"IBC uses the term Big Data in the area of health as referring to large collections of complex health-related data sets from multiple sources. Typically such data sets cover very large numbers of individuals, but analysis of all available data from one single patient under certain conditions can also be considered Big Data analysis."
Big Data: The 5 Vs

- **Volume**: The size of data
- **Velocity**: The speed at which the data is collected, processed and applied
- **Variety**: The different types of data from different sources and in different forms
- **Validity**: The meaning and impact of data
- **Value**: The quality of data
Constitution of the World Health Organization

THE STATES Parties to this Constitution declare, in conformity with the Charter of the United Nations, that the following principles are basic to the happiness, harmonious relations and security of all peoples:

*Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.*

The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.

The health of all peoples is fundamental to the attainment of peace and security and is dependent upon the fullest co-operation of individuals and States.

adopted 22 July 1946, New York
Converging Technologies and Cybernetic Loops

Rules for the digital human park
Two paradigmatic cases of breeding and taming human beings: Human germline editing and persuasive technology

Rinie van Est, Jelte Timmer, Linda Kool, Niesl Nijsingh, Virgil Rerimassie, Dirk Stemerding

„So while individuals are becoming increasingly transparent, our technological environment is becoming ever more opaque.“
Ethical Aspects

1. Autonomy and Consent
   - Scope of consent: broad and / or dynamic consent
   - Default settings

2. Privacy and confidentiality
   - Lacking guarantee of permanent anonymization
   - Freedom from being profiled and from an accordingly shaped environment

3. Ownership → Custodianship → Benefit Sharing
   - Responsibility of all stakeholders and the common good
4. Justice
   • Digital gap between and within countries
   • Non-discrimination
5. Sustainability
   • Energy
   • Environment
Recommendations

- **Aims**
  - Harvest the benefits of Big Data in healthcare and health research
  - Protect fundamental human rights
  - Foster public good
  - Keep the balance between control and trust

- **Approach**
  - Cooperation
  - Governance
  - Participation
Four crucial areas of recommended measures

1. Governance
2. Education
3. Capacity Building
4. Benefit Sharing
A multi-tiered governance framework should address and include e.g.:

i. Purpose of the database

ii. Procedures for (broad) consent, re-contact and re-consent

iii. Arrangements for ensuring the rights to access, to rectify, and to cancel data

iv. Arrangements for withdrawal

v. Arrangements for the protection of privacy

vi. Policies after the death of a participant

vii. Arrangements on ownership of the data and products derived from them

viii. Transparency of the algorithms used for pattern recognition; arrangements to check profiling of individuals or groups according to ethical considerations

ix. Arrangements for benefit sharing
• Codes of conducts
• Self-binding instruments
• Ethical policies
• Ombudsmen
• Checklists
International Agencies

• UN: International Legal Instrument on Data Protection in Health Care and Health Research
• UNESCO: Convention on the Protection of Privacy
• WHO: Agreement by App-Stores
• OECD: Framework for Sharing of Benefits from Big Data Applications
• Public data infrastructure
• Global Vigilance System
• Definition of technical standards according to the ethical principles (e.g. IEEE, regional and national institutions)
• IEA: pooling and coordination of efforts for a sustainable and responsible use of energy in Big Data management
• Environmental Protection Agencies (e.g. UN Environment9 together with WHO: Action Plan for saving rare resources; program to avoid e-waste
National Governments

• Implementation of globally accepted data protection principles

• Establishment of effective Data Controlling Agencies, working together with the Global Vigilance System → International Legal Instrument on Data Protection

• Capacity-Building including an efficient data infrastructure

• Promotion of learning healthcare systems

• Enabling effective cross-border cooperation

• Education with regard to Big Data–related skills, competences, and awareness about ethically relevant implications

• Introduction of diverse models of consent

• Protection of privacy by default as well as by design

• Implementation of a Research Ethics Committee or a similar institution overseeing commercial Big Data research

• Instruments for public and patient involvement

• Coordinated programs for communication protocols that enable energy savings