NIHPO Data Report - Pharma

Summary

This document accompanies a series of Excel spreadsheets with a customized report on a single pharmaceutical product.

The goal of each spreadsheet is to provide the user with an integrated, “Bench to Bedside” report on all Open Data available for such drug. User can save significant amounts of time and effort by not visiting a multitud eof websites to obtaint he raw information.

Each Excel file integrates information from multiple sources, including:
* US’ Food and Drug Administration (“FDA”) Drugs@FDA files.
* US’ ClinicalTrials.gov website
* European Union’s (“EU”) European Medicines Agency
* EU’s Clinical Trials

Each spreadsheet workbook contains multiple independent sheets, as follows:

Sheet Name	Purpose
Sheet: 'Drug Details - US'	Drugs@FDA allows you to search for official information about FDA approved innovator (brand name) and generic drugs and therapeutic biological products.
Sheet: 'Clinical Trials - US'	ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.
Sheet: 'Drug Details - EU - EPARS'	European public assessment reports (EPARs) are full scientific assessment reports of medicines authorised at a European Union level.
Sheet: 'Drug Details - EU - Orphan'	An orphan designation allows a pharmaceutical company to benefit from incentives from the European Union to develop a medicine for a rare disease, such as reduced fees and protection from competition once the medicine is placed on the market. Applications for orphan designation are examined by EMA's Committee for Orphan Medicinal Products (COMP), which adopts an opinion that is forwarded to the European Commission.
Sheet: 'Drug Details - EU - Pediatric'	A paediatric investigation plan (PIP) is a medicine development plan aimed at ensuring the necessary data are obtained through studies in children to support a medicine's authorisation for use in children.
Sheet: 'Drug Details - EU - Pending'	When a pharmaceutical company applies for marketing authorisation through the centralised authorisation procedure, the CHMP or CVMP gives a positive or negative recommendation, in the form of a scientific opinion, on whether a medicine should be authorised. Immediately after the opinion is adopted, EMA publishes a 'summary of opinion'.

Sheet Name	Purpose
Sheet: 'Drug Details - EU - Safety'	A periodic safety update report (PSUR) is a pharmacovigilance report submitted regularly by a marketing-authorisation holder at defined time points following a medicine's authorisation. A single assessment of related PSURs is carried out for medicines that contain the same active substance or combination of active substances, as included in the list of EU reference dates (EURD list).
Sheet: 'Clinical Trials - EU'	The European Union Clinical Trials Register allows you to search for protocol and results information on: interventional clinical trials that are conducted in the European Union (EU) and the European Economic Area (EEA); clinical trials conducted outside the EU / EEA that are linked to European paediatric-medicine development.

We obviously don’t expect every field in every sheet to be of use to you.

Rather, please look at this information as an extensive list of data points for you to pick and choose from, based on your specific needs, to create the final report you need to answer your specific questions.

Contact Us

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Sheet: 'Drug Details - US'

Drugs@FDA allows you to search for official information about FDA approved innovator (brand name) and generic drugs and therapeutic biological products.

Field Name	Notes
Application #	
Product #	
Form	
Strength	
Drug Name	
Active Ingredient	
Sponsor Name	
Marketing Status	Discontinued None (Tentative Approval) Over-the-counter Prescription
Application Docs	Contains the URLs to many documents submitted by the drug manufacturer to the FDA during the drug's approval process. For example, in the case of the drug "Cyramza," one of the documents submitted is available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/125477s030lbl.pdf That particular PDF contains many details on prescribing details for the drug: **Table 2: Adverse Reactions Occurring at Incidence Rate ≥5% and a ≥2% Difference Between Arms in Patients Receiving CYRAMZA in Study 1** **Adverse Reactions (MedDRA) System Organ Class** / **CYRAMZA (8 mg/kg) N=236** / **Placebo N=115** All Grades (Frequency %) / Grade 3-4 (Frequency %) / All Grades (Frequency %) / Grade 3-4 (Frequency %) **Gastrointestinal Disorders** Diarrhea: 14 / 1 / 9 / 2 **Metabolism and Nutrition Disorders** Hyponatremia: 6 / 3 / 2 / 1 **Nervous System Disorders** Headache: 9 / 0 / 3 / 0 **Vascular Disorders** Hypertension: 16 / 8 / 8 / 3

Sheet: 'Clinical Trials - US'

ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.

