



PRESTIGIO

2nd

PRESTIGIO Registry meet**ING** on HIV multidrug resistance

The PRESTIGIO Registry: where are we?

Antonella Castagna



Financial Disclosures

Gilead Sciences, ViiV Healthcare, Janssen-Cilag, MSD,
Menarini, Angelini, Pfizer



PRESTIGIO CENTERS

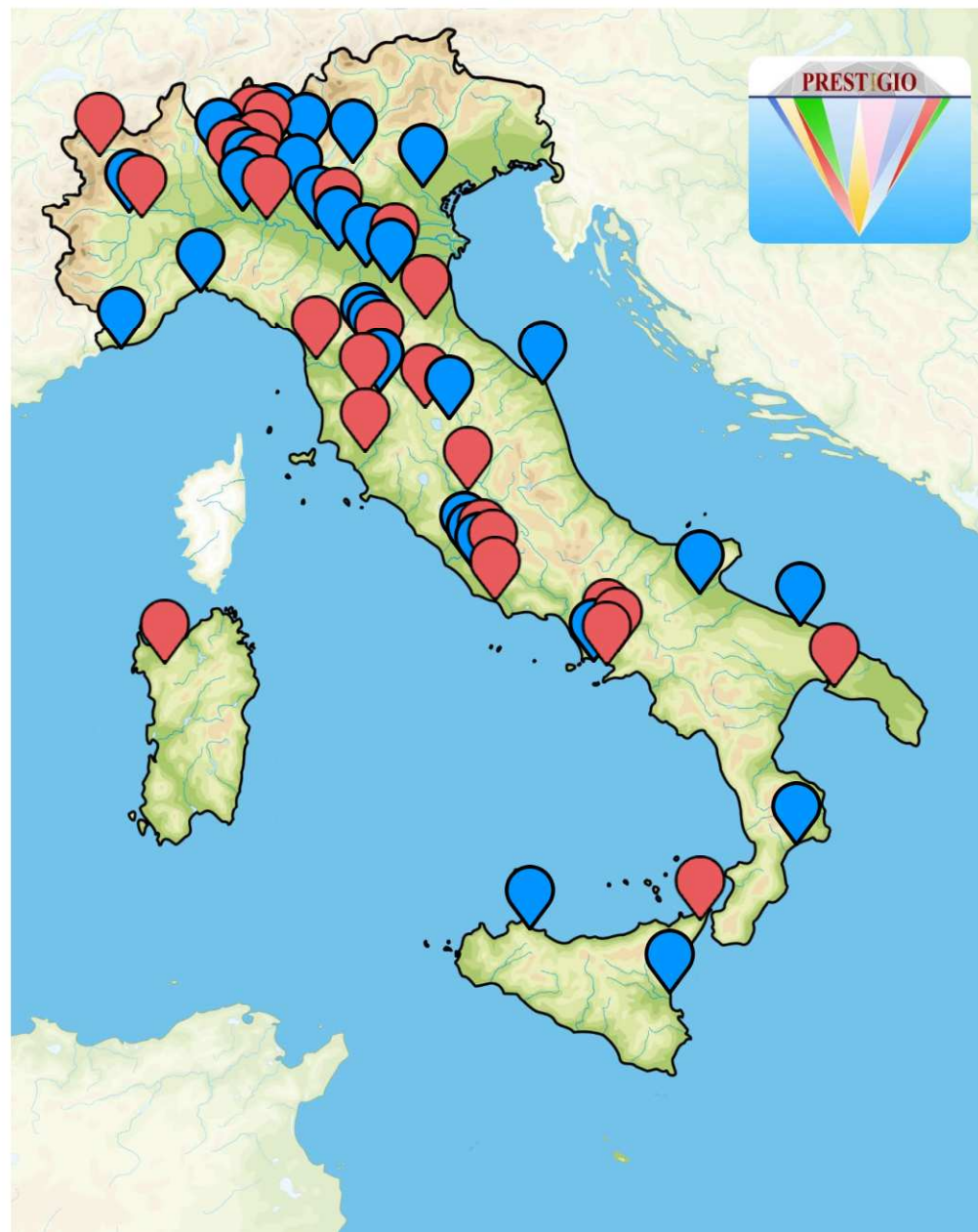
33

Active centers

26

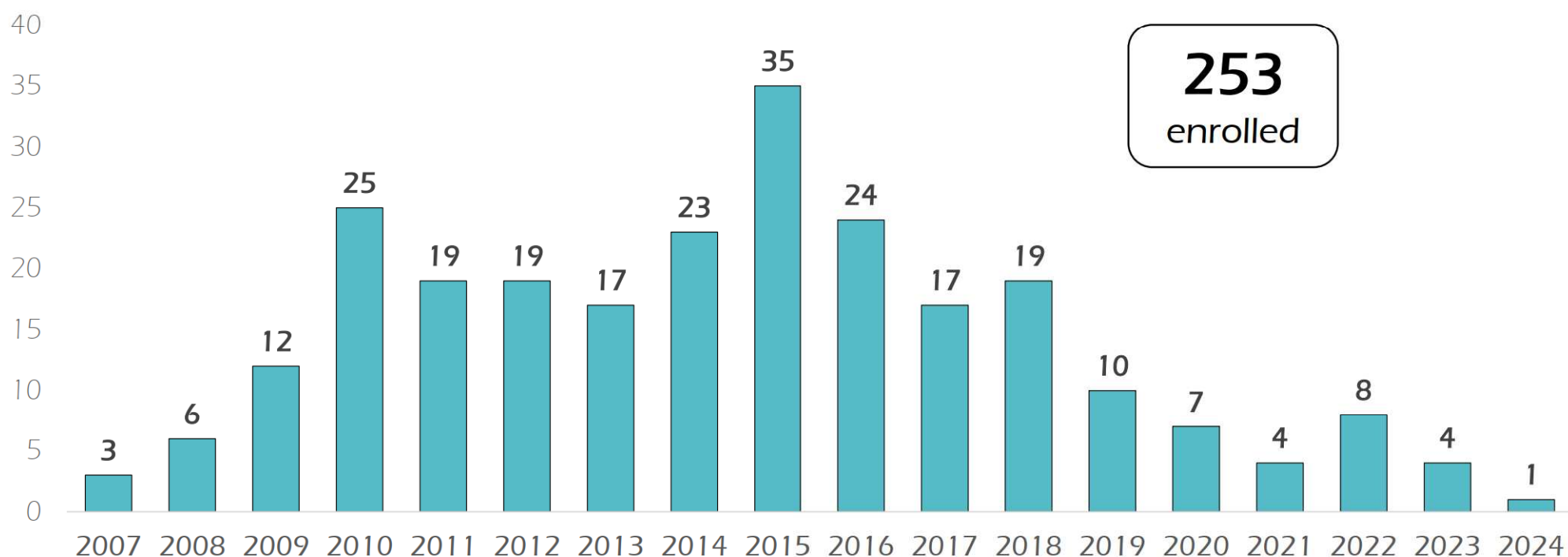
Centers pending approval

PRESTIGIO Registry meeting **ING** on HIV multidrug resistance





CALENDAR YEAR OF 4DC RESISTANCE



34 Deaths / 198 hospitalizations/ 7 Lost at follow-up / 7 Transferred

PRESTIGIO Registry meet**ING** on HIV multidrug resistance

Data updated to March 1st, 2024

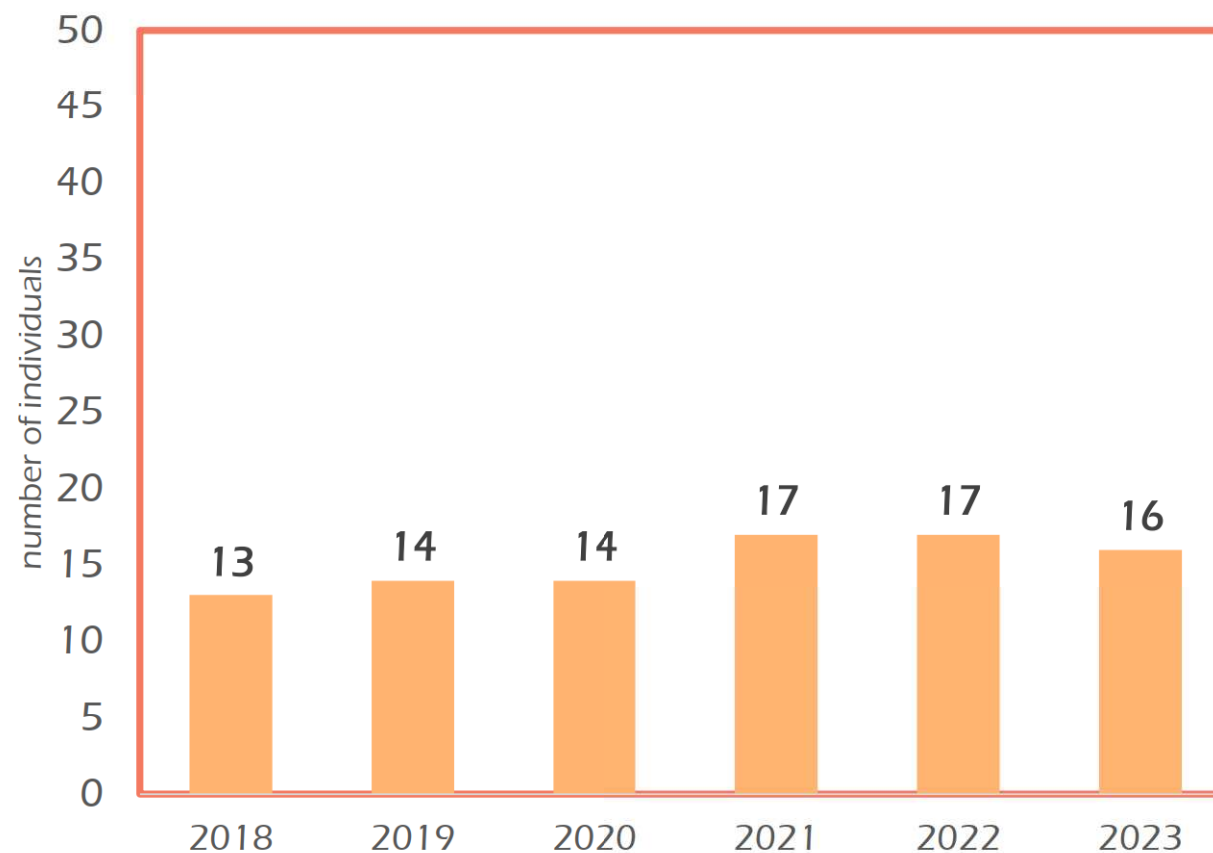


DEMOGRAPHIC CHARACTERISTICS

		Baseline (n=253)	Last available (n=205)
Age (years)		50,1 (44,2 – 55,6)	59,2 (55,0 – 62,8)
Sex at birth	Male	184 (72,7%)	143 (69,8%)
	Female	69 (27,3%)	62 (30,2%)
HIV risk factor	Hetero	67 (26,5%)	61 (29,8%)
	MSM	65 (25,7%)	50 (24,4%)
	IVDU	56 (22,1%)	44 (21,5%)
	MTCT	21 (8,3%)	17 (8,3%)
	Other	12 (4,7%)	9 (4,4%)
	Unknown	32 (12,6%)	24 (11,7%)
Years of HIV		21,8 (17,9 – 26,6)	31,6 (27,5 – 34,9)
