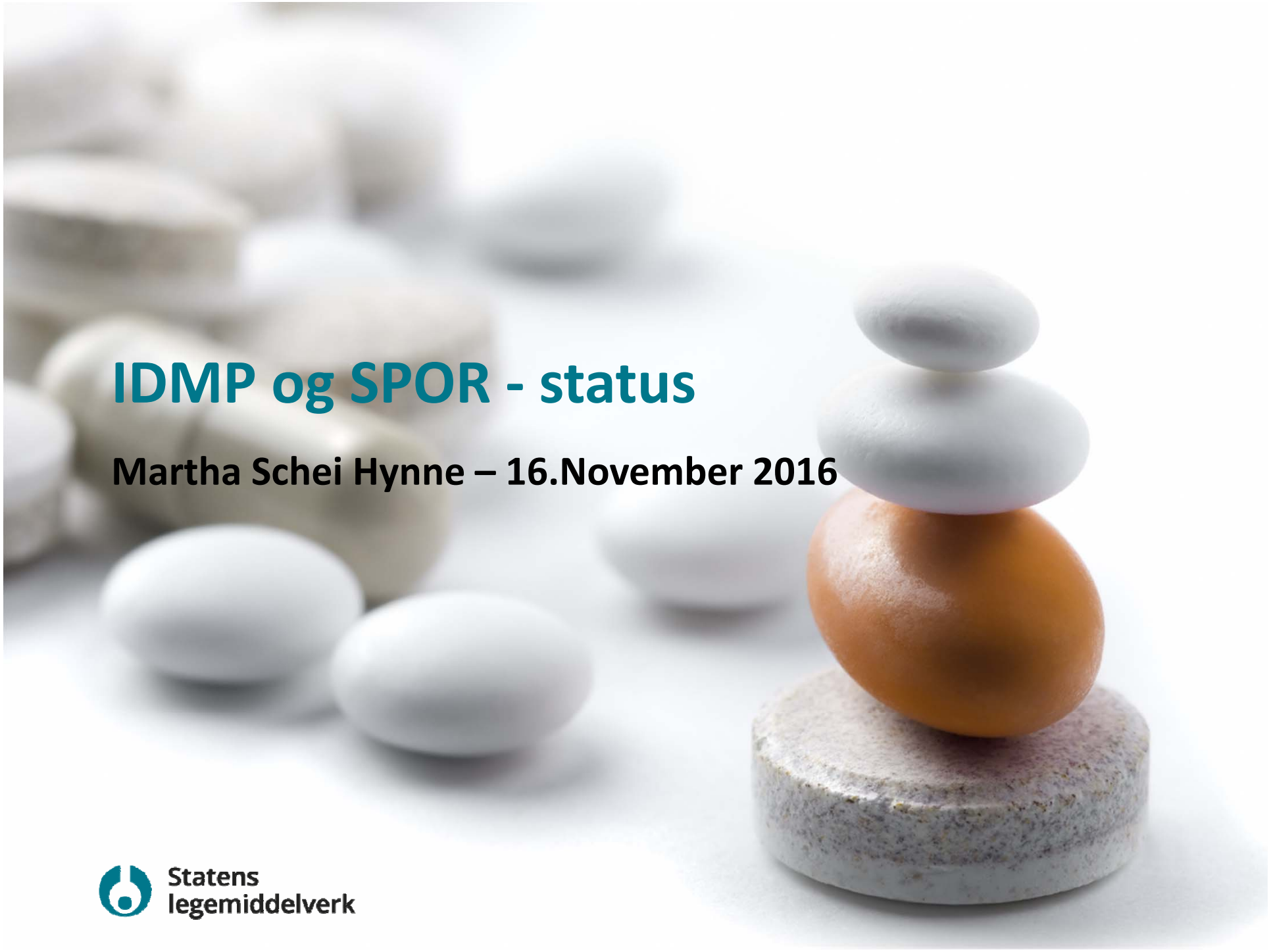
IDMP og SPOR - status

Martha Schei Hynne – 16.November 2016



Statens legemiddelverk

Hva er ISO IDMP?

- Identification of medicinal product
- Internasjonale standarder (rammeverk)

Medicinal product

- Medisinen i pakningen
- Avhengig av merkevare

Pharmaceutical product

- Medisinen når den skal gis til pasienten
- Uavhengig av merkevare

Hva er SPOR?

