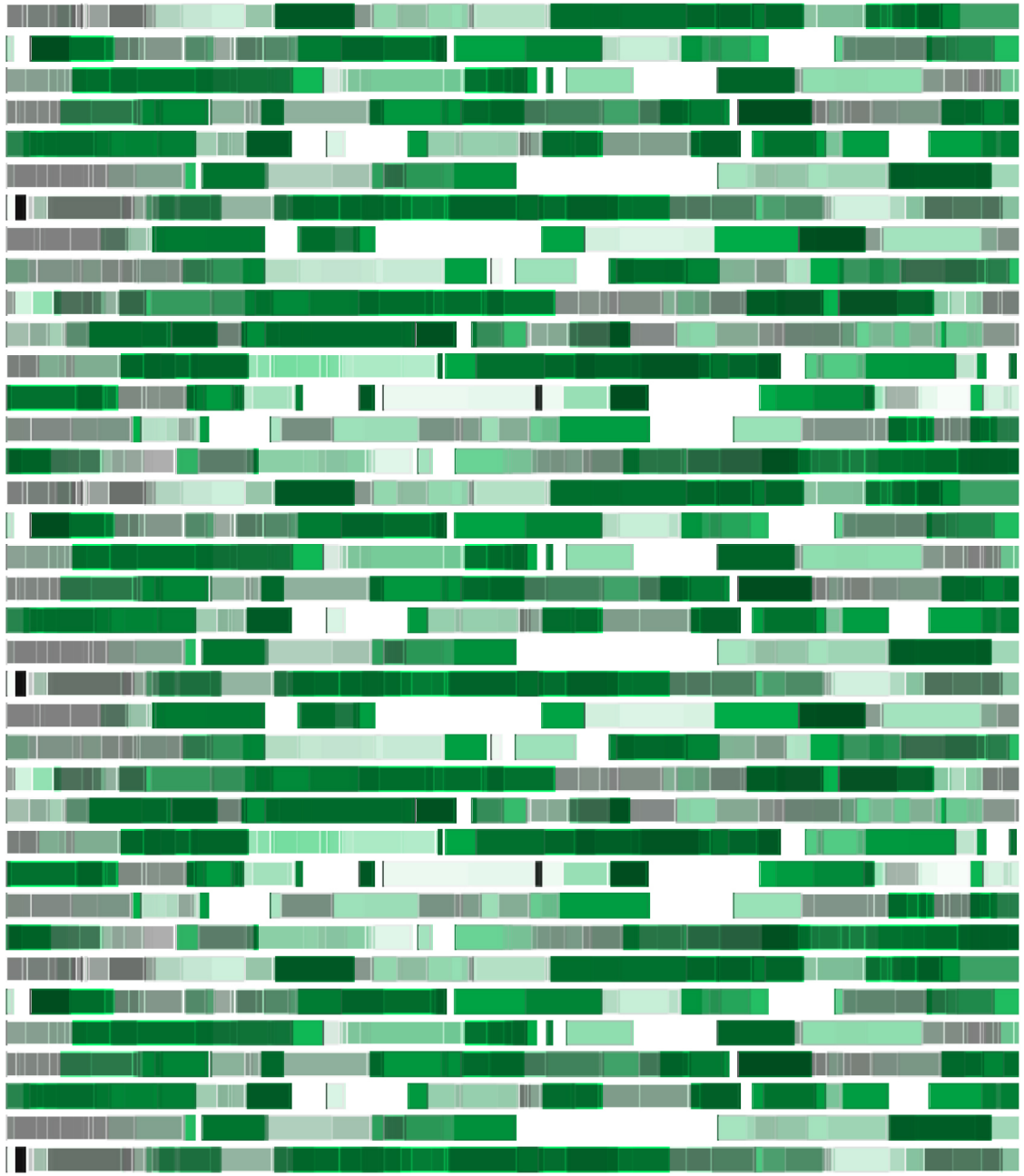
III JORNADA TRASLACIONAL DE ONCOLOGÍA DE PRECISIÓN:

A TRAVÉS DE LAS VÍAS DE SEÑALIZACIÓN

SEVILLA, 12 Y 13 DE FEBRERO DE 2026



Realidad sobre la utilización del ctDNA en la práctica clínica habitual

Beatriz Bellosillo

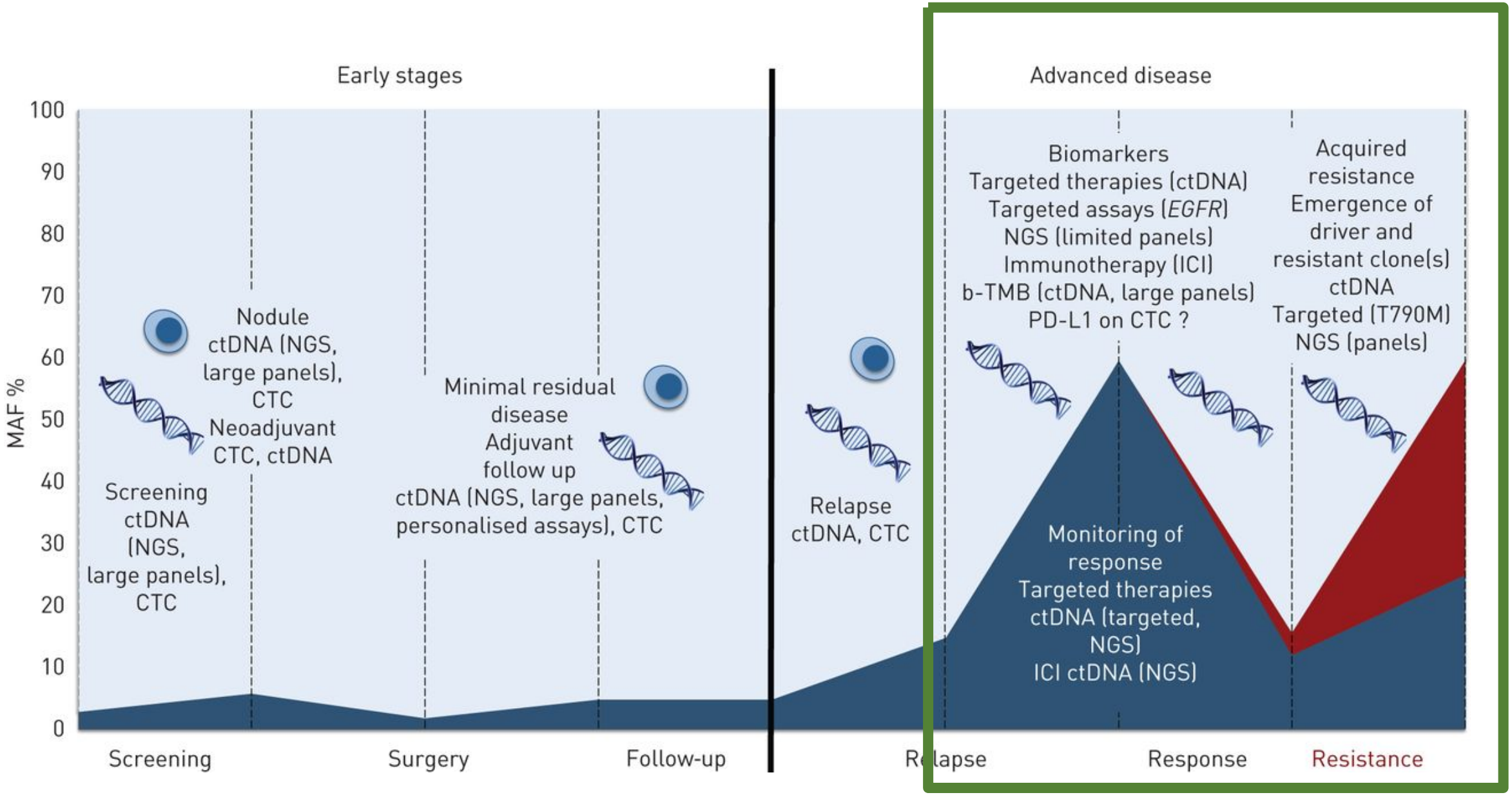
Hospital del Mar, Barcelona

Organizador por:

HENDERE HEALTHCARE

Conflicts of interest

- Speaker, Advisory Board: BMS, Incyte, Johnson&Johnson, Roche, Merck, MSD, Lilly, Astra Zeneca, Novartis, ThermoFisher, Menarini-Stemline
- Research funding: Roche, Astra Zeneca, Thermo Fisher
- Travel: Merck, BMS, Roche, Novartis, Qiagen



Guibert *et al,* 2020

ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

ANNALS OF ONCOLOGY driving innovation in oncology

SPECIAL ARTICLE

ESMO recommendations on the use of circulating tumour DNA assays for patients with cancer: a report from the ESMO Precision Medicine Working Group

J. Pascual[1], G. Attard[2], F.-C. Bidard[3,4], G. Curigliano[5,6], L. De Mattos-Arruda[7,8], M. Diehn[9], A. Italiano[10,11,12], J. Lindberg[13], J. D. Merker[14], C. Montagut[15], N. Normanno[16], K. Pantel[17], G. Pentheroudakis[18], S. Popat[19,20], J. S. Reis-Filho[21], J. Tie[22,23], J. Seoane[24,25], N. Tarazona[26,27], T. Yoshino[28] & N. C. Turner[19,20*]

ctDNA testing if tissue not available.

