	Dolexnin	Aldolor	Campol	Gripin kase	Femokid
Tachipirina	Aceta	Brontonyl	Fedramol	Pediatrix	Razimol	Paracetamol vannier	Prohodol	Nufadol	Lupipara	Paracetamol G	Farmofen	Prodeine	Boschtamol	Geralgine	Paracap
Algogen	Xcel	Dolviran nf	Delmol	Calpol sugar free	Philamol	Fada paracetamol	Pyranol	Opigesic	Tylicin	Paracetamol Ri	Quimafen	Sanidol	Detamol	Para nox	Kaidex
Apiretal	Reset	Febrim	Bamol	Tylol	Antamol	Paratral	Efferalgan maxi	Atamel	Dolopar-650	Tylidol	Ametrex	Neoparacetamc	Cepol	Vermidon	Pyrinamol
Aeknil	Atp	Andox	Wyladol	Paracetamol al	Cendol	Paracetamol lafedar	Panadol active	Ottopan	Lupigesic	Aferadol	Febrydol	Shelador	Deepol	Deminofen	Pat
Abrol	Ispha	Tylex	Askprol	Dolo	Panda	Paracetamol northia	Antipyrol	Panadol baby and i	Starmol	Paracetamol ra	Nevroseda	Dorfen	Exidol	Parcetol	Pycetol
Hopadol	Knock	Sedalmerk sedalito	Vamol	Acamoli	Feverol	Paracetamol fortbento	Omol	Analgan	Tajmol	Paracetamol te	Dolkit	Tailenol	Nafpol	Zaldaks	Parcet
Termagon	Fast	Antidol	Panafin	Perfusalgam	Grippostad heissgetra	Parageniol	Nebalgan	Lemsip	Parasult	Dolflash	Doliflam	Mapap	Amole	Termacet	Ticomol
Termalgin	Prefer	Magnidol plus	Paraheim	Dafalgan Kinder	Afebrin	Bio grip-t	Canadol	Paracetamol I	Panact	Compralsol	Veracetam	Paratex	Zuton	A-per	Xebramol
Kentamol-d	Antap	Febran	Aceferin	Dafalgan Kleinkin	Christamol	Paracetamol sintesina	Febriborin	Arthritis pain formu	Acetol	Expandox	Dolor fiebre	Cetadol	Amiphen	Minafen	Seapharmol
Doliprane	Silpa	Tempire	Acetadol	Paracod	Pyramol	Itedal	Paralget	Actron	Ezee-para	Paracetamol e	Kyofen	G-paracetamol	Nogesio	Muskazon	Parnox
Paracetamol-ratiopha	Silpol	Tempra e	Aptgesic	Kafa Paracetamol	Tiffy	Paracetamol walker	Militan	Mirasic	Bufferin	Dolitabs	Tomi	Parapain	Antipain	Paroma	Bakamol
Apo-acetaminophen	Depyrin	Xl-dol	Baropyrine	Dafalgan Odis	Qualamol	Invernosan	Coladol	Lemgrip	Anbeite	Paracetamol g	Severin	Timidal	Chen tung	Polmofen	Besopar
Alphamol	Orpa	Dolotemp	Bioseran	Paracetamol UPS/	Europain	Fiebrolito	Antigrippocaps	Contra-schmerz p	Somedon	Efferalganodis	Doltafen	Ambeedol	Shikenuoh	Ekosetol	Vitamol
Disprol	Coldex	Paracetamol merck	Cherrypyrene	Dolex	Angenol	Paracetamolito	Febradol	Paratabs	Fortolin	Paracetamol ir	Dolofar	Analpyrin	Acetal	Pharmadol	Asta
Tramil	Paradol	Paracetamol gi	Clocephen	Salpara	Energex	Fiebrol	Algivic	Geluprane	Napafen	Paracetamol iv	Firexifen	Avlopol	Konaton	Efpa	Hissopar
Para-tabs	Algina	Tempra forte	Delgin	Xumadol	Felpenol	Mejoral grip t	Muscerol	Acetalgine	Apyral	Paracetamol z	Grippo	Centamol	Tempte	Pirofen	Cetapol
Dafalgan	Anamol	Mejoralito	Higesic	Alpiny s.s. seiyak	Tygenol	Tafirol pediatrico	Acetasil	Redon	Dominal	Paracetamol h	Panacitin	Cetalgin	Alcon	Dalminette	Premol
Pe-tam	Arden	Tafirol	Melifrin	Alpiny sanken	Kenamose	Tafirol t caliente	Ferlin	Tylenol infants	Eraldor	Paracetamol s	Solpadeine	Cipladol	Pinsu	Dolal	A-mol
Veralydon	Bepamol	Acetafen	Naprinol	Aspain	Target	Inmunogrip t caliente	Parano	Feverall	Termifen	Paracetamolo	Fevadol plus	Paracitol	Anliton	Lonarid aplo	Ampol
Sanicopyrine	Betmol	Dolgan-flash	No pain	Pyretinol	Fairon	Tetradox	Paranal	Crocin	Termofin	Normaflu	Fevadol s.f.	Parapol	Cohitong	Anadin	Mypara
Zolben	Cemol inga	Son s piral	Rexidol	Calonal showa	Carmol	Rhinapan	Vemol	Plicet	Winadol	Levadol	Riagesic	Paratem	Deanton	Depon maximun	Nasa
Pamol	Cofamol	Tempra-max	Reximed	Anyrume	Acephen	Suspen	Diamol	Doloreduct	Acetaminofer	Sanipirina	Pyral	Promel	Benzen	Protalgon	Papa
Parol	Compain	Sudis	Teramol	Anyrume choseid	Tarphen	Tyrex	Kentamol	Aspac	Sinalgia	Momentum	Abimol	Remalgin	Bubdel	Amcal paracetan	Pyrimed
Pyrinazin	Dispar	Coriver	Weligesic	Anyrume s kayak	Fantadon	Hitagen	Totamol	Dolorol	Kalmedol	San paracetam	Cetal	Skymol	Panatol	Pharmacycare pa	Unicap
Treupel p	Eupyric	Acetif	Gendol	Uzu netsusamash	Orangesic	Painover	Pyracon	Prolief	Dolorfin	Daro	Paralex	Tempol	Asuton	Biomed paracet	Medmol
Duorol	Febrinil	Pharmacen	Unigesic	Calonal o	Panadol baby	Effena	Ant	Grafadon	Bebetina	Roter paraceta	Temporal	Cetajol	Poton	Paracare	Paracol
Beramol	Fepanil	Adinol	Dolexpel	Naron	Plivamed	Tinaphen	Kit	Paracets	Tamifen	Daro paracetar	Tachipirin	Micetamol	Napaton	Pacimol	Newsemol
Dolprone	Fevastin	Abatem	Leopic	Atoanon	Abrolet	Pedipan	Pacon	Dolko	Acetamin	Melabon	Menpirin	Paracid	Kntondun	Pain clear	Pyraton
Pms acetaminophen	Ifimol	Portem	Octagesic	Aphlogis	Supramol	Raperon	Pemol	Medicol	Acetaminofer	Febrectal	Vestax	Pyrac	Anzerton	Dozol	Acedol
Dolgesic	Iphamol	Panofen	Betanol	Kiofever	Dexamol kid	Talenil	Aceta-p	Acenol	Julphadol	Calmanticold	Brexin	Seridol	Chungyo	Teralgex	Acetomin
Calpol six plus	Kelvin	Icetazol	Phenomed	Anyrume merck h	Rokamol	Taspen	Cetaphen	Pcm	Acetagen	Bandol	Parstelin	Biocetamol	Lotin	Treupel	Sufucon
Calpol infant	Kemcin	Piremol	Japhet	Uzu genetsu	Vimoli	Cetophen	Foramol	Novo-gesic	Umbral	Paracetamol g	Cadafen	Pamidol	Paracedon	Paramidol	Scanol
Parmol	Larkin	Prosedal	Zestagesic	Anyrume s sato	Acamoli forte	Endapen	Paramai	Setromol	Normotemp	Paracetamol e	Relasin	Sinapol	Antone	Acetalgina	Tinten
Anacin-3	Malidens	Termotrin	Sommec	Calonal wakodo	Sensamol	Sericon	Paranol	Zolbinet	Aliv	Paracetamol k	Nupren	Genamol	Depain	Mafidol	Ancoton
Q panol	Metacin	Tempofin	Corgic	Pabron kodomo	Daleparin	Tramol	Parax	Febridol	Finalin forte	Paracetamol c	Acetaminofen m	Paracitamol	Children panat	Mebinol	Panacon
Paralyoc	Metaljin	Piralyn	Molpar	Paraceta	Algiafin	Mardi	Pardon	Fevamol	Dominalito	Parafludeten	Amifen	Anapol	Kodome merur	Dolofebril	Tonphen
Dolostop	Metaplus	Paracetamol gi arl	Calvexol	Atmiphen	Panagesic	Rootphen	Paraman	Tylenol childrens cf	Finalin pediat	Paracetamol s	Apyrene	Panacin	Pilian	Liviolex	Piant
Abenol	Pamol moxy	Paracetamol gi bru	Detramol	Sg	Calpol plus	Tylenol er	Pamogin	Tylenol extended r	Finalin	Dorico	Winadol flashtat	Fendol	Soul pattinson	Nerupol	Anti-phen
Enelfa	Paracetamol apex	Soltadol	Krispel	Neosedenal	Fendon	Tasmen	Pyrimol	Tylenol extra-stren	Acestar	Acetofen	Acetalis	Apedol	Amcal paraliev	Tapsin infantil	Fanaton
Claradol	Paracin	Quitadol	Genpyra	Towasaal a	Fevadol	Tyrex-c	Parat	Tylenol extra-stren	Vitapyrena	Pacemol	Agurin	Finimal junior	Twp paracetam	Fibrimol	Acetanin
Calonal	Paramet	Paracetamol gi ser	Replen	Atenemen	Panadrex	A.a.p	Codamol	Tylenol junior stren	Piralmin	Aliviol	Alivax	Sarutu	O/n paracetam	Supracalm	Stone
Anhiba	Pedmol	Apa	Jemygesic	Cocarl	Panacetamol	Phenceta	Kala	Grippex	Amolgin	Anatyl	Amitafen	Zinel	Cm chemadol	Dolocetamol	Aton
Anyrume s	Pyrigesic	Parakapton	Dli-paracetamol	Panaleve	Emidol	Tospan	Dechamp	Tylenol arthritis	Doloxin	Gripotermon	Feverall acetami	Pain relief infan	Sbpa paracetan	Kitadol	Pacinol
Depon	Relif	Rellief	Analgen	Panets	Medamol	Typen	Faron	Tylenol arthritis ext	Ultrafen	Parador	Feverall acetami	Arthritis Pain	Pain & fever	Mejorax	Sedol
Anaflon	Saincitamol	Acet	Gesicor	Panadol solid	Neomol	Astamol	Asumol	Paralief	Inalgex	Vick pyrena	Feverall acetami	Equate pain reli	Cw painex	Termolin	A.t.
Sifenol	Salofan	222af	Esscet	Tabalgin	Panacare	Cetamin	Siltab	Influbene n	Amerin	Tylephen	feverall acetami	Genebs	Hc painex	Detial	Napton
Mono praecimed	Soparin	Feverhalt	Rongesic	Cupanol	Cetamyl	Amiceta	Unison	Nina	Terfen	Dorib	feverall acetami	Pain reliever	Pa painex	Pirantil	Fudolon
Pyromed s	Tacinol	Pediaphen	Medic aid paracetar	Paracetamol cox	Efdol	Astafen	Acetaphen	Painamol	Temfen	Pyrimel	Tylenol extra str	Junior pain relie	Gold cross para	Tervalan	Acetamino
Mexalen	Temptal	Robigesic	Biogenerics paracet	Paldesic	Dolmax	Acecort	Parapro	Causalon	Febronol	Termo	Tylenol sore thr	Little fevers	Atasol forte	Dozic	Depyretin
Prodenas	Thermol	Tantaphen	Dentofen	Paracetamol sfp	Doli pediatrique	Alkapen	Cemol	Termofren	Isofen	Unigrip	Bodrex	Rite aid acetami	Axcel paracetar	Analpain	Lactam
Boots paracetamol for	Ultragin	Tylenol extra strength	Drilan	Miradol	Napamol	Dupen	Fara	Dexamol	Lascofen	Paralgen	Calapol	Jing di	Benylin Sore Th	Fitamol	Chinton
Paediatril	Ultrapyrin	Tylenol aches & strains	Meforagesic	Salzone	Panasorb	Koko-pedi	Nutamol	Codipar	Cymatem	Bromil gripe	Ikacetamol	Temperine	Parox	Paracil	Centona
Paralen	Relidol	Tylenol cold day/night	Milgesic	Paracetamol cupa	Pyralen	Itarenol	Aoricet	Paracetal	Laproter	Febralgin	Pamolin	Uracet	Tapsin sin cafe	Paramex	Pylinaton
Rubophen	Metamol	Togal paracetamol	Ultragesic	Paracetamol kent	Brunomol	Bioacet	Vestamol	Togal	Pafen	Cefabrina	Propyretic	Rite aid childre	Panadol 7+ Yea	Tydenol	Pymadon
Minoset	Pyrexon	Sinpro n	Aminofebrin	Calpahalal	Winpain	Flashtab	Ceton	Adol	Pirosin	Paracen	Pyrexin	CounterAct Pair	Coles paracetar	Paracit	Pyrudon
Lotemp	Aminol	Paedialgon	Defebrol	Paracetamol berk	Paramed	Taspen er	Popain	Pyralgan	Acetaminolac	Termol	Sakapara	Tactinal	Paracetamol Al	Zerin	Contonlin
Parraut	Vyrumol	Alacetan	Medgenol	Medinol	Merck-gesic	Taminol	Paradon-p	Pyrex	Dolenol	Trifen	Depanas	Children's tylen	Paracetamol P	Calpol 6	Calpol six plus su
Puernol	P-mol	Parapaed	Corgic plus	Infadrops	Rolab-paracetamol	Geworin-i	Parmosium	Benuron	Rosafen	Emsgrip	Propain	Gripin	Pinex junior	Uni-Pamol	Alpiny
Alginina	Lanol	Ausbuettels paracetam	Pynal	Fanalgic	Parapane	Acepin	Pyretal	Dolel	Dalgen	Cyfenol	Ramagesic	Dikuton	Saframol	Disprol Paracetar	Acetaminophen
								Nodolex	Adorem	Tylaflex	Debrinol	Lekadol Direkt	Children's pan	Disprol Soluble F	Gynospasmine
								Naprex	Doloproxen	Tyflen	Pyridol	Gripin Bebe		Lupocet BABY	Paracetamol-K

