EUnetHTA JA3
an update and future initiatives

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Brussel, February 15, 2018

eunethta

European Commission

Outline

- Update on WP activities
- Interaction with stakeholders/EMA
- Future perspectives/developments in EUnetHTA
  - Regional initiatives
  - Towards a permanent model

Summary of Activities in EUnetHTA JA3

- **WP4 Joint Production**
  - To produce rapid REA on pharmaceuticals and other technologies;
  - To provide a system for topic selection and prioritization, e.g. horizon scanning.
- **WP5 Evidence Generation**
  - To conduct Early Dialogues (joint HTA or parallel/joint with regulators);
  - To cooperate on additional post-launch data collection to be used in various contexts (such as MEAs, CED).
- **WP6 Quality Management**
  - To provide quality management for EUnetHTA joint products;
  - To further develop methodologies and tools for joint work if necessary.
- **WP7 National implementation and impact**
  - To facilitate the reuse and implementation of joint products at the national/local level;
  - To measure the impact of joint work in collaboration with other work packages.
- **WP1 Coordination**
- **WP2 Dissemination**
- **WP3 Evaluation**

WP4 Status Joint and Collaborative Assessments

Other technologies

planned
2 CA

ongoing
2 JA
5 CA

published
4 CA

13

Pharma technologies

published
3 JA

3

Future relevant activities for WP4

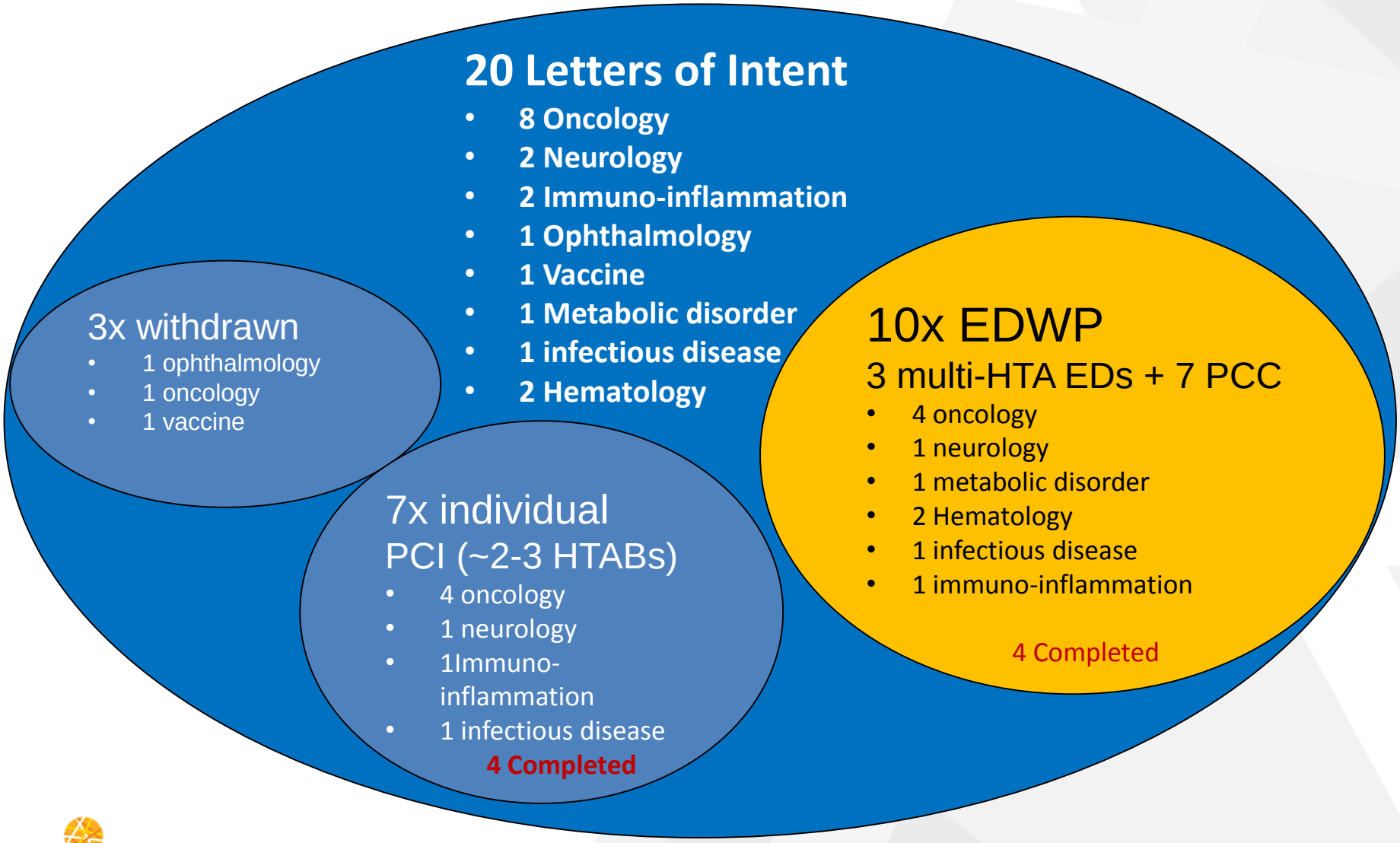
- Changes to the pharma JA
  - Simplify the production process (no draft submission file, focus on PICO)
  - Adapt EUnetHTA JA templates (readability), simplify process
  - More actively contacting manufacturers on products of interest for HTA bodies

