Clinical Trials Inspection and PHV

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The Department for Inspection of Medicinal Products reports directly to The President of The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. Inspections in particular areas are conducted by inspection teams led by lead inspectors.

Clinical trial inspections can be conducted at investigational sites, sponsor sites, CROs or other relevant locations. A clinical trial inspection is an evaluation of a process conducted simultaneously across many organizations. It often concerns completed activities and verifies whether they meet the requirements of GCP principles and applicable regulations.

Pharmacovigilance controls generally take place at marketing authorization holder’s headquarters.

Details of each type of inspection/control are presented in particular bookmarks.

Number of inspections/controls conducted by the Department for Inspection of Medicinal Products and Medical Devices.

Number of inspection conducted between 2010 and 2015 [1]

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Odnośniki
[1] https://archiwum.urpl.gov.pl/sites/default/files/DLM/wykres.JPG