



Stop TB Task Force Presentation on Economic Issues in TB Vaccine Development

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TB Vaccines: Second Global Forum

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Stop TB Task Force on Economic Issues in TB Vaccine Development

- Overview of Task Force on Economics and Product Profiles
 - 3 meetings to date, 2008-2010
 - Chair: Gerard Cunningham, Bill & Melinda Gates Foundation
 - Major interests: epidemiology/disease burden, vaccine efficacy and cost-effectiveness, target product profiles, WHO and regulatory pathways
 - Project report: Analysis of Barriers and Drivers for Introduction of New TB Vaccines

Market Research: Barriers and Drivers to Introduction of New TB Vaccines

Key Project elements

- Test 3 new TB vaccines product profiles and get feedback from decision makers or influencers in high burden countries on desired product images and safety/efficacy profile, likelihood of rapid adoption, funding aspects
- Research Methodology:
 - 86 one-on-one, structured interviews conducted by Baird's CMC expert professionals in
 - 8 high TB burden countries: Brazil, Cambodia, China, India, Mozambique, Romania, Russia, South Africa
 - Structured analysis and synthesis

Market Research: Barriers and Drivers to Introduction of New TB Vaccines

Categories of Respondents Interviewed	Percentage of Total Respondents
Senior Ministry of Health (MoH) Civil Servants responsible for vaccine introduction (or trusted advisers, in China)	11%
MoH Technical Experts involved in delivering EPI programmes	17%
Senior Ministry of Finance (MoF) Civil Servants (active or recently retired) responsible for health budgets	12%
Senior Public Health Clinicians / Paediatricians who run professional societies or who act as advisers to government	19%
NGOs with an interest in public health and children's health	20%
Parliamentarians with an interest in the field	10%
Senior journalists with an interest in the field	10%

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General Health care priorities – top ranked:

- Improved primary health care, esp. in remote locations, mother and child care, vaccine coverage, disease prevention, better management systems, chronic diseases, HIV/AIDS

TB as a Health care priority – not #1

- Overall: ***neglected and doesn't get the attention it needs***, overshadowed by higher focus on HIV, problem is big and probably increasing, but not sure because of difficulty diagnosing, better treatment and ***better vaccine*** needed

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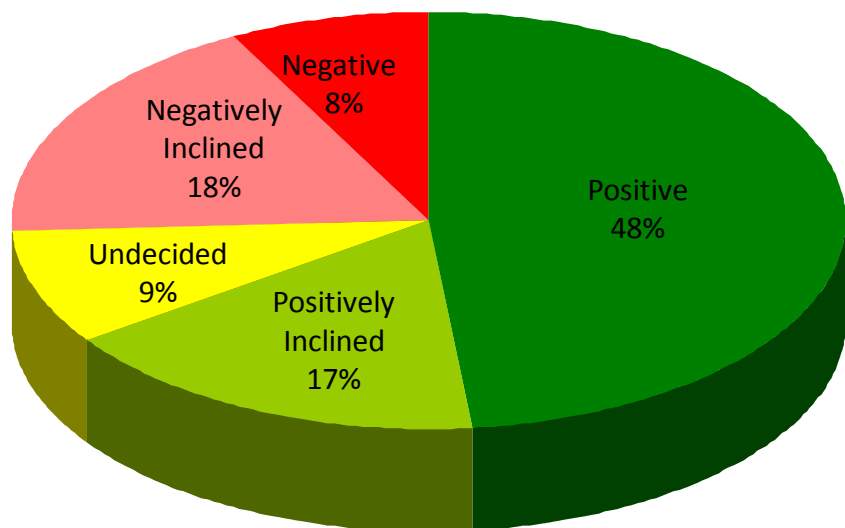
SCENARIO ONE (Show Card)

- New BCG vaccine available in 2016
- Safer in HIV+ infants
- At least as effective as current BCG
- Designed to work with second, different vaccine which will be
 - Available later than 2016
 - Will be given in infancy and early adolescence
- New BCG will cost same as current BCG

