A new era for better patient outcomes

Introducing
TruSight™ Oncology Comprehensive (EU)

illumina®

Imagine a better oncology

diagnostic environment

Current oncology patient care relies on multiple biomarker tests. This requires strict management of a limited patient biopsy sample as the iterative single-gene testing approach can lead to tissue depletion and repeat biopsies.[1-3] TruSight Oncology Comprehensive (EU) (TSO Comprehensive (EU)) is a comprehensive genomic profiling (CGP) solution that consolidates numerous individual tests into a single panel, minimizing the amount of sample needed and maximizing the ability to potentially identify an actionable alteration for better patient outcomes.

Comprehensive coverage
Clinical confidence

Conventional oncology testing approaches supply limited information that does not address all biomarkers in approved and emerging targeted therapies and immunotherapies. When a positive biomarker is not identified, patients end up receiving standard, nonmatched regimens due to a lack of better options. With TruSight Oncology Comprehensive (EU), patients can receive a CGP test that may increase their chances of being genomically matched with a potentially more effective therapy, leading to an improved outcome.[4-9]

A single CGP test can identify more clinically relevant variants than conventional tests, such as single-gene tests and hotspot NGS panels,[2,9-12] while saving time and preserving biopsy specimen. CGP enables detection of DNA plus RNA variants and complex biomarker signatures, such as tumor mutational burden (TMB) and microsatellite instability (MSI), generating a comprehensive genomic profile of the patient's tumor and increasing confidence in ensuring the right treatment decisions.

The biomarker content of TruSight Oncology Comprehensive (EU) covers :

64 Clinical guidelines

111 Drug labels

615 Clinical trials

Help inform targeted therapies for better patient outcomes

TruSight Oncology Comprehensive (EU) content includes critical biomarkers with known cancer associations as indicated in drug labels, European Society For Medical Oncology (ESMO) recommendations, and clinical trials for multiple solid tumor types.[13] The results of TruSight Oncology Comprehensive (EU) can help inform therapy decisions according to clinical guidelines.

In addition, an extensive pipeline of companion diagnostic indications that will help identify patients responsive to specific targeted and immunotherapies is under development.[14-17]

One test for multiple solid tumor types

Key actionable biomarkers covered for multiple solid tumor types.*

Genes listed contain biomarkers of clinical significance. Numbers indicate additional genes in TSO Comprehensive (EU) with biomarkers of potential clinical significance.

Breast

BRCA1
BRCA2
ERBB2
ESR1
PIK3CA

95

Colorectal

BRAF
ERBB2
KRAS
NRAS

89

Bone

EWSR1
EGFR
ERG
ETV1
ETV4
FLI1
IDH1

71

Lung

ALK
BRAF
EGFR
ERBB2
KRAS
MET
NUTM1
RET
ROS1

132

Melanoma

BRAF
KIT
NRAS

74

Ovarian

BRCA1
BRCA2
FOXL2

114

* The TruSight Oncology Comprehensive (EU) panel includes over 500 genes. To see the full gene list, view the product data sheet on www.illumina.com/tsocomprehensive

