European Medicines Agency Information and Communications Technology Standards

Published Version: CURRENT 29.0

Methodology & Techniques:

Description/Function	Primary System Method/Tool	Exception System Method/Tool (s)	Comment
Iterative development approach	Rational Unified Process at the Agency(RUP@EMEA) The Agency's customisation of Rational Unified Process (RUP)		
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)	Eclipse	JDeveloper (for Oracle BPEL and legacy)	
PL/SQL code	SQL Developer	TOAD (DBA) SQL Developer (for DBAs) SQL Navigator Pro (legacy)	
DB design	PowerDesigner (Sybase) IBM Rational Rose (Where appropriate)		
The Agency 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 10 (current version) PHP as web front end when required (controlled use)		
Data Warehousing	Oracle Warehouse Builder [client 10.2.0.2.8, repository 10.2.0.2.0]		
Version control system	CVS	MS SourceSafe (legacy for SIAMED I)	
Defect tracking	IBM Rational ClearQuest		
Testing and Quality			

Description/Function		Primary System Method/Tool	Exception System Method/Tool (s)	Comment
	Unit testing for Java development	JUnit & JUnitEE		
	Formal software testing (Integration, System, Regression, etc.)	IBM Rational Testing Suite		
	HTML, CSS Validation	W3C Validation		
	Automatic build tools	Ant and CruiseControl		• Hudson will be used in the future for continuous integration, replacing CruiseControl • Maven will be used in the future to manage a project's build, reporting and documentation from a central piece of information
	Quality control	CAST		
	Performance testing	LoadRunner		
Project Planning and Management		Microsoft Office Project Server (MOPS) - Microsoft Project 2007 with Project Web Access (PWA)		
Reporting Tool		Oracle Business Intelligence Version 10.1.3.4	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 implementation 2009
Workflow Tools		Oracle BPEL	• Trackwise for Audit Business requirements • Documentum Workflow for MMD	

Description/Function	Primary System Method/Tool	Exception System Method/Tool (s)	Comment
Survey tool	Survey Monkey		Web-based survey tool used in Directorate
HTML Editing Tool	Adobe Contribute CS4		
URL testing tool	Xenu		
Virtual meetings tool	Vitero	A pilot is currently being conducted using Adobe Connect.	Vitero is the Agency's standard and has all of the features required to carry out a virtual meeting. If there are features which are not available in Vitero and which are required to conduct virtual meetings, please send your requirements and business case justification to the Rapporteurs of STANCO for progression with STANCO at a future meeting
Help generation tool	MadCap Flare		
Animated demo tool		Turbo Demo	Specifically for MS Project
Forum software solution		jForum	Specifically for PROTECT-EU
Search engine	Google Search Appliance		
Search engine embedded in applications	Apache Lucene and Compass		
PDF Forms design	LiveCycle Designer		
PDF Forms automation	LiveCycle Workbench		

Architecture and Products:

Description/Function	Primary System Method/Tool	Exception System Method/Tool (s)	Comment
Operating System			
Server operating systems	RedHat Enterprise Linux AS 5.0	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
Laptop operating system	Windows Vista	Mac 10.5	
PDA	iPhone (if telephony is required) otherwise iPod		
Desktop operating system	Windows XP SP2 , SP3	Mac 10.x	
Third Tier			
Clustered object –relational database implemented on separate database server level	Oracle Real Applications Cluster on Oracle RDBMS 10g. Latest version to be used on Intel with Linux x86 (currently 10.2.0.3 and higher).		Oracle database format type: Hybrid, combining classical relational tables with XML type, as appropriate and applicable. XMLDB option enabled. Moving towards 11g as our upgrade path.
LDAP Directory	Oracle Internet Directory (OID), 10g (Marketing Name) actual version 10.1.4	OpenLDAP	OpenLDAP can be used for development and interoperability testing.
Java embedded Database	Derby		
Second Tier			
Clustered Application Server	Oracle Application Server 10g	Oracle [BEA] Weblogic	Oracle 10gAS

