«*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 15-1-2021

Βαρβάρα Μπαρούτσου MD ,PhD, EMAUD,GFMD

Εσωτερικός Παθολόγος

Πρόεδρος ΕΛ.Ε.Φ.Ι.

President elect IFAPP

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

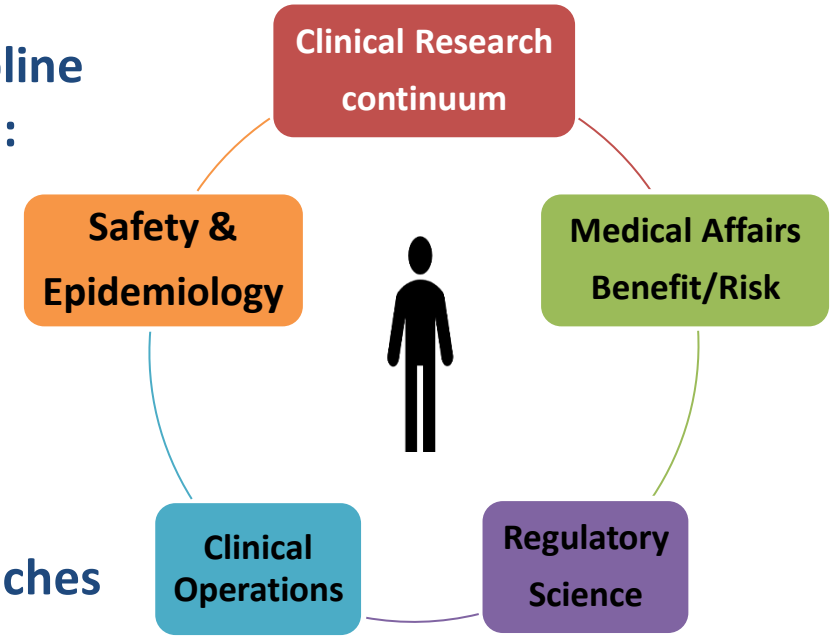
Μέρος 1 Φαρμακευτική Ιατρική & Τάσεις στην Κλινική Έρευνα

ΕΙΣΑΓΩΓΗ

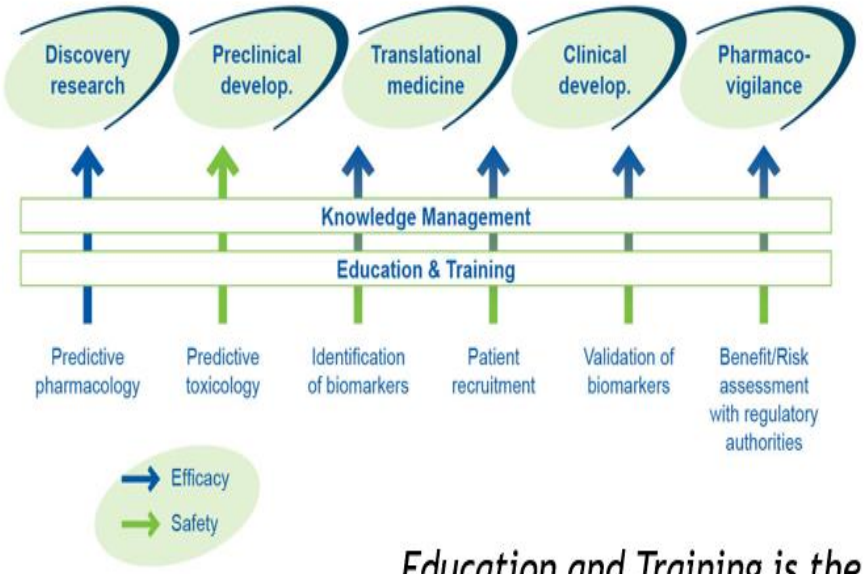
Pharmaceutical Medicine : Enhancing Patient Benefit

Pharmaceutical Medicine (Medicines Development) is the medical scientific discipline concerned with the Vision for the Future of :

- Discovery
- Development
- Evaluation
- Regulatory aspects
- Safety surveillance
- Research Continuum (RWE,Big Data)
- Evolving Medical affairs roles and approaches
- Bioethics standards
- Building capabilities of commercializing medicines for the **benefit and safety of patients and the public.**



Strategic Research Scientific Agenda



Education and Training is the foundation for the entire value chain

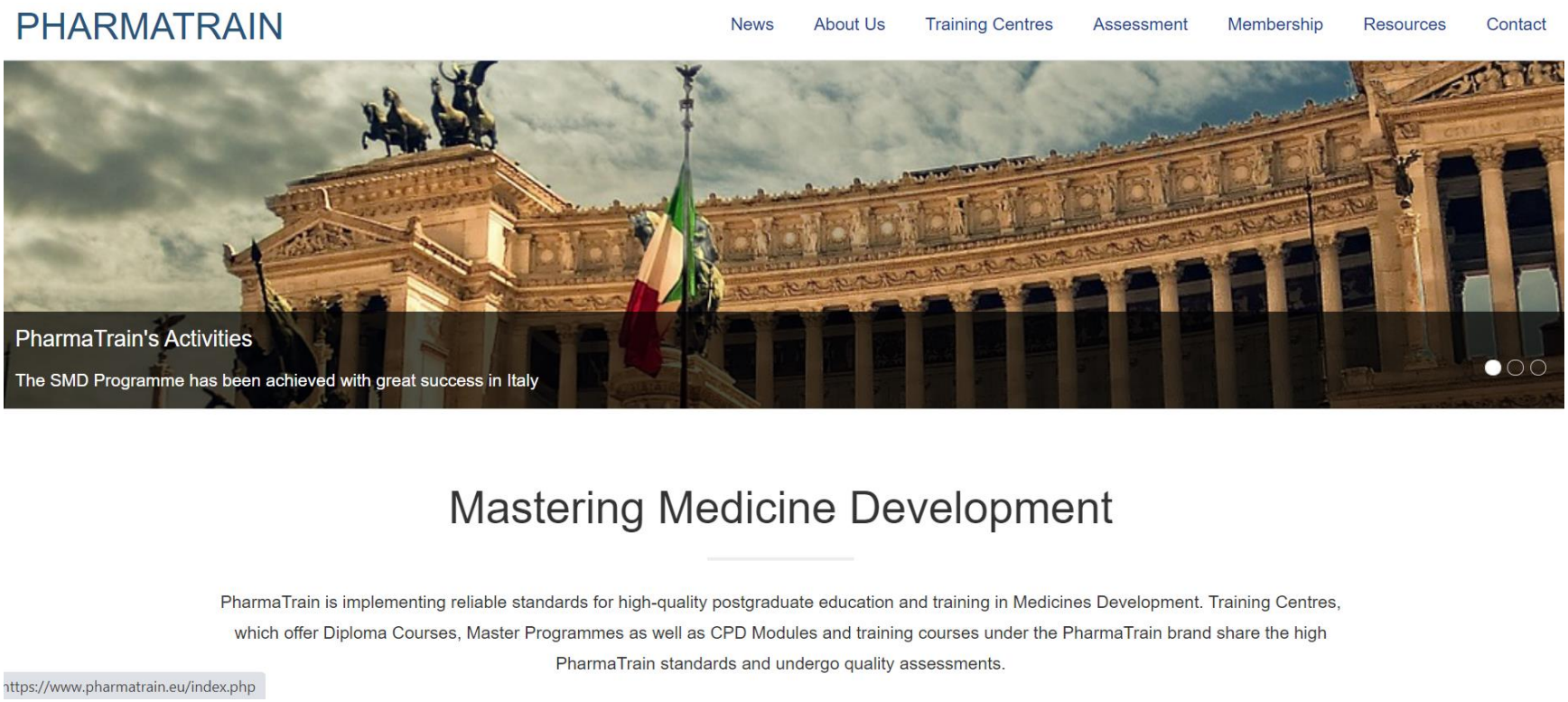
PharmaTrain Syllabus Revision Project (SRP)

- 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

Ευρωπαϊκός Οργανισμός PharmaTrain



Προγράμματα και εκπαιδευτικά κέντρα PharmaTrain

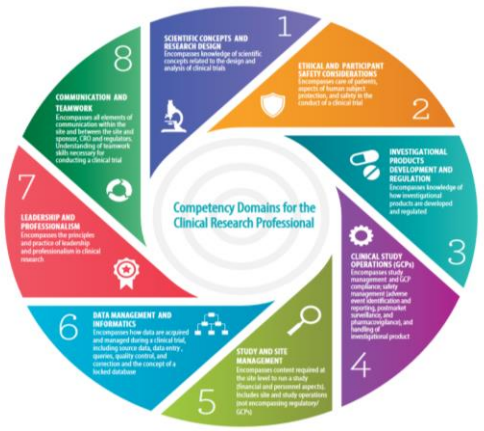
Masters / Diploma List

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

Strategic Professional Agenda

Medical Affairs In Medicines Development Certification



Strategic collaboration

King's College London
- Develop content together with IFAPP
- Program Accreditation
- Quality Standards

IFAPP and IFAPP Academy
- Offers Professional Certification
- Worldwide distribution
- Academic Operations

Private Sector: Pharma , others
- Unrestricted grants
- Inputs into the program
- Expert faculty

Blended Online Modular Program

Σημαντική εκπαιδευτική online εκπαίδευση

EL.E.F.I. Hellenic Society of Pharmaceutical Medicine a Member of...
753 followers
3w •

#EL.E.F.I. is recommending the highly esteemed #CSDD certification course in #drugdevelopment hosted by #AmericanCollegeinGreece taking place in March 2021. ...see more

The American College of Greece | Tufts Center for the Study of Drug Development - ACG Professional Certificate in Clinical Pharmacology, Drug Development and...

Επαγγελματική σταδιοδρομία στην Κλινική Έρευνα

Life Science Career Tips | Tips for PhD students & Postdocs

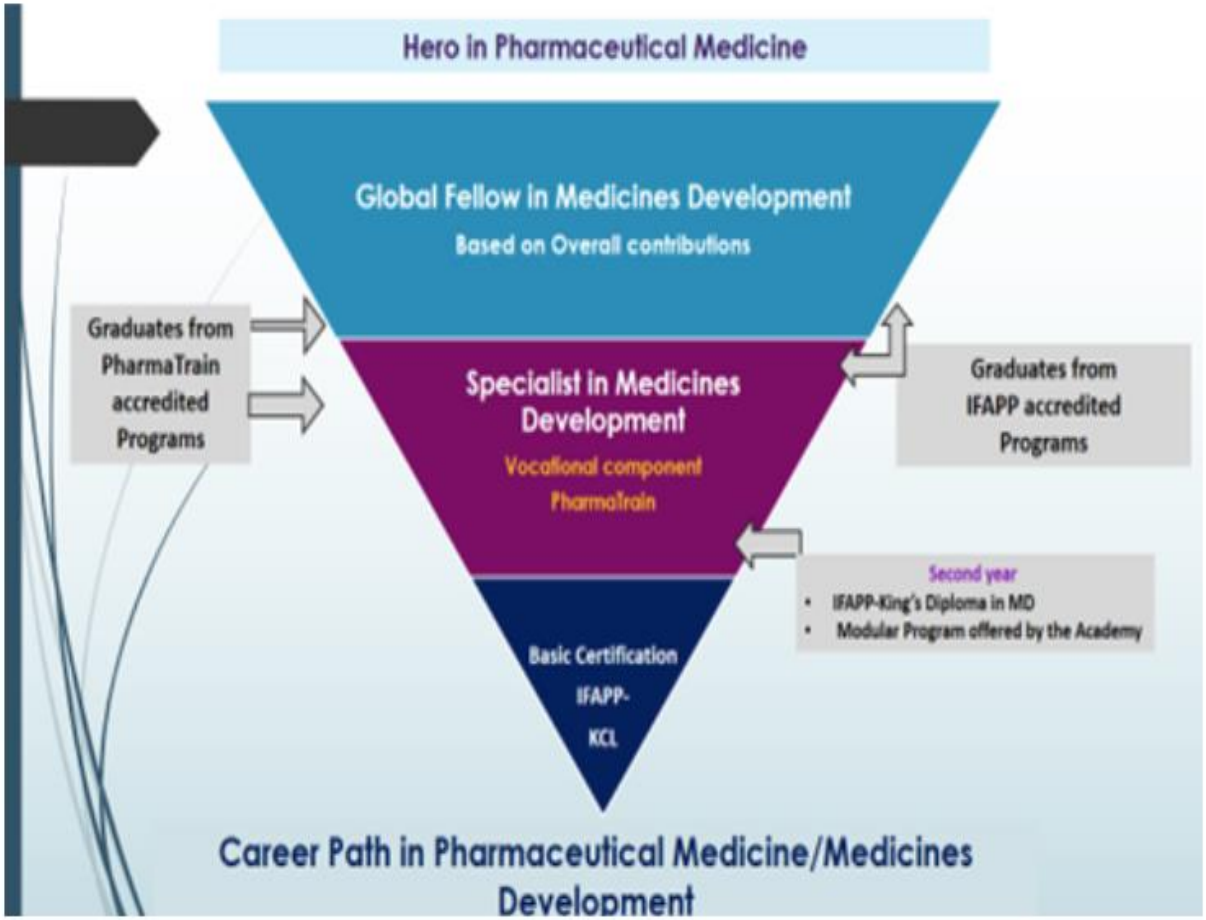
Why Clinical Research is a Hot Career Choice For 2021 and Beyond

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

Pharmaceutical Medicine/Medicines Development Career Path



Η βασική κατάρτιση των κλινικών ερευνητών 6/2014

CenterWatch

Αντίληψη δεξιοτήτων

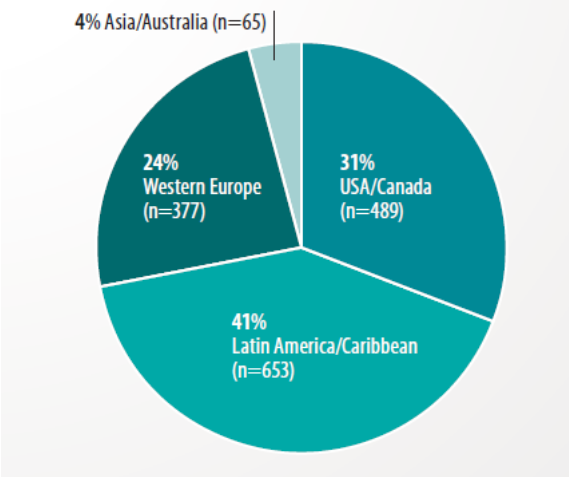


TABLE 6: Self-Perceived Competence in Domain by Academic Degree

Domains	Competence/Role (mean value)						
	No Post-Secondary Degree (n=35)	AS/AD (n=92)	Diploma (n=119)	BA/BS (n=312)	Post – BA/BS Certificate (n=133)	Masters (n=462)	Doctorate (n=330)
*Scientific Concepts and Research Design	0.2	0.2	0.3	0.3	0.3	0.5	0.7
*Ethical and Participant Safety Considerations	0.5	0.6	0.6	0.7	0.6	0.7	0.8
Medicines Development and Regulation	0.3	0.4	0.4	0.4	0.4	0.5	0.5
Clinical Trials Operations	0.6	0.6	0.6	0.7	0.7	0.7	0.8
Study and Site Management	0.5	0.7	0.6	0.5	0.7	0.6	0.6
Data Management and Informatics	0.5	0.5	0.6	0.6	0.6	0.6	0.6
Leadership and Professionalism	0.6	0.6	0.6	0.6	0.7	0.7	0.8
*Communication and Teamwork	0.5	0.5	0.5	0.5	0.6	0.7	0.7

Note: Domains tagged (*) ANOVA p < 0.0001 across domain and degree earned at 5% significance level. Shaded areas ≥ 0.6 "competent."

TABLE 7: Self-Perceived Relevance to My Position of Domain by Academic Degree

Domains	Relevance/Role (mean value)						
	No Post-Secondary Degree (n=35)	AS/AD (n=92)	Diploma (n=119)	BA/BS (n=312)	Post – BA/BS Certificate (n=133)	Masters (n=462)	Doctorate (n=330)
Scientific Concepts and Research Design	0.3	0.2	0.4	0.2	0.3	0.4	0.6
Ethical and Participant Safety Considerations	0.6	0.7	0.6	0.6	0.6	0.7	0.7
Medicines Development and Regulation	0.4	0.4	0.4	0.3	0.4	0.5	0.4
Clinical Trials Operations	0.6	0.7	0.7	0.6	0.7	0.7	0.7
Study and Site Management	0.5	0.7	0.7	0.6	0.6	0.6	0.7
Data Management and Informatics	0.6	0.6	0.6	0.5	0.6	0.6	0.6
Leadership and Professionalism	0.6	0.7	0.7	0.6	0.7	0.7	0.7
*Communication and Teamwork	0.6	0.6	0.6	0.5	0.6	0.6	0.7

Note: Domains tagged (*) ANOVA p < 0.0001 across domain and degree earned at 5% significance level. Shaded areas ≥ 0.6 "competent."

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

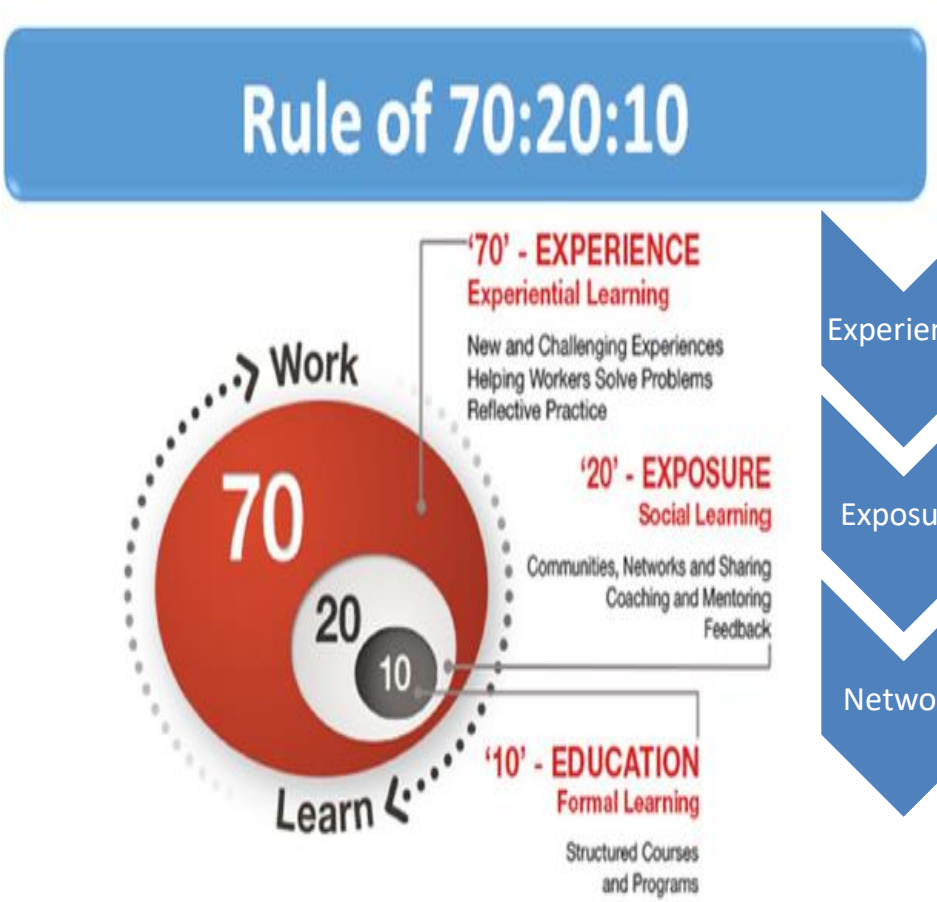
Note: ANOVA $p<0.0001$ between roles across all domains at 5% significance. Shaded area ≥ 0.6, "competent."

