



EC initiative on Next Generation sequencing

2nd Symposium : « Introduction of the Next-Generation-sequencing technology in routine analysis in the Belgian healthcare »

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Personalised Medicine: preparing the ground

2010: Preparatory workshops (-omics, biomarkers, clinical trials/regulatory, uptake)

2011: European Perspectives conference

2013: "Omics report"

Identify key challenges to be addressed by research

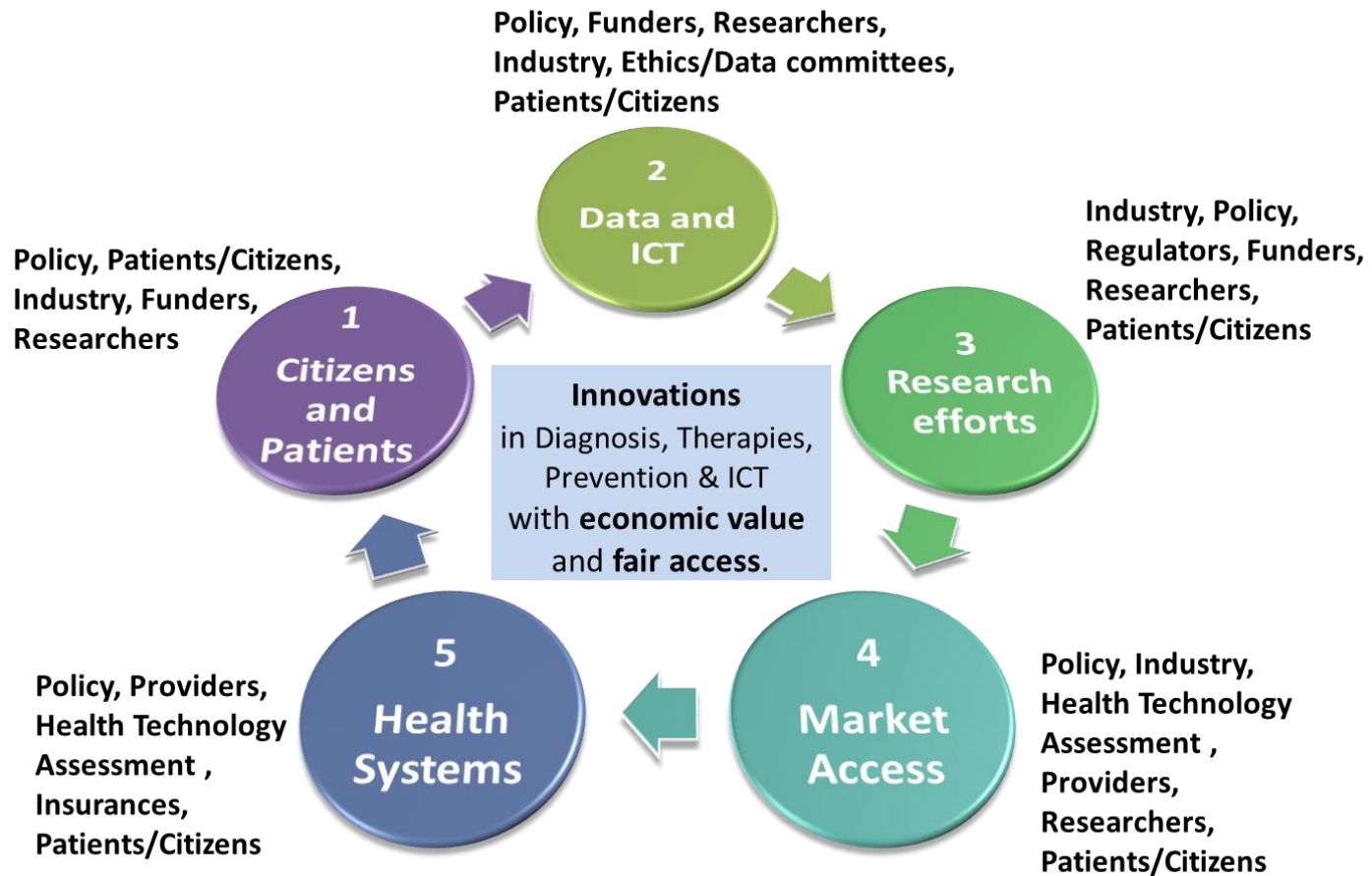


Personalised medicine – towards a definition

"Personalised medicine refers to a medical model using **characterisation of individuals' phenotypes and genotypes** (e.g. molecular profiling, medical imaging, lifestyle data) for **tailoring the right therapeutic strategy for the right person at the right time**, and/or to determine the predisposition to disease and/or to deliver timely and **targeted prevention**. Personalised medicine relates to the broader concept of **patient-centred care**, which takes into account that, in general, healthcare systems need to better respond to patient needs"



