Personalised Healthcare With AI

Enabling the Next Generation of Clinical Trials and Improving Patient Outcomes

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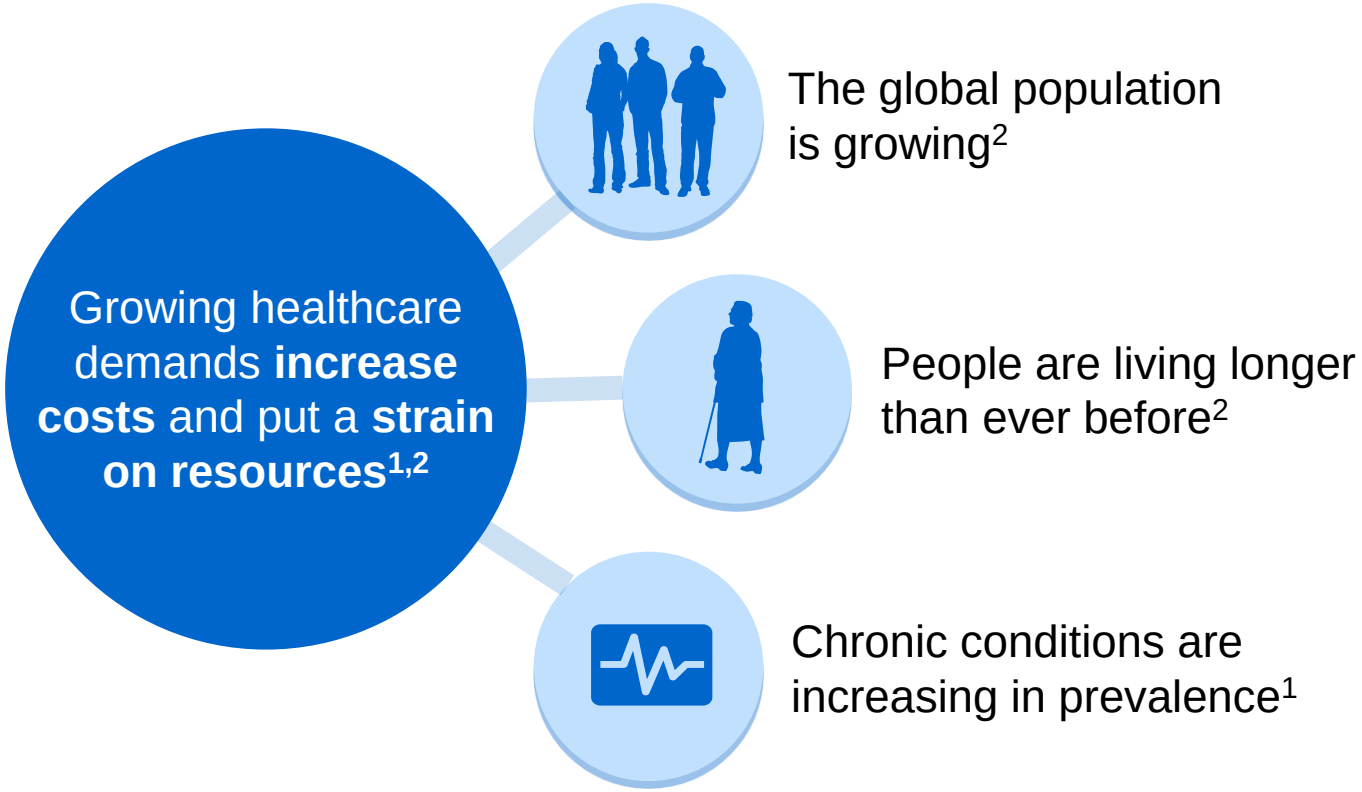
San Francisco, CA, US

Veeva ID: M-IT-00000598
Date of prep: March 2021

The Current Course of Healthcare Is Unsustainable

New Solutions Are Needed to Stay Ahead of the Demands



Profound transformations are needed to meet healthcare demands and improve patient outcomes

1. Deloitte. 2019 global health care outlook. Accessed February 23, 2021, 2020. https://www2.deloitte.com/content/dam/Deloitte/global/Documents/Life-Sciences-Health-Care/gx-lshc-hc-outlook-2019.pdf; 2. United Nations. World population prospects 2019. Accessed March 23, 2020. https://population.un.org/wpp/Publications/Files/WPP2019_Highlights.pdf

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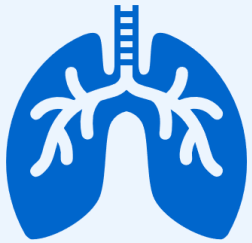
Lung Cancer Diagnosis Often Occurs Too Late

Earlier Diagnosis Can Improve Outcomes



Lung cancer caused 1.8 million deaths worldwide in 2018[1]

57% of patients are diagnosed at an advanced stage[2,a]

These patients have a 5-year survival rate of[2,a] **5.8%** ❱ With early diagnosis, the 5-year survival rate increases to[2,a] **59%**

Early diagnosis could extend the lifespan of **>0.6 million** people each year[1,2,b,c]

[a] Advanced-stage diagnosis refers to patients with metastasis at diagnosis; early diagnosis refers to patients diagnosed when the tumour is localised to primary site; based on data collected in the US SEER database 2010–2016. [b] Early diagnosis refers to patients diagnosed when the tumour is localised to primary site, based on data collected in the US SEER database 2010–2016. [c] Extrapolation is based on the number of new cases of lung cancer reported globally in 2020[1] and the 5-year survival rates from the US SEER database.[2]
SEER, Surveillance, Epidemiology, and End Results.

1. International Agency for Research on Cancer. Lung cancer fact sheet. Accessed September 30, 2020. https://gco.iarc.fr/today/data/factsheets/cancers/15-Lung-fact-sheet.pdf;
2. National Cancer Institute. SEER Program. Lung and bronchus cancer stat fact sheet. Accessed February 17, 2021. https://seer.cancer.gov/statfacts/html/lungb.html

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DLBCL Is an Aggressive, Heterogeneous Disease

Improvements in Research and Development Are Necessary

DLBCL
5-year relative survival **63.8%**[1]

40% of patients are not responding to SOC

Need better stratification to benefit more patients with lower burden on healthcare systems

Selected Large Clinical Trials in DLBCL

Trial	N	Year	Sponsor	Outcome
MAIN	787	2014	Roche	NEGATIVE
GOYA	1418	2017	Roche	NEGATIVE
PRELUDE	758	2013	Eli Lilly	NEGATIVE
REMARC	650	2019	LARO	POSITIVE
PILLAR-2	742	2016	Novartis	NEGATIVE
REMoDL-B	845	2015	Janssen	NEGATIVE
Alliance CALGB 50303	491	Ongoing	NCI	NEGATIVE
PHOENIX	838	2019	Janssen	NEGATIVE
ROBUST	570	2020	Celgene	NEGATIVE

Most recent DLBCL clinical trials have failed[2-10]

Need better enrichment to enable the next generation of clinical trials

DLBCL, diffuse large B-cell lymphoma; SOC, standard of care.

1. National Cancer Institute. SEER program: Diffuse large b-cell lymphoma stat fact sheet. Accessed February 17, 2021. https://seer.cancer.gov/statfacts/html/dlbcl.html;
2. Seymour JF et al. *Haematologica*. 2014; 99(8):1343-1349. 3. Sehn LH et al. *Blood*. 2019;134(suppl 1):4088. 4. Crump M et al. *J Clin Oncol.* 2016;34(21): 2484-2492.
5. Thieblemont C, et al. Br J Haematol. 2020;189(1):84-96. 6. Witzig TE et al. Presented at ASCO 2016; abs 7506. 7. de Tute RM et al. Presented at ASH 2015; abs 2669.
8. Bartlett NL et al. *J Clin Oncol*. 2019;37(21):1790-1799. 9. Younes A et al. *J Clin Oncol*. 2019;37(15):1285-1295. 10. Vitolo U et al. Presented at the ICML 2019; abs 005.

