

## CLINICAL RESEARCH

### WHO urges action against HIV drug resistance threat

The WHO HIV drug resistance report 2017 shows that in 6 of the 11 countries surveyed in Africa, Asia and Latin America, over 10% of people starting antiretroviral therapy had a strain of HIV that was resistant to some of the most widely used HIV medicines. Once the threshold of 10% has been reached, WHO recommends those countries urgently review their HIV treatment programmes.

**Read More:** <http://www.centerwatch.com/news-online/2017/07/25/urges-action-hiv-drug-resistance-threat/>



### EMA revises guideline on first-in-human clinical trials

First-in-human trials are a key step in medicines development, where a medicine already tested in vitro, in animals or in other preclinical studies is administered to people for the first time. Participants in these trials, often healthy volunteers, face an element of risk as the ability of researchers to predict the effects of a new medicine on people is limited before it is actually studied in humans. Only on very rare occasions, however, have participants experienced serious harm.

**Read More:** <http://www.centerwatch.com/news-online/2017/07/25/ema-revises-guideline-first-human-clinical-trials/>

### Report: 74% of medicines in development could be first-in-class treatments

Seventy-four percent of medicines in clinical development around the world are potentially first-in-class medicines, meaning they use a completely new approach to fighting a disease, according to a new report by The Analysis Group, commissioned by the Pharmaceutical Research and Manufacturers of America (PhRMA). The Biopharmaceutical Pipeline: Innovative Therapies in Clinical Development report examines the global state of the drug development pipeline and provides insights into new approaches biopharmaceutical researchers are pursuing.

**Read More:** <http://www.centerwatch.com/news-online/2017/07/20/report-74-medicines-development-first-class-treatments/>

### FDA approves Endari, first treatment for pediatric sickle cell disease

“The approval of Endari is a significant milestone for the sickle cell patient community who has not had an advancement in treatment for nearly 20 years and which now, for the first time ever, has a treatment option for children,” said Yutaka Niihara, M.D., MPH, chairman and chief executive officer of Emmaus Life Sciences. “Endari reinforces our commitment to discovering innovative therapies that help to improve the lives of people with rare diseases. We thank the FDA for its prompt review and look forward to making treatment available to patients as early as this fourth quarter.”

**Read More:** <http://www.centerwatch.com/news-online/2017/07/12/fda-approves-endari-first-treatment-pediatric-sickle-cell-disease/>