

# IL MODELLO DI BRESCIA

STEFANIA ARSUFFI  
ASST SPEDALI CIVILI DI BRESCIA



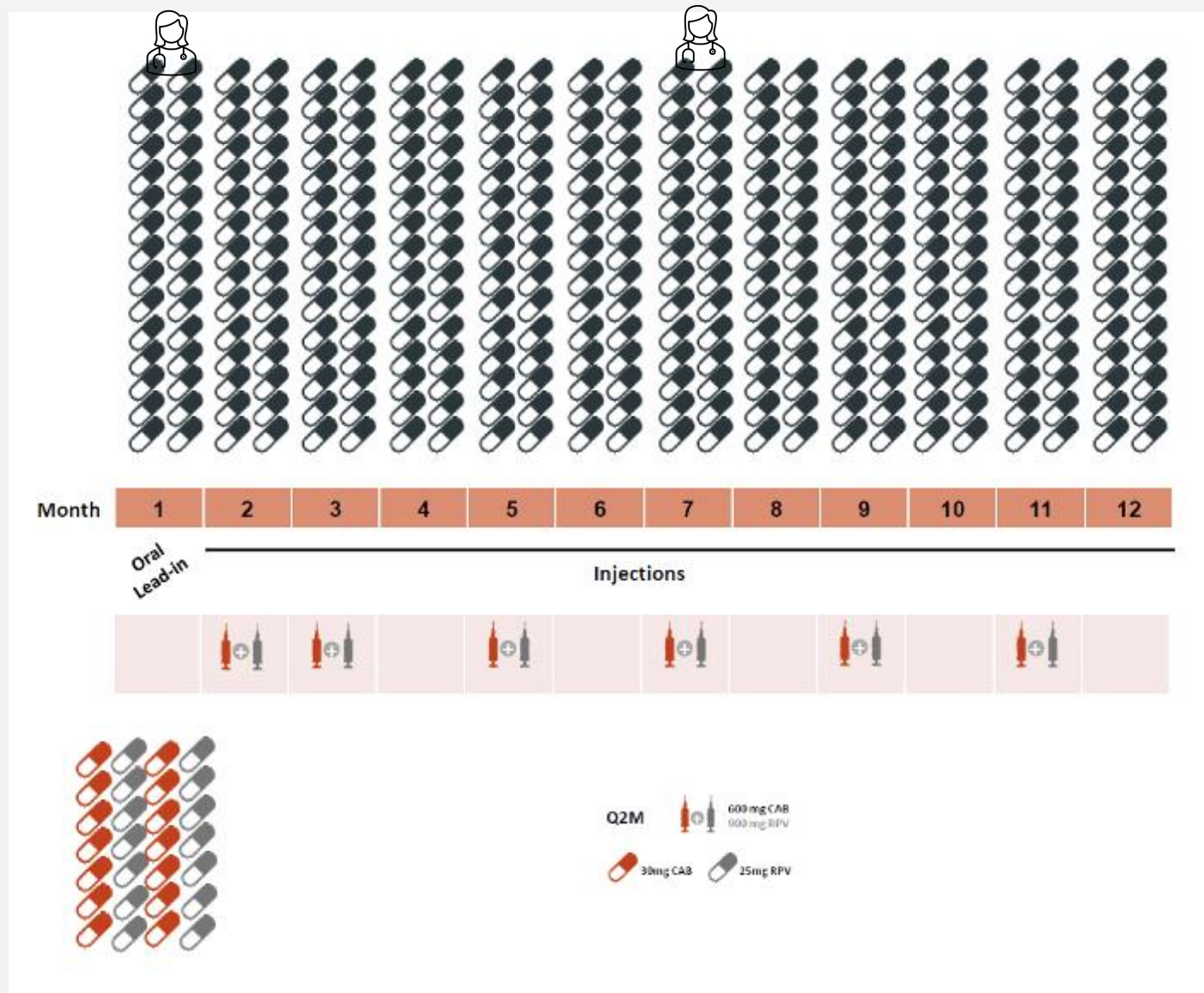
Sistema Socio Sanitario



Regione  
Lombardia

ASST Spedali Civili

# UN NUOVO PARADIGMA



# ACCETTABILITÀ

500 PLVH seguiti presso ASST Spedali Civili di Brescia

- 56% non a conoscenza di LAI-ART ad inizio 2023
- 86% interessati a LA-ART
- 64% interessati a LA-ART intramuscolo

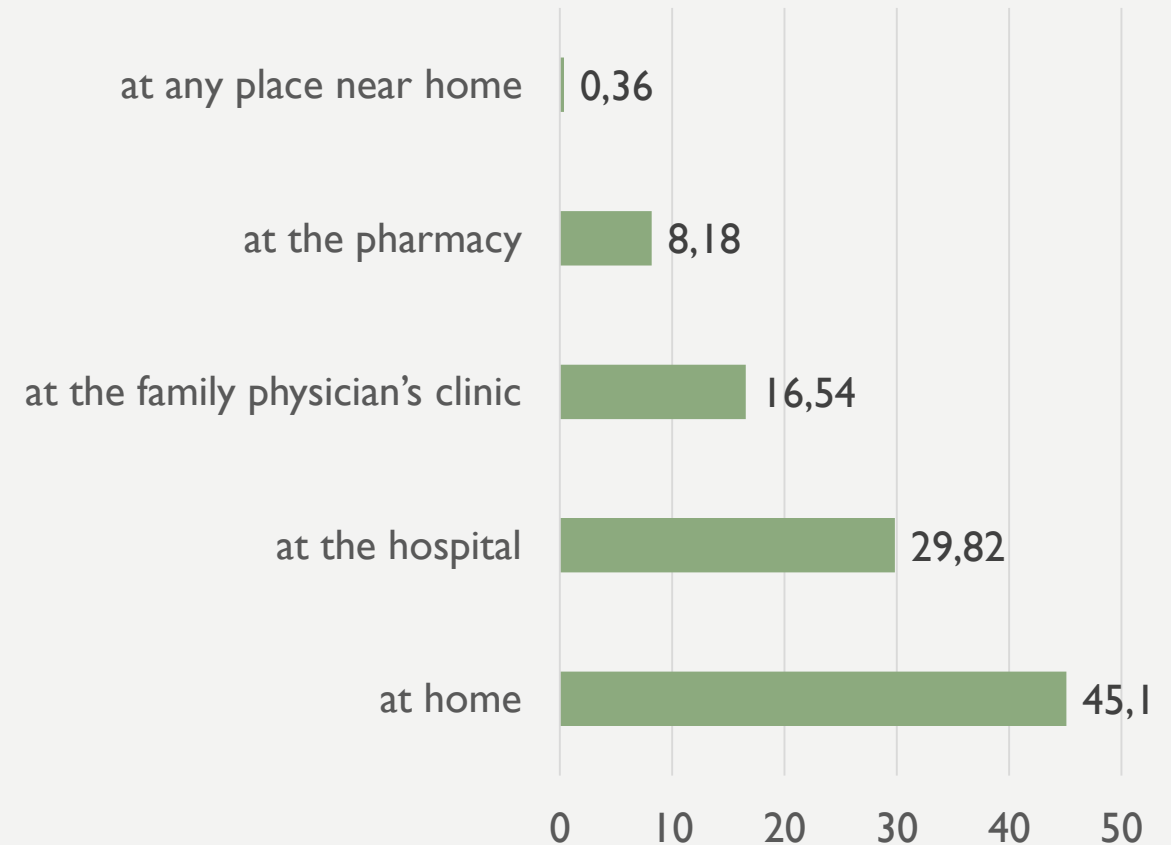
|                                       |                                                                         |
|---------------------------------------|-------------------------------------------------------------------------|
| <b>Duration of HIV infection</b>      | 22 ( $\pm$ SD 10.74) years                                              |
| <b>Current ART</b>                    | single-tablet regimen 414 (82.8%)                                       |
|                                       | 2 tablets 62 (12.4%)                                                    |
|                                       | 3 or more 24 (4.8%)                                                     |
| <b>Adherence to ART</b>               | 414 (82.8%) adherents                                                   |
|                                       | 21 (4.2%) forgot to take it at least once                               |
|                                       | 2 (0.4%) took it at different times                                     |
|                                       | 5 (1%) finished the tablets before the scheduled pickup at the pharmacy |
|                                       | 1 (0.2%) did not take the therapy correctly due to abroad travelling    |
| <b>No concomitant medications</b>     | 248 (49.6%)                                                             |
| <b>Concomitant medications (mean)</b> | 2.84 ( $\pm$ SD 2.31)                                                   |
| <b>Consideration of ART</b>           | 446 (87.62%) "ART is vital to be well"                                  |
|                                       | 34 (6.68%) "ART is exhausting, a duty"                                  |
|                                       | 15 (2.95%) "ART is a sentence"                                          |
|                                       | 14 (2.75%) "ART is a restriction to my freedom"                         |

# ACCETTABILITÀ

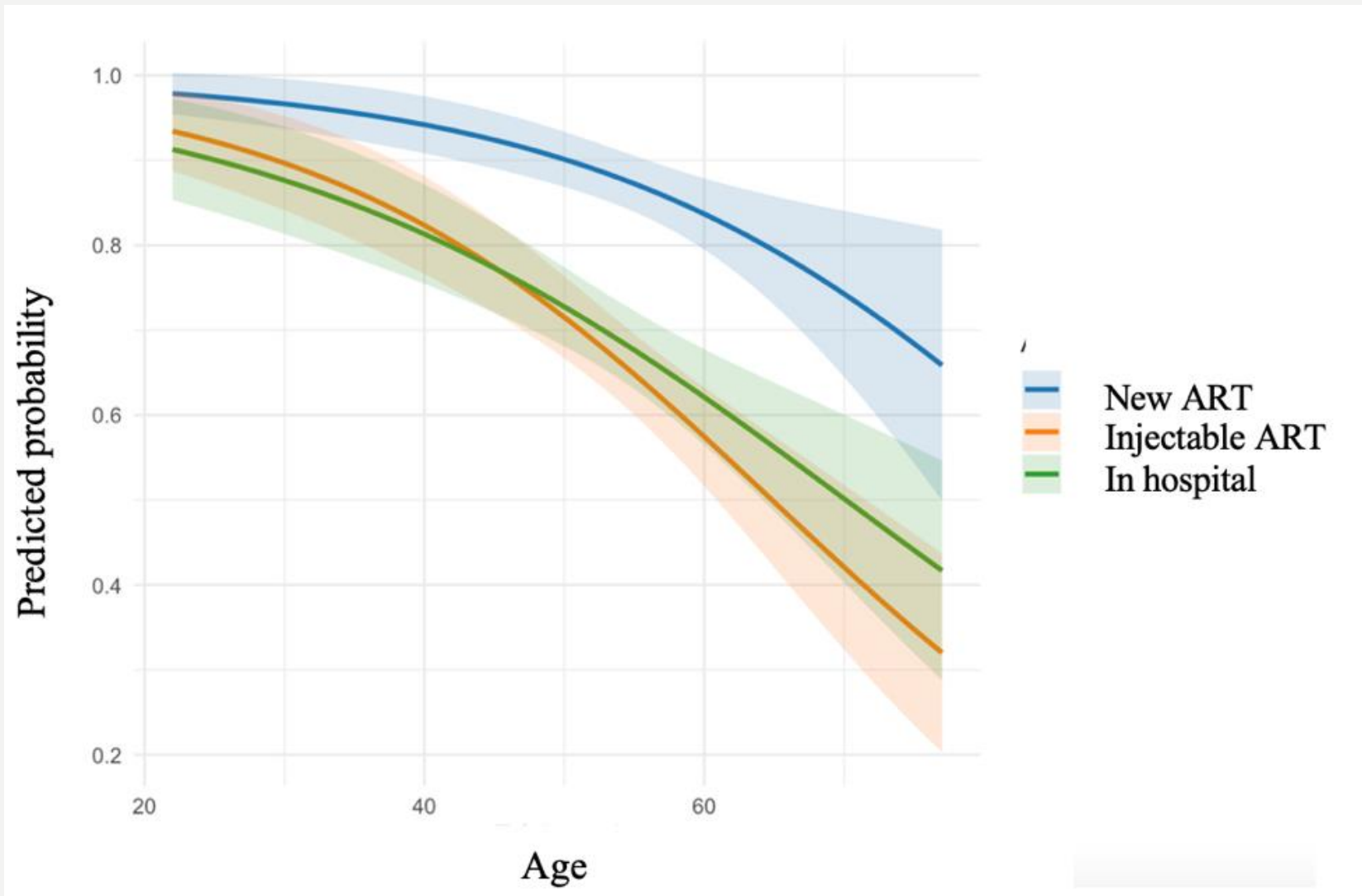
The concerns limiting the remaining patients were mainly due to:

- being accustomed to oral therapy (15.8%)
- fear of injections (6.2%)
- doubts about effectiveness (3.2%)
- number of visits to the clinic (0.6%)
- concomitant injectable therapy (0.2%).

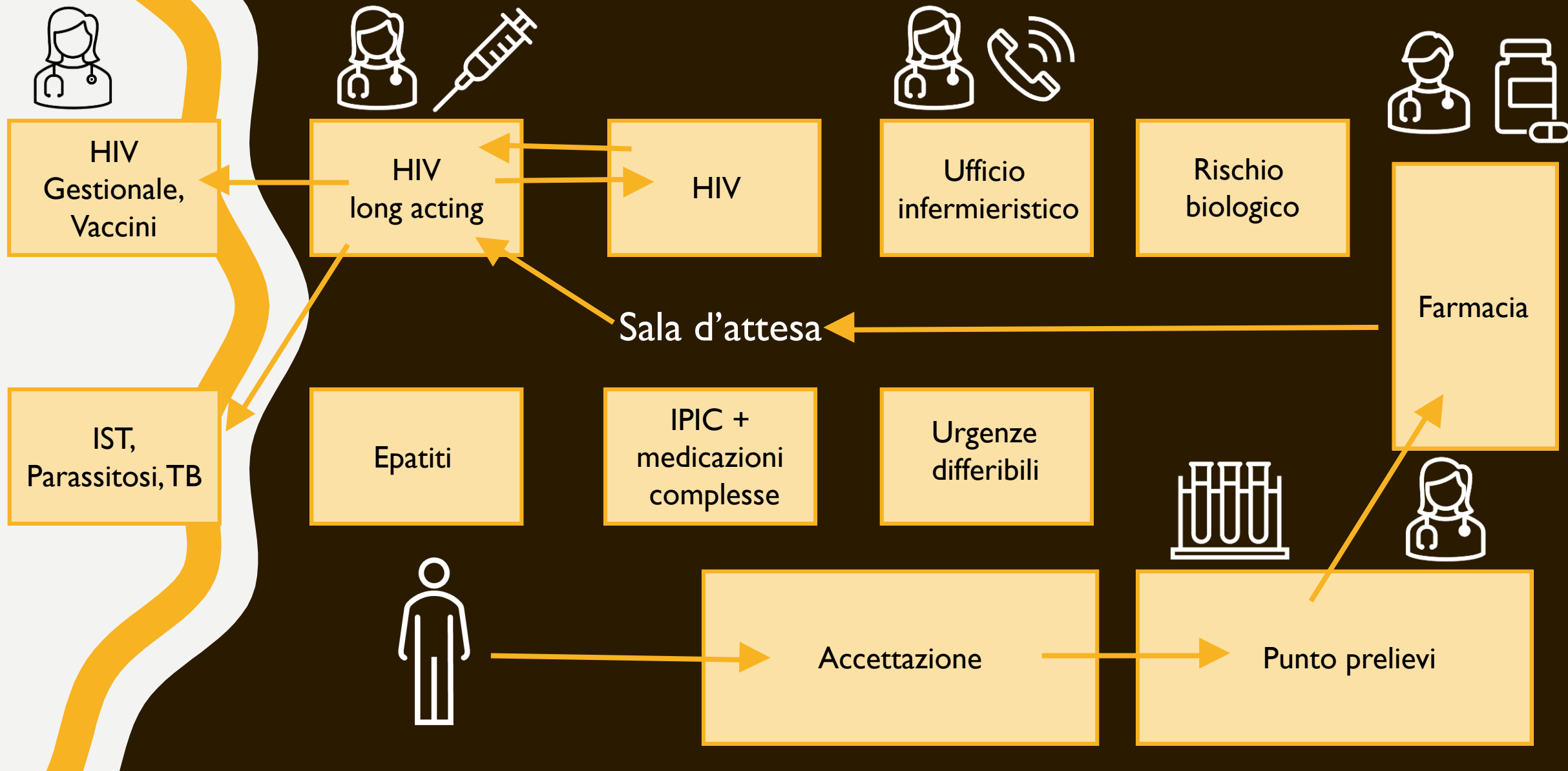
| Composite outcome      |             |             |        |
|------------------------|-------------|-------------|--------|
| Predictors             | Odds Ratios | CI          | p      |
| Età(anni)              | 0.97        | 0.95 – 0.98 | <0.001 |
| Durata infezione(anni) | 1.00        | 0.99 – 1.01 | 0.770  |
| Gender=Femmina         | 0.87        | 0.68 – 1.10 | 0.245  |
| Numero di farmaci      | 0.87        | 0.69 – 1.09 | 0.235  |
| Observations           | 392         |             |        |



