

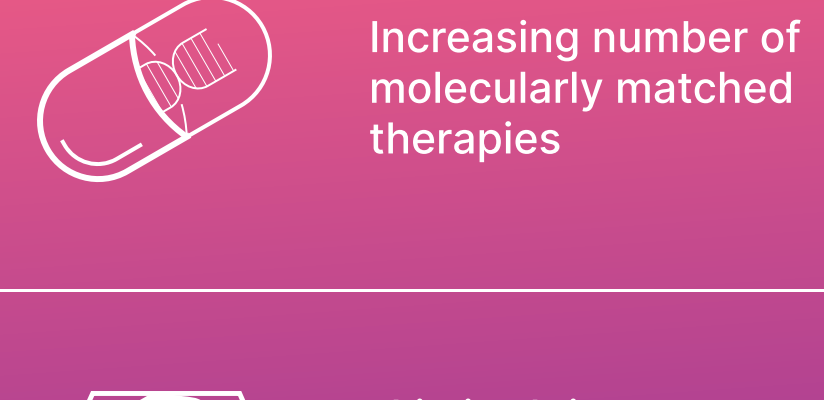
Comprehensive Genomic Profiling

Empowering broader access to precision oncology¹

Comprehensive Genomic Profiling (CGP) helps maximize the ability to detect actionable genomic alterations

PRECISION MEDICINE

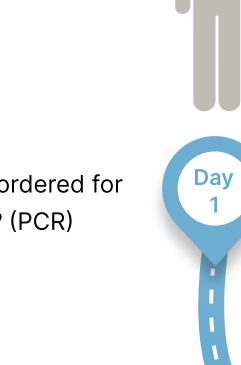
In a study of 6832 NSCLC patients, CGP was able to identify a potentially clinically relevant genomic alteration in



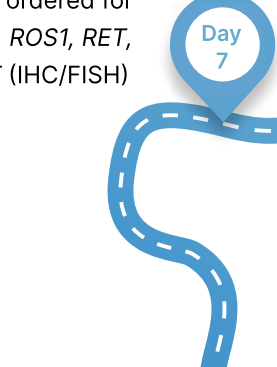
In one test, CGP addresses



Growing number of biomarkers



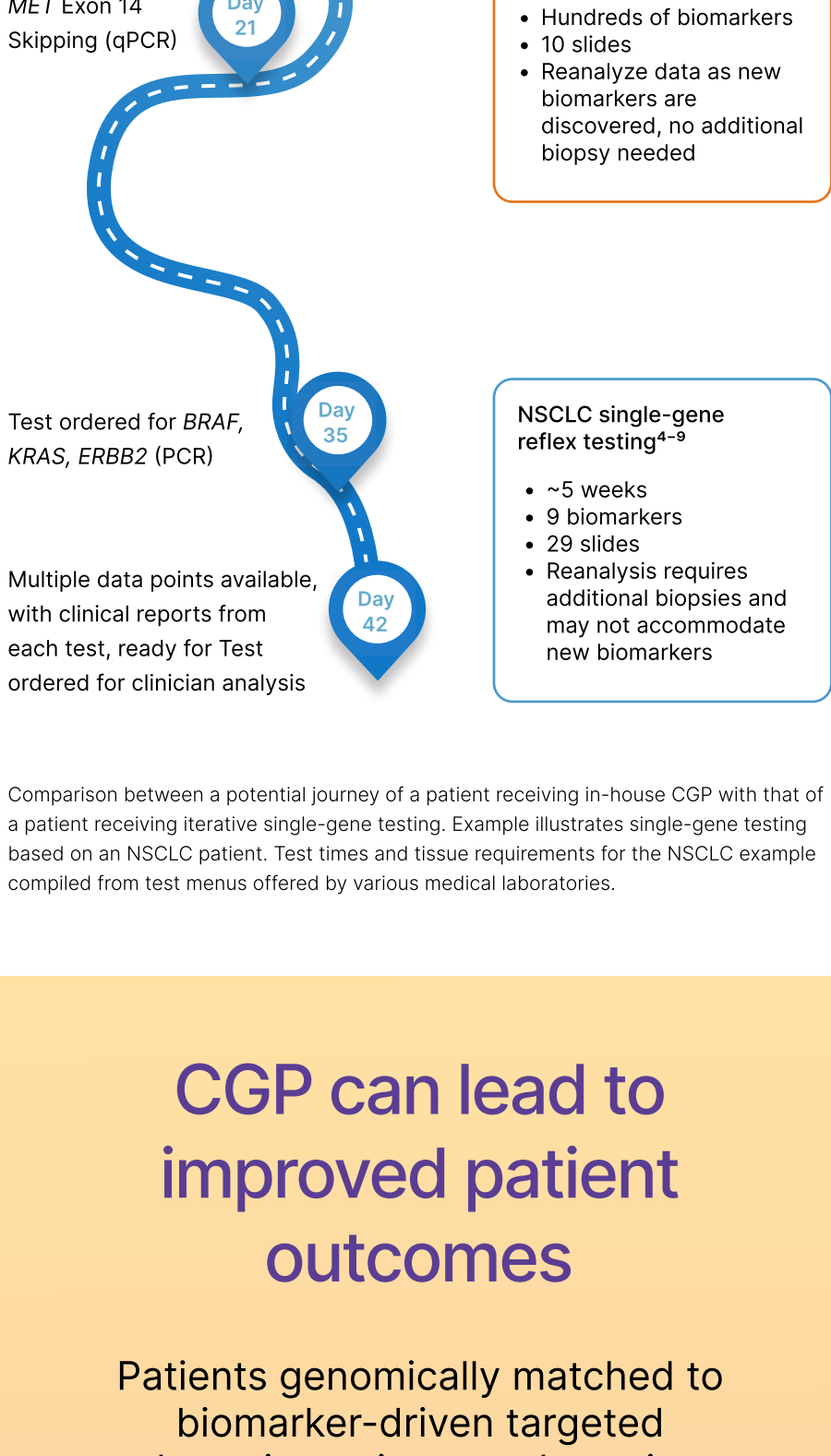
Increasing number of molecularly matched therapies



