Table 2. RN Coordination of Dalbavancin Course

	n	%
Total courses with RN interventions	32	63
Total courses with RN interventions that included > 1 outpatient dose	25	93
Total OPAT RN interventions	171	
Other OPAT Staff Interventions	27	
RN intervention per patient – mean (STD)	3.35 (5.11)	
Median	1	
Range	0-31	
Other OPAT staff intervention – mean (STD)	0.73 (1.24)	
Median	0	
Range	0-5	
RN Time Analysis *Study Period 4/26/21-5/25/21; 22 business days n=7 patients*		
Total RN time spent on dalbavancin coordination	276 minutes	
Average time spent per work day	12.5 minutes	
Average time spent per patient	39.4 (range 15-58 minutes)	
RN Time by Activity		
Prepared for and/or conducted patient care conference (OPTIONS-DC)	97	
Confirmation of dose administration	20	
Patient reminder about appointment for dose or labs	16	
Attempted to reach patient	42	
Coordination of outpatient doses (ie appt scheduling/rescheduling)	48	
Discharge documentation & order review	37	
Assisted inpatient Case Manager and/or primary team with planning prior to discharge	16	

Table 3. Treatment Course Endpoints

	n (%)
Lost to follow-up	10 (19)
30-day readmission for any reason	7 (13)
90-day readmission for any reason	10 (19)
Readmission due to infection recurrence or dalbavancin adverse effects	4 (8)
Adverse reaction	1 (2)

Conclusion. The OPAT-RN time required to coordinate outpatient DAL for patients with SUD is substantial. This enhanced coordination allows for potential cost savings to health systems.

Disclosures. **Amber C. Streifel, PharmD, BCPS**, **Melinta** (Advisor or Review Panel member) **Monica K. Sikka, MD**, **FG2** (Scientific Research Study Investigator)

626. The Efficacy and Safety of Maintenance with Doravirine Plus Two NRTIs after Initial Suppression in Adults with HIV-1 in the DRIVE-FORWARD Clinical Trial: Results from the Study Extension through 192 Weeks

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Background. DRIVE-FORWARD is a phase 3 trial with a completed double-blind period comparing doravirine (DOR) 100 mg with ritonavir-boosted darunavir (DRV/r) 800/100 mg, both administered with two nucleos(t)ide reverse transcriptase inhibitors (NRTIs; tenofovir and emtricitabine, or abacavir and lamivudine), and an ongoing open-label extension. At Week (W) 48, DOR demonstrated non-inferior efficacy to DRV/r, with a superior lipid profile. Those results were sustained at W96. Here we present efficacy and safety results through W192.

Methods. Participants who completed the 96-week double-blind phase and met inclusion criteria were eligible to receive open-label DOR plus two NRTIs in a 96-week extension. Efficacy and safety at W192 were assessed in two groups: participants initially randomized to DOR and maintained on DOR (n=259) and those who switched from DRV/r to DOR at W96 (n=233).

Results. HIV-1 RNA < 50 copies/mL were maintained through W192 in 81.1% of participants who continued DOR and 80.7% of those who switched from DRV/r to DOR. The mean increase in CD4 T-cell counts from W96 to W192 was similar for participants maintained on DOR (47 cells/mm^3) and those switched from DRV/r (53 cells/mm^3). Protocol-defined virologic failure occurred in 3.1% and 5.6% of participants maintained on DOR and switched from DRV/r, respectively, and development of genotypic resistance was low in both groups (Table 1). Discontinuation due to adverse events was also low (Table 1). Fasting LDL-cholesterol, non-HDL-cholesterol, and triglycerides showed minimal increase in participants maintained on DOR and were reduced in those switched from DRV/r to DOR (Table 1). Participants maintained on DOR had minimal weight gain after W96 (median 1 kg), and a small increase overall (median 1.9 kg, Day 1 through W192); participants who switched to DOR had a small increase after W96 (median 1.5 kg), similar to the median weight gain in the base study (DOR 1.8 kg; DRV/r 0.7 kg).

