The tripartite dimension of interaction of patients, regulators and industry

Setting the scene and objectives for the day

Jan Geissler & the EUPATI team

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Better medicines for patients: The tripartite interaction

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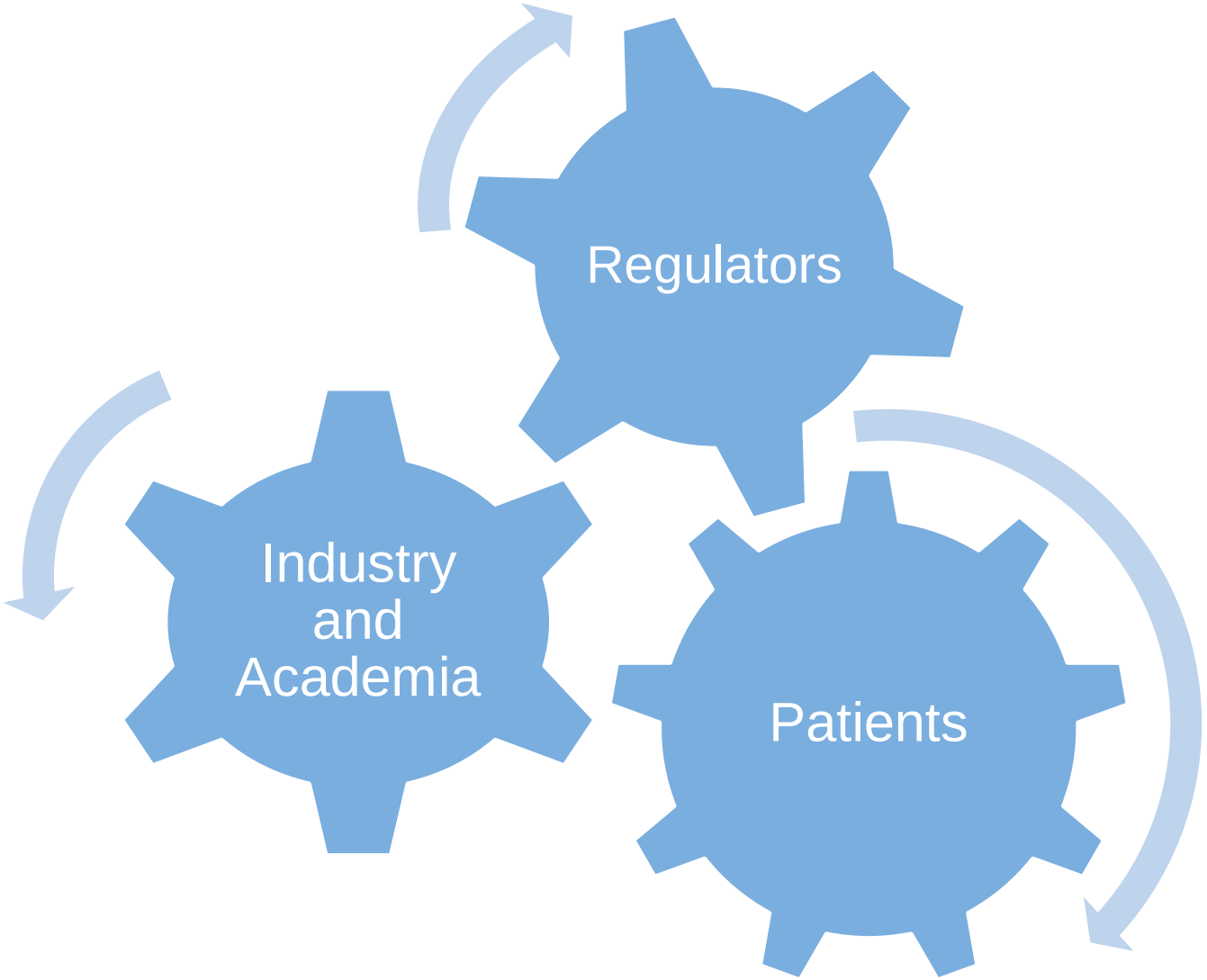
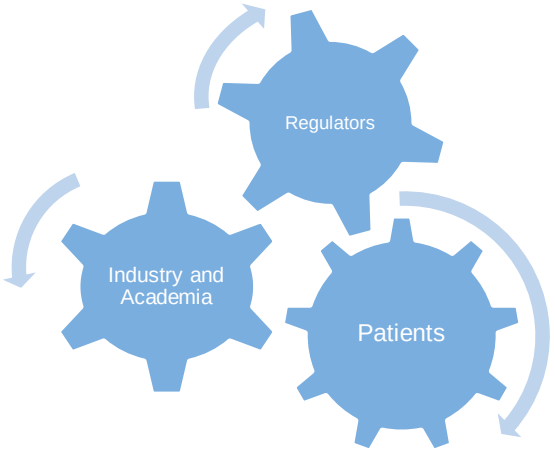


