

# Improving the Patient Experience of Clinical Trials

Eli Lilly & Company

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# Foreword

Clinical trials, undertaken with real patients, are a critical part of bringing a new medicine to life. Last year alone, more than 630,000 NHS patients in England took part in clinical research studies<sup>1</sup>, helping develop the medicines of tomorrow.

These studies are made possible by the people who agree to take part in them, allowing researchers to measure the effects of a potential new medicine and sharing how the medication affects them and the way they live their lives.

Here at Lilly, we're interested in more than just medicine. I believe that gaining a better understanding of people's experiences of clinical trials can help us improve their design and delivery, and ultimately lead to a better patient experience and better results. I want to ensure we understand the patient's experience of taking part in a clinical trial, and what we can do to improve their experience.

That's why we invited a number of respected speakers, patient groups and patient and carer representatives to join us for an open discussion. The purpose of the event was to hear ideas and opinions on how the pharmaceutical industry could improve people's experiences of clinical trials by better understanding the process from a patient's point of view. We want to make sure that patients' voices are heard when we design future trials.

This report presents the ideas and opinions shared on the day as a best practice guide that can be used by the pharmaceutical industry to improve a patient's experience of a clinical trial. We have already implemented some of the suggestions; others require further work or discussion. We must also take into account important legal or regulatory restrictions when considering how we can improve the process for patients. We have set out our progress so far, our ambitions and our limitations in a clear and transparent way.

Thank you wholeheartedly to all of the organisations and individuals who took part in this landmark event and have made this work possible.

**“ Here at Lilly,  
we're interested  
in more than  
just medicine. ”**

<sup>1</sup> [http://www.crncc.nihr.ac.uk/news/news\\_archive/figures-show-new-high-in-nhs-patients-participating-in-clinical-research](http://www.crncc.nihr.ac.uk/news/news_archive/figures-show-new-high-in-nhs-patients-participating-in-clinical-research)

# List of Attendees

The workshop brought together patients and patient representatives from the following organisations:



National Institute for Health Research (NIHR)  
Clinical Research Network



Cancer Research UK



LUPUS UK



Kidney Research UK



Diabetes UK



Alzheimer's Research UK



Muscular Dystrophy Campaign



Juvenile Diabetes Research Foundation



Parkinson's UK



Arthritis Care



Macmillan Cancer Support



Attention Deficit Disorder Information and Support Service (ADDISS)

## About Lilly

Lilly is a global healthcare leader that unites caring with discovery to make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. Lilly has been operating in the UK since 1934 and employs approximately 2,500 people throughout the country working in sales and marketing, research and development and bio-tech manufacturing.

# Overview

New medicines go through a lengthy and complex process of research and development, in which patients play a crucial role. Lilly recently hosted a workshop where patients and patient representatives from various organisations were asked to share their views and experiences of different stages of the clinical trial process and a 'patient's journey' throughout a clinical trial. The group offered valuable insights that are explored throughout this best practice manual. The report also includes a brief summary of the presentations offered throughout the day.

## Insights applicable to the whole 'patient journey':

### 1 Improve communication

People involved in clinical trials should receive regular and patient-friendly communication and information both throughout and after the end of the trial (including study results).

### 2 Improve 'customer care'

Every patient involved in a clinical trial should be made to feel valued and respected. Patients should be thanked personally by the trial staff and told how their involvement has contributed to a greater understanding of their condition, even if the trial was stopped prematurely.

### 3 Provide more opportunities to ask questions and to give and receive feedback

Trial staff should give patients the details of who to contact if they have any questions or concerns. They should also be given more opportunities to give and receive feedback to the trial staff and pharmaceutical company both during and after a trial.

### 4 Provide greater support

Taking part in a clinical trial has an emotional impact on patients and families. Trial staff and the pharmaceutical industry should think of innovative ways to offer support.

### 5 Improve logistics

Trial staff should address practical issues, such as transport, to limit the inconvenience on a patient whilst participating in a trial. Pharmaceutical companies should also consider the impact on patients when designing trial protocols.

## Insights specific to 'beginning of journey':

### 1 Increase public understanding of the value of clinical research

Many people do not understand the value of clinical research in developing innovative new medicines. Effort should be made to improve public understanding of the importance of clinical research.

### 2 Develop improved and innovative methods of patient recruitment

Better resources are needed to increase awareness of clinical trials. Many patients may not know where to find information and could miss the opportunity to take part in a trial.

