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SCIENCE MEDICINES HEALTH

EU Telematics Implementation Plan

IPA Introductory Meeting
1-2 February 2010

Presented by: Dr. Hans-Georg Wagner
Head of Information and Communications Technology

An agency of the European Union

Overview

- Introduction
- Actors
- Actions
- Systems
- Architecture
- Impact on NCAs, especially in candidate countries
- Conclusions

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Introduction

- EU Telematics is EU programme for a small number of IT systems of high added value to support regulation of medicinal products
- Firm legal basis (except for electronic submission)
- First system started in mid-90s (EudraNet)
- Responsibility for operation and development conferred to European Medicines Agency in 2002/3
- All systems required by legislation in operation with good availability levels – albeit not with complete functionality legally prescribed or desired by users

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Actors

- Regulators
  - Within EU/EEA, including European Medicines Agency
  - From applicant and candidate countries
  - Others with confidentiality agreements
  - Others with mutual recognition agreements
- Pharmaceutical Industry
- Patients and Carers
- Healthcare professionals
- EU Commission, Parliament and Council
- General Public

Actions (1)

- Regulators need to communicate securely, reliably and fast -> electronic network
- Pharmaceutical industry wants harmonised efficient submission process for applications -> standards and systems for electronic submissions and their evaluation
- Beneficial to register and track clinical trials
- Essential to monitor risk-benefit profiles pre and post authorisation -> PharmacoVigilance
- Share information on GMP inspections
- Create single database for all MP authorised in EU

Systems

- EudraNet and EudraLink
- e-Application Form, PIM LAT, PIM RS, EURS, …
- EudraCT
- EudraVigilance (OLTP and DAS)
- EudraGMP
- EudraPharm
- EUTCT
- CTS

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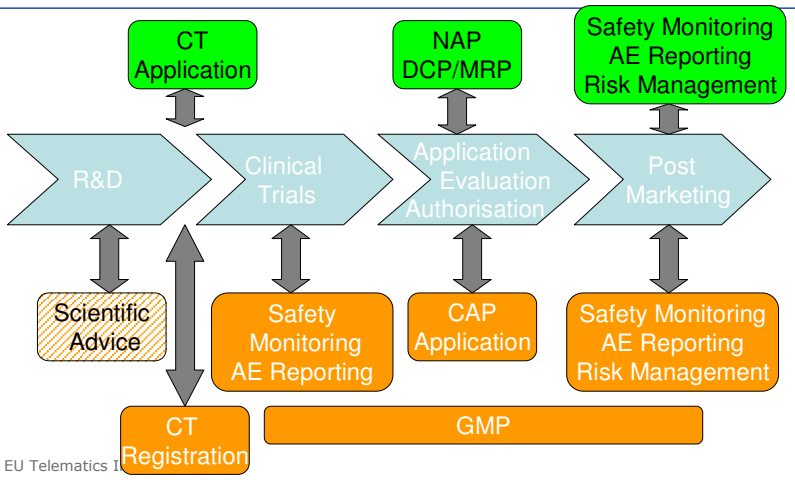
The Regulatory Life of a Medicinal Product



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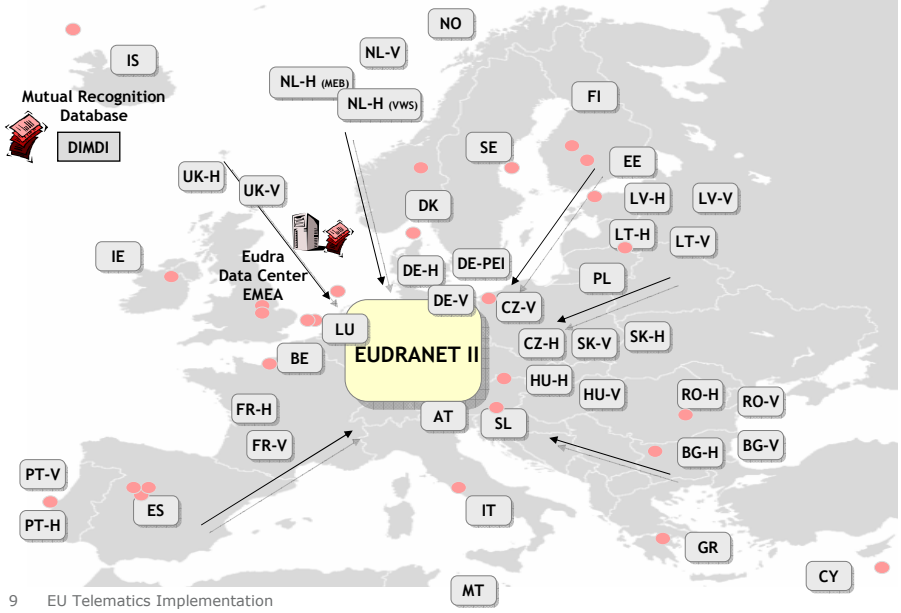
EudraNet & EudraLink

- EudraNet II is a VPN linking all EEA NCAs
- It provides secure e-mail, file transfer and access to the Eudra Portal and applications
- File size limited (e-mail attachments)
- Currently 51 (+4) organisations connected
- Annual costs for operation and support ~ € 360,000
- EudraLink caters for larger files and secure FT and e-mail with industry and other stakeholders
- Currently ~ 10,000 users; € 200,000 p.a.

