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Abstract:	This report describes the activities of the HBP Ethics and Society Programme and summarises the results from SP12 Work Packages for the Ramp-Up Phase.
Keywords:	Ethics, Society, Responsible Innovation, Foresight, Philosophy, Public Dialogue, Engagement, Stakeholders, Awareness, Governance, Regulation, Ethics Committees, EAB.

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Executive Summary

The HBP is committed to upholding and implementing the principles of Responsible Research and Innovation (RRI) in all its research and development. Subproject (SP) 12 is the hub of RRI in the Human Brain Project (HBP). This report describes the activities and results of the HBP Ethics and Society Programme for the first 30 months of the Project (the “ramp-up” phase), with a particular emphasis on the last 12 months.

WP12.1 Foresight: industrial, economic and social consequences of the HBP

In WP12.1, the Foresight Lab focussed on the three major themes of the HBP, for each of which it has delivered a Foresight Report: Foresight Report on Future Medicine (D12.1.1), Foresight Report on Future Neuroscience (D12.1.2) and Foresight Report on Future Computing/Robotics (D12.1.3).

- The report on Future Medicine identified two key areas where social, legal and ethical questions arose: a) issues of data protection and data privacy that must be considered when accessing and analysing patient records; b) the nature and consequences of the search for brain-based ‘signatures’ of psychiatric and neurodegenerative diseases, and their use in personalised medicine. The report identified a number of key “emerging challenges” and formulated a series of 18 recommendations for action to address these issues.
- The report on Future Neuroscience focused on two topics: a) building an infrastructure for Future Neuroscience, b) building a community for Future Neuroscience and made a series of recommendations under those two main headings.
- The report on Future Computing and Robotics, to be delivered in M30, will focus: 1) on the single broad category of ‘intelligent machines’ (the topic has been framed in this way because it is not clearly possible to sustain the distinctions between ‘robots’ and ‘non-robots’ on the one hand, and virtuality and materiality on the other hand), and 2) on some of the wider social and ethical challenges associated with the development of intelligent machines and robots, notably those concerning affective relations between humans and machines, and those concerning the wider socio-economic implications of the expanding use of robotics in the home, the workplace and beyond.

All these reports have been prepared on the basis of a series of research activities: extensive research on relevant literature, discussions with key experts, co-organisation of webinars, seminars and workshops with a variety of stakeholders.

WP12.2 Conceptual and philosophical issues

WP12.2 examined the philosophical and conceptual bases and implications of HBP research, and the ethical and epistemological issues raised by HBP research. During the Ramp-Up Phase, WP 12.2’s main focus was on how brain simulation can help provide a unified and multilevel understanding of the human brain, and how this understanding might give us insights into the human mind and consciousness:

- The concept of simulation: WP12.2 proposed a comprehensive practical taxonomy of simulation, and placed the goals of computer brain simulation within it. WP12.2 also discussed in greater detail the role of context in brain simulation. The results will be included in a forthcoming HBP-report (Task 12.2.1’s second Milestone report – MS220) "The Contextual Brain. The Necessity of Extraencephalic Worlds for Virtual Brains."
- In its MS219 report on how far brain simulation can explain the mechanisms of the mind, WP12.2 analysed the complexity of the human brain, and the difficulties in identifying and examining the biological, social and contextual underpinnings of mental functions that confound the study of the causes and pathophysiology of mental disorders. In forthcoming articles, Azgad GOLD & Yadin DUDAI have continued this

study and addressed the merits and limitations of animal models and computer models in the study of human mental disorders.

- Brain knowledge and consciousness disorders: WP12.2 scrutinised the numerous ethical issues raised by the neurotechnological assessment of residual consciousness in disorder of consciousness (DOC) patients. WP12.2 has explored several of these in a series of articles [6,7], one co-authored with SP3, on how to understand the relationship between brain activity, the target of neuroimaging, and mind-reading [8]. WP12.2 also explored what kind of consciousness DOC patients could retain. Finally, WP12.2 has begun exploring how to assess the capacity of DOC patients to make an appropriate, informed decision.
- WP12.2 worked on cultural imprinting on brain architecture, especially through the concept of “epigenetic rules”. WP12.2 discussed the relationships between genotype and brain phenotype, including the paradox of non-linear evolution between genome and brain complexity, the selection of cultural circuits in the brain during development, and the genesis and epigenetic transmission of cultural imprints. WP12.2 analysed the combinatorial explosion of brain representations, and the channelling of behaviour through "epigenetic rules" and top-down control of decision-making.
- WP12.2 has focused specifically on privacy related issues raised by HBP research and on privacy-related concerns raised by the possibility that brain-imaging based neuroscientific studies might provide insights into other people’s thoughts, perceptions, and emotions and thus render their cognitive freedom completely illusory. WP 12.2 is providing a critical examination of the privacy-related concerns raised by each of the HBP platforms and identifying the main conceptual tools that can be employed to address them.

WP12.3 The public, dialogue and engagement

WP12.3 has organized the different dialogue activities both with the general public, and with external experts and stakeholders. In T12.3.1, Milestone M222 was achieved in M20: the first online deliberation took place from 06.05.15 to 14.05.15. It has gathered more than 100 participants and focused on the Future Medicine component of HBP. The consultation’s results have been analysed and described in an internal report that will be made public at the end of the Ramp-Up Phase. It is attached as Annex A of the present document.

In February 2016, the Human Brain Project (HBP) hosted citizen meetings (T12.3.2) in Austria, Bulgaria, Poland, Portugal, the Netherlands and Sweden. The HBP citizen meetings were set up to provide the public with an opportunity to reflect on issues related to privacy and data protection in research projects, and to provide their ideas and opinions directly to the researchers and managers of the HBP. The meetings, and the associated materials, were all held and developed in the national languages. T12.3.3 sequentially developed activities under the three main themes of the HBP: *future medicine, future neuroscience and future ICT/robotics*. The activities related to each of the three main issues moved from activities outlining the issues toward more specific and solution-oriented stakeholder involvement activities. All activities were followed up with a newsletter outlining recommendations made during the activities.

Among the main outcomes of the stakeholder forums are the interactions and discussions initiated among external research and the HBP experts. Recommendations from the seminars have also made it into SP8 responses to Ethics Reviews of the Project (concretely the recommendation to perform an ‘Privacy Impact Assessment (PIA)’. Below, we present the recommendations coming out from the two seminars we held so far, and a few experts from commentary we received from HBP researchers following our events. All results are publicly available. Results of citizen meetings in Poland and Austria can be found in Annex B of this document.

WP12.4 Researcher awareness

The aim of WP12.4 was to foster ethical and social reflection within the HBP Consortium, and in particular among young researchers, clinicians and technology developers.

Task T12.4.1 “Ethical and Social Perceptions in the HBP” sought to explore the ethical and social perceptions of scientists in the HBP, using:

- Interviews with the initial set of directors of the HBP, which provided questions for
- A survey of the ethical and social views of HBP researchers and their perceptions of responsible research and innovation in their areas of expertise (MS225, MS226).

The survey was to be followed by specific research in areas of concern, using interviews and focus groups as well as a series of half-day workshops at major HBP sites. A change of goals was initiated by the need to respond to the requirements of EC’s ethical review (Ares(2015)927096 - 03/03/2015), which identified an inability to gain a detailed insight into the work on governance in general and compliance in particular. Addressing this required that the ethics and compliance efforts be systematically handled and be more profound in terms of the methodologies and communication tools, with the goal of strengthening the ethical and legal compliance in theProject. The report went on to determine that the ‘governance gap’ between delivery and requirements could not be bridged by the resources available to WP12.5 (Governance and Regulation) alone.

WP12.5 Governance and regulation

In direct response to the EC’s requirements, WP12.4 and WP12.5 pooled resources and began joint working on Ethics Management, which is covered in Section 7 below. After planning future activities, it was agreed that the Researcher Awareness workshops would be focused on the following activities:

- Establishment of the ethics rapporteurs (ERs) and the new Ethics Advisory Board (EAB) (Institut Pasteur, Paris, M21)
- Human data protection (HBP Summit, Madrid, M25)
- Management of ethics and compliance in large organisations and the issues raised by big data (Novartis Campus, Basel, M30)

In the meantime, the first researcher survey was closed, after receiving no more responses after M21, thereby achieving Milestones MS225 and MS226.

From M24 on, all SP12 work packages have also worked together with EAB members on a “Opinion on Data Protection and Privacy”, that shall be published soon after the end of the Ramp-Up Phase. It identifies some of the main privacy related concerns within HBP, articulates the basic ethical principles that should guide examination of the issues, and presents a brief review of the history of data protection and regulation in Europe, focusing on the current state of such regulation. They will offer final recommendations that are intended to minimize potential risks while securing the public benefit anticipated from HBP research.

1. Aim of this Document

This report will describe the activities of the HBP Ethics and Society Programme and summarise results from the work of the Foresight Lab (WP12.1), studies of ethical and philosophical issues (WP12.2), from the public awareness and researcher awareness programmes (WP12.3 and WP12.4) and from the governance and regulation activities (WP12.5).

2. Foresight Studies (WP12.1)

2.1 Goals and Nature of the Activities

WP12.1 (King's College London) aims to evaluate the potential social, ethical, legal, and economic consequences for Europe of new knowledge and technologies produced from the work of the HBP. In order to do this, it established the HBP Foresight Lab (T12.1.1), which conducts systematic foresight exercises to identify and evaluate these potential impacts. In the Ramp-Up Phase, the Foresight Lab focussed on the three major themes of the HBP, delivering a Foresight Report on Future Medicine (D12.1.1), a Foresight Report on Future Neuroscience (D12.1.2) and a Foresight Report on Future Computing/Robotics (D12.1.3).

2.2 Main Outcomes

2.2.1 Foresight Report on Future Medicine

The Foresight Lab's initial focus was on future medicine, and the its Report on Future Medicine was delivered on time, at the end of M18 (March 2015). It focussed on the work of the Medical Informatics Platform in the HBP (SP8), particularly its aim to 'federate' clinical data on patients with psychiatric and neurological diseases from hospitals and research sites in Europe and elsewhere, and to 'mine' these data in the hope of identifying 'brain signatures' of disorders which could, in the longer term, inform 'personalised medicine'.

In M1 to M18, WP12.1 undertook a series of research activities. In addition to extensive research on relevant literature, including previous reports from ethics and related bodies in various European countries, and many discussions with key experts, the Foresight Lab teams co-organised webinars, seminars and workshops with a variety of stakeholders. This it did to establish expert views, understand the responses and concerns of civil society organizations, and develop an evidence base for the analysis of the likely implications of developments in medical informatics over the next five to ten years.

In order to facilitate this work, WP12.1 developed productive collaborations with all WPs in SP12, and in particular with T12.3.3 (Danish Board of Technology Foundation), and with WP12.4 (De Montfort University),. We contributed suggestions and feedback to their tasks, while they provided us in return with ideas and material content for our task. For example, the interviews conducted by the WP Research Awareness provided data on the ethical and social perceptions among the HBP researchers. In addition, to ensure integration and maximise collaboration within SP12, a number of stakeholder consultation activities were organised in coordination with WP 12.3 (T12.3.3), and especially with P16, Fonden Teknologirådet (Danish Board of Technology Foundation). For example, the Foresight Lab held a **joint webinar with SP8 researchers and non-HBP scientists and stakeholders** in May 2014 which focussed on "Multi-level brain data federation and protection" and the "Development of 'disease signatures' and personalized medicine".

On the basis of these research activities, WP12.1 developed a series of scenarios, relating to each of the two main questions that emerged in these activities – 1) data protection and privacy, and 2) disease signatures and the 'personalisation' of medical interventions for psychiatry and neurological disorders. Each scenario hypothesised a different degree of success of the Medical Informatics Platform in achieving its objectives, explored the problems that might be faced in implementing these objectives, and dramatized potential public and stakeholder responses. WP12.1 then organised further events at which HBP scientists and stakeholders met to discuss these scenarios and comment on any new concerns. In particular, the scenarios were used to stimulate discussion during the **one-day seminar on future medicine**, held in Copenhagen on the 9th of October , with non-HBP stakeholders and SP8 researchers.

The first report on Future Medicine was prepared on the basis of this research and the evidence that The Foresight group had generated. The report identified two key areas where social, legal and ethical questions arose: a) issues of data protection and data privacy that must be considered when accessing and analysing patient records; b) the nature and consequences of the search for brain-based 'signatures' of psychiatric and neurodegenerative diseases and their use in personalised medicine. The report identified a number of key "emerging challenges" and formulated 18 recommendations for action to address these issues.

2.2.1.1 Data federation and privacy

Data protection and data privacy present major challenges for the federated organisation of the HBP Medical Informatics Platform which our Foresight research suggested will be key to the future of the Project. WP12.1 identified three such challenges that are interwoven in the multi-layered architecture of the MIP: legality, trustworthiness, and privacy. Some of these may be addressed by measures for technology management; others can be addressed by developing community building activities around the MIP, including clinicians, the pharmaceutical industry and other professional stakeholders, as well as patient groups and the general public.

On the basis of this work, and discussions with the directors and researchers of the Medical Informatics Project, WP12.1 made a number of recommendations focussing on the governance structure of the Medical Informatics Platform, the need to conduct a privacy impact audit, a research audit, and to consider scenarios for misuse; the crucial importance of obtaining informed consent wherever possible and an evaluation of the consent requirements for the MIP in the light of this; the development of protocols for the engagement of stakeholders, including patient, patient support and stakeholder groups; and the development of a public engagement and research dissemination plan.

2.2.1.2 Disease Signatures and Personalised Medicine

Many challenges are raised by the interpretation of complex biological and clinical data to identify signatures that may be clinically useful in the diagnosis and treatment of mental disorders. Further challenges arise if such signatures are used to identify predispositions or susceptibilities to disorders. These challenges include the recognition and interpretation of statistical clusters within data, identifying when a particular biological signature is an indicator for a disease, translation of findings into protocols and guidelines for clinical practice, ensuring appropriate use of disease signatures by clinicians and patients, and preparing the regulatory and governance infrastructure for what is often termed 'personalised' or 'precision' medicine. Many of these can only adequately be addressed though strong consultation and engagement with affected communities.

On the basis of our Foresight work on disease signatures, WP12.1 made a number of recommendations, intended to ensure that an effective partnership is created with patients, clinicians and other potential users of disease signatures. These focussed on the need to include patients and clinicians in a research advisory capacity; to address the implications of disease signatures in mental disorders for clinical practice and clinical ethics; to consider the clinical and ethical challenges arising when brain signatures are used in an attempt to identify pre-clinical susceptibility; the need for a communication strategy and a public engagement programme and - crucially - the engagement of other research communities and relevant regulators to develop appropriate pathways for translation of research to clinical applications.

Some of these recommendations have already been incorporated into the developing structure and processes of the MIP, others will require action by others as the work of the Human Brain Project develops. Our report was widely disseminated within and beyond the HBP, and WP12.1 is working with other WPs within SP12, and with the other members of the HBP, to encourage implementation of the recommendations. These collaborations embody the principles of Responsible Research and Innovation, and aim to ensure that the work of the HBP is directed to meet the major challenges posed by psychiatric and neurological disorders to contemporary individuals, families, communities and societies.

2.2.2 Foresight Report on Future Neuroscience

The second theme of WP12.1 focussed on future neuroscience. The Foresight Report on Future Neuroscience (D12.1.2) was delivered on time (Month 24). This work was originally planned to explore the conceptual and epistemological questions raised by different approaches to model building in neuroscience, exploring their characteristics (top-down, bottom-up) and the different relations between data and models, experimenters and modellers. However, after a technical review run by the European Commission, some relevant initiatives organised by the HBP Consortium, and a workshop organised with the support and collaboration of the Fondation Brocher (Hermance, Switzerland), it was decided to focus on the study of the possibilities, issues and practicalities in collaborative neuroscience, paying heed to the collaboration between diverse brain modelling communities and approaches.

The report thus focuses on two topics: a) building an infrastructure for Future Neuroscience, and b) building a community for Future Neuroscience. In writing the report, the Foresight Lab considered the challenges faced by the teams designing and building the Neuroinformatics and Simulation Platforms.

The Foresight Lab found that the main challenges they face broadly align with two essential components of the HBP strategic objective for Future Neuroscience: scaling small data and bridging scales. WP12.1 focused also on the factors that may determine the success or failure of potential neuroscience transitions; that is to say, the social factors involved in building a neuroscience community which can take advantage of what the HBP has to offer. These issues were studied in the frame of a short timescale, because the Foresight teams believe that they may have implications for strategic decisions that have to be made concerning the management of that aspect of the HBP’s work.

The workshop hosted by the Fondation Brocher on ‘Future Neuroscience and the Human Brain Project: Building a Neuroscience Community: community modelling and data repositories’ was organised by the Foresight Lab (WP12.1) in collaboration with Andrew Davison (SP5 and SP9) and Jeff Muller (SP13). The aim was to explore possibilities, issues and practicalities in collaborative neuroscience, with a specific focus on collaboration between diverse brain modelling communities and approaches. At present, there is considerable fragmentation of models and approaches to model building and simulation in neuroscience, and - in particular - in relation to modelling whole brains. The purpose of this workshop was thus to help develop a practical strategy for community building around brain modelling research; to build a roadmap for integrating the tools that this requires; and to clarify the role of the HBP and its Platforms so that they can provide the best and most appropriate services for the neuroscience community.

The workshop consisted of short talks from selected participants addressing these issues from their own perspective and experience, together with workshop discussions on a number of key "collaboration challenges" with the aim of making plans as to how these might be addressed. Presentations were given by various subprojects of the Human Brain Project; representatives of other brain initiatives (Open Source Brain, Open Worm, the Virtual Brain project) and data repository projects (G-Node, CARMEN, NeuroElectro); as well as researchers from different disciplinary specialties beyond neuroscience and computer science (sociology, information systems, law). Among the participants were members of the HBP SP12, clinical doctors specialized in neurology, and members of scientific research, policy, expert advisory, and ethics groups from across Europe. This diverse set of persons came together to discuss community building and consider how the neuroscience research of the immediate future can benefit the public.

Based on WP12.1 research and discussions, the Foresight Report on Future Neuroscience made a series of recommendations under two main headings.

2.2.2.1 Building an infrastructure for Future Neuroscience

In this section, we considered the challenges faced by the teams designing and building the Neuroinformatics and Simulation platforms. We found that the main challenges they face broadly align with two essential components of the HBP strategic objective for Future Neuroscience: scaling small data, and bridging scales.

A research and innovation technological infrastructure reflects and embodies a certain social organisation involving power relations. Therefore, technological fixes cannot always replace social solutions. At the individual level, incentives and success metrics for new academic profiles (curators;, 'bridge scientists', etc.) must be found to reward the sharing of data. At the interpersonal level, trust and mutual understanding should be encouraged. We recommended the development of a flexible strategy for an improved communication flow between the various individuals and entities.

We also pointed to the need for dedicated curators of data and metadata within the Neuroinformatics Platform, who have the appropriate interdisciplinary background to address the challenges of scaling up small data and bridging scales, to identify possible complementarities and to act as broker between research groups. We also drew attention to problems that might arise if the modelling and simulation work of the HBP over-privileged structural and morphological characteristics of the brain to the detriment of key aspects like plasticity and neuromodulation.

2.2.2.2 Building a community for Future Neuroscience

This section focused on the factors that may determine the success or failure of potential neuroscience transitions; that is to say, the social factors involved in building a neuroscience community which can take advantage of what the HBP has to offer.

Building an infrastructure to support Future Neuroscience must include and reach out to the broader community that can, and wants to, make use of this infrastructure. It is therefore necessary to consider how design decisions can affect the social organisation of the future research community, consulting with potential users in the design process.

Since interdisciplinary collaboration is an intrinsic part of this process, it is important that sufficient resources and time are allocated for establishing interdisciplinary work. Moreover, support should be developed for new academic profiles (curators; 'bridge scientists') and in some cases, for new methods for assessing unusual interdisciplinary research output.

A participatory research community needs to encourage individual researchers to understand their role within the community; this is why a programme of researcher awareness should aim to support researchers' knowledge of their own role and impact within the research community, and to include researchers' interactions with other potential user communities, especially clinical neuroscience and patient communities.

2.2.3 Foresight Report on Future ICT and Robotics

Information and Communication technologies play multiple roles in the vision of the HBP. On the one hand, ICT is a tool to enable the better integration of neuroscientific knowledge and the building of models and simulations. As the HBP Website puts it, the HBP:

> "aims to achieve a multi-level, integrated understanding of brain structure and function through the development and use of information and communication technologies (ICT). These technologies will enable large-scale collaboration and data sharing, reconstruction of the brain at different biological scales, federated analysis of clinical data to map diseases of the brain, and the development of brain-inspired

> computing systems. Through the HBP's ICT platforms, scientists, clinicians, and engineers will be able to perform diverse experiments and share knowledge with a common goal of unlocking the most complex structure in the universe... The development and use of ICT over the HBP's 10-year lifetime will pave the way for theProject's ultimate goal, simulation of the whole human brain" (https://www.humanbrainproject.eu/en_GB/mission).

On the other hand, the HBP's High Performance Computing Subproject (SP 7) seeks, not only to provide resources for the work of other parts of the HBP, but also to become a major driver for the development of ICT in Europe, and to undertake "path-breaking ICT technology research. Key topics for research will include novel accelerator technologies addressing highly scalable computational challenges, the use of hierarchical storage-class memory to increase available memory by more than an order of magnitude per core, and the realisation of interactive supercomputing at the exascale level, in particular interactive computational steering, visualisation and Big Data integration…" (https://www.humanbrainproject.eu/en_GB/high-performance-computing-platform).

This work is linked to that of another Subproject on Neuromorphic Computing (SP 9) which aims to develop two neuromorphic computing platforms which model biologically realistic neurons and synapses, and will ideally radically reduce power consumption (the human brain has remarkably low energy consumption of around 20 watts, many hundreds of thousands of times less than a conventional supercomputer which has a fraction of its computing power). One approach, led by the UKs SpiNNaker group has pioneered a system "using scalable digital many-core systems operating at real time with low power" … "that allows real-time simulation of networks implementing complex, non-linear neuron models. A single chip can simulate 16,000 neurons with eight million plastic synapses running in real time with an energy budget of 1W…" (see https://www.humanbrainproject.eu/en_GB/neuromorphic-computing-platform1). The other approach using hardware based Neuromorphic Physical Model (NM-PM) developed from the European FACETS program "incorporates 50*106 plastic synapses and 200,000 biologically realistic neuron models on a single 8-inch silicon wafer in 180nm process technology…" (see http://www.kip.uni-heidelberg.de/cms/vision/projects/facets/neuromorphic_hardware/), allowing it to simulate complex, non-linear neuron models in faster than real time.

Ultimately, the outputs of these two Subprojects will not only feed into the central aim of simulation of the human brain, but also link to the work of a third Subproject, Neurorobotics (SP 10), "in which a virtual robot is connected to a brain model, running on the HPC platform or on neuromorphic hardware… the HBP platform will be the first to couple robots to detailed models of the brain. This will make it possible to perform experiments exploring the link between low level brain circuitry and high-level function" (see https://www.humanbrainproject.eu/en_GB/neurorobotics-platform1).

These ambitions form the focus of the 3rd Foresight Report; delivery is anticipated to be on time by the end of March 2016. Two main strategies were used in this work. The first was to collect and analyse the views, attitudes and strategies of key stakeholders with methods from the empirical social sciences. To that end, WP12.1 carried out an extensive period of 'horizon scanning', examining the literature, both academic and popular, and identifying key themes and questions. This task was made more complicated by the fact that these issues are currently the topic of intense speculation, both fact based – as in the many reports on the implications of ICT and robotics for industry, health care, domestic life and much more – and highly speculative – as in predictions about the supplanting of humans by artificial intelligence, the 'singularity' and so forth. Nonetheless, attempting to distinguish fact from fantasy and to focus on the near term, the Foresight teams distilled a number of key themes, which they then used as the basis of webinars with key stakeholders. WP12.1 held two webinars co-organized with the Danish Board of Technology which focussed on key themes of dual use (military/civilian), intelligent machines, human-robot interaction, machine-learning, and brain computer interfaces. In these webinars, which were open to an invited audience of 25-35, WP12.1 gathered together key questions in advance, from literature and discussions with researchers inside and outside the HBP. During the webinar, together with other participants, the Foresight teams posed key questions about future directions, potential alternative pathways, risks and benefits, and recorded and analysed the debates that took place. Participants were also invited to continue the debate after the Webinar and, in this case, WP12.1 teams were delighted to see an extensive email debate between key researchers in the HBP and external experts on many issues, but notably on the theme of machine intelligence and machine consciousness. In previous reports, the Foresight Lab also used some more systematic foresight techniques, including scenario construction based on narrative and fictional short scenarios (vignettes), and then used questions concerning those scenarios to explore key questions. However, as already suggested, we are currently surrounded by such imaginary scenarios, on television and film, in discussions on the radio and the internet, so WP12.1 decided not to add its own scenarios to these, but to work on the basis of imagined near-futures already in wide circulation.

