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:

- 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.
- 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 <u>www.rzpro.cz</u>

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

ACCESS FOR NOTIFIERS AND PROFESSIONALS R2PRO aims to provide the competent authorities with rapid access to information (registered in the C2ech Republic) about products, authorized representatives, importers, distributors, persons engaged in servicing medical devices, sonnsors of clinical trials and Notified Bodie certificates issued by Notified Bodies, on incidents and corrective measures and to data on clinical trials, in order to increase the safety and effective sharing of relevant information between concerned government authorities in the field of medical devices in the C2ech Republic Persons who notified the Ministry of Health according to the legislation effective before 1.4. 2015, are considered as registered in accordance with § 26 of the new law on medical devices. If you have complied with this n your user account in the unified management of users EREG; access information will be sent on 30. 04. 2015 to data boxes and on 15. 5. 2015 by registered mail addressed to your own hands. ess to RZPRO for experts and notifiers (the "Login" in the upper left co case that you, as a handler of medical devices did not notify your activity to Ministry of Health under the legislation effective before 1. 4. 2015 or you carry out a new activity, le. after 1. 4. 2015 continue to request access to RZPRO s 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 a	ttorney			O Help
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