
MRFs: A DataFax-SAS solution for clinical monitoring and data review

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Validating Clinically Monitored CRFs

- **Visual Verification (VV)**



At the Site:

- Source Documents ⇔ CRFs
- Discrepancies (queries) documented

At PDL, in DataFax:

- CRFs with queries are visually reviewed
 - Corrections not refaxed → CRA creates QC → Validate to Level 5 (dirty)
 - Corrections refaxed → Validate to Level 5 (clean)
- CRFs with no queries are Batch Validated to Level 5 (clean)

Validating Clinically Monitored CRFs

- **Monitoring Report Form (MRF)**



At the Site (Initial Visit):

- Source Documents ⇨ CRFs
- Discrepancies documented
- Documentation on Monitoring Report Form begins

At the Site (Follow-Up Visit):

- Corrections from Initial Visit are verified on CRF
- Documentation on Monitoring Report Form is completed

Monitoring Report Form faxed to DataFax.

Completing MRFs

Protocol Number: DAC-1003 MF-1 (381)

SAC-005-001 MF-1 (381)

Site No. Patient No. Patient Initials

9988 7777

Monitored by: G-T

SCREENING VISIT: RUN-IN VISIT 2A: RUN-IN VISIT 2B:

01 JAN 03

OR

100 036 036

01 MAR 03

Sent to DataFax: 04 MAR 03

CRF# 381 15 JUL 2002

1999-000-998-11 SHIP Ch 2-019-1 14 1.0.0.0 MF2

Data Entry of MRFs

MONITORING FORM
 DAC-1000 sub MF-1 (381)
 Site No: Patient No: Patient Initials: MF-1 (381)
 1503 00103 00001
 Monitored by: P S L
 Fix to DataFax when all visits on this page have been completed
 SCREENING VISIT: 19 JUN 03
 No CRF Issues: DISCREPANCY:
 CRF # 100 109 030
 DISCREPANCY For none: For error: For missing: For other:

MONITORING FORM
 DAC-1000 sub MF-1 (381)
 Site No: Patient No: Patient Initials: MF-1 (381)
 1503 00103 00001
 Monitored by: P S L
 Fix to DataFax when all visits on this page have been completed
 SCREENING VISIT: 19 JUN 03
 No CRF Issues: DISCREPANCY:
 CRF # 100 109 030
 DISCREPANCY For none: For error: For missing: For other:

MONITORING FORM
 DAC-1000 sub MF-1 (381)
 Site No: Patient No: Patient Initials: MF-1 (381)
 1503 00103 00001
 Monitored by: P S L
 Fix to DataFax when all visits on this page have been completed
 RUN-IN VISIT 2A: 19 JUN 03
 No CRF Issues: DISCREPANCY:
 CRF # 034 032 200
 DISCREPANCY For none: For error: For missing: For other:

MONITORING FORM
 DAC-1000 sub MF-1 (381)
 Site No: Patient No: Patient Initials: MF-1 (381)
 1503 00103 00001
 Monitored by: P S L
 Fix to DataFax when all visits on this page have been completed
 RUN-IN VISIT 2B: 19 JUN 03
 No CRF Issues: DISCREPANCY:
 CRF # 034 032 200
 DISCREPANCY For none: For error: For missing: For other:

CRFs to Level 5

MONITORING FORM
 Protocol Number: DAC-1000 MF-1 (381)
 Site No: Patient No: Patient Initials: MF-1 (381)
 9988 2121
 Monitored by: K S M
 Fix to DataFax when all visits on this page have been completed
 SCREENING VISIT: 06 JAN 03
 No CRF Issues: DISCREPANCY:
 CRF # 100 105 030 106 107 121
 DISCREPANCY For none: For error: For missing: For other:

level 5.drf created and CRFs batch validated to level 5
 CRFs with 'No Issues'

CRFs to Level 5 (continued)

Protocol Number: DAC-1003 MF-1 (381)

Site No. Patient No. Patient Initials MF-1 (381) Monitored by: K S M
99-88 ZIZZ Fax to DataFax when all visits on this page have been completed F M L

MONITORING FORM

SCREENING VISIT: 06 JAN 03 No CRF issues No CRF issues No CRF issues

RUN-IN VISIT 2A: 06 JAN 03 No CRF issues No CRF issues No CRF issues

RUN-IN VISIT 2B: 06 JAN 03 No CRF issues No CRF issues No CRF issues

CRF #	1 or more errors	Resolved errors
100	<input type="checkbox"/>	<input type="checkbox"/>
105	<input type="checkbox"/>	<input type="checkbox"/>
030	<input type="checkbox"/>	<input type="checkbox"/>
106	<input type="checkbox"/>	<input type="checkbox"/>
107	<input type="checkbox"/>	<input type="checkbox"/>
121	<input type="checkbox"/>	<input type="checkbox"/>
036	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
032	<input type="checkbox"/>	<input type="checkbox"/>
200	<input type="checkbox"/>	<input type="checkbox"/>
201	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
036	<input type="checkbox"/>	<input type="checkbox"/>
032	<input type="checkbox"/>	<input type="checkbox"/>
200	<input type="checkbox"/>	<input type="checkbox"/>
201	<input type="checkbox"/>	<input type="checkbox"/>
140	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>

CRF #36 for Patient #9988

Status: clean dirty error Created: 05/20/07 15:19:00 Last Modified: 05/20/07 15:19:00

Level5.drf created and CRFs batch validated to level 5

CRFs with 'Resolved Issues' and modified date equal to or after the monitored date

CRFs to be QCd

Protocol Number: DAC-1003 MF-1 (381)

Site No. Patient No. Patient Initials MF-1 (381) Monitored by: K S M
99-88 ZIZZ Fax to DataFax when all visits on this page have been completed F M L