This analysis highlighted the many interdependencies existing between different parts of the Human Brain Project and, through them, the close and often reciprocal relations existing between the various fields of research involved, and their applicative domains. This has led the Foresight Lab to conclude that there is a need for a systematic,Project-wide review and analysis of the synergetic potential, that would lead to the development of a Responsible Research and Innovation roadmap for building on them. In order to contribute to such a roadmap, in this foresight exercise WP12.1 adopted a deliberately holistic approach to capture some of the deep interconnections existing across the HBP, and we have singled out two cross-cutting topics that help identify broad social and ethical challenges related to the potential contributions of the Human Brain Project for future ICT in the light of wider developments and trends: intelligent machines and human-machine integration. Firstly, the single broad category of ‘intelligent machines’ was considered. The topic has been framed in this way because it is not clearly possible to sustain the distinctions between ‘robots’ and ‘non-robots’ on the one hand, and virtuality and materiality on the other hand. Secondly, WP12.1 explored some of the wider social and ethical challenges associated with the development of intelligent machines and robots, notably those concerning affective relations between humans and machines, and those concerning the wider socio-economic implications of the expanding use of robotics in the home, the workplace and beyond.

2.2.3.1 Intelligent machines

Many participants in the Human Brain Project use a restrictive definition of Artificial Intelligence and argue that the Project has nothing to do with Artificial Intelligence. However, in the report, WP12.1 found that the forums and initiatives aimed at thinking through its potential beneficial and detrimental developments for society usually adopt a broader understanding of the term. For these reasons, the Foresight Lab recommends that the Human Brain Project must recognize that a number of subprojects across the Project will collectively contribute to the broader field of machine intelligence, and act upon it. Hence WP12.1 recommends that the decision makers and researchers work closely with the Social and Ethical Division, and with others outside the HBP, to engage with current debates around how to make Artificial Intelligence ethical and socially beneficial and bring the weight of publicly-funded, open research to bear on them.

On the basis of the Foresight work in this area, WP12.1 identified a number of key questions, some of them near-term concerns, of relevance to the potential outcomes of the Human Brain Project. Among the most important were: the need to consider how to regulate and control increasingly powerful and sophisticated data processing across borders where different laws might apply; the need to protect user privacy from predictive algorithms and ensure informed consent of data processing; and the question of whether society will benefit from the increased efficiency of intelligent machines or wealth will be increasingly concentrated in the hands of few individuals.

These and related questions are especially important as the Human Brain Project, one of the two Future and Emerging Technology Flagships of the European Union, enters Horizon 2020, the funding programme that will implement the Innovation Union, which outcomes are notably expected to position Europe as a world-class competitor in ICT research and digital innovation, through 'open science' and the development of innovative public-private partnerships.

The report also considered issues of human-machine integration, emphasising the need to bring humans firmly into the ICT picture and focusing on some of the relationships (already existing or expected) between the human and the machine, keeping in mind that in the context of the Human Brain Project, this means not just computer scientists and engineers but also neuroscientists, clinicians and patient, and eventually a wide array of potential users – literally, everyone. Here WP12.1 focussed on the two strands of the applicative strategy of the Neurorobotics subproject (SP10) for the operational phase of the Project: specialized robotics for industrial, household and healthcare applications; and neuroprosthetics, including neural and brain-computer interfaces. They are especially interesting for the various – and material – ways in which they can integrate with the human, thus providing a good testbed to contrast the two approaches suggested by key commentators in this area: the 'rationalistic' that tends to 'replace' the human and the 'design' which aims to 'enhance' the human.

2.2.3.2 Wider social and ethical challenges

This discussion of Human-Machine relations led onto a further analysis of the issue of 'Affective Computing'. In most discussions of artificial intelligence, it is the cognitive capacities of computers that are at the forefront. However, the increasing sophistication and greater uptake of intelligent machines raises issues of the emotional or affective dimension of the relation between humans and such intelligent machines. The recognition of emotions is an important part of human to human communication, providing the context and sometimes the content of communications. *Affective Computing* is the ability of computers to recognise human emotions and thus to be able to respond more appropriately. The broader concerns of affective computing also involve conveying such emotions, or simulations of them, accurately during interaction, as a human would expect in a conversation with another human. In this respect, the simulation of emotions might play a key role in influencing the human user, increasing persuasiveness, and perhaps seeking to generate a particular desired emotional response in the user, shaping decisions and actions at a level below that of the individual's awareness.

In this part of the report WP12.1 also considered a number of other issues, including the use of robots in care work in the home and the challenging problem of 'robot ethics' and ethics for roboticists. It also looked at the need for anticipatory Life Cycle Assessment that incorporates knowledge of the extended life cycle of the product (including materials sourcing, energy efficiency and waste or recycling planning) into the design criteria, allowing for future uncertainty and unpredicted outcomes in the results of a life cycle assessment (use, misuse, creative use, sourcing, mis-sourcing, creative sourcing, disposal, mis-disposal, creative disposal or recycling, etc.). WP12.1 considered issues of appropriate regulation for robotic innovation, and how these might affect different applications, and stressed the importance of follow-through on Foresight reports to enhance researcher awareness and the capacity of those in the HBP at all levels to reflect on the potential psychological, social and ethical implications that might follow from the translation of their (often basic) research into applications and their active engagement in the public debates on these issues.

2.2.4 Dual Use

In addition, The Foresight Lab collaborated with T12.3.3 and WP4.5, the European Institute for Theoretical Neuroscience, to organise a HBP seminar on Dual Use of Future Computing and Robotics, on 10-11 March 2016. The material coming out of this seminar will not be reported here, but will be used in future research activities of WP12.1 under the SGA1.

3. Neuroethics and Philosophy: Studies of Ethical and Philosophical Issues (WP12.2)

3.1 Goals and Nature of the Activities

WP12.2 examines the philosophical and conceptual bases and implications of HBP research, and the ethical and epistemological issues raised by HBP research.

During the Ramp-Up Phase, WP 12.2's main focus was on how brain simulation can help provide a unified and multilevel understanding of the human brain and how this understanding might give us insights into the human mind and consciousness. The task of WP12.2 is the identification, articulation, analysis, and critical assessment of relevant conceptual issues. Many of the practical ethical issues raised by the HBP and its goals are related to those of more general philosophical significance — concepts such as simulation, consciousness, human nature and identity, and problems in philosophy of mind, epistemology, and moral philosophy. WP12.2's scholarship centres on these theoretical issues. It is crucial to unveil them, both to fully capture the ethical and social implications of the HBP, and to properly address and manage them in the future. This research provides not only a conceptual analysis of implications of having a unified knowledge of the brain, but also a conceptual and ethical analysis of human brain simulation in the HBP, its limits, aspirations and implications for our understanding of consciousness and the human mind.

WP 12.2's work is especially relevant to SP2 Strategic Human Brain Data, SP3 Cognitive Architectures, SP4 Theoretical Neuroscience, SP6 Brain Simulation, and SP10 Neurorobotics. It includes bilateral discussions between members of WP12.2 and SP members, and talks dedicated to the themes of the WP made by SP representatives at public conferences. The WP has been divided into two Tasks that are closely connected: T12.2.1 Simulation and Multi-Scale Theory of the Human Brain, and T12.2.2 Brain-Mind Relationships.

3.2 Main Outcomes

3.2.1 Epistemology and Ethics of Simulation

3.2.1.1 Epistemological challenges of simulation

Simulation is a powerful method in science and engineering. However, simulation is an umbrella term, and its meaning and goals differ among disciplines. Rapid advances in neuroscience and computing draw increasing attention to large-scale brain simulations. Therefore, we asked: what is the meaning of simulation, and what should the method be expected to achieve? In their first article, Yadin DUDAI and Kathinka EVERS discussed the concept of simulation from an integrated scientific and philosophical vantage point, and pinpointed selected issues specific to brain simulation [1]. They proposed a comprehensive practical taxonomy of simulation, and placed the goals of computer brain simulation within it. They also identified and described a set of challenges and boundary conditions for current attempts at brain simulation. For example:

- The scarcity of neurobiological data: contemporary knowledge of the brain is limited, and the collection of data for large-scale brain simulation is not trivial. When federating data from different labs, even small differences in methodology and conditions can have an impact in terms of neuronal state and activity. The invariants identified may mask important features.
- Epistemic opacity: is the Vico maxim, that we can only understand what we can build, applicable to computer simulations of complex systems? Do we understand what we are able to imitate, model, or reconstruct – and in what sense?

- Representational parsimony: much of our scientific progress and understanding stems from our cognitive ability to extract and generalise laws of nature. Representational parsimony, describing the universe in a minimal number of equations, is regarded as the ultimate understanding. However, should we expect a small set of laws to adequately describe a complex adaptive system like the brain? Engaging in large-scale brain simulation is a question of knowledge-dependent timing, proper integration of multiple bottom-up and top-down approaches, and realistic expectations. This was done while interacting with a wide community of experimental and computational neuroscientists, engineers and modellers at multiple levels of analyses worldwide, inside and outside the HBP.

In their second article [2], DUDAI and EVERS discuss in greater detail the role of context in brain simulation. The results will be included in a forthcoming HBP report (Milestone 220 of Task 12.2.1) on the role of context in brain simulation: "The Contextual Brain. The Necessity of Extraencephalic Worlds for Virtual Brains." Ethical issues in simulation

The ethical analysis of brain simulation is a relatively new field of research, which is gaining an increasing multidisciplinary interest. However, at present the debate revolves mainly around the practical concerns raised by emerging neurotechnology, concerns that are not fundamentally different from those raised by emerging technologies in general. Arleen SALLES, Michele FARISCO and Kathinka EVERS have suggested that while valuable, this common approach is not enough to fully capture the issues at stake and propose the examination of conceptual understandings of the brain and of simulation in order to better grasp the ethical implications of simulation technology in particular [3]. Increasing evidence shows that values and emotions play a crucial role for explaining brain development and human behaviour. The brain is described as an emotional, selective system in which values are incorporated as necessary constraints. From a naturalistic, biological point of view, a brain is necessarily and intrinsically characterized by values, i.e. by factors which affect and eventually determine choices, selections, and decisions (e.g. moral reasoning). These values are fundamentally sensitive to reward signals: the brain determines the different degrees of relevance of the available stimuli, selects and stabilizes models of the world according to an intrinsic, and essentially reward-sensitive phenomenality [4].

The above-mentioned cerebral features (reward-sensitivity and values) thus form the basis for a biological foundation of moral reasoning. In this perspective, the capacity for moral reasoning is an intrinsic feature of the brain. This raises questions such as: if simulating the brain includes the simulation of reward-sensitivity and emotional systems, will it result in simulating moral reasoning as well? In the process of answering this, we have begun to re-examine the meaning of certain key notions, such as "simulation" and "moral reasoning". Simulating the brain could be defined as an attempt to develop a mathematical model of the cerebral functional architecture and to load it onto a computer in order to artificially reproduce its functioning. In this way, we can prospectively better describe, explain and predict cerebral activities. Within our naturalistic framework, moral reasoning is an evaluative predisposition of the brain, through its sensitivity to reward and emotional systems. This entails the acknowledgement that the context in which the brain operates plays a crucial role in shaping its reasoning, including its moral reasoning, which is an interactive feature between the brain and its natural and cultural environments. As a consequence, the extent to which brain simulation is relevant for simulating moral reasoning partly depends on its ability to simulate also the context in which the brain is located. In short, the possibility of brain simulation poses complex metaphysical and ethical questions such as: what does it really mean to simulate the human brain? If possible, how will brain simulation affect our understanding of the human mind, and the mind-body problem? Will brain simulation enable simulation of the capacity to build normative systems? WP 12.2 is engaged in developing a conceptual framework that can be used to further analyse these concerns.

3.2.2 Simulation, Mind & Consciousness

3.2.2.1 Simulating the human mind

WP12.2's second line of research focused on how simulation is connected to understanding the mind and consciousness.

In neuroscience, problem-orientated computer simulations of specific systems and functions of the brain are used extensively to test predictions, validate conclusions and models, and to guide hypothesis-driven experiments and new models at various levels of analysis. In addition, rapid advances in neuroscience and computing draw increasing levels of attention to large-scale brain simulations. Against this background, WP12.2 asks: "how far can brain simulation contribute to explaining the brain and the mind?" The analysis defines the first three goals of brain simulation:

1) Serve as part of the rapidly expanding, rich methodological and technological toolkit of modern neuroscience.
2) Serve as a device in the planning, development and testing of brain-inspired technologies, such as bionic devices and hominid robots.
3) Contribute to the understanding of the brain and the mind.

Three types of issues relate to the potential explanatory power of large-scale brain simulations. These are methodological and technical issues, conceptual and philosophical issues, and those that refer to the role of consciousness. We still know very little about the role of consciousness, and therefore consider it as an issue of "type unknown". Methodological and technical obstacles are likely to be reduced or even resolved as the field develops, but conceptual issues may stay with us irrespective of scientific advances. A major example is epistemic opacity, i.e. the cognitive inaccessibility of intermediate steps in a highly complex process or mechanism. This remains, irrespective of whether the process or mechanism can be simulated on a computer, or the phenomenological outcome can be predicted. This type of profound and long-lasting conceptual obstacle should be taken into account when managing expectations of an improved understanding of the brain and mind. These results were included in the SP12 MS219 first report on how far brain simulation can explain the mechanisms of the mind. In this report, WP12.2 analysed the complexity of the human brain, and the difficulties in identifying and examining the biological, social and contextual underpinnings of mental functions that confound the study of the causes and pathophysiology of mental disorders. Large-scale computer simulations of the human brain were recently proposed as a method to circumvent some of these difficulties. A development of previous results will be included in a forthcoming report and article mentioned above [2].

3.2.2.2 Simulating mental disorders

In two forthcoming articles, Azgad GOLD and Yadin DUDAI discuss selected conceptual and pragmatic issues related to mental illness simulation, and to computer simulation in particular [5]. The authors first address the merits and limitations of animal models and computer models in the study of human mental disorders. They highlight the need to tailor the vehicle and method of simulation to the goal of the simulation, and suggest future directions for maximising the usefulness of mental illness simulation. They argue that at the current state of knowledge, the biological-phenomenological gap in understanding mental disorders significantly limits the ability to generate high-fidelity biological and computational models of mental illness. Simulation focusing on limited realistic objectives, such as mimicking distinct biological and phenomenological attributes of specific mental symptoms, may, however, serve as a useful tool in exploring mental disorders.

3.2.3 Neurotechnology, Robotics and Consciousness Disorders

Over the last few years, neurotechnological tools and methods have been developed to assess residual consciousness in patients with DOC. Notably, the identification of activated brain areas and the real time observation of cerebral activity could potentially allow for a new form of technology-based communication, i.e. through neuroimaging or Brain-Computer Interfaces (BCI). This would entail communication be in the absence of observable external behaviour or speech, thus going beyond the behavioural manifestation of awareness. This kind of communication, which we call "cerebral communication", raises epistemological, ethical and metaphysical issues. WP12.2 has explored several of these in a series of articles [6,7], one co-authored with SP3, on how to understand the relationship between brain activity, the target of neuroimaging, and mind-reading [8]. In view of the compensatory nature of brain functioning, WP12.2 also explored what kind of consciousness disorder of consciousness (DOC) patients could retain. Finally, as these analyses develop, WP12.2 has begun exploring how to assess the capacity of DOC patients to make an appropriate, informed decision. WP12.2 has scrutinised the numerous ethical issues raised by the neurotechnological assessment of residual consciousness in DOC patients. These include how to assess residual capacity of self-determination; whether, and to what extent, a prospective cerebral communication may be valid for informed consent; and whether the prospect of direct communication with DOC patients via neurotechnology requires clinical management, and the role of legal guardians, to be revised.

The role of brain simulation in studies of consciousness, and in communication with patients, is still at the proof of concept stage. However, the theoretical possibility of its application, and empirical results achieved thus far strongly urge continued reflection on its possible clinical use and the ethical issues it may raise. To illustrate, cerebral communication with these patients raises important theoretical as well as practical issues, such as the patient's effective ability to understand and process information and integrate the information provided so as to be able to make a coherent personal decision. Also, the diagnosis of DOCs is affected by an astonishingly high rate of error, estimated as around 40%. The use of technology, including simulation, to assess covert awareness gives us a new possibility for rightly diagnosing DOCs.

Further studies are needed particularly on the following: the assessment of possible obstacles in the use of neurotechnology, such as simulation, for assessing and in the long run communicating with minimally conscious patients; refinement of the technologies in order to disentangle voluntary from involuntary brain activity; training of patients on the use of BCI; definition of the extent or type of brain damage that is still compatible with communicating through BCI; investigation of possible functional brain remapping affecting patients’ capacity to process information; and evaluation of the adequacy of patients’ understanding of the necessary information.

Moreover, the inference at the basis of present communication protocols with speechless subjects (i.e., from neuronal activity to mental and conscious activity) is problematic and deserves more attention, both empirically and conceptually [7]:

- Empirically, the important role played by the resting state in regard to consciousness, as recently revealed by neuroscience, raises the necessity to include the intrinsic activity of the brain and its changes in evaluating the relevance of the brain's reaction to external stimuli as evidence of consciousness: the sole reaction is not enough to infer conscious reaction, because we need a non-linear resting state change.
- Conceptually, the gap between brain and consciousness, even if reduced in the light of recent neuroscientific achievements, needs more theoretical work.

New neurotechnological tools for investigating consciousness and implementing new forms of communication potentially promise huge improvements of speechless subjects' life conditions with strong ethical relevance [9]. Among other possible implications, this raises the need to translate the new technologies from the lab to the bedside, i.e. to increase the clinical translation of new neurotechnologies, putting clinicians in the condition to rightly interpret and use these technologies. This technological development is also relevant in the case of other conditions than consciousness disorders [10].

3.2.4 The Brain in Social Contexts

Whilst much brain activity is spontaneous and intrinsic, the brain is also outwards-oriented and fundamentally social. The human brain juxtaposes opposite tendencies; it is engaged in highly individualistic and self-projective actions, but it also mediates co-operative social relationships. In WP12.2's analyses of the role of contexts in brain simulation, research has focused on the following domains:

3.2.4.1 Cultural Imprinting on Brain Architecture.

The human brain is an evaluative organ with reward systems engaged in learning, memory, and higher evaluative tendencies. It is our innate species-specific neuronal identity, which causes us to develop universal evaluative tendencies. These include self-interest, control-orientation, dissociation, selective sympathy, empathy, and xenophobia, some combinations of which can cause problems. As previously mentioned, our neuronal identity makes us social, but also individualistic and self-projective. However, synaptic epigenetic theories of cultural and social imprinting on our brain architecture suggest the possibility of culturally influencing these predispositions. In an analysis of epigenesis by selective stabilisation of synapses, we discussed the relationships between genotype and brain phenotype. These include the paradox of non-linear evolution between genome and brain complexity, the selection of cultural circuits in the brain during development, and the genesis and epigenetic transmission of cultural imprints. WP12.2 analysed the combinatorial explosion of brain representations, and the channelling of behaviour through "epigenetic rules" and top-down control of decision-making. In neurobiological terms, these rules are viewed as acquired patterns of connections (scaffoldings), hypothetically stored in frontal cortex long-term memory, which frame the genesis of novel representations and regulate decision-making in a top-down manner. Against that background, WP12.2 has proposed being "epigenetically proactive" [11, 12], and adapting our social structures in both the short and the long term, to benefit, influence and constructively interact with the ever developing neuronal architecture of our brains.

3.2.4.2 Human Identity

It is commonly believed that brain research will have an impact on human identity. For example, new treatments such as deep brain stimulation, neural grafting, and prostheses as clinical and therapeutic tools for treating diseased regions of the brain could raise questions about personal identity. The concern is that neuroscientific advances might alter a person's cognition, moods and behaviour, thus changing who they are as an individual. Brain simulation would raise an additional identity-related issue: if consciousness were achieved via simulation, would that be human consciousness? Attempting to answer requires understanding what is meant by "human identity". Since talk of identity can refer both to generic considerations that humans are supposed to share, and to concerns about individuals' self-conceptions and identity, it is crucial to distinguish between two kinds of identity concerns: those related to human identity (identity of humans *qua* humans), and those related to personal identity (numerical and narrative). During the Operational Phase, WP12.2 will focus on two tasks. First, the team will continue research on ethical and conceptual issues raised by a unified understanding of the brain. Special attention will be paid to the role of contexts and cultural imprinting on brain architectures, and to examining aspects of the mind, and its role in identity, consciousness and notions of the self. The second task will explore the philosophical and ethical challenges raised by rapid advances in neuroscience and computing, such as the modelling of cognitive processes in silica, which draw increasing attention to large-scale brain simulations. It will focus on consciousness, self and identity.

3.2.5 Privacy

During the Ramp-Up Phase, WP12.2 has worked on what we can consider specific and more general privacy-related concerns. We have focused specifically on privacy related issues raised by HBP research and generally on privacy related concerns raised by the possibility that brain-imaging based neuroscientific studies might provide insights into other people's thoughts, perceptions, and emotions in the absence of outwardly observable behaviour or speech and thus render their cognitive freedom completely illusory.

3.2.5.1 Neuro-Imaging and Privacy Concerns

Some non-clinical uses of neurotechnology raise unique moral challenges. At present neuro-imaging combined with complex statistical analysis allows a more detailed decoding of people's mental states. It is not unreasonable to think that Big Science projects such as HBP will move the technology beyond its current state. If so, there is the fear that some brain-imaging based neuroscientific studies will pose a novel threat, in so far as they might provide insights into other people's thoughts, perceptions, and emotions in the absence of outwardly observable behaviour or speech. In the process, they could significantly restrict people a domain that has always seemed private. What would this mean from an ethical standpoint? Would this be a problem? And how to address it?

In a forthcoming article, Arleen SALLES discusses the issue of mental privacy insofar as functional neuroimaging can reveal information about people's mental states and psychological traits [13]. SALLES highlights some efforts to approach the issue of functional neuroimaging and its possible threat to privacy in the neuroethics literature. She identifies two main strategies usually used in the discussion: the first consists in a description and discussion of what neuroimaging can and cannot do with a focus on the technical and methodological problems that bedevil the technology. The second focuses on the metaphysical assumptions about the mind underlying concerns on the subject of neuroimaging and mental privacy. Sometimes these two strategies are used jointly. There is a third strategy, less common in the neuroethics literature, that brackets technical, methodological, and metaphysical issues to put the focus on the discussion of normative questions. The questions raised are: why would neuroimaging's impinging on privacy be problematic? What is valuable about mental privacy? Would it be morally undesirable to have less of it? SALLES outlines the first two strategies clarifying their implications for the privacy debate, and then proposes to expand the normative discussion to incorporate some of the issues raised by a recent account of privacy as contextual integrity.

3.2.5.2 Privacy and Data Protection within HBP

Realizing HBP's goals (which include achieving a fuller understanding of the human brain, better diagnoses and treatment of brain disorders, and the development of new brain-like technologies) requires the collection, storage, curation and analysis of data of various sorts over extended periods of time. The promise offered by the research, however, is tempered by concerns over the extent to which it might threaten individual privacy. This is why securing privacy interests and advancing data protection measures are key concerns of the HBP.

The need to comply with the relevant regulation is uncontroversial. However, mere compliance with current regulations does not exhaust the ethical issue for two main reasons: 1- current oversight might not fully protect people from associated privacy related risks and 2- though necessary, legislation is not sufficient to make people more morally sensitive to privacy violations and more aware of the importance of respecting privacy and the need to meet the moral duties they might have towards those who provide the data.

Promoting moral sensitivity and awareness in the context of HBP requires the identification of the principles and of the relevant ethical considerations that underlie morally justified research. As co-author of SP12's Data Protection and Privacy Opinion, WP 12.2 is providing a critical examination of the privacy related concerns raised by each of the HBP platforms and identifying the main conceptual tools that can be employed to address them. This has led to an examination of the meaning and value of privacy and of the principles that ground generally accepted research ethical guidelines. Mindful of the scale of data handled by HBP researchers, we have also examined the advantages and disadvantages of some specific tools (for example, informed consent and anonymisation) that have been used to protect data. At present, we are involved together with other SP12 WPs in the formulation of final recommendations that are intended to minimize potential privacy risks while securing the public benefit anticipated from HBP research.

4. The Public, Dialogue and Engagement (WP12.3)

The goal of WP12.3 (Jean-Pierre CHANGEUX, Institut Pasteur, Lars KLÜVER, Danish Board of Technology Foundation) is to help the HBP create a constructive dialogue with public and private stakeholders and with the general public, maintaining an intense engagement with points of view external to the HBP, identifying emerging controversies, and formulating recommendations for HBP research and research priorities.

4.1 Goals and Nature of the Activities

WP12.3 is divided into three Tasks, each corresponding to a different kind of public and level of dialogue.

T12.3.1, HBP online deliberation invites large (n≥100) groups from the general public to identify and discuss their expectations and the issues arising from HBP research;

T12.3.2, European Citizens' Conventions, has the aim to involve European citizens actively in a broad and inclusive debate of the societal and ethical issues raised by the scientific work done in HBP, and the expected and actual findings achieved throughout theProject. It will gather communities of respondents and expose them to information about HBP scientific work, allowing them enough time to gain a deep understanding and express sensible recommendations.

T12.3.3 focuses on a dialogue between HBP participants and outside experts and stakeholders. The dialogue between HBP and non-HBP actors aims at strengthening the HBP researchers' understanding of the broader social, political, ethical, legal implications of their work. The HBP will raise questions of interest for researchers and experts in a wide range of fields, potentially causing controversies which can be anticipated by the forum debates. At the same time the input from the activities should be close enough to the life scientists' reality and everyday work, so that it can be directly used by them in their future work. The stakeholder activities will make use of a broad range of different means of interaction including workshops, seminars and thematic webinars.

