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DOCTORS AND PATIENTS IN THE WORLD OF DATA, ALGORITHMS AND ARTIFICIAL INTELLIGENCE

Analyses and recommendations of the Cnom

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Contents

Preface

The four important ethical principles of beneficence, autonomy, nonmaleficence and justice are the basis of medical ethics, which have been set out in a regulatory text. When they are registered to practice medicine, all doctors undertake to comply with these principles. The conditions of medical practices must correspond, at all times, to the expectations of the people and those of society. Today, society as a whole is plagued by major concerns, which are evidently affecting patients as well as doctors.

The legislator has also tasked the French National Board of Physicians to make modifications to the ethics, either by proposing a new draft of the Articles in the code, or by accepting those decided upon by the legislator, after a democratic debate. In free society, the law organises the constraints and freedoms that constitute the concept of 'social harmony'. The code of ethics followed by doctors is an element of this concept.

According to Hippocrates, doctors must observe the people in their environment to provide them with aid and medical assistance, and to restore their health. Today, and even more so in the future, people are living and will continue to live in a digital society, which can potently meet at least a part of these requirements.

And yet, all citizens are not yet equal in this digital society to receive this benefit. What is worse is that the meteoric rise of digital society, devoid of any constraints, may accentuate these inequalities. In the world of data and algorithms, in exchange for the universal ease of access and a giddy fascination regarding the vast possibilities of processing large quantities of data, people may themselves give up their freedoms. The most fragile demographic will be the most vulnerable.

Today, reality is fortunately rather more discerning. Consequently, it is imperative that we identify the risks of digital society today so that we may combat them while maintaining all the benefits that it can bring for the service of the people. With the fascinating and breakneck progress of digital technologies, the clock is indeed ticking. While there is a law for bioethics, isn't now the time when we must strive to create a law for techno-ethics?

In 2001, the Vice-president of the Council of State, Mr. Renaud Denoix de Saint-Marc, wrote, "the law must be solemn, brief and permanent. *Today, it is indiscreet, precarious and banalised."* We must take inspiration from this declaration and further such a law.

For these reasons, faced with an emerging world of massive data operations, robots, algorithms and artificial intelligence in the field of medicine, the French National Board of Physicians is deliberating and does not wish to remain silent. It has expressed its considerations in this white paper and has provided answers in the form of recommendations.

This contribution from the French National Board of Physicians, albeit possibly imperfect, aims to hasten democratic discussions so that political decisions can be taken to maintain social harmony "in the Digital Republic of free and reasonable will," to paraphrase Emmanuel Kant.

Dr. Patrick Bouet

President of the French National Board of Physicians

Dr. Jacques Lucas

Vice-president of the French National Board of Physicians

Delegate-General for Digital Technology

Introduction

By Pr.Serge Uzan and Dr. Jacques Lucas

New avenues of progress opening up every day, limits that are becoming completely possible to overcome, and announcements more akin to the stock market than healthcare professionals, are leading an increasing number of doctors to wonder, and to express their perplexity regarding their fears about the developments they are not prepared for and that appear to be evading their grasp.

These questions are often the same:
> What kind of disruptive developments are we heading towards?
> Do these developments deliver on their potential?
> How do we develop the education received by doctors, or rather by multi-disciplinary teams of care providers, to face the challenges?
> What will remain of the unique relation between doctor and patient, and what must be preserved at all costs, and particularly, how?
> We must add: what are the thoughts and wants of patients, who are the most natural allies of doctors and care providers in this adventure into the future?

While we are already immersed in the transhumanistic world of 'progress', the question is often of knowing whether we are soon headed for a 'split' transhumanism, characterised by strong artificial intelligence (AI), also called the 'Singularity', and whether tomorrow we will adopt an augmentation approach instead of a regenerative approach to medicine.

The French National Board of Physicians has wanted to take stock of the current situation and the projected developments in the short and medium term, by trying to not give in to sensational announcements, some of which will not deliver on their potential for a long time. This presentation was already made during the most recent Convention of the Board, and attracted major interest, and several questions that this white paper intends to answer, at least in part.

Our intent is not at all to reject the progress resulting from artificial intelligence, but to

Transhumanism and medicine: the scope and words used

'Classic' humanism	Transhumanism for progress	Split transhumanism
Religion **Secular humanism**		**Eugenics / From luck to choice** **Selection / criteria?** **Bio-totalitarianism**
Human intelligence	**'weak' AI Algorithms**	**'Strong' AI Singularity**
	Robots	**Cyborg**
Regenerative medicine →		**Augmentation medicine**
Life span →	**Longer** →	**Longer and better**
80-100 years	**120 years**	**500 years!**
Science-fiction		**Return to the antediluvian period!**

identify new pathways for this progress through stakeholders who provide tangible proof every day of the reality that they predict. By meeting several stakeholders, who we have thanked in the epigraph, and from medical and scientific research fields, ranging from fundamental 'robot-assisted' surgery research to new epidemiology, and by conducting discussions with stakeholders in the field of training new doctors, as well as medical students' representatives and interns, we have strived to gather the signals from the coming world, while avoiding fantasies and especially by seeking ideas that may be useful for doctors and beneficial for patients.

It has been our ceaseless endeavour to analyse the information presented to us under the lens of ethics, deontology, and frankly, humanism, which characterises the function of a care provider.

It is clear that no robot will be able to react to the words that we constantly hear from our patients' mouths: "I'm hesitant", "I am afraid", "help me", and at times even: "what would you do if I were your mother, father, sister, brother, son or daughter?"

We think that human relations will always be an essential part of medicine, regardless of the speciality, and we can never be blindly dependent on the 'decisions' taken by algorithms, devoid of any nuances, compassion and empathy.

Moreover, nothing can replace a mutually decided transgression between the doctor and the patient, because it is his or her choice and also because this is the way the sciences and medicine make progress.We, as doctors, will never forget that an illness afflicts a person, and regardless of what type it is, it 'belongs' to the patient. We help the patient, using the professional skills we have acquired, to manage all the consequences of this illness. Naturally, it is also our duty to prevent its occurrence and our role in prediction and prevention is invaluable. Increasingly, doctors are becoming 'risk managers' who will manage patients' health proactively, which will increase their confidence.

"It has been our ceaseless endeavour to analyse the information presented to us under the lens of ethics, deontology, and frankly, humanism, which characterises the function of a care provider."

It must be clearly accepted that the 'medicine of the future' will be precision medicine (we prefer this term over personalised medicine, which has always characterised the doctor-patient relation) and participative medicine.

Algorithms and artificial intelligence will be our allies, like an essential support for helping in making decisions and outlining therapeutic strategies, which no doctor can refuse. They will also become essential instruments for what is known as 'reverse search'. Today, we can observe that based on the results of 'deep learning', we have obtained results that were hitherto unknown. Based on these results, a research is carried out that allows understanding these new observations, and this is what is called 'reverse search'.This allows making new discoveries that had not been possible till now by first creating a hypothesis and then carrying out prospective tests.

Similarly, social networks, particularly sites where patients exchange information, will at times allow transforming their layman's knowledge into useful health data.

There are two examples that allow illustrating this new type of research: highlighting the harmful facts related to certain therapies, and observing new syndromic associations.

The French National Board of Physicians shall do its part in the necessary developments in training future doctors on the path of artificial intelligence and simulation in learning, but first of all towards human and social sciences.

More than ever, the ethical approach and the expression of a supporting medical deontology during the educational curriculum need to be associated with scientific medical training based on proof.

As part of these objectives aimed at training doctors, it is imperative to take into account the fact that patients have become very important and active stakeholders in healthcare, and in the development of our knowledge:

- Their associations have played a decisive role in the accelerated treatment of certain illnesses, and AIDS is a clear example of this. And this is also the case for several chronic illnesses;
- Patients and their associations are capable of communicating 'health indicators' on their social networks, which we must learn to detect and interpret, if only to avoid major catastrophes related to the side effects of certain medicinal drugs;
- The patients can become a part of the healthcare link by becoming 'accompagnateurs' and 'partner patients' in medical schools;
- Patients can become stakeholders in medical research by transforming their knowledge, previously layman in nature, into research elements and execution of clinical trials.

"Respecting peoples' privacy is the very basis of the trust they have in doctors.

Therefore, this ethical requirement must be implemented in massive data processing operations when creating algorithms."

Through this document, the French National Board of Physicians would like to alert and provide support to the entire profession in its myriad practices: clinical doctors, researchers, epidemiologists, teachers, doctors working in companies and start-ups, and so on, concerning the indications that all of them must know how to observe, analyse and use, to varying degrees.

The French National Board of Physicians also wishes to strengthen its collaboration with patients and improve its expression of loyalty and humanism. The joint doctor-patient approach will allow them to share a mutual awareness.

In this world of massive data processing operations, the Board highlights the importance of the subject of protecting private health data, that is to say, the confidentiality under which this data is covered. "Science without conscience is the soul's perdition," said Rabelais, one of history's great physicians.We must constantly remind ourselves that respecting peoples' privacy is the very basis of the trust they have in doctors. Therefore, this ethical requirement must be implemented in massive data processing operations when creating algorithms.

We are aware that our analyses in the following pages may appear to be dry to readers pressed for time or superficial for novices. However, since the world of data, robots and artificial intelligence is complex, we have tried our best to make it accessible and formulate our public recommendations in the conclusion (refer to section 6).

1

TECHNOLOGICAL TRANSFORMATIONS, INNOVATIONS AND ‘REVOLUTIONS’: WHAT EXACTLY DOES THIS MEAN?

1. Medicine of the future is already here…
2. Artificial intelligence and algorithms
3. No AI without big data
4. Robotics
5. Man-machine interfaces and interaction

The news today is overflowing with increasingly spectacular information about progress, actual or alleged, in artificial intelligence, which has become the symbol of the ongoing digital transformation. Medicine and health are subjects regularly discussed in media headlines, showcasing progress made by dedicated researchers as well as the often fantastic potential of algorithms. This profusion of articles, speeches and publications are fuelling the expectations regarding the medicine of the future, which about a decade or so ago, was christened as 'P4 medicine' (personalised, preventive, predictive and participative), and with this, there are hopes of a longer life expectancy in good health. At the same time, there are also fears; first and foremost, fear of dehumanisation and an invisible stranglehold of leading international groups with financial interests on what would then become a 'healthcare market', in which organisations would solely target profits, if not complete domination.

Reality lies between the two extreme versions, the one portrayed by the enthusiastic and gushing media and this catastrophic scenario. That is why Cnom decided it was the right time to engage in calm discussion, based on reasoned caveats, regarding the approaches we take from today to prepare for the medicine of the future. This discussion is based on the knowledge of technological innovations being used today, and the ongoing or foreseeable developments.
This is the objective of the first chapter.

1 Medicine of the future is already here…

But it is not widely shared yet... The initial digital algorithms for assistance in diagnoses have been validated, surgeons are controlling robots while their anaesthetist colleagues are testing the impact of virtual reality on patients' anxiety ...The similarity with the transport sector - which is sharing the media coverage with the 'Watsonisation' of healthcare - is enlightening. The first autonomous vehicles are now circulating on our roads, the initial tests for unmanned aircraft are planned for 2018, but we still have a few years before we can rely on this technology for our daily travels. It is now time to adapt rules, skills, habits, infrastructures and economic models based on this development.

Medicine, as it was practiced till now, fortunately consists of a strong and large aspect of humanism, at the same time that the advances made in this field were the result of scientific thought in practice, with 'Evidence Based Medicine'. This is a part of the cultural heritage of doctors and that of society.

The precursors are well underway, but generally it takes about twenty years - at least - for progress to be truly widespread. Certainly, today we are seeing these delays reducing significantly, and everything will progress much faster than in the previous century. But what holds true for the technological aspect of progress is considerably less so when it comes to its social acceptability.

- **From the technological point of view**

The digital transformation of medicine and the vision for the medicine of the future cover a plethora of scientific and technical concepts and types of progress as varied as the processing, analysis and storage of healthcare data (commonly referred to as 'big data' and 'cloud'), algorithms, artificial intelligence and machine learning, genomics (and other 'omic' data), the Internet of Things or IoT, robotics, virtual reality, augmented reality, 3D printing, and so on. All of these may be included under the acronym NBIC – Nanotechnology, Biotechnology, Information Technology and Cognitive Sciences.

But the current tendency is to refer, at times indiscriminately, to the creation or emergence of any solution similar to the 'digital revolution' as artificial intelligence.

The emphasis on the urgency of taking action in France and in Europe, faced with American and Asian players who might be leaving us far behind, is becoming increasingly critical. However, this must not overshadowthe fact the France has its own strengths in the field of medicine, its researchers, engineers, industrialists and start-up owners. The examples here and in the following chapters[4] have been given as proof of this, and they illustrate the potential of the aforementioned technologies through concrete applications.

- A brief historical reminder

The interest of doctors in expert systems like assistance for diagnosis dates back to 1960-1970. The first solutions appeared during this period - Mycin and Internist in the United States, ADM in France – but did not succeed. At the end of the 1990s, the first tools that allowed sending alerts to doctors in case the health of their patients was aggravated were available, then they were clinically validated (like Diatelic for remote monitoring of dialysis patients).

At the beginning of the new millennium, patients themselves started enjoying the benefits of self-monitoring assistance software (like Diabeo[5]).

However, in the past decade, everything has changed in scale: the calculation and storage capabilities of computers have increased exponentially, facilitating the analysis and accumulation of digital information, while the types of sensors have increased, allowing taking all kinds of readings and opening the path for the development of m-health (or mobile health) regarding which the Cnom published a white paper in January 2015[6].

2. To paraphrase William Gibson: "The future is already here, but it is shared unequally."
3. A neologism referring to the artificial intelligence computer program developed by IBM: Watson
4. These examples are just illustrations of our topic. There are certainly more of them. In no event can the citations in this document be considered as approval or endorsement from the Board.
5. The system has since evolved and benefitted from a favourable opinion of the HAS for treatment through Medical Insurance
6. https://www.conseil-national.medecin.fr/sites/default/files/medecins-sante-connectee.pdf

2 AI and algorithms

Euclid and Al-Khwarizmi up to the 'cathedrals' of today... At the same time,AI technologies have taken advantage of the progress made by 'machine learning' as highlighted by the OPECST report on AI[7].

Discoveries in the field of deep learning date back to the 1980s, boosted by the use of neural networks (that were conceived since the 1940s). Machine learning experienced "*unprecedented growth in the 2010s, with the emergence of big data and the acceleration of processor computing speeds.*"

Artificial intelligence is based on the use of algorithms. Euclid, the mathematician, had already "*invented a method for calculating the largest common denominator of two integers in the year 300 B.C.,*" while Al-Khwarizmi can lay claim to the term algorithm which is derived from his name; but "*the complexity of certain recent algorithms is such that they may be compared to cathedrals,*" note the OPECST reporters. They also specifically state that behind the concept of artificial intelligence, created about sixty years ago, there are "*highly varied technologies, in a constant state of evolution, which give rise to specific application for tasks that are already highly specialised."*

The academic table of AI domains contains five of these: natural language processing, vision (or signal processing), machine learning, multi-agent systems, and robotics.

In fact, the applications of AI are already omnipresent in our daily lives, for example, helping us park our cars, translate a letter or verbally ask a question to a search engine. But they remain 'single-task'. Thus, the AIs that regularly achieve impressive feats like beating champions at the game of go or chess are trained to do this one single task, and cannot do anything else.

