# Genomic profiling in cancer: policies and regulatory landscape for LATAM


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1

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2


3

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  - **Foundation Medicine**
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4

## Outline

1. Background
2. Precision medicine status: the physician perspective
3. Goals of precision medicine
4. Cost
5. Future of the future
6. Policies and regulatory landscape for LATAM

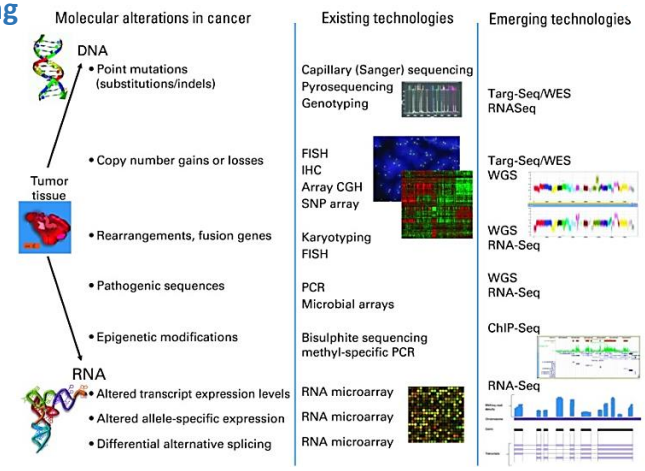
5

## Outline

1. Background

6

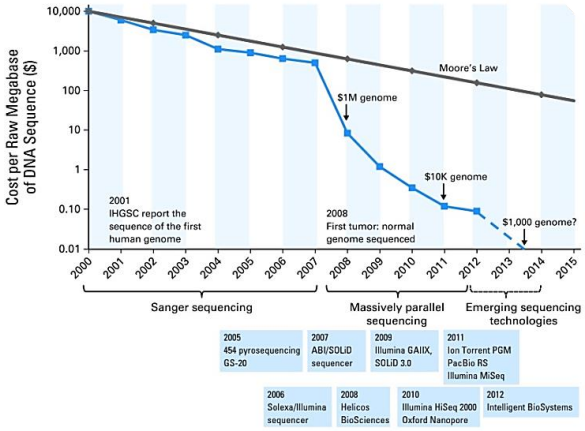
## Existing and emerging technologies for tumor genomic profiling




MacConaill – JCO 2014

7

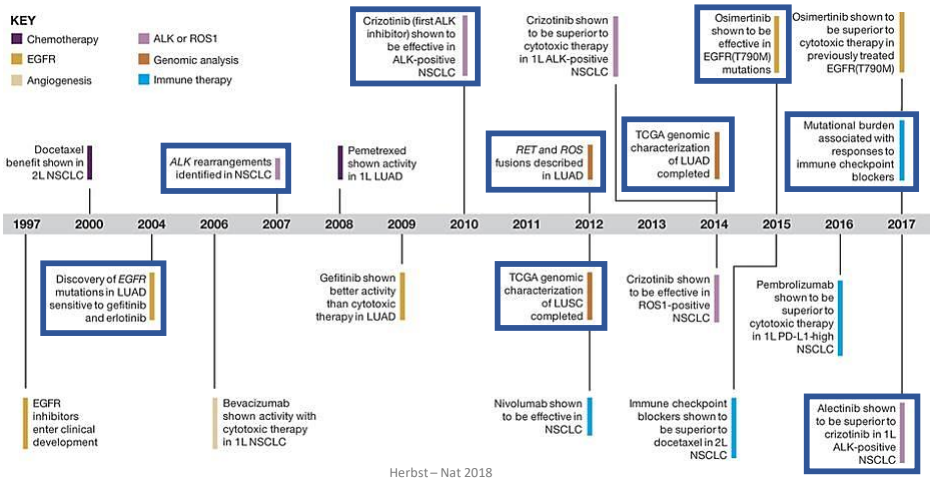
## Decrease in cost of genome sequencing facilitated by massively parallel sequencing technologies




MacConaill – JCO 2014

8

## The biology and management of non-small cell lung cancer




Herbst – Nat 2018

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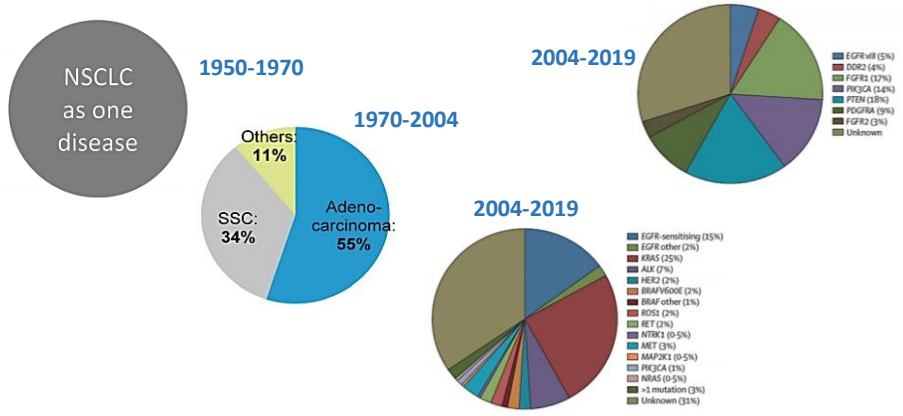
## The diagnosis of non-small cell lung cancer in the molecular era



