OncoDNA®
THE CANCER THERANOSTIC COMPANY

European User Group Meeting
OncoDEEP® Kit

21st - 22nd October 2024

Documenting the value of CGP - a Belgium Society of Medical Oncologists (BSMO) study in collaboration with Belgian NGS Laboratories: The BALLETT Study

Brigitte Maes, MD, PhD

Jessa Ziekenhuis

UHASSELT

On behalf of the BALLETT investigators, the NGS lab consortium and the nMTB

Disclosure information

Illumina is supporting the BALLETT study by providing TSO500 kits and logistical assistance; B.Maes has been an invited speaker for Illumina

OncoDNA is providing the OncoKDM sequencing data analysis software

Velsera is providing the CGW sequencing data analysis software

BALLETT is partly funded by the EU through a grant for the CAN.HEAL project (grant number 101080009)

can.heal

Funded by the European Union

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Two parallel precision oncology projects in Belgium

Belgian Society of Medical Oncologists

sciensano

BSMO

Belgian Approach for Local Laboratory Extensive Tumor Testing

BALLETT: the concept

CGP detected biomarker

Matched treatment recommendation

Collaboration of 9 Belgian NGS labs
- ✓ Fully standardized CGP testing
- ✓ Pooling of samples to reduce TAT
- ✓ Exchange of Expertise

national Molecular Tumor Board (nMTB)
- ✓ Multidisciplinary – nationwide - virtual
- ✓ Personalized treatment selection
- ✓ Standardized reporting

Broad access to CGP in Belgium

Awareness and knowledge of clinicians

BALLETT

BSMO

BALLETT

BSMO

sciensano

NGS labs (9)

Hospitals – clinical study sites (12)

Patient recruitment: June '21 – Okt '23

CGP on +/- 900 metastatic cancer patients > therapy recommendation based on molecular profile

Coordinating head investigator for Belgium: Dr. B. Maes

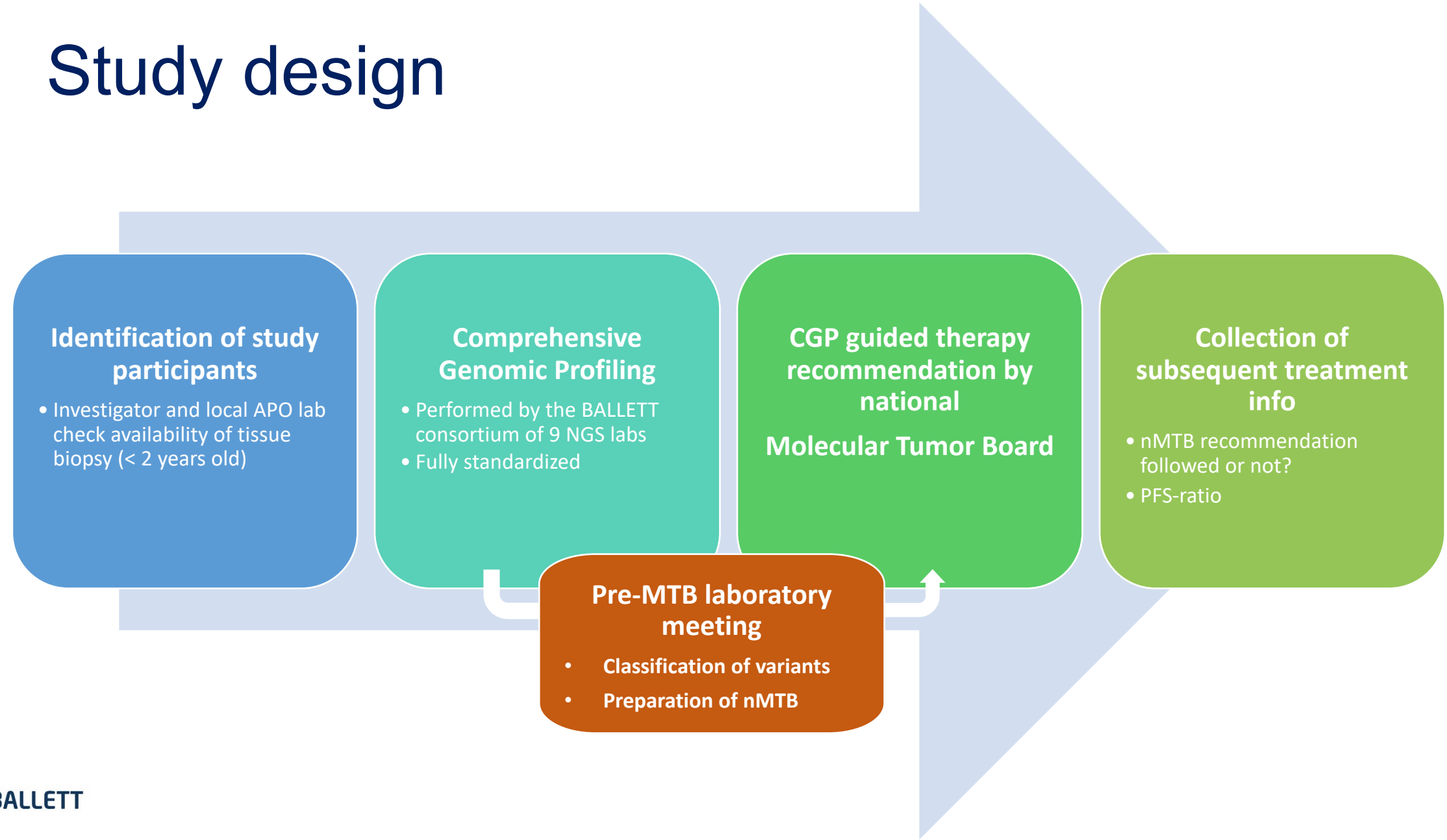
Main objectives

To organise broad ***access*** to 'Comprehensive Genomic Profiling' for patients with metastatic cancer in Belgium

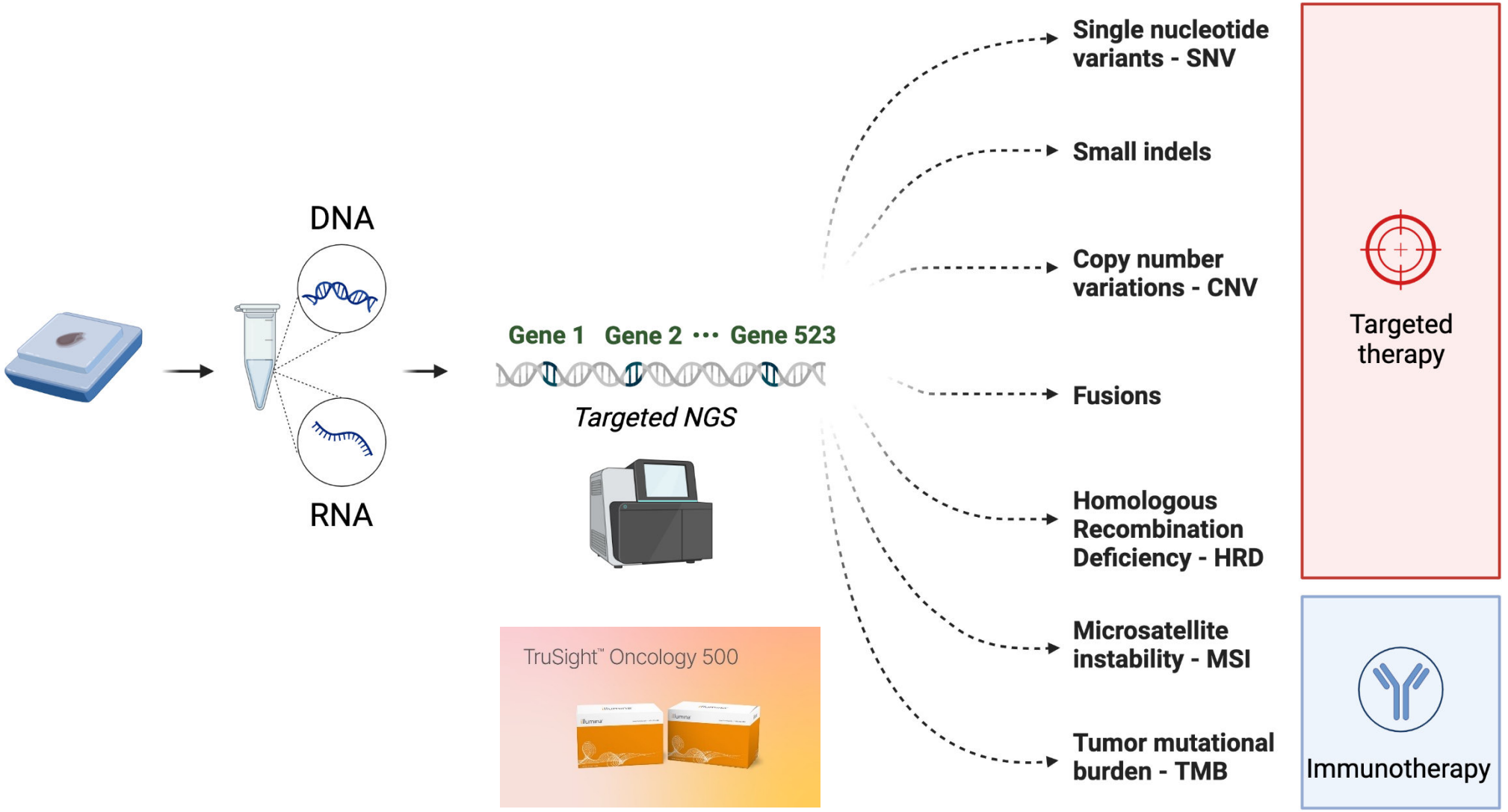
To evaluate the ***clinical value*** of CGP in "real-world" practice for offering more therapeutic options to patients

To support decision for ***reimbursement*** of CGP

Study design



Comprehensive Genomic Profiling

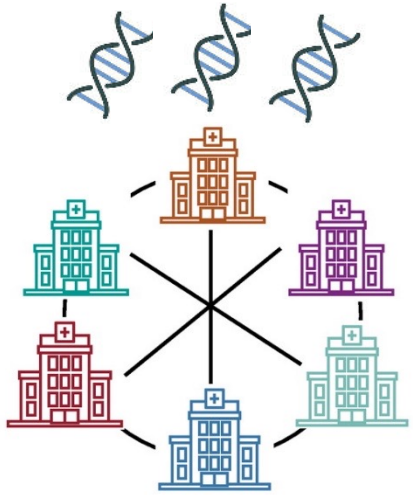


BALLETT: the national Molecular Tumor Board (nMTB)

Patients selected by local clinician

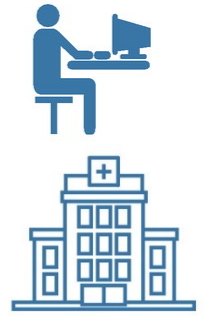
DNA prepared by local NGS lab

DNA samples collected from all hospitals



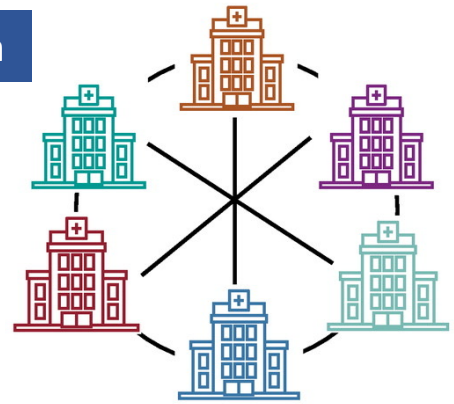
All pooled samples analysed alternating at 1 of 9 NGS labs

CGP data analysed and prepared for nMTB at local NGS labs



All patients are discussed at the **nMTB**

Every Friday at 2 pm



- Personalised treatment recommendation
- Approved drug
- Medical Need Program
- Off label drug
- Clinical trial

A report is generated and sent to the local clinician

BALLETT

Dashboard

Per patient data

ZNA05

Overview

Report

MTB discussions

Patients by MTB date

Reload data

DESIGNED BY

Jessa Ziekenhuis

Gender: Female , Age: 23
Tumortype: Brain Glioma
Diagnosis date: 31-07-2019
1 metastatic sites at inclusion
Liver metastasis: No
Lung metastasis: No
Bone metastasis: No
Brain metastasis: No
Other metastasis: lymph nodes

Number of previous treatment lines: 1
Including: Radio-chemotherapy
Most recent: Chemotherapy , Cisplatin, vincristine, lomustine
Period: 06-04-2022 to 16-02-2021
Best response: Stable Disease

PATIENT INFO | CGP RESULTS | DRUGS | MTB

INCLUSION INFO

Physician: Dr. [redacted]
Signed ICF version n°: 4
ICF signature date: 27-03-2022

DEMOGRAPHICS

Gender: Female
Age: 23
ECOG at inclusion: 0
Smoking status: No

CGP SAMPLE INFO

Lab reference of FFPE block: 22B264761
Sampling date: 17-02-2022
Metastatic site, Lymph node
Tumor cell %: 80

PATHOLOGY

Tumortype: Brain Glioma
Subtype: Other
Diagnosis date: 31-07-2019
1 metastatic sites at inclusion
Liver metastasis: No
Lung metastasis: No
Bone metastasis: No
Brain metastasis: No
Other metastasis: lymph nodes

IHC/ISH MARKERS

MARKERS

Markers	Presence
HER2	Not available
ER	Not available
PR	Not available
ALK	Not available
ROS1	Not available
pan-TRK	Not available
HPV	Not available
MMR	Not available > ?
PDL1	No

PDL1 IHC

Not applicable

TREATMENT HISTORY

Medulloblastoma
05/11/2019 untill 17/12/2019: adjuvante chemoradiotherapie (36 Gy in 20 fracties op de craniospinale as, gevolgd door boostbestraling van 18 Gy in 10 fracties op het resectiegebied; gecombineerd met wekelijkse perifere toediening van vincristin 2mg)
6/4/2022: start Cisplatin, vincristine, lomustine

BALLETT

Dashboard

Per patient data

Jessa24

Overview

Report

MTB discussions

Patients by MTB date

Reload data

DESIGNED BY

Jessa Ziekenhuis

Gender: Female , Age: 41
Tumortype: Cholangiocarcinoma
Diagnosis date: 06-08-2021
3 metastatic sites at inclusion
Liver metastasis: Yes
Lung metastasis: Yes
Bone metastasis: Yes
Brain metastasis: No
Other metastasis: /

Number of previous treatment lines: 1
Including: Chemotherapy
Most recent: Chemotherapy , cisplatinum-gemcitabine
Period: 23-08-2021 to ?
Best response: ?

