

Dummy Study XYZ

Site 110: Monitoring Checklist

Monitoring Checklist

Report Information

4Site Report Provider Name	Natalie Smith
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PREVIEW

Dummy Study XYZ

Site 110: Monitoring Checklist

TABLE OF CONTENTS

	Page
Report Introduction	3
USA, Site 110: Status Overview	4
USA, Site 110: Monitoring Report Checklist: Periodic	5
USA, Site 110, Patient 1056: Status Overview	9
USA, Site 110, Patient 1085: Status Overview	10
USA, Site 110, Patient 1089: Status Overview	11
USA, Site 110, Patient 1100: Status Overview	12
USA, Site 110, Patient 1179: Status Overview	13
USA, Site 110, Patient 1289: Status Overview	14
Concluding Remarks	15
Report Notes	16

PREVIEW

Dummy Study XYZ

Site 110: Monitoring Checklist

Report Introduction

Please review site level and patient level summaries prior to completing site visit. Data, query and sample issues should be reviewed and actioned accordingly with comments being entered in the site monitoring checklist included in this report.

PREVIEW

Dummy Study XYZ

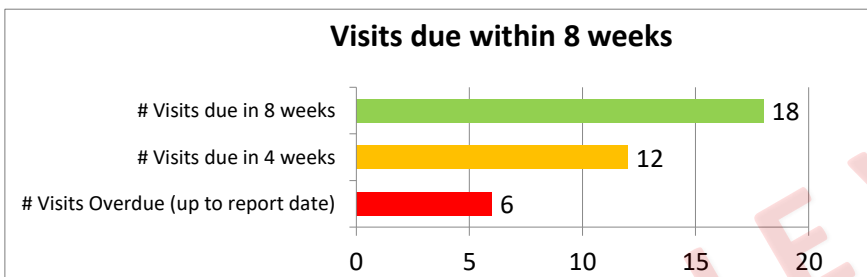
Site 110: Monitoring Checklist

USA, Site 110: Status Overview

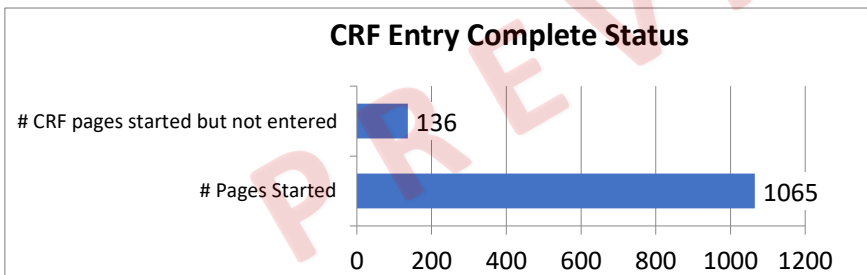
Site Information

Site Investigator Name	Dr. D. Denton
EUDRACT Number	2018-123456-01
CRA Name	William Broodie
CRA email	wBroodie@email.com
4Site Report Provider Name	Natalie Smith
4Site Report Provider email	smithn@email.com

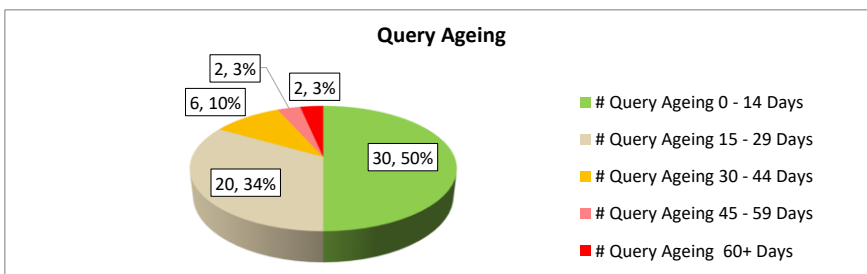
Please review the following to ensure overdue data/visits/queries are followed up during your monitoring visit (where time permits). Any ongoing issues should be documented in your Site Visit Report.



