Drug Repurposing - new opportunities

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Drug Repurposing - new opportunities

NLO (Barend Bouma): Session moderation

CBG/MEB (Leon Bongers): Requirements for a ‘successful’ drug repurposing dossier

FAST (Benien Vingerhoed) – Socially responsible drug repurposing development

3DPharmXchange (Bianca Pauly): Clinical trials with repurposed drugs

NLO (Kolja): From Lab to Clinic to Patient

Radboudumc (Maaike Oosterveer): Drug repurposing at Radboudumc

OostNL (Lema Maiwand): Drug repurposing from an investors perspective

Requirements for a ‘successful’ drug repurposing dossier; CBG/MEB (Leon Bongers)

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CBG MEB

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Requirements for a “successful” drug repurposing dossier

Leon Bongers
Board secretary (since 2007 MEB, since 2021 Board secretary)

Education: MSc Medical Biology, Amsterdam, 1991

Declarations

None

MEB within EU decision making

28 National Competent Authorities Responsible for expertise

Committee for Advanced Therapies **CAT**

Paediatric Committee **PDCO**

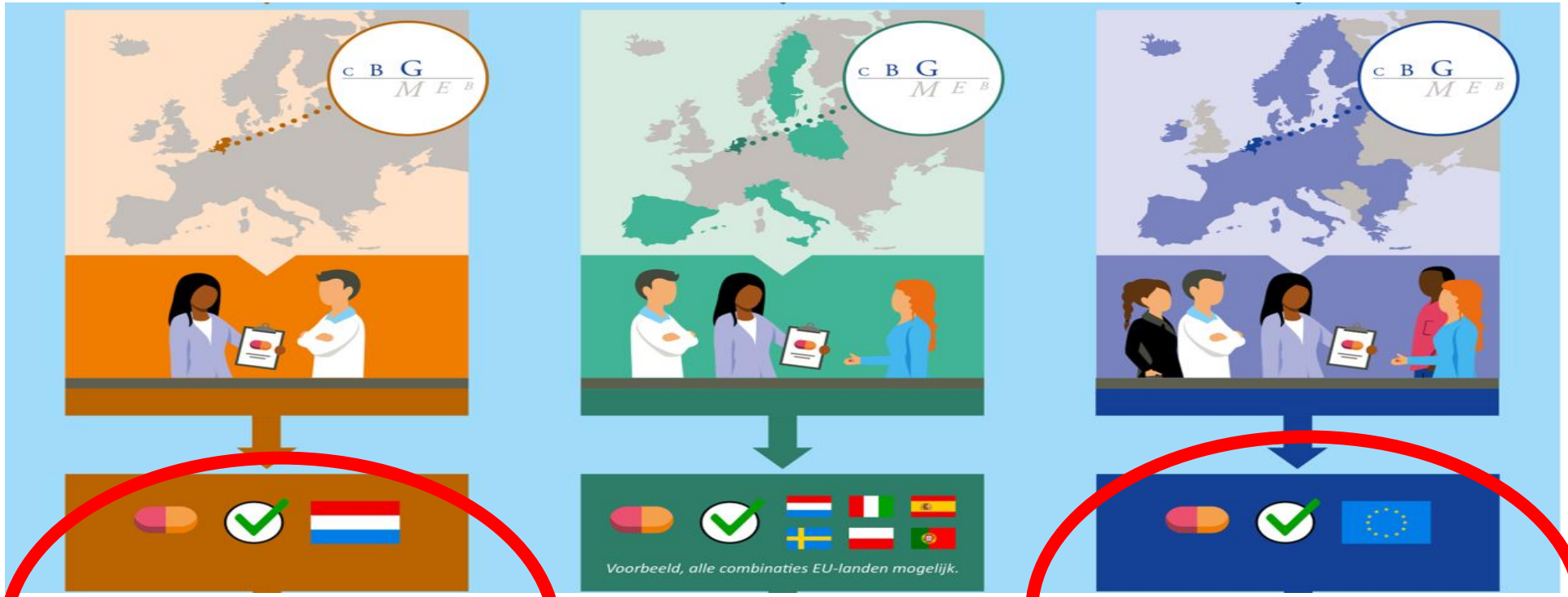
EMA Secretariat

Pharmacovigilance Risk Assessment Comittee **PRAC**

Committee for Human Medicinal Products **CHMP** and WPs

Committee for Orphan Medicinal Products **COMP**

Decision routes

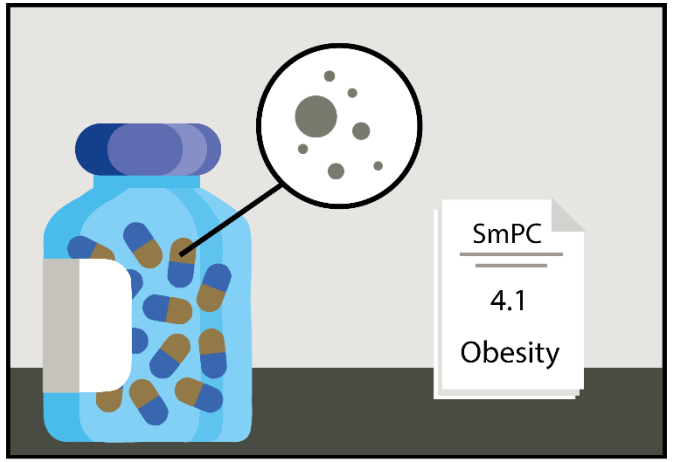


National.

Decentral.

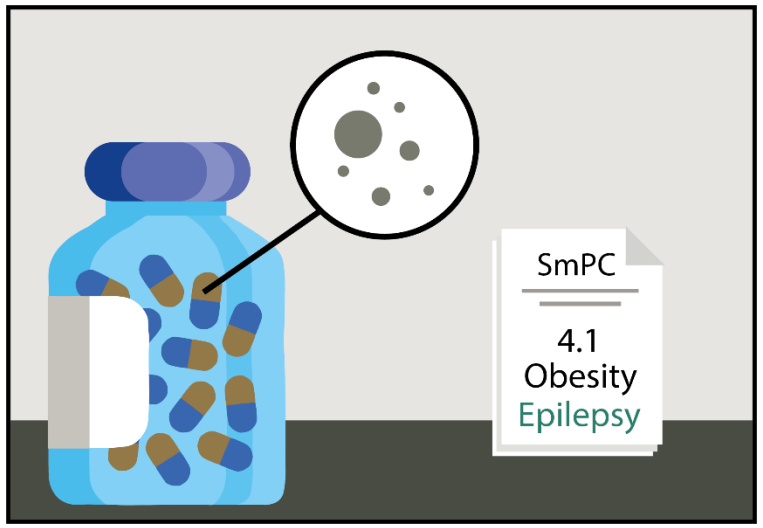
Central

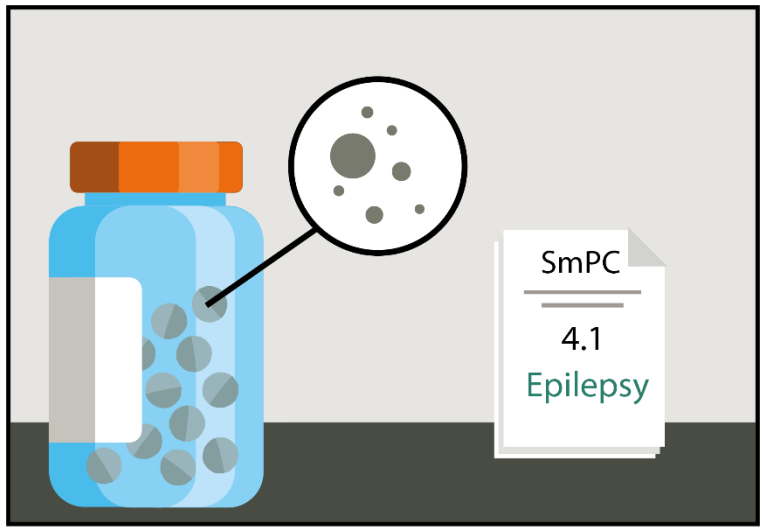
Extension of Indication vs. New MP based on known active substance



