

KURZPROTOKOLL
CA209-577

Öffentlicher Titel	Phase III Studie zu Nivolumab bei Ösophaguskarzinom nach Resektion
Wissenschaftl. Titel	A Randomized, Multicenter, Double Blind, Phase III Study of Nivolumab or Placebo in Subjects with Resected Lower Esophageal, or Gastroesophageal Junction Cancer
Kurztitel	CA209-577
Studienart	multizentrisch, Therapiestudie, randomisiert, Pharma-Studie, doppelblind, zweiarmig, kontrolliert
Studienphase	Phase III
Erkrankung	Verdauung: Magen-/Speiseröhrenkrebs (Magen-/Ösophaguskarzinom): adjuvant
Einschlusskriterien	- subjects diagnosed with Stage II/III carcinoma of the esophagus or gastroesophageal junction - subjects completed pre-operative chemoradiotherapy followed by surgery - subjects diagnosed with residual pathologic disease after being surgically rendered free of disease with negative margins following complete resection
Ausschlusskriterien	- subjects diagnosed with cervical esophageal carcinoma - subjects diagnosed with Stage IV resectable disease - subjects who did not receive concurrent chemoradiotherapy prior to surgery
Alter	18 Jahre und älter
Prüfzentren	Universitätsmedizin Frankfurt (Geschlossen) UCT-Zentrale Theodor-Stern-Kai 7 60590 Frankfurt am Main Christina Henkel Tel: 069 6301-83787 Fax: 069 6301-83788 christina.henkel@unimedizin-ffm.de
Sponsor	Bristol-Myers Squibb
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT02743494 (primäres Register) EudraCT 2015-005556-10