HTA cooperation in Europe – Major developments 2016-2019 Don’t miss your chance!

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CNA-CEF meeting November 2016, Paris

We’re in an exciting phase: there is a momentum to launch a key proposal in Europe

We’re in 2016 like we were back in 1993, with patients supporting the creation of the European Medicines Agency

Or like in 2008 when we were supporting the Commission Communication on Rare Diseases

And the proposal is

To create the **European Agency for Health Technology Assessment.**

No more, no less!

What is it about?

Health Technology Assessment HTA

- Health Technologies
  - “any intervention that can help promoting health, or the prevention, diagnosis or treatment of a chronic or acute disease, or rehabilitation of patients’ abilities”
- Aim: to inform the decision makers when deciding what to put in the healthcare basket (offer or care) or which health service to provide
  - Interface between science and decision (evidence based policy making)
- Domains :
  - **Clinical:** How does the intervention compare to other existing ones? Evaluation of the innovation
  - **Non-clinical**: economical, ethical, organisational, social aspects….

Examples of health technologies

A complex surgery intervention

- e.g. **Renal denervation** for treatment-resistant hypertension

A complex medical device

- e.g. **Biodegradable stents** for the treatment of refractory or recurrent benign **oesophageal stenosis**

A connected medical device

- e.g. a captor and a connected system to send data on pulmonary blood pressure to the clinic (HTAP)

Examples of health technologies (2)

A pharmaceutical

- e.g. **Ramucirumab** (with paclitaxel) for adult patients with advanced gastric of gastro-oesophageal junction adenocarcinoma

Organisation of care

- e.g. European References Networks in rare diseases and the evaluation of their added value
- e.g. HIV prevention strategies (Prep, PEP, and others)

Diagnostics tools

- e.g. genetic testing

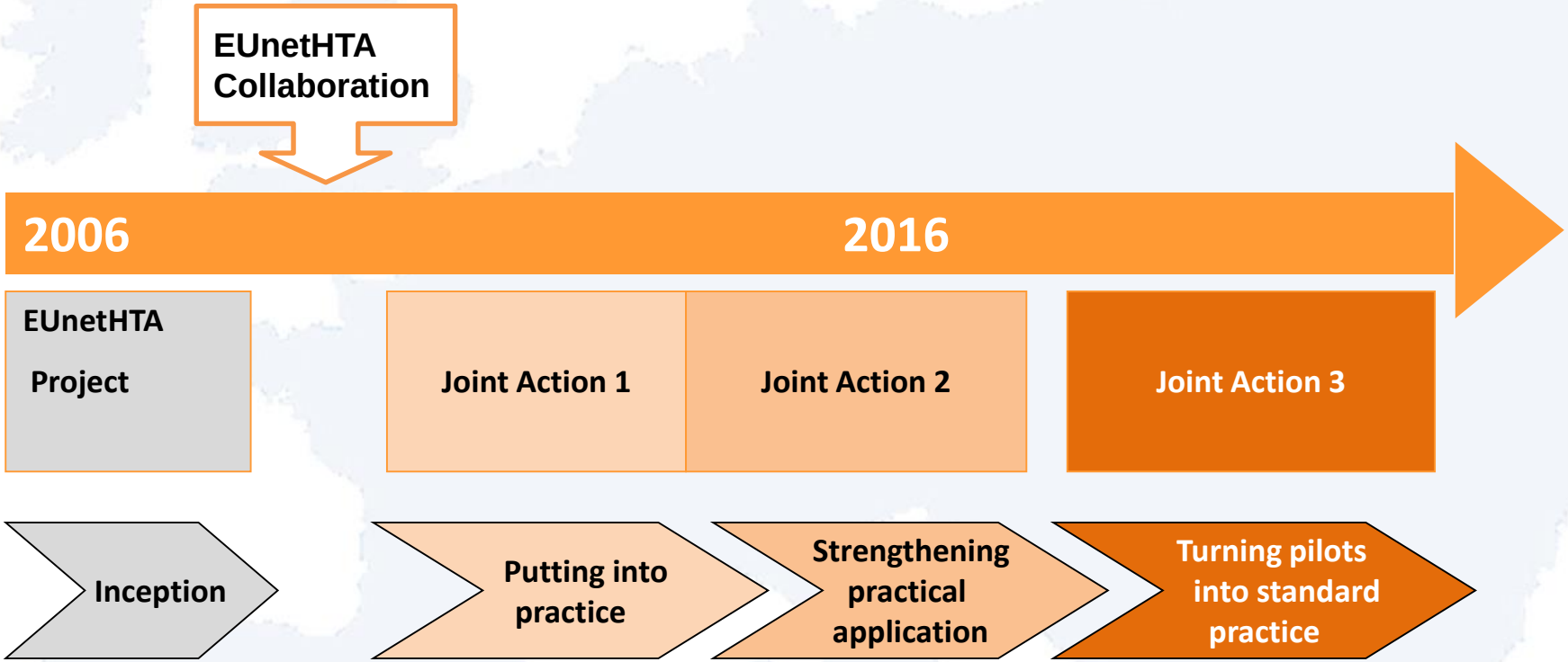
The 3 steps (pharmaceuticals)

