

# HANDBUCH Clinical Trials

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CLINICAL TRIALS**

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# 1 Grundlagen

## 1.1 Allgemeine Hinweise

Bitte nehmen Sie sich die Zeit, sich mit den in diesem Handbuch erläuterten einzelnen Funktionen vertraut zu machen.

- Sollten Sie Fehler entdecken, schicken Sie uns bitte eine E-Mail an [pharmnet-ct-helpdesk@dimdi.de](mailto:pharmnet-ct-helpdesk@dimdi.de).
- Die in diesem Handbuch abgebildeten Screenshots können z. T. kleinere Abweichungen zum derzeitigen Original-Wirksystem (aktuelle Version der Anwendung) besitzen.
- Für die Nutzung des PharmNet.Bund-Portals und seiner Anwendungen gelten die unter „Impressum“ (<http://www.pharmnet-bund.de/dynamic/de/impressum.html>) eingestellten „Erklärungen zum Internetangebot, zur Haftung, zu Links und Verlinkung, zum Urheberrecht und Datenschutz“.

## 1.2 Wer darf auf *Clinical Trials* zugreifen?

Auf *Clinical Trials* können Mitarbeiterinnen und Mitarbeiter der Bundesoberbehörden (BfArM, PEI) zugreifen. Ebenso besitzen Mitarbeiterinnen und Mitarbeiter von Landesbehörden, die für die Überwachung der klinischen Prüfungen zuständig sind, Zugriff auf die Datenbank.

## 1.3 Welche Daten sind in *Clinical Trials* enthalten?

*Clinical Trials* enthält aktuelle Informationen zu beantragten klinischen Prüfungen mit Arzneimitteln der Phase I bis IV in Deutschland. *Clinical Trials* basiert auf den Daten des Antragsformulars für klinische Prüfungen und enthält auch Daten aus den Vorgangsbearbeitungssystemen der Bundesoberbehörden.

## 1.4 Woher stammen die Daten in *Clinical Trials*?

Um eine klinische Prüfung genehmigen zu lassen, müssen Antragsteller auf der Webseite der EMA ein Antragsformular ausfüllen (siehe <https://eudract.ema.europa.eu/>). Das ausgefüllte Antragsformular wird u. a. als XML-Datei heruntergeladen. Der Antragsteller schickt diese XML-Datei zusammen mit weiteren Unterlagen an die zuständige Bundesoberbehörde (BfArM oder PEI). Die zuständige Bundesoberbehörde überprüft die Daten und übermittelt die XML-Datei anschließend an das DIMDI. Im DIMDI wird die XML-Datei in *Clinical Trials* hochgeladen.

**Hinweis:** Bitte beachten Sie bei Ihren Recherchen in *Clinical Trials*, dass ein Großteil der Daten in *Clinical Trials* von den Antragstellern stammt. Da nahezu jedes Antragsformular von einem anderen Antragsteller ausgefüllt worden ist, sind die Einträge nicht immer einheitlich. Namen können z. B. unterschiedlich geschrieben worden sein, Tippfehler können sich eingeschlichen haben!

## 2 Recherche in *Clinical Trials*

Die Recherche-Oberfläche in *Clinical Trials* ist in Anlehnung an die DIMDI SmartSearch gestaltet. Die allgemeinen Funktionalitäten der Recherche-Oberfläche sind unter dem Menüpunkt „Hilfe“ in *Clinical Trials* beschrieben.

Beachten Sie bitte folgende Hinweise, um gezielter in *Clinical Trials* suchen zu können:

- Bei der Suche im Feld "**Textfelder**" (im Suchformular "Trial information") wird der Inhalt folgender Felder durchsucht: "Title", "Lay person title", "Abbreviated title", "Medical condition", "Medical condition – lay language", "Main objective", "Secondary objectives", "Principal inclusion criteria", "Principal exclusion criteria".
- Bei der Suche im Feld „**Title**“ (im Suchformular „Trial information“) wird der Inhalt folgender Felder durchsucht: „Title“, „Lay person title“ und „Abbreviated title“.
- Bei der Suche in den Feldern „**Sponsor – contact person**“, „**Legal representative – contact person**“, „**Competent authority applicant – contact person**“, „**Ethics committee applicant – contact person**“, „**Investigator – contact person**“ und „**Network – contact person**“ wird in „First name“, „Middle Name“ und „Family Name“ gesucht.
- Bei der Suche in dem Feld „**Active substance**“ wird der Inhalt folgender Felder durchsucht: „INN/proposed INN“, „Current sponsor code“ und „Other descriptive name“.
- Bei der Suche in den Feldern „**Central technical facility**“ und „**Contract research organisation**“ wird in „Name of organisation“ und „Department“ gesucht.
- Bei der Suche in dem Feld „**Investigator – institution**“ wird in „Institution name“ und „Institution department“ gesucht.
- Umlaute werden in der Form wiedergegeben, wie sie vom Antragsteller eingegeben worden sind. Es erfolgt keine Auflösung der **Umlaute**. Eine Suche sollte daher alle möglichen Variationen der Schreibweise berücksichtigen bzw. mit einer Maskierung der betreffenden Buchstaben erfolgen (z. B. "zellul?r" statt "zellulär").

- Die meisten Felder werden bei einer Suche nur gefunden, wenn in das Suchformular der **vollständige Feldinhalt** eingegeben wird. Falls der vollständige Feldinhalt nicht bekannt ist, lässt sich der Anfang bzw. das Ende durch ein Fragezeichen "?" oder ein "\*" maskieren.

Beispiel 1:

Suche nach allen Dokumenten, in denen "Pharmafirma GmbH" als Sponsor angegeben ist:

1. Suche ohne Maskierung: Suche nach: "Pharmafirma" → 0 Treffer
2. Suche mit Maskierung: Suche nach: "Pharmafirma?" → 25 Treffer

Beispiel 2:

Suche nach allen Dokumenten, in denen "Max Mustermann" als Investigator angegeben ist:

1. Suche ohne Maskierung: Suche nach: "Mustermann" → 0 Treffer
2. Suche mit Maskierung: Suche nach: "?Mustermann?Max?" → 14 Treffer

- Die Felder „**Women of child bearing potential using contraception**“ und „**Women of child bearing potential not using contraception**“:

In dem alten Antragsformular, das bis zum 10. März 2011 verwendet worden ist, ist abgefragt worden, ob in die klinische Prüfung „Women of child bearing potential“ (F.3.3.1) eingeschlossen werden sollen. Im neuen Antragsformular, das ab dem 10. März 2011 verwendet wird, ist die Frage nach „Women of child bearing potential“ in „Women of child bearing potential not using contraception“ umgewandelt worden.

Die Antwort auf die alte Frage („Women of child bearing potential“) hat die EMA bei der Umwandlung aller Dokumente, die bereits vor dem 10. März 2011 in der Datenbank enthalten waren, als Antwort auf die neue Frage („Women of child bearing potential not using contraception“) übernommen. Diese beiden Fragen sind allerdings nicht identisch! Bei allen Dokumenten, die vor dem 10. März 2011 in *Clinical Trials* gespeichert worden sind, ist in dem Feld „Women of child bearing potential not using contraception“ also die Antwort auf die Frage „Women of child bearing potential“ enthalten. Bitte berücksichtigen Sie daher bei Ihrer Recherche das Datum, das in dem Feld „**Eingangsdatum BOB**“ eingetragen ist, um Rückschlüsse auf die Frage, die der Antragsteller beantwortet hat, ziehen zu können.

- **Bitte beachten Sie** bei der Suche in dem Feld „**Sponsor – Bundesland**“:
  - *Clinical Trials* kann das Bundesland nur richtig ausgeben, wenn der Antragsteller dieses im richtigen Format eingegeben hat (5 Ziffern). Hat der Antragsteller Buchstaben wie „D“ oder „DE“ hinzugefügt, kann die *Clinical Trials* das dazugehörige Bundesland nicht ermitteln!
  - Grenzen Sie Ihre Suche immer zusätzlich auf die Sponsoren ein, die ihren Sitz in Deutschland haben. Anderenfalls kann es zu falsch positiven Treffen kommen.
  - Bitte beachten Sie die folgenden **Beispielrecherchen**.

- Suche nach allen klinischen Prüfungen, bei denen der **Sponsor seinen Sitz in einem bestimmten Bundesland** hat:

A. Öffnen Sie das Suchformular „Trial information“:

- Suche nach: „Germany“ im Feld „Sponsor – country“  
→ Auswahl des richtigen Suchbegriffs durch Klick auf den „A-Z“-Button (siehe Screenshot: 1.)

und

- Suche nach: „Niedersachsen“ im Feld „Sponsor – Bundesland“  
→ Auswahl des richtigen Suchbegriffs durch Klick auf den „A-Z“-Button (siehe Screenshot: 2.)

