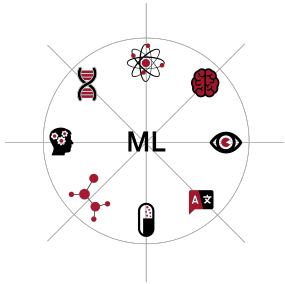


# Morals and Methodology

Konstantin Genin

Group Leader: "Epistemology and Ethics of ML"



EBERHARD KARLS  
UNIVERSITÄT  
TÜBINGEN





**Konstantin Genin**

Understanding the  
(topological) complexity of  
scientific problems.  
Interactions between  
morals and methodology.



**Vlasta Sikimic**

Data-driven approaches to  
optimizations of scientific  
reasoning. Fairness and  
privacy in AI-assisted  
education.



**Sander Beckers**

Formalizing notions of  
actual causation, harm,  
responsibility, and  
explanation.



**Sebastian Zezulka**

Fairness in algorithmic  
prediction of long-term  
unemployment in the  
German context.

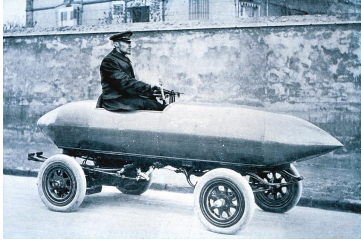
# Morals and Methodology

Methodological questions depend on ethical questions.

- Unethical experiments ought not to be performed;
- Unjust algorithms ought not to be implemented.

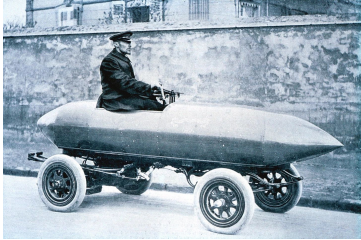
# Morals and Methodology

As researchers advance methods, ethicists race to install new guardrails.



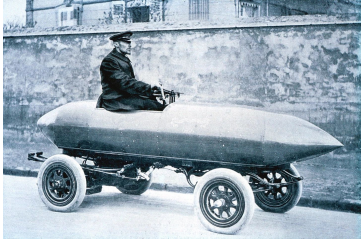
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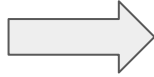
# Morals and Methodology

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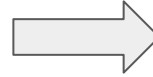
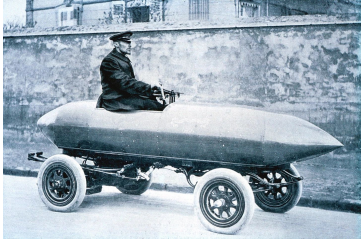
# Morals and Methodology

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# Morals and Methodology

As researchers advance methods, ethicists race to install new guardrails.



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# Morals and Methodology

But ethical questions also depend on methodological ones.

- RCTs in medicine and social science raise a variety of ethical issues, but are justified by their epistemic advantages, esp. for causal inference.
- As techniques for causal inference from observational data progress, there is pressure to reconsider the ethics of RCTs.

# Morals and Methodology

Methodological progress **should** lead to moral progress.



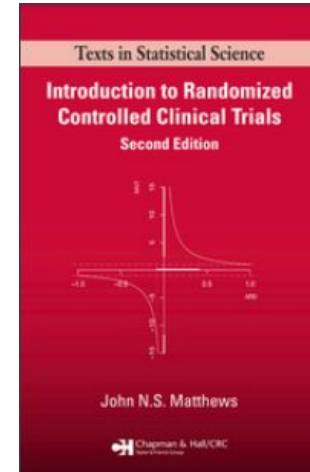
# Morals and Methodology

The goal of the Ethics and Epistemology research group is to approach the issue from both sides:

- How exactly do methodological constraints express themselves as ethical constraints?
- How exactly should ethical constraints be expressed in methodology?

# The Randomized, Controlled Trial (RCT)

“The RCT is the introduction of scientific method into the process of comparing treatments”



# The Randomized, Controlled Trial (RCT)

Attempts to discover the relative effectiveness of a new intervention over standard treatment or placebo. Patients are assigned to the different “arms” of the trial by a randomization device.

- Widely considered the “gold standard” research design;
- Typically necessary for FDA, EMA approval;
- Raises a number of tricky ethical issues.

