Integrated and STANDardized NGS workflows FOR Personalized Therapy

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Horizon 2020 - Work Programme 2018-2020
SC1-BHC-10-2019: Innovation Procurement: Next generation sequencing (NGS) for routine diagnosis

SCOPE

To implement **NGS in routine diagnostics** for personalised medicine and scale up demand-driven innovation for healthcare systems.
It should **lead to NGS tests**, **clinically validated procedures** (including sex analysis), **quality assurance schemes**, tools and methods for **data collection**, **management, analysis and interpretation,** with a view to **assist clinical decision making** and **foster medical research and innovation**.
Transferability and **cloud based NGS data analyses** should be considered, as appropriate.
Input from initiatives like the EJP Cofund on **rare diseases and ERNs** should be considered when relevant. **Ethical issues** should be addressed.

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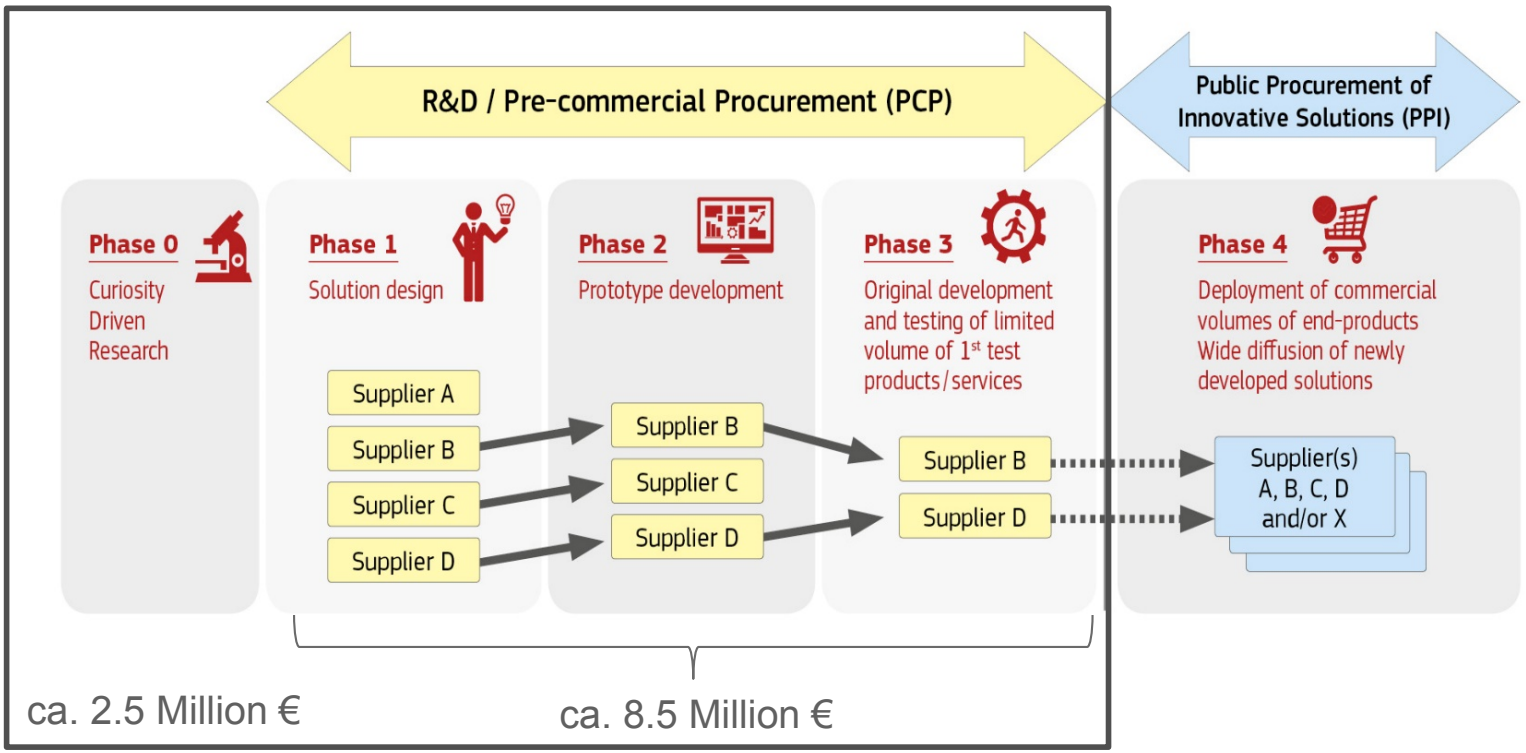
PCP TO STEER THE DEVELOPMENT OF SOLUTIONS TOWARDS CONCRETE PUBLIC SECTOR NEEDS, WHILST COMPARING/VALIDATING ALTERNATIVE SOLUTION APPROACHES FROM VARIOUS VENDORS

PPI TO ACT AS LAUNCHING CUSTOMER / EARLY ADOPTER / FIRST BUYER OF INNOVATIVE COMMERCIAL END-SOLUTIONS NEWLY ARRIVING ON THE MARKET



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Overall Objectives

A patient and clinical need-driven approach

- Increasing the benefit for patients from NGS by combining cancer gene testing with pharmacogenetics
- Application scenario: common and rare cancers in adults and children; relevance also for other diseases
- Positive health-economic effect
- Standardization & addressing regulatory requirementes (IVDR)

