



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Linking SPOR implementation and optimisation of regulatory processes - *EMA perspective*

EMA-AESGP 2nd annual bilateral meeting

11 January 2017, London, UK

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Agenda

1. Why: the business case and the potential

2. What and **How** to implement:

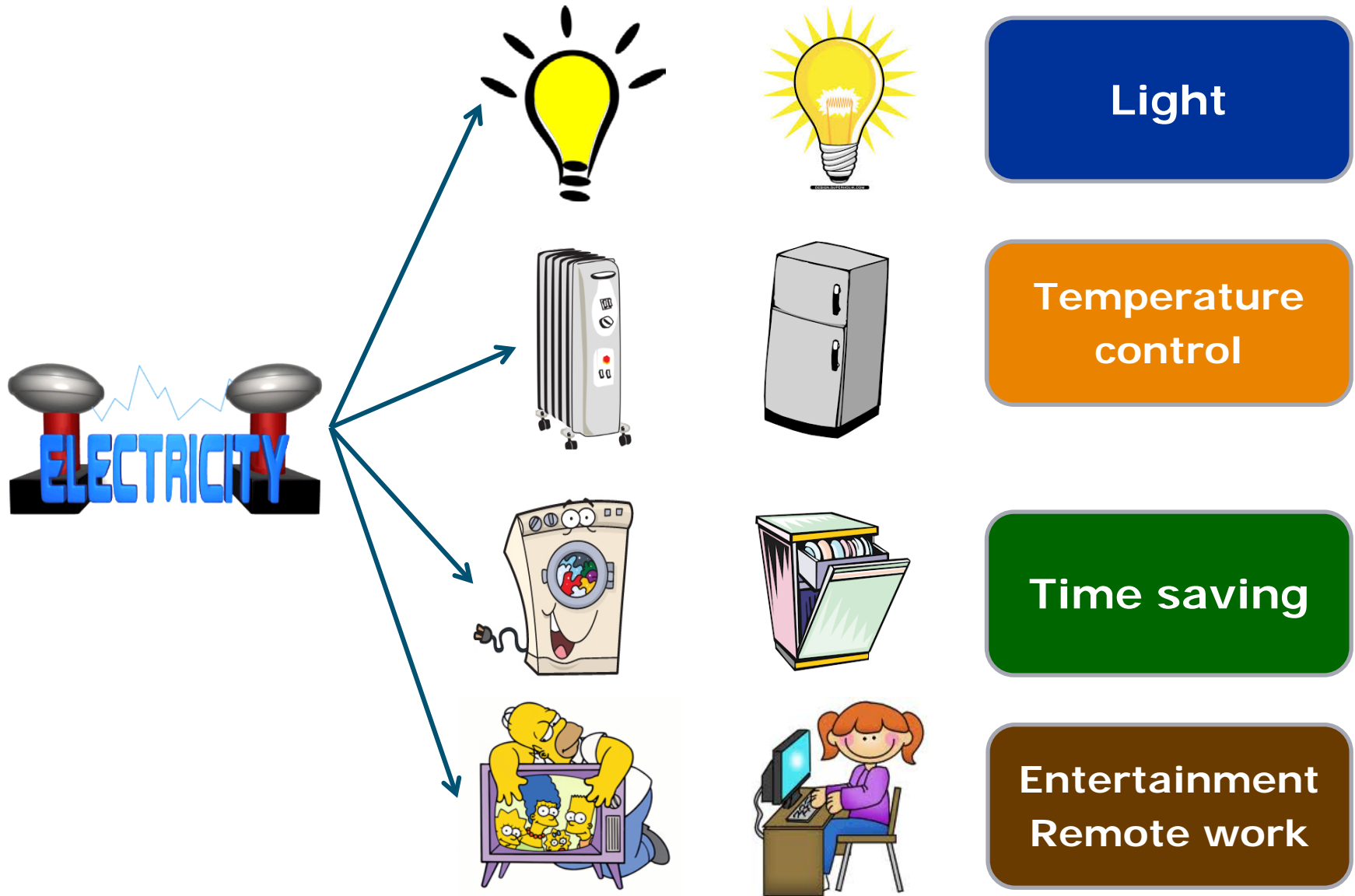
Master Data initiative through SPOR

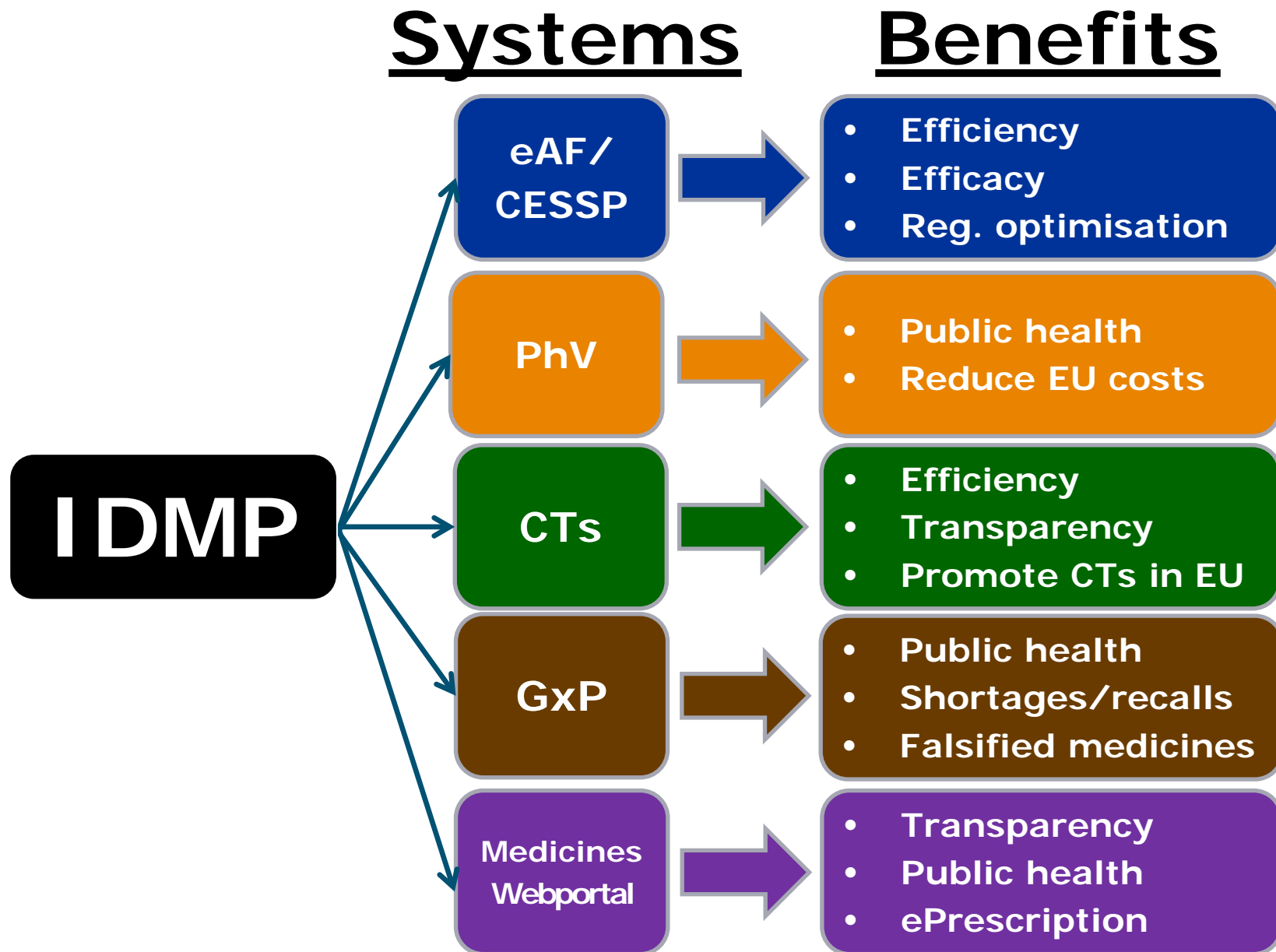
3. When to deliver the different SPOR services

Why?



