Paradigm Shift in Companion Diagnostics and the Vision for CGP in Non-Squamous NSCLC

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Background and Objectives

- In advanced or recurrent non-squamous non-small cell lung cancer (non-squamous NSCLC), genetic testing prior to initiation of first-line treatment is shifting from singleplex testing to multiplex testing.
- Meanwhile, the adoption of comprehensive genomic profiling (CGP) testing remains limited.
- This study aimed to assess trends in the use of and reasons for selecting companion diagnostics (CDx) and CGP testing using a nationwide periodic survey, and to examine future perspectives.

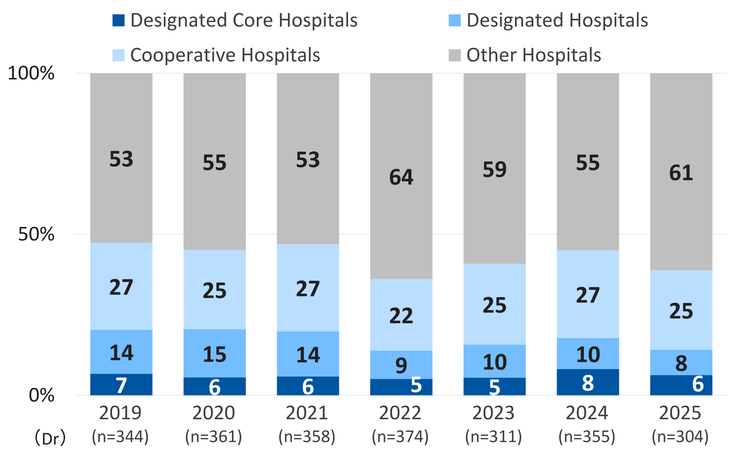
Methods

- From 2019 to 2025, web-based surveys were conducted once or twice annually among approximately 300 physicians treating lung cancer, including pulmonologists, registered with Plamed Inc.
- Longitudinal trends were analyzed in the use of singleplex and multiplex testing prior to first-line treatment for non-squamous (non-Sq) NSCLC, as well as in evaluations of each testing modality and the implementation rate of CGP testing.

Survey Period

	2019	2020	2021	2022	2023	2024	2025
Start date	11/18	11/17	11/11	10/19	10/16	10/8	10/1
End date	11/29	11/30	11/22	10/26	10/23	10/17	10/8

Respondent Background (Cancer Genomic Medicine Hospitals)



* “Other Hospitals” includes designated cancer care hospitals.

Findings

1. Companion Diagnostics Prior to First-Line Treatment

- From 2019 to 2025, the use of multiplex testing increased rapidly. Among these, Oncomine and AmoyDx were most commonly used. Although their use was similar at one point, Oncomine became the most widely used by 2025. (Fig. 1)
- In terms of evaluation criteria, AmoyDx was rated highly for TAT (turnaround time), while Oncomine was rated highly for comprehensiveness. It was suggested that shortening the TAT of Oncomine could increase physicians' willingness to use it, indicating that TAT may be an important factor in test selection. (Table 1, Fig. 2)

Fig. 1) Trends in the Breakdown of Genetic Testing Prior to Initiation of First-Line Treatment in Stage III–IV Non-Sq NSCLC

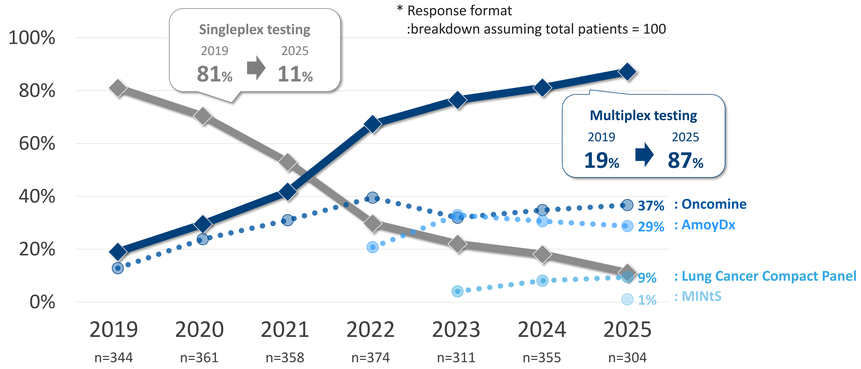


Table 1) Evaluation of AmoyDx and Oncomine (Top 3 Attributes)

* Response format: select up to 3 attributes

AmoyDx evaluation		%
1	Short TAT	27%
2	Confidence based on alignment with guidelines and evidence	21%
3	Covers clinically relevant genes and drugs physicians intend to prescribe	15%

Oncomine evaluation		%
1	Confidence based on alignment with guidelines and evidence	25%
2	High biomarker comprehensiveness, enabling a broader range of treatment options	24%
3	Covers clinically relevant genes and drugs physicians intend to prescribe	22%

2025 survey, physicians treating lung cancer(n=304)

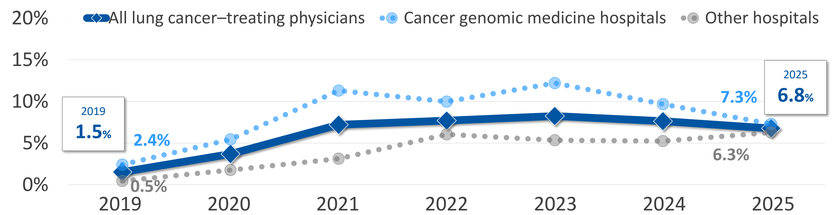
Fig. 2) Change in Willingness to Use Oncomine if TAT Is Reduced

2025 survey, physicians treating lung cancer (n=304)

2. CGP Testing

- The proportion of patients undergoing CGP testing in lung cancer increased only modestly, from 1.5% in 2019 to 6.7% in 2025 overall among physicians treating lung cancer. (Fig. 3)
- Among physicians who had not performed CGP testing in the past year, the main concerns cited were high cost and TAT, with a low likelihood of leading to treatment also identified as a key factor. A gap was observed between the need for testing in cases with undetected variants, as indicated by the Japanese Lung Cancer Society, and its actual use in real-world clinical practice. (Table 2)

Fig. 3) Trends in the Proportion of Patients Undergoing CGP Testing in Lung Cancer



	2019			2020			2021			2022			2023			2024			2025		
n	344	163	181	361	163	198	358	168	190	374	135	239	311	127	184	355	160	195	304	118	186
pts	8158	4465	3693	8903	4670	4233	9026	4493	4533	11164	4698	6466	9166	3875	5291	10900	5873	5027	9055	4400	4655

Table 2) <Non-Users> Challenges of CGP Testing (Top 5 Items)

Concerns and Challenges of CGP Testing		%	(Reference) % among CGP users
1	High cost, including patient out-of-pocket cost	55%	42%
2	Some patients cannot wait due to TAT	52%	45%
3	Even if clinical trials are identified, they cannot be actively recommended if they are far away	41%	30%
	Heavy burden associated with the expert panel		33%
5	Treatment access rate is approximately 10%	39%	37%

2025 survey: lung cancer physicians not using CGP (n=186), using CGP (n=118)

Conclusions & Implications

Genetic testing in non-Sq NSCLC is increasingly shifting toward multiplex testing, while the uptake of CGP testing remains limited. Further expansion of CGP testing will require shorter TAT and improved cost-effectiveness (particularly greater visibility of treatment access rates), along with comprehensive policy and technological support aligned with advances in drug development.