

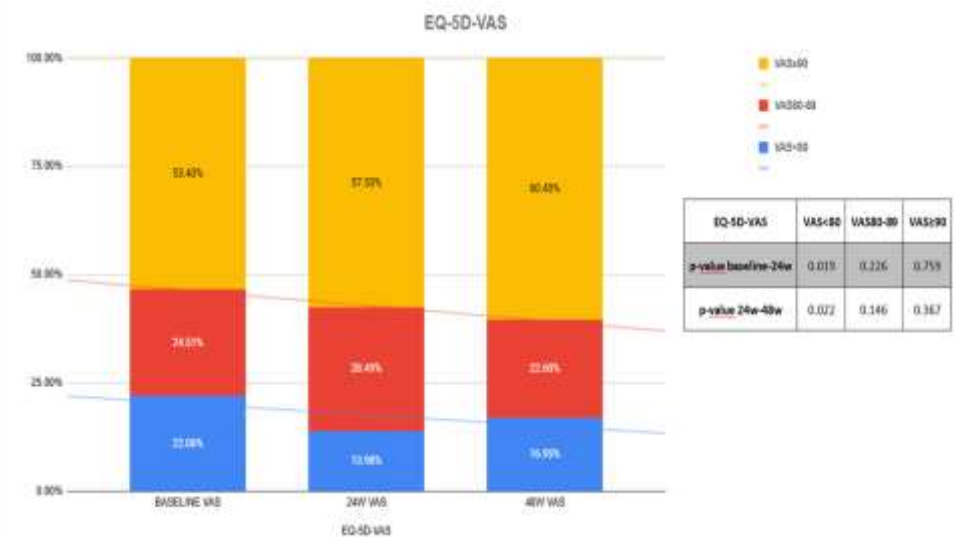
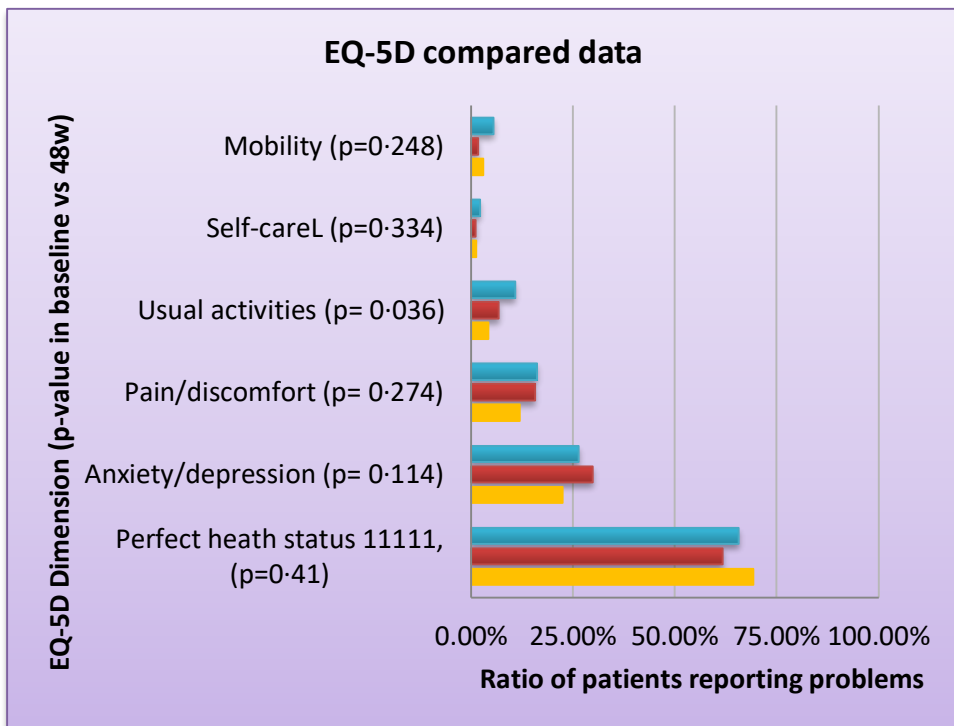
Impact of bicitgravir/emtricitabine/tenofovir alafenamide on health-related quality of life and economic outcomes in HIV care: a sub-study of the BIC-NOW clinical trial

