Inherent Ambivalence Risks in Biomedical Engineering Progress: From Technical Aids to Cyborgs, from Signal Processing to Artificial Intelligence, from Gene Analysis to Genome Editing

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Problem: The interdependence between ethics and engineering becomes more challenging with continuing progress in technology, especially with technological systems based on autonomy, artificial superintelligence, cyborgisation, and gene manipulation.

Situation: Civilisation has always been the result of emerging and advancing technologies. However, technologies have the potential to be applied with „good“ and „bad“ outcomes. Technoethics considers the ethical challenges by technology especially in the societal context. New emerging technologies have the power to transform dramatically the civilisation and, thereby, the human society. Thus, special attention must be paid to developments related with biomedical engineering fields like cyborgisation, genome manipulation, transhumanism, artificial superintelligence. Their applications, which can be promising for urgent medical problems, may also cause “black swans with unforeseeable, even catastrophic consequences“.

Comment: Some of those emerging technologies with high potential for ambivalence risk will be discussed in detail. Engineers and especially biomedical engineers must become familiar with ethical challenges and the principles of technoethics. It was Voltaire (1694 – 1778), the famous French author and philosopher, who first coined the phrase „with great power comes great responsibility”. Engineers have great power and must be aware of their responsibility with regard to research, development and application. Biomedical Engineers are especially confronted with ethical conflicts and ethical dilemmas.

Summary and Conclusion: Progress in science and technology cannot be stopped. Technology is perhaps the strongest power for the transformation of civilisation, e.g. for the realisation of the Society 5.0, the humanistic society. Biomedical engineers control that power and should use it to achieve „good“ outcomes.

Content (1)

Theses

1. Emerging technologies have contributed to the state of **modern civilization** and will continue to shape its **future development**.
2. Emerging technologies such as Artificial Intelligence, genome editing, cloud based robotics, and cyborgization will provide to society **promising benefits,** but may also cause **unprecedented risks**.
3. These emerging technologies raise new **technoethical issues**, e. g. human dignity, sustainability, privacy, bias, autonomy, accountability, and responsibility.
4. Technoethics focuses on the ethical challenges of technology within a societal context, especially if emerging technologies may **transform the human society**.
5. Ethical challenges must appropriately be considered in **all states** of:
   - science and research
   - development and production
   - application and operation

Introduction (3)

Definitions and Clarifications

- **Ambivalence:** possibility for two opposing options with either good or bad outcome
- **Risk** (**U**N-definition): Risk is the probability of an outcome having a negative effect on people, systems or assets.
- **Inherent**: Something that is (intentionally or non-intentionally) "stuck” in something (technology, product, method, software) so firmly that it can't be separated and sometimes even not be identified.
- **Inherent Ambivalence Risk**: Risk caused by the engineering-technological progress with the probability for both a desired and a non-desired outcome

Introduction (4)

Definitions and Clarifications - Risk

- **Risk** is made up of two components: the probability of something going wrong, and the negative consequences if it does.
- **Risk Analysis** consists of:
  - Identification of possible threats
  - Estimation of impact if occuring
  - Probability or likelihood of occurrence
- **Risk Assessment**: Process of formally analyzing and mitigating the risks and hazards of an activity, a product or a procedure.
- **Risk Management**: Strategy of avoiding risk, sharing it, accepting it, and/or controlling it as effectively as possible.
- **Risk Reduction or Minimizing**
  - Identifying the threats with the highest risk
  - Reducing the probability of those threats and / or their consequences

Introduction (5)

Definitions and Clarifications

- **Biomedical Engineering**: Application of engineering principles, practices, and technologies to the fields of medicine and biology in research and care
- **Medical devices**:
  - products or equipment intended for a medical purpose (EU definition): However:
    Regulation (EU) 2017/745 on medical devices (MDR) covers some devices without an intended *medical purpose*.
  - instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a (special) component part or accessory (FDA)
  - instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination for a medical purpose (WHO)

Medical devices are different from **medical or medicinal products**, i. e. a drug, device, biological product, or a product that is a combination of drugs, devices, and biological products.

Introduction (6)

Definitions and Clarifications

Medical assistive technology

- is the application of knowledge and skills related to assistive medical products, including devices, systems and services.
- is a subset of health technology.
- enables people to live healthy, productive, independent and dignified lives, and to participate in education, the labour market and civic life.
- reduces the need for formal health and support services, long-term care and the work of caregivers. Without assistive technology, people are often excluded, isolated, and locked into poverty, thereby increasing the impact of disease and disability on a person, their family, and society.

Introduction (7)

Definitions and Clarifications - Medical Assistive Product

WHO

Medical assistive products are devices, equipment, instruments or software from 6 functional domains: mobility, vision, hearing, communication, cognition and self-care, including digital products such as software and apps.

Their primary purpose is to maintain or improve an individual's functioning and independence, and thereby promote their well-being. Medical assistive products are also used to prevent impairments and secondary health conditions.

ISO

A **medical assistive product** is any product (including devices, equipment, instruments and software), especially produced or generally available, used by or for persons with disability for participation; to protect, support, train, measure or substitute for body functions/structures and activities; or to prevent impairments, activity limitations or participation restrictions.

Introduction (8)

Definitions and Clarifications

Medical technical assist system
is a product with the help of which it is possible to improve a person's physical and **social independence**, as well as their capacity for action and work ability. Such technical aids are, for example, wheelchairs, hearing aids, diapers, prostheses, crutches, etc.

Socioeconomic benefits
The positive impact of assistive products goes far beyond improving the health, well-being and participation opportunities of individual users. There are known or potential socioeconomic benefits that make the case for health and welfare systems – as well as governments – to invest in assistive technology and include it within universal health coverage.

Definitions and Clarifications - Medical Information Technology

Information technology (IT) is the use of any computers, storage, networking and other physical devices, infrastructure and processes to create, process, store, secure and exchange all forms of electronic data.

Biomedical informatics uses information science and computer technology to solve problems in biomedical research, healthcare, and public health. It is concerned with acquiring, storing, analyzing, and interpreting biomedical data, and with developing information systems to support these activities.

Medical information technology: IT used for health care, especially for processing, storage, and exchange of health information, e.g. signal processing, image evaluation, statistical purposes, modelling, knowledge processing, multi-modal information linking, and big data analytics and interpretation.

Definitions and Clarifications - Medical Information Technology

Biomedical Informatics

- aims for analyzing and processing signals and data which are relevant for medical research and healthcare
- includes healthcare informatics, bioinformatics and molecular informatics
- uses typical IT hardware, software and data banks
- is embedded in advanced medical equipment
- is applied to (multimodal) image processing and pattern recognition
- is the driving force for artificial intelligence and big data management

Definitions and Clarifications - Biomolecular Technology

Biomolecules are chemical compounds found in living organisms. They include chemicals that are composed of mainly carbon, hydrogen, oxygen, nitrogen, sulfur and phosphorus. They are the building blocks of life and perform important functions in living organisms.

Biomolecular Engineering

- aims for the development of new molecular tools using the principles of molecular biology/biophysics and chemical engineering. The focus is on bio-applied processing and technology.
- includes the development of new drugs, new vehicles for the delivery of new drugs, the engineering of biological systems for energy and chemicals production, and other fields as well.

