MHRA
Regulating Medicines and Medical Devices

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EU28: Science, Medicines, Health
A regulatory system fit for the future

Session: Going Digital

Presentation: Current Initiatives

Presented by: Andrea Johnson (MHRA), Olivier Simoen (EMA)

Version 01.01

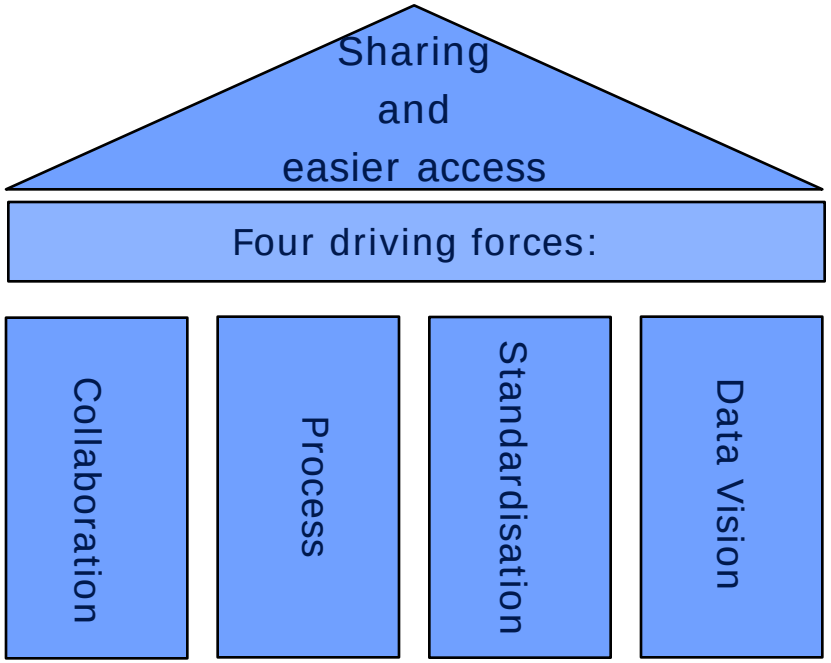
Current initiatives

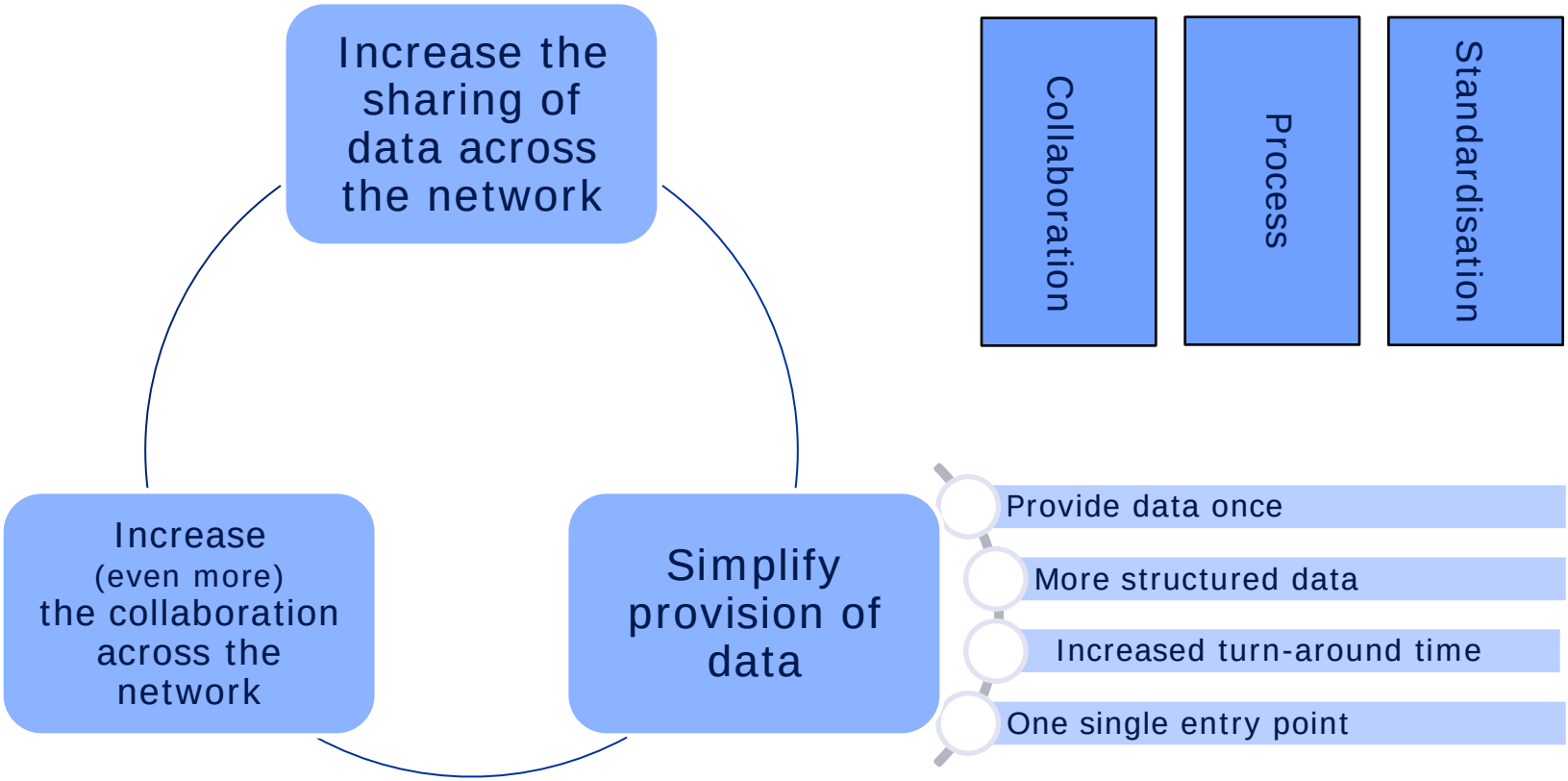
Objective of the presentation:

Provide an overview of the current initiatives in digital provision of electronic information within the EU Medicines Regulatory Network

Contents

General Principles (1/5):

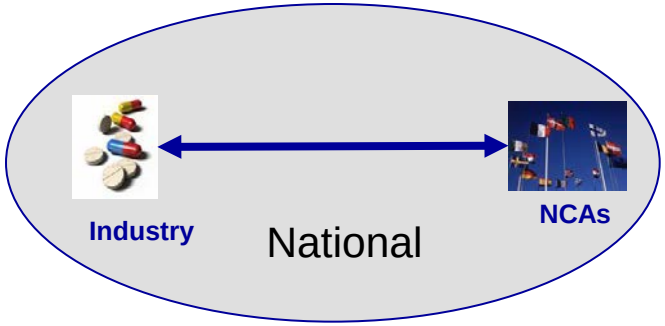


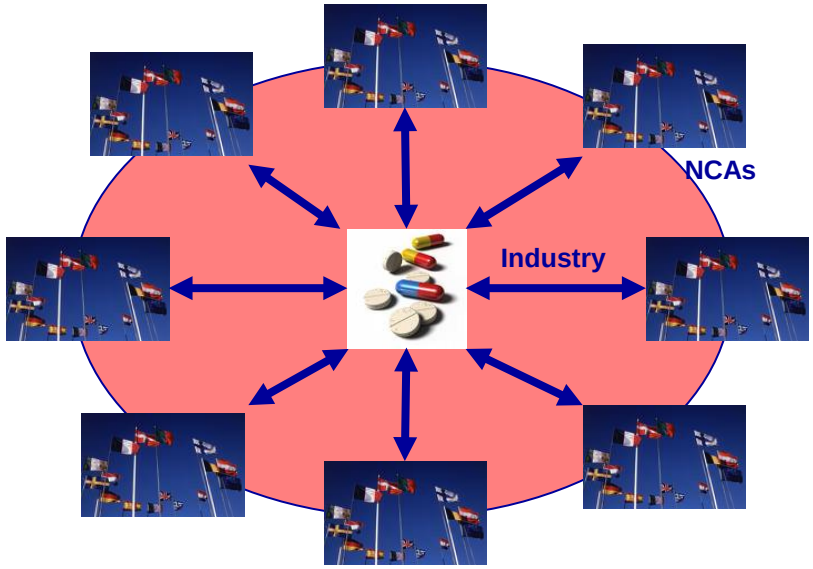


General Principles (2/5):

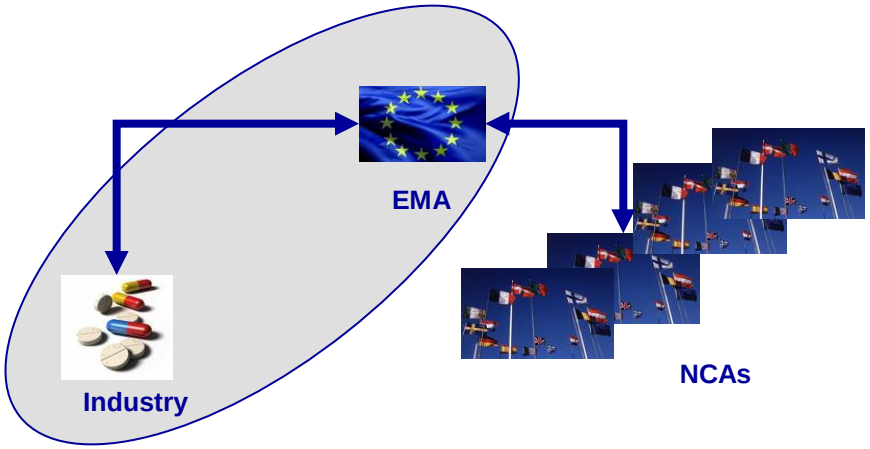
Challenges for integration and collaboration in Europe:

Processes vary





Centralised



De-Centralised

General Principles (3/5):

The EU regulatory environment

Size is strength…

…but…

…the chain is only as good as the weakest link

General Principles (4/5):

How do we effectively share?

