Working with industry in research: what do patients want?

A report from an Oxford Biomedical Research Centre/Unit workshop, May 7th 2014

This report covers the background to the event, summarises key findings and sets out an agenda for action.

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SUMMARY

Driven in part by the "wealth creation" agenda of the National Institute for Health Research (NIHR) which funds the Oxford Biomedical Research Centre and Unit (BRC/U), extensive partnerships are made between the BRC/U and the drug and biotechnology industries (collectively termed "industry" in this report), yet patients know very little about these

The BRC/U are committed to working with patients in all that they do, the NIHR wants patients to provide leadership about working with industry, and patients themselves want this

While understanding that industry exists to make money, patients want partnerships with it to be conducted openly and to meet their needs

We set out here a plan of action to integrate and progress these perspectives

Background

What was the aim of the event?

"To inform our PPI strategy on how best to make meaningful and constructive links with industry from the patient perspective."

"Industry" in this context refers to pharmaceutical (drug) companies and those that make devices and other forms of "biotechnology." The focus of the event is on these relationships in research rather than treatment.

Why did we hold this event?

In setting up BRC/Us, the National Institute for Health Research (NIHR-the part of the Department of Health that funds BRC/Us) identified links with industry as a central aim. A commitment to such joint working between BRC/Us and industry is there – our patient and public involvement (PPI) working group, Patients Active in Research (PAIR) want to identify how best to take this forward in ways that work for patients.

To our knowledge, despite industry relationships lying at the heart of much activity within BRC/Us nationally, the integration of this with PPI has not been the focus of other work. We thus see this event as the start of an important conversation and set of actions.

What did we do?

We invited all members of PAIR – patients and professionals - alongside BRC/U and other staff to hear from and debate with :

Simon Denegri - NIHR National Director for Public Participation and Engagement in Research and Chair of INVOLVE
Nick Scott-Ram - Director of Commercial Development at Oxford Academic Health Science Network
Alex Prior - Business Development Manager, Oxford BRC

The event was co-chaired by Sophie Petit-Zeman, BRC/U Director of Patient Involvement and Fraser Old, a patient member of PAIR, and was informed by patients' views of links with industry from the Healthtalkonline module on clinical trials (see Reading, below).

The event considered such issues as:

- What are the relationships between the BRC/U/Trust and industry?
- Is the nation's health and well-being agenda compatible with the wealth agenda?
- Does the relationship between the BRC/U/Trust and industry affect patients' desire to work with us?
- Do special issues arise where industry wants to pursue possible joint work in confidence?
- Where next?

The following section summarises the three presentations and notes key issues from the discussion. Where points raised were not primarily related to research work with industry but are important to PPI more generally they are noted in the appendix.

Presentations

Simon Denegri

Summary: The national agenda around linking patients and industry is "tense and fraught" yet there is strong evidence that PPI can help industry. Leadership is needed to move this forward and NIHR wants patients to drive this.

Detail: What's PPI got to do with it? "Absolutely everything" - we need to "set the bar high" in our relationships with industry.

The Association of the British Pharmaceutical Industry discussion paper, Securing a future for innovative medicines 2014 (see Reading, below) shows 80% trials do not meet recruitment targets. Other research shows overwhelming patient/public "push" to be involved in research governance, and that integrating PPI in trial design increases recruitment success (Ennis & Wykes, 2013, see Reading, below).

Academic Health Science Networks have a clear PPI mission and working with them to move this agenda forward will be key.

Arguments around confidentiality need to be strongly challenged. Is the need for it always real? Meetings where industry is making plans with organisations may need "closed" sessions, but building relationships by focusing on creating "open" sessions with patients will build confidence and reap rewards.

Learn from good examples such as links made between the National Cancer Research Institute Consumer Liaison Group (CLG) and Astra Zeneca (to be presented at INVOLVE 2014) where the CLG "standing PPI reference panel" has already completed several pieces of work and is helping trials recruit to time and target.

Alex Prior

Summary: drug/biotech companies want relationships with organisations like the BRC/U in order to:

- better understand disease;
- access patients for trials;
- access patient samples and equipment for research.

