

Ponce, Steven

From: Damre, Preethi
Sent: Wednesday, October 1, 2025 1:25 PM
To: Ifrid, Estelle; Beltran-Raygoza, Nishdallyh; Guancione, Gabrielle; Jimenez-Kurlander, Lauren; Nagpal, Deepa; Ponce, Steven; Oldziejewski, Tracy; Rajeev, Arjun
Cc: Jani, Sunilkumar; Loch, Aruny; Prasad, Shylaja; Paster-Brown, Tracy; Jacobs, Sheree
Subject: RE: CA239-0004 (KRYSTAL-4)_Standard KRIs_ and_DAQ Specifications_DTA/DTS form Vendors_ACTION REQUIRED

Dear @Beltran-Raygoza, Nishdallyh and @Ponce, Steven,

As I am on leave on Thursday and Friday, I request you to schedule call next week to go through the process and explain STAR + template to the team.

Regards,
Preethi Damre
Study Architect Lead

From: Ifrid, Estelle <Estelle.Ifrid@bms.com>
Sent: 01 October 2025 13:55
To: Beltran-Raygoza, Nishdallyh <Nishdallyh.Beltran-Raygoza@bms.com>; Guancione, Gabrielle <Gabrielle.Guancione@bms.com>; Jimenez-Kurlander, Lauren <Lauren.Jimenez-Kurlander@bms.com>; Nagpal, Deepa <Deepa.Nagpal@bms.com>; Damre, Preethi <Preethi.Damre@bms.com>; Ponce, Steven <Steven.Ponce@bms.com>; Oldziejewski, Tracy <Tracy.Oldziejewski@bms.com>; Rajeev, Arjun <Arjun.Rajeev@bms.com>
Cc: Jani, Sunilkumar <Sunilkumar.Jani@bms.com>; Loch, Aruny <Aruny.Loch@bms.com>; Prasad, Shylaja <Shylaja.Prasad@bms.com>; Paster-Brown, Tracy <tracy.paster-brown@bms.com>
Subject: RE: CA239-0004 (KRYSTAL-4)_Standard KRIs_ and_DAQ Specifications_DTA/DTS form Vendors_ACTION REQUIRED

Hi Nish,

Deepa is currently on leave, I am adding @Oldziejewski, Tracy and @Rajeev, Arjun to support here. I am not familiar with this process. I don't know if @Guancione, Gabrielle/@Jimenez-Kurlander, Lauren have already done this in the past?
Perhaps should we meet to discuss what is needed @Beltran-Raygoza, Nishdallyh ?

Thank you in advance,
Sincerely,

Estelle Ifrid, PhD
Clinical Scientist | Oncology
Global Drug Development
Email: estelle.ifrid@bms.com
Phone: +41795611146

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From: Beltran-Raygoza, Nishdallyh <Nishdallyh.Beltran-Raygoza@bms.com>

Sent: Tuesday, 30 September 2025 15:36

To: Guancione, Gabrielle <Gabrielle.Guancione@bms.com>; Jimenez-Kurlander, Lauren <Lauren.Jimenez-Kurlander@bms.com>; Nagpal, Deepa <Deepa.Nagpal@bms.com>; Damre, Preethi <Preethi.Damre@bms.com>; Ponce, Steven <Steven.Ponce@bms.com>; Ifrid, Estelle <Estelle.Ifrid@bms.com>

Cc: Jani, Sunilkumar <Sunilkumar.Jani@bms.com>; Loch, Aruny <Aruny.Loch@bms.com>; Prasad, Shylaja <Shylaja.Prasad@bms.com>; Paster-Brown, Tracy <tracy.paster-brown@bms.com>

Subject: RE: CA239-0004 (KRYSTAL-4)_Standard KRIs_ and _DAQ Specifications_DTA/DTS form Vendors_ACTION REQUIRED

Hi CA239-0004 Team,

Following up on my previous email to get the below information from you.

