A vision on voluntary European HTA collaboration

Wim Goettsch
Coordinator EUnetHTA JA3
Zorginstituut Nederland

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European Commission

European collaboration on HTA

Technologies become more ‘international’

Patients become more ‘European’

Decrease duplication on HTA assessments

Increase consistency between different national HTA assessments

- Variety in type of assessments seems to be common: does this lead to different assessment results?
- See example oncological treatments

Recommendation oncology drugs (MA 2011-2013) per country

Abbreviated indication	Brand name (generic)	HTA recommendation					
		GEMANY	THE NETHER-LANDS	FRANCE	ENGLAND/ WALES	SCOTLAND	POLAND
Bone metastases from solid tumours	1. Denosumab	Not assessed	Equal benefit	Added benefit Equal benefit	Positive	Not assessed	Negative
Breast cancer	2. Eribulin	Equal benefit Equal benefit	Added benefit	Added benefit	Negative	Negative	Negative
	3. Pertuzumab	Added benefit	Not assessed	Added benefit	Not assessed	Negative	Positive
Colorectal cancer	4. Aflibercept	Added benefit	Not assessed	Equal benefit	Negative	Negative	Positive
Gastric cancer	5. Tegafur / gimeracil / oteracil	Not assessed	Lesser benefit	Lesser benefit	Not assessed	Positive	Negative
Melanoma	6. Ipilimumab	Added benefit	Added benefit	Added benefit	Positive	Negative	Positive
	7. Vemurafenib	Added benefit	Added benefit	Added benefit	Positive	Negative	Positive
	8. Dabrafenib	Equal benefit	Not assessed	Equal benefit	Positive	Positive	Positive
Non-small-cell lung cancer	9. Afatinib	Added benefit Added benefit Equal benefit Lesser benefit	Not assessed	Equal benefit	Positive	Positive	Positive
	10. Crizotinib	Equal benefit	Not assessed	Added benefit	Negative	Negative	Negative
Prostate cancer	11. Cabazitaxel	Added benefit Added benefit	Added benefit	Added benefit	Negative	Negative	Negative
	12. Enzalutamide	Added benefit Added benefit	Not assessed	Added benefit	Positive	Positive	Positive
	13. Abiraterone	Added benefit	Equal benefit	Added benefit	Positive	Negative	Positive
Renal-cell carcinoma	14. Axitinib	Added benefit	Not assessed	Added benefit	Positive	Negative	Positive

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Relative effectiveness assessments of oncology medicines for pricing and reimbursement decisions in European countries. Kleijnen S, Lipska I, Leonardo Alves T, Meijboom K, Elsada A, Vervölgyi V, D'Andon A, Timoney A, Leufkens HG, de Boer A, Goettsch WG. Accepted by Annals of Oncology

Pharmaceutical Forum 2008 Recommendations

- Decisions on reimbursement at national level
- Relative effectiveness assessment (REA) vs cost-effectiveness assessment (CEA)
- Exchange of REA criteria/information
- Implementation of agreed good practice principles for REA
- More effectively done by existing networks

