Εθνικοί Εκπρόσωποι

Γιώργος Βασιλόπουλος, GALENICA
Δρ. Σίσσυ Κολυβά,
Ελληνικό Ινστιτούτο Παστέρ

Innovative Medicines Initiative

IMI 2:
The New European Engine for Therapeutic Innovation

innovative medicines initiative

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

€5,276 billion

IMI1 €2 billion from 2008 – 2014

IMI2 €3,276 billion from 2014 - 2024

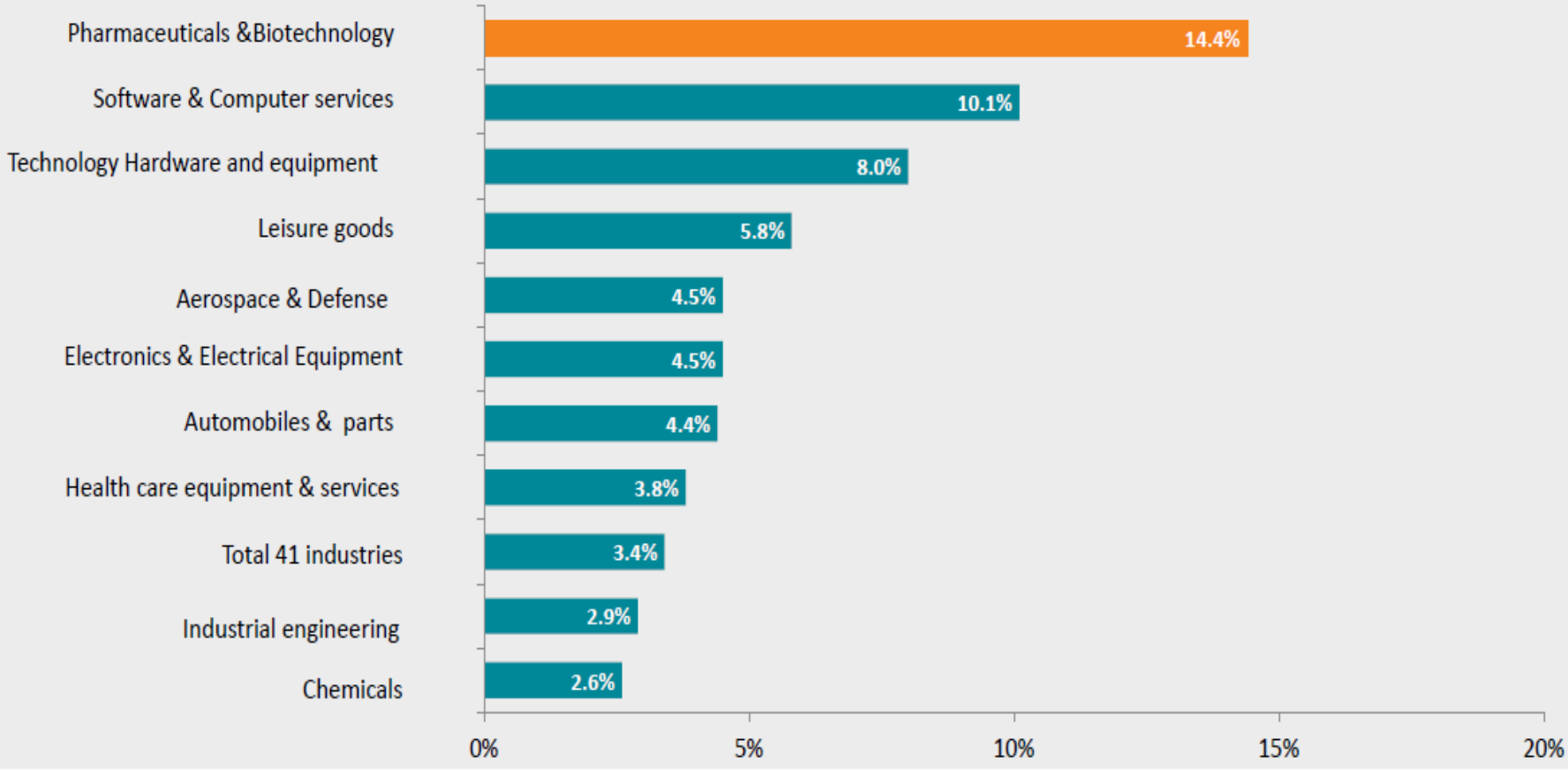
Part of the EU FP7 and Horizon 2020 R&D funding

