Session 2 - Generating evidence that meets the needs of patients and health system decision makers

EUnetHTA
Early Dialogues and beyond:
A lifecycle approach to Evidence Generation

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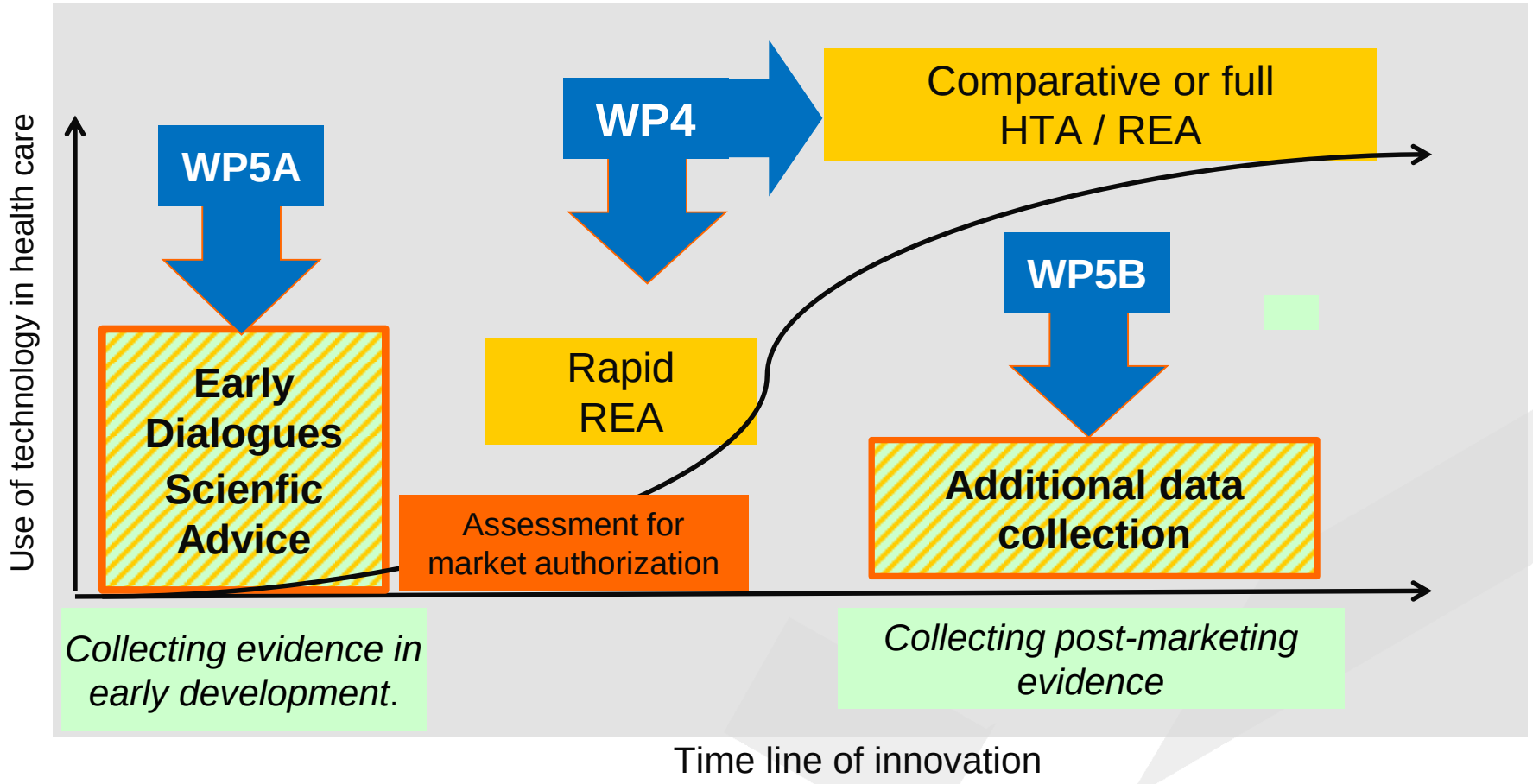
EUnetHTA : A continuum of activities

- Work Package 4: Joint/collaborative assessments
- Work Package 5: Evidence generation



Objectives of Work Package 5

The main objective of WP5 is to help to generate**, all along the technology lifecycle**, optimal and robust evidence for different stakeholders, bringing benefits for patient access and public health.

