ONCNGS PCP

oncNGS SUPPLIERS INFORMATION DAY

29th June 2022

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This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 874467

ONCNGS PCP

PCP: Next-Generation-Sequencing in Healthcare applications (acronym: oncNGS)

M. Van den Bulcke, Sciensano, Belgium

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oncNGS Market Engagement

What do we want to do today?

Key –information on oncNGS:

- General introduction (M. Van den Bulcke, Sciensano)
- Clinical and patient interest (L. Mazzarella, ICE) (video)
- Technical challenges (P. Sujobert, HCL) (video)
- oncNGS process (R. Alessandrello, AQUAS)

Feedback from the market:

- Questions through chat
- Questions through oncNGS contact on website

All presentations in this webinar will be available on the oncnGS website as document or video recording

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CANCER in EUROPE

- Cancer is one of the main public health challenges in Europe and the second leading cause of mortality, with nearly **3 million new cases** and **1.3 million deaths** in 2020.
- Cancer is in contrast to cardiovascular disease a NCD with still increasing incidence as reduction of the impact of risk factors is, although strong, not sufficient to match the effect of **ageing populations** on cancer incidence
- Every year, cancer changes the lives of patients, those around them, and affects society at large with an **economic impact of the disease around €100 billion** annually in Europe.
- There have been considerable investments in developing cancer **control guidelines** and **recommendations**, building on the outcomes of joint efforts between the European Commission (EC) and the Member States.
- Early this year, the **EU Beating Cancer Plan** and the **Mission on Cancer** were launched, a holistic strategy to reduce the cancer burden while envisioning new partnerships with civil society and across sectors.

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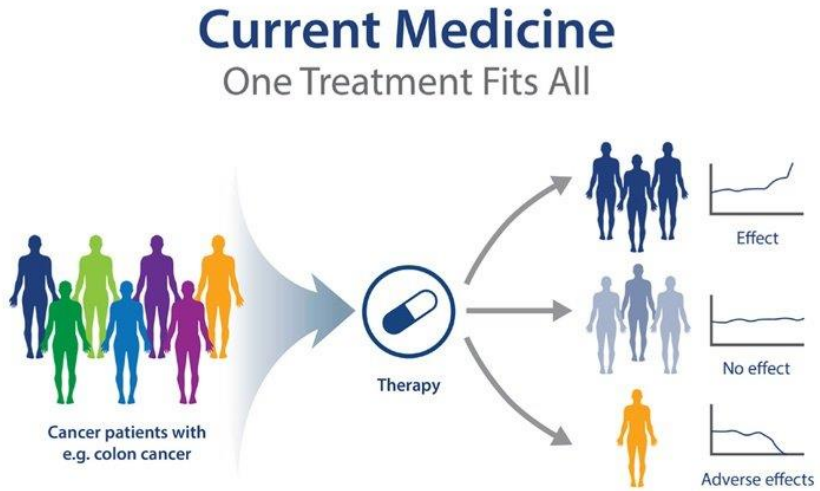
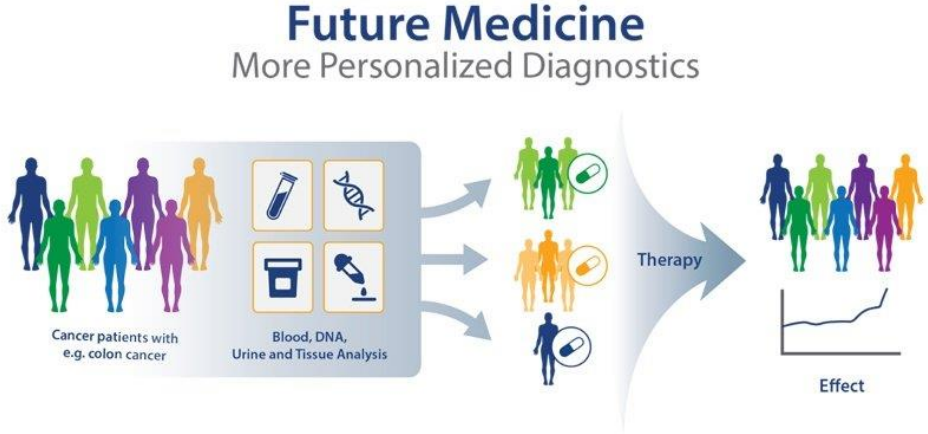
PRECISION MEDICINE & CANCER





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The challenge consists of providing:

1. efficient molecular DNA/RNA profiling of tumour-derived material in liquid biopsies by means of
2. pan-cancer tumour marker analysis kit including NGS analysis integrated with
3. an ICT decision support system including test interpretation and reporting.

Partnering countries: Be, Fr, It, Sp, Ger

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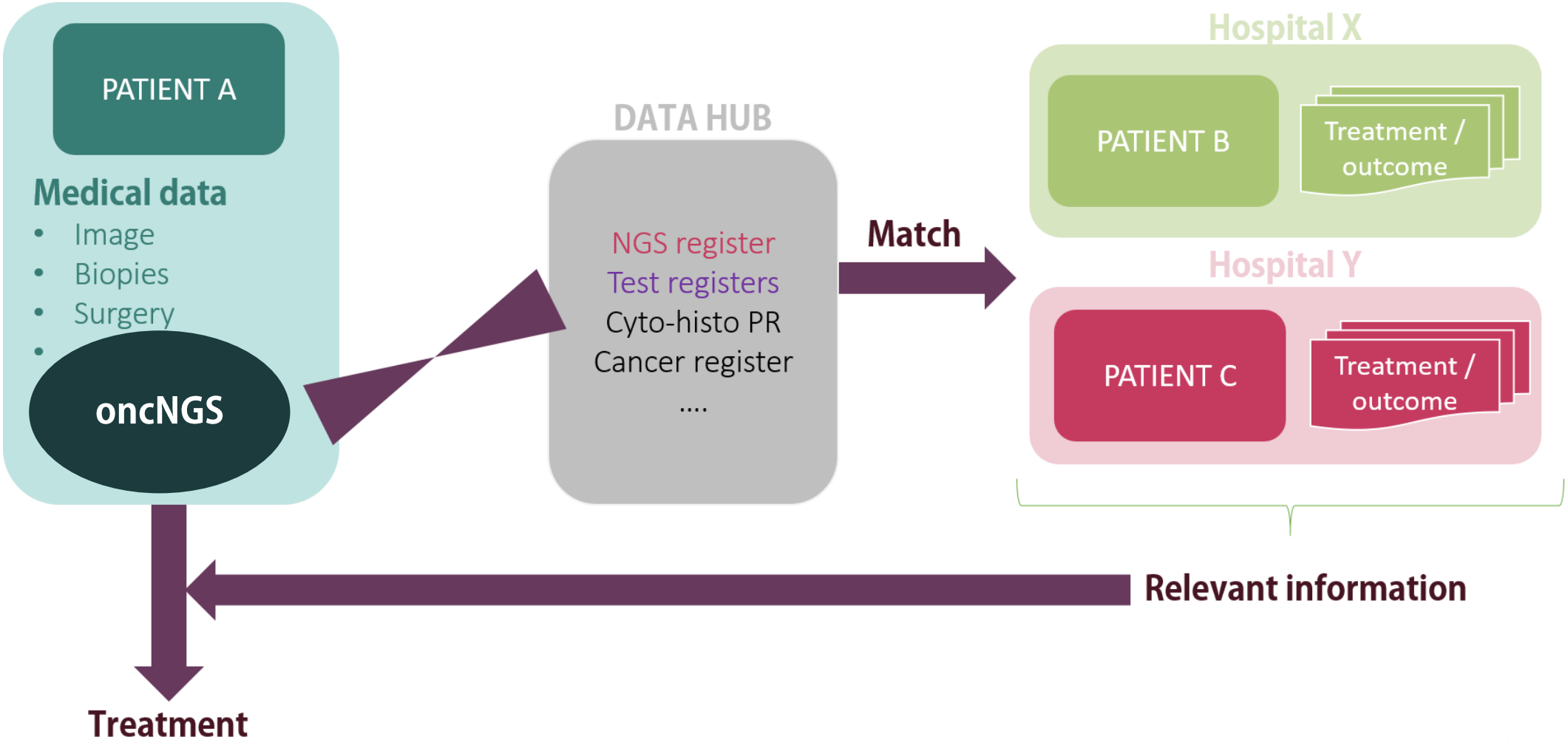
Cancer Patient Matching framework