## Insights specific to 'setting off':

### 1 Improve the informed consent materials supplied to patients

Whilst acknowledging the importance of these legal documents, pharmaceutical companies should develop 'user-friendly' patient information leaflets and informed consent forms. These can be used by trial staff to help patients understand the risks and potential benefits of participating in a particular trial.

### 2 Consider the impact on people who do not meet the trial criteria

Trial staff should deal sensitively with anyone who fails to meet the criteria for participating in a study. Screen failures should be thanked for their willingness to participate and be offered the opportunity to receive the study results.

## Insights specific to 'on the road':

### 1 Study protocols should take patient input into account

Pharmaceutical companies should involve patients when developing the design of the detailed plan of a study (called the protocol) to help answer questions and measure outcomes that are relevant to patients and carers.

### 2 Make data recording easier for patients

Where trials involve patient reported outcomes, pharmaceutical companies should develop 'user-friendly' tools for data recording.

## Insights specific to 'reaching destination':

### 1 Explain at the outset what will happen at the end of the trial

Patients should be informed that they may not be able to continue on the treatment when a trial comes to an end, if the medicine is still in development. Their doctor will advise the best alternative course of treatment.

### 2 Inform participants of trial outcomes

Patients who have been involved in a clinical trial should have the option to receive the overall results of the study and an overview of what the researchers have learnt.

### 3 Explain how to get involved in other aspects of clinical research

At the end of a study, patients should receive information about how to get involved in other aspects of clinical research (e.g. becoming a member of an ethics committee).

Throughout this report members of Lilly's medical team have responded to the above insights, setting out what Lilly is doing to improve the clinical trial process for a patient. We will actively share these learnings with the pharmaceutical industry through the Association of the British Pharmaceutical Industry (ABPI).

# The Pharmaceutical Company



## **Sue Forda**

*(Vice President, Global Regulatory Affairs International, Lilly) described the different stages in the development of a new medicine and the protections in place to ensure that patient safety is foremost at all times.*

The discovery and development of a new medicine is a long, complicated and costly process. Very few compounds successfully make it through the entire process to be approved for use in humans as a new medicine. Once a potential new medicine has been discovered and the clinical trial has been designed, regulatory and ethical approval must be obtained before the treatment can be administered to patients.

Once this is obtained, the patient recruitment process can then begin. Individuals who have signed a patient consent form will undergo a medical screening and those who are eligible to take part will be registered onto the trial.

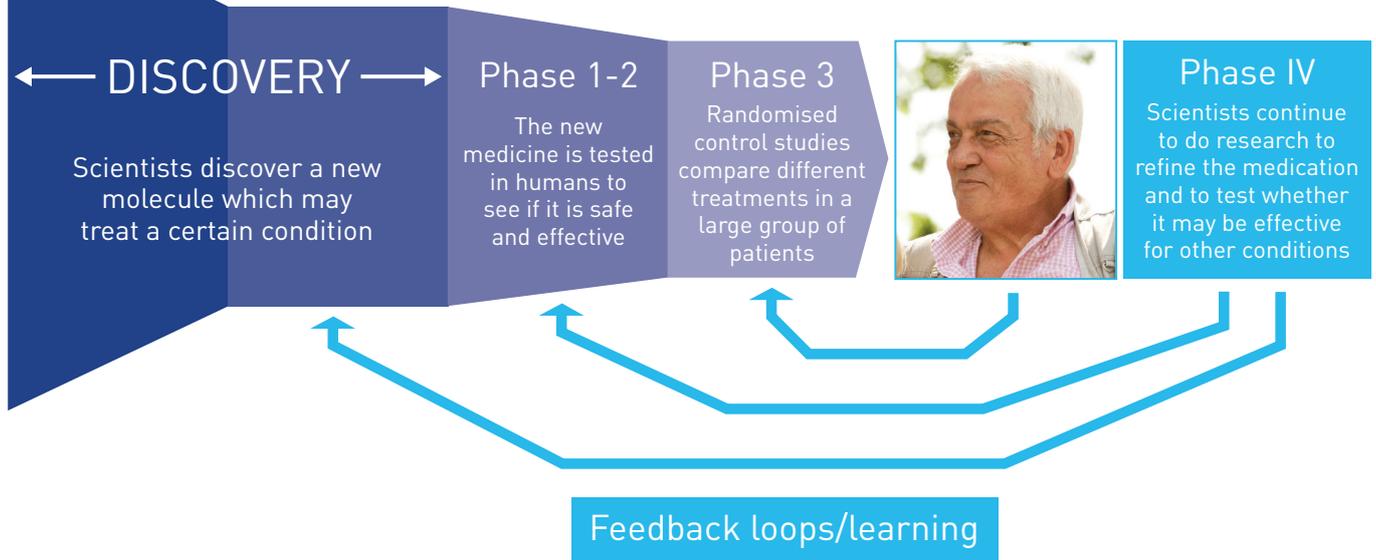
The clinical trial process is divided into three parts. In phase I trials, the new medicine is tested in humans for the first time and the main goal is to determine

