

DRIVE-AB –

DRIVING RE-INVESTMENT IN R&D AND RESPONSIBLE ANTIBIOTIC USE

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for the DRIVE-AB consortium

IMI – ND4BB

Cross-project communication & collaboration

2013-2021

COMBACTE-NET

Enabling clinical collaboration and refining clinical trial design. Clinical dev. of MEDI4893 DAV132 Minocycline iv

2013-2017

TRANSLOCATION

Research on penetration and efflux in Gram-negative bacteria-Data hub and learning from R&D experience

2014-2020

ENABLE

Discovery and development of new drugs combatting Gram-negative infections

2015-2017

DRIVE-AB

Driving re-investment in R&D and the responsible use of antibiotics

2015-2020

COMBACTE-CARE

Clinical development of antibacterial agents for Gram-negative, antibiotic-resistant pathogens

2015-2021

COMBACTE-MAGNET

European epidemiological network. Clinical dev. of MEDI3902 AIC499

2015-2020

iABC

Inhaled anti-Biotics in cystic fibrosis and non-cystic fibrosis bronchiectasis. Clinical dev. of BAL30072 Tobramycin

Development-focused

Discovery-focused

Economics & stewardship

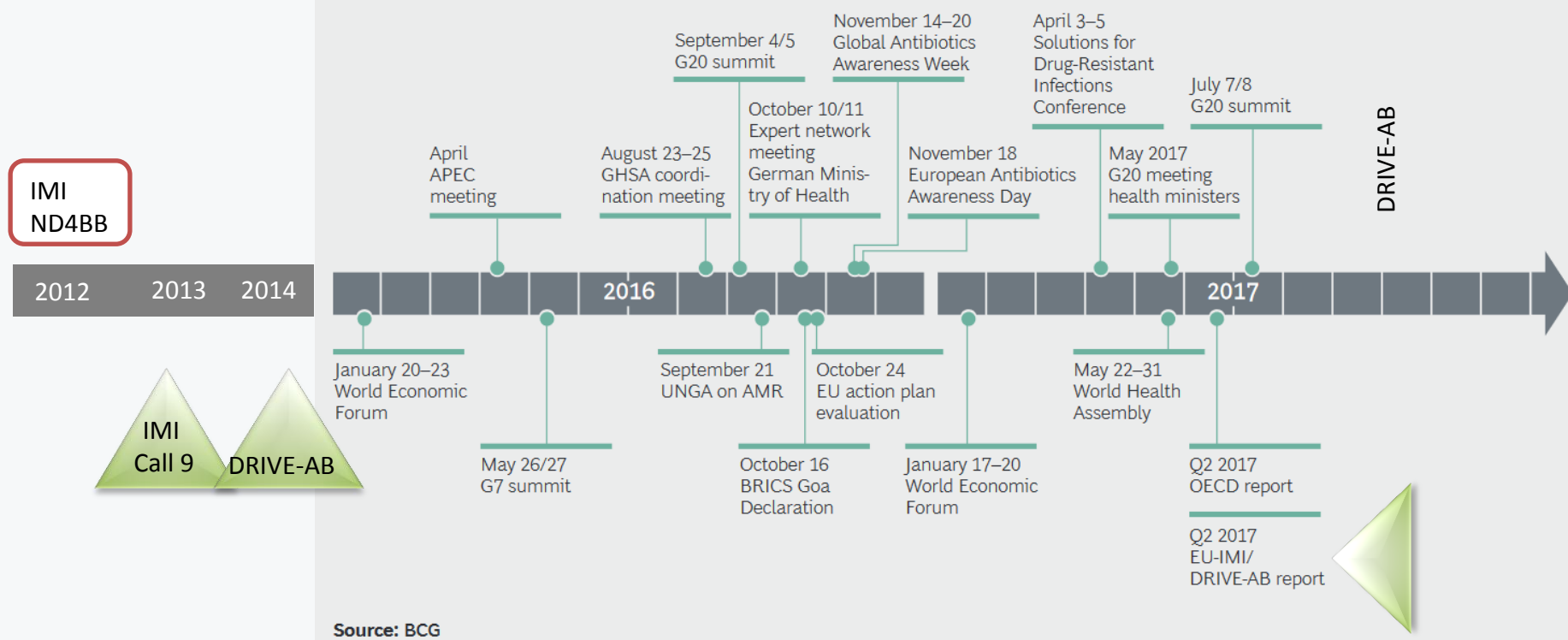
Development-focused (Gram-negative infections)

