Astellas Preparations Toward IDMP Compliant Substance Management

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IDMP @ Astellas

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- Current progress and next steps

Substance management

- Introduction
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- Processes
- Systems

Closing

INTRODUCTION OF FRITS STULP

M.Sc. In Pharmacochemistry

Worked for Yamanouchi / Astellas (1998 – 2007):

- Responsible for development and maintenance of R&D Quality System
- Manager of European SAP Competence Center / SAP Project Manager

Worked for Accenture (2007 – 2011):

- Project manager for several projects in Healthcare and Life Sciences

Independent project manager / advisor since 2011 as Mesa Arch Consulting:

- Specialized in project management of IT projects for Regulatory Compliance
- Project manager for XEVMPD compliance project for Astellas
- Lead consultant and **Program Manager for IDMP** compliance at Astellas
- **IDMP SME and practical advisor** to MAH's and Regulatory / PV software suppliers

Managing Director of Iperion Life Sciences Consultancy:

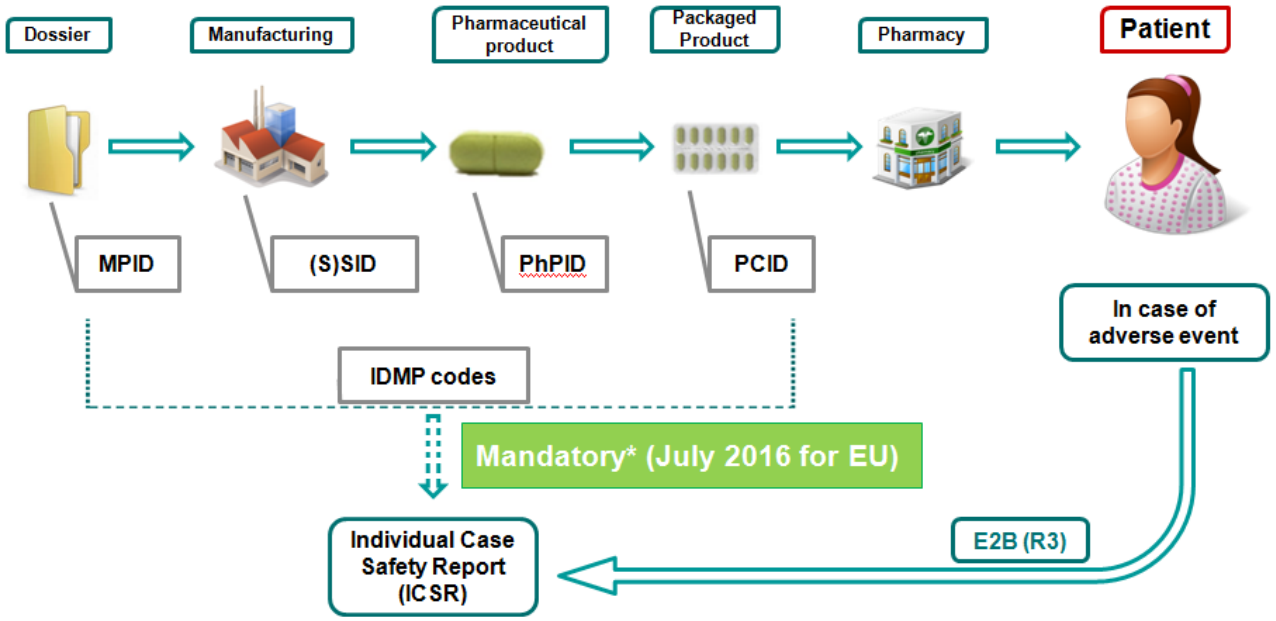
- Specialized consulting in (regulatory) compliance in life sciences (system-agnostic)
- Active speaker on several IDMP conferences

IDMP

General introduction

Identification of Medicinal Products (IDMP) is mandatory

- Regulatory requirement!
- First focus on the EU, but keeping in mind the global perspective



*dependent on E2B(R3) requirements

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IDMP

Current program status and next steps (1/2)

2012: IDMP analysis in EEA region

2013/2014: IDMP analysis extended across US and Japan/Asia

2014: IDMP Program formally initiated

The IDMP program is governed by a global IDMP Steering Committee consisting of:

- Regulatory Affairs (global chair, regional representation)
- Manufacturing & supply chain
- Pharmacovigilance
- Business Relationships & Solutions (IT)

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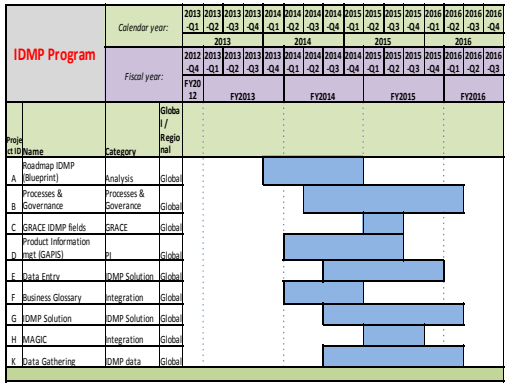
IDMP

Current program status and next steps (2/2)

Astellas is on track to reach IDMP compliance:

- **Global IDMP Blueprint, Business Glossary completed**
- **Overall IT architecture has been designed and approved**
- **New systems being implemented**
- **Adaptations to existing systems**
- **Adaptations to relevant procedures and instructions**
- **Connections of systems to integration layer**
- **User Requirements & functional designs completed, build started**
- **Data projects are being started up (incl. substance information)**



Dependent upon EC decision on timelines and/or EMA readiness!

