



Personalised Medicine: a disruptive driver of change for societal benefit

Northern Ireland Centre for Stratified Medicine

Incorporating

Centre for Personalised Medicine, Clinical Decision Making & Patient Safety

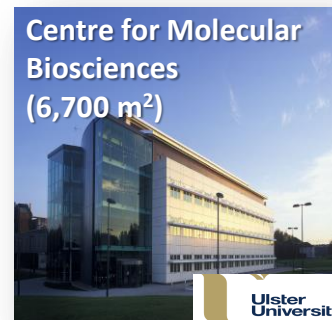
Professor Tony Bjourson (Director)

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W: <http://biomed.science.ulster.ac.uk/stratifiedmed/>
Social: <https://twitter.com/StratMedicineNI> 20



Altnagelvin
Hospital

Londonderry/Derry



Letterkenny University Hospital

Rannóg Eigeandála
Emergency Department



lyit | Institiúid Teicneolaíochta Leictir Ceannainn
Letterkenny Institute of Technology



ECME-Eastern Corridor
Medical Engineering Cent



Many Global Research
Collaborators
in EU/USA/ASIA

Definition of Personalised Medicine

Personalisation of medicine is a **continuous, fundamental process** that aims to **improve the effectiveness and efficiency of clinical practice** by better understanding **how the unique biological characteristics of individuals and their social/environmental contexts contribute to their health and disease.**

EU: ICPerMed Vision for 2030

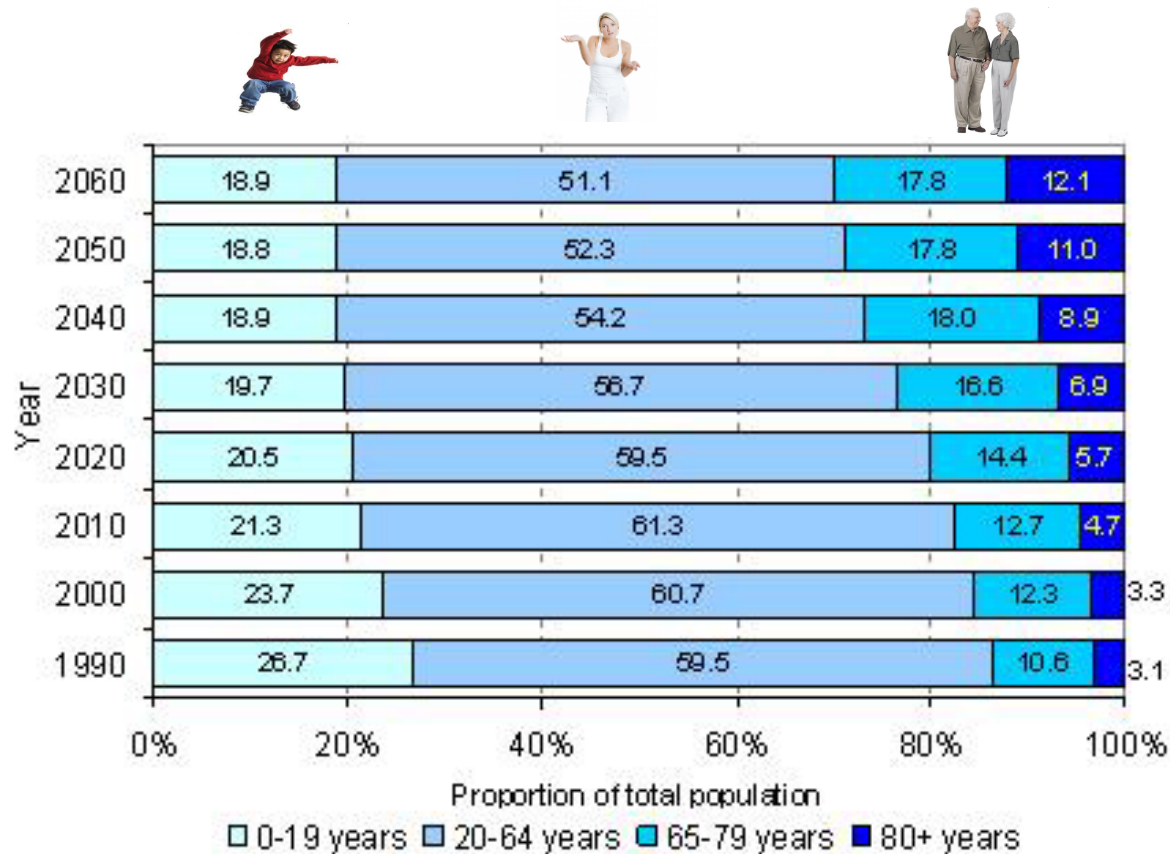
(Published September 2019)

Perspectives for Personalised Medicine in 2030

- **Perspective 1:** Informed, empowered, engaged, and responsible citizens
- **Perspective 2:** Informed, empowered, engaged, and responsible health providers
- **Perspective 3:** Healthcare systems that enable personally tailored and optimised health promotion, prevention, diagnosis, and treatment for the benefit of citizens and patients
- **Perspective 4:** Availability and optimal use of health-related information for optimised treatment, care, prevention, and research
- **Perspective 5:** Economic value by establishing the next generation of medicine

Major Challenge - an Aging Population:

Division of EU population according to age group



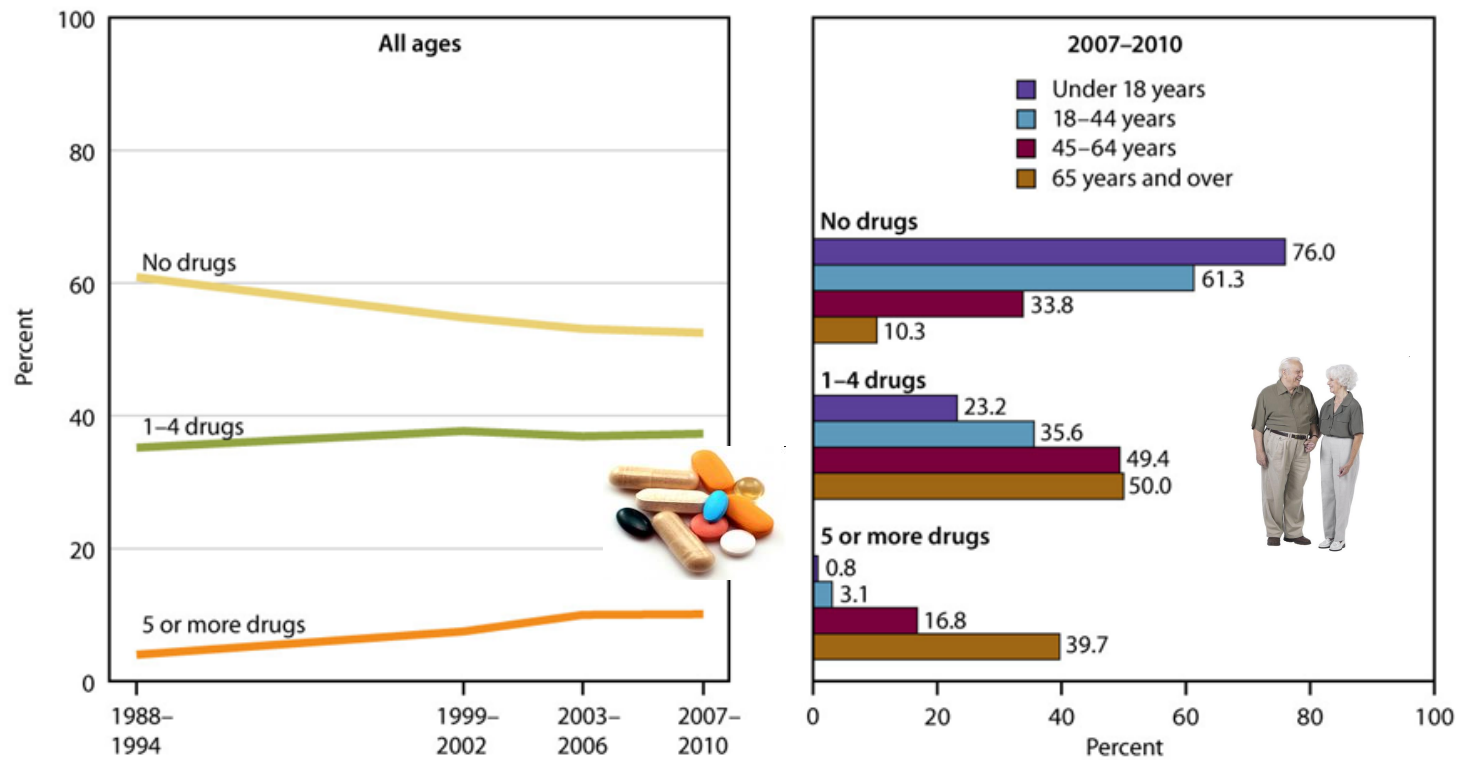
Source: Third Demography Report: population is becoming older and more diverse. European Commission - MEMO/11/209 01/04/2011

Aging Population

Everyone wants to go to heaven - Nobody wants to die

- **Elderly** – largest users of prescription drugs. - **30% of population** could be projected to be on 5-10 medicines.
- **Prescribing cascade** in the elderly (polypharmacy)

Prescription drug use

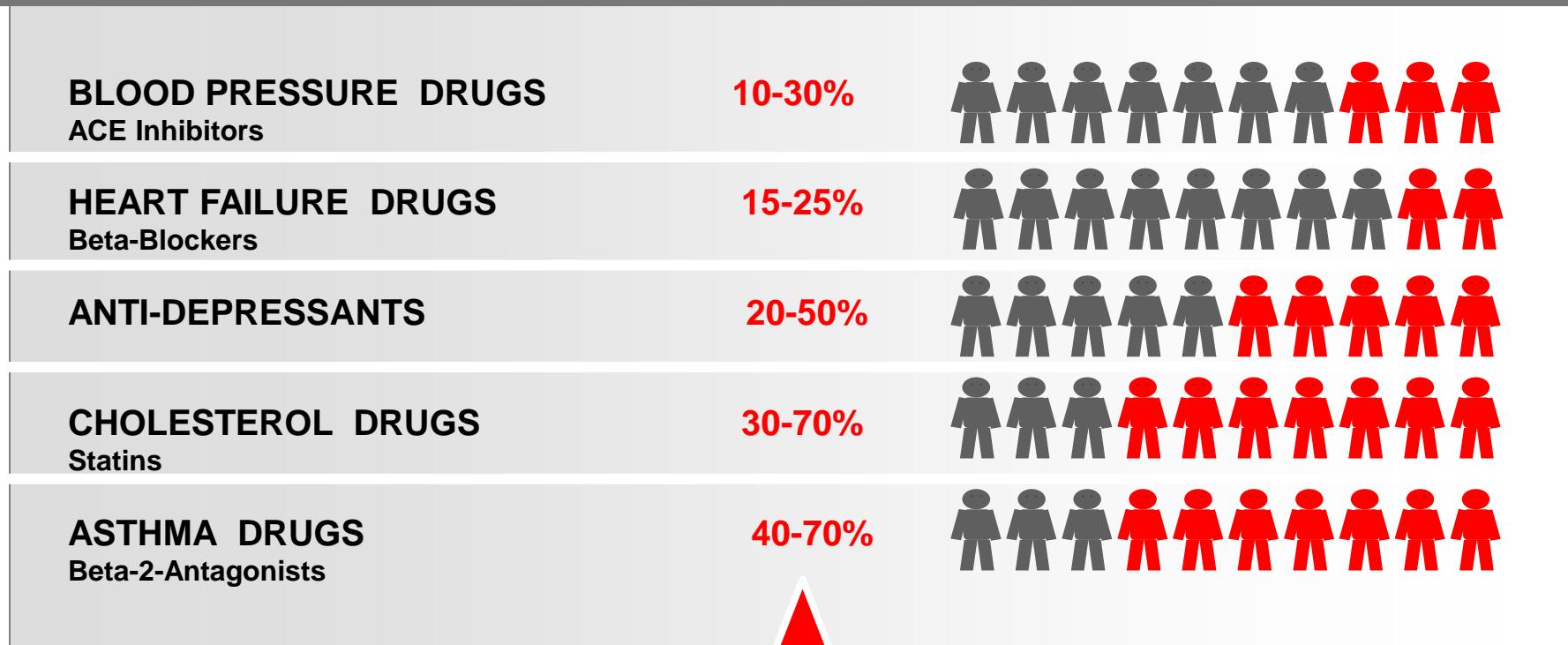


Polypharmacy- Definition

- Polypharmacy refers to the concurrent use of multiple medication items by one individual.
- The term has been used both positively and negatively
- In many circumstances polypharmacy can be therapeutically beneficial.
- Polypharmacy is common in primary and secondary care, and in care homes for older people.
- Will continue to **increase due to an ageing (and increasingly frail) population and by the increasing prevalence of multi-morbidity** (where patients may be living with several long-term conditions, often compounded by disability and/or frailty)

