สมาคมโรคเอดส์แห่งประเทศไทย
Thai AIDS Society
TAS

20th HIV/AIDS WORKSHOP 2021

ขอเชิญเข้าร่วม
VIRTUAL
CONFERENCE

21-22
สิงหาคม
2564

การดูแลรักษาผู้ติดเชื้อ เอชไอวี/เอดส์ ครั้งที่ 20

วันเสาร์ที่ 21 สิงหาคม 2564

Moderator: ศ. พญ.ศศิโสภิณ เกียรติบูรณกุล
รศ. นพ.ธนา ขอเจริญพร

08.50-09.00	เปิดการประชุม
09.00-09.30	Present and Future of HIV Treatment *ศ. นพ.เกียรติ รักษ์รุ่งธรรม*
09.30-10.00	Advanced Issues on HIV/AIDS *ผศ. นพ โอภาส พุทธเจริญ*
10.00-10.30	Advances and Implementation of HIV PrEP *ศ. พญ.ศศิโสภิณ เกียรติบูรณกุล*
10.30-11.00	HIV and COVID-19 in 2021 and Beyond *รศ. นพ.ธนา ขอเจริญพร*
11.00-11.50	Industrial Sponsored Symposium (DCH Auriga) It is Time to Switch *รศ. นพ.ธนา ขอเจริญพร* *ศ. พญ.ศศิโสภิณ เกียรติบูรณกุล (ผู้ดำเนินการบรรยาย)*
12.00-12.50	Industrial Sponsored Symposium (ViiV) Changing Recommended First-line Regimens and Future Treatment Options *ผศ. นพ.โอภาส พุทธเจริญ* *ศ. พญ.ศศิโสภิณ เกียรติบูรณกุล (ผู้ดำเนินการบรรยาย)*
13.00-14.30	Challenging Cases in ART Initiation *ผศ. นพ.ถนอมศักดิ์ อเนกธนานนท์,* *รศ. นพ.วรพจน์ ตันติศิริวัฒน์,* *ผศ. นพ.ธวัชชัย จริยะเศรษฐพงศ์* *อ. พญ.กัณฑริดา ศรีพานิชกุลชัย (ผู้ดำเนินการบรรยาย)*
14.30-16.00	Challenging Cases in Management of Opportunistic Infections *พ.อ.ฐิติวัฒน์ ช่างประดับ,* *รศ. นพ.ภิรุญ มุตสิกพันธุ์* *ผศ. พญ.พรรณศจี ดำรงค์เลิศ (ผู้ดำเนินการบรรยาย)*

วันอาทิตย์ที่ 22 สิงหาคม 2564

Moderator: ร.ต.คริส ฟูจิตนิรันดร์

08.50-09.00	เปิดการประชุม
09.00-10.00	HIV and Kidney: Progress in Renal Replacement Therapy and Renal Transplantation *นพ.วิศิษฏ์ ประสิทธิศิริกุล*
10.00-11.00	Management of Treatment Failure in INSTI Era: Interactive-case Discussion นพ.วีรวัฒน์ มโนสุทธิ, รศ .นพ.วินัย รัตนสุวรรณ ร.ต.คริส ฟูจิตนิรันดร์ *(ผู้ดำเนินการบรรยาย)*
11.00-11.50	Industrial Sponsored Symposium (Janssen) The Key Role of Protease Inhibitors in HIV Management *นพ.วีรวัฒน์ มโนสุทธิ* *ศ. พญ.ศศิโสภิณ เกียรติบูรณกุล (ผู้ดำเนินการบรรยาย)*
12.00-12.50	Industrial Sponsored Symposium (สมาคมโรคเอดส์แห่งประเทศไทยร่วมกับองค์การเภสัชกรรม) Can We Cure HBV and HCV? *พญ.อัญชลี อวิหิงสานนท์*
13.00-14.30	DTG/TLD in Children and Pregnant Women *พญ.ธังสิมา โล่ห์เลขา,* *รศ. พญ.ธันยวีร์ ภูธนกิจ,* *รศ. พญ.วนัทปรียา พงษ์สามารถ* *ศ. พญ.กุลกัญญา โชคไพบูลย์กิจ (ผู้ดำเนินการบรรยาย)*
14.30-15.30	Management and Prevention of HIV Infection in Adolescents *อ. พญ.สุพัตรา รุ่งไมตรี,* *อ. นพ.พร ทิสยากร,* *พญ.วิภาพร ทรงทวีสิน*

Global Situation (21 Aug 2021)

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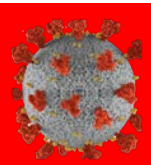
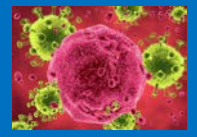
Covid-19



- Pandemic since Jan 2020 x **1.9 Yrs**
- **211.5 million** *confirmed cases*
- **4.4 million** *confirmed death*
- **Transmission:** droplets, airbourne, contact
- **Vaccines** : >6 vaccines approved
- **Effective treament** : few
- **Prevention**: Mask, Distancing, Cleaning
- **Global impact** : very high

HIV /AIDS



- Epidemic since 1981 x **40 yrs**
- **37.7 million** living with HIV
- **36 million** **d**ied from 1981-2020
- **1.5 million** New Infection/yr
- **Transmission** : sexual, blood
- **Vaccine** : unlikely up-to-now
- **Effective treament** : **Yes**
- **Prevention**: Condom, PrEP, TasP
- **Global impact** : high

Thai Situation (21 Aug 2021)

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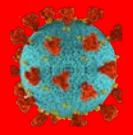
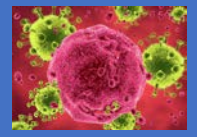
Covid-19



- Pandemic since Jan2020 **1.10 yr**
- **1,009,710** *confirmed cases*
- **8,826** *confirmed death*
- **>20,000** New cases/day
- **Partial lockdown**
- **Vaccine rollout**

HIV /AIDS



- Epidemic since 1984 x **36 yrs**
- **500 000** living with HIV
- **Total death >300,000** since 1984
- **12,000** died in 2020
- **6,600** New cases/year
- **Can we end AIDS?**
- **Complacency ?**
- **Long term: Aging and NCDs**

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HIV/AIDS remains **our challenges**

Ending AIDS 2030 !

- **Transmission** : sexual, blood
- **Vaccine** : unlikely up-to-now
- **Effective treament** : **Yes, ART**
- **Effective Prevention**: Condom use, **PrEP, TasP**
- **Global, country impact** : high

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Chula Vaccine Research Center
Faculty of Medicine, Chulalongkorn University

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Current and Future

HIV Treatment

Kiat Ruxrungtham

Professor of Medicine, School of Global Health,
ChulaVRC, Chulalongkorn University;

and HIV-NAT, Thai Red Cross AIDs Research Center

Outlines: Current and Future HIV Treatment

- DEVELOPMENT OVERVIEW IN THE PAST 40 YEARS
- CURRENT ART OPTIONS AND GUIDELINES
- NEWER REGIMENS AND OPTIONS
- NOVEL & FUTURE DRUGS IN THE PIPLINES
- REMAINING CHALLENGES

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Four Decades of HIV Therapy

Present and the Future

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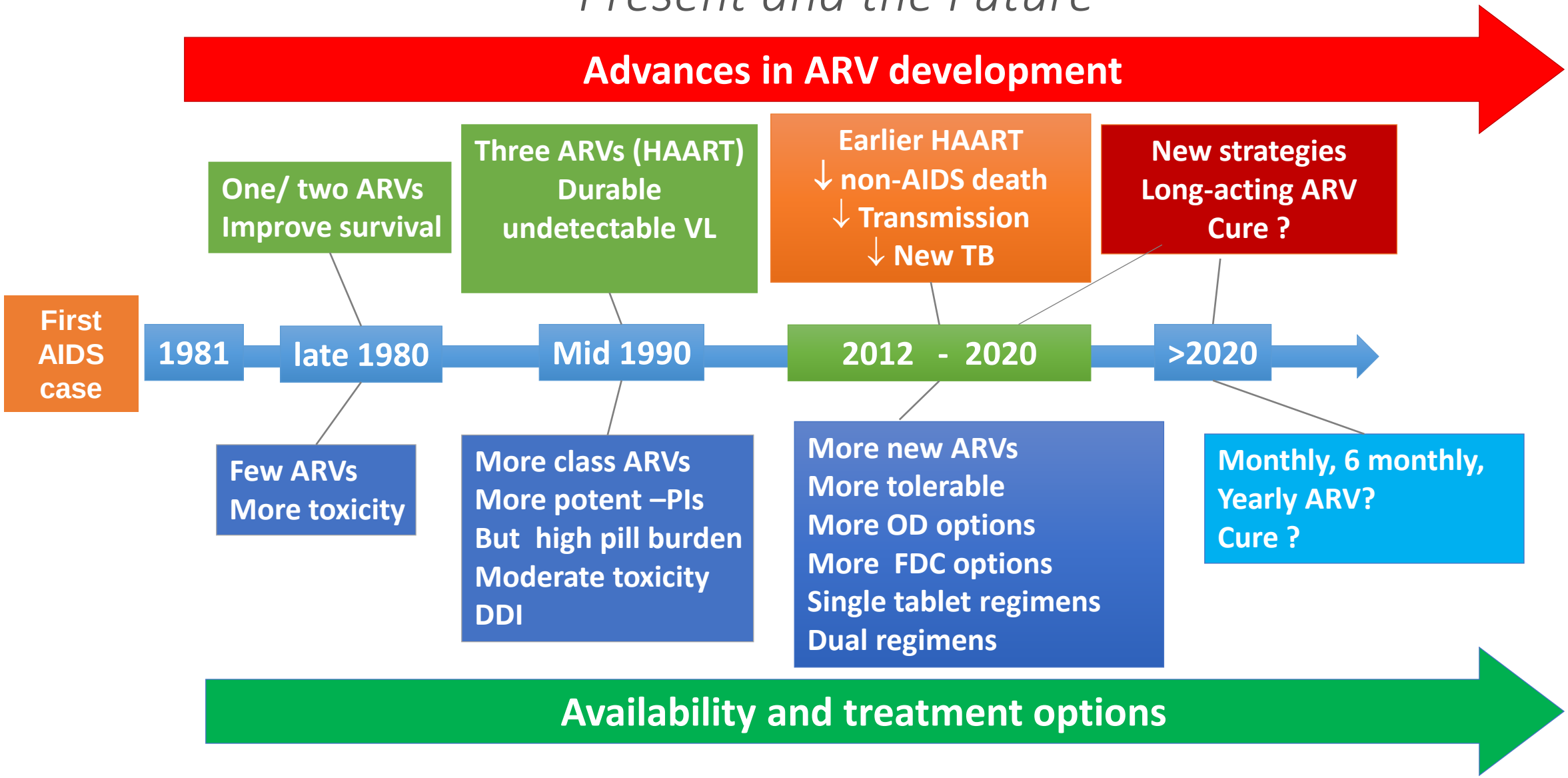

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Faculty of Medicine, Chulalongkorn University