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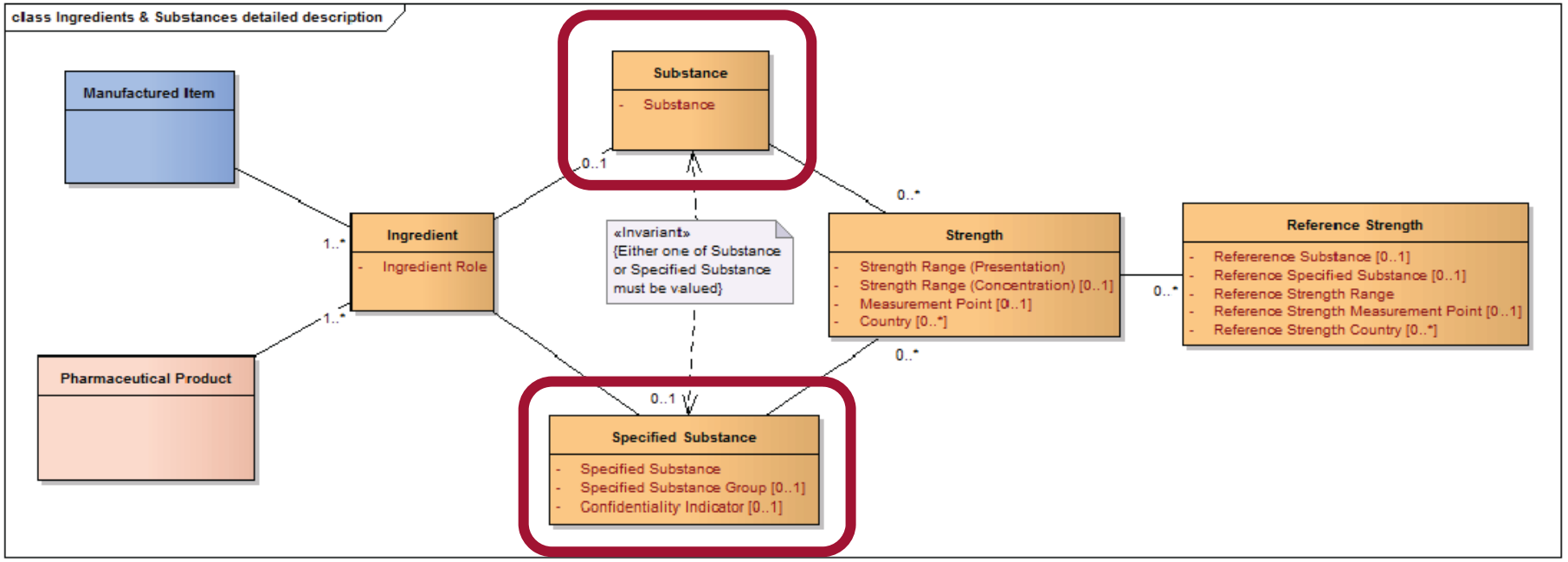
Substance Management

Introduction (1/4)

Where do we interpret that substance management is needed?



The (specified) substance shall be described in accordance with ISO 11238 and its resulting terminology. (source: ISO 11615)

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Substance Management

Introduction (2/4)

What is needed according to XML example in draft impl. gd (nov 2014)?

- Substance:

```
<definingSubstance>
  <code code="Substance Code" codeSystem="Code System (OID)"/>
  <name><!-- Substance Name --></name>
</definingSubstance>
```

[1]

1. Substance Code **2. Code System**

- Specified Substance:

```
<substanceSpecification><!-- Specified Substance -->
  <code code="Substance Specification Code" code="Code System (OID)"
        displayName="Substance Specification Name">
```

[1]

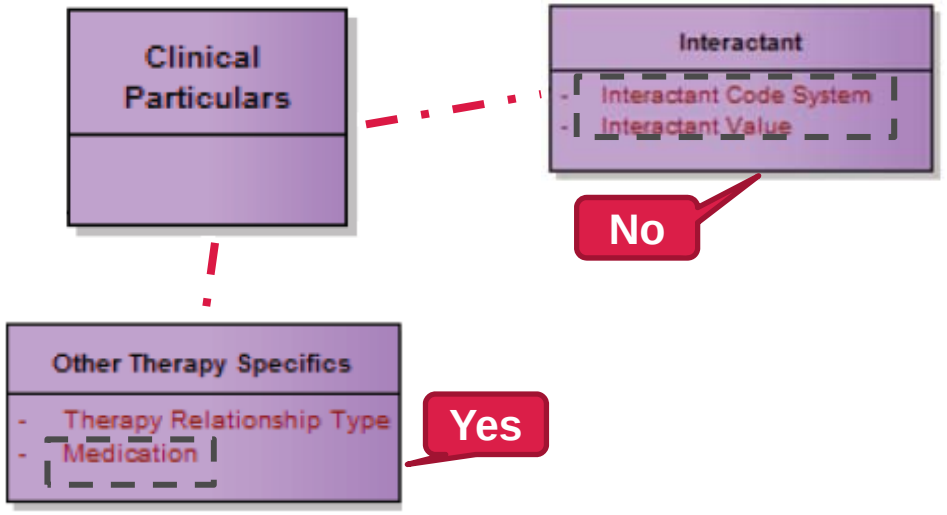
1. Substance Specification Code **2. Code System**

[1] ISO/TC 215 N1603, 2015-01-07

Substance Management

Introduction (3/4)

Do we expect to use EUSRS/GSRS for other IDMP data fields?




```
  <administrableMaterialKind>
    <code code="Interactant Value (Code)"
          codeSystem="Interactant Code System (OID)"
          displayName="Interactant Value Name"
  </administrableMaterialKind>
</administrableMaterial>
```

[1]

