Using V9 ODS LAYOUT to Simplify Generation of Individual Case Summaries
Ling Y. Chen, Rho, Inc., Newton, MA

ABSTRACT
Up until now, individual case summaries involve complicated data _null_ coding and are hard to program. This paper describes the new SAS® V9 feature ODS LAYOUT and its use in developing individual case summaries in a clinical trial setting. Some examples of the usage are shown and also some advantages and limitations are discussed. The codes included in this paper were tested using SAS V9.00 on the Windows XP operating system.

INTRODUCTION
Individual case summaries (ICS), also known as patient profiles, are sometimes presented when submitting clinical trial study reports to the FDA. They are data listings that capture a ‘snapshot’ of data for each study participant. They are usually one to a few pages long for each study participant. Each page of summary contains information for the same participant gathered from multiple data sets with varied data structures and sizes. For example, a participant’s gender, race, age, medical history, concomitant medications, and vital signs data may all be presented on a single page. Arranging each data section in a clear and logical manner while maximizing the amount of data that can be presented on a single page is the main task facing the programmer generating these summaries. In the past, programming for these summaries involved complicated data _null_ steps, which are hard to program and hard to modify. With the advent of the SAS V9 feature ODS LAYOUT, programming for these summaries has become a lot simpler.

ODS LAYOUT is experimental in both V9.0 and V9.1, but it already has some really nice features that we can use. Simply put, it allows you to put whatever you want (texts, graphs, tables, forms) wherever you want on a single page. You can also arrange them in whatever layout that fits your needs. How does it do it? It does so by dividing the page into several pre-defined regions and then specifying what goes into which region. There are two ways to define regions, one is called absolute and the other is called gridded. I will give examples of both below. ODS LAYOUT starts and ends with the following statements:

```
ods layout start;
  ... statements defining regions ...
ods layout end;
```

The statements that define regions and generate output go inside this set of statements.

EXAMPLE 1: ABSOLUTE LAYOUT

If I want to put the participant’s demographic information at the top left corner of the page and the height and weight information right beneath it, I use the following statements:

```
ods layout start;
  ods region x=0% y=5% width=30% height=45%;
  proc report data=DEMO headline headskip missing nowd spacing=2 split='|';
    where id='101';
    Column (GENDER BIRTHDT AGE RACE);
      define GENDER / display width=6 left flow 'Gender';
      define BIRTHDT / display width=9 left flow 'Date of Birth';
      define AGE / display width=3 left flow 'Age';
      define RACE / display width=18 left flow 'Race';
  run;
  ods region x=0 y=10% width=30% height=45%;
  proc report data=DEMO headline headskip missing nowd spacing=2 split='|';
    where id='101';
    Column (screen_height screen_weight rand_pop itt_pop);
      define screen_height / display width=6 left flow 'Height (Inches)';
      define screen_weight / display width=9 left flow 'Weight (Lbs)';
      define rand_pop / display width=10 left flow 'Randomized Population';
      define itt_pop / display width=10 left flow 'ITT Population';
  run;
ods layout end;
```
This is an example of using the absolute layout approach. Notice the two ODS REGION statements preceding the PROC REPORT codes. The purpose of those statements is to define regions on a page for the output to go in. The X= and Y= options specify where on the page the output should start printing. In the first ODS REGION statement above, X=0 and Y=5% options specify that the region should start at the leftmost position from the left side of the page and about 5% down from the top of the page. And in the second ODS REGION statement, the X=0 and Y=10% options specify that the region should start at the leftmost position from the left side of the page and about 10% down from the top of the page. The WIDTH= option specifies how wide the region should be, and likewise, the HEIGHT= option specifies how tall the region should be. The demographic information defined in the first PROC REPORT section will print in the region specified in the first ODS REGION statement and the height and weight information specified in the second PROC REPORT section will print in the region specified in the second ODS REGION statement.

Next, I want to add inclusion criteria, exclusion criteria, and vital signs data for this participant on the same page. I can use the same ODS REGION statements to define more regions on the page and follow those statements with PROC REPORT codes to print data in the pre-defined sections. For output and a complete program, please see the attached codes and pdf document at the end of this paper.

