

## **KURZPROTOKOLL** **SIOP RTSG 2016**

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| <b>Öffentlicher Titel</b>                        | Studie zu standardisierten Diagnostik und Therapie bei Kindern mit Wilmstumor  |
| <b>Wissenschaftl. Titel</b>                      | Umbrella Protocol SIOP RTSG 2016, Integrated research and guidelines for standardized diagnostics and therapy  |
| <b>Kurztitel</b>                                 | SIOP RTSG 2016   |
| <b>Studienart</b>                                | multizentrisch, prospektiv, Therapiestudie, offen/unverblindet, einarmig, Register, nicht-interventionelle Studie, Investigator Initiated Trial (IIT)  |
| <b>Studienphase</b>                              | nicht zutreffend   |
| <b>Erkrankung</b>                                | Kinder: andere Tumorerkrankungen: Wilmstumor (Nephroblastom)   |
| <b>Einschlusskriterien</b>                       | <ul style="list-style-type: none"><li>- All children, adolescents or young adults with a primary or relapsed renal tumour diagnosed in a participating SIOP-RTSG centre are eligible for inclusion in the SIOP 2016 UMBRELLA study. All registered and participating centres in the SIOP-RTSG study group have to enrol all their patients with renal tumours into this protocol, if the patient or the parent or the legal representative (guardian) gives informed consent. Consent needs to be given separately for the enrolment in the protocol, the sharing of data and the biological studies related to the protocol. The inclusion of patients is independent of the histology of the renal tumour, the age of the patient (except for RCC patients: &lt;18 years old) or the country of residence. All participating centres agree to be compliant with the protocol (see form above) and to provide all requested material including imaging studies and biomaterial, data and other necessary information of all their enrolled patients. This includes also follow-up information on at least a yearly basis. Recruitment of patients is aimed to be complete in all participating centres with the provision of complete data sets and requested imaging and biomaterial</li></ul> |
| <b>Ausschlusskriterien</b>                       | <ul style="list-style-type: none"><li>- The only exclusion criterion is missing informed consent. Patients who do not give or whose parents or guardians do not give consent for inclusion in the SIOP 2016 UMBRELLA study cannot be registered. As there are different consents for participation in the clinical and the biological part of the UMBRELLA protocol patients can be potentially registered if there is consent given for the clinical part only and not the biological part of the protocol. Each country in accordance with local regulations rules will provide consent forms in their language</li></ul>  |
| <b>Alter</b>                                     | Keine Altersbegrenzung   |
| <b>Prüfzentren</b>                               | <b>Universitätsklinikum Frankfurt (Aktiv)</b><br>Klinik für Kinder- und Jugendmedizin<br>Theodor-Stern-Kai 7<br>60590 Frankfurt am Main<br>Maxx Weger<br>Tel: 069 6301-84348<br><a href="mailto:Maxx.Weger@kgu.de">Maxx.Weger@kgu.de</a><br><b>Kinder- und Jugendmedizin (Aktiv)</b><br>Schwerpunkt Onkologie, Hämatologie und Hämostaseologie<br>Theodor-Stern-Kai 7<br>60590 Frankfurt am Main<br>Maxx Weger<br>Tel: 069 6301-84348<br><a href="mailto:Maxx.Weger@kgu.de">Maxx.Weger@kgu.de</a>  |
| <b>Sponsor</b>                                   | Universitätsklinikum Saarland  |
| <b>Förderer</b>                                  | Deutsche Kinderkrebshilfe  |
| <b>Registrierung in anderen Studienregistern</b> | Deutsches Register Klinischer Studien DRKS00011208   |
| <b>Links</b>                                     | <a href="#">Zu den Ein- und Ausschlusskriterien</a>  |