ND4BB Information Centre

Political momentum

DRIVE-AB's environment

FIGURE 4 | Policy discourse on antimicrobial resistance (AMR) is gaining momentum





The screenshot shows the official website of the European Council. At the top, there is a navigation bar with links to 'The European Council', 'The Council of the EU', 'Topics', 'Policies', 'Meetings', 'Documents & Publications', 'Press', and 'Contact'. A search bar and a language selection dropdown are also present. The main content area features a breadcrumb trail: 'Home > Press > Press releases and statements > Council conclusions on the next steps under a One Health approach to combat antimicrobial resistance'. The title of the press release is 'Council conclusions on the next steps under a One Health approach to combat antimicrobial resistance', dated 17/06/2016 at 11:40. Below the title, there is a list of tags: '17/06/2016', '11:40', 'Press release', '349/16', 'Social affairs', 'Health', 'Employment', and 'Consumer protection'. The text of the press release begins with '1. RECALLS the Council Recommendation of 15 November 2001 on the prudent use of antimicrobial agents in human medicine^[1] and the reports of December 2005, April 2010 from the Commission to the'. On the right side, there is a 'Press contacts' section listing 'Jérôme Unterhuber' as the Press officer.

[...]

16. UNDERLINES that in order to stimulate the development of new antimicrobials, alternative therapies and (rapid) diagnostics, EU and global coordination and cooperation on research programmes and incentives are needed and RECOGNISES the work done by **the Innovative Medicines Initiative (IMI) project DRIVE-AB** (Driving reinvestment in research and development and responsible antibiotic use), the proposals of the Antimicrobial Resistance Review team^[24] and the Joint Programming Initiative on Antimicrobial Resistance^[25] among others.

DRIVE-AB

**Developing new economic models to stimulate
innovation + sustainable use and equitable access
of novel antibiotics to meet unmet public health
needs.**



October 2014 – September 2017

DRIVE-AB objectives

- Create the building blocks for new economic models
 - Define “responsible” use of antibiotics (WP1A)
 - Set public health priorities and evaluate AMR burden (WP1B)
 - Develop antibiotic valuation models (WP1C)
- Create, test and validate new economic models that incentivize the discovery and development of new antibiotics, while ensuring both sustainable antibiotic use and equitable access (WP2)
- WP3A: coordination and management of the project
WP3B: Stakeholder platform and external communication
- Present the most promising schemes to policymakers and other stakeholders with implementation strategies