EXAMPLE 2: GRIDDED LAYOUT

Now I will use the gridded layout approach to put adverse events data and ECG results for a study participant on the same page.

```cerpt
ods layout start columns=2;
ods region;
proc report data=AEANLY headline headskip missing nowd spacing=1 split='|';
where id='101';
Column (AENUM AETEXT SYSTEMORGANCLASSNAME PREFERREDNAME STARTDT ENDDT ONGOING SERIOUS THERAPY SEVERE RELAT);
   define AENUM / display width=7 left flow 'Adverse Event Number';
   define AETEXT / display width=11 left flow 'Adverse Event Text';
   define STARTDT / display width=9 left flow 'Start Date';
   define ENDDT / display width=9 left flow 'End Date';
   define ONGOING / display width=7 left flow 'Ongoing';
   define PREFERREDNAME / display width=12 left flow 'Preferred Name';
   define SYSTEMORGANCLASSNAME / display width=12 left flow 'System Organ Class Name';
   define SERIOUS / display width=7 left flow 'Serious';
   define THERAPY / display width=10 left flow 'Drug Therapy Required';
   define SEVERE / display width=8 left flow 'Severity';
   define RELAT / display width=12 left flow 'Relationship to Study Drug';
run;
ods region;
proc report data=ECG headline headskip missing nowd spacing=1 split='|';
where id='101';
Column (PHASE ASMTDT ASMTTM RESULTS);
   define PHASE / order order=data width=12 left flow 'Study Visit';
   define ASMTDT / display width=9 left flow 'Date';
   define ASMTTM / display width=5 left flow 'Time';
   define RESULTS / display width=14 left flow 'ECG Results';
format results Secgnorm. phase Sphase. asmtdt datefmt. asmttm timefmt.;
run;
ods layout end;
```

The output of the above example can be found at the end of this paper under ‘Example 2’. What’s different here is that instead of specifying exactly where each region starts and how much space it occupies, it uses the COLUMNS=2 option to split the page into two regions. The output from the first PROC REPORT will be placed in the first half of the page while the output from the second PROC REPORT will be placed in the second half.
ADVANTAGES AND LIMITATIONS
There are advantages and limitations to both the absolute approach and the gridded approach to using ODS LAYOUT. In the absolute case, the user determines exactly what goes where and how much space each section of the report occupies. It is a lot more flexible compared to the gridded approach where regions are defined in a much coarser way. However, once you defined a region, your output is limited to the use of that region only, meaning that if your output is bigger than the region allows, only the output that can fit into that region is actually printed. So you need to be extra careful when assigning output to defined regions. For example, my vital signs data in Example 1 is split into 2 regions, one for visits 2 to 4 and the other for visits 5 to 7 because the space left on that page is not large enough for all the vital signs data to be printed into one region. The gridded approach handles this situation by ‘spilling’ the information out, therefore, you won’t need to worry about data not printing because of space issues. In Example 2, the AE data is wider than the defined space would allow, and therefore, some variables are ‘wrapped’ within the same region. However, as aforementioned, the gridded layout approach does not define regions as accurately as the absolute layout approach does.

CONCLUSION
The newly developed SAS Version 9 feature ODS LAYOUT is a really nice way for producing complicated reports, such as the individual case summaries for clinical trials report submission. It is still experimental in Version 9 and 9.1 so don’t throw away your data _null_ codes just yet. But it is promising enough to simplify coding for individual case summaries, which are cumbersome to do right now, that it is worth exploring.

REFERENCES

SAS is a registered trademark of the SAS Institute Inc. in the USA and other countries.

CONTACT INFORMATION
Your comments and questions are valued and encouraged. Please contact the author at:
Ling Yun Chen
Rho, Inc.
199 Wells Ave, Suite 302
Newton, MA 02459
617-965-8000 x26
Fax: 617-965-8014
lchen@rhoworld.com
EXAMPLE1.SAS

title1 "EXAMPLE 1: ABSOLUTE LAYOUT";
title3 "Site: 01, ID:101, Initials: HBS, Treatment: Placebo";

libname Template "c:\chen\template";
ods path (prepend) Template.Styles(read);

options orientation=landscape;
ods pdf file="c:\chen\pdf1.pdf" style=styles.table2 startpage=no;

ods layout start;