whether it is safe and well tolerated. Phase II trials try to establish whether the new medicine is effective in patients with the disease or condition under investigation. At this stage, they also examine possible side-effects of the drug and try to determine the best dose. The results are used to design phase III trials, which are randomised controlled studies that compare different treatments in a large group of patients. Phase III trials aim to establish the safety and efficacy of a new medicine compared with existing treatments. If the study meets its goal, all the information generated throughout the trial is submitted in an application for marketing authorisation. Research continues after a new medicine has been approved and phase IV trials may be performed to get a better understanding of how well the medicine works in the long term or in specific subgroups of patients.

## Medicine Development in Numbers

- Average cost of developing a new medicine is approximately £1.15 billion.
- Average time from discovery to reaching a patient is 12 years.
- For every medicine that becomes a commercial success, around 25,000 chemical compounds will be tested. On average 25 of these will have gone into clinical trials. Only five will receive approval for marketing.<sup>2</sup>

## The Medicine Development Process



### Clinical Trial Data Transparency

Lilly supports responsible sharing of clinical study data and will continue to be an engaged partner in ongoing industry-wide movement toward this goal. Lilly believes that if a medicine has been approved for use anywhere globally, or if the results obtained could prove to be of significant medical importance, then all results should be published. Lilly was the first company to voluntarily establish an online database of its clinical study results when it launched Lillytrials.com in 2004.

### Recommended Reading

**'Understanding Clinical Trials'** – a booklet published by the National Institute for Health Research (<http://nihrcrn.org.uk/index.php/publications/understanding-clinical-trials-booklet.html>)

<sup>2</sup> Association of British Pharmaceutical Industry accessed at <http://www.abpi.org.uk/industry-info/new-medicines/Pages/default.aspx>

# The NHS

## **Derek Stewart**

*(Associate Director, National Institute for Health Research (NIHR) – Clinical Research Network) explained how public involvement in clinical research can have a positive impact on the drug discovery process. The NIHR was set up by the Department of Health to create the best possible research environment in the NHS. Facilitating patient engagement is a key to this.*

People can get actively involved in clinical research in a number of ways. They can take part in clinical trials as a trial participant. They can also help shape and improve research by expressing their views on how clinical research is designed, commissioned, managed and supported. This can help to make clinical research studies more 'patient friendly'.

Patients can also play a key role in communicating the value of research, for example speaking at workshops such as this, which help to raise public awareness and understanding of the clinical trial process.

**“ It is important to use your voice effectively. Lilly are to be congratulated for their enlightened move in giving people involved in clinical research the opportunity to have their voices heard. ”**

## **Find Out More**

### **Ways to get involved**

- INVOLVE ([www.invo.org.uk](http://www.invo.org.uk)) - a national advisory group that promotes and supports greater public involvement in NHS, public health and social care research.
- NIHR Clinical Research Network website ([www.crn.nihr.ac.uk](http://www.crn.nihr.ac.uk))
- Simon Denegri's blog ([www.simondenegri.com](http://www.simondenegri.com)) - a lay review about what is going on in the world of research.
- NHS choices website ([www.nhs.uk](http://www.nhs.uk))

# The Advocacy Group



## **Dr Fiona Reddington**

*(Head of Clinical and Population Research Funding, Cancer Research UK) described Cancer Research UK (CRUK)'s role in clinical trials and how it keeps people at the heart of research.*

## About CRUK

- **Largest fund-raising medical research charity in the world**
- **Largest funder of cancer research in Europe**
- **Supports 5 institutes and 8 clinical trial units and funds over 4000 researchers in the UK**
- **Funds research into all types of cancer and along the full cancer pathway from prevention and early diagnosis to treatment**

CRUK supports research across the entire clinical trial spectrum. Since 2005 more than 210,000 patients have participated in its clinical trials. CRUK also works in partnership with the pharmaceutical industry and other charities and organisations, both in the UK and internationally to drive clinical innovation.

