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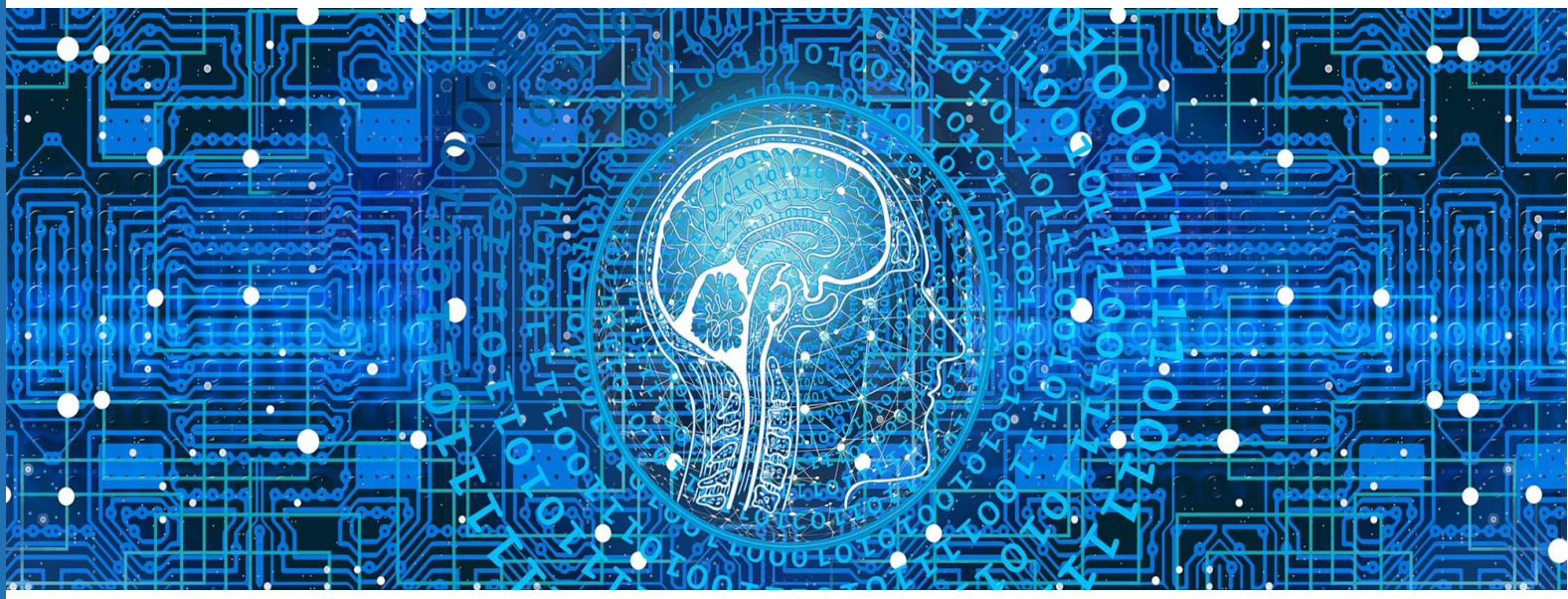

# Artificial Intelligence in healthcare: is Europe ready?

Annual lecture - Summary report

18 March 2019, Palais des Academies, Brussels

## About FEAM, The Federation of European Academies of Medicine (www.feam.eu)

FEAM is the European Federation of National Academies of Medicine and Medical Sections of Academies of Sciences. It brings together under one umbrella 19 National Academies representing thousands among the best scientists in Europe.

FEAM's mission is to promote cooperation between National Academies of Medicine and Medical Sections of Academies of Sciences in Europe; to provide a platform to formulate their collective voice on matters concerning human and animal medicine, biomedical research, education, and health with a European dimension; and to extend to the European authorities the advisory role that they exercise in their own countries on these matters.

## About the FEAM European Biomedical Policy Forum

The FEAM European Biomedical Policy Forum provides a platform for discussion on key policy issues for the biomedical community.

The Forum is an initiative from the Federation of European Academies of Medicine (FEAM). It aims to bring together representatives from academia, research charities, industry, European and national trade associations and professional bodies, regulators, public health bodies, and patient and consumers groups. If you would like further information on the FEAM European Biomedical Policy Forum or becoming a partner, please contact info@feam.eu

### Disclaimer

Opinions expressed in this report do not necessarily represent the views of all participants at the event, the Federation of European Academies of Medicine (FEAM) and its Member Academies, or the FEAM European Biomedical Policy Forum partners.

All web references were accessed in April 2019.

### Acknowledgments

FEAM warmly thanks the speakers and Jacki Davis for their contribution to the annual lecture as well as Dr Robin Fears for writing this report. FEAM is very grateful to the Belgian Royal Academy of Medicine (ARMB) for hosting the lecture and to the UK

Academy of Medical Sciences that funded this event by using a grant from the UK's Department of Business, Energy & Industrial Strategy (BEIS).