- Working group for Topic Identification, Selection and Prioritisation (TISP)
  - Both on pharma and non-pharma activities
  - Also links to horizon scanning activities

- Additional activities on Medical devices
  - EUnetHTA Task Force on HTA and medical device regulation (first meeting May 29)

- Interaction with regional initiatives (discussed later)

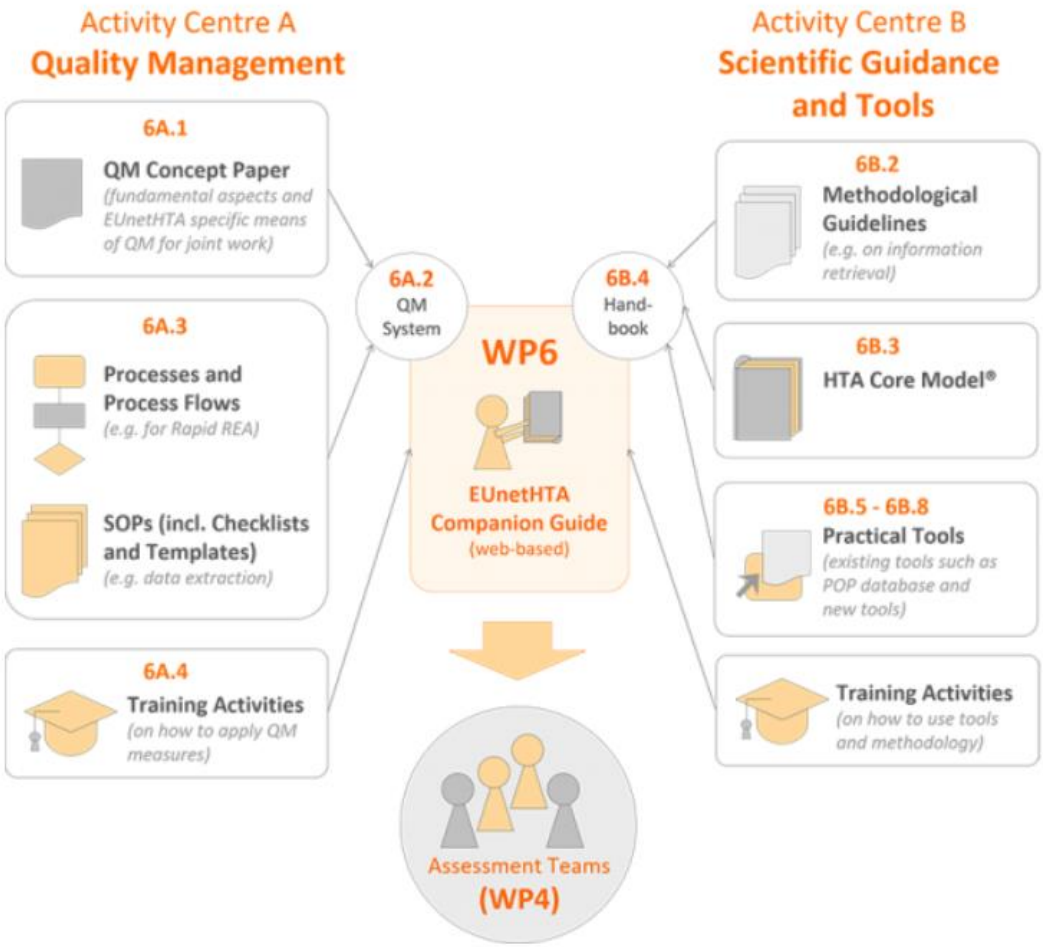
WP5A - Early Dialogues – Status since JA3 start



