EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 May 2011
EMA/147558/2010
Information and Communications Technology

Introduction to the EU telematics programme

MBTC-2010-03-005

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8670
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

An agency of the European Union

Table of contents

Terms of reference

The Management Board Telematics Committee, at its meeting in February 2010, requested that a briefing document be prepared that might be styled 'Introduction to EU Telematics Programme'. The objective of this document is to explain the high level business needs being addressed by the EU Telematics programme, to describe each of the main systems and the basis for inclusion in the work programme and also to outline how the main systems interact with each other. This document also outlines the business mechanisms in place to manage the development and implementation of the various projects.

EU Telematics: high-level business needs

The EU telematics strategy

When the EU Telematics strategy was conceived in 2000, a number of high-level strategic objectives were envisioned. These are set out in summary form below.

- Operational strategic objectives
  - support and facilitate the operation of the procedures for authorisation and supervision of medicines as established in the legislation;
  - enable competent authorities to work as part of a network with the objective of ensuring public and animal health;
  - create and then enhance the transparency of the whole EU Medicines Regulatory System and provide effective tools to disseminate information;
  - create confidence and predictability for all parties and users involved;
  - increase business efficiency and make the best use of available resources at national level, always considering interoperability of EU initiatives with systems in place in the different Member States;
- Strategic objectives at the programme level
  - concentrate on few projects with a high European added value, with a clear legal basis and obligation at Community level.

The business needs

Regulation of medicines in Europe relies upon a network of agencies working together to operate a number of processes and procedures in fulfilment of a joint mission.

The business needs are identified as:

- Access to good quality information
- Efficient use of resources through:
  - Minimisation of duplication
  - Maximisation of automation of routine tasks
  - Increased efficiency of processes through improved procedure management
  - Information sharing

- Easy, swift and reliable communication
- Appropriate security
- Secure, reliable and automated publication of information
- Cost effective systems that support the operational needs of the agencies in carrying out their functions.

EU Telematics: the systems

Systems developed as part of the EU Telematics programme are either based on a legal requirement or have evolved from a defined need or requirement within the regulatory network.

The following systems are included in the EU Telematics Master Plan.

The EU Telematics systems are the following:

- Eudranet
  - EudraLink
- EudraPharm
- EudraVigilance
- EudraCT
  - (including the Paediatrics database, which is separately referred to in legislation)
- EudraGMP
  - (including EudraGDP, which is separately referred to in legislation)
- E-submissions
  - European Union Review System (EURS)
  - Central Repository
  - Electronic Gateway
  - Electronic Application Form (eAF)
  - Product Information Management (PIM)
- EU Telematics Controlled Terms
- Eudra User Security Management
- Eudra Data Warehouse
- Communication and Tracking System (CTS)

Of these systems the following are defined in EU legislation:

- EudraNet
- EudraVigilance
- EudraPharm
- EudraCT (including the Paediatrics database, which is separately referred to in legislation)

- EudraGMP
- EudraGDP

EudraNet

Legal basis: Articles 26 and 51 of Regulation (EC) 726/2004

EudraNet is a secure network and the backbone of the European Medicines Regulatory System. It facilitates secure communication, and also enables secure access to applications hosted at the European Medicines Agency, for example, EudraGMP. All Member State competent authorities and the European Commission have access to this system and the system has been in full operation since 1995. Industry or non-regulatory organisations do not have access to EudraNet. There is a Technical Implementation Group (TIG) in place to reflect user requirements and provide feedback on performance together with ongoing issues.

The same TIG also oversees the EudraLink system for secure exchange of information.

Current status

Operation: In production for all member states since 1995

Projects: None planned in 2010; Upgrade to EudraLink foreseen to begin in 2012

Eudranet upgrade and extension project envisaged for 2014 and beyond

EudraPharm

Legal basis: Articles 57 (1) and 57 (2) of Regulation (EC) 726/2004

EudraPharm is a database designed to hold information on each medicinal product (Human and Veterinary use) authorised in the European Union, and the European Economic Area. The system is required to hold the information contained in the Summary of Product Characteristics, the Package Leaflet and the labelling. Its purpose is to provide authoritative information to all stakeholders, including in particular the general public.

Current status

Operation: In production for core information[1] and linked product information documents for medicinal products for human and veterinary use authorised via the centralised procedure since December 2006. First set of information relating to products authorised by Member State competent authorities published in January 2010. Memorandums of Understanding (MoUs) relating to the publication of information on products authorised by other national competent authorities are ongoing. Data from 16 national competent authorities are in test.

Projects: None planned in 2010, 2011 or 2012. Upgrade and extension project envisaged to start in 2013.

EudraVigilance

Legal basis: Article 6 of Directive 2001/83/EC as amended by Directive 2004/27/EC, Directive 2001/82/EC as amended by Directive 2004/24/EC, and Regulation (EC) No. 726/2004).

[1] Core information, comprising elements of the composition of a product and some details relating to the marketing authorisation, is a subset of the information described by a common information model

EudraVigilance is the EU database on adverse drug reactions that receives, processes and stores individual case safety reports for all medicines authorised in the European Union, wherever in the world the adverse reaction reported occurred. The EudraVigilance Data Analysis System (EVDAS[2]) provides the capability to analyse the data for signals. The system also receives, processes, and makes available for analysis in the same way reported suspected unexpected serious adverse reactions that occur during clinical trials.

Current status

Operation: In production for use across the European medicines regulatory network since 2001.

Projects: Development and implementation of EudraVigilance (Human) version(v) 7.x and EudraVigilance (Veterinary) v3.0;

EV Data Management; Linked with the Eudra Data Warehouse projects

EudraCT

Legal basis: Article 11 of Directive 2001/21/EC and articles 41 and 53 of Regulation (EC) No. 1901/2006

EudraCT is the EU system for the registration of clinical trials. The current project extends the functionality in line with the requirements of the Paediatric Regulation and enhancement requests from the HMA's Clinical Trials Facilitation Group (CTFG). Key amongst the changes is the publication of results and the identification and publication of certain items relating to paediatric indications within the database. Some data on the results of clinical trials will be made available to the general public. The system is used by National Competent Authorities to monitor aspects of clinical trials being undertaken in Europe.

Current Status:

Operation: The system entered into production in May 2004. The current version is version 7, which was released in 2009. Data warehouse and reporting functionality is in pilot production, linked with the Eudra Data Warehouse projects.

Projects: Version 8 of the system, which includes a substantial rewrite of existing functionality to eliminate performance and architectural weaknesses introduced through 'bolted-on' additions over the year substantially addresses the stated requirements of the CTFG and the requirements of the Paediatric Regulation.

EudraGMP

Legal basis: Article 40(4) of Directive 2004/27/EC and article 44(4) of Directive 2004/28/EC

EudraGMP facilitates the exchange of information on compliance with good manufacturing practice (GMP) among the competent regulatory authorities within the European medicines network. The system allows the submission of GMP certificates and manufacturing and importation authorisations by national competent authorities on-line and via an XML-based interface using the gateway; enables the submission of non-compliance with GMP information that results from inspection activity; allows the sharing of information on planned inspection activity on manufacturing sites in third countries; permits the consultation of the GMP, authorisation, non-compliance and inspection coordination information that results from the above submissions; and supports the exchange of information constituting 'rapid alerts' arising out of faulty manufacture. The database provides public access to information about

[2] See also the section on Eudra Data Warehouse below

manufacturing authorisations and GMP compliance certificates. Extension of EudraGMP to accommodate the requirements of good distribution practice as an anti-counterfeit measure is also foreseen.

Current status:

Operation: The system has been in production since 2007

Projects: None planned in 2010 or 2011. The next version, including the sharing of information on planned inspection activity on manufacturing sites in third countries and the exchange of information constituting 'rapid alerts' arising out of faulty manufacture, is foreseen to be started in 2012. Also foreseen for 2012 is initiation of the Good Distribution Practice Database (EudraGDP).

eSubmissions: European Union Review System (EURS)

Legal basis: None explicitly in legislation – Topic specifically targeted by EU Telematics strategy

The EURS is a system that validates, stores and presents electronically submitted marketing authorisation application dossiers for review, using the functionality of the eCTD to enable information through the lifecycle of the medicinal product to be displayed according to the requirements of the reviewer. The system was installed in each NCA dealing with medicinal products for human use, and at the EMA.

Operation: In production since 2006.

Projects: Improvements to the national cache manager are the only activities ongoing relating to the EURS itself. Linked activities, all of which are nearing completion, include establishment of the central repository and the opening of the electronic gateway at EMA (see below). In or after 2013, a project is foreseen to integrate PIM into the EURS. No decision has yet been made regarding possible changes to the technology implemented on expiry of the existing contractual arrangements.

eSubmissions: Central Repository

Legal basis: None explicitly in legislation – Topic specifically targeted by EU Telematics strategy

The central repository is an electronic filing area used to hold dossiers for marketing authorisation applications submitted electronically via the centralised procedure. Dossiers are held in this single location at EMA and made available electronically for review across the European Medicines Regulatory Network. Thus reviewers may review applications held at EMA from their own desks.