Please take note of any overdue visits and discuss with site staff strategies to get data entered as per site contract. Consider setting targets for the site.



Liaise with site to ascertain reasons for data entry blocks (CRF instructions unclear, EDC system issues, site staffing etc).



Queries over 60 days should not exist. Discuss with site staff if possible or provide feedback to data management (query wording/issues with EDC). Discuss with site the importance of timely replies.

If the report author has included a patient level section in this report, please also use this as a further aid for this monitoring visit.

Dummy Study XYZ

Site 110: Monitoring Checklist

USA, Site 110: Monitoring Report Checklist: Periodic

The below table contains the Monitoring Report Checklist: Periodic checklist. Please review and complete.

Visit Summary

	DD-MMM-YYYY	Comments (if any)		
1.1	Date of monitoring visit(s)			
1.2	Report printed:			
1.3	Report completed:			
1.4	Follow-up correspondence sent on:			
	Name	Position	Name	Position
1.5	Trial staff present:			
1.6	Monitoring staff present:			
1.7	Patients monitored:			
1.8	Next Visit date:			

Patient Recruitment

2.1	(tick)	Active Recruitment: <input type="checkbox"/>		Recruitment Closed: <input type="checkbox"/>	
	Target recruitment (as per CTMS):	Total screened:	# screen failures:	# in screening:	
	# recruited to date:	# active on study:	# withdrawn:	# completed:	

Site Personnel Evaluation

	Yes	No	NA	Comments (if applicable comment and describe any corrective actions that were initiated)	Corrective action required? (Tick)
2.2					
2.3					
2.4					
2.5					
2.6					

Dummy Study XYZ

Site 110: Monitoring Checklist

Informed Consent

	Yes	No	NA	Comments (if applicable comment and describe any corrective actions that were initiated)	Corrective action required? (Tick)
3.1 Do ALL patients have a copy of the ICF filed in the site file?					
3.2 Correct ICF version used for ALL patients?					
3.3 Informed consent is undertaken only by appropriately delegated site personnel?					
3.4 ICFs signed and dated by both patient & investigator?					
3.5 ICFs signed on the same date by the patient and research team member?					
3.6 ICF boxes been initialed by the patient (rather than ticked)?					
3.7 Consent log up to date?					
3.8 Re-consent triggering? (Have there been any amendments study documents (protocol, consent form or information sheet))					
3.9 If there have been any amendments to the consent form, information sheet or protocol, has patient re-consented appropriatey?					

Trial Master File / Study Documentation

	Yes	No	NA	Comments (if applicable comment and describe any corrective actions that were initiated)	Corrective action required? (Tick)
4.1 Screening & enrolment logs in place?					
4.2 Screening/Enrolment Logs accurate & up-to-date?					
4.3 Ethical approval granted and up-to-date?					

Dummy Study XYZ

Site 110: Monitoring Checklist

4.4	R&D approval granted and up to date?					
4.5	Regulatory approval (MHRA) granted and up to date (where applicable)?					
4.6	PI- signed Protocol on file?					
4.7	Latest Investigator Brochure & signed IB receipts on file for CTIMP studies?					
4.8	For Sponsored-CTIMPs, has the Investigator Brochure been updated or reviewed annually?					
4.9	All SAEs (initial/follow-up) on file & have they been reported to the Sponsor (R&D)?					
4.10	All SUSAR / Safety Reports on file?					
4.11	Site completing & filing source documents appropriately?					
4.12	Relevant documentation present as listed in the TMF / ISF checklist and signed where relevant? Eg Protocol, PIS, GP letter, invite letter					
4.13	Patient related documents appropriately headed & contain local contact details					
4.14	General filing of the site file in good order?					