Limited tissue biopsy

Receive appropriate therapy options sooner

Illustrative example of potential patient journeys



Receiving a potential patient journey of a patient receiving in-house CGP with that of a patient receiving iterative single-gene testing. Example illustrates single-gene testing based on an NSCLC patient. Test times and tissue requirements for the NSCLC example compiled from test menus offered by various medical laboratories.

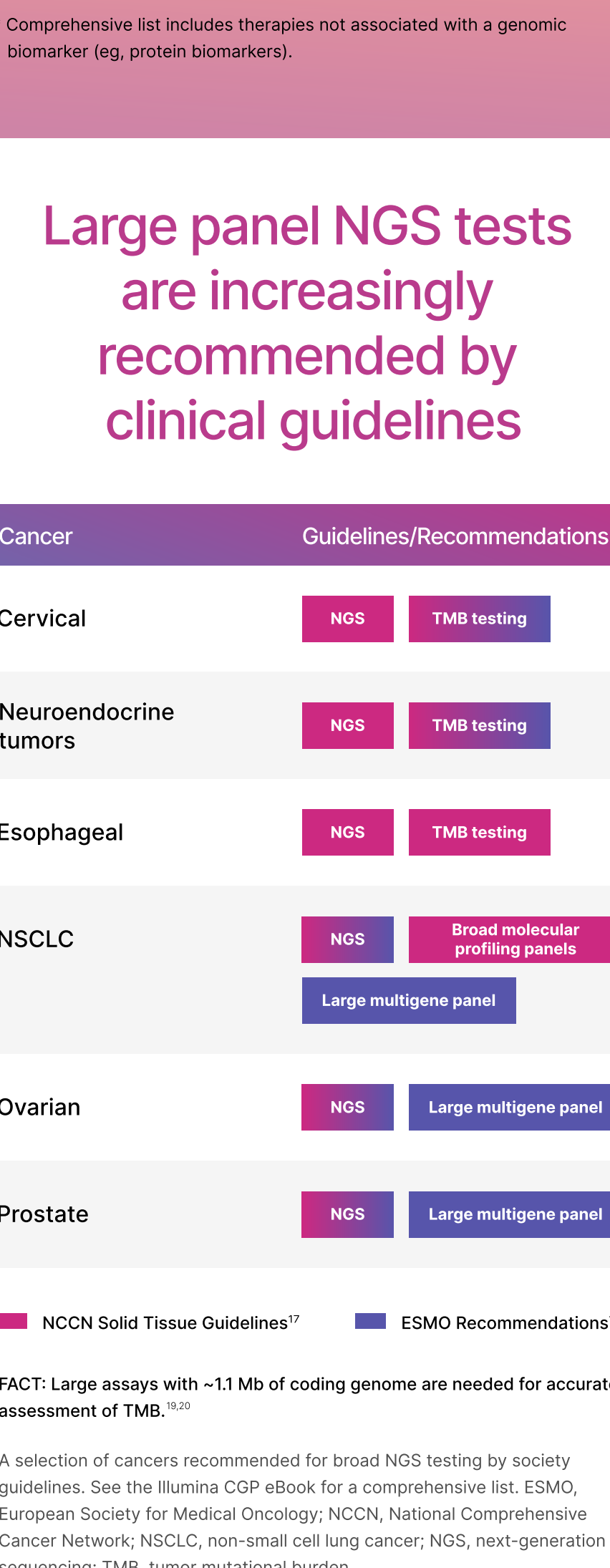
CGP can lead to improved patient outcomes

