Le développement de la médecine personnalisée et son impact éventuel sur la prise en charge cardiovasculaire

21 novembre 2015

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Pavel Hamet – Disclosures

2015

- *Grant support:* MDEI/Génome Québec, CIHR, CFI, Canada Research Chairs, PARI
- *Consultation:* Servier
- *SAB:* Pfizer, BMS, Servier, Novartis, Sanofi-Avantis
- *Speaker:* Merck, BMS, Servier, Novartis, Sanofi-Avantis, Bayer, ASTRAZENECA
- *Shareholder :* Medpharmgene, Opti-thera Clinique Medicale Angus

Au départ ce fut Hippocrate

Il est plus important de savoir quelle personne *la maladie a* que quelle maladie *la personne a*

Hippocrate le Grand ou **Hippocrate de Cos** (en grec : Ἱπποκράτης), né vers 460 av. J.-C dans l'île de Cos et mort vers 370 av. J.-C à Larissa, père de la médecine rationnelle

Évolution par la suite : médecine observationnelle
médecine basée sur l'évidence
médecine basée sur la personne

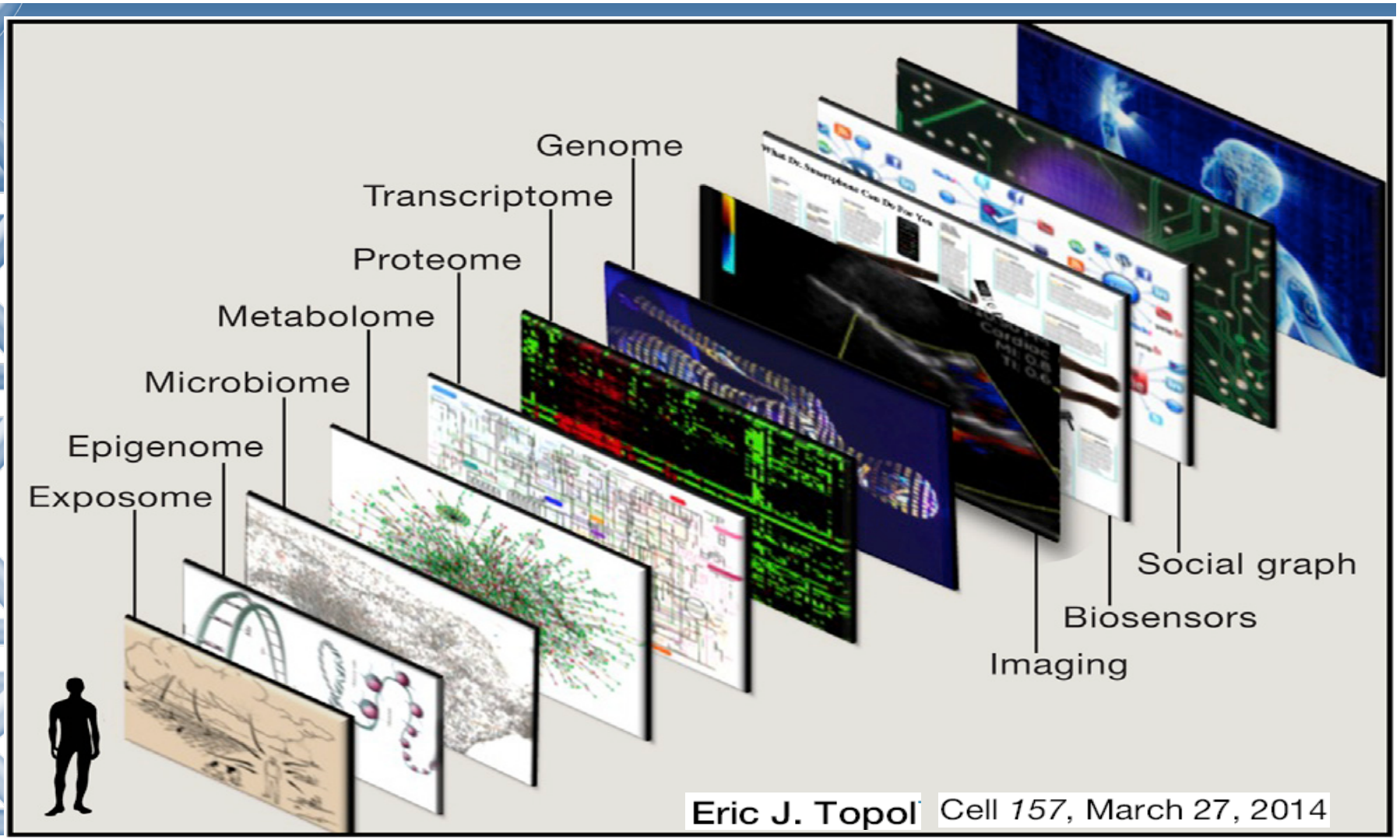
La longue route des traits mendéliens aux maladies complexes...

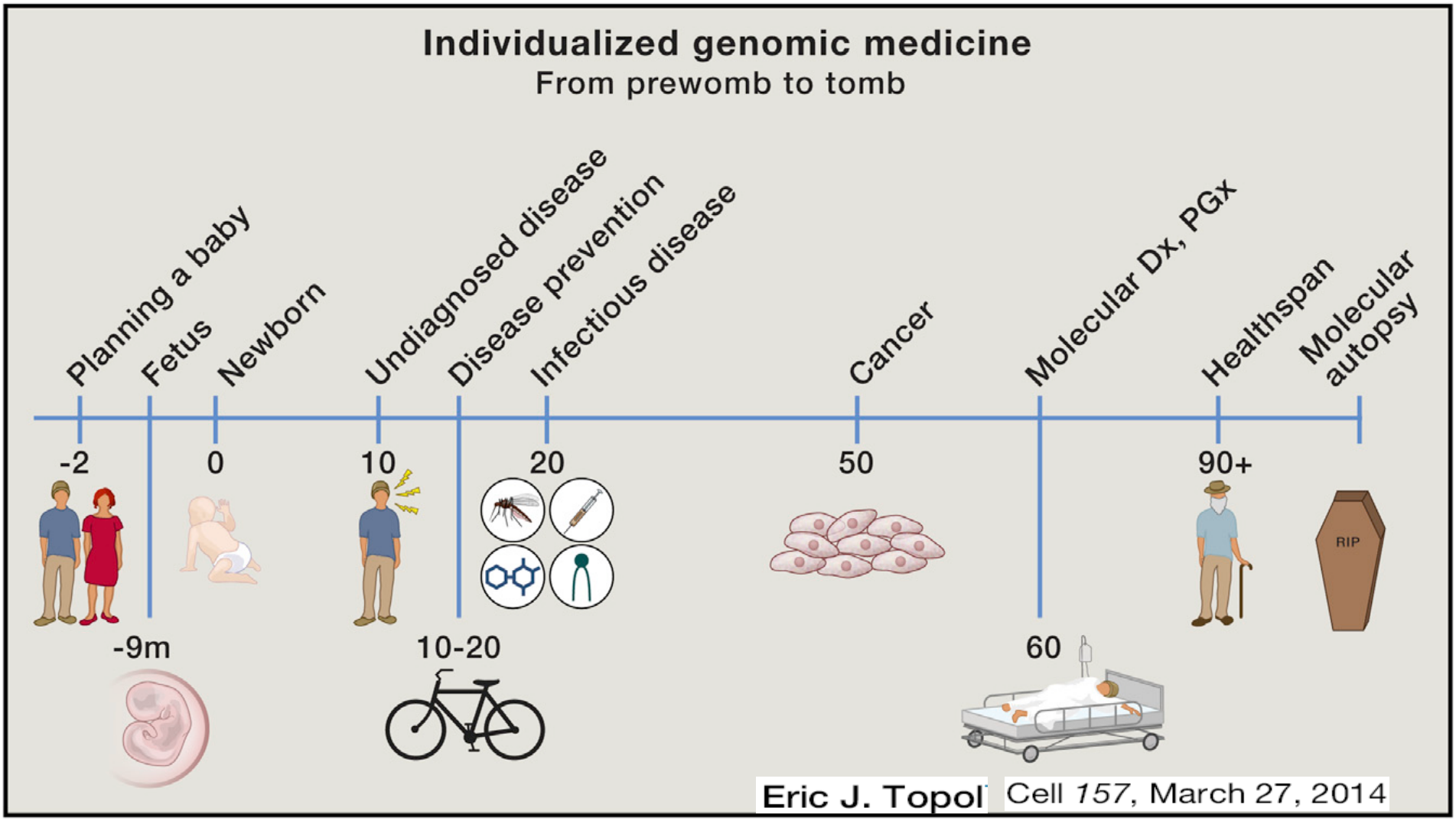
OPTI-THERA
Prédire pour prévenir
Predict to prevent

Personalized Medicine

"…. a form of healthcare that considers information about a person's genes, proteins and environment to prevent, diagnose and treat disease…" **(Cancer Institute of NIH, USA 2011)**

OPTI-THERA
Prédire pour prévenir
Predict to prevent

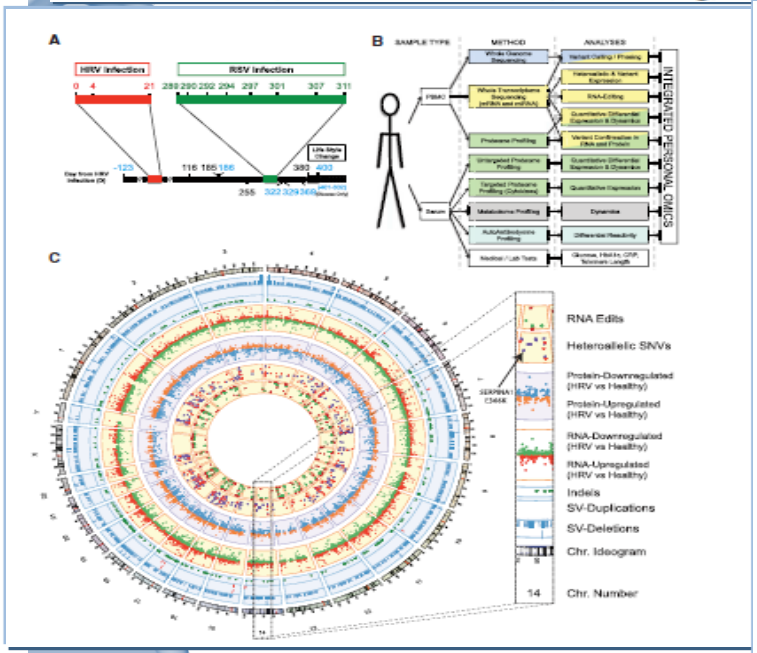

Genome
Transcriptome
Proteome
Metabolome
Microbiome
Epigenome
Exposome
Social graph
Biosensors
Imaging
Eric J. Topol
Cell 157, March 27, 2014

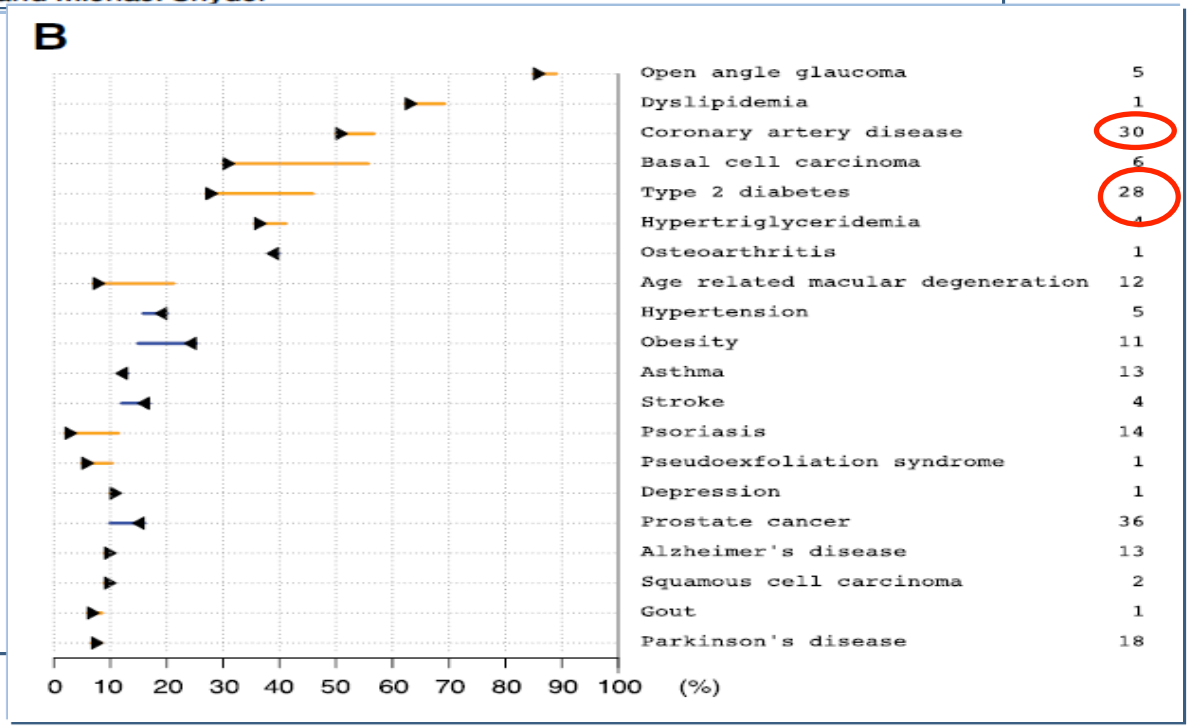

Individualized genomic medicine
From prewomb to tomb
Planning a baby
Fetus
Newborn
Undiagnosed disease
Disease prevention
Infectious disease
Cancer
Molecular Dx, PGx
Healthspan
Molecular autopsy
-2
0
10
20
50
90+
-9m
10-20
60
RIP
Eric J. Topol
Cell 157, March 27, 2014

