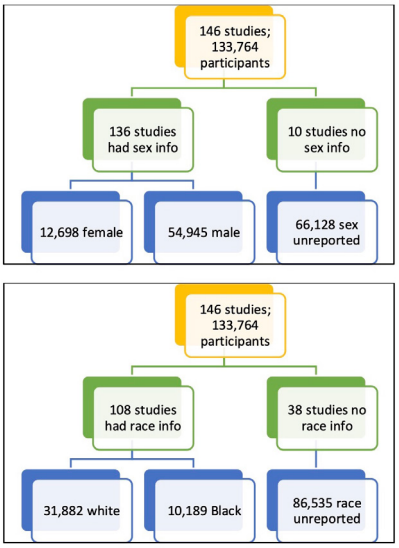
Healthcare (ViiV). The primary objective of this analysis was to characterize participant demographics in efficacy and registrational pharmaceutical studies (Phase II, III, IV, and Observational studies) from 2010–2020 that were sponsored by these four companies.

Methods: A systematic search of clinicaltrials.gov for any studies related to HIV drugs under development by the four companies during the study time period (2010-2020) was completed. Search results were screened for relevance. Registry listings for studies in final dataset (N=146) were reviewed, and study information (including phase, # of participants, dates, location, and demographics when available) were recorded. Analyses were performed in Excel to characterize trends in participant diversity by company, study phase, study location, and time period.

Results: Participant sex, which was generally reported to clinicaltrials.gov, suggests that male participants are over-recruited by 34%. Race-specific data was unreported for 65% of studies, and, when reported, suboptimal. Geographic diversity was lacking, as a majority (75%) of study sites were in the United States.

Conclusion: ATAC recommends that industry: Enroll more cisgender and transgender women, ensuring women participants are representative of the global and local HIV epidemics in race, ethnicity, and age; Enroll participants that reflect the racial and ethnic diversity of PLWHIV – including Black, Hispanic/Latinx, and Native American participants in the United States; Disaggregate data by sex, gender, race, ethnicity, and age. Disaggregate transgender women from MSM in reporting; Replace upper age limits with specific health related exclusion criteria; Prioritize enrollment of participants from impacted communities



419 W96 EFFICACY OF 4/7 DAYS MAINTENANCE ART STRATEGY: ANRS-170 QUATUOR TRIAL

Roland Landman[1], Lambert Assoumou[2], Sidonie Lambert-Niclot[3], Jonathan Bellet[4], Karine Amat[5], Clotilde Allavena[6], Christine Katlama[7], Karine Lacombe[8], Jean-Michel Molina[9], Yazdan Yazdanpanah[10], Severine Gibowski[11], Jean-Claude Alvarez[12], Jacqueline Capeau[13], Laurence Morand-Joubert[3], Pierre De Truchis[14]
[1]Institut de Médecine et Epidémiologie Appliquée Fondation Léon M'Ba, Hôpital Bichat, PARIS, France, [2]Sorbonne Université, INSERM, Institut Pierre Louis d'Epidémiologie et de Santé Publique, PARIS, France, [3]Sorbonne Université, INSERM, Institut Pierre Louis d'Epidémiologie et de Santé Publique Département de Virologie, Hôpital Saint-Antoine, PARIS, France, [4]AP-HP, Hôpitaux Universitaires Pitié Salpêtrière - Charles Foix, Sorbonne Université, INSERM, PARIS, France, [5]Institut de Médecine et Epidémiologie Appliquée, Hôpital Bichat, PARIS, France, [6]Hôpital Hôtel-Dieu, Service des Maladies Infectieuses, NANTES, France, [7]Hôpital Pitié-Salpêtrière APHP, Service des Maladies Infectieuses, PARIS, France, [8]Hôpital Saint-Antoine APHP, Service des Maladies Infectieuses, PARIS, France, [9]Hôpital Saint-Louis APHP, Service des Maladies Infectieuses, PARIS, France, [10]Université de Paris, INSERM, IAME, Hôpital Bichat-Claude Bernard, Service de Maladies Infectieuses et Tropicales, AP-HP, PARIS, France, [11]ANRS-Inserm, PARIS, France, [12]Département de Pharmacologie, Hôpital R Poincaré APHP, Inserm U-1173, Université Paris-Ile de France Ouest, Garches 92, France, GARCHES, France, [13]Sorbonne Université, INSERM UMR_S838 CRSA, Hôpital Tenon Service de Biochimie et Hormonologie, APHP, PARIS, France, [14]Hôpitaux Universitaires Paris-Ile de France-Ouest, Hôpital Raymond Poincaré APHP, Université Versailles-Saint-Quentin, GARCHES, France

