

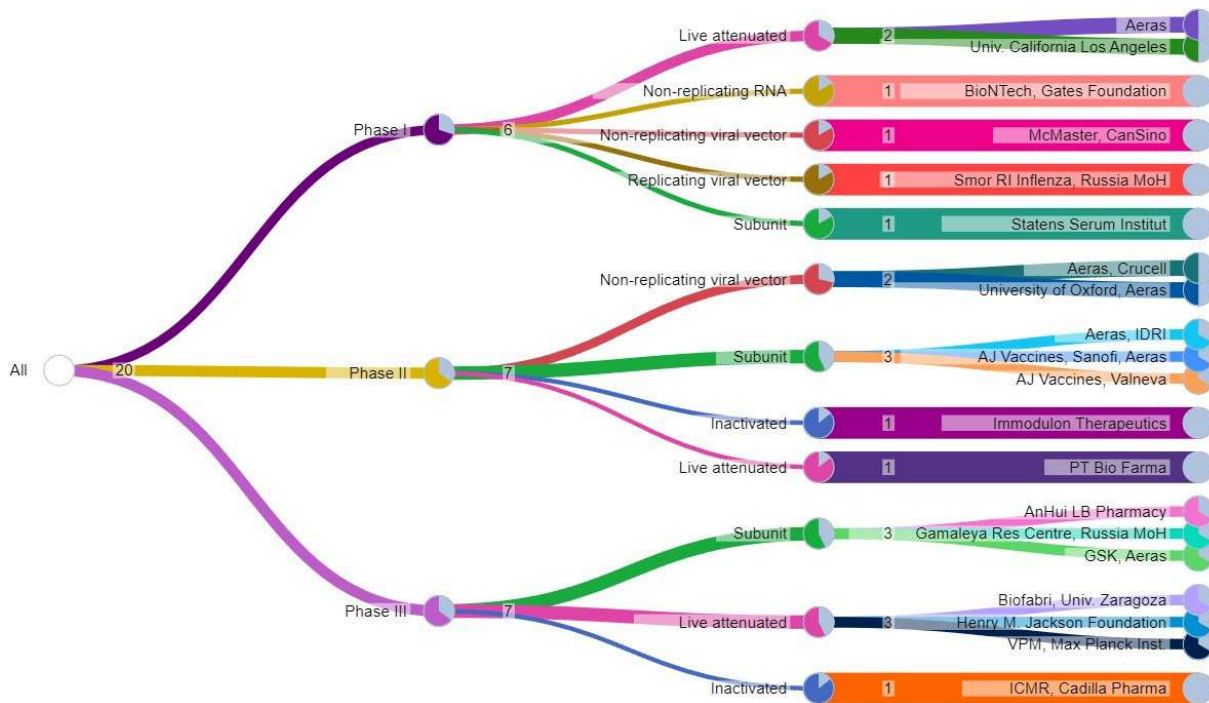
Plenary 2: Global and regional enablers for the introduction of new TB vaccines

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Manufacturer's Perspective

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Bio-Manguinhos - Fiocruz

Detailed TB Vaccine Pipeline in clinical phase by platform and leading organization



Tuberculosis vaccines in clinical development worldwide, by phase and technology. Data source: AdisInsight (extracted July/24) and other sources (Looney et al., 2023; da Costa et al., 2024; StopTBPartnership (<https://www.stoptb.org>)).

Source: Competitive Intelligence Office/Bio-Manguinhos, Fiocruz.



Lack of biomarkers



Clinical trials needs



GMP infrastructure



Harmonization of Regulatory Process

Anvisa is considered a stringent NRA for Latin America, currently in the WHO prequalification process aims to achieve level 4.

