Federal Ministry
of Education
and Research

Personalised Medicine – Action Plan

A New Approach in Research and Health Care

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Summary

The occurrence, specific form and course of a disease are dependent on many individual factors such as genetic predisposition, lifestyle, gender and age. Modern molecular biology makes it possible to identify a range of data on genetic makeup and biological processes in the body for individual patients. Personalised medicine uses this information to detect diseases at a very early stage and to prevent and treat them more effectively. This approach thus opens up a new dimension in the diagnosis and treatment of diseases.

Personalised medicine – in other words, the application of molecular-biological results and processes in the diagnosis and therapy of diseases in patient groups with the same or similar genetic dispositions – is a driver of innovation for research and health care, and also for the health care system and industry as a whole. In order to harness the potential of this new diagnosis and therapy concept, the German Federal Ministry of Education and Research (BMBF) has put in place a package of measures for strategic funding of research in personalised medicine. These funding measures are targeted at projects along the entire value chain of research and development – from the identification of molecular switches and the validation and implementation of biomarkers for diagnosis, right through to the development of personalised therapeutic processes, products and services, including the evaluation of the benefit of same.

The main goal is that patients benefit more quickly from medical therapies and products. To achieve this goal, experts from academic research, hospitals and companies are to be brought together in new partnerships. These cooperation projects will have an innovative effect on the pharmaceutical industry, on biotechnology and medical technology companies, and also on the IT sector. Project partners from the health care industry are to be included to ensure that results will be applied in the health care system.

Personalised medicine also gives rise to ethical, legal and economic issues that need to be addressed. For this reason, funding is also available for relevant accompanying research, while information and discussion platforms will be organised and supported with broad-based participation by relevant groups from society.

Between 2013 and 2016, the BMBF is providing up to 360 million euros for research and development projects. This funding will finance already up-and-running initiatives in genome research and systems biology, for example, or else will be used to initiate new funding measures. This will be supplemented by the significant funding for research and development on personalised medicine that is available within the framework of institutional support.

1. Vision: Better chances of curing patients thanks to new understanding

In just a century, we have achieved an increase in life expectancy of 30 years – due in part to major improvements in health care and the results of health research. Despite the high level of medical care available in Germany, the basic challenge still remains of developing specific, evidence-based treatment procedures that are optimally effective for individual patients and cause minimal side effects. In fact, the effectiveness of a treatment procedure can reduce to zero and the risk of unwanted side effects can increase significantly depending on genetic background, gender, age and the presence of multiple diseases. Depending on the condition being treated, only 25% to 70% of patients currently respond to the medication being administered to them. In Germany, around 2.5 billion euros are spent annually on treating undesired side effects alone.

Major research challenges still remain. However, the prerequisites for the long-term success of personalised medicine are better today than they have ever been: the foundation for a better understanding of the occurrence, prevention, diagnosis and treatment of diseases has been provided by the complete decoding of the human genome, as made possible by the rapid development of sequencing techniques and other processes for the analysis of biomaterials (e.g. blood, cells or tumour tissue). Important contributions to personalised medicine have already been achieved by computational biology processing and systematic analysis of existing data. Progress in the development of tailored treatment approaches is most advanced in the area of oncology. Similar approaches can also be identified in cardiovascular medicine, neurology and infection medicine, and in the area of metabolic disorders.

Building upon these developments, the German Federal Government has designated personalised medicine as one of six action areas in its Health Research Framework Programme.

Definition: Personalised medicine in the action plan

Personalised medicine takes into account biological factors that determine the probability of becoming ill and also influence the course and curing of diseases and the effects of therapies for every person in a unique, characteristic manner. Initially, success is expected for groups of patients with identical or similar characteristics, thus delivering so-called stratified medicine. Careful research on the factors themselves and a better understanding of complex interactions allow for the development of tailored, individual prevention and therapy procedures that will reduce the side effects of drugs and thus deliver significantly improved therapy results. The action plan and the derived activities primarily consider the influence of genes, proteins and other molecules that are of relevance to the disease and therapy; they also take into account additional applications such as individual equipment solutions (unique therapeutic products) in medical technology. The term “personalised medicine” was coined just a few years ago, and a generally applicable definition of the term does not yet exist.

