«*Βασική & Κλινική Έρευνα στην ανάπτυξη φαρμάκων και προηγμένων θεραπειών : Πως αντιλαμβάνονται και εκπληρώνουν οι επιστήμονες των βιοιατρικών επιστημών τον ρόλο τους στην σύγχρονη διεπιστημονική αυτή διαδικασία*»

«ΠΜΣ ΕΚΠΑ: Λοιμωξιολογία»

Γ εξάμηνο-Παρασκευή 9-12-2022

Dr. Βαρβάρα Μπαρούτσου,EMAUD,GFMD

Εσωτερικός Παθολόγος

Πρόεδρος ΕΛ.Ε.Φ.Ι.

IFAPP President

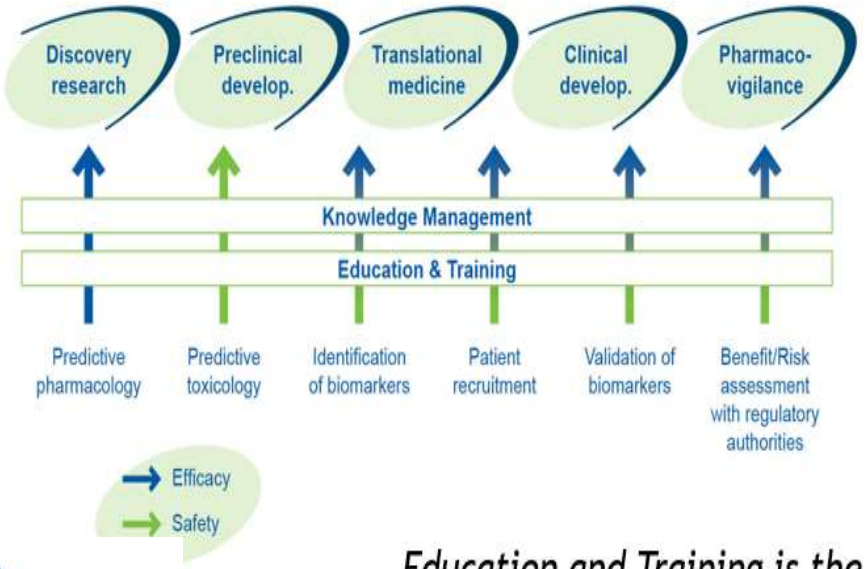
Περίγραμμα

- Μέρος 1
  - Εισαγωγή στην Φαρμακευτική Ιατρική
    - Μεταπτυχιακή εκπαίδευση, Πιστοποίηση & Συνεχιζόμενη εκπαίδευση
  - Τάσεις στην Κλινική Έρευνα & Ανάπτυξη
    - Κλινικές Δοκιμές & Μελέτες
- Μέρος 2
  - Πανδημία COVID-19
    - Επίδραση στην ανάπτυξη φαρμάκων και μοντέλων έρευνας
    - Ανάπτυξη εμβολίων
- Μέρος 3
  - Κανονιστικό πλαίσιο για τις Κλινικές Δοκιμές στην ΕΕ
- Μέρος 4
  - Η Κλινική Έρευνα στην Ελλάδα
    - Πρωτοβουλία ΕΛ.Ε.Φ.Ι.
      - Clinical Research & Clinical trials Innovation Forum

Εισαγωγή

ΜΈΡΟΣ 1
ΦΑΡΜΑΚΕΥΤΙΚΉ ΙΑΤΡΙΚΉ
& ΤΆΣΕΙΣ ΣΤΗΝ ΚΛΙΝΙΚΉ
ΈΡΕΥΝΑ

Research Scientific Postgraduate Education and continuous learning



Education and Training is the foundation for the entire value chain

PharmaTrain Syllabus Revision Project (SRP)

- AIM: To revise PharmaTrain Syllabus for Pharmaceutical Medicine / Medicines Development Science V1.0 (2/2010)
- Sponsors: IFAPP, FPM, PTF. SRP Project Centre: FPM
- Revised Syllabus V2.0 2018 available: 22 December 2017
- Roll-out revised PharmaTrain Syllabus V2.0 2018 from 1 January, 2018

Project summary

- Project Timeline: 4 Nov'16 to 31 Dec '17
- Submission of draft revisions: 30 Jun'17
- Completion of Syllabus coordination: 31 Aug'17
- Review and reconciliation: 30 Nov'17
- Revised Syllabus V2.0 available: 22 December 2017

IFAPP Pharmaceutical Medicine

ΕΛ.Ε.Φ.Ι. ΕΛΛΗΝΙΚΗ ΕΤΑΙΡΕΙΑ ΦΑΡΜΑΚΕΥΤΙΚΗΣ ΙΑΤΡΙΚΗΣ

Ευρωπαϊκός Οργανισμός PharmaTrain

Mastering Medicine Development

PharmaTrain is implementing reliable standards for high-quality postgraduate education and training in Medicines Development. Training Centres, which offer Diploma Courses, Master Programmes as well as CPD Modules and training courses under the PharmaTrain brand share the high PharmaTrain standards and undergo quality assessments.

https://www.pharmatrain.eu/index.php

innovative medicines initiative

PharmaTrain
MASTERING MEDICINES DEVELOPMENT

History

https://www.pharmatrain.eu/

Προγράμματα και εκπαιδευτικά κέντρα PharmaTrain

Masters / Diploma List

Search for anything: Course Provider, Course Name, Country, ...

Course Name	Course Provider	PharmaTrain Recognition	Country
CEMDC Cooperative European Medicines Development Course (2017-2019)	CEMDC, Semmelweis University	Centre of Excellence	Hungary
Diploma of Advanced Studies in Pharmaceutical Medicine	University of Basel - European Center of Pharmaceutical Medicine (ECPM)	Centre of Excellence	Switzerland
Drug Development Science MSc/PgDip/PgCert	King's College London	Centre of Excellence	United Kingdom
Eu2P Master Degree in Pharmacovigilance and Pharmacoepidemiology	Eu2P	PharmaTrain Centre	World Wide (Distance Learning)
Master in Preclinical and Clinical Research and Development of Drugs	University of Milano Bicocca	Centre of Excellence	Italy
Master of Advanced Studies in Medicines Development (MMD)	University of Basel - European Center of Pharmaceutical Medicine (ECPM)	Centre of Excellence	Switzerland
Master of Science in Clinical Research	Donau-Universität Krems	Centre of Excellence	Austria
MSc Pharmaceutical Medicine	University Claude Bernard Lyon, Eudipharm	Centre of Excellence	France
MSc Pharmaceutical Medicine	University of Duisburg-Essen	Centre of Excellence	Germany
MSc Preclinical and Clinical Drug Development: Scientific, Regulatory and Ethical Aspects	Catholic University Medical School, Rome	Centre of Excellence	Italy
Pharmaceutical Medicine MSc, PgDip	Trinity College Dublin	Centre of Excellence	Ireland
Post-Graduate Programme in Pharmaceutical Medicine & Medicines Development Sciences	Free University of Brussels (ULB), PHARMED	Centre of Excellence	Belgium

PharmaTrain
MASTERING MEDICINES DEVELOPMENT

IFAPP Webinar: 27 October, 2022

Objectives and Achievements of the IFAPP - PharmaTrain Collaboration

IFAPP and PharmaTrain – A successful collaboration on quality in education in pharmaceutical medicine

The IMI Project «PharmaTrain» Consortium

- EFCPM = European Federation of Course Providers in Pharmaceutical Medicine (most of the European universities offering Pharmaceutical Medicine Diploma or Master Courses), was later renamed to “PharmaTrain Federation”
- IFAPP
- Additional universities like Copenhagen, Freiburg, Strasbourg, etc.
- Learned societies like EUFEPS, Faculty of Pharmaceutical Medicine, EFGCP, DIA, EORTC, etc.
- 15 pharmaceutical companies

PharmaTrain
MASTERING MEDICINES DEVELOPMENT

From Syllabus Topics to Modular Content
Learning Outcomes and Competencies

covering the entire medicines development process

↓

180 topics

↓

14 Syllabus Sections

↓

6-12 module programmes (taught at master level)

↓

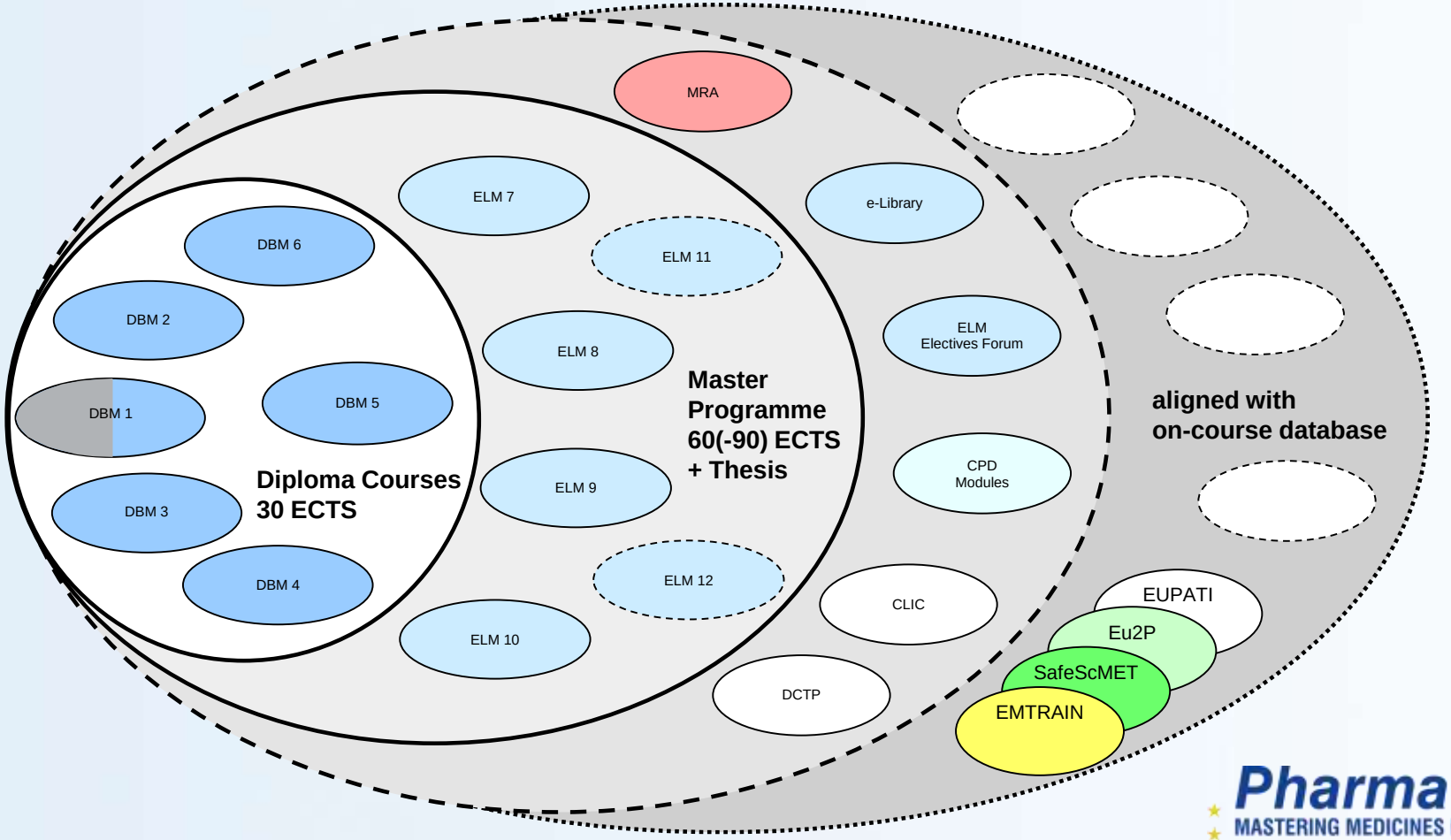
6-10 Learning outcomes per module towards Diploma/Master degree (academic)

towards a set of cognitive competencies required for Specialist title (vocational)

PharmaTrain
MASTERING MEDICINES DEVELOPMENT

PharmaTrain Modular Product Portfolio

More than 200 Modules from European and Global Partners build the integrated programmes and can be used à la carte:



PharmaTrain
MASTERING MEDICINES DEVELOPMENT

PharmaTrain Quality Criteria for Courses

A formalised and transparent QA/QC policy

1 University accreditation OR a suitable system for approving, monitoring and reviewing the training offered

2 A system for ensuring quality of teaching staff

3 Regular review of the QA/QC processes

A set of documented criteria for individual modules, courses or course programmes

4 Defined and transparent admission criteria

5 A predefined set of teaching objectives, leading to defined learning outcomes

6 Adequate facilities, infrastructure, leadership and competences

7 Assessment of the trainees' achievement according to the learning outcomes

8 A system for collecting, assessing and addressing feedback

9 Adaequate reference materials

PharmaTrain MASTERING MEDICINES DEVELOPMENT

PharmaTrain Centre Assessment Process

Recognition request by the centre
Preparation of documents and questionnaires

Nomination of 3 assessors
Preparation of the assessment visit

Assessment on-site or virtual
(1-2 assessors)

Assessment report with recommendation
Approval by the Executive Board PTF

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE RECOGNITION

PharmaTrain
MASTERING MEDICINES DEVELOPMENT
CENTRE OF EXCELLENCE

PharmaTrain
MASTERING MEDICINES DEVELOPMENT

PharmaTrain Recognition

PharmaTrain Centers of Excellence

University-based courses in pharmaceutical medicine fulfilling the PharmaTrain Centre of Excellence Recognition requirements

PharmaTrain Centers

Diploma and master programmes as well as large training organisations covering topics of the PharmaTrain Syllabus and fulfilling the PharmaTrain Centre Recognition requirements

PharmaTrain Courses

Individual “short” courses of at least 8 hours duration covering a PharmaTrain Syllabus topic and fulfilling the PharmaTrain Course Recognition requirements

PharmaTrain
MASTERING MEDICINES DEVELOPMENT

PharmaTrain Federation's and IFAPP's Global Role

Creation of a global quality environment in pharmaceutical medicine and clinical research through

- Training of different stakeholders in medicines development
  - ✓ Physicians' specialisation in pharmaceutical medicine
  - ✓ MD/Non-MD "Specialist in pharmaceutical medicine"
  - ✓ "University Professional in Clinical Trial Practices"
  - ✓ Responsibility-adapted training of investigators
- Growing the course quality recognition environment "PharmaTrain Course Recognition"
- Enabling the competence of professionals working in pharmaceutical medicine / medicines development

PharmaTrain
MASTERING MEDICINES DEVELOPMENT

Επαγγελματική σταδιοδρομία στην Κλινική Έρευνα

Life Science Career Tips | Tips for PhD students & Postdocs

Why Clinical Research is a Hot Career Choice For 2021 and Beyond

Last updated Oct 19, 2020 — 0

Imagine waking up to the news that the vaccine you relentlessly worked upon has saved millions of lives across the globe! Clinical research is one of the noblest fields that attempt to improve the quality of life! It involves translating basic and advanced research involving human subjects into novel treatments and therapies. Indeed, with medical and pharmaceutical companies growing at a fast pace, there is a huge demand for proficient clinical research professionals. Let us look at what clinical research has to offer us in the near future!

https://www.enago.com/academy/clinical-research-hot-career-2021-beyond/?utm_source=emailer&utm_medium=email&utm_campaign=news_061020

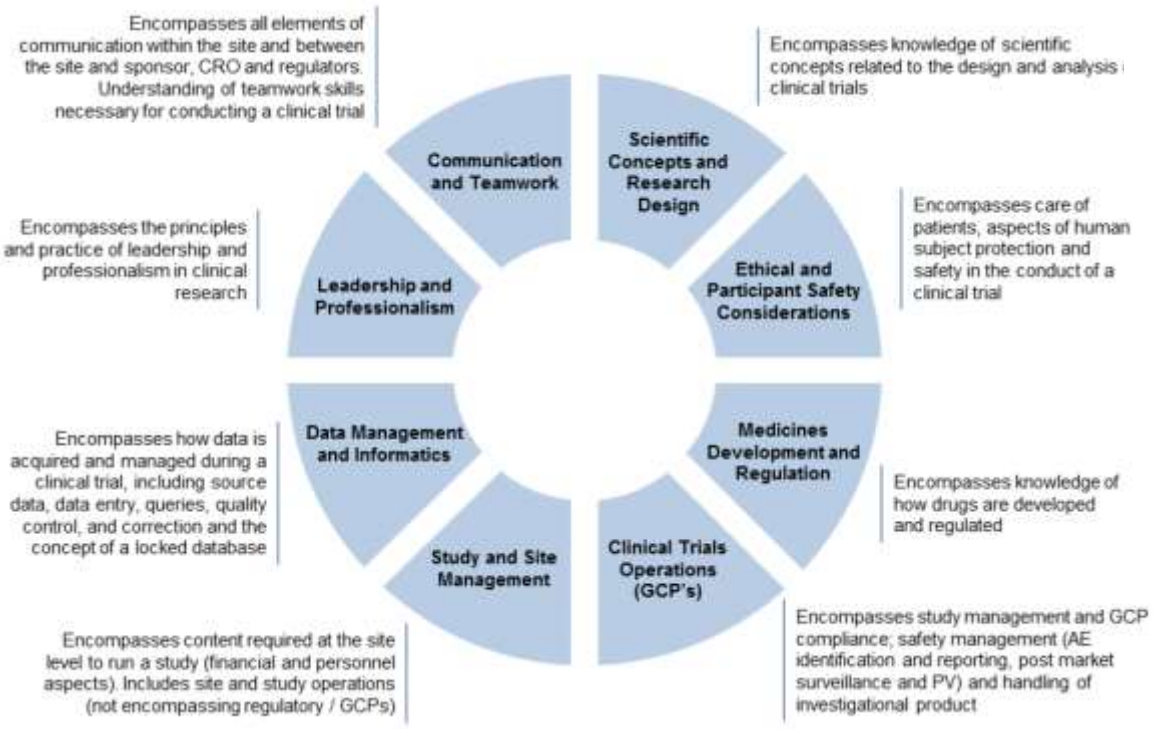
NIH Core competencies for Clinical Research

CLIC Center for Leading Innovation & Collaboration — *Amplifying research impact*

- Core competencies for Clinical and Translational Research
- Special Interest Competencies which include competencies for:
  - Pediatric Translational Research
  - Special Considerations for T1 Research
  - Academia-Industry Drug Development
  - Medical Device Innovation & Technology Transfer

https://clic-ctsa.org/education/competencies

Η βασική κατάρτιση των κλινικών ερευνητών 6/2014



MULTI-REGIONAL CLINICAL TRIALS
THE MRCT CENTER of BRIGHAM AND WOMEN'S HOSPITAL and HARVARD

https://mrctcenter.org/clinical-trial-competency/

Ατομική αντίληψη ερευνητικών ικανοτήτων ανά τομέα

TABLE 1: Self-Perceived Level of Competence in JTF Domains by Role

Domains	Competence/Role (mean value)					
	DM (n = 47)	RA (n = 90)	CRC/CRN (n = 559)	CRA (n = 177)	RM/PM (n = 357)	PI/CoPI (n = 354)
Scientific Concepts and Research Design	0.3	0.3	0.3	0.4	0.4	0.8
Ethical and Participant Safety Considerations	0.4	0.7	0.7	0.7	0.7	0.8
Medicines Development and Regulation	0.3	0.5	0.4	0.5	0.5	0.5
Clinical Trials Operations	0.4	0.6	0.6	0.8	0.7	0.8
Study and Site Management	0.3	0.4	0.5	0.6	0.7	0.7
Data Management and Informatics	0.7	0.4	0.6	0.7	0.6	0.7
Leadership and Professionalism	0.4	0.5	0.6	0.6	0.7	0.8
Communication and Teamwork	0.5	0.5	0.6	0.6	0.6	0.8

Note: ANOVA $p<0.0001$ between roles across all domains at 5% significance. Shaded area ≥ 0.6, "competent."