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Products

Substances

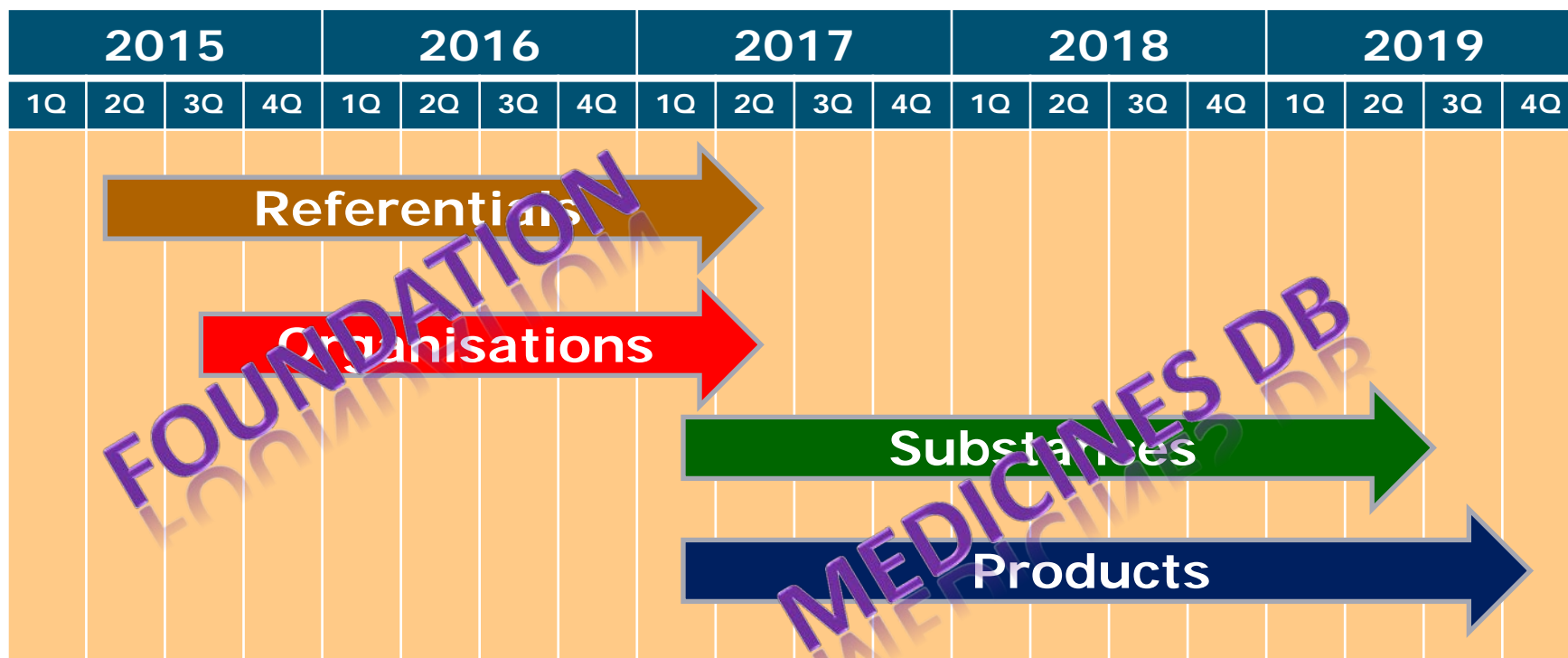
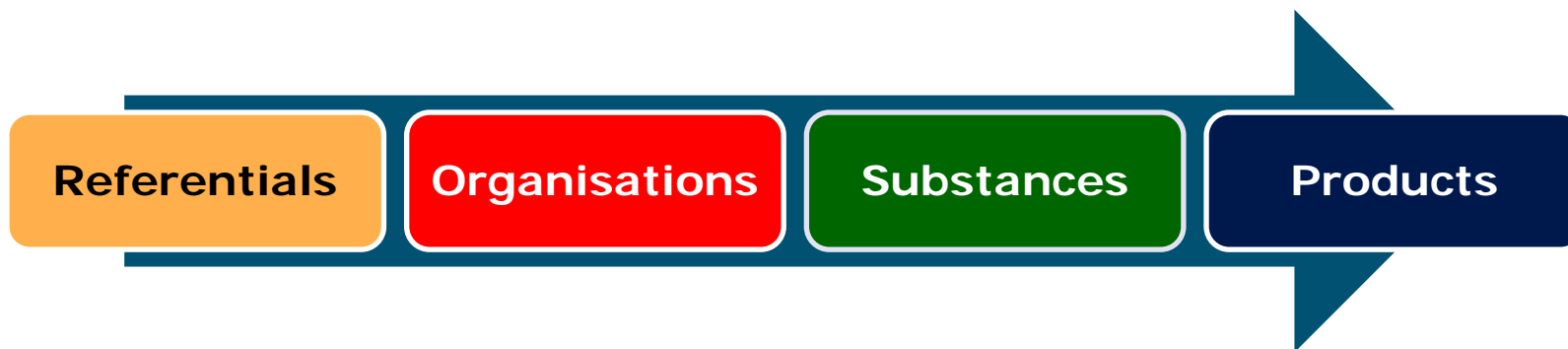
