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SCIENCE MEDICINES HEALTH

EMA SPOR master data management roadmap

EU ISO IDMP Task Force meeting – For information – March 2015

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Roadmap and the overall EMA strategy

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Roadmap approach

- Roadmap developed to meet EMA business priorities and provide stakeholder benefits
- Initial analysis based on EMA consultation, NCA input and industry position paper[1]

Stakeholder engagement

- High level approach for delivering SPOR MDM services agreed by EMA leadership
- Based on principles agreed by the EU Telematics workshop (Feb 2015):
  -Simplicity, phased approach & show value with each phase

Implementation

- EMA Referential and Organisation MDM implementation projects following the strategy and guidance defined by this roadmap
- Implementation principles for the roadmap are to be iterative, gradual and incremental to lower risks, deliver services sooner, and help stakeholder engagement

1. Principles for the implementation of ISO IDMP standards for EudraVigilance and development of a roadmap, EFPIA, 2014

Benefits of roadmap implementation

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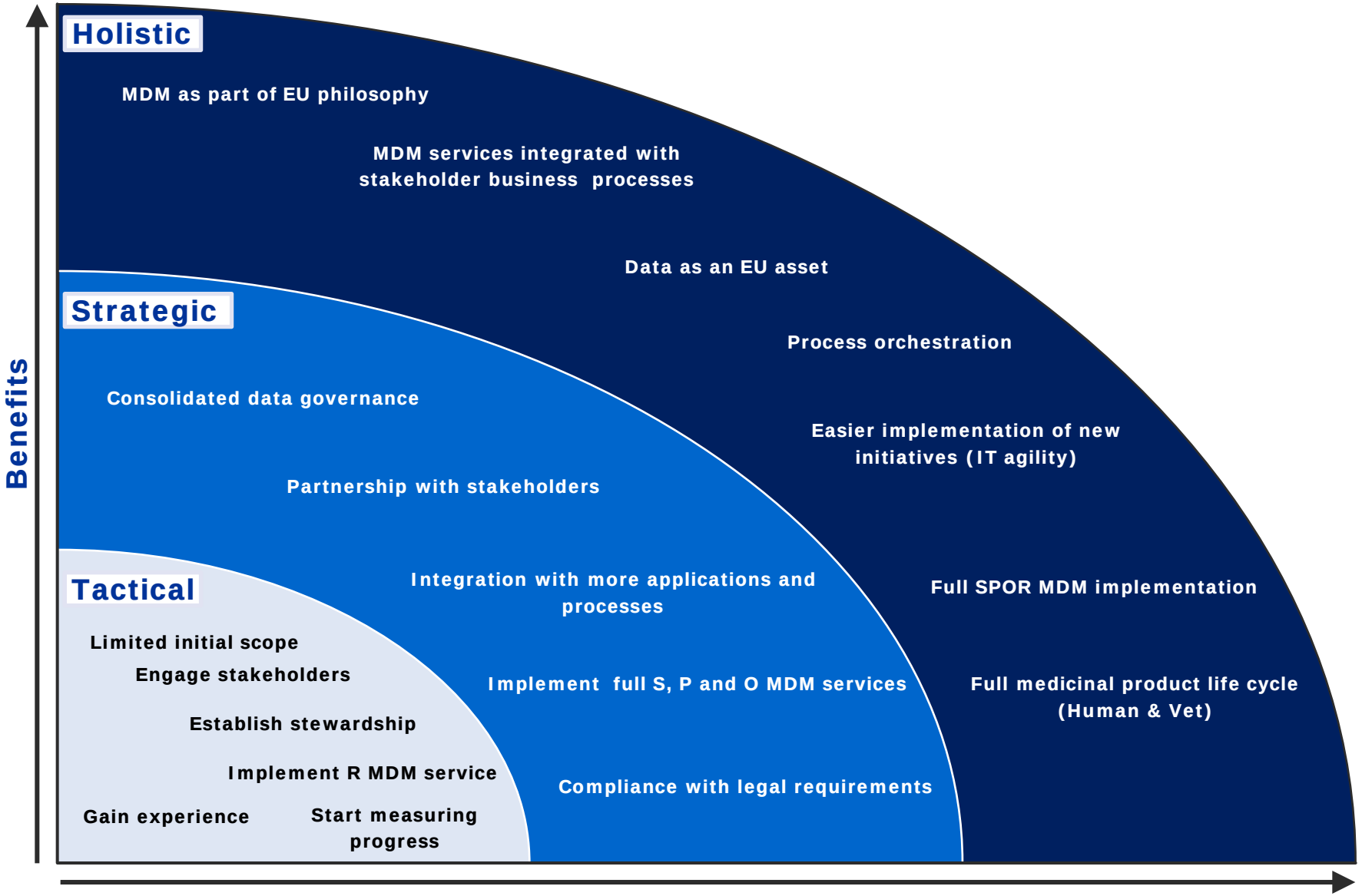