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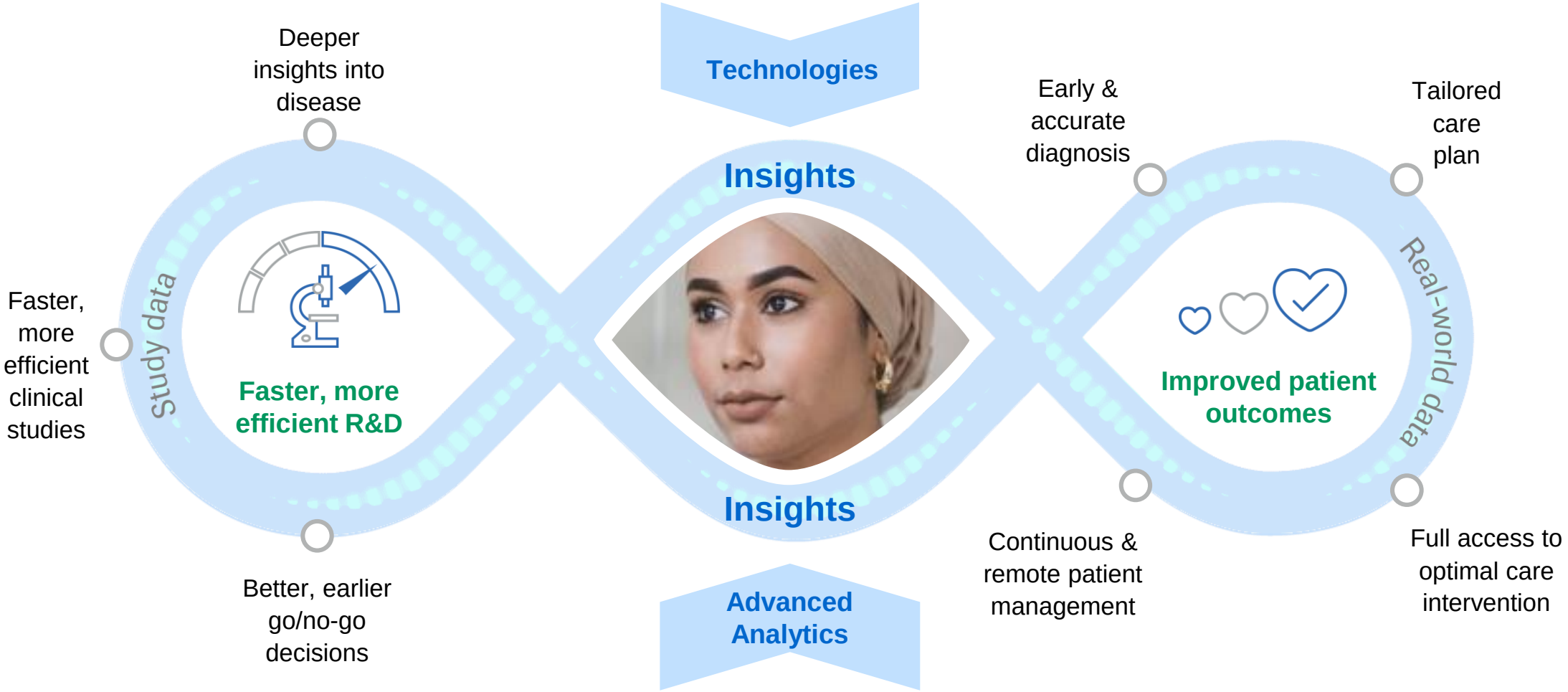
Data, Analytics, and Technology Can Accelerate R&D and Improve Patient Outcomes



R&D, research and development.

Data, Analytics, and Technology Open Up an Unprecedented Opportunity

Transforming Drug Development and Clinical Care

Increasing Availability of Medical Imaging Data

AN ESTIMATED
3.6
BILLION

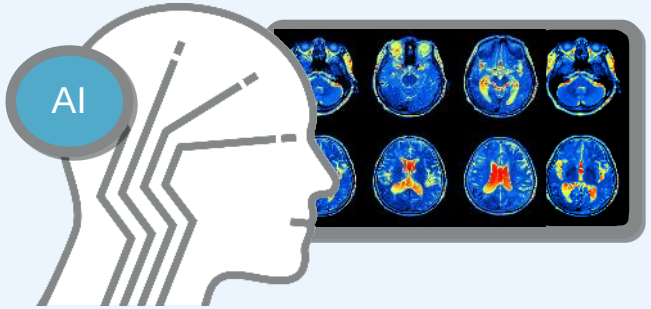
Radiological examinations are performed annually[1]

Pathology departments process up to:

500
slides/day[2]

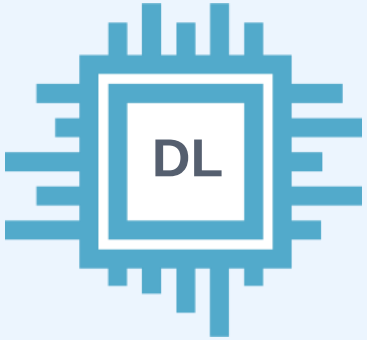
Medical images provide a valuable resource for algorithm training[3]

Advanced Analytics



Deep-learning algorithms can perform as well as humans in complex tasks[4]

Improvements in Computing Power



Increases in compute power have improved the performance of deep-learning algorithms[4]

AI, artificial intelligence; DL, deep learning.

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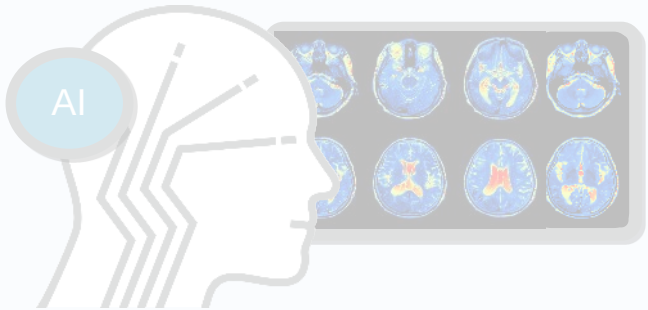