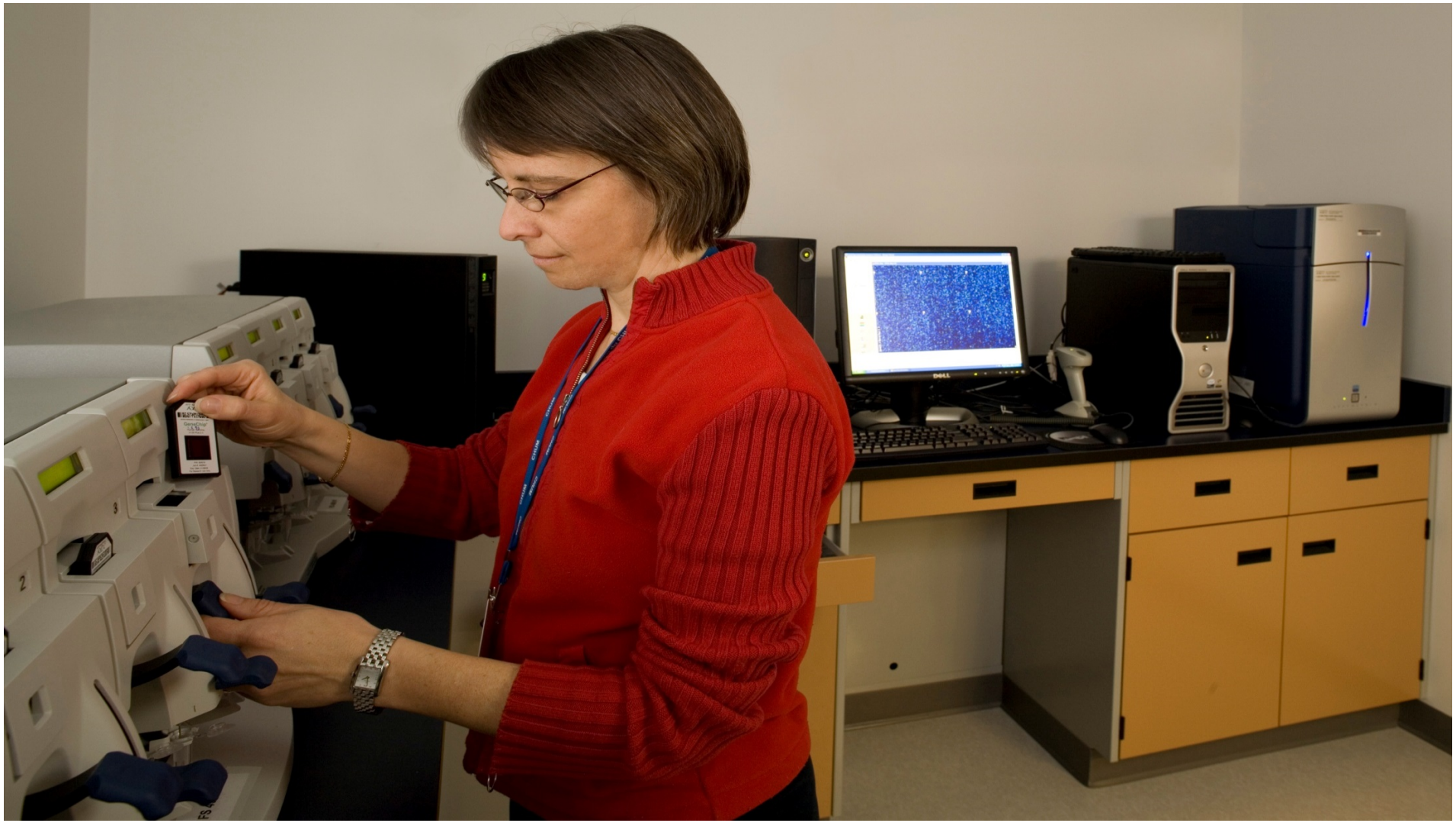
Personal Omics Profiling Reveals Dynamic Molecular and Medical Phenotypes

Cell *148*, 1293–1307, March 16, 2012

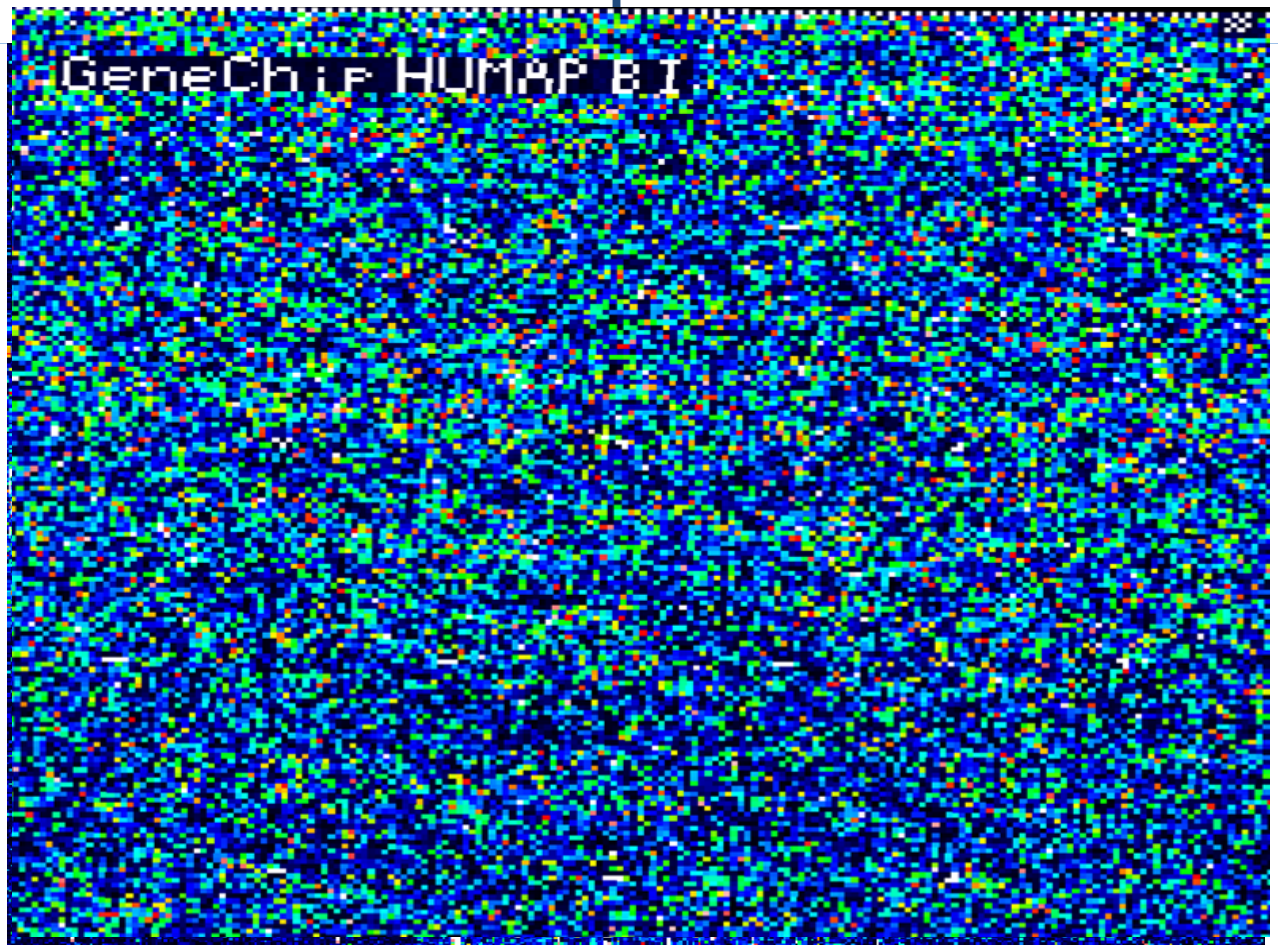
Rui Chen,[1,11] George I. Mias,[1,11] Jennifer Li-Pook-Than,[1,11] Lihua Jiang,[1,11] Hugo Y.K. Lam,[1,12] Rong Chen,[2,12] Elana Miriami,[1] Konrad J. Karczewski,[1] Manoj Hariharan,[1] Frederick E. Dewey,[3] Yong Cheng,[1] Michael J. Clark,[1] Hogune Im,[1] Lukas Habegger,[6,7] Suganthi Balasubramanian,[6,7] Maeve O'Huallachain,[1] Joel T. Dudley,[2] Sara Hillenmeyer,[1] Rajini Haraksingh,[1] Donald Sharon,[1] Ghia Euskirchen,[1] Phil Lacroute,[1] Keith Bettinger,[1] Alan P. Boyle,[1] Maya Kasowski,[1] Fabian Grubert,[1] Scott Seki,[2] Marco Garcia,[2] Michelle Whirl-Carrillo,[1] Mercedes Gallardo,[9,10] Maria A. Blasco,[9] Peter L. Greenberg,[4] Phyllis Snyder,[1] Teri E. Klein,[1] Russ B. Altman,[1,5] Atul J. Butte,[2] Euan A. Ashley,[3] Mark Gerstein,[6,7,8] Kari C. Nadeau,[2] Hua Tang,[1] and Michael Snyder[1,*]







WGS 6.0 Chip – Close view



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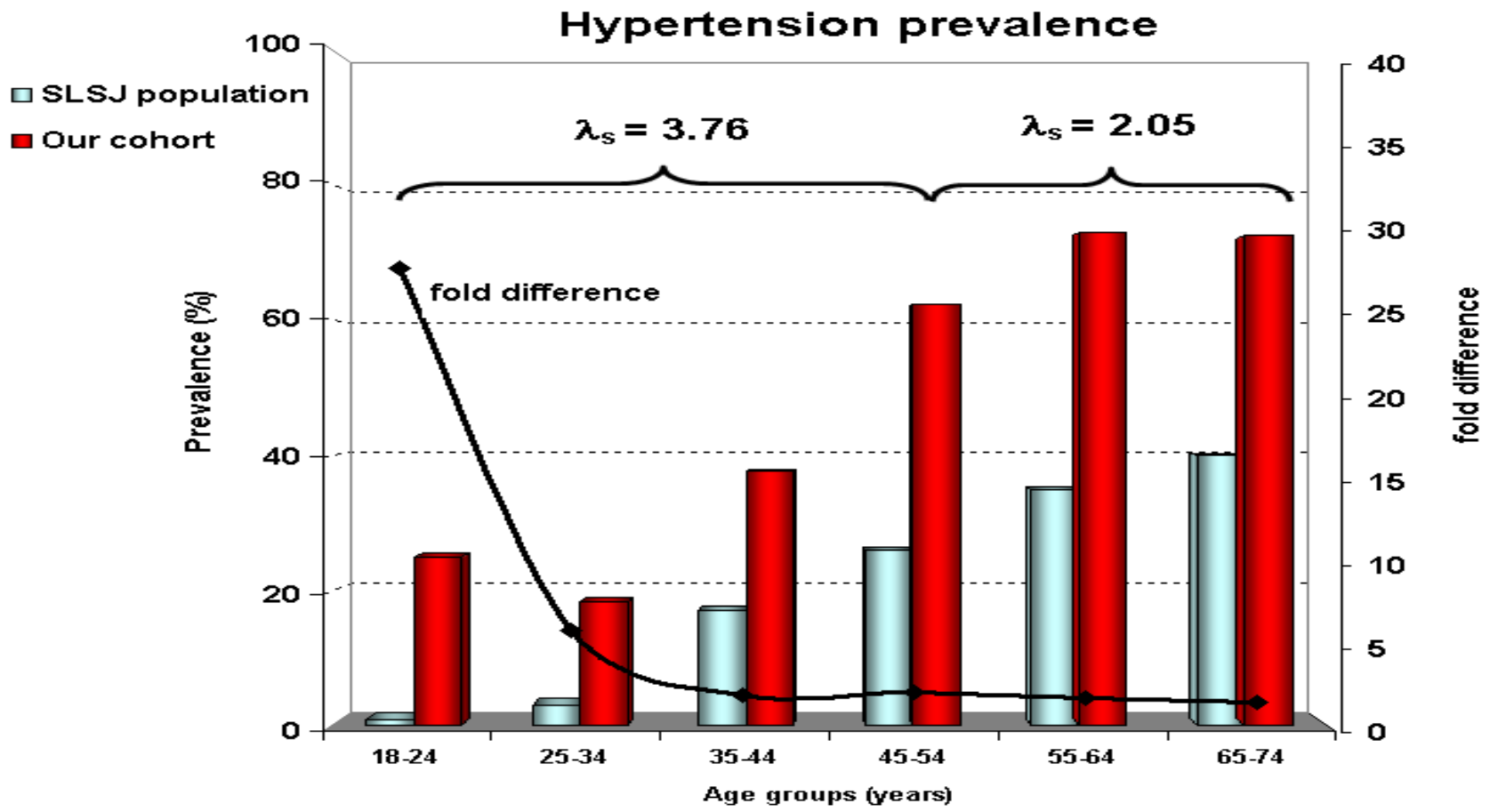
Age x environnement des maladies complexes



Heritability of complications

Myocardial infarction	**8 - 49%**
Stroke	**17 - 32%**
Albuminuria	**30 -39%**
Low glomerular filtration rate	**40 - 58%**
Hypertension	**10 - 27%**
Atrial fibrillation	**68%**
Neuropathy	**up to 31%**
Retinopathy	**24 - 52%**

CHUM
CENTRE DE RECHERCHE

OPTI-THERA
Prédire pour prévenir
Predict to prevent

Gènes *et/ou* environnement

- **Peu d'analyses sur les effets respectifs ou sur leurs interactions**
- **Héritabilité ou épidémiologie «manquante» ou simplement notre limite actuelle**
- **En déclarant que les facteurs de risque «modifiables» (TA, glycémie, cholestérol, apoB) et l'histoire familiale ont plus d'effets que la génétique, on ignore leurs déterminants génomiques intrinsèques**