Description/Function	Primary System Method/Tool	Exception System Method/Tool (s)	Comment
implementing J2EE (Web and EJB containers, etc)	(Marketing Name) actual version 10.1.3.	for Axway 4	J2EE 1.3 compliance required: developments based on JSP 1.2, EJB 2.0, Servlet 2.3
PDF Forms automation	LiveCycle Forms ES		
Portal			
Stand alone Web Server	(Oracle) 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
Data interchange protocol	XML		
Data interchange validation	DTD, XML Schema (DTD)		
Data interchange business rule validation	Schematron		
First Tier			
Thin client standards, using standard web browsers	XTHML 1.0 Strict Cascading Style Sheets 2.0 Javascript W3C Validation		Request by Directorate for Web Content Management System – WCMS [Reading Room Update] The principle of graceful degradation should be applied in all aspects of the site/templates, e.g. if Javascript is not supported then the page should still function.
Presentation server side libraries	Dynamic web pages: JSP 2.0, Servlets 2.4, JSTL 1.1, JSF 1.1 MVC support: Spring MVC Templates: Struts Tiles 2.0 JSF components - JBoss RIchFaces 3.1.x AJAX support – Direct Web Remoting (DWR) 2.0	MVC support Struts 1.x UI Components - Common-Controls	
Rich Internet Application	Adobe Flex 3	PowerBuilder	

Description/Function	Primary System Method/Tool	Exception System Method/Tool (s)	Comment
		Java with SWING (phased out)	
On Line forms	Adobe LiveCycle Forms	XFORMS	
The Agency 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 10.0		

Description/Function	Primary System Method/Tool	Exception System Method/Tool (s)	Comment
Document Management			
Electronic document management system	Documentum: Content Server Version 6.5 SP3 Webtop 6.5 SP3		The API of the current version is not recommended to be used for the creation of documents by an application. The API can be used, however for read operations. This statement should be reviewed when the new version of Documentum (6.x) is deployed.
Internal communication and collaboration	SharePoint		
Documentation tool	Javadoc IBM Rational SoDA		
Enterprise Resource Planning (ERP)			
			Solutions are being piloted with SAP ERP Central Component (ECC) v6.0
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 Agency by the IQM Audit and IQM Co-ordinators

Description/Function	Primary System Method/Tool	Exception System Method/Tool (s)	Comment
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 Corporate and EudraNet ISPs
Content scanners	Message Labs		Content Management tool under review
Internet Service Provider (ISP)	Telecity Redbus	BT	
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		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.

Description/Function	Primary System Method/Tool	Exception System Method/Tool (s)	Comment
Web streaming		Quicktime streaming	
Virtual meetings	VITERO	Abobe Connect	

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

Exchange Standards

E2B			
eCTD			
PIM			
eAF			

Naming Conventions, Guidelines and Standards

Title	Version	Doc ID	Location
The Agency Java Naming Convention	1.1	General-EMA/145634/2005	documentum\Docbases\EDMS\Information Technology\Development\Standards\EMEA Java Naming Convention
The Agency Database Standards	1.0	General-EMA/107965/2005	documentum\Docbases\EDMS\Information Technology\Development\Standards\EMEA Database Standards
Version Control Policy	2.0	Guideline-EMA/99744/2004	documentum\Docbases\EDMS\Projects\01-008-00089-Shared J2EE\Technical\Concurrent Versions System
The Agency Release Notes Template	1.0	General-EMA/513191/2006	documentum\Docbases\EDMS\Projects\01-000-00039-EUP Implementation\Source\EUP Web\Templates & Guidelines
The Agency-IT-POL-1000	1.0	EMA/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
The Agency Test Strategy	1.0	EMA/111051/2004	documentum\Docbases\EDMS\Projects\01-000-00039-EUP Implementation\Source\EUP Web\Templates & Guidelines
The Agency Change Control Process	1.0	EMA/342717/2006	documentum\Docbases\EDMS\Projects\Xsector DM&P - IT - PM\EMEA ICT Standards - StanCo
The Agency Services Naming Convention	1.0	EMA/85884/2009	documentum\Docbases\EDMS\Information Technology\Development\Standards
OWB Naming Convention	1.0	EMA/253293/2009	documentum\Docbases\EDMS\Information Technology\Development\Standards

