OncoNIM® BIOMARKER

An integral approach to genetic diagnosis in oncology

NIMGenetics
New Integrated Medical Genetics

Genetic biomarkers and precision medicine

Cancer is a disease of the genome. Each tumor is characterized by a unique molecular profile.

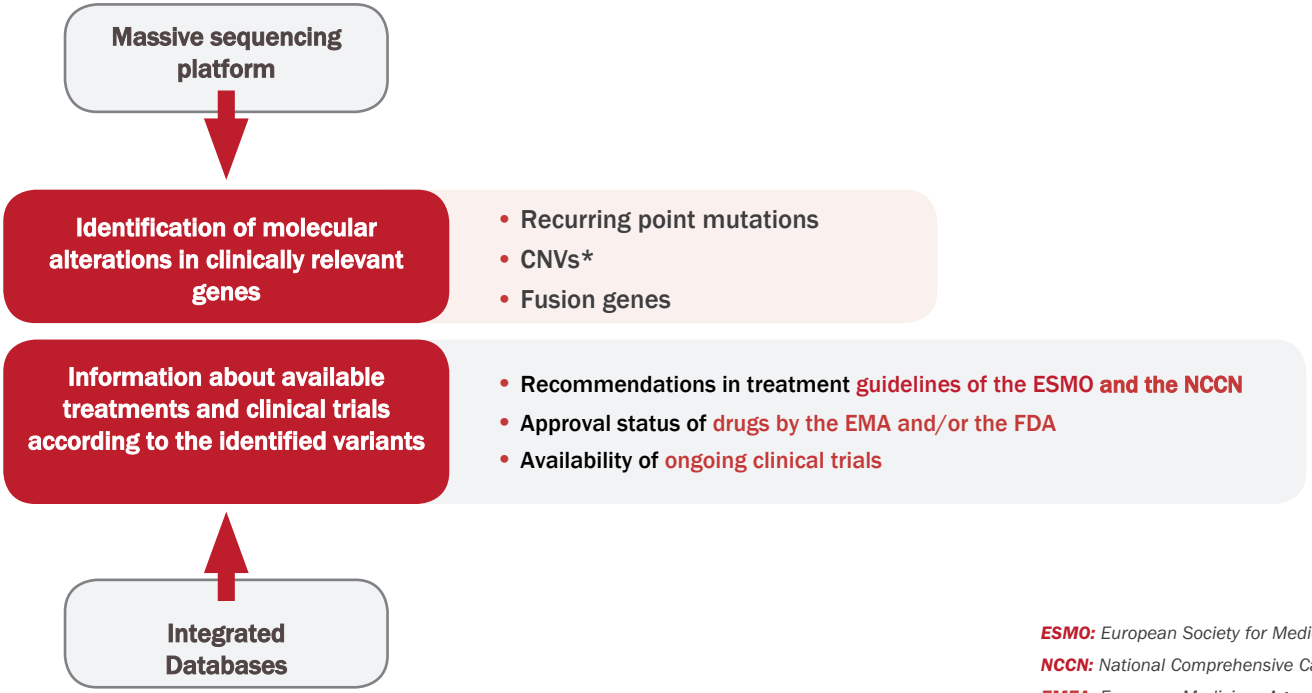
Precision Medicine is an approach to patient treatment that considers both the varability of the individual and the **specific genetic biomarkers of the tumor**

The characterization of the genetic alterations present in a tumor allows the establishment of a diagnosis, a prognosis and/or the determination of efficacy of a particular treatment, which contributes to:

- Minimize the occurence of adverse effects
- Determine the most effective therapy
- Establish the probability of response with the greatest reliability

OncoNIM® BIOMARKER

Genetic study of the tumor sample that provides information on the therapeutic options based on its mutational profile



***CNVs** (copy number variations): deletions, gains and gene amplifications*

***ESMO:** European Society for Medical Oncology*
***NCCN:** National Comprehensive Cancer Network*
***EMEA:** European Medicines Agency*
***FDA:** Food and Drug Administration*