Directive 2011/24/EU on cross-border healthcare

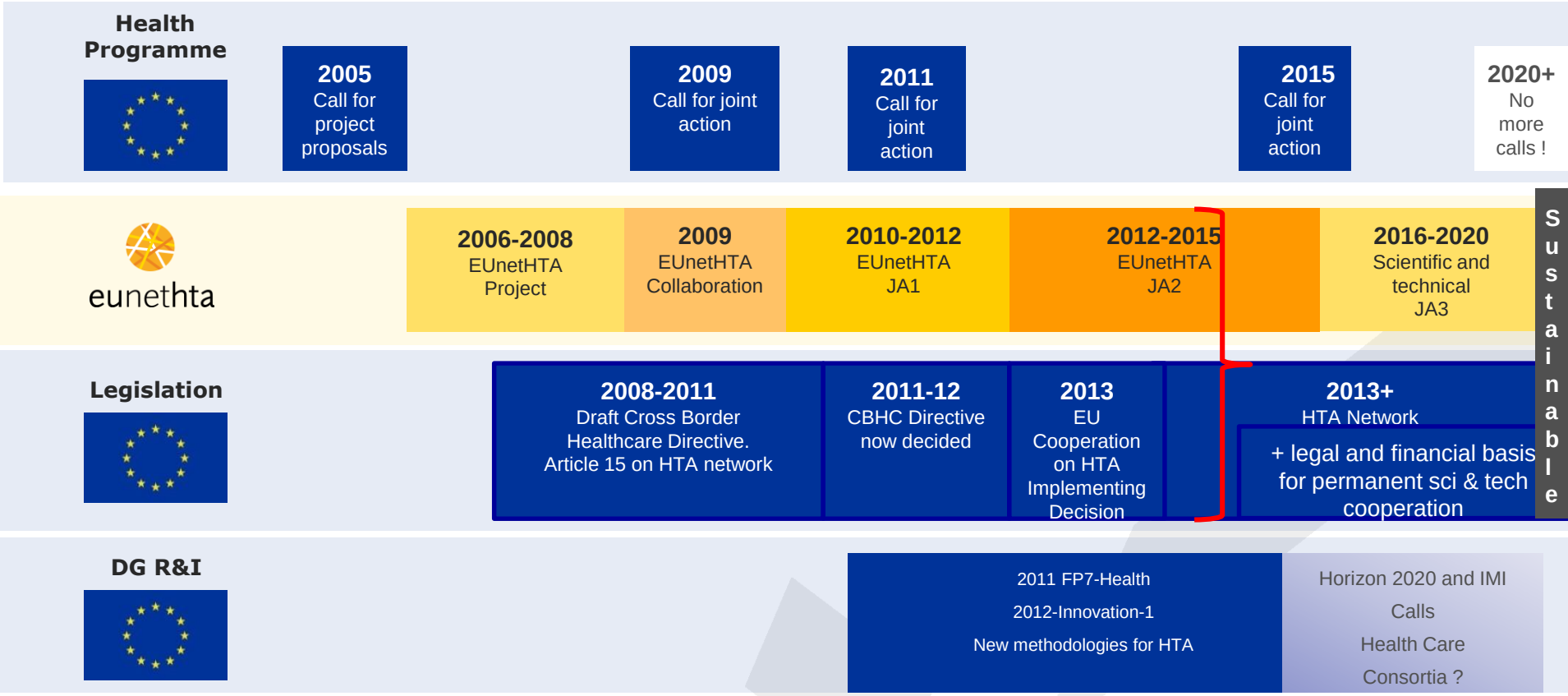
The Directive provides a detailed legal framework focused on three main areas:

- rules concerning the reimbursement of costs of cross-border healthcare
- responsibilities of the Member States with regard to cross-border healthcare
- cooperation between healthcare systems

EU Objectives in HTA Article 15 Directive 2011/24:

- Support cooperation between national HTA Authorities
- Support MS in the provision of objective, reliable, timely, transparent , comparable and transferable information […] to enable effective exchange of information
- Avoid duplication of assessments

The timeline of reaching a sustainable and permanent HTA cooperation in Europe



Possible key benefits of collaboration on HTA

- **Quality**
- **Consistency**
  - May also indirect influence decisions and support price negotiations
- **Timeliness**
  - Earlier access if added value (and value for money) is proven
- **Efficiency**
  - Reduce duplications

Consistency
Differences and similarity across Europe

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Relative Effectiveness Assessment of Pharmaceuticals: Similarities and Differences in 29 Jurisdictions

Sarah Kleijnen, MSc[1,2,], Elisabeth George, PhD[3], Scott Goulden, MSc[3], Anne d'Andon, MD[4], Pauline Vitré, PD, MSc[4], Boguslawa Osińska, MSc[5], Rafal Rdzany, PhD[5], Steffen Thirstrup, MD, PhD[6], Belen Corbacho, MSc[7], Bence Z. Nagy, MSc[8], Hubert G. Leufkens, PhD[2], Anthonius de Boer, MD, PhD[2], Wim G. Goettsch, PhD[1,2]*

[1]*College voor zorgverzekeringen, Diemen, The Netherlands;* [2]*Division of Pharmacoepidemiology and Clinical Pharmacology, Faculty of Science, Utrecht Institute for Pharmaceutical Sciences, Utrecht, The Netherlands;* [3]*The National Institute for Health and Clinical Excellence, London, UK;* [4]*Haute Autorité de santé, Paris, France;* [5]*Agency for Health Technology Assessment, Warsaw, Poland;* [6]*Institute for Rational Pharmacotherapy, Copenhagen, Denmark;* [7]*Andalusian HTA Agency, Seville, Spain;* [8]*Hungarian National Institute for Quality and Organizational Development, Budapest, Hungary*

ABSTRACT

Consistency

What is the overlap between joint and national assessments?

