

Review of the EU Clinical Trials Directive (Directive 2001/20/EC)

EPF STATEMENT

Introduction

The European Patients' Forum (EPF) welcomes this opportunity to contribute to the Commission's second public consultation on the assessment of the functioning of the Clinical Trials Directive (Directive 2001/20/EC). We believe the review process should have as its objective a better functioning, more proportionate, and *more patient-centred* approach to the design and regulation of clinical trials.

To ensure this, EPF and its members believe it is necessary to meaningfully incorporate the patients' views in the review. In particular, we strongly believe that this review is an opportunity for reform towards more patients' involvement throughout the research process, greater trust and confidence in medical research and improved participation rates.

Although the Clinical Trials Directive aimed to improve the protection of patients in relation to clinical trials, and has been partially successful, several gaps remain that should be addressed. EPF and its member organisations provided extensive input into the first round of public consultation, in 2009/2010. We identified a number of issues of key concern to patients, and we are greatly concerned that those issues have not been addressed in the Commission's concept paper.

EPF's must therefore raise again what we consider to be fundamental issues around patients' involvement in the research process. We repeat the call to the Commission, from patient communities across the European Union, to address these issues in a meaningful way, in the context of the forthcoming proposal for a review of the Directive.

Methodology of the EPF statement

A draft statement was developed on the basis of the key issues identified in EPF's first response to the public consultation in 2009/10, and with input from EPF's Policy Advisory Group. The paper was then sent to EPF's membership for comments and feedback. A final statement was developed based on input from members, and incorporating input from other health NGO allies where appropriate. This was sent to EPF's membership for final approval before submitting it to the Commission. A list of EPF membership organisations and allies that have given their support to this statement is appended. *Please note that these*

members are supportive of this statement and the principles therein, notwithstanding certain differences of opinion concerning some of the more technical issues included in the Commission's concept paper.

Why should the patients' perspective be incorporated in the legislative review?

The effectiveness of clinical trials throughout the EU is of fundamental importance for EPF and its members, as ultimately this influences patients' access to new and improved medicines and treatments responding to unmet medical needs. A good regulatory framework incorporates and balances all relevant stakeholder inputs and expectations, holding these in a creative tension, not an overly rigid, stifling framework.

EPF's members have identified several issues in the 2009-2010 consultation as key concerns from the patients' perspective. Moreover, EU funded research projects, e.g. ICREL¹ and PatientPartner², have demonstrated the need for these areas to be addressed. However, these are not addressed in the Commission's concept paper.

EPF believes that for a genuinely patient-centred vision of clinical trials, these concerns need to be considered. Our statement focuses on five key issues:

1. Ensuring meaningful patients' involvement across all aspects of clinical trials;
2. Giving patients access to quality information regarding clinical trials;
3. Meaningful informed consent;
4. Transparency concerning the results of clinical trials;
5. Access to treatments after the end of clinical trials.

Below, we address each of these issues in turn.

¹ <http://www.efgcp.be/icrel/>

² <http://patientpartner-europe.eu/>

1. Meaningful patients' involvement across all aspects of clinical trials

Meaningful patients' involvement in the clinical research process, from the "idea" stage to the proven intervention, is important for several reasons:

Patient involvement is a moral right

Patients have an obvious and central role within clinical trials: they provide the information, and they ultimately manage the personal risks attached to trials. Patients therefore have a moral right to be involved in the way clinical trials are developed, managed and evaluated.

Patient involvement leads to better design and outcomes of trials

Meaningful patient involvement helps ensure that the trials are focussed on patients, which will improve the results of trials. In recognition of this, the European Commission DG RESEARCH now includes patient involvement as an evaluation criterion in its calls for proposals under FP7 on clinical trials on certain disease-areas.³

Patients are a source of expert information on their disease, treatment and its impact on daily life. They can play an important role by helping to ensure that the issues that are identified and prioritised in the study are important to them. This *experiential knowledge* is of immense value in the process of research and development, complementing the researchers' scientific knowledge in developing therapies that are adapted to the real needs of patients.⁴ A recent INVOLVE study shows that *patients and the public always offer unique, invaluable insights*, and that their advice when designing, implementing and evaluating research invariably makes studies *more effective, more credible, and often more cost-efficient*.⁵ The 2010 "Mesa del medicamento" (the drug treatment forum of the Catalan Department of Health in Spain) recognised in its conclusions that organisations' involvement in different areas of drug research is important for fast access and accurately meeting medical needs. The forum recommends special focus on encouraging their role as promoters of research projects, contribution to the design of research protocols, participation in ethics committees, improving information for participants and reviewing the conditions for obtaining informed consent, but also for promoting mechanisms for disseminating results of research to the public and promoting public recognition of the societal value of research.

