SUMMARY OF COVID-RELATED IMPACT ON CABOTEGRAVIR AND RILPIVIRINE LONG-ACTING (CAB + RPV LA) DOSING ACROSS THE SIX ONGOING GLOBAL PHASE IIB and III CLINICAL TRIALS

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Disclosures

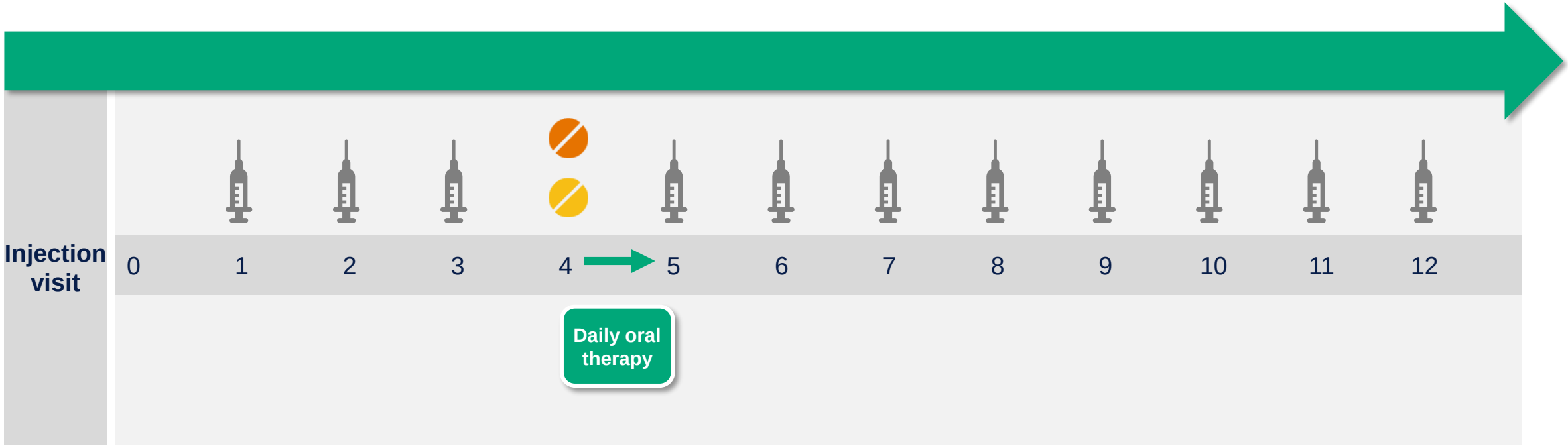
- Maggie Czarnogorski, Ronald D'Amico, Paul Benn, Cindy McCoig, Sandy Griffith, Kris Hudson, Ken Sutton, Conn Harrington, Parul Patel, and David Margolis are current or former employees of ViiV Healthcare and may own stock in GlaxoSmithKline
- Sterling Wu, Will Williams, Kai Hove, Carlos Martín Español, and Jane Fricker are employees of and own stock in GlaxoSmithKline

Introduction

- CAB + RPV LA is a novel, long-acting ART administered intramuscularly monthly or every 2 months by an HCP
- The phase III FLAIR[1] and ATLAS[2] studies demonstrated non-inferiority of monthly CAB + RPV LA to daily oral ART and the phase III ATLAS-2M[3] study demonstrated non-inferiority of every 2 months dosing of CAB + RPV LA to monthly dosing
- Adherence to the LA dosing schedule in the phase II/III clinical program has been high (~98%)[4,5]
- The global COVID-19 pandemic presents a potential challenge to participants' ability to attend scheduled clinic visits for LA dosing administration
- The current analysis assessed implementation fidelity across 6 phase II/III CAB + RPV LA clinical trials during the COVID-19 pandemic

1. Orkin et al. *N Engl J Med.* 2020;382:1124-1135. **2.** Swindells et al. *N Engl J Med.* 2020;382:1112-1123. **3.** Overton et al. CROI 2020; Virtual. Presentation 3334. **4.** Teichner et al. IDWeek 2019; Washington, DC. Presentation 884. **5.** Sutton et al. AIDS 2018; Amsterdam, the Netherlands. Poster THPEB084.

Example of Temporary Oral Therapy as an Option to Manage Interruptions in LA Dosing



IDWeek 2020™; October 21-25, 2020; Virtual

Czarnogorski et al. IDWeek 2020™; Virtual. Slides LB-8.