Therefore, they are classified under weak AI (or ANI - Artificial Narrow Intelligence), compared to a general AI, or strong AI (AGI - Artificial General Intelligence), which would be capable of solving various problems, just like a person... or even a 'Super AI' (ASI) with capabilities superior to those of a human. This ASI would represent a point of divergence, the famous 'singularity[8]', predicted in particular by the transhumanists, and regarding which a few of the leading and eminent personalities of the world are regularly issuing warnings.

Yet, for most researchers[9], artificial intelligence is a scientific discipline "*the methods of which are explained and discussed in the researchers' community, and the results are validated through rigorous experiments*."

"The complexity of certain recent algorithms is such that they can be compared to cathedrals."

The terminology used results in ambiguity and confusion with "*myths anchored in human imagination since the dawn of time*[10]*"*and with artificial intelligence in the context of science fiction.

For numerous observers and experts, the subject is so trite that it is bordering on fantasy; others are calling for a stop to this phenomenon of 'AI washing' (which involves highlighting any announcement by passing it off as an AI innovation) because there is a risk of creating a divide between public expectations and reality.

The term cognitive informatics would undoubtedly more accurately reflect the current progress of what is known as AI. Or even machine intelligence, as stated in a recent debate[11]during which psychoanalyst Serge Tisseron focussed on the risk of idealisation and the necessity of demystifying artificial intelligence: *"We are prisoners of certain words that we use daily and that create confusion between how we look at machines and how we look at people."*

7. Parliamentary office for assessment of scientific and technological choices. 'Towards controlled, useful and demystified artificial intelligence', March 2017
8. 'The myth of the singularity', Jean-Gabriel Ganascia
9. Tel Jean-Gabriel Ganascia, refer to "Artificial intelligence, towards a scheduled domination?" p. 35
10. Id.
11. Innorobo trade show, 17 May 2017

3 No AI without big data

Along with learning algorithms, big data forms the second pillar of current artificial intelligence technologies. Machine learning and deep learning techniques have more chances of giving results if they have an ample supply of 'data', and naturally, powerful computing resources, since this involves classifying, recognising, comparing, and lastly, learning and modelling algorithms and harnessing the potential of this data.

In view of the fact that data is an essential asset for the development of AI, the French Digital Council has even declared that "the value created by artificial intelligence originates from the data necessary for the learning process even more than the algorithms, which are developed in an open source environment[12]." Therefore, it is essential to control the data (refer to chap. 6).

That being said, the term big data, even though it is widely used today, has not always had a precise and stable definition[13]. It actually describes both, the characteristics of the data (volume, variety, speed) and the techniques used to process it.

In the healthcare sector, the sources of this data are particularly numerous and varied (summarised below) and a majority of these sources have the particular feature of being directly or indirectly identifying, which means that they require peoples' consent and secure computer systems.

The potential uses of big data appear to be considerable, and healthcare is one of the sectors most frequently cited by studies and reports dedicated to big data: ranging from vigilance research (pharmacovigilance, health monitoring), to the development of treatment proposal management tools or solutions for optimisation of the patient-doctor relationship. But the risks and limits related to these uses also appear to be significant, which explains their slow growth and expansion.

At University hospitals, pioneers in this field, with millions of digitalised patient records, data warehouses facilitating the creation of categories and translational research have been recently created.

Sources of health data

- **medico-administrative data generated by Health Insurance (Sniiram[14]) and hospitals (PMSI[15]);**
- **data in medical records, in hospitals and town halls;**
- **the data held by public or private stakeholders gathered from patients (clinical trials particularly) or healthcare professionals;**
- **data generated through smart devices, mobile applications, websites and search engines;**
- **socio-economic, geographic, environmental, and other types of contextual data.**

While the application of big data in genomics has not played a big part in research and treatment methods, the launch of the French Plan for Genomic Medicine 2025 has planned, from now till 2020, the deployment of a network of 12 ultra-high bandwidth sequencing platforms. The two pilot platforms were just selected and are expected to be functional at the end of 2018. This Plan has also announced the creation of a national intensive computing centre[16] capable of processing and using the volumes of data that will be generated by the platforms, and offer in-silico analyses and decision-making support tools.

As regards the SNDS medico-administrative database (National Health Data System[17]), resulting from the law of January 2016 regarding the modernisation of the healthcare system[18], the governance and terms of access have recently been finalised.

Big data in healthcare - will it deliver on its promises?

For several stakeholders, big data has the particular advantage of reshuffling research and epidemiology methods, and "*has the ambition to update new scientific realities*"(refer to chap. 4).

Let us also add that there is also a consensus that its benefits will exceed the risks, as demonstrated in the conference organised by the Ministry of Health in July 2016.

> 12
> **Ultra-high bandwidth** sequencing platforms planned in France from now to 2020.

The phenomenon is still in a nascent stage, since data creation is undergoing an exponential increase as a result of the multiplication of smart devices and onboard functionalities in smartphones. The simple geolocation feature can provide information that can be used in healthcare.

12. National AI strategy, France work group Strategy, March 2017
13. As noted in the Big Data in healthcare conference organised by the Ministry of Health on 4 July 2016
14. National Health Insurance Cross-Schemes Information System
15. Programme for medicalisation of computer systems
16. CAD or Data Collector-Analyser
17. https://www.snds.gouv.fr/SNDS/Accueil
18. Law no. 2016-41 dated 26 January 2016

4 Robotics

It most often symbolises the applications of AI in the eyes of the public. Robot-machines have the advantage of making the immaterial material, to bestow it with a physical representation.

In medicine, robotics is largely synonymous with surgery owing to the media coverage given to minimally invasive techniques, which have allowed the development of outpatient surgeries.

these famous 'robot surgeons' are in fact controlled by humans, offering increased precision and dexterity. Surgical robots, which are dominating the international market today, have been deployed in more than 80 instances in France (3000 across the world). They were invented in America.

But the French are not to be outdone, and have pushed the limits of surgery by implementing robotics in new medical disciplines.There are a few examples of this in a variety of domains:

performing remote ultrasounds (the robot in question was onboard the international space station), manipulating catheters during angioplasties while avoiding exposure to X rays, or even automating Transcranial Magnetic stimulation (TMS)...

Then there is the fact that an engineer from Montpellier designed a type of navigation robot for neurosurgeons (read below): this robot was used in about thirty hospitals across all continents before it passed under the control of an American equipment manufacturer. Another example is the Grenoble neuro-stereotaxy procedure for Parkinson's disease.

Today, digital imaging technologies are contributing to the emergence of custom surgery: they help the surgeon plan his or her operating strategy, to prepare by practicing the movements using a 3D model or a virtual clone of the organ to be operated upon (refer to chap. II).

- **Home automation**

There is an upturn in interest in home automation, owing to its potential in providing support for the treatment of vulnerable patients.

More than 100 French geriatric nursing institutions have adopted 'social robots'.

Noting that their deployment is gaining momentum (more than 100 French geriatric nursing institutions have adopted 'social robots' to limit the loss of autonomy and isolation for the elderly), while there are still no guidelines and references for good practices to use these robots correctly, the Gérontopôle of Île-de-France (Gérond'if) has carried out an in-depth study[19] over two years to analyse and understand the impact of social robots in all their aspects: clinical, organisational, economic, social, ethical, etc.

In certain retirement homes, they have already been entrusted with an organisational role, or as programmed coaches to encourage the residents to perform physical exercises or sing. Moreover, we are also seeing them used for support in helping elderly and weak persons move, instead of a wheelchair. Most often, we rely on them to help people as regards cognitive function and communication: this is illustrated by the case of a Japanese robot seal, covered with fur, which started becoming famous across the world, and was even certified as a therapeutic device in the United States.

However, all these systems are yet to prove their worth. "*We would like go far beyond the level the progress that is possible to achieve today,*" admitted Rodolphe Gelin[21], a robotics technician."Being able to detect falls, for example! But for this, we need a much higher level of artificial intelligence and learning for the robot."

"Do the patients need it?"

Bertin Nahum is continuing to explore the potential of minimally invasive robotics by creating a new company. He claims to be convinced [20] that the trend towards robotisation "*is impelled by patients' needs, which include better medical techniques. They are the biggest promoters of these new technologies. Like a number of doctors, they no longer wish to accept surgical errors and 'traditional' practices."* This angle has at times not been understood by doctors who remain convinced, and rightly so, that they do the best they can with the resources and equipment they have.

While Laurence Devillers[22], a researcher specialising in affective and social human-robot interactions (and convinced that we have to co-evolve with robots), recommends that "*we should address the fundamental ethical questions before designing and using social robots*" (refer to chap. 5).

19. Rosie (Social Robots and experiments in geriatrics), directed by P[r] Anne-Sophie Rigaud, head of the Geriatrics Centre in Broca (GH Paris Centre) and renowned for her works and publications in this domain.
https://www.gerondif.org/gerontechnologie
20. In an interview given to *The Tribune*, 25 September 2016.
25 September 2016 21 Co-author with Olivier Guilhem of: = Le robot est-ill'avenir de l'homme ? », Doc' enPoche, French documents, 2016
22. Author of:"Des robots et des hommes", Plon, March 2017
23. At the Centre of Interdisciplinary Investigation in Sciences and Humanities of the Paul-Valéry University, in Montpellier
24. The letter from the psychiatrist, January 2016

Human-robot interaction

RittaBaddoura, a doctor of psycho-analytical studies[23], is studying human-robot interaction (the subject of her thesis). Following a literature review[24], she regrets that a majority of the studies "*focus on the development of robotics rather than on the measurement and analysis of its psychological and mental impacts,*" but she observes that social robots have a therapeutic potential, "*particularly for patients with Alzheimer's disease or problems on the autistic spectrum.*"

5 Man-machine interfaces and interaction (MMI)

They are in a constant state of flux. Voice recognition, then gesture and facial recognition, virtual, augmented, or mixed reality headsets, smart glasses, and other technologies and devices are enjoying regular progress and are indeed having an impact on the adoption of innovations.

Tomorrow, will a simple thought be sufficient to send a command or ask a question to a search engine?

Will facial recognition technology be sufficiently reliable for detecting certain illnesses? A team of geneticists from the National Human Genome Research Institute in the United States recently tested this successfully to detect a rare genetic disease. While prototype brain-computer interfaces have been available for several years, they are in the experimental phase.

It appears that the keyboard and mouse shall still dominate our interactions with computers for a while, even if they are facing stern competition

from smartphone touch-screens... and we must consider the possibility that they may soon be supplanted by voice assistantsThese new communication tools are also targeted at being integrated with our homes.

Today, we are witnessing conversational agents return to the forefront, under the name of 'chatbot', fifty years after its precursor, Eliza, which simulated a psychotherapist. Thanks to the progress made by natural language processing systems, these software bots are developed primarily for commercial purposes, like customer support. They are now drawing the attention of the field of healthcare and doctors. They may well be called 'conversational', but the resources of these virtual assistants are generally limited to the databases they have access to and so the dialogue tends to be cut short if a question outside their scope of competency is asked. That does not mean we will not soon see them overtake mobile applications if their capability of offering more user-friendly and efficient interfaces is proven, and also if they are able to benefit from machine learning technologies.

The first specimens already exist in France: 'learned' coaches for sending personalised information and advice depending on the user profile, and even for supporting the user in his or her endeavours (physical activities, nutrition, quitting smoking, etc.). In the United States, conversational agents are used more in the field of mental health. In China, the local search engine (Bai-du) has launched the first chatbot that allows setting appointments with a doctor or asking him or her questions, before moving on to the next step, where the software robot assistant helps the doctor with the diagnosis.

"The resources of these virtual assistants are generally limited to the databases they have access to and so the dialogue tends to be cut short if a question outside their scope of competency is asked."

2

PRACTICING MEDICINE IN THE DIGITAL ERA

1. Dream? Nightmare? An issue in any case
2. The tools of ‘augmented’ future medicine
3. AI Doctor or Doctor + AI?
4. Modelled patient
5. Digital therapies
6. Increased inter-professional collaboration

1 Dream? Nightmare? An issue in any case

A dream for some, nightmare for others, does the following scenario portray a fiction or one of the issues for the medicine of the future?

Like he does every morning, Dr François connects to his virtual assistant, Galiena. Over the past 24 hours, the machine has gathered and analysed the data of all patients who currently need following-up: their communications and requests for appointments through email, telephone, or SMS, their biological examination results and imaging, and of course, all the physiological readings taken by the sensors. The software has worked through the night and is ready to deliver its results.

"What are the priorities for today Galiena?" asks the doctor. The assistant powers-on the electronic screen where the schedule for visits, consultations and teleconsultations is displayed, prepared using the data processing algorithms and the data from the contextual patients' database, the most recent indicators received and the updated scientific library.

Dr François opens each text bubble in turn, which provides him with the nature of each intervention scheduled by the digital assistant, he examines them carefully and makes modifications to the schedule as he sees fit.

Ms. Nicole's treatment needs to be modified substantially and he would prefer seeing her in person to assess whether she is following the new therapeutic education program, rather than set-up the teleconsultation scheduled by Galiena. He will also go to see Mr. Simon, who is still not doing so well with his sleep apnoea mask. But he replaces Mr. Guy's weekly consultation with a simple chat over the course of which he plans to send him some documents, which he asks the assistant to gather on its wiki.

This will allow him more time to examine this young patient who has come to his clinic for the first time.

Galiena reworks the schedule in a few seconds. The database is updated as per the instructions given by the doctor. The search engine initiates the requests to obtain data for Dr François' knowledge database with the summaries of the latest publications regarding the pathologies and treatments of his patients.

Galiena informs him that she has reserved his spot for the 5th E-health Research Conference for the next week. She has also placed the half-yearly order for medical material.

In some aspects, we are not that far from the most basic functionalities and services mentioned above. The incessant progress of information technology, applied to medical practice, has allowed gradually extending the scope of e-management (or electronic management) of medicine over the past 50 years. On the other hand, the emergence of digital medicine or 'NBIC medicine', born from the convergence of nano-technology, biotechnology, information technology, and cognitive sciences, is more recent.

In this breakneck technological maelstrom, we – or the Board in any case - must work towards successfully organising and ensuring the complementarity between man and machine, where the former retains the ethical capability of always having the final say.

2 The tools of ‘augmented’ future medicine

Exploring the avenues currently taken by R&D and observingthe emergence of new practices, which are today limited(even confidential) but which should expand, provides pathways for identifying the medical practice of the future.
Here are a few examples of the Doctor-AI collaboration in using virtual reality and augmented reality technologies and ‘serious games’, including simulations on virtual avatars of modelled patients.

Moreover, innovations and evaluations are continuing as regards computer systems and smart health systems, which portends a greater ease of adoption of digital tools in the context of patient-professional relations and inter-professional collaborations.

3 AI Doctor or Doctor + AI?

Automation of screening and diagnoses? Even though they have existed for about fifty years, computer systems for diagnosis and medical decisions assistance have seen their use halted for reasons that are scientific, sociological and technological. Technological frontiers have now been pushed forward... apparently without any limits (refer to chap. 1). There have been scientific studies and publications since then which compare the respective performances of doctors and algorithms in their diagnosis abilities.

The current issue involves establishing the best possible alliance between man and machine (Doctor + AI), to ‘augment’ the potential of medicine thanks to technology.

Artificial intelligence is actually capable of working considerably faster and with infinitely larger data volumes, but only for a precise task which is well defined, however the human brain still retains its supremacy when it comes to reasoning, analysing one’s environment, and communicating.