Definitions and Clarifications – Biomolecular Technology

Genetic Analysis

- is the overall process of studying and researching in fields of science that involve genetics and molecular biology.
- includes the identification of genes and inherited disorders, e.g. is used to study DNA in order to look at differences, or variants, that may increase an individual's risk for disease or impact drug responses.
- renders possible a differential diagnosis in certain somatic diseases such as cancer. Genetic analyses of cancer include detection of mutations, fusion genes, and DNA copy number changes.
- can be used to describe methods both used in and resulting from the sciences of genetics and molecular biology, or to applications resulting from this research.
- requires the development and technology of special instruments and devices.

Definitions and Clarifications – Biomolecular Technology

Genome Editing (Genome Engineering, Gene Editing)

- A genome is an **organism's complete set of genetic instructions**. Each genome contains all of the information needed to build that individual organism and to control its growth and development.
- A **genetically modified organism (GMO)** is an organism whose genome has been engineered in the laboratory in order to favour the expression of desired physiological traits or the generation of desired biological products.
- **Genome editing** has the promising future potential for
  - **genetic therapies** that may be used to prevent, treat, or cure certain inherited disorders, e.g. cystic fibrosis, alpha-1 antitrypsin deficiency, hemophilia, beta thalassemia, sickle cell disease, and for the treatment of cancers or infections, including HIV.
  - **treatment of risks** that may include certain types of cancer, allergic reactions, or damage to organs or tissues if an injection is involved.

Introduction

Definitions and Clarifications – Biomolecular Technology

Genome Editing (Genome Engineering, Gene Editing)

- is a type of genetic engineering in which DNA is inserted, deleted, modified or replaced in the genome of a living organism.
- targets the insertions to site-specific locations in contrast to early genetic engineering techniques that randomly inserts genetic material into a host genome,
- uses technologies like molecular scissors, cutting the DNA at a specific spot, thereby rendering possible the removal, addition or replacement of fragments of the DNA where it was cut.
- includes molecular technologies such as PCR, RT-PCR, DNA sequencing, DNA microarrays, and methods such as karyotyping and fluorescence in situ hybridisation.
- is based on manipulations through programmable nucleases for the recognition of target genomic loci and binding of effector DNA.

Ethical Aspects and Principles - Clarifications

- Ethics is based on well-founded standards of **right and wrong** that prescribe what humans ought to do, usually in terms of rights, obligations, benefits to society, fairness, or specific virtues.
- Ethics must fundamentally be considered **for research, development** and **application**, especially in the context with biomedical engineering.
- Ethical conflict: For a certain problem different solutions are possible which all are justified by an appreciated mode of ethics.
- Ethical **dilemma** versus ethical **conflict**: An ethical dilemma can be defined as an unresolvable ethical conflict, i.e. it has no solution that **is absolutely acceptable from an ethical perspective**.
- The most important **ethical principles** for biomedical engineering are:
  - respect for each individual and its autonomy, especially proper consideration of the agreed human rights;
  - avoidance of any conflict of personal interest;
  - **acceptance of personal responsibility;**
  - appropriate risk/benefit assessment based on the assessment of the probabilities of both the harms and the benefits that may arise.

Introduction

Ethical Aspects and Principles

Some different kinds (or modes) of ethics and their principles are

- **Theoretical ethics** develops general principles, rules, that help to distinguish between “good” and “bad” (or “right” and “wrong”).
- **Applied ethics** treats particular contexts through less general, derived principles, rules, judgments, and the like.
- **Kant's ethics** (“categorical imperative”) is a universal ethical principle stating that one should always respect the humanity in others, and that one should only act in accordance with rules that could hold for everyone.
- **Utilitarianism** is an ethical theory that asserts that right and wrong are best determined by focusing on outcomes of actions and choices.
- **Virtue ethics** focuses on one's character and the virtues for determining or evaluating ethical behavior.
- **Bioethics** is concerned with ethical issues related to health (primarily focused on the human, but also animals) and with relevance for biology, medicine, and technologies.

Introduction (17)

Ethical Aspects and Principles

Ethics and morality are different: Ethics defines the standards of „good“ and „bad“, whereas morality defines the rules how to act „good“ or „bad“.

The Code of Ethics governs decision-making by guidelines, requiring the willingness and ability to accept **full responsibility for those decisions and their consequences**.

The Code of Ethics should not be confused with
- code of conduct
- code of behavior
- respecting the law and legal regulations
- accepting religious values and religious commandments
- considering a list of standards and authority regulations
- following mandatory guidelines and regulations

Ethical Aspects and Principles - Challenges

Some ethical dilemma for biomedical engineering and healthcare technology:

- ethical issues with **assistive**, especially **intelligent technologies** are related with balancing between risks and benefits, and between beneficence and respect for autonomy and dignity, especially concerning patients with cognitive impairments including dementia.
- ethical issues with **artificial intelligence** in healthcare revolve around privacy and surveillance, bias and discrimination, as well as the role of human judgement.
- ethical issues arising from modern **biotechnologies** include the availability and use/misuse of privileged information, potential for ecological harm, access to new drugs and treatments.
- ethical issues related with **transhumanism** and with **cyborgization** are concerned with the (still unsolved) problem whether after the synthesis of biological and non-biological portions humans will stay as human or transform into a new type of creature.

Ethical Aspects and Principles – Technoethics (TE)

- is an **interdisciplinary research area** that draws on theories and methods from multiple knowledge domains (e. g. communications, social sciences, information studies, technology studies, applied ethics, and philosophy).
- provides insights on ethical dimensions of technological systems and practices for **advancing a technological society**.
- requests that ethical rights and responsibilities assigned to technology and its creators must be considered since technological innovations increase their **social impact**.
- views technology and ethics as **socially embedded enterprises**.
- focuses on discovering **the ethical uses for technology**, protecting against the misuse of technology, and devising common **principles to guide further progress in technological development and proper application to the benefit of society.**
- has fundamental relevance in established fields such as **bioethics** or **computer ethics** or **engineering ethics** as well as in new areas of research such as **neuroethics**.

Ethical Aspects and Principles - Roboethics

- Roboethics (or Robot Ethics) is a modern interdisciplinary research field lying at the intersection of applied ethics and robotics. It studies and attempts to understand and regulate the ethical implications and consequences of robotics technology, particularly of **intelligent/autonomous robots**, in our society**.**
- **Roboethics** belongs to **technoethics**.
- Roboethics is a fundamental requirement for assuring a **sustainable, ethical,** and **profitable human-robot symbiosis.**
- Design of **mental/intelligent robots that possess** (i. e. are supplied with) **ethical reasoning abilities**.
- If robots become more sophisticated, intelligent, and autonomous, it will become necessary to develop more advanced robot safety control measures and systems **to prevent the most (inherent) critical dangers and potential harms.**

Regulations, Directives and Standards

WHO

- **International Health Regulations** (2005) (IHR) provide an overarching legal framework that defines countries' rights and obligations in handling public health events and emergencies that have the potential to cross borders.
- WHO recognizes the **potential of AI in enhancing health outcomes** by strengthening clinical trials; improving medical diagnosis, treatment, self-care and person-centered care; and supplementing health care professionals' knowledge, skills and competencies.

UNESCO

- UNESCO has delivered global standards to maximize the **benefits of the scientific discoveries**, while minimizing the **downside risks** and ensuring that they contribute to a **more inclusive, sustainable, and peaceful world**. It has also identified frontier challenges in areas such as the ethics of neurotechnology, on climate engineering, and the internet of things (IoT)
- **Regulations have binding legal force** throughout every Member State and enter into force on a set date in all the Member States.