Non-small cell lung cancer	Ovarian cancer
Gastric cancer	Endometrial cancer
Pancreatic cancer	Prostate cancer
Hepatocellular cancer	Urothelial cancer
Cholangiocarcinoma	Thyroid cancer
Colorectal cancer	Soft tissue sarcoma

Pascual J et al, Ann Oncol 2022

Tumour type	Indications	ESCAT tier and level of evidence	Recommendation
Non-small-cell lung cancer	*EGFR* (for common, uncommon, exon 20 insertions, T790M and other resistance mutations e.g. C797X).	IA[120]	ctDNA genotyping recommended in treatment-naive cancer patients and resistance upon prior TKIs. Caution should be kept as ctDNA assays will miss histological trans-differentiation. ctDNA testing may not have adequate sensitivity to detect *MET* true high copy number gain as resistance mechanism to osimertinib or lorlatinib. Amplification and fusion detection is suboptimal with ctDNA assays, and should be repeated in tissue where possible.
	ALK (for fusions and acquired resistance kinase domain mutations).	IA[121-125]	
	MET (for exon 14 splice site mutations, and acquired resistance mutations)	IB[126,127]	
	KRAS (for G12C and non-tier 1 other *KRAS* mutations)	IB[128]	
	BRAF (for V600E)	IB[129,130]	
	RET (for fusions and acquired resistance kinase domain mutations)	IB[131]	
	ROS1 (for fusions and acquired resistance kinase domain mutations)	IB[132,133]	
	NTRK 1/2/3 (for fusions and acquired resistance mutations)	IC[134]	
	MET (for high-level copy number gain/amplification)	IIA[135]	
	ERBB2 (for exon 20 insertions and transmembrane mutations, and amplification)	IIB[136-138]	
	BRAF (for non-V600E class I-III mutations)	IIB[139]	
Breast cancer	*PIK3CA* mutations	IA[140]	*ESR1* mutations should preferentially be tested in ctDNA. *ERBB2* amplification and *NTRK* fusions only when advanced tissue biopsy not available.
	ERBB2 amplification	IA[141,142]	
	*BRCA*1/2 mutations	IA[143,144]	
	ESR1 mutations	IB[145,146]	
	MSI-H	IC[147]	
	NTRK 1/2/3 fusions	IC[134]	
Gastric cancer	*ERBB2* amplification	IA[148]	ctDNA testing if tissue not available or when fast turnaround time is needed for urgent therapeutic decision making.
	MSI-H	IC[147]	
	NTRK 1/2/3 fusions	IC[134]	
Pancreatic cancer	*NTRK* 1/2/3 fusions	IC[134]	ctDNA testing if tissue not available.
	MSI-H	IC[147]	
Hepatocellular cancer	MSI-H	IC[147]	ctDNA testing if tissue not available.
	NTRK 1/2/3 fusions	IC[134]	
Cholangiocarcinoma	*IDH1* mutations	IA[149]	ctDNA testing if tissue not available or when fast turnaround time is needed for urgent therapeutic decision making.
	FGFR2 fusions	IA[150]	
	MSI-H	IC[147]	
	NTRK 1/2/3 fusions	IC[134]	
Colorectal cancer	*BRAF* (for V600E mutation)	IA[151]	*KRAS/NRAS/BRAF*^{V600E}/MSI for chemotherapy-naive metastatic colorectal cancer is recommended when tissue testing is not feasible or urgent therapeutic decision making. *KRAS/NRAS/BRAF/EGFR*-ECD for pretreated patients if EGFR rechallenge is planned.
	MSI-H	IA[147,152]	
	NTRK 1/2/3 fusions	IC[134]	
	KRAS/NRAS mutations (exon 2,3,4)	N/A (resistance biomarker)	
	ERBB2 amplification	IB[57,153,154]	
	EGFR-ECD (for mutations in the extracellular domain S492, G465, S464, V441)	IB[73]	
Ovarian cancer	*BRCA*1/2 mutations	IA[155]	In women with no germline pathogenic *BRCA1/2* variant found, testing for *BRCA1/2* pathogenic or likely pathogenic somatic variants may be carried out if tissue not available.
	MSI-H	IC[147]	
Endometrial cancer	MSI-H	IC[147]	ctDNA testing if tissue not available.
Prostate cancer	*BRCA*1/2 mutations	IA[156]	*BRCA1/BRCA2/ATM* for potential PARPi therapy. Caution is needed when interpreting results of ctDNA assays due to false-positive CHIP mutations in DNA repair genes.
	MSI-H	IC[147]	
	ATM mutations	IIA[156]	
	PTEN mutations/deletions	IIA[157]	
	PALB2 mutations	IIB[156,158]	
Urothelial cancers	*FGFR* mutations	IB[159]	ctDNA testing if tissue not available.
	FGFR3 (FGFR3-TACC3) fusions	IB[159]	
	NTRK 1/2/3 fusions	IC[134]	
Thyroid cancer	*BRAF* mutations	IB[160,161]	ctDNA testing if tissue not available.
	RET mutations	IB[162,163]	
	NTRK 1/2/3 fusions	IC[134]	
Soft tissue sarcoma	*NTRK* 1/2/3 fusions	IC[134]	ctDNA testing if tissue not available.

ESCAT tier I refers to evidence for tissue target-drug match resulting in improvement of meaningful clinical outcomes (synonymous to clinical utility). ESCAT tier II refers to investigational targets that likely define a patient population that benefits from a targeted drug, but additional data are needed. Readers are directed to individual ESMO practice guidelines for detailed discussion of individual tumour types.

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Colorectal cancer	*BRAF* (for V600E mutation)	IA[147,148]	*KRAS/NRAS/BRAF* (all exons) MSI-H for chemotherapy naive metastatic colorectal cancer is recommended when tissue testing is not feasible or urgent therapeutic decision making. *KRAS/NRAS/BRAF/EGFR*-ECD for pretreated patients if EGFR rechallenge is planned.
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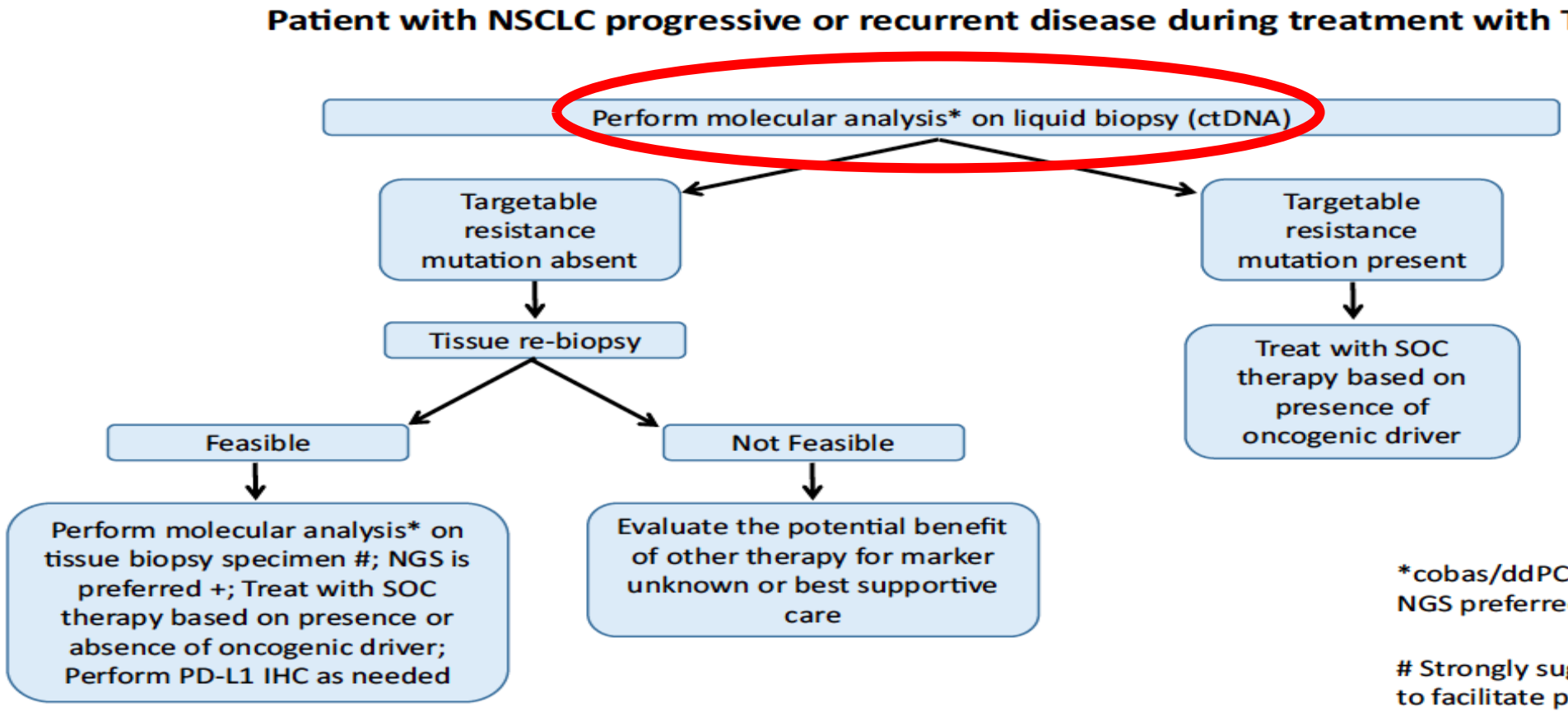
Liquid Biopsy for Advanced Non-Small Cell Lung Cancer (NSCLC): A Statement Paper from the IASLC



Rolfo *et al,* J Thor Oncol 2018

GOBIERNO DE ESPAÑA · MINISTERIO DE SANIDAD

Catálogo de Pruebas Genéticas y Genómicas

Acceso Administrador

Consulta de Información · Biblioteca · Mapa CGEN · Manual de Usuario

Inicio / Búsqueda Avanzada

Búsqueda Avanzada

Área

× Oncohematología de adultos

Grupo de Patologías

× Tumores sólidos

Patología

Seleccionar

Código CIE-10-ES Diagnósticos

Seleccionar

Código ORPHA

Seleccionar

Utilidad Clínica

Seleccionar

Tipo de Estudio Genético

Seleccionar

Tipo de Muestra

× Biopsia Líquida/Plasma (ácidos nucleicos libres circulantes)

