



New CTIS Public Portal functionalities

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Multi-stakeholder platform Advisory Group meeting

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An agency of the European Union



Article 81(4) of Regulation (EU) No. 536/2014: legal basis for the establishment a publicly accessible EU clinical trials database, while protecting commercially confidential information (CCI), personal data (PD) and confidential information on the assessment conducted by MSs

- The CTIS publication rules recently underwent a simplification process, as a result of a public consultation conducted in 2023
- The [Revised transparency rules](#) now foresee an earlier publication of key documents of interest, which increases the public engagement and trust while allowing a faster preparation of application dossier by sponsors
- For most of the trials, publication of data and documents occurs at the time of Member State decision on the application, and publication of results at the time of their submission
- Specificities are in place for early development trials on adults (e.g. Phase I, first in humans), that mainly foresee their publication to occur 30 months after end of trial in EU/EEA

- Revised [CTIS transparency rules](#) became applicable on 18 June 2024 with the launch of a new version of [CTIS public portal](#).
- Applications submitted as of 18 June follow the revised rules. For those submitted before, only structured data were published ('historical' trials)
- **Over 6100 trials** have been published so far, of which over **1560 with documents**. More than 35,600 documents in total are publicly available.



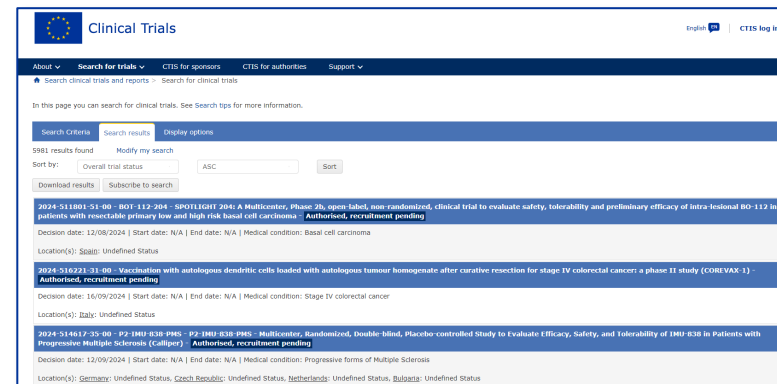
Reference guidance material: [Quick guide for users](#) & all material published on [“Transparency in CTIS” - ACT EU website](#)

All stakeholders were consulted for proposals of further improvements of the public portal, including patients, researchers and HCPs

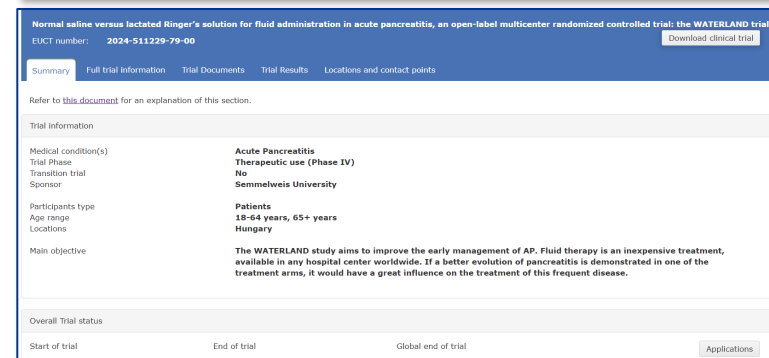
New features deployed :

- Advanced Search, users can perform more detailed searches (e.g. CT status per Member state)
- Download specific CT information
- Download results of a performed search
- RSS-feed, users can subscribe to alerts on updates
- Major user interface improvements (clearer list of search results, recruitment status always highlighted, ad hoc sections on docs and on locations and contact points, explanatory docs on each section)

<https://euclinicaltrials.eu/search-for-clinical-trials/?lang=en&EUCT=2024-512803-37-00>



