Identifying the Right Treatment for the Right Patient

Reimbursement of biomarkers and genomic profiling

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Transforming oncology care to personalized therapy

*Need for **Comprehensive Genomic Profiling** (CGP) of patients*

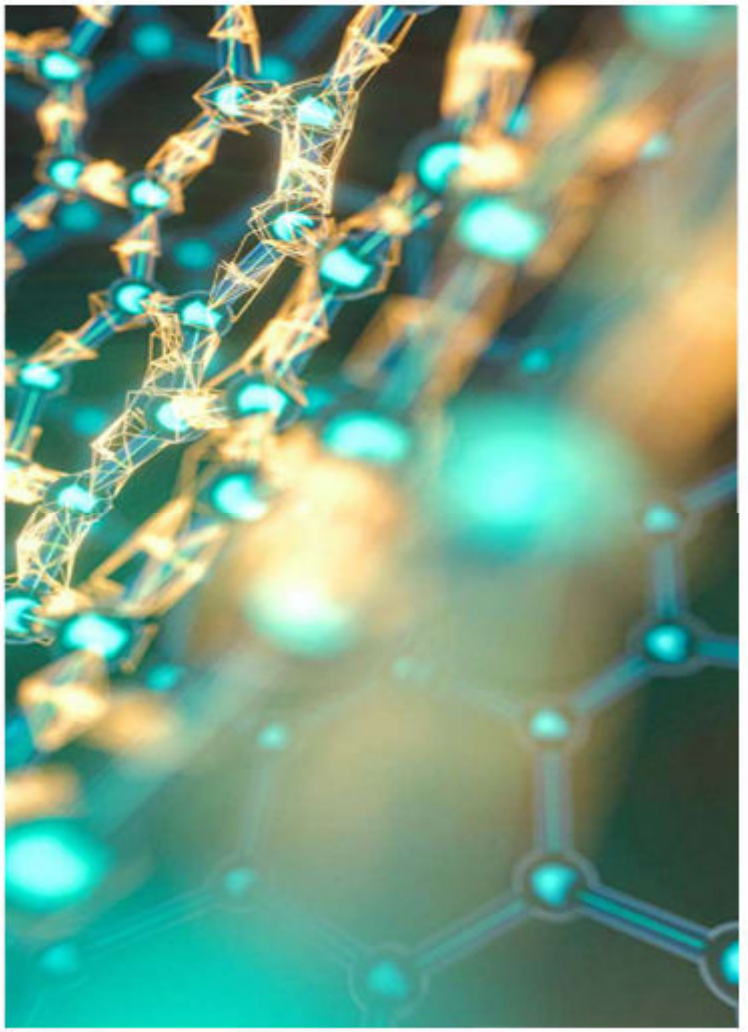
What Is Comprehensive Genomic Profiling?

Detect Multiple Biomarkers in a Single Assay

Comprehensive genomic profiling (CGP)

… is a next-generation sequencing (NGS) approach that uses a single assay to assess relevant cancer biomarkers, as established in guidelines and clinical trials, for therapy guidance.

- Achieve comprehensive coverage of pan-cancer content
- Perform tests on different sample types, such as tissue or liquid biopsies
- Save time and samples with a multiplex assay
- Reduce costs by avoiding iterative testing
- Address the needs of the oncology community both today and tomorrow



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Identification of genomic alterations through Comprehensive Genomic Profiling (CGP) as starting point