HIV Treatment Can Normalize Survival

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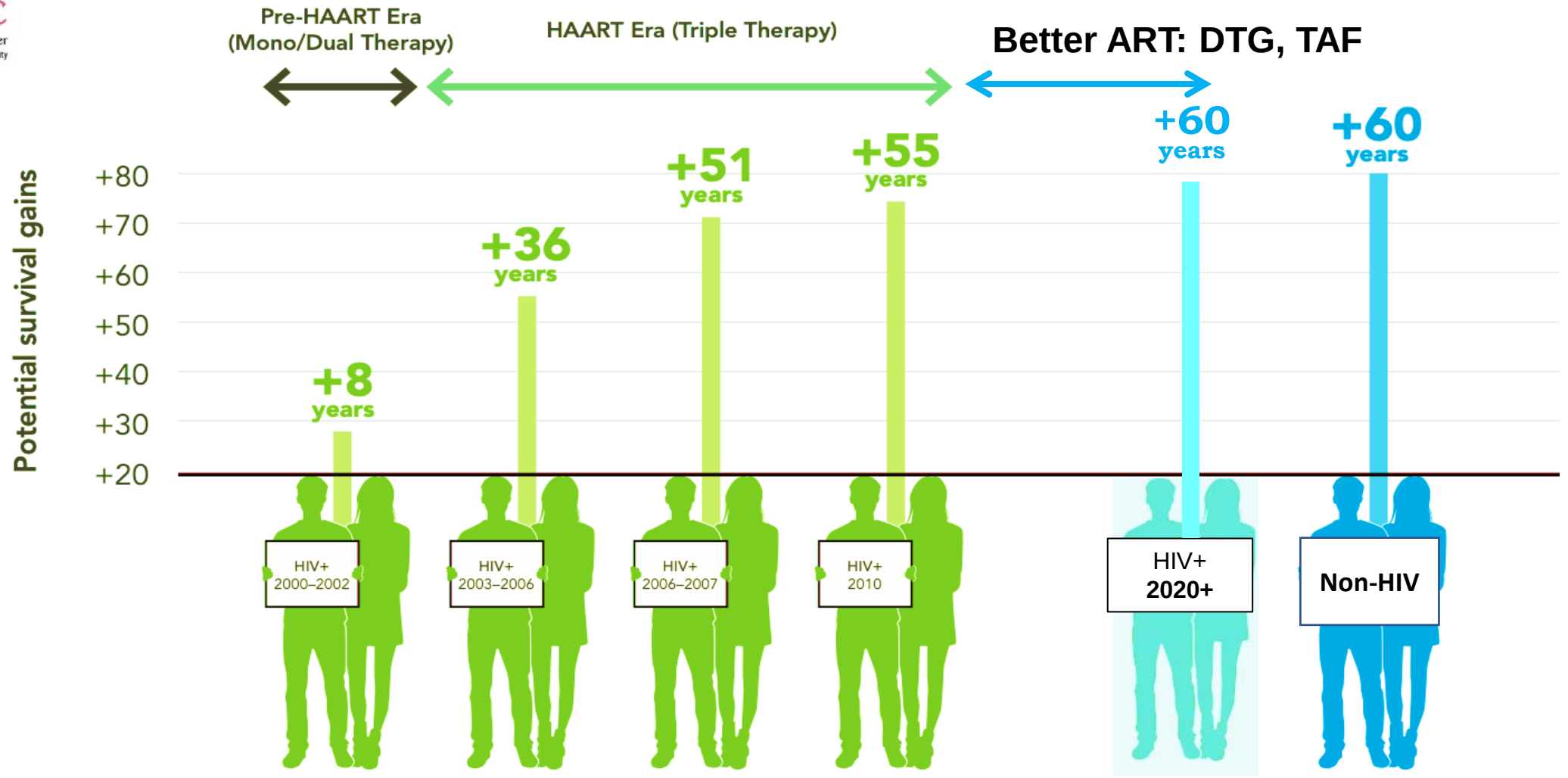

Expected impact of HIV treatment in survival of a 20 years old person living with HIV in a high income setting (different periods)

Source: Samji H et al., PLoS ONE, 2013.

Teeraananchai S, et al. Antivir Ther. 2017;22(5):393–402

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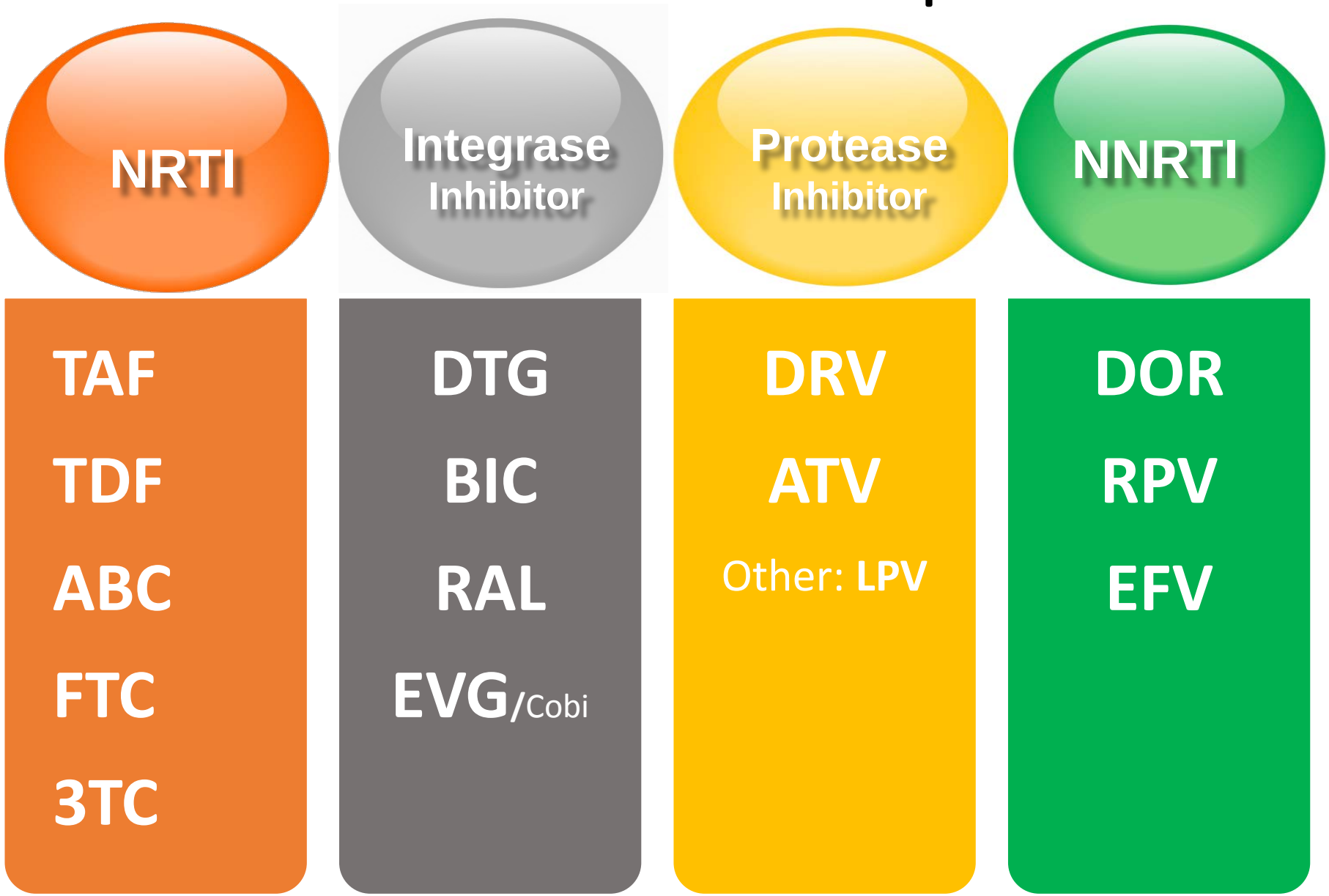
Current Oral ARV options



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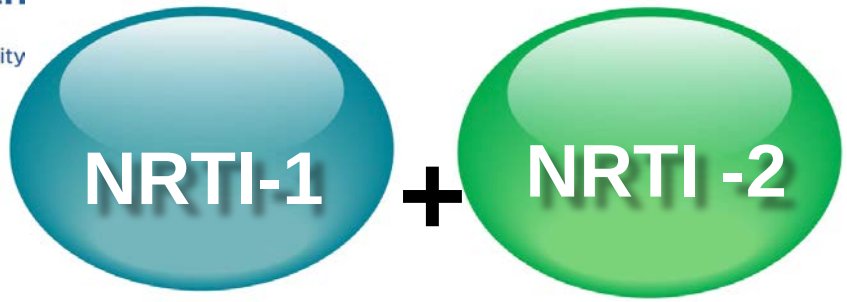


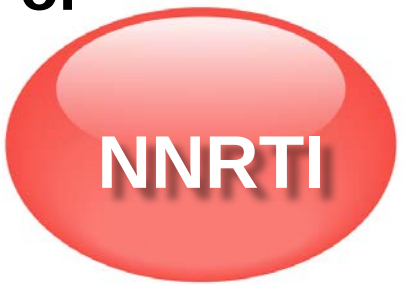
TAF
TDF
ABC*

FTC
3TC*

\+

Dolutegravir **DTG***
Bictegravir **BIC**
Elvitegravir **EVG/C**
Raltegravir **RAL**

or



Rilpivirine **RPV**
Doravirine **DOR**
Efavirenz **EFV**

or

Darunavir **DRV**
Atazanavir **ATV**
(both need a booster RTV or Cobi)

Principle of
ART combination
3-drug Regimens

***ABC only for HLA-B*5701 negative person, *ABC+3CT combined with DTG as a STR,**

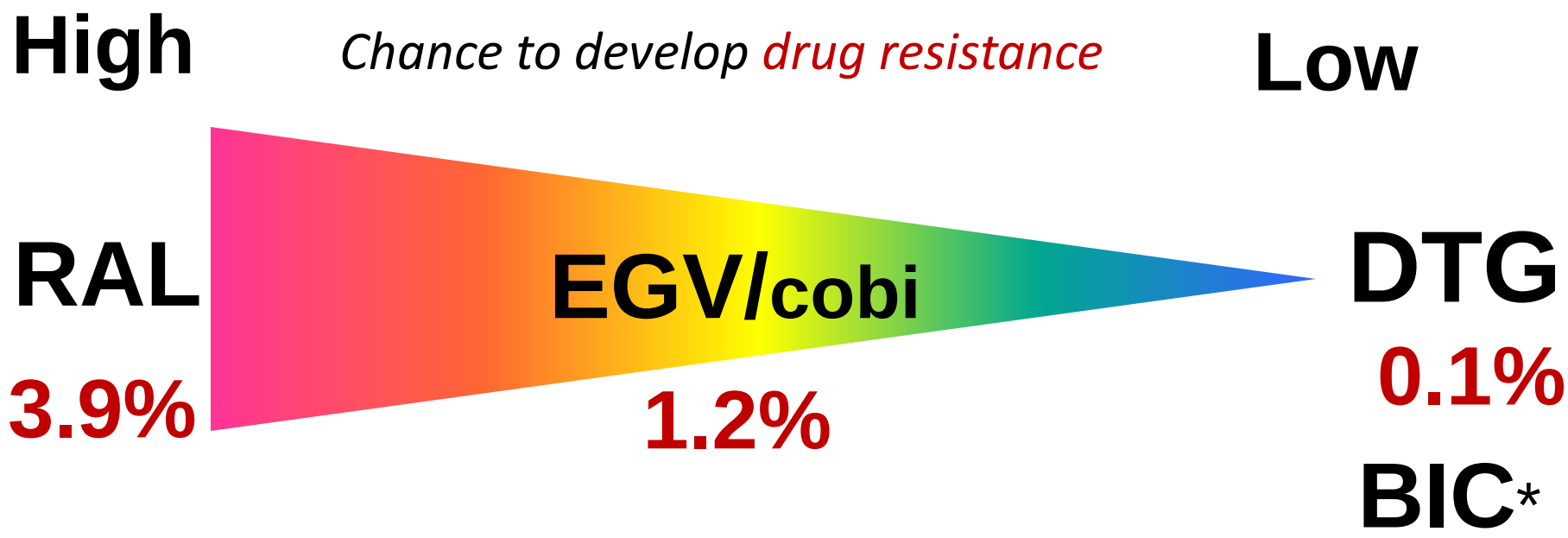
	Integrase Inhibitor	Protease Inhibitor	NNRTI
Tolerability	++++	+++	EFV ++ RPV ++++
Genetic Resistance Barrier	DTG, BIC – High RAL, EVG - Low	High	Low
Single pill regimen	DTG, EVG/c, BIC- Yes	Only 1 (only DRV/c/TAF/FTC)	Yes
Drug-Drug interaction	EVG/c - High DTG, RAL, BIC - Low	High	Low