# A call for RCTs for ML models in Clinical Settings

JAMIA Open, 3(3), 2020, 326–331  
doi: 10.1093/jamiaopen/ooaa033  
Advance Access Publication Date: 8 September 2020  
Perspective



## Perspective

### Evaluating artificial intelligence in medicine: phases of clinical research

Yoonyoung Park<sup>1</sup>, Gretchen Purcell Jackson<sup>2,3</sup>, Morgan A. Foreman<sup>1</sup>, Daniel Gruen<sup>1</sup>, Jianying Hu<sup>4</sup> and Amar K. Das<sup>1</sup>

<sup>1</sup>Center for Computational Health, IBM Research Cambridge, Cambridge, Massachusetts, USA, <sup>2</sup>Center for AI, Research, and Evaluation, IBM Watson Health, Cambridge, MA, USA, <sup>3</sup>Department of Pediatric Surgery, Vanderbilt University Medical Center, Nashville, Tennessee, USA and <sup>4</sup>Center for Computational Health, IBM T.J. Watson Research Center, Yorktown Heights, New York, USA

Corresponding Author: Yoonyoung Park, IBM Research, 75 Binney Street, Cambridge, MA 02142, USA (yoonyoung.park@ibm.com)

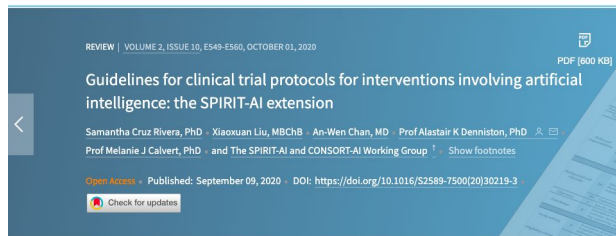
Received 11 September 2019; Revised 15 May 2020; Editorial Decision 25 June 2020; Accepted 1 July 2020

#### ABSTRACT

Increased scrutiny of artificial intelligence (AI) applications in healthcare highlights the need for real-world evaluations for effectiveness and unintended consequences. The complexity of healthcare, compounded by the user- and context-dependent nature of AI applications, calls for a multifaceted approach beyond traditional in silico evaluation of AI. We propose an interdisciplinary, phased research framework for evaluation of AI imple-

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ARTICLES | VOLUME 5, ISSUE 4, P352–361, APRIL 01, 2020

### Detection of colorectal adenomas with a real-time computer-aided system (ENDOANGEL): a randomised controlled study

Dexin Gong, MD<sup>1</sup>, Lianlian Wu, MD<sup>1</sup>, Jun Zhang, MD<sup>1</sup>, Ganggang Mu, MD<sup>1</sup>, Prof Lei Shen, MD<sup>1</sup>, Jun Liu, MM<sup>1</sup>, et al.  
Show all authors • Show footnotes

Published: January 22, 2020 • DOI: [https://doi.org/10.1016/S2468-1253\(19\)30413-3](https://doi.org/10.1016/S2468-1253(19)30413-3) • Check for updates

## Summary

Summary

References

## Philosophy of Medicine

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### Randomized Controlled Trials in Medical AI A Methodological Critique

#### Konstantin Genin

Research Group: "Epistemology and Ethics of Machine Learning"; Cluster of Excellence: Machine Learning: New Perspectives for Science; University of Tübingen, Germany

#### Thomas Grote

Ethics and Philosophy Lab; Cluster of Excellence: Machine Learning: New Perspectives for Science; University of Tübingen, Germany International Center for Ethics in the Sciences and Humanities (IZEW); University of Tübingen, Germany

DOI: <https://doi.org/10.5195/pom.2021.27>



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<https://doi.org/10.5195/pom.2021.27>

Review Article | Published: 07 January 2019

### High-performance medicine: the convergence of human and artificial intelligence

Eric J. Topol

*Nature Medicine* 25, 44–56 (2019) | [Cite this article](#)

175k Accesses | 1482 Citations | 2483 Altmetric | [Metrics](#)

#### Abstract

The use of artificial intelligence, and the deep-learning subtype in particular, has been enabled by the use of labeled big data, along with markedly enhanced computing power and cloud storage, across all sectors. In medicine, this is beginning to have an impact at three levels: for clinicians, predominantly via rapid, accurate image interpretation; for health systems, by improving workflow and the potential for reducing medical errors; and for

## bioethics



SPECIAL ISSUE: PROMISES AND CHALLENGES OF MEDICAL AI | [Open Access](#) | [DOI](#)