Joining forces from public and private bodies

* IMI 1+2
2008-2020

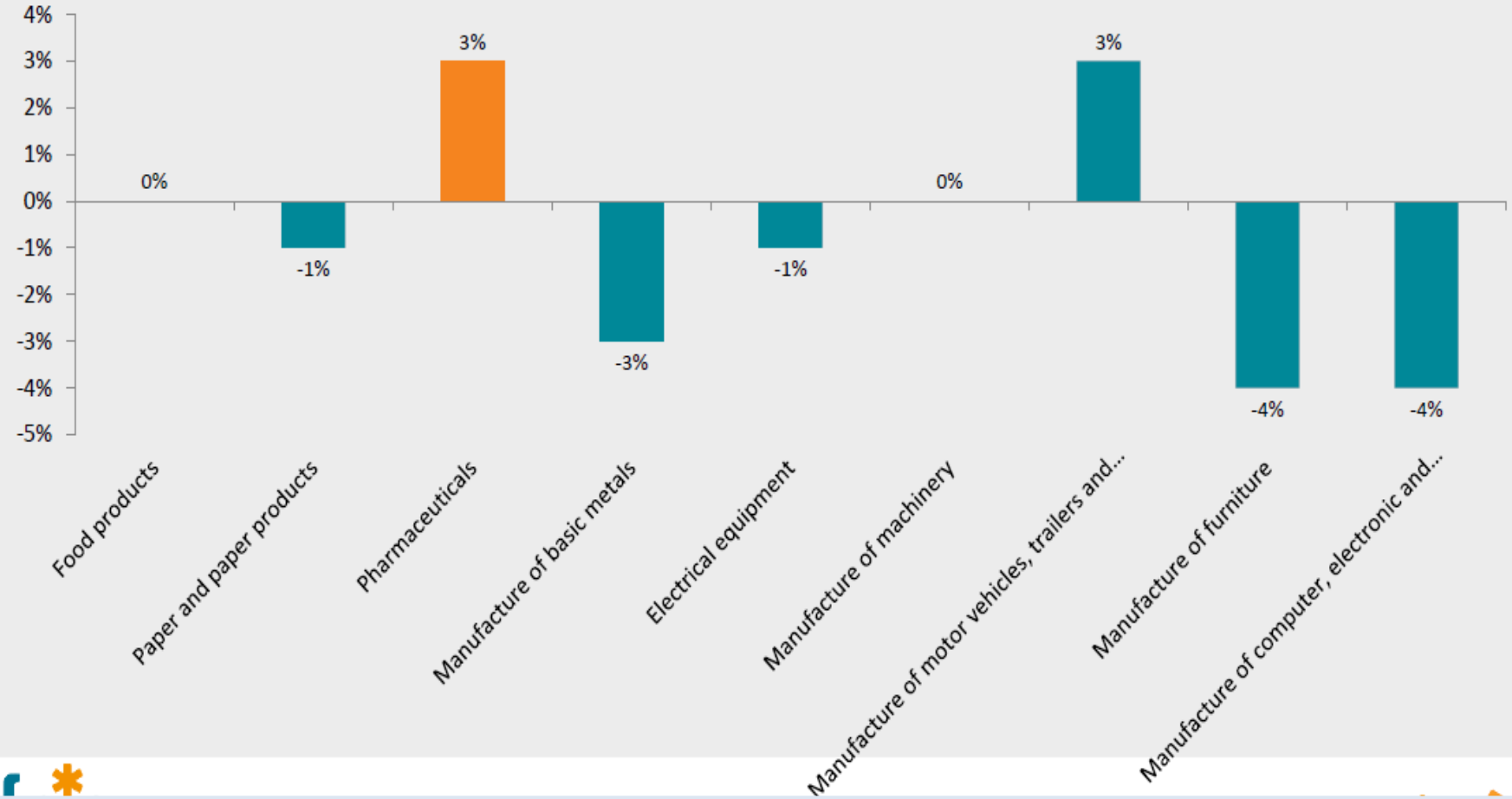
The pharmaceutical industry is the sector with the highest R&D intensity

