



European Medicines Agency
Communications and Networking

EMA Information and Communication Technology Standards

Doc. Ref. No: EMA/289231/2008

Published Version: 15.0

Methodology & Techniques:

<i>Description/Function</i>	<i>Primary System Method/Tool</i>	<i>Exception System Method/Tool (s)</i>	<i>Comment</i>
Iterative development approach	Rational Unified Process at the EMEA(RUP@EMEA) EMEA's customisation of Rational Unified Process (RUP)		
Project scope, objectives, deliverables and responsibilities defined	RUP@EMEA Vision document RUP@EMEA Software Development Plan	Project Definition Documents (PDDs)	
Results of analysis and design expressed	Unified Modelling Language, UML		
Risk driven iteration scheduling			Highest risks first
Software development methodology	OOA+OOD	Functional Approach (legacy systems)	
User requirements captured and described	IBM Rational RequisitePro Use Case Modelling IBM Rational Rose		

Tools and Techniques:

Description/Function	Primary System Method/Tool	Exception System Method/Tool (s)	Comment
Analysis and design tool	IBM Rational Rose		
Integrated development environment (IDE)	JDeveloper(Oracle)		
IDE for joint development	JDeveloper(Oracle)	Eclipse	
PL/SQL code	SQL Navigator Pro (Quest)	TOAD	
DB design	PowerDesigner (Sybase) IBM Rational Rose (Where appropriate)		
EMEA Legacy Application Development & Maintenance	PowerBuilder (Sybase), Visual Basic for Applications (including ADO), Microsoft Visual Basic 6.0, Microsoft Visual C++ 6.0, MS Access 97/2000, MS Outlook 2000 , ASPs, COM (Automation) Visual FoxPro Version 7.0 SP1		
Development of small database applications	FileMaker Version 9.0v3 (current version)		
Version control system	CVS	MS SourceSafe	Possible move from CVS to Rational ClearCase - to be evaluated
Defect tracking	IBM Rational ClearQuest		
Automatic test scripts/tools	a) Unit testing for Java development: JUnit & JUnitEE b) Formal software testing (Integration, System, Regression,etc): IBM Rational Testing Suite c) W3C Validation d) Ant and CruiseControl – automatic build tool		

<i>Description/Function</i>	<i>Primary System Method/Tool</i>	<i>Exception System Method/Tool (s)</i>	<i>Comment</i>
Project Planning and Management	Microsoft Project 2003 with Project Web Access (PWA)		
Reporting Tool	Oracle Business Intelligence Version 10.1.3.2	MicroStrategy 8 for EudraVigilance use MS-Access (currently being phased out) and Business Objects, Crystal Report - For internal use and specific programmes only.	
Software configuration management			Rational ClearCase LT under evaluation
Independent Quality Assurance			Quality audits
Service Desk System	Isilog/Business Objects		INFRA pilot to be undertaken Q3 2007
Workflow Tools	Oracle Workflow	• Trackwise for Audit Business requirements • Documentum Workflow for MMD	To be evaluated via a Proof of Concept: Oracle BPEL Business Management as part of EUTCT in Q3 2007

Architecture and Products:

<i>Description/Function</i>	<i>Primary System Method/Tool</i>	<i>Exception System Method/Tool (s)</i>	<i>Comment</i>
OPERATING SYSTEM			
Server operating systems	RedHat Enterprise Linux AS 4.0	RedHat Enterprise Linux AS 2.1 Windows 2000 Advanced Server	
Application Server			This is covered by the Server Operating systems row above
Client operating system	Windows XP SP2	Mac	
THIRD TIER			
Clustered object –relational database implemented on separate database server level	Oracle Real Applications Cluster on Oracle RDBMS 9i. Latest version to be used on Intel with Linux x86 (currently 9.2.0.6).	None	Oracle database format type: Hybrid, combining classical relational tables with XML type, as appropriate and applicable. Moving towards the development of new applications using Version 10g RDBMS with XMLDB option enabled. This should be the way forward once the evaluation is complete; the upgrade planned and the installation completed in the EMEA Infrastructure. This is under review at present.
LDAP Directory	Oracle Internet Directory (OID), 10g (Marketing Name) actual name 9.0.4.1	OpenLDAP	OpenLDAP can be used for development and interoperability testing.