Patient Engagement is a key part of CRUK's research strategy. Patient representatives hold integral positions

on the committees that decide what studies should be supported by the charity. Patient representatives also help to inform discussions on trial design at National Cancer Research Institute Clinical Study Group meetings. Additionally CRUK holds patient engagement days across the country to enable patients to get closer to research and understand how the organisations money is spent.

## Find Out More

CancerHelp ([www.cancerresearchuk.org/cancer-help](http://www.cancerresearchuk.org/cancer-help)) is a website that provides lay summaries of CRUK funded trials and reliable, easy to understand patient information about different types of cancer, the wider landscape of clinical trials and research, as well as information about cancer in general, coping with cancer, side-effects and symptoms.

# The Patient



## **Tom Haswell**

*talked about his experience of taking part in a clinical trial and his subsequent involvement in other aspects of research, highlighting the wider value of patients in research.*

In 1993, an x-ray taken during a medical examination showed that Tom had lung cancer. After undergoing further tests, he was told there was no effective treatment available and that he had just three to nine months to live. He was offered palliative radiotherapy. Three months later, he was asked whether he would like to take part in an early phase clinical trial.

**“ Certainly I will take part.  
What is a clinical trial? ”**

The trial was explained and the doctor cautioned that the treatment might not have any beneficial effect for Tom but could possibly benefit other people in the future.

**“ That in itself was enough for me.  
But I thought maybe, just maybe,  
there was something that would  
extend the short life expectancy I had  
been given and give me a bit more  
time with my family. ”**

After signing the informed consent forms and undergoing medical screening, Tom was accepted onto the trial. He received six four-week cycles of the trial drug. During the trial, he experienced a mix of emotions and said he developed a comradeship with his fellow participants during the days spent in hospital receiving chemotherapy.

**“ It was quite uplifting. People who  
were in the same situation as me were  
all looking out for each other.  
You picked up useful tips from each  
other as well. ”**

The treatment which Tom was given on the study was effective, his tumour shrunk and he survived cancer.

**“If I hadn’t been offered the chance to take part in a clinical trial, I wouldn’t be here today.”**

Tom wanted to use his experience to help others and sought opportunities to be involved in clinical research. As such, Tom is currently involved with the NIHR, National Cancer Research Institute, Scottish Cancer Research, and the Cancer Clinical Trials Unit Scotland (CACTUS). He is also a founding member of the first lung cancer patient support group. Tom attends ‘trial management group’ meetings, steering committees and ‘consumer research panel’ meetings with clinicians, researchers, oncologists, pharmacists, trial staff, and research nurses to discuss research proposals. His input helps to ensure that the patient voice is heard when designing clinical trials.

**“Simple skills, such as having an open mind, being able to listen and ask questions, and consider what will benefit patients, are all that is needed.”**

## Find Out More

**“It’s OK to ask”** - a campaign that aims to help spread the word that it’s OK for everyone to ask about clinical research (<http://www.crn.nihr.ac.uk/oktoask>).

# The Workshop

To help Lilly better understand clinical trials from a patient's perspective, over 20 patients and patient representatives took part in a series of workshop sessions. These were designed to generate discussion and capture the views of individuals who have been involved in clinical research.

The delegates were divided into groups and invited to share their thoughts and experiences at each stage of what we refer to as 'the patient journey'. The 'patient journey' describes the clinical trial process in four stages.

Each group had a facilitator to help stimulate discussion. The group's responses have been collated into general themes (i.e. those common to the whole clinical trial) and those specific to each stage of the 'patient journey'.

Lilly's Medical Team has since reflected on the group's feedback. They have responded to each point in turn. Their comments can be found on the following pages.

## 1. Beginning of the journey –

the time when a patient become aware of their diagnosis and treatment options, including the possibility of taking part in a clinical trial.

## 2. Setting off –

the period when the patient agree to take part in a trial and is screened to see if they are eligible.

## 3. On the road –

the time during the trial when a patient is undergoing treatment.