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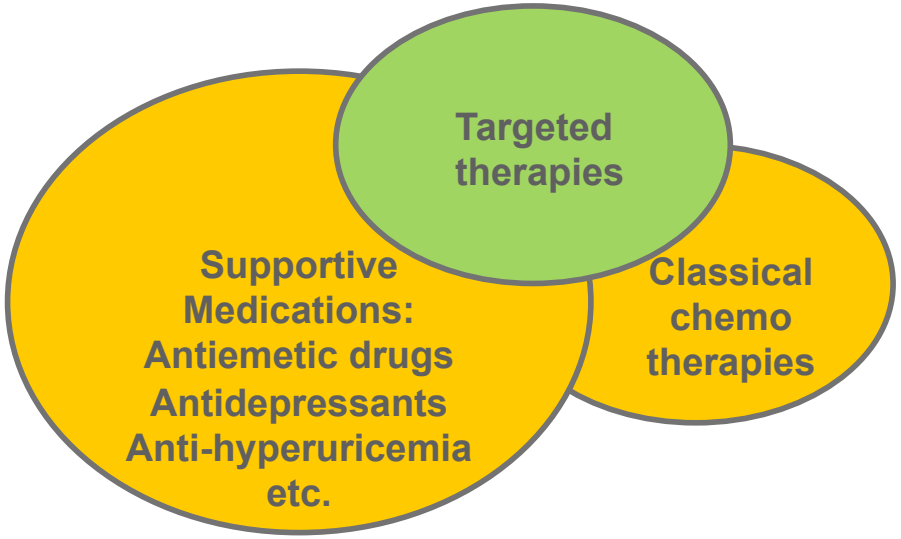
A Holistic Patient-centered Pharmacogenomics Approach

Common Cancers

Adults



Rare Cancers

Children

- To enable best therapeutic option for a specific patient including targeted therapies and supporting medications
- To take advantage of established reimbursement systems for primary diagnosis

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Consequences

More genes
Wide spectrum of genet. alterations

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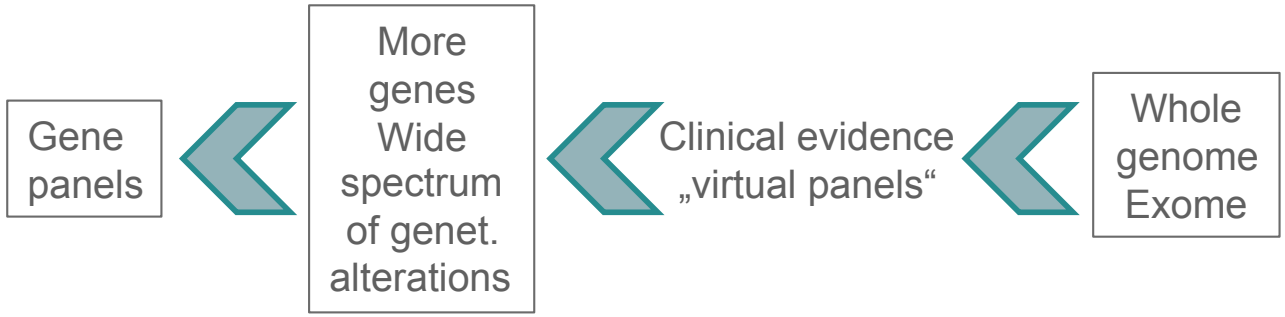
Consequences



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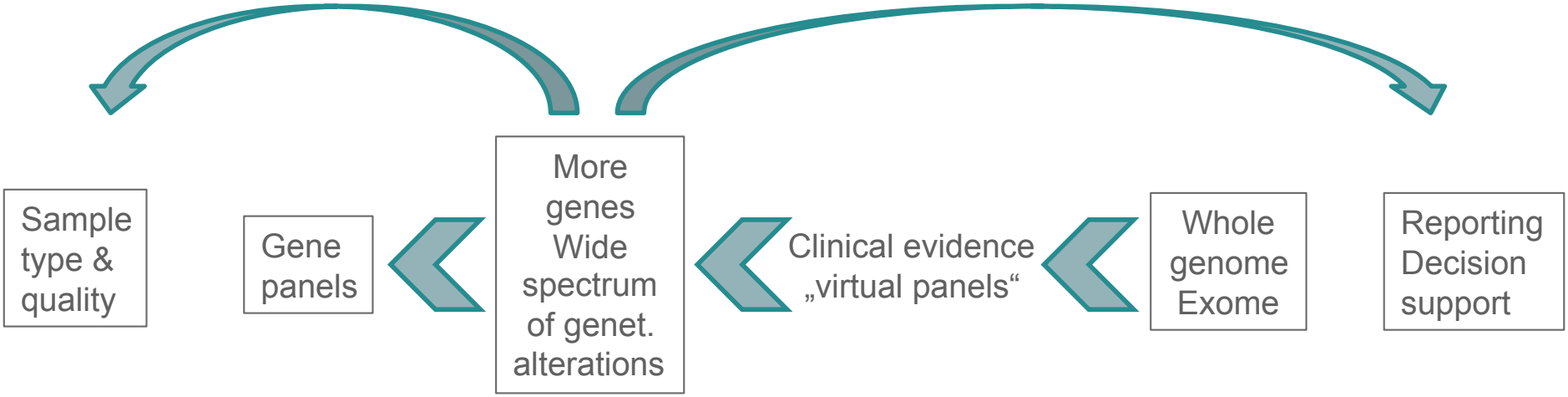
Consequences