Years of ART		18,3 (14,6 – 22,2)	27,3 (25,1 – 30,0)
Nadir CD4+	[cells/ μ L]	89 (18 – 183)	99 (23 – 181)
HBV infection		17 (6,7%)	20 (9,8%)
HCV infection		82 (32,4%)	72 (35,1%)



Hospitalizations





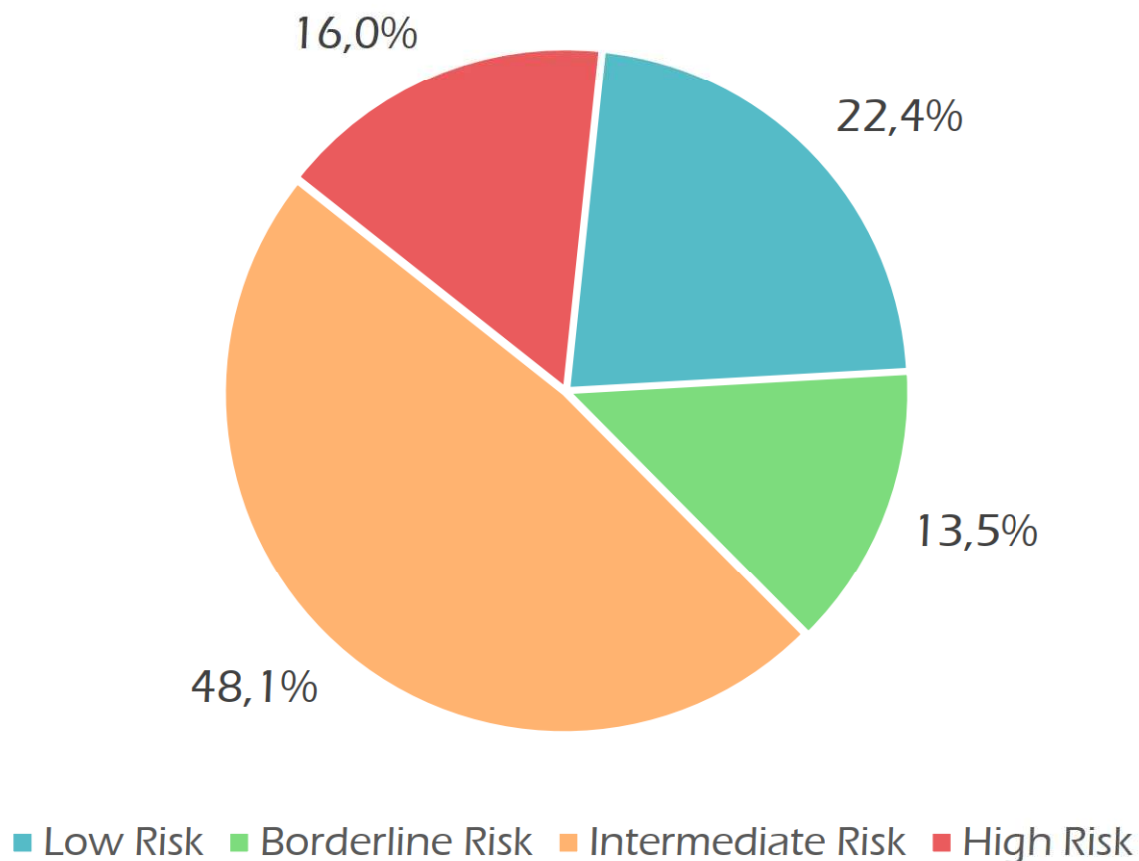
CLINICAL EVENTS

	HIV-related	
	until 2022	until 2023
C events	26	27
AIDS-defining malignancies	7	8
B events	36	39
	69	74

	non HIV-related	
	until 2022	until 2023
Non HIV-related infectious events	90	100
Neuropsychiatric diseases	47	51
Musculoskeletal diseases	29	30
CKD	32	32
Cardiovascular disorders	36	41
Non-AIDS-defining malignancies	27	30
anal carcinoma	7	8
Hodgkin's lymphoma	4	4
epatocellular carcinoma	2	2
bladder cancer	2	2
lung cancer	1	1
other malignancies	11	13
Urinary tract diseases	15	17
Liver events	14	16
Diabetes	12	13
COPD	6	6
	308	336



ASCVD Risk



This calculation is based on **ASCVD Pooled Cohort Risk Equations** (Goff 2013), valid only for age of 40 to 79 years old and person without previous ASCVD events (n=156).

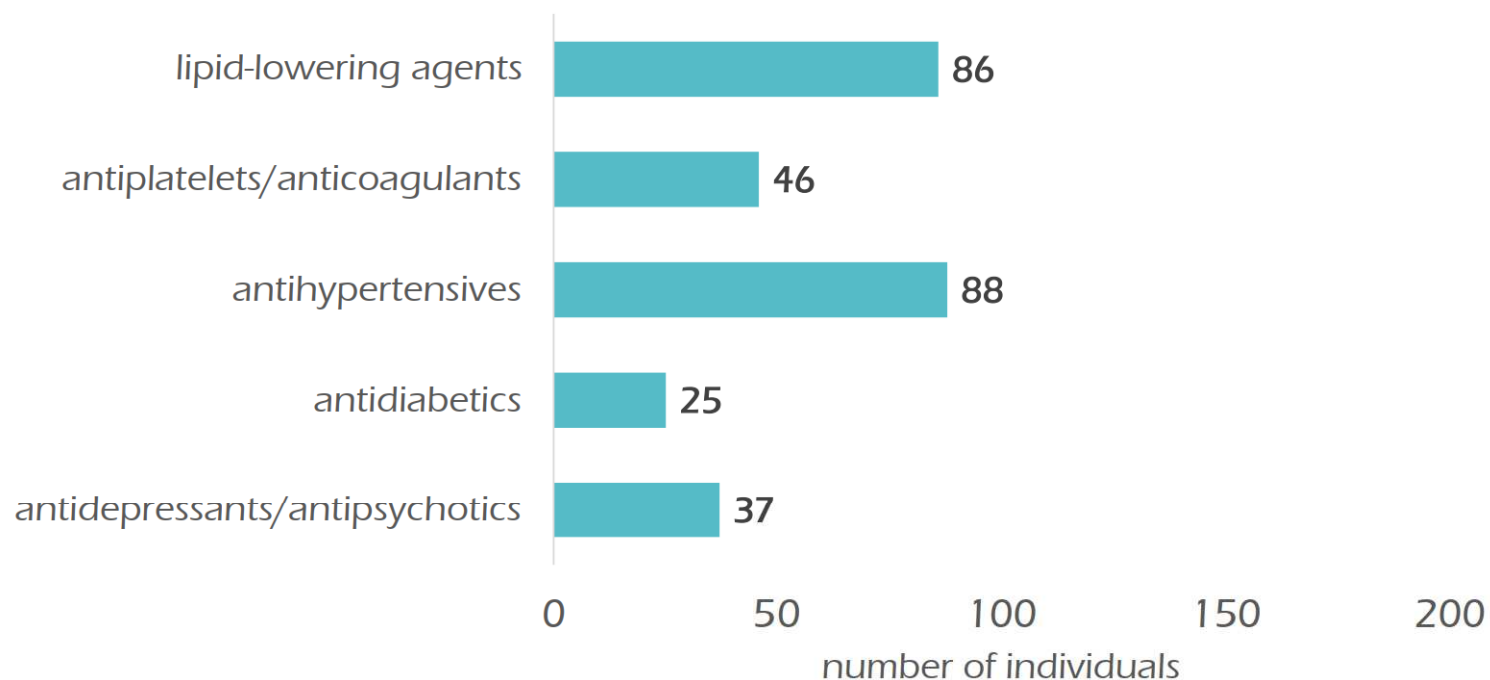
This index helps to predict the 10-year risk of hard ASCVD events and its calculation was possible using a systolic pressure of 135 mmHg for all MDRs.

