

Project management in antimicrobial drug R&D

Guest speakers: Kristina Orrling & Julie Miralves

Moderator: Sina Gerbach

Host: Astrid Pentz-Murr (GARDP)

7 June 2023



REVIVE

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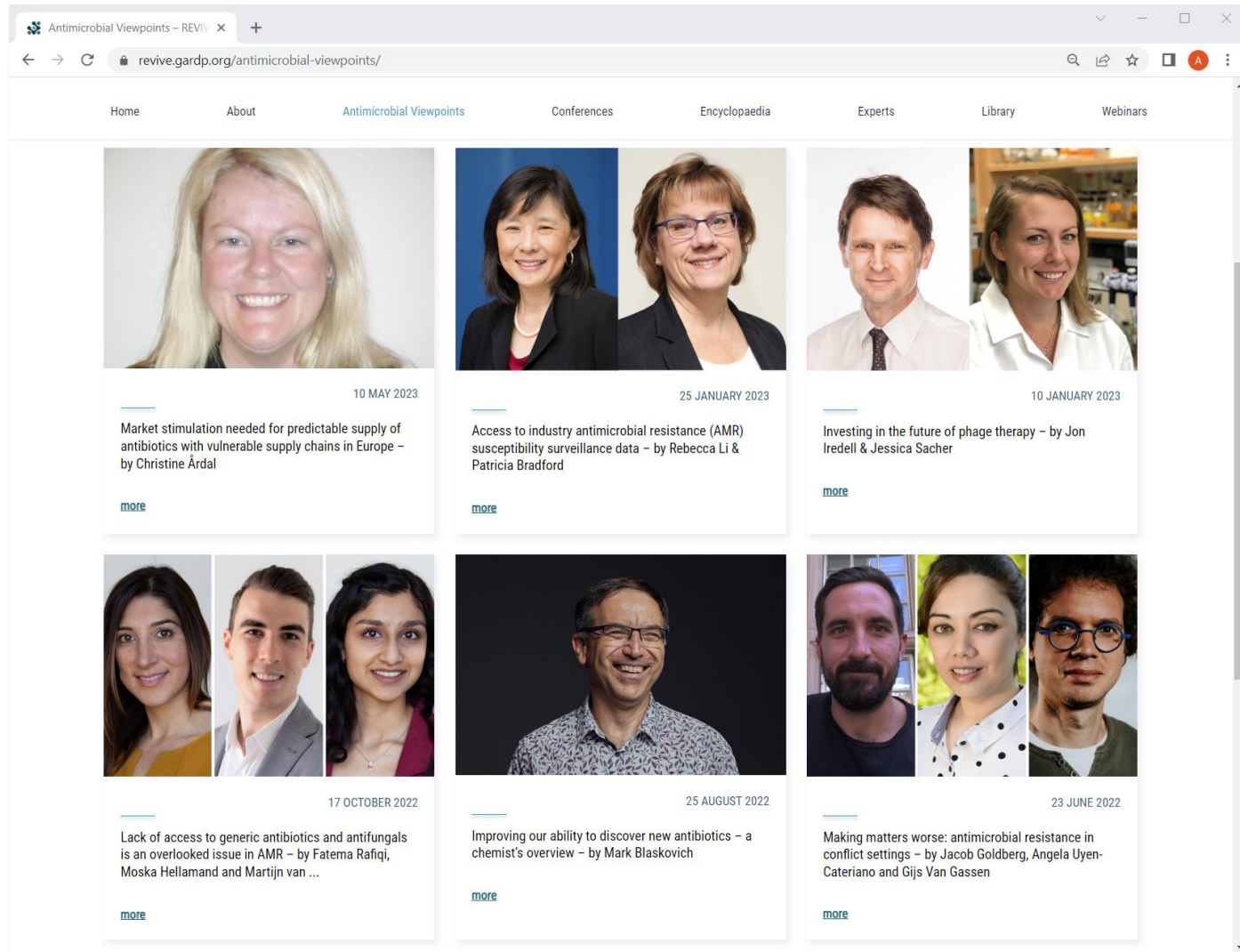
Webinar recordings

The screenshot displays a web browser window with the URL revive.gardp.org/revive-webinars/. The page features four webinar recording cards arranged in a 2x2 grid. Each card includes the REVIVE and GARDP logos, a 'LIVE WEBINAR' header, a date and time, a title, a 'Recording available' badge, and a 'more' link. The top-right corner of the browser window shows a blue watercolor-style graphic.

Webinar Title	Date & Time	Speakers	Moderator
Susceptibility testing in antibacterial drug R&D	2 March 2023, 17:00-18:30 CET (10:00-11:30 am CST)	Dee Shortridge, JDR Laboratories, USA; Rafael Canton, Hospital Ramón y Cajal, Spain	Christien Giske, Karolinska Institutet, Sweden
Delivery systems in antibacterial drug discovery	24 January 2023, 17:00-18:30 CET (10:00-11:30 am GMT, 11:00 am - 12:30 pm EST)	Sylvain Moineau, Laval University, Canada; Claus-Michael Lehr, Heinrich Heine, Germany; Joanna Mella, University of Cambridge, United Kingdom	
Influence of biological sex in infectious disease	13 December 2022, 15:30-17:00 CET (8:30 am - 10:00 am CST, 9:30 am - 11:00 am EST)	Molly Ingersoll, JDR Laboratories, France; Sabra Klein, Johns Hopkins Bloomberg School of Public Health, USA	Neeleffer Mookherjee, University of Manitoba, Canada
Regulatory aspects of balancing benefits and risks in the clinical development of antibiotics	8 November 2022, 17:00-18:30 CET (11:00 am - 12:30 pm EST)	Enrica Altari, formerly EMA; John Alexander, FDA, USA	Radu Botgros, EMA, The Netherlands

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Antimicrobial Viewpoints



Antimicrobial Viewpoints – REVIV x +

revive.gardp.org/antimicrobial-viewpoints/

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10 MAY 2023
Market stimulation needed for predictable supply of antibiotics with vulnerable supply chains in Europe – by Christine Årdal
[more](#)

25 JANUARY 2023
Access to industry antimicrobial resistance (AMR) susceptibility surveillance data – by Rebecca Li & Patricia Bradford
[more](#)

10 JANUARY 2023
Investing in the future of phage therapy – by Jon Iredell & Jessica Sacher
[more](#)

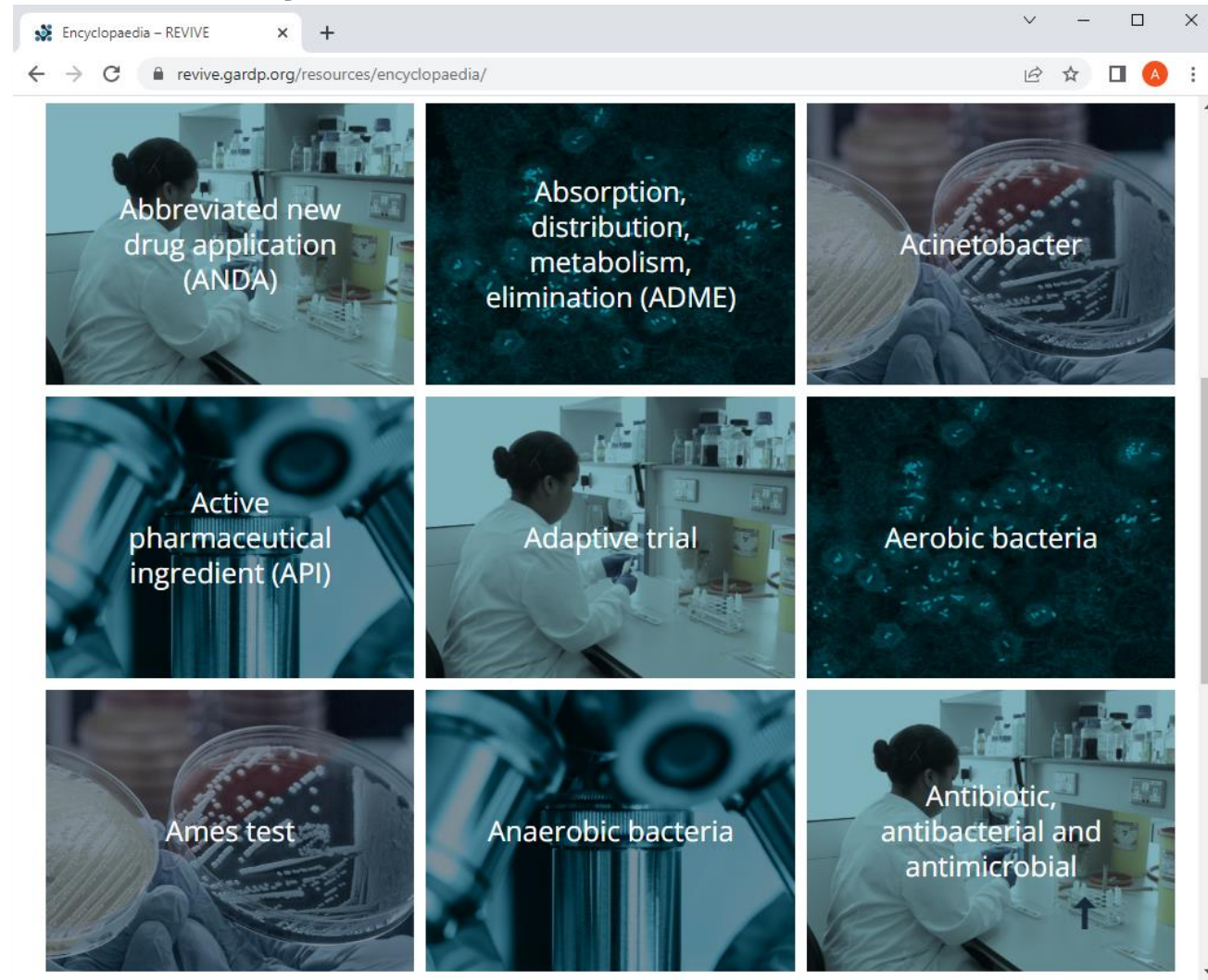
17 OCTOBER 2022
Lack of access to generic antibiotics and antifungals is an overlooked issue in AMR – by Fatema Rafiqi, Moska Hellamand and Martijn van ...
[more](#)

