

KEAP-GRACE(German Registry for **KEAP1** Alterations in non-lung solid tumors)

Multizentrische, retrospektive Erhebung von Patienten-Verläufen mit KEAP1-Mutationen in soliden Tumoren mit Ausnahme von Lungenkarzinomen

STUDY TYPE	
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CONDITION	Advanced solid tumors after comprehensive molecular profiling
DESIGN	Retrospective
OBJECTIVE(S)	<ul style="list-style-type: none"> - Mapping the landscape of <i>KEAP1</i> mutations in solid tumors (excluding NSCLC). - Analysis of clinical data of patients with said alterations in molecular tumor boards. - Collection of therapeutic regimens proposed by molecular tumor boards (MTB) for these variants. - Investigation of treatment outcomes in pre- and post-MTB-therapies with emphasis on immune checkpoint inhibitors (ICB). - Analysis of clinical outcomes and survival times of patients with <i>KEAP1</i> mutations.
INTERVENTION(S)	n/a
BACKGROUND/ RATIONALE	Some information is published on <i>KEAP1</i> mutations and their therapeutic implications in patients with lung cancer, with emphasis on a proposed resistance to radiation therapy, chemotherapy, and ICB. However, little is known about frequency of <i>KEAP1</i> mutations in non-lung solid tumors and their clinical implications regarding different oncological therapies. KEAP-GRACE seeks to address these uncertainties by collecting pathological and clinical data from patients discussed and treated in dedicated precision oncology programs to better understand the potential therapeutic implications.
COLLECTED DATA	<ul style="list-style-type: none"> - Anonymized - Results of molecular profiling <ul style="list-style-type: none"> o Type of diagnostic used o Type of <i>KEAP1</i> alteration that has been classified as pathogenic or potentially pathogenic by local investigators o Additional somatic SNVs/ Indels/ Copy Number Alterations/ Translocations/ Fusions that have been classified as pathogenic or potentially pathogenic by local investigators o Tumor cell content and variant allele fraction (if applicable) for reported alterations o PD-L1 staining, TMB and MSI (if available) - Patient demographics and clinical data <ul style="list-style-type: none"> o Tumor type and classification (using Oncotree) o Age/ Sex o Past therapies with response and duration of response o MTB recommendation o Clinical response data, including response rate, progression-free survival, and overall survival of pre- and post-MTB-treatment
SAMPLE SIZE	<ul style="list-style-type: none"> - Basic cohort: All patients discussed in molecular tumorboards in the participating centers. - Study cohort: The study cohort is recruited out of the basic cohort and encloses only patients with <i>KEAP1</i> mutations (excluding patients with lung cancer)

DURATION	12 months
PARTICIPATING CENTERS	14
FURTHER CENTERS DESIRED?	yes
NUMBER of PATIENTS	To be determined
CURRENT NUMBER of PATIENTS	<ul style="list-style-type: none">- Basic cohort: currently more than 10,000 patients discussed in the molecular tumor boards of participating centers- Study cohort: currently approximately 50 to 150 patients with KEAP1 mutations in non-lung solid tumors