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*

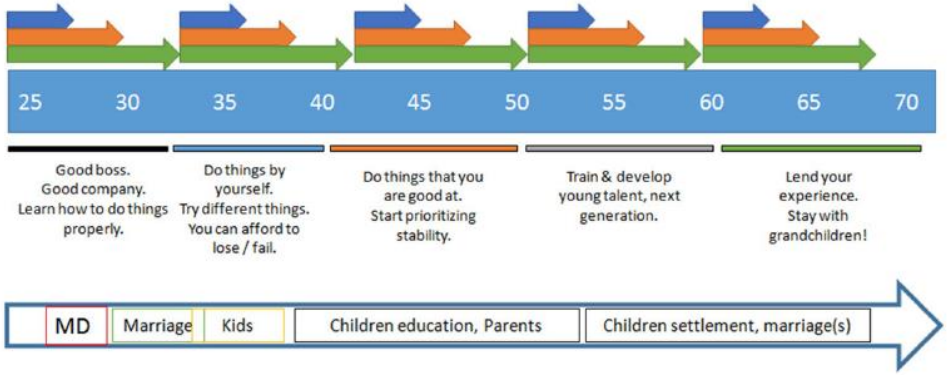
Δια βίου εκπαίδευση ερευνητών



- Experience
  - Sabbatical
- Exposure
  - Exchange program
- Network
  - Collaborative projects

A possible life-roadmap for a successful professional career

Fig. 8 Diverse mentoring approaches can have an even broader impact on careers. A career when it progresses through the right mentoring and under the influence of supportive peers, helps nudge the three key levers of job performance and career success: *ability, motivation*, and *opportunity*

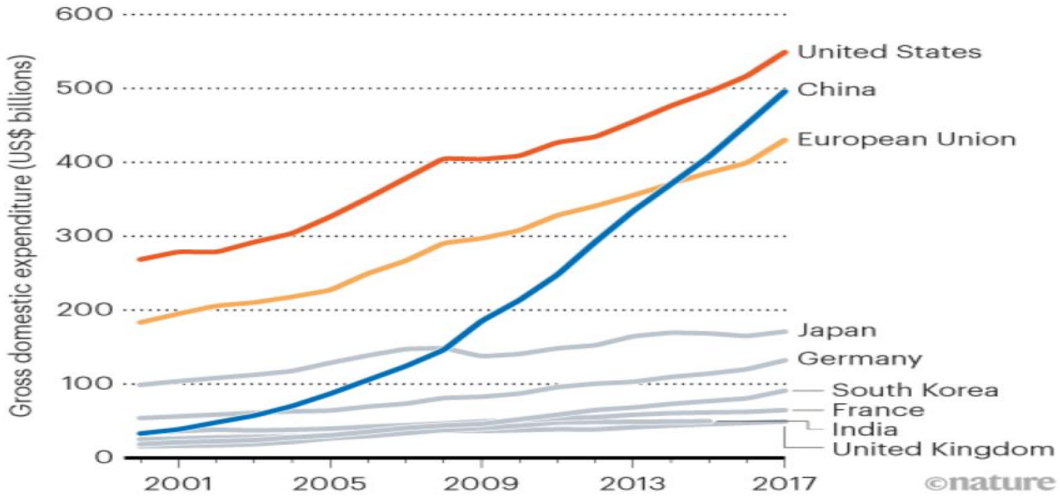


Source: Talk by Jack Ma at World Economic Forum at Davos, 2018

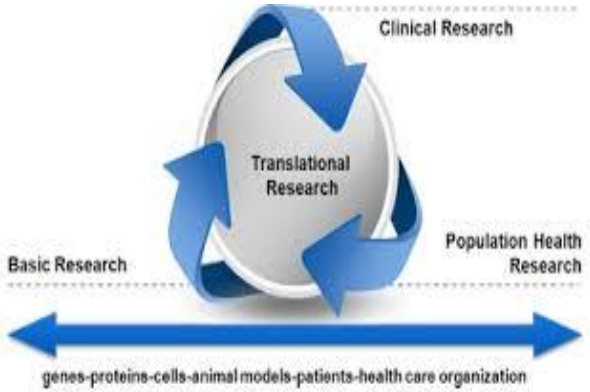
Science & Technology : Innovation ecosystem

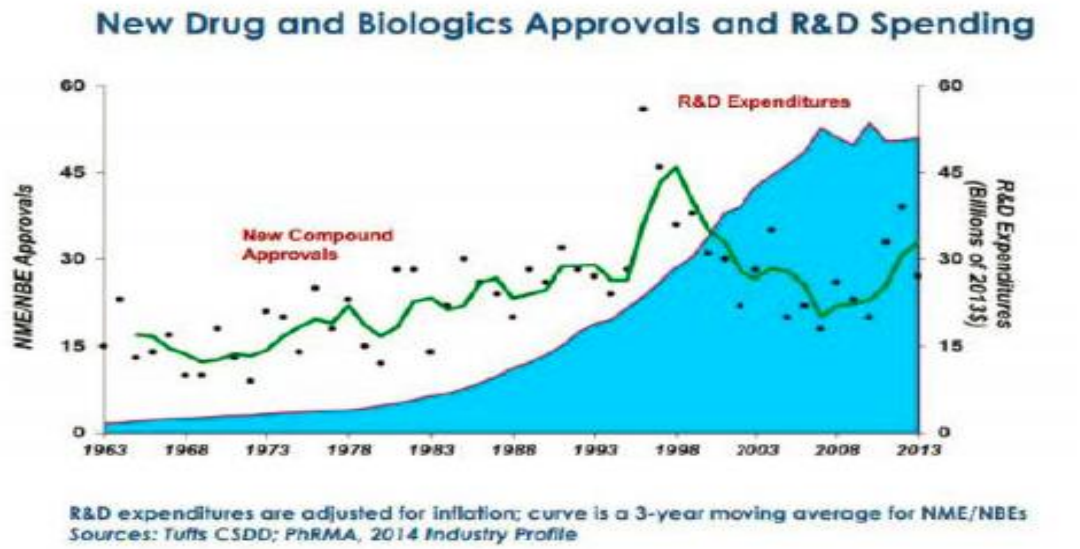
- Scientists are always probing the distant horizon
  - Inspired by curiosity
- Science responds to uncertainties with experimentation designed to create evidence
- Massive changes induced by technology that are going to transform health care
- Big Pharma as Conduit of innovation bringing fresh ,scalable ideas to life
- To Supply innovations that patients truly value

Science & Research Spending



Source: National Science Foundation

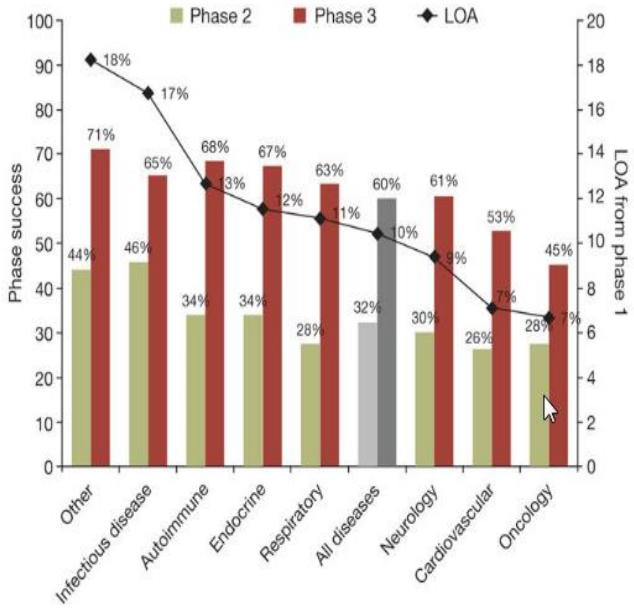




Research & Development

- High Cost & long process
- Target identification –to proof of concept pharmacology (R)
  - 30 % of total R&D cost
    - During 6 and a half years
    -
  - Clinical Development (D) Phase I –III
    - 60% of total budget
    - Mean duration of 6years
    - Likelihood of approval 9-18%
- ~ 2 billion US $, 10-12 years

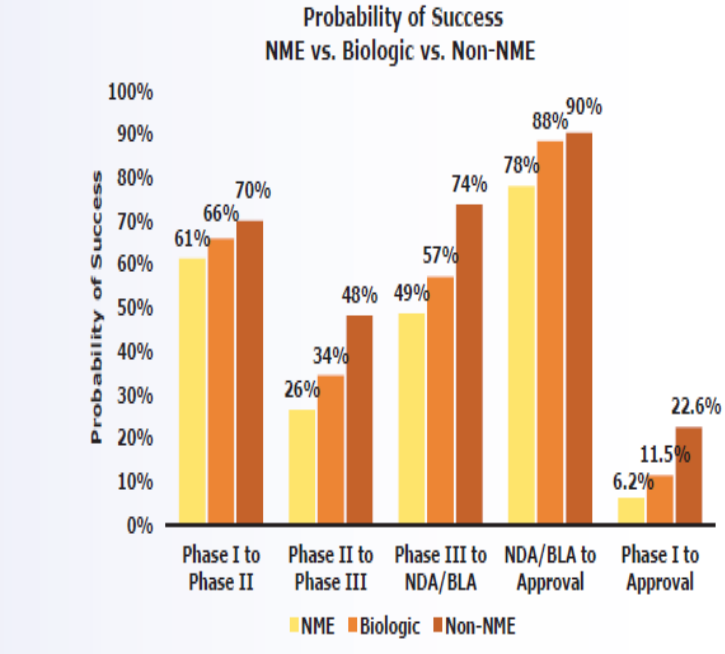
Phase success and LOA from phase I by disease for all indications.

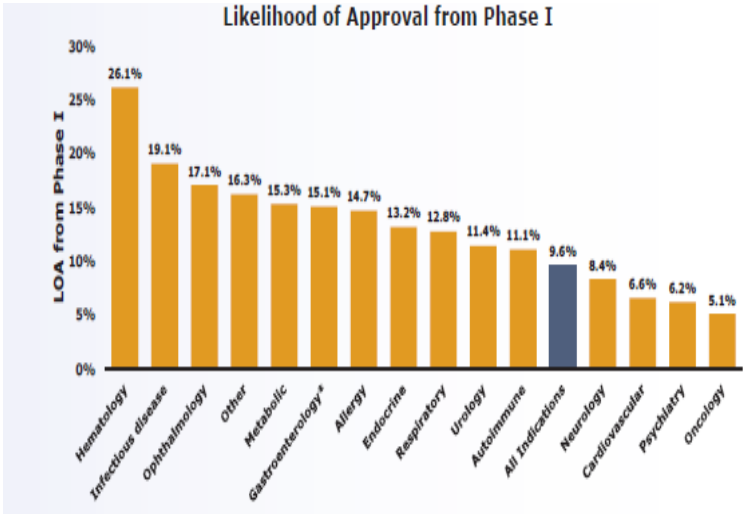


The bars represent phase 2 and phase 3 success rates and the line represents LOA from phase 1.

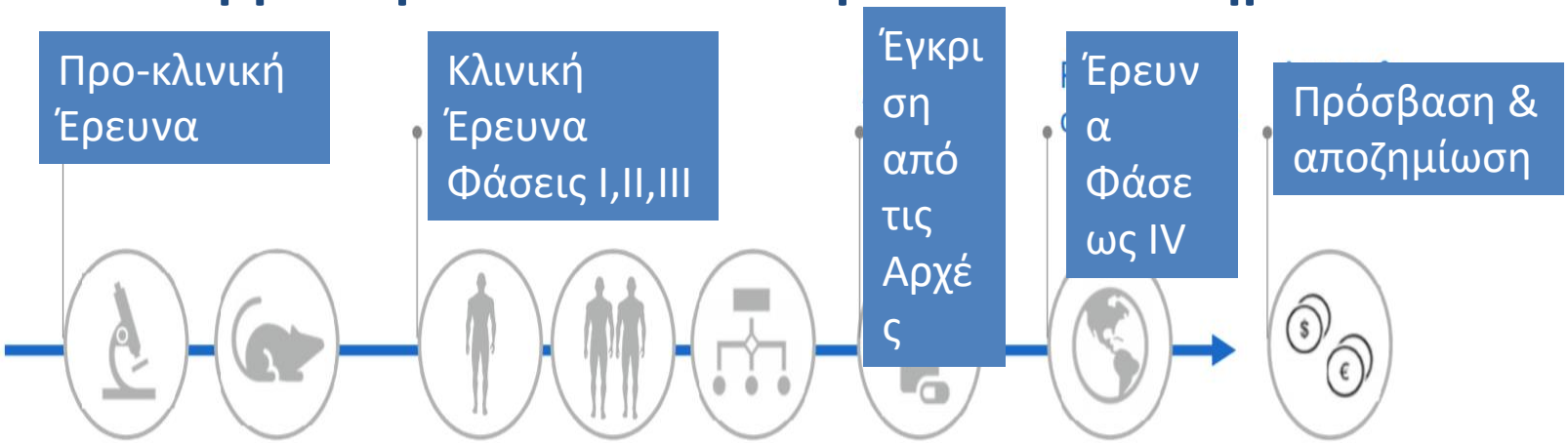
Nature Biotechnology **32**, 40–51 (2014)

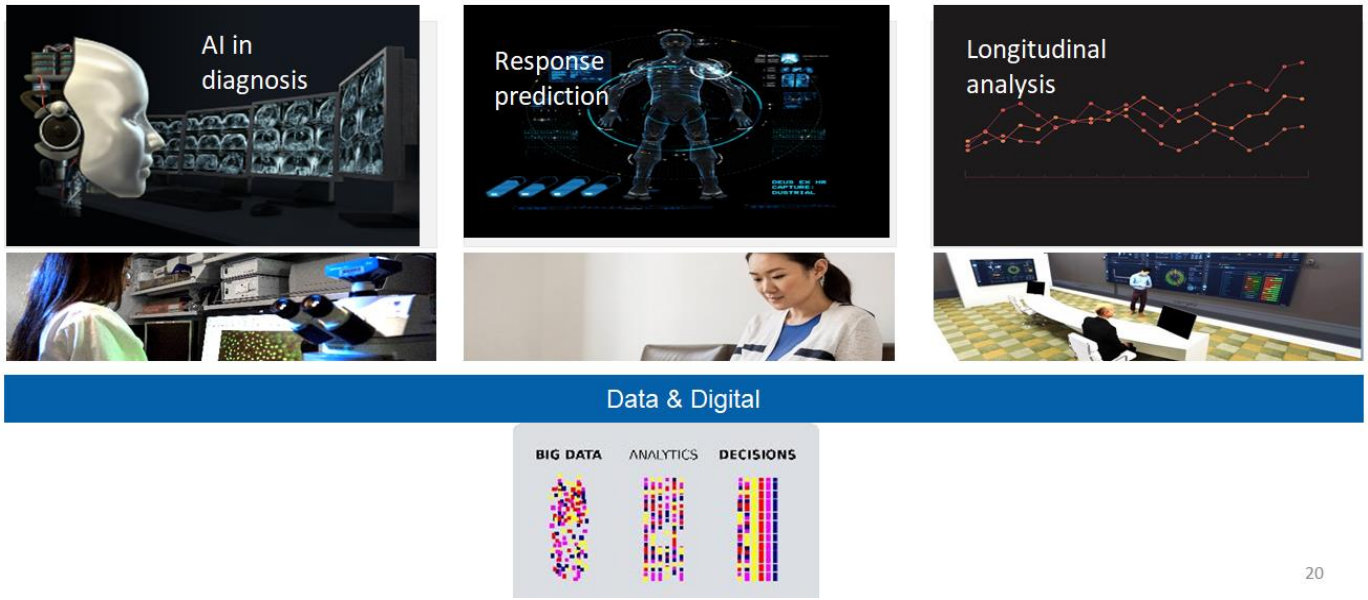
Biomed tracker Clinical Development success rates 2006-2015



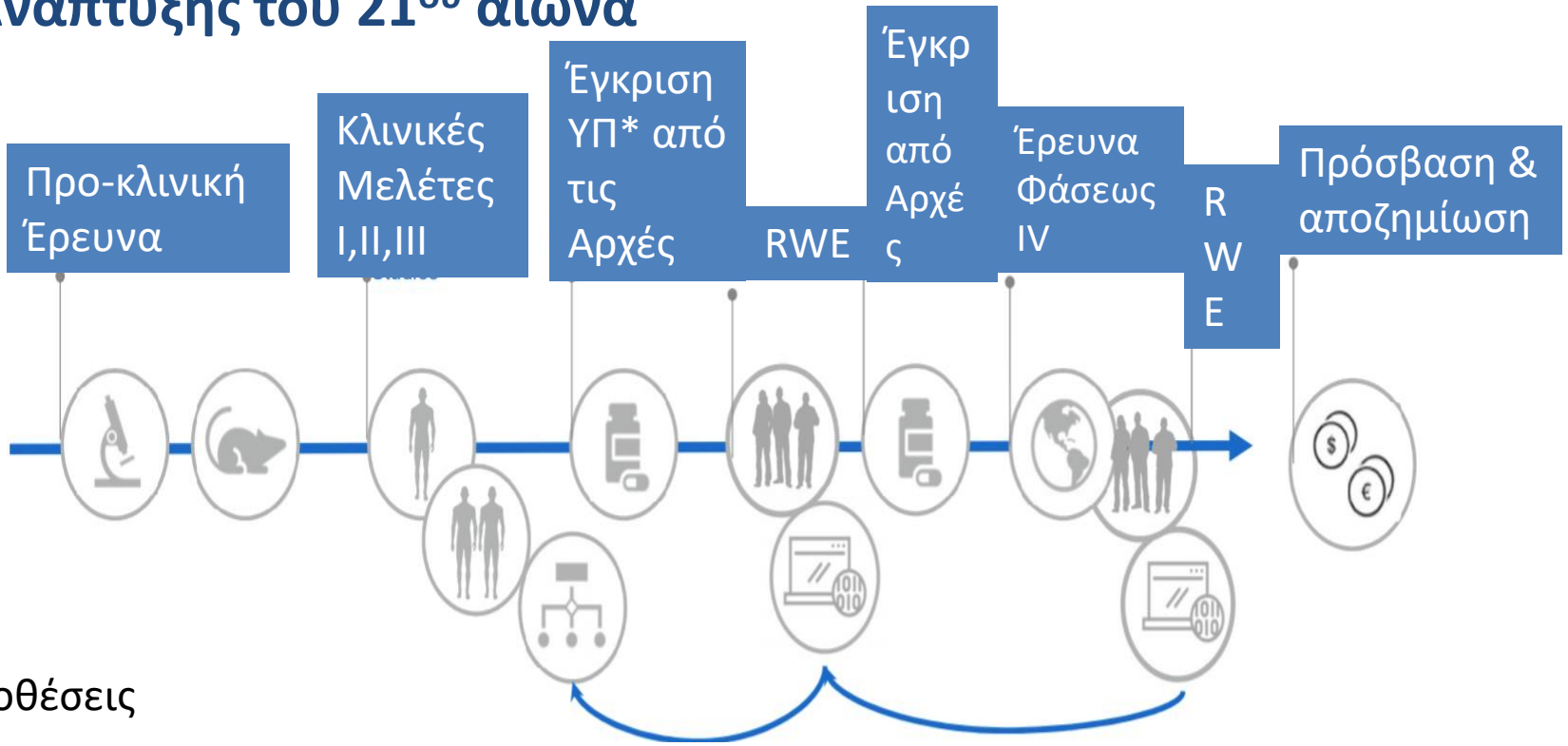


Το Μοντέλο Έρευνας και Ανάπτυξης του 20ου αιώνα δεν είναι συμβατό με τα αναλυτικά μοντέλα επιστημονικών