One drug does not fits all

Patients respond differently to the same medicine

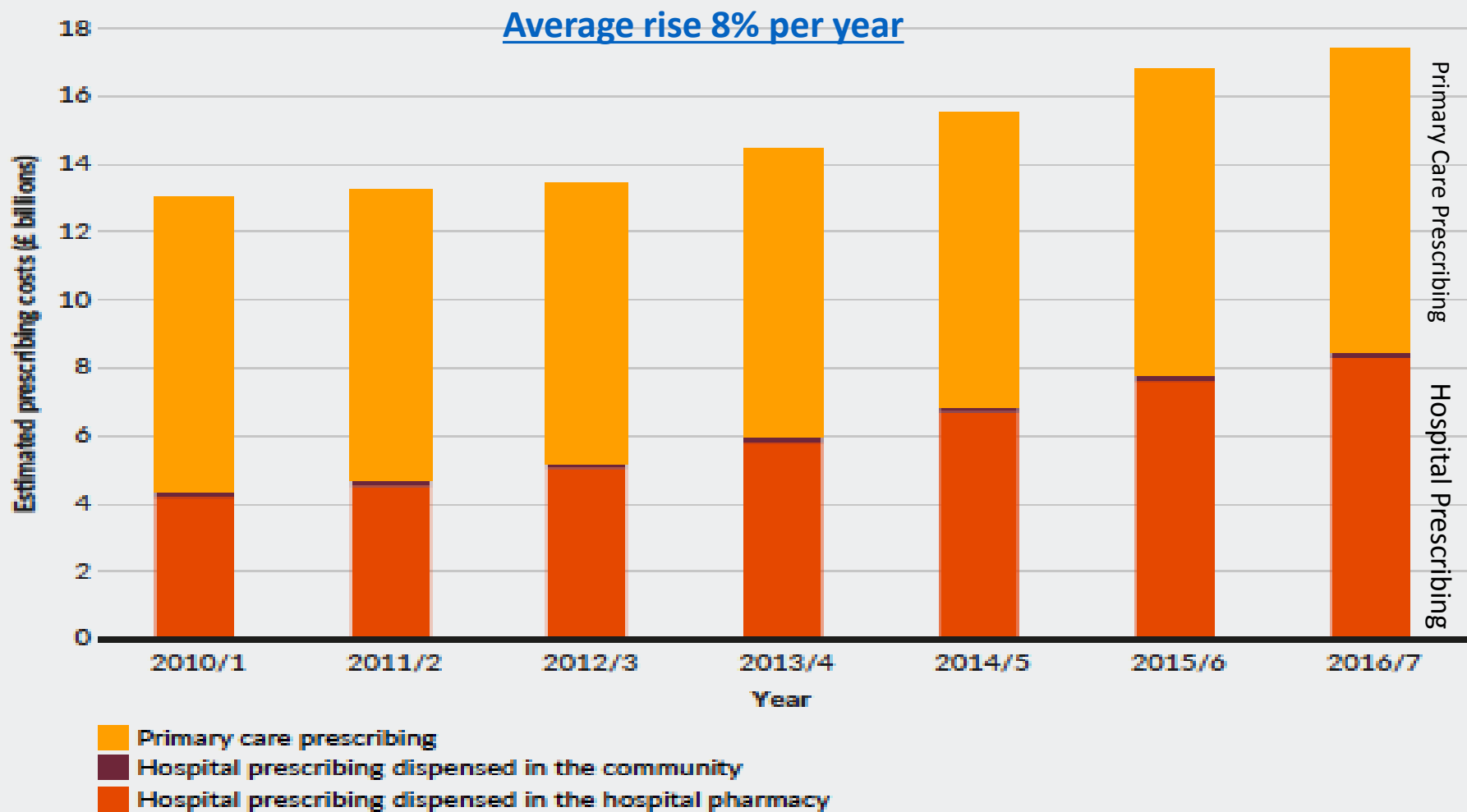


% of the population for which drug is ineffective

Hospital and Primary Care Prescribing Costs £17Bn per Year

(2010/11 to 2016/17- England)

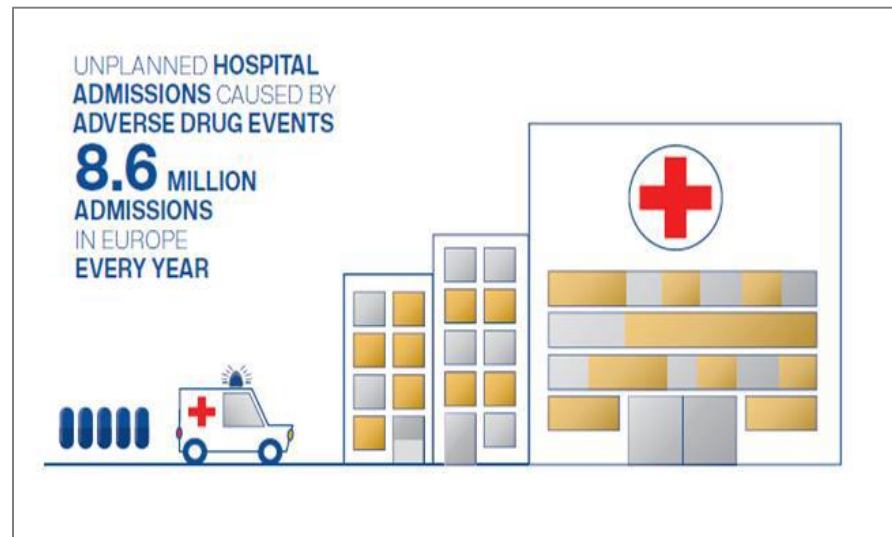
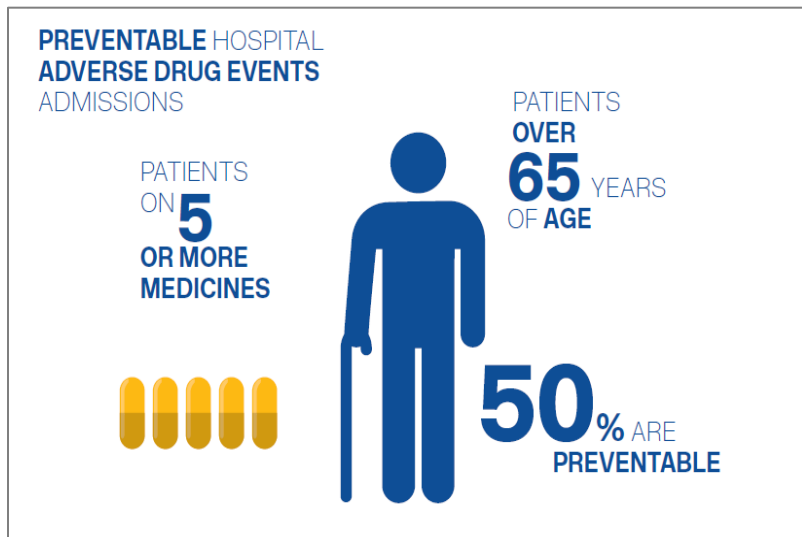
Estimated prescribing costs (£ billions) by care setting, 2010/11 to 2016/17



Medicines Value Programme

(NHS England) Cost of Medicines & Waste

- Between 5 and 10% of all hospital admissions are medicines-related
- Two thirds of medicines-related hospital admissions are preventable
- The overall NHS drugs bill (England) is £17 billion a year
- The NHS drugs bill is rising by 8% a year
- *more than the current annual increase in funding*
- 2010 report estimated national pharmaceutical waste at £300 million



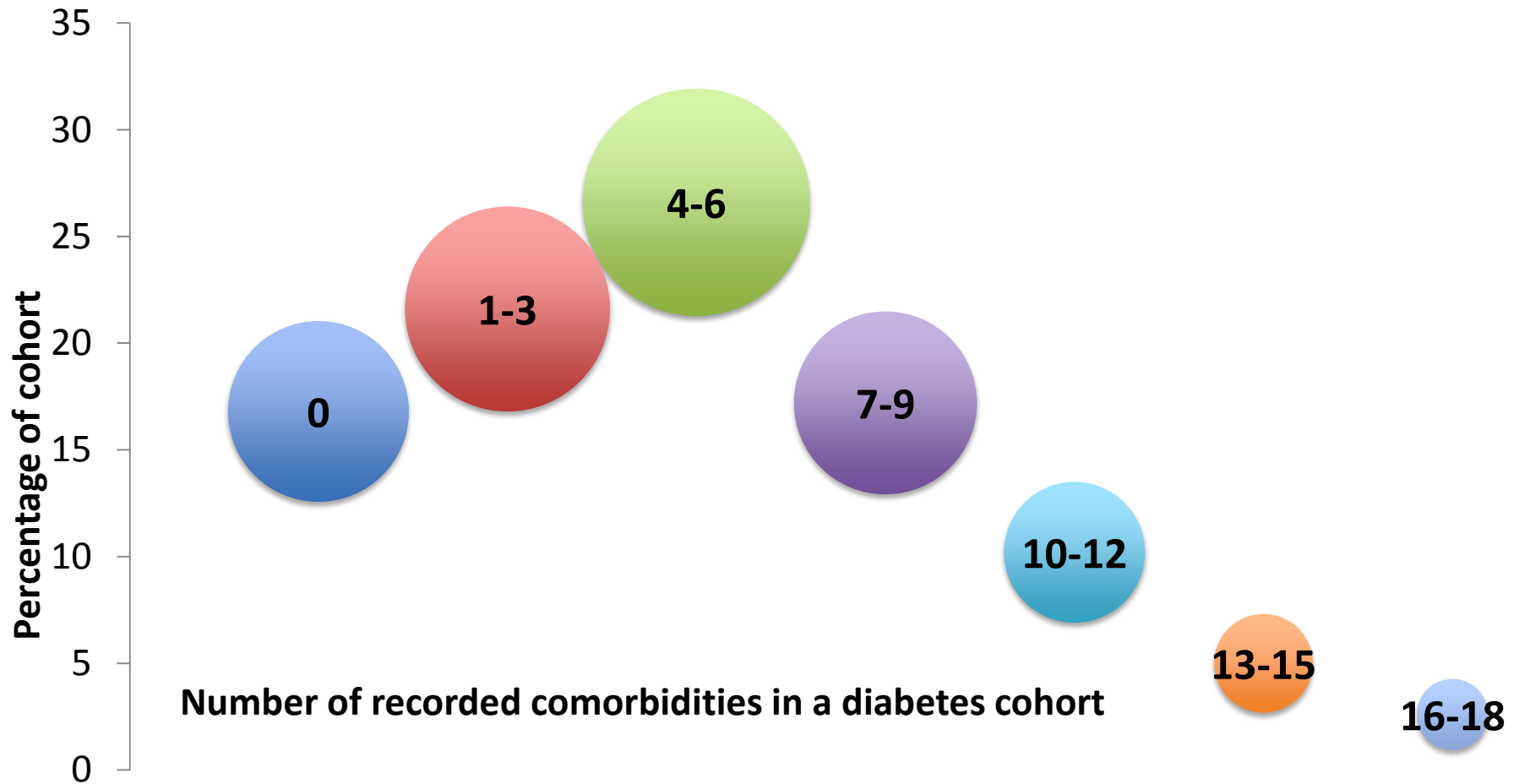
Sources:

NHS England. <https://www.england.nhs.uk/medicines/value-programme/>

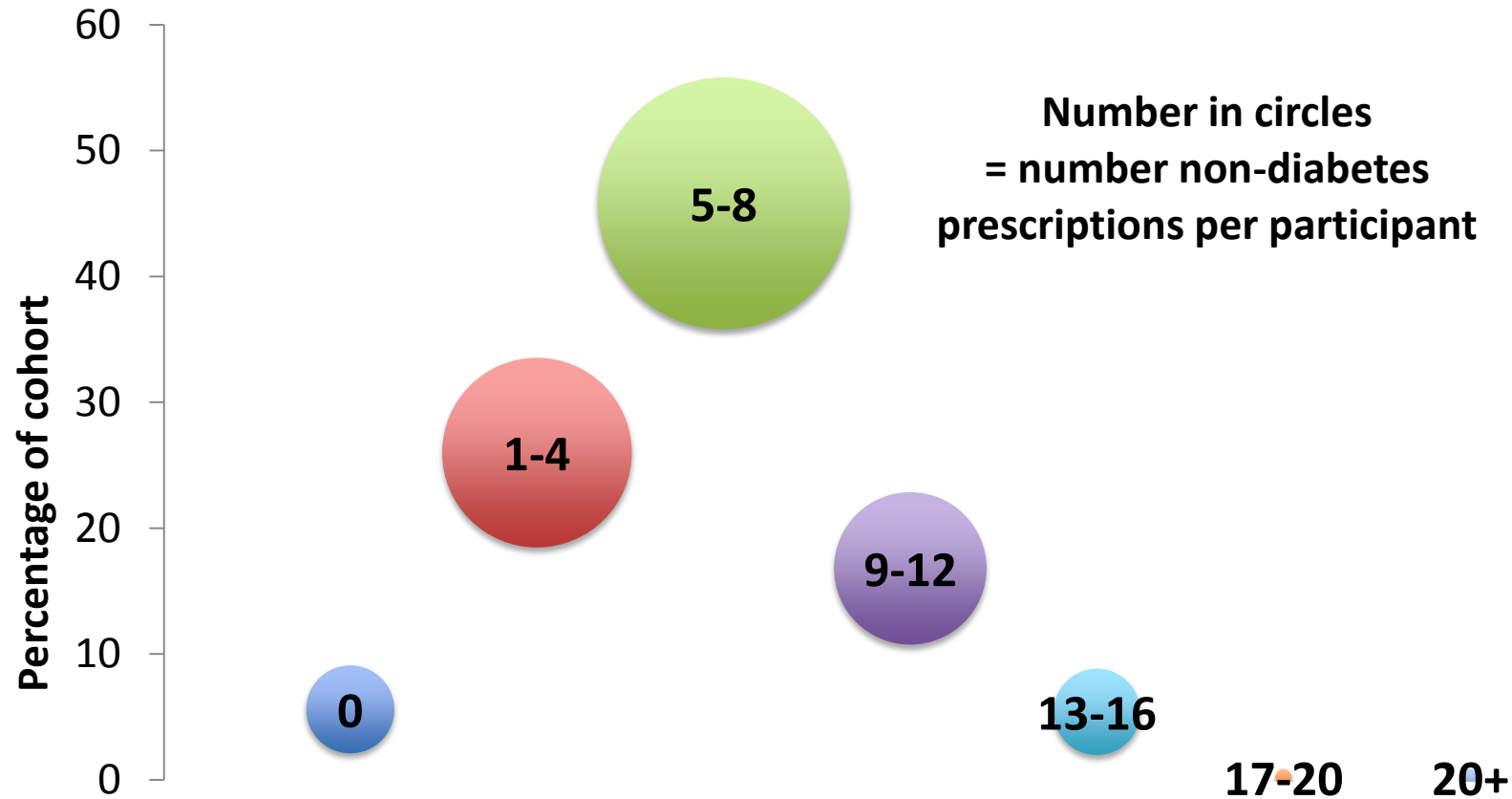
The rising cost of medicines to the NHS – what's the story? <https://www.kingsfund.org.uk/sites/default/files/2018-04/Rising-cost-of-medicines.pdf>

Scottish Government Polypharmacy Model of Care Group. *Polypharmacy Guidance, Realistic Prescribing* 3 Edition, 2018. Scottish Government <https://www.therapeutics.scot.nhs.uk/wp-content/uploads/2018/04/Polypharmacy-Guidance-2018.pdf>

83% of our Diabetic Patients (N=500) have multi-morbidity



Prescribed Non-Diabetes Drugs in our Diabetic Patients (N=500)



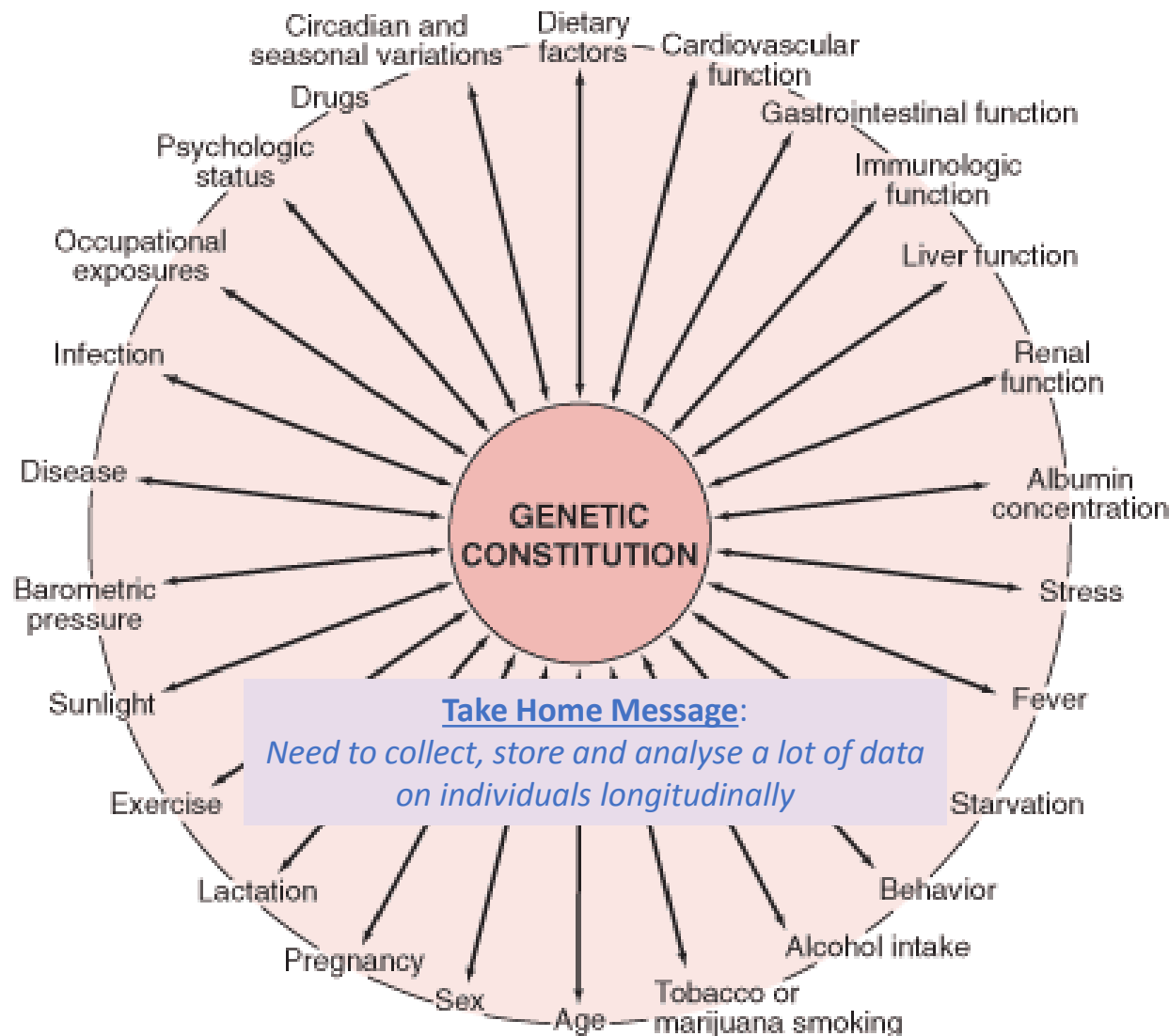
Key Challenges

- Clinical trials – many trials **exclude those with multi-morbidity**
- Elderly - highest consumers of prescription medications- often excluded
- Criteria – does not reflect majority of real life patients.
- Need to **better sub-classify complex diseases** in context of multi-morbidity.
- **Individualised drug therapies for patients with multimorbidity.**
- **Better diagnosis of subclasses & treatment selection for multimorbidity**
- clinical / end-user **education & patient compliance**



Right Treatment - Right Person - Right Time

Why Do People Respond Differently to Treatment?



People Respond Differently to a Drug Treatment

Why?

Response to a drug depends partly on the patient's characteristics and behaviors:

1. **Incorrect diagnosis** – patient does not have the condition diagnosed
2. **Patient compliance** – Lack of adherence to a dosing regimen;
3. **Errors** - misreading a prescription or administering a drug incorrectly
4. **Interference** from foods or supplements;
5. **Drug-Drug Interactions** -Interference from concurrently prescribed medications - polypharmacy
6. **Co-existence of other disorders** (comorbidities or multi-morbidities),
7. **Metabolism Differences** in drug pharmacokinetics/pharmacodynamics due to age, sex, race, genetic polymorphisms, hepatic or renal insufficiency.
8. **Inappropriate drug prescribing**

Per Med Technologies with significant impact potential on patient outcomes or health system implementation

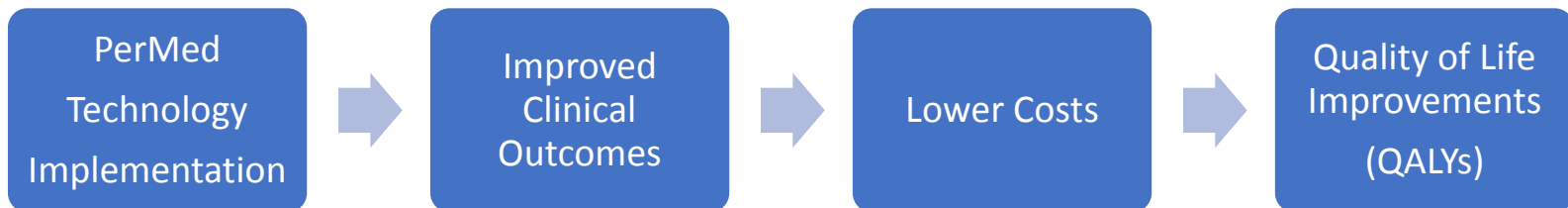
4 core technology categories needed to improve outcomes:

- 1. Molecular characterisation of individuals or disease**
e.g. genomics, metabolomics, proteomics, microbiomics, epigenomics, transcriptomics etc
 - 2. Personalised therapeutic interventions**
e.g. stem cell therapy, genome editing/therapy, robotics
 - 3. Personalised health or disease monitoring tools**
e.g. personal data capture, consumer apps, digitally enabled wearables/sensors, imaging
- supported by:*
- 4. Critical Underpinning - enabling technologies**
essential to transform performance or capabilities of above technologies
e.g. data analytics, artificial intelligence and machine learning, microfluidics, devices, nanomedicine, 3D Printing,