Conclusion. Among participants who continued DOR in the DRIVE-FORWARD open-label extension, virologic suppression and favorable safety were maintained for an additional 96 weeks. Participants who switched from DRV/r to DOR maintained virologic suppression and demonstrated favorable safety for 96 weeks.

Table 1. DRIVE-FORWARD efficacy and safety outcomes at Week 192 in participants who entered study extension (Weeks 96–192)

	Randomized to DOR arm and maintained on DOR n=259	Randomized to DRV/r arm and switched to DOR n=233
Efficacy outcomes		
HIV-1 RNA <50 copies/mL [a]	210 (81.1)	188 (80.7)
HIV-1 RNA ≥50 copies/mL [a]	10 (3.9)	20 (8.6)
No virologic data in Week 192 window [a]	39 (15.1)	25 (10.7)
HIV-1 RNA 50 to <200 copies/mL	2 (0.8)	5 (2.1)
Protocol-defined virologic failure [b]	8 (3.1)	13 (5.6)
Genotypic resistance to DOR [c]	2 (0.8)	1 (0.4)
Genotypic resistance to NRTI [c]	1 (0.4)	1 (0.4)
	Mean change (95% CI)	**Mean change (95% CI)**
CD4+ T-cell count (cells/mm^3) [d,e]	302 (267, 336)	53 (26, 81)
Safety outcomes		
One or more AE	196 (75.7)	162 (69.5)
Drug-related AE	21 (8.1)	21 (9.0)
Serious AE	17 (6.6)	16 (6.9)
Discontinued because of an AE	5 (1.9)[f]	1 (0.4)
	Mean change (95% CI)	**Mean change (95% CI)**
Fasting LDL-cholesterol (mg/dL) [e]	3.0 (0.1, 5.9)	-7.0 (-10.3, -3.7)
Fasting non-HDL-cholesterol (mg/dL) [e]	3.7 (0.4, 7.1)	-10.6 (-14.2, -6.9)
Fasting triglycerides (mg/dL) [e]	5.1 (-5.1, 15.3)	-15.8 (-26.9, -4.7)
Total cholesterol to HDL ratio [e]	-0.2 (-0.4, 0.1)	-0.4 (-0.5, -0.3)
	Median change (min, max)	**Median change (min, max)**
Weight (kg) [e]	1.9 (-35.2, 61.2)	1.5 (-15.4, 22.9)

Data shown as number (%) of participants, unless otherwise indicated.
[a] FDA Snapshot approach, at Study Week 192.
[b] Protocol-defined virologic failure (PDVF) is defined as confirmed (2 consecutive measures at least 1 week apart) HIV-1 RNA ≥50 copies/mL after initial response of HIV-1 RNA <50 copies/mL at any time during the study.
[c] Resistance was assessed in participants with PDVF and those who discontinued early and had HIV-1 RNA ≥400 copies/mL.
[d] Observed Failure approach for missing data; baseline carried forward for failures, other missing values excluded.
[e] Start = Day 1 for participants maintained on DOR; Week 96 for those who switched from DRV/r.
[f] One additional participant withdrew because of an AE with onset during the double-blind period.
AE, adverse event; CI, confidence interval; DOR, doravirine; DRV/r, ritonavir-boosted darunavir; HDL, high-density lipoprotein; LDL, low-density lipoprotein; NRTI, nucleos(t)ide reverse transcriptase inhibitor.

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627. CURE ID as a Tool for Curating and Analyzing Drugs Used in COVID-19 Clinical Trials

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Background. CURE ID is an internet-based data repository (https://cure.ncats.io/explore) developed collaboratively by FDA and NCATS/NIH. It is designed to capture real-world clinical outcome data to advance drug repurposing and to inform future clinical trials for infectious diseases with high unmet medical need. It also serves as a repository of clinical trials automatically pulled from https://www.clinicaltrials.gov into the CURE ID platform, where they were then manually curated, with the intention of keeping the infectious diseases community updated on the various clinical trials