HIV Integrase Inhibitors

Chance to develop drug resistance

Subgroup meta-analysis from clinical trials

You, PLoS One. 2016;11:e0160087



RAL vs DTG – DR rate 3.9% vs 0.1% (40-fold higher)
RAL, EVG/c: 10 major integrase mutations (N155H, Y143C/R, Q148H/R, Y143Y/H, L74L/M, E92Q, E138E/A, Y143C, Q148Q and Y143S)
DTG 13 mutations (T97T/A, E138E/D, V151V/I, N155H, Q148, Y143C/H/R, T66A and E92Q).

* Acosta RK. AAC. 2019

DTG, BIC : Options for patients who plan to start ART before having resistance test results

Food Effect

With Food

to improve absorption

- Rilpivirine
- EVG/c
- DRV or ATV,+rtv,c

Empty Stomach

to reduce AEs

- Efavirenz

No meal restriction

- Dolutegravir
- Bictegravirr
- Raltegravir
- Doravirine

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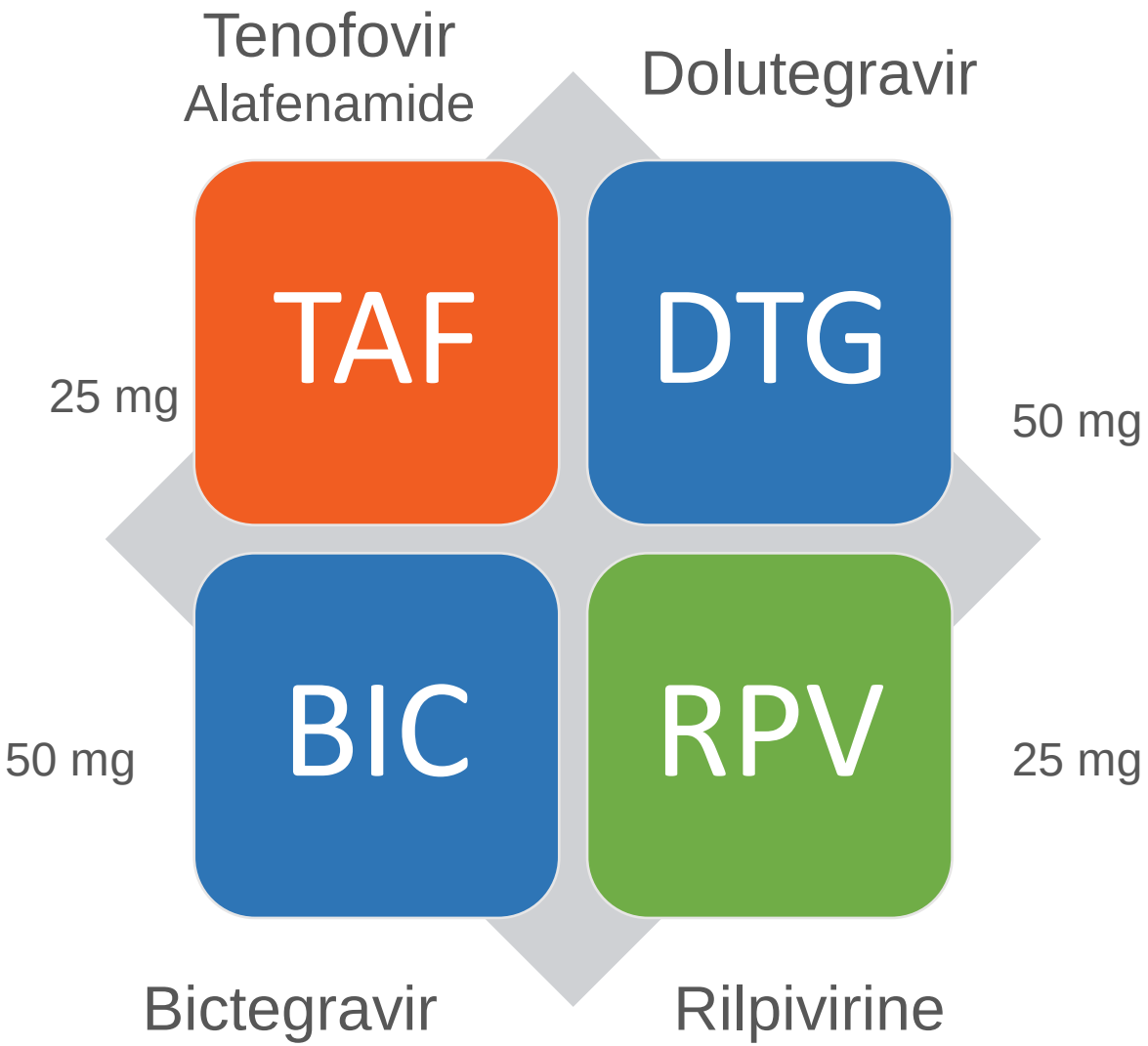
High potency ARVs lead to much **smaller doses** *and* **smaller pills**



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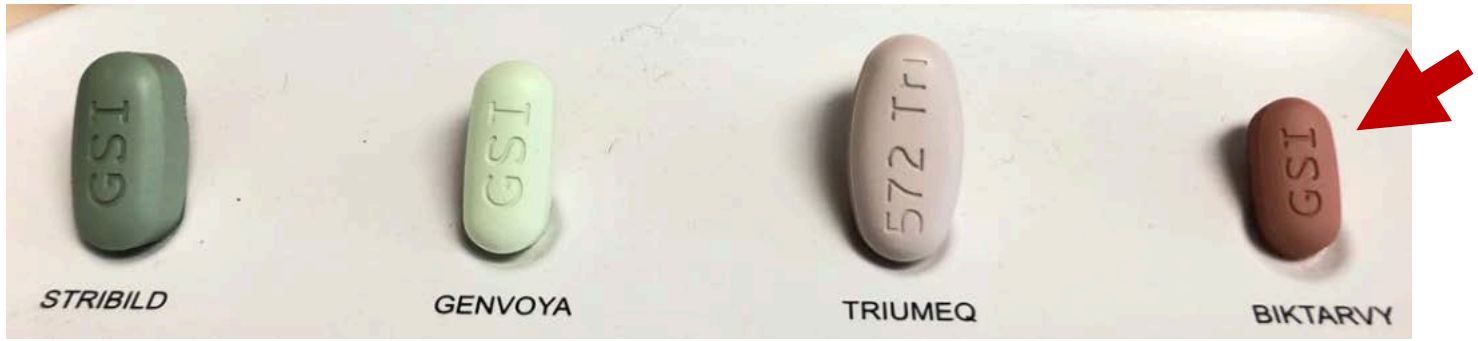
New INSTi STR: BIC/TAF/FTC

Bictegravir, Emtricitabine, Tenofovir Alafenamide (Biktarvy®)

U.S. FDA approval : Feb 2018



EGV/c/TDF/FTC	EGV/c/TAF/FTC	DTG/ABC/3TC	BIC/TAF/FTC
100/150/300/200	100/150//10/200	50/600/300	50/25/200

Carlos del Rio; @CarlosdelRio7 tweeter

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DTG-based vs other ART in Controlled Trials

First-line regimen

SPRING 2	**DTG** is ***non-inferior*** to **RAL** 96 weeks results. More DR was found in RAL, but none in DTG among those with VF
SPRING	**DTG** is ***superior*** to **EFV** **(ABC/3TC/DTG) at 48 and 144 weeks**
FLAMINGO	**DTG** is ***superior*** to **DRV/r** **at 48 and 96 weeks**
ARIA	**DTG** is ***superior*** to **ATV/r** **at 48 weeks**
GS-US-380-1490 & 1498	**DTG** is ***non-inferior*** to **BIC**

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Adult HIV Treatment Guidelines

