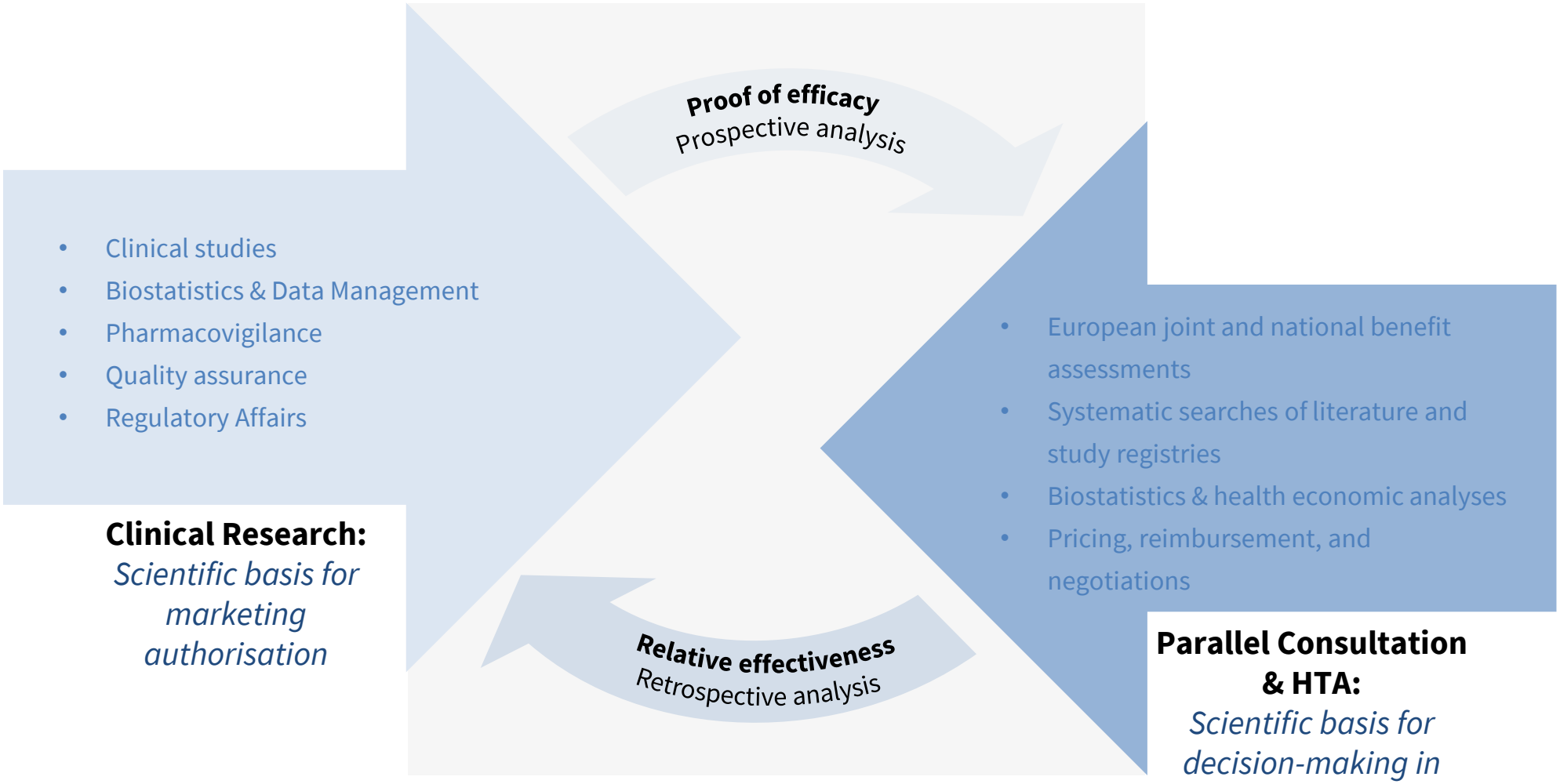
AMS
Advanced Medical Services

EU Cooperation on HTA Beyond 2020