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

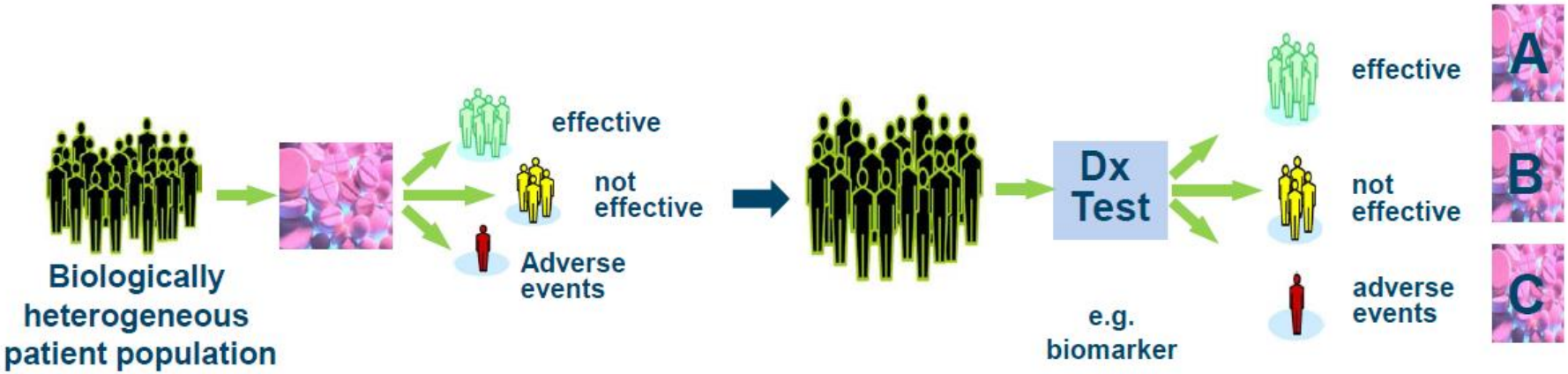


Employment in the pharmaceutical industry has proven to be more resilient than many other sectors in the EU

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



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



Trial and Error vs **Information based treatment decisions**

Graphic adapted from C. Carini, C. Fratazzi, Eur. P[illegible] 2008; 2, 39-45

IMI turns knowledge into patient outcomes

ltiple 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

IMI2 Strategic Research Agenda

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

I is evolving, with a stronger focus on the needs of patien

d 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**

4 priorities and first batch of ideas: Summary

Immunology	• Treatment of non-response and remission • Non-invasive molecular imaging of immune cells
Antimicrobial resistance	• Clinical trials networks • Accelerator of AMR R&D
Digital Health/Big Data	• Remote clinical trials • Biosensors/digital endpoints in clinical development
Modernisation of clinical trials and regulatory pathways	• Addressing the challenge of platform trials (Integrated Research Platforms)

- IMI2 - Call 15
-
- Call ID: H2020-JTI-IMI2-2018-15-TWO-STAGE Action Type: RIA – Research and Innovation Actions

