



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Patient engagement at EMA

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An agency of the European Union





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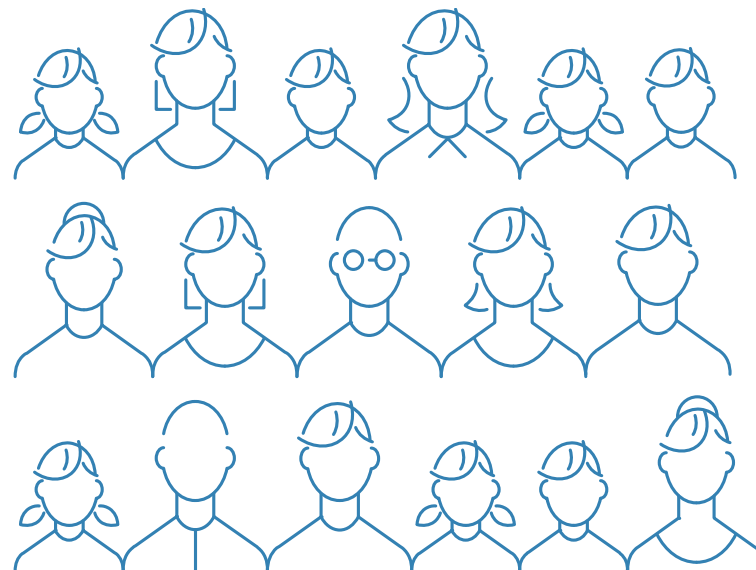
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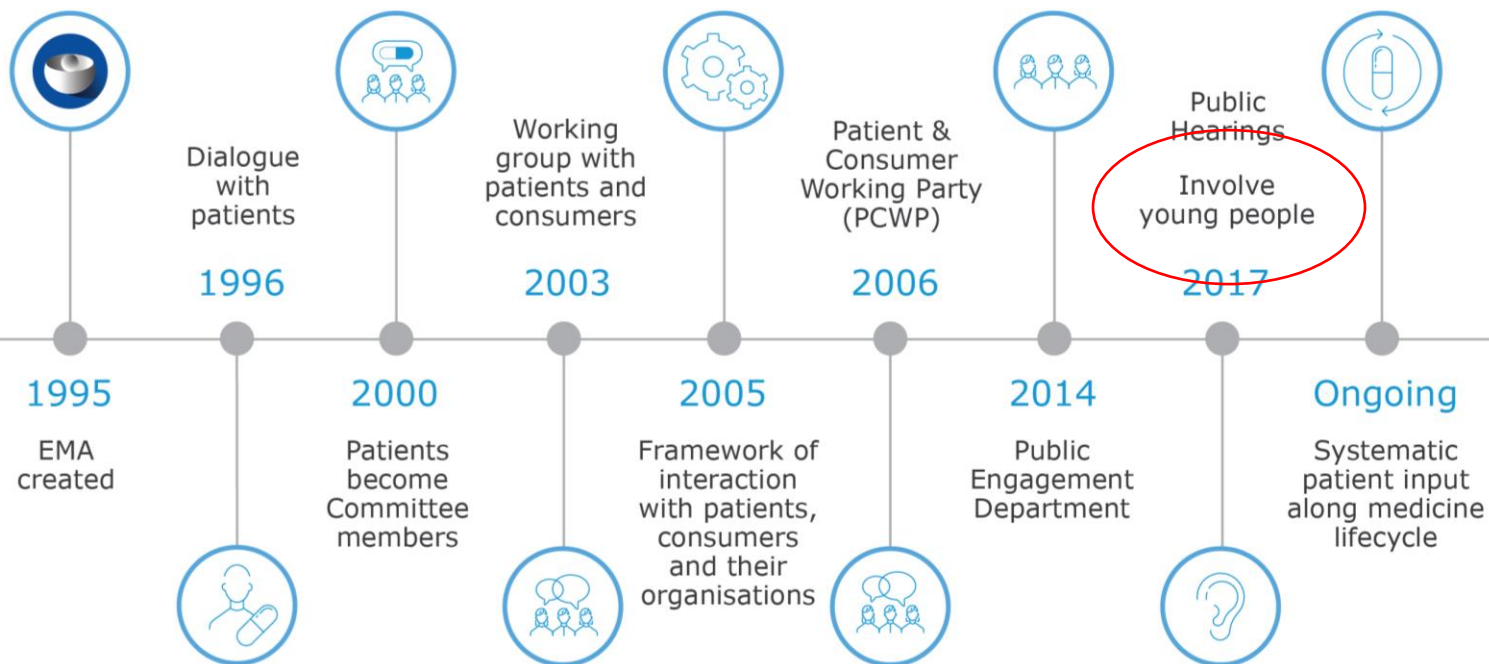