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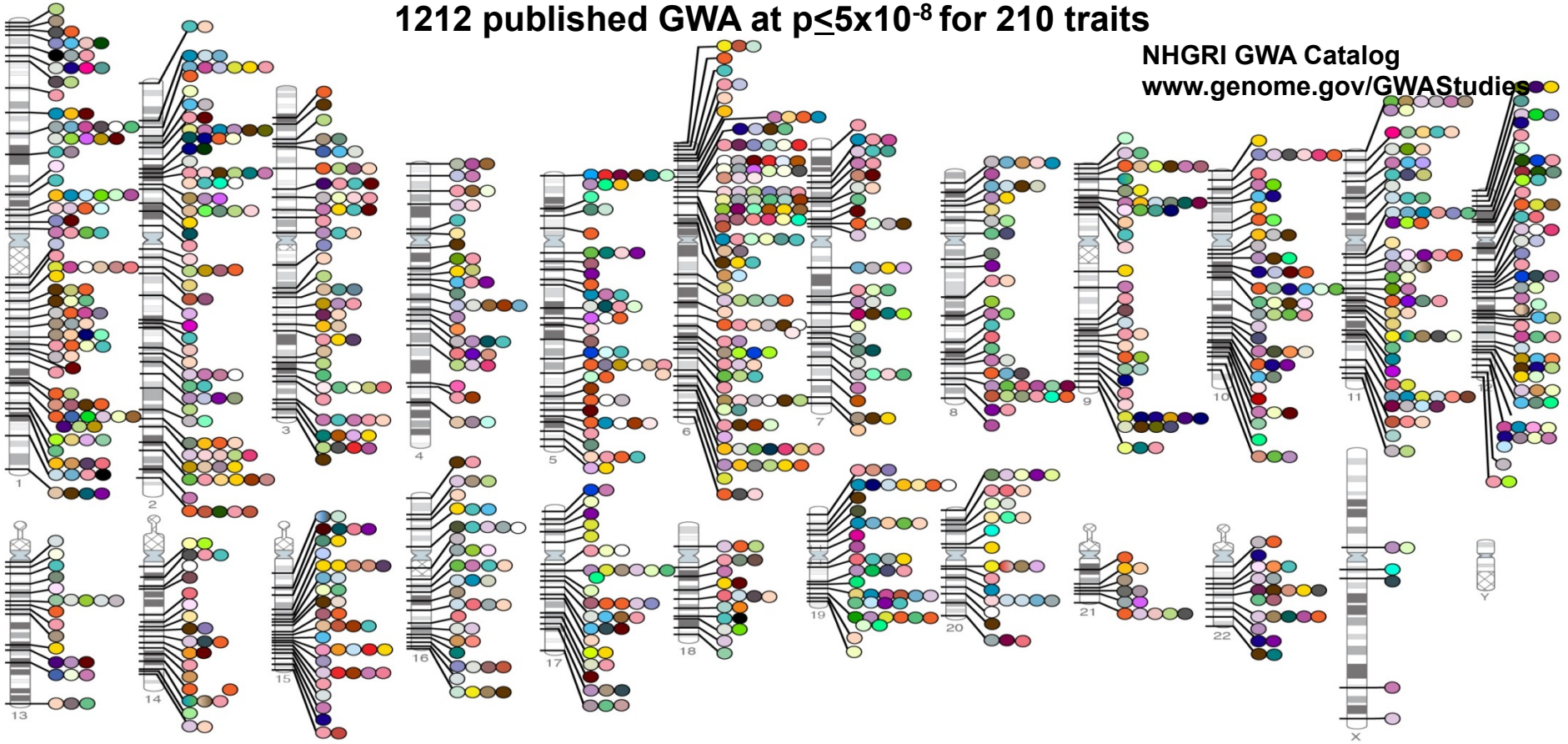
Predict to prevent

Published Genome-Wide Associations through 12/2010, 1212 published GWA at $p \leq 5 \times 10^{-8}$ for 210 traits

NHGRI GWA Catalog
www.genome.gov/GWAStudies



Limitations of GWAS in cardiovascular complications so far

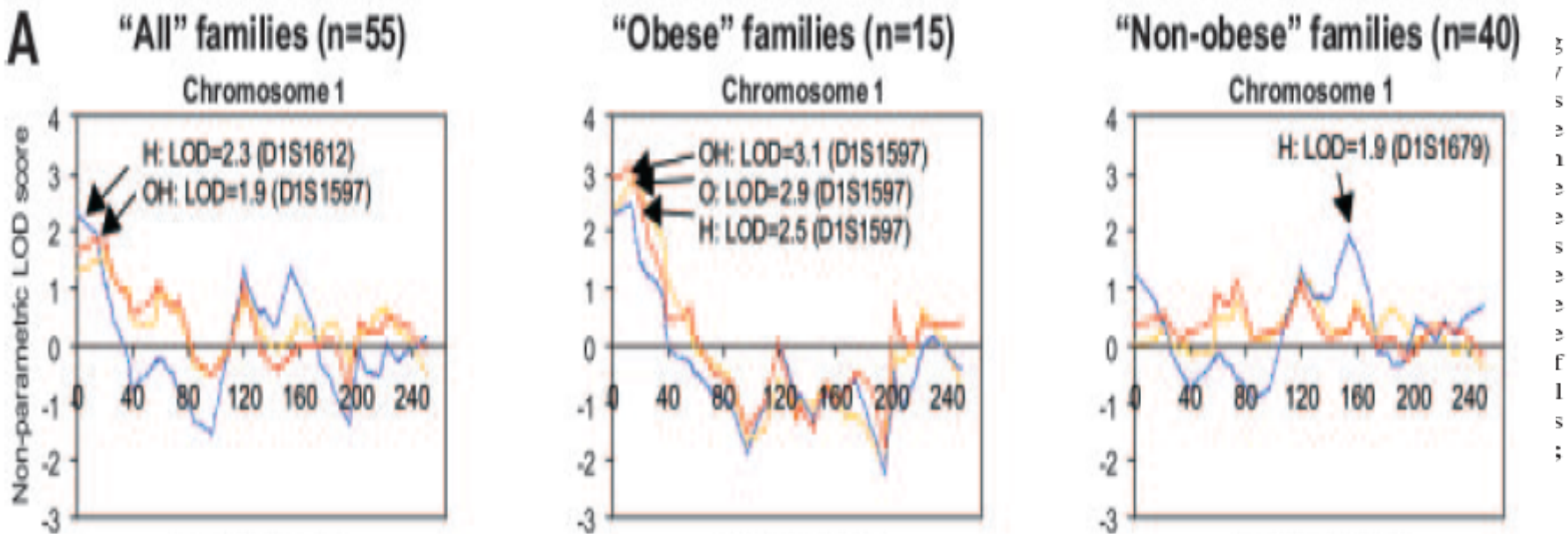
- Requirement for very large sample size
- Small variance component of major phenotypes
- Does not exclude monogenic contributions

Question: ***what are the potential reasons for these characteristics?***

- **Heterogeneity of the disease**
- **Sex/age dependent genotype impact**
- **Geoethnicity (intraethnic admixture)**
- **Interaction of alleles of risk and protection (epistasis)**
- **Implications of a large number of genes**
- **Genes vs environment (allelic penetrance)**

Genome-Wide Scan for Linkage to Obesity-Associated Hypertension in French Canadians

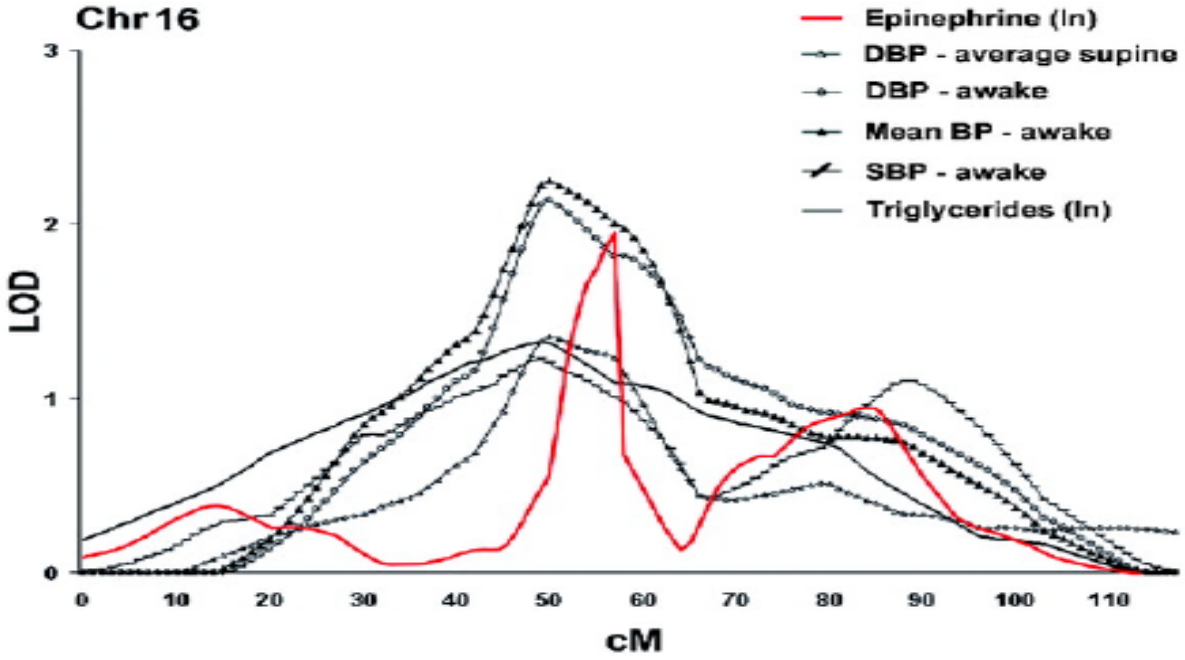
Zdenka Pausova, Daniel Gaudet, Francis Gossard, Manon Bernard, Mary L. Kaldunski, Michele Jomphe, Johanne Tremblay, Thomas J. Hudson, Gerard Bouchard, Theodore A. Kotchen, Allen W. Cowley, Pavel Hamet



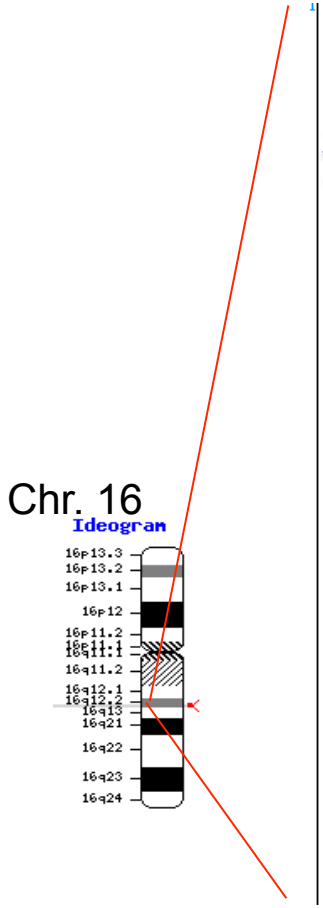
Quantitative Founder-Effect Analysis of French Canadian Families Identifies Specific Loci Contributing to Metabolic Phenotypes of Hypertension

P. Hamet,[1] E. Merlo,[2] O. Šeda,[1] U. Broeckel,[4] J. Tremblay,[1] M. Kaldunski,[4] D. Gaudet,[5] G. Bouchard,[6] B. Deslauriers,[1] F. Gagnon,[7] G. Antoniol,[8] Z. Pausová,[1] M. Labuda,[1] M. Jomphe,[6] F. Gossard,[1] G. Tremblay,[5] R. Kirova,[4] P. Tonellato,[4] S. N. Orlov,[1] J. Pintos,[1] J. Platko,[9] T. J. Hudson,[3] J. D. Rioux,[9] T. A. Kotchen,[4] and A. W. Cowley Jr.[4]

Am. J. Hum. Genet. 76:815–832, 2005



FTO Variants in Relation to Previous Findings



BMI, weight
Obesity, T2D
Waist circumference (GWAS)
BMI
Extreme obesity, BMI

16 GWAS (2007 -2009)

SBP, fat mass, BMI in French-Canadians (2005, 2009)

A common variant of the FTO gene is associated not only with increased adiposity but also with elevated blood pressure in French-Canadians
Zdenka Pausova, Catriona Aileen Syme, Michal Abarahamowicz, Yongling Xiao, Gabriel Leonard, Michel Perron, Louis Richer, Suzanne Veillette, George Davey Smith, Ondrej Seda, Johanne Tremblay, Pavel Hamet, Daniel Gaudet, and Tomas Paus
CIRCULATIONAHA/2009/857359

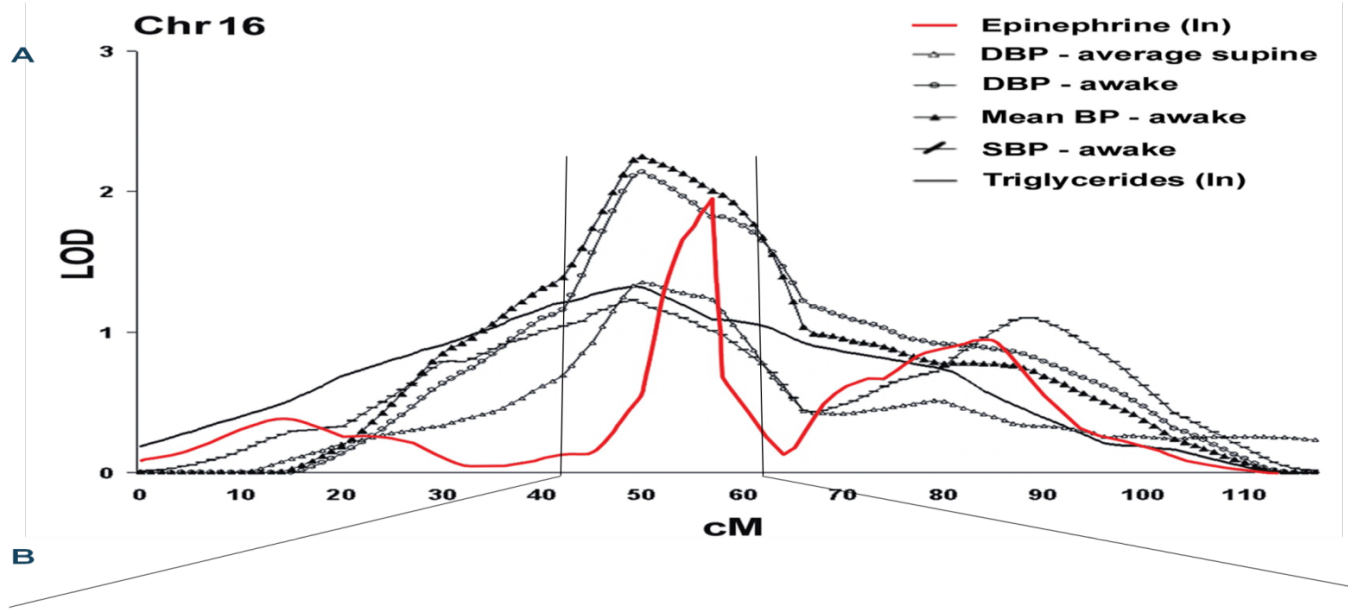
Circulation: Cardiovascular Genetics. 2009;2:260-269