CGP RESULTS | PATIENT INFO | MTB

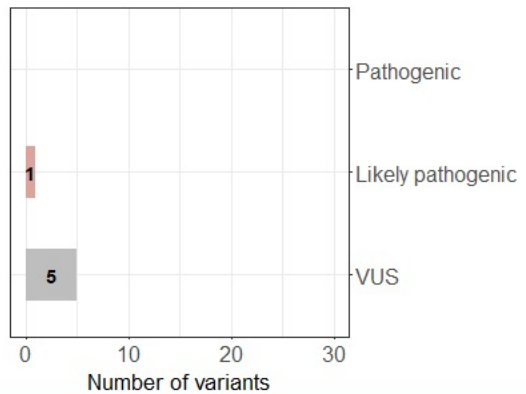
FUSION GENES

Fusion/Splice variant	Clinical class*
FGFR2-KIAA1598	TIER IA

AMPLIFICATION

Gene	Ratio	Clinical class*
MDM4	2	TIER III

NUMBER OF VARIANTS PER BIOLOGICAL CLASS



TMB
4 ns variants/Mb

MSI
Negative

CANCER PREDISPOSING GENE
BAP1
Germline variant likely? Yes

Sampling date: 06-08-2021
Primary tumor
Tumor cell %: 90

VARIANTS

Show 6 entries

Gene	HGVSc	HGVSp	Shortcode	VAF	Biological class	Validation	Clinical class*
BAP1	c.717dup	p.(Lys240Glnfs*3)	K240Qfs*	88%	Likely pathogenic	Consensus	TIER IID
PTPRD	c.4187G>A	p.(Arg1396Gln)	R1396Q	94%	VUS	Consensus	TIER III
ATM	c.6067G>A	p.(Gly2023Arg)	G2023R	50%	VUS	Consensus	TIER III
KMT2A	c.5665G>T	p.(Asp1889Tyr)	D1889Y	43%	VUS	Consensus	TIER III
SPTA1	c.6617T>C	p.(Ile2206Thr)	I2206T	31%	VUS	Consensus	TIER III
ARID1B	c.980G>C	p.(Gly327Ala)	G327A	7%	VUS	Consensus	TIER III

Showing 1 to 6 of 6 entries

Previous 1 Next

*AMP/CAP/ASCO/ACMG clinical classification system of sequence variants in cancer. Li et al, J Mol Diagn, 19(1):4-23 (2017) .

BALLETT

Dashboard

Per patient data

ZNA05

Overview

Report

MTB discussions

Patients by MTB date

Reload data

DESIGNED BY

Jessa Ziekenhuis

Gender: Female , Age: 23
Tumortype: Brain Glioma
Diagnosis date: 31-07-2019
1 metastatic sites at inclusion
Liver metastasis: No
Lung metastasis: No
Bone metastasis: No
Brain metastasis: No
Other metastasis: lymph nodes

Number of previous treatment lines: 1
Including: Radio-chemotherapy
Most recent: Chemotherapy , Cisplatin, vincristine, lomustine
Period: 06-04-2022 to 16-02-2021
Best response: Stable Disease

PATIENT INFO | CGP RESULTS | DRUGS | MTB

TIMELINE

Diagnosis: 31-07-2019
Sample: 17-02-2022
CGP results: 11-04-2022
Laboratory pre-discussion: 15-04-2022
MTB discussion: 15-04-2022
Feedback to physician: 15-04-2022

CANCER PREDISPOSING GENE
PTCH1
Germline variant likely? Yes

NOTES FOR MTB

MARKERS FOR MATCHED THERAPY

TARGETED DRUG

Gene	Pathway	Drug class	Drug name
PTCH1	Sonic hedgehog pathway	Sonic hedgehog pathway inhibitor	vismodegib, sonidegib

IMMUNOTHERAPY DRUG
None

THERAPY RECOMMENDATIONS

Priority 1

The molecular profile (PTCH1 mutated, TERTp mutated, TP53 wild-type) suggests this case belongs to the SHH-activated medulloblastoma molecular subtype. These findings may predict good response to the sonic hedgehod pathway inhibitors Erivedge (vismodegib) (Roche) and Omdomzo (sonidegib) (Novartis), approved for basal cell carcinoma. Off-label use of these drugs may be considered, eg. combined with temozolomide (see for similar case ref: https://actaneurocomms.biomedcentral.com/articles/10.1186/s40478-020-01000-w). Alternatively via DRUP trial in the Netherlands: The Drug Rediscovery Protocol (DRUP Trial) - ClinicalTrials.gov: NCT02925234 (PTCH1-mut medulloblastoma cohort)

Priority 2

/

Priority 3

/

Priority 4

/

Report preview

Download report as PDF

BALLETT BSMO

15-04-2022

To Dr. [redacted]

BALLETT patient ZNA05

Dear colleague,

Your patient was discussed by the BALLETT laboratory working group on 15-04-2022 and during the Molecular Tumor Board on 15-04-2022.

Please find below the summary of the patient data, the results of the 'Comprehensive Genomic Profiling' (performed by the TSO500 kit of Illumina) as well as the therapy recommendation(s) based on the genomic results. Please consider these recommendation(s) in view of all detailed patient factors, treatment history, contraindications, other therapy options and patient's preferences. The final treatment decision (including clinical trial eligibility assessment) is the full and sole responsibility of the treating physician.

Patient summary

Gender: Female
Age: 23
Tumor type: Brain Glioma

Metastasis: Yes
1 metastatic sites at inclusion
Liver metastasis: No

BALLETT

Dashboard

Per patient data

Enter a patientID

Overview

Report

MTB discussions

Patients by MTB date

Reload data

DESIGNED BY

Jessa Ziekenhuis

Dashboard

PATIENTS | TESTING | TUMORTYPES | ALL ABERRATIONS | SNP/MNP | AMPLIFICATIONS | FUSIONS/SPLICE VARIANTS | TMB | MSI | CLINICAL SIGNIFICANCE | THERAPY RECOMMENDATION | GERMLINE

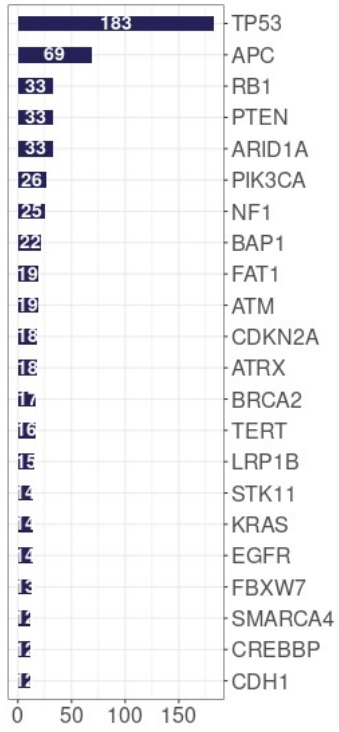
NUMBER OF UNIQUE VARIANTS IN GENES
((likely) pathogenic variants only)

Minimal number:

12 — 183

5 24 42 61 79 98 116 135 153 172183

Click on a bar to see the variants of the corresponding gene.



VARIANTS REPORTED IN BALLETT STUDY

Reset selection

Show 10 entries

Gene	HGVSc	HGVSp	Shortcode	Biological class	n
BRCA1	All	All	All	All	All
BRCA1	c.1164A>C	p.(Arg388Ser)	R388S	VUS	1
BRCA1	c.1231G>A	p.(Asp411Asn)	D411N	VUS	1
BRCA1	c.1276_1279del	p.(Ser426Argfs*3)	S426Rfs*3	Pathogenic	1
BRCA1	c.1390del	p.(Thr464Profs*11)	T464Pfs*	Pathogenic	1
BRCA1	c.1660G>A	p.(Glu554Lys)	E554K	VUS	1
BRCA1	c.1865C>T	p.(Ala622Val)	A622V	VUS	1
BRCA1	c.1907_1913del	p.(Cys636Tyrfs*13)	C636Yfs*13	Likely path...	1
BRCA1	c.199G>A	p.(Asp67Asn)	D67N	VUS	1
BRCA1	c.2086A>G	p.Thr696Ala	T696A	VUS	1
BRCA1	c.2311_2317del	p.(Pro773Leufs*)	P773Lfs*	Pathogenic	2

Showing 1 to 10 of 23 entries (filtered from 6,492 total entries) Previous 1 2 3 Next

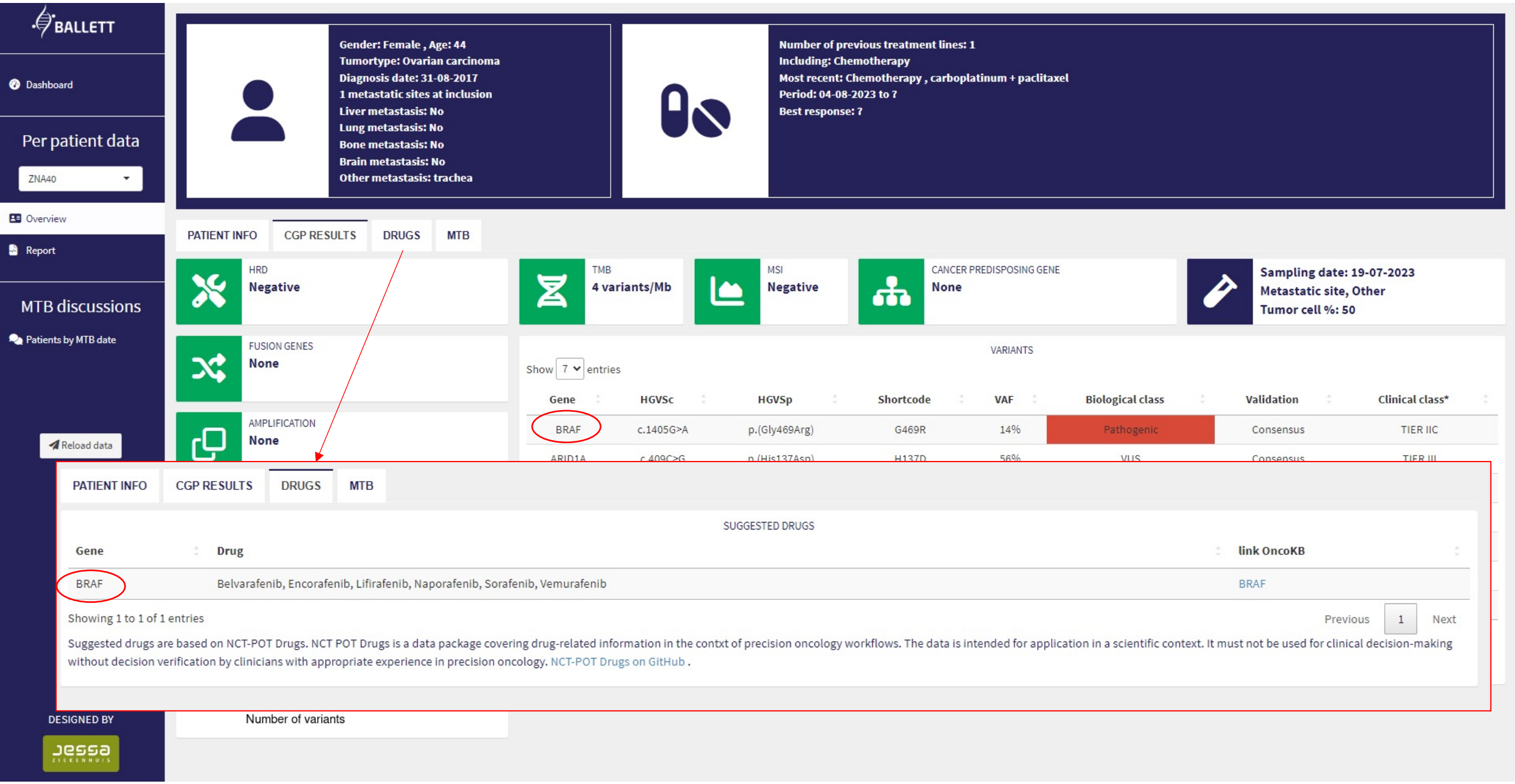
*AMP/CAP/ASCO/ACMG clinical classification system of sequence variants in cancer. Li et al, J Mol Diagn, 19(1):4-23 (2017) .

