

## **KURZPROTOKOLL** **ENLARGE**

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| <b>Öffentlicher Titel</b>                        | Nicht interventionelle Studie zu Nivolumab bei lokal fortgeschrittenem oder metastasiertem NSCLC nach primärer Chemotherapie                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Wissenschaftl. Titel</b>                      | A National, Prospective, Non-Interventional Study (NIS) of Nivolumab (BMS-936558) In Patients With Locally Advanced Or Metastatic Non-Small Cell Lung Cancer (NSCLC) With Squamous and Non-Squamous Histology (Stage IIIB/IV) After Prior Chemotherapy                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Kurztitel</b>                                 | ENLARGE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <b>Studienart</b>                                | multizentrisch, Anwendungsbeobachtung, prospektiv, offen/unverblindet, einarmig, Pharma-Studie, nicht-interventionelle Studie                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Studienphase</b>                              | nicht zutreffend                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>Erkrankung</b>                                | Lunge: Lungenkrebs: Nicht kleinzelliges Lungenkarzinom (NSCLC) - sonstige Studien                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>Einschlusskriterien</b>                       | <ul style="list-style-type: none"><li>- Histologically or cytologically confirmed diagnosis of locally advanced or metastatic NSCLC, Stage IIIB/Stage IV</li><li>- Decision to initiate a treatment with Nivolumab for the first time already undertaken by physician</li><li>- Males and Females, <math>\geq 18</math> years of age</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Ausschlusskriterien</b>                       | <ul style="list-style-type: none"><li>- Current primary diagnosis of a cancer other than advanced NSCLC. Example: A cancer other than NSCLC that requires systemic or other treatment.</li><li>- Pre-treatment with Nivolumab and/or Ipilimumab (pre-treatment with checkpoint-inhibitors other than Nivolumab and Ipilimumab, and Tyrosine Kinase Inhibitors(TKIs) is allowed)</li><li>- Current participation in an interventional clinical trial for treatment of NSCLC. (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 overall survival can be enrolled. For blinded studies, the treatment administered needs to be known)</li></ul> |
| <b>Alter</b>                                     | 18 Jahre und älter                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>Fallzahl</b>                                  | 660                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| <b>Sponsor</b>                                   | Bristol-Myers Squibb                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Registrierung in anderen Studienregistern</b> | ClinicalTrials.gov NCT02910999                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Links</b>                                     | <a href="#">Studiendokumente zum Download (roXtra)</a>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |