From National HTA to Joint Clinical Assessment: Exploring Similarities and Differences in Comparator and Outcome Selection Across Six European Health Technology Assessment Agencies



Anne Willemsen, Roisin Adams, Keltoum Merroune, Stephanie Said

ISPOR Europe 2026

Universiteit Utrecht

Pharmacoepidemiology &
Clinical Pharmacology

Zorginstituut Nederland

Meet the panel



Anne Willemsen
PhD Candidate &
JCA SG chair
ZIN, Netherlands



Dr. Roisin Adams
Head HTA Strategy
& Chair HTACG
NCPE, Ireland



Keltoum Merroune
JCA Ad Hoc
Representative
HAS, France



Dr. Stephanie Said
EU HTA coordination &
Chair JSC SG
GBA, Germany

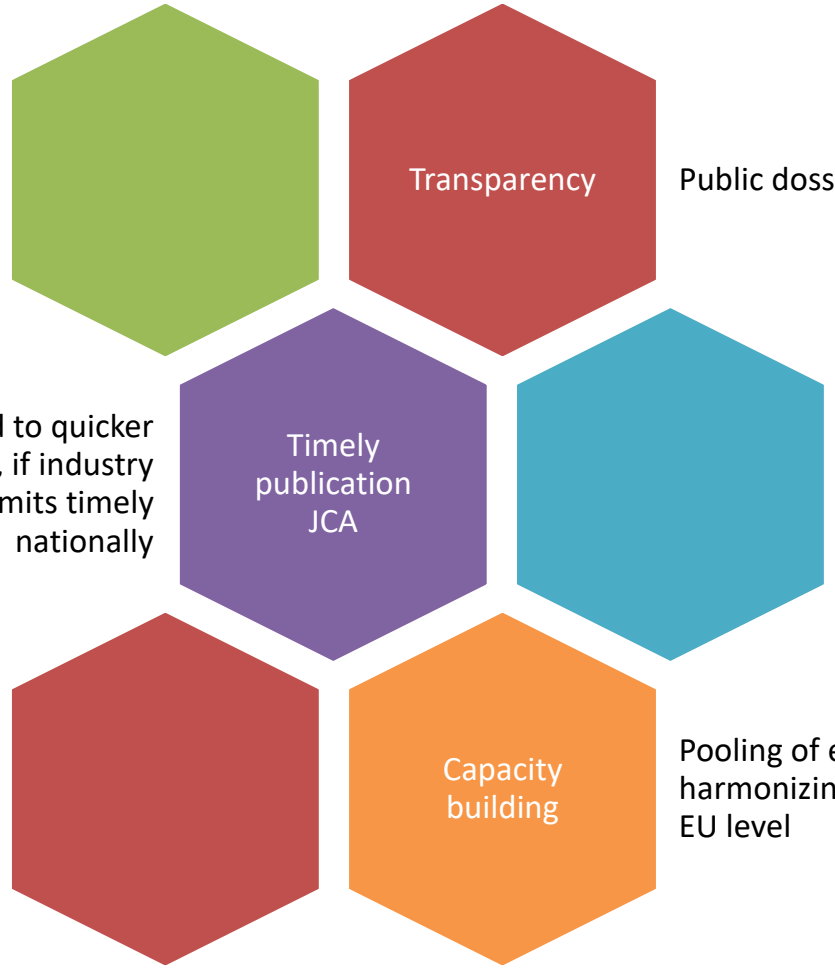
Joint Clinical Assessments – Facts and numbers

- What is a JCA <u>& what is it not!</u>
  - Jointly produced by 2 MS, clinical part only
  - Parallel timeline to MAA, yet separate procedure
  - Relative effectiveness & relative safety & uncertainties
  - **No conclusions on added value**