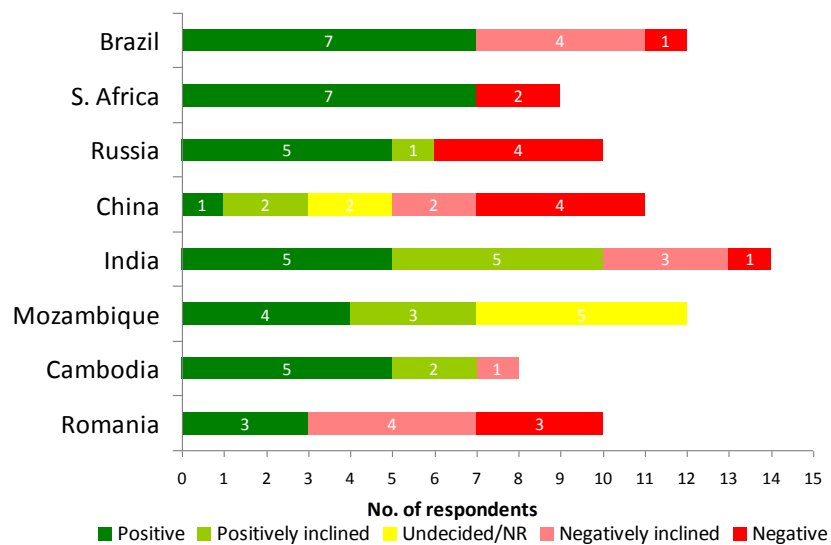
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First Reactions -- SCENARIO ONE

Overall Response



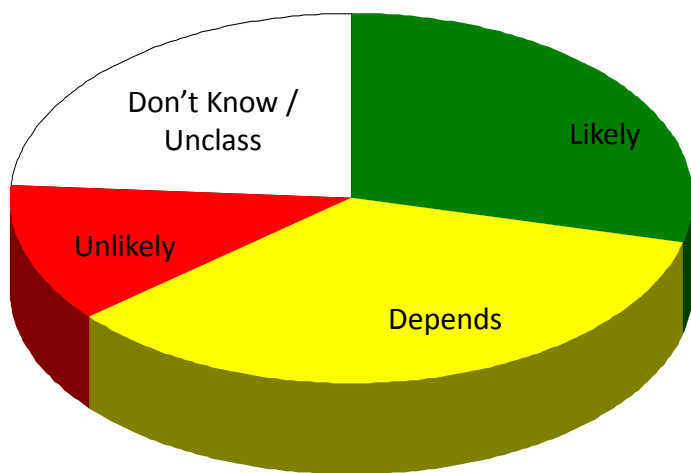
Response by Country



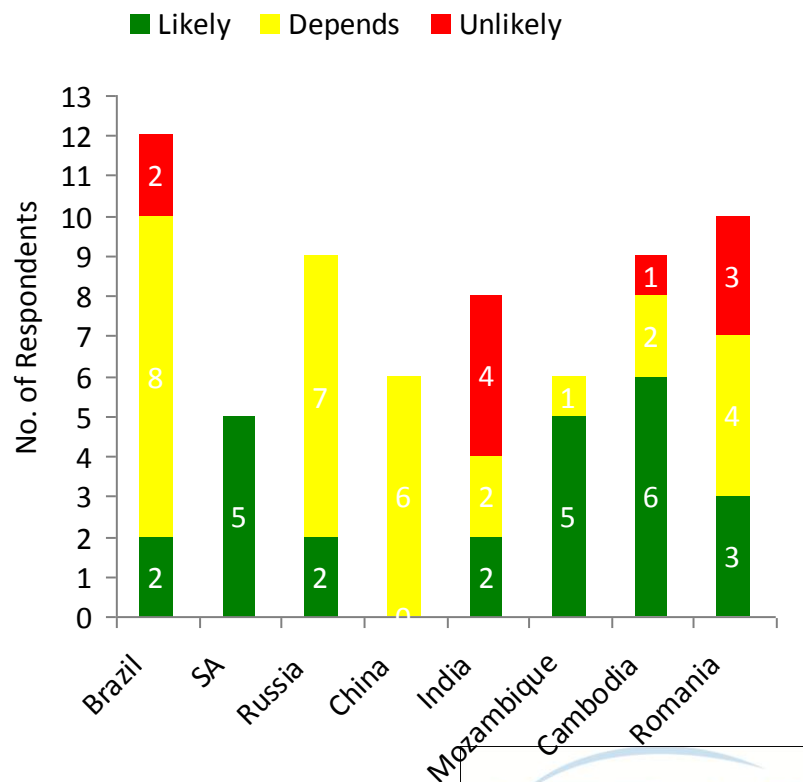
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How likely to adopt within three years of first license anywhere – SCENARIO ONE