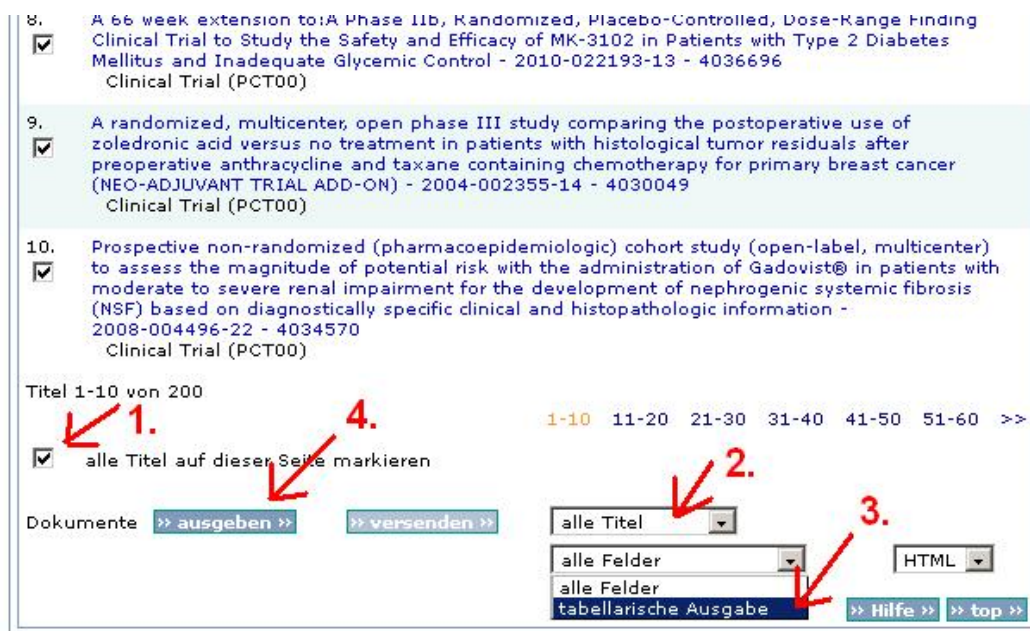
→ Klicken Sie auf „los“ (siehe Screenshot: 3.).

The screenshot shows a search interface titled 'Suche'. At the top, there is a tip: 'Tipp: Abkürzen mit ?: methylphen? oder bei Adressdaten ?Roche?'. Below this, there are two search criteria fields. The first field is labeled 'Suche nach:' and contains 'GERMANY'. The dropdown menu is set to 'Sponsor - country'. A red arrow labeled '1.' points to the 'A-Z' button next to this dropdown. The second field is labeled 'UND' and contains '?'. The dropdown menu is set to 'Sponsor - Bundesland'. A red arrow labeled '2.' points to the 'A-Z' button next to this dropdown. Below the search fields, there are two options: '» Eingabezeile hinzufügen' and '» Filter einblenden'. At the bottom right, there are three buttons: '» zurücksetzen »', '» abbrechen »', and '» los »'. A red arrow labeled '3.' points to the 'los' button. There is also a '» Home »' button above the 'los' button.

## B. Ausgabe der Treffer:

Die angegebene Trefferzahl sagt aus, wie viele klinische Prüfungen beantragt worden sind, bei denen der Sponsor seinen Sitz im gesuchten Bundesland hat. Wenn Sie wissen möchten, **wie viele verschiedene Sponsoren es mit Sitz in dem gesuchten Bundesland** gibt, so können Sie diese Anzahl nur „händisch“ ermitteln. Dazu sollten Sie sich alle Treffer tabellarisch ausgeben lassen und diese Liste Zeile für Zeile durchgehen:

- ➔ Markieren Sie die Checkbox „alle Titel auf dieser Seite markieren“ oder wählen Sie „alle Titel“ aus dem Pulldown-Menü aus (siehe Screenshot: 1. und 2.).
- ➔ Wählen Sie „tabellarische Ausgabe“ aus dem unteren Pulldown-Menü aus (siehe Screenshot: 3.).
- ➔ Klicken Sie auf „ausgeben“ (siehe Screenshot: 4.).
- ➔ Wählen Sie das Feld „Sponsor“ und alle weiteren Felder, die ausgegeben werden sollen, aus.
- ➔ Klicken Sie auf „weiter“.



8.  A 66 week extension to: A Phase IIb, Randomized, Placebo-Controlled, Dose-Range Finding Clinical Trial to Study the Safety and Efficacy of MK-3102 in Patients with Type 2 Diabetes Mellitus and Inadequate Glycemic Control - 2010-022193-13 - 4036696  
Clinical Trial (PCT00)

9.  A randomized, multicenter, open phase III study comparing the postoperative use of zoledronic acid versus no treatment in patients with histological tumor residuals after preoperative anthracycline and taxane containing chemotherapy for primary breast cancer (NEO-ADJUVANT TRIAL ADD-ON) - 2004-002355-14 - 4030049  
Clinical Trial (PCT00)

10.  Prospective non-randomized (pharmacoepidemiologic) cohort study (open-label, multicenter) to assess the magnitude of potential risk with the administration of Gadovist® in patients with moderate to severe renal impairment for the development of nephrogenic systemic fibrosis (NSF) based on diagnostically specific clinical and histopathologic information - 2008-004496-22 - 4034570  
Clinical Trial (PCT00)

Titel 1-10 von 200

alle Titel auf dieser Seite markieren

Dokumente [» ausgeben »](#) [» versenden »](#)

alle Titel

alle Felder

tabellarische Ausgabe [» Hilfe »](#) [» top »](#)

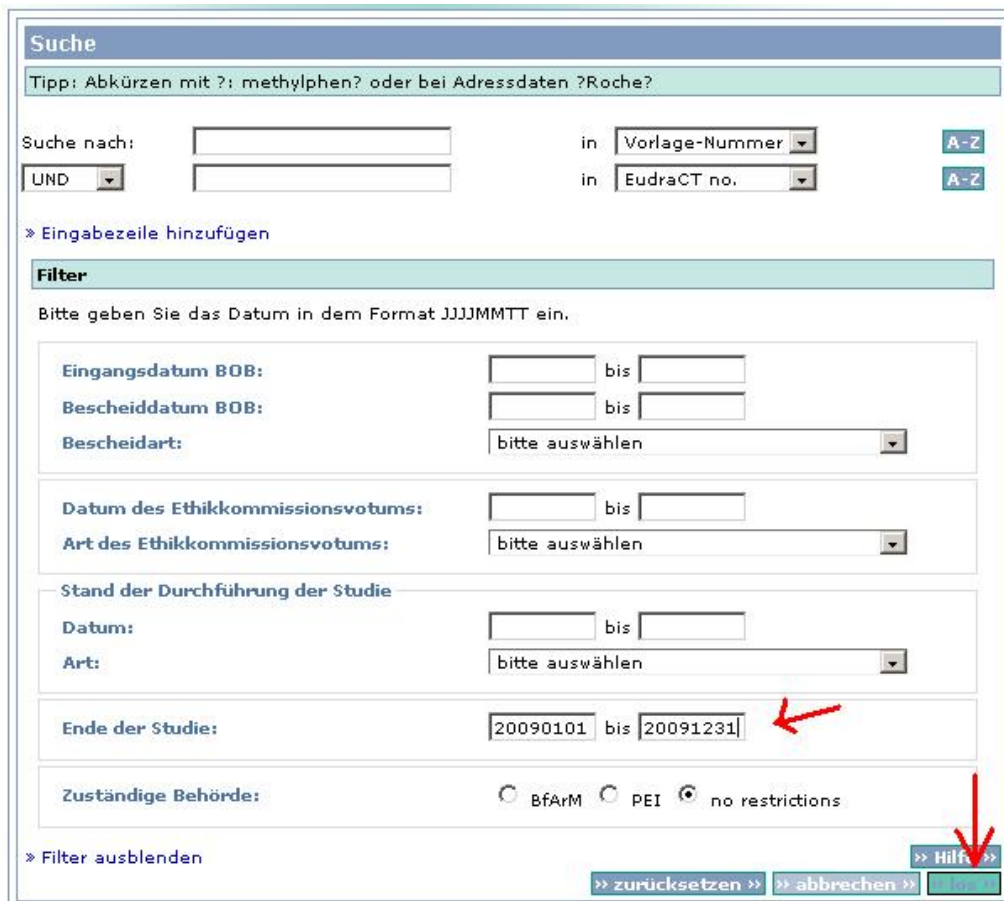
- Suche nach der Anzahl der **abgeschlossenen klinischen Prüfungen in einem bestimmten Jahr nach Sitz des Sponsors (Bundesland)**

Um alle klinischen Prüfungen in *Clinical Trials* zu finden, die z. B. im Jahr 2009 abgeschlossen worden sind und bei denen der Sponsor seinen Sitz z. B. in Niedersachsen hat, gehen Sie bitte folgendermaßen vor:

A. Öffnen Sie das Suchformular „Trial information“ und suchen Sie wie auf Seite 10 beschrieben nach allen klinischen Prüfungen, bei denen der Sponsor in Deutschland sitzt und darüberhinaus in einem bestimmten Bundesland.

B. Öffnen Sie das Suchformular „Workflow information“:

- ➔ Klicken Sie auf „Filter einblenden“.
- ➔ Geben Sie im Feld „Ende der Studie“ „20090101“ bis „20091231“ ein (siehe Screenshot: 1.).
- ➔ Klicken Sie auf „los“ (siehe Screenshot: 2.).



**Suche**

Tipp: Abkürzen mit ?: methylphen? oder bei Adressdaten ?Roche?

Suche nach:  in

in

» Eingabezeile hinzufügen

**Filter**

Bitte geben Sie das Datum in dem Format JJJJMMTT ein.

**Eingangsdatum BOB:**  bis

**Bescheiddatum BOB:**  bis

**Bescheidart:**


**Datum des Ethikkommissionsvotums:**  bis

**Art des Ethikkommissionsvotums:**

**Stand der Durchführung der Studie**


**Datum:**  bis

**Art:**

**Ende der Studie:**  bis  

**Zuständige Behörde:**  BfArM  PEI  no restrictions

» Filter ausblenden



C. Verknüpfen Sie die unter A. und B. beschriebenen Suchschritte:

- Klicken Sie auf „alle Suchschritte anzeigen“ im Abschnitt „Ergebnisse“.
- Markieren Sie die Checkboxen vor den beiden Suchschritten, die Sie verknüpfen möchten.
- Klicken Sie auf „und“.
- Im Abschnitt „Titel“ sind alle Treffer aufgelistet.

