

KURZPROTOKOLL
TIGER-Optune

Öffentlicher Titel	TumortheraPIefelder bei neu diagnostizierten Glioblastomen
Wissenschaftl. Titel	The use of TTFields for newly diagnosed GBM patients in Germany in routine clinical care – TIGER Study
Kurztitel	TIGER-Optune
Studienart	multizentrisch, prospektiv, offen/unverblindet, einarmig, nicht-interventionelle Studie
Studienphase	nicht zutreffend
Erkrankung	Nervensystem: Gliome: Glioblastom (WHO Grad IV) - Erstlinie
Einschlusskriterien	<ul style="list-style-type: none">- Newly diagnosed histologically confirmed GBM (WHO-Grade IV)- Patient within first 3 cycles of first-line tumor-specific maintenance chemotherapy- Clinical indication for TTFields treatment- Given informed consent for use and processing of data
Ausschlusskriterien	<ul style="list-style-type: none">- Present or planned pregnancy- Significant additional neurological disease (e.g. significantly increased intracerebral pressure (ICP) with a significant midline shift of the brain)- Active implanted medical device (e.g. deep brain stimulator)- Documented allergy to conductive hydrogel- Skull defect (e.g. missing bone with no replacement, bullet fragments in the skull)
Alter	18 Jahre und älter
Prüfzentren	Universitätsklinikum Frankfurt (Nachbeobachtung) Dr. Senckenbergisches Institut für Neuroonkologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Bianca Diehl Tel: 069 6301-87711 Fax: 069 6301-87713 bianca.diehl@kgu.de
Sponsor	Novocure GmbH
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03258021