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Site 110: Pre-IDMC Meeting Data Status Report

Pre-IDMC Meeting Data Status Report

Report Information

4Site Report Provider Name	Natalie Smith
4Site Report Provider email	smithn@email.com
Deliverable Reminder	IDMC 1 data review, audience: Study lead, PM,Regional/Country managers, CRAs
IDMC Meeting date	01-Mar-19

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Report Introduction

With recently reaching 225 patients randomised, we are quickly approaching the trigger that will implement our data cut off for the IDMC meeting. As a reminder, the trigger will occur when the study randomises 300 patients. Using this report shows the state of play for the above site as we approach the study's first IDMC meeting which will occur shortly after we achieve randomising 300 patients. As of 10 November 2018 we have 200 patients randomised. Using the 4Site projection utility, we anticipate the targetted 300 randomised patients around 15 January 2019.

It is imperative that we ensure all activities are all front-loaded as much as possible.

- Data entered in a timely manner (within 5 days of visit, as per guidelines)

- Queries promptly answered by sites

- Ensure protocol violations have been entered

- SAEs reported

- All patients have been monitored as per Monitoring Plan (v2.3).

This report has been arranged to give a top-down overview. It gradually drills down from country to give greatest detail at patient level.

NB: data tables have a statistical relevance indicator based on standard deviation ('SD'). This is to point out any particular data that should be given priority when followed up. It gives a weighting as to where the focused action should be, e.g. following up a 10 patient site that has 100 outstanding queries or a 1 patient site with 100 queries.

Explanations as to how some data is derived is explained in the 'Report notes' section.

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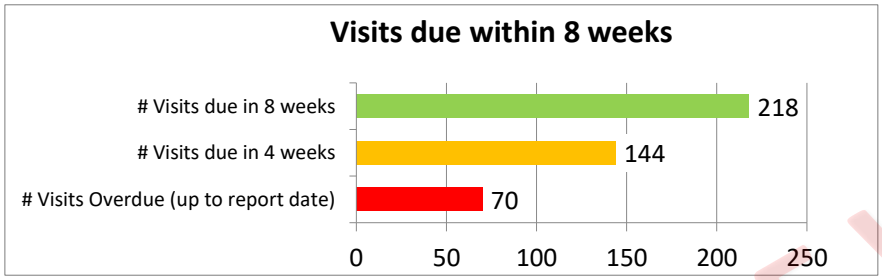
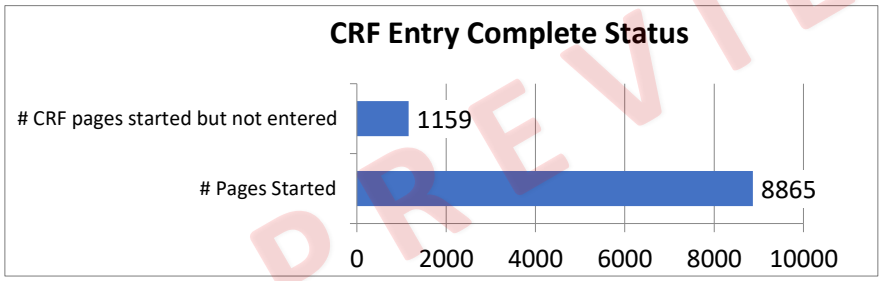
Comparison of Participating Sites

This report section has been generated with a focus on the following Site(s): 110, 118, 123, 135, 139, 145 and 165. This can be used as an aid to establish trends and differences between the included Site(s) the report author has chosen to include, in addition to how these compare with Site(s) across the study as a whole.

As we approach the IDMC, please ensure your sites have NO overdue visits. We do not have the resources to be dealing with visits that should have been entered weeks ago. Please also ensure your site staff are aware of visits occurring between now and the IDMC cut off date. Similarly, sites need to be on top of all data entry. We have a high number of pages started but not completed. Almost 10% of outstanding queries are over 60days old. This is unacceptable.



Please investigate /action as a priority any overdue visits (refer to the site-level section for detailed info). NB: data in chart is cumulative.



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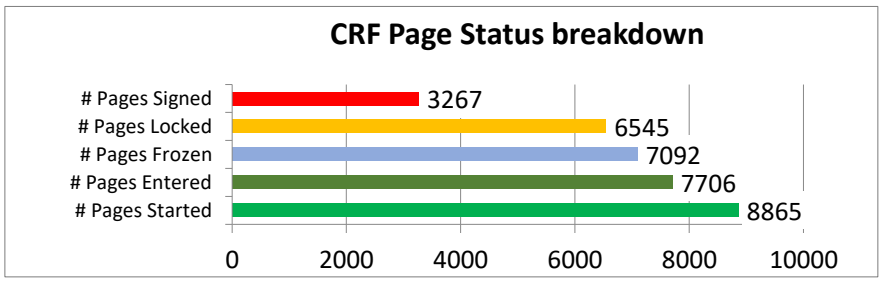
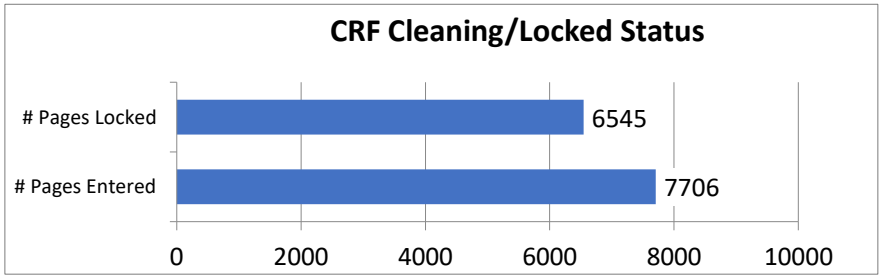


Please liaise with sites in getting all data entered. For the IDMC we do not require PI signatures, but need pages locked for this deliverable made possible with full data entry and query resolution.



Reminder: timely query resolution drives timely data cleaning and locking of pages.

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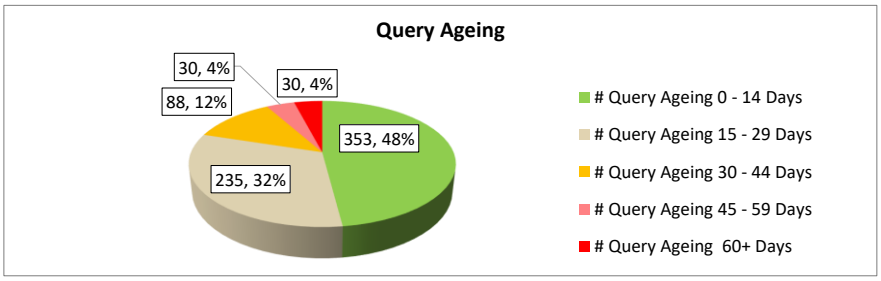
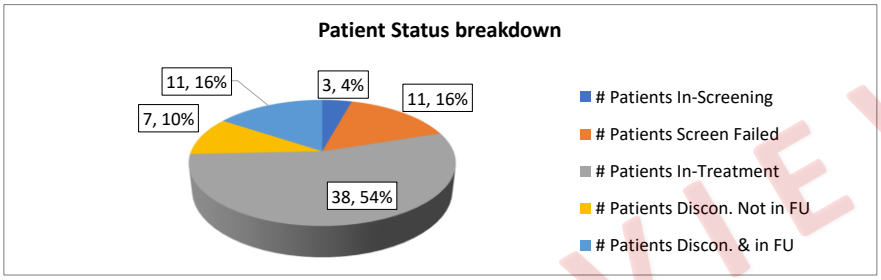


Please address all queries, but especially those of higher age. As we approach the IDMC we need to see a lot more green on the pie chart.

For patients in follow-up, please ensure their follow-up visits are up to date. This data is required for the IDMC!

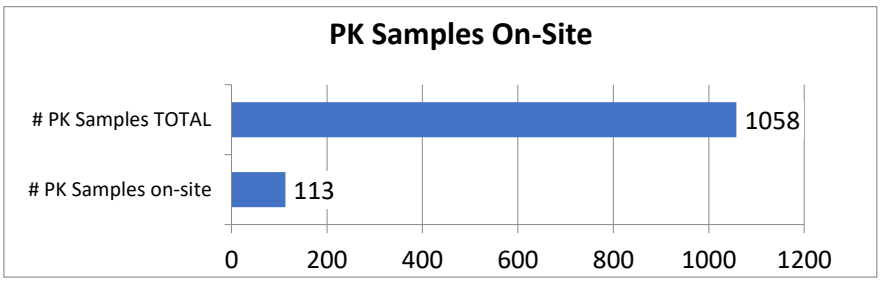
For patients discontinued, but not in follow-up, please ensure the reason for not being in follow-up is valid/correct.



The number of patients discontinued from treatment and not in follow-up was assessed across the selection for all Site(s) the lowest [Note 1]

Region	Country	Site #	# Patients	# Patients Discon. Not in FU
N.America	USA	118	9	0
N.America	USA	110	7	1
N.America	USA	123	14	1
N.America	USA	139	9	1
N.America	USA	145	14	1
N.America	USA	165	3	1
N.America	USA	135	14	2
Study avg./ Site	-	-	-	0.8

Cases are present where the number of patients discontinued from treatment and not in follow-up is above average per Site(s) across the study. Please monitor closely.
Report author note: Please check these patients to ensure they are correct not to have proceeded into the study follow-up. FU data is important for the IDMC - check we have all patients captured correctly per protocol.



