EUPATI: European Patients' Academy on Therapeutic Innovation

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The project is receiving support from the Innovative Medicines Initiative Joint Undertaking under grant agreement n° 115334, resources of which are composed of financial contribution from the European Union's Seventh Framework Programme (FP7/2007-2013) and EFPIA companies.

Health research & policy is changing at a fast pace

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

- Genome sequencing
- Translational research
- Personalised and stratified medicine
  - Small trial populations
  - Biomarkers, companion diagnostics
- Adaptive design in clinical trials
- New techniques for benefit/risk elicitation
- Need for post-marketing data
- Adaptive pathways
- HTA early dialogues, QoL, endpoints, comparators
- BUT long term pressure on health budgets – here to stay

Patients as partners of research: More needs to be done!

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*"Rare cancers will never be a priority unless the patients make it one. **Patients themselves must therefore play a larger role in driving forward the search for therapies.** They are able to see connections that have eluded scientists."*

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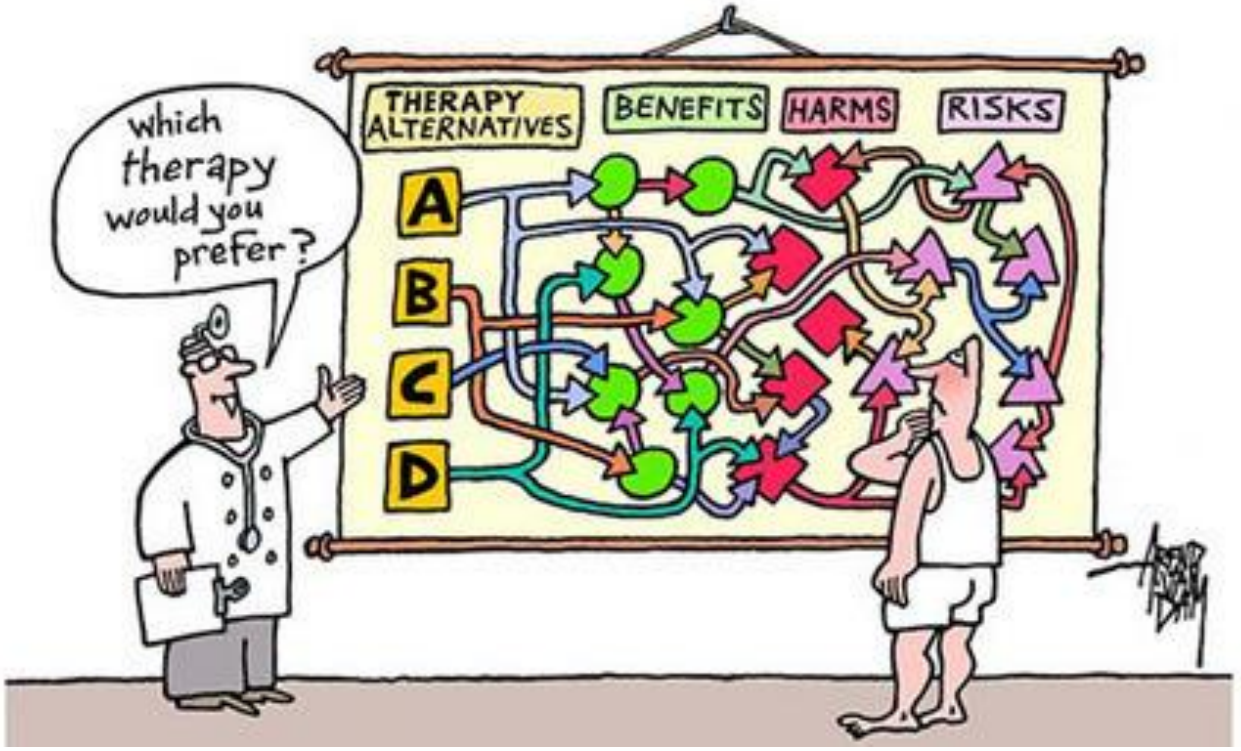
To Make Progress in Rare Cancers, Patients Must Lead the Way

Amy Dockser Marcus

Submitted January 9, 2009; accepted ... In January, 2004, I flew to New Orleans, LA, to ... treat. They recognized that when it came to SNUC,