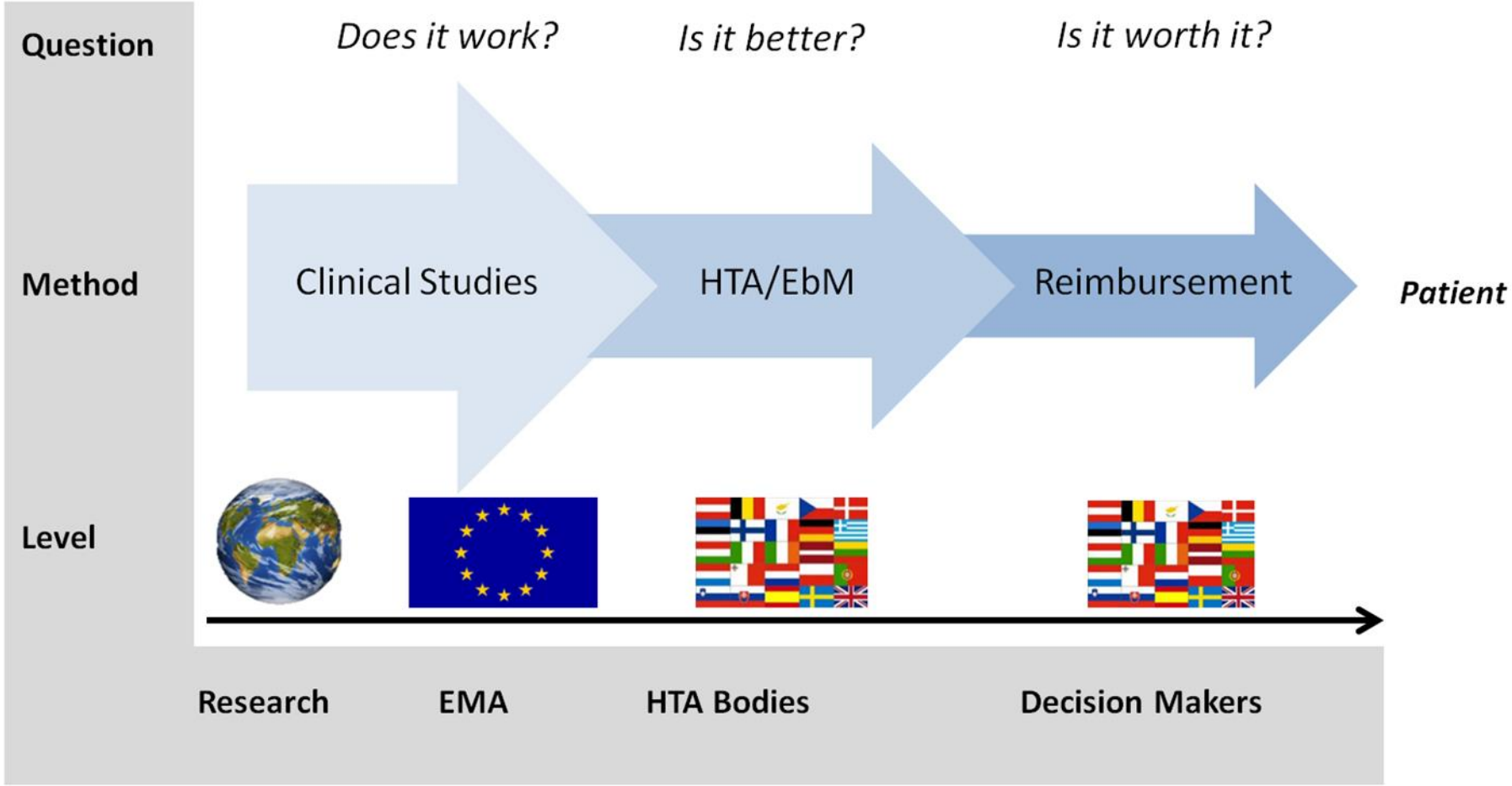
Current State, AMS Expertise and Services

