

# DRIVE-AB – DRIVING RE-INVESTMENT IN R&D AND RESPONSIBLE ANTIBIOTIC USE

## Governance and finance recommendations

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DRIVE-AB consortium

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- What?
  - How much?
  - What will we get?
  - How?

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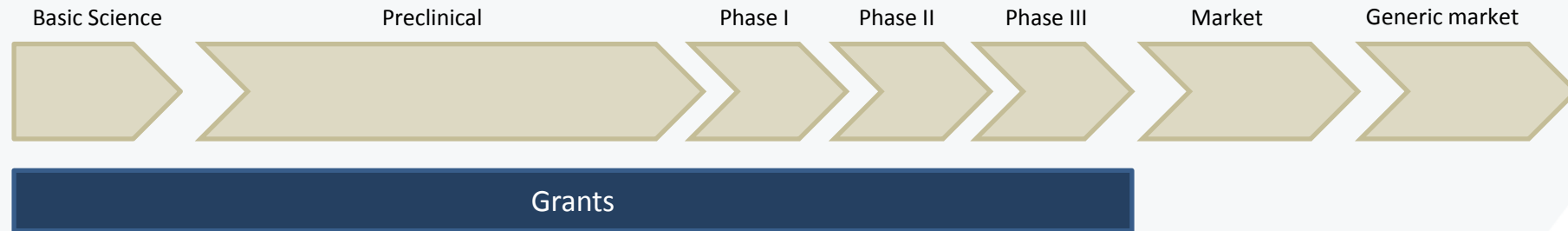
# DRIVE-AB's recommended models