Operation: In pilot production since May 2010.

Projects: Project scheduled for closure, following completion of pilot activities, in January 2011.

eSubmissions: Electronic Gateway

Legal basis: None explicitly in legislation – Topic specifically targeted by EU Telematics strategy

The gateway for the acceptance of electronic submission of marketing authorisation applications permits the receipt of eCTD and other submissions, which are then routed to the electronic repository following validation for further processing.

Operation: In pilot production since May 2010.

Projects: Project scheduled for closure, following completion of pilot activities, in January 2011.

This technology has been in use since 2001 for the electronic receipt and routing of individual case safety reports for pharmacovigilance.

eSubmissions: Electronic Application Form

Legal basis: None explicitly in legislation – Topic specifically targeted by EU Telematics strategy

On completion of this project, electronic forms for the submission of data in structured form as contained in the existing application forms developed through the Notice to Applicants Group and within EMA will be published. In addition, tools to create these forms, and to receive and validate them, will be available for use by applicants and regulatory authorities.

Operation: In pilot production since May 2010.

Projects: Project scheduled for closure, following completion of pilot activities, in January 2011.

eSubmissions: Product Information Management

Legal basis: None explicitly in legislation – Topic specifically targeted by EU Telematics strategy

PIM (Product Information Management) is a term that describes a new way of handling product information (the SPC, labelling and package leaflet, for authorisation) in the European regulatory context. The project is delivering: (1) An exchange standard; (2) Support for an all-electronic process (3) A review system for regulators; (4) A validation engine for all stakeholders; and (5) A light authoring tool for SMEs. The platform will be used for the submission and exchange of comments, and finalisation of product information initially within the centralised procedure, and ultimately across all marketing authorisation application procedures. Ultimately, it will serve as the authoritative source for information that is published through EudraPharm.

Current status

Operation: The whole of PIM has been in pilot production since 2007

Projects: Development of the system has been planned through to the end of 2010. A project to migrate all centrally authorised products through to the end of 2011 is under way. Once implemented for the Centrally Authorised Procedure, extension to the Mutual Recognition and De-centralised Procedures is foreseen, currently after 2012.

The Electronic Summary of Product Characteristics Proof of Concept is designed to establish the requirements of decision support systems with regard to the information in the Summaries of Product Characteristics. The project serves as a means of gathering requirements for the PIM data exchange standard.

EU Telematics Controlled Terms (EUTCT)

Legal basis: None explicitly in legislation (Support Project)

EUTCT is a central repository and publication system for controlled term lists used in the European Medicines Regulatory Network. It is designed as a support mechanism to the other projects as it provides a framework of terms to facilitate the exchange and interrogation of data across the various systems.

It comprises:

- An agreed set of controlled term lists (including, for example, country code, route of administration, ATC (Anatomic Therapeutic Chemical) code);

- A process and an infrastructure enabling the controlled update of the controlled term lists with agreed terms in a timely manner;
- A process to provide, wherever possible, the controlled term lists to the participating stakeholders.

The system is accessible, with differing access privileges, to NCA and other stakeholders' systems to assure consistency of use of terms throughout the European Medicines Regulatory Network, and amongst those interacting directly with the Network, for instance through application forms.

Current status:

Operation: The system has been in production across the EudraNet, and the internet, since December 2009.

Projects: Development work on the current release will be completed at the end of June 2010. A further version, taking into account international standardisation requirements, is foreseen for development over 2011.

Eudra User Security Management (EUSM)

Legal basis: None explicitly in legislation (Support project); However, Commission Decision of 7 July 2004 amending its Rules of Procedure (2004/563/EC, Euratom) is relevant

The EU telematics programme includes applications that have users from the EMA, the European Commission, NCAs and pharmaceutical industry, as well as commercial and non-commercial sponsors of clinical trials. Management of these users is in some cases independent, while the user communities largely overlap. EUSM has been conceived as a means of introducing a common system that supports the management and verification of a single set of credentials per user, for the EU Telematics applications, leading to simplified user management, reduced user management cost and greater efficiency.

Operation: EUSM as a discrete system has not been developed and is not in operation. However, security and user management policies have been developed and approved, and implementation on a system by system basis through 'single sign-on' and the Eudra Common Directory has to some extent achieved the goals. Electronic signatures, both for authentication and document signature, has not been implemented.

Projects: None planned in 2010 or 2011. Both electronic signatures and the formal EUSM are foreseen to be started in 2012.

Eudra Data Warehouse

Legal basis: None explicitly in legislation (Support project)

The Eudra Data Warehouse will be a collection of information relating to medicinal products regulated in the European Union and the EEA extracted from all the systems established through the EU Telematics programme. The warehouse will serve as a data-minable repository. It is anticipated that access will be granted, according to different permission sets to partners (NCAs), stakeholders and the public in EU telematics.

Operation: The Eudra data warehouse is currently implemented as four separate warehouses – two in full production, and two in pilot. These are:

In production:

The EudraVigilance Data Analysis System (EVDAS, for human medicinal products, in production since mid 2007)

The Eudra Data Warehouse for veterinary medicinal products (in production since early 2008)

In pilot:

The EudraCT Data Warehouse (in pilot since quarter 3, 2009)

The Project 196 Data Warehouse (for human medicinal products – in final testing). This is a proof-of-concept to speed up the 'folding-in' of the functionality for human pharmacovigilance analysis, using a different architecture than currently used for EVDAS.

Projects: The Eudra Data Warehouse project is ongoing. Over the next 12 months, The Project 196 technology will replace the data warehousing technology used in EVDAS. The Eudra data Warehouse for veterinary medicinal products will also assimilate Project 196 technology, and in subsequent years, the three separate warehouses will be merged into one.

European Communication and Tracking System (CTS)

Legal basis: Chapter IV, title 3 of Directive 2001/83/EC & Directive 2001/82/EC, articles 27-32.

The Communication and Tracking System (CTS) is the system used by the National Competent Authorities (NCAs) involved in the licensing of human and veterinary medicinal products via the mutual recognition and decentralised procedures. CTS supports the co-ordination and tracking of marketing authorisation, post licensing and work sharing procedures as monitored by the CMDs. The system serves as data provider for other applications.

Operation: In production since 1995.

EMA System – not EU Telematics: European Pharmacovigilance Issues Tracking Tool (EPITT)

Legal basis: None explicitly in legislation

EPITT is a system that effectively tracks and monitors all PhVWP recommendations, SPC implementations and all safety issues regardless of the authorising procedure of the product, as many safety issues involve multiple medicinal products across all authorising procedures.

Operation: EPITT is currently being used as a pilot.

A table summarising the legal basis for each system is included as Annex A.

EU Telematics: prioritisation criteria

The prioritisation of the projects within the EU Telematics programme is reviewed each year and set out in the EU Telematics Master Plan for the year. The criteria are also reviewed each year, but have not been changed for the current plan. The criteria applied for 2010 – 2014 have been defined at two levels as follows:

Level 1

1. Operation and maintenance of existing systems

2. Ongoing projects with deliverables in the next budget year
3. Projects defined in legislation
4. Projects not defined in legislation.

Level 2

The criteria applied to prioritise projects within the level 1 criterion for 2010 – 2014 were:

1. Promotion of efficiency gains in support of operational procedures
2. Monitoring of the risk-benefit balance of medicines
3. Systems required for the sound operation of the programme as a whole
4. Transparency and provision of information

The list of projects resulting from the application of the above prioritisation criteria and foreseen in the EU Telematics Master Plan 2010 – 2014 is included as Annex B.

