Australian HIV Observational Database (AHOD) data request

Requester: Industry
Date: April 2009

Purpose:
The company is currently working on an expansion of the PBS listing for a specific antiretroviral. The results of the analysis will be used to help determine the treatment pathway of patients with HIV and the number of patients who will be eligible to receive the specific antiretroviral if PBS expansion occurs.

The following ad-hoc report is derived from the Australian HIV Observational Database (AHOD) up to 31st of March 2008. AHOD was established in 1999, and by the end of March 2008, 2667 patients had been enrolled from 27 sexual health clinics, specialist general practices or tertiary referral centres. As the majority of patients were enrolled by 2002, the cohort is currently very treatment experienced, and therefore the data need to be interpreted appropriately.

To produce the table below several assumptions were made; many are standard to all AHOD analyses.

These include:
Patients who commenced highly active antiretroviral treatment (HAART) prior to 1 January 1997 were excluded (as this relies heavily on retrospectively reported information).
Only combinations of greater than 14 day duration were counted
A regimen change was defined as having changed/dropped at least one ARV from the immediately preceding combination

These assumptions are specified throughout the document wherever relevant.

Any reporting of AHOD data need to appropriately acknowledge these assumptions.
All data below exclude patients who commenced HAART before 1 January 1997

Question 1

What proportion of the cohort is:

HAART treatment naive (defined as not yet received HAART treatment)
Treatment experienced but PI naive (defined as not having received a PI yet)
Early PI experienced (have received only one HAART regimen containing a PI)
Highly PI experienced (have received two or more regimens containing a PI)

<table>
<thead>
<tr>
<th></th>
<th>2001</th>
<th>%</th>
<th>2007</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>HAART treatment naive</td>
<td>231</td>
<td>19.9</td>
<td>146</td>
<td>14.1</td>
</tr>
<tr>
<td>Treatment experienced but PI naive</td>
<td>262</td>
<td>22.6</td>
<td>165</td>
<td>15.9</td>
</tr>
<tr>
<td>Early PI experienced</td>
<td>283</td>
<td>24.4</td>
<td>178</td>
<td>17.1</td>
</tr>
<tr>
<td>Highly PI experienced</td>
<td>385</td>
<td>33.2</td>
<td>549</td>
<td>52.9</td>
</tr>
</tbody>
</table>

Assumptions made to determine the naïve population are as follows:

HAART naïve patients are either those who: 1. never commenced ARV, and therefore to be included in the denominator for question 1 must have been enrolled in AHOD prior to 1 January 2002 (or 2008) and considered to be in active follow-up in 2001 or 2007 respectively (ie have their last visit date recorded after 1 January 2001 (or 2007)); and 2. HAART naïve patients who commenced HAART after 31 December 2001 (or 2007) had to have been enrolled into AHOD prior to 1 January 2002 (or 2008) and also considered in active follow-up in 2001 or 2007.
**Question 2**
What proportion (%) received a protease inhibitor in their first HAART regimen?
   a) In patients whose **1st HAART regimen** was started before 1 January 2006
   b) In patients whose **1st HAART regimen** was started after 1 January 2006

<table>
<thead>
<tr>
<th>Year</th>
<th>HAART (with PI)</th>
<th>Total HAART</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
</tr>
<tr>
<td>&lt;=2005</td>
<td>679</td>
<td>47.7</td>
</tr>
<tr>
<td>&gt;=2006</td>
<td>27</td>
<td>24.5</td>
</tr>
</tbody>
</table>

**Question 3**
What proportion (%) received a protease inhibitor in their second HAART regimen?
   a) In patients whose **2nd HAART regimen** was started before 1 January 2006
   b) In patients whose **2nd HAART regimen** was started after 1 January 2006

<table>
<thead>
<tr>
<th>Year</th>
<th>HAART (with PI)</th>
<th>Total HAART</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
</tr>
<tr>
<td>&lt;=2005</td>
<td>468</td>
<td>47.0</td>
</tr>
<tr>
<td>&gt;=2006</td>
<td>50</td>
<td>32.3</td>
</tr>
</tbody>
</table>

1. Second HAART regimen was defined as a new regimen where one or more of the ARVs differed to the regimen immediately prior (including dropping of an ARV).
Question 4
What protease inhibitor is most commonly used in patients who are previously PI naive (i.e. what is the protease inhibitor that patients use in their first PI-containing regimen)?