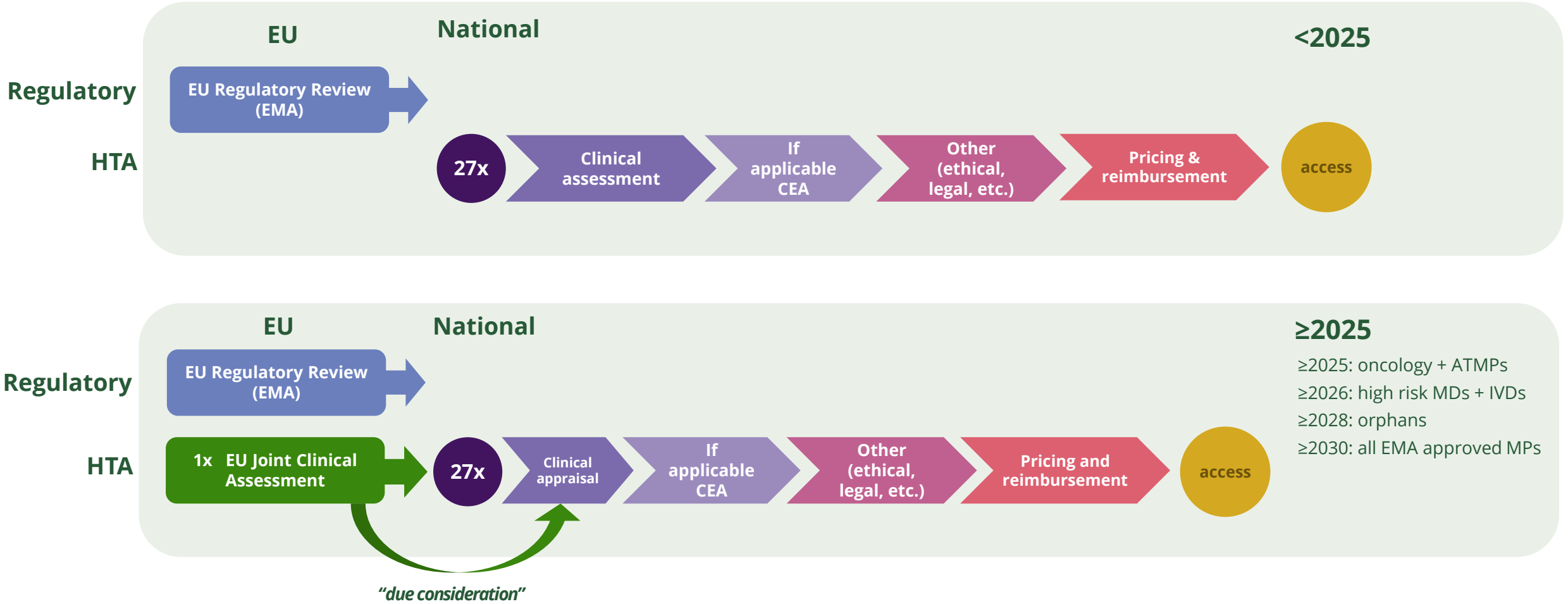
- 27 initiated JCA* since the start of the HTAR
  - 5 published; 4 discontinued
    - 1 withdrawn from EMA and 3 incompliant dossiers
  - 18 ongoing JCA
  - Also Orphan Designations (about half)

- 16 different MS took assessor and co-assessor roles
  - **19 different HTA bodies!**
- 79 experts selected in total for JCA
  - 46 % clinical expert, 43% patients, 11% carers

