

Kliinisten lääketutkimusten webinaari

CTIS-käytännön apua tutkijoille

29.05.2024

Transitiotutkimukset

-siirtymäaika 30.01.2025 asti

- Jos tutkimus ei jatku 30.01.2025 jälkeen, ei tarvitse siirtää CTIS-portaaliin
- Jos tutkimus jatkuu yli 30.01.2025, siirrettävä transito-tutkimuksena
- Vanhat direktiivinmukaiset tutkimukset: päättymisilmoitus eli End of Trial-lomake Fimeaan ja tulokset Fimeaan (synopsis) riittää, EMAaan tulokset [EudraCT-ohjelmaan](#)
- Kun tutkimus on CTIS-portaalissa, päättymiset ja tulokset ilmoitetaan siellä
- Fimean kotisivulta löytyy päivitetty [ohjeistus](#) transitiotutkimuksiin

Create new trial



Full title (English)*

Search organisation

Name

starts with ▾

ID

starts with ▾

City

starts with ▾

Country

achille

All ▾

+ New organisation

Clear

Search organisation

ID	Name	Address	City	postCode	country	phone	email	actions
☒ ORG-100032441	Achilles - testcompany	Achilles Street	Ctis Test		Cyprus			× +
☐ ORG-100011446	Achilles Therapeutics Limited	Bioscience Catalyst Gunnels Wood Road,		SG1 2FX	United Kingdom			× +

1 -2 of 2

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1

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☐ Transition Trial

Cancel

Create

Miten lisätään uusi SM (substantial modification) ja uusi jäsenmaa

The screenshot shows the Fimea workspace interface. At the top, a dark blue navigation bar contains the following tabs: **Clinical trials** (highlighted with a red box), **Notices & alerts** (with a red notification icon), **Annual safety reporting**, **RFI**, and **User administration**. Below the navigation bar, the main content area displays trial information for "Webinar 21 09 2020". A red box highlights the **Summary** tab in the left sidebar, with a red arrow pointing to it and a red text box stating "Go to the summary section in the sponsors workspace". Another red box highlights the **+ CREATE** button in the top right, with a red arrow pointing to it and a red text box stating "click on the create tab to make a substantial modification". A dropdown menu is open from the **+ CREATE** button, showing the following options: **Single trial substantial modification** (highlighted with a red box), **Multi trial substantial modification** (highlighted with a red box), **Non-substantial modification**, and **Additional MSC**. The main content area shows trial details under the heading "TRIAL INFORMATION".

TRIAL INFORMATION	
Sponsor	Test Organisation 1
Trial phase	Therapeutic exploratory (Phase II)
Therapeutic area	Diseases [C] - Respiratory Tract Diseases [C08]
Medical device	No
IMP	
Member states concerned	AT - BE
Medical conditions	Apnoea
Low intervention study	Yes
Population type	Healthy Volunteers

This is a close-up view of the dropdown menu from the **+ CREATE** button. The menu is open, showing the following options: **Single trial substantial modification** (highlighted with a red box), **Multi trial substantial modification** (highlighted with a red box), **Non-substantial modification**, and **Additional MSC**. A red arrow points from a red box labeled "submitted" to the **Single trial substantial modification** option.

Kiitos

Kliiniset lääketutkimukset asiointisähköposti: [clinicaltrials at fimea.fi](mailto:clinicaltrials@fimea.fi)