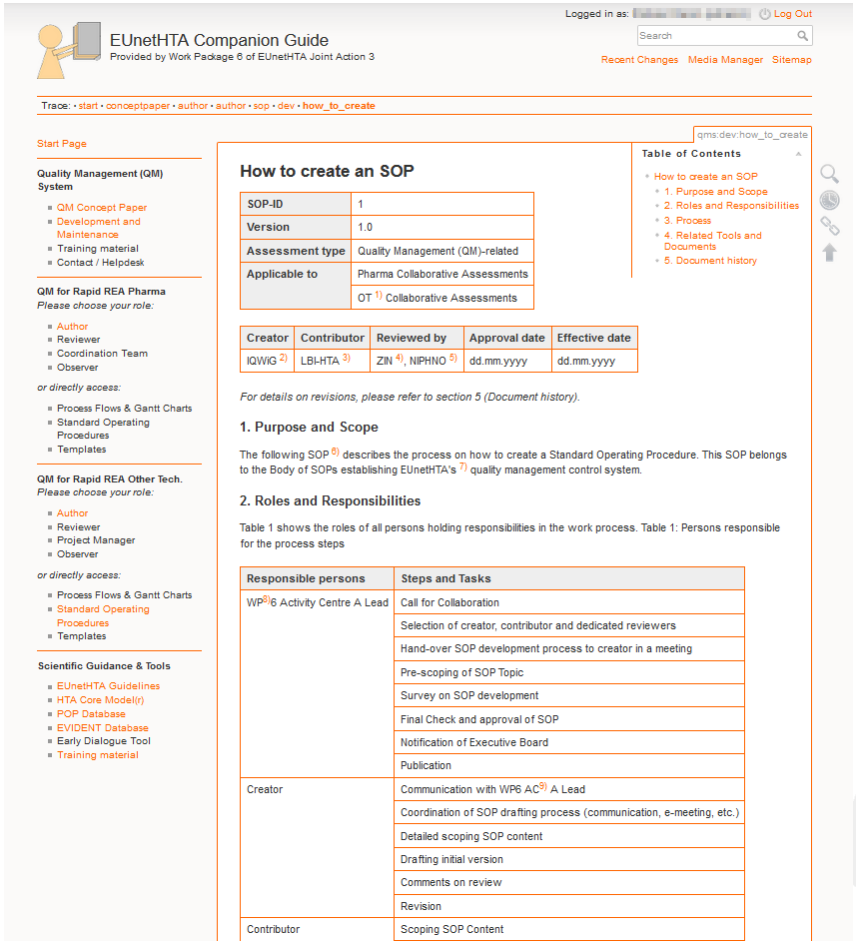
WP5B: Post Launch Evidence Generation (PLEG)

- B1- PLEG Pilots:
  - Disease specific pilots :
    - **Two ongoing**: two qualification of registries, in collaboration with EMA
  - Product-specific pilots:
    - **Calls for pilots on drugs** about to be launched (two topics proposed by AIFA and TLV)
    - **Calls for pilots on medical devices** expected in March
- B2 - Quality standards tool to evaluate registries
  - Second draft of the tool currently tested by three HTA bodies (AQuAS, avalia-t, INFARMED)
  - Third draft of the tool together with first draft of the Vision paper for independently accrediting or assuring registers: expected March 2018

WP 6 - Quality management, guidance and tools



The EUnetHTA Companion Guide - status



EUnetHTA Companion Guide
Provided by Work Package 6 of EUnetHTA Joint Action 3

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Start Page

Quality Management (QM) System
- QM Concept Paper
- Development and Maintenance
- Training material
- Contact / Helpdesk

QM for Rapid REA Pharma
Please choose your role:
- Author
- Reviewer
- Coordination Team
- Observer

or directly access:
- Process Flows & Gantt Charts
- Standard Operating Procedures
- Templates

