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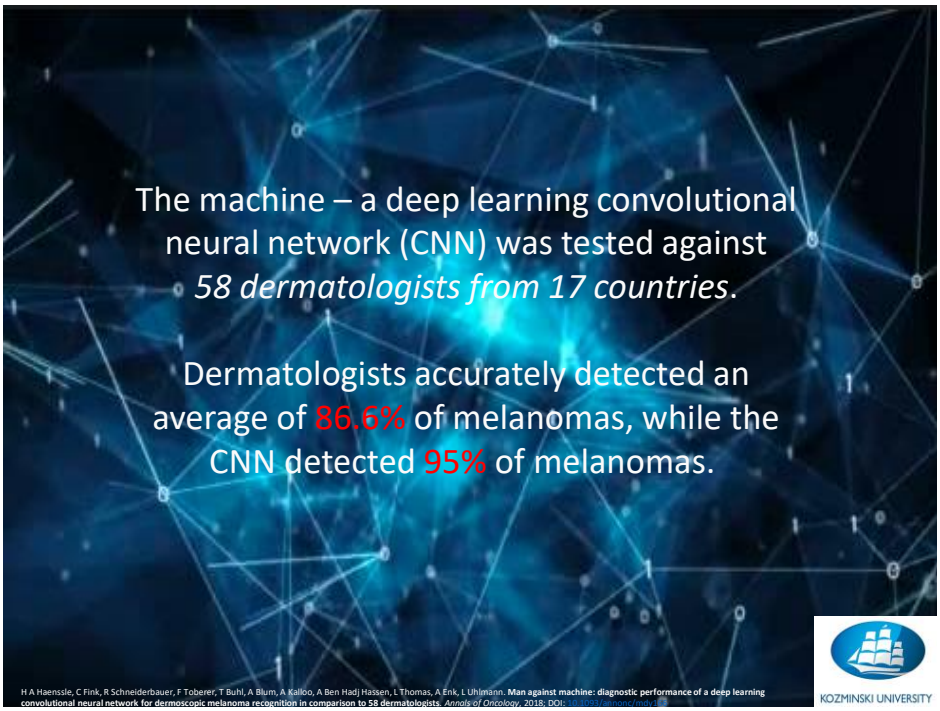
# The future of healthcare is digital & bright

***Katarzyna Kolasa, PhD***
Head of Health Economics and Healthcare Management Division, Professor Kozminski University, Warsaw, Poland



A collection of Icelandic genealogical records dating back to the 1700s.
*Jodi Gralnick | CNBC*

## deCODE in Iceland Agrees to Sequence Half of UK Biobanks Participants

NEWS PROVIDED BY
deCODE genetics
Sep 11, 2019, 11:49 ET

SHARE THIS ARTICLE

REYKJAVIK, Iceland, Sept. 11, 2019 /PRNewswire/ -- deCODE genetics in Iceland has entered into an agreement with a consortium of government, charity, researchers and world leading biopharmaceutical and healthcare companies to undertake whole genome sequencing of UK Biobank participants. The project will allow the complete sequencing of the genetic code of all 500,000 participants in the UK Biobank. This challenging project represents the single most ambitious sequencing program ever undertaken in the world.

## NHS to offer paid-for DNA tests if patients share data

26 January 2019 Share


Health Secretary Matt Hancock said he wants healthy people to become "genomic volunteers" to help scientists better understand diseases and human genetics

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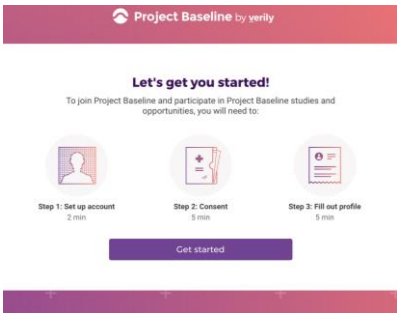