Overall Response



Response by Country



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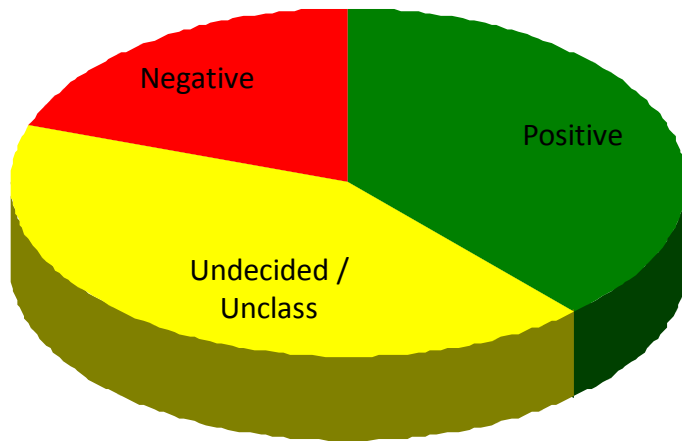
SCENARIO TWO (Show Card)

- New or old BCG and new, different vaccine in 2016
 - BCG soon after birth
 - One extra vaccination during EPI
 - Another extra vaccination in adolescence
- ***Reduction in symptomatic disease by $\geq 60\%$***
- Fewer new infections than BCG alone
- ***50% lower incidence of TB by 2050***
 - 24 million cases and 4 million deaths avoided in WHO SE Asia region
 - Similar effects in other regions
- Cost: total cost US\$4 per child

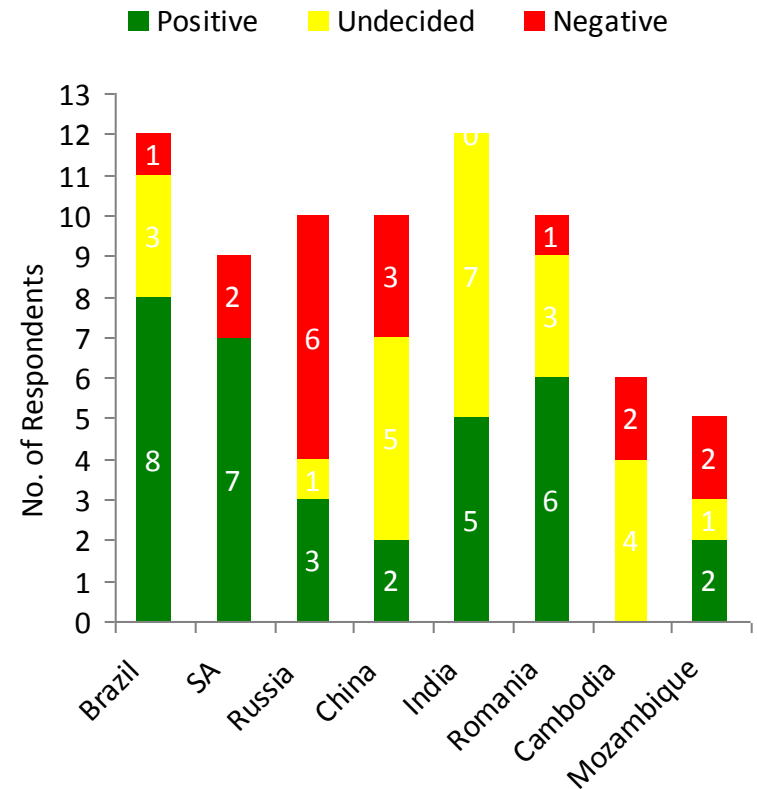
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First Reactions -- SCENARIO TWO