D. Ausgabe der Treffer:

Sie können sich jedes Dokument einzeln oder einen Teil oder alle Dokumente tabellarisch ausgeben lassen. Für die tabellarische Ausgabe gehen Sie bitte wie auf Seite 11 beschrieben vor.

### 3 Aufbau der Dokumentausgabe

Die Dokumente in *Clinical Trials* sind im Wesentlichen wie das Antragsformular für klinische Prüfungen (siehe [http://ec.europa.eu/health/files/eudralex/vol-10/application-form2009\\_en.pdf](http://ec.europa.eu/health/files/eudralex/vol-10/application-form2009_en.pdf)) aufgebaut. Im Folgenden ist dargestellt, welche Informationen in einem Dokument in *Clinical Trials* enthalten sein können.

#### Hinweise:

- In der **linken Spalte** sind die Feldbeschreibungen aufgeführt, wie sie in einem Dokument in *Clinical Trials* erscheinen.
- In der **rechten Spalte** ist anstelle eines Original-Feldinhaltes Folgendes angegeben:
  - Feldnummerierung im Antragsformular (z. B. A.4)
  - Beschreibung des Feldinhaltes (übernommen aus dem Antragsformular, z. B. Sponsor's protocol version)
  - „Y/N“, falls es sich um eine Frage handelt, die mit „ja“ oder „nein“ beantwortet werden kann. In diesem Feld kann auch die Antwort „not answered“ stehen.
  - „Multilinguales Feld“: In diesen Fällen hat der Antragsteller die Möglichkeit, den Feldinhalt nicht nur auf Englisch sondern zusätzlich in jeder beliebigen europäischen Sprache auszufüllen. In *Clinical Trials* wird neben dem englischen Feldinhalt immer auch der deutsche Feldinhalt ausgegeben, sofern der Antragsteller das Feld auch auf Deutsch ausgefüllt hat.
  - Feldname in *Clinical Trials* (z. B. CTSPONSPROTV)
- Die unter **“Workflow Information of National Competent Authority”** angegebenen Informationen stammen aus den Vorgangsbearbeitungsdatenbanken der Bundesoberbehörden (BfArM und PEI) und sind daher im EudraCT-Antragsformular nicht enthalten.
- **Felder werden nur dann ausgegeben**, wenn der Antragsteller sie ausgefüllt hat. Felder, die mit „Y“, „N“ oder „not answered“ gefüllt sein können, werden immer ausgegeben. Ausnahme: Im Bereich „Type of IMP“ (D.3.11 bis D.7) werden die Felder nur dann ausgegeben, wenn der Eintrag „Y“ lautet. Lautet der Eintrag „N“ oder „not answered“ wird das Feld nicht ausgegeben.

/1 von 1 DIMDI: Datenbank Clinical Trials (PCT00) © BMG

EudraCT-Nummer Title - Title of the trial (A2/A3)

Entry in CT-Database: Release Date

## Trial identification

<b>EudraCT number:</b>	A.2 – EudraCT number CTEUDRACTNR
<b>Full title of the trial:</b>	A.3 – Full title of the trial [multilinguales Feld] CTTI
<b>Lay person title:</b>	A.3.1 – Title of the trial for lay people, in easily understood, i.e. non-technical, language [multilinguales Feld] CTTILAY
<b>Abbreviated title:</b>	A.3.2 – Name or abbreviated title of trial where available [multilinguales Feld] CTABBRTI
<b>Sponsor's protocol code number:</b>	A.4.1 – Sponsor's protocol code number CTSPONSPROTNR
<b>Sponsor's protocol version:</b>	A.4.2 – Sponsor's protocol version CTSPONSPROTV
<b>Sponsor's protocol version date:</b>	A.4.3 – Sponsor's protocol version date CTSPONSPROTVDATE
<b>ISRCTN number:</b>	A.5.1 – ISRCTN number CTISRCTNNR
<b>US NCT number:</b>	A.5.2 – US NCT number CTUSNCTNR
<b>WHO UTRN number:</b>	A.5.3 – WHO Universal Trial Reference number (UTRN) CTWHOUTRNNR
<b>Other identifier:</b>	A.5.4 – Clinical trial identifiers from clinical trial registries other than EudraCT CTIDENTOTHER und CTIDENTOTHERNR
<b>Resubmission:</b>	A.6 – Is this a resubmission? Y / N CTRESUB
<b>Resubmission letter:</b>	A.6 – If yes, indicate the resubmission letter (First submission or resubmission letter) CTRESUBLET
<b>Trial part of a PIP:</b>	A.7 – Is the trial part of a Paediatric Investigation Plan? Y / N CTPIP
<b>PIP decision number:</b>	A.8 – EMA Decision number of Paediatric Investigation Plan CTPIPDESNR

## *Workflow information of National Competent Authority*

<b>Eingangsdatum BOB:</b>	Bundesoberbehörden Eingangsdatum VBS.BOBEINDAT
<b>Bescheiddatum BOB:</b>	Bundesoberbehörden Bescheiddatum VBS.BOBBESCHDAT
<b>Bescheidart BOB:</b>	Bundesoberbehörden Bescheidart VBS.BOBBESCHART
<b>Bescheiddatum Ethikkommission:</b>	Ethikkommissionsvotum Datum VBS.EKVOTDAT
<b>Bescheidart Ethikkommission:</b>	Ethikkommissionsvotum Art VBS.EKVOTART
<b>Vorlage-Nummer:</b>	Vorlage-Nummer VBS.VNR
<b>Stand der Studie / Datum:</b>	Datum Stand der Studie VBS.STATSTUDAT
<b>Stand der Studie / Art:</b>	Art des Standes der Studie VBS.STATSTUDART
<b>Datum / Ende der Studie in Deutschland:</b>	Datum Ende der Klinischen Studie in Deutschland VBS.KLINPRUEFENDDATDE

## *Sponsor identification*

### *Sponsor*

<b>Status of the sponsor:</b>	B.3.1 und B.3.2 – Commercial or non commercial SPSPONSSTAT
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Sponsor Organisation Name (B.1.1)  
 Sponsor Name of Person to Contact - Person's given / middle / family Name (B.1.2.1 bis B.1.2.3)  
 Sponsor Organisation Street Address (B.1.3.1)  
 Sponsor Organisation Postcode / Town or City (B1.3.3 / B.1.3.2)  
 Sponsor Organisation Bundesland  
 Sponsor Organisation Country (B.1.3.4)  
 Sponsor Organisation Telephone number (B.1.4)  
 Sponsor Organisation Fax number (B.1.5)  
 Sponsor Organisation E-Mail (B.1.6)

### *Legal representative of the sponsor in the EU*

Legal Representative of the Sponsor Organisation Name (B.2.1)  
 Legal Representative of the Sponsor Name of Person to Contact - Person's given / middle / family Name (B.2.2.1 bis B.2.2.3)  
 Legal Representative of the Sponsor Street Address (B.2.3.1)  
 Legal Representative of the Sponsor Postcode / Town or City (B.2.3.3 / B.2.3.2)  
 Legal Representative of the Sponsor Country (B.2.3.4)  
 Legal Representative of the Sponsor Telephone number (B.2.4)  
 Legal Representative of the Sponsor Fax number (B.2.5)  
 Legal Representative of the Sponsor E-Mail (B.2.6)

### *Source(s) of monetary or material support for the clinical trial*

Source of Monetary or Material Support Organisation Name (B.4.1)  
 Source of Monetary or Material Support Organisation Country (B.4.2)

### *Contact point designated by the sponsor for further information on the trial*

Contact point Organisation Name (B.5.1)  
 Contact point Organisation Functional Name (B.5.2)  
 Contact point Organisation Street Address (B.5.3.1)  
 Contact point Organisation Postcode / Town or City (B.5.3.3 / B.5.3.2)  
 Contact point Organisation Country (B.5.3.4)  
 Contact point Organisation Telephone number (B.5.4)  
 Sponsor Organisation Fax number (B.5.5)  
 Sponsor Organisation E-Mail (B.5.6)

## *Applicant identification*

### *Competent Authority (CA)*

Competent Authority Organisation Name (H.2.1)  
 Competent Authority Street Address (H.2.2.1)  
 Competent Authority Postcode / Town or City (H.2.2.3 / H.2.2.2)  
 Competent Authority Country (H.2.2.4)

### *Request for the Competent Authority*

<b>Type of the CA applicant:</b>	C.1.1 bis C.1.3 – Identification of the CA applicant for this clinical trial in this Member State. Selection by drop down list: Sponsor or Legal representative of the sponsor or person or organisation authorised by the sponsor to make the application AICAAPPTYPE
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- CA applicant Organisation Name (C.1.4.1)
- CA applicant Name of Person to Contact - Person's given / middle / family Name (C.1.4.2.1 bis C.1.4.2.3)
- CA applicant Organisation Street Address (C.1.4.3.1)
- CA applicant Organisation Postcode / Town or City (C.1.4.3.3 / C.1.4.3.2)
- CA applicant Organisation Country (C.1.4.3.4)
- CA applicant Organisation Telephone number (C.1.4.4)
- CA applicant Organisation Fax number (C.1.4.5)
- CA applicant Organisation E-Mail (C.1.4.6)