rs17823223

MACE + albuminuria
OR allelic = 0.66
$p = 4.15 \times 10^{-6}$

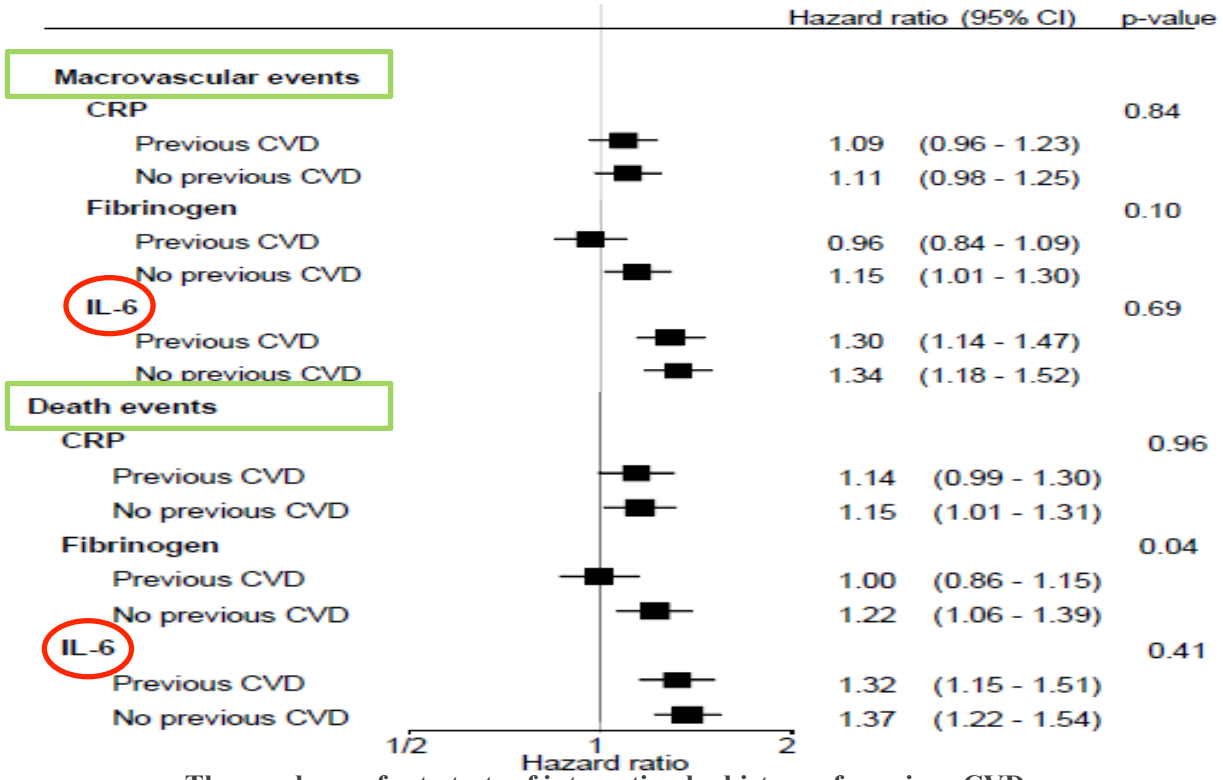
THE IMPACT OF PHARMACOLOGICAL ENVIRONMENT ON CAPACITY TO IDENTIFY THE GENETIC COMPONENTS OF HYPERTENSION

-Audrey Noël1, Ondřej Šeda1, Johanne Tremblay1, Daniel Gaudet2, Theodore A. Kotchen3, Allen W. Cowley3, Pavel Hamet1
1CRCHUM; 2Complexe hospitalier de la Sagamie; 3Medical College of Wisconsin



Phenotype	rs10492790	rs7196791	rs7202468	rs8047316	rs10521237
SBP without medication	0.01	0.009	0.02	0.01	0.02
DBP without medication	0.003	0.04	0.01	0.02	0.007
SBP with medication	0.04	0.7	0.04	0.9	0.06
DBP with medication	0.2	0.3	0.2	0.7	0.2

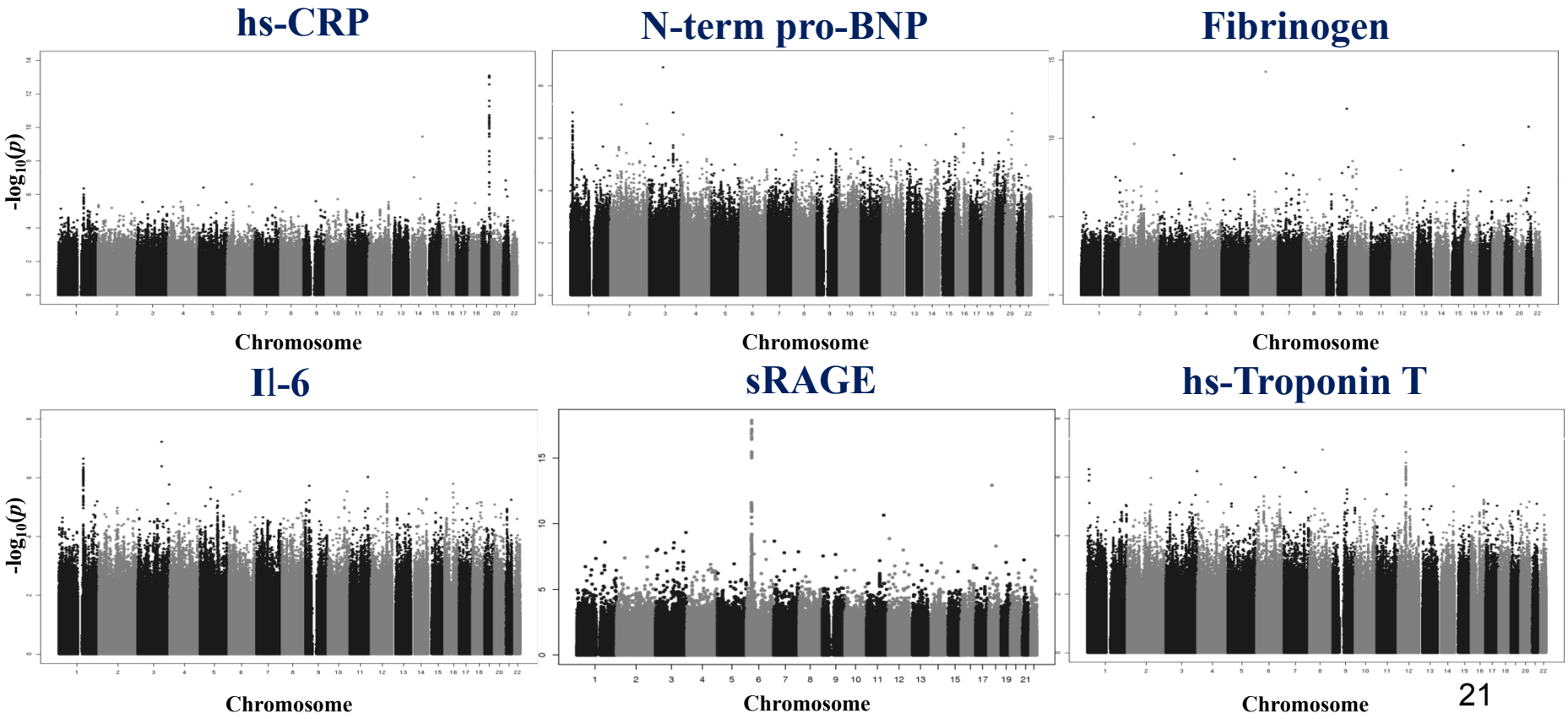
From biomarkers to genomic predictors



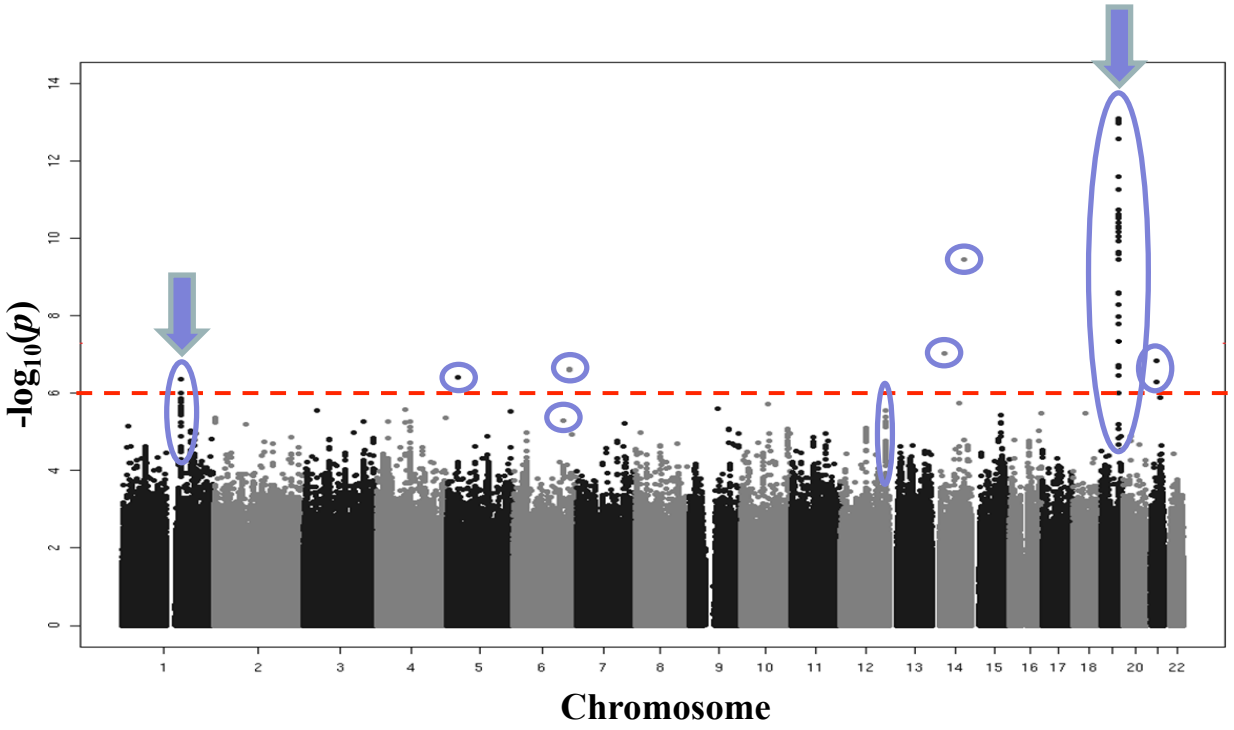
The p-values refer to tests of interaction by history of previous CVD

Lowe G. *et al. Diabetes.* Circulating Inflammatory Markers and The Risk of Vascular Complications and Mortality in People With Type 2 Diabetes Mellitus and Cardiovascular Disease or Risk Factors: The Advance Study. Nov 12 (2013)

