

estimates the likelihood of biochemical recurrence. No difference in PFS was observed between treatment strategies over a 15-year period ($p = 0.508$). However, OS was significantly associated with treatment modality after adjustment for age and CDC stage, with patients receiving radiotherapy showing the lowest OS ($p = 0.030$; Figure 1). Among the five deaths in patients with localized disease, PC was reported as the cause of death in only one case.

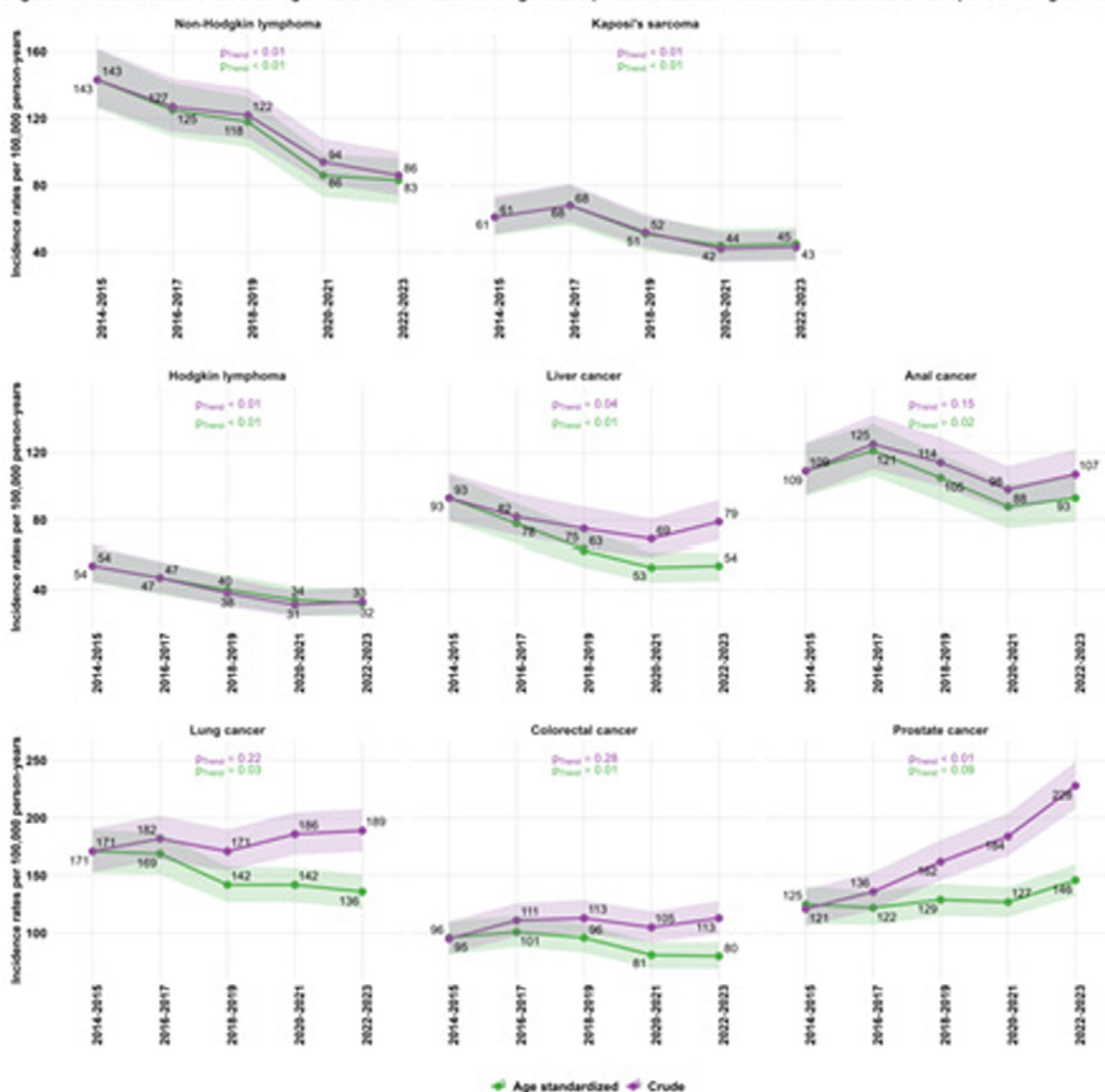
Conclusions: Compared to data from the German cancer registry, PC in PLWH occurred approximately a decade earlier (median age: 61 vs. 71 years), and more than one quarter of patients presented with metastatic disease at diagnosis. Among localized cases, 88% were classified as intermediate or high risk of biochemical recurrence after primary therapy. These findings highlight this population's need for tailored screening and treatment strategies.