4.2 Main Outcomes

4.2.1 Task 12.3.1 – Online deliberation

In T12.3.1, Milestone M222 has been achieved in M20: the first online deliberation took place from 6-14 May 2015. It has gathered more than 100 participants (French population sample) and focused on the Future Medicine component of HBP. The consultation's results have been analysed and described in a report that has been circulated amongst SP12 and will be made public at the end of the Ramp-Up Phase. It is available as Attachment 1 of the present document.

The participants have posted 3,586 messages on the platform, and the moderators have created 12 topics and 42 micro-polls. After thorough discussions about topics such as psychiatric and mental diseases in general and treatments for them, expectations towards science, big data in general and medical big data, and privacy concerns, respondents were introduced to two aspects of the HBP Medical Informatics Platform: the "brain signatures project" and the "data federation plan". The decision to focus on those aspects was motivated by the findings of earlier SP12 research activities, especially those of the Foresight Lab (T12.1.1, King's College, P32) and of the Stakeholders Forum (T12.3.3, Danish Board of Technology, P16) see [14] and [15]. Below are the exact texts describing the two key aspects of HBP SP8's program: they are deliberately kept simple, to let all the respondents understand its goals and characteristics.

The Data Federation System

- The Human Brain Project is a European scientific project, dedicated to research on the human brain, using simulation techniques and cutting-edge computing (high performance and neuromorphic computing)
- An important part of this Project focuses on the biological foundations of psychiatric and mental illness, in order to develop new medical therapies and more efficient drugs. Scientists will thus build a computing platform to gather huge volumes of data and perform statistical analysis on them.
- The HBP will use data coming from the medical records of patients cured for neurodegenerative, mental or psychiatric diseases in hospitals across Europe. Those data will be integrated into one central database according to these principles:
  - In each hospital partnering with theProject, the data contained in the patients' records will be anonymised and then sent to the central platform
  - On the central platform's side, the accredited researchers will access only aggregated data (not individual ones), i.e. sets of data coming from several individuals.

Table 1: Survey material on the "Data Federation System"

The Brain Signatures Project

- The Human Brain Project is a European scientific project, dedicated to research on the human brain, using simulation techniques and cutting-edge computing (high performance and neuromorphic computing)
- An important part of thisProject focuses on the biological foundations of psychiatric and mental illness, in order to develop new medical therapies and more efficient drugs. Scientists will thus build a computing platform to gather huge volumes of data and perform statistical analysis on them.
- The goal is to identify the neurobiological cause of mental diseases. Thanks to the advances of brain imaging, the researchers and the doctors try to understand which genetic factors or visible anomalies are responsible for psychiatric and mental diseases like schizophrenia, depression or bipolar disorder. Despite many efforts, those research programmes have not met success yet.
- The Human Brain Project's plan is to collect very large amounts of medical data and to apply statistical analysis to them, to discover "brain signatures", i.e. patterns of anomalies (of the brain or the genes) that are visible only when large volumes of data are aggregated, and are impossible to see in a few individual patients.
- If such « brain signatures » were to be found, one could understand mental and psychiatric diseases, not from the patients' apparent symptoms, but from biological data, from the "inside" (so to speak). It would make it possible:
  - To find new ways to diagnose brain diseases, by observing individuals' brains or their genetic data, and comparing them to the "brain signatures" that reveal the presence of an anomaly
  - To predict the chances to develop a mental or psychiatric disease more accurately
  - To develop new drugs and treatments

Table 2: Survey material on the "Brain Signatures Project"

Number	Start	Topic	Total No. of messages posted
1	Day 1	“Mental and psychiatric diseases”	278
2	Day 1	“Treatments for mental and psychiatric diseases”	231
3	Day 2	“Expectations towards Science”	130
4	Day 2	“Future treatments for mental and psychiatric diseases”	162
5	Day 2	“What does it mean to be “normal”?”	139
6	Day 3	“Science and Big Data”	110
7	Day 3	“The goal(s) of data sharing”	104
8	Day 3	“Sharing individual data”	94
9	Day 3	“Medical data”	131
10	Day 5	“Sensitive data”	62
11	Day 6	“Brain signatures”	139
12	Day 6	“Data Federation Plan”	96

Table 3: Topics discussed during the online deliberation

Number	Start	Poll	Total No. of answers
1	Day 2	“Mental and psychiatric diseases are brain diseases” (rating scale)	128
2	Day 2	“There is no efficient drug to treat most mental diseases” (rating scale)	128
3	Day 2	“Mental and psychiatric diseases require support treatment” (rating scale)	128
4	Day 2	“Mental and psychiatric diseases are difficult to diagnose” (rating scale)	127
5	Day 2	“Mental and psychiatric diseases are true diseases” (rating scale)	130
6	Day 2	“Mental and psychiatric diseases are not diseases of the body” (rating scale)	131
7	Day 2	“The causes of mental and psychiatric diseases are …” (ranking from 1 to 4) “environmental” / “due to accidents or shocks” / “innate” / “unknown”	131
8	Day 2	“Mental and psychiatric diseases are a social handicap” (rating scale)	137
9	Day 3	“Drugs limit the effects of the mental and psychiatric diseases but do not cure them” (rating scale)	131
10	Day 3	“One can recover from a mental or psychiatric disease” (rating scale)	123
11	Day 3	“Medicine is resourceless against mental illness” (rating scale)	125
12	Day 3	“We know almost nothing about mental and psychiatric diseases” (rating scale)	127
13	Day 3	“What is your opinion of early diagnosis?” (single choice) “It is an improvement: first signs of the disease will be postponed” / “It is dangerous: some people will be a priori considered “abnormal”” / “I don’t know”	132

14	Day 3	“Mental and psychiatric diseases require personalized diagnosis and treatment” (rating scale)	125
15	Day 3	“The most important advance in mental and psychiatric diseases’ treatment shall come from…” (single choice) “science: to find the real (physiological, genetic…) causes and to develop truly efficient drugs is priority number one” / “society: to take care of the patients in a more human and attentive manner is priority number one” / “other”	126
16	Day 3	“Who do you expect solutions to the problems raised by mental and psychiatric diseases from?” (single choice) “scientific research (genetics, biology, chemistry…)” / “psychiatry and/or psychology” / “brain surgery” / “social science” / “other”	127
17	Day 3	“According to you, what is the top priority?” (ranking) “improve the patients’ follow-up care and support to avoid their social exclusion” / “identify the causes of the mental diseases and develop new and efficient curative treatments” / “find new drugs that limit the effects of the psychiatric and mental diseases”	130
18	Day 4	“Science will find more efficient drugs in order to deal with mental diseases’ effects” (rating scale)	130
19	Day 4	“Science will make it possible to cure the mental affections” (rating scale)	128
20	Day 4	“Science will discover the causes of mental illness” (rating scale)	130
21	Day 4	“In your opinion, what is the most efficient treatment for mental and psychiatric diseases?” “Speech (psychotherapies…)”/ “chemistry (drugs…)” / other	139
22	Day 4	“Did you know about “big data”?” (single choice) “Yes I already knew that notion”/ “I had heard about it but did not really know what it was about” / No, I discover “big data” here!	117
23	Day 4	“Big data will help scientific advances” (rating scale)	112
24	Day 4	“Big data will help spying or watching over people” (rating scale)	114
25	Day 4	“It is impossible for individuals to control the use of their personal data” (rating scale)	114
26	Day 4	“Large-scale data sharing will benefit the individuals” (rating scale)	112
27	Day 4	“Large-scale data sharing will benefit the big companies” (rating scale)	116
28	Day 5	“I am afraid that my sensitive data become publicly accessible” (rating scale)	117
29	Day 5	“I feel I can control my personal data sharing” (rating scale)	119
30	Day 5	“To centralize medical data and make them workable for scientists is a good idea” (rating scale)	117
31	Day 5	“Sharing medical data will break medical confidentiality” (rating scale)	119
32	Day 5	“Medical data must remain healthcare system’s ownership ” (rating scale)	118

33	Day 6	“In your opinion, what are the most sensitive data?” (ranking) “medical data” / “banking data” / “political opinions” / “religious opinions” / “sexual preferences” / “legal precedents” / “daily life data”	122
34	Day 6	“Who must control the diffusion of medical data?” (single choice) “patients” / “doctors” / “hospitals” / “social security” / “other”	128
35	Day 6	“Are you in favour of data sharing in general?” (rating scale)	119
36	Day 6	“Are you in favour of medical data sharing?” (rating scale)	125
37	Day 7	“The “brain signatures” research programme…” (single choice) “…seems to put aside very important factors in the development of mental and psychiatric pathologies, like traumas or environment” / “seems to carry out a possible revolution in the understanding of mental and psychiatric diseases”	104
38	Day 7	“Is large scale patients’ data federation dangerous?” (single choice) “Not really, and the small risk is worth taking if new treatments can be developed” / “Yes, I am afraid that patients records will be used by third parties”	104
39	Day 7	“To detect psychiatric and mental diseases’ forerunners… ” (single choice) “is very promising: patients will be managed way sooner and the progress of the disease may be slowed down” / “worries me: it may stigmatize “persons at risk” who could very well not develop a disease”	103
40	Day 7	“What about patients’ records and their informed consent ?” (single choice) “It is a small risk worth taking: the databases are stored in hospitals and currently not used, whereas they could contribute to a major scientific breakthrough” / “This is unacceptable: no medical data should be used without the patient’s informed consent, even with a rigorous anonymization process”	104
41	Day 7	“How positive is your final opinion about the programme you have been presented?” (rating scale)	103

Table 4: Polls created during the online deliberation

The main results from the deliberation can be summarized by the following points:

- Mental diseases are perceived as “true” diseases, caused by physical factors
- Mental diseases raise major social issues (more than other diseases)
- Only management drugs exist for mental and psychiatric diseases, not curative ones
- Expectations are:
  - to develop better tools to avoid exclusion (short term)
  - better drugs, at least for symptoms’ management, and scientific understanding (middle and long term)
- Big Data in general is a source of concern

  - Big data is not a well-known concept
  - Purpose of big data in scientific contexts is not self-evident
  - Cost-benefit analysis of the consequences of large-scale data sharing: an obvious benefit for big companies, but not for individuals
- Big Data sharing in the medical field is more acceptable than big data sharing in general
- Overall understanding and appreciation of SP8 plans (federation of hospitals data and brain signatures) is positive even if social benefits of the program are not very tangible.
  - HBP future medicine component seems to have a strong scientific potential and should lead to important new discoveries
  - The general public generally trusts the scientific and medical communities with the respect for privacy and anonymization of personal data.

4.2.2 Task 12.3.2 - European citizen conventions

In February 2016, the Human Brain Project (HBP) hosted citizen meetings in Austria, Bulgaria, Poland, Portugal, the Netherlands and Sweden. The HBP citizen meetings were set up to provide the public with an opportunity to reflect on issues related to privacy and data protection in research projects, and to provide their ideas and opinions directly to the researchers and managers of the HBP. The meetings, and the associated materials, were all held and developed in the national languages. All local organisers received a standard manual with instructions and guidelines for citizen recruitment. They all received online training on recruitment in a webinar, as well as held regular online meetings with the DBT main coordinator to discuss progress and questions (the online meetings were facilitated by WebEx software). All the citizen meetings followed the same format:

- Introduction to the meetings and key points from the background information folder
- Filling in of questionnaires
- Group interviews

All local organisers worked from the same standard instruction manual for the set-up and facilitation of the meetings, as well as received individual training and instructions before hosting the meetings (using WebEx software). An introduction and sample material (e.g. background information folder, short program, and template for the PowerPoint introduction and structure of the meetings) from the EU citizen meetings can also be found on our webpage (http://www.tekno.dk/article/citizen-meetings-in-the-human-brain-project/?lang=en).

The report of the six meetings will be based on short reports of the local organisers, together with an analysis of questionnaires from each meeting. The local organisers will use a standard template for reporting. The report will include the citizen’s recommendations for how to develop a policy for privacy protection and data management. The results of the citizen meetings will also feed into the collected SP12 opinion produced as an overall SP12 result from the Ramp-Up Phase.

Where	When	Local DBT organiser(s)
Austria (Vienna)	January 30, 2016	Anja Gänsbauer & Ulrike Bechtold
Poland (Warsaw)	February 6, 2016	Zuzanna Warso
Portugal (Lisbon)	February 6, 2016	Silvia Di Marco & Mara Almeida
Bulgaria (Plovdiv)	February 13, 2016	Zoya Damianova
The Netherlands (Breda)	February 20, 2016	Tjerk Timan
Sweden (Malmö)	February 27, 2016	Edward Andersson

Table 5: Overview of the European citizen meeting in Human Brain Project in the Ramp-Up Phase

At the time of writing, the results from the meetings are being collated. In the present report we can already introduce a few preliminary findings. The results from the Austrian and Polish citizen meeting showed how citizens neither feel well-informed about the use of their personal data by third parties (Figure 3), nor do they know where to find information about how their personal data is being used.

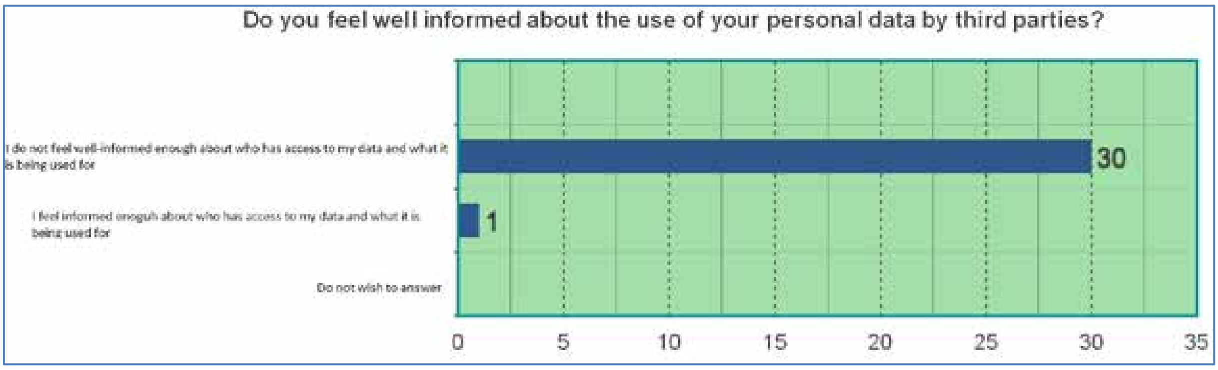

Figure 1: Results from the Austrian citizen meeting: Citizens perception of their insight into how their personal data is used by third parties

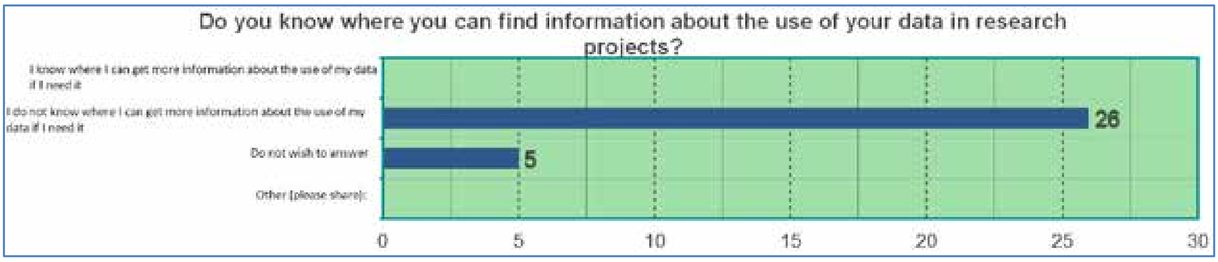

Figure 2: Results from the Austrian citizen meeting: Citizens perception of their insight into where to find information on the use of their personal data by third parties

The picture was very similar for Poland, where the majority of the participants also answered that they were unsure both about how their data is used, and how to find out for themselves how their personal data is used. The collated answers to all the questions of questionnaires can be found in Attachment 2.

Figure 3: The Polish citizen meeting on privacy and data protection in research projects. The pictures show the citizens engaged in group discussion, and filling in the questionnaires.

4.2.3 Task 12.3.3 – Stakeholder forums

T12.3.3 sequentially developed activities under the three main themes of the HBP: *future medicine, future neuroscience and future ICT/robotics*. The activities related to each of the three main issues moved from activities outlining the issues toward more specific and solution-oriented stakeholder involvement activities. All activities were followed up with a newsletter outlining recommendations made during the activities (see Tables 4, 5 and 6 for the complete overview).

Among the main outcomes of the stakeholder forums are the interactions and discussions initiated among external research and the HBP experts. Recommendations from the seminars have also made it into SP8 responses to Ethics Reviews of the Project (concretely the recommendation to perform an 'Privacy Impact Assessment (PIA)'. Below we present the recommendations coming out from the two seminars we held so far, and a few experts from commentary we received from HBP researchers following our events. All results are publicly available.

Policy options for the HBP Project:

- Clarify responsibilities: Who is responsible for data protection and security?
- Perform privacy impact assessment
- Follow 'good anonymisation practices' as laid out in EU Opinion 05/2014 on Anonymisation Techniques
- Make sure subcontractors follow good anonymisation techniques. Even better: avoid subcontracting
- Stamp data with the type of consent given
- Develop a Partnering Project on the privacy concerns in the Core Project
- Seek informed consent where at all possible
- Improve transparency and trust by:
  - Engaging in collaboration and dialogue with patient associations and external experts
  - Manage expectations by being realistic about outcomes and the research process to patients, medical professionals and the public
  - Listen to concerns and adapt accordingly

Table 6: Recommendations from the seminar "Expert dialogue on multi-level data federation in the Human Brain Project", 9 October 2014.

Recommendations from the seminar:

- Communicate more about the research being done in the Subprojects
- The Project should still have several objectives, e.g.:
  - Assist in understanding how brains fail
  - Take a particular disease or drug design as a starting point
  - Network building between internal and external researchers could be a success in itself
- Develop plans for how the horizontal integration should take place. It will not ‘just happen’.
- Find a point of connection between bottom-up and top-down approaches and create a bridge between the molecular and the cognitive level (multi-level integration)
- Prioritize building in plasticity and neuromodulation in the ICT brain models
- Set up a ‘brainstorming structure mechanism’ where crazy ideas can develop and be tested

Table 7: Recommendations from the seminar “Theory and data for advancing future neuroscience and the Human Brain Project”, 21-22 May 2015

Type of activity and date	Title	Brief description and link	HBP collaborators
Webinar on May 7th 2014	Multi-level brain data federation and protection	Experts in law, ethics and social science presented their thoughts and concerns on the data federation architecture of SP8, and HBP researchers and experts engaged in discussion. http://www.tekno.dk/article/webinar-on-future-medicine-in-the-human-brain-project/?lang=en	SP12, HBP Foresight Lab (KCL) SP8 (CHUV)
Webinar on May 7th 2014	Development of 'disease signatures' and personalised medicine	Experts in philosophy, ethics and disability studies and social science presented their thoughts and concerns on the HBP plans for developing new disease signatures, and HBP researchers and experts engaged in discussion. http://www.tekno.dk/article/the-search-for-personalised-medicine-and-new-insights-in-diagnosis-of-mental-health-illness/?lang=en	SP12, HBP Foresight Lab (KCL) SP8 (CHUV)
Workshop on October 9th 2014	Expert dialogue on multi-level data federation in the Human Brain Project	External experts in law, ethics and social science, met with the HBP SP8 researchers to develop recommendations for solutions to privacy concerns of the SP8 data federations architecture. http://www.tekno.dk/article/seminar-on-future-medicine-in-the-human-brain-project/?lang=en	HBP Foresight Lab (KCL) SP8 (CHUV
Newsletter published December 2014	Living up to privacy and informed con-sent in the Human Brain Project (HBP)	Presented the discussions and recommendations. http://www.tekno.dk/wp-content/uploads/2014/12/1-HBP-newsletter.pdf	HBP Foresight Lab (KCL) SP8 (CHUV)

Table 8: Overview of activities under the HBP key theme Future medicine

Type of activity	Title	Brief description and link	HBP collaborators
Webinar, January 7th, 2015	Dual use and neuroscience: An online debate on current developments	Experts in dual use issues presented their thoughts and concerns to a panel of HBP researcher, and together the group discussed these concerns. http://www.tekno.dk/article/dual-use-and-neuroscience-invitation-to-an-online-debate/?lang=en	SP12, HBP Foresight Lab (KCL) SP9 (KIP and UMAN)
Workshop, May 21 and 22nd, 2015	Theory and data for advancing future neuroscience and the Human Brain Project	The workshop collected (cognitive) neuroscientists external to the HBP to discuss the HBP's plans and approach. The aim was to address issues from the HBP mediation report. http://www.tekno.dk/article/opening-up-the-human-brain-project-to-the-neuroscience-community/?lang=en	SP12, Researcher Awareness (DMU) SP4 (CNRS/EITN) SP6 (EPFL) SP10 (TUM)
Newsletter, published October 2015	Opening up the Human Brain Project (HBP) to the neuroscience community	The newsletter collected up on the discussions from the workshop in Mya and the recommendations reached by the participants. http://www.tekno.dk/wp-content/uploads/2015/10/Newsletter_FutureNeuroscience_Community_HBP.pdf	

Table 9: Overview of activities under the HBP key theme Future Neuroscience

Type of activity	Title	Outcome	HBP collaborators
Webinar, October 9th, 2016	The future of robotics, brains and ICT	The webinar invited researchers outside the HBP to present their ideas and thoughts on the potential of HBP work in neuromorphic computing and robotics, and to allow for a discussion with the HBP researchers. http://www.tekno.dk/article/future-computing-and-robotics/?lang=en	SP12, HBP Foresight Lab (KCL) SP9 (KIP and UMAN)
Workshop, March 10-11, 2016	Dual use, future computing, Neurorobotics and the Human Brain Project	The workshop will pick up on the dual use issues from the webinar in 2015, and invite external experts to explore ways of mitigating dual use risk. http://www.tekno.dk/article/hbp-seminar-on-dual-use-of-future-computing-and-robotics/?lang=en	SP12, HBP Foresight Lab (KCL) SP4 (CNRS/EITN) SP7 (CSCS) SP9 (KIP and UMAN) SP10 (TUM)
Newsletter, to be published in March/April 2016		The Newsletter will collect up on the discussions and recommendations from the workshop.	

Table 10: Overview of activities under the HBP key theme Future ICT and Robotics

5. Researcher Awareness Programmes (WP12.4)

5.1 Goals and Nature of the Activities

5.1.1 Goals

The aim of WP12.4 was to foster ethical and social reflection within the HBP Consortium, and in particular among young researchers, clinicians and technology developers.

Task T12.4.1 “Ethical and Social Perceptions in the HBP” sought to explore the ethical and social perceptions of scientists in the HBP, using:

- Interviews with the initial set of directors of the HBP, which provided questions for
- A survey of the ethical and social views of HBP researchers and their perceptions of responsible research and innovation in their areas of expertise (MS225, MS226).

The survey was to be followed by specific research in areas of concern, using interviews and focus groups as well as a series of half-day workshops at major HBP sites.

A change of goals was initiated by the need to respond to the requirements of EC’s ethical review (Ares(2015)927096 - 03/03/2015), which identified an inability to gain a detailed insight into the work on governance in general and compliance in particular. Addressing this required that the ethics and compliance efforts be systematically handled and be more profound in terms of the methodologies and communication tools, with the goal of strengthening the ethical and legal compliance in theProject. The report went on to determine that the ‘governance gap’ between delivery and requirements could not be bridged with the resources available to WP12.5 (Governance and Regulation) alone.

In direct response to the EC’s requirements, WP12.4 and WP12.5 pooled resources and began joint working on Ethics Management, which is covered in Section 7 below. After planning future activities, it was agreed that the Researcher Awareness workshops would be focused on the following activities:

- Establishment of the ethics rapporteurs (ERs) and the new Ethics Advisory Board (EAB) (Institut Pasteur, Paris, M21)
- Human data protection (HBP Summit, Madrid, M25)
- Management of ethics and compliance in large organisations and the issues raised by big data (Novartis Campus, Basel, M30)

In the meantime, the first researcher survey was closed, after receiving no more responses after M21, thereby achieving Milestones MS225 and MS226.

5.1.2 Nature of activities

5.1.2.1 Director Interviews

After obtaining Human Research Ethics permission from DMU, and confirmation from WP12.5, nineteen directors and five senior staff members were identified as candidates for interview. After invitations and reminders, 20/24 (83%) directors and senior staff members were interviewed (15/19 [79%] directors and all senior staff). Interviews were conducted via telephone or Skype between December 2013 and June 2014, and lasted between 25 and 60 minutes. All interviews were transcribed in full and independently validated to ensure accurate representation of the audio recording. Analysis of 17/20 (85%) interviews from staff covering all work-packages was completed in August 2014, and after consultation and review, a final version was presented during the EU Review in M16.

5.1.2.2 First researcher survey

After obtaining Human Research Ethics permission from DMU and confirmation from WP12.5, data concerning members of SP lists and general e-mail lists were downloaded from EMDesk, and manually analysed. Although this determined who was known to the HBP, there were many people working on the Project who had not been recorded in EMDesk. A survey of participants was therefore initiated via SP13 management contacts. The survey began in M14, two months after the intended start date, and was sent to SP list members. The survey population was completed in February 2015, and further invitations were sent with a reminder in M17.