- Prosjektprogram i EMA/HMA
- Skal lage «Data management services» for «masterdata»

Hva er masterdata?

The 5 new ISO IDMP standards are all about **master data**

Master data is any non-transactional information that is considered to play a key role in the core operation of a business and is re-used for multiple purposes

Types of data:

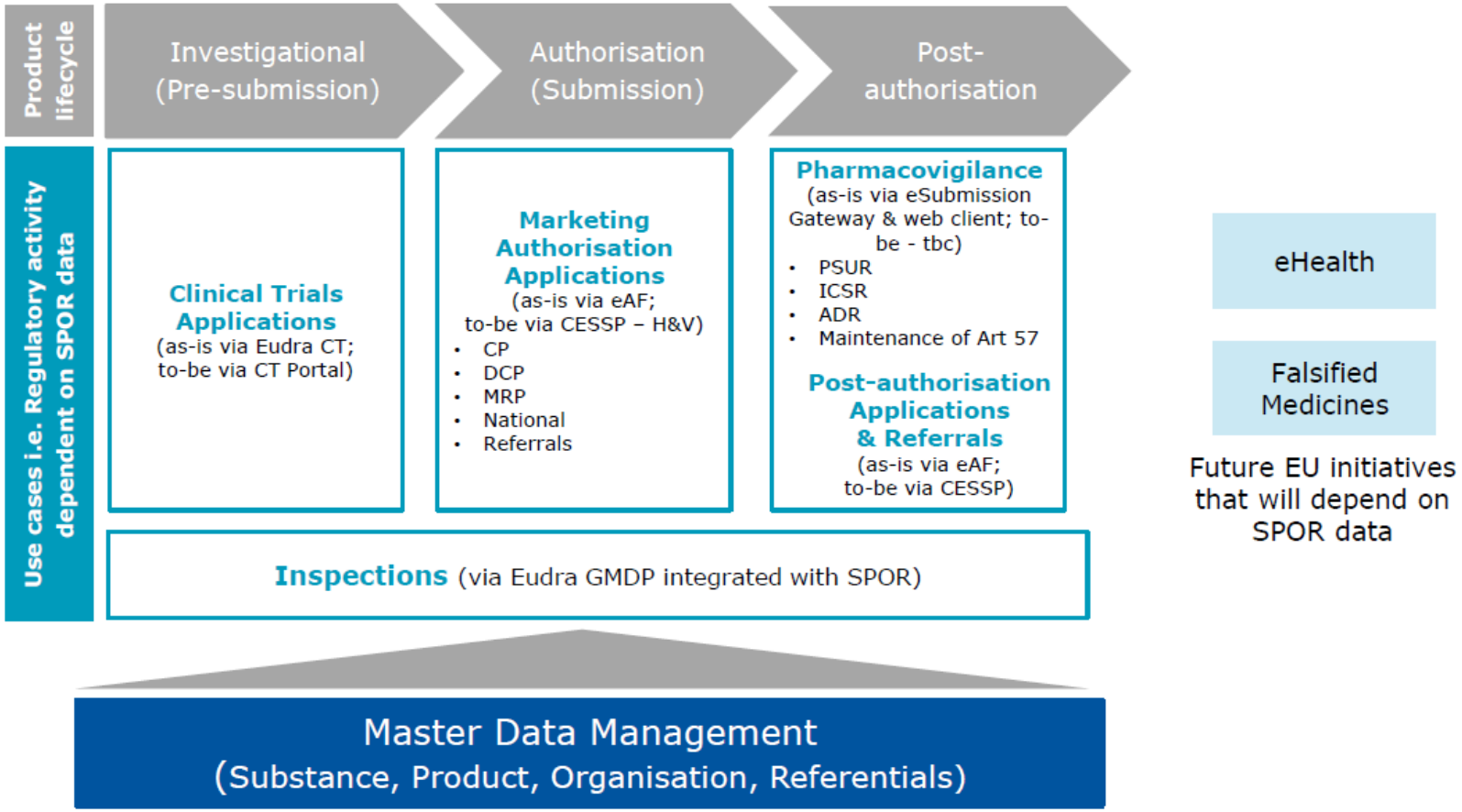
Unstructured - data found in e-mail, white papers, magazine articles, corporate intranet portals, product specifications, marketing collateral, and PDF files. (e.g. data in: product dossier, summary of product characteristics)

