

Workshop REMEDi4ALL: What's in it for funders?

Learn and discuss how REMEDi4ALL & the funders network can support your funding activities in drug repurposing.

Learn more: https://remedi4all.org/events/



5 July 2023 12:00-14:00 CEST Online

The REMEDi4ALL project has received funding from the European Union's Horizon Europe Research & Innovation programme under grant agreement No 101057442.



Welcome

Heleen van der Meer, PharmD I PhD Senior programme manager international drug repurposing



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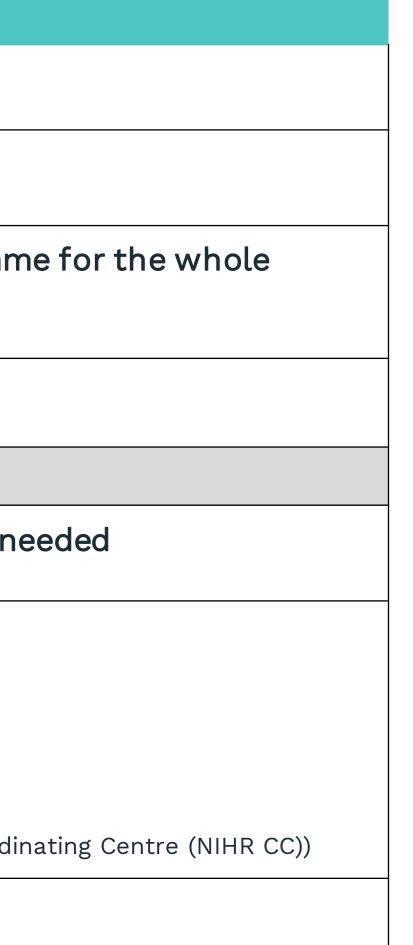


Housekeeping rules

- Workshop will be recorded for internal use only
- Slides will be shared
- Please turn microphone off
- We will ask for your input (funders) via polls
- Questions can be asked via chat

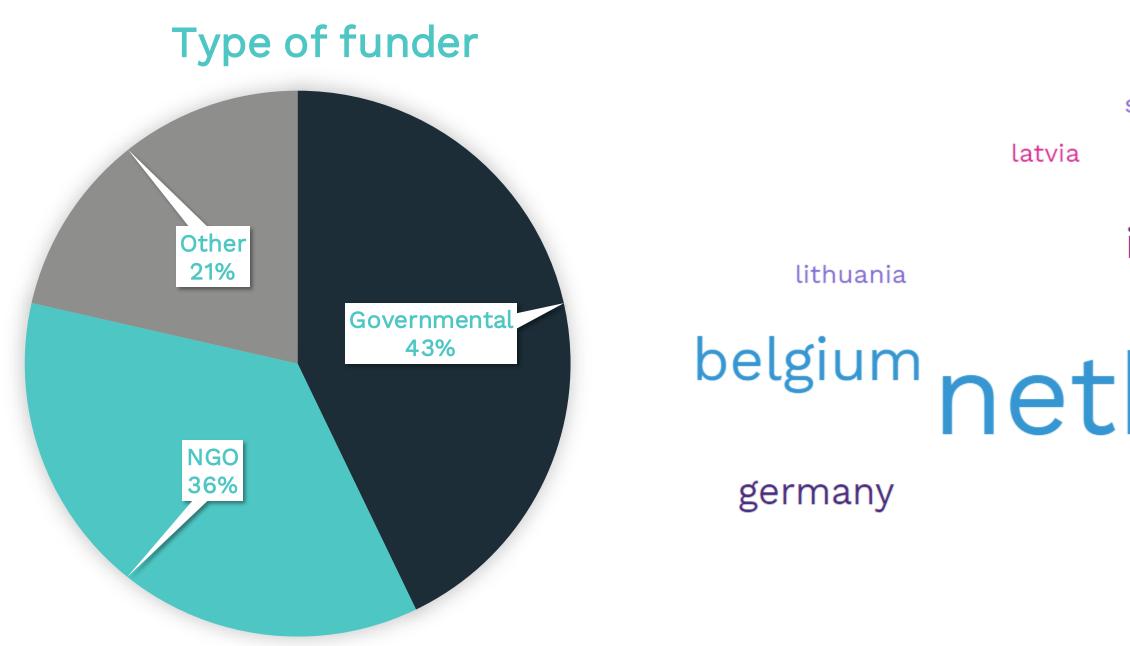


Time	Торіс		
12.00-12.05	Welcome Chair: Heleen van der Meer (ZonMw)		
12.05-12.30	Introduction REMEDi4ALL and funders network Anton Ussi (EATRIS) & Heleen van der Meer (ZonMw)		
12.30-12.40	How do you repurpose? REMEDi4ALL's training programs repurposing ecosystem Rick Thomson (BEACON: for rare diseases) + your input		
12.40-12.50	Introduction to the REMEDi4ALL Funding Decision Tool Marcell Csanadi (Syreon Research Institute) + your input		
12.50-13.00	Q&A - break		
13.00-13.20	Funding drug repurposing: barriers, solutions & incentives r Heleen van der Meer (ZonMw)		
13.20-13.45	Panel discussion Moderated by Pan Pantziarka (Anticancer Fund) <u>Panellists:</u> Joanna Davidge (LifeArc) Teun Grooters (Arega Medical) Sagair Hussain (DEBRA) Sarah Puddicombe (National Institute for Health and Care Research Coord		
13.45-14.00	Next steps for the funders network & closing Heleen van der Meer (ZonMw) + your input		





Who is in the room?





switzerland

italy usa belgium netherlands

greece

australia



THE EUROPEAN PLATFORM FOR MEDICINES REPURPOSING

Anton Ussi - Operations & Finance Director, EATRIS



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European infrastructure for translational medicine

WHY DRUG REPURPOSING?

CONCEPT

> Finding new therapeutic uses for existing medicines.

RATIONALE

Leverage knowledge previously generated on safety and effectiveness of a known drug to explore new indications.

POTENTIAL

- > Lower barrier to enter drug development: less costly and quicker
- > Bring (much needed) new therapeutic options to patients, faster
- > Ideal collaborative model for academics, SME and patients

 \rightarrow More efficient research with high social impact



WHY CREATE A DRUG REPURPOSING **PLATFORM IN EUROPE?**

Huge interest and activity in repurposing

But very fragmented

 \succ No single entity can do it all





First EU stimulus

> Mandate: defragment; create accessible eco-system

OUR VISION

An EU research and innovation ecosystem that facilitates fast, cost-effective and patient-centric development and implementation of repurposed medicines, meeting high unmet medical needs in any disease area



TWO OPERATIONAL GOALS

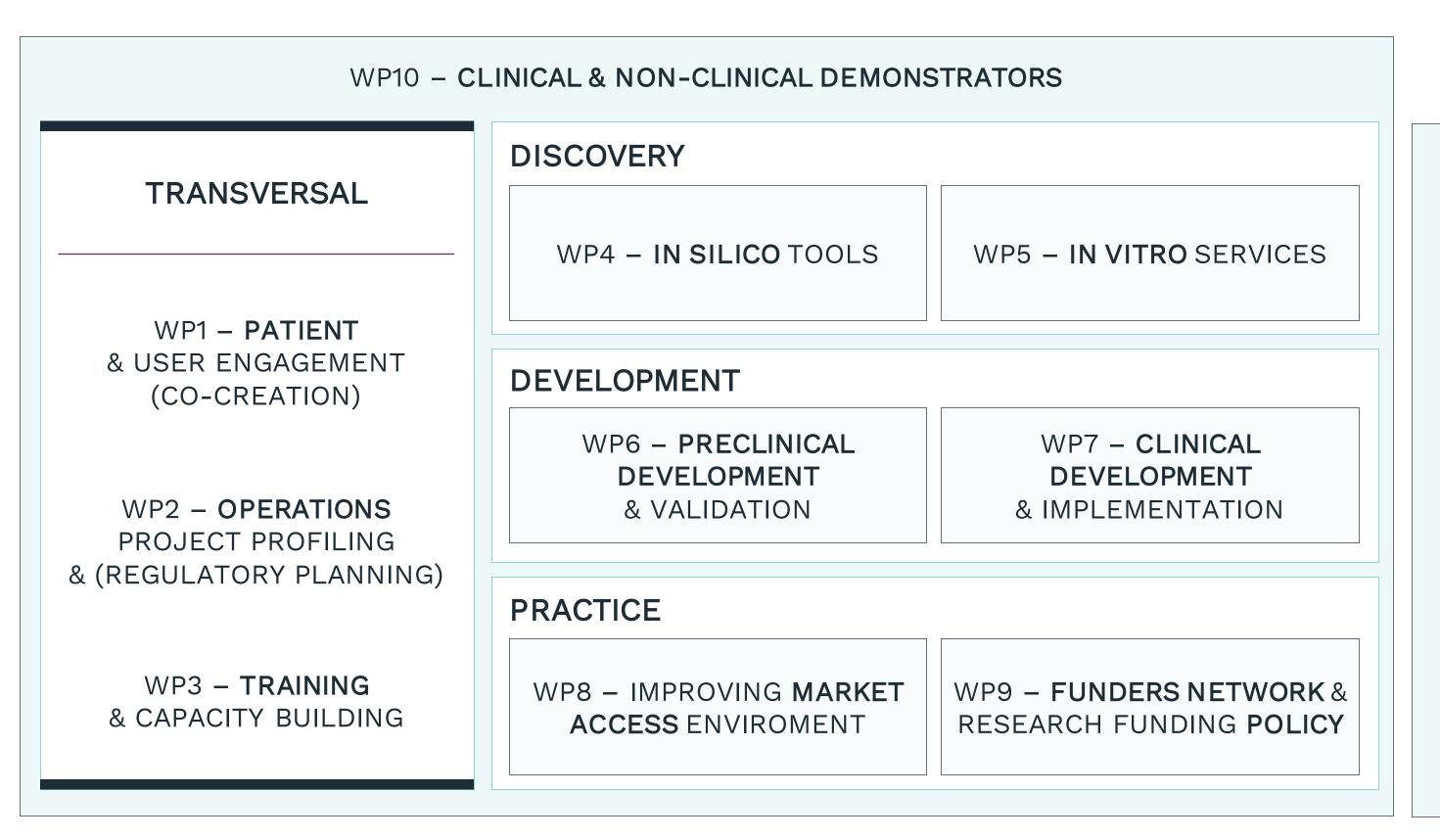
Build a complete, standardised and accessible platform served by experts in all facets of the medicine repurposing journey