5.2 Main Outcomes

5.2.1 Director Interviews

The key findings of the Director Interviews can be summarized as recognition of the need:

- To strengthen the governance of human data
- To strengthen collaboration within the HBP
- To strengthen ethical compliance, for example ensuring that animal experimentation is handled according to regulations, especially when it is the only source of data
- To strengthen collaboration with scientists outside the HBP and the general public
- To improve communication about the science of the HBP

The report has proved influential in directing some of the work of Ethics Management. Since publication of D12.6.3 the First Ethics and Society Report in M16, steps have been taken to address the governance of human data, collaboration between each of the HBP's Subprojects and SP12's Ethics Management and ethical compliance.

5.2.2 First researcher survey

Thirty-seven per cent (266/713) of HBP researchers responded to the survey between its opening in M14 and its closure in M18 after an initial invitation and subsequent reminders.

The HBP Wide survey was completed by university or affiliated institution staff in 89% (233/261) of cases. Each Subproject was represented as were each of the component work packages. Likert-scale questions were asked around the themes of data protection; intellectual property and governance of the shared platforms; animal experimentation; research excellence; applications of brain signature research; development of collaboration and responsible research and innovation. The questions ranged from "strongly disagree" to "strongly agree" in 7 steps, with neutral being the mid-step. After scoring disagreement in the range -3 (strong) to -1 (some) and agreement from 1 to 3, an average score was calculated.

In regard of data protection there was agreement (represented by a positive average score) that individual consent should be provided for all human data used in the HBP, that the HBP should share responsibility with the collecting institution for the protection of personal data, that the HBP should appoint a designated officer responsible for privacy and data protection and that it should establish best practice for medical "big data" research. Respondents were neutral (zero average score) about whether public good outweighed concerns about privacy.

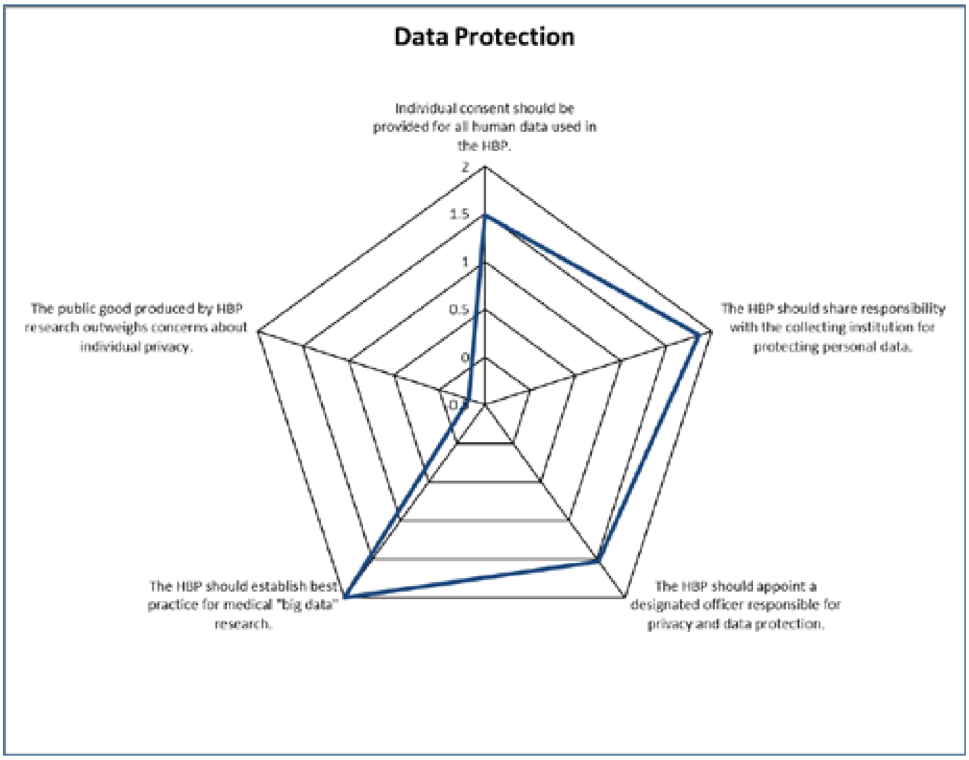

Figure 4: Radar plot of responses to questions about Data Protection.

With respect to the medical applications of HBP research, respondents agreed that the social and scientific consequences of identifying brain signatures need to be assessed by research and that the prevalence of brain signatures in the general population needs also to be assessed. They were neutral about whether it would be possible for a patient to challenge a psychiatric diagnosis based on brain signatures and against the concept that psychiatric disease can only be defined in terms of brain abnormalities.

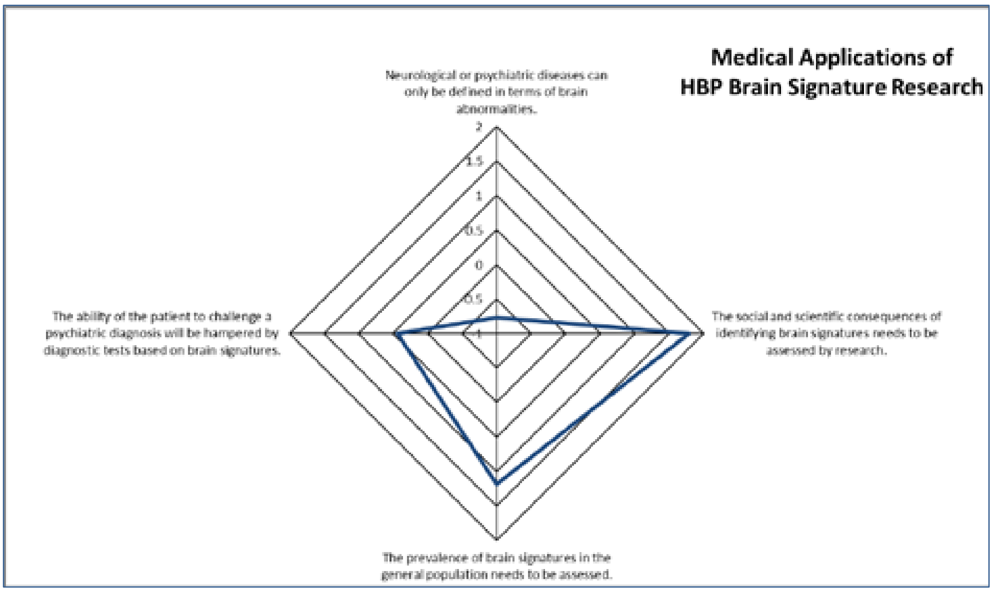

Figure 5: Radar plot of responses to questions about the medical applications of HBP research.

These responses are broadly in line with expectations one might have if the respondent were choosing an “ethical” stance; something that is borne out by analysis of the other themes in the survey. The conclusion is perhaps unsurprising because it is likely that only those who considered it important to express their views on ethical matters will have responded to the survey. In this light, a response rate of 37% suggests that a substantial minority of HBP staff are concerned about the ethical issues raised by theProject and hold broadly conventional views.

5.2.3 Workshops

5.2.3.1 Establishment of the ethics rapporteurs and the new Ethics Advisory Board

The workshop was attended by members of the Research Ethics Committee, the Ethical, Legal and Social Aspects Committee, which were to be combined to form the new EAB as well as ethics rapporteurs and SP12 members.

The EAB received reports on the results of the EC review (Ares(2015)927096 - 03/03/2015) and the consequent changes that lead to and the establishment of the Ethics Management. In addition, the EAB recommended that the Board of Directors (BoD) add an Ethics Manager to its number. (Subsequently the WP12.4 work-package leader was appointed as Ethics Manager in a non-voting role.) The merger of the ELSA and the REC was agreed as was the draft standard operating procedure (SOP), which was to go on to be ratified by the BoD in M25. More detail on the role of the EAB will be presented in section 7.

The workshop agreed that the ethics rapporteur programme should continue to be developed, with the aims to:

- Establish person-to-person relationships between the EAB, EM and each SP
- Increase mutual understanding of the technical work in each SP, as well as the ethical, social, and regulatory implications of such work.
- Encourage open discussion of the social, ethical and regulatory issues arising
- Establish a “buddy” system between the EAB and each SP
- Establish a ‘presence’ for Responsible Research and Innovation in each Subproject

The results were reflected in the creation of an Ethics Rapporteur Standard Operating Procedure which was approved by the BoD in M25. The further work of the rapporteurs is addressed in section 7.

5.2.3.2 Human Data Protection

This workshop was located in the HBP Summit in September 2015 in Madrid. It was attended by EAB members, ethics rapporteurs and SP12 members.

The workshop received presentations from the EAB about:

- Privacy models and data-anonymisation techniques
- Major trends in EU data protection law
- Ethical concepts and theories associated with privacy and data protection

After extensive discussion with many key stakeholders in the HBP, it was agreed that an opinion be written collaboratively, which brings together the research of SP12, the work of the EAB and the ERs with the aim of offering final recommendations that are intended to minimize potential risks while securing the public benefit anticipated from HBP research.

5.2.3.3 Management of ethics and compliance in large organisations and the issues raised by big data

This workshop will be attended by EAB members and ethics rapporteurs. A small number of SP12 members who supported the EAB will also be present.

At the time of writing, this workshop has yet to take place. Presentations will be made covering:

- Managing Compliance and Ethics in a Global Enterprise

- The IMI Experience – Lessons learnt in a Complex EU Flagship Program
- “Big Data” in the Context of the Pharmaceutical Industry: 2 Perspectives

In addition, there will be a number of focus groups involving the EAB and the ethics rapporteurs working on the ethical aspects of the HBP based on a set of factors identified by research following the Q-methodology.

5.2.3.4 Implications for future research

Ethical issues cannot be reduced to algorithms or prescriptions. The required moral positions need to be supported by judgements based on consideration of the relevant ethical issues. They will come not just from external “ethical experts”, but also from researchers reflecting upon the likely impact of their work.

While resistance to such work is not unusual, the precedent of raising researcher awareness, within the context of governance structures, has already been set in other areas of cutting-edge technological research such as nanotechnology and synthetic biology.

The Ramp-Up Phase of theProject has demonstrated the potential of the techniques used by researcher awareness to identify the issues that the HBP’s researchers need to consider as well as the capability to build the necessary relationships that will support the necessary reflective working.

Researcher awareness should act as a bridge between the governance and the regulation activities carried out by HBP Ethics Management and the research of SP12 Ethics and Society, each using the other’s results to refine the detail of their respective activities.

6. Governance and Regulation activities, Ethics Management (WP12.5)

6.1 Goals and Nature of the Activities

This goal of this Work Package is to support HBP decision-making on issues with significant social and/or ethical implications and to ensure that the Project fully complies with European and national legal and regulatory requirements.

As originally conceived, the Governance and Regulatory activities were to be conducted by carrying out the following tasks:

- Establishment and supporting the regular operation HBP’s Ethics, Legal and Social Aspects Committee (ELSA) and Research Ethics Committee (REC).
- Maintaining an ethics data registry
- Maintaining an information and interactive website on ethics procedures to support research ethics approval processes
- Maintain an agile responsiveness and alertness to potential, unexpected ethical, legal and social issues that may arise during the lifetime of the Project
- Communicating the official Project position on specific issues in research ethics
- Coordinating the HBP's participation in planned ethical reviews

The ELSA was to support HBP management on issues of policy and strategy whereas the REC was to support local research sites on regulatory issues and compliance. The committees were to operate by forming *ad hoc* groups to discuss specific issues as needed.

Review by the EC (Ares(2015)927096 - 03/03/2015) required that the ethics and compliance efforts be systematically handled and be more profound in terms of the methodologies and communication tools, with the goal of strengthening the ethical and legal compliance in the Project. A merger between WP12.4 and WP12.5 to create a new organizational body: Ethics Management provided the necessary resources.

The goals of ethics management evolved from those for WP12.5. They are:

- Development of the principles and implementation of Ethics Management
  - The principles of ethics management will be continually reviewed and updated as a result of feedback from the EAB, SP12 Ethics and Society research as well as close collaboration between Ethics Management and the various other organisational structures of the HBP, as well as the Board of Directors and its successors.
  - A key component of Ethics Management is the creation and maintenance of the HBP Ethics Map. This is the list and graphical representation of the various ethical and social issues that the HBP faces. The Ethics Map is populated through PORE and links with various other aspects of Ethics Management (notably HBP Ethics Registry and Ethical Issue Action Plans) as well as the broader Society and Ethics Subproject.
- Management and support of the Ethics Advisory Board (EAB)
  - The Ethics Advisory Board (EAB) is an independent body that advises the HBP on ethical, regulatory, social and philosophical issues. This body was formed by a merger between the ELSA and the REC.
- Management and support of the Ethics Rapporteurs
  - The ethics rapporteurs are nominated representatives and their deputies of each SP. Their task is to assist Ethics Management, SP12 Ethics and Society and the EAB

    in their work on ethical issues out of the research of the HBP. In discharging their role, ethics rapporteurs will be expected to:

        - Describe the activities of their SPs
        - Explain the results of their SP's research
        - Help identify potential ethical, legal or social issues
        - Make colleagues in their SP aware of the means by which they can communicate ethical, legal or social issues to ethics management
        - Participate in creating and disseminating relevant SOPs in their SPs
        - Support each other in the rapporteur role
        - Report on the implementation and impact of SOPs.

- Identification and triage of ethical issues (PORE)
    - The Point Of Registration of Ethical issues (PORE) will be an online application, which allows interested parties to submit ethical and social concerns regarding the HBP. Ethics Management will undertake initial triage and propose appropriate responses to be followed up by appropriate HBP organizational structures.
- Writing standard operating procedures
    - Practical standard operating procedures (SOP) will be written in consultation with relevant stakeholders, integrating them into broader HBP management structures and monitoring their impact. The stimulus for an SOP will either derive from SP12 research, from PORE, from recurring ethical themes or from investigation of problems arising out of the governance of the HBP.
- Ethics compliance
    - The local ethics approvals will be collected into a registry for all research undertaken within the EU, in order to ensure the permissions are pertinent and valid. This will be facilitated by the EAB who may, for example, review research that is undertaken outside the jurisdiction of the EU.
- Communication with the European Commission (EC)
    - Ethics Management will prepare responses for and following ethics reviews, provide required information, and lead HBP ethics audits.

6.2 Main Outcomes

6.2.1 Development of the principles and implementation of Ethics Management

The Ethics Management Handbook describes the role and functioning of Ethics Management within the HBP.

Following interviews with SP leaders for the Ramp-Up Phase, a survey of all Ramp-Up Task leaders and the M21 Ethics Review, ten ethical themes required further intervention in the form of an ethics action plan:

- Compliance of imported data with H2020 ethics principles
- Dual use
- Ethical consequence of management
- Ethical issues of technical infrastructure

- Ethics of HBP communications
- Misuse
- Protection of personal data
- Remote ethical issues
- Research integrity/malpractice
- Secondary use of clinical data
- Security

The ethics action plans describe the ethical issue, the Tasks affected and the response of the Task in mitigation of the issue. As a result of this analysis, the plan will leave a number of open questions. Where relevant, the Task leadership and the EAB are invited to respond.

The final stage of review will be conducted by the Ethics Reviewers appointed by the EC. If the issue is unsatisfactorily handled, it is expected that the Task leaders will appreciate the need to respond to the requests of the reviewers before going ahead with their research.

6.2.2 Management and support of the Ethics Advisory Board (EAB)

Regular meetings between the chairs of the EAB and Ethics Management are held to discuss issues arising out of the governance of the HBP. Full meetings of the EAB have been held as described in section 6.1.1.

Following its official constitution during the HBP Summit in Madrid in September 2015, the EAB contributed effectively with dealing with a particular issue and the subsequent development of a Standard Operating Procedure on Conflicts of Interest. This SOP was adopted by the BoD in January 2016. It will lead to the compilation of a registry of interests by the Coordinator and should help avoid future conflicts of interest.

In addition the EAB worked on the development of principles concerning the appointment of an Ombudsperson.

6.2.3 Management and support of the Ethics Rapporteurs

After an initial meeting (see section 6.2.3.1) to establish the ethics rapporteurs, attended by 4 rapporteur representatives of 11 applicable SPs. The meeting was held prior to BoD approval of the ethics rapporteur task and its function. A further meeting was held at the Madrid Summit to discuss human data protection and privacy (see section 6.2.3.2). This was attended by 7/10 ERs including those most relevant to the issues. Eight of 12 relevant ethics rapporteurs will be attending the next workshop in M30.

The high rate of attendance confirms that the ethics rapporteurs value their work with Ethics Management and show commitment to fulfilling their role.

6.2.4 Identification and triage of ethical issues (PORE)

To date, 34 issues have been raised through PORE, which will also be used by Ethics Management to track issues arising out of its work, so as to ensure there is an audit trail in regard of the items addressed.

Of the 34 issues, 27 (80%) were raised either by Ethics Management or the EAB and all require further action. Other HBP staff or members of the public raised the remaining issues, through the form on the publicly available website. Of these, 5/7 (71) have received a formal response and two have been triaged as not requiring any further action.

6.2.5 *Writing standard operating procedures*

Standard operating procedures have been written covering:

- SOP creation
- SP12 handbook
- SP12 communication
- Ethics Management handbook
- Ethics Map and Action Plans
- Ethics compliance
- PORE
- Management & support of the EAB
- Management & support of the Ethics Rapporteurs
- Solicitation of external expertise
- Ombudsman
- Animal research
- Human Research
- Data protection / privacy
- Intellectual Property
- Access to platforms
- Ethical Governance of the HBP

6.2.6 *Ethics compliance*

The process of ethics compliance commences with meetings with leaders and rapporteurs to identify the ethical issues arising out of the research of their SP. These have been completed for all Ramp-Up SPs and are in progress for SGA1 SPs.

On completion of these meetings, a survey is sent to each Task leader (or Principal Investigator (PI)) for the research of the HBP. This is a questionnaire designed to identify whether the proposed study raises any ethical issues according to the Horizon 2020 guidance. The survey is analysed and if issues are raised, relevant documentation or ethical approvals (translated into English, where relevant) are sought from the PI, where such documentation does not already exist in the Ethics Registry. Currently the survey is complete for Ramp-Up Tasks and is underway for SGA1 Tasks.

On receipt of the documentation, a check is made by Ethics Management staff for any outstanding issues and further action initiated according to the results. The documents and required action are recorded in the registry and the documents stored securely in a Tresorit repository – a secure cloud storage site, hosted in the EU, to which interested stakeholders can be given access by Ethics Management.

This process seeks systematically to identify all ethical issues raised by the HBP. It relies the integrity of the PI and on the process of ethical approval local to each Task. Feedback on its success will result from ethics audits and repeat Task leader meetings and surveys backed up by the work of the ethics rapporteurs and the availability of PORE.

6.2.7 Ethics Management in SGA1

During the SGA1 Ethics Management will continue to work on the various activities described above. A key component of work in the next stage will be to guide the ethical aspects of the platforms and data flows that will be part of the operational phase. This will include further development of action plans, where required of SOPs and the start of ethics audits of specific aspects such as the compliance with terms of service.

Further outreach to other groups and activities (e.g. EUREC or the US BRAIN initiative) will form part of the SGA1 activities. In preparation for the SGA1, Ethics Management will work with the EAB in order to establish principles of the Ombudsperson programme and ensure that this forms part of the new Project governance.

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Annex A: Online Deliberation: HBP Future Medicine

Document Title:	T12.3.1 Online Deliberation on Public Expectations: HBP and Future Medicine
Document Filename(1):	SP12_D12 6 4_Ethics_Society_Report_IP_20160316.docx
Date:	4 January 2016
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SP / WP / Task Involved:	SP 12 / WP12.3 / T12.3.1
Author:	Benjamin SIMMENAUER, IP, P27
Abstract:	This document reports on the methods and findings of the first online deliberation with public participation conducted in SP12. Following the schedule for all SP12 social and engagement activities, this consultation has dealt with future medicine, specifically medical data federation and personalised medicine in the HBP context. We first explain the goals and the moderation tools and techniques of HBP online deliberations, and then we present the main results in three steps: 1) general notions on mental and psychiatric diseases, 2) reflections on big data in general and in medical contexts and 3) feedback on SP8 program.
Keywords:	Public Engagement, Public Expectations, Privacy, Big Data, Brain Signatures, Data Federation, Mental disease, Psychiatric Disease, Personalized Medicine, Informed Consent, Anticipated Diagnosis.

A.1 Introduction

A.1.1 The role of T12.3.1 - Online Deliberation - in HBP

The goal of WP12.3 is “to help the HBP create a constructive dialogue with public and private stakeholders and with the general public, maintaining an intense engagement with points of view external to the HBP, identifying emerging controversies, and formulating recommendations for HBP research and research priorities”[1].

The goals of T12.3.1 (IP) are to:

1) Gather the general public’s perception of the HBP, understanding of the scientific content, its meaning and purpose

2) Recognise the public expectations towards HBP’s research and findings, the nature of the anticipated benefits, for private individuals and their personal satisfaction and wellbeing, and for individual citizens who participate in civic responsibilities as members of a democratic society

3) Obtain rapid but well-argued feedback from the general public on the ethical and social issues listed in WP12.1 (Foresight Studies), WP12.2 (Conceptual and Philosophical Studies) and WP12.4 (Researcher Awareness). T12.3.1 tries to assess the importance of

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[1] Grant agreement for: Combination of CP & CSA, Annex 1 – “Description of Work”, Grant agreement no: 604102 , 2013.

those issues in the general public's opinion, ranking them according to the perception of their significance, and explaining the reasons why the public is concerned about them.

A.1.2 Methods and tools for T12.3.1

T12.3.1 organises online interactive consultations involving a recruited sample of 100+ people and during approximately 7 days. Participants use a dedicated online restricted access platform equipped with moderating facilities (tags, creation of polls, etc.) to debate social and ethical issues or dilemmas raised by HBP research, discoveries and technologies. Participants remain anonymous and appear onscreen with a pseudo. The platform has been provided by the French institute "House of Common Knowledge (chosen by IP, according to a call for tenders that followed internal procedure rules).

Respondents to these deliberative surveys do not answer a rigid set of questions determined *a priori,* and are not interviewed individually: they are invited to share ideas, and to interact with the entire community. A team of moderators ensuring an active and substantial participation facilitates the debate. The moderators create topics with questions (like in online 'bulletin boards'), and respondents both answer the moderators and start talking to each other. Only a subset of the topics is set a priori, since the moderators also create new topics during the deliberation, according to the respondents' contributions.

l'objectif du partage de données

A votre avis, quels sont les avantages qu'il y a à mettre des données en commun? A quoi cela sert-il? Qu'est-ce qu'on y gagne? Pouvez-vous nous donner des exemples où le partage de données individuelles aboutit à un vrai avantage pour la société? Et quels sont les inconvénients? Qui utilise ces données en fin de compte?

la science et les "big data" (ou données massives)

Avec l'explosion du numérique et du web, les données disponibles dans un grand nombre de domaines (santé, vie privée, économie...) sont devenues extrêmement nombreuses (massives). De nouvelles techniques de collecte et d'analyse sont apparues pour les traiter. Elles vont affecter de façon profonde l'ensemble des secteurs de la société mais aussi certains secteurs de la recherche scientifique. Vous(...)

Le partage des données individuelles

Pour pouvoir constituer de grosses bases de données (des big data), il est nécessaire qu'une très grande quantité d'individus partagent leurs données. En utilisant la plupart des services Internet (google, facebook...), on partage des données, volontairement (par exemple sur les réseaux sociaux avec nos amis, ou sur les sites comme tripadvisor...) et involontairement aussi! Cela pose de nombreuses(...)

Qu'est-ce qu'être normal?

Le débat que nous avons en ce moment sur les maladies mentales et psychiatriques amène plusieurs d'entre vous à poser la question de ce que veut dire "être normal". En effet souvent les personnes dont on diagnostique des troubles mentaux ou psychiatriques sont jugées "anormales" ... ou inversement : c'est parce que quelqu'un ne se comporte pas "normalement" en société qu'on va en inférer qu'il(...)

Figure 1: examples of topics created by the moderators during the first online deliberation (screen capture).

The moderators also identify 'leitmotivs' in the discussions, i.e. aspects of an issue that are addressed by several participants. They create 'micro polls' accordingly, allowing the whole community engaged in the deliberation to vote on the ideas and opinions expressed by some of its individual members.

Qui doit contrôler la diffusion des données médicales ? (Pourquoi ce sondage ?)

Dans l'idéal qui est responsable de ces données et de leur partage? Et pourquoi?

Opinion des participants (128 réponses)

1 .	le patient	70 %
2 .	le médecin	20 %
3 .	autre : qui?	5 %
4 .	la securité sociale	3 %
5 .	l'hopital	2 %

Figure 2: example of a micro-poll created during the deliberation (screen capture)

This approach has the following strengths:

- It delivers both qualitative and quantitative data
- It is more realistic than other approaches, reproducing the contextual process of opinion making on complex and uncertain issues (like the consequences of HBP)
- It helps monitor the influential opinions within a group and detect potential opinion trends
- Web-based tools provide an economic and ergonomic solution to organise dialogues with several dozens of people each time, and in different European countries.

