

LI02 - The impact of AI, RWE, Precision Medicine and Mobile Health Technology on Streamlined Clinical Trials

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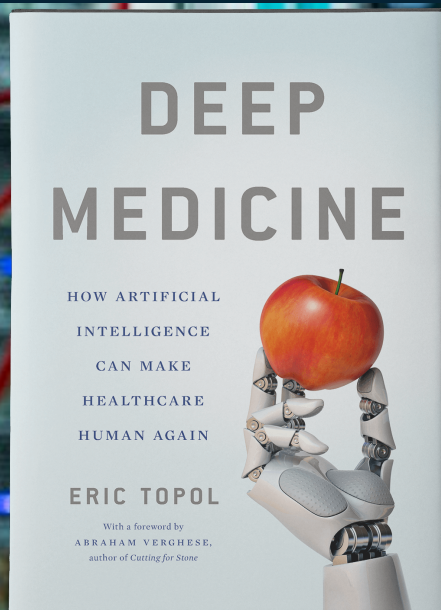
10th–13th November
RAI Amsterdam
The Netherlands

EU 2019

The Clinical Data
Science Conference

ANALYTICS

From disruption to transformation



Amsterdam Hospital, NL : Healthcare & AI

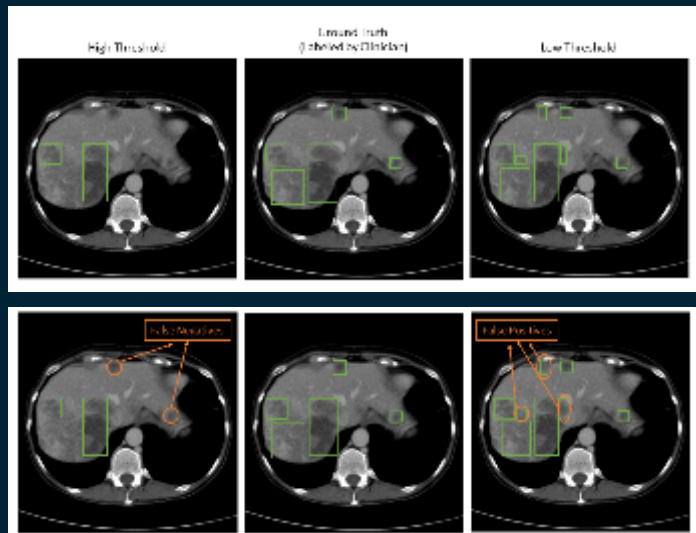
Increase speed and accuracy of tumor evaluations



Computer Vision

Use AI on CT scans to
speed up and secure
HCP decision

- Use deep learning object detection bounding box size as surrogate for tumor size?
- Can AI assist Doctors on making accurate & trustable decision



GEERT KAZEMIER
MD PhD, Professor of Surgical Oncology,
Cancer Center Amsterdam University Medical Center

Machine (deep) Learning

Semi-automatically generation of analysis programs & QC



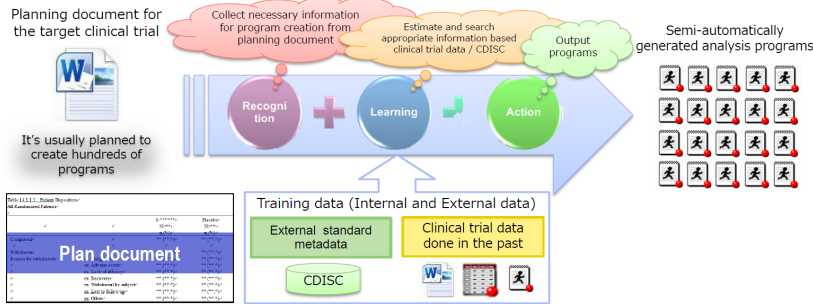
Past and Future of Our AI Making Use of Data Governance: How to Make Process/Product Innovations

Ryo Kiguchi, Shogo Miyazawa,
Masakazu Fujiwara, Yoshitake Kitanishi
SHIONOGI & CO., LTD.

