New CTIS Public Portal functionalities

27 September 2024
Multi-stakeholder platform Advisory Group meeting

Presented by Francesca Scotti
Data Analytics and Methods Taskforce, EMA

The Clinical Trial Information System publication rules

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

Launch of new CTIS Public Portal on 18 June 2024

- 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.

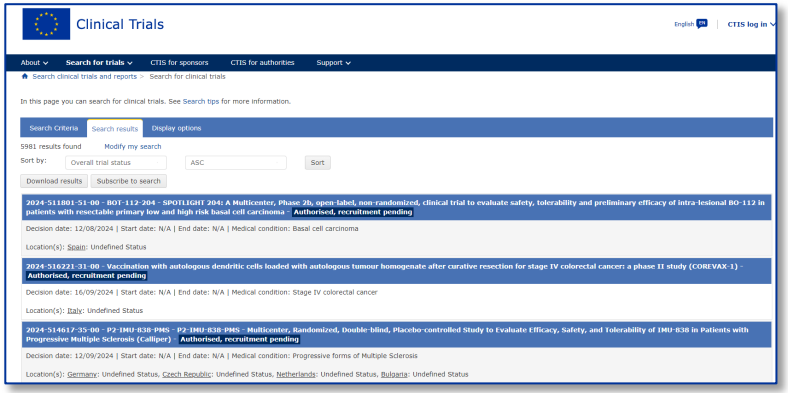
Reference guidance material: Quick guide for users & all material published on "Transparency in CTIS" - ACT EU website

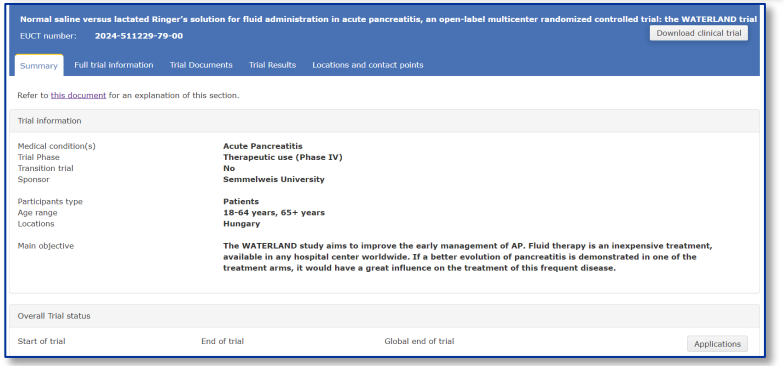
Additional features delivered on 20 September 2024

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

Former version of the CTIS public portal

Clinical Trials

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

Search clinical trials and reports > Search for clinical trials

Clinical trial search

Search Criteria | Search results | Display options

5856 results found Modify my search

Sort by: Decision date DESC Sort

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

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

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

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

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: 1

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

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

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

Former version of the CTIS public portal

Clinical Trials

English EN | CTIS log in

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

Search clinical trials and reports > Search for clinical trials

C1071032 - MAGNETISMM-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

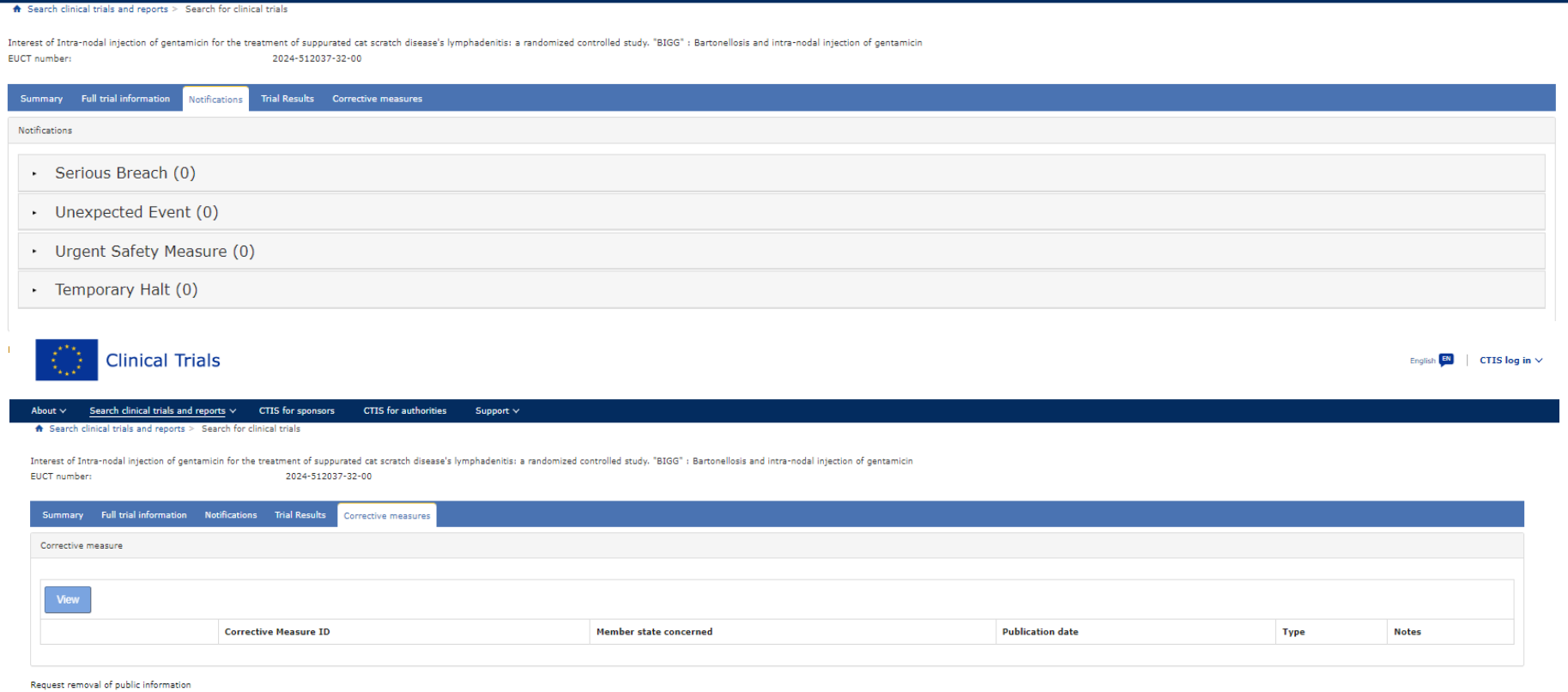
Start of trial 27/05/2024 End of trial Global end of trial

