

This is a reprint from HIV Glasgow 2022 which was originally published in Glasgow, Scotland; the references to “Merck” or “Merck KGaA” within refer to (1) Merck KGaA, Darmstadt, Germany; (2) an affiliate of Merck KGaA, Darmstadt, Germany; or (3) one of the businesses of Merck KGaA, Darmstadt, Germany, which operate as EMD Serono in the healthcare, MilliporeSigma in the life science and EMD Electronics in the electronics business in the U.S. and Canada.

There are two different, unaffiliated companies that use the name “Merck”. Merck KGaA, Darmstadt, Germany, which is providing this content, uses the firm name “Merck KGaA, Darmstadt, Germany” and the business names EMD Serono in the healthcare, MilliporeSigma in the life science and EMD Electronics in the electronics business in the U.S. and Canada. The other company, Merck & Co., Inc. holds the rights in the trademark “Merck” in the U.S. and Canada. Merck & Co., Inc. is not affiliated with or related to Merck KGaA, Darmstadt, Germany, which owns the “Merck” trademark in all other countries of the world.



# HIV-Associated Wasting in the Era of Weight Gain

Michael B. Wohlfeiler<sup>1</sup>, Rachel Palmieri Weber<sup>2</sup>, Laurence Brunet<sup>2</sup>, Javeed Siddiqui<sup>3</sup>, Michael Harbour<sup>4</sup>, Amy L. Phillips<sup>4</sup>, Brooke Hayward<sup>4</sup>, Jennifer S. Fusco<sup>2</sup>, Ricky K. Hsu<sup>5,6</sup>, Gregory P. Fusco<sup>2</sup>

<sup>1</sup> AIDS Healthcare Foundation, Miami, FL, USA; <sup>2</sup> EpiVidian, Durham, NC, USA; <sup>3</sup> TeleMed2U, Roseville, CA, USA; <sup>4</sup> EMD Serono Inc., Rockland, MA, USA, an affiliate of Merck KGaA; <sup>5</sup> NYU Langone Health, New York, NY, USA; <sup>6</sup> AIDS Healthcare Foundation, New York, NY, USA

Contact Information:  
Rachel Palmieri Weber  
1-919-619-3657  
rachel.weber@epividian.com

## BACKGROUND

- HIV-associated wasting (HIVAW) is defined as progressive, involuntary weight loss with both fat and lean muscle tissue loss
- Though weight gain and obesity are on the rise among people with HIV (PWH)<sup>1,2</sup>, wasting and unintentional weight loss are still a concern for some, despite advancements in antiretroviral therapy (ART)
- The period prevalence of HIVAW in the United States (US) was reported in claims studies as 8% in 2005-2007 and 18% in 2012-2018<sup>3,4</sup>

## OBJECTIVE

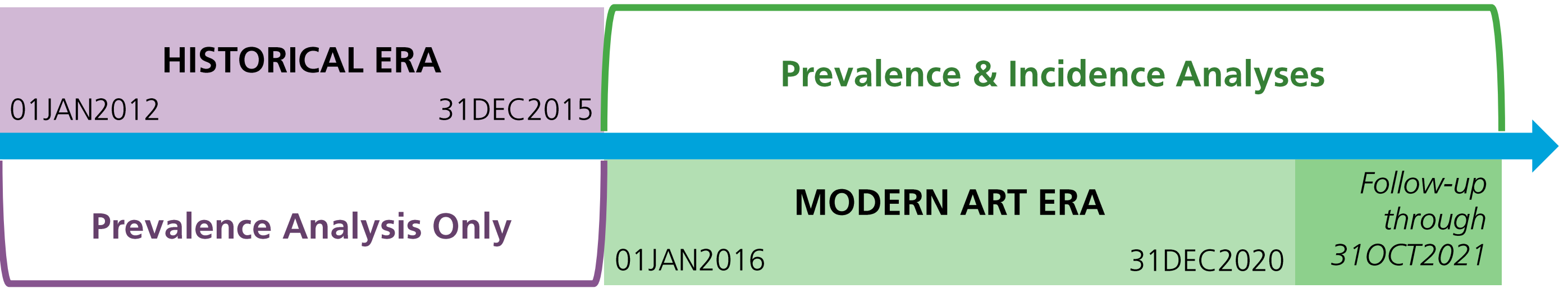
Assess the prevalence and incidence of HIVAW/low weight in the historical (2012-2015) and modern ART (2016-2020) eras in the United States.