Historically

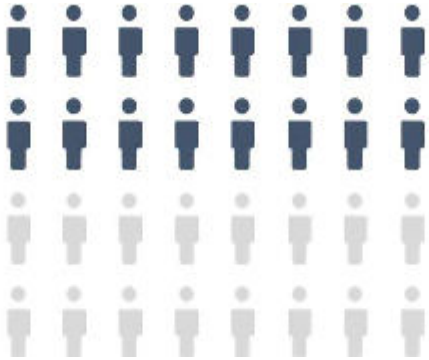
Organ-based

Therapy selected based on organ, stage and histology

More Recently

Biomarker Stratified

Therapy selected based on single or multiple biomarkers



Now

Genomic Profiling

Personalized Therapy

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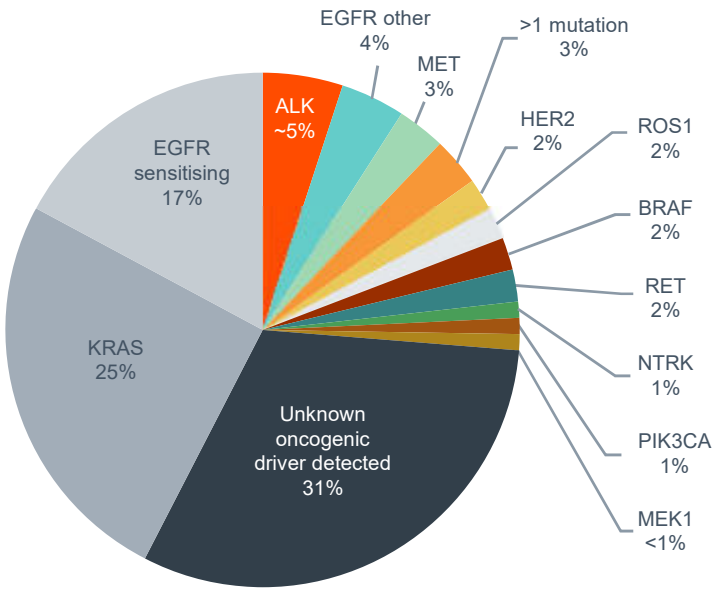
In Lung Cancer a CGP approach is required

Due to high frequency of actionable targets, available treatment options and limited tissue

Common mutations in lung cancer[1]



Identifying actionable mutations with broad molecular profiling[2]

EGFR sensitising
- Afatinib
- Erlotinib
- Erlotinib + bevacizumab▼
- Gefitinib
- Necitumumab▼
- Osimertinib▼
- JNJ-372
- U3-1402

BRAF
- Dabrafenib
- Dabrafenib / trametinib
- Vemurafenib

NTRK
- Cabozantinib▼
- DS-6051b
- Entrectinib
- Larotrectinib▼
- Repotrectinib
- Selitrectinib

ALK
- Alectinib▼
- Brigatinib▼
- Ceritinib▼
- Crizotinib
- Ensartinib
- Lorlatinib▼
- Repotrectinib

RET
- Apatinib
- Cabozantinib▼
- Lenvatinib▼
- LOXO-292
- Ponatinib▼
- Pralsetinib
- Vandetanib▼

ROS1
- Ceritinib▼
- Crizotinib
- DS-6051b
- Entrectinib
- Lorlatinib▼
- Repotrectinib

MET
- Cabozantinib▼
- Crizotinib
- Capmatinib
- Savolitinib
- Tepotinib

HER2
- Afatinib
- Dacomitinib▼
- Pertuzumab
- TAK-778
- Poziotinib
- Trastuzumab emtansine