ods region x=0 y=5% width=30% height=10%;
proc report data=DEMO headline headskip missing nowd spacing=2 split='|';
    where id='101';
    Column (GENDER BIRTHDT rhoage RACE);
    define GENDER / display width=6 left flow 'Gender';
    define BIRTHDT / display width=9 left flow 'Date of Birth';
    define rhoage / display width=3 left flow 'Age';
    define RACE / display width=18 left flow 'Race';
    format race $race. gender $sex.;
run;

ods region x=0 y=10% width=30% height=20%;
proc report data=DEMO headline headskip missing nowd spacing=2 split='|';
    where id='101';
    Column (screen_height screen_weight rand_pop itt_pop);
    define screen_height / display width=6 left flow 'Height|Inches';
    define screen_weight / display width=9 left flow 'Weight|Lbs';
    define rand_pop / display width=10 left flow 'Screening|Population';
    define itt_pop / display width=10 left flow 'ITT|Population';
run;

ods region x=35% y=5% width=64% height=45%;
proc report data=INCL headline headskip missing nowd spacing=1 split='|';
    where id='101';
    Column (INCL1 INCL2 INCL3 INCL4 INCL5 INCL6 INCL7 INCL8 INCL9 CONSENT CSENTDT);
    define CONSENT / display width=8 left flow 'Consent|Form|Signed';
    define CSENTDT / display width=9 left flow 'Date|Consent|Signed';
    define INCL1 / display width=3 left flow 'Inclusion|Criterion|1';
    define INCL2 / display width=3 left flow 'Inclusion|Criterion|2';
    define INCL3 / display width=3 left flow 'Inclusion|Criterion|3';
    define INCL4 / display width=3 left flow 'Inclusion|Criterion|4';
    define INCL5 / display width=3 left flow 'Inclusion|Criterion|5';
    define INCL6 / display width=3 left flow 'Inclusion|Criterion|6';
    define INCL7 / display width=3 left flow 'Inclusion|Criterion|7';
    define INCL8 / display width=3 left flow 'Inclusion|Criterion|8';
    define INCL9 / display width=3 left flow 'Inclusion|Criterion|9';
run;

ods region x=0% y=25% width=100% height=45%;
proc report data=EXCL headline headskip missing nowd spacing=2 split='|';
    where id='101';
    Column ( EXCL1 EXCL2 EXCL3 EXCL4 EXCL5 EXCL6 EXCL7 EXCL8 EXCL9 EXCL10 EXCL11 EXCL12 EXCL13 EXCL14 EXCL15 EXCL16 EXCL17 EXCL18 EXCL19);
    define EXCL1 / display width=3 left flow 'Exclusion|Criterion|1';
    define EXCL2 / display width=3 left flow 'Exclusion|Criterion|2';
    define EXCL3 / display width=3 left flow 'Exclusion|Criterion|3';
    define EXCL4 / display width=3 left flow 'Exclusion|Criterion|4';
    define EXCL5 / display width=3 left flow 'Exclusion|Criterion|5';
run;
define EXCL6 / display width=3 left flow 'Exclusion Criterion 6';
define EXCL7 / display width=3 left flow 'Exclusion Criterion 7';
define EXCL8 / display width=3 left flow 'Exclusion Criterion 8';
define EXCL9 / display width=3 left flow 'Exclusion Criterion 9';
define EXCL10 / display width=3 left flow 'Exclusion Criterion 10';
define EXCL11 / display width=3 left flow 'Exclusion Criterion 11';
define EXCL12 / display width=3 left flow 'Exclusion Criterion 12';
define EXCL13 / display width=3 left flow 'Exclusion Criterion 13';
define EXCL14 / display width=3 left flow 'Exclusion Criterion 14';
define EXCL15 / display width=3 left flow 'Exclusion Criterion 15';
define EXCL16 / display width=3 left flow 'Exclusion Criterion 16';
define EXCL17 / display width=3 left flow 'Exclusion Criterion 17';
define EXCL18 / display width=3 left flow 'Exclusion Criterion 18';
define EXCL19 / display width=3 left flow 'Exclusion Criterion 19';
run;