Risk Score	Severity
<5%	Low Risk
5-<7.5%	Borderline Risk
≥7.5-<20%	Intermediate Risk
≥20%	High Risk



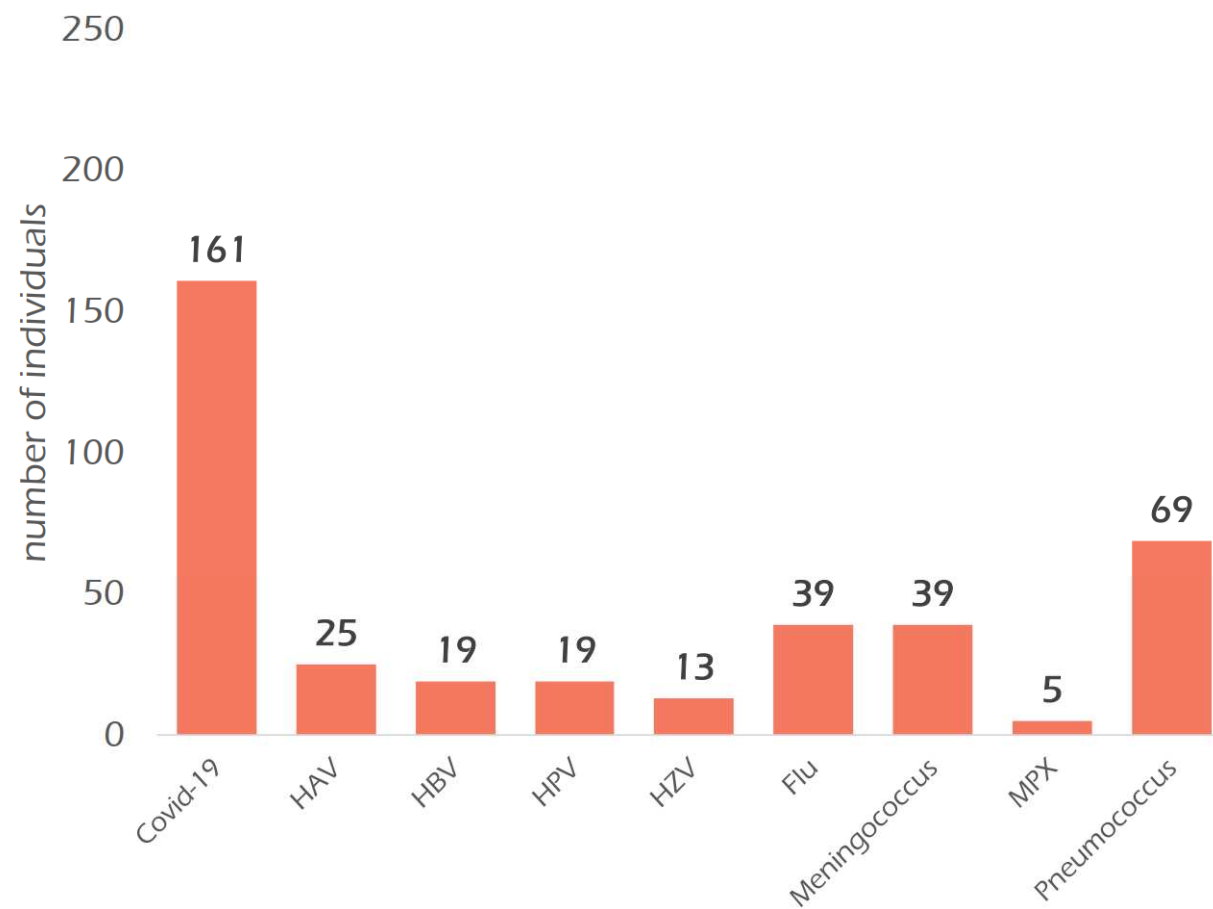
CONCOMITANT THERAPIES

last available





VACCINATIONS

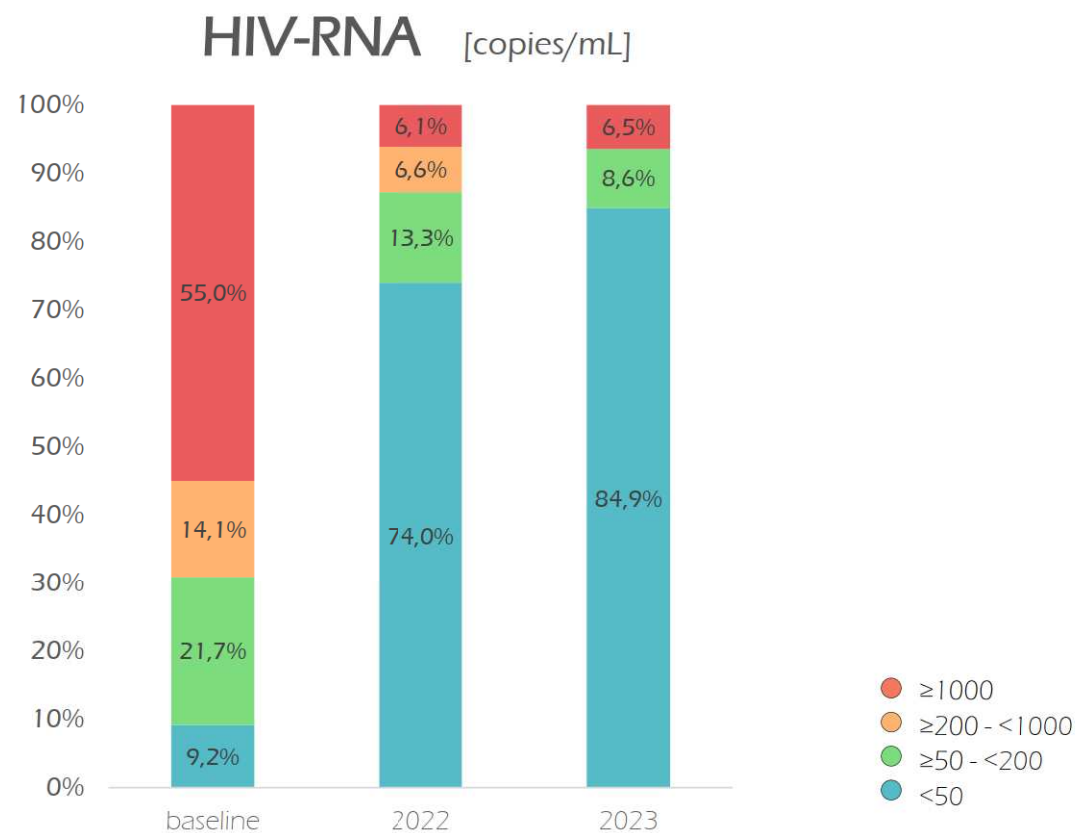


PRESTIGIO Registry meeting on HIV multidrug resistance

Data updated to March 1st, 2024

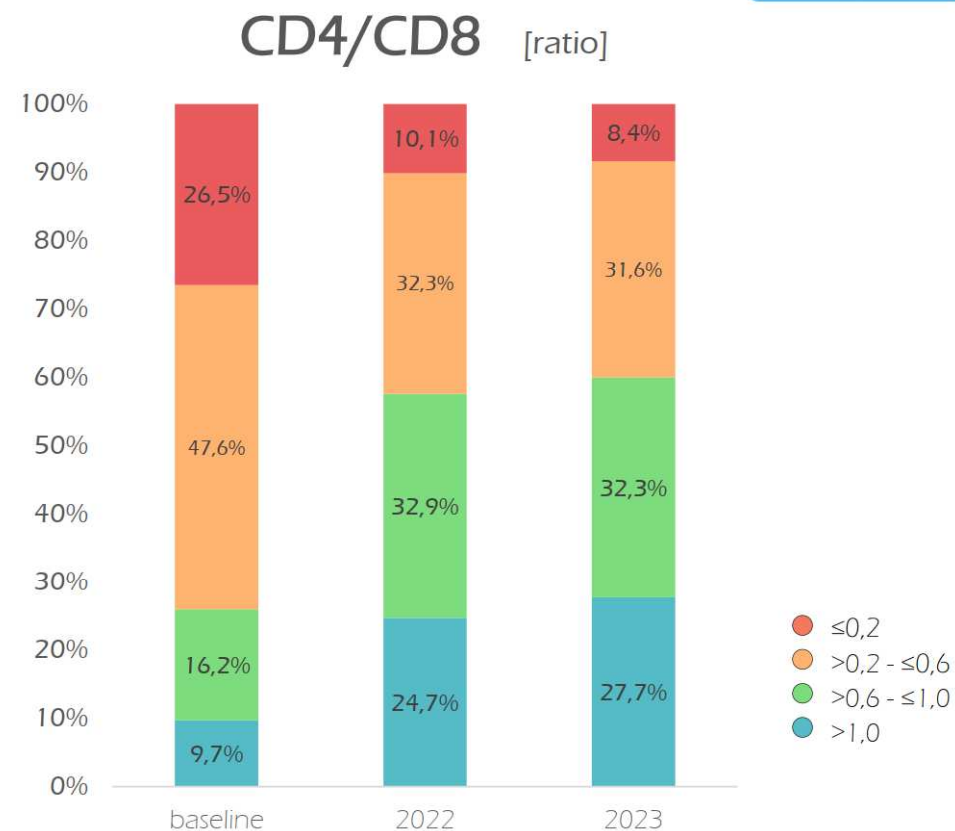
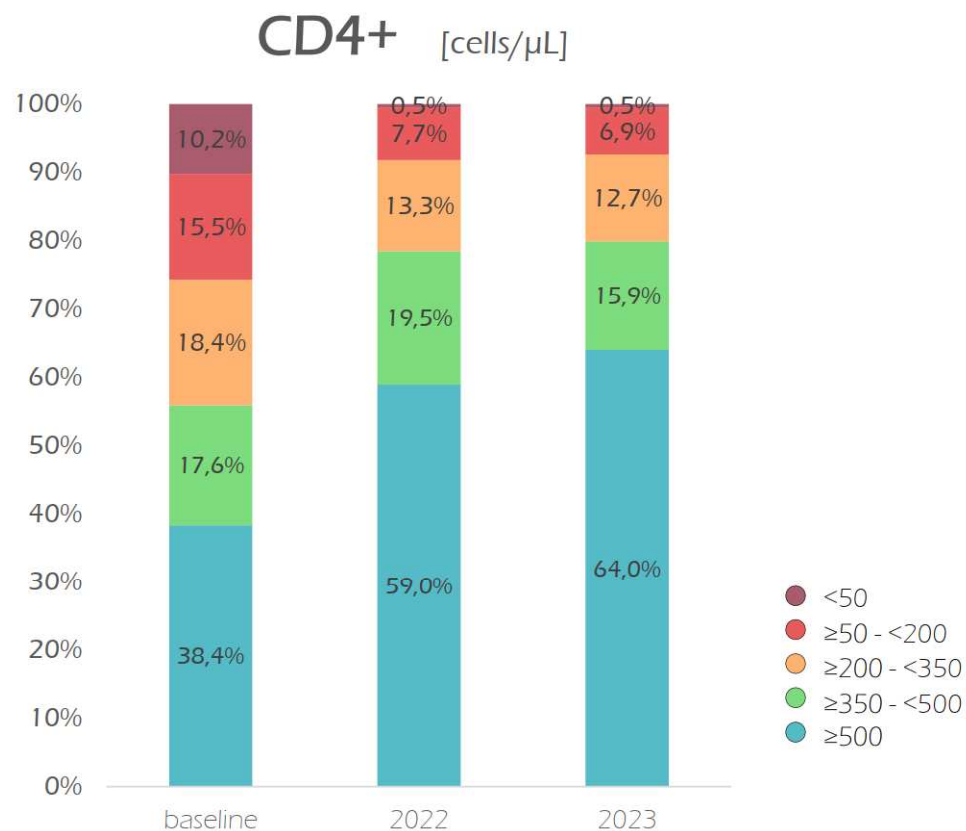


VIRAL LOAD





IMMUNOLOGICAL PROFILE





Antiretroviral drugs

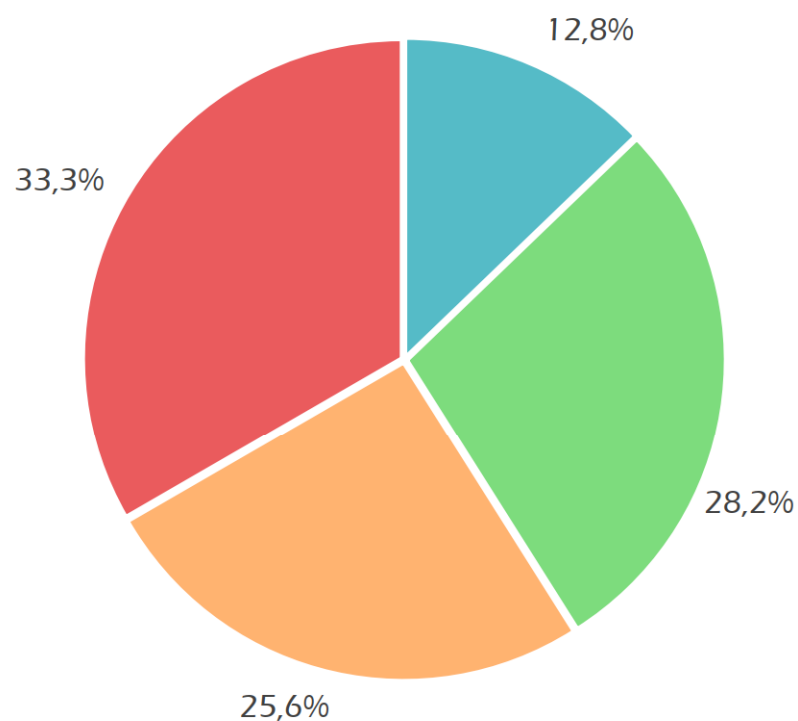


		2021 (n=205)	2022 (n=206)	2023 (n=205)
Drugs	DTG	159 (77,6%)	154 (74,8%)	153 (74,6%)