Create a think-tank that develops and advances drug repurposing policy

THE REMEDIA4LL WORKPLAN

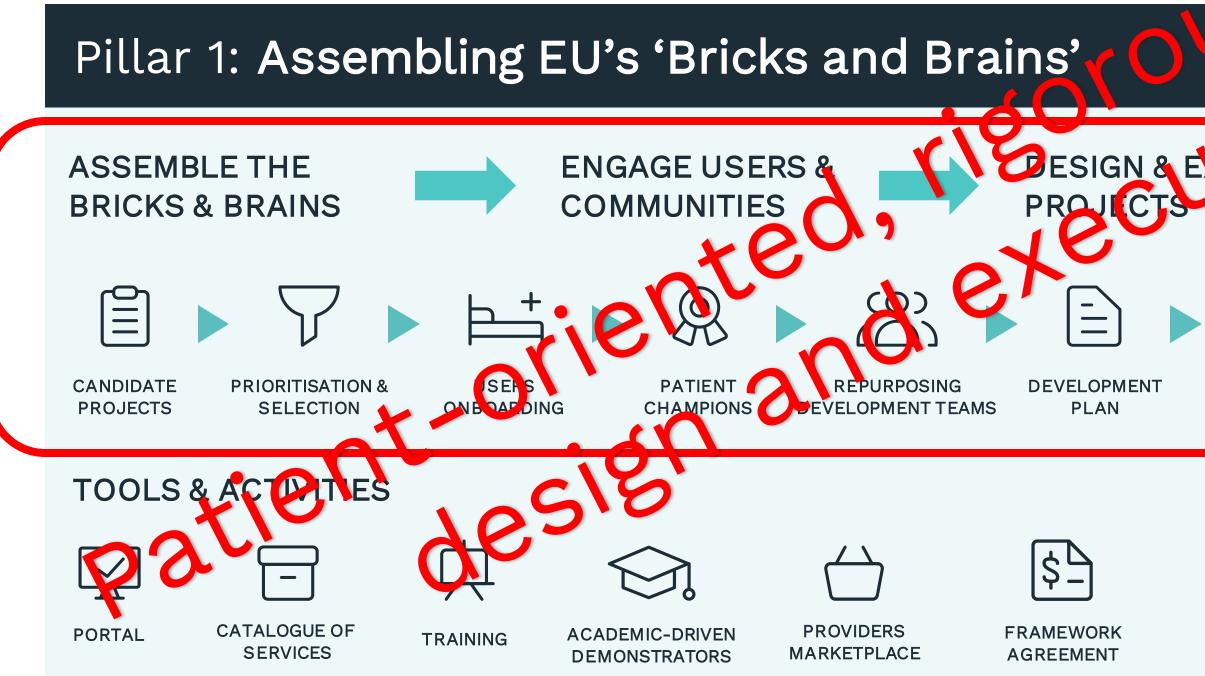


WP11 Т BUSINESS PLAN 8 COMMUNICATION



WP13 – PROJECT MANAGEMENT

A COMPLETE, ACCESSIBLE VALUE CHAIN



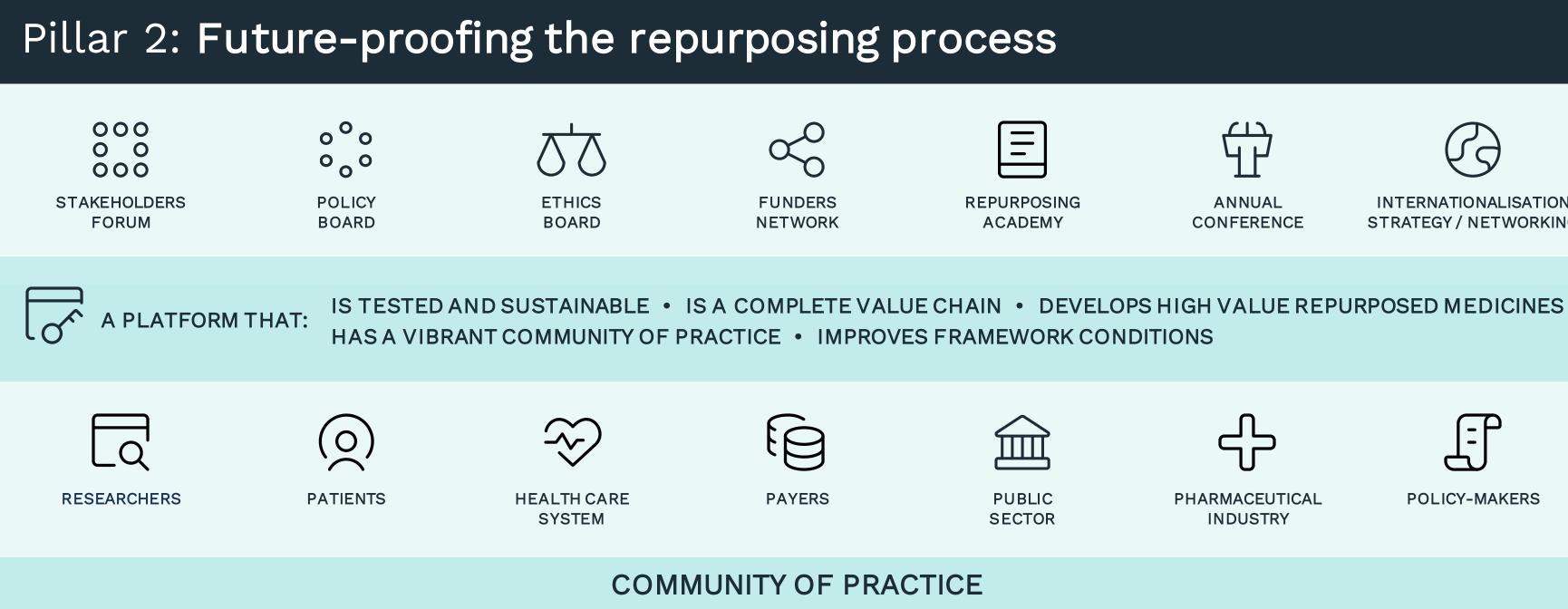
Stuc DEMONSTRATOR PROJECTS • Covid-19 • Metastatic pancreatic ductal adenocarcinoma • Multiple Sulfatase Deficiency PROJECT • Osteogenesis **EXECUTION** imperfecta FUNDING **QUALITY &** DATA RADAR REPRODUCIBILITY MANAGEMENT

RPOSING

REPL

4ALL

BRINGING ALL STAKEHOLDERS TOGETHER









ANNUAL CONFERENCE



INTERNATIONALISATION STRATEGY / NETWORKING



PHARMACEUTICAL **INDUSTRY**



POLICY-MAKERS

REMEDi4ALL PARTNERS & ASSOCIATED PARTNERS

Scientific coordination & mgt



Patient engagement





nedicines

Chemotargets





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Health technology & regulatory

syreon Research Institute



Bundesinstitut für Arzneimittel und Medizinprodukte

Clinical Research Hospitals





remedi4all.org #R4ALL #REMEDi4ALL

REPURPOSING CONCIERGE

Launched March 20th, > 50 requests since then!

~ 4 requests per week

30-min introductory call with all requesters!

