Innovazione Tecnologica e Intelligenza Artificiale

Commissione IA AOU Careggi, Firenze

27 novembre 2024

Il contesto

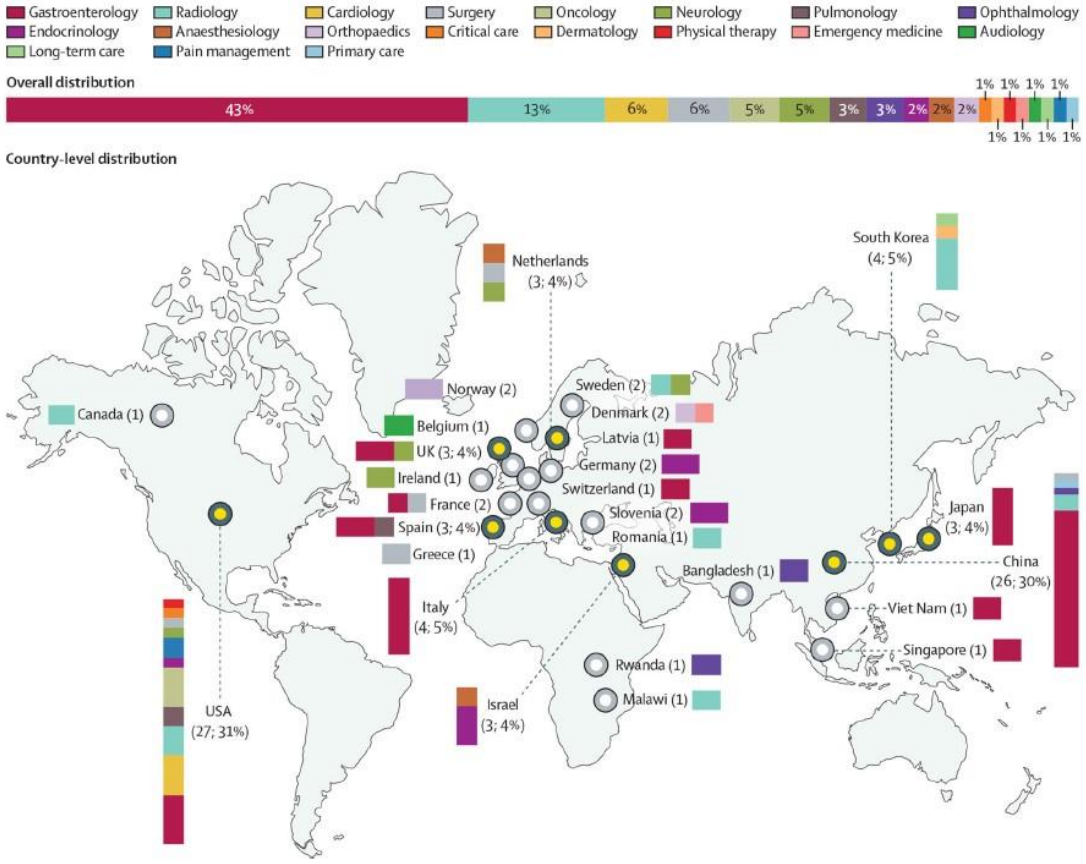

Figure 2: Randomised controlled trials of artificial intelligence in clinical practice across countries and specialties

Norway, France, Sweden, Denmark, Germany, and Slovenia each comprise 2% of the distribution. Canada, Belgium, Ireland, Greece, Latvia, Switzerland, Romania, Bangladesh, Rwanda, Malawi, Viet Nam, and Singapore each comprise 1% of the distribution.