PS06.4 | Evolving cancer incidence in persons with HIV in France between 2014-2023: a nationwide study using the French National Health Data System

E. Leye¹, V. Potard¹, J. Cadranet², C. Jacomet³, C. Katlama^{4,5}, E. Marshall¹, O. Lambotte⁶, R. Palich^{4,5}, S. Bregigeon-Ronot⁷, J.-P. Spano^{5,8}, D. Costagliola⁵, A. Makinson⁹, S. Grabar⁵

¹Sorbonne Université, INSERM, Institut Pierre Louis d'Epidémiologie et de Santé Publique, Paris, France, ²AP-HP, Hôpital Tenon, Service de Pneumologie et Oncologie Thoracique, GRCO4 Theranoscan, Sorbonne Université, Paris, France, ³Clermont-Ferrand University Hospital, Infectious Diseases Department, Clermont-Ferrand, France, ⁴AP-HP, Hôpital Pitié Salpêtrière, Service de Maladies infectieuses et tropicales, Paris, France, ⁵Sorbonne Université, INSERM, Institut Pierre Louis

Figure 1: Incidence rates of AIDS-defining cancers and non-AIDS-defining cancers (virus-associated and non-virus-associated cancers) in men living with HIV



d'Epidémiologie et de Santé Publique, AP-HP, Hôpital St Antoine, Paris, France, ⁶Université Paris Saclay, AP-HP, service de médecine interne immunologie clinique, Hôpital de Bicêtre, Inserm, CEA, UMR1184, Le Kremlin Bicêtre, France, Paris, France, ⁷Aix-Marseille Université, APHM, Hôpital Sainte-Marguerite, Marseille, France, ⁸AP-HP, Hôpital Pitié Salpêtrière, Service d'oncologie médicale, Paris, France, ⁹CHU Montpellier, Service de Maladies Infectieuses et tropicales, Université de Montpellier, INSERM U 1175, Montpellier, France