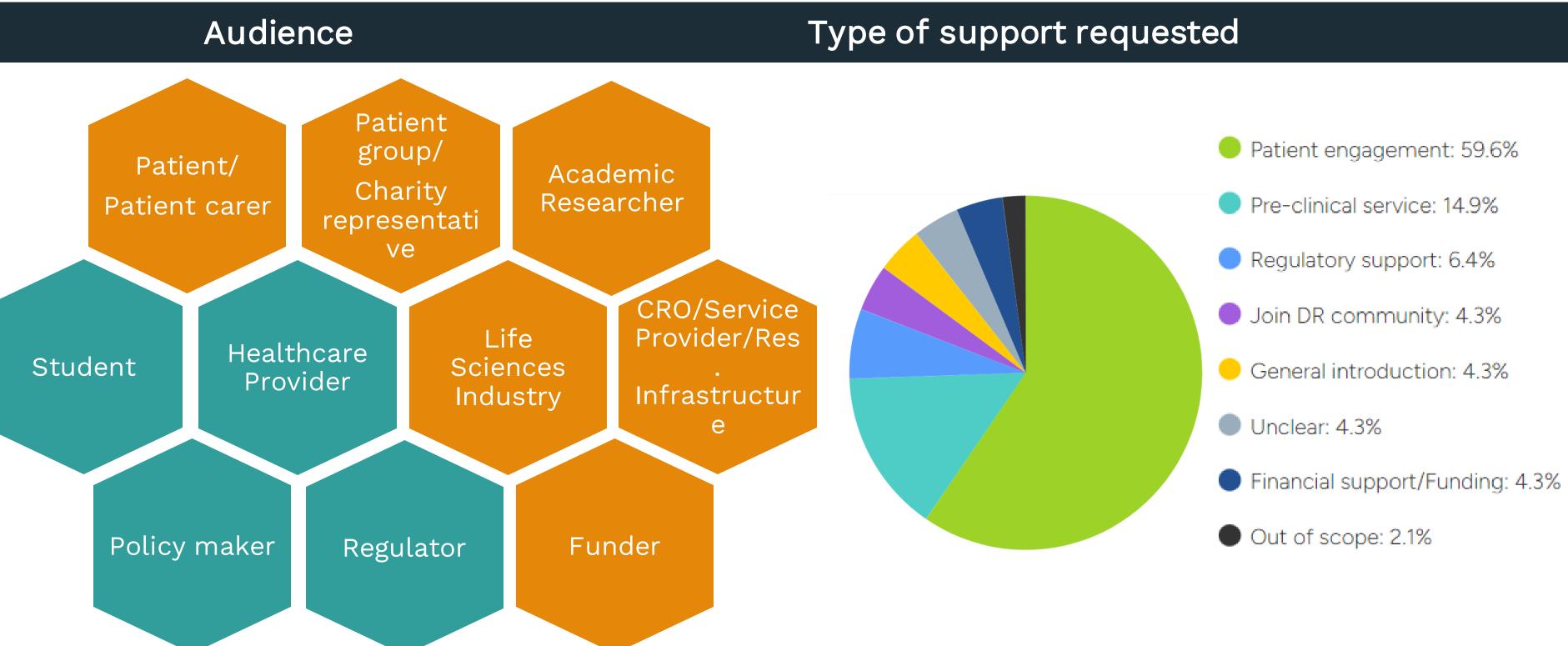
If request involves PE, EURORDIS/Beacon join first discussion





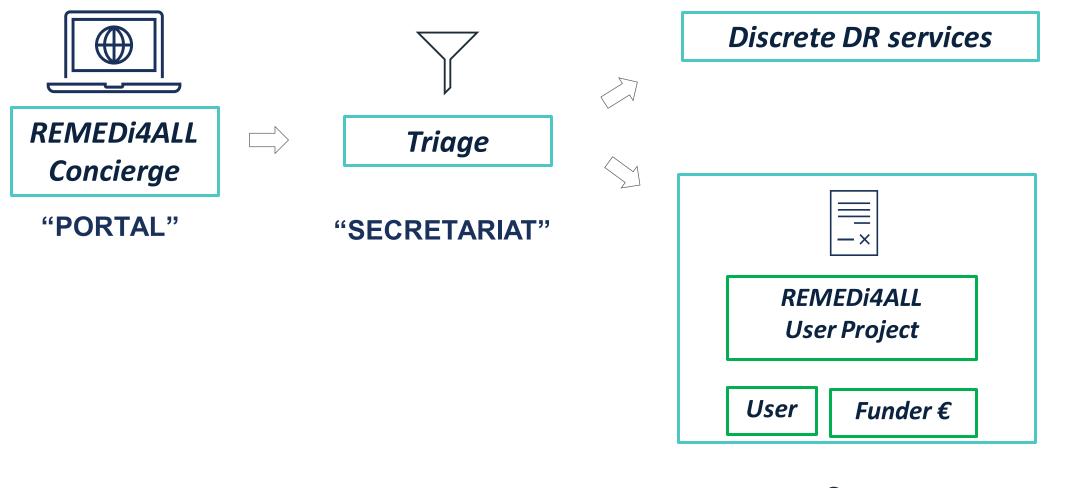


Repurposing Concierge activity





Onboarding of projects





REPURPOSING DEVELOPMENT TEAMS



patient engagement – essential co-creators

PATIENT'S NEEDS

PATIENT ENGAGMENT

5					
	DISCOVERY PHASE	PRECLINICAL DEVELOPMENT		CLINICAL DEVELOPMENT	A M/
	Learn about the disease and understand the condition from a patient's perspective			Develop patient relevant outcome measures	() () () ()
	Start partnering with patients and develop your research question based on patient's needs and priorities.			Design the clinical trial protocol Design patient facing materials	F E C F C F
	Clearly define and agree on the collaborative research goals and future steps			Develop recruitment and retention strategy	
	•	arch methodology nt inputs or PROs			\leq

PATIENT'S CARE

APPROVAL AND MARKET ACCESS POST APPROVAL SURVEILLANCE

Patients serve on EMA Advisory Committees, contribute to benefit/risk discussion, and as Patient Representatives.

Patients provide input on Risk Evaluation and mitigation stategies and feedback on Phase IV studies.

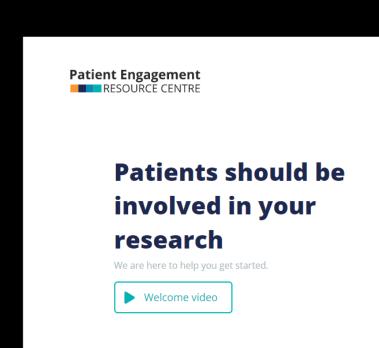
Patients provide evidence to support HTA

Including multistakeholder meetings with funders



Find out more on 2 patient-engagement.eu





Planning











This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 871096



THE TEAM





THANK YOU



remedi4all.org



in

twitter.com/REMEDi4ALL

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#R4ALL #REMEDi4ALL



Funders Network

Heleen van der Meer, PharmD I PhD

Senior programme manager international drug repurposing



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Aim of the funders network



A dynamic international network comprising diverse funders who are committed to driving drug repurposing forward.



An inclusive forum for discussion (think tanks), where we encourage you to share your funding perspective and actively engage in conversations surrounding policy matters and potential solutions to enhance the field.



Reduce fragmentation of the drug repurposing funding landscape, facilitate coordination of funding activities, create new funding streams and identify opportunities for joint calls.



We hold annual meetings where we exchange best funding practices.



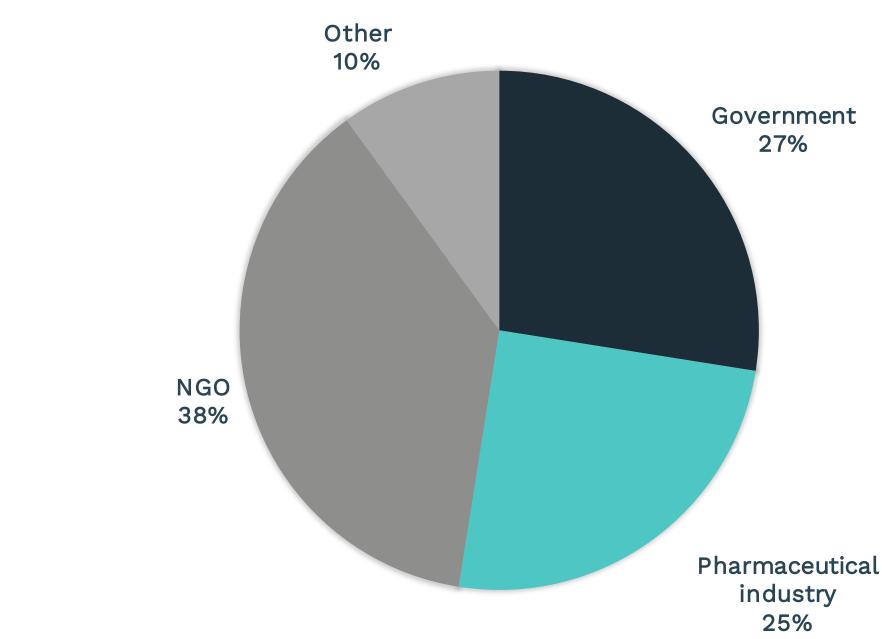
> 50 funders interested to join the funders network