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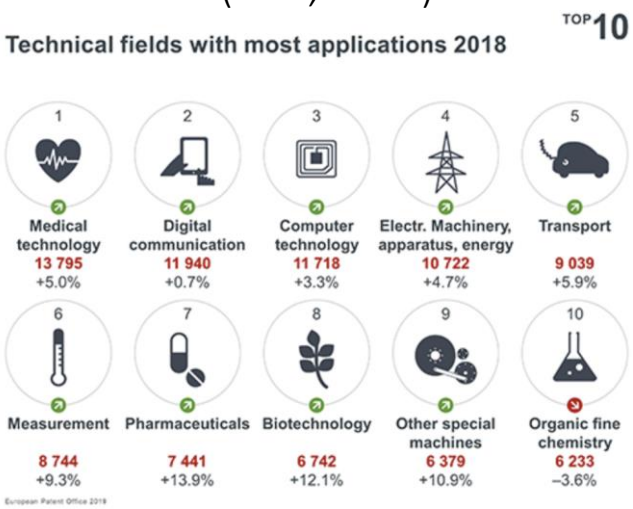
# NUMBER OF PATENT APPLICATIONS FILED (EPO, 2018)




European Patent Office, European companies and inventors file more patent applications in 2018, 12.03.2019

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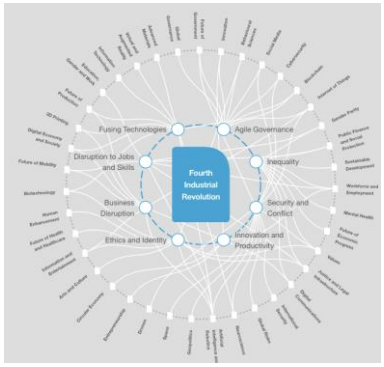
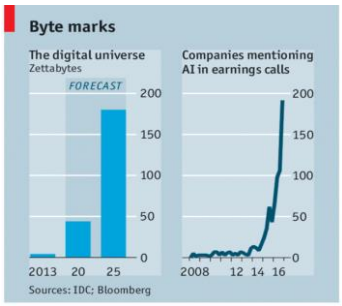
# FOURTH INDUSTRIAL REVOLUTION




BIG DATA




„4 V"

*VOLUME*

*VARIETY*

*VELOCITY*

*VERACITY*

World Economic Forum, The Fourth Industrial Revolution: what it means, how to respond, Klaus Schwab, 14.01.2016, The Economist, Data is giving rise to a new economy, 6.05.2017
Becich MJ. Information management: moving from test results to clinical information. Clin Leadersh Manag Rev. 2000;14: 296-300

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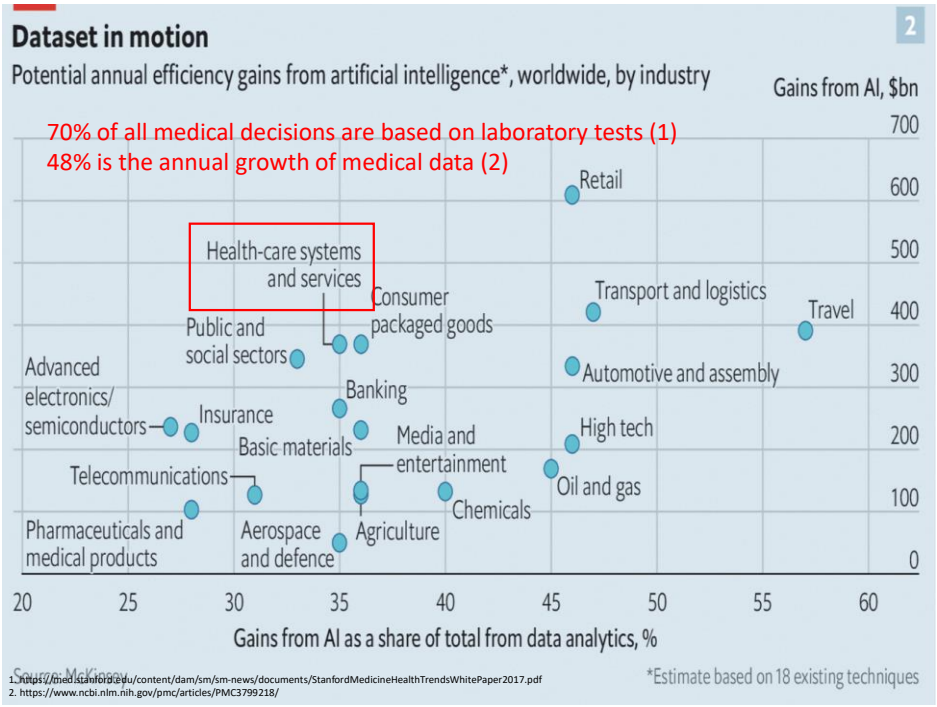


