



Prof. Dr. Ir. Pascal Verdonck MedTech Ghent University

Welcome by the theme chair

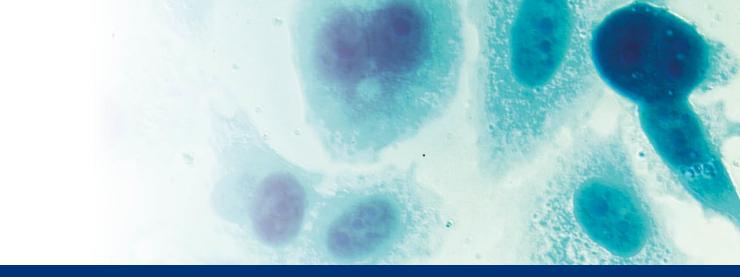


Mr. Bart Vannieuwenhuyse

Data Sciences Lead Benelux campus

Big Data and its added value in clinical research





Big data and its added value in clinical research

Pictured above: Ulcerative Colitis

Bart Vannieuwenhuyse September 2019 | Janssen Clinical Innovation

"The patients are waiting!"

To eliminate disease through developing highly innovative medical solutions for people around the world

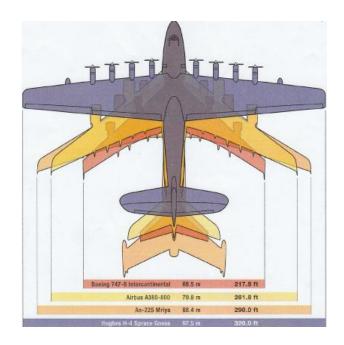


Dr. Paul Janssen

Janssen

PHARMACEUTICAL COMPANIES

Bigger = Better ??



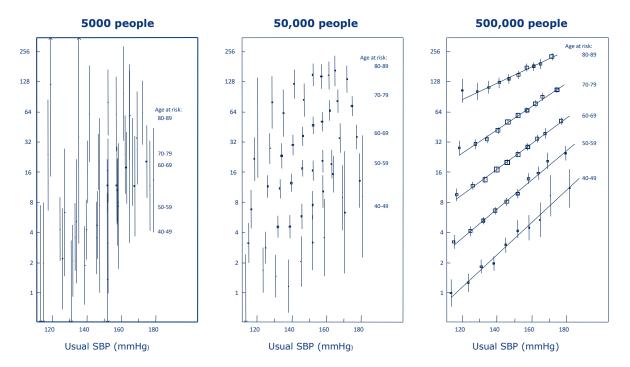


Howard Hughes' plane only flew one mile ...

Janssen

PHARMACEUTICAL COMPANIES OF Johnson Johnson

Power in numbers ...

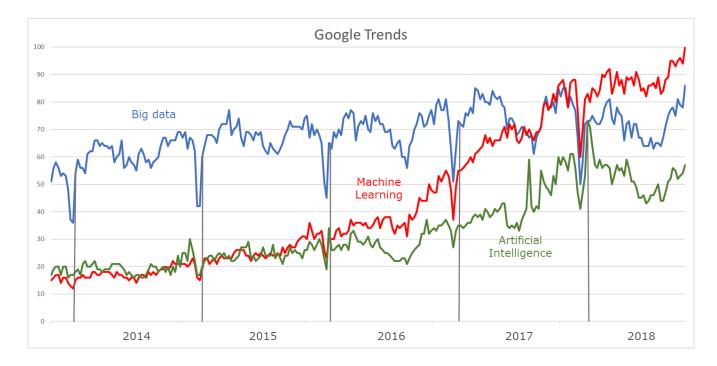


The Prospective Studies Collaboration: Lewington et al. 2002

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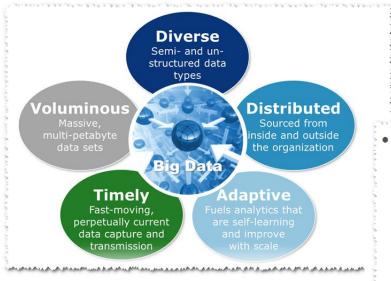
Machine Learning has overtaken Big Data



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Big data vs Real World Data

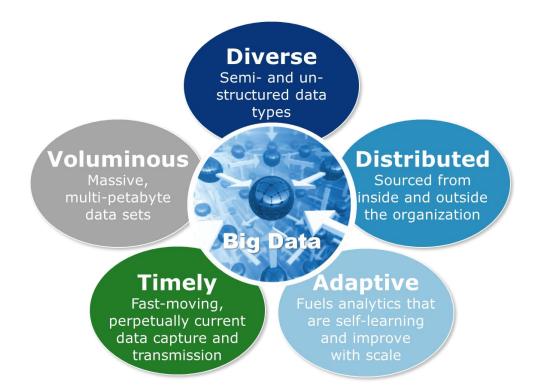


- RWE is generated using data typically collected in usual health care settings. RWE is most commonly generated using a range of non-interventional (observational) studies, including:
 - Primary data collections such as registries collecting prospective and/or retrospective data, or surveys collecting cross-sectional or retrospective information.
 - Analyses of secondary data that includes (electronic) medical records, insurance claims data, and government databases which provide data typically used for retrospective analyses.

PHARMACEUTICAL COMPANIES of Johnson Johnson

الأراف محاجلي الأخلاق المراقبة والمحاج والمحاج المحاج المحاج المحاج والمحاج والمحاج والمحاج والمحاج والمحاج

Big Data Defined

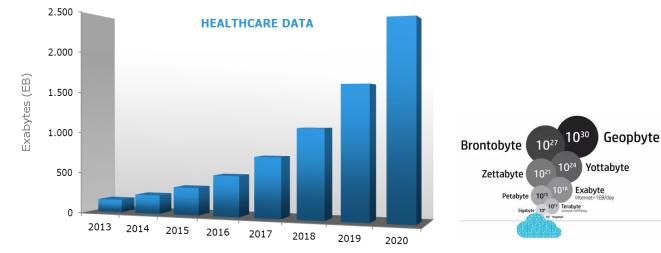


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Explosion of healthcare data

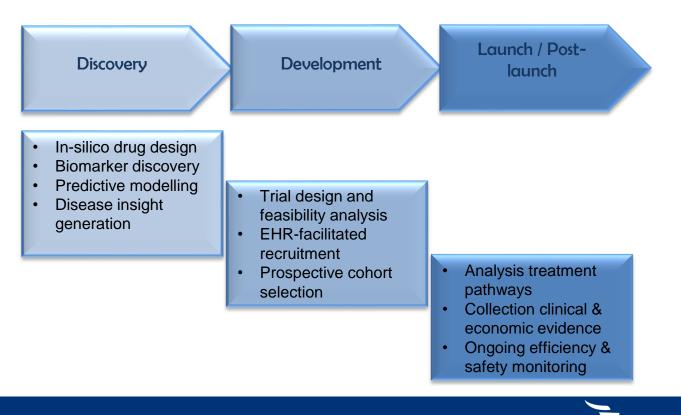
Healthcare data growth is one of the fastest across many industries. A 48% annual growth rate will lead to 2,314 Exabytes of data in 2020.



