Geometric mean [95%CI] plasma CAB and RPV Ctau at select visits				
	CAB (mcg/mL)		RPV (ng/mL)	
Visit	ATLAS	FLAIR	ATLAS	FLAIR
Week 4b (after last oral dose)	4.69 [4.47, 4.92]	5.22 [4.88, 5.57]	75.4 [70.8, 80.2]	79.1 [74.1, 84.3]
Week 8 (4 weeks after initial IM dose)	1.23 [1.13, 1.33]	1.56 [1.45, 1.68]	38.6 [36.0, 41.4]	41.2 [38.7, 43.9]
Week 48 (4 weeks after monthly IM dose)	2.84 [2.68, 3.01]	3.13 [2.95, 3.33]	90.3 [84.9, 96.0]	82.4 [77.8, 87.2]

Disclosures. **All authors:** No reported disclosures.

2496. Qualitative Thematic Analysis of Social Media Data to Assess Perceptions of Daily Oral and Long-Acting Injectable Antiretroviral Treatment among People Living with HIV

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Background. Current HIV treatment options consist of daily oral antiretroviral therapies (ART). A long-acting injectable HIV treatment is in development for monthly or every other month administration. Patient preferences for ART are important to understand and can impact retention in care, adherence and outcomes. The purpose of this study was to obtain and analyze patient perceptions of oral and injectable ART using a novel approach.

Methods. Qualitative thematic analysis was conducted to examine online discussion threads posted by people living with HIV (PLHIV) in POZ Community Forums from 2013 to 2018. Perceptions of ART were analyzed using keywords (e.g., dose, pill, daily, long-acting, injection, monthly, cabotegravir). Relevant threads were extracted, reviewed and coded using qualitative data analysis software (ATLAS.ti.8).

Results. Analyses identified 684 relevant discussion threads including 2,629 coded quotations posted by 568 PLHIV. Oral ART (2,517 quotations) was discussed more frequently than injectable ART (112). Positive statements on oral ART commonly mentioned the small number of pills (278), dose frequency (248), ease of scheduling (154), and ease-of-use (146). PLHIV also noted disadvantages of oral ART including negative emotional impact (179), difficulty with medication access (137), scheduling (131), and treatment adherence (128). Among the PLHIV discussing injectable ART, common positive comments focused on less frequent administration (34), emotional benefits of not taking a daily pill (7), potential benefits for adherence (6), overall convenience (6), and benefits for traveling (6). Some quotations (10) perceived the frequency of injections negatively, and others had negative perceptions of needles (8) or appointments required to receive injections (8).

Conclusion. ART was frequently discussed among PLHIV on this online forum. This innovative approach for obtaining and analyzing unsolicited comments revealed that while many PLHIV expressed positive views about their daily oral regimen, others perceived inconveniences and challenges. Among PLHIV who were aware of a possible long-acting injectable treatment, many viewed this potential new option as a convenient alternative with the potential to improve adherence.

Disclosures. **All authors:** No reported disclosures.

2497. Women's Perspectives on and Experiences with Long-acting Injectable Antiretroviral Therapy in the United States and Spain: the Potential Role of Gender in Patient Preferences

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Background. Adherence to antiretroviral therapy (ART) to treat HIV remains a critical global health challenge given its relationship with individual health outcomes and population-level transmission. Given barriers associated with oral ART adherence, and considerations of patients' preferences, long-acting injectable (LA) ART (cabotegravir + rilpivirine) is under development and has been shown to be non-inferior to daily oral ART in Phase III trials. While most of the trial participants have been men, as LA ART gets closer to becoming available for routine clinical use, it is critical to understand how this option is perceived by women.

Methods. We conducted in-depth interviews with 67 individuals, 53 people living with HIV (PLHIV) and 14 healthcare providers, in 11 sites in the United States and Spain participating in Phase III LA ART trials (ATLAS, ATLAS 2-M and FLAIR). Twenty percent (10/53) of trial participants interviewed were women. Interviews explored patient and provider perspectives and experiences with LA ART, and appropriate candidates and recommendations to support use. Interviews were audio-recorded, transcribed and coded using thematic content analysis.

