## **GAUTENG DEPARTMENT OF HEALTH**

**COVID-19 vaccine for Workers: Occupational Health Perspective** 

4th March 2021



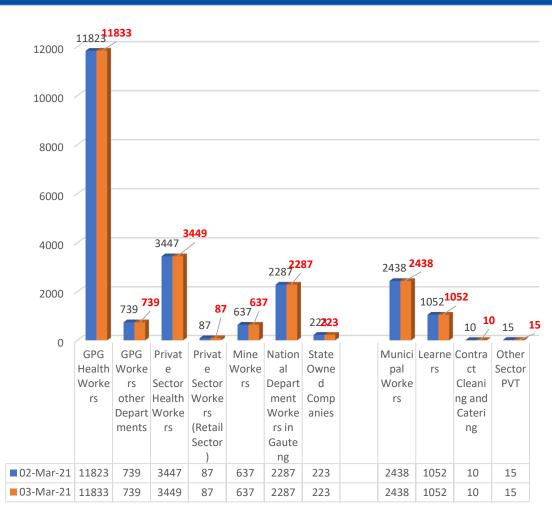






#### **SARS Cov-2 Infected workers in Gauteng. Health Workers Infected the most**

- 11833 COVID-19 Infected GDOH Health Workers. 5 New cases in the last 24 hours; 0% increase in new infections.
- 2 Demised in the last 24 hours.
- Infections in other sectors and among learners have not increased in the last 24 hours.
- Total Number who demised 98 Health Workers in the Public Sector as the 3rd March 2021.
- 2 New Infection reported in Private Sector HW on the 3<sup>rd</sup> March 2021.
- 0 New Infections in State Owned Companies







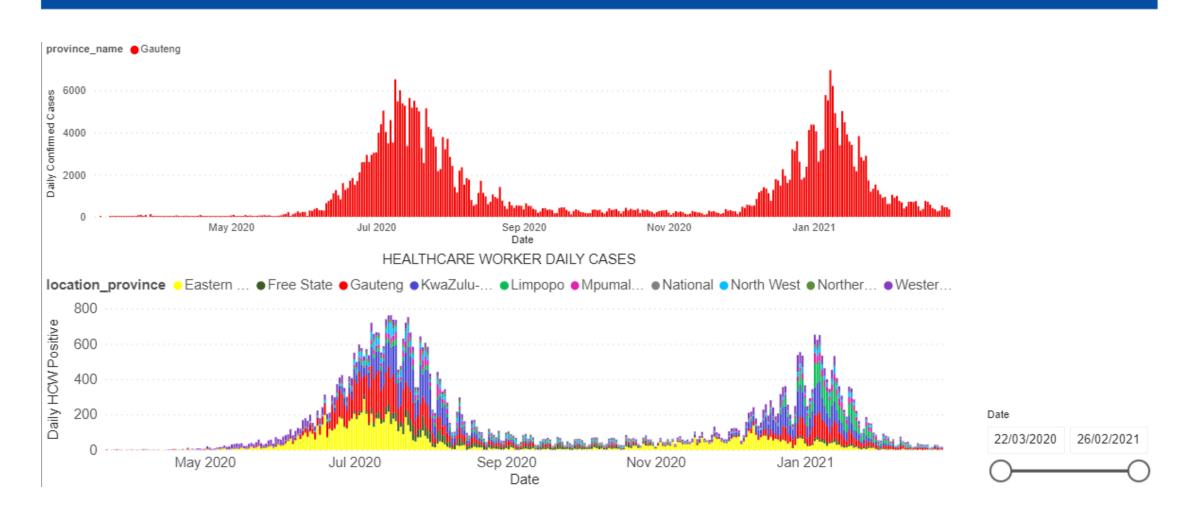
#### Decomposition tree of Gauteng Hospitalised Health Workers, Discharged, Who Died, and Transferred to there hospitals







