EMA-EUnetHTA Parallel Consultation

Current State, AMS Expertise & Services

One Data Package to Meet Different Requirements

Marketing Authorisation

- Benefit-Risk-Ratio
- Safety
- Efficacy
- Quality

Study Data

Health Technology Assessment

- Therapeutic (added) value /cost-effectiveness
- Relative Efficacy/ Effectiveness

Payers

- Value
- Affordability

Requirements for HTA may differ across Member States based on national and regional legislation

Marketing Authorisation vs. HTA – Two Different Questions

Marketing authorisation (MA)/ Clinical studies	HTA/ Evidence based medicine (EbM)
Does it work?	*Is it better?*
• **Efficacy**: „Yes or No"-decision based on **prospective** studies • Proof of efficacy based on a formal confirmatory test • Focus on primary endpoint, secondary endpoints exploratory/supportive	• Relative **Effectiveness**: **Retrospective** analysis of existing study data • Description of existing evidence: Effect size and reliability of the recommendation • Patient relevance is key: No differentiation between primary and secondary endpoints
→ *Approval based on a positive benefit-risk balance*	→ *Added value based on clinical evidence*

EMA-EUnetHTA Parallel Consultation

Enhanced collaboration between EMA and EUnetHTA: A single gateway for requests for parallel discussions (since 07/2017)

- For Initial Evidence Generation: Before start of pivotal clinical trials
- For Post Licensing Evidence Generation (PLEG)
- Simultaneous advice from EMA and HTA bodies (HTABs)
- Objective: To help generate optimal and robust evidence in an efficient development plan that satisfies the needs of both regulators and HTABs

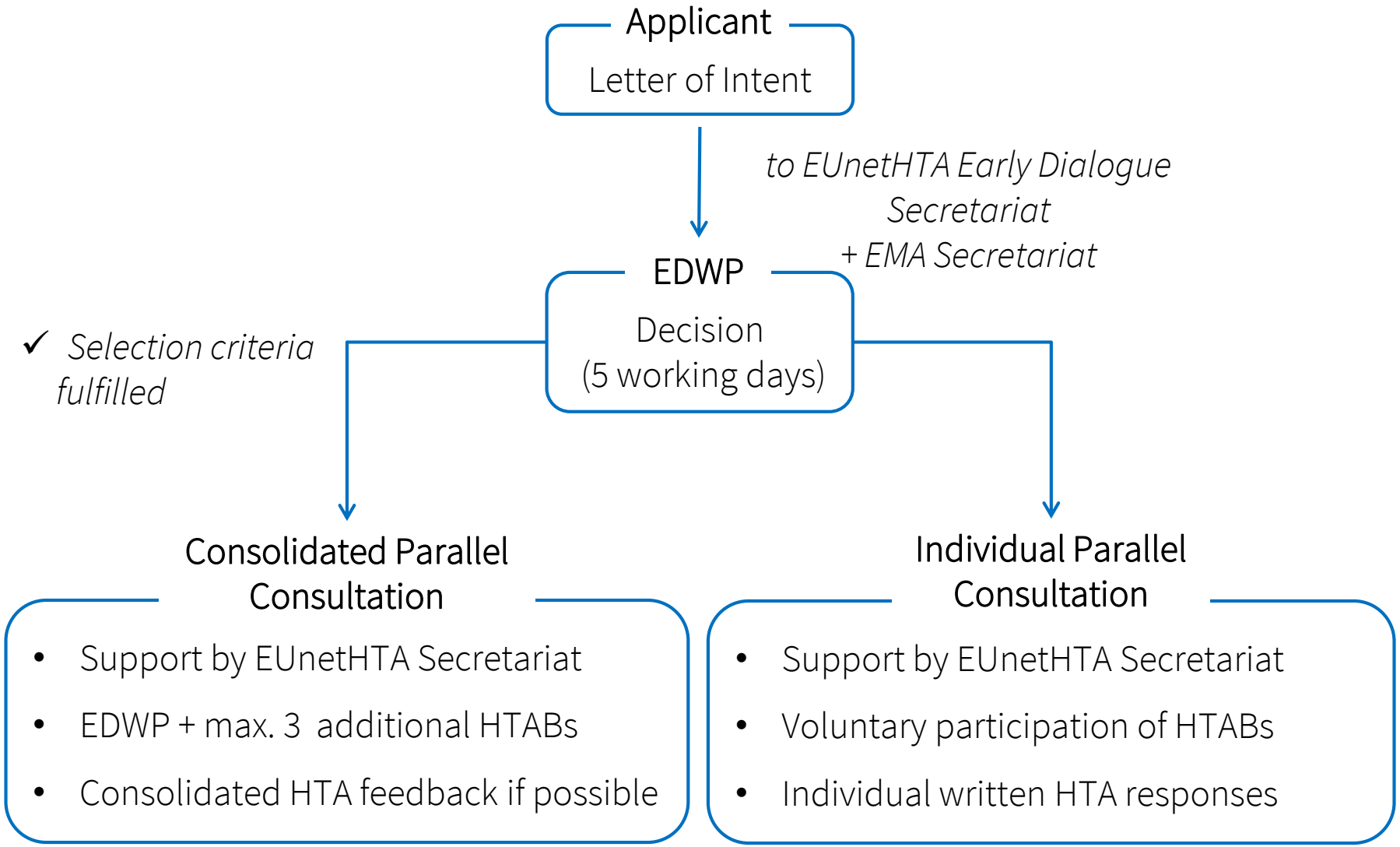
Parallel Consultation – Benefits of the platform

The Parallel Consultation procedure offers:

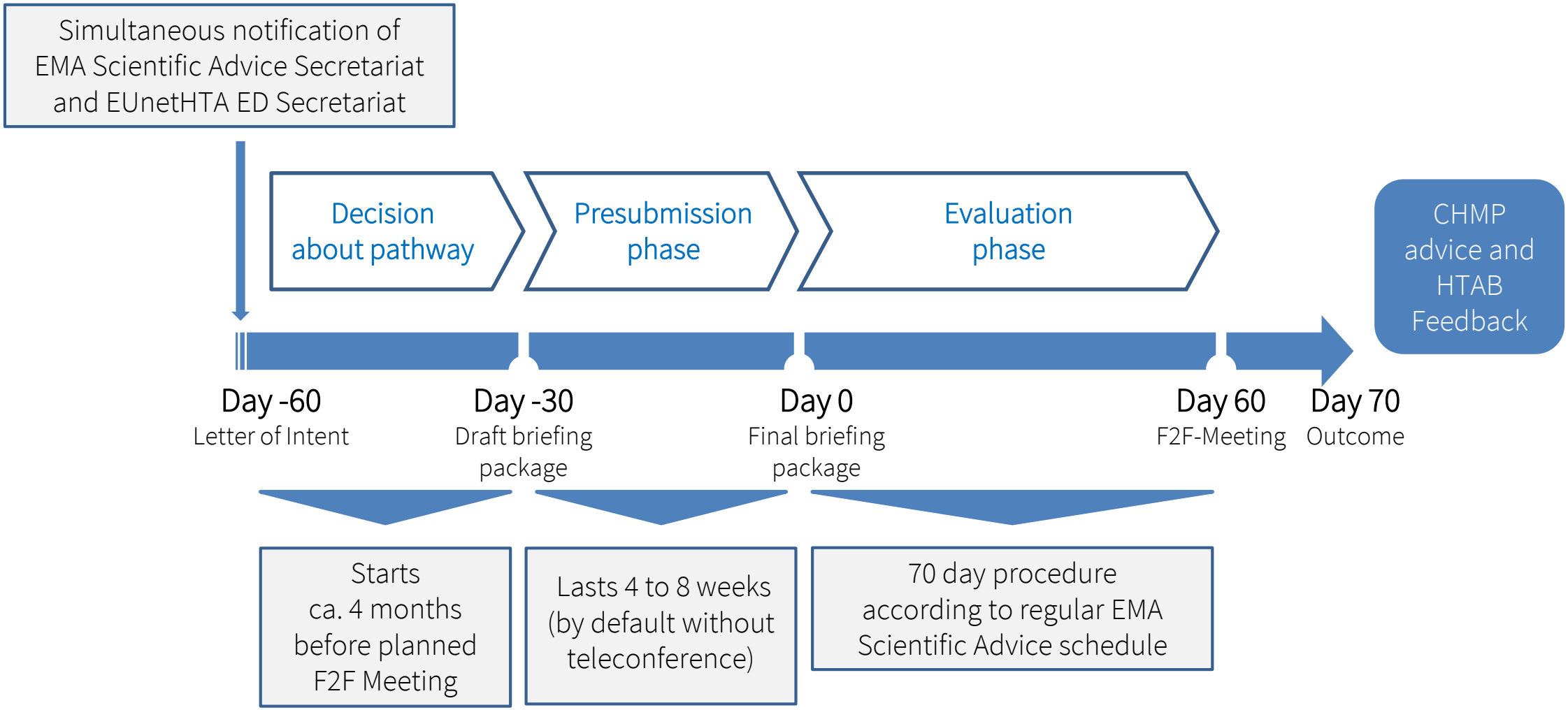
- Structured interaction between EMA & HTABs - one contact point for the applicant, common briefing document
- Improved coordination and central recruitment of HTABs by EUnetHTA ED Secretariat
- Streamlined procedure based on the EMA`s Scientific Advice timetables
- Stable group of HTABs with significant experience in EDs (EDWP)
- Inclusion of patient representatives and healthcare professionals on a routine basis

ED, Early Dialogue; **EDWP,** Early Dialogue Working Party

One Procedure – Two Pathways



Parallel Consultation Process



Reference: Guidance for Parallel Consultation: https://eunethta.eu/wp-content/uploads/2018/03/Guidance-on-Parallel-Consultation.pdf

Parallel EMA/HTAB Advice

Simultaneous feedback from Regulators and HTA Bodies: Your Benefits

- Understand different data requirements, alignment or divergence
- Optimize your evidence generation plans
- Manage and align expectations with internal and external stakeholders at an early stage

Why *AMS*?

Our Team

Our Expertise

Medical Writing

- ✓ Effective biomedical writing, clear focus on essentials
- ✓ Providing the appropriate level of detail, striking the right tone for each target group

Biostatistics

- ✓ Basic and advanced statistical analyses
- ✓ Strategic consulting, reliable programming and attractive reporting

Practical Expertise

- ✓ Numerous Scientific Advice procedures
- ✓ Requirements and mindset of authorities

Constantly up-to-date

- ✓ With recent developments regarding European HTA

Experts

- ✓ In-depth knowledge of legislative and regulative requirements
- ✓ Medical consulting

Flexibility

- ✓ Very flexible to manage projects on short notice

Close Cooperation

- ✓ With industry associations, e.g. presentations at VfA, BPI, EUCOPE, EFPIA

Continous Exchange

- ✓ With national HTA bodies and EUnetHTA

Future Situation in Europe

Early Dialogue

Marketing Authorisation

Rapid REA

Reimbursement

Common European Standard as foundation for **one** single assessment
→ basis for national uptake and
→ decision-making

Taking diverse health care systems into account

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

Interested in Learning More?

Medical Science

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