Enterprise Strategy Group 2011, Research report: North American Healthcare Provider Information

Jansser

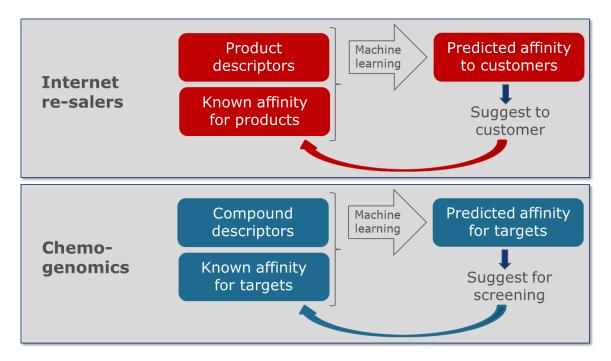
Opportunities for Real/Big data



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Developing in-silico drug design



THE **NETFLIX**-IZATION OF DRUG DISCOVERY



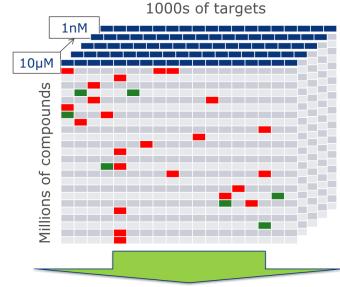
>100M data points with biochemical activities of tested compounds available for training



>100M training points



New IMI project in which 10 pharma companies collaborate

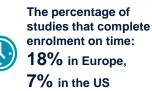


Identify and select compounds with good biochemical activity for target(s) of interest.

THE NETFLIX-IZATION OF DRUG DISCOVERY



Challenges in trial execution



Potential improvement through use of Real World Data



1/3 of protocol amendments are avoidable, at a cost of \$0.5m



Almost half of all trial delays caused by patient recruitment problems



Only **1/3** of the sites engaged in a multicentre study manage to enrol the requisite number of patients



\$

50% of today's clinical trials fail to achieve the target recruitment

Source: IMI-EHR4CR project



pharmaceutical companies of Johnnon&Johnnon



i-10

Non-profit - iHD institute

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governance &

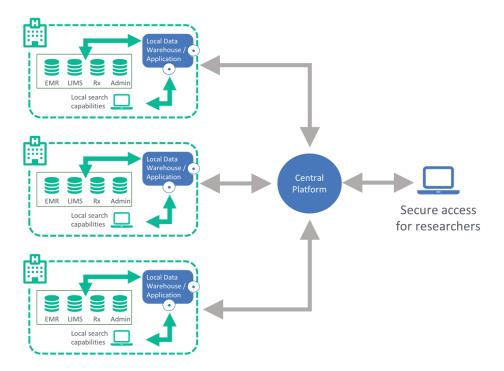
security

in 2019

34* mw

13

Stimulating the flow of data through federated networks



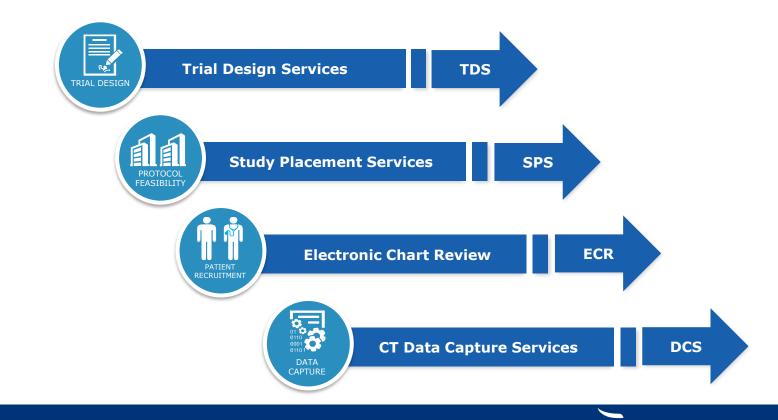
Benefits of federated networks

- Data remains under the control of the data owner
- Locally required legal and ethical approvals apply
- No patient level data leaves the owner's site, only aggregated counts, thereby ensuring patient privacy
- GDPR 'Privacy by Design'

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- Analysis is "brought to the data" rather than creating central data repository
- Use of common data model allows for efficient search / analysis across multiple data sets
- Requires close collaboration with data owners which builds trust

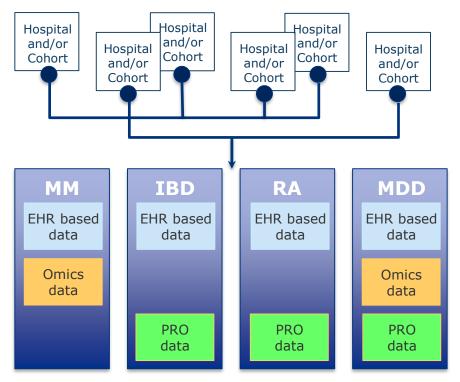
Using federated data in clinical research



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From "broad" to "deep" data



The broad network of RWD sources (hospitals, cohorts, other) can serve as starting point for enrichment (deepening).

By disease area, original RWD can be enriched based on the needs for (clinical) research, thereby creating a so called "T-shaped" data ecosystem (combining broad and deep data)

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True open science collaboration



Who We Are Who We Serve Data Standardization Software Tools Resources Join the Journey Events

Welcome to OHDSI!

The Observational Health Data Sciences and Informatics (or OHDSI, pronounced "Odyssey") program is a multi-stakeholder, interdisciplinary collaborative to bring out the value of health data through large-scale analytics. All our solutions are open-source.

OHDSI has established an international network of researchers and observational health databases with a central coordinating center housed at Columbia University.