Manhattan Plots of 6 inflammatory biomarkers

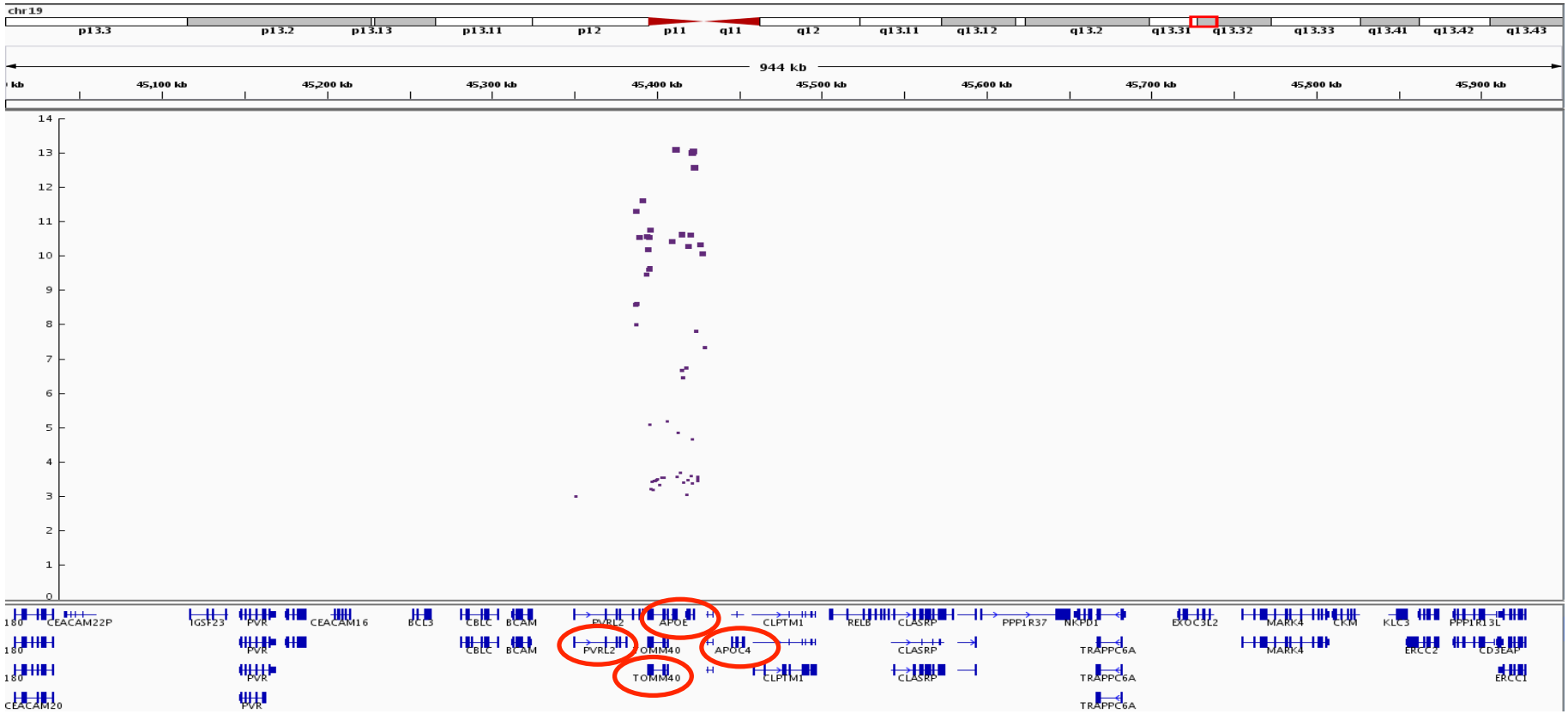


Manhattan Plot of high sensitivity-C-Reactive Protein

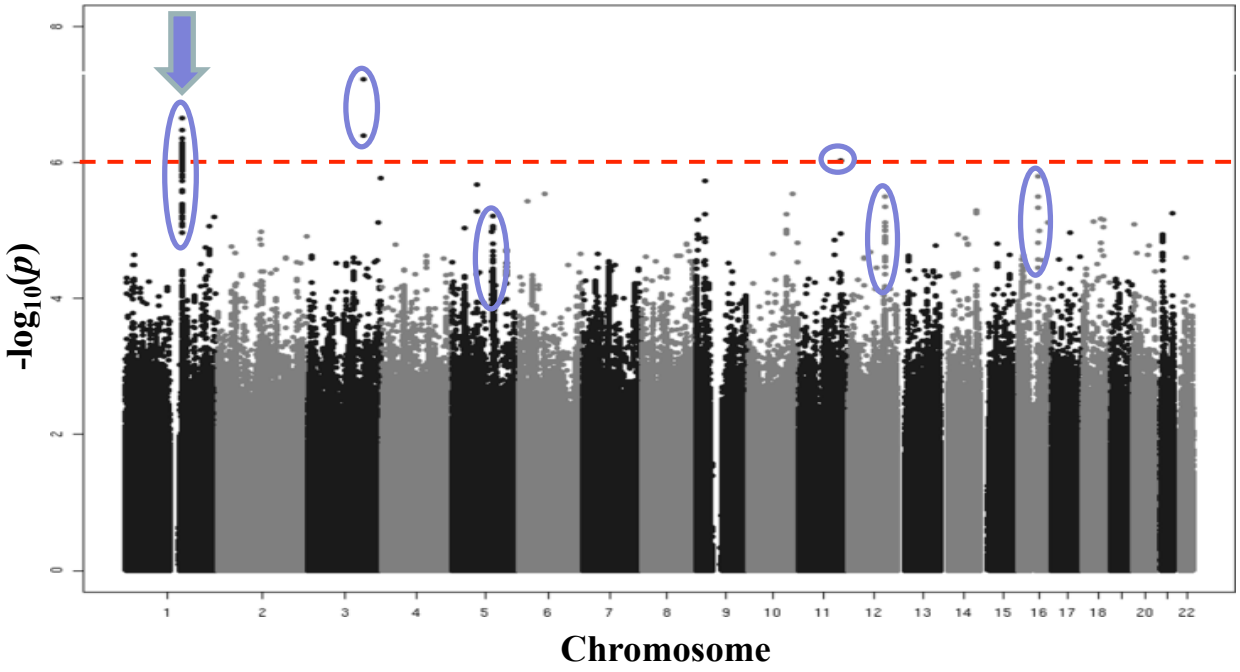


Chr1
CRPP1
(CRP)
Chr5
Pseudogenes
Chr6
SYNE1
(SGK1)
Chr14
GALC
AKAP6
Chr12
(HNF1A)
Chr19
APOE
APOC1
APOC1P1
PVRL2
TOMM40
Chr21
APP

CRP_Chr 19_Integrated Genome Viewer

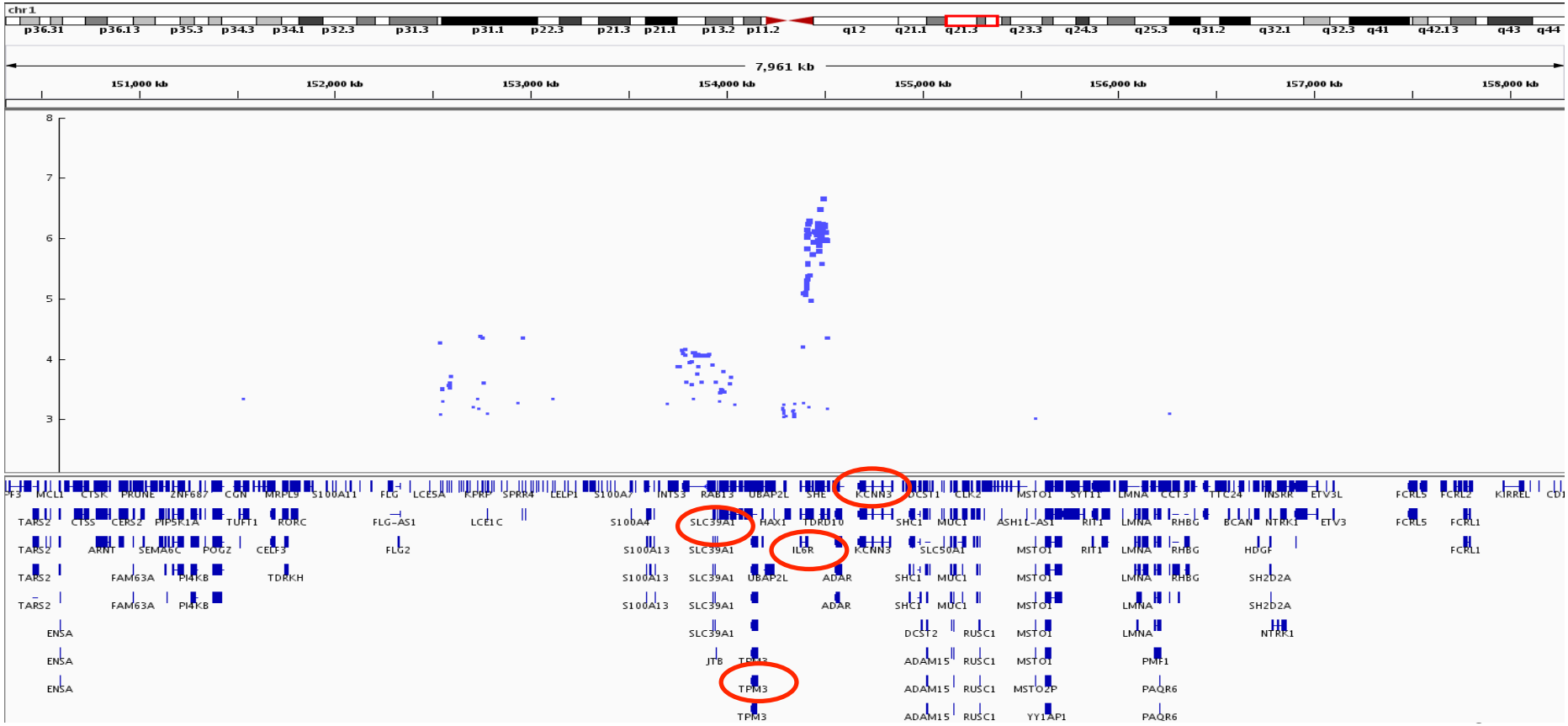


Manhattan Plot of Interleukin-6



Chr1
IL6R
TDRD10
SHE
Chr3
RPL32P9
Chr5
(MAN2A1)
Chr11
LOC101928985
Chr12
(MIR4303)
(SLC9A7P1)
Chr16
(IRX3)
(IRX5)
(CRNDE)

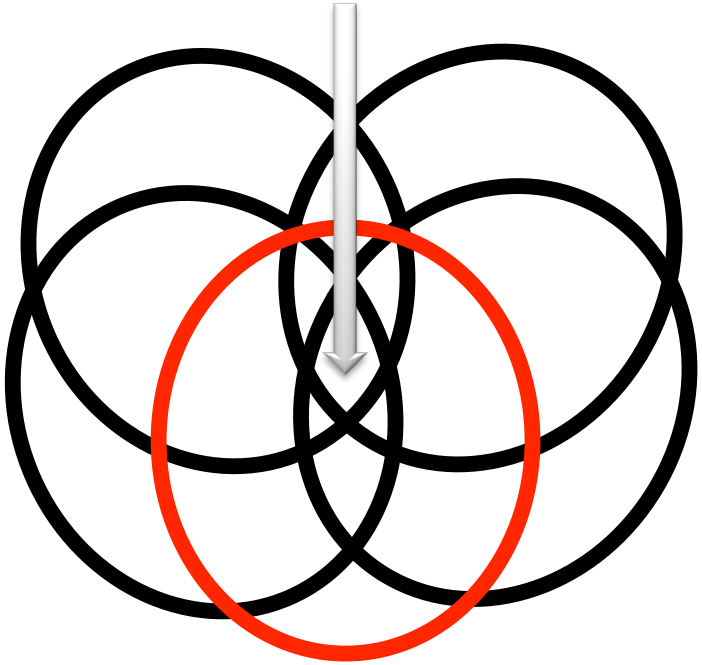
Il-6_Chr 1_Integrated Genome Viewer



166 GENES COMMON TO ALL
ENRICHED DISEASE CLASSES

NEUROLOGICAL DISEASE

CARDIOVASCULAR DISEASE



IMMUNOLOGICAL DISEASE
" among TOP 10 "
networks

INFLAMMATORY DISEASE

DIABETES MELLITUS

PROGNOMIX
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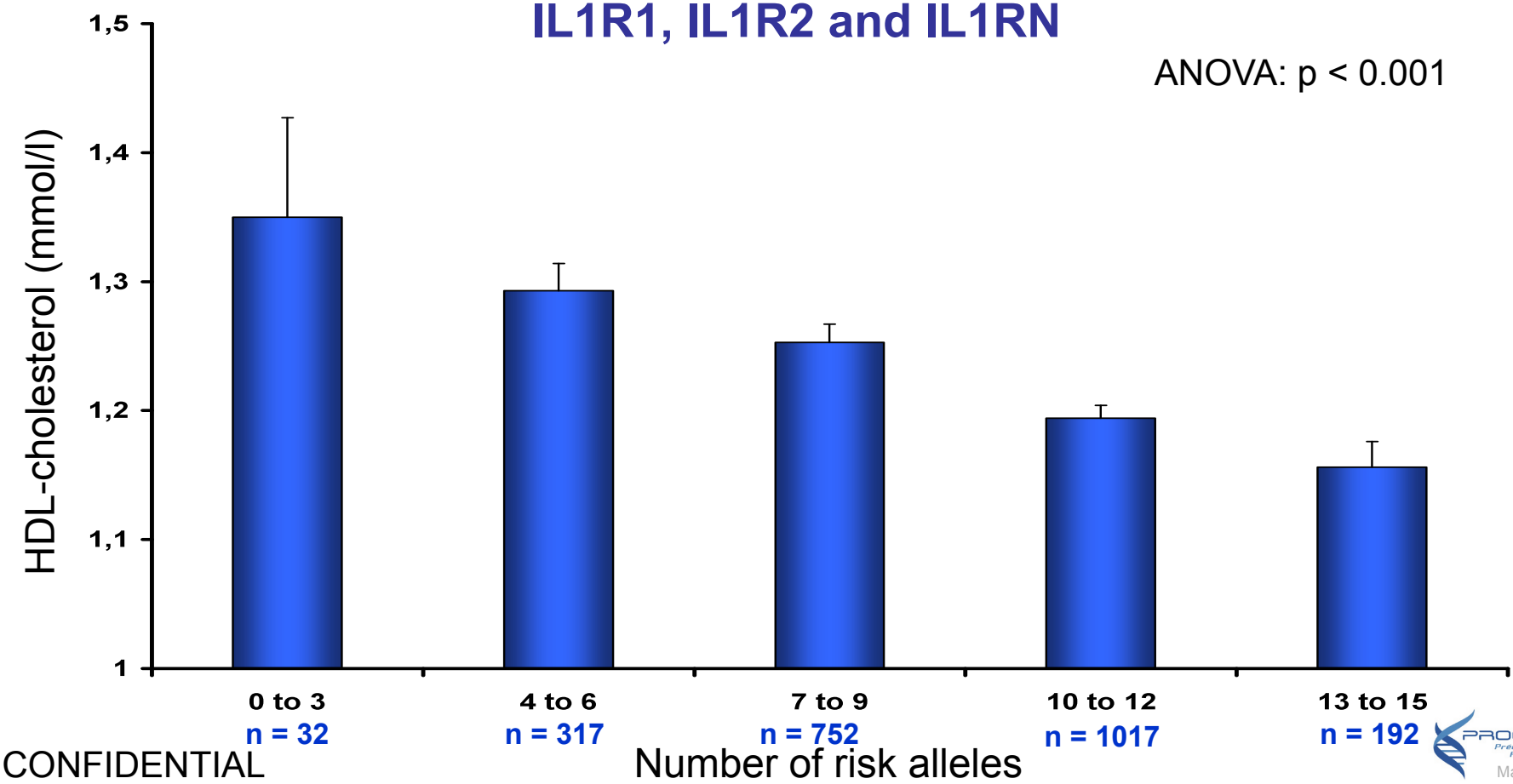
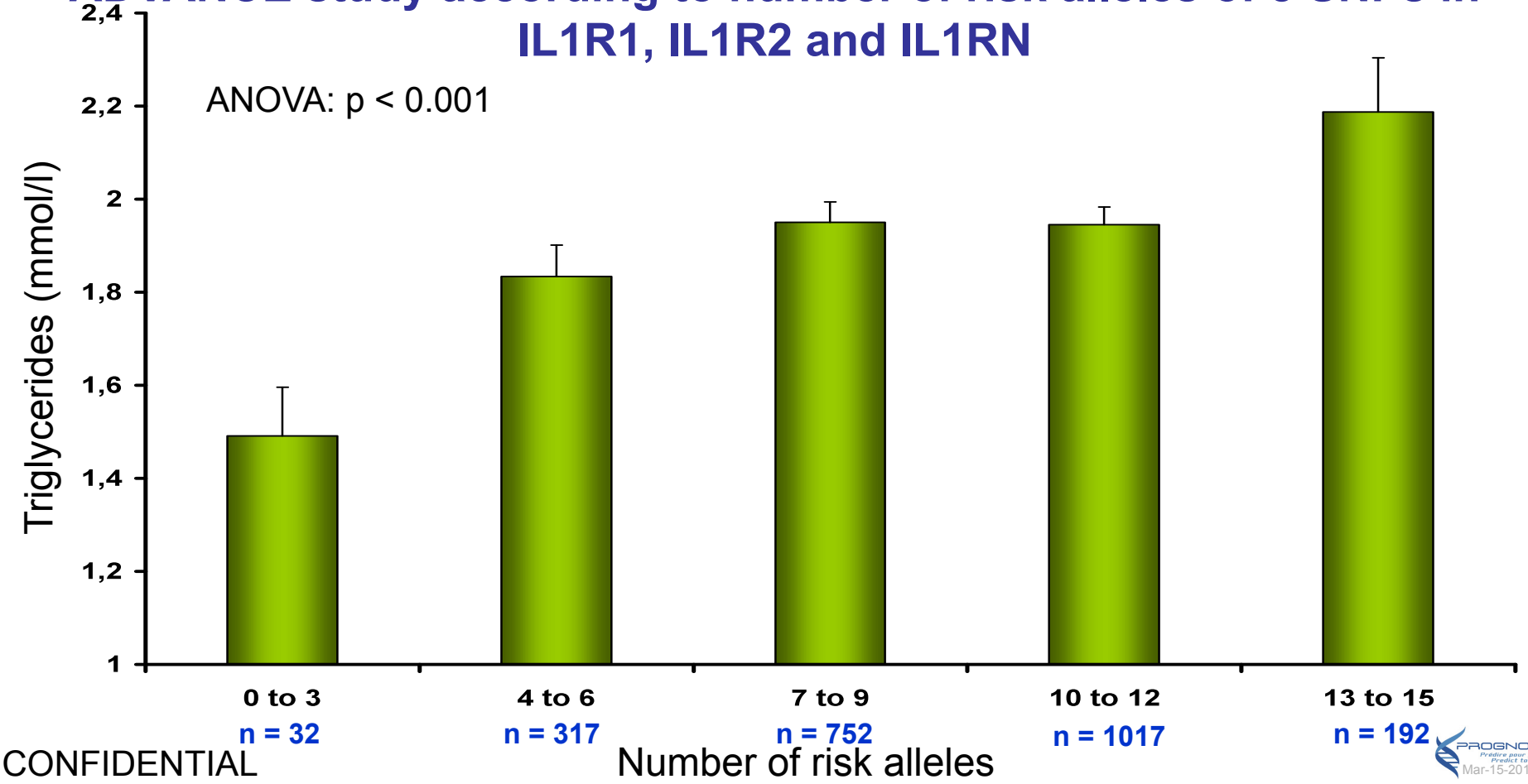
Concentrations of HDL-cholesterol in Caucasian type 2 diabetics from ADVANCE study according to number of risk alleles of 8 SNPs in IL1R1, IL1R2 and IL1RN