# ACCETTABILITÀ



# AMBULATORIO LA

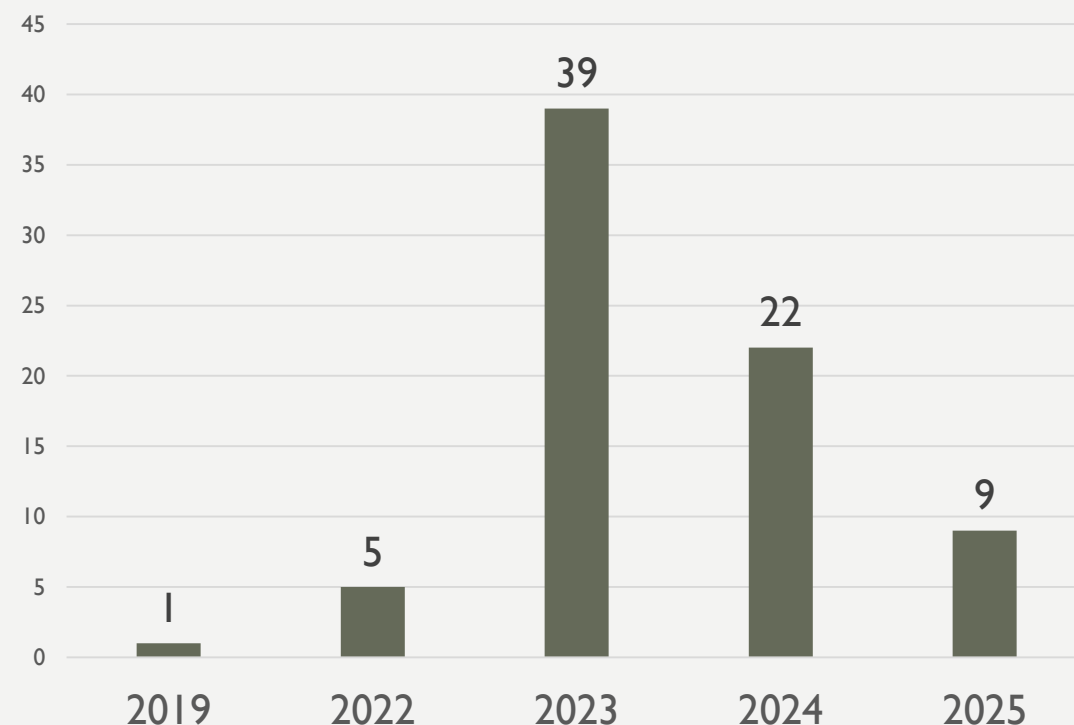
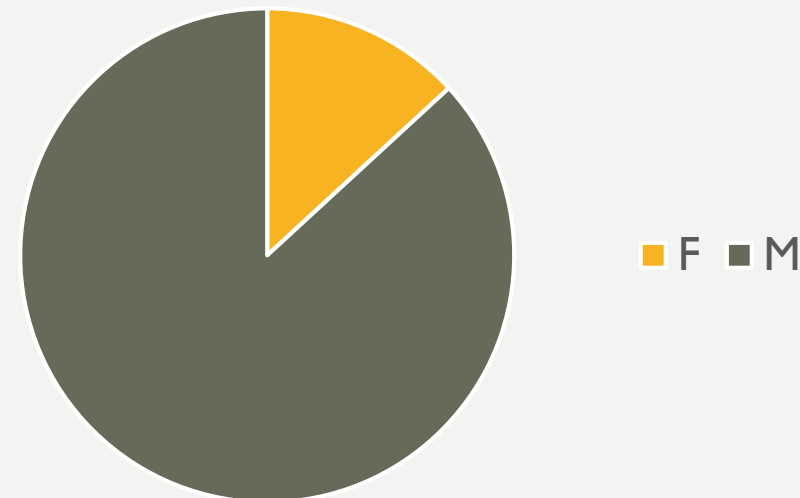


# I NOSTRI NUMERI

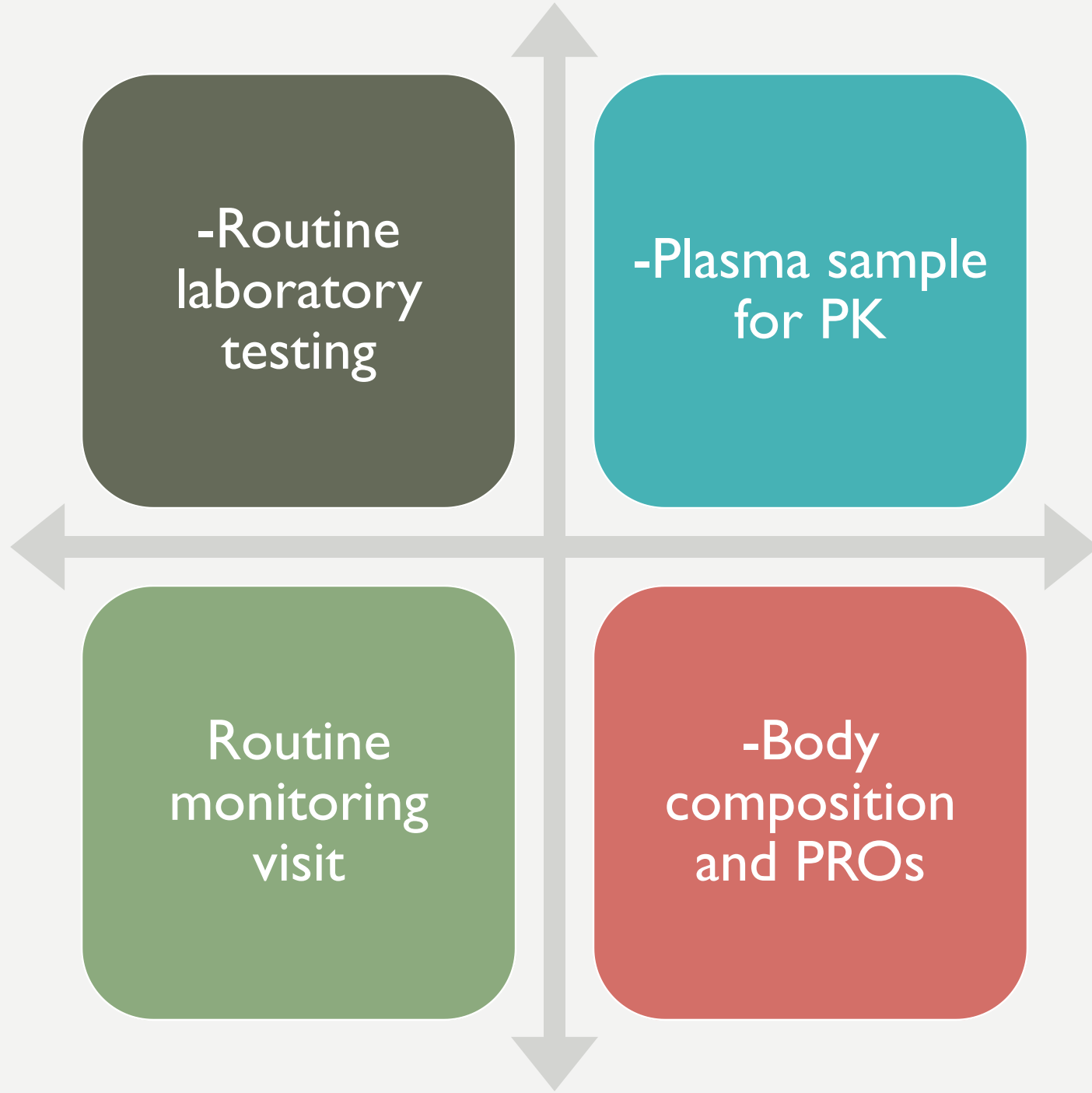
Attualmente 76 pazienti in LAI-ART

Principali motivi di sospensione:

- ISR
- Gravidanza
- Peggioramento sintomi psichiatrici
- Fallimento virologico
  - I singolo caso
  - Senza sviluppo di RAMs
  - Virosoppresso con B/F/T

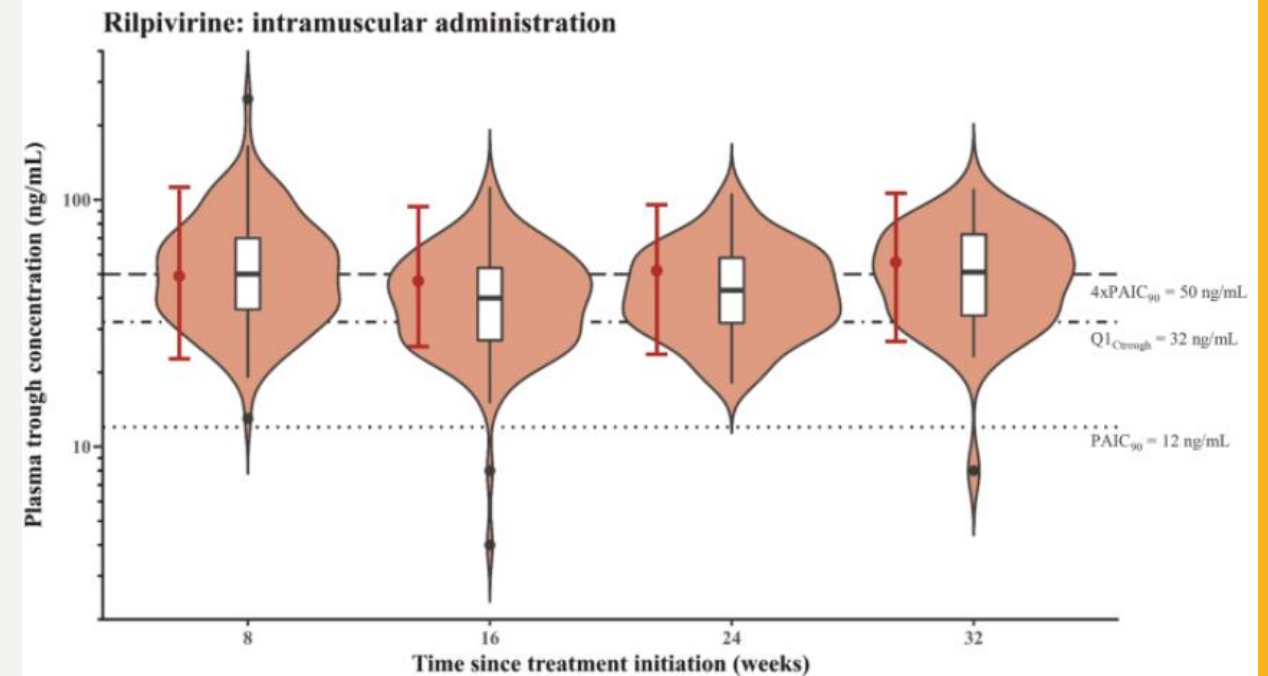
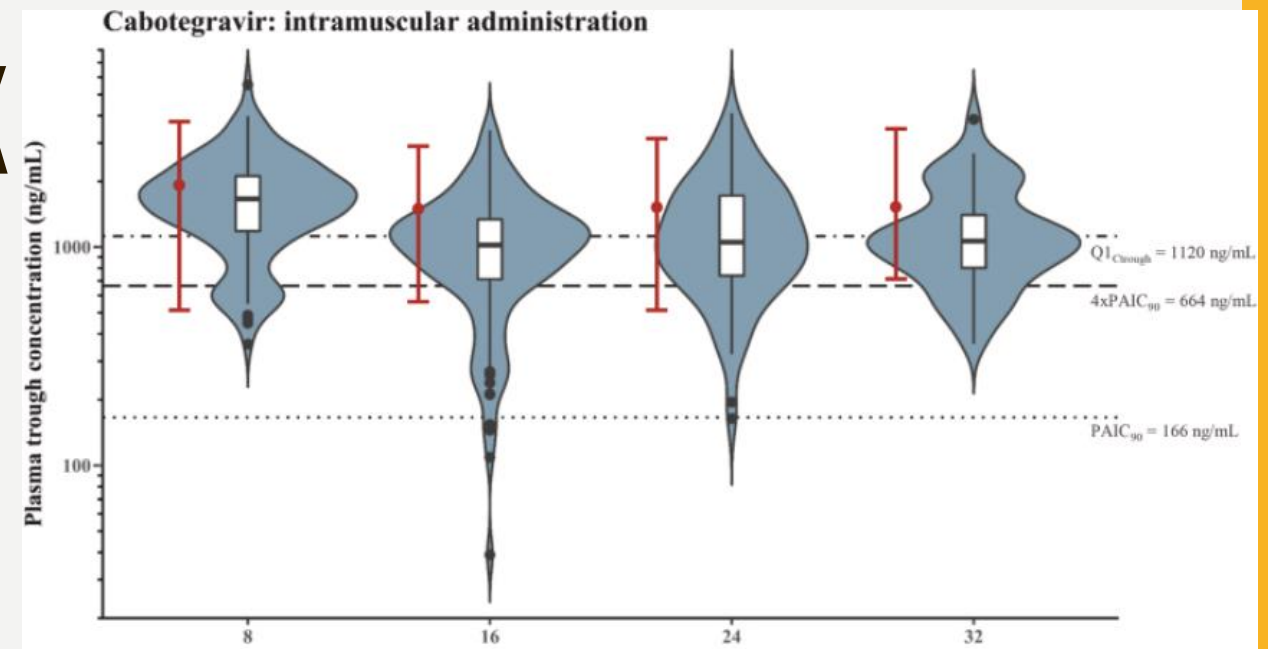
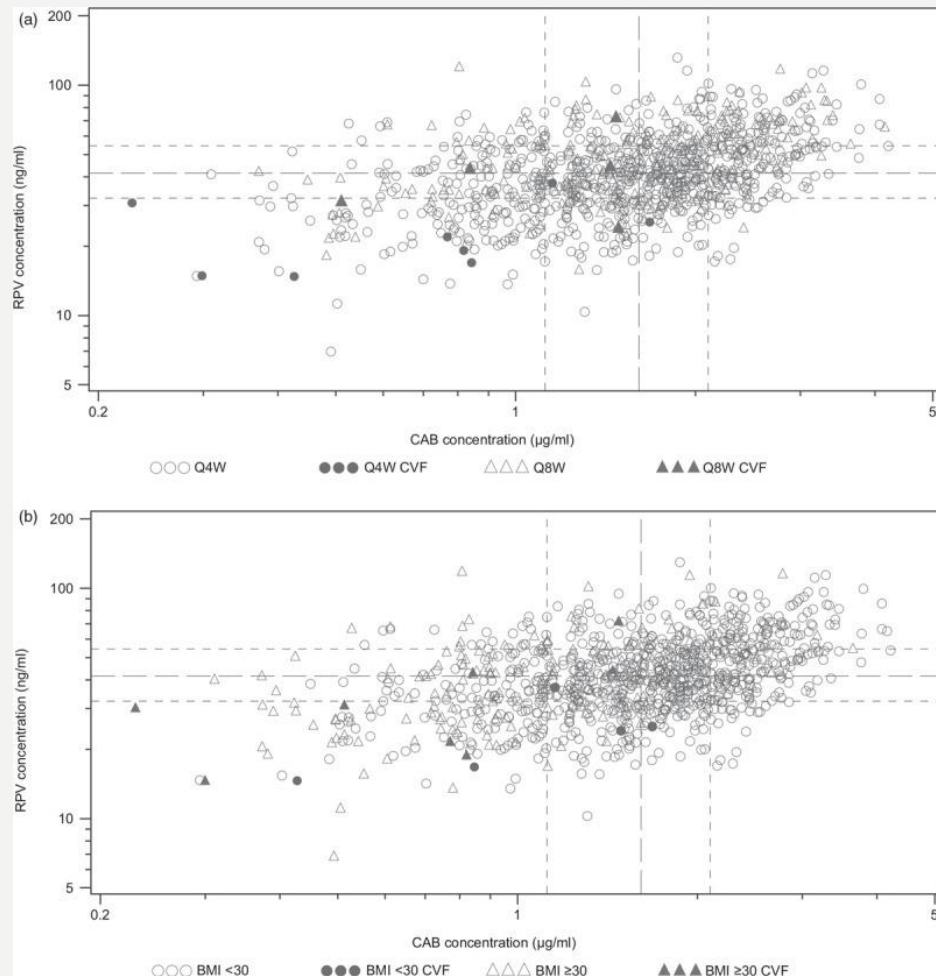


