



Compliance in the light of Digitalization

IPC Mini-Summit 2

Athens, Greece

A woman with blonde hair, wearing a dark blue short-sleeved shirt, is speaking and gesturing with her hands. She is in the foreground, looking towards the right. In the background, a woman with dark hair is looking at a laptop, and a man is partially visible. The setting appears to be a modern office or meeting room.

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Introduction

Today's panelists

Marie-Claire Pickaert

Economist

Managing Director, MCP Advice & Partnerships, Brussels, Belgium

Former Deputy Director General and Chief Ethics & Compliance Officer, European Federation of Pharmaceutical Industries and Associations (EFPIA), Brussels, Belgium

Active Member of ETHICS

Gérald Hucky

Head Group Compliance, Sonova Group; Former Compliance Audit Manager, Zimmer Biomet, Zürich, Switzerland

Niels Wohlwend

Lic. iur., M.A.E.S., Senior Director, Healthcare Compliance (HCC) Europe & Canada, Celgene; Member, EFPIA Ethics & Compliance Committee; Boudry, Canton of Neuchâtel, Switzerland

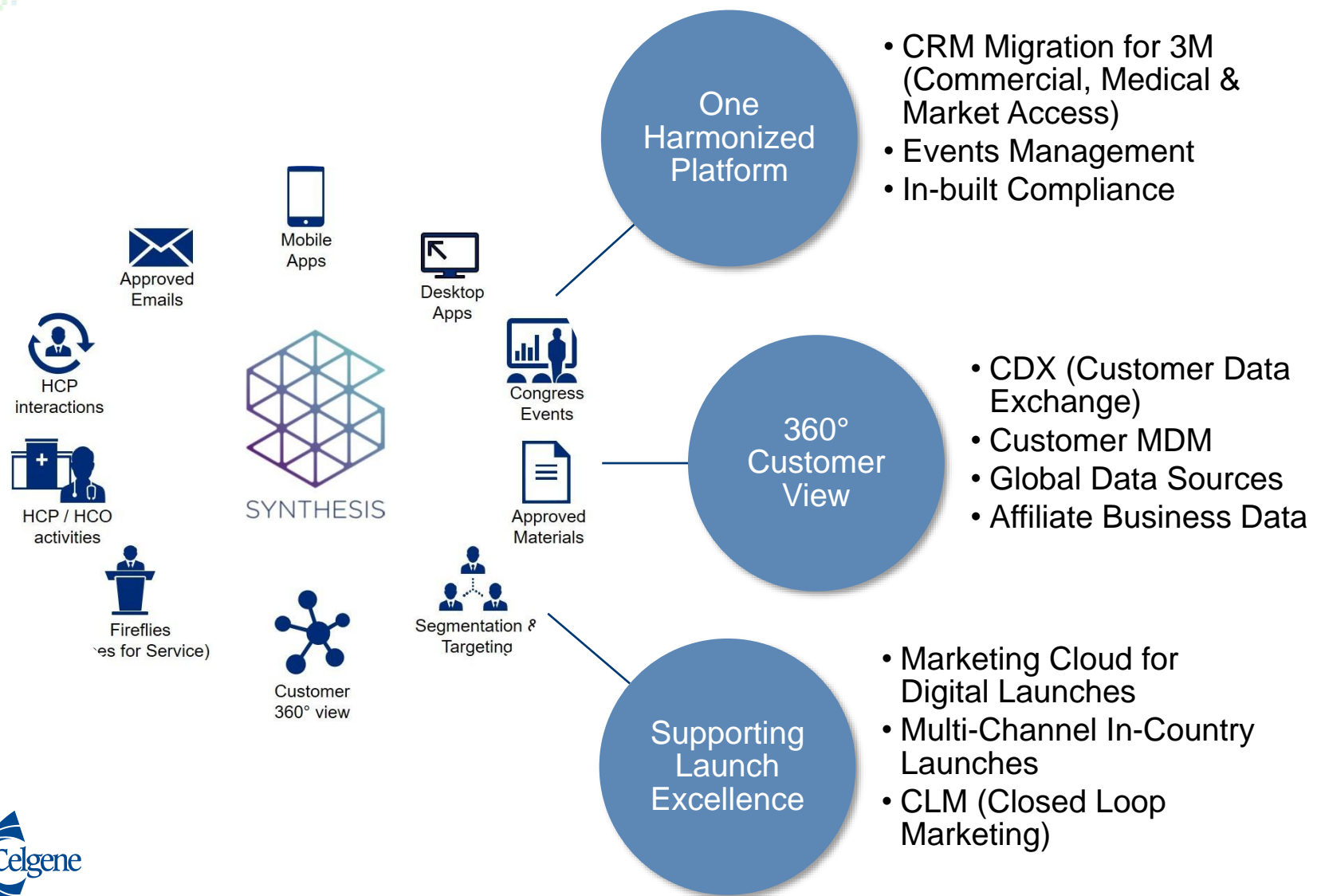
Anita Kim-Reinartz

Partner EY Germany – Forensics & Integrity Services, Head of Life Sciences and Healthcare GSA

A large, semi-transparent, light blue number '2' is positioned on the left side of the slide, serving as a background element for the title.

Compliance in the light of Digitalization

Our Synthesis Strategy is built on three pillars



- Collaboration with Global to leverage Celgene-wide assets and IP
- Establishing a 'Change Network' to engage the Affiliates on this exciting journey
- Sponsored by Global and WM Leadership Team for embedding this change in time for 16 New Product Launches