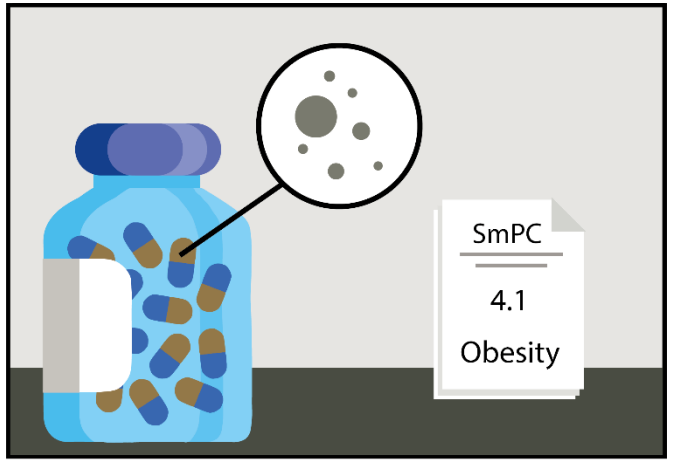
Extension of Indication
(C.I.6.a type II variation)

New MP based on known
active substance





Extension of Indication vs. New MP based on known active substance



Extension of Indication
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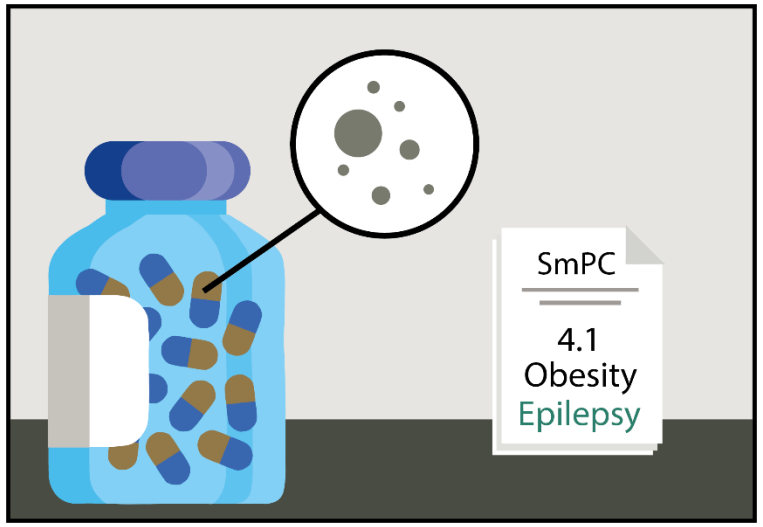
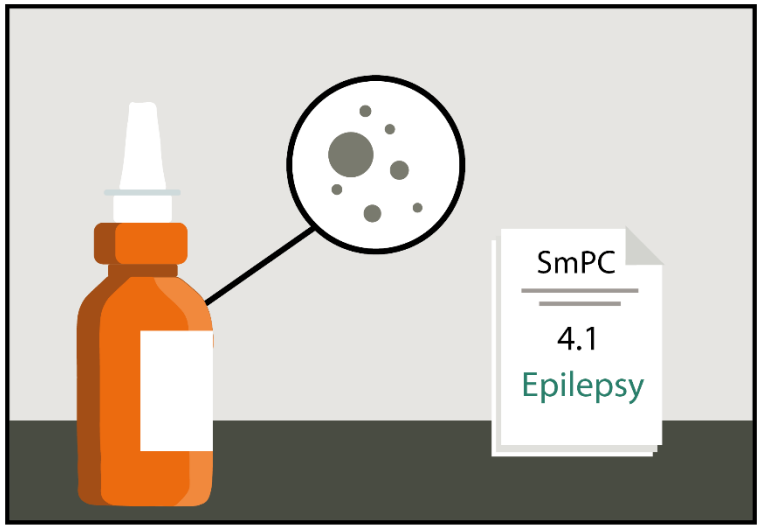
New MP based on known active substance





MEB partners in the NL

ccMo

rivm
Rijksinstituut
voor Volksgezondheid
en Milieu

Zorginstituut Nederland

Inspectie voor de Gezondheidszorg
Ministerie van Volksgezondheid,
Welzijn en Sport

CBG
MEB

Lareb
Nederlands Bijwerkingen Centrum
Netherlands Pharmacovigilance Centre

Legal obligations MEB

- assessing medicines **through national route**,
- monitoring adverse reactions and risks

Another important statutory task is

- to provide **scientific advice** to pharmaceutical companies.

Role of EMA – Mandatory scope

- The centralised procedure is compulsory for:

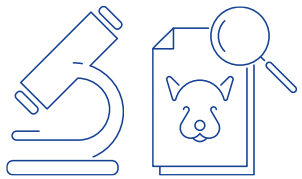
- **new active substances** to treat HIV, cancer, diabetes, neurodegenerative diseases, auto-immune and other immune dysfunctions, viral diseases,
- **medicines derived from biotechnology processes**, such as genetic engineering;
- **ATMPs**, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines;
- **orphan** medicines (medicines for rare diseases);

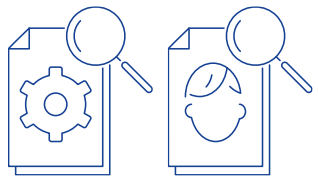
Role of EMA – Optional scope

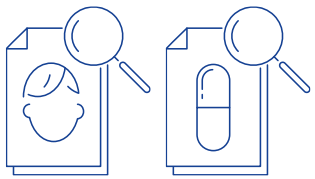
It is optional for other medicines:

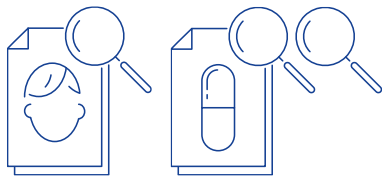
- containing new active substances for indications other than those stated above;
- that are a **significant therapeutic, scientific or technical innovation**;
- whose authorisation would be in the interest of public or animal health at EU level.

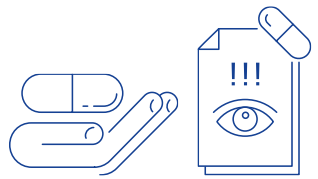
Support tools











Early Research → Non-clinical and First in Man → Clinical exploratory → Clinical confirmatory

- Authorisation
- Access decision
- Post-licensing evidence

Innovation Task Force and EU-IN

Scientific Advice (MEB) - Scientific Advice/Protocol Assistance (EMA)