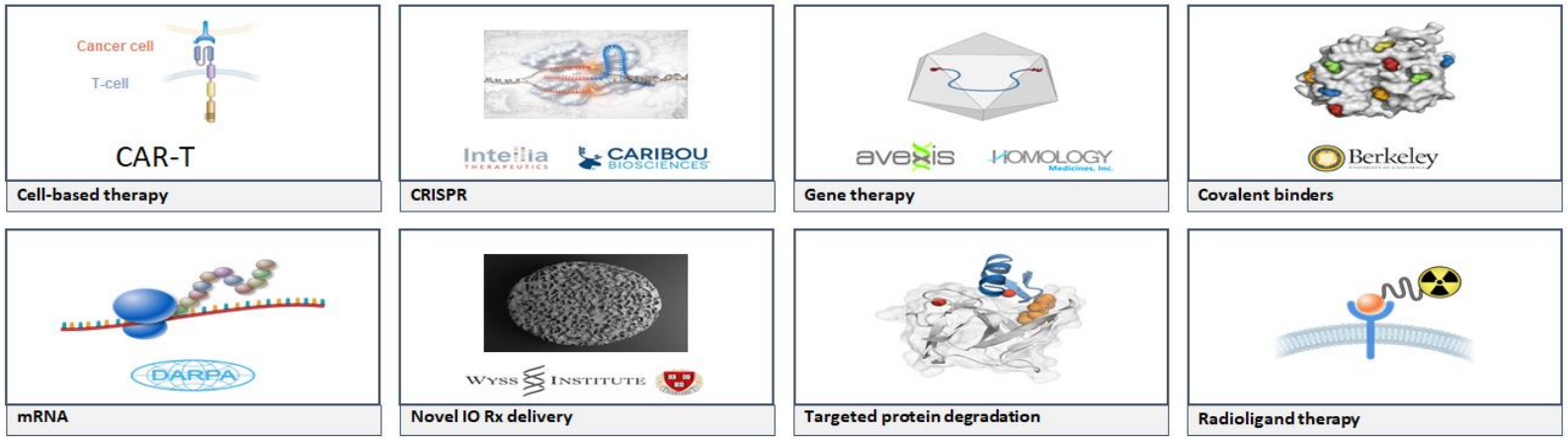




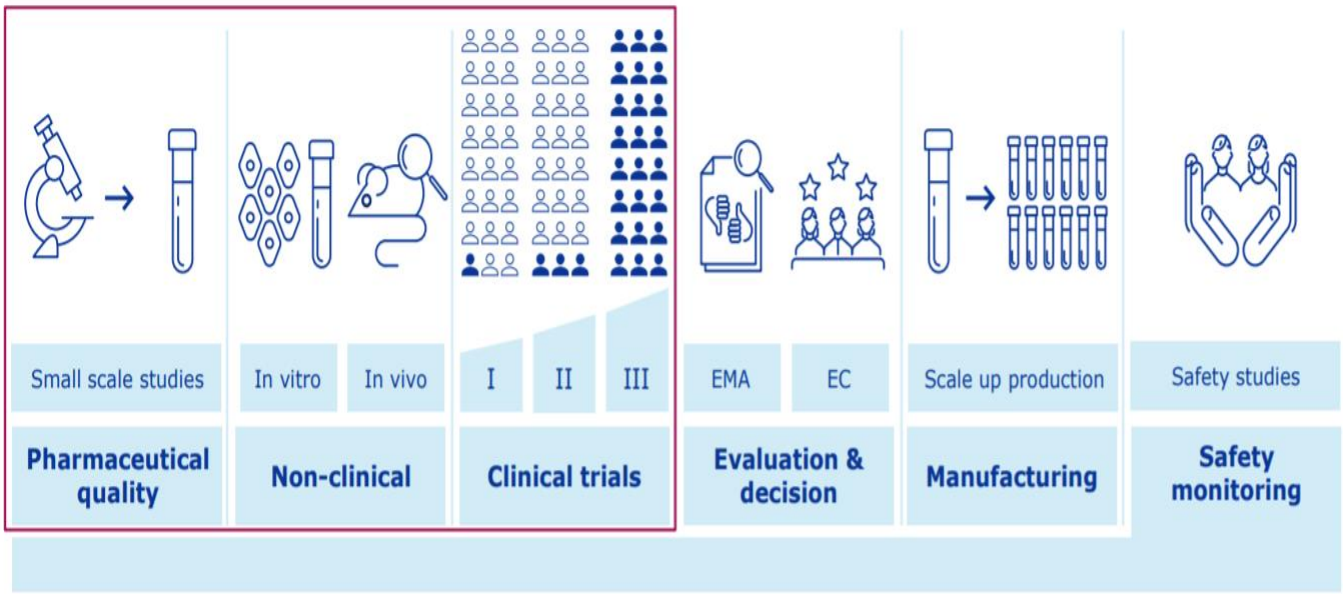
Το Αναδυόμενο Μοντέλο Υπέρ -Καινοτόμου Έρευνας και Ανάπτυξης του 21ου αιώνα



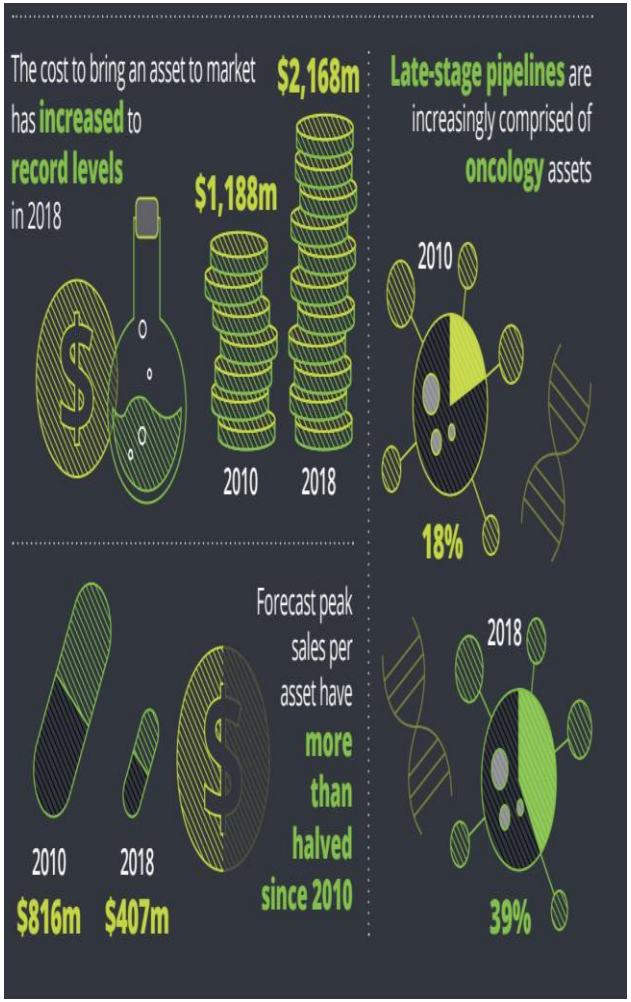
*Υπό Προϋποθέσεις

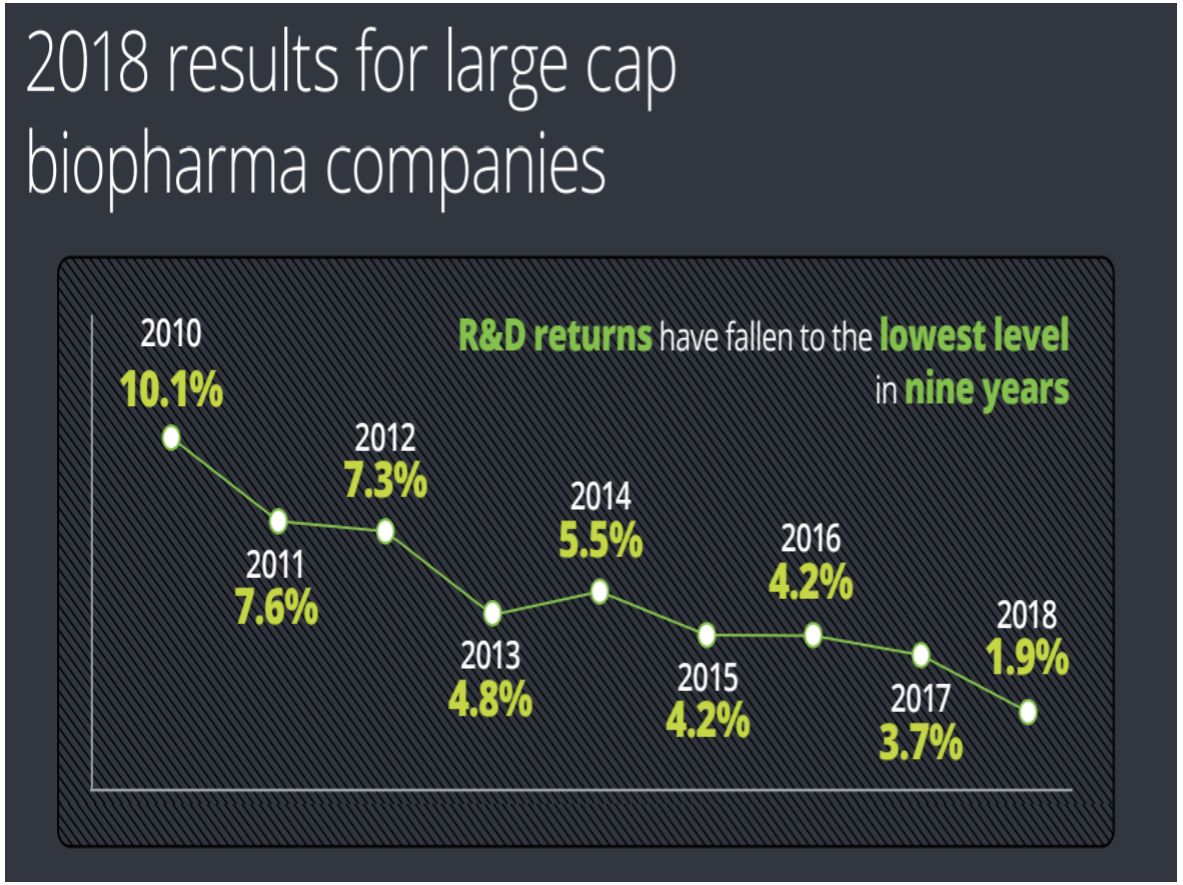


Μετά το τέλος των Κλινικών Δοκιμών ακολουθεί η Εγκριτική Διαδικασία στην Ευρωπαϊκή Ένωση για νέα φάρμακα ή εμβόλια



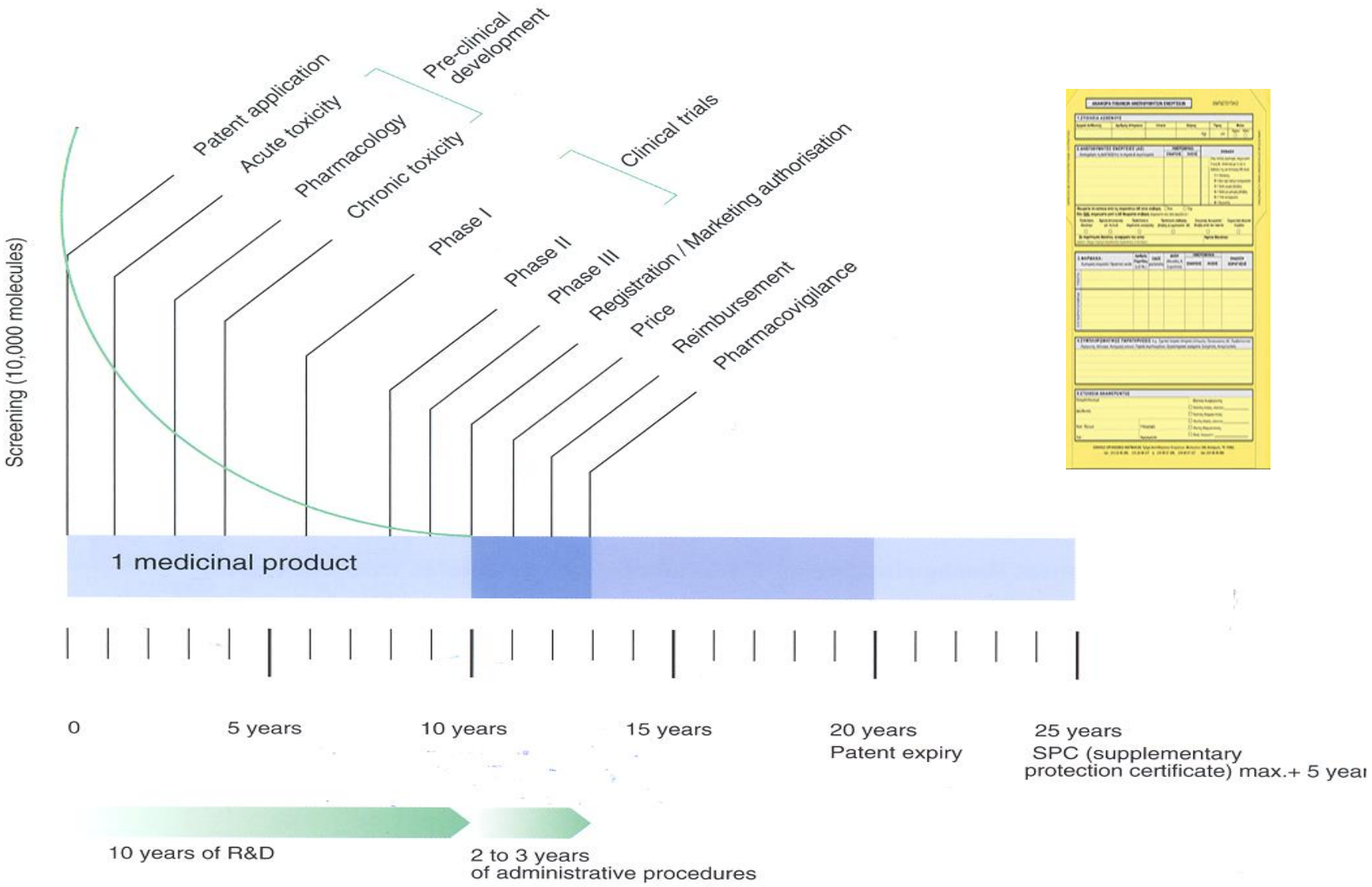
Η Ερευνα & Ανάπτυξη νέων φαρμακευτικών θεραπειών