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# Background

European authorities have been discussing for a while the opportunities of using artificial intelligence (AI) in the healthcare sector for managing, interpreting and monitoring medical data. However, although AI offers promise to improve health systems, it also brings concerns on ethical principles, and for safety, transparency and trust.

Is Europe ready to welcome and tackle the changes coming with AI? To answer this question, the FEAM Forum event organised high-level discussion from different sectors (healthcare professionals, academia, industry and the European Commission) to explore opportunities and challenges with a view to identifying recommendations on priorities to be addressed by European and national policy-makers to ensure the proper and safe use of AI in healthcare.

# Summary

The annual lecture keynote speaker Andrea Renda (Senior Research Fellow, CEPS and Member of the European Commission High Level Group on Artificial Intelligence) described how AI had potential to tackle several of the pressing socio-economic challenges in healthcare: including better and faster (real-time) diagnosis, prediction of disease outcomes and delivery of healthcare interventions, addressing healthcare staff shortages and matching of supply and demand for healthcare resources. AI is only a small part of the answer to the challenges but it will also influence and enable other emerging technologies. Advances in AI, for example to assess health status of the individual leading to mass customisation of healthcare, subject to consumer acceptance will have significant implications for business models in the pharmaceutical and pharmacy sectors as well as for clinicians.

However, there are risks, for example for equity and fairness if new approaches are costlier, for intrusion of privacy and undermining of self-determination, and for accuracy and patient safety if there are appreciable false positives and false negatives in prediction. Although AI can be better than human assessment it is never better than AI plus humans. The draft ethics guidelines from the High-Level Expert Group cover many of the concerns and now need to be embedded into the development of trustworthy AI. Criteria of trustworthy AI include compliance with the law, ethical adherence and robustness. The process checklist to follow in AI design includes the dimensions of

privacy, data governance, transparency, accountability, diversity and non-discrimination, socio-environmental well-being and safety.

Many hope that AI will increase European competitiveness and GDP but Professor Renda advised that the contribution of AI should rather be assessed in terms of the broader socio-economic values expressed in the Sustainable Development Goals. The answer to the question "Is Europe ready?" is not yet, but Europe can get ready by leading on resolving issues for data quality, 5G deployment and ethics alignment. Horizon Europe will be a great opportunity to support research and innovation on healthcare and AI.

Panellists (from academia, clinical practice, industry and the European Commission) responded to these points and expanded on key issues in preparing for AI.

- Health is different and has a higher ethical requirement. This has implications for AI risk assessment and for EU public procurement of AI in healthcare.

- What are the options for regulation? Are higher regulatory standards required because of the black box nature of some AI, which leads to loss of accountability? How should AI learning systems be continuously validated and managed? How to involve the user and developer in co-design while ensuring a standardised framework for regulating data use?

- Quality and validity of data. The quality of much clinical data needs to be improved and assessed for bias and representativeness. Peer review for validity and safety should be added to current procedures for AI development.

- Determining predictability from probabilistic models may reinforce bias. The ability of AI to identify associations must be augmented by research to ascertain causality.

- Trust in healthcare – much more must be done to build trust. This requires public engagement, for example with regard to communicating the issues relating to privacy and confidentiality in using data.

- Public-private partnership in using data. There are various concerns about commercial interests and the lack of transparency and traceability in commercial practices. But there is also recognition that the private sector adds value in

annotating data and building data sets. There is shared interest in devising models whereby both public and private sectors can gain from using patient data for patient benefit.

- Education and skills requirements must be addressed for healthcare professionals and for the public and patients. AI should not replace doctors but should be an asset for them in becoming better doctors: AI in medical practice should be enabling rather than defining.

# Report of the event

## Welcome and Introduction

Jean-Michel Foidart (Perpetual secretary, Belgian Royal Academy of Medicine) welcomed participants on behalf of the Academy to the Forum event designed to discuss AI advances in the context of social needs in Europe. Challenges are compounded by the problem that many citizens have lost confidence in the EU – but FEAM with its remit across the EU is well placed to deliver messages to the European Commission and, in particular, to its Science Advice Mechanism.

In his introduction to the programme, George Griffin (President of FEAM) expanded on the work of FEAM and its Forum in organising a series of activities to inform the European Commission and Parliament. Thanking the UK Academy of Medical Sciences for helping to finance the event, he observed that the UK academy had itself previously examined some of the issues for new data-driven technologies in healthcare[1]. AI might be regarded as an unfortunate name in some respects – it is artificial but is it intelligent? In previewing what became a pervasive theme during subsequent discussion, the potential of AI to replace healthcare professionals, Professor Griffin highlighted the importance of optimising human-human interfaces as well as human-AI interfaces.

## Keynote Lecture

Andrea Renda (Senior Research Fellow, CEPS and Member of the European Commission High Level Expert Group on Artificial Intelligence) started by reviewing the main socio-economic challenges in healthcare, assessing how AI (and other emerging technologies) might be anticipated to help tackle the challenges (Table 1).

