



**Gemeinsamer
Bundesausschuss**



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JSA in Germany with BfArM/PEI and G-BA

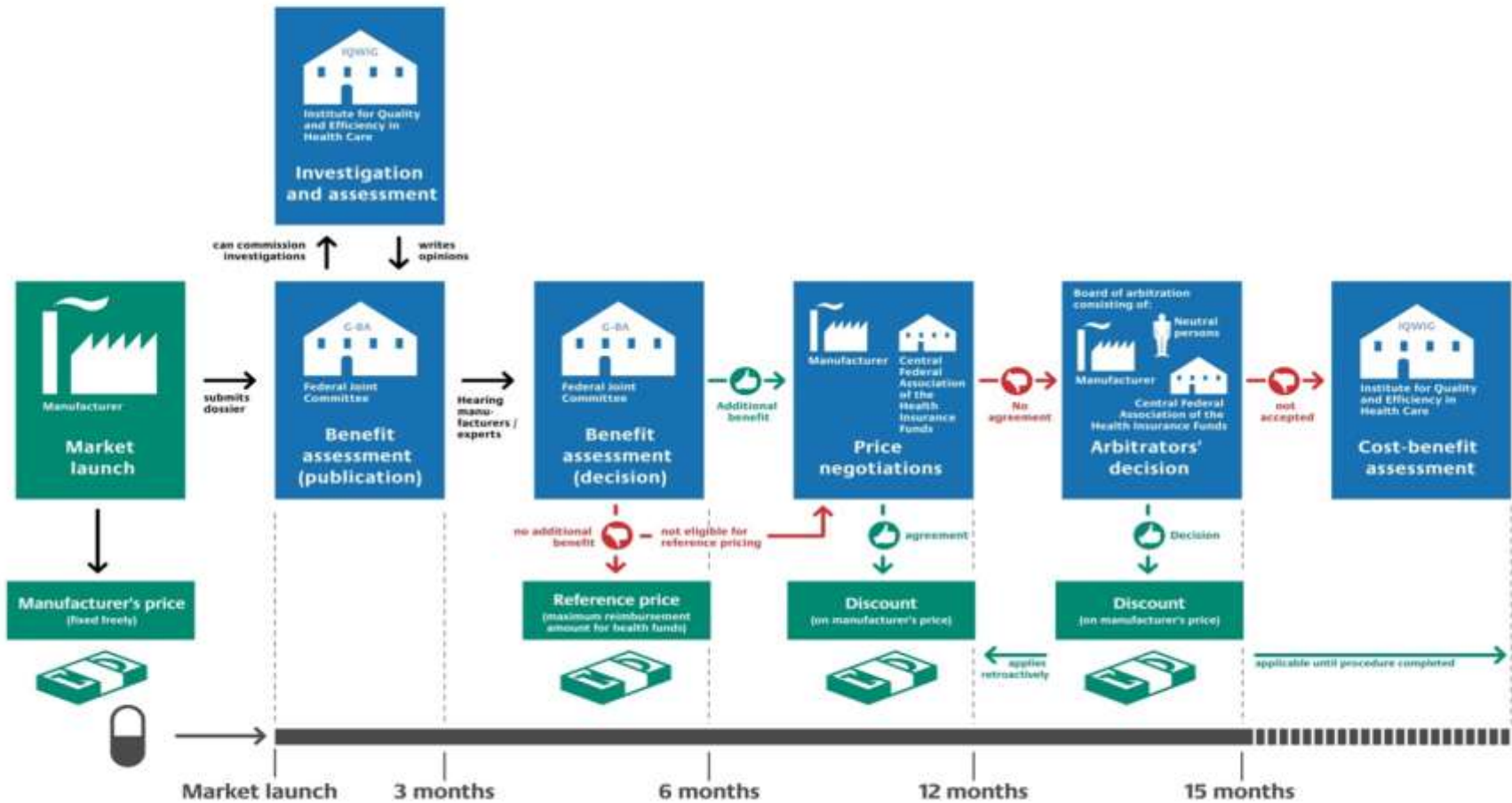
16th DGRA Annual Congress
Bonn, 8 May 2014

Thomas Mueller
Head of Pharmaceuticals Department
Federal Joint Committee (G-BA)

AMNOG in brief



Fair prices for medicinal products Pricing in the Statutory Health Insurance pursuant to the Act on the Reform of the Market for Medicinal Products (AMNOG)