Results. Overall, several salient themes emerged regarding participant's generally positive experiences transitioning from daily oral ART to injectable ART including: the importance of the clinical efficacy of LA ART, the ability to learn to manage injection side-effects over time, and the "freedom" reportedly afforded by LA ART logistically and psychosocially. Women interviewed shared many of the aforementioned positive perceptions of LA ART but also had some unique perspectives. Female participants discussed how LA ART was easier to integrate into their daily lives including managing their multiple roles and responsibilities, which often involved working full-time and taking care of themselves as well as their family and children.

Conclusion. Similar to all participants, female participants had generally positive views of LA ART. However, the gendered nature of their daily lives also led to some unique perspectives on why and how they were satisfied with LA ART that merits further exploration in future research.

Disclosures. **All authors:** No reported disclosures.

2498. Perceptions of Injectable Antiretrovirals in an Urban HIV Clinic

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Background. Although new injectable antiretrovirals (ARV) for HIV may soon be available, there is little research on patient preferences. We examined perceptions of injectable ARV among persons living with HIV (PLWH).

Methods. This cross-sectional study was conducted among PLWH presenting for an appointment at TempleHealth in Philadelphia, PA between March 11 and April 18, 2019. Respondents completed a self-administered survey comprising 29 questions about socio-demographic data, current ARV, and preferences regarding injectable ARV therapies. Responses were recorded on a 10-point Likert scale, on which responses in the 1–5 range were defined as unlikely and 6–10 range as likely to choose injectable ARV. The primary endpoint was to describe factors associated with likely vs. unlikely uptake of injectable ARV. Responses between groups were compared with Chi-square or Wilcoxon rank-sum tests.

Results. 171 patients completed a survey with a 56% response rate. Demographics were 60% male, 70% African American, 33% LGBQ-identifying, 2% transgender, with a mean age of 48 ± 13 years. Percentages of likely uptake (55%, $n = 94$) and unlikely uptake (45%, $n = 77$) were similar. Median likelihood was 7 (IQR 7–10) and varied from likely (10, IQR 8–10) and unlikely (1, IQR 1–5) cohorts. There were no differences in overall likelihood based on current number of pills or pill frequency ($P > 0.05$). A likelihood trend was found among patients who missed one or more doses per week, however current adherence was not significant (p = 0.06). Likelihood of uptake means increased as the frequency of administration decreased: 1-week (5.7 ± 3.7), 2-week (5.9 ± 3.7), 1-month (7.3 ± 3.5), 2-month (7.3 ± 3.6), and 3-month (7.7 ± 3.4). Likelihood of uptake decreased as duration of a potential injection site reaction increased: 1 day (6.2 ± 3.5), 2–3 days (4.6 ± 3.3), 4–6 days (3.6 ± 3.1), 7 days or longer (3.0 ± 3.2). Respondents preferred their doctor's office (60%) over self-injection (23%), assisted injection at home (11%), pharmacy (4%), or special injection center (2%) for administration setting.

Conclusion. Our study indicates that availability of injectable administration has potential to find acceptance among PLWH.

Disclosures. **All authors:** No reported disclosures.

2499. Perceptions of and Preferences for Oral or Long-Acting Injectable Antiretroviral Treatment Regimens in the United States and Canada

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Background. Antiretroviral treatment (ART) for patients living with HIV (PLHIV) has improved greatly, however, challenges with daily oral dosing remain. New ART options with reduced dosing frequency and innovative delivery methods may help address these challenges. This study assesses patient and physician satisfaction with current treatments and preferences for switching to a monthly or every other month long-acting injectable (LAI) ART.

