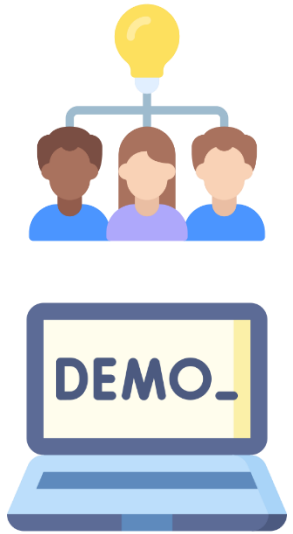
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# System Demo

**28/06/2022**

**Public System Demo**



# Welcome/Introduction

***Jean-Michel Becar**, Head of Portfolio Office, EMA*

*Please note that **this session is being live streamed.***
***It is being recorded** and **will be made available** through the **EMA Corporate Website***


*At certain points throughout the meeting, participants will be able to ask questions or give their input via the audience interaction tool **Slido**.*

*Interaction via Slido is voluntary, and you may opt to remain anonymous. If you chose to use Slido, **you consent to the processing of your personal data** as explained in the EMA Data Privacy Statement for Slido.*

# System Demo



System Demo is a major part of the **transparency goal** of the Agency's new governance: lean and agile.

It shows an integrated view on what has been built in the last 3 months (Program Increment).


It is optional. Moreover, it is recorded and published on the **Corporate website**.

It is a **Value Stream level** ceremony. Today's System Demo is a pilot, so its scope is smaller than the usual System Demos.

# Agenda

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## Product Lifecycle Management Value Stream

**1 Welcome/Introduction**
09:00 – 09:05
- ***Jean-Michel Becar***
  *Head of Portfolio Office, EMA*

**2 eAF/DADI Human Variation form**
09:05 – 09:35
- ***Kristiina Puusaari***
  *Product Co-Owner for DADI, EMA*
- ***Noel Diamant***
  *Product Co-Owner for DADI, UNICOM*

**3 Product Management Service (PMS)**
09:35 – 10:05
- ***Andrei Idu***
  *SPOR Platform Architect, EMA*
- ***Marcos Fernandez Gomez***
  *Product Co-Owner for PMS, EMA*

## Research & Development Value Stream

**4 Emergency Task Force support**
10:05 – 10:15
- ***Ecaterina Golea***
  *Product Owner for ETF, EMA*

## Monitoring Value Stream

**5 Medicines Shortages**
10:15 – 10:30
- ***Joao Ferreira***
  *Product Owner for Medicines Shortages, EMA*

**6 Q&A Session**
10:30 – 10:45
***Moderator:***
- ***Joris Wiemer***
  *Change Management Lead, EMA*

**7 Closing**
10:45 – 11:00
- ***Joris Wiemer***
  *Change Management Lead, EMA*

*The UNICOM Innovation Action has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 875299.