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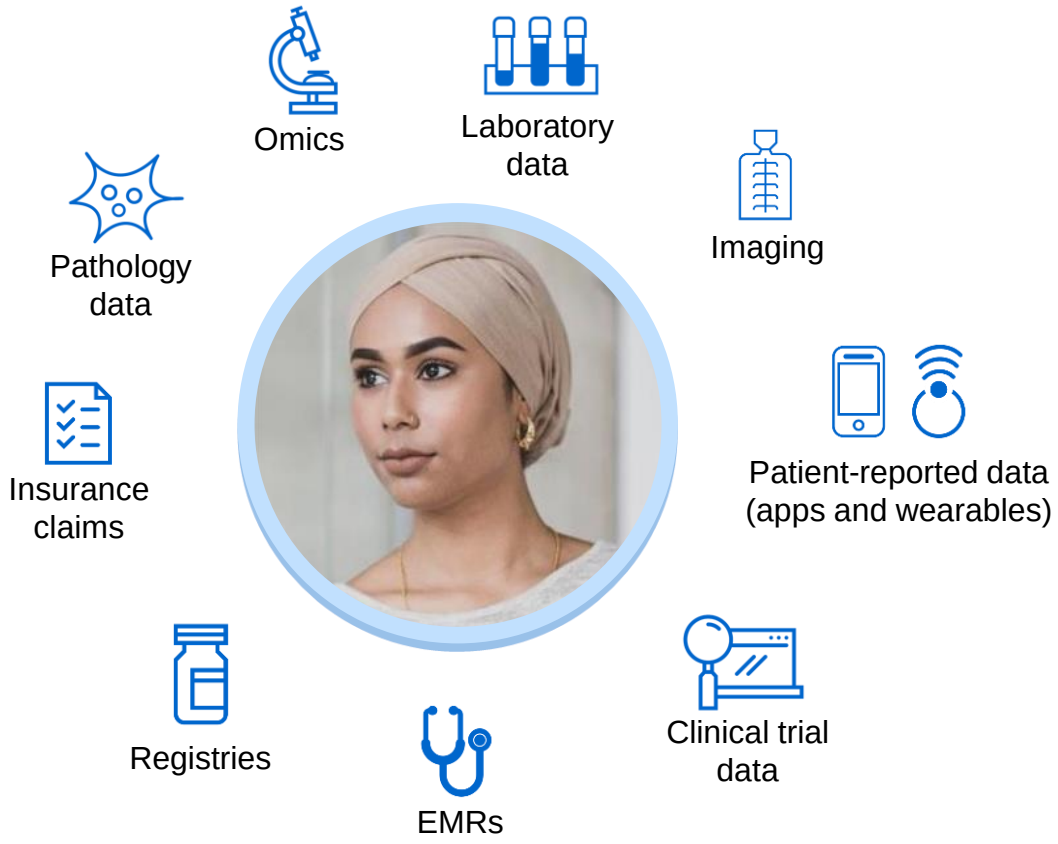
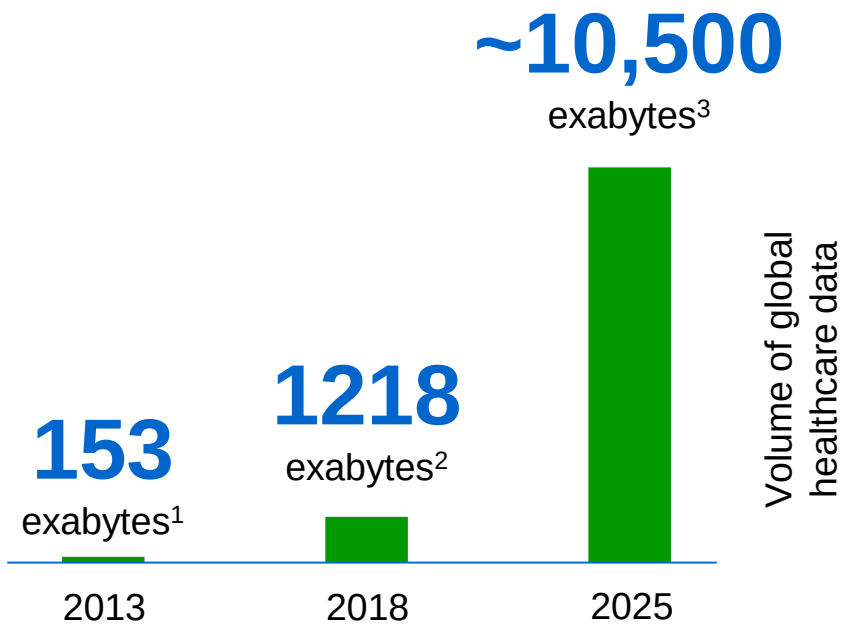
Increasing Diversity and Volumes of Healthcare Data Are Enabling a Deeper Representation of the patient

Offering the Potential to Give Each and Every Patient the Best Possible Care





The volume of global healthcare data is projected to increase by **36%** per year[2]

EMR, electronic medical record.

1. EMC with Research & Analysis by IDC. The digital universe driving data growth in healthcare. Accessed December 3, 2019. https://www.cycloneinteractive.com/cyclone/assets/File/digital-universe-healthcare-vertical-report-ar.pdf; 2. IDC White Paper: The digitization of the world - from edge to core. Accessed December 3, 2019. https://www.seagate.com/files/www-content/our-story/trends/files/idc-seagate-dataage-whitepaper.pdf; 3. IDC White Paper: Healthcare: DATCON Level 3. Accessed February 28, 2020. https://www.seagate.com/www-content/our-story/trends/files/idc-seagate-datcon-healthcare.pdf

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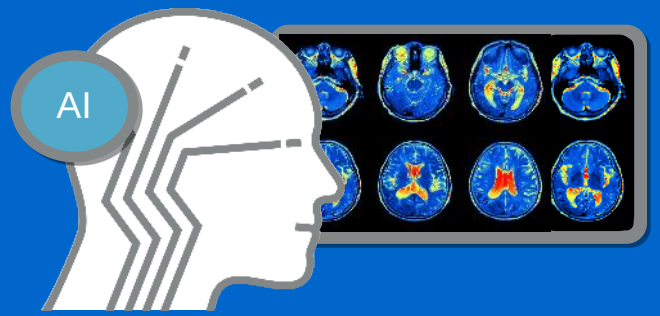

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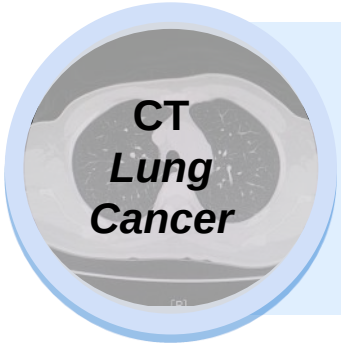
AIA Enhances Current Diagnostics to Improve Outcomes

Efforts Extend Across a Wide Range of Modalities and Therapeutic Areas

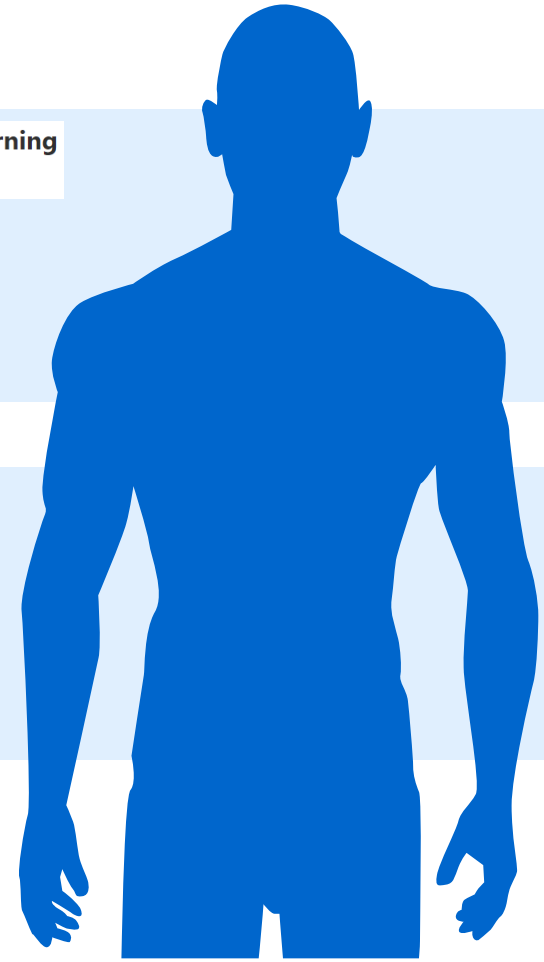
PMLR Proceedings of Machine Learning Research

AIA applied to brain MRIs can accurately predict disease progression in multiple sclerosis[1]



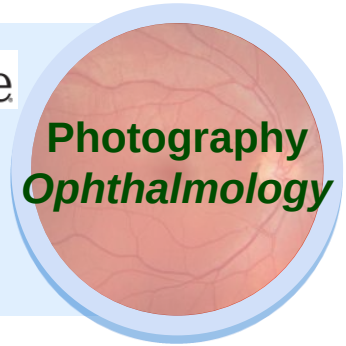
nature medicine

AIA can replicate radiologists in the accurate detection of lung cancer from CT scans[3]



American Diabetes Association. Diabetes Care

AIA can accurately diagnose diabetic retinopathy from colour fundus photographs of the eye[2]



nature medicine

AIA can predict the presence of 6 of the 10 most frequently mutated lung cancer genes from tumour biopsies[4]

AIA, advanced imaging analytics; CT, computed tomography; MRI, magnetic resonance imaging.