Paracetamol



Aspirin



DO NOT WRITE IN SHADED AREAS

USE TYPEWRITER (2 PITCHES PER INCH, SINGLE SPACING)

WHO COLLABORATING CENTRE FOR INTERNATIONAL DRUG MONITORING

REPORT OF SUSPECTED DRUG REACTION

COUNTRY

COUNTRY CASE IDENTIFICATION NO

Source of data

Report type

Country of origin

AGE

SEX M or F

ETHNIC ORIGIN

Onset of reaction Day Month Year

RECORD NUMBER

* IF FOREIGN REPORT

ADVERSE REACTION PREFERRED TERMS

ICD CODE

OUTCOME:

A RECOVERED WITHOUT SEQUELAE

B RECOVERED WITH SEQUELAE

F NOT YET RECOVERED

D DIED — DUE TO ADVERSE REACTION

C DIED — DRUG MAY BE CONTRIBUTORY

N DIED — UNRELATED TO DRUG

U UNKNOWN

IF ADVERSE REACTION IS DEATH, CAUSE OF DEATH (ICD)**

**INDICATE ICD VERSION

DRUGS: Trade name if available

S.I. (if G)

DOSAGE REGIMEN

AMOUNT

UNIT

FREQ. PER

ROUTE

DRUG ADMINISTRATION***

BEGAN

TERMINATED

REASON FOR DRUG USE ICD CODE*

*** IF EXACT DATE UNKNOWN, RECORD DURATION OR CONTINUING TO - BC according to CLOCK

NUMBER OF DRUGS IF MORE THAN SIX

NATIONAL CENTRE COMMENTS

DECHALLENGE:

1 DEFINITE IMPROVEMENT

2 PROBABLE IMPROVEMENT

3 MEDICATION CONTINUED

4 UNKNOWN

DRUG-REACTION RELATIONSHIP:

1 CERTAIN

2 PROBABLE

3 POSSIBLE

4 UNLIKELY

5 UNCLASSIFIED

6 UNCLASSIFIABLE

REDHALLENGE:

1 RECURRENCE OF SYMPTOMS

2 NO RECURRENCE

3 NO REDHALLENGE PERFORMED

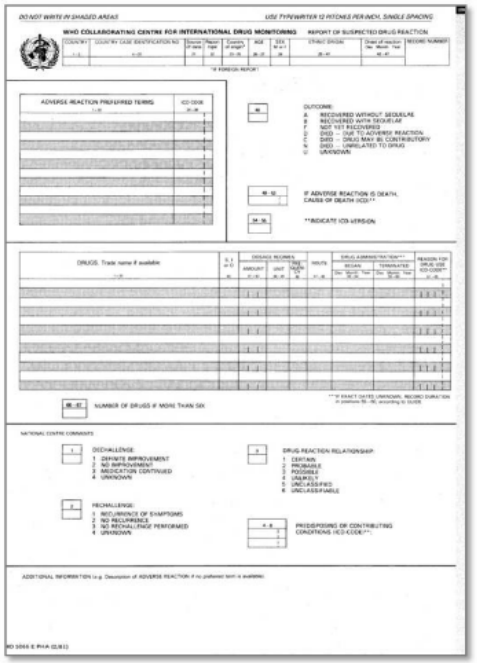
4 UNKNOWN

PREDISPOSING OR CONTRIBUTING CONDITIONS (ICD CODE)***

ADDITIONAL INFORMATION (e.g. Description of ADVERSE REACTION if no preferred term is available)

WHO 5066 E (PHA 2)(81)

Magnecyl



DO NOT WRITE IN SHADED AREAS

USE TYPEWRITER 12 PITCHES PER INCH, SINGLE SPACING

WHO COLLABORATING CENTRE FOR INTERNATIONAL DRUG MONITORING

REPORT OF SUSPECTED DRUG REACTION

ADVERSE REACTION PREFERRED TERMS

ICD CODE

OUTCOME:
A RECOVERED WITHOUT SEQUELAE
B RECOVERED WITH SEQUELAE
F NOT YET RECOVERED
D DIED — DUE TO ADVERSE REACTION
C DIED — DRUG MAY BE CONTRIBUTORY
N DIED — UNRELATED TO DRUG
U UNKNOWN