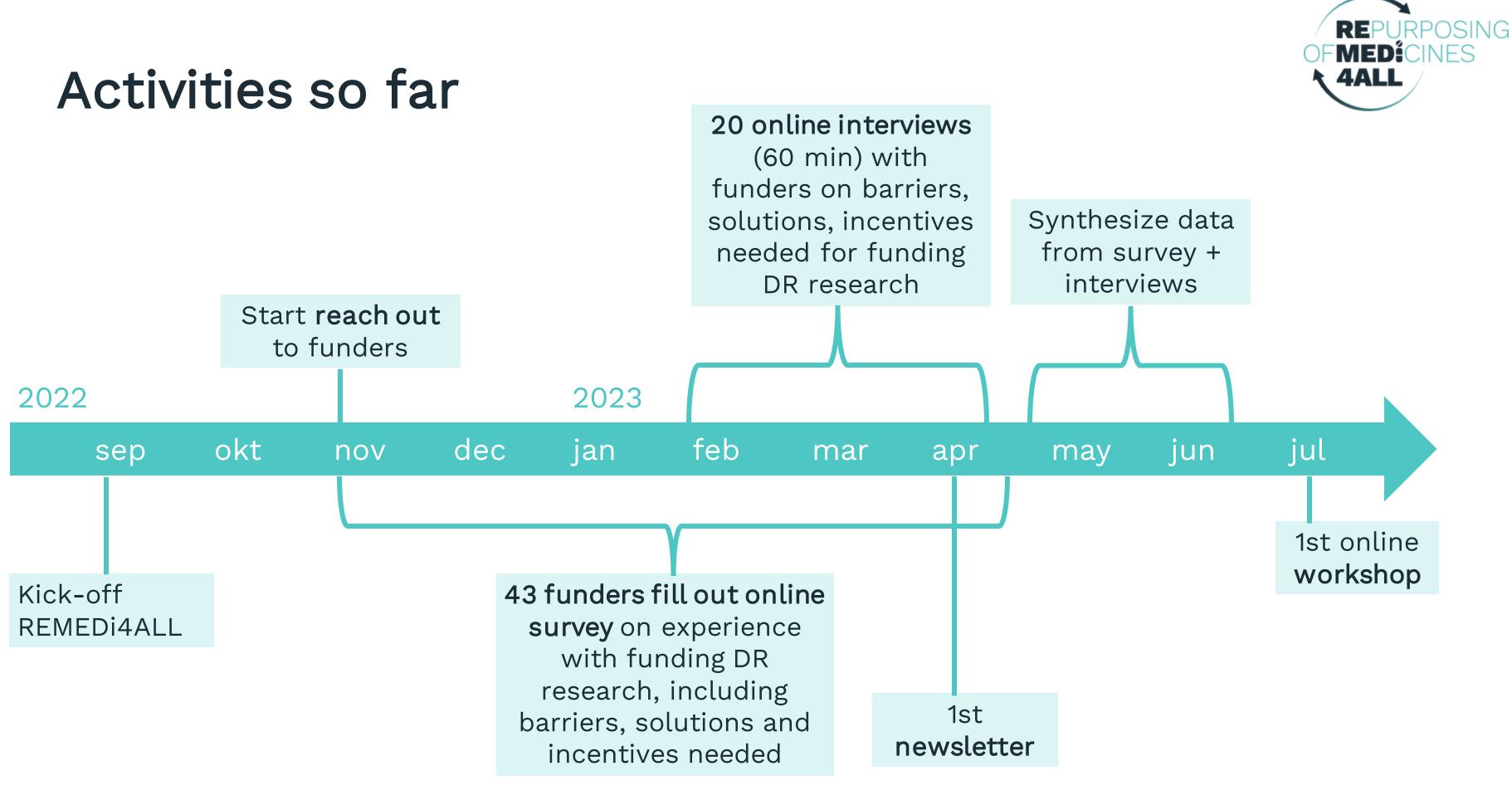




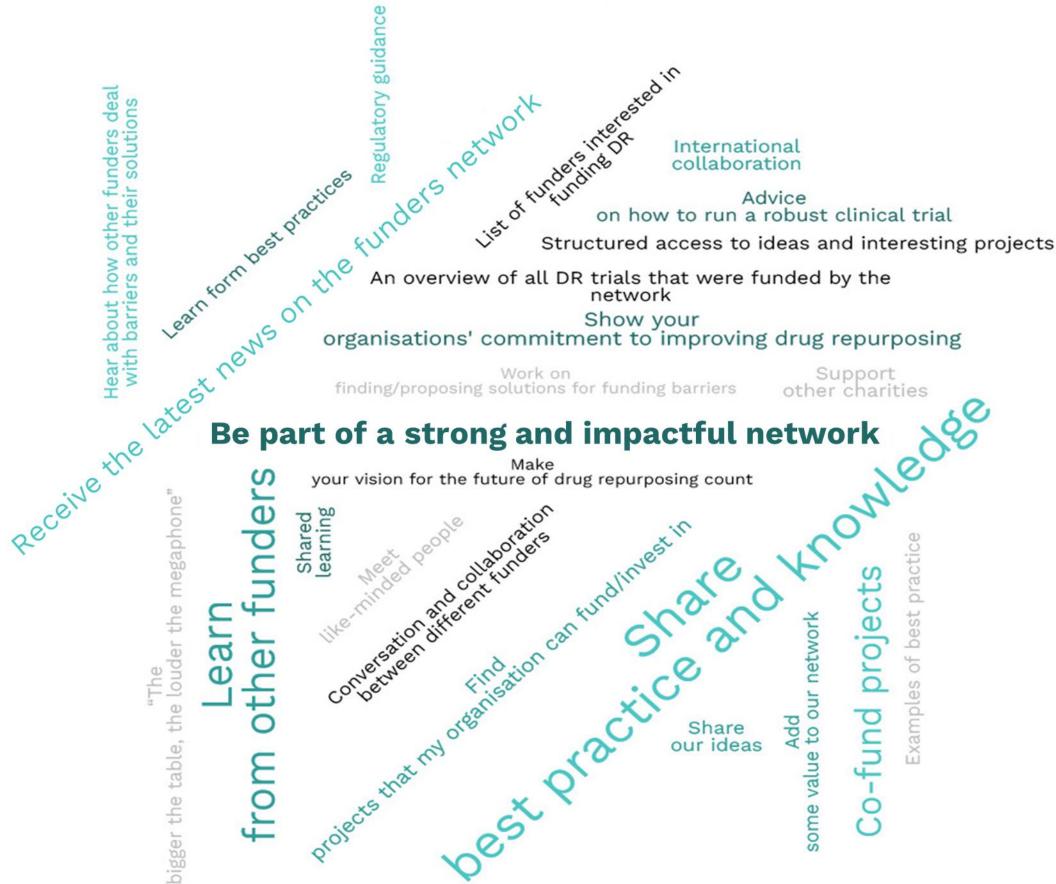
> 50 funders interested to join the funders network







Your expectations of the funders network



find solutions for funding barriers together







What's in it for funders?

Be part of

a strong and impactful international network comprising diverse funders who are committed to driving Drug Repurposing forward

a marketplace

- Find like-minded funders (e.g. funding radar, co-funding)
- Find projects to fund/invest in (e.g. multi stakeholder meetings, repurposing concierge)
- Share best funding practice (e.g. during workshops, innovative funding models)
- Learn from other funders (e.g. training, funding decision tool)

a think tank

- Engage in conversations surrounding policy matters (e.g. work package 8 on market access, policy board)
- Work on finding solutions for funding barriers

Show your organisations' commitment to improve drug repurposing Make your vision for the future of drug repurposing count Receive the latest news on the REMEDi4ALL platform and funders network





How do you repurpose? REMEDi4ALL's training programme for the whole repurposing ecosystem

Rick Thompson – CEO, Beacon: for rare diseases



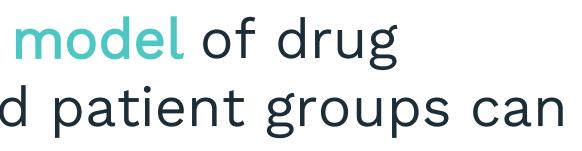
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Why repurpose?

- Repurposing offers a potentially faster route to patient impact.
- Repurposing offers a lower barrier of entry to drug development, making research in areas of low interest possible.
- Repurposing is an ideal collaborative model of drug development – academics, SMEs, and patient groups can all have a big impact.





Why train the repurposing community?