DRIVE-AB consortium



The British Society for Antimicrobial
Chemotherapy

Center for Anti-Infective Agents

Chatham House

London School of Economics and Political Science

Norwegian Institute of Public Health

Tel-Aviv Sourasky Medical Center

Radboud University Nijmegen Medical Centre

University of Antwerp

University of Geneva

University of Heidelberg

University of Lorraine

University of Rijeka

University of Strathclyde

University of Tübingen

Uppsala University

Wageningen University

UK

Austria

UK

UK

Norway

Israel

Netherlands

Belgium

Switzerland

Germany

France

Croatia

UK

Germany

Sweden

Netherlands

Astellas Pharma Europe

AstraZeneca

Merck

F. Hoffmann-La Roche

GlaxoSmithKline R&D

Pfizer

Sanofi-Aventis R&D

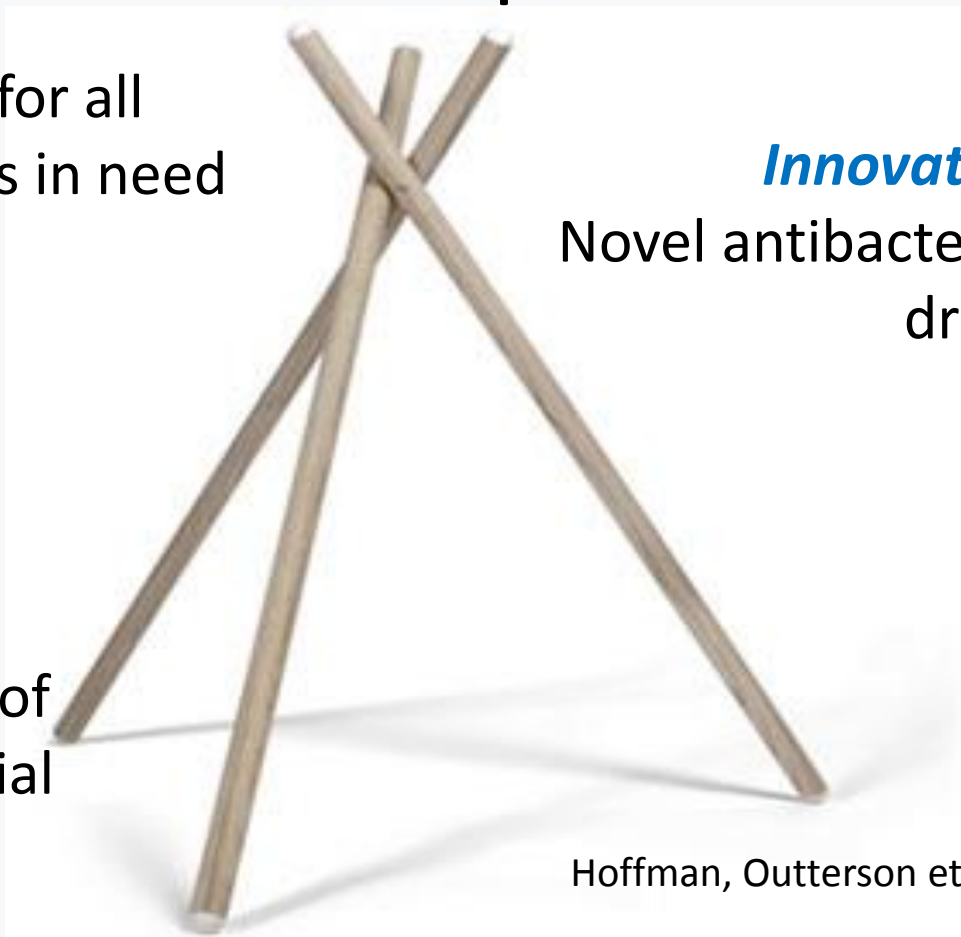
DRIVE-ABs principles

The Antibiotic Tripod

Access for all
patients in need

Innovation
Novel antibacterial
drugs

Sustainable use of
novel antibacterial
drugs



Hoffman, Outterson et al. (2015)