General Principles (5/5):

Options

- Collaborate across EU
- Tactical collaborations
  - Go Commercial…

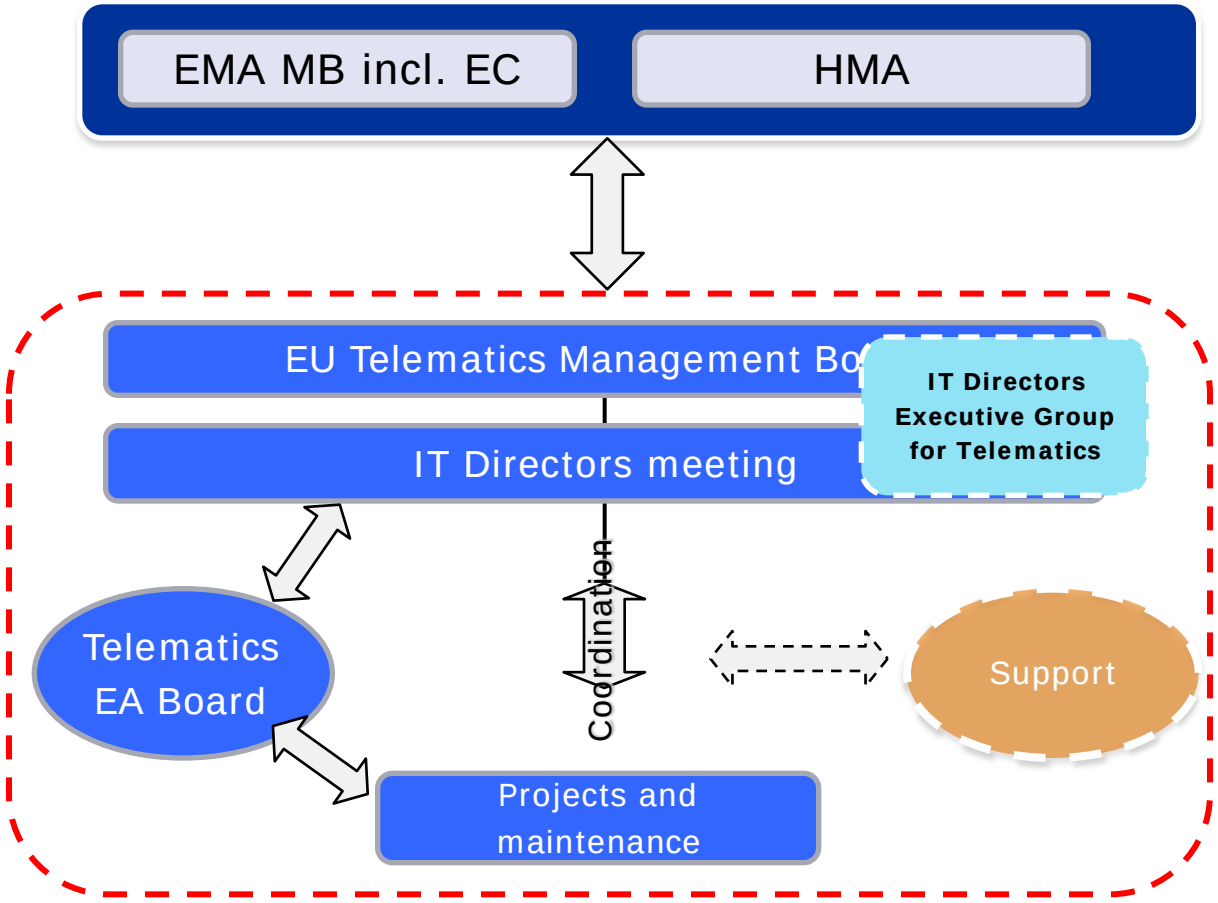
What do each of these look like and when are they planned for?