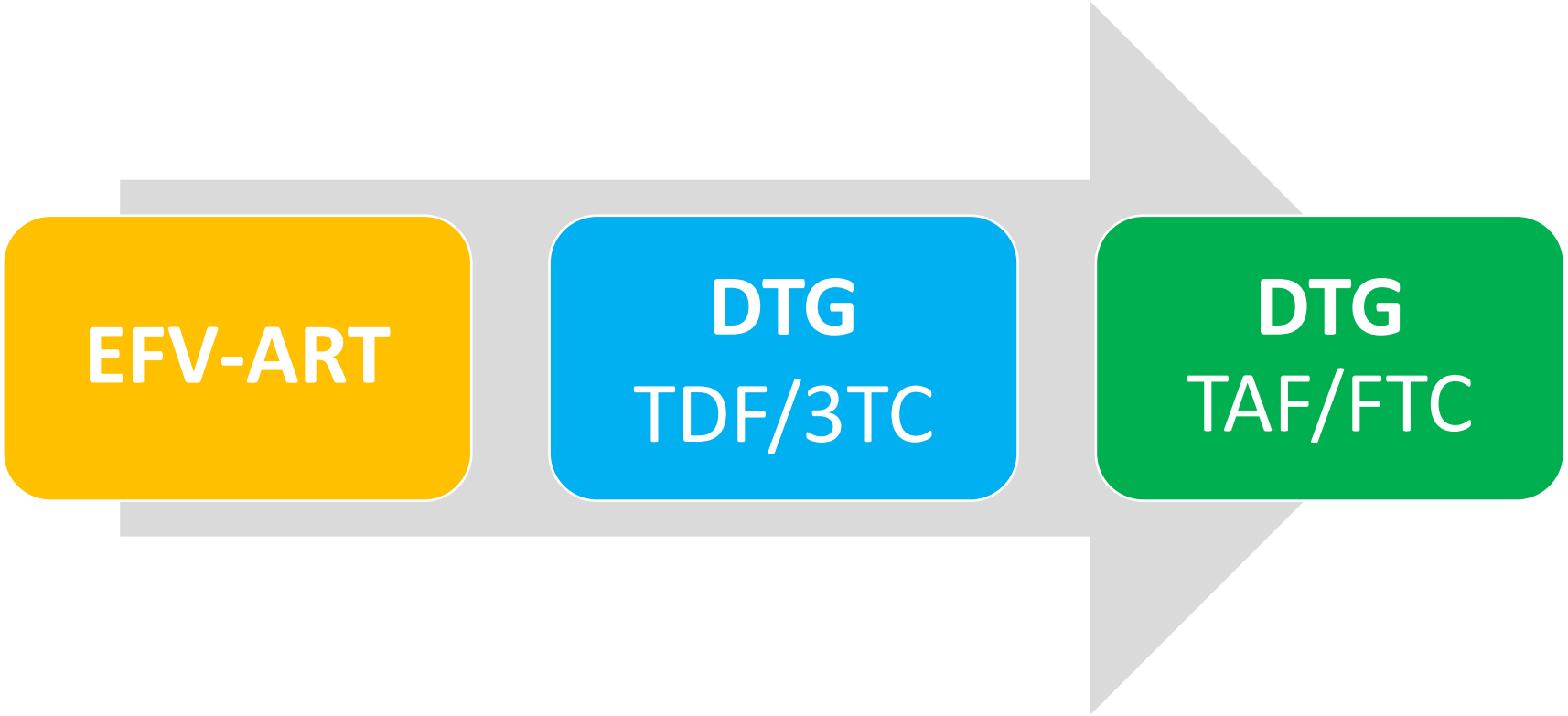
DHHS[1]	IAS-USA[2]	EACS[3]	WHO[4]
▪ **BIC**/FTC/TAF ▪ **DTG**/3TC/ABC ▪ **DTG** + FTC/(TAF or TDF) ▪ **RAL** + FTC/(TAF or TDF)	▪ **BIC**/FTC/TAF ▪ **DTG**/3TC/ABC ▪ **DTG** + FTC/TAF	▪ BIC/FTC/TAF ▪ **DTG**/3TC/ABC ▪ **DTG** + FTC/(TAF or TDF) ▪ RAL + FTC/(TAF or TDF) ▪ **RPV**/FTC/(TAF or TDF) ▪ **DRV**(COBI or RTV) + FTC/(TAF or TDF)	▪ **DTG** + (3TC or FTC)/TDF

- Recommendations may differ based on baseline HIV-1 RNA, CD4+ cell count, CrCl, eGFR, HLA-B*5701 status, HBsAg status, bone mineral density, and pregnancy status or intent

1. DHHS ART. Guidelines. October 2018. 2. Saag. JAMA. 2018;320:379. 3. EACS. 2019. 4. WHO ART. December 2018.

Slide credit: clinicaloptions.com

Current **ART options** in Thailand



Higher Potency,
Lower toxicity and,
Low cost

Why we do need more new ART options?

Current Preffered ART Regimens	Why Desire for more new options
• Highly Effective • Easy to take once daily • High barrier to drug resistance • Well-tolerated and safe	• Can be taken once a month or longer • Concern of unanticipated long-term toxicities of current ARVs • Concern of emergence of drug resistance • Less drug-drug interaction

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Future Trends

Simplify Treatment, Reduce number of drug exposure

1 Reduce from 3 to 2 drug-regimen (Daul ART)

DTG/3TC

CAB/RPV

Lenacapavir + Islatravir :
Oral or Injection

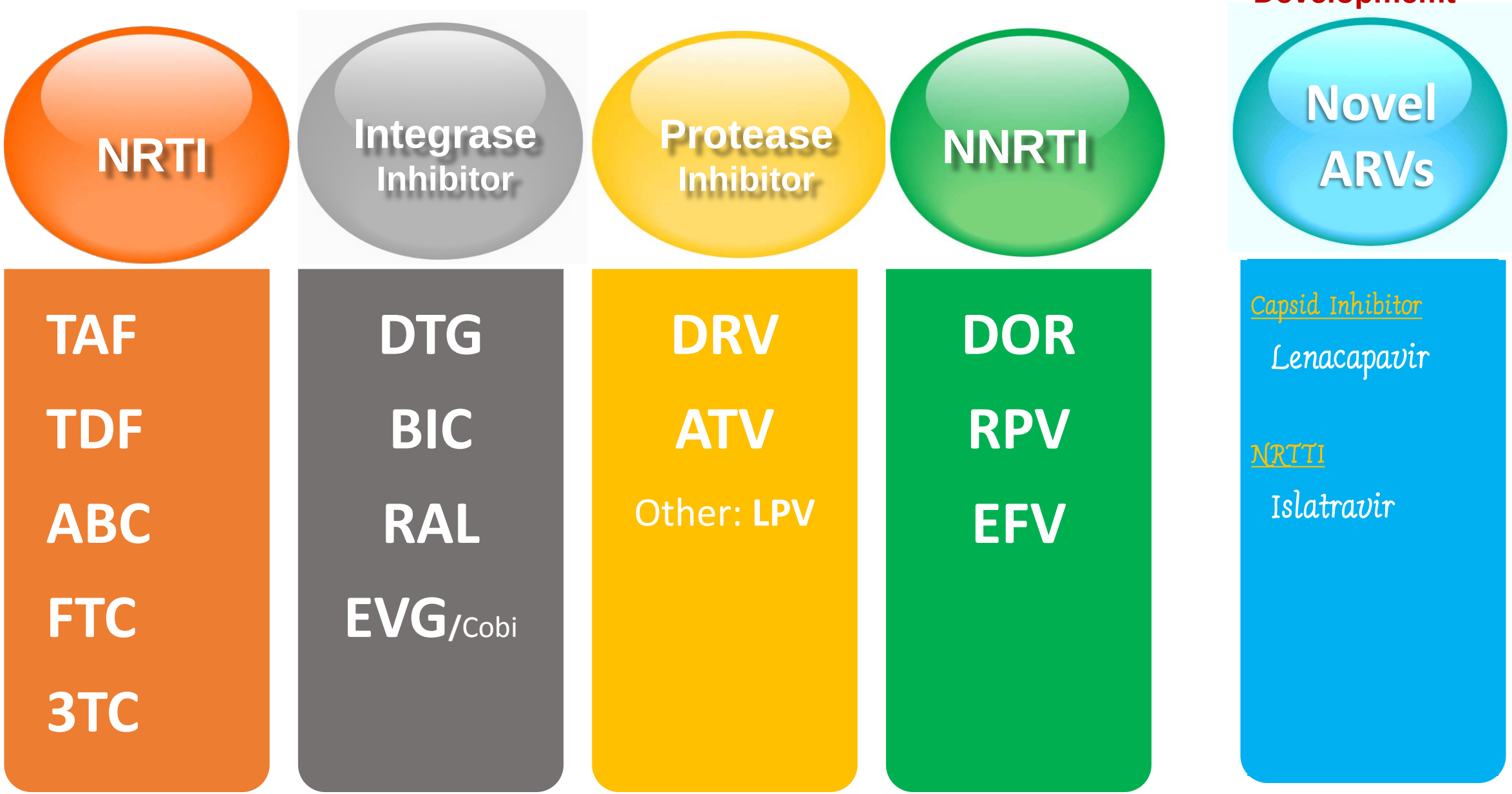
2 Reduction in dose frequency

LA injectable ARVs
LA implantable ARVs

6 Monthly Shot

Implant Device

Current and Future ARV options



Reducing Dose Frequency and Number of Drugs

Agent	MoA	Phase	Innovation
Elsulfavirine[1]	NNRTI	II/III	Long acting
Lenacapavir (GS-6207)[2]	Capsid inhibitor	I	Long acting, fewer than 3 drugs
Islatravir (MK-8591)[3,4]	NRTTI	III	Long acting, fewer than 3 drugs
Leronlimab (PRO 140)[5]	Anti-CCR5 mAb	IIb/III	Long acting, fewer than 3 drugs
CAB + RPV[6,7]	INSTI + NRTI	III	Long acting, fewer than 3 drugs
DTG/3TC[8]	INSTI/NRTI	FDA approved (initial therapy and maintenance)	Fewer than 3 drugs
DTG/RPV[9]	INSTI/NRTI	FDA approved (maintenance)	Fewer than 3 drugs
Ibalizumab[10]	mAb CD4-directed post-attachment HIV-1 inhibitor	FDA approved (multidrug resistant HIV-1)	Long acting

1. NCT02489461. 2. NCT04150068. 3. NCT04233879. 4. NCT04223778. 5. Dhody. CROI 2019. Abstr 486.
6. Swindells. NEJM. 2020;382:1112. 7. Orkin. NEJM. 2020;382:1124. 8. DTG/3TC PI. 9. DTG/RPV PI. 10. Ibalizumab PI.

Slide credit: clinicaloptions.com

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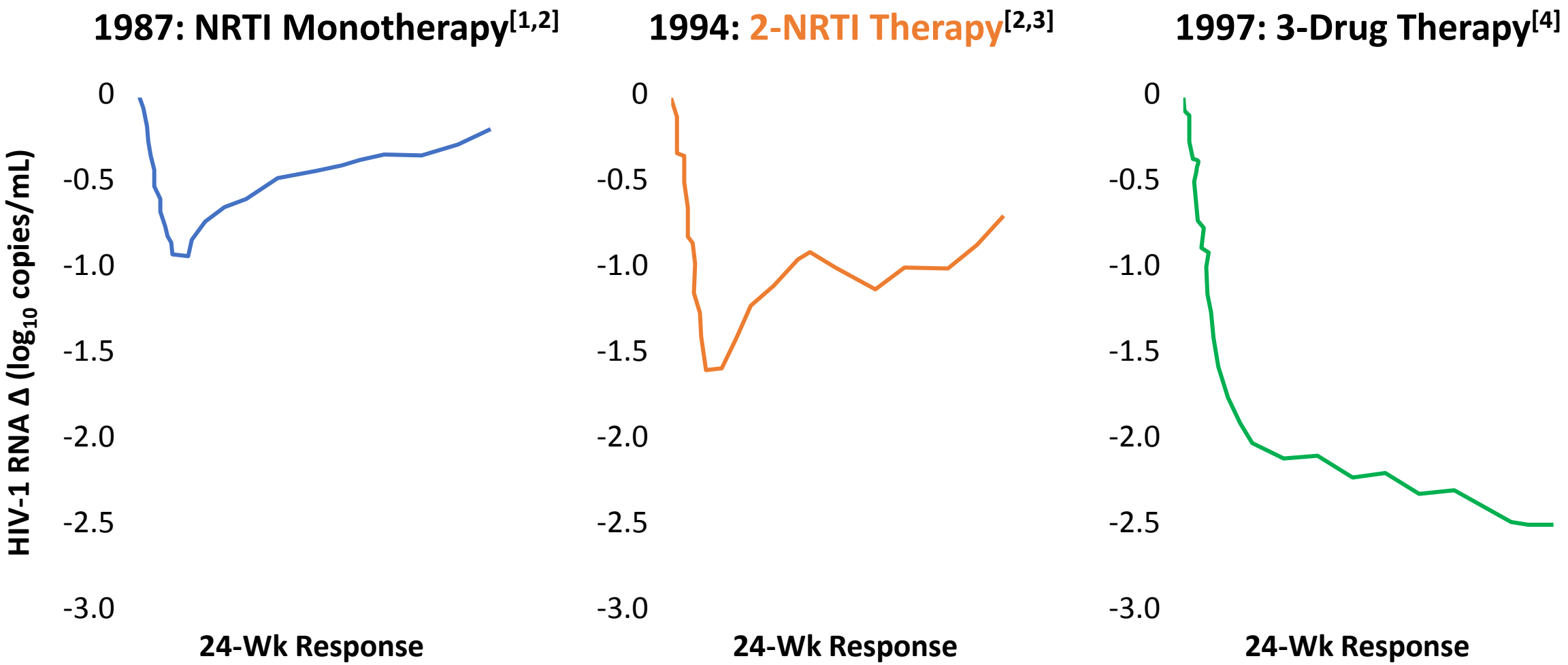
Evolution of ART: 1987-1997



1. Fischl. NEJM. 1987;317:185. 2. Harrigan. J Acquir Immune Defic Syndr Hum Retrovirol. 1995;10 Suppl 1:S34.
3. Eron. NEJM. 1995;333:1662. 4. Gulick. NEJM. 1997;337:734.

