# Incorporating Transgender and nonbinary Participants in Phase 1 Clinical Drug Trials: Current Knowledge Gaps and Considerations for Phase 1 Studies

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**Abstract**

Phase 1 clinical drug trials critically depend on the participation of healthy volunteers to evaluate the safety and pharmacokinetics of new medicinal products. Current selection criteria and health definitions often overlook the unique health profiles of transgender and nonbinary individuals, potentially excluding them from participating in these essential early-stage studies. This review aims to identify and discuss current knowledge gaps and considerations regarding the inclusion of transgender and nonbinary participants in Phase 1 clinical drug trials. We highlight the need for research on how gender-affirming hormone therapy may affect drug pharmacokinetics and call for the development of inclusive biological reference ranges that account for the physiological effects of hormone therapies.

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`Incorporating_Transgender_Participants_in_Phase_1_Clinical_Drug_Trials_V3_LW_RJF.docx` available at https://authorea.com/users/758778/articles/732945-incorporating-transgender-and-nonbinary-participants-in-phase-1-clinical-drug-trials-current-knowledge-gaps-and-considerations-for-phase-1-studies