# PRATICA CLINICA



# STUDIO CLINICI

# LAI CAB/RPV - PK



1. Cutrell AG, AIDS. 2021 | PMID: 33730748
2. Thoueille P, Lancet Reg Health Eur. 2023, PMID: 38162253

# METHODS

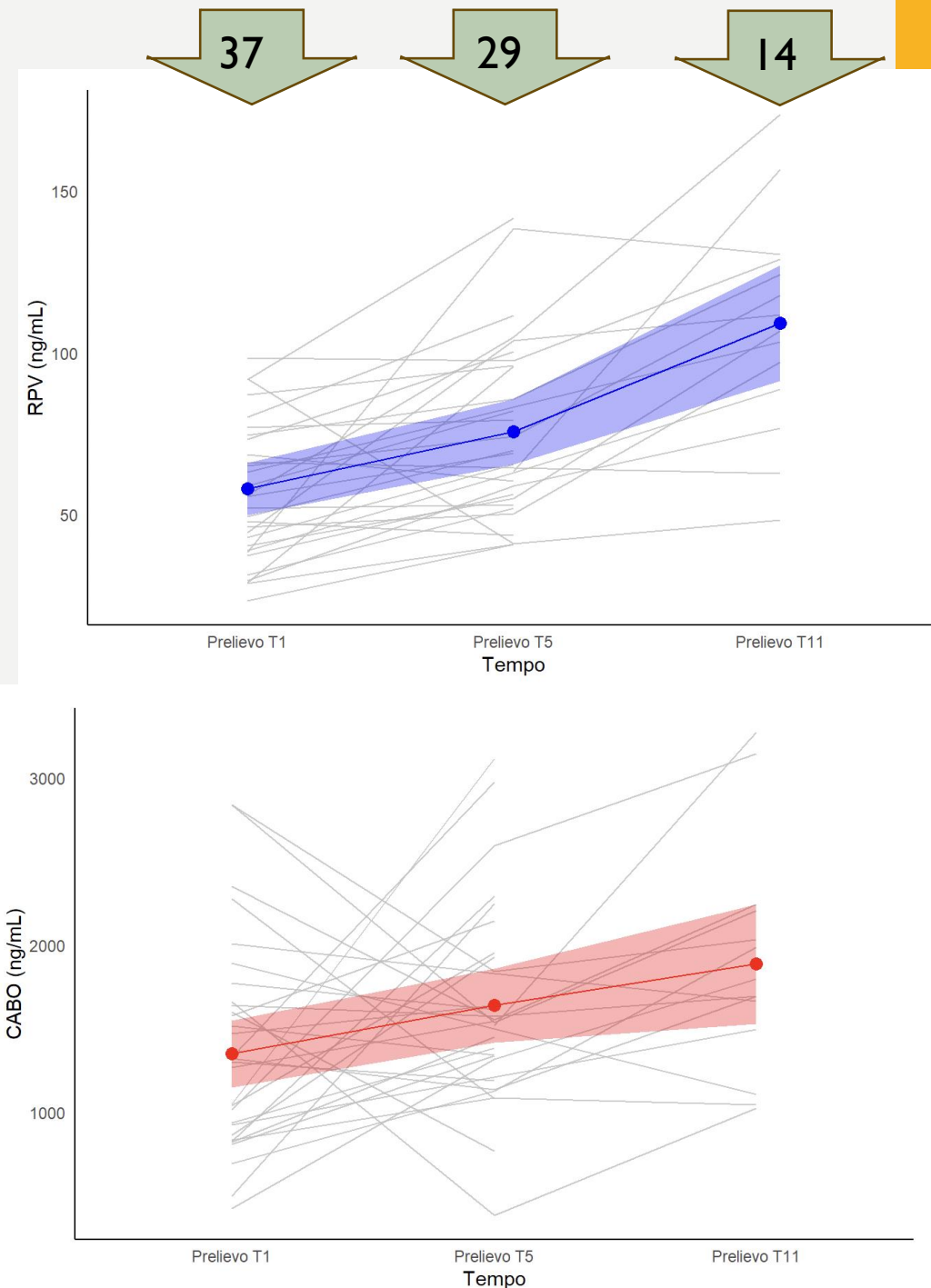
|                                       | Baseline | Week 4<br>1 month | Week 12<br>3 months | Week 20<br>5 months | Week 28<br>7 months | Week 36<br>9 months | Week 44<br>11 months | Week 52<br>13 months |
|---------------------------------------|----------|-------------------|---------------------|---------------------|---------------------|---------------------|----------------------|----------------------|
| Enrollment                            | x        |                   |                     |                     |                     |                     |                      |                      |
| Routine<br>laboratory<br>testing + PK |          | x                 |                     | x                   |                     |                     | x                    |                      |
| LAI<br>CAB/RPV                        | x        | x                 | x                   | x                   | x                   | x                   | x                    | x                    |
| Routine<br>monitoring<br>visit + PROs | x        |                   |                     |                     | x                   |                     |                      | x                    |

# PHARMACOKINETICS

| RP<br>V    |                       |
|------------|-----------------------|
| <b>TI</b>  | 57,979 (SD 24,878)    |
| <b>T5</b>  | 75,668 (SD 27,704)    |
| <b>T11</b> | 109,092 (SD 34,033)   |
| <b>CAB</b> |                       |
| <b>TI</b>  | 1351,491 (SD 622,692) |
| <b>T5</b>  | 1640 (SD 606,223)     |
| <b>T11</b> | 1888,165 (SD 685,025) |

RPV <50 ng/mL in  
23 cases (25.8%)

CAB <664 ng/mL in  
5 cases (5.4%)