### *Ethics Committee (IEC)*

- Ethics Committee Organisation Name (H.2.1)
- Ethics Committee Street Address (H.2.2.1)
- Ethics Committee Postcode / Town or City (H.2.2.3 / H.2.2.2)
- Ethics Committee Country (H.2.2.4)

### *Request for the Ethics Committee*

Type of the IEC applicant:	C.2.1 bis C.2.4 – Identification of the IEC applicant for this clinical trial in this Member State. Selection by drop-down list: Sponsor / Legal representative of the sponsor / Person or organisation authorised by the sponsor to make the application / Co-ordinating investigator (for multicentre trial) / Principal investigator (for single centre trial) AIECAPPTYPE
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- IEC applicant Organisation Name (C.2.5.1)
- IEC applicant Name of Person to Contact - Person's given / middle / family Name (C.2.5.2.1 bis C.2.5.2.3)
- IEC applicant Organisation Street Address (C.2.5.3.1)
- IEC applicant Organisation Postcode / Town or City (C.2.5.3.3 / C.2.5.3.2)
- IEC applicant Organisation Country (C.2.5.3.4)
- IEC applicant Organisation Telephone number (C.2.5.4)
- IEC applicant Organisation Fax number (C.2.5.5)
- IEC applicant Organisation E-Mail (C.2.5.6)

### *Information on the investigational medicinal product(s) / placebo(s)*

1: Product name (PR1 Product sequence number)

Product role:	D.1.2 bis D 1.3 – IMP being tested or IMP used as a comparator MPCAT
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### *IMP – Status of the investigational medicinal product*

IMP has a marketing authorisation:	D.2.1 – Has the IMP to be used in the trial a marketing authorisation? Y / N MPMAINMEMSTATE
Trade name:	D.2.1.1.1 – Trade name MPMEMSTATETRANAM
EV product code:	D.2.1.1.1.1 – EV product code (where applicable) MPEVPRODCODE

<b>Name of marketing authorisation holder:</b>	D.2.1.1.2 – Name of Marketing Authorisation holder MPMEMSTATEMAH
<b>Marketing authorisation number:</b>	D.2.1.1.3 – Marketing Authorisation number (if Marketing Authorisation granted by an EEA Member State) MPMEMSTATEAUTNUM
<b>IMP modified in relation to its marketing authorisation:</b>	D.2.1.1.4 – Is the IMP modified in relation to its Marketing Authorisation? Y / N MPMEMSTATEMOD
<b>Type of modification:</b>	D.2.1.1.4.1 – If 'Yes' to D.2.1.1.4, please specify MPMEMSTATEMODSPEC
<b>Marketing authorisation granted by:</b>	D.2.1.2 – The country that granted the Marketing Authorisation MPMEMSTATECOU
<b>Germany concerned with this application:</b>	D.2.1.2.1 – Is this the Member State concerned with this application? - Y / N MPTHISCONCMS

***IMP – Situations where any brand of drug product with marketing authorisation in the Member State may be used in the trial. Treatment is defined by:***

<b>Active substance:</b>	D.2.2.1 / D.2.2.1.1 – In the protocol, is treatment defined only by active substance? If 'Yes', give active substance in D.3.8 or D.3.9 – Y / N MPANYAUTACTSUB
<b>Combination of marketed products:</b>	D.2.2.2 / D.2.2.2.1 – In the protocol, do treatment regimens allow different combinations of marketed products used according to local clinical practice at some or all investigator sites in the MS? If 'Yes', give active substance in D.3.8 or D.3.9 - Y / N MPLOCSITEPROD
<b>ATC group:</b>	D.2.2.3 / D.2.2.3.1 – The products to be administered are defined as belonging to an ATC group. If 'Yes', give the ATC group of the applicable authorised code in the ATC code field (Level 3 or the level that can be defined) in D.3.3 - Y / N MPISATCGROUPUSED
<b>Other:</b>	D.2.2.4 – Other specification of the IMP identification - Y / N MPOTHER
<b>Other / specified:</b>	D.2.2.4.1 – If 'Yes' to D.2.2.4, please specify MPOTHDES

**IMP – Description of the investigational medicinal product:**

<b>Product name:</b>	D.3.1 – Product name where applicable MPNAME
<b>Product code:</b>	D.3.2 – Product code where applicable MPCODE
<b>ATC code:</b>	D.3.3 – ATC code, if officially registered MPATCCODE
<b>Pharmaceutical form:</b>	D.3.4 – Pharmaceutical form (use standard terms) MPPHARMFORM
<b>Specific paediatric formulation:</b>	D.3.4.1 – Is this a specific paediatric formulation? – Y / N MPPAEDFORM
<b>Route of administration:</b>	D.3.7 – Route of administration (use standard terms) MPROUTEADMIN
<b>Active substance-INN / proposed INN:</b>	D.3.8 – Name of active substance (INN or proposed INN if available) ASUINN
<b>Active substance - CAS number:</b>	D.3.9.1 – CAS number ASUCASNR
<b>Active substance – current sponsor code:</b>	D.3.9.2 – Current sponsor code for this active substance ASUSUPPCODE
<b>Active substance – other descriptive name:</b>	D.3.9.3 – Other descriptive name for this active substance ASUODESCNAME
<b>Active substance – EV substance code:</b>	D.3.9.4 – EudraVigilance substance code ASUEVSUBCODE
<b>Active substance – full molecular formula:</b>	D.3.9.5 – Full molecular formula for the active substance ASUMOLFORM
<b>Active substance – chemical / biological description:</b>	D.3.9.6 – Chemical / biological description of the active substance ASUCHEMBIOLDES
<b>Concentration type:</b>	D.3.10.2 – Active substance concentration type (“exact number”, “range”, “more than” or “up to”) ASUCONCTYPE
<b>Concentration number part 1:</b>	D.3.10.3 – Active substance concentration number 1 ASUCONCNRPART1
<b>Concentration number part 2:</b>	D.3.10.3 – Active Substance concentration number 2 (only used if D.3.10.2 is set to “range”) ASUCONCNRPART2
<b>Concentration unit:</b>	D.3.10.1 AS Concentration unit (Concentration unit) ASUCONCUNIT

## IMP – Type of the IMP

[Kommentar: Lautet der Eintrag „N“ oder „Not answered“, wird das Feld nicht ausgegeben]

<b>Active substance origin – chemical:</b>	D.3.11.1 – Does the IMP contain an active substance of chemical origin? – Y / N MPCHEMOR
<b>Active substance origin – biological / biotechnological:</b>	D.3.11.2 – Does the IMP contain an active substance of biological / biotechnological origin [other than Advanced Therapy IMP (ATIMP)]? – Y / N MPBIOOR
<b>Medicinal product type – advanced therapy IMP:</b>	D.3.11.3 – Is this an Advanced Therapy IMP (ATIMP)? – Y / N MPISADVOTHER
<b>Advanced therapy – somatic cell therapy:</b>	D.3.11.3.1 – Somatic cell therapy medicinal product? - Y / N MPISSOMCELL
<b>Somatic cell therapy origin – autologous:</b>	D.4.1.1 – Origin of cells: autologous – Y / N MPSOMCELLAUT
<b>Somatic cell therapy origin – allogeneic:</b>	D.4.1.2 – Origin of cells: allogeneic – Y / N MPSOMCELLALL
<b>Somatic cell therapy origin – xenogeneic:</b>	D.4.1.3 – Origin of cells: xenogeneic – Y / N MPSOMCELLXEN
<b>Somatic cell therapy origin – xenogeneic / species of origin:</b>	D.4.1.3.1 – If ‘Yes’ to D.4.1.3, specify species of origin MPSOMCELLXENSPECORIG
<b>Somatic cell type – stem cells:</b>	D.4.2.1 – Type of cells: stem cells – Y / N MPSOMCELLSTEM
<b>Somatic cell type – differentiated cells:</b>	D.4.2.2 – Type of cells: differentiated cells – Y / N MPSOMCELLDIFF
<b>Somatic cell type – differentiated cells / cell type:</b>	D.4.2.2.1 – If ‘Yes’ to D.4.2.2, specify the type (e.g. keratinocytes, fibroblasts, chondrocytes...) MPSOMCELLDIFFTYP
<b>Somatic cell type – others:</b>	D.4.2.3 – Type of cells: Others – Y / N MPSOMCELLLOTH
<b>Somatic cell type – others / specified:</b>	D.4.2.3.1 – If ‘Yes’ to D.4.2.3, specify MPSOMCELLLOTHSPEC

