
Co-funded by
the Health Programme
of the European Union

CAMD
Competent Authorities for Medical Devices

ansm
Agence nationale de sécurité du médicament
et des produits de santé

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Infarmed
Autoridade Nacional do Medicamento
e Produtos de Saúde, I.P.

ansm
Agence nationale de sécurité du médicament et des produits de santé

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Infarmed
Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.

Co-funded by
the Health Programme
of the European Union

# Reinforcing the market surveillance system for medical devices: key results of JAMS

Bernard Celli, Head of Inspection Division, ANSM (FR)
Nicola Hickie, Regulatory and Policy Manager, HPRA (IE)
Mariana Madureira, Coordinator of MD sector, INFARMED (PT)

**Brussels, December 12th, 2019**

# JAMS with numbers

18 Member States

3 Years

1,4€ Grant for Joint Action co-financed with MS


Co-funded by the Health Programme of the European Union

# Joint Action on Market Surveillance of medical devices

MDR articles:

- SECTION 3, Article 93 Market surveillance activities:
  - 9. The competent authorities of the Member States shall coordinate their market surveillance activities, cooperate with each other and share with each other and with the Commission the results thereof, to provide for a harmonised and high level of market surveillance in all Member States. Where appropriate, the competent authorities of the Member States shall agree on work-sharing, joint market surveillance activities and specialisation.
- CHAPTER VIII, Article 102 Cooperation:
  - 1. The competent authorities of the Member States shall cooperate with each other and with the Commission.

Co-funded by
the Health Programme
of the European Union

# Main objective: reinforcing market surveillance between member states across Europe

**Key principles:**

- Share and develop best practice, training, knowledge, and resources to increase public health protection in the medical devices sector
- Improve coordination and help to develop skills and capacity in the market surveillance network

**Scope:** Joint Manufacturer Inspection / Clinical resource & process

→ **Benefits:** improved market surveillance

→ Ensuring **a consistently high level of health and safety protection for EU patients** using medical devices

Co-funded by
the Health Programme
of the European Union

# JAMS organisation

**WP1-3**

Coordination, dissemination and evaluation

**WP4**

Joint inspections of manufacturers

**WP5**

Clinical process and resources development

Advisory Board:
WP leaders + CPME, Team NB, MedTech Europe
DG GROW (observer)

Co-funded by
the Health Programme
of the European Union

ansm
Agence nationale de sécurité du médicament et des produits de santé

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Infarmed
Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.

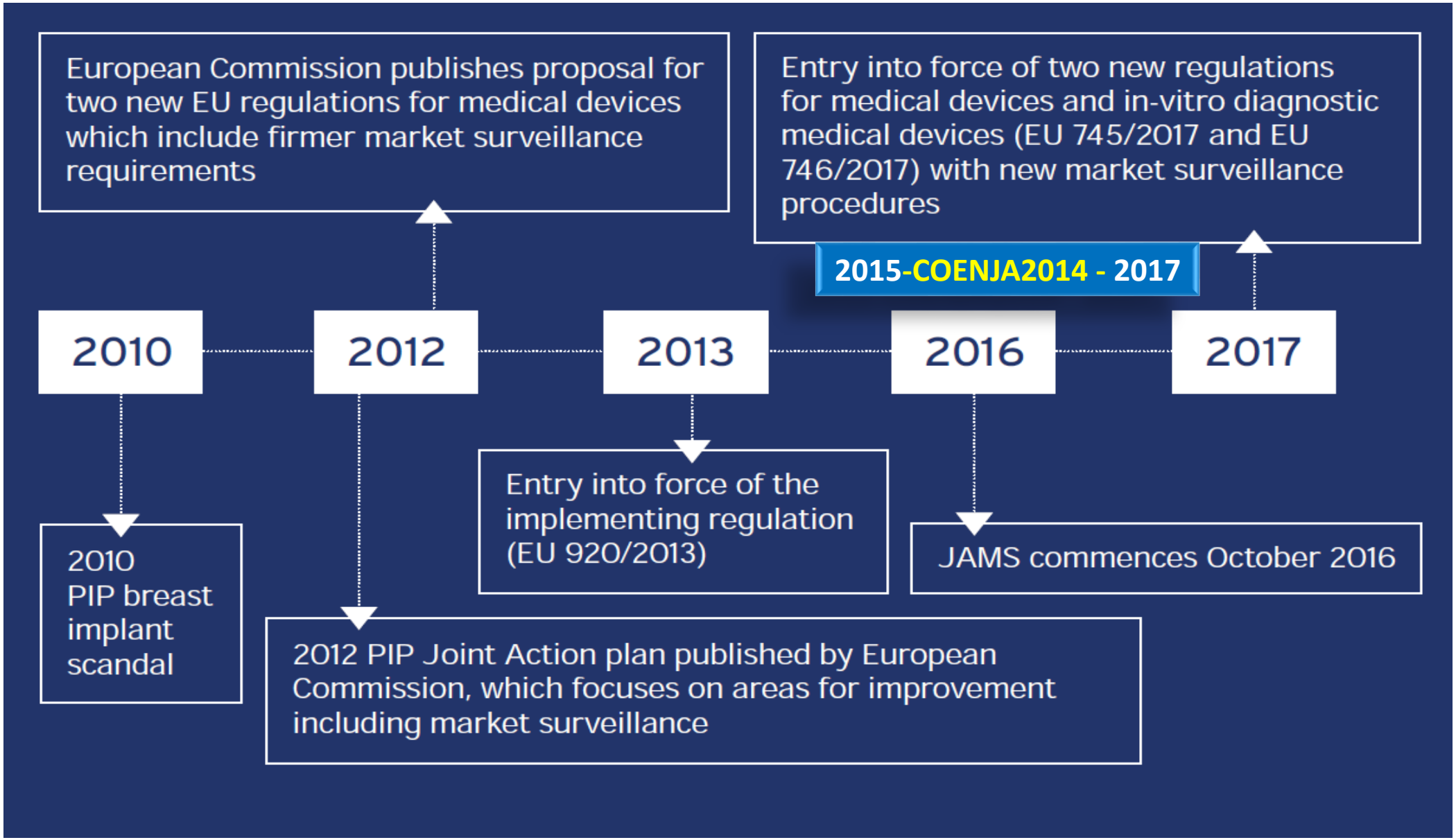
Co-funded by
the Health Programme
of the European Union

