Djibouti
Dominica
Dominican Republic
Ecuador
Egypt
El Salvador
Equatorial Guinea
Eritrea
Estonia
Ethiopia
Falkland Islands (Malvinas)
Faroe Islands
Fiji
Finland
France
French Guiana
French Polynesia
French Southern Territories
Gabon
Gambia
Georgia
Germany
Ghana
Gibraltar
Greece
Greenland
Grenada
Guadeloupe
Guam
Guatemala
Guinea
Guinea-Bissau
Guyana
Haiti
Heard Island and Mcdonald Islands
Holy See (Vatican City State)
Honduras
Hong Kong
Hungary
Iceland
India
Indonesia
Iran, Islamic Republic Of
Iraq
Ireland
Israel
Italy
Jamaica
Japan
Jordan
Kazakhstan
Kenya
Kiribati
Korea, Democratic People's Republic Of
Korea, Republic Of
Kuwait
Kyrgyzstan
Lao People's Democratic Republic
Latvia
Lebanon
Lesotho
Liberia
Libyan Arab Jamahiriya
Liechtenstein
Lithuania
Luxembourg
Macao
Macedonia, The Former Yugoslav Republic Of
Madagascar
Malawi

Malaysia
Maldives
Mali
Malta
Marshall Islands
Martinique
Mauritania
Mauritius
Mayotte
Mexico
Micronesia, Federated States Of
Moldova, Republic Of
Monaco
Mongolia
Montserrat
Morocco
Mozambique
Myanmar
Namibia
Nauru
Nepal
Netherlands
Netherlands Antilles
New Caledonia
Nicaragua
Niger
Nigeria
Niue
Norfolk Island
Northern Mariana Islands
Norway
Oman
Pakistan
Palau
Palestinian Territory, Occupied
Panama
Papua New Guinea
Paraguay
Peru
Philippines
Pitcairn
Poland
Portugal
Puerto Rico
Qatar
Reunion
Romania
Russian Federation
Rwanda
Saint Helena
Saint Kitts and Nevis
Saint Lucia
Saint Pierre and Miquelon
Saint Vincent and The Grenadines
Samoa
San Marino
Sao Tome and Principe
Saudi Arabia
Senegal
Serbia and Montenegro
Seychelles
Sierra Leone
Singapore
Slovakia
Slovenia
Solomon Islands
Somalia
South Africa
South Georgia and The South Sandwich Islands
Spain
Sri Lanka

Sudan
Suriname
Svalbard and Jan Mayen
Swaziland
Sweden
Switzerland
Syrian Arab Republic
Taiwan, Province Of China
Tajikistan
Tanzania, United Republic Of
Thailand
Timor-Leste
Togo
Tokelau
Tonga
Trinidad and Tobago
Tunisia
Turkey
Turkmenistan
Turks and Caicos Islands
Tuvalu
Uganda
Ukraine
United Arab Emirates
United Kingdom
United States of America
United States Minor Outlying Islands
Uruguay
Uzbekistan
Vanuatu
Venezuela
Viet Nam
Virgin Islands, British
Virgin Islands, U.S.
Wallis and Futuna
Western Sahara
Yemen
Zambia
Zimbabwe

14.Primary Sponsor Type: （以下より選択）
- Government funding body
- Hospital
- University
- Commercial sector/Industry
- Charities/Societies/Foundations
- Other Collaborative groups
- Individual
- Other

15.Funding Source Type: （以下より選択）
- Government funding body
- Hospital
- University
- Commercial sector/Industry
- Charities/Societies/Foundations
- Other Collaborative groups
- Self funded/Unfunded
- Other

16.Phase: （以下より選択）
- Not Applicable
- Phase 0
- Phase 1
- Phase 1 / Phase 2
- Phase 2
- Phase 2 / Phase 3
- Phase 3
- Phase 3 / Phase 4
- Phase 4

資料 9. EU Clinical Trials Register (EU-CTR) /Search for Clinical Trials
https://www.clinicaltrialsregister.eu/ctr-search/search（accessed2013.03.13）

資料 10 EU Clinical Trials Register (EU-CTR) /Search for Clinical Trials
https://www.clinicaltrialsregister.eu/ctr-search/search（accessed2013.03.13）
における「Cancer AND UFT」の検索結果より一部抜粋。

資料 11　EU Clinical Trials Register (EU-CTR) /Search for Clinical Trials
https://www.clinicaltrialsregister.eu/ctr-search/search（accessed2013.03.13）
における「Cancer AND UFT」の検索結果より「EudraCT Number: 2007-002053-24」について、「Plain Text」の「Full Trial Details」をダウンロードした情報.