25 AUGUST 2022
Improving our ability to discover new antibiotics – a chemist's overview – by Mark Blaskovich
[more](#)

23 JUNE 2022
Making matters worse: antimicrobial resistance in conflict settings – by Jacob Goldberg, Angela Uyen-Cateriano and Gijs Van Gassen
[more](#)

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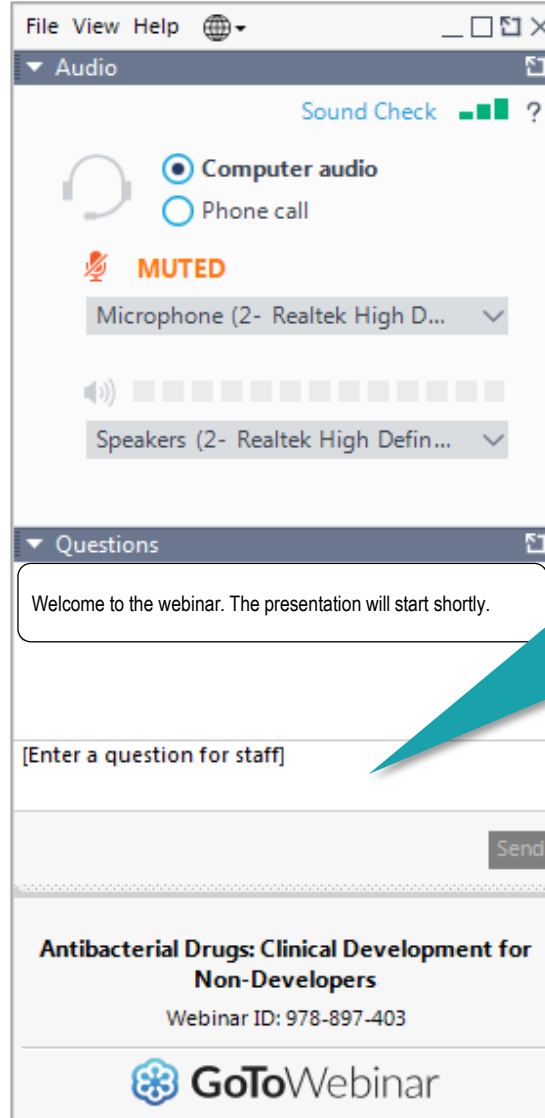
Antimicrobial Encyclopaedia



revive.gardp.org/resources/encyclopaedia

How to submit your questions

If your question is addressed to a specific speaker, please include their name when submitting the question.



The screenshot shows a GoToWebinar interface with two main sections: 'Audio' and 'Questions'. The 'Audio' section includes a 'Sound Check' indicator, radio buttons for 'Computer audio' (selected) and 'Phone call', a 'MUTED' status with a microphone icon, and dropdown menus for 'Microphone (2- Realtek High D...)' and 'Speakers (2- Realtek High Defin...)' with a volume slider. The 'Questions' section contains a text box with the message 'Welcome to the webinar. The presentation will start shortly.', a text input field with the placeholder '[Enter a question for staff]', and a 'Send' button. At the bottom, the webinar title 'Antibacterial Drugs: Clinical Development for Non-Developers' and ID 'Webinar ID: 978-897-403' are displayed, along with the GoToWebinar logo.

The presentation will be followed by an interactive Q&A session.

Please submit your questions via the 'questions' window. We will review all questions and respond to as many as possible after the presentation.

This webinar was developed in collaboration with INCATE.



<https://www.incate.net/>



Today's speakers

Project management in antimicrobial drug R&D



Kristina Orrling
Program Manager
Lygature (Netherlands)

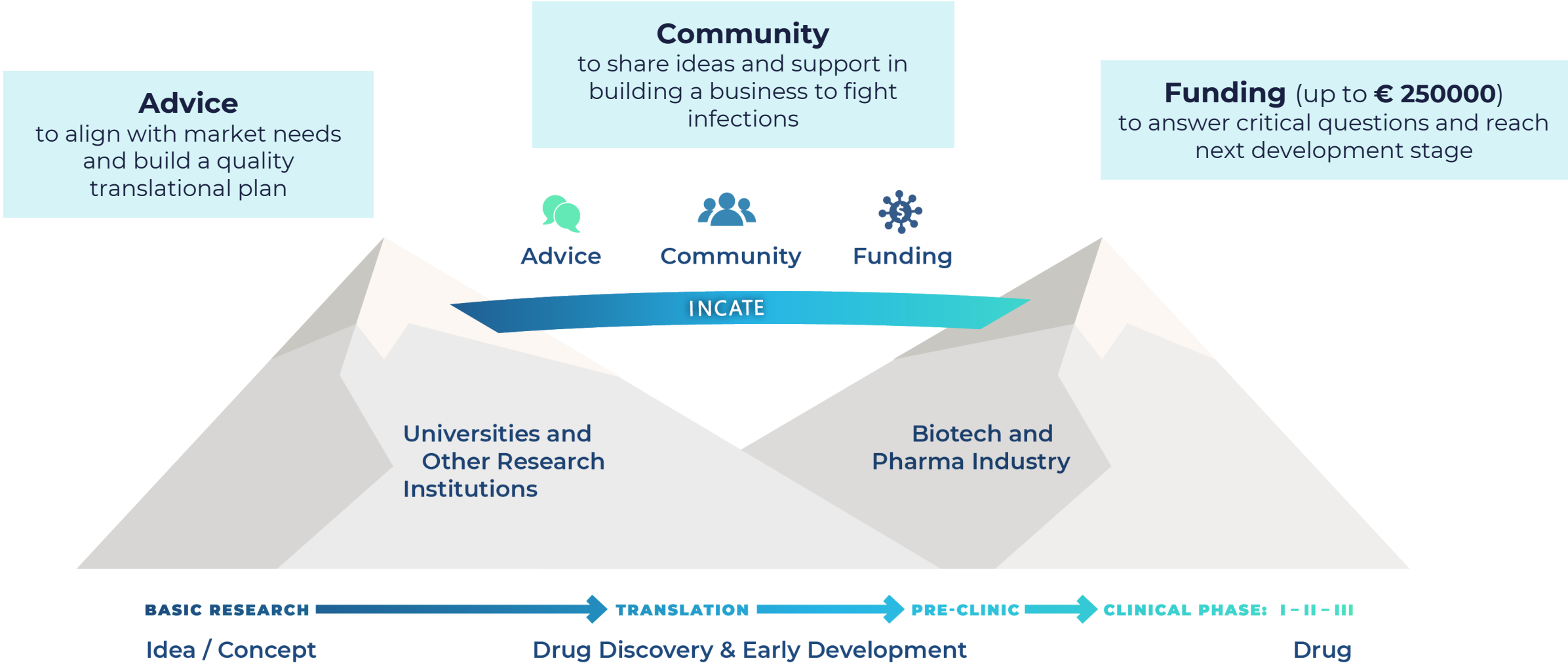


Julie Miralves
Head of R&D Portfolio & Operations Strategy
GARDP (Switzerland)



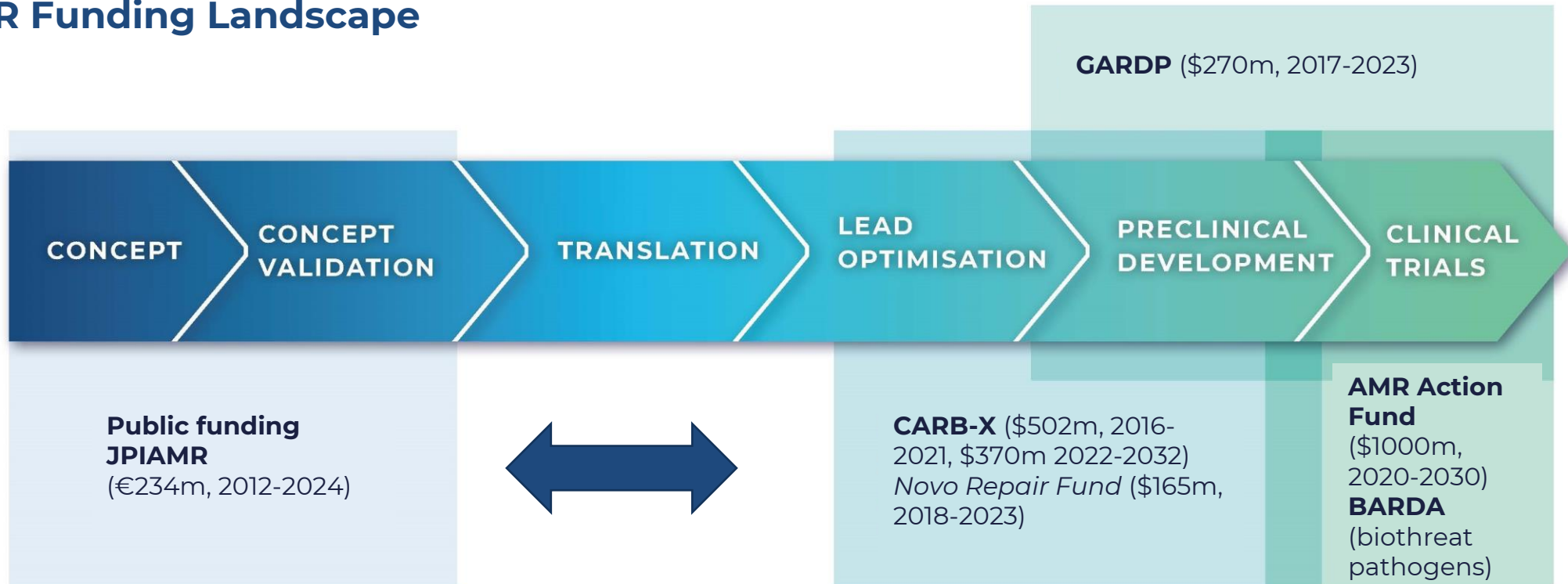
Moderator:
Sina Gerbach
Deputy Head and Development Lead of the Transfer Group Anti-infectives
Leibniz-HKI, Leibniz Institute of Natural Product Research and Infection Biology (Germany)
and
Program Manager
INCATE, Incubator for Antibacterial Therapies in Europe

INCATE will help innovators to bridge the gap from research to becoming investable companies



In the funding landscape there is a clear gap where INCATE is needed

AMR Funding Landscape



Insufficient funding to build team and evidence



Not willing to invest until project has a team and is de-risked

Contact us:



To bring your
project or company
to the next level

OR

If you would like to
join us to help
support innovators



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@INCATEurope



info@incate.net



www.incate.net



Kristina Orrling



Kristina Orrling has extensive international experience in all aspects of drug discovery, development and medical technology from over 20 years of collaborative research, with a particular interest in medicinal chemistry and infectious diseases. At Lygature, she leads the Global Health project portfolio and since joining has been leading roles in a wide range of complex, public-private partnerships, for example being the coordinator of the 31M€ IHI GNA NOW project. She holds a PhD in medicinal chemistry and a MSc Chemical Engineering with drug research specialization from Uppsala University, Sweden. She also has a Magistère de Physico-chimie from École Normale Supérieure de Lyon, France. Her professional experience includes Personal Chemistry, aka Biotage (Sweden), Mercachem (the Netherlands) and Vrije Universiteit Amsterdam (the Netherlands). She joined Top Institute Pharma, the predecessor of Lygature, in 2014.