Unmet need of patient and public on information on medicines R&D

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



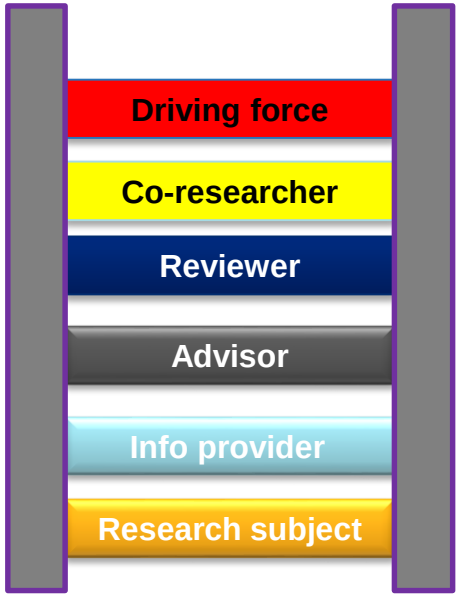
Unmet need of patient and public on information on medicines R&D

- **Patient advocates…**
  - like to advise on protocol design, informed consent, ethical review, marketing authorisation, value assessment, health policy
  - lack the education and training required to participate as a partner in medicines R&D

Patients' organisations key role in building a new environment for the development of new medicines

- Patient‘s organisations have unique insights in „real life“ and „real needs“ of patients:
  - Gap analysis in research priorities
  - Clinical trial design
  - Quality of Life measurements
  - Determining the real value of new therapies

- **Training required** to get expertise required to contribute to medicines research & development (R&D) projects



Source: PatientPartner FP7 Project (2010)

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

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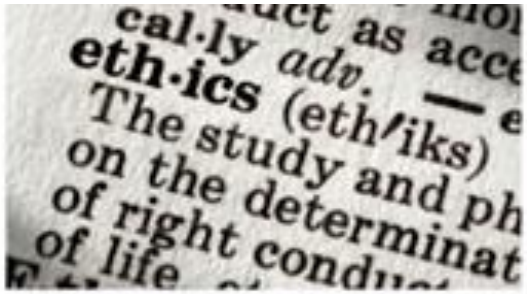

Having a patient (advocate) in every Research Ethics Committee…

Country	Inhabitants in 1,000*	Number of ethics committees	Number of ethics committees (including local ethics committees)	Ethics committees per million inhabitants
Austria	8,356.7	27		3.23
Belgium	10,741.0	35	215	3.26
Bulgaria	7,602.1	103		13.55
Czech Republic	10,474.6	9	>100	0.86
Cyprus	801.6	1		
Denmark	5,519.3	8		
Estonia	1,340.3			
Finland				
France				
				2.42
Net				1.88
Pola				1.44
Port				0.09
Roma		1		0.05
Slova	5,411.1	9	89	1.66
Slovenia	2,053.4	1		0.49
Spain	45,853.0	136		2.97
Sweden	9,259.0	8		0.86
UK	61,612.3	126		2.05

Sources: Impact on Clinical Research of European Legislation (ICREL), Final Report, Feb. 2009, and Rokus de Zeeuw 2010

If patients are to be involved in RECs on a broad level, we need more patients who understand how trials work

- 9.400 EU applications for clinical studies/year
- 5.000 clinical studies initiated in EU/year
  - 25% multinational = ~1250 studies/year
  - 4.5 Member States on average per multinational study
  - Single opinion per country assumed
- **For 1250 multinational studies, more than 5.000 ethics panels with 35.000 panelists needed**

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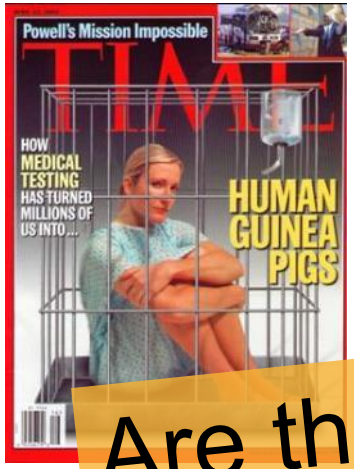