# The EMA Value Streams

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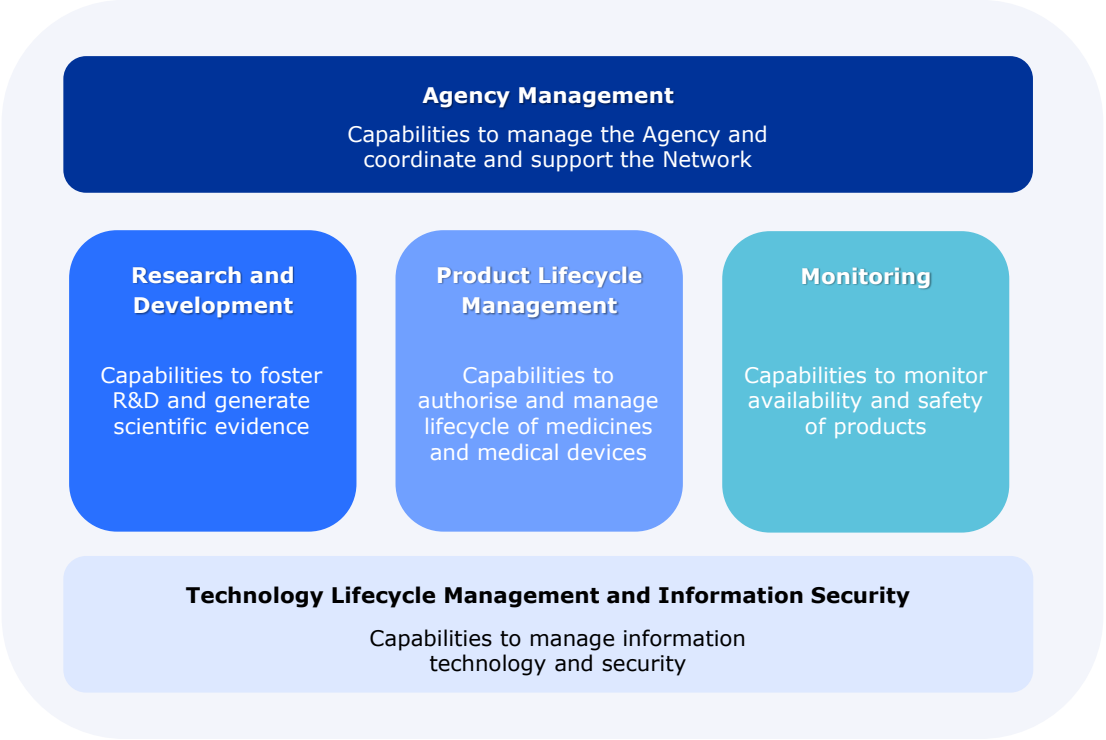

# NEXT SYSTEM DEMO: **28 September 2022**

# How to give feedback

***Joris Wiemer**, Change Management Lead, EMA*

# Send your questions via Slido

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**VS Product Life Cycle management**


**VS R&D**


**VS Monitoring**

**1. Join via the QR code or link**


**2. Send or upvote the questions you want to hear answered**


**3. Questions will be shown on the screen and managed live in the Q&A session**

# PLM VS| eAF/DADI Human Variation form

***Kristiina Puusaari**, Product Co-Owner for DADI, EMA*

***Noel Diamant**, Product Co-Owner for DADI, UNICOM**



*The UNICOM Innovation Action has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 875299.

# DADI – Q2 2022 PI objective roadmap

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**PI ACHIEVEMENTS(Q2 2022):**

- ✓ Access Management Improvement (F11140) **(DEMO)**
- ✓ Finalisation Improvements (F11531) **(DEMO)**
- ✓ Improvement of 'type(s) of change(s)' (F9932) **(DEMO)**
- ✓ FHIR *export* – Manufactured item, pharmaceutical product, ingredient, ingredient doc (252)
- ✓ PDF export – paediatric, orphan, MAH, signatories, proof of payment (250)

**DEMO**

## Access Management Improvement

- Add user's affiliation to multiple organisations, Roles and Permissions for eAF Portal, Add Co-author from same/different organization, Remove user from Organisation (and applications)

## Finalisation Improvements

- Add additional Annex checks, Update Declaration section, Update proof of payment details, Removal of filter in parallel variations

## Improvement of 'Type(s) of change('s)

- Remove duplicate scopes added in Types of changes, Art. 29 and IB unforeseen to be added



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# Principles

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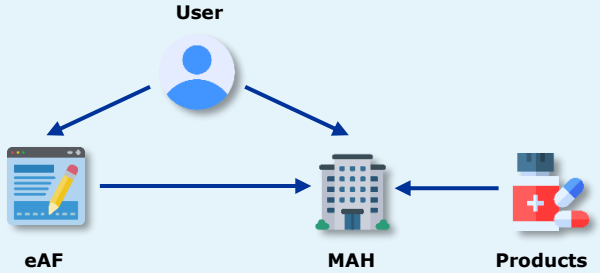
**1**