Εμπειρία επιστημόνων Χορηγών

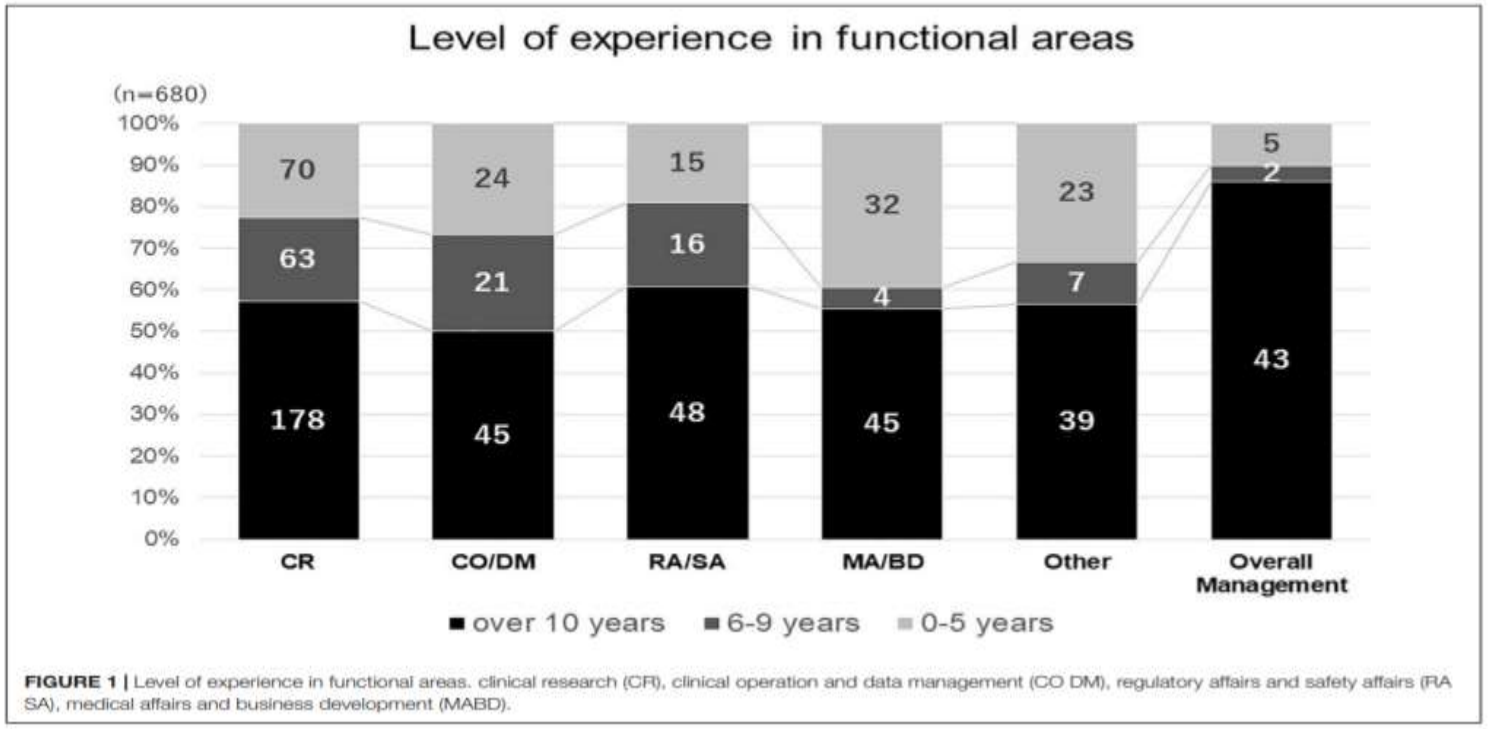


FIGURE 1 | Level of experience in functional areas. clinical research (CR), clinical operation and data management (CO DM), regulatory affairs and safety affairs (RA SA), medical affairs and business development (MABD).

Front. Pharmacol., 05 March 2019 | https://doi.org/10.3389/fphar.2019.00188

Εκπαιδευτικές ανάγκες επιστημόνων χορηγών

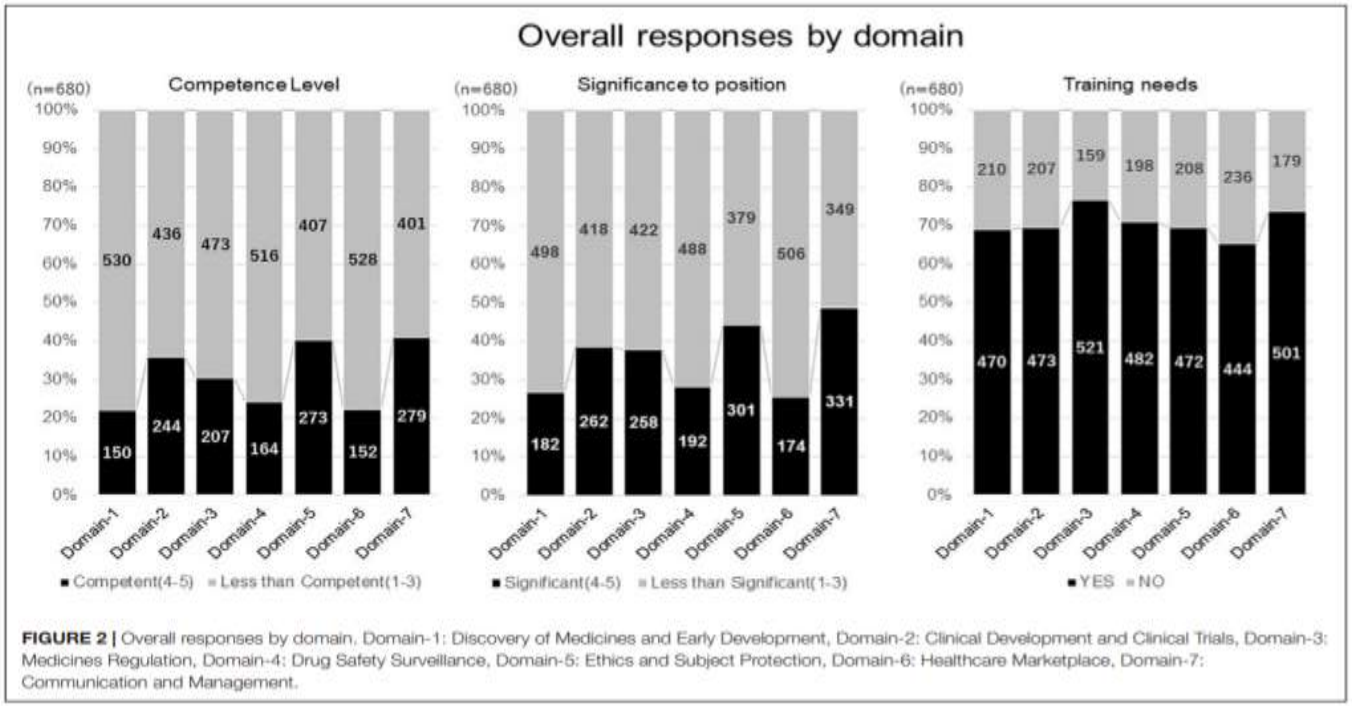


FIGURE 2 | Overall responses by domain. Domain-1: Discovery of Medicines and Early Development, Domain-2: Clinical Development and Clinical Trials, Domain-3: Medicines Regulation, Domain-4: Drug Safety Surveillance, Domain-5: Ethics and Subject Protection, Domain-6: Healthcare Marketplace, Domain-7: Communication and Management.

Front. Pharmacol., 05 March 2019 | https://doi.org/10.3389/fphar.2019.00188

Average self-assessed competency rating by role and by domain

Role	Number of respondents	Scientific concepts and research design	Ethical and safety considerations	Investigational product development and regulation	Clinical study operations	Study and site Mgt	Data Mgt and informatics	Leadership and professionalism	Communications and teamwork
Clinical research associate/monitor	52	6.9	7.4	7.3	7.9	7.7	7.3	7.9	7.5
Clinical research coordinator/study nurse	183	6.4	7.5	6.1	7.6	6.9	7.1	7.4	6.7
Educator/trainer	51	7.8	8.4	7.8	8.5	8.3	7.4	8.5	8.8
Principal investigator/co-investigator	51	7.5	8.0	6.9	7.7	7.0	6.8	8.0	7.7
Project manager/research manager	164	7.5	8.2	7.9	8.3	8.8	7.8	8.6	8.3
Regulatory affairs professional (49)	46	6.8	8.3	7.5	7.8	6.8	6.6	8.1	6.8
Average of all roles	661	6.9	7.8	7.1	8.0	7.5	7.1	8.0	7.6

Therapeutic Innovation &regulatory Science (2022) 56:607-615
https://link.springer.com/article/10.1007/s43441-022-00395-z

Average self-assessed competency rating by experience &professional certification

Self-assessed competency rating by experience

Years of experience	Number of respondents	Scientific concepts and research design	Ethical and safety considerations	Investigational product development and regulation	Clinical operations (GCPs)	Study and site management	Data management and informatics	Leadership and professionalism	Communications and teamwork
0–2	78	5.2	5.9	4.9	5.5	4.9	5.6	6.3	5.9
3–5	95	6.4	6.9	6.4	7.0	6.7	7.1	7.4	7.0
6–10	102	6.7	7.7	6.7	7.0	7.2	6.5	7.8	7.2
>10	386	7.8	8.6	7.9	8.9	8.4	7.7	8.6	8.2
Average of total	661	6.9	7.8	7.1	8.0	7.5	7.1	8.0	7.6

Self-assessed competency by professional certification

	Number of respondents	Scientific concepts and research design	Ethical and safety considerations	Investigational product development and regulation	Clinical study operations	Study and site management	Data management and informatics	Leadership and professionalism	Communication and teamwork
ACRP and/or SoCRA Certified	274	7.3	8.3	7.7	8.0	8.4	7.6	8.3	7.8
No professional certification	306	6.8	7.4	6.4	7.4	6.8	6.7	7.7	7.2

Therapeutic Innovation &regulatory Science (2022) 56:607-615
https://link.springer.com/article/10.1007/s43441-022-00395-z

ΗΠΑ ενδεικτικά προγράμματα εκπαίδευσης κλινικών ερευνητών

Sample online offerings:

- Northwestern University, Clinical and Translational Sciences Institute *Introduction to Clinical Research* Online Modules
- University of Washington, Institute of Translational Health Sciences (ITHS), Self-Directed Learning Center
- Office of Research Integrity: *The Lab*, *The Research Clinic*
- NIH: *Teaching the Responsible Conduct of Research*
- ACRP: *GCP—An introduction to ICH GCP Guidelines*
- Collaborative Institutional Training Initiative (CITI): *Populations in Research Requiring Additional Consideration*
- UC Davis: *Strengthening Provider Patient Communication Skills in Clinical Trials.*
- ***Tufts University Center for the Study of Drug Development***

Swiss Clinical Trials Organization Tools for academic researchers

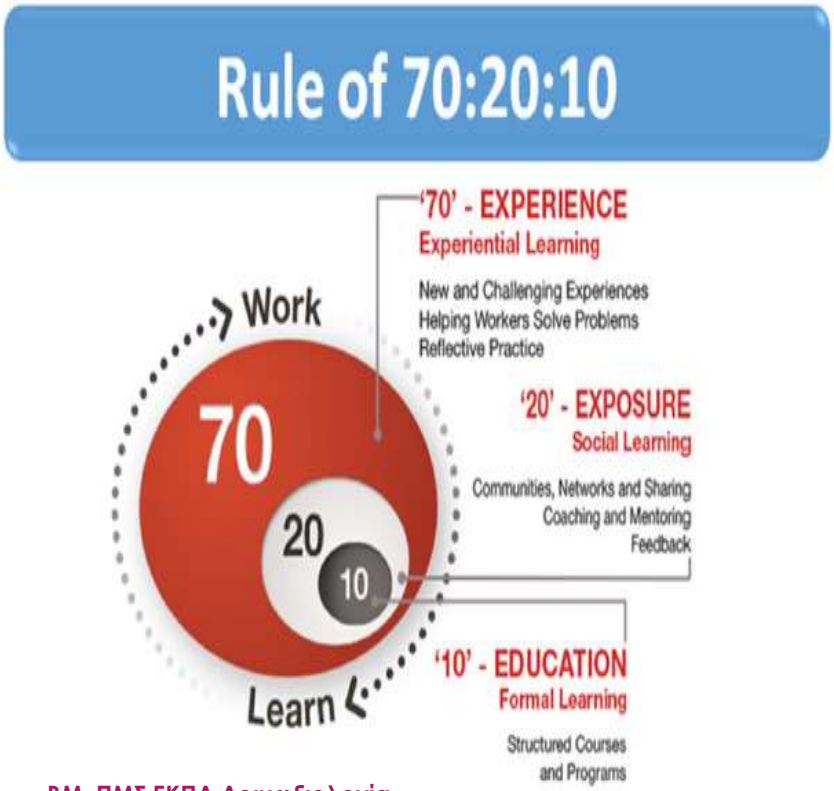
Welcome to the Tools & Resources website for clinical research professionals.

Every clinical research project comes with its own set of considerations. Having the right tools at hand is crucial for its success.