Field Name	Notes / Sample
Brief Title	
Official Title	
NCT ID	
NLM Download Date Description	
Study First Submitted Date	
Results First Submitted Date	
Disposition First Submitted Date	
Last Update Submitted Date	
Study First Submitted QC Date	
Study First Posted Date	
Study First Posted Date Type	
Results First Submitted QD Date	
Results First Posted Date	
Results First Posted Date Type	
Disposition First Submitted QC Date	
Disposition First Posted Date:130	

Field Name	Notes / Sample
Disposition First Posted Date Type	
Last Update Submitted QC Date	
Last Update Posted Date	
Last Update Posted Date Type	
Start Month Year	
Start Date Type	
Start Date	
Verification Month Year	
Verification Date	
Completion Month Year	
Completion Date Type	
Completion Date	
Primary Completion Month Year	
Primary Completion Date Type	
Primary Completion Date	
Target Duration	
Study Type	
Acronym	
Baseline Population	
Overall Status	
Last Known Status	
Phase	

Field Name	Notes / Sample
Enrollment	
Enrollment Type	
Source	
Limitations And Caveats	
Number Of Arms	
Number Of Groups	
Why Stopped	
Has Expanded Access	
Expanded Access Type Individual	
Expanded Access Type Intermediate	
Expanded Access Type Treatment	
Has DMC	
Is FDA Regulated Drug	
Is FDA Regulated Device	
Is Unapproved Device	
Is PPSD	
Is US Export	
Biospec Retention	
Biospec Description	
IPD Time Frame	
IPD Access Criteria	
IPD URL	
Plan To Share IPD	
Plan To Share IPD Description	

Field Name	Notes / Sample
Created At	
Updated At	
Baseline Counts	Group Code: B1 :: Participants (Overall) 39
Baseline Measurements	Group Code: B1 :: Ethnicity: Not Hispanic or Latino - participants (Number) 38 Group Code: B1 :: Ethnicity: Hispanic or Latino - participants (Number) 1 Group Code: B1 :: Region of Enrollment: United States - participants (Number) 39 Group Code: B1 :: Race/Ethnicity, Customized: More than one race - participants (Number) 0 Group Code: B1 :: Race/Ethnicity, Customized: Native Hawaiian or Other Pacific Islander - participants (Number) 0 Group Code: B1 :: Race/Ethnicity, Customized: American Indian or Alaska Native - participants (Number) 0 Group Code: B1 :: Race/Ethnicity, Customized: Asian - participants (Number) 1 Group Code: B1 :: Race/Ethnicity, Customized: Black or African American - participants (Number) 3 Group Code: B1 :: Race/Ethnicity, Customized: White - participants (Number) 35 Group Code: B1 :: Sex: Female, Male: - Participants (Count of Participants) 31 Group Code: B1 :: Sex: Female, Male: - Participants (Count of Participants) 8 Group Code: B1 :: Age, Customized: >=65 years - participants (Number) 12 Group Code: B1 :: Age, Customized: Between 18 and 65 years - participants (Number) 27
Brief Summary	
Detailed Description	
Condition(s)	
Interventions	
Contact(s)	
Country(ies)	
Design Group(s)	Group Type: Experimental; Title: Ramucirumab; Description: Intravenous infusion at 8 milligrams per kilogram (mg/kg) on day 1 of every 14-day cycle.

Field Name	Notes / Sample
Design Outcomes	Outcome Type: secondary; Measure: Median Duration of Overall Response; Time frame: Time of first response (CR or PR) to disease progression, initiation of other (or additional) antitumor therapy, or death due to any cause (up to 34 months); Population: ; Description: Duration of response is the interval from the date of initial documented response [confirmed complete response (CR) or partial response (PR)] to the first documented date of disease progression as classified according to Response Evaluation Criteria In Solid Tumors (RECIST version 1.0) criteria, or initiation of other (or additional) antitumor therapy is first reported, or death due to any cause. CR is the disappearance of all target and non-target lesions and the normalization of tumor marker levels. PR is having at least a 30% decrease in the sum of the longest diameter of target lesions without new lesions and progression of non-target lesions. Disease progression is having at least a 20% increase in the sum of the longest diameter of target lesions and/or unequivocal progression of a non-target lesion and/or detection of a new lesion. Data from participants who did not relapse were censored on the day of their last tumor assessment.
Designs	Allocation: ; Intervention Model: Single Group Assignment; Observational Model: ; Primary Purpose: Treatment; Time Perspective: ; Masking: None (Open Label); Masking Description: ; Intervention Model Description; Subject Masked: ; Caregiver Masked: ; Investigator Masked: ; Outcomes_assessor_masked:
Document(s)	
Drop Withdrawals	