ods region x=0% y=45% width=50% height=45%;
proc report data=SVTL headline headskip missing nowd spacing=2 split='|';
  where id='101' and phase<='4000';
  Column (PHASE TARGET ACTLTM BPSYS BPDIA HR RESP TEMP);
  define PHASE / order order=internal width=9 left flow 'Study Visit';
  define TARGET / display width=10 left flow 'Target Time';
  define ACTLTM / display width=8 left flow 'Actual Time';
  define HR / display width=8 left flow 'Heart Rate (bpm)';
  define RESP / display width=8 left flow 'Respiration (rpm)';
  define BPSYS / display width=8 left flow 'Systolic BP (mmHg)';
  define BPDIA / display width=9 left flow 'Diastolic BP (mmHg)';
  define TEMP / display width=8 left flow 'Temperature (F)';
  format bpsys bpdia hr resp temp nummiss. actltm timefmt.
    phase $phase. target $timept.;
  break after phase/skip;
run;

ods region x=51% y=45% width=50% height=45%;
options missing='';
proc report data=SVTL headline headskip missing nowd spacing=2 split='|';
  where id='101' and phase='4000';
  Column (PHASE TARGET ACTLTM BPSYS BPDIA HR RESP TEMP);
  define PHASE / order order=internal width=9 left flow 'Study Visit';
  define TARGET / display width=10 left flow 'Target Time';
  define ACTLTM / display width=8 left flow 'Actual Time';
  *define ACTLHR / display width=2 left flow 'Actual Time, Hour';
  *define ACTLMI / display width=2 left flow 'Actual Time, Minute';
  define HR / display width=8 left flow 'Heart Rate (bpm)';
  define RESP / display width=8 left flow 'Respiration (rpm)';
  define BPSYS / display width=8 left flow 'Systolic BP (mmHg)';
  define BPDIA / display width=9 left flow 'Diastolic BP (mmHg)';
  define TEMP / display width=8 left flow 'Temperature (F)';
  format bpsys bpdia hr resp temp nummiss. actltm timefmt.
    phase $phase. target $timept.;
  break after phase/skip;
run;

ods layout end;
ods pdf close;
title1 "EXAMPLE 2: GRIDDED LAYOUT";
title3 "Site: 01, ID:101, Initials: HBS, Treatment: Placebo";

libname Template "c:\chen\template";
ods path (prepend) Template.Styles(read);

options orientation=landscape;
ods pdf file="c:\chen\pdf2.pdf" style=styles.table2 startpage=no;

ods layout start COLUMNS=2;
ods region;

proc report data=AEANLY headline headskip missing nowd spacing=1 split='|';
   where id='101';
   Column (AENUM AETEXT SYSTEMORGANCLASSNAME PREFERREDNAME STARTDT ENDDT ONGOING SERIOUS THERAPY SEVERE RELAT);
   define AENUM / display width=7 left flow 'Adverse|Event|Number';
   define AETEXT / display width=11 left flow 'Adverse Event Text';
   define STARTDT / display width=9 left flow 'Start Date';
   define ENDDT / display width=9 left flow 'End Date';
   define ONGOING / display width=7 left flow 'Ongoing';
   define PREFERREDNAME / display width=12 left flow 'Preferred Name';
   define SYSTEMORGANCLASSNAME / display width=12 left flow 'System Organ Class Name';
   define SERIOUS / display width=7 left flow 'Serious';
   define THERAPY / display width=10 left flow 'Drug|Therapy|Required';
   define SEVERE / display width=8 left flow 'Severity';
   define RELAT / display width=12 left flow 'Relationship to Study Drug';
run;
ods region;

proc report data=ECG headline headskip missing nowd spacing=1 split='|';
   where id='101';
   Column (PHASE ASMTDT ASMTTM RESULTS);
   define PHASE / order order=data width=12 left flow 'Study Visit';
   define ASMTDT / display width=9 left flow 'Date';
   define ASMTTM / display width=5 left flow 'Time';
   define RESULTS / display width=14 left flow 'ECG Results';
   format results $ecgnorm. phase $phase. asmtdt datefmt. asmttm timefmt.;
run;

