
Study Roles: Making Them Work For You

Jeanine Hammar
Clinical DataFax Systems Inc.



Approach

1. What are a user's responsibilities?
2. What DataFax features are needed to perform these tasks?
3. Any restrictions?
4. If so, what DataFax features should be restricted?
5. Can tasks or edit checks be used to supplement roles?

Study Personnel - Some Examples

- Study Administrator
- Data Entry - Clinical Site (EDC)
- Data Entry - Study Staff (Fax)
- Data Manager
- Study Monitor
- Study Sponsor

Study Administrator

Admin Responsibilities

- Administer study accounts (DFsystem)
- Study setup and testing
- Maintain Development/Production links
- Execute server-side programs
- Access all data and meta data



Unrestricted access

Study Admin Role

The screenshot displays the configuration interface for the Study Admin Role. At the top, the role name is 'Admin' with a status of 'Active'. The description is 'Full administrative privileges'. Below this, there are several sections of permissions, each with a list of checkboxes:

- IDataFax**: Views (Data, Data - Import patient documents, Data - Submit PDF, Data - with Select, Fax, Fax - Create tasks, Fax - Delete new records, Fax - Raw data entry, List, List - Create views, List - Import Data, Queries, Reasons, Reports, Reports - Create lists, Status, Print/Save, Blank CRFs, Completed CRFs, DFas jobs, Data, Images, Reports, Miscellaneous, Developer, May disable edit checks, Show query status detail).
- Server & DFsetup**: Server (Export Data, Batch Edit Checks, Import Data), Setup (View, Plates, Edit Checks, Lookup Tables, Centers, Missing Map, Sort Map, Visit Map, Conditional Terminations, Conditional Cycles, Conditional Visits, Conditional Plates, QC Titles, QC Covers, QC Messages, CRF Type Map, CRF Background Map).
- DataFax Reports**: DF.Actors, DF.ATaxess, DF.ATimods, DF.CTors, DF.CTpages, DF.CTqcs, DF.CTvisus, DF.Kcenters, DF.Kimages, DF.Kkeys, DF.Kqcs, DF.Krecords, DF.Kschemas, DF.Kvisitdates, DF.Kvisitmap, DF.INDEX, DF.PTconditions, DF.PTfors, DF.PTlist, DF.PTmissing, DF.PTfocs, DF.PTschedule, DF.PTunexpected, DF.PTvises, DF.QCfax, DF.QCdiaglog, DF.QCprint, DF.QCreports, DF.QCrint, DF.QCstatus, DF.QCupdate, DF.QCview.
- Study Reports**: AE_Summary, Baseline_Stats, BatchExport_AES.

At the bottom of the screenshot is a detailed table with columns for various permissions and their status:

Get	Views	Plates	Levels	Hidden Fields	Int. Queries	Levels	Levels	Write	Data	Queries	Reasons
<input checked="" type="checkbox"/>	ALL	ALL	ALL	<input checked="" type="checkbox"/> all <input type="checkbox"/> none	<input checked="" type="checkbox"/> all <input type="checkbox"/> none	0-7	0-7	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/> C <input checked="" type="checkbox"/> M <input checked="" type="checkbox"/> D <input checked="" type="checkbox"/> L <input checked="" type="checkbox"/> P	<input checked="" type="checkbox"/> C <input checked="" type="checkbox"/> M <input checked="" type="checkbox"/> D <input checked="" type="checkbox"/> A <input checked="" type="checkbox"/> B	<input checked="" type="checkbox"/> C <input checked="" type="checkbox"/> M <input checked="" type="checkbox"/> D <input checked="" type="checkbox"/> A

Clinical Site (EDC)

Site Responsibilities

- Enter new data, reasons (Data View)
- Modify entered data, reasons
- Reply to and auto-resolve queries
- Save data, meta data (pending & level 1)
- Import supporting subject documentation
- Print/save CRFs and images

Site Restrictions

Sites should NOT be allowed to:

- Enter and save data at levels > 1
- Modify data existing at levels >3
- Perform batch saves
- Create, edit, delete or approve queries
- Access hidden fields or internal queries
- Run Datafax reports
- View data from other sites

Clinical Site Role

The screenshot displays the 'Clinical Site' configuration window. The 'Name' is 'Clinical Site' and the 'Status' is 'Active'. The description is 'Data entry and query management by site personnel'. The interface is divided into several sections for configuring permissions:

- DataFax:** Includes options for Views (Data, Import patient documents, Submit PDF, with Select, Raw data entry), List (Create views, Import Data), Reports (Create lists), and Miscellaneous (Developer, disable edit checks, Show query status detail).
- Server & DFsetup:** Includes options for Export Data, Batch Edit Checks, Import Data, Setup (View, Plates, Edit Checks, Lookup Tables, Centers, Missing Map, Sort Map, Visit Map), Conditional Terminations, Conditional Cycles, Conditional Visits, Conditional Plates, QC Titles, QC Covers, QC Messages, CRF Type Map, and CRF Background Map.
- DataFax Reports:** Includes options for DF_ATcrfs, DF_ATfaxes, DF_CTcrfs, DF_CTpages, DF_CTvisits, DF_Kcenters, DF_Kimages, DF_Kkeys, DF_Kqcs, DF_Krecords, DF_Kschema, DF_Kvisits, DF_Kvisitsdates, DF_INDEX, DF_PTconditions, DF_PTcrfs, DF_PTlist, DF_PTmissing, DF_PTqcs, DF_PTschedule, DF_PTunexpected, DF_PTvisits, DF_QCfax, DF_QCfaxlog, DF_QCprint, DF_QCreports, and DF_QC...
- Study Reports:** Includes options for AE_Summary, Baseline_Stats, and BatchExport_AEs.

Below the configuration sections is a table for defining permissions for different roles:

Site	Plates	Levels	Hidden Fields	ns.Queries	Modify Levels	Write Levels	Data	Queries	Reasons
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Site Role - Tips & Advice

- **No Data with Select**
 - removes ability to batch validate, change working mode & level, re-save Final/Incomplete records as Pending
 - retains access to pre-defined tasks
- **No Reports View**
 - but access to DF_ATmods enables page history
- **Write level includes 0 (pending)**
- **Queries Create/Modify (-)**
 - necessary if QCs can be added by edit checks
 - required for QC auto-resolution

Site Role - Tips & Advice (cont'd)

- **Queries Reply**
 - only way for EDC sites to respond to QCs
- **No Reason Approval**
 - or '-' if approved reasons can be added by dfaddresson()
- **Use Edit Checks**
 - dfneed(), dftrigger() - alter patient binder display
 - DFopen_study(), DFopen_patient_binder - pre-set user preferences, display study messages

Site Role - Tips & Advice (cont'd)

- **User-level permissions**
 - defined in Users tab (not part of Roles)
 - controls access to sites and patients
 - grants DataFax Router privileges



Data Entry (Fax)

Data Entry Responsibilities

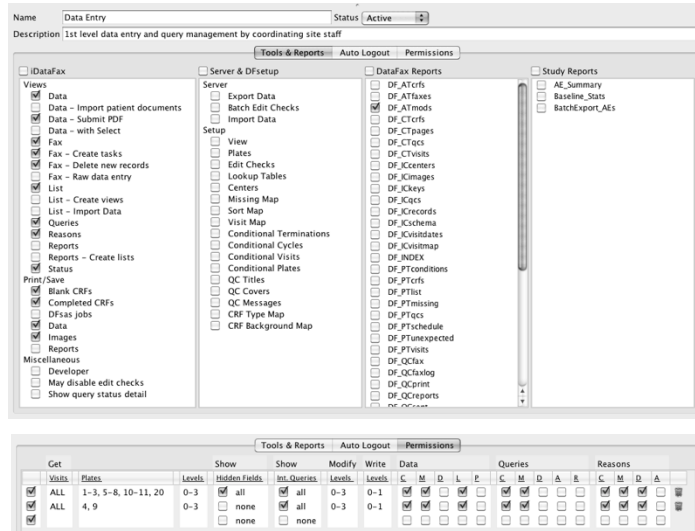
- Submit PDFs in addition to faxing
- Enter new data, reasons (Fax View)
- Modify entered data, reasons (Data View)
- Add, modify, resolve queries (including internal queries)
- Save data, meta data (pending & level 1)
- Print/save CRFs and images