Field Name	Notes / Sample
Elegibilities	Sampling Method: ; Gender: All; Minimum Age: 18 Years; Maximum Age: N/A; Healthy Volunteers: No; Population: ; Criteria: Inclusion Criteria: - The participant has histologically or cytologically confirmed clear cell RCC - The participant is â ¥ 18 years of age - The participant has an Eastern Cooperative Oncology Group performance status (ECOG PS) of 0-1 or Karnofsky Performance Status (KPS) â ¥ 80% - The participant has had a prior nephrectomy (as therapy for RCC) - The participant has metastatic RCC - The participant has a life expectancy of > 3 months - The participant has measurable disease as defined by Response Evaluation Criteria in Solid Tumors (RECIST) - The participant has received prior therapy with a TKI (sunitinib and/or sorafenib) with either disease progression on TKI therapy (progression within 60 days of the last dose of TKI) or intolerance to TKI (unable to continue therapy because of side-effects). A participant with progression during a protracted treatment break is not eligible unless the participant has had progression or intolerance as defined above - The participant has resolution of all clinically significant toxic effects of prior cancer therapy to grade â ¤ 1 by the National Cancer Institute Common Terminology Criteria for Adverse Events, version 3.0 (NCI-CTCAE) - The participant has adequate hematological functions [absolute neutrophil count (ANC) â ¥ 1500 cells per milliliter (cells/mL), hemoglobin â ¥ 9 grams per deciliter (g/dL) and platelets â ¥ 100,000 cells/mL] - The participant has adequate hepatic function [bilirubin within normal limits (WNL), aspartate transaminase (AST) and/or alanine transaminase (ALT) â ¤ 2.5 times the upper limit of normal (ULN), or â ¤ 5.0 times the ULN if the transaminase elevation is due to liver metastases] - The participant has normal renal function or mild renal dysfunction [creatinine â ¤ 2.2 milligrams per deciliter (mg/dL)] - The participant's urinary protein â ¤ 1+ on dipstick or routine urinalysis [(UA); if urine dipstick or routine analysis is â ¥ 2+, a 24-hour urine for protein must demonstrate < 1000 (milligrams) mg of protein in 24 hours to allow participation in the study] - The participant must have adequate coagulation function as defined by International Normalized Ratio (INR) â ¤ 1.8 and a partial thromboplastin time (PTT) â ¤ 1.5 X ULN. Participants on full-dose anticoagulation must be on a stable dose of oral anticoagulant or low molecular weight (LMW) heparin and if on warfarin must have a INR between 2 and 3 and have no active bleeding or pathological condition that carries a high risk of bleeding (for example, tumor involving major vessels or known varices) - The participant is able to provide informed written consent ...

Field Name	Notes / Sample
Facilities	Status: ; Name: ImClone Investigational Site; City: San Francisco; State: California; ZIP: 94115; United States Status: ; Name: ImClone Investigational Site; City: Chicago; State: Illinois; ZIP: 60637; United States Status: ; Name: ImClone Investigational Site; City: Metairie; State: Louisiana; ZIP: 70006; United States Status: ; Name: ImClone Investigational Site; City: Boston; State: Massachusetts; ZIP: 02115; United States Status: ; Name: ImClone Investigational Site; City: Flemington; State: New Jersey; ZIP: 08822; United States Status: ; Name: ImClone Investigational Site; City: Buffalo; State: New York; ZIP: 14263; United States Status: ; Name: ImClone Investigational Site; City: Cleveland; State: Ohio; ZIP: 44195; United States Status: ; Name: ImClone Investigational Site; City: Drexel Hill; State: Pennsylvania; ZIP: 19026; United States Status: ; Name: ImClone Investigational Site; City: Philadelphia; State: Pennsylvania; ZIP: 19111; United States Status: ; Name: ImClone Investigational Site; City: Arlington; State: Texas; ZIP: 76012; United States Status: ; Name: ImClone Investigational Site; City: Seattle; State: Washington; ZIP: 98109; United States
Facility Contacts	
Facility Investigators	
Intervention Other Names	Intervention ID: 7486518; Name: IMC-1121B Intervention ID: 7486518; Name: LY3009806
Interventions	Intervention Type: Biological; Name: Ramucirumab; Description: Ramucirumab is an injectable solution administered as an intravenous infusion over 1 hour at a dose of 8 mg/kg day 1 of every 14-day cycle.
IPD Information Types	
Keywords	