Transactional – data related to sales, deliveries, invoices and other monetary and non-monetary interactions. (e.g. application submission and approval dates)

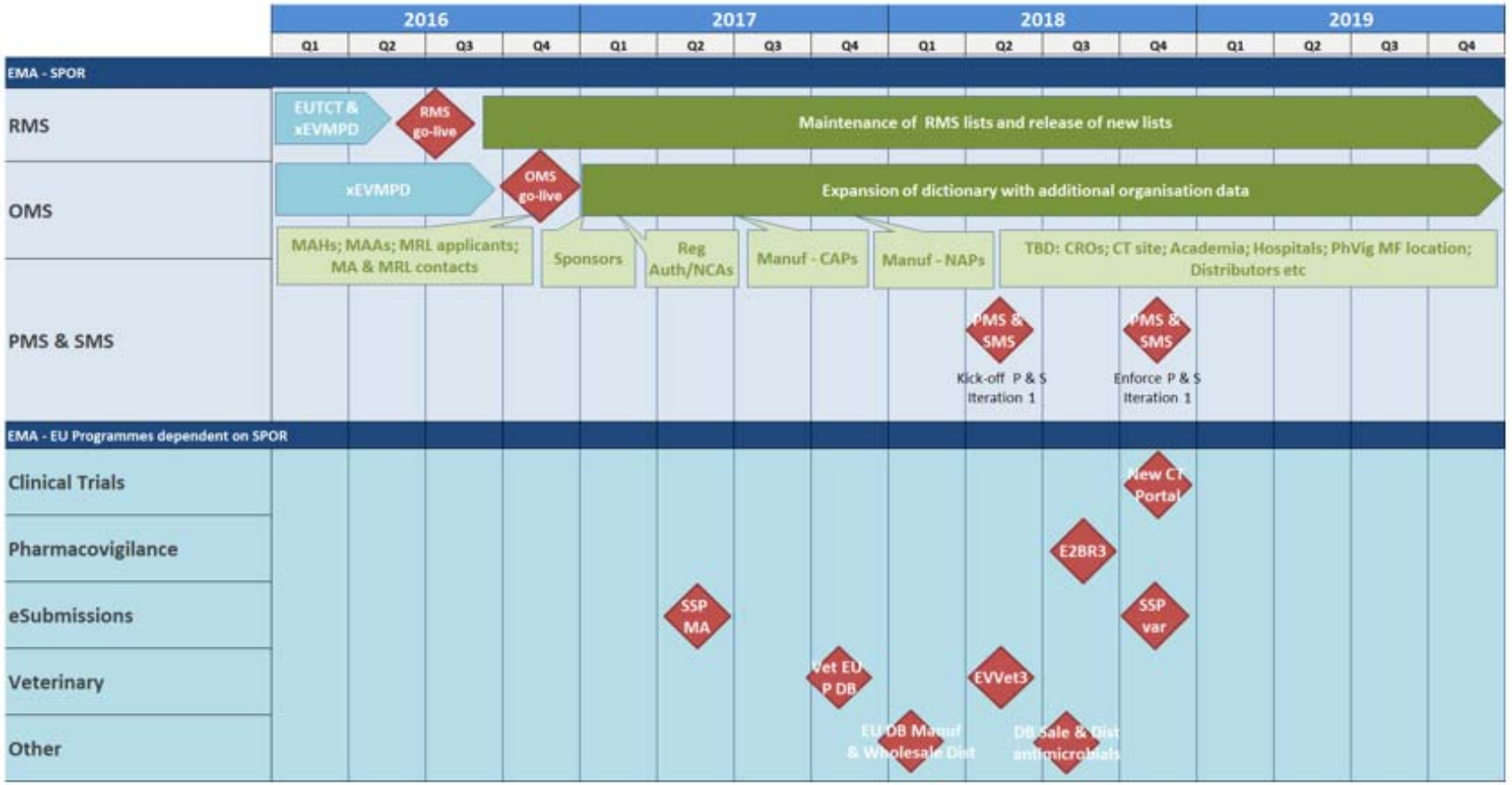
Metadata - data about other data which may reside in XML documents, report definitions, column descriptions in a database, log files, configuration files

Master – Any non-transactional data that is considered to play a key role in the core operation of a business and is re-used for multiple purposes such as customer, product, site, supplier, vendor. (e.g. Products, Substances, Organisations, Referentials)

