

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

M. Van den Bulcke, Sciensano, Belgium





oncNGS Open Market Consultation

What do we want to do today at this OMC?

Key—information on oncNGS:

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

Feedback from the market:

- Questions through chat
- Questions through oncNGS contact on website
- Questionnaire

Answers to all questions as FAQ on website oncNGS





CANCER in EUROPE

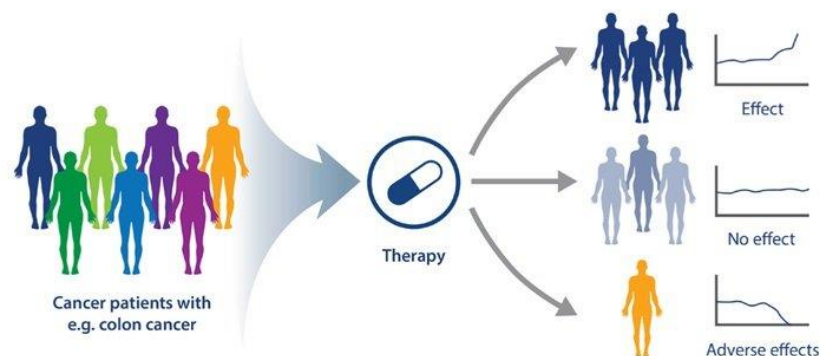
- Cancer is one of the main public health challenges in Europe and the second leading cause of mortality, with nearly **3 million new cases** and **1.3 million deaths** in 2020.
- Cancer is in contrast to cardiovascular disease a NCD with still increasing incidence as reduction of the impact of risk 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.



PRECISION MEDICINE & CANCER

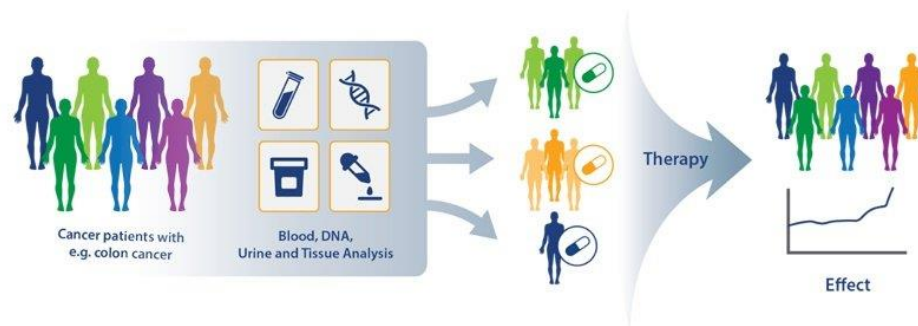
Current Medicine

One Treatment Fits All



Future Medicine

More Personalized Diagnostics





oncNGS PCP

The challenge consists of providing:

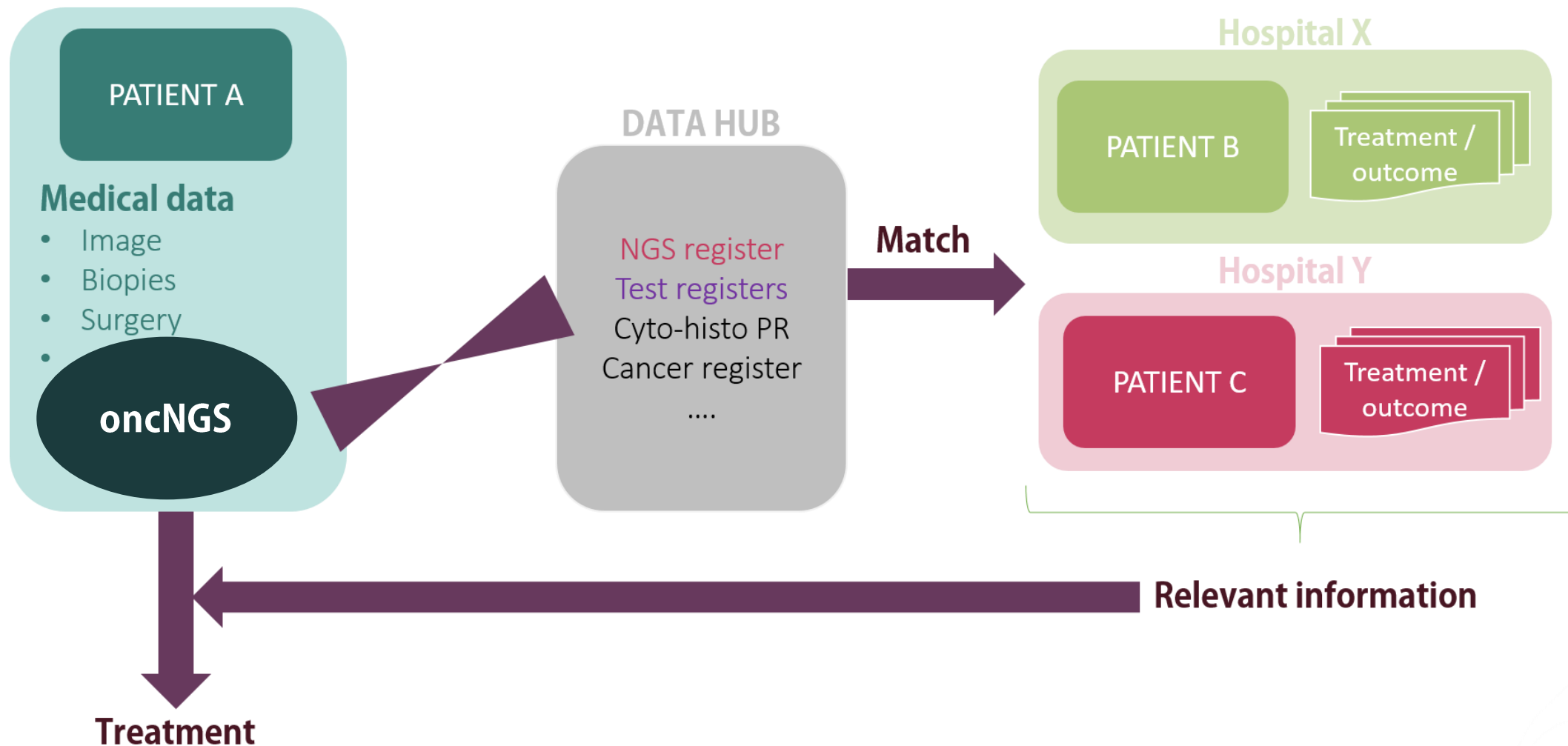
1. efficient molecular DNA/RNA profiling of tumour-derived material in liquid biopsies by means of
2. pan-cancer tumour marker analysis kit including NGS analysis integrated with
3. an ICT decision support system including test interpretation and reporting.