1. Tousignant A et al. *Proc Mach Learn Res*. 2019;102:483-492. 2. Verbraak FD et al. *Diabetes Care*. 2019;42(4):651-656. 3. Ardila D et al. *Nat Med*. 2019;25(6):954-961.
4. Coudray N et al. *Nat Med.* 2018;24(10):1559-1567.

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Whole-slide Images Are Very Information-rich

Old Technologies Have Not Been Fully Leveraged

Cancer Immunology, Immunotherapy (2020) 69:581–591
https://doi.org/10.1007/s00262-020-02481-3

ORIGINAL ARTICLE

Digital pathology-aided assessment of tumor-infiltrating T lymphocytes in advanced stage, HPV-negative head and neck tumors

Emma J. de Ruiter[1] · Reinout H. de Roest[2] · Ruud H. Brakenhoff[2] · C. René Leemans[2] · Remco de Bree[3] ·

J Pathol Inform. 2019; 10: 40.
Published online 2019 Dec 12. doi: 10.4103/jpi.jpi_65_18
PMCID: PMC6939342
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A Digital Pathology-Based Shotgun-Proteomics Approach to Biomarker Discovery in Colorectal Cancer

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Artificial intelligence-guided tissue analysis combined with immune infiltrate assessment predicts stage III colon cancer outcomes in PETACC08 study

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Research Article

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[4]*School of Pharmacy, Queen's University Belfast, Belfast, UK*

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ARTICLE OPEN

Image analysis with deep learning to predict breast cancer grade, ER status, histologic subtype, and intrinsic subtype

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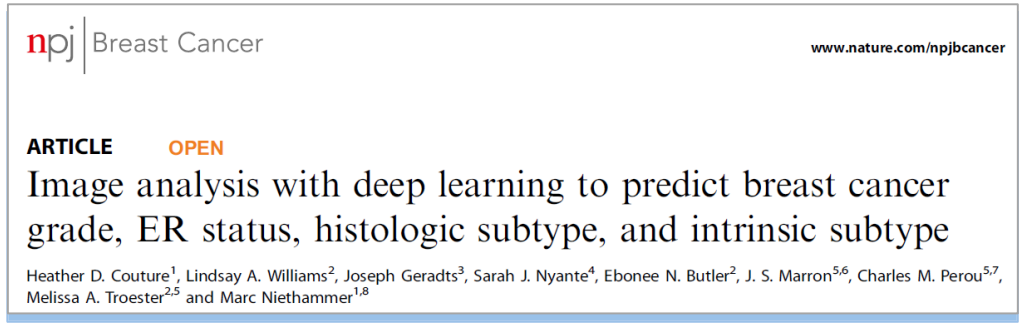

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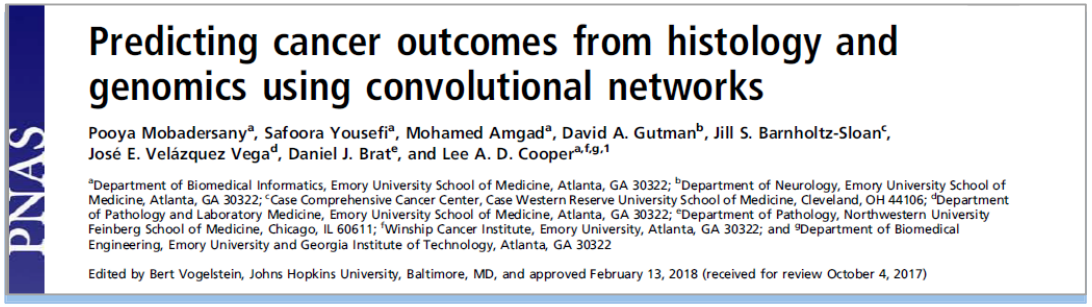

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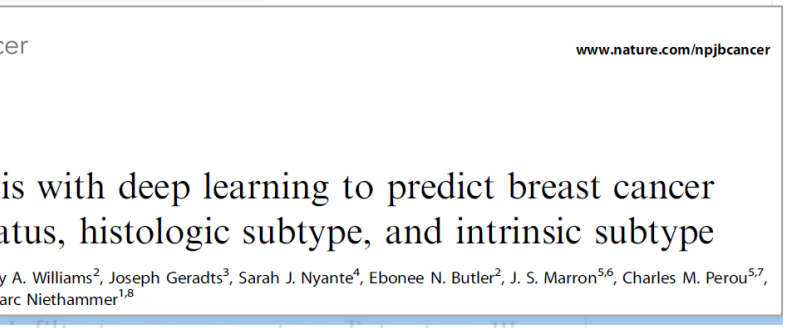
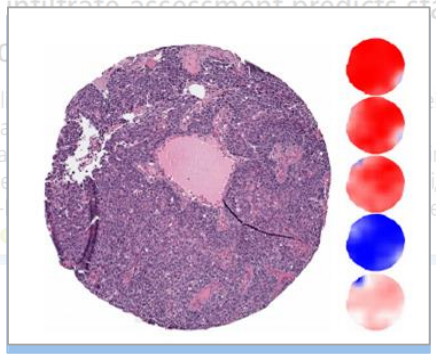
AIA Can Improve the Diagnostic Workflow





Rigorous, consistent, and speedy replication of a pathologist's diagnostic tasks at scale

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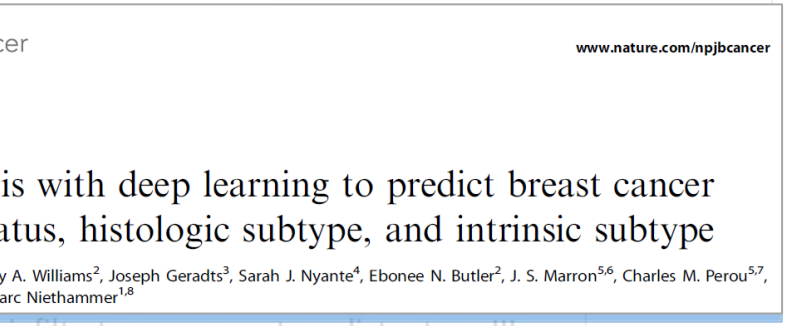
AIA Can Derive New Insight That Is Currently Beyond Human Visual Perception



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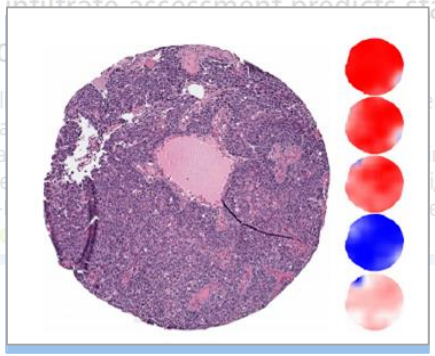