Last updated February 2020

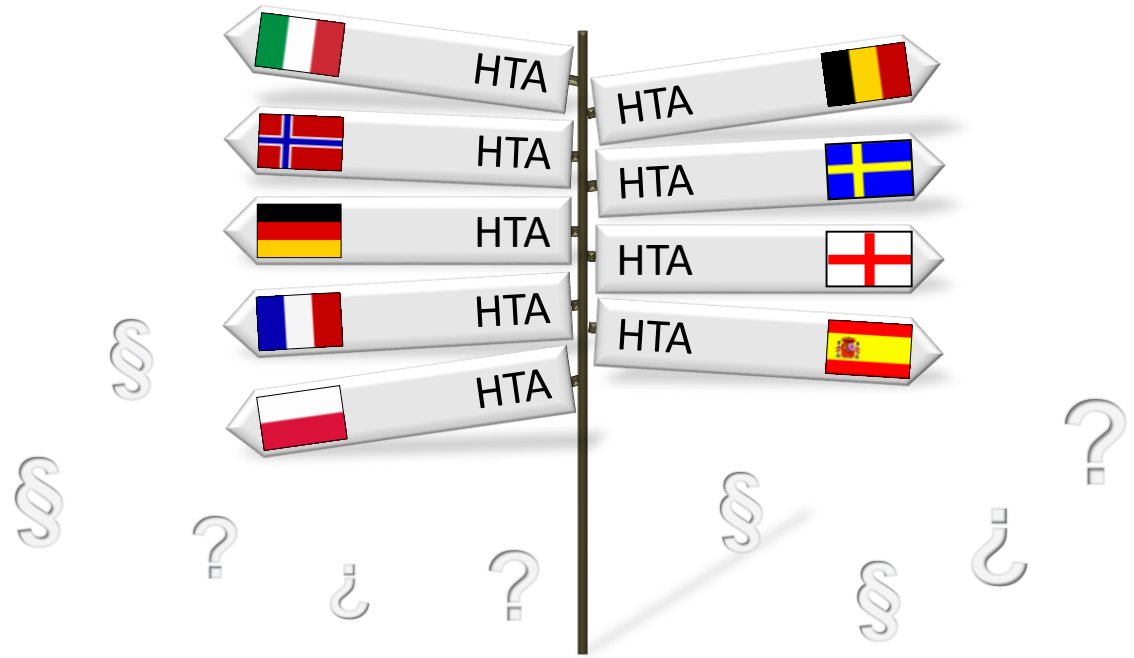
AMS - Diversity



From Global Data to National Assessment



Current Situation in Europa



Differences in

Methods *and* Data interpretation	Timelines *and* Processes	Health care systems *and* National legislations

Global Data Versus Local HTAs

Vemurafenib
(Melanom)

1 Phase-II-Study

1 Phase-III-Study
Vermurafenib vs. Dacarbazin

HTA advice

considerable additional benefit	🟢
for label population	🟢
for label population	🟢
for label population	🟢

Vedolizumab
(Colitis Ulcerosa)

