Patient Engagement at EMA

5th Industry Stakeholder Platform on R&D support

Session 8: Progressing the concept of patient-centred development in practice

Presented by Nathalie Bere / Juan Garcia on 16 November 2020
Patient Engagement, Public and Stakeholders Engagement Department

An agency of the European Union

Disclaimer

The presenter does not have any conflict of interests.

Patients to contribute directly to scientific discussions

- Committee (full voting) membership (COMP, PDCO, PRAC, CAT)
- Scientific advice / protocol assistance procedures
- Scientific Advisory Groups (SAGs) / Ad-hoc expert group meetings
- Committees direct consultations (f2f /questionnaires/surveys)
- Multi-stakeholder meetings
- Public hearings
- Review of labelling, risk minimisation measures and safety communications

Networks

Organisations; representing EU patients or consumers may express an interest to work with EMA, (eligibility criteria & application form: EMA website)

Patients and Consumers Working Party

Individuals; patient or carer can register to work with the EMA (application form on EMA website)

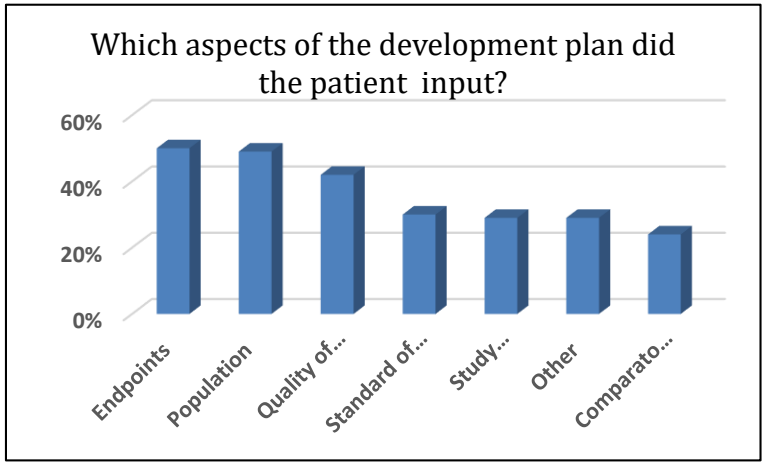
Some key aspects to successful engagement

- **Who** to engage with?
  - Create diverse group of stakeholders to consult
  - Criteria for organisations / individual participation
- **How** to engage?
  - Test and use various engagement methodologies
  - Provide appropriate training and support to enable input
  - Transparency - share relevant information / outcomes
  - Continuous monitoring and reporting
- **When** to engage?
  - All along the medicines lifecycle; begin early and don’t stop!

Continuous monitoring and measuring value / impact

EXAMPLE: 3 year survey ≈ 300 Scientific Advice procedures:

- 79% patients agreed with the proposed development plans
- 53% of the patient`s comments resulted in further discussion
- 23% of the patient`s input resulted in a modification of the final advice



REVIEW OF DOCUMENTS: 50% of comments led to changes

Looking ahead

Timely discussion:

- Revising framework of interaction
- Two levels of complementary patient engagement; enhance generation and use of patient experience data – expand methodologies for patient input during regulatory assessments, e.g. systematic early interactions, focus groups, patient preferences
- Provide guidance on collection and use of patient data
- Enrich training and support with new tools and content
- Expand capacity and network outreach
- Exchange methodologies across decision makers (e.g. HTAs)
- Also in a global context

Questions?

Further information

Contact me at Nathalie.Bere@ema.Europa.eu

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

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