Importance of Data Governance in using AI (Past)



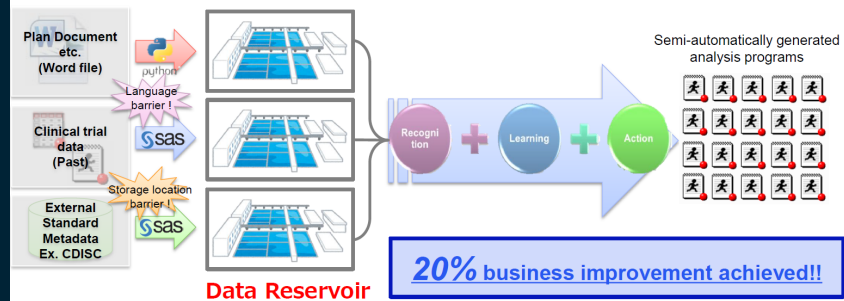
System outline and Governance strategy of AI SAS Programmer



Importance of Data Governance in using AI (Past)



Data Governance strategy in AI SAS Programmer (Ver.1.0)



<https://www.pharmasug.org/proceedings/tokyo2018/presentations/PharmaSUG-Tokyo-2018-07.pdf>

Machine (deep) Learning

Semi-automatically generation of analysis programs & QC

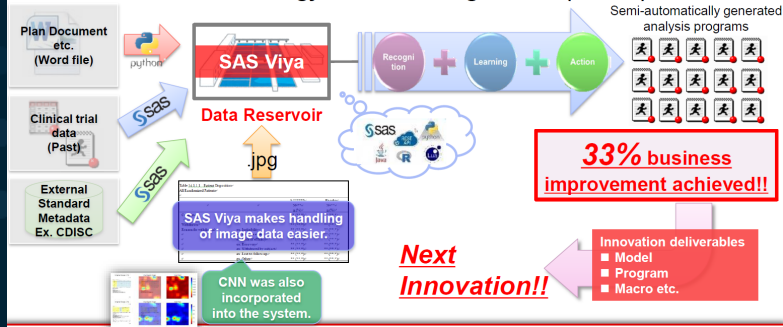


Past and Future of Our AI Making Use of Data Governance: How to Make Process/Product Innovations

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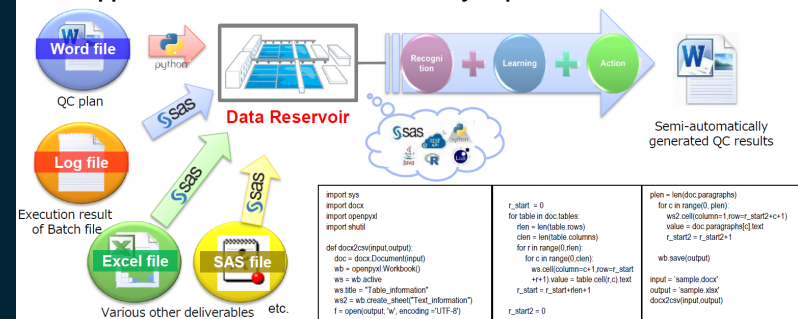
What is “True” Data Governance in AI ?(Now)

Data Governance strategy in AI SAS Programmer (Ver.2.0)