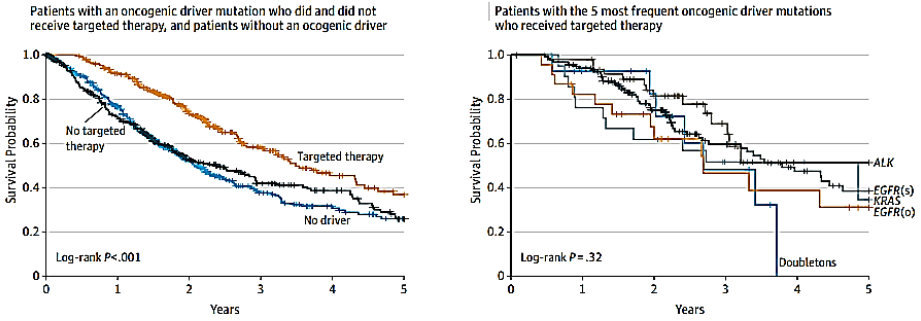

Brainard – Mod Pathol 2019

11

## Impact of genomic alterations identified in lung adenocarcinoma

Tumors from **1007** patients were tested for **at least 1 gene**, and from **733** patients for **10 genes** (full genotyping)

- Genomic alterations were identified in 466 of 733 (64%) patients with full genotyping performed
- 44% of individuals with genomic alterations detected received a matched therapy




Kris – JAMA 2014

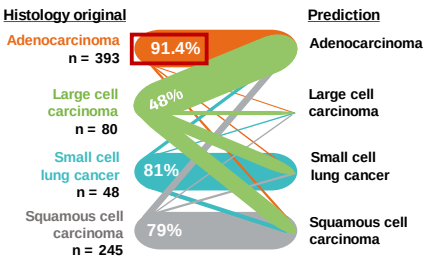
15

## Genomic alterations can challenge original histomorphological diagnoses of lung cancer

- Alterations in **28 genes in 1,127 tumor specimens** of all histological subtypes were analyzed by various methods including FISH and whole exome sequencing
- Genomic alterations were used to reclassify tumor subtype and validated by IHC
- Based on these data a diagnostic algorithm was created and prospectively tested in **5,145** lung cancer patients

**Different genomic alterations were identified both between and within tumor subtypes, challenging the original diagnosis and eliminating most cases of large cell carcinoma through reclassification**

**Semi-supervised reclassification of lung tumor samples**




Relative proportion of cases/histological subtype reclassified on basis of 18 genetic alterations; weight of lines is proportional to the fraction of cases classified to the respective subgroup

IHC: Immunohistochemistry

Clinical Lung Cancer Genome Project - Sci Transl Med 2013

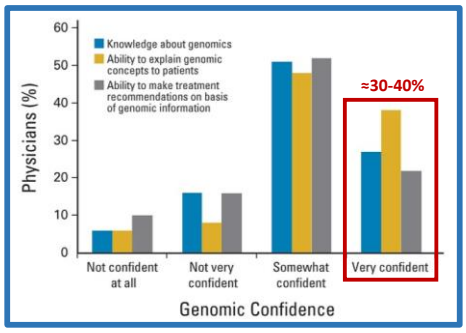
16

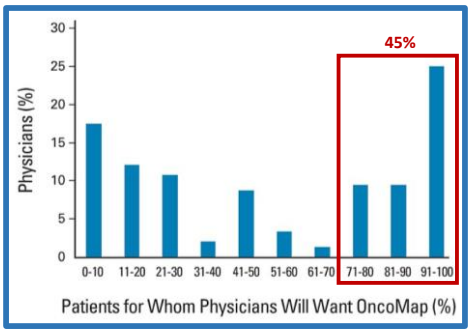
# Outline

2 **Precision medicine status: the physician perspective**

20

## Physicians' attitudes about multiplex tumor genomic testing



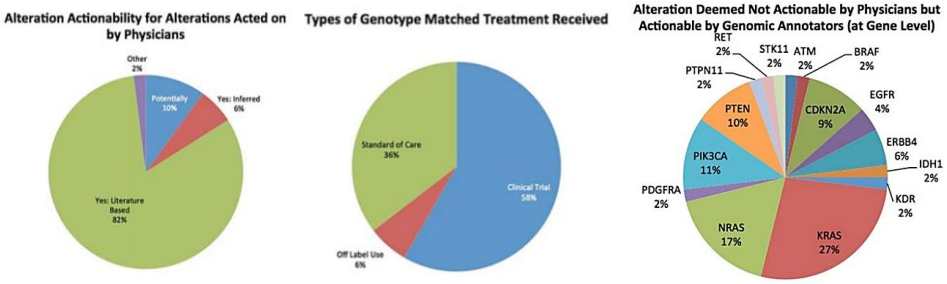




- **22%** of physicians were not confident in their knowledge of genomics, ability to explain genomic concepts to patients (**14%**), and ability to make treatment recommendations based on genomic data (**26%**)
- A genomic users reported that testing would somewhat or greatly increase patients' treatment options (**73%**), prognostic information (**62%**), and satisfaction (**80%**)

