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A practice model for personalized healthcare with a public health genomics perspective

Epidemiological and demographic transition has brought populations to an extended life expectancy in the 21st Century. The diseases of this century are complex, which stem mainly from the complex interactions of the human genome with lifestyle and environmental factors. These diseases are common, chronic and costly. Currently, the best-known prevention for complex diseases is adopting a healthy lifestyle. However, this is not achieved in many places in the world. Effective intervention models, including lifestyle changes for the prevention of these diseases, is urgently needed. In this report, we introduce a preventive healthcare model based on personalized healthcare. It is based on the application of public health genomics tools and concepts on an individual level, in order to stratify individuals according to risk groups, prevent diseases and detect them early.

KEYWORDS: chronic complex diseases ■ genetic predispositions ■ nutrigenetics ■ personalized healthcare ■ public health genomics

Life expectancy has been steadily increasing in almost all regions of the world since the beginning of the 20th Century. This happened as a result of epidemiologic and demographic transition in the world [1]. In the beginning of the 20th Century, life expectancy was below 50 years in western countries, whereas today it is above 75 years. Populations are rapidly aging.

The diseases of the 21st Century are chronic and complex, which stem mainly from the complex interaction of the human genome with lifestyle factors. Cardiovascular and cerebrovascular diseases, cancers, diabetes, obesity, osteoporosis, neurodegenerative diseases and psychiatric diseases are among major chronic and complex diseases, which account for approximately 84% of deaths and 76% of the burden of disease in high- and upper-middle-income countries [101]. The prevalence of chronic diseases increases significantly with age. Thus, the 21st Century brings us to an aged population living with chronic conditions, creating a huge burden on healthcare systems and society. Complex diseases are not only the problem of high-income/industrialized countries, but also low-income countries in the process of industrialization.

One of the biggest challenges of the health and social systems of the 21st Century is to add productivity and life quality to prolonged life years, while keeping the healthcare costs under control by reducing the burden of complex diseases. The solution lies in preventive interventions that start in earlier ages, much earlier than the onset of the complex diseases. As the

most important preventive measure, individuals must follow an appropriate and personal lifestyle plan. Giving general information and recommendations on health issues to the public has limited effectiveness to change the lifestyle of individuals. Therefore, an effective intervention model including lifestyle changes for prevention of these diseases is urgently needed.

Complex diseases, genetics & personalized healthcare

■ Complex diseases & genetics

Complex diseases are caused by the interaction of genetics with the lifestyle of an individual. In order to understand the genetic basis of diseases, we can visualize the diseases in a threshold model, as shown in **FIGURE 1**. Here, diseases are grouped into three major areas, according to the disease-causing factors.

The first group of diseases are caused by alterations in the genetic structure of human beings. Down's syndrome and cystic fibrosis are disorders caused by deleterious changes in the genes associated with the diseases. They constitute a small fraction of the burden of disease. External factors play little or no role in most of these diseases. With today's conditions, there is limited space for measures to prevent the disease occurrence in individuals carrying a genetic abnormality (see first column in **FIGURE 1**).

The second group of diseases are caused directly by external factors such as infectious diseases, injuries, poisonings and so on (see second column in **FIGURE 1**). Genetics has a very limited

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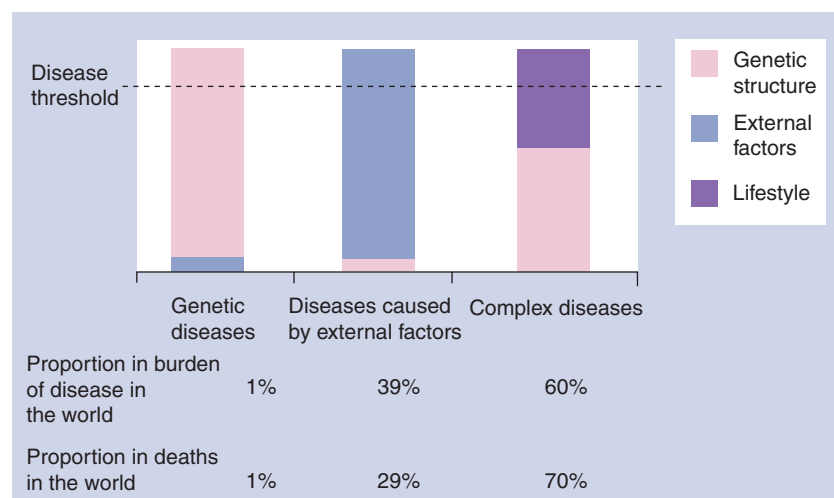


Figure 1. Diseases, genes, environment and lifestyle interaction from a disease threshold perspective.

role in these conditions. This group, especially infectious diseases within it, was the major burden of disease before the industrial revolution. The burden of disease caused by this group has reduced relatively, parallel to the developments in science and technology such as sanitation, antibiotics and vaccines.

The third group consists of disorders where common variations in genetic structure (polymorphisms) create a predisposition to the disease, but cannot cause the disease without other factors, mainly unfavorable lifestyle factors of individuals (see third column in FIGURE 1). Because of this complex nature of gene–lifestyle interaction, they are called complex diseases. Main examples include cardiovascular and cerebrovascular diseases, diabetes, osteoporosis, cancers, neurological conditions and psychiatric disorders, which are mostly late-onset chronic diseases. They arise from an individual's lifestyle and environmental factors imposed on their genetic predisposition. They consist of a large proportion of burden of disease all over the world. The burden of chronic complex diseases will continue to expand steadily as a result of demographic and epidemiological transition in the next 20 years [101].

■ Opportunities for the use of genetics in complex diseases

Since the successful completion of the Human Genome Project, we have an exponentially increasing understanding of genetic factors and complex diseases. The identification of new genes and polymorphisms that have influence in diseases is helping to understand the underlying biology of the diseases, and leading to new therapeutic approaches, as well as understanding

of how genetic variations are of influence in predisposition of different individuals to different diseases. The knowledge regarding associations of polymorphisms with complex diseases is constantly growing.

One of the success factors of nutritional interventions is prediction of the response of the individual to specific interventions. At this point, nutrigenetics is expected to play a major role. Nutrigenetics, which studies an individual's specific response to diet owing to genetic variants (polymorphisms) [2], is positioned as the emerging face of nutrition that, when considered with more classical approaches, will provide the necessary stepping stones to achieve the ambitious goal of optimizing an individual's health. Similarly, pharmacogenetics will allow us to tailor the pharmacological interventions according to the specific needs of individuals, and minimize side effects while maximizing efficacy.

The strong interaction of biological and genetic factors with lifestyle factors in the development of chronic and complex diseases has brought us to a new understanding of 'genetics', where genetics is not only related to the study of rare hereditary disorders, as understood in 'conventional' medical genetics. In the late 1990s and early 2000s, it was foreseen that genetics/genomics would revolutionize medicine [3–5], and that genetics would become a tool widely used for prediction, diagnosis and the optimization of treatment in most common diseases within the current decade [3,4].

New issues and problems arise related to various aspects of this new potential practice; such as practice models of complex genetics, nutrigenetics and pharmacogenetics; clinical utility and validity of genetic tests; and ethical, legal and social aspects. They fall under the area of public health genomics, which is defined as a multidisciplinary field concerned with the effective and responsible translation of genome-based knowledge and technologies to improve population health [102]. Public health genomics uses population-based data on genetic variation and gene–environment interactions to develop evidence-based tools for improving health and preventing disease [103].

One of the most promising implication areas of genomics lies in preventive healthcare, especially for complex diseases. Applications of personalized medicine combined with the advent of health information technology in clinical practice will bring a new kind of medical care: personalized healthcare [104]. It is healthcare that works better for each patient, based partly on

scientific information that is new, and partly on technology to make complex information useful [104].

■ Facts & challenges for the use of genetics in complex diseases

As we are approaching the end of the decade, science has made important progress in the discovery of genes and polymorphisms. However, their integration into medical practice has been limited. Current examples of the usage of common polymorphisms in clinical practice are polymorphisms in *F5* (Factor V), *F2* (Factor II) and *MTHFR* for thrombophilia and perinatology; *APOE* for cardiovascular risks and Alzheimer's disease risk; and *CYP2C9*, *CYP2C19* and *CYP2D6* for pharmacogenetics. Limited use of polymorphisms in medical practice has been the result of the fact that evidence demonstrating the effectiveness in clinical use is not fully established yet. On the other hand, the current knowledge about the above-mentioned areas already has the potential to be used for the benefit of the individual and society.

There are limitations and room for improvement for the current scientific information. Although the knowledge about associations of polymorphisms with complex diseases is constantly growing, evidence is not fully established. Current linkage analysis and genome-wide association studies are focused merely on the genotype–disease relationship. Genotype information can be investigated together with other contributing factors for assessment of disease risks (lifestyle including smoking, nutrition, and exercise; personal health history; family history; environmental exposures, and so on). On the other hand, current studies investigating the interactions between genotype and lifestyle factors are bringing limited evidence owing to small sample sizes. The limited number of prospective studies demonstrates the benefit of selected nutrition or nutritional supplement use based on selected genetic structures [6]. This type of prospective intervention study is needed for various other claims regarding nutrient–genotype interactions.

Limited information suggests that personal risk assessments and personalized recommendations can be a more effective means compared with classical approaches to change the lifestyle of the individuals [7]. In addition, the current level of technology allows us to make personalized risk assessments and develop personalized recommendations based on health information of individuals, including genetic information. There are several initiatives to benefit from genetic data to make

personalized risk assessments and recommendations [105–108]. However, the effectiveness of such applications has not been thoroughly evaluated (i.e., controlled prospective studies).

Approach of GENAR Institute

As the GENAR Institute for Public Health and Genomics Research (Ankara, Turkey), we have been working on the development of a practice model called Gentest®, which is an endeavor to face the above-mentioned challenges as an integrative preventive model that utilizes an individual's health information, lifestyle factors, biomarkers and genotype in order to prevent and detect chronic and complex diseases early in a targeted way [8] (for information on GENAR Institute, see Box 1).