Tipo de Alteración

Seleccionar

Tipo de Técnica a Utilizar

Seleccionar

Tratamiento Farmacológico Asociado ⓘ

Seleccionar

Estado

Seleccionar

Genes o Regiones a Estudiar

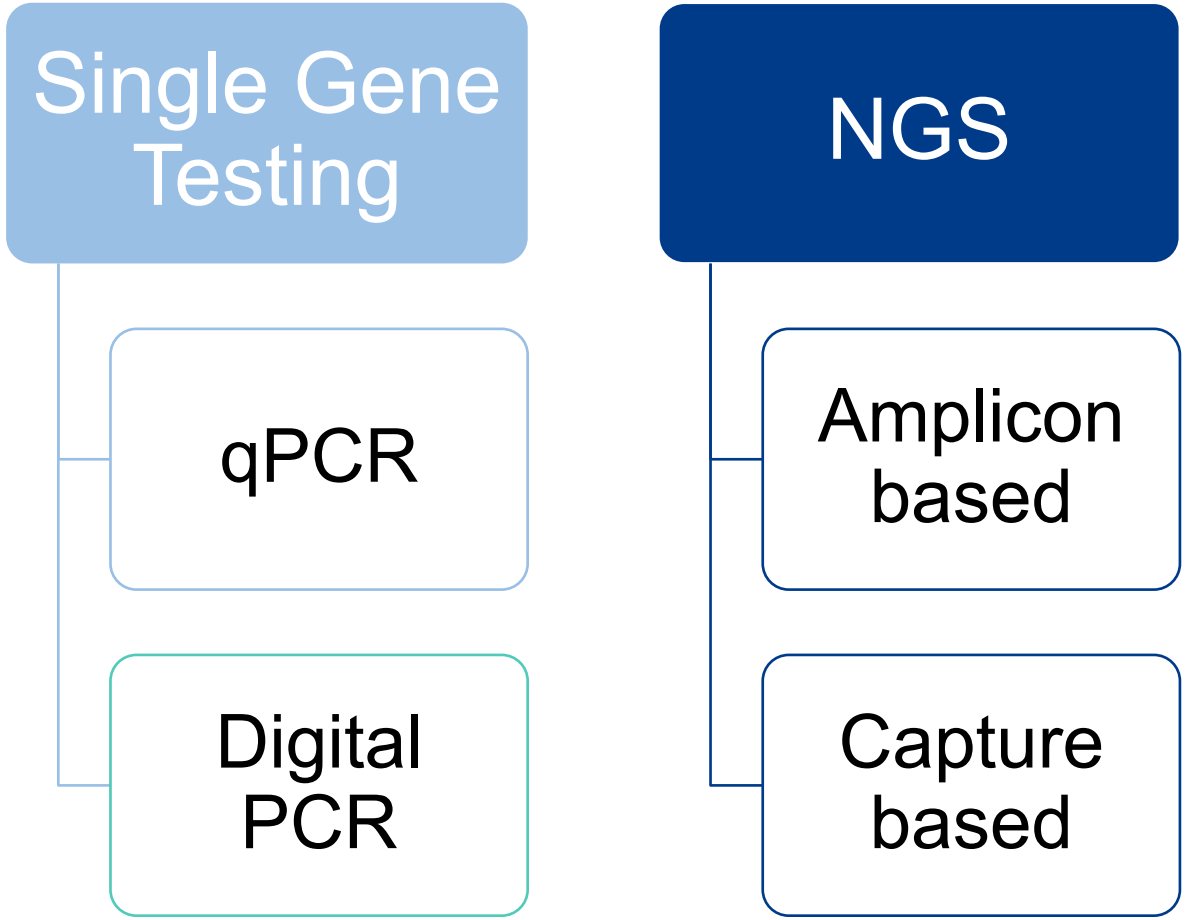
Introduzca los genes o regiones a buscar, separados por comas

Incorporación de las determinaciones en biopsia líquida en el Catálogo de Pruebas Genéticas y Genómicas

Catálogo Genético

Acciones	Estado	Área	Grupo de Patologías	Patología	Código CIE-10-ES Diagnó	Genes o Regiones a Estudiar	Tratamiento Farmacológico Asociado ⓘ	Fecha Ult. Revisión
ⓘ	ACTIVO	Oncohematología de adultos	Tumores sólidos	Cáncer de mama	C50	*ESR1*	Ver Información ⌄	11/10/2024
ⓘ	ACTIVO	Oncohematología de adultos	Tumores sólidos	Cáncer de pulmón	C34	*RET*	Inhibidor selectivo de tirosina quinasa de RET	11/10/2024
ⓘ	ACTIVO	Oncohematología de adultos	Tumores sólidos	Cáncer de pulmón	C34	*NTRK1, NTRK2, NTRK3*	Inhibidor selectivo de tirosina quinasa de NTRK	11/10/2024
ⓘ	ACTIVO	Oncohematología de adultos	Tumores sólidos	Cáncer de pulmón	C34	*MET exon 14*	Inhibidor selectivo de tirosina quinasa de MET	11/10/2024
ⓘ	ACTIVO	Oncohematología de adultos	Tumores sólidos	Cáncer de pulmón	C34	*ALK*	Inhibidor selectivo de tirosina quinasa de ALK	11/10/2024
ⓘ	ACTIVO	Oncohematología de adultos	Tumores sólidos	Cáncer de pulmón	C34	*EGFR*	Inhibidor selectivo de tirosina quinasa de EGFR	11/10/2024
ⓘ	ACTIVO	Oncohematología de adultos	Tumores sólidos	Cáncer de pulmón	C34	*KRAS G12C*	Inhibidor selectivo de tirosina quinasa de KRASG12C	11/10/2024
ⓘ	ACTIVO	Oncohematología de adultos	Tumores sólidos	Cáncer de pulmón	C34	*ROS1*	Inhibidor selectivo de tirosina quinasa de ROS1	11/10/2024
ⓘ	ACTIVO	Oncohematología de adultos	Tumores sólidos	Cáncer de pulmón	C34	EGFR inserciones exón 20	Anticuerpo bi-específico dirigido contra EGFR/MET	11/10/2024
ⓘ	ACTIVO	Oncohematología de adultos	Tumores sólidos	Cáncer de pulmón	C34	*BRAF*	Ver Información ⌄	11/10/2024

Molecular testing : single gene or NGS



Several liquid biopsy-based technologies are approved by the FDA and backed by major guidelines

March 2016

OncoBEAM™ RAS CRC Kit (CE marked EMA): CRC patients[1]

June 2016

cobas® *EGFR* Mutation Test v2: NSCLC patients for erlotinib treatment[2]

November 2017

NCCN guidelines state: *"Physicians may use a cell-free plasma DNA assay to identify EGFR mutations when tissue is limited or insufficient"*[3]

November 2017

Idylla™ ct*KRAS* and ct*NRAS-BRAF* Mutation Tests (CE marked EMA): CRC patients[4]

May 2018

IASCL release a position statement: "*Liquid biopsy can be considered at the time of initial diagnosis in all patients who need tumor molecular profiling*"[5]

May 2019

therascreen® *P1K3CA* RGQ PCR kit companion diagnostic test: Breast cancer for PI3K inhibitor treatment[6]

August 2020

Switch to NGS-based liquid biopsy approvals

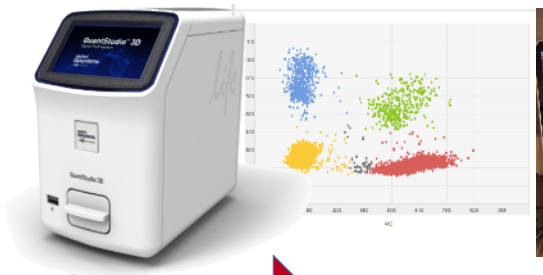
Guardant360 CDx: First liquid-based panel NGS companion diagnostic test[7]

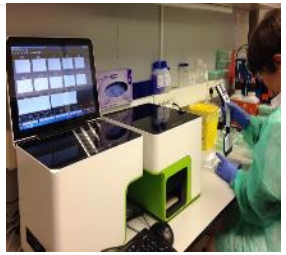
FoundationOne Liquid CDx: Liquid-based, broad-panel NGS companion diagnostic test[8]

CE: Conformité Européenne; CRC: colorectal cancer; EMA: European Medicines Agency; FDA: U.S. Food and Drug Administration; IASLC: International Association for the Study of Lung Cancer; NCCN: National Comprehensive Cancer Network; NGS: next-generation sequencing; NSCLC: non-small cell lung cancer.

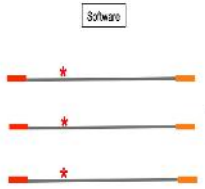
1. GMP News (2019) Available at: https://gmpnews.net/2019/08/sysmex-obtained-japanese-approval-for-oncobeam-ras-crc-kit/ (Accessed February 2020); 2. FDA press release (2016) Available at: https://www.fda.gov/drugs/resources-information-approved-drugs/cobas-egfr-mutation-test-v2 (Accessed February 2020); 3. NCCN NSCLC Guidelines V4.2017; 4. Genome Web (2017) Available at: https://www.genomeweb.com/pcr/biocartis-gets-ce-marking-two-colorectal-cancer-liquid-biopsy-tests#.XkrHImhKi70 (Accessed February 2020); 5. Rolfo, C., et al. (2018) *J Thorac Oncol* 13(9):1248-1268; 6. FDA press release (2020) Available at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-pi3k-inhibitor-breast-cancer (Accessed February 2020); 7. FDA website (2020) Available at: https://www.fda.gov/news-events/press-announcements/fda-approves-first-liquid-biopsy-next-generation-sequencing-companion-diagnostic-test (Accessed February 2021); 8. FMI website (2020) Available at: https://www.foundationmedicine.com/press-releases/445c1f9e-6cbb-488b-84ad-5f133612b721 (Accessed February 2021).

Hospital del Mar experience with NGS and liquid biopsy





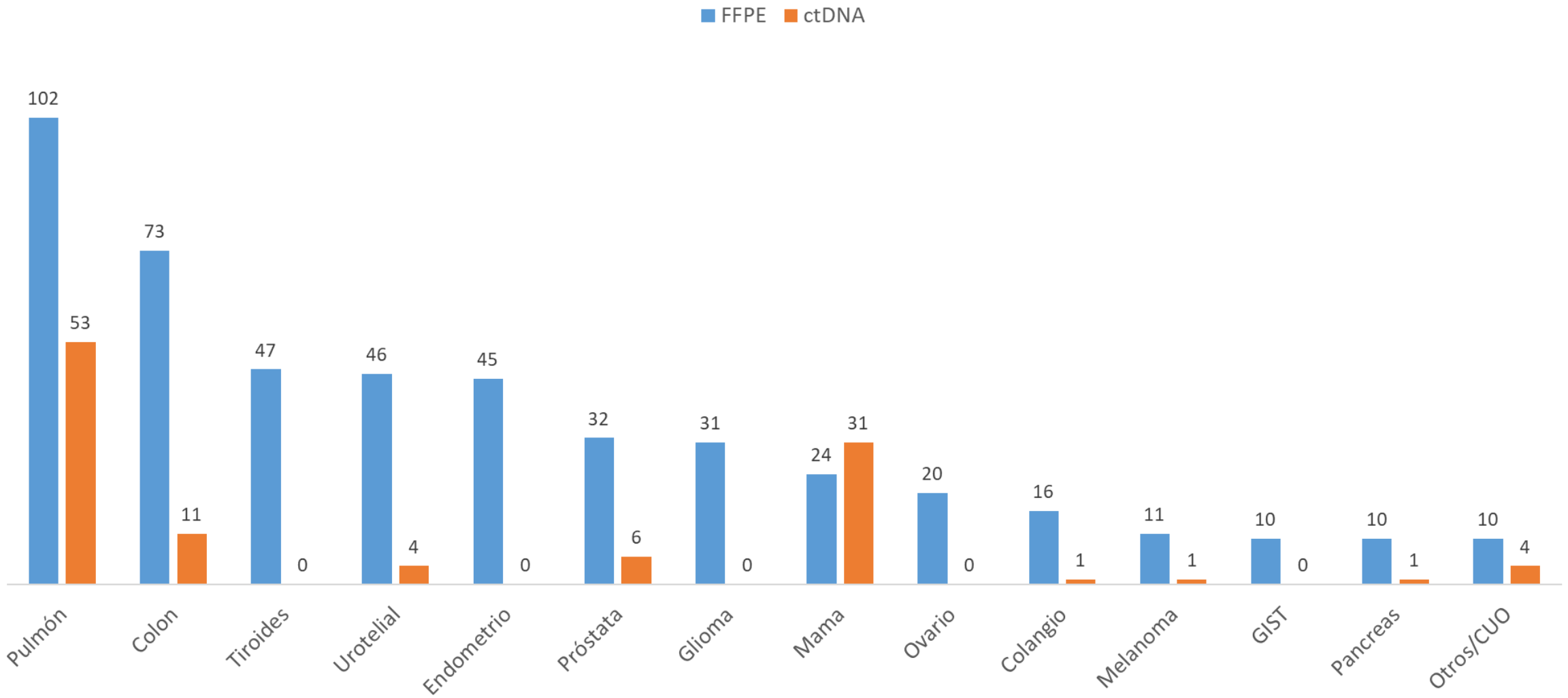
2012 2013 2015 2016



2011 2014 2015 2016 2018 2021

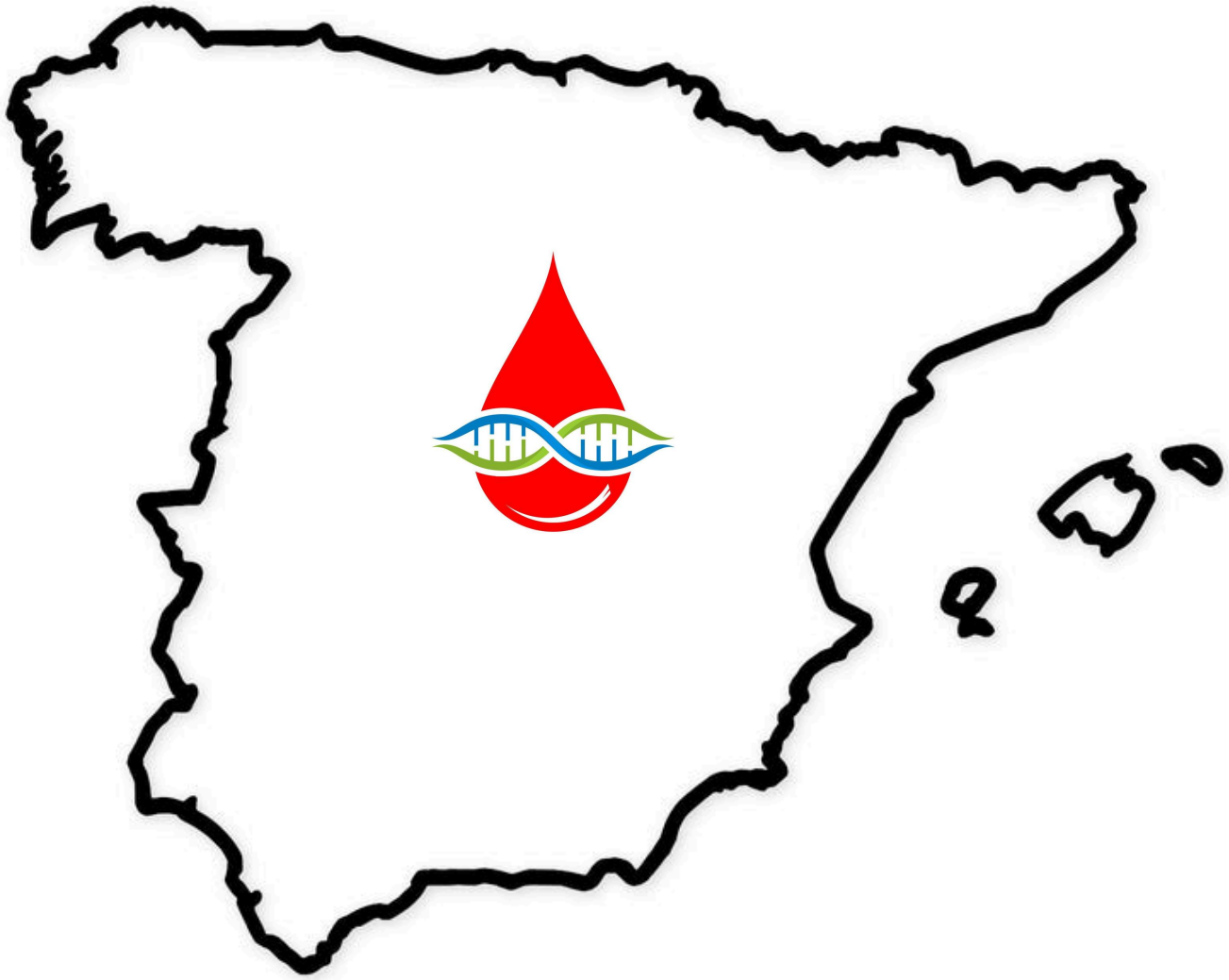
Pyrosequencing | Fluorophore-SBS NGS | Ion semiconductor-SBS NGS (Amplicons) | Integrated sequencer

Hospital del Mar - molecular testing activity (2024)

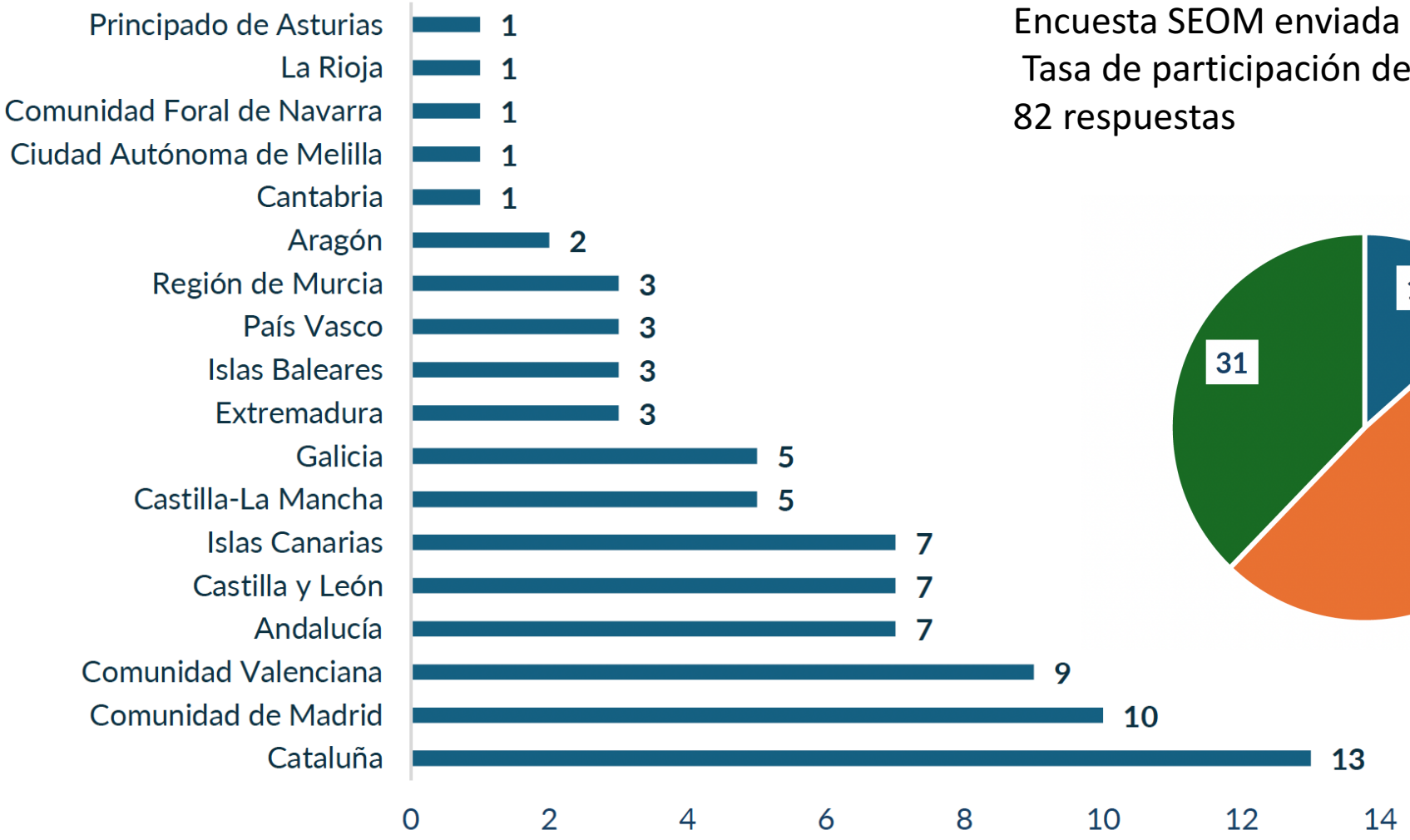


Infografía del Laboratorio de Diagnóstico Molecular,
Dr. Sergi Clavé

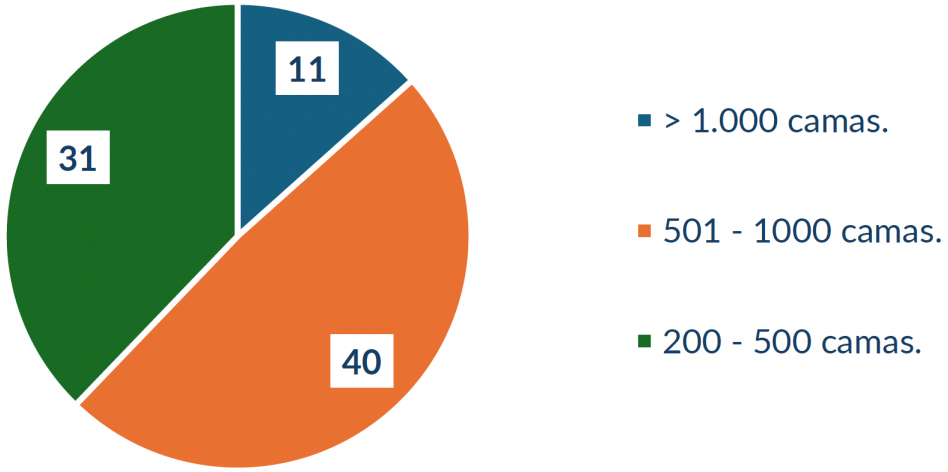
¿Cuál es la situación en España?