ods layout end;
ods pdf close;
**EXAMPLE 1: ABSOLUTE LAYOUT**

Site: 01, ID:101, Initials: HBS, Treatment: Placebo

<table>
<thead>
<tr>
<th>Gender</th>
<th>Date of Birth</th>
<th>Age</th>
<th>Race</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>20JUN1938</td>
<td>65</td>
<td>Caucasian</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Height (Inches)</th>
<th>Weight (Lbs)</th>
<th>Randomized Population</th>
<th>ITT Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>59</td>
<td>178</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exclusion Criterion</th>
<th>Exclusion Criterion</th>
<th>Exclusion Criterion</th>
<th>Exclusion Criterion</th>
<th>Exclusion Criterion</th>
<th>Exclusion Criterion</th>
<th>Exclusion Criterion</th>
<th>Exclusion Criterion</th>
<th>Exclusion Criterion</th>
<th>Exclusion Criterion</th>
<th>Exclusion Criterion</th>
<th>Exclusion Criterion</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
<td>7</td>
<td>8</td>
<td>9</td>
<td>10</td>
<td>11</td>
<td>12</td>
</tr>
<tr>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study Visit</th>
<th>Target Time</th>
<th>Actual Time</th>
<th>Systolic BP (mmHg)</th>
<th>Diastolic BP (mmHg)</th>
<th>Heart Rate (bpm)</th>
<th>Respiration (rpm)</th>
<th>Temperature (F)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- 0.5</td>
<td>9:20</td>
<td>118</td>
<td>70</td>
<td>68</td>
<td>16</td>
<td>97</td>
</tr>
<tr>
<td></td>
<td>+ 0.5</td>
<td>10:45</td>
<td>116</td>
<td>75</td>
<td>62</td>
<td>15</td>
<td>97</td>
</tr>
<tr>
<td></td>
<td>1 HOUR</td>
<td>11:15</td>
<td>118</td>
<td>77</td>
<td>60</td>
<td>14</td>
<td>96.9</td>
</tr>
<tr>
<td></td>
<td>1.5 HOURS</td>
<td>11:45</td>
<td>120</td>
<td>78</td>
<td>Not Done</td>
<td>Not Done</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2 HOURS</td>
<td>12:15</td>
<td>116</td>
<td>74</td>
<td>62</td>
<td>14</td>
<td>97.2</td>
</tr>
<tr>
<td></td>
<td>3 HOURS</td>
<td>13:15</td>
<td>114</td>
<td>74</td>
<td>62</td>
<td>14</td>
<td>98.1</td>
</tr>
<tr>
<td></td>
<td>4 HOURS</td>
<td>14:15</td>
<td>118</td>
<td>74</td>
<td>60</td>
<td>16</td>
<td>97.2</td>
</tr>
<tr>
<td>Visit 3</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- 0.5</td>
<td>11:45</td>
<td>118</td>
<td>71</td>
<td>66</td>
<td>17</td>
<td>97.5</td>
</tr>
<tr>
<td></td>
<td>+ 0.5</td>
<td>12:20</td>
<td>118</td>
<td>73</td>
<td>62</td>
<td>Not Done</td>
<td>97.6</td>
</tr>
<tr>
<td></td>
<td>1 HOUR</td>
<td>12:50</td>
<td>116</td>
<td>74</td>
<td>64</td>
<td>16</td>
<td>97.6</td>
</tr>
<tr>
<td></td>
<td>1.5 HOURS</td>
<td>13:20</td>
<td>118</td>
<td>75</td>
<td>66</td>
<td>Not Done</td>
<td>Not Done</td>
</tr>
<tr>
<td></td>
<td>2 HOURS</td>
<td>13:50</td>
<td>118</td>
<td>72</td>
<td>66</td>
<td>17</td>
<td>98.7</td>
</tr>
<tr>
<td></td>
<td>3 HOURS</td>
<td>14:50</td>
<td>114</td>
<td>70</td>
<td>64</td>
<td>16</td>
<td>98.2</td>
</tr>
<tr>
<td></td>
<td>4 HOURS</td>
<td>15:50</td>
<td>118</td>
<td>70</td>
<td>64</td>
<td>18</td>
<td>97.9</td>
</tr>
<tr>
<td>Visit 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- 0.5</td>
<td>9:05</td>
<td>116</td>
<td>72</td>
<td>60</td>
<td>15</td>
<td>97.6</td>
</tr>
<tr>
<td></td>
<td>+ 0.5</td>
<td>10:05</td>
<td>132</td>
<td>75</td>
<td>64</td>
<td>16</td>
<td>Not Done</td>
</tr>
<tr>
<td></td>
<td>1 HOUR</td>
<td>10:35</td>
<td>156</td>
<td>86</td>
<td>64</td>
<td>15</td>
<td>96.2</td>
</tr>
<tr>
<td></td>