Ensure samples at site are collected. Follow escalation processes for any block in collection. REMINDER: PK data will be looked at by the IDMC so we want to include as much data as we can.

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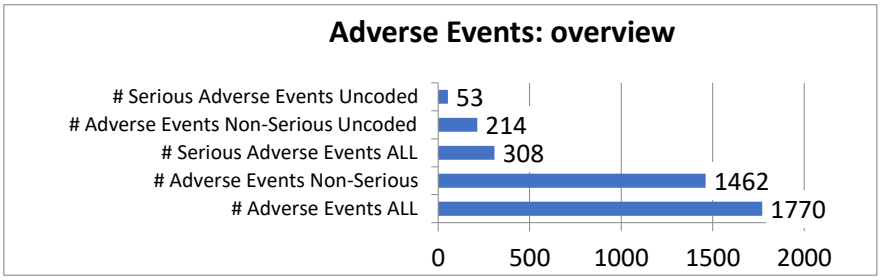

Please ensure all (S)AE coding queries are addressed.
REMINDER: safety data is a part of the IDMC.

The number of visits overdue for CRF entry was assessed to find the highest cases based on an SD of 0.5. No cases were found with statistical significance to report. Instead this metric was assessed across the selection for the highest 10 Site(s) (as a maximum) with the most number of visits overdue for CRF entry. Please see sidenotes. [Note 2]

Region	Country	Site #	# Patients	# Visits Overdue (up to report date)
N.America	USA	123	14	16
N.America	USA	145	14	15
N.America	USA	118	9	13
N.America	USA	135	14	10
N.America	USA	139	9	7
N.America	USA	110	7	6
N.America	USA	165	3	3
Study avg./ Site	-	-	-	9

Cases are present where the number of visits overdue for CRF entry is above average per Site(s) across the study. Please monitor closely.

The number of pages started but without full entry as per the CRF system was assessed to find the highest cases based on an SD of 0.5. No cases were found with statistical significance to report. Instead this metric was assessed across the selection for the highest 5 Site(s) (as a maximum) with the most number of pages started but without full entry as per the CRF system. Please see sidenotes. [Note 3]

Region	Country	Site #	# Patients	# CRF pages started but not entered
N.America	USA	135	14	245
N.America	USA	145	14	241
N.America	USA	123	14	203
N.America	USA	118	9	148
N.America	USA	110	7	136
Study avg./ Site	-	-	-	135

Cases are present where the total number of records are either average or above average when compared to number of pages started but without full entry as per the CRF system Site(s) across the study. Please monitor closely.

The number of patients that have had CRF data entry was assessed to find the lowest cases based on an SD of 0.5. No cases were found with statistical significance to report. Instead this metric was assessed across the selection for the lowest 10 Site(s) (as a maximum) with the least number of patients that have had CRF data entry. Please see sidenotes. [Note 4]

Region	Country	Site #	# Patients	# Patients CRF-Entered
N.America	USA	165	3	3
N.America	USA	110	7	7
N.America	USA	118	9	9
N.America	USA	139	9	9
N.America	USA	123	14	14
N.America	USA	135	14	14
N.America	USA	145	14	14
Study avg./ Site	-	-	-	8

Cases are present where the total number of records are either average or above average when compared to number of patients that have had CRF data entry Site(s) across the study. Please monitor closely.

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The days between visit & entry of data was assessed to find the highest cases based on an SD of 0.5. No cases were found with statistical significance to report. Instead this metric was assessed across the selection for the highest 5 Site(s) (as a maximum) with the most days between visit & entry of data. Please see sidenotes. [Note 5]

Region	Country	Site #	# Patients	Average Days to Data Entry
N.America	USA	165	3	9.82
N.America	USA	145	14	8.47
N.America	USA	110	7	8.28
N.America	USA	118	9	7.68
N.America	USA	135	14	7.63
Study avg./ Site	-	-	-	7.84

Cases are present where the total number of records are either average or above average when compared to days between visit & entry of data Site(s) across the study. Please monitor closely.

The number of PK Samples on-site was assessed to find the highest cases based on an SD of 0.5. No cases were found with statistical significance to report. Instead this metric was assessed across the selection for the highest 5 Site(s) (as a maximum) with the most number of PK Samples on-site. Please see sidenotes. [Note 6]

Region	Country	Site #	# Patients	# PK Samples on-site
N.America	USA	135	14	25
N.America	USA	123	14	24
N.America	USA	145	14	21
N.America	USA	139	9	16
N.America	USA	118	9	13
Study avg./ Site	-	-	-	13

Cases are present where the total number of records are either average or above average when compared to number of PK Samples on-site Site(s) across the study. Please monitor closely.
Report author note: Since the IDMC is looking at PK data, we need to get as many samples analysed - therefore please chase all on-site samples.

The number of uncoded Non-Serious AEs in the CRF was assessed to find the highest cases based on an SD of 0.5. No cases were found with statistical significance to report. Instead this metric was assessed across the selection for the highest 5 Site(s) (as a maximum) with the most number of uncoded Non-Serious AEs in the CRF. Please see sidenotes. [Note 7]

Region	Country	Site #	# Patients	# Adverse Events Non-Serious Uncoded
N.America	USA	135	14	48
N.America	USA	145	14	43
N.America	USA	123	14	35
N.America	USA	110	7	27
N.America	USA	118	9	23
Study avg./ Site	-	-	-	25

Cases are present where the total number of records are either average or above average when compared to number of uncoded Non-Serious AEs in the CRF Site(s) across the study. Please monitor closely.
Report author note: Safety data is required for the IDMC and will require all AEs to be coded.

The number of uncoded Serious AEs in the CRF was assessed to find the highest cases based on an SD of 0.5. No cases were found with statistical significance to report. Instead this metric was assessed across the selection for the highest 5 Site(s) (as a maximum) with the most number of uncoded Serious AEs in the CRF. Please see sidenotes. [Note 8]

Region	Country	Site #	# Patients	# Serious Adverse Events Uncoded
N.America	USA	135	14	12
N.America	USA	145	14	11
N.America	USA	123	14	8
N.America	USA	110	7	7
N.America	USA	118	9	6
Study avg./ Site	-	-	-	6

Cases are present where the total number of records are either average or above average when compared to number of uncoded Serious AEs in the CRF Site(s) across the study. Please monitor closely.
Report author note: Safety data is required for the IDMC and will require all AEs to be coded.

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The average time from query raised to query answered was assessed to find the highest cases based on an SD of 0.5. No cases were found with statistical significance to report. Instead this metric was assessed across the selection for the highest 5 Site(s) (as a maximum) with the most average time from query raised to query answered. Please see sidenotes. [Note 9]

Region	Country	Site #	# Patients	Average Days Site(s) to Answer Queries
N.America	USA	139	9	7.95
N.America	USA	123	14	7.9
N.America	USA	118	9	7.47
N.America	USA	135	14	7.42
N.America	USA	145	14	7.32
Study avg./ Site	-	-	-	7.52

Cases are present where the average time from query raised to query answered is close to the average per Site(s) across the study. These may require closer monitoring.

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N.America: Status Overview

For the attention of: Regional clinical managers. The following summaries may be of interest to see how your region compares to others. But these are areas best looked into at the site level.

The number of visits overdue for CRF entry for this Region is presented below. [Note 10]

Region	# Countries	# Sites	# Patients	# Visits Overdue (up to report date)
N.America	2	13	118	123
Study avg./ Region	-	-	-	105

This indicates that the number of visits overdue for CRF entry is above average per Region across the study. Please monitor closely.

The number of open site queries for this Region is presented below. [Note 11]

Region	# Countries	# Sites	# Patients	# Site unanswered Site Queries (Total)
N.America	2	13	118	1276
Study avg./ Region	-	-	-	1086

This indicates that the number of open site queries is above average per Region across the study. Please monitor closely.

The number of PK Samples on-site for this Region is presented below. [Note 12]

Region	# Countries	# Sites	# Patients	# PK Samples on-site
N.America	2	13	118	192
Study avg./ Region	-	-	-	165

This indicates that the number of PK Samples on-site is above average per Region across the study. Please monitor closely.

The following tables show historical metrics of interest. Please look for outlying figures and drill down to the Site Level of this report for better understanding of where issues exist.

The days between visit & entry of data for this Region is presented below. [Note 13]

Region	# Countries	# Sites	# Patients	Average Days to Data Entry
N.America	2	13	118	7.86
Study avg./ Region	-	-	-	7.84

This indicates that the days between visit & entry of data is close to the average per Region across the study. These may require closer monitoring.

The average time from query raised to query answered for this Region is presented below. [Note 14]

Region	# Countries	# Sites	# Patients	Average Days Site(s) to Answer Queries
N.America	2	13	118	7.51
Study avg./ Region	-	-	-	7.52

This indicates that the average time from query raised to query answered is close to the average per Region across the study. These may require closer monitoring.

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USA: Status Overview

For the attention of Country managers: The following summaries may be of interest to see how your country compares to others. But these are areas best looked into at the site level.