1. https://med.stanford.edu/content/dam/sm/sm-news/documents/StanfordMedicineHealthTrendsWhitePaper2017.pdf
2. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3799218/

# WHY DIGITAL HEALTH?

GDPR is here to stay..

- health challenges
- Ageing population and chronic diseases putting pressure on health budgets
- Unequal quality and access to healthcare services
- Shortage of health professionals
- Potential of digital applications and data to improve health
- Efficient and integrated healthcare systems
- Personalised health research, diagnosis and treatment
- Prevention and citizen-centred health services

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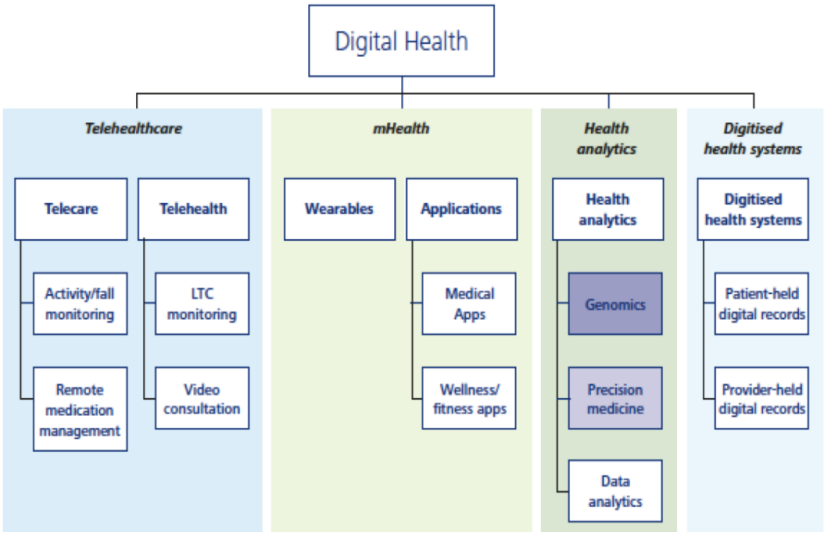


https://echalliance.com/news/382193/Trends-in-Digital-Health-for-2018.-A-quick-view-of-whats-is-going-on-in-the-digital-health-world.htm

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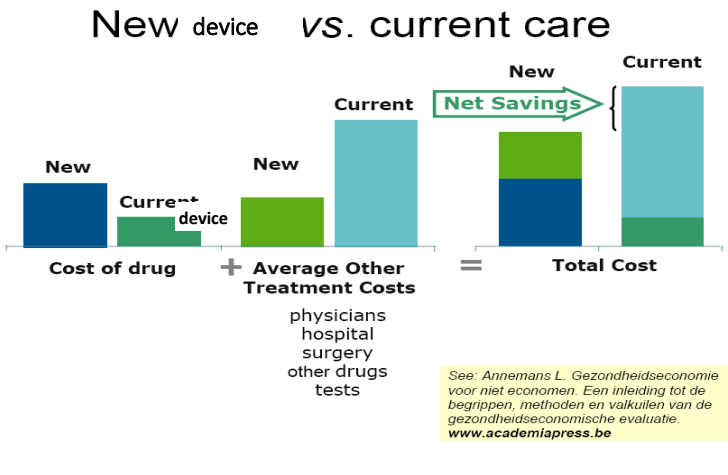