Description/Function	Primary System Method/Tool	Exception System Method/Tool (s)	Comment
Java embedded Database		Derby	Controlled Use only for PIM.
SECOND TIER			
Clustered Application Server implementing J2EE (Web and EJB containers, etc)	Oracle Application Server 9i. Oracle Application Server 10g (Marketing Name) actual name 9.0.4.1 for all NEW systems.	BEA Weblogic	Migrating to Oracle 10gAS J2EE 1.3 compliance required: developments based on JSP 1.2, EJB 2.0, Servlet 2.3
Portal	Oracle Portal	JetSpeed	
Stand alone Web Server	Apache web server	IIS	
Database access	Spring/Hibernate Data Access Objects (DAO), JDBC Calls	Enterprise Java Beans (EJB) 2.x/Toplink	.
Data Interchange	1. ICH ESTRI standard “Cyclone”Gateway (Axway) 2. HTTPS/SSL 3. EudraLink	Web Services, XML (via session beans)	1. Secure e-business between Regulators and commercial systems in line with the ICH defined ESTRI Standards
FIRST TIER			
Thin clients using standard web browsers	HTML and XHTML 1.1 or XHTML 1.0 Transitional Java Server Pages (JSP) Cascading Style Sheets STRUTS Version 1.1 JSTL W3C Validation Common-Controls UI Components Library	Javascript strictly on a must-have basis to be documented and agreed on a case by case basis due to browser independence difficulties with JavaScript (N/A to Common-Controls, since built-in and tested).	
Rich clients	Java with SWING or SWT	PowerBuilder	SWT under evaluation
On Line forms	Adobe LiveCycle Forms		
EMEA Standard Client Build	JRE 1.4.1_01		1.4.2 at the time of writing, to be checked before using later version.
PDF Reader	Adobe Acrobat Reader Version 8.0		
Rich content browser plugin	Adobe Flash Player Version 9.0		

Description/Function	Primary System Method/Tool	Exception System Method/Tool (s)	Comment
Document Management			
Electronic document management system	Documentum: Content Server Version 5.2 Documentum Desktop 5.2		
Documentation tool	Javadoc IBM Rational SoDA		
Enterprise Resource Planning (ERP)			
			Solutions are being considered and are under review e.g. SAP.
Audit Process Software			
Audit Processes (audit programme, audits, OFIs, improvement actions) and SOP/WIN management	Trackwise 6.0, SR37		Enterprise Licence for use within the EMEA by the IQM Audit and IQM Co-ordinators
Software Distribution/Deployment			
Java Package distribution	Java Web Start		
Networking and Security			
Cascaded firewalls	Checkpoint		Version NGAi
Intrusion detection systems	None		Reviewing Symantec Manhunt
Penetration Test	Retina		
Anti-Virus software	McAfee		Active Virus Defence Suite with Network Associates Support
Anti-Virus services	Message Labs		Assure anti-porn and anti-spam services on both

Description/Function	Primary System Method/Tool	Exception System Method/Tool (s)	Comment
			Corporate and EudraNet ISPs
Content scanners	Message Labs		Content Management tool under review
Internet Service Provider (ISP)	Globix	MCI	
User authentication and authorisation	Under development, EUSM Project, LDAP		PKI and digital certificates have been considered. PAM and JAAS to be considered. ActivCard also under review for Smart Card (token based)
Security Encryption	3DES, AES (IP SEC)		Encryption Tunnel
Media Encryption	PGP XP encryption for laptops		
Standard for electronic data exchange	XML (via session beans)	SGML	Uploading of documents, e.g. Adverse Drug Reaction (ADR) reports
ESTRI Gateway	Cyclone Central Cyclone Activator		The ESTRI Gateway is compliant with AS1 communication protocols.
Communications Protocols			
Transmission level	TCP/IP		
Web connectivity	HTTP; HTTPS		
Video Conferencing	H.323, H.320		H.323 is IP based, H.320 is normally ISDN based.
Web streaming	Quicktime streaming		
Character Encoding			
UTF8 (as a minimum)			The UTF-8 encoding defined in ISO 10646-1:2000 Annex D and also described in RFC 3629 as well as section 3.9 of the Unicode 4.0 standard. Further information: http://www.unicode.org/ http://www.cl.cam.ac.uk/~mgk25/unicode.html#utf-8