Methods. This is a cross-sectional online survey of PLHIV and physicians treating PLHIV in United States and Canada. A literature review, clinical expert input, and qualitative and quantitative pilots informed survey design. Eligible PLHIV were on ART for ≥ 6 months and virally suppressed (self-reported). Survey questions for patients evaluate satisfaction and adherence to current ART. Treatment preferences are assessed using a discrete choice experiment (DCE), where respondents choose between

staying on current ART, switching to another oral ART or switching to a LAI ART. DCE treatment attributes include dosing frequency, side effects, forgivability, food/mealtime restrictions, and mode of administration. Pilot data for US patients is included here; the main survey will include approximately 550 patients and 450 physicians.

Results. Of 51 PLHIV completing the pilot survey, 80% were male, mean age was 54 years, and 63% were on ART for ≥10 years. Switching ART was common, with 55% reporting changing their ART ≥ 3 times. Just under half of patients (47%) were not totally satisfied with their current ART. Most common reasons for dissatisfaction included daily reminder of having HIV (31%) and having to take medicine every day (28%). Just over a quarter of patients (28%) reported forgetting to take their ART in the prior month. Across all DCE choices, patients preferred to remain on their current treatment 47% of the time, while 45% of the time patients preferred switching to the LAI, and for the remaining 8%, patients chose switching to another oral ART regimen.

Conclusion. Despite advances in ART, treatment challenges remain. Among the treatment-experienced PLHIV in this pilot survey, over half of their choices resulted in switching to an alternative regimen, and when opting to switch, most patients preferred the long-acting injectable treatment regimen.

Disclosures. **All authors:** No reported disclosures.

2500. Fostemsavir Drug–Drug Interaction Profile, an Attachment Inhibitor and Oral Prodrug of Temsavir, for Heavily Treatment Experienced HIV-1-Infected Patients

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Background. Fostemsavir (FTR) is a first-in-class attachment inhibitor being evaluated in heavily treatment-experienced (HTE) HIV-1-infected patients. Active temsavir (TMR) binds to viral envelope glycoprotein 120 and prevents viral attachment and entry into host CD4+ T cells. TMR is primarily metabolized by esterase-mediated hydrolysis with contributions from cytochrome P450 (CYP) 3A4. TMR does not inhibit/induce major CYP or uridine diphosphate glucuronosyltransferase (UGT) enzymes and is a P-glycoprotein (P-gp) and breast cancer resistance protein (BCRP) substrate. TMR and/or its metabolites inhibit BCRP and organic anion transporter protein 1B1/3 (OATP1B1/3). FTR DDI profile informs coadministration with antiretrovirals (ARV) and other therapeutic classes.

Methods. DDI data from 13 studies were compiled to inform the impact of 17 drugs or drug combinations on TMR and the impact of TMR on 15 drugs such as ARVs, rifamycins, opioid substitutes, statins, oral contraceptives (OC), and H2-antagonsits.

Results. FTR with CYP3A4, P-gp, and/or BCRP inhibitors increase TMR concentrations; but, do not pose clinical concern at therapeutic dose. TMR may be administered with weak/moderate inducers with or without coadministration of CYP3A4, P-gp, and/or BCRP inhibitors such as RTV or COBI. Coadministration with strong inducers is contraindicated. FTR may be coadministered with RBT with or without a PK enhancer. However, co-administration of FTR with RIF is contraindicated. FTR can be given with drugs that increase gastric pH; famotidine did not impact TMR PK. TMR may increase concentrations of drugs that are substrates of OATP1B1/3 and BCRP; therefore, most statins require dose reduction (e.g., rosuvastatin dose is limited to ≤10 mg QD). TMR increased EE exposure 40% with no impact on NE; therefore, FTR may be coadministered with OCs containing ≤30 µg EE. TMR had no clinically meaningful impact on TDF, DRV/RTV, ATV/RTV, ATV, RTV, ETR, MET, or BUP/norBUP PK (Table 1).

Conclusion. FTR can be coadministered with ARVs and most common treatments used to manage HIV co-infections or comorbidities without dose adjustment of either drug except for select HMG-CoA reductase inhibitors and EE-containing OCs. Strong CYP3A inducers are contraindicated.

Table 1. FTR drug-drug interaction profile, an attachment inhibitor and oral prodrug of TMR, for heavily treatment experienced HIV-1 infected patients (data presented at geometric mean ratio, GMR).

