

Investigational sites should prepare now for EU Clinical Trials Regulation 536/2014 go-live date, January 2022



The **European Union Clinical Trials Regulation 536/2014 (EU-CTR)** aims to standardize and harmonize the conduct and management of **interventional clinical trials of phases I to IV** across the European Economic Area (EEA).

The EU-CTR goes into effect on **31st January 2022**, when the European Medical Agency's (EMA) electronic Clinical Trials Information Systems (CTIS) will go live. Between 31-Jan-2022 and 30-Jan-2023, applications for new trials can be filed either under EU-CTR or under the current Clinical Trials Directive.

All interventional clinical trials in the EEA which follow EU-CTR legislation must be submitted fully electronically via CTIS.



Details of investigational sites must be entered into the CTIS by the clinical trial applicant when creating the initial application under EU-CTR, using the [Organization Management System \(OMS\)](#).

OMS provides a central source of organization data which consists of a list of organizations with associated physical locations to be used for EEA regulatory activities. OMS is part of the centralized EU master data service covering Substance, Product, Organization, and Referential (SPOR) in relation to medicines.

Organization data are structured in OMS with unique IDs (organization ID and location ID). The OMS organization ID covers institution name and the location ID covers institution address. This information will be supplemented in CTIS by the clinical trial applicant with department name, principal investigator name and title, site phone, and email details to clearly identify an investigational site in the clinical trial application.

In order to participate in clinical trials under EU-CTR after January 2022, investigational sites should obtain an OMS organization ID and a location ID and communicate these site OMS IDs to the clinical trial applicant.

Step-By-Step Guide

Registering investigational sites as organizations in EMA's Organization Management System (SPOR - OMS)*

(In order to have them available in the CTIS predefined list of sites when submitting a clinical trial under EU Clinical Trials Regulation 536/2014)

Step 1

Required if an investigational site is not registered in OMS and the designated site user performing OMS site registration does not have an EMA account.

Registration of an unaffiliated user (from investigational site) in EMA IAM (Identification and Account Management)

- › Go to EMA Account Management homepage (IAM) – link: [EMA Account Management \(europa.eu\)](https://ema.europa.eu/iam) for self-registration and access management
- › Register an unaffiliated/simple user by selecting Create an EMA account
- › Complete the Self-service Registration form and respond to the security questions
- › In case your email is already in use, retrieve your username first. Wait for the confirmation email before accessing other EMA applications
- › After you submit EMA - Self-service Registration Form the credentials will be received over the email (user name and password)
- › In case you encounter any technical issues or errors you need to contact EMA IT Service Desk
- › Timeline: 30 minutes

Step 2

Required if an investigational site is not registered in OMS, and it can be performed once the site user has opened an EMA account (via Step 1).

Registration of the new site (entering the site name and address) in EMA OMS* (Organization Management System) through the platform named SPOR – link <https://spor.ema.europa.eu/omswi/#/>

- › Supporting documentation is required displaying the institution name and address: *any document showing the official registration name and address, such as Hospital Accreditation, etc.*
- › Go to SPOR platform [SPOR Web UI \(europa.eu\)](https://spor.ema.europa.eu/omswi/#/)
- › Login with your credentials obtained from EMA IAM
- › Select “Organization” tab in the middle of the page and then select the second “Organization” tab on the blue line below the first tab
- › Write the name of the site in the field “Organization name” and press “Search.” Then wait for the results
- › In case results are shown, verify the validity of your organization name and location details as currently recorded in OMS. If changes need to be made, proceed to Step 4
- › In case no results are shown, a new button will appear “Request new organization”

› A registration form will be opened, and mandatory data must be completed: Name and address of the organization

– Some basic principles for site registration in OMS:

- An organization, as a legal entity, groups all its physical locations within a country
- The location ID will be unique and will not change even after moving the location under another organization
- “Big” organizations e.g., Hospitals/Universities are represented by one organization and one or more locations - details of Departments are not managed in OMS. Departments with the same address will all be affiliated to the same OMS location ID