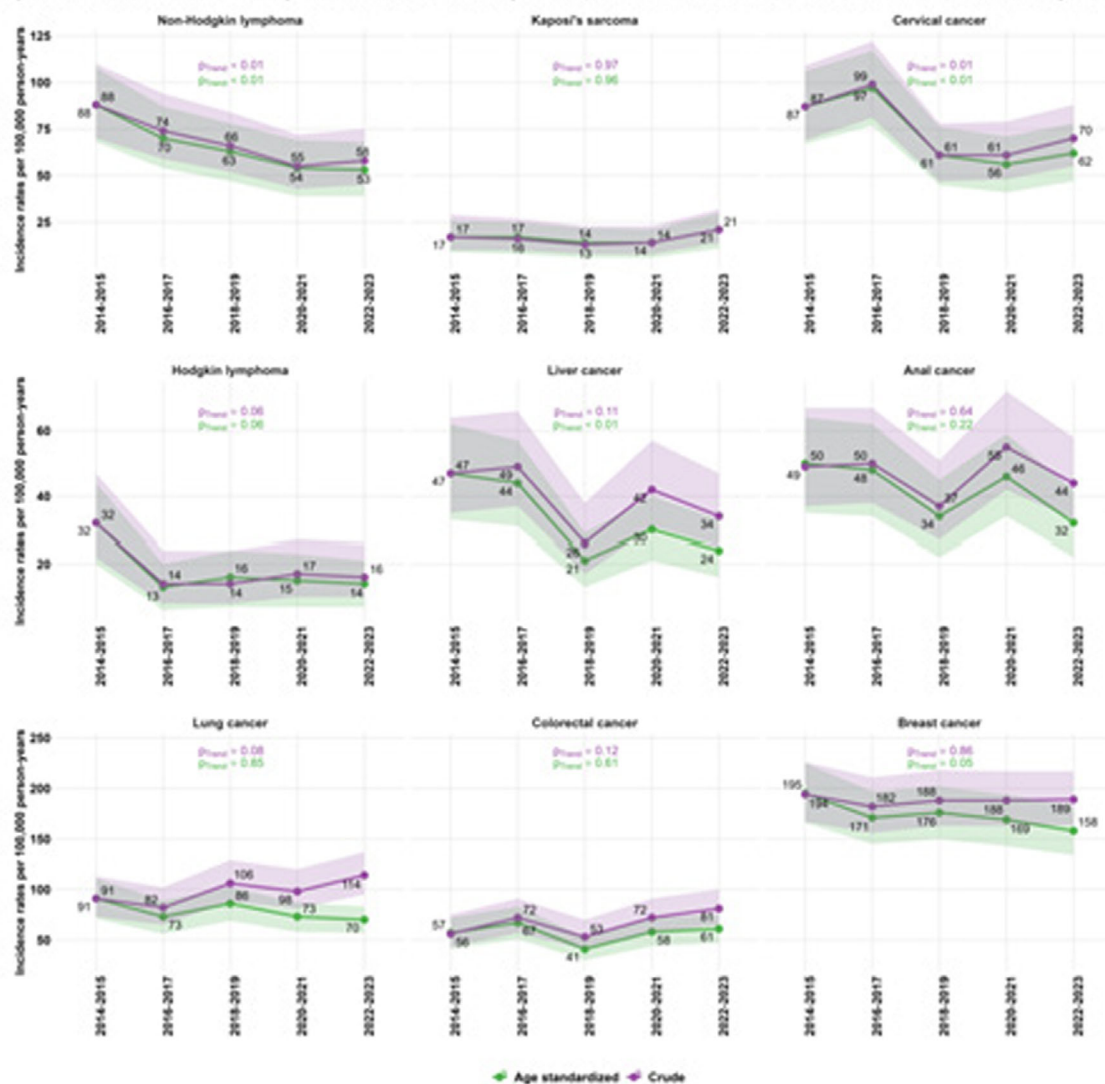
Purpose: We estimated the trends in the incidence of AIDS-defining cancers (ADC) (Non-Hodgkin lymphoma, Kaposi's sarcoma and cervical cancer) virus-associated non-AIDS-defining cancers (NADC) (Hodgkin lymphoma, liver, anal cancers) and non-virus-associated NADC (Lung, colorectal, breast, and prostate cancers) over 2014-2023.

Method: Using the French National Health Data System (SNDS), we identified all persons with HIV (PWH)

residing in France between 01/01/2014 and 31/12/2023. Only individuals aged over 18 years were included. Crude and age-standardized incidence rates were calculated by sex for five periods: 2014–2015, 2016–2017, 2018–2019, 2020–2021, and 2022–2023. Trends were tested using Poisson regression models.

Results: Overall 189,799 PWH contributed to over 1,490,000 person-years of follow-up. Among men, a significant decline in the incidences of ADC and virus-associated NADC, were observed with similar trends in both crude and age-standardized incidence, except for anal cancer, where a significant decline was only seen in age-standardized incidence. For non-virus-associated NADC, age-standardized incidence rates declined significantly for lung and colorectal cancers, despite no significant trend in crude rates. In contrast, for prostate cancer, a significant increasing trend was observed in crude incidence rates, while age-standardized incidence remained stable. (Figure1)

Figure 2: Incidence rates of AIDS-defining cancers and non-AIDS-defining cancers (virus-associated and non-virus-associated cancers) in women living with HIV



Among women, no significant trends were observed in both crude and age-standardized incidence rates, except for non-Hodgkin lymphoma and cervical cancer. In addition, for liver cancer only the age-standardized trend was significant and, for breast cancer, a decreasing trend in age-standardized incidence was of borderline significance. (Figure 2)

Conclusions: Since 2014, only the crude incidence of prostate cancer increased significantly, reflecting aging of PWH. After accounting for age difference across the calendar periods, most cancer incidence rates significantly declined in men while for women only non-Hodgkin lymphoma, cervical and liver cancer incidence rates declined. These results reflect both immunity improvement due to treatment and reduction in modifiable risk factors.