## METHODS

### Study Population and Time Periods

- OPERA® observational cohort
  - Prospectively captured, routine clinical data from electronic health records
  - >140,000 PWH as of November 2021, representing ~13% of people living with diagnosed HIV infection in the US<sup>5</sup>
- Inclusion criteria for prevalence and incidence analyses
  - People with HIV (PWH)
  - 18 years of age or older
  - In care: ≥ 1 visit in OPERA® during the specified time period
- Additional inclusion criteria for incidence analyses
  - No malignancy (except basal cell carcinoma [BCC], squamous cell carcinoma [SCC] or *in situ* cancer) within 3 years of baseline
  - No AIDS-defining opportunistic infection (OI) within 12 months of baseline
  - No prior HIVAW/low weight
- Baseline: First date when eligibility criteria were met

Figure 1. Study time periods



### HIVAW/Low Weight

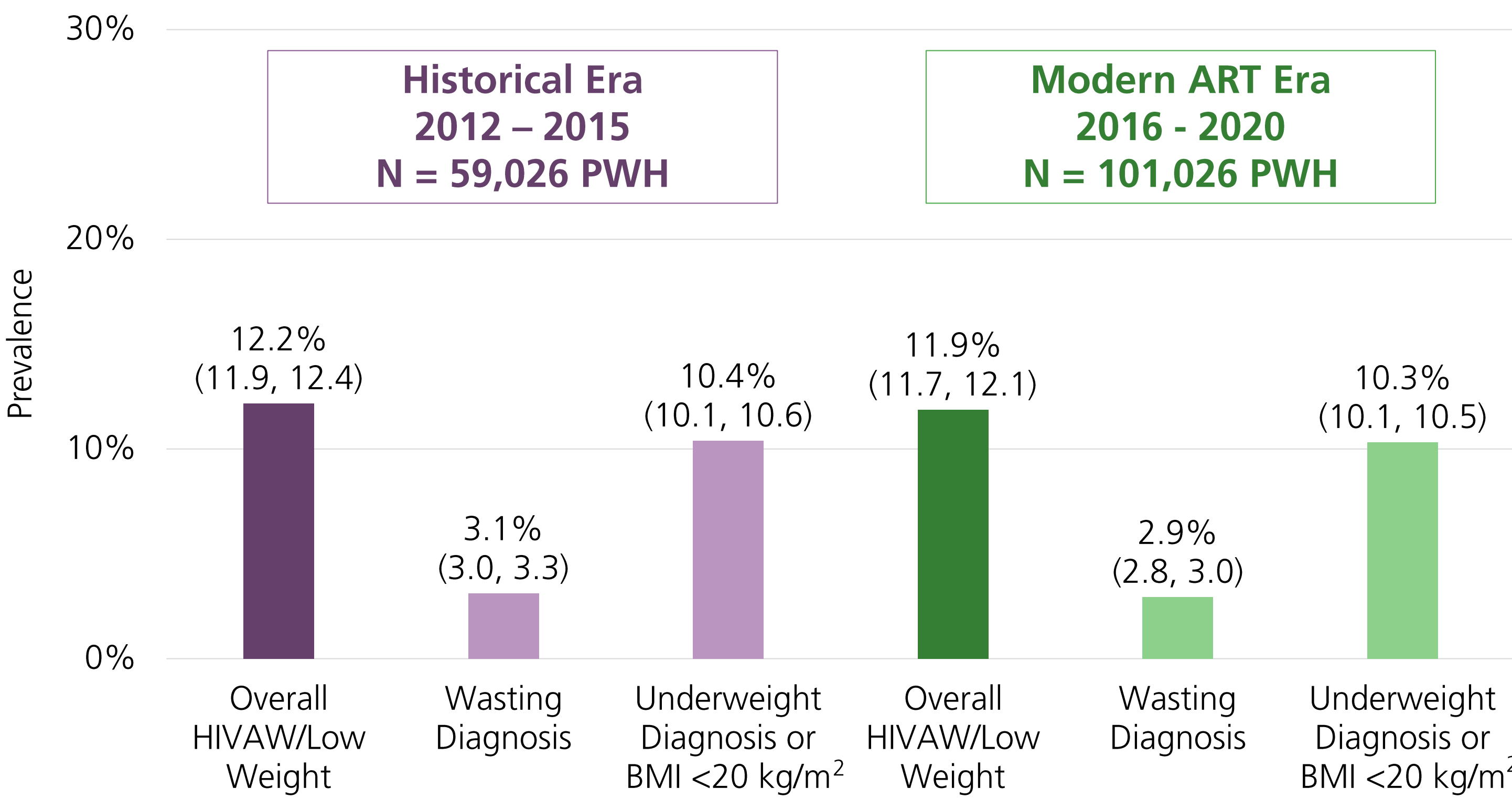
- Wasting or low body mass index (BMI)/underweight diagnosis (ICD codes, title search) or BMI < 20 kg/m<sup>2</sup> (vitals measurement)

