Use of master data and IDMP implementation

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The drivers for digital transformation of operations

Disconnected processes

Multiple interfaces

Disconnected data

Manual processing

Digital transformation underpinned by Agile methods

User friendly & integrated interfaces

Efficiency through conneced submissions & processes

Process efficiencies through automation

Facilitate exchange of structured data

Data assessment integrated in regulatory procedure

Continuous delivery of business value

Responding better, quicker and more efficiently to new challenges

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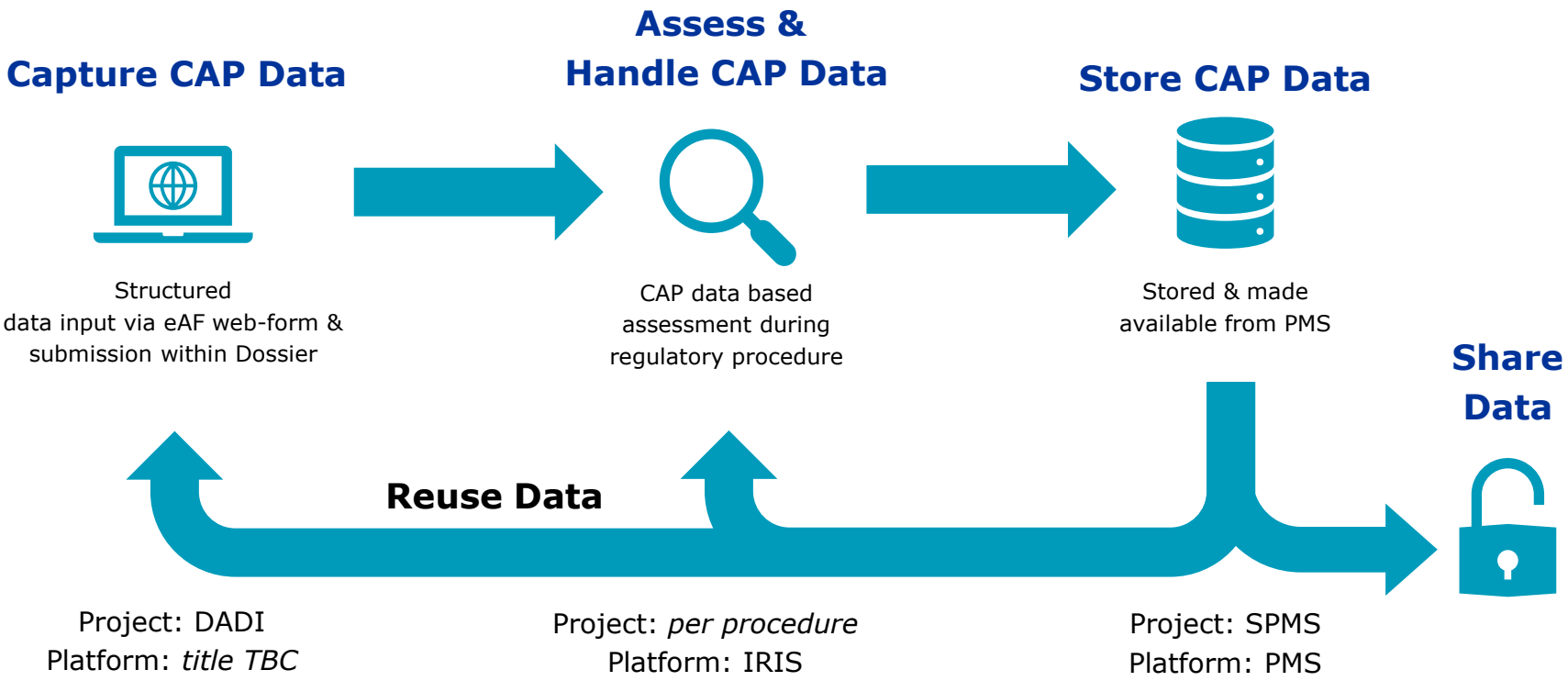
Target Operating Model for Centralised Procedure



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Implementing the Target Operating Model (TOM) step by step

- Focus first on variations forms & procedure due to volume
- Variations **eAF web-form** (DADI project) expected Q3 2022
  - Uses PMS i.e. an implementation of IDMP
  - Relies on FHIR data exchange standards to communicate with PMS
- Variations **procedure** update using IRIS platform expected in 2022
  - Regulatory procedure *will not* change with eAF web-form launch
  - Article 57 submission *will not* yet be replaced at variations web-form launch (and not in 2022)
  - The data requirement *will* change: must be PMS data

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Challenges in 2022

For Industry

- Continued dual submissions for regulatory procedure & Article 57 for the time being
- Only the new variations web-forms will support re-use of structured PMS data – *data flow & mechanism to be confirmed*
- Proactive data enrichment in advance of submissions to avoid delays – *mechanism to be confirmed*

For EMA

- Ongoing data consolidation from EMA databases & Article 57 – data quality is uncertain
- Identify the enrichment process & review mechanism that balances accuracy & feasibility

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Regulatory Business Optimisation Industry engagement in 2022

Variations web-forms
(DADI project)

- Representative participation in SME group
- Representative participation in UAT
- Demo’s accessible to all
- Regular road to launch communications & training accessible to all

Variations Procedure
(IRIS Platform)

Project in start up phase – *specific engagement TBC*

Expected:

- Representative participation in UAT

Data / PMS

- Representative participation in SME group(s) – *based on current stakeholder & focus groups*
- Demo’s accessible to all
- Representative participation in data UAT

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Conclusions

- EMA remains committed to implement IDMP into its operating model
- Different projects for different parts of the operating model – forms, procedures & storage
- Shared focus on enabling improved, data-driven, regulatory procedures
- Step by step approach - Article 57 will remain in place for now

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