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Investigation in primary care: how to act before an inspection by the European Medicines Agency (EMA)

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Background and Aim: General Practitioners (GP) involved for years in clinical trials of medicines in primary care. The European Medicines Agency (EMA) and US Food and Drug Administration (FDA) conducted inspections to verify whether the data is reliable and whether the Guide to Good Clinical Practices (GGCP) has been applied in order to gain for marketing approval of the study drug. GP shoulg remember the importance of doing a clinical trial properly.

Method and Results: All documents should be reviewed (informed consent form, analysis, patient clinical history, clinical trial history,temperature records, calibration certificates of all instruments used, compliance with the timetable of the visits, registration of adverse effects, ...).

Conclusions: GP researchers have to be very careful, organized and disciplined to properly conduct a clinical trial. Training courses, good organization and adequate monitoring equipment provided by the sponsor are critical to extrapolate the results to the population and be approved. With our experience we believe it is important to be updated each year, check that all the documents are in the study file and have a study coordinator,whocould be a team member to oversee all procedures.