PRIME support

ATMP certification

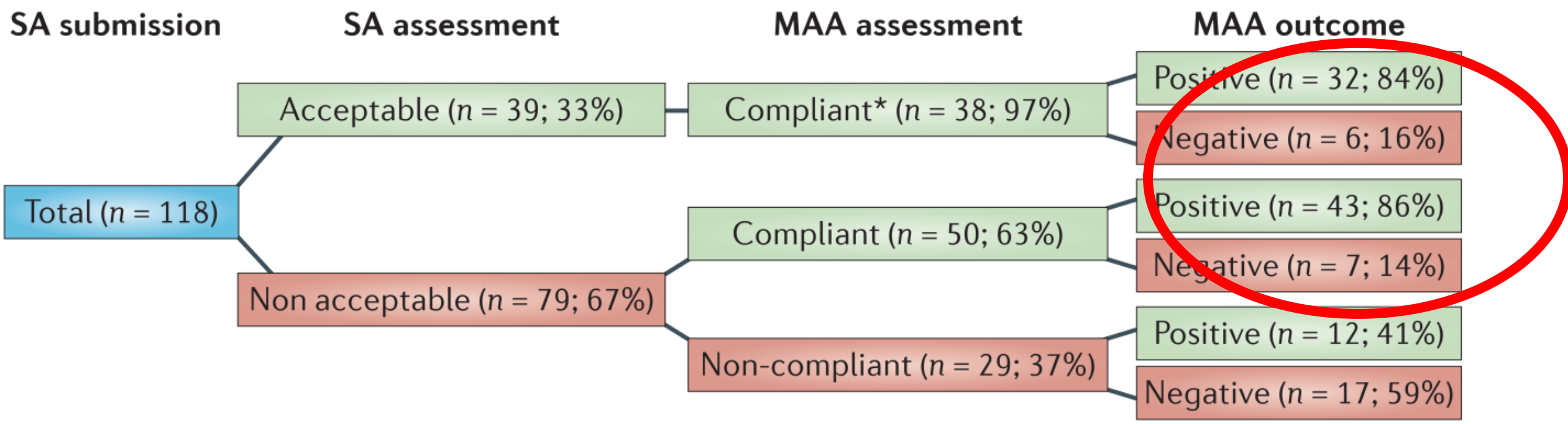
Orphan Drug Designation

Paediatric Investigation Plan

Qualification of Novel Methodologies

SME briefings

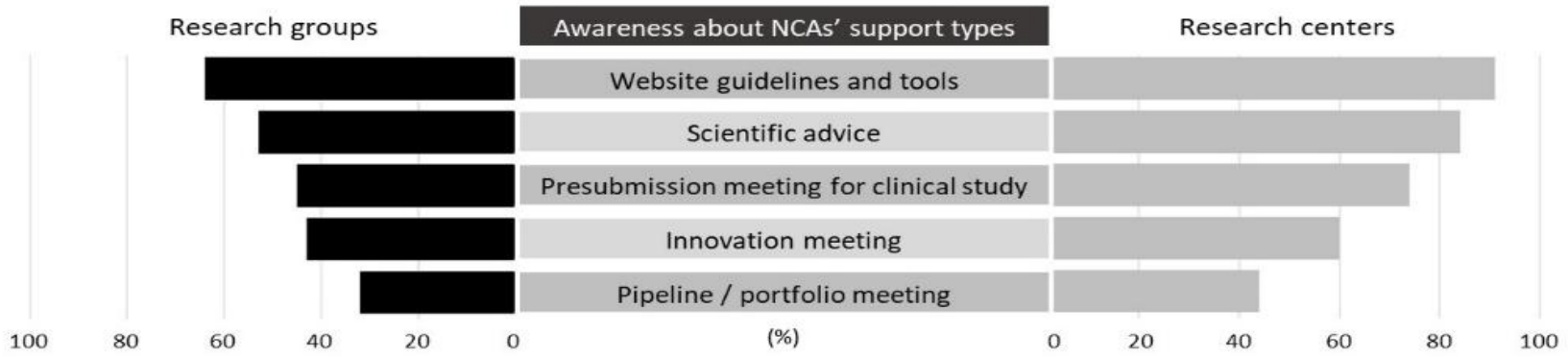
Benefit of advice

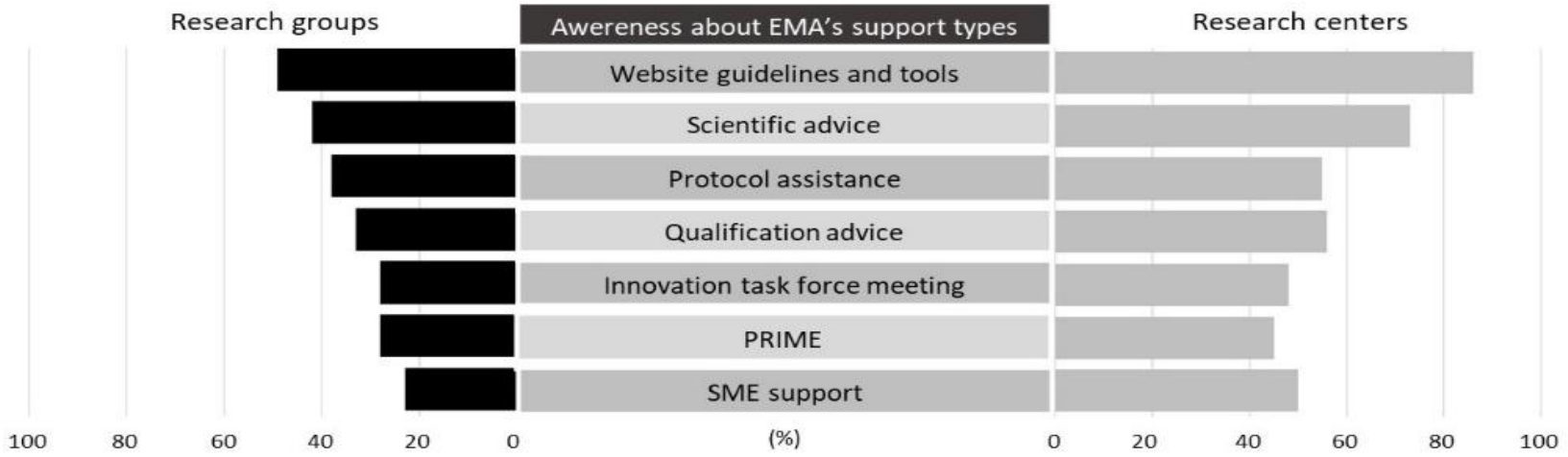


How can regulators facilitate drug repurposing? Knowledge on possibilities.

Academics‘ awareness of regulatory support

Kallio et al., 2022, CPT





Legal base

“Own” data

- Artikel 8(3) (full), 10a (Literature)
- *Own data*
- *Literature (peer reviewed, no information on older assessments)*

Abridged

- Artikel 10(1), 10(3), 10(4) files
- Generic, hybrid, biosimilar

Literature:

Indication and use > 10 years in EU

Product used in literature must be identified

Product for MA, should be similar to product in literature

BRIDGING

Overview of 9 OMPs for which the EPARs contained references to existing clinical data.

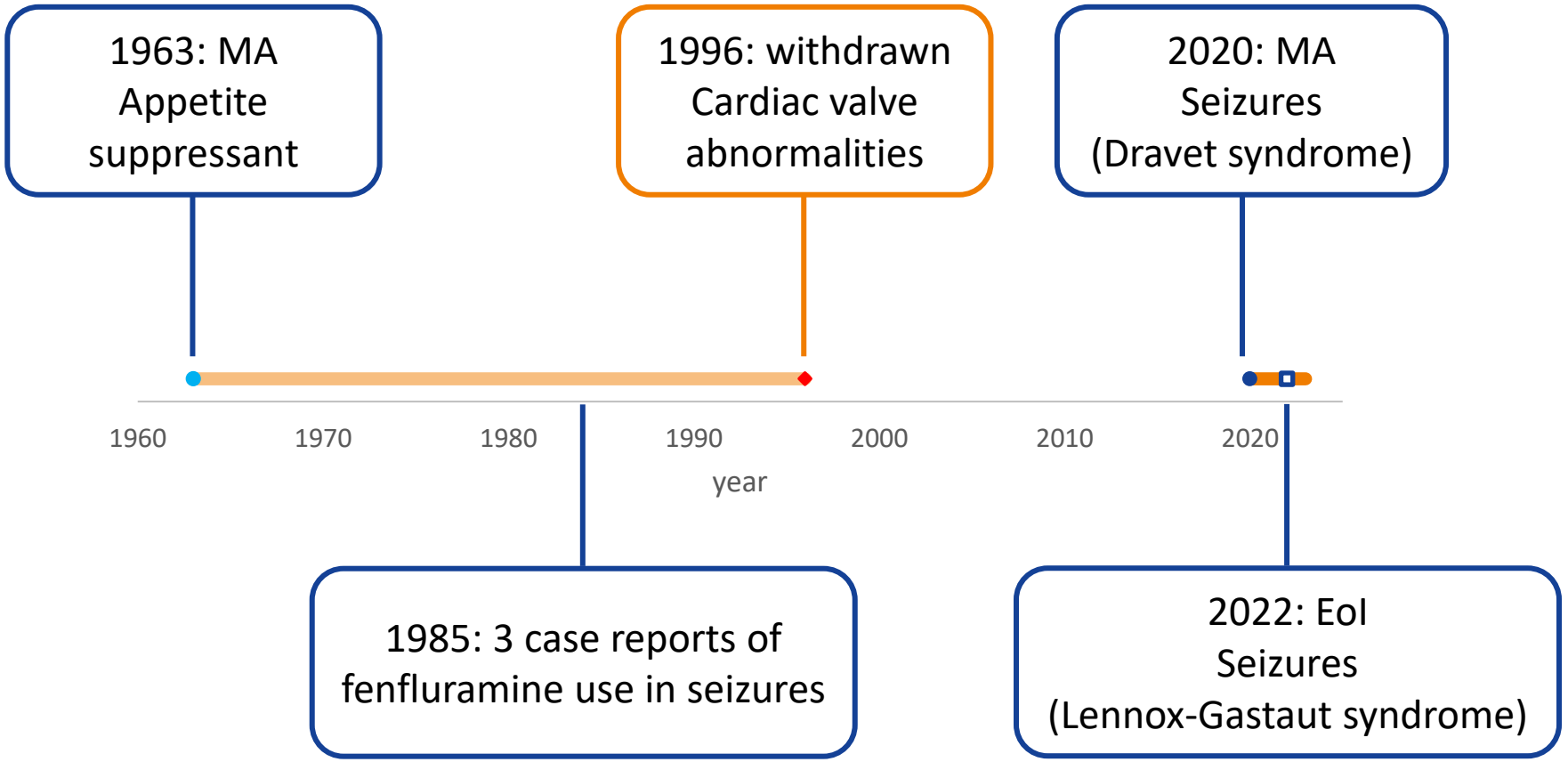
indication
inherited condition called congenital adrenal hyperplasia (CAH)
eosinophilic oesophagitis
epilepsy
chronic thromboembolic pulmonary hypertension
muscle stiffness
hypoparathyroidism
cerebrotendinous xanthomatosis
Cushing's syndrome
epidermolysis bullosa (EB)

Product name	Type of data	Source*	
		Lit	RP
Efmody	Pharmacokinetics & pharmacodynamics	X	X
Jorveza	Pharmacokinetics & pharmacodynamics	X	
	Clinical pharmacology	X	
Fintepla	Pharmacokinetics	X	
Trepulmix	Pharmacokinetics		X
	Target dose determination	X	
Namuscla	Safety	X	
Natpar	Safety	X	X
Chenodeoxycholic acid Leadiant	Bile acid kinetics	X	
	Safety		X
Ketaconazole HRA	Clinical use data	X	
Filsuvez	Pharmacokinetics & pharmacodynamics		X
	Phase III (supportive study)		X

**Lit = literature, RP = reference product.*

Example case

sevier, Inc.



