# Dear AKI Site PI and Coordinator(s):

The Data Quality Report Card was created to keep you informed as to how your site is performing in KPMP. The Report Card should be used to determine which metrics your site excels at and which metrics need improvement. During your internal discussions, it is recommended that you formulate a plan of action for metrics needing improvement.

There are some general rules below that can help you understand better:

* ‘Cumulative’ column in the report card is summarized as of the data cutoff date (6/4/2021).
* Color schemes are applied to metrics in the ‘Current Quarter’ and ‘Previous Quarter’ columns. If a dividend is 0, 0/0 is presented without any color scheme applied. There is a key for the color schemes at the bottom of the report.
* The ‘Change’ column reflects the difference from the Previous to the Current Quarter. Improvement over time is reflected with a green Up arrow; slippage over time is reflected with a red Down arrow.
* The column ‘Quarter criteria’ in this report card memo tells which participants are included in Quarter columns. For example, if Quarter criteria is date of assessment and that date of a participant belongs to current quarter (3/2/2021 - 6/4/2021), the participant is counted.
* For the Participant Reported Outcome Measures and Health Literacy Questionnaire CRFs included in the metric of Completion of ‘3m AKI Visit CRFs’, they are considered complete if they are completed either on enrollment or on 3 months AKI visit.

Sincerely,

| **Metric** | **How is the metric calculated?** | **Quarter criteria** | **Rationale for metric** |
| --- | --- | --- | --- |
| **Recruitment & retention** | | | |
| Eligibility Assessment Complete (N) | Eligibility Assessment CRF marked Complete | Date of assessment | Recruitment goals |
| Eligible (N) | Eligibility Assessment CRF Complete and results indicate participant is eligible | Date of assessment | Recruitment goals |
| Enrolled (N) | Consent CRF complete and participant signed consent | Date consent was signed by participant | Recruitment goals |
| Biopsied (N) | Kidney Biopsy Procedure Details CRF marked Complete and biopsy date and kit recorded | Biopsy date | Recruitment goals |
| % of goal (Biopsied/Goal (%)) | Number of biopsied participants / Approximate targeted number of biopsy | Biopsy date | Recruitment goals |
| Withdrew (N) | Participants who have been removed from the study via End of Study CRF indicating participant status of Withdrew from study | Date participant withdrew from study | Study retention |
| Deceased (N) | Participants who have been removed from the study via End of Study CRF indicating participant status of Deceased | Date of death | Study retention |
| Lost to Follow-up (N) | Participants who have been removed from the study via End of Study CRF indicating participant status of Lost to followup | Date participant was lost to follow-up | Study retention |
| Loss of Eligibility (N) | Participants who have been removed from the study via End of Study CRF indicating participant status of Loss of eligibility | Date participant removed from study due to loss of eligibility | Study retention |
| Retention (%) | (Number of biopsied participants – Number of participants not followed for any reason post biopsy) / Number of biopsied participants | Biopsy date | Study retention |
| **Visits & CRFs (Completed/Expected (%))** | | | |
| Visits | Total number of visits with Participant Followup CRF marked Complete and status of follow-up occurred / Total number of visits past upper limit of allowable window | Biopsy date | Visit compliance |
| CRFs | Total number of CRFs marked Complete / Total number of CRFs expected under CRFs per Timepoint metrics | Biopsy date | Data completeness |
| 28d Participant Experience Survey | Number of 28 day followup Participant Experience Survey CRF (English, Spanish, or Old version) marked Complete / Number of 28 day followup visit past upper limit of allowable window | Biopsy date | Data completeness |
| 6m Participant Experience Survey | Number of 6 months Participant Experience Survey CRF (English, Spanish version) marked Complete / Number of 6 months visit past upper limit of allowable window | Biopsy date | Data completeness |
| Completion of Enrollment CRFs (11 per timepoint) | Number of Enrollment visit CRFs (including Contact Information, Demographic Information, Participant Medical History, Personal History, Coordinator Medical History, Physical Measurements, Biosample – Blood, Biosample - Spot Urine, Biosample - Timed Urine, Biosample – Stool, and Laboratory Results) marked Complete / 11 \* Number of Enrolled participants | Date consent was signed by participant | Data completeness |
| Completion of Biopsy Visit CRFs (8 per timepoint) | Number of Biopsy visit CRFs (including Pre-Clinical Assessment - Clinician, Pre-Clinical Assessment - Investigator, Pre-Biopsy Safety CRF, Kidney Biopsy Procedure Details, Post Biopsy, Follow Up Clinical Assessment, Tissue Tracking, and Pathology Images Upload) marked Complete / 8 \* Number of Biopsied participants | Biopsy date | Data completeness |