Short term (next few months) (1/7):

- Next version of MAA H eAF implementing AF V10: June 13
- Pilot electronic submission of CT results (Pilot 2): June 13
- Pilot esignatures of EMA forms: Q3 13
  - Initially in the area of orphan drugs, paediatrics and scientific advise
  - Set of forms to be extended next
- Electronic submission of GMDP (V 5) information: May 13

Short term (next few months) (2/7):

- Implementation of the new EU Telematics governance structure: Q2 13

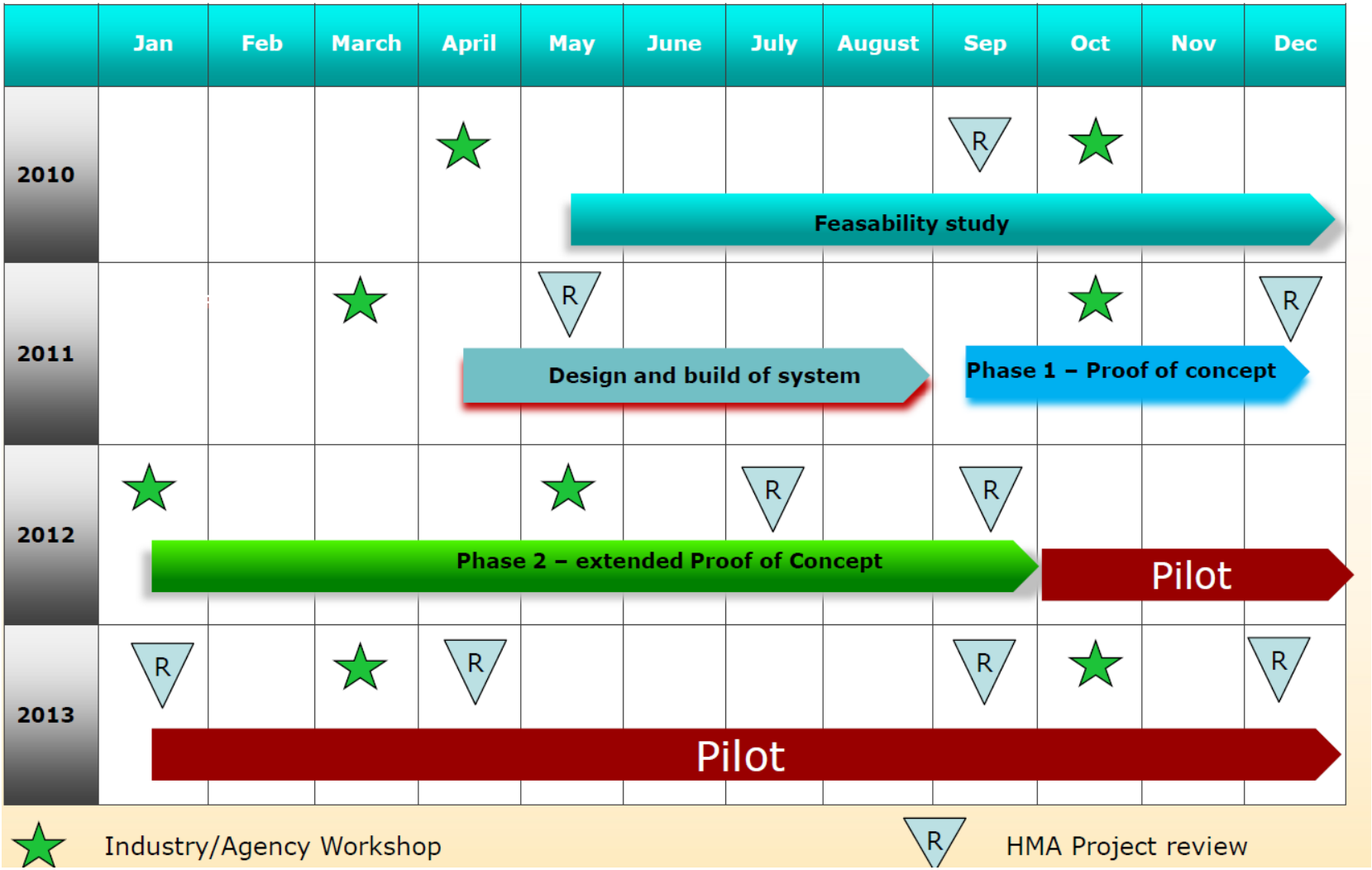


Short term (next few months) (3/7):