a) In patients whose 1st PI regimen was started before 1 January 2006, the protease inhibitor most commonly used in the 1st PI-containing regimen is:

<table>
<thead>
<tr>
<th>PI</th>
<th>&lt;=2005</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
</tr>
<tr>
<td>Indinavir</td>
<td>293</td>
</tr>
<tr>
<td>Nelfinavir</td>
<td>242</td>
</tr>
<tr>
<td>Total PI combinations</td>
<td>809</td>
</tr>
</tbody>
</table>

b) In patients whose 1st PI regimen was started after 1 January 2006, the protease inhibitor most commonly used in the 1st PI-containing regimen is:

<table>
<thead>
<tr>
<th>PI</th>
<th>&gt;=2006</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
</tr>
<tr>
<td>Atazanavir</td>
<td>24</td>
</tr>
<tr>
<td>Kaletra</td>
<td>16</td>
</tr>
<tr>
<td>Total PI combinations</td>
<td>45</td>
</tr>
</tbody>
</table>
**Question 5**
What protease inhibitor is most commonly used in patients who have failed one prior PI (i.e. what is the protease inhibitor that patients use in their second PI-containing regimen)?

a) In patients whose 2nd PI regimen\(^1\) was started before 1 January 2006, the protease inhibitor most commonly used in the 2nd PI-containing regimen is

<table>
<thead>
<tr>
<th>PI</th>
<th>&lt;=2005</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
</tr>
<tr>
<td>Indinavir</td>
<td>105</td>
</tr>
<tr>
<td>Nelfinavir</td>
<td>99</td>
</tr>
<tr>
<td><strong>Total PI combinations</strong></td>
<td><strong>536</strong></td>
</tr>
</tbody>
</table>

1. Second PI regimen is the regimen where a new PI was commenced (defined as a PI that was not used in the immediately preceding regimen)

b) In patients whose 2nd PI regimen was started after 1 January 2006, the protease inhibitor most commonly used in the 2nd PI-containing regimen is:

<table>
<thead>
<tr>
<th>PI</th>
<th>&gt;=2006</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
</tr>
<tr>
<td>Atazanavir</td>
<td>35</td>
</tr>
<tr>
<td>Kaletra</td>
<td>10</td>
</tr>
<tr>
<td><strong>Total PI combinations</strong></td>
<td><strong>74</strong></td>
</tr>
</tbody>
</table>

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17th May 2009
Note for the following questions
As the majority of patients in the AHOD are highly treatment experienced, data are provided overall (eg demographics of patients who are naive at any time point) and split by year (<=2005, and >=2006).

Second, the AHOD population from which the following tables are derived include only patients who **commenced** HAART at some time point after 1 January 1997

**Question 6**
Please provide the demographics of those patients in the cohort who are currently HAART treatment naive (i.e. not received HAART treatment yet)¹

