

## **CONNECT-TO-WIN**

End-to-end solutions for mobilizing routine CGP test data for research
Illumina

Volker Liebenberg, Head of Medical Affairs EMEA



The Digital Institute for Cancer Outcomes Research

# **Curing Cancer is a Complex Challenge**



There is no silver bullet

## **A Learning Health System**



## Making Diagnostics Simple Is Key To Beat Cancer



### Our Mission

Unlocking the Power of the Genome to Improve Human Health

## **End-to-End Solutions**





Make Precision Medicine in Oncology a reality by combining groundbreaking science and technology with a world-leading network of strategic partners



## A Menu of Solutions, From Early Surveillance to Monitoring

# Robust and flexible development of IVD tests\* from early surveillance to monitoring

#### **Partners**

- ArcherDx Stratifide Solid Tumor Panel
- ArcherDx MRD
- HTG Molecular Lung Subtyping
- HTG Molecular Head and Neck Cancer
- Invivoscribe LymphoTrack
- Otsuka Heme Panel
- Pillar Biosciences Lung and Colon Cancer
- Qiagen Cervical Dysplasia CDx
- Roche FM1 Solid Tumor Panel
- Sysmex Solid Tumor Panel

#### \*Under development

- 1. https://www.illumina.com/company/news-center/press-releases/2020/82bcf08b-d262-4ef8-a483-341716566fe6.html?langsel=/us/
- https://investors.adaptivebiotech.com/news-releases/news-release-details/adaptive-biotechnologies-enters-partnership-illumina-develop
- 3. https://corporate.qiagen.com/newsroom/press-releases/2019/20191007\_qiagen\_illumina\_ngs\_collaboration?sc\_lang=en
- $4. \ https://www.genomeweb.com/business-news/archerdx-illumina-agree-comarket-future-ivds\#.X4COJ2hKg2warderdx-illumina-agree-comarket-future-ivds\#.X4COJ2hKg2warderdx-illumina-agree-comarket-future-ivds\#.X4COJ2hKg2warderdx-illumina-agree-comarket-future-ivds\#.X4COJ2hKg2warderdx-illumina-agree-comarket-future-ivds\#.X4COJ2hKg2warderdx-illumina-agree-comarket-future-ivds\#.X4COJ2hKg2warderdx-illumina-agree-comarket-future-ivds\#.X4COJ2hKg2warderdx-illumina-agree-comarket-future-ivds\#.X4COJ2hKg2warderdx-illumina-agree-comarket-future-ivds\#.X4COJ2hKg2warderdx-illumina-agree-comarket-future-ivds\#.X4COJ2hKg2warderdx-illumina-agree-comarket-future-ivds\#.X4COJ2hKg2warderdx-illumina-agree-comarket-future-ivds#.X4COJ2hKg2warderdx-illumina-agree-comarket-future-ivds#.X4COJ2hKg2warderdx-illumina-agree-comarket-future-ivds#.X4COJ2hKg2warderdx-illumina-agree-comarket-future-ivds#.X4COJ2hKg2warderdx-illumina-agree-comarket-future-ivds#.X4COJ2hKg2warderdx-illumina-agree-comarket-future-ivds#.X4COJ2hKg2warderdx-illumina-agree-comarket-future-ivds#.X4COJ2hKg2warderdx-illumina-agree-comarket-future-ivds#.X4COJ2hKg2warderdx-illumina-agree-comarket-future-ivds#.X4COJ2hKg2warderdx-illumina-agree-comarket-future-ivds#.X4COJ2hKg2warderdx-illumina-agree-comarket-future-ivds#.X4COJ2hKg2warderdx-illumina-agree-comarket-future-ivds#.X4COJ2hKg2warderdx-illumina-agree-comarket-future-ivds#.X4COJ2hKg2warderdx-illumina-agree-comarket-future-ivd-future-ivd-future-futur$
- 5. https://www.illumina.com/company/news-center/press-releases/2018/2341745.html
- https://www.businesswire.com/news/home/20210223006239/en/QIAGEN-and-INOVIO-Expand-Collaboration-to-Develop-Next-Generation-Sequencing-NGS-Companion-Diagnostic-for-INOVIO%E2%80%99s-VGX-3100-for-Advanced-Cervical-Dysplasia