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



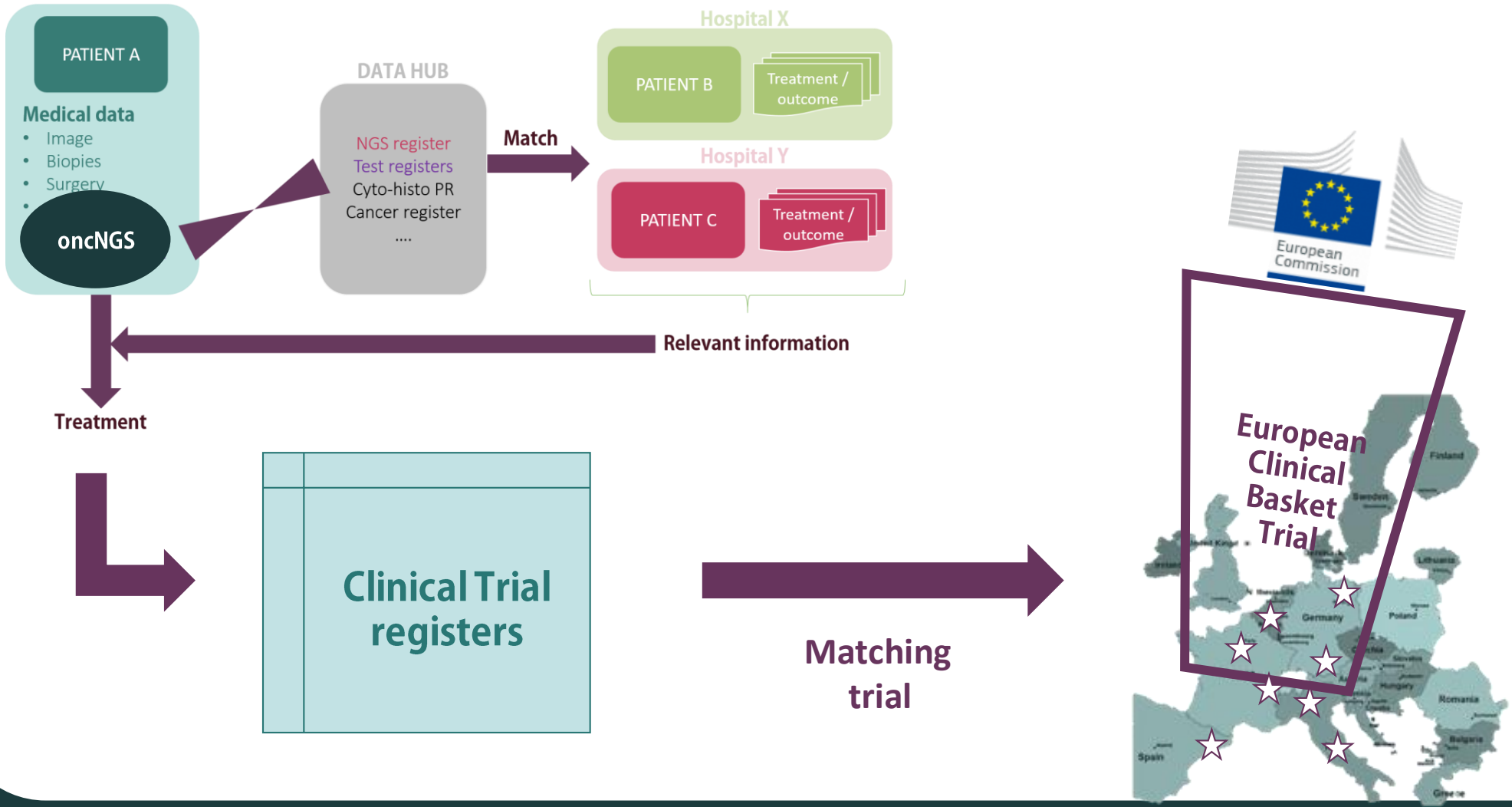


Cancer Patient Matching framework





Cancer Patient Matching framework





oncNGS PCP

- **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/>



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

oncNGS consortium: Buyers





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oncNGS consortium: Supporting Entities





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



BUYERS PROFILES



Who: National Institute of Public health

Role: coordinator of the implementation of the roadbook on NGS diagnostics in oncology – organizer of national EQA program – chair of the 'Commission on Personalised Medicine'

Interest: standardized testing and reporting guaranteeing high-quality NGS test performance for all patients – single procurement in support of HCS sustainability



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BUYERS PROFILES



INSTITUT
JULES BORDET



Who: Institut Jules Bordet is an OECl-accredited Comprehensive Cancer Center and the only multidisciplinary and integrated hospital in Belgium fully dedicated to patients with cancer.

Role: For more than 75 years, our teams have been offering patients leading-edge diagnostic and therapeutic strategies in the prevention, screening and active treatment of all types of cancer.

The Institut Bordet also carries out important research activities which every year lead to major discoveries, as well as providing high-level, specialized university training.

Interest: A key feature of the Institut Jules Bordet is the close integration of research and medical practice, which enables patients to take part in clinical studies of all the latest therapeutic modalities and to benefit as quickly as possible from the latest discoveries made in research laboratories. Numerous clinical research programs are conducted in cooperation with other cancer centers and national and international networks.



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ALLEANZA
CONTRO
IL CANCRO



BUYERS PROFILES

Who: Alliance Against Cancer (Alleanza Contro il Cancro-ACC), the largest Italian organization for cancer research, was established in 2002 by the Italian Ministry of Health as a network of six high standard institutes for comprehensive cancer patient care and research (IRCCS). The network is currently composed of 28 IRCCS (Istituti di Ricovero e Cura a Carattere Scientifico), the Italian National Institute of Health, the Italian Association of Cancer Patients (AIMaC), the Italian Sarcoma Group and the National Centre of Oncological Hadrontherapy (CNAO).

Role: The primary aim of ACC is to promote the network among oncologic institutes pursuing mainly clinical and translational research in order to bring state of the art diagnostics and advanced therapeutics to patient care.

Interest: ACC is focusing on major cancer types as well as clinical research. The mainstream of the activities is the genomic characterization of tumours, which offers an enormous number of opportunities in clinical applications: ACC points to fortify and improve the role of high-quality personalized medicine in Italian oncology, generating a more efficient approach toward the patient in order to provide new and significant perspectives in cancer research and, more importantly, the swift application of the resulting knowledge to the diagnosis and therapy of cancer patients.



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BUYERS PROFILES



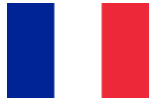
Who: The Institut Curie is composed of 1 cancer hospital and 1 research center located in 3 sites (Paris, Saint-Cloud and Orsay). Early phase clinical trials for adults are run within the Department of Drug Development and Innovation (D3i), which also manages the Molecular Tumor Board (MTB).

Role: The Institut Curie has been a pioneer in the field of precision medicine with the first randomized trial worldwide (SHIVA01) that evaluated the efficacy of matched targeted therapy based on a specific treatment algorithm, followed by the ongoing SHIVA02 trial (NCT03084757). IC has been labelled by the French National Cancer Institute (INCa) as a Comprehensive Cancer Center. The Institut Curie is highly involved in the SEQOIA platform, one of the two pioneer platforms that were selected at the national level in the context of the national program France Medecine Genomique 2025 that aim at developing high throughput sequencing in patients with cancer and rare diseases

Interest: The Genetic Molecular Platform of the Institut Curie has been granted by the INCa to perform next generation sequencing for clinical use. The MTB, launched in October 2014, aims at molecularly characterizing patient tumors in order to guide them to early phase clinical trials.



BUYERS PROFILES



Who: As a Public Centre of Excellence, «Hospices Civils de Lyon» (HCL) make up the second-largest University Hospital Network in France. Today, HCL comprise 14 multidisciplinary or specialized establishments providing a diverse range of services.

Role: For over 200 years, as a network providing expertise in all disciplines – both medical and surgical – Hospices Civils de Lyon have offered a wide range of human, technical and logistical resources to ensure that they provide care, training, research, medical innovation as well as disease prevention and health education.

Interest: The HCL have an INCa labelled platform for the molecular diagnosis of tumours, including haematological malignancies. HCL are one of the biggest centre in Europe for the treatment of haematological malignancies, and especially for lymphomas, The network devotes itself daily to its mission: contributing towards the constant improvement of the health of the French and Europeans.



BUYERS PROFILES



Who: The **Catalan Institute of Oncology (ICO)** (www.iconcologia.net) is a public non-profit institute assigned to the Catalan Health Service (CatSalut). According to the SCImago 2018 report, ICO-L'Hospitalet ranks percentile 18th in overall research and innovation at worldwide level and ranks in the 1st quartile at country level. The average annual number of publications between 2013 and 2017 is around 400.

Role: ICO's approach to the disease is comprehensive, combining, all in one organization, prevention, care, specialized training and research. ICO comprises five centers (L'Hospitalet, Badalona, Girona and Tarragona i Terres de l'Ebre) and provides cancer care for almost 45% of the adult population of Catalonia. Research and innovation is one of its main values.

Interest: ICO is a leader in cancer care in Catalonia, with a high international recognition. ICO is structured in 4 research programmes (Cancer Epidemiology, Hereditary Cancer, Translational Research/ProCURE Programme and Cancer Prevention and Control Program), and each program is fully equipped in order to meet with the basic need of the investigators.



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BUYERS PROFILES



Who: Charité is one of the largest university hospitals in Europe. All of our clinical care, research and teaching is delivered by physicians and researchers of the highest international standard. Charité is internationally renowned for its excellence in teaching and training.

Role: The Charité oncology and haematology medical centre specialises in the treatment of leukaemia, lymphoma and solid tumours. For cancer diagnostics, the centre has the most modern, university-medical methods available. The treatment always takes place in close cooperation of all departments necessary to ensure best interdisciplinary care. The goal is to ensure an individual therapy for every patient. In particular, the latest methods of immunotherapy are used here.

