

Εθνικοί Εκπρόσωποι

Γιώργος Βασιλόπουλος, GALENICA

Δρ. Σίσσυ Κολυβά, Ελληνικό
Ινστιτούτο Παστέρ



Innovative Medicines Initiative

IMI 2: The New European Engine for Therapeutic Innovation



medicines
initiative

The Innovative Medicines Initiative: the largest public-private partnership for health research worldwide

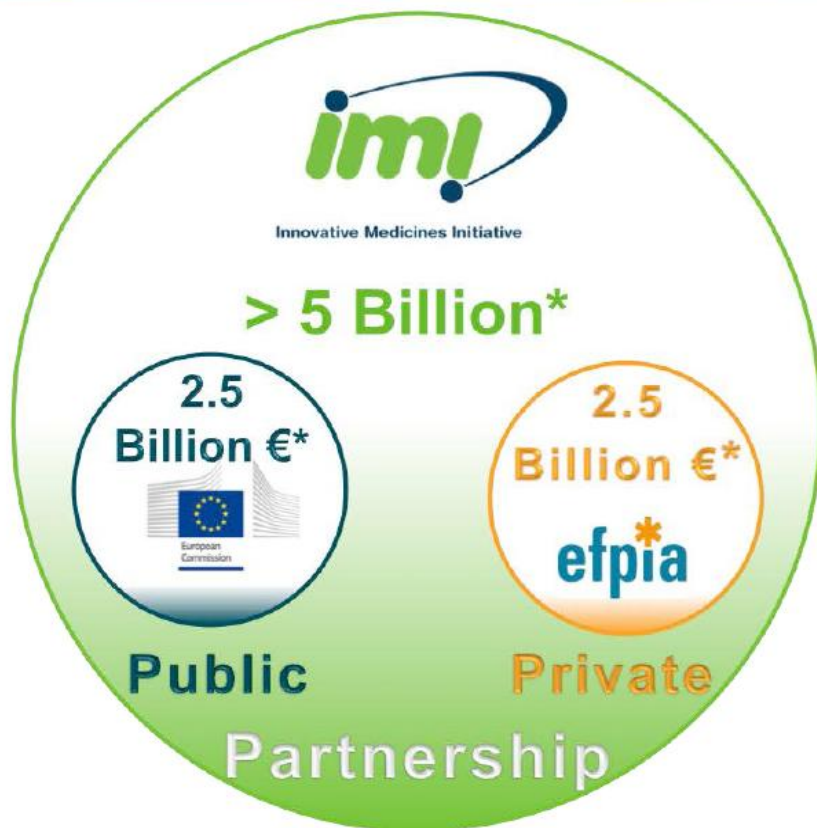
€5,276 billion

IMI1 €2 billion from 2008 – 2014

IMI2 €3,276 billion from 2014 - 2024

Part of the EU FP7 and Horizon 2020 R&D funding

Joining forces from public and private bodies

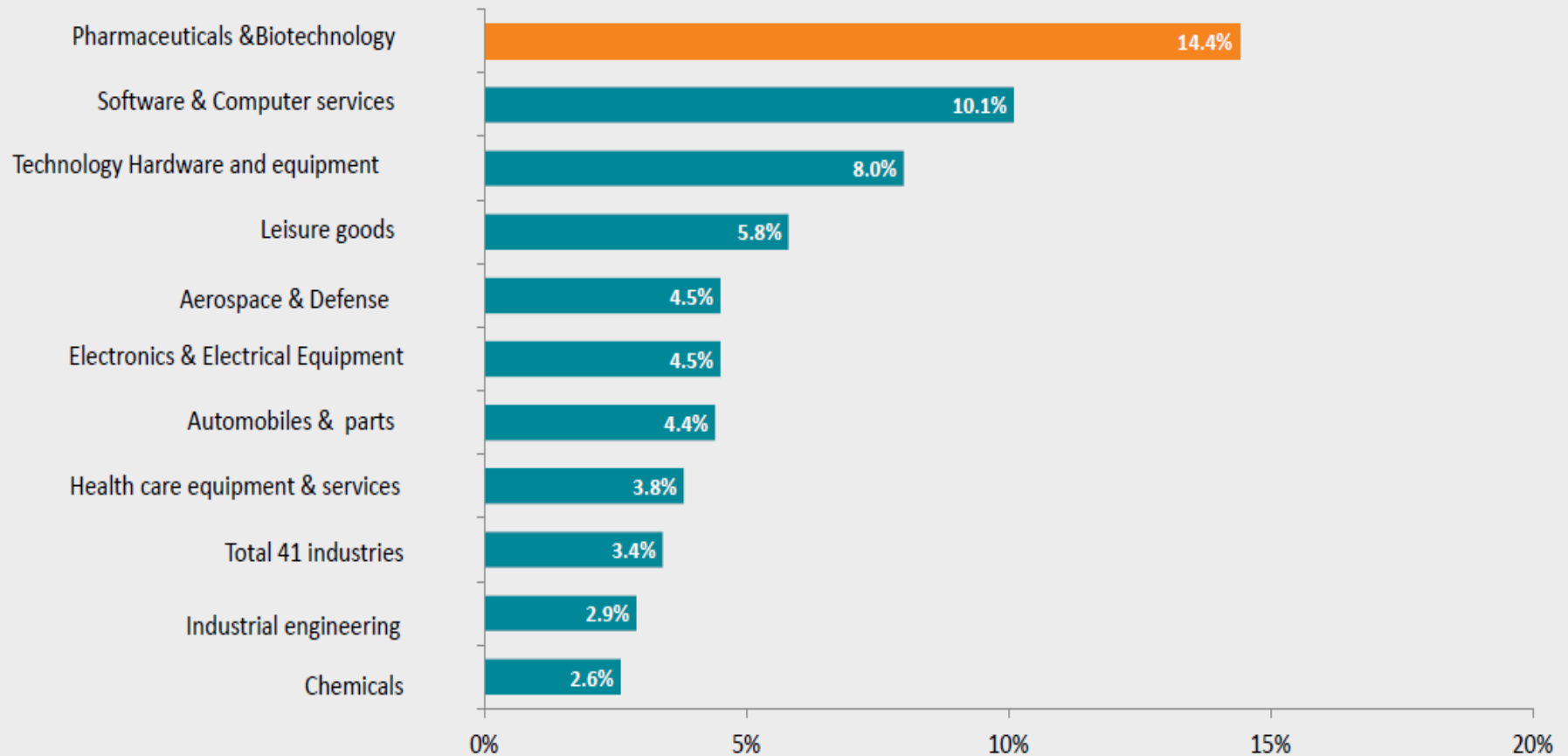


*** IMI 1+2
2008-2020**



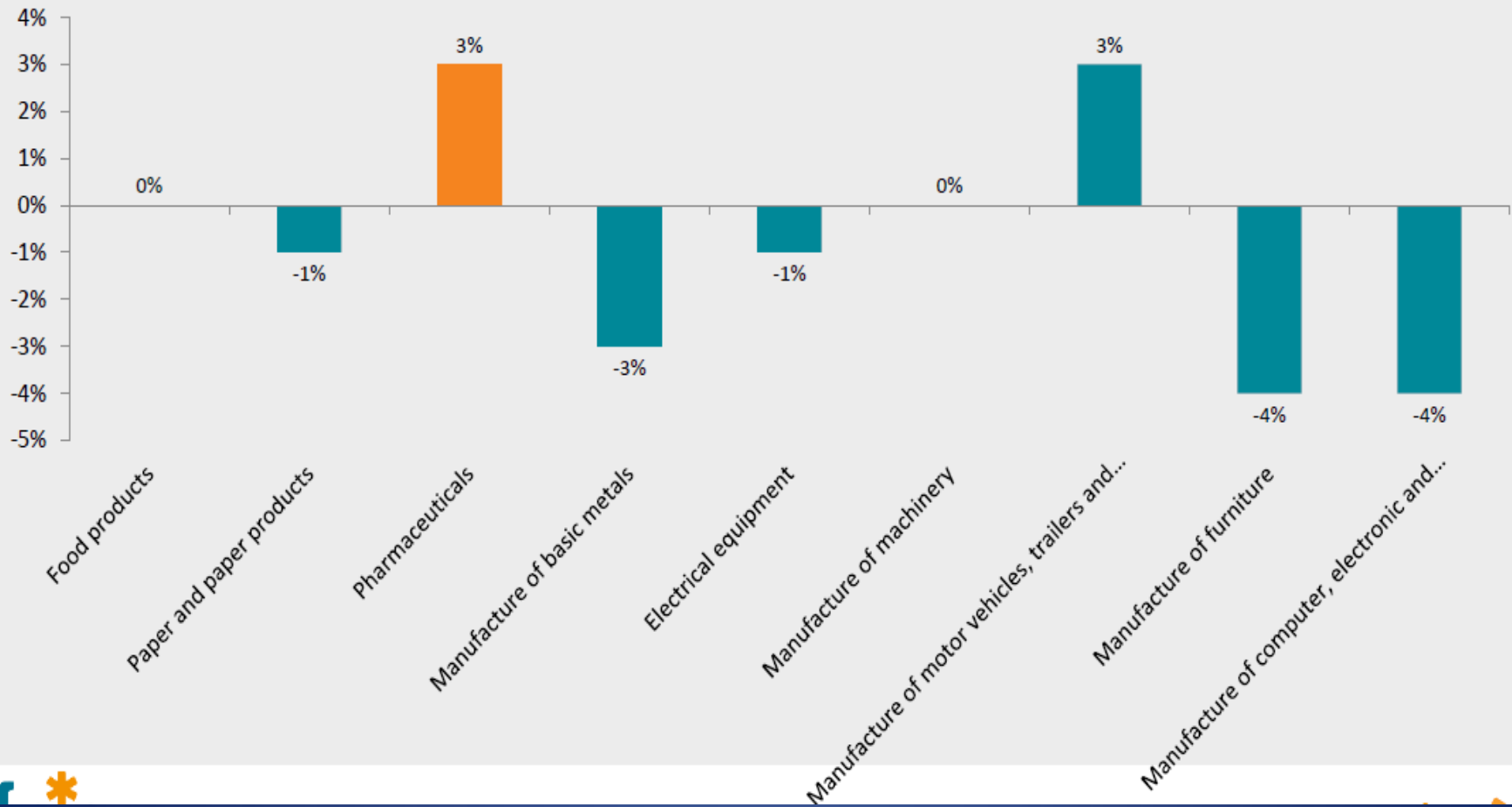
The pharmaceutical industry is the sector with the highest R&D intensity

Ranking of industrial sectors by overall R&D intensity (as percentage of net sales, 2014)