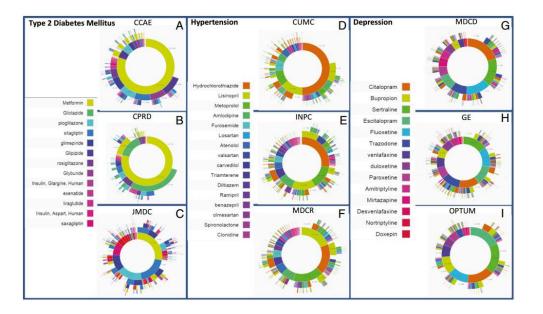


annu.onusi.org

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Power of distributed data --



Collaboration with 11 data sets representing **255Mio** subjects

Characterizing treatment pathways at scale using the OHDSI network

George Hripcsak^{ab.c.1}, Patrick B. Ryan^{cd}, Jon D. Duke^{ce}, Nigam H. Shah^{cd}, Rae Woong Park^{cg}, Vojtech Huser^{ch}, Marc A. Suchar^{cci,1,k}, Martijn J. Schuemie^{cd}, Frank J. Defalco^{cd}, Adler Perotte^{+,c}, Juan M. Banda⁻¹, Christian G. Reich⁻¹, Lisa M. Schilling^{-6,} Michael E. Mathery^{C,ce}, Panella Meeke^{-Arb}, Nicole Prat^{+,c}, and David Madigan⁻⁴



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pharmaceutical companies of Johmon-Johmon

New IMI project





Harmonised 100 million records, mapped to the OMOP common data model





Federated analytics via OHDSI tooling, ARACHNE and EMIF platforms

Impact: Improving trust and reusability of real world data for key stakeholders

Janssen

PHARMACEUTICAL COMPANIES OF Johnnon Johnnon

Conclusions

- Big data offers opportunities along the full product life cycle
- Specific analytical skills and methods are required
- Analysis and approaches to big data need to take patient / subject privacy challenges into account
- Federated approaches can help to mitigate privacy challenges

QUESTIONS

Bart Vannieuwenhuyse bvannieu@its.jnj.com

PHARMACEUTICAL COMPANIES OF Johnnon-Johnnon

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Mr. Yvon Merlière Project Director DMP, Caisse Nationale de l'assurance maladie Project DMP





Presentation of the SMR (DMP): The Shared Medical Record

12th September 2019





Sommaire







Introduction about the SMR

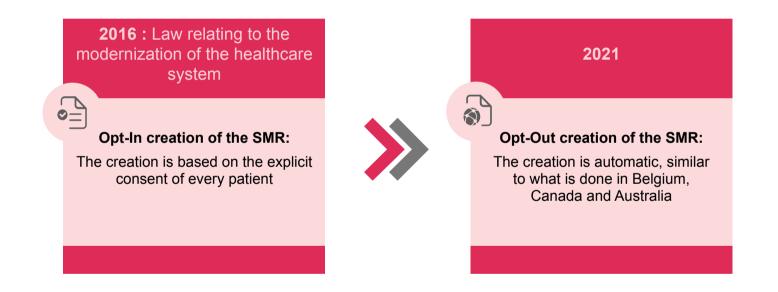




The SMR: A digital health record booklet enshrined within the French legislation



In 2016, the national Parliament enacted a law providing every French citizen with a digital health record booklet called the SMR.





DMP

Why has France developed the SMR ?



To meet patients' need of information by setting up their medical file

2002 : Law relating to the rights of patients and the quality of the healthcare system

"Patients have the right to dispose of their medical file without having to consult a physician. Medical information is accessible on the internet."



To improve disease prevention and healthcare coordination

Patients dispose of all of their medical information, especially in case of emergencies or when they go on vacation.

They can then, give access to their medical data to the new physicians they choose to consult.





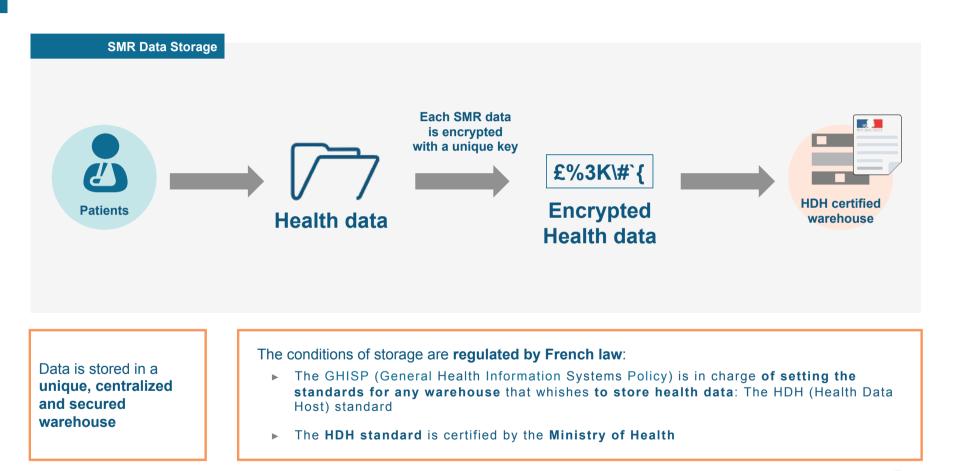
Data Security





The SMR: A highly secured service









Access regulation



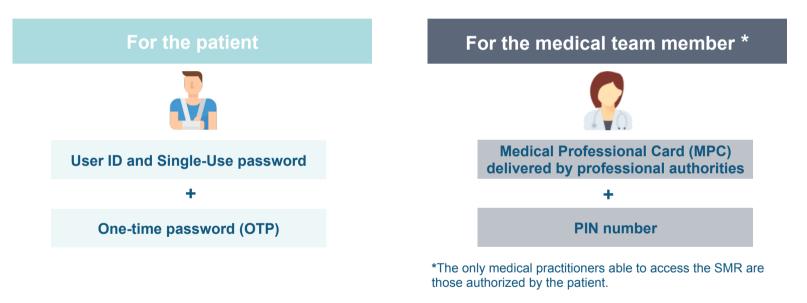


SMR Access Modalities: Restricted rights





Access to the SMR is limited to the patient and members of his medical care team. A strong twofactor authentication system has been put in place:





In light of these restrictions, it is impossible, for example, for the French Social Security System (Assurance Maladie) and/or private companies to access a patient's SMR data.