Follow-Up Action Items

None:

Action Item #	Patient Involvement?			Date Issue Identified	Status		Action Item / Corrective Action Plan
	Yes	No	NA		Open / Pending	Closed	
5.1							
5.2							

Dummy Study XYZ

Site 110: Monitoring Checklist

5.3							
5.4							
5.5							

Follow-Up Action Items Resolved from previous visit None:

Action Item #	Patient Involvement?			Date Issue Identified	Status		Action Item / Corrective Action Plan
	Yes	No	NA		Open / Pending	Closed	
	6.1						
6.2							
6.3							
6.4							
6.5							

General Comments

7

Signatures

8

Signature of Monitor/Date

Signature of Reviewer/Date

9

Printed Name and Title
Monitor

Printed Name and Title
Study manager

Monitoring Report Template 0.1

Dummy Study XYZ

Site 110: Monitoring Checklist

USA, Site 110, Patient 1056: Status Overview

Details of the number of visits overdue for CRF entry is listed below: [Note 1]

Visit	Estimated Date
Visit 8	02-Dec-18
Visit 9	16-Dec-18
Sum Total	2
Study avg./ Patient	1

Visits are found to be expectant on CRF entry up to the date the data extract was performed.

Visit windows: visit 7 is 19 days after visit 6, but the protocol schedule indicates this should be 14(+/- 3) days. Please check the CRF patient status and query with site if required.

Details of the number of open site queries is listed below: [Note 2]

Site Queries Answered	Site Open Queries Total
157	19
Study avg./ Patient	11

Queries are found to be pending a site response. Please continue to work towards answering queries in a timely manner.

Details of the number of pages started but without full entry as per the CRF system is listed below: [Note 3]

CRF Pages Started	Pages Started not fully CRF Entered
120	18
Study avg./ Patient	17

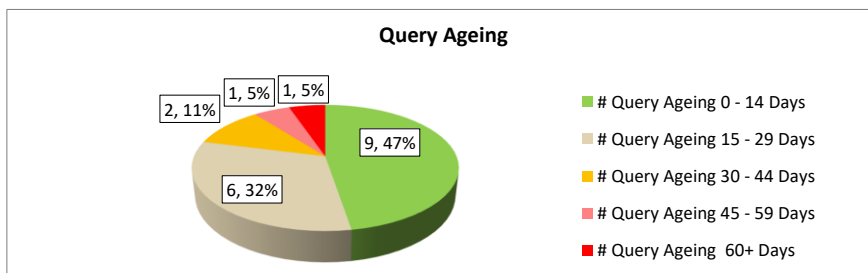
CRF pages have been identified as not being fully entered. Continued attempts to ensure timely entry is encouraged.

Details of the number of PK samples on site as per sponsor-provided lab report is listed below: [Note 4]

PK Sample ID	Sample Date
Vis05Pre15	21-Oct-18
Vis05Post15	21-Oct-18
Vis05Post60	21-Oct-18

PK samples are found to be on-site as per sponsor-provided lab report.

Report author note: Please encourage site to dispatch overdue samples.



Encourage site to answer all queries in prioritised fashion.

Dummy Study XYZ

Site 110: Monitoring Checklist

USA, Site 110, Patient 1085: Status Overview

Details of the number of visits overdue for CRF entry is listed below: [Note 5]

Visit	Estimated Date
No Findings	No Findings
Sum Total	0
Study avg./ Patient	1

No overdue visit data detected for this patient.

Details of the number of open site queries is listed below: [Note 6]

Site Queries Answered	Site Open Queries Total
23	2
Study avg./ Patient	11

Queries are found to be pending a site response. Please continue to work towards answering queries in a timely manner.