The other therapy is usually specified simply by referencing an ingredient.

```
<substanceAdministration><!-- Other Therapy -->
  <ingredient>
    <ingredientSubstance>
      <code code="Substance Code" codeSystem="Substance Code System (OID)"/>
```

[1]

if a specific formulation or particular product is required, use this form:

```
<substanceAdministration><!-- Other Therapy -->
  <administrableProduct>
    <administrableProduct>
      <code code="MPID" codeSystem="MPID Code System (OID)"/>
```

[1] ISO/TC 215 N1603, 2015-01-07

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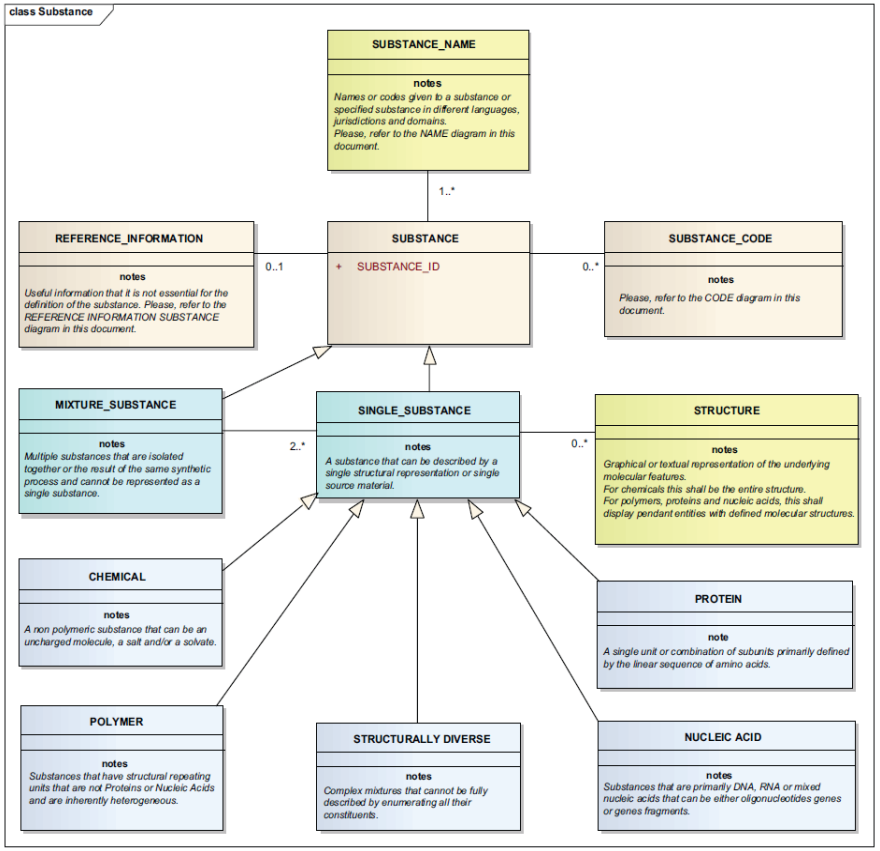
Substance Management

Introduction (4/4)

To generate IDMP compliant Substance IDs, the MAH needs to supply substance information in a manner compliant with ISO 11238.

ISO 11238 requires detailed description of ingredients:

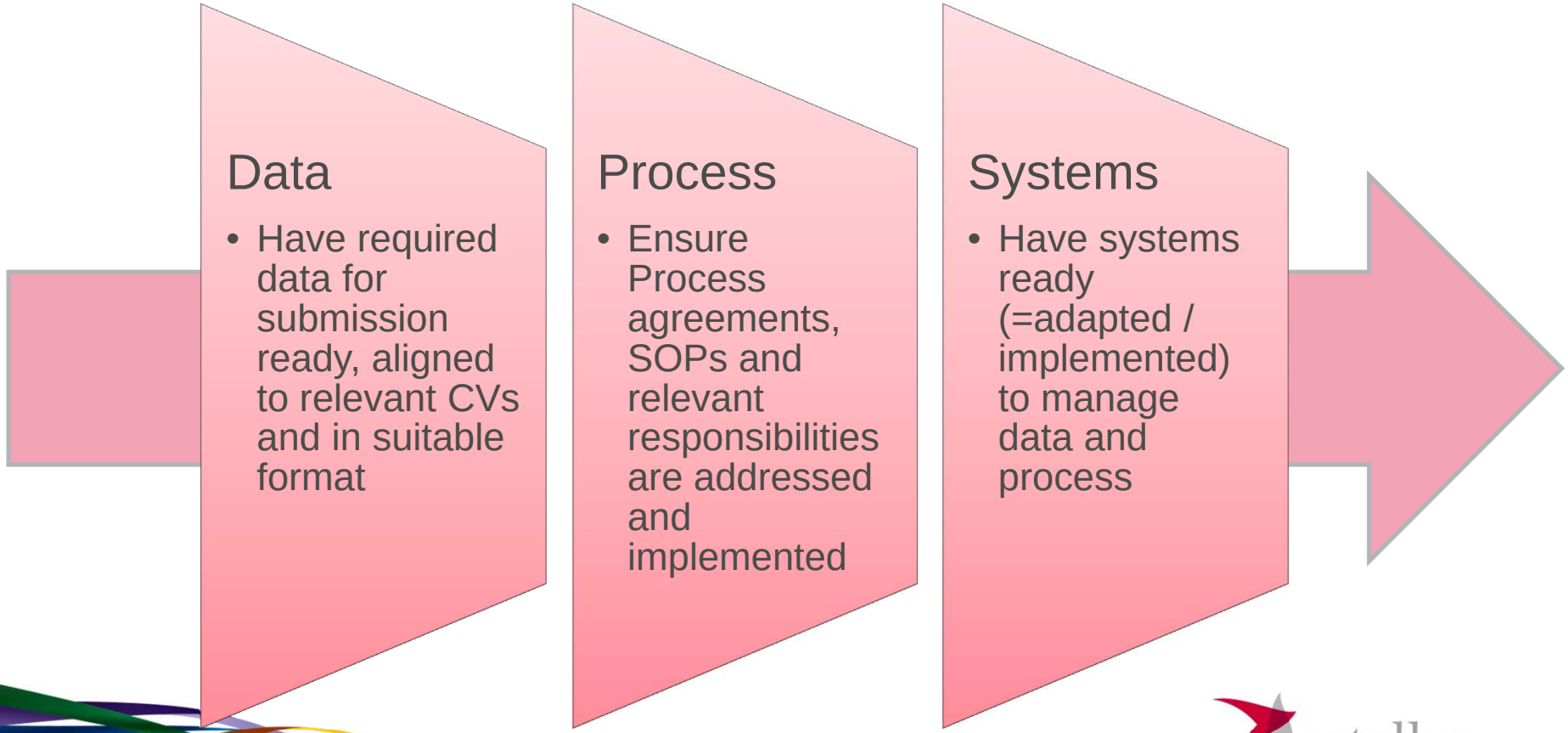
- **Substance (immutable properties):**
  - ❑ **Physico-chemical properties**
- **Specified Substance:**
  - ❑ **Monograph reference**
  - ❑ **Manufacturing information**
  - ❑ **Analytical data**