### Statistical Analyses

- Prevalence: Proportion of the total eligible study population during specified time period that ever met the criteria for HIVAW/low weight
- Incidence analyses
  - Univariate Poisson regression to estimate the incidence rate (IR) of HIVAW/low weight and 95% confidence intervals (CI)
  - Censoring events
    - Incident malignancy (except BCC, SCC, or *in situ* cancer)
    - Incident AIDS-defining OI
    - Lost to follow-up (12 months without clinical contact)
    - Death
    - End of study (31OCT2021)

## RESULTS

Figure 2. Prevalence of HIVAW/low weight, overall<sup>a</sup> and by specific criteria<sup>b</sup>, in the era of weight gain



ART, antiretroviral therapy; BMI, body mass index; HIVAW, HIV-associated wasting; kg, kilograms; m, meters; PWH, people with HIV  
<sup>a</sup> Included a wasting or low BMI/underweight diagnosis (ICD codes, title search) or BMI <20 kg/m<sup>2</sup> (dark bars)  
<sup>b</sup> Wasting diagnosis (ICD codes, title search) is reported separately from low BMI/underweight diagnosis (ICD codes, title search) and BMI <20 kg/m<sup>2</sup> (lighter bars)

Table 1. Prevalence of HIVAW/low weight by payer type

Payer Type <sup>a</sup>	Historical Era % (95% CI)	Modern ART Era % (95% CI)
Medicaid	15.3 (14.7, 15.9)	14.9 (14.4, 15.4)
Medicare	14.7 (13.9, 15.5)	14.9 (14.2, 15.6)
Commercial Ins.	10.4 (10.0, 10.9)	10.7 (10.4, 11.0)
ADAP/Ryan White	11.8 (11.3, 12.3)	11.6 (11.2, 12.0)
Other	11.5 (10.3, 12.7)	10.7 (10.0, 11.5)
No Payer Info	11.5 (10.9, 12.1)	11.2 (10.7, 11.7)

ADAP, AIDS Drug Assistance Program; ART, antiretroviral therapy; CI, confidence interval; HIVAW, HIV-associated wasting; Ins., insurance  
<sup>a</sup> Payer types are not mutually exclusive

Table 3. Incident HIVAW/low weight among 67,119 PWH in the modern ART era

Since Baseline	
Total person-years at risk	225,215
HIVAW/low weight, n (%)	4,962 (7)
Median (IQR) months to HIVAW/low weight	8.7 (1.4, 24.1)
Incidence rate, per 100 py (95% CI)	2.20 (2.14, 2.27)
Since HIV Diagnosis	
Total person-years at risk	749,868
HIVAW/low weight, n (%)	4,962 (7)
Median (IQR) months to HIVAW/low weight	64.3 (13.9, 174.3)
Incidence rate, per 100 py (95% CI)	0.66 (0.64, 0.68)

ART, antiretroviral therapy; CI, confidence interval; HIVAW, HIV-associated wasting; IQR, interquartile range; n, number; py, person-years

Table 4. Baseline demographic and clinical characteristics of 67,119 PWH in the modern ART era