Patient involvement requires systematic interaction of *all* stakeholders

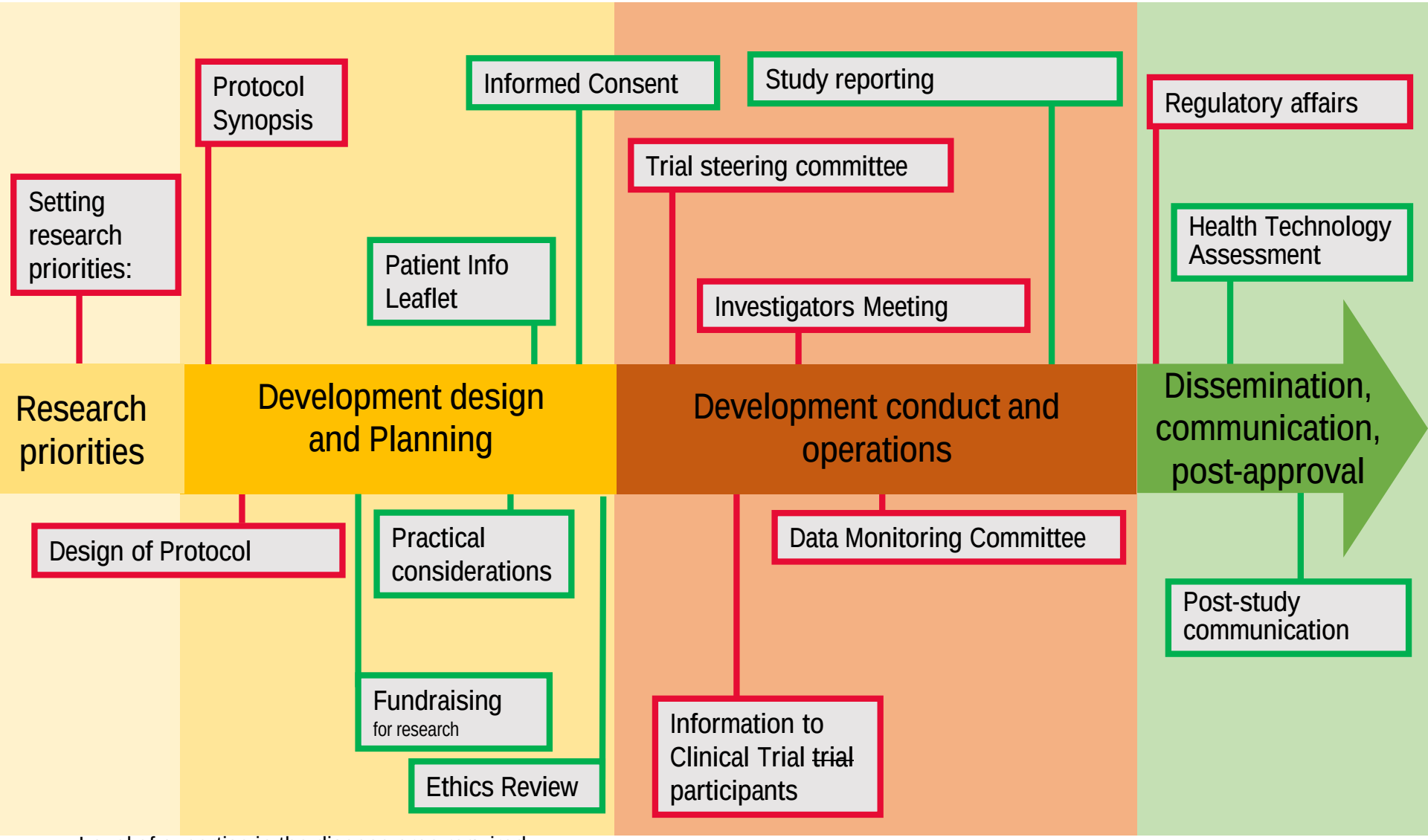
- It is acknowledged* that patients' contribution to the discovery, development and evaluation of medicines enriches
  - quality of research and development
  - quality of evidence and opinion
  - transparency, trust and mutual respect.