PATIENTS WITH VARIANT

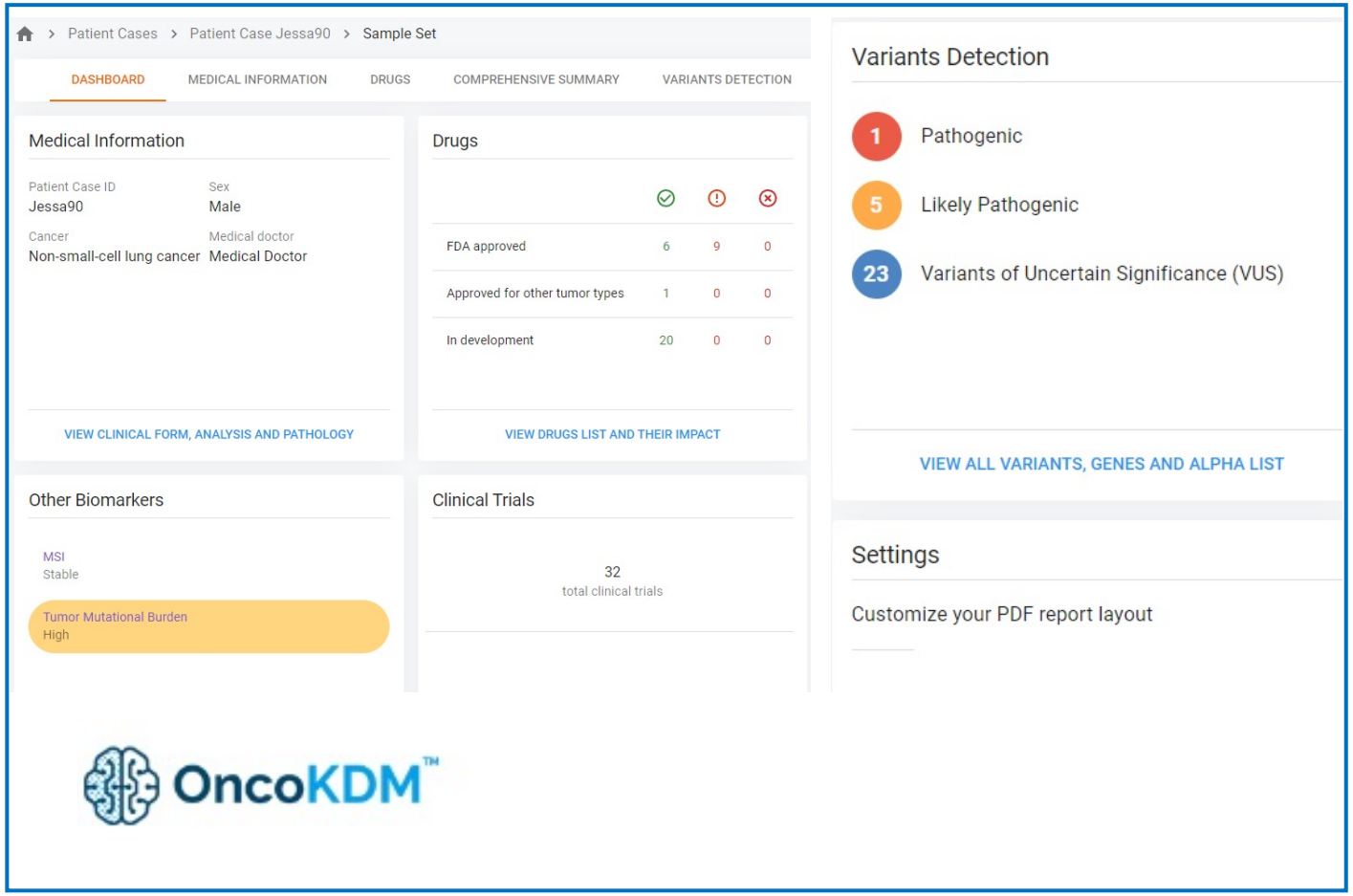
BRCA1 | c.2311_2317del | p.(Pro773Leufs*)

Patient_ID	Tumortype	Clinical class*
All	All	All
AZD071	Cholangiocarcinoma	TIER IIC
UZA46	Kidney cancer	TIER IIC

Showing 1 to 2 of 2 entries Previous 1 Next

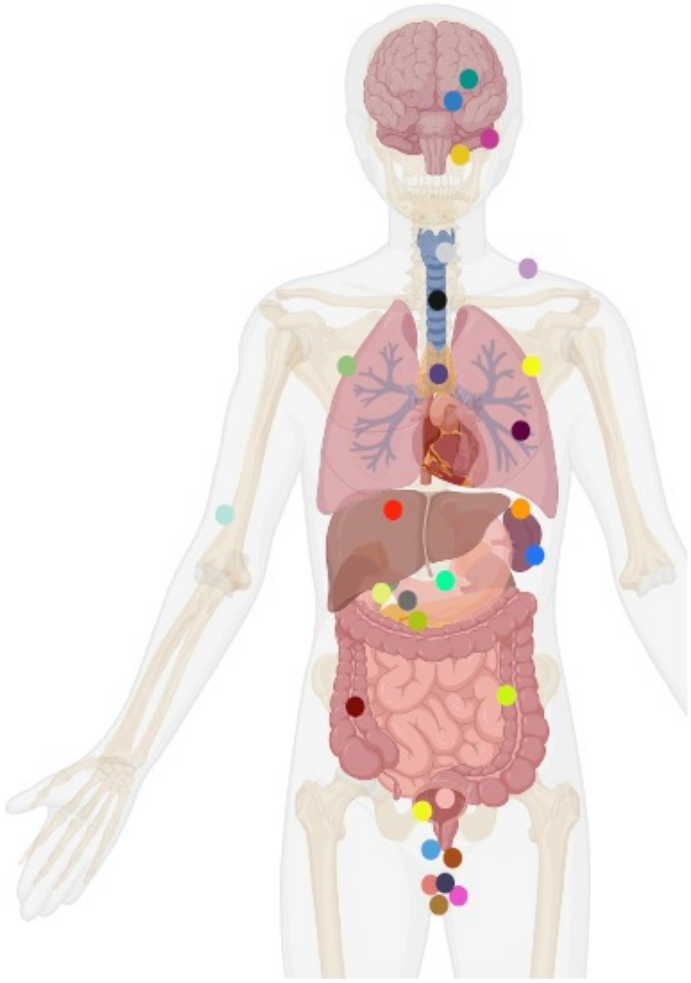

BALLETT
Dashboard
Per patient data
ZNA40
Overview
Report
MTB discussions
Patients by MTB date
Reload data
DESIGNED BY
Gender: Female , Age: 44
Tumortype: Ovarian carcinoma
Diagnosis date: 31-08-2017
1 metastatic sites at inclusion
Liver metastasis: No
Lung metastasis: No
Bone metastasis: No
Brain metastasis: No
Other metastasis: trachea
Number of previous treatment lines: 1
Including: Chemotherapy
Most recent: Chemotherapy , carboplatinum + paclitaxel
Period: 04-08-2023 to ?
Best response: ?
PATIENT INFO
CGP RESULTS
DRUGS
MTB
HRD
Negative
TMB
4 variants/Mb
MSI
Negative
CANCER PREDISPOSING GENE
None
Sampling date: 19-07-2023
Metastatic site, Other
Tumor cell %: 50
FUSION GENES
None
AMPLIFICATION
None
VARIANTS
Show 7 entries
Gene
HGVSc
HGVSp
Shortcode
VAF
Biological class
Validation
Clinical class*
BRAF
c.1405G>A
p.(Gly469Arg)
G469R
14%
Pathogenic
Consensus
TIER IIC
ARID1A
c.409C>G
p.(His137Asp)
H137D
56%
VUS
Consensus
TIER III
PATIENT INFO
CGP RESULTS
DRUGS
MTB
SUGGESTED DRUGS
Gene
Drug
link OncoKB
BRAF
Belvarafenib, Encorafenib, Lifirafenib, Naporafenib, Sorafenib, Vemurafenib
BRAF
Showing 1 to 1 of 1 entries
Previous
1
Next
Suggested drugs are based on NCT-POT Drugs. NCT POT Drugs is a data package covering drug-related information in the contxt of precision oncology workflows. The data is intended for application in a scientific context. It must not be used for clinical decision-making without decision verification by clinicians with appropriate experience in precision oncology. NCT-POT Drugs on GitHub .
Number of variants

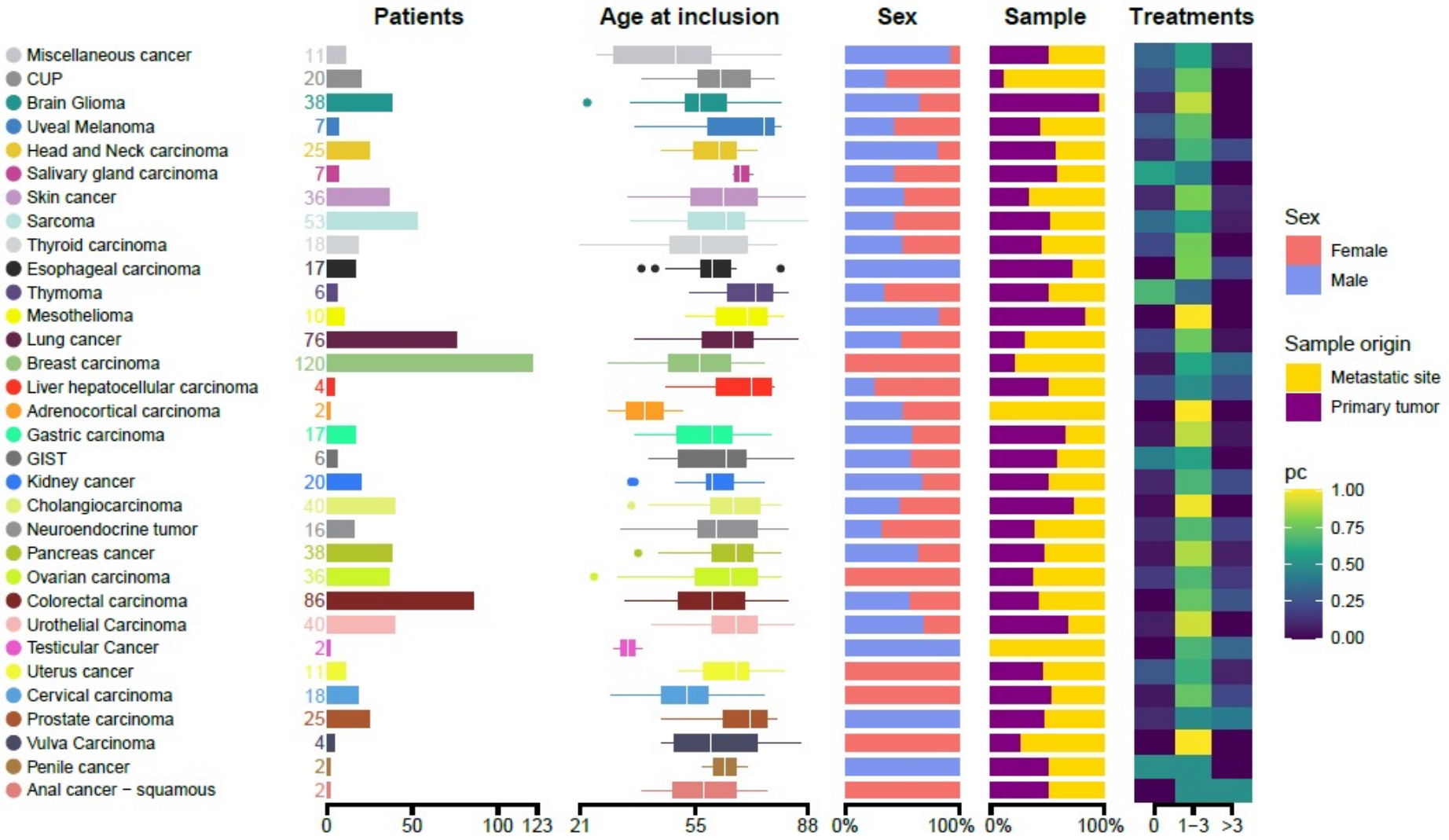
Tertiary NGS data analysis and Decision Support Systems



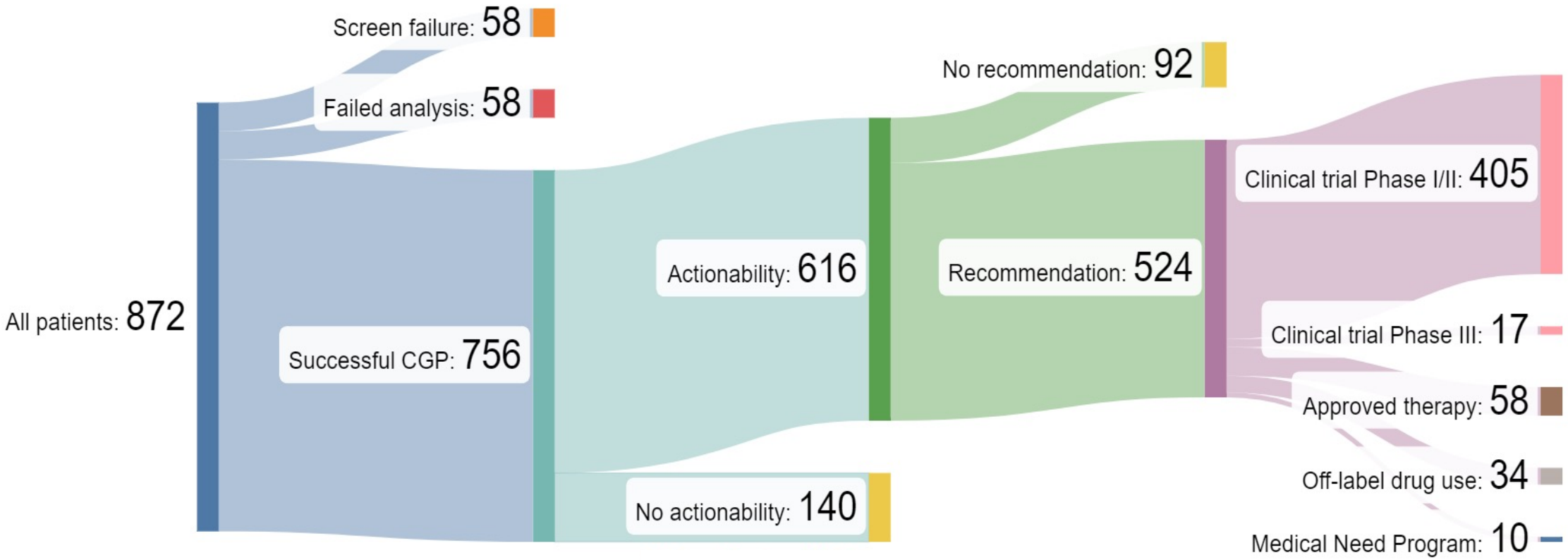
Results

Tumor types and patient characteristics (n = 813)



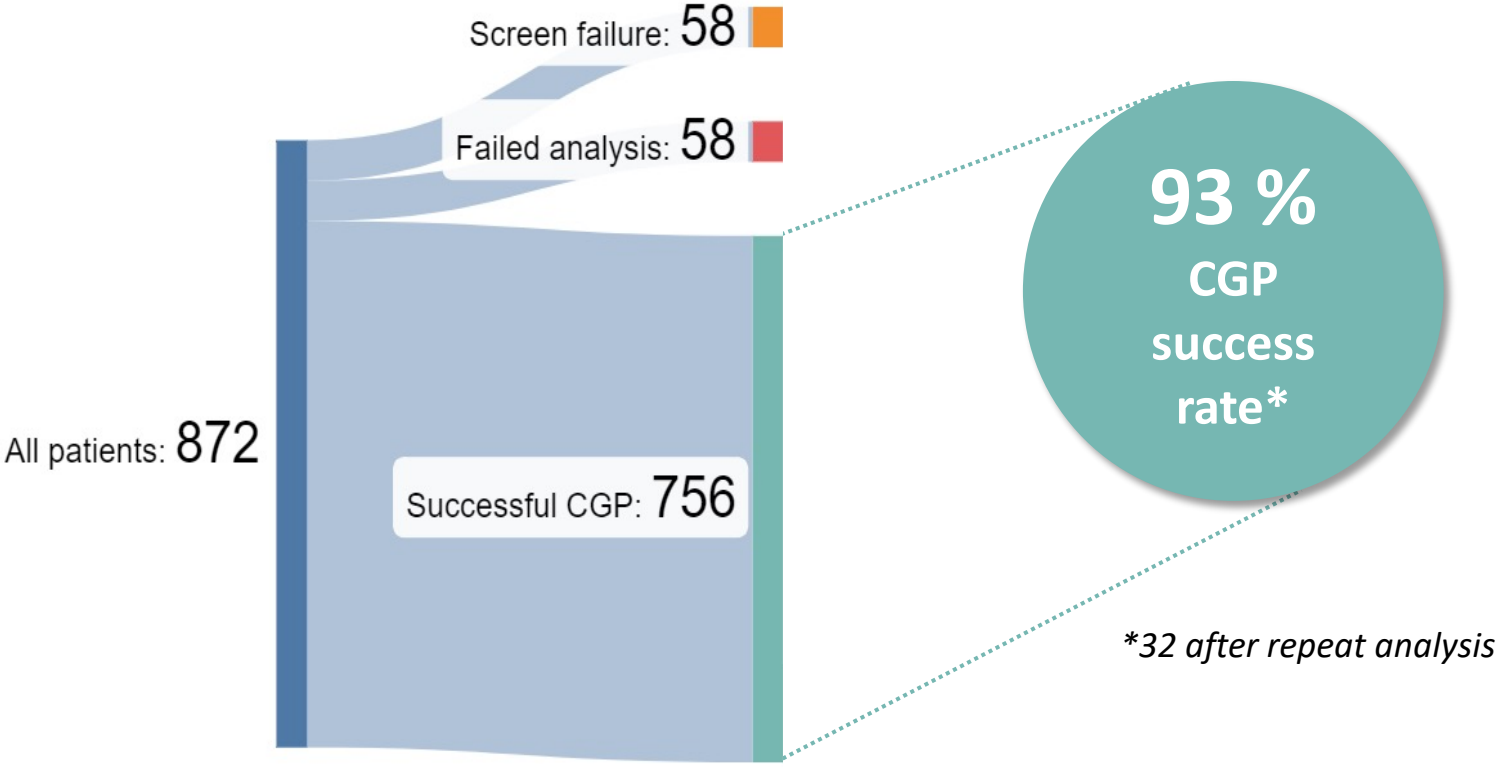


Study flow

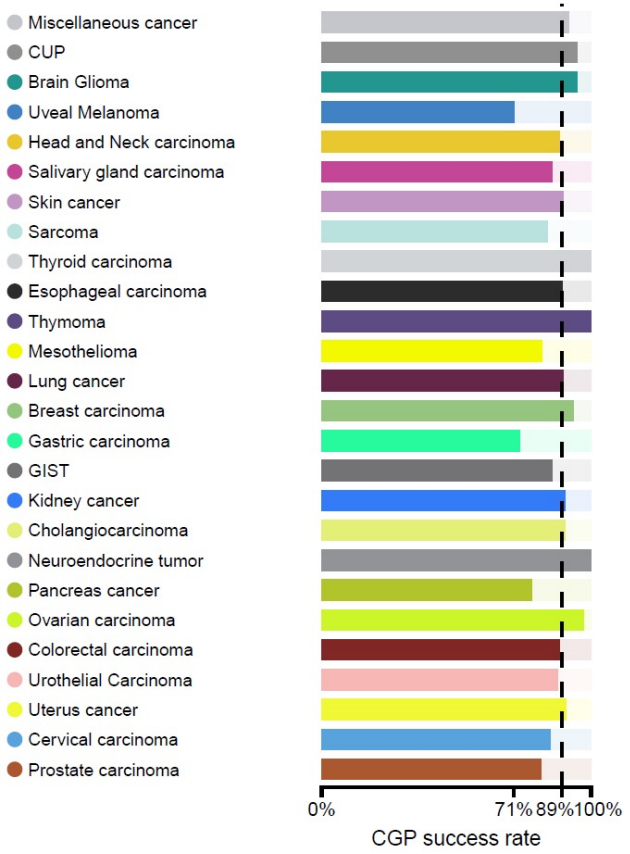

All patients: 872
Screen failure: 58
Failed analysis: 58
Successful CGP: 756
Actionability: 616
No actionability: 140
No recommendation: 92
Recommendation: 524
Clinical trial Phase I/II: 405
Clinical trial Phase III: 17
Approved therapy: 58
Off-label drug use: 34
Medical Need Program: 10

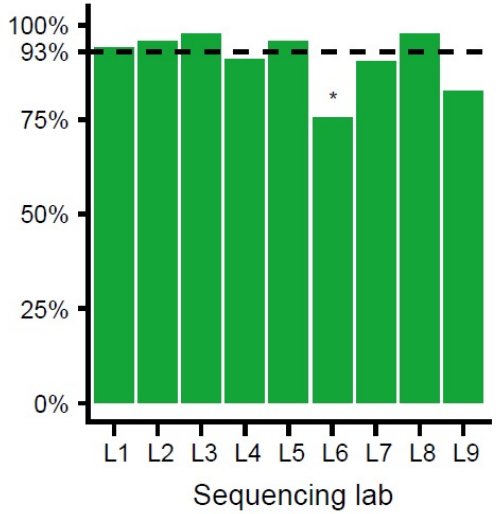
Results

CGP success rate



*32 after repeat analysis

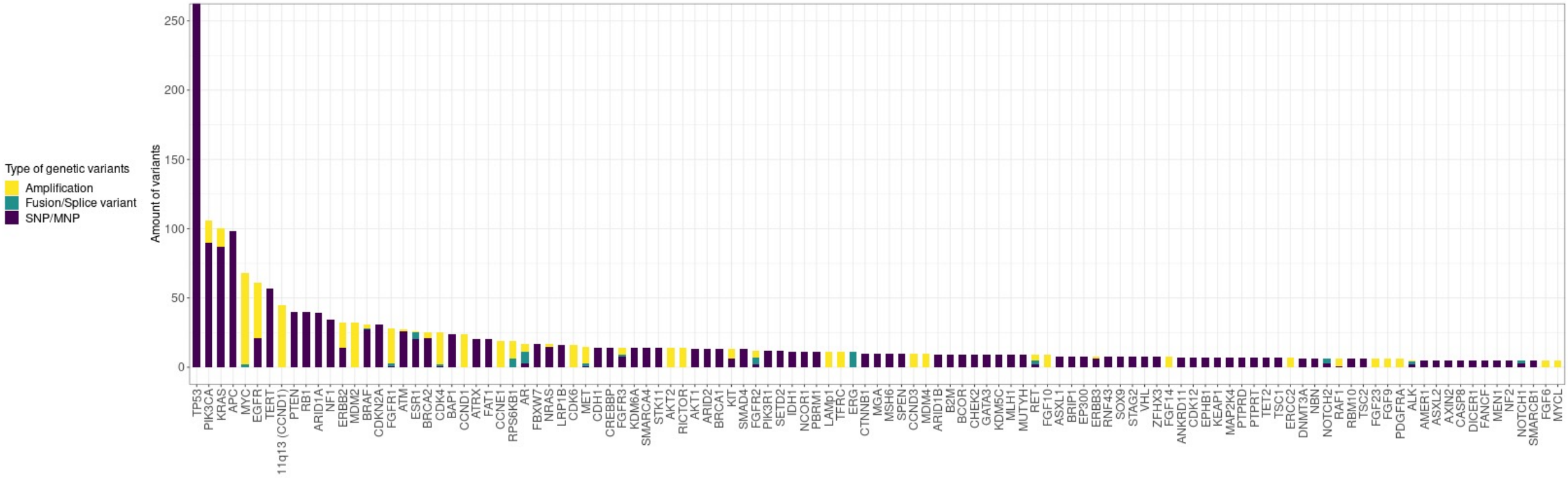




Results

All aberrations in all cases

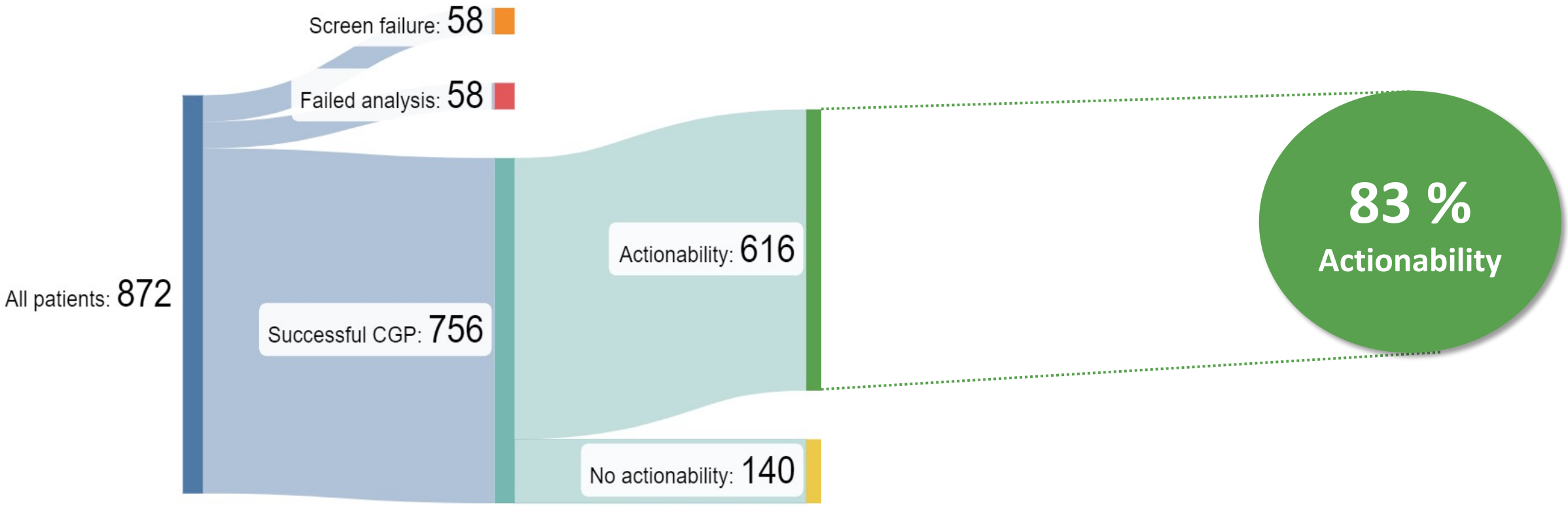
1465 SNVs and small indels, 579 amplification, 83 fusions