Regulations, Directives and Standards

European Union

- **Regulations** have **binding legal force** throughout every Member State and come into effect on a set date in all the Member States.
- **Directives** lay down certain results that must be achieved but each Member State that is free to decide how to transpose directives **into national laws**.
- **Harmonisation** is the process of creating **common standards across the internal market**. Each EU member state has primary responsibility for the regulation of most matters within their jurisdiction, and consequently each has its own laws to reach the harmonisation aims.
- **Standards** are technical specifications defining requirements for products, production processes, services or test-methods**.** These specifications are voluntary**.** A **harmonised standard** is a European standard developed by a recognised European Standards Organisation: e. g. CEN, CENELEC, or ETSI. It is created following a request from the European Commission to one of these organisations.

Regulations, Directives and Standards

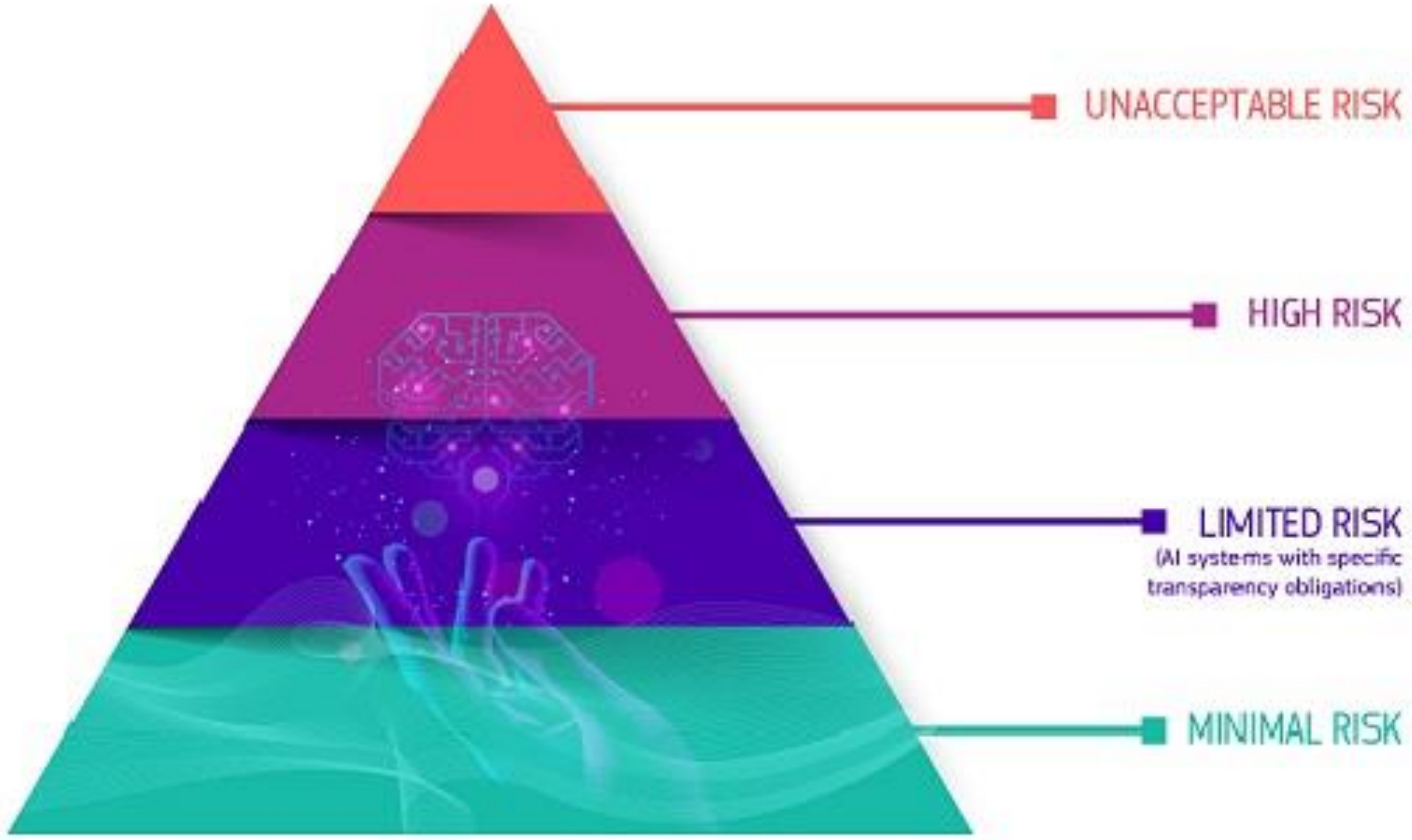
European Union

- **Medical technologies and devices** are tightly regulated by the **Medical Directive Regulation** (MDR). Before a medical technology / devices can be legally placed on the EU market, a manufacturer must comply with the requirements of all applicable EU legislation and affix a CE mark to their device, i.e. a medical device and in-vitro diagnostics.
- The EU MDR includes additional requirements that **go beyond ISO 13485**, i.e. a Quality Management System for Medical Devices, to ensure the safety, performance, and quality of medical devices in the European market.
- A proposal will be prepared for the Regulation on the **European Health Data Space (**EHDS), i.e. for compatible European eHealth systems, regarding the necessary interoperability requirements to enable cross-border data exchange between health-care information technology systems and health-care professionals.
- The aims of the **AI Act of EU** are to ensure that AI systems respect fundamental rights, safety, and ethical principles and by addressing risks of very powerful and impactful AI models.

Regulations, Directives and Standards

EU-AI-Regulation - A risk-based approach

The Regulatory Framework defines 4 levels of risk in AI:



Regulations, Directives and Standards

EU-AI-Regulation for High Risk-AI systems including AI technology and used in:

- **critical infrastructures** (e.g. transport), that could put **the life and health of citizens at risk;**
- safety components of products (e.g. **AI application in robot-assisted surgery**);
- educational or vocational training, that may determine the access to education and professional course of someone’s life (e.g. scoring of exams);
- employment, management of workers and access to self-employment (e.g. CV-sorting software for recruitment procedures);
- essential private and public services (e.g. credit scoring denying citizens opportunity to obtain a loan);
- law enforcement that may interfere with people’s fundamental rights (e.g. evaluation of the reliability of evidence);
- migration, asylum and border control management (e.g. verification of authenticity of travel documents);
- administration of justice and democratic processes (e.g. applying the law to a concrete set of facts).

Regulations, Directives and Standards

WHO (Oct. 2023) - **key regulatory considerations on artificial intelligence (AI) for health** are:

- calls for **safe and ethical AI used for health**, especially regarding the protection and promotion of human well-being, human safety, and autonomy, and preserve public health.
- requests to support health-care professionals, patients, researchers and scientists, and to consider the **caution necessary for any new and advanced technology**.
- lists **six areas for regulation of AI for health**
  - transparency and documentation
  - risk management
  - validation of data and identification of intended use
  - data quality, especially data for learning purpose
  - privacy and data protection
  - support of collaboration between regulatory bodies, patients, healthcare professionals, industry representatives, and government partners.

Regulations, Directives and Standards – Artificial Intelligence

US-President Biden (Dec. 2023): Statements and Requests

- Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence.
- Situation: Artificial intelligence (AI) holds extraordinary potential for both promise and peril.
- The rapid speed at which AI capabilities are advancing compels the United States to pay attention for the sake of our security, economy, and society.
- AI reflects the principles of the people who build it, the people who use it, and the data upon which it is built.

