EUPATI .be

European Patient's Academy on Therapeutic Innovation

Patient Involvement in Medicines Research and Development

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Chair EUPATI BE VZW

EUPATI is needed because…

- **Patients…**
  - seek up-to-date, credible, understandable information about innovation in treatments
  - are largely unaware about clinical trials, translational research, personalized medicine, pharmaco-economics etc and their key role

- **Patient advocates…**
  - have an increasingly complex and professional task of advising on protocol design, informed consent, ethical review, marketing authorization, value assessment, health policy
  - are often self-taught and have gaps in the education and training required to participate as an equal partner in medicines R&D

Patients as partners: partnership model requires a paradigm shift, and more training for patients and advocates

Patient roles in Medicines R&D (academia + industry)

- **Driving force**
- **Co-researcher**
- **Reviewer**
- **Advisor**
- **Info provider**
- **Research subject**

Source: PatientPartner FP7 Project (2010)

Competent Authorities

Policy Makers/Research Policy

HTA Agencies/Committees

Research Ethics Committees

The EUPATI objectives are directly contributing to this paradigm shift

Key objectives:

1. **Develop and disseminate objective, credible, correct and up-to-date public knowledge about medicines R&D**

2. **Build competencies & expert capacity** among patients & public

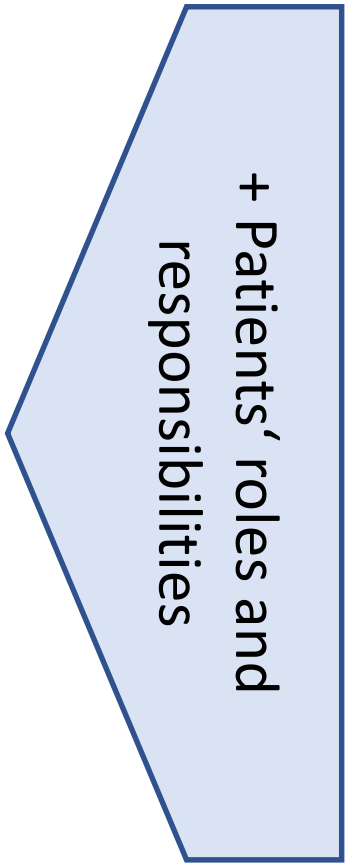
3. **Facilitate patient involvement in R&D** to collaborate in academic research, industry research, authorities and ethics committees

…and *NOT:*
develop indication- or therapy-specific information!

EUPATI empowers patients with education in key areas of medicines R&D

Educate and train patients and patient advocates with objective, credible, correct and up-to-date information about:

1. Discovery of Medicines & Planning of Medicine Development
2. Non-Clinical Testing and Pharmaceutical Development
3. Exploratory and Confirmatory Clinical Development
4. Clinical Trials
5. Regulatory Affairs, Medicinal Product Safety, Pharmacovigilance and Pharmaco-epidemiology
6. HTA principles and practices



EUPATI is developing education targeted at different levels

EUPATI Patient Experts Training Course
-- for expert patients

100 patient experts

EUPATI Educational Toolbox
-- for patient advocates

12.000 patient advocates

EUPATI Internet Library
-- for the health-interested public

100.000 individuals

English
French
German
Spanish
Polish
Italian
Russian
Dutch

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EUPATI Patient Experts Training Course
-- for expert patients