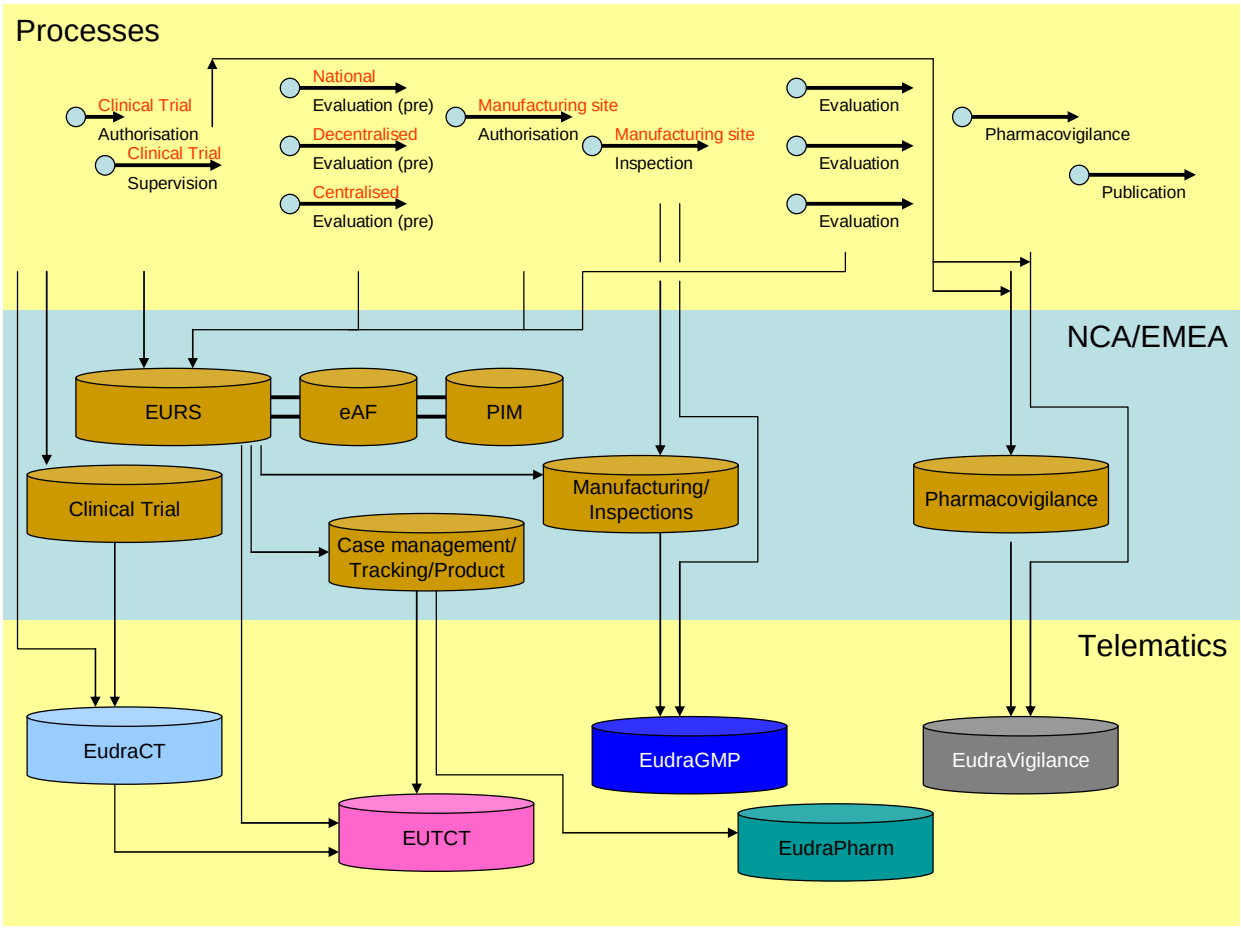
Interaction between systems

Information flows

The suite of applications put into place through the EU telematics programme has been conceived to support the processes for the regulation of medicinal products through their entire lifecycle. The EU telematics applications have also been designed in the context of a set of planning assumptions, one of which is cited in the EU Telematics Master Plan 2010 – 2014 as follows:

> "No. 5: National Competent Authorities and EMA will continue to be individually responsible for the implementation of appropriate information technology systems to support regulatory activities within their own organisations"

The EU telematics applications therefore need to communicate not only with each other, but also with the systems established within each organisation in the European Medicines Regulatory Network. The figure below illustrates the communications at a high level, in the context of the regulatory processes being supported.



The illustration comprises three layers: The top layer (yellow, and labelled 'Processes'), sets out the regulated processes during the development, authorisation and post-authorisation phases of the lifecycle of a successful medicinal product. Thus, the clinical trials are followed by the evaluation of dossiers during initial submission, authorisation and inspection of manufacturing sites as part of the overall authorisation process, and then the submission, evaluation and authorisation of variations. Also shown (explicitly post-authorisation, but also via information flows during development) are pharmacovigilance activities, and as a final 'process', the publishing of information about medicinal products.

The second layer (blue, labelled 'NCA/EMEA'), shows a generic set of systems (colour-coded brown) that might be implemented at an NCA and at EMA. Three of these systems are implemented via EU Telematics (EURS, eAF and PIM) and are concerned with the receipt, validation, processing and storage of electronically submitted information. The remainder are assumed to be agency-specific implementations to deal with the registration and monitoring of clinical trials, monitoring and controlling GxP inspections, as well as pharmacovigilance within the relevant jurisdiction. The final system assumed (Case management/Tracking/Product) is one used to assign, monitor and control the work as it is processed through the agency in question, and to store product information in support of the processes thus controlled.

The bottom layer (yellow, labelled 'Telematics') Shows the applications put into place via the EU Telematics programme.

The arrows within the diagram show, at a very high level, how information is generated as part of the regulated process, and submitted, either directly to the relevant EU Telematics system, or first to an Agency-specific system, and then to the relevant EU Telematics system.

Two communication aspects are not addressed by the diagram: (a) any potential sharing of information between the Eudra systems; and (b) the role of EUTCT as a provider of controlled terms for use by systems within the European medicines Regulatory Network, and by stakeholders submitting information to agencies.

Interoperability

Interoperability, for the purposes of the EU Telematics Master plan, is the ability of systems to exchange information such that a receiving system 'understands' the meaning of the information received in the same way as the sender system. The key underpinnings of interoperability are:

- Common Information Model
- Common Terminologies
- Data Quality

EU Telematics is endeavouring to achieve interoperability by putting into place mechanisms to provide the three elements above. Thus, the objective of a common information model is being addressed through standards, in the form of the Reference Data Model (RDM) implemented through data exchange standards. Common terminologies are to be assured through full implementation of the EU Telematics Controlled Terms (EUTCT) system, and good data quality is to be achieved through data management activities, coupled with better-controlled automated information submission and exchange.

Principal challenges

In its early years, the EU Telematics programme was focused on delivering systems as required by legislation. The required systems are in place, and now undergoing enhancement in line with new requirements, both legislated and requested on the basis of experience. The focus on delivering systems in the early years inevitably led to less emphasis being placed on making the systems work together, and in harmony with systems implemented throughout the European Medicines regulatory network. Indeed, all the harmonisation initiatives are being undertaken in the form of support projects, only indirectly supported by legislation. Thus the programme now seeks to achieve interoperability and, to the extent possible, integration between the EU telematics systems and systems in the individual organisations within the network, whilst also delivering the new features required for efficiency and quality, as well as by legislation. These objectives need to be met in the context of an increasingly harsh budgetary

environment, a landscape where organisations within the network have all made information technology investments in the light of their own priorities, and the international dimension of the common information model will need to be accommodated.

Budgetary environment

The 2010–2014 implementation plan is put into context by the available funding. The budgets for 2010 and 2011 are as proposed in the EMA's budgets and work programmes for those years, while assumptions are made for the three later years within the scope of the plan. The EU Telematics budget comprises both information technology and administrative support costs. Information technology costs (approximately 78% of the total) are incurred in maintaining and supporting existing systems on the one hand, and in building or substantially reformulating systems on the other. The latter are taken forward formally as projects. Administrative support costs (approximately 22% of the total) take the form of personnel expenditure and meeting and travel costs.

Common information model

Over a number of years, the EU Telematics programme has developed the Reference Data Model (RDM), which is defined as a set of documents comprising methodological descriptions, use cases, business and technical concepts, and a technical approach to support the seamless exchange of information between EU Telematics systems and across the European Medicines Regulatory Network.

The RDM is used to direct the technical implementation supporting the use of this information across multiple processes principally by serving as the template for defining the format in which information is exchanged, where such information is understood in the same way in separate systems. The RDM may also serve as a reference for the way in which elements of information are defined and relate to each other within systems, such that separate systems not only 'understand' and use the information in the same way, but can import and export the information in a way that is understood by other systems, generally by means of an exchange standard derived as discussed above.

The RDM is now at version 3. Further development of the RDM is to be paused in the light of the work undertaken in the frame of international Standardisation. Over the coming months, a detailed comparison of the international standards and the RDM is to be made, after which the development and implementation plans for the next version of RDM, incorporating the international standards, will be proposed.

Legacy information[3]

Problem statement

For the purposes of identifying medicinal products reported in the context of individual case safety reports, elements, which when combined serve to achieve that purpose, are currently managed through the EudraVigilance Medicinal Products Dictionary. The structures used to hold this information were originally defined within the EudraVigilance system and now need to be updated to accommodate innovative products with more complex structures, involving also a larger number of fields.

[3] For the purpose of this document, legacy information is the information that is stored in a previous version of a system or in previous storage structures and that is required for current business processes. Such data relates to activities that are historical, but which are needed for current purposes. For example, individual case safety report data that has been received in 2002 in respect of a product that is still on the market will need to be included in analyses for the purposes of signal detection.

