REPORT INTO THE GENERAL PUBLIC’S ATTITUDES TOWARDS CLINICAL RESEARCH

Prepared for IPPOSI
by
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The US National Institute of Health define Clinical Research in three parts and as follows:

1. **Patient-oriented research.** Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies.

2. **Epidemiologic and behavioural studies,**

3. **Outcomes research and health services research.**
Executive Summary

Clinical Research is a term used to describe research which involves a patient and is organised by a healthcare professional. Clinical Research includes the testing of new medicines, medical devices or vaccines but can also be used to look at new combinations of existing treatments.

In addition to the testing of medicines, clinical research includes the comparison of blood and tissue samples of healthy people with those of sick people and the collection of medical data from patients with specific conditions which can be used to observe patients’ progress and responses to differing treatments.

A key factor in facilitating Ireland’s future economic prosperity is to establish the country as a globally competitive location for clinical research. Achieving this aim would deliver both improved healthcare benefits to Irish patients and serve to achieve the broader national strategic objectives of driving a knowledge based economy and delivering high net worth jobs for Ireland.

To successfully build a world-leading clinical research infrastructure one of the key imperatives is that the public understand and strongly support clinical research in Ireland. It was against this backdrop that IPPOSI sought to commission independent market research to ascertain public awareness and understanding of clinical research.

The research highlights that the public has a low level of understanding of the term “clinical research” over and above a general recognition that it relates to “medical research”.

In the main the public struggle to differentiate between the terms “clinical research” and “clinical trials” but a general perception emerged that clinical research was undertaken in the laboratory setting with clinical trials involving the testing of pharmaceutical drugs on people/patients.

Given the public’s narrow definition of clinical trials they tend to be associated with a high level of patient risk, in particular a concern about potentially harmful drug side effects. In all focus groups respondents reported anecdotal cases of patient deaths as a result of participation in clinical drug trials.

Given the public’s inability to differentiate between clinical research and clinical trials particularly with regard to patient participation, very few were comfortable with personally participating in such research. The fear of the unknown and the perceived risk of harmful side effects appear to be the key barriers to participating in clinical research/clinical trials. The majority of the public tend to view participation in clinical research/clinical trials as an option of last resort for very sick patients.

Although the public was negatively predisposed towards personally participating in clinical research/clinical trials due to the perceived risks, they remained very supportive of the contribution such research makes to society, namely:

- Medical advancements with regard to the understanding of diseases
- Improved patient care via monitoring and access to medicines
- Knock on benefits to an economy via employment

Respondents were of the view that clinical research remained critical to finding new cures for existing diseases and that it was imperative that such research continues to facilitate medical and scientific progress.

However a key finding of the research was how the presentation of basic information about the purpose of clinical research and the degrees of participation serve to encourage an attitudinal change amongst the public. In addition information regarding patient consent, confidentiality and the presence and role of an independent ethics committee served to reassure the public about the strict protocols employed.

In particular following the presentation of factual information about the subject of clinical research a number of key findings emerged:

A notable attitudinal shift with regard to participation in clinical research

Respondents were universally more positive about the prospect of participating in clinical research. 70% of the general public reported that they “would be willing to donate blood to be used for clinical research” and 65% claimed they “would be willing to supply personal information to be used for clinical research if it is done in a confidential manner”.

In addition to the testing of medicines, clinical research includes the comparison of blood and tissue samples of healthy people with those of sick people and the collection of medical data from patients with specific conditions which can be used to observe patients’ progress and responses to differing treatments.
The rationale for respondents’ attitudinal change to participating in clinical research appears to be the result (in part) of an improved understanding of the different options to participate in clinical research. Although respondents remained uncomfortable with the prospect of partaking in a clinical drug trial, the provision of medical information, blood and tissue was deemed much less invasive and of low personal risk.

Another key factor which appears to have prompted the attitudinal change to participation was the information provided regarding the strict protocols and procedures clinical research/clinical trials employ. In particular the public were reassured by the information on patient consent, confidentiality and the role of the independent ethics committee.

A steadfast reluctance to participate in clinical drug trials

Although the factual information regarding patient consent, confidentiality and the role of the independent ethics committee served to reassure respondents somewhat about participating in clinical research few reported a willingness to engage in a clinical drug trial.

The key psychological barrier for the majority of respondents remains a reluctance to take what they perceive to be an unnecessary risk with their health by ingesting a drug with potentially harmful side effects.

A positive attitude to Ireland operating as a central hub for clinical research/clinical trials

In general respondents were very positive about the prospect of Ireland operating as a central hub in conducting clinical research and medical trials.

The key benefits of enhanced clinical research infrastructure articulated by respondents in the focus groups include:

- The creation of centres of excellence in medical expertise
- Improved quality of patient care
- Improved efficiency within the health system
- The knock on benefits to the economy via employment

Moreover the general public were of the view that “Ireland needs to be at the forefront of research, we should be out there telling people what we are doing not hiding it behind closed doors somewhere” (Male 55-65, BC1, Galway)

The research suggests therefore that a basic public information campaign about clinical research can address many of the current barriers to patient participation. Moreover it points to the need to educate the public about the opportunity to tap into the public’s readiness to participate and the positive latent support for conducting clinical research within Ireland.

1. Background & Objectives

1.1. Background

The Irish Platform for Patients’ Organisations, Science & Industry (IPPOSI) established in 2001 is a unique partnership of Patient Organisations, Science and Industry. IPPOSI’s central objective is to facilitate cooperation between stakeholders (patient organisations, clinicians, scientists, regulators, industry etc.) with a view to accelerating the development of therapies. IPPOSI’s vision is that state of the art innovations in health care are available to Irish patients at the earliest stages (source; IPPOSI website 2009).

A core component in enabling Ireland to achieve state of the art innovations in healthcare is to establish Ireland as a globally competitive location for clinical research. The issue of building the appropriate clinical research infrastructure in Ireland was the subject of a one day IPPOSI conference (13th May, Dublin Castle) at which more than 200 delegates from patients’ organisations, industry, science and public policy met to address the key question “What are the major deficits still to be faced and how are we going to tackle them?” The event and subsequent IPPOSI report identified 5 key recommendations to facilitate improved building blocks for clinical research namely:

- Standardise Ireland’s system of Ethical Review Committees
- Create formal career structures for health professionals interested in research
- Integrate internationally accredited training in good clinical practice into medical and nursing education
- Introduce practical and standard indemnity arrangements for clinical trials
- Make research a core value in healthcare
- Appoint a clinical research “supremo” in the Department of Health and Children (eg Sally Davies,
UK) with the power to create and deliver a research strategy for health in Ireland

In addition to the above recommendations, the May event also identified the critical issue of improving patient/public recruitment for clinical research.

In particular the issue of patient/public awareness and understanding/ misunderstanding of clinical research was identified and the importance of education and information to inform the public of the opportunity to participate in clinical research and clinical trials.

It was against this backdrop that IPPOSI sought to commission independent market research to ascertain public awareness and understanding of clinical research. In particular the research sought to answer a number of key questions namely:

- What is the general public’s level of awareness and understanding of clinical research?
- How does the Irish public view clinical research?
- Does the public share any common positive or negative perceptions of clinical research and/or clinical trials?
- How does the general public feel about the prospect of participating in clinical research and/or clinical trials?

The broad aim of the research was to explore the Irish public’s perceptions of clinical research and in particular the public’s attitude towards Ireland operating as a hub for ongoing clinical research and clinical trials. Furthermore the research also sought to deliver an objective benchmark of the general public’s awareness and understanding of clinical research and/or clinical trials and their positive and negative predisposition towards same.

