



National Patients'  
Organisation

Национална пациентска организация



# Companion Diagnostics & Precision Medicine

The Patients' Perspective



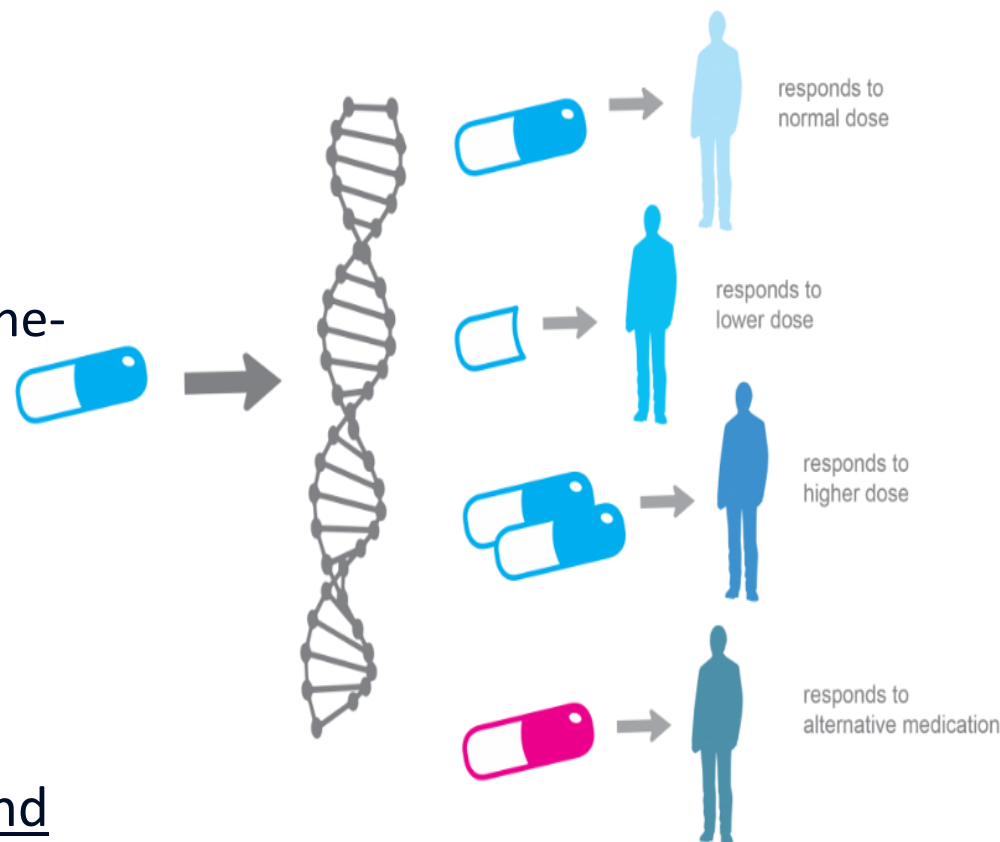
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- Chairperson of the Bulgarian National Patients' Organisation (NPO)
- Board member of the European Patients' Forum
- Secretary-General of the Patient Access Partnership (PACT)

# PM: The patients hopes

- PM is part of patient-centred healthcare
- Patients' health = public health
- Right to healthcare based on individual needs  $\neq$  one-size-fits-all
- Tailored healthcare solutions integrated as part of a *holistic approach* – treating the person, not the disease
- Promise: better health outcomes, quality of life and cost-effectiveness of resource use



# PM: The patients hopes

- ✓ Meet the unmet needs
- ✓ Improve Adherence
- ✓ Managing side effects
- ✓ Quality vs quantity of life...