PIK3CA
- LY3023414

MEK1
- Cobimetinib▼
- Selumetinib
- Trametinib

Slide includes investigational drugs that are not approved in any indication. Some drugs are not approved for use in specific indications in Europe and / or USA. Therapies marked with ▼ are subject to additional monitoring. Reporting suspected adverse reactions after authorisation of the medicinal product is important. Adverse events should be reported to your respective local office Amgen Europe B.V.: Bevazizumab; AstraZeneca AB: Osimertinib; Bayer AG: Larotrectinib; Celltrion Healthcare Hungary Kft.: Trastuzumab; Eli Lilly Nederland B.V.: Necitumumab; Eisai Europe Limited: Lenvatinib; Genzyme Europe B.V.: Vandetanib; Incyte Biosciences Distribution B.V.: Ponatinib; Ipsen Pharma: Cabozantinib; Novartis Europharm Limited: Ceritinib; Pfizer Europe MA EEIG: Lorlatinib, Dacomitinib; Roche Registration GmbH: Alectinib, Cobimetinib; Takeda Pharma A/S: Brigatinib. 1. Adapted from Tsao, A.S., et al. (2016) J Thorac Oncol 11(5):613-38; 2. NSCLC NCCN Guidelines Version 5.2019; NCT03037385; NCT03693339; NCT02967692; NCT02767804 NCT02568267; NCT02609776; NCT03834961; NCT03899792; NCT02132949; NCT03318939 NCT03091192; NCT02716116; NCT02864992; NCT00444587; NCT03260491.

Transforming oncology care to personalized therapy

Medical knowledge about clinically relevant genomic alterations is continually increasing

328 abstracts from ASCO 2018 contained the keywords ‘profiling’ or ‘targeted therapy’ in combination with ‘clinical study’ or ‘clinical trial’[1]

Clinical studies presented at major congresses

260 variants of genes are associated with cancer therapies

- Approved by PDA
- Used as standard of care or
- With demonstrated clinical evidence[2]

Clinically relevant genomic alterations

125 unique targeted therapies are approved across a range of cancers[3]

Available targeted Therapies

At least **31** unique therapies are being assessed in pan-tumour basket trials[4]

Therapies in development

1. ASCO Meeting Library. Available at: https://www.embase.com using the search string ('clinical trial' OR 'clinical study') AND ('profiling' OR 'targeted therapy') AND '2018 annual meeting of the american society of clinical oncology, asco':nc. (Accessed October 2019). ; 2. Precision Oncology Knowledge Base. Available at: http://oncokb.org/#/actionableGenes. (Accessed October 2019). 3. National Cancer Institute. Targeted cancer therapies. Available at: https://www.cancer.gov/about-cancer/treatment/types/targeted-therapies/targeted-therapies-fact-sheet#what-targeted-therapies-have-been-approved-for-specific-types-of-cancer. Accessed October 2019. ; 4. Trinity partners. ‘Oncology Basket Trials: An Emerging Paradigm Shift in Trial Design & Treatment Approach?’ May 2018. Available at: http://trinitylifesciences.com/wp-content/uploads/2019/05/Oncology_Basket_Trials_-_Trinity_Partners.pdf. Accessed October 2019).

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Transforming the oncology patient journey…

Past Patient Journey

Diagnosis happens late

Limited and slow access

Standard care plan

Inconsistent or absent management

PHC Patient Journey

Molecular diagnostics – CGP provides important treatment decision insights

Molecular diagnostic in general

Conventional molecular diagnostics overview

Conventional molecular diagnostic can't address increasing complexity of oncology care

Immunohistochemistry (IHC)[1,5]	In situ hybridisation (ISH)[2–8]	Polymerase chain reaction (PCR)-based tests[7–11]	Pyrosequencing and Sanger sequencing[7,8,12,13]
✚ Used in research and pathological laboratories	✚ Copy number variation: amplification / deletion	✚ Point mutations	✚ Point mutations
✚ Low cost and high benefit	✚ Structural alterations: gene rearrangements	✚ Small deletions	✚ Small deletions
▬ **The interpretation is qualitative and subjective**	▬ **May miss some alterations** (e.g. base substitutions, indels)	▬ **Sensitive to contamination**	▬ **Assesses specific hotspots with short reads** (pyrosequencing)
▬ **Can only evaluate one or a small number of targets at a time**	▬ **More expensive than IHC**	▬ **Short reads**	▬ **Pure DNA sample required** (Sanger)

IHC: immunohistochemistry; ISH: in situ hybridisation; PCR: polymerase chain reaction.