The two things I need from you are:

- 1) Review the list of vendors below and either approve them for inclusion in the critical data analysis or propose any additional vendors you believe should be considered.
- 2) Review the list of standard Key Risk Indicators (KRIs) below. Kindly let me know if any should be removed from the analysis, or if you would prefer to retain all of them.

@Damre, Preethi does the team still have time to provide the information above?

Preethi, please continue to provide your guidance and support to @Ponce, Steven with the specification process.

Best,

Nish

Please note I am sending this email at a time that is convenient for me, read and respond at a time that is convenient for you to foster a healthy work-life balance.

Nish Beltran-Raygoza

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From: Beltran-Raygoza, Nishdallyh

Sent: Friday, September 26, 2025 2:11 PM

To: Guancione, Gabrielle <Gabrielle.Guancione@bms.com>; Jimenez-Kurlander, Lauren <Lauren.Jimenez-Kurlander@bms.com>; Nagpal, Deepa <Deepa.Nagpal@bms.com>; Damre, Preethi <Preethi.Damre@bms.com>; Ponce, Steven <Steven.Ponce@bms.com>; Ifrid, Estelle <Estelle.Ifrid@bms.com>

Cc: Jani, Sunilkumar <Sunilkumar.Jani@bms.com>; Loch, Aruny <Aruny.Loch@bms.com>; Prasad, Shylaja <Shylaja.Prasad@bms.com>; Paster-Brown, Tracy <tracy.paster-brown@bms.com>

Subject: RE: CA239-0004 (KRYSTAL-4)_Standard KRIs_ and _DAQ Specifications_DTA/DTS form Vendors_ACTION REQUIRED

Hi CA239-0004 Team,

As you know, we are currently drafting the specifications for this study, and I will be transferring responsibility for the study to Steven Ponce effective September 30, 2025.

With your support, I would like to ensure that we complete the specifications before the transition takes place. This will help facilitate a smooth handover and maintain continuity for the project.

The two things I need from you are:

- 1) Review the list of vendors below and either approve them for inclusion in the critical data analysis or propose any additional vendors you believe should be considered.
- 2) Review the list of standard Key Risk Indicators (KRIs) below. Kindly let me know if any should be removed from the analysis, or if you would prefer to retain all of them.

Your feedback is appreciated to ensure we have the appropriate vendors and KRIs in place for this analysis.

If feedback is not provided by **EOB Monday September 29th** the specifications will be drafted with the limited information we have which will not allow us to use the STAR+ tool to its full potential for CMN reviews as complete information is necessary for full use of the tool.

Please let me know if there are any additional resources or information needed to help us meet this goal or if you would like to meet to discuss.

I appreciate your collaboration and assistance

1) Review the list of vendors below and either approve/reject or propose new vendors for inclusion in the data analysis

We can start providing the list of vendors for critical data only if we don't have all vendors we would like to include at this time, so I suggest we start with the vendors below for the critical data:

- Labcorp for KRAS and PDL-1
- Labcorp for PK lab
- Guardant health for Biomarker (ctDNA)
- Perspective (formerly Calyx): Imaging
- Vendor for PRO- is it SIGNANT HEALYH? Please confirm

Additional vendors for non-critical data can be included in version 2 of the specifications as needed, if we do not select them at this time. But is critical that we get started with the version 1 of the specifications selecting the most important vendors.

Please confirm that we can start Version 1 of Specs with the vendors proposed above, or let me know if other vendors should be included/removed from this list.

2) Review the list of standard Key Risk Indicators (KRIs) below. Kindly let me know if any should be removed from the analysis, or if you would prefer to retain all of them. Please refer to attached document for full description of the KRIs if needed.