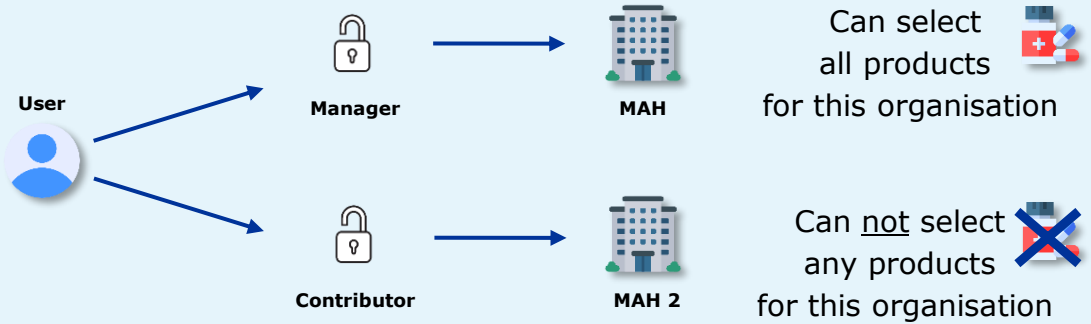
A Dataset belongs to 1 MAH and is created by a user.




Medicinal Products belong to an MAH (Location)

**2**

A user is either an applicant or part of an NCA/EMA.
A user has a role for <u>each</u> of his organisations.



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# DADI eAF user roles and grants

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| | Applicants | | | | | Regulators | | | |
|---|---|---|---|---|---|---|---|---|---|
| | From the industry | | | | | From a NCA | | From the EMA | |
| **Role name:** / **Grant:** | ***eAF Applicant Contributor*** | ***eAF Applicant Manager*** | ***eAF Applicant Coordinator*** | ****IRIS / eAF Industry Admin*** | ****External Organisation Administrator** *(optional)* | ***eAF Competent Authority User*** | ****IRIS / eAF Competent Authority Admin*** | ***eAF EMA Industry Assistant*** | ****IRIS / eAF EMA Admin*** |
| Create application | ✗ | ✓ | ✓ | ✗ | ✗ | ✓ | ✗ | ✓ | ✗ |
| Edit application | ✓ | ✓ | ✓ | ✗ | ✗ | ✓ | ✗ | ✓ | ✗ |
| Add co-author/s | ✗ | ✓ | ✓ | ✗ | ✗ | ✓ | ✗ | ✓ | ✗ |
| Be added as co-author | ✓ | ✓ | ✓ | ✗ | ✗ | ✗ | ✗ | ✗ | ✗ |
| Select products | ✗ | ✓ of that organisation | ✓ of that organisation | ✗ | ✗ | ✓ of that country | ✗ | ✓ All | ✗ |
| Select classification | ✓ | ✓ | ✓ | ✗ | ✗ | ✓ | ✗ | ✓ | ✗ |
| Finalise application | ✗ | ✓ | ✓ | ✗ | ✗ | ✓ | ✗ | ✓ | ✗ |
| Delete application | ✗ | ✓ | ✓ | ✗ | ✗ | ✓ | ✗ | ✓ | ✗ |
| Manage all applications | ✗ | ✗ | ✓ of that organisation | ✗ | ✗ | ✓ of that country | ✗ | ✓ All | ✗ |
| Approve / remove roles | ✗ | ✗ | ✗ | ✓ The following role/s:<br>• eAF Applicant Contributor,<br>• eAF Applicant Manager, or<br>• eAF Applicant Coordinator | ✓ The following role/s:<br>• IRIS / eAF Industry Admin | ✓ The following role/s:<br>• IRIS / eAF Competent Authority Admin | ✓ The following role/s:<br>• eAF Competent Authority User | ✗ | ✓ The following role/s:<br>• eAF EMA Industry Assistant,<br>• External Organisation Administrator (optional)<br>• IRIS / eAF Competent Authority Admin, or<br>• IRIS / eAF Industry Admin |



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* Admin role

# Granting access

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## Scenario 1

1. **Selecting** the user via **„Add Co-author"** from your organization
2. **Choose** the user from a list of users you have been working with

## Scenario 2

1. **Selecting** the user via **"Add Co-author"** from a different organisation (if the user is not already coordinator)
2. **Notify the User** via the portal to request a role with your MAH
3. **Associate** the user to your MAH with 1 of 3 roles

- **Contributor** - Only allow to edit explicitly shared applications
- **Manager** - Select products of this organisation (and all locations)
- **Coordinator** - Select products and see all applications