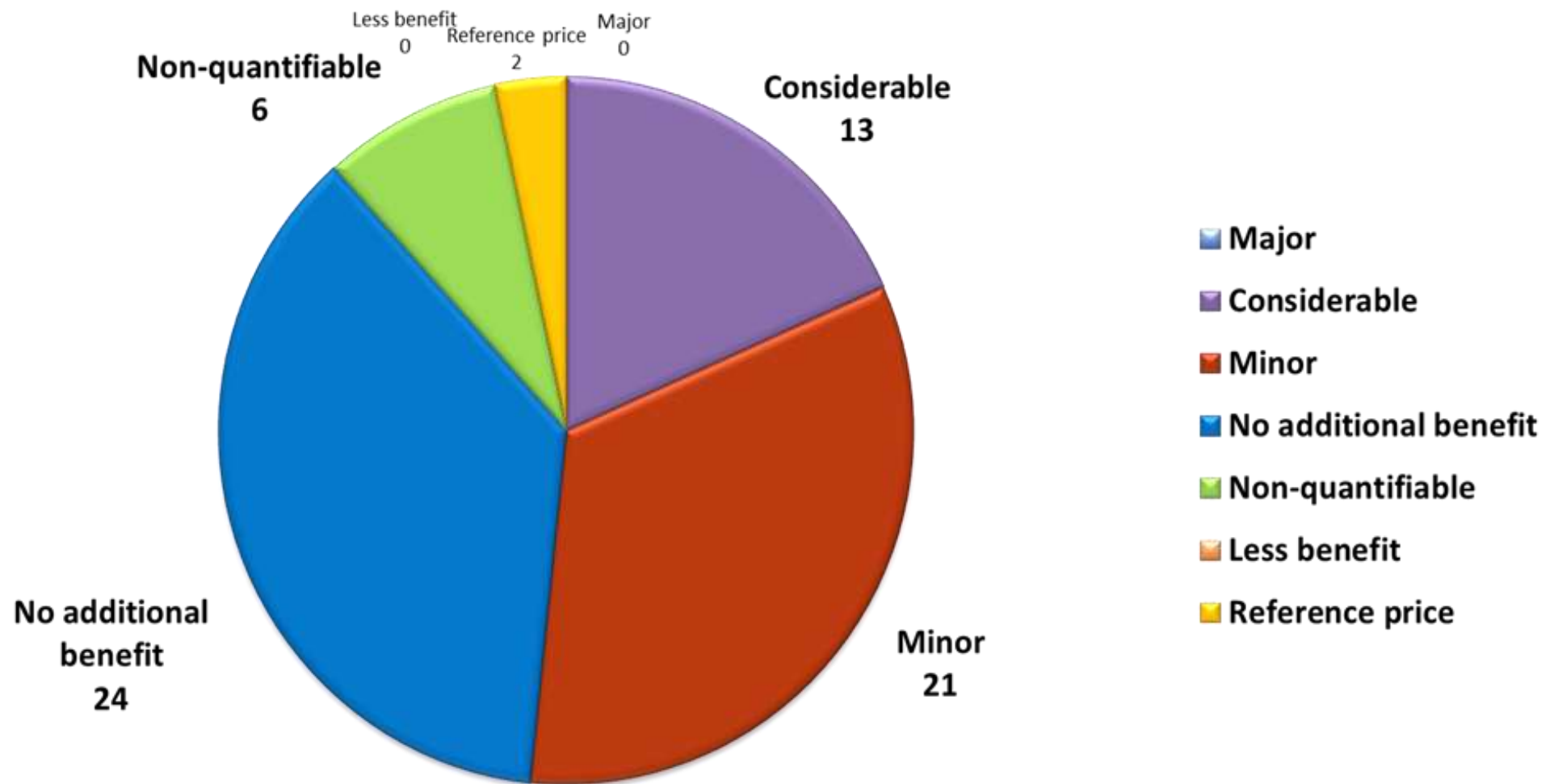


Assessment Principles - Key Point

- What is the **additional benefit** over the **appropriate comparator (standard treatment)**?
- **Quantitative extent** of additional benefit?
- Differences between **subpopulations** of patients?
- Patient-relevant endpoints: mortality, morbidity, quality of life, adverse events?
- Surrogate endpoints: Validation for patient-relevant endpoints?
- Biomarkers for relevant populations of patients?
- Lack or gaps of evidence, additional study requirements?
- Re-assessment after period of time?