Approach

Recognising that the structures to hold this information are not yet final, and that work on quality assurance of the data needs to go ahead, the approach consists of two steps:

1. Create the interim structure: Adjust the model in the EudraVigilance Medicinal Product Dictionary to match the current understanding of the structures that will be adopted when work is complete. Where extra fields are required, add them in. Use this structure to hold the data that has been processed for data quality assurance.
2. Once the structures to be used are settled, build a new structure incorporating all the necessary fields and relationships. From the moment it is ready, use this structure to hold the information that has been processed, and migrate all the processed information from the interim structure into the final structure.
3. Make available that information to all systems.

Controlled terms

An implementation strategy proposal is contained in section 9.16 of the EU Telematics Master Plan 2010 – 2014. This proposal is based on the following key assumptions:

- The CTL information that is needed to assure successful exchange of information (i.e. assuring interoperability) comprises the term identifier and the revision number ;
- There are essentially two approaches to implementation:
  - Maintain mapping between 'internal' & EUTCT lists, OR
  - Replace 'internal' list with EUTCT list.

A hybrid approach or the gradual move from one option to the other are also possible

The proposed roadmap is set out in Annex C.

Document history

Version	Who	When	What
1.0	TB	29/04/2010	Version prepared for and discussed at MBTC meeting, 29 April 2010
1.4	TB	02/06/2010	Version 1.3, with all track changes accepted and ToC moved to new page
2.1	TB	16/07/2010	Finalisation of all changes requested by MBTC EXCEPT addition of Annex of TMC Chair transitional arrangements
3.0	BEP	03/08/2010	Annex of TMC Chair transitional arrangements attached

Annex A: Summary of systems, legal bases and projects

System name	Project no.	Project name	Project Priority 2010 - 2011	Legal Bases Article(s) of Reg. (EC) 726/2004	Directive 2001/83/EC	Directive 2001/82/EC	Directive 2001/20/EC	Directive 2004/27/EC	Directive 2004/28/EC
EU Telematics Controlled Terms									
	00027	EUTCT	1						
Not system specific									
	00226	International Standardisation	2						
	00002	Reference Data Model	5						
	00010	E-Application Form	10						
Eudra Data Warehouse									
	00020	Eudra Data Warehouse	3						
	00196	Incorporation of H MPs into Eudra DWH	9						
Product Information Management									
	00014	Implementation of the PIM System	4						
	00225	PIM Information	6						
	00157	E-SPC Structure Proof of Concept	11						
	00131	PIM MRP/DCP Extension	21						
	00271	PIM Implementatiuon Phase 2	25						
EudraVigilance				26, 51	105	76			
	00231	EV Data Management	7						
	00145	EudraVigilance Human v7.x	8						
	00093	EudraVigilance veterinary v3.0	13						
	00021	EudraVigilance Human v8.x	15						
	00038	PSURs in the eCTD	20						
EudraCT							11		
	00133	EudraCT	12						
EudraGMP								40, 111	44, 80
	00148	EudraGMP	14						
	00257	EudraPhV-Inspections	16						
	00256	EudraGDP	17						
Eudra User Security Management									
	00017	EUSM	18						
EudraLink				26, 51	105	76			
	00189	EudraLink 2	19						
EudraPharm				57 1, 57 2					
	00155	EudraPharm Construction	22						
Eudranet				26, 51	105	76			
	00173	Eudranet extension	23						
European Review System									
	00287	Integration PIM-EURS	24						

Key

System in production as at 26/05/2010
System in pilot production as at 26/05/2010
Projects allocated funding in 2010, and where relevant, subsequent years
Projects provisionally allocated funding in 2012, and where relevant, subsequent years
Projects provisionally allocated funding in 2013, and where relevant, subsequent years

Annex B: Prioritised project list 2010-2014

Project Priority 2010 - 2011	Project no.	Project name	System name
		Projectsto be taken forward in 2010 and 2011	
1	00027	EUTCT	EU Telematics Controlled Terms
2	00226	International Standardisation	Not system specific
3	00020	Eudra Data Warehouse	Eudra Data Warehouse
4	00014	Implementation of the PIM System	Product Information Management
5	00002	Reference Data Model	Not system specific
6	00225	PIM Information	Product Information Management
7	00231	EV Data Management	EudraVigilance
8	00145	EudraVigilance Human v7.x	EudraVigilance
9	00196	Incorporation of H MPs into Eudra DWH	Eudra Data Warehouse
10	00010	E-Application Form	Not system specific
11	00157	E-SPC Structure Proof of Concept	Product Information Management
12	00133	EudraCT	EudraCT
13	00093	EudraVigilance veterinary v3.0	EudraVigilance
		Projects to be initiated in 2012	
14	00148	EudraGMP	EudraGMP
15	00021	EudraVigilance Human v8.x	EudraVigilance
16	00257	EudraPhV-Inspections	EudraGMP
17	00256	EudraGDP	EudraGMP
18	00017	EUSM	Eudra User Security Management
19	00189	EudraLink 2	Eudranet
		Projects to be initiated in 2013	
20	00038	PSURs in the eCTD	EudraVigilance
21	00131	PIM MRP/DCP Extension	Product Information Management
22	00155	EudraPharm Construction	EudraPharm
		Projects to be initiated in 2014 and beyond	
23	00173	Eudranet extension	Eudranet
24	00287	Integration PIM-EURS	European Review System
25	00271	PIM Implementatiuon Phase 2	Product Information Management

Annex C: Controlled terms implementation strategy

Version: 2.14

CTL Implementation Strategy

	2010	2011	2012	2013	2014
Development of CTLs					
Harmonisation with International Standards					
Implementation in Eudra Systems					
Agreement with NCAs through MoU	1				
Implementation across the EMRN					

Milestones	
1	Consensus on timing across the EMRN
	Concrete transition plan across the EMRN

The implementation of Controlled Term Lists within the Eudra Systems is anticipated to occur as follows:

Version: 2.14

CTL Implementation in the Eudra Systems (1)

	2009	2010	2011	2012	2013	2014
EudraPharm	1				7	
Electronic Application Form		2			9	
EudraCT		3,4			10	
EudraVigilance 3 (V)				5		
EudraVigilance 8 (H)					6	
EudraGMP					8	
PIM					11	

The CTLs within each batch to be implemented as set out above are listed in Annex 9.16 of the EU telematics Master Plan listed below.

Annex D: List of abbreviations

Abbreviation	Meaning
ATC	Anatomic Therapeutic Chemical
CTL	Controlled Term List
CTS	Communication and Tracking System
DCP	Decentralised Procedure
DWH	Data WareHouse
eAF	Electronic Application Form
EC	European Commission
eCTD	Electronic Common Technical Document
EMA	European Medicines Agency
EMEA	European Medicines Agency
EMRN	European Medicines Regulatory Network
EPITT	European Pharmacovigilance Issues Tracking Tool
EU	European Union
EudraCT	Eudra Clinical Trials
EURS	European Union Review System
EUSM	Eudra User Security Management
EUTCT	EU Telematics Controlled Terms
EV	EudraVigilance
EVDAS	EudraVigilance Data Analysis System
GDP	Good Distribution Practice
GMP	Good Manufacturing Practice
GxP	Good 'x' Practice
H MP	Human Medicinal Product
IT	Information Technology
JOG	Joint Operational Group
MoU	Memorandum of Understanding
MRP	Mutual Recognition Procedure
N.A.	Not Applicable
NCA	National Competent Agency
PhV	Pharmacovigilance
PhVWP	Pharmacovigilance Working Party
PIM	Product Information Management
PSUR	Periodic Safety Update Report
RDM	Reference Data Model
SMEs	Small and Medium Enterprises
SPC	Summary of Product Characteristics
TIG	Technical Implementation Group

Annex E: Legal bases

The legal bases for the different EU Telematics projects are set out below. These tables are as published in the EU Telematics Master Plan 2010-2014.