- **The doctor-AI ‘rivalry’**

It most often involves imaging data. At the end of 2016, the JAMA published a study concerning a test on a machine learning algorithm for detection of diabetic retinopathies... approved by engineers from Google. After having been taught to recognise afflicted eyes from a database of 1,28,000 images, the algorithm made a correct diagnosis with results comparable to those obtained by well-trained ophthalmologists.
A few months later, the magazine Nature covered the results of an American team on its cover, which succeeded in making an algorithm as effective as an effective dermatologist to distinguish between beauty marks and melanoma,

after having trained the algorithm using a databank of more than 1,00,000 images of cutaneous lesions associated with about 2,000 pathologies.

Though the gauntlet has been thrown by a symptom analysis platform, doctors still remain twice as capable of straightway reaching the correct diagnosis, according to a study carried out in Harvard Medical School[25]. The researchers also noted that the difference between human and software performance is less significant when the illnesses or conditions are well-known, while doctors perform better when the symptoms are less common and severe. Knowing that humans are, however, likely to make errors (in 15% of the cases), scientists have concluded that... professionals would improve their performance even more if they were complemented by algorithms. CQFD.

While the prowess of digital giants like Google (with Deep Mind) and IBM (known for its investments in the AI Watson, in the field of oncology particularly) is regularly in the spotlight, they must not overshadow the research and development efforts of a large number of new companies (even the 'old' companies in the health sector!). And not only in Silicon Valley.

- **And start-ups?**

In France, an increasing number of start-ups are exploring the potential of AI in medicine; most often, they focus on projects by doctors, IT engineers and engineers, or forge very intimate links with clinical research centres located in hospitals.

Thus, a new company[26] based on neuroimaging platform Cati[27] is aiming to use artificial intelligence to help in diagnosis, predicting clinical evaluations, and measuring the effectiveness of the treatments for central nervous system afflictions. It has currently deployed a prototype tool in hospitals, which allows the radiologists and neurologists to refine their diagnosis from the beginning of the illness: it uses the patient's MRI data to automatically measure the biomarkers, which constitute parameters that are then compared with the information from the hospital databases.

A second tool, currently in the development phase, is intended to predict the patient's progress.

Another start-up, which was started at the Institut de la vision[28], has developed an automated diagnosis solution for diabetic retinopathy using a deep learning algorithm trained using a sample of one million images. It plans to make it available in the future to detect other eye conditions and is also working on a new algorithm, and plans to explain the mechanisms used by its mathematical model to reach a certain diagnosis.

In the Necker hospital, doctors are beginning to use a reasoning engine created by a fledgling Parisian start-up [29] to improve the monitoring of patients afflicted with chronic renal failure. The solution works on a principle similar to that of IBM Watson.

For ECG analyses, a cardiologist and two polytechnic graduates combined their efforts to develop an AI based on neural networks[30], which was just approved by the Food and Drug Administration (FDA). Trained using a database of more than 5,00,000 ECGs, this AI's role is to assist doctors in detecting atrial fibrillation and other arrhythmias.

In Bordeaux, a young public medicine student from the University Hospital, who is a researcher at Inserm and the holder of a master's degree in information technology, is putting the finishing touches on a virtual assistant for prescription: "*Our aim is to create tools that integrate all sources of information on medical drugs (recommendations from scholarly associations, reports, scientific articles, etc.) that are traceable and updated,"* he recently stated to Le Monde[31].

There are countless examples of researchers, doctors, mathematicians and IT engineers... who are today working tirelessly to design the new generation of medical decision-making assistance tools. Though it is difficult to predict the timeline when they will actually be available for regular use. The examples we have given are just a simple illustration of our subject.

- **Evaluation, training**

In July 2017, American cardiologist and futurist Eric Topol[32] summarised the current progress and limitations of AI in the field of diagnostics in the Lancet[33]. *"Imagine a person communicating with a virtual doctor,"* he wrote, describing the capabilities of future applications to make diagnoses based solely on a voice, a video recording, or photos... *"Healthcare professionals will remain at the core of medical treatment,"* he declared. "*AI will improve their diagnosis capabilities by helping them save the time required for tedious observation of images."*

"*There are several obstacles slowing down the adoption of AI,"* he continued. "*The first one is the availability of data necessary for the deep learning algorithms and the collection of the necessary volume of images validated by specialists in each specific pathology. [...] We will then need to carry out clinical trials to assess the effectiveness of diagnoses made by learning algorithms."* Not to forget "*for this revolution to be successful, to train future professionals in the basis of machine learning"* if we wish for them to effectively integrate these technologies into their practice.
Lastly, "*AI is not even close to replacing doctors any time soon,"* adds Eric Topol, insofar as it does not have the capability of providing explanations for the causes of what it observes.

"In the years to come, however, AI may become an indefatigable and profitable partner for doctors by allowing them more time to focus on the complexity of each patient through individual treatment."

25. Published in December 2016: https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2565684
26. Qynapse
27. The centre for collection and processing of images (Cati) for Alzheimer's disease relies on the networking of about fifty MRI and PET machines throughout France.
28. DreamUp Vision
29. Khresterion
30. Cardiologs 31. Edition dated 8 May 2017
31. Edition dated 8 May 2017
32. Author of The Patient Will See You Now: The Future of Medicine Is in Your Hands, in 2015 and The Creative Destruction of Medicine: How the Digital Revolution Will Create Better Health Care, in 2012
33. With his colleagues from the Scripps Translational Science Institute http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2817%2931764-6/fulltext

4 Modelled patient

Personalised interventions using the patient's digital twin? With the progress made in robotics, surgeons first received the benefit of assisted surgical movements, since the 2000s.

Today, it is the progress made in imaging that is the source of the most radical transformation in surgical practices.

And 3D printing is already pushing the limits even further.

- **Digital imaging technologies**

They have contributed to the creation of personalised surgery, where each patient will have a virtual avatar created, a 'digital twin'. By facilitating the modelling of organs in three dimensions, they help the surgeon plan the operating strategy and prepare by practicing the movements using a 3D model or virtual clone of the organ.

Soon, the combination of 3D technology, robotics and augmented reality will allow modifying this strategy in real time, if needed.

These developments owe a lot to the works carried out in the Institute for Research into Cancers of the Digestive System (Ircad), created in 1994 by P[r] Jacques Marescaux and now closely associated with the Institute of Image-Guided Surgery (ICI) of the IHU Strasbourg (refer to p. 26 for a verbatim quote from P[r]Marescaux). They are also based on the research carried out by Nicolas Ayache and his team at the Inria.

Since then, a *spin-off* company of the Ircad[34] has been created, offering an online 3D modelling and cartography service based on scanner or MRI images.

Digestive surgery pioneered the use of augmented reality and the 2016 conference of the Association française de chirurgie (French Association of Surgery or AFC) counted about 150 interventions of this type in three years, placing France among the leading players in the world in this domain.

The main improvement approaches have already been explored, particularly the integration of organ deformation in the models and the development of a global standard for surgical videos to overcome the problems of interoperability of imaging equipment, which were hindering the development of hybrid surgery.
Hybrid operating rooms are starting to appear almost everywhere in France. But there aren't many platforms as of now that combine healthcare and research like the IHU Strasbourg or even Ther-A Image, inaugurated in 2013 in Rennes, with the purpose of combining the equipment and competencies of the Signal and Image Processing Laboratory of the University Hospital (University-Inserm) and of the medical industry to explore new approaches in the cardio-vascular domain.

Medical imaging for the digital patient

Considered as the pioneer in research on automated analysis of medical images and creation of personalised digital models of patients, Nicolas Ayache held the chair of Information Technology and Digital Sciences at the Collège de France, where his inaugural lecture in April 2014 was about the evolution 'of medical images for the digital patient'.
He then explained: "Preparatory images are used to create a personalised digital model of the patient, which allows planning and simulating interventions using virtual reality software. This would allow, for example, simulating the surgical movements involved in a laparoscopy on a virtual liver using visual and haptic force feedback, or training for an embolisation or an endovascular aneurysm, or even for training the surgeon to perform highly delicate eye cataract surgeries. During the intervention, which may be robot-assisted, the preparatory images are combined with the pre-operative images using *augmented reality* software. This allows virtually rendering the patient transparent, and helps the practitioner (surgeon, endoscopic surgeon, or radiologist) to adjust his instruments inside the patient's body."
This future avenue opened by the IHU Strasbourg is an example of this '*computational medicine of the future*'according to the researcher.

Medical imaging and breakthroughs in modelling have also opened up the path to assisted surgery, for which the technology is continuously being perfected.

- **Summary of these developments**

Facilitated complex interventions, with more accurate, safer, and less invasive technical movements, reduced post-operational complications and pains, and so on. The surgical team is always present, but in a completely different capacity than in a more traditional surgical procedure, even if the team still retains all its skills.

Latest ongoing revolution: 3D printing of customised healthcare devices, which several French teams have already used in the past five years, particularly for maxillofacial surgery.

The development of a modelled or virtual patient does not only concern surgical movements or interventional radiology, it also naturally impacts training (refer to chap. 3) and clinical research (refer to chap 4).

34. Visible Patient

5 Digital therapies

Serious games is the most recent arrow in the quiver of therapy. From among the ongoing clinical trials in Nice, P[r] Philippe Robert, coordinator at the Memory Resources & Research Centre (CMRR) of the CHU, is a pioneer in the design of 'serious games' intended to stimulate people suffering from cognitive impairment at a very basic level. One of these games [35] is today recognised as a healthcare device (class 1): it places the patient in control of a sub-marine and trains him in a naval battle, where he needs to use his cognitive and physical skills. There is also the advantage of facilitating the measurement of the progress of the pathology and maintaining the social connection by fostering interactions between the players and the therapist. It is already a true complement to traditional treatments.

"*Video games will never cure Alzheimer's disease,"* warns P[r] Robert.*"But they can have a major impact by improving autonomy in certain activities of daily life, and the quality of life."*

The company that developed the game [36] works in a joint laboratory (Brain e-Novation) with The French Brain and Spinal Institute (ICM) for developing 'digital therapies of the future'. It is in the process of carrying out several clinical studies, for example, for a game targeted at rehabilitating an upper limb for stroke victims and another which reduces problems in walking and balance for patients suffering from Parkinson's disease. Serious games in the field of health are still most often limited to providing information and raising awareness about prevention. They can also help the patient manage his or her illness in their daily lives... and enjoy themselves while doing it. The case of diabetes is a great example, where the number of proposals for programs, particularly for children and adolescents, has been greatly increasing.

Video games have started investing in the field of therapeutic education.

Learning while having fun or being encouraged by winning a match are effectively a major motivation factor for the patient.

These digital media certainly play a role in the treatment of patients, especially chronic patients. However - and this is the same limitation that applies to mobile health applications - professionals are unwilling to integrate serious games in their practice if their contents and effectiveness are not validated by the medical and scientific community.

- **Treatment through virtual reality**

Researchers have shown interest in virtual reality since the 1990s to treat patients with various phobias. In the United States for example, it was used to help veterans deal with Post Traumatic Stress Disorder.

Then, the headsets used to be rudimentary and particularly expensive. The explosion of the video game market has helped this type of equipment to become more accessible and enter the domain of hospital services.

In the currently recognised applications, by mobilising the brain 'in another world', immersion in a virtual reality scenario allows reducing (or completely eliminating) pain in chronic patients, and also in case of major burns or post-operative pain. Better: it is even used instead of anaesthesia in some cases.

It is also used to combat addictions and problematic food habits.

After having adopted hypnosis techniques, the head of the Emergency Service of the GroupeHospitalier Saint-Joseph in Paris decided to try a virtual reality headset as an alternative to the traditional pain management techniques for patients who were ready to try it. He plans to assess this practice in the coming months.

In the Hôpital de La Conception, at the Assistance publique-Hôpitaux de Marseille (AP-HM), the psychiatry centre is currently coordinating several studies on the effectiveness of virtual reality: in smoking de-addiction, claustrophobia and acrophobia (fear of heights), and in optimisation of relaxation in chronic anxiety patients.

Over a period of four years, DrÉricMalbos, a psychiatrist working in this division, has treated approximately 700 patients and the results have varied depending on the problems treated: *"We have observed an effectiveness rate of 80 to 90% in curing phobias, 50% of smokers did not relapse, and we observed an approximately 80% remission rate in case of post-traumatic stress,"* he declared in November 2016[37].

35. X-Torp
36. Genious 37. As part of an Arte channel documentary http://sites.arte.tv/futuremag/fr/cesmedecins-qui-soignent-grace-la-realite-virtuellefuturemag

Possibility of surgery using virtual reality in the operating theatre

Removing a brain tumour from an alert patient immersed in a virtual reality using 3D goggles: this was done for the first time in the world in January 2016 at the CHU Angers as part of a research project called Cervo (Surgery on fully conscious patient using virtual reality in the operating theatre), carried out together with the laboratory Interactions numériques santé handicap (INSH) of the ESIEA (School of Engineering). By allowing the patient to interact with utmost precision with the surgeon, the implementation of virtual reality in fully-conscious surgery has ensured even better precision of actions and has allowed performing interventions which were impossible till now.

6 Increased inter-professional collaboration

Innovations and evaluations are continuing as regards computer systems and smart health systems, which portends a greater ease of adoption of digital tools in the context of patient-professional relations and inter-professional collaborations.

- **Development of smart health**

This topic was covered in a white paper and recommendations by the Cnom in January 2015. Since then, we have observed that the progress has been modest in terms of mobile health applications, which are generally too information-intensive and not sufficiently transparent regarding the processing of collected data. At least, the developers (and testers) now have a new standard for good practices created by the HAS[38], which will soon be followed by the publication of guides intended for users, healthcare professionals, and the public; while the specifications of a public approval are most likely being defined[39].

However, we are observing in particular that the use of algorithms for interpretation of the results and remote monitoring may start being subject to scientific validation.

For example, this is true in case of self-administered blood pressure tests[40], support for treatment of type 1[41] diabetes, monitoring the complications resulting from lung cancer[42] (see below for verbatim quote from D[r] Fabrice Denis).

Knowing that every doctor will someday inevitably be faced with the question, "Doctor, do you know this app?", the French National Board of Physicians continues to encourage professional organisations and academic societies to voice their opinions on the scientific quality of applications and the

"In twenty years, it will be impossible to differentiate between the patient and his digital clone."

"When we compare the evolution of operating theatres, even those at the bleeding-edge of technology, with an aircraft cockpit, we can see that the former is still in the pre-historic era. The most important changes are the inclusion of imaging, with the possibility of planning before and during the operation, and the capability of a transparent view thanks to augmented reality. While this is not regulated today, it will be in the coming decade. And in twenty years, it will be impossible to differentiate between the patient and his digital clone. In the coming three years, there will be at least four, or even five, surgical robots on the market, integrating artificial intelligence and augmentation of the surgeon's vision.

When we talk of minimally invasive surgery, we must not forget the progress made by other specialities, like interventional gastro-enterology, which will largely benefit from the progress made in endoluminal surgery or percutaneous surgery. This then poses the question of training the surgeons.

From the moment we have tools to show that we have simulated and prepared for the intervention using the patient's own data, it is natural that this will become mandatory and will be considered a guarantee of quality.

We can also anticipate the impact that artificial intelligence will have on the doctor-patient relation. The day when a patient provides his data to an AI, which will tell him what to do after analysing 1,50,000 international articles, the former can inform his surgeon that he does not wish to get operated, but would rather prefer radiofrequency ablation, for example."

Pr Jacques Marescaux
Founder-Chairman of the Ircad

benefit of their contents in the treatment of patients[43].

As for healthcare professionals and establishments, which are now aware that the home is now necessarily a part of the treatment, they are clearly adopting digital support strategies for patients (refer to chap 5).