IF ADVERSE REACTION IS DEATH, CAUSE OF DEATH (ICD)**

**INDICATE ICD VERSION

DRUGS. Trade name if available

DOSAGE REGIMEN

AMOUNT

UNIT

DAILY DOSE

ROUTE

DRUG ADMINISTRATION***

BEGAN

TERMINATED

REASON FOR DRUG USE ICD CODE**

NUMBER OF DRUGS IF MORE THAN SIX

***IF EXACT DATE(S) UNKNOWN, RECORD DURATION

NATIONAL CENTRE COMMENTS

DECHALLENGE:
1 DEFINITE IMPROVEMENT
2 NO IMPROVEMENT
3 MEDICATION CONTINUED
4 UNKNOWN

DRUG-REACTION RELATIONSHIP:
1 CERTAIN
2 PROBABLE
3 POSSIBLE
4 UNLIKELY
5 UNCLASSIFIED
6 UNCLASSIFIABLE

RECHALLENGE:
1 RECURRENCE OF SYMPTOMS
2 NO RECURRENCE
3 NO RECHALLENGE PERFORMED
4 UNKNOWN

PREDISPOSING OR CONTRIBUTING CONDITIONS (ICD CODE)**

ADDITIONAL INFORMATION (e.g. Description of ADVERSE REACTION if no preferred term is available)

WO 1066 E PHA (5.81)

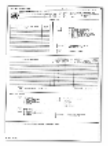
Acetys

Gel

Acetyl-salicylic acid

Aspirin

- Aspirin
- Aspirin
- Aspirin



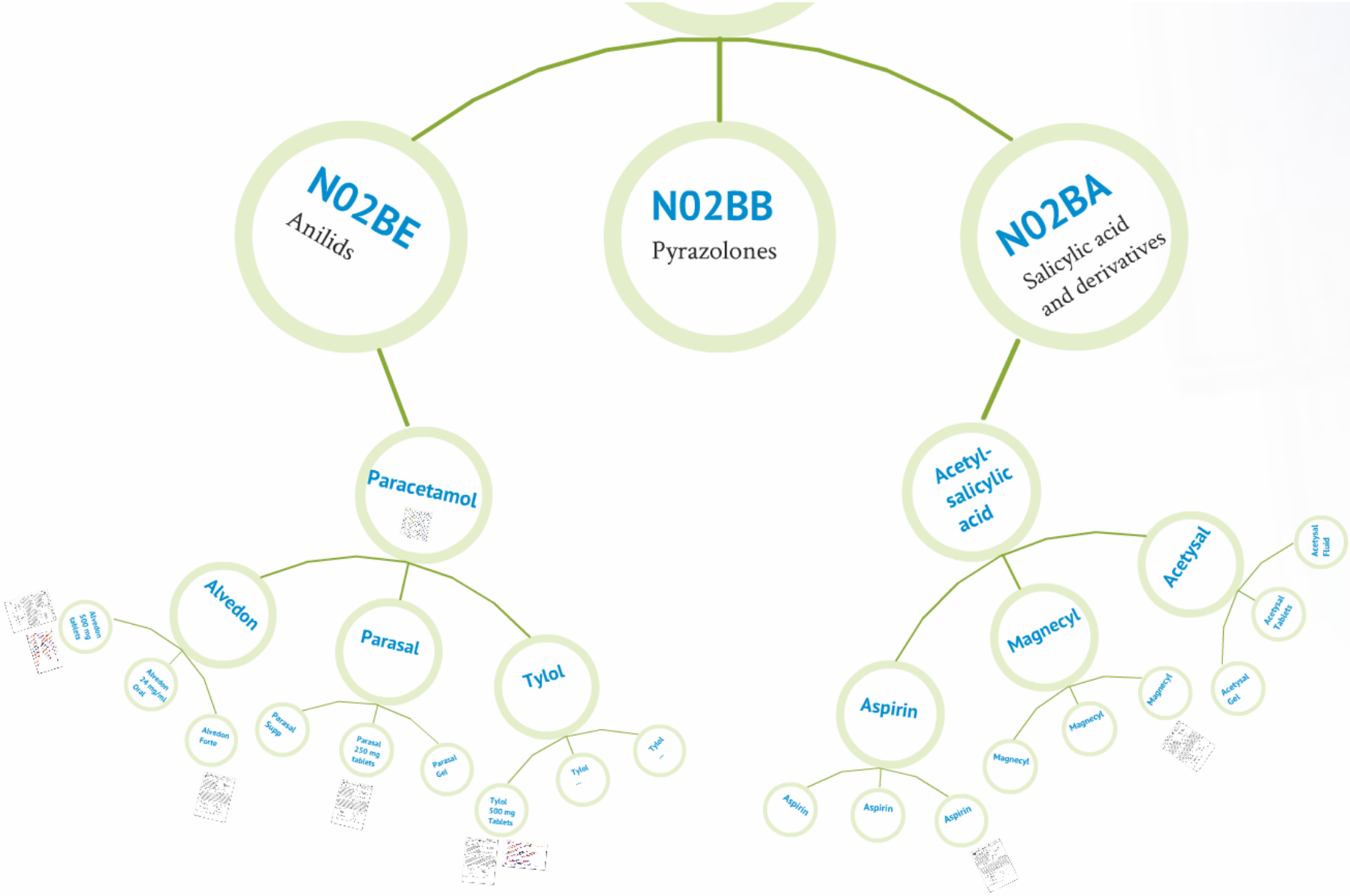
Magnecyl

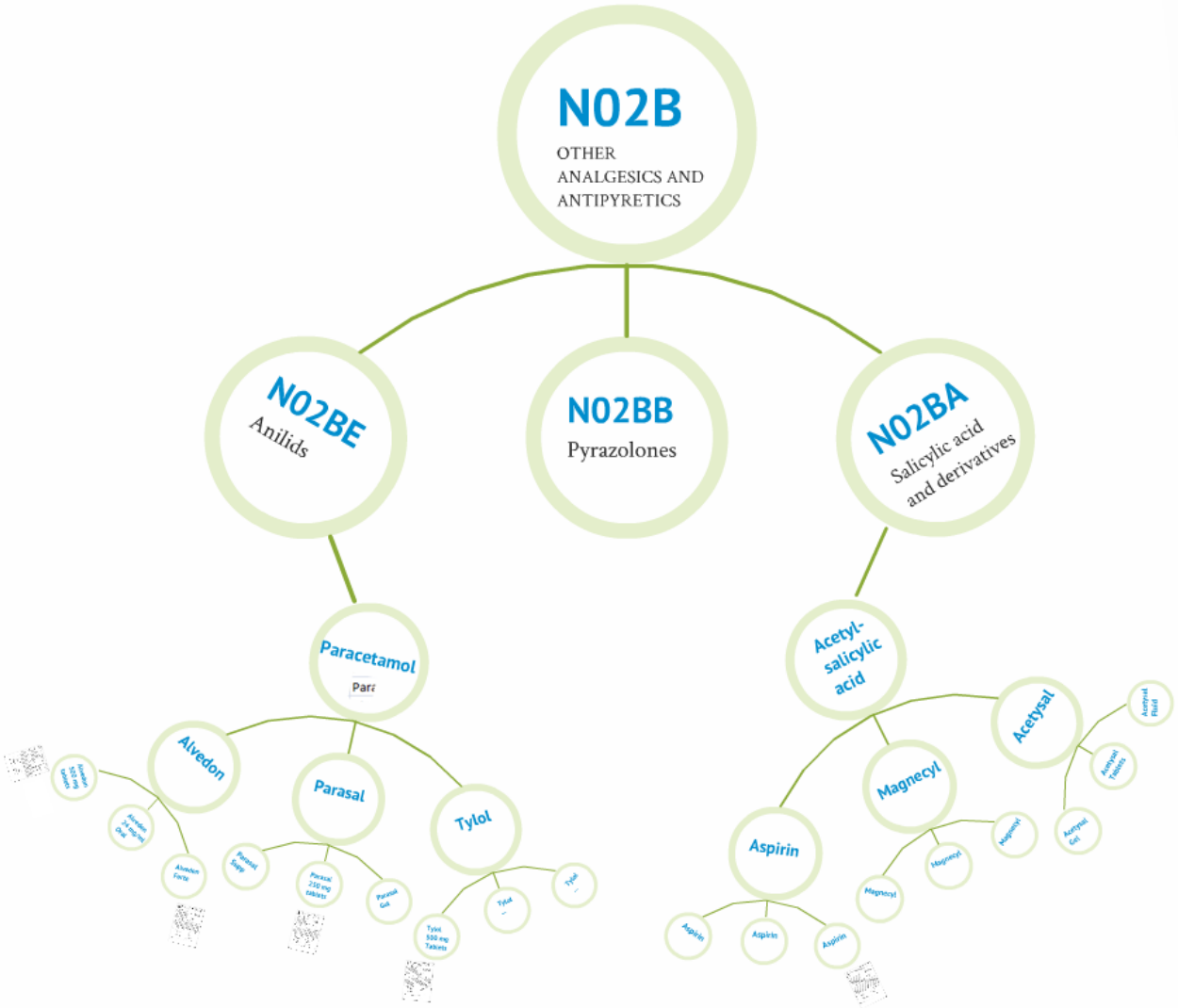
- Magnecyl
- Magnecyl
- Magnecyl



Acetysal

- Acetysal Gel
- Acetysal Tablets
- Acetysal Fluid


N02BE
Anilids
N02BB
Pyrazolones
N02BA
Salicylic acid and derivatives
Paracetamol
Acetyl-salicylic acid
Alvedon
Parasal
Tylol
Aspirin
Magnecyl
Acetysal
Alvedon 500 mg tablets
Alvedon 24 mg/ml Oral
Alvedon Forte
Parasal Supp
Parasal 250 mg tablets
Parasal Gel
Tylol 500 mg Tablets
Tylol
Tylol
Aspirin
Aspirin
Aspirin
Magnecyl
Magnecyl
Magnecyl
Acetysal Gel
Acetysal Tablets
Acetysal Fluid