Standard Kris Proposed:

Non-Serious AE Rate (AERATE)
Serious AE Rate(SAERATE)
Missed Visit Rate(MVRATE)
Off-Schedule Visit (OSVRATE)
Query Response Cycle Time(QRESPCT)
eCRF Visit-to-Entry Cycle Time(V2ECT)
Auto-Query Rate(AQRATE)
Protocol Deviation Rate(PDRATE)
Important Protocol Deviation Rate(IPDRATE)
Screen Failure Rate(SFRATE)
Early End of Treatment Rate(EEOTRATE)
Early End of Study Participation Rate (EEOSRATE)
Dose Modification Rate (IPMODRATE)
IP Non-Compliance Rate (IPNCOMPLRT)
Short cycle length rate (SHORTCYCLRT)
Rest Period Data Completeness Rate (RESTDCRATE)

Missed Assessment Rate - Response(MARATERESP)
Missed Assessment Rate- Safety(MARATESAFETY)
Missed Assessment Rate - Efficacy(MARATEEFF)
Missed Assessment Rate - Efficacy Primary (MARATEEFFP)
Missed Assessment Rate - Efficacy Secondary(MARATEEFFS)

Please confirm the above by EOB Monday

Thank you in advance for your help,

Best,

Nish

Please note I am sending this email at a time that is convenient for me, read and respond at a time that is convenient for you to foster a healthy work-life balance.

Nish Beltran-Raygoza

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From: Beltran-Raygoza, Nishdallyh

Sent: Friday, September 19, 2025 9:31 AM

To: Guancione, Gabrielle <Gabrielle.Guancione@bms.com>; Jimenez-Kurlander, Lauren <Lauren.Jimenez-Kurlander@bms.com>; Nagpal, Deepa <Deepa.Nagpal@bms.com>; Damre, Preethi <Preethi.Damre@bms.com>

Cc: Jani, Sunilkumar <Sunilkumar.Jani@bms.com>; Loch, Aruny <Aruny.Loch@bms.com>; Ifrid, Estelle <Estelle.Ifrid@bms.com>

Subject: RE: CA239-0004 (KRYSTAL-4)_Standard KRIs_ and _DAQ Specifications_DTA/DTS form Vendors_ACTION REQUIRED

Hi Team,

Following up on my request below:

We can start providing the list of vendors for critical data for now, we don't have to include all vendors at this time if we don't have them all, so I suggest we start with the vendors below:

- Labcorp for KRAS and PDL-1
- Labcorp for PK lab
- Guardant health for Biomarker (ctDNA)
- Perspective (formerly Calyx): Imaging
- Vendor for PRO- is it SIGNANT HEALYH? **Please confirm**

Please confirm that we can start Version 1 of Specs with the vendors proposed above, or let me know if other vendors should be included in this list. Additional vendors for non-critical data can be included in version 2 of the specifications as needed if we do not select them at this time. But is critical that we get started with the specifications selecting the most important vendors for version 1 of spec.

For the KRIs we just need to review the list provided (below), descriptions attached and confirm that we want to include all the KRIs proposed below in the analysis or let me know which ones I should remove.

Standard Kris Proposed

Meaningful indication of what the KRI is measuring.

Non-Serious AE Rate (AERATE)

Serious AE Rate(SAERATE)

Missed Visit Rate(MVRATE)

Off-Schedule Visit (OSVRATE)

Query Response Cycle Time(QRESPCT)

eCRF Visit-to-Entry Cycle Time(V2ECT)

Auto-Query Rate(AQRATE)

Protocol Deviation Rate(PDRATE)

Important Protocol Deviation Rate(IPDRATE)

Screen Failure Rate(SFRATE)

Early End of Treatment Rate(EEOTRATE)

Early End of Study Participation Rate (EEOSRATE)

Dose Modification Rate (IPMODRATE)

IP Non-Compliance Rate (IPNCOMPLRT)

Short cycle length rate (SHORTCYCLRT)

Rest Period Data Completeness Rate (RESTDCRATE)

Missed Assessment Rate - Response(MARATERESP)

Missed Assessment Rate- Safety(MARATESAFETY)

Missed Assessment Rate - Efficacy(MARATEEFF)

Missed Assessment Rate - Efficacy Primary (MARATEEFFP)

Missed Assessment Rate - Efficacy Secondary(MARATEEFFS)

Again, I can schedule a meeting with the Study Architect Lead (SAL), @Damre, Preethi so she can provide further clarification and address any additional questions on this request if needed. Please let me know by EOB today, I am happy to put something in the calendar to discuss.