- **Computer systems**

As regards computer systems, public commitment and support programs like Hôpitalnumérique, MessagerieSécurisée Santé or Territoire de SoinsNumérique (TSN) are starting to bear fruit by contributing towards providing professionals with solutions that facilitate collaborations and coordination. For example, TSN is also an example of the benefit in investing in an organisational innovation and not just technological.

38. https://www.has-sante.fr/portail/jcms/ c_2682685/fr/applis-sante-la-has-etablit-101 regles-de-bonne-pratique

39. Following the conclusions of the work group 28 (GT28) of CSF Santé. http://solidarites-sante.gouv fr/IMG/pdf/rapport-gt28-octobre-2016-vf-full.pdf

40. Using the software Hy-Result

41. Using the Diabeo solution that is eligible for reimbursement

42. Using Moovcare

43. French Medical Association Gazette, July-August 2017

"The use of algorithms for interpretation of results and remote monitoring may start being subject to scientific validation."

"We are trying to develop early detection in healthy people"

"The objective of the applications on which I work is to help the patient - who is involved in his own treatment - and to improve communication between the patient and doctors. I don't know what to call them; in the United States, the term used is Patient Reported Outcome (PRO). An initial application is based on the idea of detecting relapses of lung cancer from the very first symptoms, by monitoring the victim, i.e. the patient, rather than monitoring the images of the tumour development. It took us six years to progress from the idea to the clinical trial result. We have participated in prospective studies to find an algorithm to analyse all symptoms that patients need to report after every week of treatment, in short, the actual medical semiology, the criteria identified by monitoring several dozens of patients, analysing the development of the symptoms, and by correlating them with the images. We were able to create a sort of decision tree, an algorithm which has achieved a relapse detection sensitivity rate of almost 100% with relapses being detected 5 to 6 weeks earlier than scans that were taken every 3 months. Results: we are improving chances of survival and the quality of life. There are other studies in progress, about ten of them, randomised or otherwise, dealing with breast cancer, prostate cancer, lymphoma and renal cancer. We are trying to develop early detection in healthy people (for example, in case of smokers to screen COPD earlier). The clinical evaluation poses a question. Do we need randomised tests at all costs? One may think that it is not ethical to carry out randomised tests for these algorithms because we are just going to demonstrate what we all learn in medicine: the clinical aspect is important, the patients need monitoring. Would single-arm trials, which assess patients' compliance, sensitivities, specificities, comparisons with corrected historical series or large volumes of data be pertinent?Do we need specific evaluation committees, like it is currently the case in the United States?"

Dr Fabrice Denis,
Oncologist at the Victor-Hugo clinic, Le Mans and Chairman of the National Union of Radiologists-Oncologists

3

WHAT TYPE OF TRAINING FOR MEDICAL STUDENTS AND DOCTORS

1. Cnom and the Committee of Deans of Medicine: a shared vision
2. The issues
3. Training using digital technology
4. Training in digital technology
5. Focus on the Uness

The training provided to medical students and doctors represents a key element in the acceptability of the technologies and practices that are going to be developed and spread.*It requires anticipating the overview of the respective places that will be occupied by doctors, other healthcare professions, and medico-technical tools. Without underestimating the undoubted transformative power of advancements in science and technology, we would like to emphasise the core principle of any such action: machines must serve man, not enslave him.* This will justify an open and permanent vigilance regarding human progress, by identifying and combating the risks, and supporting the advantages of this 'new world'

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Training, i.e. teaching and instructing students throughout their studies and medical practice, requires anticipating an environment where 'artificial intelligences' will act as partners for doctors and care providers; these will improve their performance levels. And it also involves confirming what humans have already achieved compared to machines, and particularly the ability to empathise and be creative, or even committing a 'transgression', insists P[r] Serge Uzan, Vice-President of Health, Université Pierre-et-Marie-Curie.

1 Cnom and the Committee of Deans of Medicine: a shared vision

The scenarios associated with the progress of AI technologies are regularly fuellingchronic alarmist thought about the disappearance of jobs and professions that we know today. Is this development really inevitable? The disappearance of jobs is certainly real, but may well be counterbalanced by the creation of new functions, and thus new jobs and professions, born with the emergence of new activities. While digital technology, artificial intelligence, and robotics will effectively be more present in the provision of care and treatment of people, we will also need more engineers, IT engineers, 'data scientists', technicians, researchers, etc. to design, maintain and secure the new systems. The doctors themselves will need to find their place and must start preparing themselves for this from today.

Naturally, we cannot ignore the human and relational aspect, excluding the technological scope, which will be even more necessary to bolster with the advent of medicine that needs to be assisted, and not provided, by intelligent robots. It also seems to be clear that the healthcare professions that we know today will not suddenly disappear tomorrow, but will rather require gradual adjustments, which may at times be rapid, as the technologies progress at a compatible pace. Eventually, these medical professions will be completely transformed and renewed... This has always been the case with doctors and the art of healing; today's doctors, with the investigative and therapeutic resources available to them, no longer share any common points as regards their practice with their colleagues from the XIXth century... and even less so with the practice that Molière mocked.

Above all, these techniques can allow freeing up 'human medical time' rather than enslaving us.

This observation leads us to focus on just how crucial a role is played by training, continuous or initial, in anticipating and supporting the medicine of the future, and how important it is to adapt. Medicine no longer involves repeating ancestral knowledge, like it used to during the previous centuries. In every era, all innovative doctors have clashed with the comforting certainties of established knowledge. Today fortunately, the University itself is inclined towards innovation in its services and research laboratories, the French National Board of Physicians itself supports these developments by declaring that the principles of medical ethics and professional deontology are not dogmas befitting bygone eras.

Thus, Cnom and the Committee of Deans of Medicine share this analysis, and have entered into a partnership agreement to act in tandem, in collaboration with other professional organisations and all the stakeholders of digital society.

"We have observed a rather distinct contrast between medicine that is still taught in a highly traditional manner, and students who are completelyaware of digital methods and are already pondering about what smart medicine is likely to entail."

P
r Jean-Luc Dubois-Randé,
Chairman of the Committee of Deans of Medicine

"The Cnom is not focusing only on the single DPC tool, but is working on developing a support process for doctors aimed at periodic certification that is based on an assessment, or even self-assessment, of one's competencies and which allows increasing the value of one's career and activities."

Dr. Jacques Lucas
Vice-President of the Cnom

Like the Cnom, the Committee of Deans of Medicine has identified the '*transformation of learning conditions in a connected society where information is abundant*' as one of the decisive issues in the coming years. It has started taking action by reorganising the former UNF3S, a platform for educational resources validated by speciality colleges, and has turned it into a formidable tool for generalisation of digital technology in medical training, under the new name of Uness (refer to p. 36: Focus on the Uness).

This strategy received a fillip through the desire of 'rethinking our method of teaching and training', explained Patrick Lévy and PrJean-Luc Dubois Randé, the Chairman and the Director of the new Uness GIP[47] respectively. Digital technology is not only about knowledge, it also involves skills, and both of these are based on simulation which is discussed further in the document.

44. Refer to the Proposals of the Committee of Deans to the candidates for the Presidency of France, 20 February 2017
45. Universiténumérique francophone des sciences de la santé et du sport
46. Universiténumérique pour l'enseignement de la santé et du sport
47. Refer to the editorial of the UNF3S 2016 activity report

2 The issues

While it would be presumptuous or, in any case, audacious to accurately predict which medical professions will change or disappear, and in what manner, in the coming five to ten years, the response to this challenge naturally lies in permanent and continuous training and the creation of a continuum between the initial training and continuous training.

- **New professions?**

The University itself must be open to enlisting the support of doctors that it has trained, and who are practicing outside of the university. This is already happening with teachers and researchers in the field of general medicine. This must extend to the other disciplines. Bringing reforms to the post-doctoral and post-graduate level courses will be a step in this direction. It is necessary to implement a structure and completely decompartmentalise basic training and continuous professional development (DPC), in view of the impending risks of acceleration of obsolescence of knowledge and competencies.

This is both, a priority for the Cnom, which ensures the competency of registered doctors, and an ambition of the Committee of Deans. The national professional committees of all specialities need to align themselves in this regard.

- **Open and multi-disciplinary nature of education and training**

The necessity for open and multi-disciplinary nature of education and training is ever increasing. There is a multitude of reasons for this.

The complexity of treatments for chronic patients and vulnerable persons has resulted in the deployment of teams consisting of professionals from many domains. Their collaboration will be all the more easy and effective if they have undergone the same education or received congruent training. Digital technology can be the objective as well as facilitate the implementation of such projects.

After the initial training, it is advisable to implement silos, and the Cnom is keenly observing that the undertaking of universitisation of training is heading in this direction.

The borders which currently compartmentalise practice - and thus the training - of certain specialities are being erased through the use of new equipment and techniques. Health engineering platforms are such an example. This has already happened in digestive oncology, where certain interventions require expertise in radiology, surgery, and gastro-enterology.

Do we need training for a new 'mixed' speciality? Should we redefine the outlines of each speciality or organise their convergence? There may be many such examples in the future, where each player will require a high level of adaptability.

Doctors are not content to just use technology. An increasing number of them wish to inspire and design, individually or as a collaborative effort, and then test and assess new technologies. These activities require doctors to have knowledge and competencies, or at least a modicum of familiarity, with subjects other than those in their main curriculum, in hard sciences as well as in human and social sciences.

Universities must also prepare for the emergence of new professions that constitute an 'interface' between life sciences and engineering by facilitating multi-disciplinary academic trajectories. A few universities and schools have already opened up avenues in this direction.

According to the Cnom, training in humanities, deontology and ethics, and human relations must be strengthened in today's world, where the focus on technology is ever-increasing.

The more education becomes scientific, the more we need to focus on empathy. Doctors must always keep in mind *that they are not just fighting an illness*, but are treating a human being who is ill.

Numerous studies have proven the positive effects of doctors' empathy on their patients. "Medical empathy helps the healing process," observes P[r] Sophie Lelorrain, teacher and researcher of health psychology at the Université de Lille[48]. *"Not only have healthcare professionals not received, or have barely received, any training in this field, but they now find themselves at a disadvantage: it has been shown that natural empathy reduces as a doctor or nurse's career progresses!"* she stated, after completing her work in the field. *For lecturers, it has now been established that trying to eliminate emotions from the medical curriculum is a grave error.*

On the contrary, we need to learn how to control and channelise emotions. Academic training is perhaps not appropriate. Empathy must be 'experienced' through role-playing games, for example. "*Digital solutions like virtual simulation and serious games would be beneficial to this end."* In the same spirit, the addition of trained patients and their experience with living with their illnesses in the medical training curriculum, like certain universities have already done, will certainly contribute to this humanities training (refer to chap. 5).

48. Intervention during the SimforHealth Conference on 26 April 2017

3 Training using digital technology

The contribution of digital technology in training,and to be precise, in health-care training, is indisputable.

- **An indisputable contribution**

A learning experience that is more enjoyable, continues over time, and includes individualised training, and the development of collaborative educational practices, are at the top of the known benefits, as succinctly summarised in the white paper by Cap Digital 'Digital technology, training and health'[49].

Digital technology also has the benefit of modifying the roles of the trainer and learner, insofar as the latter becomes involved in his or her own learning process through access to online information, while the teacher becomes a guide, thus continuing the long tradition of mentoring in medicine.

For all that, digital technology must only be considered as a complementary solution for classroom training.

It helps to refresh educational methods based on a mixed learning approach: online courses made available before the classroom training to provide material for interaction with the teacher in particular. It also allows improving collaborative educational practices which encourage sharing of experiences and expertise like reverse mentoring, peer-to-peer learning, and so on.

Training using digital technology is, however, a permanent challenge owing to the acceleration of technological innovations as well as the impact that this has on organisations, education, and on the trainers themselves.

- **Never start with an actual patient**

Health simulation centres have seen a rapid growth in these past few years and this practice has reached a level of maturity that has been reflected in the creation of an academic society, SoFraSimS (French Health Scientific Society), presided over by P[r] Jean-Claude Granry (co-author of a report in the Haute Autorité de santé[50]).

Today, there are more than a hundred functioning centres and practically all the disciplines are included. Sometime after aeronautics (but with the same belief that it improves safety), the healthcare domain has adopted simulation in a broader manner in terms of training; organisation, programs and assessments have been structured, particularly using a Best Practices Guide, published at the end of 2012 by the HAS.

What can we expect?Simulation is an effective means to complement knowledge with 'practical' skills and simulated situations (for example, communication when working in a team); it facilitates the learning of technical gestures and allows recreating a variety of clinical situations, and particularly those with a high risk level.

Nevertheless, its development is not without its own difficulties. Members involved in a task to organise internships for post-graduate level medical students in 2016 have provided relevant information. They stated that there problems related to pedagogical supervision and financing of the simulation training, and were requested to brainstorm about this situation. It is even possible to create actual 'avatars' of patients, which allows anticipating a surgical intervention.

In January 2012, when P^{r} Jean-Claude Granry submitted his task report to the HAS ('*State of the Art [national and international] of simulation practices in the healthcare sector'),* he had to say the following about the situation in France:

"Simulation that is based on virtual environments is almost non-existent."

Since then, there has been no lack of initiatives, and the situation has received a recent impetus by technological progress and has been encouraged by the educational potential of healthcare training. However, these initiatives are hampered by the fact that virtual reality environments and equipment are still costly (even if the headsets, for example, are becoming increasingly accessible). Not to forget that trainers themselves need to have the time to learn the requisite skills.

That is why the Cnom and the Committee of Deans are recommending that the colleges and players involved in these developments pool their investments.

The Ilumens platform (Université Sorbonne Paris Cité) is among the active promoters of simulation training. As of today, it trains more than 5,500 people a year, be it using virtual environments, mannequins or actors.

But the private sector is increasingly making its presence felt. A new company based in Bordeaux has started the first specialised simulation platform for creation of virtual clinical cases. Its ambition: becoming the 'YouTube' of clinical cases and creating a community on the global scale.

Original concept: cases may be created by professionals themselves, who then use the tool box provided to them like in a video game, without needing to have special computer skills.

Simulation in healthcare

Simulation in healthcare corresponds to "the use of equipment (like a mannequin or procedural simulator), virtual reality, or a standardised patient, to reproduce situations or environments applicable to the domain, to teach diagnosis and therapeutic procedures, and to allow the repetition of these procedures, clinical situations, or decision-making instances for a healthcare professional or a team of professionals" http://www.has-sante.fr/portail/upload/docs/application/pdf/2012-01/ simulation_en_sante_-_rapport.pdf

Otherwise, the teacher can use the case library developed by the platform developer in collaboration with its pedagogical partners.
The very first clinical case, in which the user is completely immersed (using a headset) in a consultation with a vascular doctor, was created with assistance from a surgeon from Stanford Medicine and presented in April 2017.
Other types of devices have recently seen the light of day, and are most often the result of initiatives by start-ups. Here are a few examples: a multi-player game in which students, connected to a network, are put in a virtual operating theatre based on actual cases of adverse events; coupled with a virtual reality headset, an application allows experiencing operations from the point of view of the surgeon, for which the earlier alternative was operations being filmed in the operating theatres; a simulator allows learning the movements associated with childbirth combined with immersive 3D visualisation and haptic feedback; a digital patient in the testing phase may interact through sensors, allowing taking into considerationall the aspects of communication, even non-verbal, etc.

- **From e-learning to Moocs**

Since the beginning of the millennium, the UMVF (French Virtual Medical University), then the UNF3S, and now the Uness has represented the institutional 'digital campus' for medical university training. Its educational platforms and resources support and help develop the essential concepts of medical training through e-learning.

"The use of algorithms for interpretation of results and remote monitoring may start being subject to scientific validation."