	DRV/r	87 (42,4%)	74 (35,9%)	74 (36,1%)
	DRV/c	55 (26,8%)	61 (29,6%)	58 (28,3%)
	XTC	102 (49,8%)	108 (52,4%)	110 (53,7%)
	TAF	74 (36,1%)	79 (38,3%)	83 (40,5%)
	TDF	15 (7,3%)	15 (7,3%)	12 (5,9%)
	DOR	27 (13,2%)	32 (15,5%)	36 (17,6%)
	ETV	29 (14,1%)	24 (11,7%)	20 (9,8%)
	RPV	12 (5,9%)	11 (5,3%)	10 (4,9%)
	MVC	40 (19,5%)	43 (20,9%)	41 (20,0%)
	FTR	11 (5,4%)	24 (11,7%)	34 (16,6%)
	LEN	8 (3,9%)	8 (3,9%)	9 (5,3%)
	IBA	5 (2,4%)	8 (3,9%)	5 (2,5%)
	ISL	3 (1,5%)	3 (1,5%)	3 (1,5%)
	ENF	2 (1,0%)	4 (1,9%)	2 (1,0%)

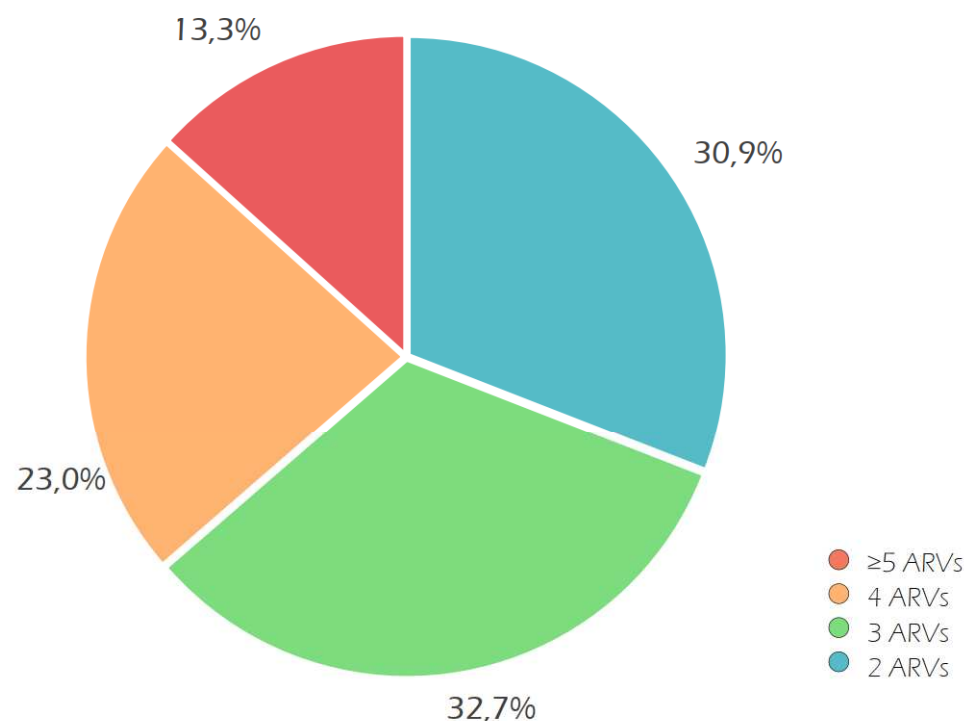


Current antiretroviral regimen

HIVRNA ≥ 50 copies/mL
(n = 39)



HIVRNA < 50 copies/mL
(n=165)