Practical applications of MDM services

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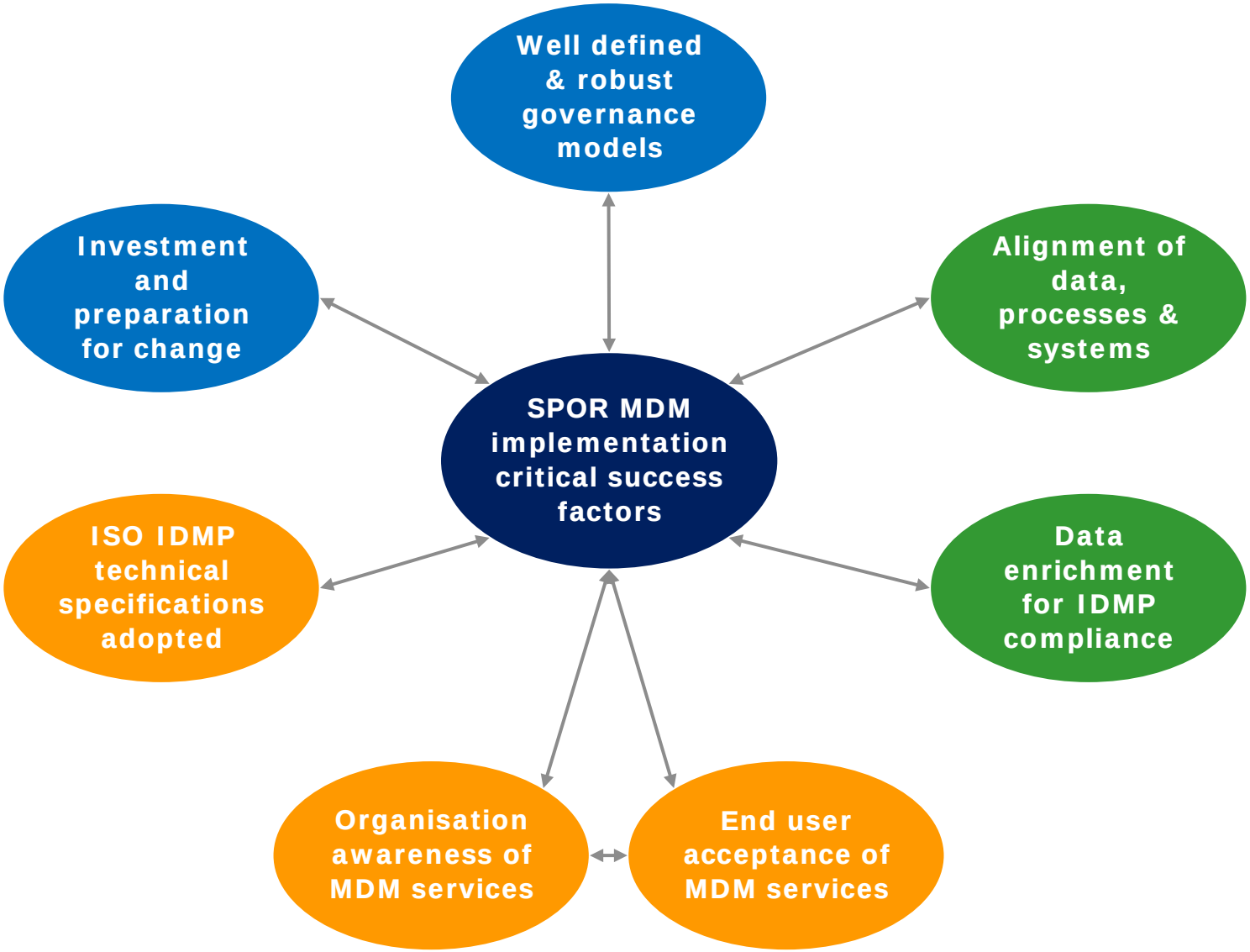
Short / Medium term

