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WORKSHOP REPORT

EFGCP Multi-Stakeholder Workshop on

Communicating Clinical Trial Results to Meet Public Needs - A Meaningful Future for Lay Summaries -

29 May 2015 – Thon Hotel EU, Brussels, Belgium

Acknowledgement

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EFGCP Multi-Stakeholder Workshop on

Communicating Clinical Trial Results to Meet Public Needs

-A Meaningful Future for Lay Summaries-

29 May 2015 – Brussels, Belgium

WORKSHOP PARTNERS

EFGCP INSTITUTIONAL MEMBERS

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Communicating Clinical Trial results to meet public needs: a meaningful future for lay summaries.

Executive summary

The concept of the lay summary is contained in the 2014 clinical trials regulation which seeks to improve the transparency of clinical trials results. Researchers will have 12 months from the end of a trial (six months for a paediatric trial) - regardless of the outcome - in which to publish the trial results and to accompany them with a summary which should be 'understandable to a lay person'. These have to be made available on an EU database, which is being established by the European Medicines Agency.

Annex V of the legislation sets out a list of ten specifications for the lay summary, but does not clarify how much detail is needed, and how each element will meet the needs of the public and patients.
The UK has volunteered to take the lead in drawing up further EU guidance to meet the legislative requirements. This is being coordinated by the Health Research Agency, which invited stakeholders to join a task force. The timetable to draw up the framework is tight, with draft guidance to be published by November 2015.

Clinical trial results are currently not routinely reported back to patients, although patients and the wider public want information: providing it is key to improving the public understanding of clinical research and increasing trust in clinical trials. Public confidence in the trials process is vital to ensure a thriving research environment that will bring innovations to patients.

The EFGCP organised a workshop to bring stakeholders together to understand the expectations of patients, clinical researchers and sponsors and to share experiences of best practice. There is an opportunity to shape the forthcoming EU guidance to produce useful summaries which will both involve and educate the public.

There was a high level of enthusiasm for cooperation, and a clear intent to honour both the letter and the spirit of the legislation. Debate centred on the best means to achieve this, and to reconcile the different perspectives of stakeholders. A number of initiatives are underway both in Europe and the US to work out principles and practices.
Concern was voiced that the provision of a lay summary should not simply be a tick-box exercise, dominated by lawyers to protect the sponsor. Guidance should not be delayed in the quest for perfection, but patient engagement had to be meaningful to achieve a useful outcome.

Discussion quickly broadened from the content of lay summaries to questions of how to include patients from the outset. It was argued that this would improve the quality of research and patient engagement, and cut waste from the clinical trials system through better focused research questions which were directed at patient needs.

Here are the main recommendations/ action points/ issues for discussion:

1. The UK - through the Health Research Authority - is taking the lead on drawing up guidance, building on a range of initiatives. Stakeholders are invited to join a task force.

2. The toolkit and guidance developed by the MRCT Center at Harvard forms a body of work that could be used as the basis for the EU system. Ongoing comment is welcome on the document. Speakers also highlighted a diverse range of initiatives: links are provided throughout the report.

3. Defining the lay summary.

There is an opportunity to define what is and is not wanted. All stakeholders at the workshop agreed that:

- There should be no mandatory translation into the 27 EU languages within the 12-month rule. One suggested starting point is to translate it into the local language(s) used in the country/region where the trial was conducted (as is the practice with consent forms
  The lay summary is not a document of legal liability. Legal aspects should be kept outside the lay summary.
- Summaries should be meaningful to patients. They should not be a tick-box exercise.
- Factual accuracy must not be lost through the process of simplification.
- A single lay summary per trial should be acceptable regardless of the country (or region) where the trial has been conducted. In the case of multi national or global clinical trials, it would be counterproductive and potentially confusing to have differing requirements across countries (or regions). This calls for a coordination of effort and global harmonisation.

4. Developing guidance.

Workshop participants were committed to the spirit and the letter of the legislation, but agreement is needed on issues such as:

- Who is the document for? The regulation explicitly mentions both the general public and patients, however, they may have different expectations Patients should be the main user audience.

