# HTA Bodies Cooperation on Early Dialogues: Recent Advances

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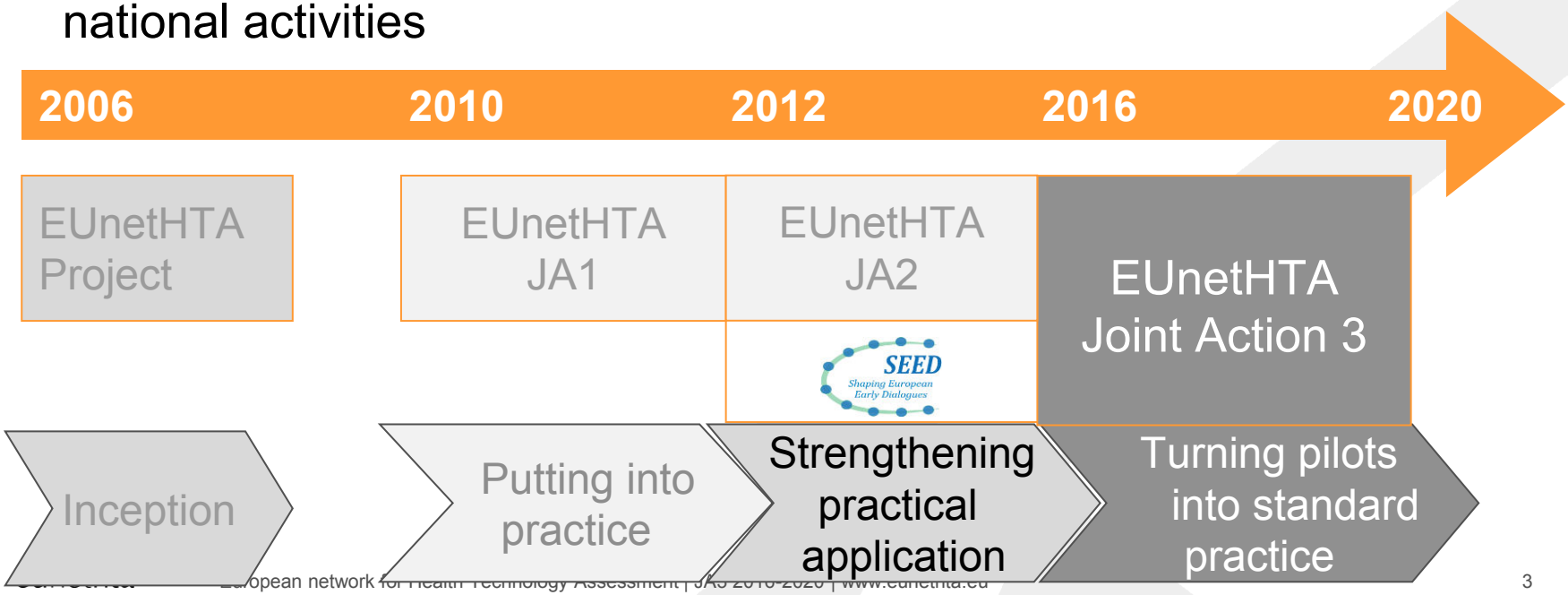
# Early Dialogue / Scientific advice

- **Definition and aim**
  - Advice given to a developer on the appropriate studies in the development of a product (medicine, device…) .
  - Advice = answers given to questions raised by the developer
  - Aim = facilitating the availability of the most appropriate data to properly evaluate a drug for Marketing Authorisation and for HTA pricing an reimbursement
- **Main characteristics**
  - Voluntary process for companies
  - Can be done at national or European level, with regulatory body or HTA bodies or both in parallel
  - May be subject to fees or not
  - Advice given is confidential and non binding

