Conducting early phase and first-in-human studies in sub-Saharan Africa

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Johannesburg, South Africa

5 October 2022

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What are early Phase and First-in Human Studies?

- Serve to **advance promising drug candidates and products** for further clinical development, representing the first step following pre-clinical research (laboratory and animal studies).
- They include **Phase 1 studies**, which are conducted to determine safety in humans, whether the product is acceptable to use and how and where the drug is taken up in the body.
- The first Phase 1 study of an active product is referred to as **first-in-human**.
- Early phase studies can also include trials designed to evaluate a prototype of a product without the active drug – a placebo. **Placebo studies** are sometimes conducted before the Phase 1 study.

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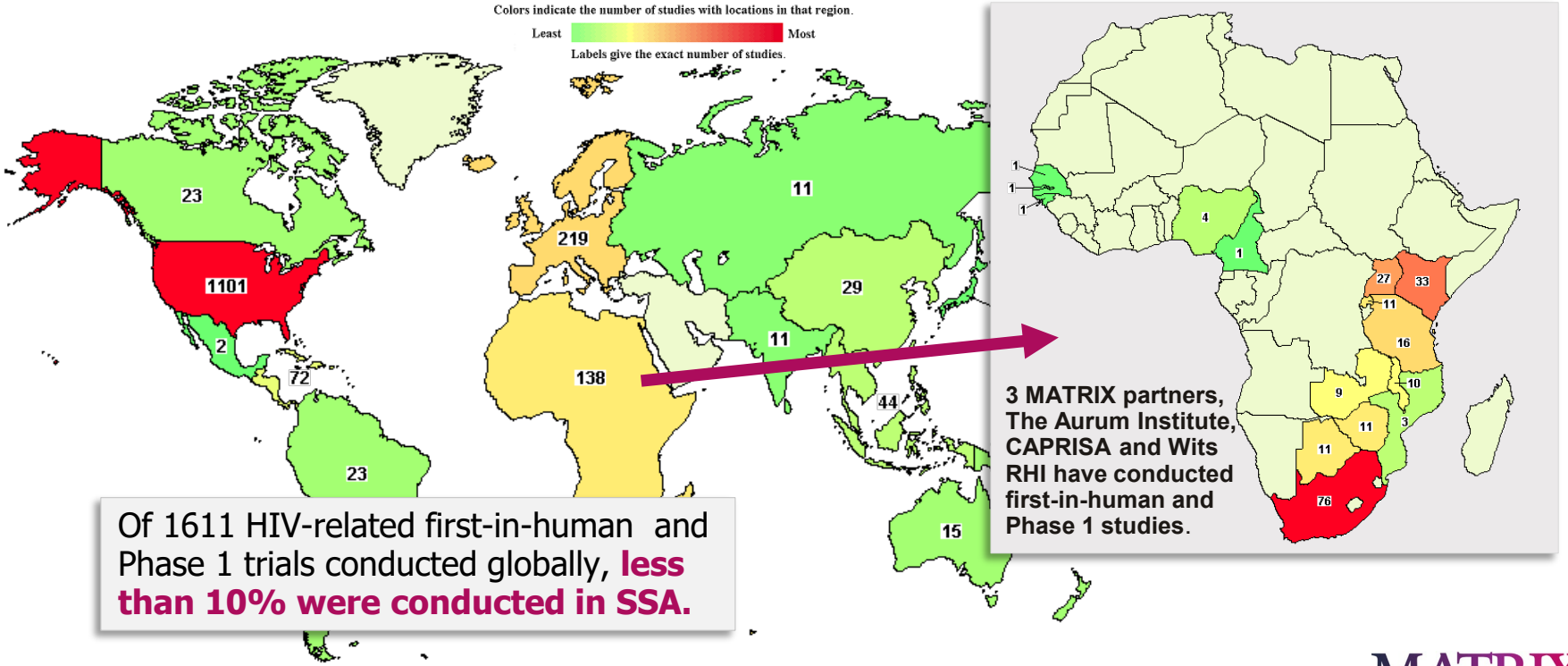
Where have first-in-human & Phase 1 HIV prevention and treatment trials been conducted?