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Can a Joint Assessment Provide Relevant Information for National/Local Relative Effectiveness Assessments? An In-Depth Comparison of Pazopanib Assessments

Sarah Kleijnen, MSc[1,2,], Mohammed Fathallah, MSc[3], Michiel W. van der Linden, MD, PhD[1], Piet Vancraeynest, MD, MScBiostat[4], Bachir Dahmani, PhD[5], Angela Timoney, MSc, MPH[6], Anthonius De Boer, MD, PhD[2], Hubertus G. Leufkens, PharmD, PhD[2], Wim G. Goettsch, PhD[1,2]*

[1]National Health Care Institute, Diemen, Netherlands; [2]Faculty of Science, Division of Pharmacoepidemiology and Clinical Pharmacology, Utrecht Institute for Pharmaceutical Sciences, Utrecht, Netherlands; [3]University of Utrecht, Utrecht, Netherlands; [4]National Institute for Health and Disability Insurance, Brussels, Belgium; [5]National Authority for Health, Paris, France; [6]Scottish Medicines Consortium and Strathclyde Institute of Pharmacy and Biomedical Sciences, University of Strathclyde, Glasgow, United Kingdom

ABSTRACT

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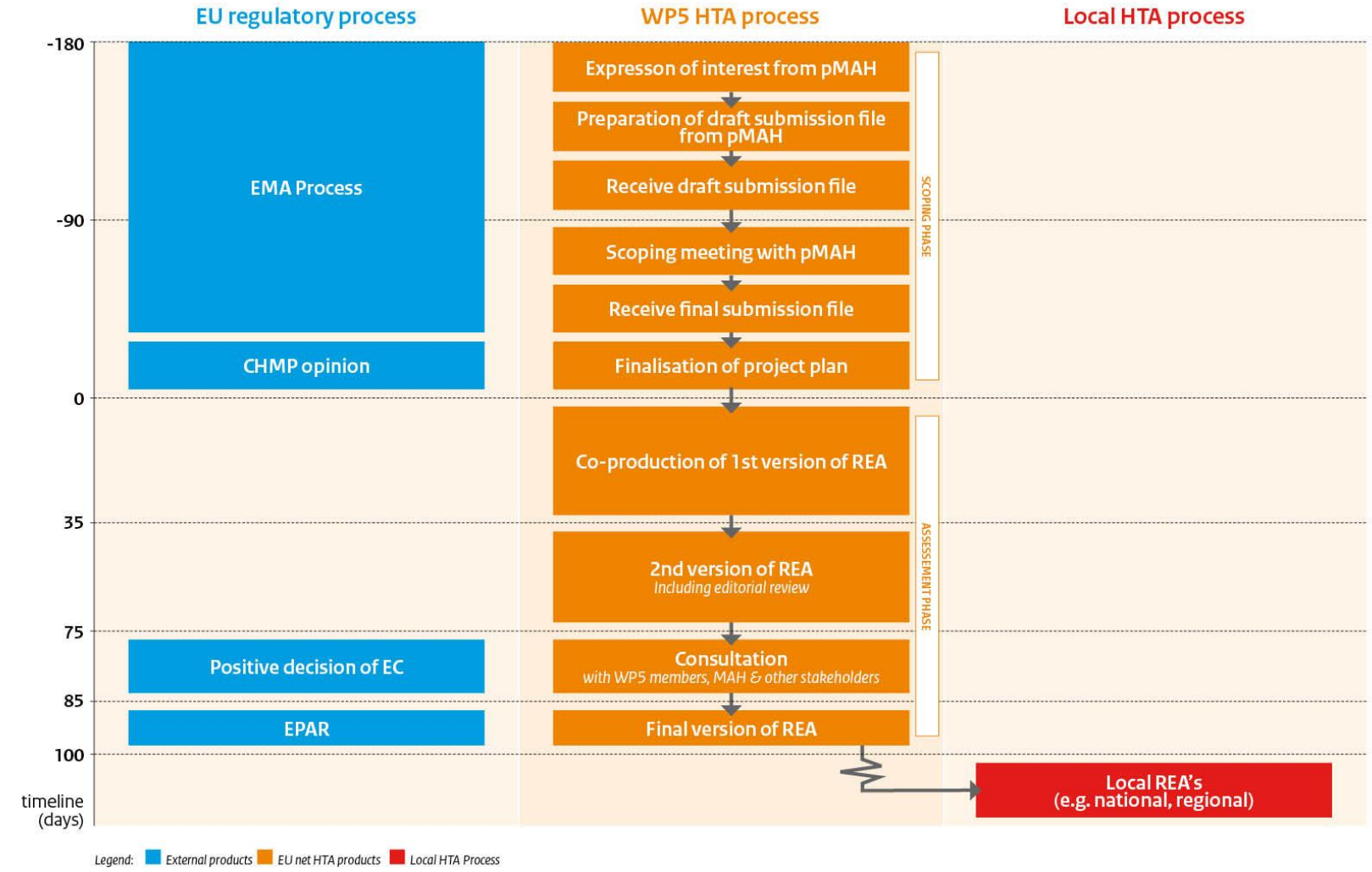
Timeliness