ANOVA: p < 0.001

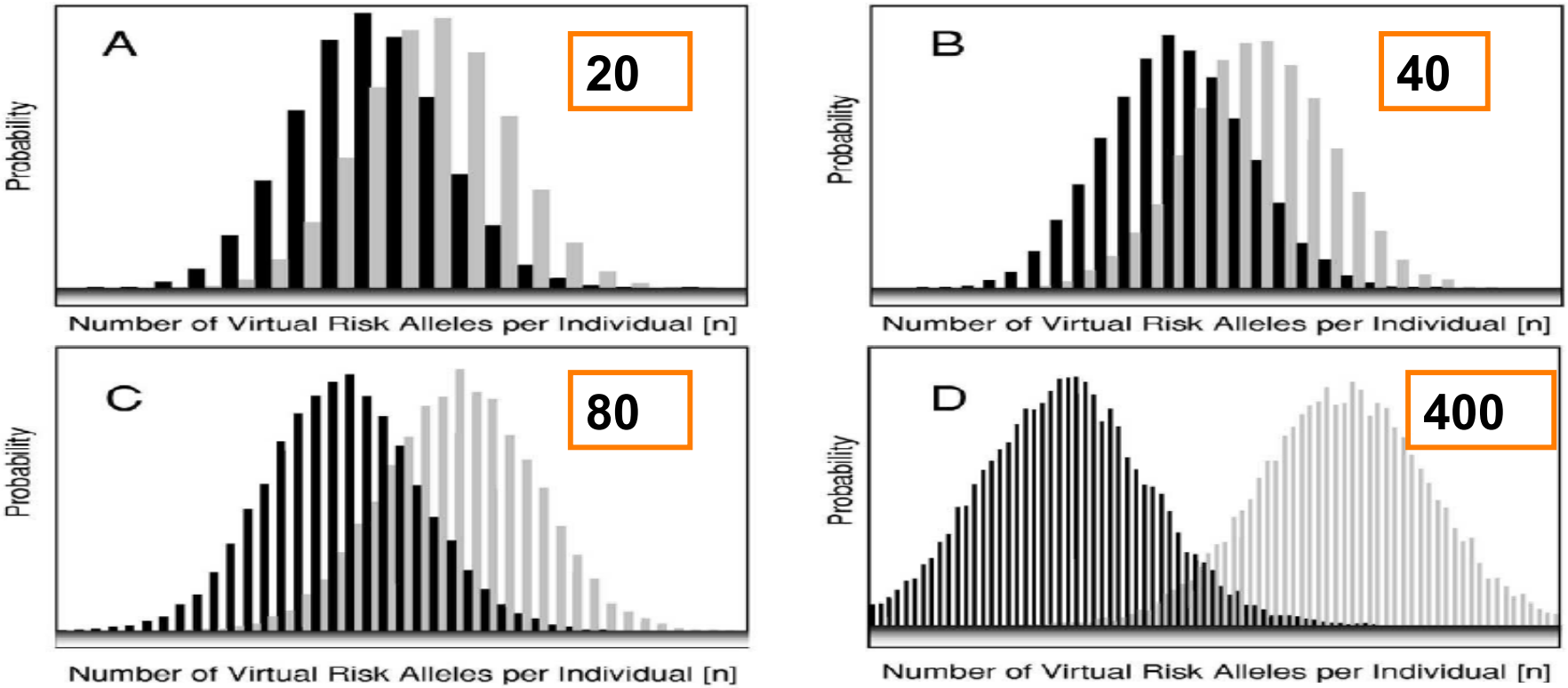


Concentrations of triglycerides in Caucasian type 2 diabetics from ADVANCE study according to number of risk alleles of 8 SNPs in IL1R1, IL1R2 and IL1RN



Analysis of several hundred genetic polymorphisms may improve assessment of the individual genetic burden for coronary artery disease

Jan R. Ortlepp[a,*], Johannes Lauscher[a], Uwe Janssens[a], Ralf Minkenberg[b], Peter Hanrath[a], Rainer Hoffmann[a]



European Journal of Internal Medicine 13 (2002) 485–492

De la médecine personnalisée vers les soins personnalisés

PMC

PERSONALIZED MEDICINE COALITION

THE CASE FOR PERSONALIZED MEDICINE

4TH EDITION 2014

THE RIGHT PERSON

Finding the right people to benefit from genomic medicine can improve disease management and lower health care costs.

THE RIGHT TEST

Getting the wrong test can misinform medical decisions and increase health care costs.

THE RIGHT INTERPRETATION

Delivers the full value of genetic information and enables physicians to make appropriate management decisions.

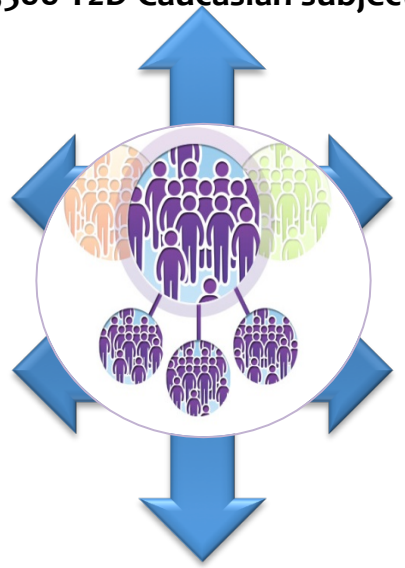
IERA
ur prévenir
to prevent

Canada/Québec efforts in Funding of Translation of Personalized Medicine into Family Practice

- **Reflection 2009** — Biomarkers for Precision Medicine — CIHR IRSC
- **Strategy 2013** — Public/Private Project in Personalized Health, 21 M$ — MONTRÉAL InVIVO
- **Competition** — Genomics in Personalized Health, 90 M$ to Quebec — GenomeCanada, CIHR IRSC
- **Ethics 2012** — Commission de l'éthique en sciences et en technologie — Commission de l'éthique en science et en technologie Québec
- **Action Feb. 2014** — Fonds de partenariat pour un Québec innovant et en santé, 120 M$ — Économie, Innovation et Exportations Québec; Santé et Services sociaux Québec; GenomeQuébec

Regroupement en soins de santé personnalisés au Québec (RSSPQ)

OPTI-THERA – Clinical Resources



ADVANCE & ADVANCE-ON
3,500 T2D Caucasian subjects

CARTaGENE
20,000 Quebec population

CKDGen
Over 150,000 CKD subjects

BHLI 3500 Chinese ADVANCE

CPTP cohort
~ 300,000 Pan-Canadian population

Post-Monica
7,000 Czech population
Prospective study

The OPTI-THERA Project

A unique public-private partnership

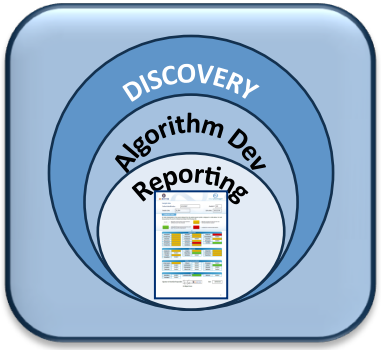
Academic R&D

Projects:
- PGx prevention study (CARTaGENE)
- Renal complications study (ADVANCE)
- Prospective Trial (Clinpradia)
- Companion diagnostic, Servier (GVK)

Clinical Populations

- ADVANCE, CKDgene
- CARTaGENE
- Clinpradia
- Servier (GVK)
- post MONICA, CPTP

Knowledge Base



Translational Medicine

Industrial Partners

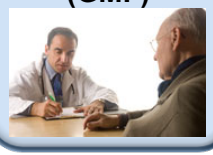
OPTI-THERA Inc.
Partner Tests
Clinical Services

CHUM

Quebec Health Networks

Santé et Services sociaux Québec

Primary Care (GMF)



OPTI-THERA – PGx prevention project

- **CARTaGENE**
  - (20,000 subject, Quebec-based population cohort, well phenotyped & consented)
- **9.8% consume >5 medications /day (~2,000 subjects)**
- **Samples for DNA and RNA available**
- **Longitudinal medical and hospitalization data accessible (RAMQ)**
- **A sub-cohort of subjects taking >5 drugs is being identified**

***Study Objective*:**

Identify pharmacogenomic factors and drug/drug interactions in CARTaGENE population. Analyze to see if ADRs and increased hospitalizations could have been predicted and prevented to decrease healthcare use and costs.

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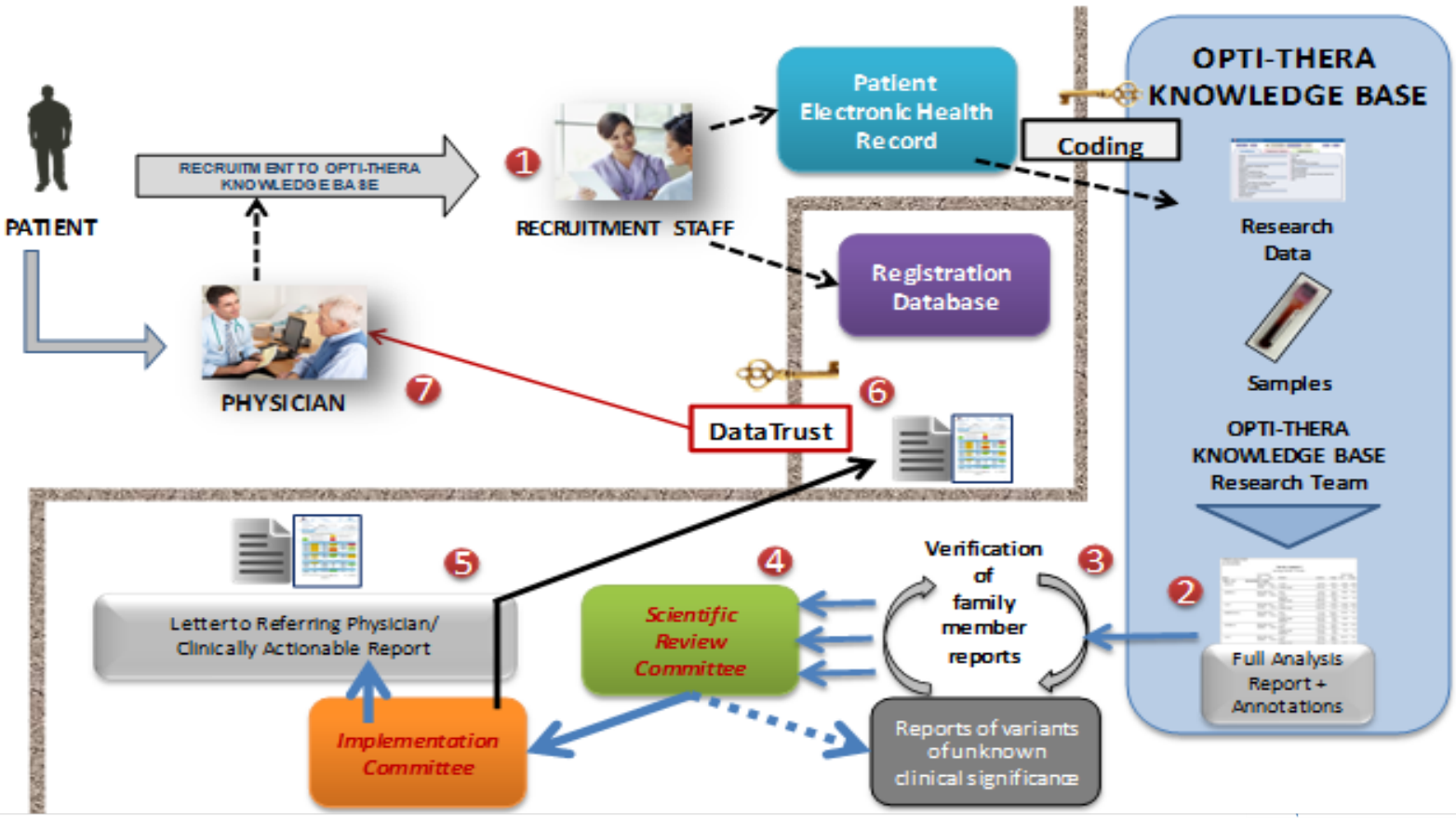
OPTI-THERA Knowledge Base and DataTrust Pathway



ADVANCE — ACTION IN DIABETES AND VASCULAR DISEASE: PRETERAX AND DIAMICRON MR CONTROLLED EVALUATION

Effects of a fixed combination of perindopril and indapamide on macrovascular and microvascular outcomes in patients with type 2 diabetes mellitus (the ADVANCE trial): a randomised controlled trial

The NEW ENGLAND JOURNAL of MEDICINE

2008 **Intensive blood glucose control and vascular outcomes in patients with type 2 diabetes**

American Diabetes Association. Diabetes Care

2009 **Combined effects of routine blood pressure lowering and intensive glucose control on macrovascular and microvascular outcomes in patients with type 2 diabetes: New results from the ADVANCE trial**

The NEW ENGLAND JOURNAL of MEDICINE

2014 **Follow-up of Blood-Pressure Lowering and Glucose Control in Type 2 Diabetes**

ADVANCE Genetic Sub-study

- The largest outcome trial in T2D to date.
- 11,140 patients in 20 countries.
- High acceptance for informed consent for the genetic studies worldwide.