## Methods:

- Model identification (n=35)
- Internal evaluation
- Stakeholder feedback

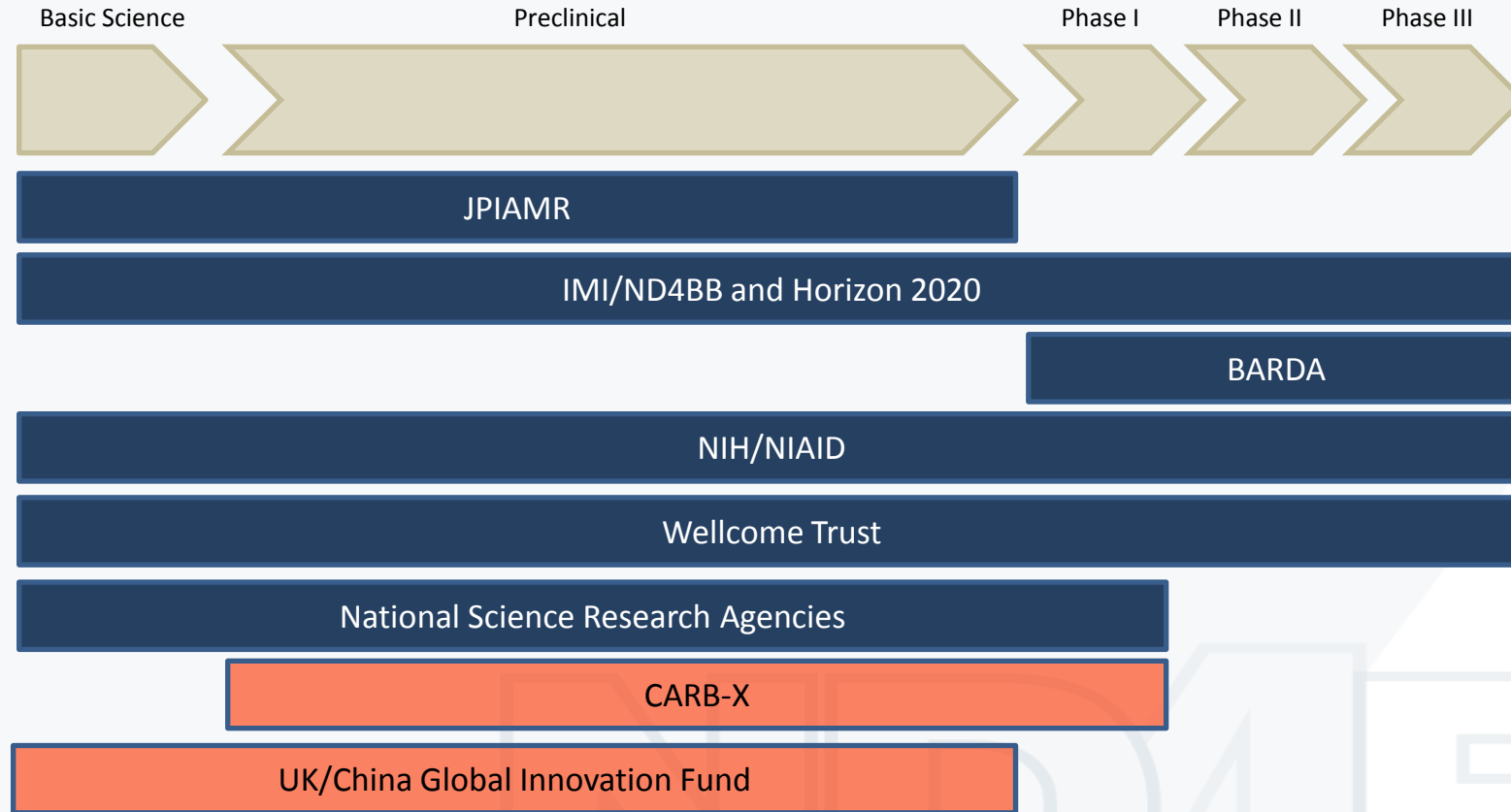


# DRIVE-AB's recommended models



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# Grants



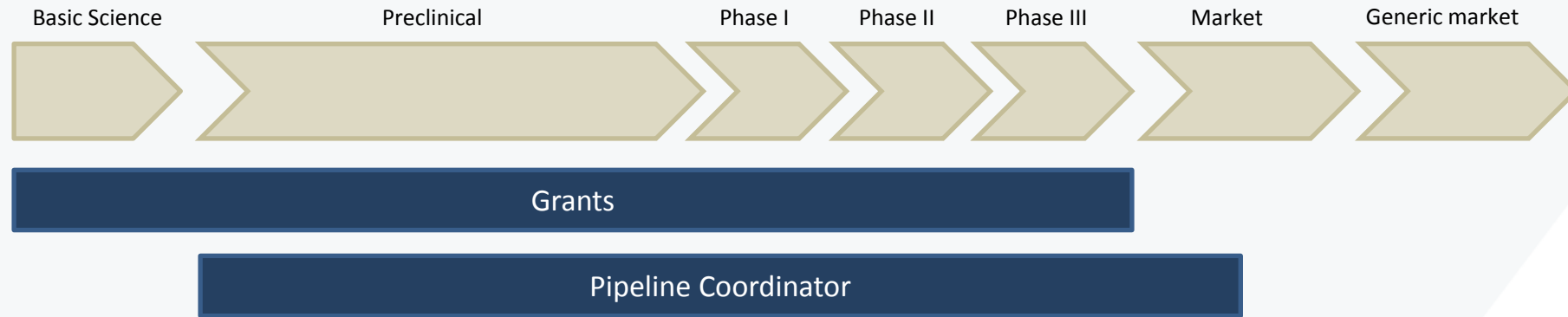
# Grants - recommendation

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- Continue to finance the USD 550 million per year and ideally increase by 50%
- Target early- and mid-stage grants until the pipeline becomes more robust
- Focus on priority pathogens
- Coordinate efforts

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# DRIVE-AB's recommended models



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# Novel antibiotic candidates

Bacteria (WHO category)	WHO (2017)	# in preclinical dev	# in clinical dev
<i>Acinetobacter baumannii</i> , carbapenem-R	Critical	52 + 14 biologics	0
<i>Pseudomonas aeruginosa</i> , carbapenem-R	Critical		1 + 2 biologics
<i>Enterobacteriaceae</i> , carbapenem-R, 3 <sup>rd</sup> -gen cep-R (ESBL+)	Critical		0
<i>Enterococcus faecium</i> , vancomycin-R	High	6	0
<i>Staphylococcus aureus</i> , methicillin-R, vancomycin-I/R	High	23 + 8 biologics	5 + 7 biologics
<i>Helicobacter pylori</i> , clarithromycin-R	High	0	0
<i>Campylobacter</i> spp., fluoroquinolone-R	High	0	0
<i>Salmonellae</i> spp., fluoroquinolone-R	High	1	0
<i>Neisseria gonorrhoeae</i> , 3 <sup>rd</sup> -gen cep-R, fluoroquinolone-R	High	1	2