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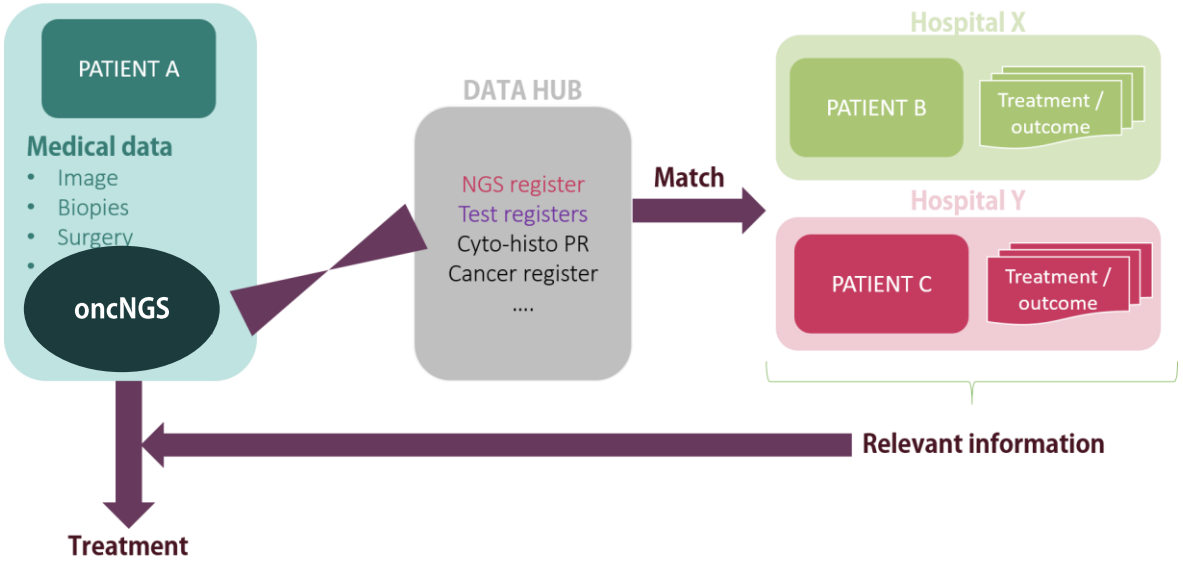
Cancer Patient Matching framework



Matching trial

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- **Scope:** Aim to develop integrated solution for testing, analysing, reporting and storage of Next-Generation-Sequencing medical data within routine healthcare diagnostics
- **Budget:** € 12 221 843,75 (90% EC contribution)
- **Reference:** https://cordis.europa.eu/project/id/874467
- **oncNGS website:** http://oncngs.eu/

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oncNGS consortium: Buyers

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oncNGS consortium: Supporting Entities

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oncNGS consortium

BUYERS	
SCIENSANO	Be
ALLEANZA CONTRO IL CANCRO	It
INSTITUT CURIE	Fr
INSTITUT CATALA D'ONCOLOGIA	Esp
INSTITUT JULES BORDET	Be
LUDWIG-MAXIMILIANS-UNIVERSITAET MUENCHEN	Ger
CHARITE - UNIVERSITAETSMEDIZIN BERLIN	Ger
HOSPICES CIVILS DE LYON	Fr
Supporting entities	
AGENCIA DE QUALITAT I AVALUACIO SANITARIES DE CATALUNYA	Esp
DE CLERCQ & PARTNERS	Be
STICHTING KANKERREGISTER - FONDATION REGISTRE DU CANCER	Be
INSTITUT NATIONAL DU CANCER GIP	Fr
FUNDACION INSTITUTO DE ESTUDIOS DE CIENCIAS DE LA SALUD DE CASTILLA Y LEON	Esp

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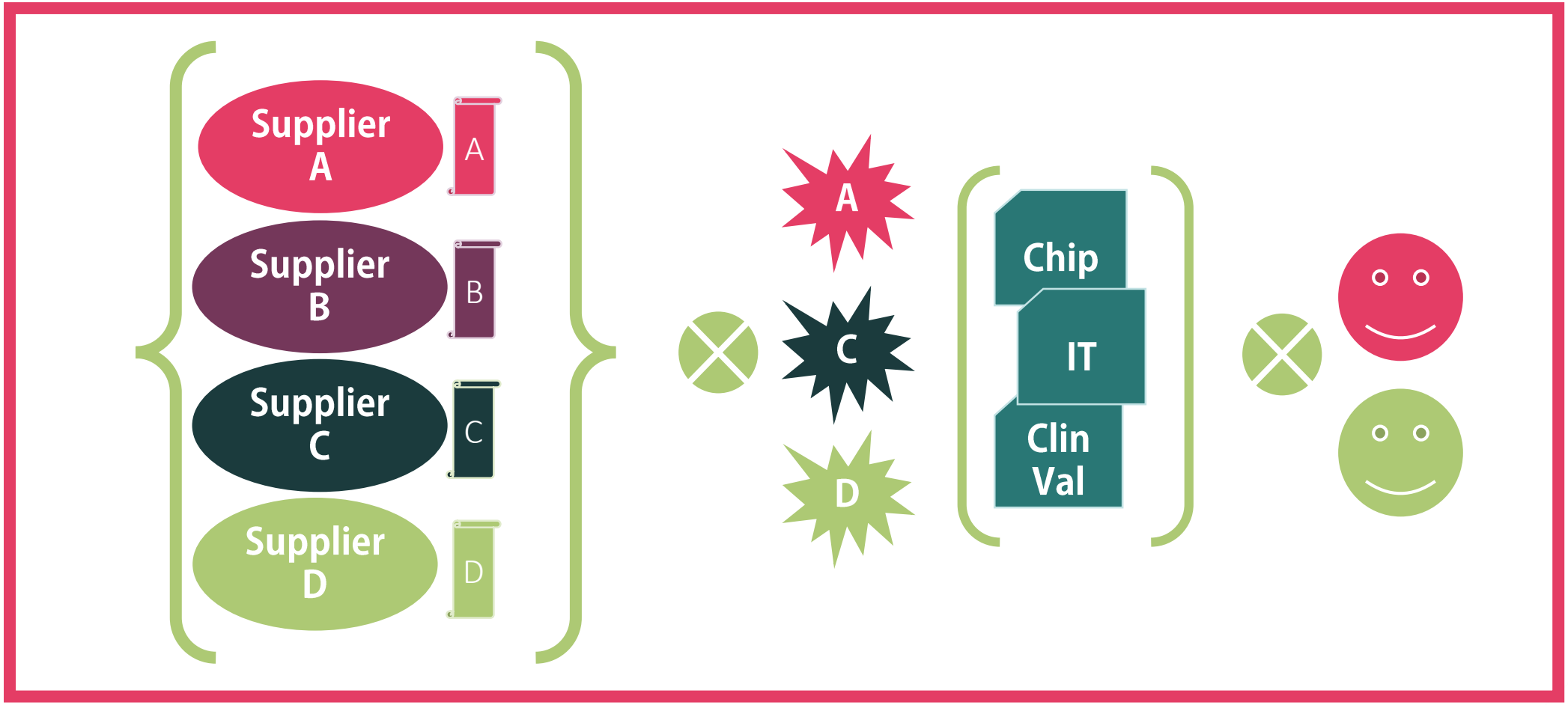
OncNGS PCP Tender process



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Deployment of oncNGS

What could/should oncNGS lead to?

- Develop **common guidelines** on implementing the oncNGS solution in oncology practice (ISO-standardization, harmonization, formalization,….)
- Develop common protocols for **data-sharing**
- Launch **cross-border purchase** procedures
- Develop tools for interactive e-Consults (**molecular tumor boards**)
- Organize joint cross-country **multi-centric clinical trials** applying oncNGS device(s)
- Develop **patient-matching tool** applying oncNGS data (s) ……

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oncNGS market in Belgium

Belgium population: 11 million

Cancer incidence: about 70.000 cases per year

OncNGS field of application: see RIZIV-INAMI NGS convention notes (Nl/Fr)

Current NGS testing consumption in all cancers/year: 12.000 tests

Reimbursement fee: 350 euro

Scope for liquid biopsies: not agreed to date

Expected: 5-10.000 tests/year

Extrapolated for oncNGS countries (200 million): about 100-200.000 tests/year

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EU oncNGS market

In oncology all in about **120 billion Euro is** projected to be spent per year by the U.S. and the EU-5.

Oncology spending in Japan and emerging countries such as China and India is expected to hit almost US$20 billion by 2022.

The global clinical **oncology next generation sequencing market** size was valued at **Euro 260 million in 2020** and is expected to grow at a compound annual growth rate (CAGR) of 14.70% from 2021 to 2028 up to **Euro 810 million**.

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General comments on changes between tenders

Overall the intentions of oncNGS remain the same but:

- Less 'Must have' – modified into '***Nice to have***'
- Increased flexibility as addressing the ***gene-panel coverage*** (modularity)
- Increased flexibility as to the integration of ***interpretation algorithms*** into the workflow (cloud services)
- **3 months tender preparation** instead of 2 in previous CfT

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NOW

External to clinical workflow

FUTURE

Internal to clinical workflow

TISSUE

NGS

- High number of alterations in genes approved by EMA (or FDA)
- Sample references for QC.
- Available large cancer panels (over 500 genes)
- Expensive

Heterogeneous samples, time-intensive, costly and sometimes impossible collection of samples

BLOOD/ PLASMA

NGS

- Only few (1-2) number of alterations in genes approved by EMA (or FDA)
- Not available sample references for QC.
- Not large cancer panels (over 500 genes)
- Expensive

Homogeneous samples, fast, cheap collection of samples

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- High number of alterations in genes approved by EMA (or FDA)
- Sample references for QC.
- Available large cancer panels (over 500 genes)
- Affordable

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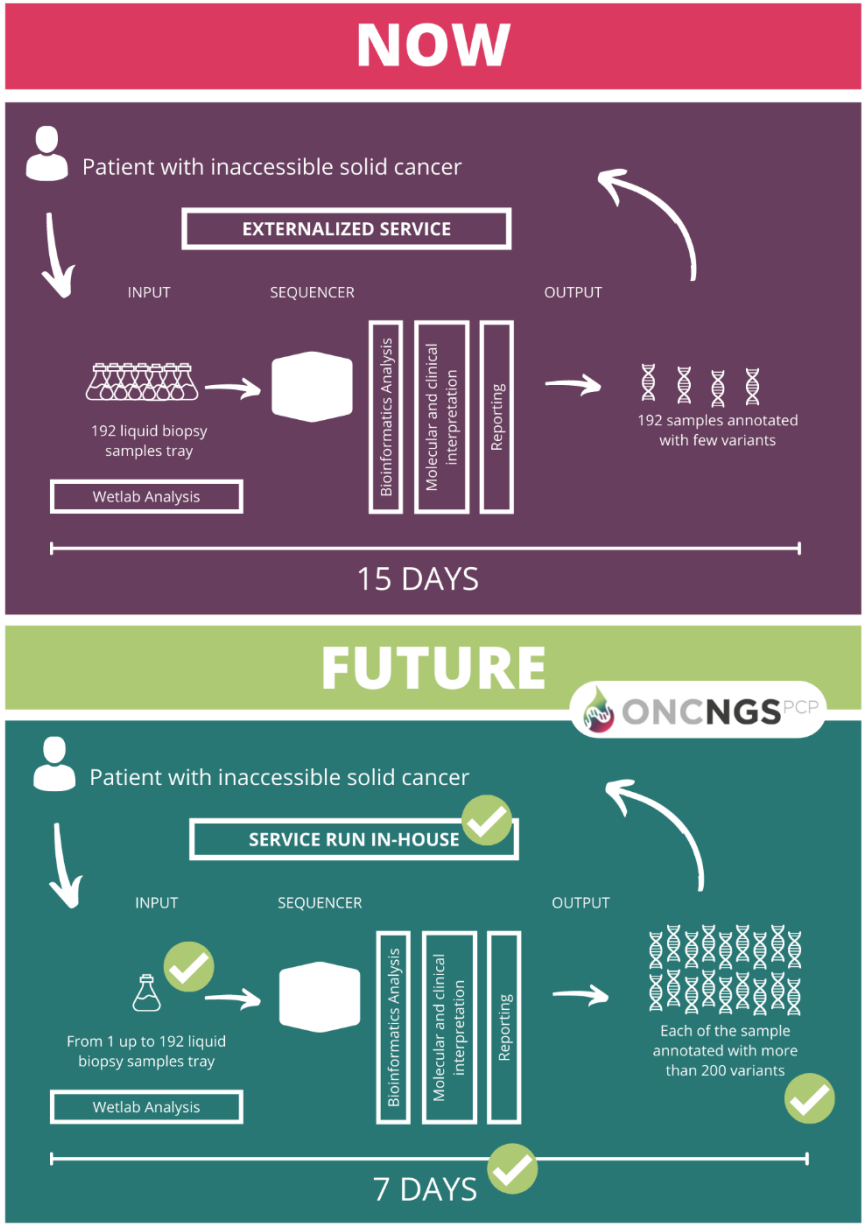

oncNGS: what is in for the patient?

L. Mazzarella – IEO, Italy

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Advantages/issues of liquid biopsies

Actual advantages

- Better accuracy in all clinical settings (not considering screening)
  - Tertiary prevention – Minimal Residual Disease after treatment for early stage
  - Monitoring disease burden and emergence of resistence in the metastatic setting
  - Identification of actionable alterations for targeted therapy (in trials or approved)
- Non-invasiveness

Current issues that may turn into advantages

- More complex alterations to be further validated (CNV, fusions, TMB/MSI/HRD etc)
- Turnaround time
- Cost
- Equality of access
- Standardized report
- Access to biomarker-driven trials
- Privacy
- Run locally vs centrally

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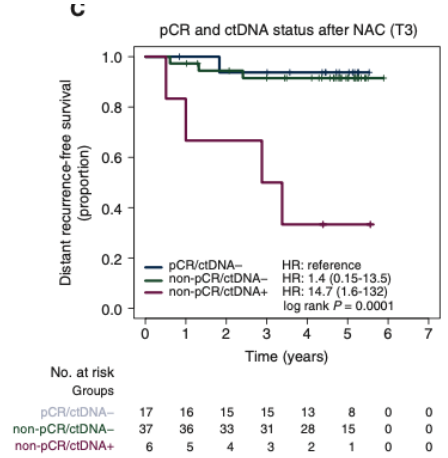
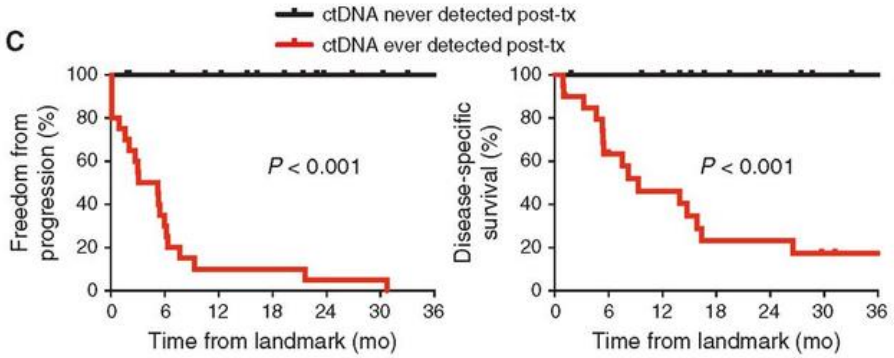
Minimal Residual Disease

- Proven accuracy in detecting MRD in multiple scenarios
- Likely to greatly overperform any predictive model (e.g. gene expression signatures in breast)