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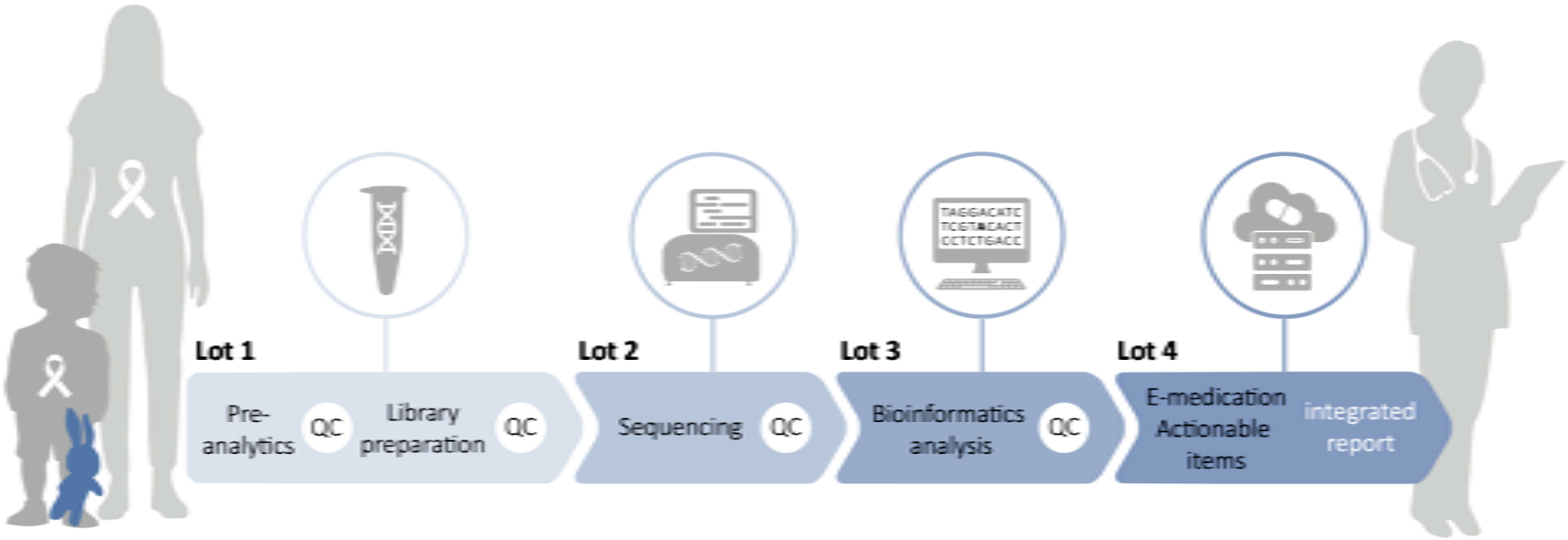
AN INTEGRATED AND STANDARDIZED NGS WORKFLOW

FROM PATIENT – TO - PATIENT



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Additional Objectives

Achieving regulatory compliance

- Integrated and standardized workflow from patient (sample) to patient (therapy decision) for improved performance and compliance with regulatory requirements
- Specifications are based on intended use (fit for purpose)
- Modularity of the workflow to address needs of rare diseases (rapid update) and to enable use of „lab-developed tests“

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European Regulatory Requirements

EN Official Journal of the European Union

REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 5 April 2017

on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

- Scientific validity – role of genetic alteration has to be known
- Analytical performance – sensitivity & specificity & metrological traceability
- Clinical performance – actionable with demonstrated benefit

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The Process

Phase 0: Preparation phase	Phase 1: Design of lots	Phase 2: Prototypes of lots	Phase 3: Fully integrated NGS workflow
Evaluation	Evaluation	Evaluation	Evaluation
01-2020 – 11-2021/ 03-2022	04-2022 – 09-2022/ 12-2022	01-2023 – 09-2023/ 12-2023	01-2024 – 01-2025/ 04-2025
Open Market Consultation (OMC) • virtual meeting (22/23-03-2021) • questionnaire (end April - mid May 2021) **Call for Tenders** (09-2021)	8-10 suppliers 10% PCP subcontracting ~770 k€ + 10% (Buyer) • all lots addressed • one lot: min 3-4 suppliers • one supplier: max 3 lots	6-8 suppliers 30% PCP subcontracting ~2.3 M€ + 10% (Buyer) • all lots addressed • one lot: min 3 suppliers • one supplier: max 3 lots	4-6 suppliers 60% PCP subcontracting ~4.6 M€ + 10% (Buyer) • all lots addressed • one lot: min 2 suppliers • one supplier: max 3 lots • 2 fully integrated NGS worklows with EQA