[1] The Academy of Medical Sciences 2018 “Our data-driven future in healthcare”.

Table 1

| Challenge to healthcare | Potential AI contribution |
|---|---|
| Demographics, particularly ageing populations | Not clear yet |
| Health staff shortages | Replace certain jobs |
| Differentiating points of care | Optimise point of care if improved data compatibility |
| Waste of resources, including over-prescribed pharmaceuticals | Better matching supply and demand |
| Rise in lifestyle diseases | Better prediction of future developments e.g. climate change health effects |
| Shifting viral disease patterns | Better prediction of future developments |
| Long diagnosis timelines | Accelerate diagnosis but may be concern for accuracy |
| Distributive inequality | Might be exacerbated e.g. for vulnerable groups |

Some of these points are discussed in further detail subsequently in the context of what can now be expected. The opportunities for using AI depend on availability of good quality, unbiased and representative, data. However, even if data-driven machine algorithms generate satisfactory diagnosis for most patients, they may not do so for rarer conditions, increasing ethical concerns about inequity.

AI should be seen as only a small part of the answer to socio-economic problems in healthcare but it will also influence and enable other components in the "new technology stack", for example a dramatic rise in interconnected smart devices and the advent of smart pills. New models for organising medical practice based on real-time signals replacing current delays in access to primary and secondary healthcare will, in turn, steer healthier behaviours via the end user interface.

Computing capacity will continue to skyrocket and its exponential growth will soon exceed the capacity of the human brain, if not human brain capability. The promise of AI and robotics is expected to lead to real-time prevention, more accurate monitoring at micro (individual) and macro (population) levels and greater efficiency in real-time assessment of impacts. Access to data on the status of the individual provides the opportunity for mass customisation of healthcare but this will have significant implications for business models in the pharmaceutical and pharmacy sectors as well as for clinicians. How soon this promise will be achieved, depends on progress in technology development but it is probable that the slowest step will be consumer acceptance.

What are the risks? Will the new era of healthcare be available for all or only those who can afford the costly new approaches? Whether new approaches will always be more costly is a matter of controversy. During the Panel discussion it was suggested, for

example, that earlier diagnosis will reduce other healthcare costs. But there will be other resource pressures on the health and welfare systems, including pressures arising from job displacement. There will be other concerns for the individual including: privacy intrusion, loss of agency and self-determination, mind manipulation, and the risk of false positives and false negatives in prediction.

Policies must be put into place to manage the various risks but concerns about the black box nature of AI approaches persist – even AI developers cannot always explain how their techniques reach their conclusion. This lack of transparency will undermine confidence by doctors and patients. Would it be better to rely only on those probabilistic algorithms that are explainable, accepting some loss of prediction power?

The strengths and limitation of robots compared to humans in healthcare have been discussed extensively in the literature[2]. Evidence to date shows that although AI can be better than human assessment (for example, in identification of metastatic breast cancer), AI is never better than AI plus humans.

Draft ethics guidelines have been published by the High-Level Expert Group[3] and cover issues for:

- Bias and discrimination
- Efficacy and fairness
- Accuracy and privacy
- The "junk" AI problem
- Inclusiveness
- Loss of identity, agency and self-determination
- Liability – who is responsible for AI decisions?
- Explainability

[2] For example, see slide presented on review of A Patel et al. "Vitality of robotics in healthcare industry: an internet of things (IoT) perspective". In "Co-creation and Participatory Design of Big Data", Springer, Berlin, 2017.

[3] "Draft ethics guidelines for trustworthy AI, on https://ec.europa.eu/digital-single-market/en/news/draft-ethics-guidelines-trustworthy-ai. The High-Level Expert Group has now proceeded to the second phase, translating ethical principles to policy. Other work of this Group is on https://ec.europa.eu/digital-single-market/en/high-level-expert-group-artificial-intelligence.

These guidelines are based on core ethical principles of respect for human autonomy, prevention of harm, fairness and responsibility, and should be embedded via the principle of process throughout the development of AI from design to algorithm completion. Criteria of trustworthy AI include compliance with the law, ethical adherence and robustness. Which requirements will be mandatory, particularly in the "design for all" model will vary according to sector. The process checklist to follow in design includes the dimensions of privacy, data governance, transparency, accountability, diversity and non-discrimination, socio-environmental well-being and safety.

Should healthcare be kept to a higher standard than other AI applications? Enhanced risk-assessment for healthcare applications is possible but whether it is desirable may depend on cost-benefit considerations. EU policy-makers could enforce stricter requirements for AI in healthcare by selecting trustworthy AI in public procurement.

Will AI increase European competitiveness? Although a role for AI in increasing GDP has been discussed on other occasions, Professor Renda advises that the contribution of AI should instead be assessed broadly, in terms of attainment of the Sustainable Development Goals.