# Reinforcing the market surveillance system for medical devices: key results of JAMS

Key results from WP4: Joint inspections of manufacturers

Mariana Madureira,
WP4 Co-leader, Coordinator of MD sector, INFARMED (PT)

**Brussels, December 12th, 2019**




Co-funded by
the Health Programme
of the European Union

# Previous initiatives…

**COEN JA 2014 (18 months) -** ***Joint Market Surveillance Actions on medical devices intended to be reprocessed*** https://webgate.ec.europa.eu/chafea_pdb/health/projects/676988/summary

- Desk review of the **reprocessing instructions** provided by the manufacturers shown that the **overall quality** of the information was **insufficient …**regarding compliance to the MDD…**class I devices** tend to be less compliant…

- (Joint) Inspections- To evaluate whether the reprocessing validation data fulfil the legal requirements. Evidence: **none of the inspected manufacturers/European authorised representatives could show reprocessing validation data being fully compliant to the legal requirements.**

New requirement in the MDR Art.52 (7) the involvement of a Notified Body is required for the conformity assessment of **class I reusable surgical instruments**.

Co-funded by
the Health Programme
of the European Union

# JAMS-WP4: Joint On-site Inspections of Manufacturers

ansm
Agence nationale de sécurité du médicament et des produits de santé



## Article 93 (1-3) MDR

*The competent authorities shall perform appropriate checks on the conformity characteristics and performance of devices including, where appropriate, a review of documentation and physical or laboratory checks …*

*To fulfil this obligations the competent authorities:*

- ❑ Desk review(…)
- ❑ Inspections of the premises of economic operators(…)
  - **Announced**
  - **Unannounced**

**…Suppliers and/or subcontractors**

**…where necessary, at facilities of professional users**

**Draw up annual surveillance activity plans**

Co-funded by
the Health Programme
of the European Union

# JAMS-WP4: Joint On-site Inspections of Manufacturers

ansm
Agence nationale de sécurité du médicament et des produits de santé

## Article 93 (9) MDR

*Competent authorities of the Member States shall **coordinate** their market surveillance activities, **cooperate** with each other **and share** with each other and with the Commission the results thereof, to provide for a **harmonised** and high level of market surveillance in all Member States.*

*Where appropriate, the competent authorities of the Member States shall agree on **work-sharing**, **joint market surveillance activities** and **specialisation**.*

Co-funded by
the Health Programme
of the European Union

# JAMS-WP4: Joint On-site Inspections of Manufacturers

## WP4 Participants

| Beneficiaries (9) | Collaborators (5) |
|---|---|
| Austria, AGES | Belgium, FAGG |
| Cyprus, CYMDA | Estonia, Terviseamet Health Board |
| France, ANSM | Latvia, VI |
| Ireland, HPRA | Norway, NOMA |
| Italy, DGDMF | UK, MHRA |
| Portugal, INFARMED | |
| Spain, AEMPS | |
| Sweden, MPA | |
| The Netherlands, NLNA | |

Co-funded by
the Health Programme
of the European Union

# What are the key objectives of JAMS – WP4

- Identify and collect the national policies on planning inspections
- Delivery tools, templates, information resources and procedures to facilitate joint inspections of manufacturers
- Map specialist expertise inspectors across the system
- Organise an inspector training course
- Identify areas and candidates to coordinate expertise at EU level



Co-funded by
the Health Programme
of the European Union

# Our deliverables

- D4.1 – Proposals Joint Inspections of MD manufacturers in Europe
- D4.2 – Guidance document «Joint Inspection Initiation»
- D4.3 – Inspectors Training Course & Establishment of Inspectors Expert Group *Under validation*
- D4.4 – Guidance on conduct of Joint Inspections *Under validation*