Randomised controlled trials evaluating artificial intelligence in clinical practice: a scoping review; *Lancet Digit Health. 2024 May ; 6(5): e367–e373*

Tre quesiti chiave

- Regolatorio
- Scientifico
- Etico

Regolatorio

Regolamento europeo Dispositivi Medici 745/2017

Regolamento europeo Diagnostici in vitro 746/2017

Food and Drug Administration (FDA) definisce e regolamenta i Software as Medical Device (SaDM) e include riflessioni su algoritmi AI

Ministero della Salute è Autorità Competente (AC) per la ricerca su DM e IVD

Scientifico

Studi Randomizzati

-Guidelines for clinical trial protocols for interventions involving artificial intelligence: the SPIRIT-AI Extension

-Reporting guidelines for clinical trial reports for interventions involving artificial intelligence: the CONSORT-AI extension

SPIRIT-AI 10 (i) Elaboration: State the inclusion and exclusion criteria at the level of participants.
SPIRIT-AI 10 (ii) Extension: State the inclusion and exclusion criteria at the level of the input data.
SPIRIT-AI 9 Extension: Describe the onsite and offsite requirements needed to integrate the AI intervention into the trial setting.

Studi single arm non comparativi

-TRIPOD+AI statement: updated guidance for reporting clinical prediction models that use regression or machine learning methods

-Protocol for development of a reporting guideline (TRIPOD-AI) and risk of bias tool (PROBAST-AI) for diagnostic and prognostic prediction model studies based on artificial intelligence

D=items relevant only to the development of a prediction model;
E=items relating solely to the evaluation of a prediction model;
D;E=items applicable to both the development and evaluation of a prediction model.

Real-time automatic detection system increases colonoscopic polyp and adenoma detection rates: a prospective randomised controlled study

Wang P, Berzin TM, Glissen Brown JR, et al. Gut 2019;68:1813–1819.

Design: In an open, non-blinded trial, consecutive patients were prospectively randomised to undergo diagnostic colonoscopy with or without assistance of a real-time automatic polyp detection system providing a simultaneous visual notice and sound alarm on polyp detection. The primary outcome was ADR. **Results**: Of 1058 patients included, 536 were randomised to standard colonoscopy, and 522 were randomised to colonoscopy with computer-aided diagnosis. The artificial intelligence (AI) system significantly increased ADR (29.1% vs 20.3%, p<0.001).

…. prima degli RCT ….
Studi single arm non comparativi

A questo livello si «posizionano» tutte le questioni relative alle fasi di addestramento e validazione degli algoritmi

Si pongono i problemi dei database sui quali le reti sono state addestrate, della loro rappresentatività, in termini di popolazioni e qualità dei dati

Si pongono i problemi relativi al percorso di validazione (su coorti diverse da quelle utilizzate per l'addestramento), sul management e sulla qualità dei dati, sui valori missing, ecc.

Etico

POSITION PAPER

Annals of Internal Medicine

Artificial Intelligence in the Provision of Health Care: An American College of Physicians Policy Position Paper

Nadia Daneshvar, JD, MPH; Deepti Pandita, MD; Shari Erickson, MPH; Lois Snyder Sulmasy, JD; and Matthew DeCamp, MD, PhD; for the ACP Medical Informatics Committee and the Ethics, Professionalism and Human Rights Committee*

Internal medicine physicians are increasingly interacting with systems that implement artificial intelligence (AI) and machine learning (ML) technologies. Some physicians and health care systems are even developing their own AI models, both within and outside of electronic health record (EHR) systems. These technologies have various applications throughout the provision of health care, such as clinical documentation, diagnostic image processing, and clinical decision support. With the growing availability of vast amounts of patient data and unprecedented levels of clinician burnout, the proliferation of these technologies is cautiously welcomed by some physicians. Others think it presents challenges to the patient–physician relationship and the professional integrity of physicians. These dispositions are understandable, given the "black box" nature of some AI models, for which specifications and development methods can be closely guarded or proprietary, along with the relative lagging or absence of appropriate regulatory scrutiny and validation. This American College of Physicians (ACP) position paper describes the College's foundational positions and recommendations regarding the use of AI- and ML-enabled tools and systems in the provision of health care. Many of the College's positions and recommendations, such as those related to patient-centeredness, privacy, and transparency, are founded on principles in the ACP Ethics Manual. They are also derived from considerations for the clinical safety and effectiveness of the tools as well as their potential consequences regarding health disparities. The College calls for more research on the clinical and ethical implications of these technologies and their effects on patient health and well-being.