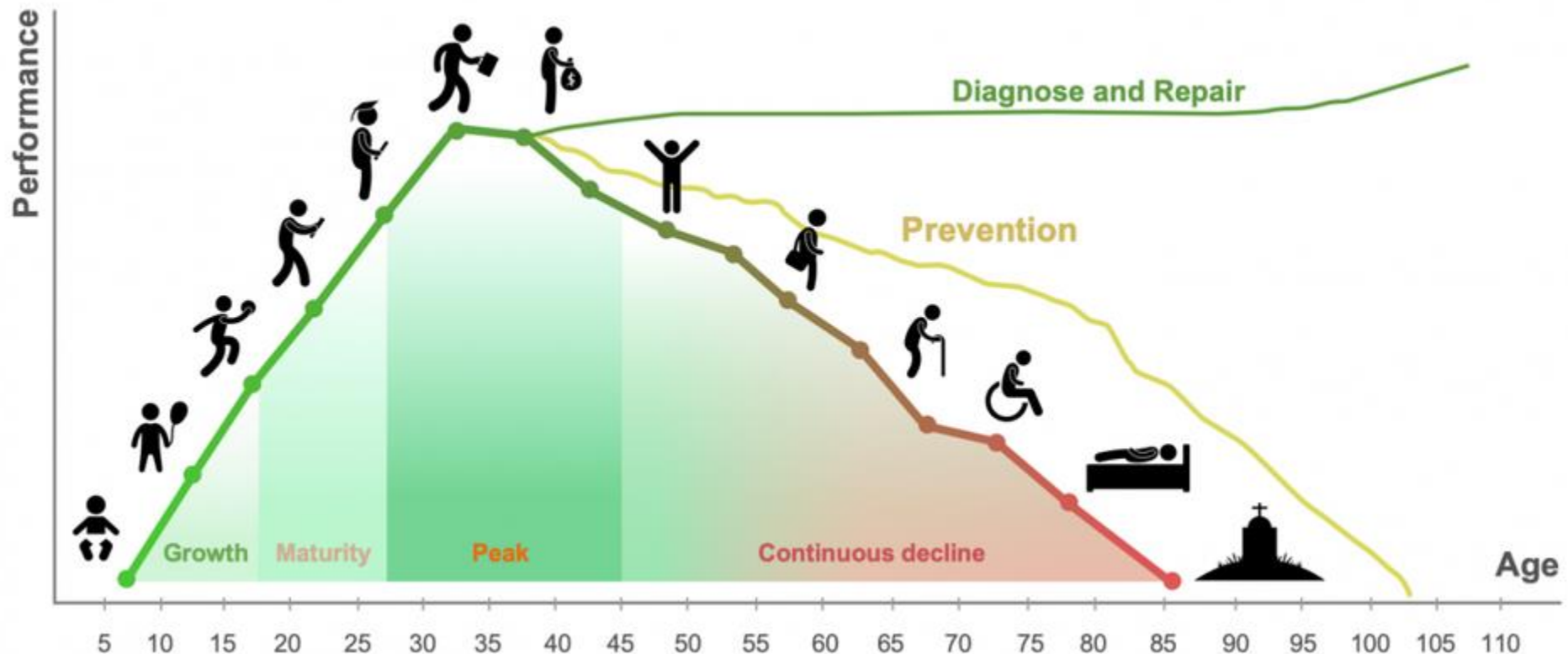
Who or What Benefits? – Challenge

Need for Convincing Evidence of Benefit / Value for:

1. **Healthy Individuals** – actionable disease prevention or delay onset
2. **Patient Value** – better diagnostics & targeted treatment for better quality of life
3. **Health Service & Care Provider** – more cost effective (NHS-NICE)
4. **Industry** - commercial opportunity sales/service value
5. **Economic Value** – *individual, Industry, healthcare provider, Payer?*
6. **Societal Value** – Overall Economic Value & Wellbeing for better quality of life



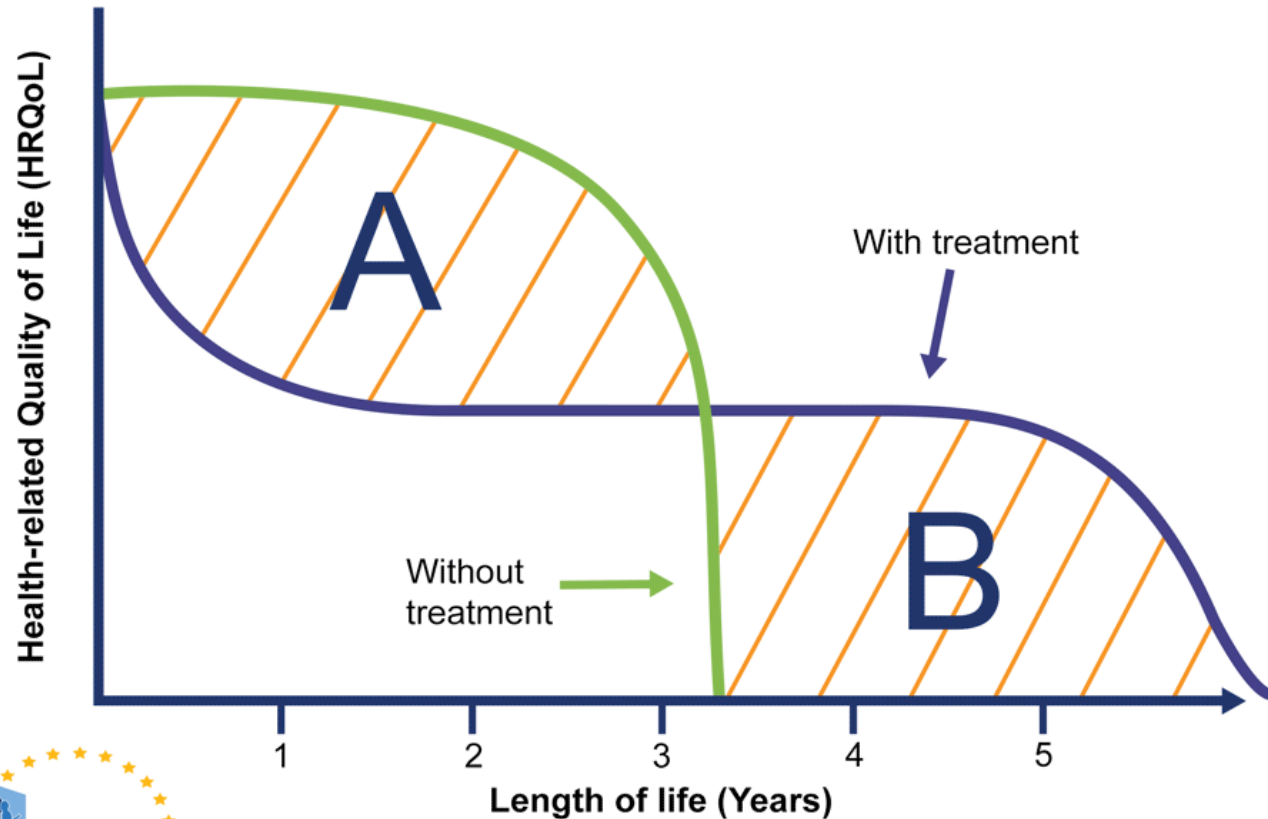
Aging does not discriminate!



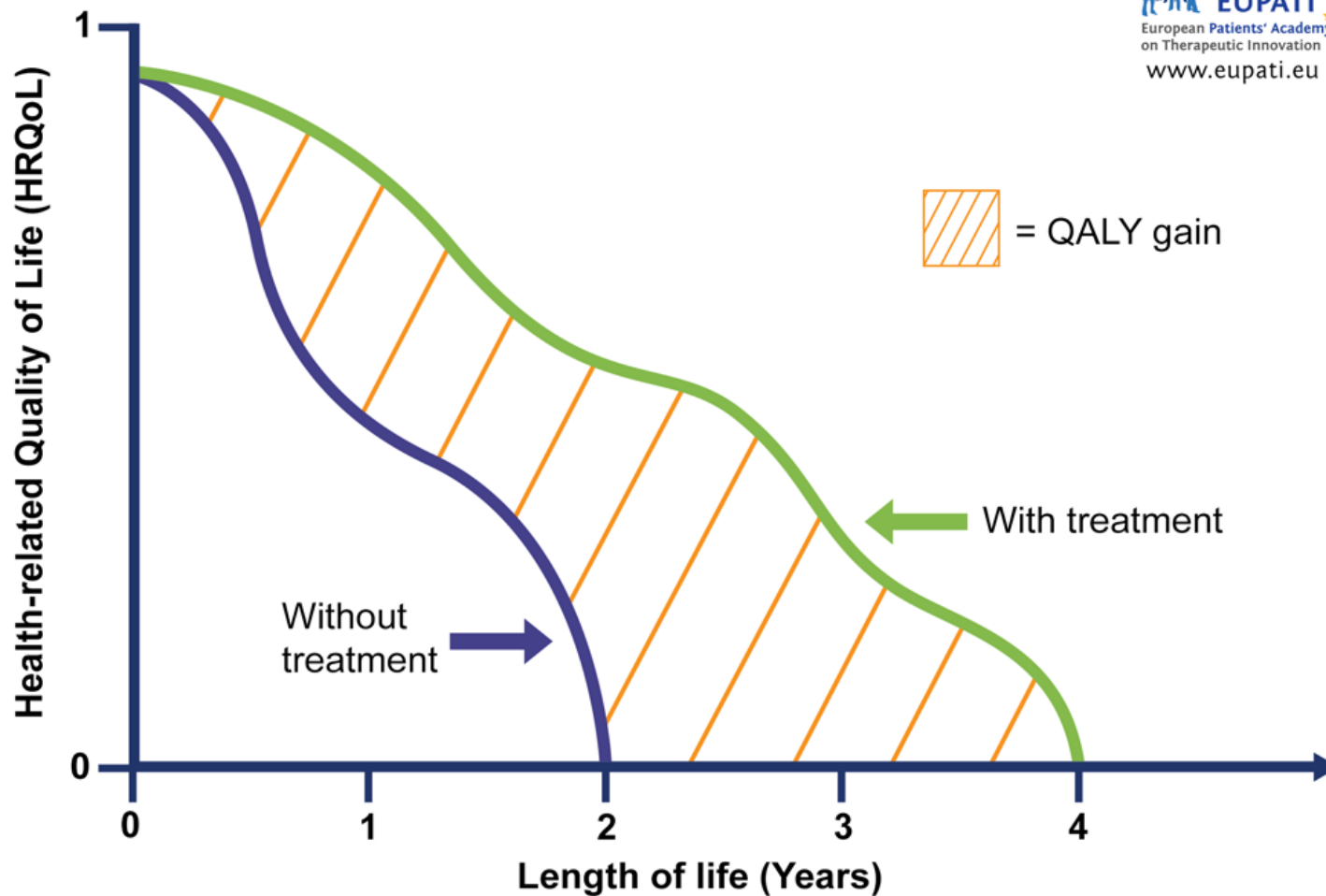
Source: <https://www.forbes.com/sites/cognitiveworld/2019/02/20/how-to-live-this-life-better-effective-altruism-in-the-context-of-longevity/>

Forbes: Alex Zhavoronkov, PhD Contributor **COGNITIVE WORLD**

The Quality-Adjusted Life-Year (QALY)



Quality-Adjusted Life-Year (QALY) gain



Personalised Medicine Infrastructure in N. Ireland



The Health Innovation Research Alliance Northern Ireland (HIRANI) is an alliance of universities, health organisations and other industry bodies, established to drive and support ambitious growth in Northern Ireland's Life & Health Sciences sector.

Global Life & Health Sciences

Turnover

Global:	£1.1 trillion
UK:	£63.5 billion
NI:	£0.8 billion
2023 Global Forecast:	£1.4 trillion