Slide credit: clinicaloptions.com

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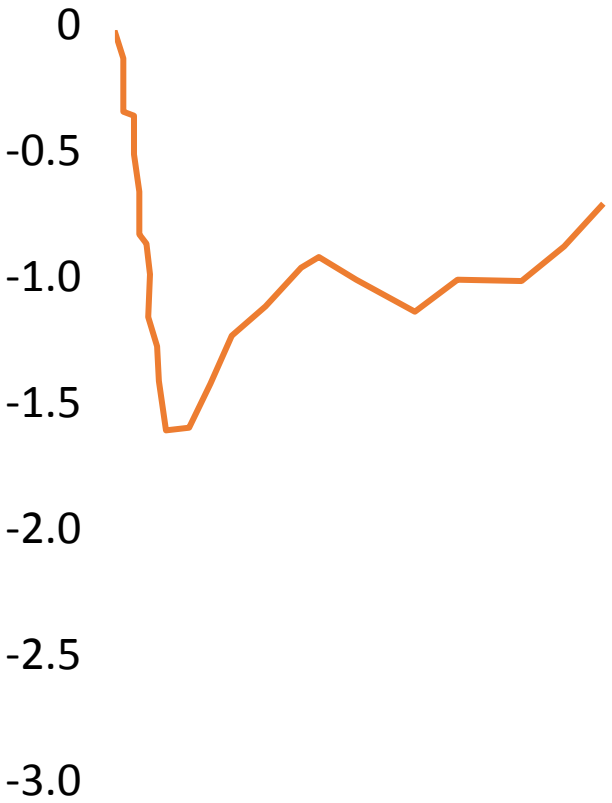
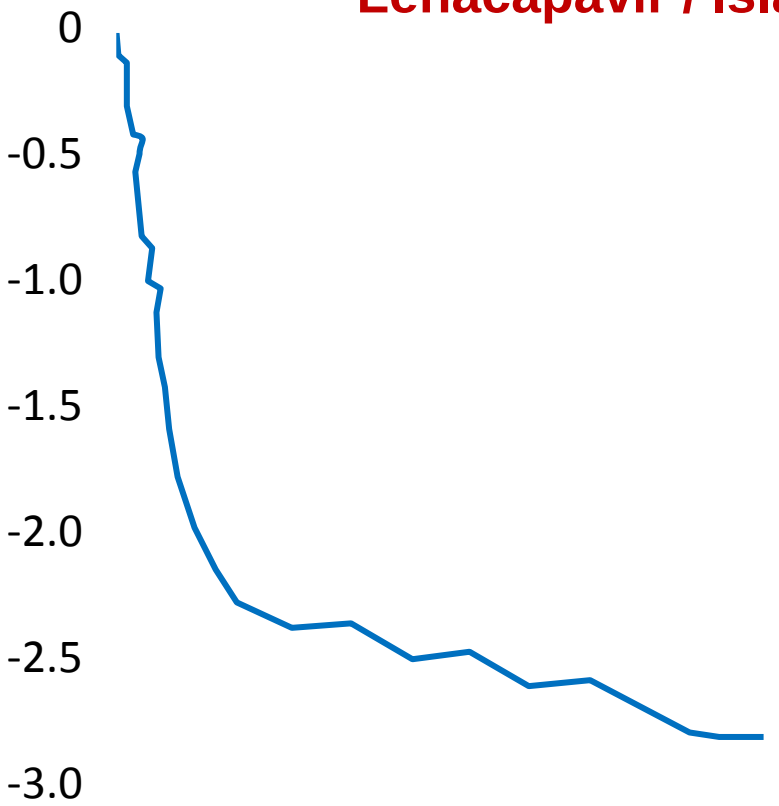
Past 2-drugs ≠ Current 2-drugs regimen

1994: 2-NRTI Therapy



24-Wk Response

>2020: 2-ARVs: DTG/3TC or LA CAB/RPV
Lenacapavir / Islatravie



24-Wk Response

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Dual ART
in Treatment Naïve Patients

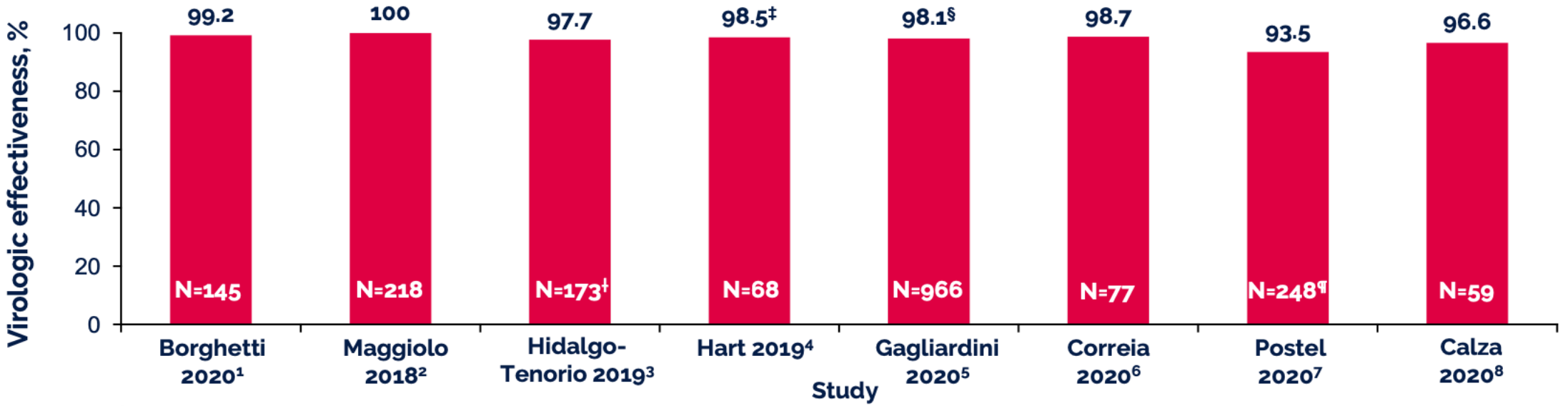
- **DTG+3TC** (Oral): FDA Approved
- **CAB+RPV**, (LA injectable) : Approval is pending
- **ISL+DOR** (Oral): Phase III Clinical development

DOVATO: VIROLOGIC EFFECTIVENESS IS HIGH ACROSS REAL-WORLD STUDIES*

Reported effectiveness outcomes vary between studies

Effectiveness : 93.5- 10(

FU range: 0.5 to 3 yea



Endpoint or time of follow-up	144 weeks	2 years	48 weeks	Mean: 0.5 years	Median: 15 months	48 weeks	6 months	12 months
Effectiveness outcome of patients on treatment with DTG + 3TC at endpoint/time of follow-up	Estimated probability of remaining free from VF	Proportion of patients without VF	Proportion of patients without VF	HIV-1 RNA <40 c/ml	Proportion of patients without virological rebound	Proportion of patients without VF	HIV-1 RNA <50 c/mL or 50–200 c/mL with subsequent HIV-1 RNA <50 c/mL	Proportion of patients without VF

Available data show real-world effectiveness is consistent with that seen in Phase III studies

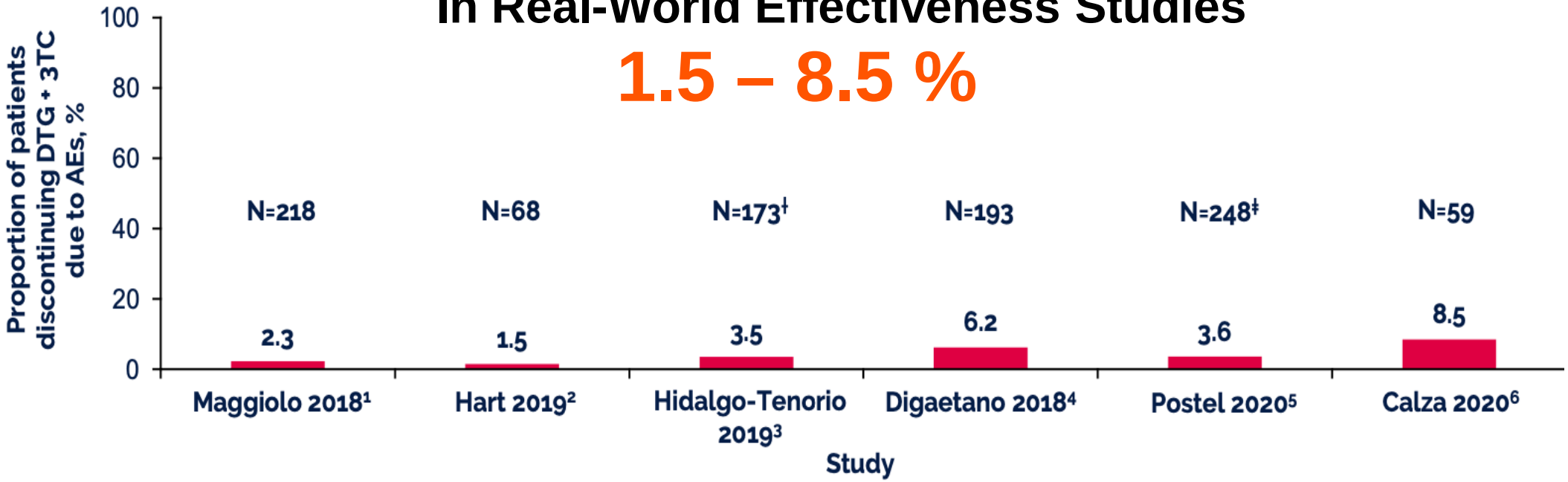
*Includes studies reporting applicable effectiveness outcomes for >50 patients receiving DTG + 3TC; ‡Full study population=177; however, 4 patients have been excluded here; ‡At least 67/68 patients on DTG + 3TC remained free of virologic failure; 1 patient experienced virologic failure in the study (total population = 96), treatment regimen was not reported; §18 virological rebound events (calculation assumes ≤1 virological rebound event per patient); ¶Effectiveness analysis set (missing=excluded). **VF,** virologic failure