Existing legal bases

EudraNet	**Article 26 of 726/2004:** *The Agency, in consultation with Member States and the Commission, shall set up a data-processing network for the rapid transmission of information to the competent Community authorities in the event of an alert relating to faulty manufacture, serious adverse reactions and other pharmacovigilance data regarding medicinal products authorised in accordance with Article 6 of Directive 2001/83/EC*. See also **articles 51 and 67, 726/2004**
EudraPharm	**Regulation 726/2004 – Art. 57 1(l):** "creating a database on medicinal products... accessible to the general public updated, and managed independently of pharmaceutical companies... facilitate the search for information already authorised for package leaflets... section on medicinal products authorised for the treatment of children... information provided to the public.. worded in an appropriate and comprehensible manner;" **Art. 57 2:** "...include the summaries of product characteristics, the patient or user package leaflet and the information shown on the labelling... developed in stages... extended to include any medicinal product placed on the market within the Community. Where appropriate... include references to data on clinical trials currently being carried out or already completed, contained in the clinical trials database..."
EudraVigilance	(**Directive 2001/82/EC** as amended by **Directive 2004/28/EC**, **Directive 2001/83/EC as amended by Directives 2002/98/EC, 2004/24/EC and 2004/27/EC, Regulation (EC) No. 726/2004** and **Directive 2001/20/EC**). The Agency, in consultation with Member States and the Commission, shall set up a data-processing network for the rapid transmission of information to the competent Community authorities in the event of an alert relating to faulty manufacture, serious adverse reactions and other pharmacovigilance data regarding medicinal products authorised in accordance with Article 6 of Directive 2001/83/EC. **Article 67 4 of Regulation 726/2004** states "Activities relating to pharmacovigilance, to the operation of communications networks and to market surveillance shall receive adequate public funding commensurate with the tasks conferred." **Regulation (EC) 45/2001** deals with the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data.
EudraCT	**Directive 2001/20/EC** (the Clinical Trial Directive), ***Recital* (9)** Information on the content, commencement and termination of a clinical trial should be available to the Member States where the trial takes place and all the other Member States should have access to the same information. A European database bringing together this information should therefore be set up, with due regard for the rules of confidentiality. **Article 11** - Exchange of information –establishes the legal basis for EudraCT and the Detailed guidance referred to in Article 11.3 has been updated to

	reflect the development of EudraCT in two Lots and published by the Commission on 26 April 2004. Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004: Articles 41, 43, 45 and 46 and Regulation (EC) no 1394/2007 Art 4.
EudraGMP	**Directive 2004/27/EC** on human medicinal products, amending **Directive 2001/83/EC**. **Article 111, sub 6 to sub 7**. *Member States shall enter the certificates of good manufacturing practice which they issue in a Community database managed by the Agency on behalf of the Community*. **Directive 2004/27/EC on human medicinal products, Article 40(4)** The Member States shall forward to the Agency a copy of the authorisation. The Agency shall enter that information on the Community database referred to in Article 111(6) • **Directive 2004/28/EC** on veterinary medicinal products, amending **Directive 2001/82/EC. Article 44(4). Article 80, sub 6 to sub 7**.

Foreseeable legal bases

As at October 2009, the following needs to be taken into consideration in the form of proposals for legislation before the European Parliament and the Council.

EudraGDP	Proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source
Pharmacovigilance	Proposal for new legislation including transparency and communication provisions

Other bases

eSubmission	**International agreement at *International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).*** ICH has defined the Electronic Common Technical Document (eCTD), which is an interface for industry to agency transfer of regulatory information while at the same time taking into consideration the facilitation of the creation, review, lifecycle management and archival of the electronic submission. This interface has been incorporated into the Notice to Applicants (EUDRALEX Volume 2B - Pharmaceutical Legislation: Notice to Applicants). **Agreement *by the Heads of Medicines Agencies, Reykjavik, 28 February 2006*** The agreement by the Heads of medicines Agencies was reported as follows: "Submission of eCTD target date – eCTD is the electronic format for the marketing authorization application developed by ICH. The end of 2009 was adopted as the target date." Harmonisation within Europe, together with efficient processing of applications

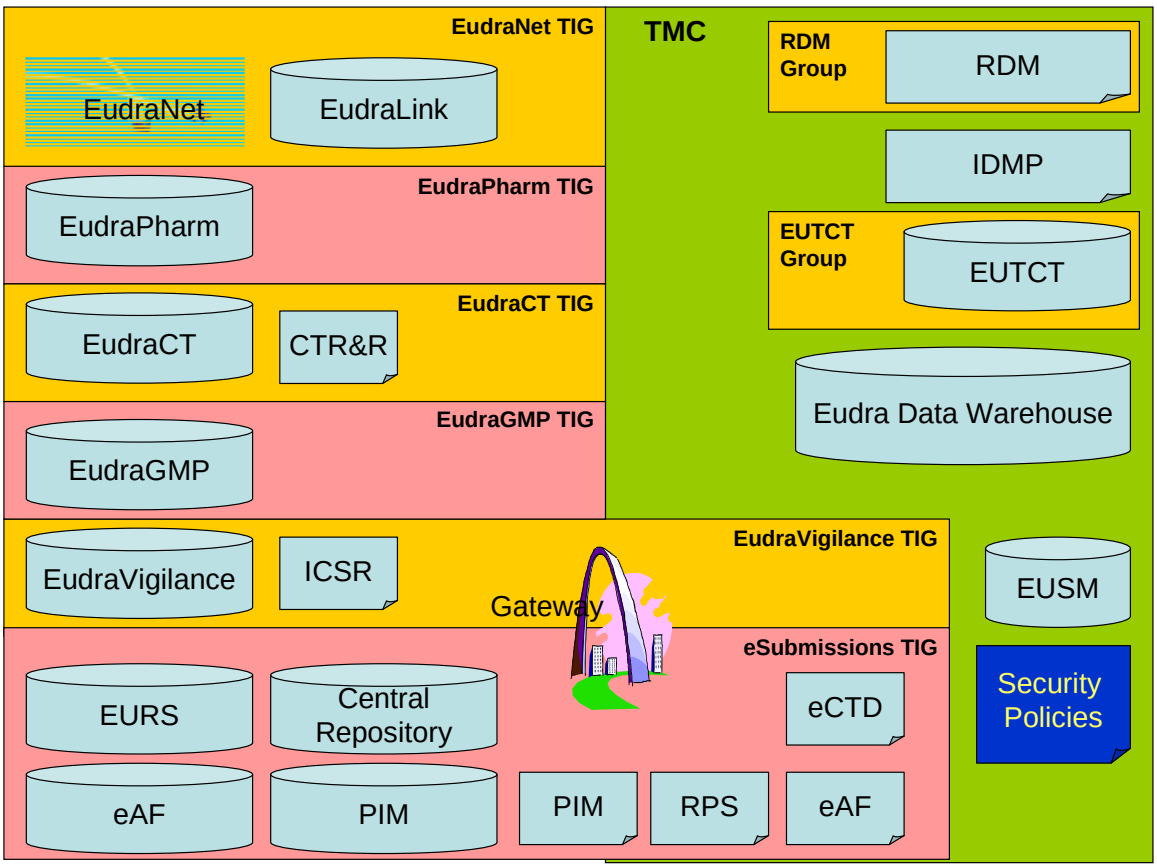
	for national and pan-European procedures, require a standard interface for the submission of structured administrative and product information, as well as a central repository that provides access to the same information from multiple NCAs simultaneously.
International Standardisation	**International agreement at *International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).*** ICH has agreed the two sets of electronic standards, those initially developed by the E2B and M5 groups with the M2 group, should be developed through robust development processes to become formally recognised International Standards. ICH has therefore proposed 6 work items through the International Standards Organization (ISO) which, once completed, should be standards recognised by ISO, CEN[4] and HL7[5].

[4] European Committee on Standardization (www.cen.eu)
[5] Health Level 7 (www.hl7.org)

Annex F: List of TIG sub groups as at 1 July 2010

TIG or Horizontal Group	Sub Group
EudraNet TIG	EudraNet III Sub-working Group
	EudraNet Sub-working Group on Virtual Meetings
EudraPharm	N.A.
EudraVigilance TIG	EV Member States User Group
	EV Veterinary Joint Implementation Group
EudraCT TIG	EudraCT JOG
	EudraCT Data Quality Sub Group
	EudraCT ICT Technical Sub Group
EudraGMP	EudraGMP IT Sub Group
eSubmission TIG	EURS Implementation
	TIGes Veterinary Sub group
	Interlinking Sub Group
	PIM Steering Committee
	PIM Working Groups (x3)
	eSubmission Harmonisation Group
	eCTD Next Major Version Sub Group
	eSubmission Change Control Board
	eAF Application Sub-Group
Telematics Management Committee	EUTCT Full Group Sub Group - EUTCT Process Definition - EUTCT Terminology
	Reference Data Model
	Eudra Data Warehouse (dormant)

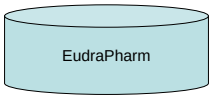
Annex G: Graphical representation of the system landscape with responsible Telematics Implementation Groups



Key

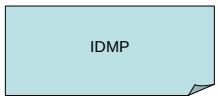
Network

Policy document



System

Electronic gateway



Standard

Annex H: Remit EudraVigilance Telematics Implementation Group

About this document

The objective of this document is to describe what the remit and responsibilities of the EudraVigilance Telematics Implementation Group (EVTIG) are and how this group interfaces with other groups.

Remit of the EVTIG

The mandate and authority of the TIG derive from the Management Structure for EU Pharmaceutical IT systems as set out by the Commission (letter of P. Brunet 22 Dec 1999), the decision of the TSC of Verona, July 2003 and discussion of the TSC of Dublin May 2004.