<b>Advanced therapy – gene therapy:</b>	D.3.11.3.2 – Gene therapy medicinal product? – Y / N MPISGENTHER
<b>Gene therapy – genes of interest:</b>	D.5.1 – Gene(s) of interest MPGENTHERGENOFINT
<b>Gene therapy – in vivo:</b>	D.5.2 – In-vivo gene therapy – Y / N MPGENTHERINVIVO
<b>Gene therapy – ex vivo:</b>	D.5.3 – Ex-vivo gene therapy – Y / N MPGENTHEREXVIVO
<b>Gene transfer – nucleic acid:</b>	D.5.4.1 – Type of gene transfer product: Nucleic acid (e.g. plasmid) – Y/N MPGENTHERNUCAC
<b>Gene transfer – nucleic acid – naked:</b>	D.5.4.1.1 – Nucleic acid naked – Y/N MPGENTHERNUCACNAK
<b>Gene transfer – nucleic acid – complexed:</b>	D.5.4.1.2 – Nucleic acid complexed – Y/N MPGENTHERNUCACCOMP
<b>Gene transfer – viral vector:</b>	D.5.4.2 – Type of gene transfer product: Viral vector – Y/N MPGENTHERVIR
<b>Gene transfer – viral vector / specified:</b>	D.5.4.2.1 – If ‘Yes’ to D.5.4.2, specify the type: adenovirus, retrovirus, AAV, ... MPGENTHERVIRSPEC
<b>Gene transfer – others:</b>	D.5.4.3 – Type of gene transfer product: Other – Y/N MPGENTHEROTH
<b>Gene transfer – others / specified:</b>	D.5.4.3.1 – If ‘Yes’ to D.5.4.3, specify MPGENTHEROTHSPEC
<b>Genetically modified somatic cells:</b>	D.5.5 – IMP contains genetically modified somatic cells – Y/N MPGENTHERGENMOD
<b>Genetically modified somatic cells origin – autologous:</b>	D.5.5.1 – Origin of cells: autologous – Y/N MPGENTHERAUT
<b>Genetically modified somatic cells origin – allogeneic:</b>	D.5.5.2 – Origin of cells: allogeneic – Y/N MPGENTHERALL
<b>Genetically modified somatic cells origin – xenogeneic:</b>	D.5.5.3 – Origin of cells: xenogeneic – Y/N MPGENTHERXEN
<b>Genetically modified somatic cells – xenogeneic / species of origin:</b>	D.5.5.3.1 – If ‘Yes’ to D.5.5.3, specify species of origin MPGENTHERXERSPECORIG
<b>Genetically modified somatic cells – type of cells:</b>	D.5.5.4 – Specification of type of cells (e.g. hematopoietic stem cells...) MPGENTHERTYPCELL

<b>Advanced therapy – tissue engineered product:</b>	D.3.11.3.3 – Tissue engineered product? – Y / N MPISTISSENG
<b>Tissue engineered product origin – autologous:</b>	D.6.1.1 – Origin of cells: autologous – Y / N MPTISSENGAUT
<b>Tissue engineered product origin – allogeneic:</b>	D.6.1.2 – Origin of cells: allogeneic – Y / N MPTISSENGALL
<b>Tissue engineered product origin – xenogeneic:</b>	D.6.1.3 – Origin of cells: xenogeneic – Y / N MPTISSENGXEN
<b>Tissue engineered product origin – xenogeneic / species of origin:</b>	D.6.1.3.1 – If ‘Yes’ to D.6.1.3, specify species of origin MPTISSENGXENSPEC
<b>Tissue engineered product type – stem cells:</b>	D.6.2.1 – Type of cells: Stem cells – Y / N MPTISSENGSTEM
<b>Tissue engineered product type – differentiated cells:</b>	D.6.2.2 – Type of cells: Differentiated cells – Y / N MPTISSENGDIFF
<b>Tissue engineered product type – differentiated cells / specified:</b>	D.6.2.2.1 – If ‘Yes’ to D.6.2.2, specify the type (e.g. keratinocytes, fibroblasts, chondrocytes) MPTISSENGDIFFSPEC
<b>Tissue engineered product type – others:</b>	D.6.2.3 – Type of cells: Others – Y / N MPTISSENGOTH
<b>Tissue engineered product type – others / specified:</b>	D.6.2.3.1 – If ‘Yes’ to D.6.2.3, specify MPTISSENGOTHSPEC
<b>Advanced therapy – combination with medical device:</b>	D.3.11.3.4 – Combination ATIMP (i.e. one involving a medical device)? – Y / N MPISCOMATIMP
<b>Combination with medical device – device description:</b>	D.7.1 – Give a brief description of the device MPCOMATIMPDEVDESC
<b>Combination with medical device – device name:</b>	D.7.2 – What is the name of the device? MPCOMATIMPDEVNA
<b>Combination with medical device – device implantable:</b>	D.7.3 – Is the device implantable? – Y / N MPCOMATIMPDEVIMP
<b>Combination with medical device – medical device:</b>	D.7.4.1 – Does this product contain a medical device? – Y / N MPCOMATIMPMEDEV
<b>Medical device – CE mark:</b>	D.7.4.1.1 – Does this medical device have a CE mark? – Y / N MPCOMATIMPMEDEVCE
<b>CE mark – notified body:</b>	D.7.4.1.1.1 – The notified body is: MPCOMATIMPMEDEVNB
<b>Combination with medical device – bio-materials:</b>	D.7.4.2 – Does this product contain bio-materials? – Y / N MPCOMATIMPBIOMAT

<b>Combination with medical device – scaffolds:</b>	D.7.4.3 – Does this product contain scaffolds? – Y / N MPCOMATIMPSCA
<b>Combination with medical device – matrices:</b>	D.7.4.4 – Does this product contain matrices? – Y / N MPCOMATIMPMAT
<b>Combination with medical device – other:</b>	D.7.4.5 – Does this product contain something else? – Y / N MPCOMATIMPOTH
<b>Combination with medical device – other / specified</b>	D.7.4.5.1 – If ‘Yes’ to D.7.4.5, specify MPCOMATIMPOTHSPEC
<b>Advanced therapy – CAT classification issued:</b>	D.3.11.3.5 – Has the Committee on Advanced Therapies (CAT) issued a classification for this product? – Y / N MPADVHERCAT
<b>CAT classification and reference number:</b>	D.3.11.3.5.1 – If ‘Yes’ to D.3.11.5, please provide that classification and its reference number MPADVHERCATCLNR
<b>Medicinal product type - combination with medical device, but no AT:</b>	D.3.11.4 – Is this a combination product that includes device, but does not involve an Advanced Therapy? – Y / N MPISCOMDEV
<b>Combination with medical device – device description:</b>	D.7.1 – Give a brief description of the device MPCOMATIMPDEVDESC
<b>Combination with medical device – device name:</b>	D.7.2 – What is the name of the device? MPCOMATIMPDEVNA
<b>Combination with medical device – device implantable:</b>	D.7.3 – Is the device implantable? – Y / N MPCOMATIMPDEVIMP
<b>Combination with medical device – medical device:</b>	D.7.4.1 – Does this product contain a medical device? – Y / N MPCOMATIMPDEV
<b>Medical device – CE mark:</b>	D.7.4.1.1 – Does this medical device have a CE mark? – Y / N MPCOMATIMPDEVCE
<b>CE mark – notified body :</b>	D.7.4.1.1.1 – The notified body is: MPCOMATIMPDEVNB
<b>Combination with medical device – bio-materials:</b>	D.7.4.2 – Does this product contain bio-materials? – Y / N MPCOMATIMPBIOMAT
<b>Combination with medical device – scaffolds:</b>	D.7.4.3 – Does this product contain scaffolds? – Y / N MPCOMATIMPSCA
<b>Combination with medical device – matrices:</b>	D.7.4.4 – Does this product contain matrices? – Y / N MPCOMATIMPMAT
<b>Combination with medical device – other:</b>	D.7.4.5 – Does this product contain something else? – Y / N MPCOMATIMPOTH
<b>Combination with medical device – other / specified:</b>	D.7.4.5.1 – If ‘Yes’ to D.7.4.5, specify MPCOMATIMPOTHSPEC

<b>Medicinal product type - radiopharmaceutical:</b>	D.3.11.5 – Is this a radiopharmaceutical medicinal product? – Y / N MPRADIOPHARM
<b>Medicinal product type - immunological (vaccine, allergen, immune serum, etc.):</b>	D.3.11.6 – Is this an immunological medicinal product (such as vaccine, allergen, immune serum)? – Y / N MPIMMUN
<b>Medicinal product type - plasma derived:</b>	D.3.11.7 – Is this a plasma derived medicinal product? – Y / N MPPLASMA
<b>Medicinal product type - extractive:</b>	D.3.11.8 – Is this an extractive medicinal product? – Y / N MPOTHEREXT
<b>Medicinal product type – recombinant:</b>	D.3.11.9 – Is this a recombinant medicinal product? – Y / N MPRECOMB
<b>Medicinal product type - containing genetically modified organisms:</b>	D.3.11.10 – Is this a medicinal product containing GMO (genetically modified organisms)? – Y / N MPGENMODORG
<b>GMO - authorisation for contained use / release granted:</b>	D.3.11.10.1 – Has the authorisation for contained use or release been granted? – Y / N MPGENMODAUTACC
<b>GMO - authorisation for contained use / release pending:</b>	D.3.11.10.2 – Is it pending? – Y / N MPGENMODAUTPEND
<b>Medicinal product type - herbal:</b>	D.3.11.11 – Is this a herbal medicinal product? – Y / N MPHERB
<b>Medicinal product type - homeopathic:</b>	D.3.11.12 – Is this a homeopathic medicinal product? – Y / N MPHOMEOPAT
<b>Medicinal product type - other:</b>	D.3.11.13 – Is this another type of medicinal product? – Y/N MPOTHMEDPROD
<b>Medicinal product type - other / specified:</b>	D.3.11.13.1 – If 'Yes' to D.3.11.13, specify MPOTHMEDPRODSPEC

<b>Mode of action:</b>	D.3.12 – Mode of action MPMODACT
<b>Medicinal product to be used in FIH clinical trial:</b>	D.3.13 – Is this an IMP to be used in a first-in-human clinical trial? – Y / N MPFIH
<b>Medicinal product used in FIH – risk factors identified:</b>	D.3.13.1 – Medicinal product to be used in a first-in-human clinical trial – Risk factors identified, according to the guidance FIH MPFIHRISK