To conclude, by restating the question "Is Europe ready?" the answer must be no, not yet. There is much more to be done in terms of quality data availability, 5G deployment, and ethics alignment. A good case can be made that one of the designated Missions for the forthcoming Horizon Europe R&D funding programme should focus on healthcare and should incorporate AI-related activities. FEAM is invited to help make this a priority for Europe, so that Europe can take a lead in preparing for and implementing AI.

## Panel Discussion: Is Europe ready?

### Moderator: Jacki Davis, journalist

*Gustave Moonen (*Member of the Belgian Royal Academy of Medicine) emphasised that it is still early in the adoption of AI but expressed a concern if the objective were to be doctor-less, autonomous medicine by analogy to driver-less cars. This would risk loss of empathy in the practice of medicine. Although there are already black boxes in healthcare, there is need for education and training for both healthcare professionals and patients to prepare for using AI and for combining AI and human intelligence. Evidence-based approaches to evaluating and using AI have to be coordinated across Europe – to support data comparability, minimise costs and share good practice.

*Nicola Perrin* (Wellcome Trust) suggested that the impact of all emerging technologies tends to be overestimated in the short-term and under-estimated in the long-term. This is going to be true for AI. While there might be some initial quick wins, it is unlikely that progress will continue at the same rate, particularly when one takes into account the difficulties of accessing high quality data.

AI will not replace doctors but doctors using AI will replace those who do not – and a more effective doctor-patient relationship can emerge. The initial impacts in clinical medicine have been in image analysis but among future impacts can be expected self-management of conditions.

*Marco Marsella* (Head of Unit, "eHealth, Well-Being and Ageing" at European Commission, DG Connect) reviewed how the European Commission is taking a balanced approach by investing in the technology while also supporting assessment of ethical and legal issues. Availability of quality data is the necessary first step in realising the potential of AI. Then, data must be used meaningfully, requiring managed access to personal health data and cultural change among newly-skilled health professionals.

*De Cunha Maluf-Burgman* (QA Regulatory Affairs Program Manager for RF & Cybersecurity, Medtronic and MedTech Europe representative) advised that good progress is being made in ethical assessment (with the High-Level Expert Group), in technical capacity (for example, faster diagnosis) and in the cultural acceptance that AI is worth adopting because it spares doctor assessment time that can then be devoted to patient care. But, in agreeing with the points made by other speakers, there must also be better healthcare strategies for data mining, if the long-term potential is to be realised.

*Stefan Platz* (Senior Vice President, Drug Safety & Metabolism, AI/Big Data/Digital Health Strategy, Astra Zeneca) identified value from the use of AI throughout pharmaceutical R&D, from toxicology through to post-marketing surveillance, and in regulatory agencies. AI can also save money by improving the supply chain and can optimise the search for new leads and intellectual property in existing compound libraries. One major ethics issue, as noted by previous speakers, relates to the prediction of patient outcome. What quality data are needed to avoid bias in models, for example if sampling only selected groups?

These initial Panel contributions and other points raised by Professor Renda were used to stimulate further Panel and audience debate on key themes.

- *Health is different and has a higher ethical requirement*. For example, in terms of respect for autonomy and avoidance of harm. To expand on the point made previously, proportionate risk assessment is important, necessitating a more

regulated market, but this will raise costs of development. When evaluating proportionality, it is particularly difficult to judge the societal acceptability of a risk that is of low probability but potentially high impact.

- *How and what to regulate*. Are algorithms being held to a higher standard than humans? The black box nature of some algorithms tends to magnify concerns about risk – is the critical issue this lack of accountability of AI? Furthermore, for regulation it must be appreciated that these are AI learning systems so continuing validation is needed rather than one-off pre-marketing approval. Regulation is also relevant to understanding medical professional liability issues. To extend the point made previously, is it the case that if the doctor follows closely what AI advises then the doctor would not be liable in the event of a bad outcome, whereas if the AI guidance were to be disregarded then professional liability might newly accrue? If so, this may be an impediment to building an optimal doctor-AI relationship. A challenge for regulation is how to operationalise the ethical principles in different circumstances. Co-design (user-developer)[2] works to an extent but bottom-up policy-making to effect this has inefficiencies: it can be difficult to reach consensus because of different cultural and behavioural biases. Therefore, top-down decisions from policy-makers may be needed to provide the framework for applying co-design. From the European Commission perspective, a balanced approach to regulating use of data can build on what was already been achieved recently with the inception of the Medical Devices Regulation and the General Data Protection Regulation: others agree but ask for work on policy options to be accelerated.