- Pharmacovigilance
  - ICSR and Art. 57 data submissions
- Clinical Trials legislation
  - Clinical Trials portal & database
- Regulatory submissions
  - eAF, Referrals, PSUR repository, eCTD, Gateway, Single submission portal

Long term

- Falsified Medicines legislation
  - EudraGMDP support
- Future initiatives
  - ePrescription
- Other regulatory submissions
  - Scientific Advice/Orphan/Paediatrics applications, Veterinary products

Critical success factors



MDM services and stakeholder readiness

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Services	Description
Registration and maintenance of master data	• Establishment of the processes and technology capability for EMA and relevant stakeholders to participate in the registration and maintenance of the master data • Service provided will be based on the agreed operating model within the EU as well as the EMA
Access and exchange of data	• Access to data may be provided systematically via system interfaces, or/and via web user interfaces. • Interfaces will need to be ISO IDMP compliant and enable data exchange and integration across systems.
Customer services	• Stakeholders consuming these EMA MDM services will require support in the form of: o Guidance documentation o Training o Direct helpdesk support

MDM services and stakeholder readiness

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Area	Requirement from stakeholders
Technology	• For reading/querying data, web services may require consumers to provide security credentials and adapt systems to make use of the new message format (HL7 v3). • Read /query functionality will be exposed through a User Interface (UI) enabling users to query directly, which can also be embedded into existing application UIs. • Security credentials are essential for users to author data/submit change requests. Functionality will also be exposed through a User Interface.
Processes	• Early engagement with EMA for change management activities during the development of MDM services is recommended
People	• Service users will need to be aware of new policies, service level agreements, and processes put in place as part of the service provisioning and consumption • EMA will provide a point of contact for communication and interaction with future service users • EMA advises the appointment of a representative or small user group to liaison for training, communication, and general support throughout the transition

