
DataFax 4 Work Flow

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Work Flow Model #1

Maximum Level (DataFax 3.5)

Defines the highest level at which a user is permitted to commit plates to the database.

Does not prevent retrieving plates from higher levels.

Does not prevent demoting plates to lower levels.

Work Flow Model #2

Separate Select & Commit Permissions

Limits the levels from which plates may be selected and levels to which plates may be committed.

Example:

Select Plates from levels: 1~3

Commit Plates to levels: 1~4

Does not prevent a user from demoting plates to lower levels.

Does not prevent users from skipping levels when promoting plates.

Work Flow Model #3 W

User Defined Work Flow Tasks

Requirements:

- associate different CRF pages with different tasks.
- specify tasks that must be performed in order.
- specify tasks that may be performed in any order.
- ensure that each required task is performed.
- avoid needless repetition of tasks.
- ensure that tasks are only performed on pages that meet the specified criteria.
- report the number of CRF pages ready for and finished each task.

Plate Meta Data

DataFax 3.5

- Validation Level: 0-7
- Record Status: clean, dirty, error

DataFax 4

- Memory of All Tasks Performed
(not just the current validation level)
- Record Status: user defined states
(enforced by user defined edit checks)

Defining Work Flow Tasks

- Task ID and Task Name
- Record Selection Criteria
 - Prior Tasks
 - Tasks which must precede the current task
 - Tasks which make the current task unnecessary
 - Last User
 - Keys: ID, Visit, Plate
 - Status
 - Data based conditions (e.g. where sex=female)
- Validation Tool
 - mode: view, edit, task, double entry
- Users/roles authorized to perform the task

Task Definition GUI

Task ID _____ Task Name _____
 Description _____

Perform task once only? yes no Task must be done ___ times.
 Prior user restrictions: none not by last user not by any previous user
task must not be repeated by same user

Record Selection Criteria
 Patients _____ Visits _____ VisitRep _____ Plates _____ PlateRep _____
 Prior Users _____ Record Statuses _____

Prior Tasks:
 - Prerequisite tasks, must be completed first, if relevant (*) _____
 - Do not perform this task if any of the following tasks have been done (!) _____

Data Selection Criteria:

Mode view edit task double entry
 Authorized Users/Roles _____

Work Flow Model #3 W

Example 1: a minimum setup

T1: users authorized to perform this task can enter new records and modify existing records. There are no work flow restrictions on what they can do.
 T2: users authorized to perform this task can change data fields on records that have been entered into the database.
 T3: users authorized to perform this task can only view records, including those waiting for data entry in the new queue.

Task ID, Name	Prior Tasks	Perform Once	Prior Users	Patients	Plates	Visits	Status
T1. validation	-	no	-	-	-	-	-
T2. edit only	*T1	no	-	-	-	-	-
T3. view only	-	no	-	-	-	-	-

Prior Tasks Legend:
 * : indicates prerequisite tasks, which if relevant, must be completed first
 ! : indicates that records are not eligible if these tasks have been performed

Note: There is no work flow management in this example.

Work Flow Model #3 W

Example 2: DataFax 3.5 style work flow

T1: new data entry, CRFs from the new fax queue or raw data entry

T2~T7: correspond to the current 7 validation levels. There are no restrictions on the order in which T2~T7 must be performed.

Task ID, Name	Prior Tasks	Perform Once	Prior Users	Patients	Plates	Visits	Status
T1. new entry	-	yes	-	-	-	-	new
T2. valid. level 2	-	no	-	-	-	-	-
T3. valid. level 3	-	no	-	-	-	-	-
T4. valid. level 4	-	no	-	-	-	-	-
T5. valid. level 5	-	no	-	-	-	-	-
T6. valid. level 6	-	no	-	-	-	-	-
T7. valid. level 7	-	no	-	-	-	-	-

Work flow management is accomplished by user defined SOPs. But the SOPs are not enforced by DataFax.

Work Flow Model #3 W

Example 3: enforced work flow

T1: new data entry has not prior task requirements

T2: occurs after T1 and must not be done by the same person who performed T1.

T3: can not be done until T2 is done.

T4: is considered urgent and thus can be done as soon as T1 has been done.

T5: can not be done on any record that is still eligible for T1,T2,T3 or T4.

Task ID, Name	Prior Tasks	Perform Once	Prior Users	Patients	Plates	Visits	Status
T1. new entry	-	yes	-	-	-	-	new
T2. double entry	*T1	yes	!prior	-	-	-	-
T3. baseline review	*T2	yes	-	-	1-7	0	-
T4 .SAE review	*T1	yes	-	-	33-34	-	sae
T5 .QC review	*T1~T4	yes	-	-	-	-	dirty

Note: Some records may skip double entry and go directly to the SAE review. As defined above such records will still be eligible for double entry and thus they will not be eligible for T5 until T2 is performed. If you do not want these records to return to double entry change Prior Tasks for T2 from *T1 to *T1,!T4.

Work Flow Model #3 W

Example 4: additional reviews by someone else

T1~T3: Bob, Dave and Jill must all review each new data record. They can do it in any order and we need to make sure they each do it only once.

T4: a clinical review occurs after the third review has been completed. There are no prior user restrictions because only the clinical staff are allowed to perform this task.

Task ID, Name	Prior Tasks	Perform Once	Prior Users	Patients	Plates	Visits	Status
T1.new entry	-	yes	-	-	-	-	new
T2.2nd review	*T1	yes	!prior	-	-	-	-
T3.3rd review	*T1,*T2	yes	!prior	-	-	-	-
T4.clinical	*T3	yes	-	-	-	-	-

!prior (i.e. not a prior user) indicates that this task can not be performed by someone who performed any of the prerequisite tasks. In the case of T3, both T1 and T2 are specified as prerequisite tasks so that !prior will ensure that T3 is not performed by either of the 2 different users who performed T1 and T2.