The EU co-funded **PatientPartner project**, in an extensive literature survey identified the following key specific benefits of patient involvement to research⁶:

- Changes in the information material given to patients;

³ http://ftp.cordis.europa.eu/pub/fp7/docs/wp/cooperation/health/a-wp-201101_en.pdf

⁴ O'Connell D, Mosconi P. An active role for patients in clinical research? *Drug Dev Res.* 2006;67(3):188; Mosconi P, Colombo C, Satolli R, Liberati A. PartecipaSalute, an Italian project to involve lay people, patients' associations and scientific-medical representatives in the health debate. *Health Expect.* 2007 Jun;10(2):194-204.

⁵ *Exploring Impact: Public involvement in NHS, public health and social care research.* November 2009, available at www.invo.org.uk/pdfs/Involve_Exploring_Impactfinal28.10.09.pdf

⁶ <http://www.patientpartner-europe.eu/en/inventory/literature/perspectives-on-active-patient-involvement-in-clinical-trials>

- Changes in the design of the study and aspects of research such as: ways of collecting data, identification of endpoints that are relevant to patients including those related to quality of life; analysis of qualitative data, research questions, tools, priorities and outcomes;
- Increased recruitment and better recruitment strategy;
- Increased response rates;
- More patient-relevant research findings and methods;
- Challenged the assumptions made by researchers;
- Wider dissemination of findings.

The EU co-funded **VALUE+ project**⁷ developed a definition of “meaningful patient involvement” and practical tools to support such involvement, both for patient organisations and for project coordinators. The project findings highlight that patients’ involvement in clinical trials improves several critical aspects of trials, such as:

- patients’ perspective on ethical and risk-benefit dilemmas;
- managing expectations;
- better adherence, which improves cost-effectiveness;
- increased confidence by patients and the public in clinical research, which can stimulate participation in research.

It can be said that there is a gradual but perceptible shift towards greater patient involvement in clinical research. Many patient organisations already plan an active role in clinical trials, and a recent survey of 205 patient organisations from 31 European countries by PatientPartner showed that involvement can take place at various levels:

- *Information Provider* (e.g. supplying information for the use in a trial, as well as information to patients on trials);
- *Advisor* (e.g. advising on informed consent forms and procedures, ethics committee, regulatory authority committee, advising a clinical research programme committee);
- *Reviewer* (e.g. trial protocol, funding request, scientific paper, patient information);
- *Co-researcher* (e.g. interviewing patients, leading focus groups or discussion sessions, gathering information or research data, co-writing scientific article or translating results into patient-friendly information);
- *Driving force* (e.g. lobbying, developing research protocol, getting a research team together, raising funds or co-financing a trial).

Experiences of patient involvement are positive

A PatientPartner survey of pharmaceutical industry experiences of patient involvement showed that though there is still relatively little experience in involving patient organisations, where this has been done the experience has been mostly positive.⁸ Patient

⁷ <http://www.eu-patient.eu/Initatives-Policy/Projects/EPF-led-EU-Projects/ValuePlus/>

⁸ <http://www.patientpartner-europe.eu/en/inventory/survey-pharma>

representatives' experiences of involvement have been very positive. A recent survey on lay and patient representatives of Ethics Committees in the UK showed that the majority of the surveyed participants felt that their views were fully taken into account in the deliberations of the committee.⁹

Patient involvement can improve declining participation rates

One of the problems facing clinical trials in Europe is declining patient participation rates.^{10,11} Greater patients' involvement in the research process will improve the patient community's understanding of, trust and confidence in clinical trials, and in medical research generally, and can help increase participation rates. This is particularly relevant to chronic neurodegenerative conditions, such as Parkinson's disease, where time is of the essence for patients' access to new medications that can have a significant impact on disease progression.