Compliance in the light of Digitalization

13th International Pharmaceutical and Medical Device Compliance Congress

Athens, Greece

April 9, 2019

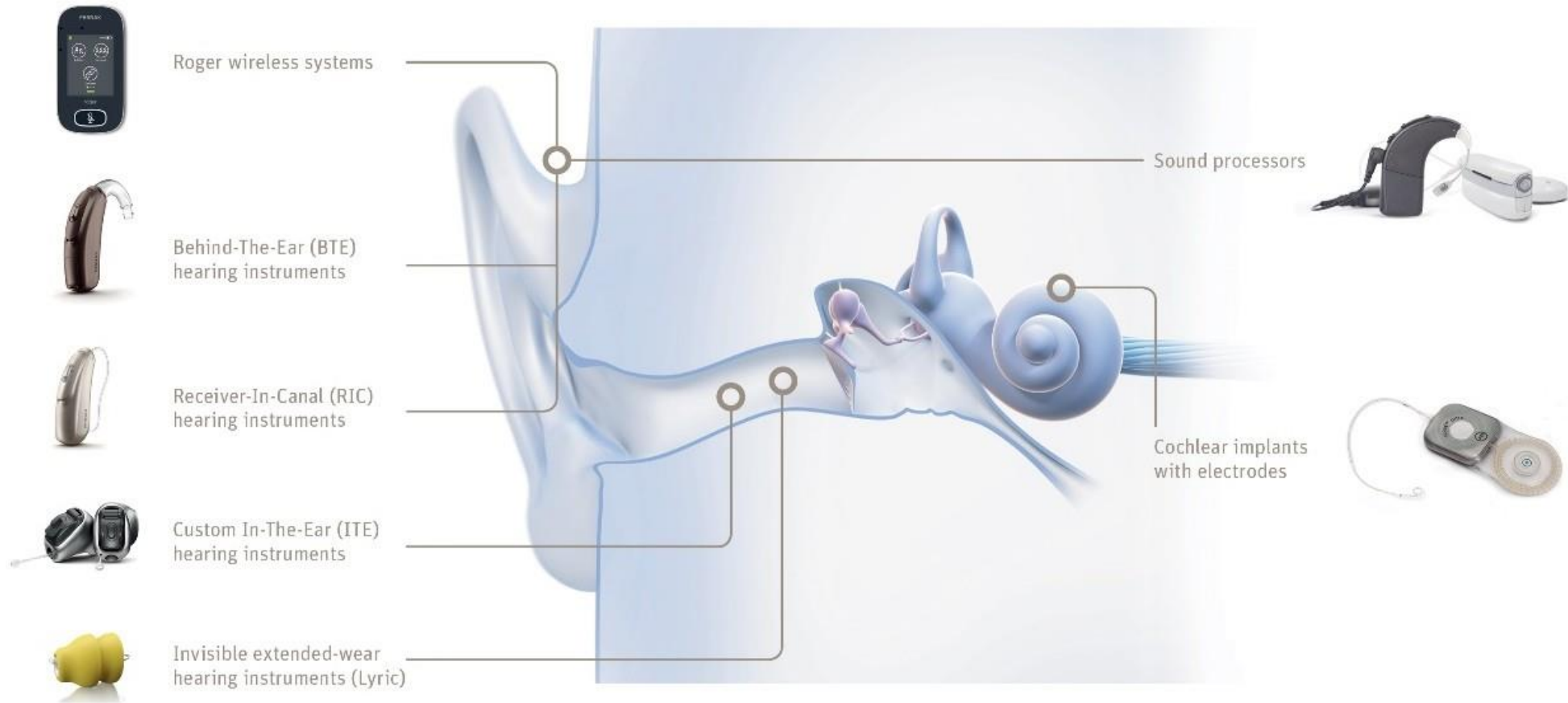
Gérald Hucky, Head Group Compliance

Sonova Introduction - Our Product and Service Offering

Hearing Instruments Business



Cochlea Implants Business



Sonova Introduction - Business Areas

Wholesalers (B2B)

Hearing instruments **PHONAK** **unitron**
HANSATON

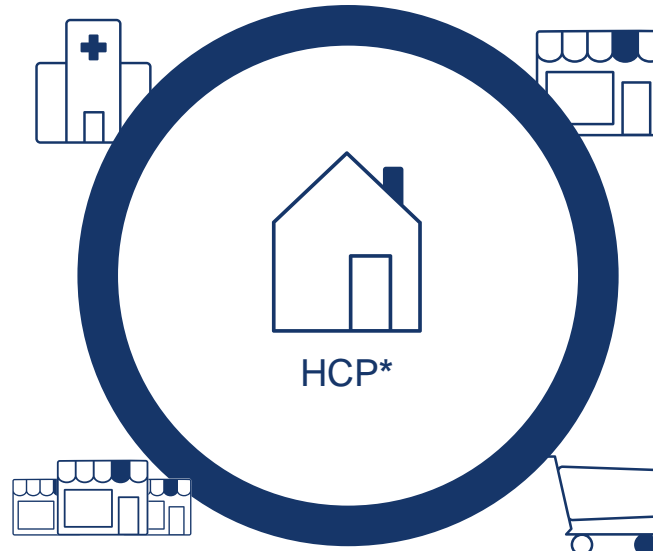


Cochlear implants **AB**



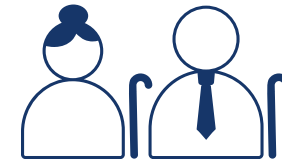
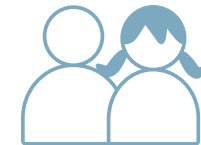
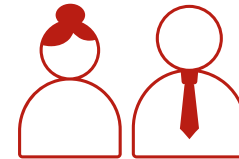
Audiological care (B2C)

Sonova **AudioNova**
Audiological Care Beyond Selling Hearing Aids



Third parties, e.g. hospitals, audiologists.

End-consumers



* HCP = Hearing Care Professional

Sonova Introduction - Numbers



2,646 mil.

Sales 2017/18

Sales 1st half

2017/18:

CHF 1,253 mil.



551.6 mil.

EBITA* 2017/18

EBITA* 1st half

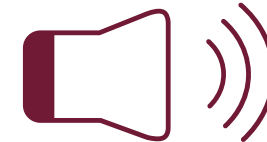
2017/18:

CHF 240.5 mil.



143 mil.

R&D expenses
2017/18



~10.3 mil.

Market capitalization
(as at 22 May 2018)