*See: Annemans L. Gezondheidseconomie voor niet economen. Een inleiding tot de begrippen, methoden en valkuilen van de gezondheidseconomische evaluatie.* ***www.academiapress.be***

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# IMPACT OF DIGITAL SOLUTIONS ON TREATMENT OUTCOMES

*Study Design*
54 female at elevated risk for breast cancer were randomized to one of two treatments:

1. standard care for weight control
2. combination of a wearable technology to monitor physical activity (Fitbit One) with a smartphone app to monitor diet (My Fitness Pal) and coaching calls from trained counselors

*Study Findings*
Women randomized to the wearable plus mHealth app plus coaching achieved significantly greater weight loss (4.4 vs. 0.08 kg; p = .004) than women randomized to standard care

Hartman SJ, Nelson SH, Cadmus-Bertram LA, Patterson RE, Parker BA, Pierce JP Am J Prev Med. 2016 Nov; 51(5):714-721.

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Study Design

*Tweet2Quit* - peer-to-peer support and accountability for maintaining commitment to quit smoking: (1) discussion questions based on tobacco treatment clinical practice guidelines and (2) individualized autofeedback based on past-day participation.

RCT with 160 smokers: 1. *Tweet2Quit* was combined with a web guide (smokefree.gov) and nicotine patch 2. web guide and nicotine patches without the Twitter support group.

Study Findings

Tobacco abstinence was reported at 60 days follow-up. *Tweet2Quit* participants reported significantly greater sustained tobacco abstinence compared with control : 40% vs. 20%; (p = .012). Engagement was high, with participants averaging 57 tweets over an average of 47 days. More tweeting was associated with quitting (p = .003).

# IMPACT OF DIGITAL SOLUTIONS ON TREATMENT OUTCOMES

Pechmann C, Delucchi K, Lakon CM, Prochaska Randomised controlled trial evaluation of Tweet2Quit: a social network quit-smoking intervention JJ Tob Control. 2017 Mar; 26(2):188-194.

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AI Platform vs personal daily monitoring

**Example 1**
AICure (identified the patient & the medication & confirmed ingestion)

Adherence was defined as the number of doses captured by the AI platform relative to the number of planned doses.

Adherence was 100% (15 of 15) and 50% (6 of 12) in the intervention and control groups, *respectively*.

**Example 2**
RCT with 28 pts diagnosed ischemic stroke receiving any anticoagulation: warfarin, dabigatran, rivaroxaban, or apixaban

Non-randomised Substudy of phase 2 trial of the α7 nicotinic receptor agonist (ABT-126) in subjects with schizophrenia.

The difference between AI platform and study Staff monitoring was **17.9%** (95% CI -2 to 37.7; *P*=.08).

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1: Labovitz, D. L., Shafner, L., Reyes Gil, M., Virmani, D. & Hanina, A. Using artificial intelligence to reduce the risk of nonadherence in patients on anticoagulation therapy. Stroke 48, 1416–1419 (2017).
2. Bain, E. E. et al. Use of a novel artificial intelligence platform on mobile devices to assess dosing compliance in a phase 2 clinical trial in subjects with schizophrenia. JMIR mhealth uhealth 5, e18 (2017).