Approach to substance management

General

For adequate (IDMP) substance management, 3 elements are important:



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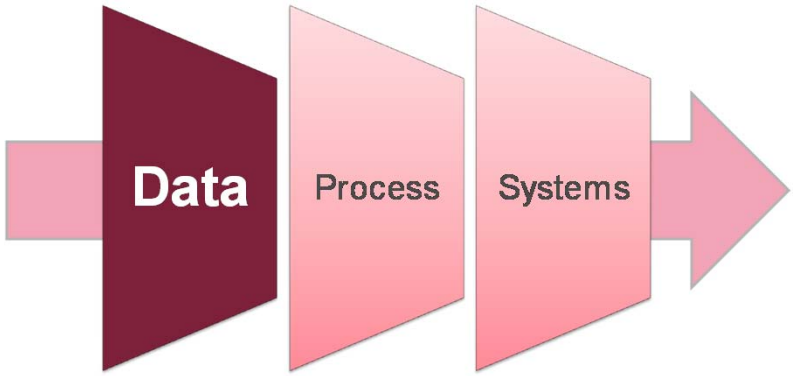

Approach to substance management

DATA

Approach to substance management

Data (1/2)

An assessment was performed:

1. Which data is required for identification, according to ISO 11238?
   - ❑ Mandatory, Optional or Conditional data
2. Where does the information reside within the company?
   - ❑ Which departments have the data?
     - ❑ In which format is the data available, text or data?
     - ➢ Define Golden Source (to-be) for each data element
   - ❖ Point to consider: Who will be the owner of the data?

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Approach to substance management

Data (2/2)

3. **Which information resides outside the company (e.g. CMO, CRO)**
   - ❑ **Are these organizations aware of IDMP requirements?**
   - ❑ **Are agreements in place to ensure timely availability, quality and maintenance of necessary data for your company?**
   - ❑ **Any industry-wide initiatives for CMO / excipient companies to address substance management in accordance with ISO 11238?**

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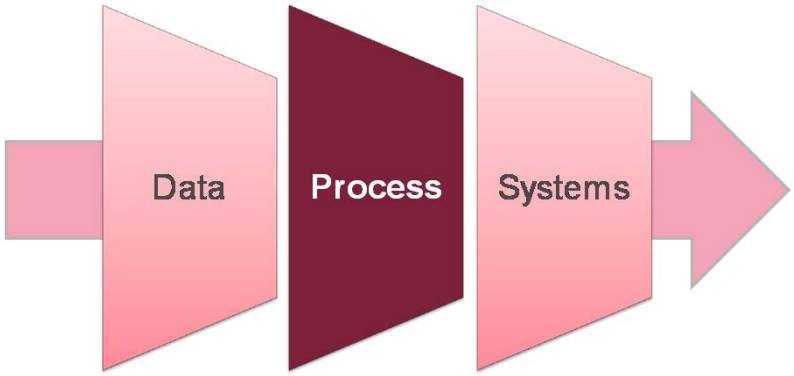


Approach to substance management

PROCESS

Approach to substance management

Process (1/4)

