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**On Behalf Of**Ben Goldacre
**Subject:** Re: EMA's about to U-turn on transparency policy?

from holidays, a couple of quick thoughts about EMA policy:

- I think, from various discussions with regulators over the past year, they are asking companies to redact their own CSRs because it costs regulators money to redact each document by hand, and they're concerned about the risks of automating redaction. While it saves costs, and so makes greater transparency more deliverable for regulators, it also clearly escalates the risks around excessive redactions.

- There are detailed tables in the discussion paper from EMA, where they say which sections in an ICH-GCP compliant CSR have no, moderate, and high risk of containing IPD or commercial plans (in the past, companies expected CSRs to be kept secret forever, so would sometimes discuss eg future plans for applications for new indications in parts of the CSR). These tables are a useful resource, and EMA will hopefully develop plans to ensure that redactions are appropriately limited to relevant sections (ie the Statistical Analysis Plan should not in general be redacted!).

- There will also need to be an appeal process for redactions: some kind of internal "first glance" review to ensure that there are no unreasonable redactions, and some kind of penalty for unreasonable redactions. At the very least, this will require EMA publicly listing all appeals against redactions, and the outcomes. This produces public accountability after unreasonable redactions, which is important, since in the absence of real penalties, naming/shaming/reputational-sting is one of the few effective tools we have to drive up standards.

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