Hi, my name is Corrado Iacono, a pharmacist and I respond as an individual.

I have only two notes:
#1
66 It is the responsibility of the trial sponsor to ensure that the lay summary is developed
67 and submitted to the EU database.

I propose that the following sentence be added at the end of the paragraph "***In the event of failure to publication of the report on time, sanctions will be applied pursuant to article 94 of Regulation 536/2014 will be applied***"

#2
I propose that another point could be added in the Annex 1 - Templates, based on the follow consideration (point 11.):

Many times, during the course of the trials, the sponsor needs to implement lot of amendments that could generate a new protocol, totally different respect at the previous version of the document. Security reason, efficacy demostration after a interim analysis, are some of the cause of these amendments . The lay summary should be completed with a timetable which report the most important amendments at the protocol respect of the first version of the document. This timetable will be a good tool for verify the data in the final article related to the trial and can be create similar the "history of changes" in the clinicaltrials.gov: https://clinicaltrials.gov/archive/NCT00467584