EudraCT Number: 2007-002053-24

This file contains full details on each clinical trial selected for download. Where multi-state trials have been downloaded full information for each of the member states/countries involved in the trial are included separately.

Summary
EudraCT Number: 2007-002053-24
Sponsor's Protocol Code Number: 07_DOG03_133
National Competent Authority: UK - MHRA
Clinical Trial Type: EEA CTA
Trial Status: Ongoing
Date on which this record was first entered in the EudraCT database: 2007-10-10
Link: https://www.clinicaltrialsregister.eu/ctr-search/trial/2007-002053-24/GB/

A. Protocol Information
A.1 Member State Concerned: UK - MHRA
A.2 EudraCT number: 2007-002053-24
A.3 Full title of the trial: A phase II study evaluating the use of concurrent cetuximab, irinotecan, oxaliplatin and UFT in the first line treatment of patients with metastatic colorectal cancer
A.3.2 Name or abbreviated title of the trial where available: e-SCOUT
A.4.1 Sponsor's protocol code number: 07_DOG03_133
A.7 Trial is part of a Paediatric Investigation Plan: Information not present in EudraCT
A.8 EMA Decision number of Paediatric Investigation Plan:

B. Sponsor Information
Sponsor 1
B.1.1 Name of Sponsor: The Christie NHS Foundation Trust
B.1.3.4 Country: United Kingdom
B.3.1 and B.3.2 Status of the sponsor: Non-Commercial
B.4 Source(s) of Monetary or Material Support for the clinical trial:
B.4.1 Name of organisation providing support:
B.4.2 Country:
B.5 Contact point designated by the sponsor for further information on the trial
B.5.1 Name of organisation:
B.5.2 Functional name of contact point:

D. IMP Identification

D.IMP: 1

D.1.2 and D.1.3 IMP Role: Test

D.2 Status of the IMP to be used in the clinical trial

D.2.1 IMP to be used in the trial has a marketing authorisation: Yes

D.2.1.1.1 Trade name: Erbitux 5mg/ml

D.2.1.1.2 Name of the Marketing Authorisation holder: Merck KGaA

D.2.1.2 Country which granted the Marketing Authorisation: European Union

D.2.5 The IMP has been designated in this indication as an orphan drug in the Community: No

D.2.5.1 Orphan drug designation number:

D.3 Description of the IMP

D.3.1 Product name: Cetuximab

D.3.2 Product code: EMD271786

D.3.4 Pharmaceutical form: Solution for infusion

D.3.4.1 Specific paediatric formulation: Information not present in EudraCT

D.3.7 Routes of administration for this IMP:

Intravenous use

D.3.11 The IMP contains an

D.3.11.1 Active substance of chemical origin: No

D.3.11.2 Active substance of biological/ biotechnological origin (other than Advanced Therapy IMP (ATIMP): Yes

D.3.11.3 Advanced Therapy IMP (ATIMP): Information not present in EudraCT

D.3.11.3.1 Somatic cell therapy medicinal product: No

D.3.11.3.2 Gene therapy medical product: No

D.3.11.3.3 Tissue Engineered Product: Information not present in EudraCT

D.3.11.3.4 Combination ATIMP (i.e. one involving a medical device): Information not present in EudraCT

D.3.11.3.5 Committee on Advanced therapies (CAT) has issued a classification for this product: Information not present in EudraCT

D.3.11.4 Combination product that includes a device, but does not involve an Advanced Therapy: Information not present in EudraCT

D.3.11.5 Radiopharmaceutical medicinal product: No

D.3.11.6 Immunological medicinal product (such as vaccine, allergen, immune serum): No

D.3.11.7 Plasma derived medicinal product: No

D.3.11.8 Extractive medicinal product: No
D.3.11.9 Recombinant medicinal product: Information not present in EudraCT
D.3.11.10 Medicinal product containing genetically modified organisms: No
D.3.11.11 Herbal medicinal product: No
D.3.11.12 Homeopathic medicinal product: No
D.3.11.13 Another type of medicinal product: Yes
D.3.11.13.1 Other medicinal product type: Monoclonal Antibody