Concomitant Drug Name	Impact on TMR GMR	Impact on Concomitant Drug GMR	
Maraviroc (MVC)	TMR ↔ Cmax ↑ 13%, AUC ↑ 10% Ct ↓ 10%	MVC ↔ Cmax ↑ 1%, AUC ↑ 25% Ct ↑ 37%	
Raltegravir (RAL)	TMR ↔*	RAL ↔*	
Etravirine (ETR)	TMR ↓ Cmax ↓ 46% AUC ↓ 50% Ct ↓ 52%	ETR ↔ Cmax ↑ 11% AUC ↑ 11% Ct ↑14%	
Tenofovir (TDF)	TMR ↔ Cmax ↓ 1% AUC ↔ 0% Ct ↑ 13%	TDF ↑ Cmax ↑ 18% AUC ↑ 19% Ct ↑ 28%	
Cobicistat (COBI)	TMR ↑ Cmax ↑ 71%, AUC ↑ 93% Ct ↑ 136%	ND	
Ritonavir (RTV)	TMR ↑ Cmax ↑ 50%, AUC ↑ 45% Ct ↑ 44%	RTV ↔ Cmax ↑ 14% AUC ↑ 9% Ct ↑ 7%	
Atazanavir (ATV)/ritonavir (RTV)	TMR ↑ Cmax ↑ 66%, AUC ↑ 54% Ct ↑ 57%	ATV ↔ Cmax ↑ 3% AUC ↑ 9% Ct ↑ 19%	RTV ↔ Cmax ↑ 2% AUC ↑ 7% Ct ↑ 22%
Darunavir (DRV)/COBI	TMR ↑ Cmax ↑ 76%, AUC ↑ 97% Ct ↑ 134%	ND	
Darunavir (DRV)/RTV	TMR ↑ Cmax ↑ 52%, AUC ↑ 63% Ct ↑ 86%	DRV ↔ Cmax ↓ 2% AUC ↓ 6% Ct ↓ 5%	RTV ↔ Cmax ↔ 0%, AUC ↑ 15% Ct ↑ 19%
Darunavir (DRV)/RTV + ETR	TMR ↑ Cmax ↑ 55%, AUC ↑ 34% Ct ↑ 33%	DRV ↓ Cmax ↓ 9% AUC ↓ 6% Ct ↓ 12%	RTV ↑ Cmax ↑ 14% AUC ↑ 9% Ct ↑ 7%	ETR ↔ Cmax ↑ 18% AUC ↑ 28% Ct ↑ 28%
Buprenorphine (BUP), Norbuprenorphine (norBUP), Methadone (R-/S-MET)	ND	BUP ↔ AUC ↑ 30% Cmax ↑ 24%	norBUP ↔ AUC ↑ 39% Cmax ↑ 24%	R-MET ↔ AUC↑ 13% Cmax ↑ 15%	S-MET ↔ AUC ↑ 15% Cmax ↑ 15%
Famotidine	TMR ↔ Cmax ↑ 1%, AUC ↑ 4% Ct ↓ 10%	ND	
Ethinyl estradiol (EE)	ND	EE ↑ AUC ↑ 39% Cmax ↑ 40%	
Norethindrone acetate (NE)	ND	NE ↔ AUC ↑ 8% Cmax ↑ 8%	
Rifabutin (RBT)	TMR ↓ Cmax ↓ 27%, AUC ↓ 30% Ct ↓ 41%	ND	
Rifabutin (RBT) + RTV	TMR ↑ Cmax ↑ 50%, AUC ↑ 66% Ct ↑ 118%	ND	
Rifampicin (RIF)	TMR ↓ Cmax ↓ 76%, AUC ↓ 82%	ND	
Rosuvastatin	ND	Rosuvastatin ↑ Cmax ↑ 78% AUC ↑ 69%	

*compared to historical data

Disclosures. **All authors:** No reported disclosures.