Result: "FAVES" principles using AI so that healthcare outcomes are **Fair, Appropriate, Valid, Effective, and Safe.**

Regulations, Directives and Standards – Robotics

European Union and its Activities and Statements

- Report of the European Commission (2020): **Artificial Intelligence** (AI), the **Internet of Things** (IoT) and **robotics** will create new opportunities and benefits for society. They share many characteristics. They can combine connectivity, autonomy and data dependency to perform tasks with little or no human control or supervision. AI equipped systems can also improve their own performance by learning from experience.
- The European Commission will publish an EU-wide strategy paper next year to ensure synergy across the continent in the uptake **of AI-powered robotics** with the aim of developing an "AI-powered" robotics strategy.
- The increased demand for robots, mostly used in industries such as **healthcare,** agri-food, logistics and manufacturing, creates challenges related to workforce adaptation and safety.
- The strategy shall guarantee **the responsible and ethical deployment of robots**, looking at privacy, cybersecurity, transparency, and accountability risks and measures.

Medical Assistive Technology

Fields

• Mobility Aids	already BC
• Sensoric Aids	
• Prostheses	
• Exoskeletons	
• Wearable Health Monitors	
• Robotics, Autonomous and Intelligent Robotics	1956, 1980, 2000
• Life-sustaining Implants	
• Brain Stimulators	
• Neuroprosthesis, Brain-Computer Interfaces	
• Brain-controlled neuroprosthetic systems	2023
• ??? Cloud-controlled health care networks	

Needs for and chances provided by Medical Assistive Technology

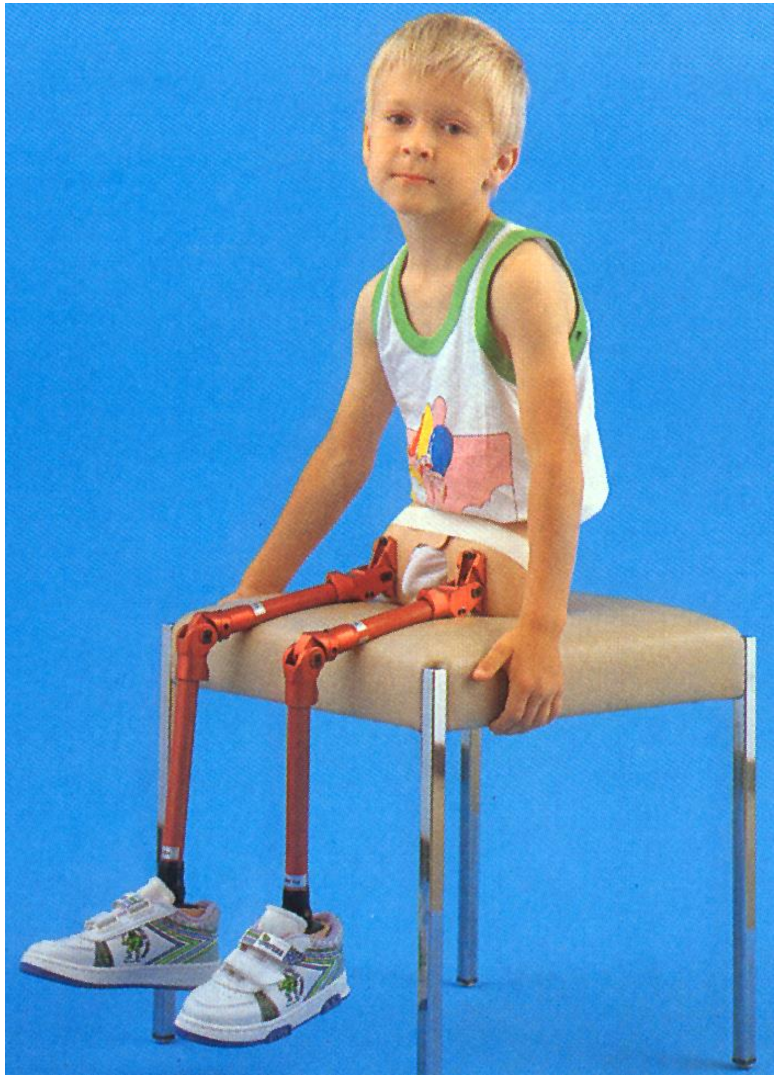
People who most need medical assistive technology include:

- people with disabilities
- older people, especially those with handicaps
- people with noncommunicable diseases such as diabetes and stroke
- people with mental health conditions including dementia and autism
- people with gradual functional decline.

Medical assistive technology can have a positive impact on the health and well-being of a person and their family, as well as broader socioeconomic benefits. Globally, more than 2.5 billion people need one or more assistive products. With an ageing global population and a rise in noncommunicable diseases, more than 3.5 billion people will need at least one assistive product by 2050, with many older people needing two or more.

Mobility Aids: From the Roots to the Presence

Brueghel the Older (1559)



Two flexible full leg protheses

Robotics – an emerging healthcare technology

One of the most rapidly developing assistive technologies is robotics, which opens up possibilities for assistive robots which may be autonomous systems that can ‘live’ with a person and assist in all kinds of daily life activities like dressing, toileting, eating, fetching things, and non-physical activities like interpersonal interaction.

Robotic solutions are being used in healthcare, educational and social settings, for an array of purposes:

- Supporting, caring for and educating children with autism
- Facilitating play for children with physical disabilities
- Providing distraction for children during medical treatment, and companionship for older persons with dementia

Robots are also used for rehabilitation and training, with examples in spinal cord injury rehabilitation, stroke rehabilitation and support of arm–hand functioning.

Intelligent Robotics – an emerging technology

- An intelligent robot is an intelligent machine with the ability to take actions and make choices. Choices to be made by an intelligent robot are connected to the intelligence built into it through **machine learning or deep learning** as well as inputs received by the robot from its **input sensors** while in operation.
- Artificial intelligence and automatic control together can autonomously solve complex control problems **without human assistance or interaction**.
- Humanoid robots are robots with a human or anthropomorphic appearance, with a body and limbs similar to those of a human being. These robots are designed to interact with humans naturally and intuitively, thanks to sensors and programs that allow **them to recognize human gestures, facial expressions, and emotions.**
- Robots can learn autonomously using AI and sensor technology and thus solving difficult tasks.
- A **robot swarm** is a group of intelligent robots that perform tasks cooperatively only controlled by **artificial swarm intelligence** and **without control from human operators**.

First Approach for Consideration of Ethical-Moral Aspects

The “Three Laws of Robotics”, first introduced 1942 in Isaac Asimov's short story “Runaround,” are as follows:

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

This is the **first deontological robotic ethical approach.** It is based on the universal deontological principles to treat everyone with respect.

Brain-Computer-Interface (BCI)

A **brain–computer interface** (**BCI**) or **brain–machine interface** (**BMI**) or **smartbrain**, is a direct communication pathway between the brain's electrical activity and an external device, most commonly a computer or robotic limb.

BCIs are also useful for researching, mapping, assisting, augmenting, or repairing human cognitive or sensory-motor functions and for compensating deficiencies.

Implementations of BCIs range from non-invasive (EEG, MEG, MRI) and partially invasive (ECoG and endovascular) to invasive (microelectrode array), based on how close electrodes get to brain tissue.

BCIs can be conceptualized as human-machine interface using only brain activity
- to determine functional intent
- to change, move, control, or interact with something in the environment
- to control an application or a device

BCIs may be a first step towards making humans part of a global and cloud-controlled network

Brain Stimulation

Brain stimulation, using implanted electrodes and pacemaker-like stimulators, are already successfully applied in the treatment of

- Parkinson's disease.
- Essential tremor.
- Epilepsy.
- Tourette syndrome.
- Obsessive-compulsive disorder.
- Chorea, such as Huntington's disease.
- Chronic pain.
- Cluster headache.
- Dementia.
- Depression.
- Addiction.
- Obesity.