Data Entry Restrictions

Data entry should NOT be allowed to:

- Access coding fields for Meds and AEs
- Enter and save data at levels > 1
- Modify data existing at levels >3
- Perform batch saves
- Reply to external queries
- Approve reasons
- Run Datafax reports

Data Entry Role



Data Entry Role - Tips & Advice

- **No Data with Select**
 - can't change working mode & level, re-save Final/Incomplete records as Pending, batch validate
 - can access pre-defined user tasks
- **No Reports View**
 - but access to DF_ATmods enables page history
- **Write level includes 0 (pending)**
- **Queries Create/Modify**
 - QCs can be added or modified manually and by edit checks
 - required for QC auto-resolution

Data Entry Role - Tips & Advice (cont'd)

- **No Queries Reply**
 - can resolve but not reply to QCs
- **2 permission rows control hidden fields**
- **Use tasks to simplify data retrieval and entry**
- **Use edit checks**
 - DFopen_study(), DFopen_patient_binder() - pre-set user preferences, display study messages

Title

Data Manager

Data Manager Responsibilities

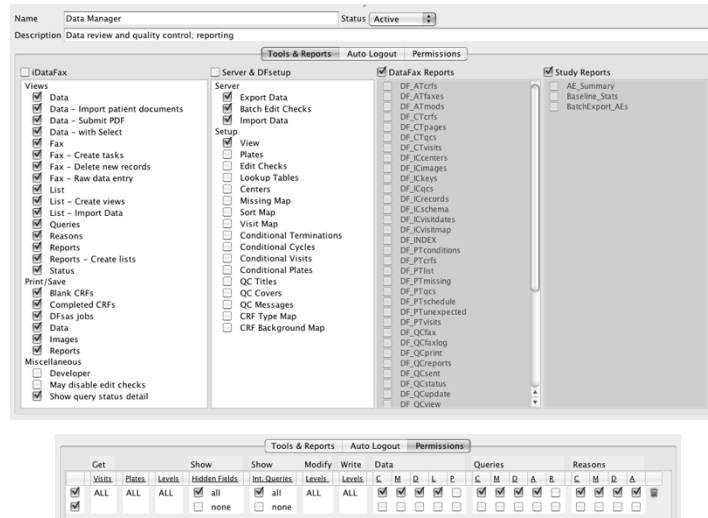
- Define user tasks
- Review and save entered data for monitoring
- Add, modify, delete, resolve, approve queries
- Add, modify, approve reasons
- Code Meds and AEs
- Review monitored data for outstanding issues
- Run DF_QCupdate (and QC reports)

Data Manager Restrictions

Data managers should NOT be allowed to:

- Modify and save pending records
- Modify edit checks and setup
- Reply to queries

Data Manager Role



Manager Role - Tips & Advice

- **Data with Select**
 - allows the creation of tasks for self/other users
 - record retrieval based on specific criteria
 - perform batch saves
- **Access to hidden fields (for coding Meds, AEs)**
- **Get/Modify/Write levels = ALL**
 - necessary for DF_QCupdate
- **No Queries Reply**
- **Use tasks for different duties**

Title

Site Monitor

Site Monitor Responsibilities

- Monitor data that has been reviewed by data manager
- Add, modify, delete queries
- Approve reasons and query replies
- Save data/meta data to level 5
 - level 5 Final = data ready for analysis
 - level 5 Incomplete = outstanding issues

Site Monitor Restrictions

Site Monitors should NOT be allowed to:

- Modify data
- Reply to queries
- Save new and pending records

Site Monitor Role

The screenshot displays the 'Site Monitor' role configuration. The role name is 'Site Monitor' and its status is 'Active'. The description is 'Source verification of data'. The interface is divided into several sections for permissions:

- DataFax:** Includes permissions for Views (Data, Data - Import patient documents, Data - Submit PDF, Data - with select, Fax, Fax - Create tasks, Fax - Delete new records, Fax - Raw data entry, List, List - Create views, List - Import Data, Queries, Reports, Reports - Create lists, Status, Print/Save, Blank CRFs, Completed CRFs, DFSas jobs, Data, Images, Reports, Miscellaneous, Developer, May disable edit checks, Show query status detail).
- Server & DFsetup:** Includes permissions for Server (Export Data, Batch Edit Checks, Import Data), Setup (View, Plates, Edit Checks, Lookup Tables, Centers, Missing Map, Sort Map, Visit Map, Conditional Terminations, Conditional Cycles, Conditional Visits, Conditional Plates, QC Titles, QC Covers, QC Messages, CRF Type Map, CRF Background Map).
- DataFax Reports:** Includes permissions for DF_ATerts, DF_ATFlaxes, DF_ATmods, DF_CTerf, DF_CTrages, DF_CTracs, DF_CTrives, DF_CCenters, DF_CRecords, DF_CImages, DF_CKeys, DF_CQcs, DF_CRecords, DF_CSchema, DF_CVisitmap, DF_CVisitdates, DF_CVisitmap, DF_PTconditions, DF_PTerf, DF_PTrlist, DF_PTmissing, DF_PTrqs, DF_PTrschedule, DF_PTrunexpected, DF_PTrives, DF_QCfax, DF_QCfaxlog, DF_QCprint, DF_QCreports, DF_QCsent, DF_QCstatus, DF_QCupdate, DF_QCview.
- Study Reports:** Includes permissions for AE_Summary, Baseline_Stats, BatchExport_AEs.

At the bottom, there is a table for 'Get' permissions:

Get	Views	Plates	Levels	Hidden Fields	Im. Queries	Levels	Levels	Data	D	L	P	Queries	Q	A	Reasons	R	A
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	5	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Monitor Role - Tips & Advice

- Access to DF_CT* and DF_PT* reports
 - these reports require access to DFexport.rpc
- Get levels 1-5
 - allows review of non-task records
- Modify levels = reviewed by manager
- Data/Reasons Modify (-)
 - allows data/reasons to be added by edit checks
- Full query permissions, excluding Reply
- Use tasks for different duties

Title

Study Sponsor

Sponsor Responsibilities

- Not responsible for day-to-day collection and management of study data



View only access

- View only monitored, level 5 data and meta data

Study Sponsor Role

Get	Plates	Levels	Hidden Fields	Show	Modify	Write	Data	Queries	Reasons
<input checked="" type="checkbox"/>	ALL	ALL	5	<input checked="" type="checkbox"/> all <input type="checkbox"/> none	<input checked="" type="checkbox"/> resolved <input type="checkbox"/> none	-	<input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> D <input type="checkbox"/> L <input type="checkbox"/> P	<input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> D <input type="checkbox"/> A <input type="checkbox"/> B	<input type="checkbox"/> C <input type="checkbox"/> M <input type="checkbox"/> D <input type="checkbox"/> A

Sponsor Role - Tips & Advice

- View only access to iDataFax views
- Study-specific reports may require DFexport.rpc
- View access to resolved internal QCs
 - can also define multiple permission rows to make internal QCs available only on certain plates
- Modify/Write (-) = view only

General Tips & Advice

- Get/Modify/Write levels
 - can be different for different visit/plate combinations
 - use '-' for 'none' instead of level = 0
 - without level 0, user can't enter new data or complete new pending records
- Data permission 'P' = password required
 - edit check function dfpassword() also works
- Set default Auto Logout in roles
 - control at user-level using edit check function dfpref()
- Need to disable a role? - don't delete it, make it inactive

Questions?

Thank You