Estudio SEOM 2025
Implantación y regulación de la Oncología de Precisión en España

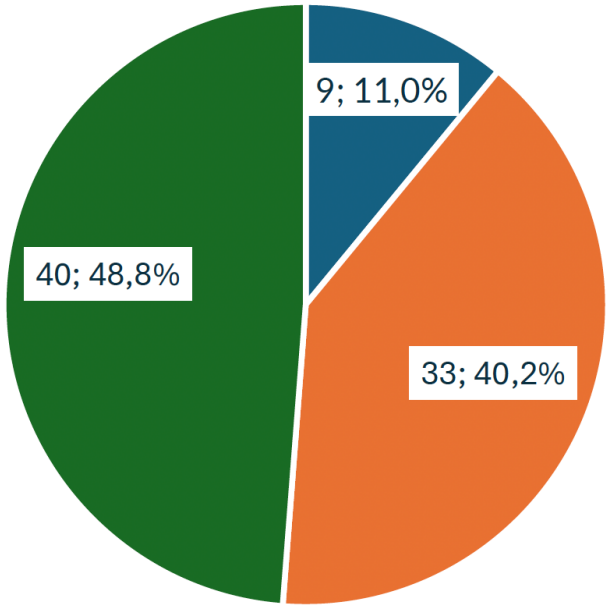


Encuesta SEOM enviada a Servicios Oncología Médica
Tasa de participación del 58, 6%
82 respuestas

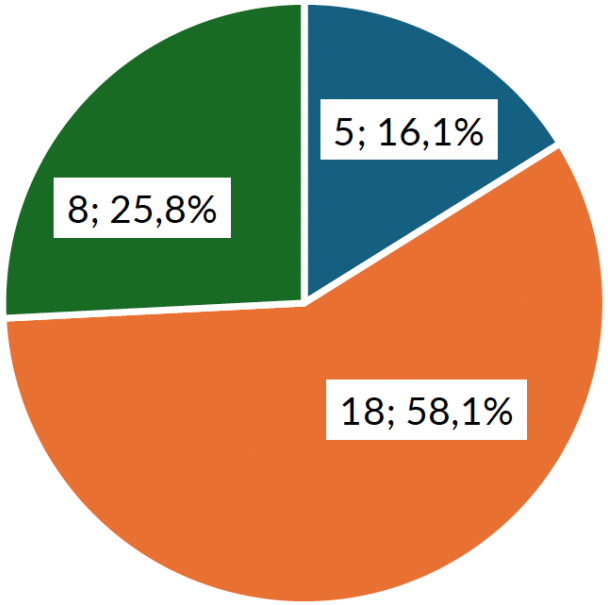


Estudio SEOM 2025
Grado de implementación de las pruebas genéticas y genómicas del Catálogo Común del SNS

Global

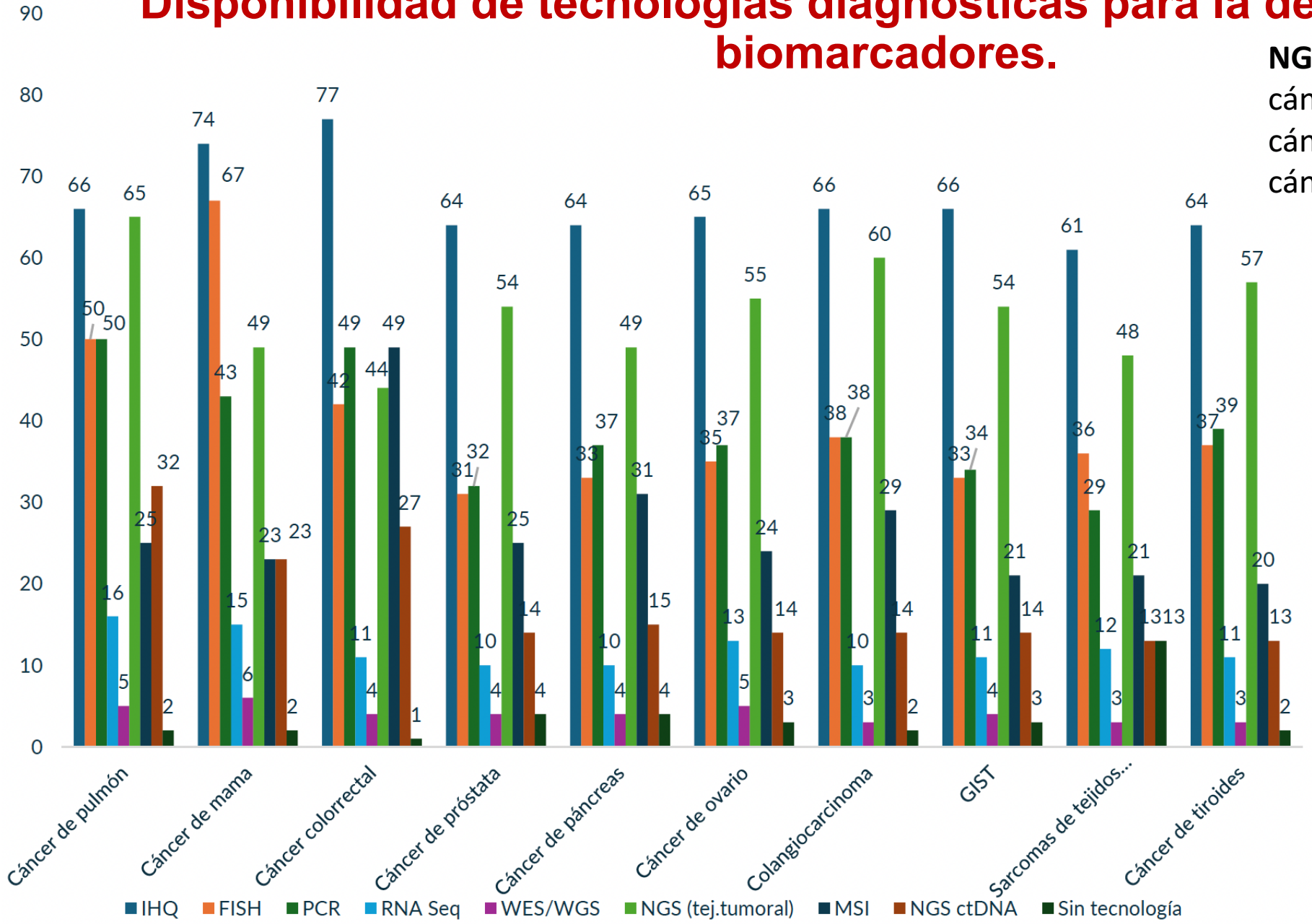


Hospitales de menor tamaño



- En proceso de implementación. Se están incorporando progresivamente, pero aún no están disponibles para todos los pacientes que lo requieren.
- Parcialmente implementadas. Solo se utilizan para algunos tipos de cáncer o en soluciones específicas.
- Totalmente implementadas. Se solicitan y utilizan de forma rutinaria en la práctica clínica.

Estudio SEOM 2025
Disponibilidad de tecnologías diagnósticas para la determinación de biomarcadores.

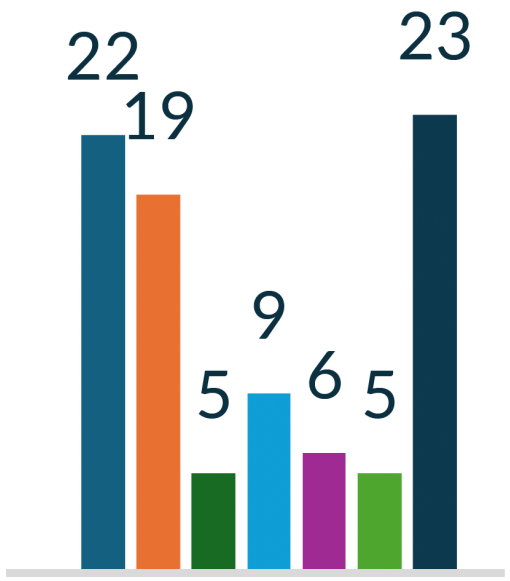


NGS (ctDNA),
cáncer de pulmón : 32 centros
cáncer colorrectal: 27 centros
cáncer de mama: 23 centros

Se observa una tendencia creciente aunque todavía en fase de expansión

Estudio SEOM 2025
Disponibilidad de tecnologías diagnósticas para la determinación de biomarcadores.

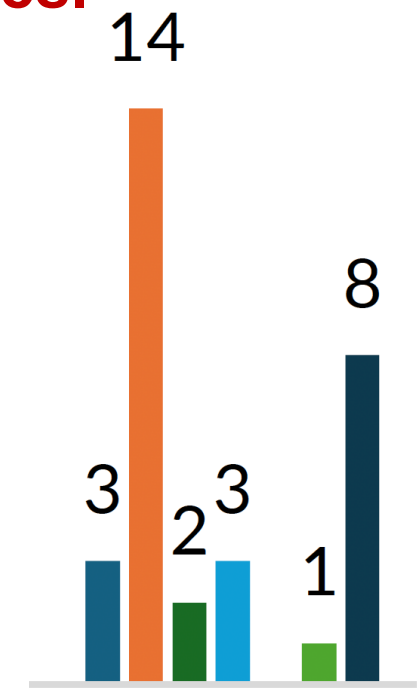
Global



NGS (panel) ctDNA

- Lab. Hospital
- Lab. Otra CCAA
- Lab. Privado . Financ. Externa
- No se dispone de esta tecnología