Large public investment required

Drug discovery

- Coordination, alignment, prioritizing of grants

Translation

- Financing solutions for SMEs

Clinical development

- PPPs
- Grants
- Master protocols
- Clinical trial networks

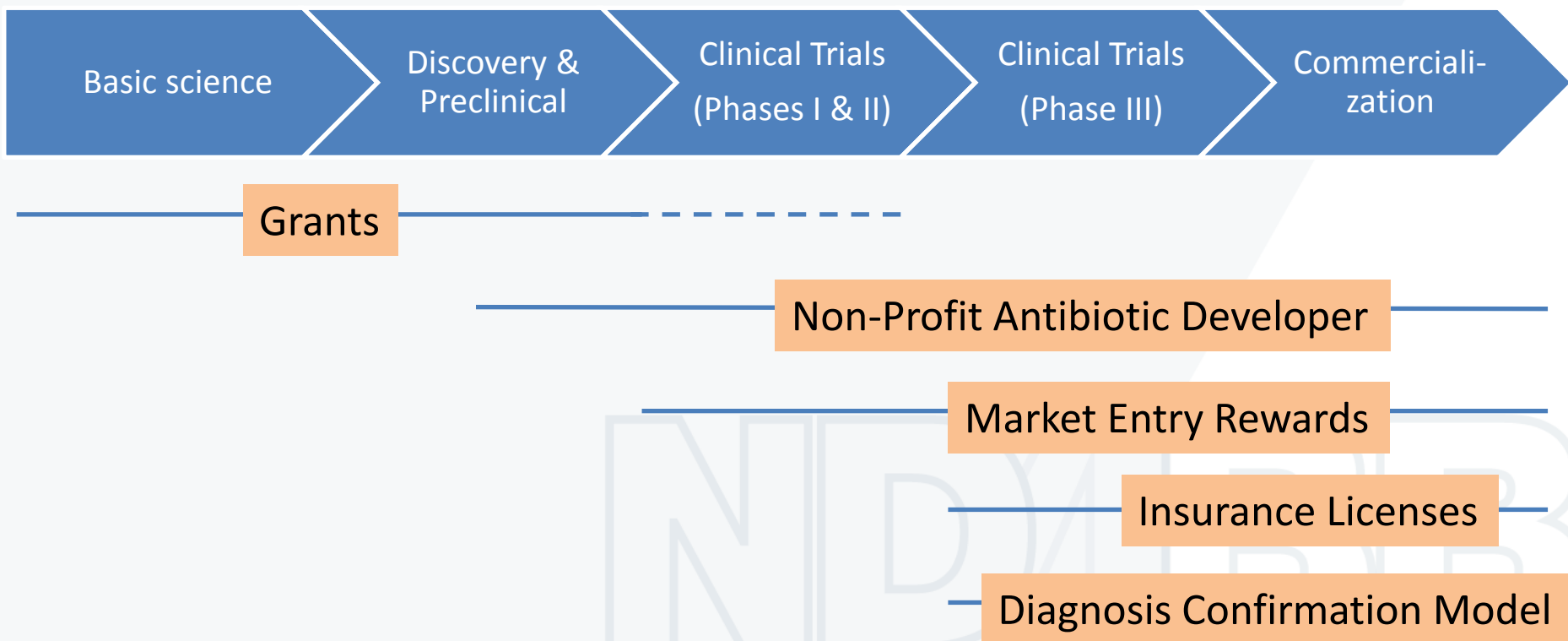
Business model

- Market entry reward

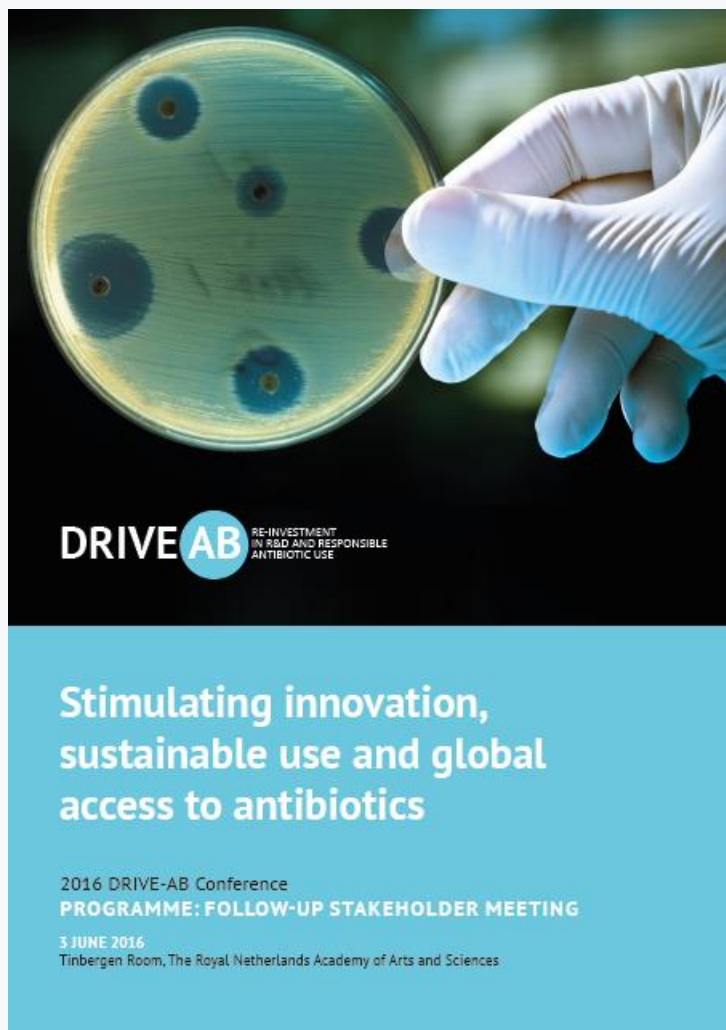
Possible incentives



DRIVE-AB's shortlist of incentives



DRIVE-AB Midterm Conference



Royal Netherlands Academy of Arts and Sciences

June 2nd plenary meeting

- 180 policy- and decision makers from EU, USA, Canada, Africa, Asia, Australia
- 4 sessions with keynote speakers and panel discussion
- Extensive briefing