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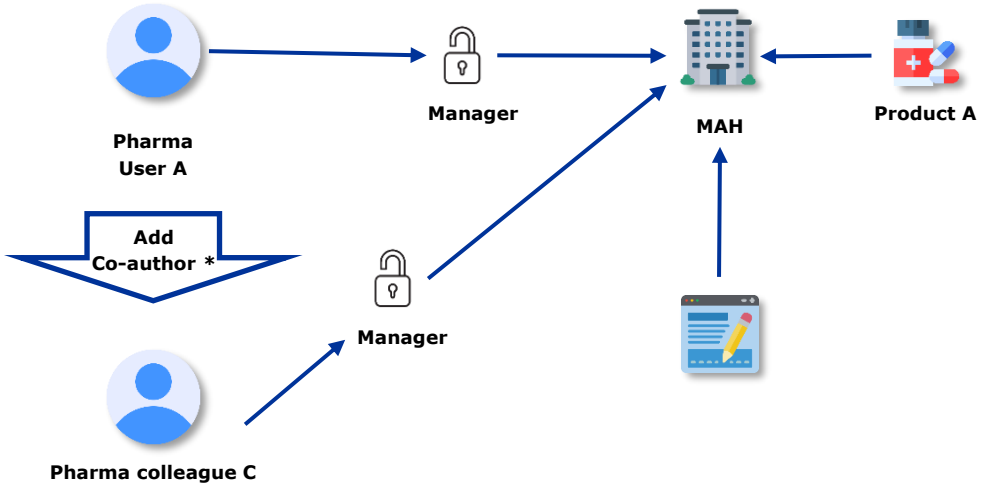
# Coauthoring with associated users

## Examples

- Colleagues within my company
- Consultancy who is allowed to see my products




- Both A and C are associated to the same organisation
- A shares with C
- C now has the same rights as A

* Add Co-author is only needed if the other participant does not already have a coordinator role



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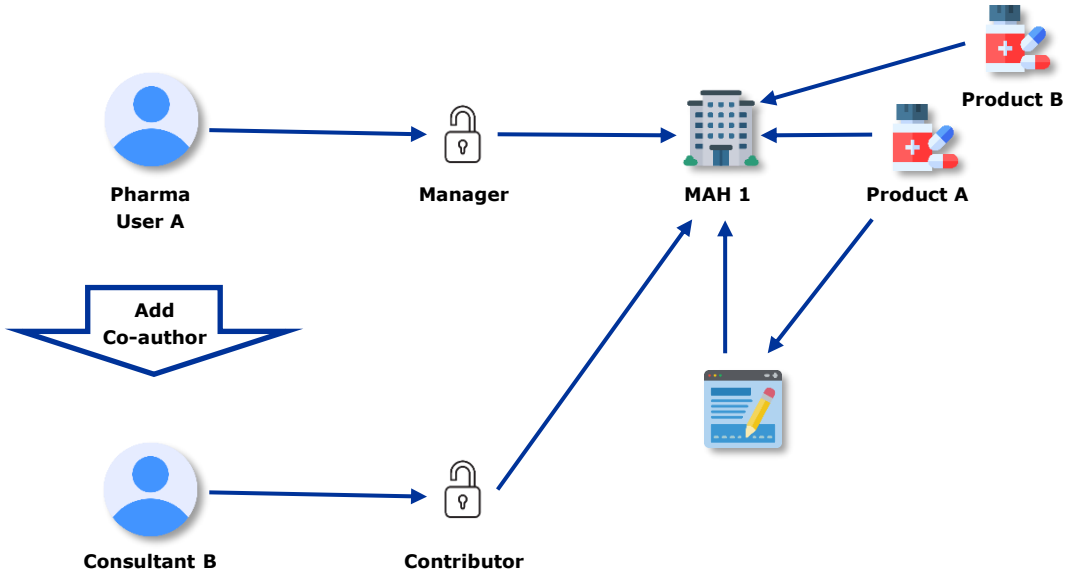
# Coauthoring on an ad-hoc basis

## Example

- Consultancy without access to products




- A works for an MAH
- B works for a consultancy who should not see all MAH 1 products

1. A shares with B
2. B gets access to the application and to product A once he has the contributor role authorised with MAH 1