1. de Matos, L.L., et al. (2010) Biomark Insights 5:9-20; 2. To, K.F., et al. (2013) J Thorac Oncol 8:883-91 ; 3. Wolff, D.J., et al. (2007) J Mol Diagn 9:134-43; 4. Ross, J.S., et al, (2016) Cancer 122: 2654-62; 5. Frampton, G.M., et al. (2013) Nat Biotechnol 31:1023-31; 6. Hu, L., et al. (2014) Biomarker Res 2:1-13; 7. NCCN NSCLC Guidelines V4.2019; 8. U.S Food and Drug Administration. List of Cleared or Approved Companion Diagnostic Devices. Available at: https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm301431.htm. (Accessed June 2019); 9. Garibyan, L. and Avashia, N. (2013) J Invest Dermatol 133:e6; 10. Hempelmann, J.A., et al. (2018) J Immunother Cancer 6:29; 11. Debode, F., et al. (2017) Biotechnol Agron Soc Environ 21:3-11; 12. Harrington, C.T., et al. (2013) Arch Pathol Lab Med 137:1296-303; 13. Stranneheim H., et al. (2012) Biotechnol J 7:1063–1073.

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Genomic profiling & the alternative liquid biopsy

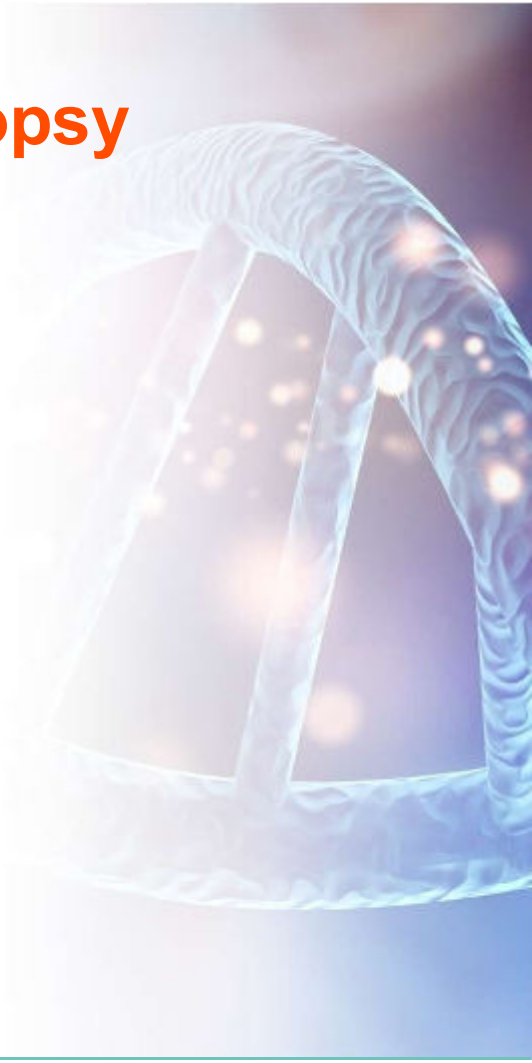
Liquid biopsy

Liquid biopsy

e.g. blood, urine, saliva or cerebrospinal fluid[1,2,4]

– ***Not yet comparable to solid biopsy with respect to evidence for clinical utility and applicability in initial cancer diagnosis and management***[2,5,6]

+ Less invasive than solid biopsy[1,2]
+ May be used when tissue biopsies cannot be performed due to inaccessibility[1,4]
+ Provides an option when tissue samples are limited or exhausted[1]
+ Requires less surgical infrastructure and has shorter turn-around time than tissue biopsy[9,5]
+ Is suitable for repeat sampling during longitudinal monitoring[2,5]
+ Can capture the genomic heterogeneity of all cancerous lesions[10]



1. Francis, G. & Stein, S. (2015) Int J Mol Sci 16:14122-42; 2. De Rubis, G., et al. (2019) Trends Pharmacol Sci 40:172-86; 3. Chouaid, C., et al., (2014) Lung Cancer 86:170-3; 4. Bardelli, A., et al. (2017) Cell 31:172–9; 5. Wan, J.C.M., et al., (2017) Nat Rev Cancer 17:223-38; 6. Mattox, A.K. (2019) Sci Transl Med 11:eeay1984; 7. Kato, S., et al. (2017) Cancer Res 77:4238-46; 8. Stevenson, M., et al. (2014) Cancer Invest 32:291–8; 9. Temilola , D.O., et al. (2019) Cells , 8, 862; doi:10.3390/cells8080862; 10. Scherer, F. (2020) in Recent Results in Cancer Research: Tumor Liquid Biopsies. Springer.