Only for buyers

PCP R&D suppliers supported by the buyers and the Consortium

NB: 50% of R&D spending has to be in the EU or associated countries

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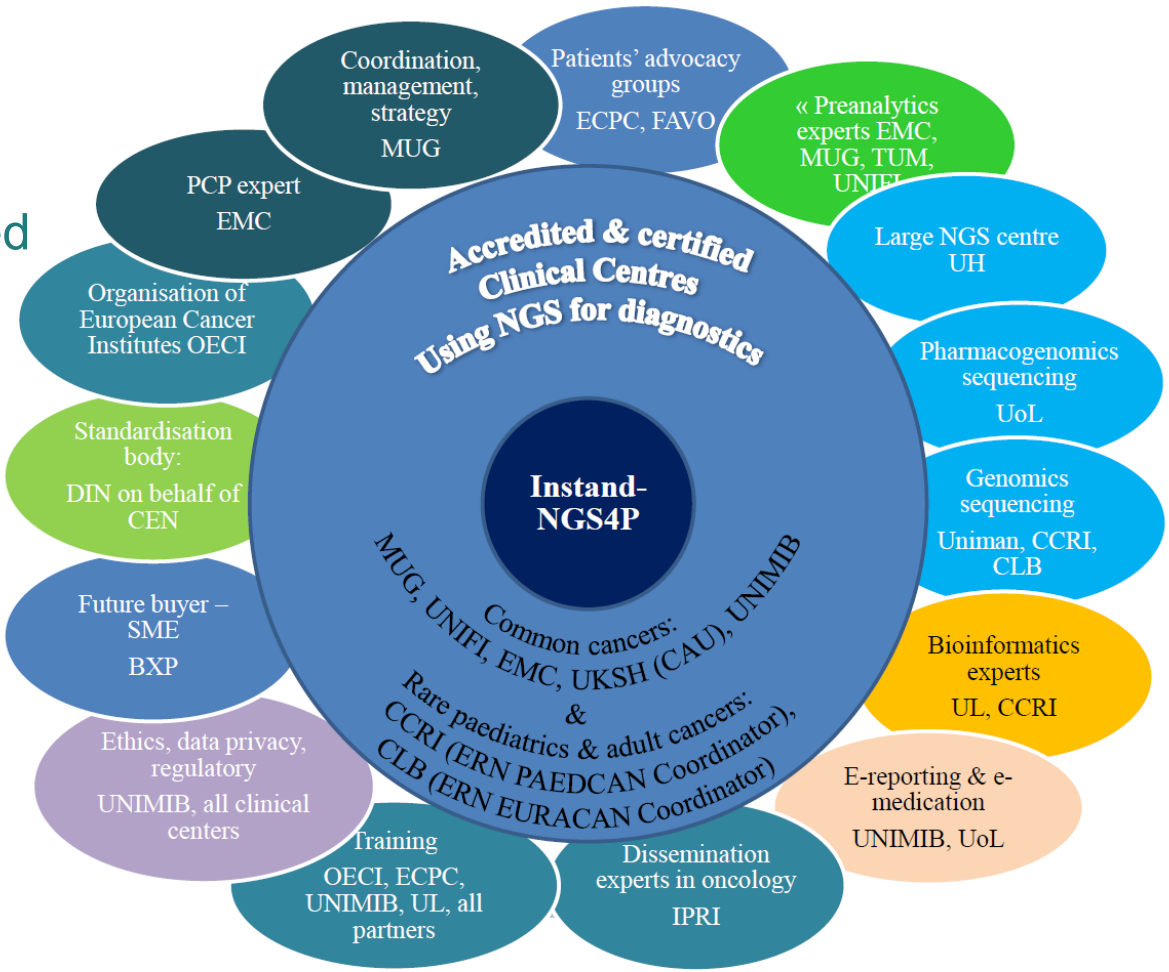
18 Partners
+ > 200 associated medical centers



10 Countries

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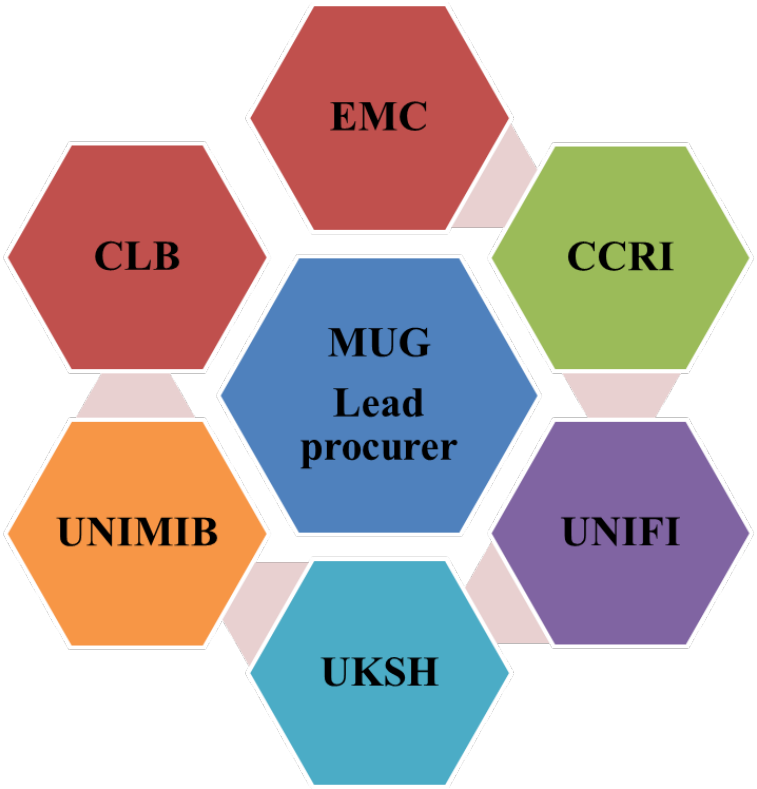
The Buyers Group