<td>1.5 HOURS</td>
<td>11:05</td>
<td>148</td>
<td>84</td>
<td>58</td>
<td>Not Done</td>
<td>Not Done</td>
</tr>
<tr>
<td></td>
<td>2 HOURS</td>
<td>11:35</td>
<td>140</td>
<td>82</td>
<td>62</td>
<td>16</td>
<td>97.2</td>
</tr>
<tr>
<td></td>
<td>3 HOURS</td>
<td>12:35</td>
<td>122</td>
<td>74</td>
<td>62</td>
<td>16</td>
<td>96.7</td>
</tr>
<tr>
<td></td>
<td>4 HOURS</td>
<td>13:35</td>
<td>130</td>
<td>72</td>
<td>60</td>
<td>16</td>
<td>97.1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study Visit</th>
<th>Target Time</th>
<th>Actual Time</th>
<th>Systolic BP (mmHg)</th>
<th>Diastolic BP (mmHg)</th>
<th>Heart Rate (bpm)</th>
<th>Respiration (rpm)</th>
<th>Temperature (F)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit 5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- 0.5</td>
<td>9:14</td>
<td>115</td>
<td>77</td>
<td>61</td>
<td>17</td>
<td>96.9</td>
</tr>
<tr>
<td></td>
<td>+ 0.5</td>
<td>10:00</td>
<td>130</td>
<td>80</td>
<td>65</td>
<td>17</td>
<td>97.3</td>
</tr>
<tr>
<td></td>
<td>1 HOUR</td>
<td>10:30</td>
<td>128</td>
<td>72</td>
<td>64</td>
<td>16</td>
<td>97</td>
</tr>
<tr>
<td></td>
<td>1.5 HOURS</td>
<td>11:00</td>
<td>140</td>
<td>72</td>
<td>Not Done</td>
<td>Not Done</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2 HOURS</td>
<td>11:30</td>
<td>130</td>
<td>74</td>
<td>68</td>
<td>17</td>
<td>97</td>
</tr>
<tr>
<td></td>
<td>3 HOURS</td>
<td>12:30</td>
<td>124</td>
<td>70</td>
<td>64</td>
<td>16</td>
<td>97.6</td>
</tr>
<tr>
<td></td>
<td>4 HOURS</td>
<td>13:30</td>
<td>120</td>
<td>70</td>
<td>70</td>
<td>16</td>
<td>97.6</td>
</tr>
<tr>
<td>Visit 6</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- 0.5</td>
<td>9:11</td>
<td>129</td>
<td>82</td>
<td>62</td>
<td>17</td>
<td>97.3</td>
</tr>
<tr>
<td></td>
<td>+ 0.5</td>
<td>10:03</td>
<td>130</td>
<td>84</td>
<td>60</td>
<td>16</td>
<td>Not Done</td>
</tr>
<tr>
<td></td>
<td>1 HOUR</td>
<td>10:31</td>
<td>130</td>
<td>80</td>
<td>66</td>
<td>16</td>
<td>97.5</td>
</tr>
<tr>
<td></td>
<td>1.5 HOURS</td>
<td>11:00</td>
<td>132</td>
<td>78</td>
<td>68</td>
<td>Not Done</td>
<td>Not Done</td>
</tr>
<tr>
<td></td>
<td>2 HOURS</td>
<td>11:32</td>
<td>124</td>
<td>82</td>
<td>64</td>
<td>16</td>
<td>97.1</td>
</tr>
<tr>
<td></td>
<td>3 HOURS</td>
<td>12:27</td>
<td>130</td>
<td>80</td>
<td>68</td>
<td>16</td>
<td>96.5</td>
</tr>
<tr>
<td></td>
<td>4 HOURS</td>
<td>13:32</td>
<td>124</td>
<td>70</td>
<td>66</td>
<td>16</td>
<td>97</td>
</tr>
<tr>
<td>Visit 7</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- 0.5</td>
<td>8:55</td>
<td>139</td>
<td>78</td>
<td>68</td>
<td>17</td>
<td>97.3</td>
</tr>
<tr>
<td></td>
<td>+ 0.5</td>
<td>9:55</td>
<td>137</td>
<td>78</td>
<td>66</td>
<td>Not Done</td>
<td>Not Done</td>
</tr>
<tr>
<td></td>
<td>1 HOUR</td>
<td>10:25</td>
<td>130</td>
<td>74</td>
<td>70</td>
<td>16</td>
<td>97.6</td>
</tr>
<tr>
<td></td>
<td>1.5 HOURS</td>
<td>10:55</td>
<td>120</td>
<td>82</td>
<td>64</td>
<td>Not Done</td>
<td>Not Done</td>
</tr>
<tr>
<td></td>
<td>2 HOURS</td>
<td>11:25</td>
<td>110</td>
<td>70</td>
<td>76</td>
<td>16</td>
<td>97.7</td>
</tr>
<tr>
<td></td>
<td>3 HOURS</td>
<td>12:25</td>
<td>122</td>
<td>80</td>
<td>68</td>
<td>16</td>
<td>96.6</td>
</tr>
<tr>
<td></td>
<td>4 HOURS</td>
<td>13:20</td>
<td>118</td>
<td>70</td>
<td>70</td>
<td>17</td>
<td>98.3</td>
</tr>
</tbody>
</table>
### Example 2: Gridded Layout