↓

https://www.sctoplatforms.ch/

Δια βίου εκπαίδευση ερευνητών



Experience
- Sabbatical

Exposure
Exchange program

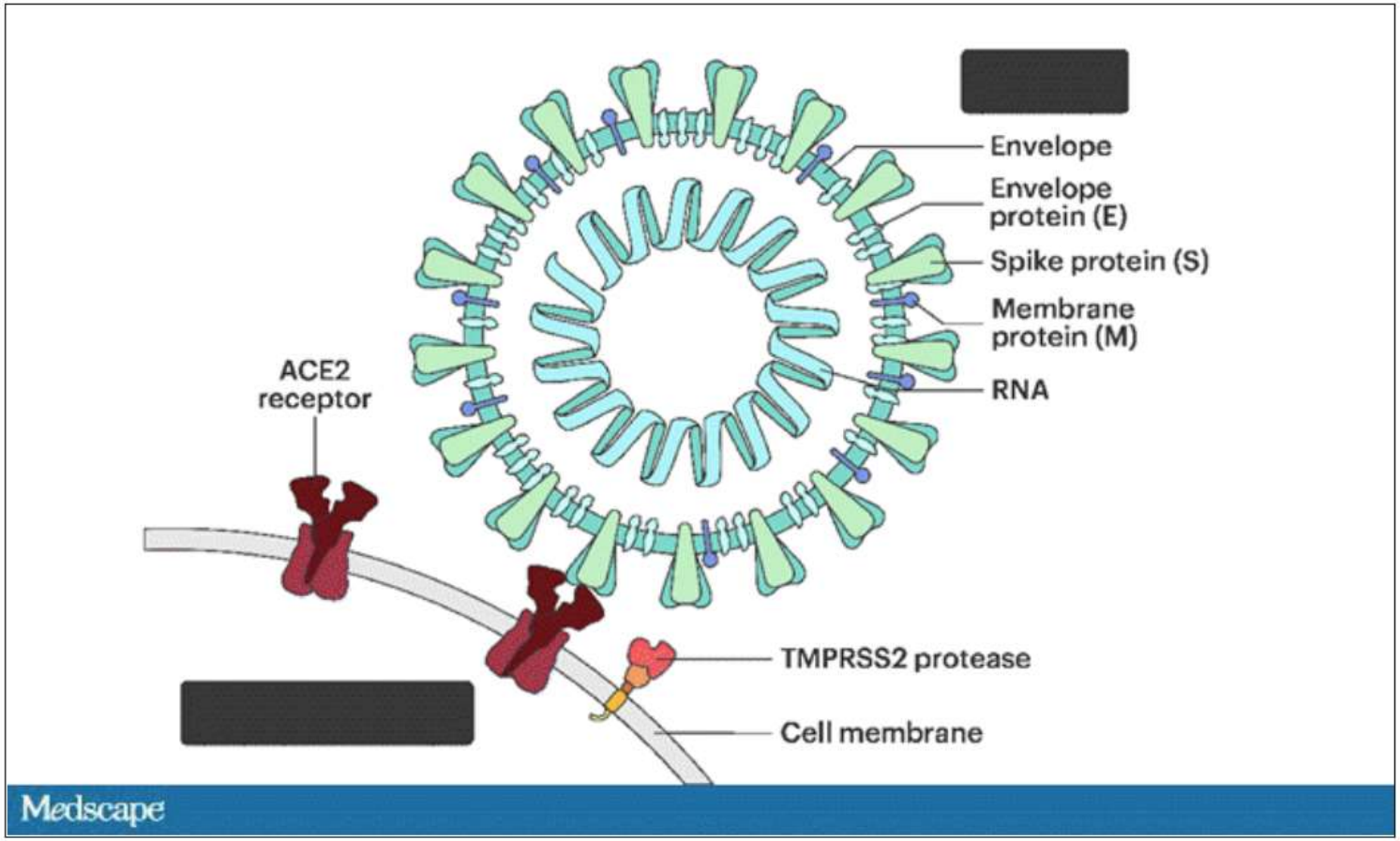
Network
- Collaborative projects

Case Study

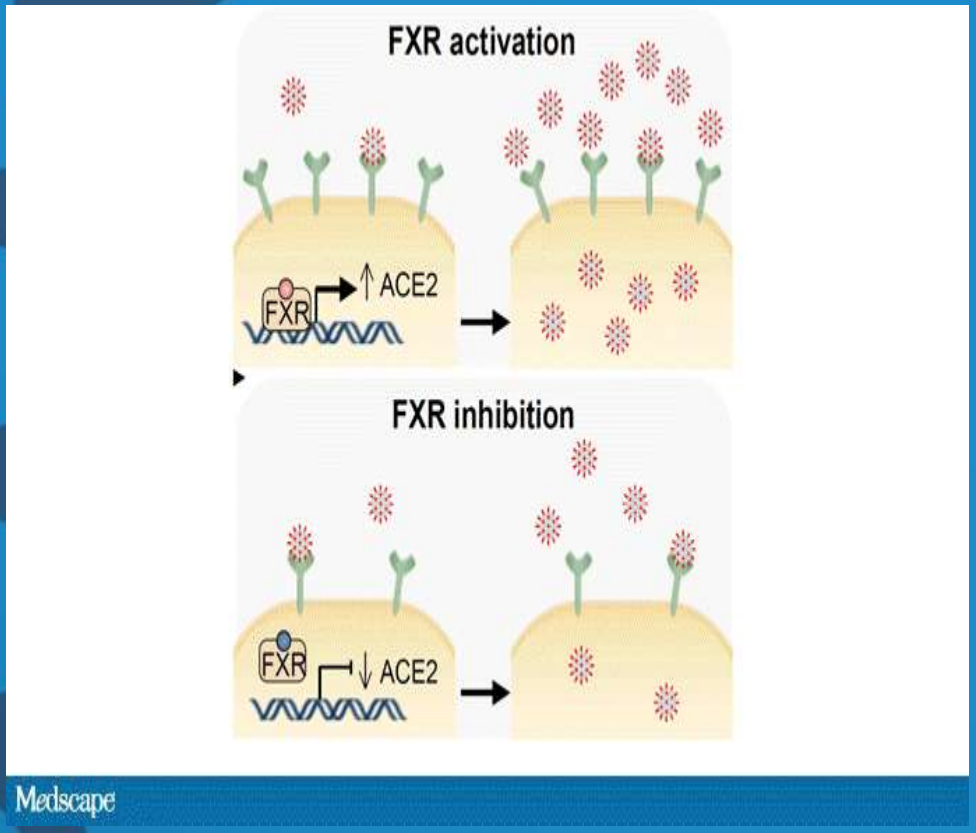
BASIC RESEARCH AND PHASE I BASED ON A BIOLOGIC PLAUSIBLE HYPOTHESIS

Repurposing of UDSA case study for Covid-19

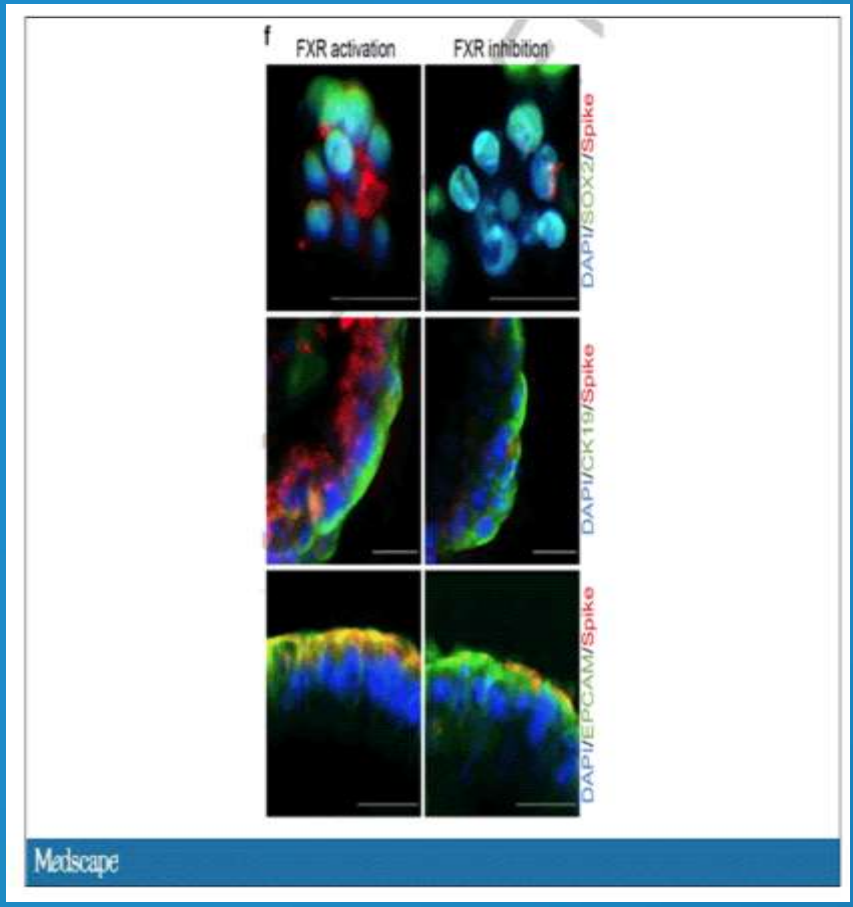
All good science starts with a biologically plausible hypothesis. In this case, the authors recognized that SARS-CoV-2, in all its variants, requires the presence of the ACE2 receptor on the surface of cells to bind.

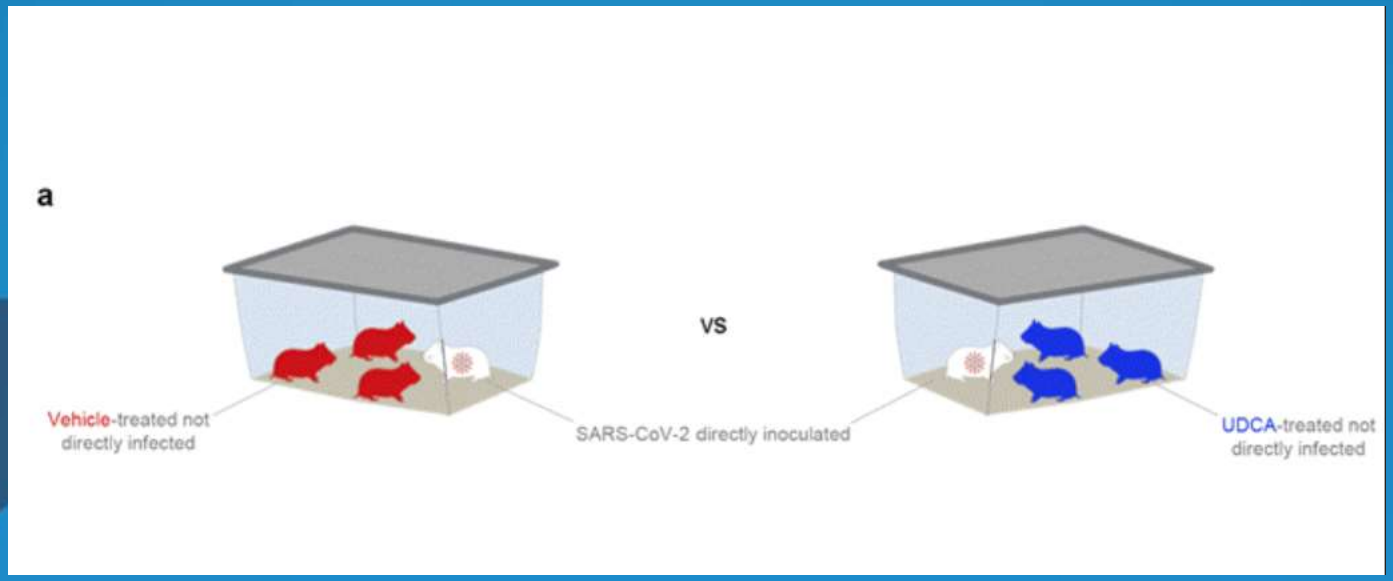


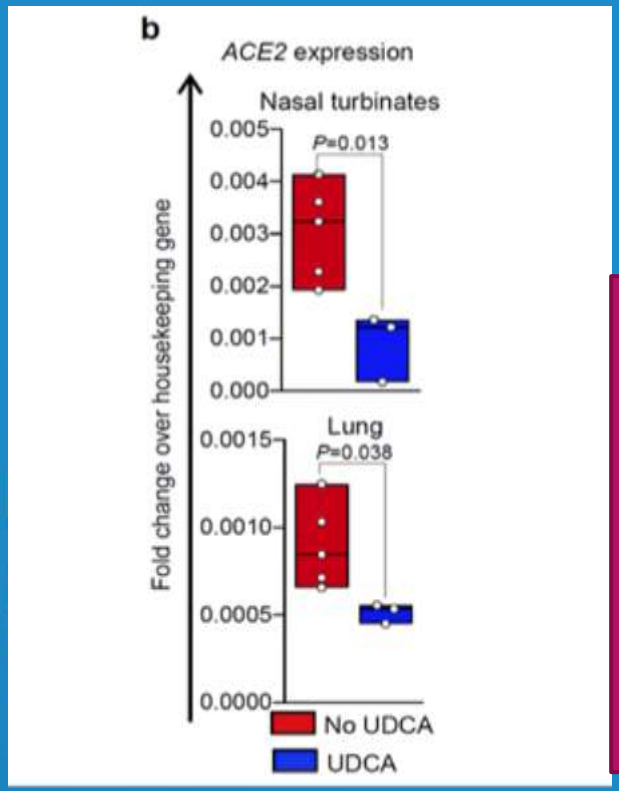
The authors first showed that the controlling transcription factor known as the farnesoid X receptor, or FXR affects ACE2 expression. Reducing the binding of FXR should therefore reduce ACE2 expression



The red staining here is spike protein; you can see that it is markedly lower in the cells exposed to UDCA (right column).