** date: 15-10-2026*

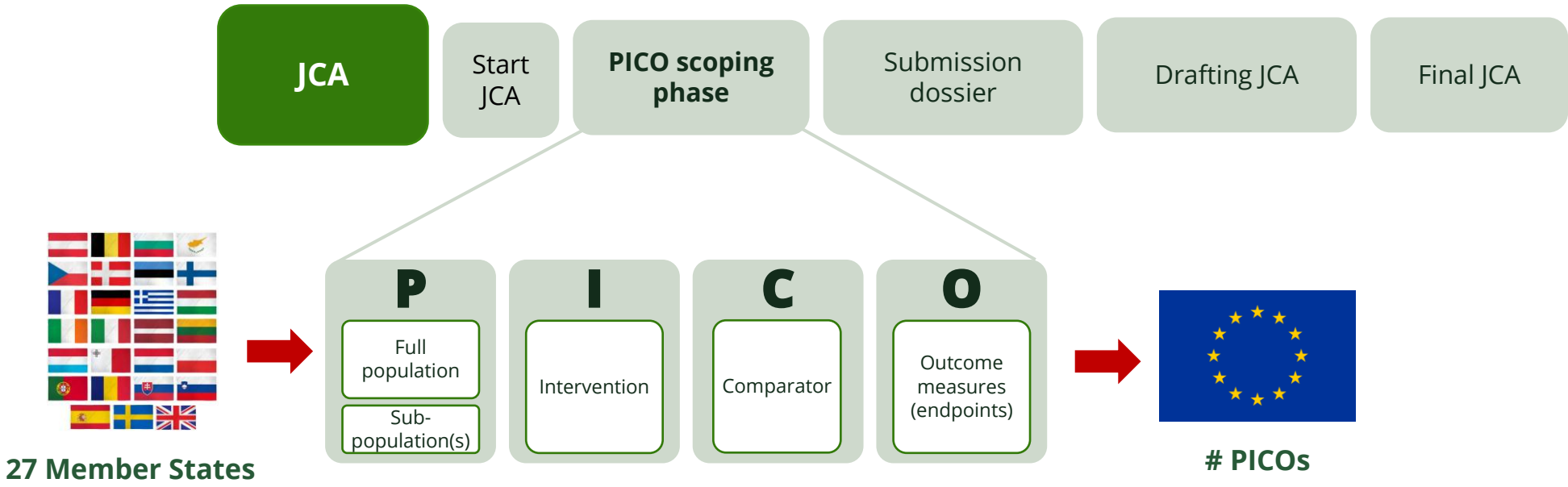


EU HTA Regulation: what has changed?