Overall Response



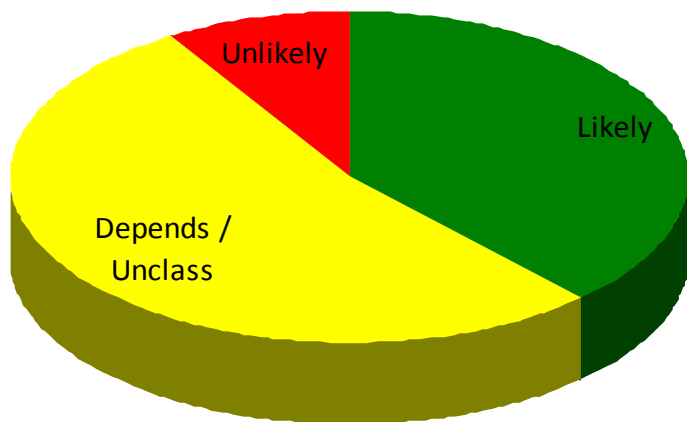
Response by Country



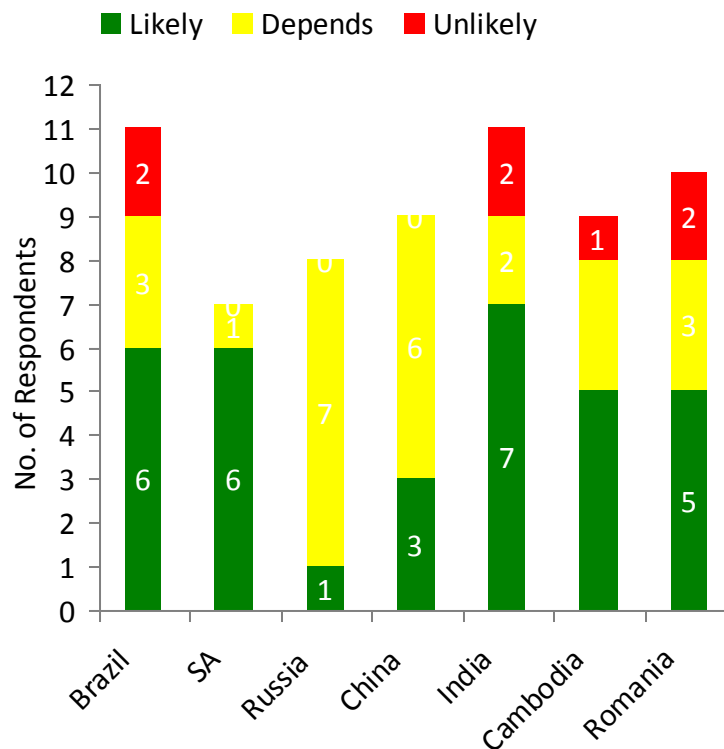
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How likely to adopt within three years of first license anywhere – SCENARIO TWO

Overall Response



Response by Country



Market Research: Barriers and Drivers to Introduction of New TB Vaccines

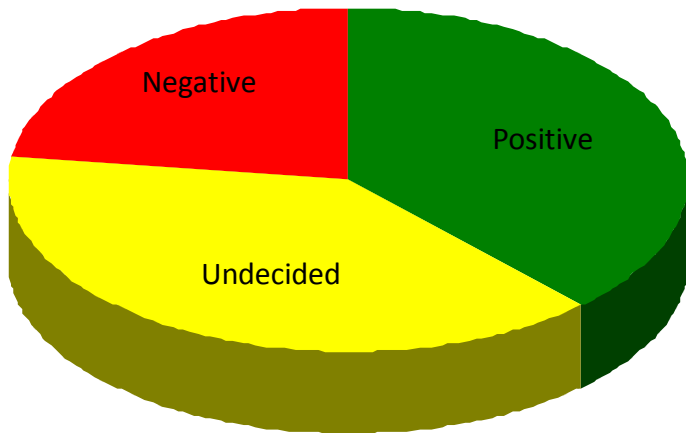
SCENARIO THREE (Show Card)