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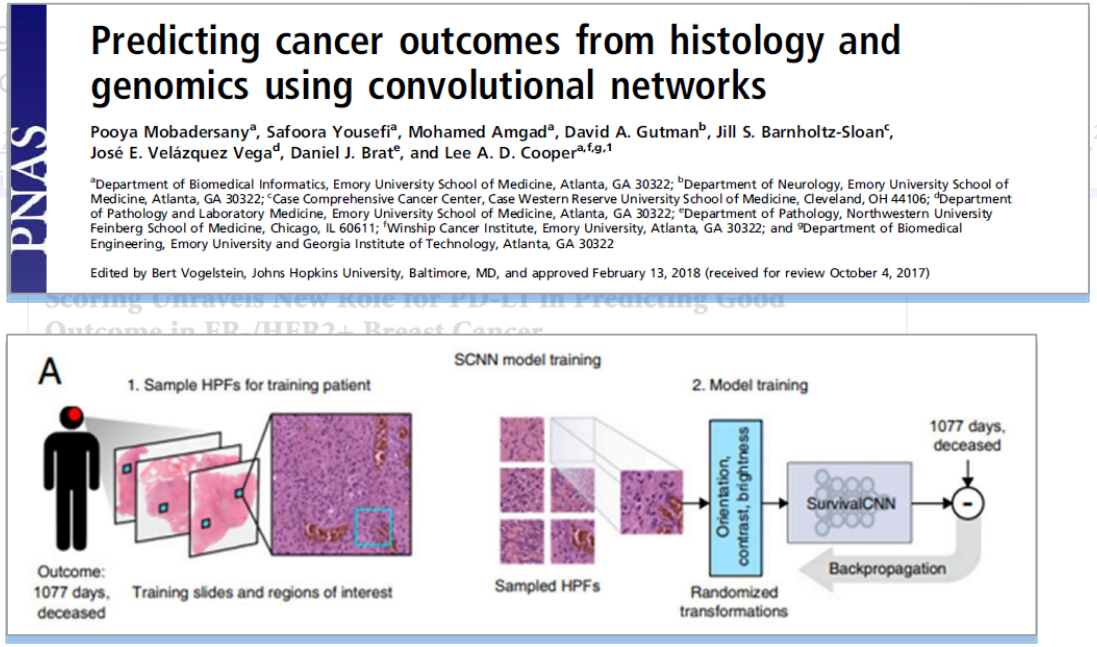

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Identifies connections across modalities to create new insight from old data[2]

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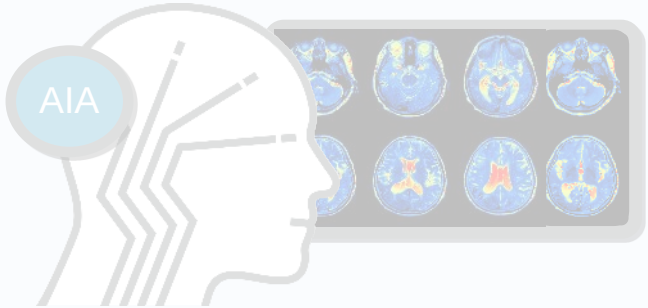
Increasing Availability of Medical Imaging Data

AN ESTIMATED **3.6 BILLION** Radiological examinations are performed annually[1]

Pathology departments process up to: **500 slides/day**[2]

Medical images provide a valuable resource for algorithm training[3]

Advanced Imaging Analytics



Deep-learning algorithms can perform as well as humans in complex tasks[4]

Improvements in Computing Power

Increases in compute power have improved the performance of deep-learning algorithms[4]

AIA, advanced imaging analytics; DL, deep learning.

1. Mettler FA Jr et al. *Radiology*. 2009;253(2):520-531. 2. Levy JJ et al. *Pac Symp Biocomput*. 2020;25:403-414. 3. Tang A et al. *Can Assoc Radiol J*. 2018;69(2):120-135.
4. Hosny A et al. *Nat Rev Cancer*. 2018;18(8):500-510.

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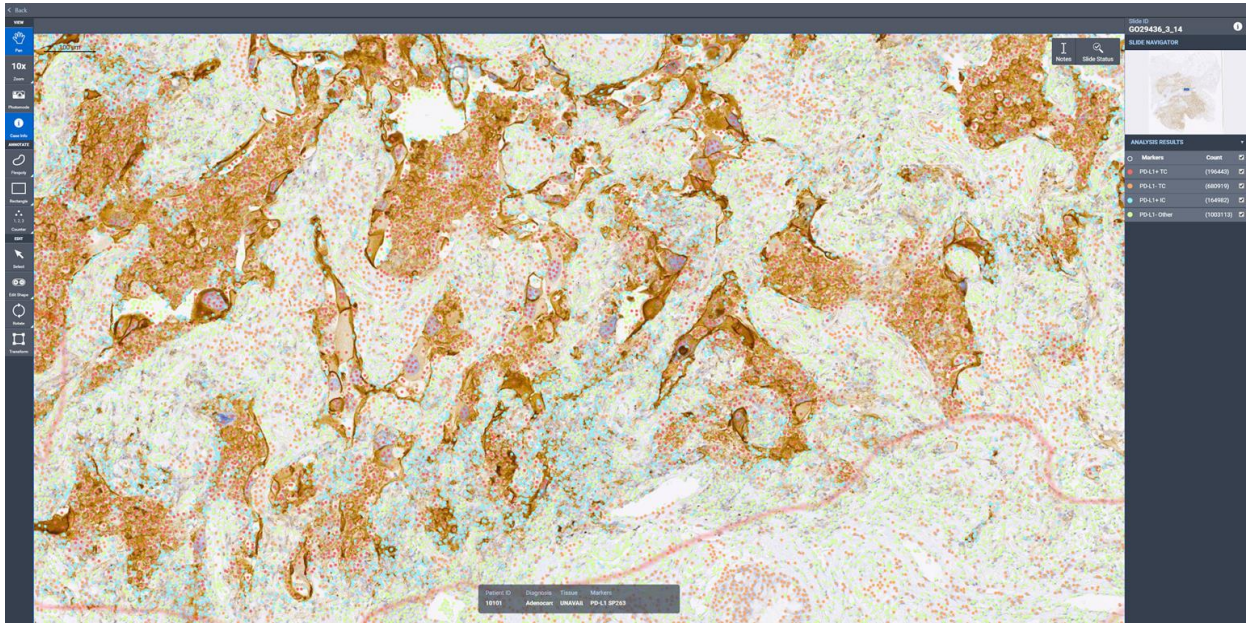
Digital Pathology Research Platform

Internally Built RDS Solution to Accelerate Pharma R&D



Initial focus on **digital pathology** and internal use: cloud-based; built for scale; **global access** within **Roche** and select **CROs**; dedicated **user support**

Insight generation through advanced **analytics apps** and extensive **APIs** enable collaborative algorithm development

