GetReal – Introduction to the project

GetReal is a three-year research project of the Innovative Medicines Initiative (IMI). The project brings together a wide range of stakeholders including regulators, health technology assessment bodies (HTAs), industry representatives, patient organisations, academics, and physicians. The primary aim of GetReal is to explore new and effective ways to include real-world evidence in the drug development process. The GetReal group is pursuing this objective by developing a range of research activities such as:

- Proposing innovative trial designs and assessing the value of information;
- Creating new decision making support, and building tools to allow for the evaluation of development programmes and use in the assessment of the value of introducing new treatments;
- Assessing existing processes, methodologies, and key research issues.

The IAPO-ELF Focus Groups

The International Alliance of Patients' Organizations' (IAPO) role within GetReal is to explore and report on patients' views and preferences on the acceptability and usefulness of real-world evidence (RWE) to estimate the effectiveness of new medicines. RWE is gaining increasing importance alongside traditional randomised clinical trials in determining health care decisions. Real world data is data that already exists; it is "derived from medical practice among heterogeneous sets of patients in real life practice settings, such as insurance claims data and clinical data from electronic health records" (The Network for Excellence in Health Innovation (NEHI) 2015).

Using real world evidence is expected to start a process according to which healthcare decisions will be made in a way that reflects more closely the characteristics of individual patients in real life. Within this scenario, IAPO is contributing to the identification of the key challenges of performing RWE research - in the design, set-up, and conduct of the research - from a patient point of view.

To capture and explore patients' perspectives extensively, IAPO is conducting a wide range of research activities. First, a survey was developed in May 2016 and was circulated amongst IAPO member organisations. Additionally, in order to ensure a more granular and qualitative understanding of patients' (and patient representatives') views, three focus groups were conducted between 18th and 22nd July 2016. The focus groups were attended, respectively, by five, four, and four participants. Two sessions were held at the IAPO offices in London, one session was held at the European Lung Foundation (ELF) in Sheffield. All participants were recruited by ELF through the ELF-run European Patient Ambassador Programme (EPAP).

EPAP is an e-learning programme to equip patients and/or their carers with the skills and knowledge which ensures their involvement in any activity relating to their healthcare is effective and impactful. One of the EPAP modules is concerned with research and development and the focus group participants were recruited from the pool of people, who had completed that particular module.

The focus groups were primarily aimed at eliciting patients' views and preferences with regard to the various design options that can characterise clinical trials, with a particular emphasis on pragmatic trials. Furthermore, the sessions were aimed at gaining a better understanding of how to best achieve patient-centredness throughout the whole research process and informed consent procedure, and the criteria patients tend to rely upon to weigh up benefits and risks of taking part in clinical research. The focus groups were moderated by Antonio Ciaglia (IAPO), Rachel Kalf (Zorginstituut Nederland/The National Health Care Institute, the Netherlands), and Kerstin Morrison (ELF).

Some Early Considerations

By looking back at the three focus group sessions that were held between 18th and 22nd July 2016, it is possible to already identify a number of frequently recurring themes and broadly shared concerns/views. In particular, two views came across as fairly strong.

1. Achieving true patient involvement by enforcing accountability

The EPAP patient ambassadors who participated and shared their views within the focus groups strongly highlighted how important it is for patients:

- To be involved at all stages of clinical research
- To be regarded as proper research partners rather than mere data suppliers to the health care professionals
- That there is accountability and that the mechanisms for this are transparent by:
  - informing participants of the outcomes of the trial they took part in *after* the trial has come to an end – this does not happen very often, but is seen as crucial by patients
  - participants receiving clear information and explanations throughout the research process on the rationale behind any decision making
  - acknowledging which outcomes their participation has helped achieve

2. The importance of high-quality information

Patients need to be able to make fully informed decisions in healthcare as well as when participating in research activities. Being able to make informed decisions is one of the primary ways in which patient involvement can actually take shape and become real.

One of the basic requirements for this to happen is accurate, thorough and easily understandable information. This is essential for the nature of the relationship between doctor and patient and the way in which the informed consent procedure is planned and carried out.

Researchers and healthcare professionals are often use and rely on highly technical terminology, or jargon. Patients feel that extra efforts should be made into trying to translate research jargon in more easily accessible language.

Ensuring that patients, too, are fully enabled to understand and make sense of the research questions that are being investigated is a first, important step towards acknowledging the potential contribution they can make as co-decision makers.

Next Steps

The focus group material has been transcribed at IAPO. The views that were contributed by the focus group participants will be analysed and used to inform the production and development of a number of informational and research outputs. These include:

- A discussion paper on patients' views and perspectives with regard to clinical research in general and practical trials in particular (to be completed approximately in October 2016).
- A discussion paper on patient-centredness in the research process, with an emphasis on real-world evidence and informed consent procedures (To be completed approximately in October 2016).
- Two research outputs based on the two discussion papers to be submitted for publication in specialised academic journals (possibly by November 2016).
- Informational leaflets for patients, industry representatives and professionals as to what matters to patients when participating in clinical trials (October 2016).
- Depending on availability and resources, this material will also be used to carry out educational activities such as webinars and dialogues.