



E2B at LEO Pharma - including MedDRA usage

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What's Up ? – Now and later

- The main issue is E2B compliance
- Additionally now:
 - better MedDRA handling, incl. browsing/coding
 - improved (and more) ARISg standard screens
 - improved performance (e.g. speed of searches)
 - reporting compliance monitoring (using SAS)
 - AE case workload monitoring (using SAS)
- Additionally later:
 - validation of Impromptu based operations
 - e-mail with attached CIOMS forms for non-E2B recipients. The expected step with automated standard letters will be skipped entirely



Cyclone Tracker

Tracker - Cyclone Interchange

File Edit View Tools Help

Database table: Runtime Copy Find Filter Refresh Help

Transactions - Runtime Table

Date	Control ID	ID	Status	Source	Orig File Name
02/23/2004 08:14:33	XML	LEO	MDN RECEIVED	SMTP	E2B00000000077.xml
02/23/2004 08:10:08	XML	LEO	SENT	EMAIL	E2B00000000077.xml
02/23/2004 08:10:02	XML	LEO	PACKAGED	PARTNER	E2B00000000077.xml
02/23/2004 08:10:02	XML	LEO	NEW	PACKAGER	E2B00000000077.xml
02/23/2004 08:09:32	XML	LEO	MDN RECEIVED	SMTP	E2B00000000076.xml
02/23/2004 08:04:18	XML	LEO	SENT	EMAIL	E2B00000000076.xml
02/23/2004 08:04:13	XML	LEO	PACKAGED	PARTNER	E2B00000000076.xml
02/23/2004 08:04:01	XML	LEO	NEW	PACKAGER	E2B00000000076.xml
02/19/2004 17:50:08	XML	LEO	MDN SENT	EMAIL	ack_E2B00000000058.xml
02/19/2004 17:50:06	XML	LEO	RECEIVED	SMTP	ack_E2B00000000058.xml
02/19/2004 17:47:35	XML	LEO	MDN RECEIVED	SMTP	E2B00000000058.xml
02/19/2004 17:45:48	XML	LEO	SENT	EMAIL	E2B00000000058.xml
02/19/2004 17:45:36	XML	LEO	PACKAGED	PARTNER	E2B00000000058.xml
02/19/2004 17:45:35	XML	LEO	NEW	PACKAGER	E2B00000000058.xml
02/19/2004 09:40:31	XML	LEO	MDN SENT	EMAIL	ack_E2B00000000056.xml
02/19/2004 09:40:26	XML	LEO	RECEIVED	SMTP	ack_E2B00000000056.xml
02/19/2004 09:36:55	XML	LEO	MDN RECEIVED	SMTP	E2B00000000056.xml
02/19/2004 09:33:50	XML	LEO	SENT	EMAIL	E2B00000000056.xml
02/19/2004 09:33:35	XML	LEO	PACKAGED	PARTNER	E2B00000000056.xml
02/19/2004 09:33:25	XML	LEO	NEW	PACKAGER	E2B00000000056.xml
02/18/2004 10:26:43	XML	LEO	MDN SENT	EMAIL	ack_E2B00000000054.xml
02/18/2004 10:26:42	XML	LEO	RECEIVED	SMTP	ack_E2B00000000054.xml
02/18/2004 10:26:12	XML	LEO	MDN RECEIVED	SMTP	E2B00000000054.xml
02/18/2004 10:24:13	XML	LEO	SENT	EMAIL	E2B00000000054.xml
02/18/2004 10:24:09	XML	LEO	PACKAGED	PARTNER	E2B00000000054.xml
02/18/2004 10:24:08	XML	LEO	NEW	PACKAGER	E2B00000000054.xml
02/18/2004 09:25:32	XML	LEO	MDN SENT	EMAIL	SafetyReport-NO-NOMAADVRE-NOMATEST-M-485.xml
02/18/2004 09:25:32	XML	LEO	MDN SENT	EMAIL	SafetyReport-NO-NOMAADVRE-NOMATEST-M-483.xml
02/18/2004 09:25:32	XML	LEO	MDN SENT	EMAIL	SafetyReport-NO-NOMAADVRE-NOMATEST-M-482.xml
02/18/2004 09:25:31	XML	LEO	MDN SENT	EMAIL	SafetyReport-NO-NOMAADVRE-NOMATEST-M-484.xml
02/18/2004 09:25:31	XML	LEO	MDN SENT	EMAIL	SafetyReport-NO-NOMAADVRE-NOMATEST-M-481.xml
02/18/2004 09:25:31	XML	LEO	MDN SENT	EMAIL	SafetyReport-NO-NOMAADVRE-NOMATEST-M-479.xml
02/18/2004 09:25:31	XML	LEO	RECEIVED	SMTP	SafetyReport-NO-NOMAADVRE-NOMATEST-M-485.xml
02/18/2004 09:25:30	XML	LEO	RECEIVED	SMTP	SafetyReport-NO-NOMAADVRE-NOMATEST-M-483.xml

