Charter for the Patient Input Platform of U-BIOPRED
version 10/02/12

Introduction
The U-BIOPRED Patient Input Platform (PIP) is a voluntary group tasked with providing
input from the patient's perspective on questions that may rise from the different work
packages and activities of U-BIOPRED.

Mission Statement
The PIP will work in a collegiate, collaborative and inclusive manner to provide patient
perspective, support and insight into the different research and dissemination processes
of U-BIOPRED, with a view to helping the research stay 'connected' to the patient
experience and needs.

Terms of Reference
• The PIP is a voluntary group comprised of members of the associated U-BIOPRED
  patient representation organisations setup to assist in evaluation, advice and
guidance on patient related issues arising within U-BIOPRED. This may be done
pro-actively and/or upon request.
• The PIP will receive necessary documents and protocols in order to provide specific
  comments from the patient's perspective, translations of parts of texts in their
own language, or the provision of ideas for activities or dissemination materials.
• The PIP will be recognised as an active "support group" by the individual work
  packages, with a view to associating a member of the PIP to each in order to
develop an active working patient representation relationship.
• Communication between the PIP members will be maintained through a separate
  members’ only digital forum as well as face-to-face meetings and the e-mail
distribution list. Communication with the wider U-BIOPRED community will be via
the general U-BIOPRED digital forum, the common e-mail distribution list, the U-
BIOPRED BioSci website, U-BIOPRED annual meetings and other ways of
communication.
• Training and support for PIP members will be initiated from expertise within the PIP
  membership or the participating U-BIOPRED patient organisations.
• Reporting responsibilities are to the U-BIOPRED WP10 steering committee in the
  form of minutes of each PIP meeting and the minimum of one annual PIP
statement. A copy of the minutes and statement will be provided to the
Management Board.
• All members of the PIP need to provide a disclosure statement regarding their
  relationship(s) to any of the participating organizations in U-BIOPRED.
• All members need to fill in a conflict of interest statement, as with any member of
  the U-BIOPRED consortium.
• Privacy and confidentiality – it is agreed that in the interests of openness the
  business of the PIP may be openly discussed outside of the PIP unless explicit
agreement has been reached that an item or issue is confidential. A summary of
the meeting minutes is available for wider disclosure via the U-BIOPRED ELF
website and via SmartSheet.
• Public statements, oral and written presentations on behalf of the PIP – it should be
  presumed that public statements regarding PIP activities are made in the spirit of
corporate representation. Such statements must be clearly distinguished from any
statements made in a personal capacity.
• The PIP is willing to add terms of reference points concerning patient involvement
  that are raised by official organizations.
Structure of the Patient Input Platform

The PIP consists of approx. 15 members (chair and co-chair non-inclusive) comprised of patients or patient representatives (parents or carers) throughout Europe. U-BIOPRED strives for an equal regional representation of patients with (severe) asthma.

Each member will be appointed for two years and may be reappointed for another 3 years.

The chair and co-chair will serve a two-year term, but he/she can be appointed to serve an additional three-year term.

Except as otherwise permitted by the steering committee of WP10, each member of the PIP shall not be directly involved in the (clinical or research) studies performed in U-BIOPRED.
Patient’s Perspective Criteria List
Criteria for evaluation of research protocols, study designs and other documents from the patient’s perspective

1. **Relevance.**

   1.1 health related quality of life
   (improvement of quality of life: physically, mentally and socially)
   1.2 Improvement of health
   (improvement of health of patient group)
   1.3 Applicable to more diseases
   (takes into account patients suffering from multiple diseases (co-morbidity) and complications)
   1.4 Improvement of care for patients
   (leads to improved care for patient group)
   1.5 Improvement of societal participation
   (improved participation in and being part of the society)
   1.6 Exploitable result
   (project result can be used in practice and associates with characteristics of patient group e.g. age, ethnicity, social economic status)
   1.7 Applicability of project result in practice
   (a plan is available how to bring the results into practice)

2. **Right of Say.**

   2.1 Patients are a source of knowledge
   (this deals with wishes, needs and sores of the patient group and acknowledges the value of disease experiences)
   2.2 Patients are equal discussion partners
   (the patient group also decides on a research project, proposal, protocol, guideline or policy)
   2.3 Patients are full citizens
   (the image of the patient group as being independent and self-thinking citizens with a chronic disease or disability)