– [Follow OMS quality standard](#) when entering organization name and address:

- Organization name comprises of ‘Name’ plus ‘Legal entity type’ (not always included)
- Multiple names can be stored, although only one name is published as the Main Name
- Preferred Main Name for organizations is in English. Organization and location details can also be submitted in other EEA official languages, but OMS will supplement the record with English translation/transcription where possible
- Abbreviations and symbols should be avoided unless they are an integral part of the organization legal name
- Other names, which can be in different languages, are stored as ‘Alternative names’
- A location address represents the physical location within an organization

- Main Address vs. Address Localized: Main Address is identified as the address in English; Address Localized refers to address representations in other languages (these are not translations)

› Then add the supporting documentation on the right side of the screen, i.e., CT authorization, to prove the official name and address of the site

› Tick the box with confirmation of data

› Submit the request and wait for EMA validators to assess the request. A confirmation for the request is provided by email to the user

› If additional documents are required, an email will be sent to the user with further instructions

› When the registration is completed, an email to confirm that the “Change request - approved” is sent to the user

› Registration is completed when the site obtains the OMS ID number (Organization ID and Location ID)

› Only data for a single location per organization can be provided with each request; therefore, if a new organization requires multiple locations a request must initially be raised to create the organization and its initial location. Once the new organization has been approved, additional requests need to be raised to add the additional locations (one request per location)

› Timelines: 3-5 business days

› More guidance: see [OMS Web User Manual](#)

Step 3

Required once an investigational site has been registered in OMS.

Designation of a site representative as SPOR – Industry Super User in EMA IAM (Identification and Account Management)

- › Industry Super User role to be requested for the main representative of the institution through EMA Account Management portal (EMA IAM) – link: [EMA Account Management \(europa.eu\)](https://ema.europa.eu/ema/ema-account-management)
- › Go to “Manage my task” and request “SPOR – Industry Super User” role
- › User affiliation letter signed by site management is required for the first Super User – to be attached to the request (see EMA template, [Z2 - SPOR Super User Affiliation Template Letter](#))
 - The person/signatory of the User affiliation letter should be someone who works for the organization to which the user will be affiliated. They should also be recognised as having sufficient authority within their organization to sign the letter. The signature of a person would be admissible if they hold a managerial role and have the requisite authority within the organization to approve the affiliation request. If the first Super User fulfils such requirements then they can also sign the letter
- › EMA recommends that each organization has at least two registered Industry Super Users
- › Any subsequent User access requests for an organization are approved by the First Super User of the requestor’s organization, also in EMA IAM (affiliation letter not required anymore)
- › The requests for the first Super User access for a specific organization are approved/rejected by the EMA Validators

- › Timelines: 2-3 business days
- › More guidance: see [SPOR User Registration Manual](#)

Step 4

Required if an investigational site has been registered in OMS, but the institution name or address needs to be revised.

Changing information of an already registered site is performed by submitting “Update organization or location” change request in EMA OMS

- › In case the sites are already registered, but the name or address of the site changed, it is necessary to submit “Update organization or location” change request in EMA OMS. This request can only be submitted by an affiliated user to the organization, named SPOR – Industry Super User (see Step 3)
- › When this step is completed (i.e., SPOR - Industry Super User is approved by EMA) go to OMS page listed above and follow the steps listed in Step 2 above. When the site name is found, you need to select “Change location” icon and fill in the new information in the form opened and add the supporting documentation
- › Supporting documentation is required to show the “old” and “new” name or address of the institution: *Additional documents may be required, such as Trade certificate or Commercial chamber certificate, and for public hospitals, any document showing the official registration name and address, such as Sanitary permit*
- › Timelines: 3-5 days

*Additional information about the registration in OMS can be accessed on OMS website various tabs: <https://spor.ema.europa.eu/omswi/#/>

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