Personalised medicine is opening up new opportunities for the treatment of patients and for innovation in the health care industry. For this reason, funding for research on personalised medicine will cover the entire spectrum from preclinical and clinical patient-oriented research, right through to the health care industry. Support will be provided for the systematic development of treatment procedures and products, with the aim of achieving quicker and more effective translation.

1.1 Patients: Providing more precise medicine through patient-tailored treatment

Personalised medicine has the potential to deliver a new level of quality in health care for patients. In the future, it will be possible to define cancer, high blood pressure or Alzheimer’s disease more precisely using molecular parameters. The starting point for medical interventions will then no longer be the disease itself,

but rather the patient with his or her individual characteristics and predispositions.

For many patients, a quick, accurate diagnosis would represent a significant improvement compared to the current situation. After all, the precise identification and classification of diseases can involve lengthy, onerous medical investigations. Existing diagnostic methods do not always provide sufficiently clear results. Alongside the physical and psychological burden for the patient, this also results in lost time and allows the disease to proceed further before a suitable therapy is started. A highly specific diagnosis would mean that patients could be treated in a precise manner in accordance with their molecular signature and other relevant factors. In terms of medical care, the following specific potentials become available (see page 10, "Short-term/long-term achievements"):

- *Targeted prevention of diseases*
  An increasing number of risk factors can be precisely identified for each individual. The aim here is to prevent, delay or alleviate the development of diseases with suitable measures based on this information. Individual parameters can be determined in the course of preventive examinations and a "prevention model" developed for every individual. Using this model, recommendations for the avoidance of diseases could then be formulated and suitable measures proposed.

- *Early detection and treatment of diseases*
  Early detection is to be significantly improved by diagnostic methods based on individual factors. These methods include biomarkers to be developed in the future as well as established methods such as imaging and other diagnostic procedures. The clear classification of early signs of diseases will facilitate early identification of medical conditions and thus allow for tailored intervention, which will ideally take place when the disease first occurs or even before it occurs. Patients will then receive targeted treatment before they have detected clear symptoms. In this way, the burden associated with disease will be reduced for the patient and a cure will become more probable.

Biomarkers for diagnosis and therapy

Biomarkers are characteristic biological features that can be measured reliably and are indicative of normal or pathological processes in the body. Possible biomarkers include genetic sequences, proteins, metabolic products or other molecules. Disease-related biomarkers could serve as so-called risk indicators (predictive biomarkers) in the future and provide information as to whether a disease is likely to occur, is already present (diagnostic biomarker) or how a disease will probably develop in an individual case (prognostic biomarker).

- *Making diagnosis more precise and deriving more effective therapies*
  Closer integration of diagnosis and therapy – also referred to as theranostics – will facilitate decision-making regarding the use of a given therapy and also allow for monitoring of the dosage and effectiveness of treatment procedures. Currently, doctors often have to identify a suitable treatment for patients using "trial and error"; in the future, however, they will be able to prescribe a therapy that will have a much greater probability of being effective. This will spare patients ineffective treatments and undesired side effects.

- *Development of new therapeutic procedures and products*
  There is still no causally effective treatment procedure available for many conditions. In the future, newly developed drugs and treatment procedures could be used from early treatment through to follow-up care of diseases in a manner more specifically tailored for patients or patient groups. As an initial step, the effectiveness of established procedures could be tested even before a certain drug is administered. The aim is significantly improved effectiveness for treatment procedures and drugs, accompanied by a minimisation of side effects – particularly in the case of multi-morbid patients.

1.2 The health care system: Deploying resources in a sustainable and efficient manner

Expert opinion is divided on how personalised medicine will affect costs in the health care system. As a general rule, innovative treatment procedures

and products result in additional costs. More intensive and sophisticated diagnosis, the production of drugs for small patient groups, the greater amount of consultation necessary and the need for additional equipment could also lead to cost increases in the case of personalised medicine. At the same time, however, more specific diagnosis could help avoid additional, time-consuming investigations and ineffective treatments and thus reduce costs. If better prevention and early detection were achieved on a broad scale and drugs were used in a more targeted manner with greater probabilities of being effective, costs would be reduced for both the health care system and the social welfare system as a whole, as periods of disease could be shortened or even avoided.