More specifically the research sought to address both qualitative and quantitative objectives accordingly:

1.2. Qualitative specific objectives:
- To explore the general public’s understanding of clinical research and/or clinical trials
- To ascertain the public’s attitudes to the practice of clinical research and/or clinical trials
  - Immediate associations
  - Positive v negative predispositions
  - Rational and emotional concerns regarding participation

1.3. Quantitative specific objectives
- To explore public perceptions of the potential benefits v drawbacks of participation in clinical research and/or clinical trials
- To explore public reaction to the prospect of Ireland operating as a hub for clinical research

2. Approach & Methodology

2.1. A two staged methodology

Given both the exploratory and quantitative objectives of the research, a two staged methodological approach was employed for the study.

Stage 1, the qualitative stage served as the exploratory phase where focus groups were used to tease out public attitudes towards clinical research and clinical trials respectively. This stage focused on probing the public’s understanding of the subject area, investigating attitudes towards clinical research and ascertaining respondents’ predisposition towards participating in clinical research and/or clinical trials.

Stage 2, served to provide an objective benchmark of public awareness and understanding of clinical research and clinical trials. Furthermore it delivers results that are representative of the Irish population and can in turn be tracked and revisited over time.

By combining a qualitative approach, focusing on an in depth exploration of the subject matter and the quantitative phase delivering a statistical measurement of public attitudes towards clinical research, this report delivers a comprehensive analysis of the Irish public’s awareness, understanding and perceptions of clinical research.
2.2. Qualitative research

Focus groups were selected as the qualitative methodology to conduct the research. Given that the subject matter (i.e. attitudes to clinical research) examined via the research was not of a particularly sensitive nature, focus groups enabled access to a larger number of respondents.

Furthermore the group dynamic and open discussion, facilitated constructive debate thus enabling any hidden motivations/concerns (on the part of respondents) to emerge regarding participation in clinical research and/or clinical trials.

A total of six focus groups were conducted in three separate locations (Dublin, Cork, and Galway) with each group comprising an equal mix of male and female respondents. Three of the six focus groups were drawn from the middle/higher socioeconomic strata (BC1) with the remainder comprising respondents from lower socioeconomic groups (C2D).

The six focus groups also spanned five specific age ranges (see Table 2.2.1) to examine if public attitudes towards clinical research varied with respondents’ age profile.

Table 2.2.1 Sample for focus groups

<table>
<thead>
<tr>
<th>Age</th>
<th>Gender</th>
<th>Social Class</th>
<th>Region</th>
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<tbody>
<tr>
<td>18-25</td>
<td>Mix</td>
<td>BC1</td>
<td>Dublin</td>
</tr>
<tr>
<td>25-34</td>
<td>Mix</td>
<td>C2D</td>
<td>Dublin</td>
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<tr>
<td>35-44</td>
<td>Mix</td>
<td>BC1</td>
<td>Cork</td>
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<tr>
<td>44-55</td>
<td>Mix</td>
<td>C2D</td>
<td>Cork</td>
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<tr>
<td>55-65</td>
<td>Mix</td>
<td>BC1</td>
<td>Galway</td>
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<tr>
<td>55-65</td>
<td>Mix</td>
<td>C2D</td>
<td>Galway</td>
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Each focus group followed a semi structured discussion outline (See Appendix) which addressed all of the objectives. As part of each group discussion, a range of carefully selected stimulus material was introduced at select stages throughout the conversation, to enable deeper exploration of key themes.

Following a spontaneous discussion on the subject of clinical research and clinical trials and the perceived merits and demerits of both, specific information was presented to each group via written text mounted on A3 show cards namely:

- An explanation of clinical research
- A range of scenarios (1-5) as to how the public/patients can participate in clinical research (ranging from the provision of personal medical information to active engagement in a clinical drug trial)
- The aims and objectives of clinical research
- How clinical research is set up
- Who can take part in clinical research
- How patient information is used
- What the risks and benefits of clinical trials are
- Why take part

The rationale for employing such pre-developed stimulus material is that it addressed the fact that many members of the public were likely to have a limited level of understanding of clinical research. Hence following the exhaustion of respondents spontaneous views of the subject area and the positive and negative predisposition towards same, respondents were presented with factual information about clinical research/trials to elicit further discussion and to explore if their attitudes changed towards the subject matter on the back of receiving “new information” on the topic.

All of the stimulus material was adapted from two key sources namely: “Understanding Clinical Trials”, UK Clinical Research collaboration, (www.ukcrc.org) and “Clinical Research, Your Participation Counts”, UCD Clinical Research Centre. All of information presented to respondents in the group discussion was sought to be factual and balanced (i.e. the information focused on the clinical research process and outlined both the potential benefits and risks of participation).

2.3. Quantitative research

Phase 2 of the project comprised a general public survey (omnibus) measuring public attitudes towards clinical research amongst 1000 members of the Irish public. The sample is representative of the wider general public hence it enables examination of the results by a range of demographic criteria (age cohort, region, gender etc.). The sample size is sufficient to deliver results which are accurate to (+- 3%) at the 95% confidence interval.

The quantitative phase provides a formal measurement of the general public’s awareness levels and understanding of clinical research and focused on the following themes:

- Awareness and understanding of clinical research
- Awareness and understanding of clinical/medical trials
• Reaction to a range of attitudinal statements regarding:
  - Conducting clinical research within Ireland
  - Willingness to participate in clinical research
  - The ethical process of conducting clinical trials

2.4 Structure of the report
The research findings can be broadly classified into the general public’s spontaneous and prompted views of clinical research/clinical trials. The spontaneous views represent the public’s attitudes to clinical research/trials garnered via the focus groups and via the omnibus survey before being presented with any factual information on the topic. In essence, these views both qualitative and quantitative represent the Irish public’s attitudes to the subject if they were questioned on the topic/theme today.

They are by definition a “truer” reflection of the current views of the Irish population regarding clinical research/clinical trials but they are also somewhat “less informed” because as the report will demonstrate the general public has only limited understanding of the subject matter.

The prompted views again, represent the attitudes of the general public acquired via the group discussions and the quantitative survey but following the presentation of factual information on the subject. Hence, they represent a “more informed view” because respondents were afforded the opportunity to reassess their attitudes to clinical research and/or clinical trials having assimilated factual information on the topic.

The information presented on the subject of clinical research/clinical trials was used, therefore, to examine if the public’s attitudes towards the subject matter changed following the receipt of new information on the theme.

The prompted views are therefore less “pure” than the spontaneous views regarding the public’s attitudes to the theme, however, they do emphasise how concise factual information about the subject can address some of the concerns and misconceptions the public has about clinical research and clinical trials.

Section 3 of the report outlines the general public’s spontaneous attitudes towards clinical research and clinical trials, perceived benefits and drawbacks and common misconceptions.

While section 4, in turn, details the public’s reaction to specific factual information about the subject and identifies respondents’ attitudinal change towards clinical research and the rationale for same.

The report concludes with section 5 which seeks to summarise the key learning points from the research and the implications for future communication with the general public going forward.

3. Spontaneous Views of Clinical Research/Clinical Trials

3.1 The Irish health service - A generally negative view
Each focus group commenced with a general preamble regarding the Irish health system. Respondents were asked to volunteer their views and experiences of the Health Service. The rationale for this approach was to gently introduce group attendees to the subject of clinical research; a topic about which they were likely to have only limited knowledge.

In addition, the discussion around the subject of the Irish health system set a context in which the topics of clinical research, clinical trials, and the issue of public participation in same could be explored.

In general, attitudes towards the Irish health service were somewhat negative. For the majority of respondents, this negative perception was not the result of direct experience with the service but via third party reportage, a friend/acquaintance and/or negative media coverage.