Ann Intern Med. 2024;177:964-967. doi:10.7326/M24-0146 **Annals.org**
For author, article, and disclosure information, see end of text.
This article was published at Annals.org on 4 June 2024.

Raccomandazioni

1) …. AI in health care must be aligned with principles of medical ethics, … enhance patient care, clinical decision making, the patient–physician relationship, and health care equity and justice

2) …clinical safety and effectiveness, as well as health equity, must be a top priority … using a continuous improvement process … testing in diverse real-world clinical contexts …

3) …should reduce rather than exacerbate disparities in health and health care… to include data from diverse populations ….

4) …the oversight of the development, deployment, and use of AI-enabled medical tools

5)… environmental impacts of AI and their mitigation should be studied and considered throughout the AI cycle

Big data, databases and algorithms: models of reality

(*in Mario Capocci, 2018*)

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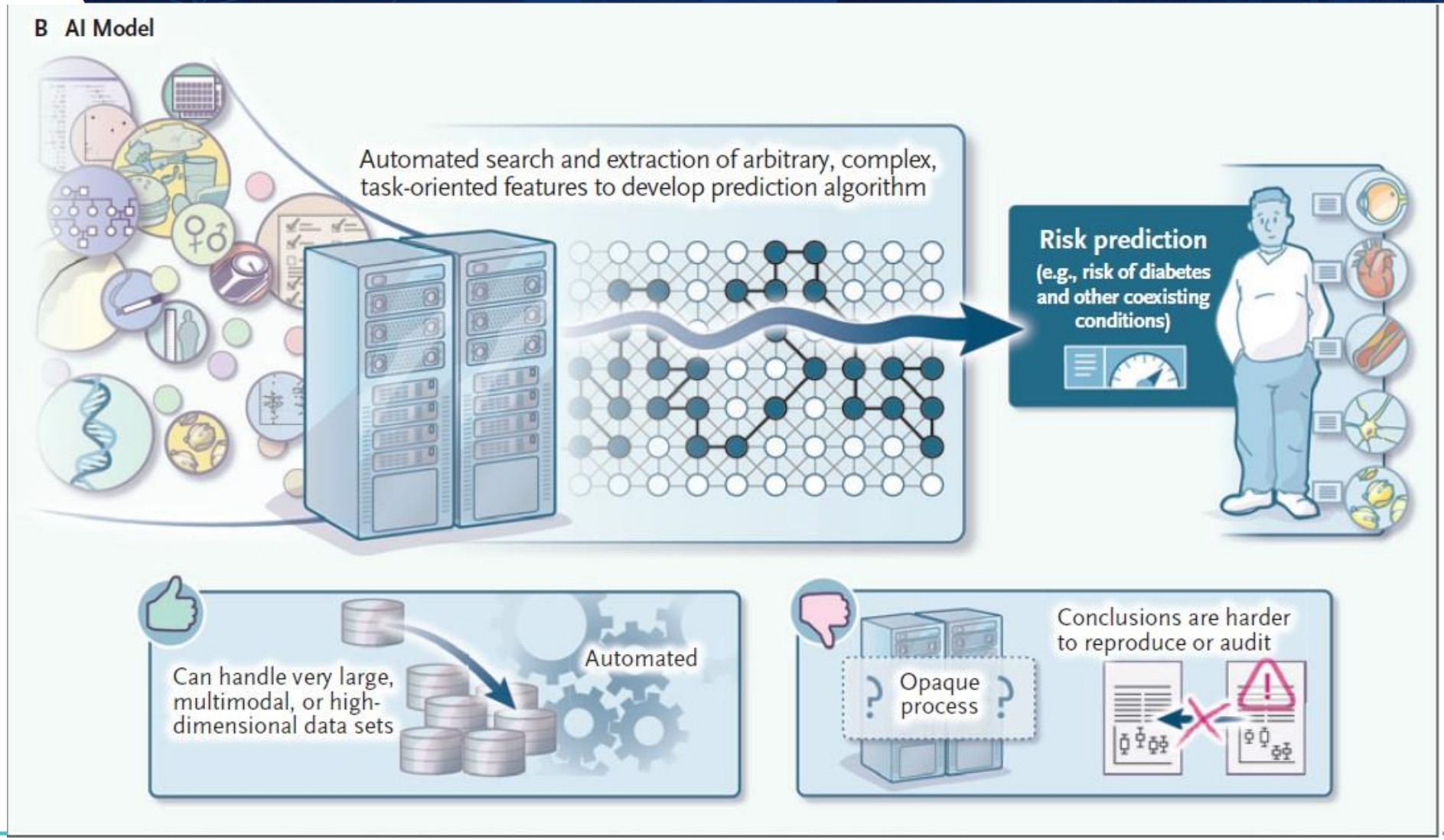