QM for Rapid REA Other Tech.
Please choose your role:
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Scientific Guidance & Tools
- EUnetHTA Guidelines
- HTA Core Model(r)
- POP Database
- EVIDENT Database
- Early Dialogue Tool
- Training material

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How to create an SOP

Table of Contents
- How to create an SOP
- 1. Purpose and Scope
- 2. Roles and Responsibilities
- 3. Process
- 4. Related Tools and Documents
- 5. Document history

SOP-ID	1
Version	1.0
Assessment type	Quality Management (QM)-related
Applicable to	Pharma Collaborative Assessments
	OT [1] Collaborative Assessments

Creator	Contributor	Reviewed by	Approval date	Effective date
IQWiG [2]	LBI-HTA [3]	ZIN [4], NIPHNO [5]	dd.mm.yyyy	dd.mm.yyyy

For details on revisions, please refer to section 5 (Document history).

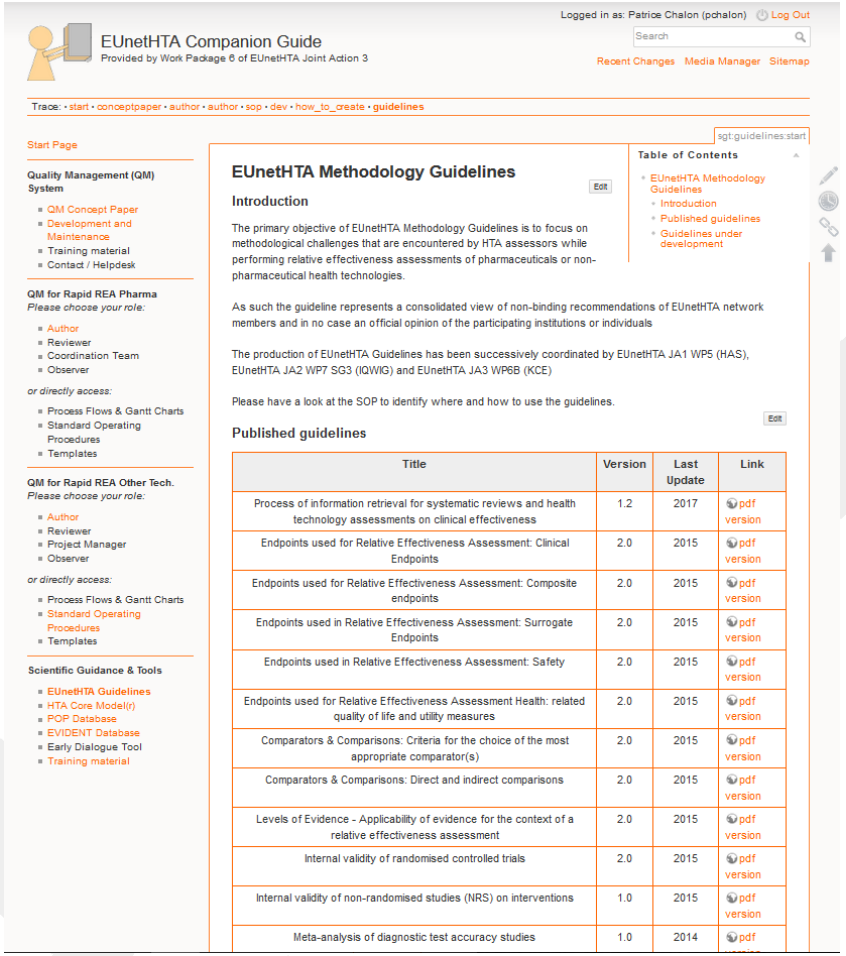
1. Purpose and Scope

The following SOP [6] describes the process on how to create a Standard Operating Procedure. This SOP belongs to the Body of SOPs establishing EUnetHTA's [7] quality management control system.