A draft of the spec is attached

For the specification draft attached, on the tab "Rules of Analysis" @Nagpal, Deepa please help me review the **visit table** and make sure the information is according to protocol and ALS, Also please help me to fill out all the cells highlighted in yellow, so @Damre, Preethi can start programing.

Please confirm the above (or request meeting) by EOB today,

Thank you in advance for your help,

Best,

Please note I am sending this email at a time that is convenient for me, read and respond at a time that is convenient for you to foster a healthy work-life balance.

Nish Beltran-Raygoza

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From: Beltran-Raygoza, Nishdallyh

Sent: Thursday, September 18, 2025 2:19 PM

To: Guancione, Gabrielle <Gabrielle.Guancione@bms.com>; Jimenez-Kurlander, Lauren <Lauren.Jimenez-Kurlander@bms.com>; Nagpal, Deepa <Deepa.Nagpal@bms.com>

Cc: Jani, Sunilkumar <Sunilkumar.Jani@bms.com>; Loch, Aruny <Aruny.Loch@bms.com>; Damre, Preethi <Preethi.Damre@bms.com>; Ifrid, Estelle <Estelle.Ifrid@bms.com>

Subject: RE: CA239-0004 (KRYSTAL-4)_Standard KRIs_ and _DAQ Specifications_DTA/DTS form Vendors_ACTION REQUIRED

Adding Deepa (DML) as well, to provide some input on the vendors that should be included in analysis.

We can start providing the **list of vendors for critical data** for now, we don't have to include all vendors at this time. Additional vendors can be included in version 2 of the specifications as needed. But is critical that we get started with the specifications selecting the most important vendors, to avoid any delays on CMN review activities of the upcoming CMN. I am aiming to have the specs ready before my last day at BMS 30Sep2025.

I can schedule a meeting with the Study Architect Lead (SAL), @Damre, Preethi so she can provide further clarification and address any additional questions on this request if needed. Please let me know

For the KRIs we just need to review the list provided (attached) if we want to keep them all we can move forward, but if you feel that some should be remove please let me know I can remove accordingly and finish KRI specs.

Thank you in advance for your help,

Best,

Nish

Please note I am sending this email at a time that is convenient for me, read and respond at a time that is convenient for you to foster a healthy work-life balance.

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From: Guancione, Gabrielle <Gabrielle.Guancione@bms.com>

Sent: Thursday, September 18, 2025 6:41 AM

To: Beltran-Raygoza, Nishdallyh <Nishdallyh.Beltran-Raygoza@bms.com>; Jimenez-Kurlander, Lauren <Lauren.Jimenez-Kurlander@bms.com>

Cc: Jani, Sunilkumar <Sunilkumar.Jani@bms.com>; Loch, Aruny <Aruny.Loch@bms.com>; Damre, Preethi <Preethi.Damre@bms.com>; Ifrid, Estelle <Estelle.Ifrid@bms.com>

Subject: RE: CA239-0004 (CRYSTAL-4)_Standard KRIs_ and _DAQ Specifications_DTA/DTS form Vendors_ACTION REQUIRED

Thanks, Nish. Including Estelle (another CS on the study).

Gabby

From: Beltran-Raygoza, Nishdallyh <Nishdallyh.Beltran-Raygoza@bms.com>

Sent: Wednesday, September 17, 2025 6:49 PM

To: Jimenez-Kurlander, Lauren <Lauren.Jimenez-Kurlander@bms.com>; Guancione, Gabrielle <Gabrielle.Guancione@bms.com>

Cc: Jani, Sunilkumar <Sunilkumar.Jani@bms.com>; Loch, Aruny <Aruny.Loch@bms.com>; Damre, Preethi <Preethi.Damre@bms.com>

Subject: FW: CA239-0004 (KRYSTAL-4)_Standard KRIs_ and _DAQ Specifications_DTA/DTS form Vendors_ACTION REQUIRED

Hi Team,

Please find attached the **standard KRIs list** I intend to include for this study in STAR+ platform. Please review and let me know in any should be removed. Please let me know if a meeting is needed to discuss.