1 Phase-III-Study
Vedolizumab vs. Placebo

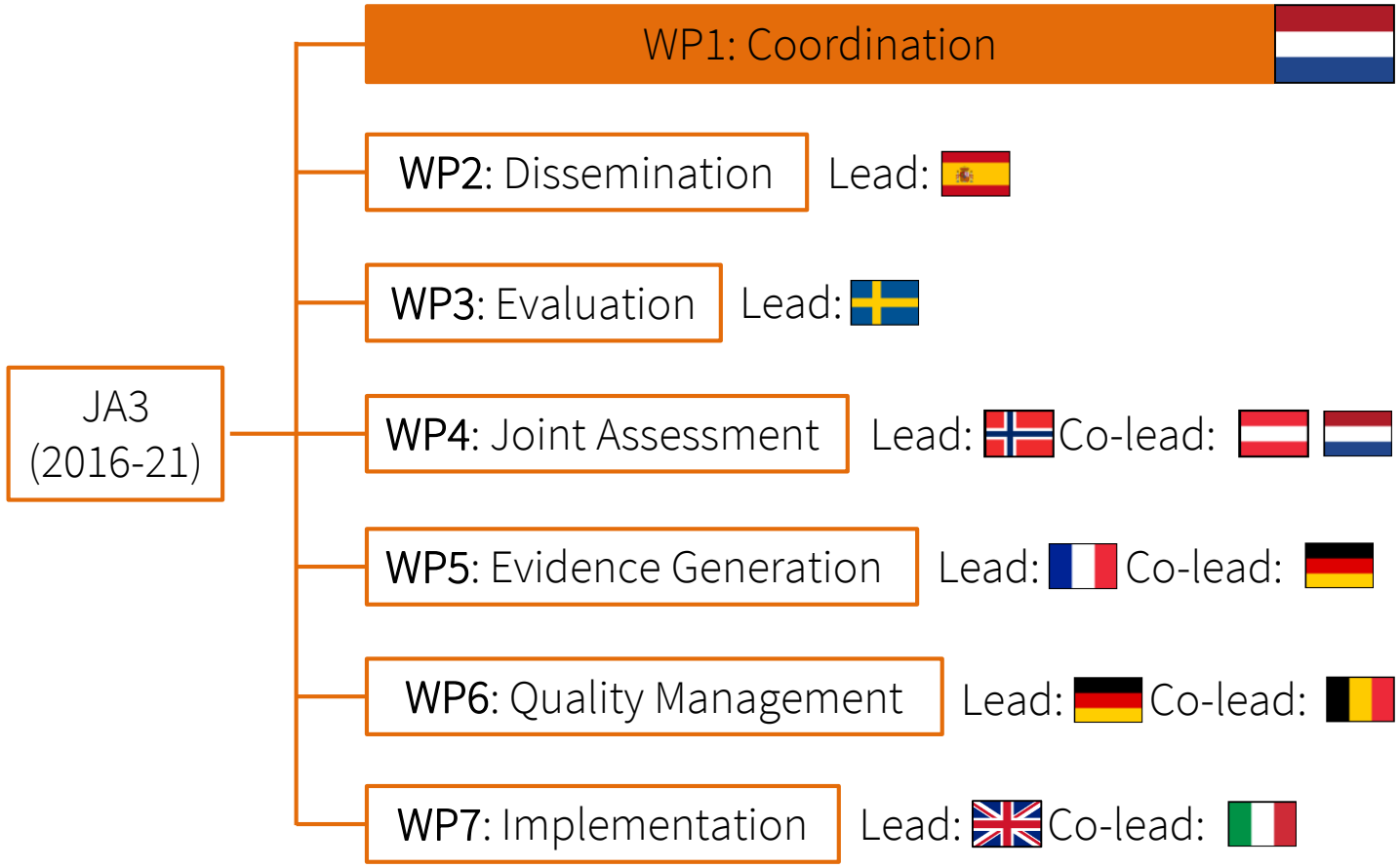
HTA advice

no additional benefit	🔴
for subpopulation	🟡
for label population	🟢
for subpopulation	🟡

EUnetHTA JA3 (2016-2021) – Objectives

- Sustainable model for permanent European cooperation on HTA
- National uptake in regional and national HTA reports

EUnetHTA JA3 - Activities



Essential Topics

Body of evidence

Broad body of evidence	Body of evidence according to legal requirements, specified by IQWiG

Comparator

Multiple comparators possible	Defined by criteria specified by the G-BA

(Surrogate) Endpoints

Clinical, surrogate and laboratory endpoints	Patient relevant endpoints and validated surrogates

Subgroups

Analysis of relevant subgroups including limitations of methodology	Multitude of subgroup analyses with risk of random results

Evidence Synthesis

Evidence synthesis according to GRADE	Thresholds for determining the extent of added benefit

The same methodology?

YES, EbM as common basis.

BUT, distinct differences in methodology:

- Context-specific statistical methods; discussion of limitations
- Magnitude of benefit according to inter-national guidelines
- Evaluation of all relevant studies
- Inclusion of clinical endpoints and surrogates
- Subgroups dependent on indication
- Evidence synthesis according to GRADE

- Strictly pre-defined statistical methods
- Assessment of added benefit according to national specifications
- Exclusion of studies due to formal reasons
- In practice, no acceptance of surrogates
- Multiple subpopulations and subgroups
- Evidence synthesis under the aspect of cost containment

Summary

Clinical research and development is global

Marketing authorisation is centralised in Europe

Methodological approaches for HTA are nationally different

Evidence base and assessment need to

- be harmonised at European level
- reflect the current state of science
- be transparent

EUnetHTA beyond 2020

- EUnetHTA Priorisation List for Joint Assessments
- Further development of EUnetHTA methods and SOPs
- National uptake

The European Advantage

A rapid REA offers

- Defined content and structure
- Systematic methodology, wider range of statistical methods
- Adequate consideration of clinical practice