Should it follow a defined template? Multiple options should be acceptable. Some flexibility should be permitted, to take account of initiatives that have already been implemented and have met with approval from research participants; or which are at an advanced stage of development with patient representatives and testing in the field; or where capacity may be in short supply e.g. for some academic researchers or SMEs; or where there are cultural differences. Others noted that a similar format across documents (templates) offers predictability, and that predictability increases comprehension.

Should the summary be dated to indicate that it has a 'shelf-life'.?(ie other research may follow).

5. Content of the lay summary.

- Is comment needed on risks / benefit of a new treatment. This analysis was beyond the scope of lay summary guidance so far developed (e.g. Harvard MRCT). Each summary could only report the evidence of the particular study it referred to.
  Negative findings and critical review of study limitations should be included to inform the public and to help manage patient expectations.

- Should there be links to a systematic review of the drug/treatment area? If so, who is going to write the lay summaries for these overview articles, which will be very important from a patient perspective. Patient organisations or academia may take a lead role in this respect.
- Should the summary provide a context to the clinical development procedure?

i.e. explain the length of process and that a medicine may not make it to market.

6. Patient involvement.

- Would it be realistic to have patients review every lay summary - would patient groups have the resources to enable this?
- Patients / patient groups should be involved in drawing up the guidance to ensure summaries are meaningful.
- There would have to be some means of monitoring standards.
- Patients wanted to be involved from the trial concept stage: this would drive up the quality of research and make it easier to produce a patient-friendly lay summary.

7. Meeting the timescales for delivery.

Speakers felt that it is possible to be timely and compliant, although it may be difficult for some SMEs and academics, from a purely resource perspective.

Preparation of the lay summary could be linked to preparation of the clinical study report; or to the abstract for an academic trial.

Where the end point of a trial is not clear cut, this information should be incorporated into the protocol so that it would be clear that a lay summary would not be available within 12 months.

8. Ethical review.

It was agreed that ethical reviews of lay summaries would not be feasible, but would create an unnecessary administrative burden.

9. EU Portal

Concerns were raised about the ease of use of the electronic interface for trial results and lay summaries. A glossary of terminology would be needed as an aid to the public.

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Introduction.

The EFGCP brought together experts at a workshop to discuss how best to implement the new EU Clinical Trials Regulation requirements to provide lay summaries to patients. The focus for discussion was the provision for a lay summary which will afford patients the opportunity to understand the value of their contribution to research, and to increase transparency of clinical trials.

Welcoming workshop delegates, Ingrid Klingmann said:
"We've always talked about lay summaries, but there's been no drive: now we have regulation". She said she was surprised to discover just how much thought had already gone into this area, but a lot of questions have to be answered "to make sure that what we implement in Europe makes sense both for patients and those asked to produce the summaries."

She said it would make sense for Europe to develop lay summary guidance in line with work done in the US, as the issues are the same on both sides of the Atlantic.
It was up to the 75 people in the room to decide what to do next: but creating a task force would make sense. Input from patient groups in the room, could help determine "what elements should be mandatory, what would be important and what would be nice to have."

Session 1: The big picture on return of results to patients

This session set the scene, and heard from three keynote speakers, representing the views of patients, industry and academia.

Patients' view:

Giulio Maria Corbelli, European Aids Treatment Group (EATG)
Researchers can communicate trial results on a one to one basis with participants, said Corbelli, but the legislation is focused on all the trial participants, and should also benefit the wider public.
The question is whether it will create a burden on the conduct of a trial, present a new opportunity for communication or be simply bureaucratic and useless.

The focus should be on involving patients from the very beginning of the research process, and at each stage providing information which can be understood by them.

Involving patient groups in the design and communication around clinical trials "is an absolute precondition" if meaningful information is to be given to trial participants and the general public. Not only would this raise awareness, but it would benefit scientific research.

Patients know what they need; they can help define the research question; review protocols to ensure they are more 'patient friendly'; and they should be involved in a patient panel to help the design of lay summaries. He cited the ladder of participation developed by Arnstein in 1969 (and variously redefined since) which would see the trial participant transformed from a research subject to a driving force for research.