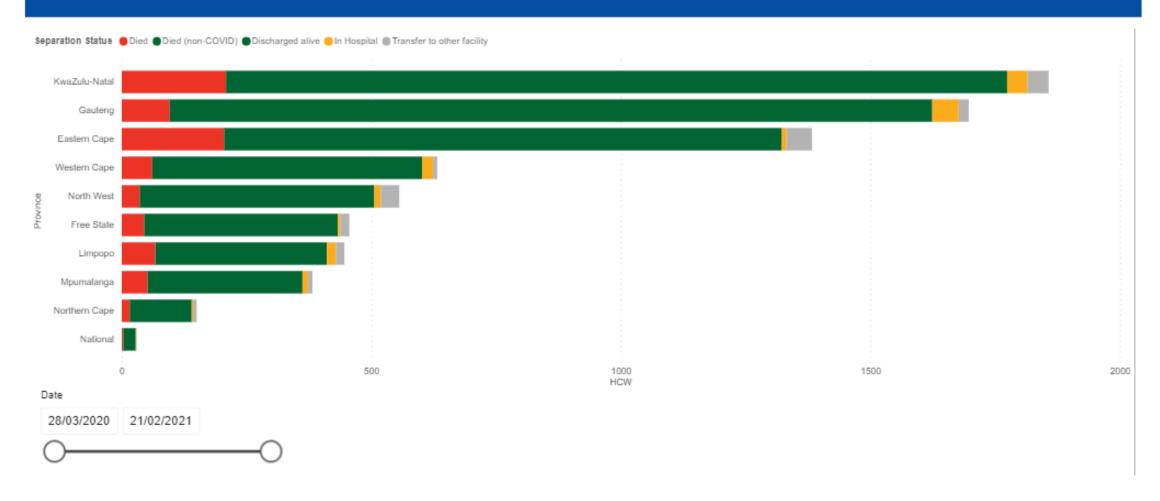
## Decline in COVID-19 infections has not come down to COVID-19infections before the fist surge







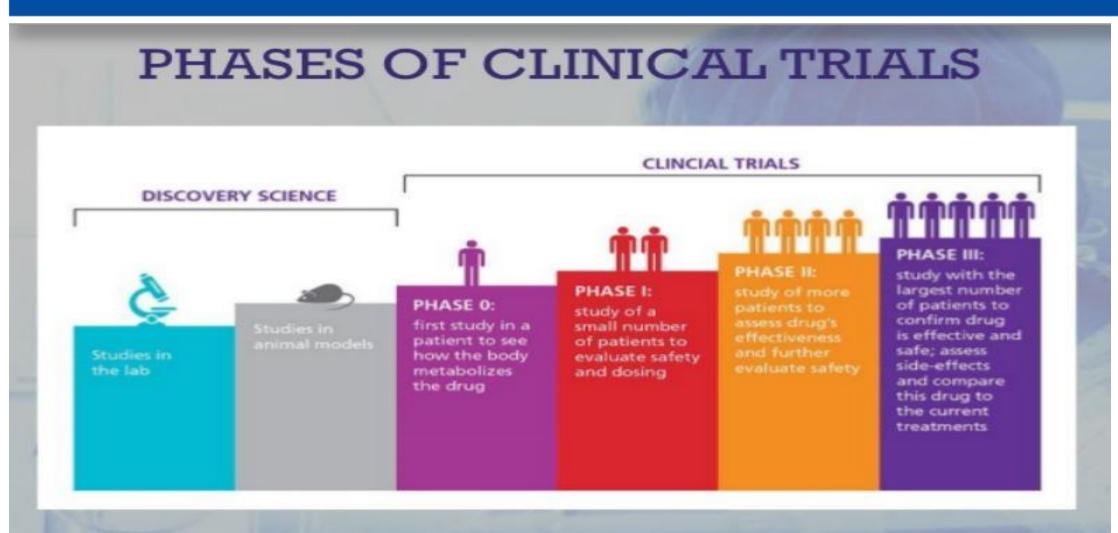
#### More Health workers hospitalised in Gauteng than any other province: Implications for post COVID-19 complications and surveillance







## Phases of Vaccination Trials







### Difference between Phases 3a and 3b of Clinical Trials

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#### Phase 3 a

- Carried out in a large number of or in special category (e.g. Ensemble Trail in SA on J&J vaccine)
- Regulatory requitement (SAHPRA)
- Generates Data on safety and efficiency

#### Phase 3b

- Extended trial of 3a after applying for approval but before launch
- Also known as "label expansion"
- To show the drug works for additional types of patients/diseases beyond the original use for which the drug was approved for marketing
- These may supplement or complete the earlier trails or may be directed to Phase IV