Logged in user: emrdk Press F1 for on-line help. Records: 66



ARISg E2B Gateway, Import log

Import Log Details - Microsoft Internet Explorer

Address: http://casereport.n3slch=ASSIGNED-ORFACI-CLIS_NSRScreenFabo0_snpid04CRFACI9E-ICPATEST-99915_app=02=06_crew6_jpr=05_fbr=fabo0_fbp=1146_rft=0606_rftV6aw6_rftV6y01=0606toE=...

E2B Gateway

Admin Password Exports Archive Error Section About

Import Log Details

ICSR Number	NO-NORMANURE-NORMTEST-M-981
Sender	NOX8
Receiver	Leo Pharmaceutical Products
Date Submitted	18-Feb-2004

Logout

Case Resulting Ad:

Detailed Description:

Processing the Safetyreport <NO-NORMANURE-REL30-000-954> of Message number <NO-NORMANURE-NORMTEST-M-981>.
Log date and time = 2004-02-23 08:09:07
Imported ADR successfully into ARIS database with ADR Number: 128_00000549(0.0)

Case submitted to workflow caseWF_ID: 6542 ADR_ID: 0000002144

Back

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ARISg Screens

The screenshot displays the ARISg MedDRA Browser interface. It features a search area with three columns: 'System organ class', 'High level group term', and 'High level term'. The search results are as follows:

System organ class	High level group term	High level term
*Nervous system disorders	Headaches	Headaches NEC

Below the search results, there are two more search fields. The first is for 'Preferred term' with 'Drug withdrawal headache' selected. The second is for 'Lower level term' with 'headache' entered, showing a list of related terms:

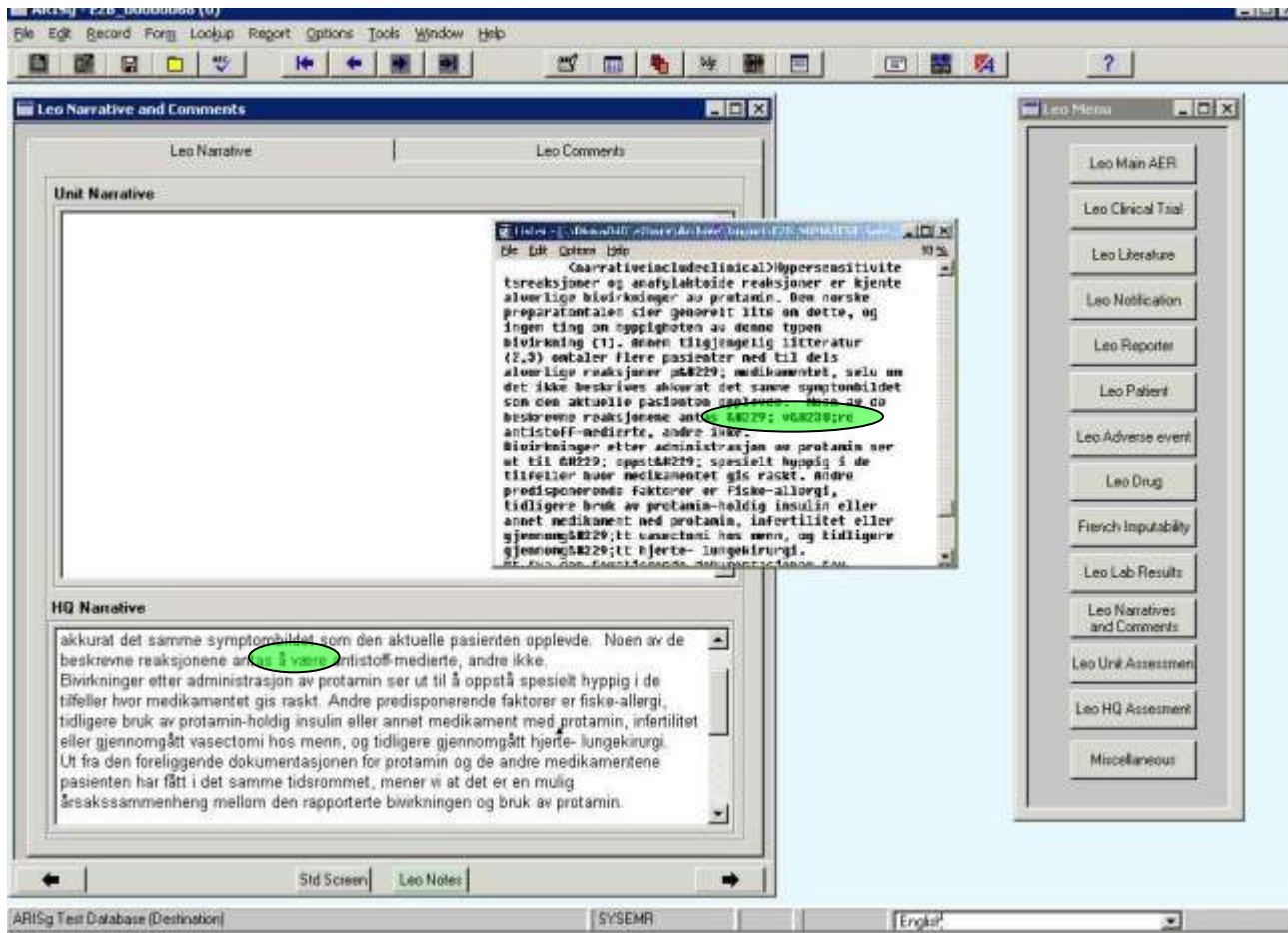
- Band-like headache
- Chronic headaches
- Cluster headaches
- Drug withdrawal headache
- Drug-induced headache
- Forehead headache
- Frequent headaches
- Frontal headache
- Headache
- Headache (except migraine) aggravated
- Headache (excl migraine) aggravated
- Headache NOS
- Headache NOS aggravated
- Headache aggravated