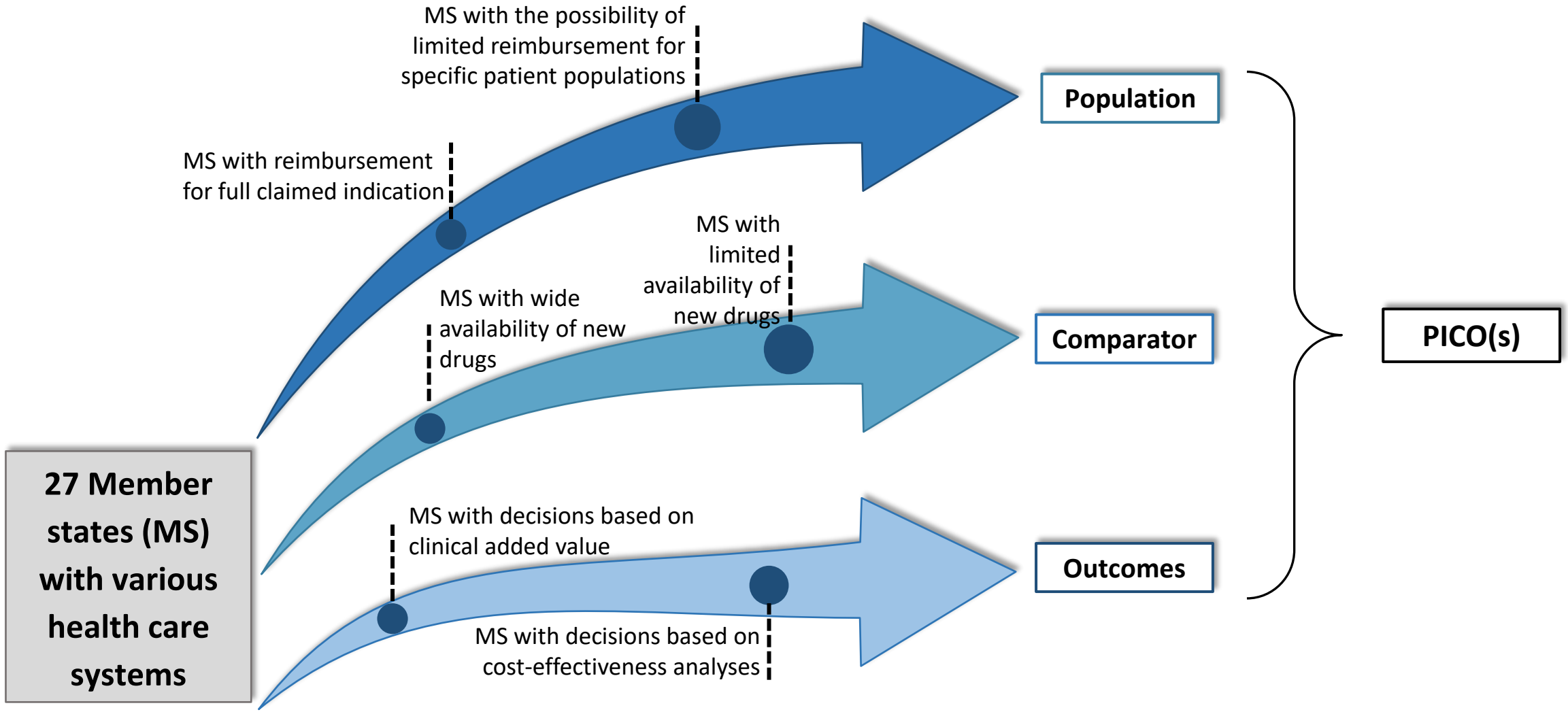


JCA scoping

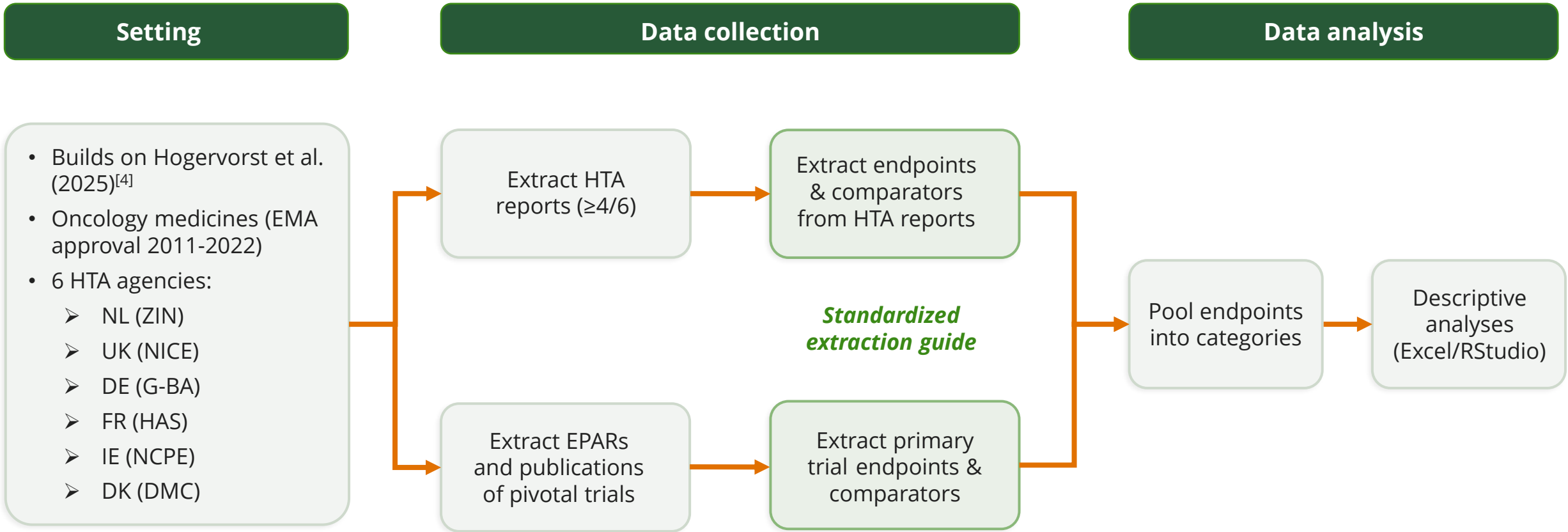
- PICO questions define JCA scope and evidence needs
- Initial PICOs drafted by assessor/co-assessor
- Member States provide feedback; PICOs consolidated into final scope