Patient involvement improves patients' commitment and adherence

Enabling meaningful patient involvement has important implications for the engagement and commitment of patients to treatment, including adherence to therapies in a trial context. Where health professionals see non-adherence or non-compliance, patients often perceive non-participation in terms of a lack of appropriate information or knowledge, poorly presented information, poor communication or attitude on the part of health professionals towards the patient.¹²

Experiences of EPF's member organisations support the above arguments. Examples include:

- *In France, the National Institute of Health and Medical Research (INSERM) has developed several research programmes with patients' cooperation, which have had positive results including: better comprehension between researchers and patients; better engagement of scientists and patients; and better patient adherence leading to more effective results. (Source: French MS League)*
- *In diabetes, some studies have involved patients sharing their experiences before, during and after the trial, via the Internet and in meetings. As an example, before the launch of detemir-insulin, a pan-European study based its information on the use of detemir-insulin not only on laboratory tests but also on the experience of people with diabetes. Patients shared experiences rapidly online, and information was disseminated much earlier than the results of the study were published. Benefits of patients' involvement have included: more patient-relevant research findings and methods; more holistic picture of the findings/observations; challenging the assumptions made by researchers (do the results mean something in*

⁹ INVOLVE project: *Survey of lay/patient members of research committees*, 2009.

¹⁰ Tables 5 and 6, Number of planned clinical trials participants (EU and global), European Commission's concept paper, p.20

¹¹ Report "Access to clinical trials: report of the deliberative event hosted by National Voices for the MHRA" (November 2009)

¹² Eldh AC, Ekman I, Ehnfors M (2008). "Considering patient non-participation in health care". *Health Expectations*, 11, pp.263-271.

everyday life?); and wider dissemination of the findings via discussion forums of people with Diabetes. (Source: IDF Europe)

- *The German liver patients' association has itself published scientific research (surveys) on quality of life issues and have actively contributed to several German guidelines; the German Hepatitis C guidelines of 2010 for example refer to the results of those surveys. The European Liver Patients' Association, ELPA, is currently conducting an online survey on patients' experience with hepatitis C, its treatment, and their expectations of future treatments. (Source: ELPA)*
- *The Spanish Clinical Research Network (CAIBER) is a new initiative to foster a patient-centred biomedical research model based on cooperation with the aim to ensure quality and quick results for patients. It is a new public consortium dependent on the Spanish Ministry of Science and Innovation via the Instituto de Salud Carlos III (ISCIII) and includes 40 hospitals in 16 Autonomous Communities. Among its aims is to promote active patients' participation in clinical research.¹³*
- *In breast cancer, the patients' organisation Europa Donna has been extensively involved in a trial called MINDACT¹⁴, through the TRANSBIG research consortium¹⁵. Europa Donna serves on the Steering Committee, Legal/Ethics Committee and Spreading of Excellence Committees for this trial. The Legal/Ethics committee deals with consent agreements, patient information sheets, transfer of biological materials and cross-border issues, to ensure that the trial is conducted in accordance with all laws/international treaties and accepted ethical standards, and to resolve ethical issues raised. The Spreading of Excellence organises the dissemination of information and documents, including those intended for patients, concerning the trial.*

Europa Donna believes its involvement has had a definite impact on the information material given to patients; the design of the study; more patient-relevant research methods and findings; challenging of the assumptions made by scientists; and better dissemination. It may have had an impact on recruitment and response rates though that is not verified. (Source: Europa Donna)

¹³ <http://www.caiber.net/>

¹⁴ Microarray for Node negative Disease may Avoid ChemoTherapy. MINDACT involves the clinical application of genomics for improved treatment tailoring, and is a study based on the "70-gene signature" identified by the Netherlands Cancer Institute as a tool to assess risk of cancer coming back. It uses microarray technology to prognostically classify early stage breast cancer patients into high and low risk of distant relapse and compare this to traditional clinico-pathological methods. MINDACT aims to prospectively validate a 70-gene poor prognosis signature identified by Dutch researchers at the Netherlands Cancer Institute using microarray technology (Van't Veer et al. Nature 2002). It will test the hypothesis that the use of this genetic signature will spare a significant proportion of women the inconvenience and morbidity of adjuvant chemotherapy. A potential reduction of 10-20% in chemotherapy prescription is expected by using this new method; for the highest incidence cancer in women this would significantly decrease treatment associated morbidity, as well as the financial burden on health care systems.