<i>Description/Function</i>	<i>Primary System Method/Tool</i>	<i>Exception System Method/Tool (s)</i>	<i>Comment</i>
Exchange Standards			
E2B			
eCTD			
PIM			
eAF			

Naming Conventions, Guidelines and Standards

Title	Version	Doc ID	Location
EMEA Java Naming Convention	1.1	General-EMEA/145634/2005	documentum\Docbases\EDMS\Information Technology\Development\Standards\EMEA Java Naming Convention
EMEA Database Standards	1.0	General-EMEA/107965/2005	documentum\Docbases\EDMS\Information Technology\Development\Standards\EMEA Database Standards
Version Control Policy	1.1	Guideline-EMEA/99744/2004	documentum\Docbases\EDMS\documentum\Projects\Xsector DM&P - IT - PM\EMEA Standards, Methodologies and Tools\Configuration Management
EMEA Release Notes Template	1.0	General-EMEA/513191/2006	documentum\Docbases\EDMS\Projects\01-000-00039-EUP Implementation\Source\EUP Web\Templates & Guidelines
EMEA-IT-POL-1000	1.0	EMEA/385007/2006	documentum\Docbases\EDMS\Information Technology\Web & Network\Eudra Data Centre\Shared Documents\Procedures\EMEA-IT-POL-1000 http://services.eudra.org/itil.html
EMEA Test Strategy	1.0	EMEA/111051/2004	documentum\Docbases\EDMS\Projects\01-000-00039-EUP Implementation\Source\EUP Web\Templates & Guidelines
EMEA Change Control Process	1.0	EMEA/342717/2006	documentum\Docbases\EDMS\Projects\02-004-00014-PIM Implementation\Change Control

Drafts in preparation and under consultation – Titles only

Title	Version	Doc ID Unique Reference	Rapporteur
Naming Convention for XML elements and Attributes	0.2	EMEA/289231/2008	Juan Rueda Montes

Guidelines for design of Web-based User Interfaces	2.2	EMEA/317626/2005	Jerry Wells
EMEA PL_SQL Standards	0.1	EMEA/135612/2005	Achilleas Voutsas
EMEA XML Naming Convention	0.2	EMEA/368475/2006	Achilleas Voutsas

Standards:

- ISO 9000:2000 (9000-1, 9004-1, 9001, 9000-3)
- ISO 10006, 10011, 10012
- X509

Please note that for all major IT projects there will be a fully independent external quality auditor with no direct or indirect contractual or organisational links to other external contractors.

Other Boundary Conditions:

- Architecture must allow some flexibility for applications that are not fully in line with EMEA standards.
- Source code must be made available to the EMEA from the early stages of development and will be managed through the EMEA version control system
- External contractors must respect EMEA rules on source code style (naming conventions, comments, and indentation), technical documentation, graphical user interfaces and user documentation.
- All source code and associated intellectual property rights developed under projects funded by the EMEA become the property of the EMEA.
- All source code, associated files and Web Sites e.g. XML, XSL, etc. must contain a copyright statement as defined by EMEA standard copyright policy

For documents and source codes you should use the following disclaimer:

© European Medicines Agency, 2008. Reproduction is authorised provided the source is acknowledged.

The year is the year of first publication of the document/source code.