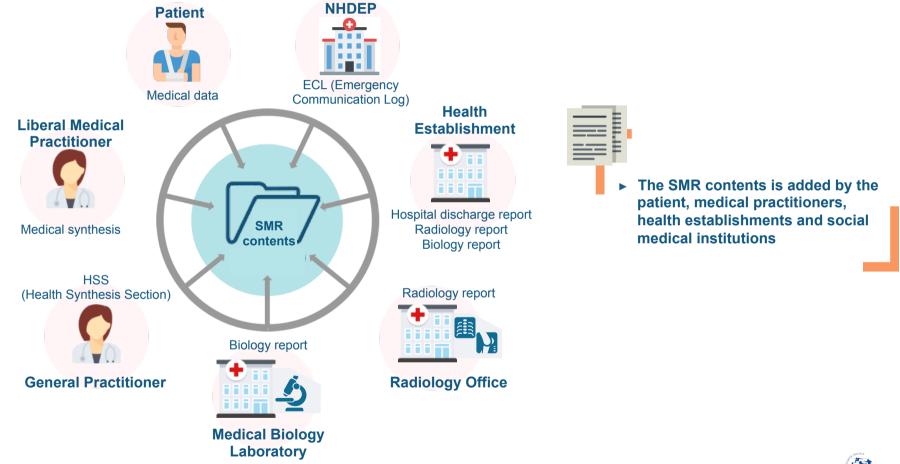
Contents of the SMR





CNAM / DDGOS / MSMR

The SMR: Filled by both the patient and his medical care team (1/2)

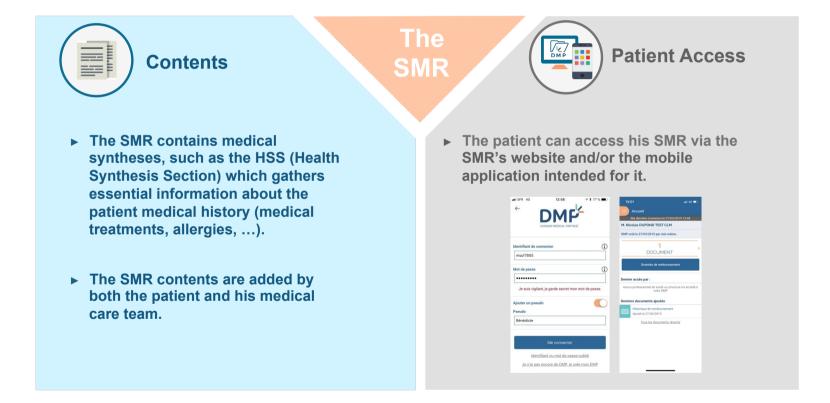






The SMR: Filled by both the patient and his medical care team (2/2)









Integration of the SMR to professional software solutions





CNAM / DDGOS / MSMR

Integration of the SMR to professional software solutions



The integration of the SMR to professional software solutions is facilitated by the interoperability framework defined at the national level, by the French Agency of Digital Health. This framework is defined to enable all health software solutions to send and receive data from one another in regulated and predefined flows.





A lot of workshops have been done in collaboration with software publishers in order to define the links between the SMR and the health professional software solutions.





Use-cases





CNAM / DDGOS / MSMR

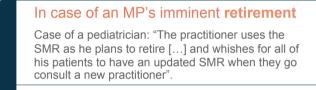
Use-cases of the SMR by medical practitioners

Survey concerning the use-cases of medical practitioners consulting the SMR



Amongst the Medical Practitioners who consult SMR the most, we find that several use-cases are directly linked to the practice of the MP, but there is also one use-case resulting from a patient request.

□ 6 use-cases linked to the practice of the MP:



Within the scope of telemedicine

Case of a pediatrician: "The practitioner uses the SMR for telemedicine".

For the follow-up of **Patients at risk**, especially on their vacation place or in case of emergency Case of a general practitioner: "The practitioner

consults the SMR and adds the HSS document for patients suffering from serious conditions".

□ 1 use-case of SMR consultation at the patient's request

To consult documents **following the hospitalization** of a patient

Case of a general practitioner: "The practitioner consults the SMRs of hospitalized patients".

To secu

To secure the work of anesthesiologists

Case of an anesthesiologist : "I consult the SMR of each and every patient to check the information they gave me about the medication they are on. 37 % of patients forget information."

To research information about a patient

Case of a pediatrician: "The practitioner systematically consults the SMR when he has no information about a patient".





Main figures and objectives

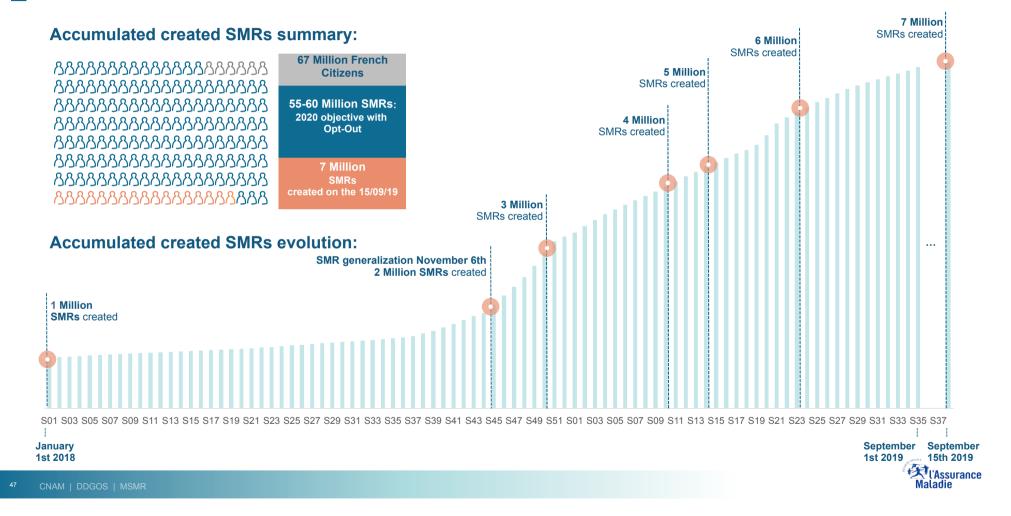




CNAM / DDGOS / MSMR

Evolution of the accumulated created SMRs





SMR Activity of various medical professions





Summary of the SMR created and number of electronic records consultations performed by the various medical professions



Summary of the active SMR medical practitioners in comparison to the total population of practitioners within the territory

City Professions (Liberal Professions)	Number of independants practicing within the territory	From January 2016 to December 2016				From September 2018 to August 2019			
		Populating MP	%	Consulting MP	%	Populating MP	%	Consulting MP	%
General practitioner	52 641	383	0,7%	840	1,6%	10 996	20,9%	23 567	44,8%
Medical Specialist	54 555	35	0,1%	56	0,1%	1 629	3,0%	3 993	7,3%
Masseur-Physiotherapist	67 860	19	0,0%	39	0,1%	98	0,1%	1 126	1,7%
Nurses	93 206	33	0,0%	126	0,1%	132	0,1%	815	0,9%
Other professions	77 562	3	0,0%	11	0,0%	144	0,2%	1 130	1,5%
Medical Biology Laboratories	3 864	6	0,2%	5	0,1%	12	0,3%	10	0,3%
Dispensing pharmacies	21 510	1	0,0%	3	0,0%	542	2,5%	2 437	11,3%



SMR Activity of HE and NHDEP





15% of Health Establishments have performed at least one SMR record action



Summary of the active SMR Health and Social Medical Institutions

HE populating SMRs	From January 2016 to December 2016	From September 2018 to August 2019
Health Establishments (HE)	52	389
Nursing Homes for Dependant Elderly People (NHDEP)	186	296
Total	238	685





Summary





CNAM / DDGOS / MSMR





The French parliament enacted a law providing every French citizen with a digital health record booklet called the SMR « Shared Medical Record »

This SMR is not mandatory. The official holder of the SMR is the patient.