2. Roles and Responsibilities

Table 1 shows the roles of all persons holding responsibilities in the work process. Table 1: Persons responsible for the process steps

Responsible persons	Steps and Tasks
WP[8]6 Activity Centre A Lead	Call for Collaboration
	Selection of creator, contributor and dedicated reviewers
	Hand-over SOP development process to creator in a meeting
	Pre-scoping of SOP Topic
	Survey on SOP development
	Final Check and approval of SOP
	Notification of Executive Board
	Publication
Creator	Communication with WP6 AC[9] A Lead
	Coordination of SOP drafting process (communication, e-meeting, etc.)
	Detailed scoping SOP content
	Drafting initial version
	Comments on review
	Revision
Contributor	Scoping SOP Content



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EUnetHTA Methodology Guidelines

Edit

Table of Contents
- EUnetHTA Methodology Guidelines
- Introduction
- Published guidelines
- Guidelines under development

Introduction

The primary objective of EUnetHTA Methodology Guidelines is to focus on methodological challenges that are encountered by HTA assessors while performing relative effectiveness assessments of pharmaceuticals or non-pharmaceutical health technologies.

As such the guideline represents a consolidated view of non-binding recommendations of EUnetHTA network members and in no case an official opinion of the participating institutions or individuals

The production of EUnetHTA Guidelines has been successively coordinated by EUnetHTA JA1 WP5 (HAS), EUnetHTA JA2 WP7 SG3 (IQWiG) and EUnetHTA JA3 WP6B (KCE)

Please have a look at the SOP to identify where and how to use the guidelines.

Edit

Published guidelines

Title	Version	Last Update	Link
Process of information retrieval for systematic reviews and health technology assessments on clinical effectiveness	1.2	2017	pdf version
Endpoints used for Relative Effectiveness Assessment: Clinical Endpoints	2.0	2015	pdf version
Endpoints used for Relative Effectiveness Assessment: Composite endpoints	2.0	2015	pdf version
Endpoints used in Relative Effectiveness Assessment: Surrogate Endpoints	2.0	2015	pdf version
Endpoints used in Relative Effectiveness Assessment: Safety	2.0	2015	pdf version
Endpoints used for Relative Effectiveness Assessment Health: related quality of life and utility measures	2.0	2015	pdf version
Comparators & Comparisons: Criteria for the choice of the most appropriate comparator(s)	2.0	2015	pdf version
Comparators & Comparisons: Direct and indirect comparisons	2.0	2015	pdf version
Levels of Evidence - Applicability of evidence for the context of a relative effectiveness assessment	2.0	2015	pdf version
Internal validity of randomised controlled trials	2.0	2015	pdf version
Internal validity of non-randomised studies (NRS) on interventions	1.0	2015	pdf version
Meta-analysis of diagnostic test accuracy studies	1.0	2014	pdf

WP 7 Status of activities

Activity	Due date	Status
Activity 1: Research and analysis	Final report Nov ’17 (deliverable)	• Final report is publically available on the EUnetHTA website
Activity 2: Case studies	Ongoing throughout JA3	• Year 1 case studies published in the activity 1 report • Year 2 case studies to take place in April and May so as to include discussion of the EC proposal for a regulation on HTA • 4 countries have volunteered for year 2
Activity 3: Technical to support development of the model of HTA cooperation	Delayed to account for publication of the EC proposal for a regulation on HTA	• Activity to be initiated following liaison with WP1

Activity 4: Implementation Network	Implementation reports to be published May 2018, Nov 2018, May 2019, Nov 2019	• Data collection procedures to gather experiences of using the EUnetHTA assessments in place
		• The first implementation report will include:
		  • a baseline to measure assessment use in JA3
		  • first implementation data from JA3 assessments

Future work

- Ongoing collection and publication of data (quantitative and qualitative) about use of the JA3 EUnetHTA assessments;
- Collaborative work with WP6B among HTA users about incorporating EUnetHTA tools and guidelines in their national procedures;
- Develop resources and run activities to support implementation of EUnetHTA outputs;
- Support the development of the model of HTA cooperation.

