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Early clinical development (ECD) trial represents the transition between the preclinical and the clinical full development. The main objective of our trials is to determine the maximum tolerated dose of a new compound. Because the data generated in these studies, are often the "first in human (FIH)" clinical data available, the clinical team is also interested in exploring efficacy/PK/PD results.

The study protocol is made flexible in order to extend and adapt the trial to the take into account any preliminary results. The preliminary results of FIH studies are used for internal decision (move or not to full development) and/or for external communications. As such, being a programmer in ECD requires to deal with flexible protocol, to report multiple analysis, several time before the database is closed/locked. Your programs must be standard (provided the analysis requested is), ready after the first data transfer available, robust and flexible to be run at any time. The challenge being to use or adapt standard programs in an exploratory domain...

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