A phased approach for the implementation

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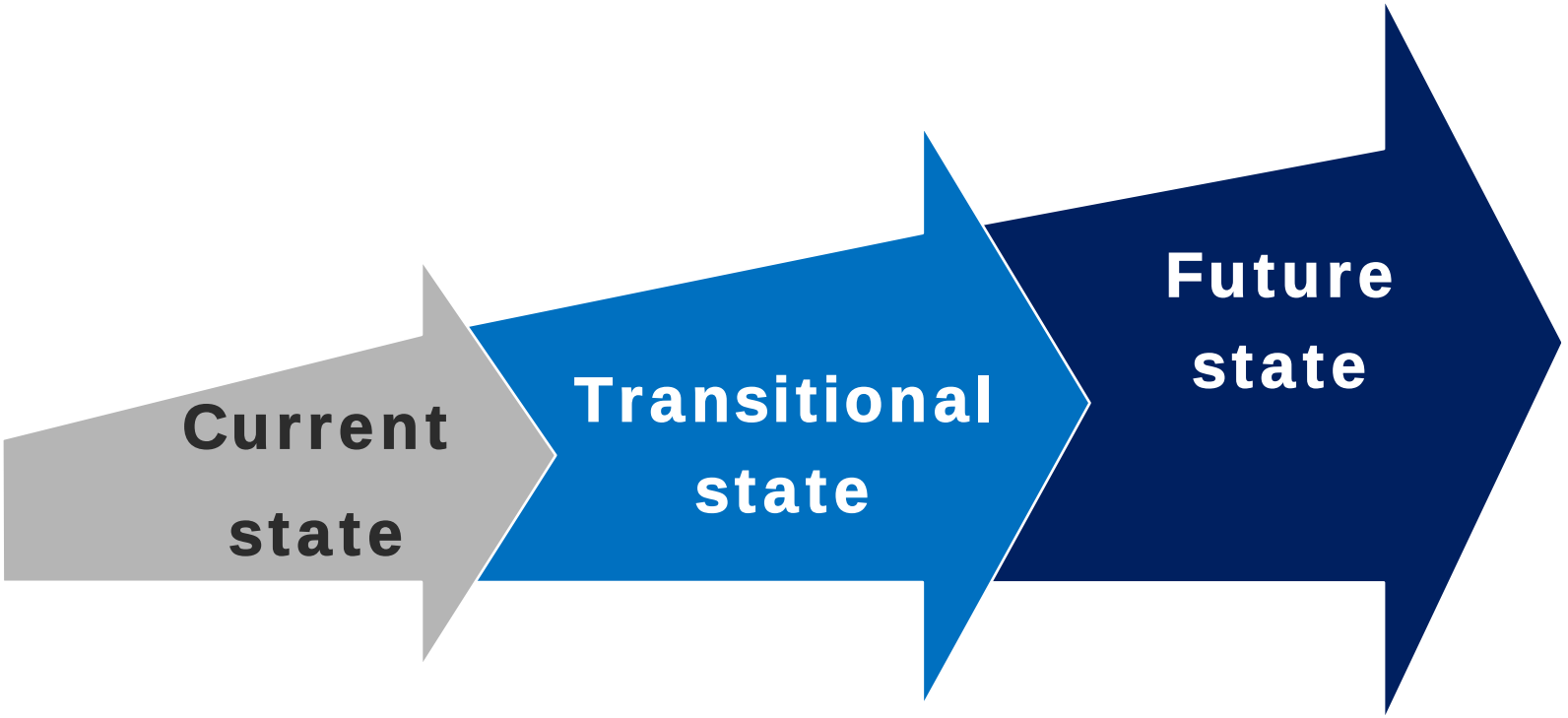
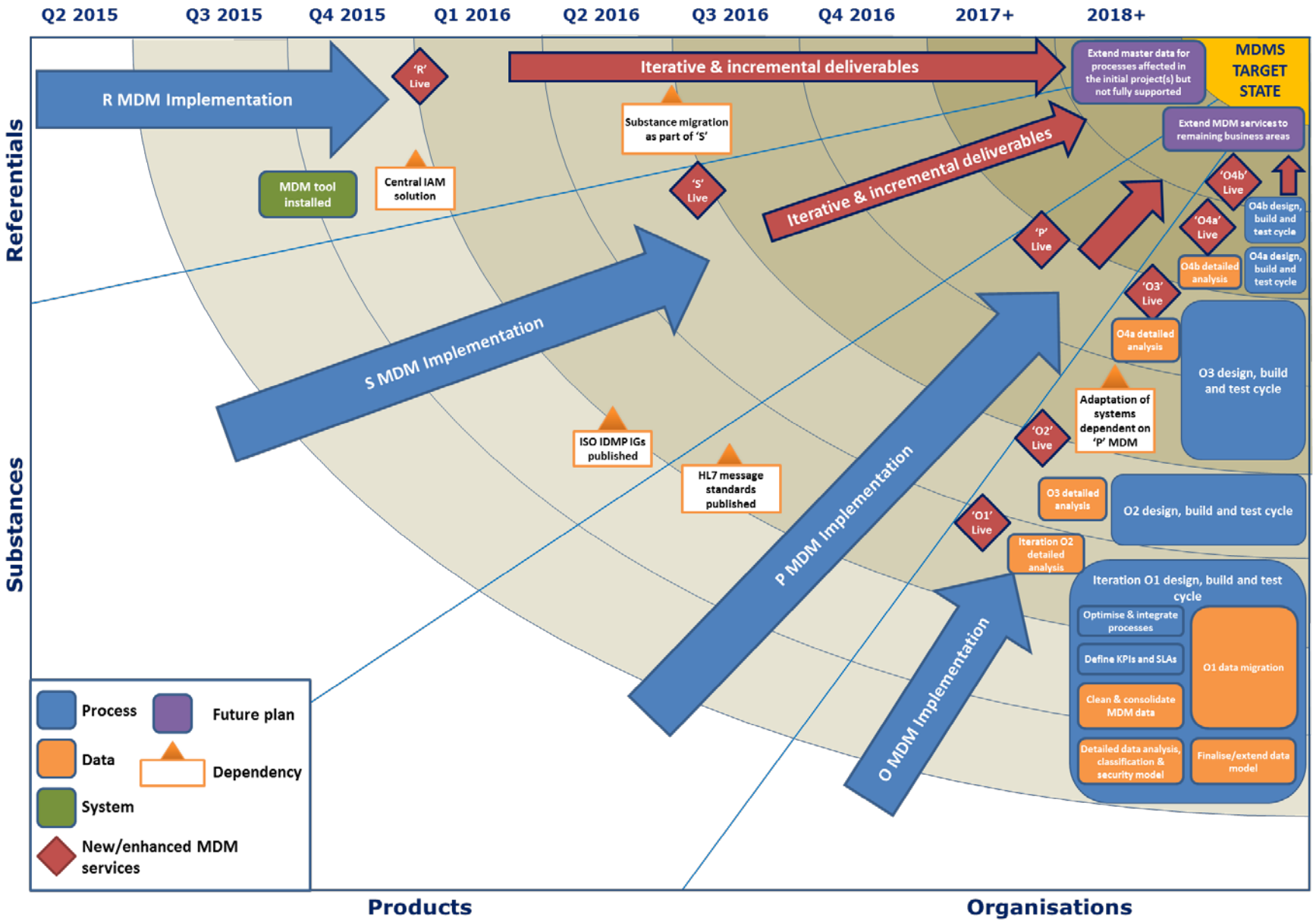