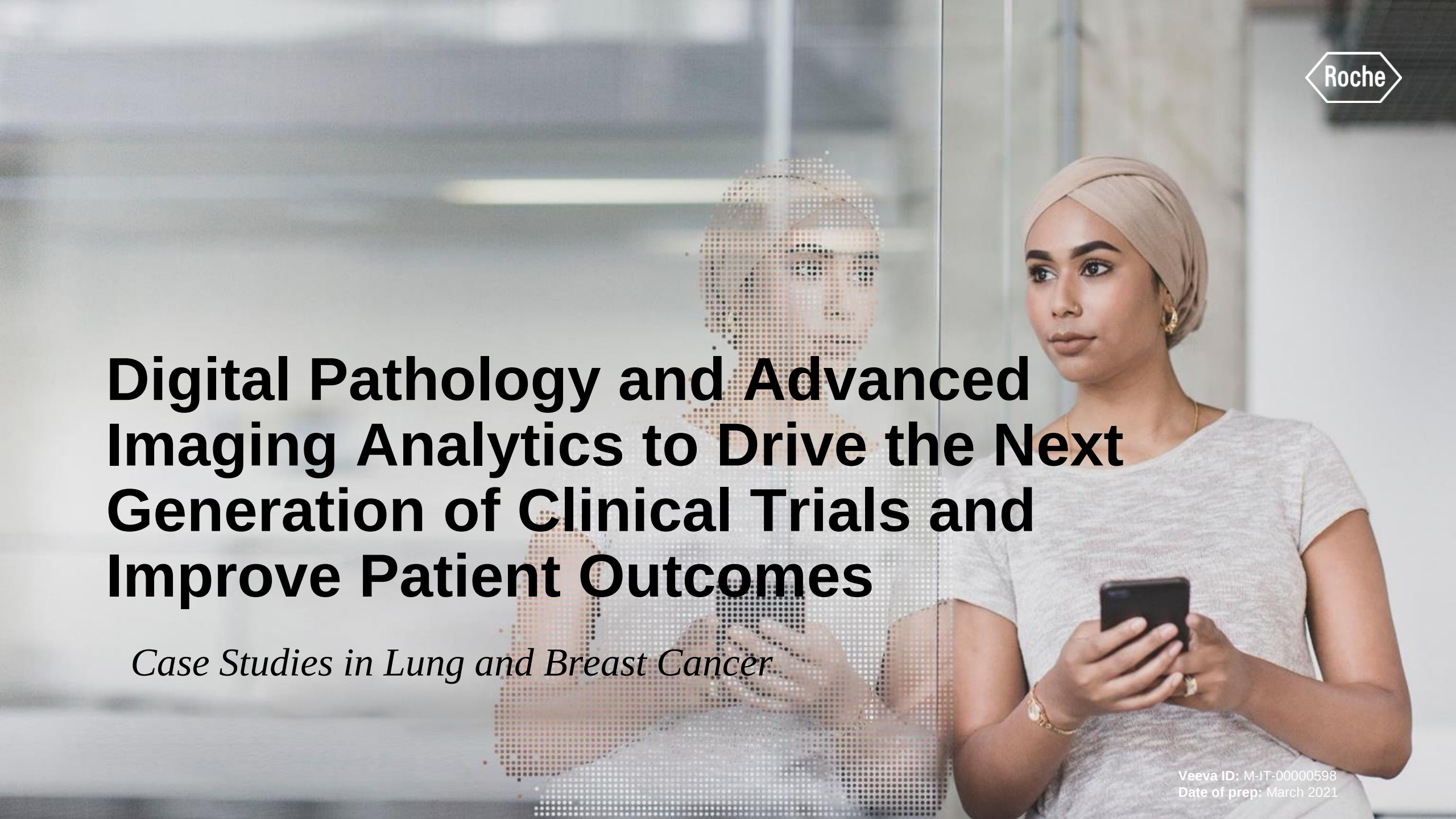
Currently **100K+ DP images** ingested from **20+ cohorts**, **250+ users** across multiple Roche Pharma teams around the world

Considering **expanding** to support **other data types** (clinical imaging, genomics, etc) to enable **integrative analytics** in the future

API, application programming interface; DP, digital pathology; CRO, clinical research organizations; R&D, research and development; RDS, research decision support.

Digital Pathology and Advanced Imaging Analytics to Drive the Next Generation of Clinical Trials and Improve Patient Outcomes

Case Studies in Lung and Breast Cancer



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1 Classification and Mutation Prediction From Histopathology Images Using Deep Learning

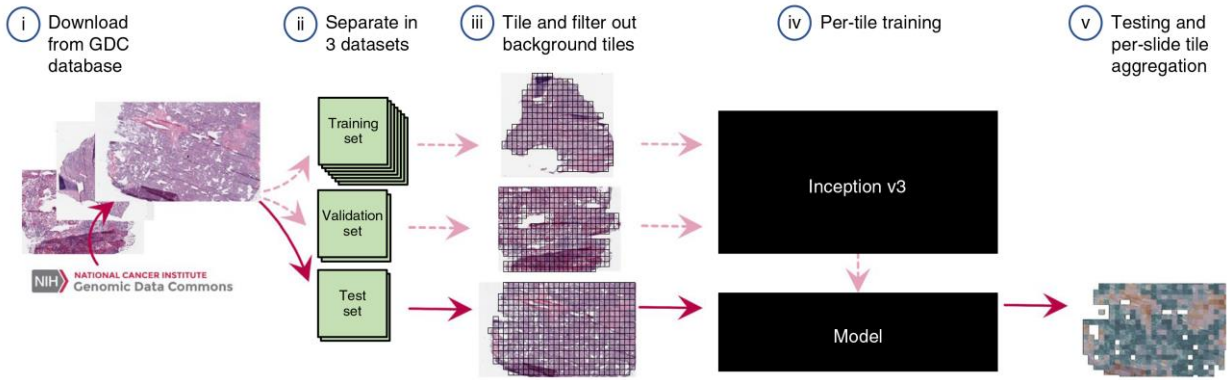
Opportunity

Improving the lung cancer diagnostic workflow

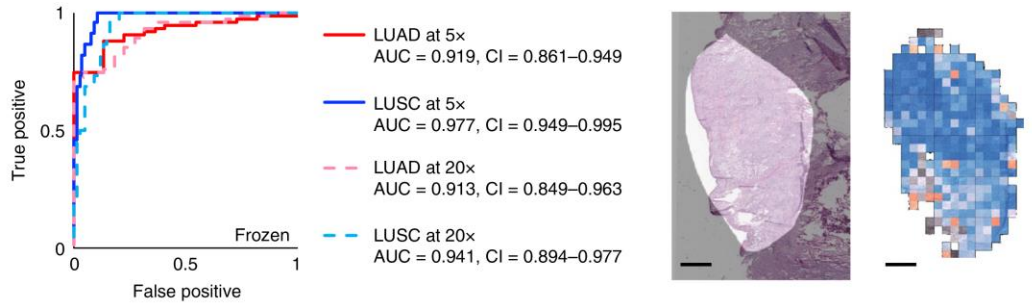
1 Classification and Mutation Prediction From Histopathology Images Using Deep Learning

Approach

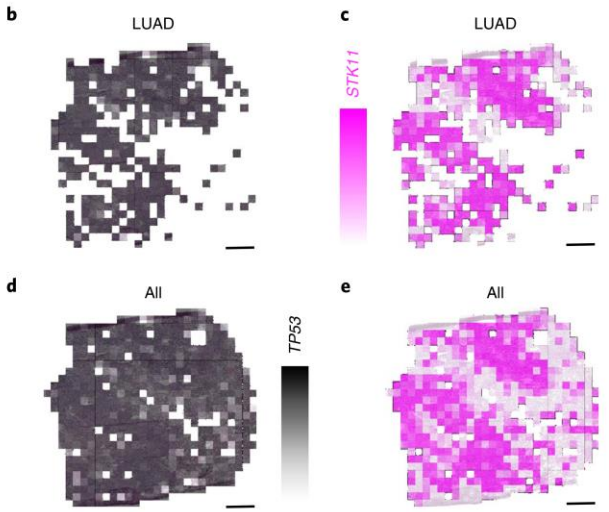
Strategy for training



Tumour presence and classification



Spatial heterogeneity of predicted mutations



AUC, area under the curve; LUAD, lung adenocarcinoma; LUSC, lung squamous cell carcinoma; TGCA, The Cancer Genome Atlas.
Coudray N et al. *Nat Med*. 2018;24(10):1559-1567.