The mission of this practice model is changing the behavior and managing the health of individuals according to their health priorities.

The conceptual framework of Gentest is presented in FIGURE 2. Its components are described in the implementation stages below.

Gentest is designed to be implemented in primary-care settings where the health professional(s) (physicians and/or dieticians) can focus on preventive healthcare interventions. For the piloting phase of the model, it is mainly practiced in the Gentest Implementation Center, which is run by GENAR. In addition, health professionals are authorized to be practitioners of Gentest after participating in training of the Turkish Society of Public Health Genomics and Nutrigenetics and the GENAR Institute.

The diseases/health areas that are undertaken in Gentest are selected based on their prevalence, the burden they create and the ability to recommend lifestyle and medical interventions

Box 1. GENAR Institute for Public Health and Genomics Research.

The GENAR Institute for Public Health and Genomics Research was established in 2004, in Hacettepe University Science Park, Ankara, Turkey. It is the third public health genomics center in Europe and a cooperating institute of Public Health Genomics European Network (PHGEN) [110]. The GENAR Institute aims to transform scientific developments in the area of biotechnology, especially those in genetics and genomics, into products and services that improve human health, quality of life and performance, and extend lifespan. The GENAR Institute has a broad range of working area, mainly on chronic complex diseases. The R&D activities focus on understanding the underlying genetic and genomic basis of these conditions and developing products based on targeted prevention, early detection and treatment strategies.

The GENAR Institute is comprised of three centers: GENAR Biotechnology and Molecular Genetics Research and Diagnostic Laboratories, which is a high-throughput molecular genetic analysis laboratory; GENAR Center for Nutrigenetics and Lifestyle Research, which focuses on quantifying the nutrition and other lifestyle factors of individuals and developing models for personalized nutrition and lifestyle advice for optimization of individual needs; and the GENAR Center for Personalized Medicine and Pharmacogenetics, which aims to catalyze transfer of developments in genetics to the health of individuals with a public health vision. There has also been an implementation center in Istanbul, Turkey, to pilot the developed models.

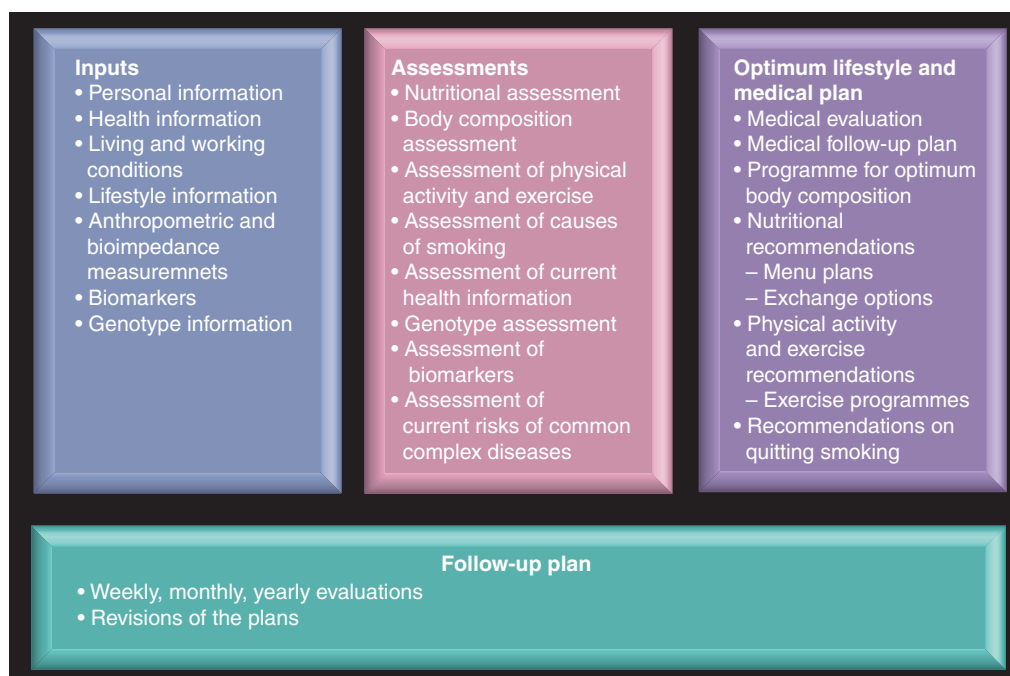


Figure 2. Conceptual framework for the Gentest practice model.

to reduce the risks or delay the onset of these diseases. Currently, the following diseases and health areas are undertaken in Gentest:

- Cardiovascular and cerebrovascular diseases;
- Insulin resistance, Type 2 diabetes and obesity;
- Inflammation;
- Osteoporosis;
- Antioxidation and detoxification mechanisms;
- Cancers in general, and the five most prevalent cancers in particular, which are lung, breast, prostate, colon and stomach.

■ Implementation stages of the practice model

Data & information collection stage

An individual who applies to the Gentest Implementation Center is first explained what Gentest is, and what it is not (see TABLE 1). The most suitable Gentest package for that individual's personal characteristics and requirements is chosen with the help of the physician.

Special attention is paid to create proper consumer expectations, as defined in TABLE 1. For this purpose, a sample Gentest, which is an anonym report of a real case, is presented to the individual. After oral and written acknowledgments explaining the issues summarized in TABLE 1, the individual signs the consent form for DNA analysis. An appointment is given to come with overnight fasting.

When the person comes to the appointment, blood and urine samples are taken. Anthropometric measurements are made using scales and a tape measure, and bioelectrical impedance is used for body composition analysis. Blood pressure and pulse is measured. The individual fills in a detailed questionnaire collecting the necessary inputs listed in Box 2 with the assistance of a health professional. Gentest Food Portion Atlas (FIGURE 3), which is developed by GENAR, is used during collection of food consumption data. It takes approximately 2 h for measurements and filling in the information form.

Blood and urine biomarker analysis are carried out by an external biochemical laboratory and the results are forwarded to the GENAR Institute. One tube of blood sample is transported to GENAR Laboratories for genetic analysis.

Assessments

The questionnaire is analyzed by the GENAR Center for Nutrigenetics and Lifestyle Research, to quantify the nutrient intake, physical activity status and causes of smoking. The current consumption status of macro- and micro-nutrients are assessed with the analysis of both food consumption records and food frequency questionnaires.

For each macro- and micro-nutrient, a minimum and maximum level of intake recommendation is determined. These nutrients include: macronutrients such as protein, carbohydrate and fat, including different saturated/unsaturated fats

Table 1. What is Gentest and what is not?

What is Gentest?	What is not Gentest?
Gentest is developed to assist health professionals and the individual in their efforts to prevent diseases and promote health	–
Gentest recommendations are subject to the evaluation of and can be changed by the health professional	–
Gentest can only be implemented through authorized health professionals (physician and/or dieticians, according to the content of the packages)	Gentest is not a direct-to-consumer service
Gentest provides information on disease predispositions and risks	Gentest does not diagnose diseases or give treatment advice. Gentest does not provide deterministic information if a person will develop a disease or not
The main purposes of the risk calculations are to provide the lifestyle and medical follow-up interventions in a targeted way and to create individual risk perception	–
Gentest gives personal recommendations to decrease one's health risks and lead a healthier life within their own genetic make-up	Being predisposed to a disease does not mean that the person will definitely develop it
Risk calculations are based on population studies and refer to the risk of subgroups of individuals carrying the characteristics of the individual subject to the test. The characteristics used for the calculations are: age, gender, health information, biomarkers, lifestyle factors and genetic make-up	Carrying the risk of the disease does not mean that the person will definitely develop it
Based on the current scientific knowledge, following the medical follow-up and lifestyle recommendations given in the Gentest report reduces one's disease risks	Following the medical follow up and lifestyle recommendations given in the Gentest report does not completely eliminate one's risks

and omega 6/omega 3 fatty acids; vitamins; minerals; and key functional foods. Recommended levels are based on age, gender, current diseases, genetic information and lifestyle information of the individuals. Recommendation algorithms are based on international and national guidelines on macro- and micro-nutrients and literature on nutrition and nutrigenetics research. The recommendations are presented both in tables and figures (for an example of figures, see FIGURE 4).

Assessment on body composition is made using anthropometric measurements and bioimpedance analysis (FIGURE 5).

Current exercise status related to eight different areas of physical fitness is assessed. These areas are cardiorespiratory fitness, muscle strength, bone strength, muscle endurance, flexibility, balance, insulin sensitivity and body composition. Currently, this assessment is based on the type, intensity, duration and frequency of the exercises carried out by the individual. More objective methods to assess the physical fitness levels of the individual are under development. The recommended level of exercise for each physical fitness area is determined according to disease risks, genetic predispositions and personal preferences (FIGURE 6).

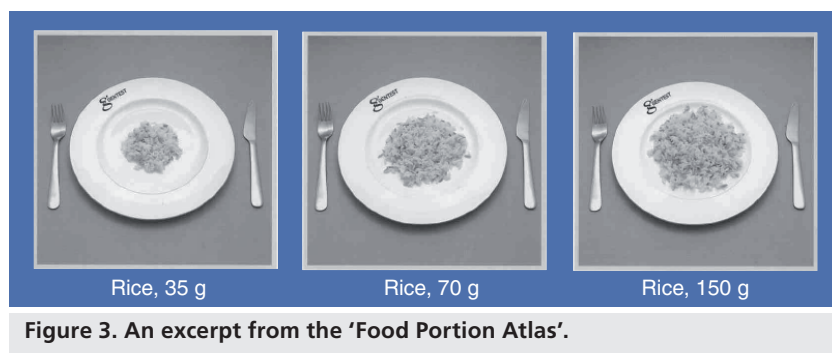
If the individual is smoking, causes of smoking are also assessed using questionnaires. The types of smoking assessed are nicotine

craving/physiological addiction, stimulation, relaxation/pleasure, crutch/tension reduction, habit and handling (hand contact with the cigarette).

In parallel to assessment of the lifestyle information, genetic analysis is carried out by GENAR Biotechnology and Molecular Genetics Research

Box 2. Inputs of Gentest.