Regulators: benefit/risks	HTA: Relative effectiveness	Reimbursement decision & pricing
Can the product work?	Does the product work and improve care?	Is society willing to pay?
In the context of a clinical trial 1 comparator	In clinical practice Compared to all other options	Based on REA and economic aspects

Different countries, different HTA practices

Data requirements in 8 countries + EUnetHTA

European Network for HTA EUnetHTA: 10 years already…

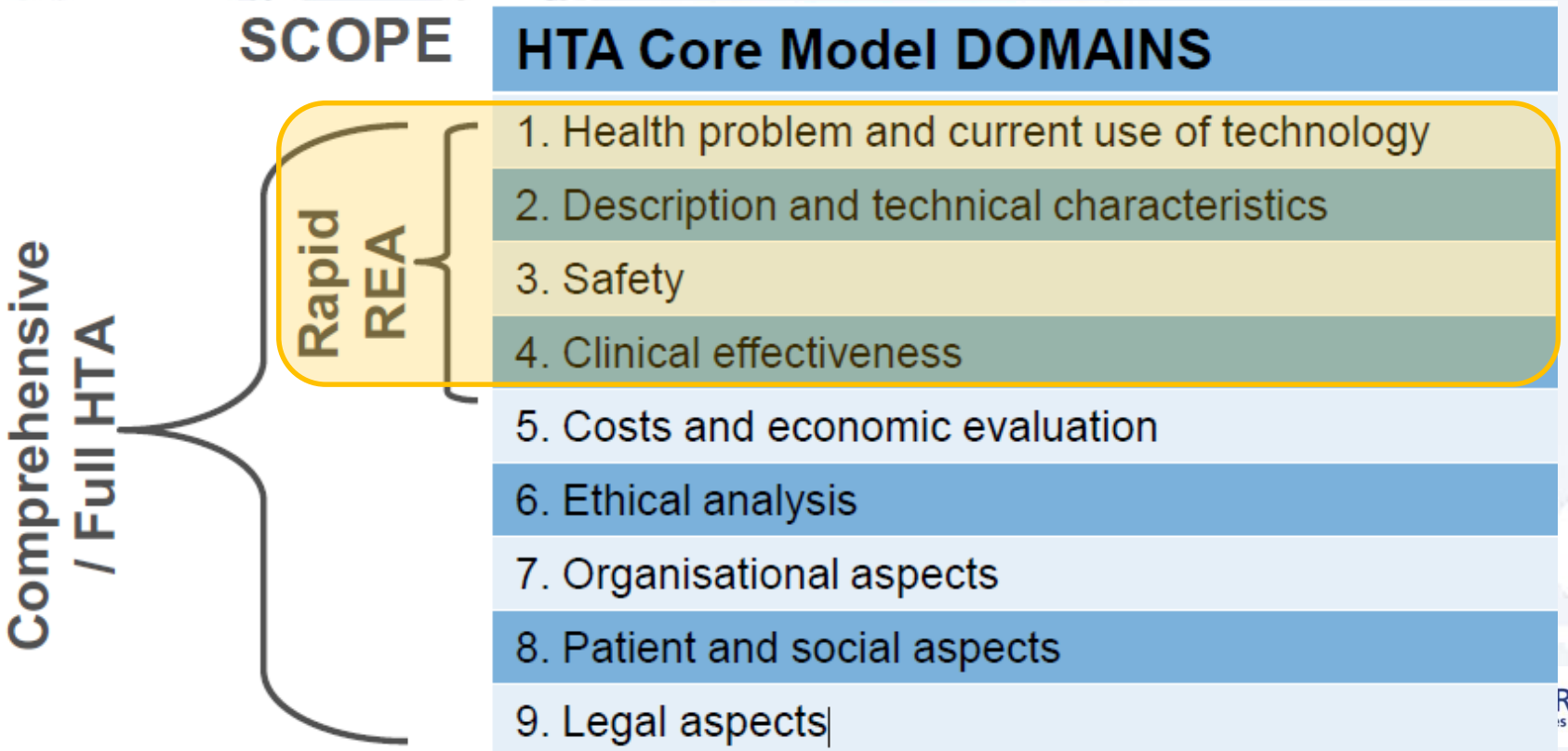


Credit: François Meyer, HAS

Joint Assessments

Two types:

- Rapid Relative Effectiveness Assessments (REA)
- Full assessment including non-clinical domains



Fair priority setting, HTA and/or appraisal

A fair HTA process should ensure	Publicity	Availability of opinions / decisions to the wider public for scrutiny
	Relevance	Stakeholders agreeing upon the "relevance" of the inputs for the opinion / decision
	Appeals	Objections and contributions to the revision of decisions
	Enforcement	"publicity", "relevance", "appeals" appropriately followed

HIQA. Guidelines for Stakeholder Engagement in HTA in Ireland.

Early Dialogue (*or: Scientific Advice*)

Aims:

- To reduce the risks that unappropriate data are submitted for HTA
- Scientific discussion between one or several developer(s) and HTA doers
- The developer: presents the planned clinical studies, asks questions (Can the approach provide the evidence needed for HTA in the future?)

What is discussed:

- Evaluation criteria (clinical ones, surrogates ones)
- Population(s) to be studied