Interest: Innovative capacity and responsible governance, for the benefit of patients and society - these are the central tenets behind all of Charité research endeavours. Committed to the highest standards of quality and sustainability, with a particular focus on the interface between basic and patient-oriented research, which seeks to foster interdisciplinary collaborations with both national and international partners.



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BUYERS PROFILES



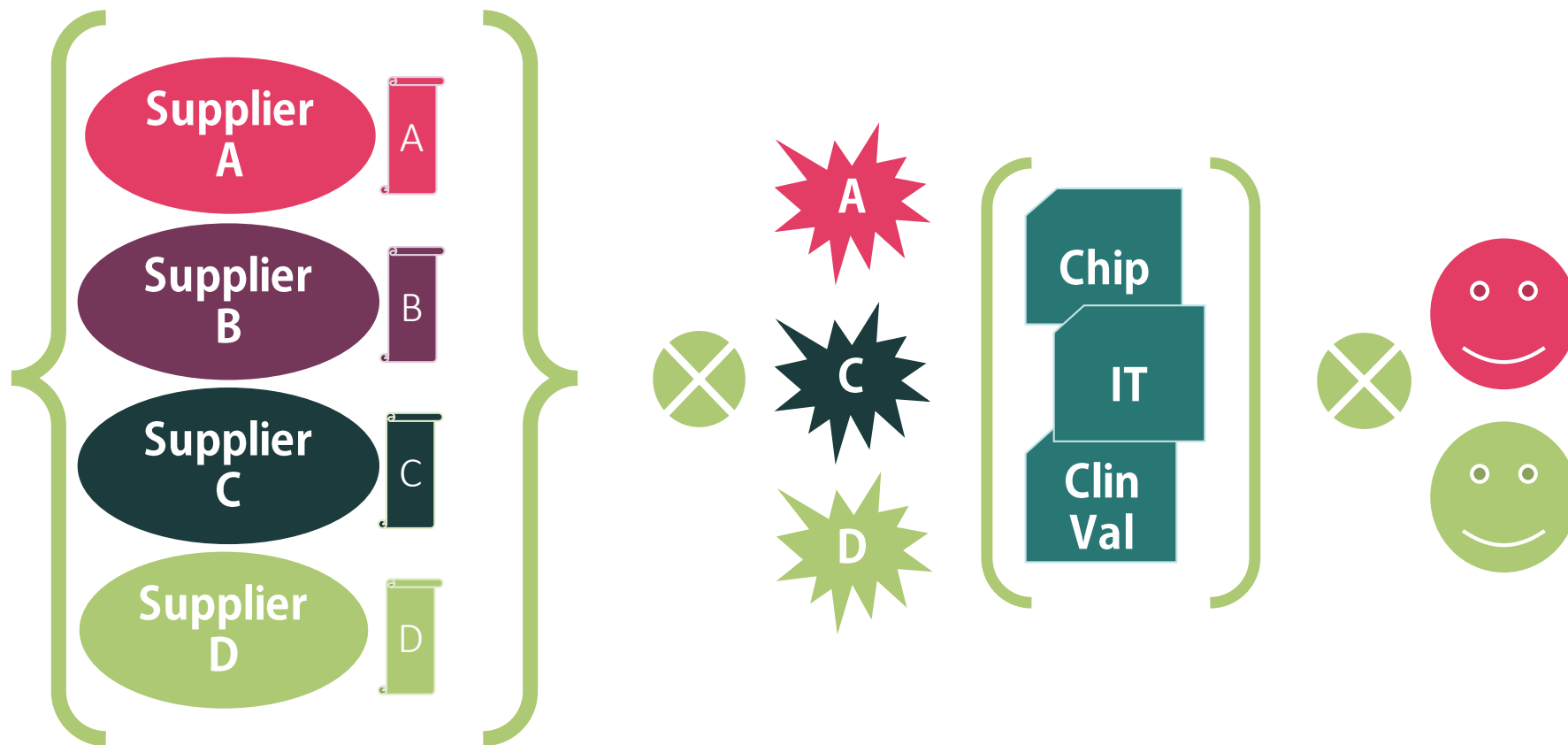
Who: The Ludwig-Maximilians University (LMU) LMU is the leading teaching and research university in Germany, ranking 1st in Germany in the latest Times Higher Education World University Ranking. LMU is a distinguished beneficiary of the German excellence initiative, and has hosted in total more than 90 ERC grants.

Role: With more than 2.000 beds, the **University Hospital of Munich (LMU)** is a highly advanced hospital with 47 clinics, institutes and departments covering all fields of medicine. With its two campuses in Grosshadern and in the city centre, it is one of the largest hospitals in Europe

Interest: Special interest is on the molecular pathogenesis of leukemia and lymphoma as well as innovative treatment strategies including novel antibodies and molecular targeted approaches like inhibitors of the B-cell receptor pathway. Within that scope, LMU played a leading role in the establishment of the international standards of care for MCL patients.

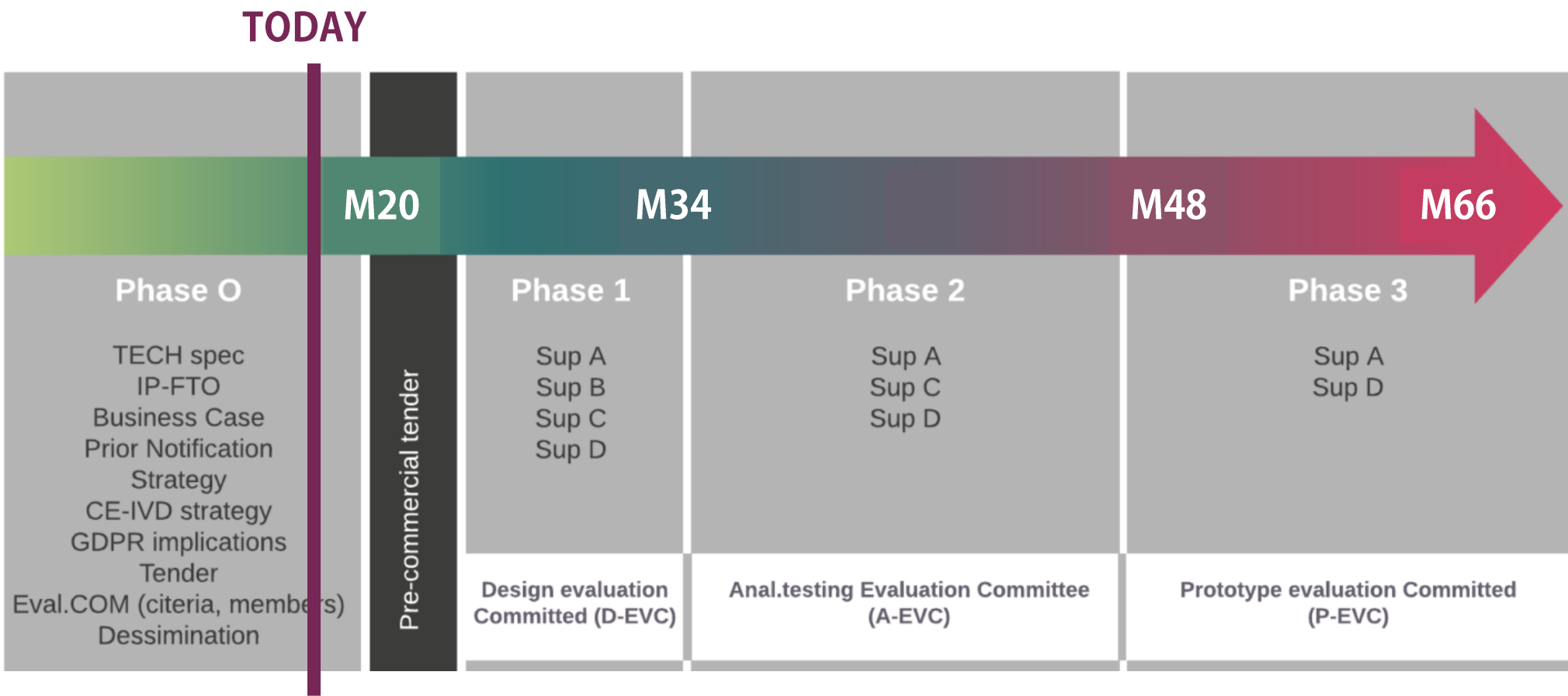


OncNGS PCP Tender process





oncNGS PCP project





Deployment of oncNGS

What could/should oncNGS lead to?