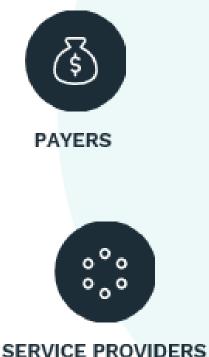


Build a complete, visible and accessible value chain for patient-centric repurposing



Create new ways of thinking about repurposing across all stakeholders







Drive policy, regulation and access changes through collaborative education







HEALTH CARE SYSTEM





PATIENTS



RESEARCHERS



POLICY-MAKERS



REGULATORS

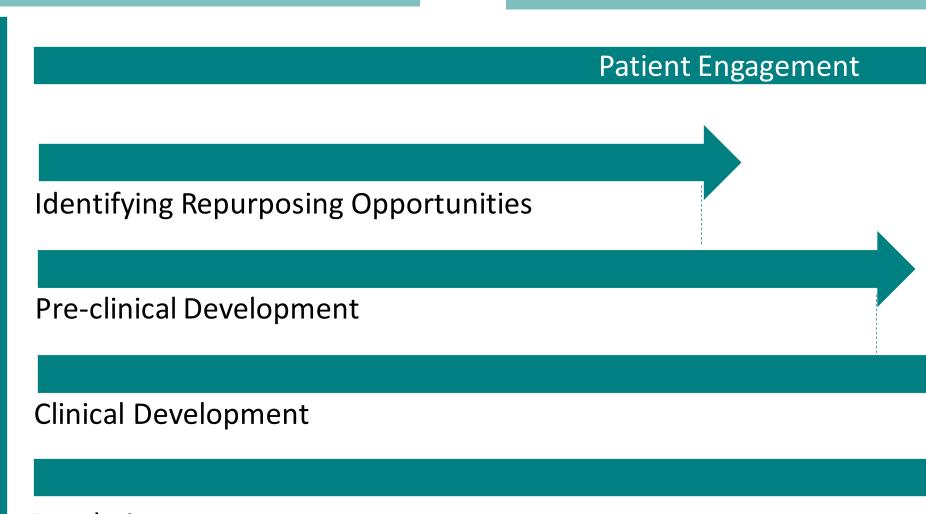
COMMUNITY

The repurposing pathway

Drug Repurposing Pathway

Funding

Collaborative models of research



Regulation

Business Models & Health Economics



Project Management

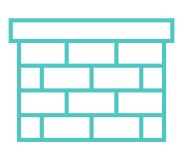
Patient Access

Transform an experimental hypothesis into a new therapy

The core aim of repurposing within REMEDi4ALL is to get a new treatment to a patient, not a new paper.



This requires a diverse range of skills and knowledge beyond the hypothesis testing skills that scientists are traditionally trained for.



This is the **biggest barrier to successful repurposing**. We think improving the skills of researchers in this area, can generate more impact from your funding!





Project Management for Scientists



How to fund each step



Who project leads should be talking to and when



How to effectively communicate with collaborators



A



Expectation management





How to choose a good manager for your project

Data – what is good data?

Regular re-focus on who the project is for

Training structure

	Level	Main training type	Delivery route	Audience
1	Why repurpose?	Why is repurposing important? Case studies and success stories. Aim to win people to the cause.	General communications, conference presentations	Industry, General public, regulators, funders, patient organisations
2	How to repurpose with patient impact	The core training curriculum, including the TPP, repo pathway, and project management	Repurposing academy, e-learning resources	Academics, patient organisations, champions, users
3	Repurposing techniques	Specific training on scientific tools and techniques. More technical knowledge.	Webinars, e-learning content, sign posting, and user mentoring	Industry, specific branches of academia or life scientists with a specific interest in repurposing



Training and support for funders

Our core training should help more researchers propose repurposing projects with a chance to reach market – good for funder impact.

Funder training ideas...

What would you like to see?







Live poll results – 33 answers

What type of training would you like to receive to support your efforts in drug repurposing?

pharmaceutical regulation Regulatory strategy understanding of trajectories Product protection drug shortages support supply patient IP patent manufacturing evidence sources^{supply and packaging} Publication moment preclinical scientists pricing is crucial



- trial environment revenue sharing **RWE** evidence
 - Funder perspective
- Marketing and manufacturing

Training and support for funders

Our core training should help more researchers propose repurposing projects with a chance to reach market – good for funder impact.

Funder training ideas...

- Í Why fund repurposing research?
- The value and implementation of great patient engagement in drug repurposing programmes
- What are the indicators of a good repurposing project?

- repurposing?





What are the routes to market, and patient impact in drug

> What makes a good repurposing PI? Finding projects with the ingredients for success.

We'd love to organise a dedicated training workshop for the REMEDi4ALL funders network soon...



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How will we deliver training?

In person training workshops

E-learning resources

Webinars



General communication

Podcast

Poll results – 40 answers

What training formats would you be happy to engage with?

In person training workshops

E-learning resources

Webinars

Podcasts

Conference talks

Other



24% 23% 30% 11%

11%

1%

Our questions to you...



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Live poll results – 14 answers

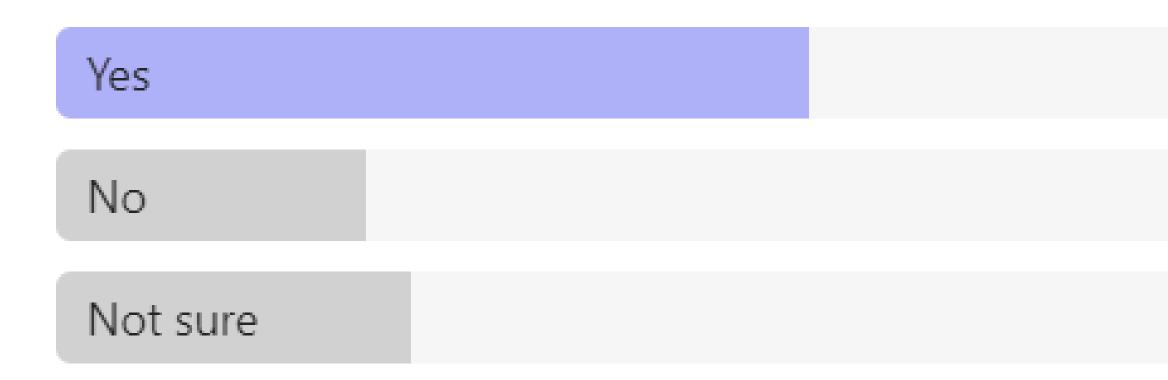
What would be the best way to target training to the funder's community?

share models Case studies Marketplace portal collaboration share challenges SHARE RD / Partnership charity network Rare Disease network **ERA4Health Partnership** portal announcements Training for payors Concrete examples SHARE SUCCESSES



Live poll results – 32 answers

Do you currently require patient engagement to be part of your funding applications?





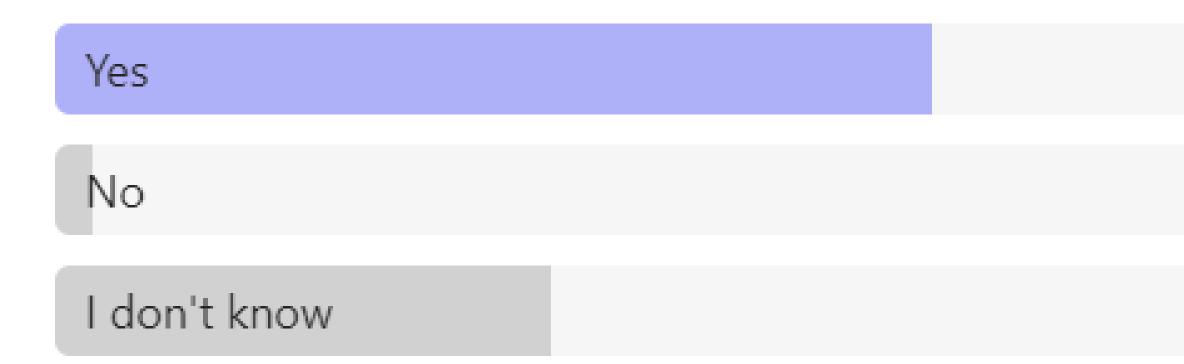




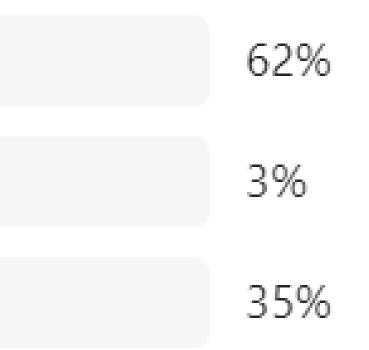
25%

Live poll results – 37 answers

Do you think the REMEDi4ALL training programme would increase the success of the projects you fund?









Introduction to the REMEDi4ALL Funding Decision Tool

Marcell Csanadi, PhD - Health economist



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Syreon Research Institute

Introducing



- Syreon aims to support **socially** driven evidence-based decisionmaking in healthcare through
 - involving key stakeholders,
 - facilitating educational activities and
 - utilizing the international networks to generate and disseminate evidence
- Syreon provides **expertise in health** economic and health policy research supporting partners throughout the lifecycle of health technologies

- Data analysis
- Epidemiology & Public Health
- Economic value
- Outcomes research
- Health policy



Main areas of research services:

Evidence synthesis

- Patient policy
- Pricing & Reimbursement

REMEDI4ALL Funding Decision Tool

Major activities in the funding work package:

- 1. Create a vibrant (DR) funding network
- 2. Funding models Develop new solutions, develop a funding radar
- 3. <u>Standardized tool for the assessment of drug repurposing candidates</u>

Who is intended to use the developed tool?

- **REMEDI4ALL consortium**: Support the project selection for onboarding + Support the future funding activities
- Members of the funders network (depending on experience and need):
 - Highlight new perspectives or criteria of the assessment
 - Provide alternative methods for assessing certain criteria
 - The REMEDI4ALL tool can provide a basis for their assessment (for funders with diverse background)



How do you currently assess the value of drug repurposing candidates?