	Incident HIVAW/low weight N = 4,962	No incident HIVAW/low weight N = 62,157
Median (IQR) age, years	40 (28, 53)	41 (31, 52)
Female sex, n (%)	926 (19)	11,389 (18)
Black race, n (%)	2,559 (52)	28,655 (46)
Hispanic ethnicity, n (%)	805 (16)	13,708 (22)
Ever on ART on or prior to baseline, n (%)	2,937 (59)	44,094 (71)
Ever on TAF on or prior to baseline, n (%)	715 (24)	12,437 (28)
Median (IQR) years from HIV diagnosis to ART initiation	3.5 (0.1, 12.4)	2.9 (0.1, 10.6)

ART, antiretroviral therapy; HIV, human immunodeficiency virus; HIVAW, HIV-associated wasting; IQR, interquartile range; n, number; TAF, tenofovir alafenamide

## DISCUSSION

- The prevalence of HIVAW/low weight was:
  - 12% in both the historical and modern ART eras; BMI vitals measurements < 20 kg/m<sup>2</sup> accounted for most cases (Figure 2)
  - Higher among PWH who reported Medicaid or Medicare as a payer (15%) compared to PWH who reported other payer types (10-12%), regardless of time period (Table 1); lower BMI is potentially associated with food insecurity, age, and disability
  - Stable at 7-8% between 2012 and 2019 but dropped to 5% in 2020 (Table 2); the small decrease may be an artifact of fewer healthcare interactions during the COVID-19 pandemic
- Among 67,119 PLWH without prior HIVAW/low weight in 2016-2020, 4,962 (7%) experienced HIVAW/low weight over follow-up (Table 3)
  - Incident HIVAW/low weight was experienced a median 5 years after HIV diagnosis (Table 3)
- PWH with incident HIVAW/low weight were more likely to be Black, less likely to be Hispanic or to have ever taken ART (specifically TAF, which has been linked to weight gain<sup>6</sup>), and experienced longer delays between HIV diagnosis and ART initiation than PWH without incident HIVAW/low weight (Table 4)

## KEY FINDINGS

- HIVAW/low weight remains a challenge for PWH and may be underappreciated by providers based on the large proportion of underweight PWH without a diagnosis of wasting.
- Increasing awareness of HIVAW could improve the care of affected individuals.

## REFERENCES

- Sax PE, Erlandson KM, Lake JE, et al. Weight Gain Following Initiation of Antiretroviral Therapy: Risk Factors in Randomized Comparative Clinical Trials. *Clin Infect Dis* 2020; 71(6): 1379-89
- Koethe JR, Jenkins CA, Lau B, Shepherd BE, Justice AC, Tate JP, et al. Rising Obesity Prevalence and Weight Gain Among Adults Starting Antiretroviral Therapy in the United States and Canada. *AIDS research and human retroviruses* 2016; 32(1):50-58.
- Siddiqui J, Phillips AL, Freedland ES, Sklar AR, Darkow T, Harley CR. Prevalence and cost of HIV-associated weight loss in a managed care population. *Current Medical Research and Opinion* 2009; 25(5):1307-1317.
- Siddiqui J, Samuel SK, Hayward B, Wirka KA, Deering KL, Harshaw Q, et al. HIV-associated wasting prevalence in the era of modern antiretroviral therapy. *Aids* 2022; 36(1):127-135.
- Centers for Disease Control and Prevention. *HIV Surveillance Report, 2020*; vol. 33. <https://www.cdc.gov/hiv/library/reports/hiv-surveillance.html>. Published May 2022. Accessed 15SEPT2022.
- Mallon PW, Brunet L, Hsu RK, Fusco JS, Mounzer KC, Prajapati G, et al. Weight gain before and after switch from TDF to TAF in a U.S. cohort study. *Journal of the International AIDS Society* 2021; 24(4):e25702.

## ACKNOWLEDGEMENTS

This research would not be possible without the generosity of PWH and their OPERA® caregivers. Additionally, we are grateful for the following individuals: Kelly Oh (SAS Programming), Robin Beckerman (Quality Assurance), Bernie Stooks and Lisa Lutz (Database Architecture & Management), and Judy Johnson (Medical Terminology Classification).

## SUPPORT

The research was funded by EMD Serono, Inc., Rockland, MA, USA, an affiliate of Merck KGaA (CrossRef Funder ID: 10.13039/100004755)