- 3,500 T2D subjects genotyped using
- Close to 10M SNPs analyzed by imputation

28 Publications to Date

OPTI-THERA
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Standard Therapy for Diabetic Nephropathy

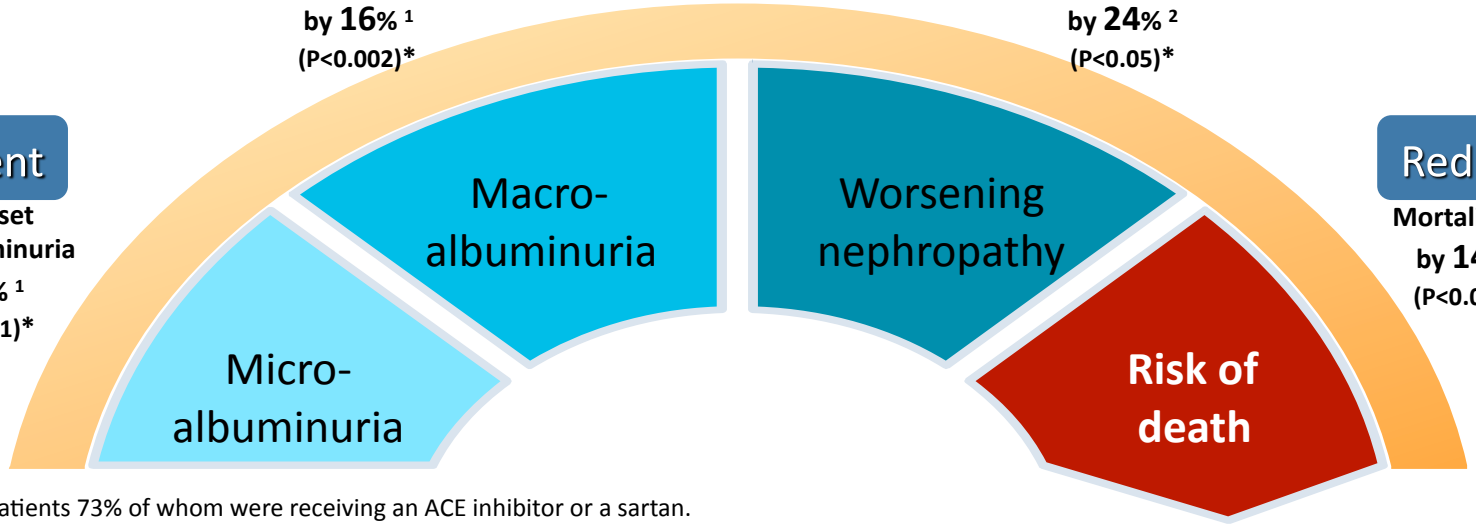
Perindopril/indapamide/gliclazide control in diabetes

Regress
≥ 1 albuminuria stage
by 16% [1]
(P<0.002)*

Retard
Worsening nephropathy**
by 24% [2]
(P<0.05)*

Prevent
New-onset microalbuminuria
by 21% [1]
(P<0.0001)*

Reduce
Mortality***
by 14% [3]
(P<0.025)*



* Versus patients 73% of whom were receiving an ACE inhibitor or a sartan.

** Development of macroalbuminuria, doubling of serum creatinine to a level of at least 2.26 mg/dL (200 µmol/L), need for renal replacement therapy, or death due to renal disease.

*** All-cause mortality.

1. de Galan BE et al. J Am Soc Nephrol. 2009;20:883-892.
2. Lambers Heerspink HJ, et al. ADVANCE Collaborative Group. Eur Heart J. 2010;31:2888-2896.
3. Patel A et al; ADVANCE Collaborative Group. Lancet. 2007;370:829-840.

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Predict to prevent

OPTI-THERA : Clinpradia Prospective Study

Prevention of diabetic nephropathy in primary care

- **Use ADVANCE trial as a discovery cohort**
- **Use CKD Gene cohort (meta-analysis) as a main validation data**

- **Perform prospective validation in Clinpradia study**
  - **Examine patients on current therapies applied in asymptomatic phase of T2D with genetic susceptibility to assess clinical utility**

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Genome-wide association study of kidney function decline in individuals of European descent

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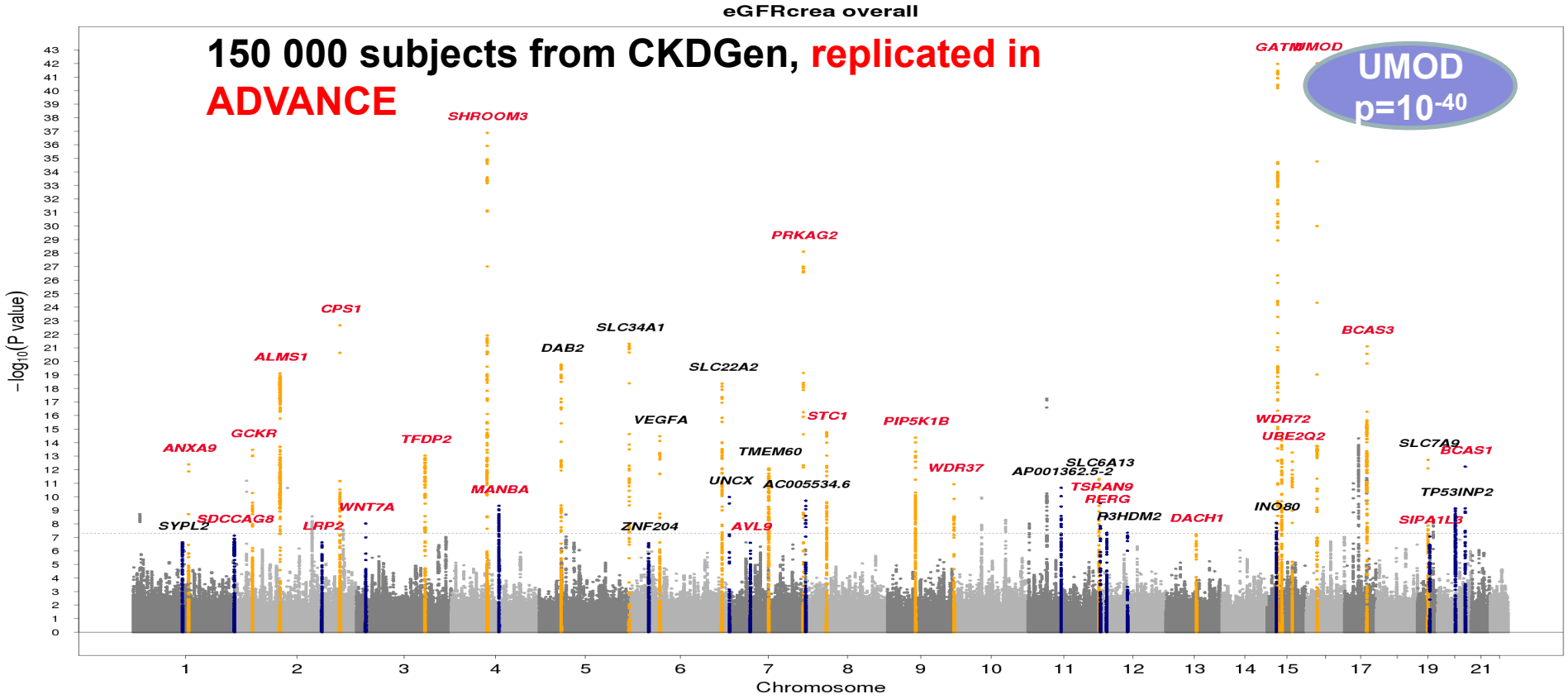
Kidney International (2015) **87**, 1017–1029

Genome-wide association study of kidney function decline in individuals of European descent

Kidney International (2015) **87**, 1017–1029



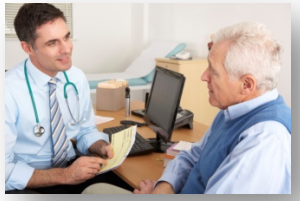
Diabetes Complications - Current Standard of Care

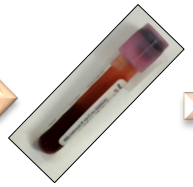
PATIENT

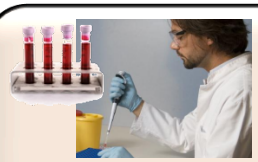
FIRST VISIT

CURRENT CARE

PHYSICIAN







CLINICAL BIOMARKER PROFILE

Years After Diagnosis

5y Microalbuminuria

ACE-I

10y Macroalbuminuria

15y Renal Failure

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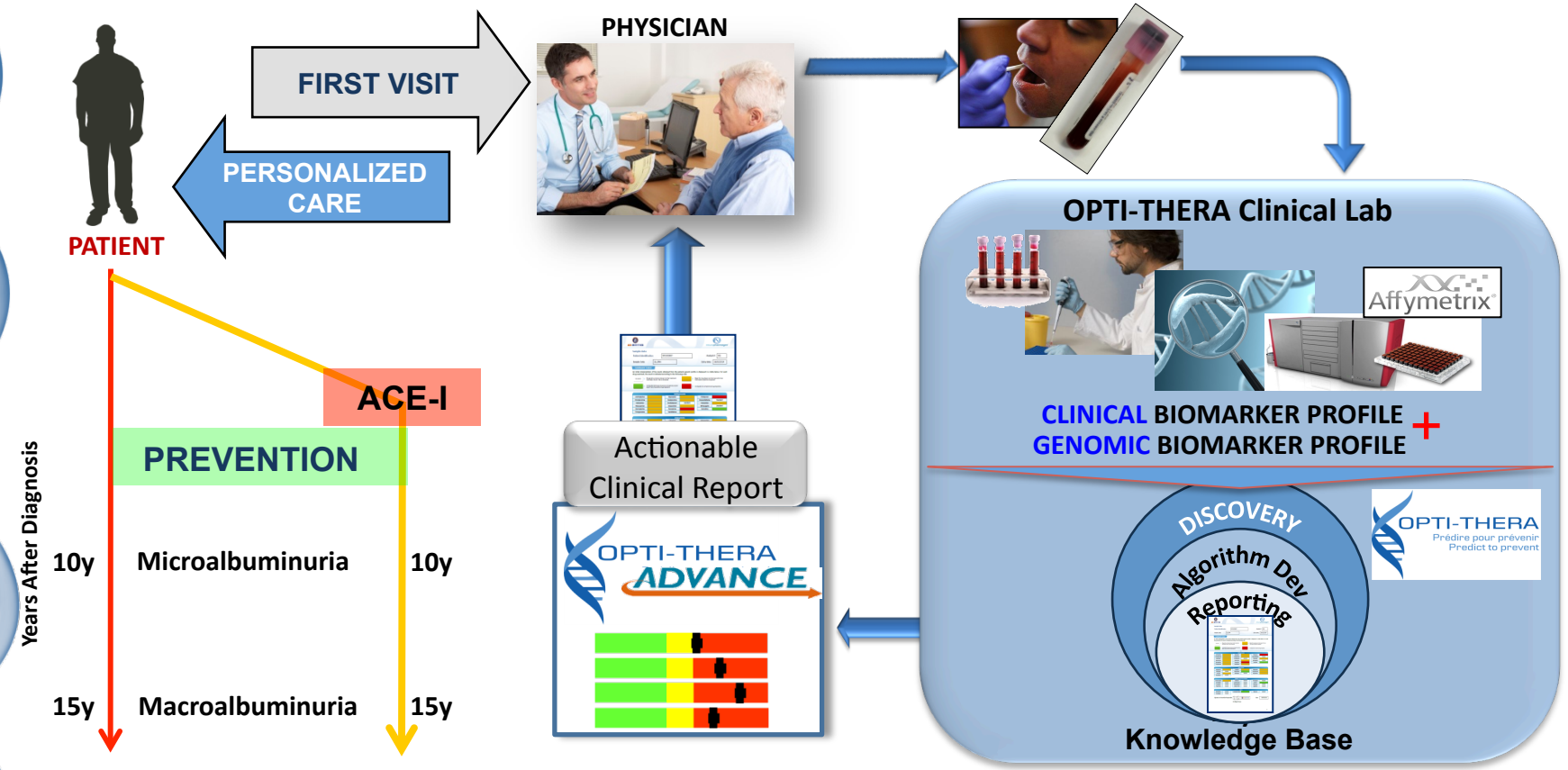
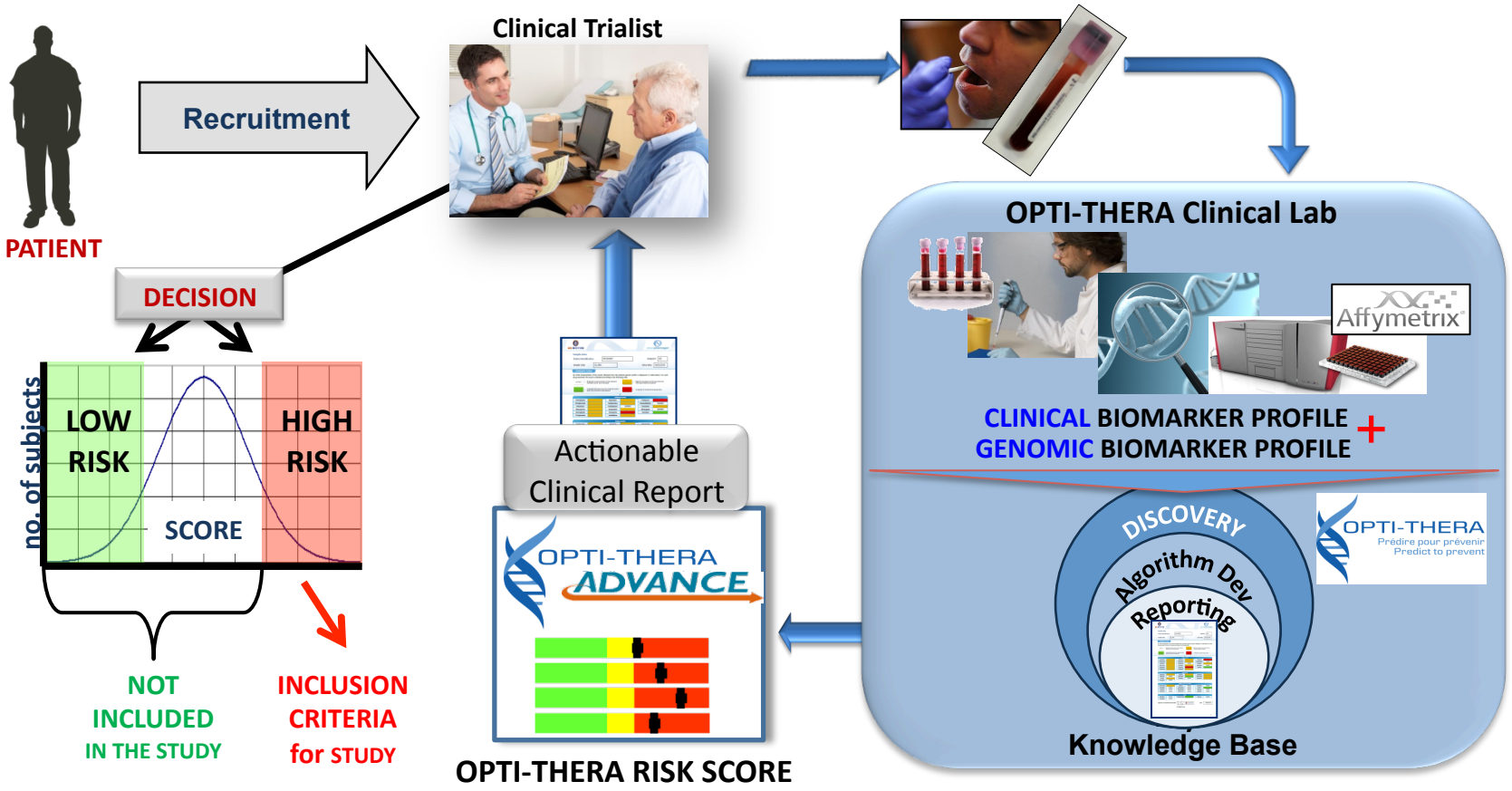
OPTI-THERA: Personalized Medicine Strategy
Diabetes Complications