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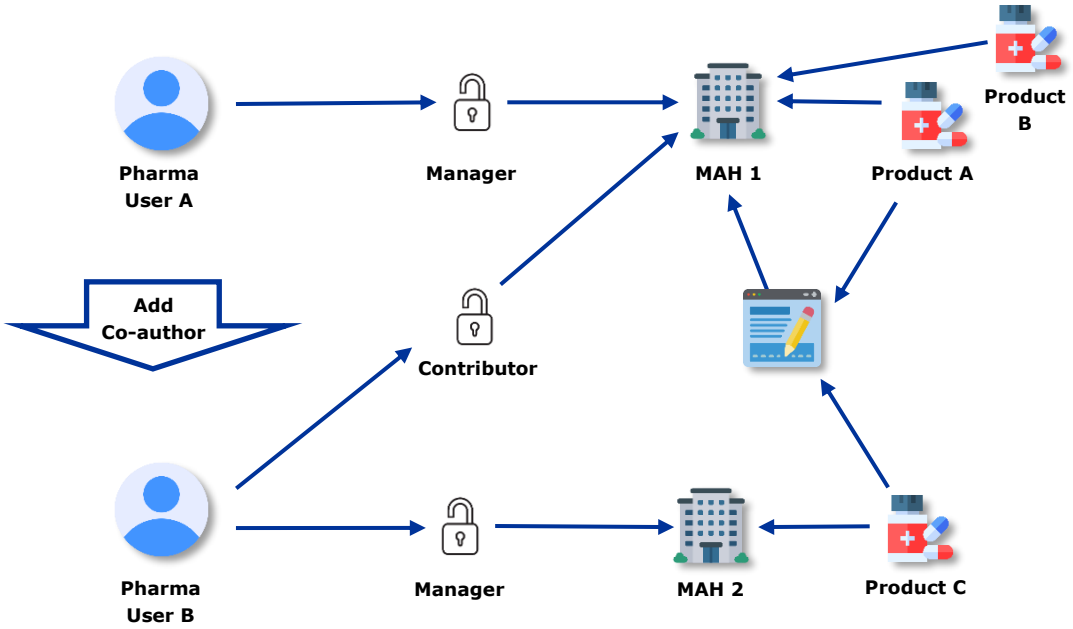
## Example

- Worksharing with other companies




- A shares with B
- B gets access to product A
- B adds product C (because manager of MAH 2)
- B cannot finalise, because contributor in MAH 1 (where the application sits)
- B cannot see product B because he is only a contributor to MAH 1



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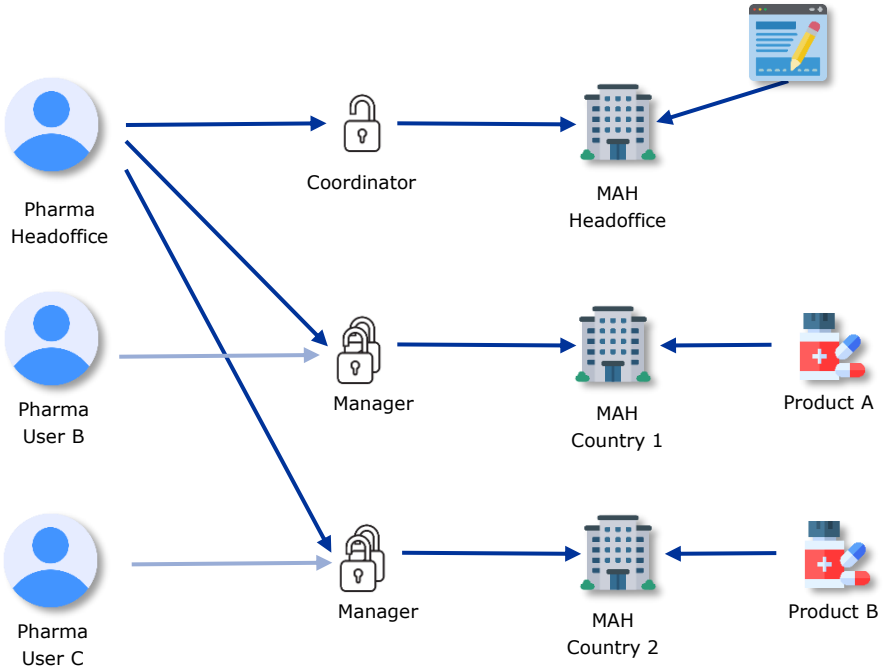
# Headoffice does distributed applications