Process for Rapid REA of Pharmaceuticals*

Figure 1: Schematic overview of the organisation of the process of the pilots - General Overview

It should be noted that these graphs represent the ideal picture; however, divergence is very possible for specific joint REA's



Efficiency
Joint pilots on REA of pharmaceuticals 2013-2015

First pilot

- Zostavax for prevention of Herpes Zoster (Sanofi-MSD), authors are ZIN (NL) and A. Gemelli (Italy). Published in September 2013

Second pilot

- Canagliflozin for treatment of diabetes type 2 (J&J), authors are FIMEA (Finland), AAZ (Croatia) and Regio Veneto (Italy). Published in February 2014

Third pilot

- **sorafenib for advanced thyroid carcinoma (Bayer), authors are AIFA (Italy) and IMFARMED (Portugal). Published in March 2015**

Fourth pilot

- **ramucirumab in combination with paclitaxel for previously treated advanced gastric and gastro-oesophageal junction cancer (Eli Lilly), authors are NOKC (Norway) and AAZ (Croatia). Published in March 2015**

Fifth pilot

- Vorapaxar for cardiovascular complications after MI (MSD), authors are HAS (France) and Ministry of Health (Slovakia). Published in June 2015

Sixth pilot

- Review of new Hepatitis C treatments. Authors are KCE and RIZIV (Belgium), HVB (Austria), AAZ (Croatia), A. Gemelli (Italy). Planned publication in December 2015