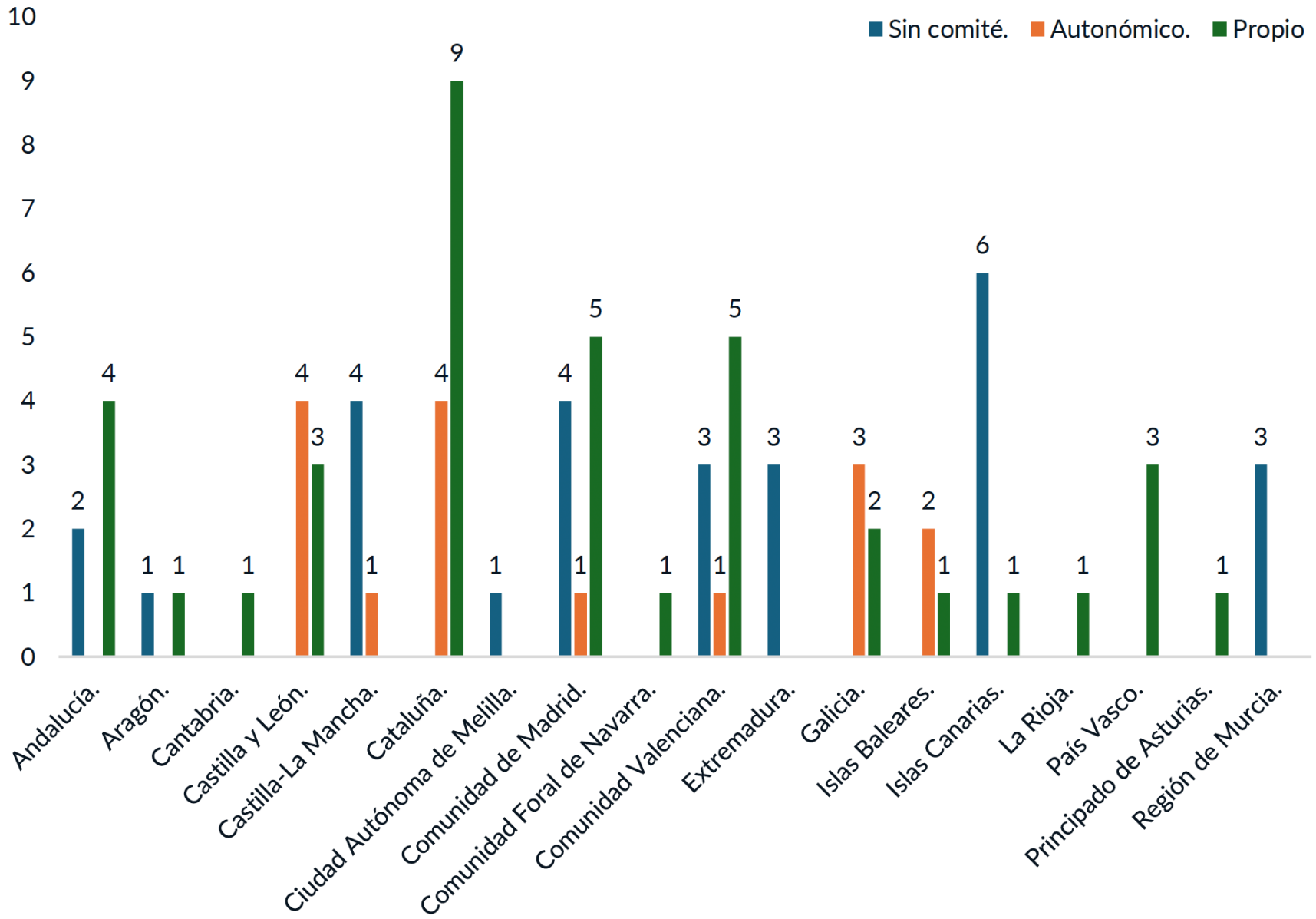
Hospitales de menor tamaño



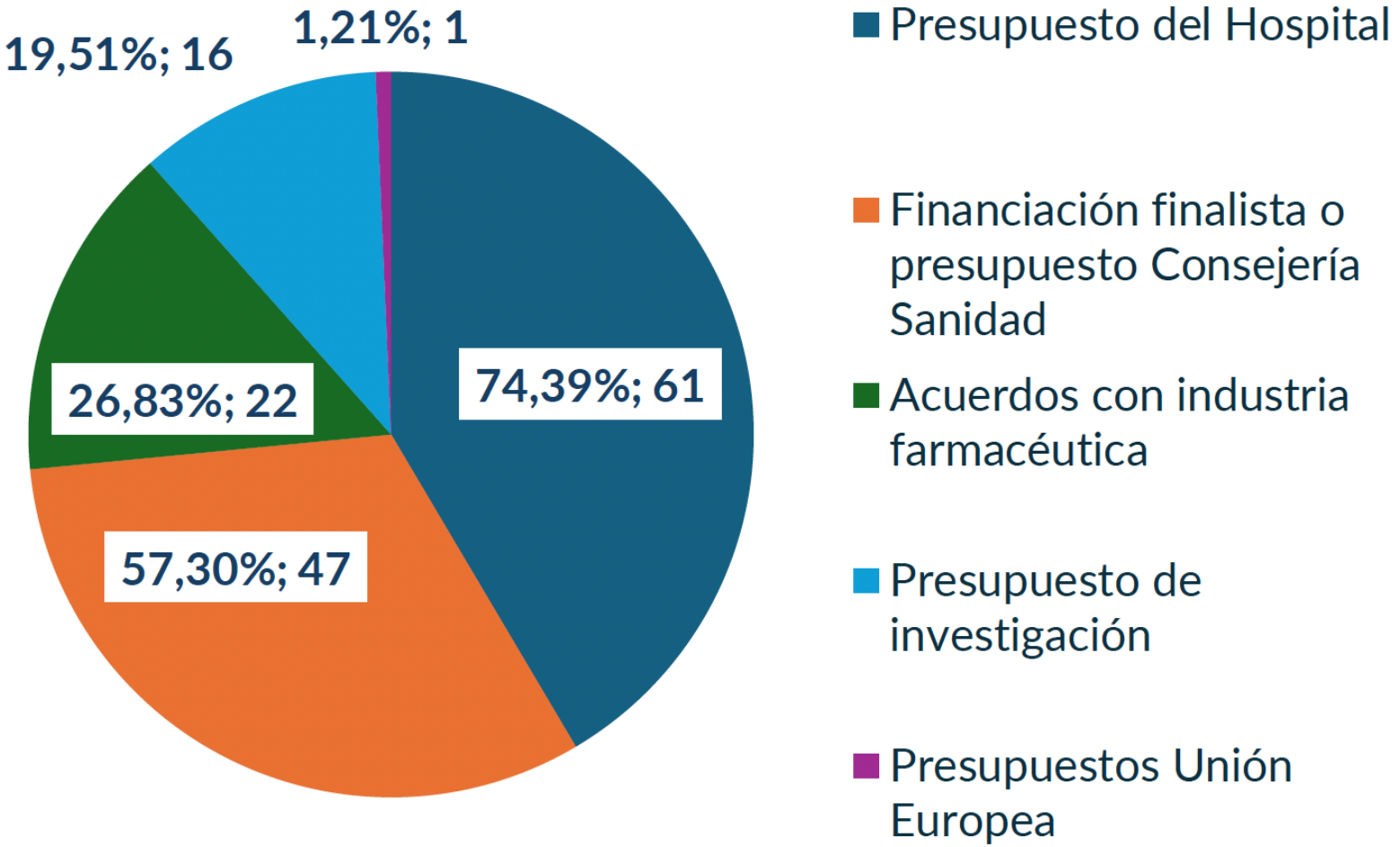
NGS (panel) ctDNA

- Lab. Ref. CCAA
- Lab. Privado conc. Hospital
- Centro invest

Estudio SEOM 2025
Acceso a Comités Moleculares



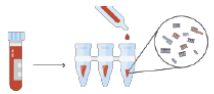
Estudio SEOM 2025
Financiación para la realización de las técnicas diagnósticas



TEST ACCESS SYSTEM ESPAÑA
Detección de mutaciones en ESR1 en CMM

Para solicitar la determinación de ESR1
Link de registro: https://test-access-system-spain.com/welcome

TODO EN UN SOLO LUGAR

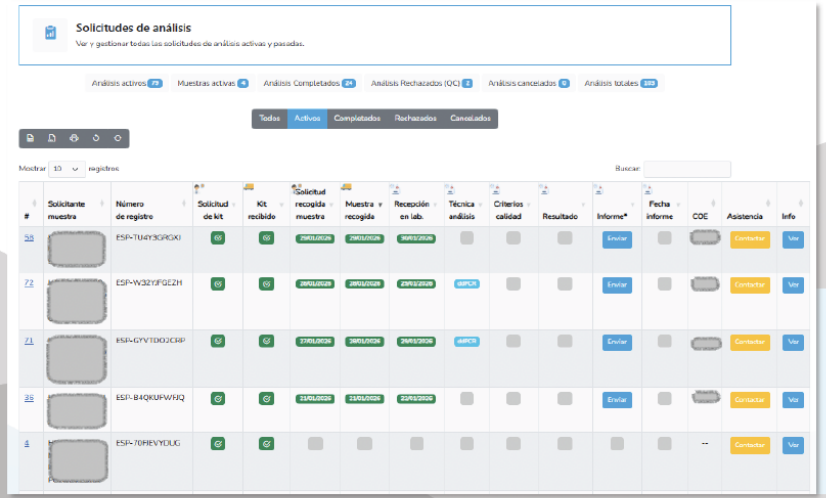


Solicite el análisis de muestras de sangre

Gestione el transporte de muestras hasta el laboratorio de excelencia (CoE)

Conozca el **estado de su solicitud** en tiempo real

Reciba un **informe** de resultados para integrarlo en la historia clínica del paciente.



Acceda a la herramienta web de TAS España: https://test-access-system-spain.com/welcome