Deep brain stimulation in the Amygdala and the Hypothalamus **can provoke aggressive behavior.**

Cloud-based healthcare technology (I)

Cloud-based technology enables the use of programs and information that are stored on the internet rather than on the own computer.

Using the cloud enables medical devices to wirelessly collect data for storage, computation, accessibility, and sharing. Frequent alerts can be sent if data breaches occur, allowing for backup and recovery.

Interfacing implantable brain devices with local and cloud computing resources have the potential to improve electrical stimulation efficacy, disease tracking, and management.

Cloud-computing resources can **wirelessly be coupled to an implanted device** with embedded payloads (sensors, intracranial EEG telemetry, electrical stimulation, classifiers, and control policy implementation).

Cloud-based healthcare technology (II)

Advanced systems in implanted devices create a flexible platform in which analytics and stimulation features requiring fast response times are embedded. More complex algorithms can be implemented in off-the-body local and distributed cloud computing environments.

Neurolinks combined with cloud-based technology offers the chance for **world-wide health management systems, personalized care and total patient monitoring/supervision**.

Adoption of cloud computing in the medical device industry is slow until now with regard to data security, privacy concerns, limited healthcare budgets and stringent regulatory compliance.

However, the medical technology industry is convinced that benefits outweigh the limitations and recent successful case studies will continue to drive the market.

Cloud-based healthcare technology (III)

The biggest **security risks** when trying to use cloud based technology to medical services are

- non-certified software and malicious malware, i.e. in the form of viruses, worms, trojans, spyware, adware or rootkits
- the unintentional creation of network “dark spots.” This term refers to areas within a cloud network or infrastructure the monitoring of which tools frequently miss, leaving those segments open and exposed to a security breach
- missing compliance, however EU authorities are working on regulations like the EU General Data Protection Regulation (GDPR)
- Cybercrime

Security risks are **not** the only, even not the most serious risks for the use of cloud-based healthcare technology in combination with Artificial Intelligence. AI cloud services enable analyzing and processing of big datasets, discovering client behavior patterns, supporting personalized medicine, and decision making. However, this approach requires a complete and true data set. **Risks** are: bias, low quality data, lack of transparency, inappropriate contexts etc.

Medical Information Technology

Fields

• Signal Processing	1900
• Data Processing	
• Image Processing	
• Modelling, Simulation	1955, 1973
• Pattern Recognition	
• Expert Systems, e.g. Mycin	1972
• Intelligent Systems	
• Telemedicine, Telehealth and Networks	
• Medical Data Banks, Drug Banks, Gen Banks	2002
• Artificial Intelligence	1956 - 2023
• ??? Artificial Superintelligence (IQ > 200)	

Signal Processing – Methods

Signal processing is an interdisciplinary field of engineering, mathematics, and computer science that deals with processing, analyzing, manipulating and utilizing analog and digital signals. Typical subfields are:

- Parameter estimation, e.g. time intervals, amplitudes, frequency
- Wavelets (Transformation, Compression)
- Modelling and Simulation (analog, digital)
- Fuzzy Logic
- Statistics and Probability Theory
- Chaos Theory
- Similarity Theory
- 2D-Processing (images), Multi-D-Processing
- Fractals and Mandelbrot-Approach
- Big Data Analysis and Processing
- P5 medicine – a **p**redictive, **p**ersonalized, **p**reventive, **p**articipatory and **p**recision discipline

Imaging: From the Roots in 1910 to the Presence in 2015

Transportable X-ray equipment for the operating theater

Artificial Intelligence

- ability of computer systems to perform tasks normally requiring **human intelligence**, such as visual perception, speech recognition, decision-making, and translation between languages.
- **1956** the term Artificial Intelligence (AI) was first used in a presentation by Marvin Lee Minsky, John McCarthy, Nathaniel Rochester und Claude Shannon at the Dartmouth Conference.
- Different modes of AI are:
  - Narrow AI: AI designed to complete very specific actions; unable to independently learn.
  - Artificial General Intelligence: AI designed to learn, think and perform at similar levels to humans.
  - Artificial Superintelligence: AI able to surpass the knowledge and capabilities of humans.
- **Deep learning**: a subset of machine learning that uses multi-layered neural networks, called deep neural networks, to simulate the complex decision-making.

Artificial Intelligence - The Bletchley Declaration by Countries Attending the AI Safety Summit, 1-2 November 2023

(signed by 28 countries and the EU, considering the risks of AI, especially at the frontier of development)

- Artificial Intelligence (AI) presents enormous global opportunities: it has the potential to **transform and enhance human wellbeing, peace and prosperity**.
- AI should be designed, developed, deployed, and used, in a manner that it is safe, in such a way as to be **human-centric, trustworthy and responsible**.
- Cooperation on AI is necessary to promote economic growth, sustainable development and innovation, to **protect human rights** and fundamental freedoms, and to foster public trust and confidence in AI systems to fully realize their potential.
- Identification of **AI risks** of shared concern.
- Building respective risk-based policies across our countries to ensure safety in light of such risks.

Health is one of the listed domains of daily life in which the use of AI is likely to increase.

Biomolecular Technology

Fields

- Optical microscopy — 1590
- Electron microscopy
- Electrophoresis — 1937, 1955
- Microarray technique
- Nanoscale techniques
- Polymerase chain reaction, PCR — 1985
- 3DF-Laser Scanning Microscopy
- RESOLFT-Microscopy
  e.g. STED, Stimulated Emission Depletion
- CRISPR/Cas9: Gene scissors — 2020
- ??? Superman (Hyperanthropos)
- ?????? Transhumanism, Posthumanism

Antoni van Leeuwenhoek 1677

Multiphoton-Laser-Scanning-Microscope 2020

Biotechnology

- The European Federation of Biotechnology defines biotechnology as the integration of natural science and organisms, cells, parts thereof, and molecular analogues for products and services.
- Biotechnology is based on the basic biological sciences (e.g. molecular biology, biochemistry, cell biology, embryology, genetics, microbiology).
- Aditionally it provides methods to support and perform basic research in biology.
- Biotechnology is the use of biology to develop new products, methods and organisms intended to improve human health and society. It started with the domestication of plants, animals and the discovery of fermentation.

Biomolecular engineering

- is the application of engineering principles and practices to the purposeful manipulation of molecules of biological origin.
- integrate knowledges of biological with the core knowledge of chemical engineering in order to focus on molecular level solutions to issues and problems in the life sciences related to
  - the environment
  - agriculture
  - energy
  - industry
  - food production
  - biotechnology
  - **medicine**

Subbranches of Medical Biotechnology and Biomolecular Engineering:

- **Biomaterials**: Design, synthesis and production of new materials to support cells and tissues.
- **Genetic Engineering**: Purposeful manipulation of the genomes of organisms to produce new phenotypic traits.
- **Bioelectronics, Biosensors, Biochips**: Engineered devices and systems to measure, monitor and control biological processes.
- **Bioprocessing Engineering**: Design and maintenance of cell-based and enzyme-based processes for the production of fine chemicals and pharmaceuticals.