Observing the developments in the use of ICT (Information and communication technologies) ineducation or continuous training of healthcare professionals, the HAS published (in April 2015)a 'design guide' that provides support to authors-trainers in creating e-learning modules.

A Mooc for concrete deontological standards

The Cnom will propose a Mooc (Massive open online course) in collaboration with the Committee of Deans of Medicine during 2018 concerning professional practice in all situations and concrete deontological standards that can help students or doctors in the precise clinical situations during which they may have doubts. "This Mooc will be available for day students in hospitals after they first come into contact with patients, and will also include the interns and all doctors in a sequential manner, communicating the appropriate practical rules of daily professional life. It shall offer the option of diversifying educational material for this training by combining texts, discussions, interviews, short videos, an animated webzine, and so on, and shall try to implement interactivity with the subscribers of the Mooc," explains Dr Jacques Lucas

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More recently, Moocs (Massive Open Online Courses) have been on the rise. The acronym was created in 2008, the year when Stanford University made its programming and engineering science courses open to the public. Moocs are therefore different than e-learning because they are open to an unlimited number of participants, they are free, and because there are no selection processes or pre-requisites. They have also highlighted the educational aspect of peer-to-peer interaction.

The first French Mooc only arrived in 2012 and the France UniversitéNumérique platform was created in 2013. But these appear to have fulfilled their role as catalysts for all types of online education by helping create awareness about the potential of digital technology in significantly augmenting educational efforts.

Since then, France UniversitéNumérique has made thirty-six chapters from the Healthcare course[51] available online: they are offered by universities, the Pasteur Institute, the Cnam, and so on.

And the annual conferences organised by the Forma-TIC Santé[52] association show that health organisations are now increasingly adopting this method of training. Noting the increase in the deployment of digital solutions in healthcare and medico-social organisations, and the lack of training opportunities for e-health in the initial and continuous professional training programs, the association started the first Mooc Initiation session for e-health in 2015. Conducted every year, it has had more than 6,000 participants since then, of which about 20% successfully completed the course. Moocs are also used in flipped classroom scenarios by the Ifsi (Institute for nursing training) for example.

49. Published in November 2016, http://www.capdigital.com/sortie-du-livre-blanc-journee-nationalenumerique-formation-et-sante/
50. https://www.has-sante.fr/portail/jcms/c_1173128/simulation-en-sante-rapport51. https://www.fun-mooc.fr/cours/#filter/subject/sante ?page=1&rpp=50
51. https://www.fun-mooc.fr/cours/#filter/subject/sante?page=1&rpp=50
52. http://www.colloqueticsante.fr/

4 Training in digital technology

The introduction of digital technology in education has presented us with numerous opportunities, and 'digital' education and training for the healthcare sector is a fundamental step towards being able to be self-taught 'using digital technology', which is accurately pointed out in the Cap Digital white paper. It actually involves "developing a detailed understanding of digital tools, adopting a critical approach as regards their use, and participating in their construction and creation."

The document also stresses upon the necessity of measuring the relevance of the innovations in digital healthcare training, so as to avoid the temptations of gadgets and to help focus the designers on good practices.

- **Digital literacy**

Today we are aware that regularly using a smartphone does not mean that you are an expert in digital technology! The students have admitted this themselves.

This expertise may be defined by the concept of 'digital literacy', the objective of which is to work towards achieving a true 'digital culture' that will allow, according to the Academy of Sciences, "handing everyone the keys to the world of the future, which will be vastly more digitalised than the present, so that they understand and consciously participate in choices and developments in this world, rather than simply putting up with it and being content to consume things made and decided upon by others."

A report from the French Digital Council dedicated to digital literacy adds that it is a lever for "social inclusion in a society and economy where digital technology plays an essential role."

The Canadian centre for digital and media literacy[53] effectively describes the key competencies of digital literacy in three words: using, understanding and creating. Use refers to technical knowledge that allows a person to use computers and the Internet easily.

Understanding means acquiring a set of competencies to analyse, assess, and consciously use the information available on the web. These competencies are part of developing a critical thinking approach

"The profound effects of an invention are noticed when we have already lost sight of its novelty.It has been a century since the steam engine was invented, and we are only right now beginning to feel the depth of its aftershocks."
Henri Bergson,
Creative Evolution

Creating means being able to produce content and effectively communicate using various digital tools and media.

53. http://habilomedias.ca

5 Focus on the Uness

While it is still necessary to consolidate the operational and budgetary aspects, the development of training rendered necessary by the changes in medicine is on the right track with the creation of the Uness.

The Universiténumérique pour l'enseignement de la santé et du sport is now the official and institutional digital portal for university education, with the objective of bringing together entities that were not a part of the UNF3S before.

In the medium term, it must offer "*not only all the items in the guidelines for post-graduate level courses and educational content of under-graduate level courses,*" but must also propose "*a complete set of digital tools that allow supporting the reform of university education through an individual portfolio, an e-learning portal, and modern knowledge assessment solutions for interns, particularly during their internships in all specialities,*" says FrédéricHuet, Head of the Medical Division and Dean, Dijon.

The portal also integrates the Système inter-universitairedématérialiséd'évaluationen santé (Sides), which allows students to learn and also appear for all their exams online. The banquenationaled'entraînement (BNE) is regularly updated and has more than 2,000 progressive clinical dossiers (DCP). Students are able to assess the educational value of these dossiers.

This policy has led to the launch of the Sides 3.0 project (Smart Healthcare Education System), which won the Dune call for tenders (Development of experimental digital universities, in the capacity of future investment projects). It will facilitate the desired orientation towards a more personalised education. It will also allow analysing the teacher's practices and to capitalise on the knowledge offered during continuous training.

4

REINVENTING RESEARCH

1. Towards precision medicine
2. Data and modelling
3. A multi-disciplinary approach
4. The patient at the core of epidemiological research
5. The risks

What can we hope from big data and artificial intelligence as regards medical research?

'Fantastic', if we are to believe the heads in Silicon Valley and other Chinese BATX[55]! (But would it still be 'medical' research, knowing that "the end is always death"?)

'Realistic and pragmatic', as is evident from the strategic plan implemented by the Inserm[56], the first biomedical research organisation in Europe, or the French Plan for Genomic Medicine 2025 (explained further below).

In any event, for several doctors and researchers, these technologies provide the opportunity to reinvent the field of research. Algorithms and artificial intelligence have the potential to lead us towards the concept of 'reverse search', to allow us to make hitherto impossible discoveries thanks to the results of deep learning.

1 Towards precision medicine

From the beginning of the XXIst century,medical research has been guided by a vision of the future of medicine, which can be currently summarised by the 4 Ps: preventive, personalised, predictive and participative. Its aim is to harness the power of precision medicine, adapted for each individual, at all the steps their health paths, from the screening and prevention to treatment and therapeutic education.

For the pharmaceutical industry, faced with a reduction in the productivity of its R&D investments, the use of big data obtained from newer sources is opening up opportunities for reducing costs and development periods of new treatments.

Digital technologies have allowed opportunities to develop clinical trials, and to optimise them, from patient recruitment to data collection, and quality monitoring.

Public authorities intend to ensure that France is at the top of the pack among the countries committed towards a precision medicine approach.

After the United Kingdom (from 2012), the United States, and China, France has proven, with its French Plan for Genomic Medicine 2025, its desire to *"introduce precision medicine in the healthcare approach and develop a national industry in this domain."*[57]

Among the fixed ten-year objectives, this plan must create *"a dynamic environment for innovation in several domains: conservation, provision and computing of big data in the field of healthcare, web-semantics and the Internet of Things, medical equipment, dematerialisation, digitalisation, and e-health... "*[58]Constructed based on sequencing platforms that cover the entire nation, a national data analysis centre and a national centre for reference, technological innovation and transfer, it uses the specificities of the 'French model', which entails a close interlocking of research, training and healthcare. And it also requires a high level of involvement of the relevant industrialists, as regards academic research and public players.

under the impetus of this plan, research will benefit, for example, from the capabilities of the Très Grand Centre de calcul (TGCC) of the CEA and thus, an infrastructure on the European scale.

Cancer, rare diseases, and diabetes will be the first disciplines to benefit from these investments. This project builds on the processing of, on an average, 2,35,000 genome sequences per year till 2020, setting the stage for an increase in the power of the system with common ailments being included in the processing after 2020.

These volumes correspond to 20,000 patients affected by rare diseases and their families (approximately 60,000 genomes) and 50,000 patients who are treated on priority because of metastatic cancers that become refractory upon treatment. A true challenge insofar as the annual capacity is currently 10,000 genomes.

As a comparison, the British Government launched the '1,00,000 genomes' project at the end of 2012 (covering rare diseases and cancer). Five years on, it has only achieved a bit more than one third of its objective[59].

55. Baidu, Alibaba, Tencent, Xiaomi
56. National Institute of Health and Medical Research
57. Refer to the French Plan for Genomic Medicine 2025
58. Id.
59. https://www.genomicsengland.co.uk/the-100000genomes-project-by-numbers/

2 Data and modelling

The Inserm, which plays a central role in the organisation ofbiology and health research in France, has made an in-depth study of the developments resulting in the emergence of precision medicine. An approach relying on the use of predictive models that implement better integration of the variability of each individual to define an optimised medical approach. As part of its 2016-2020 strategic plan, the Inserm states that *"the intelligent management of big data has become the primary lever for taking advantage of the massive information acquisition flows concerning human beings and health."*

The Institute is naturally associated with the National Health Data System (SNDS).

In this context, the Centre d'épidémiologie sur les causes médicales de décès (CepiDc), a laboratory of the Inserm responsible for the creation of statistical data for medical causes of death, the distribution of this data, and the associated studies and research, has been tasked with: execution extractions, ensuring effective provision of data from the SNDS to researchers, and providing data concerning the medical causes of death.

In the first quarter of 2016, the Research Institute signed an agreement with DassaultSystèmes, the leading software developer in France and the second in Europe, and also the world leader in 3D design and digital modelling, with the objective of accelerating the clinical research programs by deploying a virtual collaborative platform.

It shall provide the Inserm with an integrated virtual environment, facilitating open collaborative researchers and unified management of laboratories; the technology company will also offer researchers the possibility of biological and chemical modelling and simulation. There is even talk of 'Computational chemistry'.

The objective herein is to use non-structured data generated by research programs to calibrate and validate scientific models.

This agreement extends a partnership that started five years earlier as part of a consortium intended to deploy computational tools for modelling applied to testing hypotheses in clinical research.

But it will go far beyond this and will encourage the creation of new virtual clinical trial practices. Especially, it also has the benefit of paving the way for an innovative sector of digital technology in healthcare.

Big data and modelling will also contribute in a wider manner to research programs for improvement and fluidity of patient treatments, ambitions that were heralded as part of the National Healthcare Strategy.

3 A multi-disciplinary approach

The exponential growth of digital data has resulted in the emergence of new scientific approaches and data-oriented research.

Now, instead of methods consisting of formulating a hypothesis and then testing it using defined data, we can rely on analysis of an enormous volume of data, which in addition, is obtained from completely heterogeneous sources (like social networks), which will then be used to formulate hypotheses. It requires a trans-disciplinary approach, warn the players and promoters.

Invited (in 2011) by the Collège de France to discuss "major trends of biomedical innovation in the XXIst century," Elias Zehrouni[60] also stated that future research teams must transcend the limitations of their discipline (refer to frame on p. 42).

"We are heading towards (...) a future where medicine is bolstered by fundamental, multi-disciplinary, and translational research, biologists and clinicians will now rely on contributions made by physicists, chemists, mathematicians, bioinformaticians, engineers,ecologists, and human, social, and environmental science researchers."

Inserm strategic plan 2020

Research teams of the future

"The scale and complexity of the problems require scientists to transcend the limitations of their discipline. (…) we need to form non-traditional teams, combining biologists, engineers, mathematicians, physicists, IT engineers, etc. Solving the enigma of complex and chronic illnesses from obesity to cancer requires a holistic understanding of the interaction between factors like genetics, nutrition, infectious agents, environment, behaviour, and even social structures. We need new organisational models that will allow scientists to freely collaborate with a minimum of obstacles. (...) New partnerships, particularly between the public and private sectors, must be encouraged in order to provide a boost for scientific discoveries, from the lab bench to the patient's bed. They must discuss common questions in a pre-competitive manner, like for example the discovery and validation of new biomarkers."
Inaugural lecture given on 20 January 2011 at the Collège de France. Chair of Technological Innovation Liliane Bettencourt.
http://books.openedition.org/cdf/434#text#text

More recently[61], he reiterated his belief that the medicine of the future will be based on "*integration between information, technologies, and medicine*."

The organisations such as the Aviesan(Alliance nationale pour les sciences de la vie et de la santé[62]), and its Itmos (multi-bodied subject-based institutes), are working towards developing public-private partnership strategies to provide a new boost to translational research and to encourage trans-disciplinarianism.
One of the many examples of these new paths: in collaboration with the National Institute of Cancer (INCa), the Aviesan launched a call for projects in November 2016 to involve mathematicians and physicists in cancer research. A few months later, in April 2017, the Committee of Directors of French Engineering Schools became an associate partner of the Alliance: about 20% of the engineers in training work in domains associated with life sciences and healthcare.

The researches carried out in these schools are highly varied. They cover fundamental research domains (work on cell signalling, genetic variability in the metabolism of lipids, or modelling of cell migration) and more applied domains (technological development of medical imaging devices, cell targeting, data processing, etc.) and also the creation of new medical drugs or procedures under the scope of public health.

The IHUs (Hospital-University Institutes), created in 2010 "for innovation in the future of medicine, treatments, and new practices", are also proving their benefit as regards big data and digital modelling.
Created as Investments for the future, they are a combination of a university, a healthcare establishment, a research establishment and Industrialists in order to combine the efforts, in a subject-based domain, of teams of researchers and doctors, organised based on an excellence program.

If we take the example of the ICM (French Brain and Spinal Institute), which has become a major player in neuroscience research, one of its teams is working on a digital model of the brain's evolution over the course of Alzheimer's disease, with the ambition of transforming it into a predictive medicine tool (Dynamo project, DYNAmic Models).

60. A radiologist, he was the Director of the American National Institutes of Health from 2002 to 2008.Since 2011, he led the R&D division of a French pharmaceutical group with global reach.
61. In October 2016
62. Created in 2009 with new founding members:Inserm, CNRS, CEA, INRA, INRIA, CPU (Committee of University Deans), CHRU, IRD (Institute of development research), Institut Pasteur
63. https://icm-institute.org/fr/projet-dynamo/

The Dynamo project

"This project is based on our capability of collecting and processing data from thousands of people affected by or at risk of being affected by Alzheimer's disease. These various types of big data, compared with one another in highly precise mathematical dynamic models, may reveal the most reliable biomarkers for Alzheimer's disease, and the mechanisms for their activation," explain[61] **Harald Hampel, professor of neurology (ICM) and Stanley Durrleman specialist in mathematical modelling of neuroimaging data (INRIA). The objective is to create a computing tool which is available to doctors and is capable of diagnosing the disease as soon as possible, and creating a personalised progress prognosis for each patient.**

But researchers will soon see this model being duplicated...