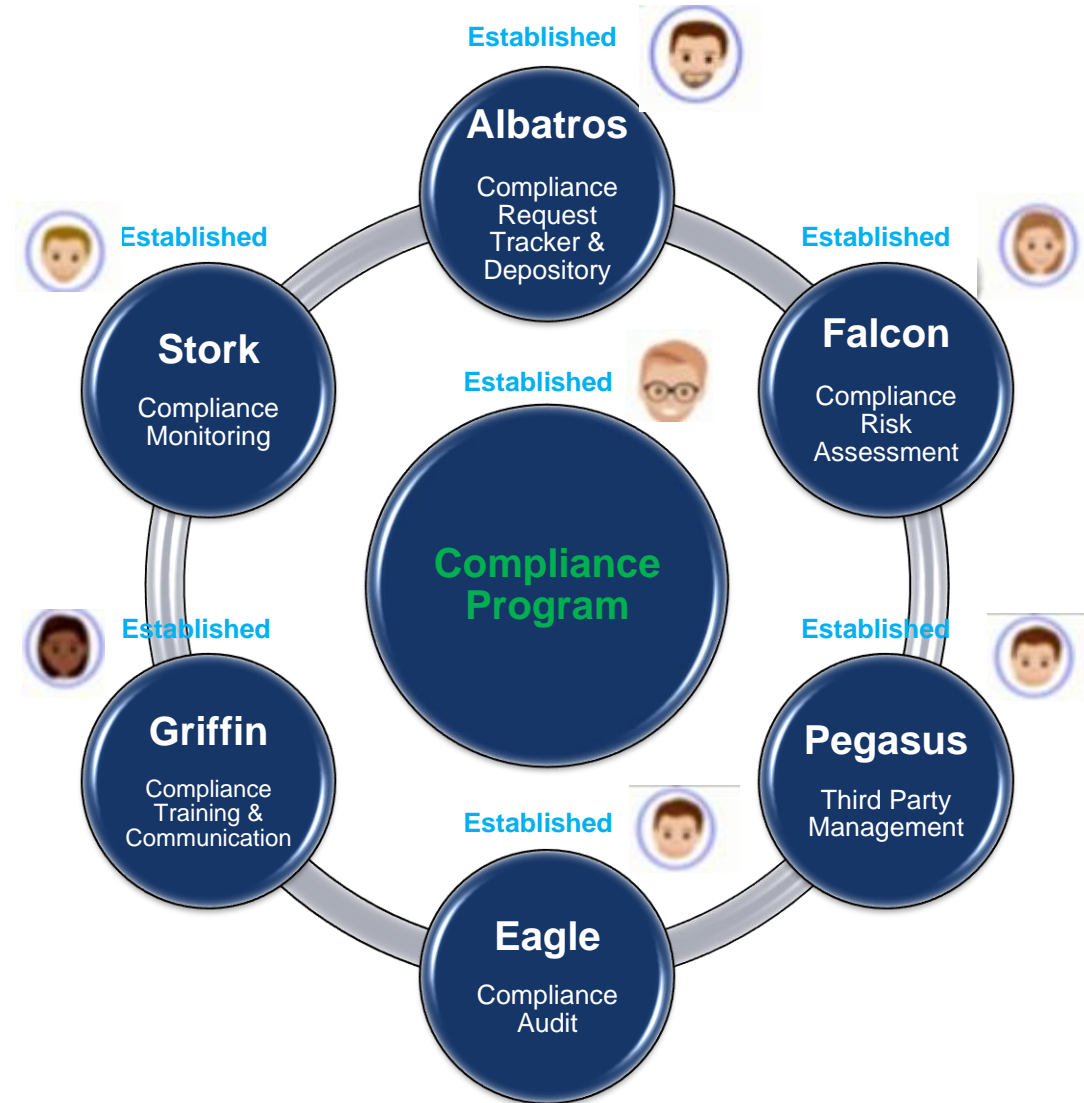


> 14,200

Employees

* EBITA: Operating profit before acquisition-related depreciation, normalized earnings

