



PROCEDURE TO CHANGE CRO'S NAME AND/OR TO NOTIFY THE CHANGE OF CRO'S PREVIOUSLY SELF-CERTIFICATED ACTIVITIES

The translation of the form has been prepared in order to help comprehension by non-Italian mother tongue users, but the official form to be sent in paper format is the Italian one

The CROs which derive from mergers, acquisitions or changes of previously self-certificated CROs and/or which change the previously self-certificated activities according to the Ministerial Decree 15th November 2011 and which are included in the PRC's list available at the link <http://ricerca-clinica.agenziafarmaco.it/it/node/50> must:

- self-certificate again via PRC
- require again the access keys for entering the OsSC database (*user id* and *password*) for the new company (only in case of change of the CRO's name), via PRC

Mandatory notifications to be sent in paper format to AIFA's GCP Inspectorate Office are:

- the printed and signed form of the new self-certification and the front and back photocopy of a valid identity document of the legal responsible person
- the form for declaring the change of the CRO's name (Annex 1) and/or the form for notifying the change of the CRO's previously self-certificated activities (Annex 2)

Mandatory notifications to be sent in paper format to AIFA's Research and Clinical Trial Unit are:

- the new keys access request form, for entering the OsSC database (see FAQ OsSC) (only in case of CRO's name change)
- the form for declaring the change of the CRO's name (Annex 1) and/or the form for notifying the change of the CRO's previously self-certificated activities (Annex 2)



Annex 1

REQUEST FOR CHANGING THE CRO'S NAME (WITHOUT ANY CHANGE OF THE CRO'S PREVIOUSLY SELF-CERTIFICATED ACTIVITIES)

I, the undersigned, as legal responsible, do hereby declare that the CRO.....:

- derives from merger, acquirement, change of self-certificated CRO according to the Ministerial Decree 15th November 2011 and listed in the public list of the PRC

Specify details of the pre-existing CRO/CROs:.....

.....

- derives from changes of the name of a self-certificated CRO according to the Ministerial Decree 15th November 2011 and listed in the public list of the PRC

Specify details of the pre-existing CRO.....

.....

I, the undersigned, as legal responsible, do hereby declare that the new CRO..... takes up all the activities performed by the CRO/CROs it derives from.

Place, date

Legal responsible's signature



Annex 2

NOTIFICATION OF THE CHANGE OF THE CRO'S PREVIOUSLY SELF-CERTIFICATED ACTIVITIES

I, the undersigned, as legal responsible, do hereby declare that the CRO.....:

from ___ / ___ / ____ (30 days from the date of the electronic notification of the self-certification) performs the following self-certificated activities, according to the Ministerial Decree 15th November 2011:

- monitoring
- auditing on clinical trials or clinical sites
- statistical analysis and data analysis
- other, specify

Place, date

Legal responsible's signature