MUG – Medical University of Graz

EMC - ERASMUS University Medical Center

CCRI – St.Anna Childern‘s Cancer Research Institute

UNIFI – University of Florence

UKSH – University Clinics of Schleswig-Holstein

UNIMIB – University of Milano Bicocca

CLB – Centre Leon Berard

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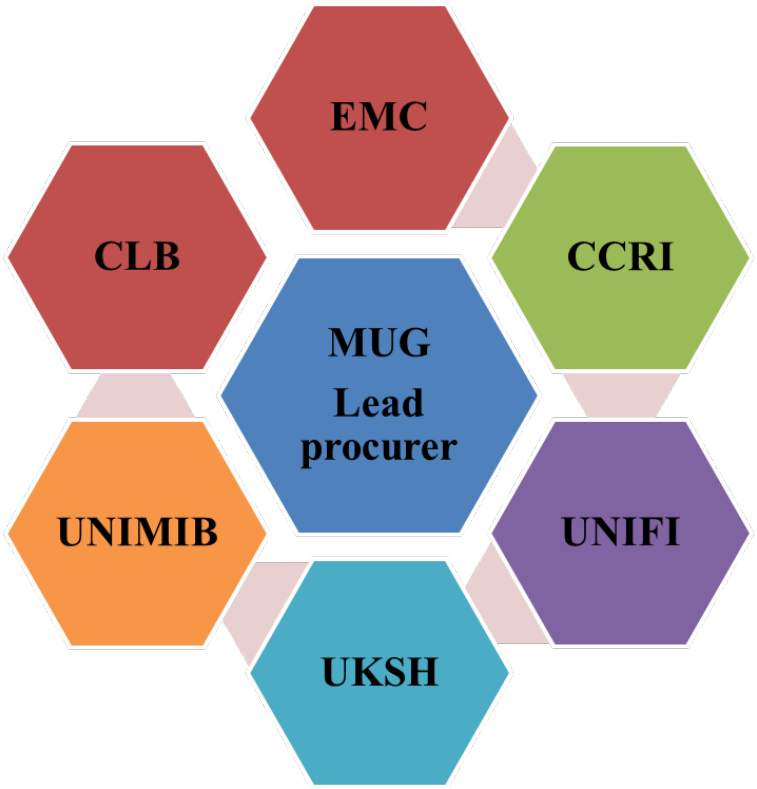
The Buyers Group



Specify medical needs

Co-fund 10% of
work performed by
solution providers

Provide test material

Test solutions

Future development partners
(e.g. clinical performance studies)

Possible future customers

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Benefits for R&D Providers

- User needs driven and market relevant requirements: co-built the next generation sequencing (NGS) for routine diagnosis in common and rare cancers
- IVDR requirements considered
- Access to quality-defined test material (produced according to ISO 20166x)
- Ethics and legal clearance
- Independent performance verification
- Access to large customers‘ and patients‘ network
- Opportunities for partnering (e.g., SMEs, Public Private Partnership)
- Access to funding (co-funding by buyers)
- Ownership of IP for the RéD providers

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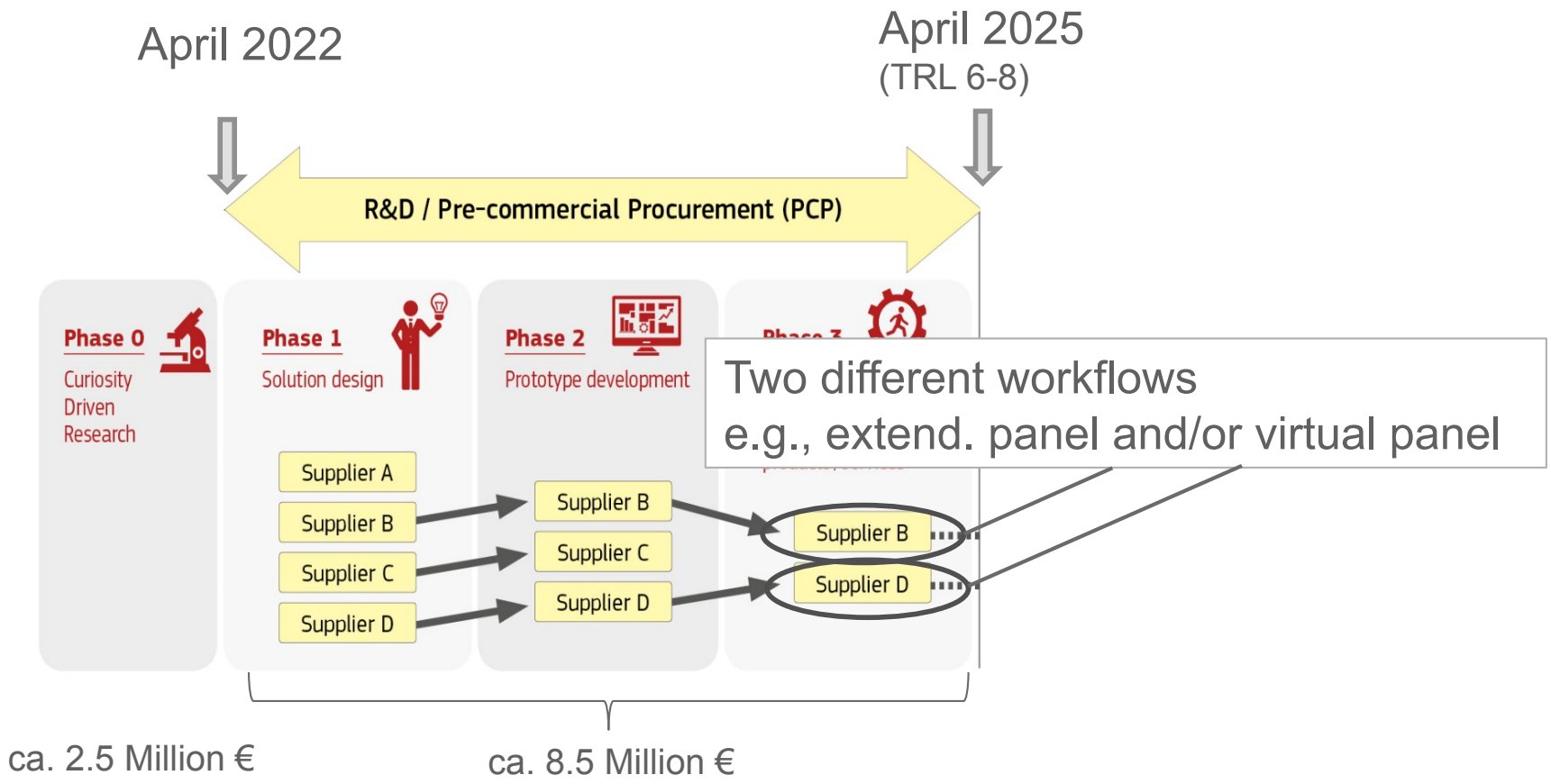