Genes with 5 or more aberrations

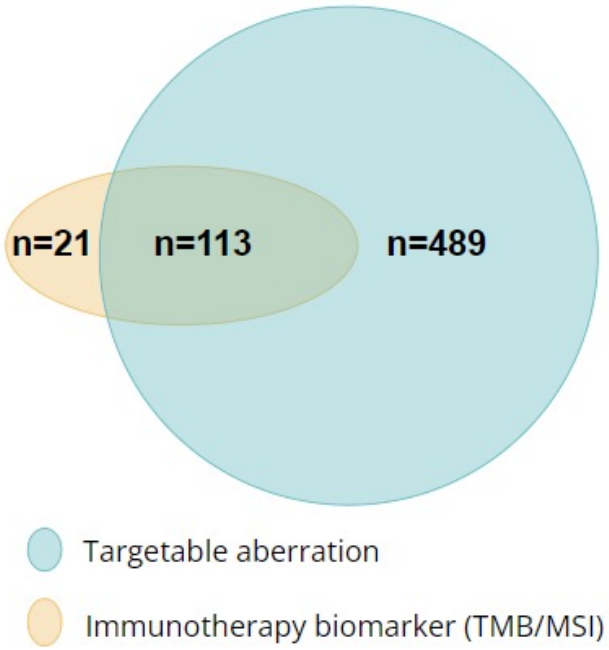
Results

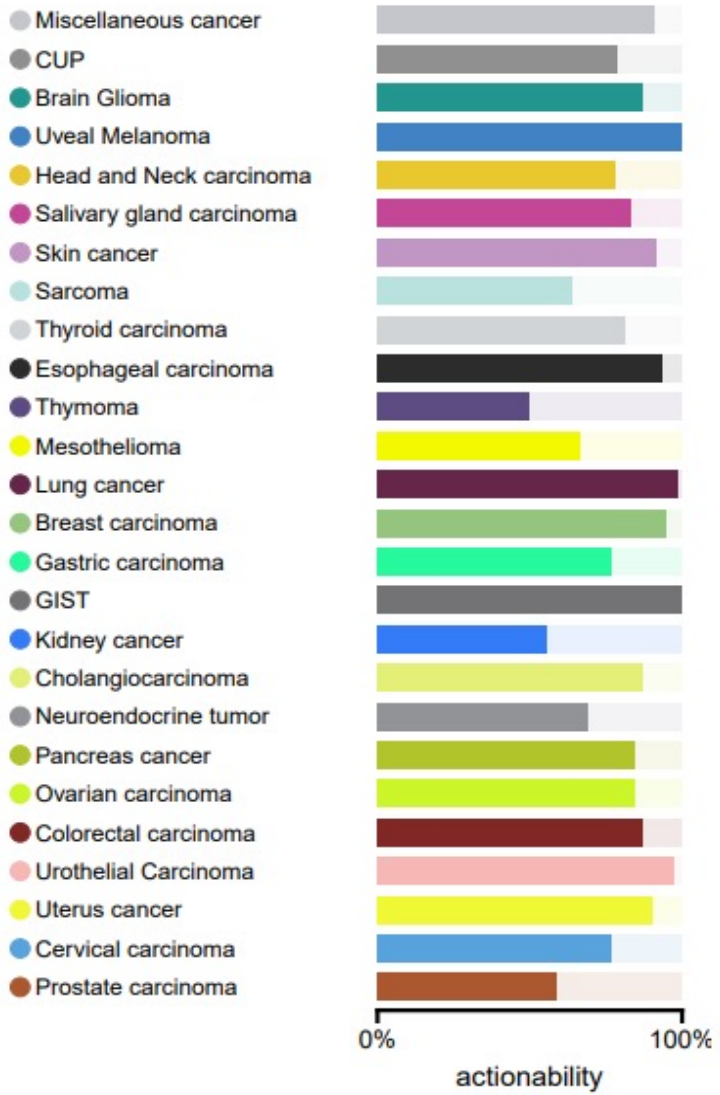
Actionability



Results

Actionability

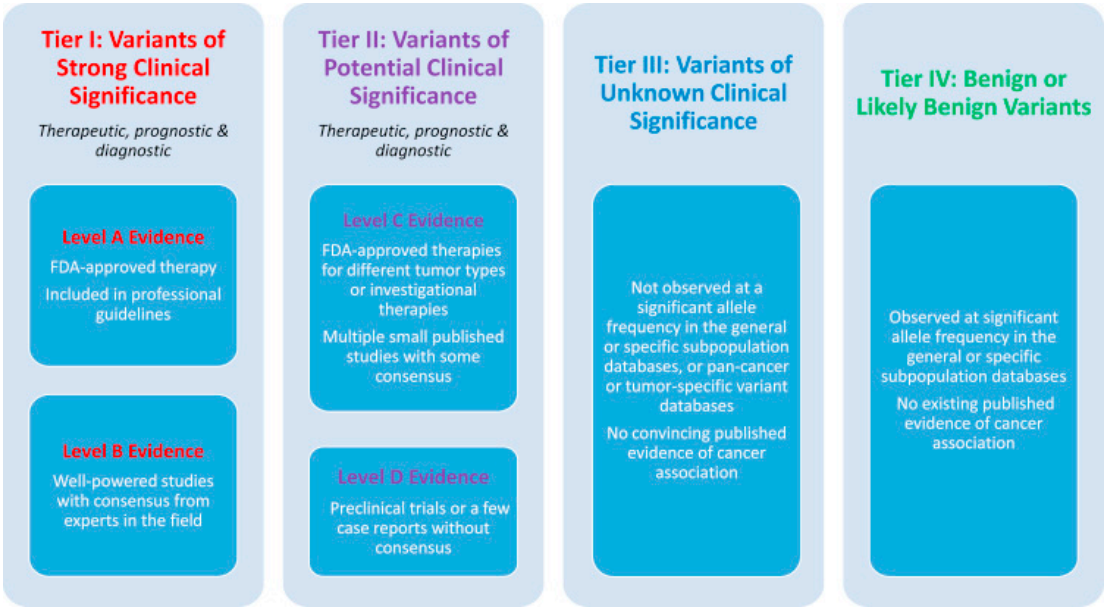


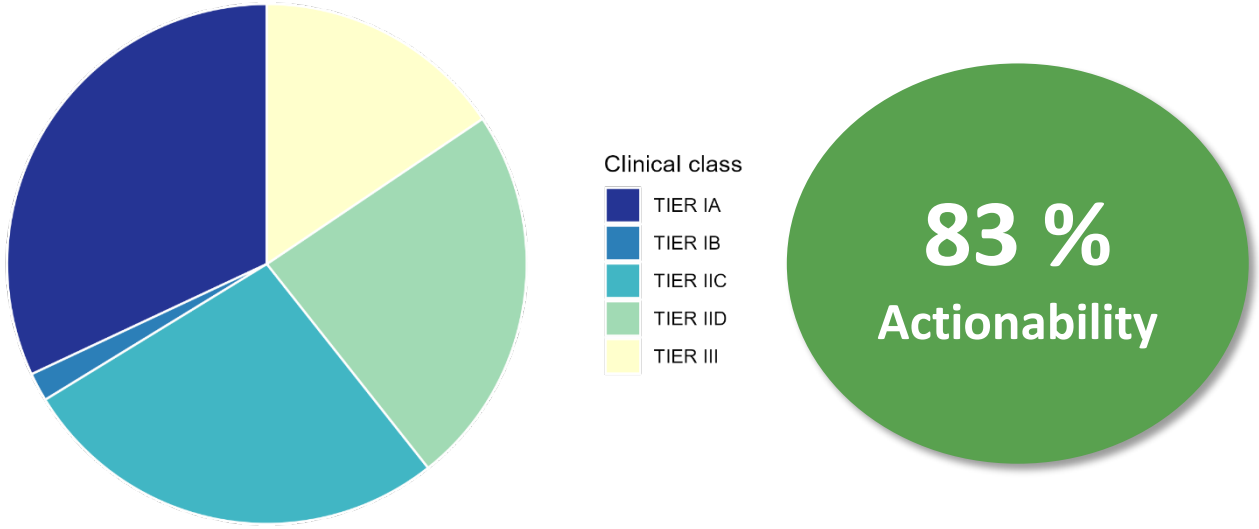


83 %
Actionability

Results

Clinical classification of biomarkers





Li et al, J Mol Diagn 2017

Results

Clinical classification of biomarkers per tumor type

Tier I: Variants of Strong Clinical Significance

Therapeutic, prognostic & diagnostic

Level A Evidence
FDA-approved therapy
Included in professional guidelines

Level B Evidence
Well-powered studies with consensus from experts in the field

Tier II: Variants of Potential Clinical Significance

Therapeutic, prognostic & diagnostic

Level C Evidence
FDA-approved therapies for different tumor types or investigational therapies
Multiple small published studies with some consensus

Level D Evidence
Preclinical trials or a few case reports without consensus

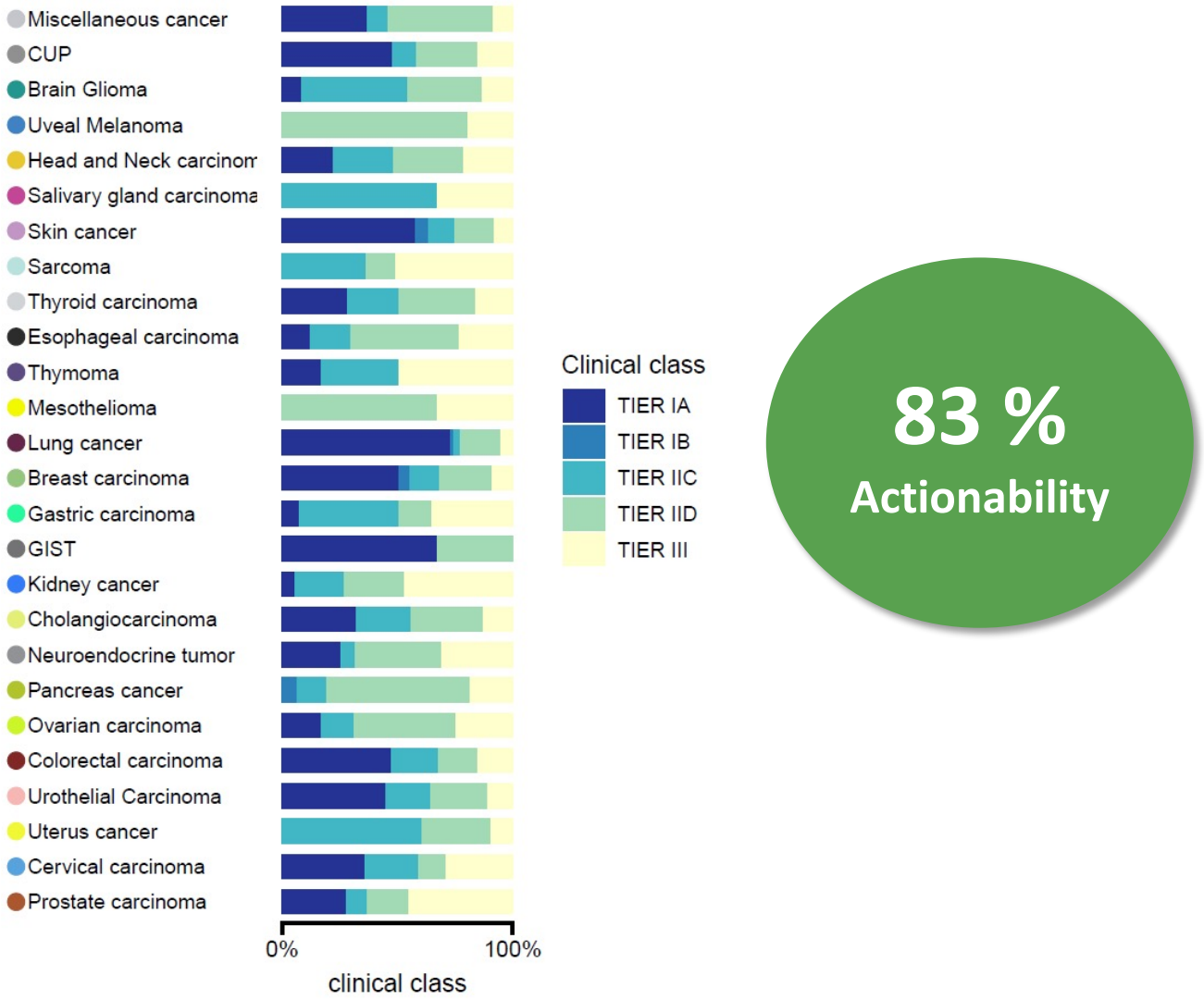
Tier III: Variants of Unknown Clinical Significance