A.1.3 Context and objectives for the first online consultation on future medicine

Following the schedule for all SP12 social and engagement activities defined in [2] (section 1.3), the consultation organized during the Ramp-Up Phase has dealt with future medicine, specifically medical data federation and personalised medicine in the HBP context. Other similar online consultations will be organized during the operational phase of HBP.

The topics for this first online consultation have been defined on the basis of the initial research done in WP12.1, WP12.4 and T12.3.3:

1) Psychiatric and mental diseases and disorders: how should they be defined? For example, what is the relation between psychiatric diseases and neurological disorders? What do we know of them? What type of knowledge do we lack the most?
2) Ways to cure psychiatric and mental diseases, and expectations of present and future science: How are they treated? How should they be treated? How could science help in curing psychiatric and mental diseases? What are the most promising scientific areas?
3) Data sharing (the topic of "big data" is introduced in a non-technical manner): what are the general perceptions of sharing personal data (e.g. people willingly sharing personal information on social networks, versus third parties collecting personal data without individuals knowing)? What are the purposes of data collection and use? What are the main benefits, costs and risks? What kinds of personal data (private life, religion, political opinions, health, etc.) are seen as most sensitive?
4) Data sharing in the biomedical field: what are the purposes of health data collection? What medical data would you agree to share, and with whom? On which conditions?

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[2] Ethics and Society Research Plan, Deliverable D12.6.1, April 2014.

What are the benefits and the risks of sharing medical data? What should remain anonymous, and what does "anonymous" mean? Who should be the "gate-keeper" (the patient, the doctor, an independent platform, or someone else)? What should the patients know about the use of their data (the specific research use of their data, only the research field, etc.)? The focus is on consent and informed consent.

5) SP8 data integration strategy plan: quick introduction to general HBP goals and tools and to SP8's specific goals, and presentation of the data integration plan. Questions for understanding the programme include: what is its goal? How will it work? Can you rephrase it? Is it an acceptable programme? What are the main benefits and risks? Examples of topics and issues to consider include: possible breaches of privacy, trust in hospitals and using data from hospitals (paid by public taxes) in databases for improving public health.
6) SP8 brain disease signature plan: presentation of the concept of disease signature. Questions for understanding this programme include: what is its goal? How will it work? Is it an acceptable programme? What are the main benefits and risks? Examples of topics and issues to consider include: what if the number of diseases increases because of the signature system? Does the Project increase or decrease self-identity security (the idea that a person is accepted with their set of abilities and that they should not be forced to accept a perception of themselves that they do not agree with)? Will doctors still be useful? Will patients require more access to, and control of, their data?

A.1.4 Factual information

A.1.4.1 Schedule

The first HBP online deliberation started on 6 May 2015, and ended on 14 May 2015. The consultation's timeline is pictured in Tables 1 and 2 below. Once started the "topics" discussed do not stop before the end of the deliberation. The respondents are not forced to participate to all the discussion threads.

A.1.4.2 Sample

The deliberation gathered 137 participants. All were to be open to scientific progress and interested in scientific discoveries. We decided to filter according to these criteria in order to improve the interactions between participants, and to avoid off-topics contribution. Therefore, respondents were asked about their knowledge of recent major scientific projects or achievements (from a list of 8). The incidence rate was of 34.7% over the online panel used for the recruitment. It could be interesting to extend the consultation to the entire general public, and thus to include the 65.3% that were not part of the survey, but then a methodological shift to classic quantitative survey might be appropriate. As a matter of fact, it is not reasonable to expect people not interested in science to be part of such an engaging deliberative protocol.

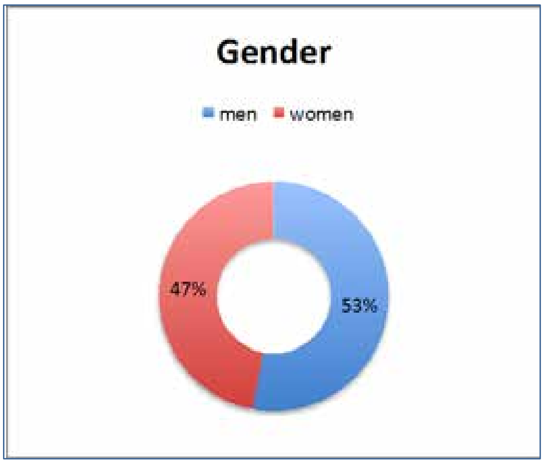

Figure 3: Gender structure

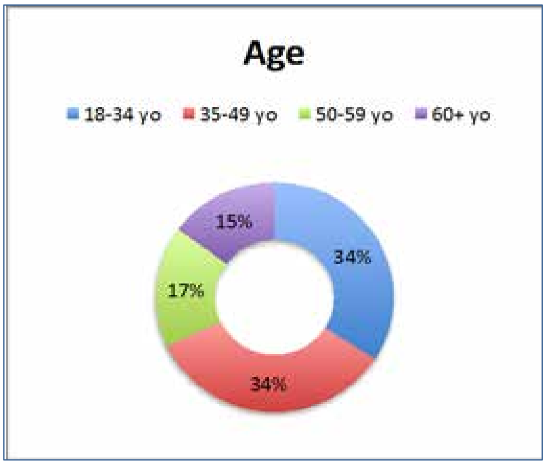

Figure 4: Age structure

Respondents were also asked if they had relatives or friends suffering from mental or psychiatric disorders, but it was not a criterion for inclusion or exclusion.

A.1.4.3 Indicators for participation

The participants have posted 3,586 messages on the platform, and the moderators have created 12 topics and 42 micro-polls.

Number	Start	Topic	Total No. of messages posted
1	Day 1	“Mental and psychiatric diseases”	278
2	Day 1	“Treatments for mental and psychiatric diseases”	231
3	Day 2	“Expectations towards Science”	130
4	Day 2	“Future treatments for mental and psychiatric diseases”	162
5	Day 2	“What does it mean to be “normal”?”	139
6	Day 3	“Science and Big Data”	110
7	Day 3	“The goal(s) of data sharing”	104
8	Day 3	“Sharing individual data”	94
9	Day 3	“Medical data”	131
10	Day 5	“Sensitive data”	62
11	Day 6	“Brain signatures”	139
12	Day 6	“Data Federation Plan”	96

Table 1: Topics discussed during the online deliberation

Number	Start	Poll	Total amount of answers
1	Day 2	“Mental and psychiatric diseases are brain diseases” (rating scale)	128
2	Day 2	“There is no efficient drug to treat most mental diseases” (rating scale)	128
3	Day 2	“Mental and psychiatric diseases require support treatment” (rating scale)	128
4	Day 2	“Mental and psychiatric diseases are difficult to diagnose” (rating scale)	127
5	Day 2	“Mental and psychiatric diseases are true diseases” (rating scale)	130
6	Day 2	“Mental and psychiatric diseases are not diseases of the body” (rating scale)	131
7	Day 2	“The causes of mental and psychiatric diseases are …” (ranking from 1 to 4) “environmental” / “due to accidents or shocks” / “innate” / “unknown”	131
8	Day 2	“Mental and psychiatric diseases are a social handicap” (rating scale)	137
9	Day 3	“Drugs limit the effects of the mental and psychiatric diseases but do not cure them” (rating scale)	131
10	Day 3	“One can recover from a mental or psychiatric disease” (rating scale)	123
11	Day 3	“Medicine is resourceless against mental illness” (rating scale)	125
12	Day 3	“We know almost nothing about mental and psychiatric diseases” (rating scale)	127
13	Day 3	“What is your opinion of early diagnosis?” (single choice) “It is an improvement: first signs of the disease will be postponed” / “It is dangerous: some people will be a priori considered “abnormal”” / “I don’t know”	132
14	Day 3	“Mental and psychiatric diseases require personalized diagnosis and treatment” (rating scale)	125
15	Day 3	“The most important advance in mental and psychiatric diseases’ treatment shall come from…” (single choice) “science: to find the real (physiological, genetic…) causes and to develop truly efficient drugs is priority number one” / “society: to take care of the patients in a more human and attentive manner is priority number one” / “other”	126
16	Day 3	“Who do you expect solutions to the problems raised by mental and psychiatric diseases from?” (single choice) “scientific research (genetics, biology, chemistry…)” / “psychiatry and/or psychology” / “brain surgery” / “social science” / “other”	127
17	Day 3	“According to you, what is the top priority?” (ranking) “improve the patients’ follow-up care and support to avoid their social exclusion” / “identify the causes of the mental diseases and develop new and efficient curative treatments” / “find new drugs that limit the effects of	130

		the psychiatric and mental diseases”	
18	Day 4	“Science will find more efficient drugs in order to deal with mental diseases’ effects” (rating scale)	130
19	Day 4	“Science will make it possible to cure the mental affections” (rating scale)	128
20	Day 4	“Science will discover the causes of mental illness” (rating scale)	130
21	Day 4	“In your opinion, what is the most efficient treatment for mental and psychiatric diseases?” “Speech (psychotherapies…)”/ “chemistry (drugs…)” / other	139
22	Day 4	“Did you know about “big data”?” (single choice) “Yes I already knew that notion”/ “I had heard about it but did not really know what it was about” / No, I discover “big data” here!	117
23	Day 4	“Big data will help scientific advances” (rating scale)	112
24	Day 4	“Big data will help spying or watching over people” (rating scale)	114
25	Day 4	“It is impossible for individuals to control the use of their personal data” (rating scale)	114
26	Day 4	“Large-scale data sharing will benefit the individuals” (rating scale)	112
27	Day 4	“Large-scale data sharing will benefit the big companies” (rating scale)	116
28	Day 5	“I am afraid that my sensitive data become publicly accessible” (rating scale)	117
29	Day 5	“I feel I can control my personal data sharing” (rating scale)	119
30	Day 5	“To centralize medical data and make them workable for scientists is a good idea” (rating scale)	117
31	Day 5	“Sharing medical data will break medical confidentiality” (rating scale)	119
32	Day 5	“Medical data must remain healthcare system’s ownership ” (rating scale)	118
33	Day 6	“In your opinion, what are the most sensitive data?” (ranking) “medical data” / “banking data” / “political opinions” / “religious opinions” / “sexual preferences” / “legal precedents” / “daily life data”	122
34	Day 6	“Who must control the diffusion of medical data?” (single choice) “patients” / “doctors” / “hospitals” / “social security” / “other”	128
35	Day 6	“Are you in favour of data sharing in general?” (rating scale)	119
36	Day 6	“Are you in favour of medical data sharing?” (rating scale)	125
37	Day 7	“The “brain signatures” research programme…” (single choice) “…seems to put aside very important factors in the development of mental and psychiatric pathologies, like traumas or environment” / “seems to carry out a possible	104

		revolution in the understanding of mental and psychiatric diseases”	
38	Day 7	“Is large scale patients’ data federation dangerous?” (single choice) “Not really, and the small risk is worth taking if new treatments can be developed” / “Yes, I am afraid that patients records will be used by third parties”	104
39	Day 7	“To detect psychiatric and mental diseases’ forerunners… ” (single choice) “is very promising: patients will be managed way sooner and the progress of the disease may be slowed down” / “worries me: it may stigmatize “persons at risk” who could very well not develop a disease”	103
40	Day 7	“What about patients’ records and their informed consent ?” (single choice) “It is a small risk worth taking: the databases are stored in hospitals and currently not used, whereas they could contribute to a major scientific breakthrough” / “This is unacceptable: no medical data should be used without the patient’s informed consent, even with a rigorous anonymization process”	104
41	Day 7	“How positive is your final opinion about the programme you have been presented?” (rating scale)	103

Table 2: Polls created during the online deliberation

A.1.5 Survey materials

On Day 6, after thorough discussions over topics such as psychiatric and mental diseases in general and treatments for them, expectations towards science, big data in general and medical big data, and privacy concerns, respondents were introduced to two aspects of the HBP Medical Informatics Platform: the “brain signatures project” and the “data federation plan”. The decision to focus on those aspects was motivated by the findings of former SP12 research activities, especially those of the Foresight Lab (T12.1.1, King’s College, P32) and of the Stakeholders Forum (T12.3.3, Danish Board of Technology, P16) see [[3]] and [[4]]. Below are the exact texts describing the two key aspects of HBP SP8’s program: they are deliberately kept simple, to let all the respondents understand its goals and characteristics.

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[3] King’s College, The HBP foresight lab: first report on future medicine, Deliverable D12.1.1, March 2015.

[4] Danish Board of Technology, Living up to Privacy and Informed Consent in the Human Brain Project, Newsletter December 2014, http://www.tekno.dk/wp-content/uploads/2014/12/1-HBP-newsletter.pdf.

The Data Federation System

- The Human Brain Project is a European scientific project, dedicated to research on the human brain, using simulation techniques and cutting-edge computing (high performance and neuromorphic computing)
- An important part of this Project focuses on the biological foundations of psychiatric and mental illness, in order to develop new medical therapies and more efficient drugs. Scientists will thus build a computing platform to gather huge volumes of data and perform statistical analysis on them.
- The HBP will use data coming from the medical records of patients cured for neurodegenerative, mental or psychiatric diseases in hospitals across Europe. Those data will be integrated into one central database according to these principles:
    - In each hospital partnering with the Project, the data contained in the patients' records will be anonymised and then sent to the central platform
    - On the central platform's side, the accredited researchers will access only aggregated data (not individual ones), i.e. sets of data coming from several individuals.

Figure 6: Survey material on the "Data Federation System"

The Brain Signatures Project

- The Human Brain Project is a European scientific project, dedicated to research on the human brain, using simulation techniques and cutting-edge computing (high performance and neuromorphic computing)
- An important part of this Project focuses on the biological foundations of psychiatric and mental illness, in order to develop new medical therapies and more efficient drugs. Scientists will thus build a computing platform to gather huge volumes of data and perform statistical analysis on them.
- The goal is to identify the neurobiological cause of mental diseases. Thanks to the advances of brain imaging, the researchers and the doctors try to understand which genetic factors or visible anomalies are responsible for psychiatric and mental diseases like schizophrenia, depression or bipolar disorder. Despite many efforts, those research programmes have not met success yet.
- The Human Brain Project's plan is to collect very large amounts of medical data and to apply statistical analysis to them, to discover "brain signatures", i.e. patterns of anomalies (of the brain or the genes) that are visible only when large volumes of data are aggregated, and are impossible to see in a few individual patients.
- If such "brain signatures" were to be found, one could understand mental and psychiatric diseases, not from the patients' apparent symptoms, but from biological data, from the "inside" (so to speak). It would make it possible:
    - To find new ways to diagnose brain diseases, by observing individuals' brains or their genetic data, and comparing them to the "brain signatures" that reveal the presence of an anomaly
    - To predict the chances to develop a mental or psychiatric disease more accurately
    - To develop new drugs and treatments

Figure 7: Survey material on the "Brain Signatures Project"

A.2 Psychiatric and Mental diseases

A.2.2 General perceptions

A.2.2.1 Mental diseases are "true" diseases

Psychiatric and mental diseases are considered as "true diseases" by all participants (average score: 9.3/10): "*It's obvious*", "*I cannot understand how they could not be considered as such*". This understanding of mental illness as a "true" disease is, for many participants, a "new thing", a sign that mind sets have changed: "*now they are seen as such, but it is recent and has not always been like that*".

Compared to other diseases, psychiatric and mental troubles are more "*complex*" and "*less well-known*". Most participants agree that they are "difficult to diagnose" (average score: 7,5/10): "*they are not visible*", "*most people can detect a fever's or a heart attack's symptoms, but not a mental disease's ones*", "*they are subject to wrong diagnoses all the time: see the expert's files in law court suits…*". Still, progress has been made, and it is not entirely true anymore that "we know almost nothing about mental and psychiatric diseases" (average score: 5.5): "*some of these troubles are very well-known already, others are the topic of research programs still in their infancy*", "*it's on progress, but the human brain's functioning is probably the most complex organ to study*".

A.2.2.2 Mental diseases are physical diseases

Most people endorse physicalism about mental and psychiatric diseases, which are generally considered as "brain diseases" (average score: 7/10): "*mental diseases are caused by a disturbed brain*". Only 3 people out of the whole group agreed with the idea that "Mental and psychiatric diseases are not diseases of the body" (average score: 4.7/10). Mental and psychiatric troubles are generally seen as the product of a combination of several factors: an innate or genetic predisposition, a contextual (social) cause, and/or a traumatic event in the individual's life.

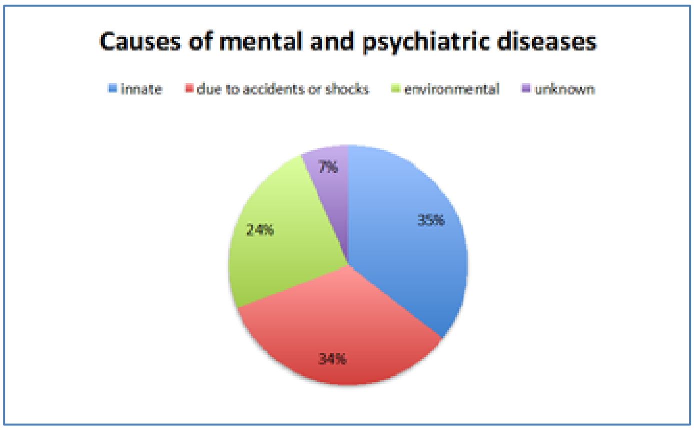


Figure 8: poll on causes of mental illness (% of rank #1 answers)

A.2.2.3 Mental diseases raise major social issues

Respondents spontaneously mention another major feature of mental illness: it raises major social issues. The idea that "mental and psychiatric diseases are a social handicap" (average score: 8.4/10) is consensual among participants: "*People affected by mental diseases are badly perceived: even if their condition is stabilized, their past record as mentally ill still harms them from a social point of view. Their reintegration into the professional world is often very difficult…*", "*they are a social handicap in the sense that us, the so-called normal people, are not able to understand the patients*", "*in this plain world, mental illness is scary, difference is scary*"

A.2.3 Treatments and expectations

A.2.3.1 Management drugs vs curative drugs

The proposition that “there is no efficient drug to treat most mental diseases” (average score: 5.8/10) is not consensual among participants, because its truth depends on the meaning of “efficiency”. On the one hand, management drugs do exist and are efficient in the sense that “*drugs help a lot and patients would not be able to live without them*” and *“people with schizophrenia have a better life when they take the “right” pills”*, but on the other hand most people agree that “Drugs limit the effects of the mental and psychiatric diseases but do not cure them” (average score: 7.5/10): “*they help, but so not cure*”, “*they make the symptoms go away… but when one stops taking the drugs, symptoms are back*”.

The lack of curative drugs makes it difficult for people to assess the possibility of a cure for mental illness, therefore most participants hesitate when they must express their agreement with the idea that “One can recover from a mental or psychiatric disease” (average score: 5.8/10): “*partly, but not completely*”, “*it must depend on the pathology… depression yes, autism, no*”. Uncertainty prevails, not scepticism though: psychiatric and mental diseases might be curable, but at the moment, there is no evidence available to support this claim.

A.2.3.2 Expectations

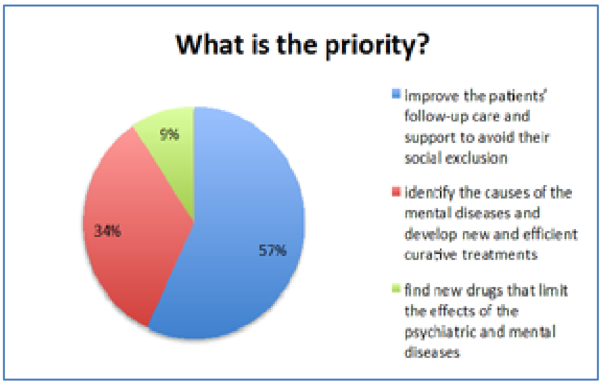


Figure 9: poll on priorities for the treatment of mental illness (% of answers)

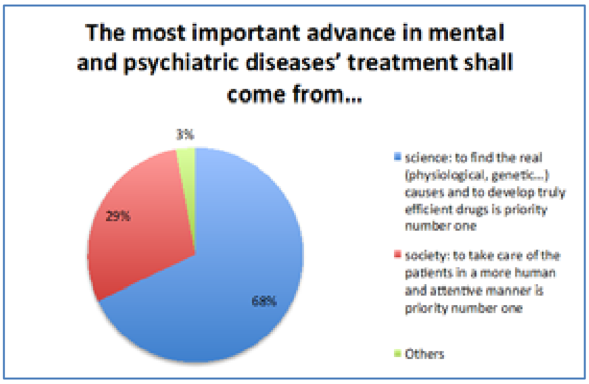


Figure 10: poll on the actors expected to solve the mental illness problems (% of answers)

Most respondents (57%) find that the priority is to “improve the patients’ follow-up care and support to avoid their social exclusion”: they expect the social problem posed by mental and psychiatric diseases to be taken care of. In comparison, the scientific goals “to identify the causes of the mental diseases and develop new and efficient curative treatments” seem less important (only 34%). But at the same time, it is largely admitted (68%) that the “most important advance in mental and psychiatric diseases’ treatment” shall come from science, and not from society (29% only). To understand this apparent contradiction, it is useful to draw a distinction between short term, middle term and long expectations: while on the long term, science should (hopefully) be able to “find the real causes and develop truly efficient drugs”, and thus contribute to solve the social issues raised by mental illness, in the meantime it is indispensable to propose and implement concrete tools to “take care of the patients in a more human and attentive manner”.

Short term expectations: better tools to avoid social exclusion

That “mental and psychiatric diseases require support treatment” (average score: 8.7/10) seems obvious to almost all participants: “*it is vital for the patient as well as for her family, who does not necessarily know how to react*”, “*an everyday care is indispensable*”.

To help containing the social damages caused by mental and psychiatric troubles and fight against patients' isolation, respondents especially mention the development of specialized facilities, properly equipped, and the necessary increase of dedicated personnel. Those solutions depend on political will and action rather than on scientific research: "*a psychological support, adapted facilities with competent people: be attentive to patients' needs is mandatory, but we lack all this… saving, saving…*".

Middle and long term expectations: better drugs (at least for symptoms' management), and scientific understanding

Most participants think that "science will find more efficient drugs in order to deal with mental diseases' effects" (average score: 7,2/10): "*I think major advances have been made over the XX*th *Century and in the XXI*st *one can expect that treatments to reduce the effects of mental diseases will improve again*", "*For sure, drugs design will go on… now, is it good news for patients, I don't know. For me, drugs are an assistance, but not an end in itself… they are not a treatment in the long run*". It is also a general belief that "science will discover the causes of mental illness" (average score: 7.4/10), but at a later stage of its development: "causes are multifactorial... if all the different disciplines working on mental illness can join and work together, that is possible…", "I think brain research makes it possible to know the damaged parts and that certain diseases are already identified. Medical imaging eventually will make it possible to detect all the forerunners of a pathology, but it will take a lot of research and of financial effort".

Remarkably, respondents do not systematically link the understanding of the causes of mental illness to the ability to cure psychiatric and mental diseases. It is not certain, for many participants, that "science will make it possible to cure the mental affections" (average score: 6.4/10): "*Maybe? But it's far from certain. Because the causes and manifestations are very different from a patient to another*", "*Science cannot do everything, especially against diseases that society mostly has generated*".

A.3 Big data

A.3.1 Big Data in general is a source of concern

A.3.1.1 Awareness of big data in general: a not so well-known concept

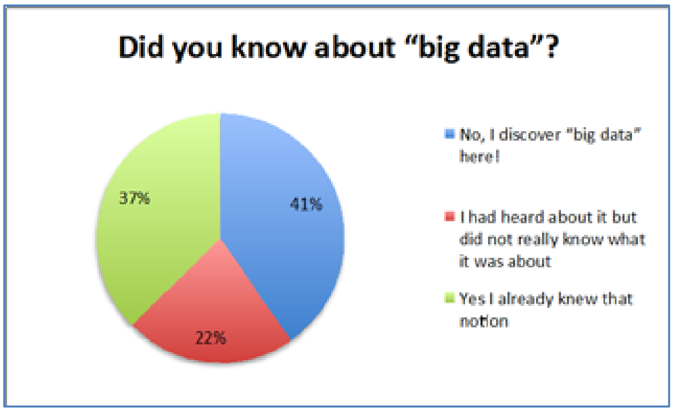


Figure 11: Poll on knowledge of big data (% of answers)

The concept of "big data", introduced in the discussion (by the moderators) as "a broad term for data sets so large or complex that traditional data processing applications are inadequate" (definition from Wikipedia: a link to the Wikipedia page on big data was provided to the respondents), is not so well-known. More than 40% of the participants had never heard the term before, and only 37% declare to be acquainted with the notion.

A3.1.2 Purpose of big data in scientific contexts is not self-evident

The link between big data and science is not obvious to the respondents. Actually, nobody spontaneously mentioned science as an area that would profit from the rise of big data. But, when asked by the moderators about the benefits of big data for science, most people agreed that "big data will help scientific advances" (average score: 6.9/10): "*I hope so because it is an enormous resource for the researchers and the doctors ton access all those data at the same place*". For the majority, it is still difficult to understand *how* big data will drive a scientific revolution, first because big data is still at an early age: "the phenomenon is still too big for us to be able to picture ourselves what the advances will come out of it. It is certainly a technical progress that will profit science". Some also argue that science cannot be reduced to data and statistical treatments but require experiments and insights and show some scepticism: "science is chemistry, intellect, experiments, theory and concrete, etc. big data will not make science progress, it will rather help on social issues like which social class is interested by what (consumption, buying products…). I don't see how big data will help to understand properties of matter or find a miracle drug against pancreatic cancer."

