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A PGP-like component in Germany? A first progress report.

Motivation

Let me first get personal: During one of my late night conversations in the Church lab (member 1992 - 94) I formulated: “My scientific mission is the introduction of the individual into science, both conceptually and concrete”. Since the early eighties I had focused on the study of human inter-individual variation, and since 1990 I was keen on pursuing this theme at the ultimate level, that is, DNA sequence. And I dreamt of entire ‘galaxies of personal genomes’ then – it seems that with the PGP the wildest dreams come true, this is as far as it can get with the pursuit of human (genetic) individuality ...

First progress

I would like to inform you now about my first efforts to develop a PGP-like component in Germany. To make a longer story short: Where do we stand: We have a foot in the door, a panel of leading experts in Germany has agreed to a model project, where the option of data release at a later stage should be prepared by including it in the wording of informed consent. Given the picture at the outset, that could not necessarily be expected.

To begin with, it was entirely clear that in particular PGP’s decision to release data – to participants and the public – represented an ‘entire reversal of given research principles’. PGP was hardly compatible with German data protection and human study principles.

In my first interaction with the Head of the Ethics Committee at the Charité in Berlin, it was made very clear that such a project was unheard of and would go far beyond the scope of the Ethics Committee; the first, and key step, would be to work out an appropriate concept for data protection with the person in charge. As a consequence, I walked to the head of the science section of the Berlin data protection agency; the first of a series of interactions, I would like to say dialogues, took place March 14, Albert

Einstein's birthday. Similarly the Berlin officer conceived this undertaking as a matter that should ultimately be presented to a nation-wide forum of data protection experts; he operated in close exchange with the Chair of the Working Group "Science" of the data protection commissioners, who also is the leading expert on bio-bank issues in Germany.

To portray the big picture that emerged in the discussions:

Guiding principle is the maximum possible protection of participating volunteers from any risk or harm. The researcher is obliged to reduce or minimize the risks in a research study, and the volunteers carry the remaining risk by giving informed consent. The principles of data security include reduction of risk through implementation of appropriate security measures in data documentation, management and processing; in particular, at present, given the lack of generally binding regulations ("a big white hole") for the use of genetic data, appropriate solutions are being developed separately for each project involving the establishment of a bio-bank. In order to minimize the risk to be able to track the data back to a certain person, it is generally mandatory to de-identify the data at the earliest stage, such that not even the researcher should be able to establish relationships between the genotypes and phenotypes. Moreover, the principle of data security is complemented by a second guiding principle, data parsimony and avoidance, that is, to collect, process, or use a minimum only of personal data, or optimally to reduce personal data completely. In this context, a clear, recognizable hypothesis-driven research purpose supports defining the minimum amount of data necessary to test the hypothesis, and represents another approach to exert maximum control. This facilitates also establishment of rules for the researcher regarding the specific use of genetic data. An additional approach to reduce risk at a more general basis is a sensible selection of volunteers; one would select those with a permanent job, socially secure, secure health and life insurances etc. In fact, the first type of PGP-like model project proposed was to study one dead person. In one of the conversations/dialogues I asked why it should not be possible that a volunteer by virtue of his free will consents exactly to the opposite, to making data from his genome transparent to himself, the researcher and others. This could basically also be understood as a preservation of the 'Recht auf informationelle Selbstbestimmung'. The feeling was that where genetic data are being related to other, phenotypic or personal data, this would ultimately mean "pulling out all the stops",

and the state (government as the official authority) has to draw the line and protect the individual from his own “foolishness”, because foolishness threatens one’s very existence (again paternalism pure). At the end, these were all general opinions and practices, however, no specific, concrete suggestions could be made on how to move forward on a PGP-like component.

The top data protection officer of the Max Planck Society in charge was in fact much more positive when it came to satisfying the regulatory requirements for a PGP-like effort. He also recognized the possibly significant scientific potential of the project. The most he felt a tremendous responsibility when it came to the potential societal, political and institutional risks involved at the given time and climate, where in particular also data protection violations, for instance in the areas of telecommunication and banking confidentiality, sent daily shock waves through the news.

Taken together, there was a notable amount of uncertainty, also ‘insecurity’, and discrepancy in opinion, even between the experts, on issues of data protection, the more as legislation is still pending in Germany and the European Union. Moreover, everybody felt that the implications of this project were far beyond his/her scope. Even if a solution could be elaborated that conformed to regulations, which was considered possible after all, nevertheless, the related issues of societal, political and institutional acceptability, in particular the impact upon the public trust in science and scientists and in the leading institutions such as the Max-Planck-Society, were considered even more complex. At last, the ethical and regulatory implications, notably the issue of conformity with key requirements for approval as set by medical ethics in Germany and in Europe needed clarification. As a consequence, I decided to move the discussion of this project to a broader forum, optimally the key experts.