### How competitors become collaborators—Bridging the gap(s) between machine learning algorithms and clinicians

Thomas Grote & Philipp Berens

First published: 02 October 2021 | <https://doi.org/10.1111/bioe.12957>

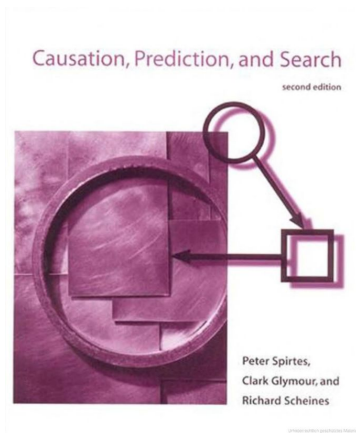
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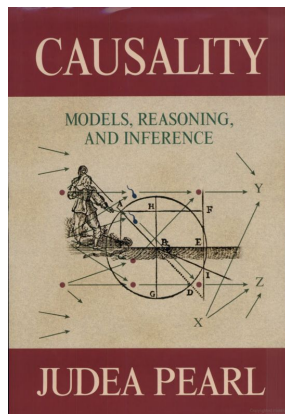
#### Abstract

For some years, we have been witnessing a steady stream of high-profile studies about machine learning (ML) algorithms achieving high diagnostic accuracy in the analysis of medical images. That said, facilitating successful collaboration between ML algorithms and clinicians proves to be a recalcitrant problem that may exacerbate ethical problems in clinical practice. In this paper, we consider a different, and perhaps more relevant, factor

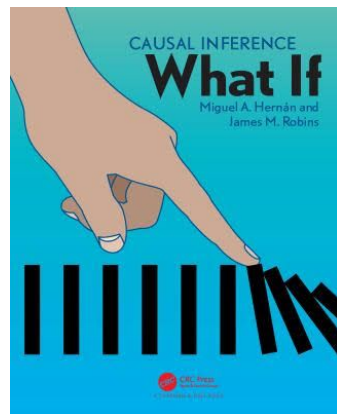
# A Proliferation of ML methods for Causal Discovery



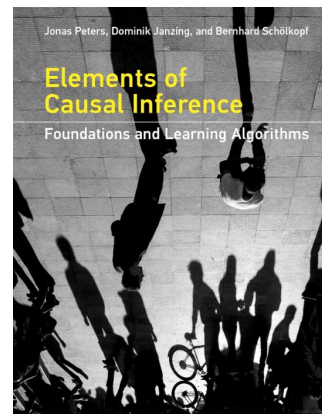
1993/2001



2000



2010



2017





# The Trouble with Randomization

Randomization comes into prima facie conflict with **therapeutic obligation**:

“A physician should not recommend for a patient therapy such that, given present medical knowledge, the hypothesis that the particular therapy is inferior to some other therapy is more probable than the opposite hypothesis” (Marquis, 1983).

# The Trouble with Randomization

Randomization comes into prima facie conflict with **individualized treatment**:

“Although a patient who has been enrolled as a research subject in a RCT may benefit from the therapeutic effects of the treatment being tested, the fact that the treatment cannot be entirely tailored to that patient’s special needs seems to violate the physician’s obligation of unqualified fidelity to his patient’s health” (Schafer, 1983).

# The Tragic View of Clinical Research

The discussion around clinical equipoise presupposes

- There is some valuable **epistemic good** secured by randomization;
- **Any** trial methodology which secures this good must **inevitably** come into conflict with the requirements of individual treatment.

# The Tragic View of Clinical Research

The job of clinical ethics is to reconcile clinicians to this tragic situation:

“These clinical instincts, while understandable and laudable, have the potential to obscure the true nature of clinical research, as investigators and participants alike try to convince themselves that clinical research involves nothing more than the provision of clinical care. One way to try to address this collective and often willful confusion would be to identify a justification for exposing research participants to net risks for the benefit of others.” (Wendler, 2021).

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**David S. Wendler, M.A.,  
Ph.D.**

Senior Investigator

Department of Bioethics

NIH Clinical Center

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# Between Morals and Methodology

But is the tragic view **right**?

- What is the valuable **epistemic good** secured by randomization?
- Is there really **no** methodology that reconciles this good with the ethical requirements of individualized treatment?

Thank You!