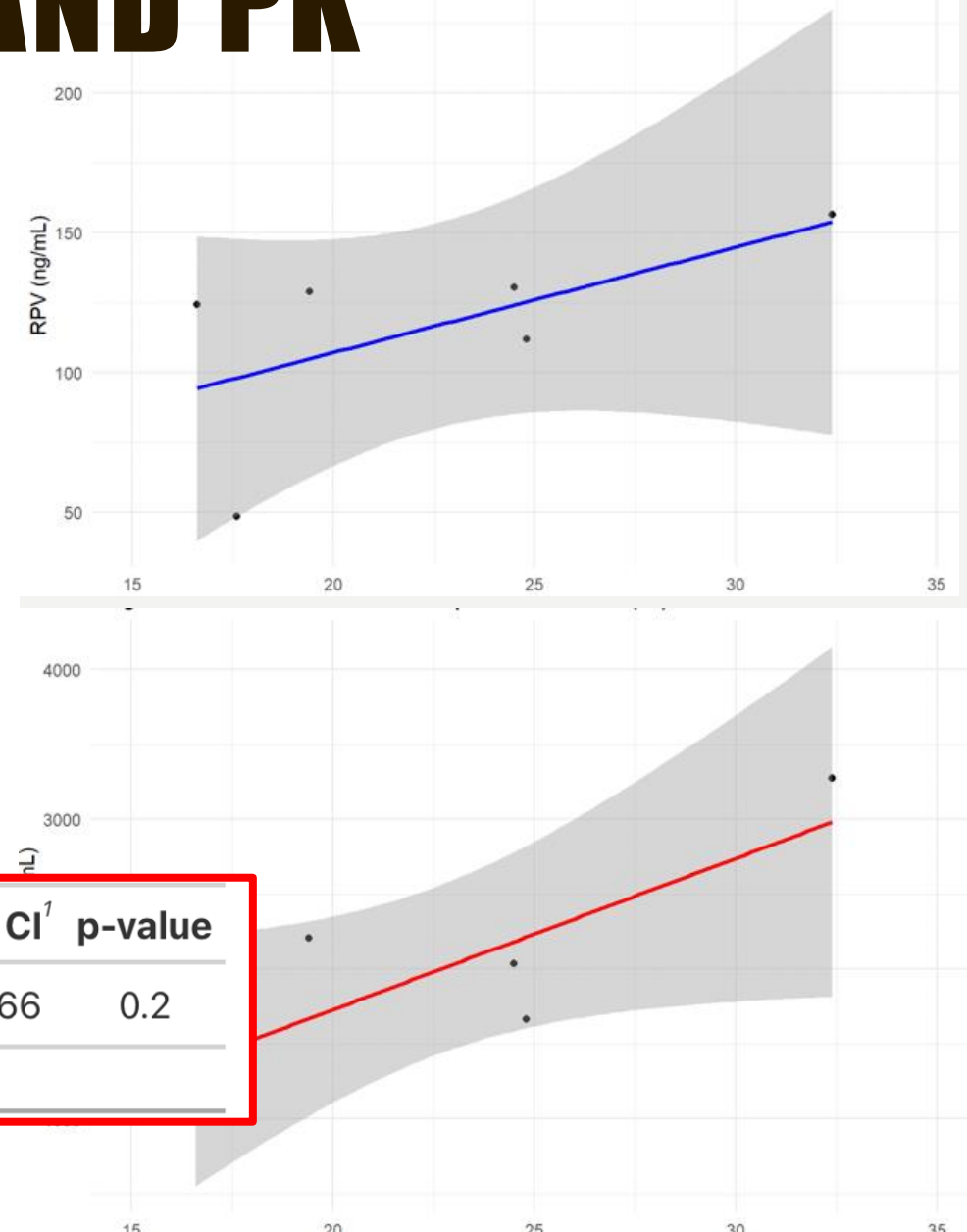


# BODY COMPOSITION AND PK

|                    | RPV T1 | RPV T5 | RPV T11 | CABO T1 | CABO T5 | CABO T11 | eta   | Peso  | Peso T11 | BMI   | BMI T11 | Massa grassa (%) | Grip strength (kg) |
|--------------------|--------|--------|---------|---------|---------|----------|-------|-------|----------|-------|---------|------------------|--------------------|
| RPV T1             | 1.00   | 0.42   | 0.05    | 0.19    | 0.17    | 0.05     | 0.15  | -0.16 | -0.16    | -0.08 | -0.19   | -0.09            | -0.11              |
| RPV T5             | 0.42   | 1.00   | 0.60    | 0.40    | 0.45    | 0.21     | 0.07  | -0.16 | -0.14    | 0.15  | 0.15    | 0.09             | 0.38               |
| RPV T11            | -0.05  | 0.60   | 1.00    | 0.53    | 0.49    | 0.73     | 0.18  | 0.27  | 0.30     | 0.28  | 0.31    | 0.61             | 0.44               |
| CABO T1            | 0.19   | 0.40   | 0.53    | 1.00    | -0.14   | 0.12     | -0.13 | -0.08 | -0.31    | -0.16 | -0.11   | 0.29             | 0.23               |
| CABO T5            | 0.17   | 0.45   | 0.49    | -0.14   | 1.00    | 0.69     | -0.05 | -0.15 | -0.09    | -0.07 | -0.05   | -0.05            | 0.04               |
| CABO T11           | 0.05   | 0.21   | 0.73    | 0.12    | 0.69    | 1.00     | 0.39  | 0.12  | 0.04     | 0.10  | -0.09   | 0.80             | 0.03               |
| eta                | 0.15   | 0.07   | 0.18    | -0.13   | 0.05    | 0.39     | 1.00  | 0.09  | 0.12     | 0.17  | 0.33    | -0.13            | 0.08               |
| Peso               | -0.16  | -0.16  | 0.27    | -0.08   | -0.15   | 0.12     | 0.09  | 1.00  | 0.83     | 0.56  | 0.77    | 0.04             | 0.43               |
| Peso T11           | -0.16  | -0.14  | 0.30    | -0.31   | -0.09   | 0.04     | 0.09  | 0.83  | 1.00     | 0.56  | 0.77    | 0.04             | 0.43               |
| BMI                | -0.08  | 0.15   | 0.28    | -0.16   | -0.07   | 0.10     | 0.17  | 0.56  | 0.56     | 1.00  | 0.77    | 0.04             | 0.43               |
| BMI T11            | -0.19  | 0.15   | 0.31    | -0.11   | -0.05   | -0.09    | 0.33  | 0.77  | 0.77     | 0.77  | 1.00    | 0.09             | 0.43               |
| Massa grassa (%)   | -0.09  | 0.09   | 0.61    | 0.29    | -0.05   | 0.80     | -0.13 | 0.04  | 0.19     | -0.04 | 0.14    | 1.00             | 0.09               |
| Grip strength (kg) | -0.11  | 0.38   | 0.44    | 0.23    | 0.04    | 0.03     | 0.08  | 0.43  | 0.55     | 0.63  | 0.67    | 0.09             | 1.00               |

| Characteristic   | Beta | 95% CI <sup>1</sup> | p-value |
|------------------|------|---------------------|---------|
| Massa grassa (%) | 26   | -14, 66             | 0.2     |

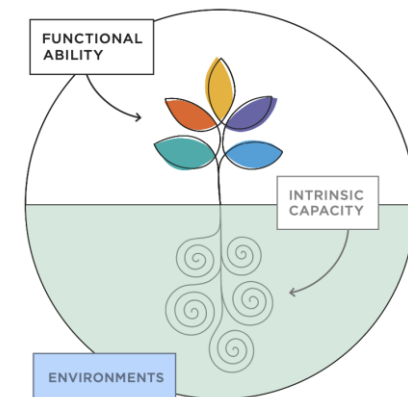
<sup>1</sup> CI = Confidence Interval



# GRIP STRENGTH AND PK

## Vitality (hand grip strength), score distribution by 5-year age groups, in 36 countries\*

Density plots visualize a distribution of people and their scores. This represents more than 121 000 older persons in 36 countries, within 7 distributions, one for each 5-year age group (60-64, 65-69, 70-74, 75-79, 80-84, 85-89, 90+ years).

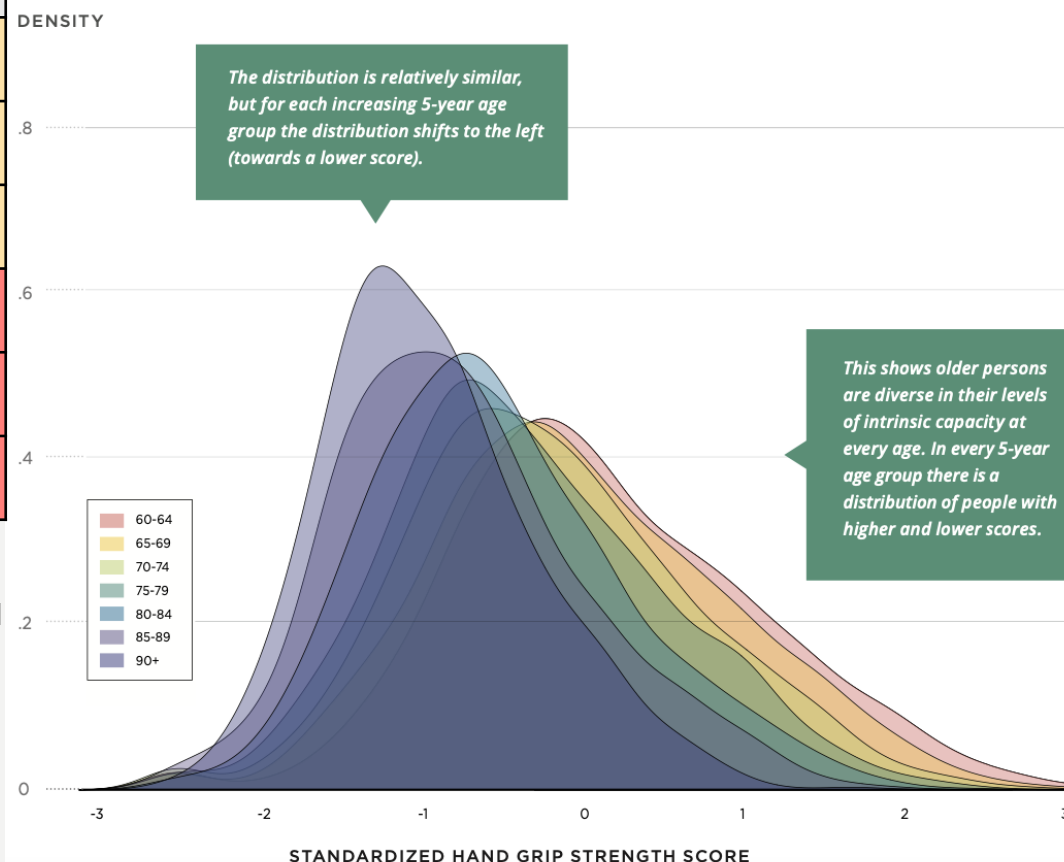


## DECADE OF HEALTHY AGEING BASELINE REPORT SUMMARY



|         | Beta   | CI inf  | CI sup | p-value |
|---------|--------|---------|--------|---------|
| RPV T1  | -0.287 | -1.461  | 0.887  | 0.616   |
| RPV T5  | 1.453  | -0.343  | 3.249  | 0.106   |
| RPV T11 | 1.617  | -1.671  | 4.904  | 0.274   |
| CAB T1  | 16.599 | -15.060 | 48.259 | 0.288   |
| CAB T5  | -2.557 | -38.927 | 33.813 | 0.884   |
| CAB T11 | 1.696  | -82.998 | 86.390 | 0.963   |

