EUnetHTA
Future of Pharmaceutical Joint Clinical Assessments

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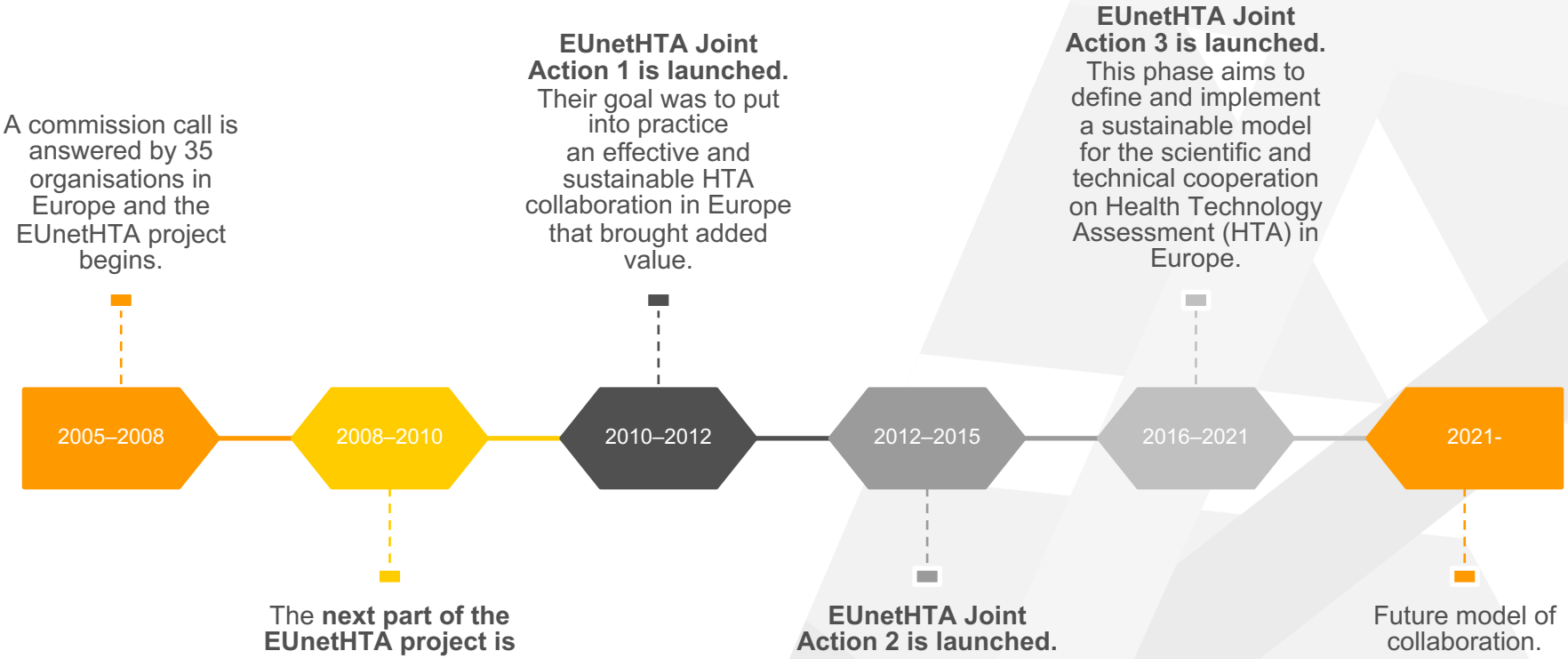
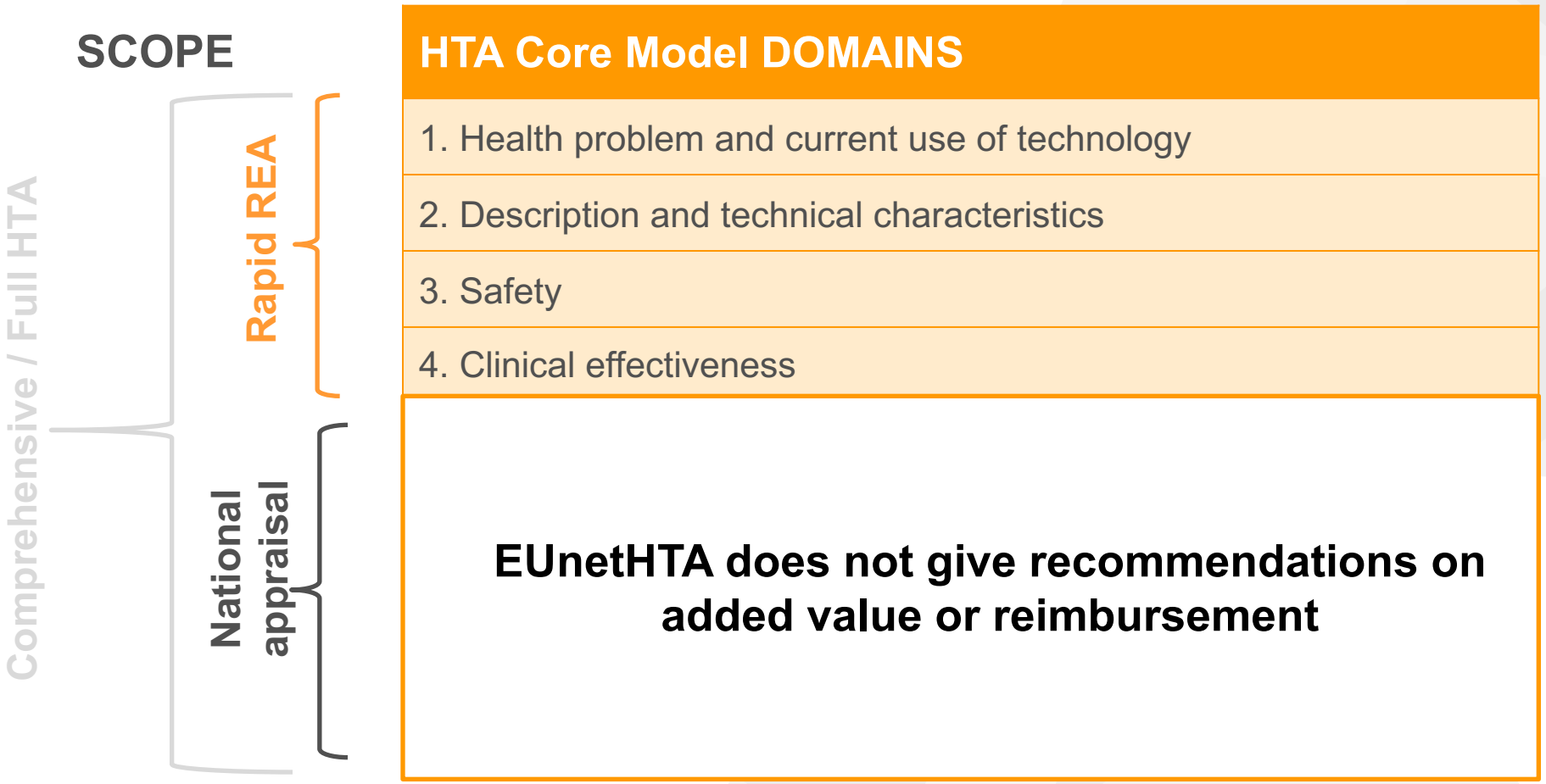
The history of EUnetHTA