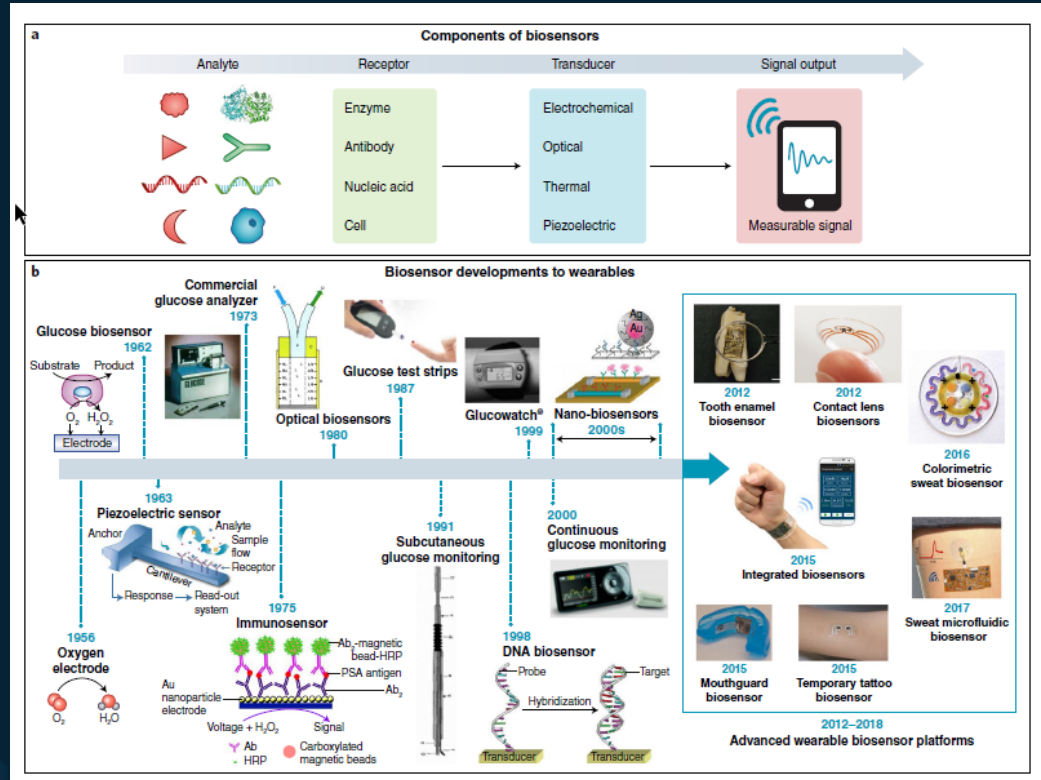
What is “True” Data Governance in AI ?(Now)

AI application which semi-automatically implement QC



<https://www.pharmasug.org/proceedings/tokyo2018/presentations/PharmaSUG-Tokyo-2018-07.pdf>

Devices & Wearable Sensors



Kim *et al.*, Nature Biotechnology, 37, 389-406 (2019)

IMI Mobilise-D : Research on Medical Device & AI

Sensor Based Analysis Movement for Quantification of Pain & Discomfort



IOT and Wearables:

Utilise data to improve the accuracy and reduce time to submission

- Can we use “smart” devices to detect patient pain and discomfort?
- Can we quantify clinically relevant evolution in patient “behaviors”?
- Using iPhone and Sensor Play software, we recorded an individual performing clinically relevant behaviors in the absence and presence of pain and/or discomfort
- These data were used to train appropriate machine learning models to score new subject’s movement.
- Using a simple accelerometer and gyroscope data, models are able to differentiate between gait that is affected by pathology and gait that is not.

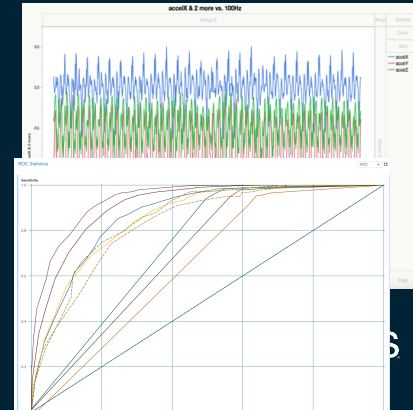


A Mathematical Implementation of a “Global Human Walking Model with Real-Time Kinematic Personification” by Boulic, Thalmann and Thalmann.

Marshall Bradley
National Center for Physical Acoustics
University of Mississippi
June 2009

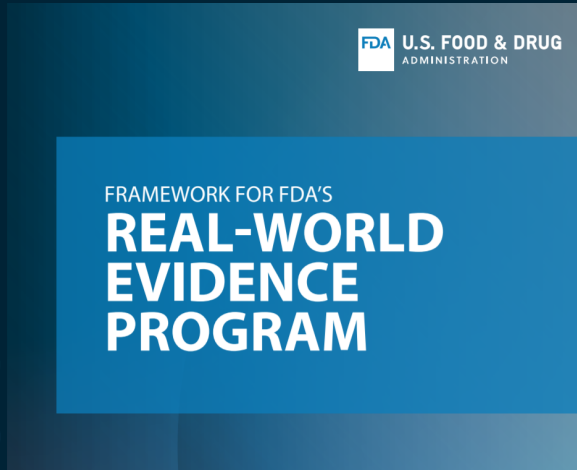
Southeastern Louisiana University
Hammond, Louisiana