¹⁵ TRANSBIG is an international research network founded in 2004, which is an EU-supported Network of Excellence. The aim of the network is to integrate, strengthen and facilitate translational and clinical breast cancer research.

Patients' representation in Ethics Committees is key

The need for more patients' involvement in Ethics Committees has been highlighted many times. In some EU Member States, patients are involved in Ethics Committees. The final report of ICREL notes that, while in 2003, 60% of the responding ECs had no patient representatives, in 2007 this was down to 52% – a slight growth of patient involvement.¹⁶

However, the majority of Ethics Committees still do not involve patients and in some EU Member States, such as the Netherlands, it is actually illegal for patients to fill the position of the lay persons. Current guidance specifies that Ethics Committees should include “lay persons qualified to represent the cultural and moral values of the community”.¹⁷ However, ***the perspective of lay persons is not equivalent to the perspective of patients. Lay persons do not possess the experiential knowledge of patients.*** It follows that the role they play in an Ethics Committee is also different. Lay persons are often ethics experts or lawyers, who have no contact with patient groups and are not able to reflect on the issues from a patient's perspective.

An illustrative example comes from the Netherlands, where a protocol for a study in the use of probiotics was reviewed by 16 of the 30 Ethics Committees. At the end of the study, it became clear that much went wrong with the study, but none of the 16 Ethics Committees who had approved it had noticed the shortcomings of the protocol from the patients' perspective. (Source: EGAN)

Patient involvement is particularly implicated in ***accurate risk assessment – avoiding either under- or overestimating risk versus potential benefit.*** Patients, who ultimately bear the personal risks of participation in research, should have the right to be involved in assessing its risks. As an example, patients with an extremely serious, life-threatening disease will very often have a different perception of risk compared to that of investigators or regulators. They may be more willing to take up higher risks for less or different benefits (such as quality of life), or a lesser guarantee of benefit. A recent report by National Voices¹⁸ highlights the importance of including patient representation in Ethics Committees to arrive at a more accurate risk-benefit assessment.

Other benefits of patient involvement in Ethics Committees include:

- Ensuring that the ethics review is truly patient-centred – protocol design, treatment schedule, identifying new patient-relevant issues including logistical and practical ones that may affect patients' participation and drop-out rate;
- Reviewing the documents and processes for informed consent, in order to ensure that all information is relevant, comprehensive and clearly understandable for patients; presenting information in a patient-friendly language;

¹⁶ ICREL final report, p. 116. http://www.efgcp.be/downloads/icrel_docs/Final_report_ICREL.pdf

¹⁷ International Ethical Guidelines for Biomedical Research Involving Human Subjects, CIOMS/WHO (2002)

¹⁸ Report “Access to clinical trials”, report of the deliberative event hosted by National Voices for the MHRA” (November 2009).

- Fostering greater trust and confidence in ethics reviews and clinical trials among the patient community;
- Fostering close contacts and exchange of information between the patient community and those conducting or sponsoring trials.

EPF recommendations

EPF and its members strongly recommend that:

1. The issue of patient involvement in ethics committees should be addressed in the review of the Clinical Trials Directive, by including specific provisions regarding patients' representation.
2. Patient organisations should be provided with adequate training in order to build capacity for taking on this sometimes very complex role.
3. More research should be done to identify good practices in patient involvement in ethics committees and experiences from different Member States, which should be shared among national Ethics Committees and stakeholders.
4. We also strongly encourage enhanced networking and cooperation of Ethics Committees across the EU.

2. Patients' access to quality information regarding clinical trials

Patients' access to quality information is closely linked, but not limited to the ethics review question above. Information is a crucial aspect having implications for patients' willingness to participate in clinical trials, as well as their commitment and adherence within trials.¹⁹ Many of EPF's members feel addressing the lack of, or inadequate quality of information around clinical trials is of paramount importance to be addressed in the review.

Patients are often not provided with sufficient and comprehensive information regarding the clinical trial. This issue is closely connected with the informed consent process, and the understanding of the risks involved in participating in a trial. However, lack of information is apparent *throughout the process*. For example, patients often do not know how to enrol in a clinical trial; they often do not know what they are participating in;²⁰ and they are not informed of the results or outcomes of the trial in which they participated.