- Personal information
 - Age
 - Gender
- Health information
 - Personal history (current and past diseases and medications)
 - Family history
- Living and working conditions
 - Occupation
 - Past and present occupational and environmental exposures
- Lifestyle information
 - Physical activity and exercise
 - Smoking and drinking habits
 - Supplement consumption
 - Nutritional habits
 - Food consumption (24 h recall and food frequency)
- Anthropometric and bioimpedance measurements
 - Height, body weight and composition
 - Waist circumference
- Biomarkers
- Genotype information



and Diagnostic Laboratories. Genetic analysis covers common polymorphisms related to common complex diseases and conditions listed above (see Approach of GENAR Institute section). For each health area, the results are presented in a table that presents information on the gene, function/role in health-related area, polymorphism and the genotype result of the individual, as well as what the result indicates for that disease/health area (for a sample page, see FIGURE 7). The number of polymorphisms studied varies from 35 to 65 in the different packages.

Polymorphisms in the health area of interest are selected qualitatively based on considering a number of aspects. The studies that show a positive association and no association are evaluated in their design, statistical power, presented odds ratios and p-values, as well as the credibility of the published journal. Frequency of the polymorphism in white Caucasians are also taken into account. Studies on gene–lifestyle interactions are also evaluated with this perspective in mind.

Biochemical markers such as blood lipids, fasting plasma glucose, liver and kidney function tests, homocysteine, high-sensitivity C-reactive

protein and fibrinogen are analyzed by external clinical laboratories. The biomarkers are selected and assessment methods are developed in light of the current medical guidelines and literature.

The results of lifestyle assessment, genetic analysis and biomarker tests are gathered in the GENAR Center for Personalized Medicine and Pharmacogenetics, in order to produce the report of the individuals.

In the GENAR Center for Personalized Medicine and Pharmacogenetics, risk assessments for the most common chronic complex diseases are made. These include myocardial infarction, stroke, Type 2 diabetes, osteoporosis and the five most common cancers (lung, breast, prostate, colon and stomach). Risk assessment algorithms are based on risk factors conveyed by various epidemiological studies and risk assessment models. The genetic analysis results are also used as a factor in risk assessment, but with very small effect sizes given the limited demonstrated effect of discovered polymorphisms on overall risks of diseases. The inputs of the risk assessment algorithms are listed in Box 2.

Risks are presented for two cases: the estimated risk using the current data and the estimated risk for the case that the recommended optimum lifestyle and medical follow-up plan is followed (for examples of risk graphics, see FIGURES 8, 9 & 10)

Risk graphics (both the current and estimated reduced risk with the optimum lifestyle and medical follow-up plan) are presented in the report for two main purposes. The first one is to provide the lifestyle and medical follow-up interventions in a targeted way. The second one

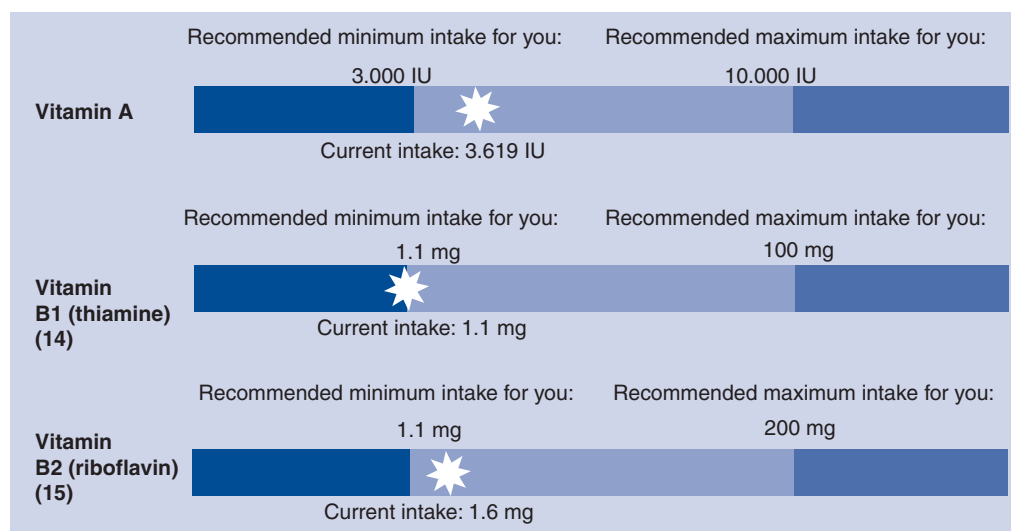


Figure 4. An excerpt from the 'Assessment of Nutrition and Nutritional Supplements' section of a Gentest report.

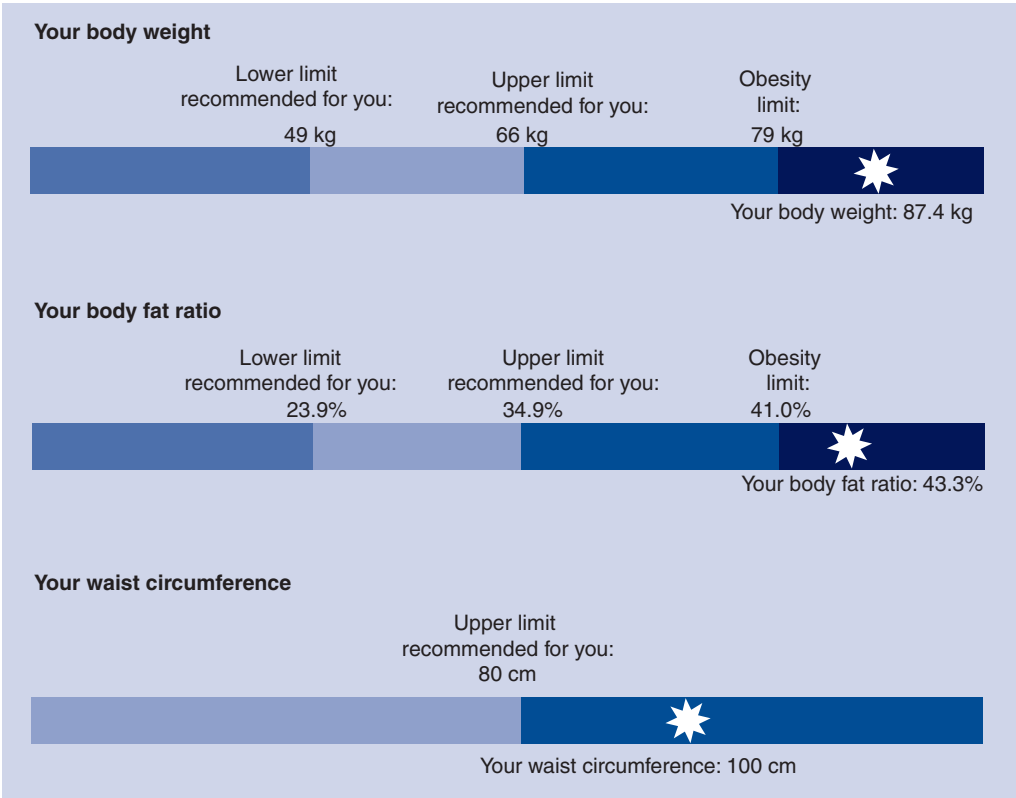


Figure 5. An excerpt from the ‘Assessment of Body Composition’ section of a Gentest report.

is to promote lifestyle changes through creating personal vulnerability perception and individual risk perception [109].

The report of an individual includes the results of the above-mentioned assessments and an ‘Optimum Lifestyle Plan’ developed for the individual. It includes a plan for reaching and/or maintaining optimum body composition, personal nutrition plans and food exchange lists, supplement plans and exercise plans. Smoking cessation recommendations are personalized according to the causes of smoking. Recommendations are given for medical follow-up with personalized screening plans. For all medical follow-up recommendations, it is highlighted that they are subject to evaluation of the physician and can be changed if necessary. If any medical problem that needs further investigation or curative interventions is detected, it is presented in the ‘physician note’, which is provided for the physician separately.

When developing methodologies for all components of Gentest, the most important decision criterion is this: for all the information and recommendations we give, there has to be good probability of benefit with no possibility of harm. This is ensured by always complying with the nutritional and medical guidelines.

For example, recommendations on the upper and lower limits of the intake of a nutrient are always within the upper and lower limits that are recommended in the nutrition guidelines. Properties that can be used to further personalize the recommendations, but not referred in the guidelines yet, such as genetic information, are used to narrow down the general recommendation range.

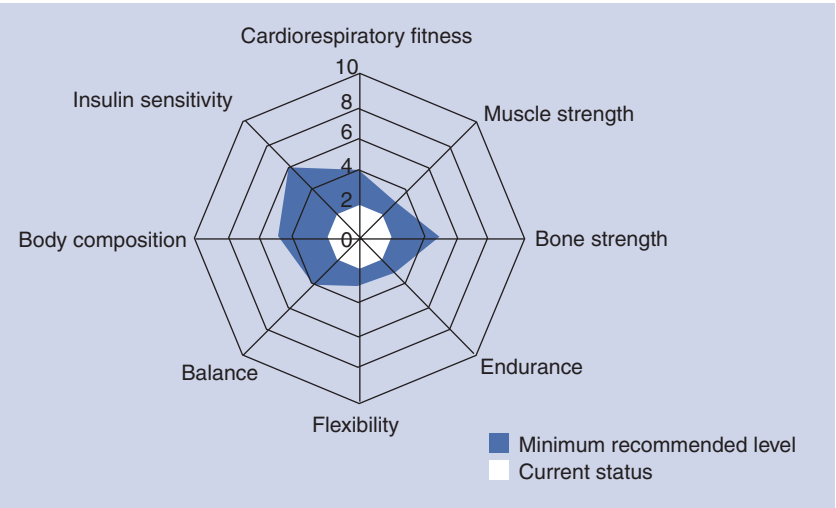


Figure 6. An excerpt from the ‘Assessment of Physical Activity and Exercise Status’ section of a Gentest report.