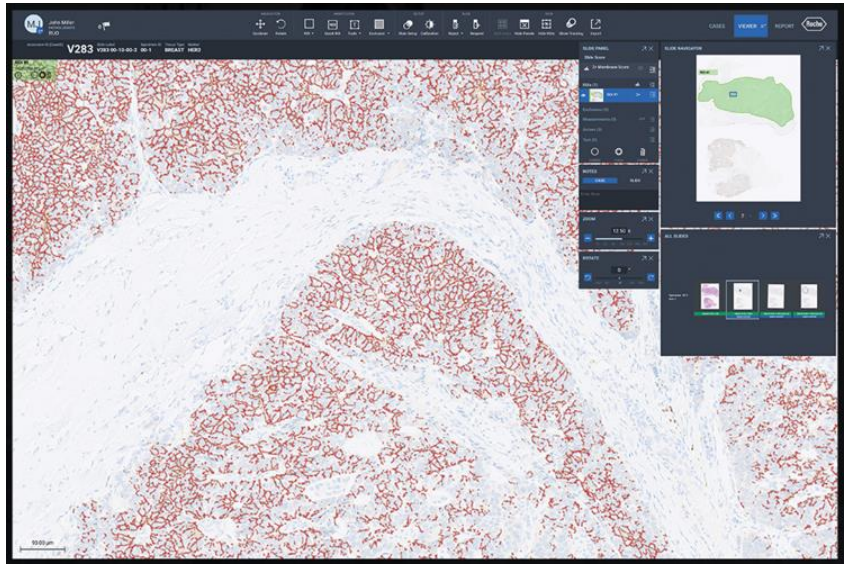
2 Integrated Digital Solutions to Aid in Clinical Decision Support

Opportunity

Optimising identification of HER2 amplification is an important predictor of targeted treatment response

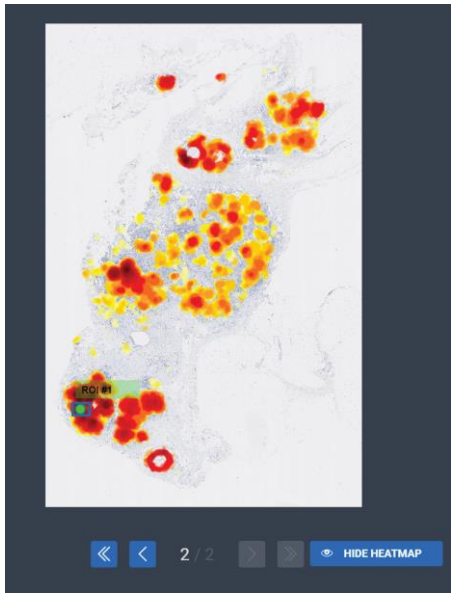
2 Integrated Digital Solutions to Aid in Clinical Decision Support

Approach



Whole-slide analysis with HER2 (4B5)[1]

Heatmap to guide pathologists to areas ideal for HER2/Chr17 ratio scoring[2]



January 11, 2021, Press Release[3]

Roche launches two digital pathology image analysis algorithms for precision patient diagnosis in breast cancer

1. Roche. Accessed February 19, 2021. https://diagnostics.roche.com/global/en/products/instruments/upath-her2-4b5-image-analysis-for-research.html; 2. Roche. Accessed February 19, 2021. https://diagnostics.roche.com/global/en/products/instruments/upath-her2-dual-ish-image-analysis-for-research.html; 3. Roche Media Release. Accessed February 19, 2021. https://www.roche.com/media/releases/med-cor-2021-01-11b.htm

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3 Prediction of Response to Treatments Using Cell Detection on Whole-slide Images

Advanced Lung Adenocarcinoma: IMpower150 Trial

Opportunity

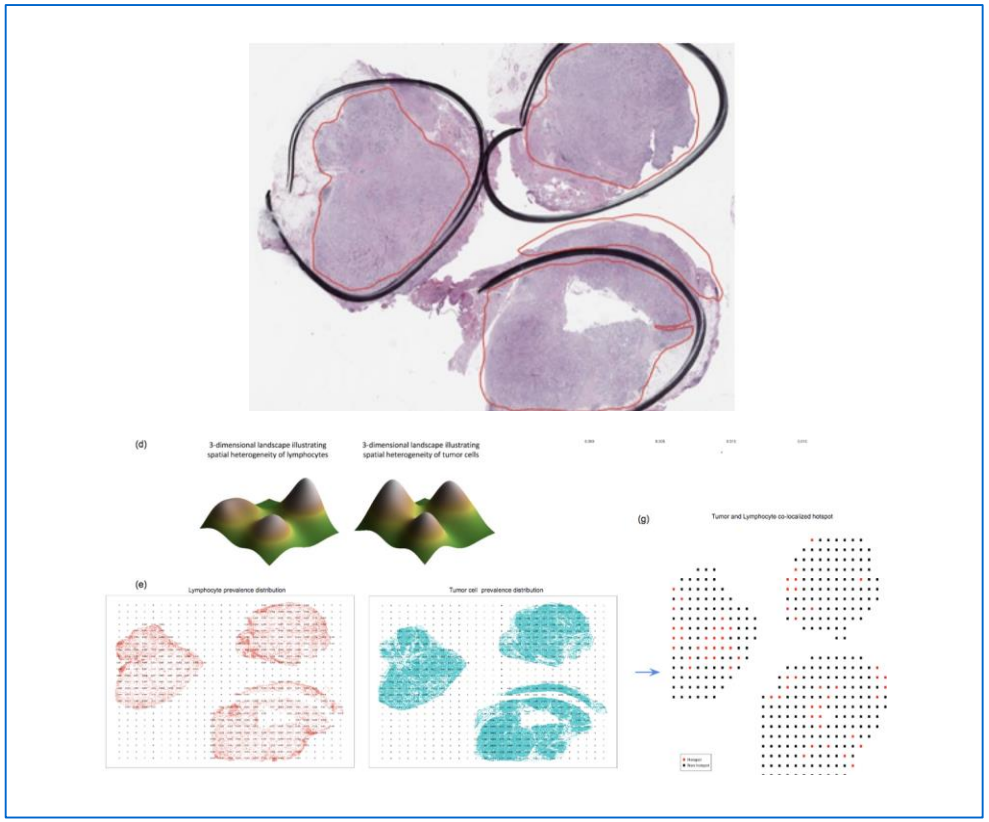
Identifying new predictive biomarkers to help differentiate efficacy between treatments

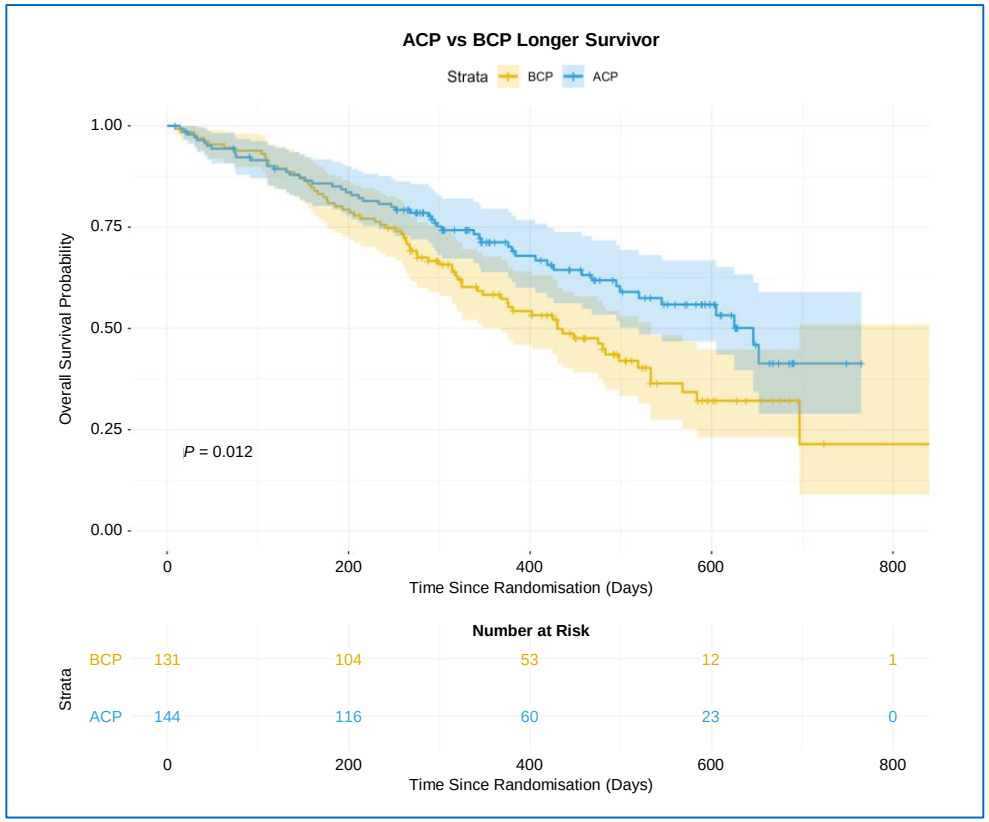
3 Prediction of Response to Treatments Using Cell Detection on Whole-slide Images