The SMR contains reports and syntheses added by the patient himself or by a member of his medical care team.

The objectives of the SMR are:

- **o** To allow the patient a better understanding of his medical information
- To offer the medical care team an easier access to the patient's medical file, in order to insure the coordination, continuity and quality of the needed medical care

The implementation of the SMR is incorporated **within the framework of the Personal Data Regulating Law in France** ("Loi informatique et libertés"):

- Centralized hosting of data
- **Respect of the security rules** as defined by the General Health Information Systems Policy (GHISP), with a restricted access to data only to members of the medical care team, who have been approved by the patient himself.

Today, 7 million SMRs have been created, with an objective of 55 to 60 million of SMRs by 2021.





Thank you for your attention

CNAM | DDGOS | MSMR









CNAM | DDGOS | MSMR

Mrs. Ann Costello

Global Franchise Lead Centralised Solutions, Roche Diagnostics International

Clinical decision support that helps in saving live





Why are we here?

"According to my doctors, I am not supposed to be talking to you now. They gave me about a year to live after I developed aggressive bladder cancer. But here I am three years later, telling you my story — almost cancer-free and living my life."

- Michael Negrin, Israel

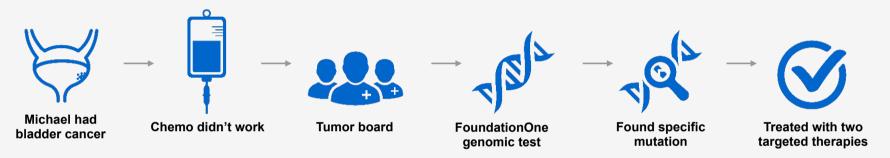
WHERE CARE LEADS

Rochi

Michael's journey



Combining the power of diagnostics, data and therapy to save his life



Today, access to multiple data sets and targeted therapies are **MAKING PATIENT CARE MORE COST-EFFECTIVE FOR HOSPITALS AND IMPROVING PATIENT OUTCOMES**



WHERE CARE LEADS



86% of all healthcare costs are associated with managing chronic disease¹



Staffing shortages continue to rise across healthcare



The **aging population** is significantly driving this rise in costs;² 61% **increase in morbidity** due to cardiac conditions, cancer and infectious disease by 2030³ Healthcare spending is projected to consume 9.5%–14% of global GDP by 2060^{4,5}



WHERE CARE LEADS

(CDC. Chronic disease organizer, <u>https://www.cdc.gov/chronic/disease</u>/overview/index.htm. June 28, 2017, Accessed October 6, 2017. www.cend.cnr/discladucuments/unclidicalear/occumental/?conten_P12.8A/IEA/WID/MP2/01715&AdocLanguageEp. Disease Burden 2030 Fact Book. Divisional Medical and Scientific Affairs June 24, 2015. OECD. Organization for Economic Cooperation and Development. OECD (2013). "What Future for Health Spending?" OECD Econom Pagratment Policy Notes. No. 19, June 2013.

By 2020, medical knowledge will double itself every...



1 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3116346

WHERE CARE LEADS

Data is accelerating changes in healthcare Opportunity to address some of the complexity



WHERE CARE LEADS

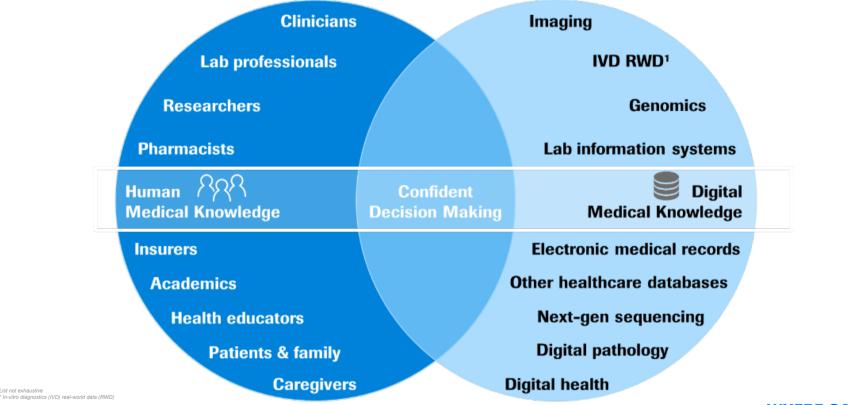
Roche

Opportunity – Data Enabled Healthcare

List not exhaustive

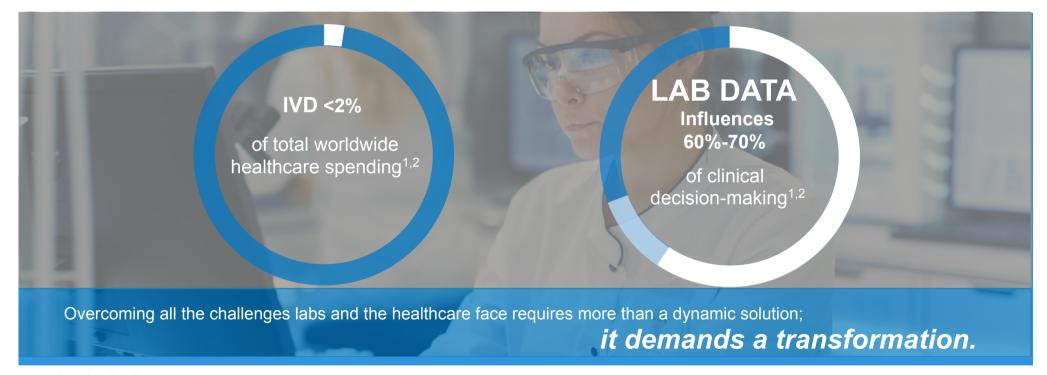


Good medicine is the result of human & digital medical knowledge



WHERE CARE LEADS

The laboratory is the engine of digital transformation Foundation for good clinical decision-making



1. European IVD Market Statistics EDMA. 2013. 2. Rohr U-P, Binder C, Dieterle T, Giusti F, Messina CGM, Toerien E, et al. (2016) The Value of In Vitro Diagnostic Testing in Medical Practice: A Status Report. PLoS ONE 11(3): e0149856. https://doi.org/10.1371/ journal.pone.0149856.

