EUPATI CASE REPORT on meaningful patient involvement in R&D and regulatory affairs

LYMPHOMA PATIENT REPRESENTATIVE AT EMA JOINT HTA SCIENTIFIC ADVICE

PROVIDED BY:
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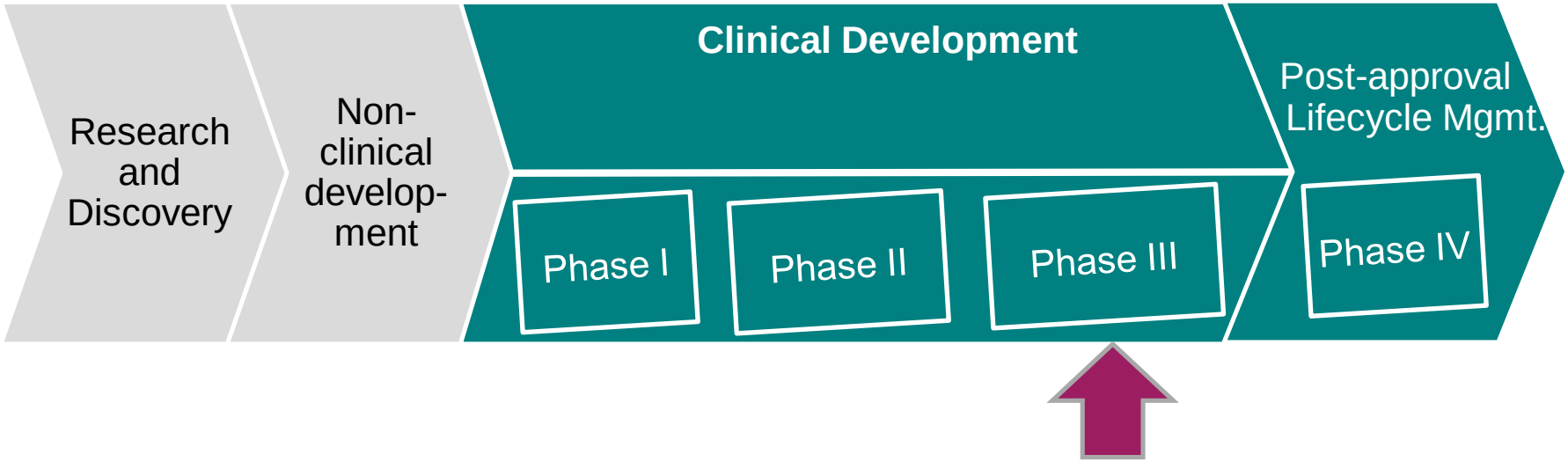
PARTNER(S) INVOLVED:
Lymphoma Patient Organisation Expert

Description of the case (how were patients involved in the R&D project? What was the objective?

INVOLVING A PATIENT EXPERT WITH EMA

- We invited a Lymphoma Patient expert to attend a “EMA-HTA Parallel Scientific Advice Meeting” to discuss a protocol in lymphoma.
- The patient involved is leader of a local Lymphoma patient organisation, experienced in the disease, was trained in clinical development.
- The patient collaborates as well with local authorities.

RESEARCH/DEVELOPMENT PHASE



Type of patient (advocates) involved

[**X**] Patients with personal disease experience

[**X**] Expert patient / patient advocate with good expertise on disease, but little R&D experience

[ ] Expert patient / patient advocate with good expertise on disease and good R&D experience

[ ] Other: [ ]

Challenges and barriers (and how they were overcome, or which ones were unresolved)

Novartis involvement was very intense:

- 2 face to face meetings, preparation with Medical and Regulatory, email, TC. The treatment to be discussed was however quite complex and need the patient to understand it well.
- The Expert patient has the impression not be included anymore by EMA in advice because of this first collaboration with industry.
- Lesson-Learned from the Novartis Patient Relations perspective:
  - Speak as early as possible to the specific NOVARTIS Drug Regulatory Affairs and Clinical Trial Leaders (6 months in advance of the SA)
  - Need of preparation efforts, quite intense
  - EMA as well involved an expert patient, but no direct questions to both from EMA
  - A slide with the patient perspective was in any case included in the slide deck sent to EMA
  - Identify the appropriate expert which has no conflict of interest with EMA
  - Inform the patient group network (in that case Lymphoma Coalition Europe)

Benefits (how has this collaboration improved R&D process(es) and the R&D outcome(s) or triggered R&D organisational change)

INTERNAL EXPOSURE TO PATIENT NEEDS

- For the first time the Unit engaged an expert patient for EMA SA meeting.
- Several people, from medical, drug regulatory affairs, commercial met the patient, understood the needs, asked for input in the protocol, specifically on Patient Reported Outcomes.

- LEARNING HOW TO PREPARE FOR AN EMA SA WHEN INCLUDING THE PATIENT
- The experience will drive and streamline future activities of this type

Discussion and learnings for the company and EUPATI

- In general this was a good first Novartis experience and learning for the future.
- We should work better with EMA and ask them to designate a specific time allocated to the invited (by the company and/or by EMA) patient experts.
- It would be good if EMA provided the patient expert with specific questions in advance.
- Clarify in advance with EMA and the patient expert invited by the company if the expert patient will be asked by EMA to collaborate in the future, or if this first collaboration with industry will make it impossible for the expert patient to be involved by EMA.