A.3.1.3 Cost-benefit analysis of the consequences of large-scale data sharing: an obvious benefit for big companies, but not for individuals

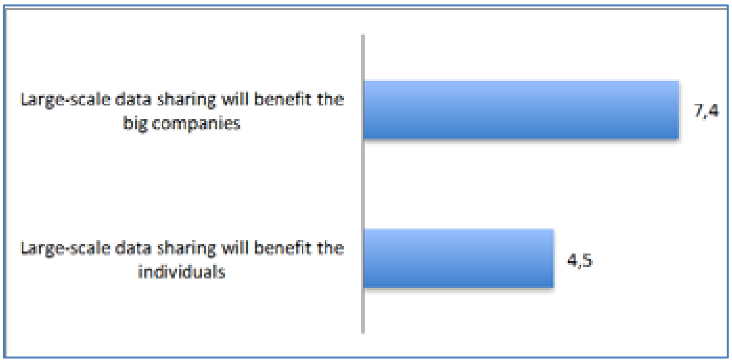


Figure 12: Polls on the purposes of large-scale data sharing (average score on 10)

The contrast between the perception of individuals' and big companies' interests in large-scale data sharing is very striking: data sharing is very beneficial to big companies (7.4/10), but not so much to individuals (4.5/10). Almost nobody relates to the idea that by a massive sharing of data, individuals will all benefit from better and more "tailored" services (which is a very common argument in favour of data sharing plans, quite represented in HBP for example).

This blindness to positive outcomes of big data for individuals comes mostly from the suspicion that "big data will help spying or watching over people" (7.3/10). Many quotes show that participants largely share this Orwellian view according to which "Big Brothers" like multinational companies and states use the Internet to monitor people's behaviours and try and manipulate them: "*even TV receivers are watching us, I don't know which TV brand place monitors in TVs to know which programs are watched*", "*What's best than to know everything of an individual, to know who she is, what she does, when, with whom and why and how she is going to act*", "*Individuals are already completely spyed (sic) and monitored*".

In this context, privacy is a major concern for most participants: a large majority feel that "It is impossible for individuals to control the use of their personal data" (7.4/10) and are personally afraid that their "sensitive data become publicly accessible" (7.2/10): "*Once the elements are entered in the system it is not possible anymore for an individual to keep control over the way his data are used*", "*We have absolutely no control over the use of our data. It is entirely impossible to get information. Where? I think we are a bit overwhelmed by the changes coming from IT and we have difficulty in understanding the* *problem in its globality. I don't even know what are the data available about me!"* Overall, people feel dispossessed of their own data, and of any possible mean to control their spread: the overall impression is a complete lack of power.

A.3.2 Big Data sharing in the medical field is more acceptable than big data sharing in general

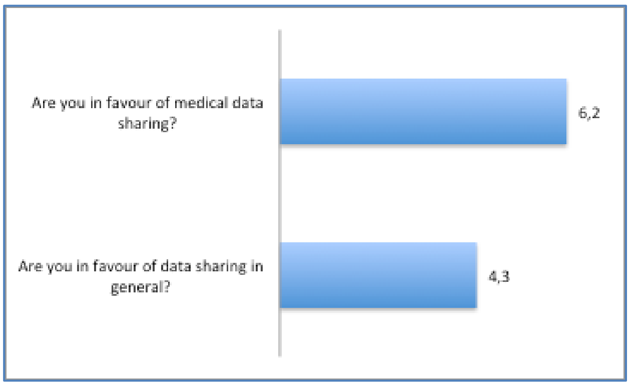


Figure 13: Polls on the data sharing in general vs in the medical field (average score on 10)

Data sharing in the medical field is significantly more popular than data sharing in general, as Figure 13 shows. The first explanation to this contrast is that medical data are not considered as the most sensitive data. People are much more worried by the disclosure of their banking data, as shows Figure 14:

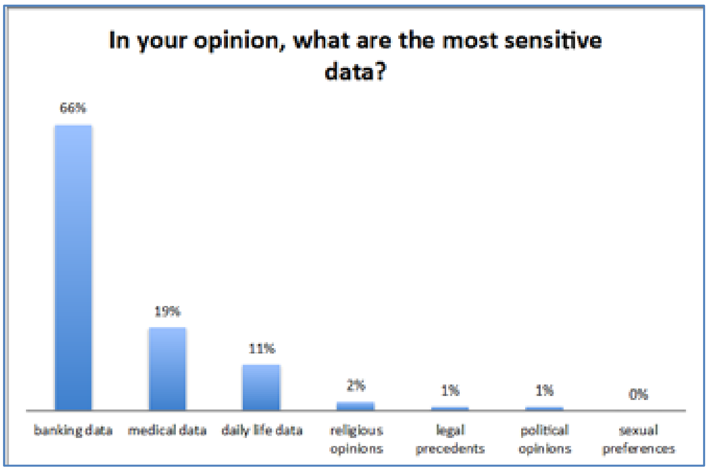


Figure 14: Poll on data sensitiveness (% of rank #1)

But the stronger acceptability of medical data sharing, compared to data sharing in general, is supported by the view that medical data are controlled by the medical institutions. As the use of medical data is seen as much more constrained and regulated than the use of data in general, it seems less dangerous to share them. Most people imagine that medical data sharing will consist only in sharing of medical records among doctors: *"I am in favour of medical data sharing, as long as doctors only will access them"*, *"It is certainly useful for doctors: they will be able to avoid prescribing drugs that can become harmful in combination with others, or to be aware of their patients' allergies for instance"*. The boundaries of institution are clearly perceived as shields against the lack of control. It is then no surprise that a large majority of participants agree that "Medical data must remain (under the) healthcare system's ownership" (average score: 8.2/10).

A.4 SP8 plans

A.4.1 Overall understanding and appreciation is positive even if social benefits of the program are not very tangible

Respondents were introduced to two aspects of the HBP Medical Informatics Platform: the "brain signatures project" and the "data federation plan" (see report in section 1.1.5 of the present document for further details).

The overall goals of SP8 are well understood and generally considered as promising: identifying the physical causes of mental diseases is the most promising way to improve their treatment and even if big data is not a familiar concept, it is generally considered plausible that a large federation of data at a European scale (like SP8 is planning) would bring a considerable amount of new resources to scientists and practitioners, and would help scientific and medical progress: "I am very enthusiast too, because I am sure that mental diseases are biological and/or chemical disorders in the brain", "It is innovative and has never been done because of a lack of means… I think the research until now has only involved small groups of patients, with the new technologies we can expect better!" "Innovative and full of hope. I would like to ask the scientists: it is the brain's biology that creates the disease through the genes, but there is also a part of the patient's experiences that could alter the genetics… in that case why would this research only deal with genetics?"

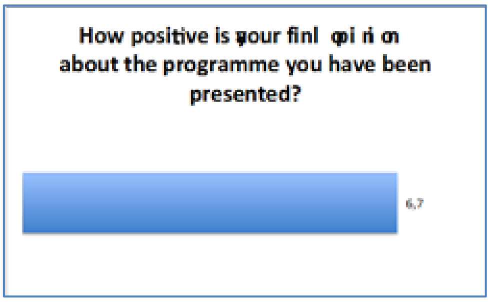


Figure 15: Poll on final appreciation of SP8 plans (score on 10)

The overall appreciation of the program is thus positive (overall score is 6.7/10, as shown on the Figure 15 above), even if its social benefits are less tangible. And as mentioned earlier (see section 2.1.3), the most prominent issues raised by mental and psychiatric disorders are not as economical (those diseases cost a lot) as social (patients are socially handicapped and excluded). In this respect HBP plans for future medicine do not seem to target immediate or short-term outcomes for the quality of life and well-being of patients (see below section 4.3 for more details).

A.4.2 Federation of medical data

As we explained in section 3.2, medical data sharing is seen as a promising source of medical progress and as much more controlled than other forms of data sharing. Therefore it is not surprising that a large majority of respondents agrees that "to centralize medical data and make them workable for scientists is a good idea" (average score: 7,5/10): federation of medical data as planned by SP8 is largely approved in principle.

A few participants point out that putting massive data together might raise security issues: non intended users like private companies could access private medical information and use it for their own interest. Respondents are not experts in huge databases management, but they feel like the federation of such massive and sensitive data will ask for complex and potentially vulnerable infrastructures. Respondents are generally aware of the non intended use of their personal data by third parties (cf. section 3), and even if they do not identify a precise flaw in the SP8 plans they have been introduced to, they expect a level of guaranteed security that will match the potential risk of leaks or non intended use that comes with any huge data federation project: *"It is difficult not to think of possible negative effects when we see that multinational companies buy personal data to develop their market shares…* bis repetita *with medical data? Wait and see…"*, *"We need strong protection mechanisms: these data bases have the best of intentions but they are quickly exploited for financial and commercial purposes…"*.

Overall, it seems that the 'good' from the data federation system planned by SP8 overcomes the bad that may consist in non-intended use of private medical records: almost 2/3 of the participants do not think that large scale patient's data federation is really dangerous, and that the small risk is worth taking in the perspective of new treatments' development (see Figure 16 below).

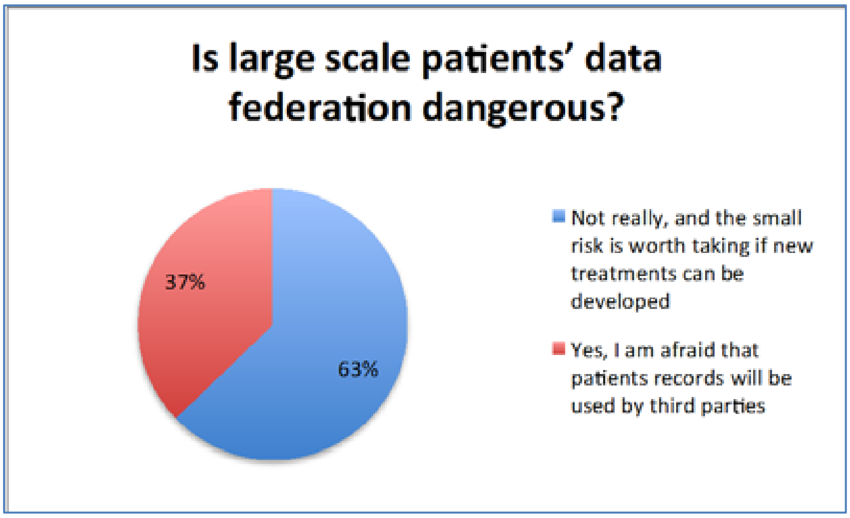


Figure 16: Poll on the perceived data federation strategy's risks (% of choice)

The anonymisation procedures envisioned by SP8 have been introduced to respondents too (see section 1.1.5) and they are welcomed very positively: almost 80% of the respondents think that the databases stored in hospitals should be used and contribute to the research planned in HBP, whereas only 20% react negatively to the probable lack of informed consent for many patients' records (see Figure 17 below). This positive appreciation of the anonymization procedures demonstrate the high expectation for the respect of privacy, and some respondents make it very clear: *"The project talks a lot about data collection, but not so much about how those data are collected! With or without patients' consent? With or without family or doctor's consent? This project is acceptable only if one can certify that the data will remain confidential and anonymous"*. It thus seems critical to keep the general public informed of the legal and ethical principles and rules that HBP will follow or create to preserve privacy. Anonymisation procedures and policies guiding requests for informed consent (with a distinction between cases where this consent can be obtained and cases where medical records will be used without patients' consent) are key elements the general public will expect to know about.

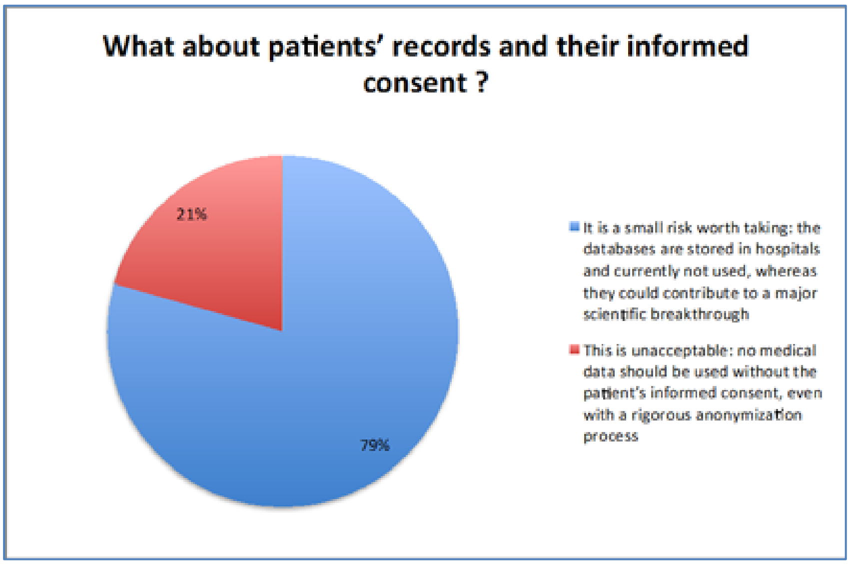


Figure 17: Poll on informed consent (% of choice)

A.4.3 Brain signatures and anticipated diagnosis

The brain signatures component of SP8 work plan is considered as a potential “revolution” in the understanding of mental and psychiatric diseases by a tight majority of respondents: it is coherent with the view that mental diseases are brain diseases (cf. section 1). In this perspective the brain signatures program is seen as a truly scientific attempt to understand the real nature of these troubles: *“it is a new approach: we don't completely understand the functioning of the brain. In my opinion, when we will understand it completely (like we do for the heart for example), we will be able to cure a tremendous amount of mental diseases”*. But 43% of the respondents still think that the Project puts aside very important factors in the development of mental pathologies, like traumas or environment (see Figure 18 below).

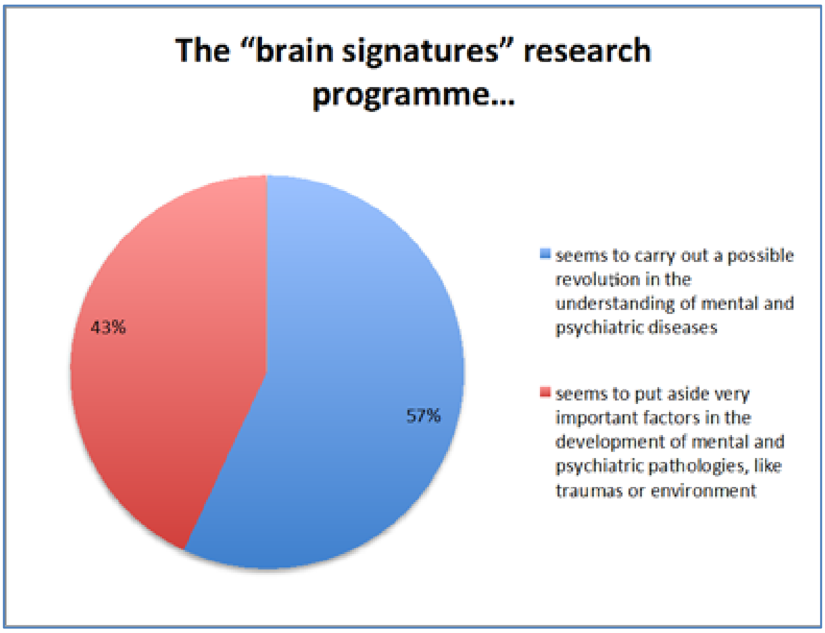


Figure 18: Poll on early diagnosis (% of choice)

This reaction to the brain signatures program is quite coherent with the findings of sections 1 and 2: mental and psychiatric troubles are generally seen as the product of a combination of several heterogeneous factors like an innate or genetic predisposition, a contextual (social) cause, and/or a traumatic event in the individual's life. Almost all participants strongly agree that "mental and psychiatric diseases require personalized diagnosis and treatment" (average score: 8.9/10). To discover brain signatures is certainly an important step in this personalized psychiatry direction, but is not perceived as a complete and definitive answer to this quest. On the contrary, many respondents still think that it must be combined with a more phenomenological approach: *"I have attended meetings on Alzheimer disease and this kind of mental trouble is deeply connected to the environement (sic) and to life events. Chemical and medical research cannot do everything"*.

Anticipated diagnosis of psychiatric and mental diseases is a rather unsettled debate. A significant majority of people (63%) thinks it may be a major source of progress, provided that the ability to detect chances to develop a pathology comes with an appropriate capability to take care of the patients in advance as well: *"It is an improvement: to discover a disease early on can help the individual to understand why he is like he is, and help his family circle too, to provide better support. It can also help the doctors to take care of the patients in advance"*, *"That way we can be more careful with potential patients and treat them earlier if the first symptoms appear"*. 37% of the participants still fear the danger of a stronger and wider social exclusion for people with chances to develop those diseases or do not know what to think on this complex matter.

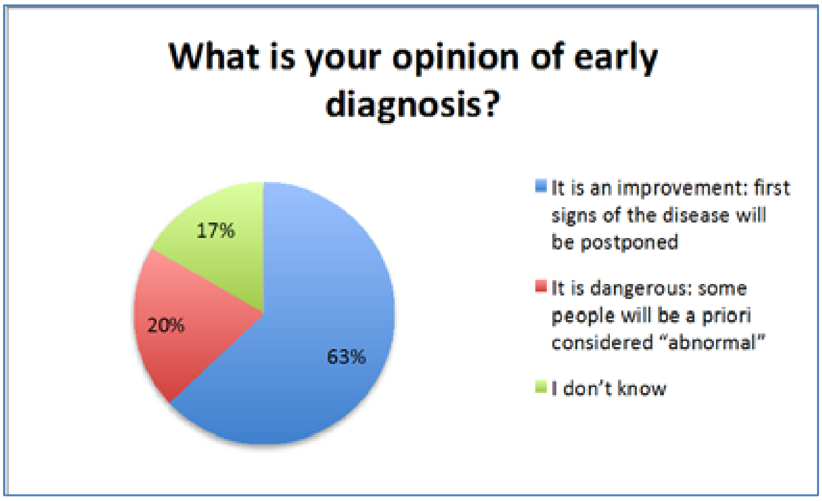


Figure 19: Poll on early diagnosis (% of choice)

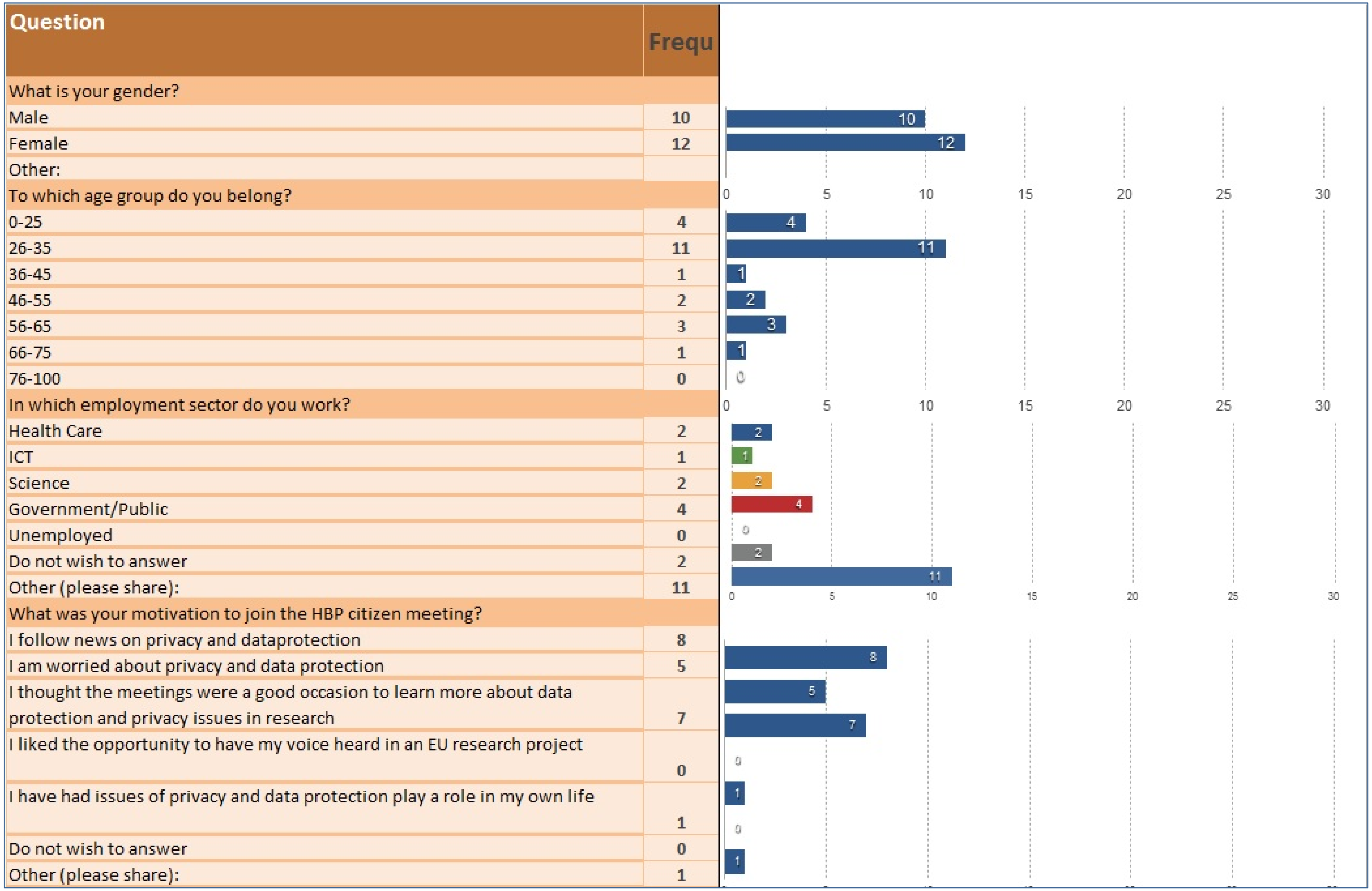
A.5 Conclusions

The main results from the deliberation can be summarized by the following points:

- Mental diseases are perceived as "true" diseases, caused by physical factors
- Mental diseases raise major social issues (more than other diseases)
- Only management drugs exist for mental and psychiatric diseases, not curative ones
- Expectations are:
  - To develop better tools to avoid exclusion (short term)
  - Better drugs, at least for symptoms' management, and scientific understanding (middle and long term)
- Big Data in general is a source of concern
  - Big data is not a well-known concept
  - Purpose of big data in scientific contexts is not self-evident

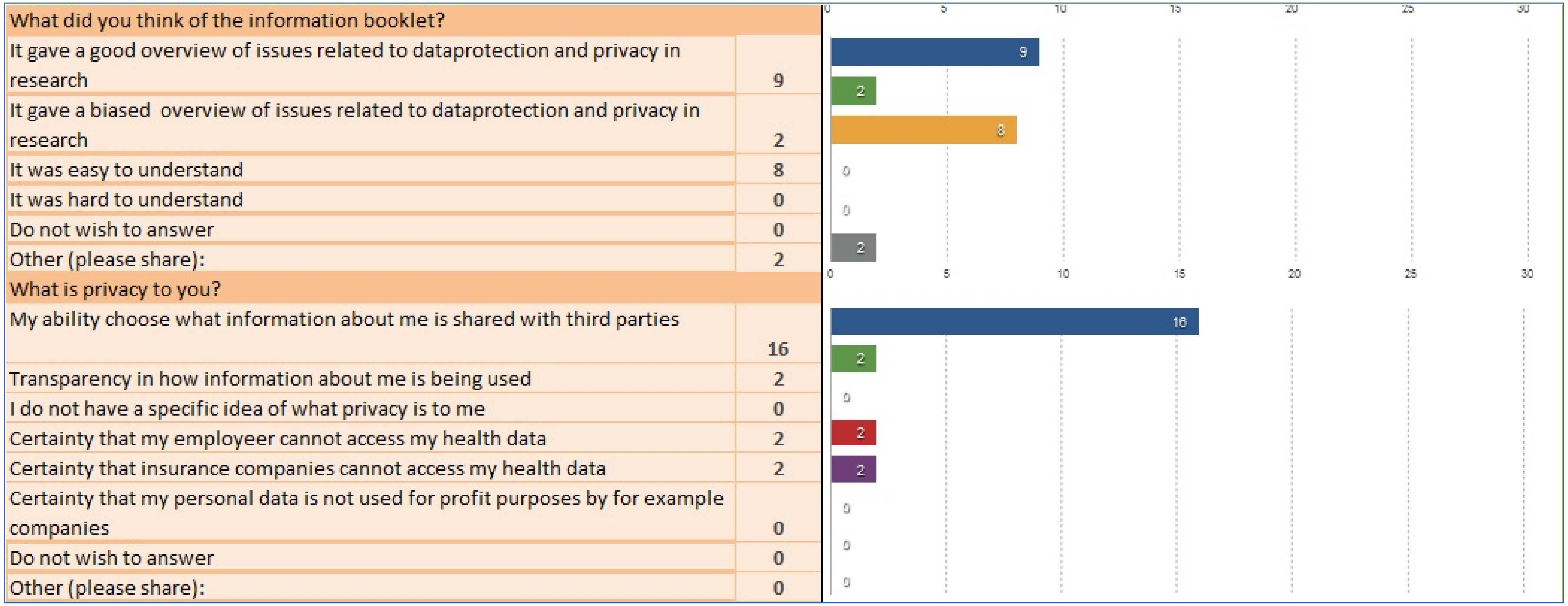
  - Cost-benefit analysis of the consequences of large-scale data sharing: an obvious benefit for big companies, but not for individuals
- Big Data sharing in the medical field is more acceptable than big data sharing in general
- Overall understanding and appreciation of SP8 plans (federation of hospitals data and brain signatures) is positive even if social benefits of the program are not very tangible.
  - HBP future medicine component seems to have a strong scientific potential and should lead to important new discoveries
  - The general public generally trusts the scientific and medical communities with the respect for privacy and anonymisation of personal data.