- Stepwise, iterative MDM implementation projects
- Data consolidation and integration
- Change management
- Partnership with industry and NCAs

Roadmap high level activity plan



Change management planning

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Thank you

Any questions?

Supporting slides

Roadmap high level activity plan

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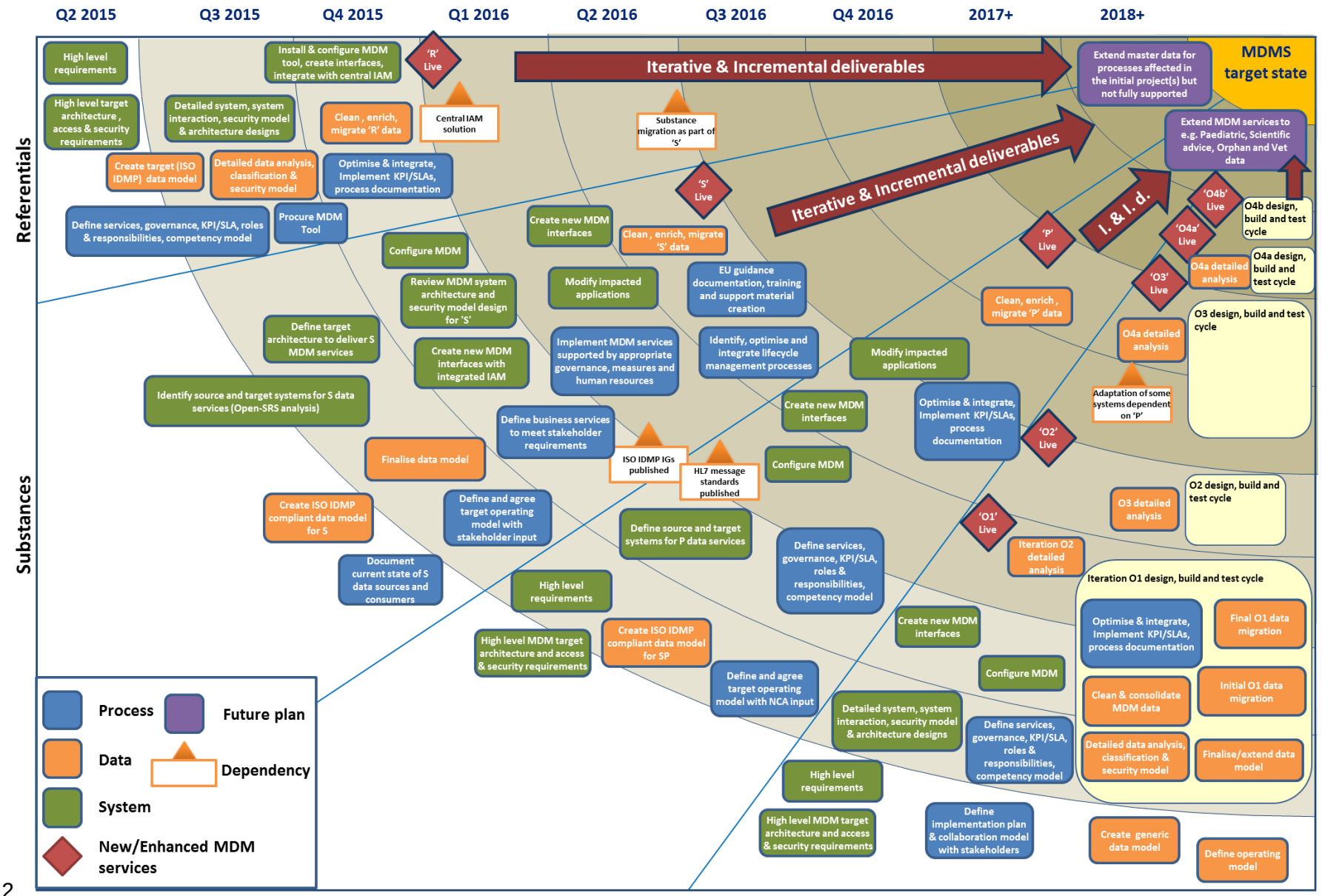

