A review of proposed models, their implementation and how they deliver on each of the pillars

David Findlay DRIVE-AB Work Package 2 & GSK

DRIVE-AB's principles

Innovation

Access

Sustainable use

Hoffman S, Outterson K, et al. JLME 2015

DRIVE-AB's shortlist of incentives

| Incentive	Type	Innovation stimulated	Required funding per annum
Grants	Push	Early phase research	
Pipeline coordinator	Push	Key health threat pathogens through discovery and development	Additional $250 ++
Market Entry Rewards	Pull	Most pressing public health threats	$1-1.25bn per AB
Continuity model	Pull	Ensures product availability post MER period	TBD on a case basis

Criteria for Market Entry Rewards

- **Targeted**….to key public health priorities.

- **Sustainable**…predictable, reliable and not subject to budget changes. A MER will not incentivise if it is likely to disappear 5 years into a 10 year development programme!

- **Transparent**….the criteria for delivering a MER should be clear and publicly available – Target Product Profiles, contract conditions, funding timelines…

- **Sufficien**t…the MER must maintain existing investment and generate new public and private capital investment into AB R&D through increasing ROI to attractive levels
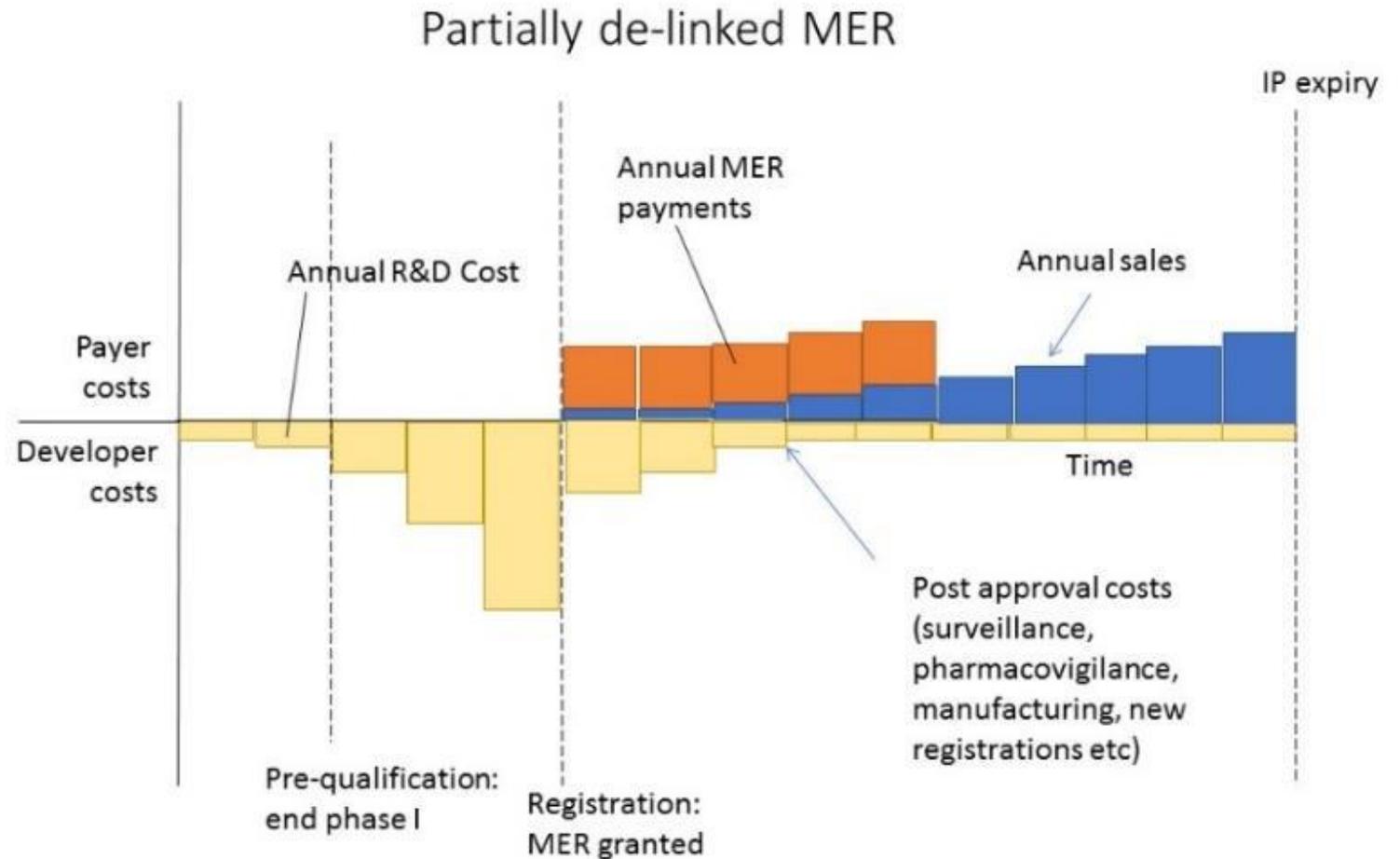
Fully de-linked MER