Field Name	Notes / Sample
Milestones	Result Group ID: 11805588; Group Code: P1; Title: NOT COMPLETED; Period: Overall Study; Description: ; Count: 0 Result Group ID: 11805588; Group Code: P1; Title: COMPLETED; Period: Overall Study; Description: ; Count: 39 Result Group ID: 11805588; Group Code: P1; Title: Received at Least 1 Dose of Study Drug; Period: Overall Study; Description: ; Count: 39 Result Group ID: 11805588; Group Code: P1; Title: STARTED; Period: Overall Study; Description: ; Count: 39
Outcome Analyses	
Outcome Measurements	Outcome ID: 3568176; Result Group ID: 11805589; Group Code: O1; Classification: Related AE leading to discontinuation; Category: ; Title: Summary Listing of Participants Reporting Drug-Related Treatment-Emergent Adverse Events; Description: Data presented are the number of participants who experienced treatment-emergent adverse events (TEAE), serious adverse events (SAE), Grade 3 or 4 TEAE, or adverse events (AE) leading to discontinuation of treatment that were considered to be related to ramucirumab. A summary of SAEs and other nonserious AEs, regardless of causality, is located in the Reported Adverse Events section.; Units: participants; param. Type: Number; Param. Value: 7; Param. value #: 7.0; Dispersion Type: ; Dispersion Value: ; Dispersion Value #: ; Dispersion Lower Limit: ; Dispersion Upper Limit: ; Explanation of NA: Outcome ID: 3568176; Result Group ID: 11805589; Group Code: O1; Classification: Related Grade 3 or 4 TEAE; Category: ; Title: Summary Listing of Participants Reporting Drug-Related Treatment-Emergent Adverse Events; Description: Data presented are the number of participants who experienced treatment-emergent adverse events (TEAE), serious adverse events (SAE), Grade 3 or 4 TEAE, or adverse events (AE) leading to discontinuation of treatment that were considered to be related to ramucirumab. A summary of SAEs and other nonserious AEs, regardless of causality, is located in the Reported Adverse Events section.; Units: participants; param. Type: Number; Param. Value: 10; Param. value #: 10.0; Dispersion Type: ; Dispersion Value: ; Dispersion Value #: ; Dispersion Lower Limit: ; Dispersion Upper Limit: ; Explanation of NA: ...

Field Name	Notes / Sample
Outcomes	Outcome Type: Secondary; Title: Minimum Concentration (Cmin) of Ramucirumab; Description: ; Time Frame: Immediately prior to the Week 32 infusion treatment [Cycle 16 (1 cycle=14 days)]; Population: Participants who received any quantity of ramucirumab and had evaluable pharmacokinetic data at the specified time point.; Anticipated Posting Date: ; Anticipated Posting Month Year: ; Units: micrograms per milliliter (mcg/mL); Units Analyzed: ; Dispersion Type: Standard Deviation; Param. Type: Mean Outcome Type: Secondary; Title: Summary Listing of Participants Reporting Drug-Related Treatment-Emergent Adverse Events; Description: Data presented are the number of participants who experienced treatment-emergent adverse events (TEAE), serious adverse events (SAE), Grade 3 or 4 TEAE, or adverse events (AE) leading to discontinuation of treatment that were considered to be related to ramucirumab. A summary of SAEs and other nonserious AEs, regardless of causality, is located in the Reported Adverse Events section.; Time Frame: First dose to study completion (up to 34 months) plus 30-day safety follow-up; Population: Intent-to-treat population: participants who received any quantity of ramucirumab.; Anticipated Posting Date: ; Anticipated Posting Month Year: ; Units: participants; Units Analyzed: ; Dispersion Type: ; Param. Type: Number Outcome Type: Secondary; Title: Maximum Concentration (Cmax) of Ramucirumab; Description: ; Time Frame: 1 hour after the end of the Week 32 infusion treatment [Cycle 16 (1 cycle=14 days)]; Population: Participants who received any quantity of ramucirumab and had evaluable pharmacokinetic data at the specified time point.; Anticipated Posting Date: ; Anticipated Posting Month Year: ; Units: micrograms per milliliter (mcg/mL); Units Analyzed: ; Dispersion Type: Standard Deviation; Param. Type: Mean Outcome Type: Secondary; Title: Median Duration of Overall Response; Description: Duration of response is the interval from the date of initial documented response [confirmed complete response (CR) or partial response (PR)] to the first documented date of disease progression as classified according to Response Evaluation Criteria In Solid Tumors (RECIST version 1.0) criteria, or initiation of other (or additional) antitumor therapy is first reported, or death due to any cause. CR is the disappearance of all target and non-target lesions and the normalization of tumor marker levels. PR is having at least a 30% decrease in the sum of the longest diameter of target lesions without new lesions and progression of non-target lesions…
Overall Officials	Role: Study Director; Name: Call 1-877-CTLILLY (1-877-285-4559) or 1-317-615-4559 Mon - Fri 9 AM - 5 PM Eastern time (UTC/GMT - 5 hours, EST); Affiliation: Eli Lilly and Company
Pending Results	