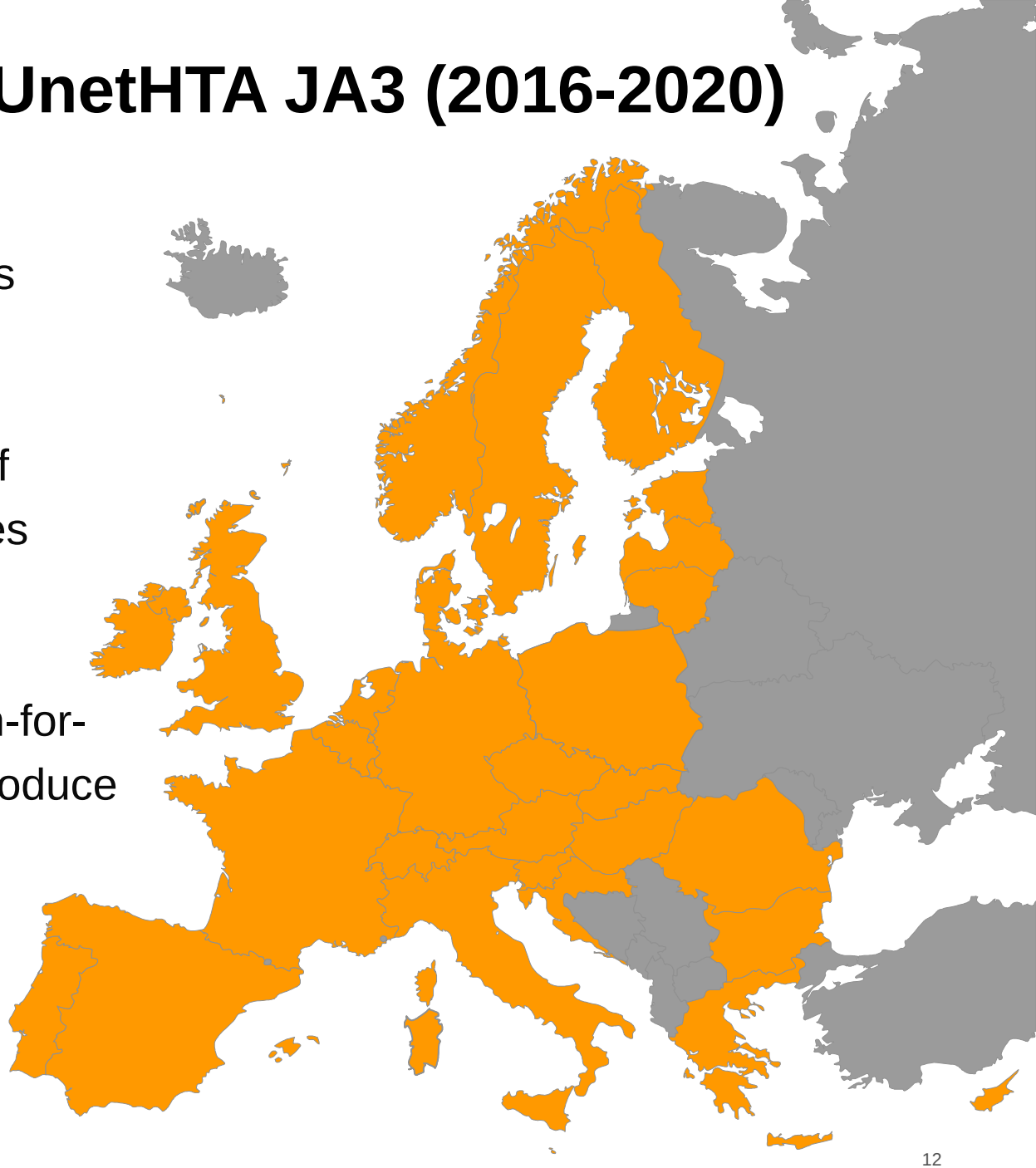
Participants in EUnetHTA JA3 (2016-2020)

EUnetHTA Partners and Collaborative Stakeholders

77 Partner organisations designated by Ministries of Health and affiliated entities

Includes large number of regional agencies and non-for-profit organisations that produce or contribute to HTA