In a fully delinked MER, *all* developer revenues associated with the eligible antibiotic would be from the MER payments for the lifetime of the IP; the antibiotic would be supplied at cost price.
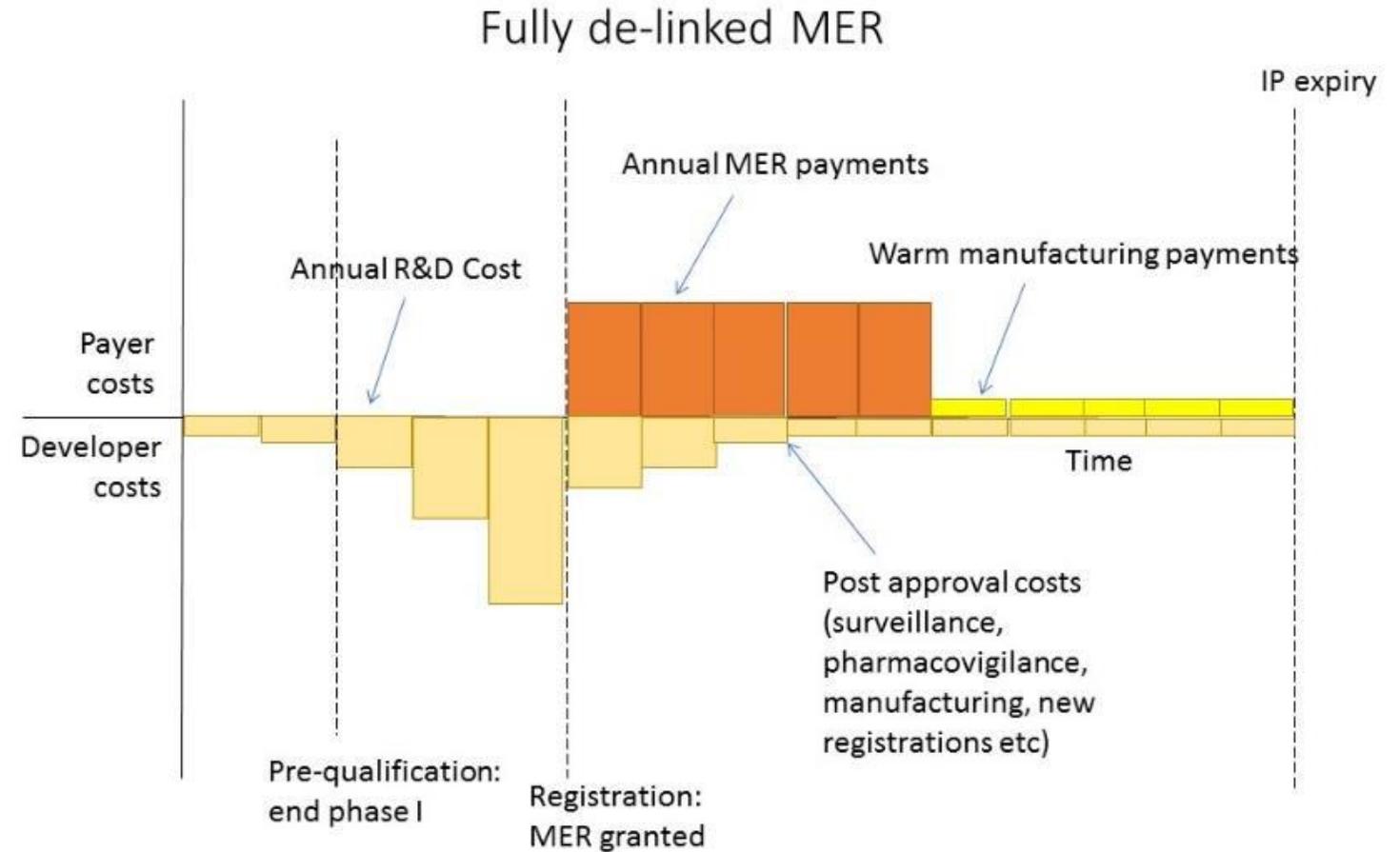

Fully de-linked MER

Partially de-linked MER

A partially delinked MER preserves some flexible market-based elements, which lowers the upfront financial commitment and allows developers to operate within their existing business model

Partially de-linked MER

Partially de-linked MER (Sales adjusted)

The MER would be offered as a set of "top-up" payments over five years that ensure the developer earns an agreed target revenue each year. If revenue from sales is greater than the MER in a given year, then there would be no MER payment and any excess revenue would be discounted from the following year's MER payment.