Employment in the pharmaceutical industry has proven to be more resilient than many other sectors in the EU

Percentage change in employment in selected industries in EU28 (2012-2014) 



Antimicrobial resistance – a growing threat



25 000

Europeans killed / year



€1.5 bn

costs to economy / year

2 new classes of antibiotics
in the last 30 years



ALZHEIMER'S DISEASE:

An urgent need for new therapeutic strategies

Major Public Health Need

- **10m** Europeans affected, will reach **14m by 2040**
- Annual cost in EU: **€180b**, will reach **250b by 2030**

Recent failures

- Inconclusive results of 3 large clinical trials:**
- solanezumab
 - bapineuzumab
 - human immunoglobulins

Hurdles to drug development

- Complexity of brain pathology**
- Patients' heterogeneity**
- Lack of validated markers for disease activity**



How IMI addresses Alzheimer's disease

IMI invests **€167 million** in 4 projects aiming at:

- Developing models to predict the efficacy of drug candidates in patients
- Connecting data on 40 millions of individuals to decipher links between genetic background, biological abnormalities, brain imaging changes, mental symptoms and disease progression
- Identifying subgroups of the disease allowing to tailor therapies according to the different causal factors involved
- **Implementing innovative trial designs**

Shared data set of patient-level data from:

- 5 companies (AstraZeneca, J&J, Eli Lilly, Lündbeck, Pfizer)
- 34 clinical trials testing second generation anti-psychotics
- 11,670 patients



Drug-placebo differences already significant:

- after 4 vs.6 wks observation
- with 40% less patients

when appropriate gender balance, symptoms
and disease duration are selected

Rabinowitz J et al., J Clin Psychiat 2014, in press

DIABETES:

Fighting the epidemic through Public-Private Partnership

Major Public Health Need

Diabetes will affect 43
million Europeans in 2030

€89 million spent on 2011
on treating diabetes and its
complications

Distrust in past-research

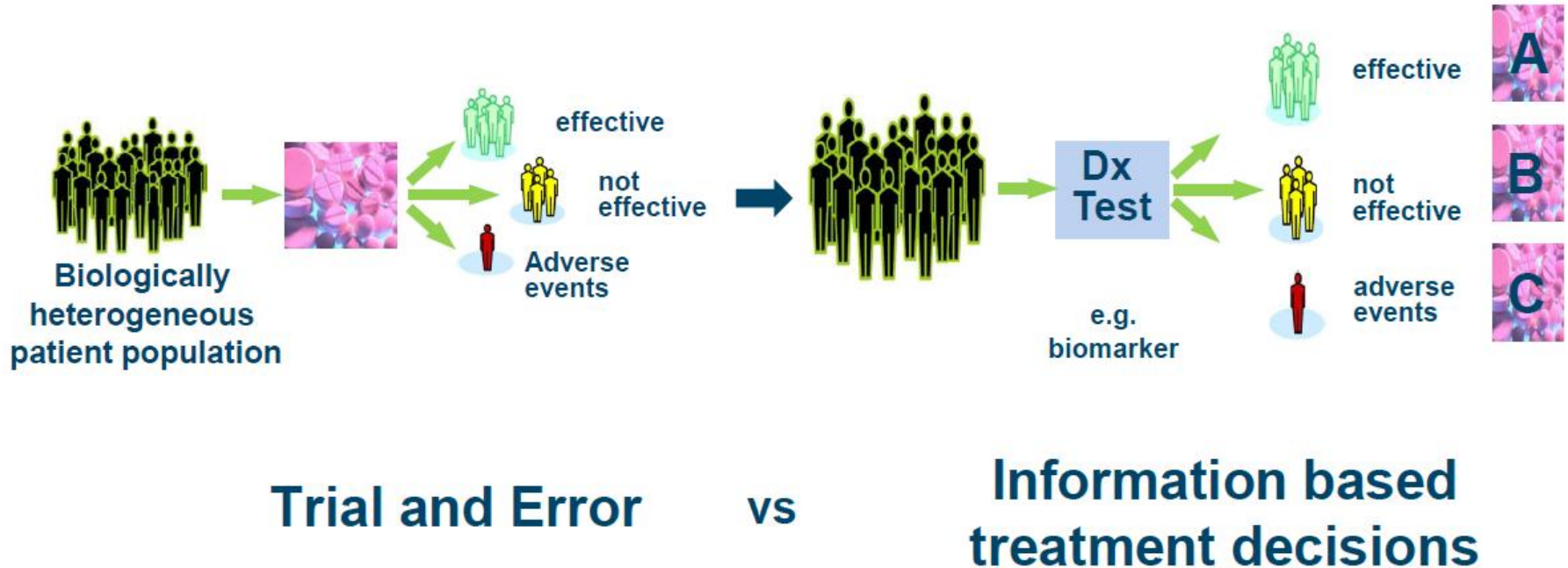
Cardiovascular
complications of
rosiglitazone and
benfluorex

Hurdles to drug development

Patients' heterogeneity

Lack of reliable markers
for disease activity and
complications

The Vision for IMI2 – The right prevention and treatment for the right patient at the right time



IMI turns knowledge into patient outcomes

Multiple companies join force and push the boundaries of precompetitive space*

Identify missing or weak links in medicines pathways that hold progress

Combine (often) proprietary knowledge, data and assets

Open them up for challenge by and collaboration with public partners

Validate proposed solutions during project lifetime in R&D practice



Address unmet medical need in areas of high burden for patient and society - for the patients



Challenge current business models and focus on value for patients and sustainable healthcare – for healthcare systems



New standards, tools and infrastructure that benefit all players and that accelerate innovation – for research ecosystem

Priority Themes

1. Neuro-degeneration
2. Immuno-inflammation
3. Metabolic disorders
4. Infection control
5. Translational Safety

Support Technologies

1. Imaging
2. ICT
3. Medical devices....

Enablers

Patient access to innovative solutions (MAPPs):

- Target validation
- Stratified medicine, precision medicine
- Innovative trials
- Data generation and interpretation
- Prevention, disease interception
- Patient adherence
- Health disease management
- Regulatory framework
- Reimbursement/patient access