In all of the focus groups common concerns emerged, namely:

- Hygiene standards—MRSA
- Protracted waiting times in Accident and Emergency units
- Bed shortages for ill patients
- Ward closures

For respondents with direct experience of the health service, results were also somewhat mixed. A small minority reported a positive experience although they also
acknowledged the negative media attention given to the quality of care delivered in Irish hospitals.

3.2 Negative perceptions of the Irish health service and the impact for public attitudes to clinical research

A key impact of public negativity towards the Irish health system is that it appears to positively influence attitudes towards the prospect of Ireland becoming a future hub for clinical research. As Section 5 of the report outlines, many respondents positively endorsed the concept of Ireland operating as a centre for clinical research because they perceive it will lead to improvements in the delivery of health services.

3.3 General public’s understanding of the term “clinical research”

In general respondents acknowledged a limited understanding of the term “clinical research”. The majority tended to associate clinical research with investigations into “finding a cure for a disease.” Respondents in the focus groups also tended to spontaneously equate clinical research with “medical research.”

However very few understood the fact that clinical research related specifically to the broad effort of research employing people/patients or material from patients for clinical investigation. Furthermore very often attendees of the focus groups confused the term “clinical research” with that of a “clinical trial” thus equating clinical research with the testing of drugs/medicines on people.

“It’s getting people to take a drug for a specific length of time and obviously test them to see how it affects them for a specific period of time” (Female, 35-44 years, BC1, Cork)

“The testing of new drug products. Testing new drugs on people to see how they react and see if people still live” (Male, 44-55 years, C2D, Cork)

Furthermore respondents often confused clinical research with pre clinical trials where tests are conducted on animals.

“Is that where they test drugs on mice” (Female, 18-24 years, BC1, Dublin)

Some respondents also associated clinical research with the exploitation of students via financial incentives to participate in what they perceive to be “high risk” clinical drug trials.

“Is it something to do with students where they go and take a tablet and see what happens” (Male, 35-44 years, BC1, Cork)

“Students do it all the time, one guy died” (Male, 55-64 years C2D, Galway)

The low level of understanding and awareness of the term “clinical research” amongst the general public that emerged in the group discussions was consistent with the findings from the omnibus survey with the general public. In the survey less than half (49%) of the Irish public claimed to understand the term “clinical research”.

Q1. Do You Understand What is Meant by the term Clinical Research:

The level of understanding of clinical research appears to be lowest amongst younger members of the public with only 32% of 18-24 year olds claiming to understand the term. Comprehension of the term “clinical research” also appears lower amongst members of the public from lower socio economic groups (46%) and farmers (31%) than those from the higher socioeconomic strata (56%).
Of the respondents who claim to understand the term “clinical research” almost one in two equate the term with “medical research”. Approximately one in ten (11%) understand the term to mean “research with patients” and “scientific research” respectively. 8% of the population associate the term with “research that takes place in a laboratory setting” and 6% with “research into new drugs to combat disease”.

### 3.4 General public’s understanding of the term “clinical/medical trials”

In general the focus group respondents reported a higher level of awareness of the term “clinical/medical trials”. The vast majority of respondents reported an understanding (albeit limited) of the term perceiving it to be “the trying out of new drugs that aren’t on the market yet”.

The qualitative findings were also borne out in the general public survey with 73% of the population claiming to understand the term “clinical trial”. A lower proportion of men (69%) than women (76%) claim to be familiar with the term while those aged 18-24 years (56%) and C2DE respondents (68%) appear less familiar than respondents from higher socioeconomic groups (82%) and those aged above 25 years (75%).

When the public’s understanding of the term clinical/medical trials was examined in greater detail in the omnibus survey the following results emerged:

- 60% understood the term to mean “trials in which drugs/medicines are tested on humans”
- 17% understood the term to mean “trials where drugs/medicines are tested on animals”
- 16% understood the term to mean “trials where sick patients are given different forms of drugs/medicines”

Although the omnibus survey suggests that 60% of the Irish public understand the term “medical/clinical trials”, deeper exploration of the issue in the focus groups demonstrated otherwise. In fact respondents in the focus groups almost always associated medical trials with the testing of “new
drugs” and very often a misconception abounds that such trials are the first time these “new drugs” are tested on human subjects.

Given the public’s narrow definition/understanding of clinical trials they tend to be associated (perhaps incorrectly) with a high level of risk. Hence, in the main respondents tended to view clinical trials as a means by which pharmaceutical companies tested the side effects and efficacy of new drugs but by using human subjects and animals to do so.

“Is it a case where they pump the virus into your system and they introduce these drugs that are going to knock it out? Is that how it works?” (Male, 44-55 years, C2D, Cork)

“I want to know what might happen. I remember years ago of guys taking tablets and something happened to them” (Male 55-65 years, C2D, Galway)

A small minority of respondents in the focus groups (usually respondents from higher socioeconomic groups) were more knowledgeable about clinical trials and were able to draw a distinction between clinical trials for consumer products (such as toothpaste, energy drinks etc.) and those for pharmaceutical medicines.

Other respondents appeared to be well informed of specific trials operating at a local or regional level.

“There are several international studies that have originated here. They’re constantly looking for new ways to administer drugs. Some professors in Galway are involved in clinical trials in the US and they get funding from the States to bring it back here” (Male, 55-65 years, C2D, Galway)

3.5 Attitudes to clinical research/clinical trials

Although respondents tended to have a less clearly defined understanding of the term “clinical research” than they did of “clinical trials”, deeper exploration of the terms in the focus groups led to debate regarding the specific differences. A considerable number of respondents suggested that clinical research was undertaken in a laboratory setting with clinical trials involving the testing of drugs on people/patients.

“You would have your clinical research before your clinical trial. A clinical trial would involve “Joe Soap”. Clinical research could be a scientist with a mouse in the labs” (Female, 44-55 years, C2D, Cork)

“I would imagine that research would come first, afterwards trials to see how the product reacted on people” (Male, 25-34 years, BC1, Dublin)

“The research will come first; the trial will follow that… the research would be more on the lab side” (Female, 35-44 years, BC1, Cork)

However despite some recognition of perceived differences between clinical research and clinical trials, the majority of respondents were unaware as to how they could participate in clinical research over and above partaking in a clinical drug trial.

More specifically, very few respondents understood the fact that one can partake in clinical research via donating medical information, blood or tissue samples hence the prospect of engaging in clinical research was met with the same concern for personal safety as participating in a clinical trial.

A clear distinction emerged between respondents’ attitudes towards personally participating in clinical research/clinical trials and their attitudes towards the value and benefits of such research to society.

At a public level, respondents were very positive towards the concept of conducting clinical trials on the grounds that they delivered a wealth of societal benefits namely:

- Medical advancements/scientific breakthroughs with regard to the understanding of diseases
- A clustering of medical expertise and knowledge in a designated location
- Improved patient care via monitoring and access to medicines
- Knock on benefits to an economy via employment

“How are they going to find out how medicine works without a case study?” (Male, 35-44 years, BC1, Cork)

“The only way they'll find a cure is by testing. They've come up with so many vaccines for kids. So much good has come out of it. I would be more for it than against it” (Female, 25-34 years, BC1, Dublin)
“I’d be a 100% in favour. Going the distance. Anything that would help going forward is good.” (Galway, 55-65 years, C2D, Galway)

However despite the positive endorsement of clinical research/clinical trials at a public level the perceived risk to the participant was deemed to be too great to warrant personal involvement in such research. Hence the issue of personal participation in clinical research evoked a high level of caution and fear.