The official remit of the EVTIG is:

> "Under the control and coordination of the TMC, the TIGs will have to deal with the practical and technical implementation of the decisions and strategies as determined by the TSC and report back on the progress being made. In particular they will be in charge of the definition of requirements for the specific IT projects." See Referenced documents: (1)

Responsibilities:

- Review & approve / reject / amend planning & quality docs:
  - Software development plan
- Input requirements:
  - One-to-one analysis interviews
  - Workshops
  - ...
- Review & approve / reject / amend requirements:
  - Vision document
  - Use cases
- Review & approve / reject / amend architecture:
  - Software architecture document
- Review & approve / reject / amend test plans:
  - UAT Test Plan(s)
  - User acceptance testing

Dual responsibility:

- User point-of-view: Requirements & testing
- Technical: SW architecture

The TIG reports on development and operation of EudraVigilance and makes recommendations for enhancement to the TMC, the TSC and to the European Commission.

The TIG is composed of representatives of the Members States Competent Authorities (EU/EEA) responsible for pharmacovigilance or pharmacovigilance IT systems, and representatives of the EMA and Commission.

Croatia, Turkey, Serbia, Bosnia-Herzegovina, Montenegro and Macedonia may attend as observers.

The TIG is composed of:

- 1 Co-Chair elected from a EEA National Competent Authority
- 1 Co-Chair representing EMA Project Management
- 1 representative per EEA National Competent Authority
- 1 observer each from Croatia and Turkey
- 1 member from EMA business Human
- 1 member from EMA business Veterinary
- 1 member from EMA ICT Software Development (I-DV-SD)
- 1 member from EMA PM (I-DV-PPM)
- 1 representative of the Commission

Specific experts may be called to participate as required.

The TIG will usually meet 4 times per year. Meetings will routinely be of one day's duration.

Additional work can be conducted by teleconference, email, and by individuals or subgroups assigned for special tasks.

The EudraVigilance TIG recognises the need to work closely with the other TIGs.

Responsibility of EVTIG members

The responsibility of EVTIG members is as defined in document 'Role Description Telematics Implementation Group Member' applicable for all TIGs.

Responsibility of EVTIG Co-chairs

The responsibility of EVTIG Members is as defined in document 'Role Description Telematics Implementation Group Chair' applicable for all TIGs.

Responsibility of EVTIG liaison

- Represents the EVTIG in a specific Group
- Briefs the EVTIG on topics discussed in that Group and vice versa.
- MS representative

Interaction with other groups

This section lists all groups with which the EVTIG interacts and the mechanism for this.

EU Telematics Management Committee

The Chair of the EVTIG reports to the EU Telematics Management Committee on all activities and deliverables of the EVTIG.

EudraVigilance Member State User Group

The EudraVigilance Member State User Group (EV MSe UG) is a sub-group of the EVTIG.

The EV MSe UG Chair is an EVTIG Member and reports to the EVTIG on the proceedings of the EV MSe UG meetings.

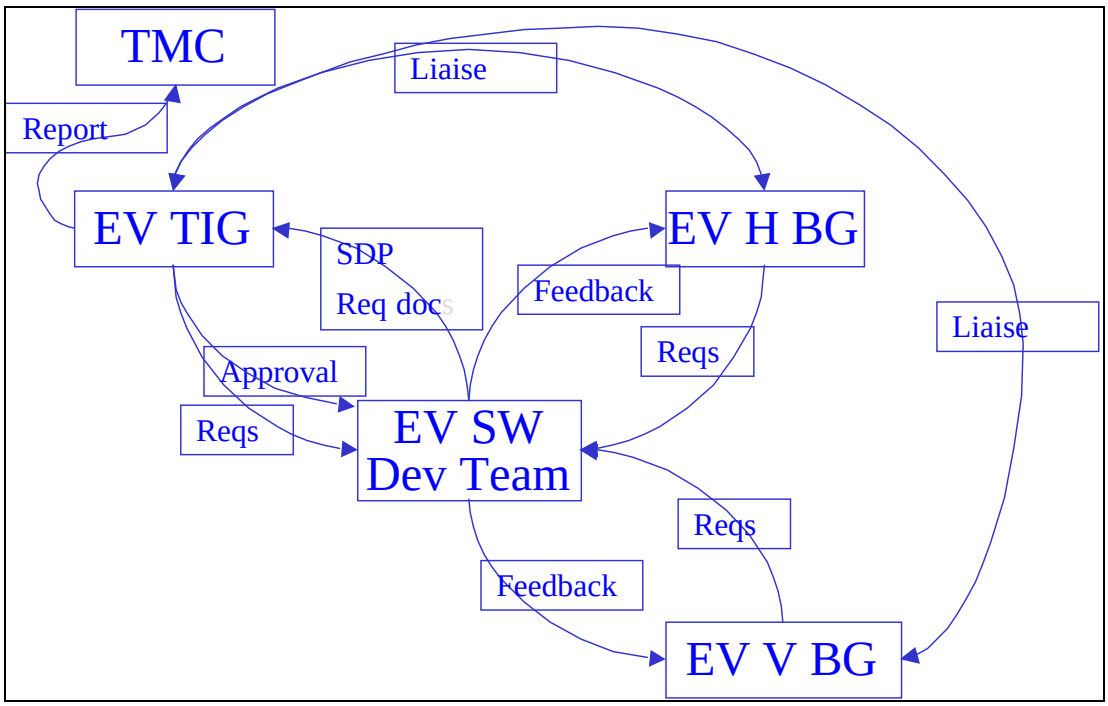
The Project Manager of the EV MSe project reports to the EVTIG on technical or project-related issues.

EudraVigilance Expert Working Group

The interaction between the two groups is explained in Figure 1[6].

The EVTIG Liaison interacts with the EV EWG.

Figure 1. Communication flows EVTIG - Business Groups



EudraVigilance Veterinary Joint Implementation Group

The interaction between the two groups is explained in Figure 1.

The EVTIG Liaison interacts with the EV Vet JIG.

[6] Note that "EV H BG" is now called "EudraVigilance Expert Working Group" and that "EV V BG" is now called "EudraVigilance Veterinary Joint Implementation Group".

EU Telematics Controlled Terms Group

The EVTIG provides input to the EUTCT (RDM) Group on the controlled terms used in EudraVigilance.

The EVTIG Liaison interacts with the EUTCT Group.

Reference Data Model Group

The EVTIG provides input to the Reference Data Model (RDM) Group on the data entities used in EudraVigilance.

The EVTIG Liaison interacts with the RDM Group.

Meetings

Quarterly plenary meetings

As stipulated in §0 Remit of the EVTIG, the EVTIG will usually meet quarterly in plenary session. Typically, these meetings would take place at the EMA's premises.

Frequent teleconference meetings

The size of the EVTIG and the frequency with which it meets mitigates the group's ability to accomplish the remit in a timely and efficient manner without the risk of compromising the quality of the review of the artefacts (e.g. Vision documents, use cases, project plans) that are presented. In addition, the group's remit allows for specific experts to be called to the EVTIG meetings but budgetary constraints limit this.

It is proposed that, in order to facilitate the fulfilment of the remit of the EVTIG, especially with respect to the practical and technical implementation of EV, the following steps be implemented:

- Establish and maintain a regular Electronic Meeting (TC) using the VITERO software system which includes teleconferencing and voting facilities. All members of the EVTIG will be invited to each TC meeting; in this way, all members of the EVTIG will have the opportunity to discuss any matters relevant to the practical and technical implementation of EV implementations in greater detail than is possible in the quarterly TIG meetings.
- The meeting could be used for:
  - Allowing members to be accompanied in the meeting by a local expert in the area that is under discussion thus increasing understanding of the problem area.
  - Establishing areas where particular EVTIG members have expertise that they are willing to impart in the areas under discussion so that these people may be proposed and adopted as spokespeople for the group in a particular problem area.
  - Discussing with spokespeople requirements that are under review in the agenda of the meeting.
  - Providing feedback and clarifying understanding gained from the business and previous meetings.
  - Further discussing of issues where discussions in the formal quarterly meetings have been curtailed due to time constraints.
  - Discussing of new and breaking issues that may come under the remit of the TIG.
  - Any others

Resource implications

Human resource cost

Activity	Estimated cost	Annual frequency	Estimated annual cost
Chairperson: Draft agenda & Liaise with Contributors	0.5pd per meeting	4	2pd
Chairperson: Prepare meeting	1pd per meeting	4	4pd
Chairperson: Chair meeting[7]	1pd per meeting	4	4pd
Chairperson: Review minutes	1pd per meeting	4	4pd
Chairperson: Follow up on various actions from meeting	1pd per meeting	4	4pd
Estimated total annual workload chairperson:			**18pd**
Meeting Organiser: Organise travel & Prepare meeting	3pd per meeting	4	12pd
Meeting Organiser: Assist in meeting to take notes	1pd per meeting	4	4pd
Meeting Organiser: Write minutes	1pd per meeting	4	4pd
Estimated total annual workload meeting organiser:			**20pd**
EMA Meeting Management & Conferences	3pd per meeting	4	12pd
Estimated total annual human resource cost:			**50pd**

Co-chair election protocol

#	Action	Duration	Deadline
	Publication of the protocol	n.a.	16/Dec/09
	Candidates inform anita.zambrini@ema.europa.eu via simple email of their candidature	3 weeks	15/Jan/10
	Publication of the list of candidates via email to all EVTIG Members	n.a.	18/Jan/10
	Election: EVTIG Members send their votes via email to anita.zambrini@ema.europa.eu. Every EVTIG Member has one equal vote.	3 weeks	05/Feb/10
	Announcement of the outcome of the election		08/Feb/10
	MS Co-Chair takes up his/her responsibility at the first EVTIG meeting	n.a.	