### *IMP – Dosing information*

<b>Maximum duration of treatment:</b>	D.3.5 – Maximum duration of treatment of a subject according to the protocol MPMAXDURIMP
<b>First dose for FIH:</b>	D.3.6.1 – First dose in first-in-human (FIH) clinical trial MPFIHDOSE
<b>First dose for FIH - dose and unit:</b>	D.3.6.1 – Dose number and unit MPFIHDOSENUM, MPFIHDOSEUNIT
<b>First dose for FIH – route of administration:</b>	D. 3.6.1 – Route of administration (relevant to first dose) MPFIHDOSEROUTE
<b>First dose for FIH – dose per day or total dose:</b>	D.3.6.1 – Per day or total MPFIHDOSEDAYTOT
<b>Maximum dose allowed:</b>	D.3.6.2 – Maximum dose allowed MPMAXDOSEIMP
<b>Maximum dose – dose and unit:</b>	D.3.6.2 – Dose number and unit MPTOTDOSENUM, MPTOTDOSEUNIT
<b>Maximum dose – route of administration:</b>	D.3.6.2 – Route of administration MPMAXDOSEROUTE
<b>Maximum dose - dose per day or total dose:</b>	D 3.6.2 – Per day or total MPMAXDOSEPERDAYIMP

## *IMP – Regulatory information*

<b>IMP submitted – full IMPD:</b>	D.2.3.1 – Full IMPD submitted – Y / N MPIMPD
<b>IMP submitted – simplified IMPD:</b>	D.2.3.2 – Simplified IMPD submitted – Y / N MPSIMPLIMPD
<b>IMP submitted – summary of product characteristics (SmPC) only:</b>	D.2.3.3 – Only summary of product characteristics (SmPC) submitted – Y / N MPPRODCHAR
<b>IMP previously authorised for a clinical trial by this sponsor in the Community:</b>	D.2.4 – Has the use of the IMP been previously authorised in a clinical trial conducted by the sponsor in the Community? – Y/N MPREVAUTINCOM
<b>IMP authorised - Member States:</b>	D.2.4.1 – If 'Yes' to D.2.4, specify which Member States MPMEMBSTATES
<b>Scientific advice related to this clinical trial:</b>	D.2.6 – Has the IMP been subject of scientific advice related to this clinical trial? – Y / N MPSCIADTRIAL
<b>Scientific advice from the CHMP:</b>	D.2.6.1.1 – From CHMP? – Y / N MPSCIADCHMP
<b>Scientific advice from a Member States Competent Authority:</b>	D.2.6.1.2 – From NCA? – Y / N MPSCIADMSCA
<b>Orphan drug designation in the Community:</b>	D.2.5 – Has the IMP been designated in this indication as an orphan product in the Community? – Y / N MPORPHDRUGINCOM
<b>Orphan drug designation number:</b>	D.2.5.1 – If 'Yes', give the orphan drug designation number MPORPHDRUGDESNUM

## *Placebo – Information on the placebo(s)*

<b>Placebo in this trial:</b>	D.8.1 – Is there a placebo? – Y / N CTISPLACEBO
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1: Placebo name (PL1; Product sequence number)

<b>Placebo related to:</b>	PR1 – D.8.5 – Which IMP(s) is it a placebo for? IMPIMPCODE
<b>Placebo - pharmaceutical form:</b>	D.8.3 – Pharmaceutical form PLPHARMFORM
<b>Placebo - route of administration:</b>	D.8.4 – Route of administration PLROUTADM

PRx Product sequence number **[Kommentar: Zu jedem IMP, das in dem Feld „Placebo related to:“ angegeben ist, werden die folgenden Informationen ausgegeben]**

<b>Placebo excipients composition – identical to IMP apart from the active substance:</b>	D.8.5.2 – Is the placebo otherwise identical to the product? – Y / N IMPPLIDENTIMP
<b>Placebo excipients composition – major ingredients, if variation from product:</b>	D.8.5.2.1 – If composition is not identical, specify the major ingredients IMPPLMAJING

### Information on manufacturer(s) / importer(s)

<b>Release granted by marketing authorisation (D.9.1):</b>	D.9.1 – Are the following conditions met: - The IMP has an MA in the EU <b>and</b> - The IMP is sourced from the EU market <b>and</b> - The IMP is used in the trial without modification (e.g. not overencapsulated) <b>and</b> - The packaging and labelling is carried out for local use only as per article 9.2 of the Directive 2005/28/EC (GCP Directive)? – Y/N RSCONMET
<b>Release granted for product(s):</b>	PR1, PR2, PR3 ... D.9.1 – Product sequence number for the products (IMPs including placebo) for which no responsible site is required RSPRODCD
<b>Site responsible for release of product(s) (D.9.2):</b>	PR1, PR2, PR3 - D.9.2 – Product sequence number for the products (IMPs including placebo) for which this is the responsible site. ASPRODCD
<b>Type of site:</b>	D.9.2.1 / D.9.2.2 – Authorisation type (As a manufacturer, importer or both?) ASAUTHTYPE

**Manufacturer / Importer Organisation Name (D.9.2.3)**  
**Manufacturer / Importer Street Address (D.9.2.4.1)**  
**Manufacturer / Importer Postcode / Town or City (D.9.2.4.3 / D.9.2.4.2)**  
**Manufacturer / Importer Country (D.9.2.4.4)**

<b>Manufacturing authorisation number:</b>	D.9.2.5 – Give the manufacturing authorisation number ASAUTHNR
<b>Reasons for no authorisation:</b>	D.9.2.5.1 – If no authorisation, give the reasons ASAUTOMREA

## Information on the trial

### General information on the trial

<b>Medical condition:</b>	E.1.1 – Specify the medical condition(s) to be investigated [multilinguales Feld] GIMEDCOND
<b>Medical condition – lay language:</b>	E.1.1.1 – Medical condition in easily understood language [multilinguales Feld] GIMEDCONDLAY
<b>Therapeutic area:</b>	E.1.1.2 – Therapeutic area GITHERAREA
<b>MedDRA version code:</b>	E.1.2 – MedDRA version GIMEDDRACLASSCDVER
<b>MedDRA level:</b>	E.1.2 – MedDRA level GIMEDDRACLASSCDLEV
<b>MedDRA classification code:</b>	E.1.2 – MedDRA classification code GIMEDDRACLASSCDCLASS
<b>MedDRA term:</b>	E.1.2 – MedDRA term GIMEDDRACLASSCDTERM
<b>MedDRA SOC term:</b>	E.1.2 – MedDRA SOC term GIMEDDRACLASSCDSOC
<b>Rare disease:</b>	E.1.3 – Is any of the conditions being studied a rare disease? – Y / N GIRAREDIS
<b>Main objective of the trial:</b>	E.2.1 – Main objective of the trial [multilinguales Feld] GIMAINOBJ
<b>Secondary objectives of trial:</b>	E.2.2 - Secondary objectives of the trial [multilinguales Feld] GISECOBJ
<b>Sub-study:</b>	E.2.3 – Is there a sub-study? – Y / N GISUBSTOR
<b>Sub-study details:</b>	E.2.3.1 – If 'Yes' to E.2.3, give full title, date and version of each sub-study and their related objectives [multilinguales Feld] GISUBSTORDET

<b>Principal inclusion criteria:</b>	E.3 – Principal inclusion criteria (list the most important) [multilinguales Feld] GIPRINCCRIT
<b>Principal exclusion criteria:</b>	E.4 – Principal exclusion criteria (list the most important) [multilinguales Feld] GIPREXCRIT
<b>Primary endpoints:</b>	E.5.1 – Primary Endpoint (repeat as necessary) [multilinguales Feld] GIPRIMENDP
<b>Primary endpoint – timepoint(s) of evaluation:</b>	E.5.1.1– Timepoint(s) of evaluation of this endpoint [multilinguales Feld] GIPRIMENDPTIEV
<b>Secondary endpoints:</b>	E.5.2 – Secondary Endpoint (repeat as necessary) [multilinguales Feld] GISECENDP
<b>Secondary endpoint – timepoint(s) of evaluation:</b>	E.5.2.1– Timepoint(s) of evaluation of this endpoint [multilinguales Feld] GISECENDPTIEV

### *Trial scope*

<b>Scope – diagnosis:</b>	E.6.1 – Diagnosis – Y / N GIDIA
<b>Scope – prophylaxis:</b>	E.6.2 – Prophylaxis – Y / N GIPRO
<b>Scope – therapy:</b>	E.6.3 – Therapy – Y / N GITHER
<b>Scope - safety:</b>	E.6.4 – Safety – Y / N GISAF
<b>Scope – efficacy:</b>	E.6.5 – Efficacy – Y / N GIEFF
<b>Scope – pharmacokinetic:</b>	E.6.6 – Pharmacokinetic – Y / N GIPHARMKI
<b>Scope – pharmacodynamic:</b>	E.6.7 – Pharmacodynamic – Y / N GIPHARMDY
<b>Scope - bioequivalence:</b>	E.6.8 – Bioequivalence – Y / N GIBIO
<b>Scope - dose response:</b>	E.6.9 – Dose response – Y / N GIDOSE
<b>Scope – pharmacogenetic:</b>	E.6.10 – Pharmacogenetic – Y / N GIPHARMGEN
<b>Scope - pharmacogenomic:</b>	E.6.11 – Pharmacogenomic – Y / N

	GIPHARMGENO
<b>Scope - pharmacoeconomic:</b>	E.6.12 – Pharmacoeconomic – Y / N GIPHARMECO
<b>Scope – others:</b>	E.6.13 – Others - Y / N GIOTH
<b>Scope – others / specified:</b>	E.6.13.1 – If 'Yes' to E.6.13, please specify [multilinguales Feld] GIOTHDET