Patients genomically matched to biomarker-driven targeted therapies or immunotherapies show improved clinical outcomes^{2,10-14}

Clinical trials available

4021

ongoing clinical trials globally linked to a cancer biomarker¹⁵



Targeted therapies available¹⁶

102*



* Comprehensive list includes therapies not associated with a genomic biomarker (eg, protein biomarkers).

Large panel NGS tests are increasingly recommended by clinical guidelines

Cancer	Guidelines/Recommendations
Cervical	NGS, TMB testing
Neuroendocrine tumors	NGS, TMB testing
Esophageal	NGS, TMB testing
NSCLC	NGS, Broad molecular profiling panels, Large multigene panel
Ovarian	NGS, Large multigene panel
Prostate	NGS, Large multigene panel

■ NCCN Solid Tissue Guidelines¹⁷ ■ ESMO Recommendations¹⁸

FACT: Large assays with ~1.1 Mb of coding genome are needed for accurate assessment of TMB.^{19,20}

A selection of the Illumina CGP eBook for a comprehensive list. ESMO, European Society for Medical Oncology; NCCN, National Comprehensive Cancer Network; NSCLC, non-small cell lung cancer; NGS, next-generation sequencing; TMB, tumor mutational burden.

Increase value by using CGP from tissue and blood biopsy samples

+15%

more clinically relevant mutations identified in mNSCLC when analysis from liquid biopsy is added to tissue²¹⁻²³