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Live poll results – 35 answers

If your organization is dealing with funding drug repurposing projects, to what extent do you see room for improvement in how you currently assess the value of drug repurposing candidates?

> 2.2 3 2 4 22% 37% 8% 31%



Exploratory work to propose a standardized tool for the assessment

Phase 1

- 1. Review the scientific and grey literature about funding drug repurposing
- 2. Collect published materials from funders who are part of the funding network (e.g. websites, other documents)
- 3. Conduct follow-up discussions with funders who were interviewed by ZonMw

Phase 2

- Propose a concept for the tool based on 1. the collected information
- 2. <u>Organize a challange meeting with active</u> <u>fundres from the funding network</u>





Identification of value assessment criteria

Evaluation process of the assessment criteria

A final concept ready to be developed

Let's hear about the criteria that you think are the most important...



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Live poll results – 56 answers

Please list the 3 most important funding criteria when evaluating a drug repurposing project.

clinical Development scientific rationale scientific quality medical purpose Development quality clinical market patients need patent medical need R Revenues scientific rigor reimbursement value scientific costs unmet need impact scientific approach



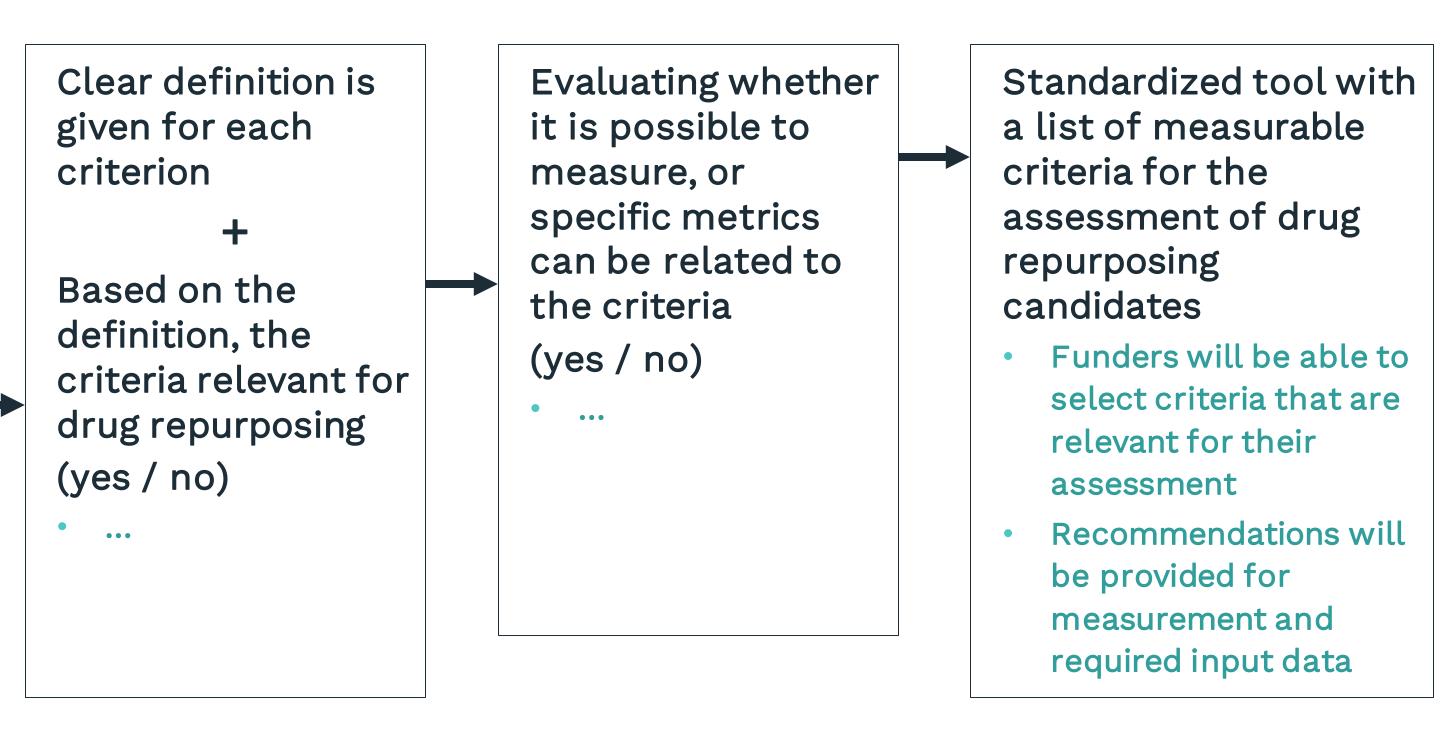
Identification of assessment criteria

We are currently conducting a transparent and documented procedure to identify relevant assessment criteria for the tool

Full list of assessment criteria from literature and funders

- Patient engagement
- Unmet medical need
- Financial return on investment
- Productivity loss / gains
- Change in behavior of society
- Innovation

...





Should we measure the expected return on investment?



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Live poll results – 38 answers

If there was a tool available for evaluation with two perspectives - financial return on investment and societal return on investment - which one would your organisation prefer to apply before making a funding decision?

Financial return on investment

Societal return on investment

Both

Neither





16%

29%

53%

3%



Q&A - break

Dunja Huijbers

Senior programme manager (Drug Rediscovery)



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Funding drug repurposing: barriers, solutions & incentives needed

Heleen van der Meer, PharmD I PhD

Senior programme manager international drug repurposing



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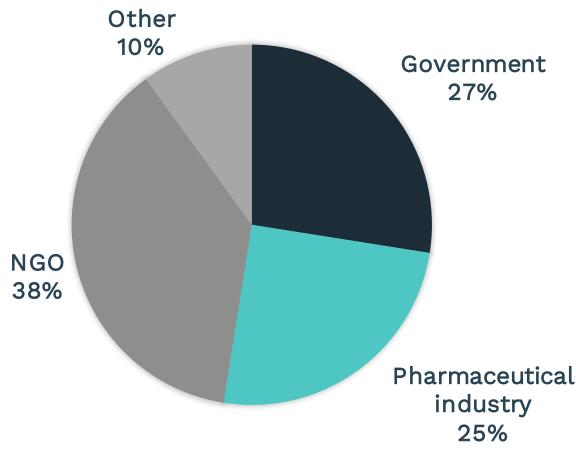


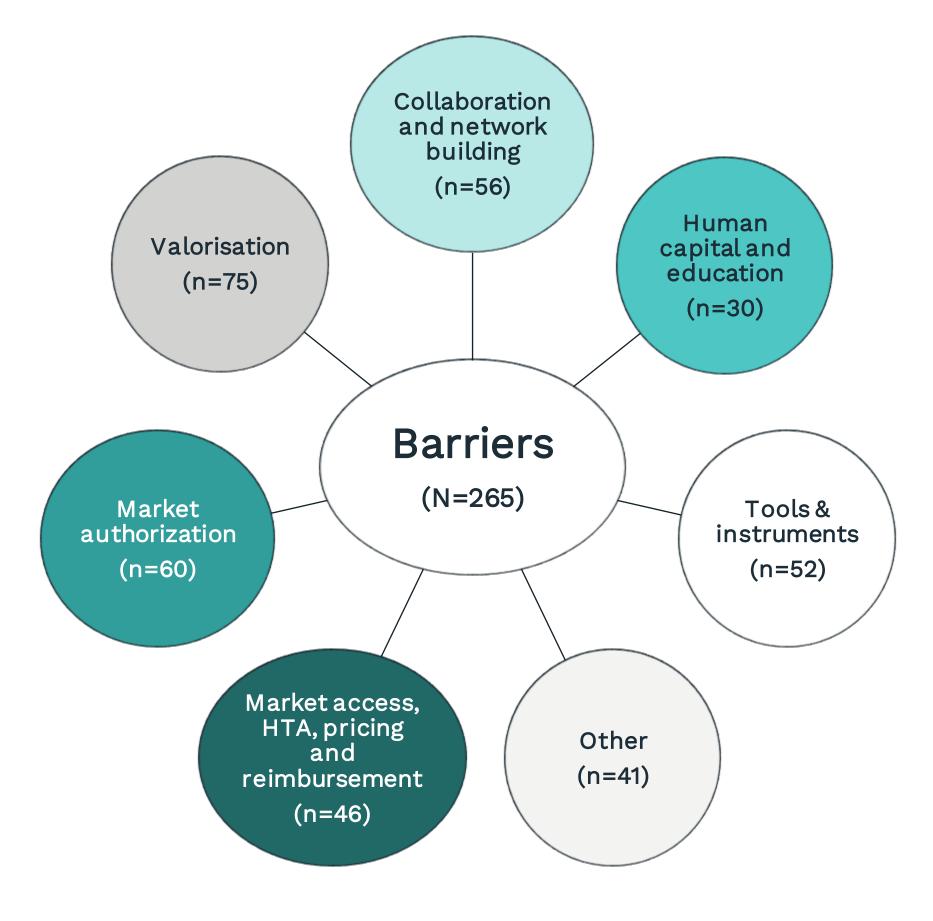
Many of you shared the barriers you face in funding drug repurposing, possible solutions and/or incentives needed from your perspective via

- online surveys (n=43)
- online interviews of 60 minutes (n=20)
- \rightarrow interviews were transcribed

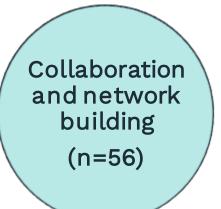
coded in Atlas.ti to identify barriers, solutions & incentives











Pharmaceutical company does not provide drug for clinical trial Long timelines for contracts and agreements

Co-funding across borders

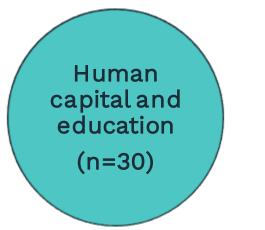
Pharmaceutical company needed for label extension State aid rules hinder funding of public-private collaborations

"...if there's no common ground, that partnership is not going to happen."