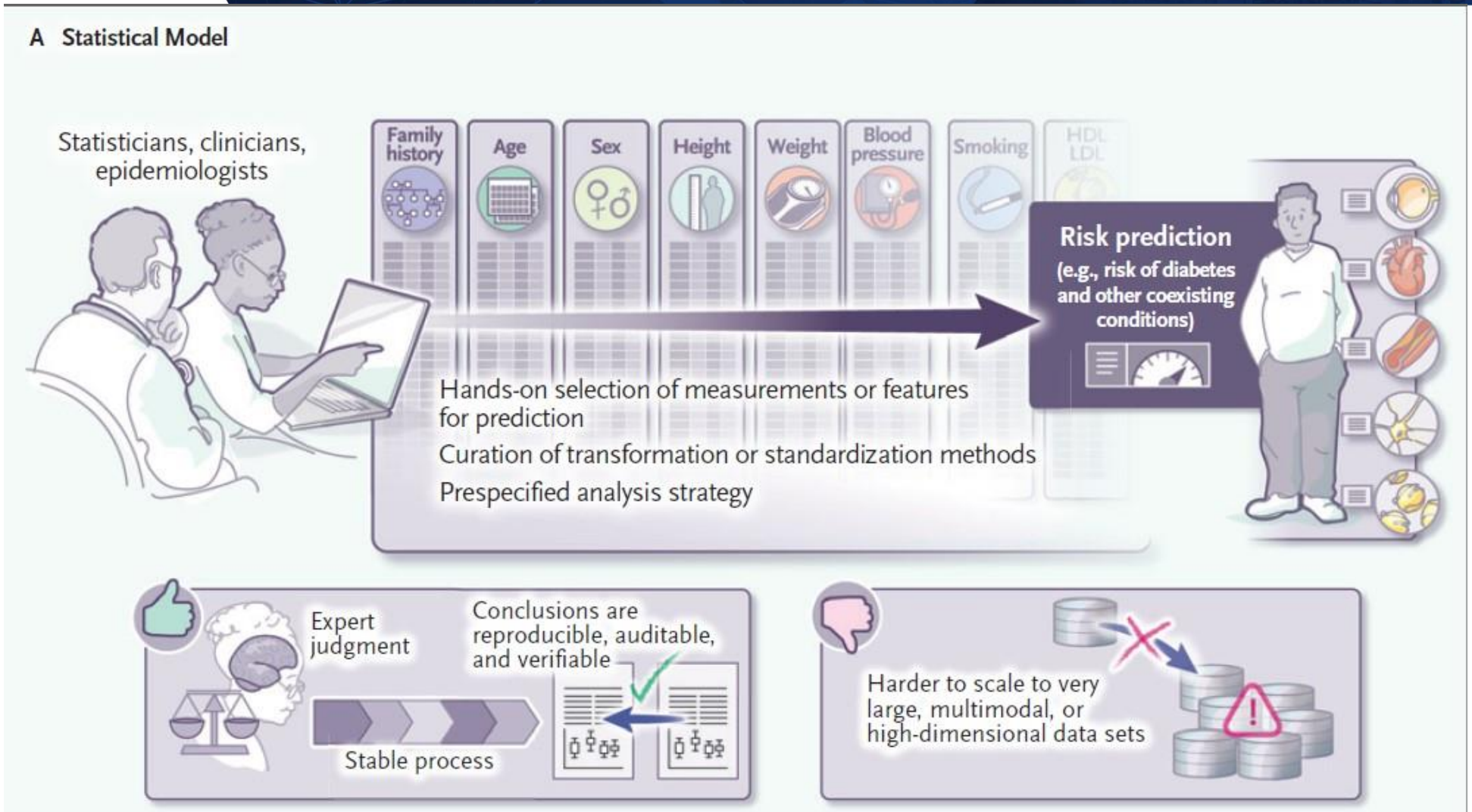
Where Medical Statistics Meets Artificial Intelligence

David J. Hunter, M.B., B.S., and Christopher Holmes, Ph.D.