Annex B: Results from HBP Citizen Meetings in Poland and Austria



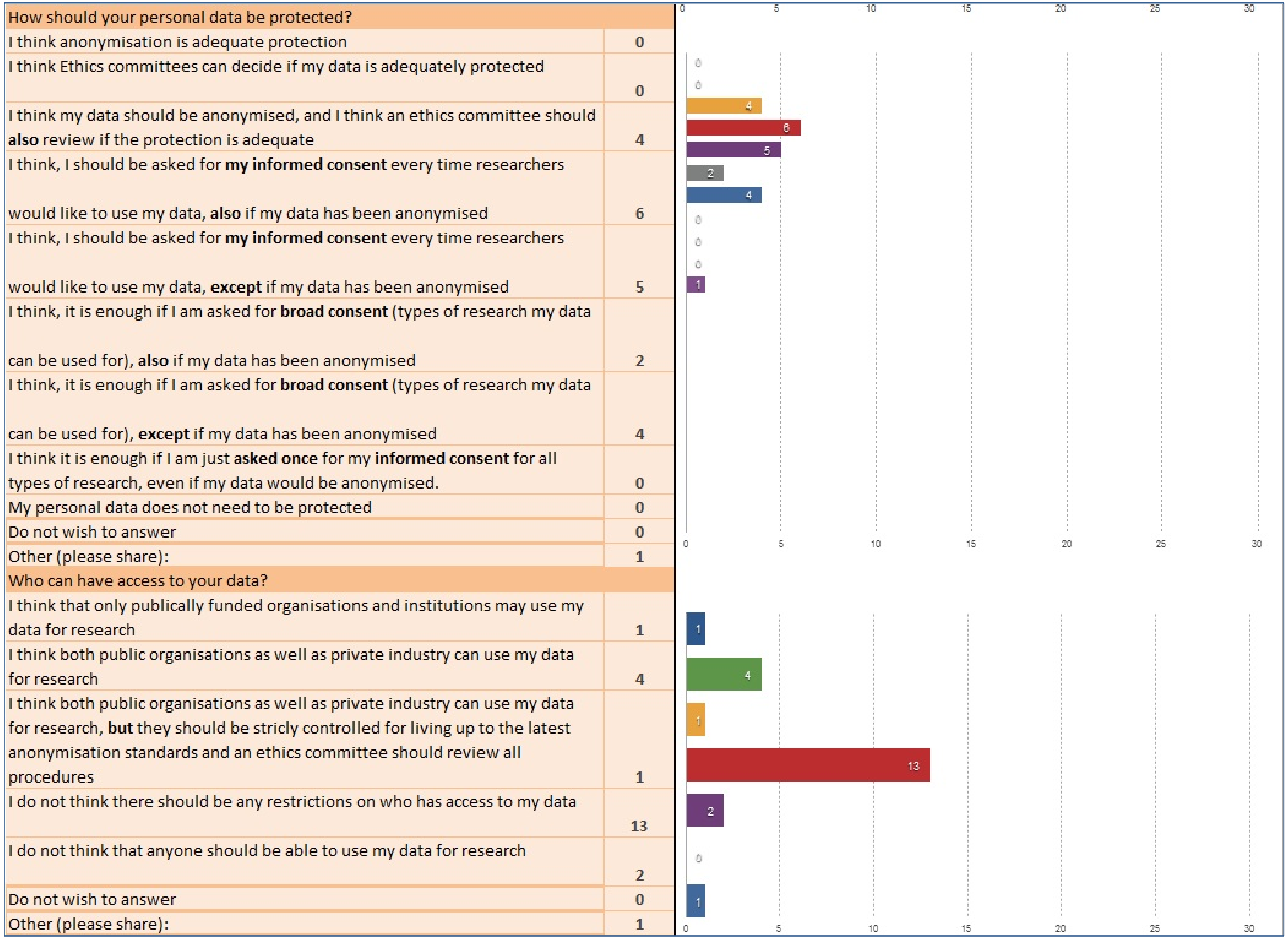
Question	Frequ
What is your gender?	
Male	10
Female	12
Other:	
To which age group do you belong?	
0-25	4
26-35	11
36-45	1
46-55	2
56-65	3
66-75	1
76-100	0
In which employment sector do you work?	
Health Care	2
ICT	1
Science	2
Government/Public	4
Unemployed	0
Do not wish to answer	2
Other (please share):	11
What was your motivation to join the HBP citizen meeting?	
I follow news on privacy and dataprotection	8
I am worried about privacy and data protection	5
I thought the meetings were a good occasion to learn more about data protection and privacy issues in research	7
I liked the opportunity to have my voice heard in an EU research project	0
I have had issues of privacy and data protection play a role in my own life	1
Do not wish to answer	0
Other (please share):	1

Figure 1: Results from the Polish HBP citizen meetings (1)



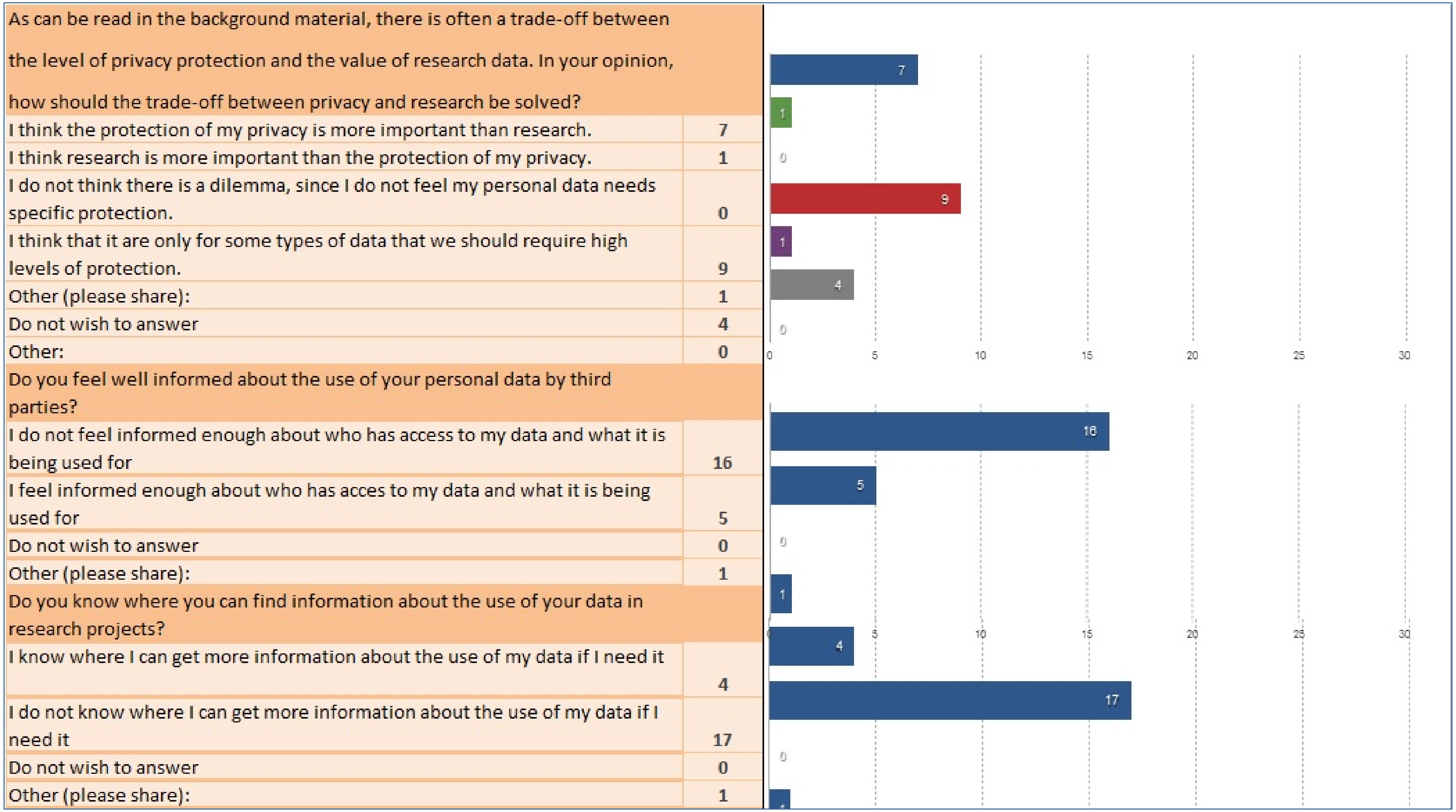
What did you think of the information booklet?	
It gave a good overview of issues related to dataprotection and privacy in research	9
It gave a biased overview of issues related to dataprotection and privacy in research	2
It was easy to understand	8
It was hard to understand	0
Do not wish to answer	0
Other (please share):	2
What is privacy to you?	
My ability choose what information about me is shared with third parties	16
Transparency in how information about me is being used	2
I do not have a specific idea of what privacy is to me	0
Certainty that my employeer cannot access my health data	2
Certainty that insurance companies cannot access my health data	2
Certainty that my personal data is not used for profit purposes by for example companies	0
Do not wish to answer	0
Other (please share):	0

Figure 2: Results from the Polish citizen meetings (2)



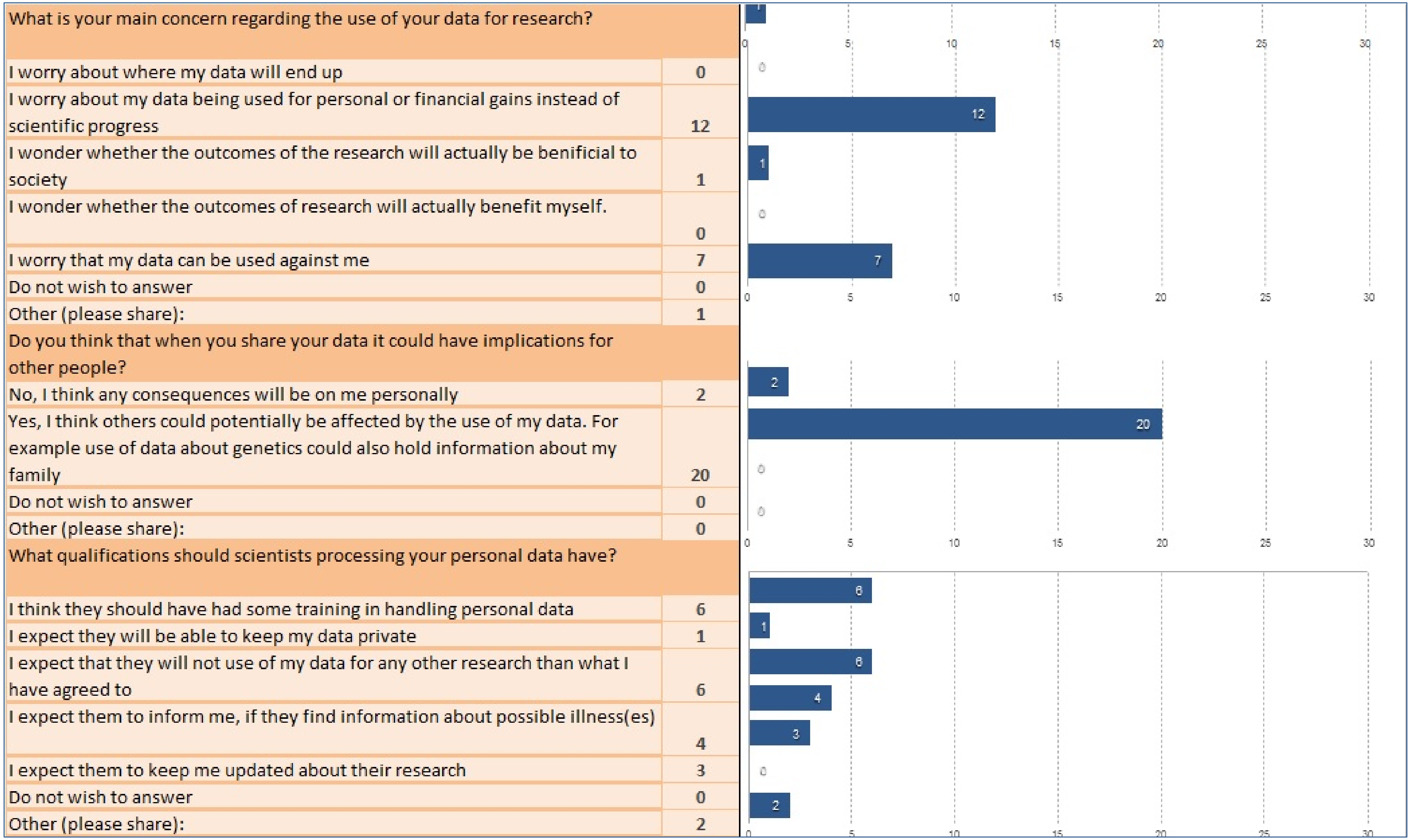
How should your personal data be protected?	
I think anonymisation is adequate protection	0
I think Ethics committees can decide if my data is adequately protected	0
I think my data should be anonymised, and I think an ethics committee should **also** review if the protection is adequate	4
I think, I should be asked for **my informed consent** every time researchers would like to use my data, **also** if my data has been anonymised	6
I think, I should be asked for **my informed consent** every time researchers would like to use my data, **except** if my data has been anonymised	5
I think, it is enough if I am asked for **broad consent** (types of research my data can be used for), **also** if my data has been anonymised	2
I think, it is enough if I am asked for **broad consent** (types of research my data can be used for), **except** if my data has been anonymised	4
I think it is enough if I am just **asked once** for my **informed consent** for all types of research, even if my data would be anonymised.	0
My personal data does not need to be protected	0
Do not wish to answer	0
Other (please share):	1
Who can have access to your data?	
I think that only publically funded organisations and institutions may use my data for research	1
I think both public organisations as well as private industry can use my data for research	4
I think both public organisations as well as private industry can use my data for research, **but** they should be stricly controlled for living up to the latest anonymisation standards and an ethics committee should review all procedures	1
I do not think there should be any restrictions on who has access to my data	13
I do not think that anyone should be able to use my data for research	2
Do not wish to answer	0
Other (please share):	1

Figure 3: Results from the Polish citizen meetings (3)



As can be read in the background material, there is often a trade-off between the level of privacy protection and the value of research data. In your opinion, how should the trade-off between privacy and research be solved?	
I think the protection of my privacy is more important than research.	7
I think research is more important than the protection of my privacy.	1
I do not think there is a dilemma, since I do not feel my personal data needs specific protection.	0
I think that it are only for some types of data that we should require high levels of protection.	9
Other (please share):	1
Do not wish to answer	4
Other:	0
Do you feel well informed about the use of your personal data by third parties?	
I do not feel informed enough about who has access to my data and what it is being used for	16
I feel informed enough about who has acces to my data and what it is being used for	5
Do not wish to answer	0
Other (please share):	1
Do you know where you can find information about the use of your data in research projects?	
I know where I can get more information about the use of my data if I need it	4
I do not know where I can get more information about the use of my data if I need it	17
Do not wish to answer	0
Other (please share):	1

Figure 4: Results from the Polish citizen meetings (4)



What is your main concern regarding the use of your data for research?	
I worry about where my data will end up	0
I worry about my data being used for personal or financial gains instead of scientific progress	12
I wonder whether the outcomes of the research will actually be benificial to society	1
I wonder whether the outcomes of research will actually benefit myself.	0
I worry that my data can be used against me	7
Do not wish to answer	0
Other (please share):	1
Do you think that when you share your data it could have implications for other people?	
No, I think any consequences will be on me personally	2
Yes, I think others could potentially be affected by the use of my data. For example use of data about genetics could also hold information about my family	20
Do not wish to answer	0
Other (please share):	0
What qualifications should scientists processing your personal data have?	
I think they should have had some training in handling personal data	6
I expect they will be able to keep my data private	1
I expect that they will not use of my data for any other research than what I have agreed to	6
I expect them to inform me, if they find information about possible illness(es)	4
I expect them to keep me updated about their research	3
Do not wish to answer	0
Other (please share):	2

Figure 5: Results from the Polish citizen meetings (5)

What do you consider private data about yourself?	
I consider data about my activities private (sports, bar visits, smoking status)	2
I consider data about my political views private	0
I consider data about my religious views private	0
I consider information about my health status private	0
I consider information about who my friends are private	0
I consider the content of my correspondence with others private	1
All of the above	17
None of the above	0
Do not wish to answer	0
Other (please share):	2
Do you think anonymisation is adequate protection of your personal data?	
Yes	1
No	1
I am not sure	5
I worry about new technological developments like e.g. super computers that can break anonymisation procedures	9
I worry about hackers breaking the anonymisation of my data	2
I worry about data brokers who live off selling data-sets, and what they might do with my data	3
I worry about what kind of research my data is being used for	1
I worry about misuse by insurance companies	0
Do not wish to answer	0
Other (please share):	0
Who do you think can legitimately collect personal information about people?	
The government	1
The government for security purposes like the prevention of terrorist attacks	1
Public institutions for research purposes	9
Business for profit purposes	0
Industry to develop medication or other health services	3
Industry to develop non-health services	0
Do not wish to answer	3
Other (please share):	5

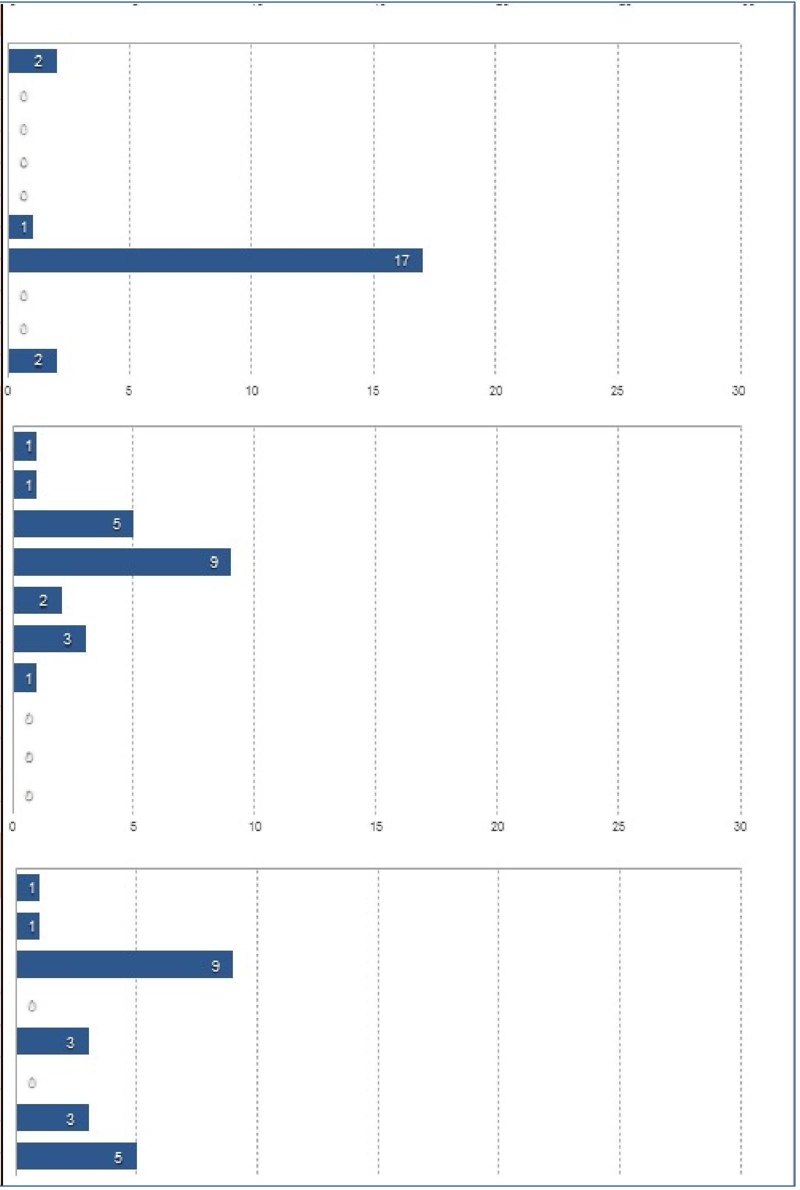
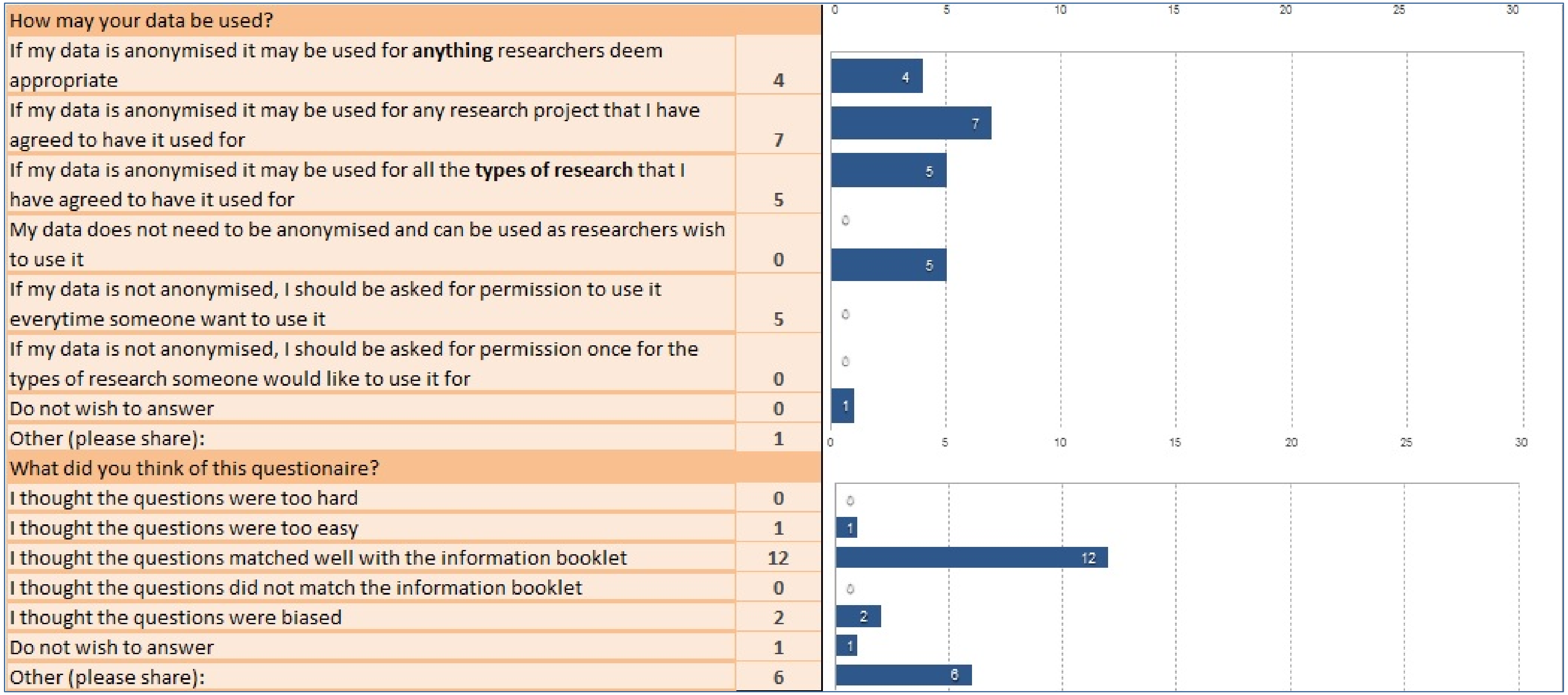
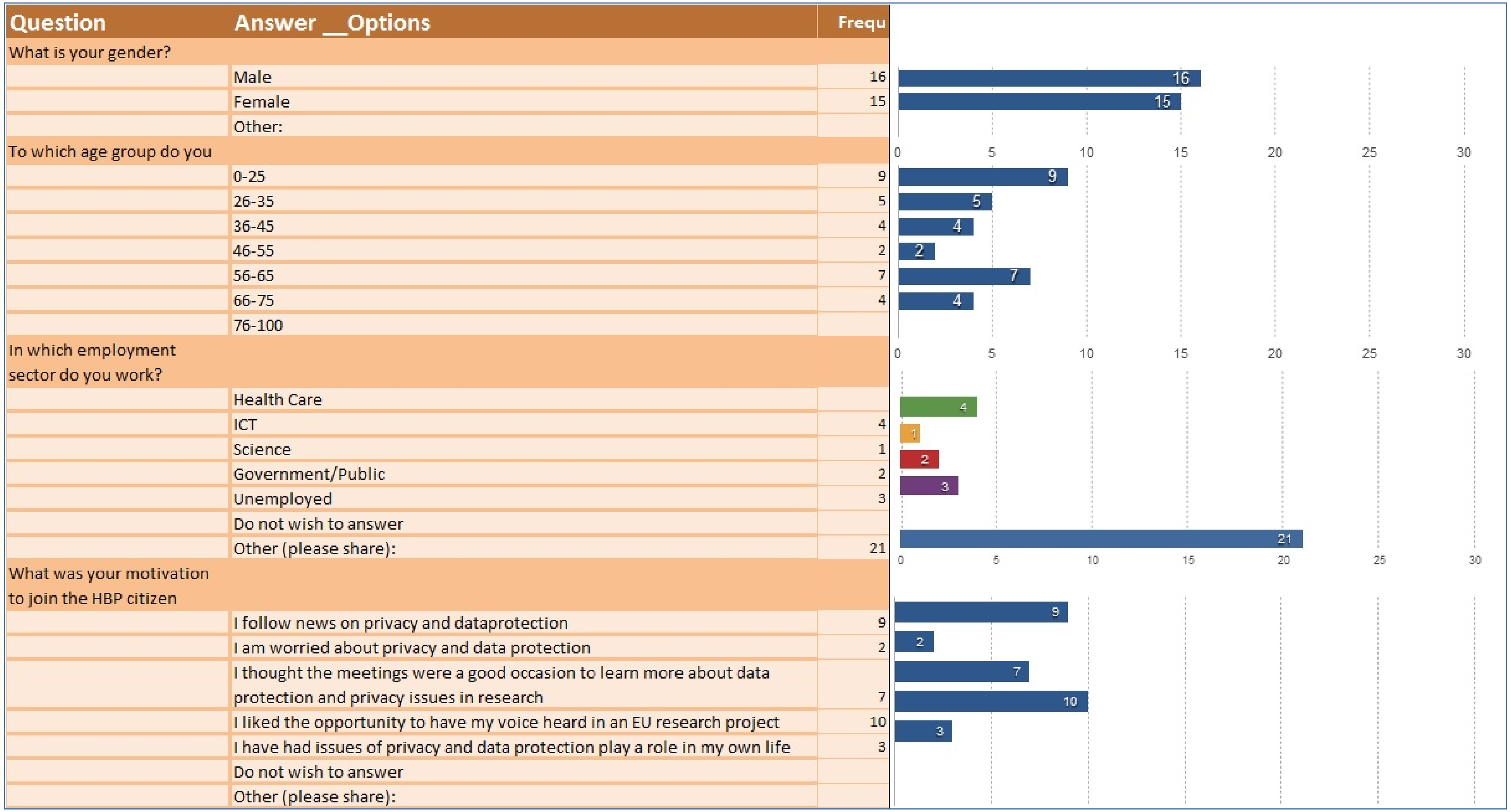