The screenshot shows the 'Clinical Trials' search results page. It features a search bar at the top with 'Search for trials' and 'CTIS for sponsors' options. Below the search bar, there are filters for 'Overall trial status' (set to 'ASC') and 'Sort'. The results list includes three entries, each with a title, status, decision date, start date, end date, and medical condition. The first entry is '2024-511801-51-00 - 801-112-204 - SPOTLIGHT 204: A Multicenter, Phase 2b, open-label, non-randomized, clinical trial to evaluate safety, tolerability and preliminary efficacy of intra-lesional 80-112 in patients with resectable primary low and high risk basal cell carcinoma - Authorized, recruitment pending'. The second entry is '2024-516221-31-00 - Vaccination with autologous dendritic cells loaded with autologous tumour homogenate after curative resection for stage IV colorectal cancer: a phase II study (COREVAX-1) - Authorized, recruitment pending'. The third entry is '2024-514617-35-00 - P2-1801-838-9985 - P2-1801-838-9985 - Multicenter, Randomized, Double-blind, Placebo-controlled Study to Evaluate Efficacy, Safety, and Tolerability of 1801-838 in Patients with Progressive Multiple Sclerosis (Calliper) - Authorized, recruitment pending'.



The screenshot shows the details page for the 'Normal saline versus lactated Ringer's solution for fluid administration in acute pancreatitis, an open-label multicenter randomized controlled trial: the WATERLAND trial'. The EUCT number is 2024-51229-79-00. The page includes a 'Download clinical trial' button and a 'Refer to this document' link. The 'Trial information' section is as follows:

Medical condition(s)	Acute Pancreatitis
Trial Phase	Therapeutic use (Phase IV)
Transition trial	No
Sponsor	Semmelweis University
Participants type	Patients
Age range	18-64 years, 65+ years
Locations	Hungary
Main objective	The WATERLAND study aims to improve the early management of AP. Fluid therapy is an inexpensive treatment, available in any hospital center worldwide. If a better evolution of pancreatitis is demonstrated in one of the treatment arms, it would have a great influence on the treatment of this frequent disease.

The 'Overall Trial status' section shows the 'Start of trial', 'End of trial', and 'Global end of trial' dates, along with an 'Applications' button.



Clinical trial search

[Search Criteria](#) [Search results](#) [Display options](#)
5856 results found [Modify my search](#)Sort by:

<input type="checkbox"/>	2024-516651-41-00 - Authorised, not started - CORTICOP_Comparison of corticosteroids versus placebo on duration of ventilatory support during severe acute exacerbations of COPD patients in the intensive care unit: a multicentre randomized controlled trial Overall start date of the trial (in the EU): N/A Overall end date of the trial (in the EU): N/A Conditions: COPD : chronic obstructive Pulmonary disease Countries where the trial is taking place (EU country code): FR: Authorised, not started Decision date: FR: 12/09/2024
<input type="checkbox"/>	2023-506935-14-01 - Authorised, not started - Intra-Arterial thrombolysis after SUCCESSful angiographic recanalization in acute large vessel occlusion stroke of the anterior circulation: the IA-SUCCESS multicenter, randomized clinical trial Overall start date of the trial (in the EU): N/A Overall end date of the trial (in the EU): N/A Conditions: Ischemic stroke Countries where the trial is taking place (EU country code): FR: Authorised, not started Decision date: FR: 12/09/2024
<input type="checkbox"/>	2023-509767-25-00 - Authorised, not started - Phase 1 Study of IMC-P115C in Advanced PRAME Positive Cancers Overall start date of the trial (in the EU): N/A Overall end date of the trial (in the EU): N/A Conditions: Advanced PRAME Positive Cancers Countries where the trial is taking place (EU country code): FR: Authorised, not started Decision date: FR: 12/09/2024
<input type="checkbox"/>	2024-511821-75-00 - Authorised, not started - Dose escalation of allogeneic Adipose derived Stroma/stem Cells for the treatment of Crohn's fistula Overall start date of the trial (in the EU): N/A Overall end date of the trial (in the EU): N/A Conditions: Crohn's fistula Countries where the trial is taking place (EU country code): FR: Authorised, not started Decision date: FR: 12/09/2024
<input type="checkbox"/>	2024-514952-34-00 - Authorised, not started - Randomized open-label controlled trial evaluating a single-dose intravenous Dalbavancin versus standard antibiotic therapy during catheterrelated bloodstream infections due to Staphylococcus aureus [DALICATH] Overall start date of the trial (in the EU): N/A Overall end date of the trial (in the EU): N/A Conditions: Catheter related bloodstream infections due to Staphylococcus aureus Countries where the trial is taking place (EU country code): FR: Authorised, not started Decision date: FR: 12/09/2024
<input type="checkbox"/>	2024-511176-32-00 - Authorised, not started - A Phase 2a Study of TPN-101 in Patients with Aicardi-Goutières Syndrome (AGS) Overall start date of the trial (in the EU): N/A Overall end date of the trial (in the EU): N/A Conditions: Aicardi-Goutières Syndrome (AGS) Countries where the trial is taking place (EU country code): FR: Authorised, not started Decision date: FR: 12/09/2024
<input type="checkbox"/>	2024-513905-29-00 - Authorised, not started - Long-Term Follow-up of Subjects With Transfusion-Dependant β -Thalassemia Treated With Ex Vivo Gene Therapy Using Autologous Hematopoietic Stem Cells Transduced With a Lentiviral Vector Overall start date of the trial (in the EU): N/A Overall end date of the trial (in the EU): N/A Conditions: Beta-thalassaemia Countries where the trial is taking place (EU country code): FR: Authorised, not started Decision date: FR: 12/09/2024
<input type="checkbox"/>	2024-512037-32-00 - Authorised, not started - Interest of Intra-nodal injection of gentamicin for the treatment of suppurated cat scratch disease's lymphadenitis: a randomized controlled study. "BIGG" : Bartonellosis and intra-nodal injection of gentamicin Overall start date of the trial (in the EU): N/A Overall end date of the trial (in the EU): N/A Conditions: Bartonellosis Countries where the trial is taking place (EU country code): FR: Authorised, not started Decision date: FR: 12/09/2024