D.8 Information on Placebo

E. General Information on the Trial
E.1 Medical condition or disease under investigation
E.1.1 Medical condition(s) being investigated: Advanced, inoperable or metastatic colorectal cancer.
MedDRA Classification
E.1.3 Condition being studied is a rare disease: No
E.2 Objective of the trial
E.2.1 Main objective of the trial: To demonstrate the response rate (RR), using the RECIST criteria, of patients with locally advanced / metastatic colorectal cancer treated with a combination of irinotecan, oxaliplatin, UFT and cetuximab.
E.2.2 Secondary objectives of the trial: To assess:
- Progression-free survival (PFS)
- Overall survival (OS; all causes of death)
- Toxicity
- Resectability of liver, lung and pelvic disease after chemotherapy
- Time to progression (TTP)
E.2.3 Trial contains a sub-study: Yes
E.2.3.1 Full title, date and version of each sub-study and their related objectives: A phase II study evaluating the use of concurrent cetuximab, irinotecan, oxaliplatin and UFT in the first line treatment of patients with metastatic colorectal cancer
Translational Research Protocol
version 1.7 - 4th January 2010.

Aims:
- To evaluate circulating levels of VEGF, soluble KDR and FGF-7, apoptotic biomarkers, CTCs and KRAS and PI-3K mutations in circulating free DNA as predictive factors of

response to chemotherapy.
- To evaluate KRAS and PI-3K expression in primary tumour biopsy specimens and post chemotherapy resected specimens, EGFR overexpression, Ki-67 expression, cleaved caspase 3 and cleaved CK 18 as predictive factors for response to Cetuximab administered with chemotherapy.
E.3 Principal inclusion criteria: - Histologically confirmed colorectal adenocarcinoma
- Patients must not have a mutation of K-ras
- Inoperable metastatic or locoregional disease
- No previous chemotherapy for established metastatic disease (adjuvant chemotherapy must have been completed > 6 months prior to trial entry.
- Measurable / evaluable disease
- Normal haematology
- Adequate renal function
- Adequate liver funtion
- Karnofsky performance status 70-100
- Negative pregnancy test for women of child-bearing potential
- Patients must give written, informed consent
- Life expectancy of at least 3 months
E.4 Principal exclusion criteria: - Patients that have a K-ras mutation
- Concurrent uncontrolled medical illness, or other previous / current malignant disease likely to interfere with protocol treatments or comparisons
- Partial / complete bowel obstruction
- Prior EFGR therapy
- Age < 18
- Chronic diarrhoea or inflammatory bowel disease
- Known DPD deficiency
- Gilbert's syndrome or other congenital abnormality of biliary transport
- Previous translant surgery requiring immunosuppressive therapy
- Regular / uncontrolled angina or cardiac arrhythmias
- Clinically relevant coronary heart disease. History of myocardial infarction in last 12 months
- Previous investigational agent in last 4 weeks
- Metastatic disease to brain
- Pregnant/lactating women
- Patients receiving therapy with haloginated antiviral drugs
- Patients who have experienced life-threatening toxicities with fluoropyrimidines

- Patients suffering from any conditions which may affect absorption of UFT / folinic acid
- Patients with known deficiency of or are on inhibitors of cytochrome P450 2A6
- Patients who have previously had radiotherapy to the abdomen / pelvis in last 6 months
- Any medical / psychological condition that in the opinion of the investigator would not enable the patient to complete the study or knowingly give informed consent

E.5 End points

E.5.1 Primary end point(s): The primary end point is the objective response rate as measured by RECIST criteria. Chemotherapy should be given for 8 weeks (2 cycles) prior to assessment.

- In patients who respond or develop stable disease, the treatment should be continued for a further 8 weeks (16 weeks in total).
- In patients who respond or develop stable disease, the treatment should be continued for a further 8 weeks (24 weeks in total).
- If a patient continues to respond or maintain stable disease after 24 weeks of treatment, then the treatment can be continued until disease progression (if cumulative toxicity is not a problem) at the discretion of the investigator in agreement with the individual patient.