Public

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH
BfArM
MHRA
swissmedic

Competent authorities

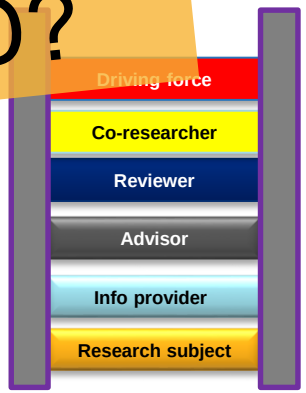
Policy makers /Research Policy

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

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

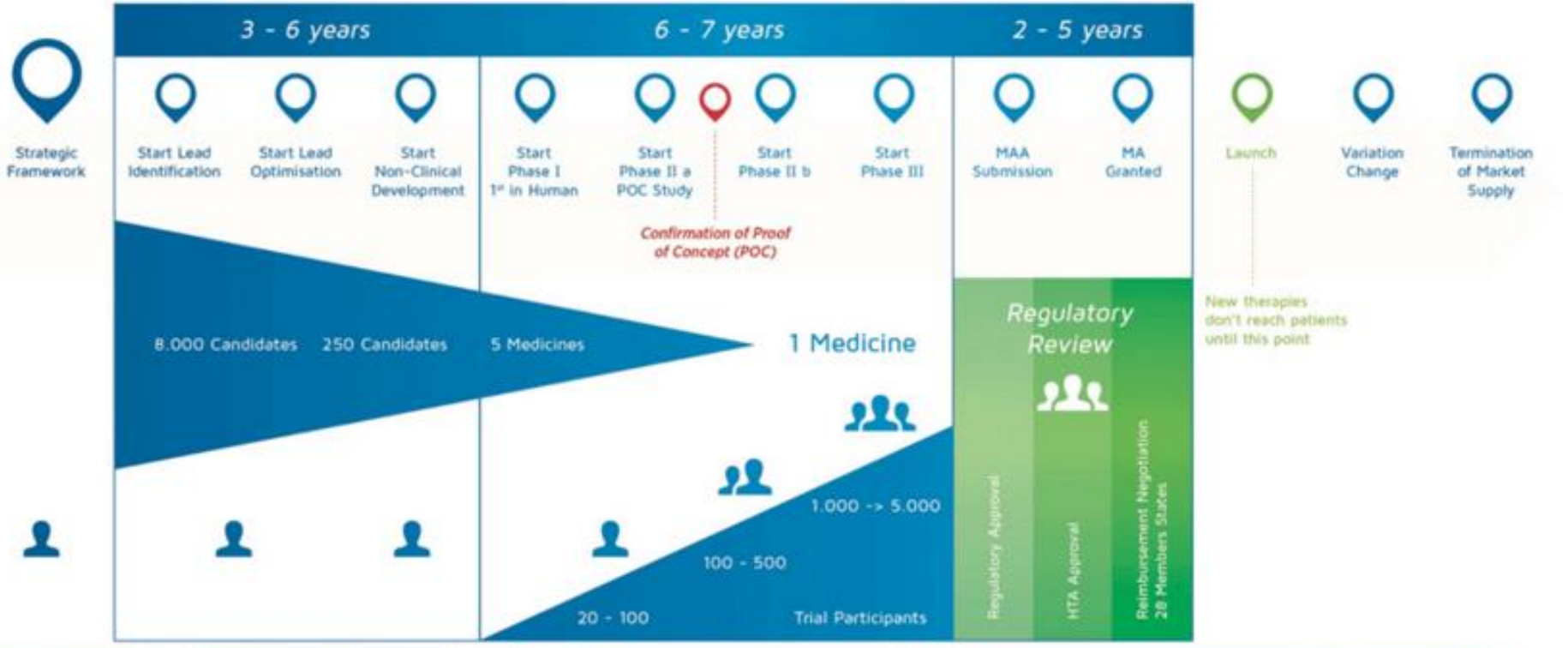
Research Ethics Committees

HTA agencies & committees



Clinical Research

Overview of Decision Points and Development Steps in Medicines R&D



Research & Discovery → Non-clinical Development → Clinical Development Phase I , II & III → Post-approval Life-cycle management & Pharmacovigilance

Patient Involvement

Decision Point

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on Therapeutic Innovation

Patients want a seat at the table. Currently, there are many empty seats.

This is why we have established the European Patients' Academy (EUPATI).

European Patients' Academy: Paradigm shift in empowering patients on medicines R&D

- Launched in early 2012, runs for 5 years, 30 consortium members, Funded by IMI JU to:

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

- **build competencies & expert capacity** among patients & public

- **facilitate patient involvement in R&D** to collaborate in academic research, industry research, authorities and ethics committees

Strong consortium & strong governance

- Coordinated by patients (EPF)
- Leading pan-EU patient umbrella groups involved in all key activities
- Strong impetus from key academic partners and research organisations
- Industry expertise in medicines R&D
- Advisory bodies & codes committed to ensure independence and good governance
  - Key experts in bioethics, genetics, HTA, economics, evidence based medicine, patient advocacy provide feedback and expertise

Areas covered by the European Patients' Academy

We do not educate about disease-specific issues or therapies, but about the process of medicines development in general. Indication-specific information or specific medicine interventions are beyond the scope of European Patients' Academy and are the remit of health professionals as well as patient organisations.

