Patients' Involvement and Empowerment

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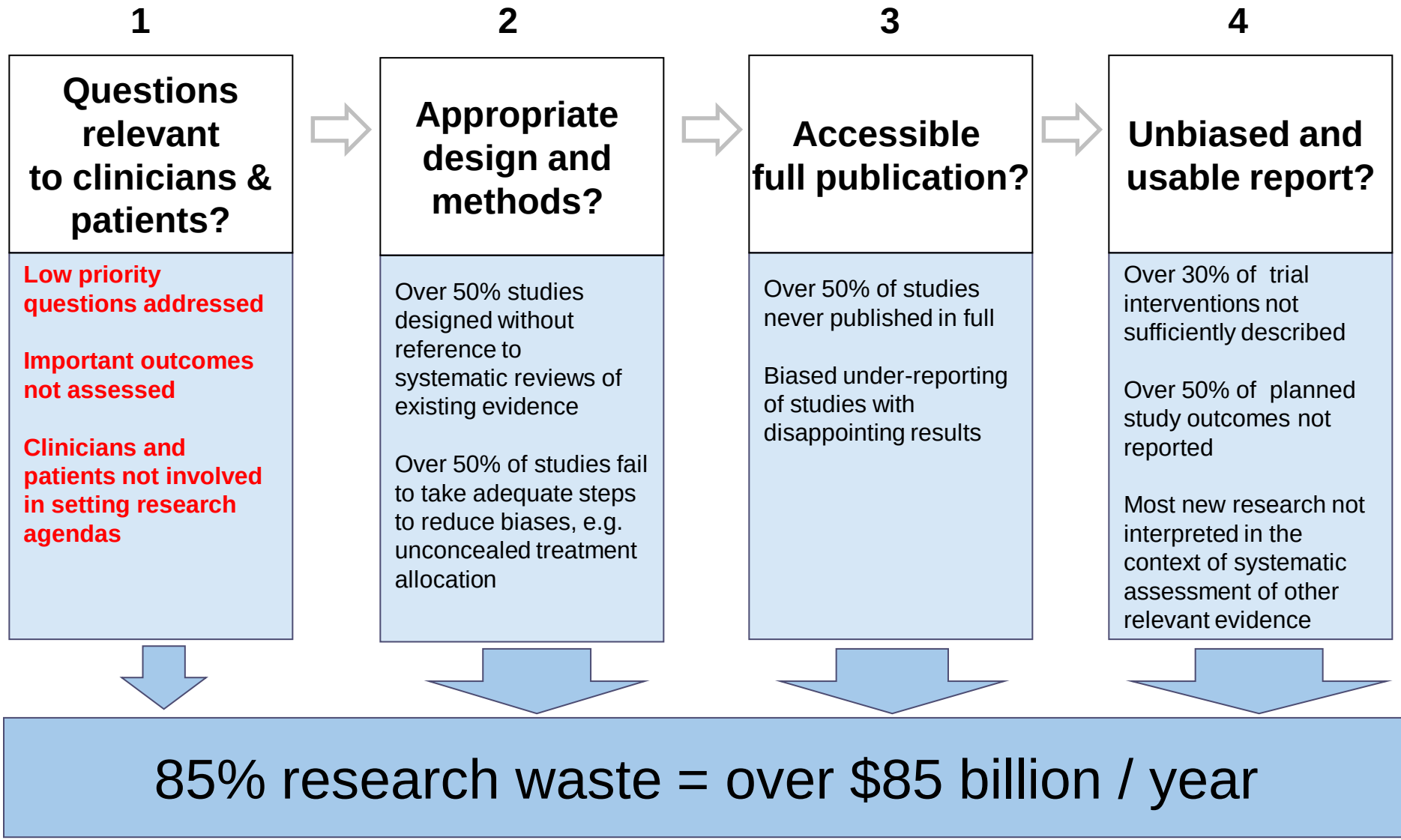
Medical landscape is changing at a fast pace