Gray – JCO 2014

21

## Physician Interpretation of Genomic Test Results and Treatment Selection



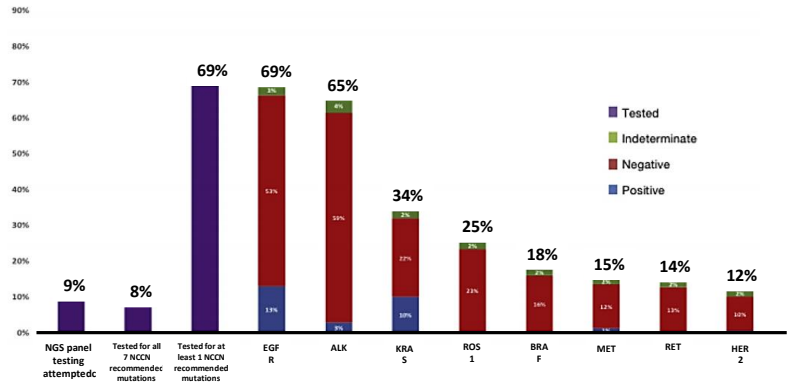

- **70%** consider that NGS analysis + PODS did improve solid tumors quality of care, whereas 30% physicians believed that it did not
- **89%** of physicians perceived that NGS improved patient satisfaction with efforts to personalize treatment options

Brusco – Cancer 2019

22

## Genomic Profiling of Advanced Non-Small Cell Lung Cancer in Community Settings: Gaps and Opportunities

**814 patients (89% with stage IV; 11% with stage IIIB)**




Gutierrez – Clin Lung Cancer 2017

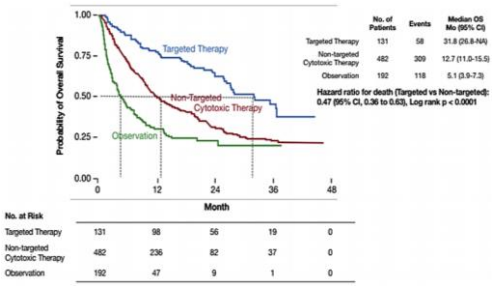
24

## Genomic Profiling of Advanced Non-Small Cell Lung Cancer in Community Settings: Gaps and Opportunities

814 patients (89% with stage IV; 11% with stage IIIB)

**Reasons for Not Testing**

| Reason for Not Testing for *EGFR*/*ALK* | n (%) |
|---|---|
| Total not tested | 335 (100) |
| Reason not reported, antineoplastic therapy started | 175 (52) |
| Reason not reported, not treated | 86 (26) |
| Insufficient tissue sample | 45 (13) |
| Rapid death | 24 (7) |
| Other | 5 (1) |




Gutierrez – Clin Lung Cancer 2017

25

## Outline

3 **Goals of precision medicine**

26

## Barriers to clinical adoption of next generation sequencing: a global Perspective

**Expert stakeholder composition (n=48)**

- 77% of the panel favored coverage of NGS testing for tumor profiling.
- 70% of the panel favored coverage of whole genome and exome sequencing for rare tumors.
- 52% of the panel favored coverage for pharmacogenetic testing.
- 29% favored coverage for disease risk prediction.

**Main barriers**

- Diagnostics companies are able to maintain proprietary databases on the substantial variety of clinically meaningful mutations found in patients.
- Different payers have different evidentiary stan-dards for assessing clinical utility, leading to inconsistent policies on coverage and reimbursement for NGS-based testing.
- Lack of standardization for reporting NGS test results.
- Payers refuse to cover NGS because the specific patient management decision to be informed by testing is unclear when NGS-based testing is ordered.

Messner – App Transl Genomics 2016

27

## Outline

4 **Cost**

28

## Next-generation sequencing – Emerging Clinical Applications and Projections to 2022

Global Clinical Next-Generation Sequencing Market, by Disease Class, Through 2022
($ Millions)

| Disease Class | 2015 | 2016 | 2017 | 2022 | CAGR% 2017-2022 |
|---|---|---|---|---|---|
| Non-cancer | 1,576.6 | 1,979.8 | 2,352.8 | 6,441.0 | 22.3 |
| Cancer | 669.5 | 778.1 | 838.8 | 4,093.2 | 37.3 |
| Total | 2,246.1 | 2,757.9 | 3,191.6 | 10,534.2 | 27.0 |

- The global clinical NGS market is estimated at approximately $3.2 billion in 2017 and is forecast to increase at a compound annual growth rate (CAGR) of **27%** to reach $10.5 billion in 2022.
- Non-cancer applications are projected to grow at a CAGR of **22.3%** to reach $6.4 billion in 2022.
- Cancer applications, have an anticipated CAGR of **37.3%**, putting this segment at close to $4.1 billion in 2022.