Bruk av SPOR i regulatoriske aktiviteter



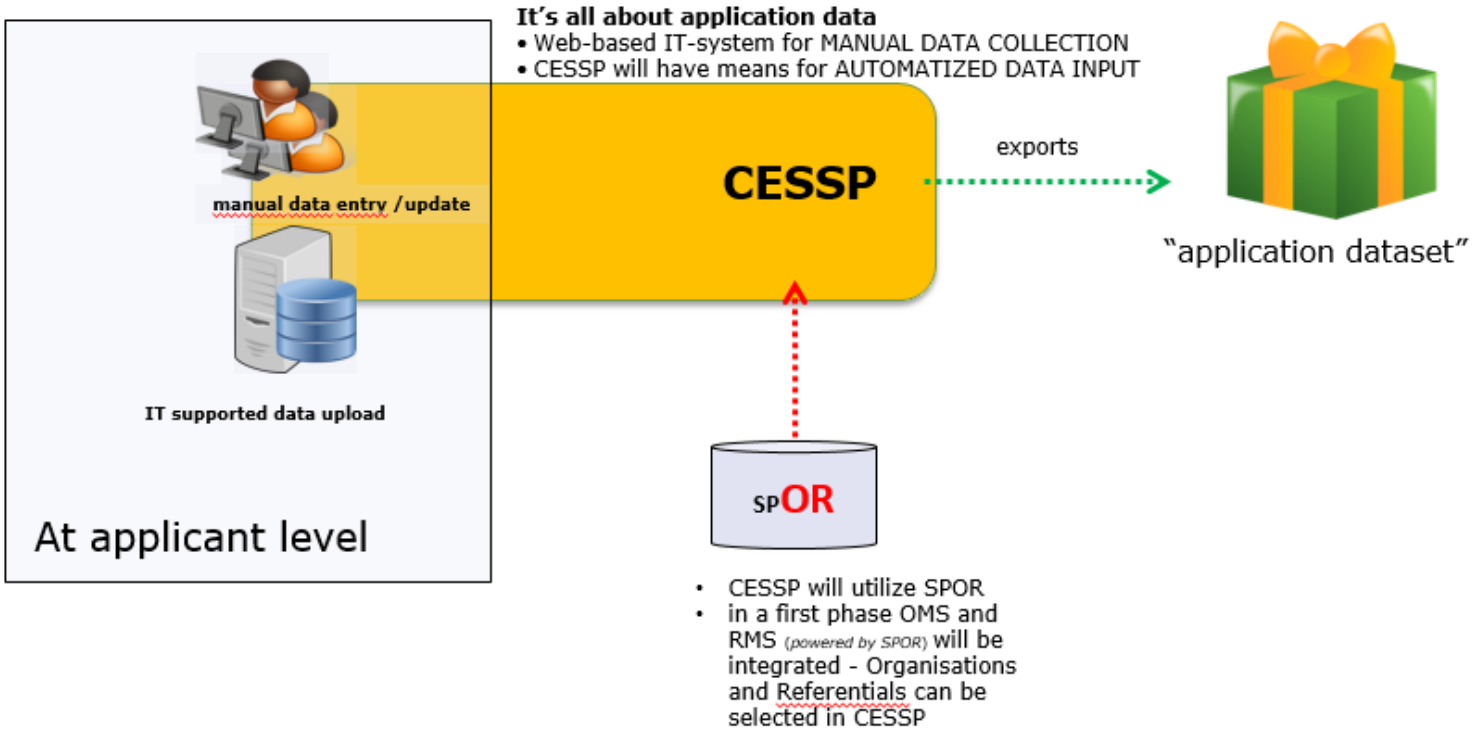
Status


2016
2017
2018
2019
Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4
EMA - SPOR
RMS
EUTCT & xEVMPD
RMS go-live
Maintenance of RMS lists and release of new lists
OMS
xEVMPD
OMS go-live
Expansion of dictionary with additional organisation data
MAHs; MAAs; MRL applicants; MA & MRL contacts
Sponsors
Reg Auth/NCAs
Manuf - CAPs
Manuf - NAPs
TBD: CROs; CT site; Academia; Hospitals; PhVig MF location; Distributors etc
PMS & SMS
PMS & SMS
Kick-off P & S Iteration 1
PMS & SMS
Enforce P & S Iteration 1
EMA - EU Programmes dependent on SPOR
Clinical Trials
New CT Portal
Pharmacovigilance
E2BR3
eSubmissions
SSP MA
SSP var
Veterinary
Vet EU P DB
EVVet3
Other
EU DB Manuf & Wholesale Dist
DB Sale & Dist antimicrobials

Hva vil endres?