- Close cooperation and partnership between the various stakeholders
  - pharmaceutical industry,
  - regulatory authorities and health technology assessment (HTA) bodies,
  - patients' and consumers' organisations,
  - healthcare professionals' organisations,
  - academia, scientific and academic societies.



* Adapted from EMA Framework

Practical roadmap on Patient Involvement in Research and Development (R&D)



Level of expertise in the disease area required:

high | medium

Source: Geissler, Ryll, Leto, Uhlenhopp EPALCO/EUPATI (2015, unpublished)

EUPATI Fellows are increasingly engaging with industry, regulators and HTA

Involvement of our EUPATI Fellows before and after the Patient Expert Training Course

Role	Before	EUPATI	After
Member of patient organisation, not actively involved	20%	→	0%
Active role in a patient organisation	60%	→	72%
Leadership role in a patient organisation	52%	→	72%
Employee of a patient organisation	20%	→	20%
Volunteer role in a patient organisation	68%	→	84%
Presenting at conferences, workshops etc.	44%	→	72%
Advising a pharmaceutical company	8%	→	52%
Advising a regulatory agency	12%	→	40%
Advising a reimbursement agency	4%	→	8%

Source: EUPATI Course 1 fellow survey, June 2016, N=25

The interaction still has challenges

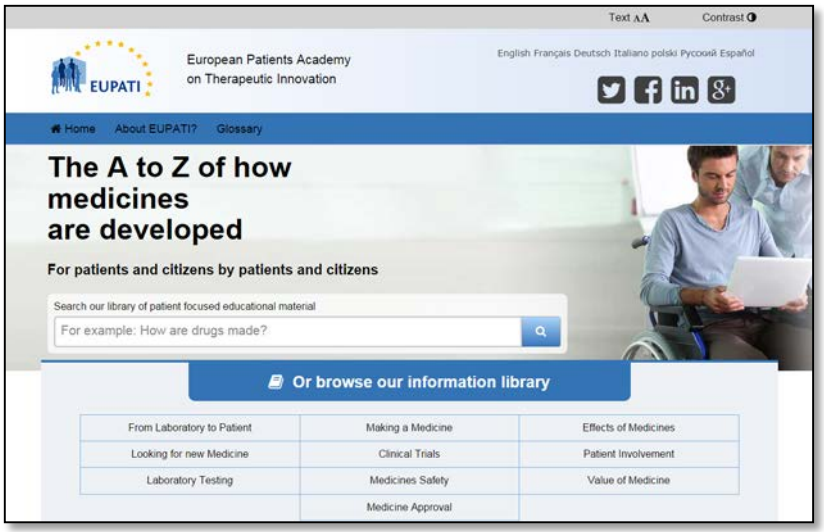
- **Cultivating our own garden, and lack of mutual learning** (across/between industry, regulators, patient organisations)
- **Perceived or real legal barriers and conflict of interest**
- **Silo-thinking and finger-pointing**, leading to mushrooming of individual, non-consolidated processes, rules and codes
- **Lack of standardised metrics** to measure benefits and impact
- **Lack of trust** (amongst agencies, industry, patient organisations, politicians, lay audience, press), absorbing energy, time and motivation
- **Lack of capacity** in patient organisations,
  lack of “universal patient experts in R&D”