# Striving to Develop a Market Leading Comprehensive Genomic Profiling Test

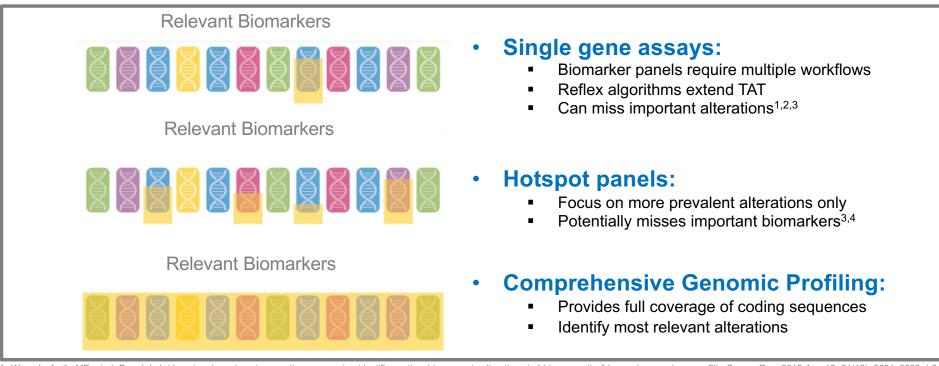
Expanded Pharma Partnerships – CDx Roadmap



- 1. Ilumina and Loxo Oncology to Partner on Developing Next-Generation Sequencing-Based Pan-Cancer Companion Diagnostics. https://www.businesswire.com/news/home/20180410005649/en/;
- 2. As Lilly deal closes, Bayer secures full rights to Loxo's Vitrakvi https://www.biopharmadive.com/news/as-lilly-deal-closes-bayer-secures-full-rights-to-loxos-vitrakvi/548584/.
- 3. Roché, Illumina Partner on Next-Generation Sequencing IVD, CDx Development, Marketing. https://www.genomeweb.com/business-news/roche-illumina-partner-next-generation-sequencing-ivd-cdx-development-marketing#.Xla-RqhKjIU
- 4. Illumina Announces New and Expanded Oncology Partnerships with Bristol Myers Squibb, Kura Oncology, Myriad Genetics, and Merck to Advance Comprehensive Genomic Profiling: https://sapac.illumina.com/company/news-center/press-releases/press-release-details.html?newsid=c8606ce8-c9ec-4c7f-9659-270952ae7bba.
- 5. KURA ONCOLOGY: HRAS mutations CDx in Head and Neck Squamous Cell Carcinomas.
- 6. BRISTOL MYERS SQUIBB: a microsatellite instability CDx, as well as the development of a diagnostic based on the content of TruSight Oncology 500 ctDNA.
- 7. MERCK: collaboration conducting a study focused on the expanded TruSight Oncology HRD offering. MYRIAD GENETICS: with time-limited exclusivity in certain markets (x-US), to develop and commercialize distributed kits for the assessment of HRD and for Myriad to expand its HRD service offerings, through a combination of TruSight Oncology content and Myriad's myChoice® CDx test

## Comprehensive Genomic Profiling

Provides more comprehensive gene coverage than hot spot panels



<sup>1.</sup> Drilon A, Wang L, Arcila ME, et al. Broad, hybrid capture-based next-generation sequencing identifies actionable genomic alterations in "driver-negative" lung adenocarcinomas. Clin Cancer Res. 2015 Aug 15; 21(16): 3631–3639. | 2... Ali SM, Hensing T, Schrock AB, et al. Comprehensive Genomic Profiling Identifies a Subset of Crizotinib-Responsive ALK-Rearranged Non-Small Cell Lung Cancer Not Detected by Fluorescence In Situ Hybridization. Oncologists. 2016 Jun; 21(6): 762-70. | 3. Suh JH, Schrock AB, Johnson A, et al. Hybrid Capture-Based Comprehensive Genomic Profiling Identifies Lung Cancer Patients with Well-Characterized Sensitizing Epidermal Growth Factor Receptor Point Mutations That Were Not Detected by Prior Molecular Testing. Oncologist. 2018 Jul; 23(7): 776–781. | 4. Schrock AB, Frampton GM, Herndon D, et al. Comprehensive Genomic Profiling Identifies Frequent Drug-Sensitive EGFR Exon 19 Deletions in NSCLC not Identified by Prior Molecular Testing. Clin Cancer Res. 2016;22(13): 3281-5.

### Comprehensive Genomic Profiling

Enabling in-house comprehensive genomic profiling from tissue and liquid biopsy samples





# Implement Assay In-House



### Integrated Workflow



### Reliable Results

Biomarker covered:

- Key Guidelines
- Clinical trials
- All relevant biomarkers
- Immuno-oncology (IO) biomarkers: TMB and MSI

Consolidate all biomarker assays into a single NGS panel, saving sample, time and costs.

Offer Precision Oncology in your institution, keep the data in-house and avoid losing samples to send-out services.

Keep the assay in the long run with a portfolio of assays that includes emerging biomarkers and has an IVD roadmap Integrated workflow from sample to report.

CGP from solid or liquid biopsy samples with similar workflows for test labs.