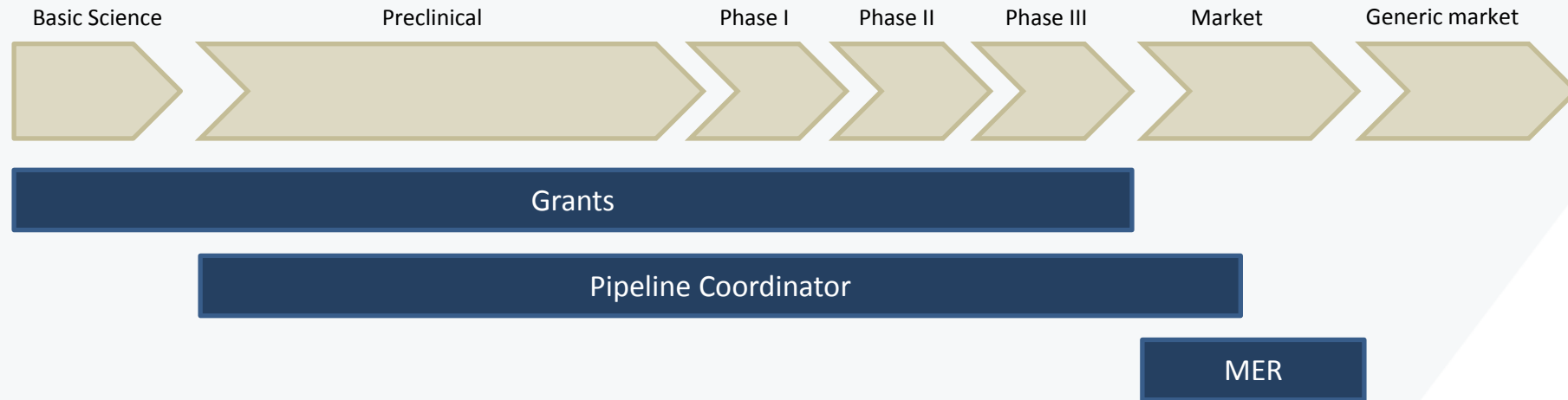


# Pipeline coordinator - recommendation

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- Continue to support (and expand support) organizations like BARDA, CARB-X, and GARDP that target and eliminate priority, public health R&D gaps and take an active portfolio management role
- Non-traditional financing may be used