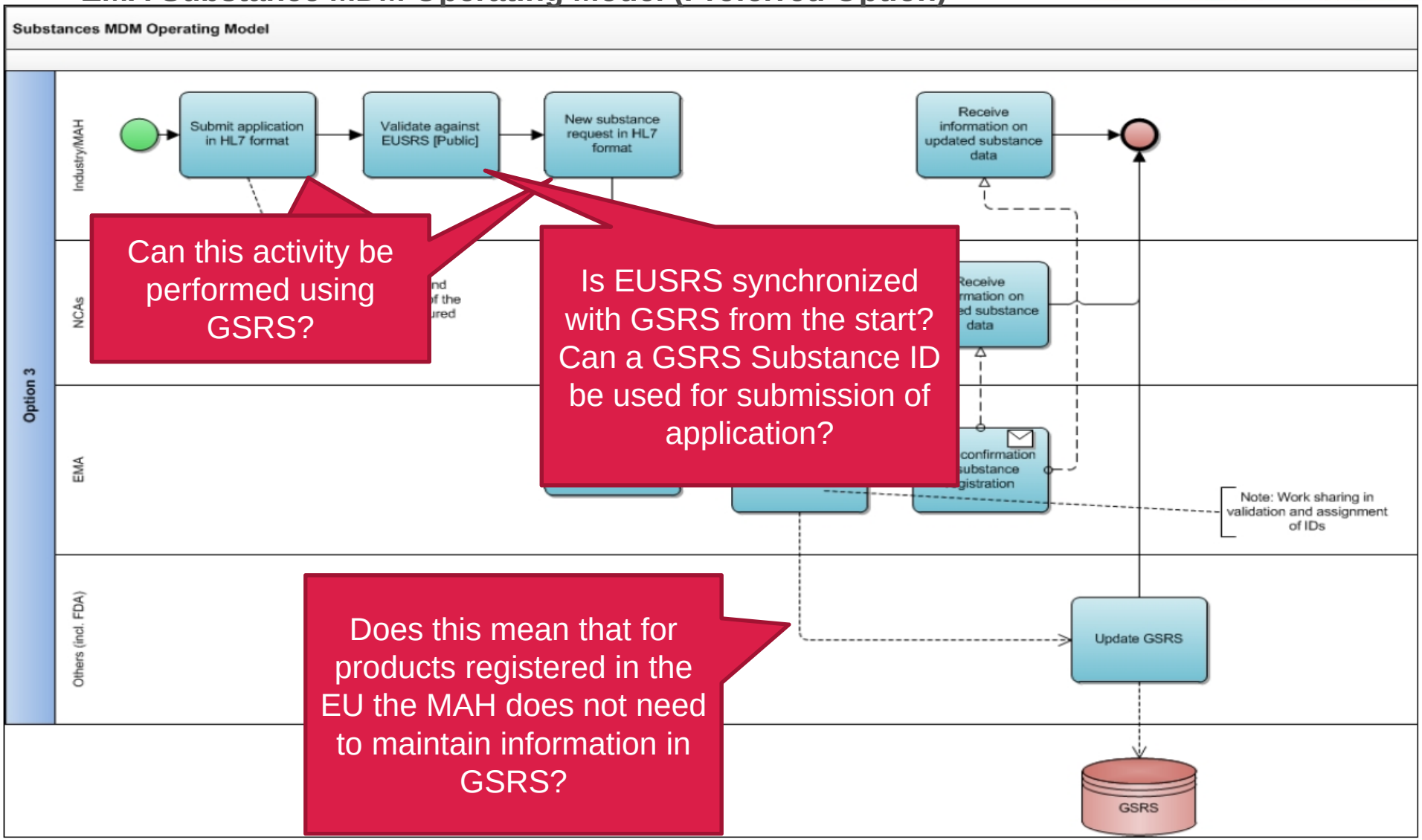
1. **Assess:**
    1. What are the current processes regarding (approved/investigational) substance data management?
    2. Analyze availability of information regarding actual data fields in the processes
2. **Define:**
    1. Define processes for (specified) substance registration
    2. Define processes for (specified) substance data maintenance
    3. Define how these processes fit into the overall IDMP process
3. **Implement:**
    1. Implement changes to current processes to ensure future compliance with IDMP regulation

Ensure alignment with maintenance process of authorities, cf. published materials of taskforce

Approach to substance management

Process (2/4)

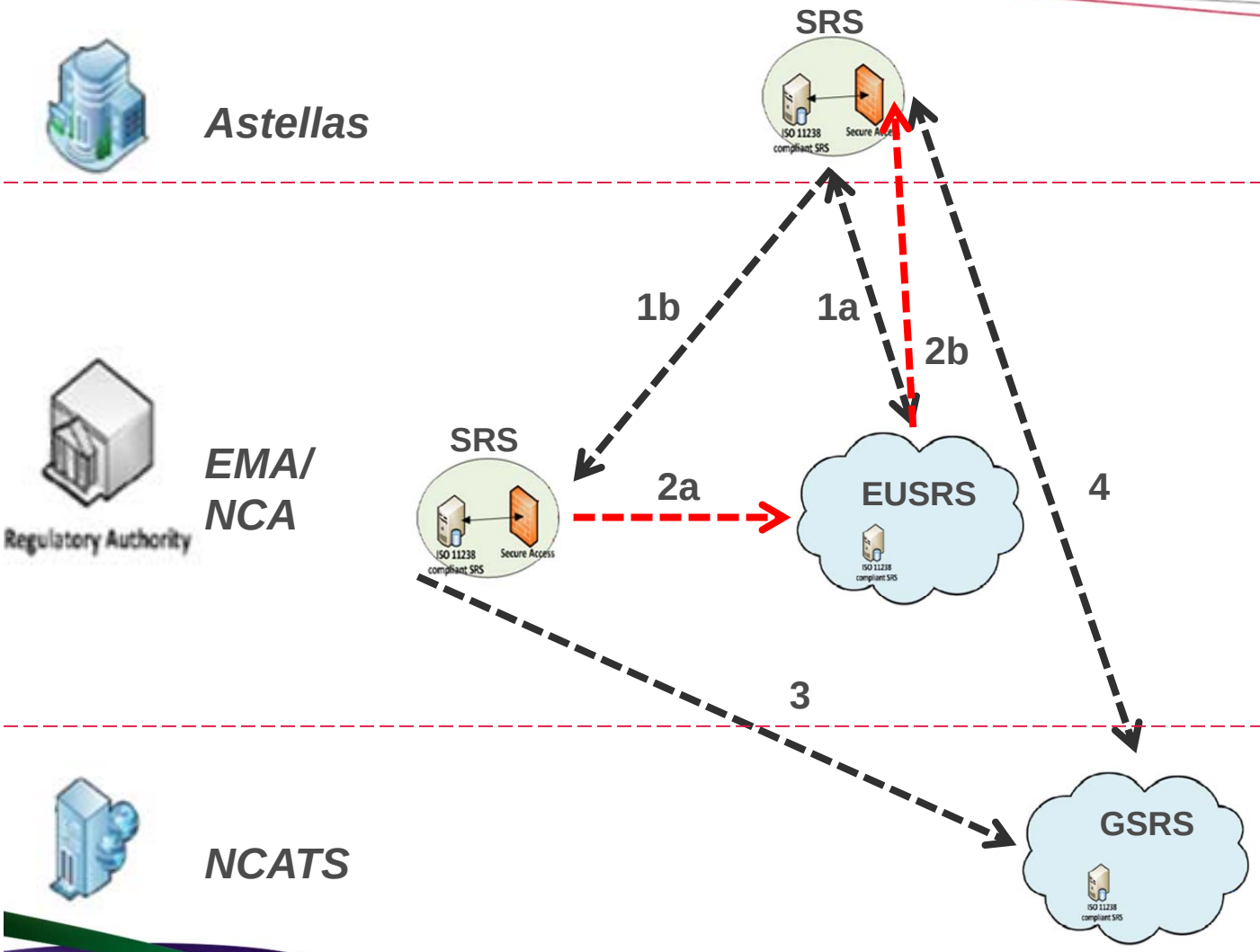
EMA Substance MDM Operating Model (Preferred Option)