1. CARDIOVASCULAR AND CEREbroVASCULAR HEALTH											
<p>▲ sign is used in case that genotype indicates predisposition to that condition, whereas ▲ sign is used in case of a favorable condition and <-> in case of a neutral situation.</p> <p>If not applicable, ∅ is used. If the predisposition to the condition decreases under some certain life style modifications or this genotype specifically responds well to a certain factor, √ sign is used under "Response to lifestyle modif." column.</p>											
Gene	Full Name	Function / Role in Related Health Area	Analyzed Polymorphism	Genotype	Allele Structure	Atherosclerosis and Atherothrombosis		Hypertension		Venous Thrombosis	
						Predisposition	Response to lifestyle modif.	Predisposition	Response to lifestyle modif.	Predisposition	Response to lifestyle modif.
APOA1	Apolipoprotein A-I	HDL Structure; Cholesterol Metabolism	G(75)A	Homozygous	AA	▲▲	√	∅		∅	
APOC3	Apolipoprotein C3	HDL, LDL, VLDL Structure; Triglyceride and Cholesterol Metabolism	C3175G	No variation	CC	▲		∅		∅	
LPL	Lipoprotein Lipase	Lipid Metabolism	C1595G	No variation	CC	▲▲	√	∅		∅	
LIPC	Hepatic Lipase	HDL Metabolism	C(514)T	Heterozygous	C/T	∅	√	∅		∅	
CETP	Cholesterol Ester Transfer Protein	HDL - LDL Cholesterol Balance	G279A	Heterozygous	G/A	▲	√	∅		∅	
PON1	Paraoxanase1	Lipid Oxidation Mechanism	Gln192Arg	No variation	Gln/Gln	▲		∅		∅	
MMP3	Matrix Metalloproteinase 3	Matrix Deposition; Atherosclerotic Mechanism	5A/6A	No variation	5A/5A	▲	√	∅		∅	
IL-6	Interleukin-6	Inflammatory Response	G(-174)C	Heterozygous	G/C	▲▲	√	∅		∅	
TNF-α	Tumor Necrosis Factor Alpha	Inflammatory Response	G(-308)A	No variation	GG	▲		∅		∅	

Figure 7. An excerpt from the 'DNA Analysis Results and Genotype Assessment Table' section of a Gentest report.

Counseling & follow up

Gentest reports are ready approximately 4–8 weeks after sample taking and filling out the questionnaire. The report is sent out to the physician who explains the report results to the individual during an hour long appointment. The nutrition programme is explained by a dietician trained in nutrigenetics.

If the individual would like to have assistance in making the lifestyle changes, the follow-up programme is started. This option is usually chosen by the overweight or obese individuals who are recommended to reach their optimum body composition.

Experiences of GENAR

The practice model has been in service for piloting purposes for approximately 2 years in Turkey. Approximately 500 individuals have used this pilot service. The results of this pilot implementation phase are being assessed and will be published in another manuscript. A noteworthy observation is that Gentest might have a better outcome for behavior change than providing general information on healthy behaviors. In particular, initiation of exercise, smoking cessation and weight loss has been observed. This observation surely needs to be confirmed with publication of related data.

We think that Gentest may have an important effect in creating awareness by informing individuals about their current lifestyle and genetic predispositions. Furthermore, it causes an attitude change by creating a vulnerability perception. Finally, it is observed that behavior change is achieved with the follow-up programme and the trainings (FIGURE 11).

Critics to the approach of the GENAR Institute

Our practice model has been presented to the scientific community at a number of occasions. These are the 1st Congress of the International Society of Nutrigenetics/Nutrigenomics (Athens, Greece, 13 November, 2007) [8], 16th European Conference on Public Health, European Public Health Association (Lisbon, Portugal, 7 November,

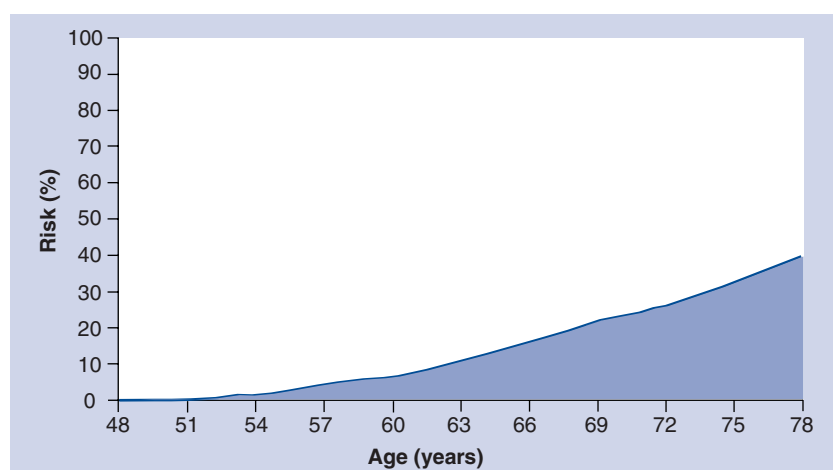


Figure 8. An excerpt from the 'Disease Risks' section of a Gentest report: 'Heart Attack Risk with Current Lifestyle in the Following 30 Years'.

2008), Conference on Public Health Genomics in Europe, Public Health Genomics European Network (Istanbul, Turkey, 26 November, 2008). The practice model being comprehensive (containing several factors such as personal, medical and lifestyle information, and genetic information), multidisciplinary, prevention-orientated and implemented through health professionals have been the appraised characteristics.

On the other hand, the main critic to this practice model has been that its effectiveness has not been demonstrated yet. Since 2004, GENAR has developed the model, piloted its components and the whole model, and further developed it with feedback. This gave GENAR the chance to see if such a model is applicable in a preventive healthcare setting, and if there is a potential benefit for the consumers. Currently, we are working on the design and implementation of research for the evaluation of the effectiveness of the proposed practice model. The effectiveness will be assessed from outcome perspective (prevention of diseases and disease complications), bioprocesses perspective (lipid profile, inflammation, glycemic control and so on), lifestyle changes and applicability. Collaboration with cohorts are also planned to further develop the algorithms.

Conclusion

Public health genomics and personalized healthcare will play major role in combating the chronic complex disease burden of the aging populations of the 21st Century. In parallel to exponentially increasing knowledge gained through research, healthcare systems need to foresee these upcoming developments and prepare for the transition. The approach of GENAR is an example of the translation of genome-based knowledge into preventive healthcare. The definition of public health genomics suggests that this translation should be effective and responsible [102]. By assuring that the information and the recommendations has good probability of benefit but has no possibility of harm, the Gentest practice model can be considered as a responsible one. However, the effectiveness has not yet been demonstrated.

Future perspective

As the populations continue to age, the burden created by complex diseases will increase. The future healthcare systems will not be able to cope with the societal and economic burden of complex diseases. An effective intervention model including lifestyle changes for prevention of these diseases is urgently needed. Like we did a century ago with the vaccines against infectious

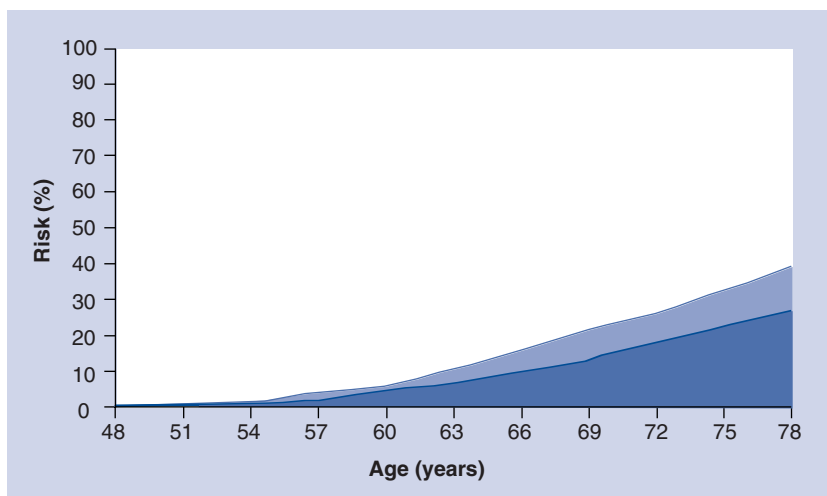


Figure 9. An excerpt from the 'Disease Risks' section of a Gentest report: 'Reduction of Heart Attack Risk in the Following 30 Years After Implementation of Optimum Lifestyle and Medical Follow-up Plan'.

diseases, the world needs a cost-effective health intervention to prevent complex diseases, as well as decrease the disability and increase the life quality of aging populations.

In order to achieve this goal, the medicine of the future needs to target the individual, rather than general public or population subgroups. Thus, healthcare practice models need to be individualized, assessing different characteristics

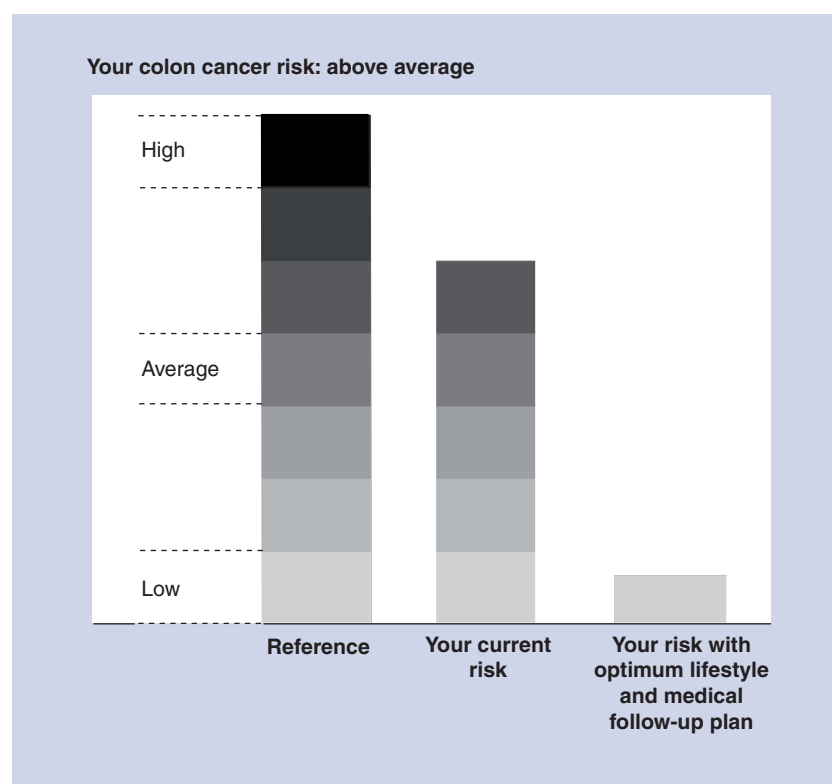


Figure 10. An excerpt from 'Disease Risks' section of a Gentest report: 'Colon Cancer Risk'.