The studies specific KRIs will be discuss and implemented in version 2 of the specifications.

Also with STAR+ implementation we need to complete **DQA specifications** and for that we need the list of vendors we would like to be included in the analysis. Please provide me with the **list of vendors** to be included, we don't have to include all vendors at this time, but we can include the most important ones. Additional vendors can be included in version 2 of the specifications as needed. Please see the vendor file attached. I can schedule a meeting with the Study Architect Lead (SAL), @Damre, Preethi so she can provide further clarification and address any additional questions on this request.

Please let me know if you have any questions or if a meeting is needed to discuss.

Best,

Nish

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From: Beltran-Raygoza, Nishdallyh

Sent: Monday, August 25, 2025 8:22 PM

To: Coxen, Erik <Erik.Coxen@bms.com>; Thompson, Christiana <Christiana.Thompson@bms.com>; Guancione, Gabrielle <Gabrielle.Guancione@bms.com>; Bushong, Judith <Judith.Bushong@bms.com>; Jani, Sunilkumar <Sunilkumar.Jani@bms.com>; Karanam, Prashin <Prashin.Karanam@bms.com>; Nagpal, Deepa <Deepa.Nagpal@bms.com>; Colin, Pierre <Pierre.Colin@bms.com>; Kapoor, Upender <Upender.Kapoor@bms.com>; Lalchandani, Varsha <varsha.lalchandani@bms.com>; Jimenez-Kurlander, Lauren <Lauren.Jimenez-Kurlander@bms.com>; Zhang, Haiyang <Haiyang.Zhang2@bms.com>; Nathani, Khushbu <Khushbu.Nathani@bms.com>; Carr, Michelle <Michelle.Carr@bms.com>; Vemula, Sai Vikram <SaiVikram.Vemula@bms.com>; Alaparthi, Suresh <suresh.alaparthi@bms.com>; Hudson, Rachel <Rachel.Hudson@bms.com>; Simmons, Tara <tara.simmons@bms.com>; Hollis, Heather <Heather.Hollis@bms.com>; Sheriff, Konnie <konnie.sheriff@bms.com>; Evans, Anne <Anne.Evans@bms.com>; Santhanam, Navaneetha <Navaneetha.Santhanam@bms.com>; Alessio, Lise <Lise.Alessio@bms.com>; Grootendorst, Diederik <Diederik.Grootendorst@bms.com>; Campbell, Yan <Yan.Campbell@bms.com>; Loch, Aruny <Aruny.Loch@bms.com>; Damre, Preethi <Preethi.Damre@bms.com>
Subject: RE: CA239-0004 (KRYSTAL-4)_DAQ Specifications_DTA/DTS form Vendors

Hi Team,

Following up on my email below. Please let me know if a meeting is needed to discuss.

With STAR+ implementation we need to complete DQA specifications for this trial, some of the information we need for the specs is the data transfer Agreement/ Specification (**DTA/DTS**) of the vendors we are planning to include in the analysis – Any vendor for eg: eCOA, Imaging which study team is interested to add for DQA analysis

If we are unsure about which vendors will be included, now is a good time to consider it. I can schedule a meeting with the Study Architect Lead (SAL), [@Damre, Preethi](#) so she can provide further clarification and address any additional questions.

I could find 19 vendors in [TMF Viewer](#)

Data Management > Database > External Data Transfer Specifications (Paper and EDC).

Please confirm if this is all the vendors that we currently have, and which ones we will include in the analysis, if you don't know yet we can meet with SAL and discuss.

Please let me know if you have any questions,

Best,

Nish

Please note I am sending this email at a time that is convenient for me, read and respond at a time that is convenient for you to foster a healthy work-life balance.