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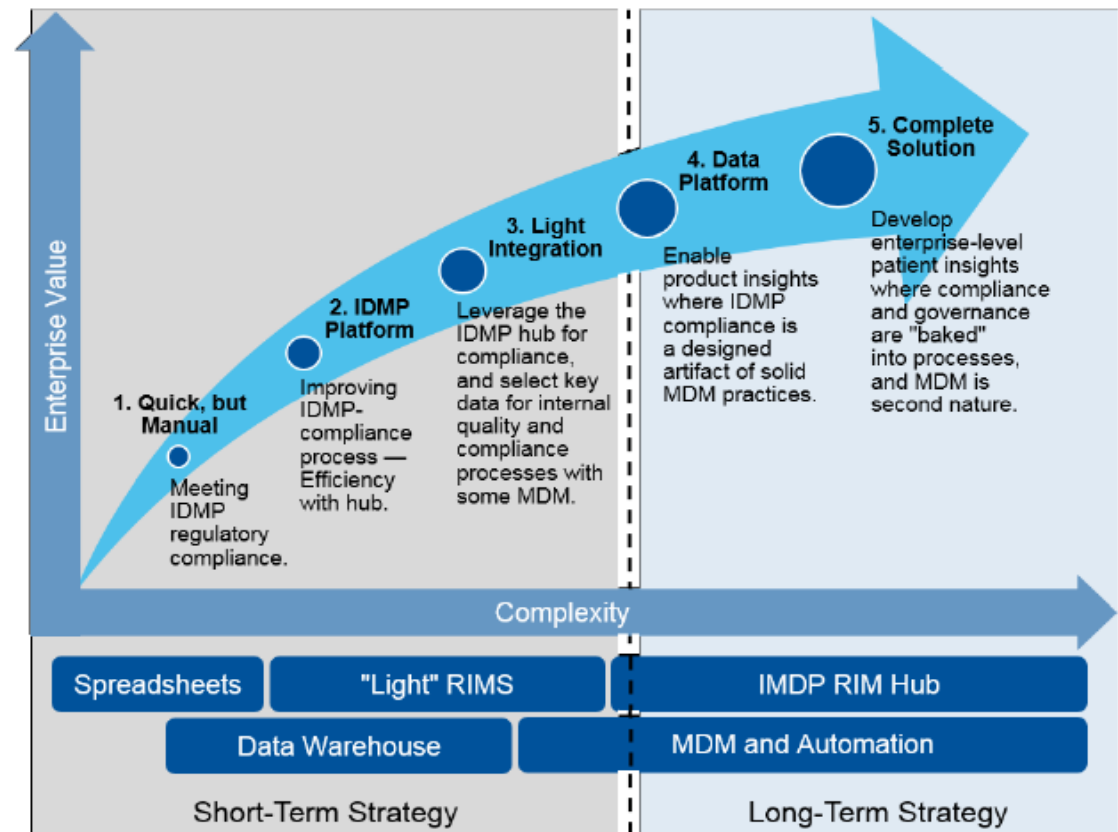
How: phase approach



