Suitability and availability of infrastructure at the research site

Clinical trials, art. 25 lit. h ClinO

Clinical trials of medical devices, art. 11 ClinO-MD, resp. 1.13 chapter II annex XV MDR

Research projects with persons (non-clinical trials), art. 15 lit. i HRO

Information on the suitability of the research site

Study team / Organisation

- Experience of members of the investigating group in conducting clinical studies
- Participating clinics/departments or external institutions (e.g. radiology, laboratory, pharmacy)

Infrastructure

- Suitability of available resources and facilities on site (rooms and equipment)
- Suitability of equipment/device / room utilisation for the study
- Emergency care (the form in which it is provided)

Patient numbers

- Number of patients treated in indication under research (per year)
- Planned number of patients for study

Research activity

- Number of ongoing studies in general and in same indication
- Handling of overlapping studies (same indication, similar inclusion/exclusion criteria)

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