Source: Deloitte, 2018

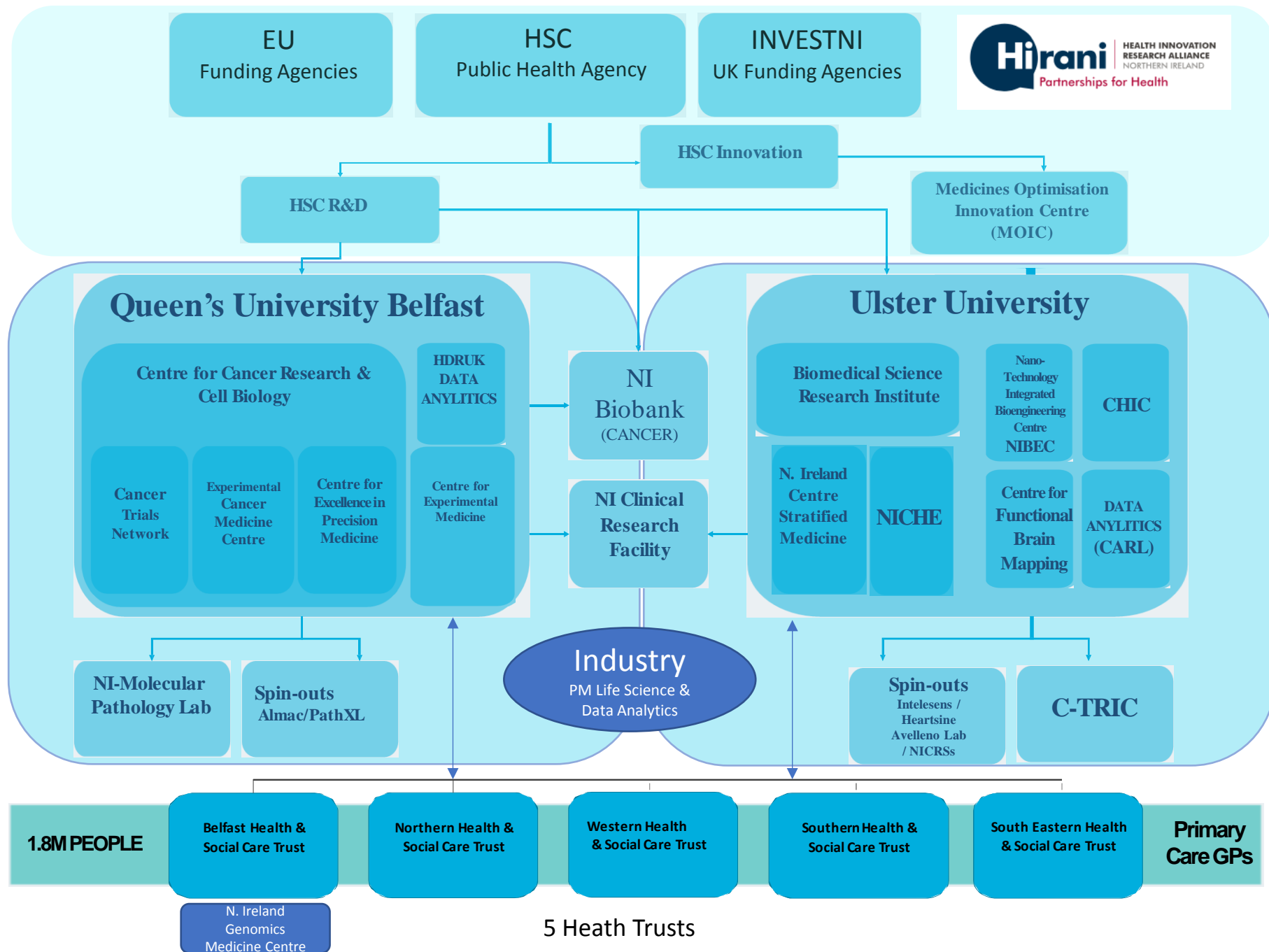
Precision Medicine

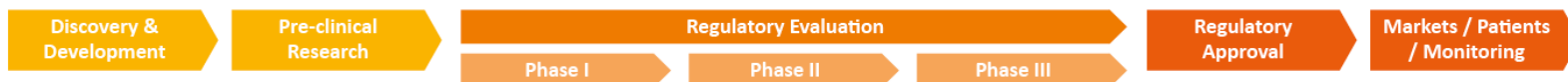
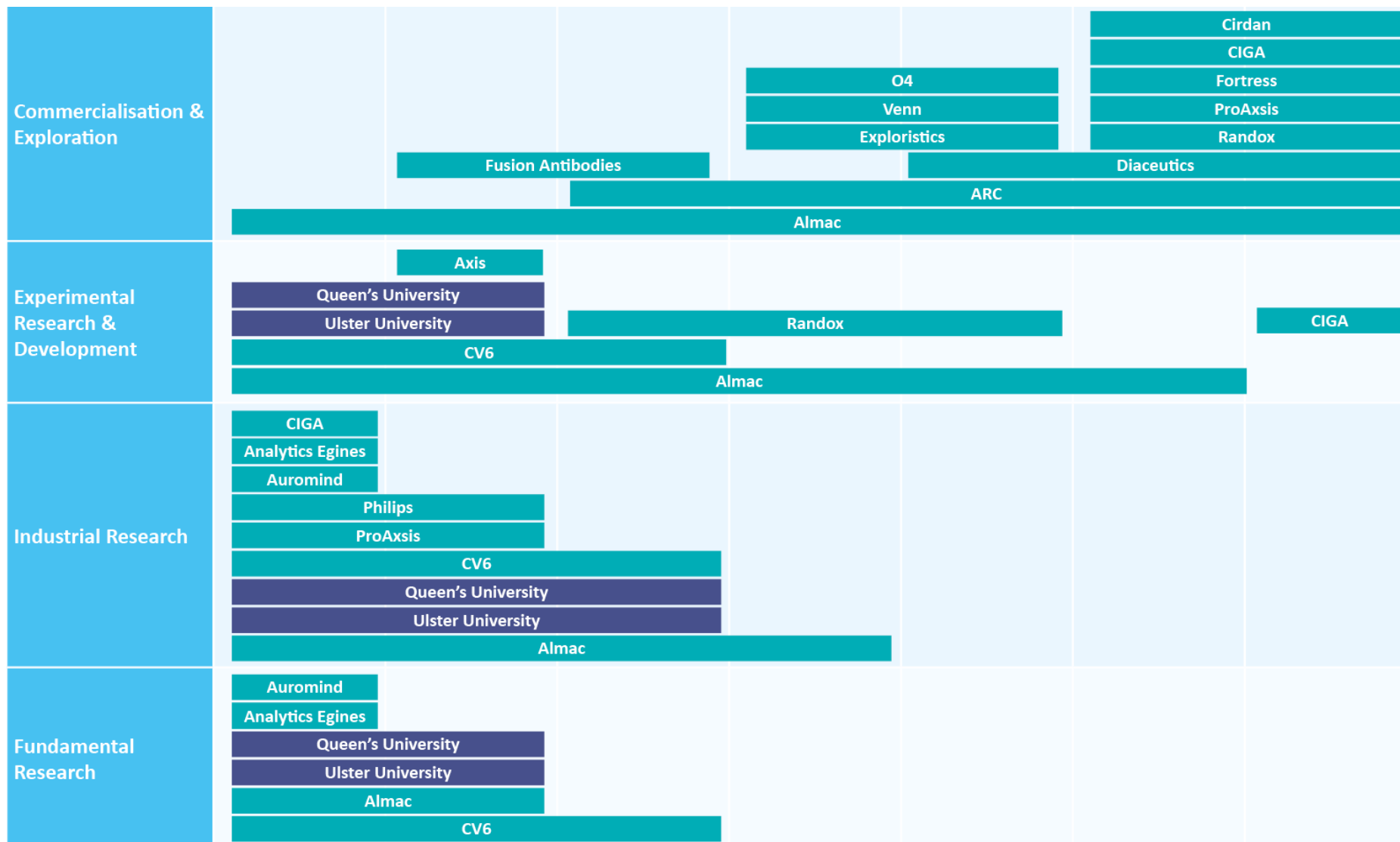
Global Market Size

2016:	£31.5 billion
2025:	~£120 billion
CAGR:	~14.7 %

Source: Journal of Precision Medicine, 2018

A competitive Life Health Sciences & PerMed Stakeholder Partnership Exists in Northern Ireland







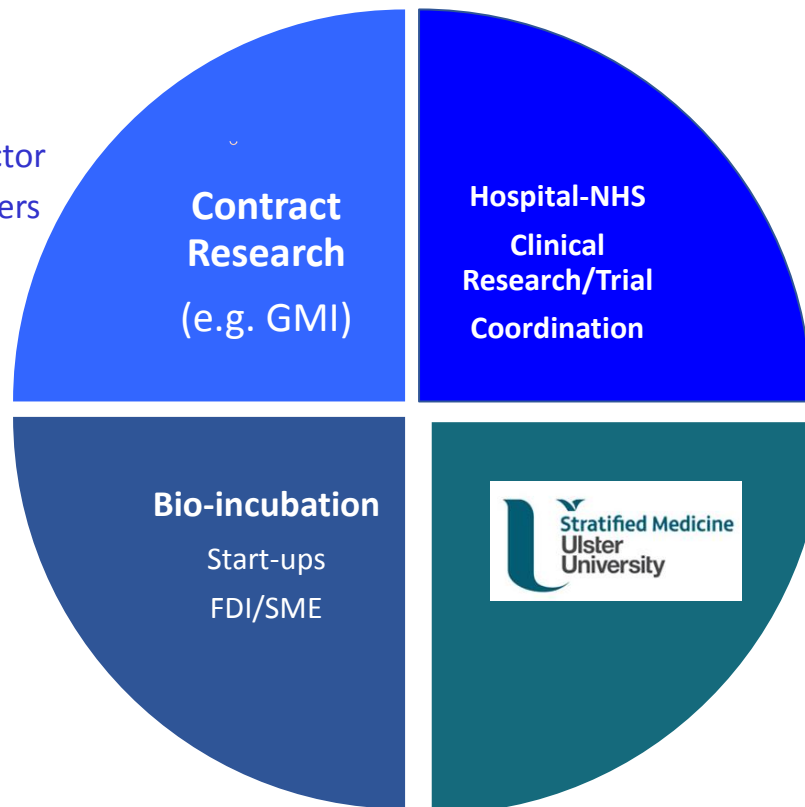
Northern Ireland
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Infrastructure & Capability

C-TRIC Company Partnership Model

Partnership Across the Health Care Value Chain

- Healthy Citizens
- Patients
- Researchers
- Pharma sector
- Medical device sector
- Health care providers
- **Governmental agencies**



The team: Research informed teaching



**Prof. Tony
Bjourson**



**Dr Paula
McClean**



**Dr Kyle
Matchett**



**Dr Catriona
Kelly**



**Dr David
Gibson**



**Dr Elaine
Murray**



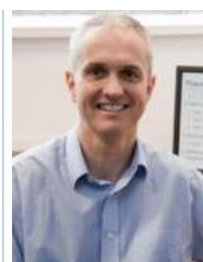
**Dr Taranjit
Singh Rai**



**Dr Stephanie
Duguez**



**Dr Sarah
Atkinson**



**Dr Andrew
McDowell**



**Dr Victoria
McGilligan**



**Dr Shu-Dong
Zhang**



**Dr Steven
Watterson**



**Dr Priyank
Shukla**



**Dr Bill
Duddy**

18 Research Associates; 30 PhD Students; 5 Administrative & Technical Support Staff; 18 Research Associates; 50 Affiliated Clinicians.

A Driver for Personalised Medicine Regionally.....

- **We currently coordinate >£26M in Stratified / Personalised Medicine Grants**
- **Northern Ireland Centre for Stratified Medicine**
(£11.5M Oct 2013) -20 academic research staff, 8 Research associates 25 PhD Researchers and 45 affiliated GP/NHS clinicians.
- **Centre for Personalised Medicine, Clinical Decision Making & Patient Safety**
(€8.6M/£7.5M awarded by EU SEUPB Jan 2017) – 14 partner organisations, academic, clinical, business, 10 PhD students and 50 affiliated clinicians
- **First Undergraduate BSc Degree in Stratified Medicine (2013)**
- **Ulster Graduate Entry Medical School (GEMS) – FIRST INTAKE Proposed 2021**
- **Major Collaboration with Genomics Medicine Ireland (GMI)**
(GMI located in C-TRIC and recruiting in N. Ireland IBD, MS Patients, Ank Spon and soon other key diseases for WGS)
- **Derry/ Londonderry City Deal Announced May 2019 -£105M**
- **Ulster Graduate Entry Medical School NIGEMS (£25M)**
- **TRIVE - Health Research Institute (£24.5M) – with £11M-Altnagelvin & £13.5M-Magee/new Strand Rd Site**

Biomarker Panels

genetic, phenotypic, imaging, and environmental to better:

To:

- Predict Disease Susceptibility
(susceptibility/risk biomarker),
- Diagnose Disease
(diagnostic biomarker-subclassify disease),
- Assess Stage & Evolution of Disease
(prognostic biomarker)
- Response to treatment
(response or predictive biomarker)
- Targeted Drug Development
(anti inflammatory, antidiabetic, AD)



Dark Hedges, County Antrim (Przemyslaw Zdrojewski)

Ulster University Personalised Medicine Program Overview



Diseases with shared environmental and/or genetic determinants

Inflammatory-Related

Ulster Patient Cohorts (7000):

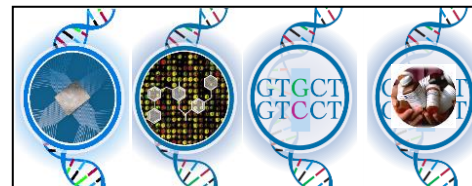
Rheumatoid Arthritis, Diabetes, Depression, Cardiovascular Disease/Stroke,
Alzheimer's Disease, Cancer, Motor Neuron Disease (including multi-morbidity)



Lifestyle Data



Clinical Data



Pan-Omic Data
Whole Genome
Focused Proteome

**Plus UK
Biobank**

Outputs: 31 IDFs/patents - Diagnostics / Predictive Bio-Markers – Clinical Decision Tools,
Spin-Out Companies, Community Health Company (Derry City Deal Proposal)

Platforms: PoC & Centralised –(Integration of Biomedicine, Data Analytics & Engineering

N. Ireland Centre for Stratified Medicine

(£11.5M Awarded 2013)

- Cardiovascular Disease
- Diabetes
- Mental Health & Alzheimer's Disease
- Rheumatoid Arthritis (Autoimmune disease)