Partially de-linked MER (sales adjusted)
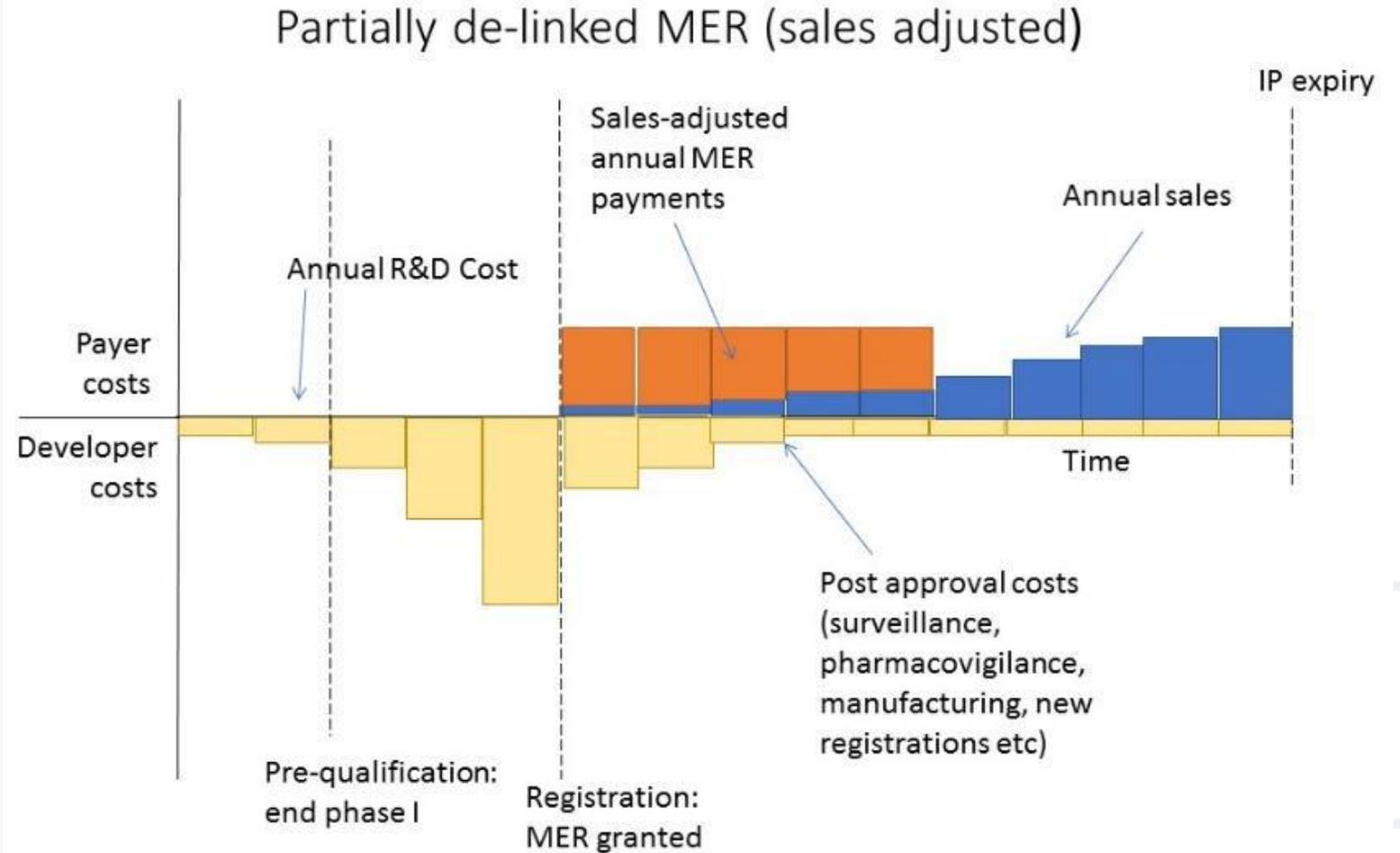
Sustainable use: DRIVE-AB recommendation

- Sustainable use measures for developers should be contractually linked to both market entry rewards and long-term supply continuity awards.