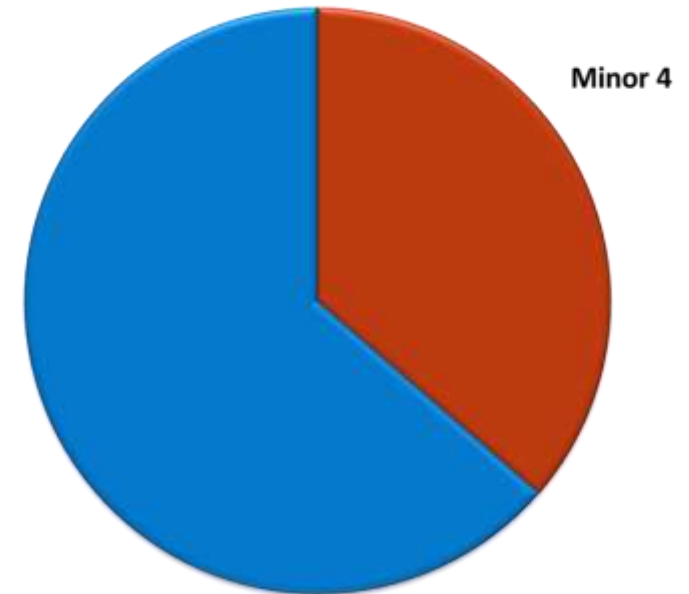
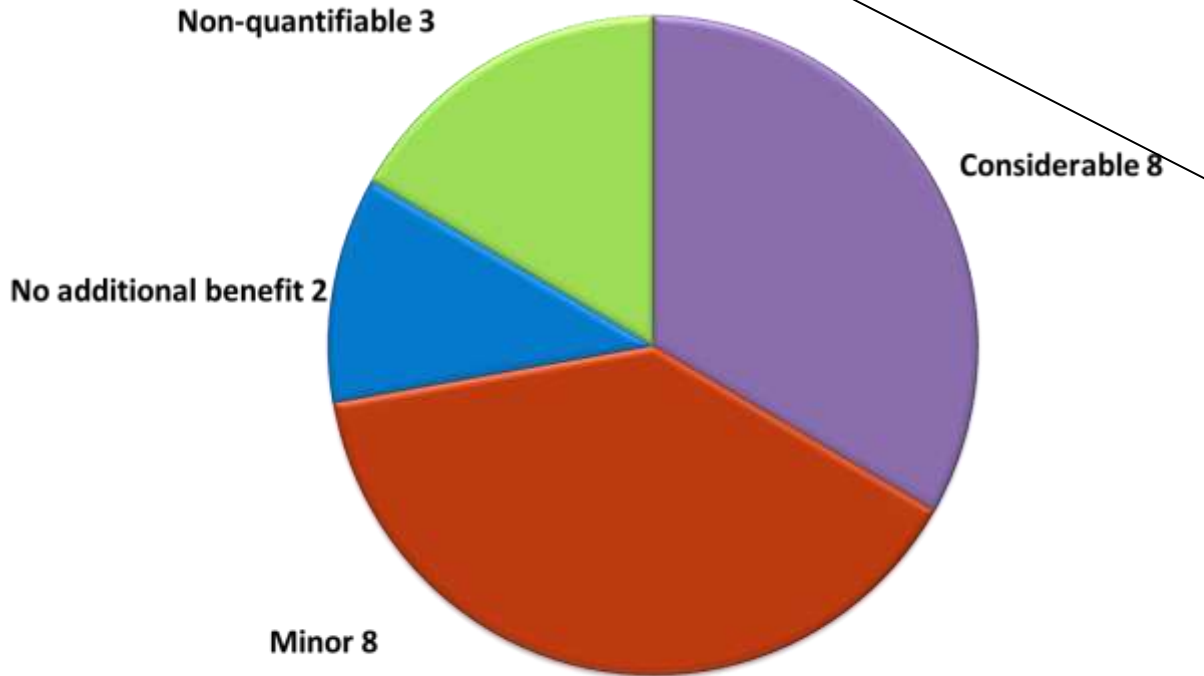


Results (February 2014, since 2011)



Resolution by therapeutic area - examples

Resolutions in „Diabetes“ (February 2014)



Resolutions in „Oncology“ (February 2014)

Price Negotiations

- results – arbitration decisions – market exit

between manufacturer and organization of statutory health insurance funds (on the basis of the G-BA resolutions)

completed Price negotiations	41
Arbitrations decisions	3
Market exit: (Aliskiren/amlodipine, collagenase clostridium histolyticum, linagliptin, linaclotide, lixisenatide, retigabine)	6



Outcome AMNOG

Free pricing for newly introduced drugs is replaced by negotiation on the basis of an **early benefit assessment**

- **No CBA, no CEA (no ICER, no threshold)**

Unchanged: Early market entry and drug availability in Germany, even for expensive drugs

- **Free pricing for first 12 months**
- **Market launch and early benefit assessment in parallel**
AMNOG does not hinder innovation; it promotes intense discussion on open scientific questions and values