June 3rd 2016 – Invitation-only session

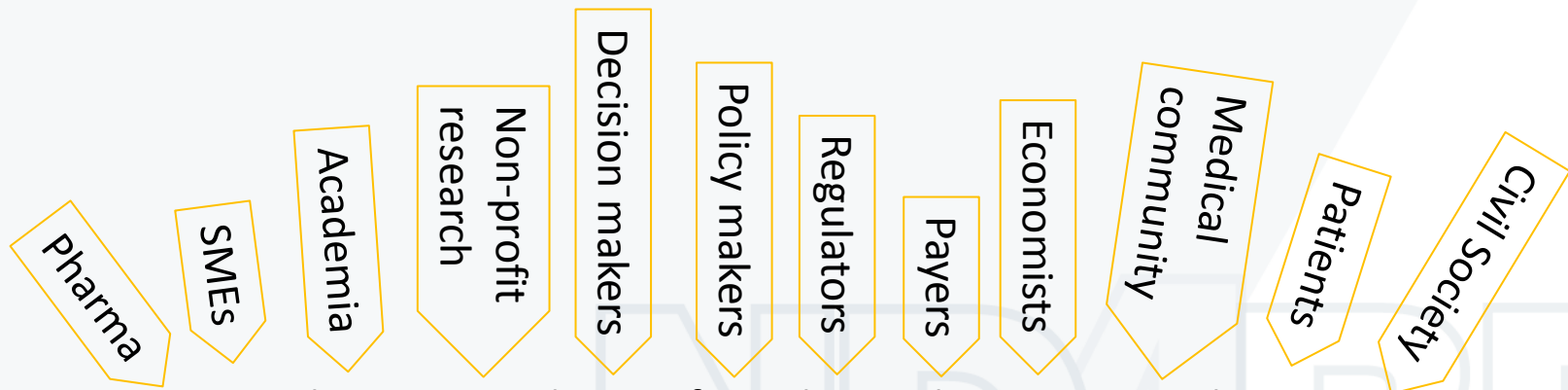
- 40 policy- and decision makers
- Discuss and get feedback on DRIVE-AB's shortlist of incentives

DRIVE-AB's challenges

- Tight timelines with high expectations
- Impact of international AMR activities/initiatives on DRIVE-AB:
 - Stakeholder exhaustion due to other AMR activities across the international agenda
 - Interference with other initiatives (e.g. UK AMR review)
- Consensus/convergence building for a wide range of partners and stakeholders

Final agenda for 2017

- Intensify engagement of policy and decision makers, key stakeholders
- Publications and laying foundation of evidence for project final recommendations
- Implementation plan
- Final stakeholder conference