The European Patient Forum has expressed concerns about the lack of framework to achieve the aims of the legislation. It notes inconsistencies between the information required in a trial summary (Annex IV of the regulation) and that required in a lay summary (Annex V). In particular, researchers are required to report on the "limitations of the study, how potential sources of bias and imprecision were addressed, and caveats" but this is not carried into Annex V. The information is equally important for lay readers and to help manage patient expectations.
http://www.eu-patient.eu/globalassets/policy/clinicaltrials/epf-lay-summary-position-march-2015.pdf

Industry view:

Solange Rohou, Astra Zeneca Director of Regulatory Affairs & Policy for Europe, and chair of the Clinical Development Committee at EFPIA.

The road to lay summaries began over ten years ago, when the European Medicines Agency introduced European Public Assessment Reports (EPARs) in 2003, which include a 'public friendly' Q&A summary.
Since then the industry has faced what she described as a tsunami of new European legislation culminating in the 2014 Clinical Trials Regulation. This has meant all functions, including clinical, regulatory affairs, pharmacovigilance and IT units working more closely together, as well as intensive work to gain company senior management 'buy in' to adapt company standards and processes. "We are all on a learning curve," she said. She stressed the industry is committed to sharing clinical trial results with patients, with the aim of enhancing research.

The new regulation would provide more consistency across and between member states: everyone would have to work together. Astra Zeneca has been working over the last few months on the issue of lay summaries, but has had to find a way to navigate the regulatory requirements and EFPIA/PhRMA principles.

Several patient-centric initiatives are already established through IMI (e.g. EUPATI) and newer ones coming along such as ADAPT SMART: this aims to get innovative medicines to patients more quickly, through approval in a specific sub-group of the population, before potential widening to a larger population. Recommendations are expected before the end of 2017.

Since 2010, EFPIA companies have been working on patient engagement. Some have worked with the Centre for Information and Study on Clinical Research Participation (CISCRP). This not-for-profit organisation informs the public and the media about clinical trial results.
Astra Zeneca has started providing patients involved in a clinical trial with an update on that trial and a 'Thank you' letter, which includes a summary of the trial results. Rohou said this had been well received by patients.

Within the EFPIA, a sub-group is working on a set of guiding principles for writing lay summaries. These are intended to guide industry sponsors so that they not only comply with EU regulations, but take account of the spirit of EFPIA-PhRMA principles of responsible clinical data sharing to provide a factual and neutral summary, which protects patient privacy, and is written in language easily understandable to the patient . The guidance is not a template, as it is recognised that flexibility is needed as sponsors navigate between the task of doing research and meeting regulatory requirements.

It is possible to comply with the new legislation in a timely manner, and for a lay summary to be clinically meaningful. One summary will address one single interventional trial, with the main conclusions emerging from the trial. The risks and benefits of a medicine should be based on the totality of the evidence, and not on the findings of a single clinical study. Work so far is not perfect, but sponsors should show their gratitude to study participants, and make sure that they are amongst the first to know the results of the trial they have taken part in. Rohou anticipates that within five years pharmaceutical and biotech companies, as well as academic sponsors, will routinely - and globally - provide results to patients.

Link to the EFPIA-PhRMA key principles of responsible clinical data sharing:
http://transparency.efpia.eu/uploads/Modules/Documents/data-sharing-prin-final.pdf
Eupati: http://www.patientsacademy.eu/index.php/en/
PROactive: http://www.proactivecopd.com/about/proactive-consortium/

Academic view:

Christoph Schuhmacher. Clinical Director of the European Clinical Research Infrastructure Network (ECRIN)

The lay summary is not straightforward. Schuhmacher pointed out that patients involved in a trial might have very different requirements for information, compared to the general public. Speaking from his perspective as a surgeon, he said patients will be highly biased in their approach to treatments. A diagnosis of gastric cancer transforms an individual member of the public into a patient.

