Life cycle approach to improve evidence generation

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Introduction and objectives of WP5

The main objective 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.

► **Initial evidence generation**

Strand A: Early Dialogues (EDs)

- Based on previous experience, continue and improve the conduct of **EDs** for drugs and devices, including parallel advice with regulators, with contribution of patients and concerned stakeholders.
- Propose and implement a new financing system based on a fee-for-service approach

► **Post-launch evidence generation**

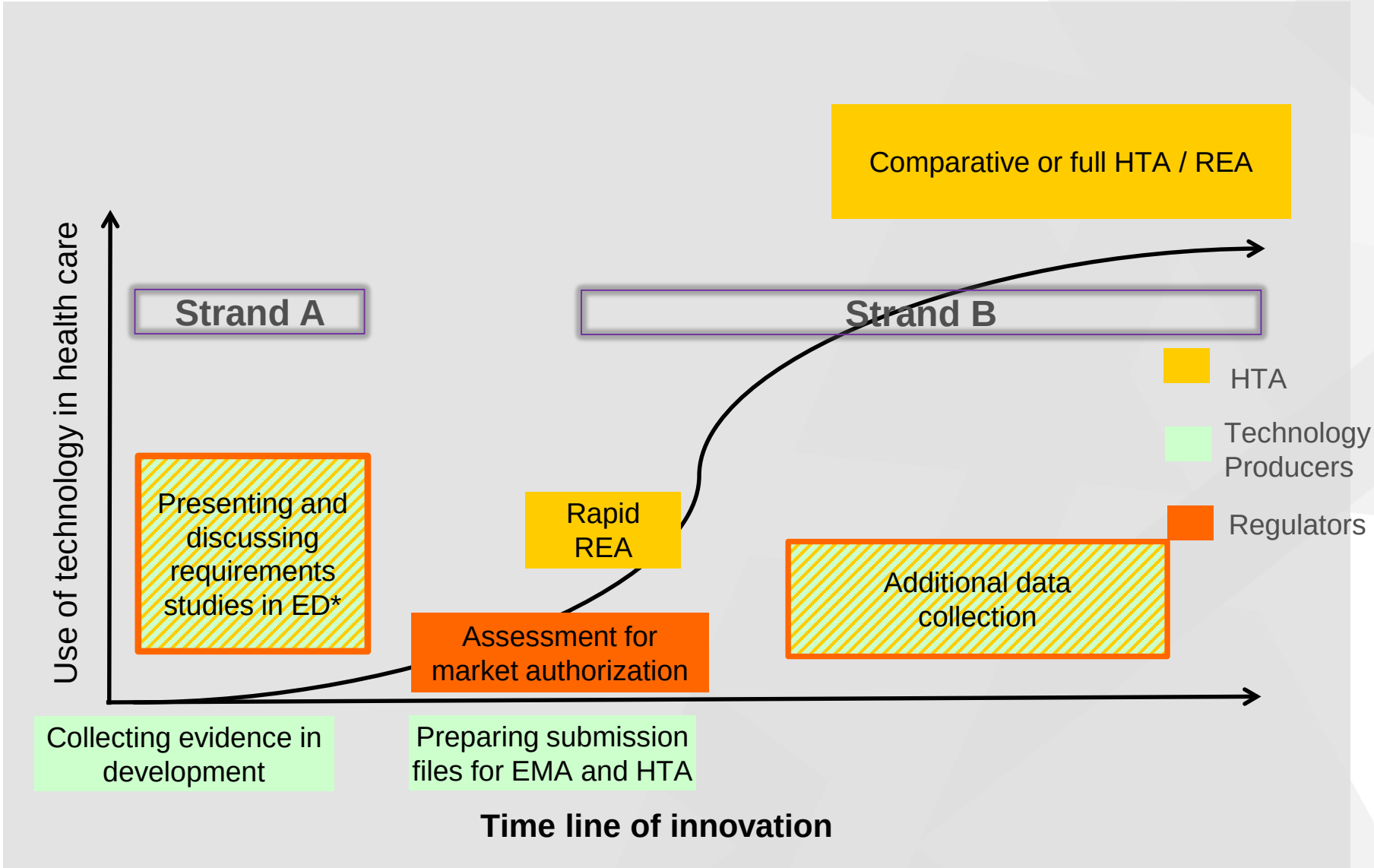
Strand B: Post-launch evidence generation (PLEG) and registries

- Improve the quality of post-launch evidence, with special focus on the use of registries as data source

→ Main activity: PLEG pilots (Strand B1)

→ Supporting activity: Standards Tool for Registries in HTA (Strand B2)