CNS†

ATRX
BRAF
EGFR
H3F3A
HIST1H3B
IDH1
IDH2
PTCH1
TERT
TP53

78

Prostate

ATM
BARD1
BRCA1
BRCA2
BRIP1
CDK12
CHEK2
FANCL
FGFR2
FGFR3
PALB2
PPP2R2A
RAD51B
RAD51C
RAD51D
RAD54L

99

Thyroid

BRAF
HRAS
KRAS
NRAS
RET
TERT

68

Uterine and cervical

ERBB2
ESR1
FOXO1
NCOA3
PAX3
PAX7
SMARCA4
SUZ12

112

Other solid tumors

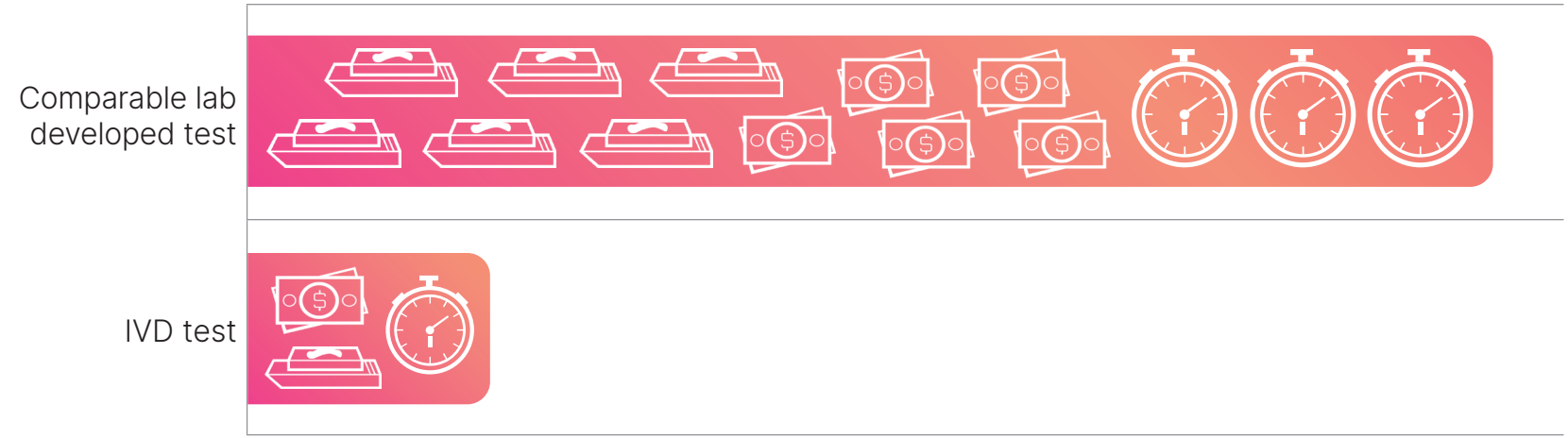
ALK
APC
BCOR
BRAF
BRCA1
BRCA2
CDK4
CIC
CTNNB1
DNAJB1
ERBB2
ERG
ETV1
ETV4
ETV6
EWSR1
FGFR2
FGFR3
FOXO1
GLI1
IDH1
KIT
KRAS
MDM2
MYOD1
NAB2
NTRK1
NTRK2
NTRK3
PAX3
PAX7
PDGFRA
RANBP2
SDHB
SMARCB1
TFE3
WT1
YAP1