Sufficient flexibility in strategic argumentation

Planning reliability, standardised process and defined timelines

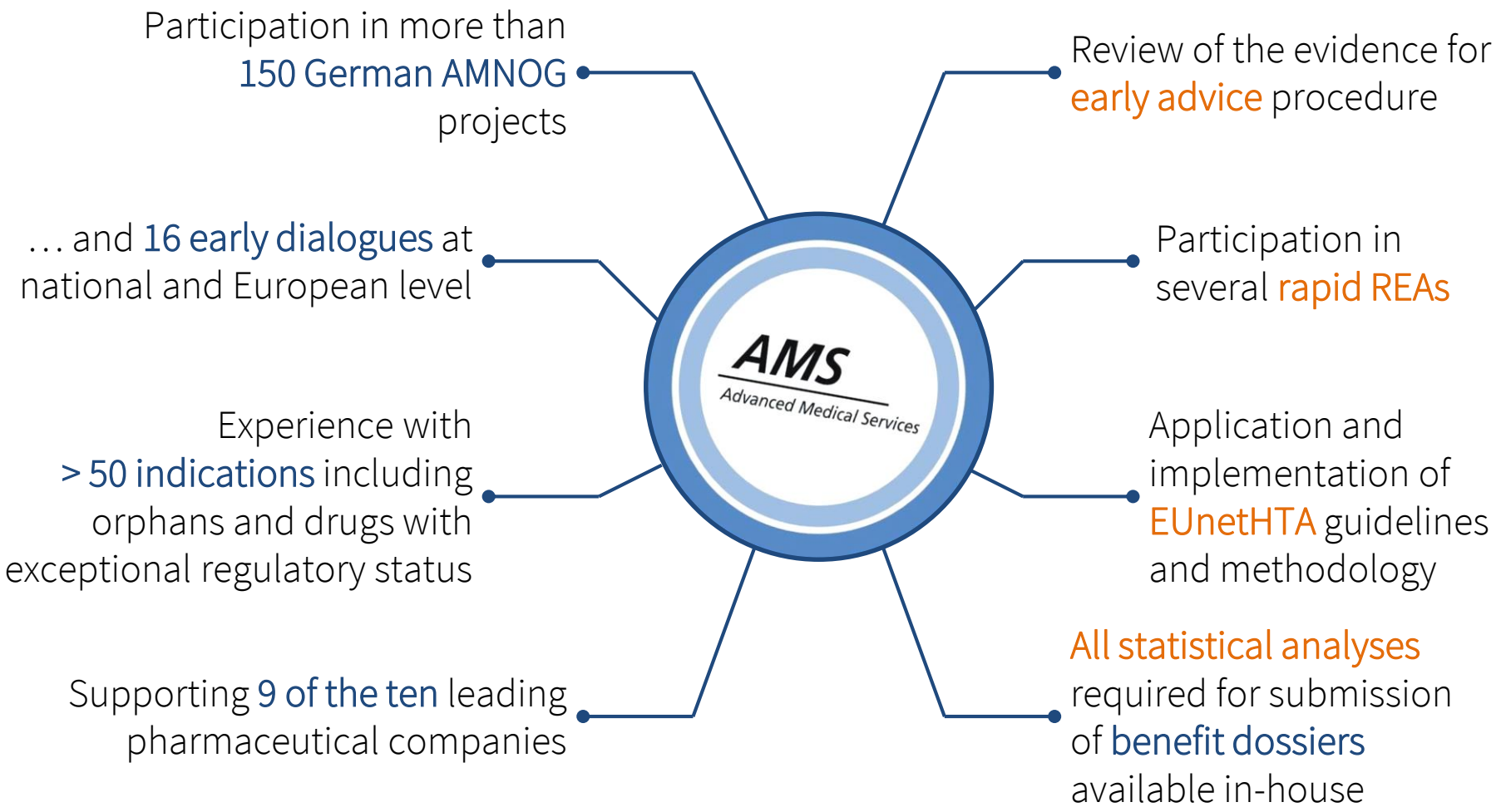
Our offering for you

Interdisciplinary team	Flexibility	Close cooperation
Experts: Medical, medical writing, regulatory, biostatistics and pharmacoeconomics	**Size:** Due to our size very flexible to manage projects on short notice	**Cooperation:** With industry associations, e.g. presentations at VfA, BPI, EUCOPE, EFPIA