A patient organisation can provide information support throughout the trials, and also help *manage the expectations of participants*, by clearly stating what the aim of the study is, and whether patients can realistically expect an immediate personal health benefit from

¹⁹ Sood et al., "Patients' attitudes and preferences about participation and recruitment strategies in clinical trials". *Mayo Clin Proc* 2009;84(3):243-247; Eldh AC, Ekman I, Ehnfors M (2008). "Considering patient non-participation in health care". *Health Expectations*, 11, pp.263-271.

²⁰ For example Edwards SJL, Lilford RJ, Hewison J, "The ethics of randomised controlled trials from the perspectives of patients, the public, and healthcare professionals". *BMJ* 1998;317:1209-12;

their participation (e.g. a cure, improved survival, or alleviated symptoms). Research shows that patients often overestimate the benefits of the treatments being studied in clinical trials, such as they will be cured quickly with a “miraculous” new substance.²¹

The initial findings of the EU-funded **RESPECT project**²² (needs of children and their families regarding participation in clinical trials) suggested that while children and parents decide to participate in trials for reasons that range from personal benefit to altruism, the concrete reality of a trial is often different from what they had initially thought. There are clearly issues around autonomous and objective decision-making, and around consent and assent: the children rely on the parents, who in turn rely on the doctors. Participants in the RESPECT project suggested that it could be helpful to have a *neutral support figure*, who would provide the information patients and parents/carers need and support their empowerment. Patient organisations, for example, could fulfil such a role.

EPF member organisations have concrete experience of providing information on clinical trials. As an example, *Europa Donna* has served for a number of years on the Spreading of Excellence committee on the MINDACT trial (see above) and has been responsible for the development, review and the organisation of the dissemination of information and educational materials on the project, both for patients (e.g. DVDs, pamphlets, consent forms and information sheets) and the public (web information, presentations, pamphlets, conferences, training courses, media material, press conferences and press releases).

Many other organisations have *extensive experience in producing patient-centred, patient-friendly information on complex scientific and medical issues*, including online through “patient university” initiatives.²³ This collective experience and expertise could be much better harnessed and used to improve the patient experience of participation in clinical trials.

3. Meaningful informed consent

Informed consent should be regarded as a pre-condition for the start of any clinical trial. It should be provided in a language which is accessible and understandable for the patient and/or their representative. Unrealistic expectations need to be dealt with at this stage; it is also important that patients do not feel that they have been coerced into participating in trials thinking that otherwise they will not get appropriate treatment.

Regrettably there are still large disparities in informed consent across the EU, both in terms of *quality and quantity of the information provided*, and the *effectiveness of the process*. Informed consent is still sometimes regarded as a sort of ritual, and not as a means by

²¹ Cheng J et al. (2000). Impact of quality of life on patient expectations regarding phase I clinical trials, *Journal of Clinical Oncology*, Vol. 18(2), pp. 421-428.

²² www.patientneeds.eu

²³ The “Patient University Project” in Barcelona, run by the University of Barcelona in cooperation with the Spanish Patients’ Forum (EPF member) and the Josep Laporte Library, and includes courses and information toolkits for patients about specific chronic diseases and disease self-management. See website: <http://www.universidadpacientes.org/index.php>

which patients are able to fully comprehend and evaluate the risks they will be taking in participating in a clinical trial.²⁴ A study in 2006 concluded that patients did not recognise written consent as primarily serving their interest; almost half believed the primary function of consent was to protect hospitals.²⁵ Furthermore, preliminary evidence from the RESPECT project indicates that in many cases the problems appear in the process rather than the documentation.²⁶

This raises the issue of how meaningful informed consent actually is, and how we can ensure that it is fit for purpose and increases the safety and confidence of the patients.

Examples from patient organisation involvement include the following:

- *Europa Donna was involved in producing a DVD for patients and their families who were potential recruits to the trial. The DVD was to be viewed only with their health care professional present, so that any questions could be answered on the spot. Research is ongoing to evaluate the usefulness of this tool.*
- *The Spanish Patients' Forum has developed extensive information resources such as the "Patients' University". Its Political Agenda asks for budgeting for specific research programmes respond to specific needs identified by patient associations; for patient association review of the conditions of obtaining informed consent and the quality of information received by patients in trials; and for generally improving the quality of the available information about drugs and research to patients and the public.²⁷ SPF recommends that researchers should be trained in how to communicate and obtain the informed consent from patients, from a patients' perspective; the development of guidelines on "patient-friendly" informed consent; and utilisation of new technologies (e.g. video) to facilitate understanding.*

²⁴ Edwards J, Lilford R, Hewison J (1998). The ethics of randomised controlled trials from the perspectives of patients, the public and health care professionals. *British Medical Journal*, 317, pp. 1209-1212.