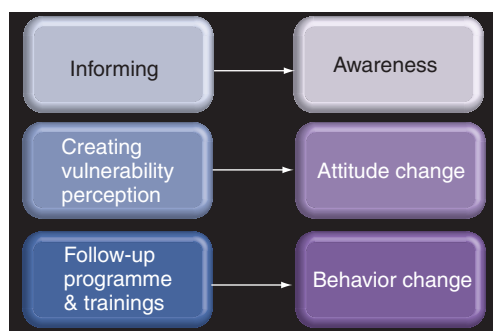


Figure 11. Model of attitude and behavior change with Gentest.

of the individuals, such as personal health data, lifestyle information and genetic information, to provide individualized interventions and recommendations. This vision is defined as 'personalized healthcare'.

Personalized healthcare holds great potential to combat the burden of complex diseases. In 5–10 years time, personalized healthcare interventions are expected to be widely utilized in primary care settings for primary and secondary prevention of complex diseases and their complications.

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Executive summary

The need for effective intervention models to combat complex diseases

- Complex diseases, which stem mainly from the complex interaction of the human genome with lifestyle and environmental factors, cause the main burden of disease in the 21st Century. Currently, the best-known prevention for complex diseases is adopting a healthy lifestyle. However, this is not achieved in many places of the world. Effective intervention models including lifestyle changes for prevention of these diseases is urgently needed.

Facts & challenges for the use of genetics in complex diseases

- In the late 1990s and early 2000s, it was foreseen that genetics/genomics would revolutionize medicine, and genetics would become a tool widely used for prediction, diagnosis and to optimize treatment in most common diseases within the current decade. As we are approaching the end of the decade, science has made important progress to discover genes and polymorphisms. However, their integration to medical practice has been limited, owing to the fact that evidence demonstrating the effectiveness of the genomic markers in clinical use is not fully established yet. On the other hand, the current knowledge about the above-mentioned areas already has the potential to be used for the benefit of the individual and society.

Approach of the GENAR Institute

- The GENAR Institute for Public Health and Genomics Research has developed a practice model called Gentest® as an integrative preventive model which utilizes individual's health information, lifestyle factors, biomarkers and genotype in order to prevent and early detect chronic and complex diseases in a targeted way. Based on the results of the aforementioned components, an optimum lifestyle plan is developed, including personal menu plans and exchange lists, exercise plans, smoking cessation recommendations based on the individual causes of smoking, and a medical follow-up plan.
- The mission of this practice model is changing the behavior and managing the health of individuals according to their health priorities. It is thought that the model creates awareness by informing individuals about their current lifestyle and genetic predispositions. Furthermore, it causes an attitude change by creating a vulnerability perception. Finally, it is observed that behavior change is achieved with the follow-up program and the trainings.

Critics to the approach of GENAR Institute

- The practice model being comprehensive (containing several factors of the individual), multidisciplinary, prevention orientated and implemented through health professionals have been the appraised characteristics. On the other hand, a critical point is raised, which is that the effectiveness of the intervention is not yet demonstrated.
- The efforts of GENAR so far has been on the development of the model and piloting its components and the whole model. The crucial future step is to conduct a research for evaluation of the effectiveness of the proposed practice model.

Conclusion

- Personalized healthcare holds a great potential to combat the burden of complex diseases, provided that the safety is ensured and the effectiveness of the utilized tests and practice models are demonstrated scientifically.

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No writing assistance was utilized in the production of this manuscript.

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■ This is the first document defining the framework of public health genomics. The Public Health Genomics Foundation (UK) website is a valuable resource for scientists and health professionals who would like to learn the concept of public health genomics, policy issues related to public health genomics, evaluation of complex biomarkers and genetic tests (www.phgfoundation.org).

103 Centers for Disease Control and Prevention, National Office of Public Health Genomics. 10 years of public health genomics at CDC 1997–2007, Atlanta, GA (2007) www.cdc.gov/genomics/about/reports/2007/index.htm (Accessed August 15, 2009)

■ CDC Office of Public Health Genomics website is a valuable resource for scientists, health professionals and the general public who would like to learn the concept of public health genomics, its scientific basis, its implementation areas and reach educational resources (www.cdc.gov/genomics/).

104 US Department of Health and Human Services, Personalized Health Care Initiative. Personalized Health Care: Opportunities, Pathways, Resources. United States Department of Health and Human Services, September 2007. www.hhs.gov/myhealthcare/news/phc-report.pdf (Accessed on July 03, 2009)

■ Important document defining the concept and vision of personalized healthcare, outlining its opportunities, the pathways to reach this vision and resources already in play within US Department of Health and Human Services. The Personalized Health Care Initiative website is a good resource to follow the reports and activities of US Department of Health and Human Services on this area (www.hhs.gov/myhealthcare/).

105 23andMe www.23andme.com

106 Navigenics www.navigenics.com

107 deCODE genetics www.decodeme.com

108 EUROGENE: eTEN Project <http://eurogene.biomed.ntua.gr/> (Accessed August 28, 2009)

■ It is of note that there are different initiatives on the usage of genomic information in the optimization of nutrition in clinical settings. One of them is the EuroGENE project funded under the E-Ten Scheme of the EU. The overall aim of EuroGENE is to validate in the European market the existing service, as well as to enhance both its security and user friendliness. The project has three pilot sites in Italy, Germany and Greece. Results of the project are expected to be disseminated soon.

109 Renner B, Schupp H, Vollmann M, Hartung FM, Schmalzle R, Panzer M: Risk perception, risk communication and health behavior change. University of Konstanz; Konstanzer Online-Publikations-System (KOPS) <http://nbn-resolving.de/urn:nbn:de:bsz:352-opus-71352> (Accessed June 6, 2009)

■ This short article can be a useful review to get acquainted with concepts in behavior change in health, in particular, risk perception.

110 Public Health Genomics European Network (PHGEN) www.phgen.eu

■ Public Health Genomics European Network (PHGEN) is an important network working for the development of Public Health Genomics in Europe. PHGEN is coordinated from the European Centre of Public Health Genomics (ECPHG) at Maastricht University in the Netherlands. PHGEN is funded by the General Directorate for Health and Consumer Protection (DG SANCO) under the Health Programme. The current phase of PHGEN focuses on preparation of the 'European Best Practice Guidelines for Quality Assurance, Provision and Use of Genome-based Information and Technologies'.

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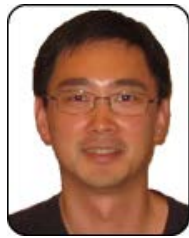
Editorial Advisory Board



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Edward Abrahams, Executive Director of the Personalized Medicine Coalition, a non-profit advocacy group representing diverse members with a interest in advancing medical progress through the adoption of personalized medicine concepts and products, brings extensive experience in industry, academia, and government to the position. As former Executive Director of the Pennsylvania Biotechnology Association, Dr Abrahams managed all aspects of the Association, including public advocacy, media relations, and educational programs, tripling its size and revenues in three years. He also spearheaded the successful effort that led to the Commonwealth of Pennsylvania's investment of \$200 million to commercialize biotechnology in that state. Previously, he had been Assistant Vice President for Federal Relations at the University of Pennsylvania, and also held a senior administrative position at Brown University. Before becoming a university lobbyist, Dr Abrahams worked seven years for the United States Congress, including as a legislative assistant to Senator Lloyd Bentsen and as an economist for the Joint Economic Committee under the chairmanship of Congressman Lee Hamilton.



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Richard Cotton AM BAgSc., Ph.D, D.Sc. (Melbourne) initiated the Mutation Research Centre, now renamed the Genomic Disorders Research Centre, in January, 1996 (www.genomic.unimelb.edu.au). He is interested in the biochemical genetics of human disease and has recently focussed on mutation. He is particularly interested in improving mutation detection technologies to make them cheaper and simpler, so that they can be more widely applied, and holds several patents in the area. He has written two books entitled "Mutation Detection", initiated the journal entitled "Human Mutation", and in 1991 initiated bi-yearly international workshops on Mutation Detection. He has also started a worldwide initiative (The HUGO Mutation Detection Database Initiative, recently formed into the Human Genome Variation Society (HGVS; www.hgvs.org) to capture and distribute lists of mutations. In June 2006, he convened a Meeting, co-sponsored by WHO, which initiated the Human Variome Project (www.humanvariomeproject.org).