The number of visits overdue for CRF entry for this Country is presented below. [Note 15]

Region	Country	# Sites	# Patients	# Visits Overdue (up to report date)
N.America	USA	8	83	85
Study avg./ Country	-	-	-	26

This indicates that the number of visits overdue for CRF entry is above average per Country across the study. Please monitor closely.

The number of open site queries for this Country is presented below. [Note 16]

Region	Country	# Sites	# Patients	# Site unanswered Site Queries (Total)
N.America	USA	8	83	893
Study avg./ Country	-	-	-	272

This indicates that the number of open site queries is above average per Country across the study. Please monitor closely.

The number of PK Samples on-site for this Country is presented below. [Note 17]

Region	Country	# Sites	# Patients	# PK Samples on-site
N.America	USA	8	83	136
Study avg./ Country	-	-	-	41

This indicates that the number of PK Samples on-site is above average per Country across the study. Please monitor closely.

The following tables show historical metrics of interest. Please look for outlying figures and drill down to the Site Level of this report for better understanding of where issues exist.

The days between visit & entry of data for this Country is presented below. [Note 18]

Region	Country	# Sites	# Patients	Average Days to Data Entry
N.America	USA	8	83	7.85
Study avg./ Country	-	-	-	7.84

This indicates that the days between visit & entry of data is close to the average per Country across the study. These may require closer monitoring.

The average time from query raised to query answered for this Country is presented below. [Note 19]

Region	Country	# Sites	# Patients	Average Days Site(s) to Answer Queries
N.America	USA	8	83	7.53
Study avg./ Country	-	-	-	7.52

This indicates that the average time from query raised to query answered is close to the average per Country across the study. These may require closer monitoring.

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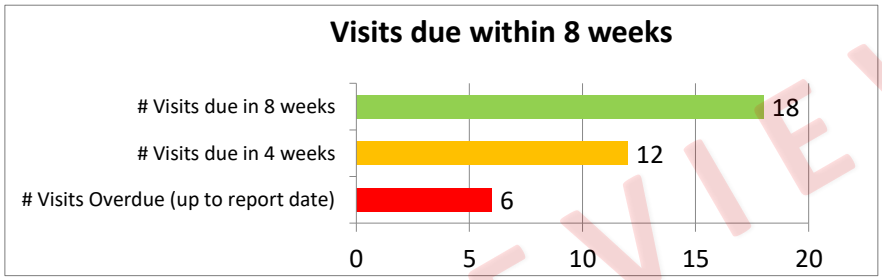
USA, Site 110: Status Overview

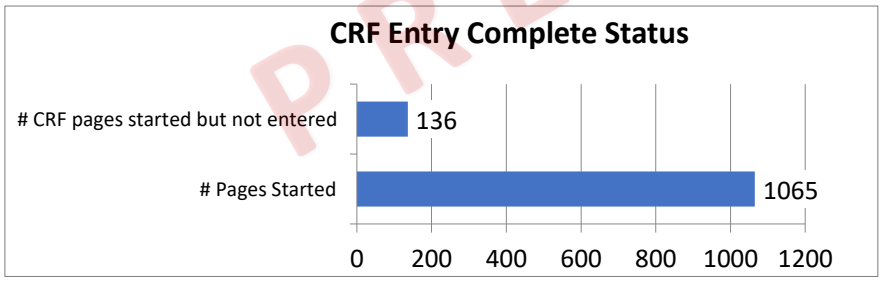
Site Information

Site Investigator Name	Dr. D. Denton
EUDRACT Number	2018-123456-01
Deliverable Reminder	IDMC 1 data review
CRA Name	William Broodie
CRA email	wBroodie@email.com
Data cut-off date	30-Jan-19
EDC Data to be entered (eob)	15-Feb-19
4Site Report Provider Name	Natalie Smith
4Site Report Provider email	smithn@email.com

The following are summaries of key metrics and overviews of this specific site that will aid in meeting the deliverable for the study's first IDMC meeting. Please also drill down to the Patient Level for more details.



Please investigate /action as a priority any overdue visits (refer to the site-level section for detailed info). NB: data in chart is cumulative.



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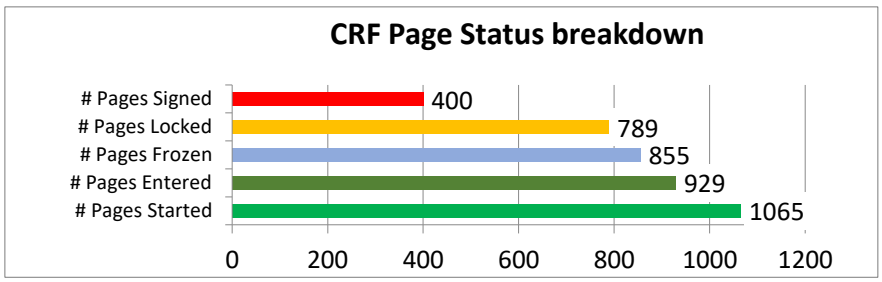

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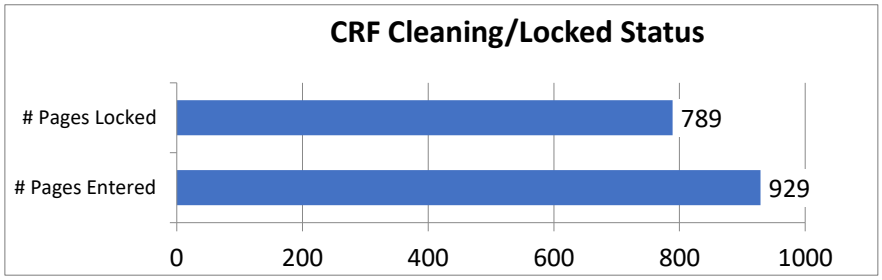
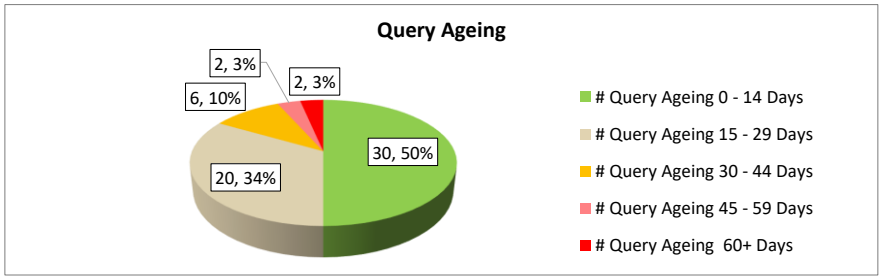


Please navigate into report to see where most of these backlogs are, and to establish why we have pages not locked (eg, open queries).



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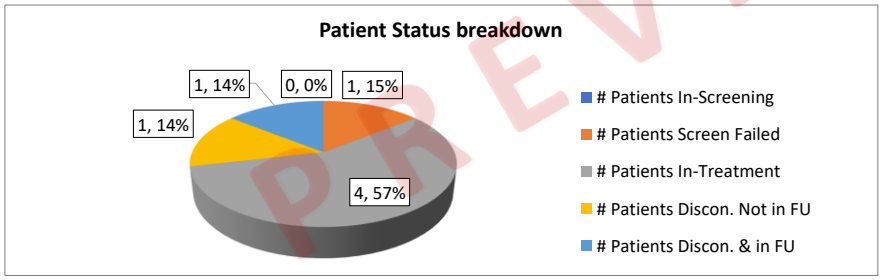
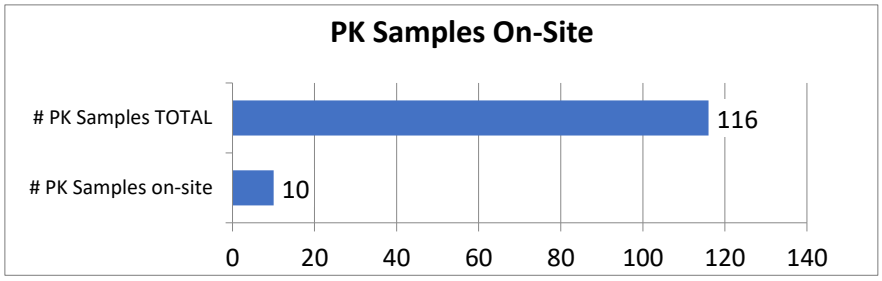
For patients discontinued, but not in follow-up, please ensure the reason for not being in follow-up is valid/correct.



The number of patients discontinued from treatment and not in follow-up for this Site is presented below. [Note 20]

Region	Country	Site #	# Patients	# Patients Discon. Not in FU
N.America	USA	110	7	1
Study avg./ Site	-	-	-	0.8

This indicates that the number of patients discontinued from treatment and not in follow-up is above average per Site across the study. Please monitor closely.



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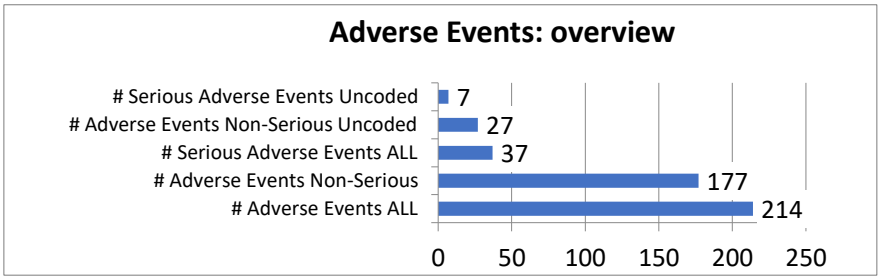

Please ensure all (S)AE coding queries are addressed.
REMINDER: safety data is a part of the IDMC.