ZIN will be the coordinator



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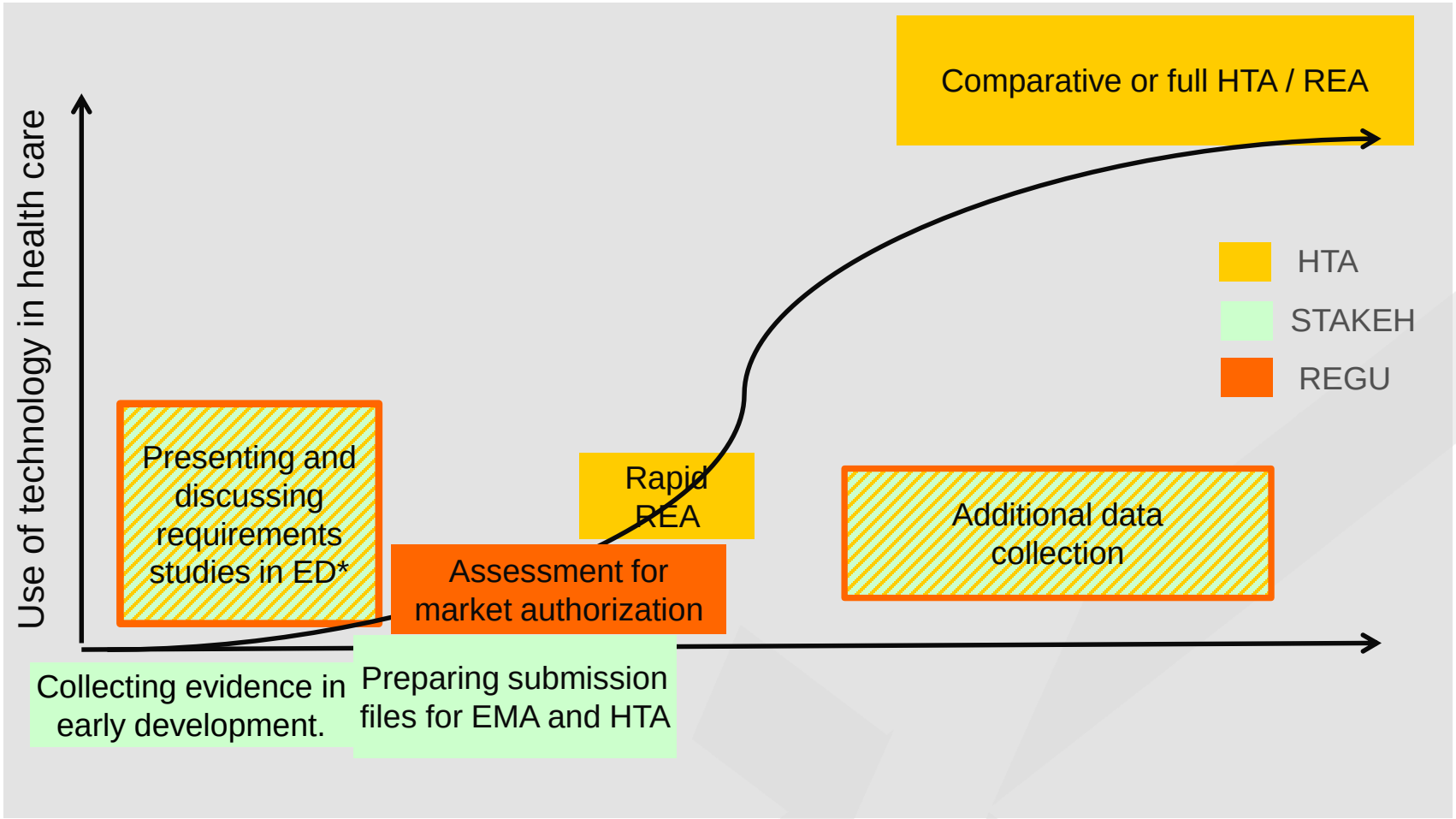
HTA in the life cycle of technologies



*Early dialogue

Summary of activities in EUnetHTA JA3

- **WP4 Produce joint and collaborative HTA reports:**
  - For pharma 37 rapid REA and for other technologies 43 rapid REA
  - Horizon scanning
- **WP5 Evidence Generation**
  - early dialogues (joint HTA or parallel/joint with regulators)
  - additional data collection linked to several activities (adaptive pathways, MEA, etc)
- **WP6 Quality Management**
  - Provides quality management for EUnetHTA products
  - Further development of electronic tools if necessary
- **WP7 National implementation and impact**
  - Supports Member States to implement reports in national setting
  - Measure impact of joint work

More active involvement of stakeholders (in particular patients)

- **Political/strategical level:**
  - These activities will be moved to the HTA Network

- **Methodology/processes**
  - By experts from stakeholders in stakeholder advisory groups (SAGs), comparable as in JA2

- **Activities on the level of single/multiple health technologies**
  - By experts from stakeholders in prioritization/topic selection, scoping and assessment
  - Funding may be available for some stakeholder reps such as patient representatives and clinicians

Conclusions on voluntary HTA collaboration in Europe

- **Structural production of joint REA reports is possible**
  - Large production of this joint REA reports between 2016-2020
  - Should lead to the structural collaboration after 2020
- **Voluntary participation is necessary**
  - There is (and will be) no legal remit to make these assessments mandatory now
  - But, due to the resource issues at national HTA level, it is expected that Member States will participate and implement in national practice
- **Questions on the nature and conclusiveness of the REA reports**
  - Currently only provides the presentation and assessment of scientific evidence
  - Will it have some form of conclusion on added clinical benefit in the future?
- **What about joint cost-effectiveness reports?**
  - Some Member States and stakeholders also support this type of collaboration
  - Other Member States and stakeholders are reluctant.

Thank you

Any questions?