<table>
<thead>
<tr>
<th>Parameter</th>
<th>N</th>
<th>Mean</th>
<th>STD</th>
<th>No. missing</th>
<th>Median</th>
<th>LQ</th>
<th>UQ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age by year cat</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;=2005</td>
<td>1422</td>
<td>40.1</td>
<td>9.9</td>
<td>0</td>
<td>38.7</td>
<td>32.5</td>
<td>46.4</td>
</tr>
<tr>
<td>&gt;=2006</td>
<td>110</td>
<td>43.9</td>
<td>10.2</td>
<td>0</td>
<td>43.5</td>
<td>36.2</td>
<td>48.9</td>
</tr>
<tr>
<td>Age overall</td>
<td>1532</td>
<td>40.3</td>
<td>10.0</td>
<td>0</td>
<td>39.0</td>
<td>32.8</td>
<td>46.6</td>
</tr>
<tr>
<td>Years since diagnosis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;=2005</td>
<td>1377</td>
<td>5.3</td>
<td>5.0</td>
<td>45</td>
<td>4.2</td>
<td>0.4</td>
<td>9.0</td>
</tr>
<tr>
<td>&gt;=2006</td>
<td>98</td>
<td>5.0</td>
<td>5.4</td>
<td>12</td>
<td>2.8</td>
<td>0.4</td>
<td>8.1</td>
</tr>
<tr>
<td>Years since diagnosis (overall)</td>
<td>1475</td>
<td>5.3</td>
<td>5.0</td>
<td>57</td>
<td>4.1</td>
<td>0.4</td>
<td>9.0</td>
</tr>
<tr>
<td>CD4 by year cat²</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;=2005</td>
<td>1104</td>
<td>350</td>
<td>246</td>
<td>0</td>
<td>318</td>
<td>178</td>
<td>470</td>
</tr>
<tr>
<td>&gt;=2006</td>
<td>92</td>
<td>322</td>
<td>219</td>
<td>0</td>
<td>272</td>
<td>181</td>
<td>395</td>
</tr>
<tr>
<td>CD4 overall</td>
<td>1196</td>
<td>348</td>
<td>244</td>
<td>0</td>
<td>310</td>
<td>180</td>
<td>461</td>
</tr>
<tr>
<td>Viral load by year cat²</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;=2005</td>
<td>1092</td>
<td>205730</td>
<td>449848</td>
<td>0</td>
<td>58150</td>
<td>10000</td>
<td>225000</td>
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<td>&gt;=2006</td>
<td>90</td>
<td>93080</td>
<td>210929</td>
<td>0</td>
<td>34250</td>
<td>2340</td>
<td>100000</td>
</tr>
<tr>
<td>Viral load overall</td>
<td>1182</td>
<td>197152</td>
<td>437250</td>
<td>0</td>
<td>55027</td>
<td>9200</td>
<td>201333</td>
</tr>
</tbody>
</table>

¹. Naive status is at the time just prior to commencing HAART.
². CD4 and viral load are within 1 year prior to commencing HAART (if more than one measure available, then the measure closest to commencing HAART was used
**Question 7**
Please provide the demographics of those patients in the cohort who are currently PI naive

<table>
<thead>
<tr>
<th>Parameter</th>
<th>N</th>
<th>Mean</th>
<th>STD</th>
<th>No. missing</th>
<th>Median</th>
<th>LQ</th>
<th>UQ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age by year cat</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;=2005</td>
<td>735</td>
<td>40.3</td>
<td>9.9</td>
<td>0</td>
<td>39.0</td>
<td>33.0</td>
<td>46.6</td>
</tr>
<tr>
<td>&gt;=2006</td>
<td>91</td>
<td>45.0</td>
<td>10.3</td>
<td>0</td>
<td>43.5</td>
<td>37.1</td>
<td>52.7</td>
</tr>
<tr>
<td>Age overall</td>
<td>826</td>
<td>40.8</td>
<td>10.0</td>
<td>0</td>
<td>39.3</td>
<td>33.6</td>
<td>47.1</td>
</tr>
<tr>
<td>Years since diagnosis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;=2005</td>
<td>711</td>
<td>5.8</td>
<td>5.1</td>
<td>24</td>
<td>4.7</td>
<td>1.0</td>
<td>9.7</td>
</tr>
<tr>
<td>&gt;=2006</td>
<td>79</td>
<td>4.8</td>
<td>4.8</td>
<td>12</td>
<td>3.3</td>
<td>0.4</td>
<td>7.8</td>
</tr>
<tr>
<td>Years since diagnosis (overall)</td>
<td>790</td>
<td>5.7</td>
<td>5.1</td>
<td>36</td>
<td>4.5</td>
<td>0.9</td>
<td>9.5</td>
</tr>
<tr>
<td>CD4 by year cat</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;=2005</td>
<td>659</td>
<td>542</td>
<td>321</td>
<td>0</td>
<td>493</td>
<td>316</td>
<td>705</td>
</tr>
<tr>
<td>&gt;=2006</td>
<td>79</td>
<td>420</td>
<td>201</td>
<td>0</td>
<td>360</td>
<td>280</td>
<td>550</td>
</tr>
<tr>
<td>CD4 overall</td>
<td>738</td>
<td>529</td>
<td>313</td>
<td>0</td>
<td>478</td>
<td>310</td>
<td>680</td>
</tr>
<tr>
<td>Viral load by year cat</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;=2005</td>
<td>657</td>
<td>21881</td>
<td>86586</td>
<td>0</td>
<td>399</td>
<td>50</td>
<td>1800</td>
</tr>
<tr>
<td>&gt;=2006</td>
<td>79</td>
<td>10630</td>
<td>27854</td>
<td>0</td>
<td>50</td>
<td>49</td>
<td>134</td>
</tr>
<tr>
<td>Viral load overall</td>
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<td>20673</td>
<td>82376</td>
<td>0</td>
<td>199.5</td>
<td>50</td>
<td>1487</td>
</tr>
</tbody>
</table>