Not observed at a significant allele frequency in the general or specific subpopulation databases, or pan-cancer or tumor-specific variant databases
No convincing published evidence of cancer association

Tier IV: Benign or Likely Benign Variants

Observed at significant allele frequency in the general or specific subpopulation databases
No existing published evidence of cancer association

Li et al, J Mol Diagn 2017



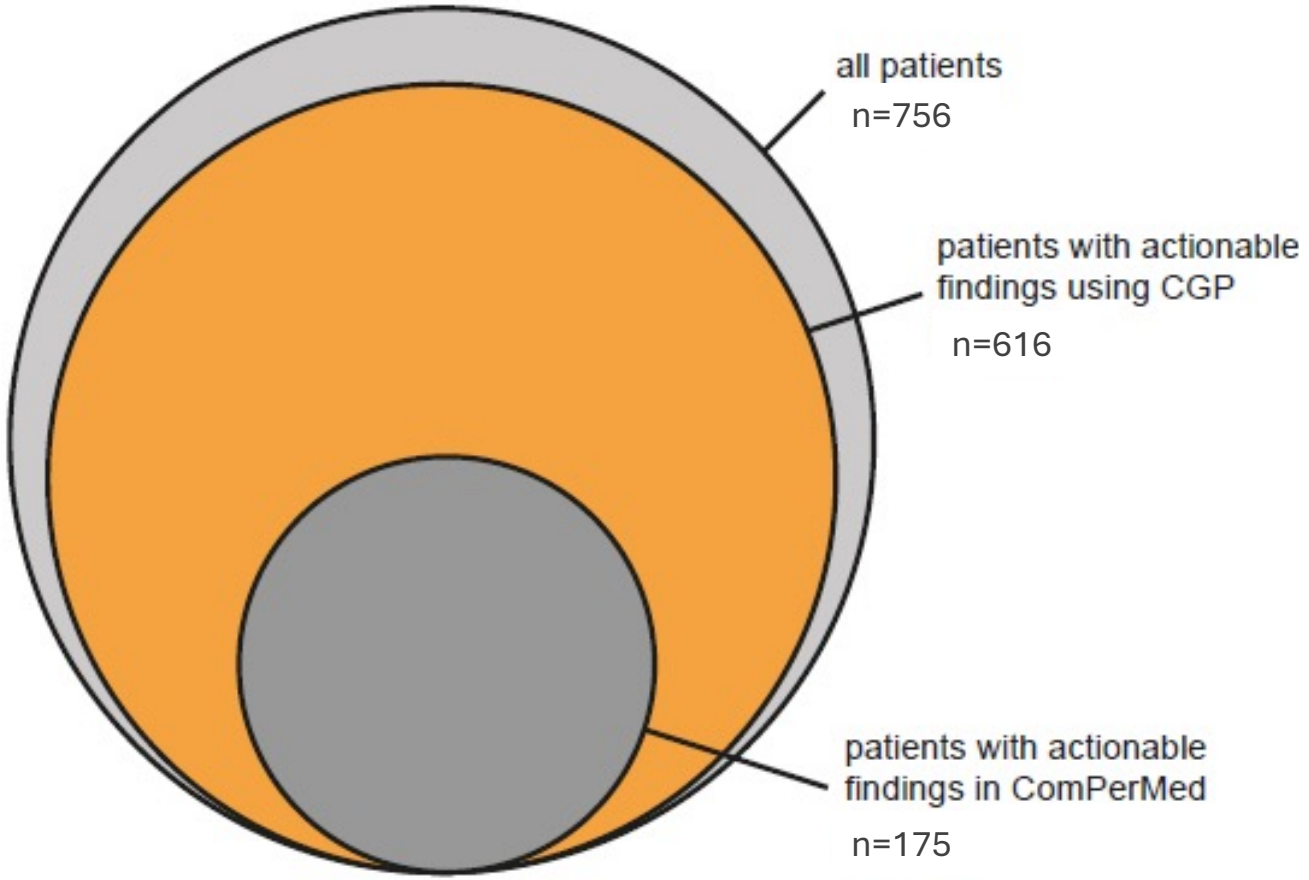
83 %
Actionability

Results

Actionability: per tumor type

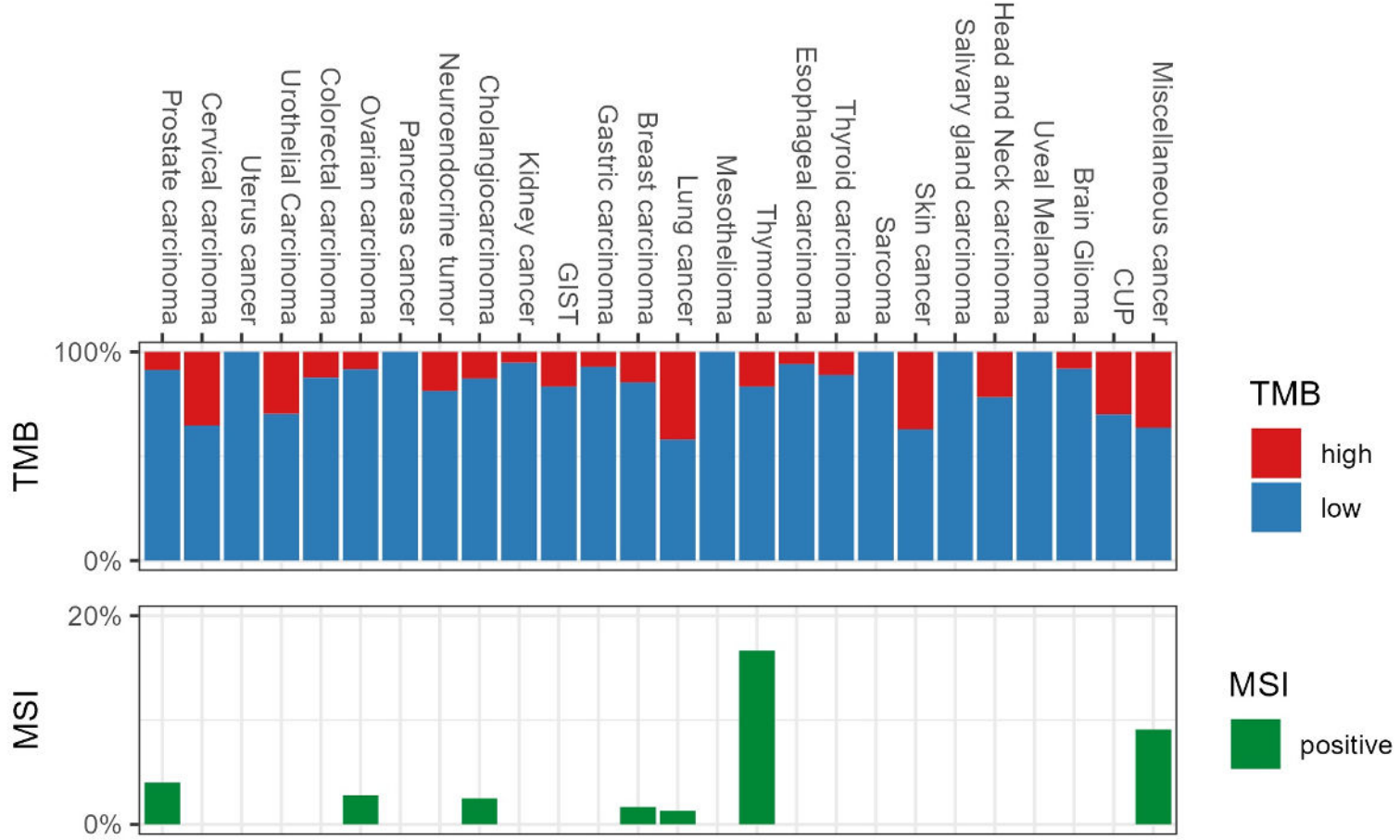
Results

Actionability: CGP versus ComPerMed



Results

Immunotherapy and PARPi biomarkers: TMB, MSI and HRD

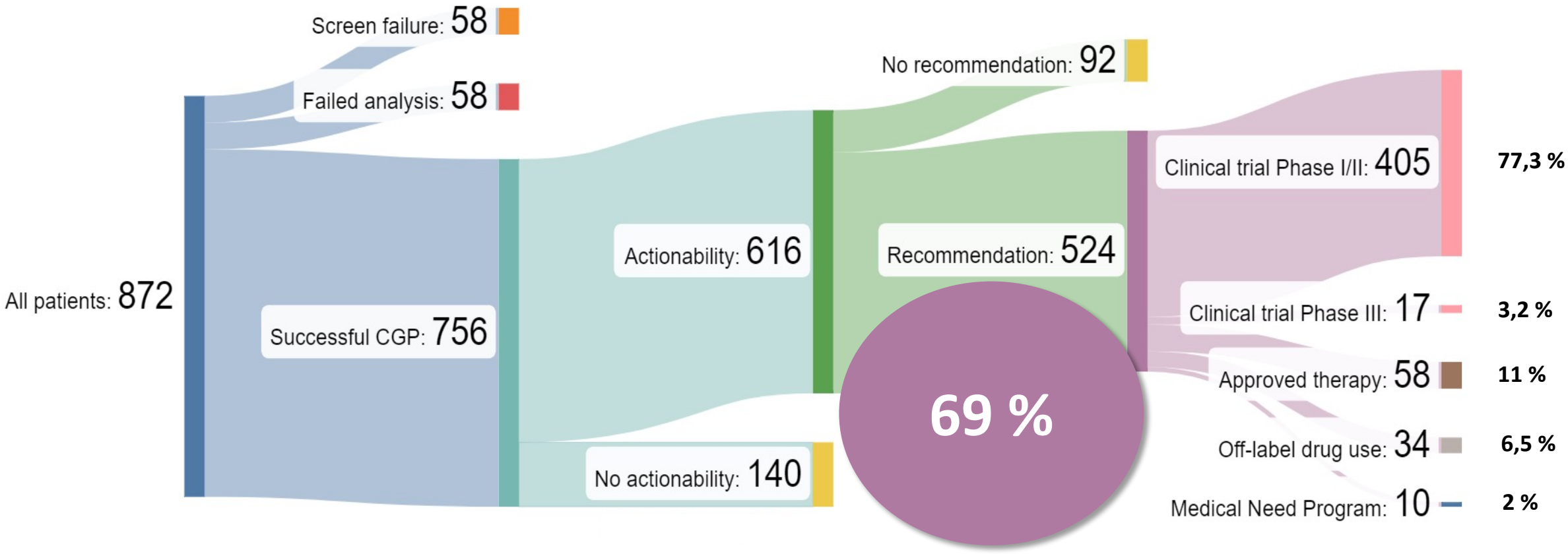


- Positive n=10
- Negative n=82
- Non-conclusive n=5

Included in CGP since April 2023 (n=97)