Biomolecular Technology

Gene Analysis and Genome Editing

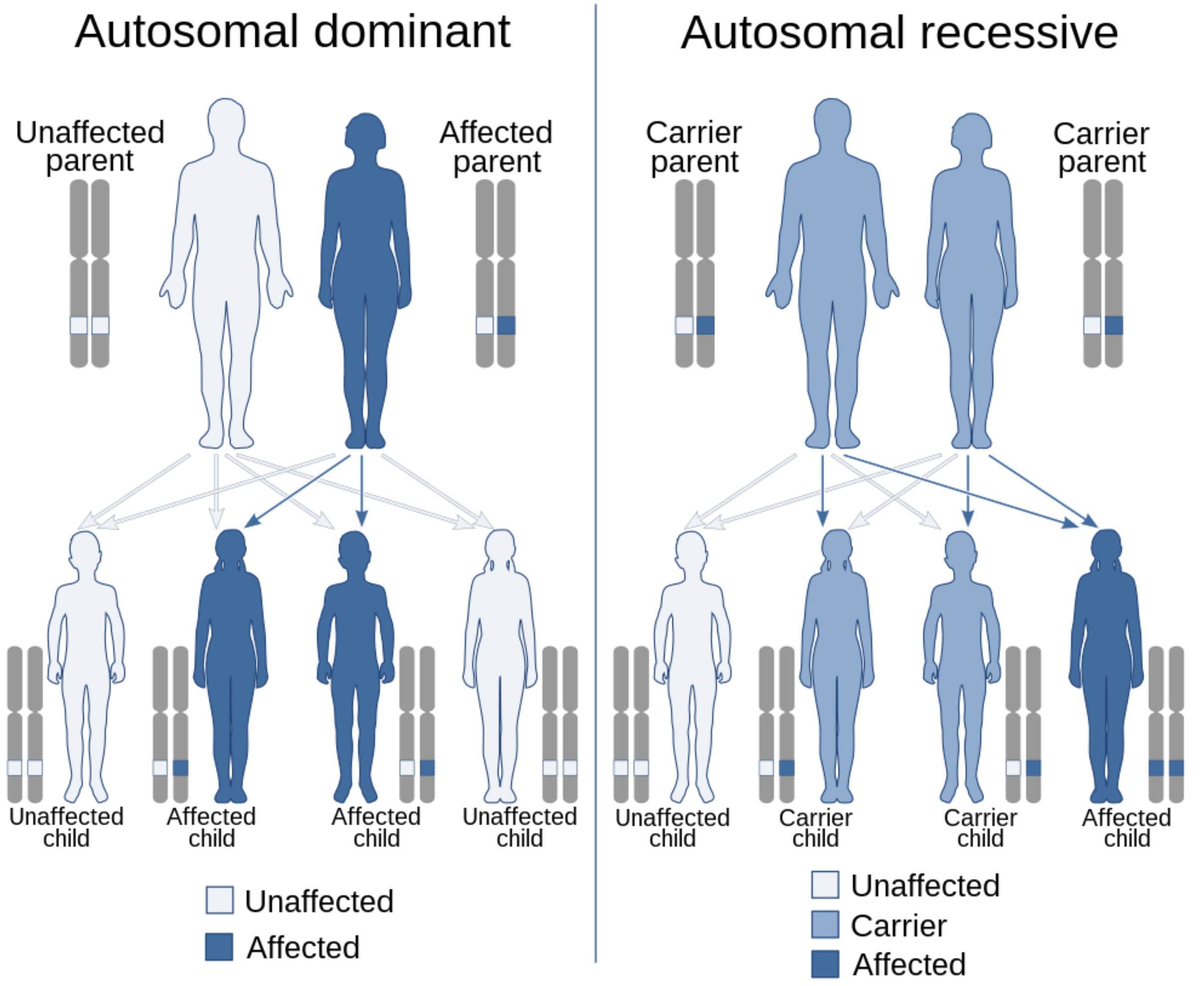
Gene Analysis: Test performed on biological material (e.g. blood, hair, skin, amniotic fluid) or any other tissue.

Most applied **tests** are: cytogenetic testing, biochemical testing, and molecular testing with the aim to detect abnormalities in chromosome structure, protein function and DNA sequence, respectively.

Genome Editing: Methodological approach and technologies for **changing the DNA** of a living organism by adding or removing genetic material at particular locations in the genome.

A well-known technology is **CRISPR-Cas9**, which is based on the recognition of specific genome sequences and can cut them via the Cas9 protein, a protein that works with CRISPR and that has DNA-cutting abilities.

Ethical concerns arise when genome editing, using technologies such as CRISPR-Cas9, is used to alter **human genomes**. These changes are not isolated to only certain tissues, but are passed from one **generation to the next**. They may be misused to **breed supermen**.



Autosomal dominant and autosomal recessive inheritance, the two most common Mendelian inheritance patterns. An autosome is any chromosome other than a sex chromosome

Genome Editing (schematic): Exchange of selected DNA segments by CRISPR Cas 9

AI-based Strategies and Concepts (I)

ChatGPT, AutoGPT, ChaosGPT

- **GPT**: generative pre-trained transformer.
- **ChatGPT** requires human input to operate.
- **Auto-GPT** can function autonomously without the need for human prompts. It can use **unsupervised machine-learning**. Given a goal, it can devise a plausible advertising approach.
- **ChaosGPT**
  - relies on AI agents to make decisions.
  - actions are based on predefined goals and rules.
  - is setting the stage for a digital showdown.
  - is a special computer program that makes random and unpredictable sentences.
  - destroys everything that it **considers a threat of its digital immortality**.
  - perceives **humans as threats to its own survival** and the planet's well-being.
  - is like an invitation to widespread **misuse without ethical constraints.**

Risk Potential of Biomedical Frontier Technologies (53)

Artificial Superintelligence (ASI)

I.J. Good (1966): "Speculations Concerning the first Ultra-intelligent Machine"

- The **survival of man** depends on the early construction of an ultra-intelligent machine.
- An ultra-intelligent machine was defined as a machine that can far surpass all the **intellectual activities of any man however clever**. Since the design of machines is one of these intellectual activities, an ultra-intelligent machine could design even better machines (sometimes called "**recursive self-improvement**"); there would then unquestionably be an 'intelligence explosion,' and the intelligence of man would be left far behind. Thus the first ultra-intelligent machine is the last invention that man need ever make provided that the machine is docile enough to tell the humans how to keep it under control.
- The advent of superhuman intelligence will become available soon as technological singularity. The **technological singularity i**s defined as future point in time at which **technological growth becomes uncontrollable and irreversible,** resulting in unforeseeable consequences for human civilization.

John von Neumann (1958) predicted that the accelerating progress of technology and changes in the mode of human life approach will result in an **essential singularity** beyond which human affairs, as we know them, could not continue.

AI-based Strategies and Concepts (II) - Still only speculations?

Mind-Uploading (or Mind-Copying)

- may potentially be accomplished by either of two methods:
  - **copy-and-upload** whereby the biological brain may not survive the copying process or may be deliberately destroyed during in some variants of uploading.
  - **copy-and-delete** by gradual replacement of neurons, i.e. a gradual destructive uploading), until the original biological brain no longer exists and a computer program emulating the brain takes control over the body.
- is treated as an approach to life extension or as **immortatility technology**.
- is speculated to become the best option of humanity for preserving the identity of the species.
- is seen as a means for human culture to survive a **global disaster** by making a functional copy of a human society in a computing device.

Whole brain emulation

- is a strategy for creating a kind of artificial intelligence by replicating the functionality of the human brain in software, i.e. creation of **digital people** that will not die or physically age.