C1071032 - MAGNETISM-32 A PHASE 3, OPEN-LABEL STUDY OF ELRANATAMAB MONOTHERAPY VERSUS ELOTUZUMB, POMALIDOMIDE, DEXAMETHASONE (EPd) OR POMALIDOMIDE, BORTEZOMIB, DEXAMETHASONE (Pvd) OR CARFILZOMIB, DEXAMETHASONE (Kd) IN PARTICIPANTS WITH RELAPSED REFRACTORY MULTIPLE MYELOMA WHO RECEIVED PRIOR ANTI-CD38 DIRECTED THERAPY

EUCT number: 2023-507871-23-00

[Summary](#)
[Full trial information](#)
[Notifications](#)
[Trial Results](#)
[Corrective measures](#)

Trial information

Medical condition(s)	Relapsed/Refractory Multiple Myeloma	Member states concerned	DE, DK, IT, ES, SE, GR, CZ, FR, NO, FI, BE, NL
Sponsor	Pfizer Inc.	Low intervention study	No
Trial Phase	Therapeutic confirmatory (Phase III)	Population type	Patients
Therapeutic area	Diseases [C] - Hemic and Lymphatic Diseases [C15]	Transition Trial	No
First submitted	15/01/2024	FIH	No
First decision	06/05/2024	Medical device	No
Last update	06/09/2024		

Overall Trial status

Start of trial 27/05/2024

End of trial

Global end of trial

[Applications](#)

Member state	Current status	Decision date	Last update	Start date	Trial				Recruitment			
					Temporary Halt	Restart	End (or early termination)	Reason for early termination	Start	End	Restart	
Norway	Authorised	06/05/2024	30/08/2024	10/06/2024						12/06/2024		
Netherlands	Authorised	06/05/2024	27/08/2024									
Italy	Authorised	07/05/2024	29/08/2024	21/06/2024						07/08/2024		
Finland	Authorised	07/05/2024	28/08/2024	12/06/2024						15/07/2024		
Czechia	Authorised	07/05/2024	30/08/2024	20/06/2024								
Denmark	Authorised	08/05/2024	29/08/2024	27/08/2024								
Sweden	Authorised	08/05/2024	30/08/2024	25/06/2024								
Germany	Authorised	08/05/2024	30/08/2024	25/06/2024								
Spain	Authorised	09/05/2024	29/08/2024	27/05/2024						26/08/2024		
Greece	Authorised	13/05/2024	28/08/2024	04/07/2024								
France	Authorised	13/05/2024	27/08/2024	03/07/2024						31/07/2024		
Belgium	Authorised	13/05/2024	06/09/2024	17/06/2024								