Innovation transforms the lives of patients with serious, lifelong conditions:

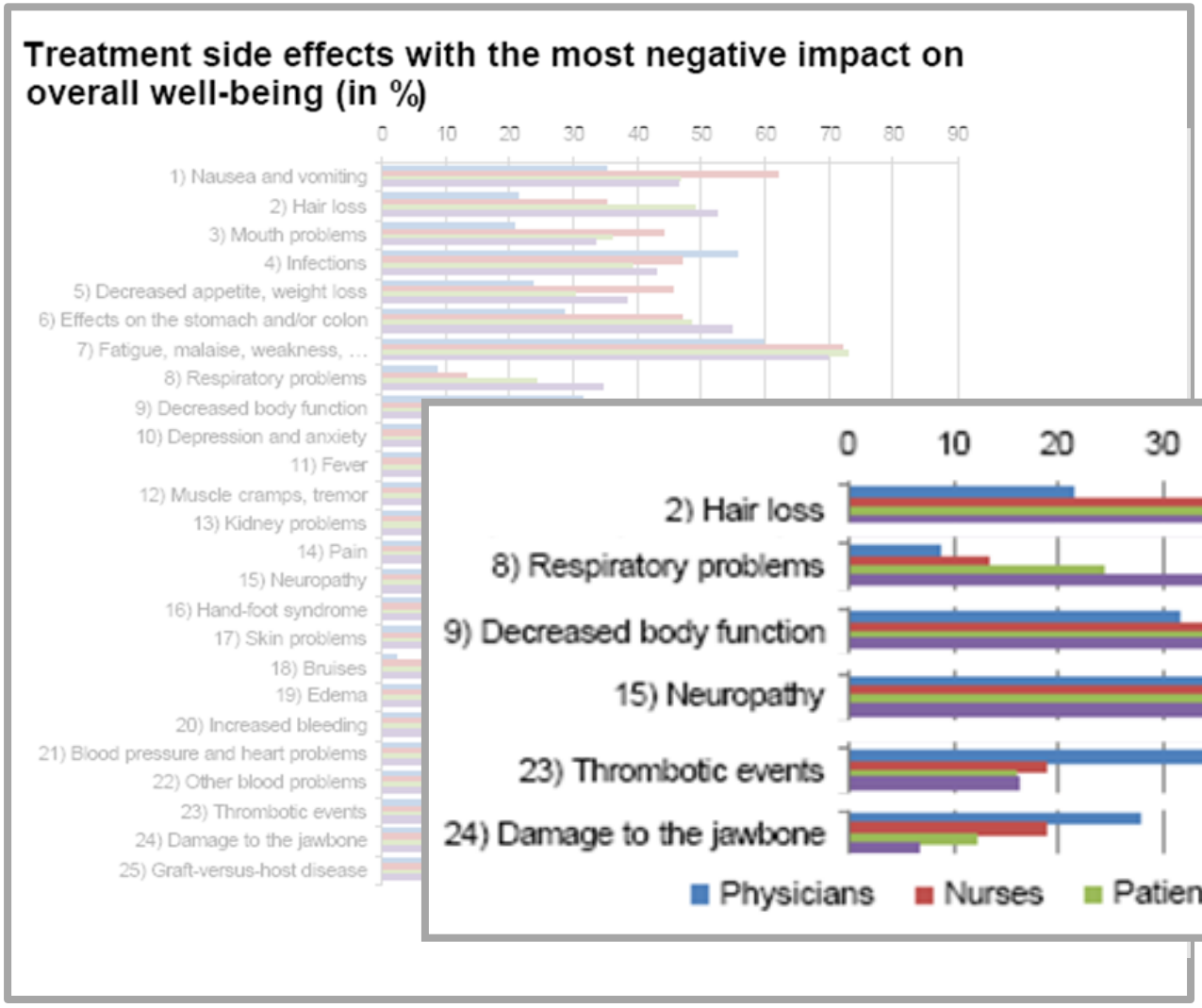
- Molecular targets/pathways
- Genome sequencing,
- Translational research
- Personalized medicine
  - Small trial populations
  - Biomarkers, companion diagnostics
- Need for post-marketing data
- Health Technology Assessment, QoL, endpoints, comparators
- BUT long term pressure on health budgets – here to stay

