

## SESSION: CLINICAL DEVELOPMENT OF NEW TB VACCINES

Co-Chairs: Monde Muyoyeta and Ann Ginsberg

Virtual Global Forum 21 April 2021

### PROGRESS!

1921 – BCG first used in infant



 2018 – BCG revaccination results announced at 5<sup>th</sup> Global Forum

45% VE (95%CI: 6.4,68.1) against sustained IGRA conversion in *M.tb*-uninfected adolescents

2019 – M72 Ph2b results published

50% VE (95%CI: 2.1,74.2) against TB disease in HIV(-), QFT+ adults with 3 years follow-up

### Section for the Study of Disease in Children.

June 9, 1931

### Preventive Vaccination Against Tuberculosis with BCG.

By Professor A. Calmette.

(Pasteur Institute, Paris.)

SINCE Robert Koch discovered the tubercle bacillus, experimental evidence has been obtained, especially during the last thirty years, that the majority of human beings are spontaneously vaccinated against tuberculosis in the first period of life by the absorption of a few bacilli present in milk or any other food, or penetrating into the organism by way of mucous membranes or even of the skin. Such spontaneous infections are nearly inevitable, because of the ubiquity of the tubercle bacillus expectorated by consumptives and propagated everywhere by dust and files contained in nearly liked with each of the same of the same

Proc R Soc Med. 1931 Sep; 24(11): 1481-1490

The NEW ENGLAND JOURNAL of MEDICINE

#### ORIGINAL ARTICLE

## Prevention of *M. tuberculosis* Infection with H4:IC31 Vaccine or BCG Revaccination

E. Nemes, H. Geldenhuys, V. Rozot, K.T. Rutkowski, F. Ratangee, N. Bilek, S. Mabwe, L. Makhethe, M. Erasmus, A. Toefy, H. Mulenga, W.A. Hanekom, S.G. Self, L.-G. Bekker, R. Ryall,\* S. Gurunathan, C.A. DiazGranados, P. Anders I. Kromann, T. Evans, R.D. Ellis, B. Landry, D.A. Hokey, R. Hopkins, A.M. Ginsberg, T.J. Scriba, and M. Hatherill, for the C-040-404 Study Team?

The NEW ENGLAND JOURNAL of MEDICINE

#### ORIGINAL ARTICLE

# Final Analysis of a Trial of M72/AS01<sub>E</sub> Vaccine to Prevent Tuberculosis

D.R. Tait, M. Hatherill, O. Van Der Meeren, A.M. Ginsberg, E. Van Brakel,
B. Salaun, T.J. Scriba, E.J. Akite, H.M. Ayles, A. Bollaerts, M.-A. Demoitié,
A. Diacon, T.G. Evans, P. Gillard, E. Hellström, J.C. Innes, M. Lempicki,
M. Malahleha, N. Martinson, D. Mesia Vela, M. Muyoyeta, V. Nduba,
T.G. Pascal, M. Tameris, F. Thienemann, R.J. Wilkinson, and F. Roman

### TAKEAWAYS FROM RECENT EFFICACY TRIALS

- Improved TB vaccines are feasible
- BCG revaccination: Potential new use of BCG protecting high risk, uninfected populations from *M.tb* infection
- M72/AS01E POC: Subunit vaccines (expressing as few as 2 *M.tb* antigens)
  can be protective <u>and</u> vaccines can be used to protect people with LTBI (QFT+)
  from developing active TB
- Empiric product development still has a role; human efficacy data are crucial for advancing TB vaccine development
- Clinical and upstream research should be conducted in parallel, continuously informing each other

BEWARE

Beware of dog(ma)!

## GLOBAL CLINICAL PIPELINE OF TB VACCINE CANDIDATES