# AI platforms

MICROSOFT HANNOVER

IBM WATSON'S ONCOLOGY

GOOGLE'S DEEPMIND

DEEP 6 ANALYTICS

FLATIRON HEALTH

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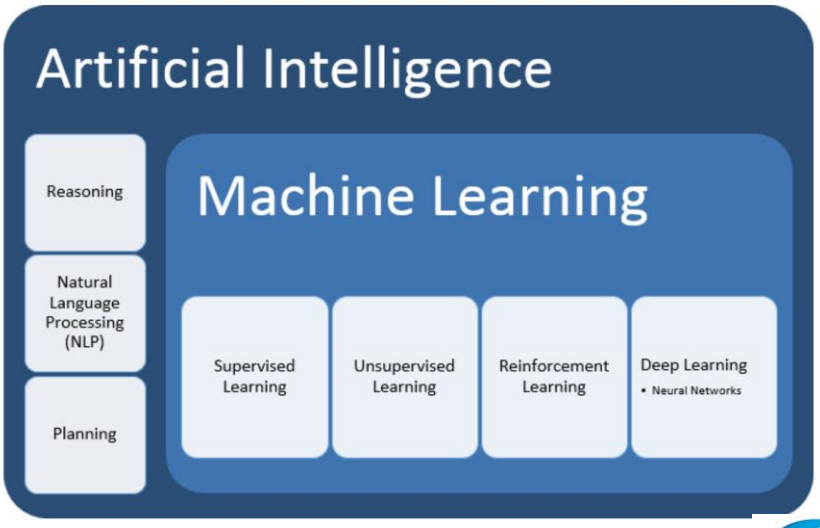


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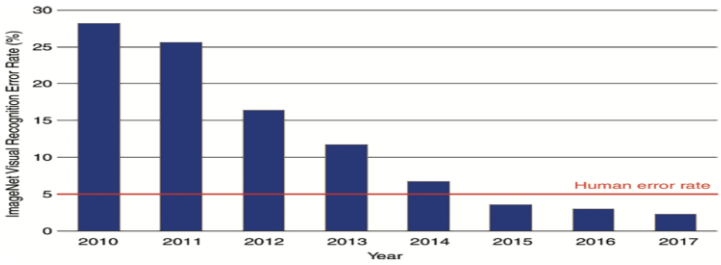
# AI for imaging

Error rates on the ImageNet Large-Scale Visual Recognition Challenge.




Example:

- 381 digitized, histological whole-slide images (WSI) from 156 patients diagnosed with head and neck cancer
- Algorithm based Convolutional neural network was able to detect and localize primary head and neck SCC on WSI with an AUC of 0.916.

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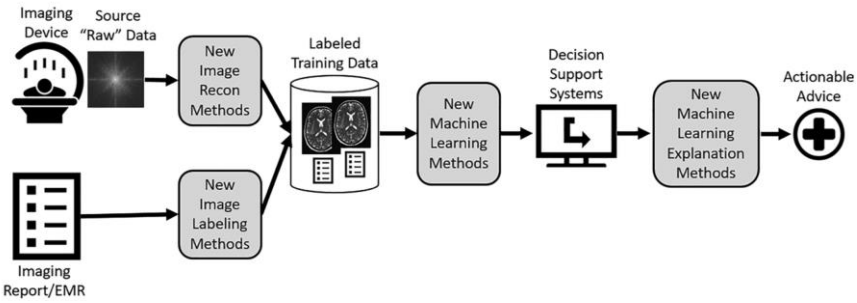
Martin Halicek, Maysam Shahedi, James. Little, Amy. Chen, Larry L. Myers, Baran D. Sumer & Baowei Fei, Scientific Reports:Head and Neck Cancer Detection in Digitized Whole-Slide Histology Using Convolutional Neural Networks 01.10.2019

# A Roadmap for Foundational Research on Artificial Intelligence in Medical Imaging




Department of Radiology, Stanford University, Stanford, CA 94305 (C.P.L., M.P.L.); Department of Radiology, Grandview Medical Center, Birmingham, Ala (B.A.); Department of Radiology, Mayo Clinic, Rochester, Minn (B.J.E.); Department of Radiology, Massachusetts General Hospital, Harvard Medical School, Boston, Mass (J.K.C.); GE Healthcare, Chicago, Ill (K.B.); Department of Radiology, Hospital of the University of Pennsylvania, Philadelphia, Pa (T.S.C., J.D.R.); Department of Radiology, Thomas Jefferson University Hospital, Philadelphia, Pa (A.E.F.); Department of Radiology, Icahn School of Medicine at Mount Sinai, New York, NY (D.S.M.); Biomedical Imaging Center, Rensselaer Polytechnic Institute, Troy, NY (G.W.); and National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, Washington, DC (K.K.). Received March 17, 2019; revision requested March 19; revision received March 24; accepted March 25