“Avoidable waste in the production and reporting of research evidence”

Iain Chalmers, Paul Glasziou, The Lancet, 15 June 2009, doi:10.1016/S0140-6736(09)60329-9



Patients have a unique perspective - example symptoms and side effects



MPe Myeloma Patients Europe

Detecting Myeloma, ways to shortening an often painful and tedious patient odyssey: results from an international survey. Myeloma Euronet (2009). 314 physicians & nurses, 260 patients & carers, 43 countries

Patients' insights can make medicines R&D better, more targeted, more effective

- Gap analysis and research priorities on real patients' needs, better target product profiling
- Better clinical trial design, eligibility criteria, PRO / quality of life, benefit/risk balance
- Better public research & health policy
- Less duplication and/or unnecessary research and expenditure

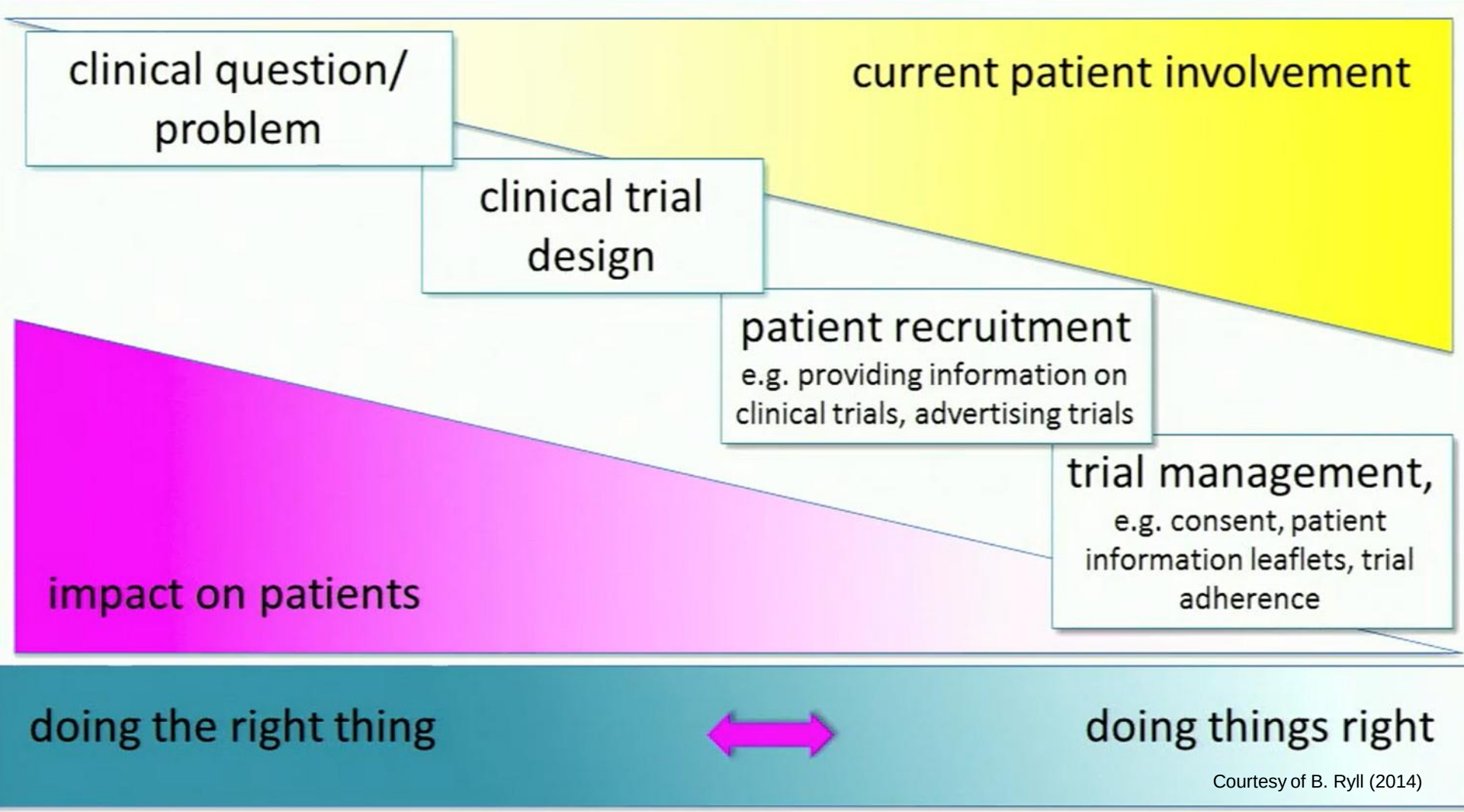
Source: PatientPartner FP7 Project (2010)