Example case

sevier, Inc.

Non-clinical data:
- Literature
- (Juvenile) toxicity
- Carcinogenicity
- DART

Non-clinical data:
- No new studies

2020 2021 2022 2023

year

Clinical data:
- Literature for pharmacokinetics
- 5x phase I, 4x phase III

Clinical data:
- New pivotal phase III trial

Take Home

- ADVICE (MEB)
- ADVICE (EMA)
- ADVICE (ZIN)

- Think internationally

CBG MEB

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GOEDE MEDICIJNEN GOED GEBRUIKT

Socially responsible drug repurposing development - FAST (Benien Vingerhoed)

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Socially responsible drug repurposing development

Benien Vingerhoed, managing director FAST

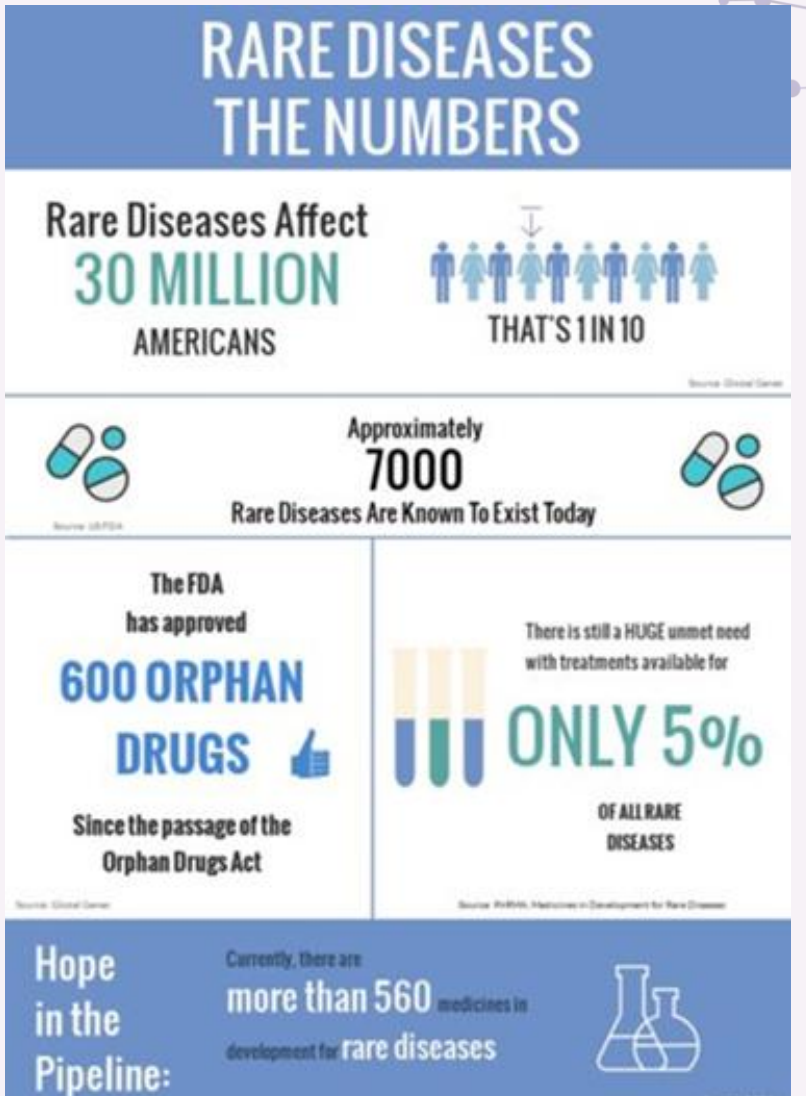
The opportunity's

Known products

Quality, safety and efficacy

Low cost

High unmet medical need

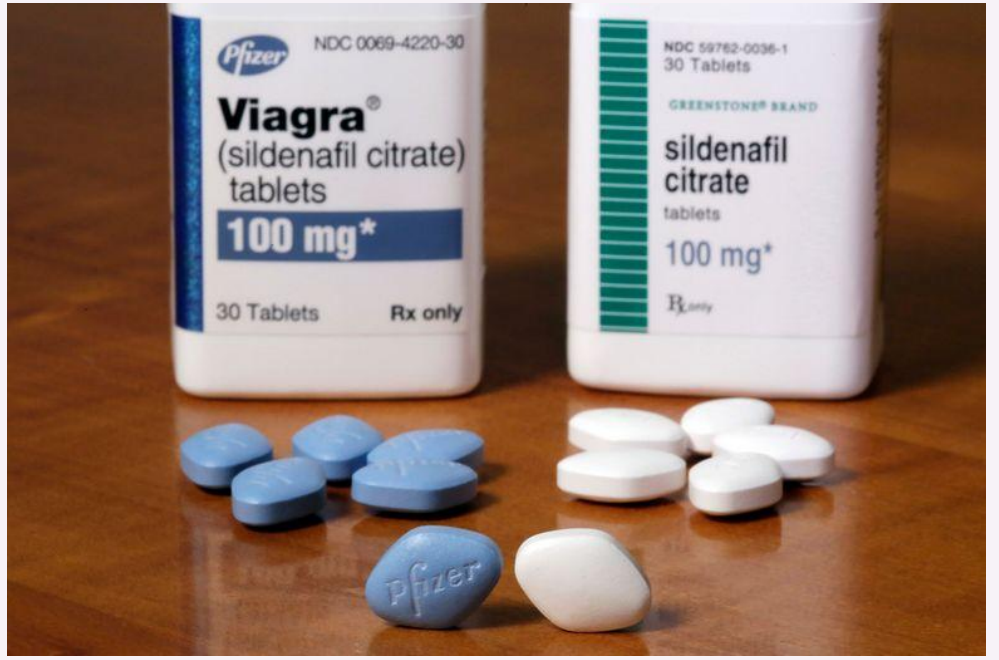


FAST

From daily practice to preferred route…

- Off label use

- Registered indication



The dilemma

Perspectives > Second Opinions

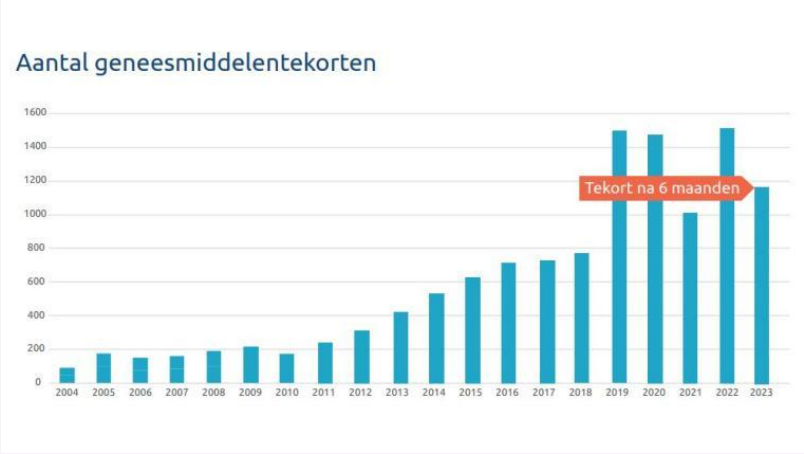
A Price Jump From Pennies to $20/Pill for the Same Drug