The number of visits overdue for CRF entry for this Site is presented below. [Note 21]

Region	Country	Site #	# Patients	# Visits Overdue (up to report date)
N.America	USA	110	7	6
Study avg./ Site	-	-	-	9

This indicates that the total number of visits overdue for CRF entry are below the average per Site across the study.

The number of pages started but without full entry as per the CRF system for this Site is presented below. [Note 22]

Region	Country	Site #	# Patients	# CRF pages started but not entered
N.America	USA	110	7	136
Study avg./ Site	-	-	-	135

This indicates that the number of pages started but without full entry as per the CRF system is close to the average per Site across the study. These may require closer monitoring.

The number of patients that have had CRF data entry for this Site is presented below. [Note 23]

Region	Country	Site #	# Patients	# Patients CRF-Entered
N.America	USA	110	7	7
Study avg./ Site	-	-	-	8

This indicates that the number of patients that have had CRF data entry is close to the average per Site across the study. These may require closer monitoring.

The days between visit & entry of data was assessed to find whether the Site had statistically high numbers based on an SD of 0.5. The metric was not found to have statistical signifance at this level, but is presented below. [Note 24]

Region	Country	Site #	# Patients	Average Days to Data Entry
N.America	USA	110	7	8.28
Study avg./ Site	-	-	-	7.84

This indicates that the days between visit & entry of data is close to the average per Site across the study. These may require closer monitoring.

The number of PK Samples on-site was assessed to find whether the Site had statistically high numbers based on an SD of 0.5. The metric was not found to have statistical signifance at this level, but is presented below. [Note 25]

Region	Country	Site #	# Patients	# PK Samples on-site
N.America	USA	110	7	10
Study avg./ Site	-	-	-	13

This indicates that the total number of PK Samples on-site are below the average per Site across the study. Report author note: Since the IDMC is looking at PK data, we need to get as many samples analysed - therefore please chase all on-site samples.

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The number of uncoded Non-Serious AEs in the CRF was assessed to find whether the Site had statistically high numbers based on an SD of 0.5. The metric was not found to have statistical signifance at this level, but is presented below. [Note 26]

Region	Country	Site #	# Patients	# Adverse Events Non-Serious Uncoded
N.America	USA	110	7	27
Study avg./ Site	-	-	-	25

This indicates that the number of uncoded Non-Serious AEs in the CRF is close to the average per Site across the study. These may require closer monitoring.
Report author note: Safety data is required for the IDMC and will require all AEs to be coded.

The number of uncoded Serious AEs in the CRF was assessed to find whether the Site had statistically high numbers based on an SD of 0.5. The metric was not found to have statistical signifance at this level, but is presented below. [Note 27]

Region	Country	Site #	# Patients	# Serious Adverse Events Uncoded
N.America	USA	110	7	7
Study avg./ Site	-	-	-	6

This indicates that the number of uncoded Serious AEs in the CRF is above average per Site across the study. Please monitor closely.
Report author note: Safety data is required for the IDMC and will require all AEs to be coded.

The average time from query raised to query answered was assessed to find whether the Site had statistically high numbers based on an SD of 0.5. The metric was not found to have statistical signifance at this level, but is presented below. [Note 28]

Region	Country	Site #	# Patients	Average Days Site(s) to Answer Queries
N.America	USA	110	7	7.06
Study avg./ Site	-	-	-	7.52

This indicates that the average time from query raised to query answered is close to the average per Site across the study. These may require closer monitoring.

Dummy Study XYZ

Site 110: Pre-IDMC Meeting Data Status Report

USA, Site 110, Patient 1056: Status Overview

Please use the below information to clear backlogs for this patient. This is the lowest level of this report and it will be necessary to utilise systems (eg, EDC) to drill down to lower levels and address issues in question.

Details of the number of visits overdue for CRF entry is listed below: [Note 29]

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 30]

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 31]

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 uncoded Non-Serious AEs in the CRF is listed below: [Note 32]

# Non-Serious AEs reported in the CRF	# Non-Serious AEs reported in the CRF & NOT coded
20	3
Study avg./ Patient	3

Non-Serious Adverse Events need to be coded. Please continue timely coding and address any potentially open queries relating to coding.

Details of the number of uncoded Serious AEs in the CRF is listed below: [Note 33]

# Serious AEs reported in the CRF	# Serious AEs reported in the CRF & NOT coded
4	1
Study avg./ Patient	1

Serious Adverse Events need to be coded. Please continue timely coding and address any potentially open queries relating to coding.

Details of the number of PK samples on site as per sponsor-provided lab report is listed below: [Note 34]

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

Table continued on next page...

Dummy Study XYZ

Site 110: Pre-IDMC Meeting Data Status Report

PK Sample ID	Sample Date
Vis05Post60	21-Oct-18

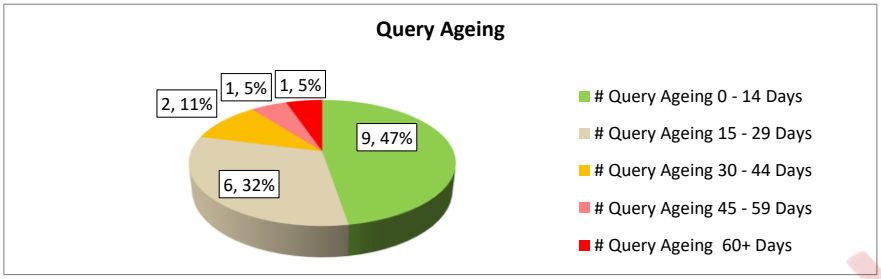
PK samples are found to be on-site as per sponsor-provided lab report.

Report author note: Please also refer to the 4Site PK tool to assist in PK sample investigations.

Details of the number of site queries that are open for over 60 days is listed below: [Note 35]

Site Open Queries Total	Site Open Queries 60+ Days
19	1
Study avg./ Patient	0

Queries are found to be pending a site response for over 60 days. Queries of such ageing may be related to open discussion within study teams or sites may have difficulty comprehending the query. Please ensure queries of this age are handled as soon as possible.



Please address all queries, but especially those of higher age. As we approach the IDMC we need to see green on the pie chart.

Dummy Study XYZ

Site 110: Pre-IDMC Meeting Data Status Report

USA, Site 110, Patient 1074: Status Overview

Please use the below information to clear backlogs for this patient. This is the lowest level of this report and it will be necessary to utilise systems (eg, EDC) to drill down to lower levels and address issues in question.

Details of the number of visits overdue for CRF entry is listed below: [Note 36]

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 37]

Site Queries Answered	Site Open Queries Total
270	0
Study avg./ Patient	11

No queries are found to be pending a site response.

Details of the number of pages started but without full entry as per the CRF system is listed below: [Note 38]

CRF Pages Started	Pages Started not fully CRF Entered
180	5
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 uncoded Non-Serious AEs in the CRF is listed below: [Note 39]

# Non-Serious AEs reported in the CRF	# Non-Serious AEs reported in the CRF & NOT coded
30	5
Study avg./ Patient	3

Non-Serious Adverse Events need to be coded. Please continue timely coding and address any potentially open queries relating to coding.

Details of the number of uncoded Serious AEs in the CRF is listed below: [Note 40]

# Serious AEs reported in the CRF	# Serious AEs reported in the CRF & NOT coded
6	1
Study avg./ Patient	1

Serious Adverse Events need to be coded. Please continue timely coding and address any potentially open queries relating to coding.

Details of the number of PK samples on site as per sponsor-provided lab report is listed below: [Note 41]

Dummy Study XYZ

Site 110: Pre-IDMC Meeting Data Status Report

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

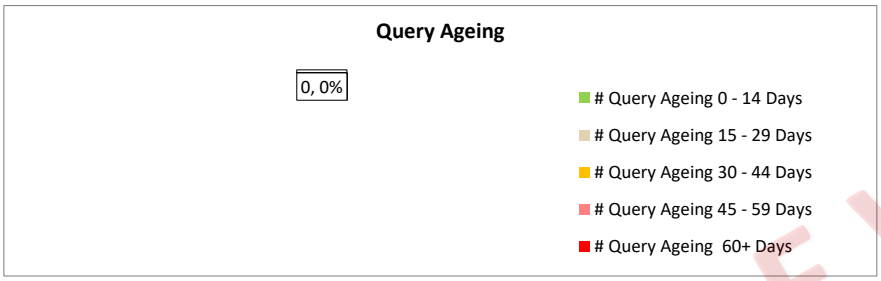
No PK samples are found to be on-site as per sponsor-provided lab report.

Report author note: Please also refer to the 4Site PK tool to assist in PK sample investigations.

Details of the number of site queries that are open for over 60 days is listed below: [Note 42]

Site Open Queries Total	Site Open Queries 60+ Days
0	0
Study avg./ Patient	0

No queries are found to be pending a site response for over 60 days.