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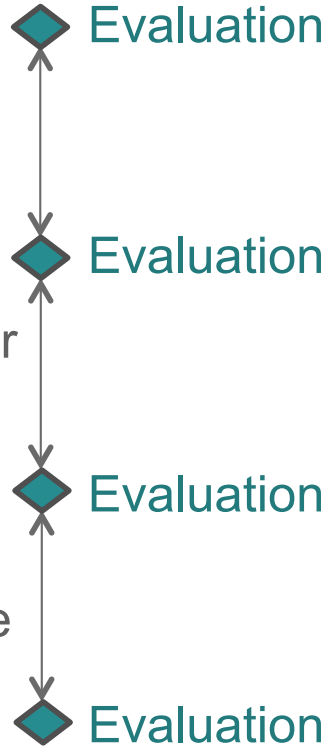
Call for Tender

One call for all 4 Lots and all 3 phases

- Phase 1: Focus on design and prototype

- Phase 2: Demonstration of performance by R&D provider using test material from buyers

- Phase 3: Integration into complete workflow; performance and usability testing by buyers (procurer)



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Criteria to be Considered

- R&D providers should address one to maximal three Lots
  Collaboration with SMEs and Public Private Partnership (PPP) is encouraged

- Specifications will be driven by intended use (clinical and patient needs) and patient safety (e.g., no drop-out, correct performance)

- Funding is available for **innovative** upgrade towards complete workflows and standardization rather than for full de novo developments (depending on the Lots) but clear progress beyond current products has to be achieved

- Innovation and feasibility are important criteria (TRL 6-8)

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Selection Criteria

✓ How well are **users' needs** addressed
Minimal and desirable needs

✓ **Innovation**
Funding is available for innovative upgrade towards complete workflows and standardization rather than for full de novo developments (depending on the Lots) but clear progress beyond current products has to be achieved

✓ **Feasibility** of proposed solution
R&D plan, specific strengths of the R&D provider (consortium)

✓ **Value for money**

0-5 points will be given for each evaluation criterion; different weights could be given for different Lots; short explanation for each evaluation (similar to evaluation of EU-projects)

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Additional Selection Criteria Phase 2

- ✓ **Performance**
  - Analytical performance (test samples and data),
  - Metrological traceability (reference material)

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Additional Selection Criteria Phase 3

- ✓ **Performance**
  - Analytical performance (verified by buyer) ,
  - Usability (tested by buyer)
- ✓ **Standardization**
- ✓ **Integration into complete workflow**