"It involves creating an unprecedented tool, which allows using big data in the healthcare sector. Initially developed to better understand and thus combat Alzheimer's disease, this model may be the springboard for a paradigm shift in the treatment of several neuro-degenerative afflictions," **summarises P^{r} Alexis Brice, Managing Director of the ICM.**

4 The patient at the core of epidemiological research

The creation of epidemiological data is a long process, with intensive requirements of human resources and a large budget. *"The challenge faced by researchers is to process the maximum amount of data, ensuring quality, from populations monitored over long periods, and to make this available at the earliest," says Guy Fagherazzi*[64]*, from the Public epidemiology and health research centre (CESP, Inserm team in Villejuif), head of the E4N group.*

With digital technologies, we have the possibility of "doing better, and in shorter spans."*The 4N study (Epidemiological study of children of the E3N women) is an example of this. The first generation of the group, which is questioned every two or three years, is monitored through a paper questionnaire. On the other hand, the second and third generations will be exclusively monitored online.*

"One of the primary axes of this research program is to create the concept of modern epidemiology, 'e-epidemiology', by integrating new technologies to gather good quality information, almost in real time, and at the same time as the interventional studies," states Guy Fagherazzi. *"We can put the patients, or the participants, at the centre of research, mobilise them, provide them with information feedback depending on the behaviour and data already available in the group, and find their position in the general population, ..."The use of smartphones, software applications and smart devices by a part of the group will allow better understanding of the influence of lifestyle, food, environmental exposure and behaviour on the risk of developing chronic pathologies, and will also help measure the impact of these technologies on behavioural modifications.*

From E3N to E4N

The objective of E4N is to study health in relation to modern lifestyle among persons of the same family, over three generations. It has extended the E3N study which is being carried out since 1990, involving 1,00,000 women who are part of the MGEN, born between 1925 and 1950. This study has resulted in the publication of more than 300 scientific articles and has provided clarity regarding public health problems like the link between hormone-replacement treatments and breast cancer. Beyond the scope of cancer, the data gathered also has applications in the study of diabetes, asthma and vein thrombosis. This data is complemented by a saliva samples bio-bank that allows extraction of DNA. E4N, which will include 2,00,000 persons over time, will thus monitor approximately 50,000 children and women from the E3N, as well as their grand-children.http://e4n.fr/

In addition to smart devices, the researchers have already foreseen that the use of serious games and technologies like virtual reality and augmented reality are contributing towards modifying the collection of information in the context of therapeutic education, for example.

Except e-epidemiology, E4N also focuses on the following among its research bases:

♦ the development of expertise regarding exposures (epigenetic and physical activity, food), influence of food on intestinal microbiota;

♦ the execution of transgenerational studies (heredity and health determinant transmission tests; genetics and epigenetics of the primary chronic pathologies in adults; study of socio-economic mobility through generations and impact on health).

Epigenetics is a research domain that has undergone a rapid expansion in the past two decades; it actually represents 'a *new approach for life'* [65] *and one of the major scientific issues for our era insofar as it will considerably enrich the current knowledge in the domain of genetics.*

Since 2012, genetics research has experienced the benefits of the discovery of 'a pair of scissors to cut DNA' (or CRISPR Cas9), by the French national Emmanuelle Charpentier[66] and the American national Jennifer Doudna. More than 3,000 laboratories in the world already use this technology, which has multiplied the possibilities of fundamental research, not only in the field of health, but also in agronomics. The rush towards therapeutic applications will not be far behind but the ethical questions still remain.

64.Cnom hearing dated 15 February 2017

65. According to the terms of the Parliamentary Office of scientific and technical choices, report dated 12 October 2016.The issues and perspectives in epigenetics in the healthcare sector. https://www.senat.fr/rap/r16-033-1/r16-033-11.pdf r16-033-11.pdf

66. Emmanuelle Charpentier is the head of the Infectious Biology Regulation department at the Helmholtz infection research centre, in Braunschweig, Germany. Her article for 'Pour la science', October 2015: http://www.pourlascience.fr/ewb_pages/a/article-crisprcas-9-l-outil-qui-revolutionne-la-genetique-35917.php

5 The risks

The exponential growth of digital data has resulted in the emergence of new scientific approaches and data-oriented research. We can cite numerous examples showing that a new dynamic is in play in terms of research in France... but this has not eliminated fears of seeing our country being left behind, despite its strengths.

This risk has been highlighted by several work groups, including the Medicine of the Future[67] work group, which was asked to approach this subject from the industrial and innovation angle.

The Cnom has particularly agreed with her analysis (refer to the Cnom recommendations) concerning the danger of losing control of our health data, an analysis that has resulted in the members of the mission to recommend "the implementation of a research and trial platform for digital healthcare methods," all the more so as we can rely on the expertise of our industrialists and University Hospitals.

Since this concern is not exclusive for the healthcare sector, it should - we hope - lead to the expected recommendations of the Villani mission concerning artificial intelligence.

“A matter of national sovereignty”

“A country which is no longer capable of analysing the data that it generates shall de facto become dependent on external solutions, without having any control thereof, which then leads to the matter of national sovereignty in terms of healthcare data. Today, medical data is not theoretically exportable. Each country thus needs to be able to process and store its own data to avoid imposition of external standards (particularly by parts manufacturers or the GAFA[68] regarding health-related smart devices).
The digital independence of France in the healthcare sector is thus a true concern. This independence may be one of the driving forces for the deployment of measures in favour of creating a research and trial platform for digital healthcare methods and the development of several associated industries.”

The Souveraineté et sécuriténationale workgroup of the #France IA[69] mission had also raised a concern regarding the importance of not depending on tools provided by foreign players for processing our data, not only for economic reasons, but also to ensure security.

We should also take note that the French Digital Council (CNNum) has initiated a public dialogue on online platforms[70], the contributions from which shall be used as inputs for the Council’s report to the government (planned for the beginning of 2018), just like the European debate it is engaged in with its counterparts.

While this initiative is not directly related to the field of healthcare and medical research, its importance to the field is undiminished, considering the development of the ‘model’ for the platforms, whether it involves participatory networksintended for patient interaction, service platforms (remote consulting, for instance)... or simply the capability of the leading players in digital technology to gather health information using their platforms directly (refer to verbatim quote above), or indirectly using the traces left by users.

Moreover, algorithms and data are not exempt from risks of bias. Researchers themselves are concerned about this.

In June 2017, the Cerna (Committee for Discussion on Research Ethics[71]) has therefore published a contributory piece about ‘research ethics in machine learning’. This awareness-raising document drew the attention and vigilance of researchers and developers towards the questions of data selection, assessment of learning systems, and liability in case of malfunctions.

The quality of the learning data is at the forefront of these recommendations (refer to verbatim quote below).

And particularly, the deep learning algorithms that allow machines to learn by themselves function like black boxes, where it is impossible to analyse the reasoning that led to the results. This opacity is a challenge for researchers... and naturally for the regulators as well. So much so that in the United States, the DARPA (Defense Advanced Research Projects Agency), launched an ‘Explainable Artificial Intelligence[72]’ program. In France, the TransAlgo initiative, developed by the Inria, was created with the purpose of providing a scientific platform and tools for assessing the transparency of algorithms.

"The transparency of algorithm-based systems is a true challenge for academic research. This requires multiple disciplinary skills and a lot of subjects that have been identified have not yet been sufficiently explored through academic research, which is why we need to redouble our research efforts. We need to develop algorithms that are 'responsible by design' that will facilitate measuring their transparency, explanation, and the traceability of their reasoning. An algorithm is said to be responsible if it follows the laws, and if it complies with certain ethical rules," explains NozhaBoujemaa, Director of Research at the Inria and head of the TransAlgo[73] project.

67. The Medicine of the future is one of the new industrial plans proposed as part of the 'New Industrial France' of the Future Investments program, in April 2017.André Syrota and Olivier Charmeil, who were assigned with the task of completing the planning, published a report on 26 April 2017.
68. Google, Amazon, Facebook, Apple
69. The report was published on 21 March 2017
70. Confidence in the era of digital platforms, 10 October - 17 November 2017 https://contribuez.cnnumerique.fr/loyaute/fr
71. Committee formed by Allistene, Alliance of sciences and Digital technology.http://cerna-ethics-allistene.org//
72. https://www.darpa.mil/program/explainableartificial-intelligence
73. https://www.inria.fr/actualite/actualites-inria/transalgo

"A formidable tool for promoting medical research"

"With deep learning, a system will tell us: 'according to the data I have, here is what needs to be done.' But it does not know why. It is like an oracle of sorts. In matters of research, we may consider it a guide to try and understand the reasons for its conclusions."

"Today, we no longer follow the system of understanding before acting. In a manner of speaking, we have gone back a few centuries in time, as though deep learning is akin to 'old wives' remedies, i.e. something that we have observed, with experience, that it works... without knowing why. In the meantime, medicine and science have been able to explain why things work or don't. Now, we observe and then find out why. In my eyes, this is a formidable tool for promoting medical research."

Raja Chatila,

Chairman of the Scientific Committee of the Health Engineering University Institute, Director of the Intelligent Systems and Robotics institute, member of the Cerna

"Information system trainers"

"The designers and trainers will ensure the quality of the learning data and the conditions for its input throughout the duration of operation of the system. The trainers of the computer system are responsible for the presence or absence of bias in the data used in the learning process, and particularly 'continuous' learning, i.e. even when the system is in use. To verify the absence of bias, they must use measurement tools that have not yet been developed." ***Research ethics in machine learning/***

5

RELATIONS BETWEEN PATIENTS AND DOCTORS: ETHICAL ISSUES IN A DIGITAL SOCIETY

1. **Patients participating in change**
2. **The ethical question**

1 Patients participating in change

Partner, volunteer or expert, patients are thoroughly involved in the evolution towards the medicine of the future.

- **Partner**

In the past two decades, the patient's place has been consolidated and expanded. In the capacity of users of the healthcare system, patients have not only recognised their rights, but also play an institutional role. With representatives in hospitals and by participating in an increasing number and type of organisations, both national and local, patients-users-citizens are becoming involved in the healthcare policy decisions.

Since this role still needs to be strengthened,the Institute for democracy in healthcare (IPDS[74]) was created in May 2015 at the initiative of the Inter-associations group on health care, the School of Public Health and the French Hospital Federation. it is tasked with training managers on the healthcare system as regards the issues and methods of health democracy, creating a resources centre, and to initiate research projects.

The 'voice of the users' is now supported by the National Union of Authorised Users' Associations (France Assos Santé[75]) whose objective is to train representatives who will work in hospitals or public health institutions and Medical Insurance companies, and ensure the correct functioning and fairness of the healthcare system.

- **Volunteer**

The deployment of information and communication technologies has resulted in the creation of e-patients, volunteer patients, or patient 2.0., who consult the Internet to search for information regarding their health. But not just that: in addition to information, this type of patient has, over the years, gained the opportunity to participate in forums or exchange platforms (concerning an illness,

"The patient is part of the solution"

"The patient must be active and provide information, he must be part of the solution and not the problem," **said Raja Chatila during the Cnom hearings, and rightly so.The advice given by William Osler, a famous diagnostician from the end of the XIXth century, has not lost its acuity, adds Serge Uzan: *"If your listen to your patient attentively, he will give you the diagnosis."* One of the modern versions of this advice is PROs (Patient related outcomes)[76]. They may be implemented through mobile applications or remote-monitoring, like the Chimio App[77], which for example, allows regularly assessing the secondary effects of a treatment from one's home, and to alert professionals if needed, and also to carry out a real-life study.**

“Developing the care providers’ empathy”

“While patients are participating in medical training, they feel that medical studies are severely lacking in the field of what they referred to as the humanities. Thus, they revealed the necessity of increasing the care providers’ empathy. Neopatients, i.e. patients from the era where knowledge is just a click away, and 70% of whom in France consult the Internet for their own health or for their family and friends, would like doctors who welcome their questions and support their desire of understanding medical decisions, or to even participate in them. [...]
In what is generally a one-sided conversation, they are trying to create a form of complicity that can allow patients to speak freely and thus reveal the invisible third parties involved in the decision like the Internet or economic and social constraints.
They are also providing doctors with the key for improving the quality of the therapeutic relations that they develop with their patients. Moreover, they provide information for understanding the healthcare system and the laws that govern it. And they don’t hesitate to adopt approaches or concepts that make sense medically, but that need to be reviewed.”
***Olivia Gross, Yannick Ruelle and RémiGagnayre, researchers and teachers at the Faculty of Medicine in Bobigny*[79].**

adverse effects of a treatment, etc.), to spread their own experiences via blogs, to follow (or question) opinion leaders through social networks, and so on.In certain cases, they have taken an interest in smart devices to better manage their health. They have also been involved in *living labs*to design innovations meeting their expectations. Today, they can freely decide to join volunteer groups for research (refer below, the example of the Seintinelles).
With the integration of remote-medicine and smart healthcare devices[78], the medicine of the future will provide better support for patients, right up to their homes or in an accommodation establishment, by giving them an opportunity to play a bigger role in their therapeutic education and monitoring.

- **Expert**

It is now accepted that illness bestows a ‘layperson’ expertise, related to the acquisition of specific knowledge concerning the citizens. This knowledge is intermingled with their experience, their information searches on websites, and their interactions on forums. They are able to complete and enrich the academic knowledge and professional experience of doctors. Today, expert patients may also participate in university degree courses; they are even called upon to take part in lessons given to care providers.

There are three faculties that govern the **Patients Universities:** the UPMC Sorbonne Universités in Paris, the Aix-Marseille Faculty of Medicine and that of Grenoble.
In Bobigny, about fifteen expert patients deliver 260 hours of lectures per year to the general medicine interns,

which is almost as much as the doctors with whom they teach in pairs (refer below).

Founder of the University of Patients at the UPMC, Catherine Tourette-Turgis has been fighting since the end of the 1990s for the creation of university degree courses open for patients. The prototype was started in Paris in 2009.

"We have more patients who are 'standing', rather than bed-ridden, when it comes to their bodies and minds," she observes[80]. *We have healthy patients - an interesting concept - and the further we delve into the future, the more healthy patients we will have, who will nevertheless be susceptible to crises, relapses, deterioration, and recurrence, which will increase the complexity of the social, professional and societal applicability of the term 'patient'.*

She thought that there is a "delay in how society sees a patient compared to the medical and therapeutic advancements."

Being a researcher, she observed that "*all the activities carried out by patients in their daily lives for maintaining their general and medical fitness*" were barely described.She thus decided to analyse these activities, and ensure 'social' visibility so that they can be recognised.

"The care provider and the patient manage the progress of the illness as they can. *Care providers cannot work without the patient's cooperation, except in cases where the patient is under anaesthesia, in which case he has willingly accepted being under the care provider's responsibility."*

"When we consider all the competencies acquired over the course of a chronic illness, for example, being able to make a decision in a situation of high uncertainty, being able to communicate regarding difficult subjects, being able to organise a health-care team, being collaborative, being able to hold out, keeping up a strong front, and so on, would not these competencies, acquired over the course of a rather hostile experience, contribute positively towards the entire community?"

This approach and these questions have resulted in Catherine Tourette-Turgis attempting to transform these people into healthcare agents, through the University of Patients.

Now, she wishes to draw attention to the fact that our healthcare system is not oriented 'towards recovery' and providing support to those who are in remission or are healing, thus leading to them feeling abandoned. A new paradigm for the medicine of the future…

- **Researchers - civil society: an original collaboration**

Supported by the National Cancer Institute, the ARC Foundation for Cancer Research and the Chantelle Group, the Seintinelles association has launched a platform for establishing relations between researchers and civil society in September 2013.

This unprecedented project encourages and allows citizens and volunteers to collaborate with researchers by participating in their studies, in order to accelerate research on all cancers. By integrating the very core of its functioning, the possibilities offered by digital technology, it expresses a kind of resurgence of the concept of unity and is part of a collaborative movement founded on the desire to contribute and act on one's own level, but together.