E.6 and E.7 Scope of the trial

E.6 Scope of the Trial

E.6.1 Diagnosis: No

E.6.2 Prophylaxis: No

E.6.3 Therapy: Yes

E.6.4 Safety: No

E.6.5 Efficacy: No

E.6.6 Pharmacokinetic: No

E.6.7 Pharmacodynamic: No

E.6.8 Bioequivalence: No

E.6.9 Dose response: No

E.6.10 Pharmacogenetic: Yes

E.6.11 Pharmacogenomic: No

E.6.12 Pharmacoeconomic: No

E.6.13 Others: No

E.7 Trial type and phase

E.7.1 Human pharmacology (Phase I): No

E.7.1.1 First administration to humans: No

E.7.1.2 Bioequivalence study: No

E.7.1.3 Other: No

E.7.1.3.1 Other trial type description:

E.7.2 Therapeutic exploratory (Phase II): Yes

E.7.3 Therapeutic confirmatory (Phase III): No

E.7.4 Therapeutic use (Phase IV): No

E.8 Design of the trial

E.8.1 Controlled: No

E.8.1.1 Randomised: No

E.8.1.2 Open: No

E.8.1.3 Single blind: No

E.8.1.4 Double blind: No

E.8.1.5 Parallel group: No

E.8.1.6 Cross over: No

E.8.1.7 Other: No

E.8.2 Comparator of controlled trial

E.8.2.1 Other medicinal product(s): Information not present in EudraCT

E.8.2.2 Placebo: Information not present in EudraCT

E.8.2.3 Other: Information not present in EudraCT

E.8.3 The trial involves single site in the Member State concerned: No

E.8.4 The trial involves multiple sites in the Member State concerned: Yes

E.8.4.1 Number of sites anticipated in Member State concerned: 5

E.8.5 The trial involves multiple Member States: No

E.8.6 Trial involving sites outside the EEA

E.8.6.1 Trial being conducted both within and outside the EEA: No

E.8.6.2 Trial being conducted completely outside of the EEA: Information not present in EudraCT

E.8.7 Trial has a data monitoring committee: Yes

E.8.8 Definition of the end of the trial and justification where it is not the last visit of the last subject undergoing the trial: The last treatment visit of the last subject undergoing the trial

E.8.9 Initial estimate of the duration of the trial

E.8.9.1 In the Member State concerned years: 2

E.8.9.1 In the Member State concerned months: 6

E.8.9.1 In the Member State concerned days: 0

F. Population of Trial Subjects

F.1 Age Range

F.1.1 Trial has subjects under 18: No

F.1.1.1 In Utero: No

F.1.1.2 Preterm newborn infants (up to gestational age < 37 weeks): No

F.1.1.3 Newborns (0-27 days): No

F.1.1.4 Infants and toddlers (28 days-23 months): No

F.1.1.5 Children (2-11years): No

F.1.1.6 Adolescents (12-17 years): No

F.1.2 Adults (18-64 years): Yes

F.1.3 Elderly (>=65 years): Yes

F.2 Gender

F.2.1 Female: Yes

F.2.2 Male: Yes

F.3 Group of trial subjects

F.3.1 Healthy volunteers: No

F.3.2 Patients: Yes

F.3.3 Specific vulnerable populations: Yes

F.3.3.1 Women of childbearing potential not using contraception : No

F.3.3.2 Women of child-bearing potential using contraception: Yes

F.3.3.3 Pregnant women: No

F.3.3.4 Nursing women: No

F.3.3.5 Emergency situation: No

F.3.3.6 Subjects incapable of giving consent personally: No

F.3.3.7 Others: No

F.4 Planned number of subjects to be included

F.4.1 In the member state: 50

F.4.2 For a multinational trial

F.4.2.2 In the whole clinical trial: 50

G. Investigator Networks to be involved in the Trial

N. Review by the Competent Authority or Ethics Committee in the country concerned

N. Competent Authority Decision: Authorised

N. Date of Competent Authority Decision: 2007-10-12

N. Ethics Committee Opinion of the trial application: Favourable

N. Ethics Committee Opinion: Reason(s) for unfavourable opinion:

N. Date of Ethics Committee Opinion: 2007-10-26

P. End of Trial

P. End of Trial Status: Ongoing

資料 12　EU Clinical Trials Register (EU-CTR)/Search for Clinical Trials/Advanced Search における Filters.