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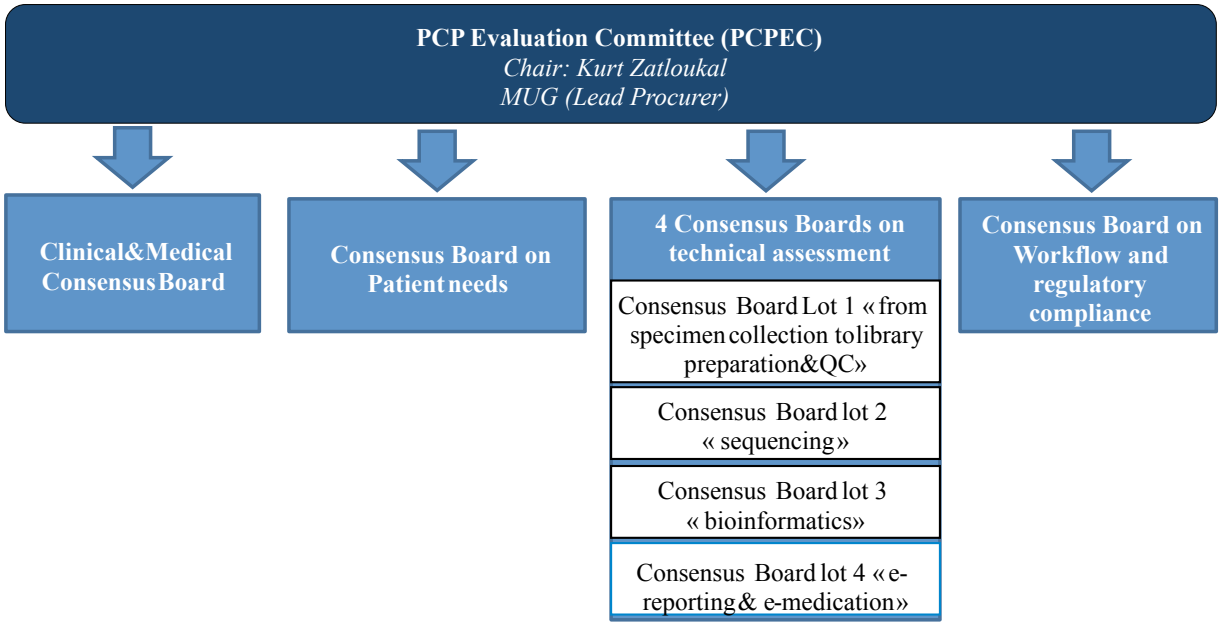
Selection Process



Need for well defined and quantifiable selection criteria

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HORIZON 2020 – WORK PROGRAMME 2018-2020

General Annexes Page 1 of 7 Extract from Part 19 – Commission Decision C(2017)7124 E.

Specific requirements for innovation procurement (PCP/PPI) supported by Horizon 2020 grants This annex applies to PCPs and PPIs for which the tender preparation and/or the call for tender implementation is supported by Horizon 2020. It applies to PCP/PPI actions (General Annex D) and other types of actions with PCP/PPI subcontracting activities.

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Tender documentation and procurement procedure

- The PCP contract notice must contain information on the **intended number of R&D providers** that will be selected (minimum three) to start the PCP, the **number of PCP phases** and the **expected duration and budget for each PCP phase**. The PCP procurement must cover the full PCP life cycle of **solution design, prototyping**, and **original development** including **testing** of a limited volume of test series products/services. Each of the three PCP phases can be split up into further phases if appropriate.
- Procurers should **avoid** the use of selection criteria based on **disproportionate qualification and financial guarantee requirements** (e.g. with regards to prior customer references and minimum turnover). Functional/performance based specifications must be used, to formulate the object of the PCP tender as a **problem to be solved**, **without prescribing a specific solution approach** to be followed. **Evaluation** of the tenders must be based on **best value for money** criteria, not just lowest price.

- The PCP process must be organised while taking care to **avoid any conflict of interests**, including in the use of external experts. Potential providers of solutions sought for by a PCP cannot be beneficiaries in an action during which this PCP is planned or undertaken.

- The PCP process must require selected R&D providers to locate the **majority of the R&D activities** for the PCP contract, including in particular the principal researcher(s) working for the PCP contract, **in the Member States or Associated Countries.**

- In PCP, procurers do not reserve the R&D results exclusively for their own use. **An R&D provider** generating results in PCP **must own the attached IPRs**. The **procurers** must enjoy **royalty-free access rights to use the R&D results for their own use**. The procurers must also enjoy the right to grant or to require participating R&D providers to grant non exclusive licenses to third parties to **exploit the results under fair and reasonable market conditions** without any right to sublicense. A call-back provision must ensure that if an R&D provider fails to commercially exploit the results within a given period after the PCP as identified in the contract or uses the results to the detriment of the public interest, including security interests, it must transfer any ownership of results to the procurers.

- The procurers must inform tenderers of the procurers' **right to publish** - after consultation with each R&D provider - public **summaries of the results of the PCP project**, including information about key R&D results attained and lessons learnt by the procurers during the PCP (e.g. on the feasibility of the explored solution approaches to meet the procurers' requirements and lessons learnt for potential future deployment of solutions). **Details should not be disclosed** that would hinder application of the law, would be contrary to the public interest, would harm the legitimate business interests of the R&D providers involved in the PCP (e.g. regarding IPR protected specificities of their individual solution approaches) or could distort fair competition between the participating R&D providers or others on the market.

- To enable the public procurers to establish the correct (**best value for money**) market price for the R&D service, in which case the presence of State aid can in principle be excluded, the distribution of rights and obligations between public procurers and R&D providers, including the allocation of IPRs, must be published in the PCP call for tender documents and the PCP call for tender must be carried out in a competitive and transparent way in line with the Treaty principles which leads to a price according to market conditions. The public procurers should ensure that the PCP contracts with R&D providers contain a financial compensation according to market conditions compared to exclusive development price for assigning IPR ownership rights to participating R&D providers, in order for the **PCP call for tender not to involve State aid**.