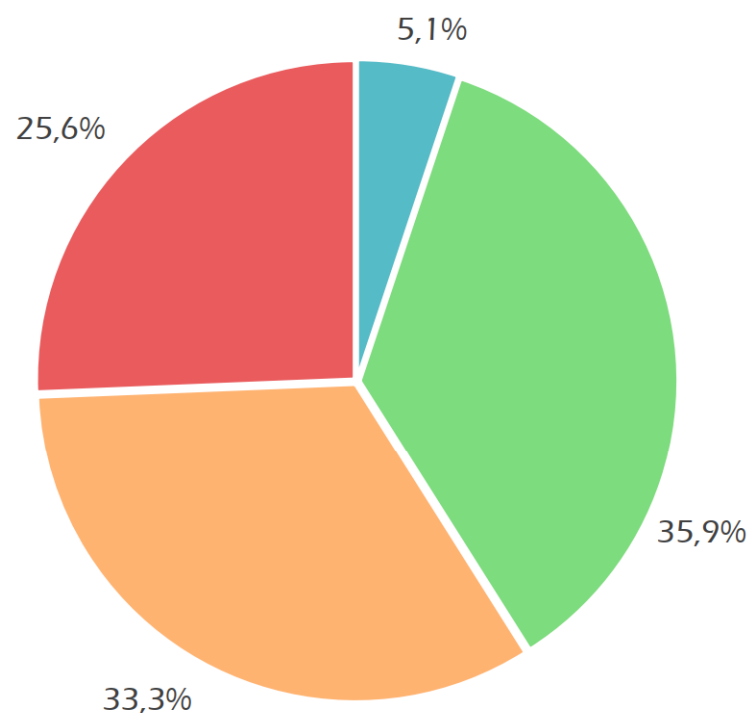
- ≥ 5 ARVs
- 4 ARVs
- 3 ARVs
- 2 ARVs



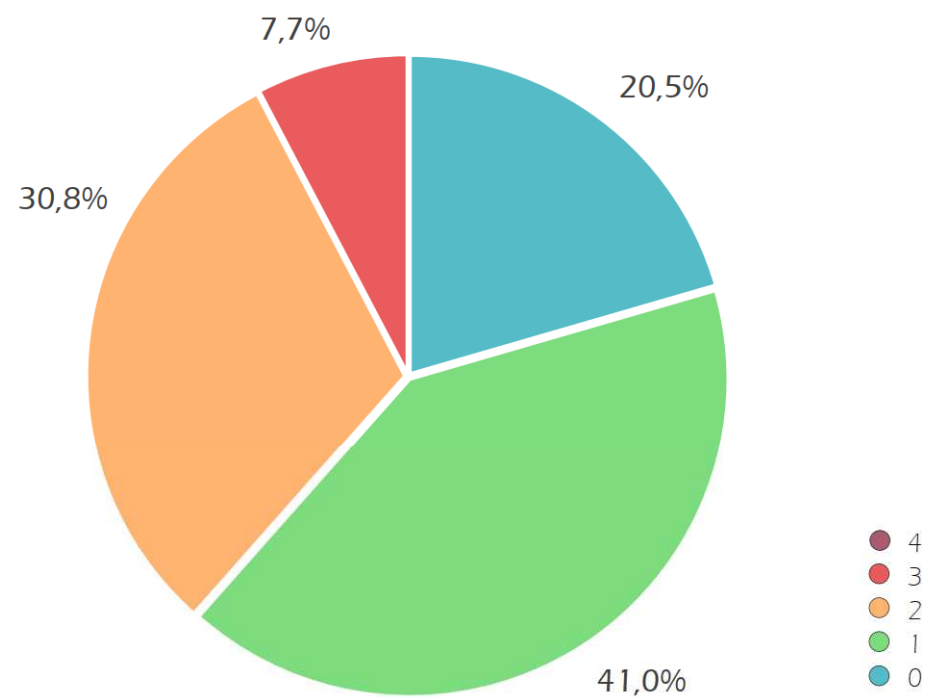
NUMBER OF FULLY ACTIVE ARVs

HIV RNA ≥ 50 copies/mL

Including FTR, LEN, IBA and ISL



Not including FTR, LEN, IBA and ISL

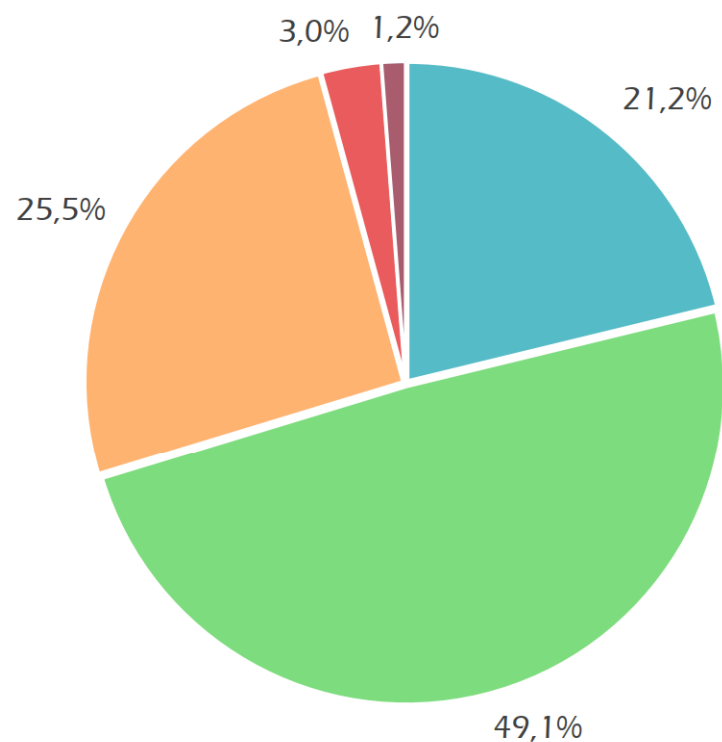




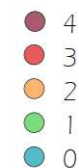
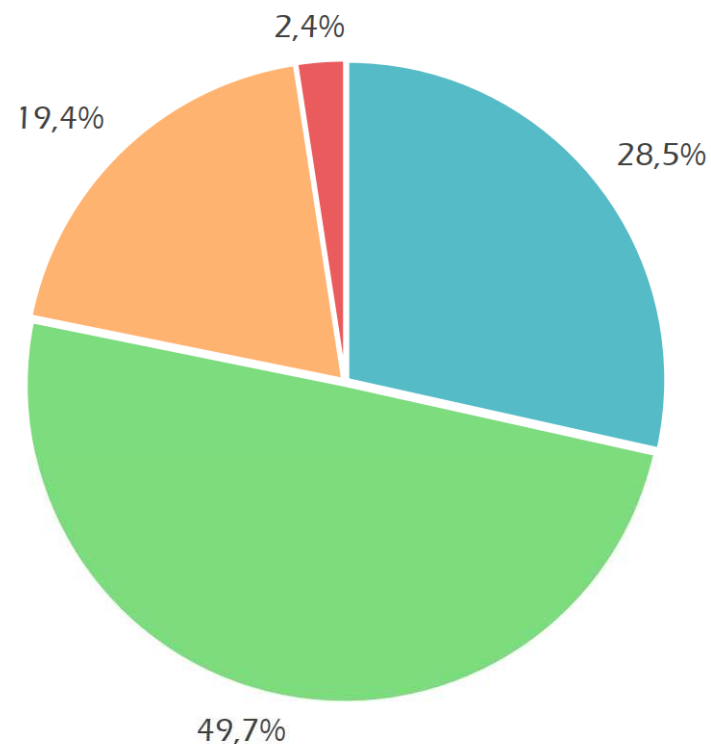
NUMBER OF FULLY ACTIVE ARVs