### *Trial phase and type*

<b>Trial phase – Phase I:</b>	E.7.1 – Human pharmacology (Phase I) – Y / N GIPHASONE
<b>First administration to humans:</b>	E.7.1.1 – First administration to humans - Y / N GIFIRSTHUMADM
<b>Bioequivalence study:</b>	E.7.1.2 – Bioequivalence study? – Y / N GIBIOEQSTUD
<b>Other type of study:</b>	E.7.1.3 – Other type of study? – Y / N GIOTHPHAS
<b>Other type of study / specified:</b>	E.7.1.3.1 – If 'other', please specify [multilinguales Feld] GIOTHPHASDET
<b>Trial phase – Phase II:</b>	E.7.2 – Therapeutic exploratory (Phase II) – Y / N GIPHASTWO
<b>Trial phase – Phase III:</b>	E.7.3 – Therapeutic confirmatory (Phase III) – Y / N GIPHASTHR
<b>Trial phase – Phase IV:</b>	E.7.4 – Therapeutic use (Phase IV) – Y / N GIPHASFOU

### *Trial design*

<b>Trial design - controlled:</b>	E.8.1. – Controlled – Y / N GICON
<b>Trial design – open:</b>	E.8.1.2 – Open – Y / N GIOP
<b>Trial design – randomised:</b>	E.8.1.1. – Randomised – Y / N GIRAN
<b>Trial design – single blind:</b>	E.8.1.3 – Single blind – Y / N GISINBL

<b>Trial design – double blind:</b>	E.8.1.4 – Double blind – Y / N GIDOUBL
<b>Trial design – parallel group:</b>	E.8.1.5 – Parallel group – Y / N GIPARGR
<b>Trial design – cross over:</b>	E.8.1.6 – Cross over – Y / N GICROV
<b>Trial design – other:</b>	E.8.1.7 – Other – Y / N GIOTHTYP
<b>Trial design – other / specified:</b>	E.8.1.7.1 – If ‘Yes’ to E.8.1.7, please specify [multilinguales Feld] GIOTHTYPDET
<b>Trial design – controlled / comparator other medicinal product:</b>	E.8.2.1. – If Controlled (E.8.1), specify the comparator: Other medicinal product(s) – Y / N GICOMMEDPROD
<b>Trial design – controlled / comparator placebo:</b>	E.8.2.2. – If controlled (E.8.1), specify the comparator: Placebo – Y/N GICOMPLAC
<b>Trial design – controlled / comparator other:</b>	E.8.2.3 – If controlled (E.8.1), specify the comparator: Other – Y / N GICOMOTH
<b>Trial design – controlled / comparator other / specified:</b>	E.8.2.3.1 – If ‘Yes’ to other, specify [multilinguales Feld] GICOMOTHDET
<b>Trial design – number of treatment arms:</b>	E.8.2.4 – Number of treatment arms in the trial GINUMTREATA
<b>Single site in Member State:</b>	E.8.3 – Single site in the Member State concerned (see also Section G) – Y/N GISINSI
<b>Multiple sites in Member State:</b>	E.8.4 – Multiple sites in the Member State concerned (see also Section G) – Y/N GIMULSI
<b>Number of sites anticipated in the Member State concerned:</b>	E.8.4.1 – Number of sites anticipated in the Member State concerned GINUMSIMEMST
<b>Multiple Member States:</b>	E.8.5 – Multiple Member States – Y / N GIMULMEMST

<b>Number of sites anticipated in the Community</b>	E.8.5 1 – Number of sites anticipated in the EEA GINUMSICOM
<b>3rd countries involved – trial conducted both within and outside EEA:</b>	E.8.6.1 – Trial being conducted both within and outside the EEA – Y / N GITHICOU
<b>3rd countries involved – trial conducted completely outside the EEA:</b>	E.8.6.2 – Trial being conducted completely outside of the EEA – Y / N GITHICOUOUTEEA
<b>3rd countries involved – planned regions:</b>	E.8.6.3 – If ‘Yes’ to E.8.6.1 or E.8.6.2, specify the regions in which the trial sites are planned (repeat as necessary) GITHICOUPLANREG
<b>3rd countries involved – number of sites anticipated outside the EEA:</b>	E.8.6.4 – If ‘Yes’ to E.8.6.1 or E.8.6.2, specify the number of sites anticipated outside of the EEA GITHICOUNUMSIOUT
<b>Data monitoring committee in this trial:</b>	E.8.7 – Trial having an independent data monitoring committee? – Y / N GIDATMONCOM
<b>Definition of the end of the trial:</b>	E.8.8 – Definition of the end of trial: If it is the last visit of the last subject, please enter “LVLS”. If it is not LVLS provide a definition [multilinguales Feld] GIENDDDEF
<b>Initial estimate of trial duration in this Member State - years:</b>	E.8.9.1 – Initial estimate of the duration of the trial in the Member State concerned – years GIESTDURMSY
<b>Initial estimate of trial duration in this Member State - months:</b>	E.8.9.1 – Initial estimate of the duration of the trial in the Member State concerned – months GIESTDURMSM
<b>Initial estimate of trial duration in this Member State - days:</b>	E.8.9.1 – Initial estimate of the duration of the trial in the Member State concerned – days GIESTDURMSD
<b>Initial estimate of trial duration worldwide - years:</b>	E.8.9.2 – Initial estimate of the duration of the trial in all countries concerned by the trial – years GIESTDURWWY
<b>Initial estimate of trial duration worldwide - months:</b>	E.8.9.2 – Initial estimate of the duration of the trial in all countries concerned by the trial – months GIESTDURWWM
<b>Initial estimate of trial duration worldwide - days:</b>	E.8.9.2 – Initial estimate of the duration of the trial in all countries concerned by the trial – days GIESTDURWWD
<b>Recruitment start date in this Member State:</b>	E.8.10.1 – Proposed date of start of recruitment in the Member State concerned GIRECRSTAMS

<b>Recruitment start date in any country:</b>	E.8.10.2 – Proposed date of start of recruitment in any country GIRECRSTAANYCOU
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## *Population of trial subjects*

### *Age span*

<b>Less than 18 years:</b>	F.1.1 – Less than 18 years [If 'Yes', specify the estimated number of subjects planned in each age range for the whole trial (Approx. number of patients)] – Y / N PTSUET
<b>Less than 18 years – number:</b>	F.1.1 – Population number under 18 PTSUETNUM
<b>In utero:</b>	F.1.1.1 – In Utero – Y / N PTSINUT
<b>In utero – number:</b>	F.1.1.1.1 – Population number in utero PTSINUTNUM
<b>Preterm newborn infants (gestational age &lt; 37 weeks):</b>	F.1.1.2 – Preterm newborn infants (up to gestational age < 37 weeks) – Y / N PTSPRENEWIN
<b>Preterm newborn infants – number:</b>	F.1.1.2.1 – Population number preterm newborn infants PTSPRENEWINNUM
<b>Newborn (0 – 27 days):</b>	F.1.1.3 – Newborn (0-27 days) – Y / N PTSNEW
<b>Newborn – number:</b>	F.1.1.3.1 – Population number newborn PTSNEWNUM
<b>Infant and toddler (28 days – 23 months):</b>	F.1.1.4 – Infant and toddler (28 days - 23months) – Y / N PTSINTOD
<b>Infant and toddler – number:</b>	F.1.1.4.1 – Population number infant and toddler PTSINTODNUM
<b>Children (2 – 11 years):</b>	F.1.1.5 – Children (2 - 11years) – Y / N PTSCHI
<b>Children – number:</b>	F.1.1.5.1. – Population number children PTSCHINUM
<b>Adolescents (12 – 17 years):</b>	F.1.1.6 – Adolescents (12 - 17 years) – Y / N PTSADO
<b>Adolescents – number:</b>	F.1.1.6.1 – Population number adolescents PTSADONUM
<b>Adults (18 – 64 years):</b>	F.1.2 – Adults (18 - 64 years) – Y / N PTSADU

<b>Adults – number:</b>	F.1.2.1. – Population number adults PTSADUNUM
<b>Elderly (&gt;= 65 years):</b>	F.1.3 – Elderly (>= 65 years) – Y / N PTSELD
<b>Elderly – number:</b>	F.1.3.1 – Population number elderly PTSELDNUM

### Gender

<b>Gender - male:</b>	F.2.2 – Male – Y / N PTSGENM
<b>Gender - female:</b>	F.2.1 – Female – Y / N PTSGENF

### Group of trial subjects

<b>Subjects - healthy volunteers:</b>	F.3.1 – Healthy volunteers – Y / N PTSHEAVOL
<b>Subjects - patients:</b>	F.3.2 – Patients – Y / N PTSPAT
<b>Subjects – specific vulnerable populations:</b>	F.3.3 – Specific vulnerable populations – Y / N PTSSPECVULPOP
<b>Subjects - women of child-bearing potential not using contraceptives:</b>	F.3.3.1 – Women of child bearing potential not using contraception – Y / N PTSWOCHIPOT
<b>Subjects - women of child-bearing potential using contraceptives:</b>	F.3.3.2 – Women of child bearing potential using contraception – Y / N PTSWOCHICON
<b>Subjects - pregnant women:</b>	F.3.3.3 – Pregnant women – Y / N PTSPREWO
<b>Subjects - nursing women:</b>	F.3.3.4 – Nursing women – Y / N PTSNURWO
<b>Subjects – emergency situation:</b>	F.3.3.5 – Emergency situation (emergency situation) – Y / N PTSEMSIT
<b>Subjects incapable of giving consent personally:</b>	F.3.3.6 – Subjects incapable of giving consent personally – Y / N PTSSUBINCCON
<b>Subjects incapable of giving consent personally / specified:</b>	F.3.3.6.1 – If 'Yes' to F.3.3.6, specify [multilinguales Feld] PTSSUBINCCONDET
<b>Subjects - other types of subjects:</b>	F.3.3.7 – Others – Y / N PTSOTHPAT