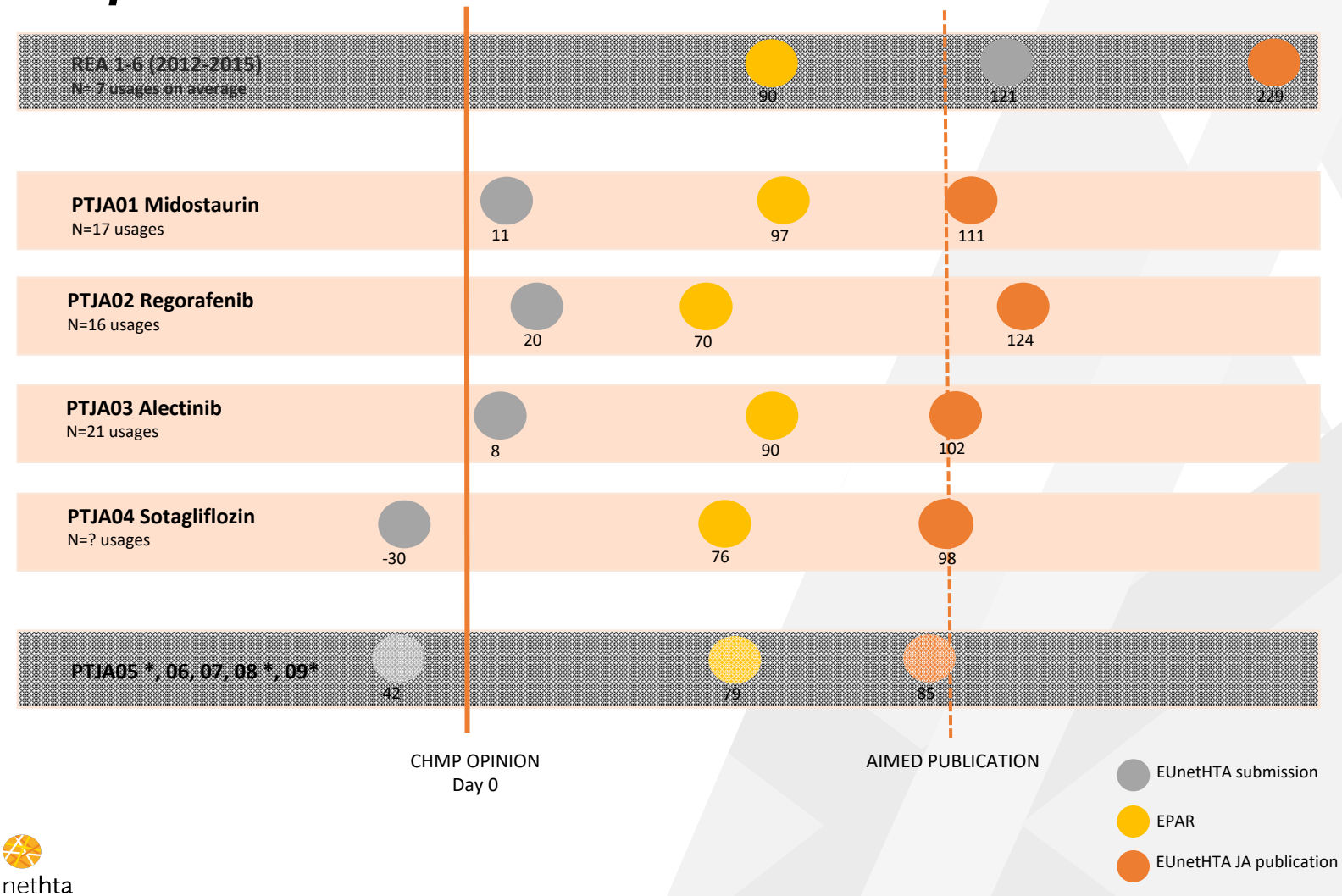
Pharmaceutical Joint Assessments JA3

Project ID	Title	Authoring team
PTJA01 **11/2017**	**Midostaurin** for Acute Myeloid Leukaemia (AML)	**Finland**, Norway *Sweden, Netherlands, France, Spain, Germany*
PTJA02 **10/2017**	**Regorafenib** for hepatocellular carcinoma (HCC)	**France**, Portugal *Croatia, Switzerland, Finland, Austria, Hungary, Spain*
PTJA03 **01/2018**	**Alectinib** for ALK+ advanced NSCLC	**Sweden**, Austria, Croatia *UK, Italy, Spain, Hungary*
PTJA04 **06/2019**	**Sotagliflozin** for Type 1 Diabetes Mellitus	**Sweden**, Netherlands, Ireland *Spain, Switzerland, Latvia, Portugal, Poland*
PTJA05	**Enasidenib** for relapsed or refractory AML	**Norway**, Spain *France, Italy, Switzerland, Scotland, Malta*
PTJA06	**Polatuzumab** vedotin for relapsed/refractory diffuse large B-cell lymphoma (DLBCL)	**Germany**, France *Czech Republic, Finland, Sweden, Portugal*
PTJA07	**Ustekinumab** for moderately to severely active ulcerative colitis (UC)	**Croatia,** Poland, Sweden *Italy, Hungary, Spain, Switzerland*
PTJA08	**Siponimod** for secondary progressive multiple sclerosis (SPMS)	**Portugal**, Ireland *Italy, Netherlands, Spain*
PTJA09	**Brolucizumab** for neovascular (wet) age-related macular degeneration (AMD)	**Finland**, Spain *France, Poland, Italy, Austria*
PTJA10	**Crizanlizumab** for Sickle Cell Disease (SCD)	**Netherlands**, Spain *France, UK, Slovenia*
PTJA11	**Cefiderocol** for gram-negative infections	**Italy**, Norway *France, Germany, Spain*
PTJA12	*Establishing assessment team*	
PTJA13	*Establishing assessment team*	

EUnetHTA HTA Core Model®



Pharma REA Production
Experiences so far



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Pharma REA production
Trend in timelines

- Increase implementation for national assessment/appraisal
  - PICO survey for EU scope Joint Assessment (JA)
  - EUnetHTA prioritisation List
  - JA available close after Market Authorisation