PS07 - Innovative mechanisms shifting the paradigm of treatment and prevention

PS07.1 | Safety and analytical treatment interruption outcomes in a clinical trial of 2 broadly neutralizing antibodies plus vesatolimod in early-treated South African women with clade C HIV-1

D. Lim¹, O. Fu¹, X. Liu¹, M. Mehrotra¹, D. SenGupta¹, T. Ndung'u^{2,3,4}, L. Gama^{5,6}, V. Pillay⁷, V. Govender⁸, V. Asari⁹, K. Dong^{10,11,4}

¹Gilead Sciences, Inc., Foster City, United States,

²University of KwaZulu-Natal, Durban, South Africa,

³Africa Health Research Institute, Durban, South Africa,

⁴Ragon Institute of Mass General, MIT, and Harvard

Medical School, Cambridge, United States, ⁵Vaccine

Research Center, NIAID, NIH, Bethesda, United States,

⁶Fundação Butantan, Sao Paulo, Brazil, ⁷Females Rising

through Education, Support, and Health (FRESH),

Durban, South Africa, ⁸The Aurum Institute NPC,

Johannesburg, South Africa, ⁹South African Medical

Research Council (SAMRC), Durban, South Africa,

¹⁰Harvard Medical School, Cambridge, United States,

¹¹Massachusetts General Hospital, Boston, United States

Purpose: Understanding the relationship between safety and viral control in HIV cure trials with an analytical treatment interruption (ATI) is paramount given the potential of additive/synergistic immunomodulating effects of investigative drugs. The objective of this analysis was to assess safety and viral control following ATI in an open-label study (NCT05281510) of 2 broadly neutralizing antibodies (bNAbs) combined with an oral Toll-like receptor-7 agonist, vesatolimod (VES), in early-treated women with clade C HIV-1 in South Africa.

Method: Twenty women living with HIV who initiated antiretroviral therapy (ART) during the hyperacute infection phase (suppressed viremia <50 copies/mL and CD4⁺ T-cell counts ≥500 cells/μL at enrollment) were treated with a biweekly regimen of VES (up to 10 doses) and 2 bNAbs, CAP256V2LS and VRC07-523LS, infused 1 week after the first VES dose. ART was stopped after the third VES dose and participants underwent ATI until they met ART restart criteria. The incidence of treatment-related adverse events (TRAEs) was examined in 3 groups of participants based on how long they remained off ART: early restart (ER; <16 weeks, n=7), delayed restart (DR; 16-44 weeks, n=7), and long-term delayed restart (LTDR; >44 weeks, n=6).

Results: Overall, study treatment was well tolerated with no serious or ≥grade 4 TRAEs (Table). Two DR participants reported grade 3 TRAEs. Across the 3 ATI outcome groups, a similar percentage of participants experienced any TRAEs or infusion-related reactions (ER, 86%; DR, 100%; and LTDR, 83%, respectively). No LTDR participants experienced pyrexia as compared with ER (43%) and DR (57%).

Conclusions: Overall, the combination of bNAbs and VES was generally safe, and safety was comparable across 3 viral control groups, suggesting the potential of an HIV cure regimen with a favorable benefit-risk profile. However, conclusions are limited given the low participant numbers and lack of placebo arm.

Table. Summary of Treatment-Related Adverse Events by ATI Outcomes

No. (%) of participants	Total N=20	ER N=7	DR N=7	LTDR N=6
TRAEs	18 (90)	6 (86)	7 (100)	5 (83)
TRAE grade 2	7 (35)	2 (29)	3 (43)	2 (33)
TRAE grade 3	2 (10)	0	2 (29)	0
Most common TRAEs (≥25% of participants)				
Infusion-related reaction	18 (90)	6 (86)	7 (100)	5 (83)
Headache	13 (65)	6 (86)	3 (43)	4 (67)
Tachycardia	8 (40)	1 (14)	5 (71)	2 (33)
Pyrexia	7 (35)	3 (43)	4 (57)	0
Chest discomfort	5 (25)	1 (14)	2 (29)	2 (33)
TR-SAEs	0	0	0	0

ER, early restart (<16 weeks); DR, delayed restart (16-44 weeks); LTDR, long-term delayed restart (>44 weeks). TR-SAEs, treatment-related serious adverse events, as assessed by the investigator.