“We need to do the right things, not just doing things right.”

-- Bettina Ryll, European Melanoma Patient Advocate, 28 Feb 2014

http://is.gd/bettinaryll

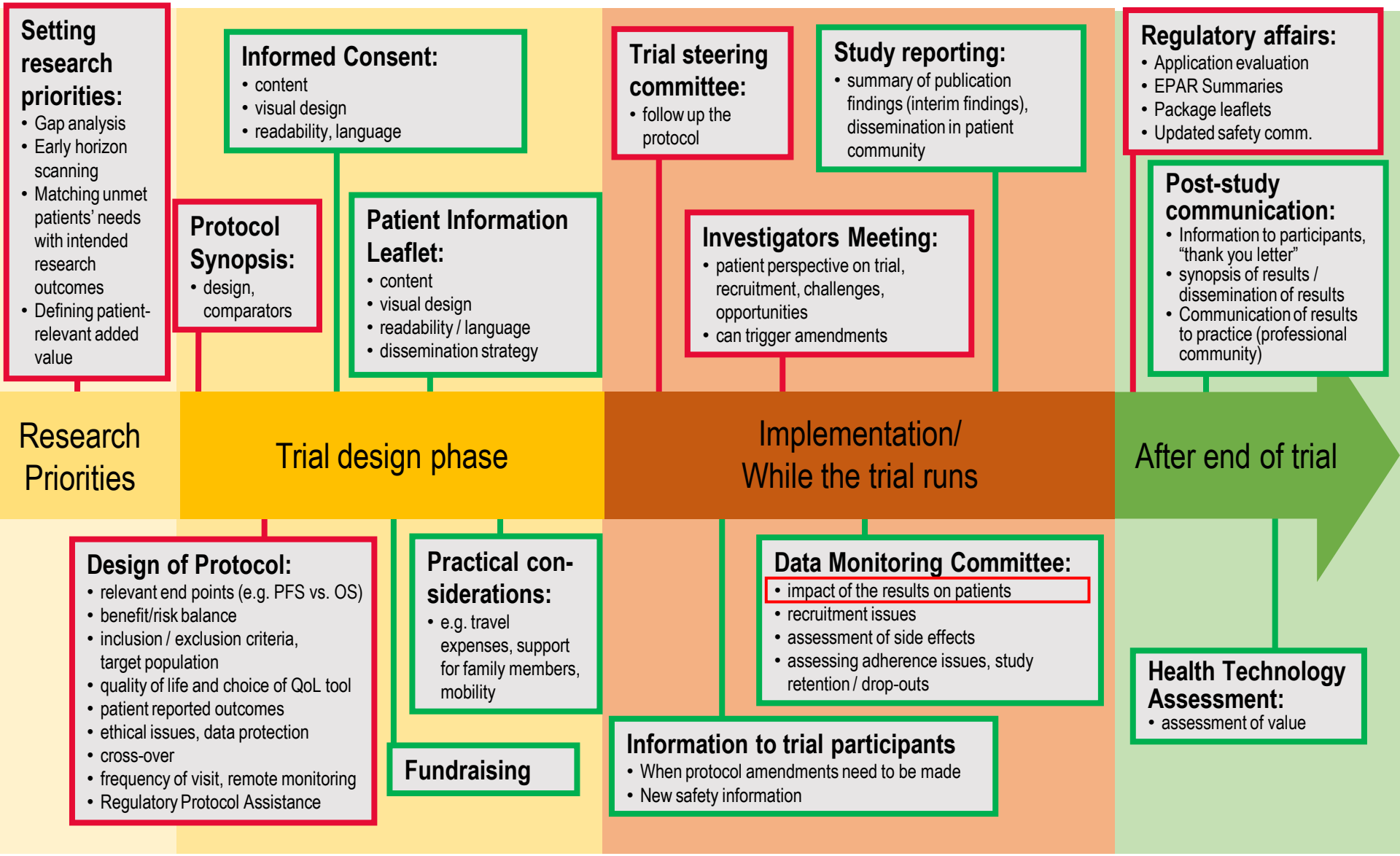
Early involvement may create highest impact, but involvement today is mostly at late phase