Email de soporte: tas.spain@crowe.es

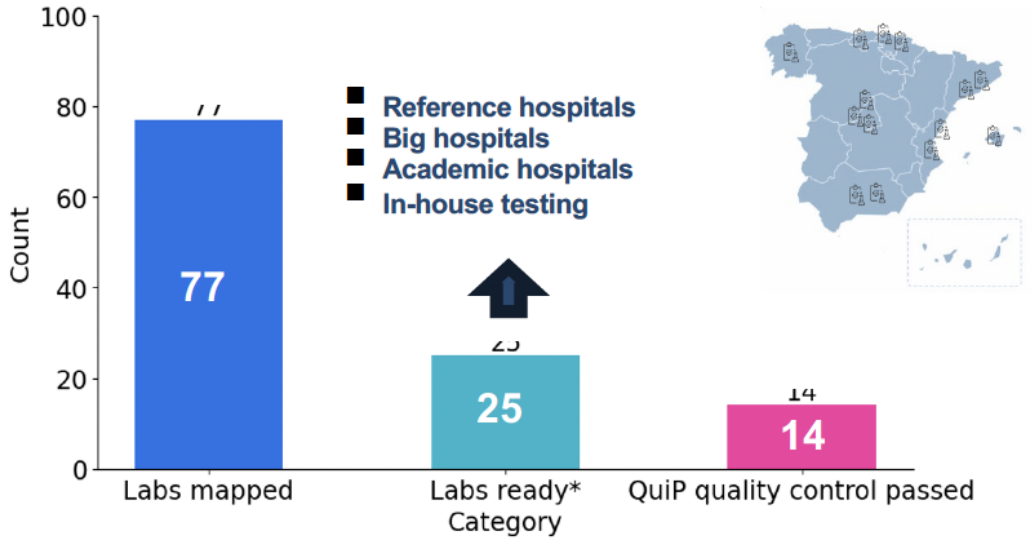
Crowe

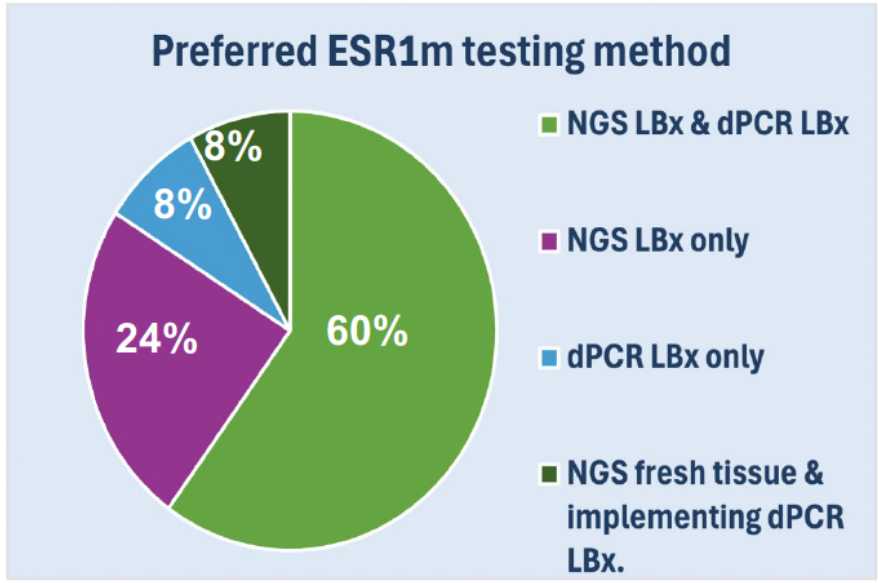
"Esta herramienta de soporte al testing ha sido desarrollada y es gestionada íntegramente por Crowe. El soporte financiero y el patrocinio para su implementación son proporcionados por Menarini Stemline. El contenido y la operativa son responsabilidad exclusiva del tercero operador."
"Esta herramienta está diseñada exclusivamente como un soporte complementario para el profesional sanitario. Los resultados obtenidos son de carácter indicativo y no vinculante, y deben ser interpretados por el médico a la luz del historial clínico completo del paciente y otras pruebas diagnósticas. La decisión terapéutica y el diagnóstico final son responsabilidad exclusiva del médico tratante, quien mantiene plenamente su autonomía clínica e independencia profesional."
"De conformidad con la normativa vigente de protección de datos (RGPD), Crowe actúa como responsable único del tratamiento de los datos personales y de salud introducidos en esta plataforma. Menarini Stemline no tiene acceso, en ningún momento, a datos identificativos de los usuarios ni a los resultados individuales obtenidos, recibiendo únicamente informes agregados y anonimizados con fines estadísticos."

SPAIN | CURRENT SITUATION ESR1m TESTING

- 25 sites ready* for ESR1m testing in Liquid biopsy
- Only research funding: ESR1m not reimbursed

Labs mapping for ESR1m in Liquid Biopsy in Spain (2025)**

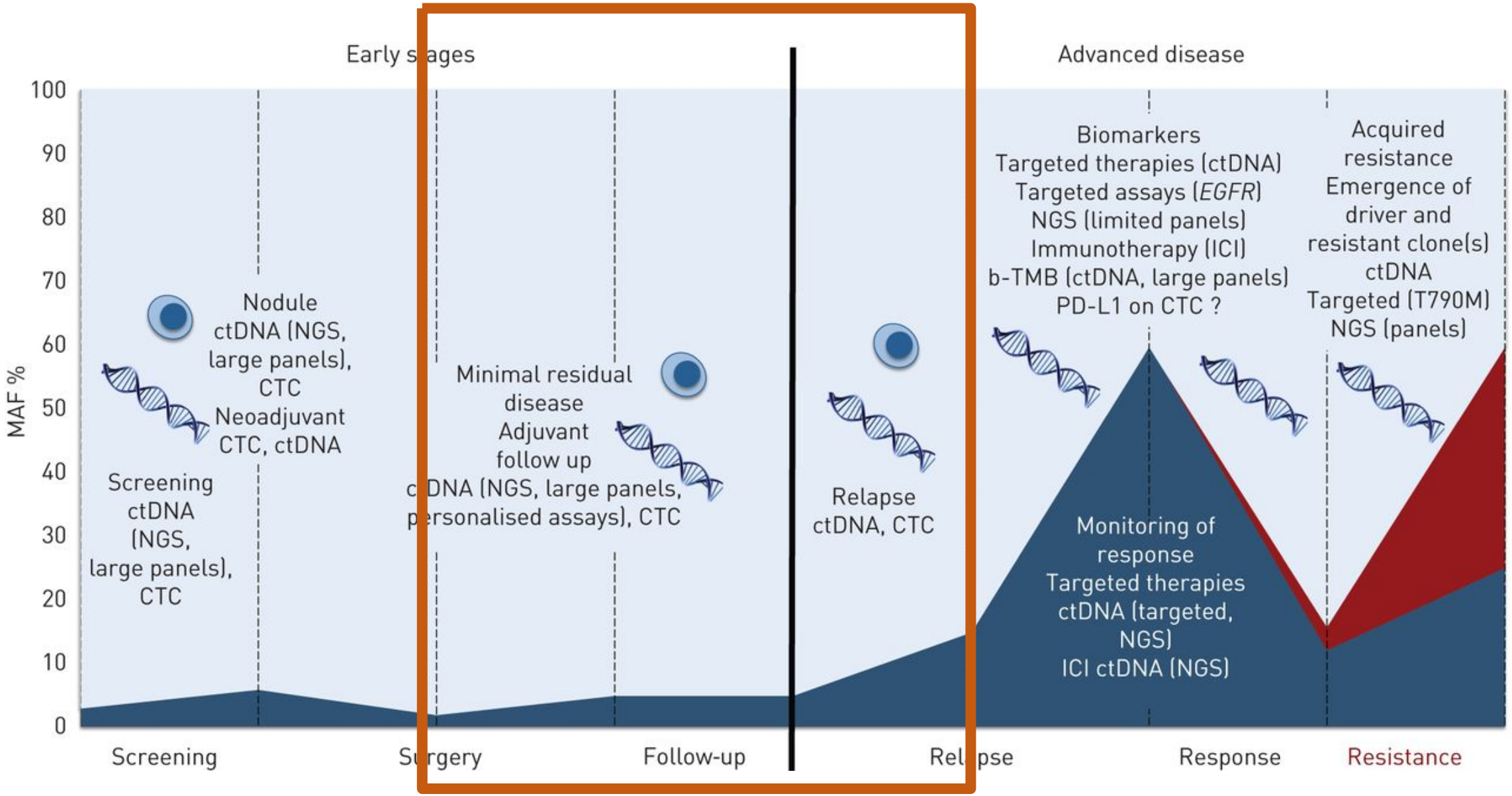




* Sites with technical capabilities for ESR1 testing but only research funding, not routine

** Information aligned and confirmed by the SEOM Precision Medicine Report (Nov 2025)

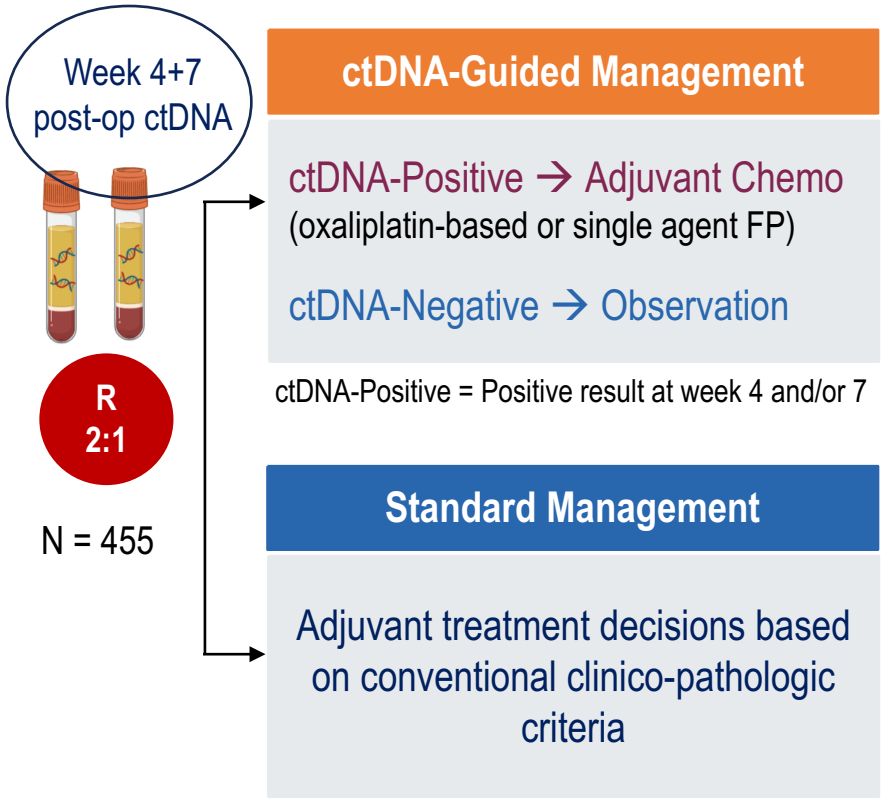
Survey conducted by Menarini Stemline.

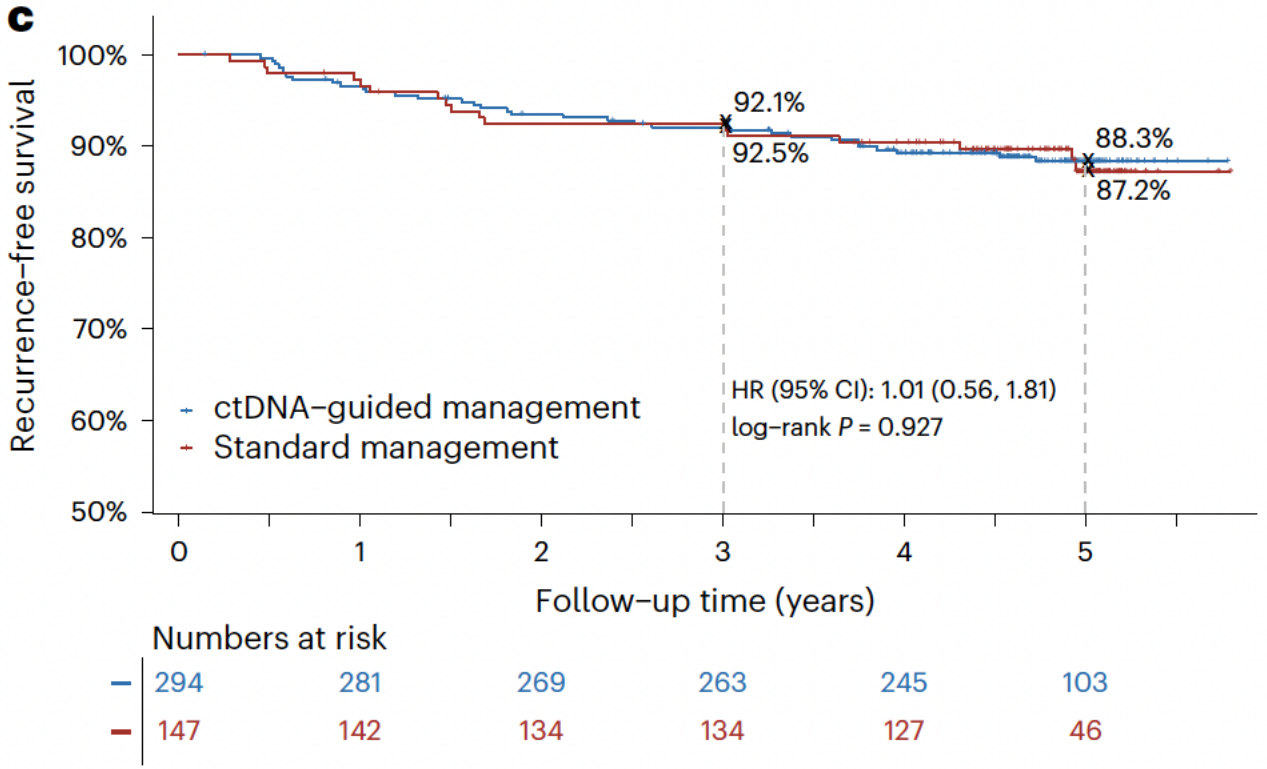


Guibert *et al,* 2020

DYNAMIC II –multicenter randomized in resected **stage II** colon cancer

ctDNA-guided approach **was not inferior** to SOC, **significantly reduced by half the proportion of patients receiving adjuvant chemotherapy** (28% vs 15%)