The patient's assumptions and perception of risk will be guided by emotion. Risk perception will differ between doctor and patient, and a patient's evaluation of risk will change during the progress of disease.

Lay summaries sit in the context of a changing landscape of ever-expanding sources of information and financial pressures on health systems, where even experts struggle to interpret findings. He cited the example of a UK study which would have suggested cancer patients ask for chemotherapy after gastrointestinal surgery, to improve survival prospects. Comparisons with a later Japanese study revealed that chemotherapy only made a difference if surgery was poor, and as a result GI surgery was radically reorganised to improve patient survival rates. "We have to be very careful with the lay summary: we need much more data and interpretation," he said.
Patients would still need to talk to their doctor, especially if the time frame in which to make a decision about care is short.

The solution is to start with improving clinical trials: simple trials with very clear endpoints are needed. At the moment, the two approaches taken in clinical trials leave too much room for interpretation. ECRIN has a set of evaluation criteria for clinical trials with a rapid review process, to ensure clinical trial quality. The criteria include: rationale for the trial; the suitability of the trial design for the question being asked; and the clinical relevance of the trial for patients and for public health.
While great care was needed with the lay summary, there are also questions of whether summaries should carry an expiry date; and whether these should be updated and linked to new trial results within the EU portal.

www.ecrin.org

Discussion points:

For language translation purposes, the required timescales are tight, especially in the case of paediatric studies (6 months only). This could be manageable if it was anticipated from early on. It was possible that the first summary could be published in a comprehensible European language, and translations added outside the 12 month time frame.

Some concerns could be met if new studies are interpreted within the context of systematic reviews. ECRIN requires a systematic review before a trial proposal is considered.

Klingmann suggested that not only did the delegates need to think about the form a lay summary should take, but better mechanisms to filter that information - through doctors, patient organisations and the media. The patient should not be left with 14-15,000 new summaries each year. Schuhmacher argued that a lay summary should have the added rider: 'talk to your doctor''.

Session 2: Current initiatives

Laurie Myers Health Literacy Strategy Leader at Merck, and Co-chair of the Multi-regional Clinical Trials Centre (MRCT) at Harvard University.

Myers described the toolkit and guidance which has been developed by MRCT for returning trial results to study participants.
The group comprises academics, industry, regulators, patient advocates and patients. It is now talking to EU stakeholders, and has modified templates to meet the new EU regulations. Ongoing feedback is requested to enable MRCT to update the guidance further.

The toolkit comprises templates for results of phase 1, phase 2/3 trials, and where the trial has closed early. It's not intended to be prescriptive but to be used as a starting point or guide.
In an ideal world could you get to an individual report for an individual patient: "You need to have a conversation with the patient but that may mean losing consistency, whereas one-way communication gets you consistency but means you can't answer questions."

The toolkit includes guidance on what information to give and to collect at the last participant study visit, including monitoring adverse effects; participant preference for receiving summary study results and how they will access them; as well as whether a third party should receive the results.
In terms of writing a summary, it should be unbiased and not contain promotional messages; and should be reviewed by independent editor(s) and patient representative(s). The use of neutral language is especially important in the US where there is at present no FDA guidance on trial reporting before approvals (unlike the regulations which are coming into force in the EU).

The guidance places emphasis on both health literacy and numeracy. Risk benefit calculation for patients is tied to numeracy: patients need a context. Those facing cancer treatment need survival rate figures, but parents of a child with asthma don't need to know how many people get a flu vaccination - only that their child should have it, said Myers.

Health literacy is the ability to make sound health decisions. Even those with adequate literacy can struggle to understand health information. If you give participants a 30 page summary most will not read it, so information needs to be digestible, with helpful formatting (e.g. headlines to organise information). Links to websites can provide layers. Well-educated people would not be insulted, rather they would appreciate the clarity of the approach.

Myers provided links to the guidance and toolkit:
http://mrct.globalhealth.harvard.edu/file/377001 http://mrct.globalhealth.harvard.edu/file/377016
http://mrct.globalhealth.harvard.edu/file/377016

Discussion points:

Concern was raised about the difficulty of pharmaceutical companies talking directly to patients. One option could be to establish patient panels, independent of the sponsor, and to have someone from outside the sponsor's organisation who could answer patients' questions.