Lead Partner: HAS

►Initial evidence generation Early Dialogues (EDs) : Strand A

Co-lead Partner: G-BA

►Post-launch evidence generation (PLEG) Strand B

Activity centers: AIFA, TLV, avalia-t, NICE

→ B1: PLEG pilots

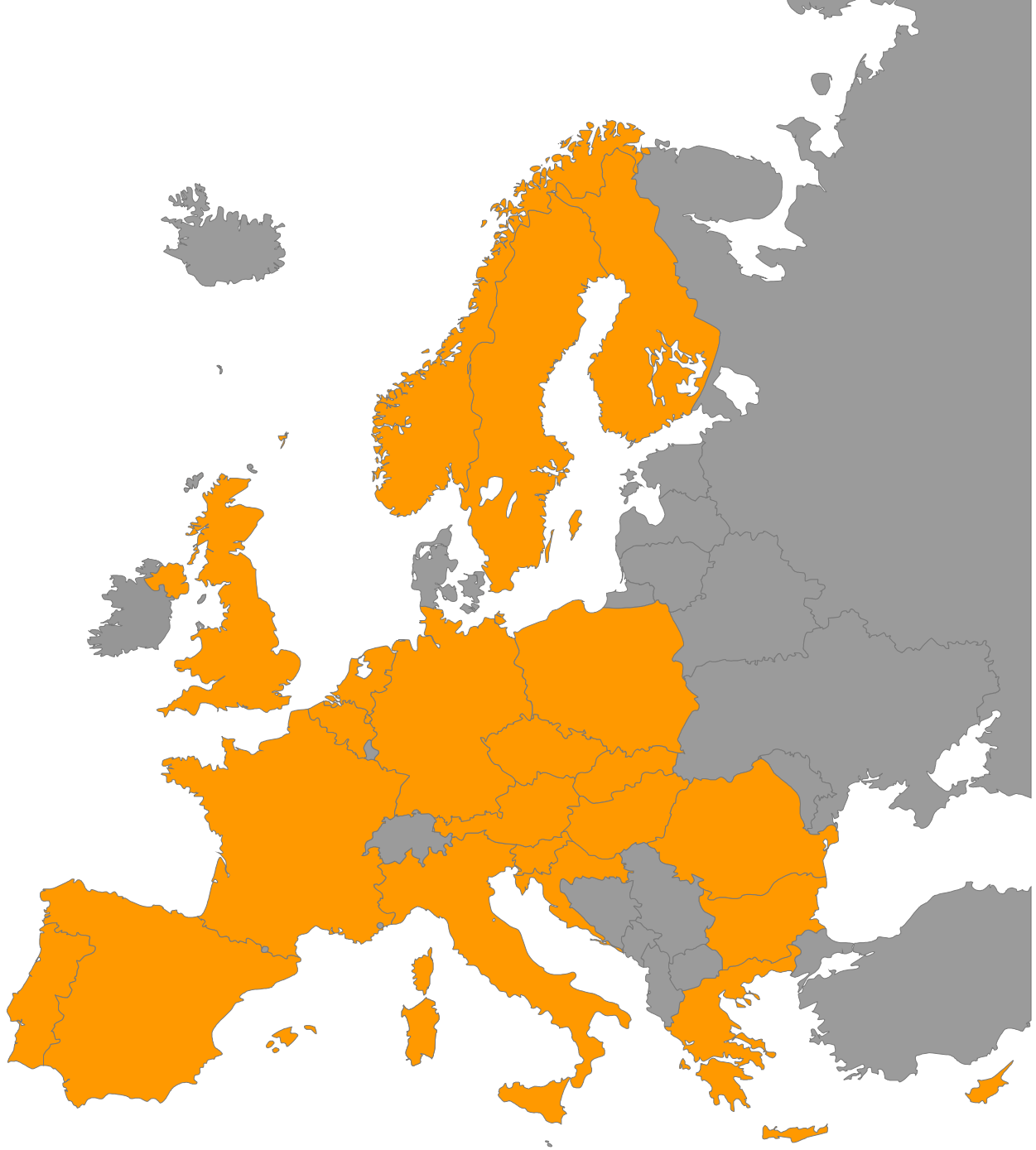
→ B2: Standards Tool for Registries in HTA