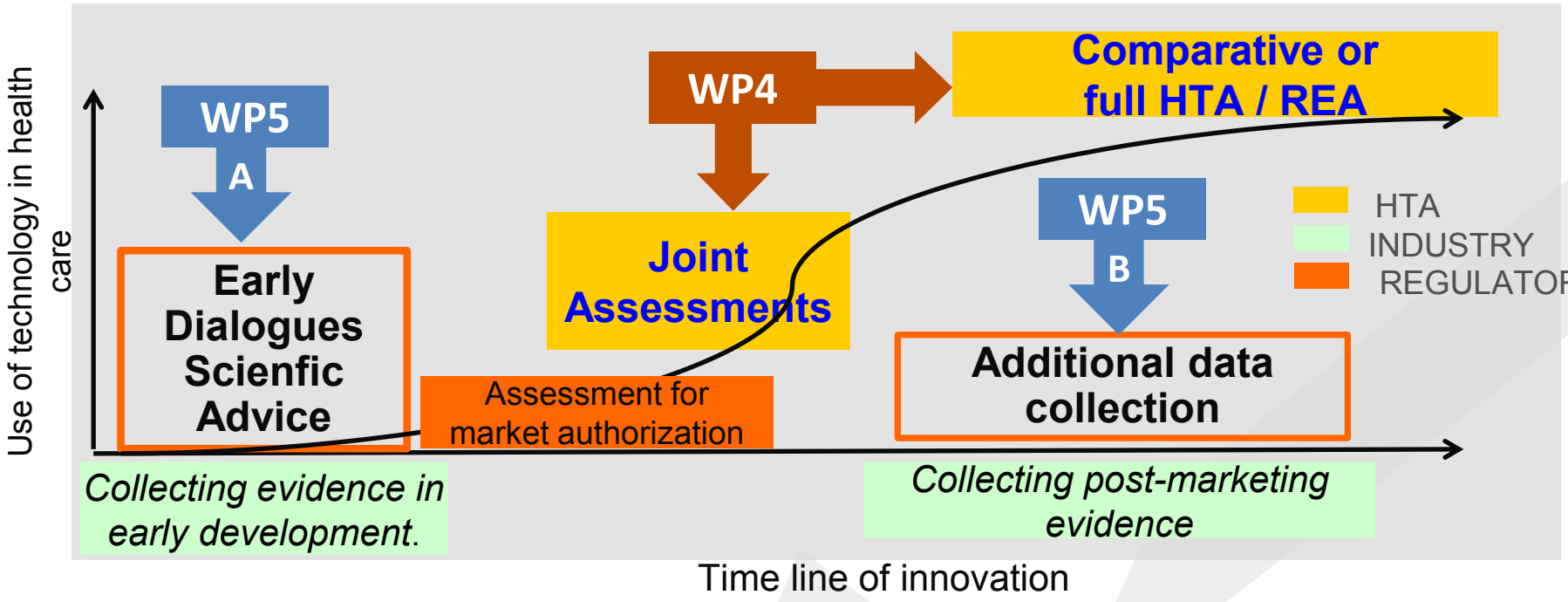
# EUnetHTA

## European network for Health Technology Assessement

- Voluntary participation, institutions named by MoH in all participating countries
- 60% of costs covered by Europe, 40% by participating institutions
- Three/Four-year project
- EUnetHTA is not a legal entity and has no permanent staff
- Some dedicated staff, most contributors participate on top of their national activities



# EUnetHTA Joint Action 3 – 2016 - 2020



# EUnetHTA Work Package 5
## Life cycle approach to Evidence Generation

*WP5 : Lead Partner HAS, Co-lead partner G-BA*

Objective of EUnetHTA WP5

- To help to generate optimal and robust evidence for different stakeholders, bringing benefits for patient access and public health.
  - **Initial evidence generation: Early dialogues**
    **WP 5 strand A**
  - **Post-launch evidence generation (PLEG)**
    **WP5 Strand B**

# Involvement of HTA bodies (HTAB) in Early Dialogues (ED) / Scientific Advice (SA)

- **SA by one single HTAB**
  - Started in 2009
  - NICE, G-BA, AIFA, HAS…
  - HTAB only or in parallel with national regulatory agency
- **SA by multiple HTABs:**
  - Started in 2012: EUnetHTA:
    13 Early Dialogues
  - Dedicated project:
    SEED Shaping European Early Dialogues:
    14 HTABs coordinated by HAS.
    11 EDs, 4 in parallel with EMA
  - EMA initiative Parallel Scientific Advice started in 2011

# Parallel Scientific Advice / Early Dialogues: situation before starting EunetHTA JA3

| | EMA-HTA<br>Parallel Scientific Advice | EMA-SEED/EUnetHTA<br>Parallel Early Dialogues |
|---|---|---|
| **Choice of HTA bodies (HTAB) involved** | Preference expressed by company | Decided by SEED partners |
| **Recruitment of participating HTABs** | Company seeks HTA availability | SEED Coordinator (HAS) |
| **Coordination role among HTABs** | HTA coordinator<br>One HTA list of issues | Yes<br>One HTA list of issues |
| **Exchanges between HTABs** | Exchange of pre-meeting HTA positions | Exchange of pre-meeting HTA positions more intensive |
| **Final outcome** | Individual written HTA answers | Compilation of HTA answers with an effort to reach consensus when possible |