- Choice of comparator(s)...

Agencies involved

- Regulators: national or European (EMA)
- HTA agencies (national level o European cooperation)

EUnetHTA and SEED: Collaborative approach

Exchanges between HTA bodies at each step

One HTA agency coordinates the process. Communications +++

- **Clarifications** on the proposal (Briefing book)
- **Key issues** to be discussed at the meeting
- Each agency shares its planned responses to the developer with other agencies
- Discussions between HTA bodies to align their **positions**
- Final responses in a joint document
- Patients participate. Proposal for a mentor at initial stages

Credit: François Meyer, HAS

Finding patients for HTA early dialogues 3-4 days (SEED/EMA/EUnetHTA) 13 patients invited for 22 seats (59%) 35 contacted (37%), 57 organisations, 284+ emails (+ phone)

Date	Condition	Type	Technology	Patients attended / contacted	POs contacted
18 Sept. 2014	Non-small C lung cancer	SEED	Medicine	0 / 1	1
8 Oct. 2014	Confidential	EMA-HTA	Medicine	1 / 2	1
3 Dec. 2014	Myasthenia Gravis	EMA-HTA	Medicine	0 / 3	2
15 Jan. 2015	Heart failure	SEED	Implantable device	2 / 2	2
22 Jan. 2015	Confidential	SEED	Medicine	2 / 5	5
12 Feb. 2015	Asthma	SEED	Medicine	1 / 4	11
13 Feb. 2015	Thyroid cancer	SEED	Diagnostic test	2 / 5	10
10 Mar. 2015	Discogenic back pain	EMA-HTA	Medicine	1 / 4	14
14 Apr. 2015	Implantable heart	SEED	Implantable device	1 / 2	2
29 June 2015	Sanfilippo syndrome	EUnetHTA	Medicine	1 / 4	4
7 July 2015	Haemophilia A	EMA-HTA	Medicine	1 / 2	2
7 Sept. 2015	Insulin dependent diab.	EUnetHTA	Device	1 / 1	3