Work Flow Model #3 W

Example 5: tasks in a specified order + edits

T2: after new data entry, safety data is reviewed on plates 12 and 18.

T3: a statistical review is performed to check for illegal and incomplete data. This review must follow the safety review for plates 12 and 18 but all other plates go to statistical review immediately after new entry.

T4: after the statistical review, all records get a clinical review to check clinical consistency and perform clinical coding of medications, other treatments and events.

T6: users authorized to do data edits can do this at any time without effecting work flow.

Task ID, Name	Prior Tasks	Perform Once	Prior Users	Patients	Plates	Visits	Status
T1.new entry	-	yes	-	-	-	-	new
T2.safety	*T1	yes	-	-	12,18	-	-
T3.stats	*T1,*T2	yes	-	-	-	-	-
T4.clinical	*T3	yes	-	-	-	-	-
T6.edit mode	*T1	no	-	-	-	-	-

Note: changes made in edit mode are recorded in the audit tables but not in the work flow tables. Thus edits do not count as prior tasks or as prior users.

Work Flow Model #3 W

Example 6: parallel reviews

T2: after new data entry, safety data is reviewed on plates 12 and 18.
 T3~T5: the statistical and clinical reviews can be done in parallel, it does not matter which one is done first, but they must follow the safety review for plates 12 and 18.
 T4&T5: 2 clinical review tasks are defined because only plates 5,6 and 9 need to be reviewed at visits 0 and 15 whereas all plates need to be reviewed at visits 1 to 14.

Task ID, Name	Prior Tasks	Perform Once	Prior User	Patients	Plates	Visits	Status
T1.new entry	-	yes	-	-	-	-	new
T2.safety	*T1	yes	-	-	12,18	-	-
T3.stats	*T1,*T2	yes	-	-	-	-	-
T4.clinical1	*T1,*T2	yes	-	-	5,6,9	0,15	-
T5.clinical2	*T1,*T2	yes	-	-	-	1-14	-

Work Flow Model #3 W

Example 7: 3 parallel reviews, 1 done twice

T2~T4: when several tasks may be performed in any order, specify the same prerequisite condition(s) for all tasks.
 T2: must be done twice, but not by the same person.
 T5: can not be done until records are no longer eligible for tasks T2,T3 and T4. In the case of T2 this means that both safety reviews must have been performed.
 Also, note that T5 is delayed until a record is clean, i.e. all QCs have been resolved and refaxes are thus no longer expected. This might be done to avoid needless repetition of T5.

Task ID, Name	Prior Tasks	Perform Once	Prior Users	Patients	Plates	Visits	Status
T1.new entry	-	yes	-	-	-	-	new
T2.safety	*T1	twice	!same	-	12,18	-	-
T3.stats	*T1	yes	-	-	-	-	-
T4.clinical	*T1	yes	-	-	-	-	-
T5.final review	*T2,*T3,*T4	yes	-	-	-	-	clean

!same can be used on tasks that must be performed more than once to indicate that they must not be performed twice by the same user.

STATUS TOOL

View: tasks to be done by all
 tasks to be done by me
 tasks completed

Tasks ID, Name	Records to be done	Current Status		
		clean	dirty	special
T1.new entry	200	100	180	20
T2.double entry	320	200	100	20
T3.baseline review	100	40	60	
T4.safety review	50	20	30	
T5.clinical review	120	75	20	25
TOTAL to be done	790	335	390	65

Click on task to launch validation tool for that task.

Issues 1/3

Record Locking

It will be necessary to lock the entire retrieval set (just like we do now in DataFax 3.5). Otherwise another user could change a record making it no longer eligible for the task being performed.

Refaxed CRF pages

A refaxed CRF page starts at the beginning regardless of which tasks have already been performed.

The task history of the old copy of the CRF is retained.

It is possible to define tasks using record status criteria to avoid performing higher level reviews until all data clarification QC notes have been resolved (see the final review in example 7).

Issues 2/3

What if a data correction changes task eligibility for a record that has already been through several tasks?

If the record is no longer eligible for a task that was done:

We can't undo the past. What's done is done. But if a task is defined as requiring repetitions, any outstanding repetitions will no longer be required.

If the record is now eligible for a task that was skipped:

The record will now appear as eligible for the skipped task, and will show up in the status tool count of tasks to be done, until it is completed. Thus a skipped task will be caught and it will be performed, although not in the desired order.

Issues 3/3

What if the key fields (patient, visit, plate) are fixed after one or more tasks have been performed?

If it does not trip duplicate resolution

All existing data and task history move to the new keys. This does not require any intervention by the user.

If it trips duplicate resolution

The user will review the 2 CRFs and the task history of both copies and decide which one is primary. The task history for this record will come from the CRF that is marked as the primary copy. The other CRF image will be kept and will appear in the audit tables. It's task history will also be retained.

Tracking Tasks Performed

TABLE - Work Flow By User

- DFWFSN - sequential number
- User ID
- Start Date & Time (set retrieval)
- Task ID
- User Explanation
purpose of the review, might be required in edit mode
- Number of records:
retrieved, modified, committed, and deleted
- Number of QC notes:
added, modified, resolved, and deleted
- End Date & Time (set release)

Tracking Tasks Performed

TABLE - tasks performed on each CRF page

- DFSN - identifies a completed CRF page
(unique keys for: patient,visit,visitrep,plate,platerep)
 - DFWFSN - identifies the work flow session
 - DFCRFID - CRF image ID
- one record for each task completed on a CRF page.
- this table is updated when a user commits a record in the validation tool.