- New or old BCG and new booster vaccine in 2016
 - One booster during EPI
 - One booster in adolescence
- ***Booster delivered by aerosol delivery device***
- ***Reduction in symptomatic disease by $\geq 60\%$***
- Fewer new infections than BCG alone
- Estimated impacts vary
 - Depending on whether vaccination of children was followed by a “catch up” universal campaign
- Cost: total cost US\$4 per child

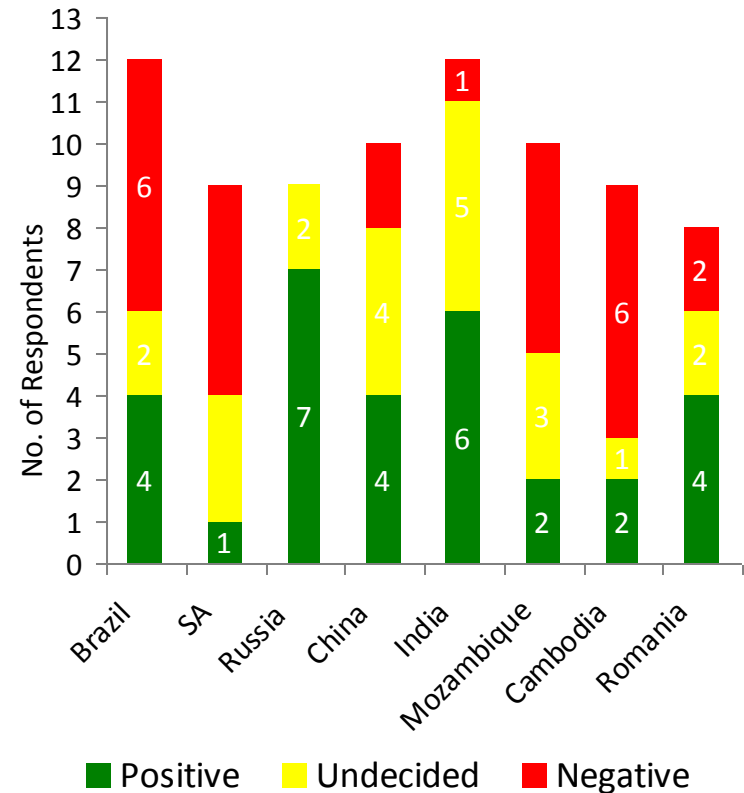
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First Reactions -- SCENARIO THREE