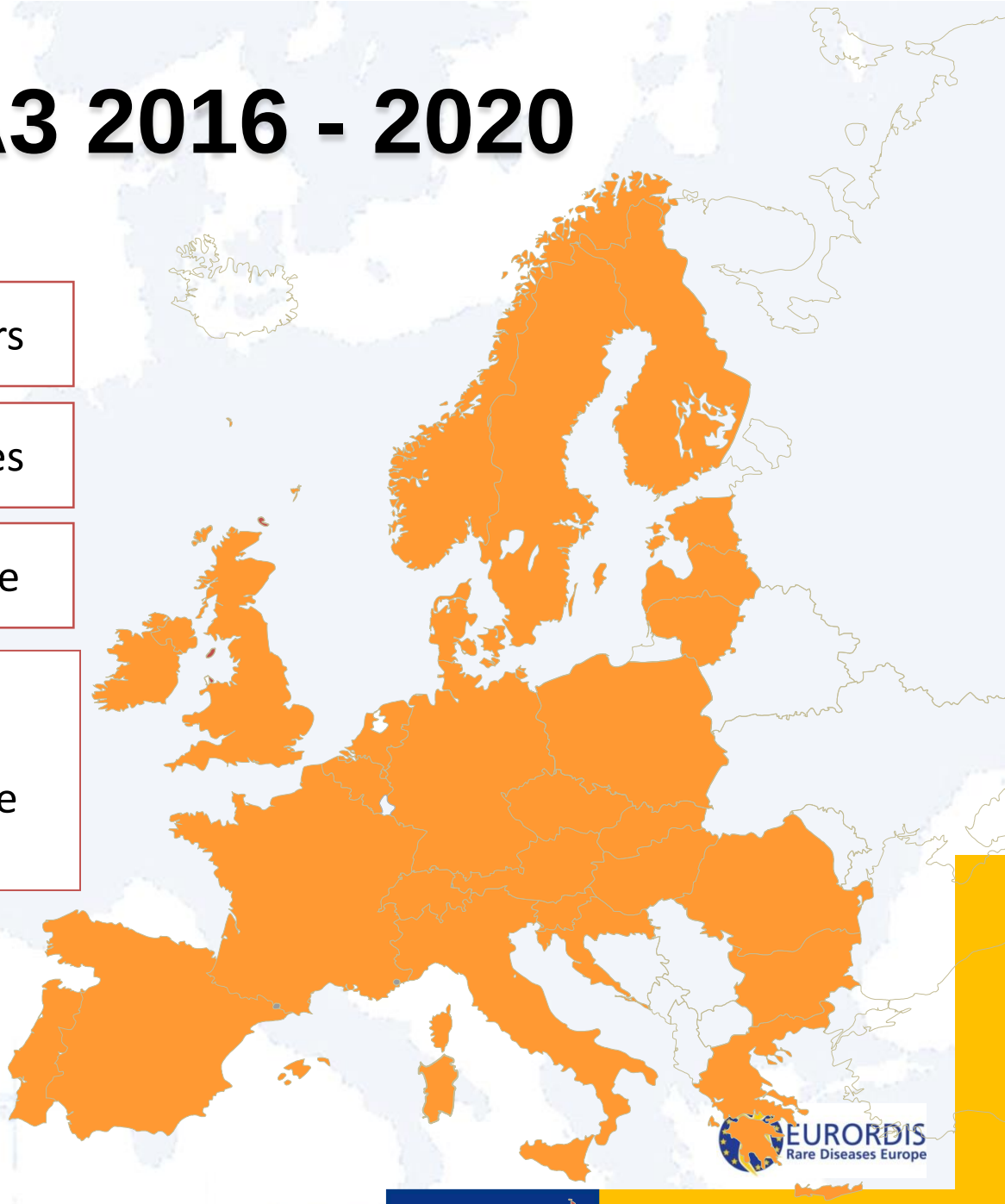
EUnetHTA JA3 2016 - 2020

79 organisations

- 61 partners
- 16 affiliates
- 1 associate

Organisations are national or regional agencies and not-for-profit organisations that produce or contribute to HTA

Project Coordinator: Dutch National Health Care Institute (ZIN)
12 Mio € EC + 8 Mio € MS