N02B
OTHER ANALGESICS AND ANTIPYRETICS
N02BE
Anilids
N02BB
Pyrazolones
N02BA
Salicylic acid and derivatives
Paracetamol
Para
Alvedon
Parasal
Tylol
Acetyl-salicylic acid
Aspirin
Magnecyl
Acetysal

With the WHO-DDs linked to ICSRs we can:

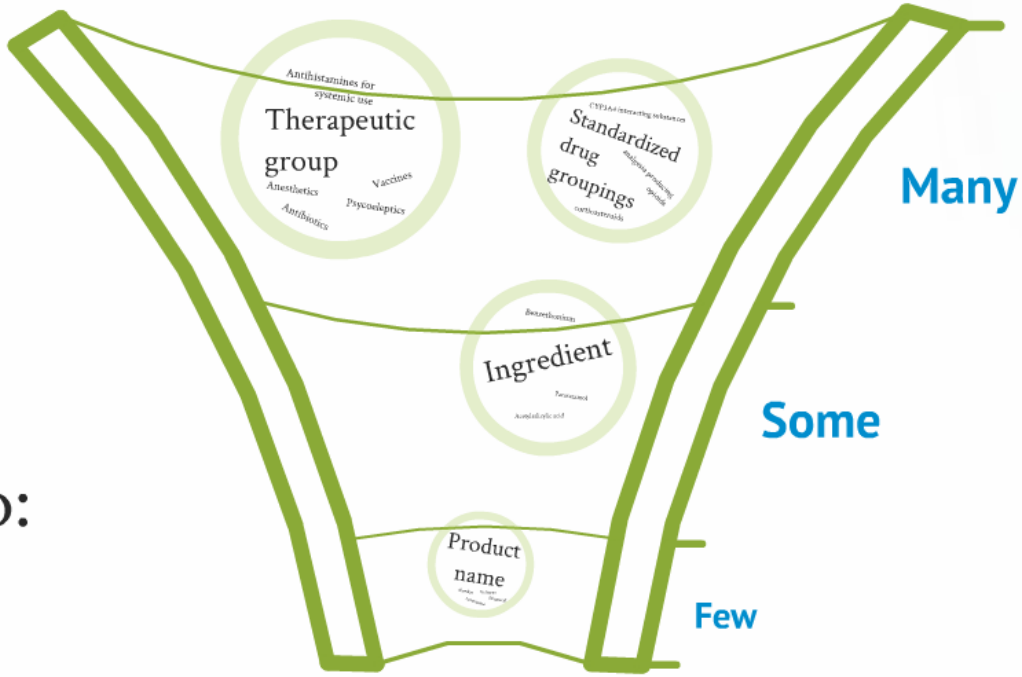


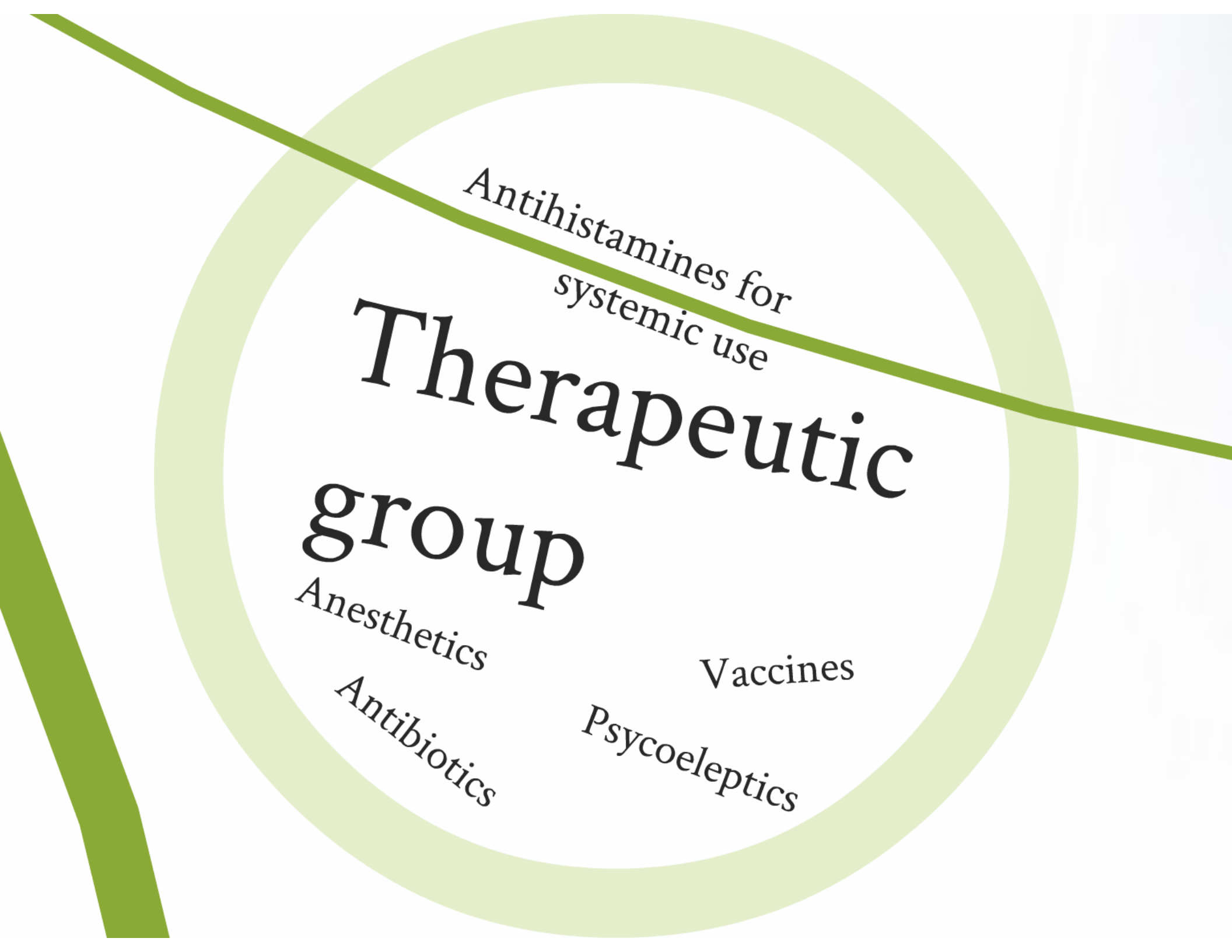
Sort

Group

Search

ICSRs according to:




Antihistamines for systemic use
Therapeutic group
Anesthetics
Antibiotics
Vaccines
Psycoeleptics

CYP3A4 interacting substances

Standardized drug groupings

analgesia producing opioids

corticosteroids

Benzethonium

Ingredient

Paracetamol

Acetylsalicylic acid

Product name

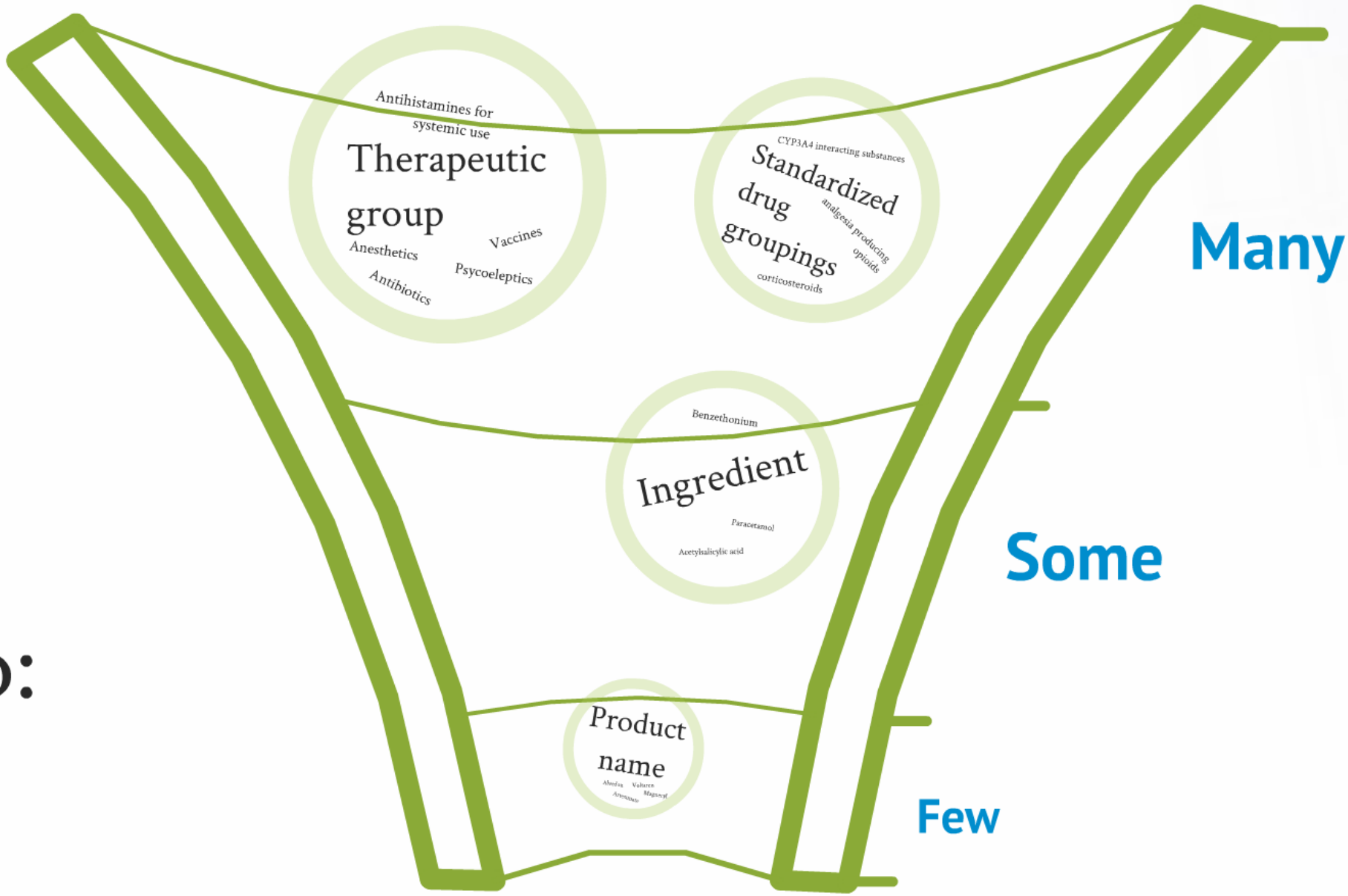
Alvedon

Voltaren

Magnecyl

Artesunate

to:


Antihistamines for systemic use
Therapeutic group
Anesthetics
Vaccines
Psycoeleptics
Antibiotics
CYP3A4 interacting substances
Standardized drug groupings
analgesia producing opioids
corticosteroids
Many
Benzethonium
Ingredient
Paracetamol
Acetylsalicylic acid
Some
Product name
Few

The PV database

The case report itself is only a small part of the minimum requirements on a PV database

WHO DDE

Sender

WHO-ART

SOC HLT PT IT

case report

Receiver(s)

MedDRA® MSSO

Submission(s)

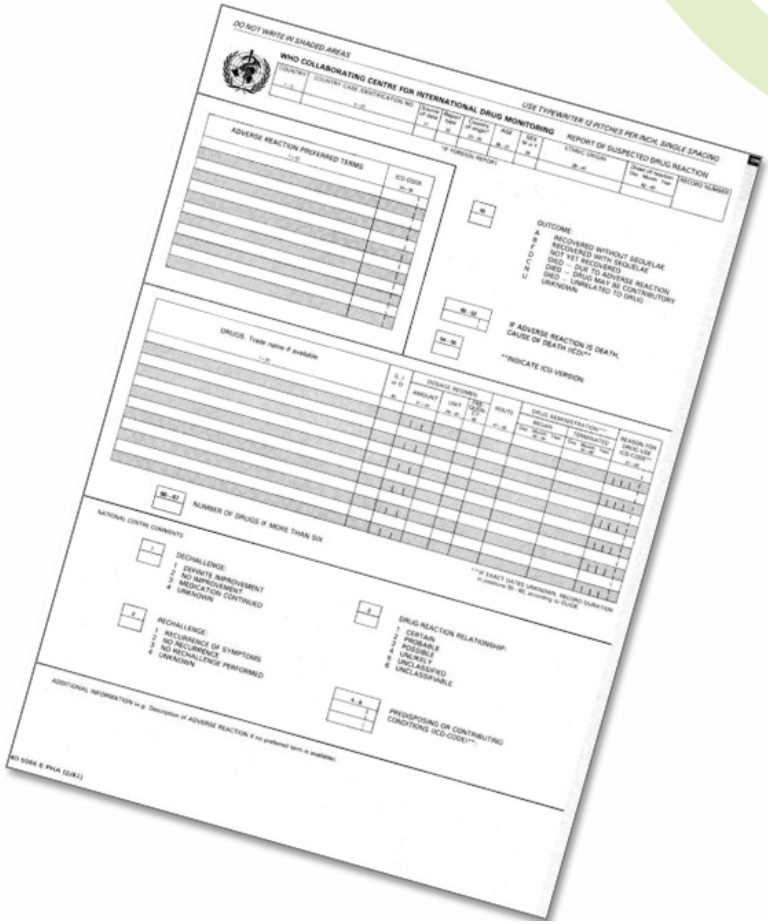
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IT