Bergin - BCC Research biotechnology reports 2019

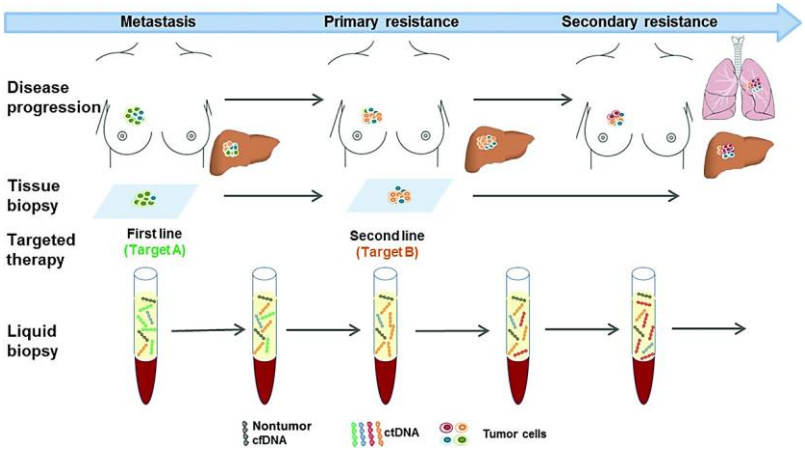
29

## Outline

5 Future of the future

31

## Circulating Tumor DNA as a Liquid Biopsy for Cancer

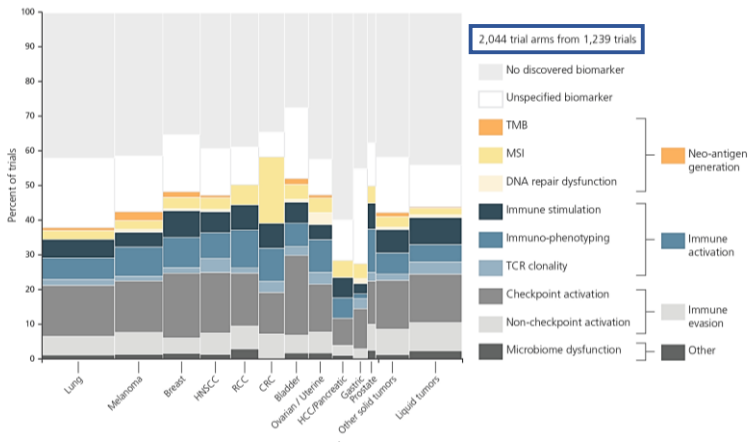



Heitzer – Clin Chem 2014

32

## Immunotherapy biomarkers assessed are broadening beyond PD-1

Biological pathways assessed in checkpoint inhibitor clinical trials by tumor type




Vada – AACR 2019

34

# Outline

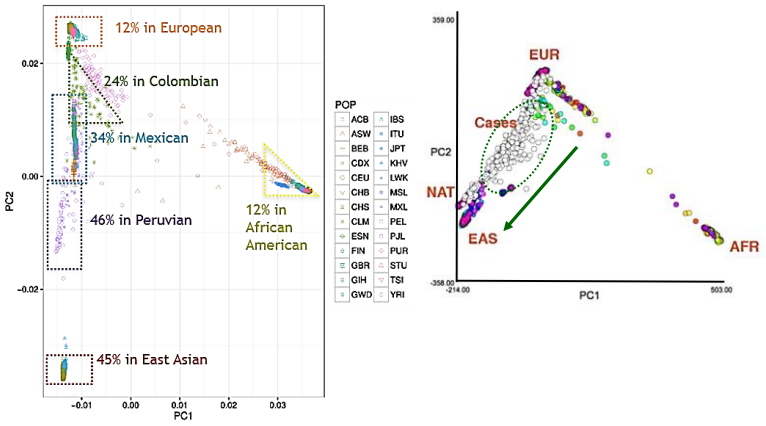
6 Policies and regulatory landscape for LATAM

36

## Tumor genomics among Hispanics

Ancestry of Latin American lung cancer: EGFR model

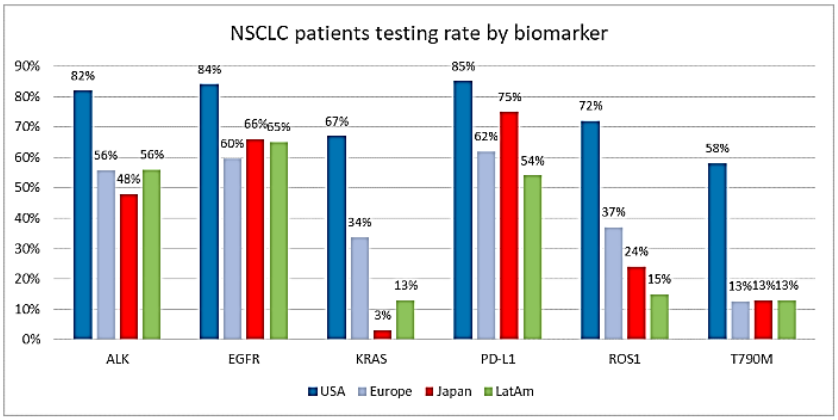
Principal Components Analysis (PCA) of genetic variants can detect population structure




Meyerson – WLCC 2018

37

## Real world evidence – compared rate of biomarker test (2018; n=4.320)




https://medimix.net/news/nsclc-biomarker-testing/

39

## Limitations to genomic evaluation in NSCLC in LATAM

- Delay in diagnosis (Adenocarcinomas tested in LATAM: 15% Brazil; 42% Argentina; 40% Colombia)
- Molecular testing depending on Pharma industry (≈85% across countries)
- Local data (regional data on molecular epidemiology)
- Access to high quality testing (Lab certification)
  - Inter observer variability (rates of concordance)
- Access to targeted drugs
- Reimbursement issues
- Design of local guidelines adapted to cruel reality
- Local research
- Education and training (pathology)

Cardona - Lung Cancer 2018

41

## Strategy to improve access to molecular testing

- National network for molecular testing in lung cancer
  - National tumor and DNA bank
- National network for clinical cancer research
  - Access within public health system
- National network for drug discovery
  - Health economics

Cardona - Lung Cancer 2018

42

## Conclusions

- We are in front of the ***next generation***, and we must be able to be part of it and practice it efficiently and cost effectively in our environment

43

The Economist INTELLIGENCE UNIT HEALTHCARE

# Personalised healthcare in Latin America: a focus on cancer

September 2019

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45

## Talk outline

1. ‘A tale of light and shadow’
2. Introducing personalised care
3. Enabling personalised care
4. Personalised care in Latin America today
5. Looking to the future