Co-funded by
the Health Programme
of the European Union

# Our deliverables

## **Deliverable D4.1** Proposals Joint Inspections of MD manufacturers in EU


Joint Action Market Surveillance: Work Package 4
Deliverable: D4.1

Proposals

Joint Inspections of Medical Device Manufacturers in Europe

**Terminology/Definitions:**

- Joint inspection of manufacturers, lead inspector

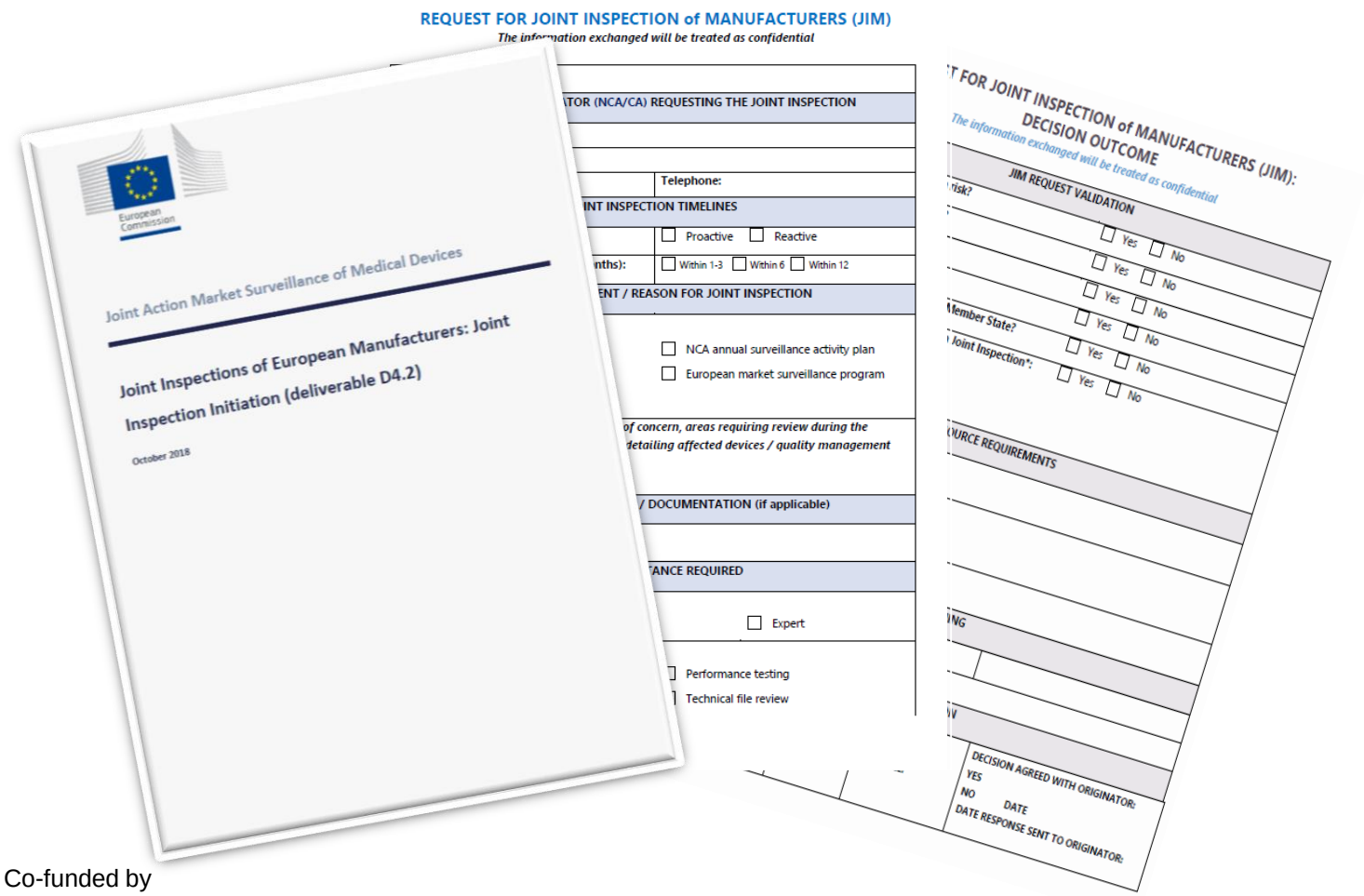
**Inspector profile:**

- Competence, qualification

Co-funded by
the Health Programme
of the European Union

# Our deliverables

## Deliverable D4.2 -Guidance document «Joint Inspection Initiation»

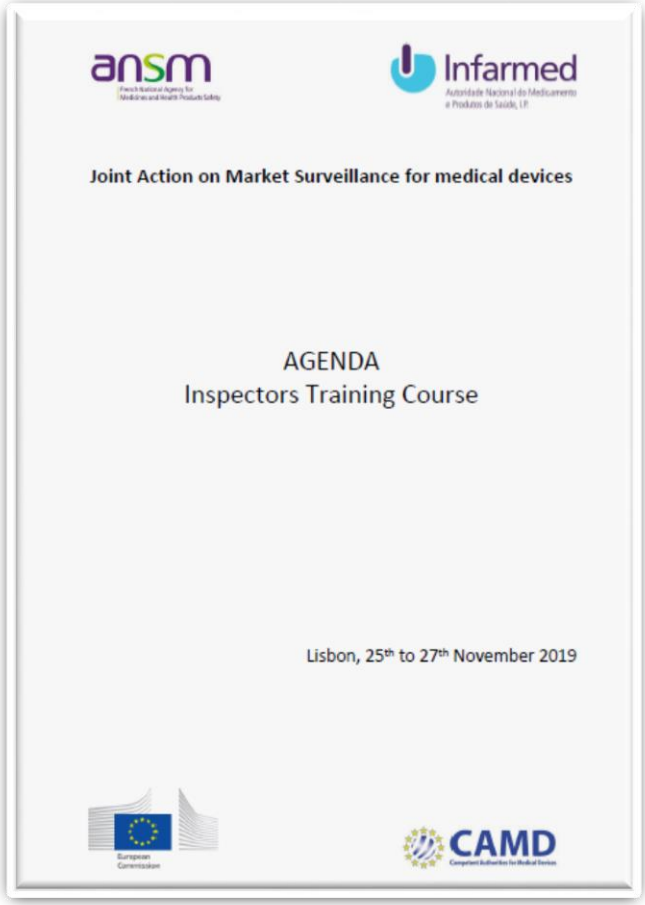



- Overview of joint inspection process
- Joint Inspector Group for medical devices
- Sources of input into the joint inspection process
- Request for joint inspection
- Joint inspection planning
- Pilot phase