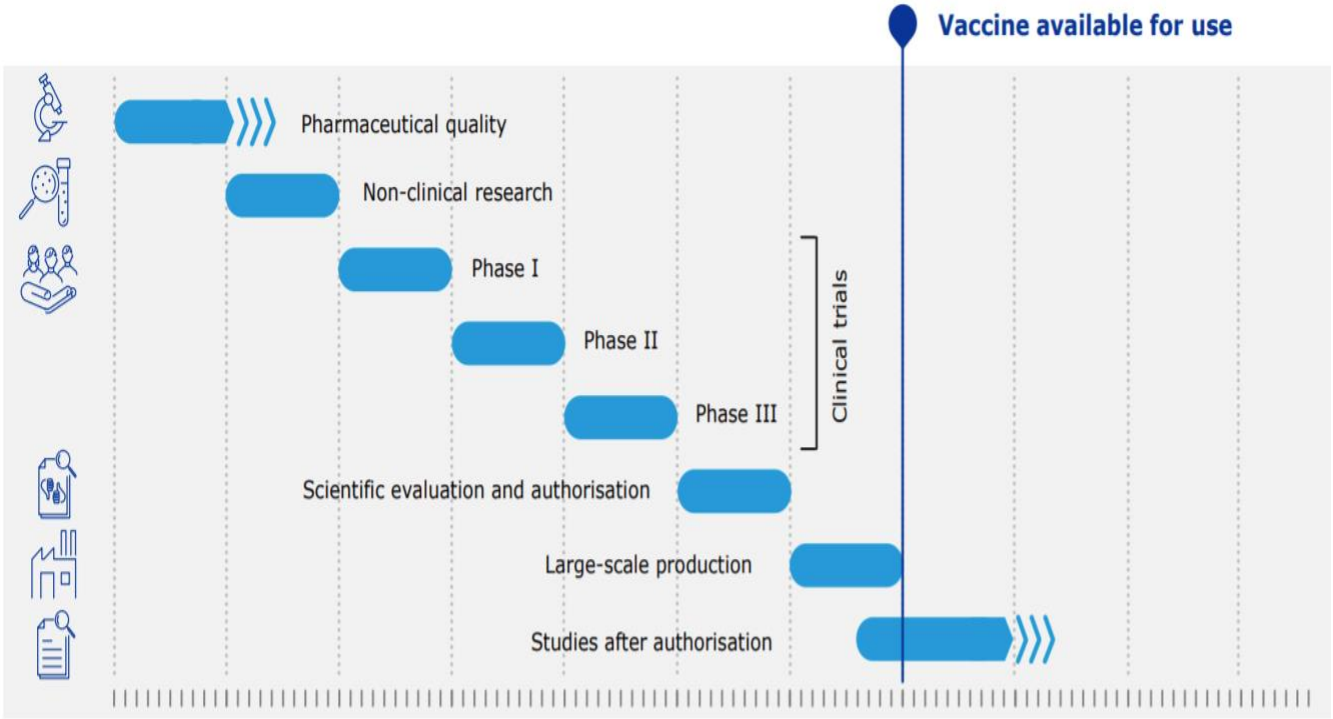


Deloitte Report 2018

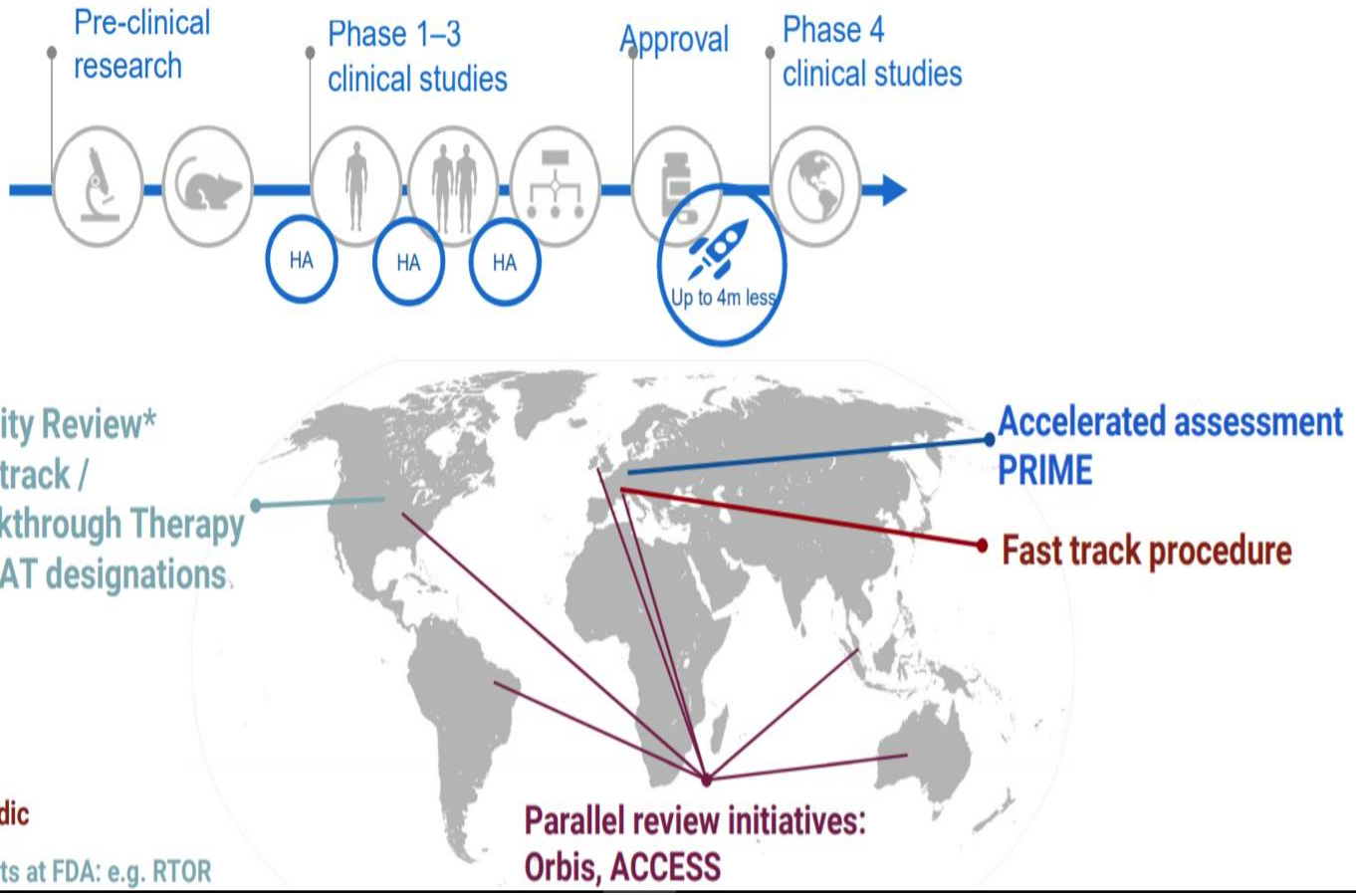
PHASES OF THE RESEARCH AND DEVELOPMENT PROCESS



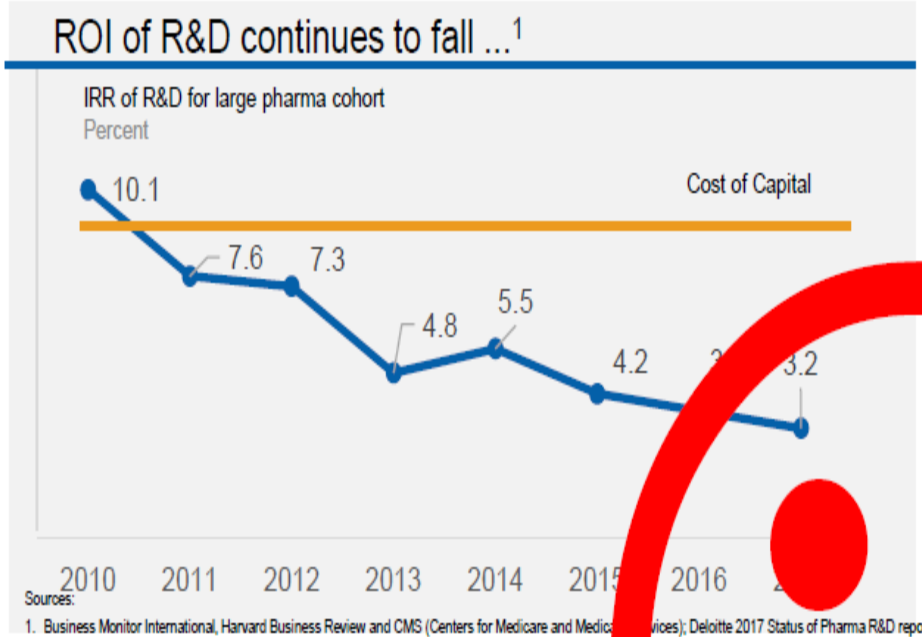
Στάδια και χρόνοι Έρευνας και Κλινικής Ανάπτυξης φαρμάκων και εμβολίων

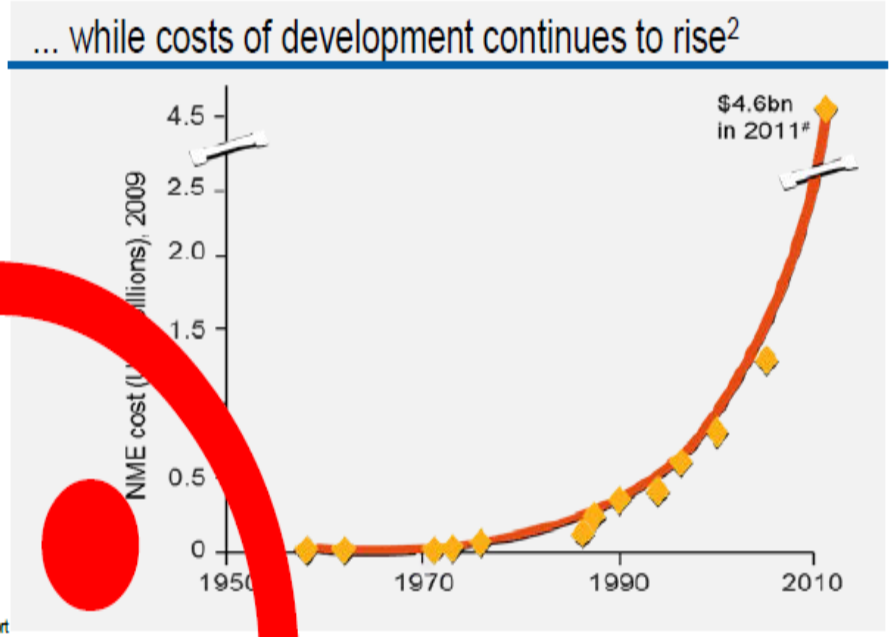


Εγκριτικές εξελίξεις στην Ευρωπαϊκή Ένωση και οι επισπεύδουσες διαδικασίες για καινοτόμες θεραπείες με πρώιμα σημαντικά δεδομένα

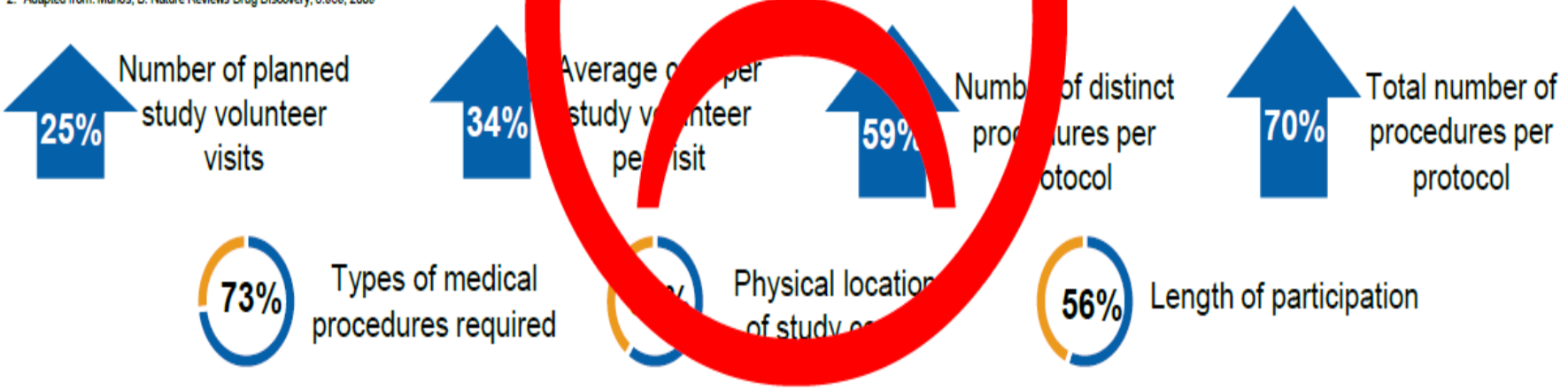


Why clinical development needs disruptive innovation





Sources:
1. Business Monitor International, Harvard Business Review and CMS (Centers for Medicare and Medica…vices); Deloitte 2017 Status of Pharma R&D report
2. Adapted from: Munos, B. Nature Reviews Drug Discovery, 8:959, 2009



Sources:
1. Getz, K. A. & Campo, R. A. New Benchmarks Characterizing Growth in Protocol Design Complexity. Ther. Innov. Regul. Sci. 52, 22–28 (2018)
2. Report from CISCRP. Perceptions & Insights Study Report on The Participation Decision-Making Process, (2017)

Rethinking drug discovery – Turning the Titanic?

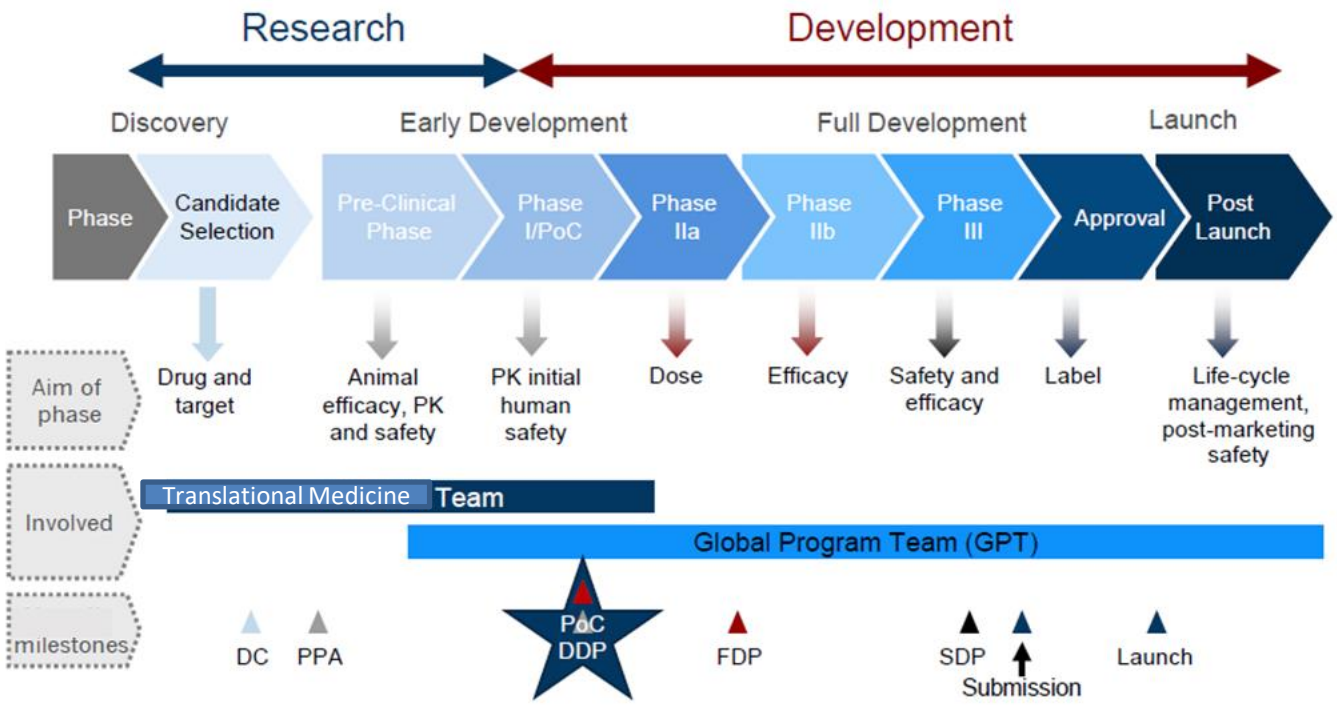
Elias A. Zerhouni, President Global R&D, Sanofi
Editorial in Science Translational Medicine, January 2014

'We must acknowledge that no single institution, company, university, country, or government has a monopoly on innovation.'

The Changing Face of Innovation

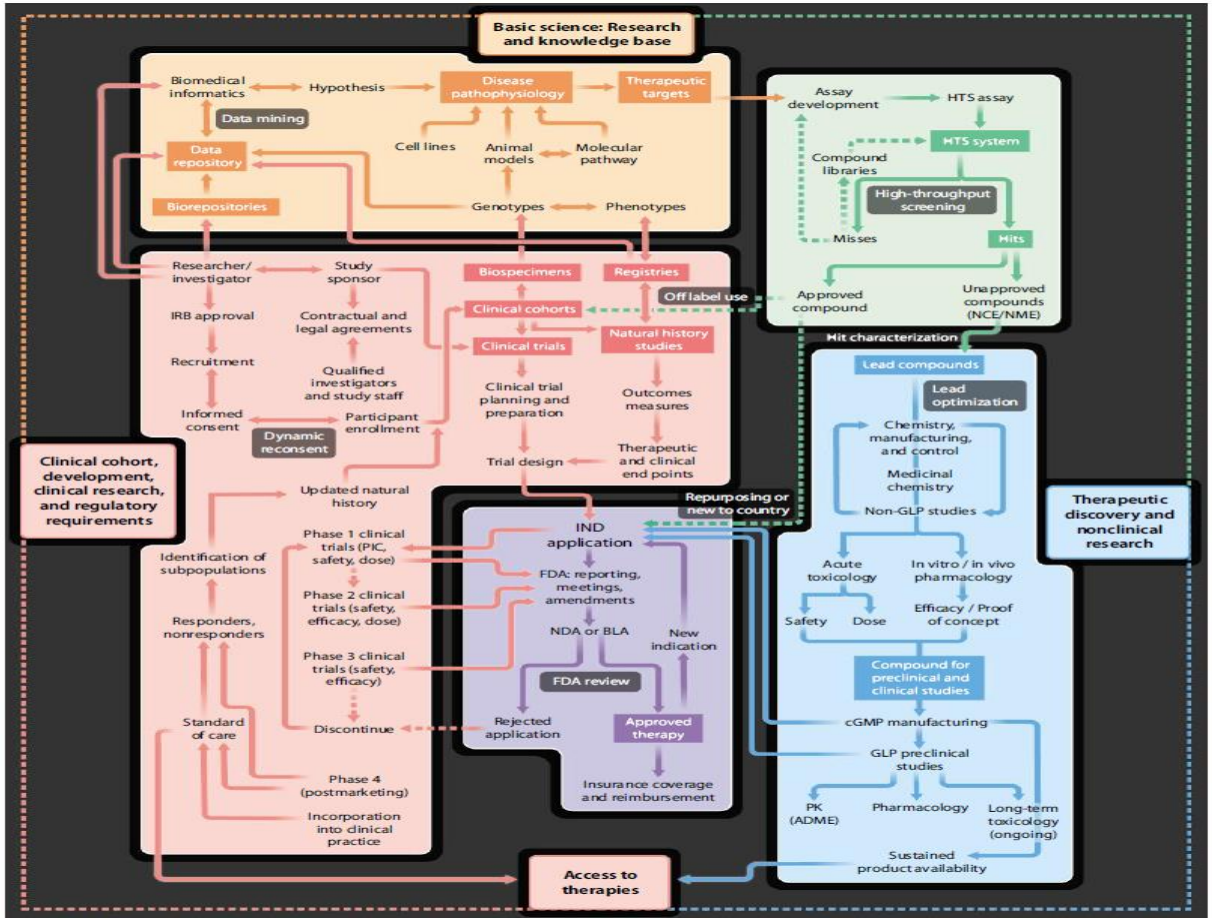
- Pharma R&D operates very differently today
- Large internal research efforts are being replaced by access to external innovation : Universities, Foundations, Bio techs
- Looking for newer R&D models, adaptive ,virtual innovation networks
- Scientific advances still hampered by lack of human disease biology understanding- Translational Medicine
- Research Collaborations building pre competitive “COMMONS’’ to enhance knowledge