Country:Austria
Belgium
Bulgaria
Cyprus
CzechRepublic
Denmark
Estonia
Finland
France
Germany
Greece
Hungary
Iceland
Ireland
Italy
Latvia
Liechtenstein
Lithuania
Luxembourg
Malta
Netherlands
Norway
Poland
Portugal
Romania
Slovakia
Slovenia
Spain
Sweden
United Kingdom
Outside EU/EEA (PIP Studies)

Age Range: Adolescent
Adult
Children
Elderly
In-Utero
Infant and Toddler
Newborn
Preterm new born infants
Under 18

Gender: Both
Female Only
Male Only

Trial Phase: Phase One
Phase Two
Phase Three
Phase Four

Trial Status: Completed
Not Authorised
Ongoing
Prematurely Ended

Prohibited by CA
Restarted
Suspended by CA
Temporarily Halted

Date Range:(カレンダー表示から日付を前後 2 箇所指定する)

Rare Diseases:（チェックを付ける）

IMP with orphan designation in the indication:（チェックを付ける）

Orphan Designation Number:（テキスト入力）

資料 13　National Institutes of Health の「Clnical Trials.gov」の「See All Studies by Topic」にて、Asthma 2159 studies(ぜん息の 2159 件の研究情報)を地図表示したもの。

Region Name	Number of Studies
World	2159
Africa [map]	45
Central America [map]	35
East Asia [map]	140
Japan	51 [studies]
Europe [map]	681
Middle East [map]	77
North America	992
Canada [map]	179 [studies]
Mexico	45 [studies]
United States [map]	860 [studies]
North Asia [map]	89
Pacifica [map]	66
South America [map]	95
South Asia [map]	30
Southeast Asia [map]	58

Hints:

Click on a [map] link to show a map of that region.

Click on a [studies] link to search within your current results for studies in that region. Use the back button to return to this list and try another region.

Studies with no locations are not included in the counts or on the map.

Studies with multiple locations are included in each region containing locations.

資料 14　The Research-Based Web Design and Usability Guidelines
http://www.usability.gov/pdfs/chapter17.pdf
の中の検索に関する推奨の一例