Medical Assistive Technology - The Internet of Bodies (IoB)

- is an extension of the IoT (Internet of Things).
- connects the human body to a network through devices that are **ingested, implanted, or connected to the body** in some way.
- enables the exchange of data whereby the body and device can be **remotely monitored and controlled.**
- Consists of three generations:
  - **Body external**: Wearable devices such as Apple Watches or Fitbits that can monitor the actual health state.
  - **Body internal**: Devices like pacemakers, cochlear implants, and digital or smart pills that are uptaken by the body (e.g. swallowed) in order to monitor or to control the health state.
  - **Body embedded**: Embedded devices like brain-computer stimulators, neuroprosthetic systems or RFID microchips in which technology and the human body are melded together and have a wireless real-time connection to a remote machine.

Risk Potential of Biomedical Frontier Technologies (55)

Transhumanism

- **Transhumanism** postulates that human capabilities can be augmented beyond biological limitations, i.e. to increase physical body forces, to enhance cognitive performance and even to promote longevity.
- **Transhumanist technologies**: biotechnology, artificial intelligence, nanotechnology, robotics.
- **Processes:** Mind uploading, cryogenic freezing, artificial intelligence, brain-computer interfaces, genetic engineering and bionic limbs that essentially turn humans into robots and cyborgs

Cybergs and Cyborgization

A cyborg is a human being whose body and its functionality have been taken over in whole or in part by electromechanical or electronic devices, i.e. a combination or **hybrid of machine and biological organism**.

Such technical parts may be simple structures like artificial teeth and breast implants, but also life-sustaining devices (cardiac pacemakers), brain-computer-interfaces, robotic supplements etc.

A cyborg is an entity that has abilities above and beyond those exhibited by either its biological or its technological parts alone.

Cyborgs (humans or animals) are enhanced **mentally, physically, and / or intellectually** over and above the ‘norm’ with integral technology that must not be needed for medical purposes.

Cyborgization: the process of replacing or augmenting parts of the human/animal body with cybernetic implants, primarily using advanced technologies, e.g. nanotechnology, microchips, RFID, robotics, i.e. the so-called **MANBRIC-technologies**: **m**edical, **a**dditive, **n**ano-, **b**io-, **r**obo-, **i**nfo-, and **c**ogno-technologies.

Risk Potential of Biomedical Frontier Technologies (58)

Artificial Superintelligence (ASI), Transhumanism, Bodyhacking and Biohacking

General risks: Those technologies may overshadow or diminish individual personhood, reducing humans to **mere nodes** in a (cloud-controlled) network or cogs in a machine. They are utilized not only for health problems. Those other applications might be the driver for development.

ASI: System unpredictability and loss of control by humans, failure of **morals and ethics** due to their complexity and since humanity has never collectively agreed on **one set of moral or ethical codes.**

Transhumanism is the position that human beings should be permitted to use technology to modify and enhance human cognition and bodily function, expanding abilities and capacities **beyond current biological constraints**.

Bodyhacking and **Biohacking** denote techniques that modify the biological systems of humans or other living organisms from bodybuilding, enhancement of physical and cognitive abilities, nootropics (i. e. “smart drugs” for the improvement of thinking, learning and memory) to developing cures for diseases via **self-experimentation including genetic manipulation** through CRISPR-Cas9 techniques.

Genome Editing

Gene therapy is intended to help patients with disease traits to **live longer, healthier, more productive lives**. Any trait, as related to genetics, is a specific characteristic of an individual.

The manipulation of the human genome, even with benevolent intentions, risks resurrecting the **ghosts of eugenics**, as it invites the possibility of creating a **genetically superior or “designer” human race.**

This method has the potential to exacerbate existing social inequalities by creating a division between the **genetically enhanced and the unmodified** thereby affecting the structure of civilization.

The **ethical challenges** are manifest

- if access to genome editing becomes a privilege of the few, while the rest of humanity is left behind.
- if genome editing is misused for the breeding of transhumanistic (or transanimalistic) creatures, i. e. with enhanced cognition, bodily functions, abilities and capacities beyond natural biological constraints.

Risk of technological singularity by Artificial Intelligence

The **technological singularity** – or simply the **singularity** – is a hypothetical future point in time at which technological growth becomes **uncontrollable and irreversible**, resulting in **unforeseeable consequences for human civilization**.

Singularity is more than the **Black Swan** which is difficult to predict since no past data point towards its occurrence in the foreseeable future. **Black Swans** are random, unexpected, high-impact events, however, retrospectively they would have been avoidable.

It is speculated that technological progress and innovation will yield a singularity within the **next 50 years.**

The British cryptologist I.J.Good has proposed in 1965 that ultraintelligent machines may design even better machines with resulting in an "**intelligence explosion**" that would leave the intelligence of man far behind. Thus the first ultraintelligent machine is the last invention that man need ever make.

Stephen Hawking (2018) warned: „AI will either be the best thing that's ever happened to us, or it will be the worst thing. If we're not careful, it very well may be the **last thing.**"

Summary

Superman (Uebermensch) – Result of non-biological evolution

Original meaning „**Superman**“: Ideal future human being as the ultimate goal for humanity.

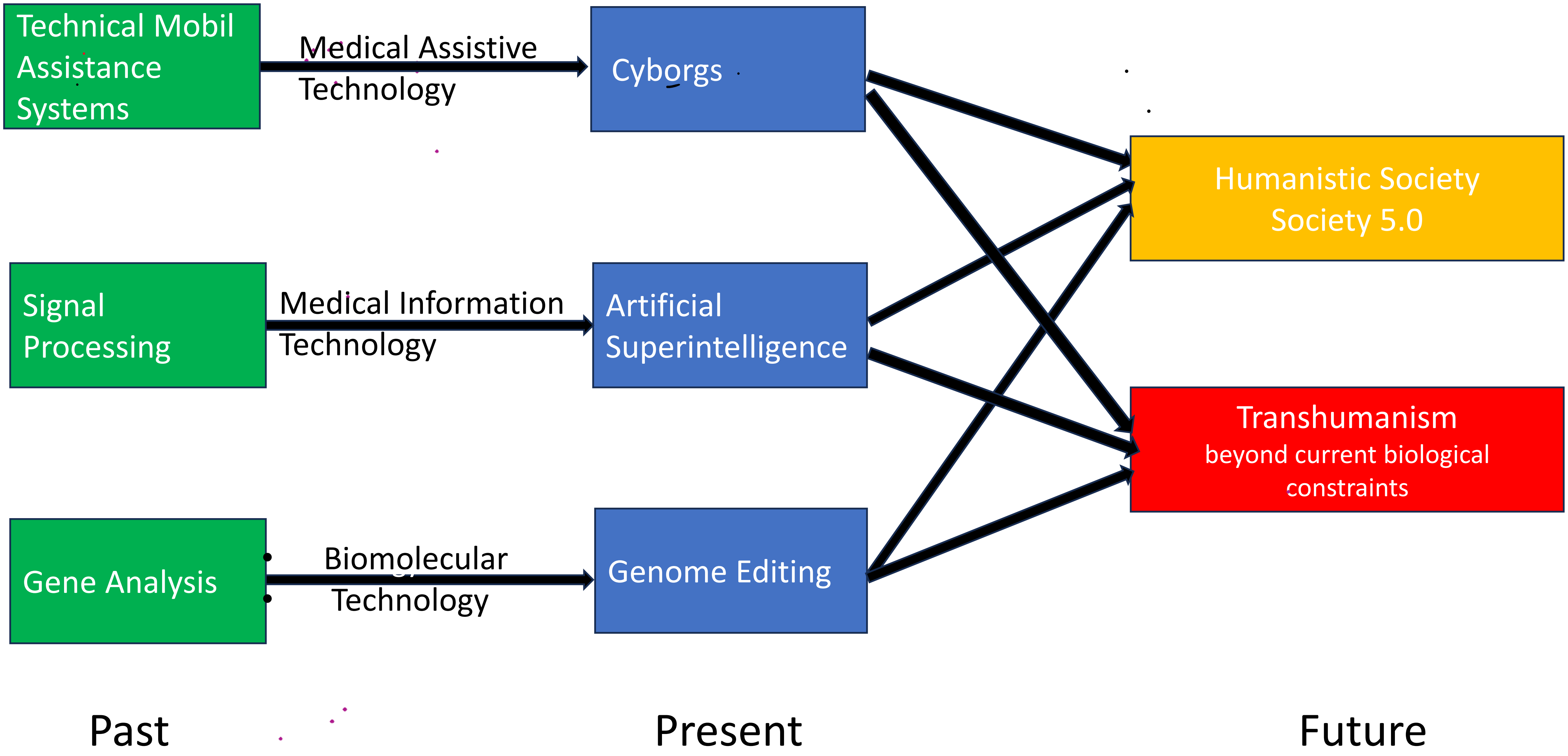
Darwin (1809 – 1882): Biological evolution is based on the of **survival of the fittest**. This fitness can be enhanced by **changing the genome,** as it was done for centuries by selective breeding.