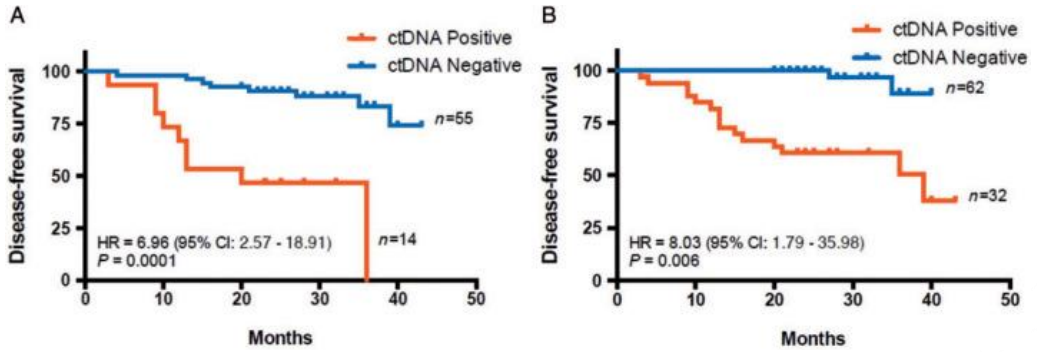
Breast (Garcia-Murillas JAMA Onc 2019)



Lung (Chaudhuri et al Canc Disc 2017)



Colorectal (Tarazona Ann Onc 2019)



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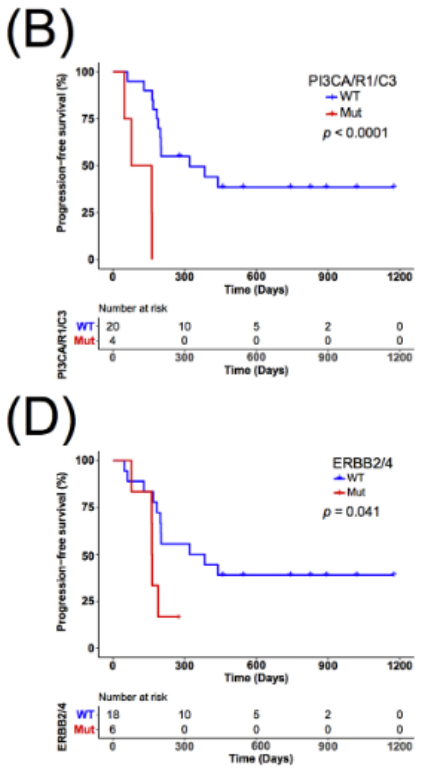
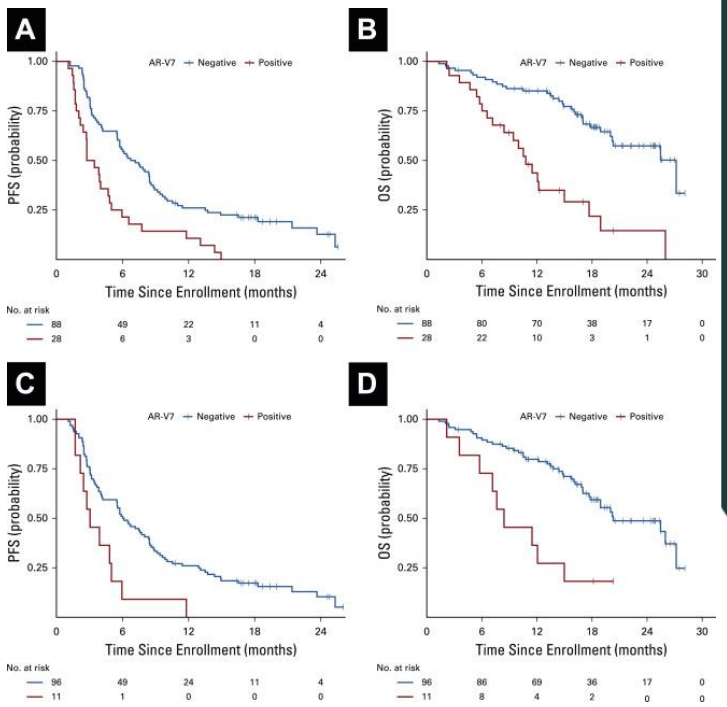
Monitoring resistance in the metastatic setting

- Established in some settings (EGFR T790M in NSCLC, KRAS in colon)
- Emerging in many other settings, also for non-SNV

HER2+ gastric, Wang et al 2019



Prostate Arv7, Armstrong et al JCO 2019



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Preference for non-invasiveness

Obvious, but now even evidence-based!

	Pts Who Preferred Blood Test Over Tissue Biopsy		**Pts Who Preferred Tissue Biopsy Over Blood Test**	
	N=372 (90%)		**N=41 (10%)**	
Wait times	Switched in response to increased wait times	Never switched (strong preference for blood test)	Switched in response to increased wait times	Never switched (strong preference for tissue biopsy)
Proportion of Patients	91%	9%	95%	5%
Number of extra weeks of wait time tolerated before switching, Mean (SD)	1.8 (2.1)	–	2.0 (3.2)	–
Test Conclusiveness	Switched in response to decreased test conclusiveness	Never switched (strong preference for blood test)	Switched in response to decreased test conclusiveness	Never switched (strong preference for tissue biopsy)
Proportion of Patients	94%	6%	96%	4%
Percentage decrease in test conclusiveness patients tolerated before switching, Mean (SD)	6.2 (8.8)	–	3.4 (7.2)	–

Abbreviation: SD, standard deviation.

Lee et al 2019 (Princess Margaret)

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The key issue: SIZE!

- How big should a LB panel be?
  - Small (few alterations) → quick, simple and inexpensive, but limited applicability
  - Large (Kb/Mb) → versatile, but slow, complex and expensive
    - Suitable for non-SNV alterations (CNV, TMB, fusions etc)

- All issues preventing more widespread LB application are a consequence of this technical dychotomy

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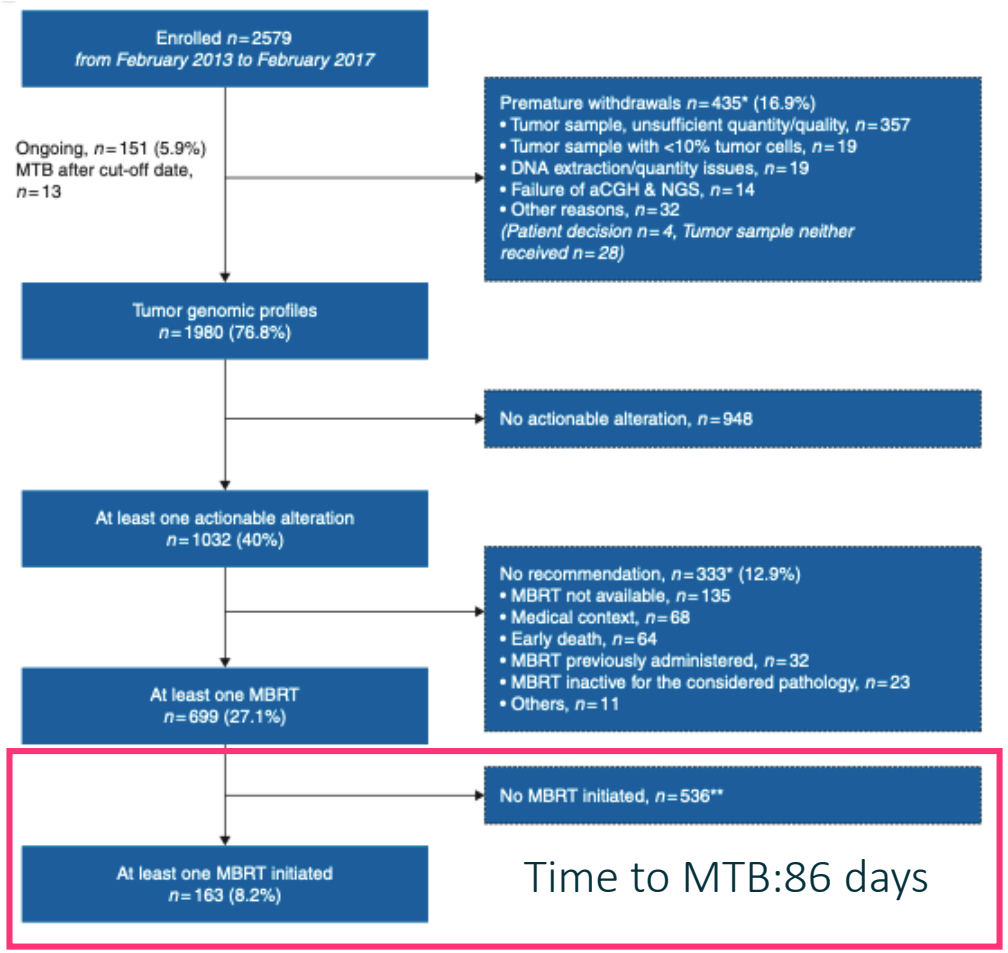
Key issue: Turnaround Time