The Science of Partnership Management

lygature pioneering medicine.
together.

Optimising outcomes in collaborative research

GARDP REVIVE June 2023

Kristina Orrling, PhD

Global Health Portfolio Lead



A collaborative project is based on two pillars

THIS DEFINES THE INPUT



Scientific plan



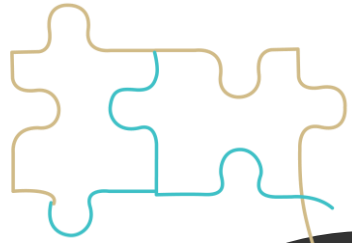
THIS DEFINES THE OUTCOME



Non-scientific part

- Governance
- Legal & IP
- Finance
- Dissemination/publication
- Stakeholder engagement
- Data management

Convergence between science and organisational skills



#Projects

>100 projects varying in size from 1 million to 200 million euros



Project duration

From 2 years to long lasting partnerships for more than 10 years



Geographical scope

Rooted in the Netherlands, connected in Europe, working with partners worldwide, realizing global impact



Project management



Scientific excellence



Organisation

Founded in 2006, Based in Utrecht, NL, 55 seasoned professionals, Not for profit, 5 million euros turnover



Project budget

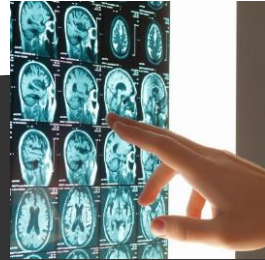
Management of in total more than 1 billion euros public-private budget



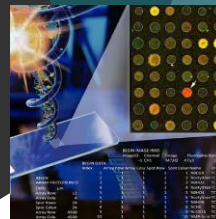
#Partners

>200 in academia, large, medium & small enterprises, governmental institutions and societal organisations

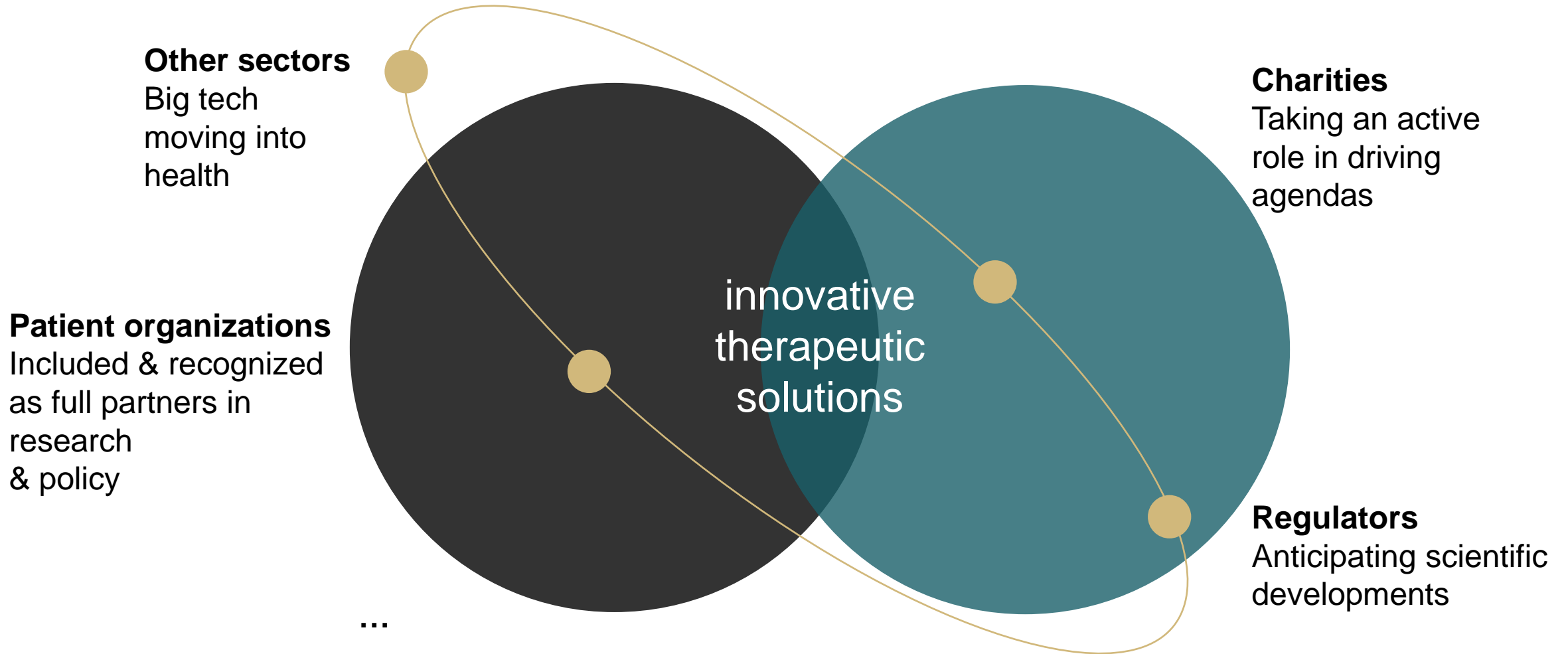
Resulting in innovative solutions for patients



innovative
therapeutic
solutions



Collaboration with all stakeholders intensifies



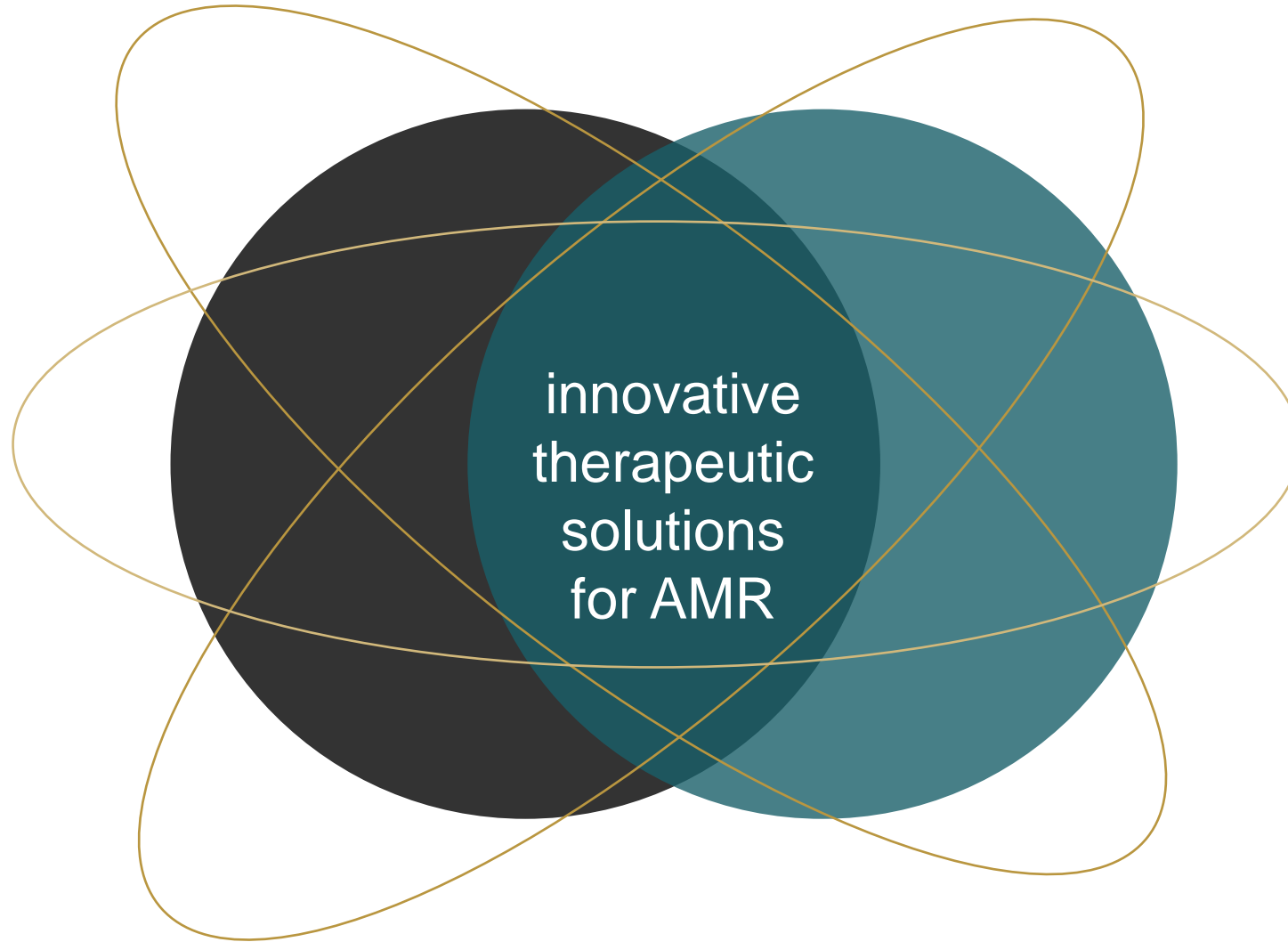
New developments and external factors impact innovation