- Countries should also commit to high-level sustainable use commitments and adherence to antibiotic-specific guidance documents developed by the World Health Organization or other relevant bodies.

- We recommend that a special working group (perhaps under the guidance of the EU commission, G20 or TATFAR) convene to develop standard sustainable use measures both for developers and governments.

MERs must be bound by sustainable use and equitable availability obligations on the developer.

- We define sustainable use as the implementation of policies targeting a range of actors to ensure the preservation of a specific, novel antibiotic.

- It is vital that any innovation incentive promotes sustainable use to ensure the longevity of the AB and continued benefit to patients

- For sustainable use activities that are within the control of developers, DRIVE-AB recommends that these obligations are contractually agreed between the funder and developer, with annual reporting.

- MER conditions should not be so numerous or complex that they make the MER unattractive to developers or too difficult to effectively administer, both from an industry and a public payer perspective.

Options for developer sustainable use measures

Pragmatic recommendation

- Sales of active ingredient outside of human medicine prohibited*
- Product promotion limited to appropriate use only. All materials reviewed at least 90 days prior to use
- Review and apply antibiotic discharge framework across supply chain (including API).
- Sales and surveillance data disclosure
- Reduce/eliminate volume-based remuneration of sales staff
- Support on-going self regulatory initiatives via the Davos Declaration and AMR Industry Alliance

Stringent recommendation

- Sales of active ingredient outside of human medicine prohibited*
- No product promotion, similar to existing FDA off-label restrictions, with defined exceptions for the dissemination of use-related information – safe harbours.
- Review and apply antibiotic discharge framework across supply chain (including API)
- Sales and surveillance data disclosure
- Eliminate inducements related to volume sales
- Externally enforce developer controls

*unless product classified by the World Organization for Animal Health's veterinary antimicrobial list as critically or highly important.

DRIVE AB — RE-INVESTMENT IN R&D AND RESPONSIBLE ANTIBIOTIC USE

imi | innovative medicines initiative   efpia
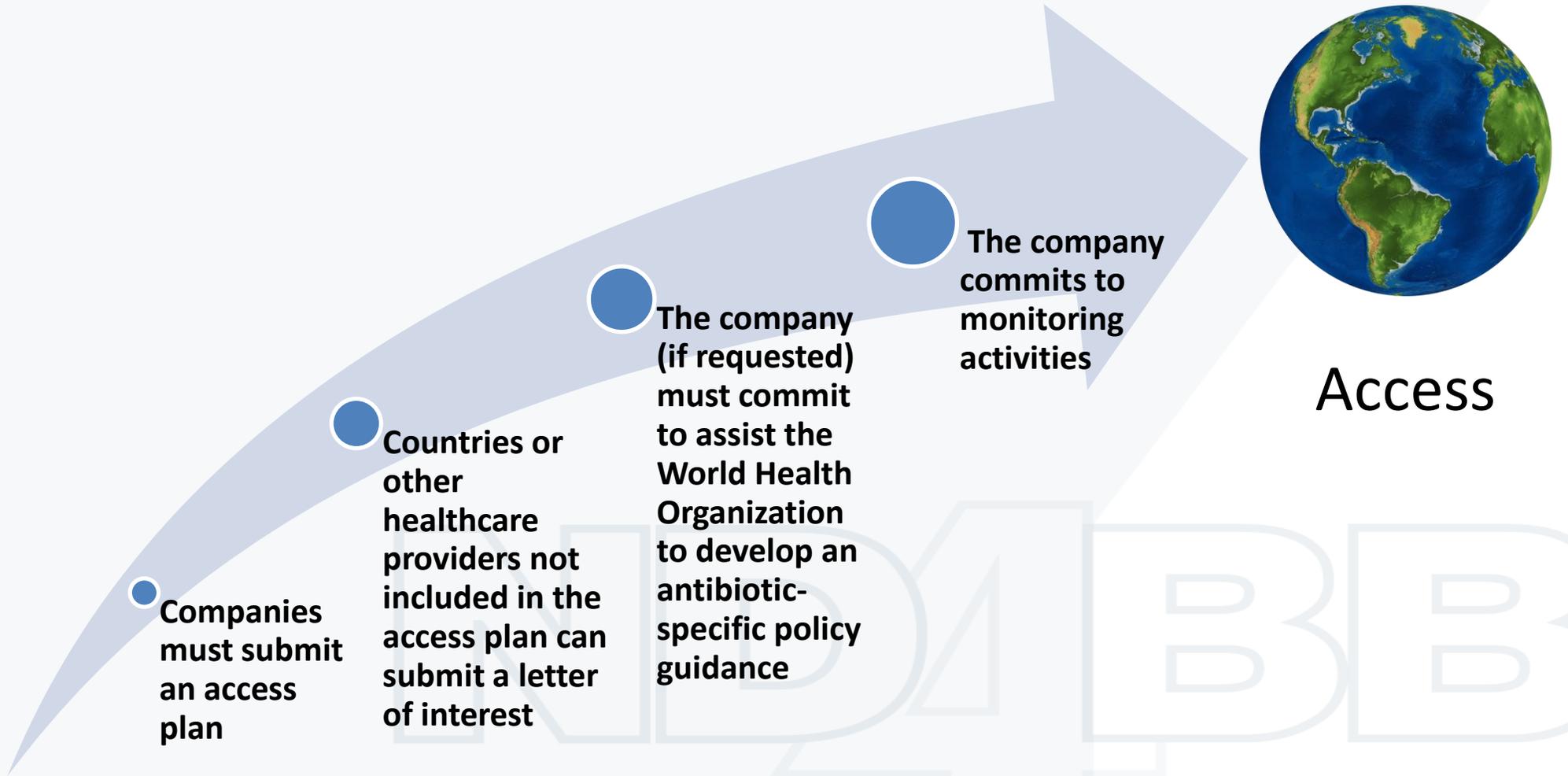
Options for country sustainable use measures

