

Agenda



- 1. Introduction to the BEAM Alliance
- 2. The role of SME in bringing innovation and new products in the field of AMR
- 3. The particular situation of SME's
- 4. What do SME need from a global and from a Swiss perspective

Disclosures Marc Gitzinger:

- CEO and Founder at BioVersys AG, a Swiss based small pharmaceutical company exclusively focused on drug discovery and development in the field of Antimicrobial Resistance (AMR)
- Vice President of the BEAM Alliance: Biotechs in Europe innovating in AntiMicrobial resistance

BEAM Alliance

Who we are:

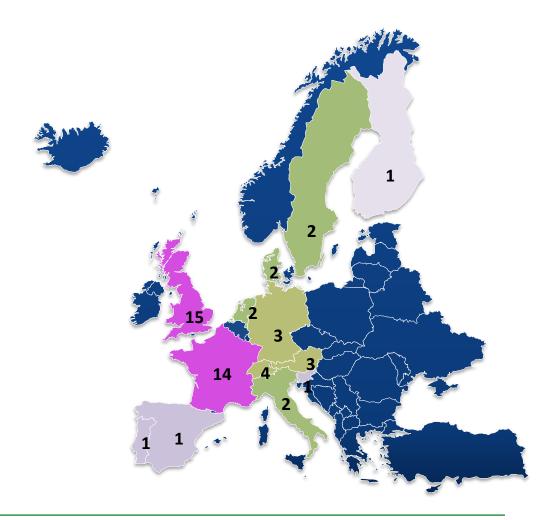






Beam is a consortium created in 2016 that represents 51 **European** biotech companies working on new **antimicrobials**

80% are antimicrobial focused

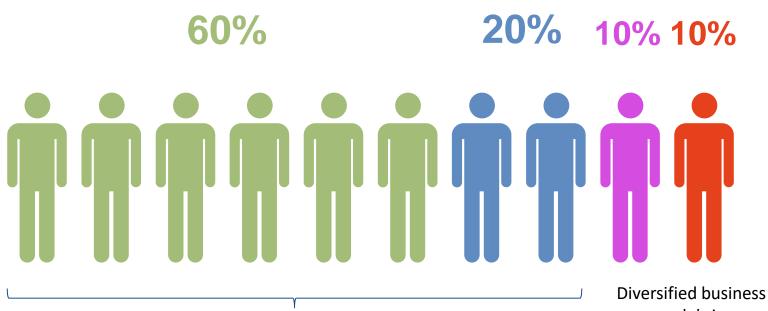


BEAM Alliance

80% are pure players in the anti-infective field







Pure players

Antibacterials – **Anti-infectives**

models in:

- Other areas of diseases
- Other than human healthcare

Source: 49 biotech companies website + survey Summer 2016

BEAM's pipeline 2017

Number of projects in antibacterials per stage





	Early Stage	Phase I	Phase II	Phase III	Market
BEAM*	130	13	10	6	1
			29		
GLOBAL**		59	67	40	
			166		
	EAM's % of global R&D	22%	15%	15%	

BEAM is a key contributor to ATM's innovation

^{**}Source: published data (WHO, + Septeos internal Data)

