



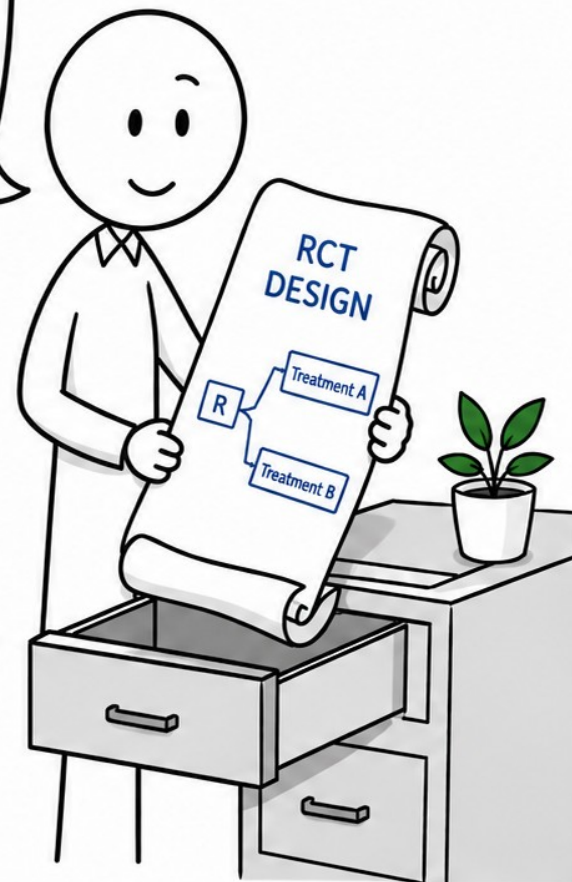
Relationship status: it's complicated

Short Topics 'reversed'
Laura Rodwell, Medicines Evaluation Board

The European regulators think that an RCT is possible and would prefer that we perform one instead of a single-arm trial.



Interesting...I still have the design of the RCT that I proposed a few months ago if you would like to see that?



Unfortunately the advice that we've received states that the trial design we proposed would not be sufficient to support regulatory decision making



I was really expecting that we would get support for our alternative proposal this time...



Questions to the panel

1. Could you please share some (general) examples of situations when advice/feedback given by regulators supported *your* preferred approach, which ultimately helped you to convince your colleagues to take that approach?

(e.g. trial design, choice of endpoint, analysis method etc.)
2. On the flip side, could you share some examples of when you were really expecting to get support from regulators on a statistical or methodological aspect, but didn't?