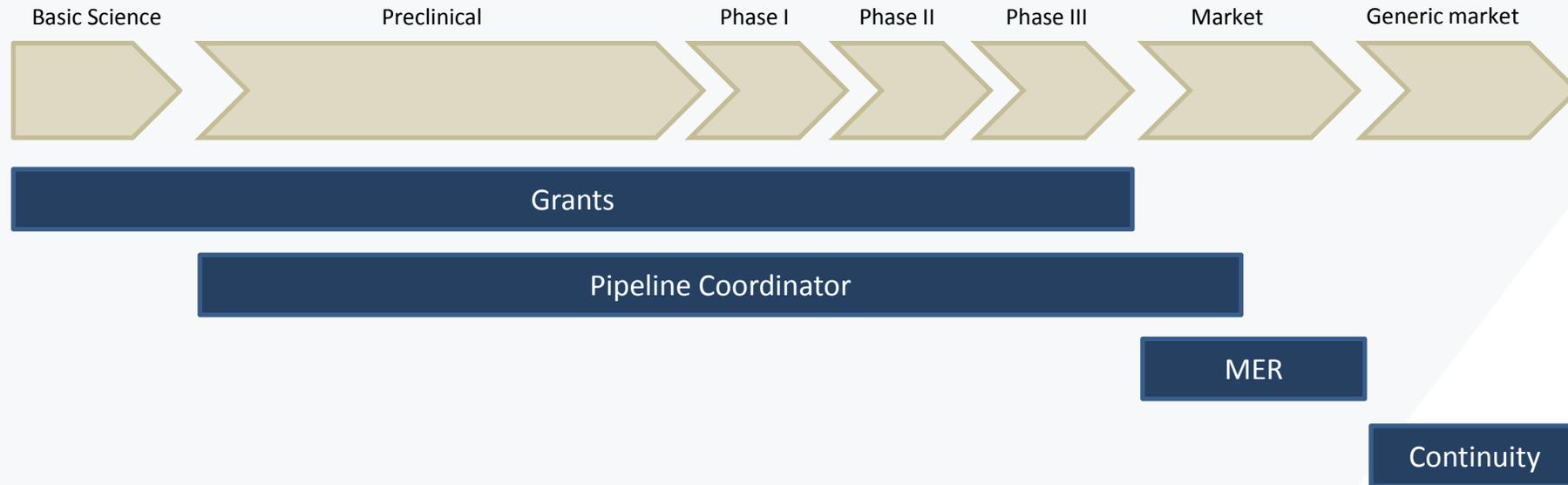# Building in equitable availability: DRIVE-AB Recommendation

- Equitable availability measures for developers should be contractually linked with both market entry rewards and long-term supply continuity awards.

- A special working group (perhaps under the guidance of the Global Antibiotic Resistance Partnership) should be convened to develop standard equitable availability measures.

Building in equitable availability

Companies must submit an access plan

Countries or other healthcare providers not included in the access plan can submit a letter of interest

The company (if requested) must commit to assist the World Health Organization to develop an antibiotic-specific policy guidance

The company commits to monitoring activities

Access

DRIVE-AB's recommended models

'Transforming the way policymakers stimulate innovation, responsible use and global access to novel antibiotics to meet public health needs'

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