— Drug pricing should be subject to stricter regulation

by Robert M Kaplan, PhD, and Michael H Weisman, MD
October 12, 2023 · 4 min read

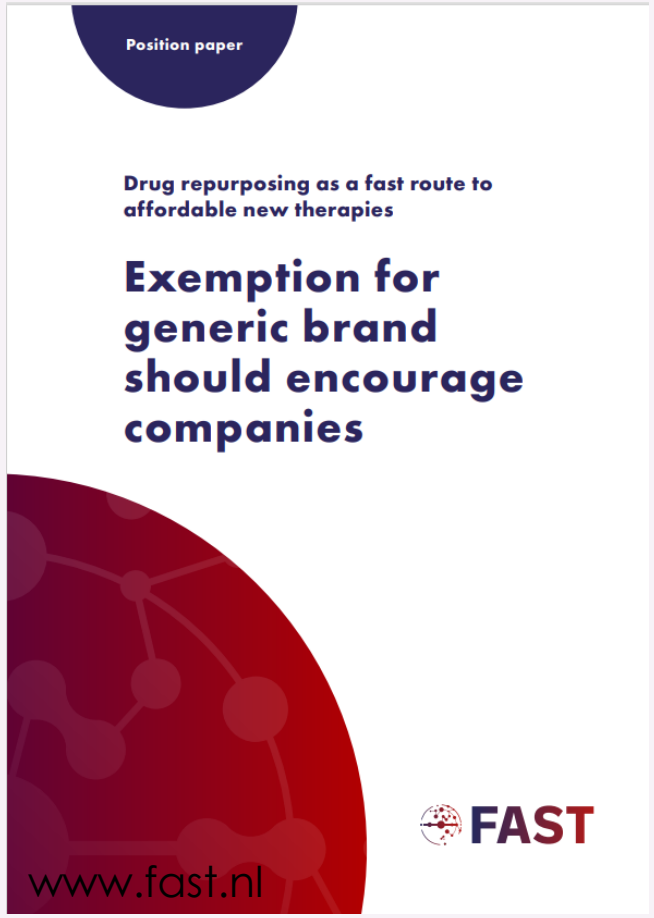
Hijackers give drug repurposing a bad name

The challenge



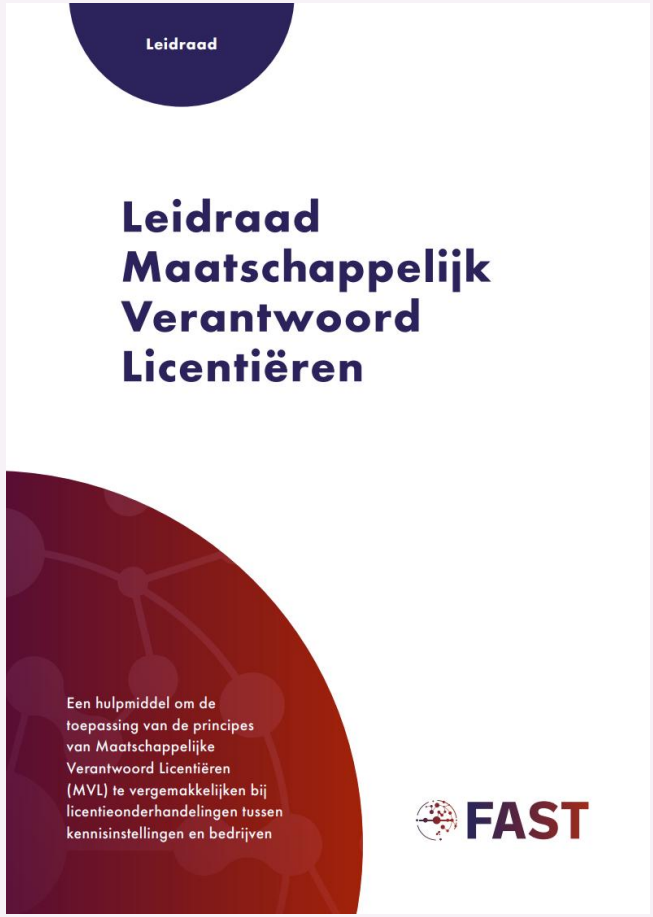
FAST

A system solution is needed…



and demonstrators to show development is possible…

..in a societal responsible way.



www.fast.nl

Technology Transfer License negotiation model for the application of Socially Responsible Licensing principles in licensing negotiations

FAST hub for Rare diseases and drug repurposing

Platform	• Connectivity between the UMCs and private parties working on therapies for rare disease and drug repurposing
Guidance	• Roadmaps and guidelines on drug repurposing and therapy development rare diseases
Pioneering	• Pilots with access models & pricing and new collaborations incl funding demonstrator projects
Research	• Research on demonstrator projects that contribute to system solutions

RARE-NL

From case to system approach

- New Public Private partnerships
- Piloting with SRL and steward ownership
- Demonstrators
  - Pepper therapeutics (with Support Casper)-phenformine for pancreatic cancer
  - Guanarep (with Orfenix) – guanabenz for white vanishing matter
- Alternative pricing models
- Drug Repurposing Venture Challenge
- REMEDI4ALL

We Are Stewards


JIMD
JOURNAL OF INHERITED METABOLIC DISEASE
SSIEM

REVIEW | Open Access

Development of medicines for rare diseases and inborn errors of metabolism: Toward novel public–private partnerships

Noa Rosenberg, Nina N. Stolwijk, Sibren van den Berg, Joris J. Heus, Vincent van der Wel, Teun van Gelder, Annet M. Bosch, Saco J. de Visser, Carla E. M. Hollak

First published: 20 March 2023 | https://doi.org/10.1002/jimd.12605 | Citations: 1


The European Journal of Health Economics
https://doi.org/10.1007/s10198-024-01731-w

ORIGINAL PAPER

Drug pricing models, no 'one-size-fits-all' approach: a systematic review and critical evaluation of pricing models in an evolving pharmaceutical landscape

Evert A. Manders[1,2] · Sibren van den Berg[1,2] · Saco J. de Visser[1,3] · Carla E. M. Hollak[1,2]

Received: 31 May 2024 / Accepted: 10 October 2024
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FAST Forum News About FAST

https://forum.fast.nl/

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- Drug Repurposing
- Medical Isotopes
- Rare Diseases
- ATMPs
- Infectious Diseases
- Therapy develop...
- Funding
- Innovative method...
- Education
- Courses
- Patient involvement

Welcome to the FAST Forum

Join our conversation on innovative therapy development

Search

FAST themes

ATMPs

Infectious Diseases

Rare Diseases

Drug Repurposing

Medical Isotopes

Featured Topics

How can the lack of formal documentation in patient involvement activities be...

ATMPs

The absence of formal documentation has been a barrier in effective patient involvement in our development

Public consultation on current regulatory testing

Difference Orphan designation and marketing authorisation

Rare Diseases

I am curious to know the difference between an orphan designation and a marketing authorisation. Does an orphan

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Thank you for your attention

info@fast.nl

088-866 3278

www.fast.nl

Clinical trials with repurposed drugs; 3DPharmXchange (Bianca Pauly)

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3D PHARM CHANGE

DEDICATED DRUG DEVELOPMENT XPERTS

Clinical trials

with repurposed drugs

Bianca Pauly

3 June 2025, From Molecule to Business event

De novo vs repurposed drug development

3D PHARM X CHANGE
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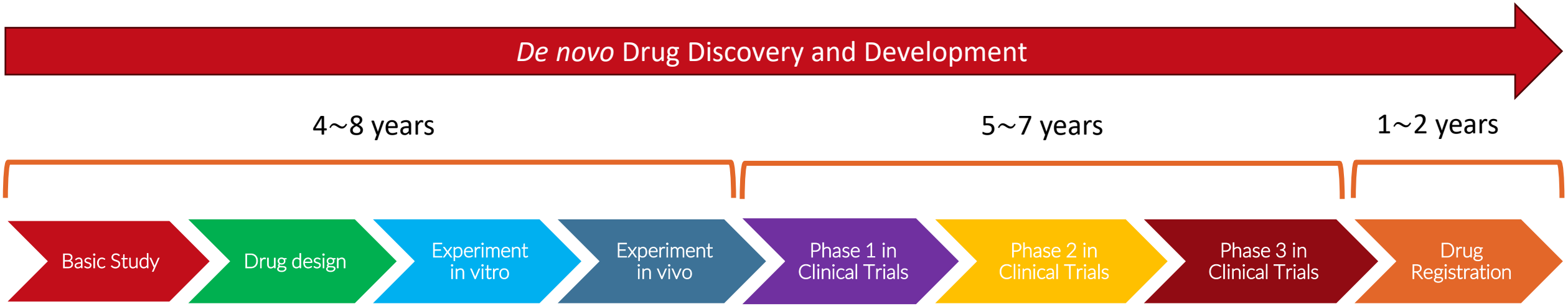

De Novo Drug Discovery and Development

- Low Success Rate
- Huge Cost and Time-consuming Development

Drug Repurposing

Drug Repurposing

- Known drug Safety
- Reduced Pharmacokinetic Uncertainty

Source: from Zhang, Z., Zhou, L., Xie, N. Nice E.C, Zhang T. Overcoming cancer therapeutic bottleneck by drug repurposing. Signal Transduction and Target Therapy 2020;5:113. used under Creative Commons CC-BY license

Repurposed drug development (non-)clinical program

3D PHARM CHANGE
DEDICATED DRUG DEVELOPMENT XPERTS

- Scenarios:
  - ❖New Indication
    - Formulation/Strength
      - Same formulation and strength
      - Same formulation, different strength
      - Different formulation and strength
    - Dose range
      - Higher/lower
    - Safety profile
      - Same / different
      - Depends on indication
      - Example: the safety profile of a cancer drug is different than if this drug will be repurposed for hypertension
    - Known Proof of Concept
      - Not known ➔ first non-clinical trials

Repurposed drug development (cont.) (non-)clinical program

3D PHARM CHANGE
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Same formulation, same or other dose

- Lower dose: None to limited non-clinical studies
- Higher dose: perform additional non-clinical study on higher dose to gather additional non-clinical data
- Probably skip phase I trial
- Phase II and III trials

Repurposed drug development (cont.)
(non-)clinical program

3D PHARM CHANGE
DEDICATED DRUG DEVELOPMENT XPERTS

Different formulation and strength/dose

- Probably full non-clinical and clinical package

➔ Ask for scientific advice for the (non-)clinical development program!