“I’d be very hesitant….. You’re going to have to sign pages of disclaimers saying, if this goes nuts, I’ve no leg to stand on. You’re going to have to sign something like that. You’re going to be paid a shed load of money but it could go bananas” (Male, 25-34 years, C2D, Dublin)

3.6 Ethical Concerns

In general respondents were informed that clinical research and medical trials are conducted by both pharmaceutical companies and academic institutions (i.e. universities). The issue of ethics emerged spontaneously in a number of groups, particularly concerning the commercial motives of pharmaceutical companies and the potential for this to negatively impact the process and outcome of medical trials.

“The amount of money that’s pumped into these things I’d say that ethics goes out the window. Its all for profit” (Male, 25-34 years, C2D, Dublin)

“Big companies can’t be impartial, if they’re doing trials they want that drug to succeed. On the one hand the companies might have a vested interest in massaging the trials so they come up with the right type of answers. Or suppressing information that makes them look bad” (Male, 55-65 years, BC1, Galway)

It appears that the ethical concerns about drug companies are based in part on the fact that some trials offer financial incentives to participants which raises public suspicion that something inappropriate is taking place. Furthermore the financial remuneration offered to participants in some clinical trials appears to raise concerns that pharmaceutical companies are targeting financially vulnerable sections of the community (i.e. students etc.)

“A daughter of a friend of mine regularly takes part….. She gets the price of her skiing holiday, but it means going in there for a week” (Female, 55-65 years, C2D, Galway)

“Sometimes you would see on the paper they are looking for people… An awful lot of students do it… They get paid fortunes depending on the symptoms of the drug… A lot of students do it” (Female, 44-55 years, C2D, Cork)

In addition it appears that the negative outcomes (i.e. unforeseen side effects, patient deaths etc.) of clinical trials are given a disproportionate weighting by the general public and are sometimes interpreted as evidence that the pharmaceutical industry is using patients in clinical trials as “guinea pigs”.

“There was one trial in England where a patient died. It can be high risk as well as low risk….Some students do it they have their blood checked every half hour. They stay there overnight and they get paid €600. There has to be huge risks involved” (Male, 44-55 years, C2D, Cork)

However in contrast some members of the public are more positive about the prospect of clinical research being conducted by pharmaceutical companies over medical or academic institutions on the grounds that they have the financial resources to ensure that best practice protocols and procedures are employed.

“I’d trust them [a company] because they have more money to throw at it” (Female, 18-25 years, BC1, Dublin)

“I would definitely want a private company doing it; I wouldn’t have anything to do with the Health Service” (Female, 44-55 years, C2D, Cork)

“I know there is a lot of research into cancers and they might be doing it in training hospitals as well. I would imagine that it would have to be extremely well controlled” (Male, 35-44 years, BC1, Cork)

3.7 Willingness to participate in clinical research/clinical trials

Given the inability of most respondents to differentiate
between clinical research and clinical trials particularly with regard to patient participation, very few were comfortable with engaging in such research.

In general respondents were of the view that participation in clinical research and clinical trials “were the same thing” both of which required the participant to try new medicines/drugs. The prospect of participation in such research therefore tended to evoke concerns over the safety of such medicines with palpable fear regarding the potential side effects from somewhat “unknown drugs”.

“There’s no way I would do a clinical trial even for money. I don’t even know how pills would end up on a supermarket shelf. I would feel a bit like a guinea pig” (Male, 55-66 years, C2D, Galway)

“I wouldn’t get involved. I wouldn’t like the risk. I think they are probably a good idea but personally I wouldn’t” (Female, 18-25 years, BC1, Dublin)

For many respondents it appears that the fear of the unknown and the perceived risk of side effects are the key barriers to participating in clinical research/clinical trials. Moreover given that the majority tend to have a limited understanding of clinical research/medical trials they struggle to understand the rationale for a person in good general health to participate in a trial.

The general maxim for the majority of respondents appears to be that “I would only participate in clinical research if I was very sick and there were limited alternative options”. Hence the public tend to view participation in clinical research/clinical trials as an option of last resort for very sick patients.

“If you were sick with a serious illness you would try anything” (Male, 55-66 years, BC1, Galway)

“If you had a life threatening illness and someone came and said, this has been researched and we are really sure of it. If you’re going to die then what harm?” (Female, 25-34 years, C2D, Dublin)

A minority of respondents were more open to the possibility of participating in such research but again a key barrier was a concern over potentially harmful side effects.

“You would have to know the side effects. But you know, never say never. I wouldn’t like to take something if I thought I was going to get sick from it.” (Male, 25-34 years, C2D, Dublin)

“I wouldn’t know what’s going to happen. As long as I was certain there were no side effects” (Male, 18-24 years, BC1, Dublin)

A very small minority were open to the prospect of participating in clinical research/clinical trials usually for altruistic reasons to contribute towards medical knowledge and out of a desire to help others. These respondents tended to be more informed about the process and protocols of clinical research/medical trials and therefore appeared less daunted by the perceived risks to their personal health and safety.

“I have three children, there was research going on each time with the three of them, with the cord or whatever. I wouldn’t have any problem as long as it wouldn’t affect me or the baby” (Female, 25-34 years, C2D, Dublin)

“I would seriously consider it even if I was well. You have to look at the bigger picture. The results might help somebody” (Female, 55-65 years, BC1, Galway)

4. Prompted Views of Clinical Research and Clinical Trials

4.1 Introduction

This component of the report details the general public’s response to factual information about clinical research and clinical trials presented via the qualitative (focus groups) and quantitative (omnibus survey) research. Moreover it charts the impact of such information on respondents’ attitudes to key themes, identifying perceptual changes accordingly.

The different research methodologies (focus groups and telephone survey) employed for this project necessitated the design of specific stimulus material (i.e. factual information about clinical research and clinical trials) for each stage of the research.

The stimulus material for the quantitative research comprised a short explanation of clinical research and a concise explanation of how patients can participate in the process. Respondents were then asked to rate the
extent to which they agreed or disagreed with a range of attitudinal statements (both positive and negative) relating to the subject (See Appendix).

The qualitative stimulus material was considerably more detailed providing respondents with information on a range of themes related to clinical research and clinical trials namely:

- An explanation of clinical research
- A range of scenarios (1-5) as to how the public/patients can participate in clinical research (ranging from the provision of personal medical information to active engagement in a clinical trial)
- The aims and objectives of clinical research
- How clinical research is set up
- Who can take part in clinical research
- Participation/How patient information is used
- What the risks and benefits of clinical trials are
- Why take part

The stimulus material was introduced once the initial discussion on clinical research and clinical trials was exhausted to enable respondents to re-examine their attitudes towards the subject and to ascertain what (if any) perceptual change emerged? The qualitative stimulus material was presented at different stages throughout the group to avoid “information overload” and to facilitate discussion around key themes.

This section now draws together the general public responses to both the qualitative and quantitative stimulus material and highlights how key information impacts the public’s attitudes to clinical research.

4.2 A notable attitudinal change to participation in clinical research

A total of five specific scenarios were presented to respondents in the focus groups to explain the different methods by which people/patients can participate in clinical research namely:

- **Scenario 1**: Supplying personal medical information
- **Scenario 2**: Donating blood for clinical examination
- **Scenario 3**: Donating tissue for clinical examination
- **Scenario 4**: Participation in a clinical trial using a non medical treatment
- **Scenario 5**: Participation in a clinical trial using a drug/medicine

In addition, other important themes regarding clinical research and clinical trials were presented to respondents in the group scenario such as the potential research outputs (i.e. disease prevention, improved survival rates etc.), patient consent, the role of the independent research ethics committee etc.

Following the presentation of the stimulus material, respondents were universally more positive about the prospect of participating in clinical research than heretofore. Almost all respondents reported a willingness to participate in scenarios 1-3 as they were viewed to be non invasive and of little risk to their health and safety.

