To whom it may concern

OBJECT: Spontaneous, Medically Advantageous for patients, Research Trials (SMART) studies.

Dear Patient, dear Politician, dear Doctor,
The aim of this pamphlet is to sensitize governments and international institutions regarding the obstacles that strongly limit research activity: the Helsinki declaration and the ethical committees are paradoxically killing patients through bureaucracy.
SMART studies are intrinsically ethical studies with medical doctors supporting them from dozen countries and without drug companies involvements and may include observational retrospective or prospective observational studies, audits, spontaneous randomized and cluster randomized trials which on all available evidence do not carry greater risks for patients that usual care and do not study new drugs or devices.
These studies don't have additional risks for patients compared with usual care, and, at the same time, the information provided by them is of fundamental importance. Local ethical committee approval is always needed for this kind of studies.
We suggest that SMART studies should follow a simplified path with involvement of an international board of experts, approval of a single central ethical committee, and, when appropriate (e.g. comparison of two widely used standard of care treatments), waiving of written informed consent, privacy disclosures and expensive additional insurances. Such complexlex and expensive step actually kills quality improvement and the development and testing of SMART studies.

We strongly encourage politicians to understand the real need of our patients and the scientific need to constantly improve patient care and encourage them help overcome this bureaucracy.

A more detailed description is available in the following pages.

Signatures

Name

I agree to disclose my identity (yes/no)

I agree to be involved in the next steps of this campaign, involving politicians and supra-national institutions (yes/no)

I already introduced the topic to ….(Name and Surname), which is involved in public administration in the quality of…. (please specify work, and nation).

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Text

Spontaneous not-for-profit research is a major driving force for medical progress.
If not-for-profit studies are independent from the influence of pharmaceutical companies, they are conceived and performed in the interest of the patients with the goal of leading to improvements in patient care.

Despite this consideration, developing and conducting public good studies is becoming increasingly difficult in many countries all over the world.
Unfortunately, the **S**pontaneous, **M**edically **A**dvantageous for patients **R**esearch **T**rials (SMART) development is forced to follow the same bureaucracy and safety assessment as pharmaceutical or for profit trials even if when such trials study, for example, minimal dose changes of drugs that have been commercialized for dozens of years.

For example, local ethical committee evaluations requires payment of a fee (the amount is generally hundreds of Euros), and specific additional insurances have to be stipulated even for non-profit studies (thousands of Euros) that compare widely used standard treatments, which are applied every day according to clinician preference in the absence of evidence that one or the other is actually better for patients. Economic resources are not enough and grants are limited in number and budget to overcome the obstacles created by bureaucracy..

SMART programs include studies which do not carry additional risks for patients beyond those of usual care and do not assess new drugs or devices and are not in the interest of drug companies.
The direct benefits for all patients included in SMART programs are linked to the Hawtorne effect (references 1-5). At the same time, the information provided by these studies is of fundamental importance to the well-being of the worldwide patient community.

We are well aware of the importance of the Declaration of Helsinki. The **Declaration of Helsinki** (with its revisions and clarifications) represents the cornerstone document of human research ethics: it contains a set of ethical principles regarding human experimentation developed for the medical community by the World Medical Association.

The fundamental principles are respect for the individual (Article 8), their right to self determination and the right to make informed decisions (Articles 20, 21 and 22) regarding participation in research, both initially and during the course of the research. The investigator's duty is solely to the patient (Articles 2, 3 and 10) or volunteer (Articles 16, 18), and while there is always a need for research (Article 6), the subject's welfare must always take precedence over the interests of science and society (Article 5), and ethical considerations must always take precedence over laws and regulations (Article 9).

We strongly agree that ethical committee evaluation and informed consent should be mandatory for high risk studies and for those initiated by pharmaceutical companies and for new drugs or devices, but less cost and less bureaucracy are appropriate for SMART studies. The need for local ethical committee approval, bureaucracy costs and specific additional insurances costs should be eliminated for SMARTs studies. This step will markedly improve the amount and quality of scientific data available to clinicians to improve their ability to make decisions in the best interest of patients.

By stopping the evolution of trial medicine, paradoxically, ethical committees' interpretation of the Helsinki declaration principles is killing patients.
Many decisions in clinical practice are made by chance or according to individual preferences, but, if systematically studied in large populations of patients, they may generate precious information to improve daily clinical practice.
In this context, a softening of the bureaucratic itinerary for SMARTs protocols by local ethical committees is needed.

In particular, we suggest a revision of current practice, and the separation of SMART studies, for which the approval of a local ethical committee, stipulation of a specific insurance and other bureaucracy are waived or markedly simplified.

In order to guarantee that the principles of Helsinki are, anyway, respected, we have developed the following proposal.

All these studies should:

1) be registered on an international on-line database (visible to everyone).
2) receive written approval from at least 15 independent physicians working in at least 5 different nations in at least 2 different continents. These physicians should have experience in research activity (at least 20 papers already published in indexed journals), and should obtain all data that they consider necessary about the work before giving their written approval.
3) Offer all the patients the best available treatment

A central Ethical Committee will need to also give approval to confirm that the studies respect the criteria of a not-for-profit SMARTs study.

References

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