Referential MDM high level activity plan

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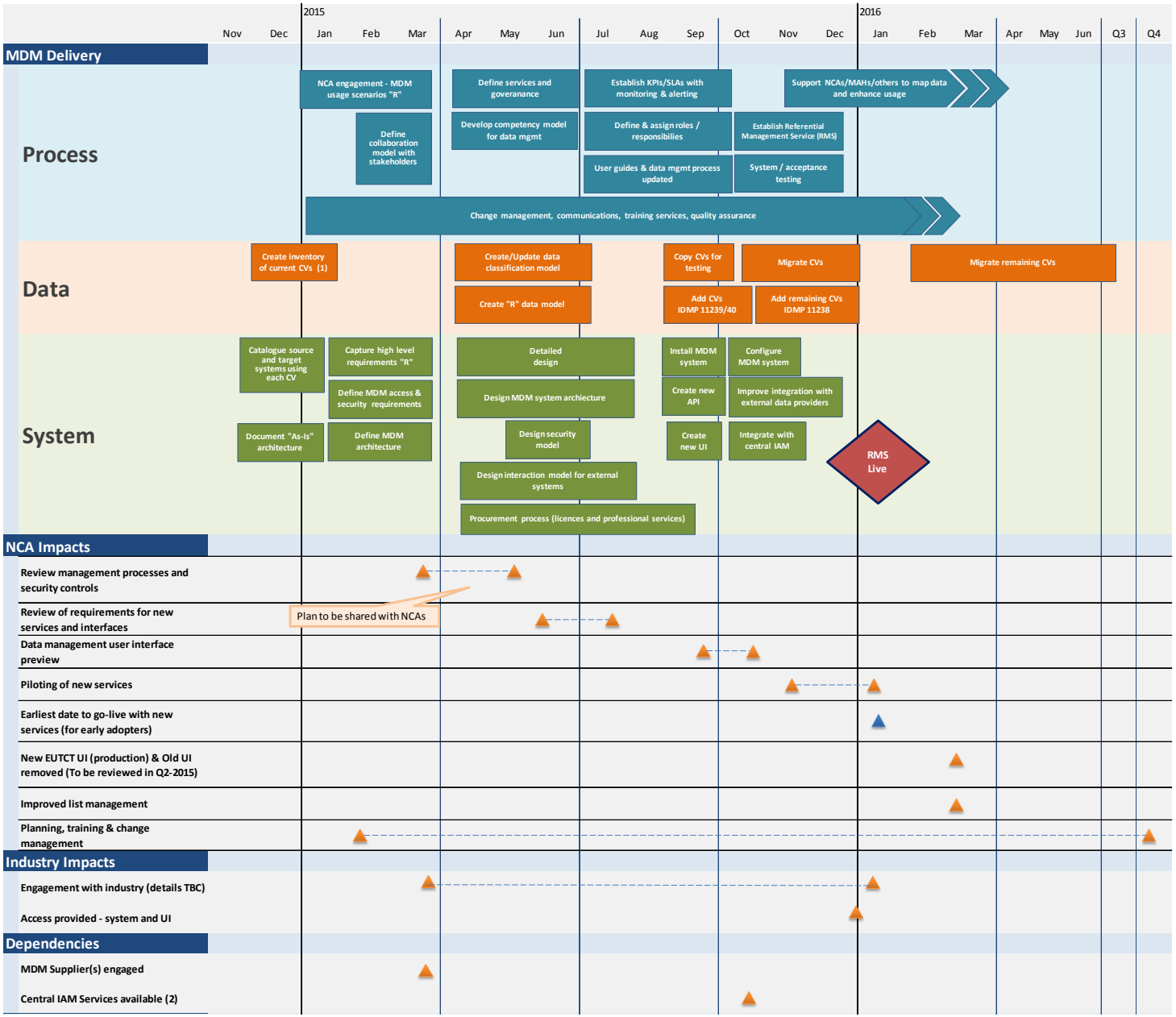