Details of the number of pages started but without full entry as per the CRF system is listed below: [Note 7]

CRF Pages Started	Pages Started not fully CRF Entered
15	0
Study avg./ Patient	17

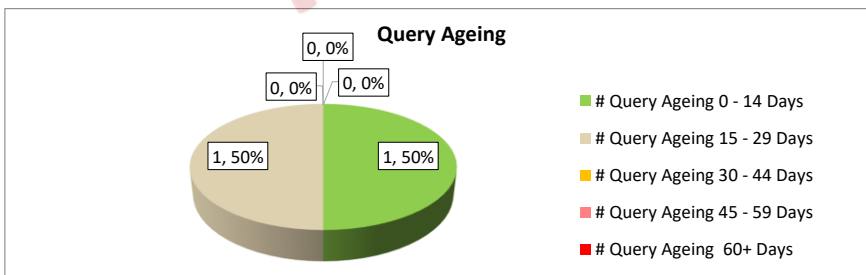
No CRF pages are without full data entry in the CRF.

Details of the number of PK samples on site as per sponsor-provided lab report is listed below: [Note 8]

PK Sample ID	Sample Date
No Findings	No Findings
Sum Total	0
Study avg./ Patient	1

No PK samples are found to be on-site as per sponsor-provided lab report.

Report author note: Please encourage site to dispatch overdue samples.



Encourage site to answer all queries in prioritised fashion.

Dummy Study XYZ

Site 110: Monitoring Checklist

USA, Site 110, Patient 1089: Status Overview

Details of the number of visits overdue for CRF entry is listed below: [Note 9]

Visit	Estimated Date
Visit 3	17-Nov-18
Visit 4	01-Dec-18
Visit 5	15-Dec-18
Sum Total	3
Study avg./ Patient	1

Visits are found to be expectant on CRF entry up to the date the data extract was performed.

Details of the number of open site queries is listed below: [Note 10]

Site Queries Answered	Site Open Queries Total
59	3
Study avg./ Patient	11

Queries are found to be pending a site response. Please continue to work towards answering queries in a timely manner.

Details of the number of pages started but without full entry as per the CRF system is listed below: [Note 11]

CRF Pages Started	Pages Started not fully CRF Entered
45	7
Study avg./ Patient	17

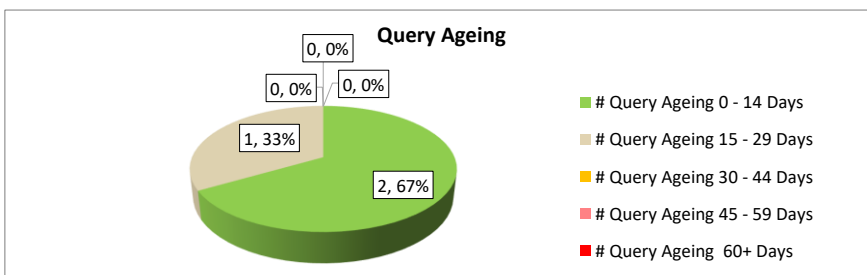
CRF pages have been identified as not being fully entered. Continued attempts to ensure timely entry is encouraged.

Details of the number of PK samples on site as per sponsor-provided lab report is listed below: [Note 12]

PK Sample ID	Sample Date
Vis01Post	17-Nov-18
Sum Total	1
Study avg./ Patient	1

PK samples are found to be on-site as per sponsor-provided lab report.

Report author note: Please encourage site to dispatch overdue samples.



Encourage site to answer all queries in prioritised fashion.

Dummy Study XYZ

Site 110: Monitoring Checklist

USA, Site 110, Patient 1100: Status Overview

Details of the number of visits overdue for CRF entry is listed below: [Note 13]

Visit	Estimated Date
No Findings	No Findings
Sum Total	0
Study avg./ Patient	1

No overdue visit data detected for this patient.

Visit chronology not as expected: date of visit 20 is before visit 19. Please check the CRF patient status and query with site if required.

Details of the number of open site queries is listed below: [Note 14]

Site Queries Answered	Site Open Queries Total
413	9
Study avg./ Patient	11

Queries are found to be pending a site response. Please continue to work towards answering queries in a timely manner.

