
Visit Maps

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Objectives

Provide a General Solution For:

- **Patient Visit Scheduling**
- **Detecting, Flagging and Tracking**
 - Overdue Visits
 - Missing CRF pages from completed visits
- **Study Monitoring Reports**
 - patient summary reports
 - center summary reports

Configuration Files

- **Visit Map**
 - lists visits, scheduling, overdue allowance, required CRF plates.
- **Conditional Plate Map**
 - lists CRF plates that are required at specified visits if a specified condition is met.
- **Conditional Termination Map**
 - lists conditions which indicate termination of patient follow-up, for a cycle, or the entire study.

Key Concepts

- **Visit / Sequence Numbers**
 - numeric identifier for each visit
- **Visit Types**
 - define behavior (e.g. baseline, follow-up, termination)
- **Visit Dates**
 - data fields that hold the date each visit occurred
- **Visit Cycles**
 - allows clustering of visits that are scheduled together relative to a common baseline

Visit / Sequence Numbers

- **Field 6**
3rd bar code or first data field on every CRF page
- **Numeric**
bar code: 0-511, or data field 0-65535
- **Unique**
different visits must have different visit numbers
each visit must have a unique descriptive label
each visit number is associated with a unique VisitDate
- **Sequential by VisitDate**
e.g. 0=baseline, 1,2,3=scheduled, 4=termination
or 5 10,20,30 40

Visit Dates

- **VisitDate style - Visit Dates**
 - for scheduling
 - for termination
 - unique for each visit number
- **SimpleDate style - All Other Dates**
 - patient medical history
 - study dates unrelated to visit scheduling
 - dates of unscheduled assessments

Visit Types

- X - screening
- P - pre-baseline
- B - baseline
- S - scheduled follow-up
- T - termination visit defined at a specific time
- W - termination visit defined within a time window
- 0 - optional assessment
- E - early termination
- A - abort all further follow-up
- R - required on termination
- r - required on arrival of the next visit
- F - final follow-up used if final cycle has a single visit

Defining a Visit

- Number - 0~65535
- Type - screening, baseline, etc.
- Label - for overdue visits on QC reports
- Due Day - days since baseline
- Overdue Allowance - days past due day
- VisitDate - which field on which plate
- Required Plates
- Optional Plates
- Missed Visit Notification Plate

3 Simple Examples

Single Visit: e.g. surveys

1 X screening

Two Visits: baseline + one follow-up

1 B baseline

2 T termination

Baseline + follow-up visits

0 B baseline

1 S 1 month follow-up

3 S 3 month follow-up

6 S 6 month follow-up

12 T 12 month termination

Extra / Optional Visits

How should interim visits be included in the visit map?

Solution #1

0 B baseline

10 S follow-up 1

20 S follow-up 2

30 S follow-up 3

40 T termination

code interim visits in
between scheduled
visit numbers

Solution #2

0 B baseline

1 S follow-up 1

2 S follow-up 2

3 S follow-up 3

4 T termination

101 O interim visit 1

102 O interim visit 2

code interim visits after
the termination visit

If interim visits have a VisitDate you must use Solution #1

Screening & Pre-Baseline Visits

- **Screening Visits (X)**
 - multiple screening visits are allowed
 - all must occur before the 1st visit of the 1st cycle
 - do not trigger visit scheduling or overdue visits
- **Pre-Baseline Visits (P)**
 - multiple pre-baseline visits are allowed
 - may appear in one or more cycles
 - must occur before the baseline visit in each cycle
 - trigger visit scheduling and overdue visits

Screening & Pre-Baseline Visits

Example

```

1  X  screening
2  P  placebo run-in visit #1
3  P  placebo run-in visit #2
4  B  baseline
5  S  1 month follow-up
6  S  3 month follow-up
7  S  6 month follow-up
8  T  12 month termination

```

- Patients who fail screening never go past visit 1
- The arrival of any post-screening visit triggers visit scheduling and testing for overdue visits.