Table 1. Findings summary and demographics

	N=25	%,(Min-Max)
Gender		
Female	9	36%
Male	16	64%
Age (ys)	69.1	(48-87)
Smoking status		
Former smokers	12	48%
Current smokers	2	8%
Never smokers	8	32%
Unknown	3	12%
Driver Mutations	**Tissue**	**Liquid**
ALK	2	1
EGFR	8	7
KRAS		5
ROS1	1	1
MET		2
RET		1
PIK3CA		2
Turnaround Time, days	**Median**	**(Min-Max)**
Liquid biopsy - Time to result		
From blood draw to results	10	(7-19)
From pathological diagnosis to blood draw	7	(-15-46)
From pathological diagnosis to liquid results	20	(-5-54)
Tissue biopsy - Time to result		
From pathological diagnosis to tissue results	21.5	(7-45)
Molecular tissue biopsy results to liquid biopsy results	5	(-29-29)

Sehayek et al WCLC 2020

Turnaround time is a key factor for trial enrolment



Tredan et al Ann Onc 2019

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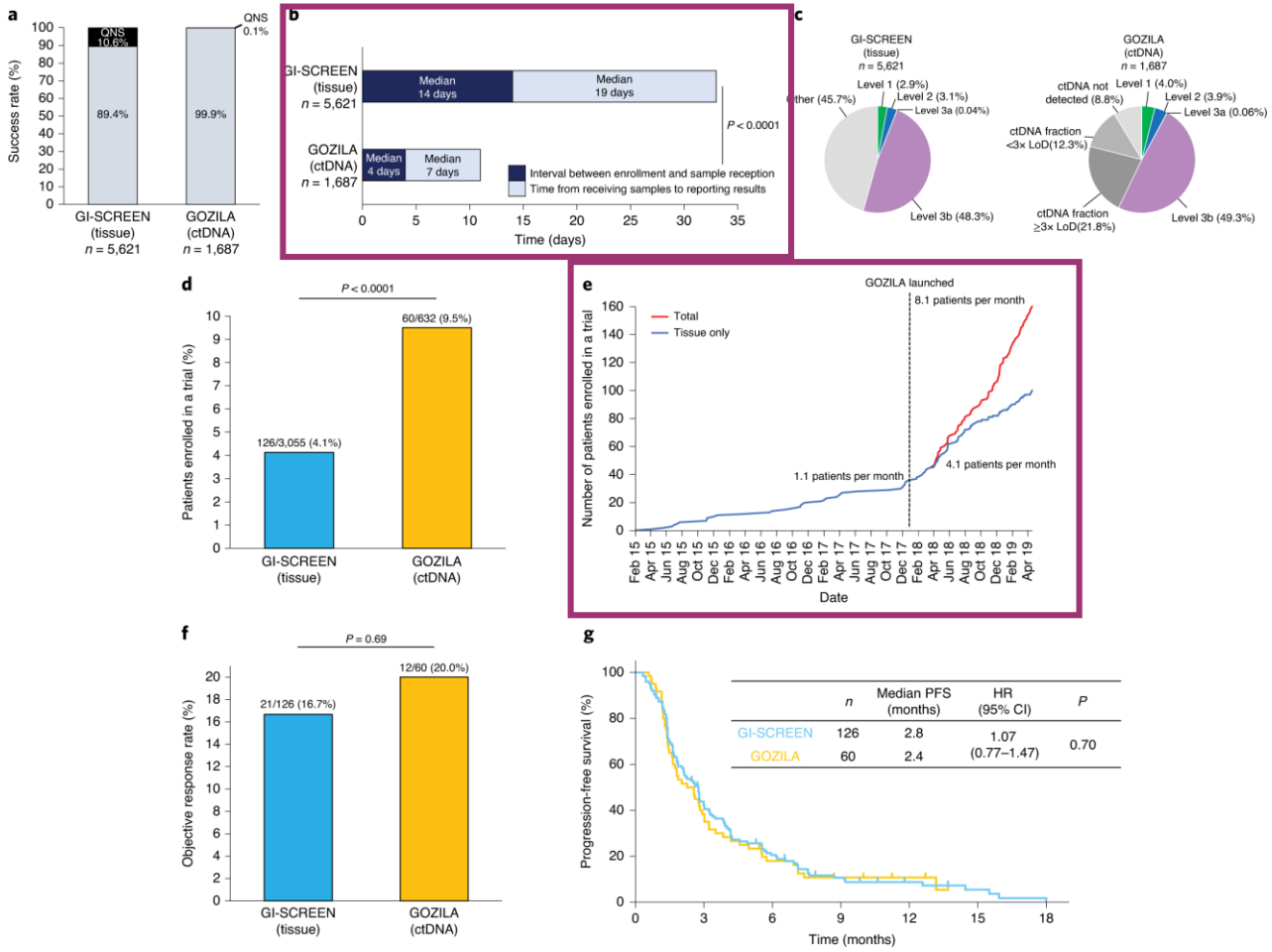
Turnaround time



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Key issue:Cost

Only viable if cost is kept very low

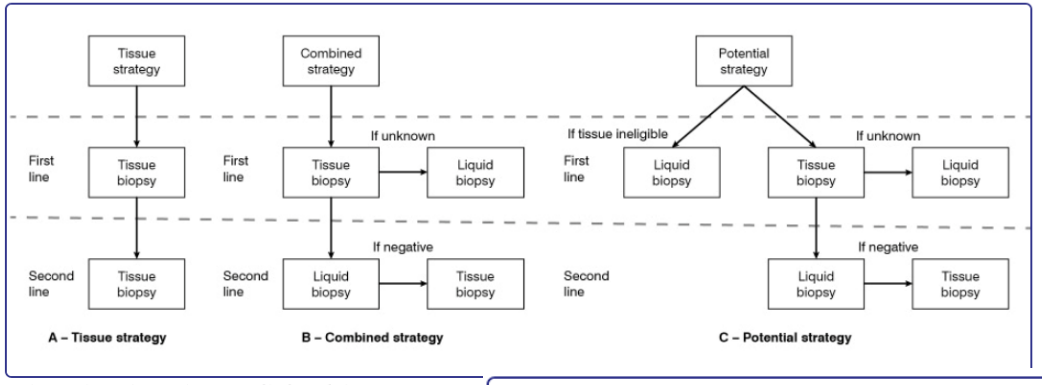

Figure 1. Diagnostic strategies compared in the analysis

Procedures	Unit cost (€)	
	Tissue biopsy	Liquid biopsy
34.24 Pleural or 33.24 bronchial biopsy	180.74	0.00
91.49.2 Venous blood sampling	0.00	2.58
DNA mutations	231.28	231.28
• 91.29.4 DNA mutation analysis	120.80	120.80
• 91.36.4 DNA digestion with restriction enzyme	51.43	51.43
• 91.36.5 Extraction of DNA or RNA	59.05	59.05
Total	412.02	233.86