- Masterdata skal
  - oppdateres ett sted
  - gjenbrukes i stedet for å vedlikeholde data flere steder

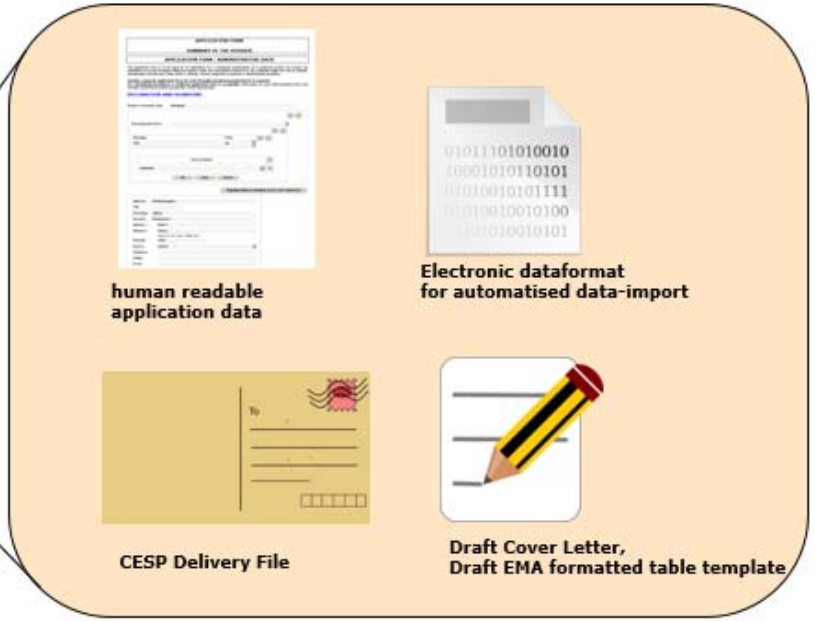
Eksempel: CESSP



CESSP

"application dataset"

contains information used in the application form and can also be reused for other purposes



Hva gjøres ved Legemiddelverket?

- Forprosjekt SPOR
  - Kartlegge muligheter, utfordringer og mulige gevinster med SPOR/IDMP
  - «Mapping» av kodeverk (referentials)

- Etterhvert: Tilpasning av systemer og prosesser

Aktiviteter for industri

- The focus of activity in 2016 relates to preparing for RMS and OMS go-live
- Industry own their plans to design, implement, test and deploy changes in alignment with SPOR delivery timelines
- Industry should undertake the following activities in order to provide a better foundation for PMS and for enforcement of use of RMS and OMS in 2017

1 **Programme participation**	• Engage with programme via Industry Change Liaisons and existing forums eg. SPOR Task Force, Sub Groups • Engage with change management activities e.g. communications and training
2 **Follow through on priorities**	• Undertake the activities below in order to be ready to actively use RMS and OMS post go-live • Follow the agreed RMS and OMS operating models post RMS and OMS go-live, which include pre-registration and ongoing maintenance of SPOR data
3 **Data mapping**	• No OMS mapping is required by Industry prior to OMS go-live • No RMS mapping is required by Industry prior to RMS go-live. • Post go-live, Industry should map against new Referentials lists and new OMS dictionary content as it is published • Post go-live, Industry should synchronise their local Organisation data against the OMS dictionary and their local Referentials data against existing RMS lists
4 **Data pre-registration**	• At OMS go-live, Industry should send requests for new/updated Organisation data relating to MAHs only. As the dictionary is expanded with other types of Organisation data, Industry will be invited to pre-register data relating to these new Organisations. • Post RMS go-live, Industry should send requests for new/updated Referentials prior to submitting an application
5 **Process change**	• Identify all data management processes that will need to be adapted in order to align local data and synchronise it with RMS and OMS on an ongoing basis
6 **Systems change**	• Identify all impacted systems and architecture that will need to be adapted in order to support the process changes identified above

Les mer

- Presentasjon fra EMA rettet mot industri

- Generelt om SPOR og IDMP på EMA sine nettsider

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Statens legemiddelverk