WHERE CARE LEADS

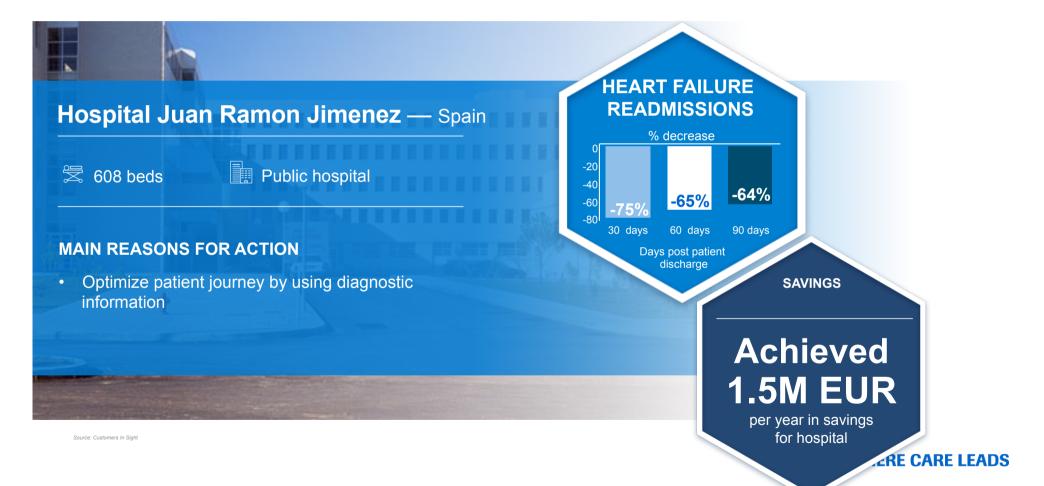
Roche

Digital Transformation at Roche Diagnostics





Patient journey optimization in heart failure





Rapid heart attack diagnosis reduces resource use *Significant savings possible in the ER with Roche cTnT-hs 1h algorithm*



. Ambavane, A. et al. (2017). PLoS One 12(11), e0187662 Cost savings vs Standard of Care (SoC,

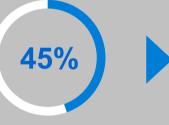
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Roche

Preeclampsia testing helps reduce pregnancy care costs Example from Germany shows savings from fewer unnecessary hospitalizations

Use of the Roche sElt-1/PIGE ratio can reduce hospitalization rates¹



24%

Expected cost saving **361 EUR** per patient* Expected annual cost savings of more than **39 mEUR** nationally in Germany^{+,2-4} sFIt-1/PIGF reimbursed by statutory health insurance in Germany, starting Oct 2019



PE: Preeclampsia; PIGF: Placental growth factor; sFIL-1: Soluble fms-like tyrosine kinase-1 "Robust to plausible changes in main parameters.
† Based on 108,968 pregnant women per year presenting with hypertensive disorders³⁻⁴. 1. Schembach Dr. BMC Health Serv Res. 2014 App 61(6)(103). 00: 101.1666/s12913-018-3406-1, 2. www.gbe-bund.de 3. Engel J, et al. Der Klinikarzt 2012, 4. Dietl A, et al. Geburtshilfe Frauenheilkd 2015

WHERE CARE LEADS

Using data from multiple sources to support decision making





NAVIFY® Decision Support Portfolio

NAVIFY[®] Tumor Board solution for oncology care teams



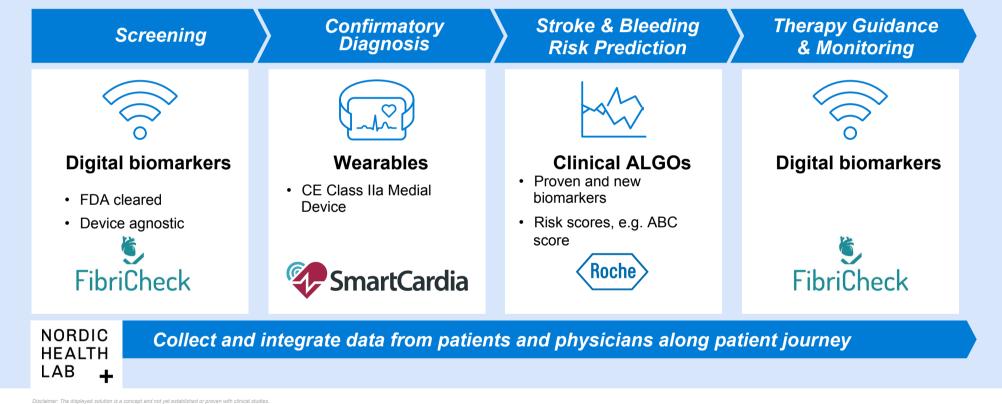
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Disease Management





Digital tools supporting Disease Management Improved diagnosis and management of atrial fibrillation patients

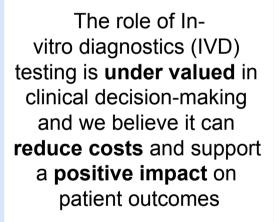


Disclaimer: All claims and data included in this presentation belong to the respective third parties. Roche is not responsible for the validity of these claims. Roche is working on research projects with these third parties.

WHERE CARE LEADS

Roch

Closing thoughts



Clinical decision support tools can **fundamentally change** the way we **diagnosis and treat** patients By leveraging the combined strengths of diagnostic testing, digital tools and therapy, we can help close the gaps in patient care and aspire to make a real difference in the lives of patients

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WHERE CARE LEADS



Doing now what patients need next

Mr. Bert Hoorne Industry Technology Strategist Az Groeninge: Applied AI in healthcare





Center Oncology/Radiotherapy



az|groeninge kortrijk

Total Surface Area: 117.422 m²

Number of medical doctors: 197

Total recognized beds: 1054



Radiation Therapy?



Why?

To cure cancer To reduce symptoms

How?