On the right side, there are search options: 'Condition' (Starts with, Contains, Exact), 'Order by' (Code, Decode), 'Current terms only' (checked), and 'Match case'. A tree view shows the hierarchy: *Nervous system disorders > Headaches > Headaches NEC > Drug withdrawal headache.

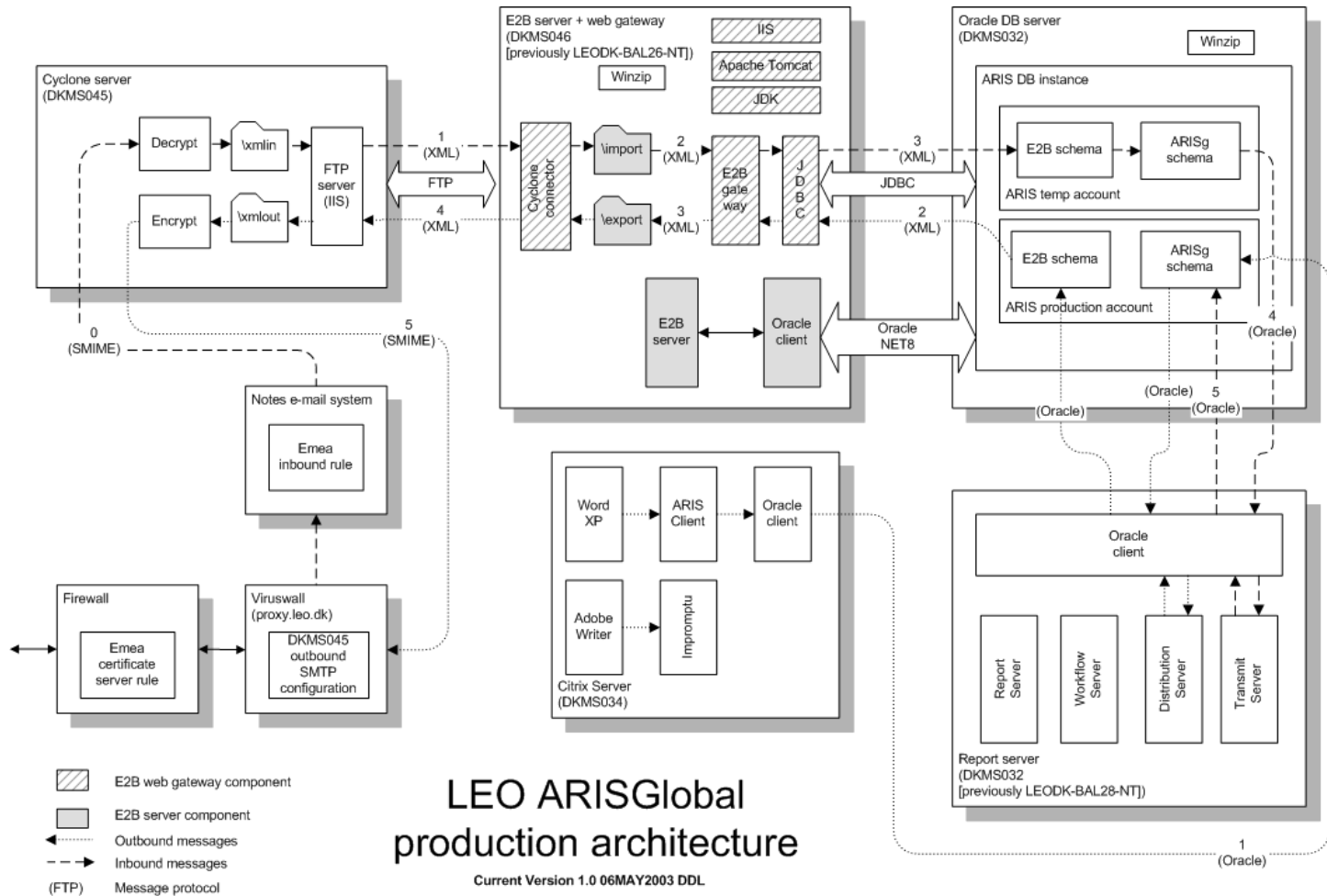
Buttons at the bottom include 'Find', 'Select', 'Close', and 'Help'. A note at the bottom states: 'Note: The SOC term with an asterisk (*) is the Primary SOC term'.



