## PS-008 INNOVATIVE CLINICAL TRIAL DESIGNS

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Since the middle of the 20th century, randomised controlled trials have provided the strongest level of evidence to inform the treatment of all diseases. In particular, trials in the 1970s and 1980s in Africa led to a highly efficacious 6-month regimen for the treatment of TB; these were followed by trials in the 1990s and 2000s which resulted in today's HAART regimens that are recommended for all patients living with HIV.

These diseases, however, still cause 1.3 million deaths every year in Africa, and further trials are needed to improve treatment and develop control strategies that will ultimately end the epidemics. Furthermore, there are many neglected diseases where few if any trials have been conducted and therefore the evidence base for treatment is extremely weak.

The randomised clinical trial is an indispensable tool for defeating poverty-related and neglected diseases in Africa, but it should not be seen as a static instrument that has remained unchanged since its first introduction in the 1940s. Innovations in clinical trial design can overcome many barriers, facilitating more efficient trials where alternatives are prohibitively long or resource-intensive. For example, adding multiple intervention arms or sequential randomisations allows for more questions being answered in a single trial, and adaptive designs permit modifications to ongoing trials in light of internal or external data, thereby making better use of limited resources.

This presentation covers the opportunities for innovation in clinical trial design in poverty-related and neglected diseases. Recent developments relate to multi-arm multi-stage and other adaptive trial designs, interpretation of non-inferiority trials, choice of comparator arms, the role of pragmatic trials, and treatment strategy trials. Specific examples will be presented, including recent TB, HIV and Ebola trials, in addition to other areas for possible progress, all with the ultimate goal of faster patient benefit.