Approach to substance management

Process (3/4)

Astellas view on possible interaction between MAH, EMA/NCA and NCATS



1a. Check availability data in public EUSRS

1b. Submit data to regulatory environment EUSRS

2a. (S)SIDs are generated and public EUSRS is updated (?)

2b. Astellas' local SRS is synchronized with public EUSRS (?)

3. (S)SIDs are uploaded to GSRS

4. Astellas' local SRS is synchronized with GSRS

Proposed by EMA

To be clarified by EMA

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Approach to substance management

Process (4/4)

How will Astellas ensure the data can be submitted, in the appropriate format, to the EMA/NCA?

Data is present in EUSRS/GSRS	Data is not present in EUSRS/GSRS
▪ QC and amend (if needed) data available in EUSRS/GSRS ▪ Use Substance ID provided by EUSRS/GSRS in IDMP submissions ▪ Maintain data in EUSRS/GSRS	▪ Register (specified) substance in EUSRS/GSRS ▪ Use Substance ID provided by EUSRS/GSRS in IDMP submissions ▪ Maintain data in EUSRS/GSRS

- ❖ External: How to ensure ownership of the data as one of the users of that substance information?
- ❖ Internal: Which department in the organization maintains the data?

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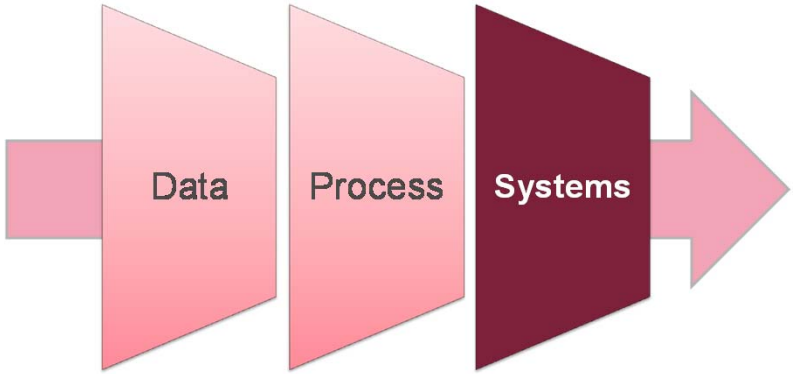
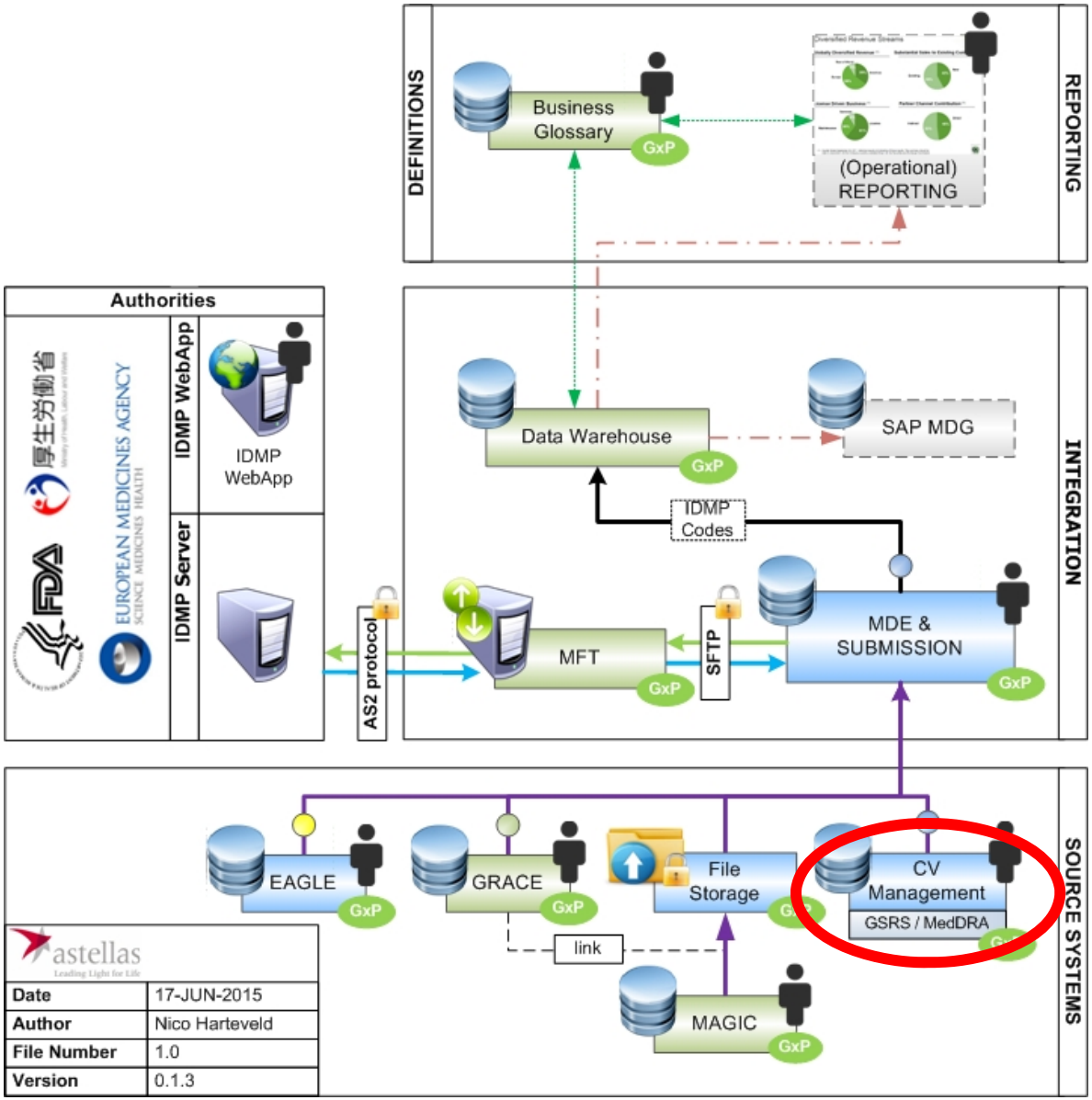