- *Quality and validity of data*. Panellists agreed that one of the biggest challenges is data validity and standardisation - and the quality of much phenotypic, observational and self-collected data could be improved. Even if data are accurate, they may not be representative, for examples data from sick patients may not be generalizable to wider populations. Furthermore, conclusions from AI approaches need to be peer reviewed for validity and safety, but this rarely happens, and accuracy in AI systems may require intrusive data gathering. Can AI itself improve the quality of data collected to use for AI, a virtuous circle? There are opportunities to do this but presently they are not well supported by public research funders or commercial investment. The various options for improving data quality raise a core question of how much effort should respectively be expended on creating a smaller, well-validated data set or on compiling a much larger data set that will include some inaccuracies.

- *Predictability.* Even when data quality is high and AI can be expected to improve prediction of treatment outcomes, there is a strategic question as to how this information should be used to transform health systems. By analogy with the policing application of AI to predict crime locations, the probabilistic expectation of predictability may reinforce a bias to over-inspect certain areas to the detriment of equity. AI identifies associations in data but much more research is required to ascertain if there is causality. AI should be used to ask as well as answer questions.

- *Trust in healthcare.* Panellists also agreed on the importance of building trust in healthcare – the issue is not specific for AI. Trust requires public engagement, not sufficiently emphasised as a feature in the High-Level Expert Group draft guidelines and the data problem is compounded by low public awareness of the current uses of health records' data. One example for building trust is provided by Sweden where the AI innovation initiative has taken a decentralised approach with local communities in dialogue on the issues relating to privacy, confidentiality and transparency in use of data. AI will likely exacerbate existing uncertainties induced by hyperbole about prospective benefits and concerns about commercial interests. Perhaps health can learn from other sectors, such as agriculture, where stakeholders share meaningful access to data without entirely open access. However, some objectives for data interoperability may require open access. Privacy and security have to be designed into systems to engender trust and lessons of good practice can be derived from the recent European Commission recommendations on Electronic Health Records, to enable data transfer. However, security by design implies human involvement in design and reinforces the point that human involvement must be retained during development and implementation of AI technologies.

- *Public-private partnership in using data.* Some will consider selling patient data problematic, even if the data are anonymised. Because the data belong to the patient, consent is required. A "rights to use" model might be a better basis for resolving tensions than an approach specifying "ownership". Companies make the point that data on their own have limited value, higher value resides in annotating data, building and curating data sets: the private sector is needed to fund these activities. Nonetheless, while recognising that the private sector adds value, there must also be some return to the public health system. And there is also a concern that if data handling is not transparent or traceable, then suspicions of data manipulation undermine doctors' and patients' confidence.

- *Education and skills*. Do doctors need new skills to take advantage of AI or is the issue rather that they will become deskilled by AI? There was general agreement in discussion that reskilling is needed for doctors to be better doctors. That is, AI should not replace doctors but should be an asset for them. Learning about AI is important to translate the patient's experience into data that can be used by AI and then to translate AI recommendations to patient care. Current trends whereby technology is leading clinicians away from patient contact could be transformed. Clinicians and data scientists working together need a common language to share the clinicians' hypothesis-driven approach and the data scientists' data-driven approach. What new skills do patients need and how should patient engagement in use of data be improved? It can be a challenge to convey the issues on use of data in a way that the lay public understand but there is evidence that patients are more receptive to requests for personal data use than are the lay public.

In concluding the discussion, Jacki Davis asked Panellists for "one thing" to help us be ready for AI. Responses reaffirmed previous points:

- ⇨ Skills, education and training, including in medical schools.
- ⇨ Engaging to inform public acceptance and tackling issues of trust to support the licence to operate.
- ⇨ Building the environment to support innovation.
- ⇨ Encompassing the AI agenda within the Sustainable Development Goals.

George Griffin closed the Forum event by congratulating all participants for their insightful comments across the spectrum research-industry-regulation-clinical practice and welcomed the serious attention being given to critical issues by the EU. Medicine and medical practice already depend completely on computers. The difference to be expected, as AI nears, is the potential for added intelligence in using the information to make decisions. AI should be enabling rather than defining.

# Annex I - Agenda

18 March 2019 (14:30 - 18:30)
Palace of the Academies, Rue Ducale 1, 1000 Brussels / Room Roi Baudouin

| | |
|---|---|
| 14:30-15:00 | **Registration and coffee** |
| 15:00-15:05 | **Welcome**<br>*Jean-Michel Foidart*<br>Perpetual secretary, Belgian Royal Academy of Medicine (ARMB) |
| 15:05-15:15 | **Introduction**<br>*George Griffin*<br>President, Federation of European Academies of Medicine (FEAM) |
| 15:15-15:45 | **Keynote lecture – Artificial Intelligence in healthcare: is Europe ready?**<br>*Andrea Renda*<br>Senior Research Fellow, Centre for European Policy Studies (CEPS) and Member of the European Commission High Level Expert Group on Artificial Intelligence |
| 15:45-17:20 | **High-level panel discussion**<br>Moderator: *Jacki Davis*, Journalist |
| | *Andrea Renda*<br>Senior Research Fellow, Centre for European Policy Studies (CEPS)<br><br>*Gustave Moonen*<br>Member of the Belgian Royal Academy of Medicine (ARMB)<br><br>*Nicola Perrin*<br>Wellcome Trust<br><br>*Marco Marsella*<br>Head of Unit 'eHealth, Well-Being and Ageing' at European Commission, DG CONNECT<br><br>*De Cunha Maluf-Burgman*<br>QA Regulatory Affairs Program Manager for RF & Cybersecurity, Medtronic (MedTech Europe representative)<br><br>*Stefan Platz*<br>Senior Vice President, Drug Safety & Metabolism (AI/Big Data/Digital Health strategy - AstraZeneca)<br><br>*The panel discussion will include a Q&A with the audience* |
| 17:20-17:30 | **Concluding remarks and next steps**<br>*FEAM* |
| 17:30-18:30 | **Networking cocktail** |