Sergio Sequera-Arquelladas¹, María J. Vivancos², David Vinuesa³, Antonio Collado⁴, Ignacio De Los Santos⁵, Patricia Sorni⁶, Noemi Cabello-Clotet⁷, Marta Montero⁸, Carlos Ramos Font⁹, Alberto Terron¹⁰, MJ Galindo¹¹, Onofre Martinez¹², P. Ryan¹³, Mohamed Omar-Mohamed¹⁴, Helena Albendin-Iglesias¹⁵, Rosario Javier¹, Miguel Ángel López-Ruz¹, Alberto Romero¹⁶, Coral García Vallecillos¹, MA Calleja¹⁷, Carmen Hidalgo-Tenorio¹.
 Unit of Infectious Diseases, Virgen de las Nieves University Hospital, Granada, IBS-Granada, UGR, Spain¹; Infectious Diseases Service, Ramón y Cajal Hospital, Madrid, CIBERINFEC ISCIII, Spain²; Unit of Infectious Diseases, San Cecilio University Hospital, Granada, Spain, IBS-Granada, CIBERINFEC ISCIII³; Unit of Infectious Diseases, Torrecardenas University Hospital, Almería, Spain⁴; Infectious Diseases Service, La Princesa University Hospital, Madrid, CIBERINFEC ISCIII, Spain⁵; Unit of Infectious Diseases, Son Llàtzer Hospital, Palma de Mallorca, Spain⁶; Infectious Diseases Unit, San Carlos Clinical Hospital, Complutense University, CIBERINFEC ISCIII, Madrid, Spain⁷; Infectious Diseases Service, La Fe University Hospital, Valencia, Spain⁸; Nuclear Medicine Service, Virgen de las Nieves University Hospital Granada, IBS-Granada, Spain⁹; Unit of Infectious Diseases, Jerez University Hospital, Cádiz, Spain¹⁰; Infectious Diseases Service, Valencia Clinical University Hospital, Spain¹¹; Unit of Infectious Diseases, Santa Lucía University Hospital, Cartagena, Spain¹²; Internal Medicine Service, Infanta Leonor University Hospital, Madrid, CIBERINFEC, ISCIII, Spain¹³; Jaén Hospital Complex, Spain¹⁴; HIV and STI Unit, Department of Internal Medicine, Virgen de la Arrixaca University Hospital, IMIB, Murcia, Spain¹⁵; Unit of Infectious Diseases, School of Medicine, Puerto Real University Hospital, INIBICA, Cadiz University, Spain¹⁶; Pharmacy in University Hospital Virgen Macarena, Seville, Spain¹⁷

