



What are the criteria regarding the selection of a reporting Member State as per Article 85(2)(c) of the Clinical Trials Regulation?

The scope of this document is to provide Member States with recommendations on criteria for the selection of the Reporting Member State (RMS).

The described mechanism for RMS selection is endorsed by national contact points on the basis of Article 5(1) paragraph 5, under their mandate in Article 85(2) of the Clinical Trials Regulation ⁽¹⁾.

If the proposed RMS is willing to become the RMS, the proposed RMS should be selected.

In case the Member State concerned proposed by the sponsor is not willing and a single Member State concerned volunteers to become the reporting Member State, the volunteering Member State concerned should be selected.

If the proposed RMS is not volunteering, the Clinical Trials Coordination and Advisory Group (CTAG) recommends to apply the following workshare criterion for the selection the RMS:

$$\frac{\text{Number of multinational clinical trials where the Member State acts as RMS}}{\text{Total number of multinational trials where the Member State participates}} \times 100.$$

Clinical trials that started as mono-national, but following an Art 14 procedure, an additional MSC was added after their initial authorisations, the workshare considers these as multinational applications.

In case more than one MSC volunteer to become the RMS, the volunteering MSC with the lowest workshare should be selected.

In case more than one MSC has the same lowest workshare, the system will assign the RMS randomly.

In case none of the Member State Concerned (MSC) volunteer to become the RMS, the one with the lowest workshare will be identified automatically by CTIS (Clinical Trials Information System) to become RMS.

The RMS will be notified in CTIS in agreement with Art 5.1. of the Regulation.

⁽¹⁾ **Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use,**

Looking at current CTIS data, in around 30% of the clinical trial applications, the proposed RMS does not accept this role and the process for RMS selection takes place.

Hence, if the proposed RMS does not agree to take up this role, the only selection criteria is the workshare, it is recommended that the sponsor of multinational clinical trials contacts the relevant national regulatory body before the submission of the Clinical Trial Application to ensure that the proposed RMS accepts this request.

This is particularly important for the application of:

- complex trials containing a reference to documentation in another ongoing clinical trial
- ‘daughter’ trials using a reference to a “mother” trial containing the approved Investigational Medicinal Product Dossier (IMPD) (EU Q&A 3.8).

Familiarity with the clinical trial in case of complex trials and/or the Investigational Medicinal Product (IMP) and, especially with the IMPD and related documentation, can facilitate the assessment. minimise redundancies and thus potentially decrease workload and improve consistency in the assessments of both the initial CTA as well as consecutive (part I) SM applications across the relevant clinical trials.