Companies will not do work unless it has the potential to be commercially important, but what typically unites researchers and the industry partner is the aim to provide better treatments for patients. Therefore understanding patients' needs is key.

Detail: Hundreds of companies work with Oxford University/Trust (and hence the BRC/U); industry money accounts for about 10% total funding into the medical sciences division.

Many different partnership models are used:

- collaborations/partnerships or larger scale "strategic alliances" where a large company wants to work in an academic or NHS setting;
- contract research (where industry pays for work to be done on its behalf);
- consultancy work/work around licensing.

The Business Development team "matchmakes" industry and researchers/clinicians to initiate research collaborations where there is mutual benefit from working together (e.g. complementary expertise). The team has also initiated a programme to connect technology companies with 'end users' of their products, including clinical staff and patients. Such work is not usually aimed at "getting ideas" from patients/staff, but "market research," helping industry position its work in light of user views.

Contract terms can be very complex to agree with industry partners, and if patients have had input to providing research ideas there may be further issues around sharing "intellectual property."

"Unmet need" must be understood from both clinicians and patients to help industry do its best work.

Money does not always change hands, or not in "direct" ways: agreement may for example be to allow industry access to patients with industry donating to a research fund, or with a company making their technology/equipment available for research at no cost to the researchers (i.e. contributions in kind).

There is scope and keenness to work more closely with patients to openly discuss the nature and purpose of BRC/U relationships with industry.

Nick Scott-Ram

Summary: We need to speed up "adoption of innovation" in the NHS, while ensuring the wealth creation agenda aligns with patient benefit. New models of interaction between industry and patients are emerging, and need to move industry from its silo mentality. The Association of the British Pharmaceutical Industry (ABPI) code of practice may be a barrier to this and is under revision. Links with industry are not only about drugs and devices: data-sharing is a crucial issue.

Detail: The NHS is very concerned with value for money, seen in discussions about pricing/reimbursement.

New partnership opportunities are emerging:

- genomics – the science of tailoring medicine to individuals;
- use of patient data;
- links with patient groups;
- links with food and other consumer groups

All of the above may impact on the nature of relationships between patients and industry.

Data-sharing is a crucial issue which needs to be developed with patients: industry needs and wants more access. What will patients allow? Should industry pay for access?

New models of treatment such as the Early Access to Medicines Scheme (which allows some drugs for serious illness to be given before they are fully tested in large scale clinical trials and thus have limited data about how effective and safe they are) highlight new ways patients and professionals can work together to make decisions.

General discussion - Key points

Profit

Industry making a profit when developing treatments is "OK" – it is acknowledged and accepted that making money is a main reason for the existence of industry

Alongside profit motive, industry states that development costs need to be recouped: for example only 5% of cancer drugs that pass stage 1 & 2 trials go on to stage 3

Trust & confidentiality

There is mistrust among patients about industry, especially the "big players" - large drug companies. Greater openness in the way they work and PPI in this would help

If agreement is made for example to allow industry access to patients, and industry in turn donates to a research fund, do patients know that this is the agreement?

If commercial confidentiality is raised as a barrier to involving patients in discussion with industry, this needs to be challenged and, if necessary, compromise

reached. It should never mean patients are excluded from the discussion from start to finish.

Priority-setting

Is money being spent on research as well as it could be if patients were more closely involved in what industry decides to do and how it does it?

Oxford and others are using methods like that of the James Lind Alliance to set research priorities that matter to patients – are we working as well as possible to ensure industry hears about (and ideally supports) research identified this way?

Other approaches such as "hackathons"/"hack days" where many different players in a given process (e.g. industry, patients and health professionals) gather to agree a project may be very valuable.

Groups vs individuals

To what extent can PPI on a large scale help inform work with industry and what must be individual? For example, initiatives such as the Early Access to Medicines Scheme might lead to different decisions made by "PPI" versus what a given patient might decide. Similarly, do views of patients and a more general "public" differ?

Where next?