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Dr. Desnick is Professor and Chairman of the Department of Genetics and Genomic Sciences at The Mount Sinai School of Medicine and Physician-in-Chief of the Department of Medical Genetics and Genomics at the Mount Sinai Hospital. In 1977, he joined the faculty of The Mount Sinai School of Medicine as the Arthur J. and Nellie Z. Cohen Professor of Pediatrics and Genetics, and Chief, Division of Medical and Molecular Genetics. In 1993, he became the first Chairman of the Department of Genetics and Genomic Sciences at The Mount Sinai School of Medicine. Dr. Desnick's research interests include molecular and biochemical genetics. He has published over 600 research papers, and chapters, including nine edited books. He is Board Certified in Clinical, Biochemical, and Molecular Genetics by the American Board of Medical Genetics and is a Fellow of the American Academy of Pediatrics. He has been the recipient of various fellowships and awards, including the E.H. Ahrens, Jr. Award for Research from the Association for Patient-Oriented Research; the Award for Excellence in Clinical Research from the National Center for Research Resources, NIH; Distinguished Alumni Award from the University of Minnesota Medical School; and an Honorary Doctor of Science degree from The Mount Sinai School of Medicine. He is a Fellow of the American Academy for the Advancement of Science and a member of the Institute of Medicine of the National Academy of Sciences. He is a member of numerous scientific societies, including the American Pediatric Society, the American Society for Clinical Investigation, and the American Association of Physicians. He is a past Director of the American Board of Medical Genetics (ABMG), a Founding Diplomat of the American College of Medical Genetics (ACMG), and a member of the Board of Directors of the ACMG Foundation. He has served on the NIH National Advisory Council for the National Center for Research Resources. He is a founder and Past-President of the Association of Professors of Human and Medical Genetics. He is a past Chair of the Council of Academic Societies of the Association of American Medical Colleges (AAMC) and currently is Chair of the AAMC.



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Dr. Charis Eng is the Chairman and founding Director of the Genomic Medicine Institute of the Cleveland Clinic Foundation, founding Director and attending clinical cancer geneticist of the institute's clinical component, the Center for Personalized Genetic Healthcare, and Professor and Vice Chairman of the Department of Genetics at Case Western Reserve University School of Medicine. She holds a joint appointment as Professor of Molecular Medicine at the Cleveland Clinic Lerner College of Medicine and is a full member of Cleveland Clinic's Taussig Cancer Center and of the CASE Comprehensive Cancer Center. Dr. Eng was recently honored with the Sondra J. and Stephen P. Hardis Endowed Chair in Cancer Genomic Medicine. She continues to hold an honorary appointment at the University of Cambridge. Dr. Eng's research interests may be broadly characterized as clinical cancer genetics translational research. Her work on *RET* testing in multiple endocrine neoplasia type 2 and the characterization of the widening clinical spectra of *PTEN* gene mutations have been acknowledged as the paradigm for the practice of clinical cancer genetics. Dr. Eng grew up in Singapore and Bristol, UK and entered the University of Chicago at the age of 16. After completing an MD and PhD at its Pritzker School of Medicine, she specialized in internal medicine at Beth Israel Hospital, Boston and trained in medical oncology at Harvard's Dana-Farber Cancer Institute. She was formally trained in clinical cancer genetics at the University of Cambridge and the Royal Marsden NHS Trust, UK, and in laboratory-based human cancer genetics by Bruce Ponder, MB, PhD. At the end of 1995, Dr. Eng returned to the Farber as Assistant Professor of Medicine, and in January, 1999 was recruited by The Ohio State University as Associate Professor of Medicine and Director of the Clinical Cancer Genetics Program. In 2001, she was honored with the conferment of the Davis Professorship and appointed Co-Director of the Division of Human Genetics in the Department of Internal Medicine. In 2002, she was promoted to Professor and Division Director, and was conferred the Klotz Endowed Chair. She moved to the Cleveland Clinic in Sept, 2005. Dr. Eng has published over 290 peer reviewed original papers in such journals as the *New England Journal of Medicine*, *JAMA*, *Lancet*, *Nature Genetics*, *Nature*, *Cell* and *Molecular Cell*. She has received numerous awards and honors including election to the American Society of Clinical Investigation, to the Association of American Physicians and as Fellow of AAAS, the Doris Duke Distinguished Clinical Scientist Award and named a Local Legend from Ohio bestowed by the American Medical Women's Association in conjunction with the US Senate on women physicians who have demonstrated commitment, originality, innovation and/or creativity in their fields of medicine. Dr. Eng is the 2005 recipient of the ATA Van Meter Award at the

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Dr Ginsburg received his M.D. and Ph.D. in biophysics from Boston University. He completed an internal medicine residency at Beth Israel Hospital in Boston. Subsequently, he pursued postdoctoral training in clinical cardiovascular medicine at Beth Israel Hospital and in molecular biology at Children's Hospital as a Bugher Foundation Fellow of the American Heart Association. In 1990 he joined the faculty of Harvard Medical School where he was Director of Preventive Cardiology led a laboratory in applied genetics in cardiovascular disease. In 1997 he joined Millennium Pharmaceuticals, Inc., as Senior Program Director for Cardiovascular Diseases. In 2000, he was appointed Vice President of Molecular and Personalized Medicine where he was responsible for developing biomarkers for disease, pharmacogenomic strategies for therapeutics and their implementation in drug development process. In September 2004, he assumed his current position at Duke University where is Professor of Medicine and Professor of Pathology and Director of the Center for Genomic Medicine in the Institute for Genome Sciences & Policy. In 2006, he was appointed as Co-Director, Duke Clinical Translational Science Institute. He has received a number of awards for his research accomplishments including the Innovator in Medicine Award from Millennium in 2004 and the Basic Research Achievement Award in Cardiovascular Medicine from Duke in 2005. He is a founding member of the Personalized Medicine Coalition and an Associate Editor for the *Journal of the American College of Cardiology*. He has been an international expert panel member for Genome Canada and was recently nominated to the Secretary of Veterans Affairs Advisory Council on Genomic Medicine.

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David Gurwitz obtained his Ph.D. from the Department of Biochemistry at Tel-Aviv University in 1986. His thesis delineated the interactions of brain muscarinic acetylcholine receptors with G proteins. During 1986-1989 he was a postgraduate fellow at the University of California Irvine. These studies have led to the discovery of the hormone-like properties of thrombin, the major blood coagulation enzyme, towards neuronal and astroglial cells, thereby opening up a new research field on the role of endogenous thrombin inhibitors in brain physiology and pathology. In 1989, David joined the Israel Institute for Biological Research, where he led the biochemistry team in a project developing M1-selective muscarinic agonists as therapeutics. The lead compound, AF102B (CevimelineTM), has received FDA approval for the treatment of Sjogren's syndrome, thereby becoming the second-ever Israeli drug receiving FDA approval. In January 1995, David was appointed to direct the *National Laboratory for the Genetics of Israeli Populations* at the Sackler Faculty of Medicine at Tel-Aviv University. The laboratory is a National Repository for human DNA samples and immortalized cell lines, representing the unique ethnic diversity of Jewish and Arab communities in Israel. Thousands of DNA samples distributed by the repository over the years have helped in numerous studies on human clinical genetics, population genetics, and pharmacogenetics. David has been teaching, since 2001, pharmacogenetics to MD students at the Tel-Aviv University, as part of their pharmacology training. Since 2003 he also teaches a 30-hour graduate course entitled "Pharmacogenetics: Towards Personalized Medicine". David has authored or co-authored over 100 scholarly articles in diverse disciplines including biochemistry, cell biology, and pharmacology. He is an associate editor or member of the editorial board of several scientific journals, including *Pharmacogenomics*; *Personalized Medicine*; *Drug Development Research*; *Trends in Molecular Medicine*. Since 2004, David represents Israel on the steering committee on pharmacogenetics of the *Organization for Economic Co-operation and Development* (OECD), and since 2005 he also consults the European Commission's *Institute for Prospective Technological Studies* (IPTS) on pharmacogenetics.



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He brings more than two decades of broad experience in life science industries and academia, and is a recognized thought leader in the field of PM strategy. One of the pioneers in advancing the PM field, Dr. Hu has accumulated rich client project experience supporting the pharmaceutical and diagnostics industries, with a particular focus on how to develop and commercialize PM drugs and / or associated diagnostics.

In addition, as high profile examples he led the effort to have established corporate PM strategies for several major pharma companies, including business model, R&D and commercialization business processes / road map, and organizational considerations.

He has been an invited speaker at many conferences on PM. With a significant list of articles published on this subject, he is also a contributor to a Decision Analysis Handbook, in which he illustrates how to apply decision analytics to addressing strategic issues in PM R&D and Commercialization.

He currently serves on the Editorial Board of the business / technical peer-reviewed journal Personalized Medicine. He has also been a member on the Dx and PM Committee of BioNJ, the PM Policy Committee of the Personalized Medicine Coalition, the Coalition to Strengthen the Future of Molecular Diagnostics, and previously the only representative from the Management Consulting industry invited to the FDA PM initiative consortium.

As part of his extracurricular activities, he holds an Adjunct Professor position at the Chinese National Human Genome Center at Shanghai, Chinese Academy of Sciences (CAS), and Senior Advisor & Visiting Professor positions at the Beijing Genomics Institute (BGI).

Dr. Hu was an early participant of the Human Genome Project, and later on intimately involved in the International HapMap Project, both considered key scientific foundation for the personalized medicine field. Previously he worked for BMS, a major pharma, Illumina, a leading personalized medicine tool company, and Curagen, a first-generation genomics company.

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Amalia M. Issa, PhD, MPH, is Professor and Chair of the Department of Health Policy and Public Health at the University of the Sciences in Philadelphia and founding Director of the Program in Personalized Medicine and Targeted Therapeutics (since 2001), and an Investigator at The Methodist Hospital Research Institute. The mission of the Program in Personalized Medicine & Targeted Therapeutics is to develop the evidence base for, promote informed decision making about, and accelerate knowledge translation of personalized medicine applications into meaningful health outcomes. The Program accomplishes its mission through state-of-the-art research, training programs, consultation to government agencies on public policy initiatives, and national and international collaborations.

A native of Montreal, Canada, Amalia holds degrees from Concordia University (Bachelor of Science in Biology), McGill University (PhD in neuropharmacology from Department of Neurology and Neurosurgery), and the UCLA School of Public Health, and has completed fellowship training at Harvard Medical School. Dr. Issa developed a unique area of translational research focused on pharmacogenomics and

personalized medicine applications, and how they will be translated and integrated into health care delivery and health systems. Dr. Issa was one of the very first scientists to conduct research and publish on translational research related to pharmacogenomics and personalized medicine, including health policy-relevant issues. Her research is positioned at the nexus of epidemiology/health services research and molecular science, and she leads an interdisciplinary team of scientists who are actively engaged in research aimed at the effective translation of the science of pharmacogenomics and personalized medicine from the laboratory bench to the bedside and to the community and policy.