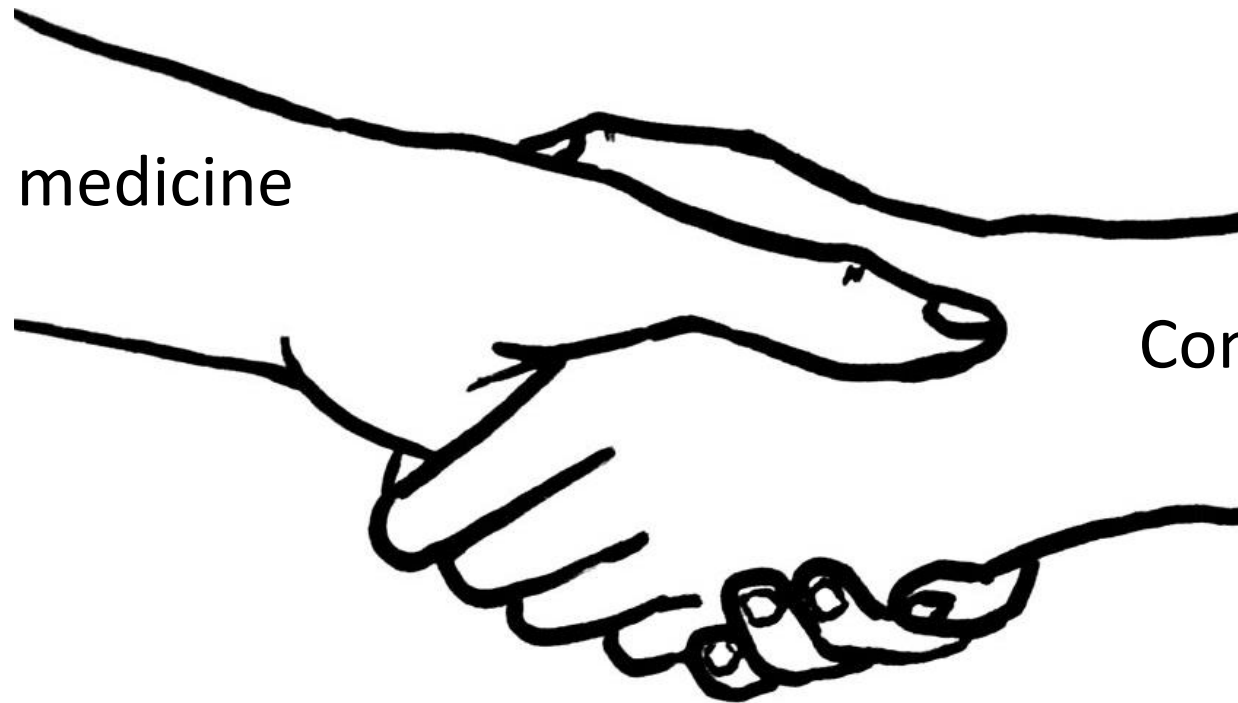


Image: Aslan Alphan

- ✓ Progress of disease / change in the nature of the disease – from lethal to chronic...

# PM: The patients hopes

Personalized medicine



Companion diagnostics

PM and CDx go hand by hand





All this is good in theory...

...but the reality is different

# Access and equity – a fundamental concern

- 🌐 Even with the current settings access equity is a social problem:
  - ✓ Huge disparities between different regions, countries, in the countries.
- 🌐 Healthcare must be based on the fundamental values of equity and solidarity
  - ✓ The Current disparities in access *are even in basic healthcare*
- 🌐 Innovative treatments tend to be costly – while governments are under pressure to cut costs



# 5A's of Access - Common understanding for access

- 🌍 **Availability:** Whether services are available in the first place.
- 🌍 **Adequacy:** Are there is an adequate and continued supply of available services.
- 🌍 **Accessibility:** Whether the services are effectively available for utilization.
- 🌍 **Affordability:** A system for financing health services so people do not suffer financial hardship when using them.
- 🌍 **Appropriateness:** Services available must be relevant and should meet the needs of *different population groups*.

**a**patient  
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partnership





🌐 CDx brings another layer of access challenges over those that we already have:

- Multiple producers of CDx
- Quality assurance and verification
- Pricing and reimbursement
- Availability of CDx after marketing authorization of medicine
- Etc...



# Possible solutions

How can patients help

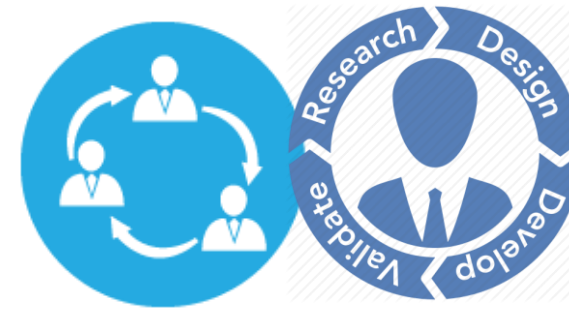
# Patients as partners = meeting unmet needs



Innovation on what matters most for patients



- Right priorities / needs
- Maximum impact & added value



Need to involve patients throughout the entire innovation chain

Co-designed research, regulatory, HTA, pricing and reimbursement, evidence-collection...