**Site:** 01, **ID:** 101, **Initials:** HBS, **Treatment:** Placebo

<table>
<thead>
<tr>
<th>Adverse Event Number</th>
<th>Adverse Event Text</th>
<th>System Organ Class Name</th>
<th>Preferred Name</th>
<th>Start Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>INSOMNIA</td>
<td>Nervous system disorders</td>
<td>Insomnia</td>
<td>20FEB2003</td>
</tr>
<tr>
<td>2</td>
<td>ANXIETY</td>
<td>Psychiatric disorders</td>
<td>Anxiety</td>
<td>20FEB2003</td>
</tr>
<tr>
<td>3</td>
<td>BLEEDING GUMS</td>
<td>Gastrointestinal disorders</td>
<td>Gingival bleeding</td>
<td>22FEB2003</td>
</tr>
<tr>
<td>4</td>
<td>DIARRHEA</td>
<td>Gastrointestinal disorders</td>
<td>Diarrhoea NOS</td>
<td>22FEB2003</td>
</tr>
<tr>
<td>5</td>
<td>COLD SWEATS</td>
<td>Skin and subcutaneous tissue disorders</td>
<td>Cold sweat</td>
<td>22FEB2003</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study Visit</th>
<th>Date</th>
<th>Time</th>
<th>ECG Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening</td>
<td></td>
<td></td>
<td>Normal</td>
</tr>
<tr>
<td>Visit 2</td>
<td>8:15</td>
<td>Abnormal (NCS)</td>
<td></td>
</tr>
<tr>
<td>Visit 3</td>
<td>13:25</td>
<td>Abnormal (NCS)</td>
<td></td>
</tr>
<tr>
<td>Visit 4</td>
<td>16:00</td>
<td>Abnormal (NCS)</td>
<td></td>
</tr>
<tr>
<td>Visit 5</td>
<td>9:10</td>
<td>Abnormal (NCS)</td>
<td></td>
</tr>
<tr>
<td>Visit 6</td>
<td>8:20</td>
<td>Abnormal (NCS)</td>
<td></td>
</tr>
<tr>
<td>Visit 7</td>
<td>13:30</td>
<td>Normal</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>End Date</th>
<th>Ongoing</th>
<th>Serious</th>
<th>Drug Therapy Required</th>
<th>Severity</th>
<th>Relationship to Study Drug</th>
</tr>
</thead>
<tbody>
<tr>
<td>27FEB2003</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Mild</td>
<td>Not Related</td>
</tr>
<tr>
<td>27FEB2003</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Mild</td>
<td>Not Related</td>
</tr>
<tr>
<td>22FEB2003</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Mild</td>
<td>Not Related</td>
</tr>
<tr>
<td>26FEB2003</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Mild</td>
<td>Not Related</td>
</tr>
<tr>
<td>26FEB2003</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Mild</td>
<td>Not Related</td>
</tr>
</tbody>
</table>