Damaging the DNA within cancer cells, destroying their ability to reproduce

Linear Accelerator: TrueBeam (Varian)

TrueBeam

TrueBeam STx





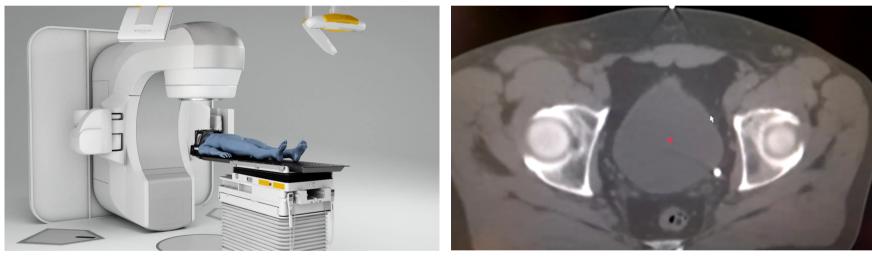
Radiotherapy - 120 leaf MLC

Radiotherapy & **Radiosurgery** - 120 leaf **High Definition** MLC

Assistive AI for radiotherapy planning



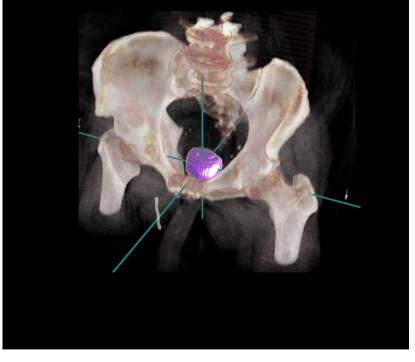
Problem: Delineating tumors and anatomy in images by hand is costly and inaccurate



A linear accelerator (linac) for radiotherapy delivery

Tracing anatomy in a popular commercial tool

The InnerEye position

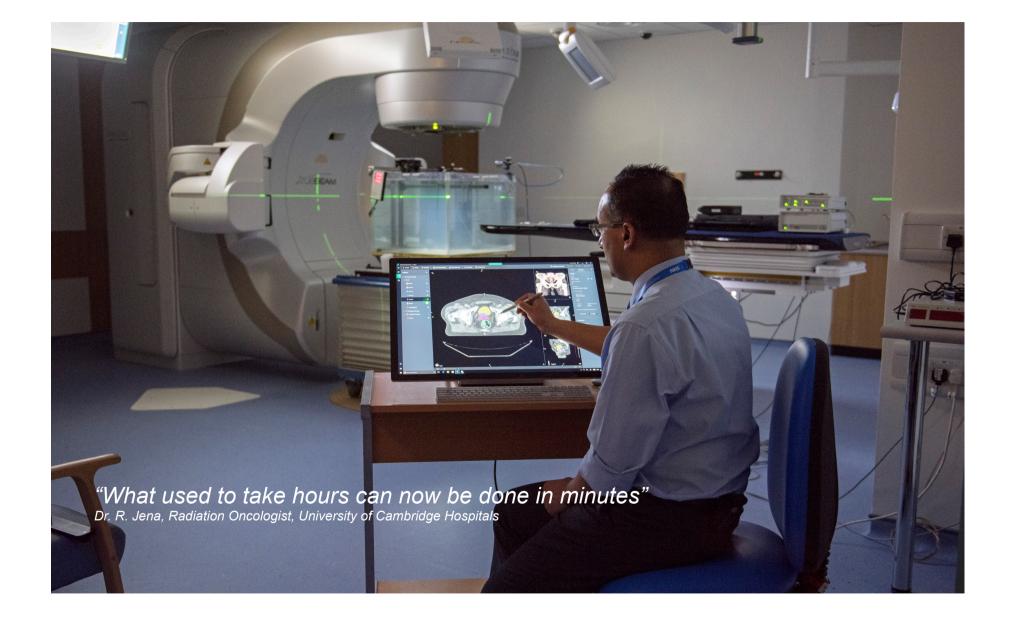




InnerEye is a <u>research project</u> that develops machine learning cloud services to

assist medical experts

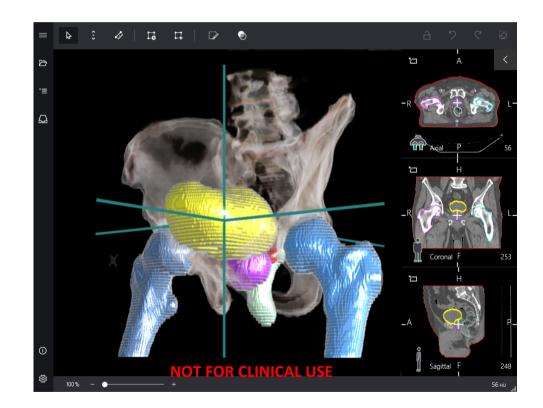
in tasks of <u>measurement</u>, <u>delineation</u> and <u>quantitative temporal assessment</u>



The 3D image segmentation app



Efficient segmentation of anatomy and pathology





FDA 510(k) clearance received on Dec 28th 2017 as class II medical device.



ML segmentation of a prostate structure set

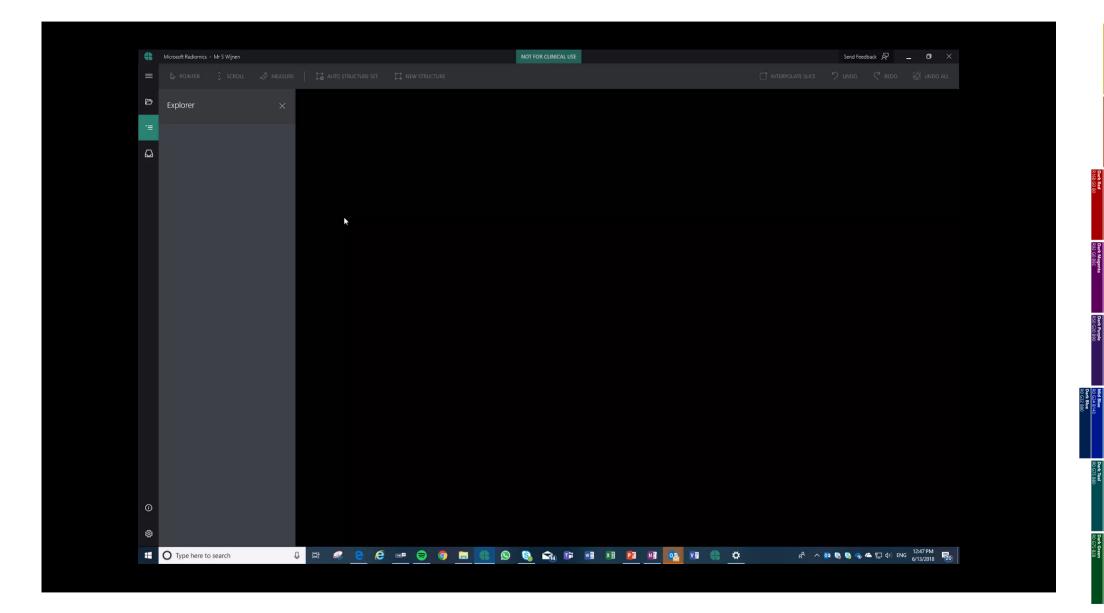
Loading CT DICOM image

Selecting the ML model: ProstateRT

Applying the ML in the cloud (approx. 58 seconds)