Maximize identification of molecularly matched therapies

One biopsy, one test, one report can lead to improved patient outcomes

References

- Morganti S, Tarantino P, Ferraro E, D'Amico P, Duso BA, Curigliano G. Next Generation Sequencing (NGS): A Revolutionary Technology in Pharmacogenomics and Personalized Medicine in Cancer. *Adv Exp Med Biol*. 2019;1168:9-30. doi: 10.1007/978-3-030-24100-1_2. PMID: 31713162
- Zehir A, Benayed R, Shah RH, et al. Mutational landscape of metastatic cancer revealed from prospective clinical sequencing of 10,000 patients [published correction appears in *Nat Med*. 2017 Aug 4;23 (8):1004]. *Nat Med*. 2017;23(6):703-713. doi:10.1038/nm.4333
- ARUP Laboratories. EGFR Mutation Detection by Pyrosequencing | ARUP Lab Test Directory. ARUP Laboratories website. <http://www.aruplab.com/Tests/Pub/2002440>. Accessed January 19, 2021.
- Piering BD, Dowdell AK, Weersalinge R, et al. Comprehensive Genomic Profiling in Patients with Advanced Cancer in a Large US Healthcare System. Poster presented at: Association for Molecular Pathology (AMP) 2020; November 16-20, 2020; virtual meeting.
- Abbott Molecular. ALK-US-CE-Clinical-PLR3_mw001_3060.pdf. Vysis ALK Break Apart FISH Probe Kit. Abbott Molecular website. http://www.molecular.abbott/sa/en-us/staticAssets/ALK-US-CE-Clinical-PLR3_mw001_3060.pdf. Accessed January 19, 2021.
- NeoGenomics Laboratories. MET Exon 14 Deletion Analysis | NeoGenomics Laboratories. NeoGenomics Laboratories website. <http://www.neogenomics.com/test-menu/met-exon-14-deletion-analysis>. Accessed January 19, 2021.
- Geisinger. Specimen collection and processing instructions for BRAF MUTATION ANALYSIS. Geisinger Medical Laboratories website. <http://www.geisingermedicallabs.com/catalog/details.cfm?tid=1740>. Accessed January 19, 2021.
- Geisinger. Specimen collection and processing instructions for KRAS MUTATION ANALYSIS. Geisinger Medical Laboratories website. <http://www.geisingermedicallabs.com/catalog/details.cfm?tid=1740>. Accessed January 19, 2021.
- Mayo Clinic Laboratories. EGFR - Specimen: EGFR Gene, Mutation Analysis, 29 Mutation Panel, Tumor. Mayo Clinic Laboratories website. <https://www.mayocliniclabs.com/test-catalog/Specimen/35404>. Accessed February 10, 2021.
- Soumerai TE, Donoghue MT, Bandlamudi C, et al. Clinical Utility of Prospective Molecular Characterization in Advanced Endometrial Cancer. *Clin Cancer Res*. 2018;24(23):5939-5947. doi:10.1158/1078-0432.CCR-18-0412
- Gutierrez ME, Choi K, Lanman RB, et al. Genomic Profiling of Advanced Non-Small Cell Lung Cancer in Community Settings: Gaps and Opportunities. *Clin Lung Cancer*. 2020;11(1):4965. doi:10.1016/j.clcc.2017.04.004
- Singal G, Miller PG, Agarwala V, et al. Association of Patient Characteristics and Tumor Genomics With Clinical Outcomes Among Patients With Non-Small Cell Lung Cancer Using a Clinicogenomic Database [published correction appears in *JAMA*. 2020 Feb 4;323(5):480]. *JAMA*. 2019;321(14):1391-1399. doi:10.1001/jama.2019.3241
- Kato S, Kim KH, Lim HJ, et al. Real-world data from a molecular tumor board demonstrates improved outcomes with a precision N-of-One strategy. *Nat Commun*. 2020;11(1):4965. doi:10.1038/s41467-020-18613-3
- Rozenblum AB, Ilouze M, Dudnik E, et al. Clinical Impact of Hybrid Capture-Based Next-Generation Sequencing on Changes in Treatment Decisions in Lung Cancer. *J Thorac Oncol*. 2017;12(2):258-268. doi: 10.1016/j.jtho.2016.10.021
- NIH US National Library of Medicine. Home - ClinicalTrials.gov. Find a study. <https://www.clinicaltrials.gov/>. Search terms included "genetic," "genomic," "DNA," or "RNA." Accessed January 25, 2021.
- NIH National Cancer Institute. Cancer Drugs - National Cancer Institute. cancer.gov website. <https://www.cancer.gov/about-cancer/treatment/types/targeted-therapies/targeted-therapies-fact-sheet>. Accessed May 28, 2021.
- National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology. https://www.nccn.org/professionals/physician_gls/default.aspx. Accessed February 10, 2021.
- Mosele F, Remon J, Mateo J, et al. Recommendations for the use of next-generation sequencing (NGS) for patients with metastatic cancers: a report from the ESMO Precision Medicine Working Group. *Ann Oncol*. 2020;31(11):1491-1505. doi:10.1016/j.annonc.2020.07.014
- Buchhalter J, Rempel E, Endris V, et al. Size matters: Dissecting key parameters for panel-based tumor mutational burden analysis. *Int J Cancer*. 2019;144(4):848-858. doi:10.1002/ijc.31878
- Chalmers ZR, Connelly CF, Fabrizio D, et al. Analysis of 100,000 human cancer genomes reveals the landscape of tumor mutational burden. *Genome Med*. 2017;9(11):34. Published 2017 Apr 19. doi:10.1186/s13073-017-0424-2
- Aggarwal C, Thompson JC, Black TA, et al. Clinical Implications of Plasma-Based Genotyping With the Delivery of Personalized Therapy in Metastatic Non-Small Cell Lung Cancer. *JAMA Oncol*. 2019;5(2):173-180. doi:10.1001/jamaoncol.2018.4305
- Leigh NB, Page RD, Raymond VM, et al. Clinical Utility of Comprehensive Cell-free DNA Analysis to Identify Genomic Biomarkers in Patients with Newly Diagnosed Metastatic Non-small Cell Lung Cancer. *Clin Cancer Res*. 2019;25(15):4691-4700. doi:10.1158/1078-0432.CCR-19-0624
- Palmero R, Taus A, Viteri S, et al. Biomarker Discovery and Outcomes for Comprehensive Cell-Free Circulating Tumor DNA Versus Standard-of-Care Tissue Testing in Advanced Non-Small Cell Lung Cancer. *JCO Precision Oncology*. 2021;5:93-102. doi:10.1200/PO.2020.0241

M-GL-00193 v1.0