Circle of the five Challenges



The International Consortium for Personalised Medicine



A topic under Societal Challenge 1:

Health, demographic change and wellbeing

SC1-BHC-10-2019:

Innovation Procurement: Next generation sequencing (NGS) for routine diagnosis

Pre-Commercial Procurement – 16 Apr 2019 – 40 M€



HORIZON 2020

SC1-BHC-10-2019:

Innovation Procurement: Next generation sequencing (NGS) for routine diagnosis

Specific Challenge:

- ***Shift to NGS approach in diagnostics***
- ***NGS allows to consider simultaneously different actionable mutations***
- ***NGS in clinical practice is hampered by various factors: cost, availability of tests, insufficient quality assurance, technological bias and complex interpretation of data.***

SC1-BHC-10-2019: Innovation Procurement: Next generation sequencing (NGS) for routine diagnosis

Scope:

- ***Implement NGS in routine diagnostics for personalised medicine and scale up demand-driven innovation for health care systems,***
- ***Include organisational, economical, technical and clinical aspects,***
- ***Consider standards, quality assurance, data issues and Ethics***

SC1-BHC-10-2019: Innovation Procurement: Next generation sequencing (NGS) for routine diagnosis

Impact:

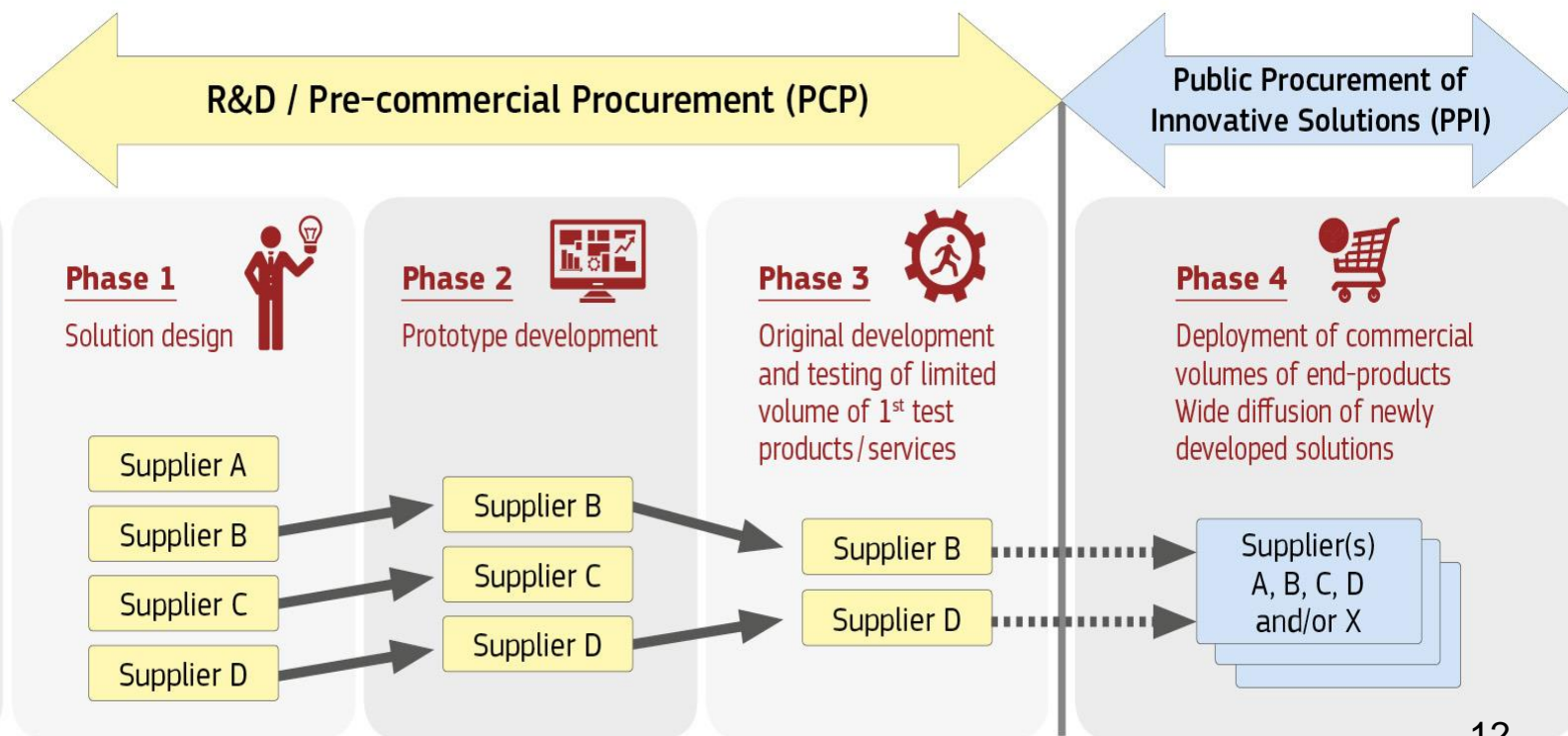
- ***New NGS platforms for diagnostics,***
- ***European standards and quality assurance schemes,***
- ***Implementation of personalised medicine,***
- ***Sustainability of healthcare systems***
- ***Benefit to European industry, in particular SMEs***