WP1 Output and Milestones in 2017

Participation, Contribution and Coordination

Reporting

Products and Services

Publication

Increased Technical and Network Capabilities

Assembly and Forum, HTA Synergy, EUnetHTA-EFPIA Technical Meeting, EUnetHTA-EMA bilaterals, Executive Board/Project Management Group Face-to-Face, involvement and contribution to European-wide symposiums and organizations

Submission of Interim Technical and Financial Report (81 partner organisations and institutions)

EUnetHTA-EMA Parallel Consultation Process (Early Dialogues) and continued production of REAs

Internal monthly summaries and quarterly EUnetHTA magazine; interview and publication pieces in journals and web

New Intranet infrastructure (400+ users): development of Project Management Tool (PMT), Advanced Address Book (AAB); 30% increase in social media base; launch of rebuilt website is imminent

WP2 activities

- **Involvement in communication activities**
- **Dissemination registry**
- **Training:**
  - Training Strategy
  - A virtual classroom with training materials for partners
  - A Welcome Package for newcomers
- **Stakeholder Involvement activities**
  - Overall Stakeholder Involvement SOP
  - Stakeholder Registry

WP 3- Evaluation

- In total 11 evaluation reports
- 3 reports have been delivered so far
  - Bi-annual report I and II
  - Yearly interim report I
- The WP has also carried out
  - Partner interviews
  - Stakeholder interviews
  - Partner survey
- 4 reports to be delivered 2018
  - Bi-annual report III, IV and V
  - Yearly interim report II

Progress Stakeholder involvement in JA3 (I)

- Cross-WP task group on involvement patient and consumers started fall 2017
  - Support involvement in WP4 and WP5 activities
  - Meeting F2F January 2018
  - Experiences with involvement shared and collected and proposal to move on

- Cross-WP task group on involvement healthcare providers will be initiated in 2018
  - Support involvement in WP4 and WP5 activities

- Interactions with pharma industry on WP4 and WP5
  - Link to Heads of Agency meeting in May 2017
  - Technical meeting with EFPIA in December 2017
    - Experiences are shared and proposals to improve were discussed
  - Individual MAH interaction in REAs

Progress Stakeholder involvement in JA3 (II)

- Interaction with MedTech industry
  - Individual MAH interaction in REAs
  - Planning a technical meeting with MedTech Industry in 2018

- Interaction with payers will be intensified
  - Based on some early interactions in a meeting with EMA in September
  - Meetings going to be planned to identify progress activities and identify gaps to progress on

- Involvement in EUnetHTA Forum 2017
  - Active contribution of stakeholders in different panels on involvement as such, horizon scanning and topic selection and role of additional data collection

EMA and EUnetHTA finalise joint work plan for 2017-2020

13 November 2017

Medicines regulator and network of Health Technology Assessment (HTA) bodies continue to strengthen their collaboration

The European Medicines Agency (EMA) and the European Network for Health Technology Assessment (EUnetHTA) have published a joint work plan outlining key areas of collaboration for the next three years.

The EMA-EUnetHTA collaboration, which began in 2010, aims to harness synergies between regulatory evaluation and health technology assessment (HTA) along the lifecycle of a medicine whilst

EUnetHTA-EMA workplan

- **early dialogue / scientific advice (WP5A)**
- **information exchange at market entry (WP4)**: the exchange of information on the CHMP opinion
- **post-authorisation data generation (WP5B)**: post-licensing evidence generation tools, such as patient registries,

EMA and EUnetHTA will also further collaborate in a number of areas including:

- concepts of unmet medical need and therapeutic innovation in view of possible synergies;
- understanding the conceptual similarities and differences between the significant benefit of orphan medicines versus their added therapeutic value.