For Web Sites:

For the web sites, they must contain a link to the EMEA important legal notice (<http://www.emea.europa.eu/htms/technical/dmp/copyrite.htm>), where the copyright disclaimer for web pages is explained, or if the web page contains its own legal notice in line with the one on the main EMEA web page, it is not necessary to include on each individual web site a copyright disclaimer. This is also in line with the European Commission's approach, where there is no copyright disclaimer put on individual web pages.

- External contractors working on EMEA IT projects must sign and comply with confidentiality agreements
- External contractors wishing to work on EMEA IT projects must disclose to the EMEA any financial interest in or organisational links to pharmaceutical industry
- External contractors must accept the EMEA standard Terms and conditions as set out in the EMEA's standard Contract.
- External contractors must accept financial and quality audits by the EMEA, the European Commission's financial control and audit services, the European Court of Auditors or by a third party nominated by the EMEA. The contractor has the right to refuse a third party audit if it can demonstrate a potential conflict of interest of the third party nominated.
- External contractors must be prepared to work on EMEA premises. While well-defined modules may be developed off-site, the iterative approach to software development requires regular presence on-site to integrate and test software. In addition, much of the data stored and processed by the EMEA are subject to special data security requirements and cannot normally leave the site.
- There is no external access by external consultants to the EMEA's networks.

Version History:

Approvals: 2008

Name	Signature	Title	Date of Issue	Version No
ICT Standards Committee	By meeting	ICT Standards Committee	27/02/2008	Published Version 15

Approvals: 2007

Name	Signature	Title	Date of Issue	Version No
Change Advisory Board (CAB)	By meeting	CAB	18/01/2007	Published Version 11
ICT Standards Committee	By meeting	ICT Standards Committee	19/04/2007	Published Version 12
ICT Standards Committee	By meeting	ICT Standards Committee	06/06/2007	Published Version 13
ICT Standards Committee	By meeting	ICT Standards Committee	10/12/2007	Published Version 14

Historical Information for Auditable Purposes:

Drafts: 2006

Version	Version Date	Author	Summary of Changes
7.3	17 February 2006	Mb on behalf of Eudra Services	Linux Version update
7.4	20 February 2006	AV on behalf of PIM	Add XHTML
7.3	17 February 2006	Mb on behalf of Eudra Services	Linux Version update
7.4	20 February 2006	AV on behalf of PIM	Add XHTML
8.1	17/05/2006	MB on behalf of Change Advisory Board (CAB)	Change name of EUP to RUP@EMA
8.1	17/05/2006	MB on behalf of Change Advisory Board (CAB)	Changed Data Interchange section, to set ICH ESTRI Gateway (Cyclone) as EMA standard
8.1	17/05/2006	MB on behalf of Change Advisory Board (CAB)	Added Naming Conventions, Guidelines and Standards section.
9.1	27/06/2006	MB	Updated versioning in line with Change Request Register

Approvals: 2006

Name	Signature	Title	Date of Issue	Version No
Hans-Georg Wagner	By meeting	HoU	03/04/2006	Version 7.4 Published as v8.0
Change Advisory Board (CAB)	By meeting	CAB	16/05/2006	Version 8.1 Published as v9.0
Change Advisory Board (CAB)	By meeting	CAB	14/09/2006	Version 9.1 Published as v10.0

Drafts: 2005

Version	Version Date	Author	Summary of Changes
1.8, 1.9, etc	15/02/2005	Heads of Sector with input of IT Developers	Revision to include: • Oracle Database Type, format and version • Visual FoxPro as legacy software • MicroStrategy for Data warehouse • Formatting Changes to this Version History Table, namely “Changes Marked” as this column is not used and column headings updated.
2.01	01/03/2005	MB	Revised version of Oracle Real Applications Cluster on Oracle RDBMS 9i to latest version 9.2.0.6 for “Intel with Linux x86”.
3.01	05/04/2005	MB & DM&P	Revision to include: • Change of name for the document • Copyright statements for source code and xml xlsn and schemas • Update of Oracle Software middle tier version • The format of this document revised.
3.02	06/04/2005	C-IT & C-PM	Various changes to the contents as shown by track changes on this version. New section – Exchange Standards added.
4.01	13/04/2005	C-IT	• Entry Change to Project Planning and Management column 2, “None” removed. • Entry Version control system, column 3 “to be evaluated” added.
4.02	18/04/2005	HGW	Reviewed by HGW resulting in the following changes: • Reporting Tool/Primary MS8 top of the list • Documentation Tool TBD removed • ERP SAP not there yet moved to being reviewed • ISP – change Uunet to MCI • General formatting
5.01	21/06/2005	C-IT & PM	The addition of a version number to structs software on 3 tiered architecture.