<b>Subjects - other types of subjects / specified:</b>	F.3.3.7.1 – If `Yes` to F.3.3.7, specify [multilinguales Feld] PTSOTHPATDET
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*Planned number of trial subjects*

<b>Number of subjects in this Member State:</b>	F.4.1 – Planned number of subjects to be included in the Member State PTSMEMST
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<b>Number of subjects in the Community:</b>	F.4.2.1 – Planned number of subjects to be included in the EEA PTSEU
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<b>Number of subjects in the whole trial:</b>	F.4.2.2 – Planned number of subjects to be included in the whole clinical trial PTSTRI
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*Plans for the treatment or care of subjects after the trial*

F.5 – Plans for treatment or care after a subject has ended his/her participation in the trial [multilinguales Feld] PTSPOTRTREDET
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## Clinical trial sites

### Investigators

Principal investigator (for single centre trial) / national coordinating investigator (for multicentre trial)

Institution-name Institution-department G.1.5.1 G.1.5.2	Investigator-qualification (MD...) G.1.4	Family-name, given-name middle-name G.1.1 bis G.1.3	Address G.1.5.3	Post-code G.1.5.5	Town/city G.1.5.4	Country G.1.5.6
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Other principal investigator(s) (for multicentre trial)

Institution-name Institution-department G.2.5.1 G.2.5.2	Investigator-qualification (MD...) G.2.4	Family-name, given-name middle-name G.2.1 bis G.2.3	Address G.2.5.3	Post-code G.2.5.5	Town/city G.2.5.4	Country G.2.5.6
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### Subcontracted central technical facilities

Central Technical Facility Organisation Name (G.3.1)

Central Technical Facility Organisation Name Department (G.3.2)

Central Technical Facility Name of Person to Contact - Person's given / middle / family Name (G.3.3.1 bis G.3.3.3)

Central Technical Facility Organisation Street Address (G.3.4.1)

Central Technical Facility Organisation Postcode / Town or City (G.3.4.3 / G.3.4.2)

Central Technical Facility Organisation Country (G.3.4.4)

Central Technical Facility Organisation Telephone No (G.3.5)

Central Technical Facility Organisation Fax No (G.3.6)

Central Technical Facility Organisation E-mail (G.3.7)

Duties subcontracted - routine clinical pathology testing:	G.3.8.1 – Routine clinical pathology testing – Y / N CTFROUPAT
Duties subcontracted - clinical chemistry:	G.3.8.2 – Clinical chemistry – Y / N CTFCHEM

<b>Duties subcontracted - clinical haematology:</b>	G.3.8.3 – Clinical haematology – Y / N CTFHAE
<b>Duties subcontracted - clinical microbiology:</b>	G.3.8.4 – Clinical microbiology – Y / N CTFMIBIO
<b>Duties subcontracted - histopathology:</b>	G.3.8.5 – Histopathology – Y / N CTFHISPAT
<b>Duties subcontracted – serology / endocrinology:</b>	G.3.8.6 – Serology / endocrinology – Y / N CTFHISEND
<b>Duties subcontracted – analytical chemistry:</b>	G.3.8.7 – Analytical chemistry – Y / N CTFANACHEM
<b>Duties subcontracted - ECG analysis/review:</b>	G.3.8.8 – ECG analysis / review – Y / N CTFECEGANA
<b>Duties subcontracted - medical image analysis/review - X-Ray, MRI, ultrasound, etc.:</b>	G.3.8.9 – Medical image analysis/ review - X-ray, MRI, ultrasound, etc – Y / N CTFMEDIMANA
<b>Duties subcontracted - primary/surrogate endpoint test:</b>	G.3.8.10 – Primary/ surrogate endpoint test – Y / N CTFENDTES
<b>Duties subcontracted - other:</b>	G.3.8.11 – Other duties subcontracted – Y / N CTFOTHDUT
<b>Duties subcontracted - other/specified:</b>	G.3.8.11.1 – If 'Yes' to G.3.7.11, specify the other duties CTFOTHDUTDES

## Networks

- Network Organisation Name (G.4.1)
- Network Name of Person to Contact - Person's given / middle / family Name (G.4.2.1 bis G.4.2.3)
- Network Organisation Street Address (G.4.3.1)
- Network Organisation Postcode / Town or City (G.4.3.3 / G.4.3.2)
- Network Organisation Country (G.4.3.4)
- Network Organisation Telephone No (G.4.4)
- Network Organisation Fax No (G.4.5)
- Network Organisation E-mail (G.4.6)

<b>Activities:</b>	G.4.7 – Activities carried out by the network NETACT
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## Subcontracted clinical research organisations (CROs)

- CRO Organisation Name (G.5.1.1)
- CRO Organisation Name Department (G.5.1.2)
- CRO Name of Person to Contact - Person's given / middle / family Name (G.5.1.3.1 bis G.5.1.3.3)
- CRO Organisation Street Address (G.5.1.4.1)
- CRO Organisation Postcode / Town or City (G.5.1.4.3 / G.5.1.4.2)
- CRO Organisation Country (G.5.1.4.4)
- CRO Organisation Telephone No (G.5.1.5)
- CRO Organisation Fax No (G.5.1.6)
- CRO Organisation E-mail (G.5.1.7)

<b>Duties subcontracted - all tasks of the sponsor:</b>	G.5.1.8 – All tasks of the sponsor – Y / N TMFSPTAS
<b>Duties subcontracted - monitoring:</b>	G.5.1.9 – Monitoring – Y / N TMFMON
<b>Duties subcontracted - regulatory:</b>	G.5.1.10 – Regulatory (e.g. preparation of applications to CA and Ethics Committee – Y / N TMFREGAID
<b>Duties subcontracted - investigator recruitment:</b>	G.5.1.11 – Investigator recruitment – Y / N TMFINVREC
<b>Duties subcontracted - IVRS - treatment randomisation:</b>	G.5.1.12 – IVRS - treatment randomisation – Y / N TMFIVRSTRE
<b>Duties subcontracted - data management:</b>	G.5.1.13 – Data Management – Y / N TMFDATMAN
<b>Duties subcontracted - e-data capture:</b>	G.5.1.14 – E-data capture – Y / N TMFEDATCAP
<b>Duties subcontracted - SUSAR reporting:</b>	G.5.1.15 – SUSAR reporting – Y / N TMFSUSREP
<b>Duties subcontracted - quality assurance auditing:</b>	G.5.1.16 – Quality assurance auditing – Y / N TMFQUASSAUD

<b>Duties subcontracted - statistical analysis:</b>	G.5.1.17 – Statistical analysis – Y / N TMFSTATANA
<b>Duties subcontracted - medical writing:</b>	G.5.1.18 – Medical writing – Y / N TMFMEDWRI
<b>Duties subcontracted - other:</b>	G.5.1.19 – Other Duties subcontracted – Y / N TMFOTHDUT
<b>Duties Subcontracted - Other / Specified:</b>	G.5.1.19.1 – If 'Yes' to G.5.1.19, specify TMFOTHDUTDES

## 4 Weitere Ausbaustufen

Als weitere mögliche Ausbaustufen sind geplant:

- In *Clinical Trials* sollen Ergebnisberichte gemäß § 42b und § 145 AMG veröffentlicht werden. Gleichzeitig soll ein Zugriff der Öffentlichkeit auf ausgewählte Informationen in *Clinical Trials* eingerichtet werden.
- Es soll eine automatisierte Weiterleitung der XML-Dateien von den Bundesoberbehörden über das DIMDI zur EMA eingerichtet werden.
- Es soll eine Umstellung auf eine barrierefreie Recherche-Oberfläche erfolgen.

## 5 Glossar

AS	Active substance
AT	Advanced Therapy
ATC	Anatomical Therapeutic Chemical (Classification System)
ATIMP	Advanced Therapy Investigational Medicinal Product
BfArM	Bundesinstitut für Arzneimittel und Medizinprodukte
BMG	Bundesministerium für Gesundheit
CA	Competent Authority
CAS	Chemical Abstracts Service
CAT	Committee on Advanced Therapies
CHMP	Committee for Medicinal Products for Human Use
CRO	Clinical Research Organisations
CT	Clinical Trial
DIMDI	Deutsches Institut für Medizinische Dokumentation und Information
ECG	Electrocardiogram
EEA	European Economic Area
EMA	European Medicines Agency
EudraCT	Datenbank der EMA zu klinischen Prüfungen
EV	EudraVigilance
FIH	First-in-human
GCP	Good Clinical Practice
GMO	Genetically Modified Organism
IEC	Independent Ethics Committee
IMP	Investigational Medicinal Product
IMPD	Investigational Medicinal Product Dossier
INN	International Non-Proprietary Name
ISRCTN	International Standardised Random Controlled Trial Number
IVRS	Interactive Voice Response System
MA	Marketing Authorisation
MAH	Marketing Authorisation Holder
MD	Doctor of Medicine
MRI	Magnetic Resonance Imaging
MS	Member State
PEI	Paul-Ehrlich-Institut
PIP	Paediatric Investigation Plan
SmPC	Summary of Product Characteristics
SUSAR	Suspected Unexpected Serious Adverse Reaction
US NCT	ClinicalTrials.gov Registry Number
WHO	World Health Organization
WHO UTRN	WHO Universal Trial Reference Number
XML	Extensible markup language (Darstellung hierarchisch strukturierter Daten in Form von Textdateien)