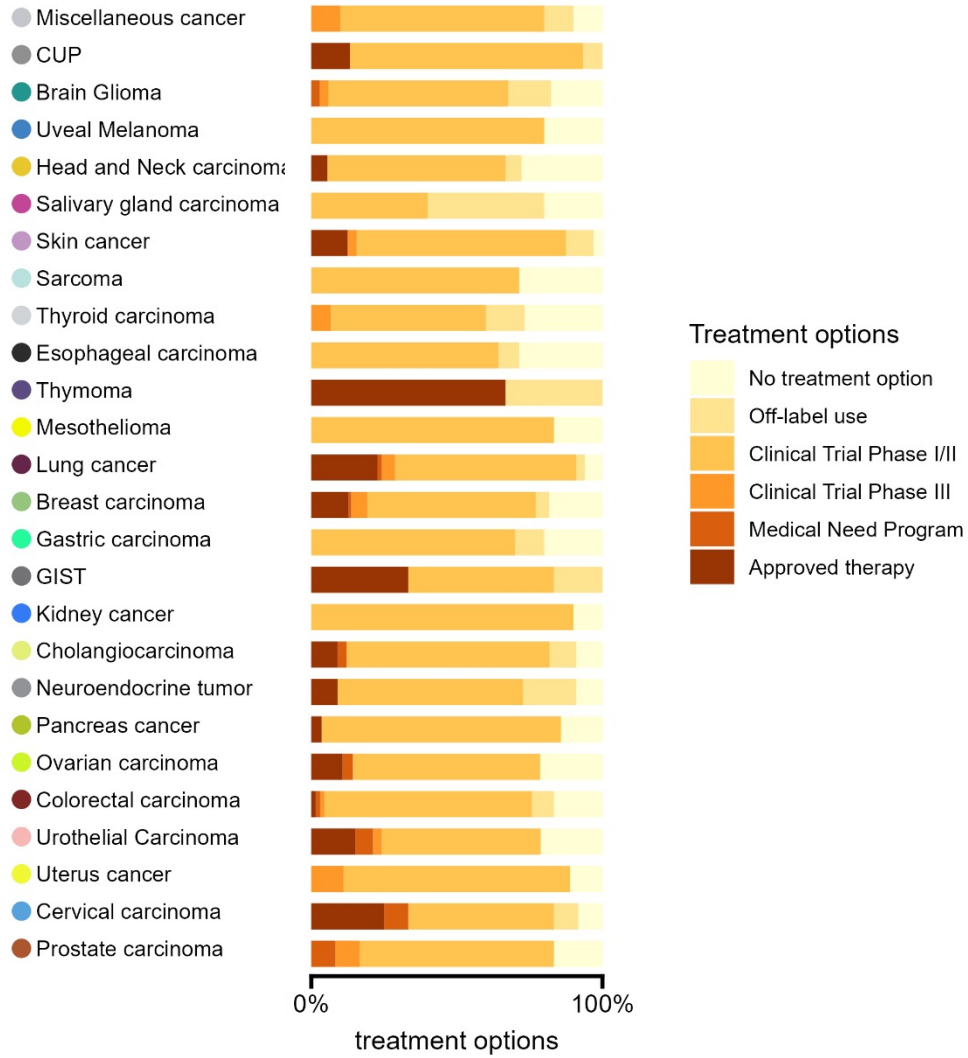
Results

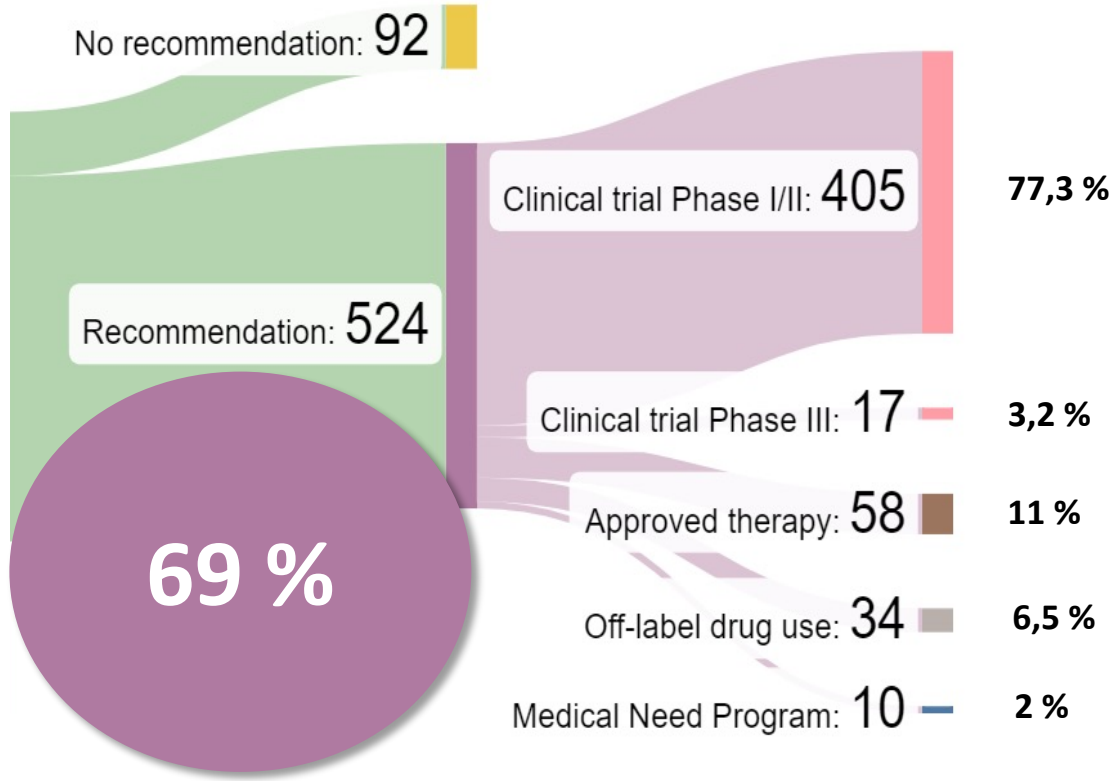
Treatment recommendations



Results

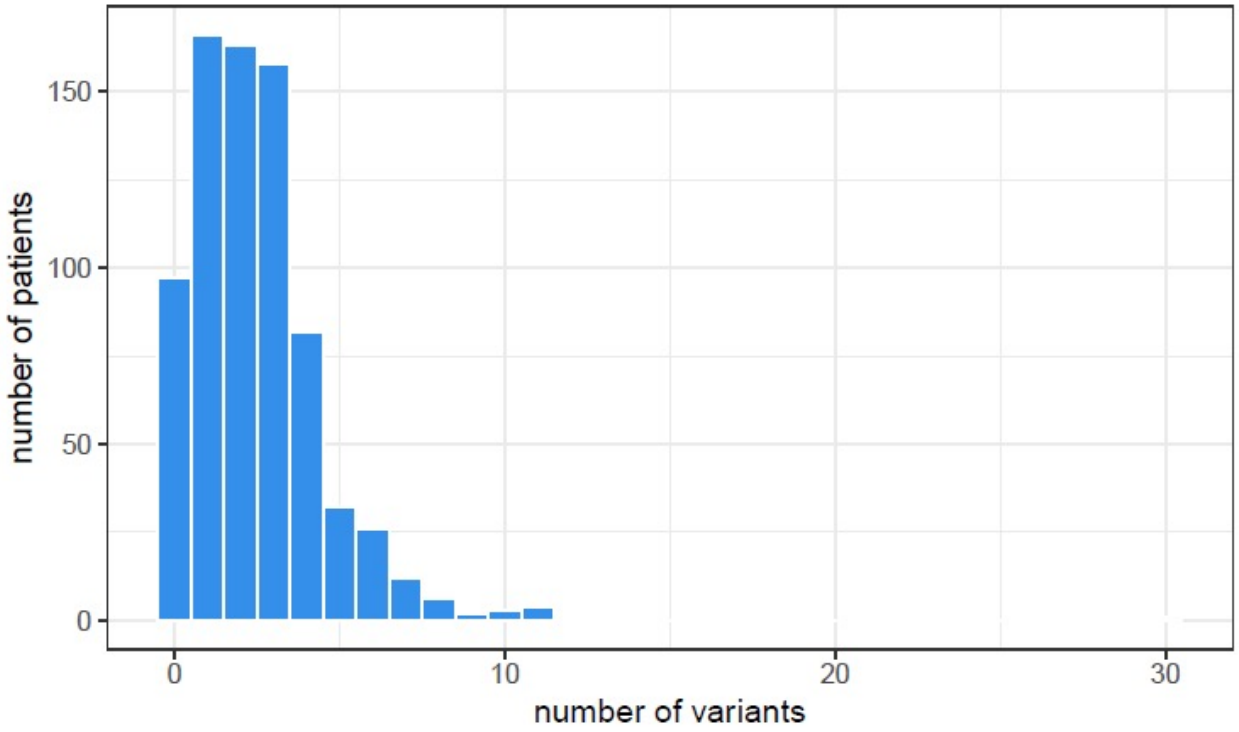
Treatment recommendations per tumor type

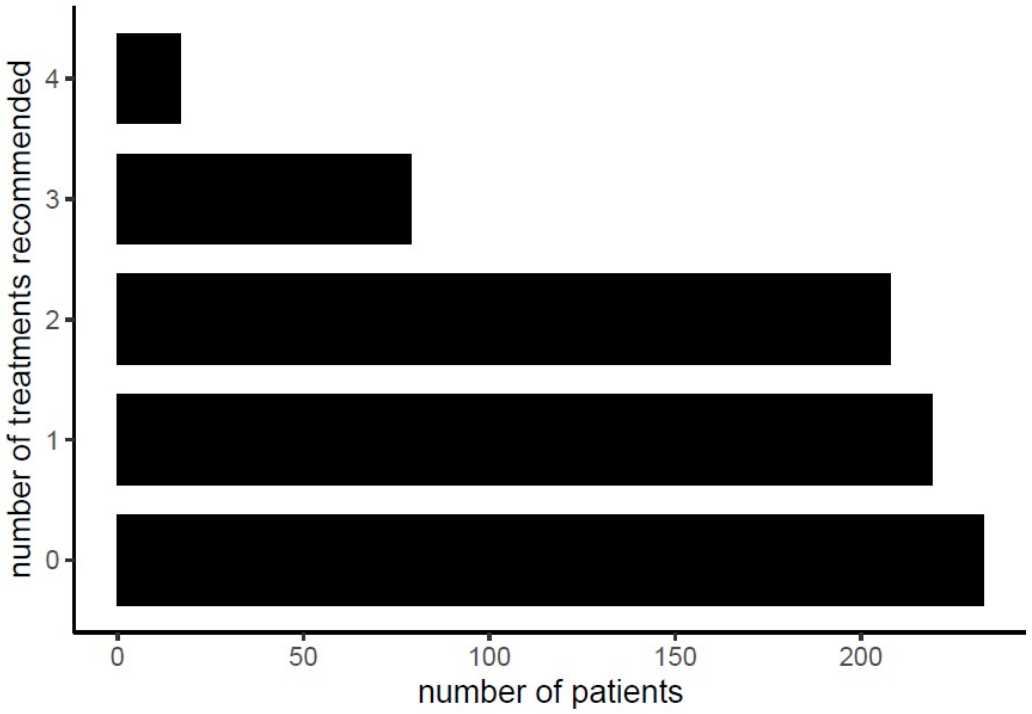




Results

Cooccurence of variants – multiple treatment recommendations per patient



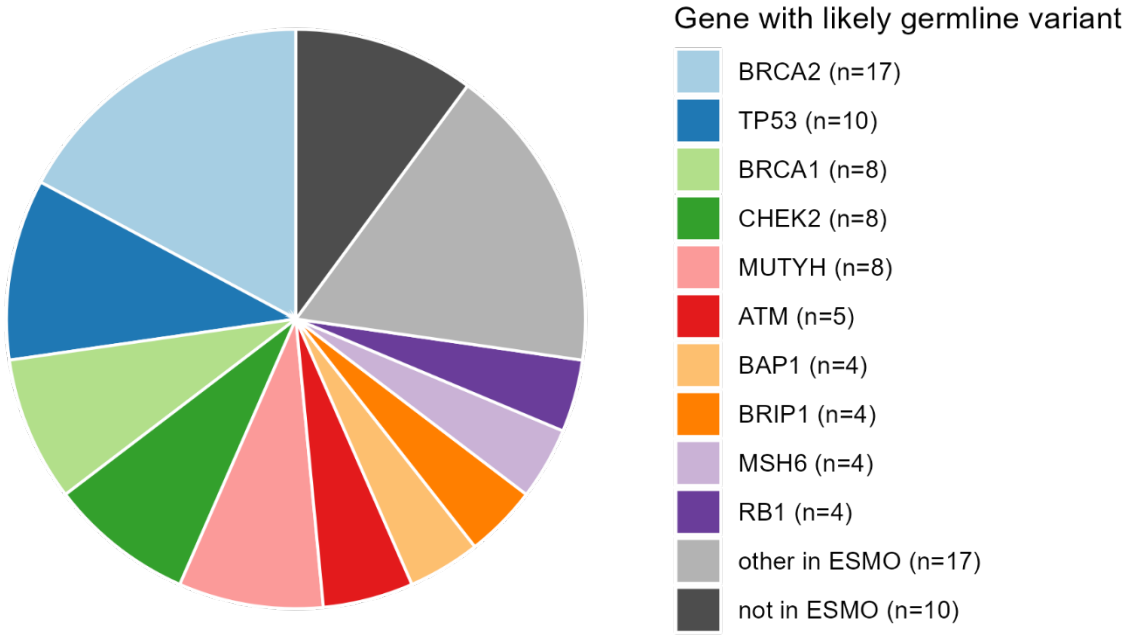


Results

Incidental findings of likely germline variants

Likely germline variant of cancer susceptibility gene (CSG) in 12 % of cases (n=90):

➡ Advice to refer for germline genetic testing and genetic counseling

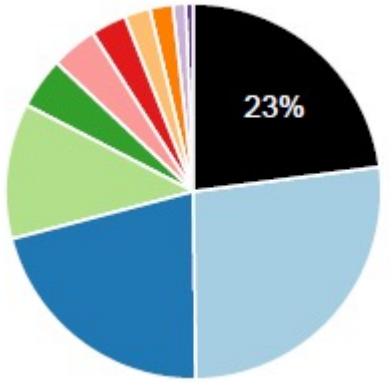


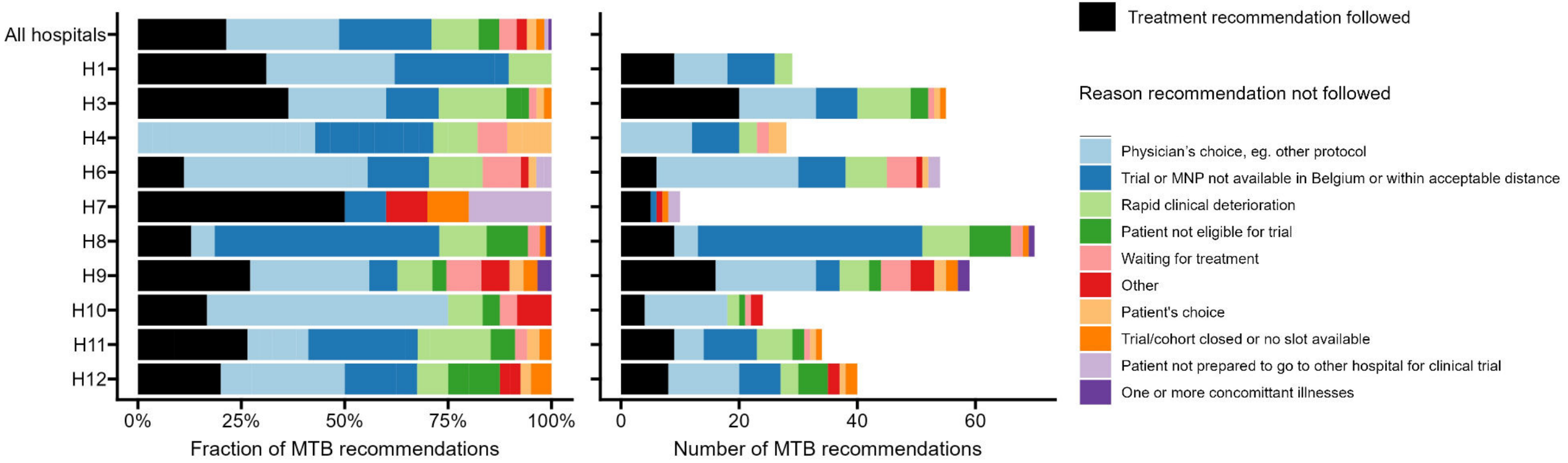
Reanalysis according to the recently updated ESMO recommendations for germline-focused analysis of tumor-only sequencing: 121 CSG variants in 111 patients (15 %)
(considering all the 40 ESMO CSG genes and all tumor types)