Patient engagement: Integral element of EMA activities

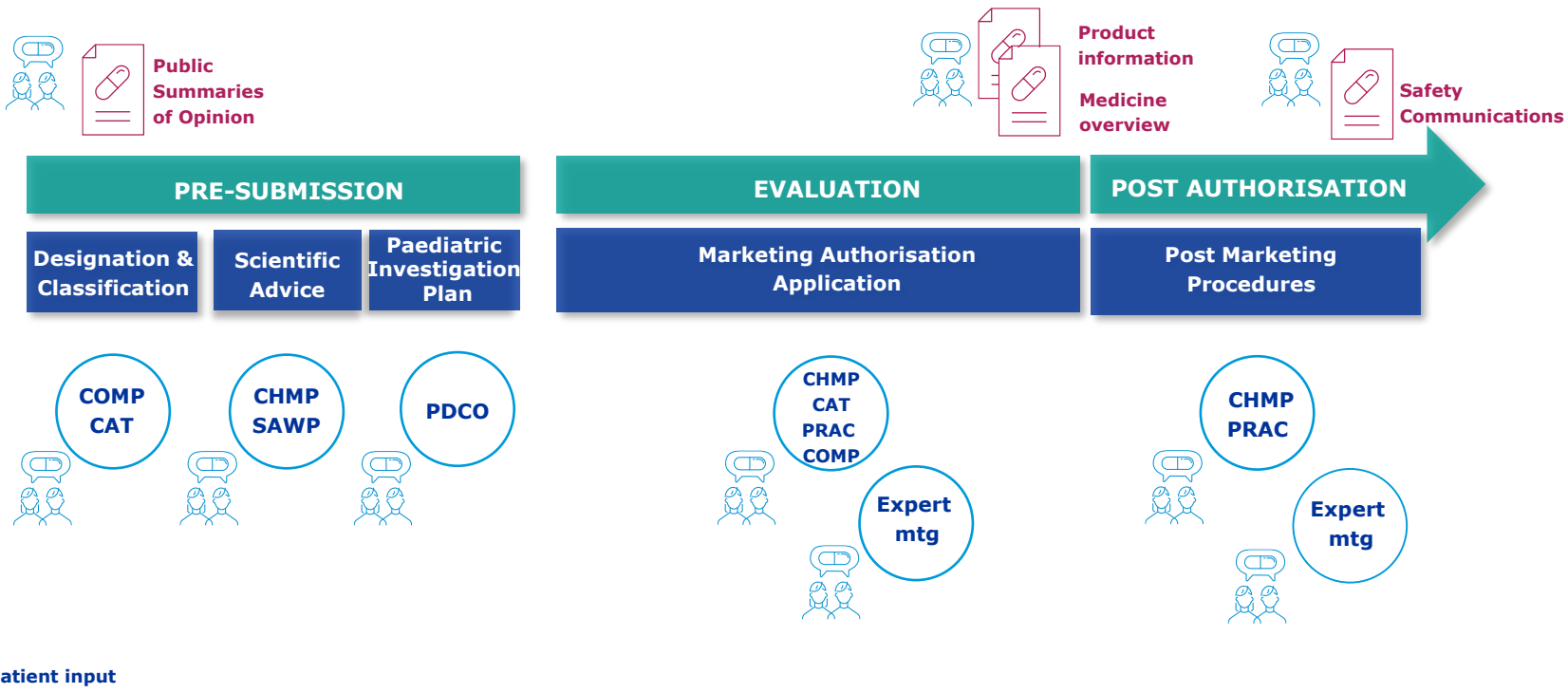




Interaction with patients: a progressive journey...



The patient voice along the medicine lifecycle





Different ways to participate:

Representing the
patient community

- Members of EMA Management Board
- Members of EMA Committees