Please address all queries, but especially those of higher age. As we approach the IDMC we need to see green on the pie chart.

Dummy Study XYZ

Site 110: Pre-IDMC Meeting Data Status Report

USA, Site 110, Patient 1085: Status Overview

Please use the below information to clear backlogs for this patient. This is the lowest level of this report and it will be necessary to utilise systems (eg, EDC) to drill down to lower levels and address issues in question.

Details of the number of visits overdue for CRF entry is listed below: [Note 43]

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 44]

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 45]

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 uncoded Non-Serious AEs in the CRF is listed below: [Note 46]

# Non-Serious AEs reported in the CRF	# Non-Serious AEs reported in the CRF & NOT coded
0	0
Study avg./ Patient	3

No Adverse Events entered in the CRF need to be coded.

Details of the number of uncoded Serious AEs in the CRF is listed below: [Note 47]

# Serious AEs reported in the CRF	# Serious AEs reported in the CRF & NOT coded
0	0
Study avg./ Patient	1

No Serious Adverse Events entered in the CRF need to be coded.

Details of the number of PK samples on site as per sponsor-provided lab report is listed below: [Note 48]

Dummy Study XYZ

Site 110: Pre-IDMC Meeting Data Status Report

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

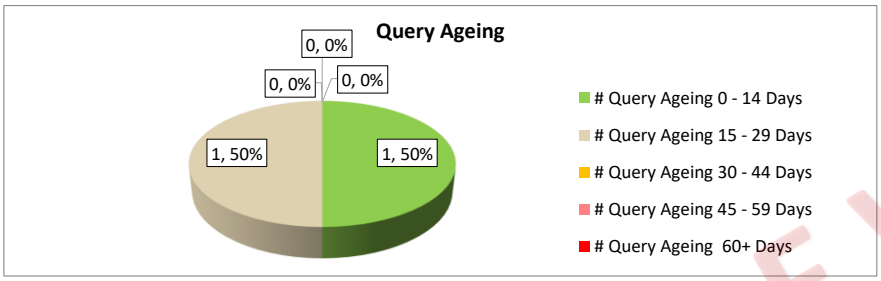
No PK samples are found to be on-site as per sponsor-provided lab report.

Report author note: Please also refer to the 4Site PK tool to assist in PK sample investigations.

Details of the number of site queries that are open for over 60 days is listed below: [Note 49]

Site Open Queries Total	Site Open Queries 60+ Days
2	0
Study avg./ Patient	0

No queries are found to be pending a site response for over 60 days.



Please address all queries, but especially those of higher age. As we approach the IDMC we need to see green on the pie chart.

Dummy Study XYZ

Site 110: Pre-IDMC Meeting Data Status Report

USA, Site 110, Patient 1089: Status Overview

Please use the below information to clear backlogs for this patient. This is the lowest level of this report and it will be necessary to utilise systems (eg, EDC) to drill down to lower levels and address issues in question.

Details of the number of visits overdue for CRF entry is listed below: [Note 50]

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 51]

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 52]

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 uncoded Non-Serious AEs in the CRF is listed below: [Note 53]

# Non-Serious AEs reported in the CRF	# Non-Serious AEs reported in the CRF & NOT coded
8	1
Study avg./ Patient	3

Non-Serious Adverse Events need to be coded. Please continue timely coding and address any potentially open queries relating to coding.

Details of the number of uncoded Serious AEs in the CRF is listed below: [Note 54]

# Serious AEs reported in the CRF	# Serious AEs reported in the CRF & NOT coded
2	0
Study avg./ Patient	1

No Serious Adverse Events entered in the CRF need to be coded.

Details of the number of PK samples on site as per sponsor-provided lab report is listed below: [Note 55]

Dummy Study XYZ

Site 110: Pre-IDMC Meeting Data Status Report

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

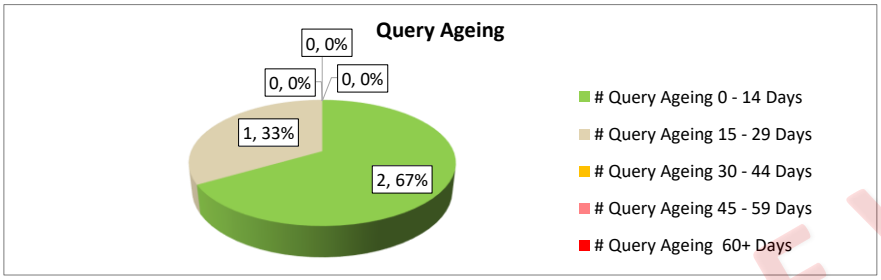
PK samples are found to be on-site as per sponsor-provided lab report.

Report author note: Please also refer to the 4Site PK tool to assist in PK sample investigations.

Details of the number of site queries that are open for over 60 days is listed below: [Note 56]

Site Open Queries Total	Site Open Queries 60+ Days
3	0
Study avg./ Patient	0

No queries are found to be pending a site response for over 60 days.



Please address all queries, but especially those of higher age. As we approach the IDMC we need to see green on the pie chart.

Dummy Study XYZ

Site 110: Pre-IDMC Meeting Data Status Report

USA, Site 110, Patient 1100: Status Overview

Please use the below information to clear backlogs for this patient. This is the lowest level of this report and it will be necessary to utilise systems (eg, EDC) to drill down to lower levels and address issues in question.

Details of the number of visits overdue for CRF entry is listed below: [Note 57]

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 58]

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 59]

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 uncoded Non-Serious AEs in the CRF is listed below: [Note 60]

# Non-Serious AEs reported in the CRF	# Non-Serious AEs reported in the CRF & NOT coded
53	8
Study avg./ Patient	3

Non-Serious Adverse Events need to be coded. Please continue timely coding and address any potentially open queries relating to coding.

Details of the number of uncoded Serious AEs in the CRF is listed below: [Note 61]

# Serious AEs reported in the CRF	# Serious AEs reported in the CRF & NOT coded
11	2
Study avg./ Patient	1

Serious Adverse Events need to be coded. Please continue timely coding and address any potentially open queries relating to coding.

Details of the number of PK samples on site as per sponsor-provided lab report is listed below: [Note 62]

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

Table continued on next page...

Dummy Study XYZ

Site 110: Pre-IDMC Meeting Data Status Report

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

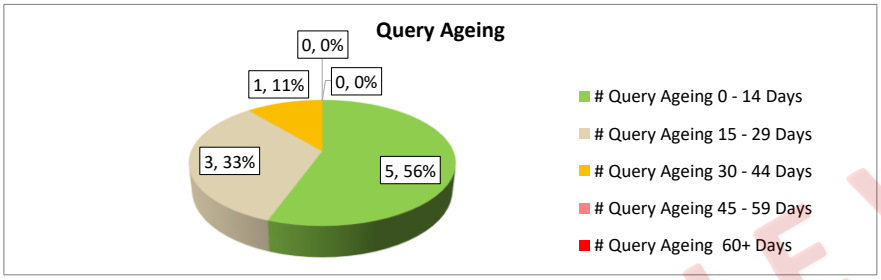
PK samples are found to be on-site as per sponsor-provided lab report.

Report author note: Please also refer to the 4Site PK tool to assist in PK sample investigations.

Details of the number of site queries that are open for over 60 days is listed below: [Note 63]

Site Open Queries Total	Site Open Queries 60+ Days
9	0
Study avg./ Patient	0

No queries are found to be pending a site response for over 60 days.



Please address all queries, but especially those of higher age. As we approach the IDMC we need to see green on the pie chart.

Dummy Study XYZ

Site 110: Pre-IDMC Meeting Data Status Report

USA, Site 110, Patient 1179: Status Overview

Please use the below information to clear backlogs for this patient. This is the lowest level of this report and it will be necessary to utilise systems (eg, EDC) to drill down to lower levels and address issues in question.

Details of the number of visits overdue for CRF entry is listed below: [Note 64]

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 65]

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 66]

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 uncoded Non-Serious AEs in the CRF is listed below: [Note 67]

# Non-Serious AEs reported in the CRF	# Non-Serious AEs reported in the CRF & NOT coded
48	7
Study avg./ Patient	3

Non-Serious Adverse Events need to be coded. Please continue timely coding and address any potentially open queries relating to coding.

Details of the number of uncoded Serious AEs in the CRF is listed below: [Note 68]

# Serious AEs reported in the CRF	# Serious AEs reported in the CRF & NOT coded
10	2
Study avg./ Patient	1

Serious Adverse Events need to be coded. Please continue timely coding and address any potentially open queries relating to coding.

Details of the number of PK samples on site as per sponsor-provided lab report is listed below: [Note 69]

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

Table continued on next page...

Dummy Study XYZ

Site 110: Pre-IDMC Meeting Data Status Report

PK Sample ID	Sample Date
Vis18Post30	17-Sep-18

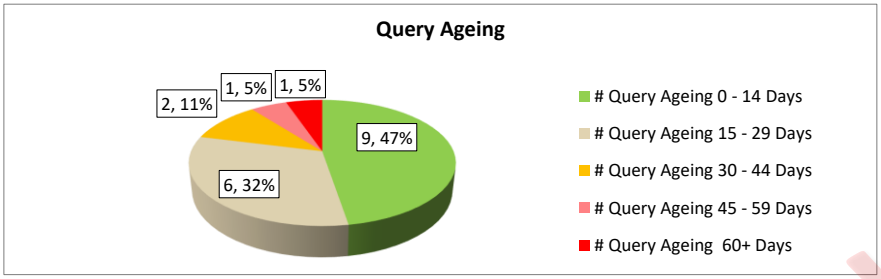
PK samples are found to be on-site as per sponsor-provided lab report.