Overall Response

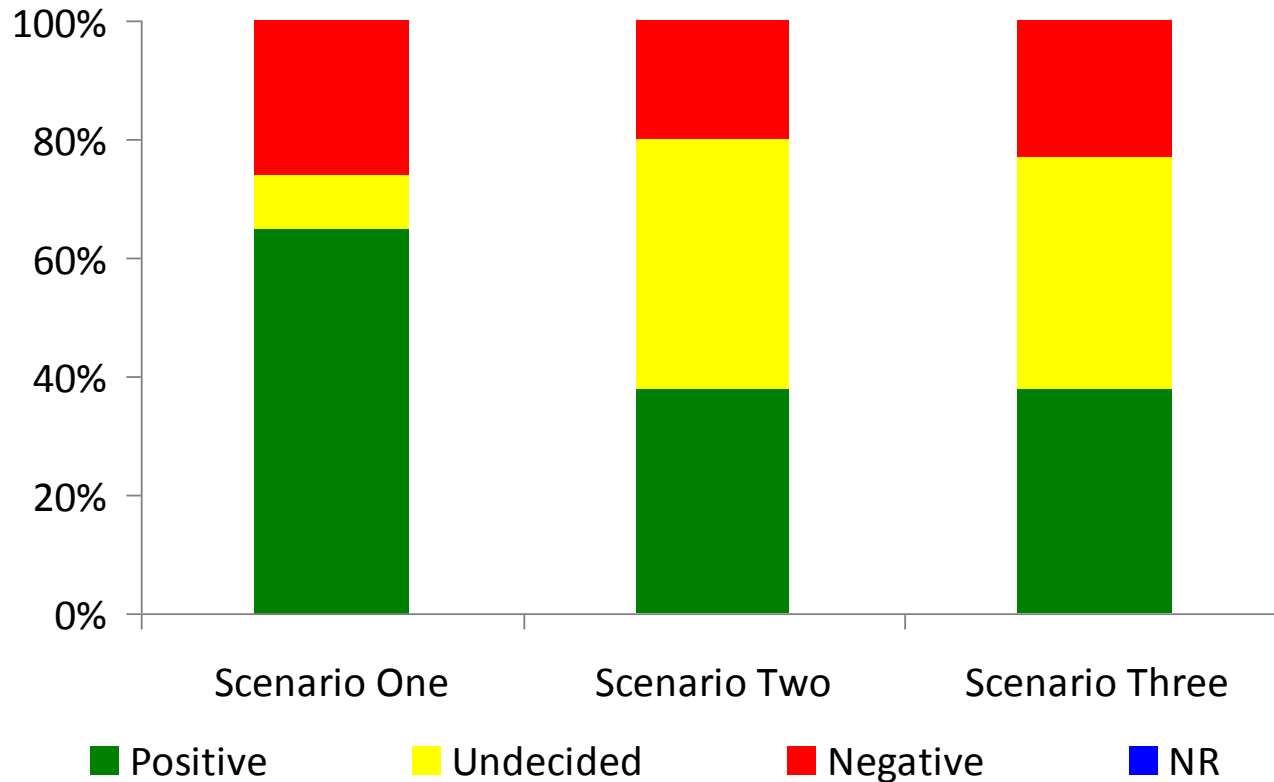


Response by Country



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First Reactions -- ALL SCENARIOS



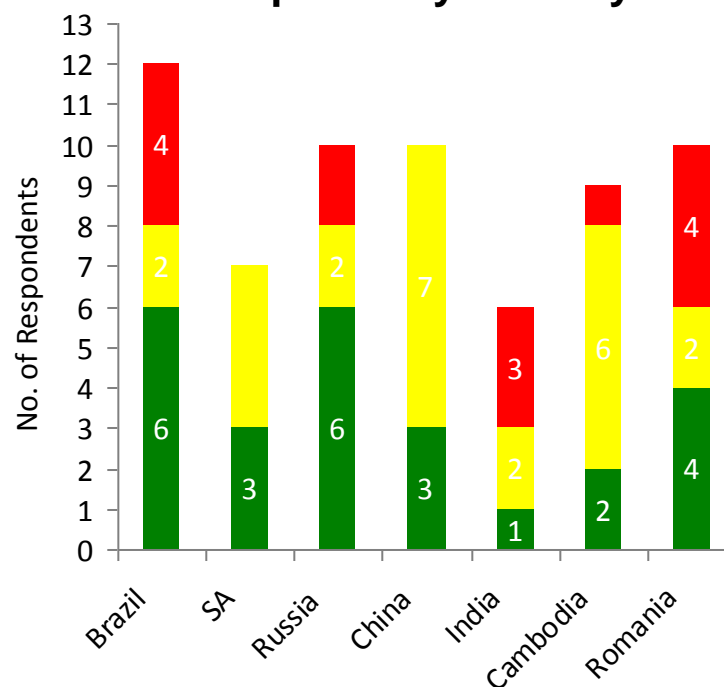
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Would you take money from existing programs for the vaccine in SCENARIO TWO?