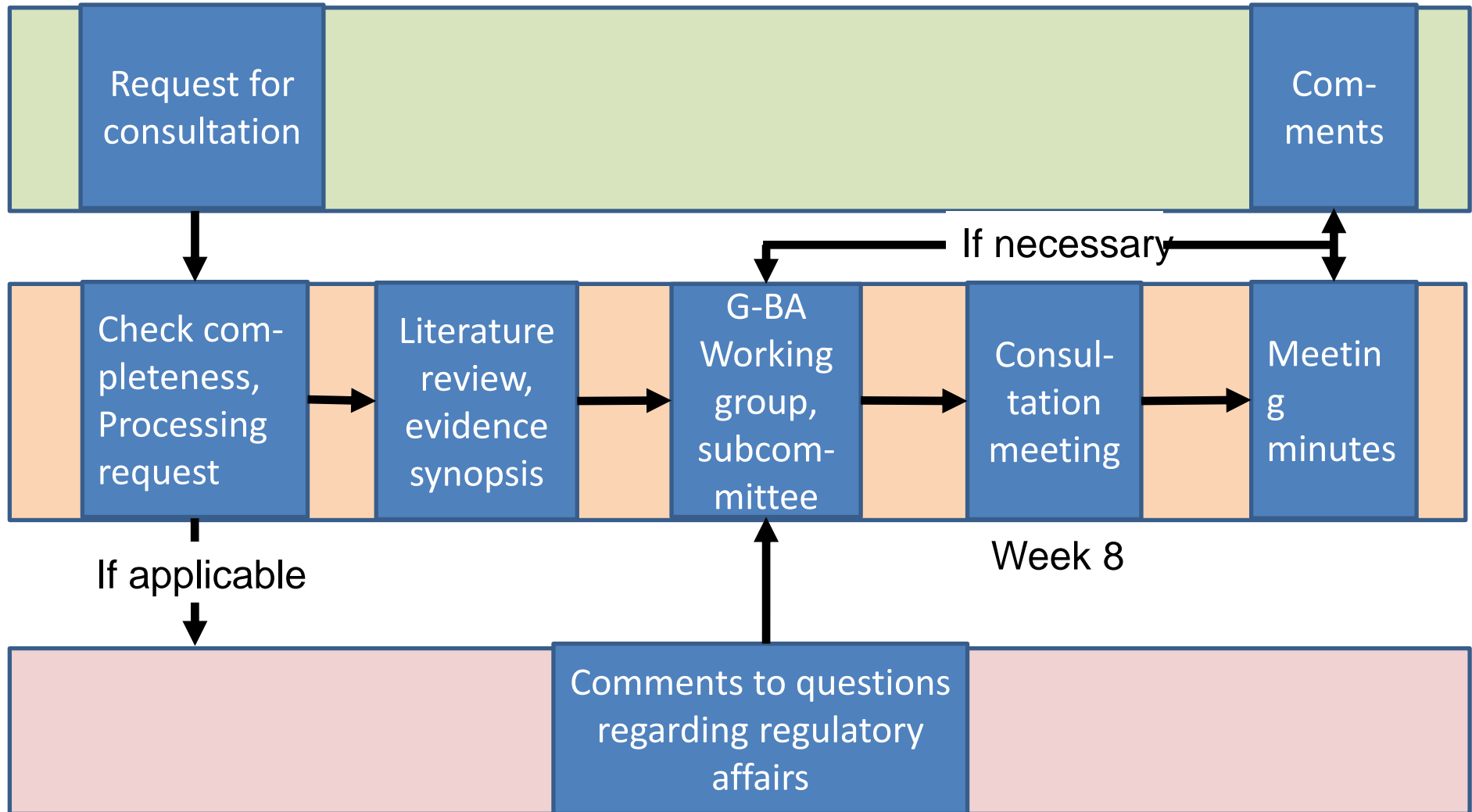
Five Ws of Consultations

- **WHO?** G-BA advises industry
- **WHAT?** In particular advice on:
 - Appropriate comparator,
 - Study design,
 - Endpoints, Biomarkers, Surrogates,
 - Patient groups.
- **WHEN?** Best before phase III, but any time is possible (e.g. phase IV)
- **WHERE?** At the G-BA office, Berlin (teleconference is possible)
- **WHY?** Assistance to undergo the procedure

Consultations with the G-BA: course

- Request for consultation
- Discussion within G-BA (working group, subcommittee): Proposal by secretary, agreement on key points
- At week 8: Consultation meeting with meeting minutes
 - Meeting minutes have to be attached to the future dossier
- If necessary: new consultation on comments of the pharmaceutical company at the G-BA office
- Fees apply
 - 2000 € - 10 000 € depending on complexity and scope of questions
 - Free of charge: Written answers concerning questions concerning procedures or dossier submission

Consultations with the G-BA: course



Participation of BfArM or PEI (national regulatory authorities)

- Standard involvement (legal base SGB V § 35b Abs. 7)
- Before phase III trial or during planning of a new clinical study

Course:

- Request for consultation before phase III or during planning of clinical study
- BfArM or PEI will be informed and get questions & complete dossier (exception: pharmaceutical company excludes participation)
- Comments of BfArM or PEI (on market authorisation aspects)
- Discussion within G-BA (considering BfArM / PEI comments)
- Consultation meeting with meeting minutes
- Comments of pharmaceutical company on meeting minutes
- If applicable new consultation on comments of the pharmaceutical company and change of meeting minutes
- BfArM or PEI get copy of final meeting minutes (exception: if pharmaceutical company denies)



Consultation: Documents

Documents to submit:

- Request form <https://www.g-ba.de/institution/themenschwerpunkte/arzneimittel/nutzenbewertung35a/anlagen/#abschnitt-2>
 - Filled in German (therapeutic area, question, positions)
 - Attachments in English accepted (e.g. Study protocols, literature)
 - Minutes of advice meetings with regulatory authorities
 - Concept of clinical studies if applicable <https://www.g-ba.de/institution/themenschwerpunkte/arzneimittel/nutzenbewertung35a/#abschnitt-7>