Report author note: Please also refer to the 4Site PK tool to assist in PK sample investigations.

Details of the number of site queries that are open for over 60 days is listed below: [Note 70]

Site Open Queries Total	Site Open Queries 60+ Days
19	1
Study avg./ Patient	0

Queries are found to be pending a site response for over 60 days. Queries of such ageing may be related to open discussion within study teams or sites may have difficulty comprehending the query. Please ensure queries of this age are handled as soon as possible.



Please address all queries, but especially those of higher age. As we approach the IDMC we need to see green on the pie chart.

Dummy Study XYZ

Site 110: Pre-IDMC Meeting Data Status Report

USA, Site 110, Patient 1289: Status Overview

Please use the below information to clear backlogs for this patient. This is the lowest level of this report and it will be necessary to utilise systems (eg, EDC) to drill down to lower levels and address issues in question.

Details of the number of visits overdue for CRF entry is listed below: [Note 71]

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 72]

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 73]

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 uncoded Non-Serious AEs in the CRF is listed below: [Note 74]

# Non-Serious AEs reported in the CRF	# Non-Serious AEs reported in the CRF & NOT coded
18	3
Study avg./ Patient	3

Non-Serious Adverse Events need to be coded. Please continue timely coding and address any potentially open queries relating to coding.

Details of the number of uncoded Serious AEs in the CRF is listed below: [Note 75]

# Serious AEs reported in the CRF	# Serious AEs reported in the CRF & NOT coded
4	1
Study avg./ Patient	1

Serious Adverse Events need to be coded. Please continue timely coding and address any potentially open queries relating to coding.

Details of the number of PK samples on site as per sponsor-provided lab report is listed below: [Note 76]

Dummy Study XYZ

Site 110: Pre-IDMC Meeting Data Status Report

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

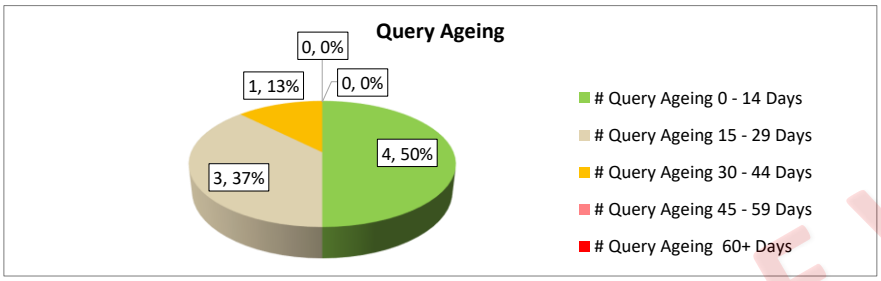
No PK samples are found to be on-site as per sponsor-provided lab report.

Report author note: Please also refer to the 4Site PK tool to assist in PK sample investigations.

Details of the number of site queries that are open for over 60 days is listed below: [Note 77]

Site Open Queries Total	Site Open Queries 60+ Days
8	0
Study avg./ Patient	0

No queries are found to be pending a site response for over 60 days.



Please address all queries, but especially those of higher age. As we approach the IDMC we need to see green on the pie chart.

Concluding Remarks

Please work closely with your internal teams and site staff to follow up with the issues included in this report. We only have 2 months prior to the IDMC cut-off at which point we need to be in good shape with our data.

Most patients will only have 1 monitoring visit prior to the data snap-shot and therefore all prioritised known issues should be followed up during this time. If you have any data questions, please direct them to your data management counterparts.

Any site issues detected during monitoring should be recorded in monitoring reports, but please also report any items that may impact the IDMC to data management and/or your country manager.

Dummy Study XYZ

Site 110: Pre-IDMC Meeting Data Status Report

Report Notes

1: The report author ran this report to include absolute counts of the number of patients discontinued from treatment and not in follow-up for the Region(s), Country(ies), Site(s) or Patient(s) under focus in the section of the report the table is included within, at a setting of a maximum of records that contribute the lowest counts. Note that if less records are present than this maximum setting, it is because the analysis was performed on less number of records than this. An average line is included in this table, and is based on this calculation: contributing counts / number of Region(s), Country(ies), Site(s) or Patient(s) (depending on report section) across the entire study, unless the item itself under analysis is already an average. The average is therefore not specific to the report author's selection, but is across the study as an entirity for comparitive purposes. Data source: CRF.

2: The report author ran this report to establish if there was a statistically significant high number of visits overdue for CRF entry for the Region(s), Country(ies), Site(s) or Patient(s) under focus in the section of the report the table is included within. Nothing of statistical signficance was established using a widely recognised mathematical Standard Deviation model (resource: https://www.bmj.com/about-bmj/resources-readers/publications/statistics-square-one/2-mean-and-standard-deviation) corrected for the the number of visits entered at a setting of 0.5 standard deviation(s). In the absence of statistically relevant findings, the report author ran the report to include absolute numbers instead. The absolute number table is based on a setting to include a maximum of 10 records that contribute the highest number of visits overdue for CRF entry. Note that if less records are present than this maximum setting, it is because the analysis was performed on less number of records than this. An average line is included in this table, and is based on this calculation: contributing counts / number of Region(s), Country(ies), Site(s) or Patient(s) (depending on report section) across the entire study, unless the item itself under analysis is already an average. The average is therefore not specific to the report author's selection, but is across the study as an entirity for comparitive purposes. Data source: CRF.

3: The report author ran this report to establish if there was a statistically significant high number of pages started but without full entry as per the CRF system for the Region(s), Country(ies), Site(s) or Patient(s) under focus in the section of the report the table is included within. Nothing of statistical signficance was established using a widely recognised mathematical Standard Deviation model (resource: https://www.bmj.com/about-bmj/resources-readers/publications/statistics-square-one/2-mean-and-standard-deviation) corrected for the number of pages CRF started but not fully entered at a setting of 0.5 standard deviation(s). In the absence of statistically relevant findings, the report author ran the report to include absolute numbers instead. The absolute number table is based on a setting to include a maximum of 5 records that contribute the highest number of pages started but without full entry as per the CRF system. Note that if less records are present than this maximum setting, it is because the analysis was performed on less number of records than this. An average line is included in this table, and is based on this calculation: contributing counts / number of Region(s), Country(ies), Site(s) or Patient(s) (depending on report section) across the entire study, unless the item itself under analysis is already an average. The average is therefore not specific to the report author's selection, but is across the study as an entirity for comparitive purposes. Data source: CRF.

4: The report author ran this report to establish if there was a statistically significant low number of patients that have had CRF data entry for the Region(s), Country(ies), Site(s) or Patient(s) under focus in the section of the report the table is included within. Nothing of statistical signficance was established using corrected for the number of patients that have had CRF data entry at a setting of 0.5 standard deviation(s). In the absence of statistically relevant findings, the report author ran the report to include absolute numbers instead. The absolute number table is based on a setting to include a maximum of 10 records that contribute the lowest number of patients that have had CRF data entry. Note that if less records are present than this maximum setting, it is because the analysis was performed on less number of records than this. An average line is included in this table, and is based on this calculation: contributing counts / number of Region(s), Country(ies), Site(s) or Patient(s) (depending on report section) across the entire study, unless the item itself under analysis is already an average. The average is therefore not specific to the report author's selection, but is across the study as an entirity for comparitive purposes. Data source: CRF.

5: The report author ran this report to establish if there was a statistically significant high days between visit & entry of data for the Region(s), Country(ies), Site(s) or Patient(s) under focus in the section of the report the table is included within. Nothing of statistical signficance was established using a widely recognised mathematical Standard Deviation model (resource: https://www.bmj.com/about-bmj/resources-readers/publications/statistics-square-one/2-mean-and-standard-deviation) corrected for the number of patients that have had CRF data entry at a setting of 0.5 standard deviation(s). In the absence of statistically relevant findings, the report author ran the report to include absolute numbers instead. The absolute number table is based on a setting to include a maximum of 5 records that contribute the highest days between visit & entry of data. Note that if less records are present than this maximum setting, it is because the analysis was performed on less number of records than this. An average line is included in this table, and is based on this calculation: contributing counts / number of Region(s), Country(ies), Site(s) or Patient(s) (depending on report section) across the entire study, unless the item itself under analysis is already an average. The average is therefore not specific to the report author's selection, but is across the study as an entirity for comparitive purposes. Data source: CRF.