1. PI naïve HAART status is defined at the time just prior to commencing a HAART regimen including a PI.
2. CD4 and viral load are within 1 year prior to commencing HAART with a PI (if more than one measure available, then the measure closest to commencing the HAART was used)
**Question 8**

Please provide the demographics of those patients who are currently early PI experienced (have received only one HAART regimen containing a PI)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>N</th>
<th>Mean</th>
<th>STD</th>
<th>No. missing</th>
<th>Median</th>
<th>LQ</th>
<th>UQ</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age by year cat</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;=2005</td>
<td>1113</td>
<td>41.1</td>
<td>10.1</td>
<td>0</td>
<td>39.7</td>
<td>33.5</td>
<td>47.4</td>
</tr>
<tr>
<td>&gt;=2006</td>
<td>139</td>
<td>44.4</td>
<td>9.8</td>
<td>0</td>
<td>43.6</td>
<td>37.2</td>
<td>50.3</td>
</tr>
<tr>
<td><strong>Age overall</strong></td>
<td>1252</td>
<td>41.5</td>
<td>10.1</td>
<td>0</td>
<td>40.2</td>
<td>34.0</td>
<td>47.6</td>
</tr>
<tr>
<td><strong>Years since diagnosis</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;=2005</td>
<td>1089</td>
<td>6.2</td>
<td>5.2</td>
<td>24</td>
<td>5.5</td>
<td>1.3</td>
<td>10.2</td>
</tr>
<tr>
<td>&gt;=2006</td>
<td>130</td>
<td>8.5</td>
<td>6.3</td>
<td>9</td>
<td>7.2</td>
<td>3.4</td>
<td>13.6</td>
</tr>
<tr>
<td><strong>Years since diagnosis</strong> (overall)</td>
<td>1219</td>
<td>6.4</td>
<td>5.4</td>
<td>33</td>
<td>5.6</td>
<td>1.4</td>
<td>10.4</td>
</tr>
<tr>
<td><strong>CD4 by year cat</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;=2005</td>
<td>971</td>
<td>542</td>
<td>311</td>
<td>0</td>
<td>500</td>
<td>310</td>
<td>735</td>
</tr>
<tr>
<td>&gt;=2006</td>
<td>128</td>
<td>589</td>
<td>285</td>
<td>0</td>
<td>540</td>
<td>395</td>
<td>718</td>
</tr>
<tr>
<td><strong>CD4 overall</strong></td>
<td>1099</td>
<td>547</td>
<td>308</td>
<td>0</td>
<td>505</td>
<td>321</td>
<td>735</td>
</tr>
<tr>
<td><strong>Viral load by year cat</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;=2005</td>
<td>954</td>
<td>16835</td>
<td>73666</td>
<td>0</td>
<td>398</td>
<td>50</td>
<td>1100</td>
</tr>
<tr>
<td>&gt;=2006</td>
<td>129</td>
<td>1418</td>
<td>9565</td>
<td>0</td>
<td>49</td>
<td>40</td>
<td>50</td>
</tr>
<tr>
<td><strong>Viral load overall</strong></td>
<td>1083</td>
<td>14998</td>
<td>69394</td>
<td>0</td>
<td>130</td>
<td>50</td>
<td>800</td>
</tr>
</tbody>
</table>

1. Only CD4 and viral load measures during the PI containing HAART are included (if more than one measure available, then the measure closest to the stop date of that regimen (or last follow-up visit) was used)
Question 9
Please provide the demographics of those patients who are highly PI experienced (have received two or more regimens containing a PI)

Two tables are provided, the first where two PIs have been used, and the second with 3 PIs