Phase II clinical trials with repurposed medicine

3D PHARM CHANGE
DEDICATED DRUG DEVELOPMENT XPERTS

- Clinical phase: most expensive, time-consuming and risky part of drug development
- Phase II trial: designed and executed in an optimal fashion

  ➔lower the chance for failure, lower the numbers needed to treat, lower the costs.

RePo4EU

- A mechanism-based approach and innovative high-precision trials, in combination with drug repurposing have the potential to make clinical trials smarter, more effective and more efficient.

REPO4EU and phase II clinical trials

3D PHARM CHANGE
DEDICATED DRUG DEVELOPMENT XPERTS

- Aim:
  Develop resources to support investigators with conducting high-quality Phase II clinical trials with repurposed drugs

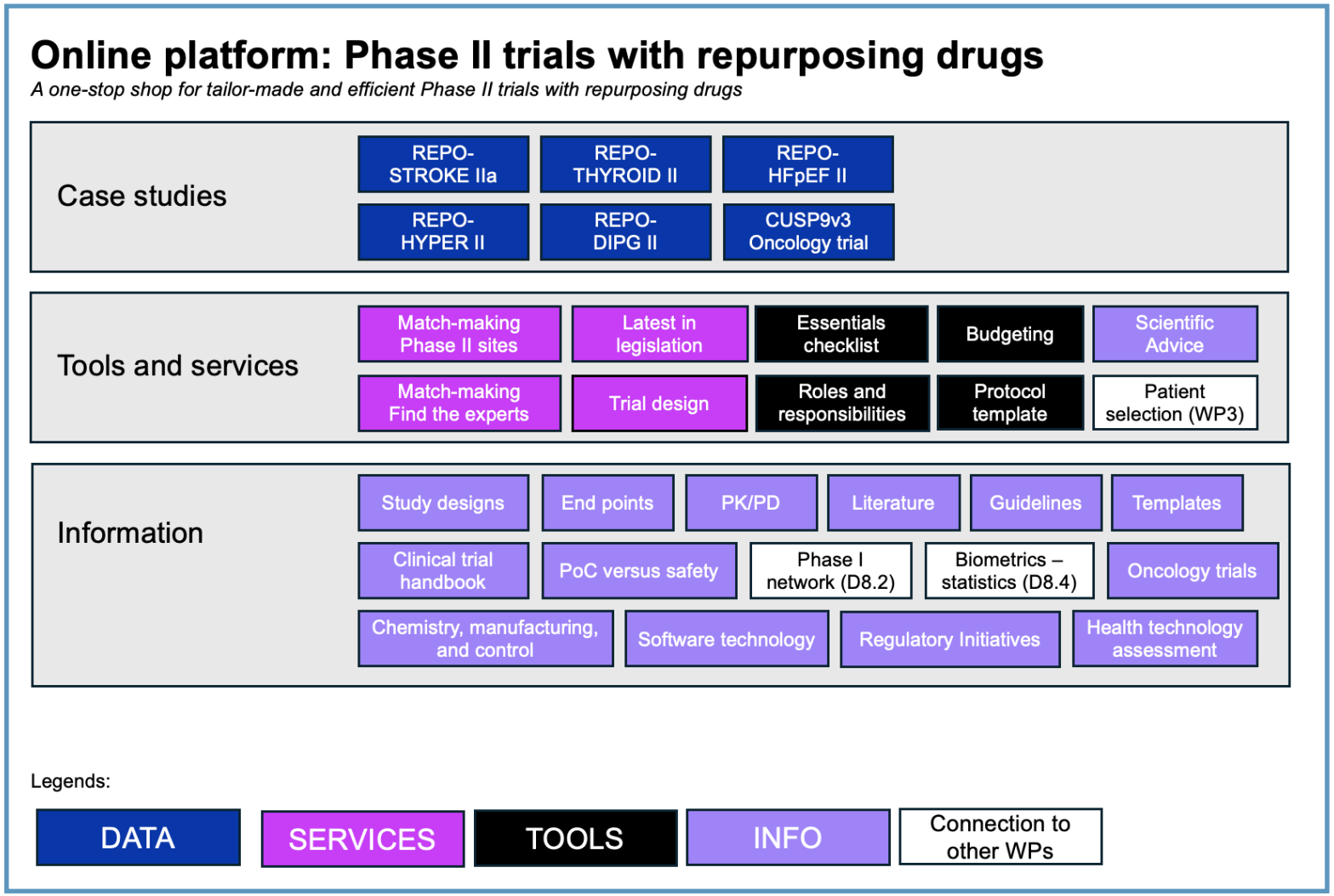
- Step 1: Compendium Phase II clinical trials with repurposed medicine including tools and services.

- Step 2: Present tools and services in the form of an online platform
  - ❖Under development

Platform Development

Making expertise widely available

3D PHARM CHANGE
DEDICATED DRUG DEVELOPMENT XPERTS



Summary

3D PHARM CHANGE
DEDICATED DRUG DEVELOPMENT XPERTS

- Deviating from the ‘original’ drug product will extend the (non-)clinical program

- The REPO4EU online platform with extensive resources and tools with the aim to support investigators will include:
  - trial design tools, a protocol template supplement and an essentials checklist
  - self registry will be made available for match-making: ‘Find the Experts’ and ‘Phase I and II Trial Centers’
  - Platform will be online in 2027

Until.....

the REPO4EU online platform is live, and you require advice or just want to validate your own concept, you can contact us

3D PHARM X CHANGE

DEDICATED DRUG DEVELOPMENT XPERTS

- 3D-PharmXchange provides drug development expert consultants in
  - Non-clinical, Toxicology
  - CMC, formulation
  - Regulatory Affairs
  - Clinical Science and Strategy
  - Clinical Operations
- Tailor-made, fit for purpose, mean & lean, cost-effective advice
- Integrated drug development strategy
- Clinical development plans
- Regulatory strategy

Your first question or consultation is free of charge

3D PHARM CHANGE

DEDICATED DRUG DEVELOPMENT XPERTS

Bianca Pauly, Senior Consultant Regulatory Affairs

bianca@3d-pxc.com
+31 6 271 403 19
Bianca Pauly
3d-pxc.com

From Lab to Clinic to Patient; NLO (Kolja Adamczyk

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FROM LAB TO CLINIC TO PATIENT

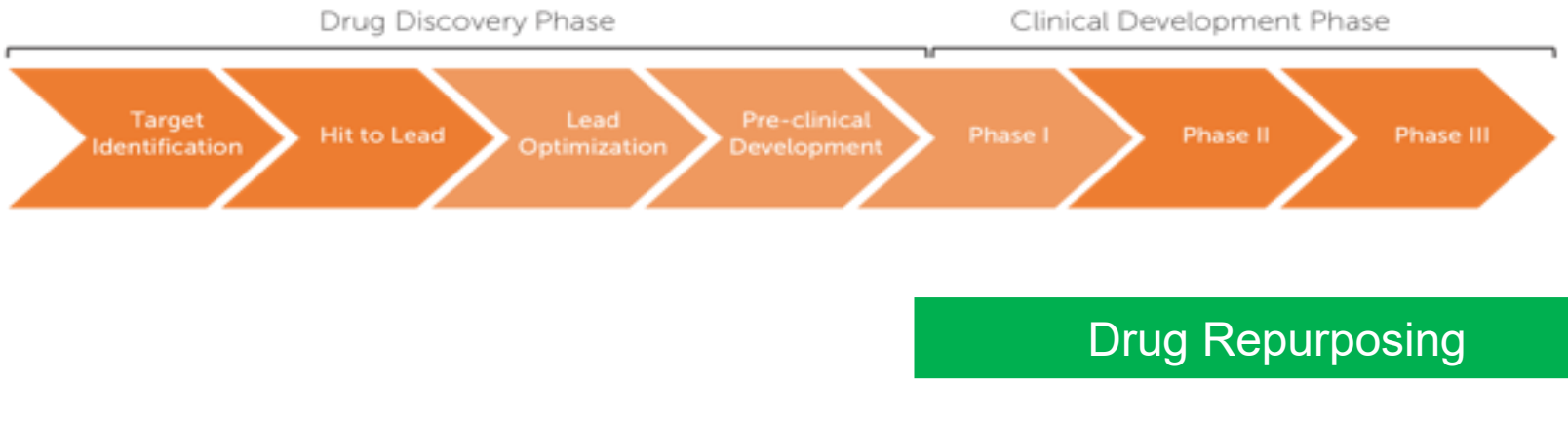
Challenges and Opportunities for Drug repurposing / patent control