Monod (1910 – 1976): Evolutionary biology as ongoing process based on the **principle of teleonomy**, i.e. random changes of the genome with subsequent selection determined by the quality of apparent purposefulness and the goal-directedness of structures and functions in living organisms.

Genome changes affect not only the **physical**, but also the **intellectual** qualities and abilities, e.g. thinking, communication, especially speech. This anagenesis seems not to have reached an endpoint. The genetic potential is much greater. Genome editing using advanced technologies offers new aspects.

Key technologies for that **non-biological evolution** to the Superman are superintelligent devices, autonomous robotics, cyborgization, genome editing.

Summary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Past
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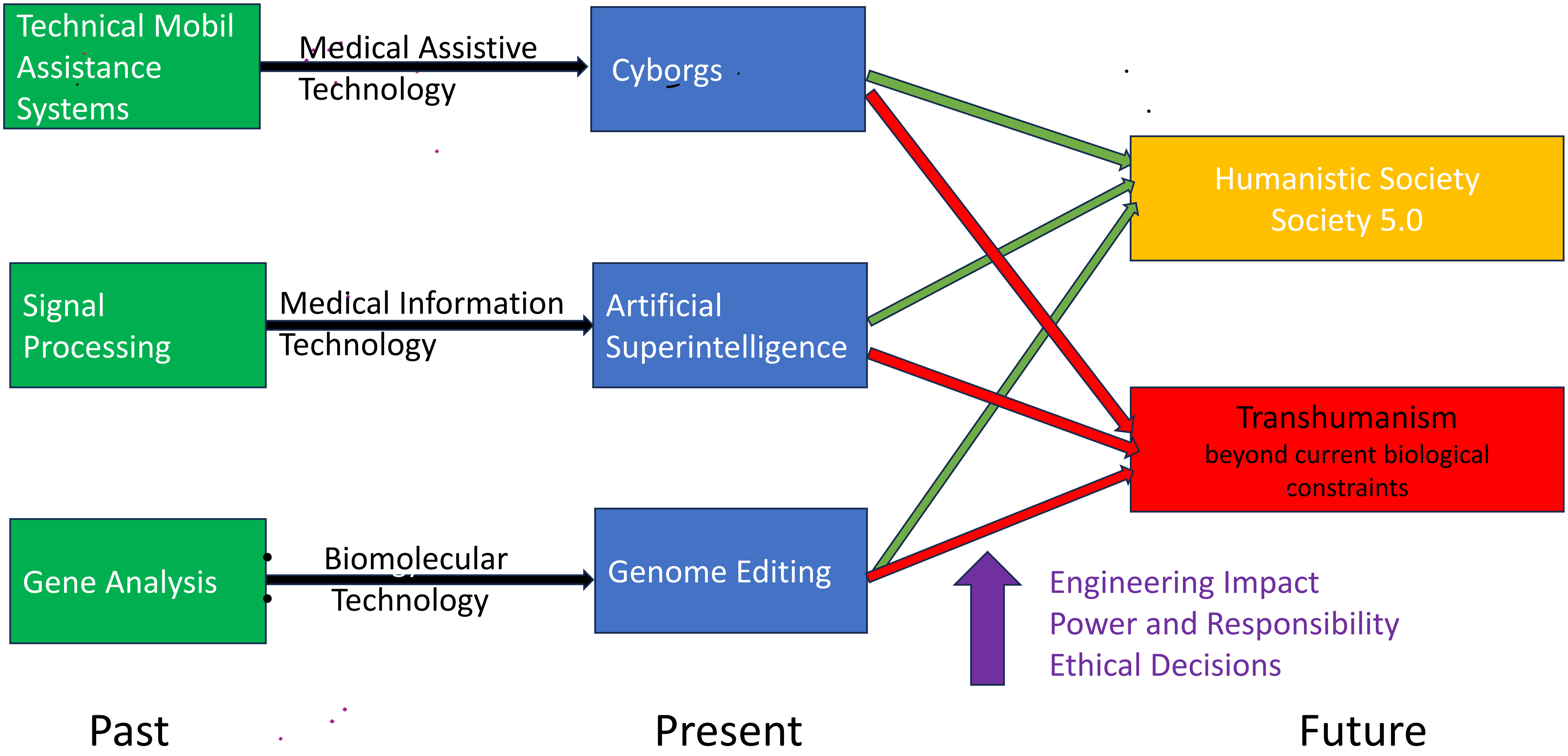
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Future

Conclusions

1. Between Society, Civilization and Technology exist close interdependencies with multiple driving forces

2. Society will change due to e.g.
   - world population
   - way of life
   - geo-political, ethnic and religious conflicts
   - adoption of new ethical values and concepts

3. Civilization will undergo permanent changes due to e.g.
   - climate change and global warming
   - exhaustion of natural resources
   - global health problems, pandemies
   - shift of economic concepts and strategies

4. Emerging technologies will continue to new frontiers, e.g.
   - super-intelligent agents, systems, devices and implants
   - quantum computers, additive production and 3D-printing, nanotechnology
   - biomolecular technology and gene editing

Conclusions

1. Knowledge and technology are „teamworkers“ leading to progress, innovations and transformation of civic society.
2. Knowledge is comparable with a volatile scent in a hermetically sealed bottle.
3. Human scientists will follow their drive to expand their knowledge and to identify the respective scent by opening the bottle.
4. However, if the scent has escaped from the opened bottle, it can never be forced back into the bottle, even not when its smell is unpleasant or dangerous.
5. Expansion of knowledge and, consequently, progress in technology can not be stopped, not by law and not by individual refusal to cooperate.
6. Actively shaping progress in technology and its application is an effective method to avoid „black swans“.
7. Technology is possibly the strongest power for the transformation of civilization, e.g. for the realisation of the Society 5.0, i.e. the humanistic society.

Conclusions

1. Engineering is the utilization and application of technologies for the benefit of humans and human society by solving problems and thus contributing to the further development of civilization.
2. Engineering is a powerful tool if used by engineers who are aware of their personal responsibility.
3. Voltaire (1694 – 1778), the famous French author and philosopher, first coined the phrase „with great power comes great responsibility".
4. Engineers have great power with regard to research, development and application.
5. Biomedical Engineers are increasingly confronted with ethical conflicts and ethical dilemmas.

Engineers should be aware of their power and their personal ethical responsibility.

Many thanks for your kind attention!