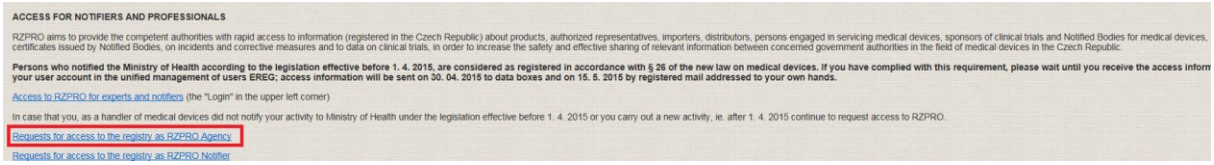
How to register a Sponsor in the Registry of Medical Devices (RZPRO) and submit application for clinical investigation (CI) conduct when represented by a contract research organisation (CRO):

In case, the Sponsor desires another person (CRO) to act on his behalf in communication with the State Institute for Drug Control in the matters of clinical investigation, the following steps have to be carried out:

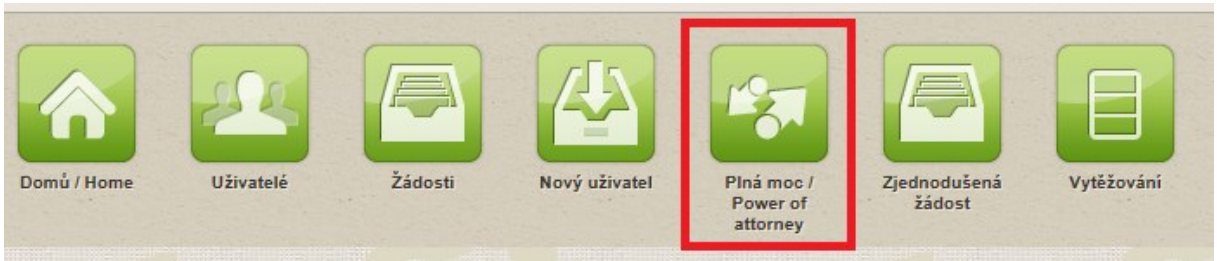
1. A Sponsor of a clinical investigation conducted at the premises of provider of healthcare services established within the territory of the Czech Republic is obliged to notify its activity in the Registry of Medical Devices (RZPRO) according to Section 26 (5) of the Act No. 268/2014 Coll., on Medical Devices prior the commencement of the CI.
2. The Sponsor shall submit a request for access to the RZPRO and further submit Entity notification see Manual No. 1 – First time login in RZPRO and registration of a person or operation https://www.niszp.cz/en/registry-medical-devices-registration-and-notification/manuals

3. The CRO shall submit a request for access to the RZPRO for Agency (accessible from www.rzpro.cz

   Use link: *Requests for access to the registry as RZPRO Agency*



4. Once the Sponsor has access to RZPRO, power of attorney may be granted to the assignee via RZRPO.
5. Power of attorney is granted to the CRO (agency) via the module „JSU“ – Power of attorney




Power of attorney
Help
Select organization
Application
RZPRO
Role
Agentura
Organization