Approach to substance management

SYSTEMS

Approach to substance management

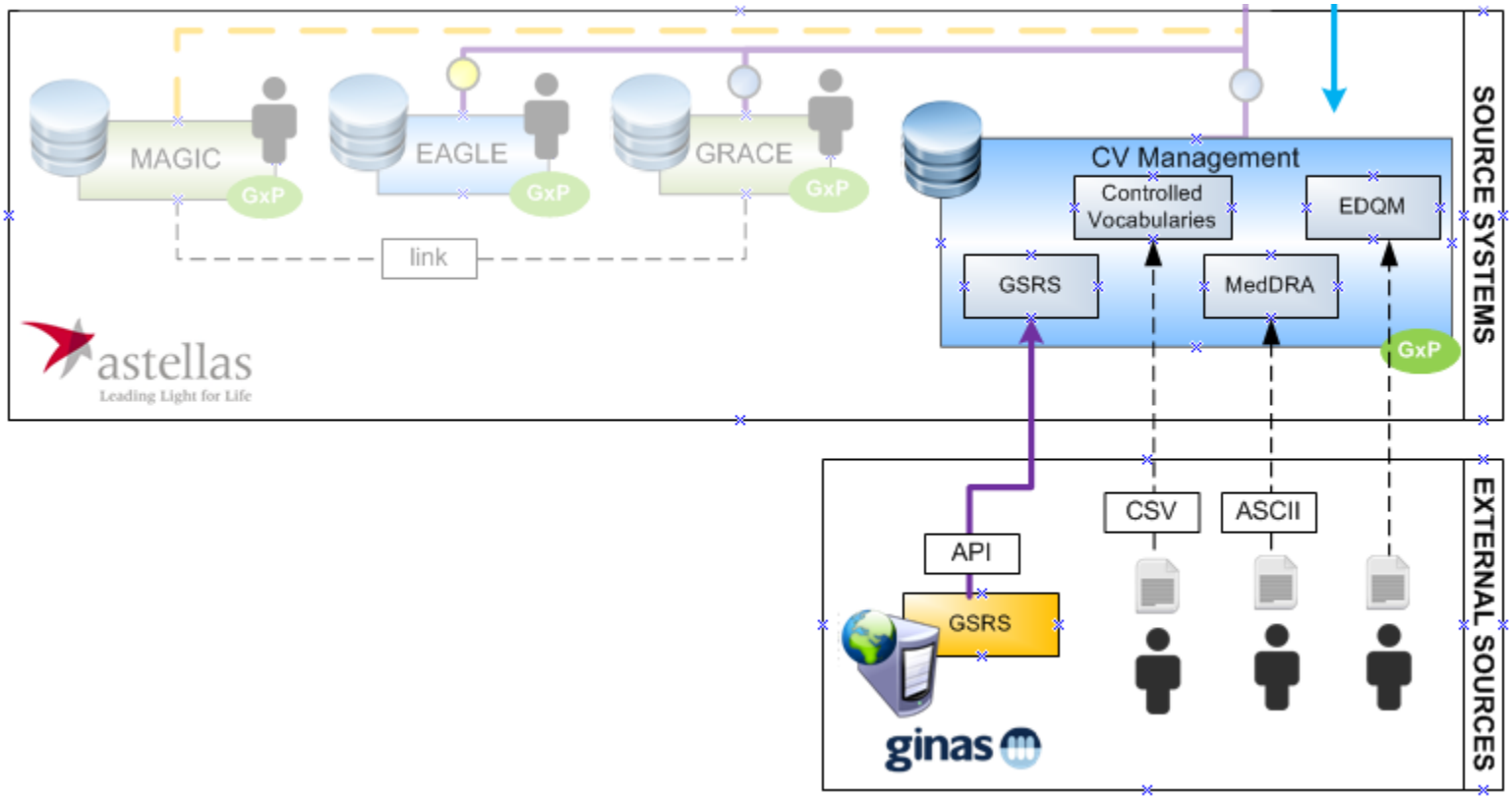
Systems (1/4)