WHO Decade of healthy ageing: baseline report – summary 2021



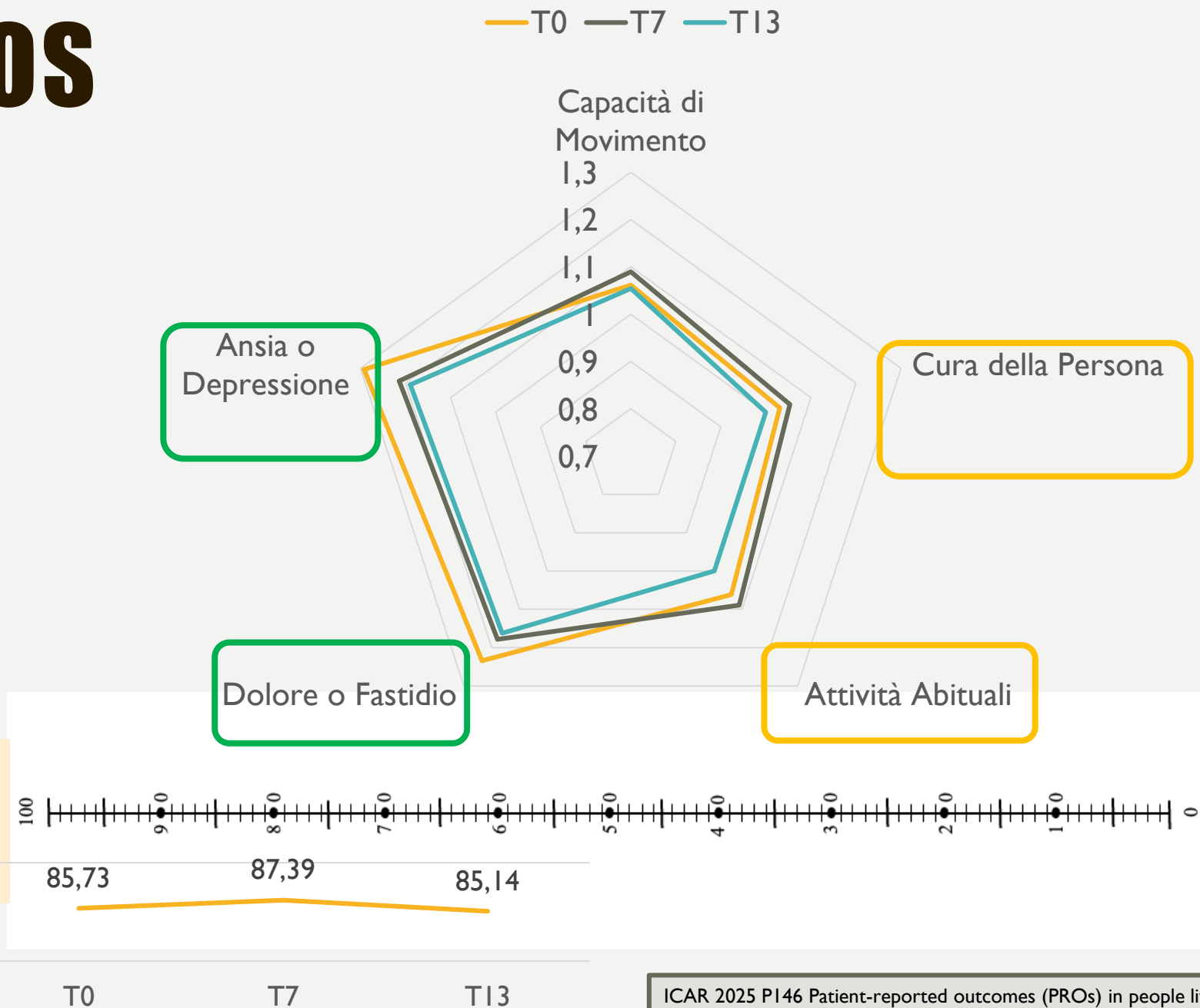
# CLINICAL FOLLOW UP

| Clinical follow up      |                |
|-------------------------|----------------|
| Undetectability         |                |
| T1                      | 37 (97,4%)     |
| T5                      | 37 (97,4%)     |
| T11                     | 26 (96,3%)     |
| Weight T11 (kg)         | 75,0 (SD 30,9) |
| BMI T11                 | 23,5 (SD 9,4)  |
| Discontinuation LAI-ART | 5              |



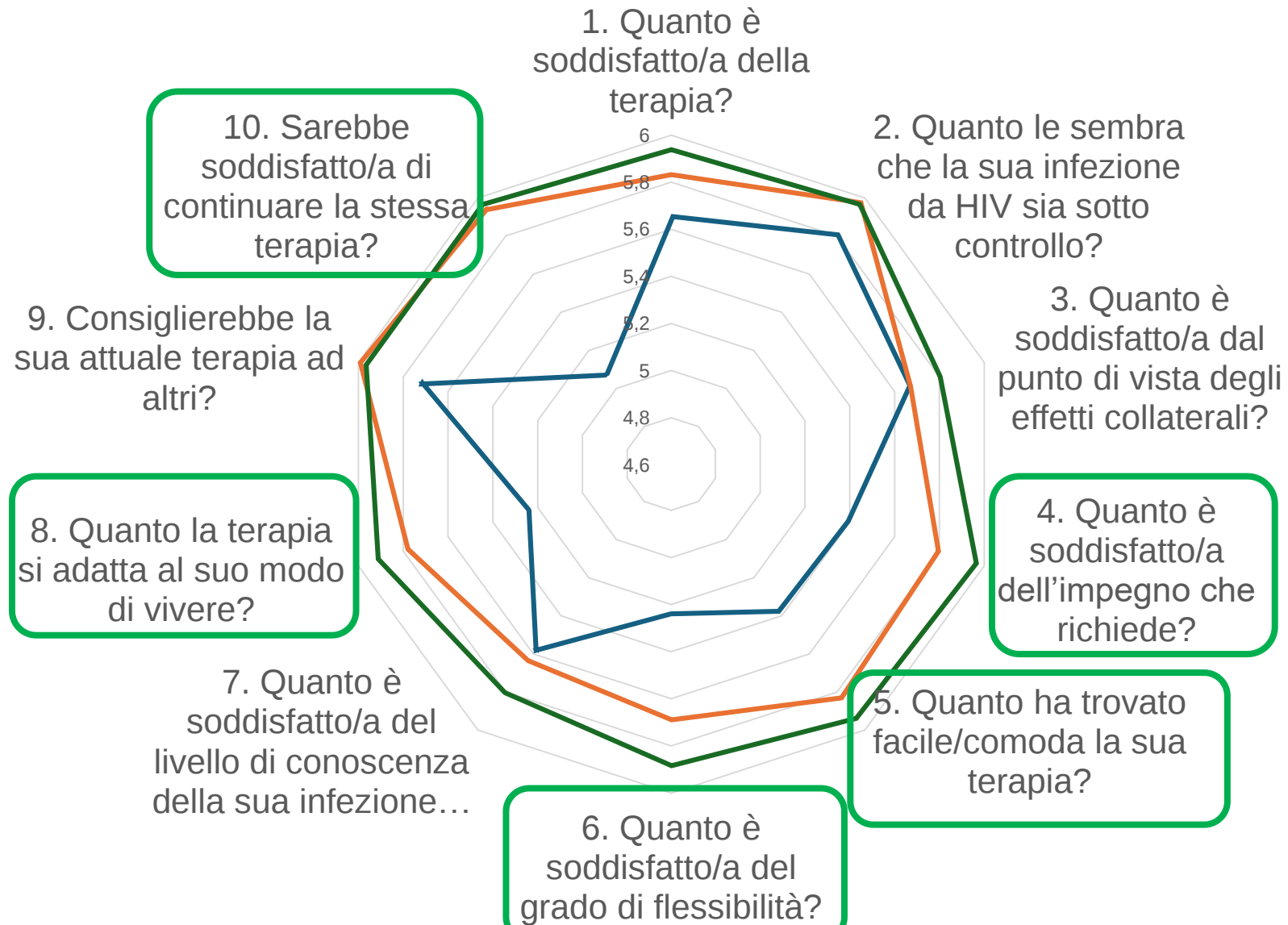
|                         |          |
|-------------------------|----------|
| Injection-site reaction | 3 (7,9%) |
| Pregnancy               | 1 (2,6%) |
| Virological failure     | 1 (2,6%) |