The mutational profile, an essential element in the era of precision medicine

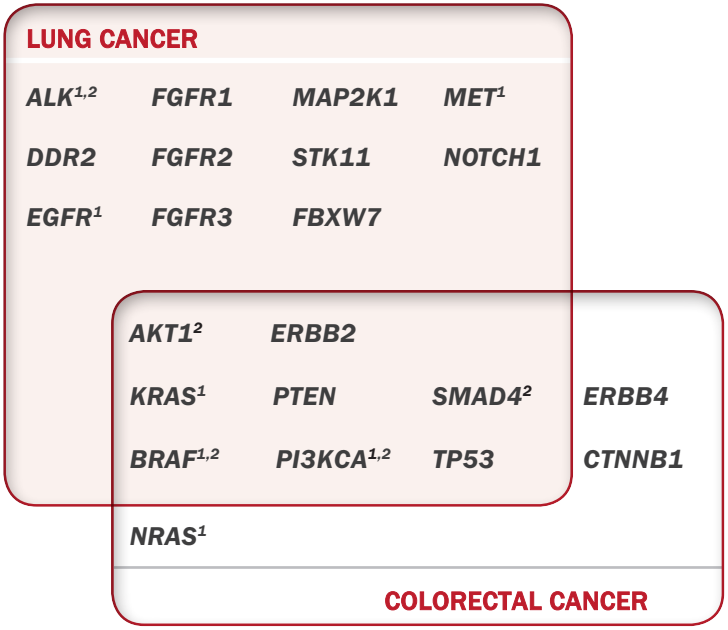
OncoNIM® BIOMARKER

Different approaches for molecular characterization of tumor samples:

OncoNIM®Biomarker Colon and Lung	OncoNIM®Biomarker Lung Fusions	OncoNIM®Biomarker Broad Spectrum
22 genes	4 genes	52 genes
Recurring point mutations	24 fusion genes/ rearrangements	Recurring point mutations CNVs Fusion genes

- Correlates the mutational profile and the treatments and clinical trials available
- Optimized for small volume samples and/or samples embedded in paraffin
- High sensitivity
- Cost effective

Sequencing platform for the detection of point mutations in colorectal and lung tumors



"The survival of patients with lung or colon cancer has improved exponentially in the last decade thanks to the application of personalized medicine based on the molecular characterization of the tumor"

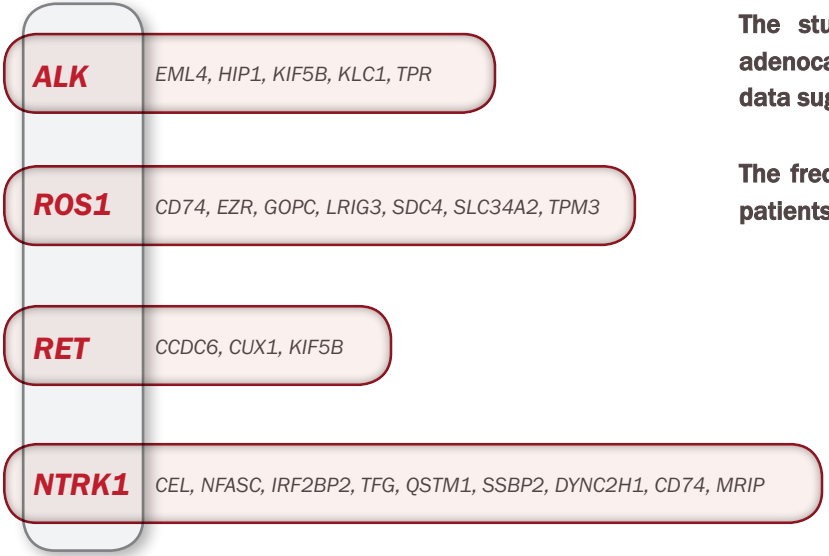
(Green ED and Guyer MS; 2011)

1) Predictor of response to treatment (resistance or sensitivity)
2) Prognostic value (increased risk of recurrence)

OncoNIM® BIOMARKER

Lung fusions

Sequencing platform for the identification of fusion genes in lung cancer



The study of ALK rearrangements is recommended in adenocarcinomas or in cases where immunohistochemistry data suggest adenocarcinomatous differentiation.