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

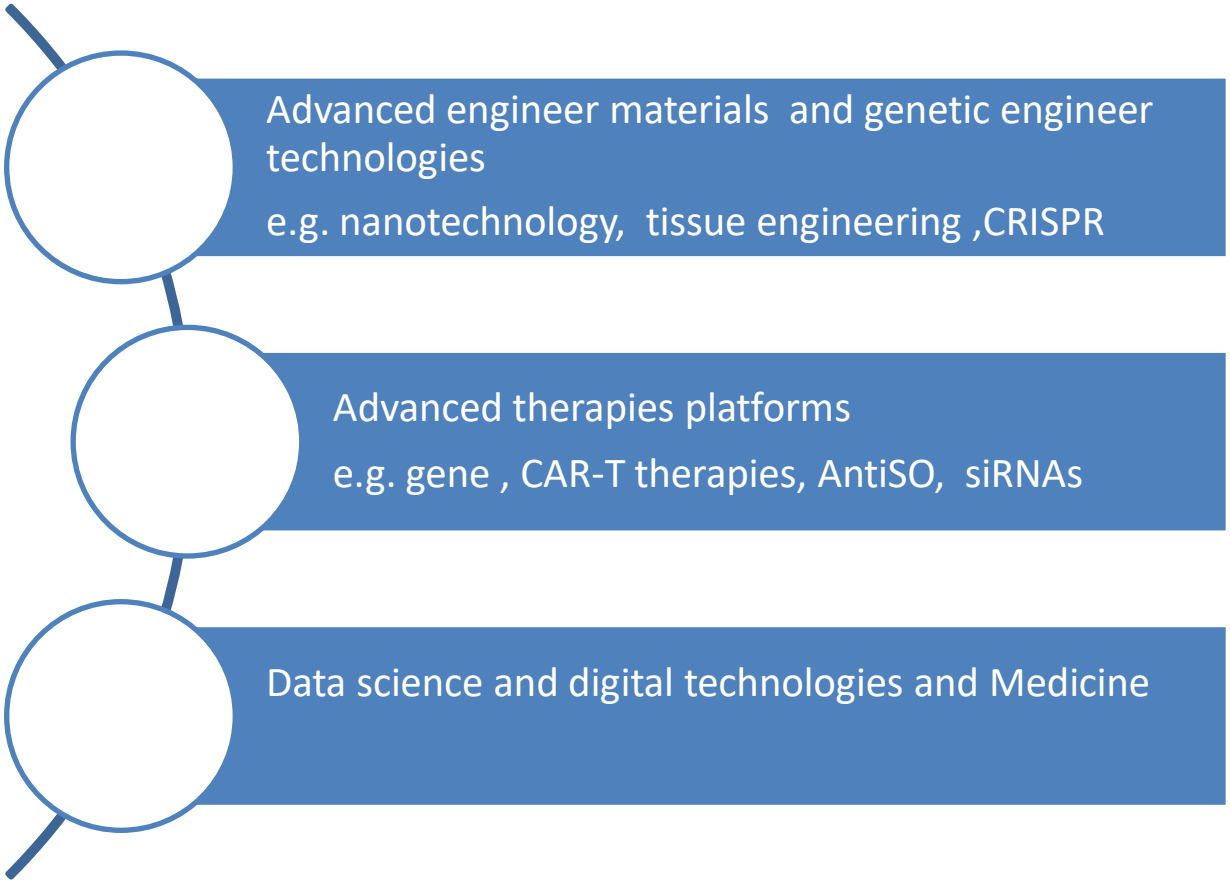


www.ScienceTranslationalMedicine.org 6 February 2013 Vol 5 Issue 171 171cm1

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]*



The Changing Face of Innovation : 21st century model



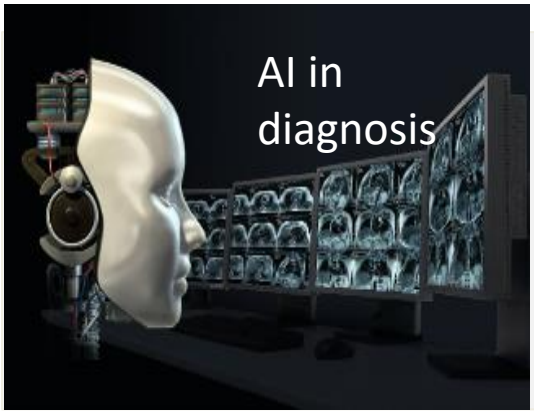
Artificial Intelligence in R&D

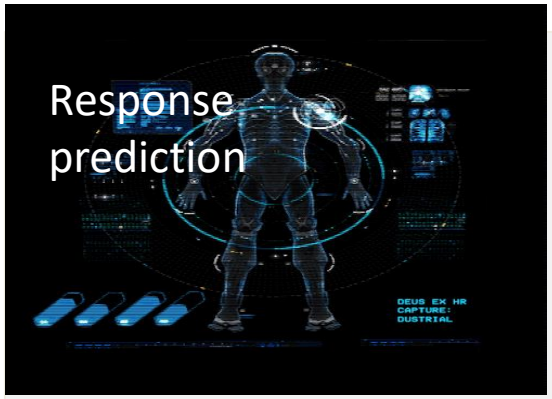
- Can AI streamline components of discovery ?

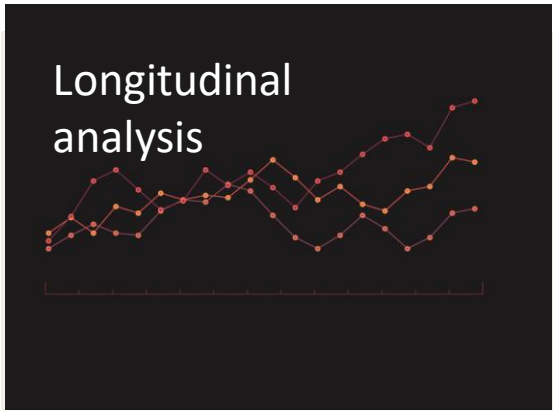
Mapping Molecular Pathways
Better uses for Existing drugs
Back to Biology
Can deep learning Make sense of Messy Biology ?
Using existing data better

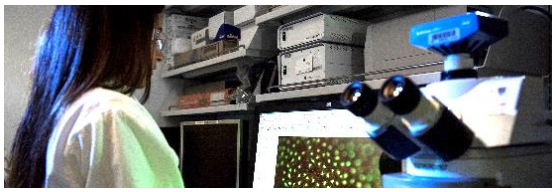
Big R& D Pharma engagement in AI with the nascent sector belies its urgent need for those solutions

Making data science and digital dreams a reality in 21st century



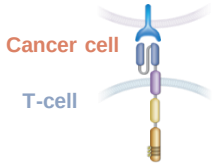






Data & Digital

Accelerating a suite of innovative and advanced therapy platforms in 21st century

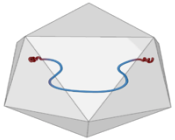


CAR-T

Cell-based therapy

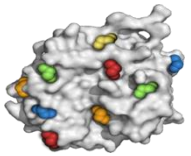
Intellia THERAPEUTICS CARIBOU BIOSCIENCES

CRISPR



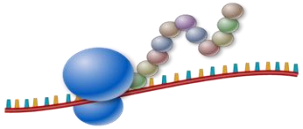
avexis HOMOLOGY Medicines, Inc.

Gene therapy



Berkeley

Covalent binders

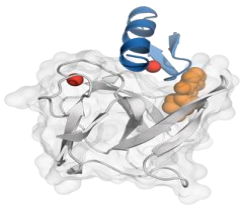


DARPA

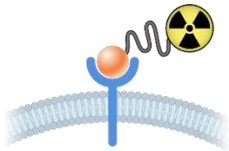
mRNA

Wyss Institute

Novel IO Rx delivery

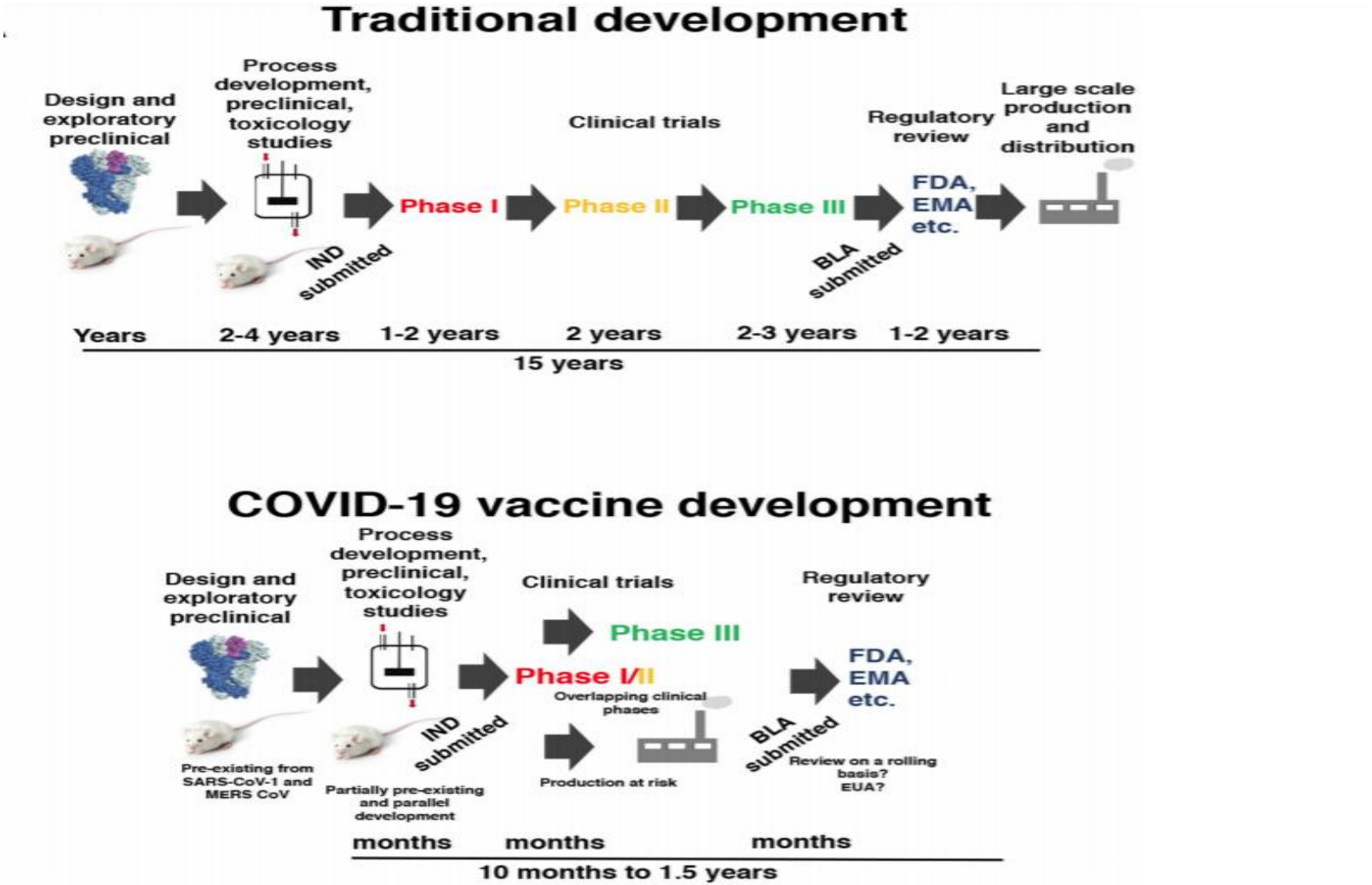


Targeted protein degradation



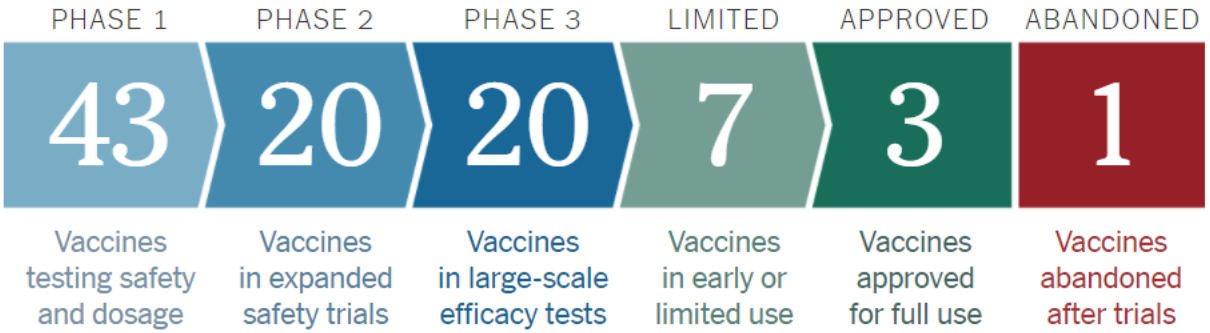
Radioligand therapy

Έρευνα & Κλινική Ανάπτυξη



Coronavirus Vaccine Tracker

By Carl Zimmer, Jonathan Corum and Sui-Lee Wee Updated Jan. 8, 2021



Vaccines typically require years of research and testing before reaching the clinic, but in 2020, scientists embarked on a race to produce safe and effective coronavirus vaccines in record time. Researchers are currently testing **64 vaccines** in clinical trials on humans, and 20 have reached the final stages of testing. At least 85 preclinical vaccines are under active investigation in animals.

Νεότερα δεδομένα έως 14/1/2021

New additions and recent updates

Jan. 6	Brazil says **Sinovac**'s vaccine has an efficacy of 78 percent.
Jan. 6	The European Union authorizes **Moderna**'s vaccine.
Jan. 4	Israel authorizes **Moderna**'s vaccine.
Jan. 4	Taiwan's **Medigen** moves to Phase 2.
Jan. 3	India authorizes a vaccine from **Bharat Biotech**.
Jan. 4	Mexico authorizes the **Oxford-AstraZeneca** vaccine.
Jan. 3	India and Argentina authorize the **Oxford-AstraZeneca** vaccine.
Jan. 3	India's **Zydus Cadila** moves to Phase 3.
Dec. 31	The W.H.O. gives emergency validation to the **Pfizer-BioNTech** vaccine.
Dec. 30	China approves the **Sinopharm** vaccine.
Dec. 30	Britain authorizes the **Oxford-AstraZeneca** vaccine for emergency use.
Dec. 30	**Sinopharm** announces an efficacy rate of 79 percent.
Dec. 28	**Novavax** begins a Phase 3 trial in the United States.

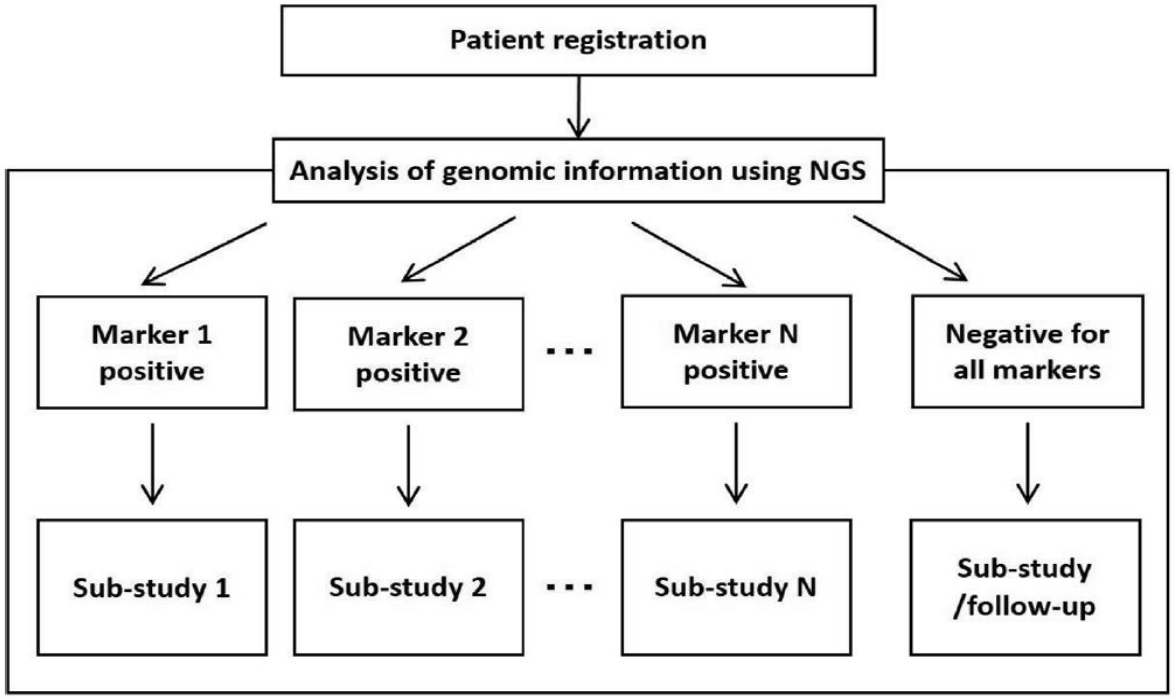
New R & D models -clinical trials

- Master or Platform Protocols
- Basket Protocols
- Umbrella Protocols
- Adaptive protocols

| BMJ 2018;360:k698 | the bmj

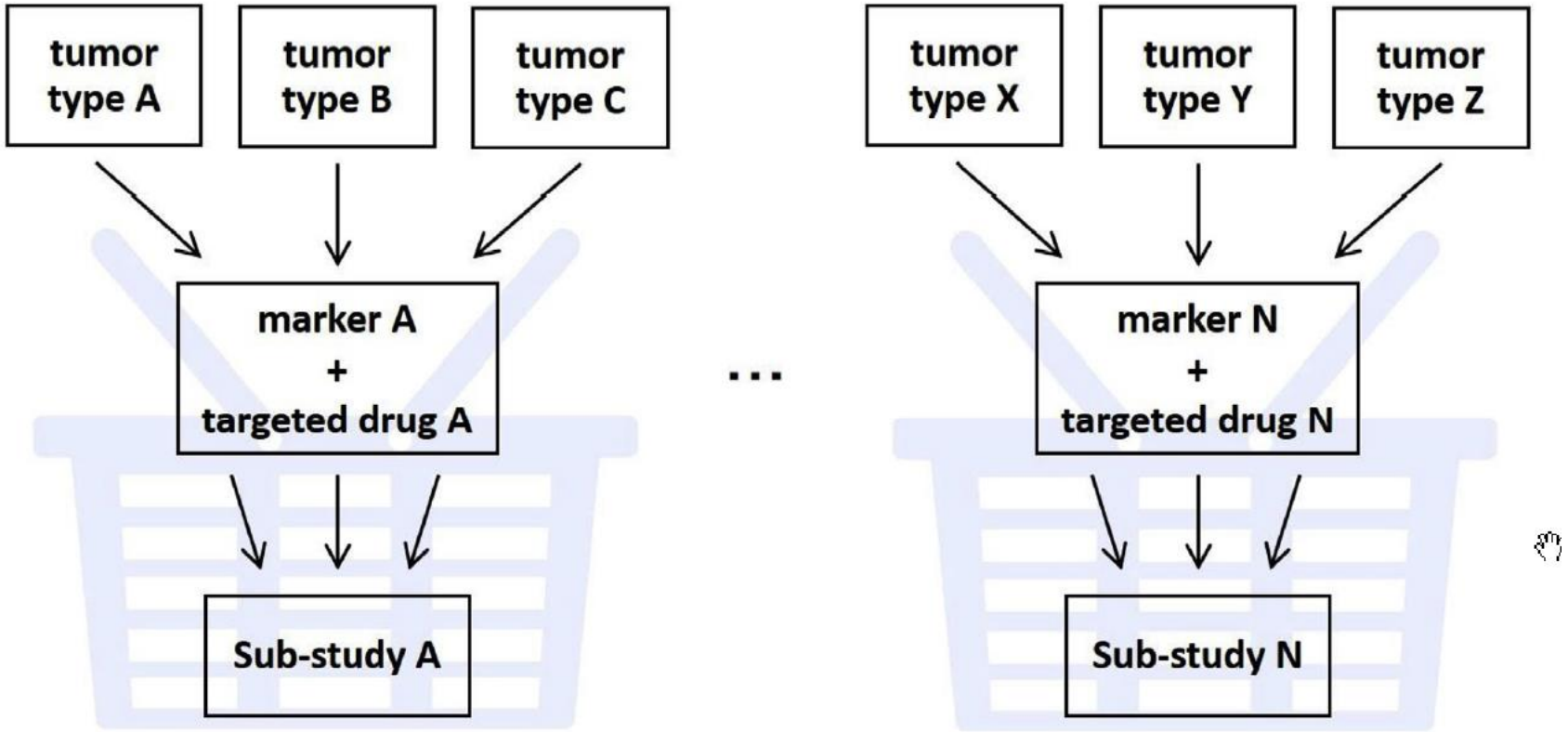
Contemp Clin Trials Commun. 2018 Dec 1,2018