Continued pioneering is needed on a systemic level

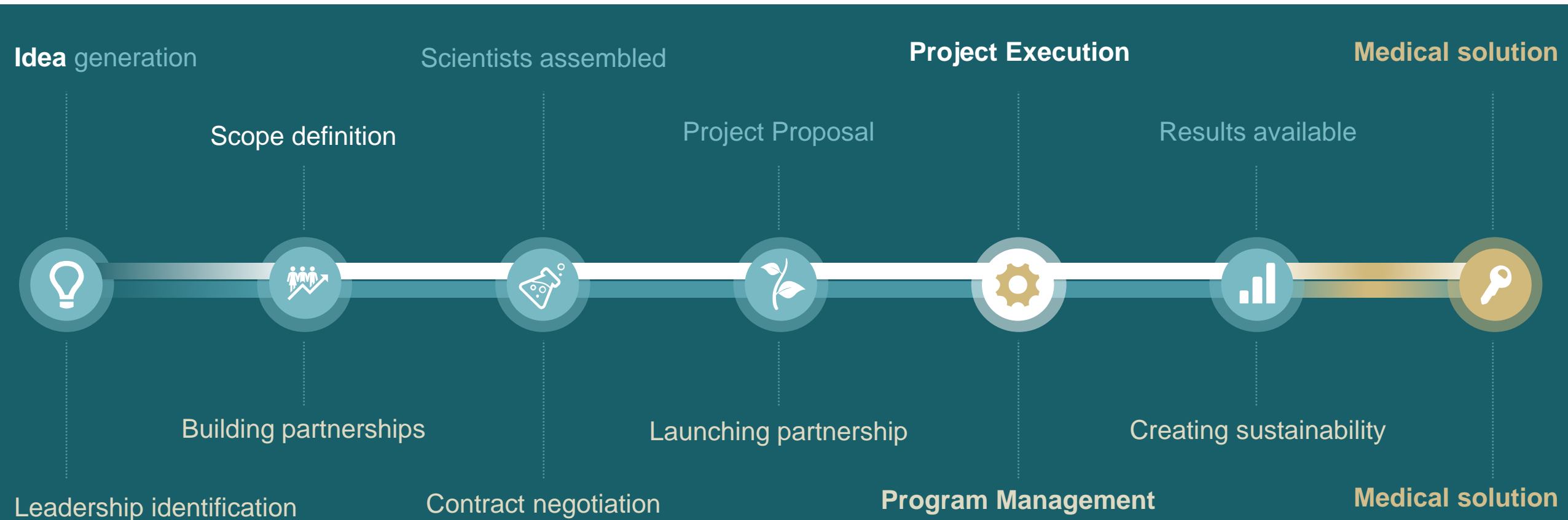


Today we discuss how to handle complex projects



From idea to success

SCIENTIFIC PROPOSAL AND NON-SCIENTIFIC PROPOSAL



BY DOING SO, LYGATURE DRIVES PARTNERSHIPS

Why collaborate?

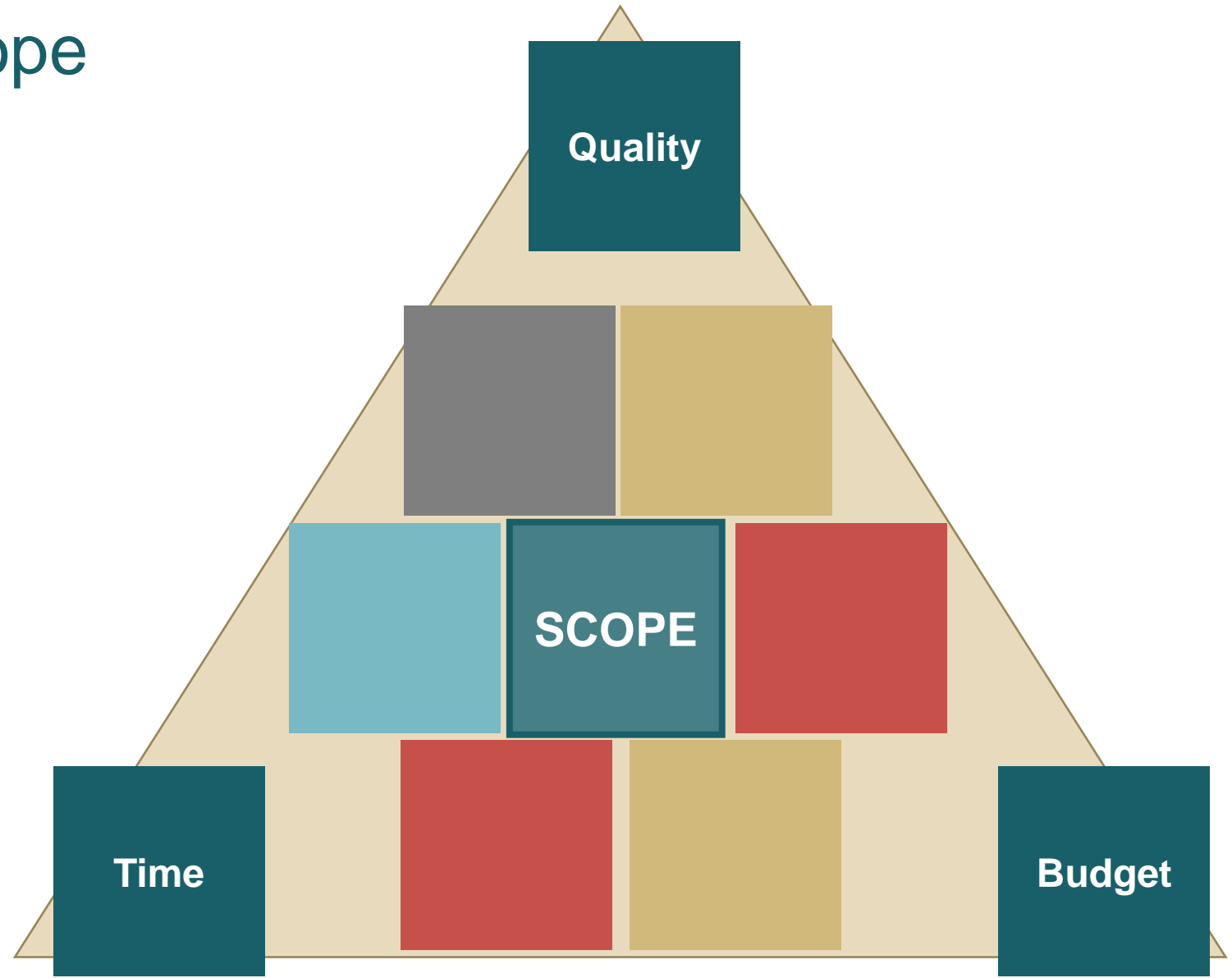
Today's medical and societal challenges are too big for one organisation to solve!

Be transparent about reasons for partnering

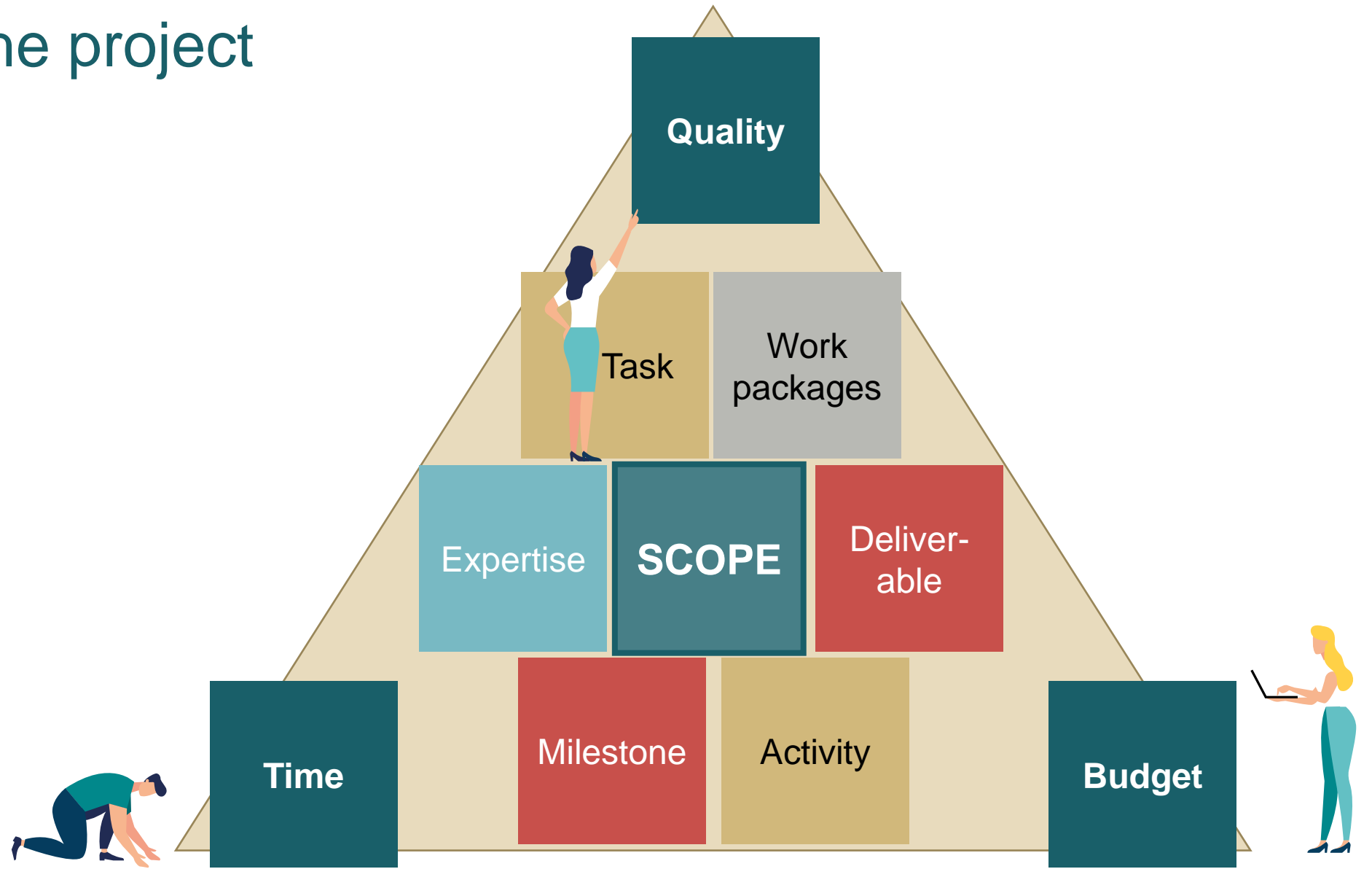
- Access to additional expertise
- Increase efficiency and reduce costs
- Accommodate multi-stakeholder interactions
- Access to “alternative” funding sources
- Sharing: data, compounds, technologies, risks...