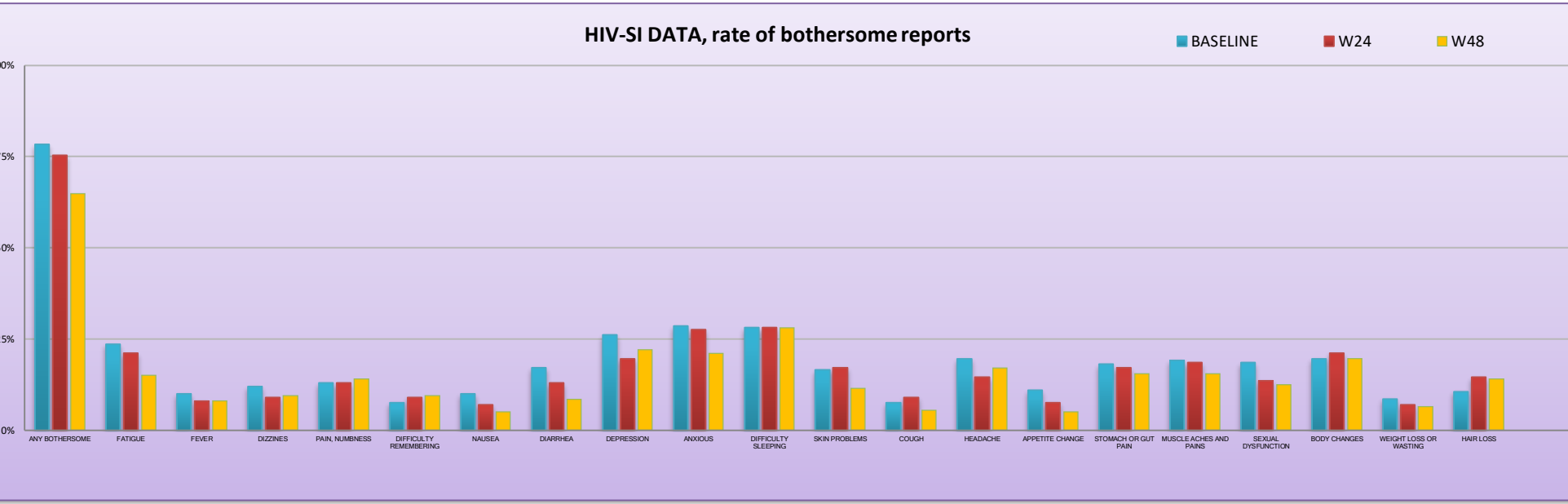
Background: The BICNOW clinical trial evaluated the effectiveness, safety, satisfaction, adherence to treatment, and retention in the system of a rapid initiation strategy with bicitgravir/emtricitabine/tenofovir alafenamide (BIC/FTC/TAF) in naïve HIV-infected individuals. It also assessed the burden of this infection on individuals and healthcare systems using various instruments, participant questionnaires, and pharmacoeconomic evaluations of this antiretroviral therapy (ART). This substudy focused on changes in the health-related quality of life (HRQoL) of participants and on the economic impact of this rapid initiation strategy.

Materials and methods: Patients were recruited for this phase IV, multicenter, open, single-branch clinical trial with 48-week follow-up between January 2020 and June 2022. HRQoL data were gathered using EQ-5D-3L and dichotomized HIV-SI questionnaires. In the cost-utility pharmacoeconomic analysis, data in the literature were used for comparators.

Results: The 208 participants had a mean age of 34 (27-44) years, 87.5% were male, 42.9% had completed higher education, and 67.1% were employed. The mean EQ-5D questionnaire score was significantly increased at 48 weeks versus baseline (0.940 ± 0.117 vs. 0.959 ± 0.083, p=0.012), and the utility value in quality-adjusted life years (QALYs) was 0.877 ± 0.093. There was a significant improvement in the “usual activities” dimension (10.8 vs 4.1% p=0.036). The Moses extreme reaction test showed a significant difference in all dimensions between participants in AIDS versus non-AIDS stage (p<0.001). HIV-SI results revealed a significantly smaller percentage of participants with bothersome symptoms at 48 weeks (75.4 vs. 62.2%, p=0.035). The pharmacoeconomic study indicated a value of €6,550.21/QALY gained with this ART.



	QALY adjusted by LY	Effectiveness PP	Cost in €/year	CEA	CUA	ICER-u
DTG/3TC	18.06	92	4851.24	52.73	268.56	350.16
BIC/FTC/TAF	20.60	98.3	5739.24	58.38	278.60	-
DRV/c/FTC/TAF	17.92	96	6094.56	63.48	340.08	-132.63



Conclusions: BIC/FTC/TAF is an appropriate, quality-of-life enhancing and pharmacoeconomically feasible option for a rapid initiation model of care in naive people living with HIV. The project was funded by a research grant from Gilead Sciences (project ISR-ES-19-10727).