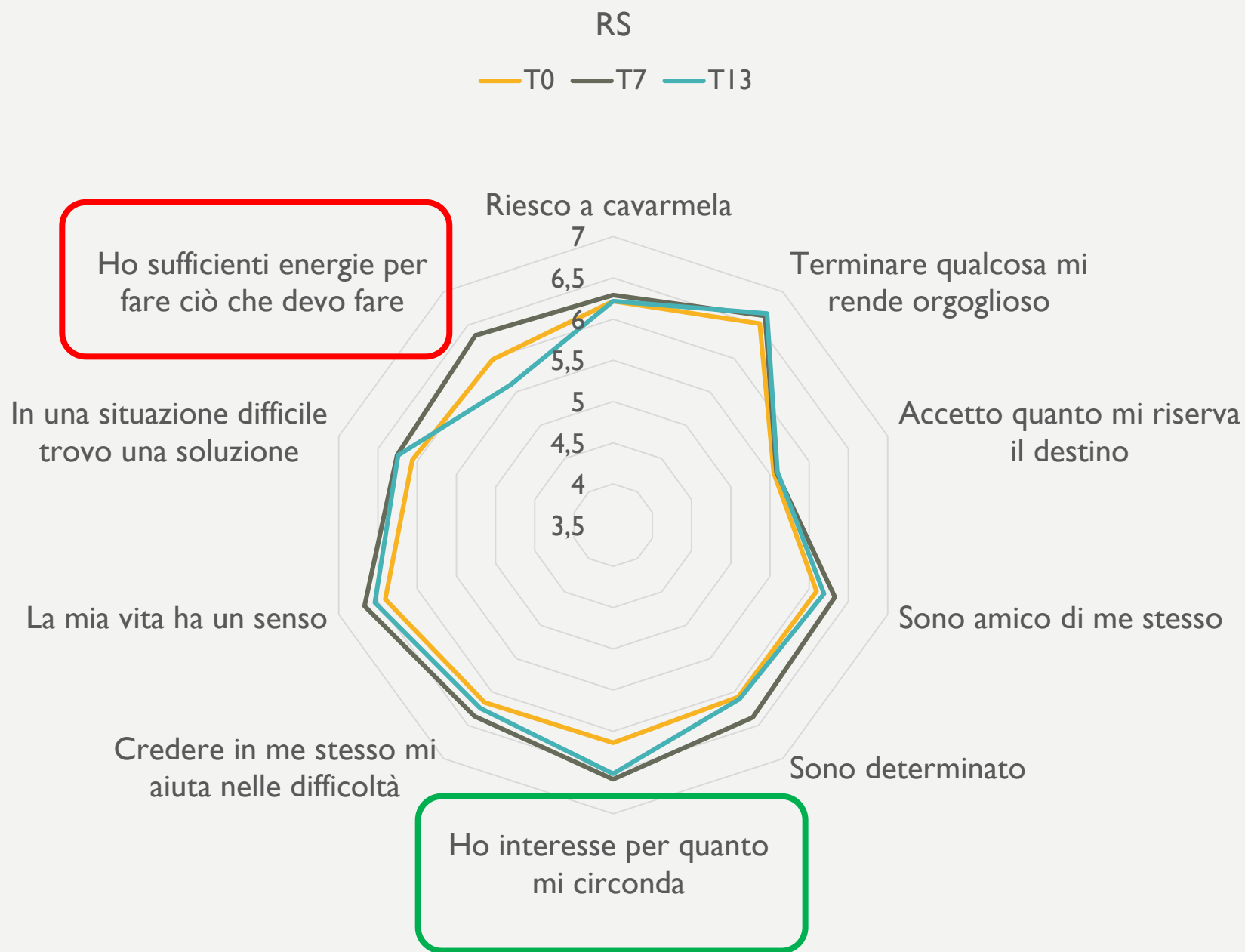
# PROS



## HIVTSQs

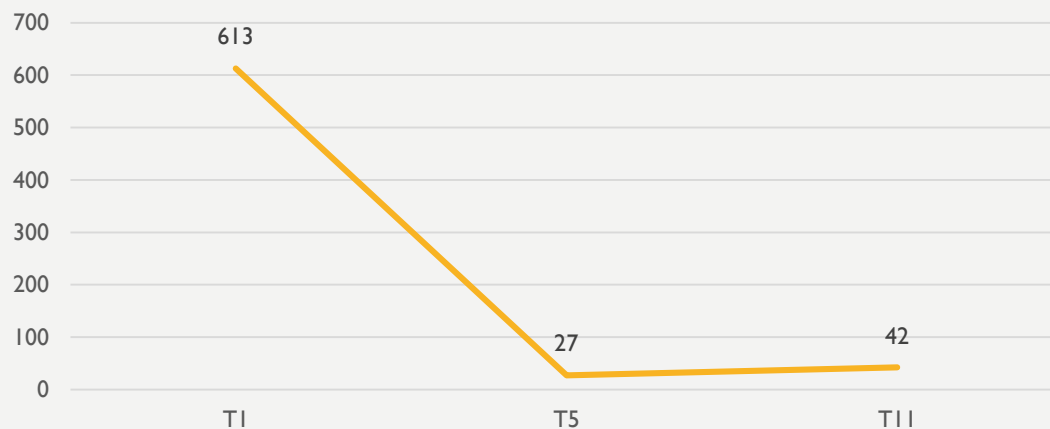
— T0 — T7 — T13



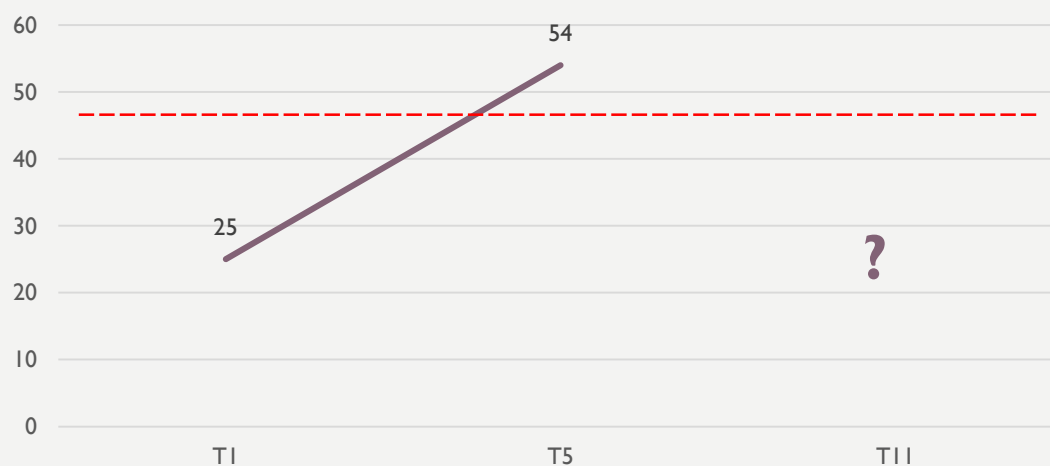


# ONE SINGLE VIROLOGICAL FAILURE

HIV RNA



RPV



Male, 38 years-old, BMI 24.9  
No comorbidities  
No concomitant medications

Subtype B  
No RAMs at GRT  
No previous virological failure  
Baseline regimen B/F/T  
Oral lead-in with CAB + RPV

No RAMs selected  
At T12 LAI CAB/RP discontinuation  
HIV RNA < 20 cp/ml with B/F/T

# COSA ABBIAMO IMPARATO DA LAI-ART?

Potenzialità  
della  
farmacocinetica

Miglioramento  
dei PROs

Impatto su  
stigma ed  
autostigma

Ruolo del team  
multidisciplinare

Importanza  
dell'integrazione  
nel percorso di  
cura



**GRAZIE!**