TranspariMED position statement

UK clinical trial transparency system: Eight benchmarks

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TranspariMED welcomes the Health Research Authority's setting up of the Research Transparency Strategy Group as part of its ongoing efforts to strengthen clinical trial transparency in the UK.

This position statement seeks to enrich and inform the initial deliberations and work of that group, and the planned subsequent consultation process, by setting out benchmarks for transparency.

A UK clinical trial transparency system that does not meet the eight benchmarks outlined above is likely to fall short of the transparency expectations of the House of Commons Science and Technology Committee, UK patients, and UK taxpayers, as well as falling short of transparency standards that have long ago become the accepted norm in other sectors.

To ensure consistent clinical trial registration and reporting in line with global best practices and existing UK rules and regulations, the future UK national clinical trial transparency system will have to incorporate the following principles, features and characteristics:

1 Comprehensive

The system should capture all interventional clinical trials (as defined by the WHO) conducted on UK soil, including device trials and trials of non-drug interventions, regardless of sponsor type and location.

2 Watertight

The system should ensure that 'no trial is left behind'. Any trials that are found to be unregistered and/or inadequately reported within the time period covered by one audit should 'remain on the books' until all outstanding issues have been resolved, or the trial is formally written off as non-registrable or its results as non-recoverable. The analogy of bank loans may be useful: a bank may either recover or write off a loan, but no loan file is ever dropped without a formal close-out.

3 Efficient

The system should be designed to be as efficient as possible in order to minimise the administrative burden it places on trial sponsors and PIs, while also minimising the costs of managing the system itself. A start-up investment into streamlining, integrating and automating audit processes to the maximum extent possible will save all stakeholders involved considerable time and resources in the long term. Note in this context that the NHS successfully manages millions of patient records; managing data on the less than 2,000 trials conducted in the UK every year should not be expensive.

4 Effective

The system should incorporate sanctions, including debarment from conducting future trials and financial penalties. Sanctions should be automatically triggered according to clear, well-defined, objective and transparent criteria, rather than being imposed on a subjective, discretionary, case-by-case basis. Note in this context that the Declaration of Helsinki clearly and unequivocally states that any failure to adequately register and/or report the results of any clinical trial is a breach of medical research ethics. The current impunity for researchers that behave unethically must end.

> ***Recommendation: In order to enable an informed debate and consultative process on the issue of sanctions, the Health Research Authority should immediately make public the legal advice it obtained in this regard, and circulate this advice to Research Transparency Strategy Group members and other key stakeholders.***

5 Supportive

The system should actively support trial sponsors in complying with global best practices. Support mechanisms worth considering in this context include:

> (a) production and dissemination of user-friendly guidance to managing entries on the three commonly used registries (EUCTR, Clinicaltrials.gov and ISRCTN)
> (b) setting up a national helpdesk for PIs and trial sponsors
> (c) setting up a peer-to-peer support network (see here for an interesting model)
> (d) conducting surveys to identify barriers to good registry management encountered by sponsors and PIs (see here for examples), and working with regulators and trial registries to remove these barriers

6 Progressive

In order to support progressive improvements in clinical trial transparency, the system should aim to continually improve the level of clinical trial transparency in the UK by setting benchmarks based on global best practices (rather than only auditing narrow regulatory compliance).[1] The system should combine this with a feedback loop through which all trial sponsors and PIs receive automated email updates on their performance against global best practices.

Note that assessing trials' performance beyond narrow regulatory compliance would be fully in line with the Health Research Authority's mandate. Without imposing any new regulations, red tape or sanctions, a broad audit scope coupled with direct feedback to stakeholders would significantly drive voluntary adherence to global best practices.

> ***Recommendation: During the next meeting, the Research Transparency Strategy Group should solicit members' suggestions for elements of trial registration and reporting to include in the audit scope, and the Health Research Authority should present a proposed list of audit elements in the draft strategy for public consultation.***

[1] For example, the system should capture data on registration timepoint (pre or post), adherence to easy-to-assess CONSORT elements (e.g. presence of registry ID number in journal abstract), and accuracy of status (ongoing/completed) stated on registries. Capturing each of these data points manually would take less than one minute per trial.

7 Transparent

All data points collected during the audit process should be made publicly available. The system should regularly make public audit reports containing line-by-line data on every individual trial and its performance against every audit criterion. In the case of trials that have been registered, each trial should be identified with its registry ID number(s). In the case of trials that have not been registered, sufficient information should be provided to allow external stakeholders to clearly identify the trial in question and those responsible for ensuring its registration, i.e. at a minimum the names of the trial's funder, sponsor, and PI.

> ***Recommendation: The Medical Research Council should immediately publish the complete line-by-line data set from its most recent trial audit, allowing individual trials to be identified, and commit to routinely making all data gathered during future audits public. This would set a strong precedent for transparency, and send a clear signal that that in future, public bodies will no longer shield non-compliant medical research stakeholders from public scrutiny.***

8 Accessible

All data points collected during the audit process should be made publicly available in an accessible format to allow secondary analysis by external parties. Audit reports should include freely downloadable data sets to facilitate their use by meta-researchers.

Note that in the past, comprehensive clinical trial audits (i.e. audits that also capture all unregistered trials in a cohort) were always limited to individual institutions or Research Ethics Committees. Nation-wide audit data will constitute an unprecedented, unique and invaluable resource for meta-researchers.

TranspariMED will continue to follow and support the work of the Research Transparency Strategy Group over the coming weeks and months.

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