HTA in the life cycle of technologies



*Early dialogue

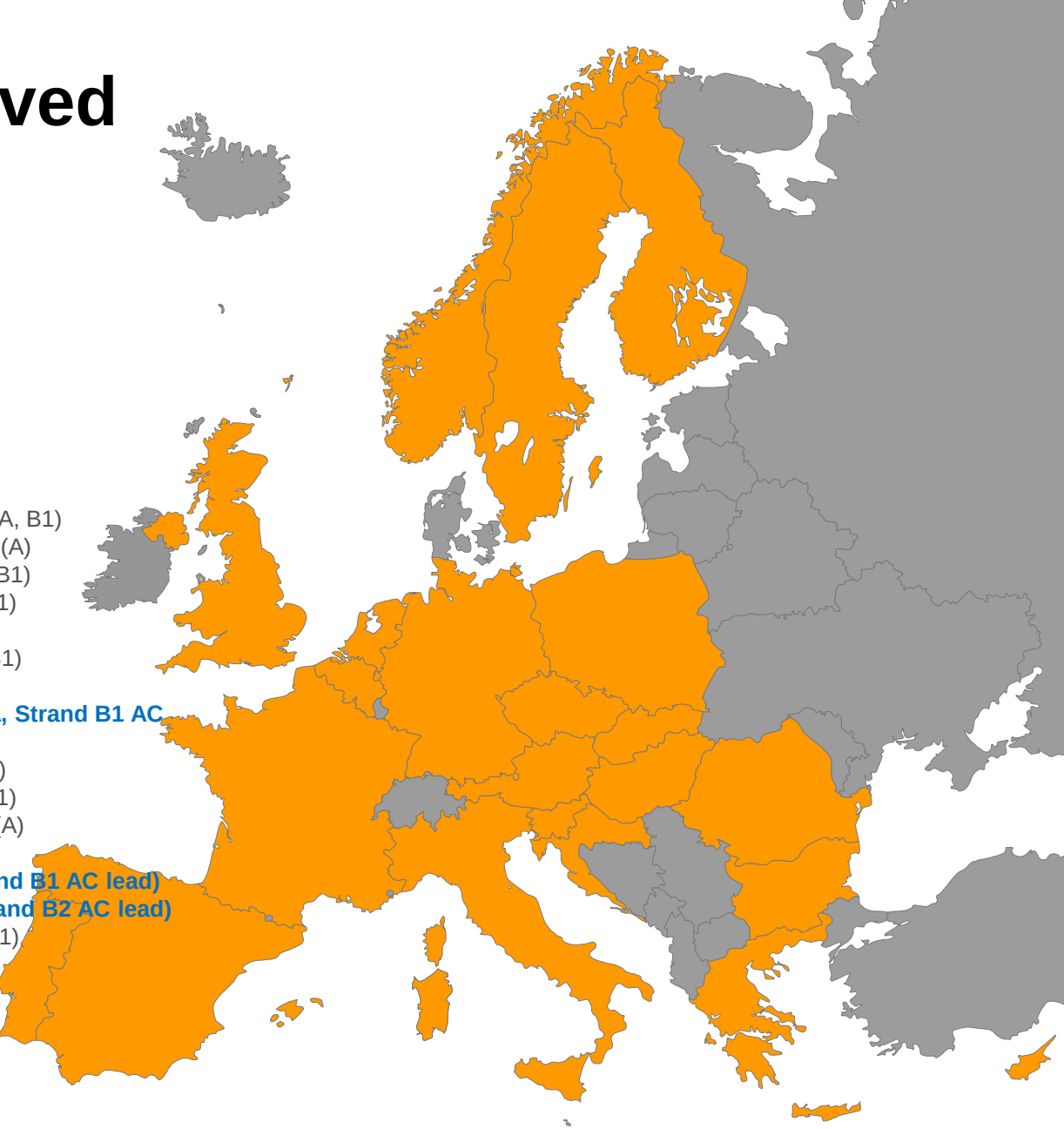
* Early Dialogue

Countries involved in WP5

- 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)