Election of the candidate is via plurality[8]. A plurality of votes is a total vote received by a candidate greater than that received by any opponent.

Document information

Open issues: (None)

Document location: D:\PROGRA~1\DOCUME~1\CTS\cache\word_metadata-86970278.doc

Document ID: EMA/147558/2010

[7] Does not take into account any travel time

[8] See Robert's Rules of Order. A full text of the public domain edition of Robert's Rules can be found at http://www.rulesonline.com/index.html. The definition therein of 'Plurality' can be found at http://www.rulesonline.com/rror--04.htm#def:Plurality.

Referenced documents

Doc ID	Title
TSC/05/2005/013	Role Description Telematics Implementation Group Member
TSC/05/2005/012	Role Description Telematics Implementation Group Chair
	(1) European Commission – DG ENTR: Doc TSC-NL 4/04 (09/Dec/99, updated 26/Jun/04) A further clarifications on the remit of the TIGs has been provided at the TSC meeting dd. 25/May/04.

Document history

Version	Who	When	What
00.03	OS	04/Jun/06	For discussion in EVTIG
00.04	OS	03/Sep/06	As per discussion in EVTIG meeting 05/Jun/07.
01.01	OS	24/Sep/06	Included the proposal for frequent TCs.
01.03	OS	15/Apr/08	Included human resource cost estimates
01.04	OS	07/Jul/09	Updated to reflect the TMC decision to add a position of MS Co-Chair
01.05	OS	30/Jul/09	Repaired locators in this doc
01.07	OS	16/Dec/09	Updated the protocol with more recent example dates
2.0	OS	16/Jun/10	Updated: Observer countries; EMEA-> EMA; Some additional clarification

Annex I: Mandate of the EudraCT Telematics Implementation Group and its Joint Operations Group

22 November 2007

The mandate and authority of the Telematics Implementation Group (TIG) and its Joint Operations Group (JOG) derives from the Management Structure for EU Pharmaceutical IT systems as set out by the Commission (letter of P. Brunet 22 Dec 1999), the decision of the Telematics Steering Committee (TSC) of Verona July 2003 and discussion of the TSC of Dublin May 2004, and article 11 of the Directive 2001/20/EC.

The TIG will be composed of representatives of the Members States Competent Authorities (EU/EEA) responsible for clinical trials, and representatives of the European Medicines Agency (EMEA) and Commission and observers from candidate countries.

The JOG will be composed of the TIG Members plus selected representatives of the commercial and non-commercial clinical trial sponsors' organisations. This is a technical group of clinical trial experts with emphasis on the user community of clinical trial experts. IT expertise will be called on when needed for specific tasks.

The EudraCT TIG and its JOG recognise the need to work closely with the other Telematics Implementation Groups (e.g. EudraVigilance), the Clinical Trial Facilitation Group (CTFG) of the Heads of Medicines Agencies (HMA), other relevant expert groups and the Telematics Management Committee (TMC).

The TIG and its JOG will be chaired by a representative of a National Competent Authority (NCA) for a renewable period of three years. The Chair will be nominated by the TSC, confirmed by the Commission and supported by the EMEA on behalf of the Commission. The TIG will make a recommendation for the Chair to the TSC and copy this recommendation to the HMA.

The mandate of the TIG is:

- To deal with practical and technical aspects of the implementation and operation of the EudraCT database including identification of user requirements for enhancements;
- To propose potential enhancements to the system based on user requirements or legislation and their priority to the TSC via the TMC;
- To develop the EudraCT database in accordance with the EU Telematics policy documents;
- To actively work with the other TIGs to promote interoperability within the systems supporting the European Medicines Regulatory Network (EUMRN);
- To report on the operation of the EudraCT database to the TMC.

The TIG will be composed of:

- The Chair;
- 1 representative from each National Competent Authority;
- 1 representative from each EEA member state;
- 1 observer from each candidate country;
- 1 member from EMEA business;
- 1 member from EMEA IT;

- 1 member from EMEA Project Management;
- 1 member from EMEA to provide support to the meeting;
- 1 representative of the Commission.

Specific experts may be called to participate as required.

The TIG Members will:

- represent their stakeholder community for the EudraCT system;
- recommend solutions to the issues raised at the TIG or JOG;
- play an active part in the oversight, promotion of use and enhancement of the EudraCT system during its operational life.

The TIG and its JOG will designate representatives, as required, to participate in other TIGs and relevant groups involved in the development of EU Telematics systems.

The TIG will usually meet 4 times per year for one day preceding the meeting of the JOG. There will be a separate agenda and proceedings for the TIG and the JOG.

Additional work will be conducted by teleconference, email, and by individuals or subgroups assigned for special tasks.

The JOG will be composed of:

- The Chair of the TIG;
- 1 representative from each National Competent Authority;
- 1 representative from each EEA member state;
- 1 observer from each candidate country;
- 1 member from EMEA business;
- 1 member from EMEA IT;
- 1 member from EMEA Project Management;
- 1 member from EMEA to provide support to the meeting;
- 1 representative of the Commission;
- Representatives of selected commercial and non-commercial clinical trial sponsors' organisations.

Specific experts may be called to participate as required.

The JOG Members will:

- represent their stakeholder community for the project;
- recommend to the TIG, solutions to the issues raised at the JOG or referred to it by the TIG;
- play an active part in the oversight, promotion of use and enhancement of the EudraCT system during its operational life.

References:

- Letter of P. Brunet 22 Dec 1999
- EU Telematics Master Plan (TSC/11/2006/003)

Annex J: Mandate of the EudraGMP Telematics Implementation Group

21 June 2010

Mandate of the EudraGMP Telematics Implementation Group (TIG)

The Telematics Steering Committee (TSC) nominated at its meeting in Dublin, May 2004, the Ad-hoc GMP Inspection Services as the Telematics Implementation Group (TIG) for the EudraGMP project.

Under the control and coordination of the Telematics Management Committee (TMC), the TIG has to deal with the practical and technical implementation of the decisions and strategies as determined by the TSC and report back on the progress being made. In particular the TIG is in charge of the definition of the requirements for the EudraGMP project. The role and responsibilities of the TIG Members are outlined in the document 'Role description – TIG Member'.

The TIG is composed of representatives of the EU/EEA Members States Competent Authorities for both Human and Veterinary products responsible for GMP inspections, and representatives of the EMEA and Commission. MRA partners may participate as observers. The representatives are responsible for ensuring that they represent the views of their agencies/organisations and for disseminating decisions of the TIG within their agencies/organisations to all concerned persons on all issues arising and relating to the activities and work of the TIG.

The TIG meets four times a year. Meetings are routinely of three day's duration but the EudraGMP project is a small part of the discussions. Additional work may be conducted by teleconference, email, and by individuals or a subgroup assigned for special tasks.

In order to assist from a technical perspective, the TIG delegates some of its work to a subgroup (EudraGMP database sub-working group) composed of IT specialists from Member States with systems in place and of GMP inspectors. The sub-working group's precise composition and meeting's frequency will be determined by the TIG, on a case by case approach, in order to ensure a high level of expertise and adequate representation of users.

The present document is therefore a declaration of the EudraGMP TIG Mandate and reflects the decision of the TIG to form the EudraGMP database sub-working group within which to manage interactions with all stakeholders.

The EudraGMP TIG recognises also the need to work closely with other telematics projects (EudraPharm, EudraCT, etc) and may designate representatives, as required, to participate in these projects.

The TIG and its sub-working group are chaired by the EMEA Head of Inspections Sector and are supported by the EMEA Communications & Networking Unit. The TIG and sub-working group Chair is responsible for the impartial chairmanship of TIG and sub-working groups meetings, and is accountable to the TMC and the relevant TIG itself in that regard for those parts of the meetings addressing telematics issues. The role and responsibilities of the Chair are outlined in the document 'Role description – TIG Chair'.