Different funder interests hinder collaboration

Pharmaceutical company does not provide (safety) data



Researcher does not know how to perform a DR trial Capacity limits

Lack of knowledge on how to get scientific advice Lack of knowledge on translating preclinical research into clinical research

"...we notice researchers and research institutes have insufficient knowledge about how to get repurposed drugs to the patient."



Lack of knowledge on registration process

Funder lacks experience with DR trials



Academic trials versus regulatory process

Regulatory process does not fit DR products

Off-label use

High costs & long timelines scientific advice

Challenge to get the regulator on board

"How do we get to a situation where we can run affordable clinical trials so that it is not costing 20 million to test a drug that's already approved?"



Different regulatory processes in different countries

Need for label extension

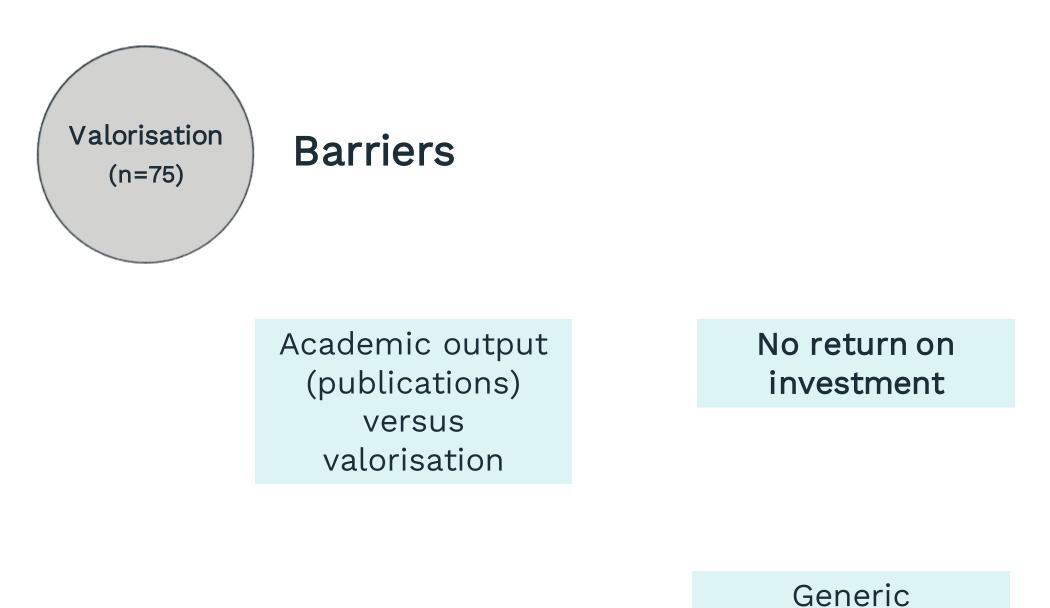


Market withdrawal Add-on is not Reim	nbursem
due to low drug allowed diffe	erent cou
Small market size High drug prices No p	oatient a
5	eimburs off-labe

"Pricing is always key, societies are asking for innovation but do not want to pay extra for additional value."







Off-label use

substitution

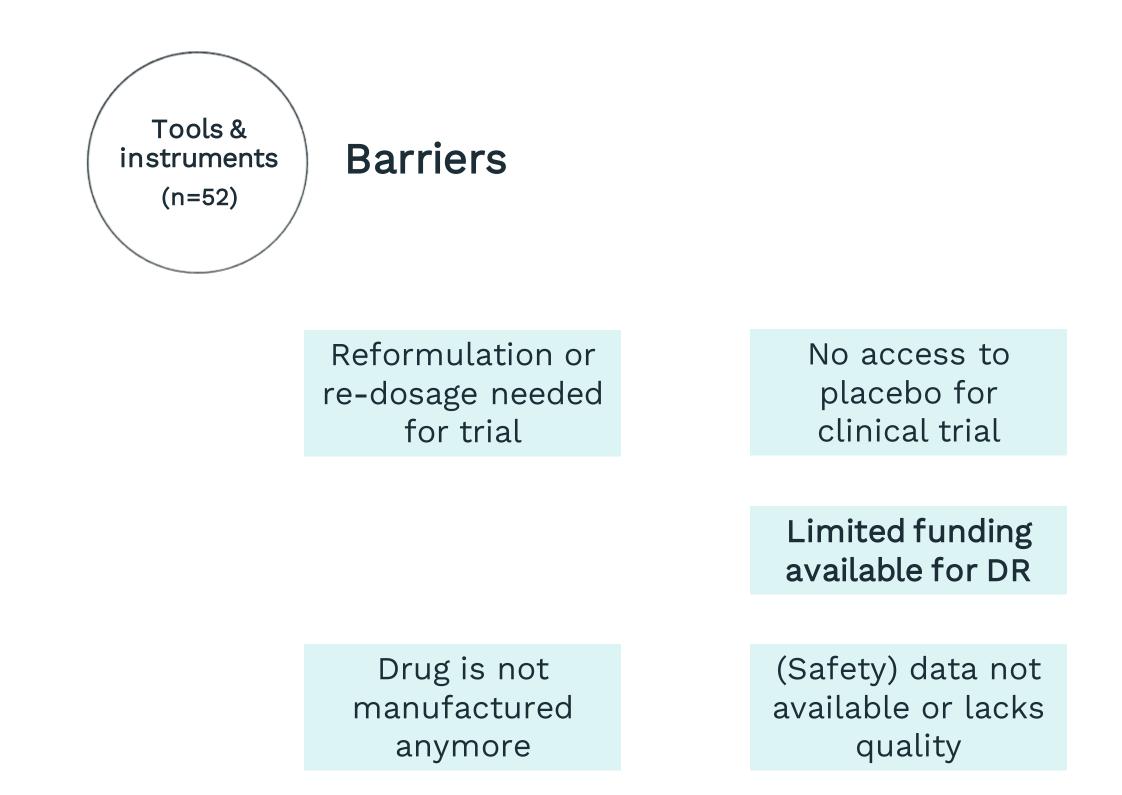
"....without a proper business case, you'll never find a fool to invest in repurposing for cheap medicines again."



Lack of scalability

Lack of data protection

One party takes all the risk

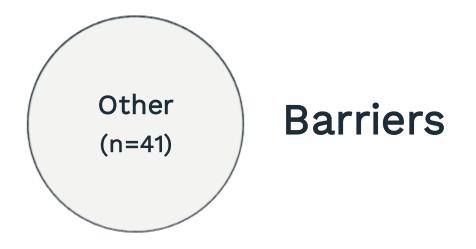


"...there is no lack of ideas by the researchers, but there is a shortage of funding."



Difficult patient recruitment

Drug not accessible for clinical trial



Ethical issues

DR research is not always called DR

DR is not seen as an important theme No funding stream dedicated to DR

Lack of highquality proposals

> Lack of DR funding applications

"...a barrier is the fact that we don't have a channel specifically for drug repurposing, which makes it also a little bit hidden..."



Lack of industry interest

Field of DR is in starting phase, the process takes time

Political decisions

"... a specific / clear / easier regulatory pathway for repurposed medicines ..."

"... the safety profile of these products [...] is known especially if you take lower doses [...] you would only need confirmation of efficacy. [..] in my opinion, you could do some kind of conditional approval based on the phase 2 study ..."

conditional approval after phase 2

aim for robust data packages coming out of phase 2

acceptance of mixed data package, only new and confirmatory efficacy data

approval in one country leads to conditional approval in other countries

additional support from authorities

more accessible scientific advice - jointly with HTA

funder is offering all applicants scientific advice by regulatory consultant / pays for scientific advice

maintaining market authorization should be less burdensome (pharmacovigilance)

if there is adequate evidence, the indicatio should be added to th label. If generic medicine, then all manufacturers should include the new indication in their labe

if company does not want to collaborate th regulator should look into data that has already been submitte and advise on new research with this medicine

Human capital and education -organisational





on ie	allow label extension without the involvement of the MAH
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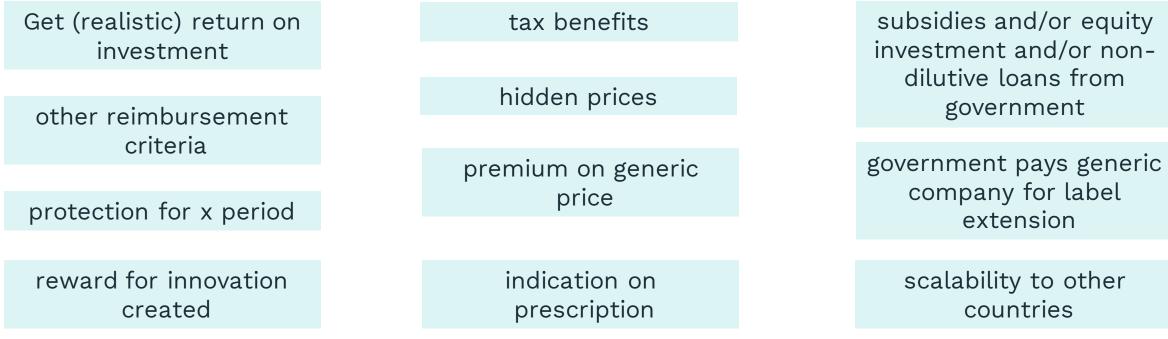
Market access. HTA, pricing and reimbursement

"... as a company you still like to make a bit of money on it because otherwise no one's going to invest in you ..."