WP5 partners

- **38 organisations**
- **22 countries**

HAS (Lead Partner)
G-BA (Co-Lead Partner)
ZIN (A, B1)
HVB (A)
KCE (A)
IPH-BE (B1)
RIZIV-INAMI (A)
NCPHA (A)
CIPH/HZJZ (A, B1, B2)
MoH Cyprus (A)
UTA (B1)
FIMEA (B1)
IQWiG (A)
EKAPTY SA (B1, B2)
NIPN (A)
AIFA (A, Strand B1 AC Lead; B2)
AGE.NA.S (A)
DGFDM IT (B1)
Veneto/CRUF (A, B1)
RER (A, B1)
UCSC GEMELLI (B1)
Hdir (A, B1)

NOMA (B1)
AOTMiT (A)
INFARMED (A, B1)
NSPHMPDB (A)
UniBA FOF (B1)
JAZMP (A, B1)
NIJZ (B2)
AQUAS (A, B1)
AEMPS (A)
AVALIA-T
(A, Strand B1 AC Lead)
OSTEBA (B1)
AETSA (A, B1)
AETS ISCIII (A)
MPA (A)
TLV
(A, Strand B1 AC Lead)
NICE
(A, Strand B2 AC Lead)
SNHTA (A, B1)



How to improve the quality of data generated during product lifecycle?

1) Initial evidence generation: Early Dialogues

Early Dialogues for pharmaceuticals

- Offer both multi-HTA and Parallel consultation with regulators (flexible approach)
- Set up of a Early Dialogue Working Party EDWP
  - HAS, G-BA, NICE, AIFA with RER, NIPN, ZIN with RIZIV INAMI
    Possible extension to Spain and Norway + Sweden
- Appoint scientific coordinator and rapporteur for each EUnetHTA ED

Early Dialogues for medical devices

- Two candidates identified, procedure, templates produced
- Launch expected Q3 2018

Early Dialogues: overview of the procedure

Letter of Intent	D -60
Applicant submits Draft Briefing Book	D-30
Written requests for Clarification sent to applicant	D-15
Final Briefing Book submitted	D 0
EUnetHTA list of issues sent to Applicant	D 32
Applicant's written answers	D 45
Applicant send slides	D 56
Face to Face meeting	D 60
Written recommendations	D 75

Early dialogues: For what technologies?

