

21 August 2020

Health Action International/TranspariMED Statement on Dutch Trial Data

It is worth noting that the methodology used in calculating the results has been used in a number of countries and has been peer reviewed¹. Nevertheless, three universities have challenged the data presented in [HAI/TranspariMED report](#) on Dutch Clinical Trial data published on 20 August 2020.

- Table 1 of the report lists “results due”, and then “with results” and “no results” as sub-categories
- The narrative of the report states on the same page that “The column ‘No results’ indicates the number of trials that are verifiably missing results in violation of European transparency rules.”

Both the narrative and the table accurately reflect the reporting performance of the three universities in question, as defined above. Trials can only be identified as “verifiably missing results in violation of European transparency rules” if they are (a) marked as completed and (b) have completion dates.

As the table below demonstrates, the trials listed by the universities are (with one exception) either still marked as “ongoing” or do not provide a completion date.

In the EU Trials Tracker, these trials are marked as having “inconsistent data”, rather than as having been “reported”. We regard this categorisation as appropriate because a clinical trial with a registry entry that contains inaccurate and/or contradictory data, or that has key data missing, cannot be regarded as having been fully reported. The sole exception is trial 2013-004108-20, whose results are not “due” in a regulatory sense as they are exempt from EU reporting requirements. Note, however, that this trial too has inconsistent data: it is listed as both Phase 1 and Phase 4.

We used the same categorisations in recent national reports on [Germany](#) and [Austria](#), which also received broad media attention. In neither country did universities or other stakeholders challenge our categorisations as inappropriate. We therefore stand by the claims made in the report, and by the data presented in Table 1.

At the same time, we note that Radboud University has uploaded clinical trial results in recent months. While these trials cannot be counted as “reported” at present under our methodology, they will appear as “reported” in future follow-up reports as appropriate and we look forward to championing Universities progress towards compliance and transparency.

¹ Goldacre, B., DeVito, N.J., Heneghan, C., Irving, F., Bacon, S., Feminger, J., Curtuis, H. (2018) *Compliance with requirement to report results on the EU Clinical Trials Register: cohort study and web resource*, BMJ 2018; 362: k3218

Disputed trials

Sponsor	Trial ID	Comment
VU University Medical Center	2013-000789-13	Marked as "ongoing"
AMC Amsterdam	2012-000680-24	Completed, results uploaded Jan 2017 Marked as completed, but no completion date provided = "inconsistent data"
Radboud	2016-001455-42	Completed, results uploaded Feb 2020 Marked as completed, but no completion date provided = "inconsistent data"
Radboud	2014-001044-38	Marked as "ongoing"
Radboud	2014-004488-19	Marked as "ongoing"
Radboud	2014-001111-39	Completed, results uploaded Sep 2019 Marked as completed, but no completion date provided = "inconsistent data"
Radboud	2013-004108-20	Completed, results uploaded Jan 2020. The Tracker marks this trial as exempt from EU reporting requirements because it is listed as a Phase I without a PIP in the register. However, the register also lists the same trial as Phase 4 (!).
Radboud	2015-005735-40	Completed, results uploaded Jan 2020. Marked as completed, but no completion date provided = "inconsistent data"
Radboud	2007-003347-73	Marked as "ongoing"
Radboud	2010-020371-22	Marked as "ongoing"
Radboud	2008-001974-33	Completed, results uploaded 10 June 2020 Marked as completed, but no completion date provided = "inconsistent data"
Radboud	2014-003306-33	Completed, results uploaded Jan 2020. Marked as completed, but no completion date provided = "inconsistent data"
Radboud	2011-005168-14	Prematurely ended, results uploaded Sep 2019 Marked as completed, but no completion date provided = "inconsistent data"
Radboud	2016-001379-66	Prematurely ended, results uploaded Mar 2018 Marked as completed, but no completion date provided = "inconsistent data"
Radboud	2012-005372-34	Marked as "ongoing"

Background explanation by Nick DeVito, EBM Data Lab (EU Trials Tracker):

"We do not use the data provided from the results page ("Global completion date") for our assessments. If we did so, we would be artificially inflating, and therefore biasing upwards, sponsor reporting rates because trials missing this "Date of the global end of the trial" date with results would be included in both the numerator and denominator, but those without a proper protocol end date and no results would not similarly be included in the denominator. If a trial has no known completion date, we cannot assess it."