Patients need an overview of the steps of personal involvement in a clinical trial. This would enable patients to take responsibility for their own health care, and reinforce the value of their participation.

Amanda Hunn. Engagement & Policy Manager, Health Research Authority

The UK is taking the lead on formulating EU guidance on lay summaries. The HRA's own work demonstrates how keen public and patients are for information. Hunn explained draft guidance had to be drawn up by November 2015. The tight timeframe means the HRA will draw on existing work, for example the Harvard MRCT toolkit, outlined by Myers.

The HRA is now a statutory body which places a duty on it to promote transparency. This has been a question on applications for ethical approval since 2008. All phase I trials now have to be registered, although there are options for deferral, provided that companies commit to registration. There are future requirements for publication/ dissemination of results. The right level of transparency is key to European competitiveness.

In developing policy, the HRA worked with Sciencewise, which helps government and agencies to develop public dialogue where science and technology are involved. The HRA project involved in-depth three-hour workshops (with homework) - with the public and with patients/clinical trial participants. Groups re-convened a week later with the opportunity to question clinical researchers. The findings showed a strong consensus amongst patients (including children and young people), and the public, on publication and sharing of results.
'What struck us," said Hunn "was how little understanding the public had of the clinical trials process: they were shocked to find that people who might be unwell would take part in a trial; they wanted to know about regulation." The public were surprised that study results are not automatically made available.
Both patients and the public wanted the HRA to take a stronger line with researchers who did not publish study findings, arguing that it was a moral obligation. Patients wanted results made available in a public space, such as an accessible website.

The HRA has shown that studies with patient involvement get faster ethical approval.
It has issued guidance (April 2015) on information which should be given to patients towards the end of a study. This applies to all interventional studies excluding phase I studies of healthy volunteers, and should include details of what will happen to participants at the end of the study, how they can access study summary findings and how those who prefer not to see findings can opt out.

The guidance builds on existing work by INVOLVE/NIHR which require lay summaries of protocol at the start of a study; with the National Institute for Health Research insisting on plain English summaries for its funded research. This will be different from the summary at the end of a trial, but would provide a platform to build on.

The HRA will set up a task force. It had been suggested that the task force could work with the patient/consumer group at EMA, but the HRA also wants industry and other stakeholders' involvement. Hunn said she was concerned that where research sponsors are outside the UK, they may not understand the importance of the work being done there. She urged participants from this workshop to work with the HRA.

Discussion points:

Cultural differences have to be taken into account both in terms of patient involvement and in writing lay summaries. Confidence about taking part in clinical trials is low amongst ethnic minorities and low socio-economic groups.

Academic institutions might struggle with lay summaries, especially where there was a single investigator, who would now have the added burden of producing a lay summary.

Lay summaries could drive up research quality: primary end points should be declared up front, and these should be the most relevant for the patient- not for the company. Questions of multiple secondary end points and their interpretation demonstrated the need for good quality clinical trials. Patients should not be over-burdened with details of multiple endpoints.

Thought would have to be given to the language used to describe trials which produced negative results. A negative finding did not mean a trial had 'failed', but all limitations or negative findings needed to be reported so that patients did not over-estimate the trial result.

How prescriptive should lay summary guidance be, and how much flexibility should sponsors have? Some delegates felt language needed to be consistent, but that each company should be able to work out how best it would communicate. Others, that
Annex V was too general, and sponsors would benefit from more detailed instructions: there should not be room for every sponsor to interpret differently. Summary writers would need detailed instructions, so they were clear they were being transparent enough.

Making a lay summary accessible did not mean that methodological rigour should be abandoned. Simple language should not allow inaccuracies to creep in.

Brevity was encouraged in summary writing, but strict word counts were not. Myers said she would "focus on how many words you need to communicate, rather than have a set number of words".