6: The report author ran this report to establish if there was a statistically significant high number of PK Samples on-site for the Region(s), Country(ies), Site(s) or Patient(s) under focus in the section of the report the table is included within. Nothing of statistical signficance was established using a widely recognised mathematical Standard Deviation model (resource: https://www.bmj.com/about-bmj/resources-readers/publications/statistics-square-one/2-mean-and-standard-deviation) corrected for the the number of PK samples taken as a total at a setting of 0.5 standard deviation(s). In the absence of statistically relevant findings, the report author ran the report to include absolute numbers instead. The absolute number table is based on a setting to include a maximum of 5 records that contribute the highest number of PK Samples on-site. Note that if less records are present than this maximum setting, it is because the analysis was performed on less number of records than this. An average line is included in this table, and is based on this calculation: contributing counts / number of Region(s), Country(ies), Site(s) or Patient(s) (depending on report section) across the entire study, unless the item itself under analysis is already an average. The average is therefore not specific to the report author's selection, but is across the study as an entirity for comparitive purposes. Data source: CRF and sponsor-provided lab report.

7: The report author ran this report to establish if there was a statistically significant high number of uncoded Non-Serious AEs in the CRF for the Region(s), Country(ies), Site(s) or Patient(s) under focus in the section of the report the table is included within. Nothing of statistical signficance was established using a widely recognised mathematical Standard Deviation model (resource: https://www.bmj.com/about-bmj/resources-readers/publications/statistics-square-one/2-mean-and-standard-deviation) corrected for the the number of all non-serious adverse events CRF entered at a setting of 0.5 standard deviation(s). In the absence of statistically relevant findings, the report author ran the report to include absolute numbers instead. The absolute number table is based on a setting to include a maximum of 5 records that contribute the highest number of uncoded Non-Serious AEs in the CRF. Note that if less records are present than this maximum setting, it is because the analysis was performed on less number of records than this. An average line is included in this table, and is based on this calculation: contributing counts / number of Region(s), Country(ies), Site(s) or Patient(s) (depending on report section) across the entire study, unless the item itself under analysis is already an average. The average is therefore not specific to the report author's selection, but is across the study as an entirity for comparitive purposes. Data source: CRF.

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8: The report author ran this report to establish if there was a statistically significant high number of uncoded Serious AEs in the CRF for the Region(s), Country(ies), Site(s) or Patient(s) under focus in the section of the report the table is included within. Nothing of statistical signficance was established using a widely recognised mathematical Standard Deviation model (resource: https://www.bmj.com/about-bmj/resources-readers/publications/statistics-square-one/2-mean-and-standard-deviation) corrected for the the number of all serious adverse events CRF entered at a setting of 0.5 standard deviation(s). In the absence of statistically relevant findings, the report author ran the report to include absolute numbers instead. The absolute number table is based on a setting to include a maximum of 5 records that contribute the highest number of uncoded Serious AEs in the CRF. Note that if less records are present than this maximum setting, it is because the analysis was performed on less number of records than this. An average line is included in this table, and is based on this calculation: contributing counts / number of Region(s), Country(ies), Site(s) or Patient(s) (depending on report section) across the entire study, unless the item itself under analysis is already an average. The average is therefore not specific to the report author's selection, but is across the study as an entirity for comparitive purposes. Data source: CRF.

9: The report author ran this report to establish if there was a statistically significant high average time from query raised to query answered for the Region(s), Country(ies), Site(s) or Patient(s) under focus in the section of the report the table is included within. Nothing of statistical signficance was established using a widely recognised mathematical Standard Deviation model (resource: https://www.bmj.com/about-bmj/resources-readers/publications/statistics-square-one/2-mean-and-standard-deviation) corrected for the the number of queries that are answered at a setting of 0.5 standard deviation(s). In the absence of statistically relevant findings, the report author ran the report to include absolute numbers instead. The absolute number table is based on a setting to include a maximum of 5 records that contribute the highest average time from query raised to query answered. Note that if less records are present than this maximum setting, it is because the analysis was performed on less number of records than this. An average line is included in this table, and is based on this calculation: contributing counts / number of Region(s), Country(ies), Site(s) or Patient(s) (depending on report section) across the entire study, unless the item itself under analysis is already an average. The average is therefore not specific to the report author's selection, but is across the study as an entirity for comparitive purposes. Data source: CRF.

10: The report author ran this report to include absolute counts of the number of visits overdue for CRF entry for the Region, Country or Site under focus in the section of the report the table is included within. An average line is included in this table, and is based on this calculation: contributing counts / number of Region(s), Country(ies), Site(s) or Patient(s) (depending on report section) across the entire study, unless the item itself under analysis is already an average. The average is therefore not specific to the report author's selection, but is across the study as an entirity for comparitive purposes. Data source: CRF.

11: The report author ran this report to include absolute counts of the number of open site queries for the Region, Country or Site under focus in the section of the report the table is included within. An average line is included in this table, and is based on this calculation: contributing counts / number of Region(s), Country(ies), Site(s) or Patient(s) (depending on report section) across the entire study, unless the item itself under analysis is already an average. The average is therefore not specific to the report author's selection, but is across the study as an entirity for comparitive purposes. Data source: CRF.

12: The report author ran this report to include absolute counts of the number of PK Samples on-site for the Region, Country or Site under focus in the section of the report the table is included within. An average line is included in this table, and is based on this calculation: contributing counts / number of Region(s), Country(ies), Site(s) or Patient(s) (depending on report section) across the entire study, unless the item itself under analysis is already an average. The average is therefore not specific to the report author's selection, but is across the study as an entirity for comparitive purposes. Data source: CRF and sponsor-provided lab report.

13: The report author ran this report to include absolute counts of the days between visit & entry of data for the Region, Country or Site under focus in the section of the report the table is included within. An average line is included in this table, and is based on this calculation: contributing counts / number of Region(s), Country(ies), Site(s) or Patient(s) (depending on report section) across the entire study, unless the item itself under analysis is already an average. The average is therefore not specific to the report author's selection, but is across the study as an entirity for comparitive purposes. Data source: CRF.

14: The report author ran this report to include absolute counts of the average time from query raised to query answered for the Region, Country or Site under focus in the section of the report the table is included within. An average line is included in this table, and is based on this calculation: contributing counts / number of Region(s), Country(ies), Site(s) or Patient(s) (depending on report section) across the entire study, unless the item itself under analysis is already an average. The average is therefore not specific to the report author's selection, but is across the study as an entirity for comparitive purposes. Data source: CRF.

15: The report author ran this report to include absolute counts of the number of visits overdue for CRF entry for the Region, Country or Site under focus in the section of the report the table is included within. An average line is included in this table, and is based on this calculation: contributing counts / number of Region(s), Country(ies), Site(s) or Patient(s) (depending on report section) across the entire study, unless the item itself under analysis is already an average. The average is therefore not specific to the report author's selection, but is across the study as an entirity for comparitive purposes. Data source: CRF.

16: The report author ran this report to include absolute counts of the number of open site queries for the Region, Country or Site under focus in the section of the report the table is included within. An average line is included in this table, and is based on this calculation: contributing counts / number of Region(s), Country(ies), Site(s) or Patient(s) (depending on report section) across the entire study, unless the item itself under analysis is already an average. The average is therefore not specific to the report author's selection, but is across the study as an entirity for comparitive purposes. Data source: CRF.

17: The report author ran this report to include absolute counts of the number of PK Samples on-site for the Region, Country or Site under focus in the section of the report the table is included within. An average line is included in this table, and is based on this calculation: contributing counts / number of Region(s), Country(ies), Site(s) or Patient(s) (depending on report section) across the entire study, unless the item itself under analysis is already an average. The average is therefore not specific to the report author's selection, but is across the study as an entirity for comparitive purposes. Data source: CRF and sponsor-provided lab report.

18: The report author ran this report to include absolute counts of the days between visit & entry of data for the Region, Country or Site under focus in the section of the report the table is included within. An average line is included in this table, and is based on this calculation: contributing counts / number of Region(s), Country(ies), Site(s) or Patient(s) (depending on report section) across the entire study, unless the item itself under analysis is already an average. The average is therefore not specific to the report author's selection, but is across the study as an entirity for comparitive purposes. Data source: CRF.

19: The report author ran this report to include absolute counts of the average time from query raised to query answered for the Region, Country or Site under focus in the section of the report the table is included within. An average line is included in this table, and is based on this calculation: contributing counts / number of Region(s), Country(ies), Site(s) or Patient(s) (depending on report section) across the entire study, unless the item itself under analysis is already an average. The average is therefore not specific to the report author's selection, but is across the study as an entirity for comparitive purposes. Data source: CRF.

20: The report author ran this report to include absolute counts of the number of patients discontinued from treatment and not in follow-up for the Region, Country or Site under focus in the section of the report the table is included within. An average line is included in this table, and is based on this calculation: contributing counts / number of Region(s), Country(ies), Site(s) or Patient(s) (depending on report section) across the entire study, unless the item itself under analysis is already an average. The average is therefore not specific to the report author's selection, but is across the study as an entirity for comparitive purposes. Data source: CRF.

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21: The report author ran this report to include absolute counts of the number of visits overdue for CRF entry for the Region, Country or Site under focus in the section of the report the table is included within. An average line is included in this table, and is based on this calculation: contributing counts / number of Region(s), Country(ies), Site(s) or Patient(s) (depending on report section) across the entire study, unless the item itself under analysis is already an average. The average is therefore not specific to the report author's selection, but is across the study as an entirity for comparitive purposes. Data source: CRF.