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CGP has low budget impact and potential to use healthcare resources more efficiently

In relation to cost and turnaround time

CGP may result in cost off-set

Through reduced hospitalization and emergency visits[1–2]

Inpatient cost: **- 47%**[1]

	Non-Precision therapy (%)	Precision therapy (%)	
Total patients[2]	**138**	**45**	
Patients with ER visits	23%	18%	⬇ -22%
Patients hospitalized	44%	31%	⬇ -29%
Number of ER visits	33%	22%	⬇ -33%
Number of hospitalization events	62%	56%	⬇ -10%

1. Haslem DS, *et al. Oncotarget* 2018 **9**:12316-12322. 2. Yencho SW (2020).Healthcare Utilization Impact of Precision Therapeutics: Hospitalization/Emergency visits. Cancer Sci Res 2020 Vol 3 Issue 2

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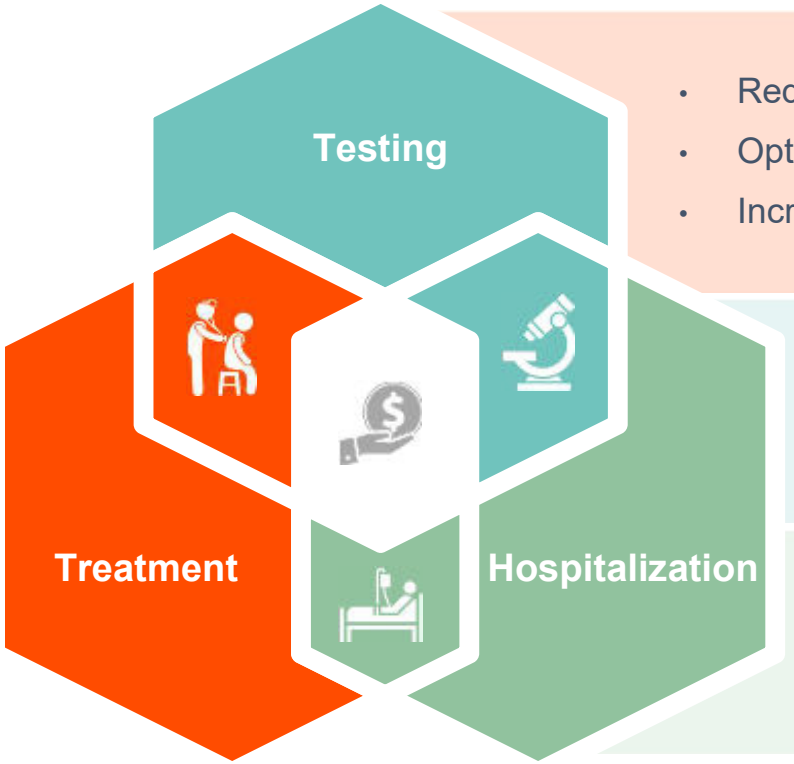
CGP may result in cost savings [1-7]

Additional cost for CGP and testing off-set by healthcare system cost-effectiveness[1]



- Reducing cytotoxic chemotherapy use
- Optimizing approved targeted and immuno-oncology therapy utilization
- Increasing clinical trial enrollment

- Eliminating unnecessary molecular tests
- Eliminating unnecessary biopsies

- Reducing emergency department visits
- Reducing hospitalizations
- Reducing pointless treatments