## PHASED APPROACH FOR VACCINE INTRODUCTION

Phase I

Phase II

Phase III

#### **Health care workers (HCW)**

All health sector workers

Target population:

1,250,000(public and private sector)

63 000 as 21% of 300 000 doses

105 000 as 21% of 500 000 doses

**Essential workers** 

Target population: 2,500,000

Persons in congregate settings

Target population: 1,100,000

Persons >60 years

Target population: 5,000,000

Persons >18 years with co-morbidities

Target population: 8,000,000

Total: 16 600 000

Other persons >18 years

Target population: 22,500,000

Open label programme

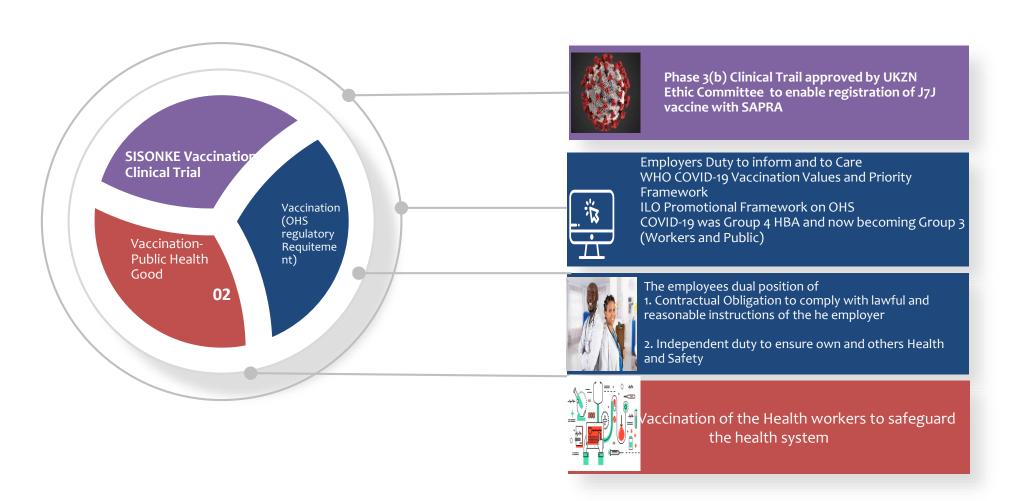
**Expansion through usual vaccination centres** 

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License for use in Open Label Programme



# ALLIGNMENT OF SISONKE Phase 3b Clinical Trail and OHS HBA categories and SA Launch of Vaccination Programme





## Duties of State, Employers, Employees regarding Vaccination and Trails



- (b) security and control of their body and
- (c) not to be subjected to medical and scientific experiments without their informed consent



s8General duties of employers to their employees

8(1) Provide and maintain as far as reasonably practicable a working environment that is safe and without risk to the health of employees.



COVID-19 is an Occupationally Compensable

S16 (a) Comp Fund payment of compensation, cost of medical aid, to or on behalf of the employees

S22 (1) The right of the employee to compensation subject to disablement

The Management of Adverse events and Serious Adverse events will be for the purposes of

- 1. Management of Clinical Trial (Phase 3b)
- 2. Management of Occupational injury and or Disease (Clinical Trial in an Occupational setting)
- 3. Management of quality of Vaccination Programme (Post Phase 3b trial)



## Conclusion

- The Vaccination of employees in a Phase 3b trial is at the same time a an Occupational Health Intervention to monitor exposure to a Hazardous Biological Agent at the work place.
  - Using suitable procedure that is standardised, sufficiently sensitive and of proven effectiveness (as determined in Phase 3a trails)
  - COVID-19 has become Group 3 Occupational Infectious Disease as classified by the Regulations of HBA
- Ethical Principles of Informed Consent to participate in Vaccination Trail, The legal obligation to participate in a employer facilitated vaccination programme, the WHO values of reciprocity in prioritisation of health workers in COVID-19 vaccines need to be balanced.
- Management of Adverse Effects and Serous Adverse Events have to be managed as COID, Clinical Trial and Quality Management issues.
- Governance of OHS programmes and Clinical trails presents opportunity to balance ethics, law, OHS Policy, programme management and imposes a culture of collaboration and transdisciplinary interaction.