²⁵ Akkad A, et al. "Patients' perceptions of written consent: questionnaire study". *British Medical Journal*. 2006 Sep; 333 (7567):528.

²⁶ Project website: www.patientneeds.eu

²⁷ <http://www.webpacientes.org>; www.universidadpacientes.org

EPF recommendations

EPF and its members recommend that:

1. Coherent and comprehensive information to patients about clinical trials should be provided, in an appropriate language and format, understandable for the patient or their representative.
2. Patient organisations or patient representatives should be involved in reviewing informed consent documents and procedures. Adequate training programmes should be available for patient advocates to enable them to take on such a role.
3. Information to patients documentation and process should ideally be evaluated ideally by patient representatives, and should include information to manage patients' expectations.
4. The risk-benefit evaluation should be explicitly linked to the informed consent phase of the trial.
5. The Directive should include a provision for the Commission to prepare guidelines, in consultation with patient organisations, on the information that should be included in informed consent documentation; while also addressing the process of obtaining informed consent.
6. More research should be done to identify best practices and challenges in informed consent, and these could be shared among national Ethics Committees across the EU.

4. Transparency concerning the results of clinical trials

At micro level, patients often have little access to the results of the clinical trial. Trial results are usually published in scientific journals to which individual patients and patient organisations often have no access. Lack of information on the results of the clinical trial in which a patient has participated has been shown to decrease the willingness to participate in a follow-up or second trial.²⁸ At macro level, even trials that have failed can reveal significant information for patient groups, particularly in certain disease areas.

EPF welcomes the positive developments linked to the EudraCT database of clinical trials, where the European Medicines Agency is currently addressing this issue, making certain results-related information accessible to the public.²⁹

²⁸ Sood A, Prasad K, Wahner L (2009). Patients' attitudes and preferences about participation and recruitment strategies in clinical trials. *Mayo Clin Proc.* 84(3), pp. 243-247.

²⁹ <https://www.clinicaltrialsregister.eu>

EPF recommendations

EPF and its members recommend that:

1. The Directive should include a provision specifying that all results of all clinical trials – including “failed” ones – shall be published in a timely manner in the EU Clinical Trials database.
2. The results-related information in the database should be developed in such a way that it will be understandable and user-friendly to lay persons and patients, including appropriate guidance for interpretation of the data.
3. We further recommend that the European Public Assessment Summary (EPAR) made available to the public should be revised to include an element describing the degree and ways in which patients/patient representatives were involved in the clinical trial process.

5. Access to treatment following the clinical trial

Free availability of the treatment being tested – assuming it turns out to be the best one for the patient – is a key issue for patients following the end of a trial. However, despite patients reporting that they would like this to be part of the protocol, access is not always available.

Ensuring appropriate access to post-trial treatment is beneficial to sponsors and researchers, as it can be a major motivation for patients’ willingness to participate in clinical trials, and thus can help sustain a high level of patient participation.

From the patients’ perspective, it should be a requirement to provide full and open information to potential trial participants on whether post-trial treatment will be available, and whether they would be expected to pay for it. However, we would suggest that there is a *moral obligation* on researchers and sponsors to secure *free – or affordable in the local context* – post-trial treatment to all trial participants.

This is particularly crucial in the context of *clinical trials conducted in third countries*. The question should be extended to consider the wider community and it should be addressed jointly by the national authorities and the trial sponsors before even starting a trial. This should however be addressed in a way that does not discourage investment in research. EPF is supportive of the language of the Declaration of Helsinki (2000 version) that “at the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study.”

One approach that has been used successfully in an insulin trial in people with type 1 diabetes, is to adopt a transition period of a certain length, such as six months after the end of a trial, during which time the sponsor will enable patients to have access to the study medication with no additional cost or a reasonable (in the local context) cost. During

this period the authorities have the opportunity to act in favour of a patient in need of the studied medication.