Co-funded by
the Health Programme
of the European Union

# Our deliverables

## Draft deliverable D4.3 Inspectors Training Course

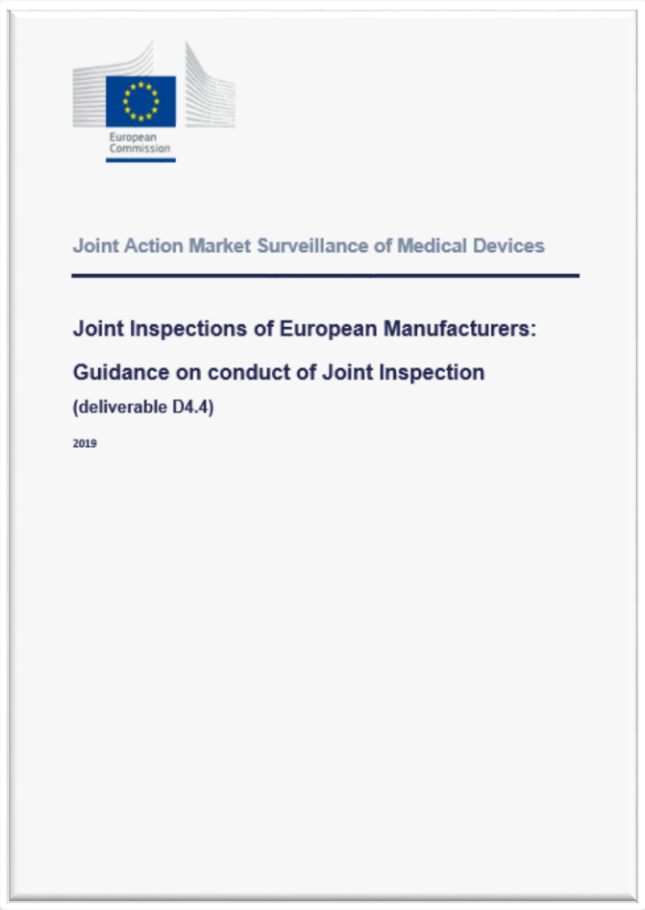



**73 participants**
**26 NCAS**

Co-funded by
the Health Programme
of the European Union

# Our deliverables

## Draft deliverable D4.4 - Guidance on conduct of Joint Inspections




- Following the process of Joint Inspection of MD manufacturers
- Harmonised necessary templates
- Post joint inspection activities

Co-funded by
the Health Programme
of the European Union

# JAMS WP4 Achievements

*Paving the way for Joint Inspections of MD Manufacturers in EU, by:*

- ✓Delivering tools, templates, information resources and procedures to facilitate joint inspections of manufacturers;
- ✓Training inspectors to perform joint inspections according to an agreed approach

Co-funded by
the Health Programme
of the European Union

# JAMS WP4 Achievements

*Contributing to the implementation of Medical Device Regulations*

Co-funded by
the Health Programme
of the European Union

ansm
Agence nationale de sécurité du médicament et des produits de santé

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Infarmed
Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.

Co-funded by
the Health Programme
of the European Union

# Reinforcing the market surveillance system for medical devices: key results of JAMS

Key results from WP5: Clinical process and resources development

Nicola Hickie
WP5 Leader, Regulatory and Policy Manager, HPRA (IE)