It is evolving, with a stronger focus on the needs of patients and society and with simpler rules and procedures

olution in scientific focus

- Stronger focus on needs of patients and society, including unmet needs
- Increased emphasis on improving patient access to innovative medicines (in addition to medicines development)
- **The right treatment for the right patient at the right time**

Idea Generation process



TOP DOWN = THINK BIG PROCESS
sponsored by Global Heads of R&D
70-80% of the budget



PROJECT PORTFOLIO =
prioritisation by Think Big Sponsors
+ InnoMedS



BOTTOM UP = SGGs
Ideation and prioritisation within
SGG area and SGG portfolio management
20-30% of the budget

Third Party
sales

Think Big process – summary

- * Global Heads of R&D drive definition of key priority research areas that will make the best use of the remaining IMI2 public and private investment
- * Commitments expected in 2018-2020:
 - * Public funding for grants for public partners: ca EUR 850 mln
 - * In-kind investment by companies: ca EUR 900 mln
- * Four areas prioritised
 - * AMR
 - * Immunology
 - * Digital health
 - * Modernisation of clinical trials

Fast-track idea generation and long-term planning

Kick off workshop and identification of 4 key priority areas

[Global Heads of R&D]

13 March – 15 May

Workshops to define the scope of 4 prioritised areas

[led by Head of R&D “sponsors”: E. Zerhouni (Sanofi), J. Reed (Roche), P. Stoffels (Janssen), P. Vallance (GSK), M. Dolsten (Pfizer)], Vas Narasimhan (Novartis)

23 June – 30 August

Development of topics in each area

[drafting teams and SGGs under the supervision of “sponsors”]

30 June – 8 November

Consultation with IMI advisory bodies for ideas planned to be launched in 2018-2019

November onwards

4 priorities and first batch of ideas: Summary

Immunology	<ul style="list-style-type: none">• Treatment of non-response and remission• Non-invasive molecular imaging of immune cells
Antimicrobial resistance	<ul style="list-style-type: none">• Clinical trials networks• Accelerator of AMR R&D
Digital Health/Big Data	<ul style="list-style-type: none">• Remote clinical trials• Biosensors/digital endpoints in clinical development
Modernisation of clinical trials and regulatory pathways	<ul style="list-style-type: none">• Addressing the challenge of platform trials (Integrated Research Platforms)

First batch of ideas: Objectives (1)

Immuno: Treatment of non-response and remission	Better control of immune related diseases. Improved patient management /personalized treatment by identification/validation of predictive biomarkers for non-response and remission
Immuno: Non-invasive molecular imaging of immune cells	Generation and validation of in-vivo immuno-probes as non-invasive early indicators of efficacy and outcomes for multiple disorders including Cancer, RA, Asthma, IBD, MS, Alzheimer's, Neuro-inflammation
AMR: Clinical trials networks	Network to provide an expert & sustained capability for AB trials in Europe and creates a significant push incentive for investment in AMR
AMR: Accelerator of AMR R&D	Accelerator provides mechanism to enhance overall industry/SME/academia success in AMR discovery (Capability Building) and provides opportunities to invest and progress assets/programs (Portfolio Building)



First batch of ideas: Objectives (2)

Digital: Remote clinical trials

The Decentralised clinical trials (DCTs), where the study comes to the patient is the new paradigm for running clinical trials. Combined with the adoption of digital endpoints, the flexibility of patient follow-up during clinical trials could reduce working costs in centralized hospitals, increase the frequency of data collection, increase data quality and improve patient retention in trials.

Digital:
Biosensors/digital endpoints in clinical development

New digital endpoints that take advantage of novel biosensor technology to increase the accuracy of endpoint measurement (including validation and regulatory acceptance) so that data can be included in the label and be used in the market to monitor real world value.