100
experts

1st course done, 2nd running

- e-learning
- Classroom style face to face teaching

EUPATI Educational Toolbox
-- for patient advocates

12.000
patient advocates

Launched on 27 Jan 2016

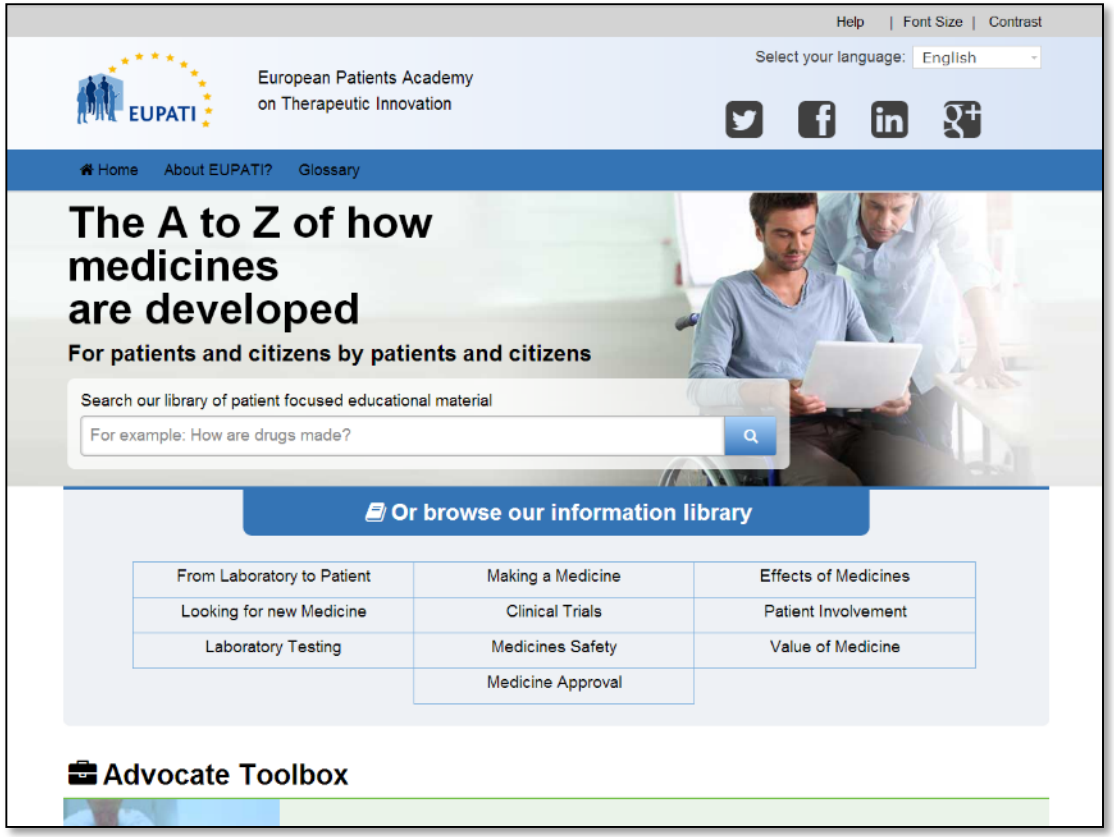
- Slide shows, factsheets, videos and webinars, glossary
- 'print ready' content

EUPATI Internet Library
-- for the health-interested public

100.000 individuals

- Encyclopaedia
- Short video documentaries
- Patient interviews
- micro-lectures (as podcasts)
- Images, diagrams

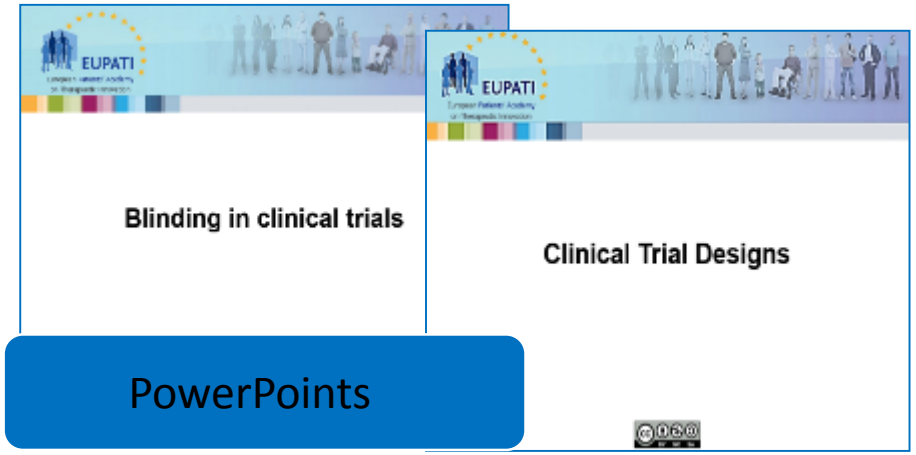
EUPATI Toolbox on Medicines R&D in 8 languages