Final recommendations for policy makers in September 2017

DRIVE-AB Conference in Brussels, 5-6. Sept 2017



Back up

ND4BB

2017 Meetings

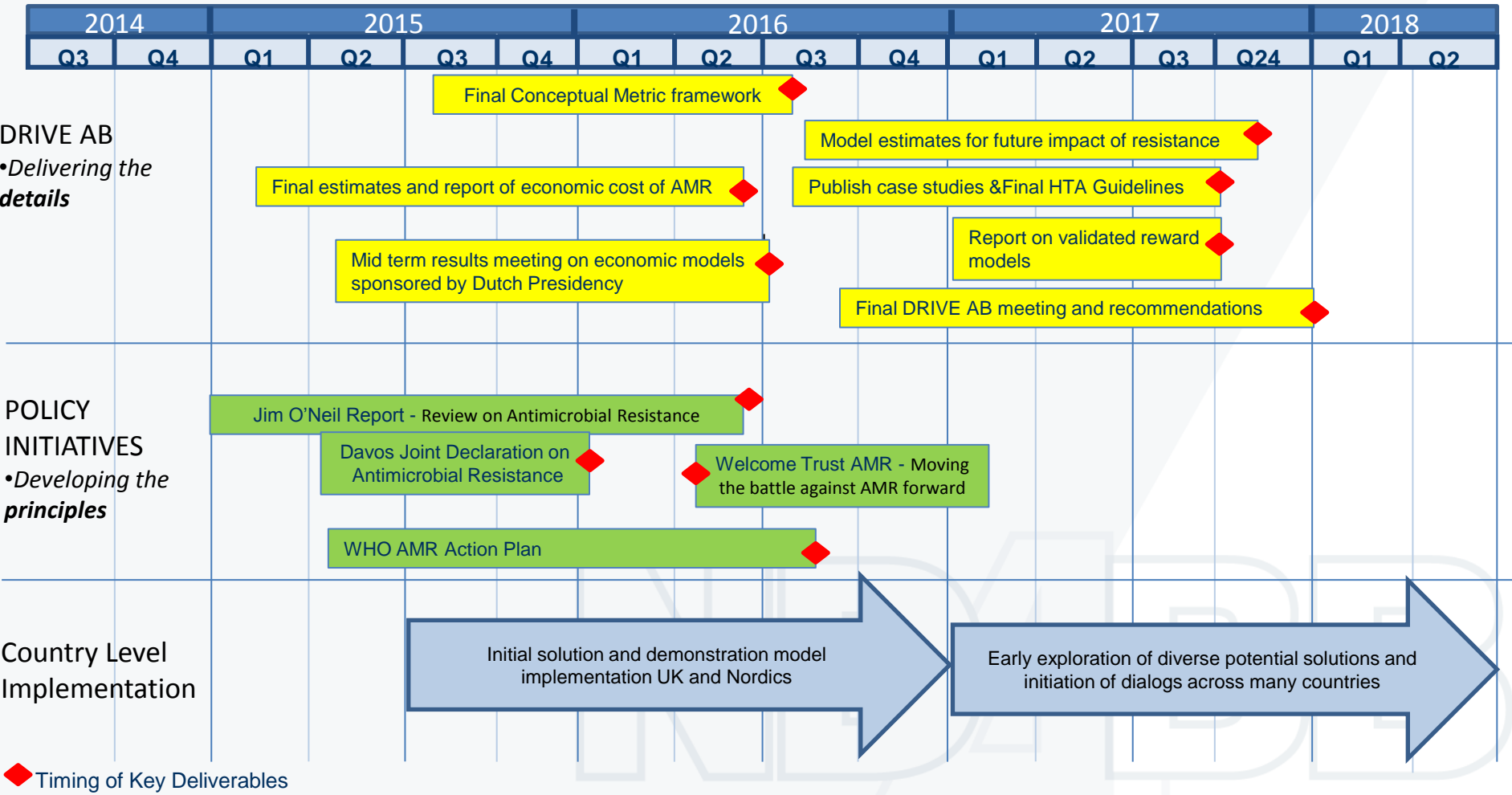
DRIVE AB organized stakeholder input meetings

- Autumn 2016: Universities Allied for Essential Medicines (UAEM) and WP2 telecon to involve CSOs
- Early 2017: SMEs and WP2 F2F to finalize reward models