Field Name	Notes / Sample
Provided Documents	
Reported Events	Result Group ID: 11805597; Group Code: E1; Time Frame: ; Event Type: serious; Default Vocab. MedDRA 10.0; Default Assessment: Systematic Assessment; Subjects Affected: 1; Subjects At Risk: 39; Description: ; Event Count: 1; Organ System: Vascular disorders; Adverse Event Term: HYPERTENSIVE CRISIS; Frequency Threshold: 0; Vocab: ; Assessment: Result Group ID: 11805597; Group Code: E1; Time Frame: ; Event Type: serious; Default Vocab. MedDRA 10.0; Default Assessment: Systematic Assessment; Subjects Affected: 1; Subjects At Risk: 39; Description: ; Event Count: 1; Organ System: Surgical and medical procedures; Adverse Event Term: SPINAL LAMINECTOMY; Frequency Threshold: 0; Vocab: ; Assessment: Result Group ID: 11805597; Group Code: E1; Time Frame: ; Event Type: serious; Default Vocab. MedDRA 10.0; Default Assessment: Systematic Assessment; Subjects Affected: 1; Subjects At Risk: 39; Description: ; Event Count: 1; Organ System: Respiratory, thoracic and mediastinal disorders; Adverse Event Term: HAEMOPTYSIS; Frequency Threshold: 0; Vocab: ; Assessment: ...
Responsible Parties	
Result Agreements	
Result Agreements	
Result Contacts	
Result Groups	
Sponsors	
Study References	
Condition(s)	

Credit: We use the files provided by the Clinical Trials Transformation Initiative.

Sheet: 'Drug Details - EU - EPARS'

European public assessment reports (EPARs) are full scientific assessment reports of medicines authorised at a European Union level.

Field Name	Notes
Medicine Name	
Therapeutic Area	
International Non-proprietary Name	The international nonproprietary name (INN) is an official generic and non-proprietary name given to a pharmaceutical drug or an active ingredient. INNs make communication more precise by providing a unique standard name for each active ingredient, to avoid prescribing errors. The INN system has been coordinated by the World Health Organization (WHO) since 1953.[1]
Active Substance	
Authorization Status	
Generic?	
Bio-similar?	
Patient Safety?	
Additional Monitoring?	
Exceptional Circumstances?	
Accelerated Assessment?	
Orphan Medicine?	
Date Refusal Marketing Auth.	
First Published	
Revision Date	
Marketing Auth. Date	
Marketing Auth. Holder	

1 https://en.wikipedia.org/wiki/International_nonproprietary_name

Field Name	Notes
Condition Indication	
Report	This field includes the URL to the full EPAR document: https://www.ema.europa.eu/en/medicines/human/EPAR/cyramza

Sheet: 'Drug Details - EU - Orphan'

An orphan designation allows a pharmaceutical company to benefit from incentives from the European Union to develop a medicine for a rare disease, such as reduced fees and protection from competition once the medicine is placed on the market. Applications for orphan designation are examined by EMA's Committee for Orphan Medicinal Products (COMP), which adopts an opinion that is forwarded to the European Commission.