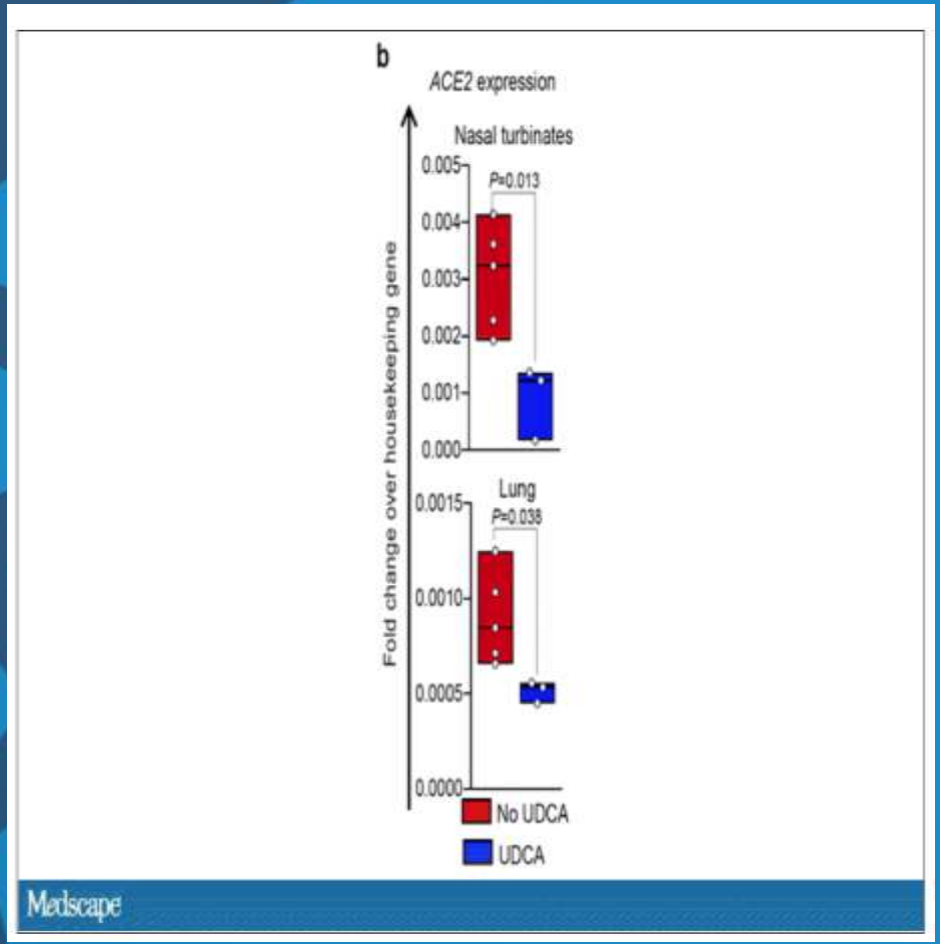


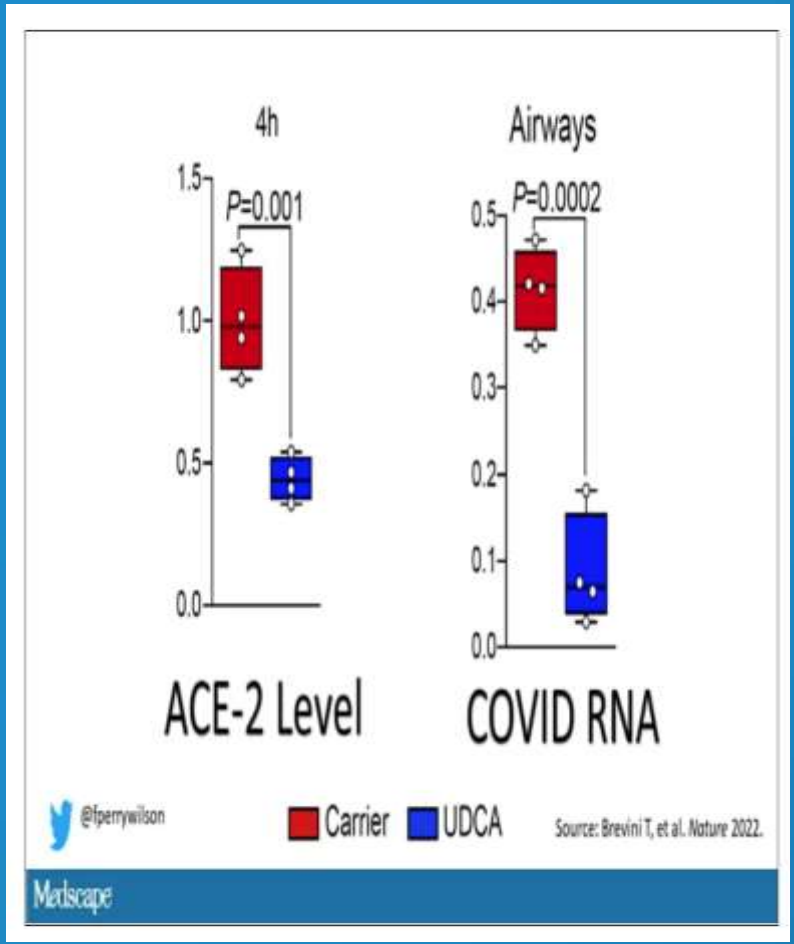




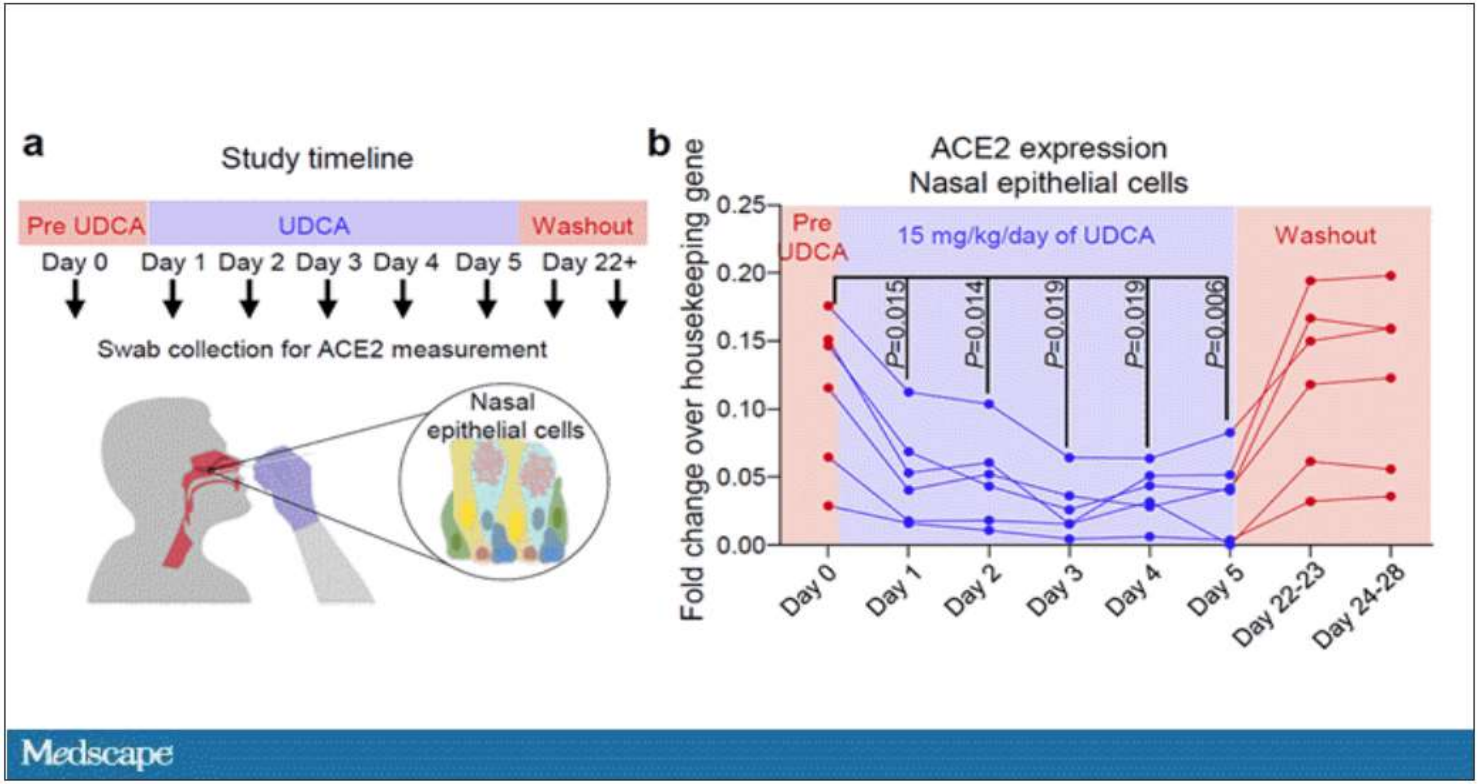
They also showed that mice and hamsters treated with UDCA had lower levels of ACE2 in their nasal passages and lung.

The authors were able to show that ACE2 levels went down in the exposed lung. And, importantly, when samples of tissue from both lungs were exposed to SARS-CoV-2, the lung tissue exposed to UDCA had lower levels of viral infection.





Eight human volunteers were recruited to take UDCA for 5 days. ACE2 levels in the nasal passages went down over the course of treatment. They confirmed those results from a proteomics dataset with several hundred people who had received UDCA for clinical reasons. Treated individuals had lower ACE2 levels.



UDCA CASE STUDY CREDITS:
IMAGE 1: *INNOVATIVE GENOMICS*
IMAGE 2: *NATURE*
IMAGE 3: *NATURE*
IMAGE 4: *NATURE*
IMAGE 5: *NATURE*
IMAGE 6: F. PERRY WILSON, MD, MSCE
IMAGE 7: *NATURE*
IMAGE 8: *NATURE*

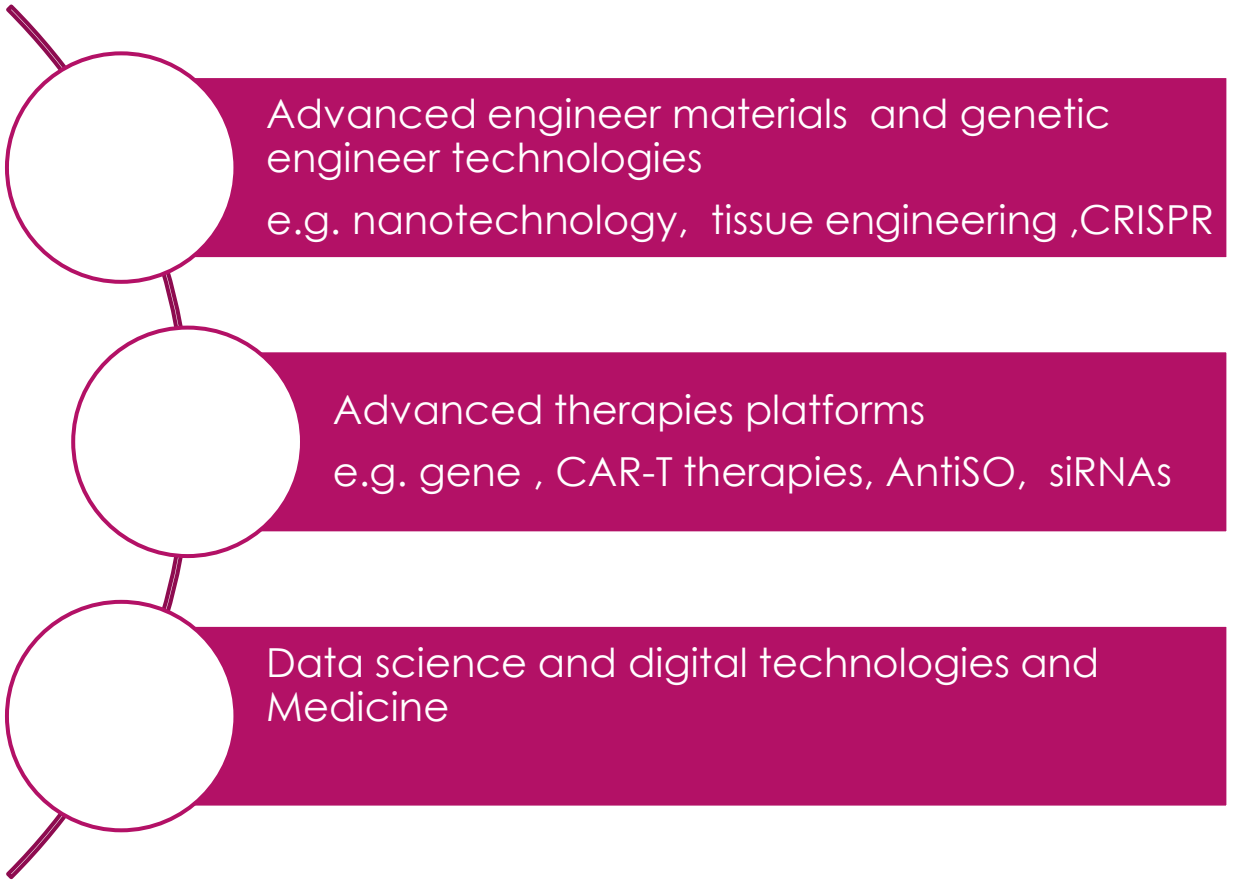
ANY VIEWS EXPRESSED ABOVE ARE THE AUTHOR'S OWN AND DO NOT NECESSARILY REFLECT THE VIEWS OF WEBMD OR MEDSCAPE.

CITE THIS: F. PERRY WILSON. HOW A CHEAP LIVER DRUG MAY BE THE KEY TO PREVENTING COVID - MEDSCAPE - DEC 05, 2022.

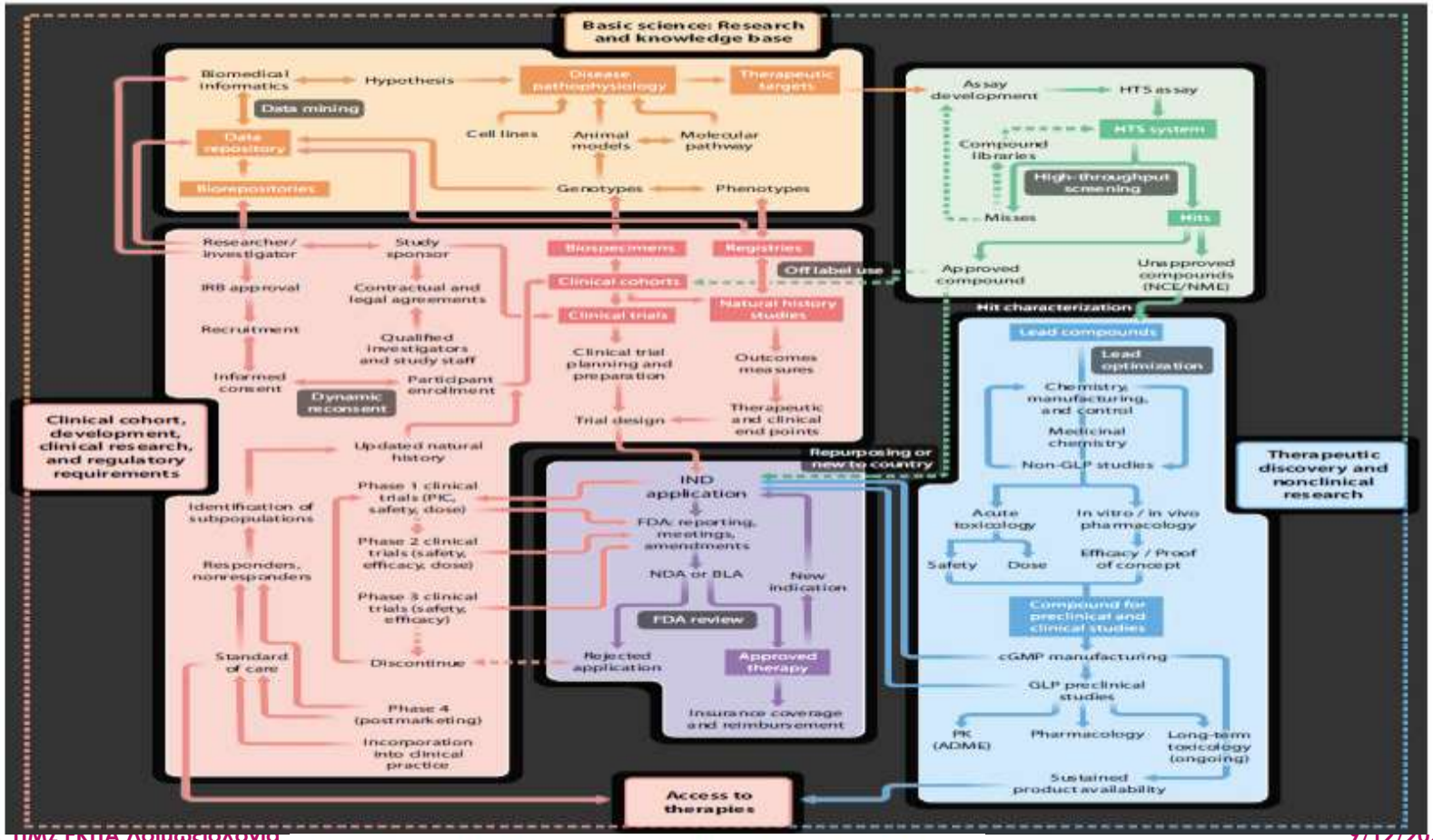
Τάσεις στην Κλινική Ερευνα

ΟΙΚΟΣΥΣΤΗΜΑ ΚΑΙΝΟΤΟΜΙΑΣ ΚΑΙ ΕΡΕΥΝΑΣ

The Changing Face of Innovation : 21st century model

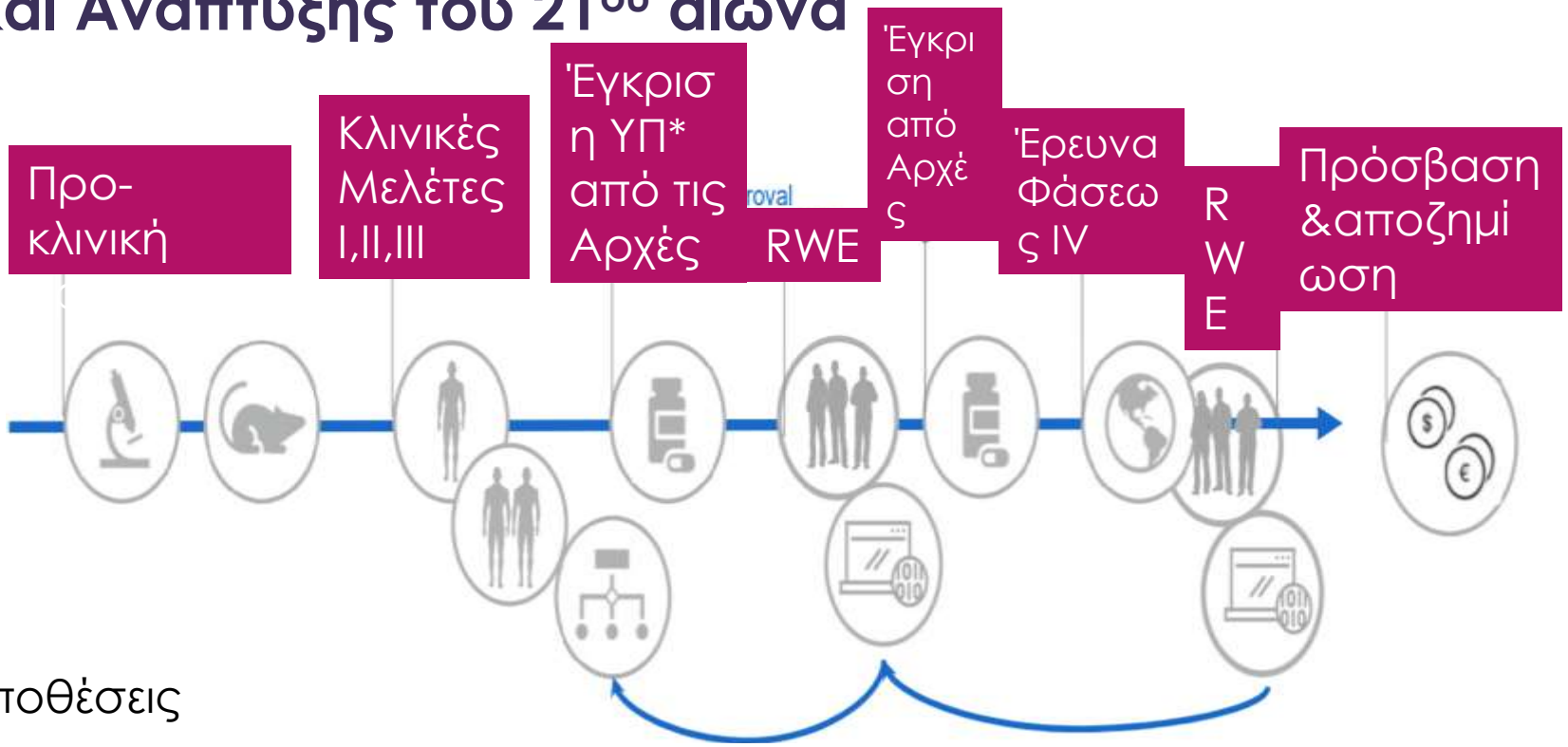


Μοντέλο R&D



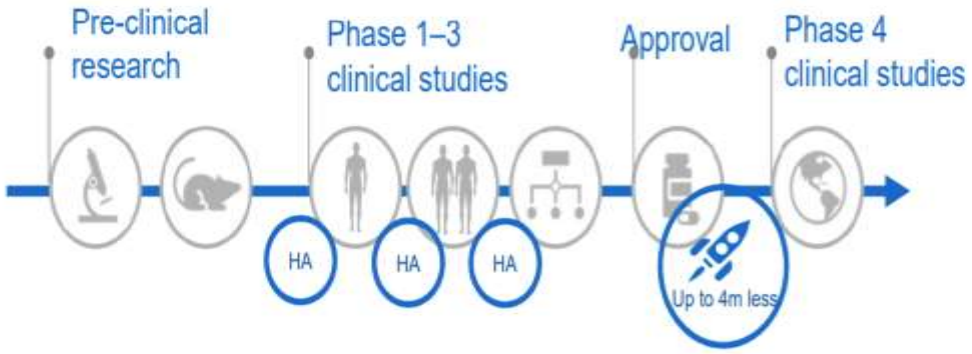
Kristin Baxter,[1,2] Elizabeth Horn,[1] Neely Gal-Edd,[1] Kristi Zonno,[1,3] James O'Leary,[1] Patrick F. Terry,[4] Sharon F. Terry[1]*