Courtesy of B. Ryll (2014)

In more concrete terms: Practical "Roadmap" of examples

across the whole R&D development life cycle

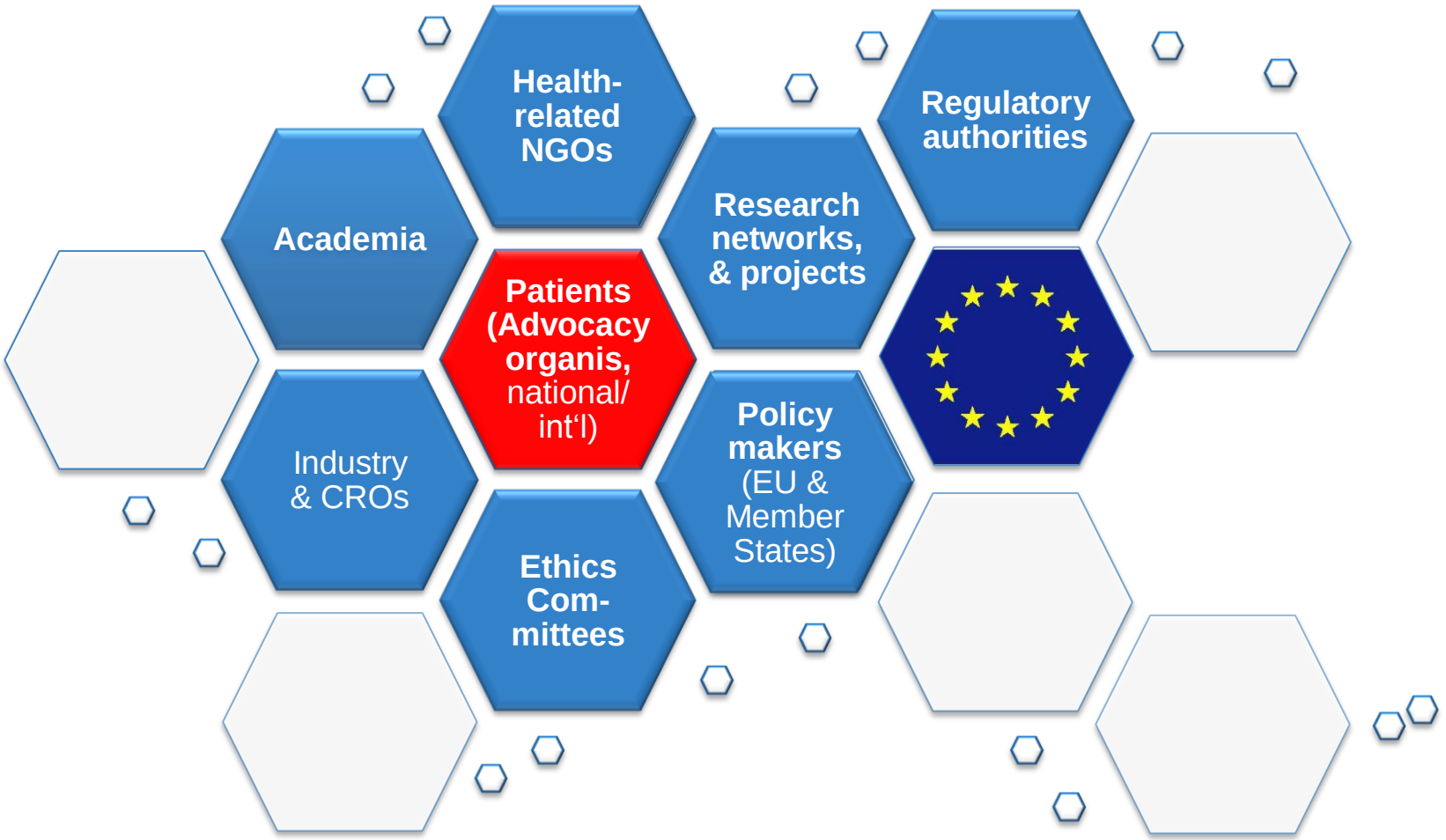


Level of expertise in the disease area required:

high | medium

Source: Geissler, Ryll, EPALCO (2014, unpublished)

To do the right things, all stakeholders must collaborate, putting the patient truly at the center



Patients have a key role in all aspects of health-related research

EUPATI
European Patients' Academy on Therapeutic Innovation

Public

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH
BfArM
MHRA
swissmedic

Competent authorities

Are there enough patient advocates to engage in R&D?

Trial protocol design, informed consent, ethical review, marketing authorization, value assessment, health policy

Policy Environment

Research Ethics Committees

HTA agencies & committees

Clinical Research

Education is key to increase the number of empowered patient advocates in R&D

- Launched Feb ’12, runs for 5 years,
  30 consortium members,
  Funded by Innovative Medicines Initiative
- Patient-led **public private partnership of patients, academia, NGOs and industry**
- will **build competencies & expert capacity to facilitate patient involvement in R&D** to collaborate in academic research, industry research, authorities and ethics committees

EUPATI
European Patients‘ Academy on Therapeutic Innovation

- www.patientsacademy.eu

Since 2012, the Patients‘ Academy is working on…

- **developing and disseminateing** accessible, well-structured and user-friendly information and education on medicines R&D
- **building expert capacity** by training patient advocates, and **competencies** among patients and the public
- **creating the leading public library** on medicines R&D: 7 languages, “creative commons” license