Digital Tools supporting the Compliance Program



13th International Pharmaceutical & Medical Device
Compliance Congress

Mini Summit 2

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Marie-Claire PICKAERT

MCP Advice & Partnerships

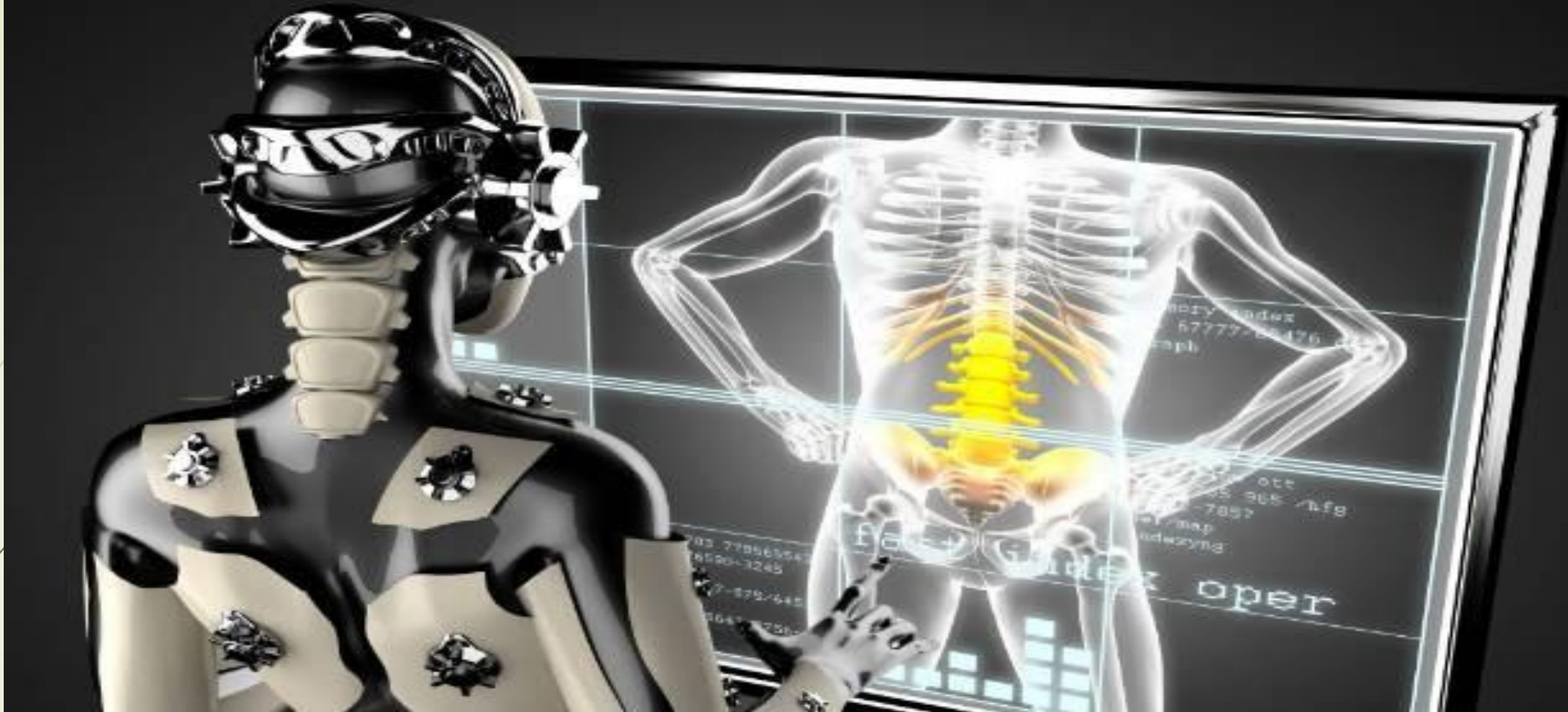
Previously Deputy Director General at EFPIA