# DRIVE-AB's recommended models

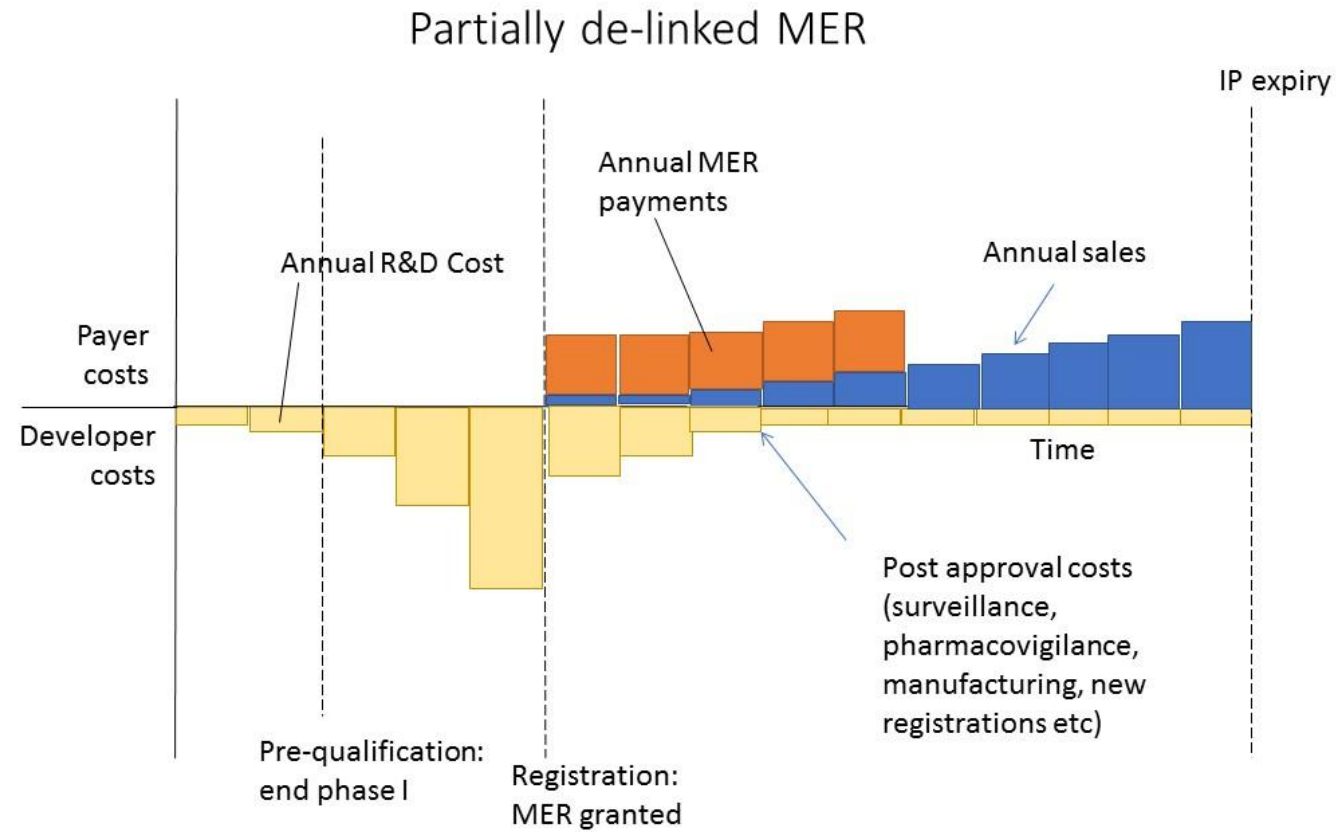


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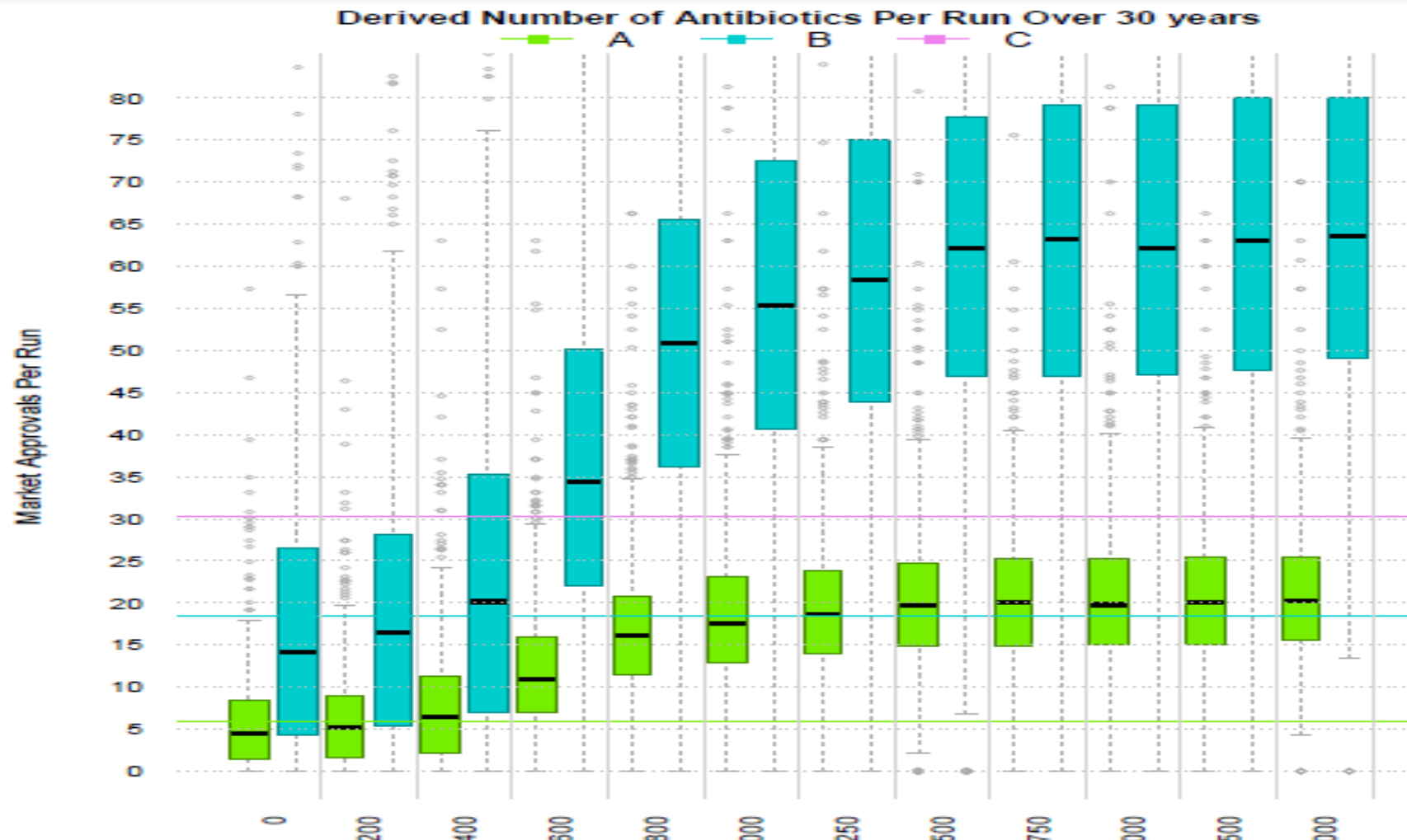
# Why a market entry reward?