Table III. Costs associated with the tissue and liquid biopsy

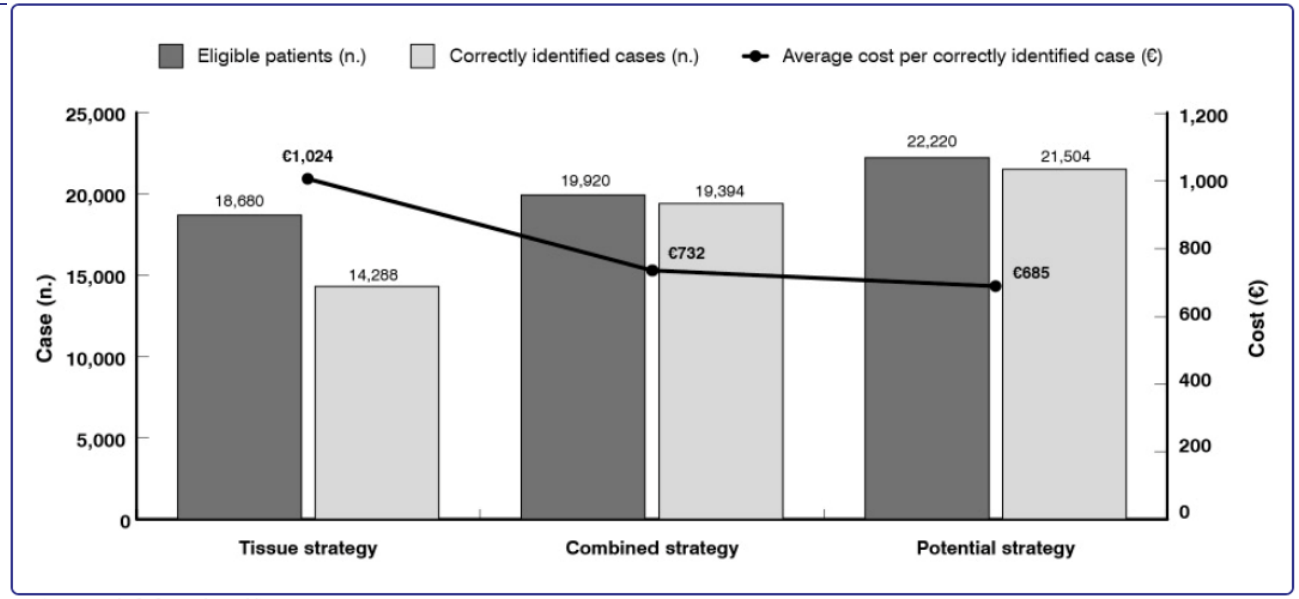

Figure 2. Results for first- and second-line treatment

Gancitano et al 2018

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Key issue: Equality of access

Review > Clinicoecon Outcomes Res. 2020 Feb 13;12:115-122.
doi: 10.2147/CEOR.S220726. eCollection 2020.

Analysis of the Cost-Effectiveness of Liquid Biopsy to Determine Treatment Change in Patients with Her2-Positive Advanced Breast Cancer in Colombia

Diana Sánchez-Calderón [1], Adriana Pedraza [2], Catalina Mancera Urrego [2], Aurelio Mejía-Mejía [2], Ana Lorena Montealegre-Páez [3], Sandra Perdomo [3]

Still little research on this, but highly likely that value-based reimbursement systems will require considerable reduction in cost for high-throughput LB

Conclusion: Including liquid biopsy in the treatment of HER2-positive advanced breast cancer was considered currently inapplicable in Colombia because it was not cost effective. Our results open a window of opportunity to improve the development and implementation of ctDNA testing in Colombia, potentially reducing current costs. More evidence is required on the utility of this test, depending on the financial capacity of Colombia and other countries.

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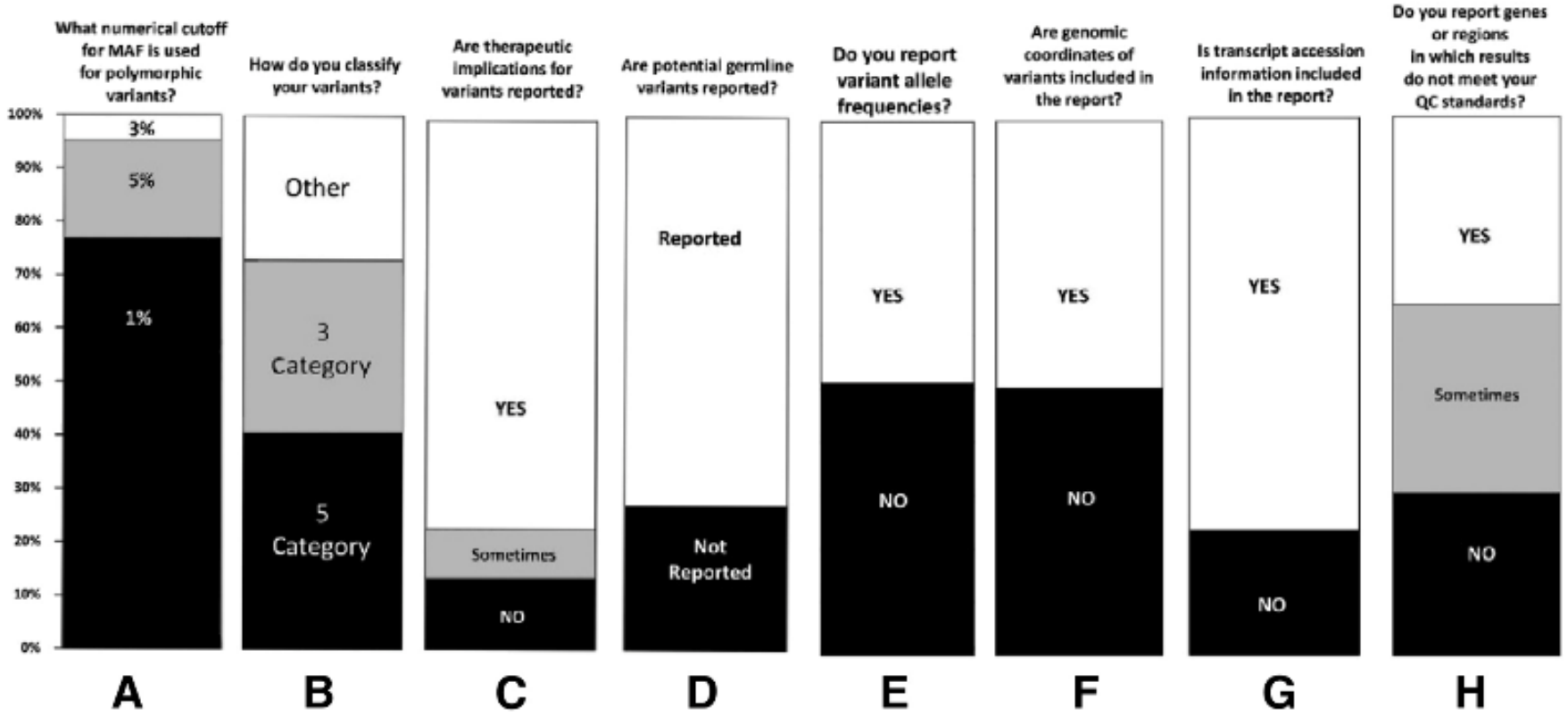
Key issue: standardized reporting