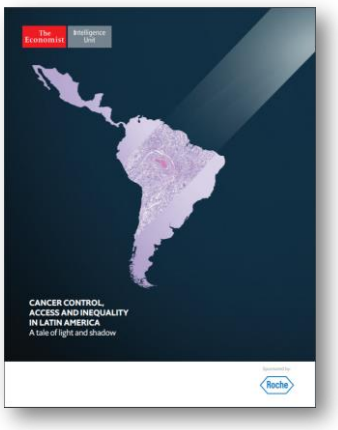
46

## ‘A tale of light and shadow’: cancer in Latin America

A 2017 EIU report. We reported that:

- In Latin America, cancer is a major public-health issue. In 2012 just over **1m people** developed the disease and it killed around **550,000**.
- Because of population ageing and population growth, cancer incidence and mortality is set to rise markedly—particularly lifestyle cancers such as lung, breast and colorectal.
- The number of cases is projected to go up by **91%** between 2012 and 2035, and deaths by **106%**.
- Economic burden is also set to rise significantly—both direct and indirect costs.
- Our call to action included a focus on:
  - Prevention and early detection
  - Budgets and resourcing
  - Inefficiencies and inequalities

- **But what role for personalised healthcare?**




47

# Introducing personalised care

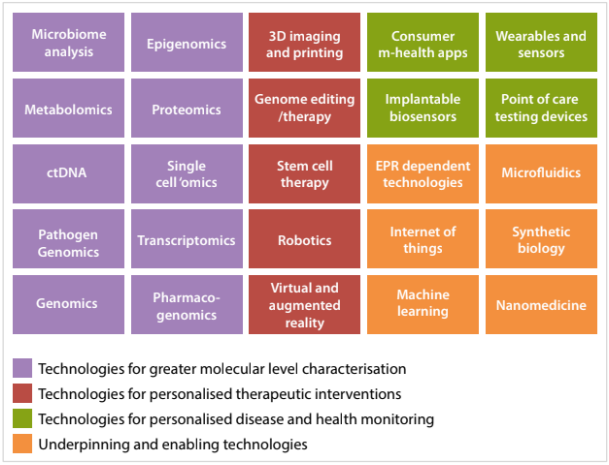
48

## What is personalised medicine?

- "The use of new methods of molecular analysis to better manage a patient's disease or predisposition to disease." – *Personalized Medicine Coalition*
- "Providing the right treatment to the right patient, at the right dose at the right time." – *European Union*
- "The tailoring of medical treatment to the individual characteristics of each patient." – *President's Council of Advisors on Science and Technology*
- "Health care that is informed by each person's unique clinical, genetic, and environmental information." – *American Medical Association*
- "A form of medicine that uses information about a person's genes, proteins, and environment to prevent, diagnose, and treat disease." – *National Cancer Institute, NIH*

49

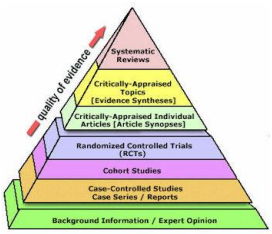
## Technologies included in personalised medicine




*Raza S, Blackburn L, Moorthie S et al. The personalised medicine technology landscape. Cambridge: PHG Foundation; 2018*

50

## Aligning personalised with evidence-based medicine

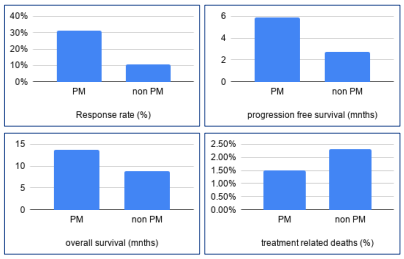

- High-resolution, high-throughput technologies in **personalised medicine** have created huge datasets. These developments are focused on the **individual.** ***N = 1***
- To some commentators, this contrasts with evidence-based medicine, which is informed by studies focussed on the **group**, from which recommendations are derived: "one size fits all". ***N = many***
- But what about **outliers**?
- Personalised medicine should be seen as an **update** to evidence based medicine. This will require global and responsible data sharing, as well as regularly updated training programs.

51

## Evidence for personalised medicine

**Precision medicine in cancers**

**570 studies** (32,149 patients). Compared outcomes for trial arms that used a personalized strategy (use of biomarkers) versus those that did not.




** Schwaederle M, Zhao M, Lee JJ, Eggermont AM, Schilsky RL, Mendelsohn J, Lazar V, Kurzrock R. Impact of Precision Medicine in Diverse Cancers: A Meta-Analysis of Phase II Clinical Trials. J Clin Oncol. 2015 Nov 10;33(32):3817-25*

**eHealth in a range of diseases**

**31 studies** were grouped into whether they concluded that eHealth is a) 'effective/cost-effective', that b) evidence is 'promising', or that c) evidence is 'limited' or 'inconsistent'.

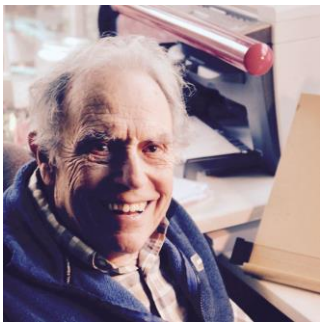
| eHealth is… | No. of papers | % of papers |
|---|---|---|
| Effective/cost effective | 7 | 23% |
| Evidence is 'promising' | 13 | 42% |
| Limited or inconsistent evidence | 11 | 35% |

65%

*** Elbert NJ, van Os-Medendorp H, van Renselaar W, Ekeland AG, Hakkaart-van Roijen L, Raat H, Nijsten TE, Pasmans SG. Effectiveness and cost-effectiveness of ehealth interventions in somatic diseases: a systematic review of systematic reviews and meta-analyses. J Med Internet Res. 2014 Apr 16;16(4):e110*

52

## But we shall beware of "genohype"



The term '**genohype**' was offered by Holtzman (*Are genetic tests adequately regulated? Science , 286 (4539), pp. 409-410, 1999*) to characterize the discourse of exaggerated claims and hyperbole attached to DNA and the effort to map the human genome.