Details of the number of pages started but without full entry as per the CRF system is listed below: [Note 15]

CRF Pages Started	Pages Started not fully CRF Entered
315	47
Study avg./ Patient	17

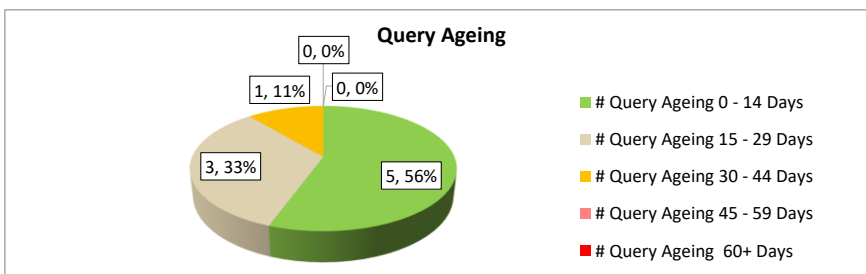
CRF pages have been identified as not being fully entered. Continued attempts to ensure timely entry is encouraged.

Details of the number of PK samples on site as per sponsor-provided lab report is listed below: [Note 16]

PK Sample ID	Sample Date
Vis19Pre15	04-Dec-18
Vis19Post15	04-Dec-18
Vis19Post30	04-Dec-18
Vis19Post45	04-Dec-18
Sum Total	4
Study avg./ Patient	1

PK samples are found to be on-site as per sponsor-provided lab report.

Report author note: Please encourage site to dispatch overdue samples.



Encourage site to answer all queries in prioritised fashion.

Dummy Study XYZ

Site 110: Monitoring Checklist

USA, Site 110, Patient 1179: Status Overview

Details of the number of visits overdue for CRF entry is listed below: [Note 17]

Visit	Estimated Date
No Findings	No Findings
Sum Total	0
Study avg./ Patient	1

No overdue visit data detected for this patient.

Details of the number of open site queries is listed below: [Note 18]

Site Queries Answered	Site Open Queries Total
373	19
Study avg./ Patient	11

Queries are found to be pending a site response. Please continue to work towards answering queries in a timely manner.

Details of the number of pages started but without full entry as per the CRF system is listed below: [Note 19]

CRF Pages Started	Pages Started not fully CRF Entered
285	43
Study avg./ Patient	17

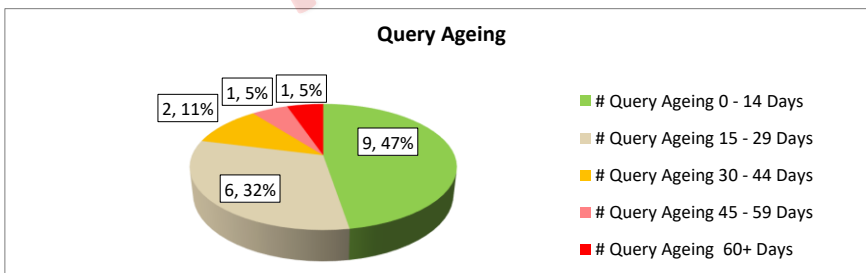
CRF pages have been identified as not being fully entered. Continued attempts to ensure timely entry is encouraged.

Details of the number of PK samples on site as per sponsor-provided lab report is listed below: [Note 20]

PK Sample ID	Sample Date
Vis18Pre15	17-Sep-18
Vis18Post15	17-Sep-18
Vis18Post30	17-Sep-18

PK samples are found to be on-site as per sponsor-provided lab report.

Report author note: Please encourage site to dispatch overdue samples.



Encourage site to answer all queries in prioritised fashion.

Dummy Study XYZ

Site 110: Monitoring Checklist

USA, Site 110, Patient 1289: Status Overview

Details of the number of visits overdue for CRF entry is listed below: [Note 21]

Visit	Estimated Date
Safety Follow Up 4	21-Nov-18
Safety Follow Up 5	05-Dec-18
Safety Follow Up 6	19-Dec-18
Sum Total	3
Study avg./ Patient	1

Visits are found to be expectant on CRF entry up to the date the data extract was performed.