"... accelerated reimbursement pathway and more clarity for repurposed medicines – cut away time that is not attributing to effectiveness/safety but adds costs ..."

"... pricing level for repurposed drugs should be set high enough to recuperate the investments needed to develop a second/third indication with the same API ..."

"pricing level should be differentiated between first indication and repurposed indication, e.g. for a certain time period or for a certain supplier that developed the repurposed indication"







harmonization of EU procedures regarding market access of valueadded medicines

price & reimbursement guidelines across EU countries must guarantee a better ROI

"... developing partnering models that bring pharma companies and their assets together with academics and their ideas for indications ..."

"... make data publicly available of products that do not reach the market, so data can be used for other indications ..."

"... accessing live assets for rare disease development in parallel with the primary indication, to multipurpose the asset while under development instead of waiting until it is on the market ..."

pharma support and commitment if trial is successful

get pharma company support for repurposing trials which are outside their development plans

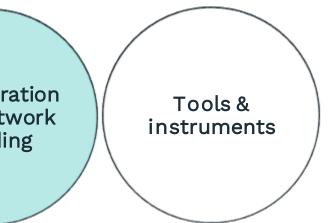
early engagement with pharmaceutical company to ensure supply of drug

> involve pharma representatives in project monitoring

set up contractual frame (one that is recognized by pharma) to facilitate negotiation with pharma group together - funding whole lifecycle awareness for whole lifecycle

find like-minded cofunders

creation of transnational framework for DR research funding





be used for other indications ..." cation, to multipurpose the asset

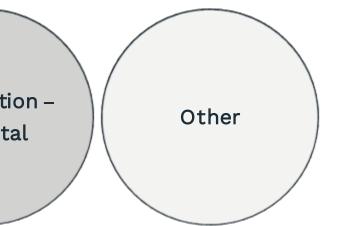
sharing publicly funded data package with generic company for label extension – stable price in return

Valorisation – Societal

"... always think of implementation, once the study has completed it has to be able to be directly implemented ..." "... somebody has to take a risk in the government field and if you're not doing that, then it's really ready to fail ..."

willingness to do something - not looking to someone else to move	DR on political agenda	an academic pharma company to produce generics for publicly funded trials	repu
	improve image of DR by showing statistics		acade grou
		erect a government supported institute to develop repurposed drugs	

having a platform for drug repurposing where all stakeholders are involved





ourposing toolkit to help lemic/charity/patient oup-led repurposing projects



REMEDi4ALL and the funders network are here to support you overcome funding barriers

Be part of

a strong and impactful international network comprising diverse funders who are committed to driving Drug Repurposing forward

a marketplace

- Find like-minded funders (e.g. funding radar, co-funding)
- Find projects to fund/invest in (e.g. within network, repurposing concierge)
- Share best funding practice (e.g. during workshops, innovative funding models)
- Learn from other funders (e.g. training, funding decision tool)

a think tank

- Engage in policy discussion (e.g. work package 8 on market access, policy board)
- Work on finding solutions for funding barriers





Panel discussion

Pan Pantziarka, PhD

Programme Director Drug Repurposing



This project has received funding from the European Union's Horizon Europe research and innovation programme under grant agreement No 101057442. Views and opinions expressed in this presentation are those of the author(s) only. They do not necessarily reflect those of the European Union who cannot be held responsible for the information it contains.



Panellists

Joanna Davidge **Teun Grooters** Sarah Puddicombe

LifeArc Arega Medical Coordinating Centre (NIHR CC)

From your perspective:

where should we as REMEDi4ALL/funders network focus in terms of solutions to the barriers that were just mentioned?



National Institute for Health and Care Research



Next steps for the funders network

Heleen van der Meer, PharmD I PhD

Senior programme manager international drug repurposing



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Next steps for the funders network

- Network is currently being created charter will follow
- Receive updates via our newsletter subscribe via https://remedi4all.org/funders/
- You may be invited for further discussion in think tanks about specific topics •
- Repurposing concierge is open for you

- Future meetings
 - MSM pancreatic cancer 14 Nov 2023
 - Workshop investment decision tool TBA
 - Annual REMEDi4ALL conference on 6-7th March 2024 in Barcelona
 - ...

What would you like for future meetings?



Live poll results – 34 answers

What would be your preferred format of future funders network meetings? E.g. workshop, speed date etc.





online meeting

open conference

Teams meetings

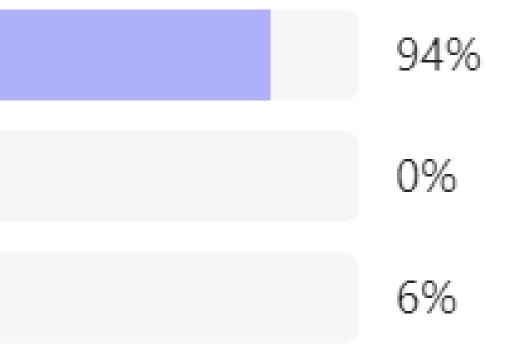
networking platforms

Live poll results – 33 answers

Does an online meeting work for you?

Yes			
No			
Maybe			





Live poll results – 33 answers

What do you take home from this workshop?





transnational collaboration

challenges and solutions

policy challenges point common mission Aligned thinking needs and intentions

Live poll results – 24 answers

From your perspective, what should be the focus in future workshops?

business models time meetings Patient Engagement indication on label frameworks for collaboration barriers - regulatory term sustainability Case studies market assessment repurposing Downstream barriers MAH commercial interests case analysis policy and reimbursement patent discussion the feasibility favor of drug overcoming barriers



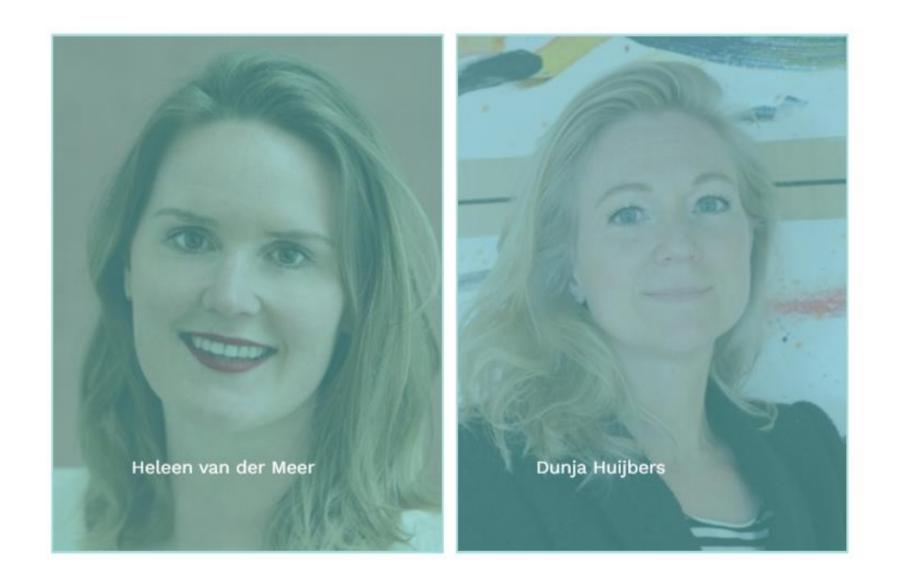
Join the Drug Repurposing Funders Network

REMEDI4ALL IS ESTABLISHING A FUNDERS NETWORK.

REMEDi4ALL is establishing a funders network, led by ZonMw and in collaboration with the Anticancer Fund, dedicated to advancing Drug **Repurposing initiatives.**

Are you a research funder involved or interested in drug repurposing?

We invite you to share your experience and ideas within the International Drug Repurposing Funders Network. Our aim is to create a dynamic international network comprising diverse funders who are committed to driving Drug Repurposing forward. In this inclusive forum for discussion, we encourage you to share your funding perspective and actively engage in conversations surrounding policy matters and potential solutions to enhance the field. We hold annual meetings where we exchange best funding practices.



Contact us: <u>REMEDi4ALL@zonmw.nl</u>