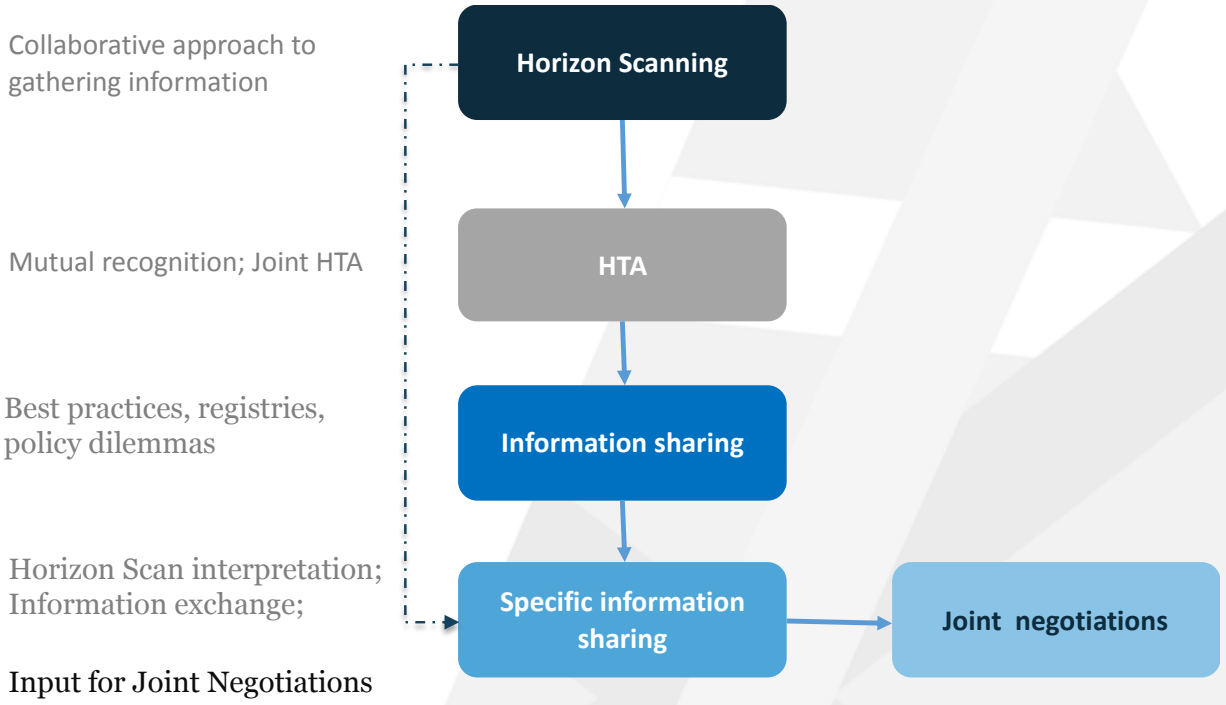
Structured through bi-annual meetings

BUT ALSO INTERACTION WITH Medical Devices Regulator (DG Grow)!

- On methodologies and guidance, starting with meeting May 29

Introduction: regional activities (Pharma)

1) FINOSE (Finland, Norway, Sweden)
2) Valleta (Cyprus, Greece, Italy, Malta, Portugal, Spain, Slovenia, Croatia, France (observer))
3) BeneluxA (Austria, Belgium, Luxemburg, Netherlands)
4) Visegrad +2 (Czech Repubic, Hungary, Poland, Slovakia + Croatia, Lithuania)



Possibilities for collaboration with regional collaboration on Pharma

	FINOSE	Valletta	BeneluxA	Visegrad+2
Horizon scanning	-	+	+	-?
Joint HTA	REA	REA	REA	-?
	CEA	CEA	CEA	-?
Information sharing	+	+	+	-?
Joint Price Negotations	-	+	+	+

Regional initiatives may also support EUnetHTA by fitting EUnetHTA and national systems, identify topics of interest and increase industry interest to participate in EUnetHTA joint REAs by offering clear pathways to national decision

Specific activities planned with regional initiatives on Pharma

Actions from WP4 LP and CoLP Pharma + WP1 LP:

- Being involved in meetings with regional networks
  - Meetings with FINOSE;
  - Meetings and sharing workplans on HTA with BeneluxA;
  - Working on contacts with the other initiatives;
  - In close collaboration with the EC.

How EUnetHTA may support in HTA activities of regional initiatives:

- Project management of the joint clinical assessments (clinical evaluation) including quality management of the process incl. methodological guidelines, the use of tools and templates and methods for patient involvement
- EUnetHTA WP4 budget

Conclusions

- EUnetHTA JA3 has progressed in activities
  - Major achievements in terms of organisation but also collaboration with EMA (for instance the early dialogues);
  - Joint assessments of REA both for pharmaceuticals and other technologies are starting off, implementation is growing;
  - It is important that the current momentum regarding the joint REA both on pharma and other technologies will be kept!

- Discussion will start on the development of EUnetHTA JA3 activities until 2020 in relation to the future permanent model
  - Deliverable in EUnetHTA JA3 GA is to support the development of permanent EU cooperation on HTA (WP1 deliverable)
  - Stepwise approach starting with constructive discussions in the EUnetHTA Executive Board with input of the European Commission on the future scenario as described in the EC proposal
  - Linked to the progress of political discussions on the current proposal of the EC.
  - Taking on board experiences and views of the stakeholders

Thank you

Any questions?