- Motor Neuron Disease-ALS
- Specific Cancers

- Systems Medicine (WGS/Clinical/Environ)
- Commercial Roadmap
- Education Training (undergraduates & workforce)

Funding: £11.5M Oct 2013 (InvestNI, HSC R&D, Ulster University)



Public Health
Agency



Centre for Personalised Medicine Clinical Decision Making & Patient Safety

(Funding: €9M/£8M April 2017 (EU SEUPB))

*Driving Stratified Medicine Framework
into hospitals, clinics & homes.....*

Applied to:

1. Cardiovascular Disease
 2. Emergency Abdominal Surgery
 3. Acute Kidney Injury
 4. Diabetes
 5. Dementia
- **Commercial Partners**

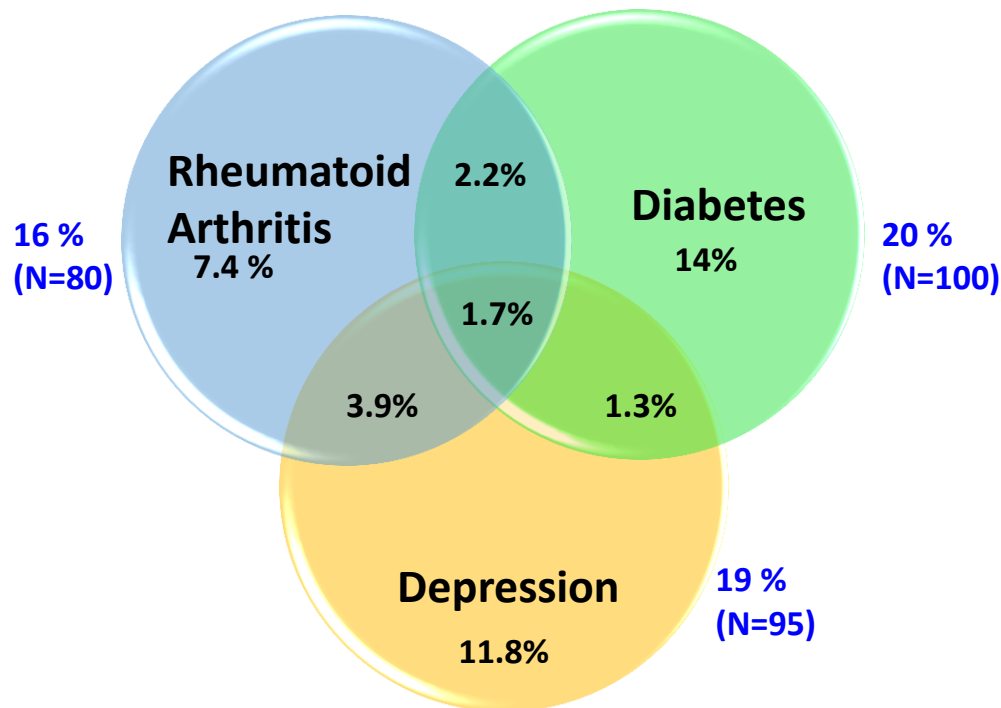
Partners



A project supported by the EU's INTERREG VA programme, managed by the Special EU Programme Body (SEUPB)

CVD Multi-Morbidities (N=500)

Shared Genetic or Environmental Determinants



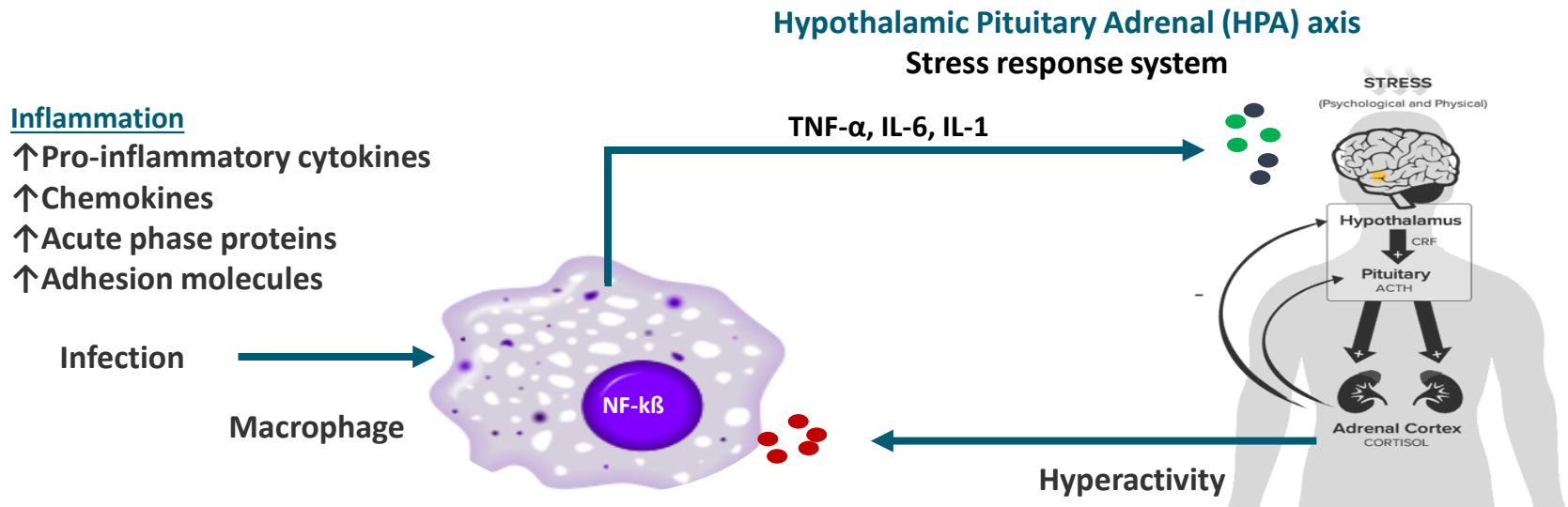
Note:

- 18% of our CVD Patient cohort have Asthma also

Example: Case Study

Links between Chronic Inflammation & Depression due to:

- Chronic inflammation is a biological cause of CVD, diabetes, arthritis, etc
- Chronic stress & increased inflammatory cytokines may drive depression via the HPA Axis



1. **Chronic disease**
2. **Environment/Diet** (me, my parents or grandparents – transgenerational epigenetics)
3. **Stress** (me, my parents or grandparents – transgenerational epigenetics)
4. **Microbiome** (Cause and/or Consequence)

Ulster University Student Well-being Study

‘There is a tsunami of third-level students with mental health problems’

Demand for counselling in colleges has jumped 40% in the past decade



NI Centre for Stratified Medicine

Elaine Murray

Tony Bjourson

UU Student Wellbeing Team

Margaret McLafferty

Siobhan O'Neill

BMSRI Genomics Group:

Rachelle Irwin

Sara-Jayne Thursby

Colum Walsh

Intelligent Systems Group:

Ben Wingfield

Martin McGinnity

Sonya Coleman

Ulster University Student Well-being Study

UU first year students

**Saliva sample; Oragene
OG-500**

**Online survey
WHO WMH CIDI**



Design	Longitudinal Study
Recruitment	Registration Week September 2015
Participants	1,646 UK & Ireland first year students consented and provided a saliva sample. 739 fully completed survey
Survey Instrument	On-line survey developed by the WMH International College Survey consortium. Validated with DSM-IV criteria.
Saliva Collection	Saliva sample taken after consent. Oragene, DNA Genotek

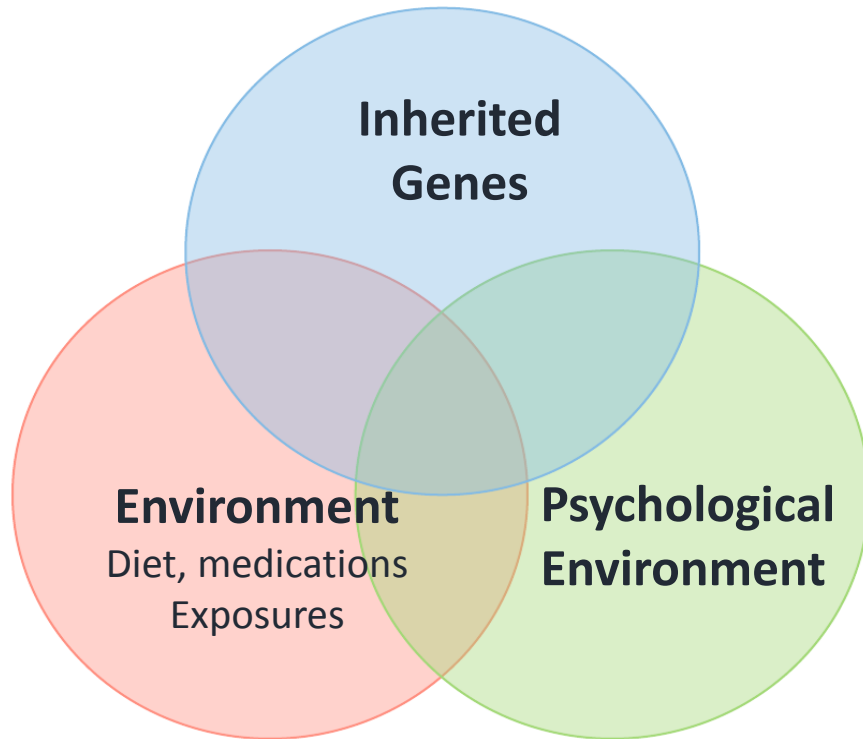
Lifetime Prevalence of Mental Health Disorders

	Total (739)		Male (274)		Female (462)		Other (3)	
Disorders	n	%	n	%	n	%	n	χ^2
Mood - MDE	186	24.2	55	19.1	128	27.7	3	6.756**
Anxiety - GAD	173	22.6	49	17.8	121	26.0	3	6.312*
Panic Disorder	49	6.3	14	4.9	35	7.5	0	1.683
Broad Mania	27	3.5	7	2.5	19	4.1	1	1.567
Alcohol dep	75	10.2	31	11.1	44	9.5	0	.329
Drug abuse/dep	23	3.1	1.5	4.8	8	1.7	0	9.102**
Suicidality	237	31.0	68	24.3	166	35.9	3	10.329**
6-month ADHD	156	20.8	52	18.7	101	21.9	3	.339
Any disorder	400	53.2	135	48.5	262	56.6	3	4.215*
One disorder	172	23.2	63	23.0	109	23.5	0	
Two disorders	80	10.9	31	11.4	49	10.6	0	
Three or more	148	19.1	41	14.1	104	22.5	3	

McLafferty M, Lapsley CR, Ennis E, Armour C, Murphy S, Bunting BP, et al. (2017) **Mental health, behavioural problems and treatment seeking among students commencing university in Northern Ireland.** *PLoS ONE* 12(12): e0188785.