- National assessment/appraisal often starts after Market Authorisation
  - JA published within 2-3 weeks after EPAR
  - Aim: publish even closer after EPAR

Advantages of EUnetHTA Joint Clinical Assessment

- Head start on national HTA- submission work
  - by preparing EUnetHTA submission dossier
- One application for European Joint Clinical Assessment

- National HTA agencies influence on scope/PICO
- Joint Clinical Assessment
  - Allows flexibility for national context where needed
- Timely availability after Market Authorisation
- Predictable and consistent European HTA process
  - Quality Assurance via tools, templates and SOPs
  - Central project management by EUnetHTA

How to use EUnetHTA assessment nationally? *Example ZIN*

- Request Ministry of Health for assessment by Zorginstituut
  - Following positive CHMP opinion
  - Hand in dossier, including EUnetHTA submission file

- Dossier requirements
  - EUnetHTA submission file: complements ‘pharmacotherapeutic dossier’
  - Additional requirements:
    - ‘GVS dossier’: justify place of drug in extramural drug reimbursement system (‘Geneesmiddelen VergoedingsSysteem’)
    - Budget Impact Analysis (BIA) dossier
    - Pharmaco-economic dossier (if ‘added therapeutic value’ is claimed and BIA > 10 million)

- Advised by an independent expert committee

EUnetHTA & Beneluxa
Conceptualisation in Dutch setting

Scoping

National/ Regional input on relevance PICO(S)

Joint Clinical Assessment

Heterogeneity between MS in PICO

To be treated as systematic review
- ➢ Verification of eligibility for national setting

National/ Regional Appraisal

- Short report Dutch / Beneluxa scope & conclusion
- If needed, add:
  + GRADE
  + CEA
- Followed by Beneluxa proces if necessary

D -210/180 → Start = CHMP = d0 → End = d90 = ~close after EPAR

Thank you!

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Timelines Joint Assessment dependent on CHMP