N Engl J Med 2023;389:1211-9.

Generalizability and Interpretation

AI algorithms have poorly defined notions of statistical degrees of freedom and the number of free parameters. Thus, traditional statistical guarantees against overoptimism cannot be used, and techniques such as cross-validation and held-out samples to mimic true out-of-sample performance must be substituted, with the tradeoff that the amount of data available for discovery is reduced. With these factors taken together, the risk is overinterpretation of the generalizability and reproducibility of results


A Statistical Model
Statisticians, clinicians, epidemiologists
Family history
Age
Sex
Height
Weight
Blood pressure
Smoking
HDL
LDL
Risk prediction
(e.g., risk of diabetes and other coexisting conditions)
Hands-on selection of measurements or features for prediction
Curation of transformation or standardization methods
Prespecified analysis strategy
Expert judgment
Conclusions are reproducible, auditable, and verifiable
Stable process
Harder to scale to very large, multimodal, or high-dimensional data sets

…. remember…. ACP document….

…should reduce rather than exacerbate disparities in health and health care… to include data from diverse populations ….

….sampling bias often leads researchers to compare white of European descent with other large groups ... Europeans and Americans … the best studied human group, they are largely overrepresented in research. Researchers institutions and regulative bodies have reacted by making the inclusion of “minorities” in research mandatory. Especially in the North-American context, where racial categories are deeply embedded, this feedback has reinforced the idea of geneticization of race (and other human traits).

big data may embody already existing socio-economic inequalities, and disparities in access to technology may reinforce such inequalities… identities based on genetic or biological conditions

P. Rabinow, Artificiality and Enlightenment: From Sociobiology to Biosociality, 1996

Riflessioni

L'assunto su cui si basa l'usabilità trasversale di reti già addestrate consiste nella invariabilità delle forme (delle relazioni e delle funzioni). Relazioni e funzioni che legano le diverse componenti analizzate sono modellizzate dalle reti secondo forme che sarebbero comuni ai topics antropologici, medici, radiologici, ecc.

I dati manipolati dalle reti sono convertiti in numeri. In origine abbiamo simboli, cioè dati espressi in forma rappresentativa, mentre la conversione in numeri, sui quali si effettuano tutte le operazioni di modellizzazione e ricerca delle relazioni, rende il materiale manipolato dalla rete, non esprimibile in forma simbolica, bensì pre-simbolica. La dizione di black-box applicata alle operazioni effettuate all'interno della rete, si riferisce, quindi, all'inesprimibilità, più che all'opacità.

Sviluppi

Pazienti sintetici (Synthpop in R)

Organi sintetici (Progetto Vital Gent University e UniPi)

Statement di AOU Careggi su governo di tecnologie AI nella cura, ricerca e organizzazione

non soltanto sulle dovute cautele in materia di:
-ruolo del personale sanitario
-equità e disparità
-sicurezza
-governo
-impatto ambientale

Attenzione agli assunti, agli impliciti di funzionamento:

Riflessione su sviluppi inattesi e allestimento misure di contenimento
Cosa significa ipotizzare la costanza delle forme delle relazioni (uso di reti già addestrate) ?
Cosa significa lavorare al livello pre-simbolico e riconvertire gli output in elementi simbolici ?

Metodi

Identificare il gruppo di lavoro

Identificare i destinatari

Ricognizione dei documenti rilevanti esistenti

Coinvolgimento degli esperti (fisico, ingegnere, informatico)

Adozione del Linguaggio appropriato

Le giuste domande, nel giusto linguaggio su uno sfondo tematizzato e non obliato (fenomenologico)