5.02	10 August 2005	1. JR/MS for the PIMM LAT project 28/07/05 2. RE for IT Developers email 10/08/05	1. Java Web Start added as a separate section under Software Distribution/Deployment 2. Amendments to 4 elements as requested.
6.1	4 October 2005	WN	All new development should use Oracle 10g RDBMS
6.2 & 6.3	10 November 2005	RE Mb	1. Small Application Development 2. FileMaker database addition 3. Formatting Changes
6.4	23 November 2005	Mb	1. Updated in line with the comments received from C& N Unit. 2. Passed to HGW for final review, comments and decisions as OWNER of the document
7.1	7 December 2005	Mb on behalf of PM Sector	New section added "Character Encoding" with UTF8
7.2	14 December 2005	Mb	Updated the name of the document. No other comments received.

Approvals: 2005

Name	Signature	Title	Date of Issue	Version No
Hans-Georg Wagner	By email	HoU	15 February 2005	Versions 1.8, 1.9, etc will be PUBLISHED V2.0
Hans-Georg Wagner	By email	HoU	1 March 2005	Version 2.01 Published as V3.0
Hans-Georg Wagner	By email	HoU	13 April 2005	Version 3.02 Published as V4.0
Hans-Georg Wagner	Annotated comments on paper copy of version 4.01 from HGW. Transferred to electronic file by MB to produce Version 4.02 created prior to the publishing of Version 5.0.	HoU	18 April 2005	Version 4.02 Published as V5.0
Hans-Georg Wagner	By email	HoU	10 August 2005	Version 5.02 Published as V6.0
Hans-Georg Wagner	By email	HoU	25 November 2005	Version 6.4 Published as V7.0

Drafts:

2003/4:

Version Date	Previous Version Date	Author	Summary of Changes
1.0	N/A	HoU	
1.1	1.0	HoU with input from IT Sector Developers	Additions under Architecture and Products and Other sections
1.2	1.1 12/02/2003	HoU with input from IT Sector Developers	Additions under Architecture and Products
1.3	1.2 01/03/2003	HoU with input from IT Sector	Updated version numbers prior to Tender
1.4	1.3 11/08/2003	HoS with input from HoU and IT Sector	Updated version following Architectural Review meeting 9.10.03
1.5	1.4 09/10/2003	David Drakeford	1. Updated version after off site Mgr meeting 2. Name of the Agency changed 3. Underlining removed from text – historical from Version 1.1
1.6	1.5 14/06/2004	HoU & Tim Buxton	1. Formatting Changes to tables 2. Update in comments field to clarify the use of the existing Reporting Tools. 3. Additions of RUP Testing Products
1.7	19/09/2004	Tim Buxton	Revision to include: • Rational Products, inclusion of ERP Tool • New version of Oracle Application Server • Other minor changes

Approvals:

2002 - 2004

Name	Signature	Title	Date of Issue	Version No
Hans-Georg Wagner	By email	HoU	14 August 2002	1.1
Hans-Georg Wagner	In meeting	HoU	1 March 2003	1.2
Hans-Georg Wagner	By email	HoU	11 August 2003	1.3
Hans-Georg Wagner	By email	HoU	09 October 2003	1.4
Hans-Georg Wagner	By email	HoU	14 June 2004	1.5
Hans-Georg Wagner	By email	HoU	20 July 2004	1.6
Hans-Georg Wagner	In meeting	HoU	21 September 2004	1.7