



The James Lind Alliance

James Lind Alliance (JLA)
Association of Medical Research Charities (AMRC)
think-tank, October 9th 2009

Does industry listen to patients and if so why?

This “Chatham House rules” meeting, supported by National Voices, drew together 30 invited delegates (AMRC & JLA secretariat/steering group members; staff from AMRC charities with strong patient group links; relevant external stakeholders) to debate the above question.

The guiding principle for the meeting was: “notwithstanding the tensions that can exist between the two sectors, there is massive potential for mutual benefit if charities and/or patient groups and industry work together.” The event thus asked how listening to and working with patients can become a vital part of the business model for the pharmaceutical industry in developing new treatments and therapies.

While AMRC has a track-record of work on relationships between industry and charities, and on patient involvement, the JLA has not to date worked with industry but is interested in the extent to which research projects indicated by patient/clinician priority-setting partnerships, could be appropriately supported by industry.

Several themes emerged, summarised here, followed by ideas for and current actions on further work.

Key messages

A “new breed” of pharma CEOs with philanthropic motives is seen to be opening up ways of joint working, and we need to ascertain how patients want to capitalise on this. Charities and industry would welcome case-studies illustrating how they can jointly set a research agenda or involve patients in devising and planning trials.

- Industry recognises the need to work with patients to change an increasingly unsustainable business model - this includes: identifying research areas - even 10-20yrs ahead; helping design trials patients want to join; providing adverse event data which may be more useful than that gathered from clinicians
- Scientists hearing from patients/carers about the impact of illness enhances their ability to devise better treatments
- The chain from R&D to commercialisation is complex. When is best to incorporate patient/clinician important outcome measures (PCIOMS)? If considered at all, this

tends to be at phase 3, yet doing so at phase 1/2 may very valuable, as this is when the science/research community may be most "isolated" from patients

- How and who can best identify what PCIOMS are?
- Can PCIOMS become integral to regulatory approval?
- Can patient input be used to help compliance, benefitting both industry and patients?

Trust and transparency

Patients and their representative groups remain wary about industry motives, especially:

- whether industry is open about trials underway
- whether trials are always published (see below)
- where industry money comes from/goes to

Despite journal editors' requirement for trial registration prospectively, non-publication remains a problem and industry-sponsored trials are less likely to be published than others.

The GSK Clinical Study Register (CSR) reflects that company's emphasis on all results being public, and published where possible. The CSR includes names of principle investigators participating in new trials, meta-analyses, observational studies and details of terminated programmes. When studies remain unpublished, the CSR provides context and interpretation.

Further work

AMRC and the JLA are keen to take several strands of the above forward, with individual drug companies and/or by engaging with the ABPI.

For AMRC, this includes gathering and publicising case-studies of charities and industry working together in mutually acceptable/beneficial ways, for JLA, to decide whether the drug industry could be involved in funding PSP outcomes and, in their apparent quest to know more about what patients want, be made more aware of the key JLA tool, UK DUETs. Joint work is underway to see whether PCIOMS can be enshrined in the drug development and approval process, and a wider "gauntlet" was thrown down over whether AMRC/JLA might work with other relevant stakeholders to undertake work promoting addressing the challenge in Testing Treatments (<http://www.jameslindlibrary.org/testing-treatments.html>) - that the three criteria under which patients should agree to participate in a trial are: (i) That the study protocol has been registered publicly; (ii) that the protocol refers to the systematic reviews of existing evidence showing that the trial is justified; and (iii) that you receive a written assurance that the full study results will be published, and sent to all participants who indicate that they wish to receive them.