- CESP – A portal for Europe

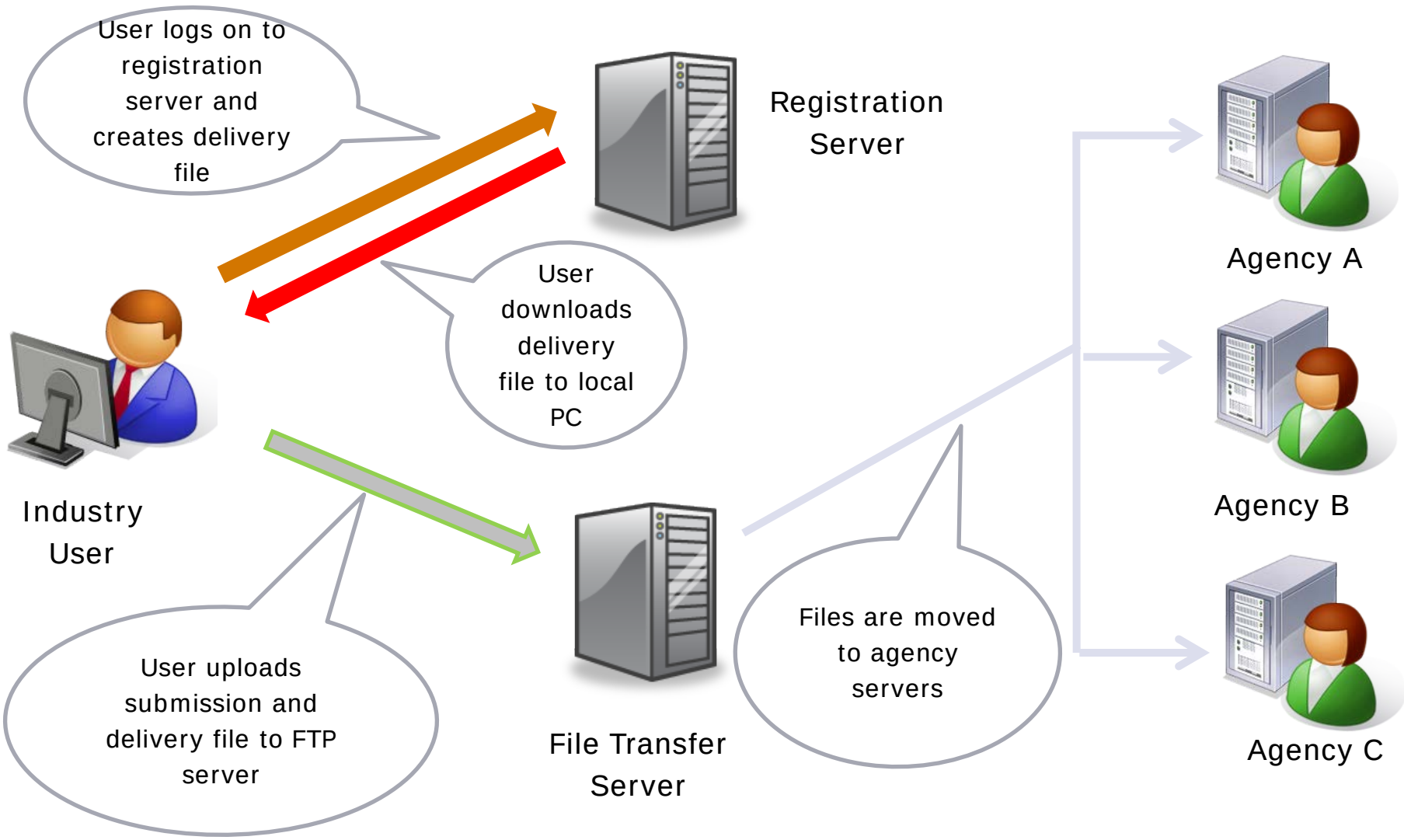
Short term (next few months) (4/7):

- CESP -Overview of Activities:



Short term (next few months) (5/7):

- CESP - Current operation:



Short term (next few months) (6/7):

- CESP - general statistics: November 2012 to March 2013:
  - Number of weeks in operation : 21
  - Number of registered companies : 420
  - Total number of submissions delivered : 9259
  - Largest submission to date : 8Gb to 18 agencies

Short term (next few months) (7/7):