From policy question to PICO

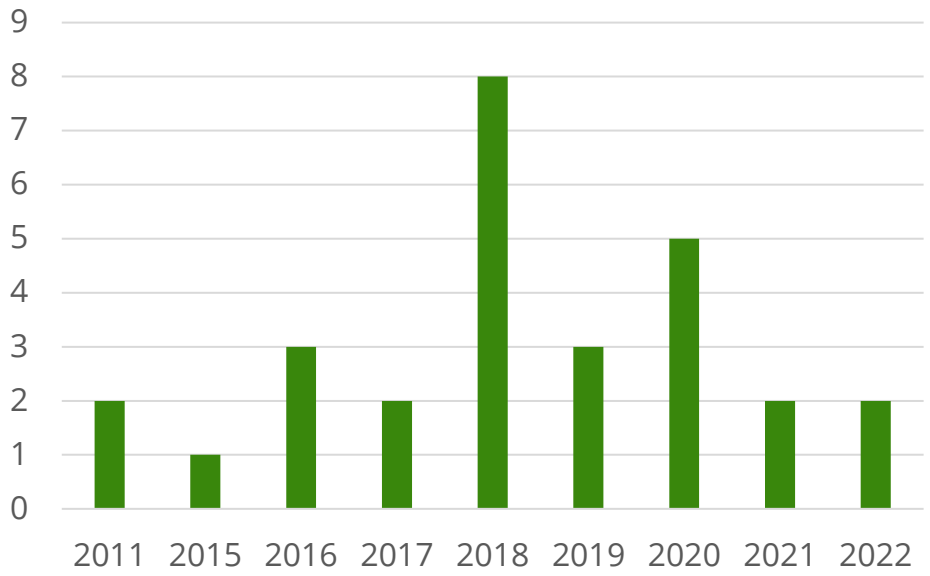


Methods


Setting
Data collection
Data analysis
Builds on Hogervorst et al. (2025)[4]
Oncology medicines (EMA approval 2011-2022)
6 HTA agencies:
NL (ZIN)
UK (NICE)
DE (G-BA)
FR (HAS)
IE (NCPE)
DK (DMC)
Extract HTA reports (≥4/6)
Extract endpoints & comparators from HTA reports
Extract EPARs and publications of pivotal trials
Extract primary trial endpoints & comparators
Standardized extraction guide
Pool endpoints into categories
Descriptive analyses (Excel/RStudio)

Results - *study cohort*

- n=20 medicines; n=28 indications (MA 2011-2022)
- 150 HTA assessments



Agency	No. of assessments
ZIN	28
NICE	28
G-BA	28
HAS	28
NCPE	21
DMC	22

Results Endpoints – Effectiveness endpoints (grouped)

- Median 7 endpoints per HTA assessment
- NICE includes most (median 14), ZIN fewest (median 4)
- Majority of endpoints (56%) included by only one agency
- Effectiveness: OS dominates
- Use of other endpoints varies more