Master protocols -Platform



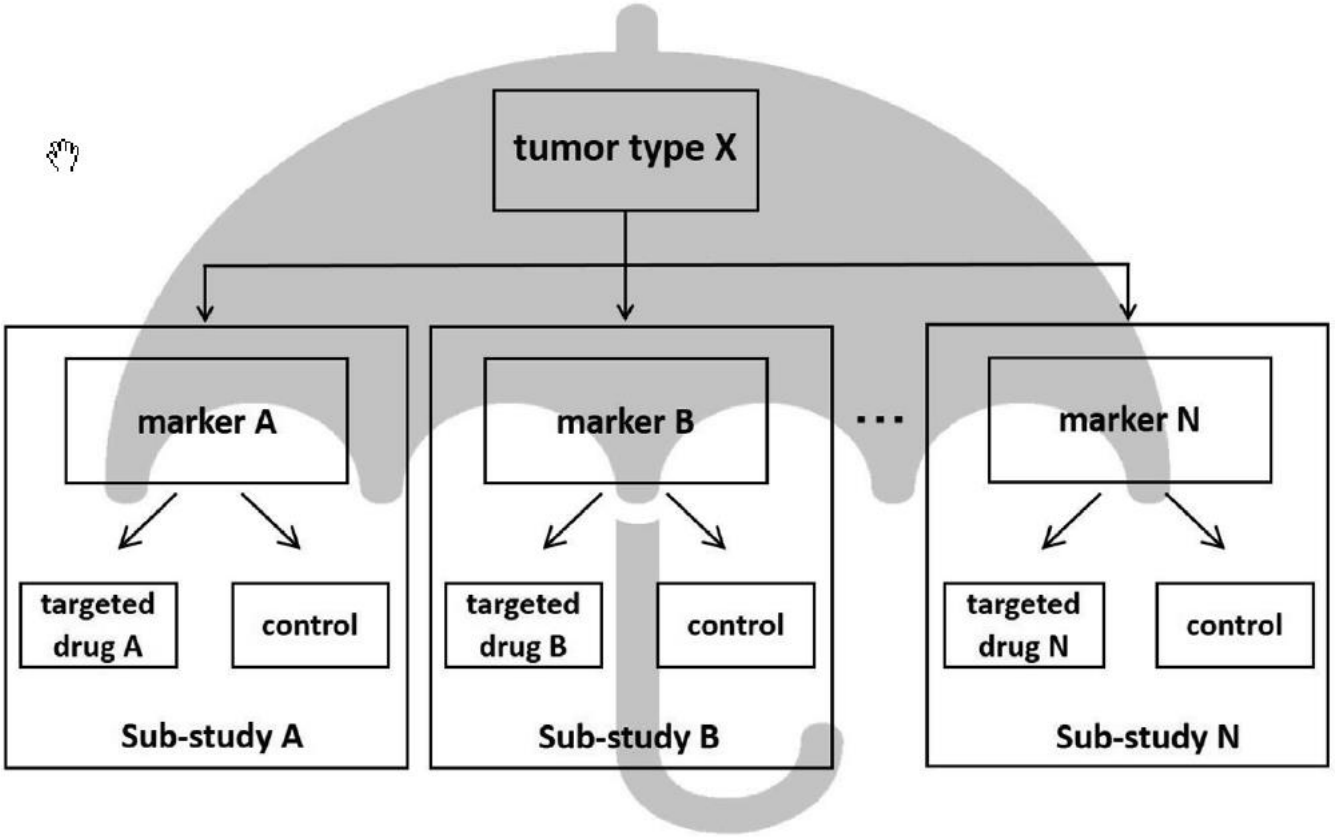
Contemporary Clinical trials Communications 12,2018,1-8
A.Hitakawa et al

Basket protocols



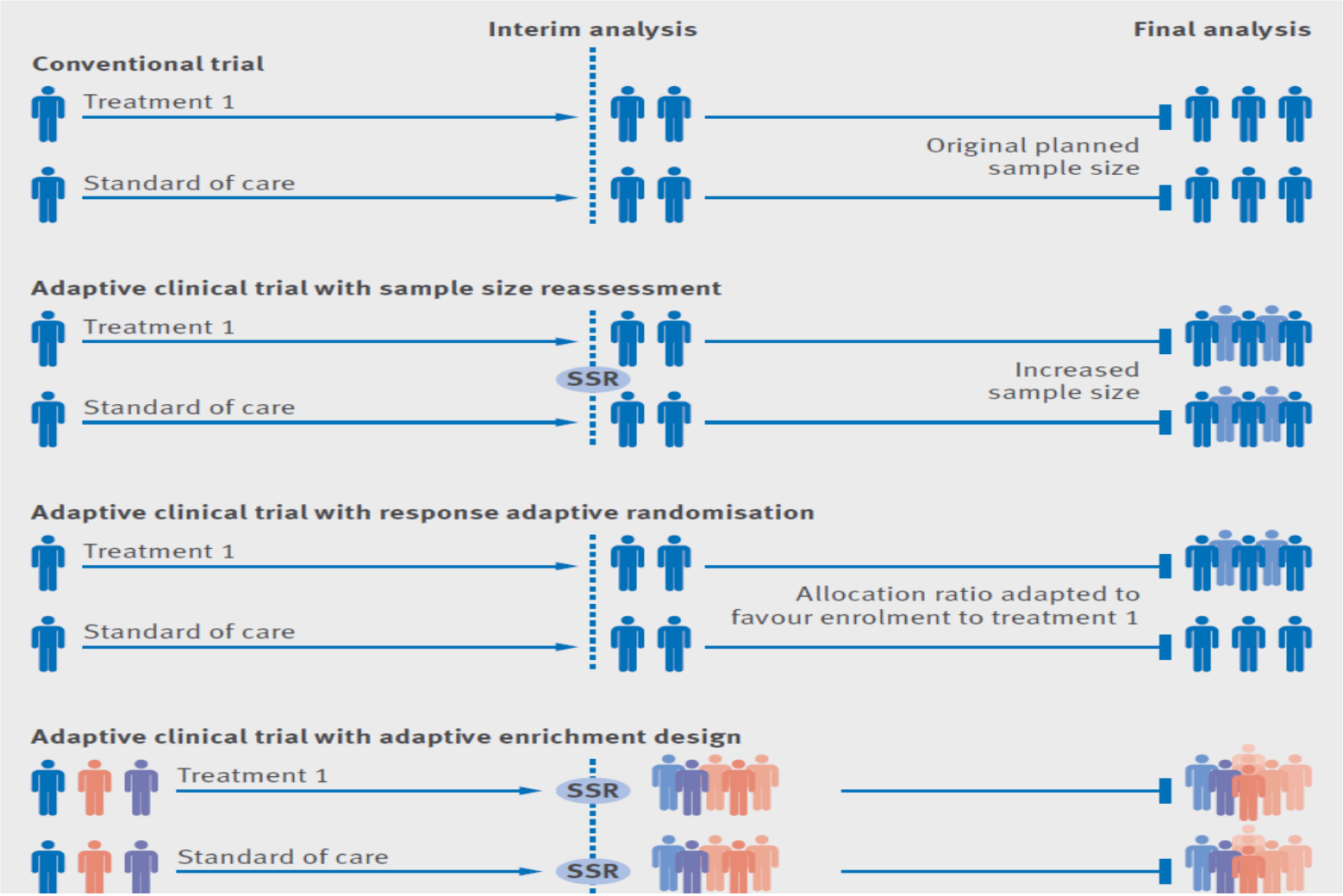
Contemporary Clinical trials Communications 12,2018,1-8
A.Hitakawa et al

Umbrella trials



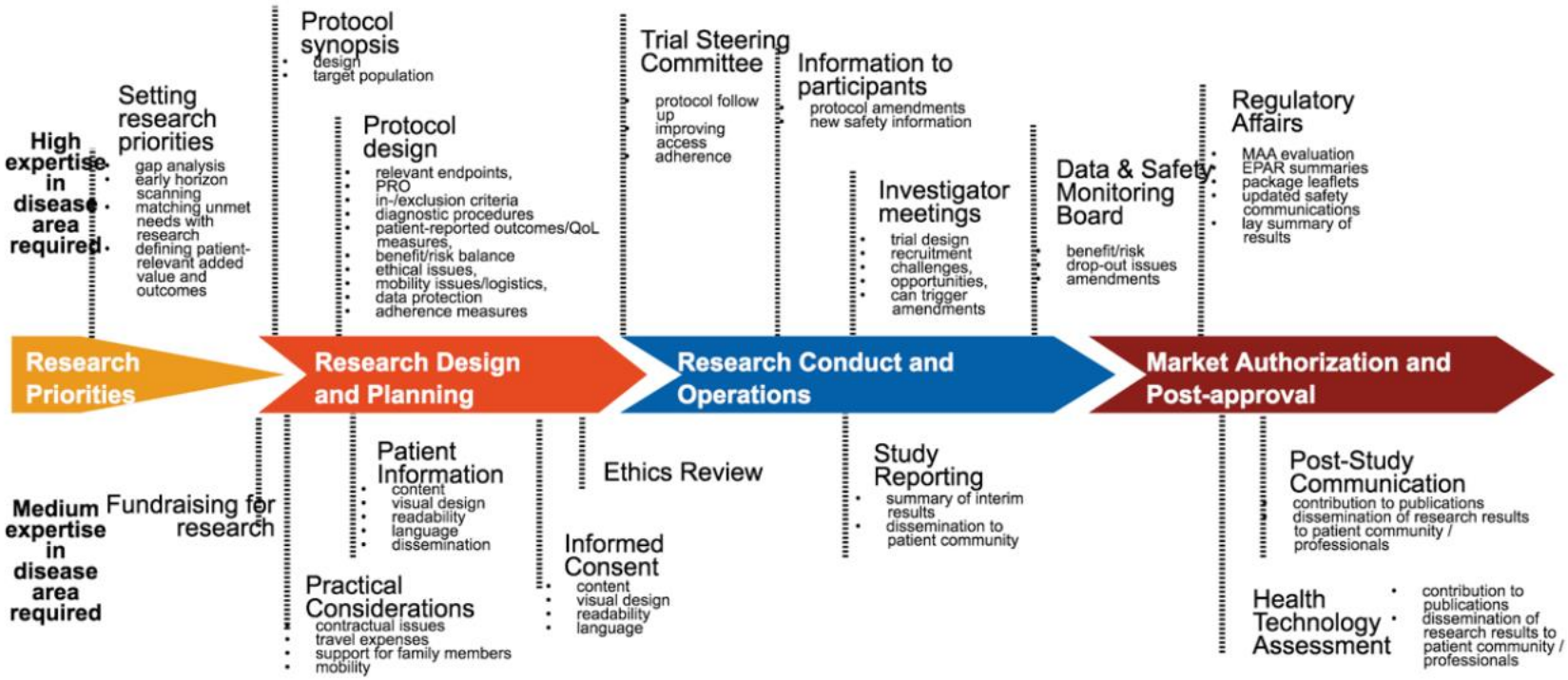
Contemporary Clinical trials Communications 12,2018,1-8
A.Hitakawa et al

Adaptive protocols



BMJ 2018;360:k698 | bmj

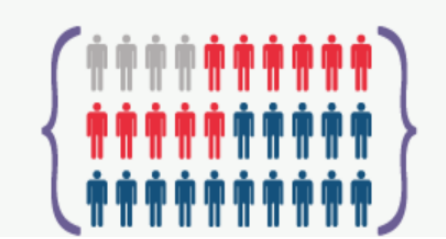
Patient involvement in medicines R&D: a practical roadmap



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 στην E&A

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance



Epidemiology*

Prospective

What are tomorrow's markets?

- Prevalence
- Incidence
- Population studies

Market Research

- what are the unmet needs?
- what are the treatment options?

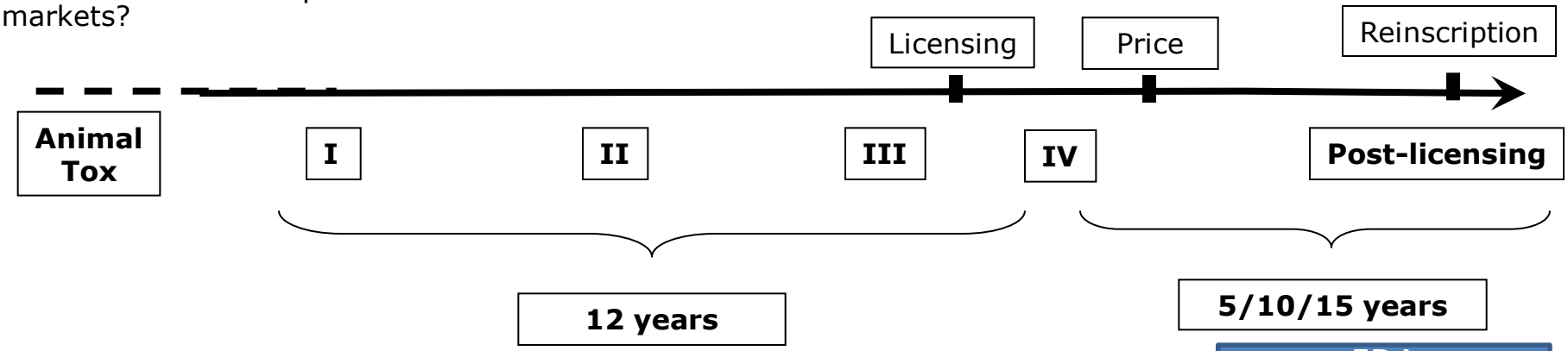
Pharmaco-economics

- Cost efficacy
- Cost benefit
- Cost-utility

EMA PASS,PAES

Real life= Pharmaco-epi

- Efficacy
- Tolerability
- Proper Use
- Performance



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

Μέρος 2 Πανδημία COVID -19

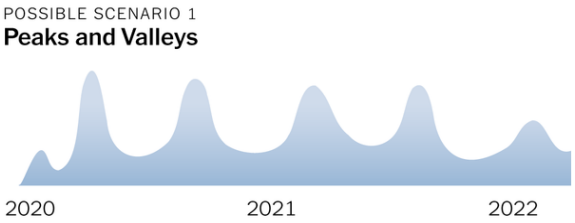
ΕΠΙΔΡΑΣΗ ΣΤΗΝ ΕΡΕΥΝΑ ΤΩΝ ΕΜΒΟΛΙΩΝ & ΦΑΡΜΑΚΩΝ

In 2020, this remarkable statement is playing out with each passing day.

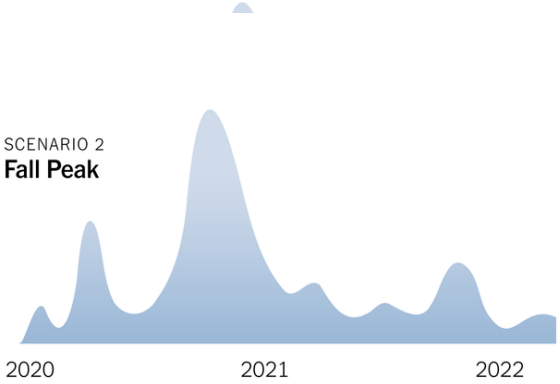
In 2006, Larry Brilliant stated that 90 percent of the epidemiologists in his confidence agreed that there would be a large pandemic—in which 1 billion people would sicken, 165 million would die, and the global economy would lose $1-3 trillion—within two generations.

Prepare for waves of infection

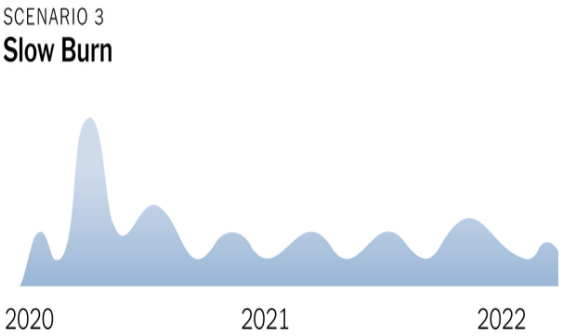
A recent analysis of May 9,2020 from the Center for Infectious Disease Research and Policy at the University of Minnesota describes the various shapes that wave might take.



The first scenario shows an initial wave of cases — the current one — followed by “peaks and valleys” that shrink over time.

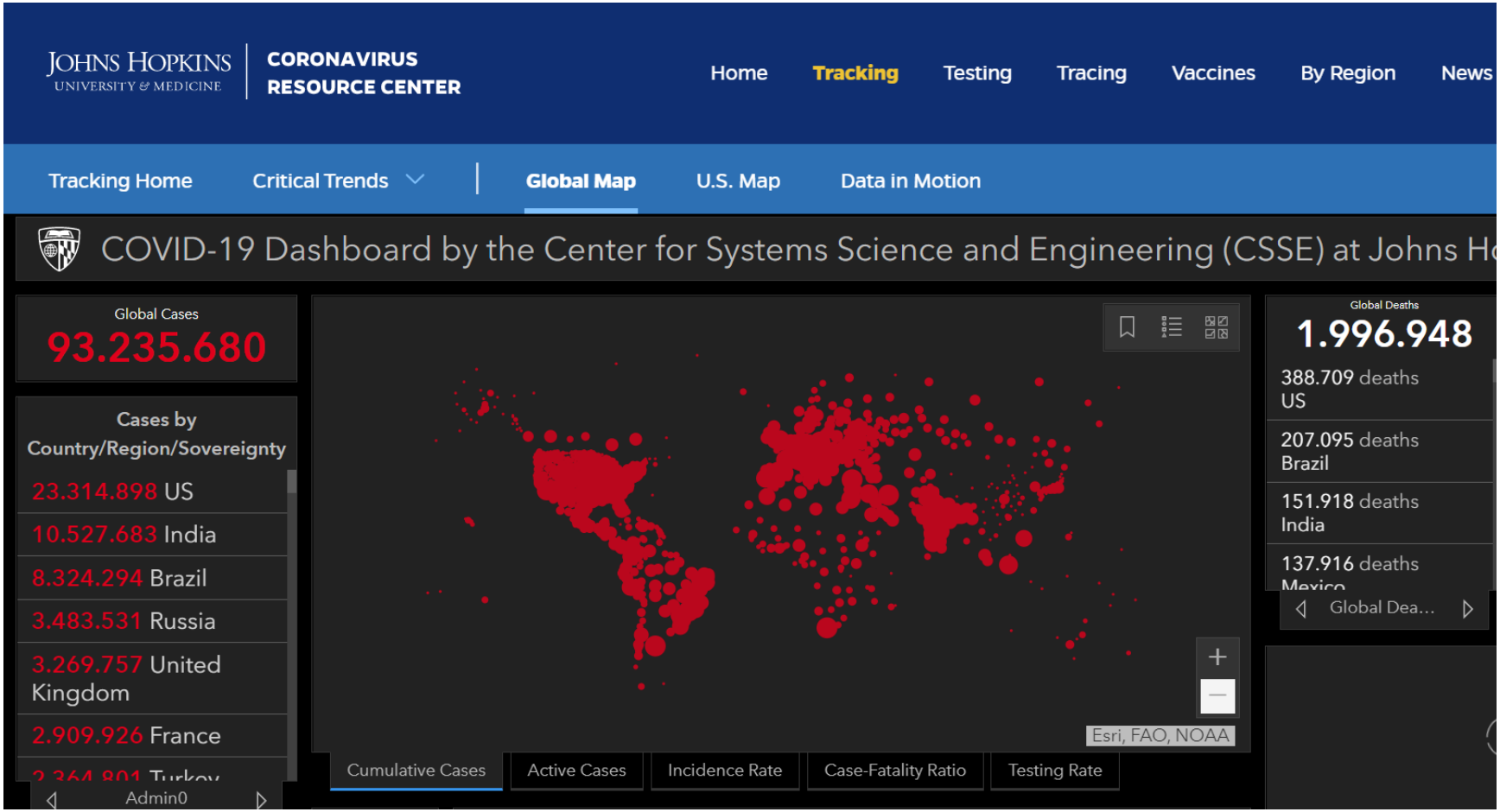


In the second, a larger “fall peak,” or possibly a winter peak, and subsequent smaller waves come after the current one. This is similar to what happened during the 1918-19 Spanish flu pandemic.