Field Name	Notes
Medicine Name	
Active Substance	
Date First Decision	
Disease Condition	
Status Orphan Desig.	
First Published	
Revision Date	
Report	This field includes the URL to the full document: https://www.ema.europa.eu/en/medicines/human/orphan-designations/eu3121004

Sheet: 'Drug Details - EU - Pediatric'

A paediatric investigation plan (PIP) is a medicine development plan aimed at ensuring the necessary data are obtained through studies in children to support a medicine's authorisation for use in children.

Field Name	Notes
Associated Name	
Active Substance	
Therapeutic Area	
Decision Date	
Decision Type	
Condition	
Compliance Check	
Comp. Opinion Date	
Comp. Proc. #	
Decision Number	
First Published	
Revision Date	
Report	This field includes the URL to the full document: https://www.ema.europa.eu/en/medicines/human/paediatric-investigation-plans/emea-002074-pip01-16

Sheet: 'Drug Details - EU - Pending'

When a pharmaceutical company applies for marketing authorisation through the centralised authorisation procedure, the CHMP or CVMP gives a positive or negative recommendation, in the form of a scientific opinion, on whether a medicine should be authorised. Immediately after the opinion is adopted, EMA publishes a 'summary of opinion'.

Field Name	Notes
Medicine Name	
International Non-proprietary Name	
Active Substance	
Therapeutic Area	
Category	
Product Number	
Patient Safety?	
Generic?	
Bio-similar?	
Accelerated Assessment?	
Orphan Medicine	
Marketing Auth. Holder	
Date Opinion	
Outcome	
App. Type	
First Published	
Revision Date	
Report	This field includes the URL to the full document: https://www.ema.europa.eu/en/medicines/human/summaries-opinion/cyramza

Sheet: 'Drug Details - EU - Safety'

A periodic safety update report (PSUR) is a pharmacovigilance report submitted regularly by a marketing-authorisation holder at defined time points following a medicine's authorisation. A single assessment of related PSURs is carried out for medicines that contain the same active substance or combination of active substances, as included in the list of EU reference dates (EURD list).

Field Name	Notes
Active Substance	
Document Title	
Reference #	
Version #	
Process #	
Outcome	
First Published	
Revision Date	
Report	This field includes the URL to the full document: https://www.ema.europa.eu/documents/psusa/oxaliplatin-cmdh-scientific-conclusions-grounds-variation-amendments-product-information-timetable/00002229/201804_en.pdf

Sheet: 'Clinical Trials - EU'

The European Union Clinical Trials Register allows you to search for protocol and results information on: interventional clinical trials that are conducted in the European Union (EU) and the European Economic Area (EEA); clinical trials conducted outside the EU / EEA that are linked to European paediatric-medicine development.

Field Name	Notes
EudraCT #	
Sponsor Protocol #	
Start Date	
Sponsor_ Name	
Full Title	
Medical Condition	
Population Age	
Gender	
Trial Results	This field contaisn the URL to the full results of the trial: https://www.clinicaltrialsregister.eu/ctr-search/trial/2010-019318-26/results
Protocol Country	This field contains the list of countries that ran a clinical trial.
Protocol Document	https://www.clinicaltrialsregister.eu/ctr-search/trial/2010-019318-26/AT https://www.clinicaltrialsregister.eu/ctr-search/trial/2010-019318-26/BE https://www.clinicaltrialsregister.eu/ctr-search/trial/2010-019318-26/BG https://www.clinicaltrialsregister.eu/ctr-search/trial/2010-019318-26/CZ https://www.clinicaltrialsregister.eu/ctr-search/trial/2010-019318-26/DE https://www.clinicaltrialsregister.eu/ctr-search/trial/2010-019318-26/ES https://www.clinicaltrialsregister.eu/ctr-search/trial/2010-019318-26/FI https://www.clinicaltrialsregister.eu/ctr-search/trial/2010-019318-26/FR https://www.clinicaltrialsregister.eu/ctr-search/trial/2010-019318-26/HU https://www.clinicaltrialsregister.eu/ctr-search/trial/2010-019318-26/IT https://www.clinicaltrialsregister.eu/ctr-search/trial/2010-019318-26/NO https://www.clinicaltrialsregister.eu/ctr-search/trial/2010-019318-26/PT https://www.clinicaltrialsregister.eu/ctr-search/trial/2010-019318-26/SE
Protocol Status	