53

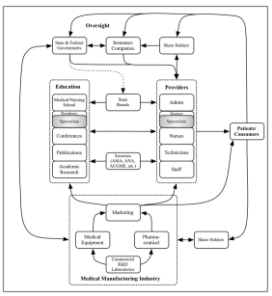
## What is personalised healthcare?

Personalised healthcare is a broader concept than personalised medicine.

It is differentiated from personalised medicine in that it is focused on a **strategic approach to patient care**--i.e. on health services as a whole--while the personalisd medicine focuses on the use of specific tools.

- *'Personalised medicine' should be used for specific tools that are available for practice in medicine (such as tests, test-drug pairs, predictive algorithms, etc) [...], whereas personalised healthcare should be used for health services that have a holistic approach to the individual to be implemented in certain contexts.*

*Cesuroglu T, Syurina E, Feron F, Krumeich A. Other side of the coin for personalised medicine and healthcare: content analysis of 'personalised' practices in the literature. BMJ Open. 2016 Jul 13;6(7):e010243*




54

## Personalised medicine *yes?* · Personalised healthcare *No?*

- We suggest that personalised medicine is available in Latin America—particularly in the private sector—but personalised healthcare is not.

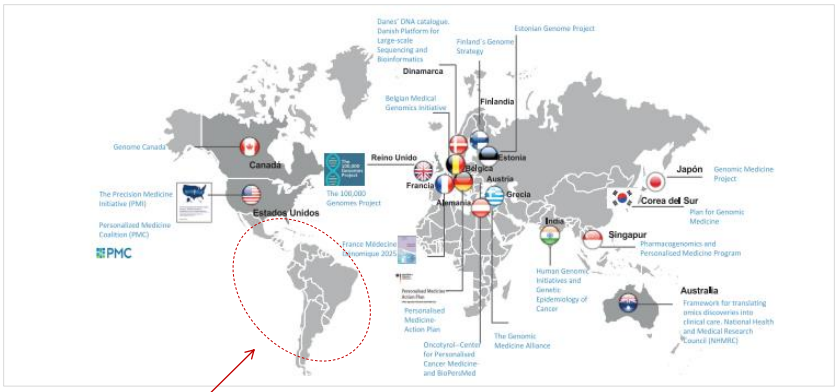
- That is, while the technologies are present and accessible to those who can afford it, there is little in the way of the institutional, regulatory and health system support necessary in order for these new technologies to transform the lives and outcomes of populations.

55

# Enabling personalised care

56

## Strategies for personalised care are found worldwide




*…except, it seems, Latin America?*

57

## Enabling factors for personalised healthcare

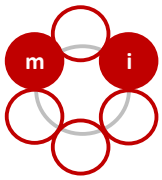
- **Medicines and technology**: for example use of targeted therapies, biomarker tests, telemedicine etc.
- **Information**: registries, clinical genomic databases, health system service evaluation
- **Governance**: NCCPs, National strategic policy plans for personalised healthcare, regulatory frameworks, framework for resolving ethical matters
- **Financing**: reimbursement, adequate R&D budget and focus
- **Human resources**: healthcare provider attitude and awareness, an adequately trained workforce, CPD
- **Service delivery**: centres of excellence; scope and use of guidelines, presence of personalised medicine 'champions'
- **People**: attitude of public, patients and society at large towards innovations

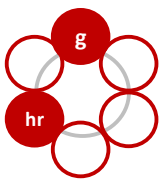

*Mikkelsen-Lopez I, Wyss K, de Savigny D. An approach to addressing governance from a health system framework perspective. BMC Int Health Hum Rights. 2011 Dec 2;11:13.*

58

## Examples of good practice: the UK

| | | |
|---|---|---|
| United Kingdom | The 100,000 Genomes Project | • Announced in December **2012**<br>• **Goal is to sequence 100,000 genomes** from NHS patients and **integrate the information to NHS records** to treat individual patients and better understand cancer, rare and infectious diseases.<br>• Scotland and England have their own national strategies. |
| England | Personalized Medicine Strategy | • Based on the 100K Project<br>• Goal is to achieve the integration of Genomic and Personalized Medicine in day-to-day health care<br>• In July **2015** a **Board of Directors** was established with representation from most NHS Directorates to work on four critical elements:<br>  • **infrastructure**<br>  • Incorporation into clinical practice<br>  • incorporation of technologies and innovations based on the knowledge generated<br>  • alignment of system policies. |

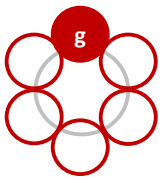


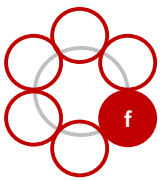




59

## Examples of good practice: US + Finland

| | | |
|---|---|---|
| USA | The Precision Medicine Initiative (PMI) | • Announced January **2015**<br>• The aim is to develop individualized patient care through advances in research, tech and policy.<br>• The initiative is based in two key elements: Study of Genomics of Cancer and the "All of Us" research program which will align biomedical data of a cohort of 1 million participants to study behavior, lifestyles and genes.<br>• The PMI has developed a l**egal framework directed towards privacy of data and use of information**. |
| Finland | Finland´s Genome Strategy | • Has 7 objectives and proposes 20 measures to achieve them, including a roadmap, which will be continuously monitored.<br>• The measures are aimed at ensuring that, by **2020**, genomic data will be used effectively in health care and the promotion of health and well-being.<br>• **The strategy has a budget of 50 million euros.** |