The third possibility shows an intense spring peak that turns into a “slow burn,” with smaller ups and downs.

Εξέλιξη της πανδημίας
14-1-2021



https://coronavirus.jhu.edu/map.html

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

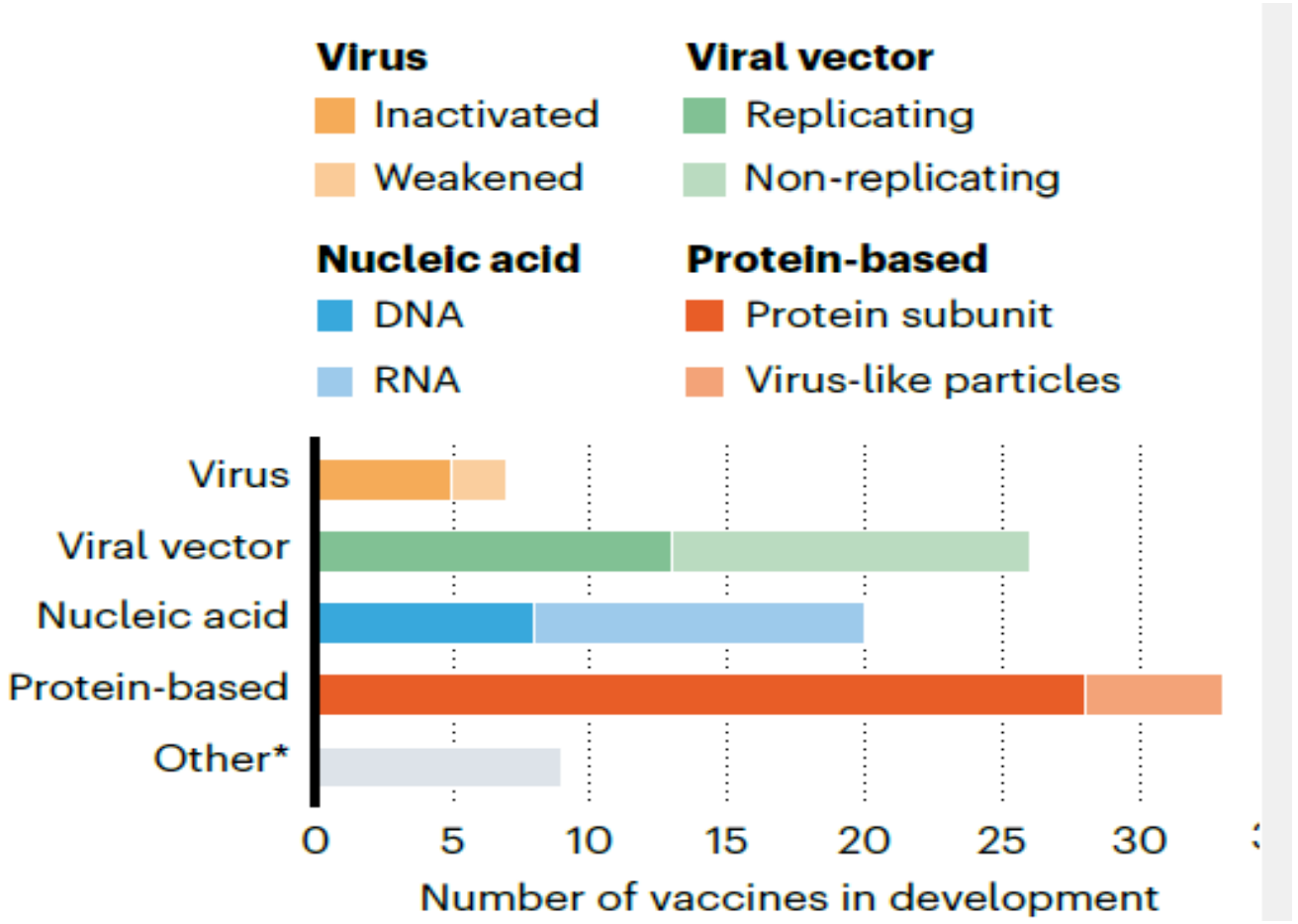
BY JOSE GUIMON, RAJNEESH NARULA

Issues in Science and Technology

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

World Economic Forum

Ευρύ φάσμα τύπων εμβολίων



Έγκριση εμβολίων έναντι COVID-19

EMA Public Stakeholders Meeting
11/12/2020

COVID-19 vaccines must be approved according to the **same standards** that apply to all medicines in the EU

STANDARD

COVID-19

Επιταχυνόμενη ,επάλληλη και επαναληπτική διαδικασία

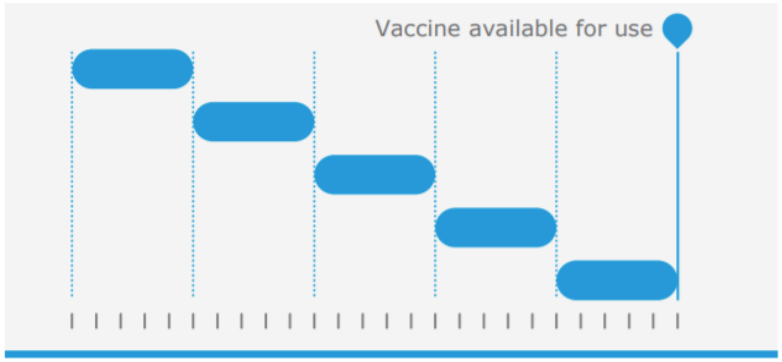
EMA Public Stakeholders Meeting
11/12/2020

STANDARD VACCINES COMPARED WITH COVID-19 VACCINES

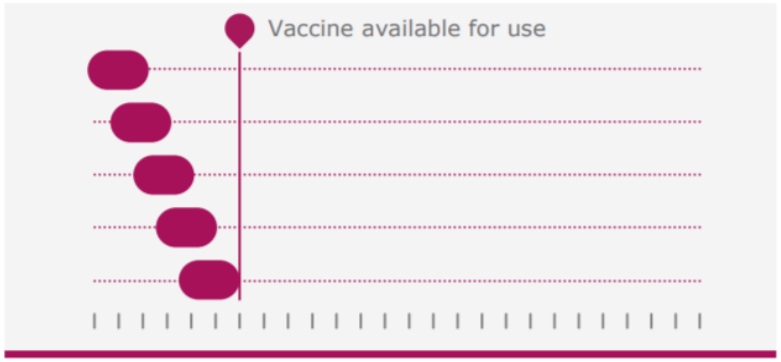
Timelines

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

STANDARD



COVID-19



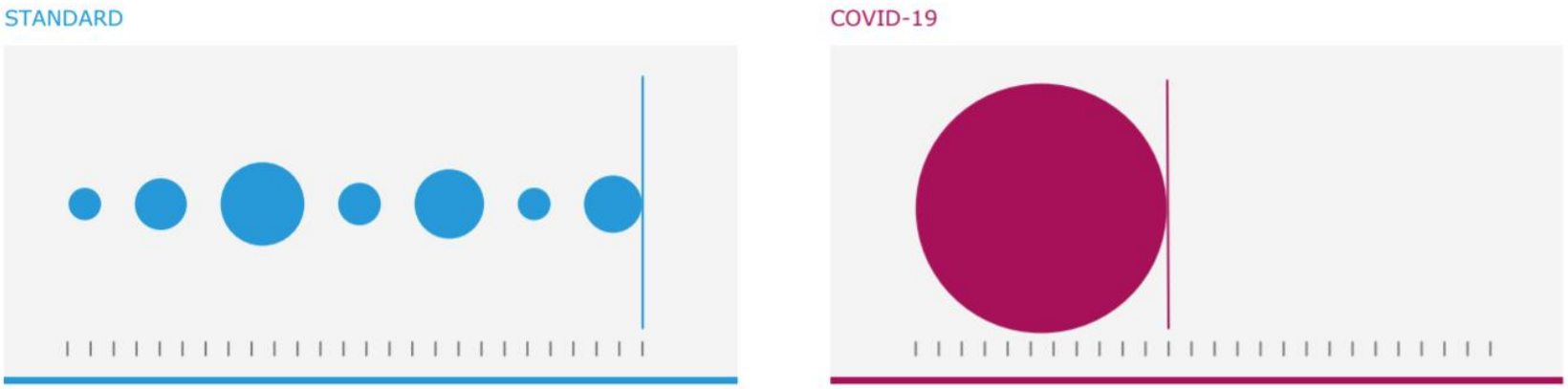
Συνεργασία και επικέντρωση στην κατεπείγουσα προτεραιότητα ανάπτυξης των Εμβολίων

EMA Public Stakeholders Meeting
11/12/2020

STANDARD VACCINES COMPARED WITH COVID-19 VACCINES

Resources

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

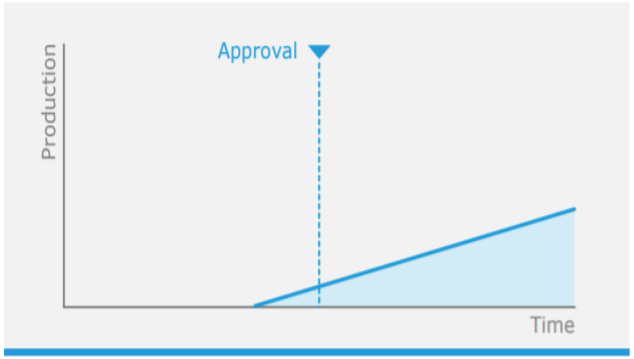
EMA Public Stakeholders Meeting
11/12/2020

STANDARD VACCINES COMPARED WITH COVID-19 VACCINES

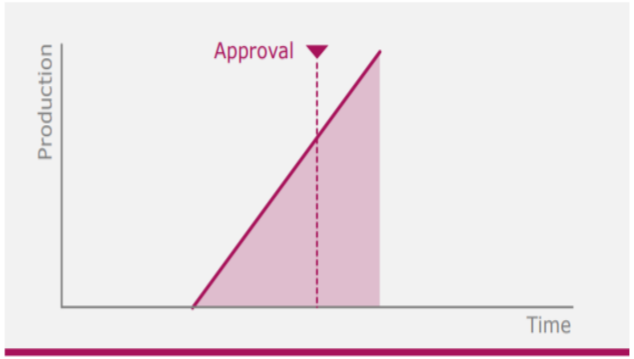
Manufacturing

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

STANDARD



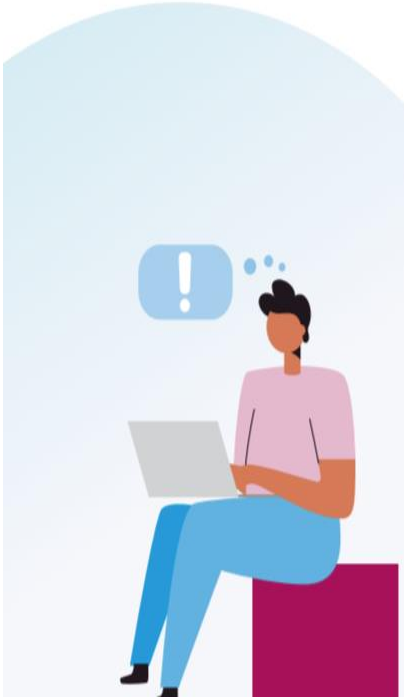
COVID-19



Συνοψίζοντας τα δεδομένα για τα εμβόλια

EMA Public Stakeholders Meeting
11/12/2020

- Έγιναν όλες οι καθιερωμένες Κλινικές Μελέτες όπως για όλα τα φάρμακα
- Τα χρονοδιαγράμματα ήταν συντομότερα διότι επικεντρώθηκαν όλες οι δυνάμεις και οι πόροι
- Οι μελέτες έγιναν σε πολύ μεγάλους πληθυσμούς ατόμων
- Έδειξαν μεγάλη μείωση νόσου από την COVID-19
- Υψηλά πρότυπα Ποιότητας ,Ασφάλειας και Αποτελεσματικότητας
- Παραμένουν κάποιες αβεβαιότητες μακροχρόνιας προστασίας και μετάδοσης στην κοινότητα



RECOVERY
Randomised Evaluation of COVID-19 Therapy

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UNIVERSITY OF OXFORD

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This national clinical trial aims to identify treatments that may be beneficial for people hospitalised with suspected or confirmed COVID-19

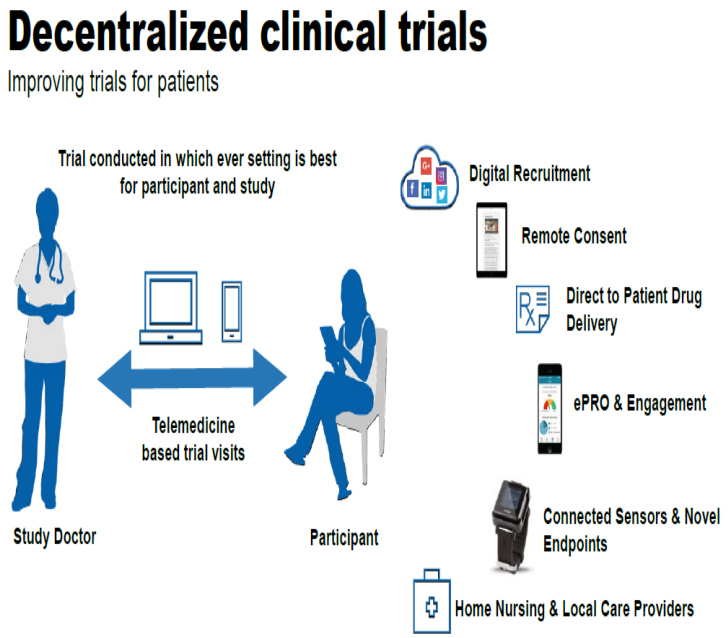
A range of potential treatments have been suggested for COVID-19 but nobody knows if any of them will turn out to be more effective in helping people recover than the usual standard of hospital care which all patients will receive. The RECOVERY Trial is currently testing some of these suggested treatments:

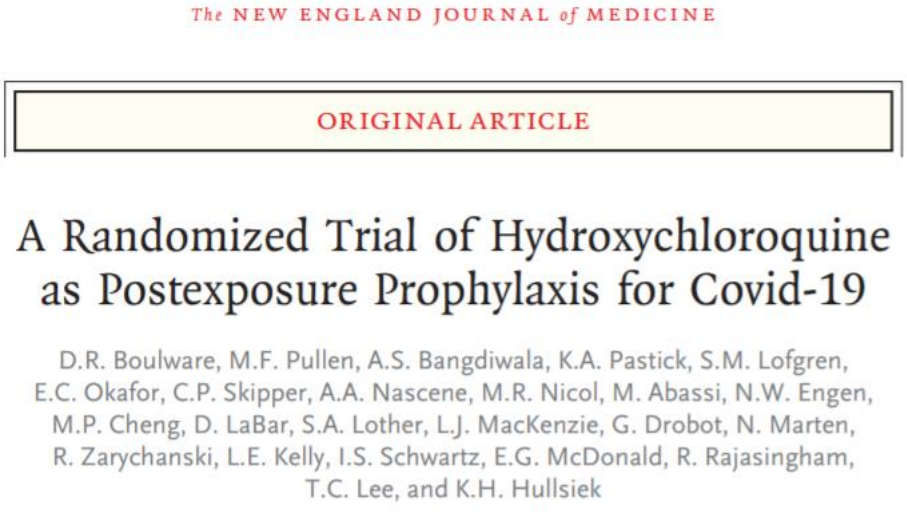
- Low-dose Dexamethasone (now only recruiting children)
- Azithromycin (a commonly used antibiotic)
- Tocilizumab (an anti-inflammatory treatment given by injection)
- Convalescent plasma (collected from donors who have recovered from COVID-19 and contains antibodies against the SARS-CoV-2 virus)
- REGN-COV2 (a combination of monoclonal antibodies directed against coronavirus).

Data from the trial are regularly reviewed so that any effective treatment can be identified

A virtual clinical trial στην διάρκεια της πανδημίας

Νέα Πραγματικότητα
Τηλεϊατρική ,Registries, RWE,PROs,Virtual trials




The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

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

D.R. Boulware, M.F. Pullen, A.S. Bangdiwala, K.A. Pastick, S.M. Lofgren, E.C. Okafor, C.P. Skipper, A.A. Nascene, M.R. Nicol, M. Abassi, N.W. Engen, M.P. Cheng, D. LaBar, S.A. Lother, L.J. MacKenzie, G. Drobot, N. Marten, R. Zarychanski, L.E. Kelly, I.S. Schwartz, E.G. McDonald, R. Rajasingham, T.C. Lee, and K.H. Hullsiek

Patient Focused Drug Development

A decentralized vs conventional model trial in Switzerland

Contemporary Clinical Trials Communications 11 (2018) 120–126

Contents lists available at ScienceDirect

Contemporary Clinical Trials Communications

journal homepage: www.elsevier.com/locate/conctc

Building clinical trials around patients: Evaluation and comparison of decentralized and conventional site models in patients with low back pain

Carsten Sommer[a], Diego Zuccolin[a], Valdo Arnera[b], Nicole Schmitz[b], Pernilla Adolfsson[c], Nicoletta Colombo[d], Raphaelle Gilg[d], Bryan McDowell[c,*]

[a] Medgate AG, Basel, Switzerland
[b] eResearchTechnology, Philadelphia, USA
[c] Novartis Pharma AG, Basel, Switzerland
[d] Novartis Pharma Schweiz AG, Rotkreuz, Switzerland

ARTICLE INFO

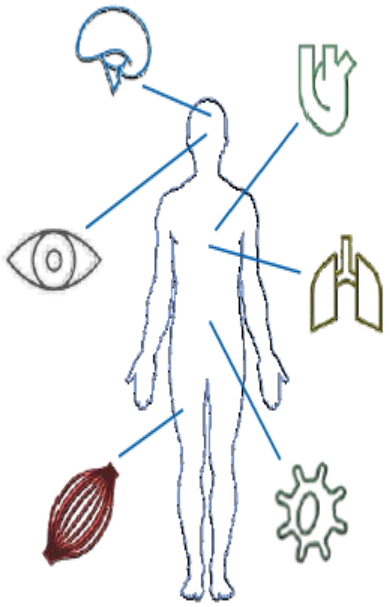
Keywords:
Decentralized clinical trial
eHealth
Patient-centric trial
Access to trials
Recruitment

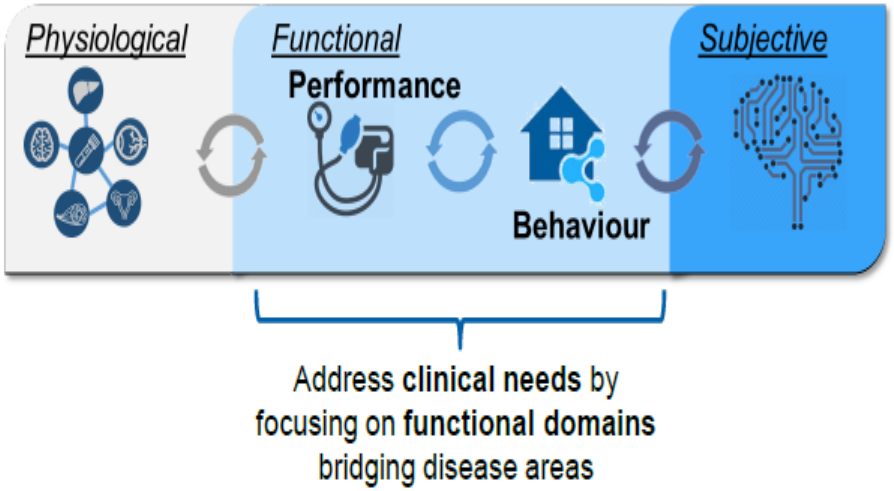
ABSTRACT

Clinical trials are slow and costly, built around the research centers that study local participants. Building clinical trials around patients in their homes and community through remote visits and monitoring could enhance recruitment and increase convenience for participants. This study evaluated different trial settings, a decentralized arm via telemedicine center (virtual study conduct), a conventional arm via health clinic (onsite study conduct) and a mixed model arm. Acute low-back pain patients (20–65 years) were recruited to this non-interventional trial in Switzerland. The study consisted of a screening period and a 2-week data collection period

Digital endpoints

Where do digital endpoints fit in?