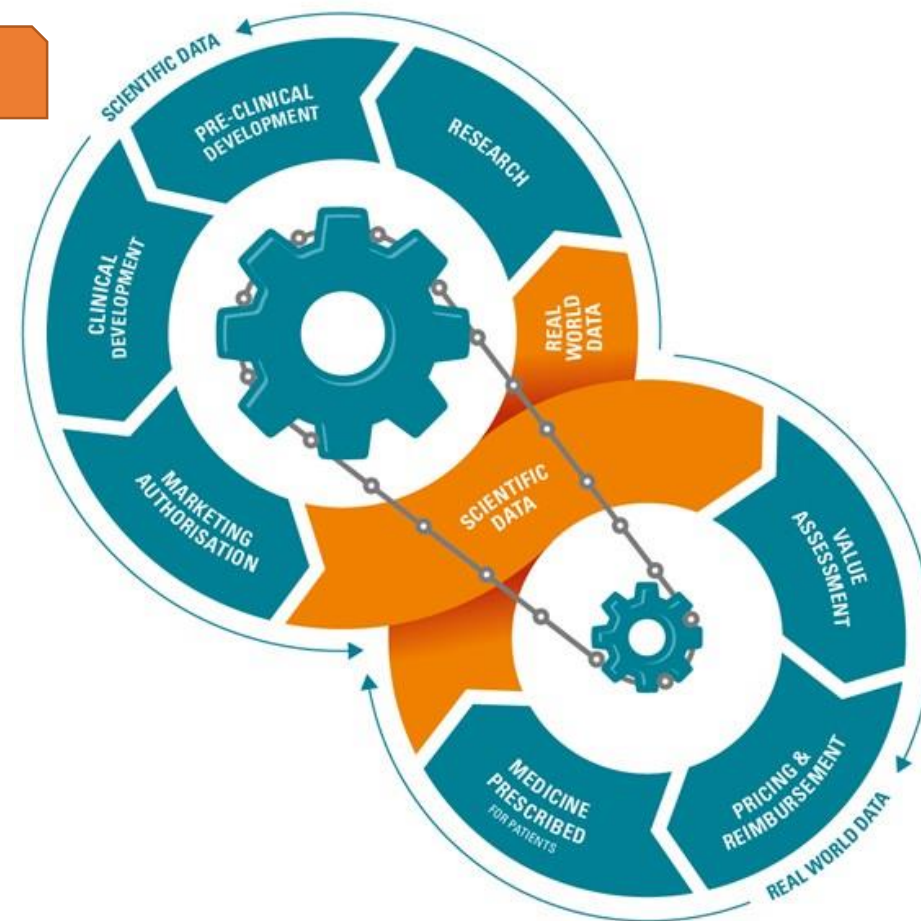


- Alignment of innovation with needs
- Strengthened trust, increased take-up

# Where are patients needed for PM and CDx?

The patients are needed through the entire life cycle:

-  Research and development
-  Health Technology Assessment
-  Patient reported outcomes
-  Real world evidence (important for reimbursement decision and pricing)
-  Role in the generic phase of the lifecycle



Source – EFPIA <https://www.efpia.eu/about-medicines/>

# Rethinking the future policies

- 🌍 Reconsidering HTA, pricing and reimbursement:
  - ✓ If one size does not fit all, then why one price of PM and CDx should fit all?
  - ✓ New policies for tailor prices in line with expected outcomes, affordability, value
  - ✓ PM and CDx should be pricizelly priced even to the individual level
- 🌍 Regulatory framework should ensure better links between PM and CDx from R&D to access
- 🌍 Regulatory change is needed to enable the implementation of the needed new access models

# General conclusion

🌍 In order to enable access and reduce inequalities for all patients:

We should make sure that patients are involved in the entire lifecycle of PM and CDx.

We should stop paying for PM and CDx as we are used to. We should price and pay for what we gain from them as a society and individuals.





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Thank you!