2501. CCR5 Targeted ARV Loaded Nanoparticle: Dual Protection for HIV Functional Cure

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Background. One of the NIH high-priority HIV/AIDS research objectives is to discover novel therapeutics aimed at developing safe, tolerable, strategies that targets cellular protein to induce long-term antiviral suppression. This current research aims at designing a novel targeted nano-formulation combining cell targeting and antiretroviral therapy to provide double protection against HIV-1.

Methods. CCR5 targeted combination antiretroviral drugs (cARV) loaded nanoparticles (NPs) were synthesized based on water-in-oil-in-water (W-O-W) emulsion methodology. For targeting CCR5+ T cells, a modified high affinity CCR5 monoclonal Ab (XFCCR5 mAb), was isolated from XF-CCR5 hybridoma cells. The XFCCR5 mAbs were covalently conjugated through their C-terminus by replacing the NHS group on FTC+DTG NPs with covalent amide bond. The CCR5 mAb binding was evaluated by SDS–PAGE methods. The CCR5-specific binding affinity of XFCCR5-FTC+DTG NP in compared with XFCCR5 monoclonal antibody (mAb) was evaluated by flow cytometry using CD4+CCR5+ TZM-bl cell line and PBMCs. The intracellular pharmacokinetic (PK) profile in TZMbl cells was evaluated by LC-MS/MS analysis, whereas *in vitro* efficacy was evaluated based on Steady-Glo® Luciferase Assay System using TZM-bl cells.

Results. XFCCR5-FTC+DTG NPs obtained averaged 173 ± 23 nm (mean ± SEM, n = 3) with 2.2 ± 0.47 mg XFCCR5 mAb bound per mg cARV NP. The formulation % entrapment efficiency of DTG and FTC respectively, to be 55 ± 1.6% and 42.6 ± 5.6%. The specific binding affinity (K_m) of XFCCR5-FTC+DTG NP and XFCCR5 mAb were estimated to be 0.0057 and 0.0377, higher compared with wild-type anti-CCR5 mAb with higher K_m value 0.303. Finally, the 4-day HIV-infection protection study result illustrates IC_{50} in case of XFCCR5-FTC+DTG NP and XFCCR5 NP to be as low as 0.0069 and 0.0031 µg/mL, respectively, compared with 1.771 µg/mL for XFCCR5 mAb (Figure 1, TZM-bl and Figure 2, PBMCs).

Conclusion. This nano-formulation aimed at duel protection by preventing HIV binding to CCR5+CD4+T cell due to CCR5 receptor blocking. These result support protection against HIV and maintenance of cARV drug levels. This novel formulation could be supportive of immune-alternative to achieve functional-cure against HIV.

Figure 1. Comparative binding affinity study in TZM-bl cells

Michaelis-Menten Best-fit values	anti-CCR5 mAb	XFCCR5 mAb	XFCCR5-FTC+DTG NP
Vmax	109.4	98.09	99.69
Km	0.3035	0.03768	0.005701

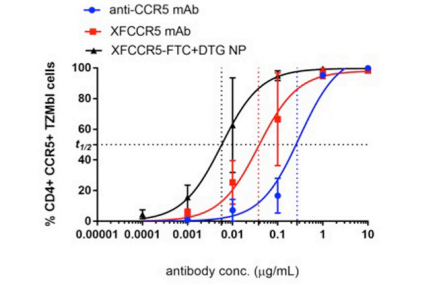
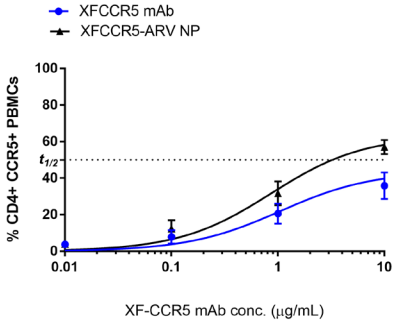


Figure 2. Binding affinity of CCR5 antibody in PBMCs

Michaelis-Menten Best-fit values	XFCCR5 mAb	XFCCR5-ARV NP
Vmax	43.91	63.3
Km	1.051	0.8634



Disclosures. **All authors:** No reported disclosures.