Advanced Lung Adenocarcinoma: IMpower150 Trial

Approach

Connecting Spatial Statistics to Clinical Outcome





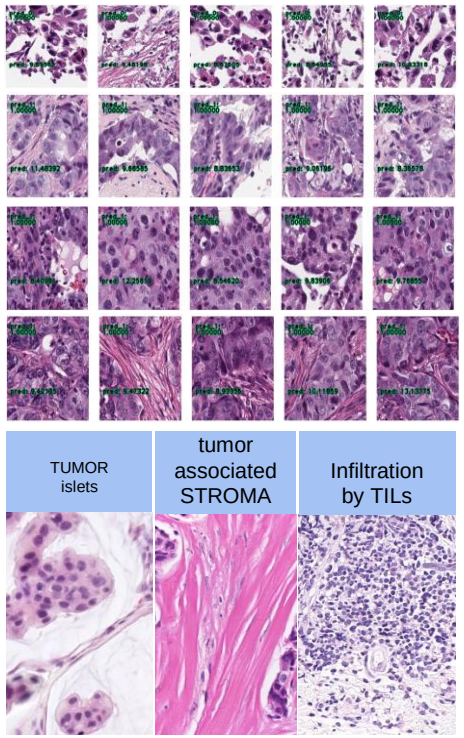
ACP, atezolizumab, carboplatin, and paclitaxel; BCP, bevacizumab, carboplatin, and paclitaxel.
Li X et al. Abstract presented at: ESMO Virtual Congress 2020; September 19-21, 2020. 1381P.

3 Prediction of Response to Treatments Using Cell Detection on Whole-slide Images

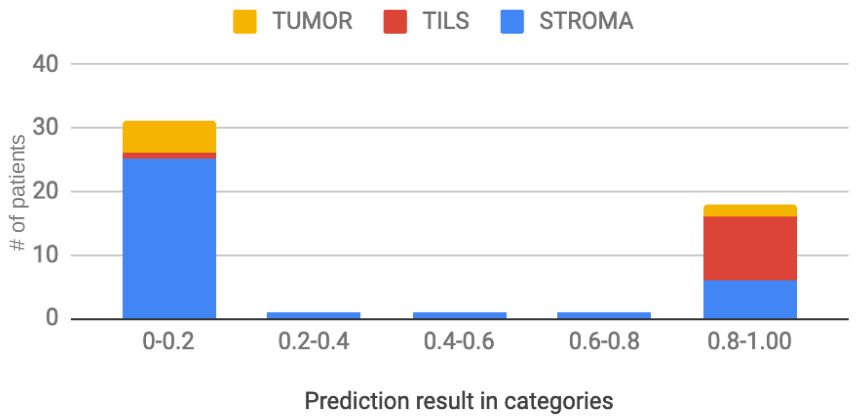
Advanced Lung Adenocarcinoma: IMpower150 Trial

Approach

Data-driven algorithms



Distribution of cell types across predictive intervals



TIL, Tumor infiltrating lymphocyte

Li X et al. Abstract presented at: ESMO Virtual Congress 2020; September 19-21, 2020. 1381P.

A Constellation of Strengths Offers Roche a Unique Position to Drive the Transformation of Healthcare

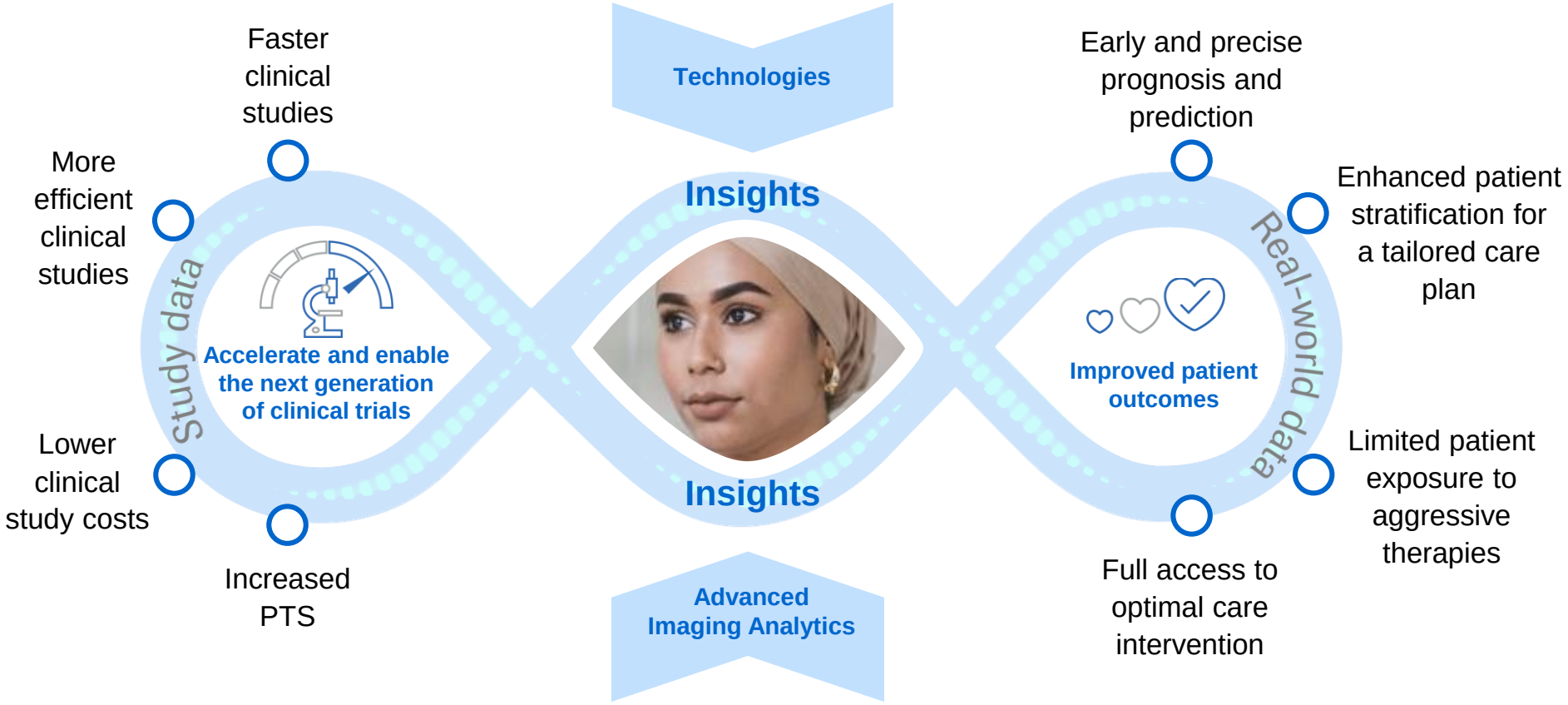
Existing digital pathology research platform

- A dedicated, globally accessed, harmonized platform to both view and analyse whole-slide images across the entire Roche group
- An agile, constantly evolving and improving research environment nurtured by research teams spread across Roche Pharmaceuticals, diagnostics, Foundation Medicine, and local affiliates

Spatial statistics derives handcrafted features that predict response to treatment in lung adenocarcinoma

- Cell-level classification performed at scale
- Opportunity to leverage other data modalities (radiology, genomics, clinical outcome) collected over the course of clinical trials to produce additional insight

Digital Pathology (AIA) Has Enormous Potential to Transform Patient Outcomes and Improve R&D Efficiency



Our ambition is to create a **more sustainable** healthcare system to ensure every patient has access to the **best possible care**

AIA, advanced imaging analytics; PTS, probability of technical success; R&D, research and development.

Doing Now What Patients Need Next