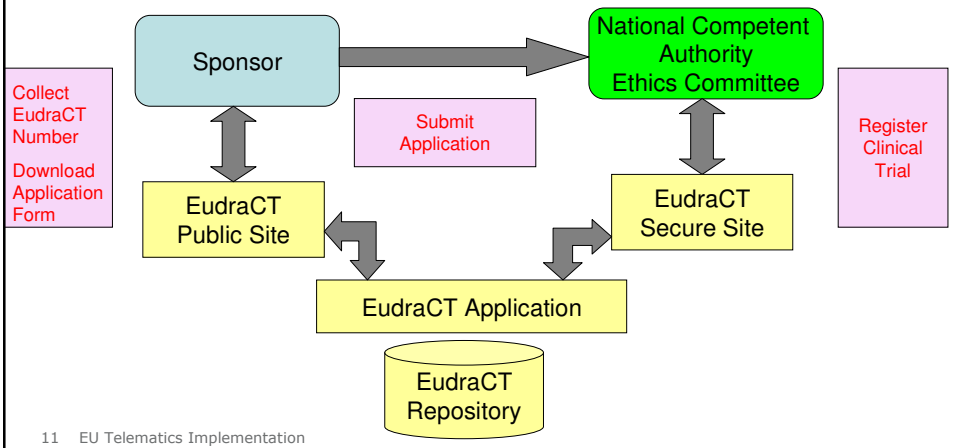
Management of EUDRANET II
51 NCAs connected



EudraCT

- Register of all clinical trials in EU/EEA and beyond
- Public site to obtain unique CT number and to download CTA form
- CTA form submitted to NCAs and Ethics Committees
- NCA submits CT details to confidential site
- Information on stopped trials shared
- All regulators have unlimited access
- Public has access to subset of information
- Now more than 24,000 trials registered

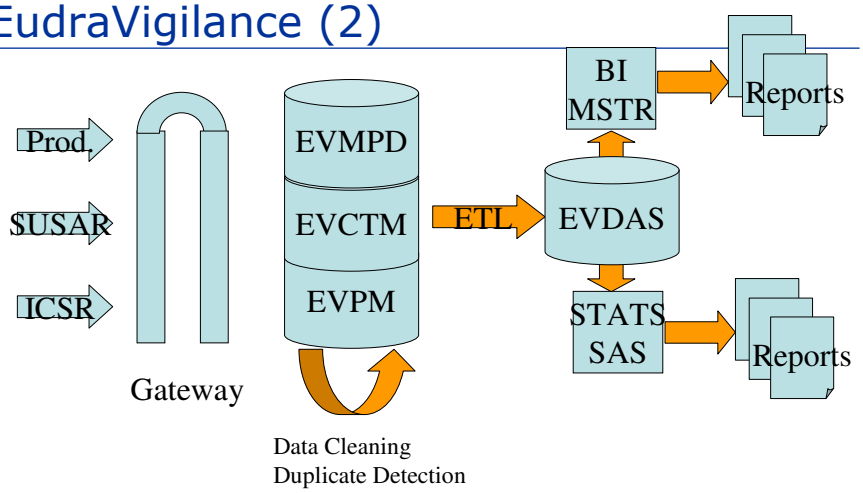
EudraCT (2)



EudraVigilance

- OLTP system to receive, validate, register and process adverse event reports (>3M reports, 6,500 registered users)
- Data Warehouse with Business Intelligence and Statistical Evaluation System (e.g. Reaction Monitoring, Signal Detection)
- Unlimited access for regulators
- Limited access for industry
- Public access to pre-defined reports in future
- Issues with data quality and duplicates

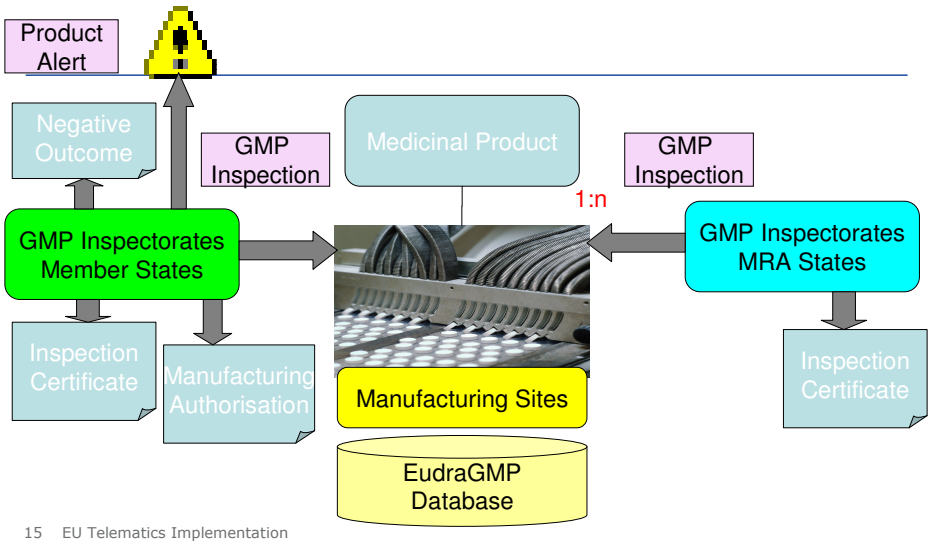
EudraVigilance (2)