## 4. Reaching the destination –

the stage when the patient reaches the end of the trial and transitions back into the care of their doctor.

# General Themes

The group identified five general themes relevant to the entire 'patient journey'.

## 1 | Improve communication

People involved in clinical trials want to receive regular communication and information of a high quality. Many patients would like to be kept informed throughout a trial and to receive a summary of the results after the trial has been completed. Research teams should find improved and innovative ways of communicating regularly with patients.

People should be given the contact details of a person who they can reach out to, should they have any questions.

### Lilly Says...

“ In line with international guidelines, patients should be given the name of a person to contact in the informed consent documents that they receive. If this does not happen we recommend the patient reports this to the trial staff.

At Lilly, we ensure that all our informed consent information includes a named contact and encourage patients to get in touch with any questions they may have.

Following feedback from the workshops, we are now considering developing a patient newsletter. This would require ethics approval and it will take us some time to work out exactly how this would look and what level of information it would contain.

However we recognise that communication is extremely important and we are committed to improving this. ”

## 2 | Improve 'customer care'

Every patient involved in a clinical trial should be made to feel valued and respected. Patients should be thanked personally by the research team and told how their involvement has contributed to an improved understanding of their condition, even if the trial was stopped prematurely.

“ People want to feel valued for the work they are putting in and the time they are giving up. ”

### Lilly Says...

“ Lilly does send Thank You letters and following feedback from patients, the company is looking at ways to make patients feel more valued for their involvement in clinical trials, i.e. by providing a more personal and meaningful thank you. The UK is involved in this project and we look forward to expanding this initiative to all our UK trials.

Ethical approval is required to provide a Thank You card to patients and the trial staff need to be willing to distribute such materials. We also recognise that every patient is different and so any communication should include an 'opt-out' for those who wish to limit the amount of correspondence they receive in regards to the clinical trial. ”

### **3 | Provide more opportunities to ask questions and to give and receive feedback**

Members of the group said that they would like to receive individualised feedback during a trial. They would also like to be given the opportunity to give feedback to the trial staff about their experiences, especially about how their daily lives were affected by being on the trial.

**“ I would like to know that if I ask for feedback I will get it. ”**

**“ One way to make people feel valued is to ask them, to listen to the answers, and to do your absolute best to do something about it. ”**

Various methods for giving and receiving feedback could be used. Suggestions included a trial website with individualised passwords to enable patients to access their own results for example their monthly blood test results. Creation of a trial blog would also give patients a platform for providing feedback to the investigators. Patient feedback could also be gathered using questionnaires. All feedback methods should be flexible so that individuals can choose whether or not to use them.

### **4 | Provide greater support**

The group unanimously agreed that taking part in a clinical trial can have an emotional impact on patients, families and friends. This should be recognised. Some patients may be reluctant to participate in a trial because their family or friends are not supportive or because they do not want to add to the burden on their family, for example, taking them to appointments. Also, emotions may change during different stages of the patient journey.

**“ It can be quite hard on a person if their friends and family are not supportive of the decisions they are making. ”**

### **Lilly Says...**

**“ As a company we currently provide opportunities for trial staff to feedback any thoughts or comments about the trial. We recognise this may not always adequately cover issues from a patient’s point of view and we are developing a tool that will collect patient feedback after the first and last visit.**

In an ideal world we would like to facilitate a lot more opportunities for patients to feedback. However, we believe this is a good start. We will keep the group updated in regards to the development of this tool. ”

**“ People react in different ways; it is not a one size fits all. ”**

The group put forward a number of ideas about how patients could be better supported. By developing partnerships with patient groups and charities, pharmaceutical companies could ensure patients have greater support. Trial staff could set up a virtual patient forum for peer support during a trial or arrange for patients to have individualised support from someone who has previously taken part in a clinical trial. Carers would also benefit from this type of support. Pharmaceutical companies could fund charities and patient organisations to provide support to patients during a trial.

For trials that are stopped prematurely, patients should be contacted personally by trial staff with an explanation. Charities or patient organisations could also be informed such that they can provide support and reassurance, if they are contacted by an affected individual.

## Lilly Says...

“ Patient organisations and support groups are a source of expert information and can provide vital support. We currently work closely with a number of charities in regards to disease awareness programmes for example in Alzheimer’s disease and Diabetes. We will review our current partnerships and see where we can offer greater information on clinical trials.