Dr. Issa is internationally recognized in the field of personalized medicine, and has published numerous papers, many widely cited, in pharmacogenomics and personalized medicine, clinical pharmacology, neuropharmacology and drug safety. She has served or is serving as the principal investigator on a number of

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technologies pose to traditional biomedical ethics. She is an affiliate member of the NIH Pharmacogenetics Research Network (PGRN), member of HUGO, and of the Public Population Project in Genomics (P3G) Consortium.



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Dr. Miller is Vice President and Head of Personalized Healthcare and Biomarkers Strategy, Portfolio and Alliances for AstraZeneca Pharmaceuticals. He also serves as Chairman of the Board of Biomarker Strategies, a live tissue based cancer diagnostics company. Prior to joining AstraZeneca, Dr. Miller founded CDx Vision, LLC, a consulting firm to the global biopharmaceutical industry specializing in personalized medicine and companion diagnostic strategy. Dr. Miller also served as Vice President and General Manager of Genzyme Analytical Services. Analytical Services, now part of LabCorp, is a division of Genzyme Genetics providing pathology-based pre-clinical and clinical trial services for biomarker and companion diagnostic development to the biopharmaceutical community worldwide. Dr. Miller previously led the Research and Development efforts of Genzyme Genetics bringing novel tests and leading edge technologies to the clinical



laboratory. In addition to his responsibilities to Genzyme Genetics, Dr. Miller was also responsible for originating and developing the pharmacogenetics and biomarker efforts used in a variety of clinical programs within Genzyme Corporation. Dr. Miller is a member of the Clinical Sciences Committee of the Personalized Medicine Coalition and served as a member of the EFPIA Pharmacogenetics ad hoc group. Dr. Miller received his Ph.D. in Experimental Pathology from Roswell Park Memorial Institute, a graduate division of the State University of New York at Buffalo. He completed his postdoctoral work in molecular hematology and viral leukemogenesis at Memorial Sloan Kettering Cancer Center and molecular genetics at the University of Miami School of Medicine.

Milos PM, Helicos BioSciences Corporation, USA



Ollier B, Salford Royal Teaching Hospital, UK
Professor Bill Ollier is Professor of Immunogenetics and Director of the Centre for Integrated Genomic Medical Research, within the School of Translational Medicine in The University of Manchester, UK, and Honorary Professor in the Faculty of Veterinary Sciences, University of Liverpool, UK. His main research interests are the genetic basis of immune response, autoimmunity, HLA and disease and analysis of complex genetic phenotypes in both man and companion animals. He has published over 400 peer reviewed publications in these areas.

Payne K, University of Manchester, UK

Petricoin EF, Theranostics Health, Inc., UK

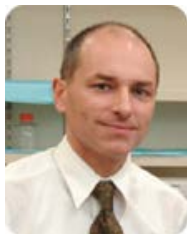


Phillips KA, University of California, San Francisco, USA
Kathryn A. Phillips Ph.D. is Professor of Health Economics and Health Services Research at the University of California, San Francisco (UCSF). She holds appointments in the Department of Clinical Pharmacy at the UCSF School of Pharmacy, the UCSF Institute for Health Policy Studies, and the UCSF Comprehensive Cancer Center. Dr Phillips has degrees from the University of California-Berkeley, Harvard University, and the University of Texas at Austin. Her research focuses on the impact of personalized medicine on clinical care, health economics, and health policy, particularly in the area of cancer screening and treatment. Dr Phillips conducts cross-disciplinary research across the basic, clinical, and social sciences and also across academia, industry, and government. She is serving as the Principal Investigator on several NIH and foundation grants. Dr Phillips serves as an advisor to many government and industry groups including the IOM, FDA, HHS, SACGHS, CDC, and NCI as well as start-up companies and venture capital firms. She has published more than 80 peer-reviewed articles in policy and clinical journals, including *JAMA*, *New England Journal of Medicine*, and *Health Affairs* and serves on the boards of several journals.

Prainsack B, University of Vienna, AT
Dr Barbara Prainsack, a trained political scientist, is Senior Lecturer at the Centre for Biomedicine & Society at King's College London (<http://www.kcl.ac.uk/schools/sspp/cbas/>). Prior to joining King's, she directed an international collaborative project on the governance of genomics in a global context (<http://www.univie.ac.at/transformation/GwB/>) and served as the Deputy Director of the Life Science



Governance Research Platform at the University of Vienna (directed by Herbert Gottweis). Barbara has worked and published extensively at the interface of biosciences & biotechnology and regulation & governance. Together with David Gurwitz, she recently guest-edited a Special Focus Issue of Personalized Medicine on Medical and Forensic DNA databases (November 2007). She was a Visiting Fellow at the ESRC Centre for Economic and Social Aspects of Genomics, Cardiff University, Wales, UK (winter 2006/07); a Visiting Professor at the Institute for International Studies at Ramkamhaeng University, Bangkok, Thailand (fall 2005); and a Visiting Fellow at the Department of Social and Behavioral Sciences at the University of California, San Francisco (spring 2002). Barbara also collaborates closely with the Twin Research & Genetic Epidemiology Unit at St. Thomas' Campus, King's College London (<http://www.twinsuk.ac.uk/publications.html>). Barbara has just been appointed a member of the National Bioethics Council in Austria, which advises the federal government on regulatory matters regarding biomedicine, biosciences, and biotechnology.



Puztai L, MD Anderson Cancer Center, USA

Dr Puztai received his Doctor of Medicine (MD) degree from the Semmelweis University of Medicine in Budapest, Hungary in 1987. Subsequently he studied at the University of Oxford in England where he received his Doctor of Philosophy degree (D.Phil.) in 1993. He completed his graduate medical training at the University of Rochester in New York and at the U.T. MD Anderson Cancer Center (MDACC) in Houston. He has joined the faculty of MDACC in 1999 where he is currently Associate Professor of Medicine. He is board certified in Internal Medicine and Medical Oncology, and is a member of several professional societies including the American Society of Clinical Oncology and the American Association for Cancer Research. He has received several international awards including the Soros Scholarship by the George Soros Foundation, New York, the Overseas Research Students Award from the Vice-chancellors and Principals of the Universities of the United Kingdom, a Career Development Award from the US Department of Defense Breast Cancer Research Program and the MD Anderson Aventis Drug Development Award. He has published over 100 peer-reviewed articles on the biology and treatment of breast cancer. He is editor of a book on cell proliferation and cancer and also contributed chapters to numerous books such as the Oxford Textbook of Pathology, Computational and Statistical Approaches to Genomics, Molecular Oncology of Breast Cancer, Molecular Pathology in Clinical Practice and the Textbook of Breast Cancer. Dr Puztai's current research focuses on the developing pharmacogenomic markers of response to therapy and identifying methods to select the optimal treatment for individual patients. His research also includes identification of novel therapeutic targets. He is principal investigator of several clinical trials investigating new drugs and leads the pharmacogenomic program at the Department of Breast Medical Oncology of MDACC. His research is supported by grants from the National Cancer Institute, the US Department of Defense, the Breast Cancer Research Foundation and philanthropic research grants.



Rosenkrans W, MIT Center for Biomedical Innovation, USA

Wayne Rosenkrans is currently Scientific and Medical Strategy Director for External Medical Relations at AstraZeneca Pharmaceuticals. In that role he has responsibility for long-range strategy development supporting AstraZeneca's external scientific alliances and policy. He is also Chairman and President of the board of directors of the Personalized Medicine Coalition, a Washington DC based organization working with government and other agencies on evolving health policy for personalized medicine. Previous positions include Global Director, Intelligence Affairs at AstraZeneca, and Associate Director and Head of Strategic Intelligence for SmithKline Beecham Pharmaceuticals R&D. He is a recipient of the Society of Competitive Intelligence Professionals (SCIP) Fellows Award, and a former President of the Society. He has presented at various forums on aspects of strategy development, strategic early warning, and strategic intelligence. He holds an S.B. in Biology from MIT, a Ph.D. in Cell and Molecular Biology from Boston Univ., and received post-doctoral training in Cancer and Radiation Biology at the Univ. of Rochester. Other interest areas include martial arts (Tang Soo Do), antique/classic cars, and aviation history.



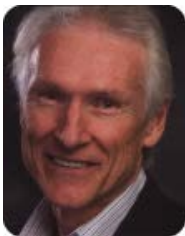
Rothstein M, University of Louisville School of Medicine, USA

Mark A. Rothstein holds the Herbert F. Boehl (pronounced "Bail") Chair of Law and Medicine and is Director of the Institute for Bioethics, Health Policy and Law at the University of Louisville School of Medicine. He received his B.A. from the University of Pittsburgh and his J.D. from Georgetown University. Professor Rothstein is a leading authority on the ethical, legal, and social implications of genetics, privacy, occupational health, employment law, and public health law. He is Chair of the Subcommittee on Privacy and Confidentiality of the National Committee on Vital and Health Statistics, the statutory advisory committee to the Secretary of Health and Human Services on health information policy, including the privacy regulations of the Health Insurance Portability and Accountability Act. He is also President of the American Society of Law, Medicine and Ethics. He is the author or editor of 19 books and numerous articles in medical, legal, public health, and other scholarly journals.



Roukos D, Ioannina University, Greece

Professor Dimitrios Roukos has graduated from Athens University School of Medicine, Greece and completed his surgical training and Ph.D from J.W.Goethe-University Hospital in Frankfurt a.M., Germany. He has published over 145 papers (PubMed/ISI/Scopus), of which four innovative works on genetics, genomics, cancer sequencing, systems biology and molecular networks in reputed journals and 37 editorials with an overall impact factor of ~900. These papers have received ~3000 citations with an h-index=41. He is leader of Translational Research in European Union Network of Excellence (EUNE) for gastric cancer and leader in Personalized Cancer Medicine, Biobank in Ioannina University (Greece). He has been invited speaker and consensus member in multiple International Cancer Meetings. He acts as Editor-in-Chief, Associate Editor and Editorial board member in reputed journals. Dr. Roukos is reviewer with honorarium in national (UK, Netherlands, Italy, Canada and Asian countries) and international large research projects (grants) and multiple reputed journals.