Active Member of ETHICS

From Digitisation to Machine Learning





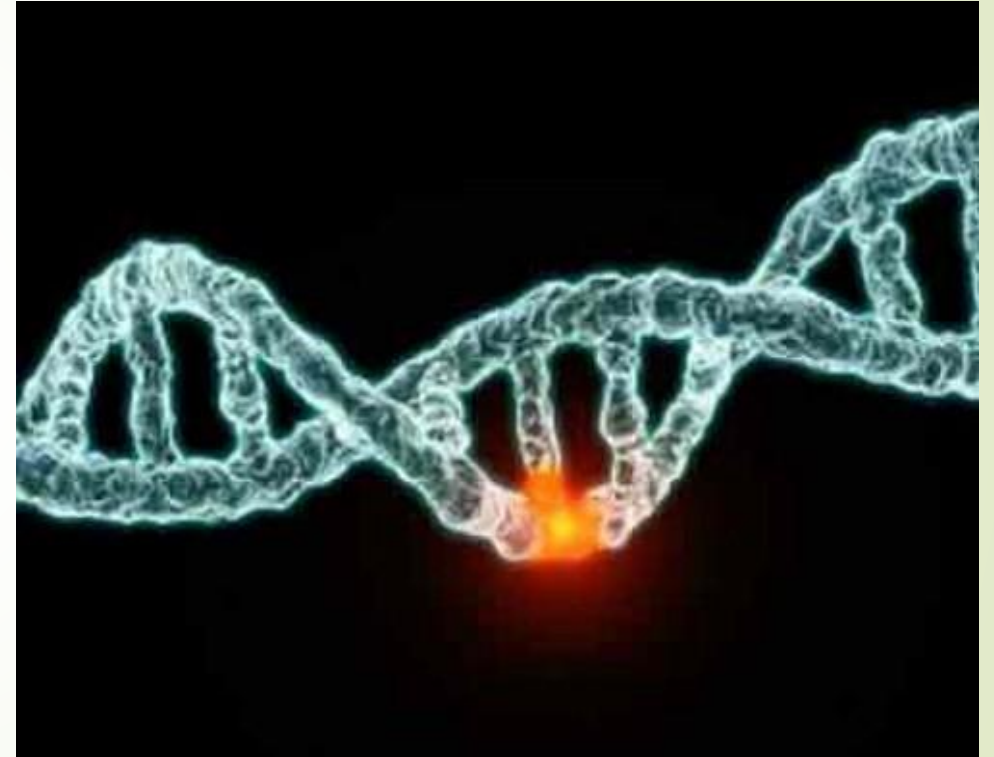
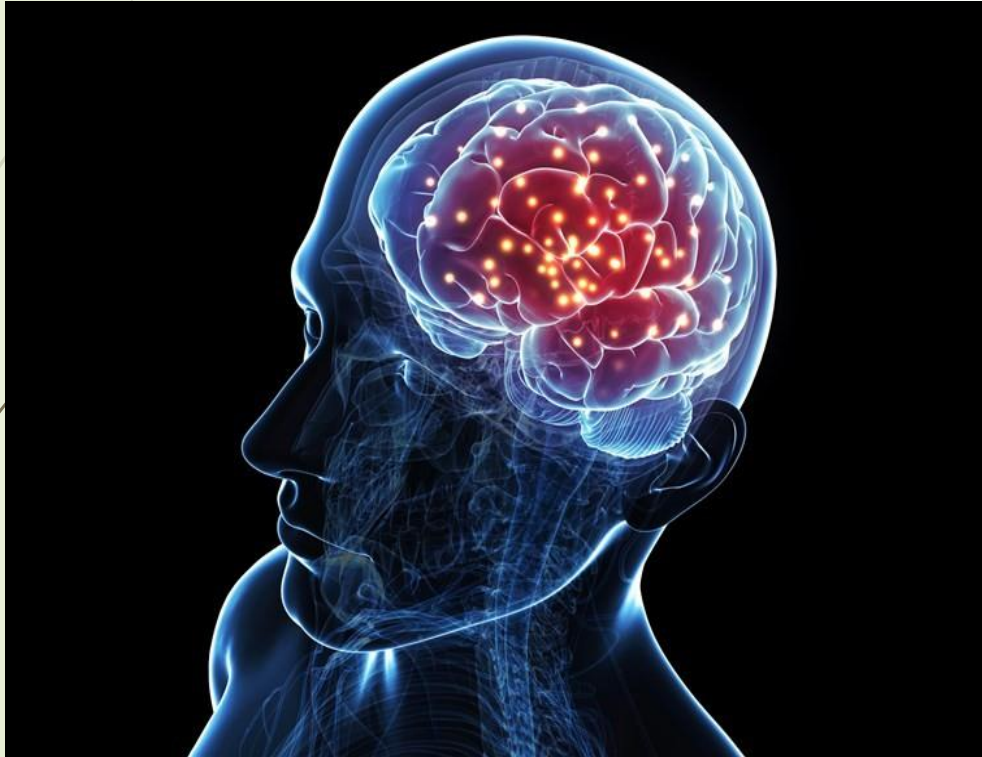


Human Augmentation represents mechanical and electronic additions to the human body to improve various body functions. In the healthcare sector, augmentation may include bionics, organ replacement, exoskeletons, and robotics to provide assistance to those that have physical impairments.

Entering the TRANS-HUMAN Era

Repairing the Brain or...