Background: Intermittent treatment could improve the convenience, tolerability and cost of ART. We have previously demonstrated in the QUATUOR trial the non-inferiority of maintenance 4 days-a-week (4/7days) versus 7/7days in patients (pts) under triple therapy with either PI, NNRTI, or InSTI based regimen: 95.6% vs 97.2% treatment success at W48. ClinicalTrials.gov:NCT03256422. We report here the W96 results

Methods: Randomized, open-label, multicenter parallel trial evaluating the efficacy and safety of a maintenance 4/7days. Pts with plasma viral load (VL)<50 copies/mL for at least 12 months were randomly assigned in a 1:1 ratio to immediate switch to a 4/7days (4/7-I) at D0 or to a deferred switch to 4/7 days (4/7-D) at W48. The primary endpoint for the present analysis was the Kaplan-Meier estimated proportion of participants under the 4/7-days strategy (4/7-I group 0-96 weeks and 4/7-D group 48-96 weeks) with treatment success (VL< 50 copies/mL and no treatment strategy modification) at week 96

Results: Overall, 621 pts on 4/7-days strategy were analyzed (318 in 4/7-I group and 303 in 4/7-D group). The 3rd agent drug class was NNRTI for 286 (46%), InSTI for 300 (48%), and PI for 35 (6%). At W96, therapeutic success with the 4/7-days strategy was 92.6% [95% CI 90.2-95.2] and virological failure (VF, defined as 2 consecutive VL ≥50 copies/mL) was 4.2% [2.2-6.3]. Of the 318 pts in the 4/7-I group, 14 underwent therapeutic failure including 6 VF until W48 and 11 after W48 (7 VF). Among the 303 pts who switched to 4/7-days strategy at W48, 10 had therapeutic failure (6 VF) after W48. Regarding the 3rd agent class, VF was observed in 5.3% [1.8-8.6] with NNRTI, and 2.4% [0.6-4.1] with InSTI at W96. Overall, among the 19 VF, drug resistance mutations appeared in 7 pts, 2 to nucleoside analogs (NA) alone, 4 to NA and NNRTI, 1 to NA and InSTI (raltegravir). No significant adverse events, biological changes or changes in the level of pro-inflammatory markers were observed with the 4/7-days strategy until W96, except a gain of +4 ml/min (IQR -2;+6) in eGFR, p<0.001

Conclusion: The efficacy result of 4/7-days strategy was sustained at W96, with a low rate of viral failure, particularly with InSTI based regimen. This 4 consecutive days-on and 3 days-off reduced the cost ART maintenance regimens and represents a real, workable, alternative to the recommended maintenance therapy

420 STRUCTURAL BASIS FOR VIRAL RESISTANCE TO LONG-ACTING HIV-1 CAPSID INHIBITOR GS-6207

Stephanie M. Bester[1], Reed Haney[1], Daniel Adu-Ampratwum[2], James Fuchs[2], Mamuka Kvaratskhelia[1]
[1]University of Colorado Anschutz Medical Campus, Aurora, CO, USA, [2]The Ohio State University, Columbus, Ohio, USA

Background: GS-6207 (Lenacapavir, Gilead Sciences) is an experimental long-acting and highly potent HIV-1 capsid (CA) inhibitor. Viral breakthrough assays in cell culture identified a number of HIV-1 CA substitutions including M66I, Q67H, N74D and Q67H/N74D that confer substantial resistance to the inhibitor.