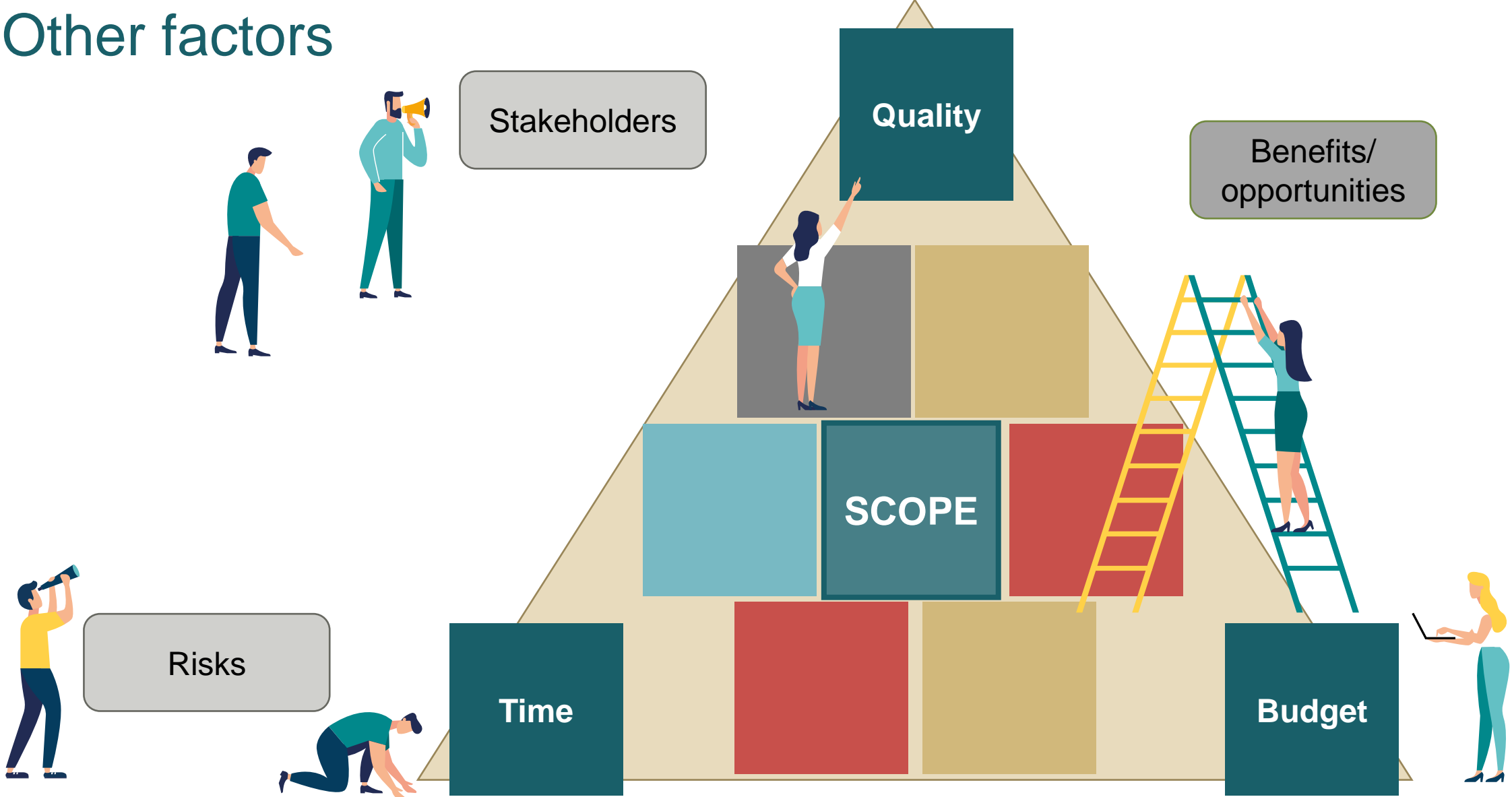
Defining the scope



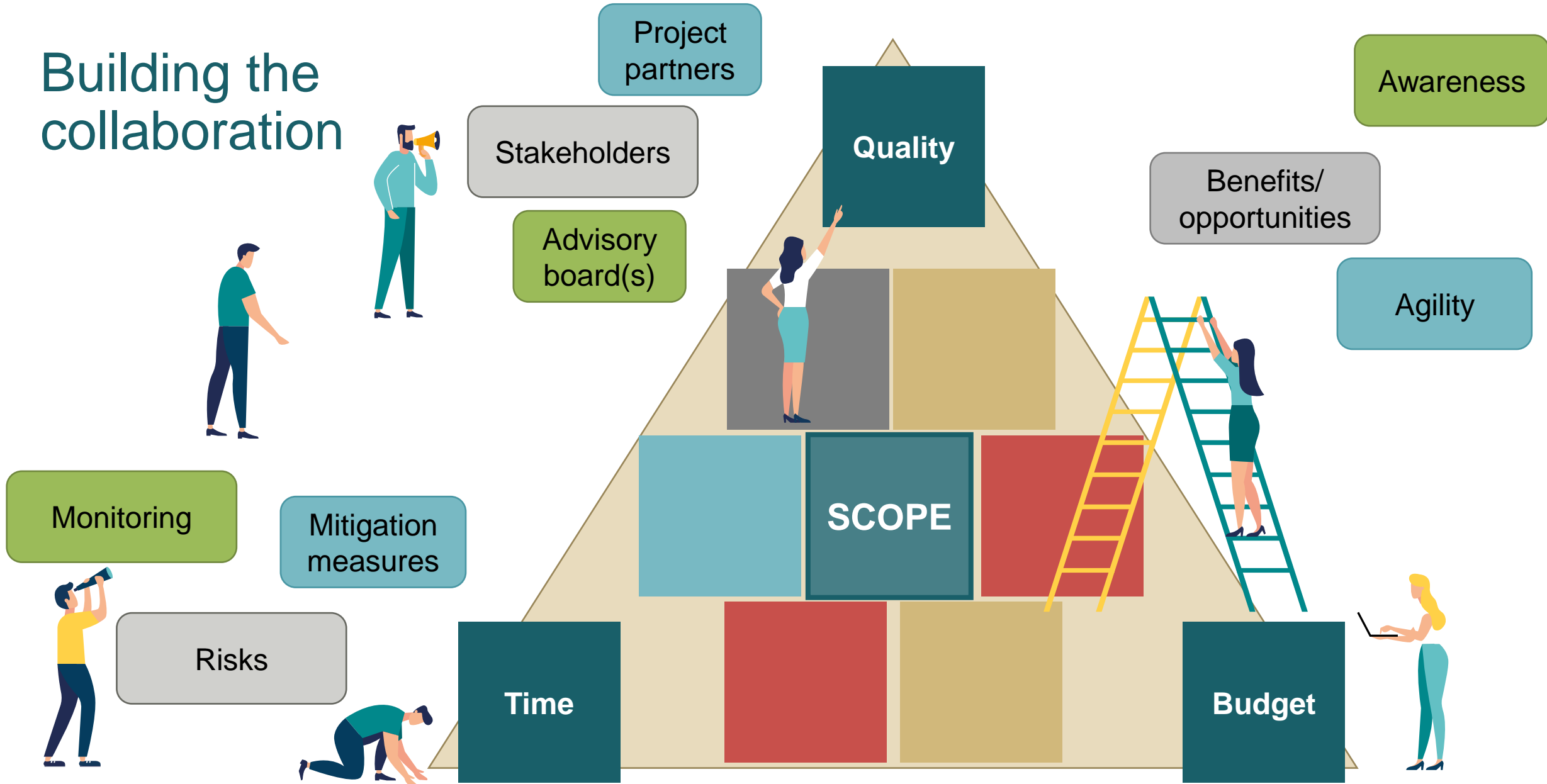
Building the project



Other factors



Building the collaboration



Building a successful partnership

Be clear about the objective

- Clear **project plan**, with clear **timelines** and **tasks** per partner
- Realistic **budget** per partner
- Be aware of and acknowledge **imbalances**
- Define a challenging yet realistic **concrete end-result** on forehand

This way, a win-win for all partners can be created



Collaboration & partnerships

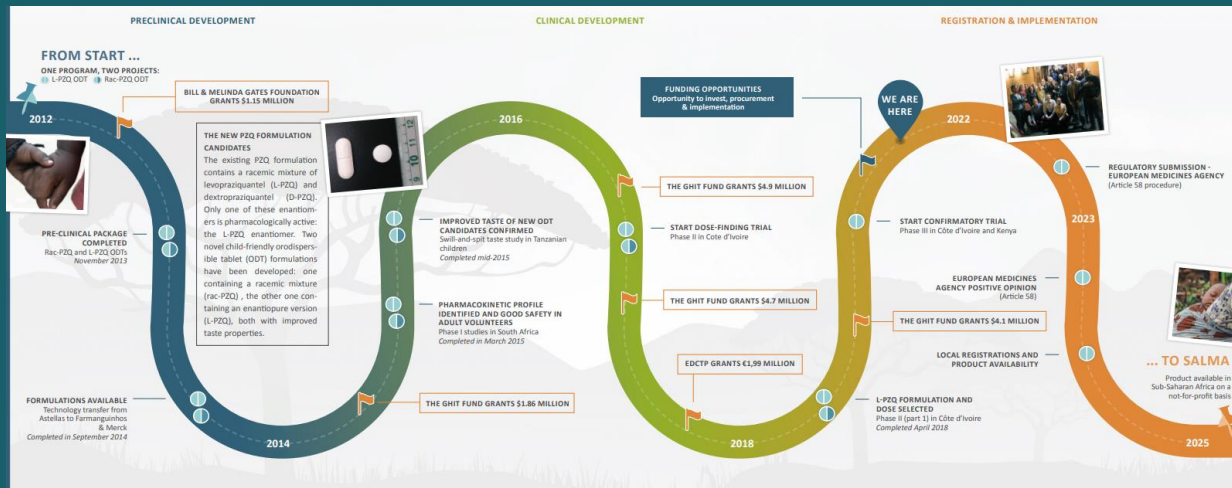
There is *no* typical Partnership:

- 🍃 1:1, multiparty, or multi-stakeholder
- 🍃 Country specific, EU, LMICs, global
- 🍃 Public funding vs private funding
- 🍃 “Support from” or “collaboration with” private party(s) funding
- 🍃 Focus: drug research, biomarker, clinical, registry, medical technology, regulatory, setting up infrastructure,
- 🍃 NGO – industry; industry – academia; industry – industry; public – private partnership



Changing dynamics from R&D to commercialization/roll-out

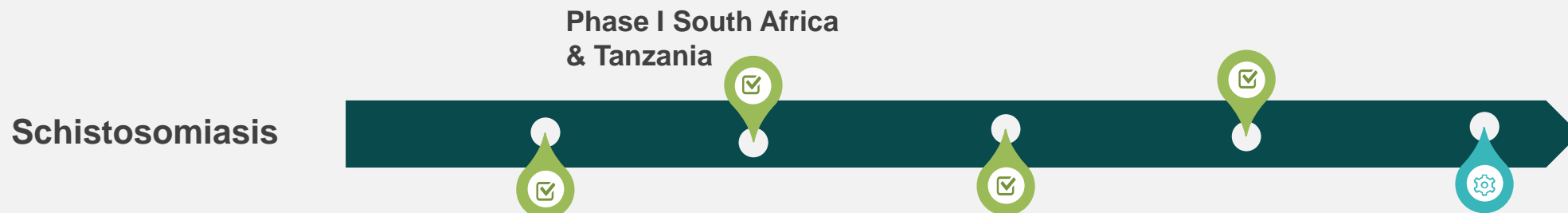
The impact on the collaboration as the stakes get higher



- Increasing investments are needed
- New functions and capabilities are required
- More people and stakeholders are involved
- Strategic importance increases

Example: The Pediatric Praziquantel consortium

(2012-present)



Phase I South Africa & Tanzania

Smaller, better tasting, easily dispersing tablet for pre-school aged children



Phase II dose-finding in Côte d'Ivoire

Phase III trials in Kenya & Côte d'Ivoire

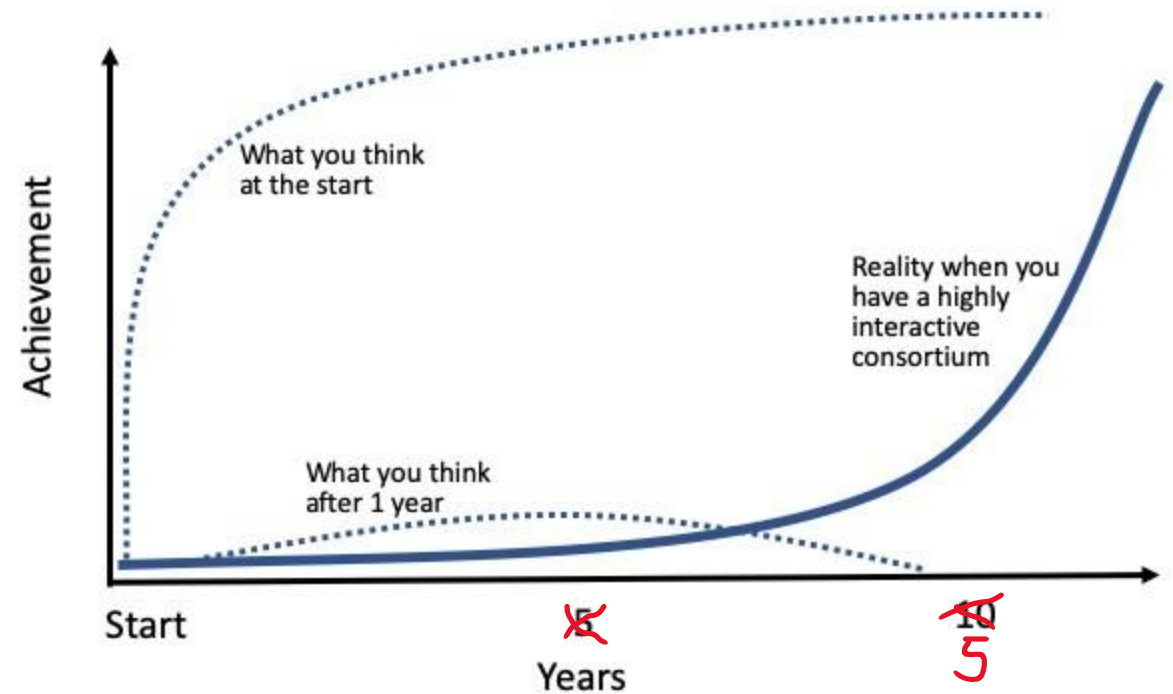


Project challenges: Manage expectations



"Most people overestimate what they can do in **one year** and underestimate what they can do in ~~ten~~ ⁵ years."

Bill Gates



c.f. Scott Wagers

<https://www.linkedin.com/pulse/what-think-when-you-concerned-consortium-project-moving-scott-wagers/>

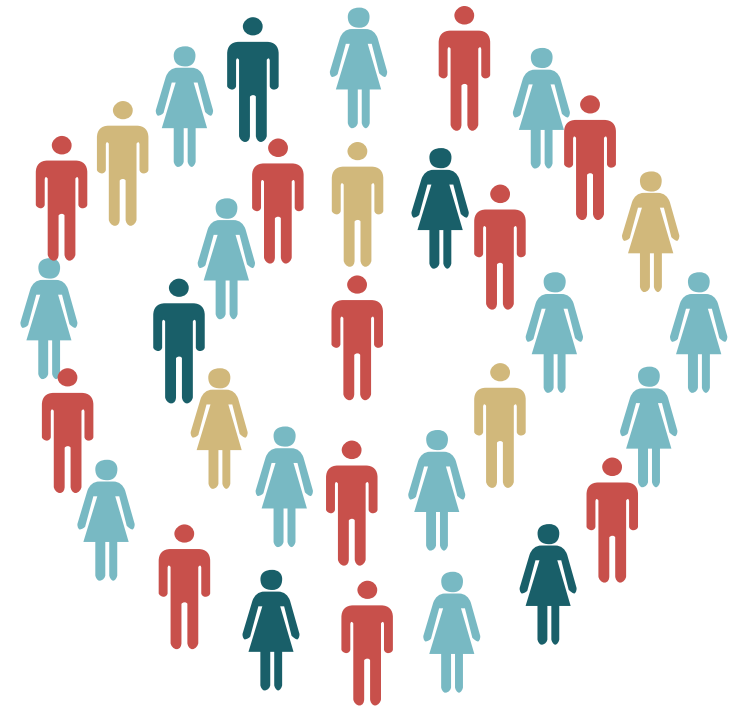
Partnership Challenges: Building trust

Structure => transparency and predictability

- Governance structure
- Decision making process
- Legal framework
- Infrastructure
(incl. secure and safe sharing of documents and knowledge)
- Meeting routines

Communication => creates awareness and horizon

- Internally within the partnership
- To upper management of the collaboration partners
- Externally to all stakeholders (identify the stakeholders!)
- Recognise early progress and successes
(also the smallest are significant in the beginning)
- Knowledge exchange

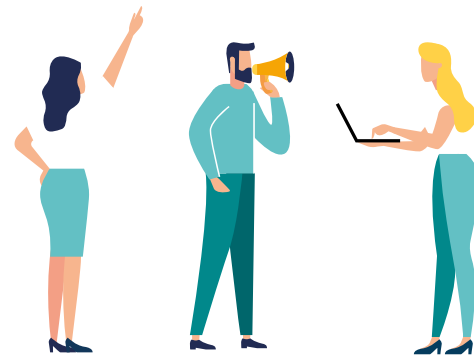


Partnership challenges: Discussions & disagreements

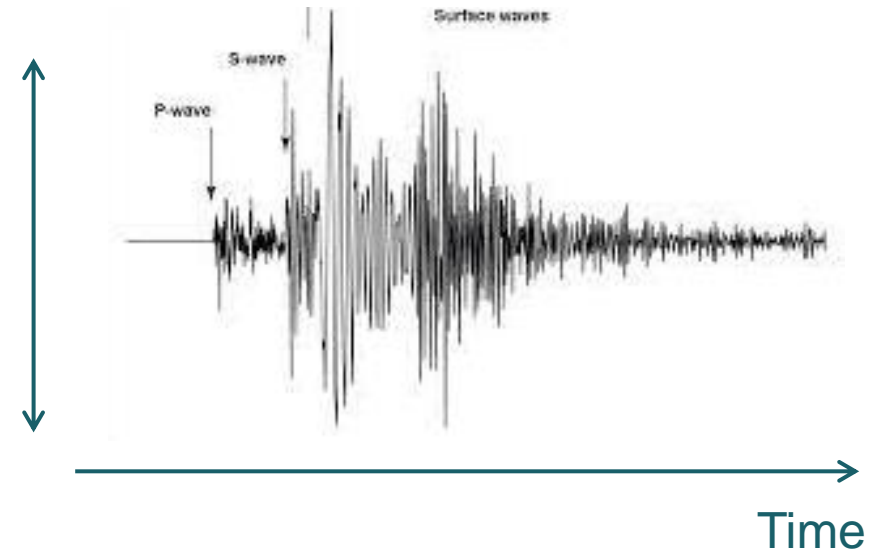
Phases of a collaboration

Dr Bruce Tuckman

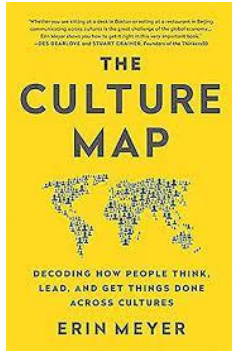
1. Forming
2. Norming
3. Storming
4. Performing
5. *Adjourning*