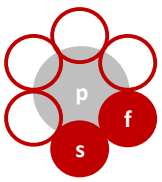


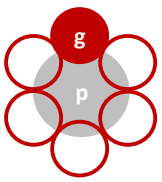




60

## Examples of good practice: Western Europe

| | | |
|---|---|---|
| Germany | Personalized Medicine Action Plan | • Presented in February **2013**<br>• Addressed three areas: Development of specific health resources, relationship with industry and the need for communication.<br>• The action plan proposes short term objectives in **quicker diagnostics, improved treatments, more funding for personalized medicine and better understanding by society**. |
| France | France Médecine Génomique 2025 | • Published in **2016**<br>• **Ethics are central to the plan: considering impact on patients**, health system, research, training and wider economy.<br>• The model applied is based on shared access to data collected at national level.<br>• It aims to perform approx 235,000 genome sequences per year, of rare disease patients & their families and patients with metastatic or treatment-refractory cancers. |




61

## Denmark, though, is often ranked best for PM in Europe

What is Denmark doing well? The 'six principles' offers some insight:

1. The Danish efforts within Personalised Medicine are to focus on the **patients**. Genome sequencing is to be used for treatment purposes and in research projects.
2. Confidentiality, the individual's right to self-determination, protection of information and **research ethics** approval are paramount.
3. The use of Personalised Medicine as a standard offer in the healthcare system must be **evidence-based** and **economically sustainable**.
4. Genome sequencing and data processing must be based in the **public sector**.
5. The national infrastructure and adopted standards must be used, and **data must be shared** securely for the benefit of future research and treatment.
6. The distribution of research funds as part of the strategy must take place in **competition** – and research projects should in principle be nationwide.

*Personalised medicine for the benefit of patients. Clear diagnosis · Targeted treatment · Strengthened research. Summary. National strategy for personalised medicine 2017-2020. Copenhagen: The Ministry of Health; 2016*

62

## How are personalised medicines reimbursed?

A review compared how **42 countries** made coverage and pricing decisions for **personalized medicine** and **orphan drugs**, on the basis that these two share many characteristics. Both target:

1. Small patient populations
2. Have uncertainties regarding efficacy and safety at payer submission
3. Frequently have high prices.

But while studies of orphan drugs were conducted across all countries, personalized medicine pricing and coverage was only evaluated in the US and parts of Europe and Australia.

There is a lack of clarity as to what constitutes "quality evidence".

### *Payers need better comparative effectiveness evidence*

The author suggested the establishment of national registries to help inform studies and identify assist with post-market surveillance.

*Degtiar I. A review of international coverage and pricing strategies for personalized medicine and orphan drugs. Health Policy Amst Neth. 2017 Dec;121(12):1240–8.*

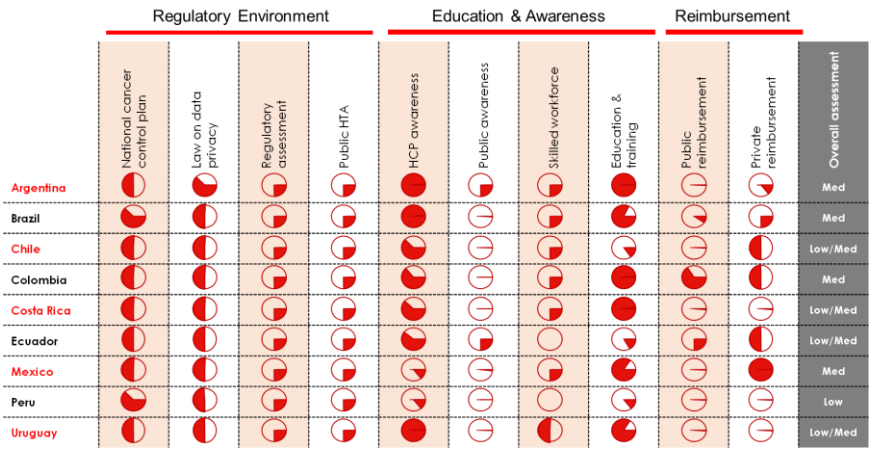
63

# Personalised care in Latin America today

64

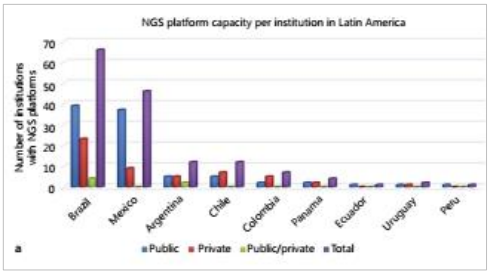
## Assessing the landscape in Latin America

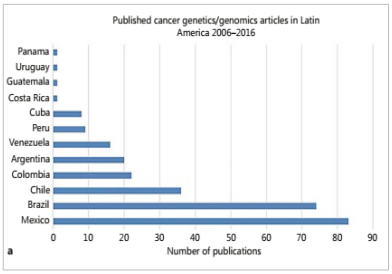
**Interim results**




65

## Brazil and Mexico are most active countries in genomics




- Of the 14 Latin American countries with NCCPs, only Brazil, Peru and El Salvador mention specifically the use of genetic tests as a strategy for early detection of cancer
- All NCCPs incorporate strategies for increasing the economic investment in technology and specialized treatment with the final goal of improving cancer diagnosis and care, but specific mention of investment in infrastructure for genomic analyses is lacking