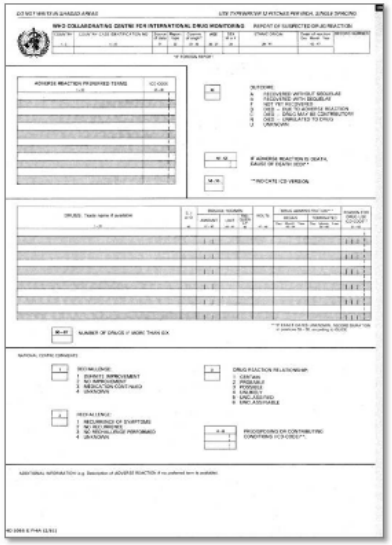
Osteoarthritis




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IT

Joint effusion



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```

PT

Arthropathy

IT

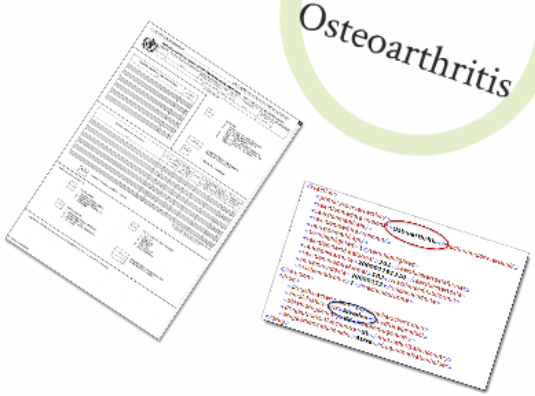
Osteoarthritis

IT

Joint inflammation

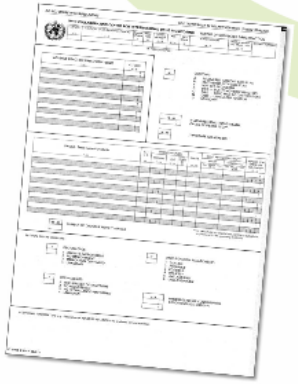
IT

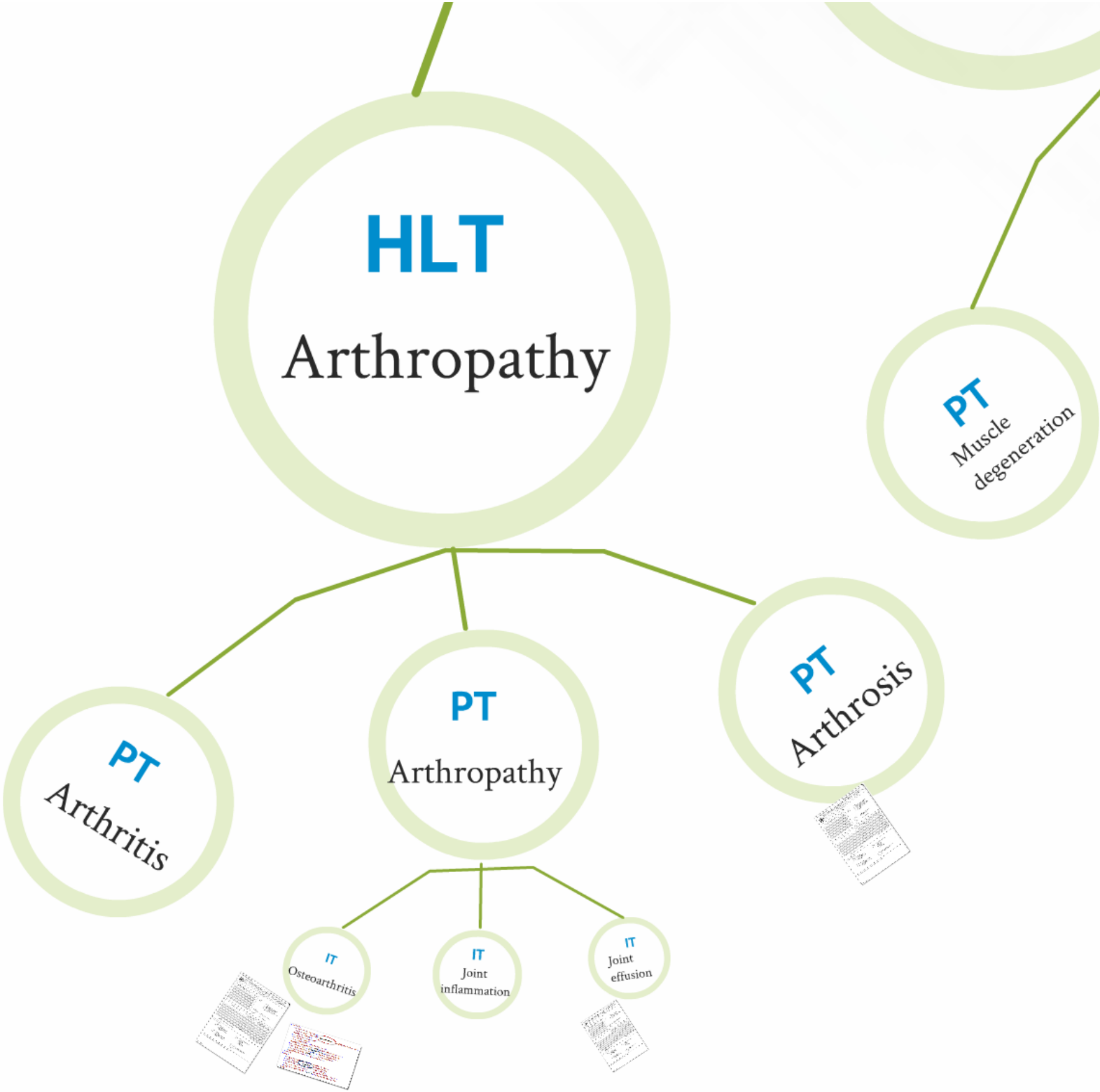
Joint effusion

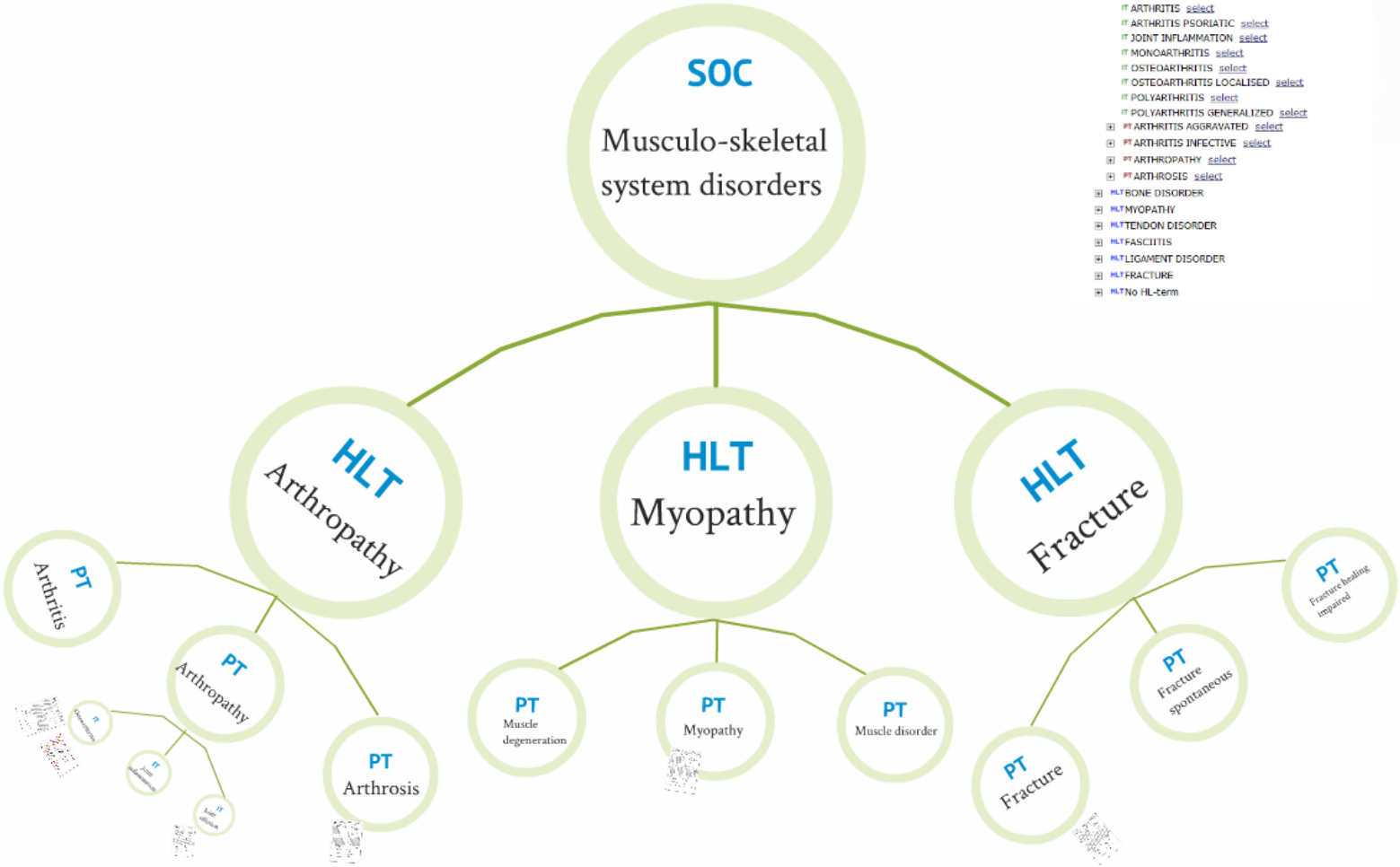


PT

Arthrosis




HLT
Arthropathy
PT
Muscle degeneration
PT
Arthritis
PT
Arthropathy
PT
Arthrosis
IT
Osteoarthritis
IT
Joint inflammation
IT
Joint effusion



- SOC Musculo-skeletal system disorders
  - HLT ARTHROPATHY
    - PT ARTHRITIS select
      - IT ARTHRITIS select
      - IT ARTHRITIS PSORIATIC select
      - IT JOINT INFLAMMATION select
      - IT MONOARTHRITIS select
      - IT OSTEOARTHRITIS select
      - IT OSTEOARTHRITIS LOCALISED select
      - IT POLYARTHRITIS select
      - IT POLYARTHRITIS GENERALIZED select
    - PT ARTHRITIS AGGRAVATED select
    - PT ARTHRITIS INFECTIVE select
    - PT ARTHROPATHY select
    - PT ARTHROSIS select
  - HLT BONE DISORDER
  - HLT MYOPATHY
  - HLT TENDON DISORDER
  - HLT FASCIITIS
  - HLT LIGAMENT DISORDER
  - HLT FRACTURE
  - HLT No HL-term

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Sender

WHO-ART

SOC HLT PT IT

case report

Receiver(s)

MedDRA® MSSO

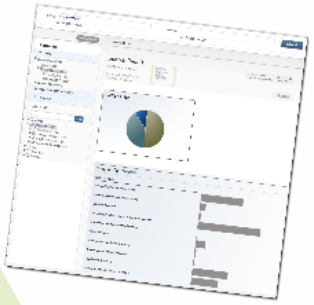
Submission(s)

The PV Data Management System













Data entry

Quality and correctness

- Mandatory fields, error checks, logical checks...

User-friendliness

- For ease of data entry but also in interpretation of interface, avoidance of ambiguous messages

Confidentiality

- What can be collected and what can later be shared

Timeliness

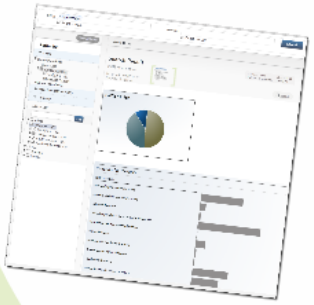
- To keep internal deadlines and regulatory demands

The PV Data Management System













Analysis and Data Retrieval

We need tools to:

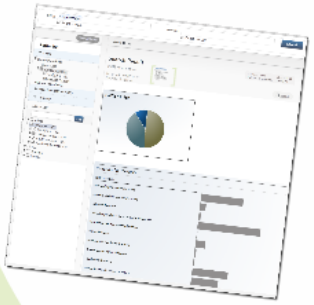
- Filter and sort data for analysis
- Data mining
- Drug/ADR profiles
- Line listings
- Retrieval of administrative data
- Quarterly and yearly statistics
- Performance
- ...

The PV Data Management System













Access (1)

How do you get access to the data

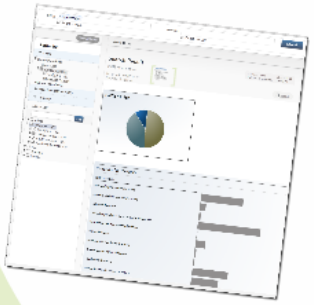
- Via software installed on the desktop (client tools)
- Client tools via VPN (Virtual Private Network)
- Via internet (Cloud solutions)

The PV Data Management System













Access (2) (data access)

Only authorized users shall have access to the data and normally there is a need for different access levels

- User name and password or higher security demands

Protection

Data should be encrypted when sent over for example the internet

- Also important to consider when sending data to external receivers

Traceability

- You should be able to track changes via some kind of audit trail
- Also relevant for historical/deleted data

Only authorized users shall have access to the data and normally there is a need for different access levels

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Protection

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Traceability

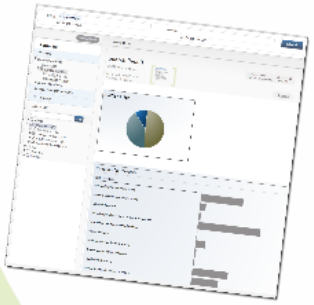
- You should be able to track changes via some kind of audit trail
- Also relevant for historical/deleted data

The PV Data Management System













Backup and Recovery

Protection of physical hardware/media

- Servers
- Backup media, disks or tapes
- Physical separation of backup and data

  Preferably in different locations that would not be affected by for example a fire at the same time



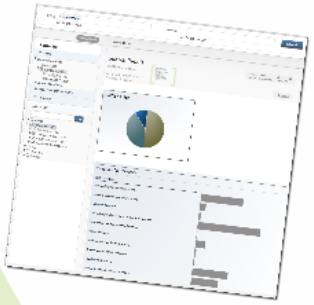
It is extremely important
- not only to back up data -
but also to test that the data
can be restored from backup