In addition we have created a ‘Clinical Trial Toolkit’ which is available on our Lilly.co.uk website. This includes a series of resources, including this report along with a number of useful websites where patients and patient organisations can find out about clinical trials that are ongoing and the clinical trial process in general.

It is interesting that the group mentioned peer-to-peer networks, which can be a great way in which patients can support each other. However we have to be mindful that the sharing of experiences by trial participants can, in certain circumstances, jeopardise the integrity of the data in a clinical trial. ”

**“ Ongoing contact is really important. Companies should work with patient groups to keep the support going ”**

**“ The support group in the memory clinic was for both the patient and the carer and that was brilliant. Because you were in the support group you were more likely to take part in a trial. The most useful information I got was from the support group. ”**

## **5 | Improve logistics**

The group were keen for trial staff to address practical issues such as travel arrangements and the time of appointments to limit the inconvenience to the patient. Additionally it would be helpful if the trial staff

set out exactly what kind of tests a patient can expect and when, such that they can plan ahead accordingly. Trial staff could assist by helping to make travel arrangements, provide hotels for people travelling long distances, offer free parking at hospitals, and ensure patients do not have to walk long distances to consulting rooms. Trial visits could be at a time and place that is convenient for the patient.

**“ As a carer of someone with dementia, I felt under-supported and under-valued, especially in terms of the practical aspects of supporting the person getting to the trial. I would like to have had more help with travel in particular. ”**

**“ It is all very well having major centres for trials, but it is always good if patients can receive treatment locally. Some people will not take part in a trial because they can't face the travel. ”**

## Lilly Says...

“ We understand that taking part in a clinical trial can be stressful for both the patient and those around them. We are making efforts to limit the logistical impact on families taking part in our clinical trials.

It is the responsibility of the trial staff to consider practical elements such as travel and the time of appointments to make the experience as patient friendly as possible. The insights from the workshop, contained in this report, have been used to produce a resource to help educate trial staff such that they consider the patient-voice and cater for it accordingly.

At a global level we are also piloting a rechargeable card which can be pre-loaded with funds to help patients meet the costs of travel and hotel stays rather than reclaiming expenses after the event. We will monitor this pilot and should it be successful, look to implement a similar system in the UK. However when doing so, we would need to consider any tax issues and ensure that the system is in compliance with ethical and legal framework.

In regards to design of the trial, we are developing a 'trial simulation' where Lilly staff can interact with experts and patient advocates to try out protocols in a simulated manner prior to the trial beginning.

Days such as the Patient Day in December and this report are also crucial to gain patient insight and help us design more patient friendly clinical trials. ”

# Themes specific to:

## 1. Beginning of the journey –

the time when a patient become aware of their diagnosis and treatment options, including the possibility of taking part in a clinical trial.

### 1 | Increase public understanding of the value of clinical research

The group stressed the point that the general public do not understand the value of clinical research or the process of drug development. In addition, sometimes media coverage regarding the pharmaceutical industry,

specifically around transparency, can make some people reluctant to get involved in clinical trials.

The pharmaceutical industry should work in partnership with the NHS, patient organisations and charities to improve public understanding. Pharmaceutical companies should operate more transparently, with an emphasis on collaboration and sharing of information and resources.

### Lilly Says...

“ Lilly believes companies must act to earn the trust of the public they serve. To support this trust, Lilly supports responsible sharing of clinical study data and will continue to be an engaged partner in ongoing industry-wide movement toward this goal. Lilly was the first company to voluntarily establish an online database of its clinical study results when it launched Lillytrials.com in 2004.

We are also very keen to work in partnership and are currently working together with a number of charities and patient organisations to develop disease awareness campaigns. We will look at our current partnerships and see where we can offer greater information on clinical trials such that they can support patients accordingly.

In addition we have produced a ‘Clinical Trial Toolkit’, which will be available on our website. This comprises of a series of resources, including this report along with a number of useful websites where patients and patient organisations can find out about the clinical trial process and what clinical trials are currently ongoing.

We will be sharing this report with the ABPI such that the pharmaceutical industry, as a whole, can learn from the insights offered on the day. ”

## 2 | Develop improved and innovative methods of patient recruitment

**“ Patients need to know there is such a thing as a clinical trial. ”**

Many people miss the opportunity to take part in clinical research as they do not know where to find information regarding clinical trials. Their doctor may not be aware of trials which are ongoing and as such cannot provide the right kind of information.