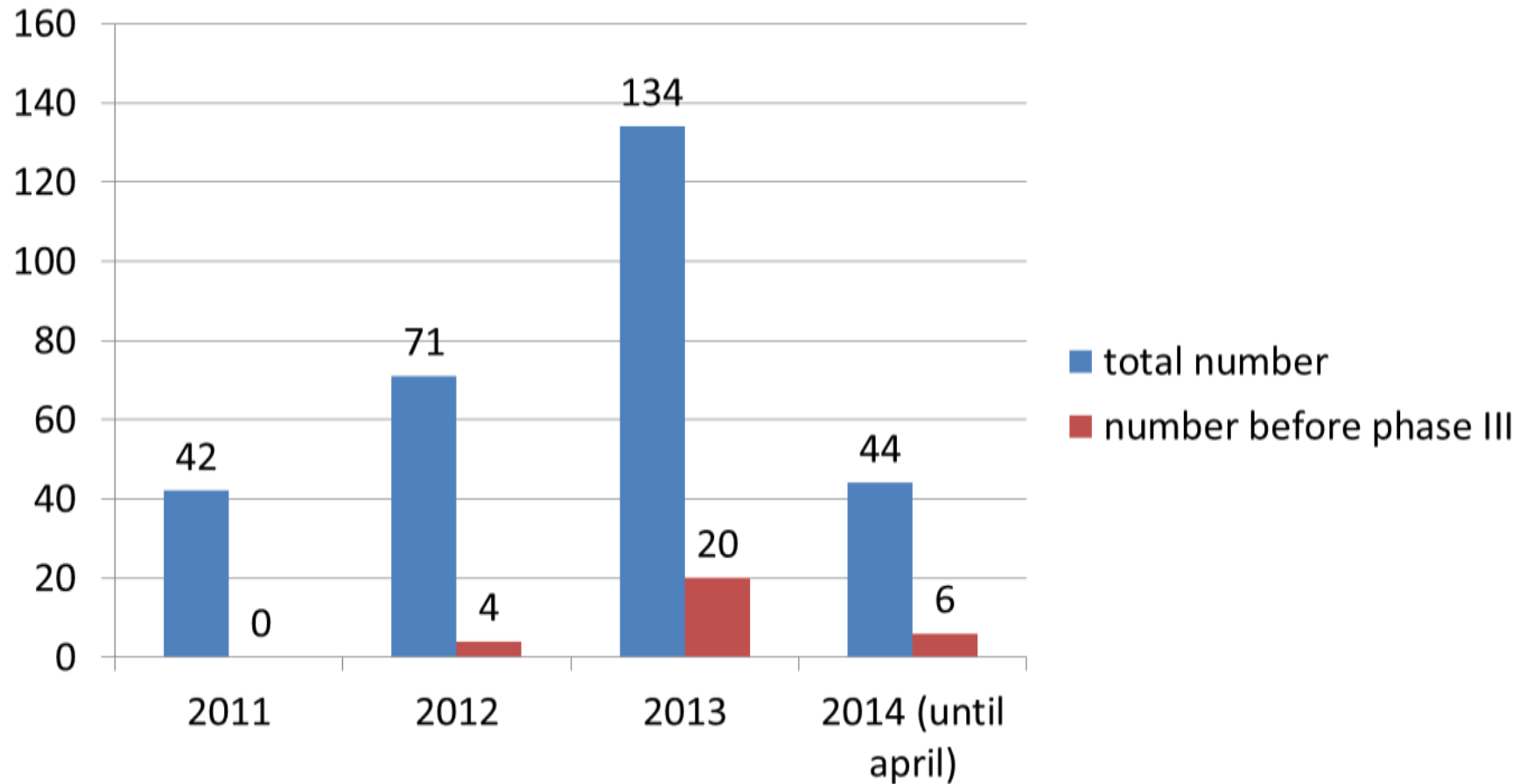
Documents provided after the advice meeting

- Meeting minutes
- Systematic literature survey (standard treatments in the claimed indication)
- Overview about all treatments considered as comparator
- Comments of BfArM or PEI on marketing authorization aspects (if applicable)