Search

17:1 Ensure Usable Search Results

Relative Importance: ❶❷❸❹❺

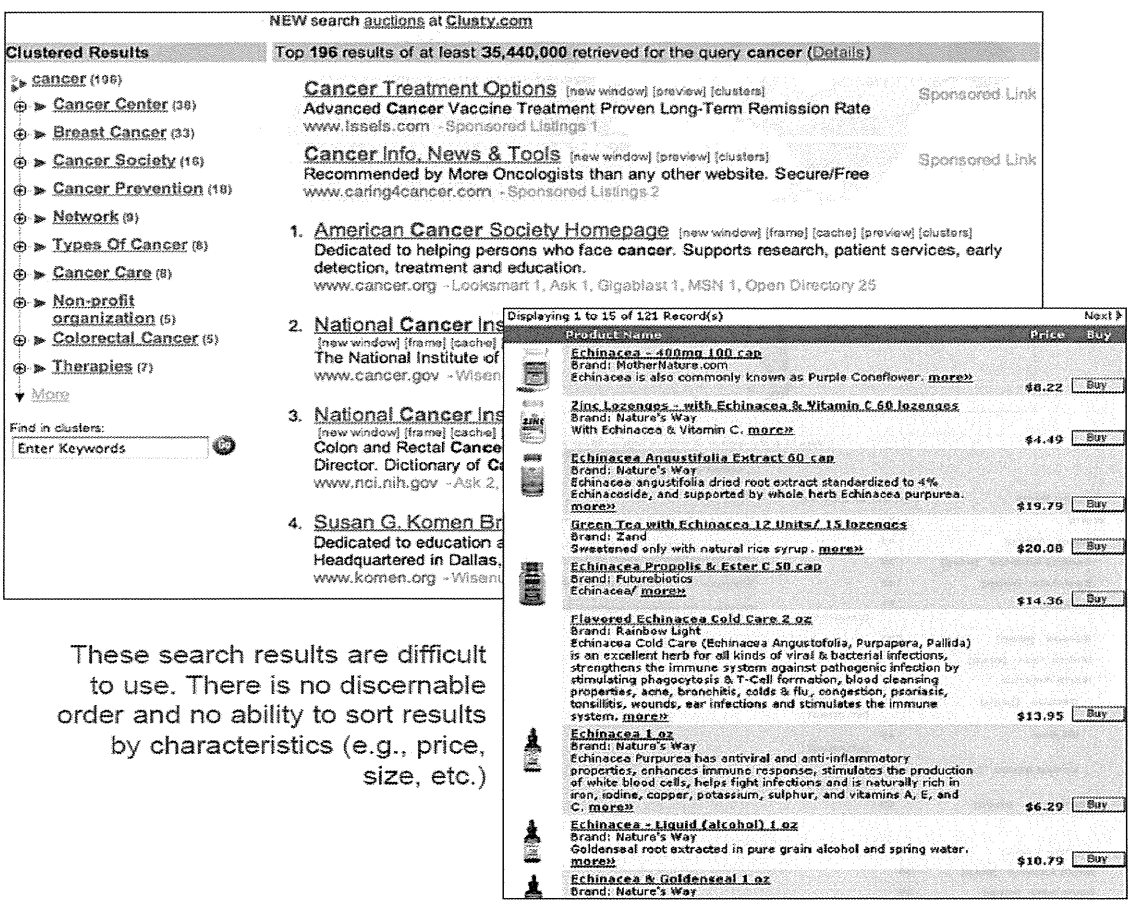
Strength of Evidence: ❶❷❸○○

Guideline: Ensure that the results of user searches provide the precise information being sought, and in a format that matches users' expectations.

Comments: Users want to be able to use the results of a search to continue solving their problem. When users are confused by the search results, or do not immediately find what they are searching for, they become frustrated.

Sources: Amento, et al., 1999; Bailey and Koyani, 2004; Dumais, Cutrell and Chen, 2001; Nielsen, 2001a; Nielsen, et al., 2000; Pollock and Hockley, 1996; Rosenfeld and Morville, 2002; Spool, et al., 1997.

Example: Returned search results in the main panel contain snippets of the searched page with the user's search terms highlighted (allowing the user to gain a sense of the context in which the terms are used) and a clustered list of related search terms is contained in the left panel.



These search results are difficult to use. There is no discernable order and no ability to sort results by characteristics (e.g., price, size, etc.)

See page xxii for detailed descriptions of the rating scales ❶❷❸❹○

資料1. グロッサリーに収載する用語の候補案

ACCEPTS HEALTHY VOLUNTEERS
ACTIVE COMPARATOR ARM
Active Substance
Active substance of biotechnological origin
Active substance of chemical origin
Active Substance(s)
ACTIVE, NOT RECRUITING
Adjuvants
Adolescents (12-17 years)
Adults (18-64 years)
Advanced Therapy IMP (ATIMP)
Adverse Event
ADVERSE EVENT
ALLOCATION
ARM
ARM TYPE
ATC Code(s)
ATC(Anatomic, therapeutic, chemical.)
Authorisation Status
Authorised By
BASELINE CHARACTERISTICS
bg (Abbreviation for the Bulgarian language.)
Bioequivalence study
Biotechnology
BLINDING (or Masking)
CAT (classification of advanced therapy medicinal products) classification
CE mark(European conformity Marking)
Centralised Procedure
CERTAIN AGREEMENTS
Chemical Abstract Services (CAS)number
Classification code (MedDRA)
Classification- Indicates the annex of Regulation (EEC) No 2377/90 where the active substance is listed and its maximum residue limit (MRL) is established. This applies to veterinary products only.
CLINICAL STUDY
Clinical Trial (CT)
CLINICAL TRIAL (or Interventional Study)
CLINICALTRIALS.GOV IDENTIFIER (NCT NUMBER)
CLOSED STUDIES
Closed Studies
COLLABORATOR
Combination ATIMP (Advanced Therapy Investigational Medicinal Product)
Comparator
Competent Authority (CA)/National Competent Authority (NCA)
COMPLETED
Concentration unit
CONDITION
Controlled
CONTROLLED TRIAL
Countries in which trial sites are planned
Country which granted the Marketing Authorisation
Cross over