Antibiotic	Regulatory approval (US)	Sales in US in 2015 (millions)
<i>Ceftazidime/avibactam</i>	2015	35.8
<i>Tedizolid phosphate</i>	2014	37
<i>Dalbavancin</i>	2014	20.3
<i>Oritavancin</i>	2014	9.1
<i>Fidaxomicin</i>	2011	39.8
<i>Ceftaroline fosamil</i>	2010	118.5
<i>Telavancin</i>	2009	9.4

# Market entry reward



# Market entry reward – simulated results



# Market entry reward – simulated results

Over 30 years, a MER is simulated to result in:

MER Global Amount	Novel classes	Incremental innovation
USD 0	4	15
USD 1b (partially delinked) or 1.25b (fully delinked)	19	55

Against priority pathogens

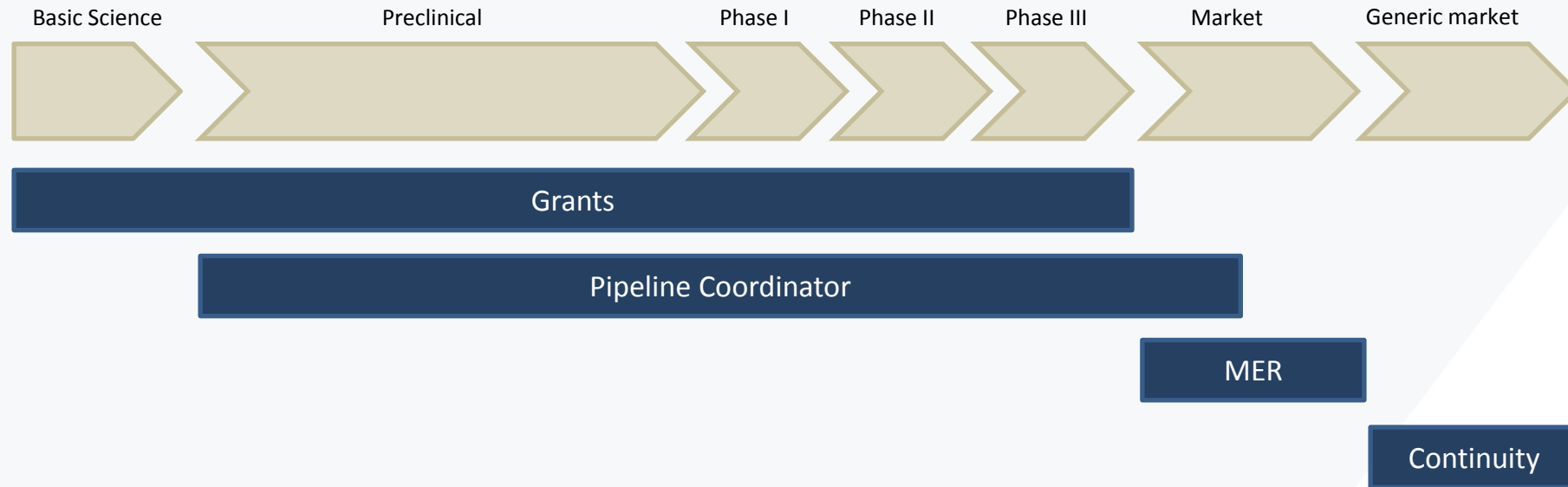
# Market entry reward - recommendation

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- Implement a market entry reward for a 20-year time period
- Can start with a three- to five-year pilot

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# DRIVE-AB's recommended models



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# Long-term continuity model

