99003014028000

Modul	Sachverhalt
Leistungsschlüssel	99003014028000
Leistungsbezeichnung I	
Leistungsbezeichnung II	Medicinal products; notification of a clinical trial
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Bayern
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	
Leistungsgruppierung	
Verrichtungskennung	
SDG-Informationsbereich	
Lagen Portalverbund	
Einheitlicher Ansprechpartner	
Fachlich freigegeben am	17.04.2025

Modul	Sachverhalt
Fachlich freigegen durch	Bayerisches Staatsministerium für Gesundheit, Pflege und Prävention (Bavarian State Ministry of Health, Care and Prevention)
Handlungsgrundlage	https://www.gesetze-im-internet.de/amg_1976/BJNR024480976.html#BJNR024480976BJNG000605310 https://www.gesetze-im-internet.de/amg_1976/BJNR024480976.html#BJNR024480976BJNG000605310 https://www.gesetze-im-internet.de/tamg/__79.html https://www.gesetze-im-internet.de/tamg/__79.html https://www.gesetze-bayern.de/Content/Document/BayZustVAMUeB/true https://www.gesetze-bayern.de/Content/Document/BayZustVAMUeB/true https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=celex:32014R0536 https://eur-lex.europa.eu/legal-content/DE/TXT/?uri=celex:32014R0536
Teaser	Clinical trials under the German Medicinal Products Act are subject to notification.
Volltext	Anyone wishing to conduct clinical trials in accordance with §§ 40ff. German Medicines Act (AMG) must notify the government responsible for the notifying party (sponsor, CRO, laboratory, test facility). Responsibilities • Government of Upper Franconia: responsible for the administrative districts of Upper Palatinate, Upper Franconia, Middle Franconia and Lower Franconia • Government of Upper Bavaria: responsible for the administrative districts of Upper Bavaria, Lower Bavaria and Swabia
Erforderliche Unterlagen	
Voraussetzungen	The requirements for the clinical trial are set out in Section 40 et seq. AMG. Extract of general requirementsIn addition to the requirements set out in Regulation (EU) No. 536/2014, a clinical trial may only be conducted as long as

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	1. there is a sponsor or a representative of the sponsor for purely national clinical trials and for clinical trials conducted nationally and in third countries who is based in a Member State of the European Union or in another state party to the Agreement on the European Economic Area, 2. the person on whom the clinical trial is to be conducted (person concerned) is not placed in an institution by court or official order, 3. in the event that a human being is killed or the body or health of a human being is injured during the conduct of the clinical trial, insurance exists which also provides benefits if no one else is liable for the damage, in accordance with the following conditions: 4. according to the state of scientific knowledge, in relation to the purpose of the clinical trial of a medicinal product consisting of or containing a genetically modified organism or a combination of genetically modified organisms, unacceptable adverse effects are not to be expected on 5. it takes place in an appropriate facility in accordance with Article 50 in conjunction with point 67 of Annex I to Regulation (EU) No 536/2014.
Kosten	Costs for the notification confirmation: €50 to €5,000 (according to the list of costs - tariff no. 7.IX.8 / tariff item 1.1.4.3) They are to be borne by the advertiser.
Verfahrensablauf	For clinical trials with medicinal products that fall within the scope of Regulation (EU) No. 536/2014, the notification must be made online (see "Online procedure").
Bearbeitungsdauer	The notification can be confirmed once all the necessary documents have been submitted and any outstanding issues have been clarified.
Frist	The AMG does not set deadlines.
weiterführende Informationen	
Hinweise	

Modul	Sachverhalt
Rechtsbehelf	Administrative court action
Kurztext	
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	BayernPortal, BayernPortal