cs(Abbreviation for the Czech language.)
Current sponsor code
da(Abbreviation for the Danish language.)
Data Monitoring Committee
DATA MONITORING COMMITTEE (DMC)
Data Provider
Date of Competent Authority Decision
Date of Ethics Committee Opinion
Date of the global end of the trial
de(Abbreviation for the German language)
Description of the IMP
Diagnosis
DMC
Domain
Dose response
Double blind
DOUBLE BLIND MASKING
EEA(European Economic Area)
Efficacy
el(Abbreviation for the Greek language)
Elderly (>=65 years)
ELIGIBILITY CRITERIA
EMA Decision number of Paediatric
Investigation Plan (PIP).
EMA(European Medicines Agency)
Emergency situation
en(Abbreviation for the English language)
ENROLLING BY INVITATION
ENROLLMENT
es(Abbreviation for the Spanish language)
et(Abbreviation for the Estonian language)
Ethics Committee (EC)
EU Authorisation Number
EU(Abbreviation for European Union. This is
the Union of the following Member States:
Belgium, Bulgaria, Czech Republic, Denmark,
Germany, Estonia, Greece, Spain, France,
Ireland, Italy, Cyprus, Latvia, Lithuania,
Luxembourg, Hungary, Malta, Netherlands,
Austria, Poland, Portugal, Romania, Slovenia,
Slovakia, Finland, Sweden, United Kingdom.)
EU(European Union.)
EudraCT (European Union Drug Regulating
Authorities Clinical Trials)
European Medicines Agency
EV Substance Code
EV(EudraVigilance)Product Code
Excipients
EXCLUSION CRITERIA
EXPANDED ACCESS
EXPERIMENTAL ARM
Extractive medicinal product
FACTORIAL DESIGN
FDA
FDAAA 801
fi(Abbreviation for the Finnish language)
First human administration
FIRST RECEIVED DATE
FOOD AND DRUG ADMINISTRATION (FDA)
FOOD AND DRUG ADMINISTRATION AMENDMENTS ACT, SECTION 801 (FDAAA 801)

Formulation
fr(Abbreviation for the French language)
Full title of the trial
Functional name of contact point
FUNDER TYPE
GENDERS ELIGIBLE FOR STUDY
Gene therapy medical product
Generic
GMO (genetically modified organism) or genetically engineered organism (GEO)
HAS DATA MONITORING COMMITTEE (DMC)
HAS RESULTS
HEALTH AUTHORITY
Healthy volunteers
Herbal medicinal product
Homeopathic medicinal product
hu(Abbreviation for the Hungarian language)
Human pharmacology (Phase I)
HUMAN SUBJECTS REVIEW BOARD
IEC (Independent Ethics Committee) Opinion of amendment
Immunological medicinal product
IMP(Investigational Medicinal Product)
In the whole clinical trial
In Utero
In Vivo
INCLUSION CRITERIA
Indication
Infants and toddlers (28 days–23
INFORMED CONSENT
Ingredients
INN (International Non-proprietary name) - Proposed INN
INTERVENTION
INTERVENTION MODEL (Design)
INTERVENTION NAME
INTERVENTION TYPE
INTERVENTIONAL STUDY (or Clinical Trial)
Interventional trial
INVESTIGATIONAL NEW DRUG
Investigator
INVESTIGATOR
is(Abbreviation for the Icelandic language)
ISRCTN number (International Standard Randomised Controlled Trial Number)
it(Abbreviation for the Italian language)
IVRS (Interactive Voice Response System)
Labelling
LAST UPDATED DATE
LAST VERIFIED DATE
Latest Variation
Legal Representative of Sponsor
lt(Abbreviation for the Lithuanian language)
lv(Abbreviation for the Latvian language)
MAH (Marketing Authorisation Holder)
Main objective of the trial
Marker Residue
Marketing Authorisation
Marketing Authorisation (MA)
Marketing Authorisation Holder