Pharma Industry Views 2017

# HTA/regulatory scientific advice Experience and ways moving forward from sponsor's perspective









Presented at "Industry stakeholder platform on research and development support" 25/04/2017, EMA, London

# Industry views – April 2017

- **Call for a single European HTA/reg SA process**
  - Parallel Advice between HTA and regulators needed : single global development plan
  - But: separate advice from regulatory and HTA and national HTA advice should be possible as well, processes are complementary
- **Further improvements needed (based on EMA PSA and EUnetHTA/SEED)**
  - Simplify logistics: single point of contact/project management
  - More consistent & predictable HTA engagement, with dedicated resources and capacity building across HTAs
  - Clear, aligned and written output from HTA advice

# Industry views – April 2017 (Cont.)

- **General process**
  - Advice should be possible at all stages of product lifecycle
    - Early stage
    - Pre Phase III
    - Post-launch period
  - Process should be open to all development products,
    - including new value added elements for products with well-known active substance. No selection or prioritization.
  - Concise process

- **The output can inform a future joint European assessment of relative efficacy at time of launch**

# List of EUnetHTA actions for ED/SA (1)

- **Provide a strong process for Parallel consultations with EMA**
  - Parallel consultations launched in July 2017
- **While maintaining  multi-HTA Early Dialogues**
  - Available since January 2017
- **Improvement of logistics:**
  - Central EUnetHTA ED secretariat at HAS (Lead Partner) EUnetHTA-HAS@has-sante.fr
- **“More consistent & predictable HTA engagement”**
  - Set up of a Working Party

# List of EUnetHTA actions for ED/SA (2)

- **“Clear, aligned and written output from HTA advice”**
  - Increase cooperation and coordination by appointing a rapporteur and a scientific coordinator for each ED/SA
- **No selection criteria, all products to be accepted?**
  - EUnetHTA budget limits: Selection necessary for EUnetHTA involvement
  - Parallel consultation possible for products not selected by EUnetHTA Working Party : participation of HTA bodies on a voluntary basis (with no use of EUnetHTA budget)
- **Life cycle approach**
  - Activities on Post-Launch Evidence Generation (PLEG)

# Patients involvement

- **Past experience: First tested in SEED project (2013-2015)**
  - Strong support of EURORDIS for patient recruitment and preparation of their intervention
- **Several approaches tested in the frame of limited resources**
  - Interview of Individual Patients  in all cases
  - Interview and more active participation of Patients representatives
  - Participation in the face-to-face meeting with the company not systematic (may become systematic soon)
- **Dedicated task force at EUnetHTA  level**
  - Global harmonised policy for all Work Packages

# Early Dialogue Working Party (EDWP)

## Gathers HTA bodies with important experience and cover various countries

EDWP members are HTA bodies experienced in collaborative EDs:

- with adequate expertise, availability and budget
- with high commitment to participate in EDs

Currently

- France (HAS)
- Germany (G-BA)
- UK (NICE)
- Italy (AIFA, RER as alternate)
- NL (ZIN) and BE (RIZIV INAMI) – Shared seat
- Hungary (NIPN)

Possible extension to Scandinavian countries (NOMA and TLV), Spain

# Selection criteria for EDWP involvement

- **Primary criteria**
  - A new mode of action for the indication
  - AND targeting a life-threatening or chronically debilitating disease
  - AND responding to unmet need (no treatment or only unsatisfactory treatment available)
- **Secondary criteria**
  - Selected EDs should represent a wide array of topics, therapeutic areas etc.(e.g. orphan, ATMPs, antibiotics, oncology)