Of 1611 HIV-related first-in-human and Phase 1 trials conducted globally, **less than 10% were conducted in SSA.**

Source: https://ClinicalTrials.gov

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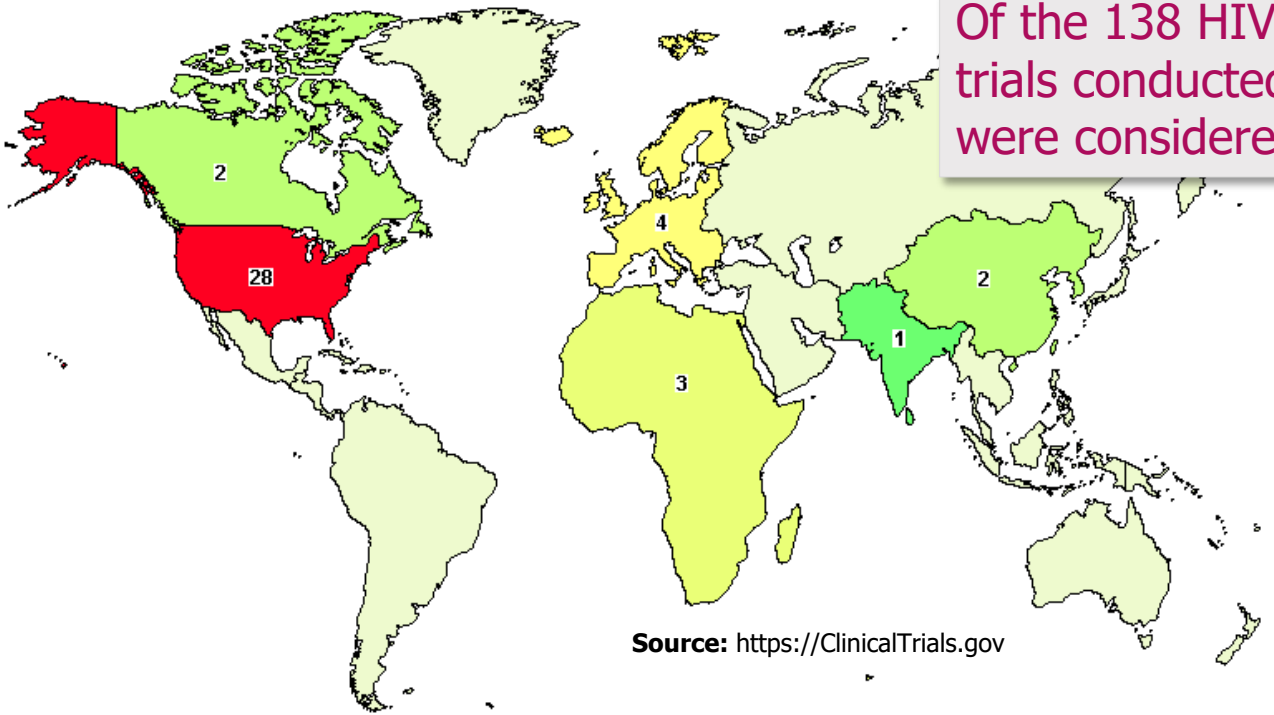
How many of these Phase 1 trials were first-in-human studies?



Of the 138 HIV-related Phase 1 trials conducted in Africa, only 3 were considered first-in-human.

Source: https://ClinicalTrials.gov

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Why should more early phase studies be conducted in SSA?

- Conducting **placebo studies** and **Phase 1 clinical trials** in SSA will:
  - Allow for **specificity in data** in the populations the products are intended for,
  - enhance **capacity** for innovation (investigators, sites, infrastructure),
  - advance **regulatory** science,
  - drive **R&D** and delivery agendas.

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Early phase studies under MATRIX

- MATRIX believes in the importance of early phase studies being conducted in SSA – in addition to the United States.
- Early phase studies among African women will **provide specific data on the safety and acceptability of new products** – so that relevant information is available earlier in the process and a more promising product can advance to Phase II (and possibly Phase III) evaluation.
- Matrix will be conducting early phase studies beginning in 2023, and to the extent possible, will **prioritize inclusion of young women and female sex workers in its studies**, and evaluation of products that could potentially be used by pregnant and breastfeeding women living in high incidence settings in Sub-Saharan Africa.

What is involved in the conduct of early phase studies?

- **Many different tests**, exams and procedures are required -- blood draws, pelvic exams, tissue sampling, etc.
- Studies are short (a few weeks or months) but with several study visits within that time - so it's **intense for both the participant and site staff**.
- **Safety oversight is key**, and additional specialists and staff may be needed in the laboratory, clinics, pharmacy and regulatory affairs.
- Inclusion and exclusion **criteria for enrolment likely to be very narrowly defined**.
- For the participant, there is **potential for risk** and **few benefits**

In Summary

- Conducting early phase clinical trials in SSA is critical for helping to help advance promising drug candidates and products for further clinical development by collecting data earlier in the process in the populations these products are intended for
- Very few have been conducted in SSA
- Safety in trial participants is a key consideration when conducting early phase clinical trials

Acknowledgements

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This program was made possible by the generous support of the American people through the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) and the U.S. Agency for International Development (USAID).

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