Figure 6: Results from the Polish citizen meetings (6)



How may your data be used?	
If my data is anonymised it may be used for **anything** researchers deem appropriate	4
If my data is anonymised it may be used for any research project that I have agreed to have it used for	7
If my data is anonymised it may be used for all the **types of research** that I have agreed to have it used for	5
My data does not need to be anonymised and can be used as researchers wish to use it	0
If my data is not anonymised, I should be asked for permission to use it everytime someone want to use it	5
If my data is not anonymised, I should be asked for permission once for the types of research someone would like to use it for	0
Do not wish to answer	0
Other (please share):	1
What did you think of this questionaire?	
I thought the questions were too hard	0
I thought the questions were too easy	1
I thought the questions matched well with the information booklet	12
I thought the questions did not match the information booklet	0
I thought the questions were biased	2
Do not wish to answer	1
Other (please share):	6

Figure 7: Results from the Polish citizen meetings (7)



Question	Answer __Options	Frequ
What is your gender?		
	Male	16
	Female	15
	Other:	
To which age group do you		
	0-25	9
	26-35	5
	36-45	4
	46-55	2
	56-65	7
	66-75	4
	76-100	
In which employment sector do you work?		
	Health Care	
	ICT	4
	Science	1
	Government/Public	2
	Unemployed	3
	Do not wish to answer	
	Other (please share):	21
What was your motivation to join the HBP citizen		
	I follow news on privacy and dataprotection	9
	I am worried about privacy and data protection	2
	I thought the meetings were a good occasion to learn more about data protection and privacy issues in research	7
	I liked the opportunity to have my voice heard in an EU research project	10
	I have had issues of privacy and data protection play a role in my own life	3
	Do not wish to answer	
	Other (please share):	

Figure 8: Results from the Austrian citizen meetings (1)

What did you think of the information booklet?		
	It gave a good overview of issues related to dataprotection and privacy in	22
	It gave a biased overview of issues related to dataprotection and privacy in	2
	It was easy to understand	3
	It was hard to understand	4
	Do not wish to answer	
	Other (please share):	
What is privacy to you?		
	My ability choose what information about me is shared with third parties	26
	Transparency in how information about me is being used	2
	I do not have a specific idea of what privacy is to me	
	Certainty that my employeer cannot access my health data	
	Certainty that insurance companies cannot access my health data	
	Certainty that my personal data is not used for profit purposes by for	1
	Do not wish to answer	
	Other (please share):	2
How should your personal data be protected?		
	I think anonymisation is adequate protection	0
	I think Ethics committees can decide if my data is adequately protected	1
	I think my data should be anonymised, and I think an ethics committee should **also** review if the protection is adequate	8
	I think, I should be asked for **my informed consent** every time researchers would like to use my data, **also** if my data has been anonymised	9
	I think, I should be asked for **my informed consent** every time researchers would like to use my data, **except** if my data has been anonymised	4
	I think, it is enough if I am asked for **broad consent** (types of research my data can be used for), **also** if my data has been anonymised	2
	I think, it is enough if I am asked for **broad consent** (types of research my data can be used for), **except** if my data has been anonymised	5
	I think it is enough if I am just **asked once** for my **informed consent** for all types of research, even if my data would be anonymised.	2
	My personal data does not need to be protected	
	Do not wish to answer	
	Other (please share):	

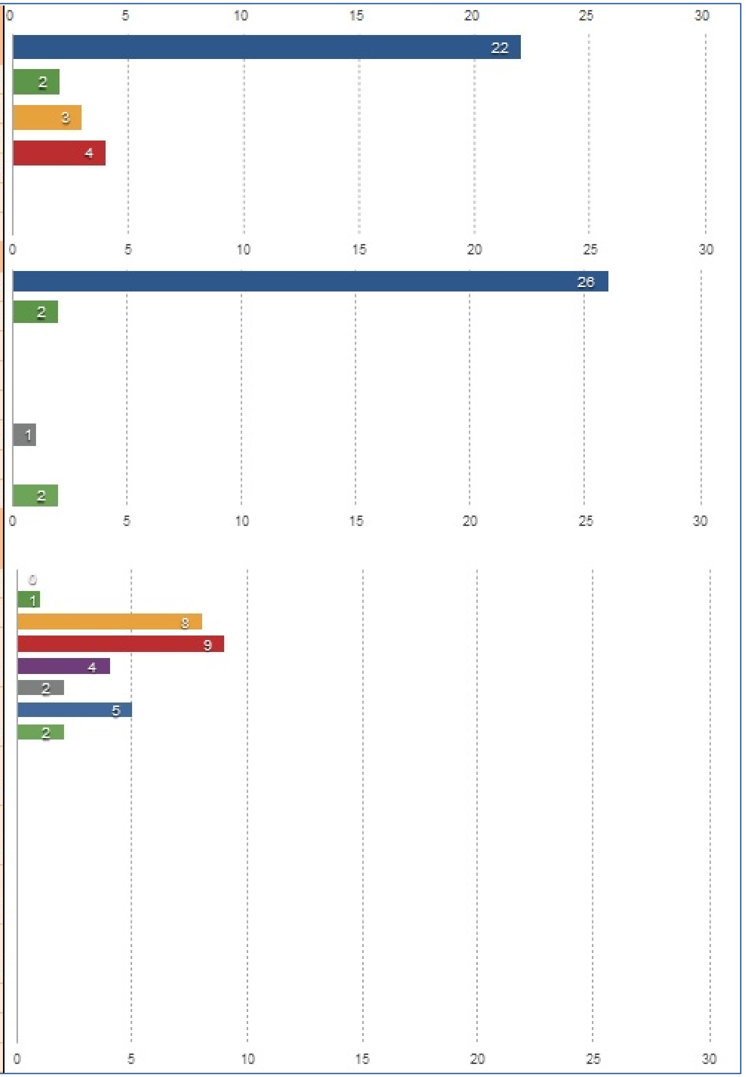


Figure 9: Results from the Austrian citizen meetings (2)

Who can have access to		
	I think that only publically funded organisations and institutions may use my data for research	1
	I think both public organisations as well as private industry can use my data	10
	I think both public organisations as well as private industry can use my data for research, **but** they should be stricly controlled for living up to the latest anonymisation standards and an ethics committee should review all	1
	I do not think there should be any restrictions on who has access to my data	16
	I do not think that anyone should be able to use my data for research	3
	Do not wish to answer	
	Other (please share):	0
As can be read in the background material, there is often a trade-off between the level of privacy protection and the value of research data. In your opinion, how should		
	I think the protection of my privacy is more important than research.	4
	I think research is more important than the protection of my privacy.	4
	I do not think there is a dilemma, since I do not feel my personal data needs specific protection.	0
	I think that it are only for some types of data that we should require high levels of protection.	20
	Other (please share):	
	Do not wish to answer	2
	Other:	0
Do you feel well informed about the use of your personal data by third		
	I do not feel informed enough about who has access to my data and what it is being used for	30
	I feel informed enough about who has acces to my data and what it is being	1
	Do not wish to answer	
	Other (please share):	

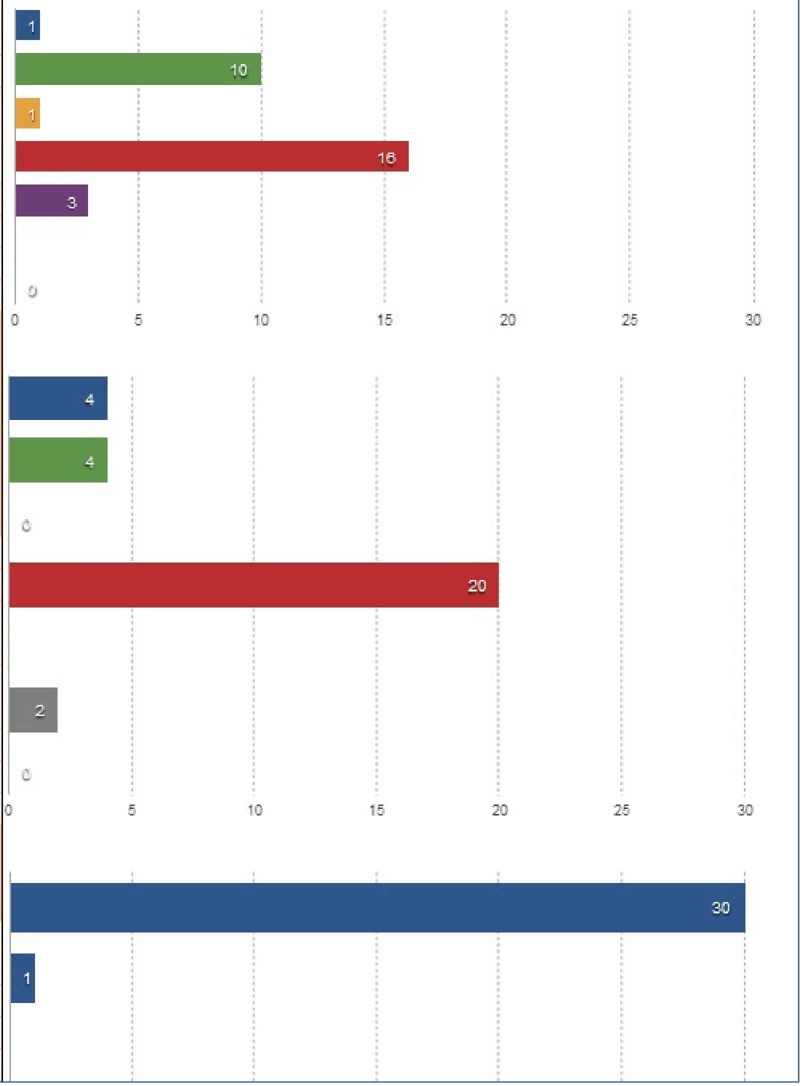
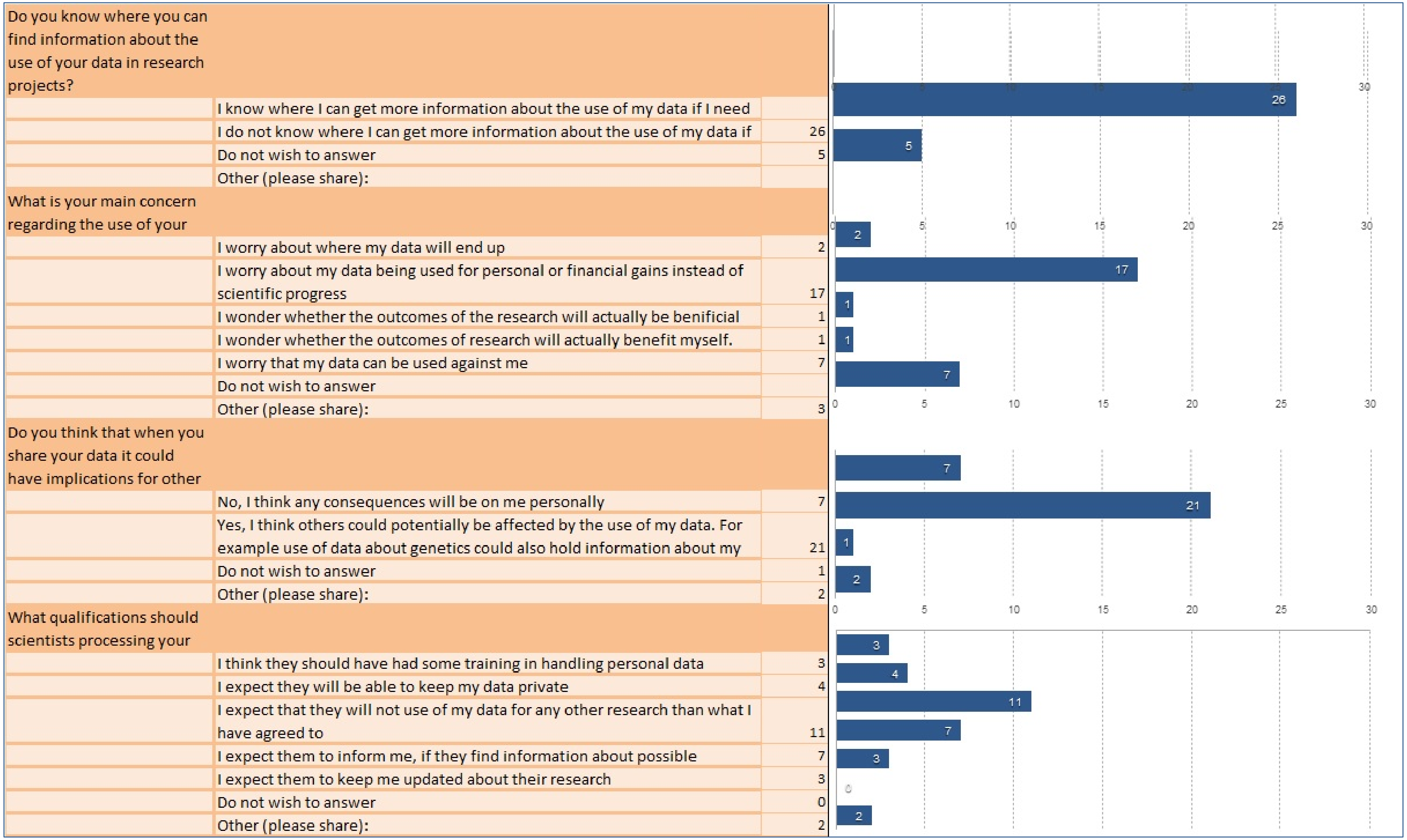


Figure 10: Results from the Austrian citizen meetings (3)



Do you know where you can find information about the use of your data in research projects?		
	I know where I can get more information about the use of my data if I need	
	I do not know where I can get more information about the use of my data if	26
	Do not wish to answer	5
	Other (please share):	
What is your main concern regarding the use of your		
	I worry about where my data will end up	2
	I worry about my data being used for personal or financial gains instead of scientific progress	17
	I wonder whether the outcomes of the research will actually be benificial	1
	I wonder whether the outcomes of research will actually benefit myself.	1
	I worry that my data can be used against me	7
	Do not wish to answer	
	Other (please share):	3
Do you think that when you share your data it could have implications for other		
	No, I think any consequences will be on me personally	7
	Yes, I think others could potentially be affected by the use of my data. For example use of data about genetics could also hold information about my	21
	Do not wish to answer	1
	Other (please share):	2
What qualifications should scientists processing your		
	I think they should have had some training in handling personal data	3
	I expect they will be able to keep my data private	4
	I expect that they will not use of my data for any other research than what I have agreed to	11
	I expect them to inform me, if they find information about possible	7
	I expect them to keep me updated about their research	3
	Do not wish to answer	0
	Other (please share):	2

Figure 11: Results from the Austrian citizen meetings (4)

What do you consider private data about yourself?		
	I consider data about my activities private (sports, bar visits, smoking	1
	I consider data about my political views private	1
	I consider data about my religious views private	0
	I consider information about my health status private	1
	I consider information about who my friends are private	1
	I consider the content of my correspondence with others private	1
	All of the above	24
	None of the above	0
	Do not wish to answer	0
	Other (please share):	2
Do you think anonymisation is adequate protection of your personal data?		
	Yes	2
	No	4
	I am not sure	7
	I worry about new technological developments like e.g. super computers that can break anonymisation procedures	4
	I worry about hackers breaking the anonymisation of my data	1
	I worry about data brokers who live off selling data-sets, and what they might do with my data	8
	I worry about what kind of research my data is being used for	1
	I worry about misuse by insurance companies	2
	Do not wish to answer	0
	Other (please share):	2
Who do you think can legitimately collect personal information about		
	The government	2
	The government for security purposes like the prevention of terrorist	11
	Public institutions for research purposes	6
	Business for profit purposes	1
	Industry to develop medication or other health services	3
	Industry to develop non-health services	0
	Do not wish to answer	3
	Other (please share):	5

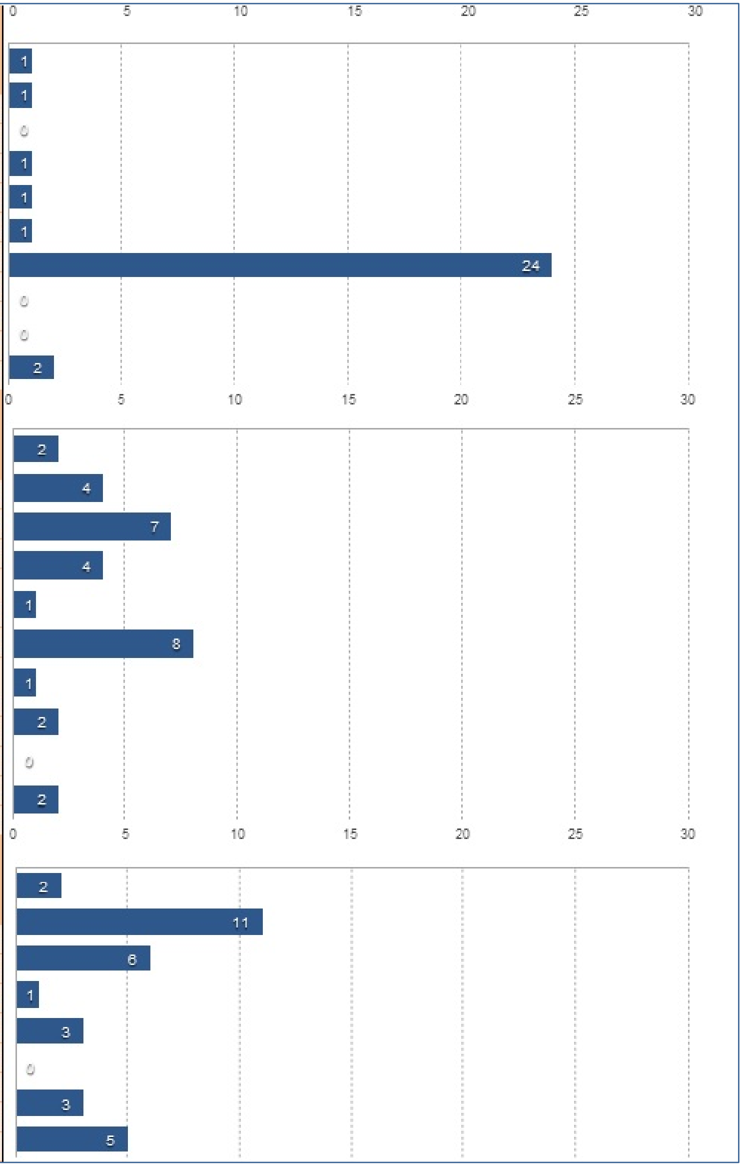
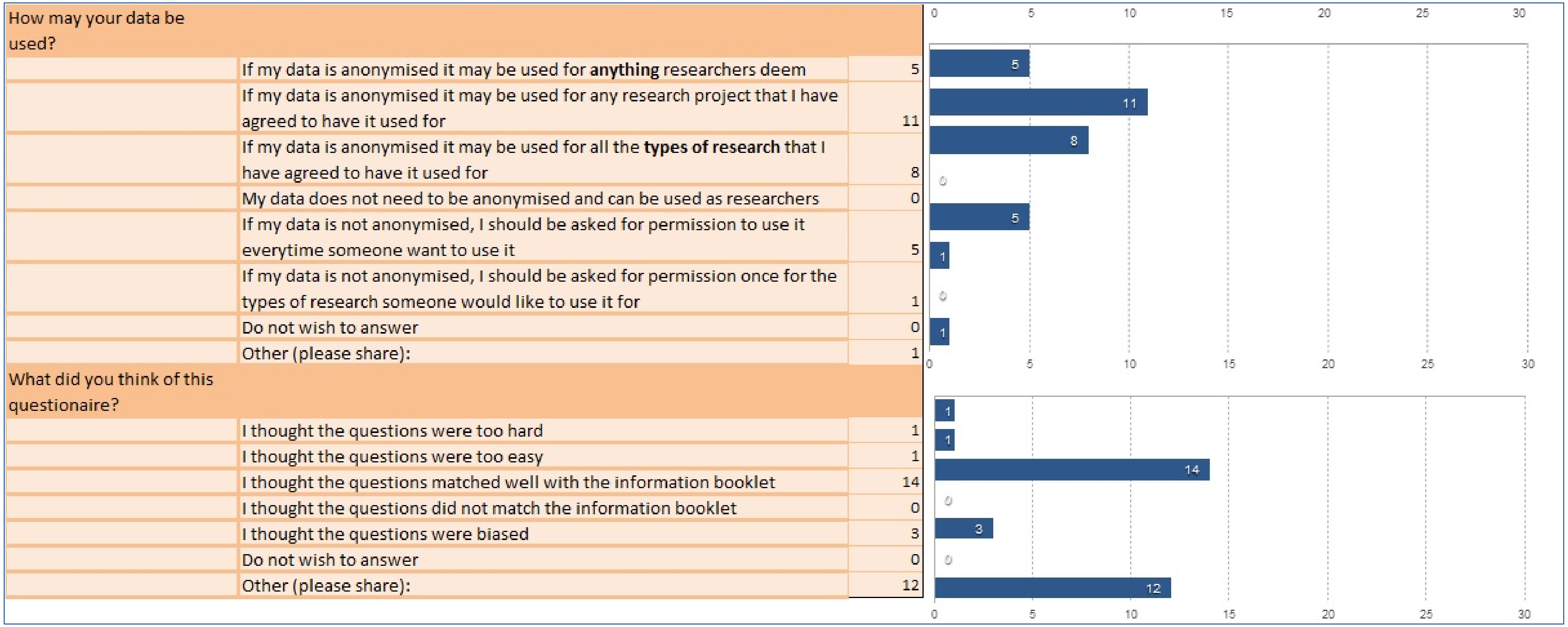


Figure 12: Results from the Austrian citizen meetings (5)



How may your data be used?		
	If my data is anonymised it may be used for **anything** researchers deem	5
	If my data is anonymised it may be used for any research project that I have agreed to have it used for	11
	If my data is anonymised it may be used for all the **types of research** that I have agreed to have it used for	8
	My data does not need to be anonymised and can be used as researchers	0
	If my data is not anonymised, I should be asked for permission to use it everytime someone want to use it	5
	If my data is not anonymised, I should be asked for permission once for the types of research someone would like to use it for	1
	Do not wish to answer	0
	Other (please share):	1
What did you think of this questionaire?		
	I thought the questions were too hard	1
	I thought the questions were too easy	1
	I thought the questions matched well with the information booklet	14
	I thought the questions did not match the information booklet	0
	I thought the questions were biased	3
	Do not wish to answer	0
	Other (please share):	12

Figure 13: Results from the Austrian citizen meetings (6)