Modifying the Genome



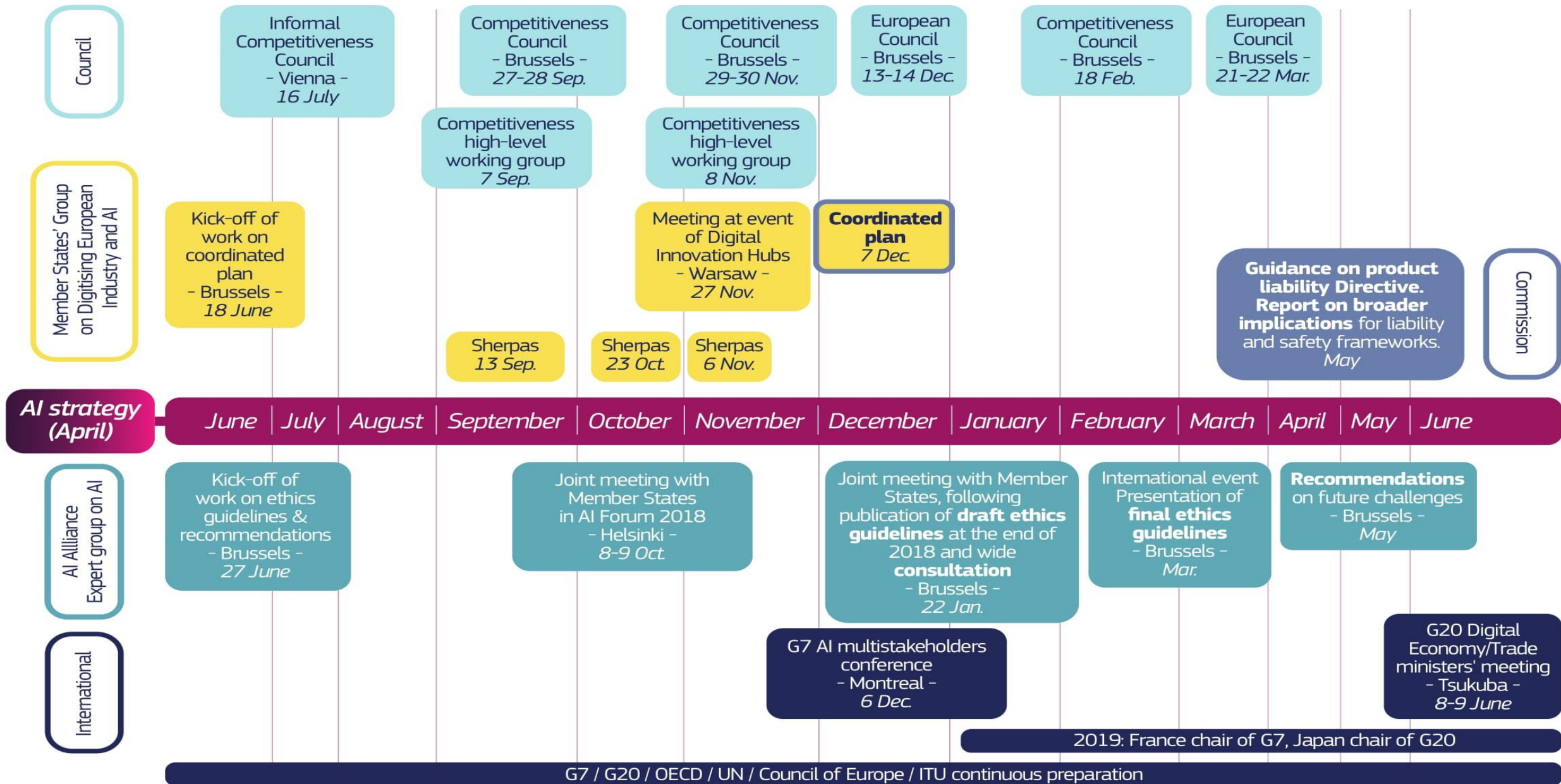
Don't fear digital health technology, but be aware of its potential dark sides

Physicians, patients, regulators, and all other stakeholders must prepare for the coming waves of change. To do that, we need to start talking openly about the potential dangers and ethical issues that arise from what humans will do to machines.

- ❖ What is the scope of medical and genetic data privacy?
- ❖ Who owns medical and genetic data? What to do with biohackers?
- ❖ How to regulate gene editing?
- ❖ Where is the boundary of enhancing physical or cognitive human capabilities?
- ❖ What to do with biological differences widening the gap of the haves and have-nots?
- ❖ Could we define where is the boundary to augment life?
- ❖ Will we sue robots or algorithms for medical malpractice?
- ❖ How do we prepare for cyber attacks against medical devices and systems?

ARTIFICIAL INTELLIGENCE (AI) FOR EUROPE – ROADMAP

Draft working document – European Commission – 7 December 2018



From ROBOT to ARTIFICIAL INTELLIGENCE



PCF Athens 9 April 2019

The Three Laws of Asimov (1950) were devised to protect humans from interactions with robots.

They are:

- 1. A robot may not injure a human being** or, through inaction, allow a human being to come to harm
- 2. A robot must obey the orders given it by human beings** except where such orders would **conflict with the First Law**
- 3. A robot must protect its own existence** as long as such protection does not **conflict with the First or Second Laws**

Thank you for your attention!