EUPATI has impact and has come with positive side effects, sustainability is key

- 5 years ago, EUPATI was formed to develop training material and run the Patient Expert Training Course
- The “EUPATI boat” navigated safely through some stormy seas
- **EUPATI comes with positive side effects:**
  - **Many patients and their organisations** have greatly improved on their collaboration with industry, or initiated interaction at levels not seen before
  - **NCA & EMA initiated or increased new collaborations** and improved existing ones. Trained patient experts knock at their doors & look for opportunities to provide input
  - **HTA: Slow processes under national jurisdiction** – some encouraging developments, and more patients trained on HTA methodologies than ever before
  - **Ethics:** Very disparate processes at national level, but increasing opportunities for patients. Increasing awareness of value of patient involvement in ethics committees
- **To date, rather little interest by public sponsors to support this movement,** even though patients act in the interest of society!
- **EUPATI long-term sustainability is of major public health interest.**

EUPATI will continue!

- EUPATI is the only dedicated training institution and trusted brand on patient involvement in medicines R&D.
- EUPATI is hugely successful
  - ~100 EUPATI Fellows
  - >32.500 unique users of the Toolbox
  - >16 national EUPATI platforms
- The current IMI1 funding will end in January 2017
- EUPATI will continue as an EPF-led tripartite programme to harvest the fruits
- During the “bridging phase”, EUPATI will focus on exploitation of Toolbox and will keep content up to date.



Let’s go! Objectives for today

- **Share views, experience and learnings** in pilot projects and evolution of processes of regulators, industry and patients, building on our 2014 workshop

- **Help ensure that the tripartite interaction is understood, respected and trusted** by all stakeholders and the public at large.

- **Regulatory work stream:**
  - **Learn from pilot projects** and regular/systematic involvement of patients both on EU and NCA level
  - **Support interaction** of regulators with patients

- **Industry work stream:**
  - **Discuss progress on evolution of industry processes** to involve patients in **all** aspects of medicines R&D (e.g. clinical development plans, clinical trial design and conduct, compliance processes, patient information)
  - **Encourage patient involvement earlier** in a more meaningful, systematic manner

Today's agenda

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10:00 **Setting the scene – patients, regulators and industry perspective**

11:30 (12:30 Lunch)

Parallel work stream: INDUSTRY

How industry processes and "actual implementation" has changed to involve patients in R&D: Cases and discussion

Parallel work stream: REGULATORS

Sharing how EMA and NCAs approach and/or implement patient involvement in regulatory authorities' processes: Cases and discussion

14:30 **Report from the two work streams**

15:00 **Discussion**

How does that all fit together? Risks, independence, mishaps, educational needs, guidance documents

16:00

How does this all fit together?
Intended outcome when we part today.

- **Clear overview of regulators', industry and patients' respective viewpoints.**
- **Shared experience and learnings** of pilot projects and evolution of processes within regulatory and industry.
- **Discussed challenges and bottlenecks** around potential conflicts of interest in collaboration within the 'triangle' of patient organisations, regulators and industry.
- **Developed collaborative solutions and safeguards** to drive and nurture the collaboration.
- **Provided input into EUPATI guidance documents** on interaction of patients/organisations with regulators, HTA, industry, ethics committees


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Let's go!

Backup slides

Everybody is building frameworks…