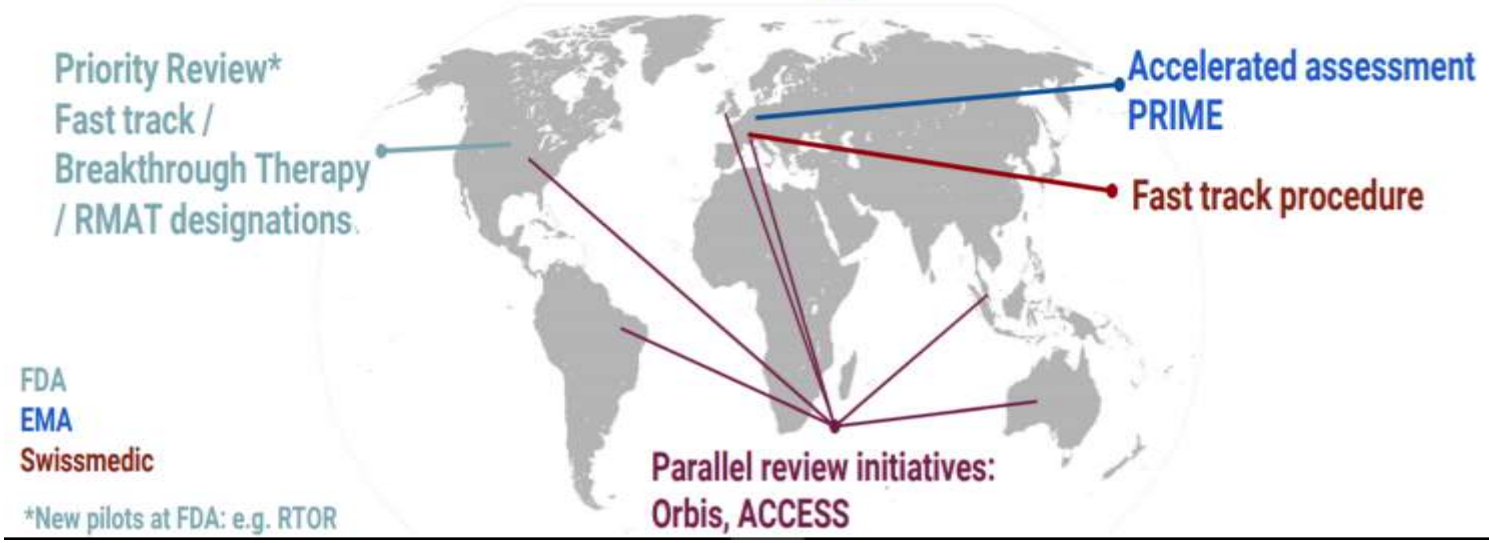
Το Αναδυόμενο Μοντέλο Υπέρ -Καινοτόμου Έρευνας και Ανάπτυξης του 21ου αιώνα



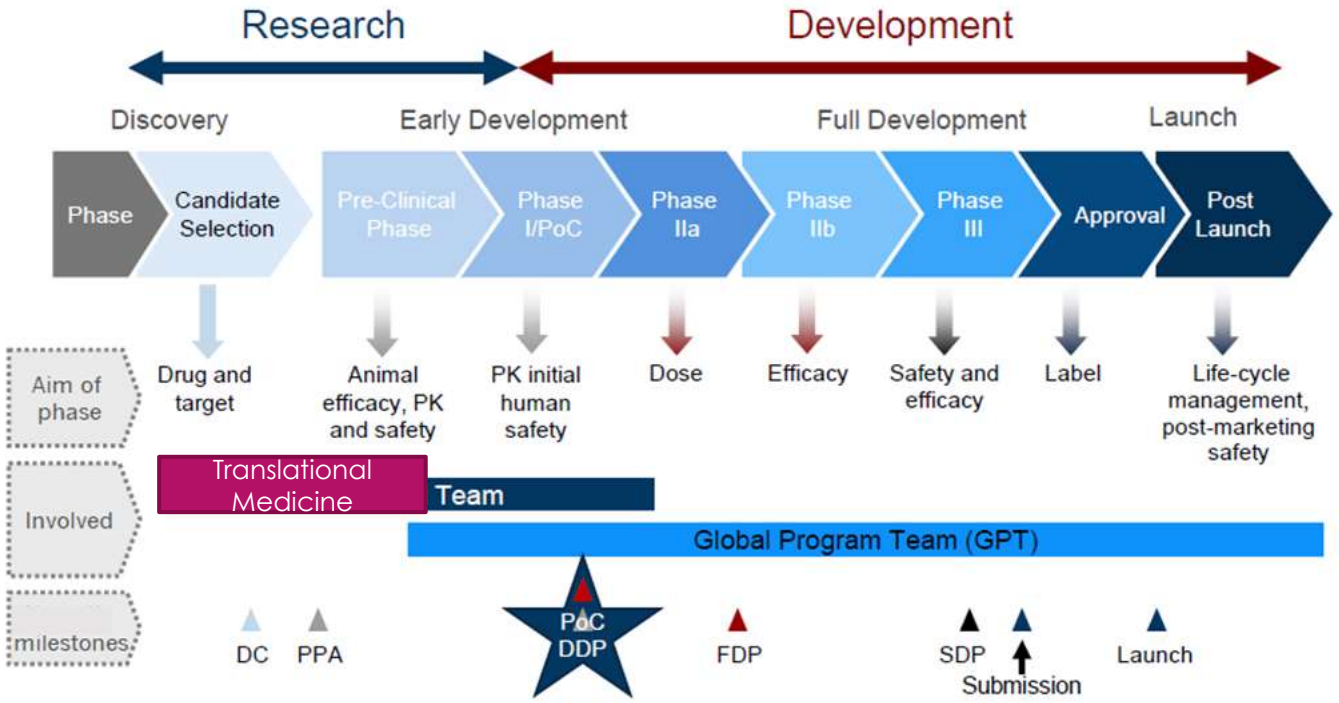
*Υπό Προϋποθέσεις

Εγκριτικές εξελίξεις στην Ευρωπαϊκή Ένωση και οι επισπεύδουσες διαδικασίες για καινοτόμες θεραπείες με πρώιμα σημαντικά δεδομένα

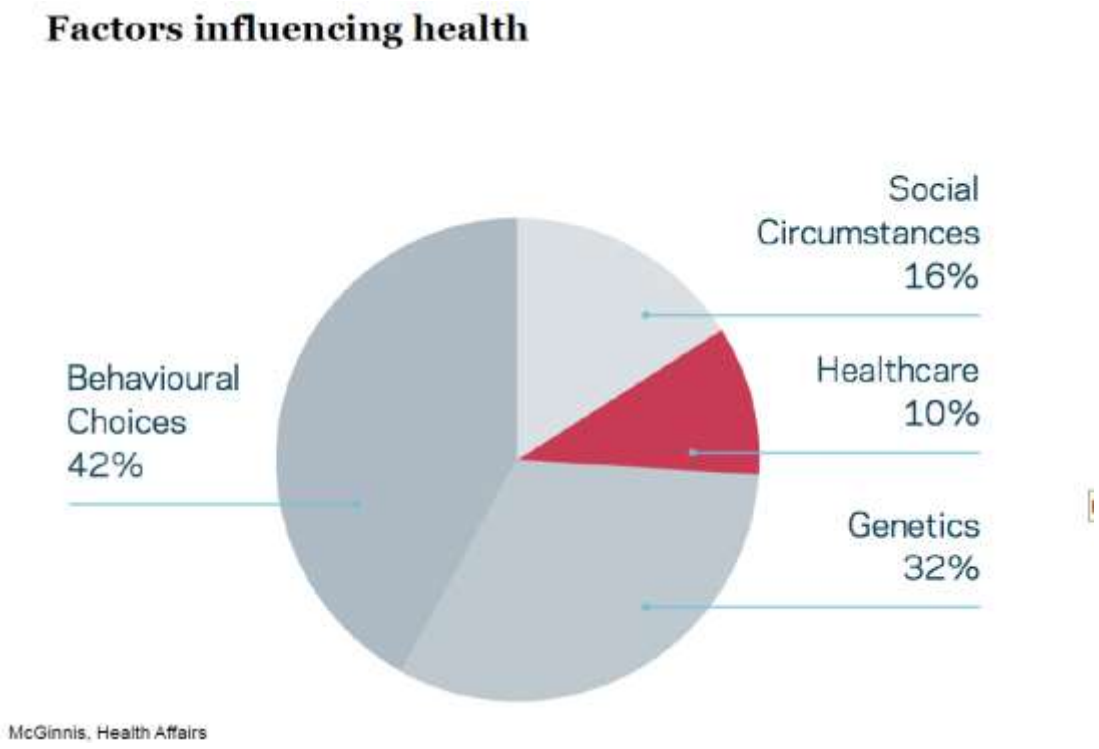




The Changing Face of Innovation : 21st century R&D model



Προς την εξατομικευμένη ιατρική



Ιατρική Ακριβείας

Precision medicine

«An emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle for each person."

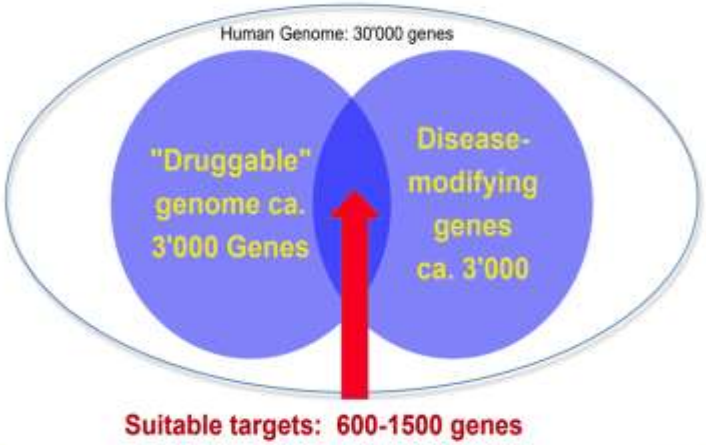
Γονιδιωματική και Θεραπείες Στόχευσης

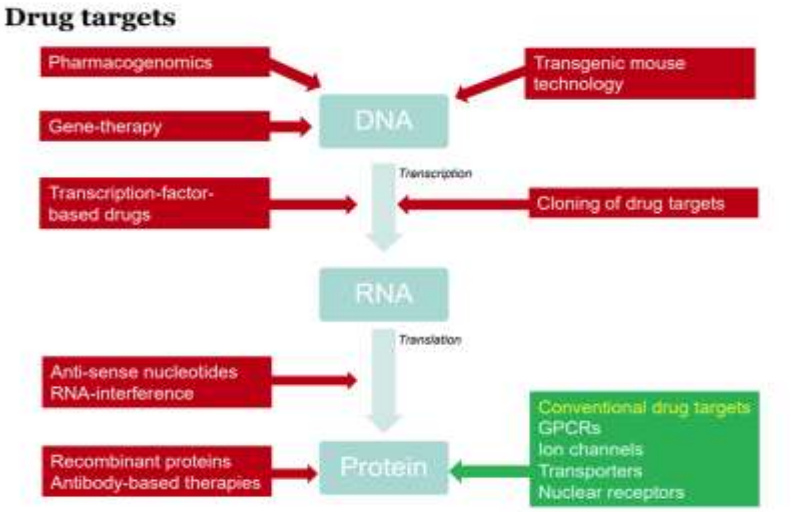
Genomics and therapeutics

Identifying new drug **targets** using genomic information	**Repurposing** existing drugs for new indications basedon new genomic information	Developing drugs **targeted** at specific mutations
Using genomic technologies to **stratify** the intensity of drug therapy	Using genomic information to improve drug **dosing**	Using genomic information to **prevent adverse drug reactions**

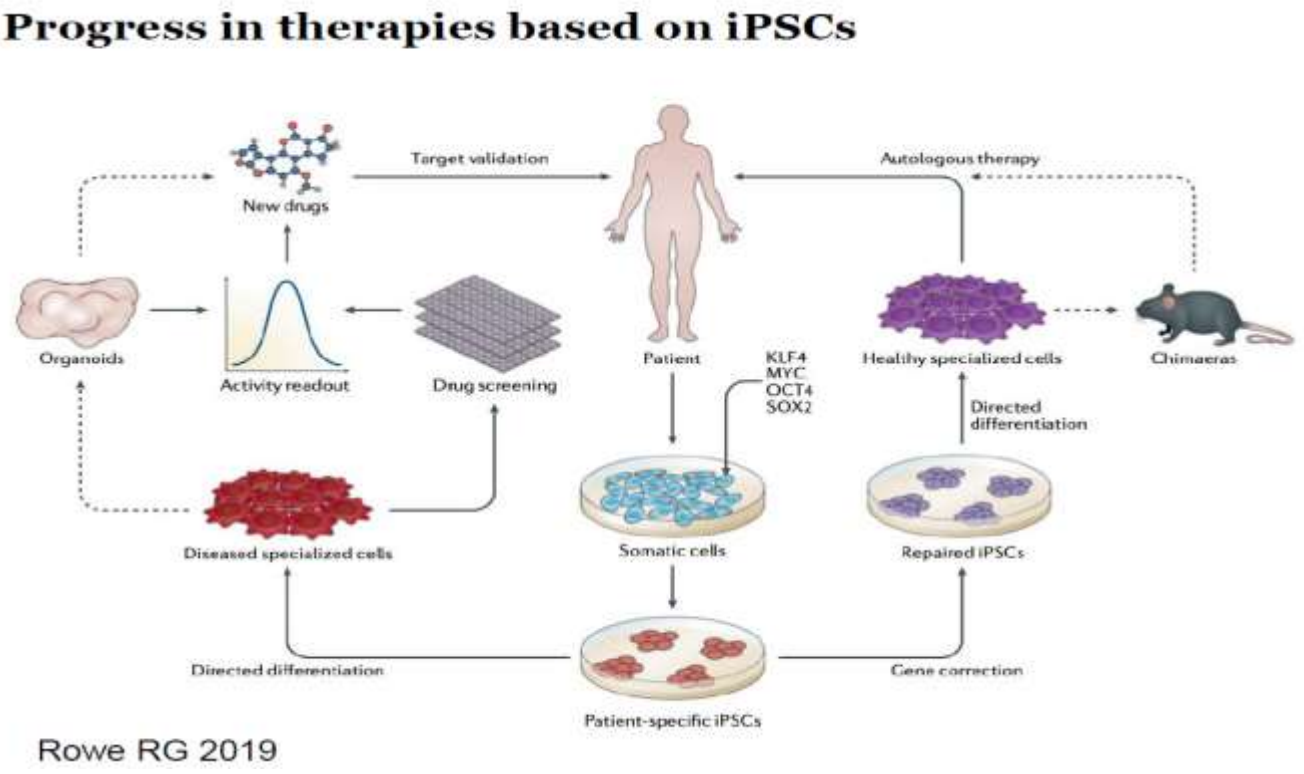
Γονιδίωμα και θεραπευτικοί στόχοι

Genome and Drug targets





Εξελίξεις στην Βασική Προκλινική Ερευνα



Εγκριτικές εξελίξεις στις ΗΠΑ και στην Ευρώπη

Clinical Pharmacology & Therapeutics

Review | Open Access

Randomized Controlled Trials Versus Real World Evidence: Neither Magic Nor Myth

Hans-Georg Eichler, Francesco Pignatti, Brigitte Schwarzer-Daum, Ana Hidalgo-Simon, Irmgard Eichler, Peter Arlett, Anthony Humphreys, Spiros Vamvakas, Nikolai Brun, Guido Rasi