ARISg Screens



Quite simple, really...



LEO ARISGlobal production architecture

Current Version 1.0 06MAY2003 DDL

Based on V1.2 04/02/03 of 'LEO ARISGlobal' architecture (week 10)

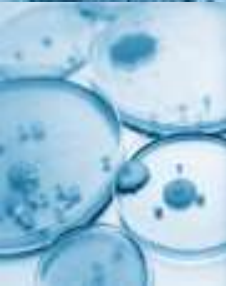




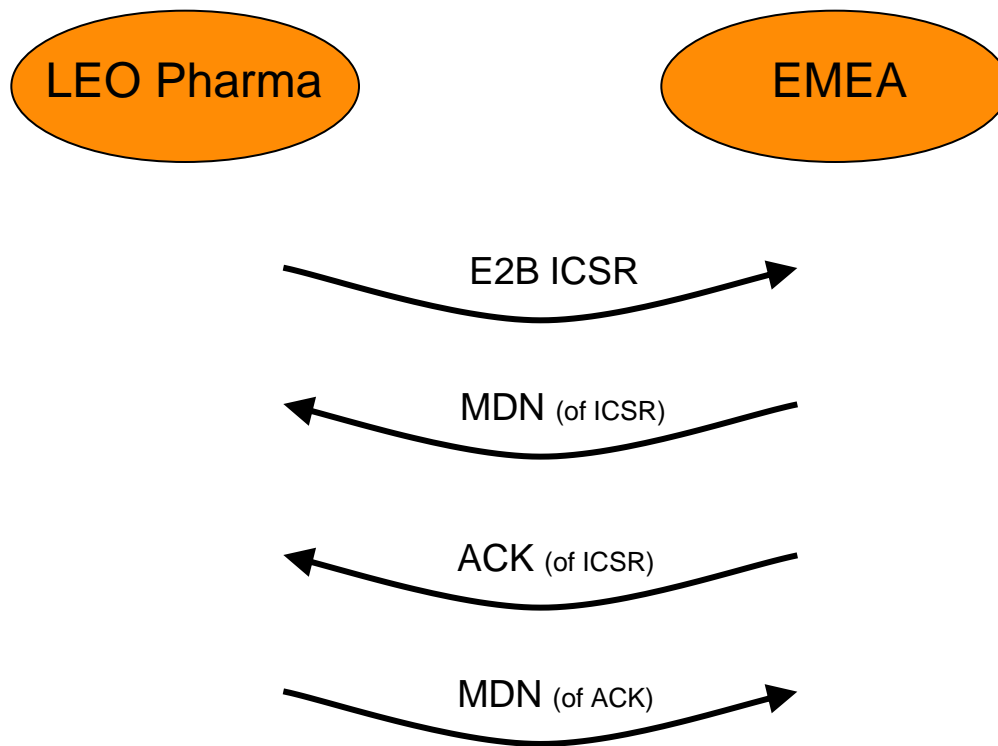
Scope

- Transmission of electronic Individual Case Safety Reports (ICSRs) to EMEA and EU National Authorities
- Receipt of electronic ICSRs from EU National Authorities
- Marketed products (later also study cases)
- Other 'communication partners':
 - non-EU Authorities
 - License partners





E2B transmission LEO -> EMEA





Functional process - outgoing

- Create case in ARISg as per LEO standards
- Review ARISg distribution list, edit as needed
- In AG E2B Gateway:
 - review candidate cases for export
 - export relevant case(s)
- In AG E2B Gateway:
 - verify incoming MDN(s)
 - verify positive ACK(s)





