Twitter Thread by Hilda Bastian, PhD

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@hildabast

Meanwhile, a few days ago the EMA published its EPAR (public assessment report) on the Moderna vax (HT @pajz_) https://t.co/LHW4rGgFwV It's 169 pages ...1/n

...There was "a major objection" to the US manufacturing sites, so they were withdrawn. Complete transfer for Europe to Swiss manufacturing due to conclude soon. (There have been Qs in the US about a batch there https://t.co/g573j7uFNQ)...2/n

...If you're interested in the chemical & biological aspects of this vaccine, there are pages for you to dig into - not an area I have any expertise in. Small amount of detail of reproductive toxicity study (in rats): no cause for concern....3/n

...The clinical trial data is from November, as for the FDA data. There's more detail than in the FDA report, though, of the phase 2 study, which hasn't been published. 600 people: a lot of data on immunogenicity (but not cell-mediated immunity)...4/n

...More methodological data on blinding etc for the phase 3 trial & *a lot more data* than in the FDA report. And take a moment to appreciate this: 30,000 people enrolled in less than 3 months. Giant thank you's due all round ...5/n

...In my posts, I've pointed to FDA report someone with apparent severe Covid-19 not adjudicated or in Moderna's analyses. Now we know why: no cases before dose 2 & not all suspected ones were adjudicated. That's not reassuring, though they conclude "no substantial bias" ... 6/n

...Like FDA, EMA point to person with severe Covid-19 in the vaccine group. Overall, data on severity reassured them, but "the cases overall seem mostly mild, which is a limitation of the dataset". "No definitive conclusion on clinical efficacy after one dose can be drawn" ...7/n

...They also conclude the definition of severe Covid-19 "could have been more stringent from a clinical perspective". They say open questions remain about the lower bound for the confidence interval of efficacy, partly because of the case ascertainment issue, so... 8/n

...they want more data in a final report by December 2022 before considering approval. Serious adverse events seem similar to FDA's conclusions (but I haven't cross-checked case by case). Apropos today's other discussion: 7,520 people were aged 65+...9/n

...Conclusion? This is a far better report than the FDA's one on this vaccine: it's the "go to". Not comfortable that the unadjudicated person with severe Covid signals a bigger issue, but very glad the EMA is on it. 10/10