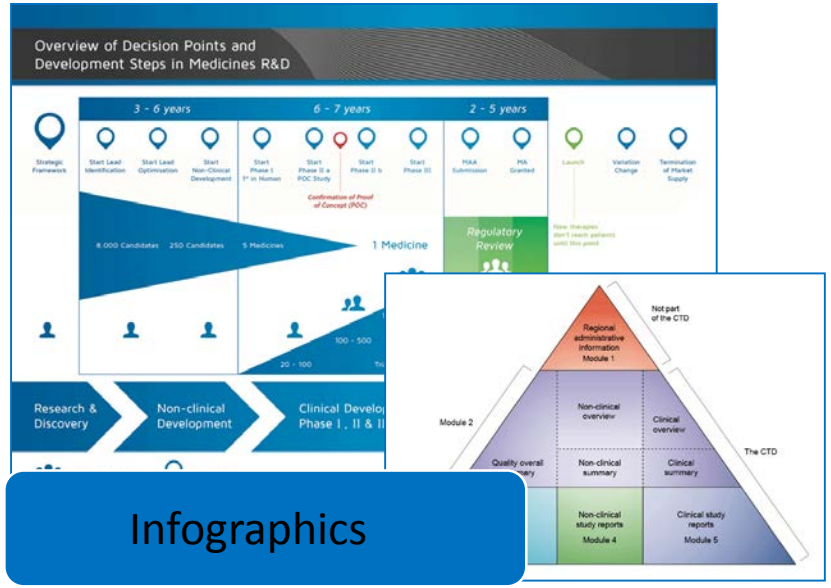
- Fact sheets, detailed papers, PPTs, videos, illustrations, glossary.
- In English, French, Italian, Spanish, German, Polish, Russian and Dutch.