HIVRNA <50 copies/mL

Including FTR, LEN, IBA and ISL



Not including FTR, LEN, IBA and ISL

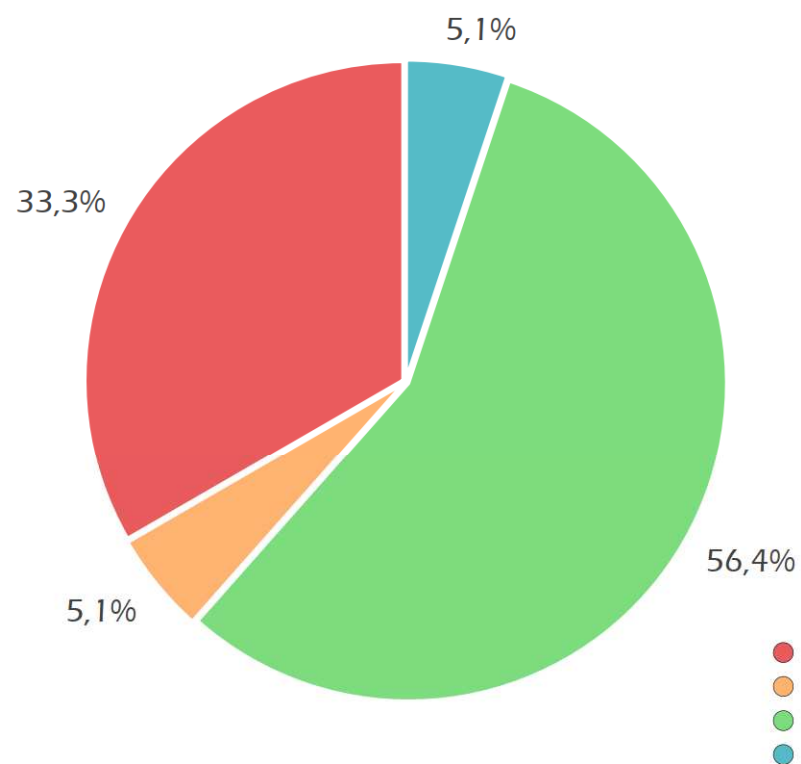




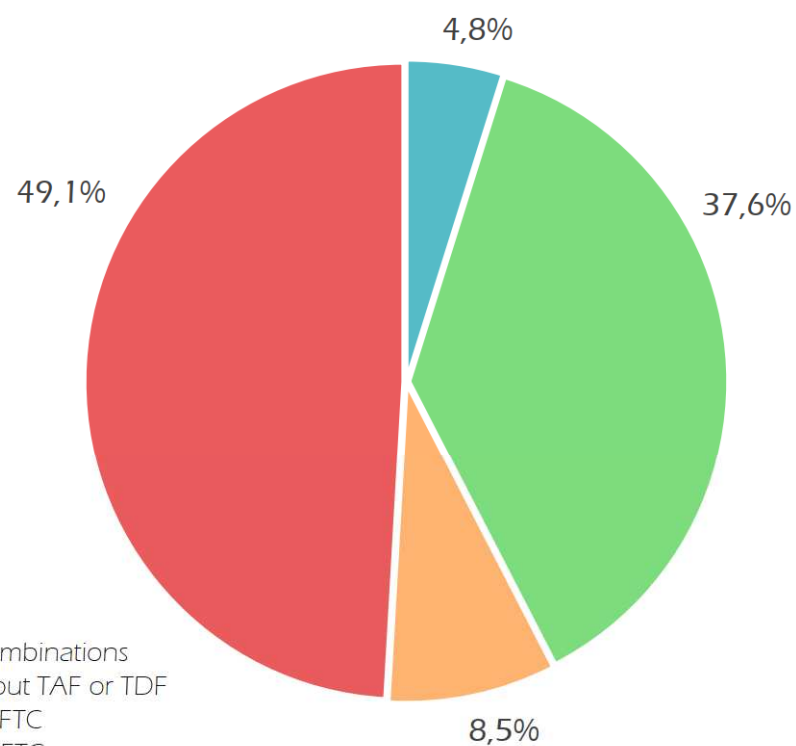
NRTIs



HIVRNA ≥ 50 copies/mL