Harmonized processes allow to generate high-quality genomic data and enable its aggregation for research use.

illumına<sup>®</sup>

## Generating Insights from Data is Challenging



Scaling Up Infrastructure

to address petabyte-scale datasets is costly and resource intensive



**Data Silos** 

hinder collaboration and stifle the pace of innovation



Maintaining Security, Privacy, and Compliance

is non-trivial and requires substantial investment and regular audit checks



Building and Deploying New Workflows

involves navigating many systems, technologies, and leads to inefficiencies



Limited Informatics Resources

are shared across groups, distracting from scientific focus and driving novel insights

# ICA Provides Flexible, Interoperable Components to Power Data Insights



Out-of-the-box integration with Illumina sequencing systems

Process data with prepackaged DRAGEN™ pipelines or build custom tools and workflows Combine and query – omics data and real-world evidence to extract knowledge from cohorts

Data science workbench to derive new data insights

Accelerate discoveries on a global scale

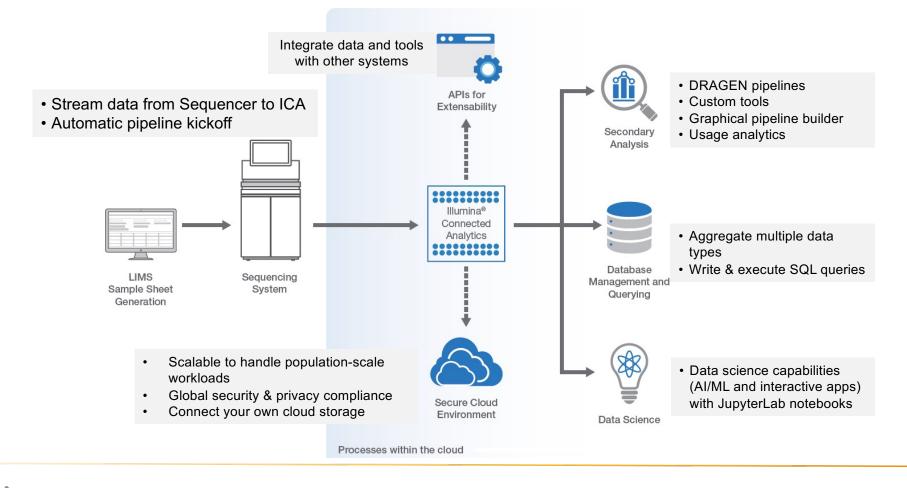
**SCALE** 

**SECURITY** 

**INSIGHTS** 

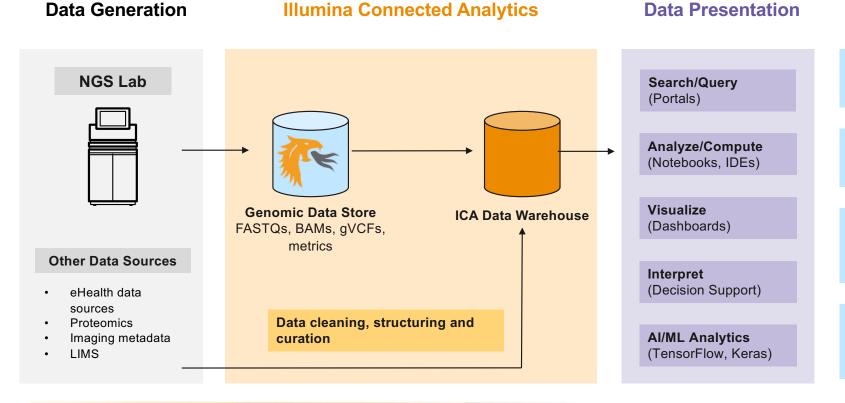


## ICA: A Cloud Platform for Advanced Genomic Data Analysis





# Data can be Presented in Many Ways to Power Different Use Cases



## Stakeholders / Use Cases

#### Pharma Research & Early Dev

 Data asset for mining, novel biomarker discovery.

#### Pharma Development, Mktg

 RWD, RWE for post-market surveillance, pricing, validation

#### Pharma + Health System

 Programmatic alerts for eligible clinical trial enrollees. Clinical trial site selection.

#### **Health System + Payers**

 Patient wellness, stratification schemes based on genomics to prevent unnecessary procedures

# Early Access Story | University of Melbourne Center for Cancer Research



ICA + DRAGEN reduces time to result and improves workflow reliability

## Cloud-based bioinformatics platform fast-tracking genomic analysis

Researchers at the University of Melbourne Centre for Cancer Research (UMCCR) have established a reliable, scalable and fast bioinformatics platform to analyse the genomic data of hundreds of cancer patients.