Dose Titration Visits - version 1

Dose titration may require 1-3 visits.
Baseline occurs when some criterion is met.

Multiple Baseline Visits

0 X screening
1 P start of treatment
2 B dose titration visit 1
3 B dose titration visit 2
4 B dose titration visit 3
...

The 1st baseline is required, all others are optional.
Each patient's baseline = last type B visit received.

Dose Titration Visits - version 2

Dose titration requires exactly 1-3 visits.
Baseline occurs on the 3rd titration visit.

Multiple Pre-Baseline Visits

0 X screening
1 P start of treatment
2 P dose titration visit 1
3 P dose titration visit 2
4 B dose titration visit 3
...

All pre-baseline visits are required.

Baseline visit, used for follow-up scheduling,
occurs at visit 4 for all patients.

Type R and r Required Visits

- Type r
 - required upon arrival of the next scheduled visit.
- Type R
 - required upon termination of the cycle in which it is defined.
 - if it has a due date which precedes the termination date.

Type R and r Required Visits

Example

```
1 X screening
2 P placebo run-in visit
3 B baseline
4 r lab test results
5 S 1 month follow-up
6 S 3 month follow-up
7 S 6 month follow-up
8 T 12 month termination
9 R patient diary
#due day = 30, i.e. required provided the patient
#does not terminate within the 1st 30 days.
```

Unscheduled Reports

- Adverse events, hospitalizations, etc.
- Reported only if they occur.
- Visit type O (optional).
- Need a sequence number (in place of a visit number).
- Sequence numbers > termination visit.
- Page map entry for QC reports.
- Must not use the VisitDate style.

Outcome Event Reports

ACE STROKE REPORT FORM

DataFax #007	Pltets D15	Stroke Report #	<input type="text"/>
Patient No. <input type="text"/>	Patient Initials <input type="text"/>	Onset Date	<input type="text"/>
	<small>F M L</small>	<small>month day year</small>	

- Sequence Numbering:
 - e.g. Set format = 3nn, range 301~399
- Page identifier for QC reports:
 - “Stroke Report 01”
 - page map = Stroke Report %{S.2}

Outcome Event Reports

0 B baseline
1 S 1 month follow-up
3 S 3 month follow-up
...
60 T final 5 year follow-up
301 O stroke report #1
302 O stroke report #2
401 O MI report #1
402 O MI report #2

Terminating Patient Follow-up

- Arrival of a Termination Visit
 - types: T, E, A, W, F
- Arrival of a Termination Form
 - Setup Tool: Plate-Edit dialog
 - set “Plate signals early termination”
- Arrival of a Termination Value
 - defined in the conditional termination map

Termination Visits

- Normal Termination (T)
 - last scheduled visit in a cycle
 - defined as occurring a fixed number of days since baseline
- Termination Window (W)
 - last visit occurs in a defined time window
- Early Termination (E)
 - terminates the cycle in which it is defined
- Abort Visit (A)
 - terminates all patient follow-up for all cycles
- Final Visit (F)
 - final scheduled visit following multiple cycles

Normal & Early Termination

Example

```
1 X screening
2 P placebo run-in visit #1
3 P placebo run-in visit #2
4 B baseline
5 S 1 month follow-up
6 S 3 month follow-up
7 S 6 month follow-up
8 T 12 month termination
91 E run-in failure report
92 E lost to follow-up report
93 A death report
```

Termination in a Multi-cycle Visit Map

```

  1  C  Treatment Cycle #1
 10  B  cycle 1 baseline
 11  S  cycle 1 - 1 month follow-up
 13  S  cycle 1 - 3 month follow-up
 16  T  cycle 1 - 6 month follow-up
 19  E  cycle 1 - treatment failure

  2  C  Treatment Cycle #2
 20  B  cycle 2 baseline
 21  S  cycle 2 - 1 month follow-up
 23  S  cycle 2 - 3 month follow-up
 26  T  cycle 2 - 6 month follow-up
 29  E  cycle 2 - treatment failure
 91  A  death report
 92  A  treatment toxicity report

```

Termination Windows

Example

Patient enrollment occurs over 3 years starting Jan 1, 2000.