- Topic 1: Integrated research platforms enabling patient-centric drug development
- Topic 2: Blockchain Enabled Healthcare
- Topic 3: Microenvironment imposed signatures in tissue and liquid biopsies in immune-mediated diseases
- Topic 4: Emerging translational safety technologies and tools for interrogating human immuno-biology
- Topic 5: Development and validation of translational platforms in support of synaptopathy drug discovery
- Topic 6: Digital endpoints in neurodegenerative and immune-mediated diseases

IMI2 - Call 15

Call ID: H2020-JTI-IMI2-2018-15-TWO-STAGE Action Type: RIA – Research and Innovation Actions

- Topics under the **IMI2 Antimicrobial Resistance** (AMR) Accelerator programme
- Topic 7: AMR Accelerator programme Pillar A: Capability Building Network to accelerate and validate scientific discoveries
- Topic 8: AMR Accelerator programme Pillar B: Tuberculosis drug development network to accelerate and validate scientific discoveries and advance the R&D pipeline of new and innovative agents to address the global tuberculosis epidemic

Indicative budget

From EFPIA companies and IMI2 Associated Partners:
EUR 214 847 000
From the IMI2 JU: **EUR 171 875 862**

Key dates and deadlines
Publication date: 18 July 2018
Stage 1 submission start date: 18 July 2018
Stage 1 submission deadline: 24 October 2018
Stage 2 submission deadline: 15 May 2019

Topic 1: Integrated research platforms enabling patient-centric drug development

There is a **clear shortage** of (i) investigators & investigational sites for phase 2-3 clinical trials, (ii) patients for enrolment in such trials, (iii) sharing of insights and use of real-world data, and (iv) investigations of combination treatments, in particular from different sponsors.

The action create best practices, tools and guidelines for establishing **multi-company platform trials** by leveraging, extending and improving concepts from previous pioneering multi-company platform trials to new disease areas.
The proposal is divided into (i) a set of common foundational elements applicable to all disease areas, (ii) clinical networks and networks of patient-level data and (iii) disease-specific integrated research platforms in several disease areas: major depressive disorder (MDD), tuberculosis (TB), non-alcoholic steatohepatitis (NASH) and neurofibromatosis (NF).

TOPIC : Blockchain Enabled Healthcare

- The overall objective of the agile project generated by this topic is to establish a common **blockchain ecosystem for pharmaceutical development**, manufacturing, and distribution that provides an incentive and serves as the basis for all participants to engage, adopt, and benefit from.

- The project will initially establish **an effective governance organisation** and approach to enable continuous improvement and open competition among service providers, while ensuring that critical factors such as data integrity, privacy, regulatory compliance and efficiency are built into a ‘Healthcare Foundation’ which serves as an integration layer between underlying blockchain technologies and the business application layer

TOPIC : Microenvironment imposed signatures in tissue and liquid biopsies in immune- mediated diseases

This topic aims to profile tissue-specific microenvironments to improve knowledge of pathophysiology of various immune-mediated diseases (such as inflammatory bowel disease: Crohn's disease and ulcerative colitis; and skin related diseases e.g. atopic dermatitis, cutaneous lupus, psoriasis) and identify signatures that can be correlated in body fluids (i.e. blood), 'circulating signatures', to inform on disease progression and to monitor treatment.

TOPIC : Microenvironment imposed signatures in tissue and liquid biopsies in immune- mediated diseases

1. Identify and evolve the state-of-the-art **novel technologies to interrogate both immune and non-immune cells** in target tissues at **single cell level** to better understand pathways regulating disease and to define tissue/disease-specific signatures, which can be correlated in peripheral blood. **The technologies** for the identified signature need to be adaptable and of sufficient robustness for **use in clinical trial.**
2. **Evaluate above technologies** in existing clinical retrospective cohorts as well as samples from ongoing clinical trials made accessible by both academic and industry partners.
3. **Perform a bespoke, enabling clinical study to verify signatures.** This will be a non-interventional prospective study, run as a collaborative effort between industry and academic partners.