The mandate of the TIG is:

- To arrive at an agreed common user requirement specification.
- To review and comment on the technical specification.
- To participate in tests of software deliverables.
- To introduce and review change requests

- To represent the Member State competent authorities in the final acceptance of the systems and its documentation.
- To act as conduits for the flow of project information back to the National Agencies.
- To support and coordinate the implementation of EudraGMP
- To report on project status to the TMC on a periodic basis
- To highlight issues to the TMC if and when appropriate

References

- EudraGMP Vision Document
- EudraGMP Project Definition Document
- TSC minutes (Dublin, May 2004)
- Role Description - TIG Chair
- Role Description - TIG Member
- EudraGMP telematics fiche

Annex K: Telematics Implementation Group on Electronic Submission (TIGes) – terms of reference

Introduction

The Terms of Reference of the TIGes derives from the Management Structure for EU Pharmaceutical IT systems as set out by the European Commission in the Strategy Paper on Telematics in the Pharmaceutical sector, as amended by the decision of the Telematics Steering Committee (TSC) on 8th September, 2004 (Revised version 10) and the Implementation Plan for Telematics in the Pharmaceutical Sector, version 12.5.3 revised by TSC in November 2004.

Objectives

The main objective of this IT strategy is the reinforcement of appropriate communication between stakeholders (general public, industry, Member States, European Commission and EMEA) to support pharmaceutical regulatory activities for both human and veterinary medicines.

The TIGes should develop standard specifications for electronic data exchange of eCTD in Europe consistent with ICH standards and requirements for IT systems for implementation of standards that would permit submission, validation and evaluation of applications for marketing authorisation using eCTD.

Composition

The TIGes shall be composed of representatives of the National Competent Authorities (EU/EEA, from both the human and veterinary sector), the EMEA, and the European Commission. Representatives from Industry associations should be invited to participate in the Group's working parties.

Vendors

Vendors and software developers cannot become TIGes members. However, they may be invited to participate in breakout sessions or subgroups to help with specific issues. They should act on behalf of a member of the TIGes and its role should be recorded in the minutes of the meeting in which they participate.

Reporting

The TIGes shall be chaired by France and will report to the Telematics Management Committee.

Subgroups

The TIGes may constitute working subgroups to address specific issues within the remit of the group on its own authority. It will receive the reports of the subgroups, and incorporate the work of such subgroups as it sees fit.

Meetings

EMEA shall host the meetings of the TIGes and reimbursement of travel and accommodation costs for participation of delegates shall be covered as per EMEA's reimbursement rules.

Tasks

The TIGes will:

- ICH eCTD completion and implementation
- Definition of EU regional standards according to ICH standards
- Definition of exchange standards for Application Form information and Product Information
- Application(s) to handle e-submission by national competent authorities and EMEA (and industry where appropriate)
- Ensuring interoperability with EU Telematics Systems

Document history

Version	Who	When	What
0.1	MB	April 2007	Initial draft

Annex L: Telematics Management Committee Working Group on Dictionaries (the 'Dictionaries Group') – terms of reference

Document number TSC/05/2005/011

The Terms of Reference of the Dictionaries Group derive from the Management Structure for EU Pharmaceutical IT systems as set out by the European Commission (letter of P. Brunet 22 Dec 1999), as amended by the decision of the Telematics Steering Committee on 7 September, 2004.

The Dictionaries Group shall be composed of representatives of the Member States Competent Authorities (EU/EEA, dealing with medicines both for human and veterinary use), the EMEA, and the European Commission and other stakeholders as follows:

- The Chair
- 1 Member per Member State; Member State representatives have to represent both the human and the veterinary side, and the associated TIGs, i.e. EudraVigilance, EudraCT, Eudra GMP, e-submission, Database and Tracking and CTS.
- 1 Member for EMEA
- 1 Member for DG Enterprise
- 1 observer each from Bulgarian and Romanian National Competent Authorities

Other stakeholders should be invited to participate in the Group's working parties.

The Dictionaries Group shall be chaired by [to be completed under the authority of the TMC] and will report to the Telematics Management Committee.

The Dictionaries Group may constitute one or more working parties/task forces to work on specific issues within the remit of the group on its own authority, receive the reports of such Task Forces, and incorporate the work of such Task Forces as it sees fit.

Working with the EMEA, the Dictionaries Group will:

a. Define the controlled terms that should be used within the EuroPharm database, and thus centrally for all the databases within the EU regulatory community. This definition should include the initial versions that should be used, together with the levels that should be incorporated (e.g. level [x] of the ATC code). The definition should also determine the national translations that should be used, together with any 'non-standard' extensions that should be incorporated; and

b. Define the process whereby changes to the controlled terms over time should be proposed, accepted provisionally, approved for inclusion and incorporated definitively on an ongoing basis.

The Dictionaries Group will work closely with the TMC sub-working group dealing with the reference data model.

The Dictionaries Group shall be dissolved on the day following the elapsing of eighteen months from the date on which the TSC has approved the creation of the Group.

Document history

Version	Who	When	What
0.1	TB	12/10/2004	Initial draft
0.2	TB	02/11/2004	Second draft, addressing comments of Chair of EuroPharm TIG
1.0	TB	03/11/2004	Draft for circulation to TMC; Circulated
1.1	TB	04/11/2004	Amend typographical errors in line re Bulgaria & Romania; Amend authority of chair to TMC (Comments from HGW); Add reporting line to TMC.
1.2	TB	15/11/2004	Add 'sunset' clause
1.3	TB	19/04/2005	Add TSC reference number
2.0	Mb	12/05/2005	Updated in line with the requirements following the TSC 4 May 2005 as detailed in email dated 4 May 2005 from TB to Mb.
2.1	Mb	12/05/2005	Additional change in line with update following the TSC 4 May 2005 as detailed in email dated 4 May 2005 from TB to Mb.
2.2	AZ	25/05/2005	Administration for the Dictionaries Meeting – no changes
2.3	Mb	19/10/2005	Updated in line with the comments from the Dictionaries Group on 17/10/05
3.0	TB	21/10/2005	Change highlighting removed.

Annex M: Current TIG[9] Chairs, length of service and transitional arrangements

TIG chairs currently in office

The table below lists the TIG chairs currently in office, together with the date of appointment where formally documented.

Name of TIG Chair	Name of TIG/TMC sub-group	Term start date	Proposed term-end date
David Drakeford	Eudranet TIG	19 December 2001	31 December 2010
Victor Mendonca	EudraPharm TIG	1 April 2006	31 March 2011
Olivier Simoen	EudraVigilance TIG	24 January 2005	30 June 2011
Fergus Sweeney a.i.	EudraCT[10] TIG	November 2009	31 December 2010
David Cockburn	EudraGMP[11] TIG[12]		30 June 2011
Miguel Bley	eSubmission TIG	5 December 2000	31 December 2010
Tim Buxton	EUTCT[13] sub-group of the TMC	23 November 2005	31 March 2011
Tim Buxton Thomas Balzer	RDM[14] sub-group of the TMC	1 December 2003	31 March 2011

Transitional arrangements

A three phase approach is proposed, whereby formal appointment or re-appointment of TIG chairs by the MBTC takes place over the period between 1 September 2010 and 30 June 2011. It is further proposed that the appointment or re-appointment is undertaken using the MBTC TIG chair appointment procedure, the Start Date of which for each appointment is six months before the term expiry date proposed in the table above. The phased approach is presented in tabular form below, showing three TIG chairs in the first wave, three in the second, and three in the third.

Name of TIG Chair	Name of TIG/TMC sub-group	Appointment Procedure Start Date	Proposed term-end date
David Drakeford	Eudranet TIG	1 July 2010	31 December 2010
Fergus Sweeney *a.i.*	EudraCT[15] TIG	1 July 2010	31 December 2010
Miguel Bley	eSubmission TIG	1 July 2010	31 December 2010
Victor Mendonca	EudraPharm TIG	1 October 2010	31 March 2011
Tim Buxton	EUTCT[16] sub-group of the TMC	1 October 2010	31 March 2011
Tim Buxton Thomas Balzer	RDM[17] sub-group of the TMC	1 October 2010	31 March 2011
Olivier Simoen	EudraVigilance TIG	1 January 2010	30 June 2011
David Cockburn	EudraGMP[18] TIG	1 January 2010	30 June 2011

[9] Telematics Implementation Group
[10] Eudra Clinical Trials
[11] Eudra Good Manufacturing Practice
[12] The EudraGMP TIG is the Ad-hoc Inspectors Group acting in that capacity
[13] EU Telematics Controlled Terms
[14] Reference Data Model
[15] Eudra Clinical Trials
[16] EU Telematics Controlled Terms
[17] Reference Data Model

Annex N: Chair of the Telematics Management Committee: transitional arrangements

4 August 2010
MBTC-2010-08-003
Information and Communications Technology

Current TMC chair

The current chair of the Telematics Management Committee (TMC) is the Head of the Information and Communications Technology Unit at the European Medicines Agency. He has been in post since January 2003.

Transitional arrangements

It is proposed that the Chair of the TMC submits his resignation to the MBTC with effect from 6 October 2010, such that his term will end on 6 April 2011. In accordance with the appointment procedure, EMA will be invited to propose a candidate for the role. The appointment procedure will be followed, and the appointed person will take up his or her duties on 7 April 2011.

[18] Eudra Good Manufacturing Practice