Patient follow-up occurs every 6 months.

Maximum follow-up for any patient is 5 years.

Final follow-up for ongoing patients between Sep 1 and Nov 31, 2005.

```

  0  B  baseline
  6  S  6 month follow-up
 12  S  12 month follow-up
 18  S  18 month follow-up
 24  S  2 yr follow-up
  ...
 60  T  5 yr follow-up
 99  W  between Sep 1 and Nov 31, 2005

```

Termination Window Methods

between 2005/09/01~2005/11/31 .5

for patients still under follow-up the date of the termination visit (99) is calculated by taking the date of the first follow-up occurring after Sep 1 and scaling it back half way (.5) to Sep 1.

after 2005/06/01

the first follow-up scheduled after June 1 becomes the termination visit, e.g. if visit 48 falls on July 1 it is converted to visit 99 on July 1.

before 2005/12/01

the last scheduled follow-up occurring before Dec 1st is converted to the termination visit (99).

on 2005/09/15

all patients still under follow-up have the final termination visit (99) scheduled on Sep 15, 2005.

Conditional Termination Maps

```

1  C  Treatment Cycle #1
10 B  cycle 1 baseline
11 S  cycle 1 - 1 month follow-up
13 S  cycle 1 - 3 month follow-up
16 T  cycle 1 - 6 month follow-up
19 E  cycle 1 - treatment failure

2  C  Treatment Cycle #2
20 B  cycle 2 baseline
21 S  cycle 2 - 1 month follow-up
23 S  cycle 2 - 3 month follow-up
26 T  cycle 2 - 6 month follow-up
29 E  cycle 2 - treatment failure
91 A  death report
92 A  treatment toxicity report

```

Conditional Termination Map

~/mystudy/lib/DFcterm_map

Type|Visit|Plate|Field|Value

Example:

```
# terminate cycle 1 and 2 for lack of adequate treatment effect
# may occur at assessment 13 or 23, form 100, question 25 equals 1
E|13|100|25|1
E|23|100|25|1
# abort all follow-up if toxicity is too great at any follow-up visit
# assessment 11,13,16,21,23,26, form 20 field 44 is not equal to 2
A|11|20|44|!2
A|13|20|44|!2
...
```

Conditional Termination Map Values

~/mystudy/lib/DFcterm_map

Type|Visit|Plate|Field|Value

a number	1, 2, 99, ...
less than	<1, <5, ...
greater than	>0, >44, ...
not a number	!0, !2, ...
blank	nothing, not even a space
not blank	!, not followed by space
match	~died

Visit Cycles

- A Set of Visits scheduled from a common baseline
- Cycle Identifiers
 - numbered sequentially, descriptive label
- Cycle Types
 - required, optional, conditional
- Due day and overdue allowance
- Scheduled From
 - start of cycle 1 (1st pre-baseline or baseline visit)
 - baseline or termination of preceding cycle
 - if conditional, date on which condition was triggered
 - the date of a specified visit

A Simple Multi-Cycle Visit Map

```

1  C  Treatment Cycle #1
10 B  cycle 1 baseline
11 S  cycle 1 - 1 month follow-up
13 S  cycle 1 - 3 month follow-up
16 T  cycle 1 - 6 month follow-up

#Cycle 2 is required if field 33 on
#plate 44 at visit 16 = 2 ("yes")and
#starts 7 days after visit 16 and is
#overdue when 7 days late.
2  C  Treatment Cycle #2
20 B  cycle 2 baseline
21 S  cycle 2 - 1 month follow-up
23 S  cycle 2 - 3 month follow-up
26 T  cycle 2 - 6 month follow-up