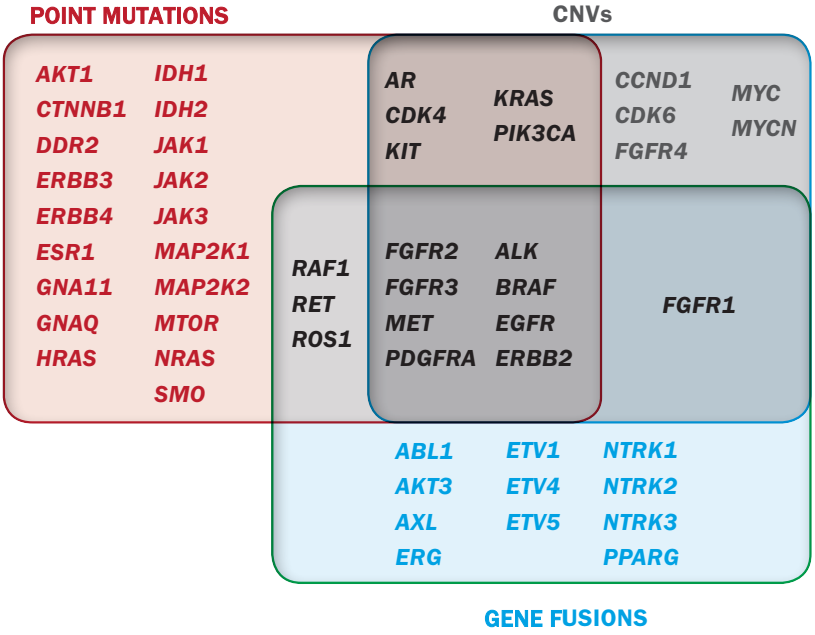
The frequency of ALK fusion proteins is as high as 10% in patients who smoke little or who do not smoke

Targeted therapies in patients whose tumors present rearrangements of the ALK or ROS1 genes are examples of successful cancer therapy

OncoNIM® BIOMARKER

Broad Spectrum

Sequencing platform for the simultaneous detection of recurring point mutations, CNVs and fusions in solid tumors



Point mutations: 35 genes
CNVs: 19 genes
Gene fusions: 23 genes

Aimed at patients with tumors...

...advanced or disseminated

In cases of resistance to therapeutic options with conventional therapies.

...at an early stage

After the initial diagnosis, to maximize treatment options and to minimize adverse effects.

...rare or of unknown origin

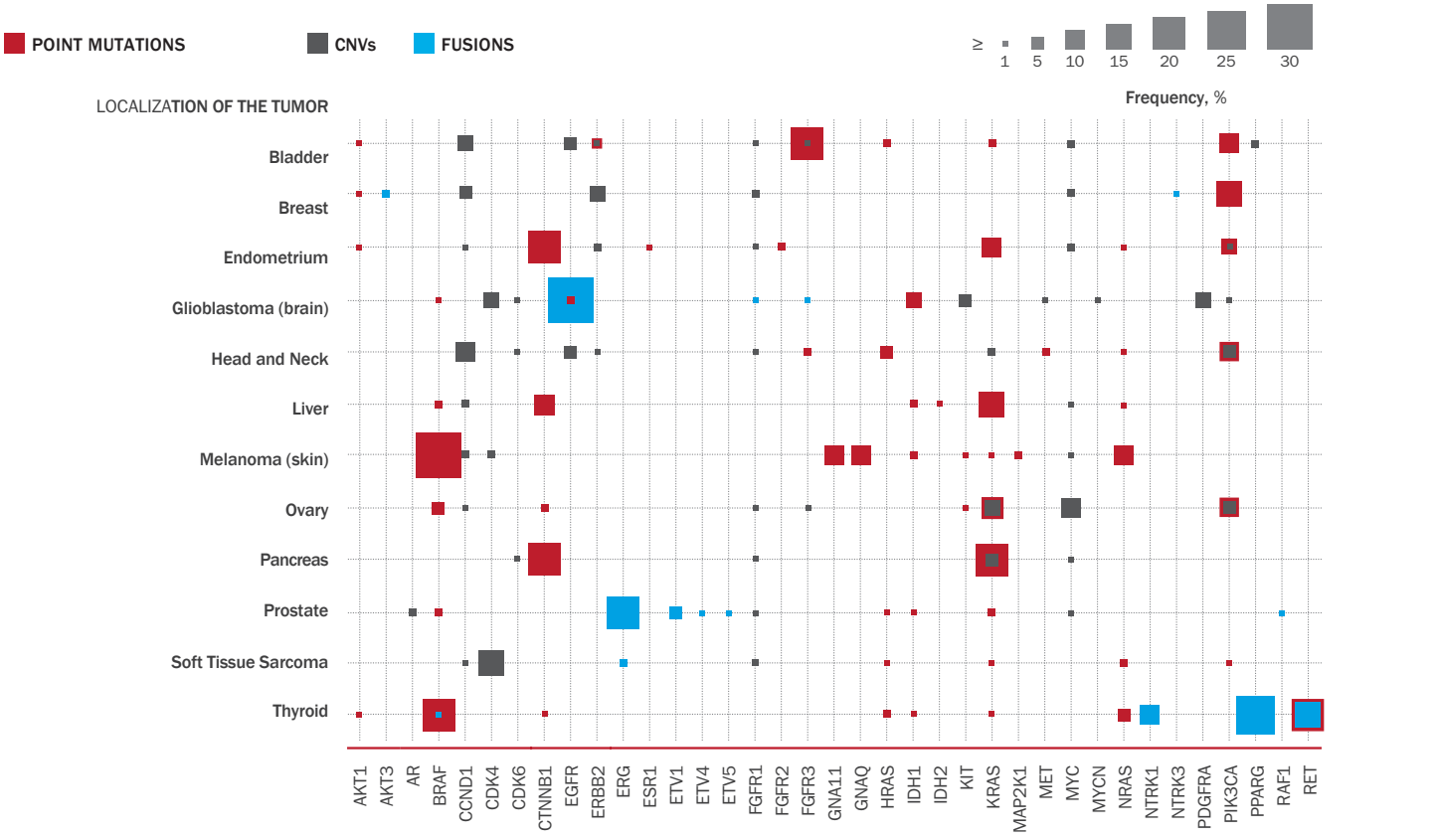
given the lack of established therapeutic protocols, the best option to find the most appropriate therapy.