Survey from Association for Molecular pathology (n=44), Li et al J MolDiag 2017



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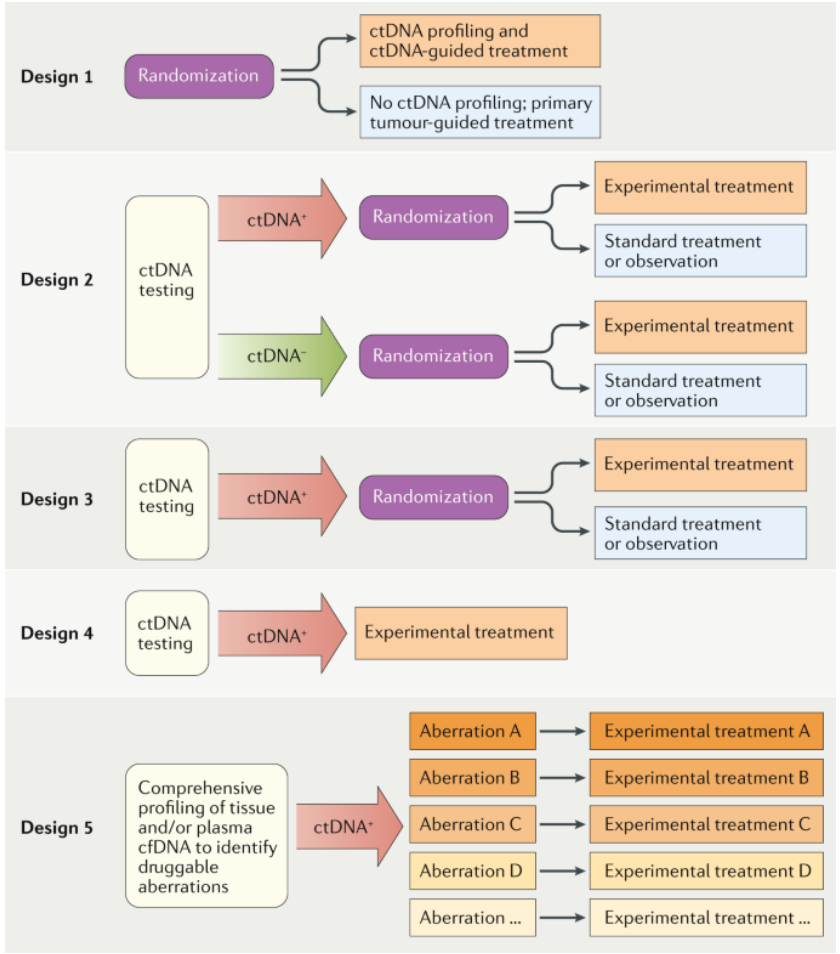
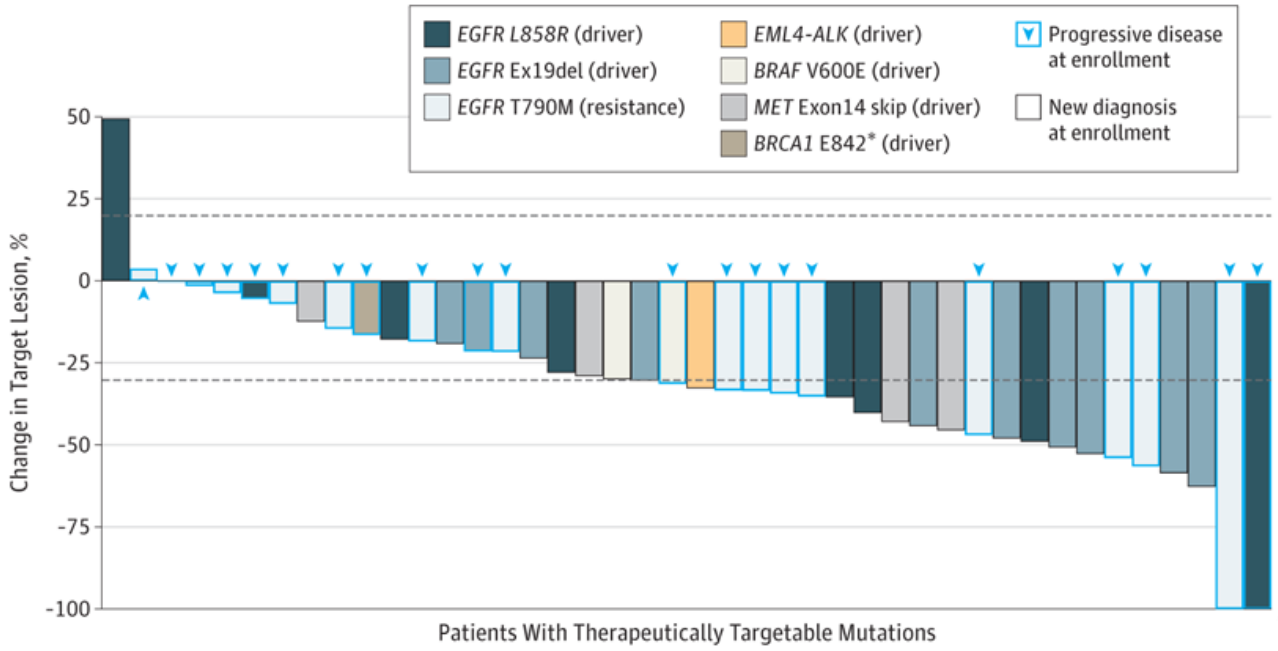
Key issue: access to trials





Aggarwal JAMA onc oct 2018

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Key issue: centralized vs decentralized model

Centralised model optimal in the initial phase to rationalise resources and maintain accuracy standards,

However

- Demand is growing
- Issues on privacy and accountability
- Issues on sample shipment/degradation
- Issues on logistics
- Turnaround time
- Decentralisation or «hub and spoke» model fovored over company centralisation

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Conclusion

- Liquid biopsy-based disease assessment is, in principle superior to tissue-based biopsy and therefore highly desirable as:
  - More tolerated by patients
  - More accurate in detecting MRD
  - Highly sensitive (though not 100%) in monitoring metastatic disease
  - Potentially more sensitive in identifying emergence of resistence mutations
  - Potentially more effective in allocating patients to trials
- Major issues remain regarding
  - Panel size and range of alterations (CNV, translocations etc)
  - Cost → sustainability --> size of garget population → equality of access
  - Local implementation must be favored over central implementation

oncNGS: the technical challenge "bringing together what has been separated."

P. Sujobert– CHU-Lyon, France

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Liquid versus solid biopsies

Current challenges of cancer genomics:

- Spatial heterogeneity
- Temporal heterogeneity
- Monitoring of treatment response
- Measurement of residual disease
- Early detection of relapses

Liquid biopsies allow to obtain an overall view of cancer heterogeneity, and identifies targets for monitoring treatment responses.

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Liquid versus solid biopsies

	Solid biopsy	Liquid biopsy
Spatial heterogeneity	-	++
Target identification	+	++
Available material	+/-	++
Non-invasive	-	++
Histology	++	-
Standardization	+	++

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Technical challenges liquid biopsies

Preanalytics: obtaining a good ctDNA

- **Sampling:**
  - blood or other fluids?
  - time of sampling

- **Prenalaytical techniques:**
  - avoid WBC lysis (sampling tube, transportation, fast separation of plasma)
  - ctDNA extraction and quantification
  - conservation of ctDNA

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Technical challenges liquid biopsies

Analytics: obtaining informative results

- Informativity: one test for all patients
- Sensitivity, reproducibility, robustness
- Limited wet lab handling
- Standardized bioinformatics
- Standardized report

- Clinically useful: time to result (less than 10 days), price for value
- Flexibility: fits for one or many samples, panel adaptable to scientific evolutions

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R&D needs

State-of-art panel design
- Maximal informativity
- All clinically relevant targets should be assesed (diagnostic, predictive, prognostic, therapeutic)
- Price in line with standard-of-care application

Wet lab practice
- Automation
- Internal quality controls
- Limited 'Time on hands'

Optimal bioinformatics
- Standardization
- Open access
- Data interoperability
- Databases
- GDPR

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Market opportunities

ctDNA analysis will become standard of care for the analyse of the molecular landscape of advanced cancers