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From: Beltran-Raygoza, Nishdallyh

Sent: Wednesday, August 20, 2025 12:52 PM

To: Coxen, Erik <Erik.Coxen@bms.com>; Thompson, Christiana <Christiana.Thompson@bms.com>; Guancione, Gabrielle <Gabrielle.Guancione@bms.com>; Bushong, Judith <Judith.Bushong@bms.com>; Jani, Sunilkumar <Sunilkumar.Jani@bms.com>; Karanam, Prashin <Prashin.Karanam@bms.com>; Nagpal, Deepa <Deepa.Nagpal@bms.com>; Colin, Pierre <Pierre.Colin@bms.com>; Kapoor, Upender <Upender.Kapoor@bms.com>; Lalchandani, Varsha <varsha.lalchandani@bms.com>; Jimenez-Kurlander, Lauren <Lauren.Jimenez-Kurlander@bms.com>; Zhang, Haiyang <Haiyang.Zhang2@bms.com>; Nathani, Khushbu <Khushbu.Nathani@bms.com>; Carr, Michelle <Michelle.Carr@bms.com>; Vemula, Sai Vikram <SaiVikram.Vemula@bms.com>; Alaparthi, Suresh <suresh.alaparthi@bms.com>; Hudson, Rachel <Rachel.Hudson@bms.com>; Simmons, Tara <tara.simmons@bms.com>; Hollis, Heather <Heather.Hollis@bms.com>; Sheriff, Konnie <konnie.sheriff@bms.com>; Evans, Anne <Anne.Evans@bms.com>; Santhanam, Navaneetha <Navaneetha.Santhanam@bms.com>; Alessio, Lise <Lise.Alessio@bms.com>; Grootendorst, Diederik <Diederik.Grootendorst@bms.com>; Campbell, Yan <Yan.Campbell@bms.com>; Loch, Aruny <Aruny.Loch@bms.com>

Cc: Hotaling, Skylar <skylar.hotaling@bms.com>

Subject: CA239-0004 (KRYSTAL-4)_DAQ Specifications_DTA/DTS form Vendors

Hi Team,

As it was notified by Amy Sweet, this study was selected for STAR+ implementation.

The KO meetings invites for the RBM framework implementation were sent by RML, Yan Campbell, she will go over the implementation process during upcoming KO meeting.

In the mean time please note that Data Quality Assessment(DQA) specifications are in progress, and I would like to ask if team already has an idea of the vendors that we would like to have in (DQA) analysis?

- DQA is a comprehensive statistical monitoring that can surface findings that would not be detected by other traditional methods of data surveillance. While DQA highlights the data is critical and endpoint related, that is not the sole focus. DQA can come from any kind of data collected in

the study including common/ordinary procedures, but such findings could be indicative of how accurate and precise processes are and how sites are following their procedures.

In order to complete DQA specifications we need to send the data transfer agreement or Specification **(DTA/DTS)** of the vendors we are planning to include in the analysis – Any vendor for eg: eCOA, Imaging which study team is interested to add for DQA analysis

I could find 19 vendors in [TMF Viewer](#)

Data Management > Database > External Data Transfer Specifications (Paper and EDC)

If we are unsure about which vendors will be included, now is a good time to consider this. I can schedule a meeting with the Study Architect Lead (SAL), Damre, and Preethi so they can provide further clarification and address any additional questions.

Please let me know if you have any questions,

Best,

Nish

Please note I am sending this email at a time that is convenient for me, read and respond at a time that is convenient for you to foster a healthy work-life balance.