1. Borghetti A, et al. Clin Infect Dis 2020;cia313; **2.** Maggiolo F, et al. HIV Glasgow 2018. Poster P104; **3.** Hidalgo-Tenorio C, et al. Medicine 2019;98:1–7; **4.** Hart J, et al. BHIVA 2019. Poster P9; **5.** Gagliardini R, et al. CROI 2020. Poster 486; **6.** Correia RMA & Carvalho AC. AIDS 2020. Poster PEB0235; **7.** Postel N, et al. HIV Glasgow 2020; Virtual. Poster P044; **8.** Calza L, et al. J Antimicrob Chemother 2020;75:3327–33

DTG/3TC has low AEs-discontinuation rate

In Real-World Effectiveness Studies

1.5 – 8.5 %



Endpoint or time of follow-up	2 years	Mean: 0.5 years	48 weeks	Median: 94 days (for those who discontinued)	6 months	12 months
Cohort study type	Prospective, multicentre	Observational, retrospective single-centre	Observational, retrospective multicentre	Observational, retrospective single-centre	Prospective, non-interventional	Observational, retrospective, single-centre

1. Maggiolo F, et al. HIV Glasgow 2018. Abstract P104; 2. Hart J, et al. BHIVA 2019. Poster P9 3. Hidalgo-Tenorio C, et al. Medicine 2019;98:e16813; 4. Digaetano M, et al. HIV Glasgow 2018. Poster P203 5. Postel N, et al. HIV Glasgow 2020; Virtual. Poster P044; 6. Calza L, et al. J Antimicrob Chemother 2020;75:3327–33

DTG/3TC dual regimen
Confirmed Virological Withdrawal (CVW)

Study	DTG/3TC	DTG/TDF or TAF/FTC
GEMINI (3 years)	2 %	1 %
TANGO (2 years)	0 %	0 %
Real-World (0.5-3 yrs) 16 studies	0 %	0 %

2-Drug Regimens and Implementing in **Asia**

Two Drug Regimen	Hig-income countries	LMICs	Indication
Dolutegravir + lamivudine (**DTG / 3TC**) - STR	STR-Dovato	Not available	First-line, and switch option
Dolutegravir + rilpivirine (**DTG / RPV**) - STR	STR-Juluca	Not available	Switch in VL suppressed >6 mo
LA Cabotegravir + rilpivirine (**CAB/RPV-LA**) injectable	May be available	Not available	In VL suppressed patients, and an oral lead-in with CAB+RPV is needed

Some Pracrtical Considerations

for DTG/3TC, DTG/RPV vs TAF-based ARTs

Study	DTG/3TC	DTG/RPV	TAF/FTC/DTG or BIC
HBV	+ 1 anti-HBV	+ 2 anti-HBV	√
CKD with dialysis	Adjust 3TC dose	√	Adjust FTC dose
Food-restriction	no	yes	no
PPI co-admister	√	X	√
Anticid Al, Mg, +/- Ca-	2 hrs before or 6 hrs after DTG	2 hrs before or 6 hrs after DTG	2 hrs before or 6 hrs after DTG, BIC
Obesity	May gain weight	May gain weight	Gain more weight

Islatravir (EFdA, MK-8591):
Nucleoside Reverse Transcriptase Translocation Inhibitors
(NRTTI)

AIDSinfo

Drugs

Home > Drugs > Islatravir

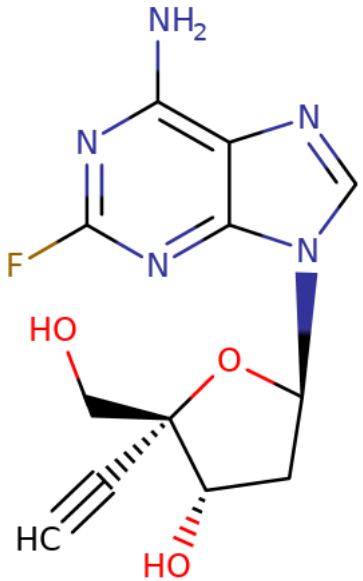
Enter Search Term(s)

+ Patient Version

− Health Professional

- Drug Information
  - Pharmacology
  - Clinical Trials
  - Adverse Events
  - Drug Interactions

Islatravir



Other Names: EFdA, ISL, MK-8591

Drug Class: Nucleoside Reverse Transcriptase Translocation Inhibitors

Molecular Formula: C_{12} H_{12} F N_5 O_3

Registry Number: 865363-93-5 (CAS)

Chemical Name: 4'-Ethynyl-2-fluoro-2'-deoxyadenosine

Chemical Class: Purine Nucleosides

Organization: Merck Sharp & Dohme Corp.

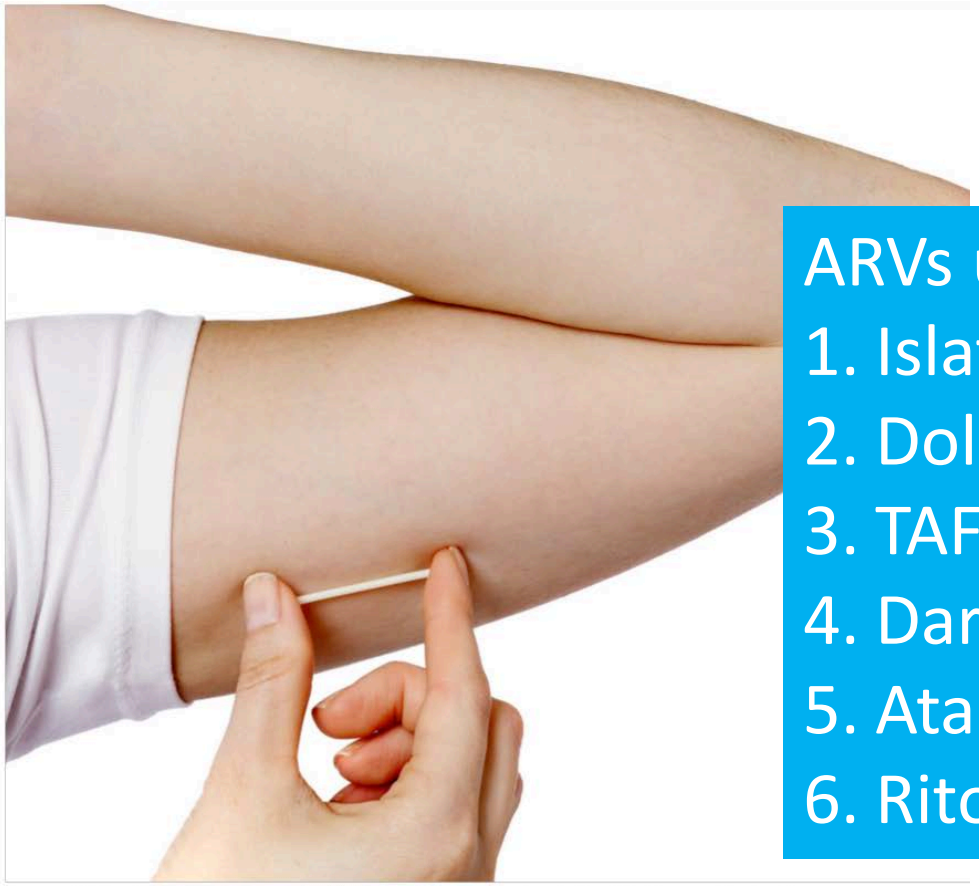
Phase of Development: Islatravir is in Phase 2b development for HIV treatment. Islatravir is also being developed for HIV prevention.

Oral can be dosed q weekly

HEALTH

A teeny-tiny arm implant could, one day, prevent HIV for a full year

Morgan Hines USA TODAY
Published 4:27 p.m. ET Jul. 26, 2019



A model holds the Nexplanon hormonal implant for birth control- the same implant device would be used to administer Islatravir for HIV prevention. *Merck Via AP*

GETTING UNDER YOUR SKIN

Bill and Melinda Gates are now backing a tiny implantable drug pump designed to prevent HIV infection

December 31, 2016

By **Neha Thirani Bagri**

ARVs under implantable development

1. Islatravir
2. Dolutegravir
3. TAF
4. Darunavir
5. Atazanavir
6. Ritonavir

S. Rahima Benhabbour, *Nature Communications*, 2019;

NEXT-GENERATION ISLATRAVIR IMPLANTS PROJECTED TO PROVIDE YEARLY HIV PROPHYLAXIS

Abstract Body

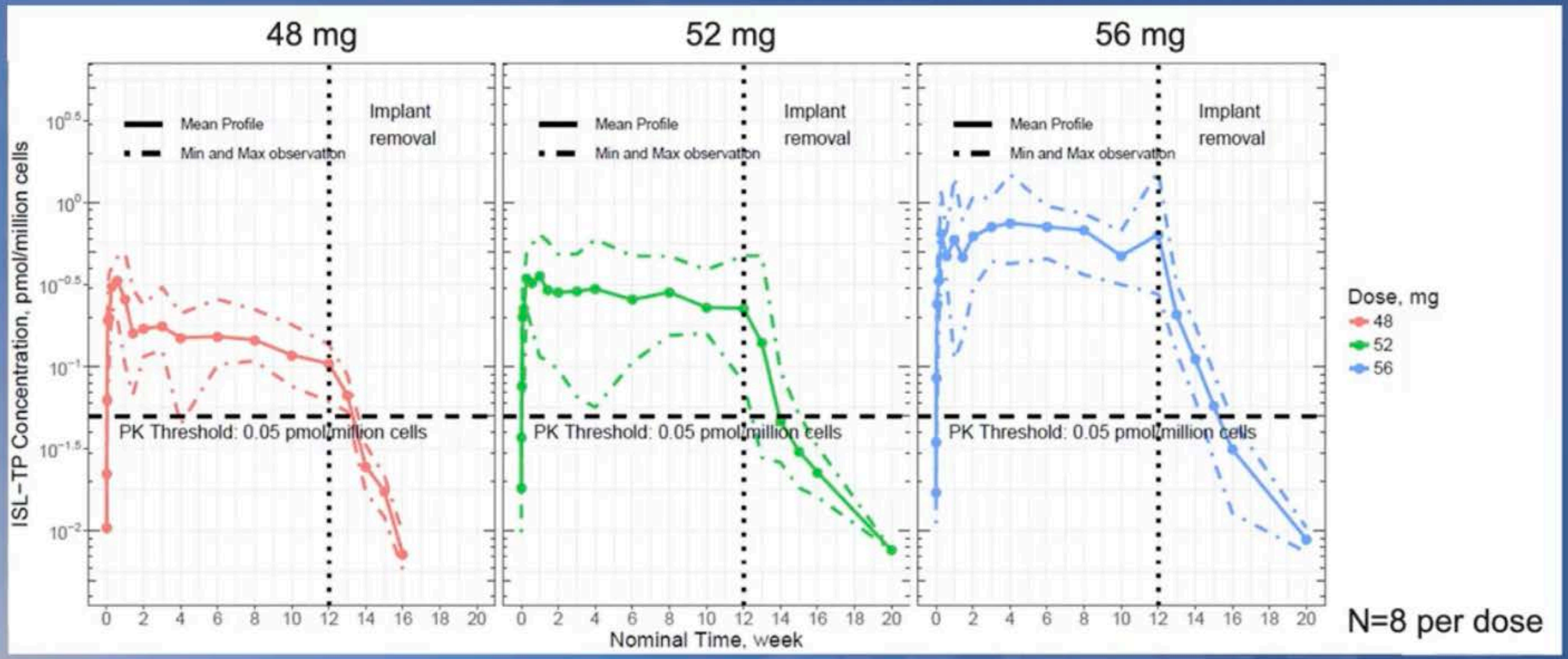
Islatravir (MK-8591, EFdA)
Implant NNRTTI

Preexposure prophylaxis (PrEP) with antiretroviral drugs has demonstrated efficacy in reducing new HIV infections, although efficacy is tightly linked to good adherence, especially in women. Islatravir (MK-8591) is a nucleoside reverse transcriptase translocation inhibitor with high potency and long t1/2, currently in development for PrEP as an oral monthly pill. In addition, prototype islatravir implants (containing only polymer and islatravir) have demonstrated the potential for yearly administration for PrEP.