EUnetHTA Joint Action 3

Objective: to define and implement a sustainable EU cooperation on HTA, on a voluntary basis and well funded

Joint assessments:

- 37 on pharmaceuticals, 43 on medical devices
- Return on investment: time gained, less duplication

Early dialogues

- New funding: fee for service?
- **Additional evidence to be generated** when patient access starts

Organisation and governance

DG Santé and CHAFEA

EUnetHTA Assembly

Executive Board

Workpackage 1 Coordination - Directorate Dutch Health Care Institute

Workpackage 2 Dissemination	Workpackage 3 Evaluation	Workpackage 4 Joint Assessment	Workpackage 5 Evidence	Workpackage 6 Quality management	Workpackage 7 Implementation
Lead: ISCIII	Lead: TLV	Lead: NIPHNO Co-lead: LBI ZIN	Lead: HAS Co-lead: GBA	Lead: IQWiG Co-lead: KCE	Lead: NICE Co-lead: Agenas
Spain	Sweden	Norway	Austria	Netherlands	Germany
United Kingdom	Belgium	Croatia	Cyprus	Czech Republic	Denmark
Finland	France	Greece	Hungary	Ireland	Latvia
Malta	Poland	Portugal	Romania	Slovakia	Slovenia
Italy	Estonia	Lithuania	Bulgaria		

EURORDIS Rare Diseases Europe

Important issues / limits

National use of joint work

Industry willingness to play

Contribution of patients in joint work

- Scoping
- Assessment
- Reporting
- Early dialogues
- Post-launch evidence generation
- Methodological guidelines…

Limit: lack of sustainable funding

Commission Initiative

- The current model of HTA cooperation at EU level is **not financially sustainable over time**
- This is because the funding of the current Joint Action - through the Public Health Programme - ends in 2020
- The Third Health Programme is not expected to fund recurrent actions/interventions, including Joint Actions.
- Without EU funding, it is unlikely that the cooperation would continue.

EC consultation on Policy options

Option 1	Option 2	Option 3	Option 4	Option 5
Status quo – voluntary cooperation until 2020	Long-term voluntary cooperation (beyond 2020)	Cooperation through the collection, sharing and use of common tools and data	Cooperation on production of joint REA reports	Cooperation on production of joint Full HTA reports

Key characteristics	Option 1 The status quo –voluntary cooperation on HTA (until 2020)	Option 2 Long term voluntary cooperation on HTA (beyond 2020)	Option 3 Cooperation on collection, sharing and use of common tools and data	Option 4 Cooperation on the production of joint REA reports	Option 5 Cooperation on the production of joint full HTA reports
Regulatory	Non-legislative	Non-legislative	Legislative	Legislative	Legislative
Participation of HTA bodies and industry	Voluntary	Voluntary	Compulsory (tools) Voluntary (HTA)	Compulsory (tools) Voluntary / compulsory (HTA)	Compulsory (tools) Voluntary / compulsory (HTA)
Uptake joint output	Voluntary	Voluntary	Compulsory for tools	Compulsory for tools and REA	Compulsory
Financing	Largely depending on EU budget Ending 2020	Largely depending on EU budget Long-term	Mixed funding model (EU budget + MS + industry contribution) Long-term	Mixed funding model (EU budget + MS + industry contribution) Long-term	Mixed funding model (EU budget + MS + industry contribution) Long-term
Main joint output					
a. Common Tools/templates	(✓)	(✓)	✓	✓	✓
b. Joint REA	(✓)	(✓)	(✓)	✓	✓
c. Joint Full HTA	(✓)	(✓)	(✓)	(✓)	✓
d. Early Dialogue	(✓)	(✓)	✓	✓	✓

(✓) Partial delivery ✓ Full delivery

Next steps

- Inception Impact Assessment: public consultation here (21 October 2016 – 13 January 2017)
  - And 3 studies (two mapping studies on existing differences, one study on the impact of each of the options) → Mid 2017
  - Report on impact and decision on next steps: End 2017
- Possible proposal for legislative changes **2018!**
- High participation of the public needed to backup MEPs report and Commission's proposal
- EURORDIS will prepare responses to the consultation, each EURORDIS member should send a response

