

## Supporting registration of child-focused clinical trials in Africa: The Child Strategy project

Child-focused health care workers are compelled to prescribe medicines that lack adequate dosage guidelines for children, as dosing is often derived from data extrapolated from adult studies.<sup>1-3</sup> Given that the pharmacokinetics and pharmacodynamics of treatments are often unknown for children, and that effectiveness may vary according to age, developmental stage and body size, there is an urgent need to study diagnostic and therapeutic interventions in children to increase the evidence base.<sup>4-7</sup> A 2005 report of African HIV trial activity identified 77 randomised controlled HIV/AIDS trials prior to 2004.<sup>8</sup> Analysis revealed poor representation of children and adolescents.<sup>9</sup> Currently there is no database dedicated to collating child-focused clinical research for the African continent. Our aim is to summarise evolving efforts for such a resource.

Before the launch of the Pan African Clinical Trials Registry (PACTR) ([www.pactr.org](http://www.pactr.org)) in September 2009, there was no concerted effort among African nations to collect and monitor information on trial activity in any formalised and cohesive manner. The PACTR was developed in response to this need and aims to increase clinical trial registration in Africa through its user-friendly open-access repository. PACTR is currently the only African member of the World Health Organization (WHO)'s Network of Primary Registries. This expanding initiative provides data to the International Clinical Trials Registry Platform (ICTRP), thereby increasing visibility of African clinical trials.<sup>10,11</sup>

Combining the lack of trial registration repositories in Africa with the paucity of research globally on interventions and medications for children,<sup>12,13</sup> there is clearly a need to develop a better understanding of the clinical trial landscape in the region, especially for infants and children. In October 2009, the PACTR initiated the Africa-region Child Strategy, partnering with the WHO and complementing its ongoing activities.

In December 2009, the Child Strategy was formally launched as a sub-project of the PACTR ([www.pactr.org](http://www.pactr.org)). The Strategy's objectives include developing an awareness of the global and continental need to register and conduct paediatric clinical trial research within the region, encouraging trials in the region to include children as participants, and increasing the number of registered trials enrolling children in Africa. Presentations at relevant conferences and agenda-setting meetings have increased awareness of these activities.<sup>14,15</sup>

The registry staff developed a database of child-focused stakeholders in Africa aiming to facilitate networking of researchers, funders, institutions, non-profit organisations, development agencies and policymakers. The main purpose is to increase collaboration and information sharing through regular communication and future collaborative meetings. The Child Strategy's dedicated Special Interest Group advises on the development of the research network and focused advocacy activities.

Trialists are encouraged to register in the first WHO-endorsed primary registry on the African continent, thus helping to fill in gaps about knowledge of African trial activity. The initiative continues

to look for opportunities to disseminate these important activities further and looks to readers, and stakeholders, to inform us of venues through which this can be done. We welcome input. Those interested in becoming involved in the Child Strategy or seeking more information about the PACTR or the Child Strategy should visit the registry website [www.pactr.org](http://www.pactr.org).

**Conflicts of interest.** We are members of the Africa-region Child Strategy Special Interest Group. Involvement in this group is voluntary and no payment is received in exchange for time committed to the project. No additional benefits are provided to group members.

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