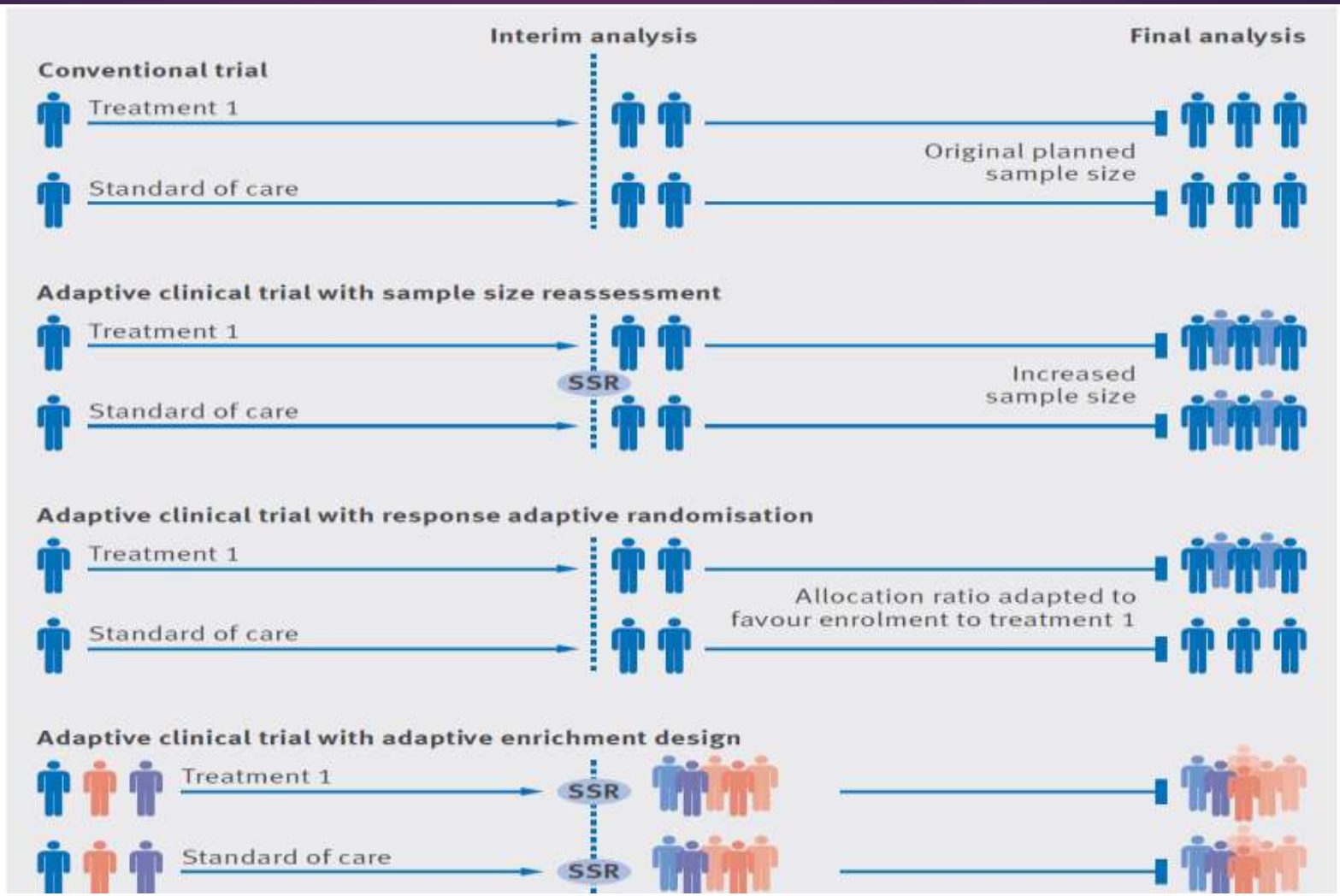
First published: 16 October 2020 | https://doi.org/10.1002/cpt.2083

Randomized Controlled Trials Versus Real World Evidence: Neither Magic Nor Myth

Hans-Georg Eichler[1,2,*], Francesco Pignatti[1], Brigitte Schwarzer-Daum[2,3], Ana Hidalgo-Simon[1], Irmgard Eichler[1], Peter Arlett[1,4], Anthony Humphreys[1], Spiros Vamvakas[1], Nikolai Brun[5] and Guido Rasi[1,6]

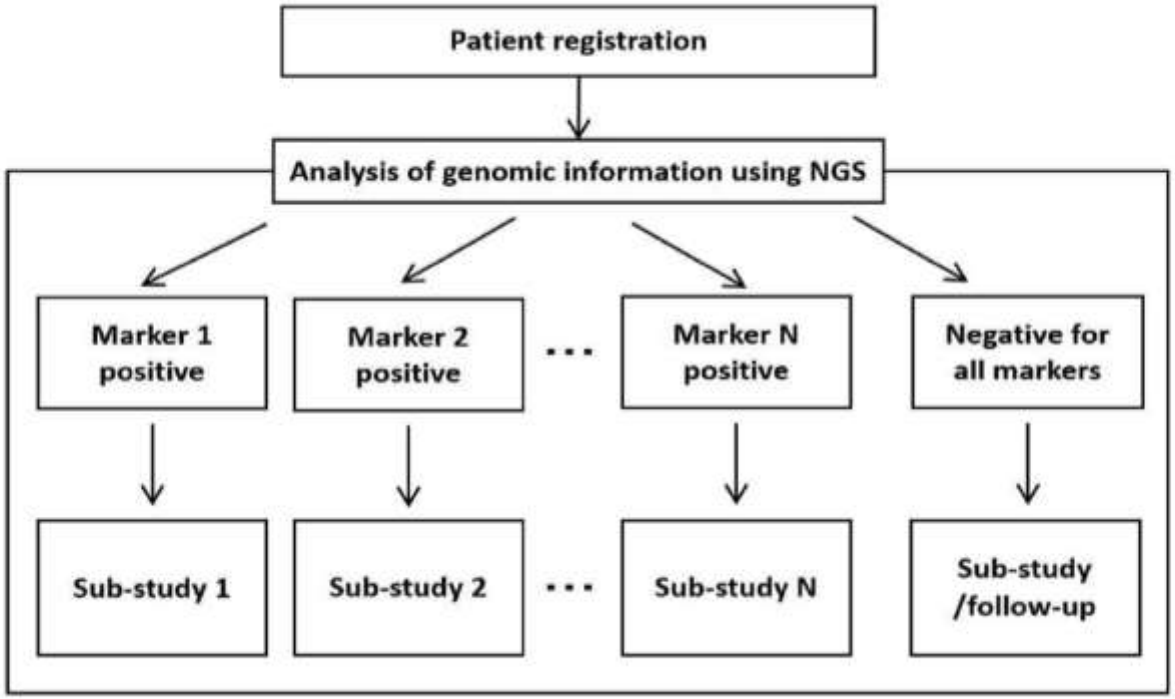
Compared with drugs from the blockbuster era, recently authorized drugs and those expected in the future present a heterogenous mix of chemicals, biologicals, and cell and gene therapies, a sizable fraction being for rare diseases, and even individualized treatments or individualized combinations. The shift in the nature of products entails secular trends for the definitions of "drugs" and "target population" and for clinical use and evidence generation. We discuss that the lessons learned from evidence generation for 20th century medicines may have limited relevance for 21st century medicines. We explain why the future is not about randomized controlled trials (RCTs) vs. real-world evidence (RWE) but RCTs and RWE—not just for the assessment of safety but also of effectiveness. Finally, we highlight that,

Adaptive protocols : Μελέτες Προσαρμοστικού Σχεδιασμού



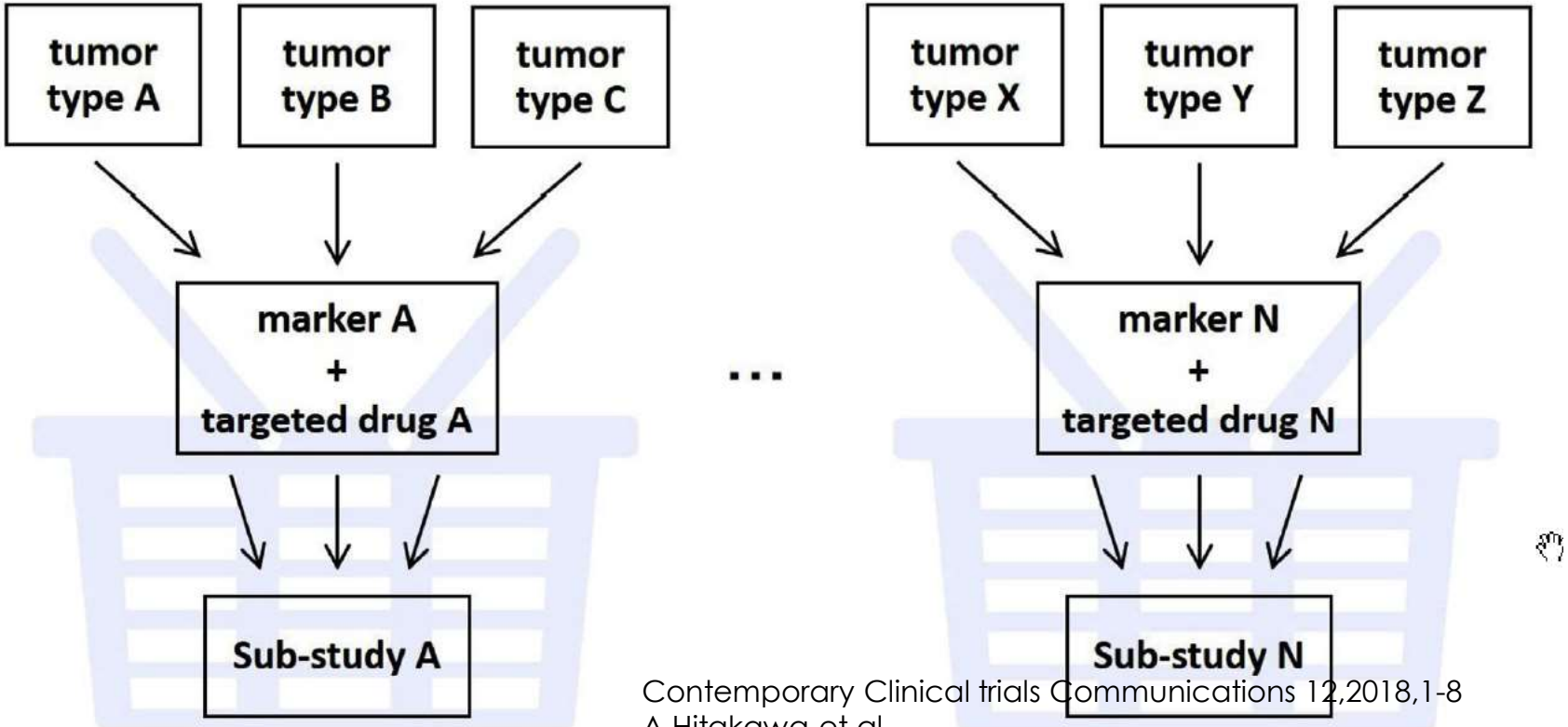
BMJ 2018;360:k698 | bmj

Master protocols -Platform



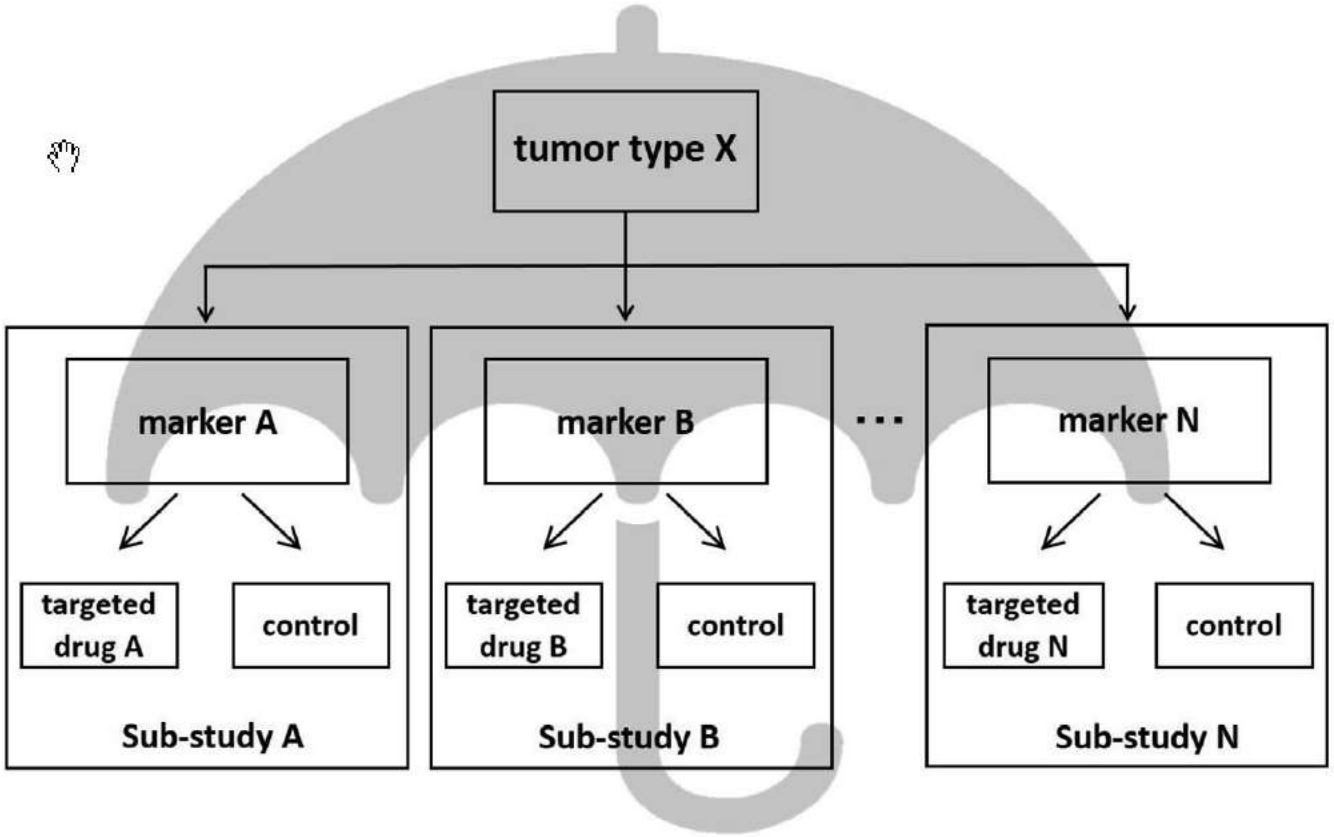
Contemporary Clinical trials Communications 12,2018,1-8
A.Hitakawa et al

Basket protocols



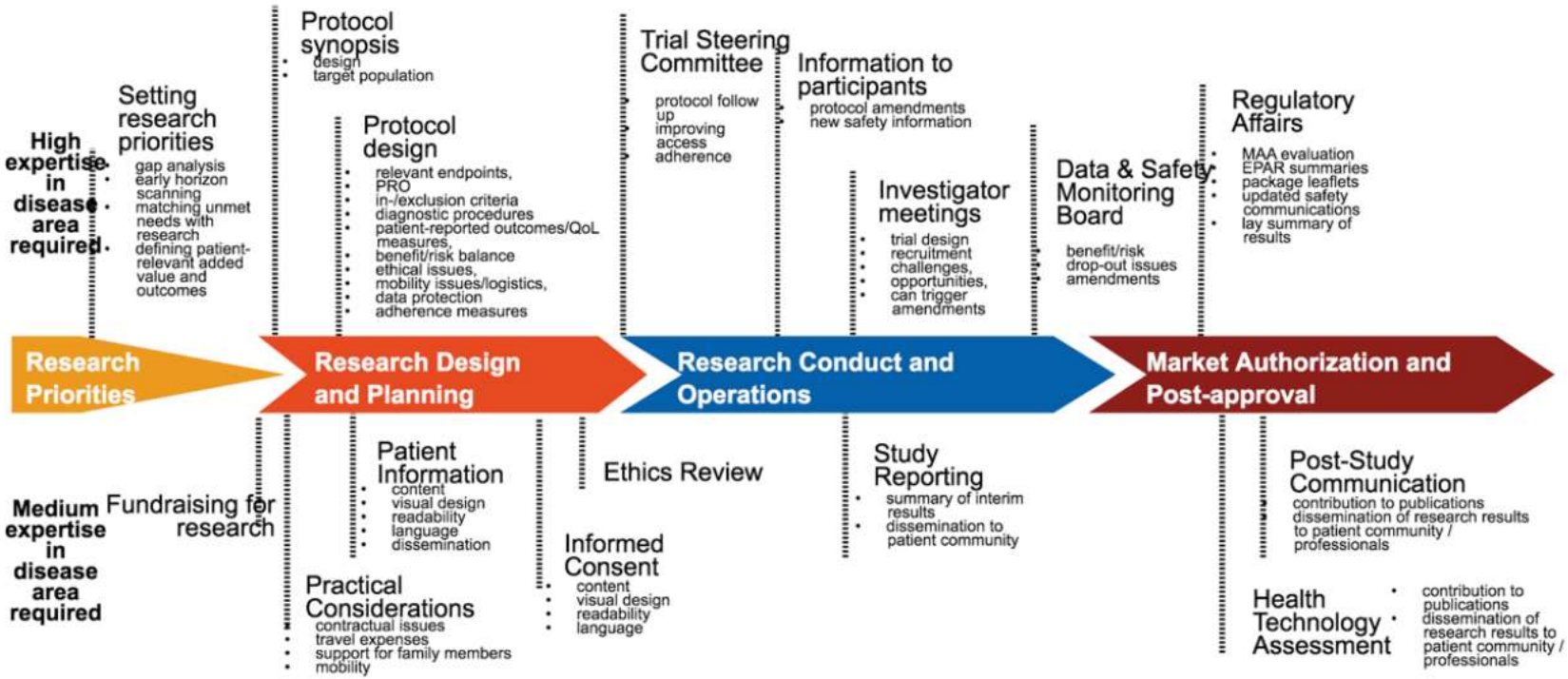
Contemporary Clinical trials Communications 12,2018,1-8
A.Hitakawa et al

Umbrella trials



- Contemporary Clinical trials Communications 12,2018,1-8 A.Hitakawa et al

Patient involvement in medicines R&D: a practical roadmap

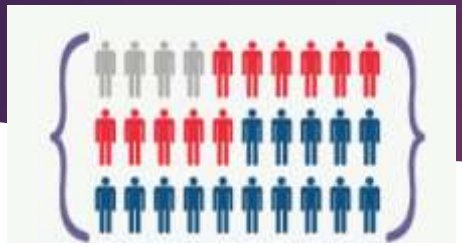


Improving Patient Involvement in Medicines Research and Development: A Practical Roadmap. Geissler, Ryll, Leto, Uhlenhopp, Therapeutic Innovation & Regulatory Science (2017), doi: 10.1177/2168479017706405, and at www.eupati.eu

Η Επιδημιολογία & Φαρμακοεπιδημιολογία την E&A

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

EMA PASS,PAES



Prospective

What are tomorrow's medical unmet needs?