A patient status conflict exists: at Safety Follow Up 2 the patient status indicates patient was not expecting further visits. Please check the CRF patient status and query with site if required.

Details of the number of open site queries is listed below: [Note 22]

Site Queries Answered	Site Open Queries Total
137	8
Study avg./ Patient	11

Queries are found to be pending a site response. Please continue to work towards answering queries in a timely manner.

Details of the number of pages started but without full entry as per the CRF system is listed below: [Note 23]

CRF Pages Started	Pages Started not fully CRF Entered
105	16
Study avg./ Patient	17

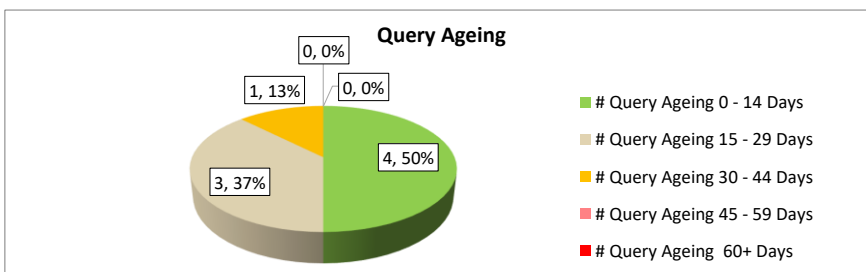
CRF pages have been identified as not being fully entered. Continued attempts to ensure timely entry is encouraged.

Details of the number of PK samples on site as per sponsor-provided lab report is listed below: [Note 24]

PK Sample ID	Sample Date
No Findings	No Findings
Sum Total	0
Study avg./ Patient	1

No PK samples are found to be on-site as per sponsor-provided lab report.

Report author note: Please encourage site to dispatch overdue samples.



Encourage site to answer all queries in prioritised fashion.

Dummy Study XYZ

Site 110: Monitoring Checklist

Concluding Remarks

Thank you for your review of this report and continued collaboration with this site. Any contact details provided in this report are to be used to discuss items specific to the report itself. However, please follow approved communication processes for any other types of issues that may exist.