“No problem 1-3. At the 5th scenario I would be concerned if the risks ended up happening” (Female, 18-25 years, BC1, Dublin)

“If you have an operation and you lose some skin, there’s no point in it. They might as well use it.” (Male, 18-25 years, BC1, Dublin)

“I would agree with the blood and with the medical information. I wouldn’t throw myself in to be tested for a new drug” (Female, 55-65 years, C2D, Galway)

“I wouldn’t have any problem with it. It’s straight forward blood and tissue” (Male, 55-65 years, BC1, Galway)

The rationale for respondents’ attitudinal change to participating in clinical research appears to be the result in part to the recognition that the public can participate in research without the need to engage in a drug trial.

Another key factor which appears to have prompted the attitudinal change to participation was the information provided regarding the strict protocols and procedures clinical research/clinical trials employ. In particular the public were reassured by the information on patient consent, confidentiality and the role of the independent ethics committee. All such information seemed to address previous ethical concerns about the process.

However some key questions did emerge in the group discussion most notably about the anonymity of medical data or personal material supplied for clinical research. In particular some respondents raised concerns about the security risk of clinical research databases. Furthermore a minority expressed concerns as to the legal obligations to inform an insurance company in the event of any medical
complication emerging from donated material.

“The database would need to be safe” (Female, 44-55 years, C2D, Cork)

“Would the database be anonymous so that the people viewing it would not be able to see who you are” (Male, 55-65 years, BC1, Galway)

“Would you need to inform an insurance company if your blood came back with a problem” (Male, 35-44 years, BC1, Cork)

The issue of the public’s willingness to participate in clinical research was also reinforced in the findings of the omnibus survey with 70% of the general public reporting that they “would be willing to donate blood to be used for clinical research” and 65% claiming they “would be willing to supply personal information to be used for clinical research if it is done in a confidential manner”.

Interestingly a lower proportion of people in the 18-24 year age cohort claimed to be willing to donate either blood (64%) or personal medical information (58%) for the purposes of clinical research.

4.3 A steadfast reluctance to participate in clinical drug trials

Although the factual information regarding clinical research served to reassure respondents somewhat about the perceived risks, only a minority reported a willingness to engage in a clinical drug trial. In particular, very few respondents were prepared to undergo a trial which involved the taking of a medicine unless they were severely ill.

The key psychological barrier for the majority of respondents remains a reluctance to take what they perceive to be an unnecessary risk with their health by ingesting a drug with potentially harmful side effects.

“Non drug is fine, I wouldn’t try new drugs personally, I wouldn’t try something new for no other reason than research” (Male, 55-65 years, C2D, Galway)

“Unfortunately there will be mistakes made and they won’t be positive results as well. You’ll probably read in 50 years of people who died as a result of trying something” (Female, 25-34 years, C2D, Dublin)

“I wouldn’t mind the first 3... However for the 4th and 5th ones. For me I think it’s a step too far” (Male, 44-55 years, C2D, Cork)

However respondents reported an increased willingness to participate in clinical trials in the event that they, or a close member of their family, was very ill.

“I wouldn’t draw a line if I was sick” (Female, 18-25 years, BC1, Dublin)

“...I think... it might be a case if you were ill and someone would say, do you want to give this a shot?” (Female, 25-34 years, C2D, Dublin)

“If you got into a situation or if one of your family needed it, you would be delighted for it” (Male, 55-65 years, C2D, Galway)

“If you thought for a moment that you had heart disease or something like that you would do anything to think there was light at the end of the tunnel” (Male, 44-55 years, C2D, Cork)

The issue of patients willingness to participate in clinical trials was also examined in the omnibus survey with approximately 40% of the public claiming that “they would only participate in a clinical trial if they were very sick” with a further 20% undecided on the issue of participation.

In addition 28% claim they would not want a family member taking part in a clinical trial with a further 22% undecided.
Conversely a minority of people reported an attitudinal change (post presentation of the stimulus material) with regard to a willingness to participate in a clinical drug trial. The rationale for their attitudinal change appears to be the result of an improved understanding (following a review of the factual information) of the contribution such trials make to improvements in medicine (i.e. finding cures for diseases etc.). In addition such respondents appear to be motivated by a desire to give something back to society.

“I think I would go the whole hog, because I feel I would want to be part of something like that. It’s like giving blood, you come out and you feel you’ve done something good” (Female, 55-65 years, BC1, Galway)

4.4 Ethical standards and public reassurance

As evidenced from the spontaneous views that emerged in the group discussions, concerns around the ethics of clinical trials are a key concern for the majority of respondents

The issue of ethics and clinical research was also examined in the omnibus survey and emerged as a divisive issue. Only 50% of the general public agreed with the statement that “clinical trials are run in an ethical manner” with 17% disagreeing and 27% undecided.

However the provision of information about the rigorous process and strict parameters employed in clinical research served to reassure respondents about the ethical standards employed. In particular the key issues the public seek reassurance on concerning clinical research and clinical trials include:

- **Patient confidentiality**: “I’m glad to hear about the confidentiality part of it. For instance if you did donate blood and they did find something wrong with you, your health insurance company is not going to get a hold of it and all of a sudden your health insurance goes through the roof” (Female, 25-34 years, C2D, Dublin)

- **Rigour**: “It seems very complex. It says that it goes through a set of doctors and nurses, then another set of doctors. I’d be confident that it is very much researched into and that its taken very seriously” (Male, 18-25 years, BC1, Dublin)

- **Consent**: “The consent thing is very reassuring. It seems to be a bit more stringent. They give people as much information as they can before they say yes, so it is an informed decision” (Female, 55-65 years, C2D, Galway)
• Ethics committee: “The information about the ethics committee is very important, there should be a code of ethics in every business but especially in medicine” (Male, 55-65 years, BC1, Galway)

4.5 Attitudes to Biobanks

Little concern emerged amongst respondents towards the storage of personal material (blood, tissue etc.) to be used for future clinical testing. The only point of concern was that personal material might be used for human cloning.

“I’d have no problem about the testing of my blood once it’s gone it’s gone” (Male, 25-34 years, C2D, Dublin)

“I wouldn’t have any problem with blood or tissue being kept, its not part of you anymore. The only thing I would be worried about is cloning” (Female, 18-25 years, BC1, Dublin)

“If they removed my gall bladder they can test away on that, sure it’s not going to affect my health” (Male, 44-55 years, C2D, Cork)

“I wouldn’t have any problem with them taking the placenta because it’s just going to be thrown in the bin….. That doesn’t bother me they are going to gain from it” (Female, 25-34 years, C2D, Dublin)

4.6 Key motives driving participation in clinical research

Respondents universally endorsed the benefits of conducting clinical research, be they for the individual patient (improved patient care), society (advancements in medical knowledge), the wider economy (employment). However the key motives that appear to motivate the public to engage in clinical research can be classified as follows:

• Humanism: Respondents appear to be motivated by a desire to help their fellow man particularly those people who they view to be most in need (the sick and those suffering from as yet incurable disease)

Respondents were of the view that participating in clinical research can aid in finding cures for diseases (cancer, MS etc.).

“You feel it would benefit other people” (Female 18-25, BC1, Dublin)

“It’s a good thing if you’re going to help someone else you want to feel like your helping” (Female, 55-65, C2D, Galway)

“You’d have a feeling of goodwill afterwards” (Male, 55-65, C2D, Galway)

“If it’s for the benefit of other people, you would have a feeling of goodwill afterwards” (Male, 18-25 years, BC1, Dublin)

“As long as it was going to be used for good” (Female, 55-65 years, C2D, Galway)

• National pride: Respondents also reported a desire to assist Ireland to be at the “cutting edge” of medicine, employing “best practice” in terms of treatment modalities and delivering an excellent standard of care to patients.