Thus, I organized a Round Table entitled ‘A Personal Genome Project in Germany?’ with the leading experts (and national opinion leaders) in all areas involved, the areas of data protection and IT, biomedical ethics and philosophy, social science, public health, human molecular genetics and genome science. The goal was to explore, whether, how, and to what extent a German component of the PGP could be realized, taking also the European context into account.

The Round Table was in conjunction with a Dahlem-Lecture on the PGP at the Max-Planck-Institute I had invited George to, and followed the lecture; thus, the participants had the opportunity to have a direct exchange with the Principal Investigator and “world-famous” professor from Harvard Medical School, and in particular also to obtain background information on the Harvard Institutional Review Board (IRB) approval process, and approaches towards risk management. All invited came. The Chair of the Working Committee of Medical Ethics Commissions in Germany, at the same time Chair of the Steering Committee on ‘Bioethics’ at the Council of Europe in Brussels, even interrupted his vacation, and another national opinion leader, Member of the German Ethics Council and former candidate for German Presidency even cancelled a conflicting event at the Berlin-Brandenburg Academy of Sciences. Naturally I also had invited Jeantine.

Needless to say that George did a fantastic job. All participants were actually pretty happy about two and half very interesting hours and discussions.

Preliminary outcomes were:

- There exists a basic consensus about the usefulness of a first model project involving a limited number of selected individuals, under the condition that personal data will not be made publicly accessible in the way it is intended by the Harvard-PGP. The option of public availability at a later stage, however, should be prepared for by including it in the wording of the informed consent; actual publication will, however, require explicit consent (that is, re-consent) at a later stage.
- In this context, there is clear consensus about the requirement that a German PGP-like initiative will have to be adapted in order to be compatible with the specific existing legal and institutional framework as well as with the political and societal environment.
- A German PGP-component will be able to use the advantage of following the development of the Harvard-PGP with a delay, which will allow building on experiences and insights gained in the ongoing research project in the US – thus, I do hope that you will move forward fast.

- The discussion on publication of volunteers' comprehensive data sets could be opened again, once the scientific and societal values suggest that doing so will yield substantial benefits to all parties involved;
- Related to the point above: a close monitoring of the media coverage in the US and in Europe of the publications from and the public acceptance of the PGP.
- At last it appeared helpful to stimulate (local) media coverage of the Harvard-PGP to test its public acceptance in Germany / European context.

A next step would be to work out a draft position paper as a working basis. Altogether, this is not bad for the first half of a year.

Also, I do have already identified first suitable candidates ready to play a leading role in a German PGP-like component. To bring the report on my first attempts to a close, I would like to communicate to you now a mission statement from the first PGP-volunteer, Ursula Goldmann-Posch.

Ursula Goldmann-Posch is a breast cancer patient and a medical journalist, founder and member of the executive board of the patient self help organizations 'mamazone - women and genomics against breast cancer' (www.mamazone.de), PATH-Foundation - The Patients' Tumor Bank of Hope (www.stiftung-path.org) and the PONS-Foundation for a better Follow-up of Breast Cancer (www.pons-stiftung.org). Goldmann-Posch is author of well-known books such as 'The lump above my heart', and 'The breast cancer survival book'. Her voice:

"I am convinced that even the ordinary patient is responsible for contributing to progress in research on human disease. I have demonstrated this by being the founder of the World's first tumour bank run by women with breast cancer for women with breast cancer, with over 20,000 samples to date.

"Each of us should, if and where possible, establish the basic right to know, or not to know, our personal genome, and should neither be prevented from obtaining, nor protected against, such knowledge.

"When I make my personal and medical records publicly available to the scientific community I do it not only from a sense of global responsibility for scientific research, but also out of personal curiosity in my genes. Knowledge does empower, even though it may not mean a cure.

“The future success of science must be based on a partnership between researchers and patients. Science can only motivate people to play an active part in research if there is a balance between giving and receiving information. When an individual patient has laid bare their medical records, they must have the right to free reciprocal communication of the results and outcome of research. It is the patient, after all, who makes these results possible through his willingness to participate.”

At the end, I do want to thank George for his continued support as well as Jeantine for help; I would like to exchange with all of you PGP-10 in admiration of your generosity and courage, and those involved in this effort personally, and establish close ties across the ocean for mutual support.