



## Round table discussion on Precision Medicine and Personalized Health "Companion diagnostics and precision medicine: regulatory and uptake barriers to patient access"

## 27 September 2018 (15:00-18:30)

## Hotel Mon Repos - 131 rue de Lausanne, Geneva, Switzerland

## Agenda

presentations: 15:50-16:10 CDx in oncology	15:00-15:30	Registration
Prof. George Griffin, President, Federation of European Academies of Medicine (FEAM)         15:40-15:50       Introduction Prof. Peter Meier-Abt, Vice-President, Swiss Academy of Medical Sciences (SAMS) – Meeting Chair Improving links between CDx and medicines - Regulatory barriers and possible solutions. Impulse presentations:         15:50-16:10       CDx in oncology Prof. Christophe Le Tourneau, Head, Department of Drug Development and Innovation, Curie Institute, Paris         16:10-16:30       CDx in other therapeutic areas Dr. Thorsten Gutjahr, VP, Global Head of Companion Diagnostics, AstraZeneca         16:30-16:50       Current regulatory framework and ongoing EMA initiatives Dr. Marisa Papaluca, Senior Scientific Advisor & Dr. Falk Ehmann, Science and Innovation Support, European Medicines Agency (EMA)         16:50-17:05       Coffee break         17:05-17:20       Physicians' perspective Dr. Daniel Widmer, Vice-President, European Union of General Practitioners/Family Physicians (UEMO)         17:20-17:35       Genetic laboratories' perspective Prof. Vincent Mooser, Head Clinical Chemistry, CHUV - Lausanne University Hospital         17:35-17:50       Patients' perspective Dr. Stanimir Hasardzhiev, General Secretary, Patient Access Partnership and Board Member, European Patients' Forum         17:50-18:20       Discussion with all participants: Moderators: - Prof. Peter Meier-Abt, Vice-President, Swiss Academy of Medical Sciences - Prof. Stefan Constantinescu, Vice-President, Federation of European Academies of Medicine	15:30-15:40	
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Proposed questions for discussion:		Proposed questions for discussion:
• Development phase: how can we generate evidence during the development of medicines		• Development phase: how can we generate evidence during the development of medicines
that support the validation of CDx? And also move beyond oncology, e.g. into cardiovascular o	1	that support the validation of CDx? And also move beyond oncology, e.g. into cardiovascular or
respiratory diseases?	1	respiratory diseases?
• Post-approval phase: How can we monitor, evaluate and maximise relevant uptake as well as	1	• Post-approval phase: How can we monitor, evaluate and maximise relevant uptake as well as
ensure quality measures of CDx testing in clinical practice?	l .	ensure quality measures of CDx testing in clinical practice?
<ul> <li>Companion vs complementary diagnostics: what are the regulatory challenges?</li> </ul>	l .	Companion vs complementary diagnostics: what are the regulatory challenges?
What could be the role of the European Medicine Agency, Notified Bodies, National	l .	What could be the role of the European Medicine Agency, Notified Bodies, National
Competent Authorities and other stakeholders (clinicians, patients, etc.)?	l .	
18:20-18:30 Concluding remarks and perspectives	18:20-18:30	Concluding remarks and perspectives
Prof. Peter Meier-Abt, Vice President, Swiss Academy of Medical Sciences (SAMS)		Prof. Potor Mojor Abt. Vice President Swiss Academy of Medical Sciences (SAMS)