

**KURZPROTOKOLL**  
**IO102-012**

<b>Öffentlicher Titel</b>	Phase I/II Studie zu IO102 plus Pembrolizumab als Erstlinientherapie beim metastasierten nicht-kleinzelligen Lungenkarzinom
<b>Wissenschaftl. Titel</b>	An Open-label, Randomized, Phase I/II Trial Investigating the Safety and Efficacy of IO102 in Combination with Pembrolizumab, with or without Chemotherapy, as First-line Treatment for Patients with Metastatic Non-Small Cell Lung Cancer
<b>Kurztitel</b>	IO102-012
<b>Studienart</b>	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig
<b>Studienphase</b>	Phase II
<b>Erkrankung</b>	Lunge: Lungenkrebs: Nicht kleinzelliges Lungenkarzinom (NSCLC) - Erstlinie
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"><li>- histologically or cytologically confirmed metastatic NSCLC (Cohort A) or non-squamous NSCLC (Cohort B), who have not received prior treatment for metastatic NSCLC</li><li>- No known sensitizing EGFR or ALK mutations</li><li>- Solitary metastases must be biopsied to confirm the diagnosis metastasis from NSCLC</li></ul>
<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"><li>- prior treatment with a checkpoint inhibitor of e.g PD1/PD-L1/PD-L2, CTLA4, OX-40, and/or CD137</li><li>- prior systemic anti-cancer therapy in the first line setting for the participant's metastatic disease (treatment with chemotherapy and/or radiation as part of neoadjuvant/adjuvant therapy is allowed as long as completed at least 6 months prior to diagnosis of metastatic disease).</li></ul>
<b>Alter</b>	18 Jahre und älter
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<b>Sponsor</b>	IO Biotech Aps
<b>Registrierung in anderen Studienregistern</b>	ClinicalTrials.gov NCT03562871 (primäres Register) EudraCT 2018-000139-28