Representing *their own organisation*

- Patients and Consumers Working Party (PCWP)
- EMA consultations
- Workshops

Patients as *individual experts*

- Scientific Advice procedures
- Expert meetings
- Committee consultations
- Review of documents



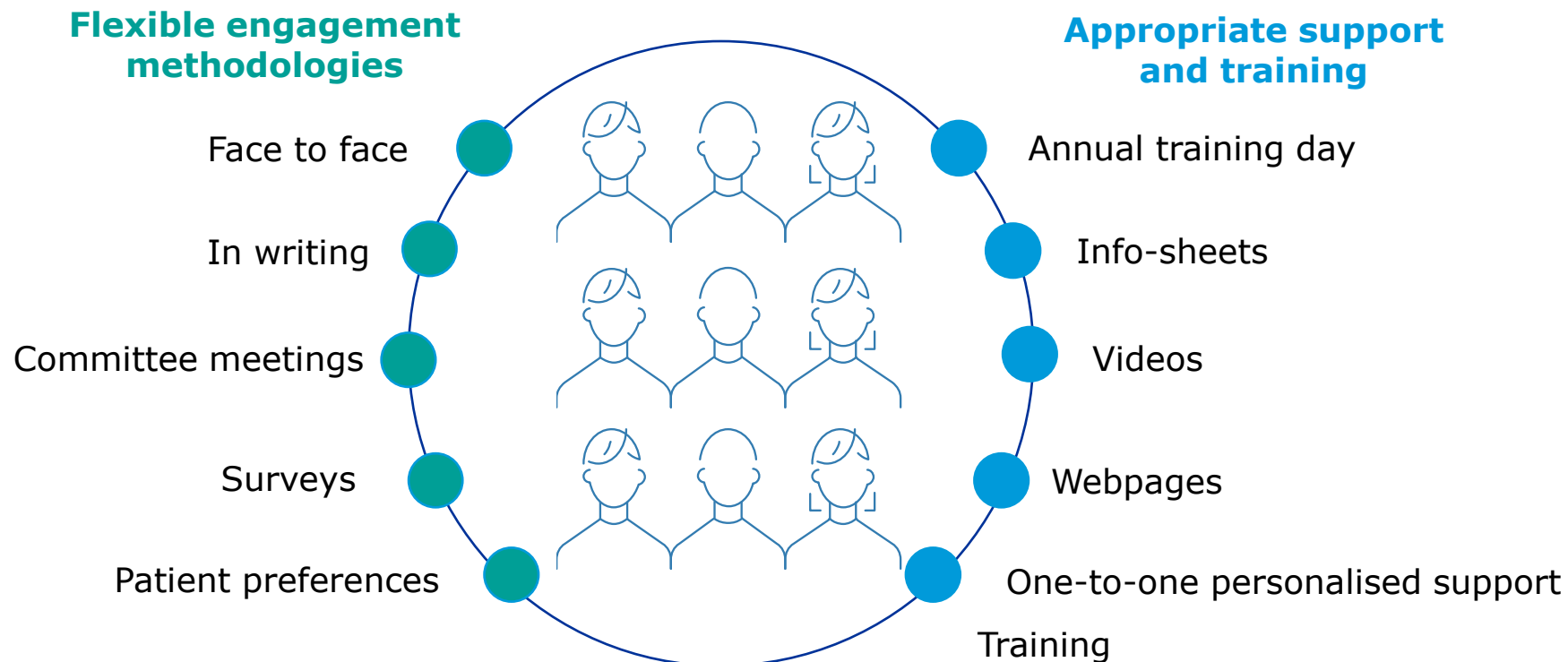
Opportunities for young patients to contribute