**“ It is a ‘mission’ to find trial information. ”**

**“ How do you even hear about a trial? Can you rely on the clinician to recommend you for a trial? How are people being recruited? That is a really important issue. Who has that responsibility? ”**

Better resources are needed to increase levels of public awareness of clinical trials, and for recruiting patients into clinical trials. People should have easy access to information about clinical trials, presented in a way that is clear and simple to understand. Pharmaceutical companies and trial staff could develop improved and innovative ways to promote and disseminate information about clinical trials to increase patient awareness and recruitment.

### Lilly Says...

**“ Our Clinical Trial Toolkit includes links to [www.clinicaltrials.gov](http://www.clinicaltrials.gov) – an online registry of all trials which are currently taking place and recruiting for patients.**

Lilly has recently introduced an E-recruitment campaign using social media to recruit patients for a phase III studies in rheumatoid arthritis.

Patients will be approached to hear more about the trial via online health networks. Patients will then be directed to a study website where they will be invited to complete a pre-screening questionnaire. If a patient meets the pre-screening criteria, a local research site will contact the patient to discuss the study further.

This is the first time Lilly has used E-recruitment in the UK. If this is successful we will look to replicate the format for other trials. ”

# Themes specific to:

## 2. Setting off –

the period when the patient agree to take part in a trial and is screened to see if they are eligible.

### 1 | **Improve the informed consent materials supplied to patients**

Attendees reported that the informed consent materials are very complicated and difficult to understand, especially for patients who are feeling unwell. Some people felt that they were not given sufficient information to make a fully informed decision and parts of the patient information sheet, for example the long list of potential side-effects, were off-putting.

Patients should be given more time to read and absorb the information supplied. Trial staff should also be available to discuss the information in more depth, if required. The group also suggested that pharmaceutical

companies could work in partnership with patient groups to develop 'user-friendly' informed consent forms and information leaflets. Videos, diagrams and pictures may aid the process of obtaining informed consent. Trial staff should gauge the understanding of the person signing the consent form and provide further information or support if appropriate.

**“ Nothing is better than someone speaking to you. ”**

**“ Get patients involved in developing informed consent forms, patient information leaflets and the protocol. ”**

## Lilly Says...

“ Informed consent documents are important legal documents which are designed to protect both the patient and the organisation conducting the trial. However, we recognise that efforts could be made to make these documents patient-friendly and easier to understand.

Lilly has sought feedback from consumer groups and research networks to review patient information sheets and informed consent documents for selected UK studies. We believe this feedback has resulted in much improved patient materials. In addition, the Health Research Authority is updating and developing guidance on online information sheets and consent forms. Once this is available (publication expected in 2014) Lilly will utilise the guidance to improve the information given to patients taking part in our trials. ”

## 2 | Consider the impact on people who do not meet the trial criteria

The time and expense of attending screening assessments, as well as the emotional impact of being ‘tested’, can have a negative impact on a patient’s experience of a clinical trial.

Trial staff should manage a patient’s expectations ahead of the medical screening and support any patient who fails to meet the criteria for participating in the study. These individuals should be thanked for their willingness to participate and could be offered the opportunity to receive the study results.

## Lilly Says...

“ This is a very valuable insight. The insights from the workshop, contained in this report, have been used to produce a resource to help educate trial staff such that they can support patients more effectively. ”

# Themes specific to:

## 3. On the road –

the time during the trial when a patient is undergoing treatment.

### 1 | Study protocols should be more flexible and involve patients in their design

The group felt that pharmaceutical companies should involve patients in the design of a study such that it includes outcomes that are relevant to patients and carers.

Pharmaceutical companies could also make study protocols more flexible so that certain trial procedures could be individually tailored. For example, trial staff could treat or assess patients at home or in local hospitals, if appropriate.

**“ You should look more creatively at procurement solutions. You might want to bring the service to the patient. ”**

### Lilly Says...

“ We understand that patients would like the trial personalised around their unique situation. However we must be very careful to maintain a standardised environment to protect the integrity of the trial results.

As previously mentioned, at a global level, we are developing a ‘trial simulation’ where Lilly staff can interact with experts and patient advocates to test trial protocols before the trial starts.