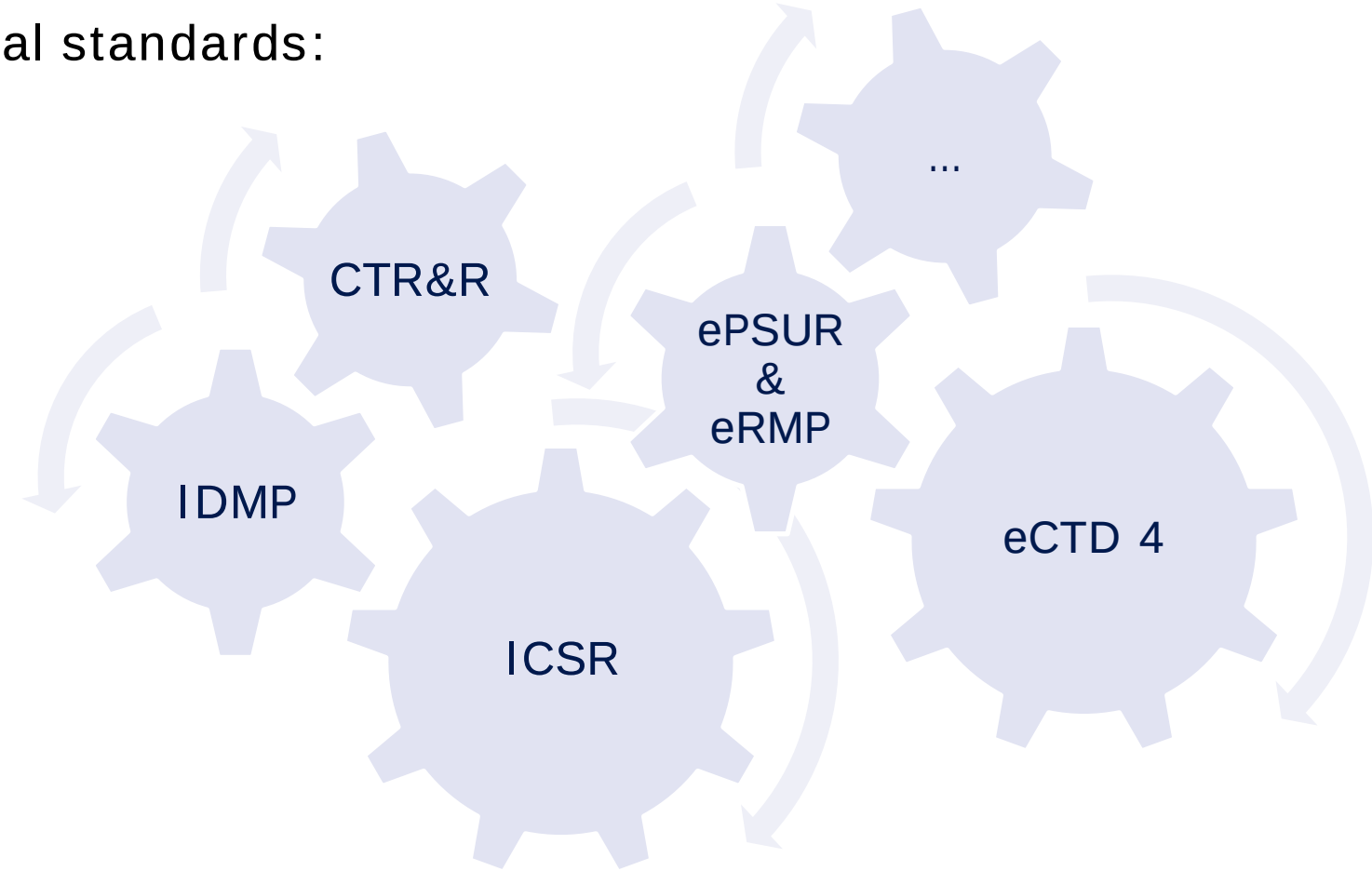
- Falsified Medicines Directive (FMD)
  - Initiative to look at Broker Registrations across Europe
  - Spanish and UK are leading on this initiative working with other interested MS
  - Concept:
    - XML forms
    - Central data repository for MS interrogation
  - Possible EMA involvement

Medium term (one year from here) (1/2):

- Introduction of esignatures of more EMA forms
- EU Medicines web portal
- Electronic submission of updates of product information according to art 57 (of Reg 2012/1235)
- Common Repository: Access for NCAs to CAP MAA info

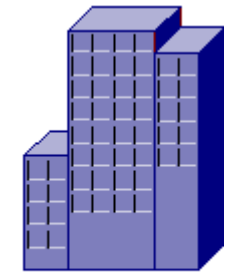
Medium term (one year from here) (2/2):

- International standards:



Long term (1/3):

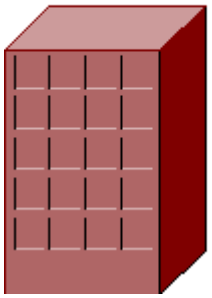
- CESP medium-to-long term initial vision:



Industry

An option for industry to build eCTDs directly in CESP

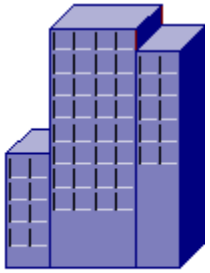
Agency



Agency can download submissions, upload tracking information and RFI Data

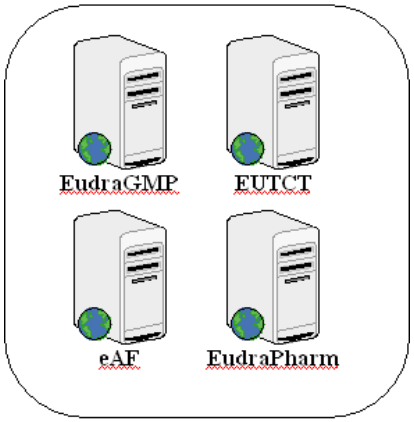
European Submission and Tracking System

Submissions can be loaded directly into CESP, all responses and requests come back via CESP



Industry

International and EU vocabularies and dictionaries



European Systems

European systems can provide and receive information

Long term (next few years) (2/3):

- Common Repository *should* contain also PSURs, RMPs and MRP/DCP submissions
- Integration CESP and EMA eSub GW
- EU Medicines Submission Portal *should*:
  - Combine CESP and eSubmission Website
  - Be published by EMA and HMA
  - Allow Submission of National Procedure, MRP/DCP, Centralised Procedure Applications
  - Contain information on all subjects: Submission, eAF, eCTD Standards, etc.

