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Breakout session 6: How should patients be involved in the regulatory process?

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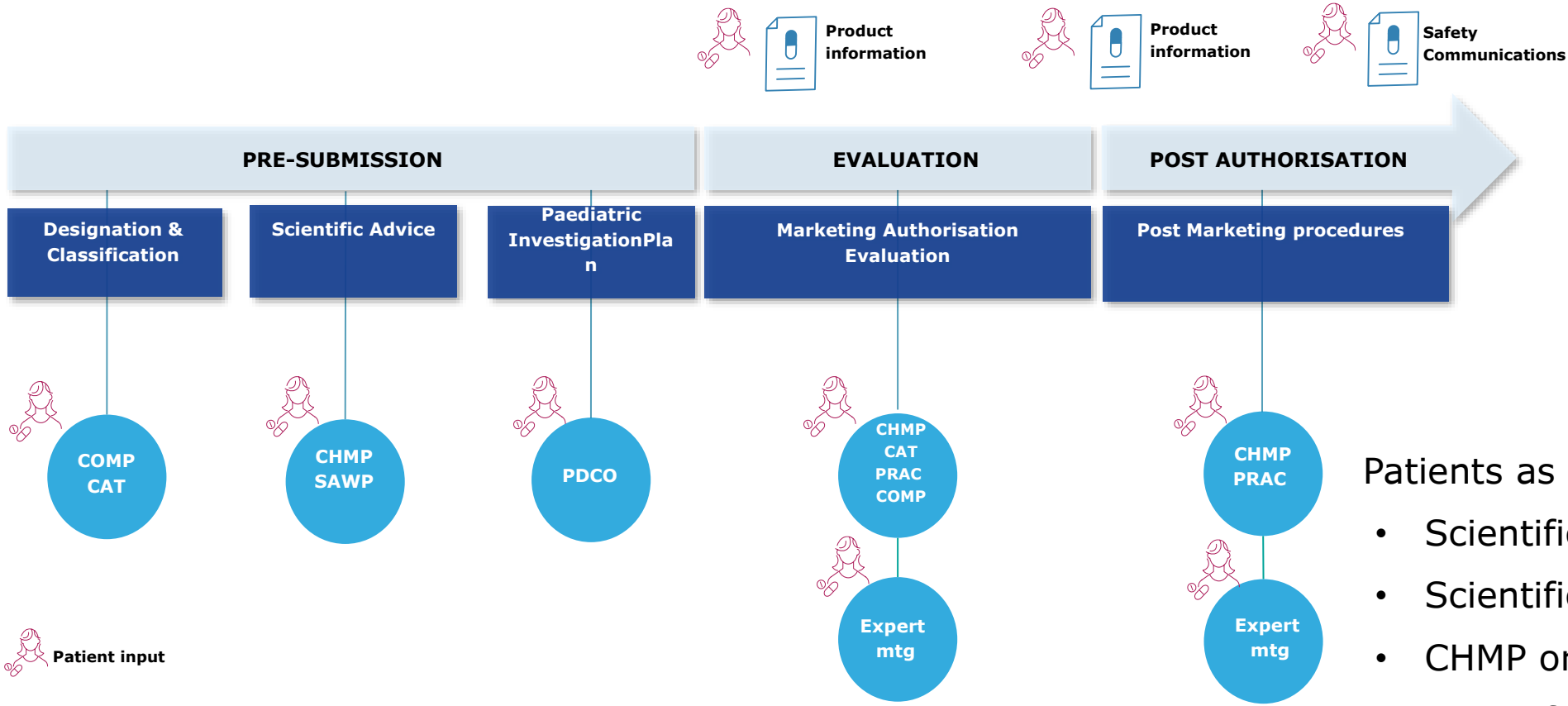
A meeting of the ESC Cardiovascular Round Table (CRT) with contribution from the European Medicines Agency (EMA): “Unmet Needs in Cardiovascular Diseases focusing on patient-benefit risk and patient-reported outcomes”, 19 & 20 February 2025, Amsterdam

Overview: when and where patients are involved



Patients as committee members:

- COMP, CAT, PDCO, PRAC

Patient organisations:

- CHMP early dialogue

Patients as individual experts:

- Scientific advice/protocol assistance
- Scientific advisory groups/AHEGs
- CHMP oral explanations
- Scientific committee consultations
- Review of documents

Discussion points

- Learning the current involvement of patients during the EMA process
  - Including upcoming opportunity for data transfer between industry-collected patient insights during trial design to the EMA patient representatives
- Additional opportunities:
  - English as a language barrier – invest in translation tools? Are there safe apps for simultaneous translation (e.g. systron?)?
  - Not all patients can contribute similarly – are there different profiles to consider?
  - Geographic representation given the heterogeneity of the European Health settings → local subteams working on localization?
  - Patient group working on clinical endpoint as well as PROs/PED
  - Industry to consider publication of the patient insights collected during their trial design process
  - For our white-paper: industry partners to share summary of their ongoing patient engagement activities (structured format?) to the writing group

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Thank you

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