^{*}Source : 48 biotech companies website + survey Summer 2016

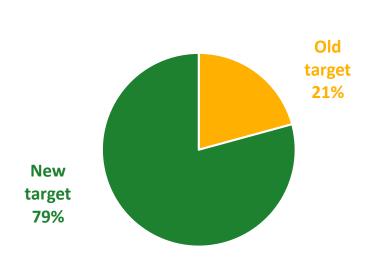
BEAM Alliance

European pioneers in the field of AMR R&D





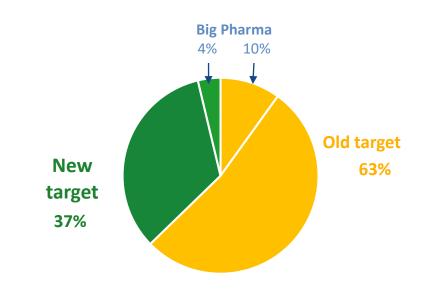
BEAM 's pipeline



Spectrum

G+	Both	G-
10%	60%	30%

Non-BEAM pipeline



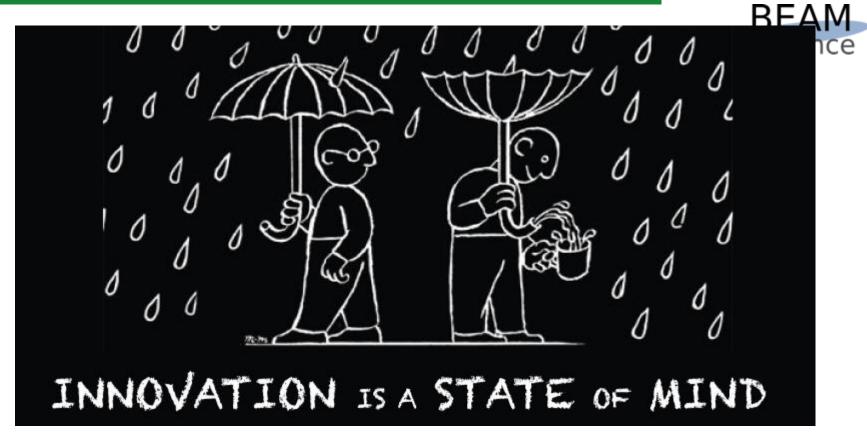
Spectrum

G+	Both	G-
46%	34%	19%

SME's are the innovation engine

SME's fill the innovation gap



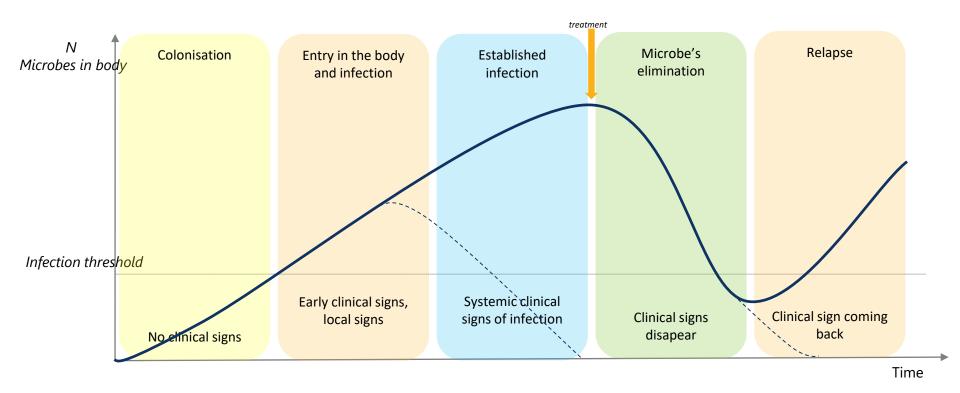


- From prophylaxis to treatment, boosters, anti-virulence or protection
- All pathogens for which a risk is assumed/identified
- Can be disruptive, paradigm shift in patient management algorithms

From no infection to no infection...