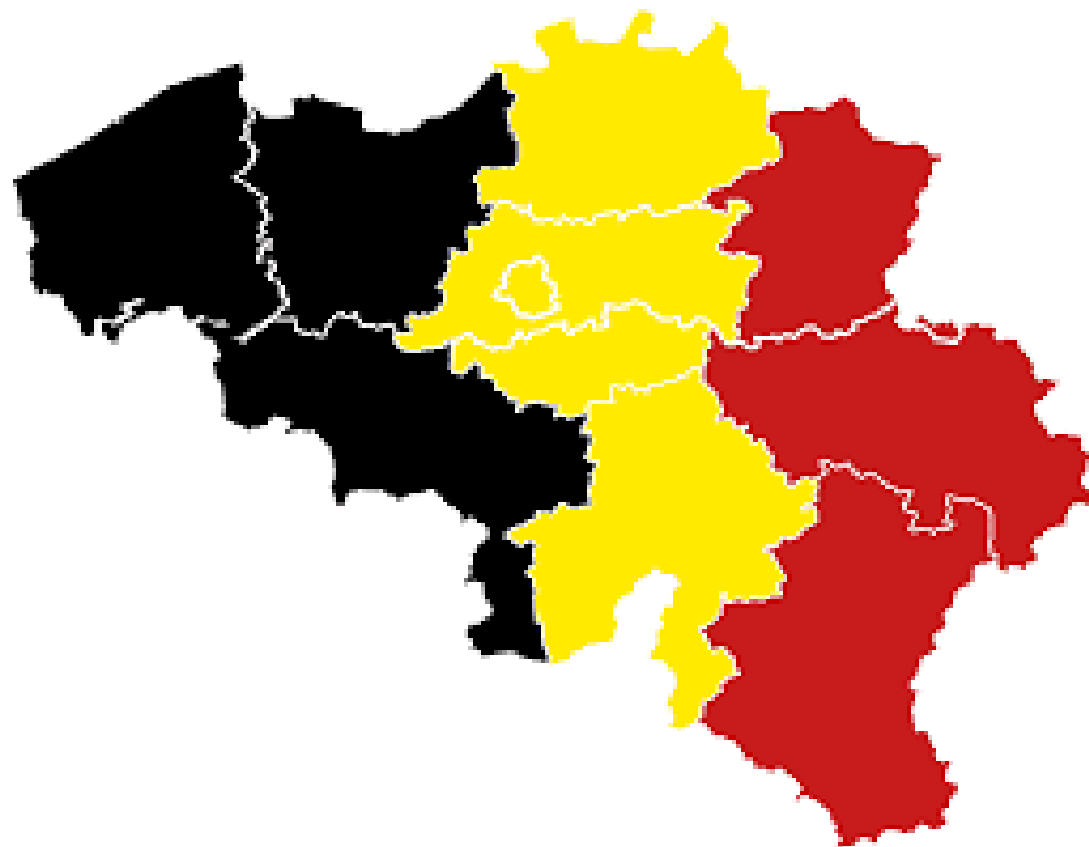
- Develop **common guidelines** on implementing the oncNGS solution in oncology practice (ISO-standardization, harmonization, formalization,....)
- Develop common protocols for **data-sharing**
- Launch **cross-border purchase** procedures
- Develop tools for interactive e-Consults (**molecular tumor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





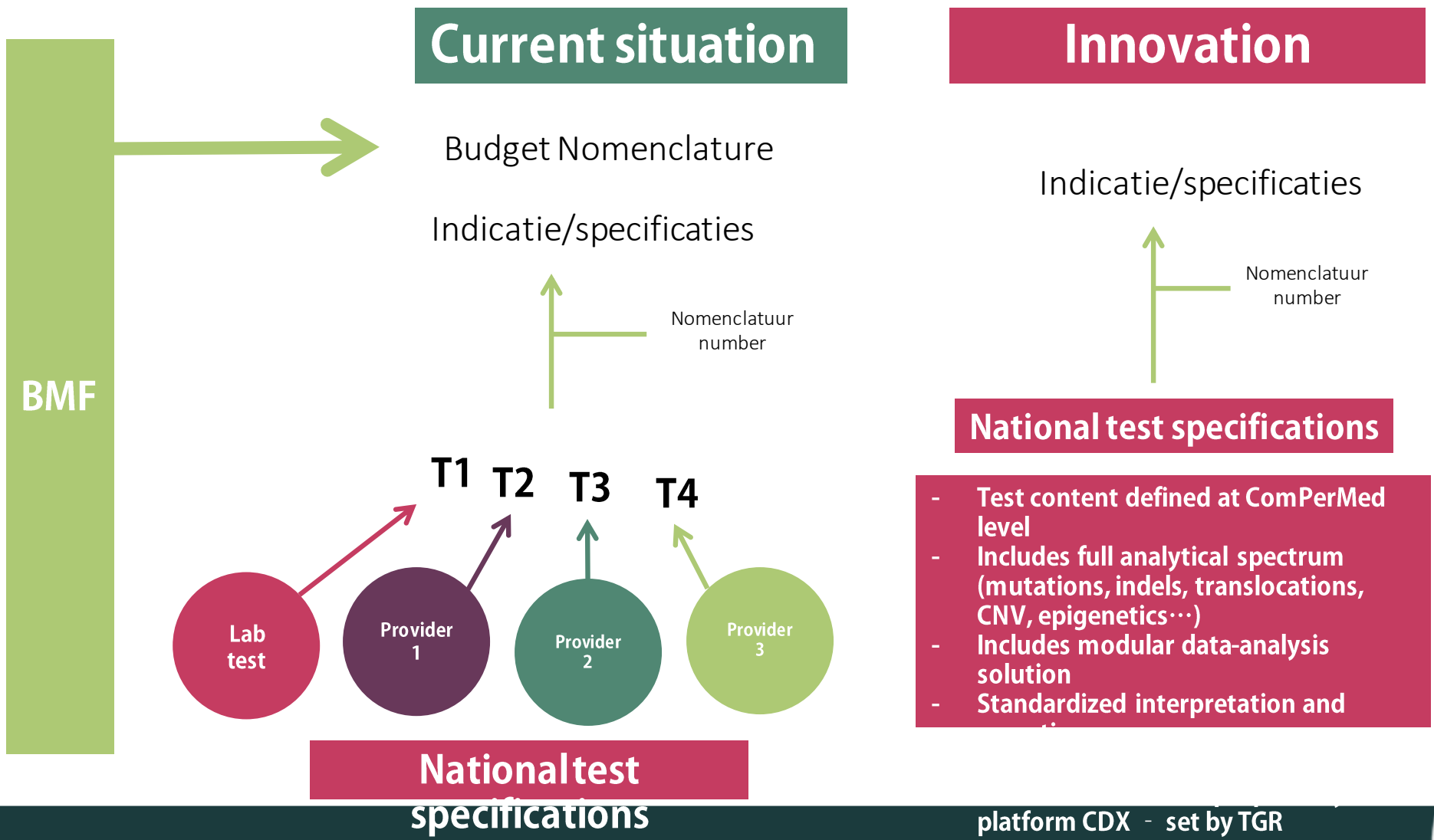
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Belgian oncNGS Landscape





RIZIV reimbursement - molecular diagnostics in Cancer





Innovative Pre-Commercial Procurement (PCP)

Indicatie/specificaties



Nomenclatuur
number

“National “Test



National test

Public Procurement

Selection of most appropriate solution at
ComPerMed /platform CDX level

Open Call to market for
propositions of solutions

- Test content defined at ComPerMed level
- Includes full analytical spectrum (mutations, indels, translocations, CNV, epigenetics...)
- Includes modular data-analysis solution
- Standardized interpretation and reporting
- Life cycle mechanism
- Max reimbursement proposal by platform CDX -



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



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**.



oncNGS: what is in for the patient?