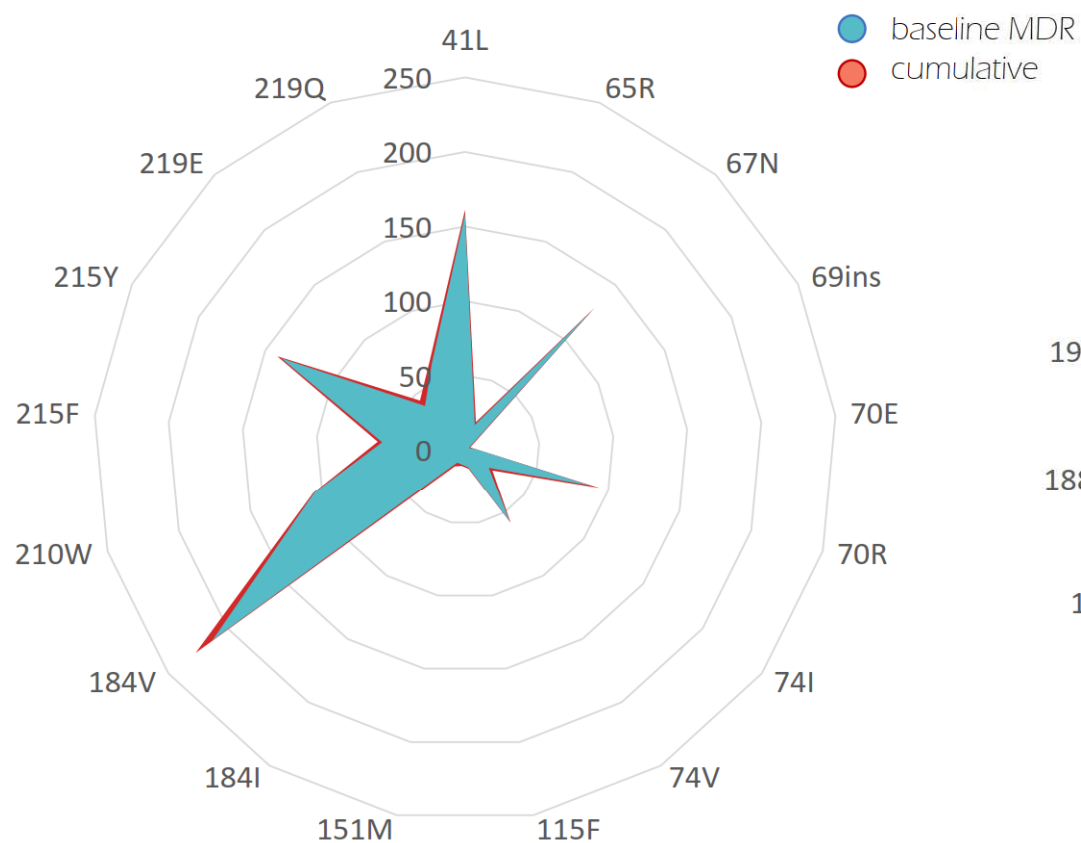
HIVRNA < 50 copies/mL



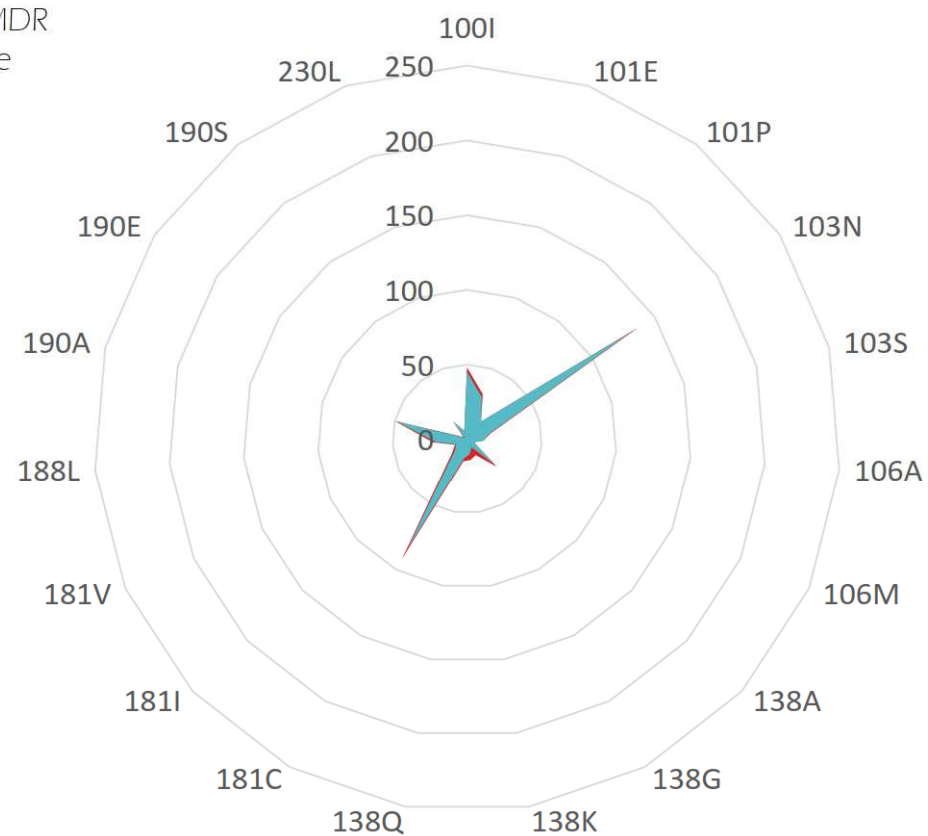


MAJOR RESISTANCE MUTATIONS

NRTI

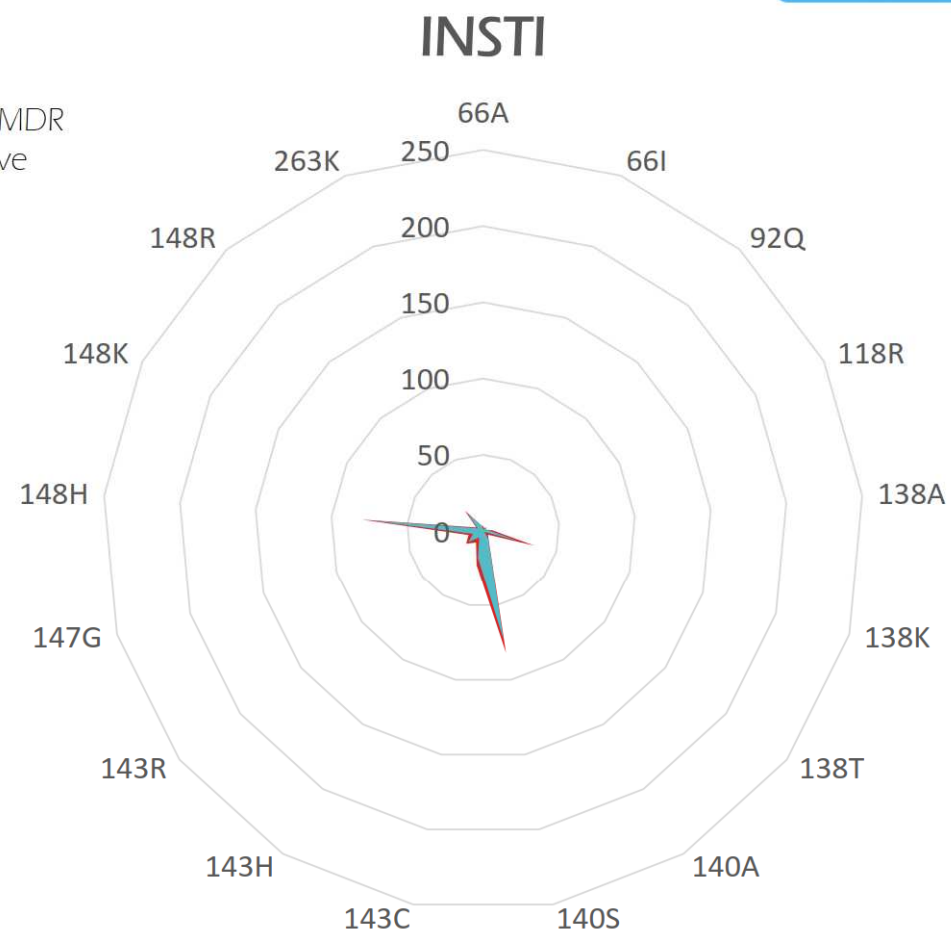
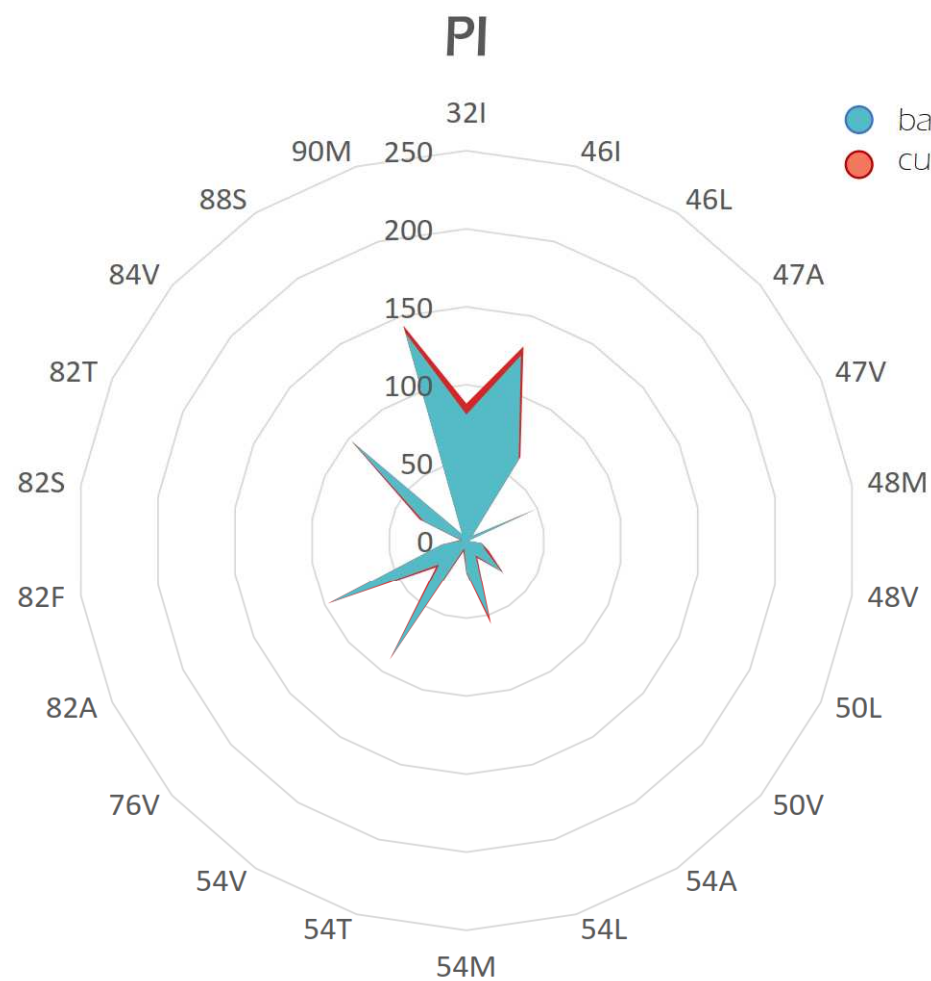


