Study Protocol No	**AIO-TRK-0221**
EudraCT Number	**2017-003780-35**
Study title	Randomized phase II, open-label efficacy and safety study of second-line durvalumab plus tremelimumab versus platinum-based chemotherapy alone in patients with NSCLC and first-line checkpoint-inhibitor therapy followed by 2 cycles of platinum-based chemotherapy (Re-Check)
Sponsor	AIO-Studien-gGmbH Kuno-Fischer-Str. 8 14057 Berlin Germany
Principal Investigator/ Study Chair	Prof. Dr. Niels Reinmuth, Asklepios Fachkliniken München-Gauting, Germany
Design	Two armed, randomized, multicenter, open-label phase II study
Clinical Phase	II
Patient number (planned)	230 registered, 196 randomized
Patient number (actual)	0

Former Sponsor: CESAR Central European Society for Anticancer Drug Research – EWIV, Wien

Former Protocol Code: CESAR C-II-012

The study AIO-TRK-0221 Re-Check was first submitted to the Ethics Committee in Munich in December 2017 by the Sponsor CESAR-EWIV, but did not gain a favorable opinion. The study was subsequently re-designed and gained a favorable EC opinion in April 2019 and regulatory approval in October 2019. However, due to the beginning of the COVID-19 pandemic, study sites could not be initiated, and patient recruitment thus not be started.

In 2022, the study was transferred to the sponsorship of AIO-Studien-gGmbH, and the study design was adapted to reflect the therapeutic landscape current at the time. The protocol was approved by the competent authority and gained a favorable EC opinion in April 2022, and study sites were initiated. However, it soon became evident that patient recruitment would be very difficult. The Sponsor therefore decided to terminate the study without any enrolled patient in August 2022.

Since no patients were enrolled in the study, no results can be reported.