L. Mazzearella – 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 resistance in the metastatic setting
 - Identification of actionable alterations for targeted therapy (in trials or approved)
- Non-invasiveness

Current issues that may turn into advantages

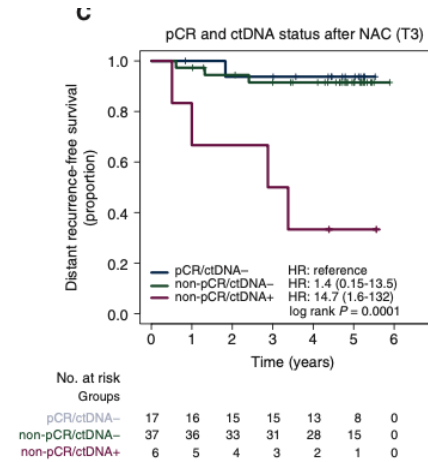
- More complex alterations to be further validated (CNV, fusions, TMB/MSI/HRD etc)
- Turnaround time
- Cost
- Equality of access
- Standardized report
- Access to biomarker-driven trials
- Privacy
- Run locally vs centrally



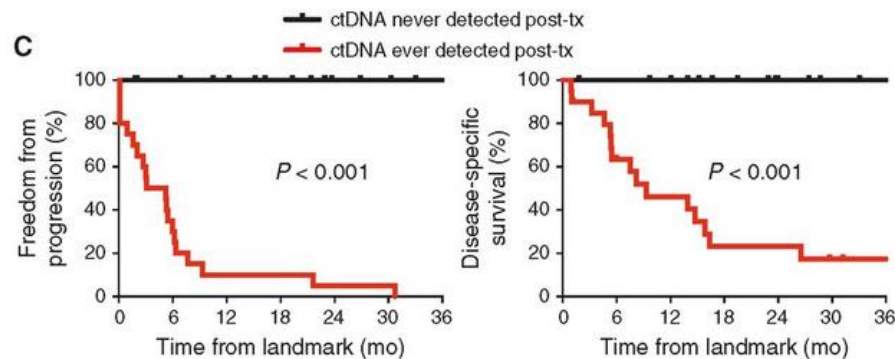
Minimal Residual Disease

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

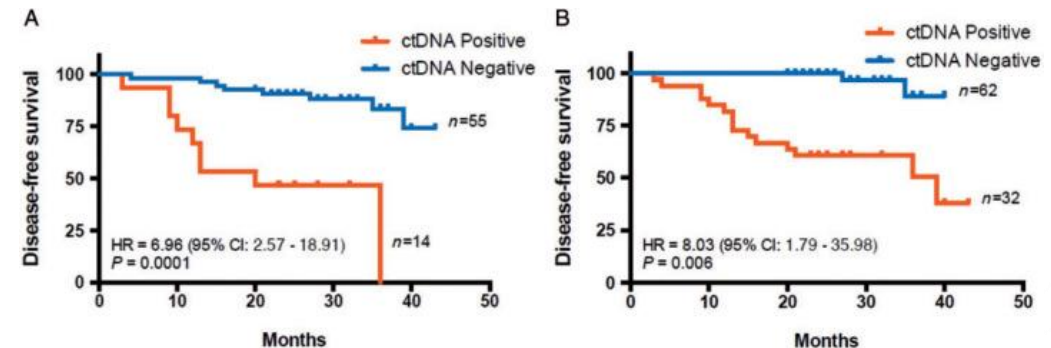
Breast (Garcia-Murillas JAMA Onc 2019)



Lung (Chaudhuri et al Canc Disc 2017)



Colorectal (Tarazona Ann Onc 2019)





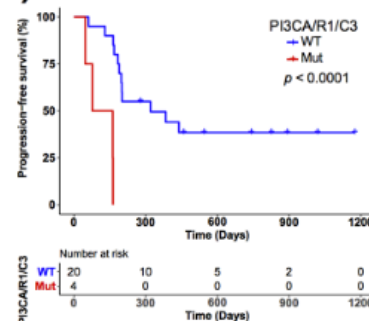
Monitoring resistance in the metastatic setting

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

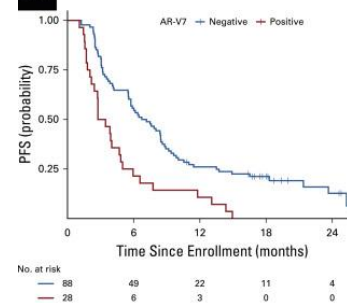
HER2+ gastric, Wang et al 2019

Prostate Arv7, Armstrong et al JCO 2019

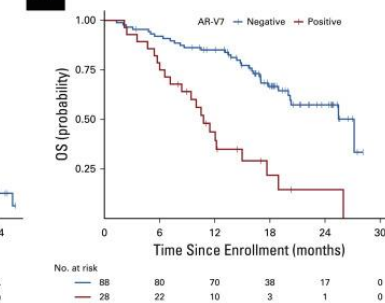
(B)



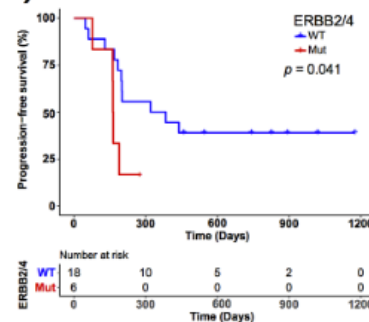
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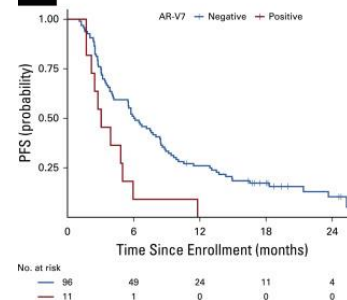
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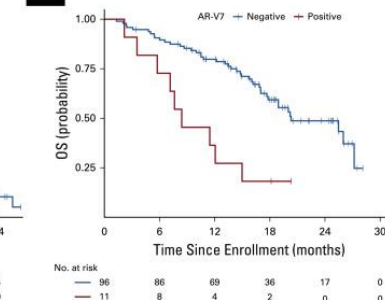
(D)



C



D





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)



