



ENHANCING LUNG CANCER OUTCOMES IN ITALY

From Leading Access to Equitable, Data-Driven Precision Care

EXECUTIVE SUMMARY

Italy ranks among Europe's top-tier systems for lung cancer care, with universal health coverage, comprehensive reimbursement of targeted therapies, and well-established oncology networks. National guidelines support routine biomarker testing and immunotherapy access, and participation in EU-funded research is robust. Yet survival outcomes still lag behind Western European averages, driven by persistent late-stage diagnosis, regional variability in care quality, and inconsistent implementation of re-testing protocols.

As a **Leading-level system**, Italy's next frontier is scaling precision medicine nationwide — ensuring uniform testing, fast-tracked drug access, and early-stage diagnosis through systematic screening.

INTRODUCTION

With over **41,000 new lung cancer cases annually**, Italy faces one of the highest lung cancer burdens in Europe. High smoking prevalence and an aging population contribute to incidence, while air pollution and occupational exposure add complexity. Italy has long embraced **personalized therapy** for lung cancer: EGFR, ALK, ROS1, BRAF, KRAS, MET, RET, and PD-L1 testing are reimbursed, and access to therapies like osimertinib, alectinib, lorlatinib, and pembrolizumab is widespread.

However, **screening is not yet implemented nationally, and regional inequalities** in diagnostic timelines, molecular testing turnaround, and access to clinical trials limit system-wide impact. To reduce mortality and improve quality of life, Italy must expand early detection and harmonize delivery across all regions.

CURRENT FRAMEWORK/SITUATION

Italy's **Servizio Sanitario Nazionale (SSN)** offers universal cancer care via public and accredited hospitals. Oncology is organized through regional networks, with centers of excellence in Milan, Rome, Bologna, Turin, and Naples. National and regional guidelines align with **AIOM**, ESMO, and AIFA decisions.

Testing for key mutations is available through regional laboratories and public reimbursement, but re-biopsy practices at disease progression and newer markers (e.g., HER2, NTRK) are inconsistently applied. Access to innovative therapies may face reimbursement delays due to AIFA timelines. Clinical trials are active in major centers but are less accessible in southern and rural regions.



LUNG CANCER IN ITALY

Key Issues and Policy Recommendations

Pillar	Fact	Barrier	Policy Recommendations
Infrastructure	Italy has a strong public system and regional oncology networks...	...but variation exists in imaging access, biopsy capacity, and test turnaround between north and south.	Standardize lung cancer care protocols and equip all regions with core diagnostic infrastructure.
Access to Treatment	Most EMA-approved therapies are reimbursed through AIFA....	...but delays in market access and budget negotiations can postpone availability.	Create fast-track access pathways for OS-beneficial therapies post-EMA approval.
Research & Innovation	Italy leads in EU-sponsored lung cancer trials through AIOM and IRCCS centers...	...but participation is concentrated in urban academic hospitals.	Expand trial access to peripheral hospitals via shared investigator models and digital tools.
Awareness & Education	Italy runs national smoking cessation and cancer awareness campaigns...	...but public understanding of lung cancer in non-smokers and the value of early detection is low.	Launch new messaging targeting never-smokers, women, and underserved regions.
Survival Rates	5-year survival remains lower than in France or Germany...	...due to high rates of late-stage diagnosis and regional access gaps.	Introduce national LDCT screening and track stage-at-diagnosis metrics by region.
Early Detection & Palliative Care	Pilot LDCT screening projects exist (e.g., RISP in Lombardy)...	...but no national rollout, and primary care lacks structured referral pathways.	Scale LDCT pilots into a nationwide screening framework and involve GPs in early detection.
Biomarker	EGFR, ALK, PD-L1, KRAS, and other tests are widely reimbursed...	...but reflex testing for HER2, RET, and NTRK is inconsistent, especially at relapse.	Update national guidelines to mandate comprehensive testing at diagnosis and re-biopsy.
Clinical Guidelines	AIOM guidelines are robust and ESMO-aligned...	...but adherence and updates vary regionally.	Implement nationwide audits and certification tied to real-world implementation.
Reimbursement	AIFA reimburses most therapies within months of EMA approval...	...but budget controls and regional variation can delay hospital-level access.	Align regional funding mechanisms and expedite AIFA appraisal for lung cancer drugs.
Screening	LDCT is available in some regions (e.g., Milan, Veneto)...	...but lacks a coordinated national program.	Create a national LDCT screening strategy targeting high-risk populations aged 55–74.

CONCLUSION

Italy has established a strong foundation for lung cancer care, with access to diagnostics, therapies, and guidelines among the best in Europe. However, to reduce mortality and maximize precision care benefits, Italy must tackle geographic disparities, expand early detection, and streamline biomarker and therapy access. Leveraging its regional strength, Italy can lead in equitable implementation—ensuring that excellence reaches every patient, regardless of location.



KEY POLICY MESSAGES

- 1** Italy ensures wide access to diagnostics and therapies, but regional disparities persist in testing speed, trial participation, and re-testing.
- 2** Comprehensive biomarker testing must include HER2, NTRK, and progression re-biopsy.
- 3** A national LDCT lung screening program is needed to diagnose cases earlier and reduce late-stage burden.
- 4** AIFA timelines must be optimized for rapid access to innovative treatments.

CALL TO ACTION

- **Launch a national LDCT screening initiative**, scaling regional pilots and linking with smoking cessation programs.
- **Mandate comprehensive biomarker testing** (HER2, NTRK, MET, RET) at diagnosis and upon progression.
- **Accelerate AIFA reimbursement timelines** for high-impact therapies and unify regional procurement pathways.
- **Fund diagnostic and pathology infrastructure** in under-resourced southern and rural areas.
- **Integrate mutation-stratified survival tracking** into regional cancer registries to drive outcome-based planning.