Nish Beltran-Raygoza

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From: Beltran-Raygoza, Nishdallyh

Sent: Monday, April 7, 2025 10:05 AM

To: Coxen, Erik <Erik.Coxen@bms.com>; Thompson, Christiana <Christiana.Thompson@bms.com>; Guancione, Gabrielle <Gabrielle.Guancione@bms.com>; Bushong, Judith <Judith.Bushong@bms.com>; Jani, Sunilkumar <Sunilkumar.Jani@bms.com>; Karanam, Prashin <Prashin.Karanam@bms.com>; Nagpal, Deepa <Deepa.Nagpal@bms.com>; Colin, Pierre <Pierre.Colin@bms.com>; Kapoor, Upender <Upender.Kapoor@bms.com>; Lalchandani, Varsha <varsha.lalchandani@bms.com>; Jimenez-Kurlander, Lauren <Lauren.Jimenez-Kurlander@bms.com>; Zhang, Haiyang <Haiyang.Zhang2@bms.com>; Nathani, Khushbu <Khushbu.Nathani@bms.com>; Carr, Michelle <Michelle.Carr@bms.com>; Hotaling, Skylar <Skylar.Hotaling@bms.com>; Vemula, Sai Vikram <SaiVikram.Vemula@bms.com>; Alaparthi, Suresh <suresh.alaparthi@bms.com>; Coira, Christopher <Christopher.Coira@bms.com>; Hudson, Rachel <Rachel.Hudson@bms.com>; Simmons, Tara <tara.simmons@bms.com>; Hollis, Heather <Heather.Hollis@bms.com>; Sheriff, Konnie <konnie.sheriff@bms.com>; Evans, Anne <Anne.Evans@bms.com>; Santhanam, Navaneetha <Navaneetha.Santhanam@bms.com>; Alessio, Lise <Lise.Alessio@bms.com>; Grootendorst, Diederik <Diederik.Grootendorst@bms.com>

Subject: CA239-0004_Review_Central Monitoring Strategy Plan (CMSP)

Dear All,

This email is to confirm that Version 1 of the CMSP has been finalized and signed off in TMF.

BMS-TMF-13380998

[Veeva Vault - Central Monitoring Strategy Plan 07 Apr 2025, Page 1](#)

Best Regards,
Nish

-----Original Appointment-----

From: Beltran-Raygoza, Nishdallyh

Sent: Tuesday, February 4, 2025 1:04 PM

To: Coxen, Erik; Thompson, Christiana; Guancione, Gabrielle; Bushong, Judith; Jani, Sunilkumar; Karanam, Prashin; Nagpal, Deepa; Colin, Pierre; Kapoor, Upender; Lalchandani, Varsha; Jimenez-Kurlander, Lauren; Zhang, Haiyang; Nathani, Khushbu; Carr, Michelle; Hotaling, Skylar; Vemula, Sai Vikram; Alaparthi, Suresh; Coira, Christopher; Hudson, Rachel; Simmons, Tara; Hollis, Heather; Sheriff, Konnie; Evans, Anne; Santhanam, Navaneetha; Alessio, Lise; Grootendorst, Diederik

Subject: CA239-0004_Review_Central Monitoring Strategy Plan (CMSP)

When: Wednesday, February 19, 2025 1:00 PM-2:00 PM (UTC-08:00) Pacific Time (US & Canada).

Where: Microsoft Teams Meeting

Hi Team,

This meeting is to review and discuss the Central Monitoring Strategy Plan (CMSP) for study CA239-0004.

Your insights are valuable to ensure that our monitoring strategy is robust, effective, and aligned with our risk management objectives. With help of the risk review team (RRT) we will select/pre-define both the standard and study specific key risk indicators (KRIs) that will help us to monitor and detect potential issues in the study.

Action:

Risk Review Team (RRT) Evaluates the attached CMSP draft and confirm the following:

- Relevant risks that can be quantified via analytics are captured.

- Agreed upon mitigation and control owners and actions.
- Analytic review strategy required to support the study assessments are document

RRT please note in column I on the attached document (analytic name) there are some analytics strikethrough, this is because I considered that these KRIs are not applicable for this study, however I still need to get alignment from the study team prior to removing them from CMSP. For the same column, for analytics highlighted in yellow, I determined that these might be applicable for the study but need further discussion with the team.

- Attend CMSP Review meeting to discuss the above bullet points

CMN overview presentation and CMSP are attached, if you have any specific questions or concerns you would like to address during the meeting, please feel free to share them in advance.

