Stem Cell Science and GSK Urge Trials Reporting

What do Stem cell science and GSK have in common? There is an excellent post By Dr. Alexey Bersenev, a stem cell scientist on the transparency of clinical Trials. There an excerpt below. It is well worth reading the entire article as this goes into depth as to how registering all trials and reporting them helps science.

GSK has also committed to All Trials Now and states they are working to develop a system where researchers will be able request access to detailed anonymised patient level data that sit behind the results of our clinical trials to enable additional scientific inquiry and analyses to help further scientific knowledge. See more of details of the GSK statement here.

Dr. Alexey Bersenev shares:

More and more clinical trials are getting registered in public databases. Partly, because it’s mandated by government agencies, but also because of our understanding the importance of information transparency. I’d speculate that now most of cell therapy clinical trials get registered in databases. But how good are we at posting results and analyzing the data from these trials? Unfortunately, we are very bad at it:

The best evidence shows that half of all the clinical trials ever conducted and completed on the treatments in use today have never been published in academic journals. Trials with positive or flattering results, unsurprisingly, are about twice as likely to be published – and this is true for both academic research and industry studies.
The studies, supported this evidence and were published in PLoS (1/2) who also support All Trials Now reporting.

The problem is that the results of trials are hidden deliberately. Even though FDA Amendments Act of 2007 required to post results of all trials, registered in ClinicalTrials.gov, within a year after completion, nobody follows the rule.

The price that we pay for this non-transparency could be horrific:

This cannot be acceptable. Withholding data not only misleads doctors and patients; it’s an insult to the patients, who have participated in clinical trials believing that they were helping to improve medical knowledge.

Unfortunately, it’s not just a problem of BigPharma. The situation with cell therapy trials is not better. Stem Cell Science and GSK Urge Trials Reporting. According analysis of Emily Culme-Seymour, less than 1% of cell therapy trials have results posted in database:

https://twitter.com/cells_nnm/status/197412760806625283

When I narrowed down a search to “stem cell” and to the last 2 years, I was able to find only 5 trials with posted results:

NCT00145587
NCT00203203
NCT00684060
NCT01193660
NCT01110252

No results were posted from industry-sponsored trials. Please
note, that currently, only NCT platform allows the posting of results. But this database takes > 70% of all international registries in cell therapy. So, we don’t have posted results not because of web-platform limitation, but because of unwillingness of professionals to do this.

The lack of transparency and publication/ reporting bias represent fundamental flaw of medical research in modern evidence-based medicine. It is unacceptable. It is a medical research fraud! How can we fix it? The fix is easy. If you’re professional – just do it! Always report and publish results timely and openly, irrespective of outcome! Think about patients and progression of the field! If you’re a regulator – enforce accurate registration of trials and results reporting. If you’re a patient – demand the full information as soon as possible. Right now, all of us can sign a petition to support registration and results reporting of all trials. The project AllTrials has been recently launched and, so far, got nearly 30,000 signatures.

The Medical Research Council, major journals, Cochrane and even Wellcome trust have all signed on. The time is ripe for well placed change with All Trials Registered and All Trials Reported leading the charge. Signing on is for everyone who cares about research and health care!