Picture: Associate Professor Oliver Hofmann's (front, second from right) Genomics Platform Group, based at the University of

### Challenge

- >24h post-sequencing to achieve analysis result
- Manual data transfer, analysis, QC

### Solution

- Automated analysis & report delivery through ICA
- DRAGEN on ICA → 3X reduction in time to QC report

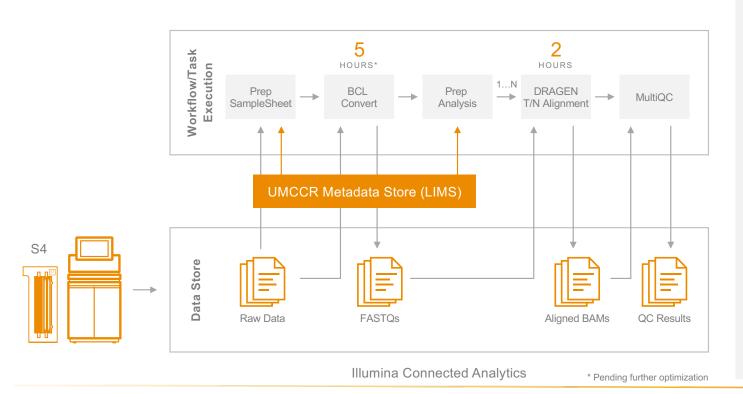
https://mdhs.unimelb.edu.au/centre-for-cancer-research/news-and-events/cloud-based-bioinformatics-platform-fast-tracking-genomic-analysis



# Early Access Story | University of Melbourne Center for Cancer Research



Rapid WGS Alignment & QC using IAP & DRAGEN™



"With Illumina Connected Analytics, we can easily contribute our own analysis and get it up and running with a few lines of code, leveraging the speed and quality of Illumina's existing DRAGEN technology without having to host and maintain our own computational infrastructure."

- Assoc. Prof Oliver Hofman

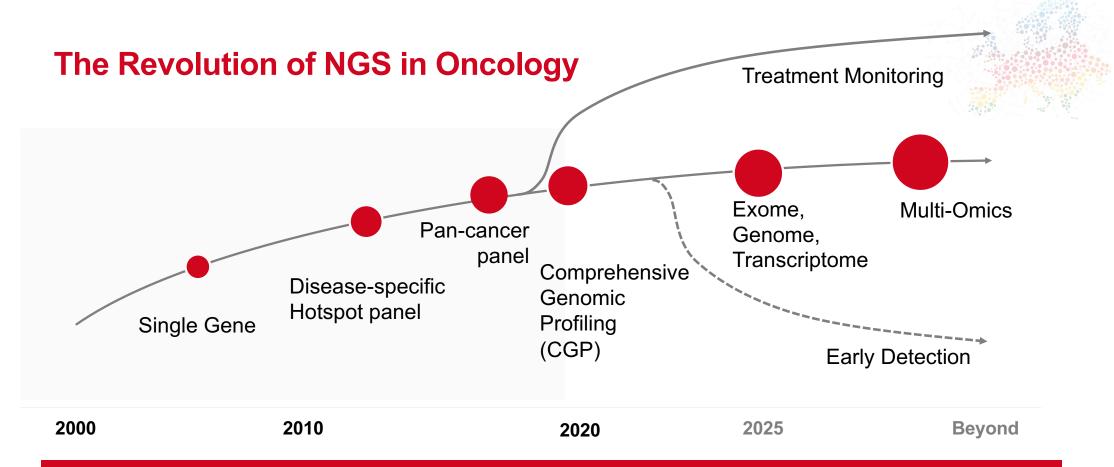


### **Conclusion – Critical Enablers to Success**

### Making Personalized Medicine in oncology a reality together

- Combine groundbreaking science and technology with a world-leading network of partners
- Establish local end-to-end CGP solutions covering all relevant biomarkers
- Integrate high-quality clinical and genomics data in a secure analytical infrastructure
- EU-wide governance framework to mange access and use of data for research and routine
- Cooperation and funding to implement and drive change





The adoption of technology will accelerate with sequencing becoming more affordable



# **DigiCore**

## Let's CONNECT-TO-WIN



# Our Data Privacy and Security Safeguards Adhere to ISO Standards

### Our Position on Data Privacy

We create and develop advances in technology to improve human health by unlocking the power of the genome. To support this mission, Illumina collects and processes personal data in a variety of manners. We believe that responsible data stewardship, built on a foundation of strong privacy and data security protections, is essential to promote trust and support innovation.

Illumina is committed to handling personal data according to applicable laws and the following guiding principles:

- **1. Transparency:** We clearly communicate our privacy practices and how we use personal data.
- 2. Responsible Stewardship: We protect personal data to keep it confidential and secure.
- Ethical Use: We only collect and use personal data in a lawful and transparent manner for purposes that further our mission to improve human health by unlocking the power of the genome.
- 4. Accountability: We are committed to compliance with all legal requirements and promoting internal practices to achieve the highest standards for personal data privacy