PREVIEW

Dummy Study XYZ

Site 110: Monitoring Checklist

Report Notes

- 1: The report author ran this report to include the number of visits overdue for CRF entry for patient ID#1056. Please note that the prediction of visits due is based on correct CRF data entry, and is driven by the correct entry of patient statuses. Any unexpected visit due flagging must be assessed for correct data entry in the first instance. Data source: CRF. 4Site programmed check output includes: QueryID03. If needed, quote these checks in communication with report provider.
- 2: The report author ran this report to include the number of open site queries for patient ID#1056. Please note this metric is based on the date the data source was extracted. Data source: CRF.
- 3: The report author ran this report to include the number of pages started but without full entry as per the CRF system for patient ID#1056. Please note this metric is based on the date the data source was extracted. Data source: CRF.
- 4: The report author ran this report to include the number of PK samples on site as per sponsor-provided lab report for patient ID#1056. Please note that the prediction of PK samples found to be on-site is based on the sponsor-provided lab report and will only display a maximum of 10 samples on site for any given patient. Data source: Sponsor-provided lab report.
- 5: The report author ran this report to include the number of visits overdue for CRF entry for patient ID#1085. Please note that the prediction of visits due is based on correct CRF data entry, and is driven by the correct entry of patient statuses. Any unexpected visit due flagging must be assessed for correct data entry in the first instance. Data source: CRF.
- 6: The report author ran this report to include the number of open site queries for patient ID#1085. Please note this metric is based on the date the data source was extracted. Data source: CRF.
- 7: The report author ran this report to include the number of pages started but without full entry as per the CRF system for patient ID#1085. Please note this metric is based on the date the data source was extracted. Data source: CRF.
- 8: The report author ran this report to include the number of PK samples on site as per sponsor-provided lab report for patient ID#1085. Please note that the prediction of PK samples found to be on-site is based on the sponsor-provided lab report and will only display a maximum of 10 samples on site for any given patient. Data source: Sponsor-provided lab report.
- 9: The report author ran this report to include the number of visits overdue for CRF entry for patient ID#1089. Please note that the prediction of visits due is based on correct CRF data entry, and is driven by the correct entry of patient statuses. Any unexpected visit due flagging must be assessed for correct data entry in the first instance. Data source: CRF.
- 10: The report author ran this report to include the number of open site queries for patient ID#1089. Please note this metric is based on the date the data source was extracted. Data source: CRF.
- 11: The report author ran this report to include the number of pages started but without full entry as per the CRF system for patient ID#1089. Please note this metric is based on the date the data source was extracted. Data source: CRF.
- 12: The report author ran this report to include the number of PK samples on site as per sponsor-provided lab report for patient ID#1089. Please note that the prediction of PK samples found to be on-site is based on the sponsor-provided lab report and will only display a maximum of 10 samples on site for any given patient. Data source: Sponsor-provided lab report.
- 13: The report author ran this report to include the number of visits overdue for CRF entry for patient ID#1100. Please note that the prediction of visits due is based on correct CRF data entry, and is driven by the correct entry of patient statuses. Any unexpected visit due flagging must be assessed for correct data entry in the first instance. Data source: CRF. 4Site programmed check output includes: QueryID02. If needed, quote these checks in communication with report provider.
- 14: The report author ran this report to include the number of open site queries for patient ID#1100. Please note this metric is based on the date the data source was extracted. Data source: CRF.
- 15: The report author ran this report to include the number of pages started but without full entry as per the CRF system for patient ID#1100. Please note this metric is based on the date the data source was extracted. Data source: CRF.
- 16: The report author ran this report to include the number of PK samples on site as per sponsor-provided lab report for patient ID#1100. Please note that the prediction of PK samples found to be on-site is based on the sponsor-provided lab report and will only display a maximum of 10 samples on site for any given patient. Data source: Sponsor-provided lab report.
- 17: The report author ran this report to include the number of visits overdue for CRF entry for patient ID#1179. Please note that the prediction of visits due is based on correct CRF data entry, and is driven by the correct entry of patient statuses. Any unexpected visit due flagging must be assessed for correct data entry in the first instance. Data source: CRF.
- 18: The report author ran this report to include the number of open site queries for patient ID#1179. Please note this metric is based on the date the data source was extracted. Data source: CRF.
- 19: The report author ran this report to include the number of pages started but without full entry as per the CRF system for patient ID#1179. Please note this metric is based on the date the data source was extracted. Data source: CRF.
- 20: The report author ran this report to include the number of PK samples on site as per sponsor-provided lab report for patient ID#1179. Please note that the prediction of PK samples found to be on-site is based on the sponsor-provided lab report and will only display a maximum of 10 samples on site for any given patient. Data source: Sponsor-provided lab report.
- 21: The report author ran this report to include the number of visits overdue for CRF entry for patient ID#1289. Please note that the prediction of visits due is based on correct CRF data entry, and is driven by the correct entry of patient statuses. Any unexpected visit due flagging must be assessed for correct data entry in the first instance. Data source: CRF. 4Site programmed check output includes: QueryID01. If needed, quote these checks in communication with report provider.
- 22: The report author ran this report to include the number of open site queries for patient ID#1289. Please note this metric is based on the date the data source was extracted. Data source: CRF.

Dummy Study XYZ

Site 110: Monitoring Checklist

23: The report author ran this report to include the number of pages started but without full entry as per the CRF system for patient ID#1289. Please note this metric is based on the date the data source was extracted. Data source: CRF.

24: The report author ran this report to include the number of PK samples on site as per sponsor-provided lab report for patient ID#1289. Please note that the prediction of PK samples found to be on-site is based on the sponsor-provided lab report and will only display a maximum of 10 samples on site for any given patient. Data source: Sponsor-provided lab report.

PREVIEW