Contents lists available at ScienceDirect

 **International Journal of Antimicrobial Agents**

journal homepage: [www.elsevier.com/locate/ijantimicag](http://www.elsevier.com/locate/ijantimicag)



Short Communication

**Forgotten antibiotics: a follow-up inventory study in Europe, the USA, Canada and Australia <sup>☆</sup>**



Céline Pulcini <sup>a\*</sup>, Simone Mohrs <sup>b</sup>, Bojana Beovic <sup>c</sup>, Inge Gyssens <sup>d,e</sup>,  
Ursula Theuretzbacher <sup>f</sup>, Otto Cars <sup>b</sup> on behalf of the ESCMID Study Group for Antibiotic Policies (ESGAP), ReAct Working Group on Old Antibiotics <sup>1</sup>

“In conclusion, despite the ongoing bacterial resistance crisis, the situation regarding the availability of ‘forgotten antibiotics’ has worsened since 2011.”

in 13 countries and decreased in 17. In conclusion, despite the ongoing bacterial resistance crisis, the situation regarding the availability of ‘forgotten antibiotics’ has worsened since 2011. Urgent measures are needed to ensure better availability of these antibiotics on a global scale as a conservation measure to ensure sustainable and responsible use of antibiotics.

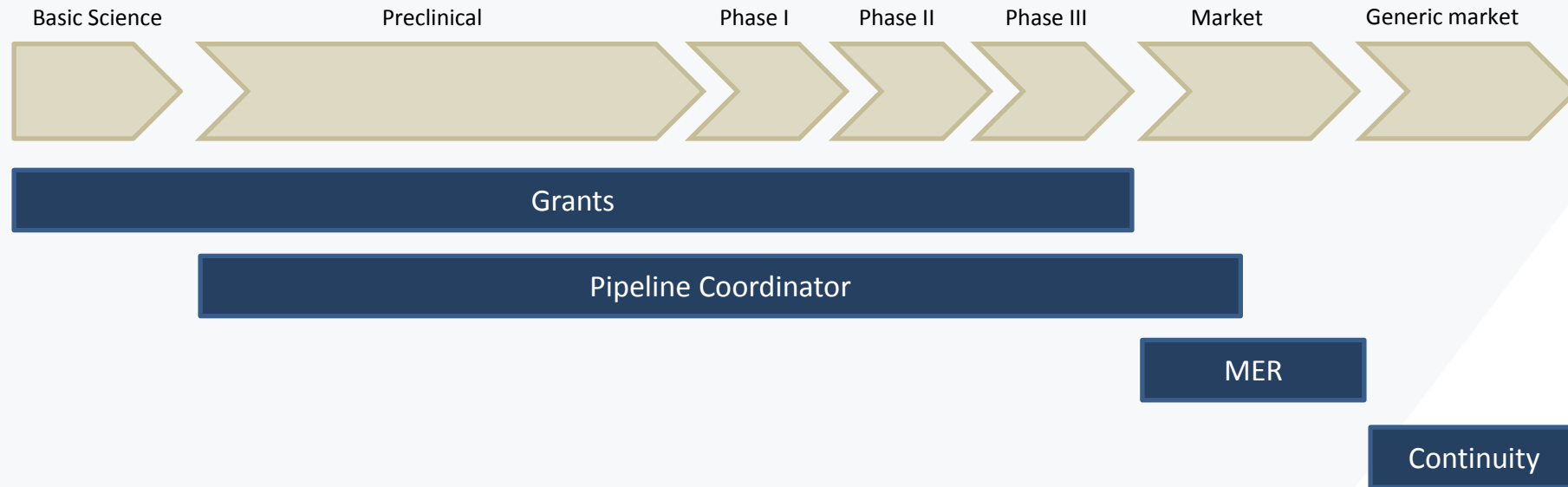
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# Continuity model - recommendation

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- (Testing a long-term supply continuity model can also test the implementation of a national market entry reward.)
- Test of a delinked model for an antibiotic with a fragile supply chain but included as an “access” antibiotic on WHO’s Essential Medicine List (e.g., benzylpenicillin)