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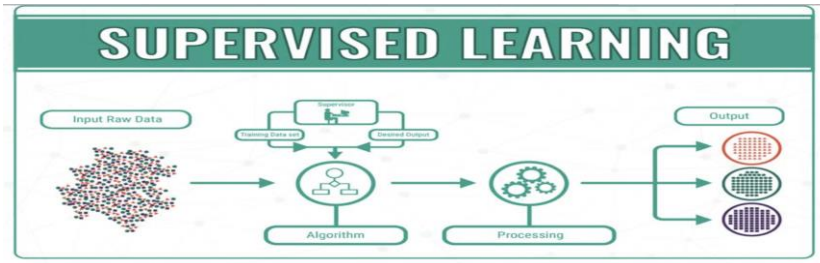


***Example 1 Predict CVD outcomes***

- Database of 423,604 individuals without CVD at baseline (UK Biobank).
- 5 ML algorithms (AutoPrognosis) with 200 iterations of the Bayesian optimization procedure.
- Prediction of CVD risk based on 473 available variables.
- Out of 4,801 CVD cases recorded within 5 years from baseline, *correctly predict 368 more cases compared to the Framingham score.*

***Example 2: Predict CVD outcomes***

- Database of 200,000 echocardiograph images.
- CNN (Convolutional neural network) trained to recognize 15 standard echocardiographic views, using a training and validation set of over and a test set of 20,000.
- It *outperformed board-certified echocardiographers* with an overall accuracy of 91.7%.

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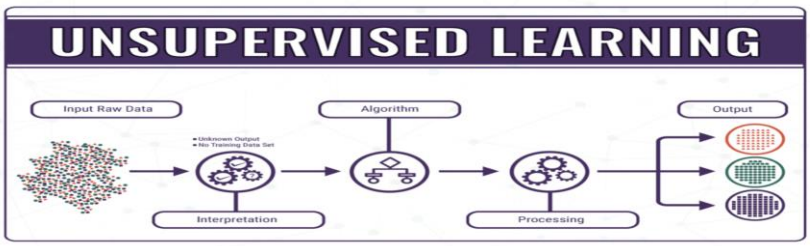
1: Madani A, Arnaout R, Mofrad M, et al. Fast and accurate view classification of echocardiograms using deep learning. NPJ Digit Med. doi: 10.1038/s41746-017-0013-1. Published Online First: 21 March 2018.) 2. www.ncbi.nlm.nih.gov/pmc/articles/PMC6519796/




***Example 1 Behavior identification algorithm (BIA) AI for elderly care:***

- Sensor data collection for the elderly living alone in smart home.
- Event Order, Time Length Similarity and Time Interval Similarity features were studied to identify behaviors' patterns.

***Example 2 Personalized paths for PD patients categorization***

- Two inertial devices were used to capture the motion of the lower and upper limbs respectively, while performing six motor tasks in the group of patients with Parkinson disease (PD).
- Forty-one kinematic features were extracted to describe the performance of each subject.
- It reached accuracy equal to 0.950 to differentiate patients between mild and advanced, and 0.817 across mild vs moderate vs severe.

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1: Cuijuan Shang ; Chih-Yung Chang ; Guilin Chen ; Shenghui Zhao ; Haibao Chen, IEEE, BIA: Behavior Identification Algorithm using Unsupervised Learning Based on Sensor Data for Home Elderly, 24.09.2019, 2: Rovini E, Fiorini L, Esposito D, Maremmani C, Cavallo F., IEEE Int Conf Rehabil Robot Fine Motor Assessment With Unsupervised Learning For Personalized Rehabilitation in Parkinson Disease., 06.2019

# Ethics of AI

- Is it is safe and effective?
- Who is allowed to use or interpret the data?
- How AI integrates into evolving clinical care models?
- Should machine-generated results need to be confirmed by a physician?
- How will the technology fit into reimbursement systems?
- Who is at fault in the case of errors to name a few?