SMEs explore the issue of AMR from all perspectives



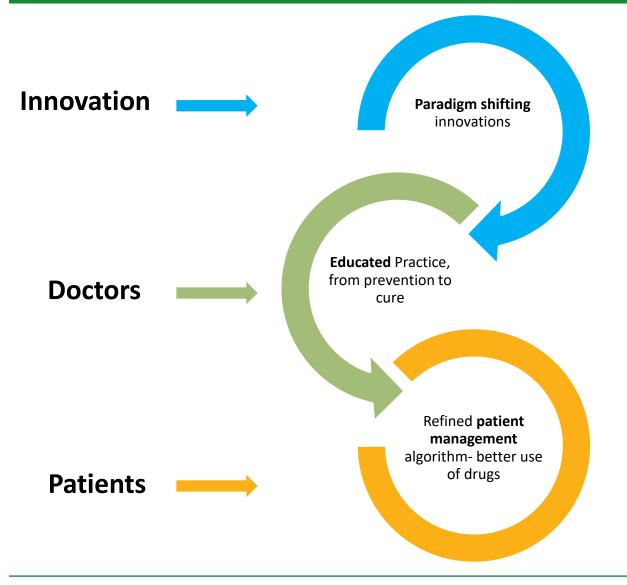


Focus on PATIENT FIRST

We are activists – a better ecosystem from R&D to Patient Care







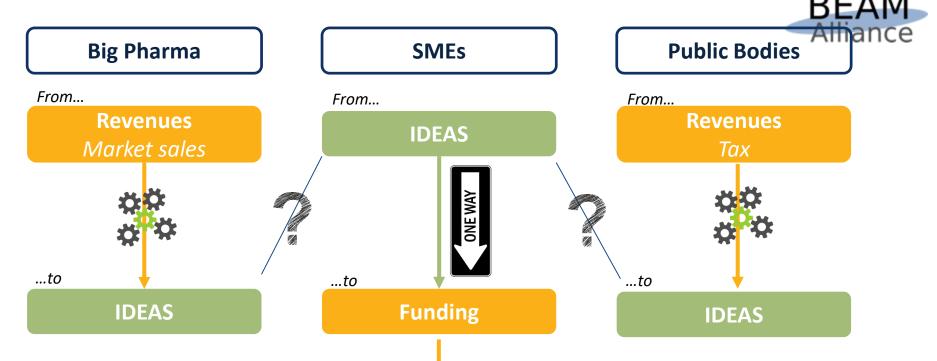


Better efficacy of ATMs Sustainable Use

SMEs are the Innovation Engine

Understanding what SME can do and what not





Risk financing, purely based on Return on Invest
Beyond the technological risk, a market risk/failure cannot be accepted

DISRUPTION

DOING THE SAME DOING NEW THINGS A BIT THINGS A BIT THINGS MAKE THE OLD THINGS OBSOLETE

BEAM Alliance in the AMR ecosystem

They support SMEs – BEAM is the hub to engage with SMEs











Department of Health









CARB-X

Xccelerating global antibacterial innovation



access to medicine FOUNDATION





BEAM Alliance voices the needs of SMEs

Improvements for the development process and to attract Private Capital



BEAM Alliance

What is lacking in the AMR investment space to pursue R&D and attract/retain investors:

- 1. Identification of patient population: surveillance data is in its infancy, we would need to better assess what are the practices, use of diagnostic and the actual drivers for selected treatment algorithm. In hospital and in the community.
- **2. Value for innovation reaching the market:** a pricing that integrates the medical need addressed, the reduction in treatment time, ICU/hospitalization time, the protection against further spread of a superbug threat, the social impact...
- 3. Clear Development path: a European designation equivalent to QIDP and/or breakthrough/PRIME designation for rare deadly infections, the path for early discussions on trial design for novel approaches
- **4. Differentiation criteria:** suitable evaluation criteria as many innovative targets cannot be assessed by MIC PK/PD
- **5. Appetite from large pharma players:** results from the lack of the above-mentioned aspects

BEAM Alliance – The Swiss perspective



- Position of Switzerland on the global action plan on AMR
 - What is the Swiss strategy to incentivize AMR innovation again (Pull: Market Entry Rewards, IP protection, market exclusivity, voucher and Push: Grants, Phase Entry Rewards)
- Clear Development path: Clear path forward to allow discussion on the right trial design for novel approaches (number of patients, infection sites/types, relevance PK/PD, patient pooling), accelerated market access
- Stronger focus on R&D and innovation incentives within the StAR
 - NRP72 follow up
 - Further "Push" incentives, also for SME (alone or on a global, EU level)
- Involvement of SME: Integrate SME as discussion partners within the National Strategy plans via SBA, BEAM or SME directly

Building a sustainable environment

To reinvigorate the AMR R&D field





Early Stage

Clinical Stage

Market

Enable

Quantity **Diversity** Quality

of R&D projects

Ensure

Predictable Reliable

Designation Clinical Guidelines Reward for the Societal Value of drugs

SUSTAINABLE environment for **INNOVATION**