Kolja Adamczyk – patent attorney pharma & life sciences

3 June 2025

Ultimate goal: new medicine in the pharmacy

Development for Drug Repurposing



- Known Drug Safety
- Reduced Pharmacokinetic Uncertainty

Examples of Success

- **thalidomide**: originally used as a sedative, now repurposed for multiple myeloma
- **propranolol**: originally, injectable for treating high blood pressure, thereafter developed as an oral drug for rare disease hemangioma

Drug repurposing to obtain new medical treatments

Opportunities:

1. **Faster Development**: safety profile of the drug is already known
2. **Potentially Lower Development Costs**: initial steps in drug discovery and development are omitted
3. **Reduced Development Risk**: Known pharmacokinetics and toxicity data lower the risk of failure in clinical trials
4. **New Uses for known Drugs**: Serving unmet medical needs and supporting personalized medicine

Challenges:

1. **Control**: on Development of Medical treatment / Patent control (!)
2. **Regulatory:** complexity and lack of streamlined approval pathways
3. **Data:** Need for robust data and innovative identification methods
4. **Pricing and Reimbursement**: Current frameworks don't support repurposed drugs

DRUG REPURPOSING, what is it?

For today's discussion the **definition** of drug repurposing is:

Generic off-patent drug molecule for use in the treatment of a new indication

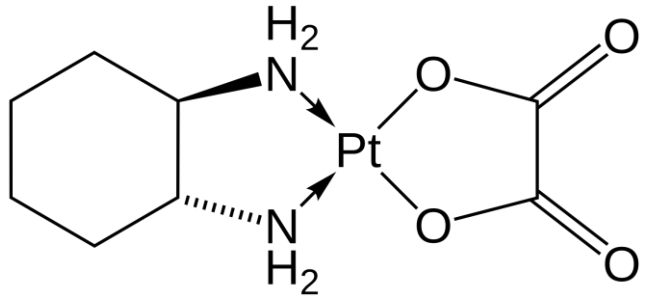
- can involve:
  - a new formulation
  - a new dose
  - a new dosage regimen
  - a new route of administration
  - a combination with further drug molecules (synergy! → network biology)
  - a new diagnostics assay

Example: 3D-printed cancer drug repurposing‡

Successful pre-clinical repurposing of **oxaliplatin**

Intravenous formulation → 3D-printed tablet, oral dosage form

Colon cancer animal model: equally efficacious with a better safety profile



Patenting opportunities:

- Reformulation
- Dosage
- Route of administration
- Efficacy vs. side effects

raising funds for 1st in human clinical trial

EUROPEAN PATENT AND TRADEMARK ATTORNEYS

‡ **Taken from**: Seyedeh Zahra Mirdamadian, Jaleh Varshosaz, Mohsen Minaiyan, Azade Taheri, 3D printed tablets containing oxaliplatin loaded alginate nanoparticles for colon cancer targeted delivery. An in vitro/in vivo study, International Journal of Biological Macromolecules Volume 205, 30 April 2022, Pages 90-109, https://doi.org/10.1016/j.ijbiomac.2022.02.080Get rights and content

WHY IS PATENTING BENEFICIAL

Comfort for investors - necessary funding
financial resources are required for clinical trials / registration

Pricing & Reimbursement (fair, reasonable)
Discussing and negotiating only possible with the patent proprietor of the repurposed drug

Control development / Market monopoly
for the generic drug for the repurposed new indication

Off-label use of the drug can be prevented or stopped
based on patent infringement

IP checklist for Drug Repurposing: road to clinic - details

PATENT STRATEGY

- **understand basics of the system – prevent self-created issues**
- understand cost milestones (quite predictable)
- **can never create patent strategy too LATE // review and address while executing**

PHARMA LEGISLATION / MARKET ENTRY

- Clinical trials regulation / market authorization
- pricing – reimbursement options

OWNERSHIP

- *NDA is not enough*
- employment contracts
- consultancy agreements
- joint research / contract research
- in-licensing

FREEDOM-TO-OPERATE

- **Generic drug?**
- competitor patent landscape
- stepwise – but identify major issues early

SPIN-OUT DUE DILIGENCE

- **proper chain of title for patents acquired?**
- sensible approach to cost-sharing and decision power?
- ensure you understand license terms
- **does patent scope match your activities?**
- access to follow-up inventions (~ University research group)?

SECRECY

- NDA's
- way of working / need to know
- **Awareness role**/ training

IP-RELATED LEGAL ISSUES

- Handling personal (e.g. patient) data? Data mining? ➔ EU Data legislation *(GDPR, non-personal data, data governance act, data act, digital markets / digital services acts, AI act)*
- **loans / grants / tax incentives for innovation** (Rijksdienst voor Ondernemend Nederland (rvo.nl))

→ Reference material: you can ask you copy
Disclaimer: this is not a complete list; seek expert counsel

Any questions? Feel free to reach out

Kolja Adamczyk
European and Dutch Patent Attorney
(Pharma & Life Sciences)

adamczyk@nlo.eu
+316 82789121

please, send an email if you
want a copy of the slides

Barend Bouma
European and Dutch Patent Attorney
(Pharma & Life Sciences)

bouma@nlo.eu
+316 13269542

Drug repurposing at Radboudumc; Maaike Oosterveer

briskr

pivotpark
Europe's foremost biopharmaceutical campus

SMB
Facilities & Support in Life Sciences

HealthValley
NETHERLANDS

Drug repurposing at the Radboudumc

collaborating to Accelerate patient Access to Available and Affordable therapies

Maaike Oosterveer, PhD

From Molecule 2 Business event

03-06-2025

Radboudumc

Therapy Accelerator for Rare Diseases

Radboudumc

university medical center

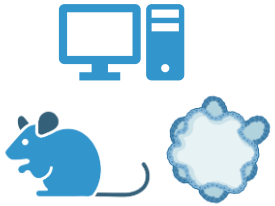
To have a significant impact on health and healthcare