WHY PCP at EU level?

- **Support the quality and efficiency of public services with breakthrough solutions.**
- **Encourage public bodies around Europe to work together on public sector needs.**
- **Address issues of common European interest, especially where cross-border cooperation can help.**
- **Support European research activities**



PCP to steer the development of solutions towards concrete public sector needs, whilst comparing/validating alternative solution approaches from various vendors
PPI to act as launching customer / early adopter / first buyer of innovative commercial end-solutions newly arriving on the market





PCP Actions (90% funding rate)

Provide EU co-financing for an actual PCP procurement (one joint PCP procurement per action) + for related coordination and networking activities (e.g. to prepare, manage and follow-up the PCP call for tender)

Minimum 3 independent participants from 3 different MS or AC, of which minimum 2 public procurers (buyers group) from 2 different MS or AC



❑ Buyers group

- Beneficiaries that **provide the financial commitment** for procurement.
- Represent the **demand side** for the innovations, have a critical mass and aim for ambitious quality/efficiency improvements in area of public interest.

❑ Lead procurer

- **Public procurer** in project appointed by the buyers group to lead and coordinate the procurement,

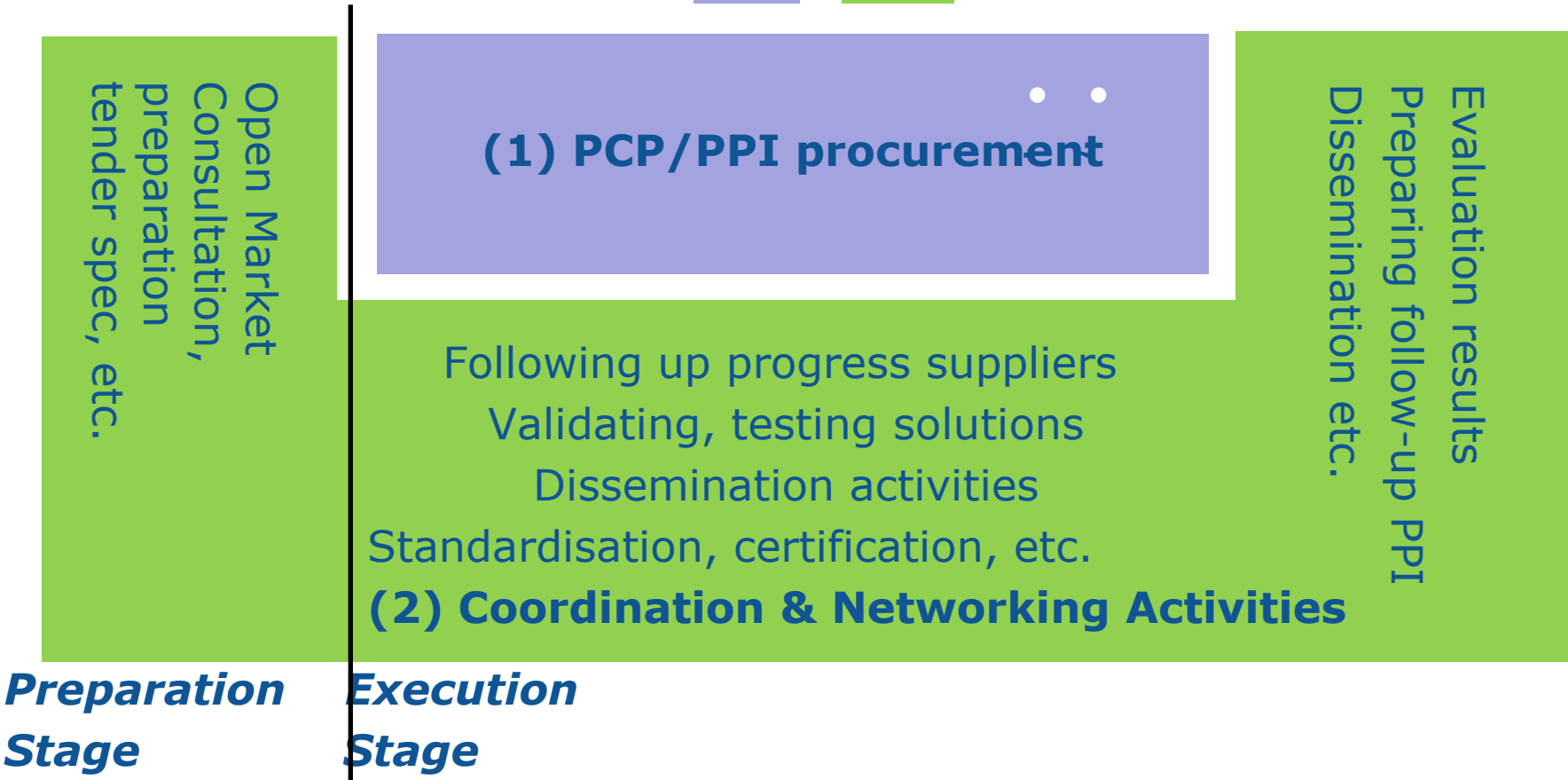
❑ Subcontractors

- Tenderers selected by the buyers group & lead procurer to provide the R&D services.
- **Do 'NOT' enter the grant agreement with the EC.**

PCP and PPI actions – What is covered



PCP/PPI actions co-finance (1) + (2)



Every project goes through a preparation stage and an execution stage



□ Preparation stage

- **Open market consultation** /verification of market readiness to meet procurement needs,