The new options would lead to additional challenges in everyday medical practice: in order to implement the resulting, increasingly specific diagnostic and therapeutic procedures, new equipment and IT will become necessary and doctors and other medical specialists will need specific training.

1.3 The health care industry: Driving new products and procedures

The health care industry is already very much aware of the field of personalised medicine. Small and medium-sized biotechnology and medical technology companies are excelling here as innovators and are proving to be attractive partners for medium-sized and large pharmaceutical companies. In tumour therapy in particular, diagnostic procedures are already available that can predict the effect of a drug and thus facilitate targeted treatment. Knowledge gained in the area of personalised medicine can be of benefit to all actors who wish to introduce innovative diagnostic and therapeutic agents into clinical practice. The following specific opportunities result here for the health care industry:

- *Closing of innovation gaps*
  Falling productivity in drug development and the gradual expiration of patent protection for many "blockbuster" drugs are global challenges faced by the pharmaceutical industry that are threatening the competitiveness of Germany as a location for the pharmaceutical sector. Personalised diagnostic and therapeutic procedures offer enormous potential to close innovation gaps. In particular, participants in partnerships with companies from the biotechnology, pharma and other relevant industrial sectors and with academic research will have an opportunity to become highly innovative and successful players in the market.

- *Reduction of R&D costs*
  The analysis of individual profiles – including relevant factors such as genes and lifestyle – allows for the classification (stratification) of patient groups and thus also for a reduction in the costs of carrying out tailored clinical studies with fewer test subjects. This can speed up the approval process and, at the same time, reduce the risk of failures in drug development. New drugs can be granted approval more quickly and become available earlier to patients.

- *Optimisation of the proof of effectiveness*
  The parallel development of therapy and diagnosis improves the potential for fulfilling the increasingly stringent requirements for the proof of effectiveness for therapies. Such evidence is a prerequisite for the reimbursement of costs by statutory health insurance, which in turn allows innovative drugs to become accessible to the majority of patients in Germany. In addition, companion diagnostics will offer improved therapy monitoring. In this way, treatment regimens can be adapted more quickly.

- *Expanded use of approved drugs*
  New methods in molecular biology allow for a more targeted use of known substances and the proof of efficacy for additional indications. In this way, the scope of applications and market potential of approved drugs can be expanded.

1.4 Society: Assuming greater responsibility for our behaviour

Personalised medicine opens up new opportunities for society as a whole and for individuals, as it offers everybody significantly greater scope for decision-making with regard to personal health. This applies above all to the detection of risks of disease

and to the selection of preventive and therapeutic procedures. This creates a potential for more self-determination, but may also lead to an expectation by society that individuals assume greater responsibility themselves.

Another issue here is the balance between the protection of personal data and the potential for saving lives with this data. There is great interest in personalised medicine, but the general public remains poorly informed about this subject. It is necessary to initiate dialogue between natural scientists, medical professionals and the fields of the humanities, law and the social sciences, and to include the public sphere in this dialogue on a permanent basis. The aim of this interdisciplinary dialogue is to help to create a framework that is accepted by society for the application of personalised medicine.

2. Programme: The new priorities of BMBF funding

In just a few years, personalised medicine has developed considerable momentum around the world and is becoming an established field in its own right. For example, around 1.2 billion euros of funding has been made available for personalised medicine in the EU's 7th Framework Research Programme. The National Institutes of Health (NIH) and the Food and Drug Administration (FDA) in the United States developed a joint roadmap in June 2010 that aims to accelerate the development of new drugs and ensure the safety of diagnostic and genetic tests. The "Stratified Medicine Innovation Platform" (SMIP) was established in the United Kingdom in 2010 – this is a joint initiative of the Department for Business, Innovation and Skills and the Medical Research Council (MRC). Major foundations such as the Wellcome Trust are also dealing with this subject.

Since the mid-1990s, the BMBF has provided extensive funding to projects that have developed important foundations for personalised medicine. Examples here include funding measures such as the National Genome Research Network, the innovation competitions for systems biology, the Translation Centres for Regenerative Medicine, application-oriented research on innovative therapies and molecular diagnosis, and the BioRN, m[4] und CI3 excellence clusters[1]. In this way, high-performance cooperation networks and research structures have been established in Germany that create the knowledge basis and technological foundations for personalised medicine. As a result of this funding, Germany is now an important and attractive partner in major international projects.