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 dichotomy





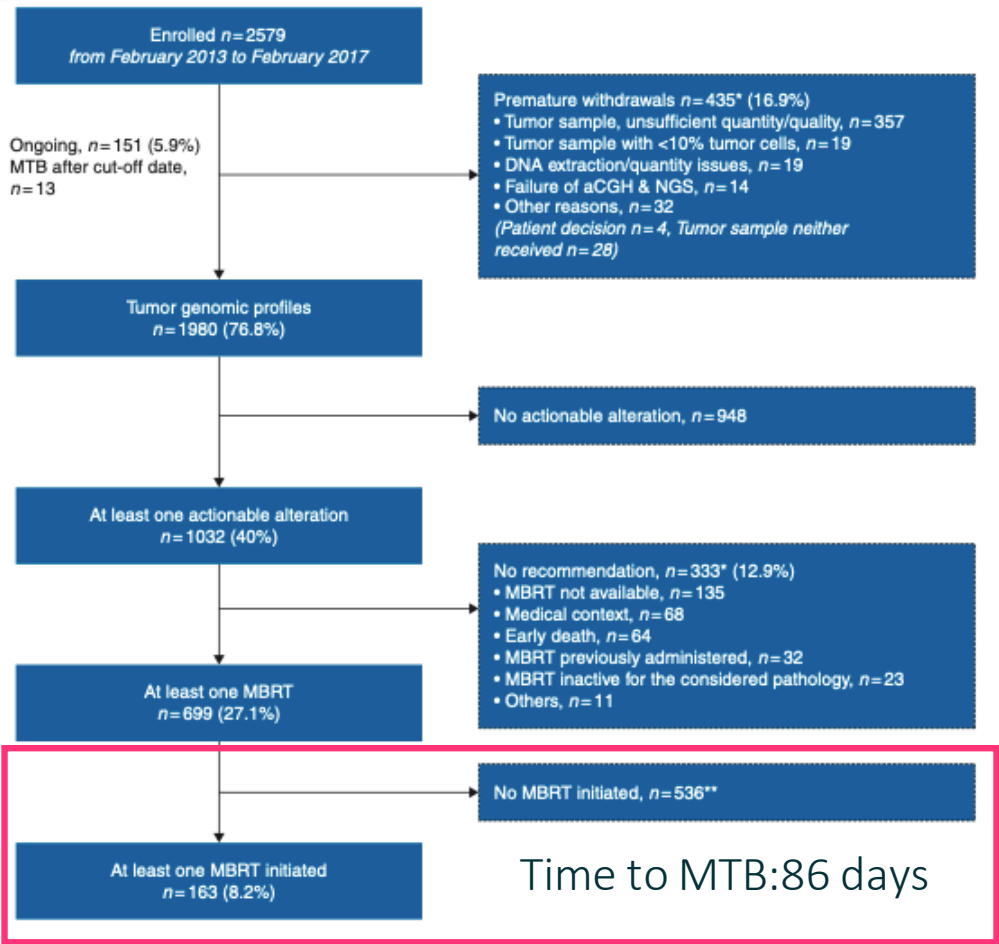
Key issue: Turnaround Time

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

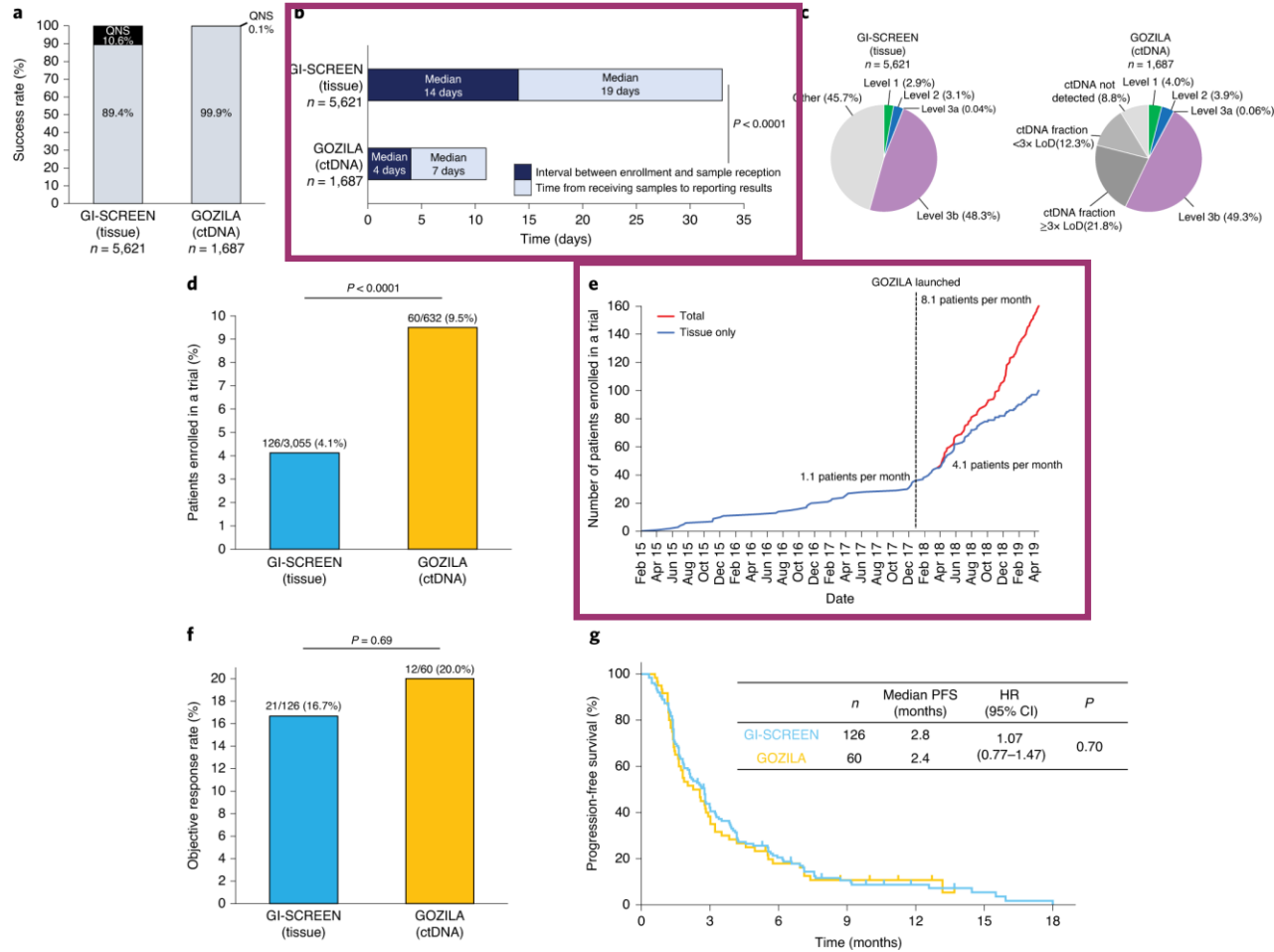
Turnaround time is a key factor for trial enrolment



