lygature pioneering medicine. together.

Artificial intelligence in medicine development without the hot air

Lygature Partnership MeetUp 29 October 2019

Objective for today's session

- Explore the true opportunities of AI for medicine development
- A healthy and realistic discussion about how AI can contribute in the coming years, and identify implications for regulation.

Today's speakers

- Dr. Pawel Widera - Research Associate, Interdisciplinary Computing and Complex BioSystems group at Newcastle University, UK
- Prof. Bram van Ginneken - Professor of Medical Image Analysis at Radboud University Medical Center, the Netherlands; chair of the Diagnostic Image Analysis Group
- Prof. dr. Kit Roes, Professor of Biostatistics at Radboud University/Radboudumc, chair of the Methodology work group at the College ter Beoordeling van Geneesmiddelen (Medicines Evaluation Board), and a member of the Biostatistics Working Party at the European Medicines Agency

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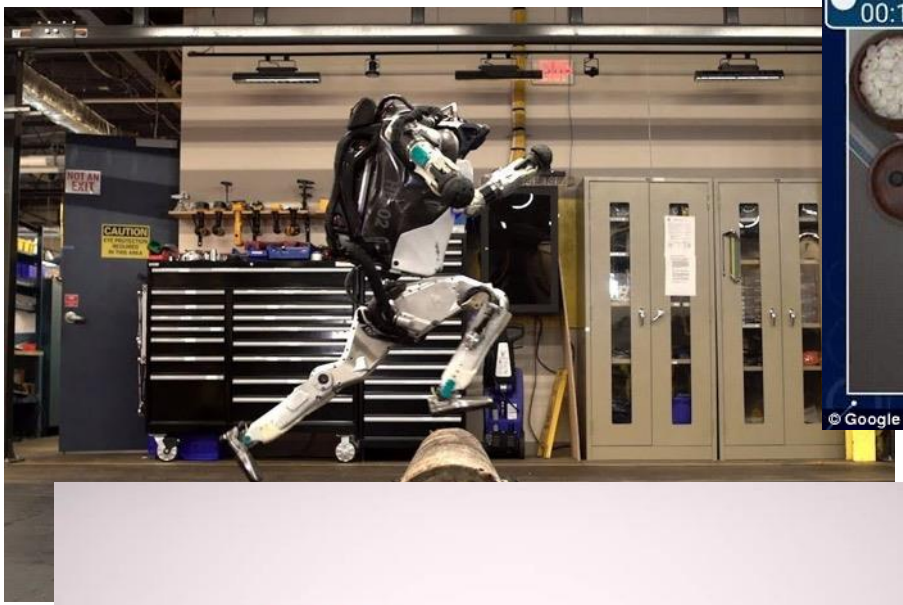
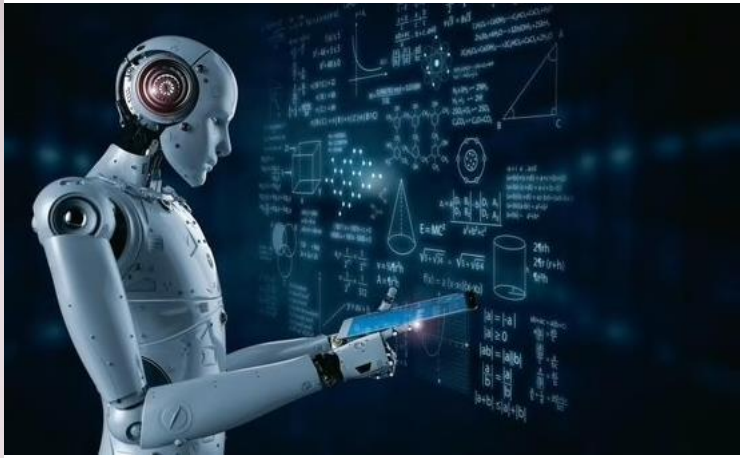
- Prof. dr. Bert Leufkens, Professor of Pharmaceutical Policy and Regulatory Science at Utrecht University, former Chair of the College ter Beoordeling van Geneesmiddelen (Medicines Evaluation Board), and former CHMP member at the EMA.

Artificial intelligence



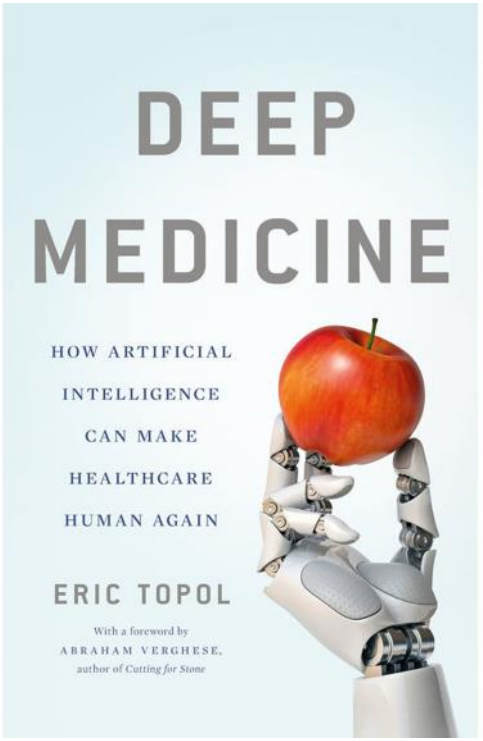


FINANCIAL TIMES

Novartis and Microsoft join forces to develop drugs using AI

Five-year agreement is one of the most expansive tie-ups between big pharma and big tech

1 Oct 2019



nature

SPOTLIGHT · 30 MAY 2018

How artificial intelligence is changing drug discovery

Machine learning and other technologies are expected to make the hunt for new pharmaceuticals quicker, cheaper and more effective.