- **Agreed common tender specifications** + Joint procurement agreement,
- **Financial commitment.**

□ Execution stage

- **Joint procurement** of the R&D services,
- **Follow-up** of suppliers and validation of results. Comparison of solution performance to common criteria in real-life conditions,
- **Dissemination/exploitation** of results,

Other activities (e.g. preparation of follow-up PPI, contribution to standardisation / regulation / certification)



❑ **Direct costs: Max 90% of eligible costs for PCP**

▪ **Eligible costs include:**

- Price of **R&D services** procured,
- Eligible **coordination and networking** activities,
- **In-kind contributions** (e.g. third parties making resources available for testing of solutions)
- **VAT** is eligible if not deductible,

- **Coordination and networking activities: max 30% of total requested grant.**

❑ **Plus 25% for indirect costs**

Excluded: procurement price or on 3rd party resources not used on beneficiary premises

❑ **Pre-financing** (1st at start, 2nd before execution)



In the proposal, the consortium shall already identify

- **A concrete 'common challenge' on which the procurement will focus**
- **Key Performance Indicators (targeted quality/efficiency improvements)**
- **How this challenge fits in the innovation strategy / plans of the participating procurers**

One joint call for tender published EU wide

- One joint evaluation of offers based on common tender specs**
- One lead procurer awarding all contracts in the name and on behalf of all procurers in buyers group**
- One joint total budget (grouping financial commitments of all procurers in buyers group) from which all R&D providers are paid**



Thank you

www.ec.europa.eu/research/health

www.ec.europa.eu/research/horizon2020