This event was funded by the UK Academy of Medical Sciences using a grant from the UK's Department of Business, Energy & Industrial Strategy (BEIS).

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# Annex II - Speakers' biographies

## Jacki Davis

*Moderator, Journalist*

Jacki Davis is an experienced journalist, speaker and moderator of high-level events both in Brussels and in EU national capitals, the editor of many publications, a regular broadcaster on television and radio news programmes, and a Senior Adviser and member of the Governing Board of the European Policy Centre think tank. Jacki has been based in Brussels for 25 years, and was previously Communications Director of the European Policy Centre think tank; Editor-in-Chief of E!Sharp magazine; and launch editor of European Voice, the Brussels-based weekly newspaper then owned by The Economist (now Politico). Jacki has moderated many conferences in Brussels and in EU Member States, and also has extensive experience in planning events.

## Jean-Michel Foidart

*Perpetual secretary, Belgian Royal Academy of Medicine (ARMB)*

J.M. Foidart is an MD, PhD trained in Obstetrics and Gynecology (Ob-Gyn), in part in the United States (1976-1979) at the Johns Hopkins University Hospital, Baltimore, and in Belgium, Finland and France. He spent 3 years as a biochemist at the National Institutes of Health in Bethesda, Maryland, USA. He became in 1988, professor and chairman of the Dept of Cell Biology at the University of Liege (ULg), Belgium. He then established a large and well renowned laboratory that owns many patents. He contributed from 1989 until 1996 to the clinical development of a new oral contraceptive containing Drospirenone. In 1996, he became chairman of the Dept of Ob-Gyn ULg, until 2012. From 2012 until 2015 he was extraordinary Professor at University of Liège, Belgium and chairman of the Interdisciplinary Group of Genomics and Proteomics (600 researchers). He is presently Board member and the chairman of the Scientific Board at MITHRA, a Belgian company that he created in 1999 with François Fornieri. His main research interest is in experimental reproductive endocrinology and oncology. He played a pivotal role in the development of Levosert, an intra-uterine system releasing small amounts of levonorgestrel. Professor Foidart is a member of many national and international scientific committees. He is a past president of the Belgian Society of Biology and of the Belgian Society of Gynecology. He is past General Secretary of the European Society of Gynecology and a former Board member at the International Federation of Gynecology and Obstetrics in London (FIGO) and presently a member of the Board of the International Society of Gynecological Endocrinology. He has been an invited lecturer at the Universities of Paris VII and Paris XI and is the recipient of several international awards from Belgian (Chaires Francqui 1995 and 1996), and French Universities. He has received many honorary and scientific distinctions. He is Dr. Honoris Causae at the University la Sorbonne-Pierre et Marie Curie, (Paris 2010) and Paul Sabatier

Toulouse (2012). Professor Foidart was awarded in 2006, to the "Prix Maisin", highest distinction for medical achievement of the National Research Foundation in Belgium and is Officier de l'Ordre de Léopold II and Commandeur de l'Ordre de la Couronne. He organized more than 30 International Congresses in the fields of Contraception, Reproductive Endocrinology and Menopause. He has published over 800 manuscripts, 26 chapters in books, and more than 40 invited reviews, in outstanding journals with a mean H index of 104, that were cited more than 40.000 times. Professor Foidart is a member of the French and Belgian Academies of Medicine of which he is presently the Perpetual Secretary. He has been appointed in 2018, Treasurer of the European Federation of the Academies of Medicine.