## Example

- Headoffice setting up applications and adds details of members



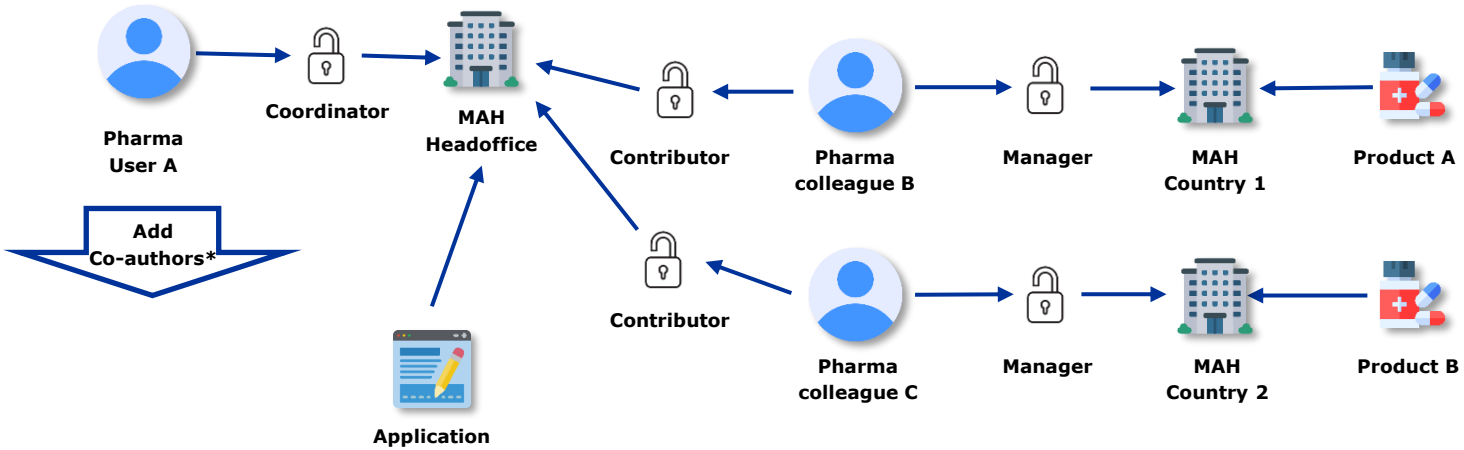

- Headoffice creates the application and adds all necessary products and data
- They do not see applications from other Countries

# Headoffice of a multinational company submits

## Examples

- Headoffice setting up applications
- Each member adds their details

- A creates the application and invites B and C to contribute
- B and C add their products
- A finalises and adds the application to the dossier




* Add Co-author is only needed if the other participant does not already have a coordinator role



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# PLM VS |Product Management Service (PMS)

***Andrei Idu**, SPOR Platform Architect, EMA*

***Marcos Fernandez Gomez**, Product Co-Owner for PMS, EMA*

# Epics & Features in 2022

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Legend:
- **Blue:** PMS Epics & features
- **Green:** DADI Epics & features
- **Red**: prioritized & ongoing features

## SIAMED Integration

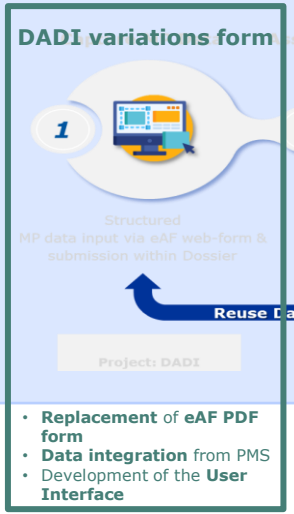
- **Migrating** H&V CAP data from EMA database to PMS and keeping it **continuously updated**
- **Pushing data** that may have been updated in PMS (e.g. corrections, consolidation with Art 57 data ) back **into EMA DB** so it can be **re-used** in Regulatory procedures