- **facilitating patient involvement in R&D** to partner up with academia, authorities, industry, ethics committees

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

To bring this to life, EUPATI develops education targeted at different levels

EUPATI Patient Experts Training Course
-- for expert patients

100 patient advocates

EUPATI Educational Toolbox
-- for patient advocates

12.000 patient advocates

EUPATI Internet Library
-- for the health-interested public

100.000 individuals

English

English
French
German
Spanish
Polish
Italian
Russian

Conclusions

- Collaboration will make academia, industry and patient organisations more efficient in fulfilling their respective tasks
- Selection of research objectives will be more relevant
- Medicines development will be faster and cheaper
- Reliability of the data will increase
- Patients' confidence in medicines development will increase
- Access to new treatments will be more transparent and fair
- Patients' interests will be represented more strongly in the whole clinical development process
- Future challenges in the development of new treatment concepts will require the concerted efforts of all partners, willing to develop these treatment options together as quickly and successfully as possible

My Vision for 2025

It will be “normal” for the pharmaceutical and medical device industry to involve patients in all areas of treatment development planning and organisation

as it is “normal” today

to outsource R&D execution tasks to a large extent and to collaborate with research SMEs instead of acquiring them.

Academia will have developed their own methodology on efficiently involving patients into their research projects

pushed by the requirements of the public funding organisations.