Session 3: How to communicate successfully to the patient community

Khafil Moudachirou. peer educator, AIDES .

Moudachirou reported on patient engagement in the Ipergay study of Pre-exposure prophylaxis (PrEP) as an HIV prevention tool.
Aides is a member of the trial's scientific committee and is also involved with support and counseling for participants after enrollment in the trial, as well as focus groups.

Participants get access to information on sexual health and receive regular follow-ups from health professionals. Regular contact (e.g. through emails) is encouraged to make sure participants have a good understanding of the study, and periodically they are asked to complete online checks to make sure they are following protocols.

Important lessons had been learned about the time needed to build and implement the consultation process with participants, and confusion about objectives i.e. PrEP as a tool and PrEP as research, had to be overcome. But participants had been empowered and a new partnership built with the community of researchers.

David Leventhal, Director of Clinical Innovation, Pfizer

Pfizer has set up an online patient community - Pfizer link - enabling Pfizer to communicate with patients who have completed Pfizer studies. It came about because patients were asking for more information.

Its aim is to "influence public perception of clinical research and make sure participants feel it was worthwhile" '. Leventhal said he was surprised to find that 95% of patients did not find out about study results, nor did the Principle Investigators (PIs) who conducted the study for industry.

At their last study visit, patients are invited to opt-in to Pfizer link, and to opt in to get progressively more levels of information. A firewall between the patient community and Pfizer means the company cannot identify patients who sign up.
Enrolment has been encouraging at 30-40% of trial participants - over 4000 patients so far. Patients had been involved in the design of both Pfizer-link and lay summaries, which had helped make the business case.

Leventhal described the initiative as a huge operational change: “it was a big deal - we had to make sure everybody bought into it, including the PI”. Under the old model, a patient was gone for ever after the completion of a trial. Now patient reported outcomes will have tremendous value in driving Pfizer’s long term research.

Pfizer had adopted summaries into the return of clinical study reports. Summary writing begins after a draft clinical study report is approved, and it is validated at US 6-8th grade (11-14 years) reading level. Summaries are created in print, audio or on webpages depending on participants’ preferences. All Phase IIb and Phase III studies which started in 2014 will have a lay summary after the clinical study report is published.

Lay language summary translations are checked by clinical teams for accuracy. Pfizer has also piloted a native language Japanese lay summary, in an attempt to take account of cultural differences. In Japan the relationship between patient and PI is sacrosanct, which is a huge cultural difference from the US and EU. The company will post lay summaries wherever national requirements stipulate, so it will also deliver through the EU portal.

The company has also started a pilot on returning patient clinical trial data, using the ‘blue button’ system developed by the military, whereby patients can download their clinical data to share with doctors involved in their continuing care. This has been trialed in ten studies. The data is aged, because it can’t be provided to participants until after the study has closed and the database locked, but feedback is very positive.

https://www.pfizerlink.com
http://www.va.gov/BLUEBUTTON/Blue_Button_Getting_Started.asp

Panel discussion points:

Jan Geissler director of European Patients Academy on Therapeutic Innovation (EUPATI) welcomed a legal framework for work that has been done in the patient advocacy field for some years: “Now we see the diversity of how it can be implemented - not just implemented but implemented in such a way that patients actually benefit.”
But he cautioned that lay summaries should not be dominated by lawyers, as had discussions on informed consent.

He urged monitoring of uptake - how do we know if patients are actually reading the summaries?

Was patient involvement good for research procedure? Leventhal said getting feedback from patients is directly related to clinical trial quality and influences how we do a study.

Patients should be involved both at the design stage and in how results get communicated to a wider community, in order to attract participants to trials. Some may be waiting on the outcome of one trial, before deciding to participate in another. A lack of information had put patients off trial participation.

Rohou said that in her company, oncologists had raised questions about meeting lay summary submission deadlines. If the study does not have a ”Last patient/Last visit” end point, this should be detailed in the protocol so that it is clear that a summary will not be available within 12 months. Otherwise, the lay summary should be routinely written close to the drafting of the clinical study report.