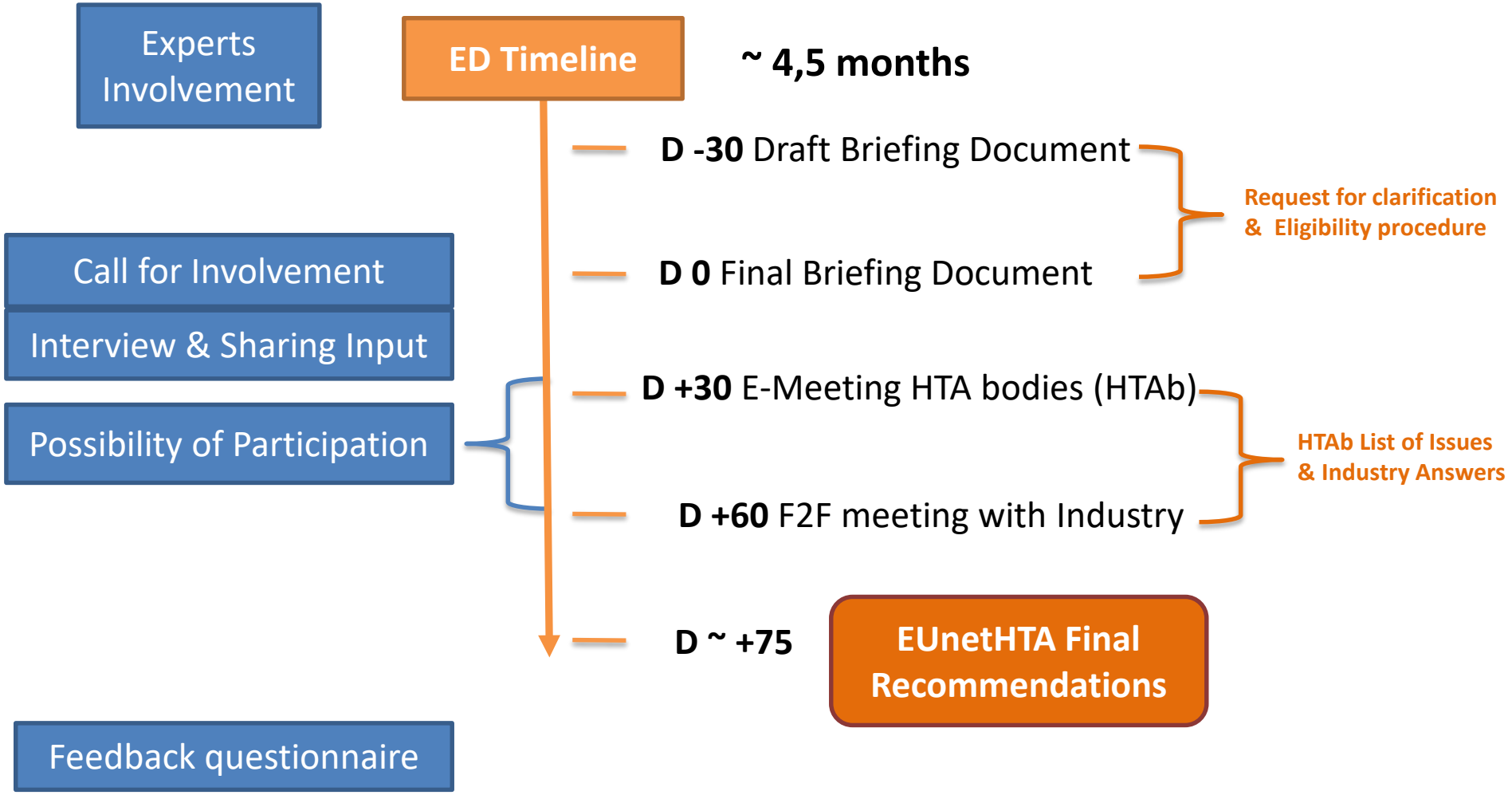
NOMA (B1)
AOTMiT (A)
INFARMED (A, B1)
NSPHMPDB (A)
UniBA FOF (B1)
JAZMP (A, B1)
NIJZ (B2)
AQUAS (A, B1)
AEMPS (A)
AVALIA-T (A, Strand B1 AC lead)
OSTEBA (B1)
AETSA (A, B1)
AETS ISCIII (A)
MPA (A)
TLV (A, Strand B1 AC lead)
NICE (A, Strand B2 AC lead)
SNHTA (A, B1)



EUnetHTA Early Dialogues
Objectives and Principles

- The advice given during a EUnetHTA EDMD:
  - Provides consolidated advice including for **both common advice** (where the participating HTABs are in agreement) but also allows room for **individual HTAB positions**;
  - Is **based on the global evidence generation plan submitted by the Applicant** in the EDMD Application and is valid only within this context;
  - Is **non-binding both for HTABs and for Applicants** as recommendations are based on the state of science at the time the advice is given;
  - **Does not predetermine the outcome of the assessment** performed later by the individual HTA agencies on that technology.