<https://doi.org/10.1371/journal.pone.0188785>

Gene-Environment Interactions in the Pathology of Depression

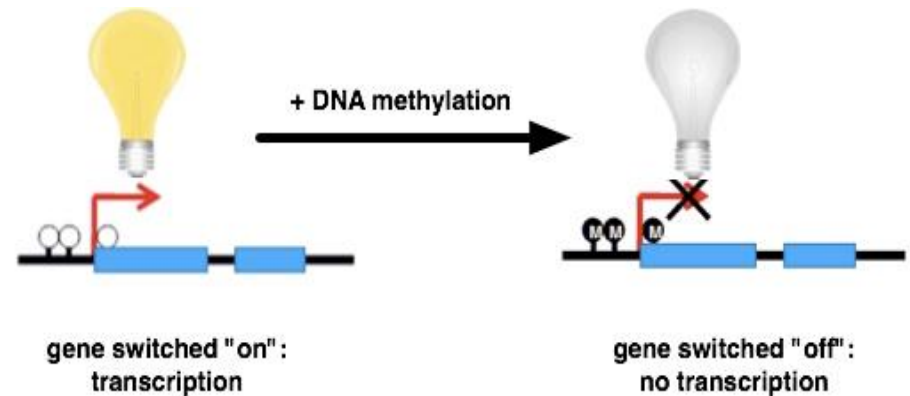


Engel GL et al 1977

Epigenetics

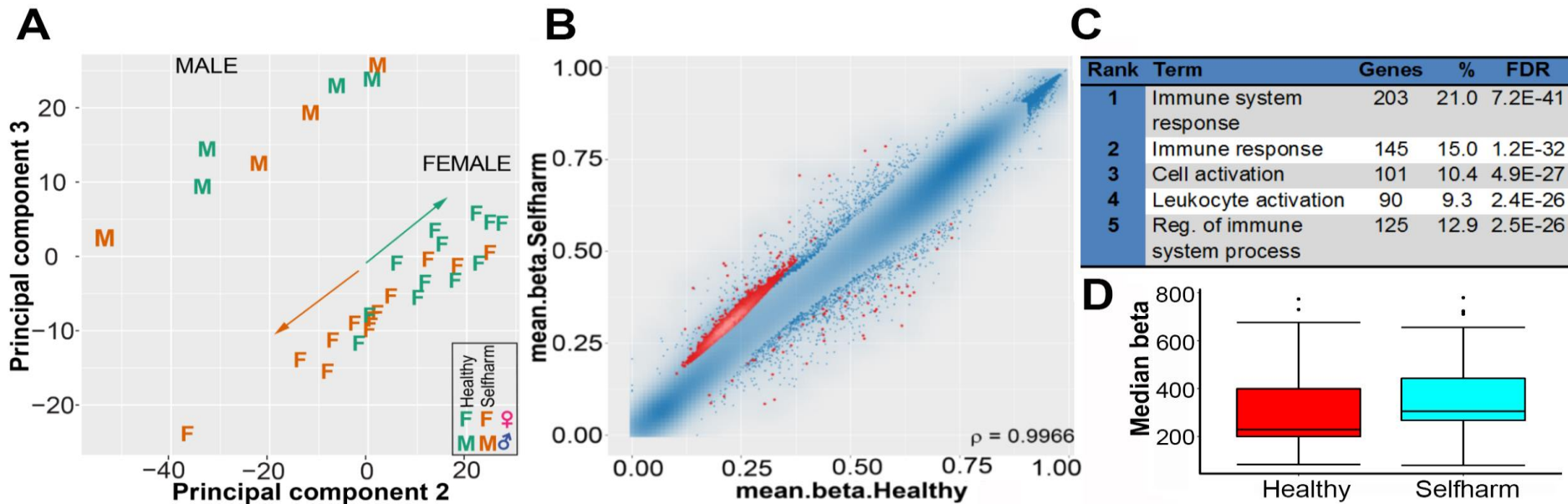
Change in phenotype
without a change in
genotype

e.g. DNA Methylation



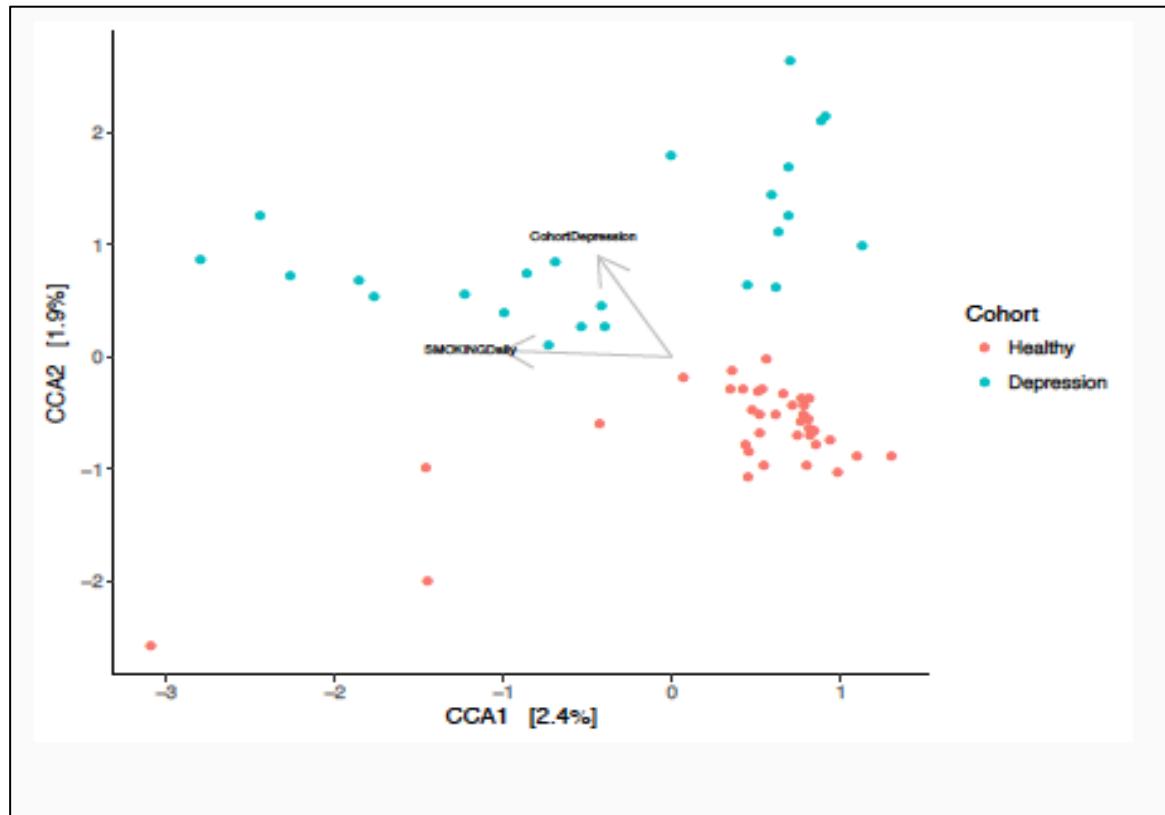
Methylome Profiling of Young Adults with Depression

- Link with Immune Response.



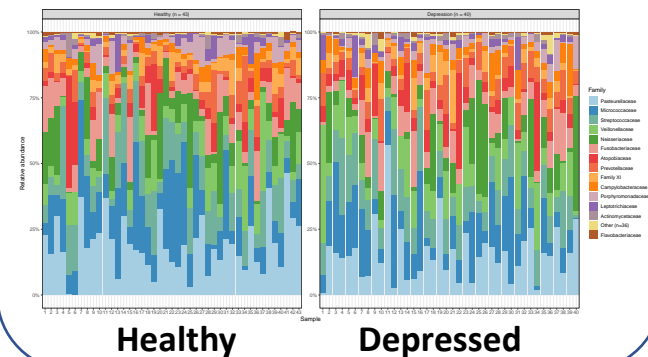
Oral Microbiome markers of Depression.

Cohort	No.	Age	Female	Male	Depression Score	Antidepressant last 7 days	Antidepressant last 12 months
Depressed	45	21.9	33	11	10.1	6	13
Healthy	45	20.4	31	14	34.5	0	0



Canonical correspondence analysis shows separation of depression and healthy controls based on overall microbiome composition – markers of depression

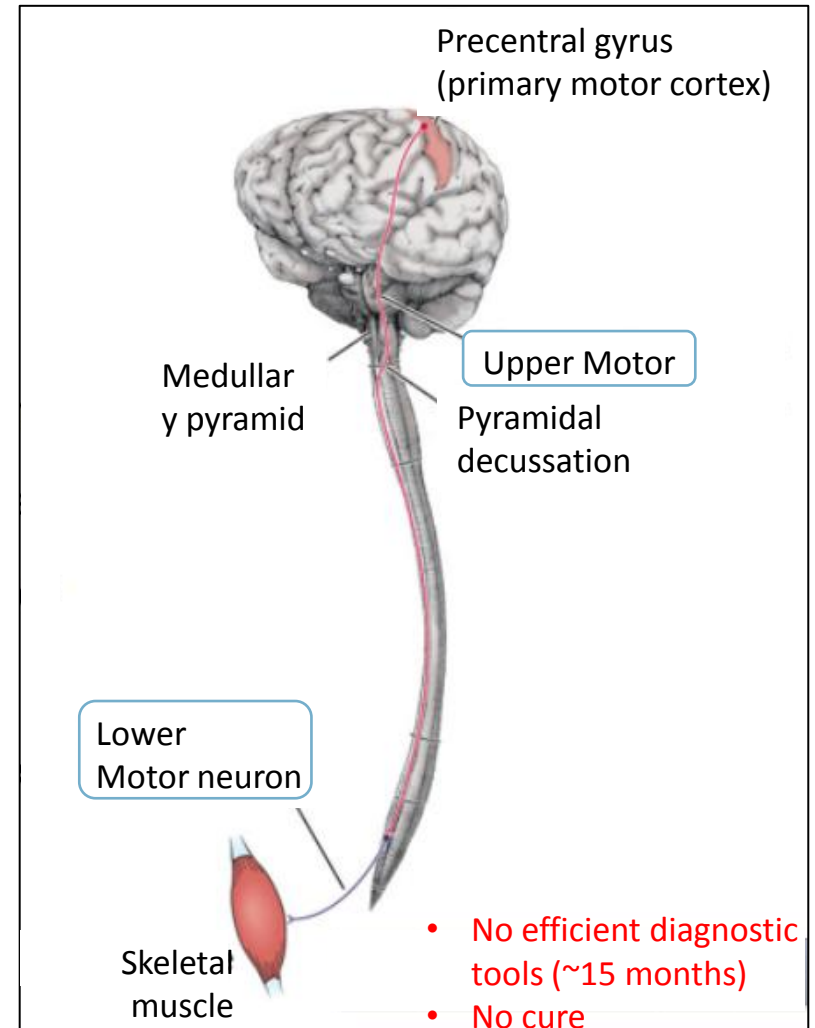
Phyla distribution (Top 15)



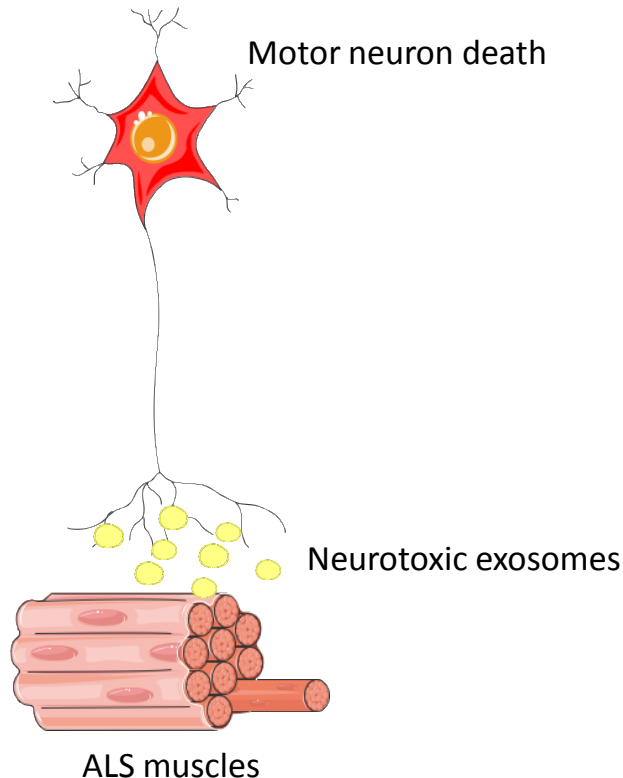
ALS: MND



- 90-95% sporadic cases
- Affect more Male
- Average age of onset: 55-70 years old
- Life expectancy: 5 years after the first symptoms

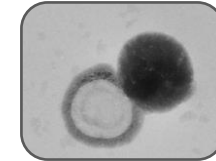


Explore and identify that muscle secretes neurotoxic vesicles in ALS



EXPLORE THE CONTENT OF THE ALS EXOSOMES FOR DIAGNOSTIC AND THERAPEUTIC PURPOSE

ALS exosomes
are neurotoxic



Exploration of the exosomes content

Identification
of secreted
toxic
candidates

OMICS ANALYSIS
RNA-seq
transcriptome
proteome
miRNA-seq
metabolome
lipidome
glycomics
epigenomics
genomics

Identification
of potential
biomarkers

Correction of the
exosome neurotoxicity

Development of
diagnostic/prognostic
biomarker kits

Perspectives

We have optimized a strategy to extract muscle exosomes in any body fluids

A

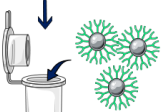
200 ul serum samples



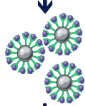
Precipitate total exosomes



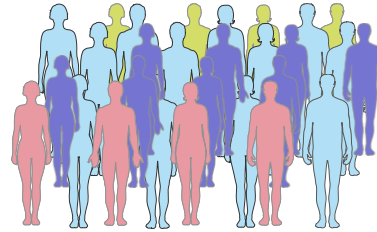
Add magnetic beads coated with membrane muscle protein antibodies