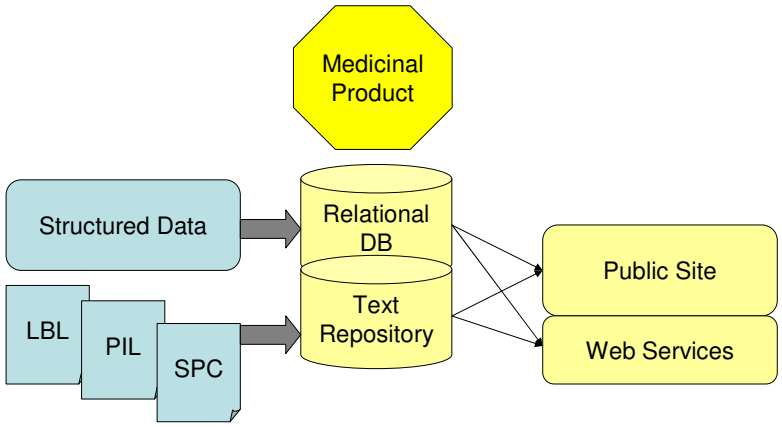
EudraGMP

- System to store information on manufacturing sites
- System to share outcome of GMP inspections (including negative outcome)
- System to communicate product alerts
- Full access to all regulators
- Read access to MRA partners
- Access to limited data set for public
- Future write access for MRA partners

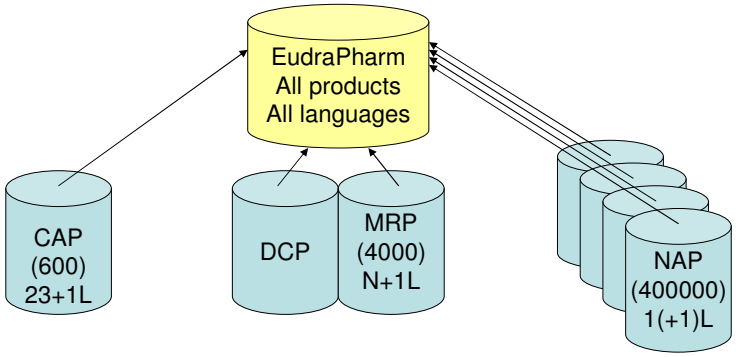
EudraGMP (2)



EudraPharm (1)



EudraPharm (2)



e-Submission (1)

- Agreed specification for electronic submission of applications for MA (eCTD) – will become ISO standard by 2012
- Only electronic format accepted by European Medicines Agency for submission of MAAs
- Feasibility study for single regulatory portal for e-submission for all authorisation routes
- Electronic application form
- Electronic product information management (PIM) system (LAT and PRS)

e-Submission (2)

- Common review system for eCTDs and NeeS (EURS)
- Electronic submission of eCTDs to European Medicines Agency through secure gateway from January 2010
- Electronic Common Repository for use by all regulators (all authorisation routes?) by end 2010.
- Next major version of eCTD likely to be RPS 3.0 (HL7->ISO) to include bi-directional data exchange between applicant and regulator(s)

Supporting Systems & Standards

- Reference Data Model
- EU Telematics Controlled Terminologies, EUTCT

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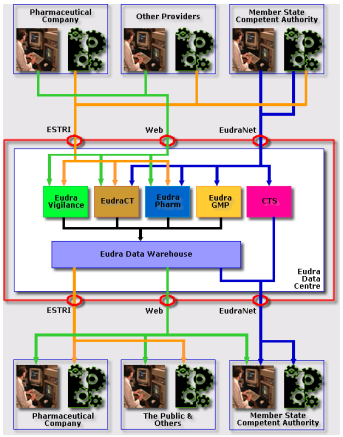
System Architecture (1)



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Impact on NCAs

- NCA systems must supply data to EU systems -> identical data model or at least mapping of data models to RDM (cost impact?)
- All NCAs must introduce EU wide controlled terminology lists -> EUTCT
- EU systems must provide information for use by NCA systems -> web services?
- NCAs are invited to participate in the governance of EU Telematics systems -> TIGs
- Symmetrical Broadband connection of > 2 MB/s

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Conclusions

- Ambitious programme
- Completion planned for 2013, but may slip further
- Requires effort from NCAs to base their new systems on reference data model and to use EU Telematics Controlled Terminologies
- Continued challenges of data quality, data currency, completeness