Is it ok to access and analyse accumulating data in open-label studies?

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Background

- In a double-blind clinical trial, individual patient treatment assignment is not known until randomisation codes are accessed and applied to the dataset after database lock
  - It is accepted that accessing and analysing data by treatment group outside formal (interim or final) analysis is not to be undertaken
- In open-label studies (whether randomised, or single-arm) individual patient treatment assignment is known – to the investigator, to the patient and to the Sponsor
  - A Sponsor might find it attractive to monitor accumulating study data, eg,
    to check aspects of study conduct, the suitability of analysis methods,
    validity of assumptions in the sample size calculation,
    to plan future studies or portfolio-level decisions.

    These investigations would be more informative if done by treatment group

Questions

What is the regulator's view on Sponsors accessing and analysing (even descriptively) the accumulating study data by treatment group in open-label trials, including single-arm trials?

Under what circumstances are regulators comfortable with Sponsors having access to accumulating data in open-label trials?

Would any concerns remain if data access and analysis is done without any intention to modify study conduct or analysis?

Do regulators expect sponsors to have SOPs to guide, or to prevent, access by treatment group to accumulating study data?