Applications

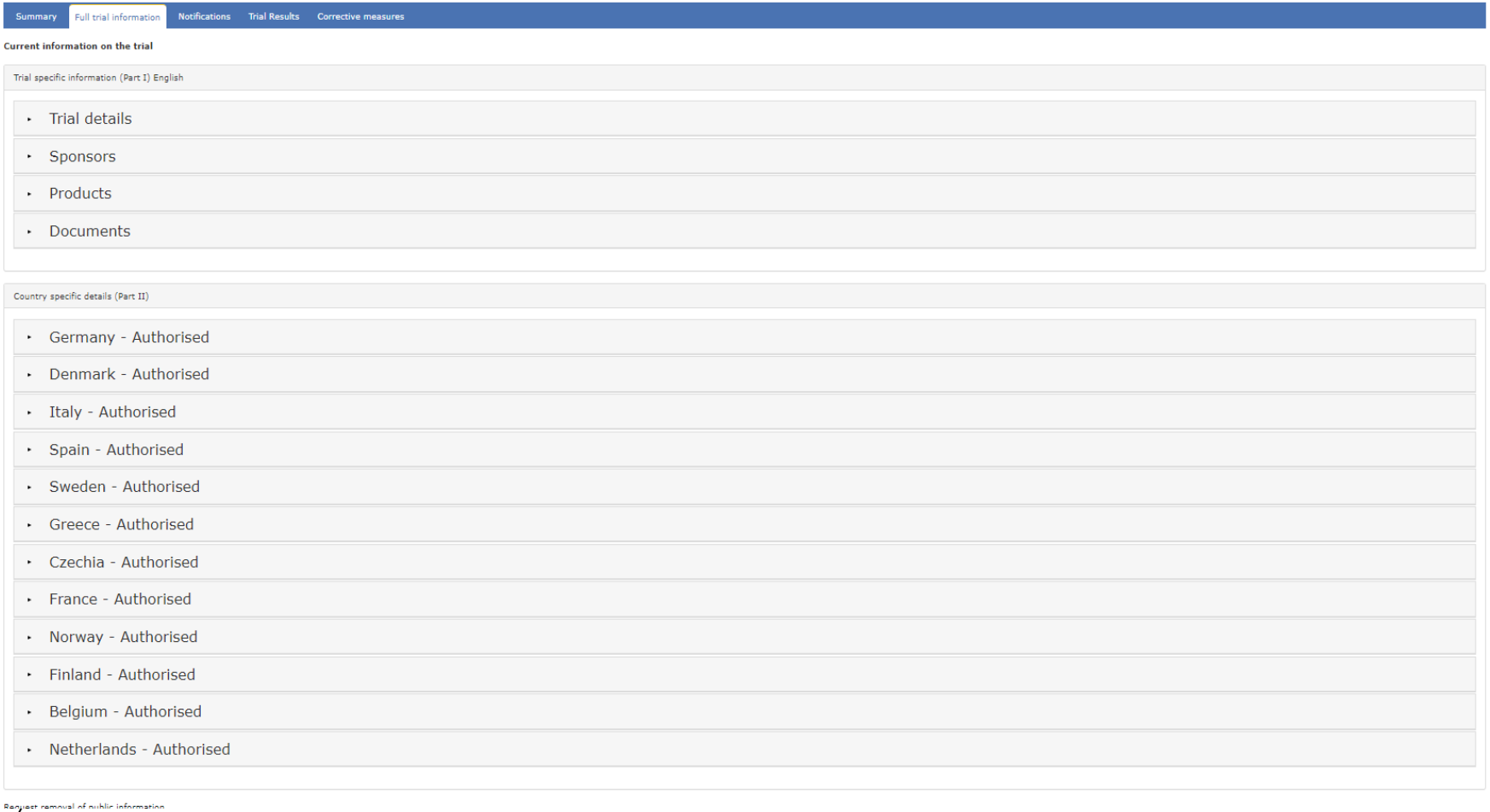
				Trial					Recruitment		
Member state	Current status	Decision date	Last update	Start date	Temporary Halt	Restart	End (or early termination)	Reason for early termination	Start	End	Restart
Norway	Authorised	06/05/2024	30/08/2024	10/06/2024					12/06/2024		
Netherlands	Authorised	06/05/2024	27/08/2024								
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							

Request removal of public information

Former version of the CTIS public portal



Former version of the CTIS public portal



Former version of the CTIS public portal

Current information on the trial

Trial specific information (Part I) English

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
○	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_2024-516651-41-00_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