TOPIC : Emerging translational safety technologies and tools for interrogating human immuno-biology

This topic aims to establish a public-private consortium that will enhance translational safety assessment approaches for immunomodulatory therapeutics (spanning oncology and non-oncology indications), with an emphasis on evaluating human-relevance.

- Development of innovative comparative (cross-species) in situ and ex vivo molecular, biochemical tools and cellular profiling of immune cells (including patient-derived clinical samples) and association with functional/phenotypic endpoints to enable;
- Establishment, refinement and validation of non-clinical tools and models to enable the development of novel classes of immunomodulatory medicines supporting in vitro-in vivo and cross-species translation.

TOPIC : Development and validation of translational platforms in support of synaptopathy drug discovery

The identification and validation of robust, sensitive and translational platforms capable of quantifying synaptic alterations both preclinically and clinically. Such platforms should be fit for purpose to detect and quantify dynamically both disease and treatment effects. Finally, we need to demonstrate the value of these new tools and methods for supporting drug discovery and development efforts across a spectrum of therapeutic CNS indications. At least one of the four major brain disorders namely **Alzheimer's, Parkinson's disease, major depression and schizophrenia, and ideally at least two, one in the neurodegenerative and one in the psychiatric/neurodevelopmental field.**

- Deep clinical phenotyping of CNS disorder patients to enable the development of robust tools to measure disease and treatment effects on the synapse.
- Characterisation of existing and development of novel preclinical synaptopathy disease models

TOPIC : Digital endpoints in neurodegenerative and immune-mediated diseases

Neurodegenerative movement disorders (NMD) and immune mediated inflammatory diseases (IMID) can cause considerable disability and morbidity in spite of the availability of approved treatments. Recent estimates suggest that neurodegenerative disorders are becoming one of the fastest growing costs for healthcare systems. Movement disorders, in particular Parkinson's disease (PD), affect about 1.2 million European citizens, a number set to double by 2050 While rarer, the burden of Huntington's disease can be up to 5 times higher than that of PD patients.

Digital technology, in particular remote monitoring systems, if properly implemented and validated, could provide a critical help in improving measurements of efficacy by increasing sensitivity and precision, reducing variability, and enhancing their ecological validity making them closer to the actual unmet needs of patients. This project will develop a technology platform to collect and analyse sensor/generated datasets, principally high resolution passively and actively collected digital measurements, i.e. actigraphy, socialisation parameters and momentary self-reported assessments, mainly using (but not limited to) wearables and smartphone sensors and apps.

AMR Accelerator programme Pillar A: Capability Building Network to accelerate and validate scientific discoveries

There are significant scientific challenges to the discovery and development of new agents to treat and prevent AMR infections, including those caused by Gram-positive and Gram-negative bacteria, Mycobacterium tuberculosis, and non-tubercular mycobacteria (NTM). Models, approaches, and tools to support antibiotic drug development need to be validated and shared more widely to serve the AMR community. Alternative approaches to treating infections and platforms that enhance the success for vaccines and monoclonal antibodies require robust validation. The AMR Accelerator will provide, under one operational structure, a wide-ranging series of projects that will address many of the scientific challenges in AMR.

AMR Accelerator programme Pillar A: Capability Building Network to accelerate and validate scientific discoveries

The Capability Building Network (CBN), Pillar A of the IMI2 AMR Accelerator programme, will work to address the innovation gap in the AMR space by enabling pre-competitive research in the treatment and prevention of multi-drug resistant infections.

AMR strategy on a global scale;

conduct pre-competitive research aimed to (1) provide learnings derived from shared vaccine and/or antibacterial clinical trial data; (2) improve understanding of variability and translatability of **animal models of bacterial infection**.

