

## **KURZPROTOKOLL CHAPLIN**

<b>Öffentlicher Titel</b>	eHealth Monitoring bei Atezolizumab-Behandlung von metastasiertem nicht-kleinzelligem oder kleinzelligem Lungenkrebs
<b>Wissenschaftl. Titel</b>	Multicenter study to evaluate the impact of eHealth monitoring on overall survival in patients with metastatic non-squamous NSCLC or extensive-stage SCLC under first-line treatment with atezolizumab and platinum-based chemotherapy
<b>Kurztitel</b>	CHAPLIN
<b>Studienart</b>	Anwendungsbeobachtung, prospektiv, randomisiert, offen/unverblindet, Pharma-Studie, nicht-interventionelle Studie, zweiarmig
<b>Erkrankung</b>	Lunge: Lungenkrebs: Kleinzelliges Lungenkarzinom (SCLC) - sonstige Studien Lunge: Lungenkrebs: Nicht kleinzelliges Lungenkarzinom (NSCLC) - sonstige Studien
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"><li>- Histologically or cytologically confirmed stage IV non-squamous NSCLC or histologically or cytologically confirmed extensive-stage SCLC, respectively</li><li>- Indication and decision for approved therapy with atezolizumab and bevacizumab in combination with carboplatin and paclitaxel induction followed by atezolizumab/bevacizumab maintenance therapy in accordance with the current German SmPC of atezolizumab for first-line treatment of stage IV non-squamous NSCLC, atezolizumab in combination with carboplatin and nab-paclitaxel induction followed by atezolizumab maintenance therapy in accordance to the current German SmPC of atezolizumab for first-line treatment of stage IV nonsquamous NSCLC, atezolizumab in combination with carboplatin and etoposide induction followed by atezolizumab maintenance therapy in accordance to the current German SmPC of atezolizumab for first-line treatment of extensive-stage SCLC</li><li>- Aged <math>\geq 18</math> years</li><li>- Eastern Cooperative Oncology Group (ECOG) 0-2</li><li>- In possession of a web-connected, frequently used, electronic device (smartphone, tablet, Personal Computer (PC))</li><li>- Willingness and ability to participate at an initial training and to regularly use the webbased application tool CANKADO</li><li>- Fluent in written and spoken German</li><li>- Willingness and ability to participate at the digital or paper-based questionnaire project</li><li>- Written (signed and dated) informed consent</li></ul>
<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"><li>- Prior treatment for stage IV non-squamous NSCLC or prior systemic treatment for extensive-stage SCLC</li><li>- Active/symptomatic central nervous system (CNS) metastases</li><li>- History of or active pneumonitis and drug-induced pneumonitis - history of radiation pneumonitis in the radiation field (fibrosis) is permitted</li><li>- Autoimmune or chronic viral diseases, idiopathic pulmonary fibrosis, organizing pneumonia</li><li>- Known infection of human immunodeficiency virus (HIV)</li><li>- Severe infection within four weeks prior to randomization</li><li>- Significant cardiovascular disease</li><li>- History of severe (or known) hypersensitivity to chimeric or humanized antibodies or fusion proteins or any component of atezolizumab formulation</li><li>- Pregnant or breast-feeding women</li></ul>
<b>Alter</b>	18 Jahre und älter

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<b>Prüfzentren</b>	<b>Universitätsklinikum Gießen und Marburg, Standort Marburg</b> (Geschlossen) Comprehensive Cancer Center Baldingerstraße 35043 Marburg Mariana May Tel: 06421 58 67022 <a href="mailto:mariana.may@uk-gm.de">mariana.may@uk-gm.de</a>
<b>Sponsor</b>	iOMEDICO
<b>Registrierung in anderen Studienregistern</b>	ClinicalTrials.gov NCT03911219 (primäres Register)