



**Webscout:**

## Personalised medicine

by Joeyn Flauaus

How can we guarantee that patients will benefit from taking drugs and how can side effects be reduced? Currently it looks like the future of medicine lies in personalised medicine as personalised medicine addresses these problems by tying dosing and therapeutic selection decisions to a diagnostic test, which is often genetically based. Every patient is unique with a unique genetic setting. These days we take drugs according to the one-size-fits-all approach ignoring that individuals react differently to drugs. Now there is a shift towards an individually tailored approach based on molecular diagnostics taking into account the differences in our genetic settings.

Pharmacogenomics, the study of how individual genetic differences affect drug response, is a field that is contributing significantly to personalised medicine. The knowledge of the way individuals respond to drugs can lead to maximum efficacy with minimal side effects. Consequently, the right drug and the right quantity can be selected. The Federal Drug Agency (FDA) has already indicated that they want pharmacogenomic data collected during clinical trials.

Don't think that the shift towards personalised medicine will only happen some time in future. Tests that evaluate the genetic basis for drug metabolism and define eligibility for targeted oncological therapies are already on the market. Pharmaceutical and biotechnology companies are turning more and more to personalised medicine to help improve the drug development process and speed the approval of new drugs.

I have put together a selection of websites on personalised medicine to invite you to form your own opinion on how the new era of personalised medicine will revolutionise the drug development process.

**<http://www.personalizedmedicinecoalition.org>**

The Personalized Medicine Coalition (PMC): the non-profit group PMC comprises a broad spectrum of academic, industrial, patient, provider, and payer communities. Their website provides all kinds of information on the topic of personalised medicine. The group seeks to provide an understanding of the concept and the health benefits of personalised medicine.

**<http://www.fda.gov/cber/gdlns/pharmdtasub.htm>**

The FDA Guidance for Industry for Pharmacogenomic Data Submissions: the specific criteria and recommendations for submission of pharmacogenomic data are provided in this guidance. The guidance also provides informa-

tion on how the FDA will or will not make use of pharmacogenomic data in regulatory decisions.

**<http://www.pharmgkb.org>**

The Pharmacogenetics and Pharmacogenomics Knowledge Base (PharmGKB) is a publicly available research tool developed by Stanford University with funding from the National Institutes of Health (NIH). Their aim is to establish knowledge about the relations among drugs, diseases and genes, including their variations and gene products. You can search extensive data bases (e.g., by drugs, genes, and diseases) to find information of particular relevance for pharmacogenetics and pharmacogenomics.

**Realizing the Potential of Pharmacogenomics—  
Opportunities and Challenges:**

**[http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS\\_PGx\\_report.pdf](http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS_PGx_report.pdf)**

This report of the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS) on pharmacogenomics describes the opportunities originating from that field as well as the challenges in terms of product development and integration into clinical and public health practice. A number of recommendations and considerations in relation to pharmacogenomics research and development are provided.

If you find a web site that should be mentioned in the next issue, or if you have any other comments or suggestions, please email me at: [Joeyn.Flauaus@sanofi-aventis.com](mailto:Joeyn.Flauaus@sanofi-aventis.com).

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## Ghostwriting on Youtube

Lanie Adamson, a member of AMWA who has been very active in the crusade for ethics in medical writing, has a piece in Youtube at <http://www.youtube.com/watch?v=u5IsErsBWtI>. The ghostwriting controversy is featured in the last of the three segments after chocolate and fitness.

Thanks to Adam Jacobs [ajacobs@dianthus.co.uk](mailto:ajacobs@dianthus.co.uk) for this information.