Kuzbari, Z. et al. *Annals of oncology* **34**, 215-227 (2023)

Results

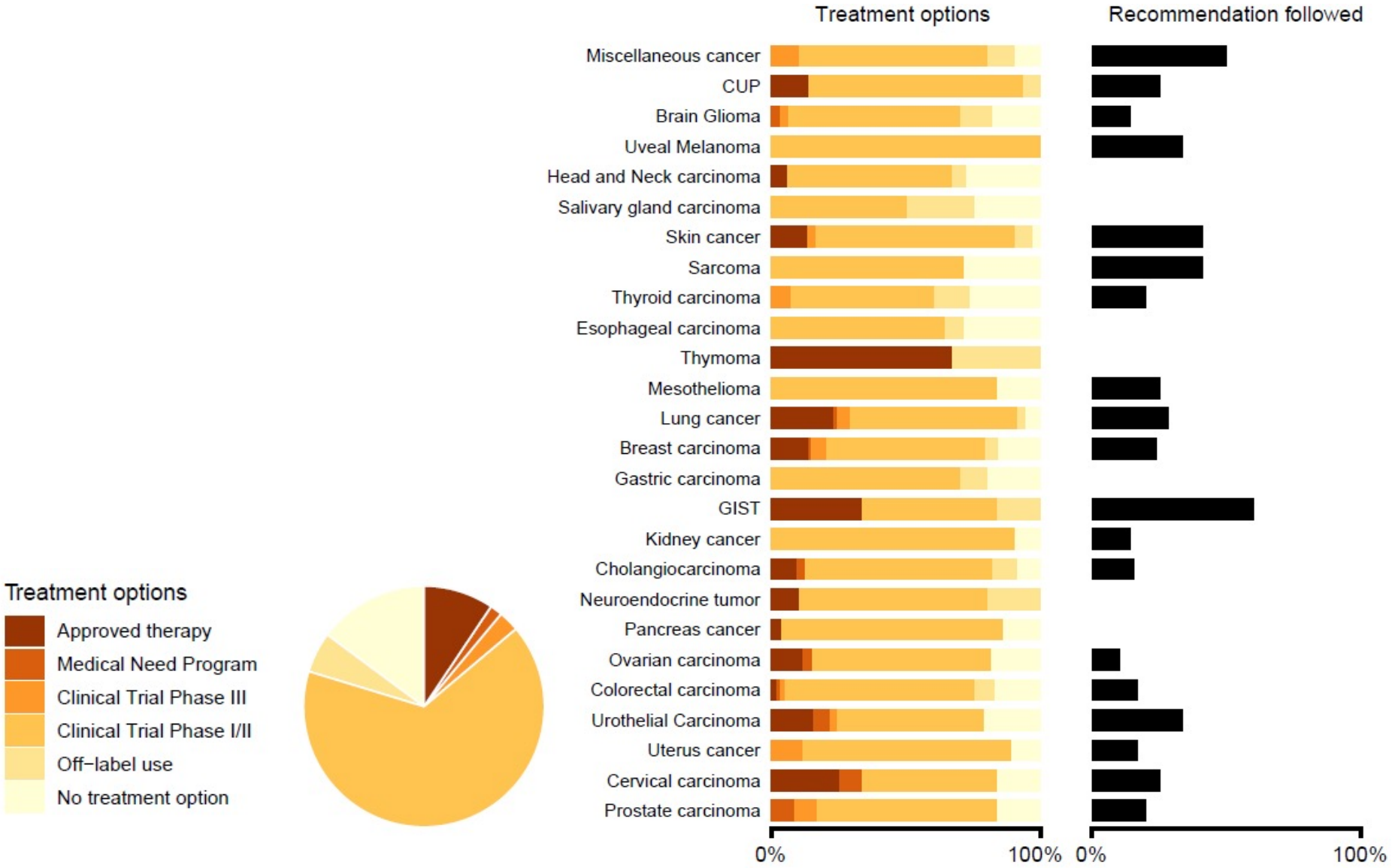
Uptake of treatment recommendations per hospital





Results

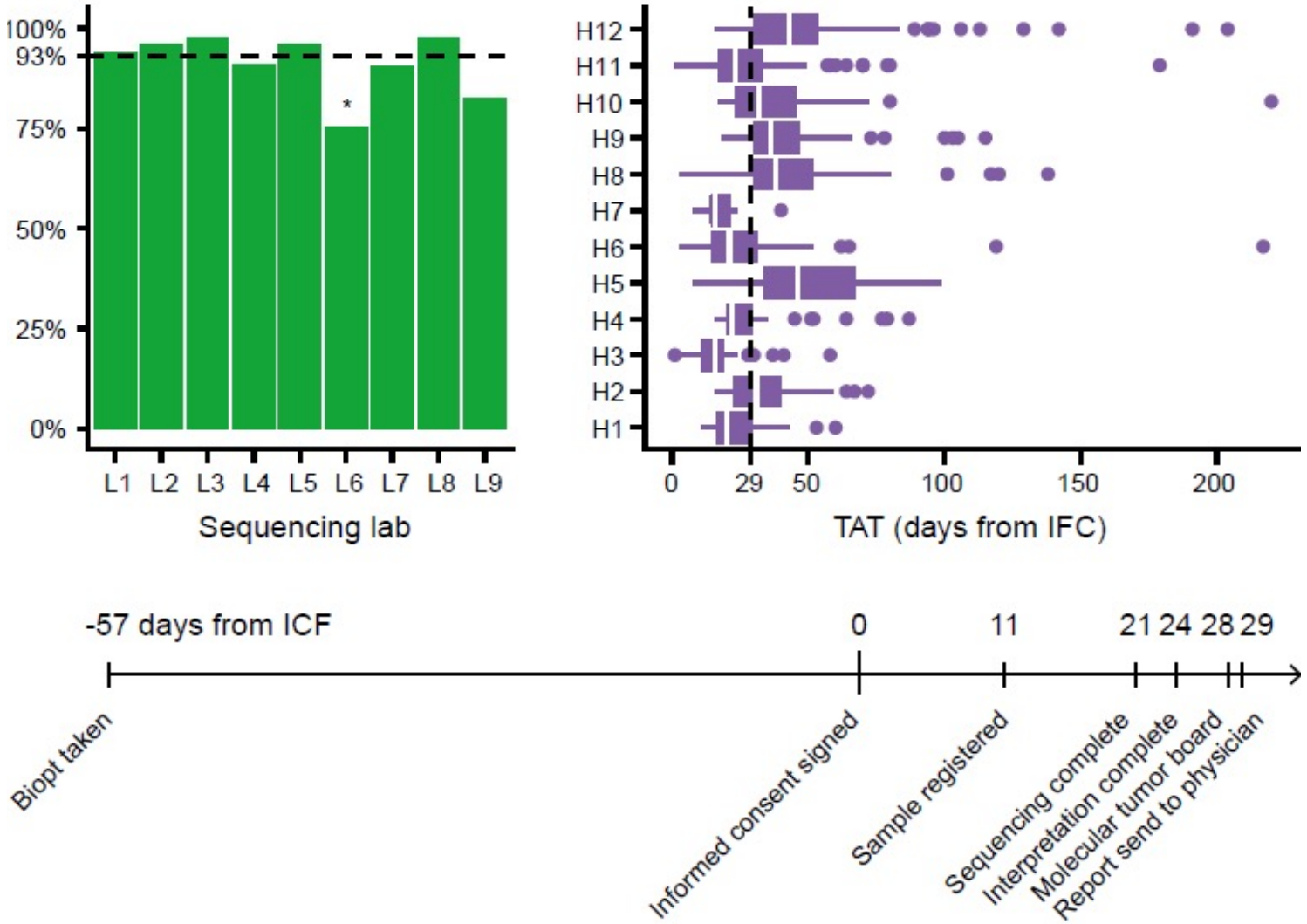
Uptake of treatment recommendations per tumor type



23 %

Results

Turn around times



- median TAT from inclusion to the nMTB report = 29 days
- 95% of the reports available within 66 days
- median TAT differed significantly between the hospitals (range: 18 days - 45 days, $p < 0.0001$, Anova).

Conclusions

- **Access** of patients to CGP
- Consortium of NGS labs working closely together and **exchanging expertise**
- **Standardization** of CGP in Belgium
- **nMTB** is a valuable framework for close collaboration of lab people and clinicians contributing to optimal patient management
- **BALLETT app**
- Study data analysis shows that:
  - **83 %** of cases has at least one (potentially) **actionable** variant and/or an immunotherapy biomarker
  - **69 %** of patients received a **treatment recommendation** based on CGP and nMTB discussion
  - **12 %** of patients received advice for **germline** genetic testing and counselling
  - **23 %** of patients were **treated** according to the CGP based treatment recommendation

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Limitations and challenges

- Standardization of clinical variant classification
  - Consistency
  - Evolving evidence
- Standardization and prioritization of therapy recommendation
- Consistency in the treatment uptake across hospitals
  - recommendations for selecting patients for CGP and dealing with treatment advises
- Access to treatments – Belgian DRUP-like trial desirable
- Clinical benefit yet to be determined based on the follow-up of the patients
- Limitations of the TSO500 CGP assay (HRD add-on, DRAGEN, cost, deletions, limited fusion panel)

Study of the comparison of OncoDeep versus TSO500

Sept. 2024	TSO500 (Illumina)	OncoDEEP (OncoDNA)
Total size	1.9 Mb	1.8 Mb

Detection at DNA level

	# genes	
SNVs and indels	523	638
CNV	514[&]	614
LOH	514[&,*]	41
	pan-tumor biomarkers	
MSI	Yes	Yes
TMB	Yes	Yes
HRD	Yes[&,*]	Yes

[&] *using DRAGEN analysis*

** as an add-on to the assay*

Detection at RNA level

	# driver genes	
Fusions	55	13
Splice variants	3	9

	TSO500 (Illumina)	OncoDEEP (OncoDNA)
		Pre-analytics
Recommended input	DNA: 40 ng RNA: 40 ng	DNA: 40 ng RNA: 80 ng dried
		Library prep
DNA Fragmentation	Shearing	Enzymatic
Use of UMIs	Yes	No
Normalisation	With beads	Quantification and dilution
		Hybridization capture
Pooling before hyb	No	Yes (8 samples)
# Hybridization times	Overnight + 2.5h	Overnight
		Automation
Instrument	MOA STAR	STARlet
max # samples	96	24
Hands-on-time	1.5 h	2 h
		Sequencing on a NextSeq550
Read length	2 x 101 bp	2 x 74 bp
#Samples per run	8; DNA + RNA	24; DNA + RNA
Flowcell NextSeq550Dx	HO v2.5 -300 cycles	HO v2.5 -150 cycles
		Data analysis
Sec and tert analysis	ICI (add-on)	OncoKDM

Coming soon

# diagnostic DNA samples	234
DNA extraction method	
# reference DNA samples	11
Based on TSO500 results	
# SNVs and indels	674
# amplifications (FC ≥6)	31
# MSI-High (>20%)	9
# TMB-High (>16)	22
# HRD pos (GIS ≥ 42)	0

# diagnostic samples with rearrangements	67
RNA extraction method	
# reference RNA samples	8
Based on TSO500 results	
# gene fusions	172
# splice variants (AR, EGFR, MET)	20

jessa ZIEKENHUIS · UZ GENT · az sint-jan brugge - oostende av · IPG · UMC Utrecht · Maastricht · Erasmus MC

Study of the comparison of OncoDeep versus TSO500

Analysis of Comprehensive Genomic Profiling of Solid Tumors with a Novel Assay for Broad Analysis in Clinical Diagnostics

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A Study to Examine the Clinical Value of Comprehensive Genomic Profiling Performed by Belgian NGS Laboratories: a Belgian Precision Study of the BSMO in Collaboration With the Cancer Centre - Full Text View - ClinicalTrials.gov: NCT05058937