The PV Data Management System





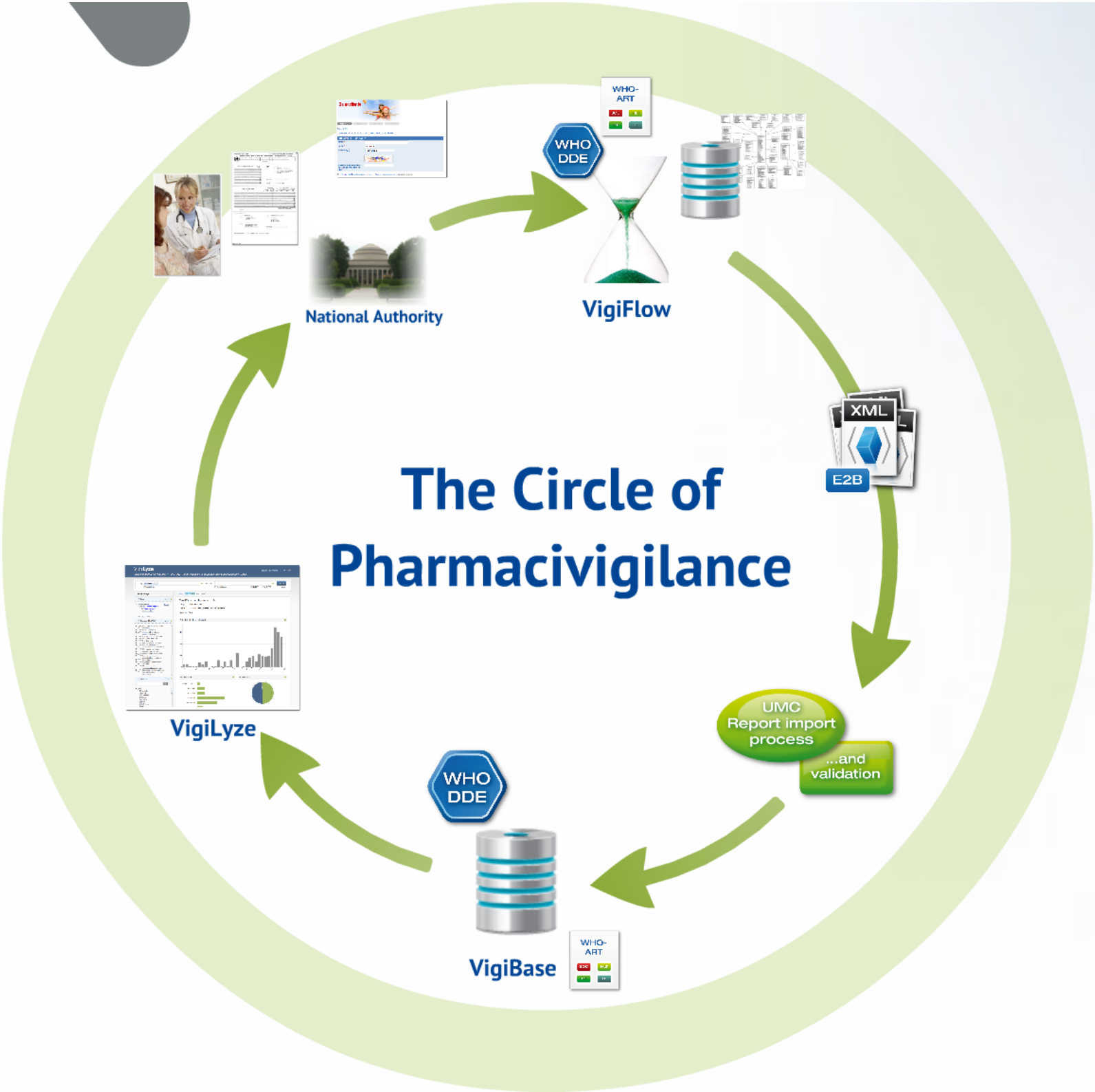


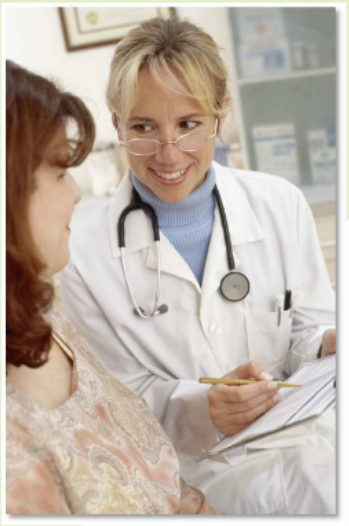


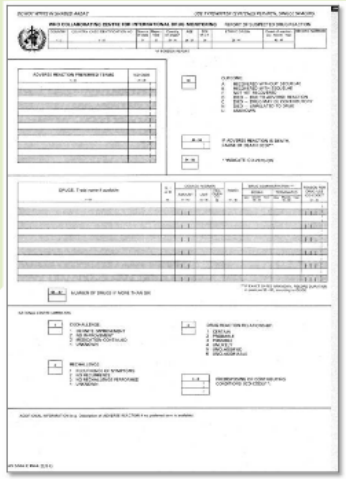




The Circle of Pharmacivigilance











National Authority

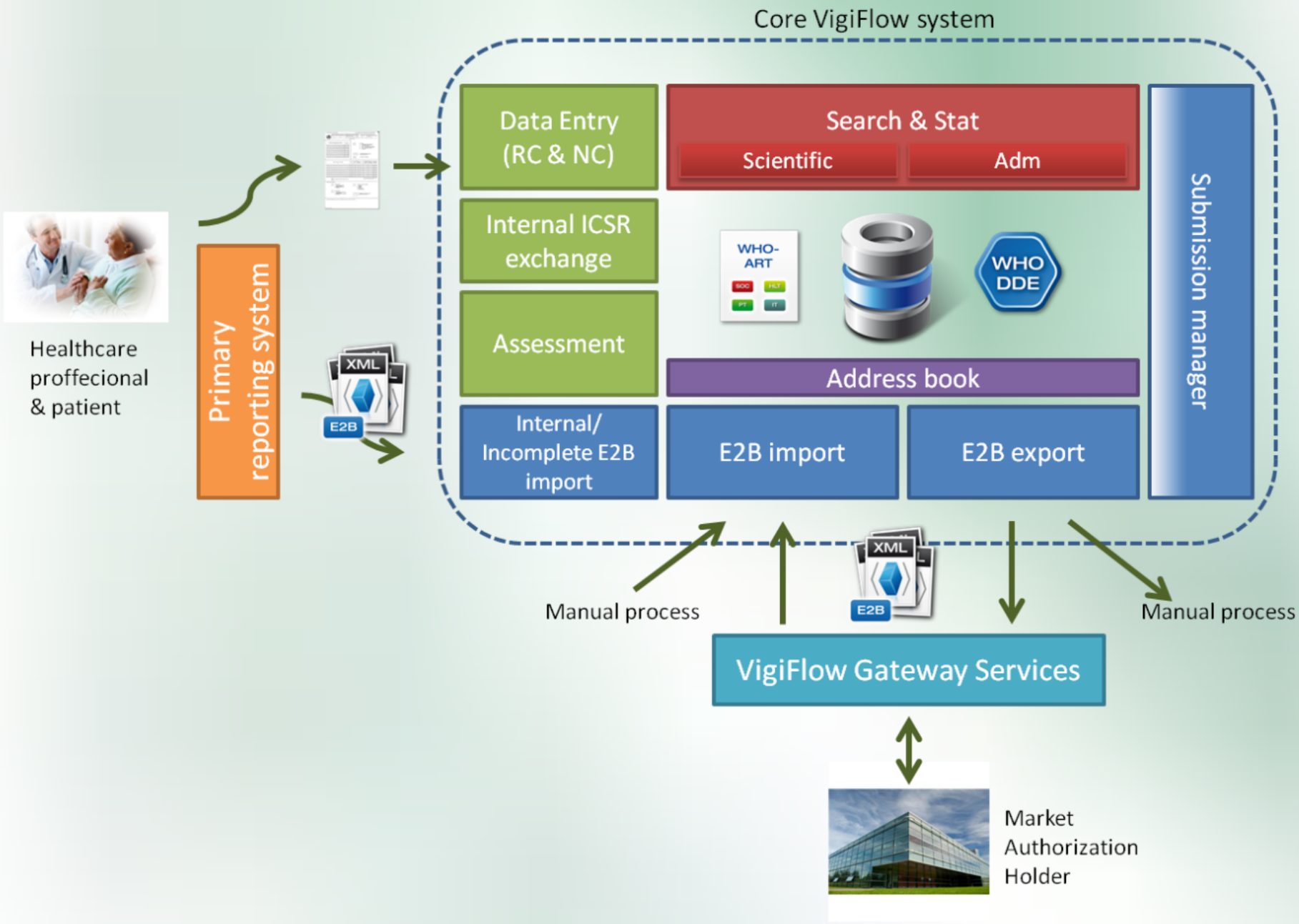








VigiFlow


Core VigiFlow system
Data Entry (RC & NC)
Search & Stat
Scientific
Adm
Internal ICSR exchange
Assessment
WHO-ART
WHO DDE
Address book
Submission manager
Internal/ Incomplete E2B import
E2B import
E2B export
Healthcare proffecional & patient
Primary reporting system
XML
E2B
Manual process
Manual process
VigiFlow Gateway Services
Market Authorization Holder