AMR Accelerator programme Pillar B: Tuberculosis drug development network to accelerate and validate scientific discoveries and advance the R&D pipeline of new and innovative agents to address the global tuberculosis epidemic

There are significant scientific challenges to the discovery and development of new agents to treat and prevent AMR infections, including those caused by Gram-positive and Gram-negative bacteria, Mycobacterium tuberculosis, and non-tubercular mycobacteria (NTM). The AMR Accelerator will provide, under one operational structure, a wide-ranging series of projects that will address many of the scientific challenges in AMR.

AMR Accelerator programme Pillar B: Tuberculosis drug development (cont).

(1) coordinate, profile and progress the portfolio of anti-TB compounds existing within the industry consortium (EFPIA companies and Associated Partners) from the advanced lead stage through Phase 1 (candidates ready to enter into Ph-2 clinical studies);
(2) identify preferred drug partners for preclinical combination studies that will facilitate the design of combination regimens consisting of new TB drugs with an indication for the treatment of any form, including MDR, of TB (pan-TB regimen);
(3) create additional tools and technologies to progress anti-TB compounds, and to provide learnings derived from the analysis of shared anti-TB clinical trial data;
(4) develop new alternative anti-tubercular drugs (host-defence or virulence approaches);
(5) act as an interface with stakeholders in the TB field and explore synergies and collaboration with the action resulting from IMI2 JU Call 15, topic 7 and potential TB-focused actions from IMI2 JU Call 16 as well as other AMR initiatives.

https://www.imi.europa.eu/apply-funding/open-calls/imi2-call-15

Useful information

Sign up to / catch up on the IMI2 – Call 15-16 webinars.

Read our tips for applicants and advice on finding project partners.

ERA-NETs

Δράσεις Ευρωπαϊκής E&T Συνεργασίας (6)

Γ & Δ ΦΑΣΗ ERANET : ΠΡΟΚΗΡΥΞΕΙΣ 2018 & 2019

Τίτλος	Ερευνητικά Πεδία	Χώρες	προϋπολογισμός ΕΠΑΝΕΚ	Σύνολο ERANet
CHIST-ERA (ICT)	Big data and process modelling for smart industry (BDSI)	**FR,** AT, BE, BL,CA, CZ, EE, FI, EL, IE, IT, LT, PL, RO, ES, SK, CH, TR, UK	1.50m€	14.3m€
E-RARE-3	Rare Diseases	**FR,** AT, BE, CA, DE, EL, HU, IL, IT, LV, PL, RO, ES, FI, CZ, NL, TR	0.5m€	18.5m€
EURONANOMED-3	Regenerative medicine, Diagnostics, Targeted delivery systems	**ES,** FR, BE, EL, DE, IL, IT, LV, LT, NO, PL, PT, RO, ES, SK, EE, NL, CA, TW, TR	0.6m€	14m€
TRANSCAN-2	Translational research on rare cancers	**IT,** AT, BE, FR, DE, EL, HU, IL, LV, PL, PT, ES, NL, TR, EE, NO, SK, SI, TW	1m€	17m€
Cofund on Blue Bioeconomy (BlueBio)	Aquaculture, Seafood processing, Fisheries, Marine biotech	**NO,** BE, FR, DE, EL, EE, ES, IT, AR, RO, NL, IS, HR, FI, DK, IE, PT, SE	0.7m€	25.4m€
ACT ERANET	Accelerating CCS technologies as a new low-carbon energy vector	**NO,** FR, DE, EL, ES, RO, NL, UK, USA, CH, TR	0.8m€	~35m€
SOLAR ERANET	integrated PV, Operation and diagnosis of PV plants CSP low cost and next	**CH,** AT, CY, FR, DE, EL, ES, PL, NL, UK, SE, TR	0.5m€	~30m€