ICH and PIC/S Member

ANVISA => Mercosul agreement

ANVISA => FDA “Mutual confidentiality agreement”

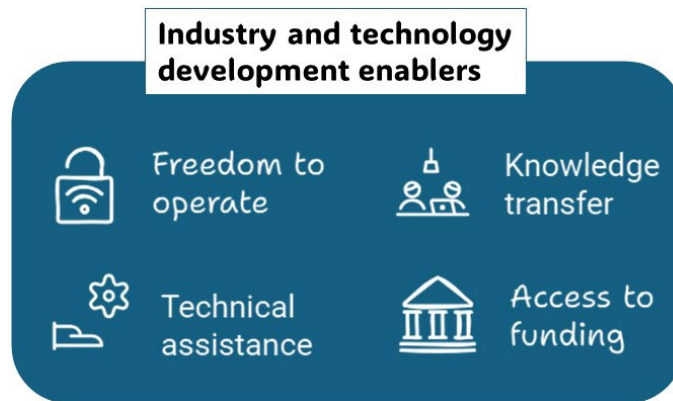
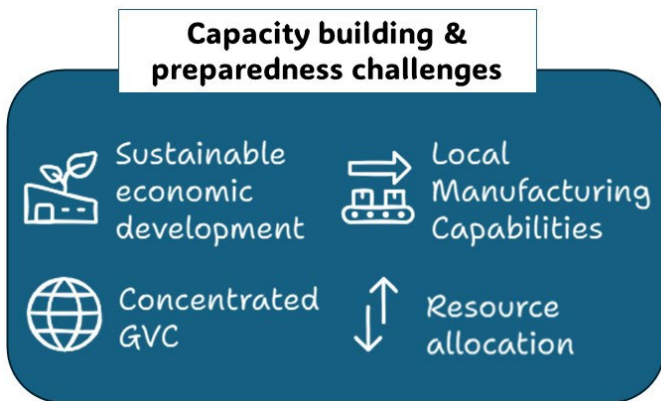
ANVISA => EMA “OPEN Program”

EMA = EU-M4ALL and PRIME tools



Main challenges and enablers for vaccine capacity building in developing countries

LMICs differ significantly in terms of industrial and technological capabilities, and all of them in different degrees face similar challenges. To assure timely and equitable access to vaccines these countries need FTO, technical assistance, access to adequate and long-term funding, and fair TT agreements





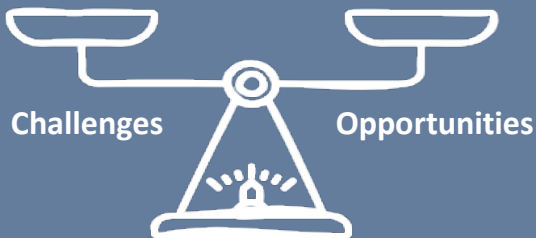
There is no one-size fits all solution

Partnering is not trivial. South-south and north-south collaboration has opportunities and challenges. Hybrid strategies, provided equitable access is granted, where health is a human right, and sustainable business models is a two-edged sword for all partners





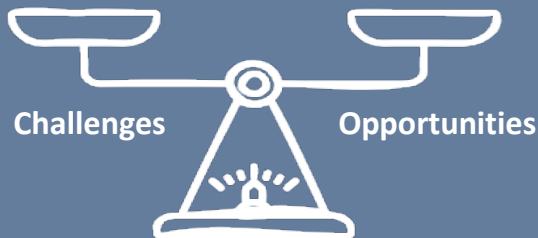
Challenges and opportunities in South-south partnerships

- | | |
|---|--|
|  Public policy alignment |  Build resilient health systems |
|  Long-term financing |  Supply chain development |
|  Adequate infrastructure |  Regional collaboration |
|  Resource limitations |  Local solutions |



Challenges and opportunities in North-south partnerships

- | | |
|---|--|
|  Freedom to operate |  Technical assistance |
|  neglecting local needs |  Timely access to products |
|  inequitable power dynamics |  Global Distribution Networks |
|  Dependency on external aid |  Knowledge transfer |





Thank you
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