*Torres Á, Oliver J, Frecha C, Montealegre AL, Quezada-Urbán R, Díaz-Velásquez CE, et al. Cancer Genomic Resources and Present Needs in the Latin American Region. Public Health Genomics. 2017;20(3):194-201.*

66

## Local example (infrastructure, training & research): Mexico

**The National Institute of Genomic Medicine (INMEGEN)**
Date: 2004

Mexico was one of the earliest adopters of personalized medicine. There is a lot of interest in **local genetic diversity**. In 2000, strategic planning for genomic medicine began, from a feasibility study and a multi-institutional consortium effort, to the creation of a National Institute of Genomic Medicine (INMEGEN) in 2004. The objectives of the Institute are to:


- **Build** an innovative organizational design: INMEGEN system
- **Establish** the initial infrastructure
- **Make** strategic alliances for the Nationwide Development of Genomic Medicine
- **Perform** high-quality scientific research in genomic medicine
- **Apply** world-class genomic technology to common health problems
- **Reach** excellence in teaching and training programs
- **Support** scientific research and academic programs
- **Comply** and investigate on ethical, social, and legal issues
- **Translate** scientific knowledge into products and services

67

## Local example (data collection, sharing & awareness): Brazil

### Brazilian Initiative on Precision Medicine (BIPMed)

Date: 2015

The Initiative's objective is to focus on development of **genomic databases and data sharing**. Latin America's first public and free human genome database, incorporating:

- BIPMed-WES-db: from Whole Exome Sequencing
- BIPMed-Array-db: from microarray-based experiments
- BIPMed-EE-db: specific mutations in patients with epileptic encephalopathies
- BIPMed Craniofacial Anomalies
- BIPMed-BRCA


### Human Genome and Stem-Cell Research Center (HUGCEL)

Date: 2013

Description: The Human Genome and Stem-Cell Research Center (HUG-CEL) at the University of São Paulo (USP) expands the scope of the original Human Genome Research Center (HGRC/RIDC I) that was established in 2000. The current center has been expanded to include research on:

- Stem cell and human genetic disease
- Diagnostic services (including **counseling**)
- Educational and teaching programs, including **outreach** to high school students and teachers, health workers and science journalists

68

## Local example (research and patient-focussed): Argentina

### Precision Medicine Initiative

Date: 2017

Aim is to establish the scientific know-how and protocols required to **implement "omic" technologies** in the clinical practice, by performing a proof of concept of the process in a small number of patients.


Healthcare institutions with NGS equipment and research groups from academia were included in the project, which was developed following the creation of the *Argentinean Genomic and Bioinformatic Platforms* in 2012. This 4-year project, with the help and financing of the *National Ministry of Science and Technology (MINCyT)*, aimed to develop **genomic and bioinformatic** knowledge and facilitate those services to public and private parties. During this period the first three whole genomes were entirely sequenced.

Following this in 2016, the "100 Exomes Campaign" was launched, to sequence 100 exomes of patients with rare genetic disorders.

69

## A diversity of approaches for a diverse country: Colombia

### A brief summary

Genetic services clustered in the main cities: Bogota, Medellin, Cali, and Barranquilla.

There is a state laboratory but it is limited in funding and resources. Most testing is performed in private laboratories, often affiliated with an academic institution.

Patient organisations include:
- Colombian Foundation for Cystic Fibrosis
- the Colombian league for haemophiliacs
- the association for lysosomal storage disorders
- Huntington's disease
- Cleft lip and palate

Colombia has formal genetics training for medical professionals (a three year residency program). Genetics is also part of the medical school curriculum, although there are **no genetic counsellors** in Colombia.

**The Colombian Society of Genetics** is tasked with advancing the field.


70

# Looking to the future

71

## Interim conclusions

- Some promising **local developments**, such as seen in Mexico, Brazil, Argentina. Institutes and collaborations could be used as a base from which to build.

- Inclusions of the use of personalised approaches, such as the genetic tests as a strategy for early detection of cancer, is a rarity in Latin American **National Cancer Control Plans.**
  - **Consider including personalised care in the next iteration of plans, and/or have a separate personalised care strategic plan**

- **Lack of reimbursement** and access to drugs and therapies remain as major barriers. Most countries have **HTA** organisations, although they often don't know how to deal with personalised healthcare.
  - **Consider encouraging HTA organisations to reach out to expertise and assess wider societal value when evaluating personalised medicine**

72

## Interim conclusions

- The development of the necessary **IT tools and data registries** (particularly national, or at least linked regional) remain in their infancy. The use of registries will help allow build a body of evidence to help assess, develop and evolve personalised medicine.

- Many providers exist, but **quality assurance** is sometimes lacking. Registries can also help encourage a degree of standardisation across laboratories.
  - **Consider building registries of suitable quality and scope, and systems to encourage sharing of (protected and with clear ownership) data**

- **Public awareness** of personalized healthcare is low. Patients are not empowered to talk to their doctors about genomic profiling. UK experience has found that when people are informed of the potential of (e.g.) genomic profiling, they tend to respond enthusiastically—as long as (e.g.) data privacy and use is regulated.
  - **Consider raising awareness and genomic literacy through public campaigns, and establishment of genetic counsellors**

73

## The EIU paper—coming in 2020

The EIU public policy paper will ask what can countries in the region do to transition from scattered, ad hoc availability of personalised medicine, to a person-centred, equitable and sustainable personalised healthcare system?


74

## Thank you

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75