Contract implementation

- The PCP contract that will be concluded with each selected tenderer must take the form of one **single framework agreement covering all PCP phases**, which does not involve contract renegotiations after contract award. This framework agreement must contain **information on the future procedure for implementing the different phases (through specific contracts), including the format of the intermediate evaluations (incl. evaluation criteria and weightings)** after the solution design and prototype development phases.
- For PCPs implemented by a group of procurers, the R&D service contracts are awarded by the lead procurer and all selected tenderers can be paid by the lead procurer, or pro rata by each procurer in the buyers group according to the share of the individual financial contribution of each procurer of the total PCP procurement budget.

Contracting

Each winning tenderer gets:

- ✓ 1 framework agreement to participate in the PCP
- ✓ 1 specific contract per PCP phase (solution design, prototyping, testing)

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EU-Commission Tempates

PCP Framework Agreement

Disclaimer: This model contract is aimed at assisting H2020 PCP grant beneficiaries. It is provided for information purposes only and is not intended to replace professional legal advice. It can be used as a starting point, but beneficiaries remain responsible for adapting it to their situation and checking compliance with the applicable law. Neither the European Commission nor its executive agencies and funding bodies (or any person acting on their behalf) can be held responsible for the use made of this model.

In order to comply with the conditions of the H2020 grant agreement, the framework agreements should contain at least the following elements/provisions:

PREAMBLE

This is a framework agreement ("Agreement" or "Framework Agreement") between the following parties:

on the one part,

the "lead procurer", [insert details of the lead procurer],

acting in the name and on behalf of the *[*other*]* procurers in the buyers group (together with the lead procurer: "procurers"):

1. [insert the details of the procurers in the buyers group (NOT of preferred partners or third giving in-kind contributions to the PCP!)]

EU-Commission Tempates

PCP Specific contract for phase *[*1*][*2*][*3*]*

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Specific contracts must contain at least the following elements/provisions:

PREAMBLE

Similar set-up as the framework agreement: Lead procurer concludes and signs in in the name and on behalf of the buyers group.

Annex the contractor's offer.

TERMS AND CONDITIONS

Article 1 — Subject of the contract

This Specific Contract defines the specific terms and conditions for the implementation of the PCP procurement of R&D services set out in Article XX — for the *[*1st*][*2rd*][*3rd*]* PCP phase.

Article XX — Duration

Next Steps

- Publication of OMC questionnaire
  - Broader insight
  - Quantitative data
  - Possible publication on patient and medical needs
  - Opportunity to provide confidential information to the consortium
    → special questions for R&D providers

- Provide partnering platform on website

- Present results from OMC incl. Questionnaire on website

- Webinars
  - Tendering process (28.4.2021)
  - Partnering; pitches from solution providers (18.5.2021, register via **www.instandngs4p.eu**)

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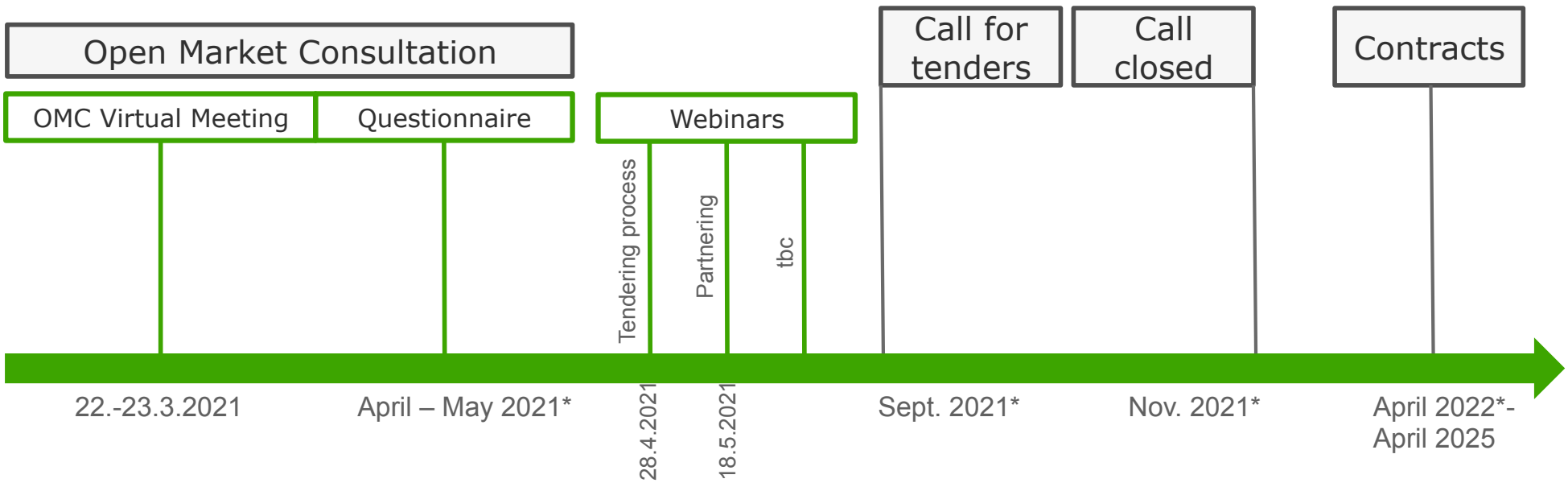
Timelines



*: Dates will be announced at www.instandngs4p.eu

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The Team

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Looking forward to collaboration and thank you for your attention!

http://www.instandngs4p.eu/

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Questions ?

http://www.instandngs4p.eu/

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