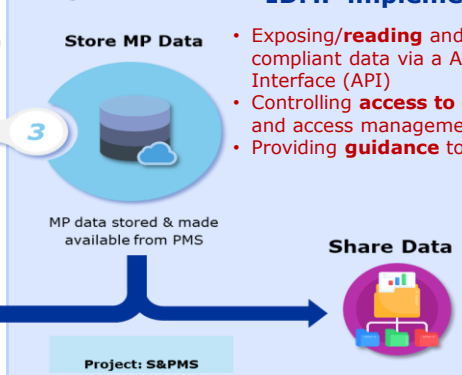
## Art 57 Integration

- **Migrating** H CAP & NAP data from XEVMPD database to PMS and keeping it **continuously updated**
- **For each CAP product consolidation data coming from both EMA DB and XEVMPD/Industry**
- **Pushing data** that may have been updated in PMS (e.g. new approved CAP data, corrections) back **into XEVMPD** so it can be **re-used** in PharmacoVigilance procedures

## Support end-to-end Regulatory process

- Allowing to **correct/complete Product data** – separate from regulatory procedures
- **Importing product data from DADI** message to update PMS with approved data




## IDMP implementation

- Exposing/**reading** and **creating/updating** IDMP compliant data via a Application Programming Interface (API)
- Controlling **access to data** via user permissions and access management
- Providing **guidance** to users - EU IG



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# PMS Product Vision– Q3 2022 PI objective roadmap

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**PI ACHIEVEMENTS(Q2 2022):**

- First round External UAT
- Resolution of bug fixes from Initial Load to PMS
- Initial work on Art. 57 to PMS Deltas **(DEMO)**
- Initial work on IDs lifecycle
- Security Access and Management implemented in SIT **(DEMO)**
- Start discussion of two possible new EPICS

**DEMO**

## Security and Access Management to PMS API

- Demo on how the access to the API will be granted and what information can be shown in the API

## xEVMPD to PMS deltas

- Update of a record in xEVMPD and check that the change is propagated to PMS



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# System Demo: let’s see it working!




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# R&D VS |The Emergency Task Force

Scientific advice procedure during emergencies

***Ecaterina Golea**, Project Management Coordinator, Health Threats and Vaccines Strategy, EMA*

***Ahmet Deveci,** Dynamics Specialist Consultant, CapGemini*

# The new regulation - Emergency Task Force (ETF)

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## Regulation (EU) 2022/123 (1st March)

- The ETF is now legally established within the Agency as an advisory expert group
- ETF objectives during a public health emergency (PHE) and for preparedness
- New procedures established  for medicines related to a declared PHE or emerging pathogens
- Today focus on scientific advice procedure

**Scientific Advice**

- Assessed by ETF directly
- Includes Quality, Non-clinical, Clinical, CT protocols
- Free of charge; 20 dd timetable if accelerated



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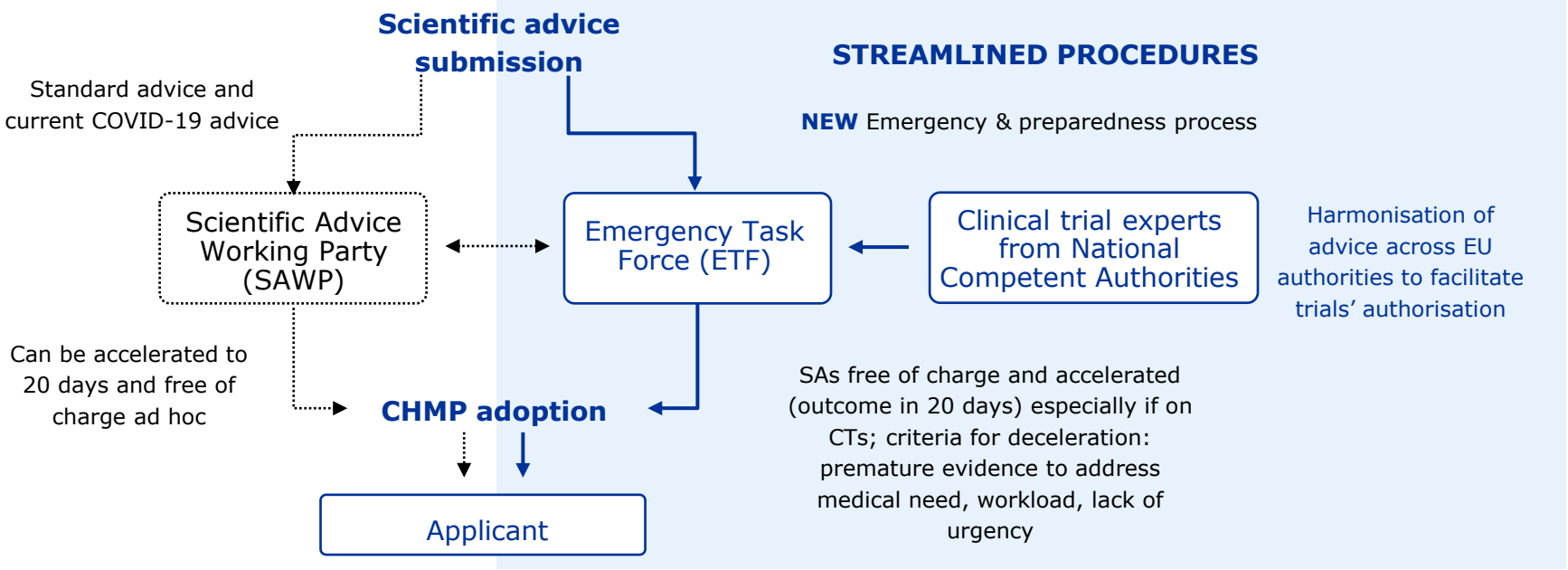
# ETF - Scientific advice and support to clinical trials