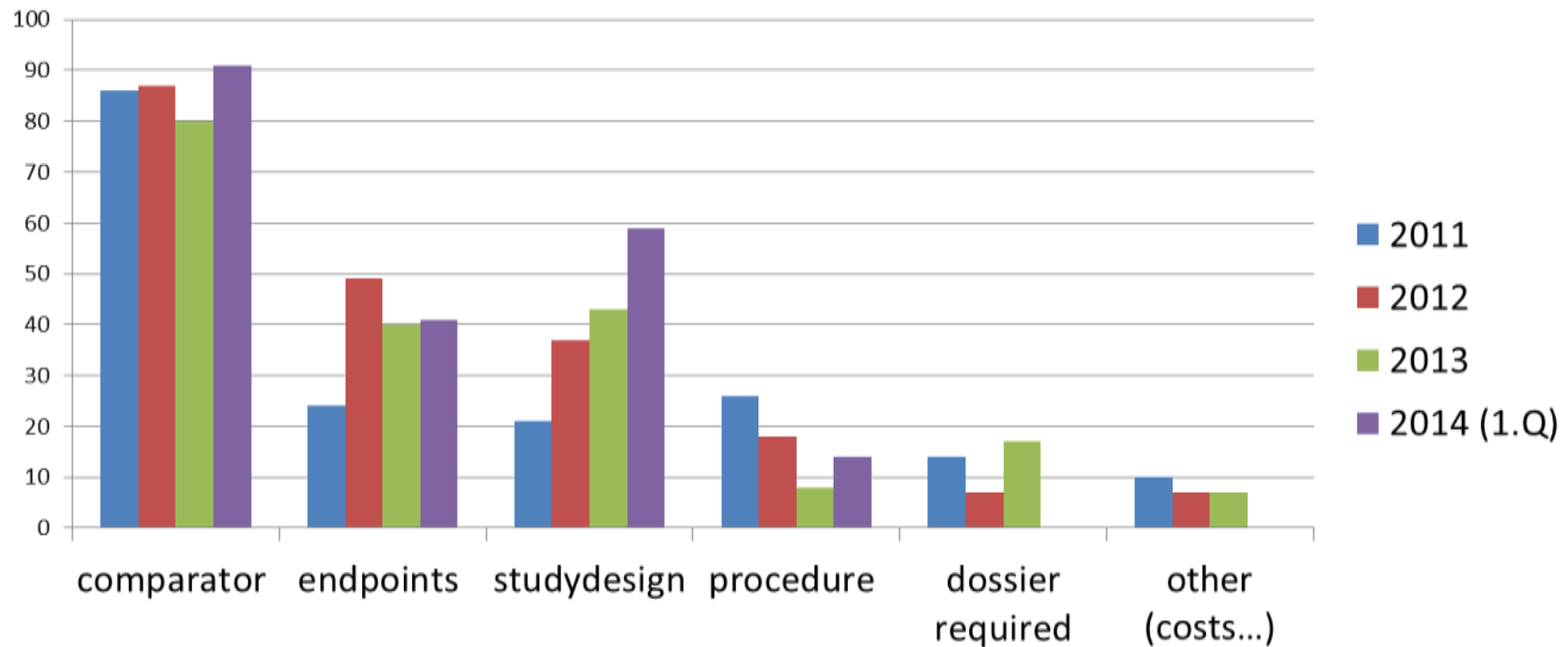
Consultations: Facts and Figures

Number of consultations



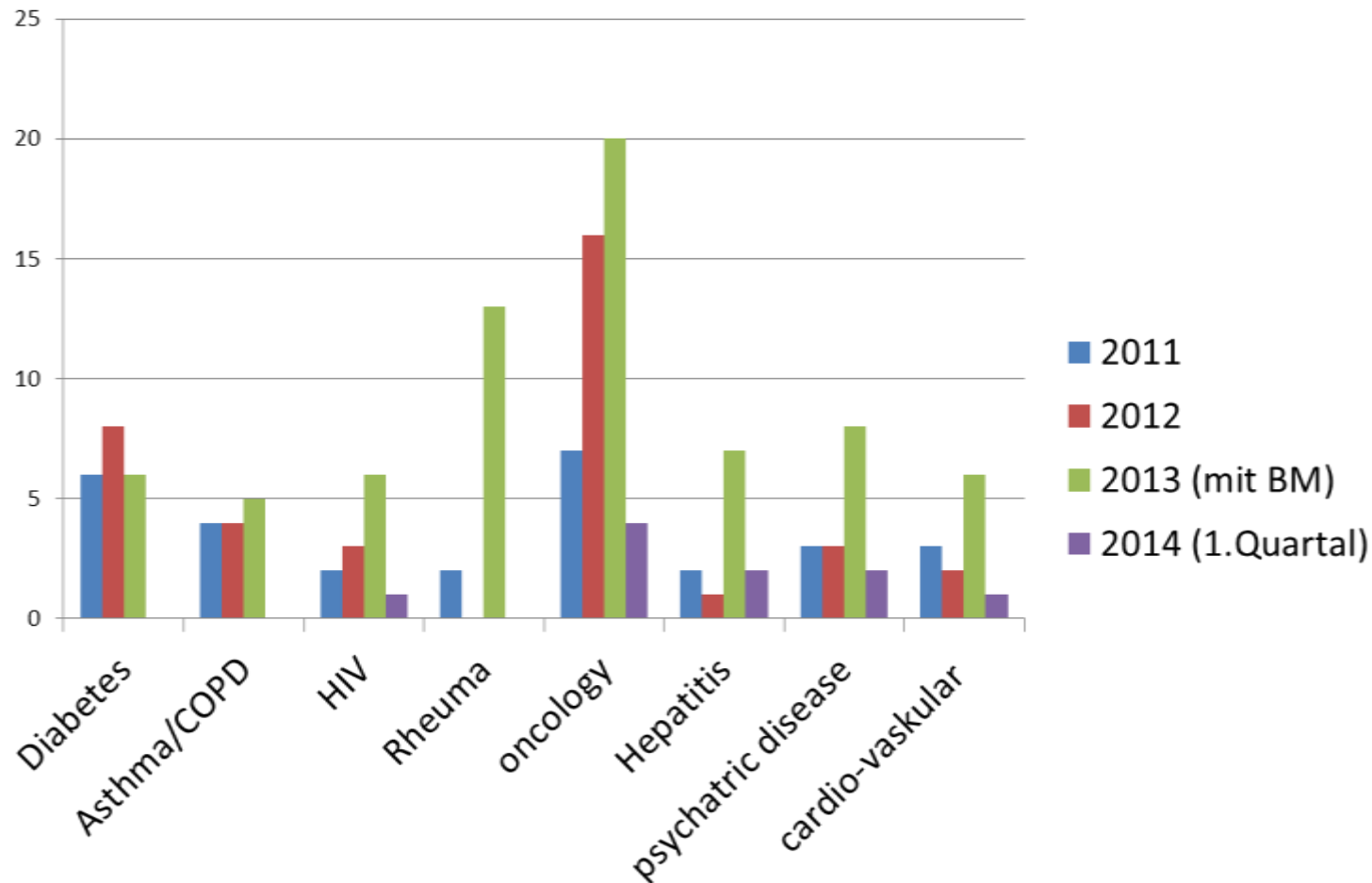
Consultations: Facts and Figures

proportion of topics



- Main focus on questions regarding comparator
- Increasing interest on comments to study design
- Questions regarding procedure drop

Consultations: Facts and Figures selected therapeutics areas



Experiences from interaction with regulatory bodies

- Dealing with comparators: lack of evidence, off-label-use, no comparators, missing data accessibility
- Dealing with (patient relevant) endpoints and validity
- Dealing with surrogates (incl. discussions with experts)
- Dealing with conditional approval (time limited resolutions)
- Data generation after authorization (safety and efficacy)
- Dealing with uncertainties: early crossover, open label studies, indirect comparison,
- Study – population: label differs from investigated population



Pilot- /Project- joint/parallel advice with EMA and other European HTA agencies (May 2014)