Nic Fleming

The Economist

Health care

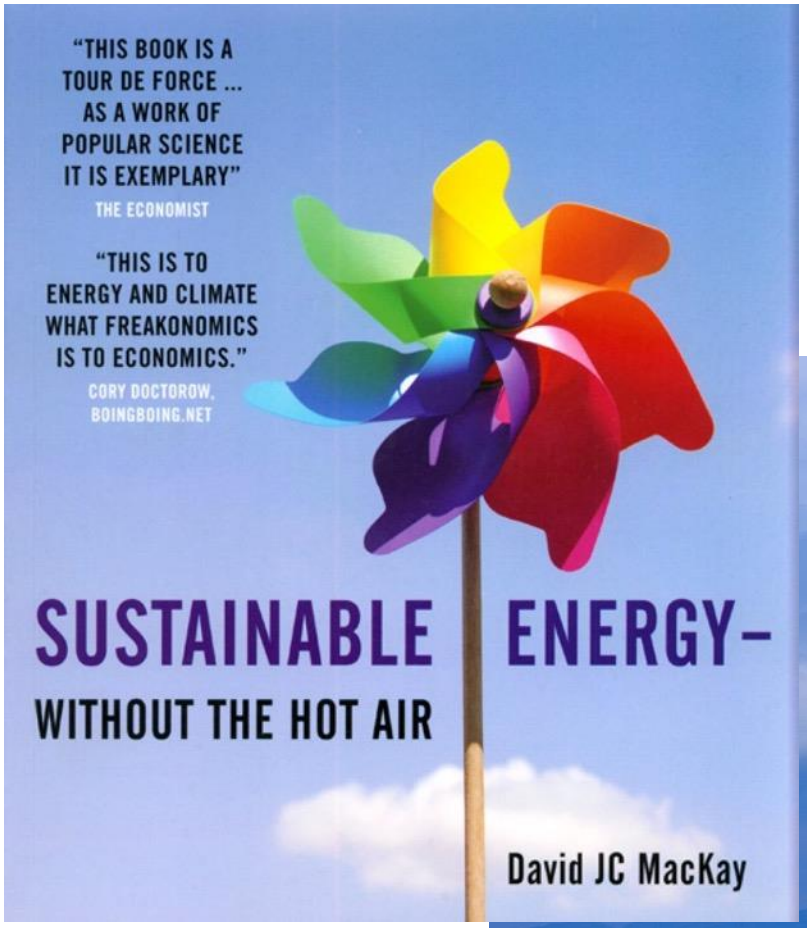
Will artificial intelligence help to crack biology?

Silicon Valley has the squidgy worlds of biology and disease in its sights

The New York Times

Making New Drugs With a Dose of Artificial Intelligence

5 Feb 2019


"THIS BOOK IS A TOUR DE FORCE ... AS A WORK OF POPULAR SCIENCE IT IS EXEMPLARY"
THE ECONOMIST
"THIS IS TO ENERGY AND CLIMATE WHAT FREAKONOMICS IS TO ECONOMICS."
CORY DOCTOROW, BOINGBOING.NET
SUSTAINABLE ENERGY–
WITHOUT THE HOT AIR
David JC MacKay

Lygature's Regulatory Innovation portfolio

- Dialogue & knowledge sharing
- Dissemination & agenda setting
- Research & innovation
- Pilots & implementation

RSNN
Regulatory Science Netwerk Nederland

ESCHER
THE LYGATURE PLATFORM FOR REGULATORY INNOVATION

ADAPTSMART

RADAR-AD

Non Biological Complex Drugs working group

CBG MEB

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

FDA

National | European | International


"We need to regulate AI before it becomes a danger to humanity"
- Elon Musk

Artificial intelligence in clinical development and regulatory affairs – **preparing for the future**

Artificial Intelligence (AI) is set to transform healthcare product development with enormous potential to benefit patients, but also to other stakeholders including regulators and industry. This progress will present new challenges to the systems in place which regulate these products. Stakeholders must now work together to ensure the current regulatory systems evolve in time to embrace the future benefits of AI. This article reviews several areas where AI is being applied in healthcare product development which test current regulatory frameworks, or are topics that will need further consultation between industry and regulators to determine the optimal way to regulate these products in the future.

Authors

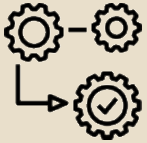
Artificial Intelligence Consortium members: ***Stan Van Belkum****, Deputy Director CBG/MEB, Chair of the regulatory Optimisation Group;* ***Nikolai Brun****, Director, Medical Evaluation and Biostatistics, Danish Medicines Agency;* ***Scott Cleve****, Head of Regulatory Operations, Boehringer Ingelheim;* ***Pat McGovern****, Global Head Innovation, Regulatory Affairs, Novartis;* ***Murray Lumpkin****, Lead for Global Regulatory Systems Initiatives, Bill and Melinda Gates Foundation;* ***Paul-Etienne Schaeffer****, Regulatory Science and Policy Associate, Sanofi;* ***Timm Pauli,*** *Head of Regulatory Operations, Pharmalex* ***Jonathan Trethowan****, VP Regulatory and Scientific Policy, PharmaLex;* ***Tilo Netzer****, CEO, PharmaLex.*

Opportunities for the use of AI in clinical development and regulatory affairs

Assessment of inclusion/exclusion criteria in clinical trials using AI tools

Use of AI for identification of clinical activity in Phase II clinical trials

Extraction of data from unstructured documents



Automation of administrative work

The use of AI in clinical development and regulatory affairs

- How to validate AI-based software that is constantly “learning”.
- How to assess safety signals from new AI-based clinical endpoints.
- How to organise the review of complex medical technologies which apply AI.
- AI systems need data – who owns the patients’ data?

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