**Brussels, December 12th, 2019**

# Reinforcing market surveillance for medical devices

## Report from WP5

**June 2016**
- Political agreement on MDR/ IVDR

**Oct 2016**
- JAMS project commences

**May 2020**
- Implementation of MDR

Co-funded by
the Health Programme
of the European Union

# Key Deliverables of JAMS WP5

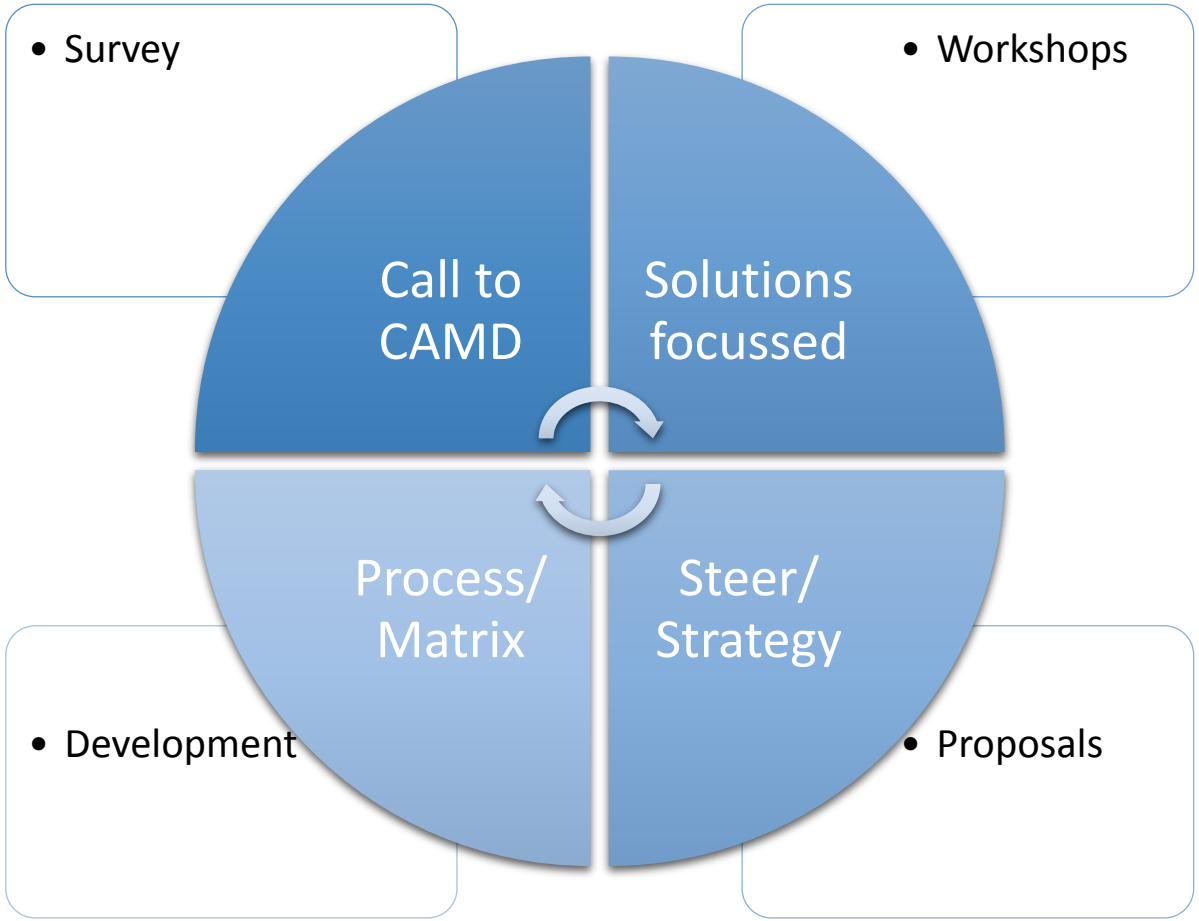
Establish communication platform & protocols for information exchange

Identify training & development needs for evaluation of clinical data

Identify process to prioritise devices requiring Common Specifications

Co-funded by
the Health Programme
of the European Union

# Work Plan




Co-funded by
the Health Programme
of the European Union

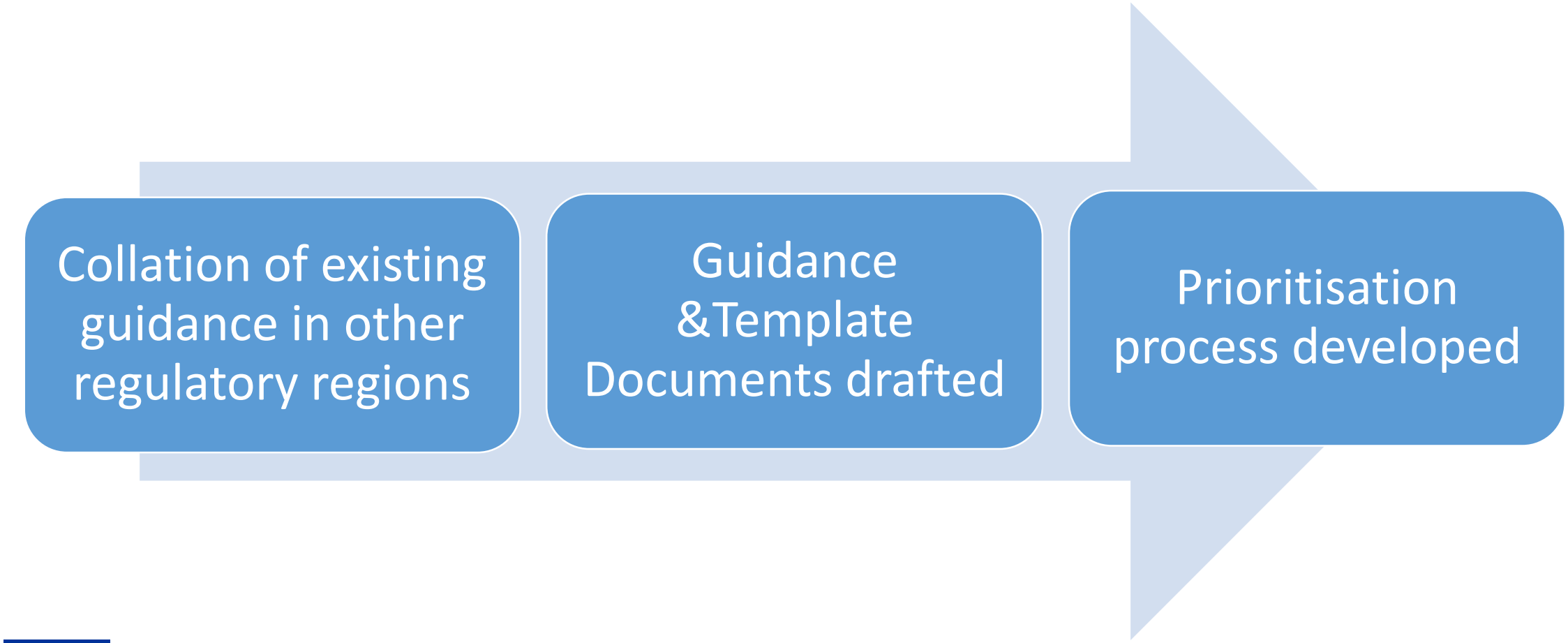
# Who is involved?