Epidemiology*

- Prevalence
- Incidence
- Population studies

Market Research

- what are the evidence gaps?
- what are the treatment options?

Pharmaco-economics

- Cost effectviness
- Cost benefit
- Cost-utility

Real life= Pharmaco-epi

- Efficacy
- Tolerability
- Proper Use
- Performance

Licensing | Price | Reinscription

Animal Tox | **I** | **II** | **III** | **IV** | **Post-licensing**

12 years

5/10/15 years

FDA postmarketing studies

* Types of Studies

There are four primary types of epidemiology studies. They are:

1. **Cohort studies** — A cohort (group) of individuals with exposure to a chemical and a cohort without exposure are followed over time to compare disease occurrence.
2. **Case control studies** — Individuals with a disease (such as cancer) are compared with similar individuals without the disease to determine if there is an association of the disease with prior exposure to an agent.
3. **Cross-sectional studies** — The prevalence of a disease or clinical parameter among one or more exposed groups is studied, such as:
   - The prevalence of respiratory conditions among furniture makers.
4. **Ecological studies** – The incidence of a disease in one geographical area is compared to that of another area, such as:
   - Cancer mortality in areas with hazardous waste sites as compared to similar areas without waste sites.

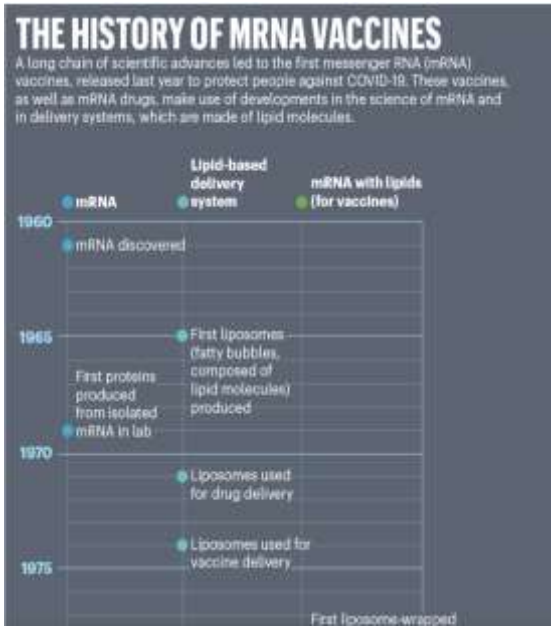
ispe International Society for Pharmacoepidemiology

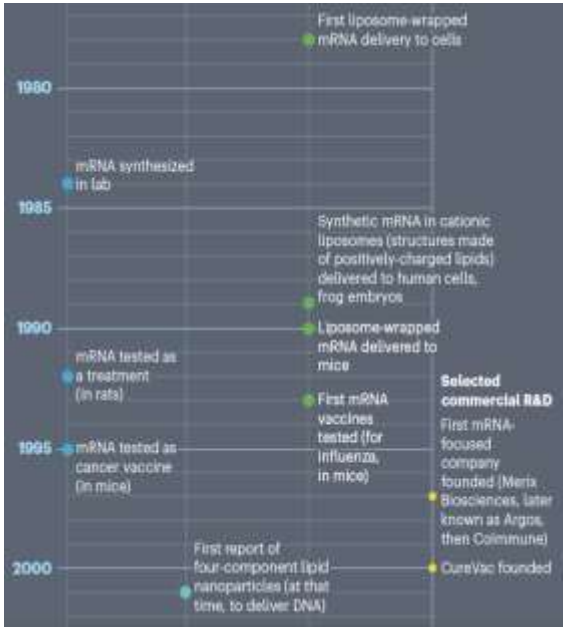
Η πανδημία και ανάπτυξη των εμβολίων έναντι της COVID-19

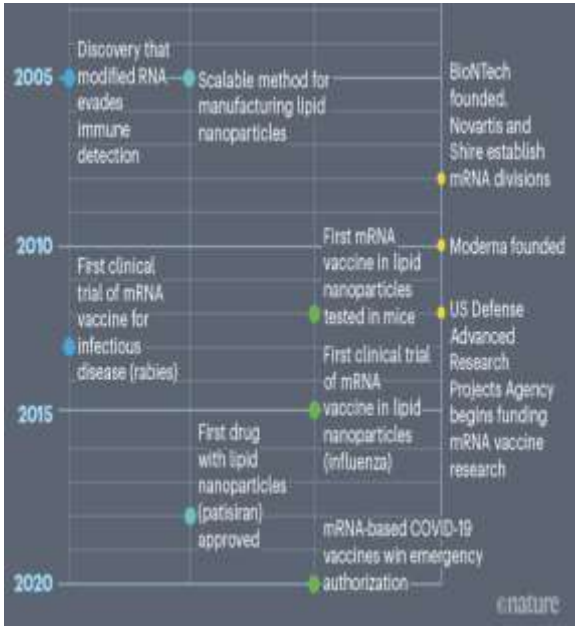
- διαφορετ μοντελου ερευνας

ΧΡΌΝΟΙ ΑΝΆΠΤΥΞΗΣ ΚΑΙ ΕΠΙΤΆΧΥΝΣΗ ΔΙΑΔΙΚΑΣΙΏΝ

Η έρευνα των MRNA εμβολίων ξεκινά το 1960

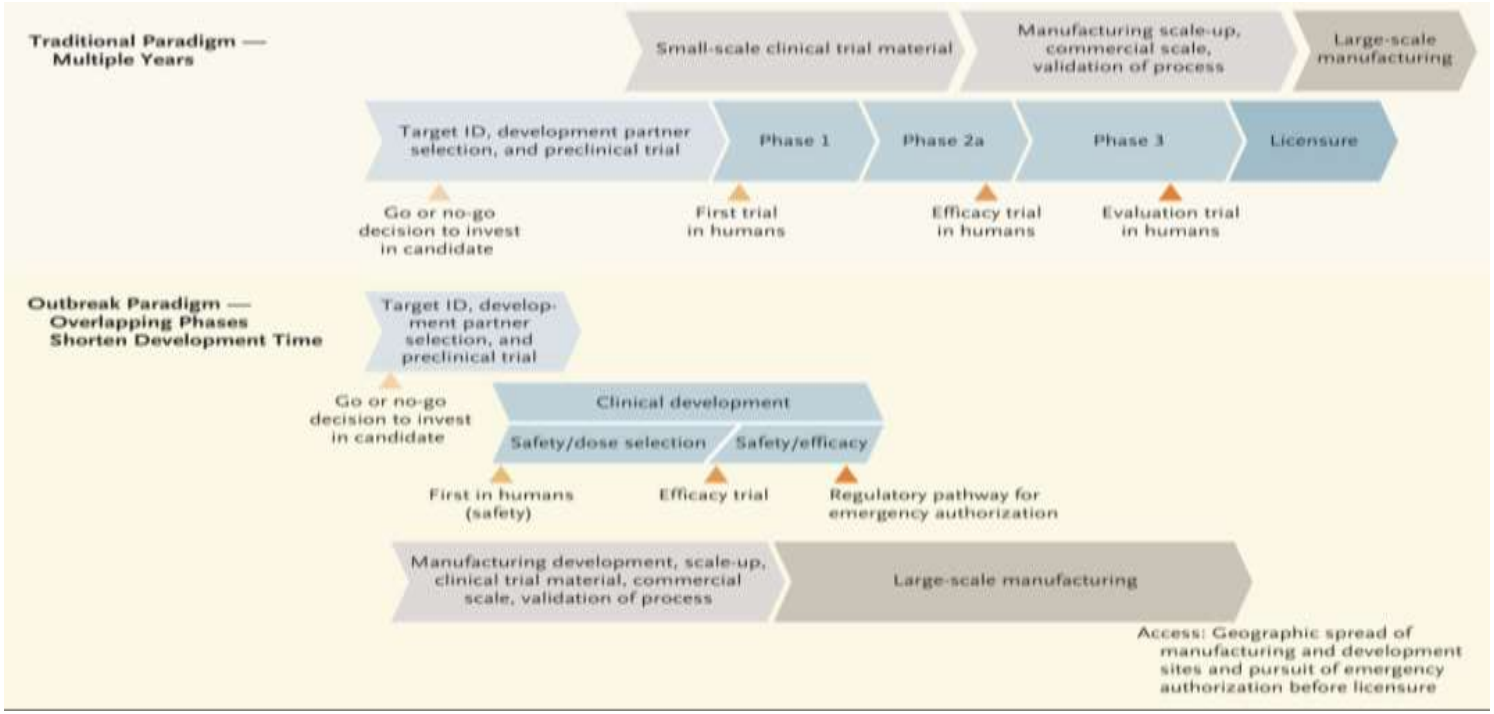






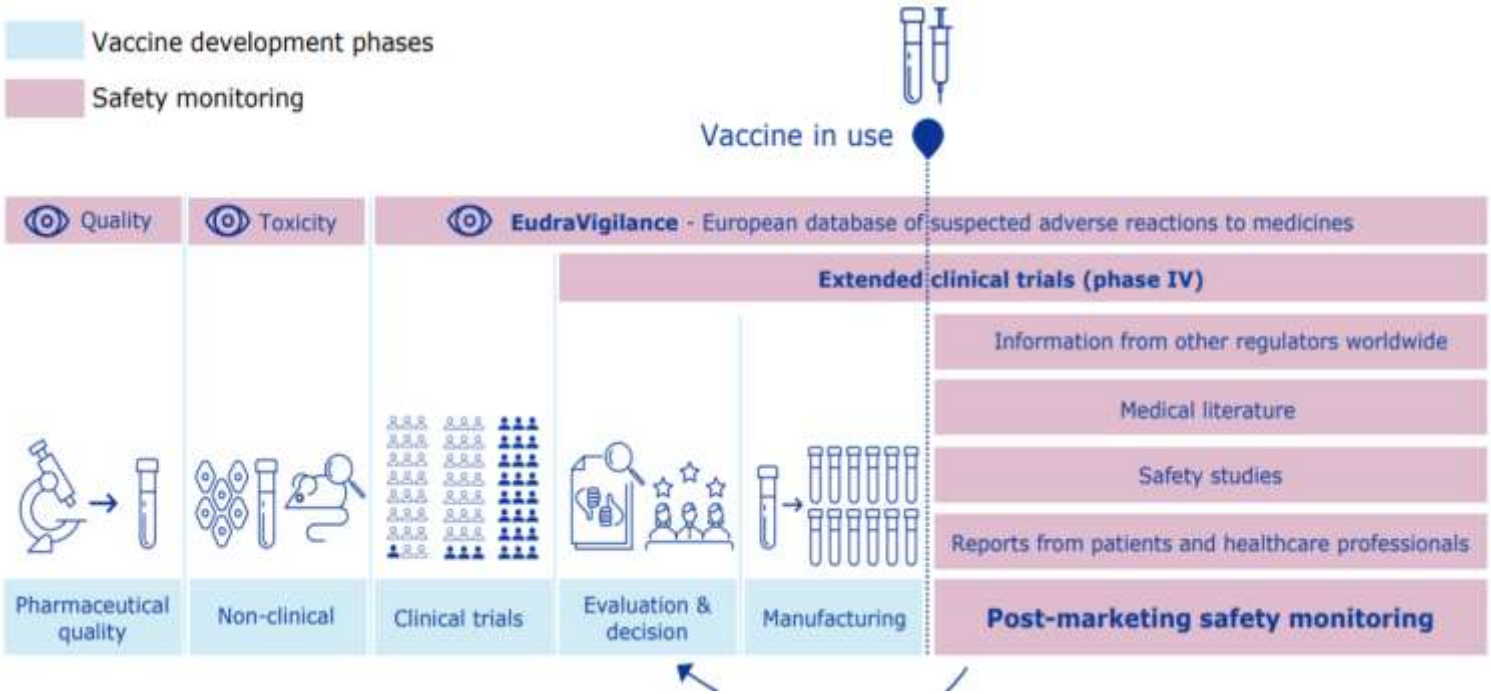
https://www.nature.com/articles/d41586-021-02483 Oct 22, 2021
w?utm_source=Nature+Briefing&utm_campaign=41794890cb-briefing-dy-20210914&utm_medium=email&utm_term=0_c9dfd39373-41794890cb-44721677

R&D paradigm shift with Covid-19



https://www.nejm.org/doi/full/10.1056/NEJMp2005630
NEJM May 2020

Προεγκριτική και Μετεγκριτική παρακολούθηση ασφάλειας εμβολίων



EMA Public Stakeholders Meeting 11/12/2020

Εξαιρετικά πρωτόγνωρη ευρύτατη ερευνητική συνεργασία& όσμωση

- Unprecedented levels of collaboration, information-sharing, innovation
- Permanent adoption of R+D-accelerating COVID-19 measures is a top FDA priority
- Active discussions regarding how to sustain the momentum to ensure rapid vaccine/therapeutic development
- Many lessons learned about the need for better preparedness

World Health Organization

Commitment and call to action: Global collaboration to accelerate new COVID-19 health technologies

A Global Collaboration to Accelerate the Development, Production and Equitable Access to New COVID-19 diagnostics, therapeutics and vaccines

A Happy Exception: The Pandemic Is Driving Global Scientific Collaboration

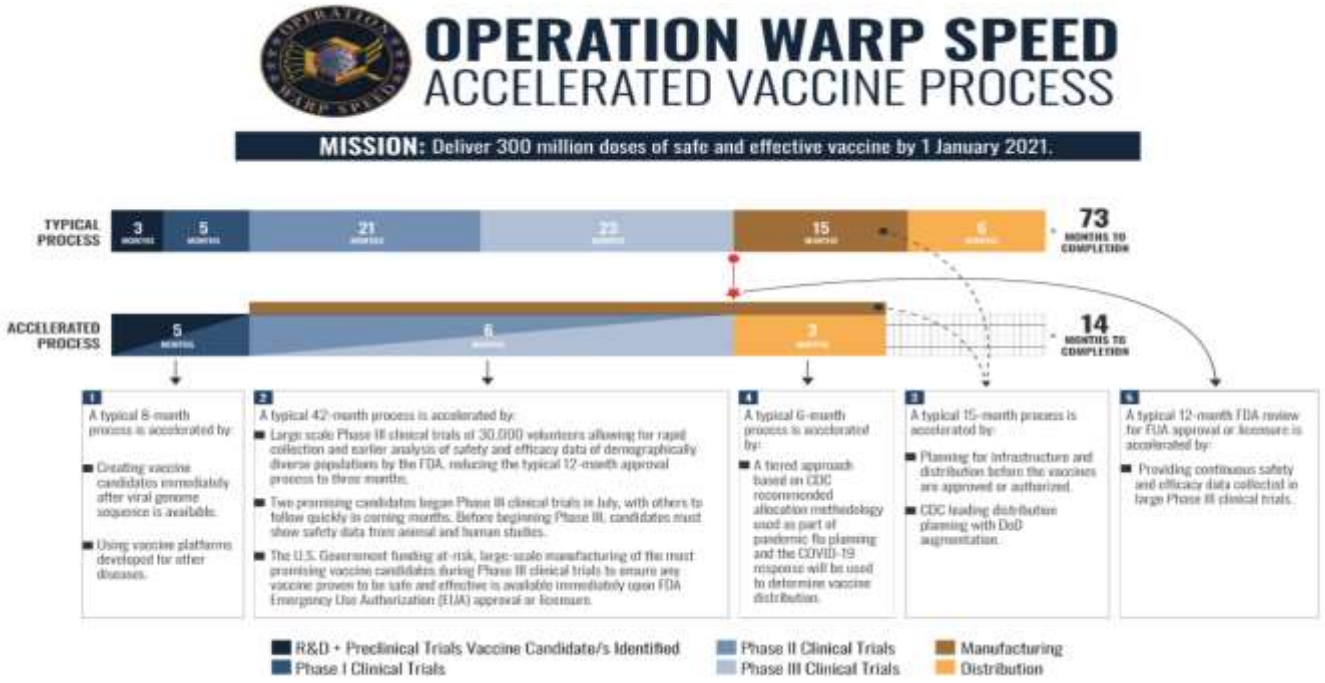
BY JOSE GUIMON, RAJNEESH NARULA

Issues in Science and Technology

COVID-19: Collaboration is the engine of global science – especially for developing countries

World Economic Forum

Operations Warp Speed- under NIH

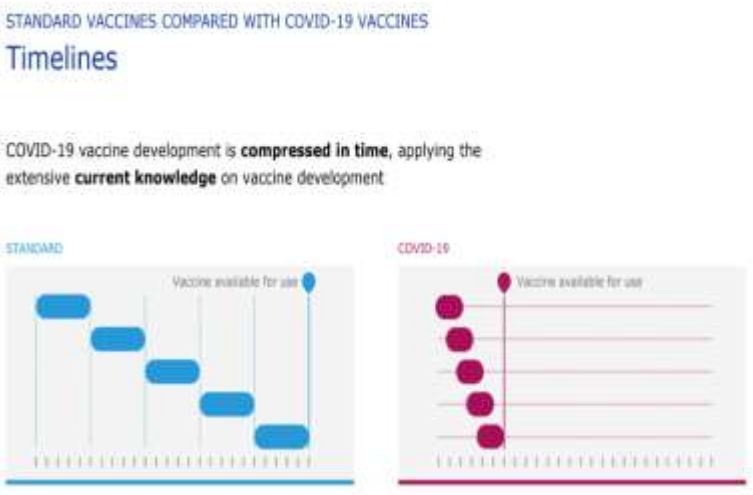


All risk taken is financial, logistical, resourcing and not on safety and efficacy. Bureaucratic obstacles removed and saving time from gaps between phases .

