

An analysis performed during a study to compare the experimental groups with regard to the effectiveness or safety of an intervention, when the situation requires.

Note: Interim analyses must be planned in the protocol (their number, the time of their application, the criteria underlying them, etc.). They differ from the standard analysis, which is performed at the end of the follow-up period provided for in the study protocol. The number of subjects in a study must reflect the planned number of interim analyses.