Pull down muscle exosomes



Route for biomarkers for ALS



Companion diagnostic/prognostic



Open the exploration of muscle vesicles in other physiological & pathological context

Role of muscle exosomes in other conditions

ageing



neuromuscular disorders



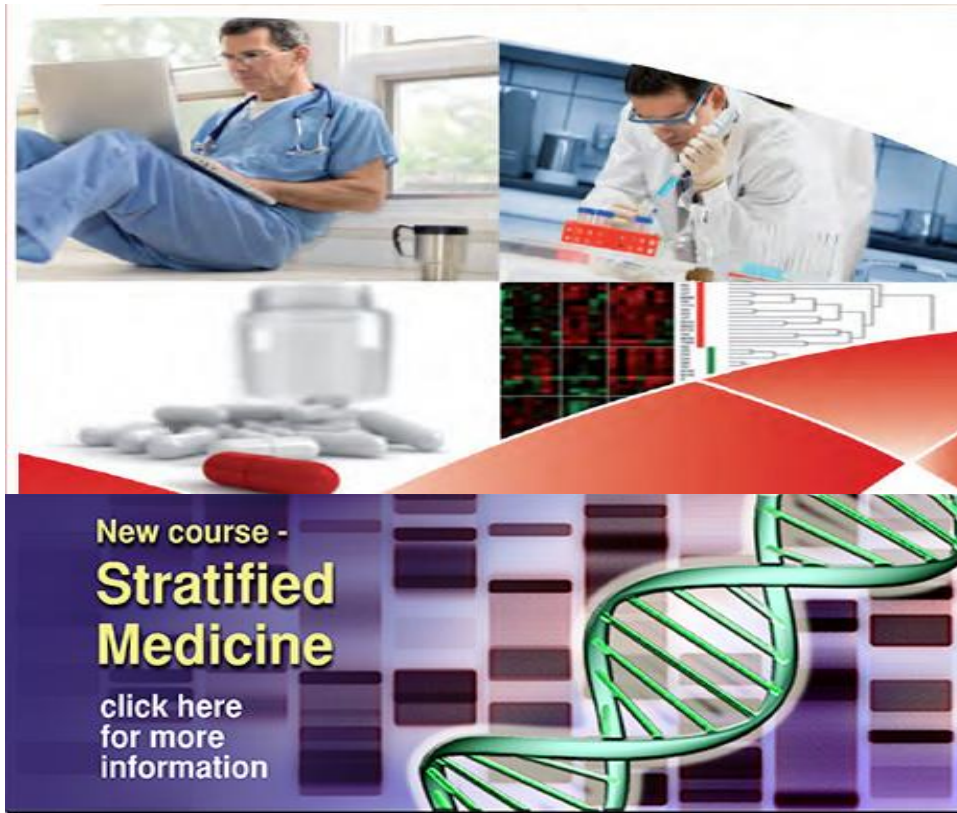
exercise



obesity



Unmet Need: *Provision of the Skilled Trained Workforce*



New course -
**Stratified
Medicine**

click here
for more
information

Training the next generation of skilled staff in stratified medicine

Offer undergraduate & post-graduate courses in Stratified Medicine.

Graduate Entry Medical School (2020)

-focus on primary care

(Now Recruiting Dean & Professor of Medical School)

Stratified Medicine BSc Degree & Postgraduate courses

Web:

<http://study.ulster.ac.uk/prospectus/course/201415/2911>

Facebook:

<https://www.facebook.com/personnalisedhealth>

Twitter:

<https://twitter.com/StratMedicineNI>

Personalised Medicine Skills Challenge

BSc Hons Degree & Postgraduate Courses



Modules in Personalised Medicine & Data Analytics

Biochemistry and Cell Biology
 Anatomy and Systems based Physiology
 Mathematical Methods
 Genetic Inheritance and Variation in Human Disease
 Biocomputing and Programming
 Inflammatory and Immunological Disease
 Pharmacology and Pharmacogenomics
 Stats and computing methods
 Cellular and Molecular Pathophysiology
 Biomedical Informatics
 DNA sequencing and omic technologies
 Ethics Regulatory process and clinical trial design
 Optional Placement Year
 Multi-omics and systems biology
 Clinical or fundamental research design
 Clinical decision making and health economics
 Clinical Research project
 Applied Bioinformatics
 Neurological and psychiatric disorders

Training the next generation of skilled staff in stratified medicine (biomedicine, data analytics and clinical research)

We offer undergraduate Personalised Medicine (& post-graduate courses in Personalised Medicine accredited by IBMS)

*Graduate Entry Medical School (2020)
 -focus on primary care
 (Now Recruiting Dean & Professor of Medical School)*

Stratified Medicine BSc Degree & Postgraduate courses

Web:
<http://study.ulster.ac.uk/prospectus/course/201415/2911>

Facebook:
<https://www.facebook.com/personnalisedhealth>

Twitter:
<https://twitter.com/StratMedicineNI>

Derry City Deal: Future Plan (£44M)

What will HRI-THRIVE do?

Spade-ready research centers of excellence....

Innovation Research Centers for Sustainability:

- **Centre for Pediatric Oncology** (£10.5M)
Dr Kyle Matchett
- **Centre for Neuromuscular Disease** (9.5M)
Dr Stephanie Duguez
- **Centre for Personalised Medicine & Multimorbidity**
(£7.5M) *Professor Tony Bjourson*
- **Research & Innovation in Quality Improvement Institute**
RIQII (£9M) *Dr Ann Kilgallan*
- **Centre for Vascular Medicine** (£9.8M)
Professor Aaron Peace, Dr Victoria McGilligan
- **Centre for Neuropsychiatric Research**
Dr Elaine Murray, Dr Paula McClean
- **Personalised Medicine Data Analytics Centre** (£5M)
Drs Watterson, Shukla, Duddy, Zhang-Collaborative with CARL
- **Centre for Orthopedic Surgery Research** (£5M)
All NICSMS Staff & WHSCT

The Research Arm of Medical School

Based at:

- **Altnagelvin - C-TRIC**
- Secondary Care Focus
- **Magee: New Health Research**
- Primary & Community Focus
- **Recruitment Clinics**
- Strabane-Derry GP Hubs
- **Mobile Clinic Vehicles**



Dark Hedges, County Antrim (Przemysław Zdrojewski)

Derry City Deal: Future Plan

What will HRI-THRIVE do?

2. *Spade-ready* commercial projects....

Business & Community Innovation:

- **Community-Owned Health Company**
Modelled on the financial services credit Union
- **Genomics Medicine Ireland (GMI) Partnerships**
Genomic sequencing contract research
- **IT/Data Health Company Partnerships**
Pharma, Diagnostics, Data analytics, Healthcare Sectors
- **Company Creation & Spin-ins**
APP and decision tool development
- **New High-Value Jobs – contract research**
(Research-Teaching-Commercial)



Pharmacogenomic Testing (PGx) Challenges

Even for genes with strong evidence base

- implementation is lagging due to:

- Lack of laboratory capacity & capability to perform PGx testing
- Lack awareness & education among relevant healthcare professionals of PGx testing and its implications for patient care
- Lack of PGx clinical guidelines approved for use within UK health systems
- Lack of mechanisms to incorporate PGx data into clinical decision making and care pathways
- Lack of integration of PGx data including into electronic health records, electronic prescribing systems and clinical decision support tools

Source: The personalised medicine technology landscape PHG Foundation (2018) 978-1-907198-31-1

<https://www.phgfoundation.org/documents/phgf-personalised-medicine-technology-landscape-report-50918.pdf>

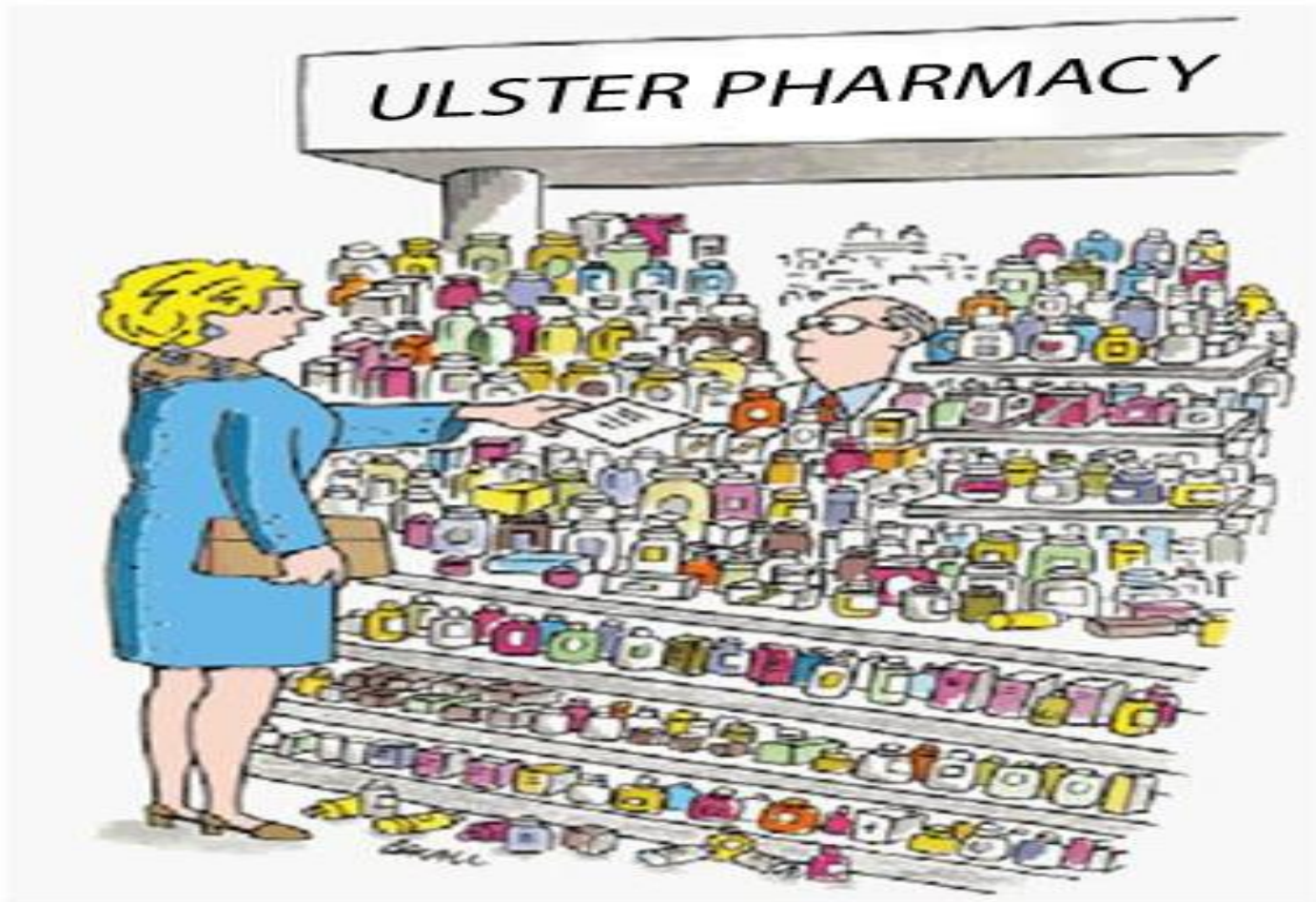
Data Challenges & Commercial Opportunities

- Data is only useful if it is of sufficient quality - quality of input determines quality of output ('garbage in, garbage out' problem).
- Data needs to be well characterised and compatible/harmonised data
- Management of personal data - ethical, legal, security and governance aspects
- Clinical decision-making needs complex data presented in an easily interpretable form - suitable for the different end-users- *creates commercial opportunities*.
- Need uncomplicated interfaces fully integrated into the working lives of clinicians and individuals – *where the rubber meets the road*

Major Technological Challenge

- Dynamically integrate physiological data **over an individual's lifetime –of equal importance** to the integration of static 'omics data in order to predict susceptibility and identify appropriate treatment options.
- Integrated networks need to allow **on-going collection, storage and cross-referencing of individual information with local environmental data.**

Medicines Optimisation (Medicine Appropriateness Index, MAI)



“Here’s my DNA sequence – who can review my medications ? ”

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Cardiovascular Disease

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Inflammatory Disease

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PhD Students

(40 PhD Students)

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2 PhD Students – under recruitment

3. Acute Kidney Injury

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2 PhD Students – under recruitment

4. Diabetes

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2 PhD Students – under recruitment

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Point of Care Testing

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Biomarkers-generic framework

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