Approach to substance management

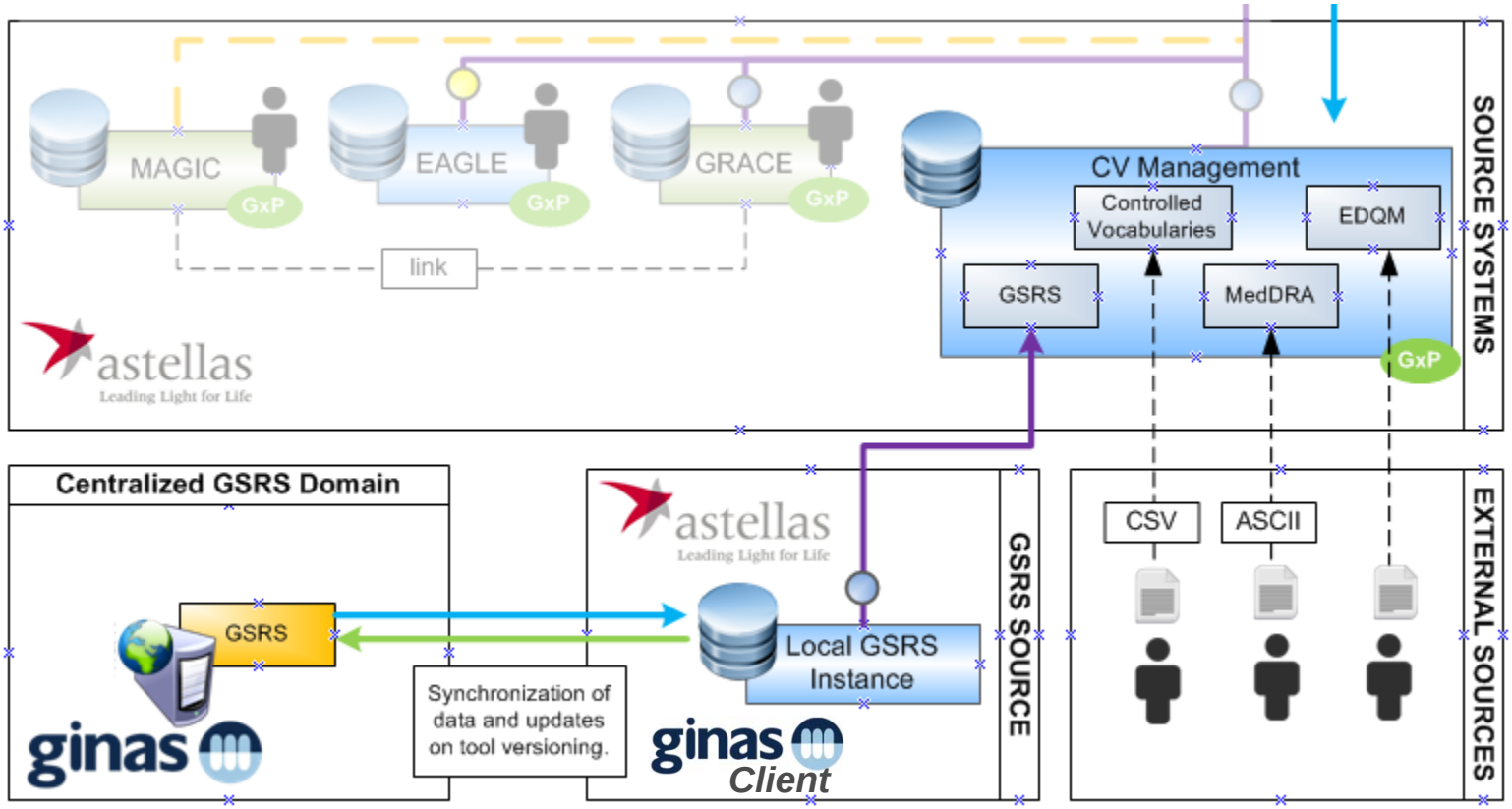
Systems (2/4)

Closer look at CV Management including current POC (API)



Approach to substance management

Systems (3/4)



1. What are the expectations around the future roadmap concerning GSRS?
   - Will data be sent or synchronized if a centralized approach is taken?
   - Will client versions be updated automatically?
2. Will history of data be kept within the local or centralized solution? (e.g. different versions of code sets?)
3. Which technology will be used for the local as well as the centralized instances?

Approach to substance management

Systems (4/4)

- **Points to consider:**
  - **Employ a local instance of GSRS?**
    - **How does this fit in your IT landscape?**
    - **Are there additional benefits for your company (e.g. centralized substance information management)?**
  - **Employ the central GSRS instance?**
    - **How does this fit in your IT landscape (e.g. inter-communication with your applications)**
  - **How to ensure safety of sensitive information (e.g. INDs, manufacturing processes)**
  - **How to ensure release management of your GSRS?**
  - **And upon go-live of IDMP in EEA, US and JP:**
    - **Will there be three regional SRS systems and one global? And how to ensure consistency of your data as MAH/substance owner?**

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Conclusion/Summary

- **We wanted to share this as examples of discussions and challenges a MAH goes into upon implementing IDMP substance management..**
- **Please keep in mind that for a “smooth” implementation and maintenance, it would be good to:**
  - Avoid double/triple maintenance
  - Give as much clarity as possible, as early and practical as possible
  - Keep consistency in substance management requirements from all agencies
  - Stimulate / support CMOs/excipient producers to tackle these challenges as well
  - Realize that concerns will remain on confidentiality, especially IMP related
  - …..

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Thank you for your attention!
And please contact me for any feedback.

Frits Stulp

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