Sadée W, The Ohio State University, USA

Wolfgang Sadée is Felts Mercer Professor of Medicine and Pharmacology, Chair, Department of Pharmacology, and Director, Program in Pharmacogenomics, College of Medicine, at The Ohio State University, Columbus. He also holds appointments in Pharmacy, Medical Genetics, and Psychiatry, and is member of OSU Comprehensive Cancer Center, Center for Personalized Health Care, and Davis Heart and Lung Research Institute. He has received a doctorate in Pharmaceutical Chemistry at the FU Berlin in 1968, and has served on the pharmacy faculties of USC and UCSF until 2002. Dr. Sadée's research focuses on pharmacogenomics, drug discovery, and drug addiction, with over 300 research papers and monographs. He has served as founding editor of Pharmaceutical Research and The AAPS Journal, and has received the AAPS Distinguished Scientist Award.



Sakul H, Pfizer, Worldwide Clinical Research Department, USA

Hakan is a Senior Director in the Molecular Medicine Group where he serves as the Global Head of Diagnostics, leading Pfizer's Diagnostics effort across all therapeutic areas. Hakan is a native of Turkey where he completed his BS and MS degrees. After earning his PhD degree in Quantitative Genetics at the University of Minnesota as a Rotary Foundation Scholar in 1990, he completed a postdoctoral program at the University of California-Davis in quantitative genetics, animal genetics and international agriculture. After spending 4 years working in the biotech industry in human genetics and pharmacogenomics, Hakan joined Parke-Davis as Director of Human Genetics, Statistical Genetics and Pharmacogenetics programs. Due to site closure shortly after Pfizer's merger with Warner-Lambert, he moved to Ardaïs Corporation in Boston, Massachusetts as Vice President of Statistical Genomics. At the end of 2001, he returned to Pfizer as Director and Site Head for Clinical Pharmacogenomics in Groton/New London Laboratories. Hakan was promoted to Senior Director in mid-2005 and was responsible for Clinical Pharmacogenomics programs in CNS and Infectious Diseases prior to assuming his current role. Hakan has authored over 30 scientific refereed articles, several book chapters, and served as invited speaker on many panels and scientific meetings. He represents Pfizer on the Clinical Science and Technology Committee of Personalized Medicine Coalition, and on the Research Tools and Molecular Diagnostics Sub Team of BIO. Hakan is keenly interested in applications of diagnostics, pharmacogenomics and other -omics to the pharmaceutical pipeline as an enabler, and their applications in improving and individualizing patient care.

Shin J-G, Inje University College of Medicine, KR

Dr. Jae-Gook Shin is currently Professor of Pharmacology and Director of Pharmacogenomics Research Center at Inje University college of Medicine, Busan, Korea. He is also serving as Deputy Director of Clinical Trail Center at Inje University Busan Paik Hospital and Professor of Clinical Pharmacology. He established Pharmacogenomics Research Center in his university and was appointed to the director of the center in 2003. He received several awards including: the Merck Sharp & Dohme International Fellowship Award in Clinical Pharmacology, funded by Merck Foundation, in 1997, a 12th Outstanding Research Award in Science and Technology from The Korean Federation of Science and



Technology Societies in 2002 and the 1st Distinguished Scholar Award from Inje University in 2005. He has published more than 100 papers in the area of clinical pharmacology including pharmacogenetics and genomics, pharmacokinetics and pharmacodynamic modeling, population pharmacokinetics, drug metabolism, drug interactions etc. He also serves as an Editorial Board member of Pharmacogenetics and Genomics.



Siest G, Universite Henri Poincare Nancy, France

Pr Gérard Siest received his pharmacy diploma, his specialization in laboratory medicine and his PhD from the Universities of Strasbourg and Nancy. He was Professor of Biochemistry, Molecular Biology and Molecular Pharmacology and in charge of the direction of the Center for Preventive Medicine laboratory and some years later all the research of this health screening organization. He developed a research team linked to CNRS and INSERM dealing with drug metabolism, more particularly the UDPGTs and on the Genetic influence on laboratory tests and on Reference values. Two proteins were studied more deeply: apolipoprotein E and gammaglutamyltransferase. He created and was in charge of the regional post graduate course on drug metabolism and biochemical pharmacology. He was president of the European Society of Biochemical pharmacology and of the International Federation of Clinical Chemistry (IFCC) for 6 years. He is currently founding president of the European Society of Pharmacogenetics and Theranostics (ESPT), Editor in Chief of the journal Drug Metabolism and Drug Interactions (DMDI) and involved in many board of pharmacogenomics and laboratory medicine journals. He has published over 600 peer review

publications. The scientific conferences organized every two years, in Santorini (Greece) under his responsibility are very successful. The next one will be held from 30 September to 2 October 2012.

Stephan DA, The Institute for Individualized Health, USA

Tempfer C, Ruhr University Bochum, DE

Terzic A, Mayo Clinic, USA



Tolias P, Stevens Institute of Technology, USA

Peter Tolias, PhD, is currently Director, Bioinnovation Program and Research Professor, Department of Chemistry, Chemical Biology and Biomedical Engineering at the Stevens Institute of Technology. He is also an Adjunct Professor of Molecular Genetics, Microbiology & Immunology at the UMDNJ-Robert Wood Johnson Medical School, the recipient of over three dozen grants, contracts, awards and honors, the co-founder of several diagnostic and biotechnology companies and holds board and scientific advisory memberships on scientific journals, corporations, non-profits and universities. He is formerly the Executive Director of the Institute of Genomic Medicine, Research Director of the Autism Center and Professor of Pediatrics at the UMDNJ-New Jersey Medical School. Previously, he served as Worldwide Vice President of Advanced Research and Technology Assessment, at Ortho-Clinical Diagnostics - a Johnson & Johnson company - and Executive Vice President of Corporate Development at Rosetta Genomics. Earlier in his career, he was an Associate Professor of Microbiology & Molecular Genetics at UMDNJ-New Jersey Medical School, an Associate Member of the Public Health Research Institute and

earlier as an Assistant Member. He obtained his Ph.D. from McGill University, was a post-doctoral fellow at Harvard University and received executive training at the Wharton Business School of University of Pennsylvania.

Torr-Brown, S, Writer and Consultant, USA

Dr Torr-Brown is a British native with almost 20 years experience as a leader in the pharmaceutical industry. She completed a Ph.D in



Physiology and Medicine from St George's Hospital Medical School at the University of London, UK, followed by a post-doctoral fellowship at Washington University in St Louis. Dr Torr-Brown now owns a consulting business focused on the dynamic interplay between science and medicine, particularly in the area of personalized medicine. In addition to various scientific roles, Dr Torr-Brown has been a group leader for Thrombosis Research at GD Searle, a Director of Knowledge Management at Monsanto, and most recently Head of Science and Technology for Worldwide Drug Safety Evaluation at Pfizer. While at Pfizer, Dr Torr-Brown created a cross-company network of 30 diverse executives to explore potential futures for the industry in the light of the changing external environment. Topics examined included personalized medicine, emerging regulatory challenges, the public's perception of science and drug companies, and the expanding opportunities in global health. Dr Torr-Brown is particularly interested in science at the edge of what is accepted by the mainstream, as a source of breakthroughs in understanding human health and wellness. She is currently writing a book on the future of medicine in the information age that focuses on personalized medicine, patient beliefs about science and medicine, and the impact of ubiquitous information on innovation and practice in medicine. Since leaving the industry in 2006, Dr Torr-Brown has worked with numerous pharmaceutical, biotech and retail companies to bridge the gap between the patient experience of health and disease and innovation in R&D from bench to bedside. Current projects are focused on diseases of aging and on the regulatory and ethical challenges posed by personalized medicine. She is also directs strategy and vision development for a local United Way food center of which she is a Board member, and is affiliated with numerous scientific and technical societies.

Trepicchio WL, Millennium Pharmaceuticals, USA

Waldman S, Thomas Jefferson University, Philadelphia, USA



Wu A, University of California, San Francisco, USA
Alan H.B. Wu, Ph.D., is Chief of Clinical Chemistry, Toxicology, and Pharmacogenomics at San Francisco General Hospital and Professor of Laboratory Medicine, University of California, San Francisco. He received B.S. degrees in chemistry and biology at Purdue University, West Lafayette, Indiana, and a Ph.D. degree in analytical chemistry at the University of Illinois, Champaign-Urbana, Illinois. He completed a postdoctoral fellowship in clinical chemistry at Hartford Hospital. He is certified by the American Board of Clinical Chemistry in Clinical Chemistry and Toxicological Chemistry. Dr. Wu has previously held faculty positions at the University of Texas Medical Center, Houston, and the University of Connecticut, Farmington, and clinical chemistry laboratory directorships at Hermann Hospital and L.B. Johnson Hospital in Houston, and Hartford Hospital in Hartford CT. His research interests have been in the area of cardiac biomarkers, analytical and clinical toxicology, and clinical pharmacogenomics. As such, he is involved with bringing research technology and discovery from the research bench to clinical practice. Dr. Wu has over 300 publications in peer reviewed journals, books and book chapters, and lectures worldwide.



Zika E, European Research Council Executive Agency, BE
Eleni Zika is currently a research programme manager at the Medical Research Council. Previously she was a research fellow in the 'Agriculture and Life Sciences in the Economy' unit of the Institute for Prospective Technological Studies of the European Commission where her work focused on the socio-economic impacts of biotechnology, including pharmacogenetics. Prior to that, she was as a Christine Mirzayan Science and Technology Policy Fellow at the US National Academies, where she performed research on the role of intellectual property in research innovation, particularly as related to genomics and proteomics. She received her PhD in Genetics and Molecular Biology from the University of North Carolina at Chapel Hill, USA. Her graduate work focused on the regulation of immunity but also on the ethical, legal and social implications of genetics.

Zineh I, US FDA, USA

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