ERAPerMed

- Αφορά διάδοχο σχήμα του ERA NET Cofund της δράσης συντονισμού και στήριξης του ΠΠ7 “Personalised Medicine 2020 and beyond – Preparing Europe for leading the global way (PerMed)” που ξεκίνησε το 2013. Το είδος έρευνας που διεξάγεται συνδέεται με κλινικές δοκιμές. Ο γενικός στόχος της πρώτης κοινής διακρατικής πρόσκλησης υποβολής προτάσεων για το ERAnet είναι η χρηματοδότηση σχεδίων που παρουσιάζουν κλινική σκοπιμότητα σε πολύπλοκες ασθένειες (συμπεριλαμβανομένων πολυπαραγοντικών, μονογονιδιακών και άλλων ασθενειών).
-
-

ERAPerMed

- Το ERA PerMed υποστηρίζεται από 31 εταίρους, Αυστρία, Βέλγιο, Καναδάς (Κεμπέκ), Κροατία, Δανία, Εσθονία, Φινλανδία, Γαλλία, Γερμανία (Σαξονία), Ουγγαρία, Ιρλανδία, Ισραήλ, Ιταλία, Λομβαρδία, Λουξεμβούργο, Ολλανδία, τη Νορβηγία, την Πολωνία, τη Ρουμανία, την Ισπανία (κοινότητες Καταλονία & Ναβάρα), Σουηδία και Τουρκία με συντονίστρια χώρα την Ισπανία, Nacional Institute of Health Carlos III – Instituto de Salud Carlos III και συγχρηματοδοτείται από την Ευρωπαϊκή Επιτροπή.
- Κοινές εθνικές ερευνητικές στρατηγικές, να προωθηθεί η αριστεία, να ενισχυθεί η ανταγωνιστικότητα των ευρωπαίων παραγόντων στους πρωθυπουργούς και να ενισχυθεί η ευρωπαϊκή συνεργασία με τρίτες χώρες, οι 31 χρηματοδοτικοί οργανισμοί συμφώνησαν να ξεκινήσουν την πρώτη κοινή διακρατική πρόσκληση για συνεργατικά καινοτόμα ερευνητικά προγράμματα στην εξατομικευμένη ιατρική. Οι οργανισμοί χρηματοδότησης που συμμετέχουν στην πρόσκληση υποβολής προτάσεων επιθυμούν ιδιαίτερα να προωθήσουν την καινοτόμο διεπιστημονική συνεργασία και να ενθαρρύνουν τις μεταφραστικές ερευνητικές προτάσεις.

ERAPerMed

2η προκήρυξη σε προετοιμασία (θα συμμετάσχει η ΓΓΕΤ)

NEURON

Το ERA-NET NEURON Cofund συντονίζει ευρωπαϊκά και διεθνή προγράμματα χρηματοδότησης στον τομέα έρευνας των ασθενειών που σχετίζονται με τον εγκέφαλο και τις διαταραχές του νευρικού συστήματος. Βασική δραστηριότητα είναι η υλοποίηση κοινών διακρατικών προσκλήσεων για την υποβολή ερευνητικών προτάσεων.

Το NEURON Cofund θα αναπτύξει και θα προσπαθήσει να δώσει προτάσεις για (i) την επέκταση της ανταλλαγής δεδομένων, (ii) την προώθηση δεδομένων για τη δημιουργία μητρώων ασθενών, και (iii) τη συμμετοχή ενδιαφερομένων και ενσωμάτωση άλλων πρωτοβουλιών, όπως οργανώσεις ασθενών. Στο χρηματοδοτικό δίκτυο συμμετέχουν 28 χρηματοδοτικοί οργανισμοί. Μέχρι στιγμής έχει δημοσιεύσει 4 προκηρύξεις.

5η προκήρυξη σε προετοιμασία (θα συμμετάσχει η ΓΓΕΤ) με 1 Μ€.

Ευχαριστώ πολύ για την προσοχή σας

Δρ. Σ. Κολυβά
Ελληνικό Ινστιτούτο Παστέρ
s.kolyva@pasteur.gr