“Ireland needs to be at the forefront of research, we should be out there telling people what we are doing not hiding it behind closed doors somewhere” (Male 55-65, BC1, Galway)

4.7 Attitude to Ireland operating as a central hub for clinical research/clinical trials

In general respondents were very positive about the prospect of Ireland operating as a central hub in conducting clinical research and medical trials.

The key benefits articulated by respondents in the focus groups include:

• The creation of centres of excellence in medical expertise
• Improved quality of patient care
• Improved efficiency within the health system
• The knock on benefits to the economy via employment
Many respondents were of the view that Ireland should be at the forefront of clinical research as it offers an opportunity for Ireland to create expertise in the delivery of new medical treatment modalities. Moreover respondents reported that by focusing resources on creating such medical centres of excellence in clinical research, Ireland would be in a position to attract international medical expertise to place Ireland at the “cutting edge” of new developments in science and medicine.

“It would prove that we are at the cutting edge of research globally”. (Male, 44-55 years, C2D, Cork)

The influx of medical expertise to the country was viewed to offer Irish people the opportunity to train and develop new skills and knowledge.

It would benefit young people also because they can learn from the international experts and ultimately we can become leaders in the field” (Female, 55-65 years, BC1, Galway)

Improved quality of patient care

Many respondents perceived that by Ireland positioning itself as a central hub in conducting clinical research it affords patients access to a better quality of medical care.

“It could improve patient care. If it’s going to help people then it should be advertised.” (Female, 18-25 years, BC1, Dublin)

“I think you would get a better quality of care because the doctors would be paying more attention to you” (Female, 55-65 years, C2D, Galway)

In addition to the possibility of improved patient care, respondents also pointed to the potential for clinical research to lead to medical advancements/medical breakthroughs which would have a benefit to patients and the country respectively

“……..It’s doing good, it’s finding cures. If you can cure an incurable disease then go for it” (Female, 35-44 years, BC1, Cork)

“They might get a breakthrough or a cure. People would get better” (Male, 25-34 years, C2D, Dublin)

This positive endorsement of Ireland as a future hub for medical research also emerged from the omnibus survey with 77% of the population agreeing that conducting research in Ireland was a good idea. Interestingly a higher proportion of men (80%) were positive about the idea than women (73%). Respondents from higher socioeconomic groups (79%) were also more supportive than those from a less affluent background (74%).

Improved efficiency in the health system

Given the vociferous criticism of the Irish health system, many respondents perceived that by creating centres of excellence in clinical research in Ireland it would in turn lead to improved efficiencies in the Irish health service. This view appears to be rooted in a belief that by conducting continuous clinical research and medical trials within the hospital setting, the best practice protocols and efficiencies employed will in turn influence how other services are delivered within hospitals.

“It would be a way of growing and improving efficiency. It could speed up the process of being seen in A&E”. (Female, 18-25 years, BC1, Dublin)

“We need to move on and sort the hospitals out” (Male, 25-34 years, C2D, Dublin)

“If it could improve the health system at the moment, it would be a major benefit” (Female, 55-65 years, C2D, Galway)
“There might be less money wasted instead of flushing it down the drain” (Male, 18-25 years, BC1, Dublin)

Knock on benefits to the economy
Respondents were also very positive about the potential knock on benefits to the economy of Ireland becoming a centre of excellence for clinical research. One key benefit to the Irish economy was that of employment, in particular the up-skilling of an educated workforce to sustain the “knowledge economy”. In addition, creating such a hub for clinical research was viewed to offer young people an outlet to train and learn “best practice” in the field thus avoiding the potential of losing a highly skilled workforce to emigration (i.e. “brain drain”).

It’s jobs and if we have an educated workforce it’s a good thing that they can stay and do their research in Ireland. It’s good for the economy and our image abroad. That kind of thing” (Male, 44-55 years, C2D, Cork)

“Why not keep smart people here rather than having them go overseas” (Male, 18-25 years, BC1, Dublin)

Furthermore a growth in clinical research expertise was viewed to be an attractive incentive to entice additional international investment into Ireland with the potential for employment in manufacturing. Such an outcome tended to be very positively received given the current economic situation.

“It could attract more companies” (Female, 18-25 years, BC1, Dublin)

“Wherever the money would be coming from, it would be landing here. I think that scenario is a win-win. We’d welcome it in the current climate” (Female, 44-55 years, C2D, Cork)

“And if successful there a good chance that it could be manufactured in Ireland” (Male, 44-55 years, C2D, Cork)

“I think an Irish company recently came up with a cure for Parkinson’s. That’s going to bring in huge revenue” (Female, 25-34 years, C2D, Dublin)

“The first thing I thought of is people like Pfizer in Cork. They’d be bringing revenue to the country” (Male, 25-34 years, C2D, Dublin)
5. Conclusions

As the research outlines, public dissatisfaction with the Irish health service has created an opportunity to promote the benefits of Ireland becoming a future hub for clinical research. However to do so, any future communication campaign will need to overcome the obstacle of the low level of public understanding of clinical research/clinical trials and common misconceptions about patient risk.

Given the public’s inability to differentiate between clinical research and clinical trials both tend to be associated with a high level of patient risk, in particular a concern about potentially harmful drug side effects. Both word of mouth and perhaps disproportionate media coverage of the negative outcome of some clinical trials (patient deaths, drug withdrawals etc.) appear to have heightened public concerns. Hence very few members of the public are comfortable with participating in clinical research.

This fear of the unknown and the perceived risk of harmful side effects appear to be the key barriers to participating in clinical research/clinical trials. Moreover the public’s limited understanding of the process of both clinical research and/or clinical trials gives rise to a “rigid” mindset which fails to consider the possibility that a person in “full” health can partake in clinical research.

However basic information about the purpose of clinical research and the degrees of participation serve to encourage public participation. Moreover information regarding patient consent, confidentiality and the presence and role of an independent ethics committee also appear to go a long way in reassuring the public about the strict protocols employed.

This research suggests that a basic public information campaign about clinical research/clinical trials would address many of the current barriers to patient participation namely:

- Limited understanding of the different scenarios (i.e. donating blood, providing medical information etc.) by which members of the public can participate in clinical research
- Ethical concerns as to how such research/trials are managed/conducted
- Common misconceptions about patient risk

On a positive note the research indicates that an opportunity exists to tap into the public’s readiness to participate, with 70% of the general public reporting that they “would be willing to donate blood to be used for clinical research” and 65% claiming they “would be willing to supply personal information to be used for clinical research if it is done in a confidential manner”.

One key obstacle that any future communication campaign will struggle to address is the public’s reluctance to participate in clinical drug trials. The key psychological barrier for the majority of respondents appears to be that they are unwilling to take what they perceive to be an unnecessary risk with their health by ingesting a drug with potentially harmful side effects.

However although the public remain disinclined towards personally participating in a clinical drug trial due to the perceived risks, they remain very supportive of the contribution such research makes to society, namely:

- Medical advancements in the understanding of diseases
- Improved patient care via monitoring and access to medicines
- Knock on benefits to an economy via employment

Furthermore the public strongly endorsed the role of clinical research perceiving it to be critical to medical and scientific innovation.

Perhaps the most encouraging finding of the research is the public’s support for the prospect of Ireland operating as a focal point for clinical research/clinical trials. In the main the public were of the view that Ireland should be at the forefront of clinical research as it afforded an opportunity to create expertise in the delivery of new treatment modalities.

Many of the public also held the view that by Ireland positioning itself as a centre of excellence in conducting clinical research it facilitates patients access to improved medical care.