I look forward to a productive discussion.

Best regards,

Nish Beltran

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From: Beltran-Raygoza, Nishdallyh

Sent: Friday, January 31, 2025 5:38 PM

To: Coxen, Erik <Erik.Coxen@bms.com>; Thompson, Christiana <Christiana.Thompson@bms.com>; Guancione, Gabrielle <Gabrielle.Guancione@bms.com>; Bushong, Judith <Judith.Bushong@bms.com>; Jani, Sunilkumar <Sunilkumar.Jani@bms.com>; Karanam, Prashin <Prashin.Karanam@bms.com>; Nagpal, Deepa <Deepa.Nagpal@bms.com>; Colin, Pierre <Pierre.Colin@bms.com>; Kapoor, Upender <Upender.Kapoor@bms.com>; Lalchandani, Varsha <varsha.lalchandani@bms.com>; Jimenez-Kurlander, Lauren <Lauren.Jimenez-Kurlander@bms.com>; Zhang, Haiyang <Haiyang.Zhang2@bms.com>; Nathani, Khushbu <Khushbu.Nathani@bms.com>; Carr, Michelle <Michelle.Carr@bms.com>; Hotaling, Skylar <Skylar.Hotaling@bms.com>; Vemula, Sai Vikram <SaiVikram.Vemula@bms.com>; Alaparthi, Suresh <suresh.alaparthi@bms.com>; Coira, Christopher <Christopher.Coira@bms.com>; Hudson, Rachel <Rachel.Hudson@bms.com>; Simmons, Tara <tara.simmons@bms.com>; Hollis, Heather <Heather.Hollis@bms.com>; Sheriff, Konnie <konnie.sheriff@bms.com>; Evans, Anne <Anne.Evans@bms.com>; Santhanam, Navaneetha <Navaneetha.Santhanam@bms.com>; Alessio, Lise <Lise.Alessio@bms.com>; Grootendorst, Diederik <Diederik.Grootendorst@bms.com>

Subject: CA239-0004_Central Monitoring Strategy Plan (CMSP)_draft

Hi Team,

Please find attached the first draft of the **Central Monitoring Strategy Plan (CMSP)** for study CA239-0004 for your review.

The purpose of the CMSP is to outline the approach and methodologies for Central Monitoring to ensure data quality, patient safety, and regulatory compliance. CMSP will enable early identification and resolution of issues in these areas.

With help of the risk review team (RRT) we will select/pre-define both the standard and study specific key risk indicators (KRIs) that will help us to monitor and detect potential issues in the study.

Action:

Risk Review Team (RRT) Evaluates the CMSP and confirm the following:

- Relevant risks that can be quantified via analytics are captured.
- Agreed upon mitigation and control owners and actions.
- Analytic review strategy required to support the study assessments are document

RRT please note in column I on the attached document (analytic name) there are some analytics strikethrough, this is because I considered that these KRIs are not applicable for this study, however I still need to get alignment from the study team prior to removing them from CMSP. For the same column, for analytics highlighted in yellow, I determined that these might be applicable for the study but need further discussion with the team.

- Attend CMSP Review meeting to discuss the above bullet points

Central Monitor:

- Schedule a CMPS review meeting
- Addresses all comments by the RRT during CMSP review meetings
- Routes CMSP for approval via eTMF workflow to the following:
 - Global Trial Manager (GTM), Data Management Lead (DML), Clinical Scientist (CS)
- Ensures an approved CMSP is available in study Trial Master File before First Patient First Visit (FPFV).
- Monitor KRIs and communicate to the team every 4-12 weeks in the form of a Central Monitoring Review which will be part of the revamp DQST slide deck.

- Centralized monitoring review supports the identification of data integrity issues. Centralized monitoring review complies with SOP: DOC-707043, *Centralized Monitoring Start-up, Maintenance, and Close Out*.

Also find attached an **CMN Overview Presentation** in case you need a refresher on what is Central Monitoring.

Please let me know if you have any questions.

Thanks,

Nish