Substance MDM high level activity plan

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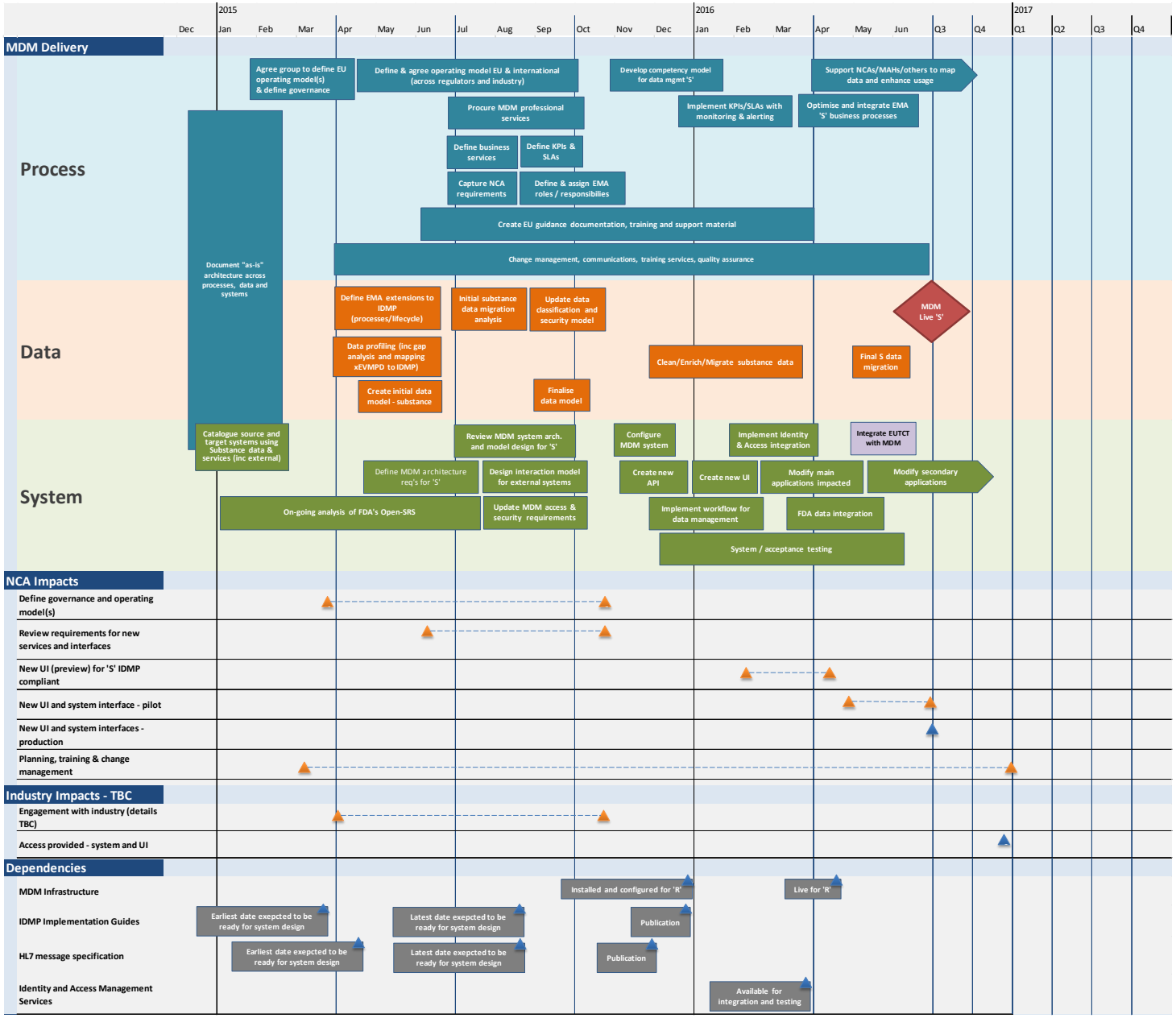