Long term (next few years) (3/3):

- Use of RPS (eCTD 4) for esubmission of MAA information
- Completion of EMA Online strategy: New B2B portal; EU Medicines Web portal; New extranet for extended collaboration with NCAs
- Implementation of EMA Data Architecture roadmap (tier 1)
- eSubmission vision
  - One submission mechanism, entry point, process, output
  - "The ultimate aim of eSubmission is **full dematerialisation** of the exchange of regulatory information between applicants and the Network and between regulatory authorities within the Network, enabling **electronic collaborative processes** and **transparency** throughout the medicinal product life-cycle. "

MHRA-Specific Initiatives (1/5):

Options for effectively sharing

- Collaborate across EU
- **TACTICAL COLLABORATIONS**
- Go Commercial...

MHRA-Specific Initiatives (2/5):

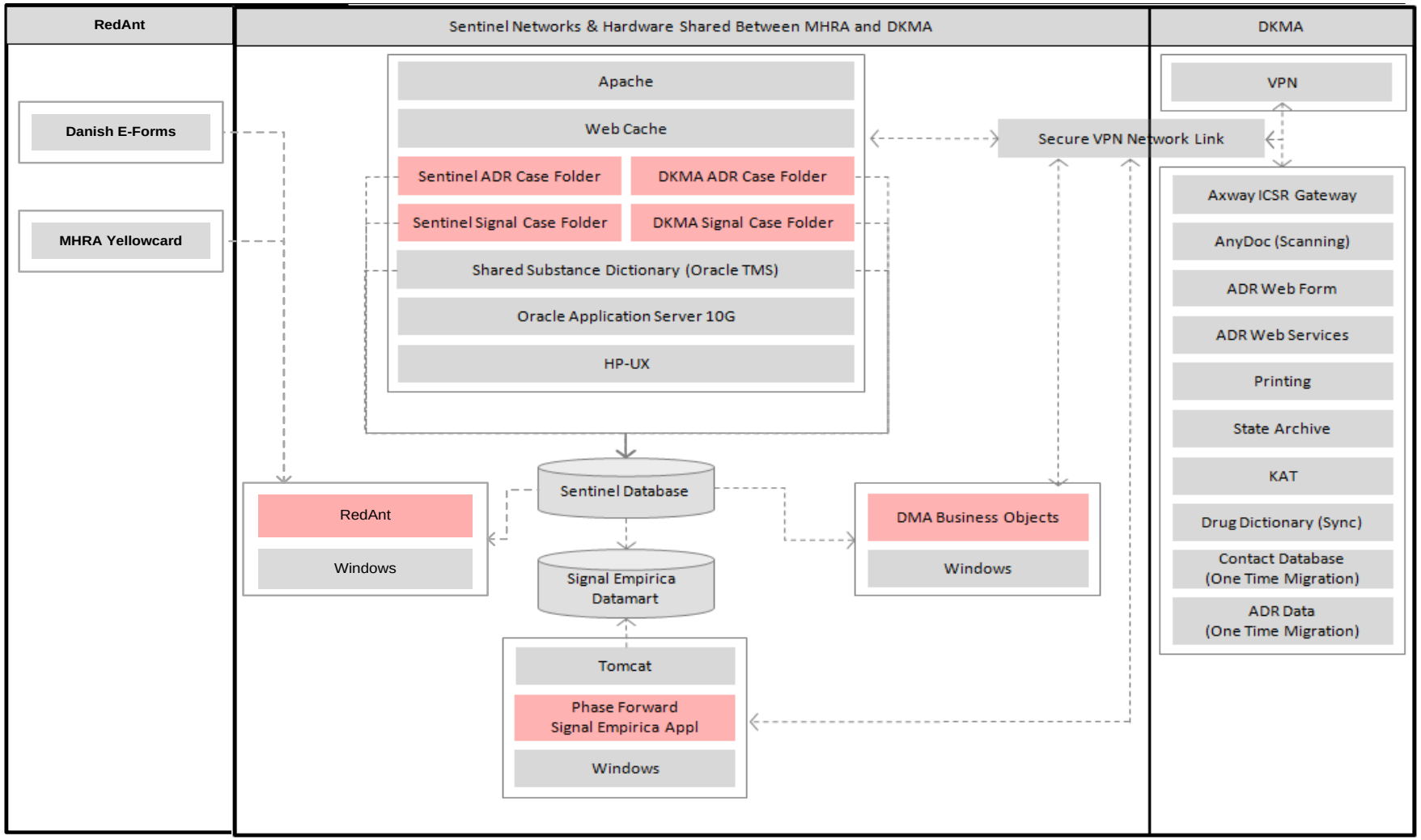
MHRA Medicines IT strategy developed in 2002 and implemented 2003-6 as the Sentinel system