Tredan et al Ann Onc 2019



Turnaround time





Key issue:Cost

Only viable if cost is kept very low

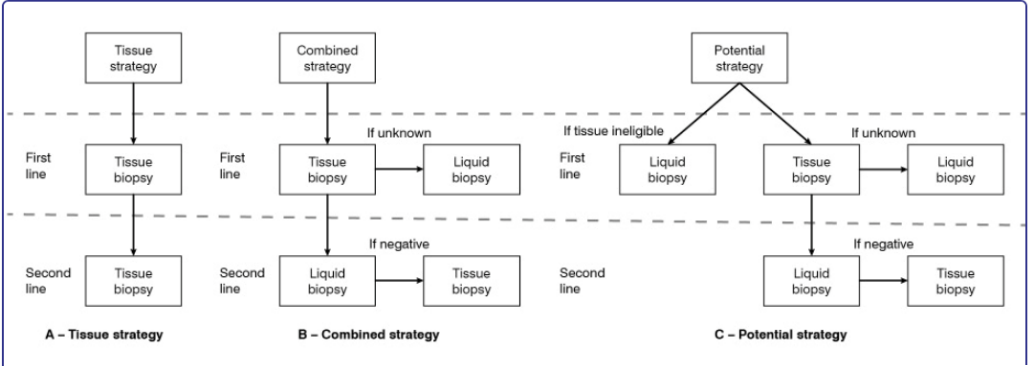


Figure 1. Diagnostic strategies compared in the analysis

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

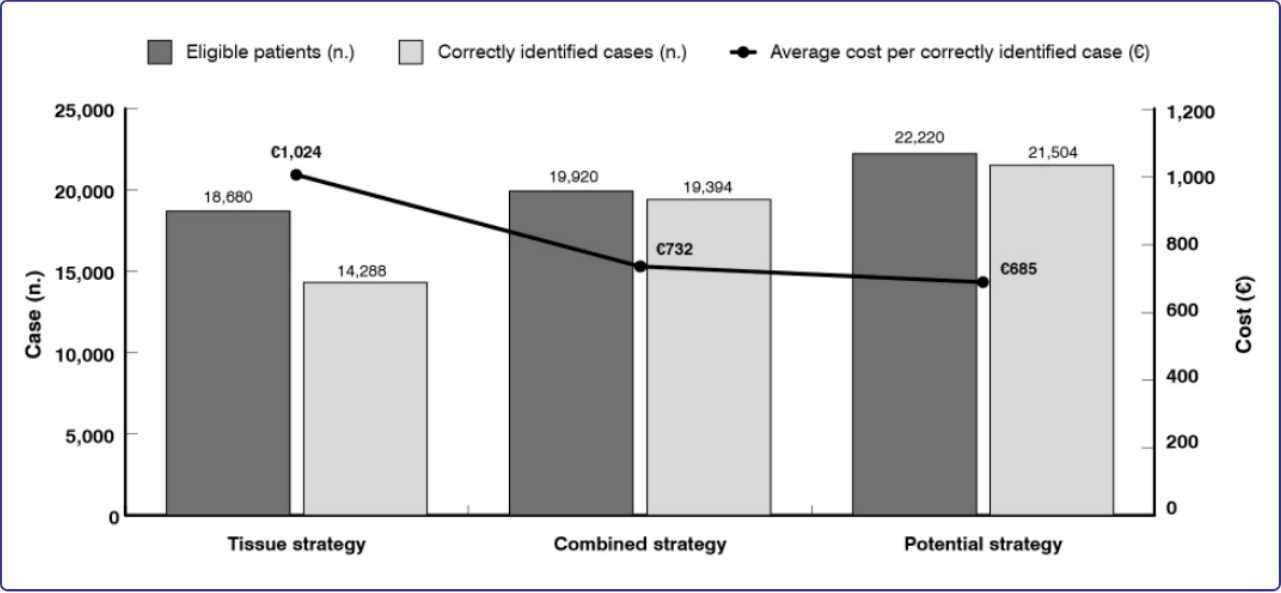


Figure 2. Results for first- and second-line treatment



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

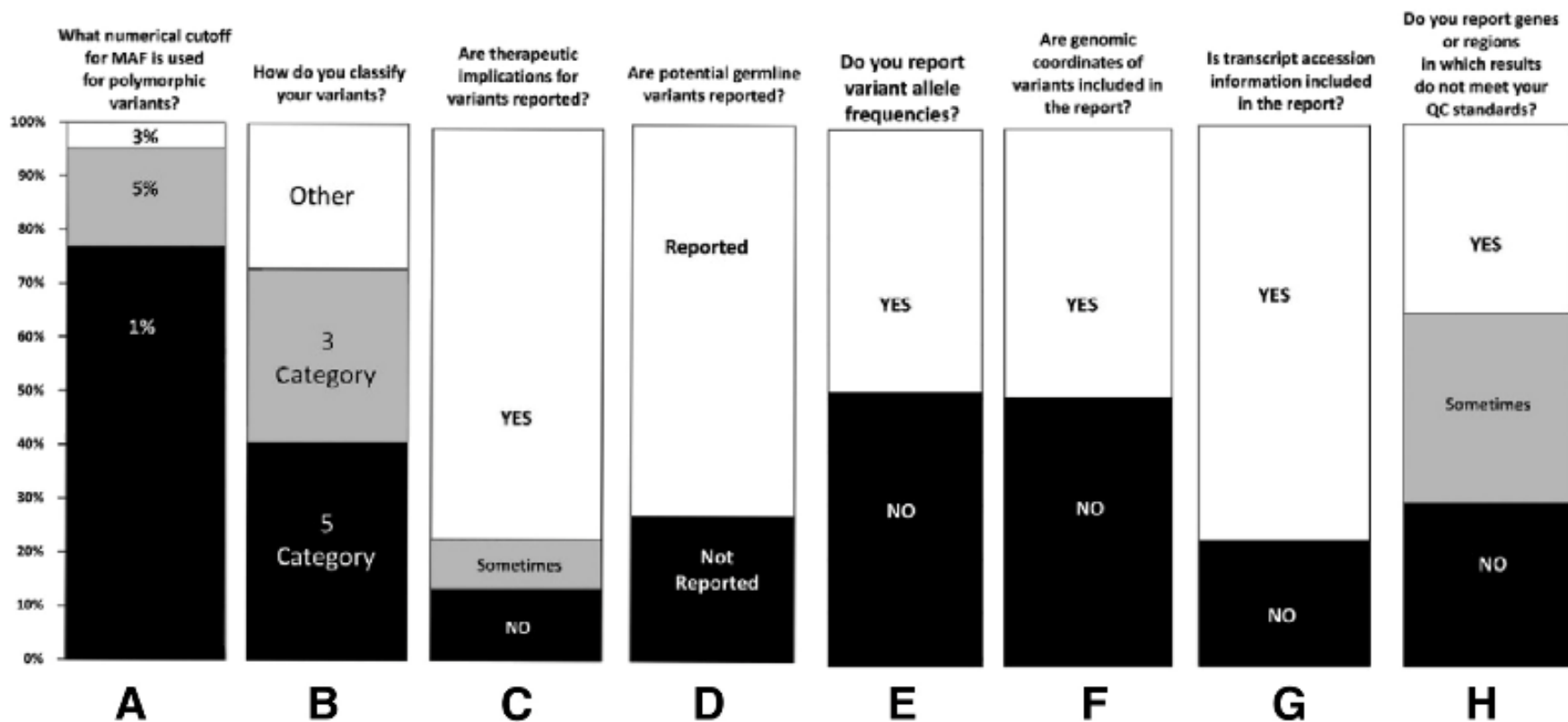
Still little research on this, but highly likely that value-based reimbursement systems will require considerable reduction in cost for high-throughput LB

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.



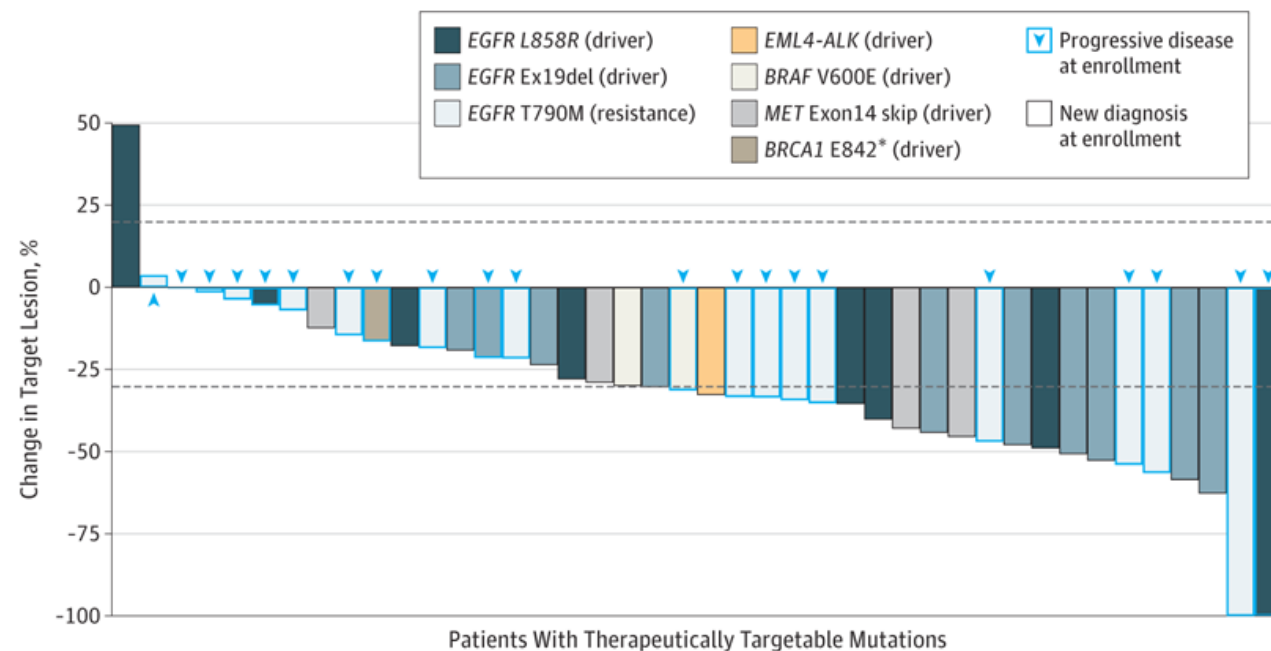
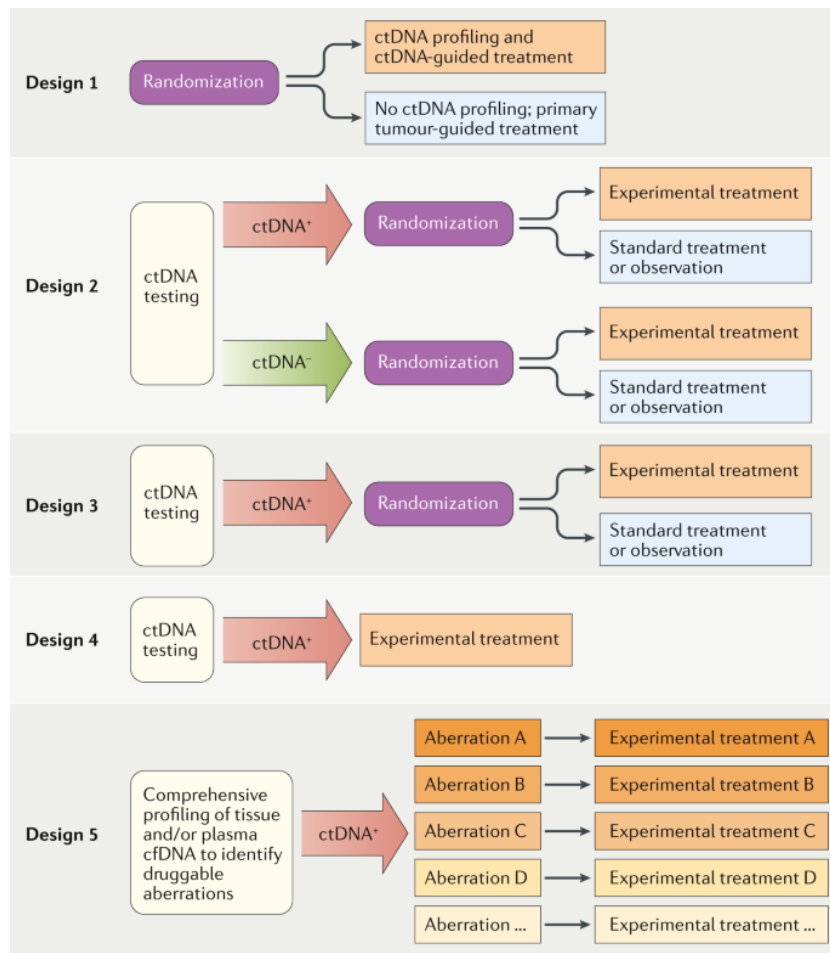
Key issue: standardized reporting

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





Key issue: access to trials





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 favored over company centralisation



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 resistance 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 target 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.