178

† Central nervous system

Become a precision medicine provider
Offer CGP testing in your institution

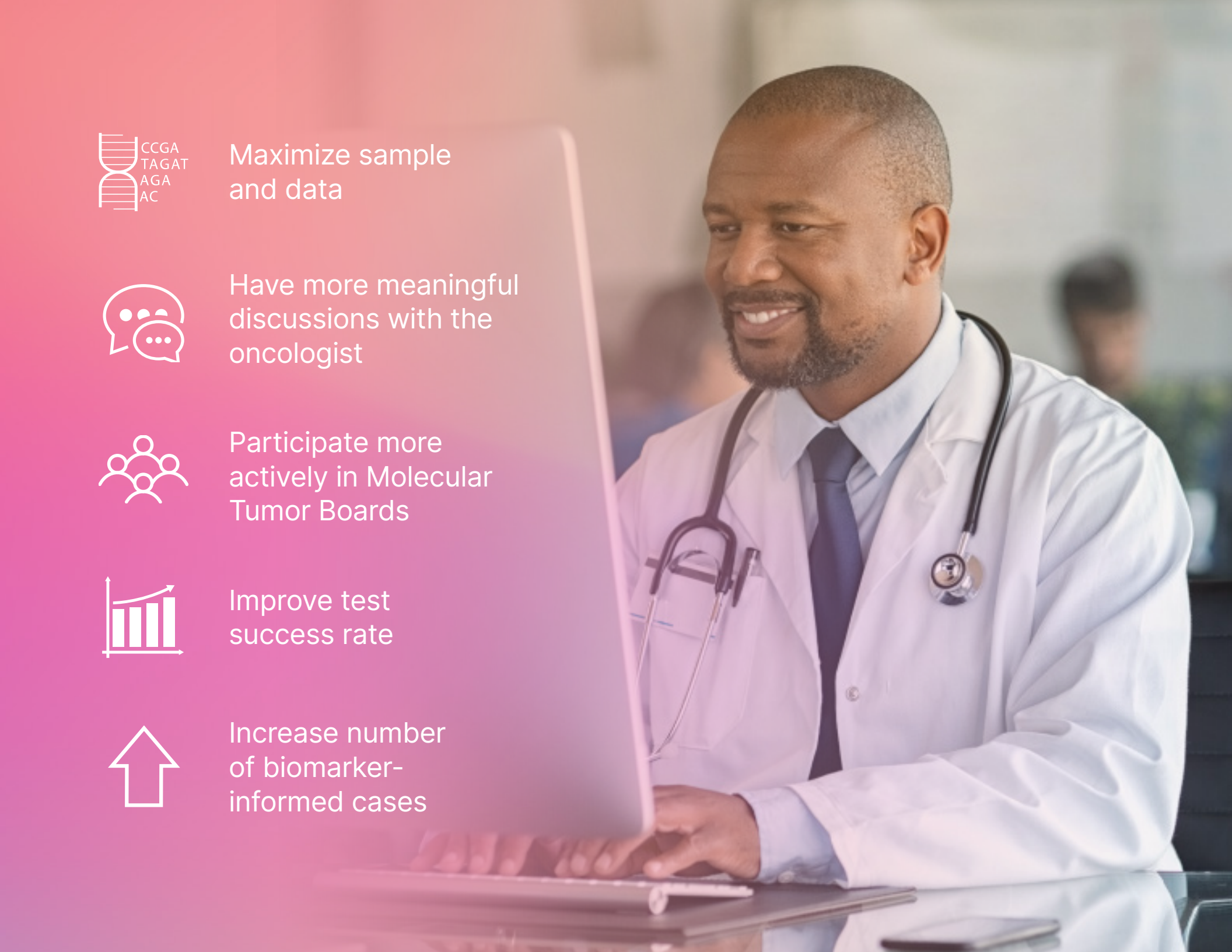
Bring CGP testing into your lab with TSO Comprehensive (EU) and enjoy the benefits of being a precision medicine provider. Offering the test in your institution allows you to better manage the sample logistics, keep the data internally for future studies, affect success rates, and, ultimately, the rate of biomarker-informed cases.



Time and resources to implement test*

TSO Comprehensive is a CE-marked IVD solution heavily tested by Illumina. It requires ISO 15189 performance verification, which is less burdensome than the validation required by a test developed in the lab.

*Illustrative example; not meant to provide a precise comparison of time and resources