Moreover the public also reported how operating as a hub for clinical research serves to sustain the “knowledge economy” and affords medical/scientific trainees access to medical expertise. In time such a clustering of knowledge can lead to research and development opportunities and employment “spin offs”.
Appendix

IPPOSI Public Awareness

Group Discussion Topic Guide

Introduction

We’re here to talk about the area of medical care and advancements in treatments for diseases etc.

Respondent Profile (Warm Up)

• Introduction:
  - Name
  - Martial status, children,
  - Job
  - Have you always lived in Ireland?

State of the Irish Health Service (Warm Up)

• Looking first of all at the state of the Irish Health Service:
  - What are your views on the current system?
  - Experiences, etc.
  - Improving v dis-improving? Why?
  - How optimistic are you that the Irish Health Service will improve over the next five to ten years? Why do you say this?

Awareness and Understanding of Clinical Research

• When I use the term clinical research what if anything springs to mind? Probe individual responses?

• Do you feel you understand the term? Yes v no. What if anything do you think the term means?

• When I use the word clinical or medical trial what if anything comes to mind? Probe individual responses?

- Is this a term that you feel you understand? What if anything do you think it means?

- If respondents are aware or familiar with the term “Clinical trial” (or if they perceive themselves to be familiar with the term). How do you feel about the process of conducting clinical trials?
  - Positive v negative
  - Do you think there are any benefits to conducting clinical trials?
  - Do you have any concerns about the running of clinical trials?

Brief explanation of the term clinical research on an A4 board in consumer friendly language (see draft Show Card 1 & 2)

• Based on the information you have heard how do you feel now about the process of conducting clinical research?
  - Positive v negative. Why?

  - At what point (i.e. Scenario 1 – Scenario 5) if at all would you be willing to participate in the clinical research process? Why?

  - At what stage of your illness (mild, moderate, severe) do you think you would have to be to consider participating in clinical research?

  - What if any concerns would you have about participating in the research process?

    • Fear of the unknown

    • Uncertain about the quality or standard of care you might receive

    • Question if used as a “lab rat” or “guinea pig”

  - What if any benefits do you think there might be to participating in clinical research?
• Improved medical care
  • Access to new/better medicines
  • Do you feel that Ireland is a suitable location to conduct such clinical research? Yes v no. Why v why not?
  • Would you support/endorse Ireland conducting such research? Why v why not?
  • To what extent would you think Ireland currently conducts clinical research?
  • Who do you think organises/manages individual clinical research (i.e. Universities, pharmaceutical companies etc.).
    - Does it matter if it is the pharmaceutical company/academic institution that manages or conducts the clinical research? Why?
  • What benefits if any might arise out of Ireland conducting clinical research?
    - For the country
    - For patients etc.
    - For the treatment of a particular disease/condition
    - For individual institutions (hospitals, organisations etc.)
    - Is there any information you feel you did not need to hear?
    - Is there any information missing that you would like to know?
    - In your view, from the information you have just heard, what is the most powerful argument to
      a) Encourage you to participate in a clinical research. Why?
      b) Encourage you to support Ireland as a location for conducting clinical research. Why?

Presentation of key information and benefits of clinical research (See draft Show Cards 2–8)
• Based on the new information you have heard how do you feel now about the process of conducting clinical research?
  - Positive v negative?
  - Has your view changed? If so why?
• Of the information you have heard about clinical research what information do you feel is most important for you to know?

Presentation of the patient case study of clinical trial via DVD (i.e. Jennifer Moran MS sufferer)
• Reaction?
  - Does seeing or hearing a patient describe the experience of a clinical trial change your view of clinical trials? If so how?
  - Ask Group if they were tasked with the job of explaining to the general public about the benefits of conducting clinical trials in Ireland what information would they provide
  - What media would they use?
• Any other comments or suggestions?

Thanks & close
Clinical Research

Clinical research is patient-focused research involving either the direct participation of patients or the use of their personal health information, blood or tissue samples.

Clinical research helps us to learn more about specific diseases and their symptoms. Clinical trials are another type of clinical research where patient responses to different medications and treatments are compared to see which is the most effective.

In all cases patient consent must be sought and received before the clinical research can be undertaken.
Show Card 2:
Options/Degrees of Clinical Research Participation

<table>
<thead>
<tr>
<th>Scenario 1</th>
<th>Scenario 2</th>
<th>Scenario 3</th>
<th>Scenario 4</th>
<th>Scenario 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient supplies personal medical Information in a confidential manner (eg. Medical history)</td>
<td>Patient donates blood for examination in a clinical laboratory</td>
<td>Patient donates tissue post surgery for examination in a clinical laboratory</td>
<td>Patient takes part in a clinical trial by using or trying a non medical treatment (such as a medical device, pace maker etc.)</td>
<td>Patient takes part in a medical trial which involves taking a drug or medicine</td>
</tr>
</tbody>
</table>

→

| Might be used to develop a National Register (i.e. Cystic Fibrosis Sufferers) | Blood samples can be analysed to understand the causes of a disease and to develop new treatments | Patient tissue (skin etc.) is analysed to understand the causes of disease and to develop new treatments | Patient agrees to try a form of non drug treatment (Physiotherapy, counselling, new form of prosthetic) to see how effective the treatment is | Patient agrees to try a form of drug treatment (Current drug in combination or a new drug) to see how effective the treatment is |
Show Card 3:

Clinical Research

Clinical research covers a broad range of different types of research.

For example:

- Clinical Research is often used to test new medicines or vaccines but can also be used to look at new combinations of existing medicines

- It can also be used to test whether giving a treatment in a different way will make it more effective or reduce any side effects

- Some clinical research tries to establish ways to prevent a particular disease occurring in healthy persons who have never had the disease or to prevent a disease from returning.

- Clinical research is not always about testing medicines, it can used in many ways:

  - Examining and comparing blood and tissue samples of healthy people with those of sick people to better understand a disease

  - Collection of medical data from patients with a specific disease eg. Cystic Fibrosis (CF). This information would then be used to build up a national registry or database of patients with a particular condition. This would help researchers and clinicians to see how well patients are responding to treatments as information would be regularly updated on the database/registry.

(Source: Adapted from “Understanding Clinical Trials”, UK Clinical Research Collaboration. www.ukcrc.org)
Show Card 4:

Clinical Research is conducted to answer specific questions about health and illness.

It aims to find out the best ways to:

- Prevent disease and reduce the number of people who become ill
- Treat illness to improve survival or increase the number of people cured
- Improve the quality of life of people living with the illness (reducing side effects etc.)

Why is Clinical Research Important?

- Clinical research is the best way to compare different approaches to preventing and treating illness and health problems. Health professionals and patients need the evidence from clinical research to know which treatments work best. Many treatments that are now in common use in healthcare were tested in clinical research.

- Clinical research aims to improve patient health by seeking new ways to treat, cure and even prevent the many diseases that affect us all.

Conducting clinical research in Ireland not only leads to improved knowledge of medical treatments for patients it can also provide economic benefits to the country by creating and sustaining careers in cutting edge research.

(Source: Adapted from “Understanding Clinical Trials”, UK Clinical Research Collaboration. www.ukcrc.org)
Show Card 5:

How is clinical research set up?

- Clinical research is designed by doctors and other specialists. Input is sought from a wide variety of people including patients. They work together to decide what questions the research needs to answer.

- Funding for a research is typically provided by a pharmaceutical company, Academic Institution or National Funding Body.

- Doctors, nurses, patients, trial managers and representatives from pharmaceutical companies work together to design the best possible clinical research proposal.