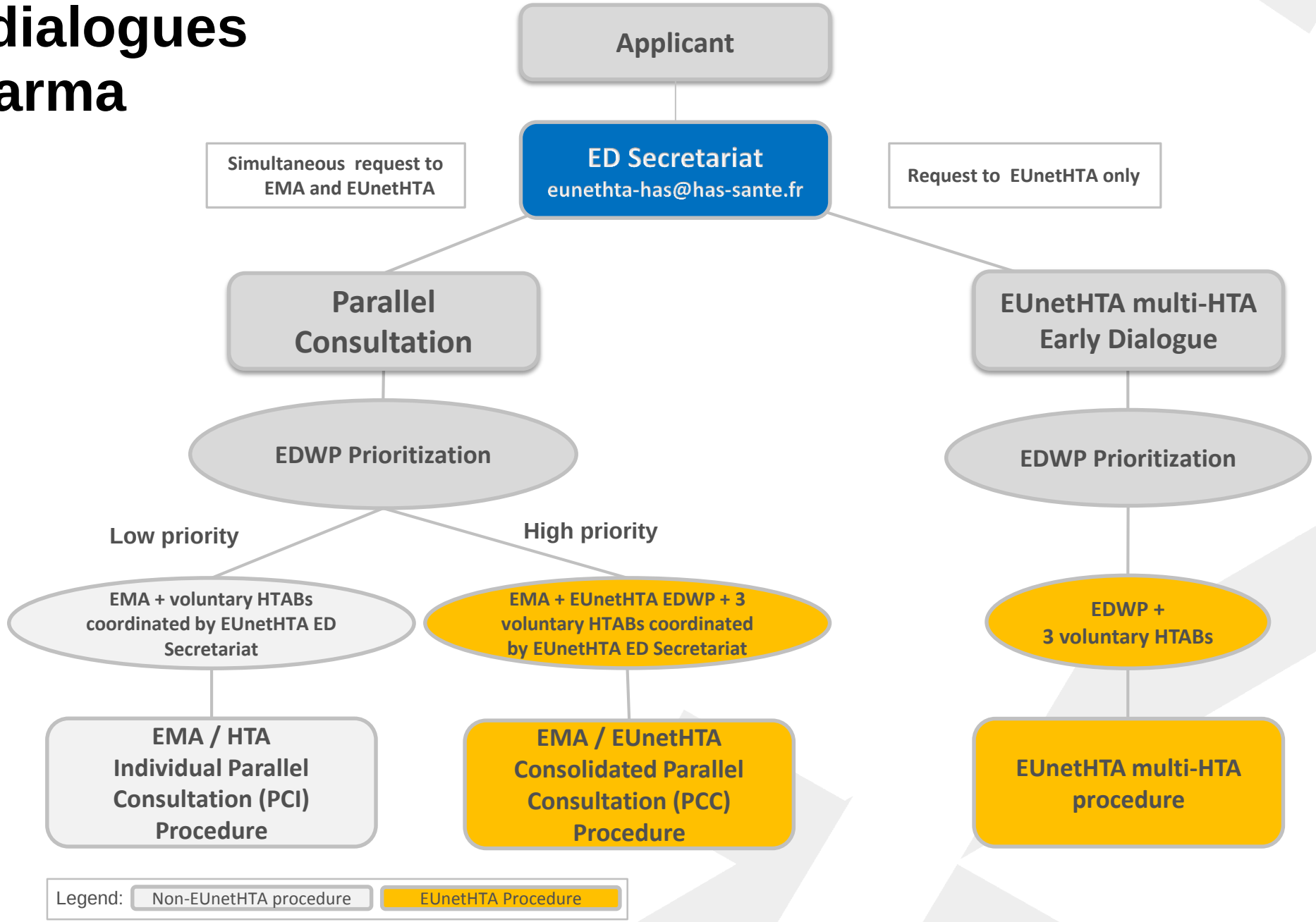
- **Pharmaceuticals:**
  Selection criteria for EUnetHTA EDs (with involvement of EDWP):
  - A new mode of action for the indication
  - AND targeting a life-threatening or chronically debilitating disease
  - AND responding to unmet need (no treatment or only unsatisfactory treatment available)

- **Medical devices:**
  Selection criteria for EDs:
  - MDs classified as class IIb and III, in vitro diagnostic and digital MDs with following criteria:
    - Unmet medical need
    - Potential impact on patients, public health, or healthcare systems

Patient involvement: testing various approaches

Approach	Patient contribution deliverables	Patient time	Use to date
Interview Individual Patients (living with the condition) in local language, collecting general feedback on the disease + answer to specific questions related to the dossier (Min: 2 countries)	- Minutes of the interview in annex - Mention of patient contribution in final EUnetHTA recommendations - Feedback questionnaire	~2 days of work	5 EDs with interview individual patients (France, UK, Spain)
Interview national Patient representative (living with the condition/carer) in local language collecting general feedback on the disease + patient representative position on applicant dossier	- Minutes of the interview in annex - Mention of patient contribution in final EUnetHTA recommendations - Feedback questionnaire	~5 days of work	7 EDs with interview of a German patient representative (German patients representative involved in any ED when G-BA participates)
Participation of EU patient representative (living with the condition/carer) to the overall ED process including interview with coordinator, F2F meeting, review final recommendation	- Minutes of the interview in annex - Review final EUnetHTA recommendations - Feedback questionnaire	~7 days of work	3 EDs with an EU patient representative participating to overall ED process

Early dialogues for pharma



Early Dialogues
Current status

May 2018

33 Letters of Intent

Requests	Therapeutic field (from letter of intent)
1	Auto-immune disease/dysfunction
12	Cancer
3	Neurodegenerative disorder
2	Vaccines (postponed)
1	Viral disease
14	Other (ex: asthma, hemophilia, migraine etc.)