EUnetHTA EDMD main steps



Experimentation of a 3 pronged approach to expert involvement in ED

Approach	Patient contribution deliverables	HCP contribution deliverables
Approach 1: Individual patient/HCP - interviewed regarding the disease and their experience	• Minutes of the interview • Patient contribution visible in final EUnetHTA recommendations • Feedback questionnaire	• Minutes of the interview • Feedback questionnaire
Approach 2: Approach 1 + discussion with local HTAB regarding submission file (without applicant)	• Minutes of the interview • Patient contribution visible in final EUnetHTA recommendations • Feedback questionnaire	• Minutes of the interview • Feedback questionnaire
Approach 3: Expert; Approach 2 + discussion with all participating HTABs regarding the submission file and participation in the F2F meeting with the applicant	• Minutes of the interview • Share final EUnetHTA recommendations • Feedback questionnaire	• Minutes of the interview • Feedback questionnaire

Specificities of EUnetHTA ED

- **Centralised project management by the EUnetHTA ED Secretariat**

eunethta-has@has-sante.fr

- **Creation of EDMD WP**

– composed of AVALIA-T (ES), HAS (FR), NICE (UK), and RER (IT).

– primary responsibilities include:

  - Assessment all Early Dialogue requests for acceptability.
  - Provide feedback to the EUnetHTA ED Secretariat regarding procedural and template revisions.
  - Take turns acting as Scientific Coordinator and Rapporteur for EUnetHTA EDs

- **Priorisation process**

- **Cost currently covered by EUnetHTA or by fees for NICE.**
  - **In the future, new financing system based on fee-for-service approach**

EDMD Experience during JA3

- **3 Drafts of Briefing books submitted**
  - 1 nanotechnology in oncology
  - 1 MD and associated services in metabolic disease
  - 1 MD in cardiology
- **Only one ED conducted**
  - conducted to test the procedure with the participation of 8 HTAb
  - 4 clinical experts including one during closed HTAb meeting the morning of the F2F
  - no patient expert
- **2 procedures cancelled by the applicant during clarification phase**
  - Topics for clarification included:
    - Target population/ positioning
    - Functionality of the MD/procedure required for use
    - Regulatory status
    - Information on previous trials
    - Further detailed on proposed study

All documents available on

https://www.eunethta.eu/services/early-dialogues-for-medical-devices/

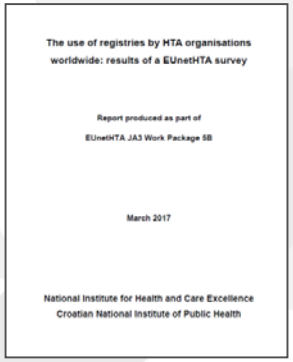
- EUnetHTA Multi-HTA Early Dialogues for Medical Devices Guidance Document
- EUnetHTA EDMD Briefing Book Template
- Submission deadlines for EDMD
- EUnetHTA Declaration of Interest and Confidentiality Undertaking (DOICU) Form
- EUnetHTA DOICU handling Procedure Guidelines

Questions about EUnetHTA EDs should be directed to the EUnetHTA ED Secretariat (eunethta-has@has-sante.fr).

WP5B: Registry quality standards (REQueST)

Objectives

- **Adapt** existing quality standards for registries* into a practical tool for use of registry data in HTA
- Build upon the work of PARENT Joint action (the Patient Registries InitiaTive)


The use of registries by HTA organisations worldwide: results of a EUnetHTA survey

Report produced as part of
EUnetHTA JA3 Work Package 5B

March 2017

National Institute for Health and Care Excellence
Croatian National Institute of Public Health

Highlights thus far

- Report on current use of registry data by HTA bodies
- **Registry Evaluation and Quality Standards Tool (REQueST)** draft
- Vision paper on the sustainable availability of REQueST draft
- Tool testing by three EUnetHTA partners (end Jan ‘19)

Next steps

- Production of the upgraded versions of REQueST and its vision paper (on-going
- **Public consultation on REQueST and its vision paper (June 2019)**
- **Production of final versions (Sep ‘19)**

*** Registries =** An organized system that collects, analyses, and dessiminates the data and information on a group of people defined by a particular disease, condition, exposure or health-related service, and that serves a predetermined scientific, clinical or/and public health (policy) purpose

WP5B: Pilots arising from HTA

Evidence gaps based on initial HTA

→ Based on national or Joint assessment

Agree on requirements for PLEG

→
- Definition of the **common research question** and the **minimum data set**
- Advice on methodology for data collection

Set-up the data collection

→ Done by national HTA in ongoing pilots

Organisation and financing of data collection out of EUnetHTA scope

Data Analyses

→ Compilation and analyses of common data

Re-Assessment

→ National or Joint re-assessment

WP4 WP5B

Identifying and developing tailored methodologies – how can Industry and EUnetHTA work together?