- Pilots EUnetHTA (Lead Partner HAS, France):
 - 10 G-BA participations
- Pilots of multi-stakeholder consultations in early-stage drug development, EMA:
 - 10 G-BA participations

Interaction G-BA – Regulators - HTA



HTA Network activities (BMG/G-BA)



EMA-multi-HTA
Pilots for parallel scientific advice



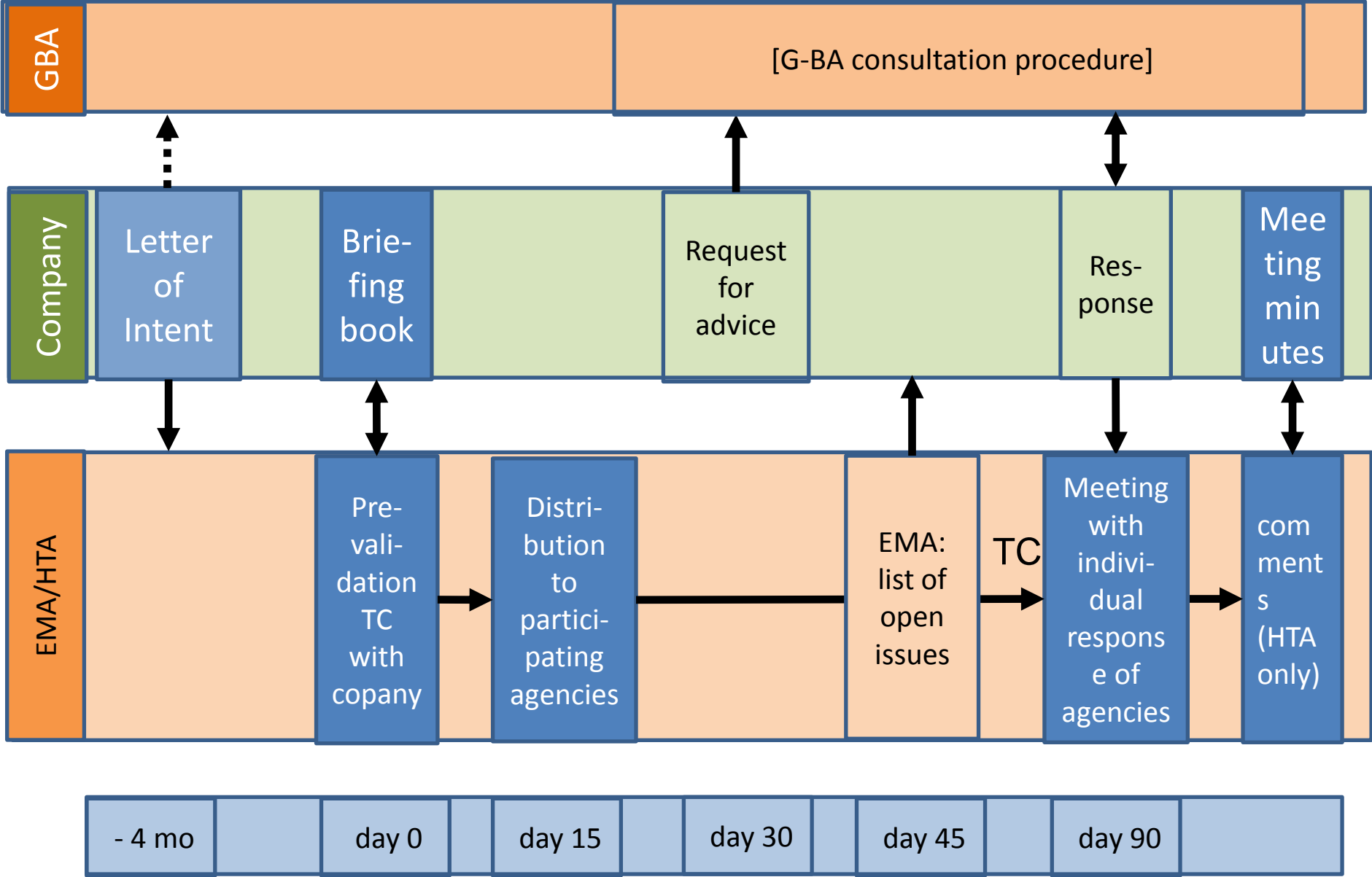
2012 – 2015
EUnetHTA
JA2

2016 – 2020
Scientific and technical
cooperation

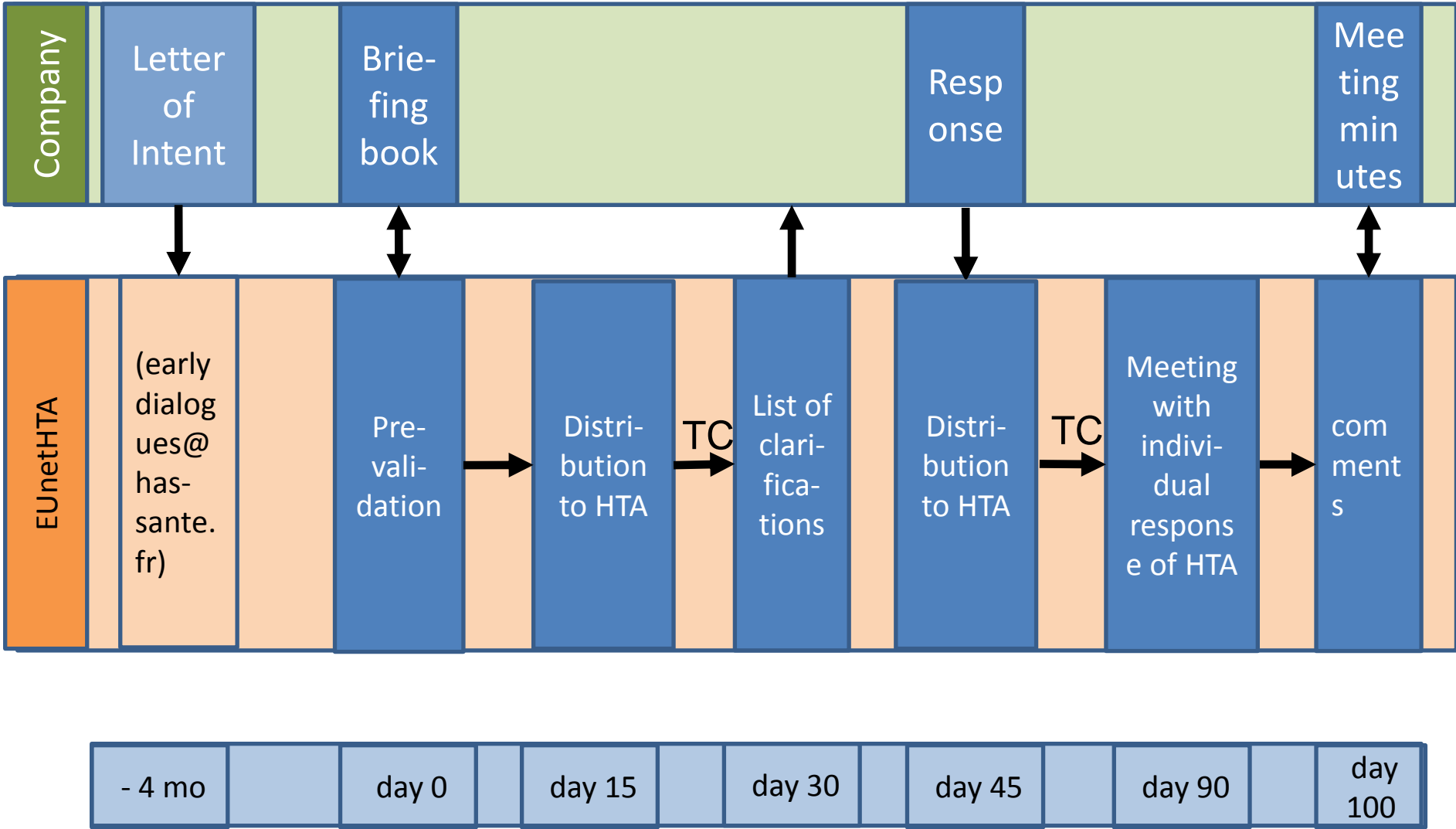
SEED
(Shaping European
Early Dialogues)

2014 - 2015
10 multi-HTA pilots

Parallel Scientific advice (EMA + HTAs)



Early Dialogue SEED / Eunetha



Licensing and HTA: Harmonization?

- Licensing: Focus on safety and product quality
- HTA: Focus on (additional) benefit, value, listing decisions, reimbursement, budgets, allocation, opportunity costs
- Clinical trials = evidence basis for both licensing and HTA decisions
- Clinical trials = need early & global organization, resources (human, financial and time)
- Possible harmonization for: study design, patient groups, integration of standard of care (active control), relevant endpoints, relevant clinical difference (effect size)
- No harmonization for: appraisal of effects, listing decisions, willingness (and ability) to pay
- EMA/HTA advices: first positive step, but need for further development (legal framework, coordination, HTA involvement)