Overall Response



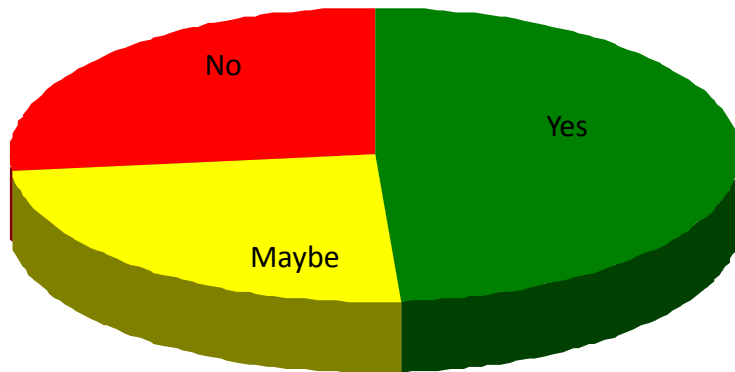
Response by Country



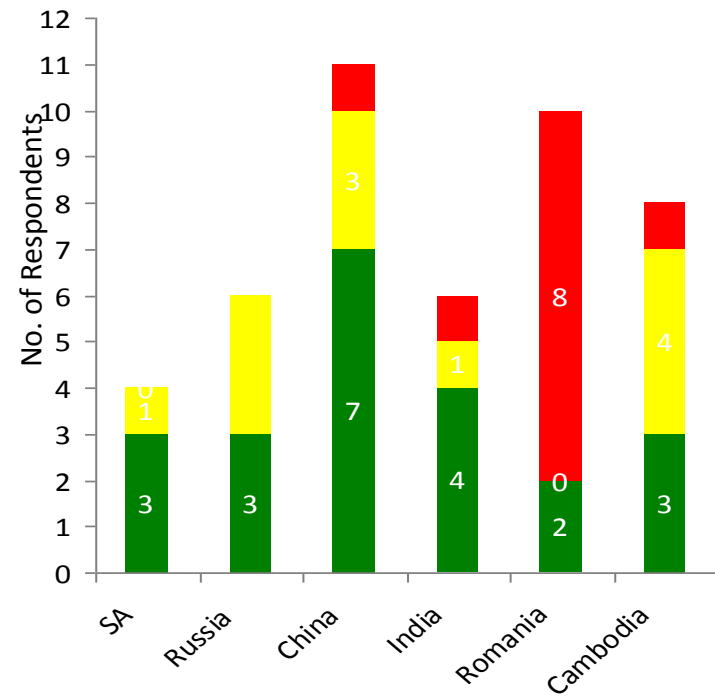
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If 80% donor co-funding were available, would you cut other programs to meet your country's 20% share?

Overall Response



Response by Country



Market Research: Barriers and Drivers to Introduction of New TB Vaccines

Conclusions – I: key Barriers and **Drivers**, lessons learned:

- Wide recognition that TB is serious and neglected problem; MDR-TB threat
- Widespread dissatisfaction with current BCGs
- Likely demand for using a partially effective vaccine against TB that is better than BCG
- Willingness to commit to rapid introduction
- FDA or EMEA approval will speed adoption
- Willingness to spend money out of existing budgets for prime-boost; private sector

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Conclusions – II: key **Barriers**, Drivers, lessons learned

- Modest benefits not seen for many (20-30) years
- Fatalism about TB – lack of political will and competing priorities, e.g., HIV/AIDS
- Waiting for strong efficacy data, esp. in own country
- Some resistance, but not so much, to adolescent boosting
- Some skepticism about aerosol delivery

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Conclusions – III: key Barriers, Drivers, **Lessons Learned**

- There is a great deal of heterogeneity of responses both within and between countries; assumptions may have affected some responses, e.g., re new BCG efficacy
- Strong efficacy data will be a critical success factor for introduction, including in-country data
- Cost, if kept low, not likely to be major issue; not an issue in private markets
- Education and preparation will be necessary, but raising awareness and expectations too high needs to be avoided

Market Research: Barriers and Drivers to Introduction of New TB Vaccines

Acknowledgements:

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