...difficult to treat

for the identification of new alterations causing relapse to previous treatments

OncoNIM® BIOMARKER

Each tumor has a specific molecular profile, defined as the set of its genetic biomarkers. Knowing this profile facilitates access to more effective and safer treatments or clinical trials for the patient.



OncoNIM® BIOMARKER

SAMPLE FOR NIMGENETICS

Tumor sample

Always accompanied with:
H&E-stained section indicating the tumor area and the anatomopathological report

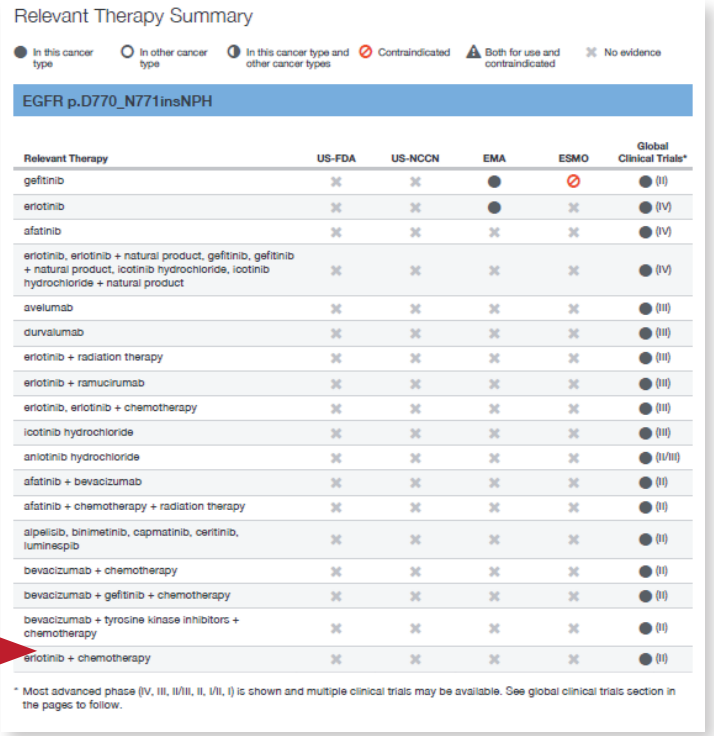
↓

Molecular profile by NGS

↓

Identification of mutations

→ **CLINICAL REPORT**



Relevant Therapy Summary

● In this cancer type ○ In other cancer type ◑ In this cancer type and other cancer types ⊘ Contraindicated ⚠ Both for use and contraindicated ✕ No evidence

EGFR p.D770_N771insNPH

Relevant Therapy	US-FDA	US-NCCN	EMA	ESMO	Global Clinical Trials*
gefitinib	✕	✕	●	⊘	● (II)
erlotinib	✕	✕	●	✕	● (IV)
afatinib	✕	✕	✕	✕	● (IV)
erlotinib, erlotinib + natural product, gefitinib, gefitinib + natural product, icotinib hydrochloride, icotinib hydrochloride + natural product	✕	✕	✕	✕	● (IV)
avelumab	✕	✕	✕	✕	● (III)
durvalumab	✕	✕	✕	✕	● (III)
erlotinib + radiation therapy	✕	✕	✕	✕	● (III)
erlotinib + ramucirumab	✕	✕	✕	✕	● (III)
erlotinib, erlotinib + chemotherapy	✕	✕	✕	✕	● (III)
icotinib hydrochloride	✕	✕	✕	✕	● (III)
anlotinib hydrochloride	✕	✕	✕	✕	● (II/III)
afatinib + bevacizumab	✕	✕	✕	✕	● (II)
afatinib + chemotherapy + radiation therapy	✕	✕	✕	✕	● (II)
alpelisib, binimetinib, capmatinib, ceritinib, lumiscpib	✕	✕	✕	✕	● (II)
bevacizumab + chemotherapy	✕	✕	✕	✕	● (II)
bevacizumab + gefitinib + chemotherapy	✕	✕	✕	✕	● (II)
bevacizumab + tyrosine kinase inhibitors + chemotherapy	✕	✕	✕	✕	● (II)
erlotinib + chemotherapy	✕	✕	✕	✕	● (II)

* Most advanced phase (IV, III, II/III, II, I/II, I) is shown and multiple clinical trials may be available. See global clinical trials section in the pages to follow.

- Database with the world´s largest compendium of genomic information on cancer
- Identification and prioritization of possible therapeutic strategies

Why OncoNIM® Biomarker

ADVANTAGES	BENEFITS
Simultaneous analysis of multiple genetic biomarkers optimized to maximize the performance of tumor samples: • High sensitivity • Minimal sample requirements • From parrafin-embedded samples • Reduction in the number of studies needed	Selection of the most appropriate therapy for each patient.
Updated information on treatments and clinical trials available based on the identified genetic profile.	Minimization of adverse effects. Detection of sub-populations responsible for treatment resitance and relapse. Exclusion of ineffective treatments. Obtaining the mutational profile in rare tumors to identify effective treatments.

Our laboratories follow the quality controls of the EMQN (European Molecular Genetics Quality Network).

NIMGenetics
New Integrated Medical Genetics

SPAIN
Parque Científico de Madrid
Faraday, 7 (Campus de Cantoblanco)
28049 Madrid
Tel. +34 91 037 83 54
M. +34 672 060 393

BRASIL
Rua Elvira Ferraz, nº 250, Cj. 211
Itaim - Sao Pauolo, SP.
CEP: 04552-040
Tel. +55 11 3044 1813

MEXICO
World Trade Center
Montecito, 38 - Piso 35 - Oficina 10
Col. Nápoles - 03810 Ciudad de México
Tel. +52 55 68232076

PORTUGAL
Complexo Interdisciplinar da Universidade de Lisboa
Salas 2.12 e 2.14
Avenida Prof. Gama Pinto nº 2,
1649-003 Lisboa
Tel. +351 932 34 80 32

La Suma de Todos
Comunidad de Madrid

NIMGenetics is a Genetics Diagnosis center authorized by the Health and Consumer Department for the Community of Madrid, being duly registered under Nº CS10673

CAT-09; Rev,01; 03/02/2017

www.nimgenetics.com

GenQA Genomics Quality Assessment
ISO 9001 BUREAU VERITAS Certification
CDTI Centro para el Desarrollo Tecnológico Industrial
Gobierno de España · Ministerio de Economía y Competitividad
Financiada por: e enisa Ministerio de Industria, Energía y Turismo
ENAC Ensayos Nº 1212/LE2336
CEQAS Cytogenetic External Quality Assessment Service
EMQN The European Molecular Genetics Quality Network
ERIC european research initiative on CLL