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(a) Three samples in criminal ID photo set $S_c$.

(b) Three samples in non-criminal ID photo set $S_n$

The study of 1856 facial images of Chinese,
male (aged 18-55)
half convicted criminals

Based on ML analysis discriminating structural features for predicting criminality were identified:

- lip curvature,
- eye inner corner distance and
- nose-mouth angle

Xiaolin Wu, Xi Zhang, Automated Inference on Criminality using Face Images, 13.11.2016

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# The world of real world data!!!


- Among 215 clinical trials conducted for 32 innovative MDs, *only 15% of them were randomized controlled trials (RCTs)* and more than 50% included fewer than 30 patients (1).
- Out of 82 studies included in the systematic review of ML for medical imaging, 72 and 10 used retrospectively **and prospectively** collected data (2).
- Only 25 studies did an out-of-sample external validation. *Out of these 25 studies, only 14 used* the same sample for the out-of-sample validation to compare performance between deep learning algorithms and health-care professionals (2).


1. Maresova P, et al, The potential of medical device industry in technological and economical context. Ther Clin Risk Manag 2015;11:1505–1514. Boudard A. Clinical studies of innovative medical devices: what level of evidence for hospital-based health technology assessment?J Eval Clin Pract 2013 Aug;19(4):697-702. Bednarska E, Bryant D, Devereaux PJ. Orthopaedic surgeons prefer to participate in expertise-based randomized trials.Clin Orthop Relat Res. 2008;466(7):1734–44.
2. The Lancet, A comparison of deep learning performance against health-care professionals in detecting diseases from medical imaging: a systematic review and meta-analysis, Xiaoxuan Liu, Livia Faes, Aditya U Kale, Siegfried K Wagner, Dun Jack Fu, Alice Bruynseels, Thushika Mahendiran, Gabriella Moraes, Mohith Shamdas, Christoph Kern, Joseph R Ledsam, Martin K Schmid, Konstantinos Balaskas, Eric J Topol, Lucas M Bachmann, Pearse A Keane, Alastair K Denniston, 10.2019


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*Contains Nonbinding Recommendations*

*Draft – Not for Implementation*

**Clinical Decision Support Software**

**Draft Guidance for Industry and Food and Drug Administration Staff**

***DRAFT GUIDANCE***

**This draft guidance document is being distributed for comment purposes only.**

**Document issued on September 27, 2019.**

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Evidence standards framework for digital health technologies

1:The Economist, Technology firms vie for billions in data-analytics contracts, 05.09.2019, 2:U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research, Office of Combination Products in the Office of the Commissioner, Draft Guidance for Industry and Food and Drug Administration Staff, 27.09.2019, 3: National Institute for Health and Care Excellence, Home About/What we do/Our programmes/Evidence standards framework for digital health technologies

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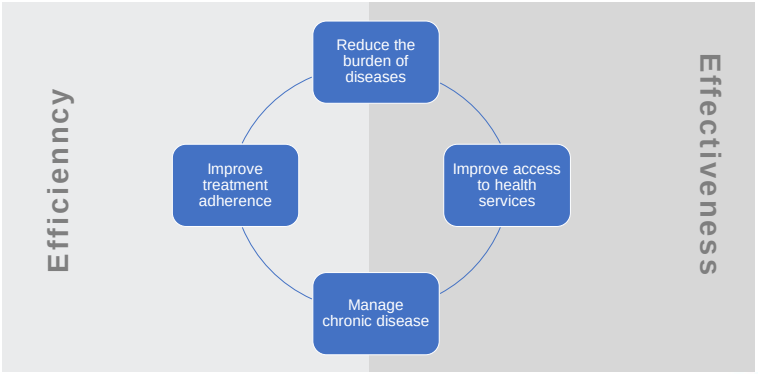
# THE NEED FOR NEW VALUE ASSESSMENT FRAMEWORK IN THE ERA DIGITAL HEALTH

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