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Interventional Vs. Non-Interventional Study Classification in the European Union: Would my Study Remain Non-Interventional if I use Direct-to-Patient Contact Methods?

The debate on when a NIS qualifies as an interventional study started in 2010 and is not resolved. It resurfaced with the new EU Regulation on clinical trials that introduced a new category of studies in the post-authorization setting -- the 'Low-intervention clinical trial'. The criteria for this new category of study can be confusing with the non-interventional study definition. Waiting for further official clarification on this topic, EMA recently advised sponsors to provide sound analysis and arguments to ECs and competent local authorities on a case by case basis when discussing classification of a study as non-interventional.

The use of direct to patient contacts in post-authorization prospective cohort follow up may open room for discussion: could such proactive contacts performed outside a clinical care visit still be seen as normal clinical practice (thus non-interventional) or necessarily considered as additional diagnostic or monitoring procedures (thus interventional)? From our experience, direct to patient contacts seem to have a very limited impact on study classification, however, it is prudent to be prepared for potential discussions using the orientation criteria as proposed in this presentation. Consensual review, fine-tuning and validation of these criteria would be beneficial to enhance common understanding of study classification.