Researchers in the fields of biology, medicine, sociology, psychology and even economicsrely on the Seintinelles. They can save several weeks, even months, from the volunteer recruitment process. Today, the association has almost 19,000 Seintinelles (of which 4% are men, 39% are former patients and 61% are not patients). www.seintinelles.com

74. https://democratiesante.wordpress.com
75. http://france-assos-sante.org
76. These were discussed in a conference of the HAS on 16 November 2016 https://www.has-sante.fr/portail/jcms/c_2672110/fr/colloque-has-la-dynamiquepatient-innover-et-mesurer-paris-16-novembre-2016
77.https://applichimio.com
78. Refer to the previous white papers of the Cnom to know more about this subject
79.LeMonde,12septembre2016http://www.lemonde.fr/festival/article/2016/09/12/les-patientsenseignants-une-revolution-dans-la-formation-desmedecins_4996489_4415198.html
80. Cnom Hearing dated 15 February 2017

2 The ethical question

The ethical issues of digital technology are not new. The points of discussion were stated in a communication from the Permanent National Commission of the Council, during their first council conference in 2015[81].

- **The need for ethics in digital technology**

In the same year, the Cnom was encouraged by a publication adopted during the plenary session[82] '*to ensure ethical use of smart healthcare technologies*. However, observing that the 'uses of m-health have already posed the initial threats to social unity and integrity, through the monitoring and dependency on people', the Cnom has also warned people 'about the consequences of the underlying economic model of smart health that is based on using data'.Since then, it has also stated its desire to have these subjects discussed during open and public debates.

These recommendations are currently gathering momentum since the collection of big data has intensified, supervised machine learning is starting to create its first algorithms for aid in diagnosis, and social robots have been deployed, particularly in retirement homes.

The acceleration of technological progress and digital transformation related to these domains of AI, big data and robotics has resulted in **new ethical questions** and requires **establishing new standards** as regards design as well as uses.

In particular, the issues of private life and data protection, control over one's personal data, and algorithmic biases owing to bad quality of data processing, are taking a new dimension; same goes for the concepts of predictive analysis, liability associated with decisions taken by self-learning machines, and reliability of the online service platforms.

For the majority, these ethical questions are not purely specific to the healthcare sector and medical practice, but require a global level of awareness-raising related to ethical and societal issues raised by algorithms and AI. Calls for ethical discussions regarding digital technology have been increasing lately.

In this regard, the Cnom is highly appreciative of the **Villani mission,** which intends to stimulate debates on the national scale and for all domains.

The Cnom also supports the Cnil as regards organising a series

A smokescreen...

"Can the desire of these new giants be just to get themselves off the hook or to create a smokescreen to avoid dealing with the actual ethical problems caused in the short term by artificial intelligence technologies, such as the use of data or respecting the privacy of information? Your reporters have not come to a conclusion, and we would like to give the benefit of the doubt to the creators of these initiatives."

OPECST report 'Towards controlled, useful and demystified artificial intelligence', March 2017

of meetings following the recent publication of the resulting public report[83]. It fulfils a legal requirement for a Digital Republic[84] that was stipulated by the Committee to result in "a discussion regarding the ethical problems and societal questions raised by the evolution of digital technology."

After the completion of their work that started in 2017, the OPECST[85] envoys have, for their part, proposed**"entrusting a national artificial intelligence and robotics ethics institute with an organisational role as regards public debate concerning ethical questions surrounding these technologies.[86]"**

For its part, the National Ethics Consulting Committee for Life Sciences and Health (CCNE) has indicated that it does not wish to discuss the subject of artificial intelligence before 2018, while its chairman indicated that he wishes to initiate this discussion in collaboration with his Canadian counterpart[87].

On the other hand, the Espaceéthique of the Île-de-France region has undertaken, since 2015, a discussion regarding big data that has resulted in the publication, 'Big data and biomedical practices' [88] (summarised below).

In France, researchers were among the very first to provide a structure to their discussions and recommendations, particularly by creating the Cerna[89] (refer to chap. 4). Industrialists have also undertaken a few initiatives. In 2016, the Association of large French corporations (Cigref) has thus published two reports on 'the ethics of digital technology' and 'governance of artificial intelligence in large corporations'. In the Anglo-Saxon world, industrialists are financing several institutes and foundations that have ethical objectives... but in line with the most varied trends of thought, a desire for an ethical framework for AI development in keeping with transhumanist movements.

"We need to develop ethics based on vigilance and discussion."

Members of the OPECST, who have prepared a broad overview, have acknowledged the need for discussion, particularly "concerning the specific objectives of the GAFAMI[90] and Elon Musk[91] through numerous initiatives" (Refer to frame below).

- **What is the framework of ethical discussion for digital technology in healthcare?**

An interdisciplinary task force was convened in the spring of 2015 under the direction of Emmanuel Hirsch, Director of the Espaceéthique of Île-de-France. Its work, dedicated to "Big data and biomedical practices" from the point of view of "ethical and societal implications in research and healthcare treatments," has resulted in the publication of more than 70 pages that the reader should refer to. Therein, the Cnom has presented the broad guidelines insofar as it is agrees precisely with the ordinal issues.

The "big data phenomenon" must not only be analysed as a technological revolution, "which is currently the case for the most part," but is however, rather reductive, declared the participants of this task force. It is necessary to "approach it like a phenomenon that is cultural as well as technological and scientific."

It has highlighted **four major issues and developments**: the limitations of a knowledge creation approach that is not in keeping with the traditional biomedical research methods, transformation of the research landscape itself and of its influence on the directions it will head, ethical implications of large scale data collection on the concept of consent, and the question of the end purposes of this collection.

Reiterating that large scale data creation "is intended to update recent scientific truths," the Espaceéthique pointed out the advantage of transitioning from a 'hypothesis science' to a 'discovery science'.

At the same time, it has warned of the difficulties involved in research that may be said to be 'agnostic', and particularly emphasizes on the risks of working with a "crude or even deformed reflection of reality," being confronted by "incomprehensible gaps in knowledge" considering the heterogeneity of the data, and "supporting existing knowledge" by correlating hypotheses with existing knowledge.

As regards the organisation of research and the choice of its approaches, it has called for vigilance, stating that big data provides "the conditions for an unprecedented scale and costs for research projects" in a situation where the creation of tools entails "giving precedence to a completely different logic": there is a risk of prioritising resources that could prove to be of more use somewhere else. An ethical discussion concerning big data shall necessarily have to take into account the purposes of data collection... that are not yet easy to identify. Beyond the economic issues, our collective responsibility mandates that we should ensure that the end result of these new approaches is "true added autonomy for citizens" and that the end result is not "a factor for discrimination and a socio-economic determinant."

Lastly, the principles and rules of peoples' consent appear to be difficult to explain in all contexts, particularly in the context of "high bandwidth genome sequencing used as a genetic test" and "smart devices." Therefore, it will involve "preparing collective and political consent forms," knowing that this issue is "a democratic issue of the highest order that involves ensuring a form of collective control over the use of our data and avoiding forms of algorithmic governmentality or new forms of monitoring," warned the discussion group.

Respectively the director and a lecturer at the Medical Ethics Centre of the Lille Catholic University, Jean-Philippe Cobbaut and Alain Loute have given us their observations regarding the framework in which an ethical debate concerning the use of digital technology in healthcare[92] must be carried out.

"We must also discuss professional practices and the integration of new professions and technological third parties in the same way as the ethics in terms of organisation and (re)distribution of powers."

According to Jean-Philippe Cobbaut, it is necessary to develop **ethics based on vigilance** and discussion, in a more or less permanent manner, in view of the emerging technologies and their implications. The difficulty in anticipating what they are capable of producing actually requires all the individuals involved to become sort of "participants of ethical debate."

Alain Loute reveals the risk of "colonisation of the future" by the players engaged in "the techno-scientific promises business."Like in the case of Espaceéthique of Ile de-France, he has also issued a warning as regards the "market that is played at this level, with a strategy for capturing investment resources for research. *This is a very strong trend in the medical field. One just needs to look at the manner in which certain documents or reports present future scenarios using their declarations and roadmaps. The debates concerning transhumanism for example, pose certain future evolution hypotheses with such certainty that they contradict the very basis of democratic and pluralist debate regarding the issues and possible potentialities of technologies."*

He recommends implementing '**by design' ethics (which means, from the design phase)**

, facilitated by the existence of proven experimental approaches, such as scenario-building techniques[93], normative assessment approaches and ethical, legal, and social impact assessments[94].

We must also keep in mind that it is necessary to discuss professional practices and the integration of new professions and technological third parties in the same way as the ethics in terms of organisation and (re)distribution of powers. "Does an innovation constitute an additional tool for a professional? Does it replace another tool and create a dependency, a form of systemic slavery? Does the delegation of decision-making power to machines go hand-in-hand with the concentration of power in other hands?"

81. Dr Alex Mozar
82. White paper about smart health
83. Complete report on the Cnil site
84. Law dated 7 October 2016, Article 59
85. Parliamentary office for assessment of scientific and technological choices. Report 'Towards controlled, useful and demystified artificial intelligence', March 2017
86. Proposal no. 4
87. http://www.ccne-ethique.fr/sites/default/files/publications/le_mot_du_president_vf_3.pdf
88. http://www.espace-ethique.org/sites/default/files/Cahier%20de%20IEE%20Big%20Data%202015.pdf
89. Committee for discussion about Research Ethics in Sciences and Technologies in Digital technology in the Allistene (Alliance of sciences and digital technology)
Its first report, in 2014, concerned 'research ethics in robotics'
90. Google, Amazon, Facebook, Apple
Microsoft, Intel
91. The founder of Tesla and Space X considers AI to be a threat
92. Cnom hearing dated 22 March 2017
93. For example, using fiction to explore the possible impacts of technology
94. Like the Elsi program (Ethical, Legal and Social Implications) that supported the Human Genome project since the 1990s

6

Cnom recommendations

1 Technology must be used in the service of people and society. “Free people and society, not enslaved by technological giants”: this fundamental ethical principle must be reaffirmed in these times, where the most excessive dystopias and utopias receive media coverage. The Board recommends that the rules of substantive law be used to protect this fundamental ethical principle.

2 These protective legal rules must have an international scope of application. France and Europe, from the political angle, must make this one of their major projects. Technology must be used to serve a model of society which reaffirms the characteristics of our humanity.

3 It is imperative that the progress expected from artificial intelligence, big data, and robotics profits everyone and does not worsen social, socio-economic, or cultural divides. Our society, through its democratic and republican organisation, must particularly ensure that the progress derived from these technologies, in terms of screening, in-depth knowledge of illnesses and risks of their occurrence, does not affect our solidarity-based model of social protection, but contributes towards reducing inequalities and risks of exclusion.

4 In the healthcare sector, technologies must first be used to improve the capabilities of doctors and teams of care providers in better understanding and treating the illnesses and diseases, to support the principle of independence of the individual, to “*cure sometimes, treat often, comfort always*”[95] the ill, fragile and dependent people. The Cnom recommends that the development and use of technologies must not aim at replacing the medical decision shared with the patient, which remains singular.

5 The Cnom also recommends widely sharing the benefits of these technologies in all domains of prevention, primary and secondary, for the benefit of people, and allowing them to preserve and conserve their independence.

6 Future transformations will be as profound as those that have accompanied the invention of writing, and then printing. This will require efforts towards education, information, and widening the scope of public debate. The debate regarding the impact of artificial intelligence technologies and big data collection is not only for experts, but for everyone. The Cnom recommends that the public authority organise this debate, which is the only authority capable of shedding light on parliamentary deliberations, whether on a national or European scale.

7 Ignorance is among the first concepts to be fought against because it can leave the door open for pseudo-technico-scientific snake oil salesmen to prey on naive and gullible people. The Board thus recommends that the public authority support the emergence of the free health-care information public service provided for by the law, by combining it with works from scientific companies and free and critical thought “*about patient empowerment*” and medical blogs like the expression of health democracy, within the context of an editorial charter to be created together by all stakeholders.

8 The Board recommends ensuring that this type of technological determinism does not result in apparent passivity of the society, which would feel powerless to voice its concerns. It draws attention to the fact that social or professional apprehensions that can neither be expressed nor receive suitable answers to concerns, may result in violent rejection when faced with excessively radical, sudden, imposed and improperly explained developments.

9 The Cnom recommends that users, patients, doctors and other healthcare professionals be committed to the concept of data and algorithms, without any crippling fears or dogmatic vehemence. It is by participating, by themselves or jointly, in the design and execution of smart objects and systems specifically to meet their requirements, that they will be able to usefully guide the industrial sector rather than allowing the laws of the market to be imposed upon them. In this situation, the medical and scientific organisations and professional bodies must support the ambition of the digital economy in France.

10 As part of the National Health Strategy (SNS) adopted by the government, the Cnom recommends that the development of technical devices using artificial intelligence must be guided towards an industrial market for assistance in medical decision-making and no longer towards an approach where it would dictate an algorithm-based decision to the doctor and the patient, which it would impose upon them without accepting criticism or transgression. The French National Board of Physicians recommends that public authorities support these approaches for the development of the digital health economy, particularly using the coordination forum represented by the recently created Digital Health Strategic Board.

11 Parliamentary tasks and debates[96] are on the rise, rightly so, with the primary purpose of providing clarity to the public authorities. The Board is playing its role fully in this regard and highlights the importance of transparent information and diversified ethical analyses concerning the concrete requirements of users of healthcare systems and professionals, in all their aspects: medical, medico-social, and also human and social. This white paper represents a first step towards raising the awareness that the Cnom wishes to magnify through public debate.

12 The Cnom would like to ensure that the technological tools used by healthcare professionals as well as patients are reliable, intuitive, and regularly updated by their developers, and that the data these tools collect and process is protected from intrusions. It recommends that these guarantees will be provided to patients and doctors through public approval.

13 The Cnom recommends encouraging research in natural language processing (text mining) to describe observations and notes in a simple manner and to thus use comprehension-oriented artificial intelligence to assess, measure and create practical indicators. Similarly, devices for interfacing with other computer systems must also allow this interfacing without requiring any coding.

14 The Cnom recommends that the HAS and scientific societies establish their recommendations in a structured format, in French, to ensure that software developers can integrate them directly into the smart tools they may create, like decision-making assistance systems.

96.OPECST report: 'Towards controlled, useful and demystified artificial intelligence', 15 March 2017

The Cnom also recommends that the Government promote semantic inter-operability, by providing reference terminology in the healthcare and social sectors.

15 The training, initial and continuous, plays a crucial role in anticipating and supporting the 'medicine of the future'. The Cnom considers it crucial that, from now, doctors be trained according to the context in which they will practice their profession, in which technology will play a major role in the clinical aspect.

16 The Cnom also recommends that in the initial training curriculum, and subsequently as part of continuous professional development, there should be a bigger role played by simulation using interactive digital tools, either as part of situational learning or for understanding the technical expertise required for dexterous movements or investigations.

17 The University as a whole, and the medicine faculties in particular, must integrate education in digital technology by focusing on the transversal nature of sciences like mathematics, physics, information technology, medicine and human sciences.

18 The Cnom recommends that foreseeable professional developments must be taken into account during the demographic determination of various medical specialists to be trained during their university curricula and in the contents of these trainings. This not only concerns new professions, delegated practices, and advanced practices, but also, owing to the tasks that can be completed in five to ten years, systems with integrated artificial intelligence.This discussion needs to take place soon. The Cnom also recommends developing, from among the healthcare professions training for 'data scientists' and doctors who have completed both, medicine and engineering education.