Methods

- Data from 1744 participants who were active in phase II/III CAB + RPV LA clinical trials from December 1, 2019, to September 15, 2020, were aggregated and analyzed
- A COVID-19–impacted visit was defined as a modified[a] dosing visit; reasons for the COVID-19–impacted visit were determined by the study investigator, and mitigation strategy used to maintain continuous ART was approved by the medical monitor
- Summary statistics including frequency, proportion, and mean were reported
- Data collection is continuously ongoing and updates will be provided in future reports

Trial	Phase	Participants on CAB included in analysis, n[b] (N=1744)	IM LA dosing schedule
LATTE-2[1]	IIb	215	Q4W Q8W
FLAIR[2]	III	443	Q4W
ATLAS[3]	III	46	Q4W
ATLAS-2M[4]	III	927	Q4W Q8W
POLAR	IIb	88	Q2M
CUSTOMIZE[5]	IIIb	25	Q1M

[a]Oral therapy was provided to patient because patient was not able to attend clinic or LA dosing was rescheduled.
[b]Active participants as of September 15, 2020.

1. Margolis et al. *Lancet*. 2017;390:1499-1510. **2.** Orkin et al. *N Engl J Med.* 2020;382:1124-1135.
3. Swindells et al. *N Engl J Med.* 2020;382:1112-1123. **4.** Overton et al. CROI 2020; Virtual. Presentation 3334.
5. Czarnogorski et al. AIDS 2020; Virtual. Poster LBPEE42.

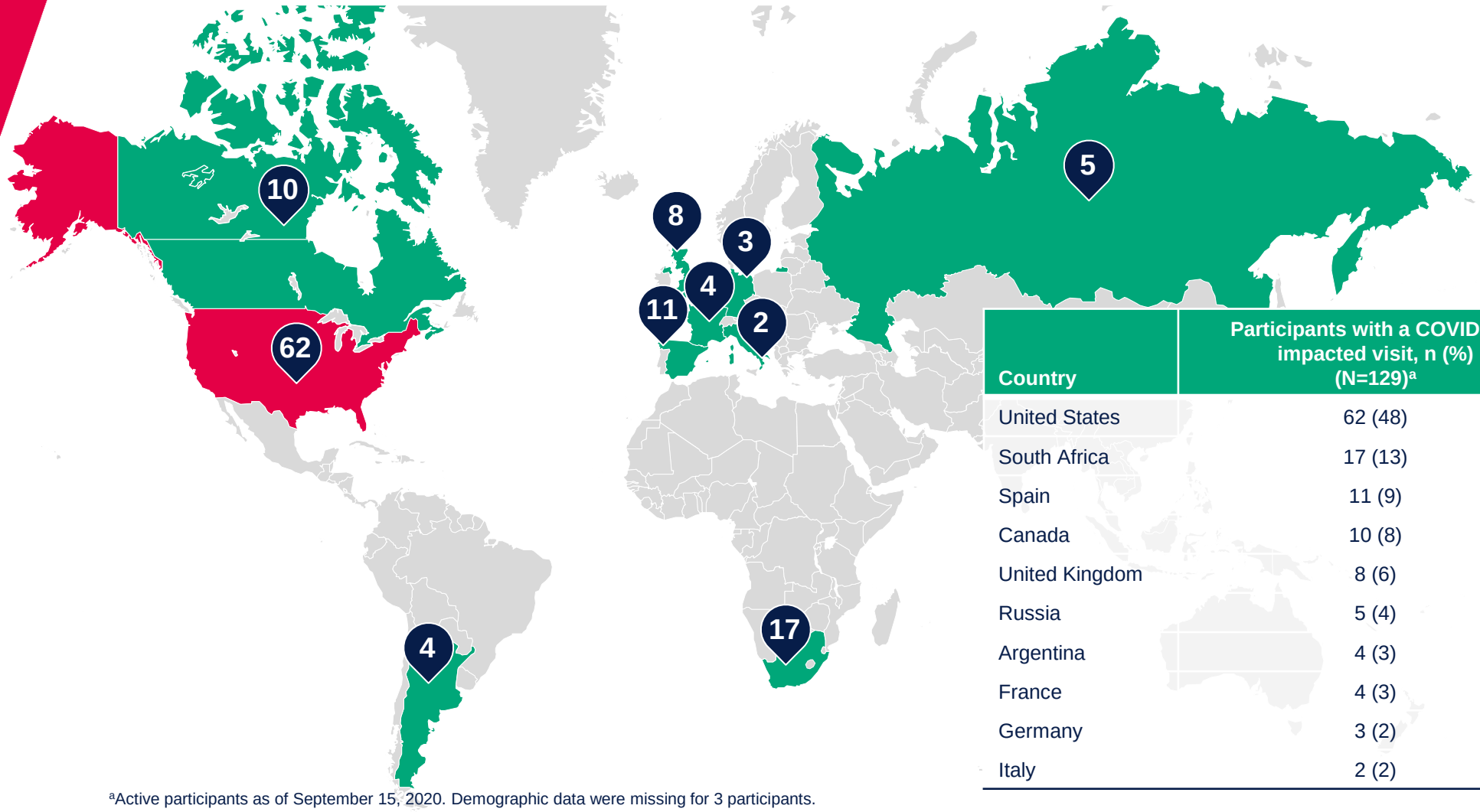
Characteristics of Participants With a COVID-19–Impacted Visit