Marketing Authorisation Holder (MAH)
MASKING (or Blinding)
MedDRA (Medical Dictionary for Regulatory Activities)Classification
MedDRA Level –SOC (System Organ Class) HLGT (High Level Group Term) HLT (High Level Term) PT (Preferred Term) LLT (Lowest Level Term).
Medical condition in easily understood
Medical condition(s) investigated
MRL (maximum residue limit)
mt(Abbreviation for the Maltese language)
Multinational trial
Multiple Member States
Multiple sites in the Member State concerned
Name of organisation
Name or abbreviated title of the trial
National Authorisation Number
National Competent Authorities
NCT NUMBER (or ClinicalTrials.gov Identifier)
Newborns (0–27 days)
nl(Abbreviation for the Dutch language)
NO INTERVENTION ARM
no(Abbreviation for the Norwegian language)
NOT YET RECRUITING
Number of sites anticipated in Member State concerned
Number of sites anticipated in the EEA(European Economic Area)
Number of sites anticipated outside of the EEA
Number of treatment arms in the trial
Nursing women
Objective of the trial
OBSERVATIONAL STUDY
OBSERVATIONAL STUDY MODEL (Design)
OPEN LABEL
Open or Closed Studies
OPEN STUDIES
Open Studies
Open Trial
Orphan Designation
Orphan drug
Orphan drug designation number
OTHER ADVERSE EVENT
Other descriptive name
OTHER IDs
Other Provisions
OTHER STUDY ID NUMBERS
OUTCOME MEASURE
Package Approval Date
Package Authorisation Status
Package Code
Package Leaflet
Package Legal Status
Package Name
Package Renewal Date
Package Variation Date
Packaging
Paediatric Investigation Plan (PIP)
PARALLEL DESIGN

Parallel group
PARTICIPANT FLOW
Patients
Pharmaceutical form
Pharmaceutical Form
Pharmacodynamic
Pharmacoeconomic
Pharmacogenetic
Pharmacogenomic
Pharmacokinetic
PHASE
Phase I
Phase II
Phase III
Phase IV
PIP Addressee/Addressee of PIP Decision
PIP(Paediatric Investigation Plan)
pl(Abbreviation for the Polish language)
Placebo
PLACEBO
PLACEBO COMPARATOR ARM
Planned number of subjects
Plasma derived medicinal product
Post Trial Treatment
Presentation
Preterm newborn infants
PRIMARY COMPLETION DATE
Primary end point(s)
PRIMARY OUTCOME MEASURE
PRIMARY PURPOSE
Principal exclusion criteria
Principal inclusion criteria
PRINCIPAL INVESTIGATOR (PI)
Procedure
Product code
Product Legal Status
Product name
Product Name
Product Renewal Date
Product Type
Prophylaxis
Proposed date of start of recruitment
Protocol
PROTOCOL
pt(Abbreviation for the Portuguese language)
PUBLICATIONS
Radiopharmaceutical medicinal product
Randomised
RANDOMIZED ALLOCATION
RANK
Rare disease
Recombinant
RECORD
RECRUITING
RECRUITMENT STATUS
REGISTRATION
REGISTRY
Renewal
REPORTING (OR COMPARISON) GROUP
RESPONSIBLE PARTY

RESULTS DATABASE
RESULTS FIRST RECEIVED DATE
RESULTS SUBMISSION
ro(Abbreviation for the Romanian language)
Route of Administration
Routes of administration
RSS(Really Simple Syndication)
Safety
Scope of the trial
Secondary end point(s)
Secondary objectives of the trial
SECONDARY OUTCOME MEASURE
SERIOUS ADVERSE EVENT
SHAM COMPARATOR ARM
Single blind
SINGLE BLIND MASKING
SINGLE GROUP DESIGN
Single site in the Member State concerned
sk(Abbreviation for the Slovak language)
sl(Abbreviation for the Slovenian language)
Somatic cell therapy medicinal product
Source(s) of Monetary or Material Support for the clinical trial
Specific paediatric formulation
Specific vulnerable populations
Sponsor
SPONSOR (LEAD)
Sponsor Country
Sponsor' s protocol code number
SPONSOR-INVESTIGATOR
Start Date
STATUS
Status of the sponsor
Strength
STUDY COMPLETION DATE
STUDY DESIGN
STUDY RECORD
STUDY START DATE
STUDY TYPE
Subject
Subjects incapable of giving consent personally
Summary of Product Characteristics
Summary of Product Characteristics (SmPC)
SUSAR(Suspected Unexpected Serious Adverse Reactions)
SUSPENDED
sv(Abbreviation for the Swedish language)
Target Population
Target Species
Target Tissues
TERMINATED
Therapeutic Area
TIME FRAME, OUTCOME MEASURE
Tissue Engineered Product
TITLE ACRONYM
Title of the trial for lay people
Trade name
Trial being conducted both within and outside the EEA(European Economic Area)