Drug Repurposing: our share

Medical Need

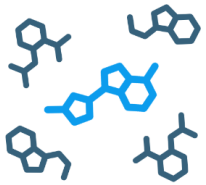
diagnostics

Target identification



data/AI
(personalised) model systems

Preclinical PoC



Dose optimisation

PK/PD modeling

Clinical PoC

trial design / statistics
phase I studies

Clincal validation and registration

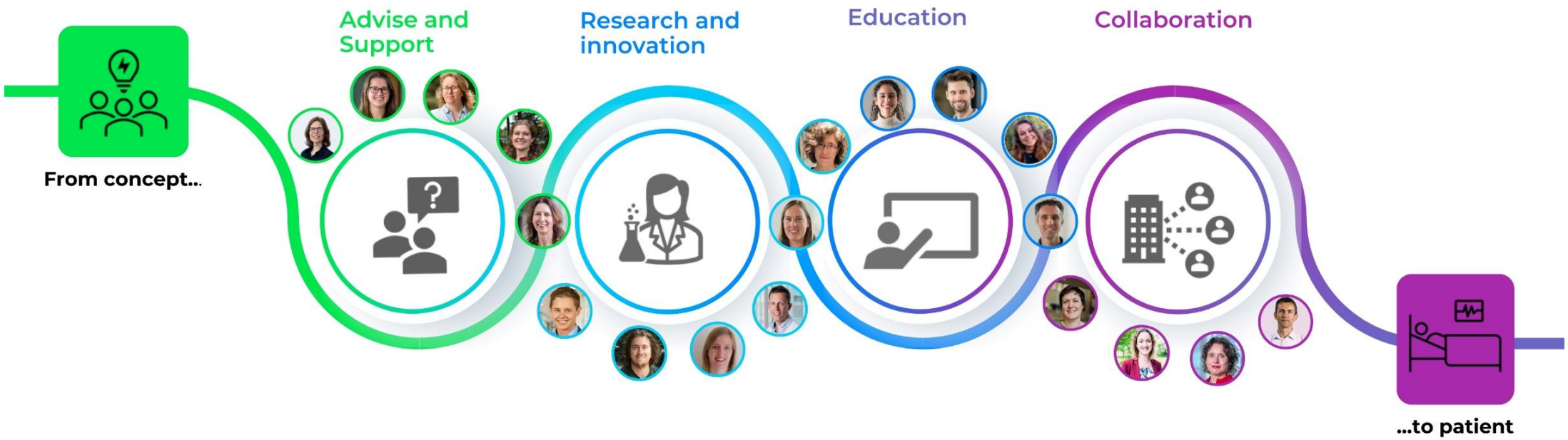
Radboudumc

private partners

Radboudumc
university medical center

Therapy Accelerator for Rare Diseases

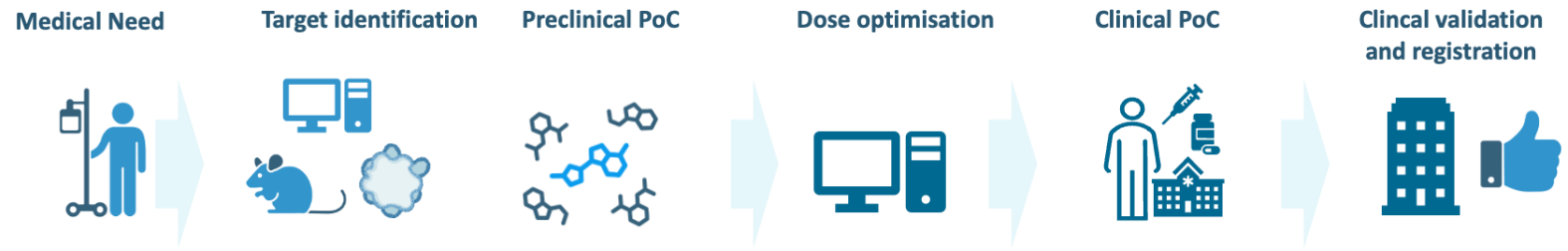
connect, educate, integrate, and collaborate to accelerate



Radboudumc
university medical center

Our position within the drug repurposing ecosystem

Let’s connect and move forward together!



Radboudumc YOU?

maaike.oosterveer@radboudumc.nl

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Drug repurposing from an investors perspective; OostNL (Lema Maiwand)

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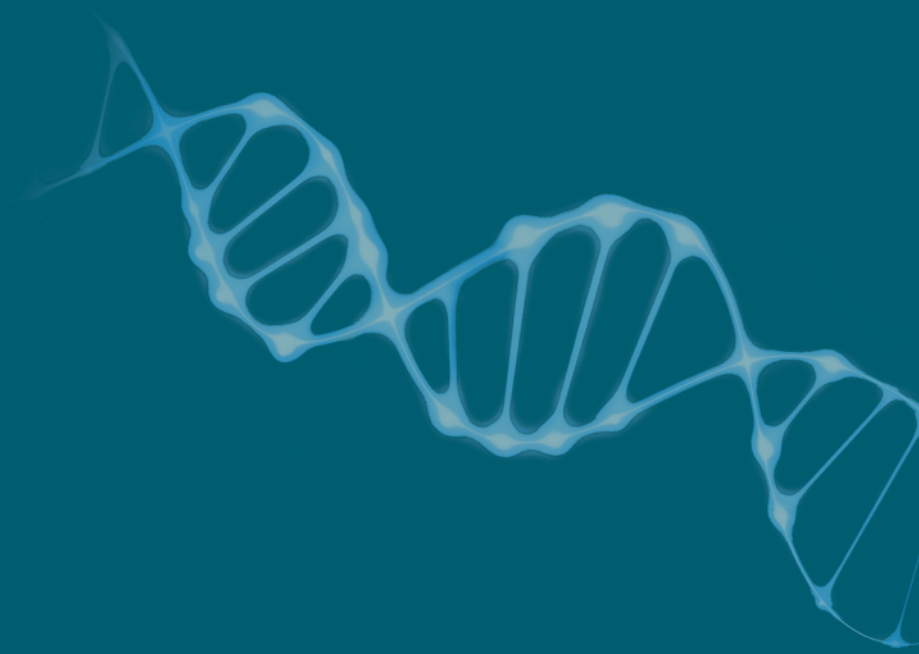
Drug repurposing

An investor's perspective

Lema Meiwand
Oost NL

Disclaimer



Regional Development Agency Oost NL

- Capital, Business Development, and International
- Focus on Gelderland & Overijssel
- Health: Medtech – Diagnostics – Pharma
- Approx. 40 health portfolio companies

Fund information

- Public evergreen investment fund
- Need for regional and societal impact
- Total investment up to 5 milion per company
- (Pre-) seed to series A/B

Important aspects for investors

- Technology
  - Proven (pre-) clinical data
  - Patent and a clear Patent strategy
- Businesscase
  - Clear unmet medical need
  - Market size
  - Reimbursement & pricing strategy
- Team
  - Validated experience
  - Complete team
- Exit
  - Clear exit strategy
  - Interest from pharmaceutical companies in specific field
- Co-funding
  - Strong consortium with enough capital and expertise

Vision on Drug Repurposing from private investors

- Different definitions and views on repurposing

- Drug repurposing is less attractive
  - Difficult to get any protection through patents
  - Low reward for investors
  - Risk for Off-Label Use
  - Difficult to get a good reimbursement strategy
  - No interest from big pharma

Successes in repurposing

BRAND NAME	ORIGINAL INDICATION	NEW INDICATION (YEAR)	PHARMA COMPANY	ANNUAL SALES[a]
GEMZAR	Anti-viral	Various Cancers (Various)	Lilly	$1.72B
EVISTA	Osteoporosis	Invasive Breast Cancer (2007)	Lilly	$1.09B[b]
PROSCAR[c]	Hypertension	BPH (1992)	Merck	$741.4M
PROPECIA[c]	Hypertension	Male Pattern Baldness (1997)	Merck	$429.1M
REVLIMID	Structural Analogue[d]	Multiple Myeloma (2006)	Celgene	$4.28B
REVATIO[e]	Angina/ED	PA Hypertension (2005)	Pfizer	$525.0M
RITUXAN	Various Cancers	Rheumatoid Arthritis (2004)	Biogen/IDEC[f] & Roche	$1.2B[g]
TECFIDERA	Psoriasis	Multiple Sclerosis (2013)	Biogen/IDEC[f]	$2.91B
THALOMID	Anti-Nausea	Leprosy (1998)	Celgene	
		Multiple Myeloma (2006)	Celgene	$535.2M
VIAGRA[e]	Angina	Erectile Dysfunction (1998)	Pfizer	$2.05B

Arakis	Acquired (2005)	Bought by Sosei – $187.5M
Aspreva Pharmaceuticals	Acquired (2007)	Bought by Galenica – $915M
ChemgeneX Pharmaceuticals	Acquired (2011)	Bought by Cephalon – $230M
Cypress Bioscience	Acquired (2010)	Bought by PEG Ramius & Royalty Pharma – $255M
Daniolabs	Acquired (2007)	Bought by VASTox – $25M
Hypnion	Acquired (2007)	Bought by Lilly – $315M
Saegis Pharmaceuticals	Acquired (2006)	Bought by Lundbeck A/S – $27M
Somaxon Pharmaceuticals	Acquired (2012)	Bought by Pernix Therapeutic Holdings – $25M
Synosia Therapeutics	Acquired (2011)	Bought by Biotie – $121.5M
Vela Pharmaceuticals	Acquired (2006)	Bought by Pharmos – $29.7M
BM Systems	Active	Pharma Services, Platform Technology
BioVista	Active	Pharma Services & Drug Candidate Pipeline
Camargo Pharma	Active	Consulting – Focus on FDA 505(B)(2) Process
Celentyx	Active	Pharma Service & Drug Candidate Pipeline-Immune
CureHunter	Active	Pharma Services & Drug Candidate Pipeline

Opportunities Repurposing

Big effect on healthcare:

- Reduce costs in healthcare system
- Potential impact by moving intramural care to extramural care

Current drugs can be repurposed for rare diseases

Faster impact as the route to market is shorter

Opportunities from Oost NL's perspective

Less capital needed to develop drug

Follow-up investment can be based on clinical data

Lower failure risk due to more (pre-) clinical data

Faster route to exit as drug development is shorter

What does Oost NL look for in DR companies?

- A (unmet) medical need
- Patent and patent strategy
- (pre-) clinical data set

As for the DR focus:

- New formulation
- New drug product with approved API
- New route of application
- Combinations of API
- Combination with applicator (device)
- New release profile

Thank you
for your attention

East Netherlands
Development Agency