## George Griffin

*President, Federation of European Academies of Medicine (FEAM)*

Prof. George Griffin gained BSc in Pharmacology and Molecular Biology at King's College London Sciences, where he was awarded the Delegacy Prize for Excellence in Preclinical Science. He was awarded PhD in Cell Biology/Biochemistry, University of Hull, and returned to clinical studies at St George, University of London, where he was awarded the MBBS. Professor Griffin's postgraduate training paralleled basic and clinical science. During this time, he was awarded a Harkness Fellowship of the Commonwealth Fund of New York at Harvard Medical School. On return to the UK, he continued clinical training at Royal Postgraduate Medical School where he was tutor in Medicine, and the National Hospital for Nervous Diseases. He then returned to St George's as lecturer and was awarded a Wellcome Trust Senior Lectureship and became consultant physician on the Clinical Infection Unit where he was instrumental in developing an internationally renowned research unit twinned to the Clinical Unit. He held prestigious research fellowships in the University of Michigan and National Institutes of Health. He has chaired scientific advisory boards in major pharmaceutical industry in the USA and UK. He has been chair and member of major Wellcome, Medical Research Council and Gates Foundation committees. He was censor at the Royal College of Physicians (https://www.rcplondon.ac.uk/) and was made a member of the Academy of Medical Sciences in which he has been elected to become foreign secretary and council member. He was appointed to the board of Public Health England where he will help shape strategy for research and clinical development. Professor Griffin was awarded the distinction of CBE in 2018 (Commander of the British Empire) for his research and its contribution to Public Health.

His research has focussed on the host response to infection at cell, molecular and whole body level. Such work involves immune and metabolic responses in vivo in humans. Furthermore cell and molecular studies include culture of human mucosal explants and definition of macrophage activation in vitro by microbial agents. A macrophage is a cell which ingests particles (microorganisms or host cells) for destruction and immune presentation. It is important in intracellular infection and also produces cytokines (a category of signaling molecules) as part of the immune response. Professor Griffin's principal clinical contributions to knowledge have been in the characterisation of intestinal disease in HIV infection, mechanism of weight loss in HIV and definition of loss of mucosal immune response in advanced HIV infection. The dominant cell and molecular achievements have been the characterisation of NF-kb, a crucial factor maintaining macrophage differentiation and the role this transcription

factor plays during tuberculosis infection of the macrophage and the mechanism of enhanced HIV transcription in such cells. More recently he has characterised the role of co-infection of HIV infected cells with herpes virus in enhanced HIV transcription in the genital epithelium.

## Andrea Renda

*Senior Research Fellow and Head of Global Governance, Regulation, Innovation and the Digital Economy (CEPS)*

Andrea Renda is a Senior Research Fellow at the Centre for European Policy Studies (CEPS), where he directs a research group on Global Governance, Regulation, Innovation and the Digital Economy (GRID). He is a non-resident Senior Fellow at Duke University's Kenan Institute for Ethics. From September 2017, he holds the "Google Chair" for Digital Innovation at the College of Europe in Bruges (Belgium). For this academic year (2018/2019), he is also a Fellow of the Columbia Institute of Tele-information (CITI) at Columbia University, New York. His current research interests fall at the intersection of technology and policymaking and include regulation and policy evaluation, regulatory governance, innovation and competition policies, and the ethical and policy challenges of emerging digital technologies. He is a Member of the High-Level Group on Economic and Social Impacts of Research of the European Commission, DG RTD; a member of the European Commission High Level Expert Group on Artificial Intelligence; a member of the European Commission's Blockchain Observatory and Forum; and a member of the Italian Expert Group on AI set up by the Italian Ministry of Economic Development. He leads the CEPS Task Forces on Artificial Intelligence and Blockchain.

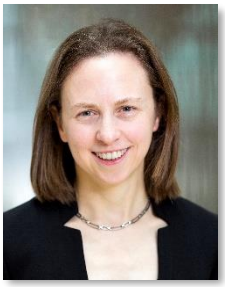
## Gustave Moonen

*Professor emeritus of Neurology University of Liège Belgium*

Gustave Moonen MD, PhD FEAN. Titular member and former president of the Royal Academy of Medicine, Belgium. Honorary member of the European Academy of Neurology. After graduating as MD in 1971 and training in Neurology, Gustave Moonen has been until 1987 a tenure scientist at the National Fund for Scientific Research focussing on developmental neuroscience. During that period, he did work at the CNRS (Pr P. Mandel, Institut de neurochimie Strasbourg), NICHD (Dr P.G. Nelson,Developmental neurobiology branch) Bethesda and UCSD (Pr S. Varon, department of biology). He then became Chairman of the dept of physiology at the University of Liège. His main topics of interest were biology of glial cells, neuronal migration, inner ear biology and neuropharmacology of antiepileptic drugs. In 1999, he was appointed as chairman of the Dpt of neurology at the university hospital in Liège with particular interest in MS, disorders of consciousness and neuroimaging. He retired from that position in 2012 but remains an active clinical neurologist.

## Nicola Perrin

*Head of Data for Science and Health - Wellcome Trust*



Nicola Perrin is leading the development of a new strategic priority for Wellcome, looking at Data for Science and Health. She previously established Understanding Patient Data, to support better conversations about how health information can be used to improve care and research. From 2007-2016, Nicola was Head of Policy at Wellcome, responsible for leading policy development and advocacy work at Wellcome. Particular areas of focus included research base funding, innovation in the NHS, and data sharing. Prior to joining Wellcome, Nicola worked at the Nuffield Council on Bioethics as Communications and External Affairs Manager, and before that, she was an exhibition manager at the Science Museum. Nicola is a Trustee of the Association of Medical Research Charities.