MONITORING FORM

SCREENING VISIT: 06 JAN 03 No CRF issues No CRF issues No CRF issues

RUN-IN VISIT 2A: 06 JAN 03 No CRF issues No CRF issues No CRF issues

RUN-IN VISIT 2B: 06 JAN 03 No CRF issues No CRF issues No CRF issues

CRF #	1 or more errors	Resolved errors
100	<input type="checkbox"/>	<input type="checkbox"/>
105	<input type="checkbox"/>	<input type="checkbox"/>
030	<input type="checkbox"/>	<input type="checkbox"/>
106	<input type="checkbox"/>	<input type="checkbox"/>
107	<input type="checkbox"/>	<input type="checkbox"/>
121	<input type="checkbox"/>	<input type="checkbox"/>
036	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
032	<input type="checkbox"/>	<input type="checkbox"/>
200	<input type="checkbox"/>	<input type="checkbox"/>
201	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
036	<input type="checkbox"/>	<input type="checkbox"/>
032	<input type="checkbox"/>	<input type="checkbox"/>
200	<input type="checkbox"/>	<input type="checkbox"/>
201	<input type="checkbox"/>	<input type="checkbox"/>
140	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>

CRF #36 for Patient #9988

Status: clean dirty error Created: 05/20/07 11:21:50 Last Modified: 05/20/07 11:21:50

addqcs.drf created and batch edit check run to add QC and move CRF to level 5

CRFs documented as having 'Resolved Issues' and with a modified date prior to the monitored date

Missing CRFs ??

Protocol Number: DAC-1003 MF-1 (381)

Site No. Patient No. Patient Initials MF-1 (381)

99-88 21212

MONITORING FORM

Monitored by: K S M

SCREENING VISIT: 06 JAN 03

RUN-IN VISIT 2A: 06 JAN 03

RUN-IN VISIT 2B: 06 JAN 03

CRF #	No CRF Issues	DISCREPANCY	CRF #	No CRF Issues	DISCREPANCY	CRF #	No CRF Issues	DISCREPANCY
100	<input type="checkbox"/>	<input checked="" type="checkbox"/>	036	<input checked="" type="checkbox"/>	<input type="checkbox"/>	036	<input type="checkbox"/>	<input type="checkbox"/>
105	<input type="checkbox"/>	<input type="checkbox"/>	032	<input type="checkbox"/>	<input type="checkbox"/>	032	<input type="checkbox"/>	<input type="checkbox"/>
030	<input type="checkbox"/>	<input type="checkbox"/>	200	<input type="checkbox"/>	<input type="checkbox"/>	200	<input type="checkbox"/>	<input type="checkbox"/>
106	<input type="checkbox"/>	<input type="checkbox"/>	201	<input type="checkbox"/>	<input type="checkbox"/>	201	<input type="checkbox"/>	<input type="checkbox"/>
107	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	140	<input type="checkbox"/>	<input type="checkbox"/>
121	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>

SAS listing is generated for the Clinical Data Coordinator (CDC). The CDC investigates these issues and adds QCs or has the CRA modify the MRF as needed

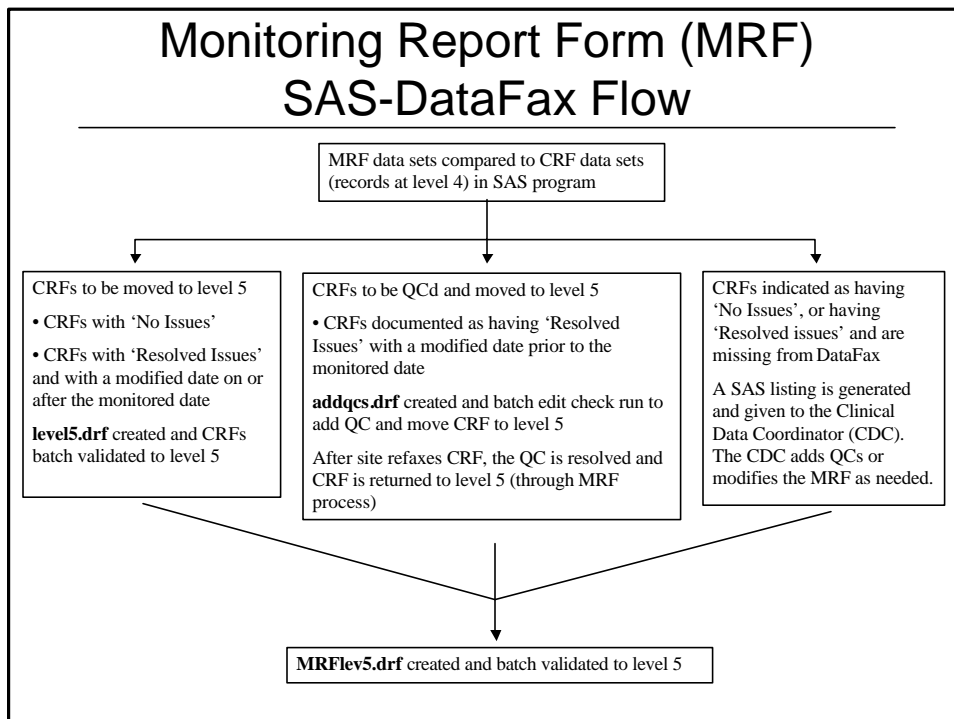
CRFs indicated as having 'No Issues'

or

having 'Resolved Issues'

that are missing from DataFax

Monitoring Report Form (MRF) SAS-DataFax Flow



Lessons Learned/Issues

- Training in the completion of MRFs
- Compromise
- If at first you don't succeed.....modify
- Did I mention training??