# Process – steps

BB = Briefing book
Contains documentation on the product and list of questions

eunethta
European network for Health Technology Assessment

EUROPEAN MEDICINES AGENCY

## Applicant

Day - 60 — Applicant sends **letter of intent** to

Day - 30 — Applicant sends **draft BB** to

Day - 2 — Applicant sends **final BB** to

Day + 45 — Applicant sends **response to list of issues** to

EUnetHTA ED Secretariat

**&**

EMA secretariat

## EMA/EUnetHTA

Prioritization by EDWP according to **selection criteria**

**Clarification request** on draft BB — Day - 15

**List of Issues** — Day + 30

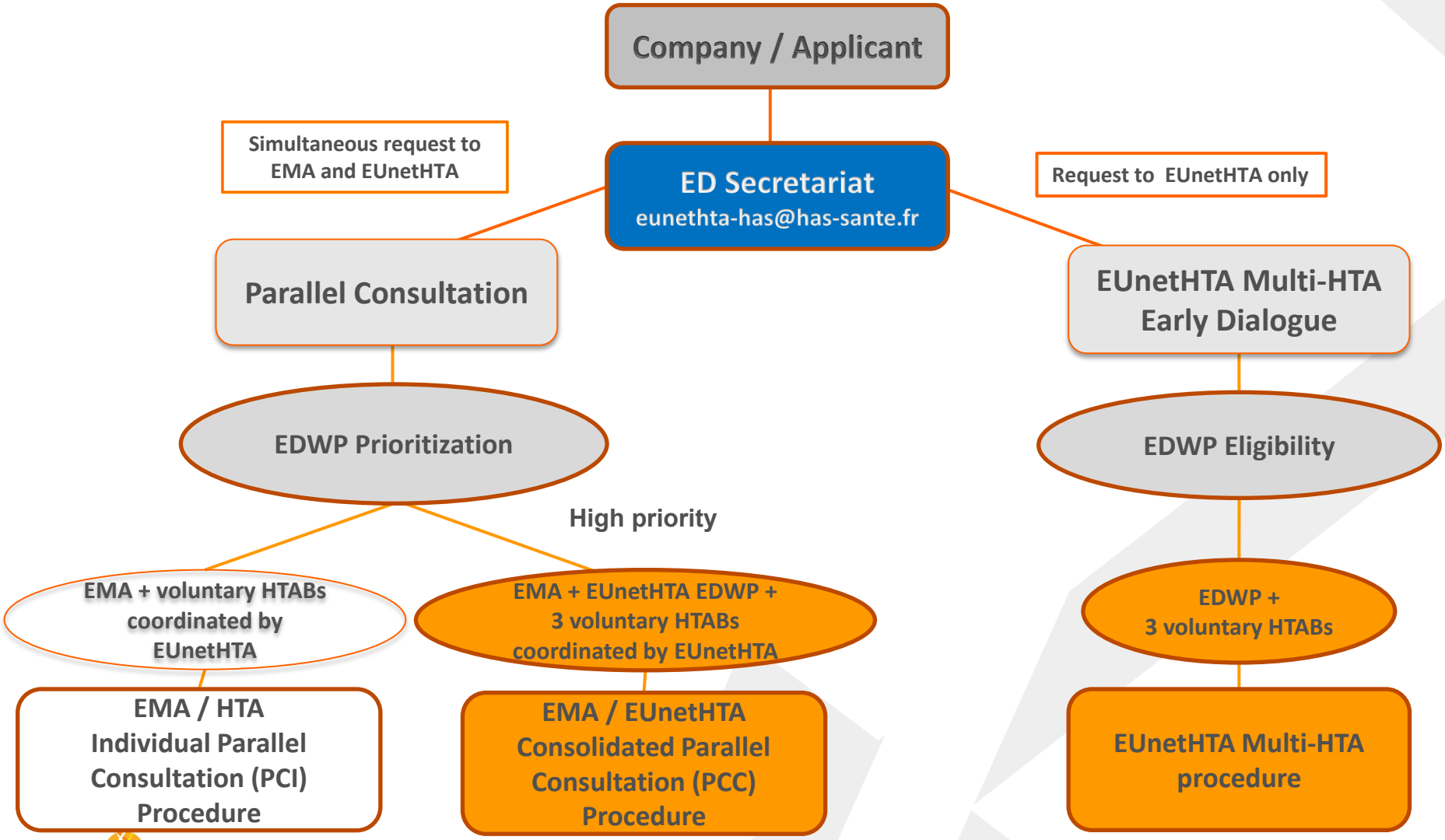
# Process – steps

eunethta
European network for Health Technology Assessment

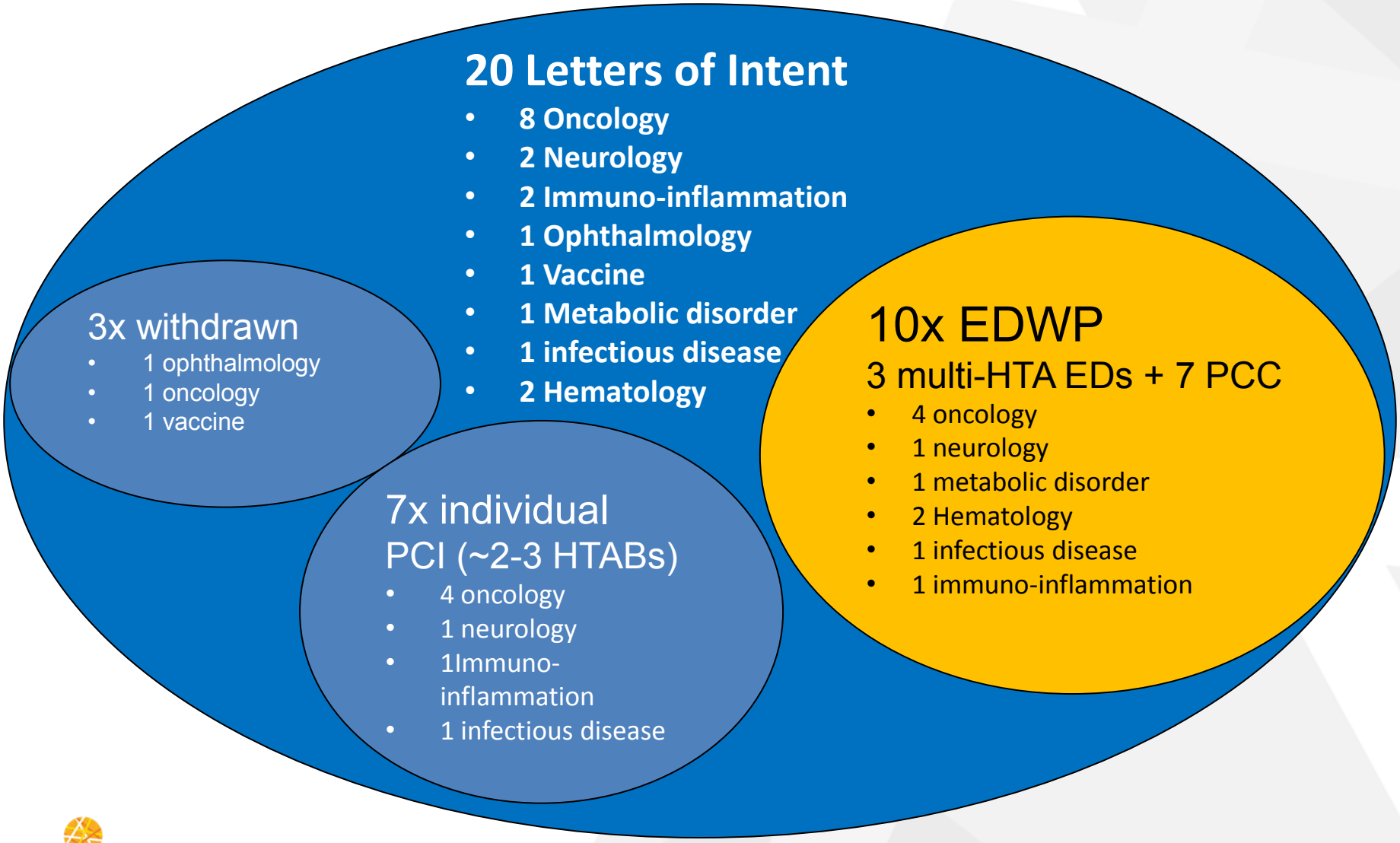
EUROPEAN MEDICINES AGENCY

| | Applicant | | EMA/EUnetHTA | |
|---|---|---|---|---|
| Day + 56 | Applicant sends **power point presentation** to | EUnetHTA ED Secretariat & EMA secretariat | *Optional discussion of late changes* | Day ~50 |
| Day + 60 | Face to face meeting with the Applicant, EMA and EUnetHTA EDC (max 3 h) | | | |
| Day + 67 | Applicants sends **minutes** to | EUnetHTA ED Secretariat & EMA secretariat | **Final advice letter/final written recommendations** | Day +70/+75 |

# Procedures for ED / SA with multiple HTA bodies



# WP5A - Early Dialogues – Status since JA3 start



# Collaboration on Post Launch Evidence Generation (PLEG)

- PLEGs can be a topic for questions during an Early Dialogue / Parallel Consultations

*Work package 5 Strand B actions*

- Collaborative actions with the EMA on Registries
  - Qualification of registries: 2 pilots, one on a rare disease
- Drug specific pilots on collaboration between HTA bodies for the requests of PLEG
  - Two pilots being launched, one on an orphan drug
  - Collaboration on
    - analysing evidence gaps
    - defining research questions
    - Data or results pooling once data collection processes are put in place

# Thank you

## Any questions?