A patient reported outcome (PRO) is defined as any report of an outcome that comes directly from the patient without interpretation of the patient's response by a clinician or anyone else. In clinical trials, PRO instruments can be used to measure the effect of a medical intervention on one or more concepts such as symptoms, functioning, severity of disease, health status and quality of life (QoL). As HIV became a chronic condition, there is a strong case for evaluating the impact of antiretroviral therapies on broader aspects of patient's lives, including psychological health and emotional adjustment. This is particularly true in a cohort setting such as ICONA. Until recently, no measures of patient-reported outcomes had been included in ICONA. Baseline data from 135 participants were available. This included 122 men (mean age 42.97 [11.99]) and 13 women (mean age 47.46 [14.32]). A total of 107 patients were on CART (N=65; NNRTI: N=23; PI: N=15/18-regimen) and 28 patients were pre-treatment. CART status details are provided in Table 1, a, b, c.

### Results

#### Table 1a – Mode of treatment

<table>
<thead>
<tr>
<th>Mode of Treatment</th>
<th>All Participants</th>
<th>On-Treatment</th>
<th>Pre-Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIVDQoL</td>
<td>118</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIVDQoL</td>
<td>118</td>
<td></td>
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</tr>
<tr>
<td>HIVDQoL</td>
<td>118</td>
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<td></td>
</tr>
</tbody>
</table>

#### Table 1b – CD4+ cell count/mmC at baseline

<table>
<thead>
<tr>
<th>CD4 count</th>
<th>All Participants</th>
<th>On-Treatment</th>
<th>Pre-Treatment</th>
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</thead>
<tbody>
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<td>24</td>
<td>25</td>
</tr>
<tr>
<td>HIVDQoL</td>
<td>500-749</td>
<td>43</td>
<td>42</td>
</tr>
<tr>
<td>HIVDQoL</td>
<td>750-1000</td>
<td>40</td>
<td>42</td>
</tr>
</tbody>
</table>

#### Table 1c – HIV-RNA/µl at baseline

<table>
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<tr>
<th>HIV-RNA</th>
<th>All Participants</th>
<th>On-Treatment</th>
<th>Pre-Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIVDQoL</td>
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<td>39</td>
</tr>
<tr>
<td>HIVDQoL</td>
<td>&lt;200</td>
<td>89</td>
<td>89</td>
</tr>
</tbody>
</table>

#### Figure 2 – Health status (EQ-5D VAS)

As shown in Table 2 health status but not QoL was found to differ by mode of treatment.

#### Figure 3: Generic quality of life (HIVDQoL)

Although both generic QoL and health status were worse in older (vs younger) people living with HIV, the two outcomes showed different patterns in relation to clinical variables, with cART-treated patients reporting better QoL but no difference in perceived health compared with pretreatment patients. QoL, but not perceived health, was also better in patients with CD4 counts >200. Perceived health, but not QoL, differed with mode of HIV transmission. QoL is not a simple reflection of health status and it is important to measure both outcomes.

### Acknowledgments

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**Health status and Quality of life in people living with HIV (PLWH): results from the ICONA cohort.**

To determine the impact of HIV infection and its treatment on QoL and health status in HIV-infected patients enrolled in ICONA.

### AIMS

The ICONA foundation study cohort is an observational multicentric cohort of individuals infected with HIV. Patients enrolled in this analysis were, newly diagnosed, pre-treatment patients, and those with >6 months of CART.

### STUDY DESIGN AND METHODS

The ICONA foundation study cohort is an observational multicentric cohort of individuals infected with HIV. Patients enrolled in this analysis were, newly diagnosed, pre-treatment patients, and those with >6 months of CART.

### RESULTS

The following template of the ADOQoL for diabetes11,12 and the HIVDQoL questionnaire is a condition-specific, individualised, measured of the impact of HIV on individual's QoL.13 It includes two overview items plus 6 condition-specific domain items. The first overview item asks participants to rate their generic ‘present QoL’ using a 7-point Likert scale, ranging from 3 (excellent) to -3 (extremely bad). The present analysis uses data from the overview generic ‘present QoL’ item only [see Figure 1]. Quality of life is defined in the questionnaire’s instructions as ‘how good or bad you feel your life is to be’.

Analyses included non-parametric tests of difference and correlation analyses.

### Figure 1: HIVDQoL. Overview Item 1: Present Quality of life (scoring for demonstration purposes only)