1. Haslem DS, et al. Oncotarget 2018 9:12316–12322; 2. Pennell NA, et al. JCO Precision Oncol 2019;3; Available at: https://ascopubs.org/doi/pdf/10.1200/PO.18.00356; Accessed June 2020; 3. Nesline MK, et al. Oncotarget 2019; 10:4616–4629; 4. Reitsma M. et al. J Manag Care Spec Pharm 2019; 25: 601–611; 5. Signorovitch J, et al. J Clin Oncol 2017; 35 (Suppl 15): 6599–6599; 6 Conway J and Marino I. Am J Manag Care 2016; 22 (Suppl 12): SP439–SP443; 7. Anhorn R, et al. Value Health 2017; 20: A575; 8. Herrero Fernandez M et al, Frontiers in Pharmacology 2019, 10:1210 9. Saiyed MM J of Clinical Pharmacy and Therapeutics, 2017 Jun;42(3):251-258.

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Reimbursement of Biomarkers in Greece

The current situation, trends & prospects

Legal Framework in Greece

FEK 1511/b/06.06.2014

20445

ΕΦΗΜΕΡΙΣ ΤΗΣ ΚΥΒΕΡΝΗΣΕΩΣ

ΤΗΣ ΕΛΛΗΝΙΚΗΣ ΔΗΜΟΚΡΑΤΙΑΣ

ΤΕΥΧΟΣ ΔΕΥΤΕΡΟ Αρ. Φύλλου 1511

6 Ιουνίου 2014

ΑΠΟΦΑΣΕΙΣ

Αριθμ. 49516 (1)

Διατάξεις Συνταγογράφησης και Αποζημίωσης Ογκολογικών Φαρμάκων.