Outputs from cross-SGG review

(subject to confirmation)

Immuno: 2018

Immuno (Think Big)	Targeted immune intervention for treatment of non-response and remission
Immuno (Think Big)	Non-invasive molecular imaging of immune cells
Immuno	Immunology and the microbiome (TBC)

Immuno: 2019

Immuno (Think Big)	Characterisation of human immunology mechanisms
Immuno (Think Big)	Early disease interception of immune dependent disease
Immuno (Think Big)	Emerging technologies and tools for interrogating human immunobiology
Immuno	Fibrosis
Immuno	Enhance understanding of early respiratory disease

Infections Control: 2018

Infections (Think Big)	Sustainable European antibacterial clinical trial network	
Infections (Think Big)	AMR Accelerator	
Infections	Progress in tuberculosis research (TBC)	to be reviewed in light of IRP and AMR

Infections Control: 2019

Infections	Novel immunisation technologies for next generation vaccines	Sources of in kind to be discussed
Infections	Coordination and Support Action for future vaccines R&D	Other financial instruments investigated (H2020)
Infections	Hepatitis B therapeutics and improved preparedness (pilot initiative)	

Digital & Clinical Trials: 2018

Digital & CT (Think Big)	Centre of excellence - decentralized, remote clinical trials
Digital & CT (Think Big)	Digital Transformation of Clinical Trials Endpoints
Digital & CT (Think Big)	Integrated research platform for patient-centric drug development <ul style="list-style-type: none">• <i>Common elements of IRPs + Clinical Trials Network</i>• <i>Two IRPs: Major Depressive Disorder & TB</i>

Digital & Clinical Trials: 2019 - 2020

Digital & CT (Think Big)	Data Lakes	Focal point of projects for sharing placebo arms data?
Digital & CT (Think Big)	Integrated research platform for patient-centric drug development <ul style="list-style-type: none">• IRPs on Smouldering Multiple Myeloma, NASH, Prostate Cancer, Crohn	

Diabetes & Translational Safety: 2018

DMD	The role of the gut Microbiome as modulator of type 1 Diabetes (TBC)	Call process to be defined
TS	Translational microphysiological systems	
TS	Dosing in specific populations	

Diabetes & Translational Safety: 2019

DMD	A clinical reference baseline database in support of flexible clinical trial designs in the area of metabolic diseases	To be connected with Data Lakes (placebo arms data)
DMD	Future of Diabetes/Metabolic Disorder healthcare CSA	
TS	Human metabolism, disposition and pharmacokinetics	

Neurodegeneration: 2018

ND	Synaptic plasticity	
ND	Premotor Parkinson's disease	
ND	Personalised treatment for Parkinson's disease patients	One of the two PD projects, TBC
ND	Identification and validation of novel pain targets / pathways with disease-modifying potential	Readiness for 2018 to be confirmed for pain related projects - TBC
ND	Pain in rare diseases	
ND	Clinical endpoints in headache medicine	

Neurodegeneration: 2019

ND	Immune system and Alzheimer's disease	
ND	Tau imaging	
ND	New genes as Alzheimer's disease modifiers	
ND	Progress in experimental modelling of Alzheimer's disease	
ND	Early markers of progression in Alzheimer's disease	

Oncology and other: 2018

Onco	Big data in oncology	
Non SGG	ATMPs manufacturing	To be connected with SGG onco?

Oncology and other: 2019

Onco	Beyond patient stratification	
Onco	Increasing context specificity	
Onco	Immune oncology	Potential fit with Think Big Immuno
Onco	Cell free DNA – liquid biopsy	Connection with Transbioline TBC
Non SGG	Novel approaches for clinical study of ATMPs	

Future topics

- Assessment of the uniqueness of diabetic cardiomyopathy relative to other forms of heart failure using unbiased pheno-mapping approaches
- Genome-environment interactions in inflammatory skin disease

Future topics

- The value of diagnostics to combat antimicrobial resistance by optimising antibiotic use
- Mitochondrial dysfunction in neurodegeneration

Future topics

- Human tumour microenvironment immunoprofiling
- CONCEPTION – continuum of evidence from pregnancy exposures, reproductive toxicology and breastfeeding to improve outcomes now
- Improving the preclinical prediction of adverse effects of pharmaceuticals on the nervous system

Future topics

- Translational safety biomarker pipeline (TRANSBIOLINE): enabling development and implementation of novel safety biomarkers in clinical trials and diagnosis of disease
- This programme includes the following topics:
 - Cardiovascular diseases and diabetes
 - Respiratory diseases
 - Neurodegenerative diseases
 - Rare/orphan diseases

Ευχαριστώ πολύ για την προσοχή σας

Δρ. Σ. Κολυβά