Transparency of information

Suchen

Kontakt

FAQ

English

Startseite



**Gemeinsamer
Bundesausschuss**

Institution

Informationsarchiv

Der Gemeinsame Bundesausschuss (G-BA) ist das oberste Beschlussgremium der gemeinsamen Selbstverwaltung der Ärzte, Zahnärzte, Psychotherapeuten, Krankenhäuser und Krankenkassen in Deutschland.



|| [Slideshow anhalten](#)

Er bestimmt in Form von Richtlinien den Leistungskatalog der gesetzlichen Krankenversicherung (GKV) für mehr als 70 Millionen Versicherte und legt damit fest, welche Leistungen der medizinischen Versorgung von der GKV erstattet werden. Darüber hinaus beschließt der G-BA Maßnahmen der Qualitätssicherung für den ambulanten und stationären Bereich des Gesundheitswesens.

Der Bereich **Institution** informiert über:

- [Struktur und Mitglieder](#)
- [Gesetzlicher Auftrag und Arbeitsweise](#)
- [Themenschwerpunkte](#)
- [Service](#)
- [Presse](#)

Das **Informationsarchiv** bietet Zugriff auf:

- [Beratungsthemen](#)
- [Beschlüsse](#)
- [Richtlinien](#)
- [Abschlussberichte](#)
- [Frühe Nutzenbewertung \(§ 35a SGB V\)](#)

> GKV-Versorgungsstrukturgesetz

Wechsel der Amtsperiode

4. Qualitätssicherungskonferenz

E-Mail-Infodienst

Stellenangebote

Ausschreibungen

[Was ändert sich für den G-BA?](#)



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