PS1.299

European Medicines Agency (EMA) inspection: strategy to follow in clinical trials

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Background: An inspection by regulatory authorities is always hard for researchers. It requires a lot of time and good preparation.
Aim: To instruct General Practitioners (GP) that participate in clinical drug trials how to prepare for an inspection.
Methods and Results: We recommend the following strategy: 1- To train researchers in the legal aspects of the country (in Spain a Royal Decree and the international Guide of Good Clinical Practices GGCP exist). 2- To review the protocol and the applied amendments. 3- To review and manage all documents of the study file. 4- To know the number of patients enrolled (randomized, screen failures, prematurely discontinued and retired…). 5- To know the adverse effects. 6-To know the protocol violations (errors in medication, mistakes related to temperature record, the timing of visits). 7- To provide certificates of all calibrated instruments used (balance, centrifuge, thermometers, blood pressure...). 8-To have GGCP certificates obtained in the two years prior to the beginning of the study. 9- To prepare a complete and updated Curriculum Vitae emphasizing the field of research (clinical trials and projects including those not paid for).10-To present his/her historical achievements and motivations. And 11- To teach researchers how to answer the inspectors' questions (precise, sure, confident, rigorous...).
Conclusion: An inspection of a clinical trial is useful for improving and preventing failures in the future