- De-identifying the image
- Compression and transmission to the cloud
- Returning the contours

Visualization of the contours axial and in 3D







Health



Reproducibility

Dark Magenta R92 G0 B92

Dark Green R0 G75 B28



Explainability

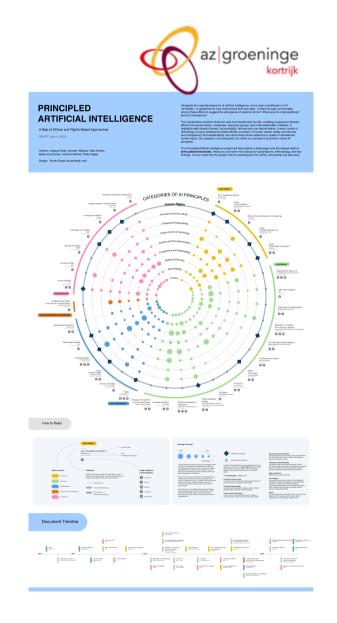


Security

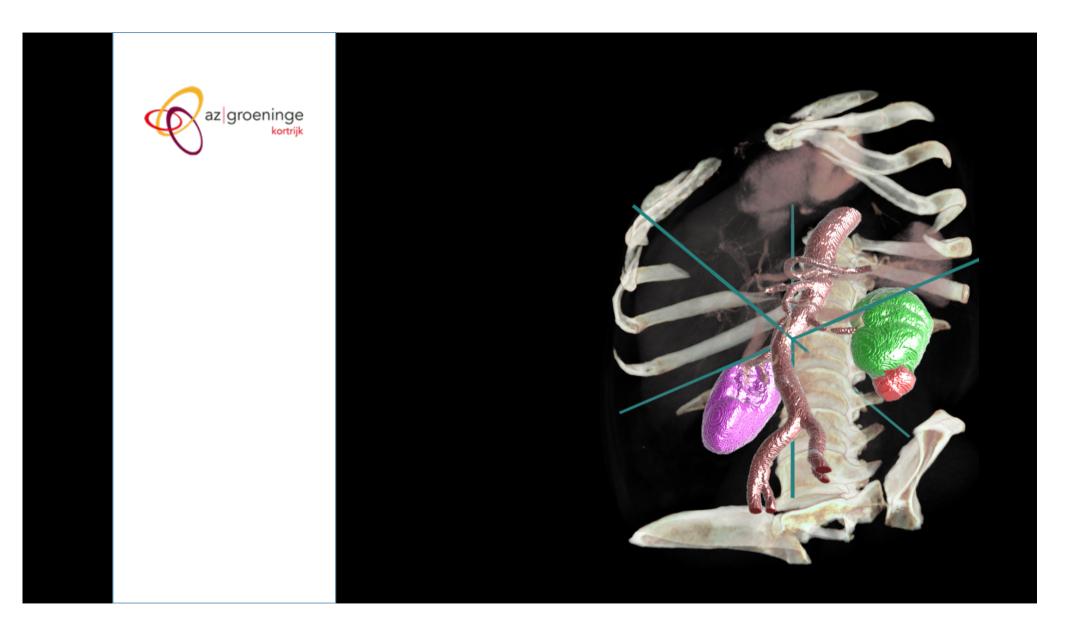
Integrety - Trust

7 key requirements that AI systems should meet in order to be deemed trustworthy

- 1. Human agency and oversight
- 2. Technical Robustness and safety
- 3. Privacy and data governance
- 4. Transparency
- 5. Diversity
- 6. Societal and environmental well-being
- 7. Accountability



85



Other A.I. Possibilities

az|groeninge

Hicrosoft

Medical conversations to medical intelligence



Project EmpowerMD

Medical conversations to medical intelligence

Mr. Felix Wandel EMEA Business Unit Leader of SPI, Johnson & Johnson, Medical Devices EMEA

CareAdvantage Experience Introduction



Johnson 4 Johnson

FAMILY OF COMPANIES

Solving starts with listening.

CareAdvantage | Johnnon-Johnnon

We are here to help hospitals and healthcare providers achieve the triple aim



How we operate

Needs Identification

Discuss challenges and perform analysis to define opportunities where we can help



Co-Creation

Working together to understand how your needs can be addressed using our capabilities



Desired Results

Tailor the approach to deliver results and measurable impact

We believe solving starts with listening.

CareAdvantage

Johnson Johnson

Our tailored capabilities address your specific needs

Patient	Operating Room	Hospital	Financing	Surgical
Pathways	Optimization	Logistics	Solutions	Excellence
Designed to help hospitals put patients at the centre of care; engaging them from hospital to home. We aim to improve outcomes and patient experience, while eliminating inefficiencies and reducing cost of care.	Lack of operating room capacity is a constant challenge for many hospitals. To address this, we aim to help operating rooms run more efficiently, enabling the surgical team to operate on more patients.	Many hospitals are now expected to deliver improved outcomes more efficiently. We focus on co- creating tailored solutions that help streamline resources, workflows, and processes, ultimately reducing time and costs.	Hospitals are under pressure to do more with less. We offer a range of financing solutions to enable investment capabilities and support innovation where hospitals and healthcare providers need it the most.	Designed to elevate care to new heights of surgical excellence. We develop world class technologies to enhance surgical performance, help optimize surgeon skills and knowledge, and guide patients successfully to full recovery.

CareAdvantage Johnson Johnson

What you will see today

care4today[®]

Connecting the health care team and patients throughout the entire patient pathway through portals and apps



SPI is developed to enable surgeons to choreograph their OR, guiding the entire care team seamlessly through every surgery. It achieves this through a system of synchronized workflows, effortless documentation and real-life learning



C-SATS, part of the Johnson & Johnson Family of Companies, is an accurate and objective surgical skills assessment system, designed to help health care professionals continuously improve. *In Pilot stage and limited rollout.*

What you will see today



CareAdvantage Johnson Johnson

Instructions for workshop

- Group to be split into 3 groups
- Each rotation will be 15 minutes
- You will have a chance to rotate through all 3 stations





Theme workshops:

Pre-Surgical/Patient Engagement Experience (Care4Today)

Intraoperative standardization & digitalization (SPI)

Post-operative peer review and feedback (C-SATs)



THANK YOU FOR YOUR ATTENTION

WISHING YOU AN INSPIRATIONAL TOUR

SAFE TRIP BACK TO THE MEET & GREET CENTER