16 Individual Parallel Consultations (PCI) With ~1-3 HTABs

13 EUnetHTA EDs
Involving EDWP
Multi HTA or PCC
5 Cancer
1 Neurodegenerative disorder
1 Viral disease
6 Other

7 Completed (as of 18/05)

2 withdrawn (by the company)
2 declined (procedure not followed)

Preview of next year
WP5A – Early Dialogues

- Composition of the EDWP
  - addition of Nordic (NOMA/TLV) and/or Spanish seat(s)?
- Explore development of tools for EDs
  - → Secretariat tools to manage high number of requests
  - → Training “new” ED participants especially those taking Scientific Coordination and Rapporteur roles for the first time
- Stabilize rotation schedule for Scientific Coordination responsibilities
- Conduct first non-pharma EDs
- Discuss involvement of HCPs
- New financing mechanism

How to improve the quality of data generated during product lifecycle?

2) Post-launch evidence generation (PLEG)

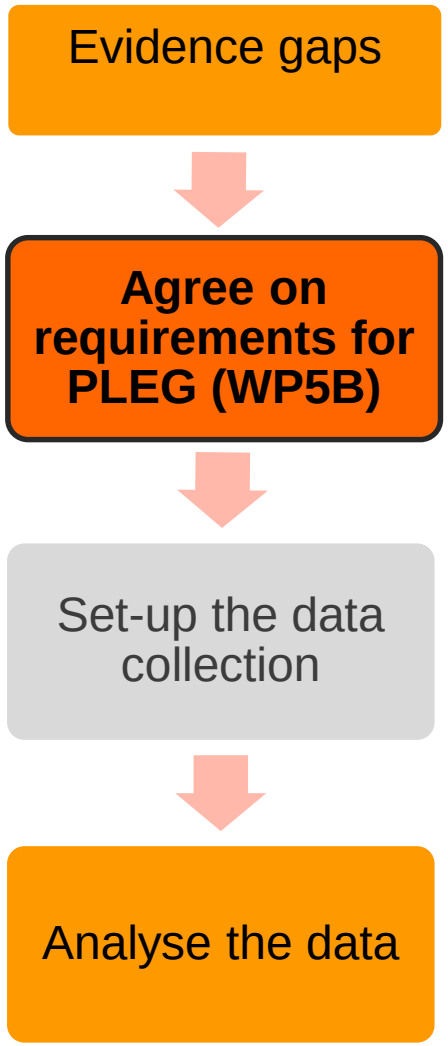
WP5 Strand B: 2 activities

- multi-stakeholder **cross-border pilots** on post-launch evidence generation**,** for drugs and non-drug technologies (strand B1)
- standards Tool for Registers in HTA (strand B2)

In order to:

- improve the quality of post-launch evidence (registries in particular)
- prepare future PLEG activities (confirm possible levels of collaboration ; develop procedures and tools)

Current status PLEG pilots



Multi-stakeholder cross-border pilots

Product specific pilots arising from HTA

- Based on WP5B activity centers proposals.
- Two ongoing pilots, one planned:
  - Orphan drug, AIFA
    Start: April 2018.
    7 partners participating.
  - Breast cancer, TLV
    Start: May 2018.
  - Expected end (both pilots) mid-2019.
  - Medical device – avalia-t
    Upcoming.

Disease/registry specific collaborative pilots

- Registry qualification exercise:
  - Following the EMA procedure for the Qualification of novel methodologies for drug development.
  - Pilot outcome from EUnetHTA side: Qualification **advice** on the topics discussed (quality aspects and registry data set).
- Two pilots carried out

Some challenges (and opportunities)

- **Product specific pilots:** topic selection and pilot conduct can be complex (differences in national PLEG timings and procedures)
- **Registries:** Working with existing registries may be challenging (heterogeneous situation)
  - Registry qualification exercise to be further defined: following the EMA procedure sometimes challenging, possibility for other cooperations (non-drug technologies)?
- **Global commitment ?**
  - Company engaging for Early Dialogue, Joint Assessment, PLEG ?

Thank you

Any questions?

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