- Scientific advice procedures (development plans) meeting or in writing
- Committee expert group meetings
- Committee direct consultations (f2f /questionnaire)
- Stakeholder meetings (medicine-related)
- Review of labelling, risk minimisation measures and safety communications (appropriate language / increase awareness)
- Public hearings



Vital elements

 One size does not fit all!





Patient networks

- **Any organisation** representing EU patients or consumers can express an interest to work with EMA

(eligibility criteria & application form: [EMA website](#))

- **Any individual** patient or carer can register to work with the EMA

(application form on [EMA website](#))





Requirements for involvement in EMA activities

- EMA has to ensure its experts (including staff and MB) do not have any financial or other interests that could affect their impartiality.
- [Policy on handling of competing interests of scientific committee members and experts](#)

All experts participating in EMA medicine related activities need to have:

- Up-to-date **DoI, e-CV & Expert Nomination** form (tick box option for patients)
- Valid for 1 year
- Includes confidentiality undertaking
- Published on the EMA website in the [European experts list](#)



DoI *electronic form*

SECTION 1: PERSONAL DETAILS

SECTION 2: PUBLIC DECLARATION OF INTERESTS

- *2.1 Employment*
- *2.2 Consultancy*
- *2.3 Strategic advisory role*
- *2.4 Financial interests*
- *2.5 Principal investigator*
- *2.6 Investigator*
- *2.7 Grant / Funding to organisation/institution*
- *2.8 Close family member interest*
- *2.9 Any other interests or facts*



SECTION 3: CONFIDENTIALITY UNDERTAKING



Consultancy for a pharmaceutical company

Is

any activity where the expert provides *any kind* of advice (including training) to a pharmaceutical company regardless of what is being discussed or contractual arrangements or any form of remuneration.





Grant or other funding to an organisation/institution

Is

any funding received from a pharmaceutical company by an organisation/institution to which the expert belongs, or for which he/she performs any kind of activity, and which is used to support any activity of the expert whether or not it is related to research work.

Patients :

- Who are **volunteers** with their organisation do not have to include funding related to their organisation on their DOI, unless they are committee / working party member/alternate.
- who are **employees** of their organisation do have to include funding related to their organisation on their DOI under 2.7.



Involvement in EMA activities - examples

- 1. Alopecia;** PDCO reached out to young people with experience of hair loss to understand their views about a potential treatment = 33 responses/15 countries
- 2. Hormonal contraceptive;** PDCO asked young girls what they felt about different dosing options (how often to take the pill)
- 3. AADC deficiency** (very rare); PDCO wanted to better understand needs and desired improvements versus the acceptable risks of a treatment
- 4. Haemophilia;** a young boy joined a Scientific Advice meeting with his father and shared his views on dosing and change over of medicines.
- 5. ALS & Epidermolysis Bullosa** COMP invited young patients to the plenary meeting to share their experiences in terms of the burden of the conditions

Why is patient engagement important?

- Engaging with patients:
 - Brings **everyday aspects** of living with a disease **into scientific discussions**
 - Helps **bridge the gap** between clinical trial data and real world data
 - Increases **awareness and understanding: TRUST**
- Engagement should be **mutually beneficial** - Learn together what format works best;
 - Be prepared – understand your role – provide relevant information



Everyone has a role to play to ensure engagement happens



Engaging with patients leads to **more meaningful outcomes** for everyone!



Questions?



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