Effectiveness endpoints (grouped) in HTA assessments

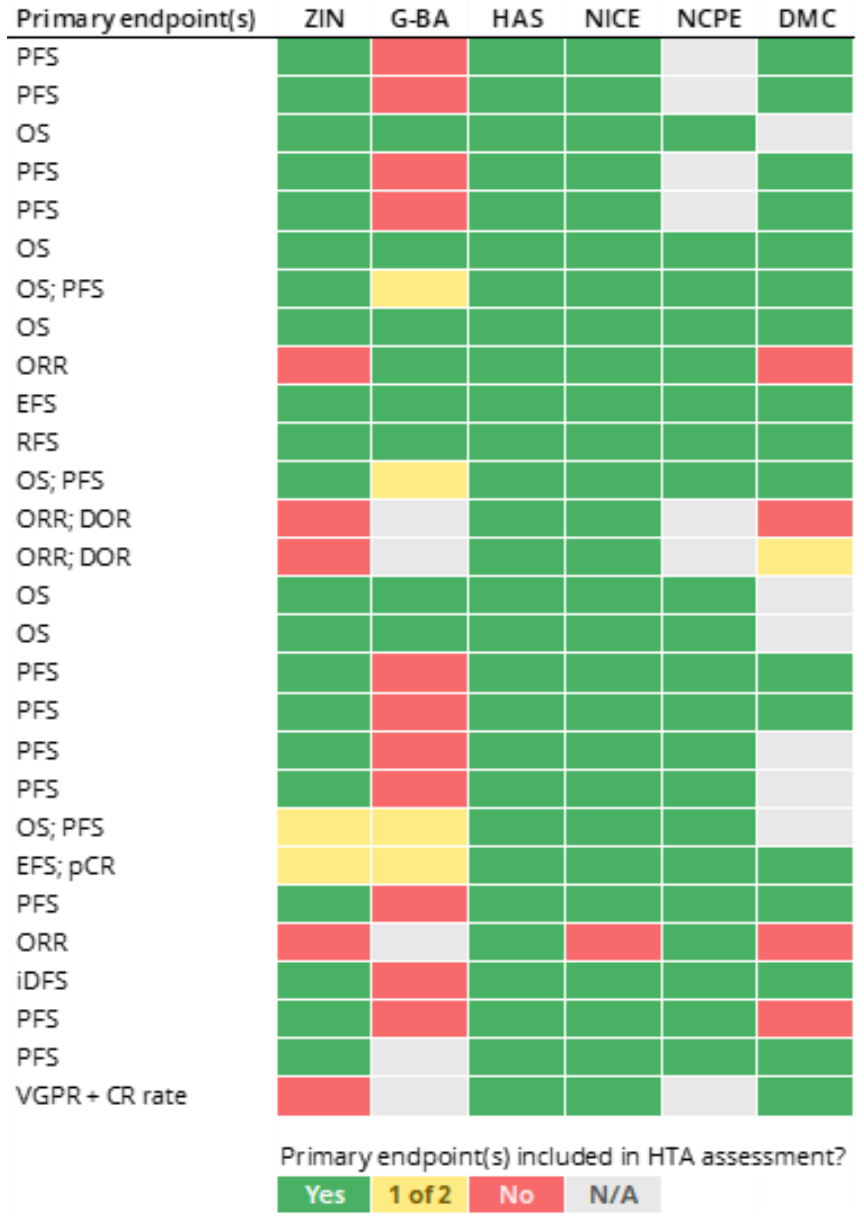
Endpoint	ZIN	NICE	G-BA	HAS	NCPE	DMC
OS	23	27	23	25	17	20
PFS	20	24	0	20	16	17
time-to-event (other)	11	22	7	11	9	8
response-related	6	64	1	27	12	8
HRQoL	8	28	44	8	7	19
other	0	1	4	1	0	1
Total no. assessments	28	28	23	28	21	22

Results Endpoints – *trial vs. HTA*

Primary endpoint(s) trial assessed by HTA?