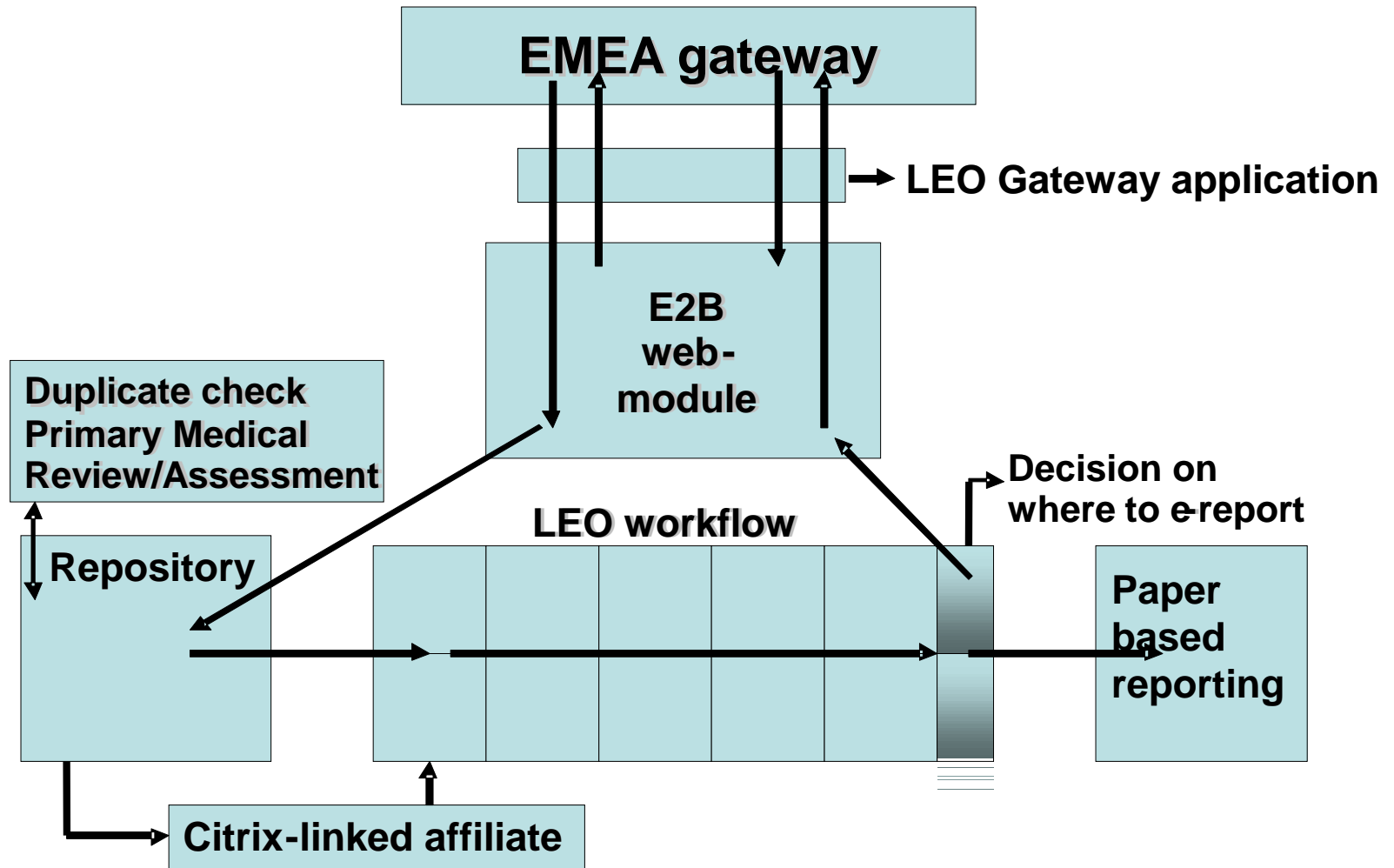
Functional process - incoming

- In AG E2B Gateway:
 - import incoming cases to repository db
- In AG E2B Gateway:
 - verify outgoing MDN(s)
 - verify sending of positive ACK(s)
- In ARISg repository db:
 - review case for LEO relevancy
 - duplicate checks
 - transmit to prod. db OR logically delete
- In ARISg production db:
 - case evaluation, completion of "mandatory LEO fields"
 - route and complete case in LEO workflow process





ARISg E2B Project





E2B XML and MedDRA

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.<reaction>
<primarysourcereaction>HEADACHE</primarysourcereaction>
<reactionmeddraversionllt>6.1</reactionmeddraversionllt>
<reactionmeddrallt>10019211</reactionmeddrallt>
<reactionmeddraversionpt>6.1</reactionmeddraversionpt>
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<reactionstartdateformat>102</reactionstartdateformat>
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<reactionenddateformat>102</reactionenddateformat>
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<reactionduration>7</reactionduration>
<reactiondurationunit>804</reactiondurationunit>
<reactionfirsttime>1</reactionfirsttime>
<reactionfirsttimeunit>804</reactionfirsttimeunit>
<reactionoutcome>1</reactionoutcome>
</reaction>
.
.
.
.

```

VERBATIM = REPORTED TERM
MedDRA VERSION NUMBER
MedDRA LLT CODE NUMBER
MedDRA VERSION NUMBER
MedDRA PT CODE NUMBER



E2B XML and MedDRA

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.<reaction>
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VERBATIM = REPORTED TERM

MedDRA VERSION NUMBER
MedDRA LLT CODE NUMBER
MedDRA VERSION NUMBER
MedDRA PT CODE NUMBER

VERBATIM = REPORTED TERM

- Shows road to the 'point-of-entry' in the dictionary
- Allows for evaluation of proper coding
- Will/will not fit with other party's coding conventions
- Identification of duplicates (e.g. via other reporting sources)



E2B XML and MedDRA