Abstract: The human motion algorithms from the paper “A Global Human Walking Model with Real-Time Kinematic Personification” by Boulic, Thalmann and Thalmann have been implemented in the *Mathematica*-programming language. The algorithms have been modified and extended to enable the motion of a 3-D stick figure. The velocity of 19 body parts (points on the stick figure) are computed as a function of time in the human walk cycle. Model predictions are visually consistent with actual human walking and Doppler acoustic sonar measurements made at the National Center for Physical Acoustics.



Real World Evidence

Regulatory & Industry perspectives



<https://www.fda.gov/media/120060/download> (Dec 2018)



<https://bipartisanpolicy.org/report/expanding-the-use-of-realworld-evidence-in-regulatory-and-value-based-payment-decision-making-for-drugs-and-biologics/> (Aug 2019)

Real World Evidence

Regulatory & Industry perspectives



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

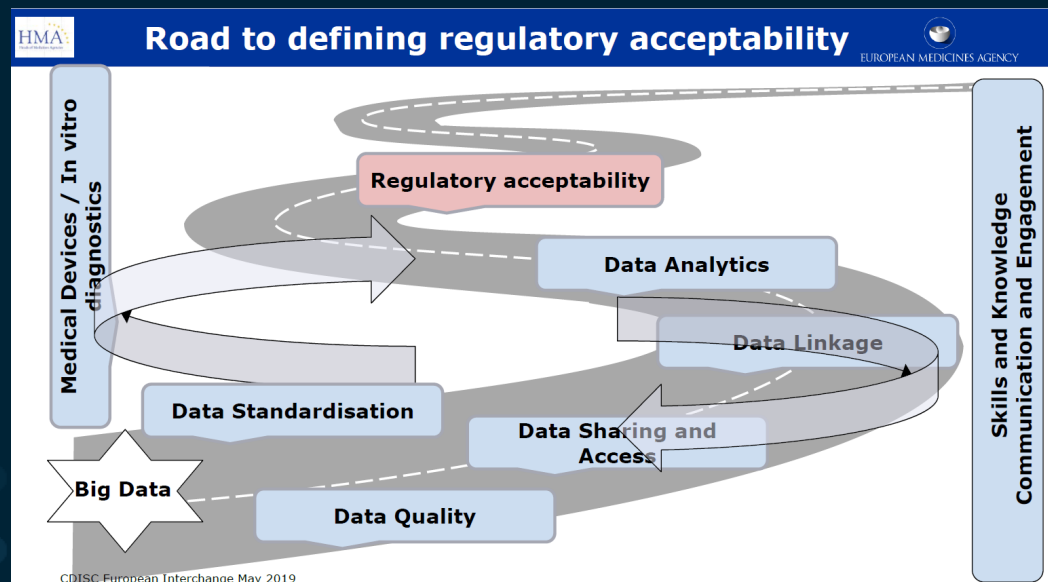
Big Data – Challenges and Opportunities

Moving forward with recommendations from the HMA-EMA Joint Big Data taskforce

Dr Alison Cave
Principal Scientific Administrator
Pharmacovigilance and Epidemiology Department
CDISC European Exchange May 2019



An agency of the European Union



Real World Evidence

Recent Examples (Jan, 2018)

J&J performed a pragmatic real-world trial, a randomized trial that used measures that are collected in clinical practice

*“INVEGA SUSTENNA® (paliperidone palmitate), a once-monthly schizophrenia treatment, is the first and only antipsychotic to have the U.S. Food and Drug Administration (FDA) **approve the inclusion of real-world data in its product labeling**”*

<https://www.janssen.com/landmark-schizophrenia-data-bring-hope-breaking-cycle-hospitalization-and-incarceration-receive-fda>

[What's scary, and appealing, about real-world evidence \(StatNews 2019\)](#)