NNRTI





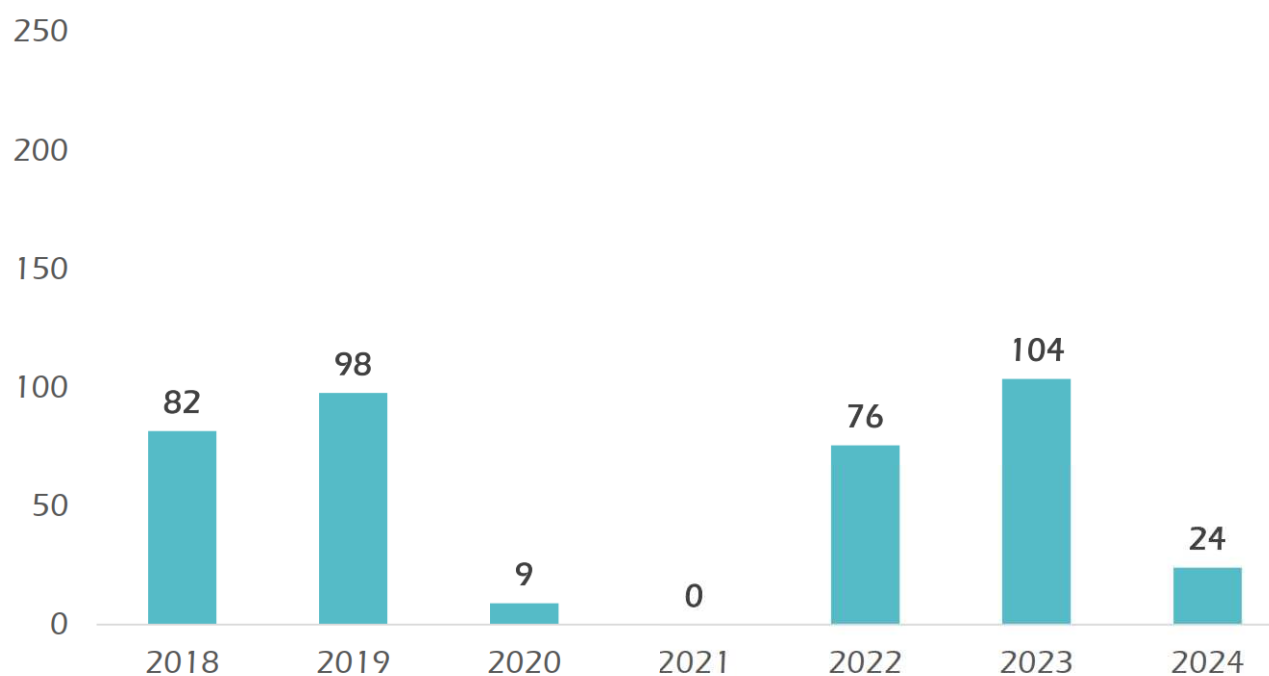
MAJOR RESISTANCE MUTATIONS





PLASMA AND PBMCs COLLECTED

Individuals with samples

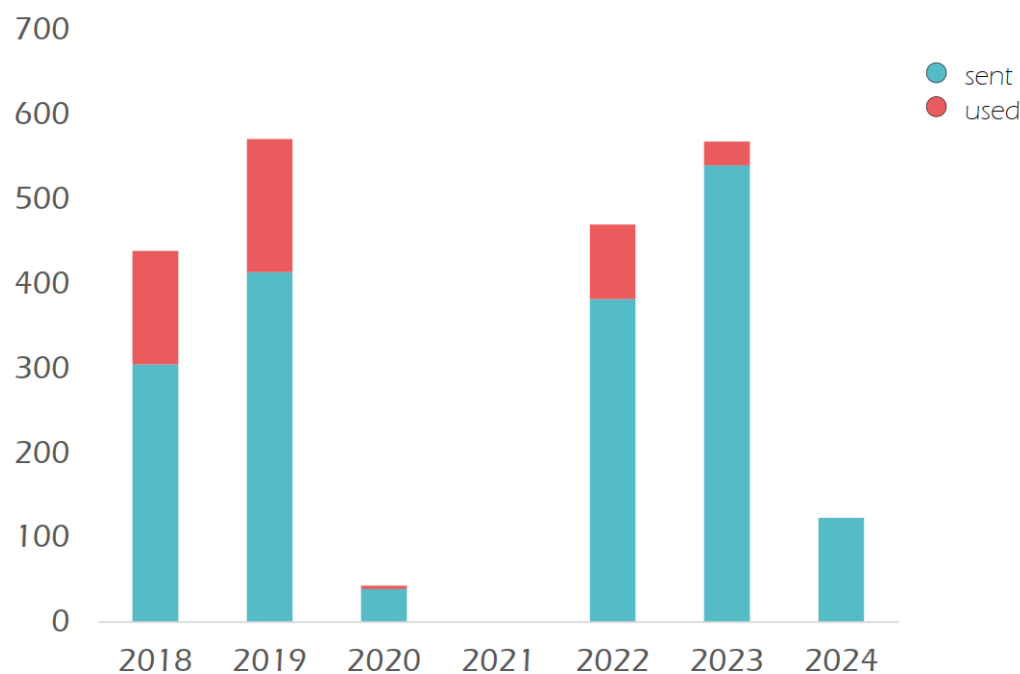




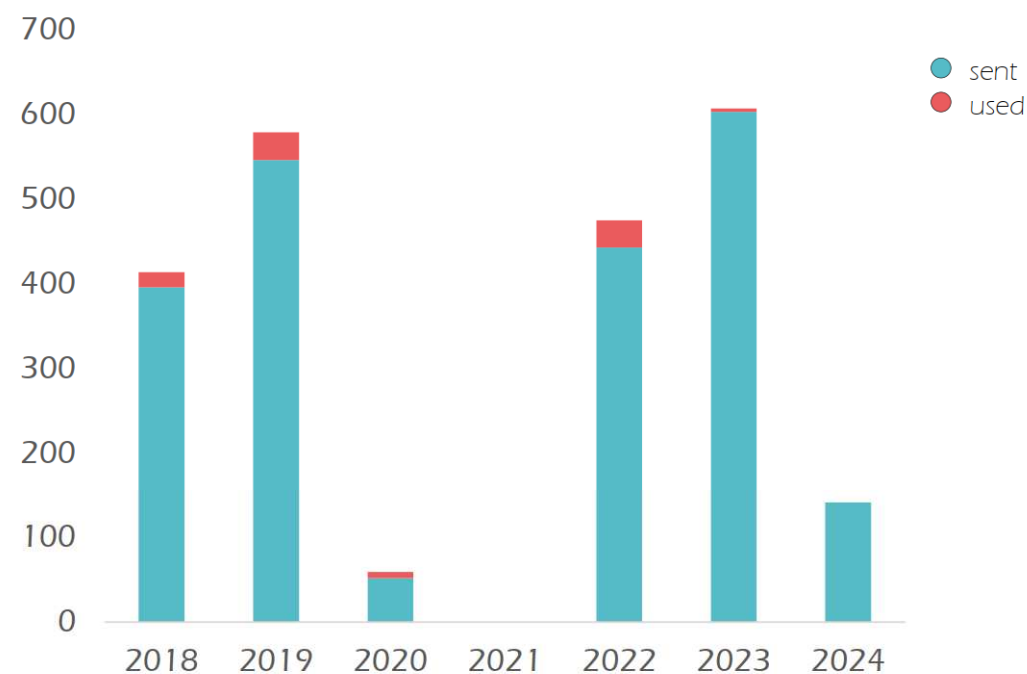
PLASMA AND PBMCs COLLECTED



PBMC's aliquots

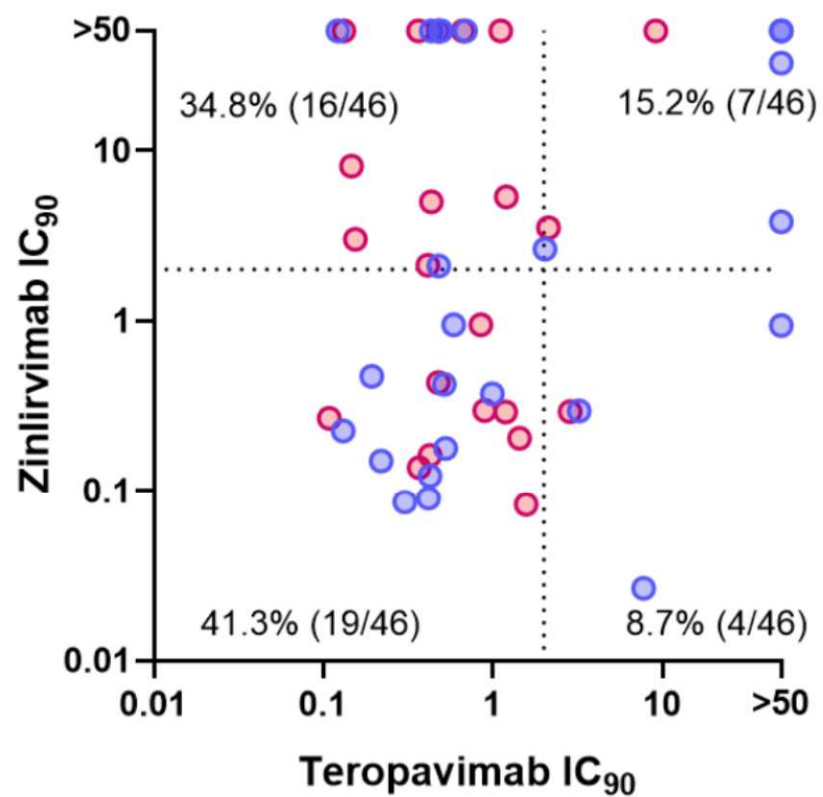


PLASMA aliquots





BNABS in PRESTIGIO



*sensitivity threshold <2,00

PRESTIGIO Registry meet**ING** on HIV multidrug resistance

● sensitive *

● not sensitive



DELFINO Study

Doravirine + Lenacapavir + Fostemsavir
in PWH enrolled in the Prestigio Registry

A bPI, INSTI (and NRTI) sparing strategy to improve QOL

40 People with HIV-1:

- age ≥ 18 years
- Enrolled in PRESTIGIO Registry
- Detectable or undetectable VL
- non-CRF_01AE strain
- no previous virological failure during LEN- and/or FTR-containing regimens
- Susceptibility to DOR

DOR + LEN + FTR*

Primary endpoint HIV-RNA < 50 copies/mL at 26 weeks

* Plus F/TAF if HBCab pos, HBSab neg

PRESTIGIO Registry meet**ING** on HIV multidrug resistance



ACKNOWLEDGMENTS



STEERING COMMITTEE: Antonella Castagna (Coordinatore), Vincenzo Spagnuolo (Coordinatore operativo), Daniele Armenia, Stefano Bonora, Leonardo Calza, Anna Maria Cattelan, Giovanni Cenderello, Adriana Cervo, Laura Comi, Antonio Di Biagio, Emanuele Focà, Roberta Gagliardini, Andrea Giacomelli, Filippo Lagi, Giulia Marchetti, Stefano Rusconi, Francesco Saladini, Maria Santoro, Maurizio Zazzi

VIROLOGY TEAM AND BIOLOGICAL BANK: Andrea Galli, Daniele Armenia, Francesco Saladini, Maria Santoro, Maurizio Zazzi, BioRep SRL

STUDY COORDINATORS: Elisabetta Carini, Sabrina Bagaglio, Girolamo Piromalli

STATISTICAL AND MONITORING TEAM: Riccardo Lolatto, Sara Diotallevi

ENROLLING CENTERS: *ANCONA:* Marcello Tavio, Alessandra Mataloni Paggi; *BARI:* Annalisa Saracino, Flavia Balena; *BERGAMO:* Laura Comi, Daniela Valenti, Claudia Suardi; *BOLOGNA:* Pierluigi Viale, Leonardo Calza, Federica Malerba, Silvia Cretella, Riccardo Riccardi; *BRESCIA:* Francesco Castelli, Emanuele Focà, Davide Minisci, Francesca Pennati; *BUSTO ARSIZIO:* Barbara Menzaghi, Maddalena Farinazzo; *CATANIA:* Bruno Cacopardo, Maurizio Celesia, Michele Salvatore Paternò Raddusa, Carmen Giarratana; *CATANZARO:* Paolo Fusco, Vincenzo Olivadese; *CREMONA:* Angelo Pan, Chiara Fornabaio, Paola Brambilla; *FIRENZE:* Alessandro Bartoloni, Filippo Lagi, Paola Corsi, Seble Tekle Kiro, Filippo Ducci, Susanna Giachè, Cecilia Costa, Alessio Bellucci, Elisa Mirabelli; *FOGGIA:* Teresa Santantonio, Sergio Lo Caputo, Sergio Ferrara, Arianna Narducci; *GENOVA:* Emanuele Pontali, Marcello Feasi, Antonio Sarà, Matteo Bassetti, Antonio Di Biagio, Sabrina Bianchi; *MILANO:* Antonella Castagna, Vincenzo Spagnuolo, Elisabetta Carini, Sabrina Bagaglio, Riccardo Lolatto, Andrea Galli, Sara Diotallevi, Rebecka Papaioannu, Tommaso Clemente, Girolamo Piromalli, Spinello Antinori, Andrea Giacomelli, Tiziana Formenti, Fabiola Schiavo, Giulia Marchetti, Lidia Gazzola, Fabiana Trionfo Fineo, Massimo Puoti, Cristina Moioli, Federico D'Amico; *MODENA:* Cristina Mussini, Adriana Cervo; *NAPOLI:* Elio Manzillo, Amedeo Lanzardo; *PADOVA:* Anna Maria Cattelan, Maria Mazzitelli; *PALERMO:* Antonio Cascio, Marcello Trizzino; *PARMA:* Elisa Fronti, Diletta Laccabue, Federica Carli; *PAVIA:* Roberto Gulminetti, Layla Pagnucco, Mattia Demitri; *PERUGIA:* Daniela Francisci, Giuseppe De Socio, Elisabetta Schiaroli; *REGGIO EMILIA:* Elisa Garlassi, Romina Corsini; *ROMA:* Roberta Gagliardini, Marisa Fusto, Loredana Sarmati, Vincenzo Malagnino, Tiziana Mulas, Mirko Compagno Carlo Torti, Simona Di Giambenedetto, Silvia Lamonica, Pierluigi Francesco Salvo; *SANREMO:* Giovanni Cenderello, Rachele Pincino; *SIENA:* Mario Tumbarello, Massimiliano Fabbiani, Francesca Panza, Ilaria Rancan; *TORINO:* Giovanni Di Perri, Stefano Bonora, Micol Ferrara, Andrea Calcagno, Silvia Fantino; *VERONA:* Stefano Nardi, Marta Fiscon

SUPPORTED BY: ViiV Healthcare, Gilead Sciences, MSD, Janssen-Cilag

PRESTIGIO Registry meet**ING** on HIV multidrug resistance