Personalized medicine: 1 cancer -> 1 molecular analysis -> targeted therapy

And ctDNA for the longitudinal monitoring of cancer…

oncNGS PCP: the process

R. Alessandrello - AQuAS (Agència de Qualitat i Avaluació Sanitàries de Catalunya), Spain

Salut/ Agència de Qualitat i Avaluació Sanitàries de Catalunya

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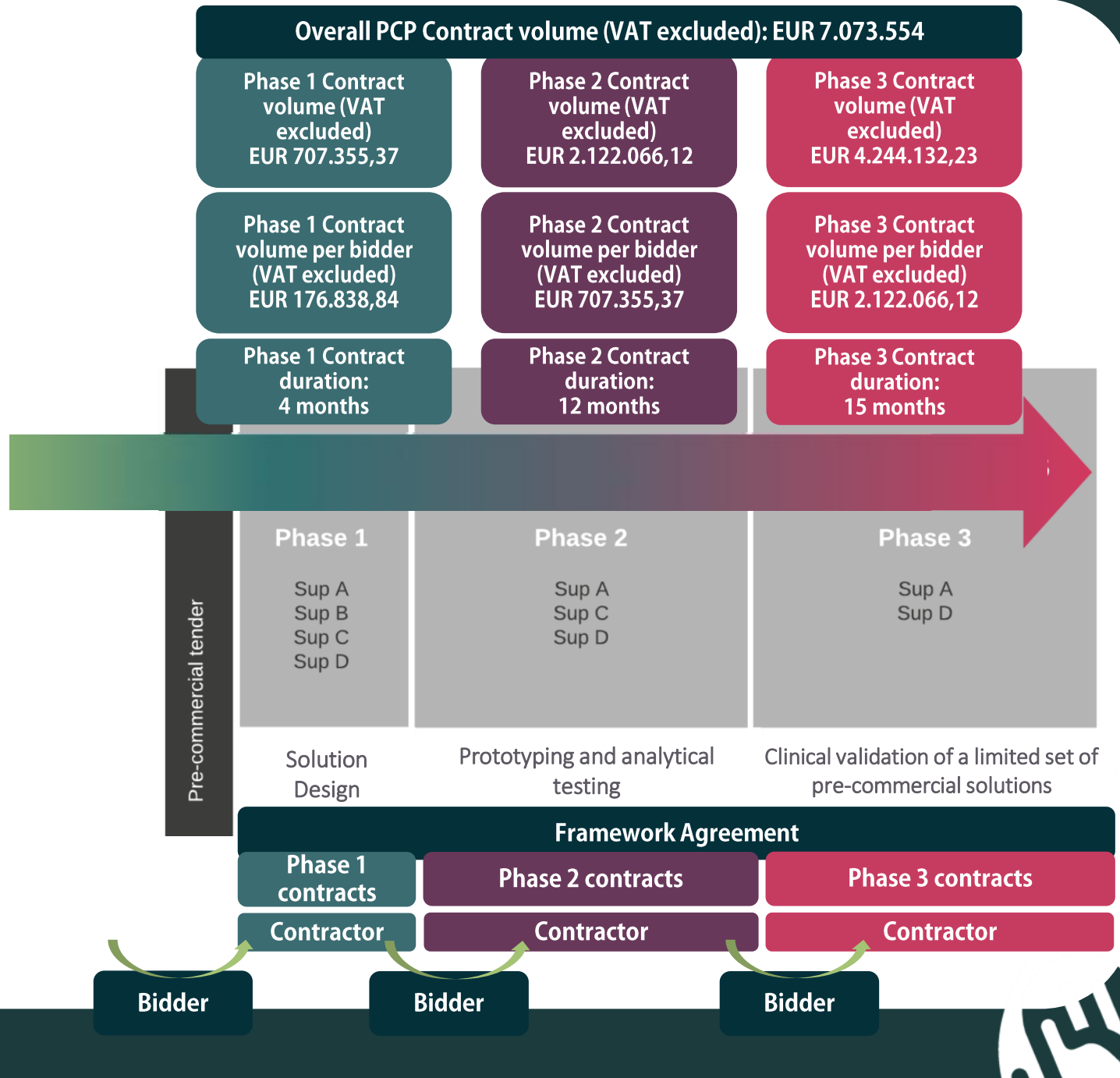
oncNGS Pre-Commercial Procurement Procedure



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TFEU and Public Procurement Principles

- ✓ Transparency: all the information on the public procurement process must be made available to all public procurement stakeholders.
- ✓ Equal treatment: and non discrimination: all suppliers/service providers should be subject to the same conditions (comparable situations are not treated differently and that different situations are not treated similarly unless such a difference or similarity in treatment can be justified objectively) and no discriminated on the grounds of nationality under the TFEU.
- ✓ Mutual recognition: reports and certificates issued by the authorities of any member state shall also be valid in all other EU and EEA states.
- ✓ Open Competition: public procurement requirements should be open to all qualified organizations and individuals. Any procurement practices that prevent, restrict or distort this competition and any subsequent PPI shall be avoided.
- ✓ Proportionality: requirements and conditions in the procurement should be reasonable in proportion to the object of procurement. Measures taken by the contracting authority may not go beyond what is necessary for the procurement in question.
- ✓ Sound financial management: contracts will be designed, awarded and monitored in line with the principles of economy, efficiency and effectiveness.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 874467

Procedure compliancy with H2020 rules

This procurement receives funding from the European Union's Horizon 2020 Research and Innovation Programme, under grant agreement n° 874467. The EU has given a grant for this procurement, but is not participating as a contracting authority in the procurement.

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 874467

Procedure compliancy with H2020 rules

'Pre-commercial procurement' means:

- **procurement of R&D services :** can cover activities such as solution exploration and design, prototyping, up to the original development of a limited volume of first products or services in the form of a test series.
- **risk benefit sharing under market conditions**: procurers share with suppliers at market price the benefits and risks related to the IPRs resulting from the R&D
- **competitive development in phases**:
  - buy the R&D from several competing R&D providers in parallel, to compare and identify the best value for money solutions on the market to address the PCP challenge
  - the R&D is also split in phases (solution design, prototyping, original development and validation / testing of the first products)
- clear **separation between the procurement of the R&D services procured from the deployment of commercial volumes of end-products:** refers to the complementarity of PCP, which focuses on the R&D phase before commercialization, and PPI, which does not focus on R&D but on the commercialization/diffusion of solutions. Procurers can but are not obliged to procure at market price R&D results from a PCP.

Annex E. Specific requirements for innovation procurement (PCP/PPI) supported by Horizon 2020 grants
EC WORK PROGRAMME 2018-2020

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 874467

Procedure compliancy with H2020 rules

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.

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Procedure compliancy with H2020 rules: sharing risk and benefits

PCP procures R&D services at market price, thus providing contractors with a transparent, competitive and reliable source of financing for the early stages of their research and development.

Giving each contractor the ownership of the IPRs attached to the results it generates during the PCP means that they can widely exploit the newly developed solutions commercially.

In return, the tendered price must contain a financial compensation for keeping the IPR ownership compared to the case where the IPRs would be transferred to the procurers (the tendered price must be the 'non-exclusive development price').

Moreover, the **procurers must receive rights to use the R&D results for internal use and licensing rights subject to certain conditions.**

EC H2020 Guidance PCP procurement documents
Version 2.1
07 January 2020

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Exemption from EU public procurement directives, the WTO Government Procurement Agreement (GPA) and EU state aid rules

PCP procurements are **exempted from the EU public procurement directives** because the procurers do not retain all the benefits of the R&D (the IPR ownership stays with the contractors).

They are also **exempted from the WTO Government Procurement Agreement (GPA)** because this Agreement does not cover R&D services (the PCP being limited to such services — and any subsequent PPI procurements relating to commercial-scale supply of such solutions not being part of the PCP procurement).

PCP procurements **do not constitute state aid under the EU state aid rules** if they are implemented as defined in the PCP communication , namely by following an open, transparent, competitive procedure with risk- and benefit-sharing at market price. (The division of all rights and obligations (including IPRs) and the selection and award criteria for all phases must be published at the outset; the PCP must be limited to R&D services and clearly separated from any potential follow-up PPI procurements; PCP contractors may not be given any preferential treatment in a subsequent procurement for provision of the final products or services on a commercial scale.)

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Procedure compliancy with H2020 rules: sharing risk and benefits

Bidders:

- Tender will be open to any type of natural or legal persons
- It will be possible to submit bids either individually or in association or consortium with other bidders (under no circumstances it will be allowed to any natural or legal person to submit more than one bid)
- Subcontracting possible

Place of performance:

PCP is open to all operators on equal terms, regardless of the size, geographical location or governance structure. There is, however, a place of performance requirement that they must perform a predefined minimum percentage of 51% of the contracted R&D services in EU Member States or Horizon 2020 associated countries. (*Guidance PCP procurement documents*)

Language:

Offers may be submitted in English. All communication (before, during and after the procurement) can be made in English (*Guidance PCP procurement documents*)

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POST oncNGS Procedure