Key principles

- transparency of data across business processes
- Electronic information is the master

MHRA-Specific Initiatives (3/5):

Sharing Short-long term



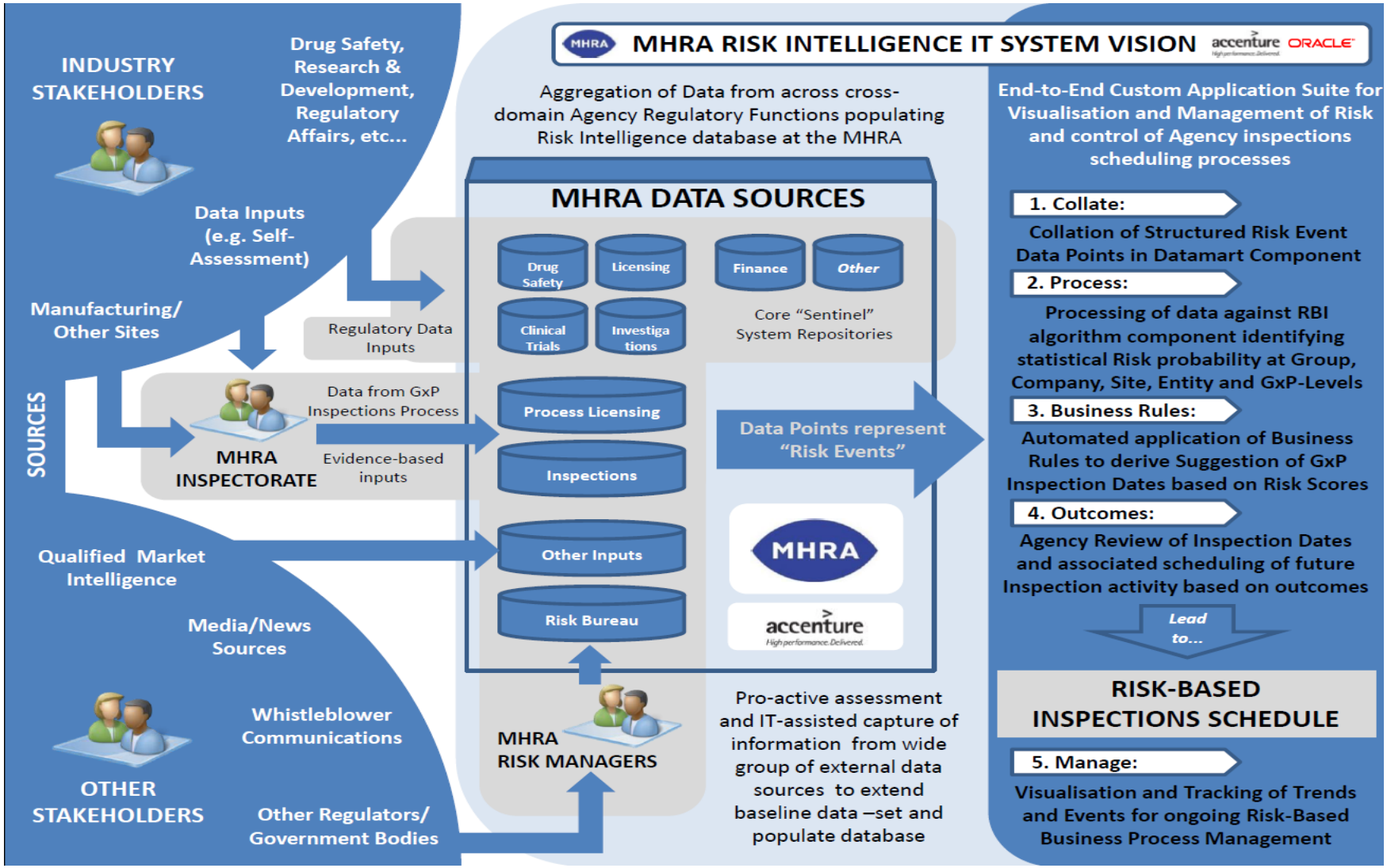
MHRA-Specific Initiatives (4/5):

Options for effectively sharing

- Collaborate across EU
- Tactical collaborations
- Go Commercial...

MHRA-Specific Initiatives (5/5):

Medium to Long term – Risk Based Inspections



Thank you