Product MDM high level activity plan

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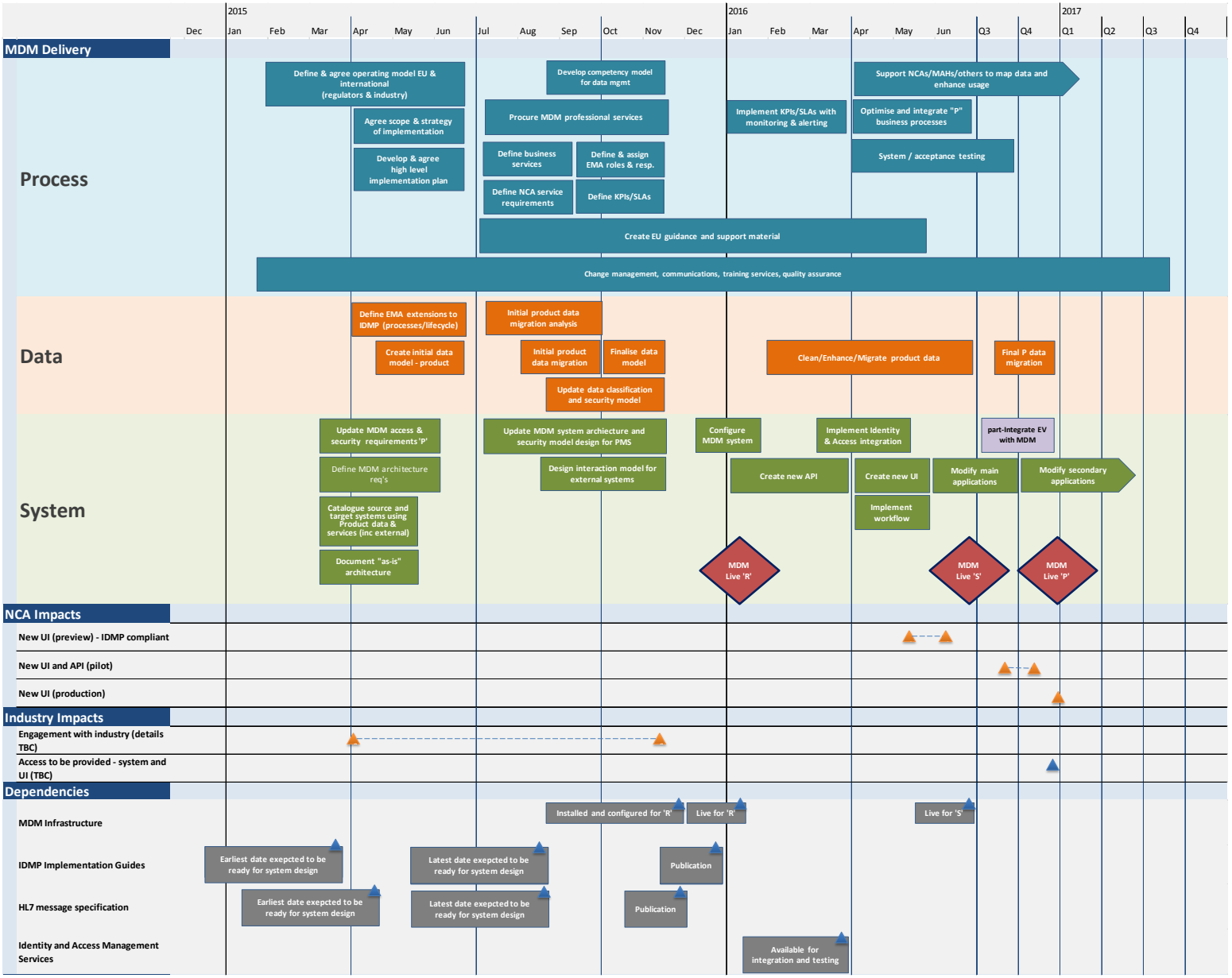

Organisation MDM high level activity plan

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