| Beneficiaries (6) | Collaborating Stakeholders (7) |
|---|---|
| AGES (AT) | BfArM (DE) |
| ANSM (FR) | CYMDA (CY) |
| DGDMF (IT) | DKMA (DK) |
| HPRA (IE) | Halmed (HR) |
| INFARMED (PT) | AEMPS (ES) |
| NLNA (NL) | Terviseamet (EE) |
| | MHRA (UK) |

Co-funded by
the Health Programme
of the European Union

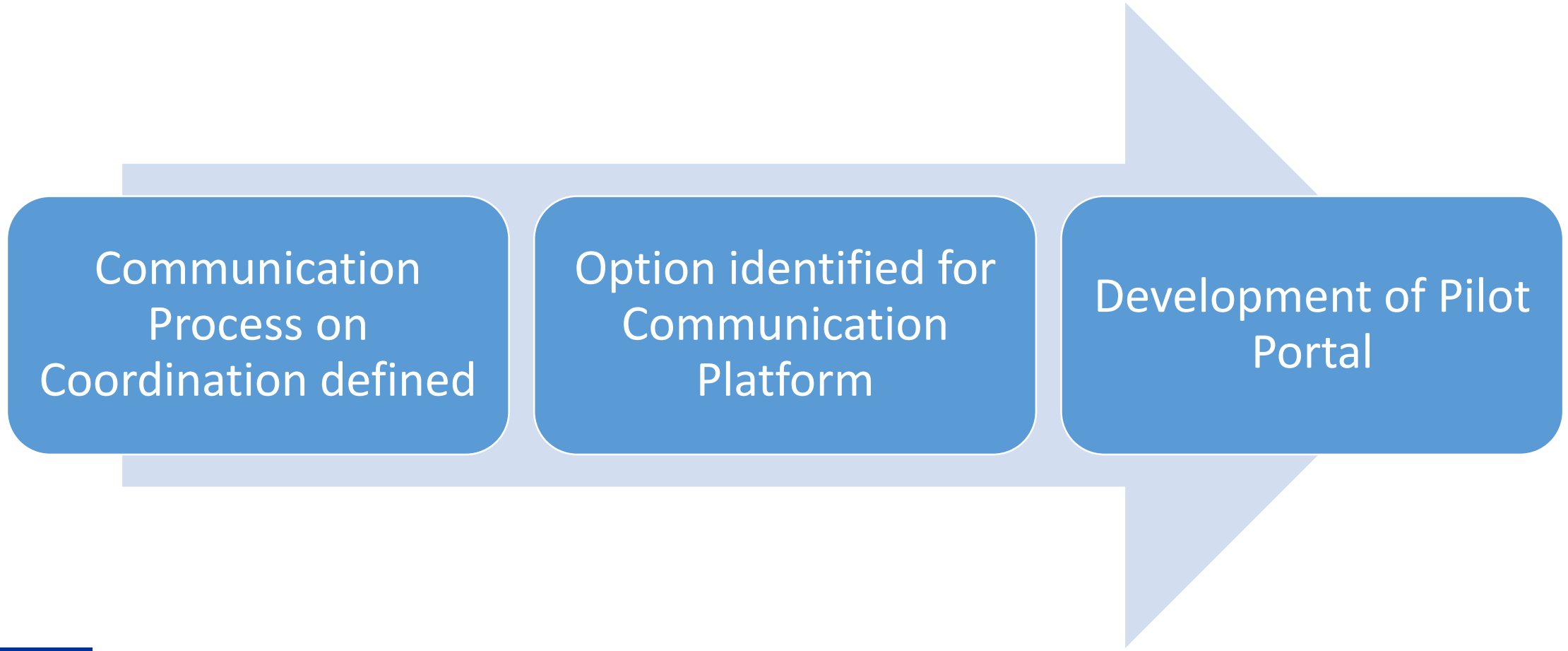
# What has been delivered:

# CS prioritisation process



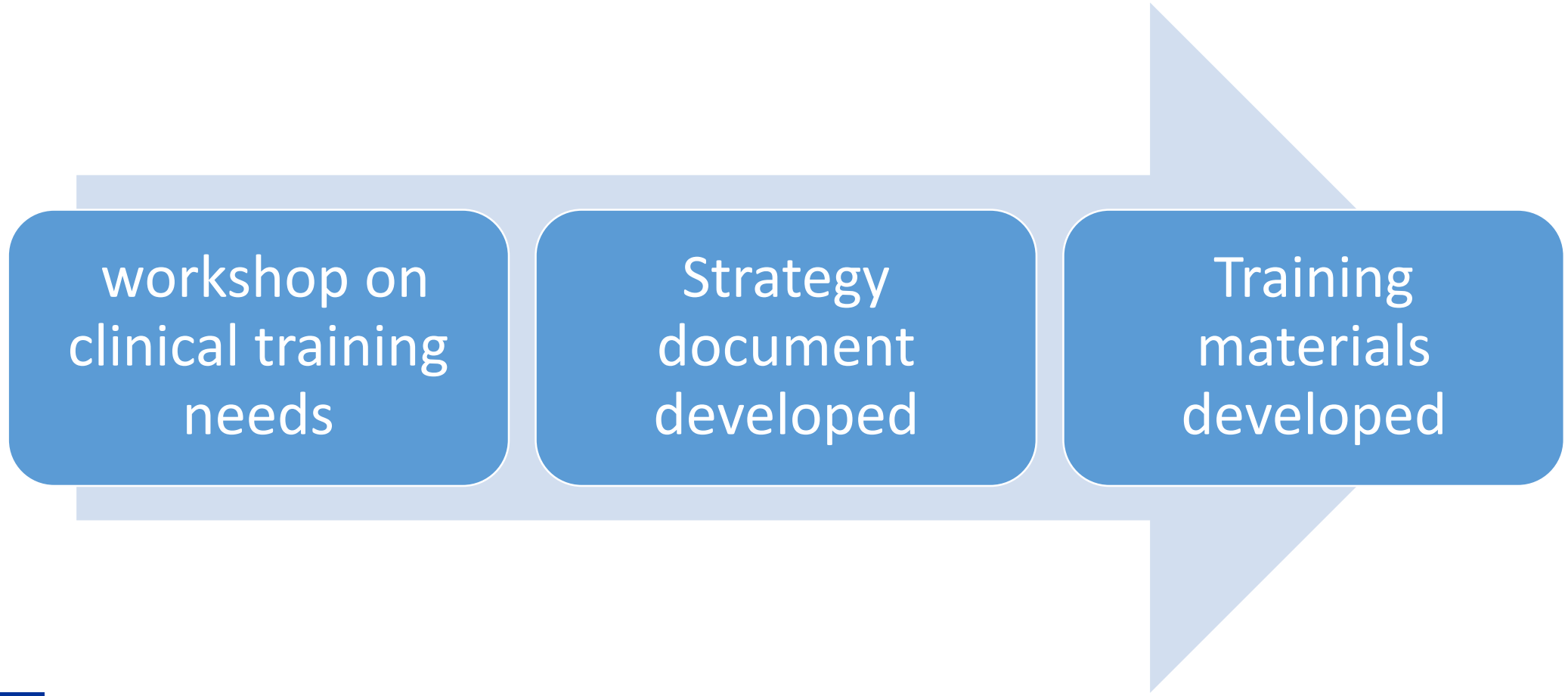

Co-funded by
the Health Programme
of the European Union

# Coordination process and Communication portal



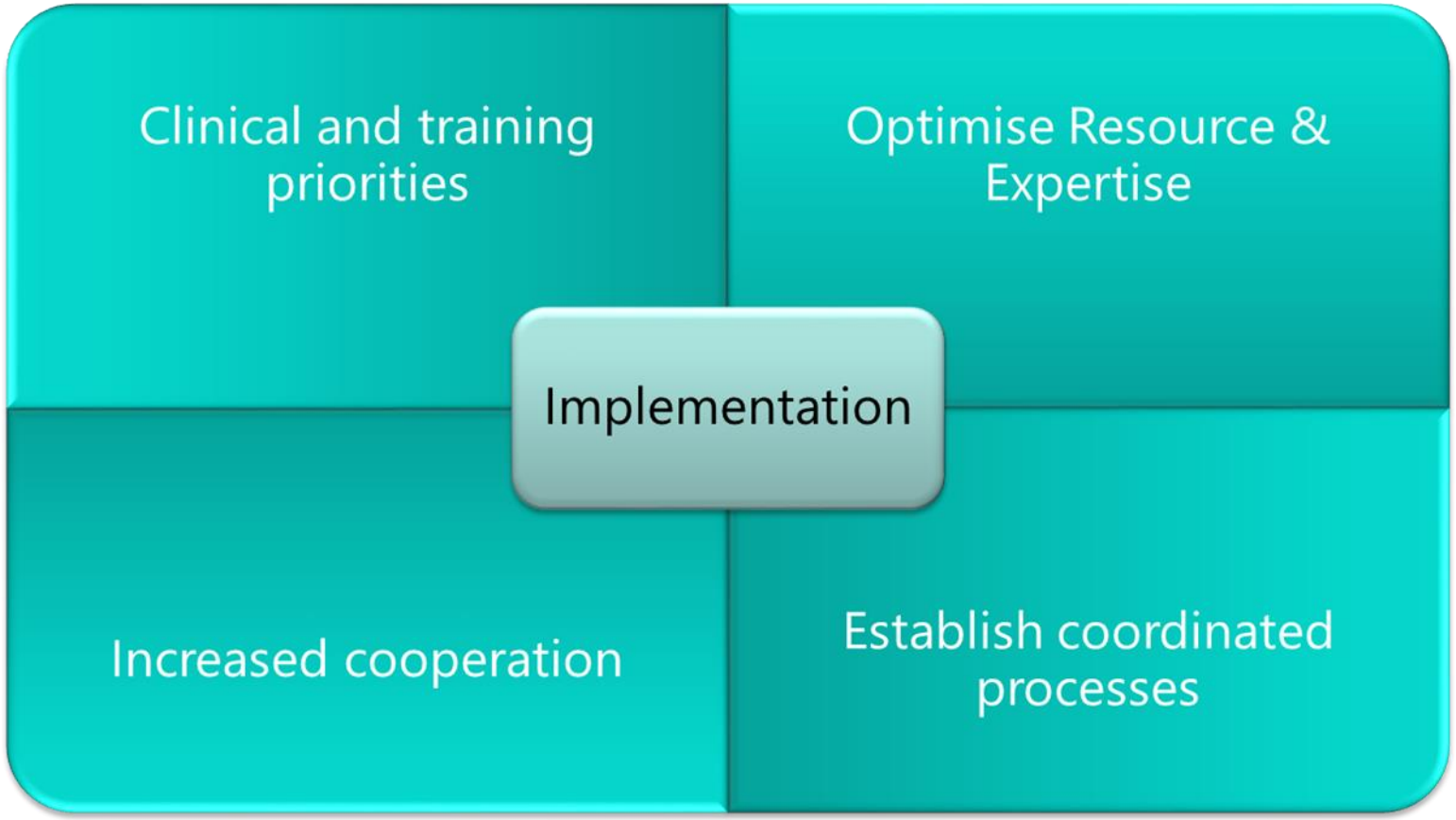

Co-funded by
the Health Programme
of the European Union

# Clinical Training Materials Developed




Co-funded by
the Health Programme
of the European Union

# Benefits gained and alignment with MDR



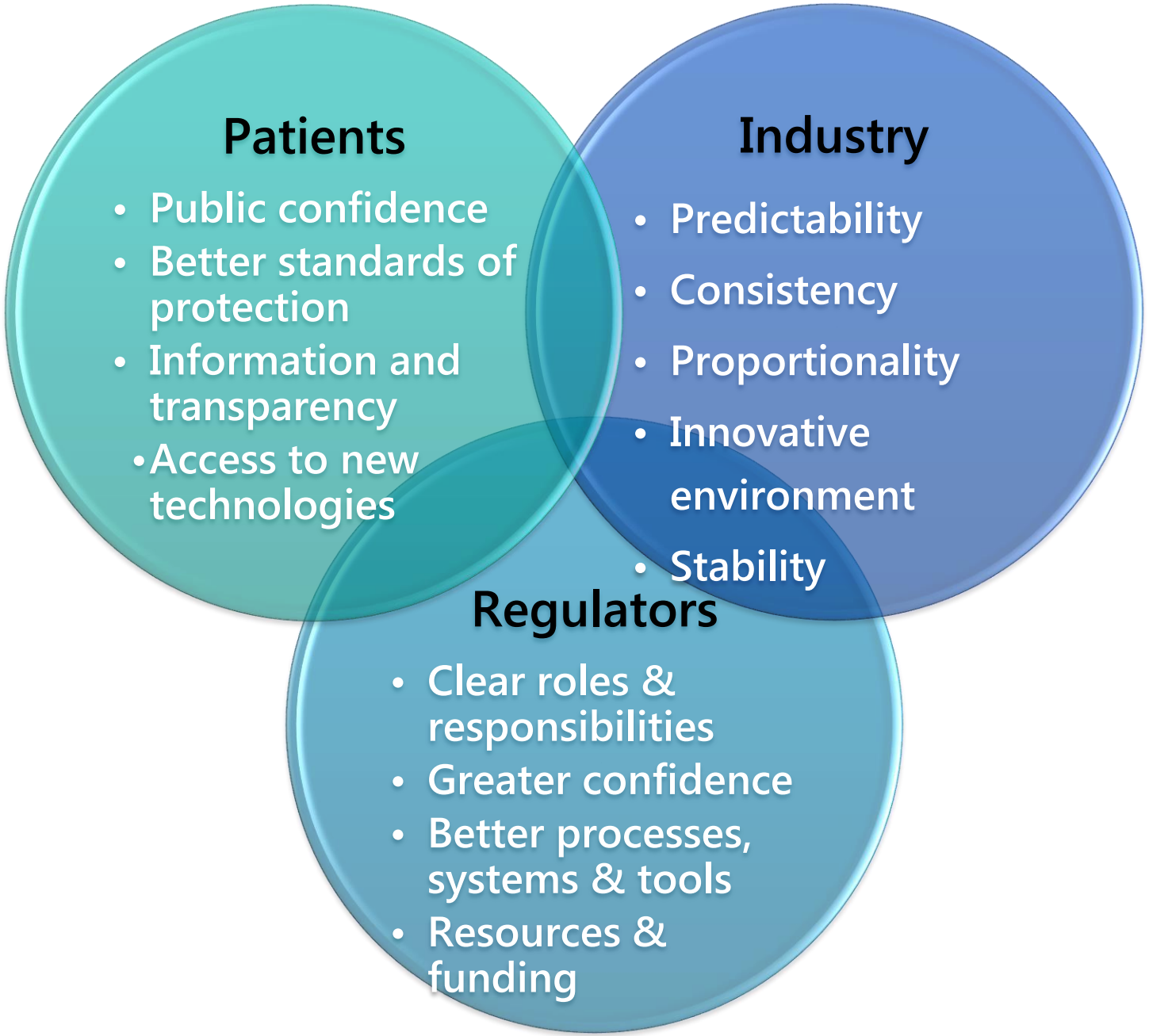

Co-funded by
the Health Programme
of the European Union

# Next Steps

- Continue to develop and use learnings from this process
- Commission – tools for prioritising Common Specifications
- NCAs – training materials and future development areas identified
- NCAs and working groups – process for coordinating on market surveillance issues
- NCAs and working groups – tool for real time exchange of information

Co-funded by
the Health Programme
of the European Union

# Conclusion




Co-funded by
the Health Programme
of the European Union

## JAMS Project team contact :

**Lara LAINE-LEMARCHAND** – JAMS Project coordinator, ANSM
lara.laine-lemarchand@ansm.sante.fr

**Angélique NIKOUE** – JAMS Project assistant, ANSM
angelique.nikoue@ansm.sante.fr

**Mariana MADUREIRA and Christine GRASMICK** – WP4 Co-leaders, INFARMED and ANSM
mariana.madureira@infarmed.pt ; Christine.GRASMICK@ansm.sante.fr

**Nicola HICKIE** – WP5 leader, HPRA
nicola.hickie@hpra.ie

*This conference is part of the project / joint action '723964 / JAMS' which has received funding from the European Union's Health Programme (2014-2020).*

Co-funded by
the Health Programme
of the European Union