**Table 9a: Demographics when patients have received two PI containing regimens**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>N</th>
<th>Mean</th>
<th>STD</th>
<th>No. missing</th>
<th>Median</th>
<th>LQ</th>
<th>UQ</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age by year cat</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;2005</td>
<td>802</td>
<td>42.5</td>
<td>9.9</td>
<td>0</td>
<td>41.3</td>
<td>35.2</td>
<td>49.1</td>
</tr>
<tr>
<td>&gt;=2006</td>
<td>121</td>
<td>48.1</td>
<td>10.8</td>
<td>0</td>
<td>45.6</td>
<td>40.7</td>
<td>55.4</td>
</tr>
<tr>
<td><strong>Age overall</strong></td>
<td>923</td>
<td>43.3</td>
<td>10.2</td>
<td>0</td>
<td>41.8</td>
<td>35.9</td>
<td>50.0</td>
</tr>
<tr>
<td><strong>Years since diagnosis</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;2005</td>
<td>790</td>
<td>7.7</td>
<td>5.2</td>
<td>12</td>
<td>6.9</td>
<td>3.1</td>
<td>11.7</td>
</tr>
<tr>
<td>&gt;=2006</td>
<td>119</td>
<td>10.8</td>
<td>6.3</td>
<td>2</td>
<td>9.5</td>
<td>5.8</td>
<td>15.9</td>
</tr>
<tr>
<td><strong>Years since diagnosis (overall)</strong></td>
<td>909</td>
<td>8.1</td>
<td>5.5</td>
<td>14</td>
<td>7.3</td>
<td>3.5</td>
<td>12.1</td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>&lt;2005</td>
<td>704</td>
<td>539</td>
<td>330</td>
<td>0</td>
<td>490</td>
<td>297</td>
<td>720</td>
</tr>
<tr>
<td>&gt;=2006</td>
<td>109</td>
<td>583</td>
<td>329</td>
<td>0</td>
<td>510</td>
<td>380</td>
<td>730</td>
</tr>
<tr>
<td><strong>CD4 overall</strong></td>
<td>813</td>
<td>545</td>
<td>330</td>
<td>0</td>
<td>500</td>
<td>312</td>
<td>720</td>
</tr>
<tr>
<td><strong>Viral load by year cat</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;2005</td>
<td>700</td>
<td>17498</td>
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<td>0</td>
<td>87.5</td>
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<td>1050</td>
</tr>
<tr>
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<td>110</td>
<td>2781</td>
<td>19034</td>
<td>0</td>
<td>49</td>
<td>40</td>
<td>50</td>
</tr>
<tr>
<td><strong>Viral load overall</strong></td>
<td>810</td>
<td>15500</td>
<td>78999</td>
<td>0</td>
<td>50</td>
<td>49</td>
<td>550</td>
</tr>
</tbody>
</table>

1. Only CD4 and viral load measures during the PI containing HAART are included (if more than one measure available, then the measure closest to the stop date of that regimen (or last follow-up visit) was used)
### Table 9b: Demographics when patients have received at least 3 PI containing regimens

<table>
<thead>
<tr>
<th>Parameter</th>
<th>N</th>
<th>Mean</th>
<th>STD</th>
<th>No. missing</th>
<th>Median</th>
<th>LQ</th>
<th>UQ</th>
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<td>524</td>
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<td>10.4</td>
<td>0</td>
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<td>0</td>
<td>43.5</td>
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<td></td>
<td></td>
</tr>
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<td>8.9</td>
<td>5.2</td>
<td>4</td>
<td>8.5</td>
<td>6.6</td>
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<td>2</td>
<td>10.3</td>
<td>7.6</td>
<td>15.4</td>
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<tr>
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<td>9.4</td>
<td>5.3</td>
<td>6</td>
<td>9.0</td>
<td>5.1</td>
<td>13.6</td>
</tr>
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<td>306</td>
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<td>482</td>
<td>290</td>
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</tr>
<tr>
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<td>624</td>
<td>336</td>
<td>0</td>
<td>600</td>
<td>379</td>
<td>809</td>
</tr>
<tr>
<td><strong>CD4 overall</strong></td>
<td>573</td>
<td>541</td>
<td>314</td>
<td>0</td>
<td>500</td>
<td>310</td>
<td>730</td>
</tr>
<tr>
<td><strong>Viral load by year cat</strong></td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
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<td>49</td>
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<td>49</td>
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<td>65574</td>
<td>0</td>
<td>50</td>
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<td>400</td>
</tr>
</tbody>
</table>

1. Only CD4 and viral load measures during the PI containing HAART are included (if more than one measure available, then the measure closest to the stop date of that regimen (or last follow-up visit) was used)