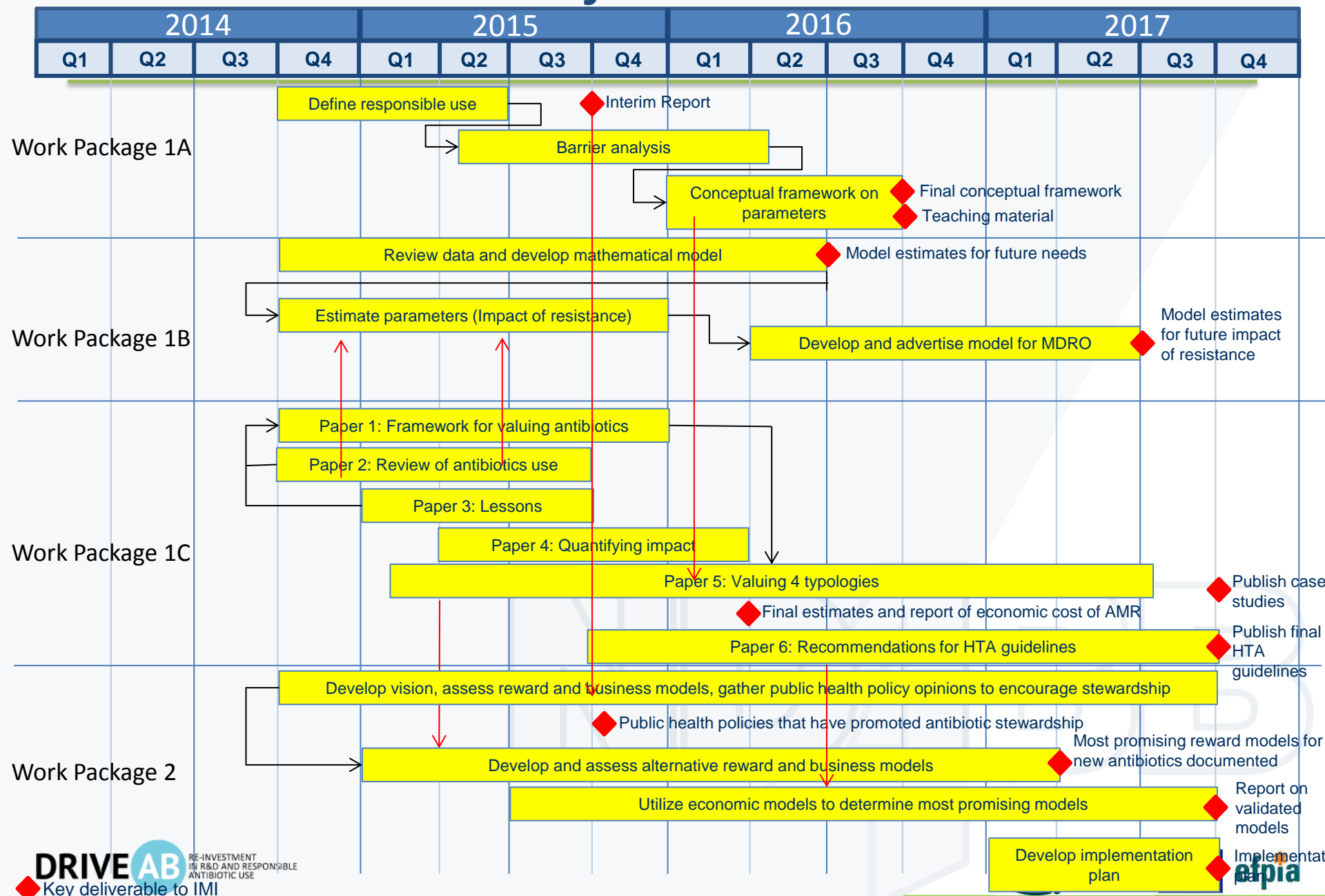
DRIVE AB organized policy meetings

- Brocher event
- Side event of next year's World Health Assembly
- WP1C workshop with NICE
- Final DRIVE-AB conference

The Journey to Alternative Economic Models



DRIVE-AB Project Plan



DRIVE-AB Conference in Amsterdam



Jos van der Meer, President European Academies' Science Advisory Council, Royal Netherlands Academy of Arts and Sciences

Angelique Berg, Director General at Department of Health, Ministry of Health, Welfare and Sport, The Netherlands

Martin Seychell, European Commission, European Commission, DG SANTE

Dame Sally Davies, Department of Health, England

Marie-Paule Kieny, World Health Organization

Marc Sprenger, World Health Organization

Dominique Monnet, European Centre for Disease Prevention and Control

Arjun Srinivasan, U.S. Centers for Disease Control and Prevention

Suwit Wibulpolprasert, International Health Policy Program, Ministry of Public Health, Thailand

Shiva Dustdar, European Investment Bank

Joe Larsen, US Biomedical Advanced Research and Development Authority

Lynn Marks, GSK Senior Clinical Advisor to the Infectious Disease Therapy Area Unit

Julie Gerberding, MSD, Executive Vice President for Strategic Communications, Global Public Policy and Population Health

Anja Schreijer, Independent Consultant in Antimicrobial Resistance, WHO/Europe

Betuel Sigauque, Manhica Health Research Centre, Mozambique

Jean-Pierre Paccaud, Drugs for Neglected Diseases *initiative* and Global Antibiotic Research and Development partnership

Florence Séjourné, BEAM Alliance

David Heymann, Chatham House and DRIVE-AB partner

Jeremy Knox, Review on Antimicrobial Resistance, United Kingdom

Marc Mendelson, Federation of Infectious Diseases Societies of Southern Africa

Manica Balasegaram, Médecins Sans Frontières Access Campaign

Christian Brun-Buisson, Ministerial Delegate on AMR, Ministry of Social Affairs and Health, France



DRIVE-AB's shortlist of incentives

Incentive/Model	Type	Type of innovation stimulated	De-linkage
Grants	Push	Early phase research	n/a
Non-Profit Antibiotic Developer	Push	Incremental innovation and development with a higher risk profile	n/a
Diagnosis Confirmation Model	Pull	Greater diversity of broad and narrow-spectrum antibiotics with significant improvements	No
Insurance Licenses	Pull	Rarely used, emergency antibiotics	Yes
Market Entry Rewards	Pull	Most pressing public health threats	Yes