In order to build upon these developments and harness the potential available, the German Federal Government announced at the end of 2010 that personalised medicine would be one of the six fields of action in its Health Research Framework Programme. With the "Personalised Medicine: A New Approach in Research and Health Care" action plan, new measures are being initiated that build upon successful previous funding activities. Recommendations from the Health Research Council and the Industry-Science Research Alliance have served as input into the structuring of future research funding. Up to 360 million euros of project funding has been earmarked for the implementation of the action plan between 2013 and 2016; this will be supplemented by significant amounts of institutional funding.

Major national research institutions are working on developments that will help to deliver personalised medicine and are currently developing specific concepts and strategies aimed at integrating this field into their research activities. Personalised medicine is an integral component of the research strategy of the German Health Research Centres (DZG). Their complementary focus to project funding will help to establish efficient research capacities for personalised medicine in Germany. The Max Planck Society is also making a significant contribution to personalised medicine. The basic research it is carrying out is facilitating technological breakthroughs that are applied in personalised medicine projects. The Helmholtz Association is planning to expand this area as a special strategic interdisciplinary task within the framework of its programme-oriented funding. Application-related basic research and translational research are to be bundled and progressed in a coordinated manner within an interdisciplinary alliance. Within the Fraunhofer Society, institutes from various fields are involved in interdisciplinary cooperation to identify biomarkers for various diseases, for example. A number of institutes within the Leibniz Association are investigating disease causes and contributing to the personalisation of medicine; particular areas of expertise here are nutrition research and the analysis of environmental factors.

The identification of biomarkers is a focus of university research. Basic research into personalised medicine at universities is supported by the German Research Foundation in particular – as part of collaborative research centres, for example. Selected universities are partners within BMBF-funded excel-

1 BioRN: Cell-based and molecular medicine in the Rhine-Neckar metropolitan region; m4: Munich Biotech Cluster for personalised medicine and targeted therapies; CI3: Cluster for personalised immune intervention in the Rhine-Main region

lence clusters focused on personalised medicine. In addition, a number of universities are partners within the German Health Research Centres.

Alongside German research institutions and universities, various other funding bodies, such as ministries and foundations, are also involved in international activities. For example, a "Coordination and Support Action" (CSA) on personalised medicine that is coordinated by Germany is currently being prepared within the 7th EU Framework Research Programme.

As an interdisciplinary subject, personalised medicine also has an impact on other fields of action in the Health Research Framework Programme. In cases where funding seems promising but the main focus lies in another field of action, measures are classified in that field of action. Research funding within the personalised medicine field of action will be evaluated as part of consideration of the German Federal Government's Health Research Framework Programme.

2.1 Funding goals

With its funding measures, the BMBF primarily aims to improve understanding of individual factors in the development of diseases and carry out research on possible ways of influencing disease course in a beneficial way. Potential applications of research results are to be clinically validated, and new procedures and products are to be developed. One goal here is to remove barriers between the various phases of the innovation cycle – for example, in the translation of findings from bench to bedside or from clinical validation into product development.

Dynamic developments in basic research – for example, in genome research and in other analytical techniques – are the driving force behind personalised medicine. Targeted development of these approaches and their application to medical issues provide the foundation for more accurate diagnosis and for innovative therapies. The promotion of systems medicine, which generates this knowledge and aims to transfer it into medical care for the benefit of patients, is thus playing a prominent role here.

The benefit of personalised medicine for patients, its importance within health care and its market potential for the health care industry depend very much on the availability of powerful and meaningful biomarkers in clinical practice. To achieve this goal, comprehensive analysis of biomarker candidates should not only include the assessment of their diagnostic value, but also take into account regulatory and market-related requirements. For this reason, the validation of promising biomarkers in clinical studies is to be supported; these biomarkers will then be used to develop personalised preventive and therapeutic options.