Liquid versus solid biopsies

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



Technical challenges liquid biopsies

Prenalytics: obtaining a good ctDNA

- **Sampling:**
 - blood or other fluids?
 - time of sampling
- **Prenalytical techniques:**
 - avoid WBC lysis (sampling tube, transportation, fast separation of plasma)
 - ctDNA extraction and quantification
 - conservation of ctDNA



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



R&D needs

State-of-art panel design

- Maximal informativity
- All clinically relevant targets should be assessed (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



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





Why OMC?

To cross-check before initiating the procurement:

- ✓ the desired minimum requirements for the innovative solutions and the market maturity to satisfy them
- ✓ the prior analysis and regulatory / standardization environment
- ✓ whether the assumptions of the business case are realistically achievable by the market
- ✓ the feasibility and market acceptance of the envisaged contract set-up

It provides feedback on how to raise interest from the market to answer to the upcoming call for tender and what/how many players on the market are more likely to respond





OMC Methodology

Three steps process

1. Open Events

11th May 2021 (10h-12h CEST)

12th May 2021 (16h-18h CEST)

2. Questionnaire

Published on the webpage

from May 13th 2021 - till May 20th 2021 (deadline for questionnaire completion)

3. Online meetings with each respondent to the questionnaire

From May 21st 2021

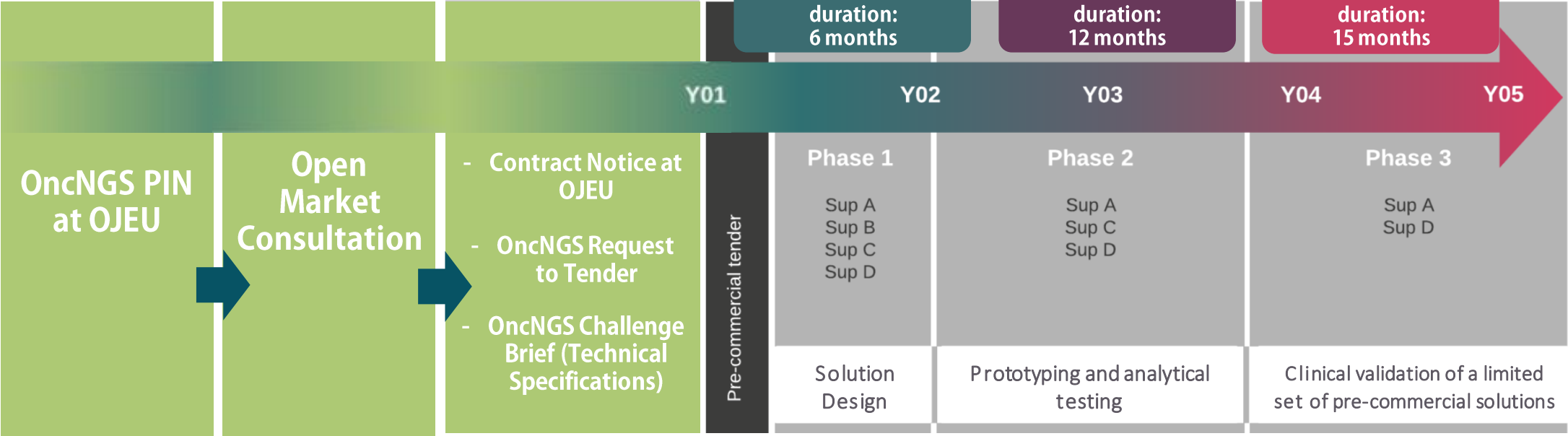
Fill –up the questionnaire and book a slot in advance!





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

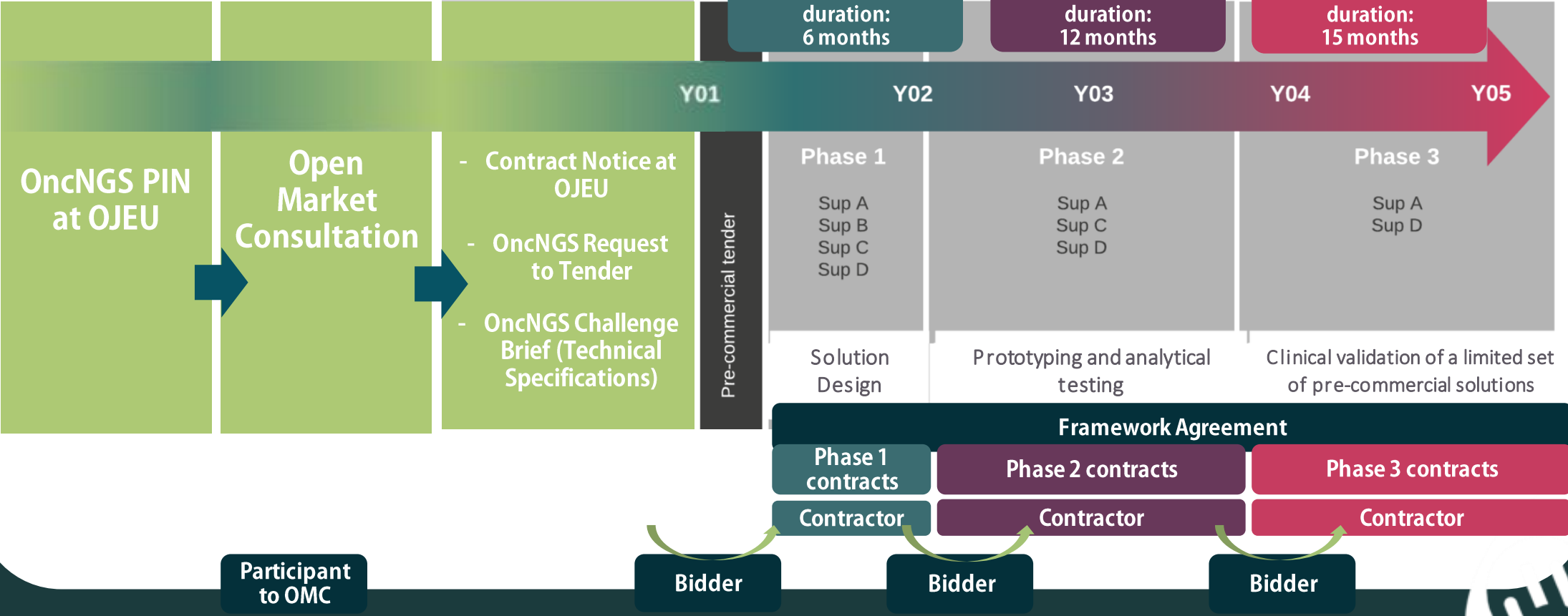
oncNGS procedure





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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.



Any mean to enquire oncNGS Buyers?

- Please submit any question/enquiry through the web page <http://oncngs.eu/index.php/contact-us/>
- Independently of the channel used to submit your question/enquiry (OMC event, OMC on line meeting, other channels) the question will be made public in an anonymized way and will be answered publicly from a **FAQs** section that will be made available at oncNGS web page





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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.





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.



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.



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.



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.)



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 will be possible but limited to a %

Place of performance:

More than 50% of the contracted R&D services are performed 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*)



POST oncNGS Procedure