22: The report author ran this report to include absolute counts of the number of pages started but without full entry as per the CRF system for the Region, Country or Site under focus in the section of the report the table is included within. An average line is included in this table, and is based on this calculation: contributing counts / number of Region(s), Country(ies), Site(s) or Patient(s) (depending on report section) across the entire study, unless the item itself under analysis is already an average. The average is therefore not specific to the report author's selection, but is across the study as an entirity for comparitive purposes. Data source: CRF.

23: The report author ran this report to include absolute counts of the number of patients that have had CRF data entry for the Region, Country or Site under focus in the section of the report the table is included within. An average line is included in this table, and is based on this calculation: contributing counts / number of Region(s), Country(ies), Site(s) or Patient(s) (depending on report section) across the entire study, unless the item itself under analysis is already an average. The average is therefore not specific to the report author's selection, but is across the study as an entirity for comparitive purposes. Data source: CRF.

24: The report author ran this report to establish if there was a statistically significant high days between visit & entry of data for the Region, Country or Site under focus in the section of the report the table is included within. Nothing of statistical signficance was established using a widely recognised mathematical Standard Deviation model (resource: https://www.bmj.com/about-bmj/resources-readers/publications/statistics-square-one/2-mean-and-standard-deviation) corrected for the number of patients that have had CRF data entry at a setting of 0.5 standard deviation(s). In the absence of statistically relevant findings, the report author ran the report to include the absolute numbers instead. An average line is included in this table, and is based on this calculation: contributing counts / number of Region(s), Country(ies), Site(s) or Patient(s) (depending on report section) across the entire study, unless the item itself under analysis is already an average. The average is therefore not specific to the report author's selection, but is across the study as an entirity for comparitive purposes. Data source: CRF.

25: The report author ran this report to establish if there was a statistically significant high number of PK Samples on-site for the Region, Country or Site under focus in the section of the report the table is included within. Nothing of statistical signficance was established using a widely recognised mathematical Standard Deviation model (resource: https://www.bmj.com/about-bmj/resources-readers/publications/statistics-square-one/2-mean-and-standard-deviation) corrected for the the number of PK samples taken as a total at a setting of 0.5 standard deviation(s). In the absence of statistically relevant findings, the report author ran the report to include the absolute numbers instead. An average line is included in this table, and is based on this calculation: contributing counts / number of Region(s), Country(ies), Site(s) or Patient(s) (depending on report section) across the entire study, unless the item itself under analysis is already an average. The average is therefore not specific to the report author's selection, but is across the study as an entirity for comparitive purposes. Data source: CRF and sponsor-provided lab report.

26: The report author ran this report to establish if there was a statistically significant high number of uncoded Non-Serious AEs in the CRF for the Region, Country or Site under focus in the section of the report the table is included within. Nothing of statistical signficance was established using a widely recognised mathematical Standard Deviation model (resource: https://www.bmj.com/about-bmj/resources-readers/publications/statistics-square-one/2-mean-and-standard-deviation) corrected for the the number of all non-serious adverse events CRF entered at a setting of 0.5 standard deviation(s). In the absence of statistically relevant findings, the report author ran the report to include the absolute numbers instead. An average line is included in this table, and is based on this calculation: contributing counts / number of Region(s), Country(ies), Site(s) or Patient(s) (depending on report section) across the entire study, unless the item itself under analysis is already an average. The average is therefore not specific to the report author's selection, but is across the study as an entirity for comparitive purposes. Data source: CRF.

27: The report author ran this report to establish if there was a statistically significant high number of uncoded Serious AEs in the CRF for the Region, Country or Site under focus in the section of the report the table is included within. Nothing of statistical signficance was established using a widely recognised mathematical Standard Deviation model (resource: https://www.bmj.com/about-bmj/resources-readers/publications/statistics-square-one/2-mean-and-standard-deviation) corrected for the the number of all serious adverse events CRF entered at a setting of 0.5 standard deviation(s). In the absence of statistically relevant findings, the report author ran the report to include the absolute numbers instead. An average line is included in this table, and is based on this calculation: contributing counts / number of Region(s), Country(ies), Site(s) or Patient(s) (depending on report section) across the entire study, unless the item itself under analysis is already an average. The average is therefore not specific to the report author's selection, but is across the study as an entirity for comparitive purposes. Data source: CRF.

28: The report author ran this report to establish if there was a statistically significant high average time from query raised to query answered for the Region, Country or Site under focus in the section of the report the table is included within. Nothing of statistical signficance was established using a widely recognised mathematical Standard Deviation model (resource: https://www.bmj.com/about-bmj/resources-readers/publications/statistics-square-one/2-mean-and-standard-deviation) corrected for the the number of queries that are answered at a setting of 0.5 standard deviation(s). In the absence of statistically relevant findings, the report author ran the report to include the absolute numbers instead. An average line is included in this table, and is based on this calculation: contributing counts / number of Region(s), Country(ies), Site(s) or Patient(s) (depending on report section) across the entire study, unless the item itself under analysis is already an average. The average is therefore not specific to the report author's selection, but is across the study as an entirity for comparitive purposes. Data source: CRF.

29: 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.

30: 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.

31: 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.

32: The report author ran this report to include the number of uncoded Non-Serious AEs in the CRF for patient ID#1056. Please note this metric is based on the date the data source was extracted. Data source: CRF.

33: The report author ran this report to include the number of uncoded Serious AEs in the CRF for patient ID#1056. Please note this metric is based on the date the data source was extracted. Data source: CRF.

34: 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.

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35: The report author ran this report to include the number of site queries that are open for over 60 days for patient ID#1056. Please note this metric is based on the date the data source was extracted. Data source: CRF.

36: The report author ran this report to include the number of visits overdue for CRF entry for patient ID#1074. 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.

37: The report author ran this report to include the number of open site queries for patient ID#1074. Please note this metric is based on the date the data source was extracted. Data source: CRF.

38: 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#1074. Please note this metric is based on the date the data source was extracted. Data source: CRF.

39: The report author ran this report to include the number of uncoded Non-Serious AEs in the CRF for patient ID#1074. Please note this metric is based on the date the data source was extracted. Data source: CRF.

40: The report author ran this report to include the number of uncoded Serious AEs in the CRF for patient ID#1074. Please note this metric is based on the date the data source was extracted. Data source: CRF.

41: The report author ran this report to include the number of PK samples on site as per sponsor-provided lab report for patient ID#1074. 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.

42: The report author ran this report to include the number of site queries that are open for over 60 days for patient ID#1074. Please note this metric is based on the date the data source was extracted. Data source: CRF.

43: 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.

44: 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.

45: 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.

46: The report author ran this report to include the number of uncoded Non-Serious AEs in the CRF for patient ID#1085. Please note this metric is based on the date the data source was extracted. Data source: CRF.

47: The report author ran this report to include the number of uncoded Serious AEs in the CRF for patient ID#1085. Please note this metric is based on the date the data source was extracted. Data source: CRF.

48: 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.

49: The report author ran this report to include the number of site queries that are open for over 60 days for patient ID#1085. Please note this metric is based on the date the data source was extracted. Data source: CRF.

50: 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.

51: 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.

52: 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.

53: The report author ran this report to include the number of uncoded Non-Serious AEs in the CRF for patient ID#1089. Please note this metric is based on the date the data source was extracted. Data source: CRF.

54: The report author ran this report to include the number of uncoded Serious AEs in the CRF for patient ID#1089. Please note this metric is based on the date the data source was extracted. Data source: CRF.

55: 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.

56: The report author ran this report to include the number of site queries that are open for over 60 days for patient ID#1089. Please note this metric is based on the date the data source was extracted. Data source: CRF.

57: 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.

58: 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.

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59: 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.

60: The report author ran this report to include the number of uncoded Non-Serious AEs in the CRF for patient ID#1100. Please note this metric is based on the date the data source was extracted. Data source: CRF.

61: The report author ran this report to include the number of uncoded Serious AEs in the CRF for patient ID#1100. Please note this metric is based on the date the data source was extracted. Data source: CRF.

62: 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.

63: The report author ran this report to include the number of site queries that are open for over 60 days for patient ID#1100. Please note this metric is based on the date the data source was extracted. Data source: CRF.

64: 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.

65: 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.

66: 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.

67: The report author ran this report to include the number of uncoded Non-Serious AEs in the CRF for patient ID#1179. Please note this metric is based on the date the data source was extracted. Data source: CRF.

68: The report author ran this report to include the number of uncoded Serious AEs in the CRF for patient ID#1179. Please note this metric is based on the date the data source was extracted. Data source: CRF.

69: 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.

70: The report author ran this report to include the number of site queries that are open for over 60 days for patient ID#1179. Please note this metric is based on the date the data source was extracted. Data source: CRF.

71: 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.

72: 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.

73: 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.

74: The report author ran this report to include the number of uncoded Non-Serious AEs in the CRF for patient ID#1289. Please note this metric is based on the date the data source was extracted. Data source: CRF.

75: The report author ran this report to include the number of uncoded Serious AEs in the CRF for patient ID#1289. Please note this metric is based on the date the data source was extracted. Data source: CRF.

76: 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.

77: The report author ran this report to include the number of site queries that are open for over 60 days for patient ID#1289. Please note this metric is based on the date the data source was extracted. Data source: CRF.