Reference: “Real World Evidence in Clinical development, life cycle management and/or repurposing”
(Julijana Dukanovic, Andrew Leary – Dr. Regenold GmbH, SAS HLS Exec Forum Basel, 25 June 2019)

Real World Evidence

Recent Examples (Apr, 2019)

Pfizer Uses EHR Data to Support Expanded Indication for Breast Cancer Drug

“The approval is based on RWD from electronic health records and post-marketing reports of Ibrance™ in male patients sourced from three databases: IQVIA Insurance database, Flatiron Health Breast Cancer database and the Pfizer global safety database”



<https://www.raps.org/news-and-articles/news-articles/2019/4/pfizer-uses-ehr-data-to-support-expanded-indication>

Reference: “Real World Evidence in Clinical development, life cycle management and/or repurposing”
(Julijana Dukanovic, Andrew Leary – Dr. Regenold GmbH, SAS HLS Exec Forum Basel, 25 June 2019)

From regulation to opportunity



Personal data protection



AI/ML regulation



Data Transparency



Ethical rules

Data protection in the pharma sector: a many-headed hydra



24.04.2019

In an Expert View piece, Oliver Kidd, senior associate at

Cleary & Gottlieb, provides an overview of the current state

MORE ON THIS STORY

How to spend like a leading

Why GDPR Is Still Creating Problems in the Enterprise



By David Roe | Sep 25, 2019

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CHANNEL: Information Management



Following four years of preparation and debate, GDPR was approved by the European Parliament in April 2016, the official texts and regulation of the directive were then published in all of the official languages of the EU in May 2016. The legislation came into force across the European Union on May 25, 2018.

The parliament warned that any company doing business in a European country and used personal data of EU citizens, no matter where that company was headquartered, would have to comply with the regulation.



Personal data protection



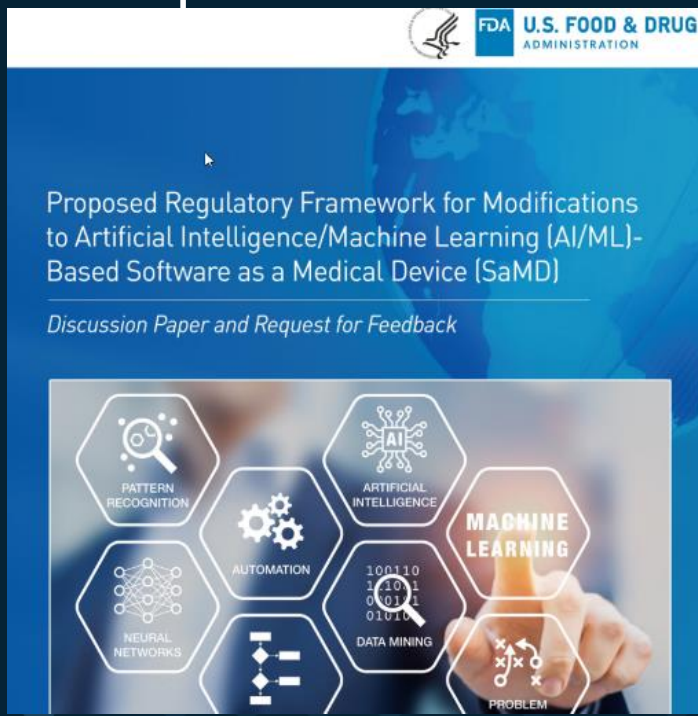
AI/ML regulation



Data Transparency



Ethical rules





Personal data protection



AI/ML regulation



Data Transparency



Ethical rules

<https://www.thepharmaletter.com/event/clinical-trial-data-transparency-forum>



Personal data protection



AI/ML regulation



Data Transparency



Ethical rules

- ✓ it is clear that a combination of explainable AI - where you can see what input elements contributed to the decision - and risk management of the remaining unexplained parts, just like we do with unexplained clinical treatments will be needed
- ✓ AI will need to be treated like any therapy : based on evidence, not on complete understanding of causality.



From analytics to clinical practice (reality)

Monitor & Predict the risk of hospital-acquired infections

“It is estimated that every 10th patient is affected by an infection while hospitalized, and that over 3,000 patients in Denmark per year die because of their infections. But until now, no one knew the actual infection rates, or exactly when and where to make a precise effort to prevent them...”

