

OECD WORKSHOP ON POLICY ISSUES FOR THE DEVELOPMENT AND USE OF BIOMARKERS IN HEALTH

Draft Agenda

6-7 October 2008

Wellcome Trust Conference Center, Hinxton, United Kingdom

The impact of biotechnologies on medical research is intensifying. Because of new highly performing technologies, we are better able to understand and explore disease and drug mechanisms, which in turn could lead to major changes in the approach of patient care. This evolution in medicine is closely associated with an increased interest in the discovery of biomarkers.

A biomarker is, according to the NIH, “a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacologic responses to a therapeutic intervention.” Many safe and effective biomarkers already exist, especially those which early on presented easily demonstrable scientific and clinical evidence. Now the research, industrial and medical communities are looking for diagnostics and treatments that will be based on much more complex molecular biomarkers. It will be increasingly difficult to establish a base of evidence tying these biomarkers to pathologies and to establish their clinical pertinence.

Biomarkers are of great importance because they will be the basis for the development of the tomorrow’s medical tests and targeted therapies. They could prove a major driver in the emergence of molecular medicine. Yet despite enthusiasm for biomarkers and the large number and types of actors involved in developing them, biomarker identification, validation, regulation and use in drug discovery and medical tests development, are still in their early stages.

This workshop is an opportunity for experts and the policy community to discuss together draft analytical reports and the policy actions suggested therein about how to improve the development and use of biomarkers in research and in health care. Workshop participants will be asked to comment on the draft reports; to discuss policy needs; and to make recommendations for further work that the OECD, or other organisations, might undertake.

In each session, background analytical papers will be presented and then followed by a panel discussion. The goal of each session is to bring out, in a lively interactive discussion, the main policy messages to be communicated to governments.

The reports, discussion at the Workshop and recommendations will be collated into a Policy Report to be delivered to the OECD’s Working Party on Biotechnology in November 2008 and, if agreed by member Countries, will subsequently be published.

POLICY ISSUES FOR THE DEVELOPMENT AND USE OF BIOMARKERS IN HEALTH

DAY 1 – 6 OCTOBER 2008

Chairman: *Serdar SAVAS*, CEO, Genomics for Life, Turkey

14:00	Registration and Coffee
14:30	Welcome and introduction <i>OECD Secretariat</i>
SESSION 1: INTRODUCTION	
<i>This session will introduce what biomarkers are and why they are so important for patient care improvement. The discussion should focus on what makes research on biomarkers today substantially different from the past; what this departure means in terms of scientific and clinical opportunities; and what policy issues it raises for governments.</i>	
14:40	Introduction to Biomarkers Policy Challenges and Workshop sessions <i>OECD Secretariat</i>
15:00	Evaluation and Regulation of Biomarkers – A Public Health Perspective <i>Ron ZIMMERN</i> , Executive Director, PHG Foundation, United Kingdom
SESSION 2: EVIDENCE BASE AND KNOWLEDGE SHARING AROUND BIOMARKERS DATA	
<i>This session will describe why biomarker knowledge integration and sharing is necessary and what are some of the main difficulties associated with doing so. It will identify different approaches for improving integration and sharing of data (for examples industry incentives to stimulate data sharing, systems or databases that provide access to knowledge for the public, computer storage). It will raise the question of whether governments should be involved in promoting the sharing, access and/or use of biomarker data and if so how. It will present thoughts on how to generate useful and relevant data that will allow an evidence-base decision making that is fundamental to biomarker evaluation.</i>	
15:15	Perspectives based on the analytical papers <ul style="list-style-type: none">• The Vision of Industry <i>David POLVERARI</i>, Technical Director, Atragène, France• Creating an Evidence-base <i>Peter FURNESS</i>, Vice President, RCPATH, United Kingdom
15:45	Panel questions and discussion with the audience <i>David POLVERARI</i> , Technical Director, Atragène, France <i>Noboru YUMOTO</i> , Vice-President, AIST board of trustees, Japan <i>Peter FURNESS</i> , Vice President, RCPATH, United Kingdom

16:45 – COFFEE BREAK

SESSION 3: THE CLINICAL EVALUATION OF BIOMARKERS

This session will elucidate why a crucial challenge for biomarker development is the evaluation of biomarkers for clinical use. It will address the central questions of clinical evaluation: what are the different levels of validation; how should government treat the discovery of new biomarkers, new therapeutic targets and medical tests and; are there efficient systems of validation in place already? The objective is to give governments a clearer sense of how to approach the discovery of new biomarkers, therapeutic targets and medical tests at a national and international level.

17:00

Perspectives based on the analytical paper

Ralph COATES, Associate Director for Science, Centers for Disease Control and Prevention, CDC Atlanta, United States

17:20

Panel questions and discussion with the audience

Anne MARQUET, Exploratory Medicine Science and Operations Manager, Merck Serono International

Chris PRICE, Visiting Professor in Clinical Biochemistry at the University of Oxford, United Kingdom

Ralph COATES, Associate Director for Science, Centers for Disease Control and Prevention, CDC Atlanta, United States

18:30 – End of first day meeting

20:00 – DINNER

DAY 2 – 7 OCTOBER 2008

Chairman: *Serdar SAVAS*, CEO, Genomics for Life, Turkey

SESSION 4: REGULATION AND POLICY

This session will focus on some of the regulatory policy issues that arise from the accelerated development of biomarkers. There appears to be consensus that some form of regulatory control over and above what is presently available is likely to be needed, but the extent to which this should be carried out within a statutory framework (and the form of any extra-statutory controls) is a matter of debate and controversy. The pros and cons of statutory regulation will be discussed as will the options for extra-statutory mechanisms of control. The risk stratification of biomarkers within the regulatory framework has also been much discussed, but exactly what we mean by 'risk' in this context and how the concept of 'safety' is to be conceptualised are policy issues that need further exploration. Governments should start to give this subject higher priority in their deliberations on health and innovation policy.

09:00	Perspectives based on the Analytical paper <i>Ron ZIMMERN</i> , Executive Director, PHG Foundation, United Kingdom
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09:30	Panel questions and discussion with the audience <i>Susanne LUDGATE</i> , Medical Director of MHRA, United Kingdom <i>Ron ZIMMERN</i> , Executive Director, PHG foundation, United Kingdom
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10:30 – COFFEE BREAK

SESSION 5: INNOVATION AND COMMERCIAL PERSPECTIVES

This session will discuss how industry is reacting and contributing to biomarker development. How are firms using biomarkers in drug and medical tests development? Are there different industry approaches? What are company hopes and what are the challenges they face? The session will also ask what actions by governments could influence biomarker development and use by industry.

11:00	Perspectives based on the analytical paper <i>Arsia AMIR-ASLANI</i> , Managing Director, Araxes Associates, France
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11:30	Panel questions and discussion with the audience <i>Arsia AMIR-ASLANI</i> , Managing Director, Araxes Associates, France <i>Laszlo TAKÁCS</i> , General Director, Biosystem International, France <i>Chris CHAMBERLAIN</i> , Biomarker Expert (Inflammation), Pharma Development, Roche Products, United Kingdom
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12:30 – LUNCH

SESSION 6: WHAT NEXT?

In this session participants will review the policy recommendations made in earlier sessions about what governments can do to facilitate the development of biomarkers for research, industrial use (medical testing and drug development), and for health care sector uptake. The OECD Secretariat will outline some possible options for future work and ask participants for their opinions and recommendations.

13:30	Presentations of options for future work <i>OECD Secretariat</i>
14:00	Open Discussion
14:30	Closing Remarks