- Before clinical research can be undertaken it must be approved by an independent research ethics committee (that includes doctors, nurses, other medical staff, members of the general public and sometimes lawyers) who decide whether or not the research is ethical.

(Source: Adapted from “Understanding Clinical Trials”, UK Clinical Research Collaboration. www.ukcrc.org)
Show Card 6:

STEP 1: Who can take part in clinical research?

- All research has guidelines about how it must be conducted and who can take part. These are called eligibility criteria. Eligibility criteria are used to ensure that the research includes the sort of people who may benefit from the treatment and to make sure that people who take part are not exposed to avoidable risks.

  Some clinical research only includes people in a certain age group, or of one sex or at a particular stage of their illness.

- Staff at a hospital or centre review patients’ charts to identify individuals who might be suitable to take part in clinical research. If a patient is found to be a good candidate the person may be asked if they would like to take part.

  Everything about the research is explained to the patient in great detail and the patient is given plenty of time to make his or her decision. It is very important that those who choose to take part in the clinical research feel entirely comfortable about doing so.

STEP 2: Consent

- When a patient is asked to participate in clinical research, the next step is to provide the person with all the information he or she will need to make up his/her mind.

- The patient is given a patient information sheet explaining the purpose of the research, length of time it will take, procedures involved etc.

- If the patient is happy to participate he/she is asked to sign a consent form
STEP 3: Participation

- Taking part in clinical research usually involves visiting a centre (a hospital) at specified times. Depending on the type of study these visits may include:
  - Having a medical examination
  - Completing a questionnaire
  - Giving a blood sample
  - Taking agreed medication

- In the event that a patient’s condition requires surgery he or she may be asked to donate a tissue sample.

As part of a patient’s surgery, some tissue may be removed which is usually discarded. In cases such as this, a patient is asked to donate some of the discarded tissue to the research team for examination in the laboratory.

STEP 4: How is Patient Information Used?

- The information gathered from patients/persons in clinical research is completely confidential. The information is stored in a computer database and not used without patient consent.

- Depending on the type of clinical research a patient’s information may be used in a variety of ways
  - Blood or tissue samples may be compared with specimens from unaffected volunteers
  - Compare the medical information of patients to determine how effective one treatment is against another or against no treatment
Show Card 8:

In Ireland the term Clinical Trials generally refers to studies of drug or medical device treatments on patients and these trials are generally sponsored or managed by Pharmaceutical or Medical Device companies. In Irish hospitals it is estimated that Clinical Trials make up 20% of Clinical Research activities.

What are the risks and benefits of clinical trials?

Clinical trials are carefully designed to minimise the risks and maximise the benefits to all who take part, whatever treatment they receive. Some trials will have very little risk involved.

However, the risks of a trial may be greater when less is known about the treatment being tested. Before any drugs are first given to people, they will have been developed in a laboratory and checked for safety in animals.

In all trials the treatment may cause side effects that doctors cannot predict and that you may not be expecting. Patients will be told everything that the researchers know about any possible risks and side effects and why the trial is necessary so that you can make an informed choice about whether to take part.

If you take part in a trial you will be monitored regularly during and after the study. You will have regular tests and you may be asked some extra questions about how you are feeling. You may also be asked to fill out questionnaires or to keep a diary. Sometimes this means going to your hospital or GP more often than you would normally.

The benefit of this extra attention is that any changes in your health, whether or not they are related to the treatment you are having, are frequently picked up and acted upon earlier than if you were not in a trial.

It is important to remember that not everyone receives a new treatment in a clinical trial. Patients will not know if they are taking a new treatment, an existing treatment or placebo.

(Placebo is an inert compound identical in appearance to material being tested in experimental research, which may or may not be known to the physician or patient, administered to distinguish between drug action and suggestive effect of the material under study).

A clinical trial needs to compare a new treatment with the standard treatment already in use, if there is one, or a new treatment versus a placebo.

Some people in a trial will therefore receive the standard treatment, or the placebo but, until the results of the trial are analysed, no one will know which treatment is better. ‘New’ does not always mean ‘better’ and you may not be worse off if you do not receive a new treatment.

(Source: Adapted from “Understanding Clinical Trials”, UK Clinical Research Collaboration. www.ukcrc.org)
Show Card 9:

“If none of this was being done, sure we’d be getting nowhere... It’s given me great hope that some day it will be cured. Maybe not in time for me, but in time for somebody else, and that’s a marvellous plus, because I was involved in that.” (Participant in lung fibrosis study)

Why take part?

There are many advantages to taking part in a clinical study. You will be monitored very closely throughout, and have access to a team of experts at all times.

However there are much wider benefits. The role of the patient in the trial is absolutely central, and through your participation, we hope to increase our understanding of many of the world’s most serious illnesses.

We cannot stress just how valuable this contribution is without the voluntary involvement of the participants, there would be no research programme.

By participating in a study, you are joining a team whose goal is to generate new medical knowledge, with the ultimate aim of finding new and better ways to treat or even cure serious diseases.

We firmly believe that in making the decision to take part, each patient is making a real and valuable contribution to improving the health care of our own and future generations

(Source: “Clinical Research, Your Participation Counts”. UCD Clinical Research Centre)
Clinical Research Omnibus Survey 2009

ASK ALL

Q1
Do you understand what is meant by the term “clinical research?”
1 Yes GO TO Q2
2 No GO TO Q3

ASK IF YES (CODE 1 AT Q1) OTHERS GO TO Q2
(DO NOT READ OUT MULTI CODE POSSIBLE)

Q2.
What is your understanding of the term clinical research?
1) Scientific research
2) Research that takes place in a laboratory setting
3) Medical research
4) Research with patients or in a hospital
5) Other (specify – verbatims required)
6) Don’t know

Q3.
Do you understand the term “clinical or medical trials?”
1 Yes GO TO Q4
2 No GO TO Q5

ASK IF YES (CODE 1 AT Q3) OTHERS GO TO Q5
(DO NOT READ OUT MULTI CODE POSSIBLE)

Q4.
What is your understanding of the term clinical or medical trials?
1) Trials where sick patients are given different forms of medicines/drugs
2) Trials in which drugs/medicines are tested on humans
3) Trials where different medicines/drugs are tested on animals
4) Trials that take place in a hospital setting
5) Other (specify – verbatims required)
6) Don’t know

Q5
Clinical research involves the participation of patients or samples from patients (such as blood or tissue samples) to help us learn more about specific diseases and their symptoms. Typically patients can participate by supplying personal medical information, donating blood or tissue samples for examination in a medical laboratory or by entering a clinical trial where patient responses to different medications and treatments are compared to see which is the most effective.

In all cases patient consent must be sought and received before the clinical research can be undertaken

I will now read out a list of general statements relating to clinical research, to what extent do you agree or disagree with the following statements. Using a 5 point scale where 5 means you strongly agree and 1 means you strongly disagree

READ OUT (ROTATE)

1. I think carrying out clinical research in Ireland with the aim of developing new ways to treat many diseases is a good idea
2. I would be willing to donate blood to be used for clinical research
3. I would be willing to supply personal medical information for medical research if it is done in a confidential manner
4. I would be willing to participate in clinical research
5. I would only participate in clinical research if I was very sick
6. I believe that clinical trials are run in an ethical manner
7. I am against running clinical research because I think they use humans as “guinea pigs”
8. I would not want a family member of mine taking part in a clinical trial

1) Strongly Disagree
2) Disagree
3) Neither Agree nor Disagree
4) Agree
5) Strongly Agree
IPPOSI is very grateful for the support from all our members, who have worked effortlessly to bring about this major initiative. The idea devised by the IPPOSI Clinical Research Think Tank could not have been realised without the generous contributions of our sponsors.