Interest of Intra-nodal injection of gentamicin for the treatment of suppurated cat scratch disease's lymphadenitis: a randomized controlled study, "BIGG" : Bartonellosis and intra-nodal injection of gentamicin
EUCT number: 2024-512037-32-00

Summary Full trial information Notifications Trial Results Corrective measures

Notifications

- Serious Breach (0)
- Unexpected Event (0)
- Urgent Safety Measure (0)
- Temporary Halt (0)



Clinical Trials

English  | CTIS log in

About Search clinical trials and reports CTIS for sponsors CTIS for authorities Support

Interest of Intra-nodal injection of gentamicin for the treatment of suppurated cat scratch disease's lymphadenitis: a randomized controlled study, "BIGG" : Bartonellosis and intra-nodal injection of gentamicin
EUCT number: 2024-512037-32-00

Summary Full trial information Notifications Trial Results Corrective measures

Corrective measure

View

Corrective Measure ID	Member state concerned	Publication date	Type	Notes
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Request removal of public information

Current information on the trial

Trial specific information (Part I) English

- Trial details
- Sponsors
- Products
- Documents

Country specific details (Part II)

- Germany - Authorised
- Denmark - Authorised
- Italy - Authorised
- Spain - Authorised
- Sweden - Authorised
- Greece - Authorised
- Czechia - Authorised
- France - Authorised
- Norway - Authorised
- Finland - Authorised
- Belgium - Authorised
- Netherlands - Authorised

- Trial details

- Trial identifiers

- Trial information

- Protocol information

- Scientific Advice and Paediatric Investigation Plan

- Associated Clinical Trial

- References

- Countries outside the European Economic Area

- Sponsors

	OMS ID	Name	Organisation type	Country	Type	Status	Scientific contact point	Public contact point	Third parties
<input type="radio"/>	ORG-100010438	Centre Hospitalier De Versailles	Hospital/Clinic/Other health care facility	France	Non-Commercial	Active	project manager	project manager	0

- Products

- Role: Test Name: METHYLPREDNISOLONE VIATRIS 120 mg, poudre pour solution injectable (IM-IV)

- Role: Placebo Name: SODIUM CHLORURE 0,9 % BIOLUZ, solution injectable, poche

- Documents

Attached documents

Title	File type	Document Type
D1_Protocol_2024-S16651-41-00_public	PDF	Protocol (for publication)
E2_SmPC_methylprednisolone_viatris_120mg	PDF	Summary of Product Characteristics (SmPC) (for publication)

Back up slides

Principles of revised CTIS transparency rules



- Clinical trials are made publicly available as per timelines based on their development phase (trial category) and population age
- For most of the trials publication of data and documents occurs at the time of Member State decision on the application
- Summary of results and of Clinical Study Reports are published upon submission to CTIS

Category	Trial type	Publication rules
Category 1 Pharmaceutical development clinical trials	Phase I, Phase 0, Bioequivalence, similarity trials for biosimilars, equivalence trials	On adults: most info (structured data/docs) is published 30 months after EU/EEA End of Trial On paediatrics: structured data published at decision date, documents published at submission of results
Category 2 Therapeutic exploratory & confirmatory clinical trials	Phase I and phase II integrated, Phase II, Phase II and phase III integrated, Phase III clinical trials	All info published upon decision date, except for details on product dosage of integrated phase I and II (published 30 months after EoT)
Category 3 Therapeutic use clinical trials	Phase III and phase IV integrated, phase IV trials	All info published upon decision date

Transparency rules: reference documents

- [Revised transparency rules](#)
- [Quick guide for users](#)
- [Guidance document on how to approach the protection of personal data and commercially confidential information \(CCI\) while using CTIS](#) and its [Annex I](#)
- [Q&A on the protection of CCI and Personal Data while using CTIS](#)
- [List of CTIS application fields and documents \(with publication details\)](#)
- [List of CTIS notifications fields and documents \(with publication details\)](#)
- [CTIS Bitesize talk on the transparency rules](#)