Should summaries be updated as more information, such as survival rates, becomes available? Some results may not be clear cut, and time would be needed to digest the value of the intervention. Summaries could make clear that newer information could be available. But regular updating is not feasible resource-wise.

Patients would benefit from an explanation of the clinical development process: a timeline to put the trial in context of overall drug development.

Would patient organisations have the resources to review 14,000 summaries every year? Patient representatives were clear that a way had to be found to bring them into the process. Most probably when developing the guidance or testing templates.

The internet is giving patients access to a wealth of information e.g. 'patients like me' websites, therefore patients will, in practice, have the possibility of exchanging information and receiving relevant data prior to the publication of the lay summary. The question is how meaningful will the lay summary be if the data is far behind the "real-time reporting"?

Session 4: A vision for the lay summary

Sir Nick Partridge, Chair of the Clinical Priorities Advisory Group for NHS England

Partridge said he'd heard lots of different potential starting points and perceived barriers, but observed how quickly the debate had broadened from providing information at the end of a trial, to involving the public from the outset.

He was bemused that returning results to patients is still seen as problematic: 23 years ago, HIV patients who took part in the Concorde study on AZT were given the trial result on the same day as it was published. Moreover, they were told whether they had been taking AZT or a placebo.

He said his vision for lay summaries would be more ambitious than just returning results to patients.

The demand for information is there. Research by the Wellcome Trust in 2012, showed the scale of public interest in biomedical research, especially in areas such as drug and vaccine development: the public were impatient for information and wanted it to be available on websites, rather than having it reported through the media.

Lay summaries can improve science communication and cooperation between scientists.
Financial pressures on healthcare systems make this important: involving patients and asking meaningful questions can avoid costly wastage in medical research.

Getting access to health literature can help patients manage their health as 'informed patients'.

There were a lot of first steps: Harvard MRCT toolkit; Pfizer-link; NIHR plain English summary requirements; the INVOLVE campaign 'Make it Clear' . There were challenges to be overcome but "we know this is worth doing" he said.

Guidance and templates must not become just a tick box exercise. Everyone would need to raise their sights.
A vast investment is being made in life sciences research: how do we maximise the return?
Are there things we should just stop doing? Should we be asking fewer and better questions that patients and doctors know are the right ones?

http://eprints.whiterose.ac.uk/79609/1/Lay%20summaries%20LP%20final.pdf
http://www.invo.org.uk/resource-centre/plain-english-summaries/
http://www.access2understanding.org/guidance/

Panel discussion points:

Angelika Joos MSD Europe/ EFPIA said globally operating businesses want to create just one summary, 12 months after finishing a trial.
She cautioned against creating an 'administrative nightmare': it would be nearly impossible for ethics committees to review 14,000 summaries a year, nor was it realistic that patients could review every summary.

If good EU guidance is developed, with input from patients, it will be trustworthy and relevant.

Having a summary is one thing, but efforts should be directed at how to make it useful to the communities: what is meaningful information; what are the metrics to demonstrate its usefulness?

The question of providing risk/benefit analysis was raised at several points during the day's proceedings. One lay summary was only one part of the evidence: to have a risk benefit analysis would mean that all the evidence would have to be available.
Several delegates suggested that providing context might help readers: to explain that a clinical trial is a lengthy process, and that some medicines might not make it to market.

There was a huge opportunity for the EU clinical trials database to become a key reference point. It therefore has to be easy to use.

There was disagreement on imposing specific templates. Some delegates would prefer a general framework and principles with flexibility to transpose them into daily practice, (especially if they are already testing and/or using templates that have been developed with patient representatives). The quality of the content was the key.
Others felt a consistent format would be helpful to patients; templates allow for predictability, which increases comprehension. Templates could be built on. The most problematic element might be comments and outcomes fields (Annex V).

Quality control: how are sub-standard summaries weeded out?

The lay summary was ultimately about helping to demystify science: a more informed population would make it easier to do research.
Summaries might not be perfect, nor cater for all needs, but patient groups had a very important role to play in increasing health and scientific literacy, so people could make judgements for themselves.