## Marco Marsella

*Head of the "eHealth, Well-being, and Ageing" Unit - DG CONNECT - of the European Commission*

Marco Marsella is Head of the "eHealth, Well-being, and Ageing" Unit in the Directorate General for Communications Networks, Content and Technology (DG CONNECT) of the European Commission. From 2016 to June 2018, Marco Marsella was leading the Unit responsible for the Web Accessibility Directive, Safer Internet and Language Technologies. He has worked on policy development, innovation and research implementation in the areas of digital content, technologies for learning, e-inclusion and assistive technologies.

## Martha De Cunha Maluf-Burgman

*QA Regulatory Affairs Program Manager for RF & Cybersecurity Regulatory Affairs EMEA – RF CoE (Medtronic)*

Martha brings over 23 years of International, Institutional, Governmental and Regulatory Affairs experience on Telecommunications/telemedicine, Satellites and Medical Devices Industry in countries and regions such as Argentina, Canada, Latin America, Europe and EMEA Regions. Martha has Bachelor in Mechanical Engineering, Masters in International Relations and Marketing Management from the University of El Salvador in Argentina along with the State University of New York at Albany, and a Bachelor of Political Science from the University of El Salvador, and she also has a post-grade in Communications Regulation from the University of Buenos Aires. Martha maintains ongoing professional affiliations and networking with many governments, competent authorities in Healthcare and Telecommunications sectors, and institutions, trade associations and international Fora. Martha currently works for Medtronic Bakken Research Center B.V. in The Netherlands as Quality Regulatory Affairs Program Manager for Radio Frequencies and Cybersecurity and represents her company in

MedTech Europe (MTE), where she has been elected to represent MTE in the ENISA's eHealth Security Experts Group and appointed to represent MTE as Medical Device representative to the Cybersecurity Task Force within the European Commission. She also represents her company in Bluetooth SIG and in IEEE PHD Cybersecurity Ad Hoc team. Martha advocates on Radio Frequency and Cybersecurity regulatory related matters. Martha also works in innovation as inventor and she has filed 3 patents for Medtronic and is working on more patent submissions. Previous to Medtronic she was Regulatory Affairs Director of New Skies Satellites (today SES). She has been based in The Hague for 11 years and adopted the Dutch Nationality (Argentine of origin).

## Stefan Platz

*Vice President of Drug Safety and Metabolism within AstraZeneca's Innovative Medicines and Early Development unit (IMED)*

Stefan Platz is the Vice President of Drug Safety and Metabolism within AstraZeneca's Innovative Medicines and Early Development unit (IMED). In this role, Stefan is responsible for the non-clinical safety assessment of the drug candidates in discovery and development, leading a global team across Sweden, UK and the US. Stefan is also the sponsor for data integration and AI on behalf of the IMED Leadership Team. Stefan has a degree in veterinary medicine from the University of Munich and is a German certified veterinary pathologist as well as Diplomate of the American Board of Toxicology. He started his career in 1996 at Boehringer-Ingelheim. Before joining AstraZeneca in February 2012, Stefan led the non-clinical safety organisations for Hoffmann-La Roche in both Basel and Palo Alto. During this time period he also had extended periods of strategic responsibilities for the early safety screening as well as biologics safety. Stefan is particularly interested in exploring novel approaches and technologies to better predict human safety based on in vitro and in silico data. Recent investments by AstraZeneca in micro-physiological systems may help to understand safety risks in patients based on a dynamic cell system mimicking full organ functionality. Together with modelling and simulation of human data this might accelerate drug development and result in a reduction in number of animals used in preclinical testing. Stefan is leading the AZ2025 Workstream for Data and AI as well as the sponsor for data integration and AI on behalf of the IMED Leadership Team.

# About FEAM, The Federation of European Academies of Medicine (www.feam.eu)

FEAM is the European umbrella group of national Academies of Medicine and Medical Sections of Academies of Sciences. It brings together 18 national Academies representing over 5000 among the best biomedical scientists in Europe.

FEAM's mission is to promote cooperation between national Academies of Medicine and Medical Sections of Academies of Sciences in Europe; to provide them with a platform to formulate their collective voice on matters concerning human and animal medicine, biomedical research, education, and health with a European dimension; and to extend to the European authorities the advisory role that they exercise in their own countries on these matters.

# About the FEAM European Biomedical Policy Forum

The FEAM European Biomedical Policy Forum provides a platform for discussion on key policy issues for the biomedical community.

The Forum is an initiative from the Federation of European Academies of Medicine (FEAM). It aims to bring together representatives from academia, research charities, industry, European and national trade associations and professional bodies, regulators, public health bodies, and patient and consumers groups.

If you would like further information on the FEAM European Biomedical Policy Forum or becoming a partner, please contact elisa.corritore@feam.eu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