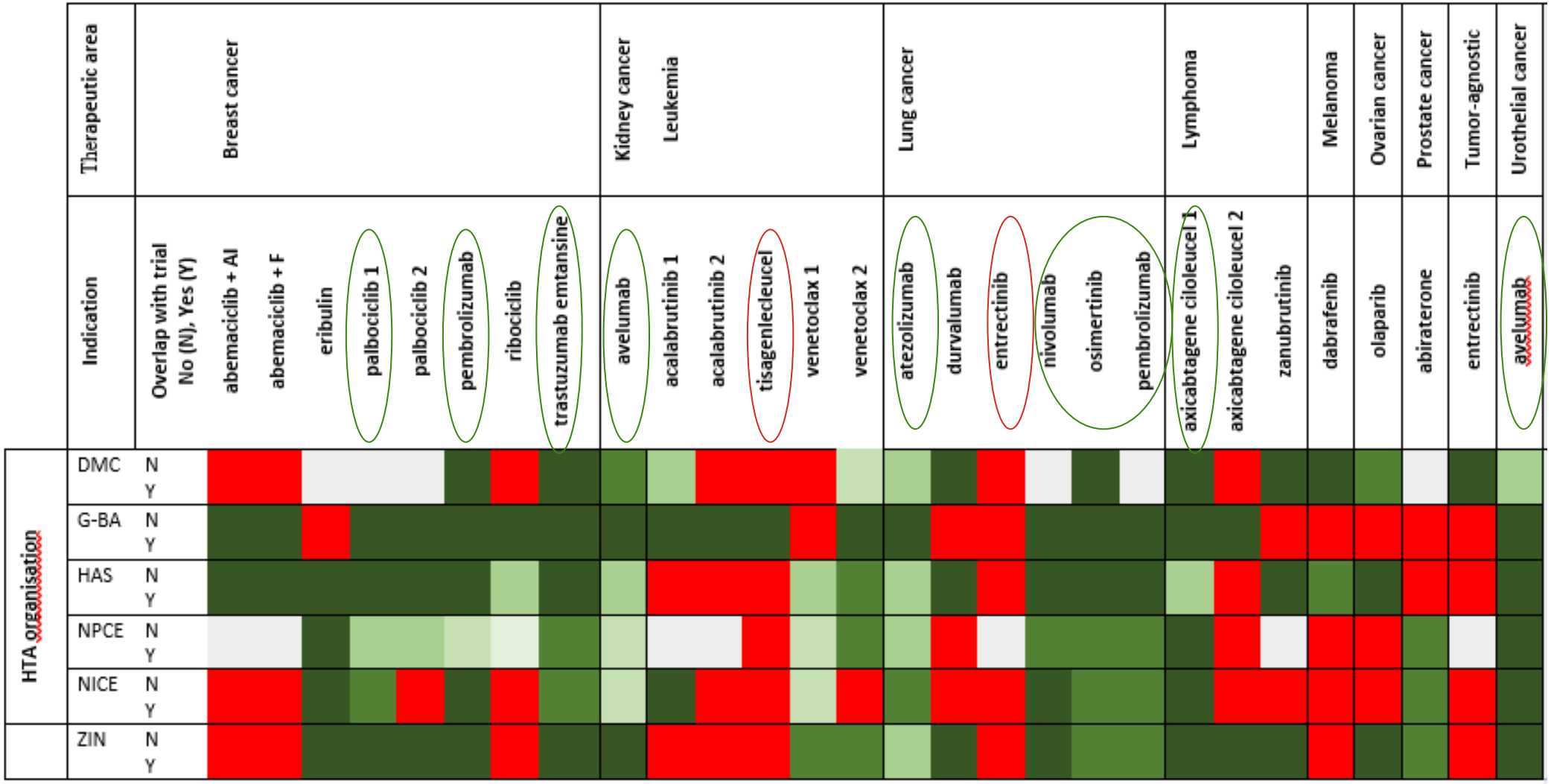
Yes (81%)	Partially (5%)	No (14%)

- Primary endpoint(s) were included in 81% of HTA assessments; partially or fully omitted in the rest
- Correspondence highest for OS; lower for other endpoints (e.g. PFS, ORR)
- G-BA most divergent (driven by PFS rejection)



HRQoL & safety endpoints excluded for this analysis

Results Comparator – *trial vs. HTA*



**the colors do not indicate a value judgement*

Panel discussion



Anne Willemsen
PhD Candidate &
JCA SG chair
ZIN, Netherlands



Dr. Roisin Adams
Head HTA Strategy
& Chair HTACG
NCPE, Ireland



Keltoum Merroune
JCA Ad Hoc
Representative
HAS, France



Dr. Stephanie Said
EU HTA coordination &
Chair JSC SG
GBA, Germany