```

Conditional Cycles

```
~/mystudy/lib/DFvisit_map
...|Visit|Plate|Field|Value|{repeat for each condition}
a number          1, 2, 99, ...
less than         <1, <140, ...
greater than      >0, >44, ...
not a number      !0, !2, ...
blank             nothing, not even a space
not blank         !, not followed by space
match             ~died
```

Multi-Cycle Example

```
0 X screening visit
Cycle 1- initial treatment cycle
  1000 B baseline for initial treatment
  1007 S day 7 follow-up
  1030 T day 30 end of treatment
  1059 O optional follow-up
Cycle 2 - re-treatment conditional on visit 1030 or 1059
         due 7 days after condition is met
  2000 B baseline for 2nd treatment
  2007 S day 7 follow-up
  2030 T day 30 end of treatment
Cycle 3 - required follow-up visits, every 60 days
         starting 30 days after end of last treatment
  3030 B day 30 since end of treatment
  3090 S day 90 since end of treatment
  ...
  3330 T final follow-up
Cycle 4 - end of study assessment, required immediately
         following visit 3330 or on early termination
  4000 F final assessment
  5000 R patient diary forms
```

Overdue Visit Calculations

General Rules:

- screening visits and the first baseline or pre-baseline visit are overdue upon arrival of any visit with a higher visit number
- scheduled visits are overdue upon arrival of any other scheduled visit with a higher visit number, or upon expiry of the overdue allowance.
- type r visits are only overdue if the next schedule visit has arrived or is itself overdue.
- type R visits are overdue upon termination of the cycle in which they are defined provided they were scheduled to occur before the termination date.
- optional, early termination and abort visits are never called overdue.

Overdue Visit Calculations

Exceptions

Scheduled due date follows termination date

- visits are not considered overdue if their scheduled target date follows the cycle termination VisitDate.

Baseline or Pre-Baseline VisitDate unknown

- visits can not be determined to be overdue, due to expiry of their overdue allowance, if their baseline VisitDate is missing.

Termination VisitDate unknown

- if a termination visit arrives but it's VisitDate is unknown, visits which may possibly have been scheduled to occur after the unknown termination date can not be determined to be overdue.

Overdue Visit Calculations

Example

```

0 X screening visit
1 P first dose 10 days pre-baseline
2 B baseline day 0, overdue if >2 days late
3 r lab test results
4 O optional visit
5 S due on day 91, overdue if >6 days late
6 T due on day 183, overdue if >9 days late

```

- visit 0 is overdue upon arrival of any of visits 1-6.
- visit 1 is overdue upon arrival of any of visits 2-6.
- visit 2 is overdue 13 days after visit 1, or on arrival of visits 5 or 6.
- visit 3 is overdue if visit 5 has arrived or is itself overdue.
- visit 4 is never overdue
- visit 5 is overdue 98 days following baseline or on arrival of visit 6.
- visit 6 is overdue 193 days following baseline.

Visit Map Testing

- Test the visit map before printing CRFs
- Use DF_ICvisitmap to check for errors
- Use raw data entry (ID, visit#, VisitDate) to test scenarios of interest.
- Run DF_QCupdate to create:
 - next scheduled visit (~work/DFX_schedule)
 - overdue visit and missing plate QCs
- Run Reports:
 - DF_QCupdate - check accuracy and formatting
 - DF_PTvisits - summary of visits in, next, overdue
 - DF_PTmissing - summary of overdue visits and missing plates

VisitMap Quality Control

Minimize QC Report Errors by using:

- edit checks to minimize data entry errors in keys fields and VisitDates
- DF_ICkeys to detect inconsistencies in patient initials and in ID, plate and visit keys
- DF_ICvisitdates to catch inconsistent and illegal VisitDates
- DF_PTvisits -E and -L options to check for VisitDates far off schedule

Final Thoughts

- Design It As Simple As Possible
- Test It As Much As Possible
- Get the Inputs as Clean As Possible
- Read the documentation
 - Visit Map chapter in the Study Planning Guide
 - Online help for DF_QCupdate