The Patients' Academy: Patient Advocate Toolbox – Formats

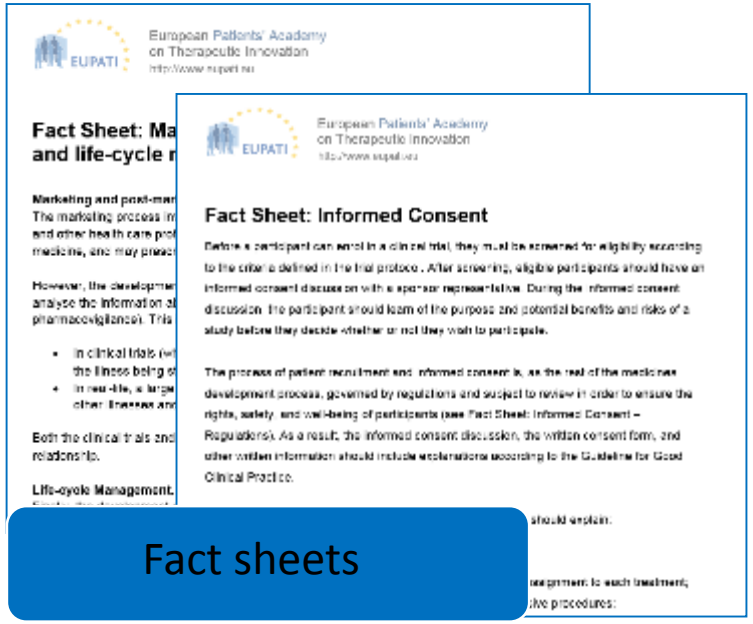
Articles



PowerPoints



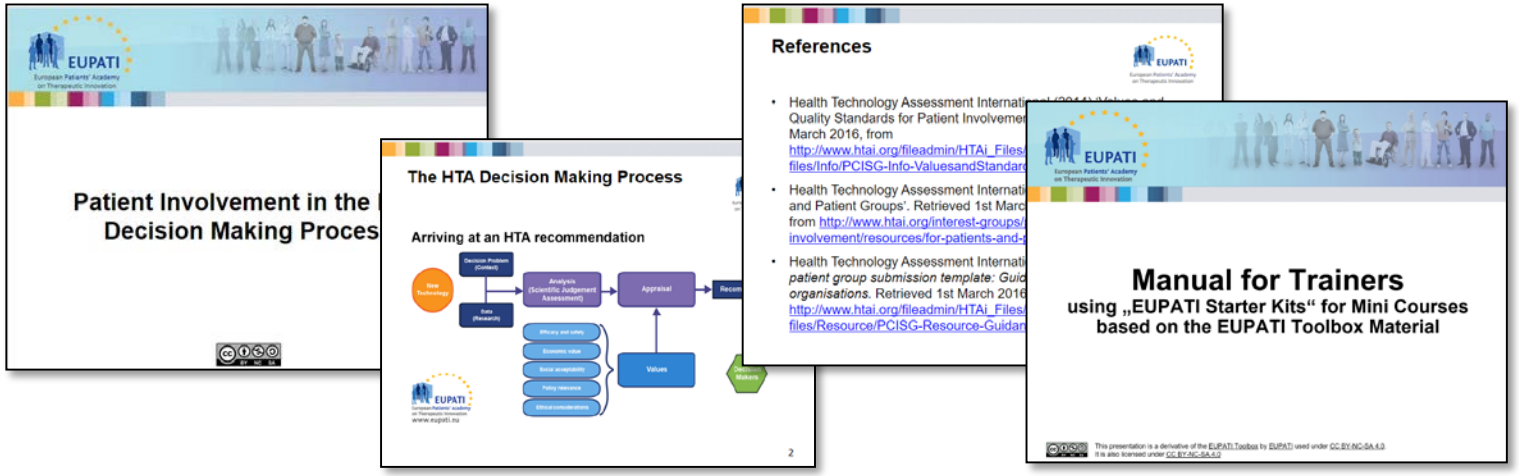
Infographics



Fact sheets

EUPATI Mini-Course Starter Kits: Resource to prepare and run mini-courses

- Core set of PPT slides, outlining a specific area of R&D and how patients can get involved, plus additional links of EUPATI Toolbox resources, case studies and exercises, plus Trainers Manual
- Patient involvement in…
  - Setting research priorities
  - Ethics Committees
  - Data Monitoring Committees
  - Trial Steering Committees
  - Scientific advice
  - Protocol design
  - Product information, informed consent and patient information to trial participants
  - Medicines safety
  - Health Technology Assessment



Reflecting European diversity: 8 languages, 12 countries

8 most frequently spoken languages:

- **English**
- **French**
- **German**
- **Spanish**
- **Polish**
- **Italian**
- **Russian**
- **Dutch**

12 countries:

UK, Ireland, Malta, France, Luxemburg, Belgium, Germany, Austria, Switzerland, Spain, Italy and Poland, plus Russian-speaking population in Central and Eastern Europe

Plus additional countries and languages in preparation by the community, e.g. Danish,
Romanian, …

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EUPATI BE VZW

About the Belgian ENP

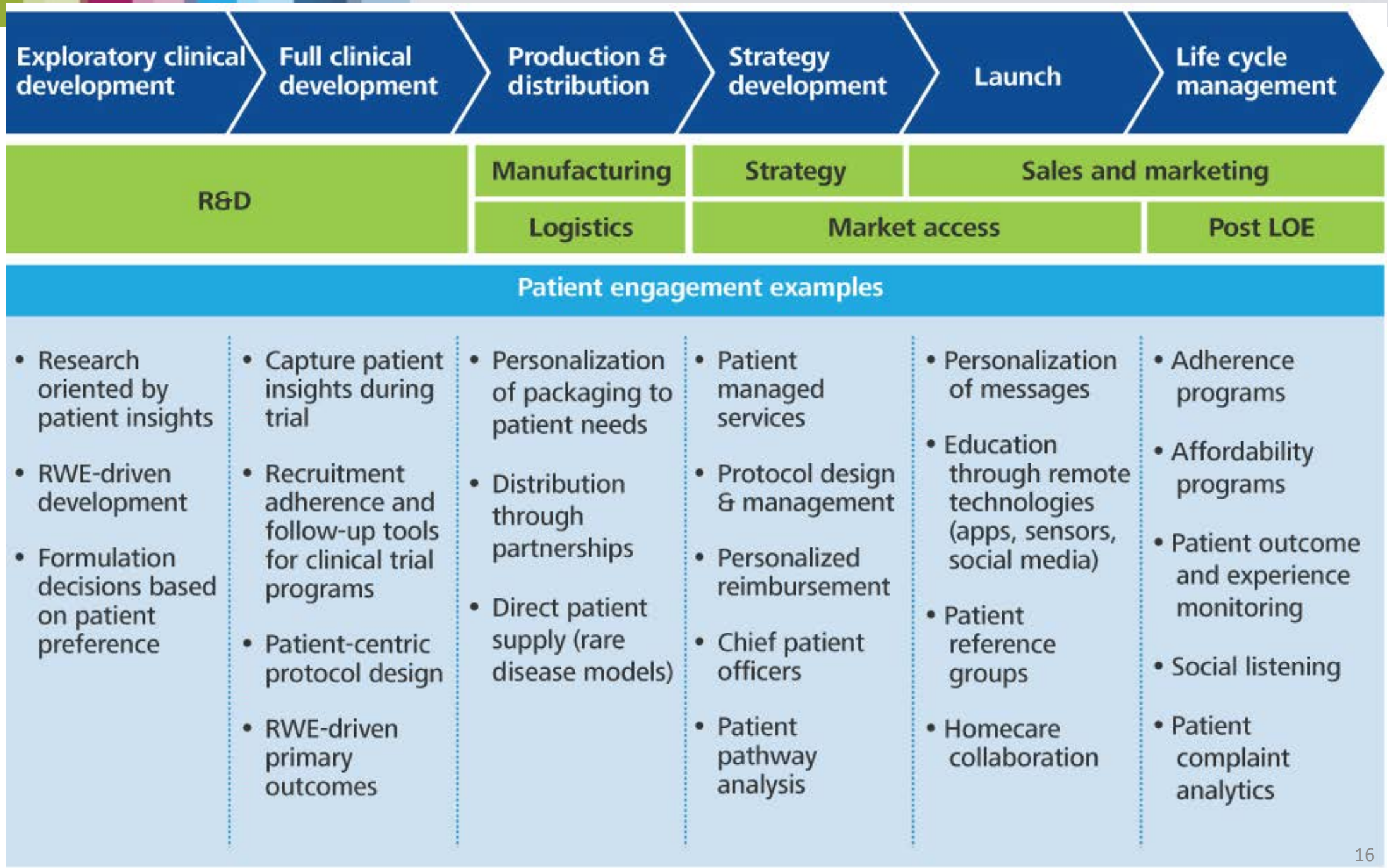
- The EUPATI National Platform (ENP) in Belgium brings together patient, academic and industry representatives who want to work in partnership to **promote patient education** and **enhance patient involvement** in the Belgian medicines research and development (R&D) process