Radiopaque next-generation islatravir-eluting implants were studied preclinically to establish general tolerability and assess pharmacokinetics (PK) of islatravir parent and active islatravir-TP (triphosphate). These data, along with data from an SIV challenge study and from previous Phase 1 trials, formed the basis for establishing a threshold islatravir-TP concentration of 0.05 pmol/million cells in PBMCs. In this double-blind placebo-controlled multicenter Phase 1 trial, a single islatravir-eluting (48 mg, 52 mg or 56 mg) or placebo implant was placed in participants at low risk of HIV infection for 12 weeks. Safety and tolerability, as well as PK for islatravir parent and islatravir-TP from plasma and PBMCs, was collected throughout placement and for 8 weeks post removal.

Implants were generally well tolerated, and there was no clear dose-dependent difference in implant-related adverse events (Table 1A). Active islatravir-TP levels were above target for all implants throughout implant placement (Table 1B). Data from this trial and from in vitro assessments of the ISL implants suggest that implants of >52 mg will achieve mean ISL-TP concentrations above the PK threshold at 52 weeks.

Intracellular ISL-TP PK threshold of 0.05 pmol/10^6 cells maintained throughout placement for two highest doses



- 56 mg implant ISL-TP concentrations comparable to 62 mg from previous study
- Half-life after removal of implant similar to half-life of orally dosed ISL ($t_{1/2}$ for 56 mg is ~198 hr)

Randolph P Matthews CROI 2021
Merck & Co, Inc, Kenilworth, NJ, USA

Advantages of Long-acting Implantable ARV

- Can be dose once or twice a year
- If there is a side effect to the drug(s), or become pregnant, the implant can be easily removed
- Can avoid non-adherence issues

Key Advances in ART ?

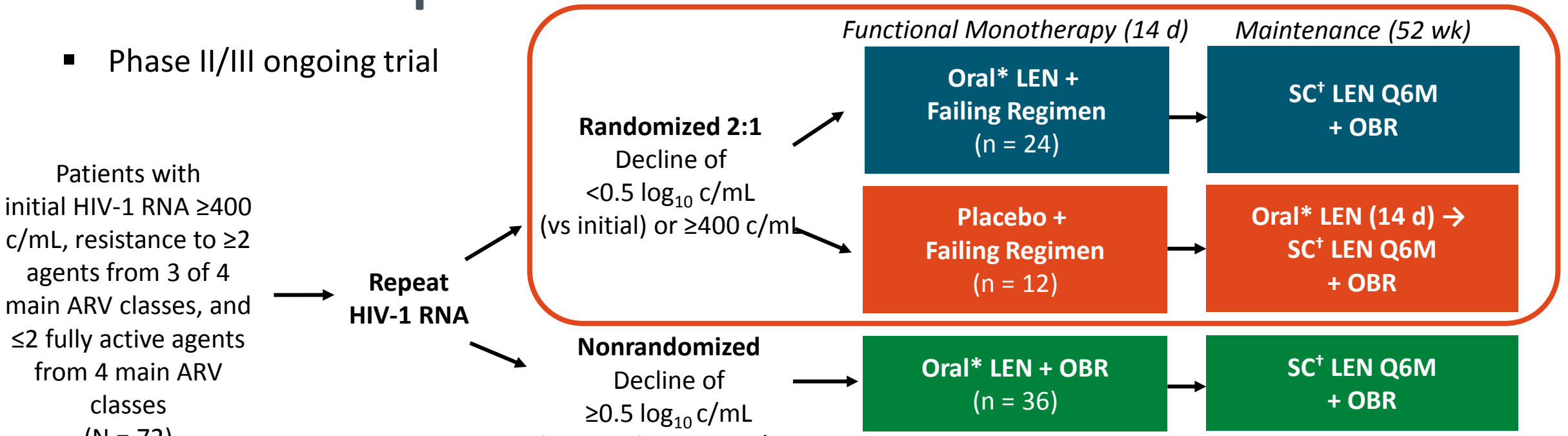
in the past 4 decades and beyond

1. ↓ Pill number and pill size
2. ↓ Toxicity
3. ↓ Drug-Drug Interaction
4. No food restriction
5. May ↓ from 3- to 2-Drug regimen
6. Advantages of Treatment-as-Prevention (TasP) and PrEP
7. ↓ dosing frequency may be to once yearly

OD → Yearly

CAPELLA: Wk 26 Analysis of Lenacapavir in Heavily Treatment-Experienced PWH

- Phase II/III ongoing trial



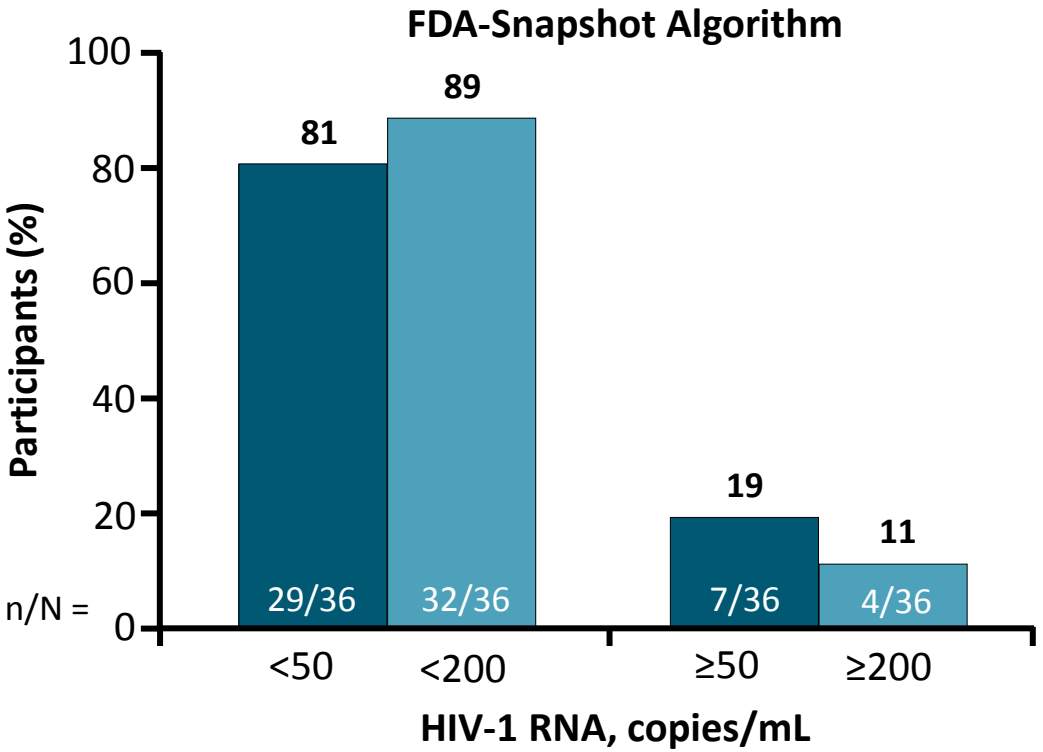
*Oral LEN administered as 600 mg on Days 1 and 2, 300 mg on Day 8.
†SC LEN administered as 927 mg (2 x 1.5 mL) in the abdomen on Day 15.

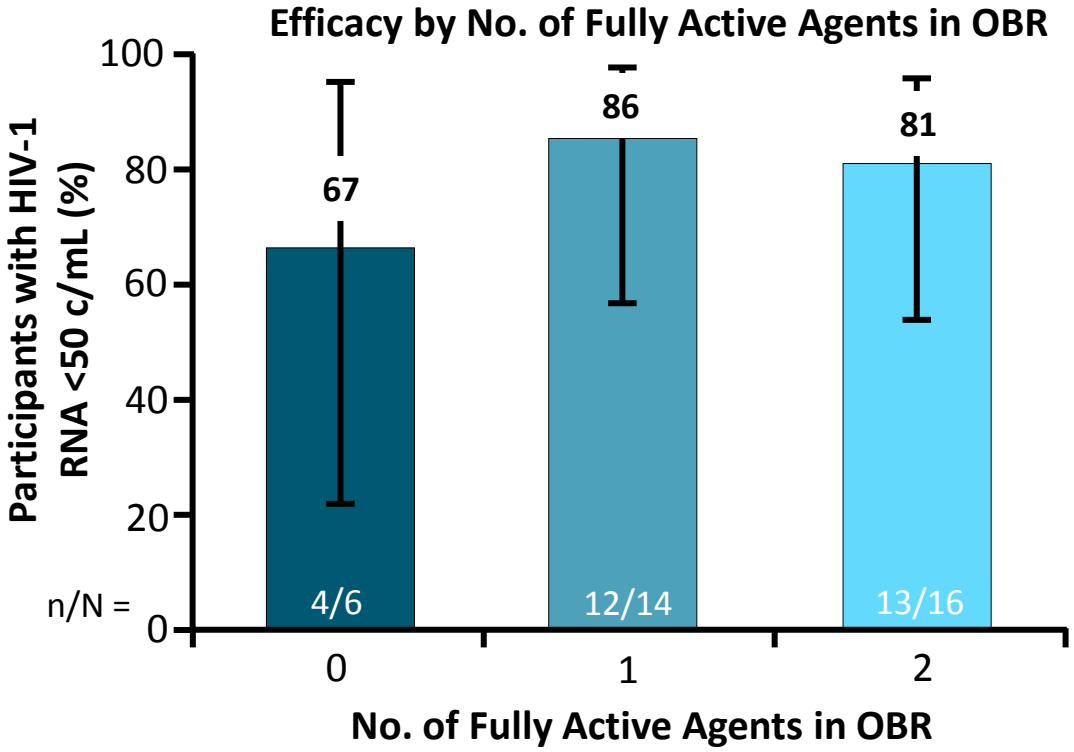
- Participants with known BL resistance to ≥2 drugs in class - NRTI: 99%, NNRTI: 97%, PI: 81%, INSTI: 69%
- Primary endpoint achieved in prior analysis: ≥0.5-log decline in HIV-1 RNA with oral LEN 88% vs placebo 17% at Day 14 in randomized cohort (*P* <.0001)[1]
- **Secondary endpoints: HIV-1 RNA <50 c/mL, <200 c/mL at Wk 26 in randomized cohort**[2]

1. Segal-Maurer. CROI 2021. 2. Molina. IAS 2021. Abstr OALX01LB02.

Slide credit: clinicaloptions.com

CAPELLA Secondary Endpoints: Wk 26 Efficacy in Randomized Cohort





- **Mean change in CD4+ cell count: +81 cells/mm^3**
- Proportion of participants with very low CD4+ cell count (<50 cells/mm^3) **decreased from 22% (8 of 36) at baseline** to **0% (0 of 34) at Wk 26**

Molina. IAS 2021. Abstr OALX01LB02.