3. **Ethics and Safety.**

   3.1 The method is the least aggravating in relation to the goal
   (this is the least burdening way reaching the goal – there is no less burdening alternative for the patient group)
   3.2 Safety of participants in the study
   (side effects, discomfort, aftermath, and after care are being taken care of by the project, and this is known to participants)
   3.3 Freedom of Choice
   (participant signs in full freedom to participate in the study or not without reduction in the quality of basic health care provision)
   3.4 Rules, codes, social norms and values
   (the project adheres to behavioural codes, professional codes and legal medical regulations and laws regarding research with humans)
   3.5 Human dignity
   (the project leaders regard participants in a holistic way and do not regard the disease only)
   3.6 Responsibility and Carefulness
   (the project leaders informs the own physician about the project if the participant approves to this. Participants know the complaint procedure)
   3.7 Information about the project results
   (project results will be fed back to participants and the patient group in lay terms i.e. in terms that can be understood by 95% of the national population)
Total scores of:
1. relevance (max. 70 points)
2. right of say (max. 30 points)
3. ethics and safety (max. 70 points)

To each aspect 10 points (highest and best appreciated) can be given maximally.

Neutral score of 5 points: aspect is not described and should not be described in the protocol.
Score 0 – 5 points: aspect is not described, but should be described in the protocol.
   Protocol must be improved!
Score 5 – 10 points: aspect is described in the protocol.

Your comments to each of the 3 paragraphs:
Please provide both positive and negative aspects

1. Relevance

2. Right of Say

3. Ethics and Safety

Your advice to the project leaders:
Endorse without comment: yes / no
Modify according to your comments: yes / no

Your name:
Date:

# criteria based on:
Clarification of the criteria.

Relevance
1.1 health related quality of life
The expected project results improve the quality of life of the patient group (physically, mentally or socially). Less physical limitations during daily activities caused by health-related problems like climbing stairs, body washing, clothing and shopping. Less mental limitations due to feelings of anxiety or depression. Less social limitations due to the way the disease affects the possibilities to act in a family, participate at work or spare time activities, or to visit family or friends.

1.2 Improvement of health
This is important for improvement of health of the patient group.

1.3 Applicable to more diseases
The description pays attention to comorbidities and/or complications, is there any relevance to other diseases. There is no need for unnecessary replication in other diseases.

1.4 Improvement of care for patients
The expected project result leads indeed to an improved health care as experienced by patients.

1.5 Improvement of societal participation
Improved possibilities to participate in the society: e.g. being volunteer at school or elsewhere, being member of a society, or being employed.

1.6 Exploitable result
The expected project results are utilisable for the patient group.

1.7 Applicability of project result in practice
The project plan also contains an implementation plan how results can be brought into practice – if not then the patient group will not profit.

Right to say
2.1 Patients are a source of knowledge
The project is also based on wishes and needs of the patient group. Acknowledgement of the value of patient’s disease experiences is given next to professional knowledge.

2.2 Patients are equal discussion partners
The patient group is one of the parties in the project, and involved in e.g. negotiations on study design, study execution, evaluation, dissemination and implementation. The project information is available in lay terms and understandable by 95% of the population. Feedback of the project results will also be done in lay terms.

2.3 Patients are full citizens
Within the project patients are being regarded as full, self-conscious and emancipated citizens, and are not being regarded as unemancipated and dependent citizens.

Ethics and Safety
3.1 The method is the least aggravating in relation to the goal
If the project result seems relevant for other diseases then the project leaders should inform the research and care field about this (principle of universality). Are the benefits from the project higher than the burden (e.g. a better drug for asthma versus patients undergoing an intervention to see whether the drug makes them better or sicker). What is the risk of failing to work, go to school or participate in social activities? This is the only way to reach the goals. There are no alternatives less burdening for patients available based on the informed consent.

3.2 Safety of participants in the study
In case of patient-bound research the project leaders take care of providing a suitable insurance for participants related to disease burden, failure to work, study or participate in social activities. Side effects, discomfort, aftermath, and after care are being taken care of by the project, and this is known to participants.

3.3 Freedom of Choice
Participants will be provided (written) information in lay terms about the project, and more than 24h to think about their participation. The information is given as a patient informed consent form, which includes the freedom to make their own choice to participate (yes or no). It should be stated explicitly that their choice will not affect the quality of health care provided by their caregivers. Participants will also get written information on the complaint procedure.

3.4 Rules, codes, social norms and values
The project leaders have follow the legal (local and national) regulations and laws, and rules regarding behavioural and professional codes.
3.5 Human dignity
The project leaders have a holistic view about the participants – hence they not only view the patient part but also an individual with a family, friends, education or being employed, and with spare time. The project leaders avoid that participants feel helpless or ashamed.

3.6 Responsibility and Carefulness
The project leaders and scientists take care of the participants in the best possible way. The project leaders should provide information to the patient’s physician about participation and potential consequences of the research (i.e. side effects, discomfort etc.).

Information about the project results
Project results should be provided to the patient group and participants in lay terms.