



AGENDA
CLINICAL TRIALS STAKEHOLDER WORKSHOP
31 MAY 2019

Time: 09H00-15H30

Venue: PRF Auditorium

National Institute for Communicable Diseases

National Health Laboratory Services Premises

1 Modderfontein Road

Sandringham

2031

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|-------------|--|------------------|
| 9h00-9h10 | Opening and Welcome | Prof Paul Ruff |
| 9h10-9h20 | Introduction of Participants | Prof Paul Ruff |
| 9h20-9h30 | Objectives of the meeting | Prof Paul Ruff |
| 9h30-9h45 | ITG Presentation | Ms Zola Makubalo |
| 9h45-10h15 | Ethics in Clinical Trials | Dr Clement Penny |
| 10h15-10h30 | Status of SAHPRA (Clinical Trials) | Dr Dorah Diale |
| 10h30-10h45 | Face to face/teleconference meetings with applicants | Dr Dorah Diale |

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| | /channels of communication with SAHPRA | |
| 10h45-11h00 | CTC Policy Development and Progress | Ms Kedibone Malatji |
| 11h00-11h30 | T EA BREAK | |
| 11h30-12h00 | Updated SAGCP Guidelines (from 2006 to 2019) | Prof Lesley Burgess |
| 12h00-12h15 | Revised Clinical Trial Form 2 for Protocol amendments | Prof Lesley Burgess |
| 12h15-13h30 | LUNCH | |
| 13H30-13H45 | Requirements for rollover studies | Prof Olakunle Towobola |
| 13H45-14h00 | Non-commercial studies (Academic studies and IITs) | Prof Paul Ruff |
| 14h00-14h15 | Export/Import Permits of Clinical Trials Material | Ms Lineo Motopi |
| 14h15-14h40 | Medical Device Studies including Cardiac Devices | Ms Andrea Julsing / Prof Patrick Commerford |
| 14h40-15h00 | GCP Inspections | Ms Susan Khoza |
| 15h00-15h15 | General comments | Participants |
| 15h15-15h30 | Closure | Prof Ruff |