Ο ΥΠΟΥΡΓΟΣ ΥΓΕΙΑΣ

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ΑΝΙΧΝΕΥΣΗ ΜΕΤΑΛΛΑΞΕΩΝ NRAS (2,3,4) ΣΕ ΙΣΤΟΛΟΓΙΚΟ Η ΚΥΤΤΑΡΟΛΟΓΙΚΟ ΥΛΙΚΟ	ΚΑΡΚΙΝΟΣ ΠΑΧΕΟΥ ΕΝΤΕΡΟΥ	160
ΑΝΑΛΥΣΗ ΜΙΚΡΟΔΟΡΥΦΟΡΙΚΗΣ ΑΣΤΑΘΕΙΑΣ DNA ΟΓΚΟΥ (MSI)	ΚΑΡΚΙΝΟΣ ΠΑΧΕΟΥ ΕΝΤΕΡΟΥ	120
ΑΝΟΣΟΙΣΤΟΧΗΜΙΚΗ ΜΕΛΕΤΗ ΜΙΚΡΟΔΟΡΥΦΟΡΙΚΗΣ ΑΣΤΑΘΕΙΑΣ ΣΕ ΙΣΤΟΛΟΓΙΚΟ ΥΛΙΚΟ (4 ΑΝΤΙΣΩΜΑΤΑ)	ΚΑΡΚΙΝΟΣ ΠΑΧΕΟΥ ΕΝΤΕΡΟΥ	80
ΑΝΙΧΝΕΥΣΗ ΜΕΤΑΛΛΑΞΕΩΝ ΓΟΝΙΔΙΟΥ EGFR (ΕΞΩΝΙΑ 18,19,20,21) ΣΕ ΙΣΤΟΛΟΓΙΚΟ ΥΛΙΚΟ	ΜΗ-ΜΙΚΡΟΚΥΤΤΑΡΙΚΟ ΚΑΡΚΙΝΩΜΑ ΠΝΕΥΜΟΝΟΣ	160
ΑΝΙΧΝΕΥΣΗ ΑΝΤΙΜΕΤΑΘΕΣΗΣ ΓΟΝΙΔΙΟΥ ALK ΣΕ ΙΣΤΟΛΟΓΙΚΟ ΥΛΙΚΟ ΜΕ IN SITU ΙΒΡΙΔΙΣΜΟ	ΜΗ-ΜΙΚΡΟΚΥΤΤΑΡΙΚΟ ΚΑΡΚΙΝΩΜΑ ΠΝΕΥΜΟΝΟΣ	120
ΑΝΙΧΝΕΥΣΗ ΑΝΤΙΜΕΤΑΘΕΣΗΣ ΓΟΝΙΔΙΟΥ ALK ΣΕ ΙΣΤΟΛΟΓΙΚΟ ΥΛΙΚΟ ΜΕ ΑΝΟΣΟΙΣΤΟΧΗΜΕΙΑ	ΜΗ-ΜΙΚΡΟΚΥΤΤΑΡΙΚΟ ΚΑΡΚΙΝΩΜΑ ΠΝΕΥΜΟΝΟΣ	40
ΑΝΙΧΝΕΥΣΗ ΜΕΤΑΛΛΑΞΗΣ BRAF V600E (εξώνια 11,15) ΣΕ ΙΣΤΟΛΟΓΙΚΟ ΥΛΙΚΟ	ΜΕΛΑΝΩΜΑ	130 (το ένα 75)
ΑΝΙΧΝΕΥΣΗ ΥΠΕΡΕΚΦΡΑΣΗΣ Η ΜΕΤΑΛΛΑΞΕΩΝ ΣΤΑ ΓΟΝΙΔΙΑ C-KIT/PDGFR	ΣΤΡΩΜΑΤΙΚΟΙ ΟΓΚΟΙ ΓΑΣΤΡΕΝΤΕΡΙΚΟΥ	70 ΑΝΑ ΜΕΤΑΛΑΞΗ
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ΜΕΛΕΤΗ ΥΠΕΡΕΚΦΡΑΣΗΣ HER2 ΓΟΝΙΔΙΟΥ ΜΕ IN SITU ΙΒΡΙΔΙΣΜΟ (CISH, FISH)	ΚΑΡΚΙΝΟΣ ΜΑΣΤΟΥ ΚΑΙ ΣΤΟΜΑΧΙ	150
ΑΝΟΣΟΙΣΤΟΧΗΜΙΚΗ ΜΕΛΕΤΗ ΟΙΣΤΡΟΓΟΝΙΚΩΝ ΚΑΙ ΠΡΟΓΕΝΕΣΤΟΝΙΚΩΝ ΥΠΟΔΟΧΕΩΝ	ΚΑΡΚΙΝΟΣ ΜΑΣΤΟΥ ΚΑΙ ΩΟΘΗΚΩΝ	40
ΑΝΙΧΝΕΥΣΗ ΑΝΤΙΜΕΤΑΘΕΣΗΣ Bcr-Abl ΜΕ RT-PCR	ΧΡΟΝΙΑ ΜΥΕΛΟΓΕΝΗΣ ΛΕΥΧΑΙΜΙΑ	120
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ΑΝΙΧΝΕΥΣΗ ΧΙΜΑΙΡΙΚΩΝ ΜΕΤΑΓΡΑΦΩΝ BCR/ABL ΜΕ ΠΟΣΟΤΙΚΗ REAL-TIME PCR	ΧΡΟΝΙΑ ΚΑΙ ΟΞΕΙΑ ΜΥΕΛΟΓΕΝΗ ΛΕΥΧΑΙΜΙΑ, ΜΥΕΛΟΥΠΕΡΠΛΑΣΤΙΚΑ ΝΕΟΠΛΑΣΜΑΤΑ, ΟΞΕΙΑ ΛΕΜΦΟΒΛΑΣΤΙΚΗ ΛΕΥΧΑΙΜΙΑ	120
ΑΝΙΧΝΕΥΣΗ ΧΙΜΑΙΡΙΚΩΝ ΜΕΤΑΓΡΑΦΩΝ PML/RARA ΜΕ ΠΟΣΟΤΙΚΗ PCR	ΟΞΕΙΑ ΜΥΕΛΟΓΕΝΗ ΛΕΥΧΑΙΜΙΑ	80
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ΑΝΙΧΝΕΥΣΗ ΜΕΤΑΛΛΑΞΕΩΝ JAK2/V617F ΜΕ ΑΛΛΗΛΟΕΙΔΙΚΗ PCR	ΜΥΕΛΟΥΠΕΡΠΛΑΣΤΙΚΑ ΝΕΟΠΛΑΣΜΑΤΑ	80
ΚΑΡΥΟΤΥΠΟΣ ΜΥΕΛΟΥ/ΠΕΡΙΦΕΡΙΚΟΥ ΑΙΜΑΤΟΣ ΑΣΘΕΝΩΝ ΜΕ ΚΑΚΟΗΘΗ ΝΟΣΗΜΑΤΑ ΜΕ ΤΗ ΧΡΗΣΗ ΜΙΤΟΓΟΝΩΝ (καλ. 24, 48, 72 ώρες)	ΧΡΟΝΙΑ ΚΑΙ ΟΞΕΙΑ ΜΥΕΛΟΓΕΝΗ ΛΕΥΧΑΙΜΙΑ ΜΥΕΛΟΔΥΣΠΛΑΣΤΙΚΟ ΣΥΝΔΡΟΜΟ, ΜΥΕΛΟΥΠΕΡΠΛΑΣΤΙΚΑ ΝΕΟΠΛΑΣΜΑΤΑ	160
ΜΟΡΙΑΚΗ ΚΥΤΤΑΡΟΓΕΝΕΤΙΚΗ ΜΕΛΕΤΗ (FISH) ΜΕ ΧΡΗΣΗ ΜΟΝΑΔΙΚΟΥ ΑΝΙΧΝΕΥΤΗ	ΟΞΕΙΑ ΜΥΕΛΟΓΕΝΗ ΛΕΥΧΑΙΜΙΑ ΚΑΙ ΜΥΕΛΟΔΥΣΠΛΑΣΤΙΚΑ ΣΥΝΔΡΟΜΑ	150 (Για κάθε επιπλέον ανιχνευτή 80)