ssment

Address book

ernal/
plete E2B
port

E2B import

E2B export

anager

Manual process

XML

E2B

Manual process

VigiFlow Gateway Services



Market
Authorization
Holder



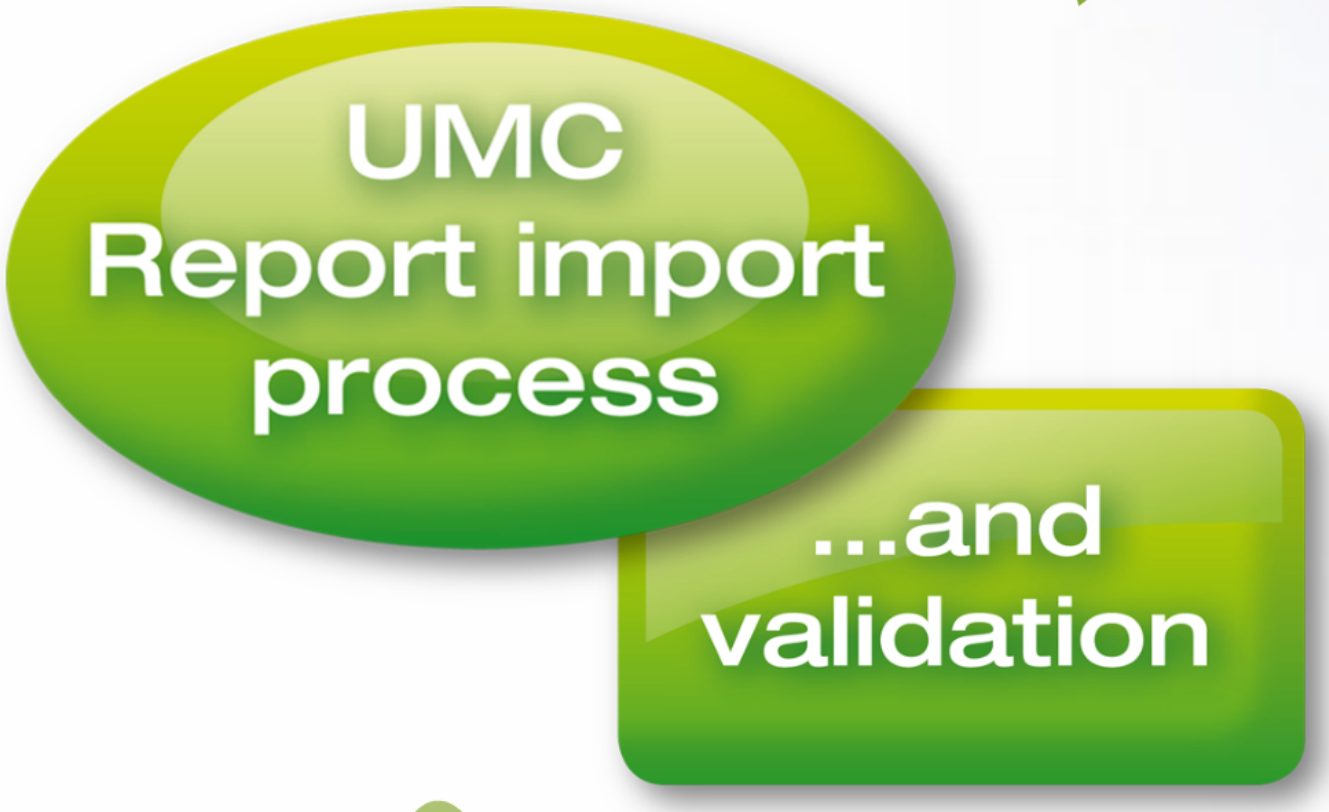






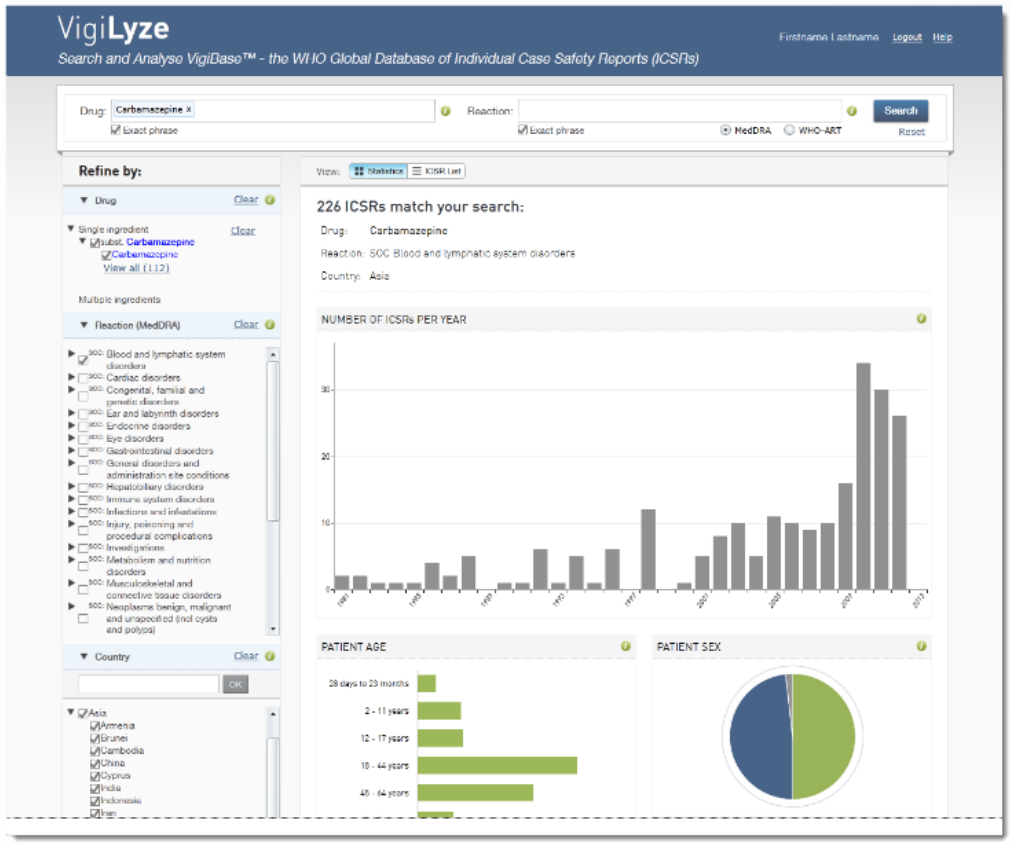
VigiFlow


XML
E2B


UMC
Report import
process
...and
validation

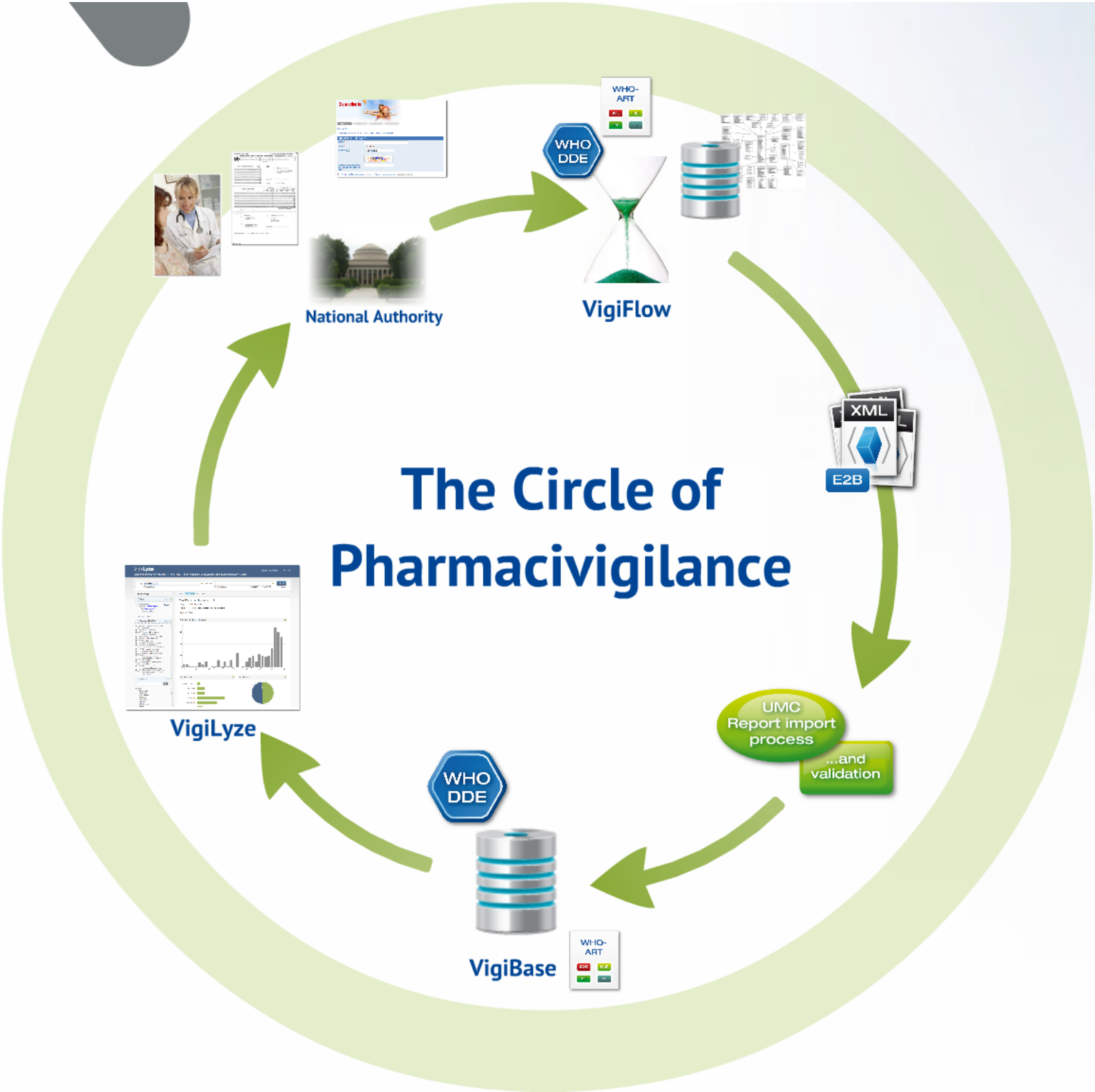

WHO
DDE
VigiBase
WHO-
ART
SOC
HLT
PT
IT

Pha



VigiLyze

The Circle of Pharmacivigilance



PV Data Management

Magnus Wallberg

Uppsala, May 22, 2013



the UPPSALA MONITORING CENTRE