We heard about the ABPI Code of Practice that sets out how industry should work with patient groups (the focus of the Code is not exclusively research relationships) and we also heard that this can obstruct constructive relationships because industry is scared of contravening the code, or, at least at times, may use this as a reason for shirking from engagement with patients/patient groups.

We also heard about the many forces that drive close relationships between Oxford BRC/U and industry, and about the current lack of – and desire for - PPI in the development and implementation of these.

We thus propose below an agenda for action which sets ideals and targets for Oxford.

As with much BRC/U PPI work this will also act as best practice for the Trust as a whole. We also hope it may act as a starting point – an informal code of practice - for other similar organisations wanting to bridge the PPI/industry divide and hope to work with NOCRI – the NIHR Office for Clinical Research Infrastructure (NOCRI) – to promote it. The remit of NOCRI is *"NOCRI brings simplicity to the clinical research environment in the UK, and promotes opportunities for partnership and collaboration with NIHR infrastructure. For industry, we offer a fast, easy and consistent single point of entry to world-leading investigators in world-class facilities, with access to patients across the NHS. This ranges from signposting companies to the appropriate parts of the NIHR, making introductions, supporting the set-up of collaborations between industry and academic/NHS partners and ensuring these relationships are managed effectively."*

Inevitably in a discussion of this sort, issues were raised not only about research but about wider interactions between industry and patients (for example in

treatment). As the focus here is on developing PPI with industry for research, broader messages are summarised in the appendix.

Oxford BRC/U: PPI and Industry – Action Points

Set up a subgroup of patients from PAIR to work with the BRC/U Business Development team to:

- fully understand the points at which patients currently provide input into joint projects between industry and the BRC & BRU
- identify gaps where patients want greater involvement, at strategic and/or individual project levels
- identify whether it is desirable/possible to set up a "ledger" where basic details of all joint industry BRC/U projects are publically available
- assess feasibility and resource implications (for the BRC/U, researchers and patients alike), alongside confidentiality implications, to compile a mutually agreed action plan
- consider how best to work on other issues of mutual concern as these arise, such as data-sharing with industry
- Work with the above team and our Oxford Academic Health Science Network partners to ensure industry knows about research priorities identified through JLA priority setting partnerships; aspire to research into at least one JLA priority funded by industry within a year
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Work with the NIHR Office for Clinical Research Infrastructure, the Oxford Academic Health Science Network, Association of the British Pharmaceutical Industry and BRC/U networks to disseminate our action plans more widely

Review the plan annually and adapt it where necessary

Appendix - Issues of concern not related to the core topic

Lack of feedback from research studies – PPI participants often need better feedback than they get

Can GPs be a port of call about research? Patients have a right under the NHS Constitution to be involved in research but do GPs have time or knowledge to discuss this with them?

Clinical Commissioning Groups that include GP practices have a statutory obligation to promote research and are paid to do so

The Electronic Patient Record may have value in connecting outcome data with GPs and making it available at consultation

What sort of PPI contributes to patient trust in research? The Health Research Authority has some information on this and there is anecdotal evidence for the value of information transferred from patients to patients/peer-to-peer recruitment into research

Is money being spent as well as possible on research – i.e. why are there so many drug trials when what patients say they want to know more about other treatments? We are addressing this through e.g. our JLA work (see Lancet series – increasing value, reducing waste 2014 – see Reading)

Reading

Healthtalkonline module about clinical trials: http://healthtalkonline.org/peoples-experiences/medical-research/clinical-trials/funding-and-publishing-trials.

ABPI discussion paper "Securing a future for innovative medicines: a discussion paper"
(2014)

Ennis L, Wykes T. Impact of patient involvement in mental health research: longitudinal study. British Journal Psychiatry, 2013. Nov;203(5):381-6. doi: 10.1192/bjp.bp.112.119818. Epub 2013 Sep 12.

Lancet series – Increasing value, reducing waste (2014):
http://www.thelancet.com/series/research

A good read: http://www.pharmafile.com/news/186931/we-can-t-go-patients-must-come-first

ENDS