Adding value in clinical research

Basel, Switzerland, 1 June 2017

This symposium celebrated the 10th anniversary of the Swiss Clinical Trial Unit network, which supports academic clinical researchers during the planning, implementation, analysis and publication of their research projects. The organisers took this opportunity to look at how different participants in this process contribute to improving the relevance, reproducibility and transparency of patient-oriented research. I was invited to describe measures being taken by editors.

The symposium opened with an excellent keynote lecture on value and waste in clinical research by Professor Rustam Al-Shahi Salman from the University of Edinburgh. Rustam was a co-author of *The Lancet*'s 2014 series, Increasing Value, Reducing Waste, and is an active member of the Reward Alliance that has developed from that series. Short talks followed on specific Swiss and European networks for research infrastructure. It was encouraging to hear from Christiane Pauli-Magnus, Vice-President of the Swiss Clinical Trials Organisation, that quantitative indicators are being put into place to monitor progress, mapping to the five steps outlined in *The Lancet* series. The Swiss Biobanking platform described by Christine Currat is a national coordination platform for biobanks in all fields of research: human, animal, plants and microbiology that assists with quality control, access and transparency. Only one year old, its first step is to create an inventory of biobanks within different hospitals and produce a catalogue of those willing to share samples and data, following high quality standards. The Biobanking and BioMolecular Resources Research Infrastructure (BBMRI), presented by Michaela Mayrhofer, is an EU infrastructure project that will put over 250 biobanks in 30 countries 'on the map', so that researchers can find and re-use existing resources. Another EU infrastructre project is the European Clinical Research Infrastructure Network (ECRIN), which supports the conduct of clinical trials across borders by protocol review and management, quality assurance and data centre certification, and capacity building projects. Christine Kubiak described how it provides tools to address regulatory and ethical requirements in different countries. A Scientific Board assesses the relevance and quality of projects to be supported by publicly funded infrastructure in terms of study registration, commitment to publish whatever results, data sharing; whether the trial hypothesis addresses a real and relevant question and trial methodology.

The afternoon session opened most unusually with a magic show by Thomas Zlaps, whose patter incorporated all the buzz words of biomedical research, particularly genetics and neuroimaging, as well as futuristic technological developments such as spray books, ingested via an oral spray and absorbed directly into the brain, while the magical sleight of hand had us all amazed and enthralled.

Two talks by Swiss and UK funders were followed by my presentation. I described *The Lancet*'s efforts to ensure authors have conducted a literature search, at least before publication, if not at the start of their research project, by insisting that they report the details in a Research in Context panel that summarises what was known before and what this paper adds to that knowledge. We also check that papers adhere to the study protocol, where there is one, and follow reporting guidelines, such as CONSORT and PRISMA. This often means negotiating with authors for the inclusion of additional outcome data and nearly always means asking for additional methodological and statistical information. All Research Articles then undergo review by at least two clinicians and a dedicated statistical reviewer. One recent development is to provide a template study profile in our Instructions for Authors that encourages full reporting of all participants screened for a study and reasons for their inclusion at different stages – based on CONSORT but valid for many types of study. *Lancet* journals do publish negative studies: preferably those that report a definitive negative that changes clinical practice or shows that a novel intervention should not be introduced, but some of the newer journals in *The Lancet* family, including *Lancet Psychiatry*, will publish less conclusive or even failed studies, if the methodology is sound, the topic of clinical importance and the paper represents the current state of the field. Finally, I described the EASE SAGER guidelines and encouraged the audience to use them.

The conference ended with an Oxford Union-style debate that asserted, this house believes that big data will revolutionise personalised medicine. Stephen Senn, a well-known statistician, gave an ebullient speech against the motion and persuaded over 20% of the audience to change their votes by the end of the debate.

So, overall, not much to be learned as an editor but I think it is important that we engage with the research community, show them what we as editors are doing and illustrate some examples of good publishing practice.

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