Characteristic	Participants with a COVID-19–impacted visit (N=129)[a]	Total participants in all trials (N=2071)[b]
Sex, n (%)		
Female	25 (19)	474 (23)
Male	101 (78)	1597 (77)
Race, n (%)		
White	86 (67)	1510 (73)
Black or African American	36 (28)	391 (19)
Other	4 (3)[c]	170 (8)[d]
Median age, y	36	39
Region, n (%)		
North America	72 (56)	785 (38)
Europe	33 (26)	1010 (49)
South Africa	17 (13)	131 (6)
Latin America	4 (3)	63 (3)

- From December 1, 2019, to September 15, 2020, 129 of 1744 (7.4%) active participants in CAB + RPV LA clinical studies had injection visits impacted by COVID-19

[a]Demographic data were missing for 3 participants. [b]Includes all participants on CAB + RPV LA regardless of whether they attended visits during the analysis period. [c]Other includes Asian (n=2), American Indian or Alaska native (n=1), and Native Hawaiian or other Pacific Islander (n=1). [d]Other includes Asian (n=89), American Indian or Alaska native (n=53), multiple races (n=22), and Native Hawaiian or other Pacific Islander (n=6).

Geographic Distribution of Participants With a COVID-19–Impacted Visit



Country	Participants with a COVID-19–impacted visit, n (%) (N=129)[a]	Total participants from all trials, n (%) (N=2071)
United States	62 (48)	647 (31)
South Africa	17 (13)	131 (6)
Spain	11 (9)	349 (17)
Canada	10 (8)	138 (7)
United Kingdom	8 (6)	16 (1)
Russia	5 (4)	239 (12)
Argentina	4 (3)	41 (2)
France	4 (3)	124 (6)
Germany	3 (2)	177 (9)
Italy	2 (2)	72 (3)

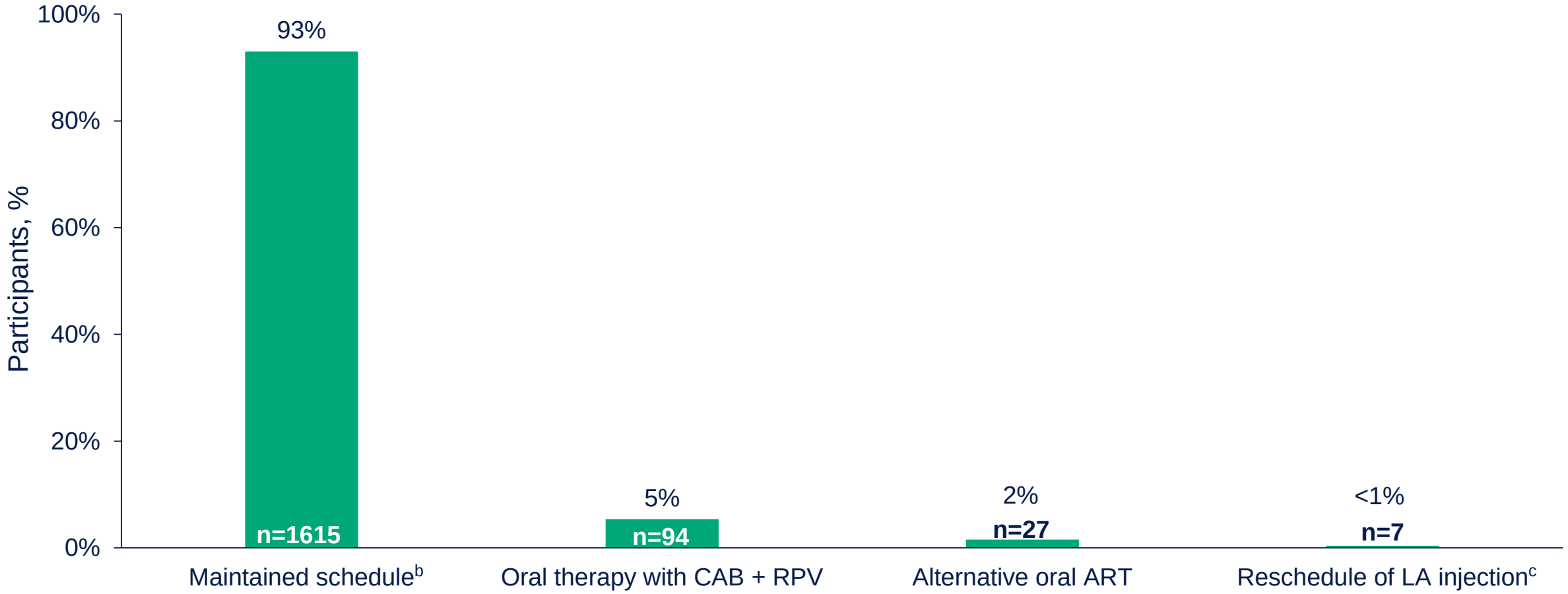
[a]Active participants as of September 15, 2020. Demographic data were missing for 3 participants.