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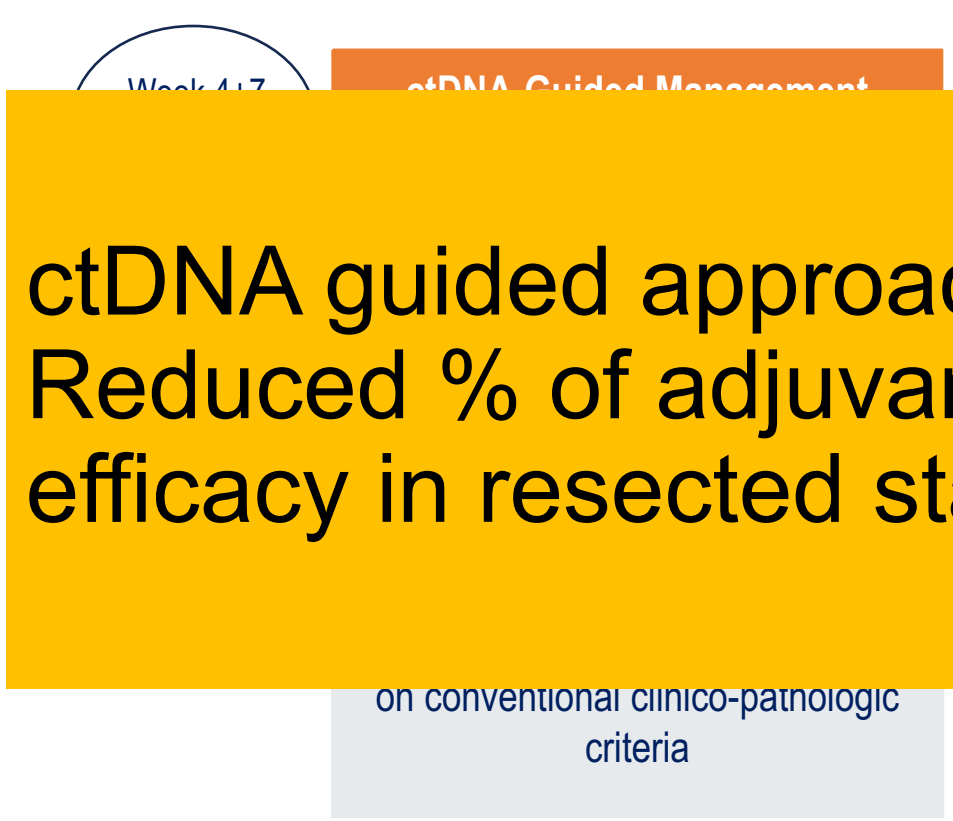
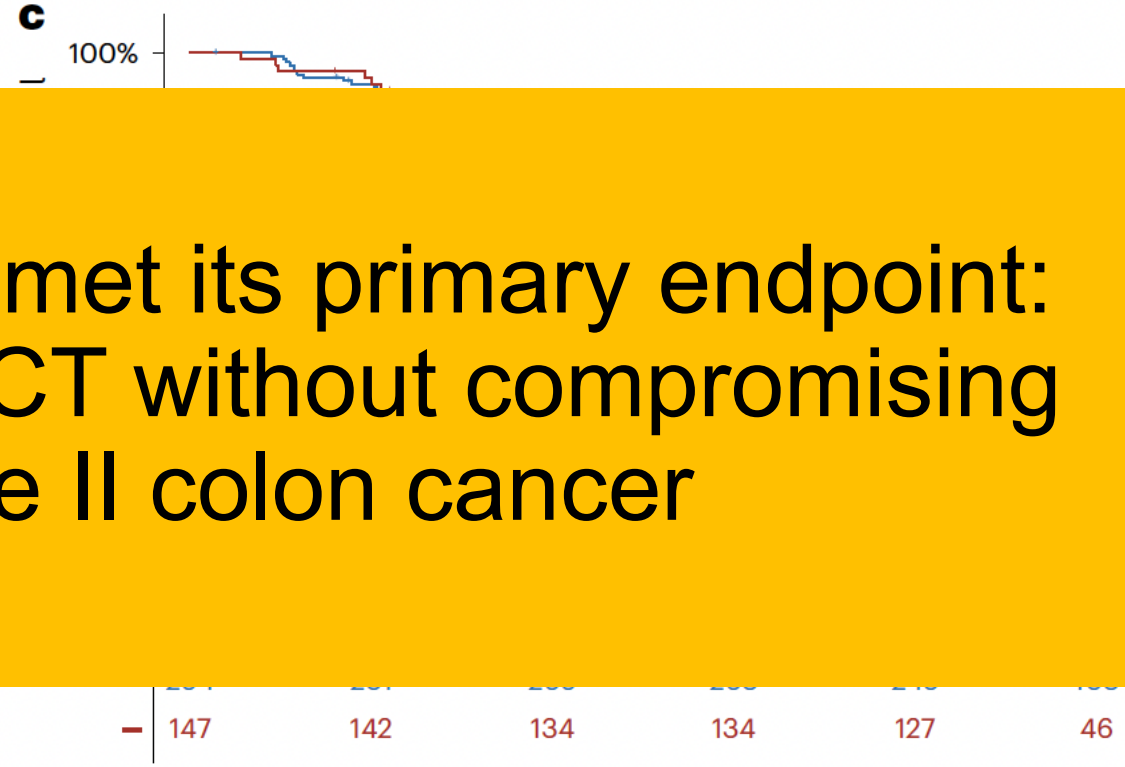




ctDNA guided approach met its primary endpoint: Reduced % of adjuvant CT without compromising efficacy in resected stage II colon cancer

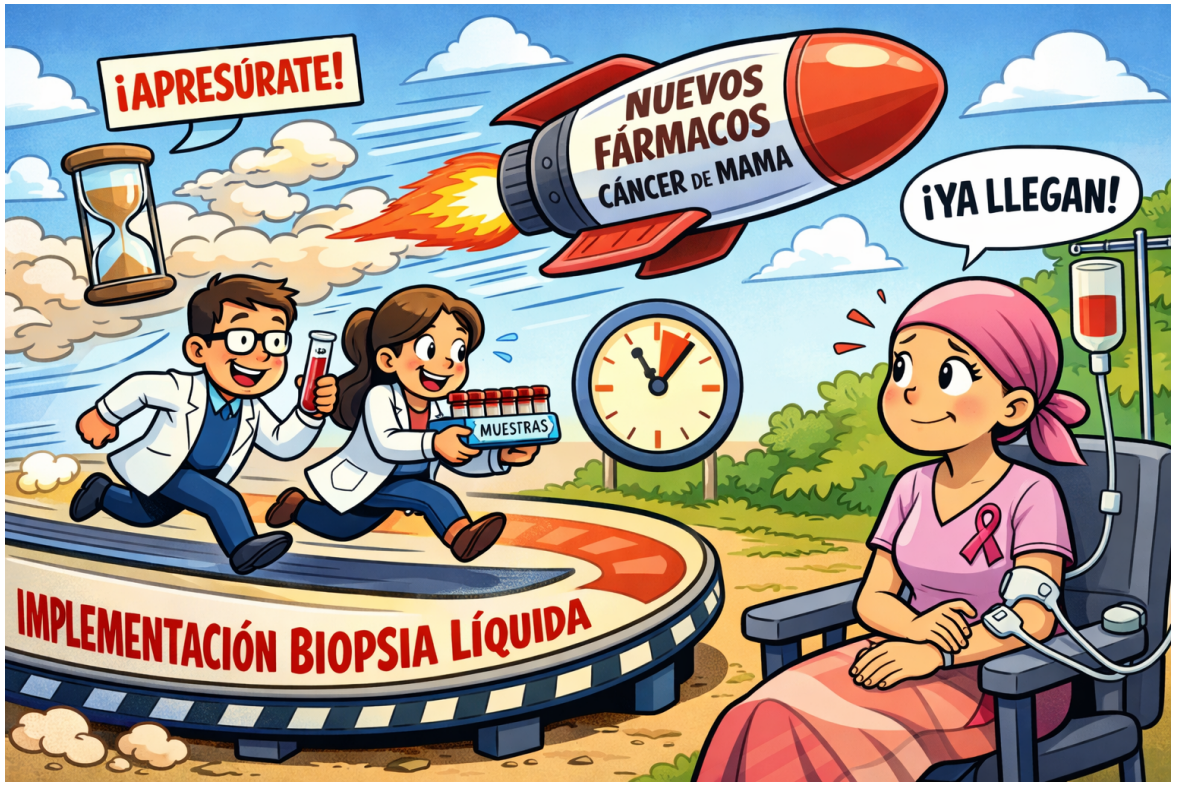
Mensajes claves de la presentación

La incorporación de la biopsia líquida en práctica asistencial sigue siendo limitada a pesar de las recomendaciones y la incorporación en la cartera de servicios de pruebas genéticas y genómicas

Existe una necesidad de incorporar este abordaje en la cartera de servicios asistencial de los centros

Se observa una tendencia creciente en la incorporación de la biopsia líquida, pero todavía hay camino para recorrer

Se plantean cambios de paradigma que se apoyan en las determinaciones de biopsia líquida – es necesario que el sistema incorpore esta tecnología en la realidad asistencial



GRacias!

II JORNADA TRASLACIONAL DE ONCOLOGÍA DE PRECISIÓN: A TRAVÉS DE LAS VÍAS DE SEÑALIZACIÓN

SEVILLA, 6 Y 7 DE FEBRERO DE 2025