EPF recommendations

EPF and its member organisations recommend that:

1. Information requirements should include the provision of full and open information to potential trial participants on post-trial treatment, its availability and potential cost.
2. National competent authorities and trial sponsors should be required to consider options for securing free, or affordable in the local context, post-trial treatment to all trial participants and the wider community where appropriate, before research is even started.
3. Sponsors should be required to describe in the trial protocol and in the clinical study report the provisions made with respect to access to treatment post trial.

CONCLUSIONS

There is a demand for patients with serious diseases and conditions to participate in relevant, high quality research – and well-designed clinical trials are an essential component of this. A revision of the Clinical Trials Directive provides an opportunity to create a regulatory framework that builds on this commitment to research and development.

The European Patients' Forum is committed to work closely with the European Institutions and stakeholders in translating the vision and the core issues outlined in this statement into effective, patient-centred EU legislation on clinical trials.

For more information please do not hesitate to contact Nicola Bedlington, EPF Director (nicola.bedlington@eu-patient.eu) or Kaisa Immonen-Charalambous, EPF Policy Officer (kaisa.immonen.charalambous@eu-patient.eu).

The European Patients' Forum (EPF) was founded in 2003 to become the collective patients' voice at EU level, manifesting the solidarity, power and unity of the EU patients' movement. EPF currently represents 50 member organisations, which are chronic disease-specific patient organisations working at European level, and national coalitions of patients organisations. Collectively they reflect the voice of over 150 million patients living with various chronic diseases in the European Union. EPF's vision for the future is high quality, patient-centred, equitable healthcare throughout the European Union.

APPENDIX

List of EPF member patient organisations and allies supporting this statement (in alphabetical order)

EPF full and associate members:

Association for the Protection of Patients' Rights (Slovak Republic)
Age Related Macular Degeneration (AMD) Alliance International
Association of European Coeliac Societies – AO ECS
Associazione Patologie Autoimmuni Internazionale
Coalition of Patients' Organizations with Chronic Diseases, Romania
Collectif inter associatif Sur la Santé (CISS), France
Confederation for Health Protection (KZZ), Bulgaria
Council of Representatives of Patients' organizations of Lithuania – LPOAT
Estonian Chamber of Disabled People
Europa Donna – The European Breast Cancer Coalition
European Alliance of Neuro-Muscular Disorders Association – EAMDA
European Cleft Association
European Coalition of Positive People
European Federation of Allergy and Airways Diseases Patients' Associations – EFA
European Federation of Associations of Families of People with Mental Illness – EUFAMI
European Federation of Associations of Patients with Haemochromatosis – EFAPH
European Federation of Crohn's and Ulcerative Colitis Associations – EFCCA
European Federation of Homeopathic Patients' Associations
European Genetic Alliances Network – EGAN
European Headache Alliance
European Heart and Lung Transplant Federation
European Infertility Alliance
European Institute of Women's Health – Associate Member
European Kidney Patients' Federation – CEAPIR
European Liver Patients' Association – ELPA
European Men's Health Forum
European Multiple Sclerosis Platform – EMSP
European Network of (ex)users and survivors of psychiatry – ENUSP
European Parkinson's Disease Association – EPDA
European Umbrella Organisation for Psoriasis Movements - EUROPSO
Federation of Patients and Consumer Organisations in the Netherlands
Federation of Polish Patients
Fertility Europe
Spanish Patients' Forum – Foro Español de Pacientes
GAMIAN Europe – Global Alliance of Mental Illness Advocacy Networks
Hungarian Osteoporosis Patient Association
International Diabetes Federation (IDF) Region Europe
International Patient Organisation for Primary Immunodeficiencies – IPOPI
Lupus Europe

Malta Health Network
Mental Health Europe
National Patients' Organisation (NPO), Bulgaria
National Voices, UK
Pancyprian Federation Of Patients Associations and Friends, Cyprus
Retina Europe
SUSTENTO – The Latvian Umbrella Body For Disability Organizations

Allied organisations

International Alliance of Patients' Organizations (IAPO)
The PatientPartner project

Please note: EPF's member organisations listed above are united in their support of the principles outlined in this Statement, even though they may have differences of opinion on certain technical questions addressed in the Commission concept paper.