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A Biomarkers HTA procedure is necessary

As payers have become more critical and put more weight on examining the added value of a diagnostic when making coverage decisions, the need for HTA has increased.

Evaluating the health outcomes of biomarkers is **particularly challenging** because diagnostics themselves do not influence long-term outcomes directly but rather impact the subsequent care process

In examining the effectiveness of a diagnostic biomarker, one needs to take into account

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(1) the **accuracy** of the diagnostic test,
(2) the **impact** of the diagnostic on therapeutic decisions and
(3) the **effectiveness** of the therapies selected

An HTA can be characterized by 3 phases:

Assessment: critical review of scientific evidence
Appraisal: review of the assessment with consideration of all other (policy) factors make a recommendation
Decision-making: implementation of the recommendation

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What are the main questions that we have to address towards to a "*good*" HTA process

A list of possible questions

Organization:

- How is the HTA body regulated?
- What is the relationship with MoH?
- Are there legal or policy constraints?

Methods & processes:

- What domains are assessed (e.g. clinical, ethical, economic)?
- How are analyses conducted?

Dissemination:

- In what timeframe?
- To whom are the recommendations given?
- What is the content of communication?

Area of Authority:

- What technologies require a decision?
- What assessments are required?
- How are third parties (e.g EOPE, PAGs) involved?
- What is the level of transparency and accountability?

Decision:

- Is an expert committee required?
- What is the link to the decision-maker?
- What are the values of the decision-maker?

Implementation:

- How are decisions implemented?
- What is the result of a recommendation?

Impact:

- Who is being impacted?
- What is a relevant measure of impact?
- What are the decision outputs?

Doing now what patients need next