<https://www.sas.com/danish/customers/the-region-of-southern-denmark.html>



Community based genetics study uses Machine learning and AI to improve population health in Nevada



In an ongoing landmark population study, Healthy Nevada uses SAS to analyze data from over 50,000 enrollees to identify genetic and environmental factors impacting their health and quality of life

https://www.sas.com/en_us/webinars/real-world-evidence-convergence.html#formsuccess

IMI Pioneer – The European Network of Excellence for BIG data in Prostate Cancer



PIONEER will harness the power of prostate cancer research from stakeholders including clinician payers and most importantly patients so that every individual patient receives the right time.

Prof. James N'Dow, PIONEER Coordinator



Erik Briens, prostate cancer patient, Belgium

The PIONEER project and its application of real-world data to answer unknown questions relating to prostate cancer is very important for patients. Clinical trials are done with highly selected patients, thus many subpopulations (e.g. patients with kidney problems) are excluded. Once new medicines received market authorisation all patients can be treated with them, but really we have no data on their benefit to patients in the untested subpopulations. Big Data and real-world data can deliver the answer to this question: "Do patients in subgroups benefit?". The answer to this question has the potential to protect patients from unwanted side effects from medicines that may in fact have no benefit to them. It also enables saving across healthcare systems; ultimately, making our healthcare systems more sustainable. This is just one example of many, so yes, PIONEER and the BD480 programme is of high importance to patients.



Ken Mastris, prostate cancer patient, United Kingdom

It's time for more research on prostate cancer. Overall, it affects nearly as many people as breast cancer, but up to now has received comparatively minimum research funding, and progress made in this field has been limited when compared to other major cancer types. Insufficient knowledge of patient characteristics and risk factors at time of diagnosis means that deciding which patients will have the best outcome with specific treatments is challenging at best. Big Data if properly combined and analysed can bridge this knowledge gap. Therefore, the goals of the BD480 programme and PIONEER will help future patients. I hope it brings early stratification of patients at diagnosis so patients can make the right choice of treatment for them guided by their urologist. Fixing the gaps in the patient journey will benefit all.



Conclusion



OPERATIONAL EFFICIENCY

- Reducing physician burnout
- Meaningfully connect different data sources
- Financial impact, cost, fraud and abuse
- Workflow optimization (simulation, DL)
- Clinical trial operations
- Manufacturing quality

**Efficiency increase of health
care and clinical development**



CLINICAL SCIENCE & POP HEALTH

- Deep learning for computer vision and biological signals
- IoMT : wearables, devices and modern clinical trials
- Patient engagement : chatbots
- RWE – cohort analysis – matching patients, enrolment simulation

**Faster access to care and
support for physician**



REGULATION AND GOVERNANCE

- Ethical AI
- Enterprise implementation and repeatability
- Data privacy
- Traceability

Risk, governance, auditability

... interested for a deeper dive ?

ANALYTICS IN 20

A webinar series for health care and life sciences professionals.

Next-Generation Clinical Trials On-Demand

Part 1:
Overview



Part 2:
Demonstration

We discuss the opportunity and impact of real-world data and evolving AI techniques on modernizing clinical trials. [Learn More.](#)

Making a Difference in the Opioid Epidemic: Data and Analytics Sept. 26 · 1 p.m. ET

Part 1:
Overview



Part 2:
Demonstration

We take a fresh look at issues intensifying the opioid crisis and share real-life examples of analytics saving lives. [Learn More.](#)

Pharma 4.0: Modernizing Manufacturing With Analytics Oct. 17 · 1 p.m. ET

Part 1:
Overview



Part 2:
Demonstration

We discuss the role of analytics in pharmaceutical manufacturing and the improvements that come as a result. [Learn More.](#)

Can Health Care Professionals See the Future With AI and Computer Vision? Nov. 7 · 1 p.m. ET

Part 1:
Overview



Part 2:
Demonstration

We take a look at true adoption of AI in clinical and operational workflows, including a real-life example of AI deployment. [Learn More.](#)

https://www.sas.com/en_us/offers/19q3/hls-in-20-webinars.html