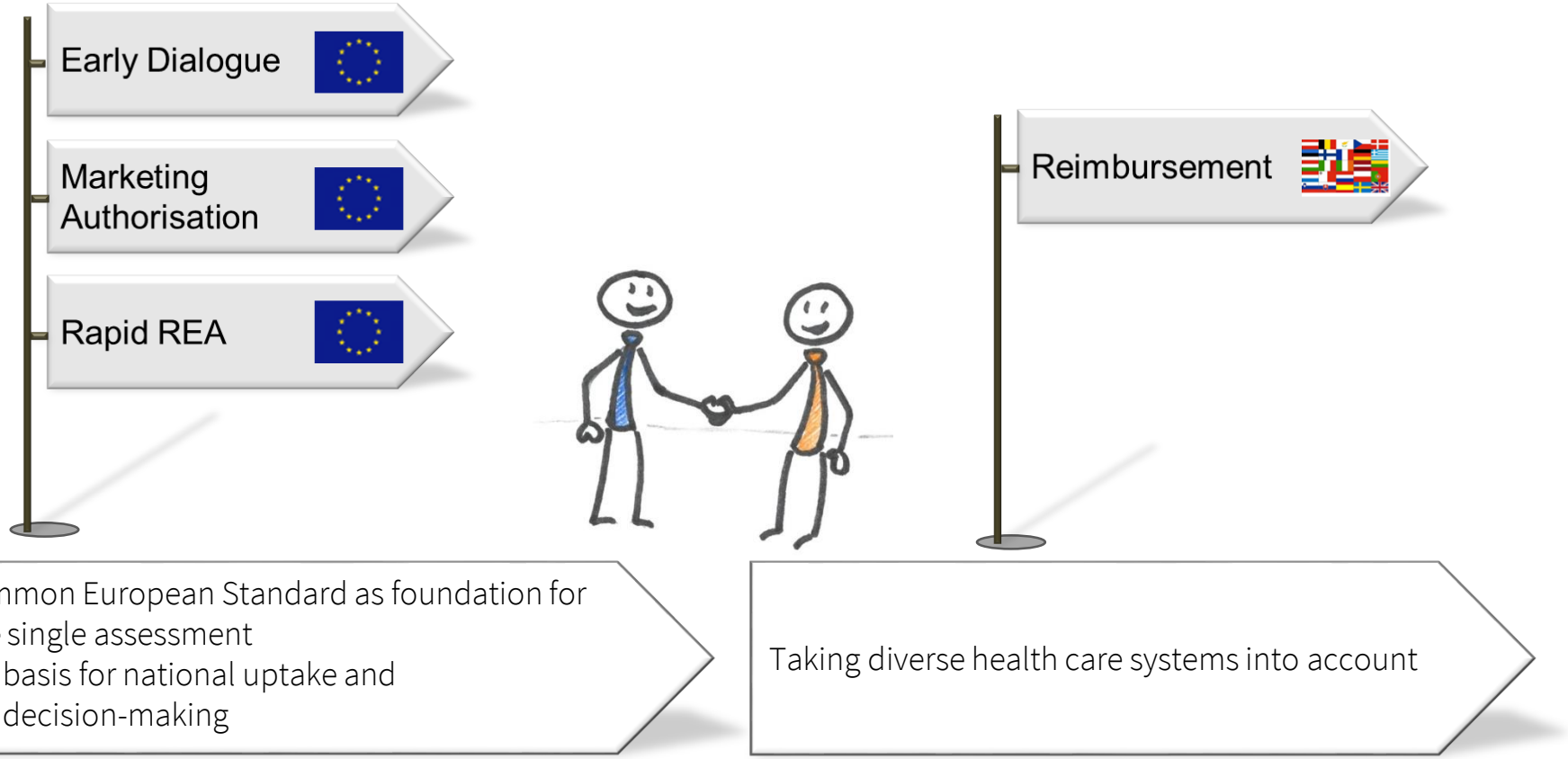
Constantly up-to-date	Years of experience	Continuous exchange
Up-to-date: With recent developments regarding EU HTA: In-depth analysis EUnetHTA guidelines, pilot rapid REAs, templates	**Experience:** Long-term expertise as established service provider for value assessments in Germany, globally and on a European level	**Exchange:** With national HTA bodies and EUnetHTA

VfA, Verband der forschenden Arzneimittelhersteller (German Association of Researching Pharmaceutical Manufacturers); **BPI,** Bundesverband der pharmazeutischen Industrie (Federal Association of the pharmaceutical industry); **EUCOPE,** European Confederation of Pharmaceutical Entrepreneurs; **EUnetHTA,** European network for Health Technology Assessment; **REA**s, rapid effectiveness assessment; **SA**, Scientific Advice

Our Experiences



Future Situation in Europe



- ✓ Stronger European voice in global clinical development
- ✓ Better business predictability

EU Cooperation on HTA – Developments & Improvements

Why now?

- Participate in the cooperation at this stage - the EUnetHTA's JA3 has been prolonged until 2021
- Improve the common understanding of HTA requirements - the methodology underlying the upcoming EU HTA will be strongly shaped by the current EUnetHTA methods and guidances.
- Contribute to the development of a learning system – the overall process is still being adapted on the stakeholder's feedback and experience
- Be prepared for the European HTA cooperation beyond 2021

Get used to the changing environment, it is going to change, anyway!

Interested in Learning More?

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