Maximize sample and data

Have more meaningful discussions with the oncologist

Participate more actively in Molecular Tumor Boards

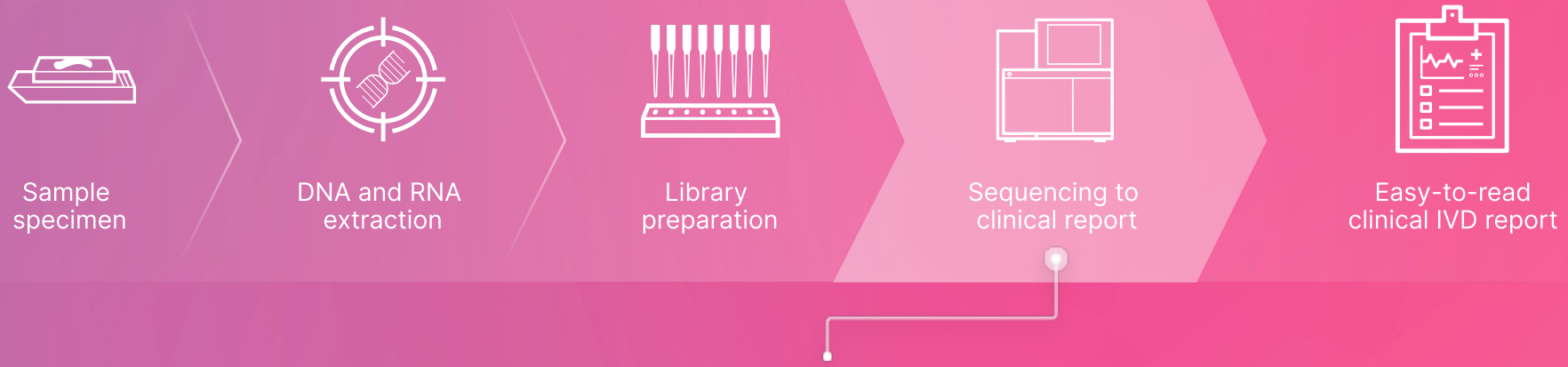
Improve test success rate

Increase number of biomarker-informed cases

From sample to report in just 4 to 5 days

Rely on a CE-marked, IVD, sample-to-answer solution that can be implemented easily, empowering you to generate test results quickly and accurately.

Fully automated sequencing and data analysis



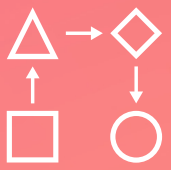
360 degree support from day one

Rest assured that you will receive our comprehensive level of support with TruSight Oncology Comprehensive (EU):

Onboarding plans

Training and certification

Marketing and educational tools through our VIP portal



Verification protocols

Ongoing technical support

Illumina Lighthouse VIP portal

Easily find resources to help you educate your customers on the benefits of comprehensive genomic profiling.

cgplighthouse.illumina.com

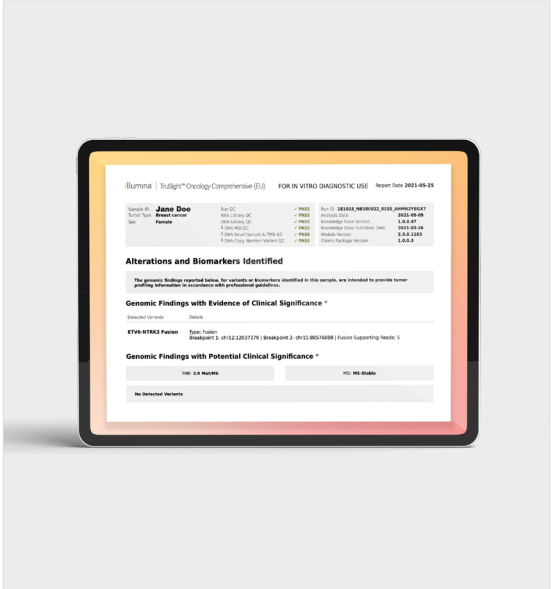
TruSight Oncology Comprehensive (EU)
A sample-to-answer solution

Library prep reagents

CE-marked IVD reagents in a kitted format for simple test implementation and reliable results.

NextSeq 550Dx System

A CE-marked IVD instrument that delivers the consistency and reliability clinical labs need.



Clinical IVD report

Actionable biomarker findings displayed in an easy-to-read IVD report.

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Intended use

TruSight Oncology Comprehensive (EU) is an *in vitro* diagnostic test that uses targeted next generation sequencing to detect variants in 517 genes using nucleic acids extracted from formalin-fixed, paraffin embedded (FFPE) tumor tissue samples from cancer patients with solid malignant neoplasms using the Illumina® NextSeq™ 550Dx instrument. The test can be used to detect single nucleotide variants, multinucleotide variants, insertions, deletions and gene amplifications from DNA, and gene fusions and splice variants from RNA. The test also reports a Tumor Mutational Burden (TMB) score and Microsatellite Instability (MSI) status.

The test is intended to provide tumor profiling information for use by qualified healthcare professionals in accordance with professional guidelines and is not conclusive or prescriptive for labeled use of any specific therapeutic product.

Contact your Illumina sales representative to find out more about TruSight Oncology Comprehensive (EU)

www.illumina.com/tsocomprehensive

For *In Vitro* Diagnostic Use.
Not available in all regions and countries.

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