The design of clinical studies will also have to be adapted. This is essential in order to test the safety and efficacy of new procedures and products for small groups or individual patients. Accordingly, relevant concepts and new developments will be supported. In addition, need-oriented studies on therapy improvement and studies on new standards with regard to regulatory approval and cost-effectiveness evaluation are required in order to transfer innovations into medical practice for the benefit of patients.

In order to facilitate the implementation of procedures and products and to harness the economic potential of personalised medicine, partnerships between academia, clinics and industry are to be supported.

Certain important research goals in the area of personalised medicine can only be achieved within the context of international mega-projects. By actively participating in these projects, German researchers can benefit from synergies in terms of knowledge exchange and research infrastructures that result from worldwide networking of research institutions and their researchers.

Ethical, legal and social issues must also be considered at an early stage to ensure that new developments such as personalised medicine are used in a responsible manner. For this reason, relevant studies are being commissioned and information and communication platforms are being developed – these include interactive information sources on the Internet, discussion events and specialist information

for various media. These information services are structured in a dialogue-oriented manner and deal with all aspects of personalised medicine.

The planned funding measures aim to establish results that promote the development of new approaches to prevention and treatment and also create the societal and legal framework conditions for the acceptance and application of personalised medicine. Examples of expected short-term and medium-to-long-term achievements are listed here:

Short-term achievements (1-5 years)

- Faster and more precise diagnosis on the basis of validated biomarkers
- Improved treatments thanks to closer linking of diagnosis with therapy and the integration of data into research and medical practice
- Increased investment in personalised medicine by the health care industry
- Better public understanding of personalised medicine

Long-term achievements (6-10 years)

- Reduction of side effects thanks to targeted drugs
- Avoidance of ineffective treatments
- Accelerated market entry for personalised medicine products and services
- Establishment of more patient-tailored medicine

2.2 Funding measures

The following funding measures cover the innovation chain from basic biomedical research and translational research, right through to commercial implementation. They take into account the necessity of creating societal acceptance as well as a legal framework that facilitates the application of personalised medicine.

2.2.1 Identification: Better understanding of diseases

The e:Med research and funding concept

Research efforts up to now have made one thing particularly clear: research limited to the analysis of single factors fails to provide a full understanding of the pathogenesis of many diseases. In addition, major diseases are of multi-factorial origin and exhibit highly variable individual courses. Lifestyle factors, such as nutrition and physical activity, as well as environmental influences play an important role in modifying the course of diseases. These factors influence the individual genetic and physiological processes in humans – one person may fall ill, while another will not. The focus of future research and funding activities will be the investigation of this complex interaction. How do the various levels in the system affect each other? Which mechanisms act in what way, where and under what conditions, and how are they regulated or how can they be manipulated?

e:Med is a research and funding concept that seeks to pave the way for this system-oriented research into disease by combining approaches and methods from the life sciences with those from information technology. Systems medicine requires large, meaningful data sets from different sources– from genetic information through to clinical data such as blood test results or imaging data. The research approaches employed in systems medicine are being driven by dynamic technological advances in the life sciences. In particular, these advances include major improvements in techniques for collecting and processing large sets of genetic, cell-biological, physiological and visual data at ever-lower costs. The resulting enormous volumes of medically relevant data can be analysed and used only with the help of state-of-the-art information technologies (e:Med).

The new “Demonstrators for personalised medicine” funding measure supports pilot projects that demonstrate how data from high-throughput research can directly enhance personalised prevention, diagnosis and therapy. Modern high-throughput techniques, along with advances in bioinformatics, now make it possible to collect and analyse ever-greater

volumes of medically relevant data systematically and at reasonable costs. Although the data sets involved contain large amounts of information, little research has been carried out to date regarding the prognostic, diagnostic and therapeutic value of this data in individualised medicine. The information sciences must play a greater role here in making such data available for clinical application. For this reason, support will be provided for the development of innovative methods and (bioinformatics) tools that can determine the direct benefits and applicability of systems-oriented approaches, drawing on data from high-throughput research. So-called "omics" data sets – such as genomic, transcriptomic, epigenomic and metabolomic data – and data on clinical phenotypes and environmental factors are to be used to this end. This work will emphasize ways of making data available, of usefully integrating and analyzing data, and of applying pertinent mathematical models. There must be prospective clinical applications in all cases. The "Demonstrators for personalised medicine" funding measure provides a suitable framework for support of research cooperation between academic research and biotechnology companies.

