FEAM EUROPEAN BIOMEDICAL POLICY FORUM

FEAM Federation of European Academies of Medicine

## 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

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