Drafts in preparation and under consultation – Titles only

Title	Version	Doc ID Unique Reference	Rapporteur
Naming Convention for XML elements and Attributes	0.2	EMA/193130/2012	Juan Rueda Montes
Guidelines for design of Web-based User Interfaces	2.2	EMA/317626/2005	Jerry Wells
The Agency PL_SQL Standards	0.1	EMA/135612/2005	Achilleas Voutsas
The Agency XML Naming Convention	0.2	EMA/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 the Agency standards.
- Source code must be made available to the Agency from the early stages of development and will be managed through the Agency version control system
- External contractors must respect the Agency 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 Agency become the property of the Agency.
- All source code, associated files and Web Sites e.g. XML, XSL,etc. must contain a copyright statement as defined by the Agency standard copyright policy

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

© European Medicines Agency, 2010. 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 the Agency important legal notice (http://www.ema.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 the Agency 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 the Agency IT projects must sign and comply with confidentiality agreements
- External contractors wishing to work on the Agency IT projects must disclose to the Agency any financial interest in or organisational links to pharmaceutical industry
- External contractors must accept the Agency standard Terms and conditions as set out in the Agency's standard Contract.
- External contractors must accept financial and quality audits by the Agency, the European Commission's financial control and audit services, the European Court of Auditors or by a third party nominated by the Agency. 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 the Agency 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 Agency are subject to special data security requirements and cannot normally leave the site.
- There is no external access by external consultants to the Agency's networks.

Version History:

Approvals: 2011

Name	Signature	Title	Date of Issue	Version No
ICT Standards Committee	As per the actions in the minutes 11/05/2011	ICT Standards Committee	11/05/2011	Published Version 28

Historical Information for Auditable Purposes:

Approvals: 2010

Name	Signature	Title	Date of Issue	Version No
ICT Standards Committee	As per the actions in the minutes 15/9/2009	ICT Standards Committee	08/01/2010	Published Version 23
ICT Standards Committee	Changes made for the Agency's new corporate identity	ICT Standards Committee	08/01/2010	Published Version 24
ICT Standards Committee	Updates made to the Virtual Meeting Tool	ICT Standards Committee	19/01/2010	Published Version 25
ICT Standards Committee	Update made to Rich content browser plugin	ICT Standards Committee	19/01/2010	Published Version 26
ICT Standards Committee	Update made inline with the new corporate identity	ICT Standards Committee	09/06/2010	Published Version 27

Approvals: 2009

Name	Signature	Title	Date of Issue	Version No
ICT Standards Committee	By meeting	ICT Standards Committee	20/1/2009	Published Version 17
ICT Standards Committee	By meeting	ICT Standards Committee	17/2/2009	Published Version 18
ICT Standards Committee	By meeting	ICT Standards Committee	27/3/2009	Published Version 19
ICT Standards Committee	By meeting	ICT Standards Committee	21/4/2009	Published Version 20
ICT Standards Committee	By meeting	ICT Standards Committee	24/6/2009	Published Version 21
ICT Standards Committee	By meeting	ICT Standards Committee	15/09/2009	Published Version 22

Approvals: 2008

Name	Signature	Title	Date of Issue	Version No
ICT Standards Committee	By meeting	ICT Standards Committee	27/02/2008	Published Version 15
ICT Standards Committee	By meeting	ICT Standards Committee	20/06/2008	Published Version 16

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	19/04/2007	Published Version 12

		Committee		
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

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@EMEA
8.1	17/05/2006	MB on behalf of Change Advisory Board (CAB)	Changed Data Interchange section, to set ICH ESTRI Gateway (Cyclone) as EMEA 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	JR/MS for the PIMM LAT project 28/07/05 RE for IT Developers email 10/08/05	Java Web Start added as a separate section under Software Distribution/Deployment 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	Small Application Development FileMaker database addition Formatting Changes
6.4	23 November 2005	Mb	Updated in line with the comments received from C& N Unit. 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 - 2004

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	Updated version after off site Mgr meeting Name of the Agency changed Underlining removed from text – historical from Version 1.1
1.6	1.5 14/06/2004	HoU & Tim Buxton	Formatting Changes to tables Update in comments field to clarify the use of the existing Reporting Tools. 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