Amplitude of discussion

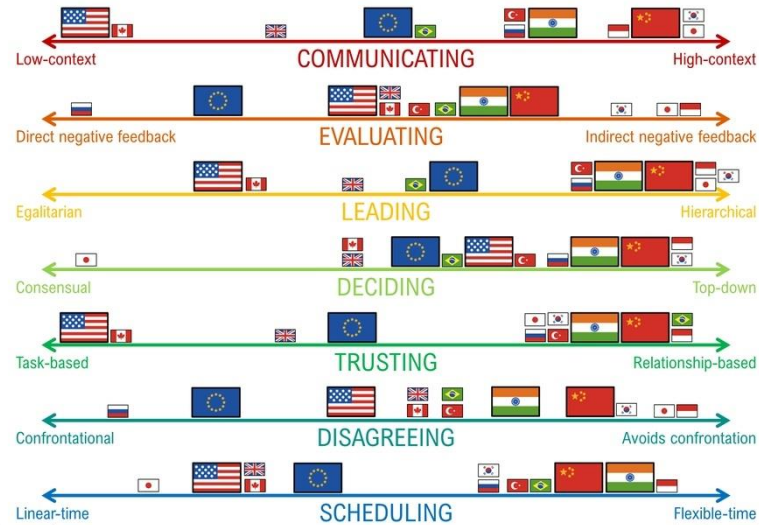


Acknowledge differences



“THE CULTURE MAP”

of top 10 economies according to Erin Meyer's “The Culture Map”



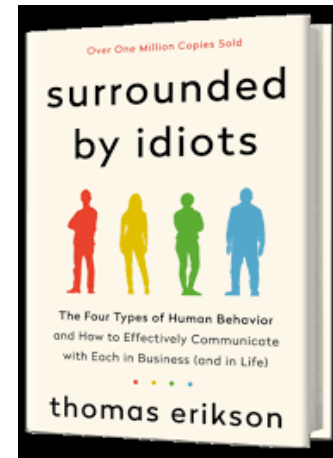
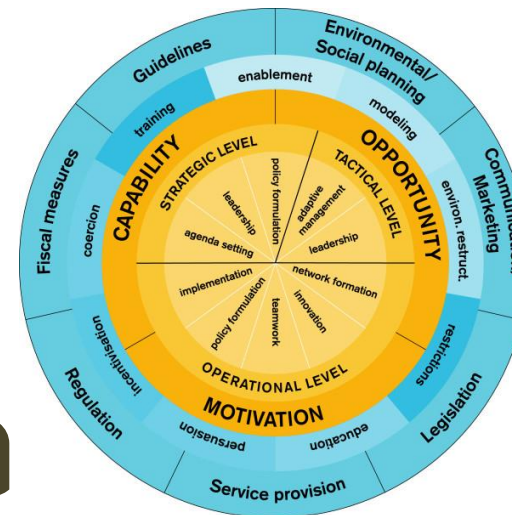
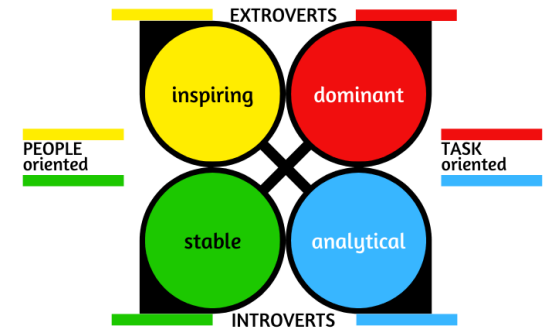
Top 10 economy size:
(by GDP nominal 2022 data)
United States: 25 trillion \$
China: 20 trillion \$
European Union: 17 trillion \$
Japan: 5 trillion \$
India: 4 trillion \$
UK: 3 trillion \$
Canada: 2 trillion \$
Brazil: 2 trillion \$
Russia: 2 trillion \$
S. Korea: 2 trillion \$

“The Culture Map” looks at how people communicate, make decisions, lead, and approach time. “The Culture Map” does not look at religion, political system, or world view aspects of countries. Large and highly populated countries, especially the US, China, and India are internally culturally very diverse, so these values are just averages. Values for the EU are based on average EU member states values and balanced by their population sizes.

facebook.com/maps.us.eu reddit.com/u/maps_us_eu instagram.com/maps.us.eu twitter.com/maps_us_eu

Top 10 economy size (PPP):
(by total GDP PPP 2022 data)
China: 30 trillion \$
United States: 25 trillion \$
European Union: 24 trillion \$
India: 12 trillion \$
Japan: 6 trillion \$
Russia: 4 trillion \$
Indonesia: 4 trillion \$
UK: 4 trillion \$
Brazil: 4 trillion \$
Turkey: 3 trillion \$

Source: ErinMeyer.com: Culture Map 2022



We are pioneering medicine.
together.



THANKS FOR LISTENING

Do you have any questions? Please contact us:

Kristina.Orrling@lygature.org

www.lygature.org



We are pioneering medicine.
together.

Julie Miralves



Julie Miralves joined GARPD in October 2019 as R&D Portfolio and Planning Leader and is now Head of R&D Portfolio & Operations Strategy. She developed her hands-on expertise in project planning and portfolio management through several positions in the healthcare industry. She started her career as a Senior Consultant at LowendalMasai in Paris, France, providing support and advice to biotech and pharmaceutical companies regarding their innovation funding and management strategy. She then joined a French biotech company, Ariana Pharma in Paris as a Project Manager and was responsible of the development and operational management of large collaborative R&D programs in oncology and chronic diseases. Prior to joining GARDP, she was a Country Operations Manager at IQVIA, in charge of the implementation in France of a novel European oncology data platform in hospitals and clinical centers for the CODE initiative. She holds a PhD in Immunology from the University Paul Sabatier of Toulouse, France, completed by a postdoctoral position at both the Ecole Normale Supérieure and the Collège de France in Paris, France. She has also been an independent scientific expert for the IMI2 initiative of the European Commission and EFPIA.



Project management in antimicrobial drug R&D

Key challenges in project management for drug development projects
| *Some personal thoughts on how to tackle them*

7 June 2023 | REVIVE Webinar

Julie Miralves, PhD

Head of R&D Portfolio and Operations Strategy, GARDP



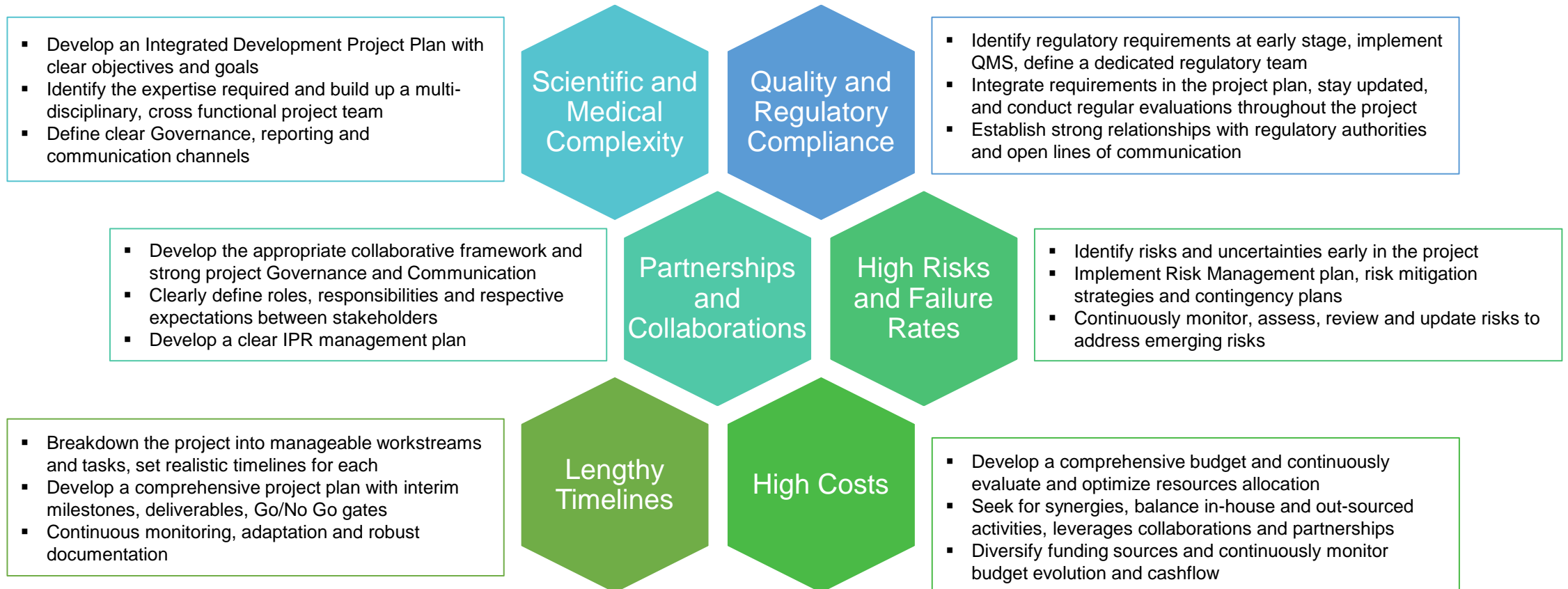
Key challenges in project management for drug development projects

Outline

- Specificities and key challenges of drug development projects from a project management perspective
- Specific challenges of antimicrobial drug development projects
- Addressing these challenges, some personal thoughts
 - *Implementing project management as an integrated project function and a framework to address these challenges*
 - *Building a collaborative and cross functional team to address the complexity and evolving challenges*
 - *Beyond planning, integrating forecasts/scenarios and risks for lengthy timelines management*

Specificities and key challenges of drug development projects from a project management perspective

Drug development projects differ from other types of projects due to their complex and interdisciplinary nature, regulatory requirements, high uncertainty, which require an adaptation of the PM approaches.



Specific challenges of antimicrobial drug development projects

Antimicrobial drug development specificities exacerbate even more the complexity of designing, implementing and managing drug development projects.

- **Antimicrobial resistance (AMR), prevalence of resistance genes and the epidemiology dynamic**
 - Mechanisms of resistance, prevalence of the resistance genes in the target population, resistance patterns varying across geographies and evolving over time pose additional challenges. This requires to conduct thorough surveillance and prevalence studies of resistance patterns. Consider with attention the pharmacokinetics and pharmacodynamics of antimicrobial drugs is crucial since an inappropriate use could impact the development of resistant strains. Exploration of novel mechanisms of action is increasingly challenging.
- **Clinical trial design and patients' population recruitment**
 - Designing clinical trial for antimicrobial drug faces unique challenges: heterogeneity of the infectious diseases, variability of the resistance/susceptibility patterns in the target populations, and potential emerging resistance during the period of the development, complexity in determining the appropriate control group, and in selecting the right study population. Enrolling patients who meet the specific enrolment criteria can be difficult particularly when targeting infections with low incidence or resistant to the standard of care. Inclusion of vulnerable populations also raise ethical considerations.
- **Evolving and diverse regulatory landscape**
 - The regulatory landscape for antimicrobial drugs is complex and continuously evolving, ensuring compliance throughout the clinical trials and overall project lifecycle is therefore a significant challenge. Regulatory agencies have specific and heterogeneous requirements for the approval of antimicrobial drugs, which also consider the urgent unmet medical needs.