- The National Platform is led by an Executive Committee – or a National Team – which shares information among members and grows the discussion around national patient involvement issues and opportunities. The Team meets regularly and provides ongoing management and administrative support to the Platform.

+ 15 members and growing

Roadmap – long term

- Establish a reputational organization that should be the reference center for educating patients in the field of patient participation in medicine R&D
- Organize yearly stakeholder meetings, next to the advisory meetings
- Areas to focus on:
  - **Policy**: address the importance of patient-centric initiatives and patient participation on a multi-stakeholder level
  - **Awareness**: dissemination of the EUPATI program
  - **Education**: participate in delivering educational tools in the national languages for patients to become educated in the field of drug development


Exploratory clinical development
Full clinical development
Production & distribution
Strategy development
Launch
Life cycle management
R&D
Manufacturing
Logistics
Strategy
Sales and marketing
Market access
Post LOE
Patient engagement examples
• Research oriented by patient insights
• RWE-driven development
• Formulation decisions based on patient preference
• Capture patient insights during trial
• Recruitment adherence and follow-up tools for clinical trial programs
• Patient-centric protocol design
• RWE-driven primary outcomes
• Personalization of packaging to patient needs
• Distribution through partnerships
• Direct patient supply (rare disease models)
• Patient managed services
• Protocol design & management
• Personalized reimbursement
• Chief patient officers
• Patient pathway analysis
• Personalization of messages
• Education through remote technologies (apps, sensors, social media)
• Patient reference groups
• Homecare collaboration
• Adherence programs
• Affordability programs
• Patient outcome and experience monitoring
• Social listening
• Patient complaint analytics

Roadmap short term - 2017

- June – Sept
  - Assemble the Advisory Board and sign the ENP statutes
  - Ex Com: go through the educational modules
  - Financially:
    - Prepare funding strategy of the ENP and apply for grants
    - Prepare policy on budget / financials
- Sept-Nov:
  - Communication about the existence and objectives of ENP
  - Collaborate in the dissemination of EUPATI educational toolboxes
  - Stakeholder mapping and needs assessment (questionnaire) : results to be presented during a one day workshop at the end of 2017
- Dec 2017:
  - Host a one day workshop in end 2017 to share national patient involvement best practices.
    - Overview course material
    - Presentation of results of stakeholder mapping and needs assessment
    - How make it more accessible - collect feedback on current modules and make it lighter
  - Agree on roadmap 2018 based on needs assessment

Timeline 2017

First ex com

First adv board

Kick-off initiative

Filing of statutes for EUPATI BE VZW

Agree on roadmap + preparations

Need assessment + Stakeholder mapping

Translation of the kits in NL and FR

One day workshop + approval roadmap 2018

Survey – Stakeholder and Ecosystem Mapping

- See the survey:
  - please fill it out now!
- Next meeting:
  - Oct 12 to elaborate on the stakeholder and ecosystem mapping
- End of year workshop :
  - results of the survey = the gaps in the Belgian ecosystem + action plan to close the gaps

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Thank you!

Visit eupati.be and become a member!