Slide credit: clinicaloptions.com

Gilead Sciences Seeks Approval for Twice-Annual HIV-1 Medication

Published: Jun 29, 2021 | By Alex Keown

JOSH EDELSON/AFP via Getty Images

Gilead Sciences is aiming to win regulatory approval for the first HIV-1 treatment administered twice per year. On Monday, the company submitted a New Drug Application to the U.S. **Food and Drug Administration (FDA)** for lenacapavir, an investigational, long-acting HIV-1 capsid inhibitor.

Lenacapavir submitted to FDA as long-acting treatmen for MDR HIV

1 July 2021. Related: Antiretrovirals.

Simon Collins, HIV i-Base

On 28 June 2021, Gilead Sciences submitted a new drug application to the US FDA for lenacapavir as a treatment for HIV in people with multiple drug resistance MDR. [1]

An application to the EMA in Europe will follow in the next months, with final decisions expected to take a year. Submission to the MHRA in the UK is likely to follow the EU decision. Over this extended period, a limited programme will hopefully enable access for individuals in critical need, although details have not yet been released.

Lenacapavir is a capsid inhibitor, and as the first drug in a new class, will have activity against HIV that has developed resistance to other antiretroviral drugs. It need to be used in a combination with other drugs that are active in order to prevent drug resistance.

The application is based on results from the phase 2/3 CAPELLA trial presented at CROI 2021.

Remaining
Major Challenges

School of Global Health
Faculty of Medicine
Chulalongkorn University

HIV-NAT

Equity to access to new ARV options

Current ARV Option

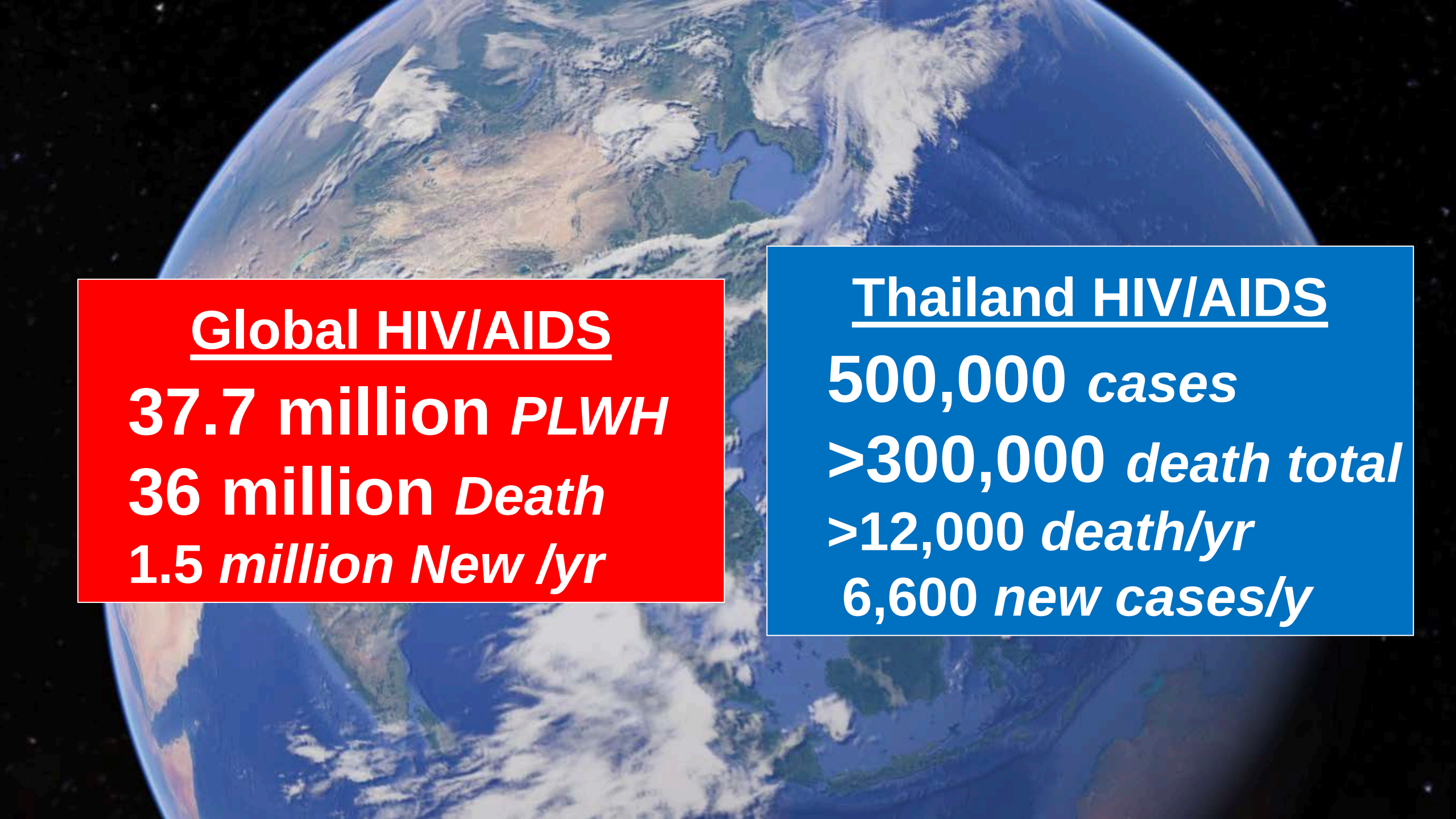
DTG-based regimen

Access for all is feasible

Future ARV Options

LA Injectable Implant ARV Yearly

Access for all is unlikely



Global HIV/AIDS

37.7 million ***PLWH***

36 million ***Death***

1.5 ***million New /yr***

Thailand HIV/AIDS

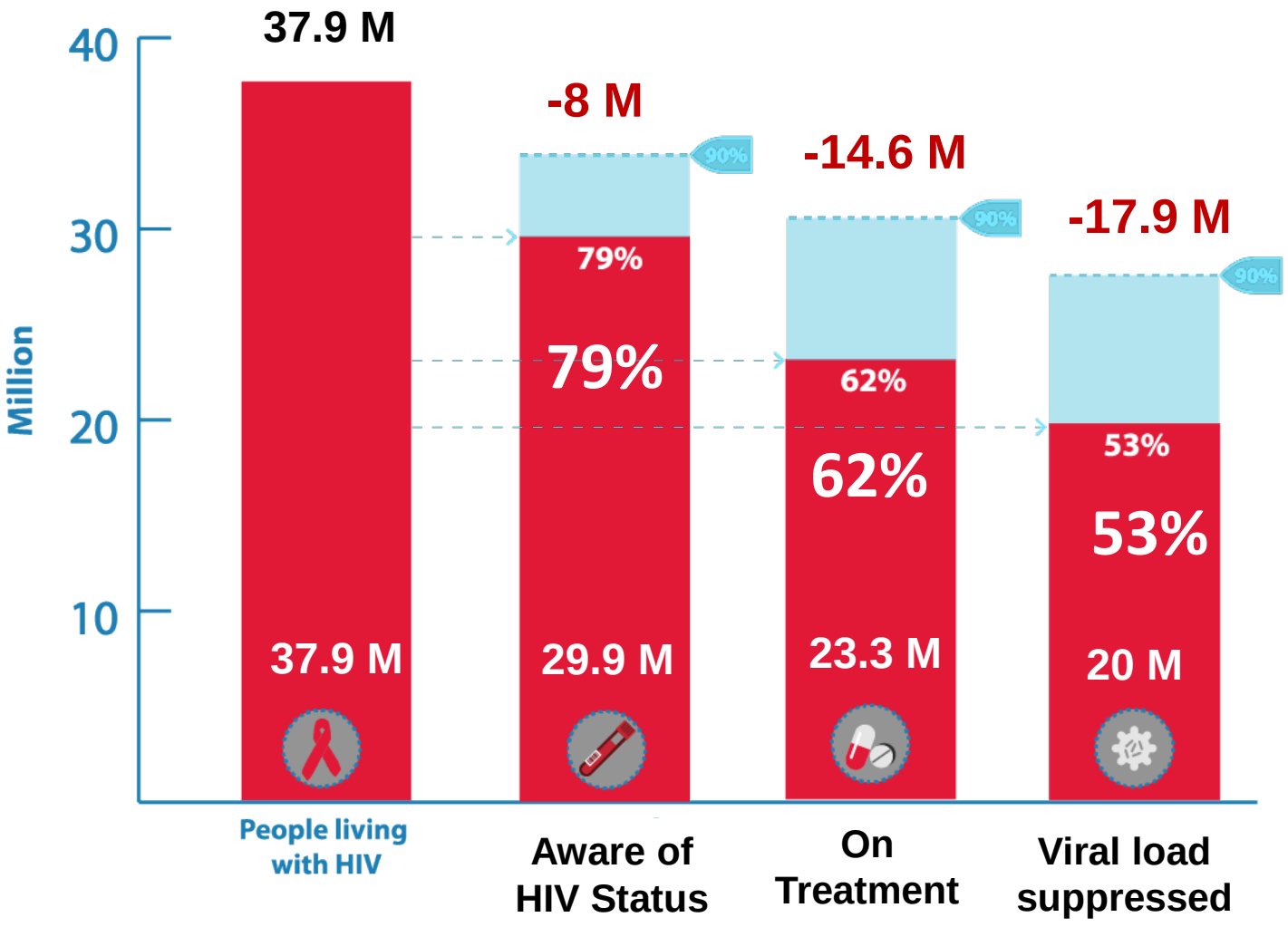
500,000 ***cases***

>300,000 ***death total***

>12,000 ***death/yr***

6,600 ***new cases/y***

HIV testing and care continuum, global (2018)



Source: UNAIDS/WHO estimates

UNAIDS | WHO WE ARE

TURNING THE TIDE OF THE HIV EPIDEMIC IN THAILAND

17 JANUARY 2020

Prof. Praphan Phanuphak

"The region cannot achieve the 90–90–90 targets by 2020 at the current pace. "We need to think out of the box and do thing differently not as usually"

CHULALONGKORN
UNIVERSITY

School of
Global Health
Faculty of Medicine
Chulalongkorn University

Thank You