Implementing project management as an integrated project function and a framework to address these challenges

Designing the appropriate project management approach involves tailoring the approach to fit the project specificities, challenges and organizational context.

Key principles

- Project Management is a **Function** or discipline of drug development project as other technical functions and must be fully embedded in the project team
 - With defined roles, responsibilities, leadership, and authority on key decision for the project
 - It is embodied mainly by **Project Manager** and **Project Leader**
- Project Management is also a **Framework** which must be deployed across all functions involved in a project and across the organisational structure
 - Project Management is a combination of principles, approaches, tools, process, etc. which provide a **common structure** for project design, planning, monitoring, controlling
 - A key point for successful project management is **foster the PM culture/ mindset within the whole team**

Design an *ad hoc* model

Key steps to design the appropriate project management approach include:

- Clearly articulate the goals, scope, deliverables and expected outcomes of the project in an **Integrated Development Project Plan**
- Assess the project characteristics, constraints, environment - overall and for each key workstream
- Identify internal and external stakeholders
- Identify the organisational and project operating models



Select the most suitable project management methodology

- Waterfall, Agile, Scrum, Kanban, Lean, Adaptive PM, Critical path method, Critical chain PM, Prince 2, PMBOK, etc.

For drug development projects, a **hybrid approach** for project management is usually recommended with **collaborative, flexible,** and self-explanatory tools easily used by all team members

A hybrid approach allows to **tailor the project management framework** to the project and organisation specificity and to respect each function or workstream requirements

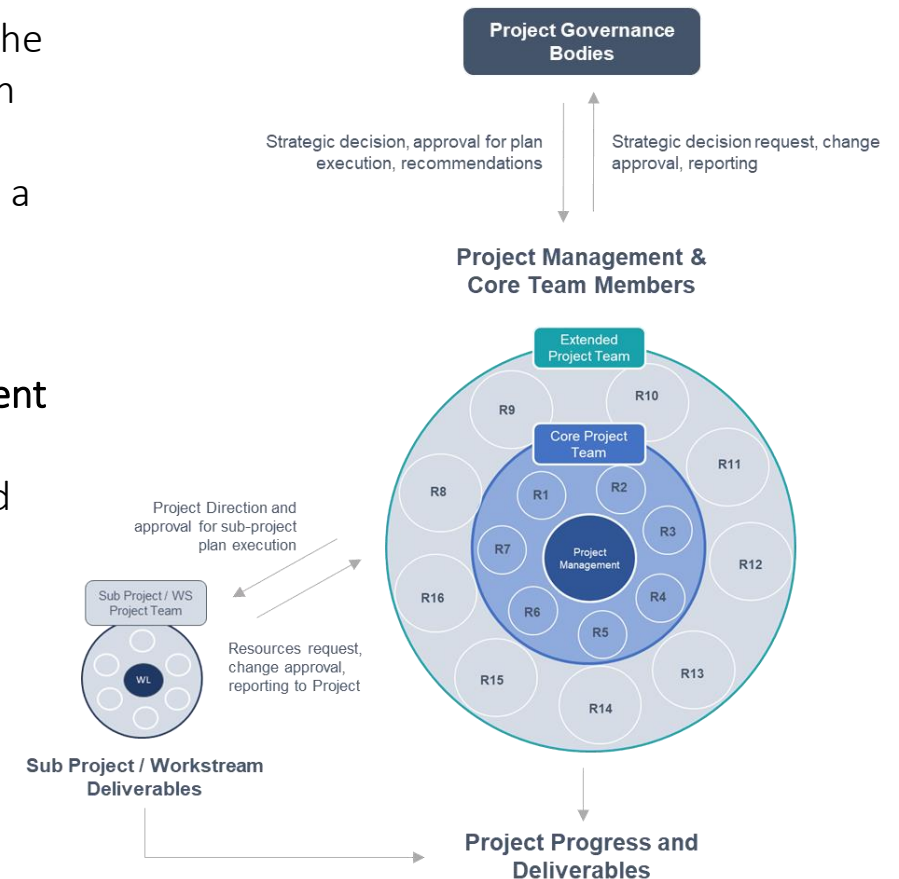
Implement an evolving framework

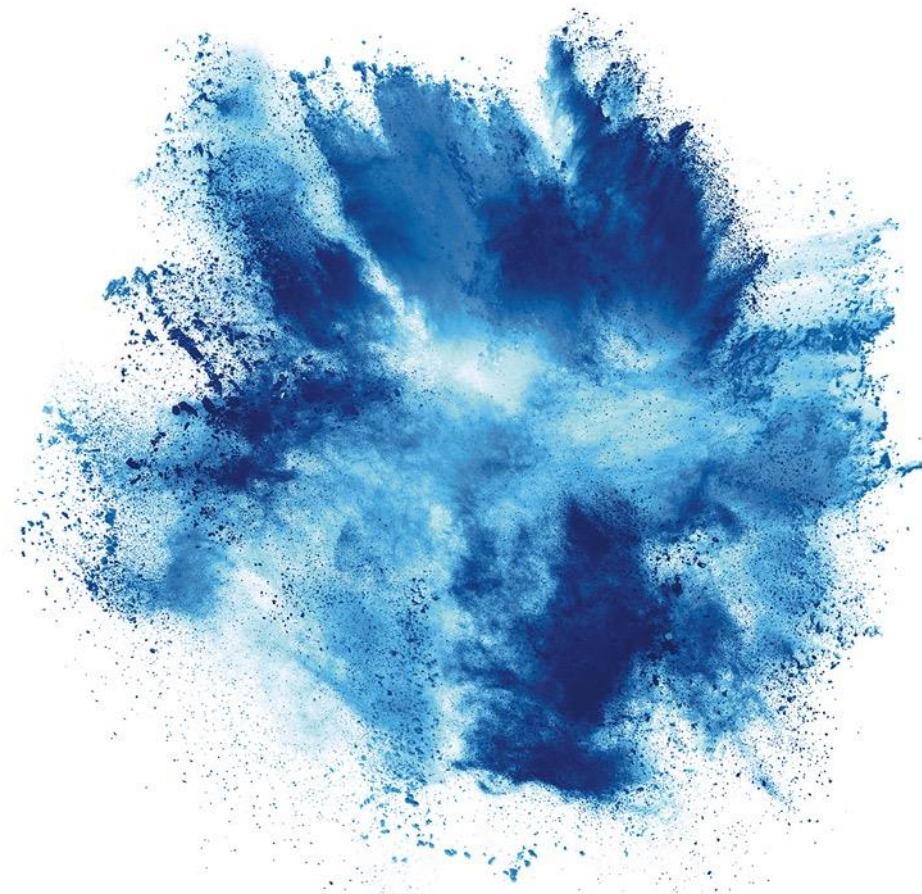
- Project management plan, tools and process, balancing standards and flexible tools - as a common structure across functions and workstreams
(e.g., *Timelines, Budget and financial management, Resources plan and allocation matrix, Scope and Quality content management, Stakeholders engagement, Reporting and monitoring, Communication and dissemination, etc.*)
- Define the project Governance (structure, roles responsibilities, project teams)
- Define the project monitoring and control, including reporting mechanisms
- Implement continuous adaptation and change management approaches

Remain **flexible and dynamic**, and adapt the project management framework throughout the lifecycle of the project

Building a collaborative and cross functional team to address the complexity and evolving challenges

- **ONE Project approach** - Breaking silos between functions and disciplines with a collaborative, cross functional team model which evolve with the project lifecycle
 - **Core project team**, key cross functional expertise, composition depending on the specific objectives, needs and challenges and evolving with project progression
 - **Extended project team** gathering all supportive functions
 - **Specific task force** (sub project team) to handle specific workstreams requiring a focus on a given technical perimeter or expertise
- **Clear roles and responsibilities**
 - Beyond the usual RACI, emphasize the **ownership** and give a clear **empowerment** to individuals, in particular **clear delegation**
 - Clarify the respective and reciprocal **expectations** between team members and **functions**, regularly review and update
- **Strong governance and clear communication paths**
 - Clarify the **decision-making roles** at the individual level, at the project teams' level, at the organisation level and with the **strategic partners** involved
 - Define clear **reporting and communication process** with both bottom-up and a top-down flows
 - Make sure to **record and communicate** clearly the **decisions taken** and **changes** adopted





 GARDP

www.gardp.org

Today's speakers

Project management in antimicrobial drug R&D



Kristina Orrling
Program Manager
Lygature (Netherlands)



Julie Miralves
Head of R&D Portfolio & Operations Strategy
GARDP (Switzerland)



Moderator:
Sina Gerbach
Deputy Head and Development Lead of the Transfer Group Anti-infectives
Leibniz-HKI, Leibniz Institute of Natural Product Research and Infection Biology (Germany)
and
Program Manager
INCATE, Incubator for Antibacterial Therapies in Europe (Germany)

New webinars will be announced soon

- »» On the REVIVE website (revive.gardp.org/webinars)
- »» In our newsletters
- »» On Twitter and LinkedIn



SAVE THE DATE

ANTIMICROBIAL CHEMOTHERAPY CONFERENCE (ACC) 2024

February | **6-7** | 2024

GARDP and BSAC are delighted to announce that the free virtual Antimicrobial Chemotherapy Conference will take place again next year in collaboration with the European Clinical Research Alliance on Infectious Diseases and the Netherlands Antibiotic Development Platform.

The scientific programme as well as the call for abstracts for posters and short oral presentations will be announced later in the year.





GARDP Travel Award

Applications now open!

The GARDP Travel Award was created to support researchers from low- and middle-income countries who work on R&D of new treatments for drug-resistant infections to attend in-person conferences and training courses in the field of antibiotic research and development.

Find more information about eligibility criteria and the application process here:
revive.gardp.org/gardp-travel-award

Important dates:

- Application deadline: 26 June 2023, 8:00 am CEST
- Shortlisted applicants will be requested to submit a short video between 26 June and 3 July
- Final decisions will be communicated between 10 and 31 July
- Eligible events have to take place between 1 September 2023 and 31 August 2024



 GARDP



Thank you for joining us