# DRIVE-AB's recommended models



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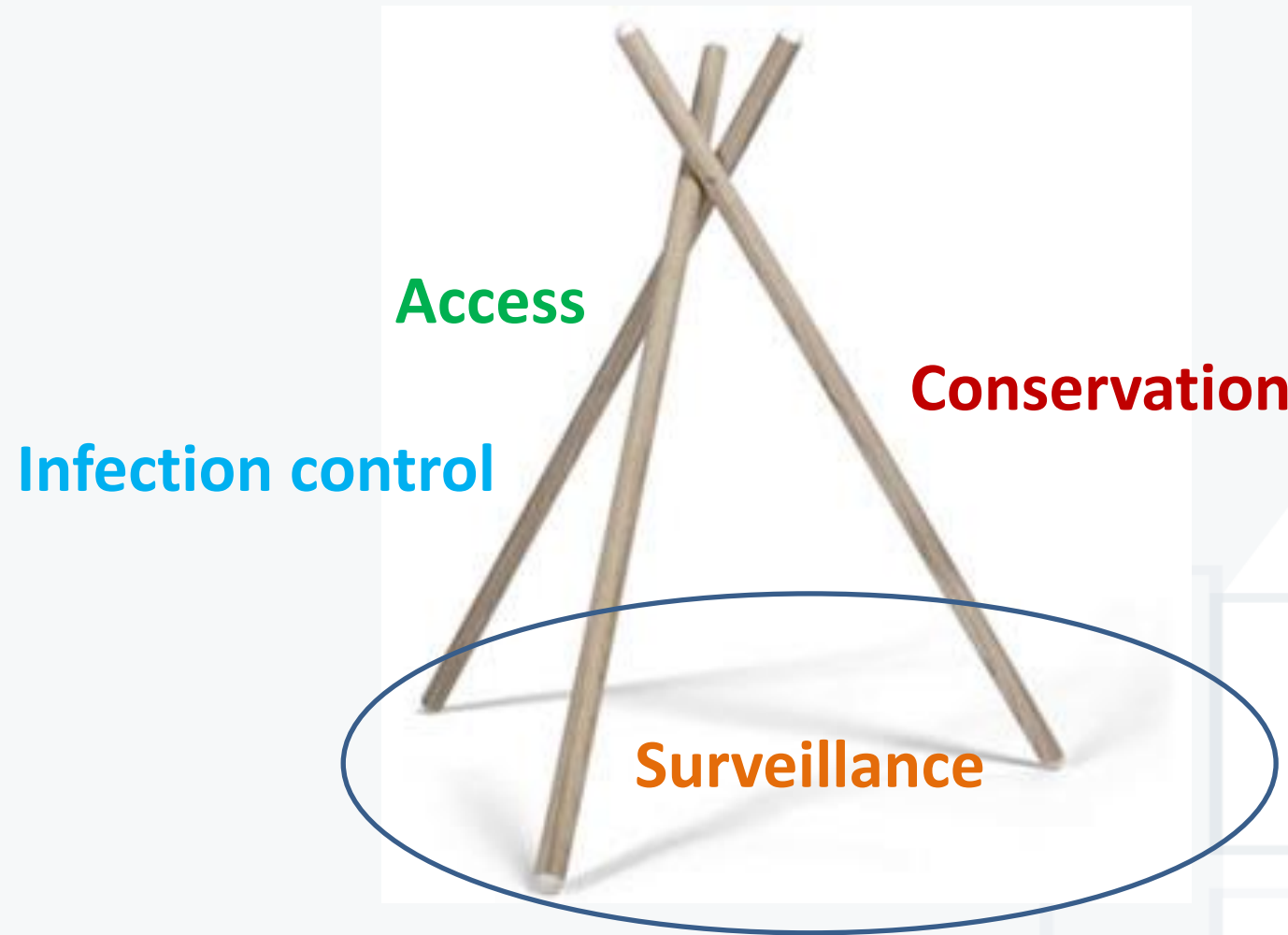
# How much financing is needed?

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We estimate the cost of implementing our recommendations to start at **USD 800 million per year in 2018**, increasing to **USD 1 billion per year in about 2020**, and to **USD 1.2 billion in about 2021**, including USD 550 million spent today.