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# Applicant portal – Administrative information tab

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***Process types: Initial and FU Scientific Advice - Human***

**1. Is this a request for standard Scientific Advice?*** ○ Yes ○ No

**2. Is this a request for a declared Public Health Emergency? (art. 15 and 16 of Regulation (EU) 2022/123 )*** ○ Yes ○ No

**Please specify the public health emergency**

**Appears when the answer is Yes**

**3. Is this a request for a potential Public Health Emergency?*** ○ Yes ○ No

**Please specify the pathogen**

(drop down list)

**Appears when the answer is Yes**

**Please indicate in which country a CTA is submitted or intended to be submitted**

(drop down list)

**Fee reduction**

* Mandatory information – only one can be yes



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# Monitoring VS |Medicines Shortages

***Joao Ferreira,*** *Medicines Shortages Product Owner, EMA*

# Feature

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- ✓ Registration of an Industry – Single Point of Contact (i-SPOC) according to Regulation (EU) 2022/ 123) in the IRIS portal



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# i-SPOC for MAHs: overview

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- Establishment of a list of **single points of contact for MAHs** for all medicinal products authorized in the Union and the deadline to do so is specified in Regulation EU 2022/123:
  - Article 9: *"the agency shall establish and maintain a list of single points of contact for marketing authorisation holders for all medicinal products authorised in the Union"*
  - Article 10: *"Marketing authorisation holders for medicinal products authorised in the Union shall provide the information for the purposes of Article 9(1), point (e), of this Regulation* ***by 2 September 2022****"*
- Primary objective: MAHs to have an identified i-SPOC so that EMA can engage with such contact should the MAH have medicinal products be included in the lists of critical medicines according Regulation (EU) 2022/123.
- To fulfill these requirements, MAHs will be requested to enter the required information into the **IRIS online platform.**
- Registration start **date: 28th June 2022**



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# i-SPOC for MAHs: IRIS system registration process

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## 2 step registration process

- **STEP 1 (IAM, preliminary requirement):** to create an EMA Account and appropriate role in IAM
  - for any type of submission in IRIS, MAH users need an EMA account and an appropriate role in IRIS, to login into IRIS.
  - *Note: Only users with manager role in IAM/IRIS can register an i-SPOC. Incoming rollout: IAM registration to be further improved in Q3 2022*
- **STEP 2 (IRIS, submission):** Login into the IRIS Portal with EMA account credentials and create a new submission for the registration of an i-SPOC.

## User guide and video DEMO will be available on IRIS platform

- Technical support is available through EMA's service desk
- Publication of news item is planned for w/c 27 June 2022
- Individual communication to all MAHs in the Union (through ServiceDesk)



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# Q&A Session

***Joris Wiemer**, Change Management Lead, EMA*

# Closing

***Joris Wiemer**, Change Management Lead, EMA*

# Further information

http://esubmission.ema.europa.eu/cessp/cessp.htm

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