Recommendations:

1. Understand your data, processes and IT systems
2. Start simple: build a system to maintain compliance
3. Do it in a way that you can escalate it and increase the benefits

Figure 4. Both Enterprise Value and Complexity Increase Depending on Your IDMP Strategy



Source: Gartner (January 2016)

Delayed and confusing IDMP compliance requirements demand life science CIOs pursue a two-part strategy. Gartner. 21 January 2016



1. Awareness and understanding
2. Conduct data assessment
3. Collect IDMP data and map against SPOR
4. Establish governance structure
5. Synchronised data with SPOR
6. Identify processes and systems to reuse data
7. Integrate the systems and processes

Example of Referentials data mapping


As-is

Different vocabularies are used across different NCAs



After SPOR implementation

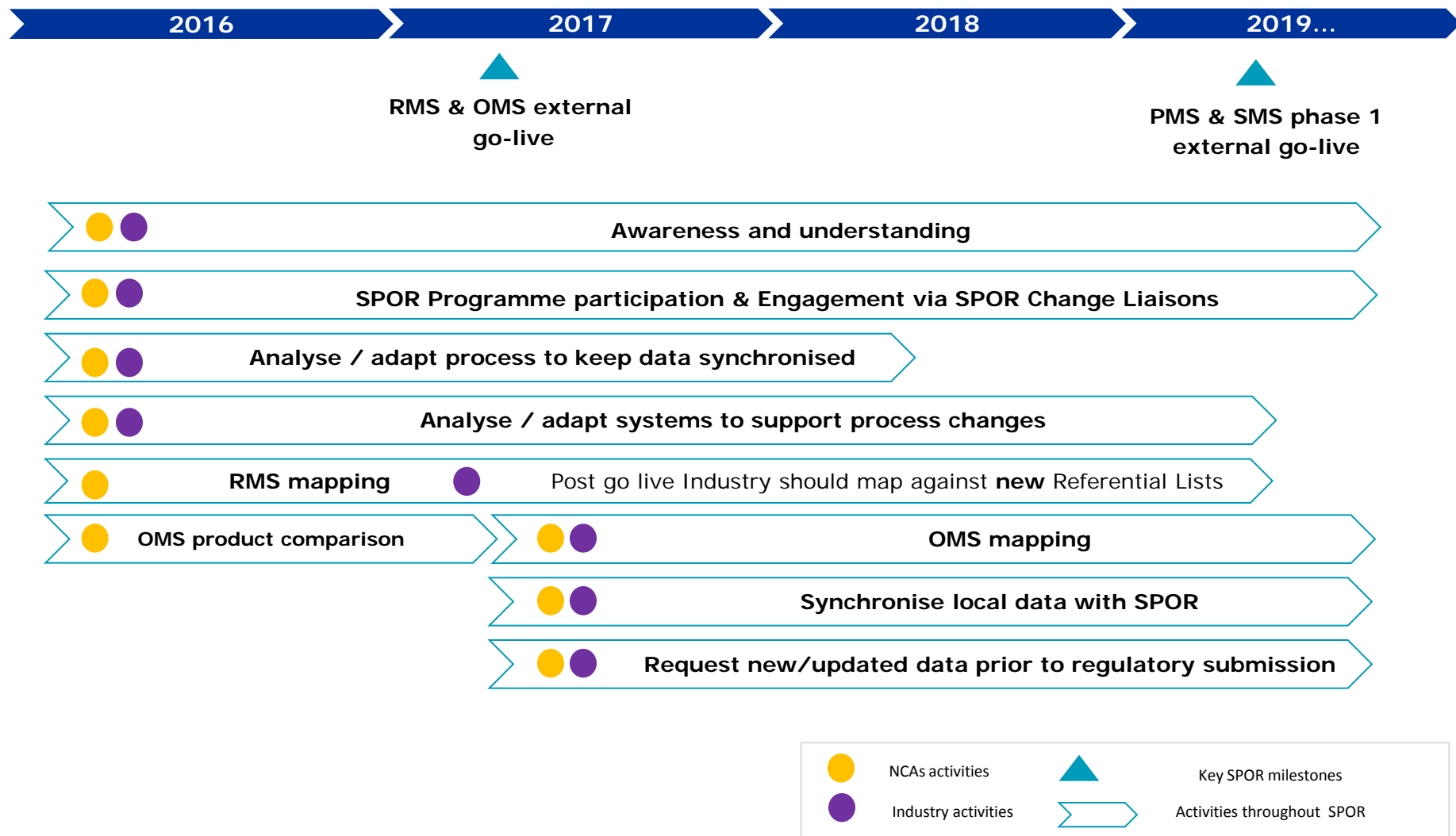
EU-wide standard terms



Term: Capsule, hard
ID: 123456789101
Synonyms:

- Capsule
- Hard capsule
- Caps

What: NCAs and Industry involvement



Note: Indicative timelines, revised plan for SPOR will be published in coming weeks following the re-planning. More information will be provided through SPOR Change Liaison Network



In summary

- SPOR will act as the vehicle for implementation of ISO IDMP standards
- SPOR will be the home of an EU-wide source of validated data that can be re-used by EMA, NCAs and Industry in support of regulatory activities
- SPOR data management services will enable the realisation of benefits at all stages of the product lifecycle due to future integration of regulatory processes
- Implementation of RMS and OMS is the first step in a phased approach to roll-out of SPOR and of other Programmes dependent on SPOR data
- In order to be ready for the future changes brought about by SPOR and by integration with other programmes, Industry and NCAs should prepare now to ensure they have the foundations in place through alignment with RMS and OMS

Benefits

- Efficiency
- Efficacy
- Regul. optimisation

- Public health
- Reduce EU costs

- Efficiency
- Transparency
- Promote CTs in EU

- Public health
- Shortages/recalls
- Falsified medicines

- Transparency
- Public health
- ePrescription

“In the long history of humankind (and animal kind, too) those who learned to collaborate and improvise most effectively have prevailed.

Charles Darwin



Thank you for your attention

Further information

http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000645.jsp

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