19 The evolutions in medical professions and the obsolescence of knowledge and skills are looming threats that appear to be progressing faster than in the past. They are making it all the more important to ensure training throughout life, without a break between initial training and continuous training. It will require better articulation and de-compartmentalisation between disciplines. In a world which is becoming increasingly technical and technological, we will need to bolster education regarding ethical questions, human relations and professional deontology. This change has already been implemented jointly, and within their respective fields of competency, by the Committee of Deans of Medicine and the French National Board of Physicians, with the inclusion of the National Professional Specialities Committees and training organisations. It has resulted in, among other things, the creation of the Universiténumérique pour l'enseignement de la santé et du sport. This requires significant efforts from each of the players and from the entire ecosystem in order to encourage true digital literacy. The Cnom recommends that the Government should support these approaches.

20 Declaring that, in the world of data, robots, algorithms, and artificial intelligence, human and machine intelligence are complementary and not antagonistic, the Cnom recommends carrying out research that will anticipate the potential impacts of technologies in ethical, social and legal terms, to promote 'ethics by design'**97** in the same manner as we need to give priority to 'protection of privacy by design'[98].

97. Ethics by design
98. Privacy by design

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21 It also recommends encouraging research and implementation of systems for assessment, control, and traceability of methods and models based on algorithms, and particularly the machine learning systems used in healthcare.

22 It undertakes to examine the legal regime of liability: that of the doctor as part of decision-making assistance and that of the designers of the algorithms as regards the reliability of data used and the terms of its processing.

23 At the same time, the Cnom recommends that awareness be raised among healthcare players (hospitals, doctors, researchers, etc.) regarding the value of data and the benefits of adopting a form of collective control. They must also know that the quality of data affects the results of big data processing.

24 The use of big data has an enormous advantage, particularly in the field of public healthcare. Most of the Western countries have committed to the adoption of 'open data'. France is following this approach with the necessary caution that the Cnom is supporting through its contributions and presence in the National Healthcare Data Institute. The Cnom reiterates that ensuring medical confidentiality regarding personal health data must be applicable for big data processing and using this data must not allow identification of a person, since there is a risk of this resulting in discrimination. There are legal rules concerning authorisation for access to public databases and processing the data therein. These rules must be supported by their translation into criminal law with sanctions to the extent of considering the intrusion in private life and a computer system to be a fundamental taboo.

25 Patients, just like healthcare professionals, whose data is collected and stored, must receive a guarantee that if the data is stored outside of national territory, it shall be subject to the same requirements in terms of security and availability.

26 For all that, we think it is essential that access to public healthcare databases must be widened, and a positive image of this processing must be conveyed, from the risk/benefit angle for our healthcare system, and for the benefit of all citizens. At the same time, the Cnom recommends that access authorisations for researches be made public, since these researches would involve a risk of indirect re-identification of the people from whom the data is collected, and that the results of the research be published.

27 However, we are observing that citizens are disseminating their personal health data, in even bigger quantities, through the use of various applications or smart devices. This personal data may be collected in private databases, without any control or regulation. It may be used for different purposes, mainly commercial, than those for which the user provided the data. It is possible that the public is still not aware of this, unless it is indifferent owing to the services that it gets by doing so. The French National Board of Physicians recommends that this subject be included in the highest level of public debate.

28 Applicable in May 2018, the European Regulation for Data Protection has implemented requirements and has thus engaged the liability of the processing manager[99].This shall contribute towards raising public awareness regarding control of their personal data.

99. Within the meaning of the Computers and Freedoms law.

The implementation of the European regulation in France has provided an opportunity for the public authority, and to the Cnil, to organise a public debate that we wish to initiate.This debate should allow knowing, among other things, the extent to which the public wishes to protect their healthcare data, whether they can consider this data as public property, particularly in terms of research, and if so, within what limits and under what conditions. This is what the Cnom recommends.

29 A major part of the activities in the digital world, including in healthcare, is becoming powerful through innovation, at times disruptive. The Cnom estimates that it is not necessary to try and establish rules for everything, nor to regulate everything through decrees. Contrarily, it recommends that qualified authorities should issue flexible legal rules, as per the principle of *'soft law'* prevalent in Anglo-Saxon countries. According to the Cnom, this method of regulation, which is considerably more agile when faced with digital disruption, shall preserve and support the agile innovation capabilities while ensuring compliance with the security and legal rights of the people.

30 Since the Cnom is part of the regulatory authorities to whom the public and professionals turn to obtain answers and guarantees regarding these topics, we are ready to co-draft the necessary recommendations in partnership with, among others, the French National Authority for Health, the National Commission for Computers and Freedoms, the French Digital Council, and so on.

31 In order to guide the works required for drafting these 'soft law' recommendations, the Cnom also recommends the creation of a national observatory for artificial intelligence and robotics in healthcare, which will record their results and the evolution of uses.

32 The digital transformation of health, organisations, professions and uses will not be possible without the digital investments required in all the territories of the Nation, in terms of infrastructure. The Board observes that the digital chasm still exists, and notes that the expression 'medical deserts' territorially covers, in a rather spectacular manner, other 'legal deserts' like public services, and also 'digital deserts' created owing to a lack of Internet access and broadband. The Cnom recommends that efforts should be taken, particularly financial efforts in terms of equipment, to ensure that the entire nation has access to broadband Internet. This ambition is intended to guarantee equality of rights in use of digital technology. These efforts must be accelerated, particularly in vulnerable zones, to prevent the digital chasm from widening as regards access to healthcare and treatment innovations. Particular attention must be paid to overseas departments.

33 Lastly, the Cnom warns that the data infrastructure and collection and processing platforms are a major issue in terms of scientific, economic and cyber-security aspects. The location of these infrastructures and platforms, their operation, purposes, and regulation represent a major sovereignty issue to ensure that, tomorrow, France and Europe are not turned into vassals by supranational Digital Giants.

The French National Board of Physicians expects all its members to respect the principles of medical ethics and professional deontology, and is aware of the necessity of its involvement in the answers to be provided for questions raised by technological developments, and therefore it has undertaken to support the recommendations it has communicated to its counterparts in the Member States of the European Union and the Permanent European Doctor's Board, as well as before the general assemblies of the World Medical Organisation, to ensure that their intended meaning is conveyed and defended on a very large scale.

7

Thoughts by P^r^ Jean-Gabriel Ganascia,
September 2017

AI, big data and scientific dogmata

It was just about more than twenty five years ago that after I had recently published my first book on artificial intelligence, I had the honour of being invited by professors Jean Bernard and Marcel Bessis for an informal discussion. After completing the preliminaries of our first meeting, Marcel Bessis explained to me that with a group of friends who regularly meet to honour the memory of Paul Valéry, they had discussed if it was possible to build a machine that would respond to current affairs like Paul Valéry himself would have if he were alive, by referring to the notes and books that he had bequeathed to us. This would virtually bring the great man back to life on computers through his writings. At the time, I did not wish to go down this path that I considered too arduous for achieving immediate results; also

I proposed to Marcel Bessis and Jean Bernard that we should focus our discussions on rational reconstruction of past scientific discoveries and the possibilities promised by nascent learning technologies. Both of them were quite enthusiastic, Jean Bernard especially so, because he saw automatic processing of empirical data by machines as the source for new discoveries. According to him, at a given point in time, most researchers would approach problems in a similar way, because they were prisoners of what he called dogmata, which shackled their imagination and made them blind towards new hypotheses. But, he also thought that overcoming these dogmata, machines would contribute to making new discoveries. Though I respected him immensely and agreed with him about the negative role played by dogmata, I thought that machines would also have their own equivalent of dogmata concerning

the description and distribution of examples as well as the various parameters of learning systems.To convince him of this, one of my students, Vincent Corruble, and I extracted an old medical encyclopaedia containing descriptions of scurvy episodes that we entered in a machine learning system by varying the representation and implicit knowledge.We then observed that, according to the formulations, different hypotheses were presented, through conjecture, regarding the causes of scurvy; some stated the presence of fruits and vegetables in the diet, others explained the illness based on moisture, which referred to Galen's theory about circulation of bodily fluids, while others stated the cold weather or psychological causes.

A quarter century later, the machine learning technologies have improved significantly. Simultaneously, the digitalisation of patient data and the development of computer systems in hospitals have generated a vast amount of data. All this has been foreshadowing the large-scale use of machine learning in all healthcare sectors. Spectacular results are sure to follow. As an example, an article that appeared in February 2017 in the periodical *Nature* showed that, thanks to the use of deep learning technology, it is possible to make an early diagnosis of melanoma based on photographs of moles taken using a mobile phone. The interest shown by Marcel BESSIS and Jean Bernard in the use of artificial intelligence in medicine has now been justified in retrospect. However, the reservations that I had are valid just as much today, or even more so, as they were in the past, for at least two reasons.

The first one is that machines cannot discover knowledge by themselves. There is no doubt that they are capable of processing a large number of cases very effectively, and in this regard, can far exceed our own understanding and our capability of learning from our experiences. But at the same time, the examples and the manner in which we present them have a considerable impact on the results; their formulation conveys implicit knowledge that corresponds in some manner to the dogmata that Jean Bernard spoke about.In this regard, machines cannot free us from our dogmata; they just renew them. But, in doing so, do they help us become aware of these dogmata and to change them?

This question dovetails with the second reason for which we may have reservations about the current use of machine learning in the healthcare sector and that is the opacity of results. Today, the technologies that have gathered momentum, particularly deep learning, are detecting correlations between descriptors. Yet, in most cases, these descriptors are expressed as linear combinations of indicators that are extremely difficult, or even impossible, to interpret. This means that the machine's recommendations, whether they are diagnosis suggestions or decisions, do not contain any justifications other than statistics. To be convinced of their well-foundedness, one would need to explain them, which would involve unfolding the sequence of arguments and reasons that led to these results. Failing this, it would be difficult to accept the computer's proposals, because this would involve blindly accepting the result of the calculation and thus abdicating one's responsibilities, since it would not be possible to justify the decisions taken per se. In other words, not only will we not be free of dogmata, but we would just be accepting more of them, just like the words of an authority that no one believes any longer.

Even so, we must not throw the baby out with the bathwater: if used correctly, artificial intelligence and big data processing will result in significant progress in the healthcare sector. This holds true in case of processing signals transmitted by sensors, interpretation of images, assistance in diagnosis, and in a broader manner, assistance in decision-making, searching for information in bibliographical databases, early detection of diseases or weak signals, and so on.

But for this, we first need to be aware of the implicit knowledge hidden behind the formulation of data that we use, in other words, the dogmata that we ourselves enter into the machines.We then need to learn how to master the parameters of learning systems, which will be possible through data science. Lastly, it will be necessary to develop techniques for interpreting the learning systems' results, in order to understand the knowledge provided by the machines and the possible derivations based on it.

Thoughts by

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And man shall create the monster!

In an article in *Nature*, a team led by K. Schaefer recently confirmed that genomic alterations present some dangers: The famous molecular splicer CRISPR Cas9 has been used to make hundreds of unforeseen changes to the genome. The concept of genomics has its own bugs, which may occur outside of our control. For its part, the American Advanced Research Project Agency (DRPA) has developed the Targeted Neuroplasticity Training (TNT) program, intended to mobilise the peripheral nervous system to facilitate learning. It is planning to conduct trials using healthy humans for this intelligence bodybuilding idea!

There we have it: this great geneto-digital kitchen where an increasingly elaborate hodgepodge is being concocted, going beyond the recovery of injured, deformed, or ill humans, these attempted combined biological and digital alterations are teeming with the demiurgic desire to augment healthy humans by improving cognitive and physical capabilities.

The future may hold the transformation of man, ungainly and slow, into a cyborg extending his supremacy over the universe to smite down death itself, and take his rightful place atop Mount Olympus. An over-the-top and self-important program that is ignorant of even the few things about humans that we understand. When Mark Zuckerberg promises to eradicate diseases in 2100, we are mired in his spell! An absurd prophecy for a lost world, riding high on the intoxication of the most ruinous digital hallucinogens.

The mistakes inherent in any nascent research, secondary to our inability to control human beings, must not be the cause for hindering progress. Being the surgeon that I am, by keeping abreast with new techniques in robotics, I have exposed patients to unforeseen accidents, which, once explained and corrected, have never occurred again.

It is thus out of the question to limit this quest for understanding nature to heal vulnerable humans, through the sterile principle of precaution that paves the way for refusing everything for the fear of the risk.On the other hand, the technical applications derived from these researches will have to pass through the scrutiny of ethics for the good of humanity: understanding the world to heal humans afflicted by a disease makes sense; treating a healthy person simply to augment his capabilities with the sole purpose of 'always more', to become an immortal superhero is unacceptable for me. We will inevitably end up creating a monster with an unknown anatomy and intellectual prowess. After we have used our brains and hands to create and give birth to this monstrosity, we will understand just how far is going too far, and we will then destroy it and vow never to repeat the experiment, swallowed by a sense of panic after having played with fire.

Why should we accept human augmentation? Based on what principle should I augment my capabilities, me, just a poor Sapiens with an average intelligence quotient, walking at five kilometres an hour, on two feet, with dulled senses and a failing memory, already incapable of competing with intelligent machines in games like chess, go, and poker? Let me be, with my fragility, my shortcomings, and my errors! These 'defects' are what make me human, deeply human, because they help me understand others, and help and share with them. Understand that I am on a profound quest to exist in close collaboration with men, women, and children who inhabit our blue globe, and I do not need to be faster, stronger or smarter to know how to love. This is a dream for retarded children who do not understand that desire is rooted in time, nor that our presence in the world is made up of several forms of intelligence among which computing is the least important to live together, to sing and dance!

Here we are, marching back into an era where we covet brute force, tempted to dominate the universe by ravaging it. Modern-day Attilas armed with data centers! And in the war playing out for supremacy over smart devices, America and Asia are unquestionably so far ahead in artificial intelligence and robotics, that Europe is equivalent to a prehistoric tribe of humans mumbling in their cave. We are playing in the second division. Will we be capable of offering the world a different vision or project, without being trapped by outdated concepts?

Even though chemical and hormonal steroids are banned in the Olympic Games, under the guise of a hypothetical well-being, we are being sold 'digital steroids' that are becoming increasingly dangerous, because they are distributed without any quest for meaning in our mortal lives, with new lethal artificial paradises, dealt by global drug cartels, the GAFAMI AND BATX, in the image of the two-faced God Janus, combining the best and worst.For the love of God, let us only take the best of it! Which makes mutual ethical choices a necessity. Everything boils down to risk-benefit, a balance between the good and the bad that medicine has been judged by since the ancient times, with the Hippocratic statement of primum non nocere, "first, do no harm"! Yes to the development of science to heal us, no to silicon-coated totalitarianism to control us under the pretext of improving us! Everything is orchestrated through the lens of Dollars and Yuans to entrap us in the mould of an idyllic vision of a 'superior' man. We have already come to know 'the new man', they won't get me again! The global digital sects that preach about immortality and try to reduce Nations to the level of puppets gesticulating in the emptiness are engaging in the worst form of collective deviance that is being accepted docilely.

I want a world that is not encompassed in a hard disk, profiting a superior class of techno-savvy individuals, when children are starving by the millions in the Horn of Africa. I am trying to use these overpowered technological tools without restrictions for the benefit of the suffering, without trying to augment my own capabilities when I am almost completely healthy. I refuse the diktat of those who, under the illusion of liberating us, are just lining their pockets by enslaving us in an underhanded manner.I value love and fraternity above all other values, because they are an amalgamation of respecting others, sharing, and acknowledging the knowledge of our vulnerability, which makes me Human.

We need to tackle this crucial question head-on. Let us launch the World Consultation on Human Being, by creating a true digital Convention of Parties (COP) to discuss our global actions and bring everyone together so that we are not enshrouded by the horror of digital technology.

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