

CASE STUDY:

A Retrospective, Cross-sectional, Non-interventional Epidemiological Study in Non-small Cell Lung Cancers (NSCLC)

- **The first non-interventional epidemiology study** in NSCLC conducted in different countries in the MENA region. This has resulted in, for the first time, generation of important data on the prevalence of ALK rearrangement in the Middle East and North Africa.
- **This study has additionally supported the development of molecular testing platforms** and expertise in these countries and has also assessed the concordance between the immunohistochemistry (IHC) and fluorescent in situ hybridization (FISH) tests being performed in these countries.
- **Ergomed provided full services for this study**, including regulatory, project management, monitoring, data management and medical writing services, resulting in a high level of client satisfaction.

Study summary:

6 study sites across 5 countries: Egypt, Saudi Arabia, United Arab Emirates, Lebanon and Morocco

448 samples retrospectively collected from study center tissue banks, were analyzed for anaplastic lymphoma kinase (ALK) gene rearrangement using the Ventana ALK-IHC method at each of the centers.

The primary aim of this retrospective study was to estimate the prevalence of ALK rearrangement in the MENA population using NSCLC clinical samples, as the existing epidemiological data is very limited.

Additional assessments included the association between ALK rearrangement and clinical and pathological parameters, and the concordance between two testing methods for ALK rearrangement detection - Vysis fluorescent *in situ* hybridization (FISH) and Ventana ALK-immunohistochemistry (IHC).

Challenges	Ergomed's solutions
Limited availability of pathologists trained on using ALK tests	A dedicated trainer was available to train pathologists across the 6 sites. Thorough training helped leverage pathologists' capabilities in managing procedures.
Informed Consent Form (ICF) not possible for all samples	The Ergomed Regulatory team managed to obtain ICF waivers across all site Institutional Review Boards (IRB) and countries' authorities where applicable.
Complex logistics of delivering ALK test kits	Provision of ALK test kits to sites was closely managed by the Ergomed Project Management team ensuring redistribution of kits between those sites with an excess/shortage, thus reducing delays.
Use of paper case report forms (CRF)	Paper CRF quantities needed to be in line with the available ALK kits. The Ergomed team managed CRF distribution centrally based on testing rate per each site, improving timely CRF completion and data quality.

Publications:

The study results were presented at the ESMO Virtual Annual Meeting on 19-21 September 2020. Additional publications are planned for the end of 2020.



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To learn more about Ergomed's oncology and Real-World Evidence expertise, please contact us at:

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