Ταχεία ανάπτυξη εμβολίων έναντι COVID-19

- Νέες πλατφόρμες για την παραγωγή εμβολίων είχαν ήδη τεκμηρίωση και προ-κλινικές μελέτες
- Υπερταχεία αλληλούχηση του ιού για την επείγουσα ανάπτυξη αντιγόνων για ενσωμάτωση στα εμβόλια
- Τα στάδια ανάπτυξης των εμβολίων εξελίσσονταν παράλληλα
- Ο επιπολασμός της νόσου ήταν πολύ υψηλός και η νοσηρότητα και θνητότητα απειλητική
- Τάχιστη εθελοντική εισαγωγή/στρατολόγηση ατόμων στις Κλινικές δοκιμές
- Η παραγωγή των εμβολίων εξελισσόταν παράλληλα με την διεξαγωγή των Κλινικών Δοκιμών

EMA Public Stakeholders Meeting Dec 11, 2020



NEJM COVID-19 educational material Jan 2021

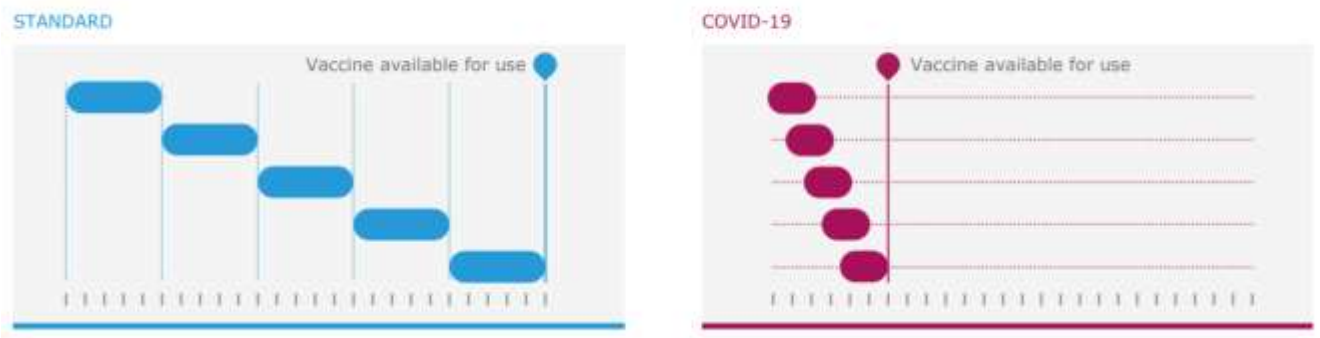
Επιταχυνόμενη ,επάλληλη και επαναληπτική διαδικασία

EMA Public Stakeholders Meeting
11/12/2020

STANDARD VACCINES COMPARED WITH COVID-19 VACCINES

Timelines

COVID-19 vaccine development is **compressed in time**, applying the extensive **current knowledge** on vaccine development



Συνεργασία και επικέντρωση στην κατεπείγουσα προτεραιότητα ανάπτυξης των Εμβολίων

STANDARD VACCINES COMPARED WITH COVID-19 VACCINES

Resources

EMA Public Stakeholders Meeting
11/12/2020

COVID-19 vaccine development **mobilises more resources simultaneously**

Οι Αρχές επιβλέπουν στενά και εξαρχής την έρευνα των εμβολίων διπλασιάζοντας το δυναμικό τους και επιταχύνουν την διαδικασία

EMA Public Stakeholders Meeting
11/12/2020

STANDARD VACCINES COMPARED WITH COVID-19 VACCINES

Expert Task Force & continuous dialogue

COVID-19 vaccine development is supported by early, continuous dialogue between developers and a dedicated group of regulatory experts **EMA COVID-19 Task Force**

Παραγωγή των εμβολίων ξεκινά νωρίτερα για να είναι άμεσα διαθέσιμα

STANDARD VACCINES COMPARED WITH COVID-19 VACCINES

Manufacturing

EMA Public Stakeholders Meeting
11/12/2020

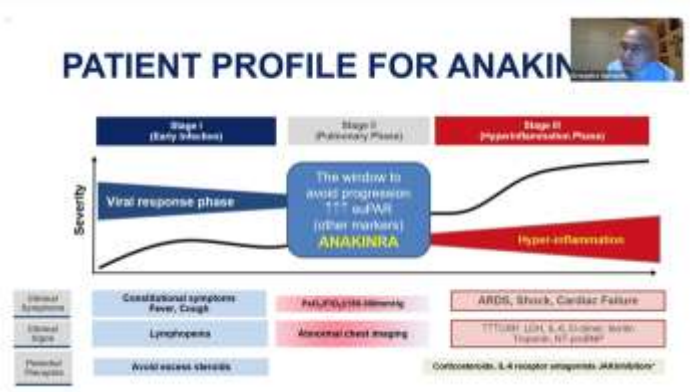
Companies are **expanding** manufacturing and production **capacity** to ensure efficient vaccine deployment

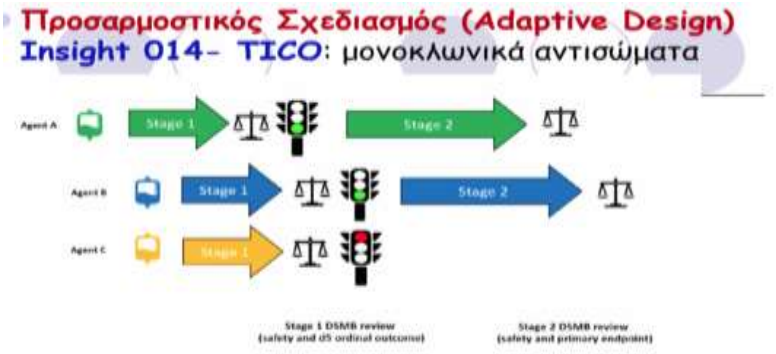
STANDARD

COVID-19

COVID-19 therapies efforts

- WHO Solidarity adaptive trials
- Oxford UK Recovery adaptive trial
- Monoclonal antibodies
- Antiviral Rx
- Repurposing efforts
  - Anakinra





Επιπτώσεις στις κλινικές μελέτες στην διάρκεια της πανδημίας

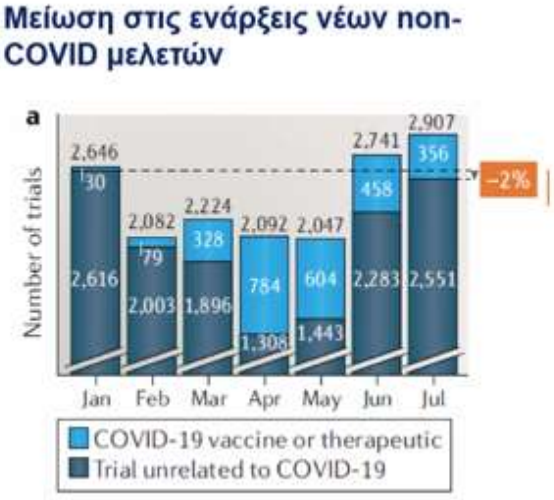
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

A Randomized Trial of Hydroxychloroquine as Postexposure Prophylaxis for Covid-19

Νέα Πραγματικότητα

Τηλεϊατρική ,Registries, RWE,PROs, Εξ αποστάσεως μελέτες



ΚΑΝΟΝΙΣΤΙΚΟ ΠΛΑΙΣΙΟ ΚΛΙΝΙΚΩΝ ΔΟΚΙΜΩΝ

ΕΥΡΩΠΑΙΚΗ ΕΝΩΣΗ &ΕΛΛΑΔΑ

Clinical Trials in the EU – what has changed over time?

...Before May 2004

National rules, different processes/requirements for authorisation in each EU Member States

...resulted in delays and

...Directive 2001/20/EC

(since 1 May 2004)

First step to harmonise processes and requirements for clinical trial authorisations

Introduction of e-application form

...Regulation (EU) No. 536/2014

(published May 2014)

Full harmonisation and combined assessment of multinational trials (after full functionality of the EU portal and EU database)

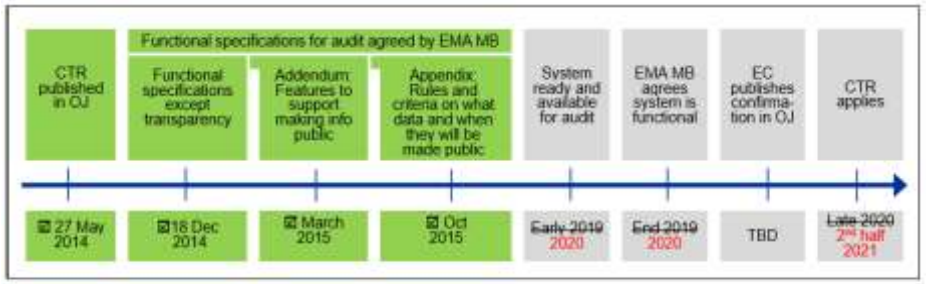
e-submission

Federal Institute for Drugs and Medical Devices

Karl Broich | CT authorisation in the EU: present and future | 09 May 2018

CTR 536/2014

- **Expectations**
- **74% positive**
  - Harmonization
  - Acceleration of decisions
  - Shorter timelines for Member States and Sponsors
  - Facilitation of Multi state trials
  - Enhanced transparency
- 38% challenges - concerns



Source: EMA 2019 (CTR: Clinical Trials Regulation; OJ: Official Journal of the EU; EC: European Commission; MB: Management Board), updated timelines in red

Χρόνος έγκρισης :45 ημερών -αντί 60 ημέρες

Σε ισχύ από 31/1/2022- μεταβατική περίοδος

Υποχρεωτική κατάθεση με τον ΝΚ 31/1/2023

CTIS new user friendly tool

- Centralized e submission
- **SINGLE DOSSIER**
- Coordinated reviews
- **SINGLE OPINION**

EMA portal end 2021

Challenges*

- **Readiness** in EU countries
- **Impact on ECs**
- **Lack of clarity or reduced scrutiny** on patients rights in special populations
- **Complex trial designs**

*Source : P.Galanis 31/5/2019,37,1,FebArchives Athens Medical Society www.mednet.gr

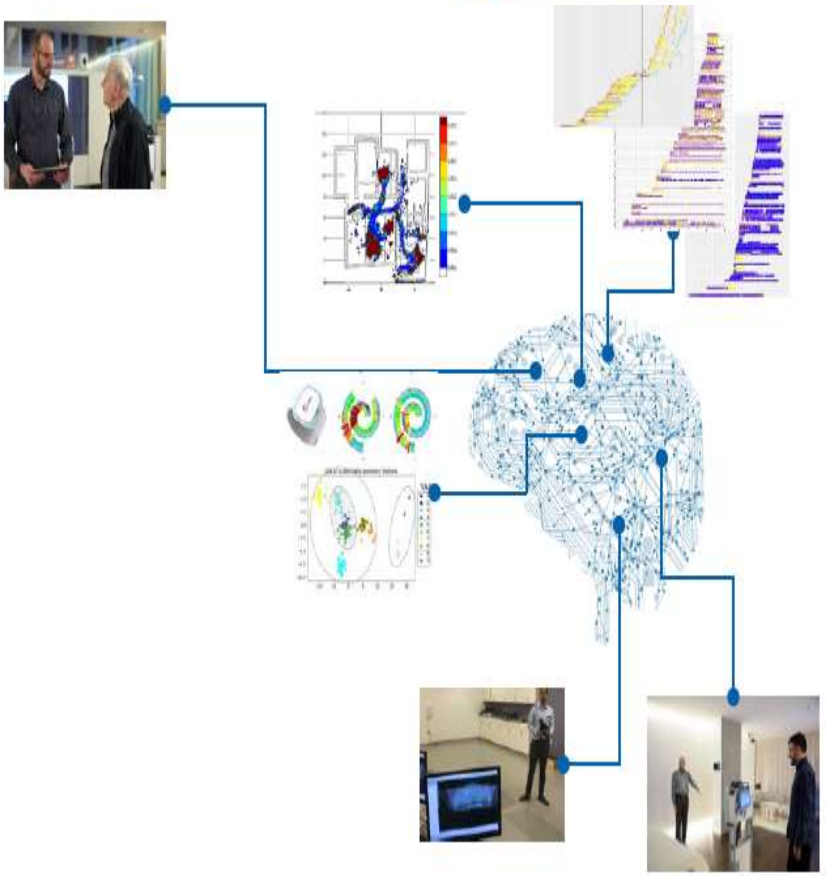
https://www.ema.europa.eu/en/human-regulatory/research-development/clinical-trials/clinical-trials-information-system-training-supportr 2020

ΠΡΩΤΟΒΟΥΛΙΑ ΕΛ.Ε.Φ.Ι. για την κλινική έρευνα &τις κλινικές δοκιμές

ΕΛΛΗΝΙΚΟ ΠΕΡΙΒΑΛΛΟΝ

Με επίκεντρο τον ασθενή
Μετασχηματισμός για την Κλινική Έρευνα

ΕΛ.Ε.Φ.Ι.
ΕΛΛΗΝΙΚΗ ΕΤΑΙΡΕΙΑ ΦΑΡΜΑΚΕΥΤΙΚΗΣ ΙΑΤΡΙΚΗΣ



Εθνικός Σχεδιασμός

- Στόχους και υποχρεώσεις των φορέων και εταίρων
- Δείκτες αποδοτικότητας
- Σύνδεση Βασικής και Μεταφραστικής έρευνας
- Ψηφιακός μετασχηματισμός κουλτούρα συνεργασιών, νοοτροπία αλλαγής
- Κέντρα Κλινικών Μελετών
  - Δικτύων Κλινικής Έρευνας
- RWD –RWE

Κλινικές Μελέτες :Ετοιμότητα για το Μέλλον

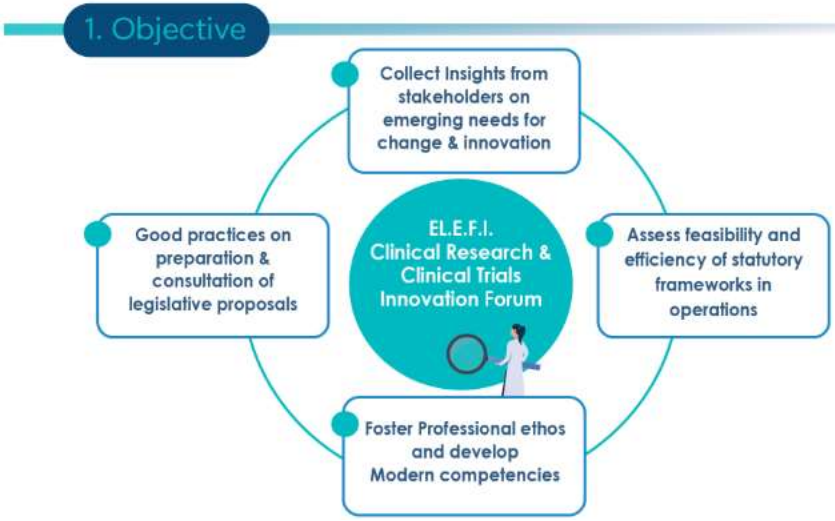
- **Άμεσα & γρήγορα -Low hanging fruits**: Επίλυση νομοθετικών προβλημάτων & Επικαιροποίηση προτύπου, βελτίωση της εφαρμογής του πλαισίου & υπογραφής συμβάσεων : Μείωση Χρόνου ,Κόστους και Υστερήσεων

- **Δεοντολογικό πλαίσιο για ΜΠΚΜ & RWE**
  - **ΕΣΥ**

- **Μεσοπρόθεσμα -The not so low hanging fruits**: Ψηφιοποίηση εγκρίσεων &υπογραφής συμβάσεων , Μητρώο ερευνητών , Μητρώα Ασθενειών , Μητρώο Κλινικών Δοκιμών & Μελετών
  Ατομικός Ηλεκτρονικός Φάκελος Υγείας:
  σενάριο κλινικών δοκιμών

- **Μακροπρόθεσμα -The moonshots**: Δια λειτουργικές Ψηφιακές πλατφόρμες (EHR, RWD, bio- gene-banks)

EL.E.F.I. Initiative
Clinical Research & Clinical Trials
Innovation Forum



Συμπερασματικά

- Μεταφραστική έρευνα- πανεπιστημιακά κέντρα
- Επιδημιολογική έρευνα για τα χρόνια νοσήματα και προτεραιότητες στην έρευνα
- Ενίσχυση Μητρώων Ασθενών- Χρήση (EMR) ΑΗΦΥ ή εθνικό ηλεκτρονικό φάκελο Υγείας
- RWD – RWE studies για την διαμόρφωση τοπικών οδηγιών
- Διασύνδεση με διεθνή και τοπικά Δίκτυα Ερευνητών
- Συμμετοχή σε Consortia με Βιοφαρμακευτική και ,

  Μη κερδοσκοπικούς φορείς, ευρωπαϊκούς φορείς,

  ενώσεις ασθενών
- Συνεχιζόμενη εκπαίδευση
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