

KURZPROTOKOLL
HANNA (CA209-99K)

Öffentlicher Titel	Nicht-interventionelle Studie mit Nivolumab bei progredienten Kopf-Hals-Tumoren nach platinbasierter Therapie
Wissenschaftl. Titel	Eine nationale, prospektive, nicht-interventionelle Studie (NIS) mit Nivolumab (BMS-936558) bei Patienten mit Plattenepithelkarzinomen im Kopf-Hals-Bereich, die eine Tumorprogression während oder nach einer platinbasierten Therapie aufweisen.
Kurztitel	HANNA (CA209-99K)
Studienart	multizentrisch, Anwendungsbeobachtung, prospektiv, offen/unverblindet, einarmig, Pharma-Studie, nicht-interventionelle Studie
Studienphase	nicht zutreffend
Erkrankung	Kopf-Hals: Kopf-Hals-Tumoren: sonstige Studien für Kopf-Hals-Tumoren
Einschlusskriterien	- Adult patients (at least 18 years of age at time of treatment decision) - Diagnosis of SCCHN and patients are progressing on or after platinum-based therapy - Diagnosis of SCCHN has been confirmed by histology or cytology (either at initial diagnosis or any time later during the course of the disease) - Treatment decision to initiate a treatment with nivolumab for the first time for the treatment of SCCHN (according to the label approved in Germany) has already been taken - Patients who provided informed consent to participate in the study
Ausschlusskriterien	- Patients with a current primary diagnosis of a cancer other than SCCHN, ie, a cancer other than SCCHN that requires systemic or other treatment, or has not been treated curatively (as per discretion of the investigator) - Patients previously treated with nivolumab and/or ipilimumab, an anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CTLA-4 antibody, or any other antibody or drug specifically targeting T-cell co-stimulation or immune checkpoint pathways (applicable for any indication) - Patients currently included in an interventional clinical trial for their SCCHN. Patients who have completed their participation in an interventional trial; or who are not receiving study drug anymore and who are only followed-up for OS can be enrolled
Alter	18 Jahre und älter
Prüfzentren	Universitätsklinikum Gießen und Marburg, Standort Gießen (Aktiv) Hals-, Nasen- und Ohrenheilkunde Rudolf-Buchheim-Straße 8 35392 Gießen Dr. med. Christine Langer Tel: 00641 98543701 Universitätsmedizin Frankfurt (Nachbeobachtung) Klinik für Strahlentherapie und Onkologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Dr. Maximilian Fleischmann Tel: 069 6301 5130 studien-strahlen@unimedizin-ffm.de
Sponsor	Bristol-Myers Squibb
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03114163