**Tracey Brown**, Managing Director, Sense About Science, and **Dr Helen Jamison**, Deputy Director, Science Media Centre, gave evidence to Commons S&T committee 15 May 2013:

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**Tracey Brown:** No,

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<http://www.publications.parliament.uk/pa/cm201314/cmselect/cmsctech/104/130515.htm>

Q119 **Chair:** So you are arguing in favour of full release of information. What impact do you think that would have on the pharmaceutical industry?

**Tracey Brown:** When you say full release of information, I should just clarify that. It is helpful to think of this at four levels. One is the registration of trials; that is level 1. That has been a problem, certainly historically, although there have been some improvements since the 2007 FDA regulations and other interventions. We do not even have the contents list, if you like, of what has been done, never mind being able to track down some of the results. That is something that reviewers who are looking across a whole range of studies really struggle with; they spend a lot of time just trying to find out what has actually been done but been left in a cupboard somewhere. Registration is about knowing what the trial is for and registering the protocols.

The second level of information, which is what AllTrials is calling for, is the basic summary of the clinical study report. That says what was actually found, what the primary outcomes were and what the protocols were. We would like to see as much information there as possible, but that certainly gives you some indication of what research has been done and how it has been undertaken.

The area for quite a lot of discussion at the moment is what I would call level 3, which is the full clinical study report. That contains in many cases quite a lot. It is a very large report-quite often, it even runs to thousands of pages-and it may contain quite a lot of individual patient data, things that might be tracked to individual patients or other things that constitute reasons why people might be concerned. There is a discussion about the release of those. I just note that we are seeing their release by the European Medicines Agency already for those drugs that they have them for.

Then there is the fourth level, which is individual patient data. A lot of very productive discussion is going on about how to establish good protocols for sharing that among the research community-for example, setting out the same requirements for secondary research as you would for primary research, looking at the same data.

**Dr Helen Jamison:** There is probably not a great deal that we at the Science Media Centre can comment on from that perspective, because we do not have so much expertise in this area, but I think that one of the things that the pharmaceutical industry might need to consider in a move towards greater openness is the impact in terms of how they communicate the results of those clinical trials and that data. One thing that we have struggled with in the past when responding to controversial and difficult stories in the headlines about clinical trials and other areas more generally is that there is sometimes a reluctance on the part of industry to engage when an issue is on the front pages. Often, that can be the case with scientists and academics who are slightly related to Government as well. The impact of that is that, generally, it leaves a bit of a vacuum at a time when actually more information is needed. At the Science Media Centre, we often become very reliant then on independent academics based in universities. So I think a move towards greater openness on the part of industry would be a very good thing, but it would have to get down to grass-roots level in terms of how they engage with the national news as well as the public and the rest of the scientific community.

Q120 **Pamela Nash:** Ms Brown, just to be clear, is the aim of the AllTrials campaign to have all four levels published?

**Tracey Brown:** No, the aim of the AllTrials campaign is to ensure that levels 1 and 2 are published. Levels 1 and 2 do not have a huge amount of practical implication. It’s just a shocker that they are not published already. Levels 3 and 4-level 4 particularly has a certain practical implication, depending on the organisation. The requirements of level 3-what would be an equivalent to a clinical study report; there are such things, but for an academic, for example-just need to be ironed out and worked on. It is not a huge barrier to publishing that information. There is quite important information at level 3 about serious adverse events, for example, that may need to be shared, but that just takes a little more work and thinking about.

We are really pleased that, in signing up to AllTrials, GlaxoSmithKline, for example, committed to publishing a lot of their level 3 data. Obviously, we are going to look at what they encounter in doing that. That is an ongoing discussion with them. A lot of the people who have signed up to AllTrials are committed to that, too, but what we want to do is just to get past the idea that secrecy is okay. That is really the ultimate aim ofAllTrials. It is just to find out what people have done and what they have found, at a very basic level, and then we can go on to look at some of the implications of sharing that.

Q121 **Chair:** Can I just halt things there for a moment? In your written evidence, you say: "For all trials (phase 2 and above) conducted since 1990…Full clinical study reports, or equivalent, should be made publicly available." That is what you are saying, is it?

**Tracey Brown:** Yes. The thing is that what has come about from that discussion is that because people have not been particularly thinking about publication, within clinical study reports are bits of information that people want to redact. I have set it out as four clear lines of information. The reality is, of course, that it is much messier than that. Clinical study reports contain individual patient data, and there is some discussion about that, but it is the full findings that we would want to see. Having said that, I am now looking at some of the discussion that is going on between some parties about publishing information on serious adverse events-

Q122 **Chair:** So in the context of level 3 and the word "full", you don’t quite mean that; you mean "qualified full".

**Tracey Brown:** What we are finding out is that "full" means something different for different people, depending on what they have included in that. I think we need to keep this idea of levels of information to try to have sensible discussions about it, but we need to look at what different parties-the differences between academics and those who are providing regulator information and so on-have got in that "full". We are saying, "Open your box." We do not know however if different people are putting different things in each of the boxes.

Q123 **Chair:** It would be helpful for clarity if you could reflect on your written evidence and what you have just said, and perhaps drop us a note on that.

**Tracey Brown:** I will do that, because there have been three very important discussions since the submission of written evidence that I would like to share with you. I will update you on those.

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