1. **Discovery of Medicines & Planning of Medicines 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. **Health Technology Assessment and the economics: how the value of a new therapy is determined**

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

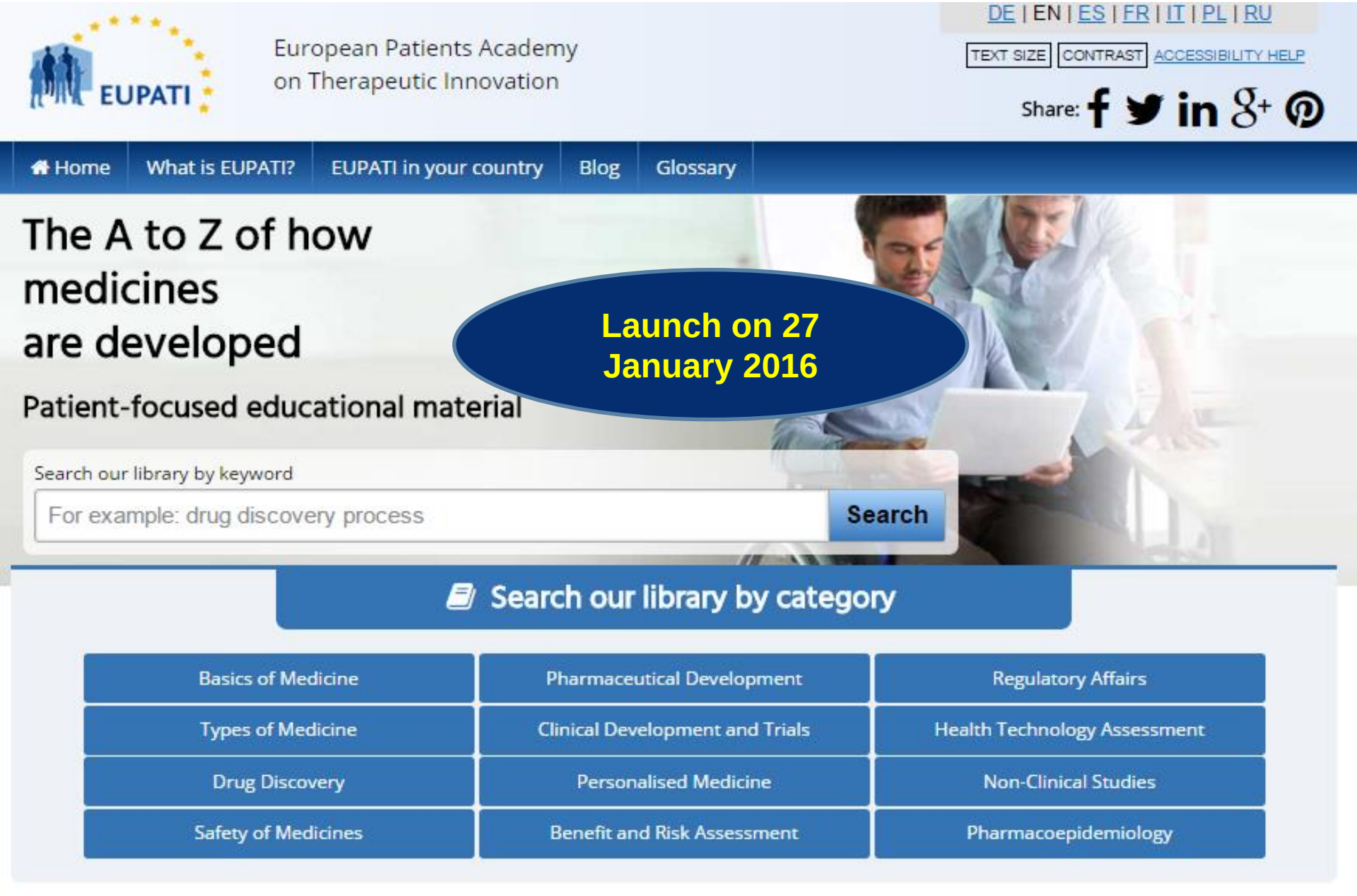
100.000
individuals

English

English
French
German
Spanish
Polish
Italian
Russian

EUPATI Patient Experts Training Course: cycles (2014-2015 and 2015-2016)

EUPATI Toolbox



EUPATI National Platforms: Partnership on the country level

EUPATI National Platform set to to:

- **make sure EUPATI understands educational needs** in R&D on national level when developing content

- **disseminate EUPATI's existing training material and information** on the national level

- **To raise public interest about EUPATI** in 12 countries

AT
CH
DE
ES
FR
IT
IE
LUX
MT
PL
UK
DK
SK
RO
GR

What‘s next?

- Need to continue to train patients at expert level
- Continue to develop educational material and tools for patient advocates (Toolbox) and lay patients (Library) keeping abreast of latest developments on medicines R&D + further languages
- Promote patient engagement at all levels + support patients engaging meaningfully across the board

What‘s next?

- Foster attitude change among stakeholders to embrace patient centered innovation by promoting patients involvement in all aspects of medicines R&D, including ethics committees, regulatory bodies, and HTA

Thank You

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