2.2.2 Validation and implementation: Testing and translation of findings into clinical practice and the health care industry

The aim is to translate the preventive, diagnostic and therapeutic approaches of personalised medicine into clinical practice for the benefit of patients. A critical element here is the validation of biomarkers. Up to now, numerous "potential" biomarkers have been identified, but in most cases their actual clinical value has not yet been verified. There is a significant need for research and development in this area in the coming years.

Validated biomarkers will allow for the identification of individual patients or patient groups for whom certain prevention or treatment strategies appear promising. The development of diagnostic procedures and therapeutic agents goes hand in hand here. In the future, the analysis of biomarkers will allow doctors to choose the most promising treatment strategies. As regards the identification and validation of new targets for therapy, there is a challenge in interrelating molecular, patient-specific information to the occurrence of intended effects and side effects in studies in a systematic manner. This challenge applies both to new developments and approved active substances, and also to drug combinations that are used in the treatment of multi-morbid patients. The use of these drugs could be structured in an individual manner in order to improve their tolerability.

Strategic partnerships between various participants from academic research and the health care industry are required for the translation of research results into clinical practice. Support will be provided to set up cooperation projects and alliances that aim to develop innovative products and procedures for the benefit of patients. To achieve this aim, these collaborative projects will have to (i) validate innovative molecular biomarkers with regard to their potential for personalised medicine, (ii) carry out pre-clinical research and phase I and II clinical trials in order to develop indication-specific therapeutic and preventive personalised medicine approaches, or (iii) evaluate clinical benefit with regard to the improvement of care.

The "Innovations for personalised medicine" funding measure is organised in three phases. In the first phase, actors from research, clinics and industry will be invited to a partnering workshop to discuss strategic concepts for the development of personalised diagnosis and therapy. The aim of this "innovation marketplace" is to promote the development of new ideas and to foster the formation of new teams. This will result in cooperation between various participants who need to be networked if their ideas are to be implemented. For small and medium-sized enterprises in particular, an opportunity is to be created to harness their expertise in innovation in partnerships with other actors from the fields of research and industry.

In the second phase of funding, those teams with the most promising concepts will receive short-term development grants to specify their consortium concepts in more detail and to test the feasibility of these concepts. Support will be provided for the development of a research and development plan for scientific and technical implementation and of a strategy for commercial realisation of the project idea. In the third phase, the implementation of the best projects will be supported.

With regard to the implementation of personalised medicine approaches, graduates of life-science courses are to be given the opportunity to carry out research themselves in companies. As well as helping to train young professionals for roles in the health care industry, this also has the effect of fostering new types of partnerships between academic research and industry.

The introduction of personalised medicine approaches with a proven record of success also requires new methods and tools in various research areas. Support will be provided for the development and testing of methods and tools if they can demonstrate their broad importance and applicability – for example, in the case of new clinical trial designs.

2.2.3 Dialogue: Analysis of societal consequences

Studies on ethical, legal and social issues

In order to identify the consequences of personalised medicine for patients and the health care system, it is also necessary to consider the ethical, legal and social aspects of this innovative research approach. The framework conditions und normative issues are central to societal debate on personalised medicine. Which demands can society make of an individual with regard to health care once an increased risk of disease is present? Does awareness of a risk result in an obligation for every individual to behave in a manner that is adapted for their individual health status? Who should have access to data on individual disease risk? These and other questions must be analysed as part of interdisciplinary dialogue and balanced solutions need to be developed.

Since 1997, the BMBF has been offering various lines of funding for research projects on issues that arise due to progress in the modern life sciences. It has thus been possible to draw on established instruments in this funding area in dealing with issues that arise from the development of personalised medicine. Support for interdisciplinary research alliances appears to be particularly well suited for dealing with the multi-facetted issues associated with the introduction of personalised medicine. However, other instruments can also be employed, such as summer schools where young researchers from relevant disciplines can improve their interdisciplinary working and communication skills.

The aim of dialogue between the public, politicians, researchers, health care institutions and other relevant stakeholders is to create an accepted framework for dealing with personalised medicine and to harness the potential of personalised medicine for the good of society as a whole.

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