

# EU Telematics Strategy for Veterinary Medicines - Status Update

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EMA/IFAH-Europe Infoday  
13-14 March 2014

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# Update on development of EU Telematics Strategy for Veterinary Medicines

- Why have a strategic vision for veterinary IT?
- The project to date
- The emerging vision and how this could be implemented over the period 2014 – 2017 (work in progress)
- Update on revised governance structure and engagement of stakeholders

# Why have an EU Telematics Strategy for Veterinary medicines?

- To create and make available pan-EU systems and databases for key tasks such as eSubmission and pharmacovigilance that are needed in the interests of the efficiency of the Network, partners and stakeholders
- To foster interoperability, or possibly harmonisation, of the disparate set of IT systems and data repositories that currently exist across the Network
- Resources in the veterinary domain are very limited and IT investments need to be made carefully and strategically to maximise return on investment

# Why have an EU Telematics Strategy for veterinary medicines?

- New legislation to be published in 2014 is anticipated to promote availability, create a genuine single market for VMPs and reduce administrative burden; improved IT systems will be key in realising this vision
- A coordinated approach from the Network as a whole is required with appropriate engagement of stakeholders to ensure that the solutions match their needs

# “Strategy and implementation plan for Veterinary IT Systems” – EMA project

- An EU Telematics project developed in collaboration with IT representatives from BE, FR and UK in October 2013
  - Allows **EMA** to clarify how it proposes further to promote integration and harmonisation of data, and provide tools for their analysis (e.g. for veterinary pharmacovigilance)
  - To enable **NCAs** to further develop and integrate their national systems in a wider European network of veterinary IT
- Delivered under the new governance and methodology for EU Telematics

# The Strategic Vision

The **vision** is for the veterinary network to act as a Virtual Organisation through collaboration aiming at further integration and centralisation of several data systems.

The **strategy** is to identify and develop common standards and service components that promote further integration.

The **tactics** involve developing a set of programmes and projects with defined budgets and timelines for delivery

# High-level Roadmap stage plan

Stage Description  
& Main Activities

## Stage 0 (Q4 2013)

### Planning/High-level Definition

- Collaboration between EMA and FR, BE, UK NCAs to develop the strategy and plan.

## Stage 1 Short Term (2014)

### Satisfy immediate needs/ Detailed Roadmap Definition

- Start of Involvement of whole NCA Network in the Roadmap process
- Satisfy immediate needs
- Governance under operation and making input to strategic and specific project deliverables
- Requirements Analysis for medium/long term.
- Legislation published

## Stage 2 Medium Term (2015/2016)

### Design and Build specific roadmap elements

- Agreement and development of data standards
- Analysis of the network's Target Operating Model requirements and if required, design of new model
- IT Solutions definition
- Iterative implementation of solutions

## Stage 3 Long Term (2017-)

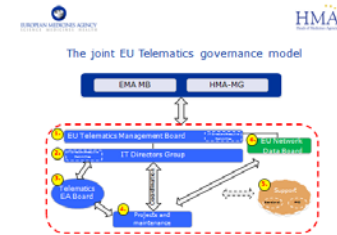
### Deploy/Operate

- Continue iterative implementation
- Continuous improvement
- Governance structure and roadmap review

# Involvement of industry

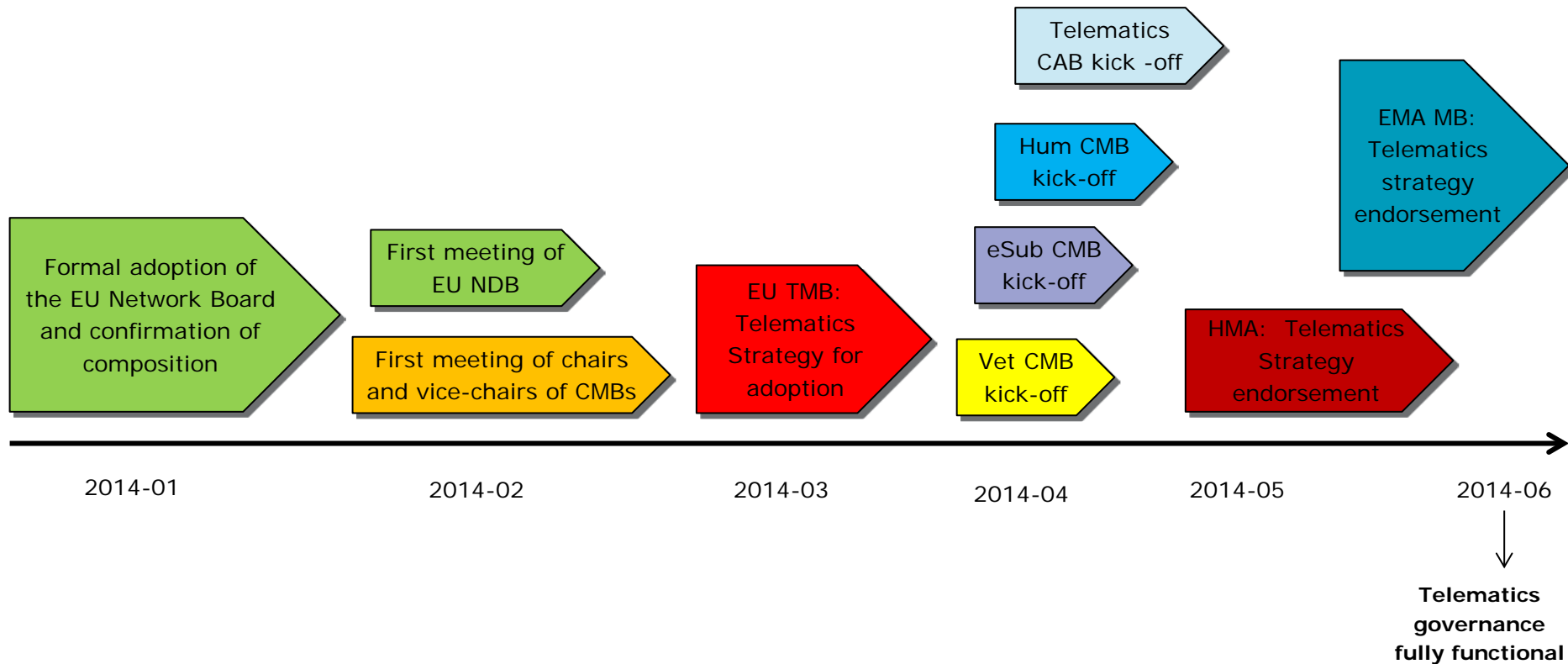
- Engagement and support of industry will be a key element in successful delivery of the strategy
- Revised EU Telematics governance includes establishing mechanisms for stakeholder engagement during development and subsequent operation of relevant IT systems
- In the veterinary domain this includes
  - Vet Change Management Board
  - eSubmission Change Management Board for veterinary topics
  - Programmes and projects arising from the EU Telematics Strategy for veterinary medicines

Format for stakeholder engagement to be developed as part of the planning process for each board/programme/project





# Telematics governance implementation timeline



# Summary – EU Telematics Strategy for Veterinary Medicines

- For the first time there will be an integrated strategy underpinning the development and operation of EU IT systems in support of veterinary medicines
- The revised governance structure for EU Telematics creates an integrated system involving NCAs, EMA, and the European Commission with defined and appropriate input from stakeholders, including industry
- The aim in future is to deliver functionality by means of short, incremental, IT projects to defined timelines and budgets through a gated governance structure