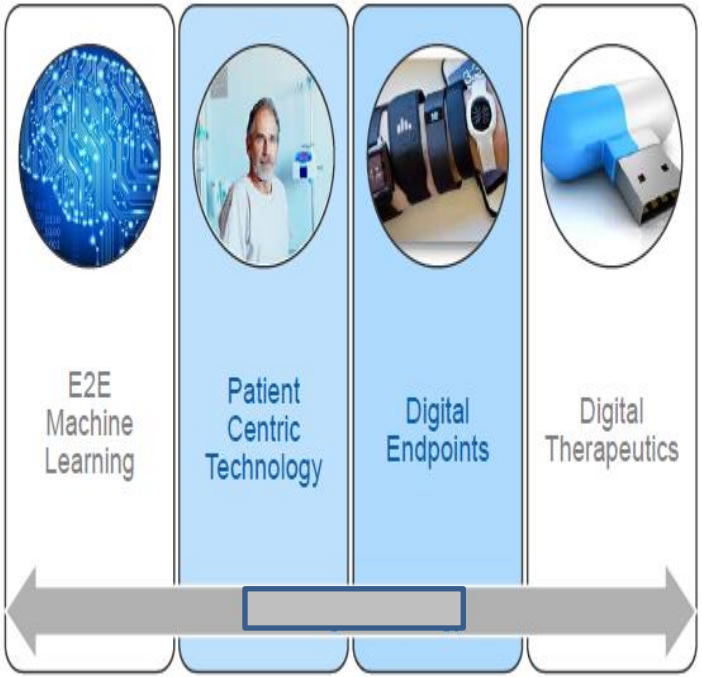
Digital endpoints can provide **competitive advantage**
... through **lowering burden** and **generating novel insights**
... to enable building a **better chain of evidence** to advance our medicines

- https://www.youtube.com/watch?v=QCF5rqUvnoo
- https://onlinelibrary.wiley.com/doi/abs/10.1002/cpt.866

Κλινικές Μελέτες και Τεχνητή Νοημοσύνη

Analytics, technology, clinical trials – journey

"The right therapy, to the right patient, at the right time"



innovative medicines initiative

Europe's partnership for health

Trials@Home

Center of excellence – remote decentralised clinical trials

Ongoing | IMI2 | Clinical trial design , Digital health , Real-world data, evidence , Regulatory and HTA processes

Summary

In a conventional clinical trial, patients have to make regular trips to the clinic for check-ups to monitor their condition. Many patients are understandably put off by the distance to the clinic and how often they would be expected to make the trip, and many patients who initially join trials drop out for logistics reasons. Digital technologies and wearable devices mean it is now possible to assess patients remotely – while they are at home, or going about their daily lives. If used during clinical trials, they could dramatically reduce the number of times patients are expected to visit the clinic.

Trials@Home aims to explore the potential of digital technologies for use in 'remote decentralised clinical trials' (RDCTs). They will develop and test methods to streamline data collection as well as patient recruitment and retention. They will also discuss RDCTs with patients as well as regulators, payers, health technology assessment bodies (HTAs) and ethics bodies, to ensure that the project outcomes can be implemented. At the heart of the project is a study in which one group of patients will have the conventional clinical trial experience with regular clinic visits; a second group of patients will participate completely remotely, and a third group will follow a partly conventional / partly RDCT approach. The project will use the results

FACTS & FIGURES

Start Date	01/09/2019
End Date	31/08/2024
Call	IMI2 - Call 14
Grant agreement number	831458

Type of Action:
RIA (Research and Innovation Action)

Contributions	**€**
IMI Funding	19 036 998
EFPIA in kind	19 248 295
Other	45 977
Total Cost	38 331 270

PROJECT LINKS

Twitter
@TrialsatHome

ΕΥΡΩΠΑΙΚΗ ΕΝΩΣΗ &ΕΛΛΑΔΑ

ΚΑΝΟΝΙΣΤΙΚΟ ΠΛΑΙΣΙΟ ΚΛΙΝΙΚΩΝ ΔΟΚΙΜΩΝ

Στοχεύοντας την Ανάπτυξη της Κλινικής ‘Ερευνας για την εξεύρεση νέων καινοτόμων θεραπειών στην ΕΕ

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)

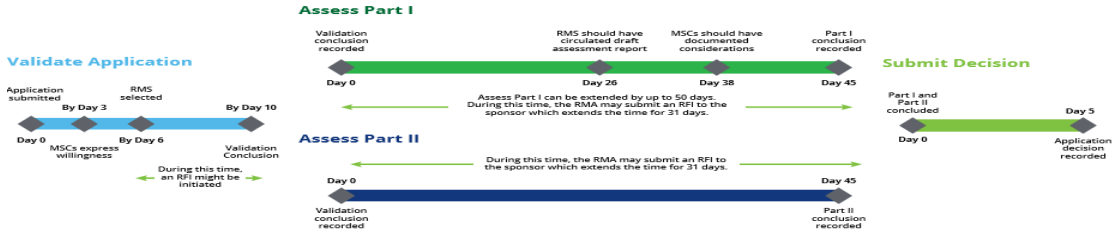
Full harmonisation and combined assessment of multinational trials (after full functionality of the EU portal and EU database)

e-submission

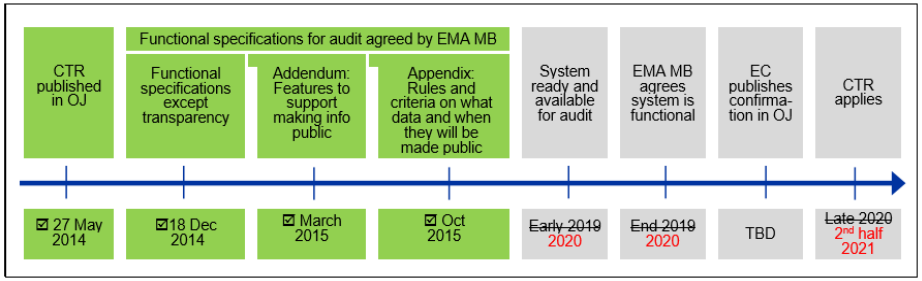
Federal Institute for Drugs and Medical Devices

Karl Broich | CT authorisation in the EU: present and future | 09 March 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
-15 ημέρες

Clinical Trial Regulation 536/2014

CTIS new user friendly tool

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

EMA portal early 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,Febr 2020 Archives Athens Medical Society
www.mednet.gr

ΕΛΛΗΝΙΚΟ ΠΕΡΙΒΑΛΛΟΝ

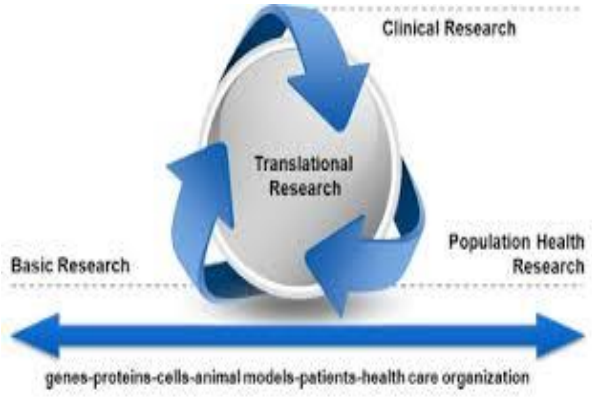
ΠΡΩΤΟΒΟΥΛΙΑ ΕΛ.Ε.Φ.Ι. ΓΙΑ ΤΗΝ ΚΛΙΝΙΚΗ ΕΡΕΥΝΑ &ΤΙς ΚΛΙΝΙΚΕΣ ΔΟΚΙΜΕΣ

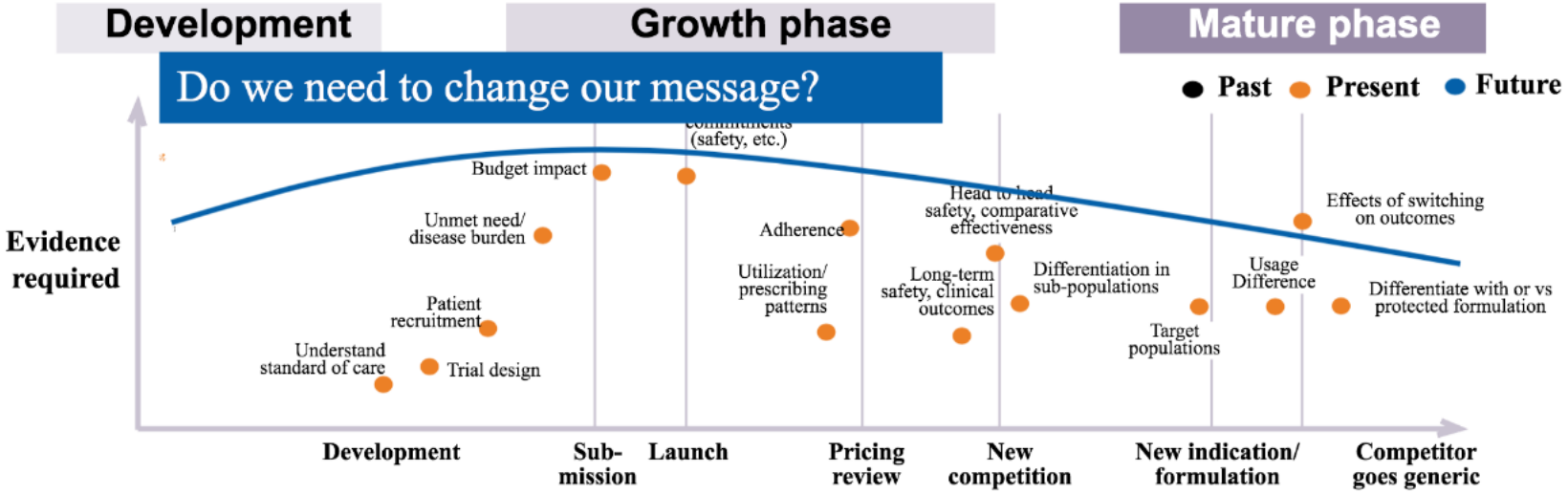
Κύριες αρχές ΕΛ.Ε.Φ.Ι.

- **Διασφάλιση του ερευνητικού συνεχούς**
  - προκλινικής έρευνας, μεταφραστικής έρευνας,
  - κλινικών δοκιμών,
  - κλινοεπιδημιολογικών μελετών –RWE , και
  - μελετών οικονομικής τεκμηρίωσης για την- ΑΤΥ
- **Ασθενοκεντρική προσέγγιση –Patient Focused Drug Development**
- **Κουλτούρα έρευνας , συνεργασιών και συστηματικού διαλόγου** με τις Ενώσεις Ασθενών ,επιστημονικών φορέων, ερευνητών ,θεσμικών φορέων Φαρμακοβιομηχανίας & CRO και Αρχών
- **Στρατηγικό μετασχηματισμό των προτεραιοτήτων**
  - χρήσης νέων τεχνολογιών για την σε πραγματικό χρόνο παρακολούθηση έγκρισης, έναρξης ,εξέλιξης και υλοποίησης των κλινικών δοκιμών ,
  - επιχειρησιακής αριστείας στην **διαχείριση των αλλαγών**
- **Συνεχιζόμενη εκπαίδευση και πιστοποίηση των επιστημόνων Κλινικής Έρευνας** στο ραγδαία εξελισσόμενο επιστημονικό , βιοηθικό , τεχνολογικό, κανονιστικό γίγνεσθαι
  - IFAPP Academy Kings' College Certification Program ,Diploma , MSc degree

Ερευνητικό συνεχές

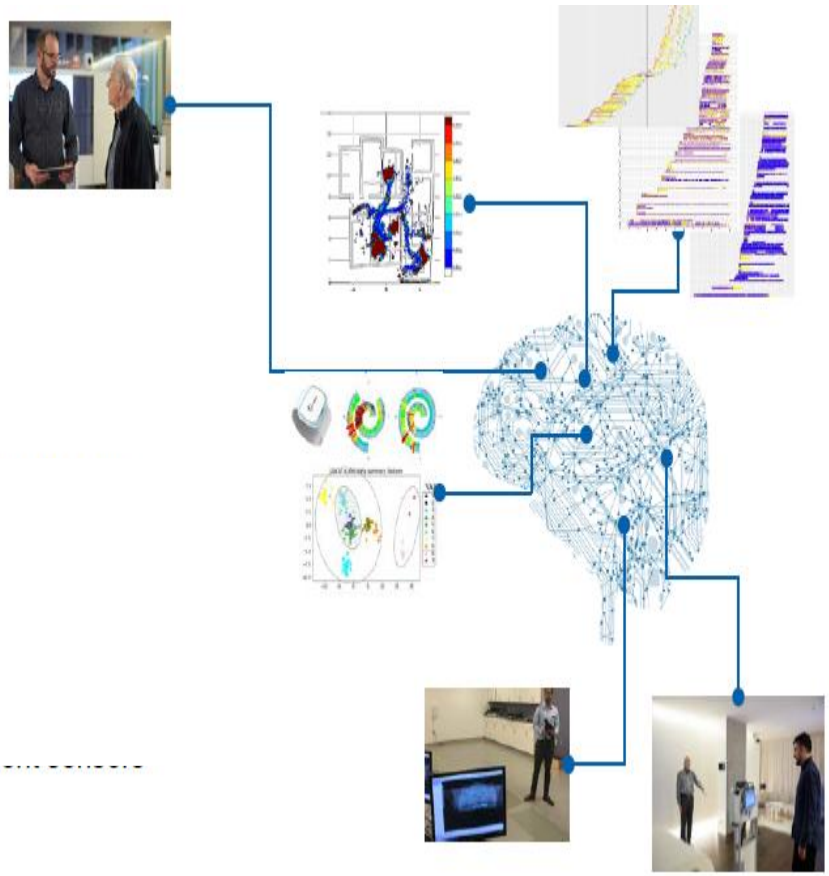
Research Continuum





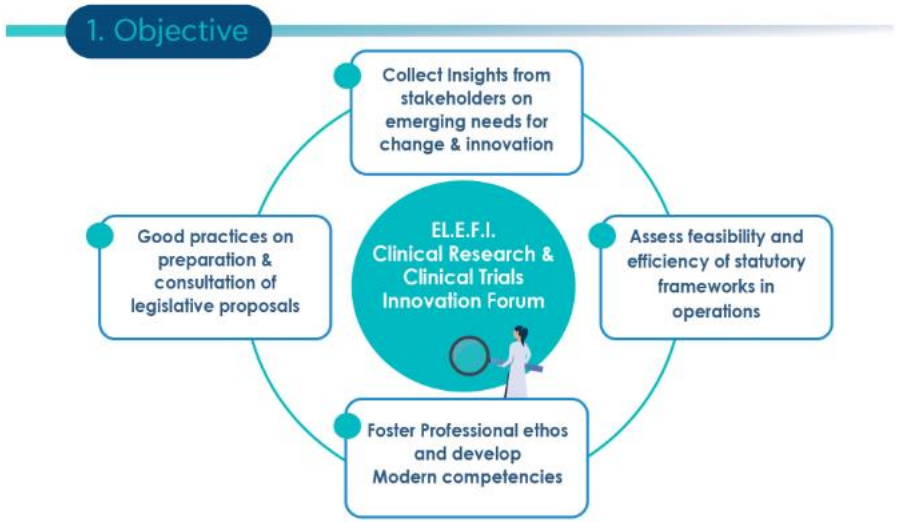
Με επίκεντρο τον ασθενή

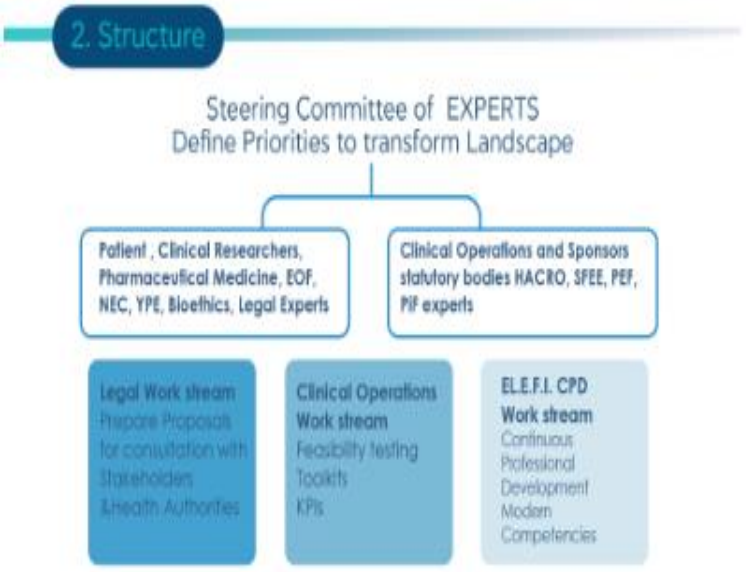
ΕΛ.Ε.Φ.Ι.
ΕΛΛΗΝΙΚΗ ΕΤΑΙΡΕΙΑ
ΦΑΡΜΑΚΕΥΤΙΚΗΣ
ΙΑΤΡΙΚΗΣ



Στρατηγικός μετασχηματισμός ως Προτεραιότητα για την Κλινική Έρευνα

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





Κύκλος συναντήσεων του 1ου εξαμήνου 2021

Σας ευχαριστώ πολύ για την προσοχή σας

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ΕΛ.Ε.Φ.Ι.

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