In addition, we are currently partnering with CRUK and the Experimental Cancer Medicine Centre to develop clinical trials in oncology. We can learn a lot from partnering with organisations like CRUK who have a strong patient voice and understanding which can feed into protocol design. ”

## 2 | Make data recording easier for participants

Patients report that the constant monitoring and recording of data can be a difficult and onerous task, especially when they feel unwell. Pharmaceutical companies should develop 'user-friendly' tools for patients to capture trial data.

**“ You are dealing with constant monitoring and constant recording of values. The daily data capture is the bit that interferes with my life. ”**

**“ Even though the trial itself was interesting, the tools were so bad I considered possibly leaving the trial. ”**

### Lilly Says...

**“ This is a very interesting point. Where pharmaceutical companies are asking patients to record data, it makes sense that tools are made available to make this as easy as possible. We will look at our trials which include patient recorded outcomes and ways in which we can make the data recording easier whilst ensuring the security of this information. ”**

# Themes specific to:

## 4. Reaching the destination –

the stage when the patient reaches the end of the trial and transitions back into the care of their doctor.

### 1 | Explain at the outset what will happen at the end of the trial

Many patients want to know what will happen to them at the end of a trial. They may be concerned about going back onto another treatment or wonder if they can continue the trial medication if they appear to be benefiting from it.

Trial staff should inform patients before they begin a trial what will happen to them at the end of it, especially in regards to what ongoing treatment, if any, is available.

Patients may need support especially if there are no treatments available other than the medication under study. They also need to be prepared for a potential reduction in the levels of medical attention they receive once the study comes to an end, for example fewer clinic appointments that were part of the clinical trial design.

**“ It would be outrageous to be put back onto an ineffective treatment after the trial ”**

## Lilly Says...

“ We understand a patient’s frustrations that the medicine in development is not immediately available following the clinical trial. There is also a regulatory process that must be followed in order to gain ‘marketing authorisation’ before a drug can be brought to market, which can take up several years. This is an industry wide issue.

However, the MHRA are considering an early access scheme and further information can be found on their website [www.MHRA.gov.uk](http://www.MHRA.gov.uk) in addition, for certain conditions a compassionate use trial may be available at the end of the study. ”

## 2 | Inform participants of trial outcomes

Patients who have been involved in clinical trials generally want to know the results of the trial and what the pharmaceutical company has learnt. The trial staff should make sure this information reaches those patients who want it, in a format they can understand. Trial staff could ascertain whether a patient wants to receive a summary of the study findings at the outset and

### Lilly Says...

“Lilly posts summaries of all our clinical trials on [www.clinicaltrials.gov](http://www.clinicaltrials.gov). There are also discussions underway as to how companies will post results on EudraCT, The European Medicines Agencies Clinical Trial Database.

Internally we are currently exploring the best way to communicate results to patients. Pilots are underway at a global level to provide study results in a lay format which can be distributed to patients who opted in to receive such information.

Careful consideration and ethics approval may be required before this is rolled out in the UK. For example we have received feedback from certain trial staff, especially in oncology, that providing patients with lay summaries for negative studies may not always be appropriate. However we recognise that it is important to keep patients informed, if they so wish, and we are committed to making improvements in this area.”

who should be kept informed if the patient unfortunately dies during the trial. Post-trial information could be shared with patients or relatives by posting updates on a trial website.

“What was the point? I want to know what the benefits of the trial were at the end for me and others.”

“Don't be afraid to contact relatives if a trial participant dies.”

## 3 | Explain how to get involved in other aspects of clinical research

Once a trial has concluded, patients should be provided with information regarding how they can be involved in clinical research, other than as a trial participant. For example, the group would like information about how they could become a member of an ethics committee.

“I want to be involved.”

### Lilly Says...

“The Patient Day was an excellent way to introduce to the group the numerous ways in which patients can be involved in Clinical Trials – not just as participants.

Our Clinical Trial Toolkit include numerous resources signposting patients to organisations who seek patient representatives to help improve the way clinical research is undertaken in the UK.”

# Thank you

Lilly warmly thanks all the delegates for attending the workshop and for their willingness to share personal experiences and insights relevant to 'the patient's journey' through a clinical trial. This feedback will help Lilly focus on what matters to patients and implement changes to improve the patient experience of clinical trials.

We hope you find this report useful and our responses carefully considered. We will actively share this report with the Association of the British Pharmaceutical Industry to ensure that the industry as a whole can benefit from the insights offered by patients and patient representatives.