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<reactiondurationunit>804</reactiondurationunit>
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<reactionfirsttimeunit>804</reactionfirsttimeunit>
<reactionoutcome>1</reactionoutcome>
</reaction>

VERBATIM = REPORTED TERM
MedDRA VERSION NUMBER
MedDRA LLT CODE NUMBER
MedDRA VERSION NUMBER
MedDRA PT CODE NUMBER

MedDRA VERSION NUMBER

-To uniquely resolve 'code numbers'
to literal text strings

-Impacts on your choice of MedDRA
versioning policy within your
organisation

-E.g. the most recent version released
from the MSSO (and the version
immediately prior)



E2B XML and MedDRA

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.<reaction>
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<reactionfirsttimeunit>804</reactionfirsttimeunit>
<reactionoutcome>1</reactionoutcome>
</reaction>

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VERBATIM = REPORTED TERM
MedDRA VERSION NUMBER
MedDRA LLT CODE NUMBER
MedDRA VERSION NUMBER
MedDRA PT CODE NUMBER

MedDRA LLT/PT CODE NUMBERS




- The old 'transatlantic' debate: LLTs or PTs ?
- Re-think: when is a LLT most appropriate ?
- And when is the PT the most appropriate?
- Single case/event vs. summary ?
- LLT is the level of entry when coding
- If you have (LLT+version), PT can be looked-up in dictionary...
- whereas (PT+version) cannot uniquely point to your coding LLT





E2B XML and MedDRA

- recommendations

- 
- 
- 
- Always supply what is perceived as the 'originally reported' term/diagnosis (= 'verbatim'). This helps the recipient to understand your MedDRA coding.
 - If e.g. EMEA will only accept the most recent version plus the prior version, then you cannot work with older versions !
 - Do supply the LLT code; the recipient can resolve this into the complete MedDRA hierarchy (PT, P.SOC etc. etc.)
 - If you have recipients who absolute need to receive also the PT code, then, by all means, do supply the PT code – in addition to the LLT code !