Opportunities

- Legislative proposal with EU agency backed by Commissioner Andrukaitis / EC
- Legislative proposal with EU agency backed by MEPs
- Legislative proposal with EU agency backed by some MS
- What about us? Lobbying +++++++

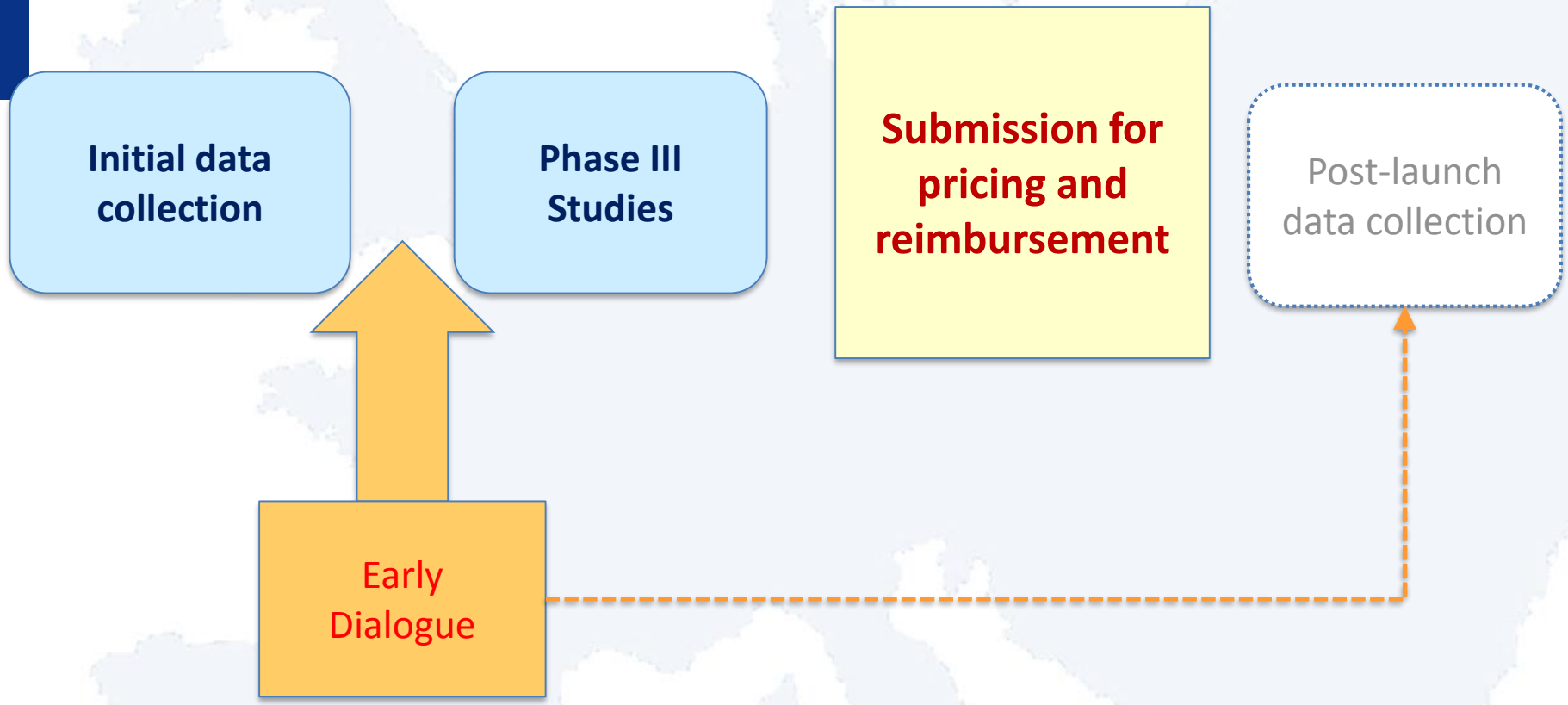
Possibility to create a European Agency for HTA: a launch window 2016-2017

Unlike for the EMA where only Aids groups participated 1995-2000, all patients can already give their opinion

For the time being: **HTA Network call for expression of interest** to you!

And EUnetHTA expects your participation

ED: Timing



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