OPTI-THERA: Companion Diagnostic Strategy

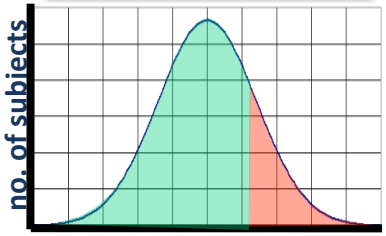
Patient Stratification



OPTI-THERA: Companion Diagnostic Strategy

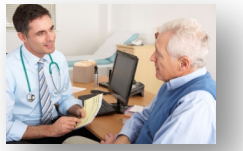
Addressing Unmet Medical Needs

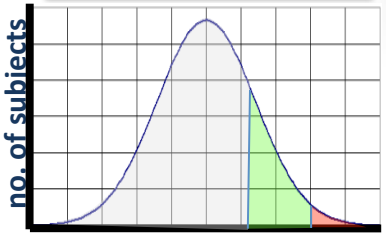
Standard Therapies
"One size fits all"



70% Treated | 30% Untreated

New Personalized Therapies





70% Conventional Treatment | 20% New | 10% Untreated

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Biomarker R&D
Patient Stratification

SERVIER

Partner Drug Development

UNMET
Clinical Need

NCE
New Therapy

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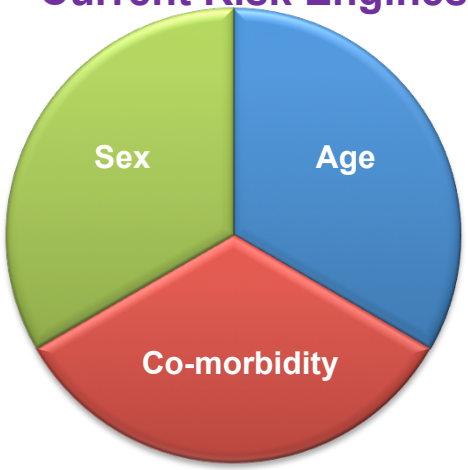
Companion
Diagnostic

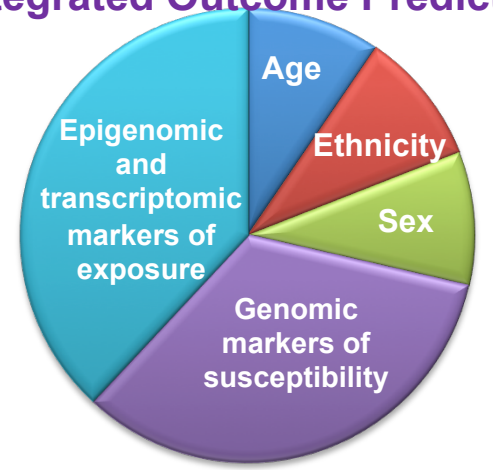
From Outcome Markers to Predictive Markers

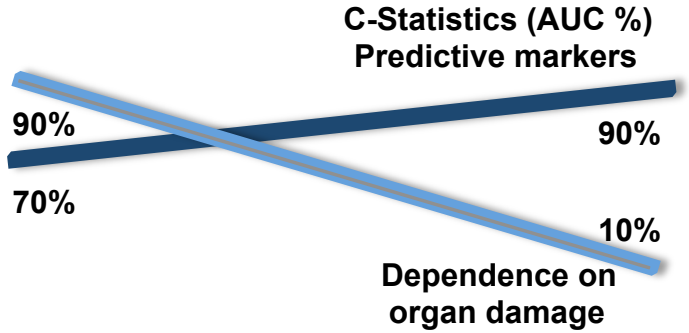
Current Risk Engines



Progressive (Stepwise) Replacement of Content

Integrated Outcome Predictors





SNPs, CNVs, epigenomic and transcriptomic markers of susceptibility, telomeres, ethnicity markers

BP, microalbuminuria, HbA1c, atrial fibrillation, LDL, retinopathy, MI, stroke

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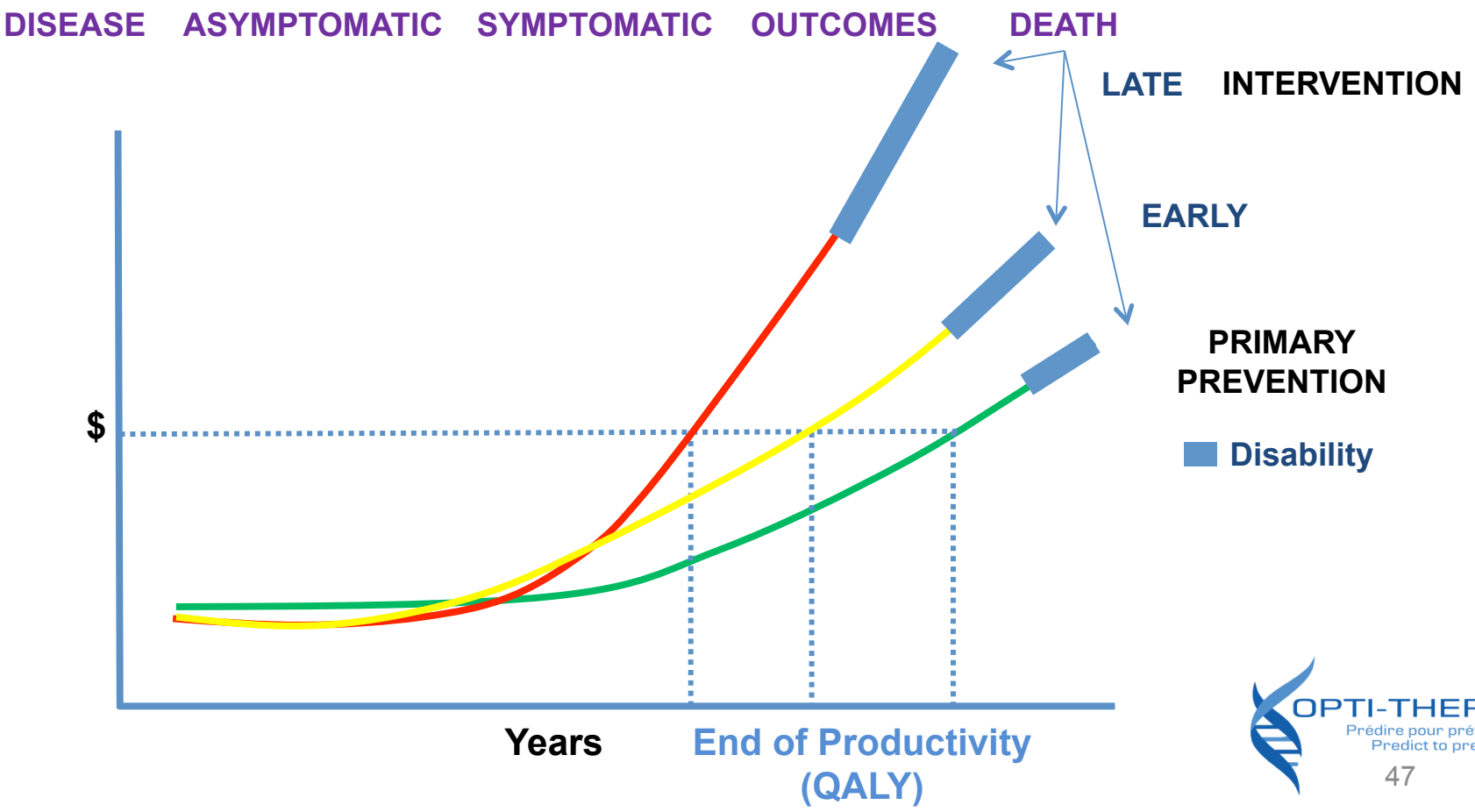
SOCIOECONOMIC IMPACT
AS A FUNCTION OF INTERVENTION TIMING



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Barrières dans l'application clinique de la génomique

- **Manque d'essais cliniques prospectifs**
- **Résistance au changement**
  - **usagés**
  - **administrateurs de la santé**
  - **médecins**
  - **industrie**
- **Problèmes éthiques non résolus**

- ***Un long cheminement de la médecine de l'art vers la science***

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LES SOINS DE SANTÉ « PERSONNALISÉS »:

PRUDENCE ET BALISES

LES RECOMMANDATIONS DE LA COMMISSION

Commission de l'éthique en science et en technologie
29 janvier 2015

Les recommandations

Considérant que des données probantes doivent appuyer l'implantation des SSP et que les tests génétiques qui se retrouvent sur le marché doivent avoir démontré leur validité scientifique et leur utilité clinique,

la Commission recommande :

Recommandation nº 1

Aux organismes qui financent et réglementent la recherche, aux chercheurs et à l'Institut national d'excellence en santé et services sociaux (INESSS) de réaffirmer le principe de l'utilité clinique et de la validité dans la décision clinique pour démontrer l'effet bénéfique de cette information sur la qualité de vie et la longévité des patients.

Les recommandations

Considérant les risques d'une mauvaise interprétation des tests génétiques et leurs effets sur la santé physique et psychologique des citoyens,

la Commission recommande :

Recommandation nº 3

Que le ministre de la Santé et des Services sociaux, en concertation avec les ordres professionnels concernés, informe la population des limites et de la fiabilité des tests génétiques et des dangers liés à une mauvaise utilisation et à une mauvaise interprétation de ceux-ci;

Que les ordres professionnels s'assurent que leurs membres sont conscients de ces limites et des risques potentiels des tests génétiques pour la santé;

Que l'Office de la protection du consommateur se penche sur la publicité relative aux tests vendus au Québec directement aux consommateurs pour s'assurer que les citoyens sont bien protégés.

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- T2D patients from 20 countries and 124 centres
- CKDgene : Caroline Fox ,Linda Kao, Carsten Bogen & our 99 co-investigators

Économie, Innovation et Exportations Québec

Fonds de partenariat pour un Québec innovant et en santé

National Research Council Canada / Conseil national de recherches Canada

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Canada Research Chairs

Canada Foundation for Innovation / Fondation canadienne pour l'innovation

medpharmgene Individual care within reach

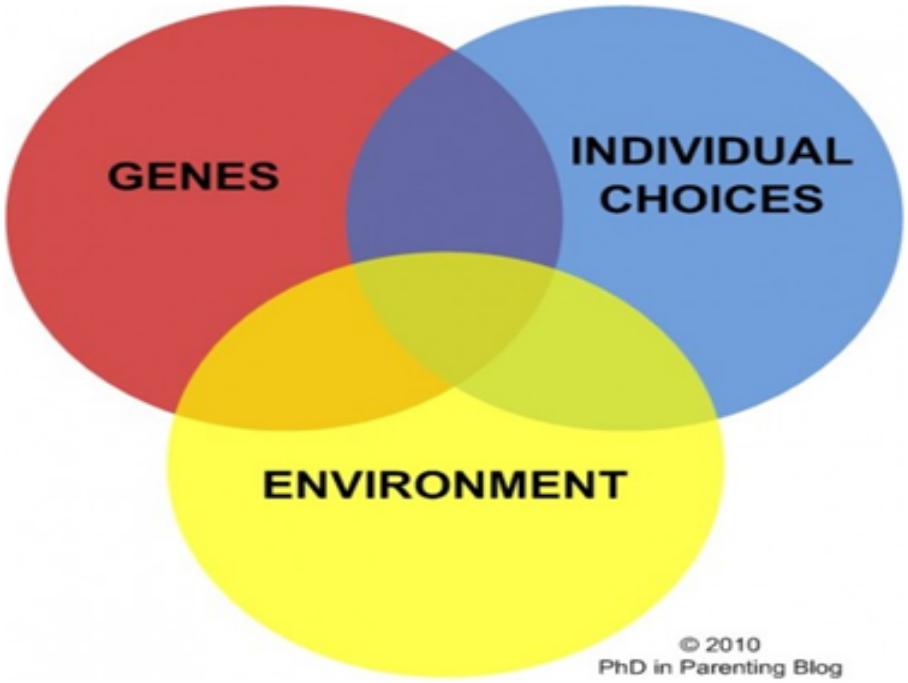
GenomeQuébec

IRSC CIHR

CRCHUM CENTRE DE RECHERCHE

CKD Gen CONSORTIUM

Médecine personnalisée



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