| Completion of 24h Follow-up CRF (1 per timepoint) | Number of 24 hour followup visit CRF (24 Hour Participant Followup) marked Complete / Number of 24 hour followup visit past upper limit of allowable window | Past 48 hours since biopsy | Data completeness |
| Completion of AKI-only CRFs (up to 7 days) (5 per timepoint) | Number of AKI-only visit CRFs (including Biosample - Spot Urine, AKI Hospitalization, AKI Daily Measurements, AKI Daily Progress Note, and Biosample - Blood AKI) marked Complete / 5 \* Number of AKI-only visit past upper limit of allowable window | Past 7 days since biopsy | Data completeness |
| Completion of 14d Follow-up CRF (1 per timepoint) | Number of 14 day followup visit CRFs (Participant Followup) marked Complete / Number of 14 day followup visit past upper limit of allowable window | Past 20 days since biopsy | Data completeness |
| Completion of 28d Follow-up CRFs (2 per timepoint) | Number of 28 day followup visit CRFs (including Participant Followup, and Participant Experience Survey) marked Complete / 2 \* Number of 28 day followup visit past upper limit of allowable window | Past 34 days since biopsy | Data completeness |
| Completion of 3m AKI Visit CRFs (7 per timepoint) | Number of 3 months - AKI-Only visit CRFs (including Participant Followup, Physical Measurements, Biosample – Blood, Biosample - Spot Urine, Participant Reported Outcome Measures, Health Literacy Questionnaire, and Laboratory Results) marked Complete / 7 \* Number of 3 months - AKI-Only visit past upper limit of allowable window | Past 4 months since biopsy | Data completeness |
| Completion of 6m Phone Visit CRFs (4 per timepoint) | Number of 6 months visit CRFs (including Participant Followup, Follow Up Medical Events, Laboratory Results, and Participant Experience Survey) marked Complete / 4 \* Number of 6 months visit past upper limit of allowable window | Past 9 months since biopsy | Data completeness |
| Completion of 12m Visit CRFs (8 per timepoint) | Number of 12 months visit CRFs (including Participant Followup, Health Literacy Questionnaire, Follow Up Medical Events, Follow Up Personal History, Laboratory Results, Biosample – Blood, and Biosample - Spot Urine) marked Complete / 8 \* Number of 12 months visit past upper limit of allowable window | Past 15 months since biopsy | Data completeness |
| Return of Biopsy Results within 1 Month | Number of participants who were contacted for the reason of Biopsy results provided within 1 month of biopsy date / Number of biopsied participants past a month from biopsy | Past a month since biopsy | Data completeness and timeliness |
| **Biospecimens** | | | |
| Blood Samples Frozen within 2 Hours/Total Blood Samples Collected (%) | Total number of blood samples where maximum time from collection to frozen is less than 2 hours / Total number of blood samples collected | Biosample collection date | Biosample compliance and timeliness |
| Spot Urine Samples Frozen within 4 Hours/Total Spot Urine Samples Collected (%) | Total number of spot urine samples where maximum time from collection to frozen is less than 4 hours / Total number of blood samples collected | Biosample collection date | Biosample compliance and timeliness |
| ACD Received at CBR within 24 Hours of Collection/Total ACD Collected (%) | Number of ACD with status of Complete and where timing between ACD collection and receipt at CBR is less than 24 hours / Number of ACD collection with status of Complete | ACD collection date | Biosample compliance and timeliness |
| Number of Shipments without Issues\*/Total Number of Shipments (%) | Number of shipments without incorrect temperature and incorrect shipping conditions issues / Total number of shipments sent | Shipment date | Data quality Biospecimen tracking |
| Core 3 Triaged <5 Minutes after Harvest/Total Number of Core 3 Obtained (%) | Number of Core 3 (Cryostor or LN2) where vial processing time is less than 5 minutes / Number of Core 3 obtained | Biopsy date | Biosample compliance and timeliness |
| Number of Core Components Triaged <10 Minutes after Harvest/Total Number of Core Components Obtained (%) | Total number of Core components where vial processing time is less than 10 minutes / Total number of Core components (5 components: Core1 Form, Core1 OCT, Core1 Glut, Core2 OCT, and Core3 Cryostor or LN2) obtained | Biopsy date | Biosample compliance and timeliness |
| Cryostor Shipped to CBR within 1 Week of Biopsy/Total Number of Kit A Biopsies (%) | Number of Cryostor spent less than 1 week at RS from biopsy before shipment to CBR / Number of Cryostor created at RS | Tissue created date at RS – same as Biopsy Date | Biosample compliance and timeliness |
| Biopsy Cases without Freeze Artifacts Reported by TIS/Total Number of OCT Samples Obtained (%) | Number of OCT counts without TIS review of severe freezing artifact / Number of OCT procured | N/A | Data quality |