Reasons for COVID-19–Impacted Visits

Reasons for missed visit, n (%)	All participants impacted by COVID-19 (n=129)	Participants who received oral CAB + RPV (n=94)	Participants who received alternative oral ART (n=27)
Clinic closure/Staffing constraints	54 (42)	30 (32)	24 (89)
Confirmed/Suspected COVID-19	18 (14)	18 (19)	0
Self-quarantine	11 (9)	10 (11)	0
COVID-19–related travel restrictions	7 (5)	6 (6)	1 (4)
Refusal to attend the clinic visit	6 (5)	6 (6)	0
Other	33 (26)[a]	24 (26)	2 (7)

[a]Other: the majority of reasons originally coded as other have further been shown to be due to travel restrictions.

Most LA Dosing Visits During the COVID-19 Pandemic Proceeded as Planned—Few Participants Had COVID-19–Impacted Visits; Most Used Temporary Oral Therapy to Maintain Continuous ART[a]



[a]One participant was removed from the study. [b]Attended an injection visit within the planned ± 7-day window. [c]Attended an injection visit 1 day before or up to 5 days after the treatment window.

Temporary Alternative Oral ART for COVID-19–Impacted Visits

- For a planned missed injection visit, physicians prioritized oral CAB + RPV for temporary oral therapy
- If oral CAB + RPV was unavailable, physicians were allowed to choose an alternative oral ART; 81% of participants were started on a DTG-based regimen

Alternative oral ART, n (%)	Participants using alternative oral ART for COVID-19–impacted visits (N=27)
DTG/RPV or DTG + RPV	11 (41)
DTG/ABC/3TC	10 (37)
EVG/COBI/TAF/FTC	2 (7)
EFV/TDF/FTC	1 (4)
BIC/TAF/FTC	1 (4)
DRV/r/TDF/FTC	1 (4)
DTG + TDF/FTC	1 (4)

Follow-up Observations of Participants Receiving Oral Therapy for COVID-19–Impacted Visits

- The median duration of oral therapy to cover the COVID-19 impacted visit(s) thus far is 51 days (IQR, 27 to 69)[a]
- As of October 19, 2020, 110 of 121 (91%) participants who transitioned to temporary oral therapy have restarted LA therapy, and disposition of remaining participants is in progress
- No suspected or confirmed virologic failures have been observed as a consequence of COVID-19-impacted visits

IQR, interquartile range.

[a]Data for median duration were available for 103 participants as of September 15, 2020.

Conclusions

- Despite the impact of the global COVID-19 pandemic on healthcare services, there have been no ART interruptions among participants in CAB + RPV LA clinical trials
- The vast majority (93%) of participants' injection visits occurred as planned
- The few participants with missed injection visits were maintained on continuous ART by temporarily switching to oral therapy, most often with oral CAB + RPV or an alternative oral ART
- No instances of virologic failure or HIV-1 RNA ≥50 c/mL have been observed among CAB + RPV LA clinical trial participants with COVID-19–impacted visits
- Flexibility of dosing of the regimen, with ability to switch to temporary oral therapy, has facilitated continuous ART provision and implementation fidelity in 6 active CAB + RPV LA clinical trials during the global COVID-19 pandemic