- Fill the preclinical pipeline
- Two market entry rewards (one from about 2019 and the other from about 2021)

# Not to replace essential funding for...



# Governance

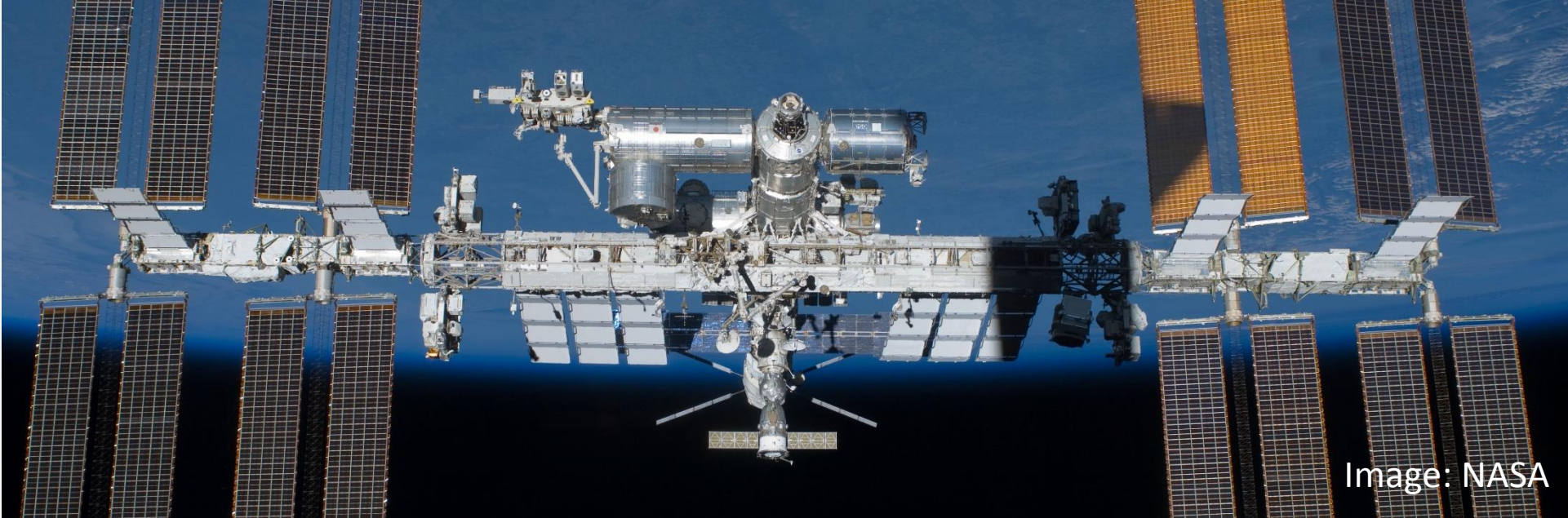
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What can be learned from other models:

- Financing arrangements
- Governance structure

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# Example - ISS



- Bilateral agreements with US
- No pooled budget

# Example - CERN



- USD 1.2 billion per year (operating budget)
- Outputs are not proprietary
- Agreed 50+ years ago; practical problems with conventions



# Example - CEPI

## CEPI

New vaccines  
for a safer world

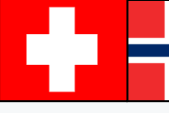
Coalition for Epidemic  
Preparedness Innovations

- MERS-CoV, Lassa and Nipah viruses
- Financed through different sources including development aid
- USD 120 to 200 million per year

# Antibiotic financing characteristics

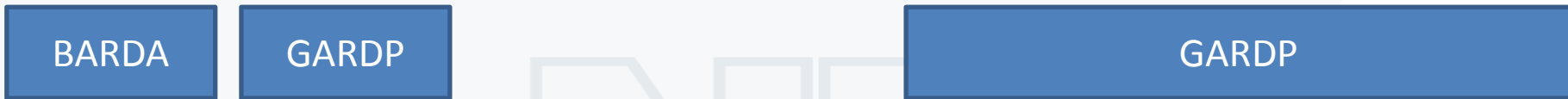
Attribute	Characteristic
Financing needs	Significant
Financing sources	Ministries of health and/or science and technology
Established funding mechanisms	Yes
Need for unilateral participation	Not to support innovation

# Collaboration (illustrative example only)



Coordination Alliance of like-minded nations willing to commit to same principles

G20 AMR R&D Collaboration Hub



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- What? Four interdependent and cohesive models
  - How much? USD 800m - 1.2 billion per year (including existing financing)
  - What will we get? Pipeline aligned with priority public health needs and two novel antibiotics in next five years
  - How? Commitments to shared goals



DRIVE-AB ([www.drive-ab.eu](http://www.drive-ab.eu)) is supported by the Innovative Medicines Initiative (IMI) Joint Undertaking ([www.imi.europa.eu](http://www.imi.europa.eu)) under grant agreement no. 115618, resources of which are composed of financial contribution from the European Union's Seventh Framework Programme (FP7/2007-2013) and EFPIA (European Federation of Pharmaceutical Industries and Associations) companies' in kind contribution.

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